

Clinical Trial Report

Trial ID: NN5401-3594

**A 26-Week, Multinational, Multicentre, Open-label,
Two-arm, Parallel, Randomised, Treat-to-target Trial
Comparing Efficacy and Safety of NN5401 Once-daily
Plus Meal-time Insulin Aspart for the Remaining Meals
vs. Basal-Bolus Treatment with Insulin Detemir Plus
Meal-time Insulin Aspart in Subjects with Type 1
Diabetes**

~~This confidential document is the property of Novo Nordisk. No unpublished information contained herein may be disclosed without prior written approval from Novo Nordisk. Access to this document must be restricted to relevant parties.~~

1 Title Page

Title of Trial	A 26-week, multinational, multi-centre, open-labelled, two-arm, parallel, randomised, treat-to-target trial comparing efficacy and safety of NN5401 once daily plus meal-time insulin aspart for the remaining meals vs. basal-bolus treatment with insulin detemir plus meal-time insulin aspart in subjects with type 1 diabetes
Trial ID	NN5401-3594
Development Phase	Phase 3a
Trial Registration ID no.	NCT00978627
IND Number (U.S .only)	IND 73,198
EudraCT Number	2008-005769-71
Japanese Trial Number	Not Applicable
Generic Name	Insulin degludec/insulin aspart (IDegAsp)
Indication	Diabetes mellitus
Investigator(s)	There were 79 principal investigators. [REDACTED], MD was appointed signatory investigator: [REDACTED]
Trial Site(s)	The trial was conducted at 79 sites in 9 countries: Denmark (3 sites), Poland (6 sites), Romania (8 sites), France (3 sites), United Kingdom (8 sites), Russian Federation (11 sites), Israel (4 sites), Australia (7 sites), and United States (29 sites)
Trial Initiated	25 August 2009
Trial Completed	31 May 2010
Sponsor	Novo Nordisk A/S, Denmark
International Medical Director	[REDACTED] Novo Nordisk A/S
International Trial Manager	[REDACTED] Novo Nordisk A/S
Local Trial Managers	[REDACTED] all Novo Nordisk A/S
Trial Statisticians	[REDACTED] Novo Nordisk A/S [REDACTED] Novo Nordisk A/S [REDACTED] Novo Nordisk A/S

NN5401 IDegAsp
Trial ID: NN5401-3594
Clinical Trial Report
Report Body

~~CONFIDENTIAL~~

Date:	14 June 2011	Novo Nordisk
Version:	3.0	
Status:	Final	
Page:	3 of 1733	

Trial Medical Writers	Novo Nordisk A/S,
Report Date	19 May 2011

The trial was conducted in accordance with the Declaration of Helsinki¹ and ICH Good Clinical Practice²

2 **Synopsis**

Refer to separate document.

3 Table of Contents for the Individual Clinical Study

	Page
1 Title Page	2
2 Synopsis	4
3 Table of Contents for the Individual Clinical Study Report	5
4 List of Abbreviations and Definition of Terms	26
5 Ethics	28
5.1 Independent Ethics Committee (IEC) or Institutional Review Board (IRB).....	28
5.2 Ethical Conduct of the Trial.....	28
5.3 Patient Information and Consent.....	28
6 Investigators and Trial Administrative Structure	29
7 Introduction	33
7.1 Therapeutic Area.....	33
7.2 IDegAsp.....	33
7.3 IDet.....	34
7.4 IAsp.....	34
7.5 Rationale for the Trial.....	35
8 Trial Objectives	36
9 Investigational Plan	37
9.1 Overall Trial Design and Plan: Description.....	37
9.2 Discussion of Trial Design, Including the Choice of Control Groups.....	38
9.3 Selection of Trial Population.....	39
9.3.1 Inclusion Criteria.....	39
9.3.2 Exclusion Criteria.....	40
9.3.3 Removal of Subjects from Therapy and Assessment.....	42
9.4 Treatments.....	43
9.4.1 Treatments Administered.....	43
9.4.2 Identity of Investigational Products.....	44
9.4.3 Method of Assigning Patients to Treatment Groups.....	46
9.4.4 Selection of Doses in the Trial.....	46
9.4.5 Selection and Timing of Dose for Each Subject.....	47
9.4.6 Blinding.....	49
9.4.7 Prior and Concomitant Therapy.....	50
9.4.8 Treatment Compliance.....	50
9.5 Efficacy and Safety Variables.....	51
9.5.1 Efficacy and Safety Measurements Assessed and Flow Chart.....	51
9.5.1.1 Flow Chart.....	51
9.5.1.2 Efficacy Assessments.....	56
9.5.1.3 Safety Assessments.....	59
9.5.1.4 Assessments of Demographic and other Baseline Characteristics.....	68
9.5.2 Appropriateness of Measurements.....	68
9.5.3 Primary Efficacy Variable.....	68
9.5.4 Drug Concentration Measurements.....	68

9.6 Data Quality Assurance	68
9.7 Statistical Methods Planned in the Protocol and Determination of Sample Size.....	69
9.7.1 General Considerations.....	69
9.7.2 Endpoints in Relation to the Objectives and Hypotheses.....	69
9.7.3 Definition of Analysis Sets.....	71
9.7.4 Statistical Analyses.....	72
9.7.4.1 Primary Endpoint.....	72
9.7.4.2 Confirmatory Secondary Endpoints.....	73
9.7.4.3 Supportive Secondary Endpoints.....	74
9.7.4.4 Safety Endpoints	77
9.7.5 Interim Analyses.....	81
9.7.6 Sequential Safety Analysis/Safety Monitoring.....	81
9.7.7 Exploratory Statistical Analyses for Pharmacogenetics and Biomarkers.....	81
9.7.8 PK and PD Modelling.....	81
9.7.9 Health Economics and/or Patient Reported Outcomes.....	81
9.7.10 Determination of Sample Size	81
9.8 Changes in the Conduct of the Trial or Planned Analyses.....	83
9.8.1 Protocol Amendments and General Procedural Deviations	83
9.8.2 Changes to the Statistical Analysis Plan.....	85
10 Trial Subjects.....	87
10.1 Disposition of Subjects	87
10.2 Protocol Deviations.....	89
10.2.1 Important Protocol Deviations.....	89
10.2.2 Important Deviations at Trial Site Level	89
10.2.3 Important Deviations at Subject Level	89
11 Efficacy Evaluation	93
11.1 Data Sets Analysed	93
11.2 Demographic and Other Baseline Characteristics.....	94
11.3 Measurements of Treatment Compliance	100
11.4 Efficacy Results	101
11.4.1 Analysis of Efficacy	101
11.4.1.1 Summary of Confirmatory Testing.....	101
11.4.1.2 HbA1c – Primary Endpoint	102
11.4.1.3 Responders for HbA1c.....	104
11.4.1.4 Fasting Plasma Glucose	107
11.4.1.5 9-point Self-measured Plasma Glucose Profile	109
11.4.1.6 SMPG Values Used for Dose Adjustment.....	112
11.4.2 PK and PD Modelling.....	115
11.4.3 Quality of Life Assessments.....	115
11.4.4 Statistical/Analytical Issues	116
11.4.4.1 Handling of Dropouts or Missing Data.....	116
11.4.5 Efficacy Conclusions.....	116
12 Safety Evaluation.....	118
12.1 Extent of Exposure.....	118
12.1.1 Exposure to Trial Products	118

12.1.2 Dosing During the Trial.....	118
12.1.2.1 Insulin Regimen and Dosing Time	118
12.1.2.2 Insulin Dose	120
12.1.2.3 Insulin Dose Ratio at End of Trial	126
12.1.2.4 Difference between Titration Algorithm Dose and Prescribed Dose.....	127
12.1.2.5 Difference between Prescribed Dose and Actual Dose.....	128
12.2 Adverse Events	128
12.2.1 Brief Summary of Adverse Events	128
12.2.2 Analysis of Adverse Events.....	130
12.2.2.1 Adverse Events by Relationship to Investigational Product (IDegAsp or IDet)....	132
12.2.2.2 Adverse Events by Relationship to Bolus Insulin.....	132
12.2.2.3 Adverse Events by Relationship to the Insulin Delivery Device	136
12.2.2.4 Adverse Events by Severity	136
12.3 Deaths, Other Serious Adverse Events and Other Significant Adverse Events.....	136
12.3.1 Deaths	136
12.3.2 Other Serious Adverse Events	136
12.3.3 Other Significant Adverse Events	139
12.3.3.1 Adverse Events leading to Withdrawal.....	139
12.3.3.2 Adverse Events leading to Dose Reduction.....	140
12.3.3.3 Adverse Events leading to Significant Additional Concomitant Medication	140
12.3.3.4 Medical Events of Special Interest	141
12.4 Hypoglycaemia	141
12.4.1 Introduction to Hypoglycaemic Episodes.....	141
12.4.2 Confirmed Hypoglycaemic Episodes	142
12.4.3 Severe Hypoglycaemia	144
12.4.4 Nocturnal Hypoglycaemic Episodes.....	145
12.4.4.1 Nocturnal Severe Hypoglycaemia	147
12.4.5 ADA Classified Hypoglycaemic Episodes	148
12.5 Clinical Laboratory Evaluation.....	149
12.5.1 Evaluation of Insulin Antibodies.....	149
12.5.1.1 Cross-reacting Insulin Antibodies.....	149
12.5.1.2 Specific Insulin Antibodies.....	151
12.5.1.3 Total Insulin Antibodies	151
12.5.2 Evaluation of Each Laboratory Parameter.....	151
12.5.2.1 Laboratory Values over Time	151
12.5.2.2 Individual Subject Changes	152
12.5.2.3 Individual Clinically Significant Abnormalities	152
12.6 Vital Signs, Physical Findings and Other Observations Related to Safety	153
12.6.1 Vital Signs	153
12.6.2 Physical Examination	153
12.6.3 ECG	153
12.6.4 Fundoscopy / Fundusphotography.....	153
12.6.5 Body Weight and Body Mass Index.....	154
12.7 Safety Conclusions.....	156
13 Discussion and Overall Conclusions	158

14 Tables, Figures and Graph Referred to but not Included in the Text.....	163
14.1 Demographic Data	163
14.1.1: Subject Disposition - Summary	164
14.1.2: Subject Disposition by Country – Summary - All Subjects	165
14.1.3: Time to Discontinuation - Full Analysis Set	167
14.1.4: Subject Disposition by Week - Summary - Full Analysis Set	168
14.1.5: Reasons for Discontinuation from Week 12 and onwards - Full Analysis Set	169
14.1.6: Demographics and Baseline Characteristics - Summary - Full Analysis Set	170
14.1.7: Baseline and Diabetes Characteristics – Descriptive Statistics - Full Analysis Set	171
14.1.8: Anti-diabetic Treatment Regimen at Screening - Full Analysis Set	172
14.1.9: Insulin Type at Screening - Full Analysis Set	173
14.1.10: Diabetes Complications at Screening - Summary - Full Analysis Set	174
14.1.11: Concomitant Illness at Screening - Summary - Full Analysis Set	175
14.1.12: Concomitant Medication at Screening – Summary - Full Analysis Set	186
14.1.13: Concomitant Medication Started after Screening – Summary - Full Analysis Set	208
14.2 Efficacy Data	238
14.2.1: Exposure - Descriptive Statistics - Safety Analysis Set	239
14.2.2: Exposure by Treatment Week - Summary - Safety Analysis Set	240
14.2.3: Exposure by Sex and Treatment Week - Summary - Safety Analysis Set	241
14.2.4: Exposure by Race and Treatment Week - Summary - Safety Analysis Set	242
14.2.5: Exposure by Ethnicity and Treatment Week - Summary - Safety Analysis Set	244
14.2.6: Exposure by Age Group (Adults and Elderly) and Treatment Week - Summary - Safety Analysis Set	245
14.2.7: Exposure - Empirical Distribution Plot - Safety Analysis Set	246
14.2.8: IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	247
14.2.9: IDegAsp/Comparator Insulin Dose (Prescribed) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	250
14.2.10: IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	253
14.2.11: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	256
14.2.12: Daily IDegAsp/Comparator (Prescribed) in Units by Treatment Week - Mean Plot - Safety Analysis Set	257
14.2.13: Daily IDegAsp/Comparator (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set	258
14.2.14: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	259
14.2.15: Daily IDegAsp/Comparator Insulin Dose (Prescribed) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	260
14.2.16: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	261
14.2.17: Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	262
14.2.18: Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	265

14.2.19: Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	268
14.2.20: Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	271
14.2.21: Basal Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	272
14.2.22: Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set	273
14.2.23: Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set	274
14.2.24: Daily Bolus Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	275
14.2.25: Basal Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	276
14.2.26: Daily Bolus Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	277
14.2.27: Basal Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	278
14.2.28: Total Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	279
14.2.29: Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	282
14.2.30: Total Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	285
14.2.31: Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	288
14.2.32: Total Daily Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	291
14.2.33: Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set.....	292
14.2.34: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set	293
14.2.35: Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set.....	294
14.2.36: Total Daily Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	295
14.2.37: Total Daily Bolus Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	296
14.2.38: Total Daily Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	297
14.2.39: Total Daily Bolus Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	298
14.2.40: Insulin Dose Ratio after 26 Weeks of Treatment - Summary - Safety Analysis Set..	299
14.2.41: Basal-Bolus split after 26 Weeks of Treatment - Summary - Safety Analysis Set	299
14.2.42: IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set	300
14.2.43: IDet Doses in Units per Injection Time by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	301

14.2.44: Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	302
14.2.45: Prescribed minus Titration Algorithm Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	305
14.2.46: Daily IDegAsp Dose in Units by Treatment Week - Prescribed, Actual and Titration Algorithm Dose - Mean Plot - Safety Analysis Set	308
14.2.47: Daily IDet Insulin Dose in Units by Treatment Week - Prescribed, Actual and Titration Algorithm Dose – Mean Plot - Safety Analysis Set.....	309
14.2.48: Confirmatory Statistical Analyses - Full Analysis Set	310
14.2.49: HbA1c (%) by Treatment Week – Descriptive Statistics - Full Analysis Set	311
14.2.50: HbA1c (%) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set.....	312
14.2.51: HbA1c (%) after 26 Weeks of Treatment - Primary Statistical Analysis - Full Analysis Set	313
14.2.52: HbA1c (%) after 26 Weeks of Treatment - Parameter Estimates on Observed Scale - Full Analysis Set	314
14.2.53: HbA1c (%) after 26 Weeks of Treatment - Statistical Sensitivity Analysis - PP Analysis Set	315
14.2.54: HbA1c (%) after 26 Weeks of Treatment - Statistical Sensitivity Analysis - Simple Model - Full Analysis Set.....	316
14.2.55: HbA1c (%) after 26 Weeks of Treatment - Statistical Sensitivity Analysis - Repeated Measurement Model - Full Analysis Set.....	317
14.2.56: HbA1c (%) by Treatment Week – Mean Plot - Full Analysis Set.....	317
14.2.57: HbA1c (%) by Treatment Week – Change from Baseline - Mean Plot - Full Analysis Set	318
14.2.58: HbA1c (%) by Treatment Week – Change from Baseline - Mean Plot - PP Analysis Set	319
14.2.59: HbA1c (%) after 26 Weeks of Treatment – Empirical Distribution Plot - Full Analysis Set	320
14.2.60: HbA1c (%) after 26 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set.....	321
14.2.61: Responder for HbA1c by Treatment Week – Summary - Full Analysis Set.....	322
14.2.62: Responder for HbA1c at End of Trial - Statistical Analysis - Full Analysis Set.....	323
14.2.63: Responder for HbA1c at End of Trial Without Hypoglycaemia – Summary - Full Analysis Set	324
14.2.64: HbA1c<7.0% at End of Trial Without Severe Hypoglycaemia - Confirmatory Statistical Analysis - Full Analysis Set	326
14.2.65: HbA1c<7.0% at End of Trial Without Severe Hypoglycaemia - Parameter Estimates on Mean Scale - Full Analysis Set.....	327
14.2.66: Responder for HbA1c at End of Trial Without Hypoglycaemia - Statistical Analysis - Full Analysis Set.....	328
14.2.67: Fasting Plasma Glucose (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set.....	329
14.2.68: Fasting Plasma Glucose (mmol/L) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set.....	330
14.2.69: Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment - Confirmatory Statistical Analysis - Full Analysis Set.....	331

14.2.70: Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment - Parameter Estimates on Observed Scale - Full Analysis Set	332
14.2.71: Fasting Plasma Glucose (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set	333
14.2.72: Fasting Plasma Glucose (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set	334
14.2.73: Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set	335
14.2.74: Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set	336
14.2.75: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set.....	337
14.2.76: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set	339
14.2.77: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Weeks - Mean Plot - IDegAsp OD - Full Analysis Set.....	341
14.2.78: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Weeks - Mean Plot - IDet - Full Analysis Set.....	342
14.2.79: 9-point Self Measured Plasma Glucose Profile (mmol/L) at Baseline - Mean Plot - Full Analysis Set.....	343
14.2.80: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 12 Weeks - Mean Plot - Full Analysis Set	344
14.2.81: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 16 Weeks - Mean Plot - Full Analysis Set	345
14.2.82: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks - Mean Plot - Full Analysis Set	346
14.2.83: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set.....	347
14.2.84: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set.....	348
14.2.85: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set.....	349
14.2.86: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set.....	350
14.2.87: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set	351
14.2.88: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set	352
14.2.89: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set..	353
14.2.90: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week - Descriptive Statistics - Full Analysis Set.....	354
14.2.91: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set	355
14.2.92: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set.....	356
14.2.93: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set.....	357

14.2.94: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set.....	358
14.2.95: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set	359
14.2.96: Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) – Descriptive Statistics - Full Analysis Set.....	360
14.2.97: Prandial Increment by Treatment Week – Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set	364
14.2.98: Prandial Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Statistical Analysis - Full Analysis Set	368
14.2.99: Breakfast Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set.....	369
14.2.100: Breakfast Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	370
14.2.101: Breakfast Increment after 26 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	371
14.2.102: Lunch Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set.....	372
14.2.103: Lunch Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set	373
14.2.104: Lunch Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	374
14.2.105: Lunch Increment after 26 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	375
14.2.106: Main Evening Meal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set	376
14.2.107: Main Evening Meal Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set..	377
14.2.108: Main Evening Meal Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	378
14.2.109: Main Evening Meal Increment after 26 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	379
14.2.110: All Meals Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set.....	380
14.2.111: All Meals Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set	381
14.2.112: All Meals Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	382
14.2.113: Nocturnal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) – Descriptive Statistics - Full Analysis Set.....	383
14.2.114: Nocturnal Increment by Treatment Week – Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set	386

14.2.115: Nocturnal Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Statistical Analysis - Full Analysis Set.....	389
14.2.116: Nocturnal Increment (Bedtime to 04:00) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) -Mean Plot - Full Analysis Set	390
14.2.117: Nocturnal Increment (Bedtime to 04:00) by Treatment Week - Change from Baseline – 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set	391
14.2.118: Nocturnal Increment (Bedtime to 04:00) after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	392
14.2.119: Nocturnal Increment (Bedtime to 04:00) after 26 Weeks of Treatment– Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	393
14.2.120: Nocturnal Increment (Bedtime to Breakfast) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set	394
14.2.121: Nocturnal Increment (Bedtime to Breakfast) by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set	395
14.2.122: Nocturnal Increment (Bedtime to Breakfast) after 26 Weeks of Treatment -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	396
14.2.123: Nocturnal Increment (Bedtime to Breakfast) after 26 Weeks of Treatment – Change from Baseline -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	397
14.2.124: Nocturnal Increment (04:00 to Breakfast) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) – Mean Plot - Full Analysis Set.....	398
14.2.125: Nocturnal Increment (04:00 to Breakfast) by Treatment Week - Change from Baseline – 9-point Self Measured Plasma Glucose Profile (mmol/L) – Mean Plot - Full Analysis Set.....	399
14.2.126: Nocturnal Increment (04:00 to Breakfast) after 26 Weeks of Treatment -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	400
14.2.127: Nocturnal Increment (04:00 to Breakfast) after 26 Weeks of Treatment – Change from Baseline -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	401
14.2.128: Self Measured Plasma Glucose for Dose Adjustment (mmol/L) – Descriptive Statistics - Full Analysis Set	402
14.2.129: Self Measured Plasma Glucose for Dose Adjustment after 26 Treatment Weeks - Statistical Analysis - Full Analysis Set.....	418
14.2.130: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set.....	419
14.2.131: Mean Before Lunch Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set.....	420
14.2.132: Mean Before Main Evening Meal Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set	421
14.2.133: Mean Before Bedtime Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set.....	422
14.2.134: Within-Subject Variation in Self Measured Plasma Glucose for Dose Adjustment after 26 Treatment Weeks - Statistical Analysis - Full Analysis Set.....	423

14.2.135: Before Breakfast Titration Target (SMPG<5 mmol/L) by Treatment Week – Summary - Full Analysis Set	424
14.2.136: Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set	427
14.2.137: Time to Titration Target is Met for the First Time (Treatment Week) – Descriptive Statistics - Full Analysis Set	428
14.2.138: Time to Titration Target is Met for the First Time (Treatment Week) - Statistical Analysis - Full Analysis Set	429
14.2.139: Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health - Descriptive Statistics - Full Analysis Set	430
14.2.140: Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health - Descriptive Statistics - Full Analysis Set	435
14.2.141: Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health - Change from Baseline - Descriptive Statistics - Full Analysis Set	440
14.2.142: Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health - Change from Baseline - Descriptive Statistics - Full Analysis Set	445
14.2.143: Health Related Quality of Life (SF-36) Scores after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set	450
14.2.144: Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set	451
14.2.145: Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set	455
14.2.146: Diabetes Medication Satisfaction (DiabMedSat) Scores after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set	459
14.2.147: Diabetes Productivity Measure (DPM) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set	460
14.2.148: Diabetes Productivity Measure (DPM) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set	462
14.2.149: Diabetes Productivity Measure (DPM) Scores after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set	464
14.2.150: Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set	465
14.2.151: Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set	471
14.2.152: Treatment Related Impact Measures - Diabetes (TRIM-D) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set	477
14.2.153: Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics - Full Analysis Set	479
14.2.154: Hypoglycaemic Questionnaire - Question 4 to 7 by Treatment Week - Descriptive Statistics - Full Analysis Set	491
14.2.155: Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics - Full Analysis Set	499
14.2.156: Hypoglycaemic Questionnaire - Question 9 by Treatment Week - Descriptive Statistics - Full Analysis Set	513
14.2.157: Hypoglycaemic Questionnaire - Question 10 by Treatment Week - Descriptive Statistics - Full Analysis Set	515
14.2.158: Hypoglycaemic Questionnaire - Question 11 to 12 by Treatment Week - Descriptive Statistics - Full Analysis Set	522

14.2.159: Hypoglycaemic Questionnaire - Question 13 by Treatment Week - Descriptive Statistics - Full Analysis Set	529
14.2.160: Hypoglycaemic Questionnaire - Question 14 by Treatment Week - Descriptive Statistics - Full Analysis Set	533
14.3 Safety Data.....	537
14.3.1 Displays of Adverse Events.....	537
14.3.1.1: Adverse Events - Treatment Emergent - Summary - Safety Analysis Set.....	538
14.3.1.2: Serious Adverse Events – Treatment Emergent - Summary - Safety Analysis Set.....	539
14.3.1.3: Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 5\%$]- Treatment Emergent - Summary - Safety Analysis Set.....	540
14.3.1.4: Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$]- Treatment Emergent - Summary - Safety Analysis Set.....	541
14.3.1.5: Serious Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 5\%$]- Treatment Emergent - Summary - Safety Analysis Set.....	545
14.3.1.6: Serious Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$]- Treatment Emergent - Summary - Safety Analysis Set.....	546
14.3.1.7: Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	547
14.3.1.8: Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	560
14.3.1.9: Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set.....	562
14.3.1.10: Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set.....	565
14.3.1.11: Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	568
14.3.1.12: Serious Adverse Events Possibly or Probably Related Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	569
14.3.1.13: Serious Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set.....	570
14.3.1.14: Serious Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	571
14.3.1.15: Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	572
14.3.1.16: Severe Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	574
14.3.1.17: Severe Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term – Treatment Emergent - Summary - Safety Analysis Set.....	575
14.3.1.18: Severe Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	576
14.3.1.19: Serious Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	577

14.3.1.20: Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	579
14.3.1.21: Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	585
14.3.1.22: Adverse Events Leading To Dose Reduction - Treatment Emergent - Summary - Safety Analysis Set.....	596
14.3.1.23: Neoplasms by System Organ Class and Preferred Term - Summary - Safety Analysis Set.....	597
14.3.1.24: Allergic Reaction (Immunogenicity) by System Organ Class and Preferred Term - Summary - Safety Analysis Set.....	598
14.3.1.25: Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	599
14.3.1.26: Adjudicated Cardiovascular Events - Treatment Emergent - Summary - Safety Analysis Set.....	601
14.3.1.27: Injection Site Reaction by System Organ Class and Preferred Term - Summary - Safety Analysis Set.....	602
14.3.1.28: Injection Site Reactions - Mean Cumulative Function - Safety Analysis Set.....	603
14.3.1.29: Medication Errors - Treatment Emergent - Summary - Safety Analysis Set.....	604
14.3.1.30: Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set.....	605
14.3.1.31: Nocturnal Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set.....	606
14.3.1.32: Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set.....	607
14.3.1.33: Nocturnal Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set.....	609
14.3.1.34: Hypoglycaemic Episodes - Treatment Emergent - Statistical Analysis - Full Analysis Set.....	611
14.3.1.35: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent – Confirmatory Statistical Analysis - Full Analysis Set.....	612
14.3.1.36: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Parameter Estimates on Mean Scale - Full Analysis Set.....	613
14.3.1.37: Severe Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set.....	614
14.3.1.38: Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set.....	615
14.3.1.39: Severe Hypoglycaemic Episodes - Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	616
14.3.1.40: Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	617
14.3.1.41: Severe Hypoglycaemic Episodes – Treatment Emergent - Cumulative Frequency over Day - Safety Analysis Set.....	618
14.3.1.42: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set.....	619
14.3.1.43: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set.....	620
14.3.1.44: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	621

14.3.1.45: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set	622
14.3.1.46: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Cumulative Frequency over Day - Safety Analysis Set.....	623
14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events	624
14.3.2.1: Treatment Emergent Serious Adverse Events - Safety Analysis Set.....	624
14.3.2.2: Treatment Emergent Adverse Events with Fatal Outcome - Safety Analysis Set.....	643
14.3.2.3: Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set.....	644
14.3.2.4: Adverse Events Leading to Withdrawal - Full Analysis Set	655
14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events	658
Abbreviation Statement	658
14.3.4 Abnormal Laboratory Value Listing (each patient).....	765
14.3.4.1: Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set.....	765
14.3.4.2: Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set.....	783
14.3.4.3: Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set.....	808
14.3.4.4: Urinalysis With Positive Test Results - Safety Analysis Set.....	846
14.3.5 Laboratory Displays	864
14.3.5.1: Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	865
14.3.5.2: Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set.....	874
14.3.5.3: Biochemistry by Treatment Week - Summary - Safety Analysis Set.....	883
14.3.5.4: Biochemistry – Shift Table – Baseline to Week 26 – Safety Analysis Set.....	887
14.3.5.5: Biochemistry - Alanine Amino Serum - Box Plot - Safety Analysis Set.....	890
14.3.5.6: Biochemistry - Alanine Amino Serum after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	891
14.3.5.7: Biochemistry - Albumin Serum - Box Plot - Safety Analysis Set.....	892
14.3.5.8: Biochemistry - Albumin Serum after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	893
14.3.5.9: Biochemistry - Total Bilirubin - Box Plot - Safety Analysis Set.....	894
14.3.5.10: Biochemistry - Total Bilirubin after 26 Weeks of Treatment – Empirical Distribution Plot - Safety Analysis Set.....	895
14.3.5.11: Biochemistry - AST - Box Plot- Safety Analysis Set.....	896
14.3.5.12: Biochemistry - AST after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	897
14.3.5.13: Biochemistry - Creatinine - Box Plot - Safety Analysis Set.....	898
14.3.5.14: Biochemistry - Creatinine after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	899
14.3.5.15: Biochemistry - Alkaline phosphatase - Box Plot - Safety Analysis Set	900
14.3.5.16: Biochemistry - Alkaline phosphatase after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	901
14.3.5.17: Biochemistry - Total Protein - Box Plot - Safety Analysis Set.....	902

14.3.5.18: Biochemistry - Total Protein after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	903
14.3.5.19: Biochemistry - Sodium - Box Plot - Safety Analysis Set.....	904
14.3.5.20: Biochemistry - Sodium after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	905
14.3.5.21: Biochemistry - Potassium - Box Plot - Safety Analysis Set.....	906
14.3.5.22: Biochemistry - Potassium after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	907
14.3.5.23: Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	908
14.3.5.24: Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set.....	918
14.3.5.25: Haematology by Treatment Week - Summary - Safety Analysis Set.....	928
14.3.5.26: Haematology – Shift Table – Baseline to Week 26 – Safety Analysis Set.....	932
14.3.5.27: Haematology - Neutrophils - Box Plot - Safety Analysis Set.....	935
14.3.5.28: Haematology- Neutrophils after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	936
14.3.5.29: Haematology - Lymphocytes - Box Plot - Safety Analysis Set.....	937
14.3.5.30: Haematology - Lymphocytes after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	938
14.3.5.31: Haematology - Monocytes - Box Plot - Safety Analysis Set.....	939
14.3.5.32: Haematology - Monocytes after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	940
14.3.5.33: Haematology - Eosinophils - Box Plot - Safety Analysis Set.....	941
14.3.5.34: Haematology - Eosinophils after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	942
14.3.5.35: Haematology - Basophils - Box Plot - Safety Analysis Set.....	943
14.3.5.36: Haematology - Basophils after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	944
14.3.5.37: Haematology - Erythrocytes - Box Plot - Safety Analysis Set.....	945
14.3.5.38: Haematology - Erythrocytes after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	946
14.3.5.39: Haematology - Haematocrit - Box Plot - Safety Analysis Set.....	947
14.3.5.40: Haematology - Haematocrit after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	948
14.3.5.41: Haematology - Haemoglobin - Box Plot - Safety Analysis Set.....	949
14.3.5.42: Haematology - Haemoglobin after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	950
14.3.5.43: Haematology - Leukocytes - Box Plot - Safety Analysis Set.....	951
14.3.5.44: Haematology - Leukocytes after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	952
14.3.5.45: Haematology - Thrombocytes - Box Plot - Safety Analysis Set.....	953
14.3.5.46: Haematology - Thrombocytes after 26 Weeks of Treatment - Empirical	
Distribution Plot - Safety Analysis Set.....	954
14.3.5.47: Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	955
14.3.5.48: Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set.....	959

14.3.5.49: Lipids after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set.....	963
14.3.5.50: Lipids by Treatment Week - Summary - Safety Analysis Set.....	965
14.3.5.51: Lipids – Shift Table – Baseline to Week 26 – Safety Analysis Set.....	967
14.3.5.52: Lipid - HDL Cholesterol - Box Plot - Safety Analysis Set.....	968
14.3.5.53: Lipid - HDL Cholesterol after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	969
14.3.5.54: Lipid - LDL Cholesterol - Box Plot - Safety Analysis Set.....	970
14.3.5.55: Lipid - LDL Cholesterol after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	971
14.3.5.56: Lipid - Tot. Chol. Serum - Box Plot - Safety Analysis Set.....	972
14.3.5.57: Lipid - Tot. Chol. Serum after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	973
14.3.5.58: Lipid - Triglycerides Serum - Box Plot - Safety Analysis Set.....	974
14.3.5.59: Lipid - Triglycerides Serum after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	975
14.3.5.60: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	976
14.3.5.61: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set.....	977
14.3.5.62: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Summary - Safety Analysis Set.....	978
14.3.5.63: Urinary Albumin-to-Creatinine Ratio – Shift Table – Baseline to Week 26 – Safety Analysis Set.....	979
14.3.5.64: Urinary Albumin-to-Creatinine Ratio - Box Plot - Safety Analysis Set.....	980
14.3.5.65: Urinary Albumin-to-Creatinine Ratio after 26 Weeks of Treatment – Empirical Distribution Plot - Safety Analysis Set.....	981
14.3.5.66: Urine by Sticks - Summary - Safety Analysis Set.....	982
14.3.5.67: Urine by Sticks – Shift Table – Baseline to Week 26 – Safety Analysis Set.....	983
14.3.6 Other Safety Observations Displays.....	984
14.3.6.1: Physical Examination by Treatment Week - Summary - Safety Analysis Set.....	985
14.3.6.2: Physical Examination - Shift Table - Baseline to Week 26 - Safety Analysis Set.....	992
14.3.6.3: Vital Signs by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	994
14.3.6.4: Vital Signs by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set.....	997
14.3.6.5: Diastolic Blood Pressure - Mean Plot - Safety Analysis Set.....	1000
14.3.6.6: Diastolic Blood Pressure - Change from Baseline - Mean Plot - Safety Analysis Set.....	1001
14.3.6.7: Diastolic Blood Pressure after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	1002
14.3.6.8: Systolic Blood Pressure - Mean Plot - Safety Analysis Set.....	1003
14.3.6.9: Systolic Blood Pressure - Change from Baseline - Mean Plot - Safety Analysis Set.....	1004
14.3.6.10: Systolic Blood Pressure after 26 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set.....	1005
14.3.6.11: Pulse - Mean Plot - Safety Analysis Set.....	1006
14.3.6.12: Pulse - Change from Baseline - Mean Plot - Safety Analysis Set.....	1007

14.3.6.13: Pulse after 26 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set.....	1008
14.3.6.14: ECG by Treatment Week - Summary - Safety Analysis Set	1009
14.3.6.15: ECG - Shift Table - Baseline to Week 26 - Safety Analysis Set	1010
14.3.6.16: Funduscopy / Fundusphotography by Treatment Week - Summary - Safety Analysis Set.....	1011
14.3.6.17: Funduscopy / Fundusphotography - Shift Table - Baseline to Week 26 - Safety Analysis Set.....	1013
14.3.6.18: Body Weight and BMI by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1014
14.3.6.19: Body Weight and BMI by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set.....	1016
14.3.6.20: Body Weight after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set.....	1018
14.3.6.21: Body Weight - Mean Plot - Safety Analysis Set.....	1019
14.3.6.22: Body Weight – Change from Baseline - Mean Plot - Safety Analysis Set	1020
14.3.6.23: Body weight after 26 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set.....	1021
14.3.6.24: Body weight after 26 Weeks of Treatment - Change from Baseline Empirical Distribution Plot - Safety Analysis Set.....	1022
14.3.6.25: Specific Antibodies (%B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1023
14.3.6.26: Insulin Degludec Specific Antibodies (%B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1024
14.3.6.27: IDet Specific Antibodies (%B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set	1025
14.3.6.28: Cross-reacting Antibodies to Human Insulin (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1026
14.3.6.29: Total Antibodies (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1027
14.3.6.30: Insulin 454 / Comparator Specific Antibodies (% B/T) - Mean Plot - Safety Analysis Set.....	1028
14.3.6.31: Insulin 454 / Comparator Specific Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set.....	1029
14.3.6.32: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Safety Analysis Set.....	1030
14.3.6.33: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set.....	1031
14.3.6.34: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Safety Analysis Set.....	1032
14.3.6.35: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Observed Values - Safety Analysis Set	1033
14.3.6.36: Total Antibodies (% B/T) - Mean Plot - Safety Analysis Set.....	1034
14.3.6.37: Total Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set.....	1035
14.3.6.38: Insulin Degludec /Comparator Specific Antibodies (% B/T) against HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set.....	1036

14.3.6.39: Insulin Aspart Specific Antibodies (% B/T) against HbA1c (%) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set.....	1037
14.3.6.40: Insulin Degludec / Comparator Specific Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set.....	1038
14.3.6.41: Insulin Aspart Specific Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set	1039
14.3.6.42: Cross-reacting Antibodies to Human Insulin (% B/T) against HbA1c (%) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set.....	1040
14.3.6.43: Cross-reacting Antibodies to Human Insulin (% B/T) against Change from Baseline in HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set.....	1041
14.3.6.44: Total Antibodies (% B/T) against HbA1c (%) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set.....	1042
14.3.6.45: Total Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set.....	1043
14.3.6.46: Insulin Degludec / Comparator Specific Antibodies (% B/T) against Total Insulin Dose (U/kg) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set.....	1044
14.3.6.47: Insulin Aspart Specific Antibodies (% B/T) against Total Insulin Dose (U/kg) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set.....	1045
14.3.6.48: Cross-reacting Antibodies to Human Insulin (% B/T) against Total Insulin Dose (U/kg) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set.....	1046
14.3.6.49: Total Antibodies (% B/T) against Total Insulin Dose (U/kg) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set.....	1047
14.3.7 Other Safety Observations Lists	1048
14.3.7.1: Vital Signs - Safety Analysis Set.....	1048
14.3.7.2: ECG Findings - Safety Analysis Set.....	1085
14.3.7.3: Fundoscopy / Fundusphotography Findings - Safety Analysis Set	1128
14.3.7.4: Antibodies - Safety Analysis Set	1215
14.3.7.5: Physical Examination Findings - Safety Analysis Set.....	1454
14.3.7.6: Body Measurements - Safety Analysis Set.....	1697
15 Reference List	1731

List of In-Text Figures

	Page
Figure 9–1 Trial Design.....	37
Figure 9–2 Classification of Hypoglycaemia According to ADA.....	64
Figure 9–3 Hierarchical Testing Procedure.....	70
Figure 11–1 HbA1c (%) by Treatment Week - Mean Plot - Full Analysis Set.....	102
Figure 11–2 Fasting Plasma Glucose (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set	108
Figure 11–3 9-point Self Measured Plasma Glucose Profile (mmol/L) at Baseline (Left) and After 26 Weeks (Right) - LOCF - Mean Plot - Full Analysis Set.....	110
Figure 11–4 Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set.....	114
Figure 12–1 Total Daily Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	121
Figure 12–2 Basal Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	123
Figure 12–3 Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	125
Figure 12–4 Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	143
Figure 12–5 Severe Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	144
Figure 12–6 Confirmed Nocturnal Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set	146
Figure 12–7 Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function.....	148
Figure 12–8 Cross-reacting Antibodies to Human Insulin (%B/T) – Mean Plot – Safety Analysis Set	149
Figure 12–9 Body Weight – Mean Plot – Full Analysis Set	155

List of In-Text Tables

	Page
Table 6–1 Contract Research Organisations	31
Table 9–1 Trial Products	44
Table 9–2 Start Dose of IDet.....	47
Table 9–3 Increase of IDegAsp or Evening IDet	48
Table 9–4 Reduction of IDegAsp or Evening IDet	48
Table 9–5 Increase of Morning IDet	48
Table 9–6 Reduction of Morning IDet	49
Table 9–7 Titration of Mealtime IAsp.....	49
Table 9–8 Trial Flow Chart	52
Table 9–9 Flow Chart of Phone Contacts.....	54
Table 9–10 9 point Profile (SMPG) (()) with Additional 4 point Profiles (SMPG) (X).....	58
Table 9–11 Specifications Assumed for Sample Size Calculation.....	82
Table 9–12 Sensitivity of Sample Size (Integers) to Variations in SD and Power	83
Table 9–13 Anticipated Number of Subjects in FAS and PP Analysis Set.....	83
Table 9–14 Substantial Amendments.....	84
Table 10–1 Subject Disposition - Summary.....	88
Table 10–2 Important Protocol Deviations	90
Table 11–1 Subject Disposition - Summary.....	93
Table 11–2 Demographics and Baseline Characteristics - Summary - Full Analysis Set.....	95
Table 11–3 Baseline and Diabetes Characteristics - Descriptive Statistics - Full Analysis Set.....	96
Table 11–4 Anti-diabetic Treatment Regimen at Screening - Full Analysis Set.....	97
Table 11–5 Diabetes Complications at Screening - Summary - Full Analysis Set	99
Table 11–6 Confirmatory Statistical Analyses - Full Analysis Set.....	101
Table 11–7 HbA1c (%) after 26 Weeks of Treatment - Primary Statistical Analysis - Full Analysis Set	103
Table 11–8 HbA1c (%) after 26 Weeks of Treatment - Statistical Sensitivity Analysis - PP Analysis Set	104
Table 11–9 Responder for HbA1c at End of Trial – Summary – Full Analysis Set	105
Table 11–10 Responder for HbA1c at End of Trial - Statistical Analysis - Full Analysis Set.....	105
Table 11–11 Responder for HbA1c at End of Trial Without Hypoglycaemia - Summary - Full Analysis Set	106
Table 11–12 HbA1c<7.0% at End of Trial Without Severe Hypoglycaemia - Confirmatory Statistical Analysis - Full Analysis Set.....	107
Table 11–13 Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment - Confirmatory Statistical Analysis - Full Analysis Set.....	109
Table 11–14 Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set	111
Table 11–15 Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set	113
Table 12–1 Exposure - Descriptive Statistics - Safety Analysis Set	118
Table 12–2 Presentations of Insulin Doses in the IDegAsp group.....	119
Table 12–3 IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set	119

Table 12–4 Total Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	121
Table 12–5 Total Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	122
Table 12–6 Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	123
Table 12–7 Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	124
Table 12–8 Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	125
Table 12–9 Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	126
Table 12–10 Insulin Dose Ratio after 26 Weeks of Treatment - Summary - Safety Analysis Set.....	127
Table 12–11 Insulin Doses and Dose Ratio at Week 26	127
Table 12–12 Adverse Events - Treatment Emergent – Summary – Safety Analysis Set.....	129
Table 12–13 Adverse Events by System Organ Class and Preferred Term - Most Frequent (>=5%) – Treatment Emergent - Summary - Safety Analysis Set.....	130
Table 12–14 Adverse Events Possibly or Probably Related to IDegAsp or IDet by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set	134
Table 12–15 Serious Adverse Events – Treatment Emergent - Summary - Safety Analysis Set.....	137
Table 12–16 Serious Adverse Events Possibly or Probably Related to IDegAsp or Comparator by System Organ Class and Preferred Term -Treatment Emergent – Summary - Safety Analysis Set	138
Table 12–17 Subjects with Adverse Events leading to Withdrawal.....	140
Table 12–18 Hypoglycaemic Episodes by Classification – Treatment Emergent – Summary - Safety Analysis Set	142
Table 12–19 Nocturnal Hypoglycaemic Episodes by Classification – Treatment Emergent – Summary - Safety Analysis Set	145
Table 12–20 Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent – Confirmatory Statistical Analysis – Full Analysis Set.....	147
Table 12–21 Cross-reacting Antibodies to Human Insulin (%B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set	150

List of Appendices

16.1 Study Information

- 16.1.1 Protocol and Protocol Amendments
- 16.1.2 Sample Case Report Forms
- 16.1.3 List of Independent Ethics Committees or Institutional Review Boards
- 16.1.4 List and Description of Investigators and Other Important Participants in the Study
- 16.1.5 Signatures of Principal or Coordinating Investigator(s)
- 16.1.6 Listing of Patients Receiving Test Drug(s)/Investigational Product(s) from Specific Batches
- 16.1.7 Randomisation Scheme and Codes
- 16.1.8 Audit Certificates
- 16.1.9 Documentation of Statistical Methods
- 16.1.10 Documentation of Inter-laboratory Standardisation Methods and Quality Assurance Procedures
- 16.1.11 Publications based on the Study
- 16.1.12 Important Publications Referenced in the Report

16.2 Patient Data Listings

- 16.2.1 Discontinued Patients
- 16.2.2 Protocol Deviations
- 16.2.3 Patients Excluded from the Efficacy Analysis
- 16.2.4 Demographic Data
- 16.2.5 Compliance and/or Drug Concentration Data
- 16.2.6 Individual Efficacy Response Data
- 16.2.7 Adverse Event Listings (Each Patient)
- 16.2.8 Listing of Individual Laboratory Measurements by Patient

16.3 Case Report Forms

- 16.3.1 CRFs for Deaths, other Serious Adverse Events, and Withdrawals for AE
- 16.3.2 Other CRFs submitted

16.4 Individual Patient Data Listings (U.S. Archival Listings)

4 List of Abbreviations and Definition of Terms

Abbreviations

ACS	acute coronary syndrome
ADA	American Diabetes Association
AE	adverse event
ALAT	alanine aminotransferase
ANOVA	analysis of variance
AP	alkaline phosphatase
AST	aspartate aminotransferase
BB	basal-bolus
BID	twice daily
BMI	body mass index
CCC	Customer Complaint Centre
CCDS	company core data sheet
CI	confidence interval
CRF	case report form
CPMP/EWP	Committee for Proprietary Medicinal Products/Efficacy Working Party
CRO	contract research organisation
CTR	clinical trial report
CV	coefficient of variance
DBP	diastolic blood pressure
DiabMedSat	Diabetes Medication Satisfaction Questionnaire
DPM	Diabetes Productivity Measure
DUN	dispensing unit number
EAC	external event adjudication committee
ECG	electrocardiogram
eCRF	electronic case report form
EDC	electronic data capture
EMA	European Medicines Agency
FAS	full analysis set
FDA	Food and Drug Administration
FPG	fasting plasma glucose
GCP	Good Clinical Practice
HbA _{1c}	glycosylated haemoglobin A1c
HDL	high density lipoprotein
Hg	mercury
IAsp	insulin aspart
ICH	International Conference on Harmonisation
ID	identification
IDeg	insulin degludec
IDegAsp	insulin degludec/insulin aspart
IDet	insulin detemir
IEC	independent ethics committee
IgE	immunoglobulin E
IGlar	insulin glargine
IRB	independent review board

ITT	intention to treat
IV/WRS	interactive voice/web response system
LDL	low density lipoprotein
LOCF	last observation carried forward
MACE	major adverse cardiovascular event
MAO	monoaminooxidase
MAR	missing at random
MedDRA	Medical Dictionary for Regulatory Activities
MESI	medical events of special interest
NPH	Neutral Protamine Hagedorn
NYHA	New York Heart Association
OD	once daily
PD	protocol deviation
PG	plasma glucose
PP	per protocol
PRO	patient reported outcome
PT	preferred term
PYE	patient years of exposure
SAE	serious adverse event
SBP	systolic blood pressure
SD	standard deviation
SF-36, v2	Short-Form 36 health survey, version 2
SGOT	serum glutamic oxalocetic transaminase
SGPT	serum glutamic pyruvic transaminase
SmPC	summary of product characteristics
SMPG	self-measured plasma glucose
SMQ	Standard MedDRA query
SOC	system organ class
TEAE	treatment emergent adverse event
TG	triglycerides
TMS	Thesaurus Management System
TRIM-D	Treatment Related Impact Measure – Diabetes
U.K.	United Kingdom
U.S.	United States

Definition of Terms

IDegAsp (F): The IDegAsp drug product consists of two drug substances (70 volume% IDeg + 30 volume% IAsp) 100 U/mL

Insulin 454: Synonym previously used for IDeg drug substance

SIAC: Soluble Insulin Analogue Combination, NN5401. Synonym previously used for IDegAsp

5 Ethics

5.1 Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

The protocol, the protocol amendments ([Appendix 16.1.1](#)), the consent form, and the subject information sheet were reviewed and/or approved by health authorities, according to local regulations, and by the local IEC ([Appendix 16.1.3](#)), prior to trial initiation.

5.2 Ethical Conduct of the Trial

The trial was performed in accordance with the "Declaration of Helsinki"¹ and its amendments in force at the initiation of the trial. The trial also followed International Conference on Harmonisation (ICH) Good Clinical Practice (GCP).²

The trial followed the Code of Federal Regulations, Title 21, parts 312, 50 and 56.

5.3 Patient Information and Consent

The subjects were informed verbally and in writing that they could withdraw from the trial at any time for any reason. Consent was to be obtained in writing prior to any trial-related activities and the investigators were to retain the consent forms. The consent forms were available to Novo Nordisk A/S for inspection. The master subject information sheet and consent form are in [Appendix 16.1.3](#).

The subjects were covered by the sponsor's insurance according to local legal requirements.

6 Investigators and Trial Administrative Structure

Trial Sites

The trial was conducted at 79 sites in 9 countries: Denmark (3 sites), Poland (6 sites), Romania (8 sites), France (3 sites), United Kingdom ([U.K.] 8 sites), Russian Federation (11 sites), Israel (4 sites), Australia (7 sites) and United States ([U.S.] 29 sites).

One principal investigator was appointed for each trial site. A list of the principal investigators, sub-investigators and other important persons who were involved in the conduct of the trial, and their curricula vitae are provided in [Appendix 16.1.4](#).

The following investigator has been designated signatory investigator for the trial (see [Appendix 16.1.5](#)):

- 

Sponsor

Novo Nordisk A/S was responsible for the protocol, electronic case report form (eCRF), interactive voice/web response system (IV/WRS) supply of trial products and auxillary supplies, monitoring, data management, statistics and the clinical trial report (CTR). Novo Nordisk A/S also provided a system for electronic data capture (EDC). The system and support services were provided by Phase Forward. Sample CRFs are found in [Appendix 16.1.2](#).

Novo Nordisk A/S has constituted an internal safety committee to perform ongoing safety surveillance. The safety committee was blinded to the treatment but could recommend unblinding of the data to be assessed by an independent ad hoc group if appropriate.

An independent external event adjudication committee (EAC) (see [Appendix 16.1.4](#)) was constituted for the trial to perform ongoing adjudication, standardisation and assessment of cardiovascular events in accordance with predefined classifications. The following events were to be evaluated and adjudicated by the EAC in an independent and blinded manner:

- Acute Coronary Syndrome (including myocardial infarction)
- Stroke
- Cardiovascular death

The titration of insulin doses was monitored by [REDACTED] and reviewed by an internal titration committee composed of members from Novo Nordisk A/S, and any significant changes from the titration algorithm were addressed.

Contract Research Organisation

The following contract research organisations (CROs) were used ([Table 6–1](#)):

[illegible]

Name	Address	Responsibility
EDC		
[REDACTED]	[REDACTED]	[REDACTED]
IV/WRS		
[REDACTED]	[REDACTED]	[REDACTED]
Data management		
[REDACTED]	[REDACTED]	[REDACTED]

All laboratories used identical, standardised analysis methods and reference ranges; see [Appendix 16.1.10](#). Laboratories were responsible for sending the data electronically to Novo Nordisk A/S.

7 Introduction

7.1 Therapeutic Area

Diabetes mellitus is characterised by chronic hyperglycaemia and encompasses various metabolic disorders. It is generally classified according to aetiological factors, where type 1 diabetes mellitus and type 2 diabetes mellitus constitute the vast majority of cases.

The natural pattern of endogenous insulin secretion can be divided into two components: basal secretion and meal-related secretion. Subjects with type 1 diabetes mellitus are lacking insulin secretion entirely and therefore need complete exogenous insulin replacement to cover basal as well as meal-related (bolus) insulin requirements.

A number of landmark studies have demonstrated the importance of maintaining tight glycaemic control to reduce the risk of long-term complications associated with type 1 diabetes mellitus.³⁻⁶ In general, it is recommended to aim for an glycosylated haemoglobin (HbA_{1c}) < 7.0%, without significant hypoglycaemia.⁷

Insulin analogues have been developed to closely mimic endogenous insulin secretion as compared with human insulin preparations and are now an established part of diabetes management. Currently, insulin detemir (IDet) and insulin glargine (IGlar) cannot be mixed with any rapid-acting insulin analogues due to formulation issues.⁸⁻¹¹ This has prompted the development of insulin degludec (IDeg), an ultra-long-acting insulin that is intended for use as a basal insulin as well as in a co-formulation with insulin aspart (IAsp).

7.2 IDegAsp

Insulin degludec/insulin aspart (IDegAsp) is a combination of ultra-long-acting IDeg with rapid-acting IAsp, formulated to maintain the ability of IDeg to form multi-hexamers at the injection site without interfering with the rapid release of IAsp monomers into the circulation. IDegAsp is formulated such that IDeg exists as di-hexamers and IAsp as hexamers. After subcutaneous injection, IDeg di-hexamers assemble to form soluble and stable multi-hexamers, creating a depot of insulin in the subcutaneous tissue, while IAsp hexamers promptly separate into monomers that rapidly enter the circulation. IDeg monomers gradually separate from the multi-hexamers, resulting in a slow and continuous delivery of IDeg into the circulation.

IDegAsp will provide main meal coverage as well as at least 24-hour basal coverage for people with diabetes mellitus when used once daily, and will therefore offer distinct advantages (i.e., greater ease of use and compliance, and reduced hypoglycaemia) over existing insulin therapies. As IDegAsp is soluble, the product can be injected immediately, without any mixing

IDeg differs from human insulin in that the threonine in position B30 has been omitted, and a side-chain consisting of a glutamic acid spacer with a fatty acid attached to position B29.

IAsp is homologous to human insulin, except that proline is substituted with aspartic acid at position B28. The rapid action of IAsp is related to a weakened tendency of the insulin molecules to self-associate because of this modification, leading to faster absorption as compared with human insulin.

IDegAsp is designed to result in similar or improved glycaemic control compared to treatment with currently available insulin products. The basal component of IDegAsp, IDeg, is even longer-acting than currently available basal insulin analogues.¹² This is believed to result in an even more stable and predictable insulin profile with lower day-to-day variation in fasting plasma glucose (FPG) than those attained with the currently available insulin analogues. A significantly (four times) lower within-subject variability in glucose-lowering activity compared with IGlax has recently been demonstrated.¹³

7.3 IDet

IDet (Levemir[®]) is a long-acting soluble insulin analogue, indicated for treatment of diabetes mellitus in combination with oral antidiabetic agents and as part of a basal-bolus insulin regimen.

In IDet, the threonine at position B30 of the human insulin molecule has been omitted, and a C14 fatty-acid side-chain has been attached directly to position B29.¹⁴

The protracted action of IDet (up to 24 h) is mediated by strong self-association of IDet molecules at the injection site and albumin binding via the fatty-acid side-chain. These combined mechanisms of protraction provide a more reproducible absorption and action profile of IDet with less pronounced peak effect and lower within-subject variation, compared to Neutral Protamine Hagedorn (NPH) insulin, thus providing lower mean and day-to-day variability in FPG, lower risk of nocturnal hypoglycaemia and less body-weight gain.¹⁵⁻¹⁷

For further details, refer to the current versions of summary of product characteristics (SmPC) for IDet and the U.S. Label Information and any updates of these documents.^{8,9}

7.4 IAsp

IAsp (NovoRapid[®], NovoLog[®]) is a rapid-acting analogue indicated for the treatment of diabetes mellitus. IAsp is also one of the active substances in IDegAsp (see above).

Compared with human insulin, IAsp has a faster onset and a shorter duration of action, resulting in superior postprandial glycaemic control by means of lowering total glucose excursion following a meal, both in subjects with type 1 diabetes mellitus,¹⁸⁻²⁰ and in subjects with type 2 diabetes

mellitus.²¹⁻²³ This also allows IAsp to be injected immediately before (or even soon after) a meal, in contrast to soluble human insulin products.

For further details, refer to the current version of the SmPC²⁴ and the U.S. Label Information²⁵ and any updates of these documents.

7.5 Rationale for the Trial

Standard care in type 1 diabetes mellitus is the basal-bolus (BB) therapy, where short-acting insulin is injected prior to each meal and long-acting insulin is injected once daily (OD) or twice daily (BID) to cover the basal insulin requirements. This regimen has proven to be successful in reducing the incidence of late diabetic complications as shown in the Diabetes Control and Complication Trial.³ However, low and relatively constant basal insulin levels are difficult to obtain with the currently available long-acting insulin preparations. IDegAsp represents a new class of soluble insulin combination products comprising the ultra-long-acting basal insulin, IDeg, and the rapid-acting insulin, IAsp. Treatment with IDegAsp OD has shown to provide prandial coverage of the main meal on top of a stable, ultra-long-acting basal coverage in subjects with type 2 diabetes mellitus.¹³ Thus, treatment with IDegAsp OD plus IAsp for the additional meals is expected to offer a safe and intensive treatment regimen with the convenience of fewer injections than the current BB regimens. Clear separation of the bolus and basal component in IDegAsp gives the possibility for dosing IDegAsp at any meal and to change the time of injection. It is expected that the stable activity profile and long duration of action of the basal component is largely unaffected by the timing of the IDegAsp dose.

This trial will be used to document the efficacy and safety in subjects with type 1 diabetes mellitus, of BB treatment with IDegAsp administered OD at any meal in combination with IAsp.

All subjects in this trial were offered to participate in a 26-week extension trial subsequent to the follow-up visit, with the purpose of investigating long-term safety and compare efficacy after 52 weeks of treatment.

8 Trial Objectives

As stated in the protocol and amendments, (included in [Appendix 16.1.1](#)), the objectives of the trial were as follows:

Primary Objective:

To confirm efficacy of IDegAsp OD + meal-time IAsp for the remaining meals in controlling glycaemia with respect to change from baseline in HbA_{1c} after 26 weeks of treatment. This was done by comparing the difference in change from baseline in HbA_{1c} after 26 weeks of treatment between IDegAsp OD + meal-time IAsp for the remaining meals and IDet + meal-time IAsp to a non-inferiority limit of 0.4%, and if non-inferiority was confirmed to a superiority limit of 0%.

Secondary Objectives:

To confirm superiority of IDegAsp OD + meal-time IAsp for remaining meals over IDet + meal-time IAsp after 26 weeks of treatment in terms of:

- FPG measured at a central laboratory
- Frequency of responders for HbA_{1c} without hypoglycaemic episodes
- Nocturnal hypoglycaemic episodes

To compare efficacy and safety after 26 weeks of treatment in terms of:

- 9-point profile, self-measured plasma glucose (SMPG)
- SMPG for dose adjustments
- Frequency of responders for HbA_{1c}
- Adverse events (AEs)
- Hypoglycaemic episodes
- Clinical and laboratory assessments
- Insulin antibodies
- Body weight
- Insulin dose
- Patient reported outcome (PRO)

9 Investigational Plan

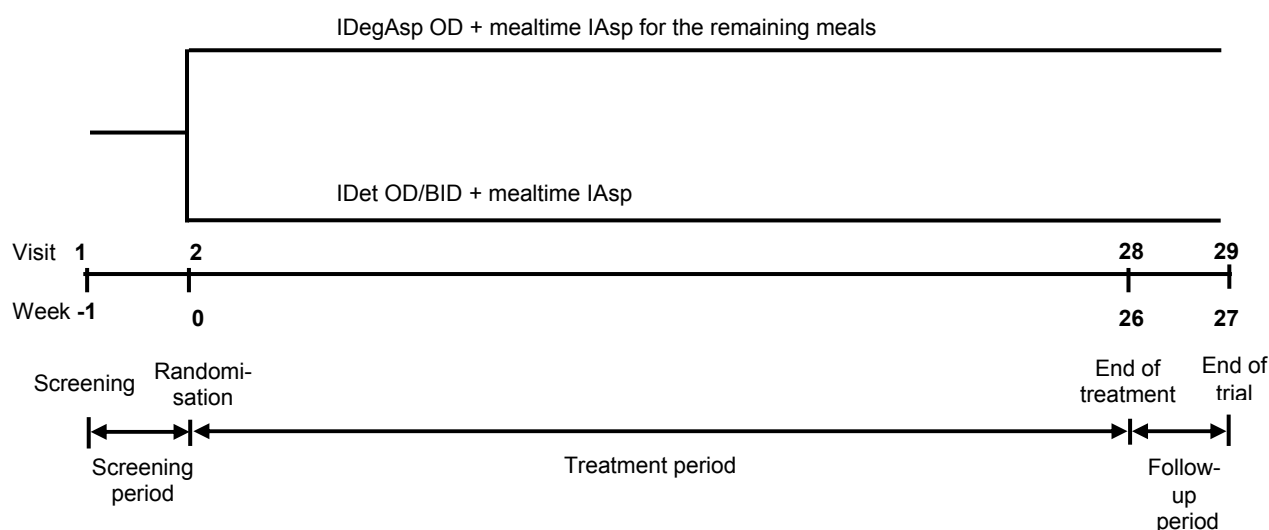
9.1 Overall Trial Design and Plan: Description

This trial was a multinational, multi-centre, open-labelled, randomised (2:1), two-arm parallel group, efficacy/safety trial of 26 weeks' duration comparing IDegAsp OD + mealtime IAsp with IDet + mealtime IAsp in subjects diagnosed with type 1 diabetes mellitus. IDegAsp was dosed OD with the meal that ensured the most optimal coverage of both basal and bolus requirements, and IDet was dosed OD in the evening with the possibility of switching to BID dosing after 8 weeks of treatment (see Section 9.4.5). Stratification was carried out according to previous insulin regimen with the categories BB regimen or other insulin regimen. There was a 1-week follow-up period after the 26 weeks treatment period, in which subjects were treated with NPH insulin BID + mealtime IAsp.

The trial population constituted a typical population with type 1 diabetes mellitus who would benefit from intensified therapy, applying a treat-to-target concept.

The randomisation was carried out in a 2:1 manner to IDegAsp OD (at any meal) and IAsp at the remaining meals or IDet and mealtime IAsp.

For a schematic overview of the trial design, refer to [Figure 9–1](#) below.



IDegAsp = insulin degludec/insulin aspart; IDet = insulin detemir; OD = once daily

Figure 9–1 Trial Design

The planned number of subjects to be screened (754), randomised (528) and complete the trial (447) was based on the sample size calculation outlined in Section 9.7.10.

All subjects were offered to participate in a 26-week extension trial (NN5401-3645) following the 1-week follow-up period. The purpose of the extension trial was to investigate long-term safety and to compare efficacy after 52 weeks of treatment. A separate protocol, subject information and informed consent form was prepared for the extension trial. Verbal and written information was provided to the subjects and the informed consent form was signed by the subject and the investigator.

See Section [9.5.1.1](#) for detailed flow charts summarising the frequency and timing of visits and the assessments performed at each visit.

No interim analyses were performed in this study. An internal Novo Nordisk A/S safety committee performed ongoing safety surveillance during the trial. The titration of insulin doses was monitored by [REDACTED] and reviewed by an internal titration committee composed of members from Novo Nordisk A/S, and any significant changes from the titration algorithm were addressed.

9.2 Discussion of Trial Design, Including the Choice of Control Groups

Control Groups

IDet and mealtime IAsp were the active controls in the trial.

Trial Design

The parallel design was chosen instead of a cross-over design in order to avoid the risk of a carry-over effect and to keep the treatment period as short as possible.

The 26-week treatment period was expected to be sufficient to initiate and optimise the new treatment regimens and to evaluate the effect as measured by HbA_{1c}. Likewise, an exposure period of this duration was considered appropriate to confirm the safety of IDegAsp. The 26 weeks of treatment was followed by at least 7 days follow-up to ensure that all IDegAsp was washed out when measuring insulin antibodies.

The multinational approach was to ensure that the results were applicable for subjects with different ethnic/racial characteristics across regions.

The weekly visits/phone contacts were chosen to ensure:

- Optimal titration based on SMPG values
- Optimisation of compliance

Assignment and Blinding

The subjects were randomised in a 2:1 manner using an IV/WRS. See Section [9.4.3](#) for further details regarding treatment allocation.

An open-label trial design was chosen as the two treatment regimens required different number of daily injections, and the unequal randomisation was performed in order to ensure an adequate number of subjects exposed to IDegAsp in the entire clinical programme.

9.3 Selection of Trial Population

9.3.1 Inclusion Criteria

1. Informed consent obtained before any trial-related activities. (Trial related activities were defined as any procedure that would not have been performed during normal management of the subject)
2. Male or female ≥ 18 years of age
3. Type 1 diabetes mellitus (diagnosed clinically) for ≥ 12 months
4. Ongoing daily treatment with insulin (in a BB regimen, premix insulin regimen, self-mix regimen) for at least 12 months prior to Visit 1
5. HbA_{1c} 7.0-10.0% (both inclusive) by central laboratory analysis
6. Body mass index (BMI) ≤ 35.0 kg/m²
7. Ability and willingness to adhere to the protocol including performance of SMPG profiles according to the protocol
8. Subject was likely to comply with the investigators instruction.

Rationale for Inclusion Criteria

The bullet numbers correspond to the numbering of the inclusion criteria.

1. In accordance with the Helsinki Declaration, human subjects had to consent participation in a clinical trial
2. As adolescents are not the focus in the current stage of the development program, the inclusion of adolescents are not warranted in accordance with the Helsinki Declaration and ICH guidelines
3. To assure certainty of type 1 diabetes mellitus diagnosis
4. All subjects required insulin and were used to inject themselves with insulin and perform SMPG
5. In order to assure that the subjects were able to control the disease to a certain degree, an upper limit of HbA_{1c} was included. An HbA_{1c} of < 7.0 % is the identified goal for good glycaemic control by the ADA. Subjects optimized on current anti-diabetic therapy with an HbA_{1c} $\geq 7.0\%$ are considered in focus for additional antidiabetic therapy.
6. To include a wide distribution of subjects while limiting participation of individuals with severe insulin resistance
7. Self-explanatory
8. Self-explanatory

9.3.2 Exclusion Criteria

1. Treatment with other insulin regimens than those listed in inclusion criterion number 4 within 3 months prior to Visit 1
2. BB regimen with basal insulin injected BID
3. Use within the last 3 months prior to Visit 1 of any other antidiabetic glucose lowering drug than insulin
4. Anticipated change in concomitant medication known to interfere significantly with glucose metabolism, such as systemic corticosteroids, beta-blockers, monoaminooxidase (MAO) inhibitors
5. Anticipated significant lifestyle changes during the trial, shift work (including permanent night/evening shift workers), as well as highly variable eating habits
6. Cardiovascular disease, within the last 6 months prior to Visit 1, defined as: stroke; decompensated heart failure New York Heart Association (NYHA)²⁶ class III or IV; myocardial infarction; unstable angina pectoris; or coronary arterial bypass graft or angioplasty
7. Uncontrolled treated/untreated severe hypertension (systolic blood pressure ≥ 180 millimetre [mm] mercury [Hg] and/or diastolic blood pressure ≥ 100 mmHg)
8. Impaired liver function, defined as alanine aminotransferase (ALAT) ≥ 2.5 times upper limit of normal (1 retest analysed at the central laboratory within a week of receipt of the results was permitted with the result of the last sample being conclusive)
9. Impaired renal function defined as serum-creatinine ≥ 180 $\mu\text{mol/L}$ (≥ 2 mg/dL). One (1) retest analysed at the central laboratory within a week of receipt of the results was permitted with the result of the last sample being conclusive
10. Recurrent severe hypoglycaemia (more than 1 severe hypoglycaemic event during the last 12 months) or hypoglycaemic unawareness as judged by the investigator or hospitalisation for diabetic ketoacidosis during the previous 6 months
11. Proliferative retinopathy or maculopathy requiring treatment according to the investigator
12. Pregnancy, breast-feeding, the intention of becoming pregnant or not using adequate contraceptive measures according to local requirements (for Germany: implants, injectables, combined oral contraceptives, hormonal intrauterine device, sexual abstinence or vasectomised partner; for U.K.: Adequate contraceptive measures were defined as established use of oral, injected or implanted hormonal methods of contraception, sterilisation, intrauterine device or intrauterine system, or consistent use of barrier methods)
13. Cancer and medical history of cancer (except basal cell skin cancer or squamous cell skin cancer)
14. Any clinically significant disease or disorder, which in the investigator's opinion could have interfered with the results of the trial
15. Mental incapacity, psychiatric disorder, unwillingness or language barriers precluding adequate understanding or co-operation, including subject not able to read or write
16. Previous participation in this trial. Participation was defined as randomised. Re-screening of screening failures was allowed only once within the limits of the recruitment period.

17. Known or suspected allergy to any of the trial products or related products
18. Receipt of any investigational drug within 1 month prior Visit 1
19. Donation of blood or participation in other trials within 1 month prior to Visit 1.
20. Known or suspected abuse of alcohol, narcotics or illicit drugs

Subjects randomised in error (not fulfilling the inclusion and/or exclusion criteria) were to be withdrawn immediately from the trial.

Rationale for Exclusion Criteria

The bullet numbers correspond to the numbering of the exclusion criteria.

1. Only subjects treated with an insulin regimen typical for type 1 diabetes mellitus (as listed in inclusion criteria number.4) were included in this trial
2. For safety reasons all subjects were to start the trial on basal insulin OD
3. To minimise confounding factors in assessment of IDegAsp effect on HbA_{1c}
4. Changes in dose of drugs interfering significantly with the glucose levels were not allowed as they could have influenced HbA_{1c} (the primary endpoint)
5. For safety reasons since IDegAsp has a prandial insulin component
6. Including subjects with serious and recently active heart conditions, as the ones listed, in a treat-to-target trial could have created a higher risk than benefit
7. Including subjects with severe uncontrolled hypertension in a treat-to-target trial would have created a higher risk than benefit
8. Including subjects with liver enzyme values indicating impaired liver function was a safety issue
9. Including subjects with advanced renal disease in a treat-to-target trial could have created a higher risk than benefit
10. Including subjects with recurrent severe hypoglycaemia or hypoglycaemic unawareness in a treat-to-target trial could have created a higher risk than benefit
11. Including subjects with proliferative retinopathy or maculopathy requiring treatment in a treat-to-target trial could have created a higher risk than benefit due to the risk of worsening of the condition
12. Standard requirement for participation in clinical trials with new chemical or biological entities
13. Cancer is a severe condition associated with increased mortality. It may affect different organs with a variety of types, and be at different stages. Since it was impossible to be specific for each of the types/stages, subjects with known cancer were not included in the trial due to increased mortality risk due to cancer. In addition, participation in a trial could have been an additional burden for the subject on top of the treatment and diagnostic procedures related to their cancer. Subjects with history of any cancer were not included for the same reasons, as to exclude the possibility of its recurrence or actual presence even in the cases of 5-year (or longer) survival. Subjects with basal cell skin cancer or squamous cell skin cancer were allowed as these cancers were not associated with high mortality risk

14. These conditions could have confounded trial results
15. To avoid inclusion of subjects that could not have been able to adhere to trial treatment and procedures
16. Standard requirement for participation in clinical trials
17. To avoid risk of allergic reactions as they could have put the subjects at risk
18. Standard requirement for participation in clinical trials
19. Donating blood could have lowered HbA_{1c} and thus could have influenced key inclusion criteria
20. Subjects abusing alcohol, narcotics or illicit drugs could be unable to adhere to trial treatment and procedures

9.3.3 Removal of Subjects from Therapy and Assessment

The subject could choose to withdraw from the trial at any time.

The subject could be withdrawn from the trial at the discretion of the investigator due to safety concerns or if judged non-compliant with trial procedures.

A subject was to be withdrawn if the following applied:

1. Pregnancy or intention of becoming pregnant
2. Hypoglycaemia during the treatment period posing a safety problem as judged by the investigator
3. Protocol deviation having influence on efficacy or safety data as judged by the investigator
4. Subjects randomised in error (not fulfilling the inclusion and/or exclusion criteria)
5. Initiation or significant change of any systemic treatment which in the investigator's opinion could have interfered with glucose metabolism (inhaled corticosteroids were allowed)
6. Donation of blood or participation in other trials throughout the trial
7. Lack of effect: After Week 12, if the subject had not had reduction in HbA_{1c} and had a prebreakfast SMPG reading > 13.3 mmol/L (240 mg/dL) on 3 consecutive days despite appropriate dose adjustments. The subject contacted the investigator and came in for an unscheduled visit as soon as possible (within 1 week). The next scheduled visit was not awaited. An FPG was obtained and analysed by the central laboratory. If this FPG exceeded 13.3 mmol/L (>240 mg/dL) and no treatable intercurrent cause for the hyperglycaemia was diagnosed, the subject was withdrawn.

Rationales for Withdrawal Criteria

The bullet numbers correspond to the numbering of the withdrawal criteria.

1. Standard requirement for clinical trials with new chemical or biological entities
2. Safety issue
3. Important protocol deviations had to be considered by the investigator if they had influenced on efficacy and safety
4. Self-explanatory

5. Changes in dose of drugs interfering significantly with the glucose levels were not allowed as they could have influenced HbA_{1c} (the primary endpoint)
6. Donating blood could have lowered HbA_{1c} and thus influenced key efficacy criteria. It is a standard requirement that participation in another trial was not allowed
7. Subjects could not be exposed for a long time to ineffective treatment. Twelve (12) weeks reflected clinical practice to allow adequate titration and obtain a valid HbA_{1c} measurement

A withdrawn subject was to be called in for a follow-up visit minimum 1 week after the last treatment and within the allowed visit window. See [Table 9–8](#) and [Table 9–9](#) for further details.

In case a subject was being prematurely withdrawn from the trial, the investigator was to ensure that the procedures for Visit 28 (end-of-treatment visit) and Visit 29 (follow-up visit) were to be undertaken, if possible. Subjects were to be switched to NPH insulin and mealtime IAsp at the end-of-treatment visit until the follow-up visit (if these were done on different days).

A withdrawal session had to be completed in the IV/WRS. The primary reason (AE, non-compliance with protocol or other) for discontinuation was to be specified in the eCRF. Even if the subject was not able to attend the visit, trial products were to be returned, the end of trial form was to be completed, the drug accountability in IV/WRS was to be performed and the affirmation statement (case book) was to be signed.

If the subject withdrew their previously given informed consent, the subject's data were to be handled as follows:

- Data collected were to be used as part of the per protocol (PP) population/full analysis set (FAS) according to the intention to treat (ITT) principle
- Safety events were to be reported to International Product Safety, Novo Nordisk A/S and/or regulatory authorities

Subjects who were withdrawn after randomisation were not replaced. Predicted withdrawal rate was 15%; see Section [9.7.10](#).

9.4 Treatments

9.4.1 Treatments Administered

All insulin products used in this trial were to be injected in the abdomen, upper arm (deltoid region) or thighs. Rotation of injection sites within a given region was to be recommended.

All subjects randomised to IDegAsp were to be instructed to administer IDegAsp OD at any main meal as described in Section [9.4.5](#). IAsp was used for bolus administration at the remaining main meals and was to be injected just before the meals.

All subjects randomised to IDet were to be instructed to initiate IDet OD. IDet was to be dosed at the evening meal or at bedtime according to local practice, and as described in Section 9.4.5. IAsp was used for bolus administration and was to be injected just before each main meal. In case of inadequate glycaemic control at Visit 10 or later (i.e., after at least 8 weeks of treatment and optimisation of dosing), the investigator was to consider adding a second dose of IDet in the morning, based on the fulfilment of specific criteria, as listed in Section 9.4.4.

During the treatment period the dose of insulin was adjusted according to SMPG measurements. The insulin dose adjustments were to follow the titration guidelines stated in the protocol. A central titration committee at Novo Nordisk A/S followed up on repeated deviation from the titration algorithm.

At visit 28 (end of treatment), subjects were instructed to switch basal insulin treatment to the intermediate-acting insulin NPH injected BID + mealtime IAsp until the follow-up visit (Visit 29).

Refer to sections 9.4.4 and 9.4.5 for details about dosing of the insulin products.

9.4.2 Identity of Investigational Products

The trial products during the treatment were as follows:

- IDegAsp 100 U/mL, 3 mL FlexPen®
- IDet (Levemir®) 100 U/mL, 3 mL FlexPen®
- IAsp (NovoRapid®, NovoLog®) 100 U/mL, 3 mL FlexPen®
- NPH Insulin (Insulatard®, Protaphane®, Novolin N™) 100 U/mL, 3 mL FlexPen®

Novo Nordisk A/S, Denmark, provided the trial products. Details of the preparations including batch numbers are shown in Table 9–1. For batch numbers for each subject, refer to Appendix 16.1.6.

Table 9–1 Trial Products

Trial Product	Dose	Batch Number	Expiry Date
IDegAsp (F) 100 U/mL, 3 mL FlexPen®	Individual	XP50558	07 January 2011
IDet (Levemir®) 100 U/mL, 3 mL FlexPen®	Individual	EU, AU, IO: XP51112	19 February 2011
		U.S.: XP50990	28 February 2011
IAsp (NovoRapid®, NovoLog®) 100 U/mL, 3 mL FlexPen®	Individual	EU, AU, IO: XP50716	15 July 2011
		U.S.: XP51084	12 September 2011
NPH Insulin (Insulatard®, Protaphane®, Novolin N™) 100 U/mL, 3 mL FlexPen®	Individual	XP51117	19 April 2011

AU = Australia; EU = European union; IDegAsp = insulin degludec/insulin aspart; IDet = insulin detemir; IAsp = insulin aspart; IO = International Operations (Israel, Russian Federation); NPH = Neutral Protamine Hagedorn; U.S. = United States.

All insulin products were administered via the FlexPen[®] insulin delivery device and were to be stored between 2°C and 8°C and were not allowed to freeze. The investigator was to ensure the availability of proper storage conditions and keep a temperature log to document the right temperature interval. The temperatures during storage were to be monitored by a calibrated, stationary and continuously recording system. In case of storage outside the temperature range the investigator was to contact the monitor. Trial products stored outside the temperature range were not to be used and were to be stored separately within allowed temperature ranges until after evaluation of condition performed by Novo Nordisk A/S. Fifteen (15) minutes outside the indicated range was considered negligible and allowed, and were not to be recorded as a deviation. Returned trial product(s) (partly used or unused including empty packaging material) was to be stored separately from non-allocated trial products.

Once opened (i.e., during use), IDet and NPH insulin were to be stored according to approved labelling. IDegAsp was to be kept at a temperature below 30°C and was not to be refrigerated. Insulin preparations (both not in-use and in-use) were not to be exposed to excessive heat or direct sunlight. The product was not to be used if it did not appear clear and colourless.

Trial products were packaged and labelled by Novo Nordisk A/S, Denmark. Labelling was in accordance with local law and trial requirements. Each investigator site was to be supplied with sufficient trial products for the trial on an ongoing basis controlled by the IV/WRS. Dispensing units were to be prepared and distributed to the sites according to enrolment and randomisation. Note that the trial product labelling was different from the labelling of the marketed or to be marketed products.

The subjects were to be provided with directions for the use of IDegAsp, IAsp, IDet and NPH insulin. These were to be distributed separately by the investigator according to the flow charts (see [Table 9–8](#) and [Table 9–9](#)). The distribution was to be documented in the subject notes.

None of the insulin products were used after the expiry date.

Auxiliary Supply

The following were also supplied by Novo Nordisk A/S:

- Needles for insulin pens
- Blood glucose meters, including lancets, plasma-calibrated test strips and control solutions

9.4.3 Method of Assigning Patients to Treatment Groups

Subjects enrolled in the trial at Visit 1 were to be provided with a Subject Participation Card stating that the subject was participating in the trial and contact details (site address, investigator name and telephone number). Eligible subjects were to be randomised in a 2:1 manner using an IV/WRS to 1 of the following 2 treatment groups:

- IDegAsp OD + IAsp
- IDet OD + IAsp

This unequal randomisation was performed in order to ensure an adequate number of subjects were exposed to IDegAsp during the clinical development program.

Randomisation was stratified with respect to previous insulin regimen with the categories

- BB regimen or
- Other insulin regimen

The randomisation scheme is provided in [Appendix 16.1.7](#).

9.4.4 Selection of Doses in the Trial

Initiation of IDegAsp + IAsp

Subjects Currently on Basal-Bolus Therapy

Subjects were to be initiated on the same number of basal unit as the subject received prior to randomisation, based on results from the clinical pharmacology trials and phase 2 trials. When transferring the subjects to the treatment with IDegAsp, a switch table was to be used (see Appendix C of the Protocol in [Appendix 16.1.1](#)). The table provides information on the exact amount of basal and bolus units and the corresponding number of IDegAsp units.

Subjects Currently on Premix/Self-mix Therapy

Based on data from previous studies performed in the same regions as this trial, subjects were to initiate the IDegAsp regimen with an approximately 1:1 ratio between basal and bolus insulin. Current total daily insulin dose (before randomisation) was to be calculated, and 70% of the total daily insulin dose was to be prescribed as IDegAsp OD, while 30% of the total daily insulin dose was to be split and given as IAsp at the remaining main meals.

Refer to section [9.4.5](#) for details on the titration of IDegAsp and IDet.

Initiation of IDet + IAsp

For subjects randomised to IDet + IAsp the starting dose of IDet should be determined according to [Table 9–2](#).

Table 9–2 Start Dose of IDet

Prior treatment	Start dose of IDet once daily
NPH or other basal insulin	Prescribe the same number of units once daily at the evening meal or at bedtime.
Premixed or self-mixed insulin	Calculate the total daily basal insulin component and prescribe the same total daily basal dose as IDet given once daily at the evening meal or at bedtime. If prior basal insulin component was taken more than once daily, dose reduction should be considered according to the investigator's discretion.

IDet: insulin detemir; NPH: Neutral Protamine Hagedorn

Similarly, the subjects were to continue the same doses of IAsp at mealtime as taken prior to randomisation; see Appendix C of the Protocol in [Appendix 16.1.1](#) for details.

Initiation of a Second Dose of IDet

In case of inadequate glycaemic control at Visit 10 or later (i.e., after at least 8 weeks of treatment and optimisation of dosing), the investigator was to consider adding a second dose of IDet if the following three criteria were fulfilled:

- Lack of improvement in glycaemic control, i.e.
 - For subjects with baseline HbA_{1c} < 8.0%: any deterioration of HbA_{1c} or
 - For subjects with baseline HbA_{1c} between 8.0% and 10%: (both inclusive): improvement in HbA_{1c} which was less than 0.5 %-point
- Mean predinner PG > 6.0 mmol/L (108 mg/dL)
- No treatable concurrent disease causing hyperglycaemia had been diagnosed

The second dose of IDet was to be started at 4U at breakfast.

9.4.5 Selection and Timing of Dose for Each Subject

Titration of Basal Insulin (IDegAsp or IDet Evening Dose)

Subjects randomised to IDegAsp were to inject IDegAsp OD with the meal that ensured the most optimal coverage of both basal and bolus insulin requirements for the prescribed IDegAsp dose, as decided by the investigator and subject together. IDegAsp could be injected at any of the main meals but was only to be injected OD. Furthermore, the injection of IDegAsp could be moved to another main meal during the course of the trial. Subjects randomised to treatment with IDet were to inject IDet OD at the evening meal or at bedtime, according to local practice and at the same time each day. Increase of IDegAsp or IDet dose was to be done based on the mean prebreakfast plasma

glucose (PG) from the preceding 3 days. The insulin dose adjustments were to be performed according to the titration guidelines shown in [Table 9–3](#) and [Table 9–4](#) (see Appendix C of the Protocol in [Appendix 16.1.1](#)).

Table 9–3 Increase of IDegAsp or Evening IDet

Mean prebreakfast PG		Adjustment of IDegAsp or IDet U
mmol/L	mg/dL	
< 5.0	< 90	No adjustment
< 10.0	< 180	+ 2
< 15.0	< 270	+ 4
≥ 15.0	≥ 270	+ 6

PG = Plasma Glucose; IDegAsp = Insulin degludec/insulin aspart; IDet = insulin detemir

If one or more low PG values occurred without any obvious explanation, the IDegAsp or IDet dose was to be reduced according to the lowest SMPG value, see [Table 9–4](#).

Table 9–4 Reduction of IDegAsp or Evening IDet

Prebreakfast PG		Adjustment of IDegAsp or IDet U
mmol/L	mg/dL	
< 3.1	< 56	- 4 (for a dose of >45 U, suggest a dose reduction of 10%)
≤ 3.9	≤ 70	- 2 (for a dose of >45 U, suggest a dose reduction of 5%)

PG = Plasma glucose; IDegAsp = Insulin degludec/insulin aspart; IDet = insulin detemir

Titration of Morning IDet

Increase of the morning IDet dose was to be based on the mean predinner PG from the preceding 3 days using the titration algorithm in [Table 9–5](#).

Table 9–5 Increase of Morning IDet

Mean predinner PG		Adjustment of IDet U
mmol/L	mg/dL	
< 5.0	< 90	No adjustment
< 10.0	< 180	+ 2
< 15.0	< 270	+ 4
≥ 15.0	≥ 270	+ 6

PG = plasma glucose; IDet = insulin detemir

If one or more low PG values occurred without any obvious explanation, the dose of IDet was reduced according to the lowest SMPG value, see [Table 9–6](#).

Table 9–6 Reduction of Morning IDet

Predinner PG		Adjustment of IDet U
mmol/L	mg/dL	
< 3.1	< 56	- 4 (for a dose of >45 U, suggest a dose reduction of 10%)
≤ 3.9	≤ 70	- 2 (for a dose of >45 U, suggest a dose reduction of 5%)

PG = plasma glucose; IDet = insulin detemir

Titration of Bolus Insulin (IAsp)

Any increase of the IAsp was to be based on the mean pre-prandial PG using the titration algorithm [Table 9–7](#).

Table 9–7 Titration of Mealtime IAsp

Mean premeal PG		Adjustment of IAsp U
mmol/L	mg/dL	
< 5.0	< 90	0
< 8.0	< 144	+2
< 10.0	< 180	+3
≥ 10.0	≥ 180	+4

PG = plasma glucose; IAsp = insulin aspart

The prebreakfast IAsp dose was to be titrated according to the mean prelunch PG. The prelunch IAsp dose was to be titrated according to the mean predinner PG. The predinner IAsp dose was to be titrated according to the mean bedtime PG. The subject was allowed to inject an additional bolus dose of IAsp in order to cover an additional main meal.

Treatment with NPH Insulin During Follow-up

At Visit 28, subjects in both treatment groups were instructed to switch to treatment with NPH insulin for the 1-week follow-up period. Since NPH insulin is an intermediate-acting insulin, it was to be administered BID. Subjects randomised to IDet + IAsp were to reduce their total daily basal dose at end of treatment by 20% and divide by two to be administered morning and evening. Subjects randomised to IDegAsp + IAsp were to determine their total daily basal dose at end of treatment, reduce it by 20% and divide by 2 to be administered morning and evening. IAsp was used for bolus administration and was to be injected just before each main meal.

9.4.6 Blinding

This was an open-label trial and there was no blinding of investigators and subjects.

See Section [9.2](#) for further details regarding assignment and blinding of trial products.

9.4.7 Prior and Concomitant Therapy

Details of all concomitant illnesses, medical history and concomitant medication were to be recorded at trial entry (i.e., at Visit 1). Any changes in concomitant medication were to be recorded at each subsequent visit. If the change in concomitant medication influenced the subject's eligibility to continue in the trial, the sponsor was to be informed.

Concomitant Illness

Concomitant illness was defined as any illness present at the start of the trial (i.e. Visit 1).

Concomitant Medication

Concomitant medication was defined as any medication other than the trial products that was taken during the trial, including at screening.

The following medications and treatments were not allowed in this trial and are listed in the exclusion criteria in Section [9.3.2](#) and withdrawal criteria in Section [9.3.3](#).

1. Treatment with other insulin regimens than those listed in inclusion criterion number 4 within 3 months prior to Visit 1
2. BB regimen with basal insulin injected BID
3. Use within the last 3 months prior to Visit 1 of any other antidiabetic glucose lowering drug than insulin
4. Anticipated change in concomitant medication known to interfere significantly with glucose metabolism, such as systemic corticosteroids, beta-blockers and MAO inhibitors

9.4.8 Treatment Compliance

At each visit, the investigator was to emphasise the necessity for the subject to adhere to trial procedures in order to encourage subject compliance. The subject compliance was to be assessed by monitoring of drug accountability at Visits 6, 10, 18, 28 and 29 (see Section [9.5.1.1](#)). The unused amount of trial product was to be assessed against the dispensed amount and, in case of discrepancies; the subject was to be asked. Substantial failure to comply with the prescribed insulin dosage regimen was to lead to withdrawal of the subject.

In addition, the investigator was to assess the compliance of the subject at each visit based on a review of glycaemic control, adherence of the visit schedule, completion of the subject's diary including the SMPG profiles. If a subject was discovered to be non-compliant, the investigator was to inform the subject of the importance of taking trial products as directed.

9.5 Efficacy and Safety Variables

9.5.1 Efficacy and Safety Measurements Assessed and Flow Chart

9.5.1.1 Flow Chart

The trial consisted of a screening visit (Visit 1), a 26-week treatment period (Visit 2 to Visit 28) after which a follow-up visit (Visit 29) was to be performed.

Procedures for the scheduled visits and phone contacts are described in the section below and in the flowcharts (see [Table 9–8](#) and [Table 9–9](#)).

If a planned phone contact for some reason was not performed according to the visit schedule, the investigator was to ensure that the phone contact was performed within 3 working days after the originally planned phone contact.

Table 9–8 Trial Flow Chart

Trial NN5401-3594 Type 1	Screen	Rand	0-26 weeks Visit window ±3 days														FU
Visit Number (V)	V1	V2	V3	V4	V6	V8	V10	V12	V14	V16	V18	V22	V26	V28	V29		
 Phone Contact number (P) ¹ (For details see separate flowchart below)	P5 P7 P9 P11 P13 P15 P17 P19 P23 P27 P20 P24 P21 P25																
Time of visit ⁴ (weeks)	-1 ²	0	1	2	4	6	8	10	12	14	16	20	24	26	27 ³		
Visit window (days)			±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	-3	+5		
SUBJECT RELATED INFO/ASSESSMENTS																	
Informed consent	x																
In/Exclusion criteria	x	x															
Randomisation		x ⁵															
Withdrawal criteria			x	x	x	x	x	x	x	x	x	x	x	x			
Demography	x																
Diagnosis of diabetes	x																
Concomitant illness/Medical history	x																
Concomitant medication	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Height	x																
Body weight	x	x ⁶							x ⁶		x ⁶			x ⁶			
EFFICACY																	
Fasting plasma glucose ⁶		x							x		x			x			
HbA _{1c}	x	x					x		x		x	x		x			
4-point profile ⁷		x	x	x	x	x	x	x	x	x	x	x	x	x	x		
9-point profile ⁸		x							x		x			x			
SAFETY																	
Adverse events	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Insulin antibodies ⁶		x							x					x	x		
Biochemistry	x													x			
Haematology	x													x			
Lipids ⁶		x												x			
Urinalysis	x													x			
Pregnancy test ⁹	x													x			
Urine Albumin/creatinine ratio		x												x			
ECG – 12 lead	x ¹⁰													x			
Eye examination (funduscopy/fundusphotography)	x ¹⁰													x ¹¹			
Hypoglycaemic episodes		x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Hypo event questionnaire ¹²		x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Physical examination	x													x			
Vital signs	x													x			
OTHER ASSESSMENTS																	
PRO questionnaires ¹³		x							x					x			
End of trial															x		
TRIAL MATERIAL																	
IV/WRS call	x	x			x		x				x			x	x		
Drug accountability (IV/WRS)					x		x				x			x	x		
Dispensing visit		x			x		x				x			x			

[illegible]

FU = follow-up; IDegAsp = insulin degludec/insulin aspart; IDet = insulin detemir; ECG = electrocardiogram; PRO = patient reported outcome; IV/WRS = interactive voice/web response system

1. A phone contact was converted to a visit if for instance, further titration attention was needed.
2. Screening took place approximately 1 week prior to randomisation.
3. Follow-up visit was not to be performed earlier than 7 days after Visit 28/end-of-treatment.
4. Time of visit was always to be calculated in relation to the actual date of the randomisation visit.
5. In case of retesting of laboratory samples, randomisation was not to be performed before the results of the retest were obtained and the investigator had confirmed that the subject complied with the inclusion/exclusion criteria. The retesting was to be performed within the screening period of approximately 1 week.
6. Fasting visits: The subjects had to attend Visits 2, 14, 18, 28 and 29 fasting, having consumed only water since midnight, for measurement of lipids (Visits 2 and 28), weight and fasting plasma glucose (Visits 2, 14, 18, and 28) and insulin antibodies (Visits 2, 14, 28 and 29). No diabetes medication was allowed on the day of the visit before the blood sample was drawn. If the subjects attended the trial site in a non-fasting condition, the visit was to be re-scheduled within the next two working days.
7. 4-point profiles (self-measured plasma glucose [SMPG]) were preferably to be taken on the 3 consecutive days just before Visits 2-29. Measurements, in both treatment arms, were to be taken before breakfast, lunch, main evening meal and bedtime.
8. 9-point profiles (SMPG) were to be started in the morning 2 days before Visits 2, 14, 18 and 28. Measurements were to be performed before and after (90 minutes after the start of the meal) breakfast, lunch, main evening meal, before bedtime, at 4 a.m. and before breakfast on the following day. Note that the 9-point profile was overlapping with the 4-point profile.

9. Pregnancy test: At Visits 1 and 28, a blood pregnancy test was to be performed in women of child bearing potential. During the trial, a urine pregnancy test was to be performed if a menstrual period was missed or whenever pregnancy was suspected. If at phone contacts, subjects report missed menstrual period, the subject was to attend the site for a urine pregnancy test.

10. Electrocardiogram and fundoscopy/fundusphotography performed within 8 weeks before Visit 2 were acceptable if results were available at the visit.

11. Fundoscopy/fundusphotography performed within a period of 2 weeks before Visit 28 was acceptable, if results were available at the visit.

12. A hypoglycaemic event questionnaire was to be used at all visits, but only if a subject reported to have experienced 1 or more hypoglycaemic events (symptomatic or asymptomatic) since last visit or phone contact.

13. Patient reported outcome (PRO) questionnaires; a battery of several PRO questionnaires evaluated health related quality of life, treatment satisfaction and preferences. The PRO questionnaires were to be filled in by the subject at the visits, preferably before any other trial related procedures, in a confidential manner.

14. Only the total dose of IAsp was to be recorded and only on the last day before Visit 29

15. Dose of insulin neutral protamine Hagedorn during Days 1, 3 and 5 after Visit 28 (last treatment visit) and on the day just before Visit 29.

16. Instruction was to be done in the start of the trial and if required.

Table 9–9 Flow Chart of Phone Contacts

Phone contact number (P) ¹	P 5	P 7	P 9	P 11	P 13	P 15	P 17	P 19	P 20	P 21	P 23	P 24	P 25	P 27
Time of Phone contact ² (weeks)	3	5	7	9	11	13	15	17	18	19	21	22	23	25
Visit window (days)	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3
SUBJECT RELATED INFO/ASSESSMENTS														
Withdrawal criteria	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Concomitant medication	x	x	x	x	x	x	x	x	x	x	x	x	x	x
EFFICACY														
SMPG profile ³	x	x	x	x	x	x	x	x	x	x	x	x	x	x
SAFETY														
Adverse events	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Hypoglycaemic episodes	x	x	x	x	x	x	x	x	x	x	x	x	x	x
TRIAL MATERIAL														
Date, dose and time (time point) of trial insulin, on 3 days before visit	x	x	x	x	x	x	x	x	x	x	x	x	x	x
New (prescribed) dose of trial insulin	x	x	x	x	x	x	x	x	x	x	x	x	x	x

SMPG = self-measured plasma glucose.

1. A phone contact could be converted to a visit if for instance further titration attention was needed.
2. Time of visit was always to be calculated in relation to the actual date of the randomisation visit.
3. 4-point profiles self-measured plasma glucose was preferably to be taken on the 3 consecutive days just before each phone contact. Measurements, in both treatments arms, were to be taken before breakfast, lunch, main evening meal and bedtime

Screening Visit (Visit 1)

Screening was to take place approximately 1 week prior to randomisation. Before screening took place, subjects were to be provided with written information about the trial and the procedures involved, in accordance with local requirements. Subjects were to be fully informed, orally and in

writing, of their responsibilities and rights while participating in the trial, as well as of possible advantages/disadvantages when being treated with the trial medication (IDegAsp + IAsp or IDet + IAsp). Subjects were to be given the opportunity to ask questions, and to have ample time to consider participation. The informed consent process was to take place before the screening visit (Visit 1). Subjects who participated in the trial were to sign and date the informed consent form before any trial-related procedures.

All subjects were to be provided with a copy of their own signed and dated informed consent form(s).

If the investigator was not the subject's primary physician, the investigator was to notify the primary physician about the subject's trial participation. If required, permission from the subject was to be requested.

Subjects were to continue on their current diabetes treatment until the randomisation visit (Visit 2), and they were not to be supplied with any trial medication until then.

At screening, the subjects were assigned unique subject identification (ID) which remained the same throughout the trial. The subject ID consisted of 6 digits (the first 3 digits indicating site number and the last 3 digits indicating subject number).

The following were to be performed and/or recorded in the eCRF in addition to what was already described in the flowcharts (see [Table 9-8](#) and [Table 9-9](#)):

- Signed informed consent form(s), date and time
- Demography:
 - Date of birth
 - Sex
 - Race[#]
 - Ethnicity[#]
- Diagnosis of diabetes:
 - Date of diagnosis of diabetes
- Diabetes treatment history (concomitant medication):
 - Current diabetes treatment (prior to the screening visit (Visit 1) and until randomisation)
 - Dose of current diabetes treatment
 - Start date of current diabetes treatment

[#] Collection of race and ethnicity was not performed in France, as this was not authorised by the French law.

Randomisation Visit (Visit 2) to Follow-up Visit

For randomisation visit (Visit 2) to follow-up visit (Visit 29), see [Table 9-8](#) and [Table 9-9](#).

For further details on trial procedures, refer to the trial protocol and protocol amendments in [Appendix 16.1.1](#). Changes to the protocol are summarised in Section [9.8](#).

After end of IDegAsp + IAsp or IDet + IAsp treatment or if the trial insulin treatment was discontinued earlier than expected, the investigator was to ensure that the procedures for Visit 28 (end-of-treatment visit), the follow-up period and Visit 29 (follow-up visit) were undertaken.

After the follow-up visit, or if the subject did not wish to complete the follow-up period, the subject was to be transferred to a suitable marketed product as recommended by the investigator. If transferred to another insulin product after treatment with IDegAsp, careful titration of the subsequent antidiabetic treatment was to be carried out based on glucose measurements (SMPGs) due to the long effect and half-life of IDegAsp (IDeg component).

All subjects were offered to participate in an extension trial (NN5401-3645) following the 1-week follow-up period. A separate protocol, subject information and informed consent form was prepared for the extension trial. Verbal and written information was provided to the subjects and the informed consent form was signed by the subject and the investigator.

9.5.1.2 Efficacy Assessments

The following efficacy variables were assessed:

- HbA_{1c}
- FPG
- SMPG
 - 4-point profiles (SMPG)
 - 9-point profile (SMPG) with additional 4-point profiles (SMPG)
- PRO questionnaires
 - Treatment Related Impact Measure - Diabetes (TRIM-D)
 - Diabetes Medication Satisfaction Questionnaire (DiabMedSat)
 - Diabetes Productivity Measure Questionnaire (DPM)
 - Short-form 36 version 2 Health Survey (SF-36 v2)

The timing of assessments is outlined in the trial flow charts (see [Table 9–8](#) and [Table 9–9](#)).

For laboratory analysis of efficacy and safety parameters, a total of approximately 120 mL blood could be drawn during the approximately 28 weeks of the trial. The laboratory analyses were performed by a central laboratory unless otherwise specified. Descriptions of assay methods and reference ranges are provided in [Appendix 16.1.10](#).

Laboratory samples could be drawn at another day than when the visit was performed as long as it was performed within the visit window. For some of the samples drawn during the trial it was required for the sensitivity of the analysis that the subject was fasting.

For information about endpoints derived from the efficacy assessment, refer to Section [9.7.4](#).

HbA_{1c}

- Blood samples for HbA_{1c} were to be analysed using a Bio-Rad high performance liquid chromatography method. HbA_{1c} samples were to be collected at Visits 1, 2, 10, 14, 18, 22 and 28. The assay method used was a National Glycohaemoglobin Standardization Program certified method, see [Appendix 16.1.10](#).

FPG

The FPG samples were to be analysed using a Roche enzymatic method; see [Appendix 16.1.10](#). FPG samples were to be collected at Visits 2, 14, 18 and 28. The subjects had to attend these visits fasting.

Self-Measured Plasma Glucose

At Visit 1, subjects were to be provided with glucose meters and instructions for use and calibration for SMPG measurement, for details, see the Section 8.2.3 of the protocol ([Appendix 16.1.1](#)).

4-point Profiles (SMPG)

Subjects were asked to perform SMPG measurements at four different time points; before breakfast, lunch, main evening meal and bedtime. Measurements were preferably to be performed on three consecutive days just before each scheduled visit or telephone contact using the glucose meter provided. SMPG measurements before breakfast were preferably to be performed after having consumed only water since midnight. All SMPG measurements were to be performed before insulin injection. These measurements were required for optimal insulin dose adjustment and maintenance as described in the titration guideline in Appendix C of the protocol ([Appendix 16.1.1](#)).

It was important that the days of SMPG measurements were the same as the days where insulin doses were recorded.

9-point profile (SMPG) with Additional 4-point Profiles (SMPG)

Subjects were instructed to perform a 9-point profile with additional 4-point profiles on the three days immediately before Visits 2, 14, 18 and 28.

The PG levels were to be measured and recorded in the diary at the following time points, always starting with the measurement before breakfast on Day 1 (3 days before site visit).

Table 9–10 9-point Profile (SMPG) (✓) with Additional 4-point Profiles (SMPG) (X)

Time point	Day 1	Day 2	Day 3
Before breakfast	X	✓	✓
90 minutes after the start of breakfast		✓	
Before lunch	X	✓	X
90 minutes. after the start of lunch		✓	
Before main evening meal	X	✓	X
90 minutes after the start of main evening meal		✓	
Before bedtime	X	✓	X
At 04:00 am		✓	

The time was to be recorded for the measurements marked with ‘✓’ in [Table 9–10](#).

Patient Reported Outcome Questionnaires

Patient Reported Outcomes (PROs) were to be assessed by a PRO battery consisting of 4 questionnaires (see Appendix E of the protocol, [Appendix 16.1.1](#)):

- Treatment Related Impact Measure – Diabetes (TRIM-D)
- Diabetes Medication Satisfaction Questionnaire (DiabMedSat)
- Diabetes Productivity Measure (DPM)
- Short-Form 36 Health Survey, Version 2 (SF-36, v2)

The PRO battery comprised 3 disease-specific questionnaires (DiabMedSat, DPM and TRIM-D)²⁷ and one generic (SF 36, v2) questionnaire.²⁸⁻³⁰ Moreover, an exploratory interview-guided PRO questionnaire (see Appendix E of the protocol, [Appendix 16.1.1](#)) was used to investigate the consequences of hypoglycaemic episodes.

The PRO battery was to be administered at selected scheduled visits (see [Table 9–8](#) and [Table 9–9](#)), and it should preferably be completed after conclusion of all fasting-related activities but before any other visit-related activities. The PRO battery should be completed by the subject him/herself (the answers were to be kept confidential) and was designed to minimise the subject’s time consumption (approximately 20 minutes). All questionnaires were supplied in linguistically validated versions in all languages relevant for this trial.

Hypoglycaemia Questionnaire

A hypoglycaemia questionnaire was to be used at all visits, but only if a subject reported to have experienced symptoms of one or more hypoglycaemic episodes (symptomatic or asymptomatic) since last visit or phone contact. The investigator or a trial coordinator completed the questionnaire in an interview.

9.5.1.3 Safety Assessments

Adverse Events

Adverse Events (AEs) were to be recorded by the subjects in the diaries and were to be transcribed from the diaries to the eCRF.

Adverse Event Definitions

An AE is defined as any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. This included events from the first trial related activity after the subject had signed the informed consent form. The following were not to be recorded as AEs:

- Pre-planned procedure, unless the condition for which the procedure was planned had worsened from the first trial-related activity after the subject had signed the informed consent form.
- Pre-existing conditions found as a result of screening procedures. These were to be recorded as medical history/concomitant illness.

Serious Adverse Event

A serious adverse event (SAE) is an experience that at any dose resulted in any of the following:

- Death
- A life-threatening[#] experience
- In-subject hospitalisation[#] or prolongation of existing hospitalisation
- A persistent or significant disability/incapacity[#]
- A congenital anomaly/birth defect
- Important medical events[#] that may not have resulted in death, be life-threatening[#], or required hospitalisation[#] may have been considered a SAE when, based upon appropriate medical judgement, they may have jeopardised the subject and may have required medical or surgical intervention to prevent one of the outcomes listed in this definition.

[#] The term life-threatening in the definition of SAE refers to an event in which the subject was at risk of death at the time of the event. It does not refer to an event, which hypothetically might have caused death if it was more severe.

[#] The term “hospitalisation” describes a period of at least 24 h.

[#] The term “disability/incapacity” means that following the event the subject or clinical investigation subject has significant, persistent or permanent change, impairment, damage or disruption in his body function or structure, physical activity and/or quality of life.

[#] The term “important medical events” means events, which may jeopardise the subject or require intervention to prevent a seriousness criterion. It can be AEs that suggest a significant hazard or put the subject or clinical investigation subject at risk, such as drug-interactions, contra-indications or precautions, occurrence of malignancies or development of drug dependency or drug abuse.

Non-Serious Adverse Event

A non-serious AE is any AE, which does not fulfil the definition of an SAE.

Medical Events of Special Interest

Reporting of medical events of special interest (MESI) was used as a tool to collect additional information on special adverse events. Events such as medication errors (e.g., wrong drug administration or wrong route of administration) and suspected transmission of an infectious agent via a trial product were always considered as MESIs.

MESIs were always to be reported to the department responsible for global product safety using both the AE form and the safety information form, irrespective of seriousness. MESIs were to be reported within the same timelines as for SAEs.

In addition to the above, the following will also be considered as MESIs for this trial and should be handled as such:

- **Severe hypoglycaemia:** any episode of hypoglycaemia, which fulfils the American Diabetes Association (ADA) definition for a severe hypoglycaemia, that is an episode requiring assistance of another person to actively administer carbohydrate, glucagons or other resuscitative actions, was to be reported always to the department responsible for global product safety on an AE form and safety information form irrespective of seriousness.
- **Cardiovascular events:** cardiovascular events which were suspected as related to acute coronary syndrome (ACS), stroke or cardiovascular death were to be reported always to the department responsible for global product safety on an AE form and safety information form irrespective of seriousness. See Appendix D of Protocol ([Appendix 16.1.1](#)) for definitions of cardiovascular events.
- **Neoplasms:** all types of neoplasm events, that is benign, malignant and unspecified (including cysts and polyps) were to be reported always to the department responsible for global product safety on an AE form and safety information form irrespectively of seriousness. Medical history and important follow-up data includes information about malignancy versus non-malignancy, preferably histologically verified.
- **Immunogenicity:** events which in the opinion of the investigator were causally related to immune mechanisms to trial product, for example acute immunoglobulin E (IgE) mediated reactions (clinical signs may include anaphylactic reactions, angioedema and urticaria) and delayed type hypersensitivity (clinical signs may include various types of skin rashes), were to be reported always to the department responsible for global product safety on an AE form and safety information form irrespective of seriousness.

In the event that the investigator chose not to report the above specified AEs as MESIs, there could be discrepancies between the protocol defined MESIs and the actual reported MESIs

For further information regarding MESIs, see Appendix D to the protocol ([Appendix 16.1.1](#)).

Severity Assessment Definitions:

- Mild: No or transient symptoms, no interference with the subjects daily activities
- Moderate: Marked symptoms, moderate interference with the subjects daily activities
- Severe: Considerable interference with the subjects daily activities, unacceptable

Relation to Trial Product[#] Assessment Definitions:

- Probable: Good reasons and sufficient documentation to assume a causal relationship
- Possible: A causal relationship was conceivable and cannot be dismissed
- Unlikely: The event was most likely related to an aetiology other than the trial product

[#]; IDegAsp, IAsp, IDet and NPH insulin was included in the relationship assessment.

Device Relation

Any device related issues were to be reported by the investigator to Novo Nordisk A/S.

Technical complaints are reported as part Novo Nordisk's continuous aggregated surveillance of device complaints. The technical complaint data are entered into the Novo Nordisk complaint handling system (COCPIT), where after they are investigated further. The results of the investigations are reported to the Novo Nordisk department responsible for safety surveillance on an ongoing basis. All AEs related to technical complaints are reported in the clinical trial report, Section [12.2.2.3](#).

Recording of Injection Site Reactions

Injection site reactions reported either spontaneously or in the subject's diary were to be recorded on the AE form in the eCRF including the following information:

1. Previous allergy. If yes, specify
2. History of current reaction(s)
 - a. Was the skin normal before the event? If no, specify
 - b. Time of appearance after injection
 - c. Time and date of last injection
 - d. Associated local symptoms (burning, pain, numbness, itching)
 - e. Associated systemic symptoms (malaise, fatigue, fever, etc.)
 - f. Duration
 - g. What, if anything, has relieved the symptoms, (e.g. did reaction disappear spontaneously during continued administration of trial drug or was trial drug discontinued)?
 - h. Type(s) of insulin taken prior to onset
 - i. Number of units
 - j. New or multi-used needle
 - k. Injection angle (vertical, oblique)

- l. Injection into skin fold or flat skin
 - m. Unusual discomfort during injection
3. Clinical examination and detailed description, including:
 - a. The time between injection and inspection of the reaction
 - b. The anatomical site of reaction
 - c. Measurement of the size of the reaction
 - d. Dermatological description of the reaction (redness, swelling, macula, haemorrhage/bleeding)

Outcome Categories and Definitions:

- Recovered: Fully recovered, or by medical or surgical treatment the condition had returned to the level observed at the first trial related activity after the subject signed the informed consent form
- Recovering: The condition was improving and the subject was expected to recover from the event. This term was only used when the subject had completed the trial
- Recovered with sequelae: As a result of the AE, the subject suffered persistent and significant disability/incapacity (e.g., became blind, deaf, paralysed). Any AE recovered with sequelae was rated as an SAE
- Not recovered
- Fatal
- Unknown: This term was used in cases where the subject was lost to follow-up

Reporting of Adverse Events

All events meeting the definition of an AE were to be collected and reported.

At each contact with the trial site (visit or telephone, excluding safety visits, where the subject was not seeing the investigator or his staff (e.g., visits to the laboratory)), the subject was to be asked about AEs.

Sponsor's assessment of expectedness was to be done according to the reference documents:

- Novo Nordisk A/S investigational products IDegAsp: the IDegAsp IB and updates hereof ¹²
- Novo Nordisk A/S marketed products IDet, IAsp and NPH insulin: current version of company core data sheets (CCDS) and any updates hereof ³¹⁻³³

The subject was asked about AEs (mentioned as 'Medical problems' in the diary) in the following way: "Have you experienced any medical problems since the last contact?"

All AEs either observed by the investigator or reported spontaneously by the subjects were to be recorded by the investigator and evaluated. All AEs were to be recorded by the investigator on the AE form in the EDC application.

The investigator was required to report SAEs to Novo Nordisk A/S within 24 h. The investigator was to complete the AE form in the EDC application and the safety information form on the paper CRFs and forward to Novo Nordisk A/S within five calendar days.

Coding of Adverse Events

All the AEs were coded using Medical Dictionary for Regulatory Activities (MedDRA version 13.0). Non-serious AEs were coded locally by Novo Nordisk A/S personnel or a CRO using the semi-automated Thesaurus Management System (TMS). SAEs were coded by medically qualified staff at International Product Safety, Novo Nordisk A/S,

Treatment and Follow-up of Adverse Events

Any AEs that occurred during the trial were to be treated by established standards of care. All serious AEs and any non-serious AEs that were severe or probably or possibly related to the trial product were to be followed up until the subject recovered, stabilised, recovered with sequelae, or died. However, cases of chronic conditions could be closed with an outcome of “recovering” or “not recovered”.

All other AEs were to be followed until the outcome of the event was “recovering” (for chronic conditions), or “recovered” or until the end of the post-treatment follow-up visit (Visit 20), whichever came first, and until all queries related to these AEs had been resolved.

If subjects died from another event, these cases could be closed with an outcome of “recovering” or “not recovered”.

The investigator was to ensure that the worst-case severity and seriousness was kept consistent through the series of AE forms and related AE follow-up forms.

Other Safety Variables

Hypoglycaemic Episodes

Hypoglycaemic episodes were defined and classified according to the following:

ADA Hypoglycaemic Episode Definition – Classification³⁴

ADA definitions and classification of hypoglycaemia are used for the statistical analyses. According to the ADA, the definition of a hypoglycaemic episode (refer to [Figure 9–2](#)) is categorised as:

Severe hypoglycaemia: an episode requiring assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions.

Documented symptomatic hypoglycaemia: an episode during which typical symptoms of hypoglycaemia are accompanied by a measured PG concentration ≤ 3.9 mmol/L (70 mg/dL).

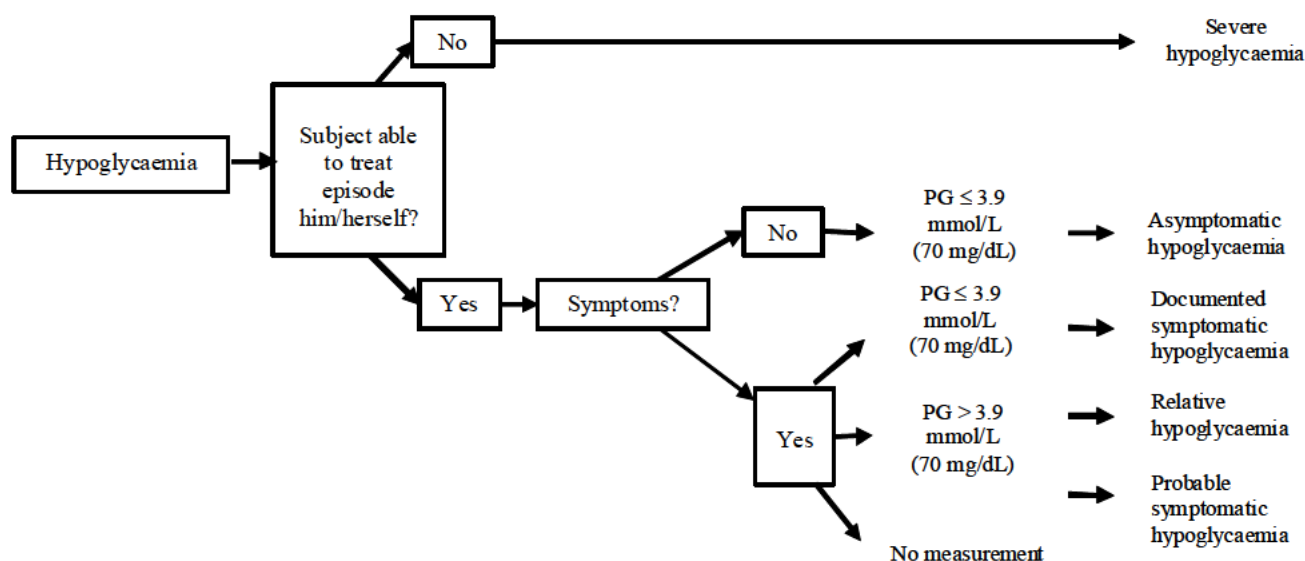
Asymptomatic hypoglycaemia: an episode not accompanied by typical symptoms of hypoglycaemia, but with a measured PG concentration ≤ 3.9 mmol/L (70 mg/dL).

Probable symptomatic hypoglycaemia: an episode during which symptoms of hypoglycaemia are not accompanied by a PG determination (but that was presumably caused by a PG concentration ≤ 3.9 mmol/L [70 mg/dL]).

Relative hypoglycaemia: an episode during which the person with diabetes reports any of the typical symptoms of hypoglycaemia, and interprets those as indicative of hypoglycaemia, but with a measured PG concentration > 3.9 mmol/L (70 mg/dL).

Unclassifiable: In case a hypoglycaemic episode could not be allocated into any of the above groups it is listed as "unclassifiable".

Hypoglycaemic episodes were only recorded as adverse events if they fulfilled the definition of an SAE or if reported as a MESI case of severe hypoglycaemia.



PG = plasma glucose

Figure 9–2 Classification of Hypoglycaemia According to ADA

Additional Definition of Confirmed Hypoglycaemic Episodes

The pool of severe and minor hypoglycaemic episodes is referred to as confirmed hypoglycaemic episodes (See also [9.8.2](#)).

Minor hypoglycaemic episodes are defined as:

- An episode with symptoms consistent with hypoglycaemia with confirmation by PG < 3.1 mmol/L (56 mg/dL) or full blood glucose < 2.8 mmol/L (50 mg/dL) and which is handled by the subject himself/herself.
- Or any asymptomatic PG value < 3.1 mmol/L (56 mg/dL) or full blood glucose value < 2.8 mmol/L (50 mg/dL).

In normal physiology, hypoglycaemia symptoms occur at a full blood glucose level of approximately < 2.8 mmol/L (50 mg/dL) / PG level of < 3.1 mmol/L (56 mg/dL). Therefore Novo Nordisk A/S has used this cut-off value to define minor hypoglycaemia.

Insulin Dose

During the trial, starting at randomisation visit (Visit 2), the subjects were instructed to report the date, time point and insulin dose in their diary on preferably 3 consecutive days before each visit. The days where the insulin doses were recorded were to be the same days as when the SMPGs were recorded. The recommended insulin doses were calculated automatically in the eCRF based on recommendations from the insulin titration guideline.

Physical Examination

Physical examination was carried out at Visits 1 and 28:

- Head, ears, eyes, nose, throat, neck
- Respiratory system
- Cardiovascular system
- Gastrointestinal system including mouth
- Musculoskeletal system
- Central and peripheral nervous system
- Skin

In the case of an “abnormal, clinically significant” finding, the investigator was to comment in the subject notes and, if it occurred at Visit 1, record this on the medical history/concomitant illness form.

Any clinically significant worsening from baseline was to be reported as an AE.

Vital Signs

Diastolic and systolic blood pressures and pulse were to be measured at Visits 1 and 28. Measurements were to be performed with the subject sitting after having rested in a chair for

5 minutes. For blood pressure at screening visit (Visit 1), three measurements were to be performed and all three values were to be entered into the eCRF. Any clinically significant worsening of the result from baseline was to be reported as an AE.

Eye Examination

At Visits 1 and 28, funduscopy/fundusphotography was to be performed by the investigator, a local ophthalmologist or an optometrist according to local practice. Funduscopy/fundusphotography performed within 8 weeks before Visit 2 and 2 weeks before Visit 28 were acceptable, if results were available at the visits, respectively.

The result of the examination was to be evaluated by the investigator as:

- “normal”
- “abnormal, not clinically significant” or
- “abnormal, clinically significant”.

Any clinically significant worsening of the funduscopy/fundusphotography since baseline was to be reported as an AE.

ECG (12 lead)

At Visits 1 and 28, an ECG was to be performed and interpreted locally by the investigator according to the following categories:

- “normal”
- “abnormal, not clinically significant” or
- “abnormal, clinically significant”.

ECG performed within 8 weeks before Visit 2 was acceptable, if result was available at the visit.

In case of abnormal, clinically significant ECG at Visit 1 this was to be recorded on medical history/concomitant illness form. Any clinically significant worsening of the ECG since baseline was to be reported as an AE.

Clinical Laboratory Tests

For laboratory analysis of efficacy and safety parameters a total of approximately 120 mL blood could be drawn during the approximately 28 weeks of the trial. The laboratory analyses were performed by a central laboratory unless otherwise specified. Descriptions of assay methods and reference ranges are provided in [Appendix 16.1.10](#).

Laboratory samples could be drawn at another day than when the visit was performed, as long as it was within the visit window (e.g., if the subject was not fasting).

At Visits 1 and 28, the following laboratory assessments were to be performed:

- Haematology (haemoglobin, leucocytes, thrombocytes, erythrocytes, haematocrit, differential counts)
- Biochemistry (creatinine, total protein, ALAT/serum glutamic pyruvic transaminase (SGPT), aspartate aminotransferase (AST)/serum glutamic oxalocetic transaminase (SGOT), alkaline phosphatase (AP), sodium, potassium, albumin, total bilirubin)
- Lipid profile (low density lipoprotein [LDL], high density lipoprotein [HDL], triglycerides [TG] and total cholesterol)
- Blood pregnancy test was performed for females of childbearing potential. Additionally, at any time during the trial if a menstrual period was missed, a urine pregnancy test (stick) was performed locally
- Urinary albumin-to-creatinine ratio assessed in spot urine
- Urine by sticks (tests for blood, protein, ketones)
- Antibodies

Serum samples for determination of antibodies for IDeg specific, IDet specific, IAsp specific and antibodies cross-reacting to human insulin were to be taken from subjects.

The determination of antibodies was performed at a central laboratory using a validated subtraction Radio Immuno Assay (RIA) method ([Appendix 16.1.10](#), Analytical Report No. AAA81977). Serum samples were mixed with radio-labelled IDeg, IAsp IDet or human insulin and incubated overnight. Antigen/antibody complexes were precipitated using polyethylene glycol and bound radioactivity in the precipitate was used to express antibody binding (% bound/total radioactivity: %B/T).

Pregnancy

Subjects were to notify the investigator immediately if they became pregnant. The investigator was to report any pregnancy reported during the trial to Novo Nordisk A/S, except for pregnancies occurring in the screening period. On enrolment, subjects were to give consent to the investigator reporting any pregnancy during the trial to Novo Nordisk A/S and to provide information about pregnancy, delivery and the health of the infant until age one month.

The investigator was to report information on pregnancy and follow-up within 14 calendar days of obtaining the information. If the pregnancy resulted in an abnormal outcome, such as congenital abnormalities, foetal death, spontaneous abortion, or serious AEs in the neonate, this information was to be forwarded to the department responsible for global product safety within 72 hours from receipt.

For pregnancies in partners of trial subjects, in case of an AE (with a causal relationship evaluated as possible or probable by the investigator) in the foetus, newborn infant(s) or infant(s)/toddler(s) of a trial subject's partner, who was potentially exposed to the trial product via the trial subject, the pregnancy and the AE was to be reported on the same forms as for a subject in the trial.

9.5.1.4 Assessments of Demographic and other Baseline Characteristics

The following baseline characteristics were to be recorded at Visit 1 only:

- Demography (date of birth, gender, race[#], ethnicity[#])
- Diabetes data (history, complications and current therapy)
- Medical history, concomitant illnesses

[#] Collection of race and ethnicity was not performed in France, as this was not authorised by French law.

Height

At screening visit (Visit 1), height (without shoes) was to be measured in inches or metres and recorded with two decimal places.

Body mass index

BMI was calculated using the eCRF. BMI calculation: $\text{BMI kg/m}^2 = \text{Body weight (kg)} / (\text{Height (m)} \times \text{Height (m)})$ ($\text{kg/m}^2 = [\text{lb/in}^2 \times 703]$).

Body weight

Body weight was to be measured in kilogram (kg) or pounds (lb) without coat and shoes. Body weight was to be recorded to 1 decimal place. The subjects were to attend these visits fasting (i.e., only intake of water since midnight was allowed) except for screening visit (Visit 1).

9.5.2 Appropriateness of Measurements

The efficacy and safety assessments were standard for this type of trial.

9.5.3 Primary Efficacy Variable

In the European Medicines Agency (EMA) note for guidance on clinical investigation of medicinal products for the treatment of diabetes mellitus and the Food and Drug Administration (FDA) Guidance for Industry on Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention, HbA_{1c} is considered the most widely accepted measure of overall, long-term glucose control in both type 1 and type 2 diabetes mellitus.^{35,36} Thus HbA_{1c} was included as the only currently accepted biomarker of glucose control.

9.5.4 Drug Concentration Measurements

No drug concentration measurements were performed during this trial.

9.6 Data Quality Assurance

The trial was conducted in accordance with Declaration of Helsinki¹ and ICH Good Clinical Practice².

The trial was monitored by the sponsor by means of on-site visits, telephone calls, and regular inspection of the case report forms (CRFs) with sufficient frequency (6–8 weeks) to verify the following: subject enrolment; compliance with the protocol; the completeness and accuracy of data entered in the CRFs by verification against original source documents; compliance in the use of trial product, drug accountability and recording of AEs.

The trial went through internal routine GCP audits in Denmark (Novo Nordisk A/S headquarters), U.S. (2 sites), Romania (1 site), Russian Federation (2 sites) and Australia (2 sites); see [Appendix 16.1.8](#).

9.7 Statistical Methods Planned in the Protocol and Determination of Sample Size

9.7.1 General Considerations

This statistical section describes the planned statistical analyses as described in the trial protocol ([Appendix 16.1.1](#)). Any changes from the planned analyses are described in Section [9.8.2](#).

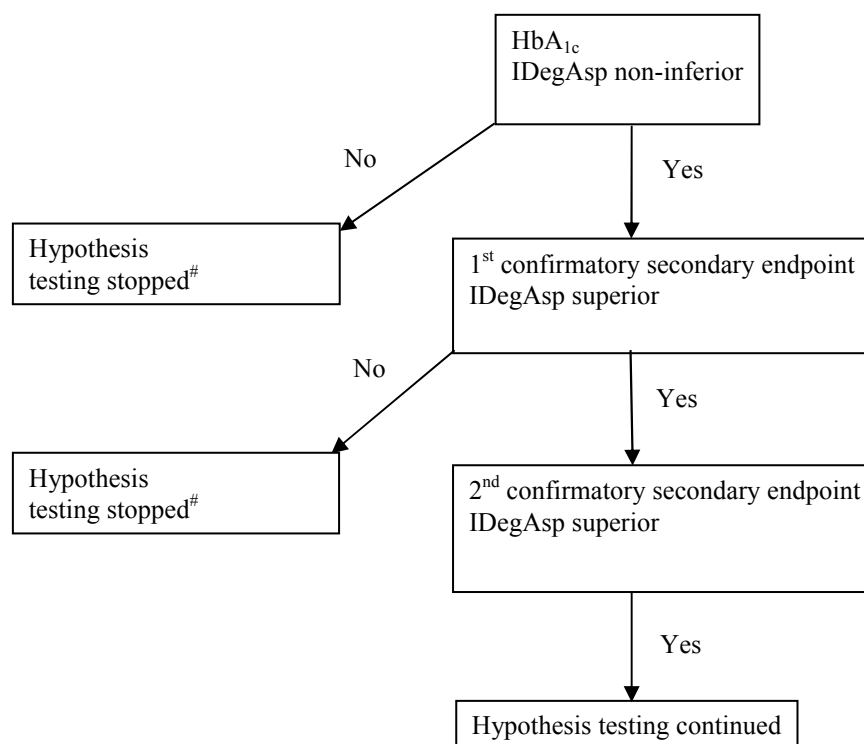
9.7.2 Endpoints in Relation to the Objectives and Hypotheses

Analyses of efficacy endpoints including analyses of patient reported outcome, and confirmatory analyses on confirmed hypoglycaemia and nocturnal confirmed hypoglycaemia, were based on the Full Analysis Set (FAS). The primary efficacy analysis was repeated on the per protocol (PP) analysis set in accordance with guidelines of the Committee for Proprietary Medicinal Products (CPMP) and (CPMP/EWP/482/99).³⁷

Secondary confirmatory (Section [9.7.4.2](#)) and supportive efficacy (Section [9.7.4.3](#)) endpoints and PRO endpoints (Section [11.4.3](#)) were summarised using the FAS. Safety endpoints (Section [9.7.4.4](#)) were summarised using the safety analysis set.

The impact of protocol deviations and outliers was to be investigated further in sensitivity analyses if deemed relevant.

The primary objective of this trial was to confirm efficacy of the investigational product in terms of glycaemic control as assessed by HbA_{1c}. If efficacy of the investigational product could be confirmed as assessed by comparing the mean HbA_{1c} difference to a non-inferiority limit of 0.4%, the trial also aimed to show superiority of the investigational product over IDet for a number of confirmatory secondary endpoints. The family-wise type I error rate was to be controlled in the strong sense using a hierarchical (fixed sequence) testing procedure. This was based on an *a priori* ordering of the null-hypotheses and testing them in this order using the two-sided 95% CI approach until an insignificant result appears. The effect was that superiority only was confirmed for endpoints where all previous null-hypotheses had been rejected; see [Figure 9–3](#).



[#]Analysis performed, but no formal hypothesis testing is performed (no p-value calculated)

Figure 9–3 Hierarchical Testing Procedure

In addition, if non-inferiority for the primary endpoint could be confirmed and the 95% CI for the HbA_{1c} mean treatment difference not only was entirely below 0.4% but also below zero, this was to be considered as evidence of superiority of the investigational product over IDet in terms of change from baseline in HbA_{1c} after 26 weeks of treatment.

Only endpoints derived after 26 weeks of treatment were to be analysed statistically. Unless otherwise specified missing values were to be imputed using the Last Observation Carried Forward (LOCF) method as recommended for its transparency in the FDA guidance.³⁶

In the following section “end of trial” means a subject’s last end of trial visit excluding the follow-up visit.

All endpoints were to be summarised descriptively at each visit by treatment and in total using observed data. At 26 weeks of treatment descriptive statistics were to be given both based on observed and LOCF imputed data. Endpoints that were analysed untransformed and endpoints that were not formally analysed were summarised by the arithmetic mean, standard deviation (SD), median, and minimum and maximum value. Endpoints that were analysed log-transformed were summarised by the geometric mean, CV, median, minimum and maximum value.

LOCF imputed data was to be used as the basis for plotting data if not otherwise specified.

Presentation of results from a statistical analysis was to include the estimated mean treatment effects (LSMeans) for absolute values and change from baseline, if applicable. Estimated mean treatment differences (or ratios) were to be presented together with two-sided 95% CIs for all endpoints analysed statistically. P-values were only to be presented for the primary and the confirmatory secondary endpoints for which formal statistical testing was performed. The other endpoints were to be considered supportive and/or explorative in nature and no p-values were to be presented.

For endpoints measured over time mean values were to be plotted to explore the trajectory over time. For survival endpoints, Kaplan-Meier plots were to be presented for each treatment. Data collected before randomisation was only to be summarised descriptively.

9.7.3 Definition of Analysis Sets

The following analysis sets were defined in accordance with the ICH-E9 guidance:³⁸

- Full analysis set (FAS): included all randomised subjects. In exceptional cases subjects from the FAS could be eliminated. In such cases the elimination was to be justified and documented. The statistical evaluation of the FAS was to follow the intention to treat (ITT) principle and subjects were to contribute to the evaluation “as randomised”.
- Per protocol (PP) analysis set: included subjects without any major protocol violations that may have affected the primary endpoint. Moreover, subjects must have been exposed to the investigational product or its comparator for more than 12 weeks and must have had a valid assessment necessary for deriving the primary endpoint. Subjects in the PP set were to contribute to the evaluation “as treated”.
- Safety analysis set: included all subjects receiving at least one dose of the investigational product or its comparator. Subjects in the safety set were to contribute to the evaluation “as treated”.

Randomised subjects who were lost to follow-up and where no exposure information of the IDegAsp or IDet was available after randomisation were to be handled as unexposed. Subjects who received only trial medication other than IDegAsp or IDet were to be reported separately.

Before data were released for statistical analysis a blinded review of all data was to take place to identify protocol deviations that may potentially have affected the results. This review was to be performed without revealing which trial product the subjects were assigned to. The blinding of the trial products was to be maintained for everyone involved in defining the analysis sets until data were released for statistical analysis. Furthermore, extreme values and outliers were to be identified

by the statistician during programming and data review according to ICH-E9, using a fake randomisation.³⁸

Subjects who were exposed to trial products <12 weeks and who did not have a valid assessment of HbA_{1c} after randomisation were excluded from the PP analysis, as were subjects who violated the selection criteria in the trial. The decision to exclude any subject or observation from the statistical analysis was the responsibility of the study group. The subjects or observations to be excluded and the reason for their exclusion were to be documented and signed by all parties, prior to release of the clinical trial database. The documentation was to be stored together with the remaining trial documentation.

9.7.4 Statistical Analyses

9.7.4.1 Primary Endpoint

The primary endpoint was change from baseline in HbA_{1c} (%) after 26 weeks of treatment.

Statistical Analysis

Change from baseline in HbA_{1c} (%) after 26 weeks of treatment was to be analysed using an Analysis of Variance (ANOVA) method with treatment, antidiabetic therapy at screening, sex and region (Australia, Europe or North America) as fixed factors, and age and baseline HbA_{1c} as covariates. The antidiabetic therapy at screening was a factor with two levels according to stratification:

1. Basal-bolus insulin regimen
2. Other insulin regimen

The model was to be fitted to all the data simultaneously (all treatment groups) and from this model the relevant treatment differences were to be estimated.

Non-inferiority was to be considered confirmed if the upper bound of the two-sided 95% CI was below or equal to 0.4% or equivalent if the p-value for the one-sided test of

$H_0: D > 0.4\%$ against $H_A: D \leq 0.4\%$,

was less than or equal to 2.5%, where D is the treatment difference (investigational product minus comparator).

If non-inferiority was confirmed, the superiority of the investigational product over comparator was to be investigated. Superiority was to be considered confirmed if the upper bound of the two-sided 95% CI from the analysis of the FAS was below 0%.

Sensitivity Analysis

Sensitivity analyses were to be performed using only the FAS.

All observed HbA_{1c} measurements available post randomisation at scheduled measurement times were also to be analysed in a linear mixed model using an unstructured residual covariance matrix (if possible). This approach relies on the assumption that data are missing at random (MAR) according to the taxonomy of Rubin.³⁹ The results were to be compared to the results of the LOCF method for dealing with missing data. Any marked difference concerning treatment differences between the MAR and LOCF approach were to be commented upon.

Change in HbA_{1c} from baseline was also to be analysed using a model with only treatment as fixed factor and baseline HbA_{1c} as covariate to assess the sensitivity of the results to inclusion/exclusion of fixed factors and covariates.

9.7.4.2 Confirmatory Secondary Endpoints

Provided that non-inferiority was confirmed for the primary endpoint, a number of confirmatory secondary endpoints were to be tested to confirm superiority of the investigational product over comparator.

The confirmatory secondary endpoints are given below together with the direction of the test for superiority. The order of the endpoints defines the testing sequence.

1. Change from baseline in FPG after 26 weeks of treatment (analysed at central laboratory)
 - superiority was to be considered confirmed if the 95% CI for the treatment difference (investigational product minus comparator) was entirely below zero
2. Responder without hypoglycaemic episodes (HbA_{1c} <7.0% at end of trial and no severe hypoglycaemic episodes during the last 12 weeks of treatment including only subjects exposed for at least 12 weeks)
 - superiority was to be considered confirmed if the 95% CI for the odds ratio (investigational product / comparator) was entirely above one
3. Number of treatment emergent nocturnal (00:00-05:59 a.m.) severe or minor hypoglycaemic episodes
 - superiority was to be considered confirmed if the 95% CI for the relative risk (investigational product / comparator) was entirely below one

Change in Fasting Plasma Glucose from Baseline

FPG was to be assessed on fasting subjects from whom blood samples were to be analysed at a central laboratory.

Change from baseline in FPG after 26 weeks of treatment was to be analysed using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age and baseline FPG as covariates.

Responder Without Hypoglycaemic Episodes

Responder without hypoglycaemic episodes is a dichotomous endpoint (responder/non-responder) that was defined based on whether a subject met the ADA HbA_{1c} target (HbA_{1c} < 7.0%) at end of trial without treatment emergent severe hypoglycaemic episodes during the last 12 weeks of treatment. A hypoglycaemic episode was defined as treatment emergent if the onset of the episode was on or after the first day of exposure to randomised treatment and no later than 7 days after the last day of randomised treatment. The endpoint was only to be defined for subjects that had been exposed to the investigational product or comparator for at least 12 weeks.

Responder analysis was to be based on a logistic regression model using treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age and baseline HbA_{1c} as covariates.

Number of Treatment Emergent Nocturnal Confirmed Hypoglycaemic Episodes

This counting endpoint was defined as the sum of number of severe hypoglycaemic episodes according to the ADA classification and the number of minor hypoglycaemic episodes (PG < 3.1 mmol/L), which is an additional group of hypoglycaemic episodes as further detailed in Section [9.5.1.3](#). A hypoglycaemic episode was defined as treatment emergent if the onset of the episode was on or after the first day of exposure to randomised treatment and no later than 7 days after the last day of randomised treatment. The nocturnal period was considered as the period between 00:00 and 05:59 a.m. (both included). Any treatment emergent severe or minor hypoglycaemic episodes that had time of onset during this period were to be considered nocturnal.

The number of hypoglycaemic episodes was to be analysed using a negative binomial regression model with a log-link function and the logarithm of the time period in which a hypoglycaemic episode was considered treatment emergent as offset. The model was to include treatment, antidiabetic therapy at screening, sex, region as fixed factors and age as covariate.

9.7.4.3 Supportive Secondary Endpoints

The timing of assessments is outlined in the Trial Flow chart ([Table 9–8](#) and [Table 9–9](#)).

HbA_{1c} Responder Endpoint

A dichotomous endpoint (responder/non-responder) was to be defined based on whether a subject met the ADA HbA_{1c} target (HbA_{1c} < 7.0%).

A dichotomous endpoint was to be defined based on whether this treatment target was achieved at end of trial without hypoglycaemic episodes in the last 12 weeks of treatment considering severe episodes only, and severe and minor episodes together (i.e., confirmed episodes). Severe

hypoglycaemic episodes were defined according to the ADA classification while minor hypoglycaemic episodes (PG < 3.1 mmol/l) is an additional group further detailed in Section [9.5.1.3](#). The endpoint was only to be defined for subjects that had been exposed for at least 12 weeks.

The responder endpoints were to be analysed separately based on a logistic regression model using treatment, antidiabetic therapy at screening, sex and region as fixed factors and age and baseline HbA_{1c} as covariates.

Self-measured Plasma Glucose

Self-measured plasma glucose (SMPG) was to be measured at prescribed time points in terms of the 9-point profiles and glucose measurements used for insulin dose adjustments.

9-point Profile

A 9-point profile (SMPG) was to include measurements before and 90 minutes after breakfast, lunch and dinner (main evening meal), measurements prior to bedtime and at 4 a.m., and one before breakfast the following day (see [Table 9–10](#)).

The endpoints from the 9-point profiles were to be

- 9-point profile (SMPG)
- Mean of the 9-point profile (SMPG)
- Fluctuation in 9-point profile (SMPG)
- Prandial PG increment
- Changes between nocturnal SMPG measurements

The mean of 9-point profile was defined as the area under the profile calculated using the trapezoidal method divided by the measurement time. The fluctuation in the 9-point profile was defined as

$$\frac{1}{T} \int_0^T |PG(t) - \overline{PG}| dt,$$

where T , $PG(t)$ and $\overline{PG}$ denotes the length of the profile, the PG value at time t and the mean of the profile, respectively.

Prandial PG increment for each meal was to be derived from the 9-point profile as the difference between PG values available 90 minutes after meal and before meal. Mean prandial PG increment over all meals was to be derived as the mean of all available meal increments.

Change in nocturnal PG was to be assessed by considering the differences between PG values available prior bedtime, at 4 a.m. and the before breakfast value the following day: (4 a.m. PG value minus prior bedtime PG value), (before breakfast PG value minus prior bedtime PG value) and (before breakfast PG value minus 4 a.m. PG value).

A mixed effect model was to be fitted to the 9-point profile data. The model was to include treatment, time, interaction between treatment and time, antidiabetic therapy at screening, sex and region as fixed factors and age as covariates and subject as random effect. From the model mean profile by treatment and relevant treatment differences were to be estimated and explored.

Mean and fluctuation in the 9-point profile, prandial PG increment and nocturnal PG endpoints was to be analysed separately using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age as covariate. For the analysis of the mean of the 9-point profile the corresponding mean at baseline was to be included as a covariate. Fluctuation in the 9-point profile was to be logarithm transformed before analysed and the mean profile value was to be included as an additional covariate. For the analysis of the endpoint describing the change in nocturnal PG the base of the corresponding increment was to be included as an additional covariate.

SMPG Values Used for Dosing

The SMPG values used for dose adjustment were to be collected and recorded by the subjects for three consecutive days prior to visit and were to include measurements before main meals (2-4 times daily). Dose adjustment of basal insulin was based on the subjects before breakfast value, and this value should always have been obtained even if a subject does not eat breakfast. The titration algorithm including information on adjustment of bolus insulin is detailed in the Insulin Titration Guideline ([Appendix 16.1.1](#), [Appendix C](#)).

The endpoints from the SMPG values used for dose adjustment were to be

- Mean PG before meals
- Responder for PG titration target
- Time from randomisation (measured in weeks) to achieve titration target(s)
- Within-subject variability as measured by coefficient of variance (CV%)

The mean PG before meal was to be calculated at each visit using the available data and separately for each meal where data is available.

The mean of before breakfast PG values was to be analysed using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age as covariates.

From the mean before breakfast PG value at each visit a dichotomous endpoint (responder/non-responder) was to be derived showing if a subject had achieved the titration target.

Two survival endpoints were to be derived describing the time from randomisation to the date a subject met the titration target for the first time, and the time to a subject met the titration target and stayed on the target for the remaining treatment period.

The survival endpoints was to be analysed separately in a Cox proportional hazards model including treatment, antidiabetic therapy at screening, sex and region as fixed factors and age as covariate. An analysis was also to be performed for the time to all titration targets were met. Subjects that were lost for follow-up without meeting the target and subjects that never met the target during treatment were to be censored at the last day of treatment.

The logarithm transformed SMPG values available before breakfast were to be analysed as repeated measures in a linear mixed model with treatment, antidiabetic therapy at screening, sex and region as fixed factors and age as covariate and subject as random factor. The model was to assume independent within- and between-subject errors with variances depending on treatment. Within-subject variability as measured by CV% for a treatment could be calculated from the corresponding residual variance σ^2 as $CV\% = 100\sqrt{(\exp(\sigma^2) - 1)}$. The CI for the CV ratio between treatments was to be calculated using the delta method.

9.7.4.4 Safety Endpoints

The following safety endpoints were assessed:

- Adverse events
- Number of hypoglycaemic episodes

Safety and tolerability was assessed throughout the trial by

- Clinical evaluations
 - physical examination
 - fundoscopy/fundusphotography
 - 12-lead ECG
 - vital signs
- Central laboratory assessments
 - biochemistry
 - haematology
 - lipids
 - antibodies
 - urinary albumin-to-creatinine ratio assessed in spot urine
 - urine by sticks (tests for blood, protein and ketones)
- Body weight
- Insulin dose

Adverse Events

AEs were to be coded using the most recent version of MedDRA coding. All AEs were to be presented based on system organ class and preferred terms.

A treatment emergent adverse event (TEAE) was defined as an event that had onset date on or after the first day of exposure to randomised treatment and no later than 7 days after the last day of randomised treatment.

TEAEs were summarised descriptively whereas AE's not defined as treatment emergent are presented in listings. The summaries of TEAEs were made displaying the number of subjects with at least one event, the percentage of subjects with at least one event, the number of events and the event rate per 100 years. These summaries were done by seriousness, severity, relation to insulin treatment, relation to device, withdrawal due to AEs and outcome.

Furthermore summary tables based on system organ class and preferred term were made for

- All TEAEs
- Serious TEAEs
- Possibly or probably related TEAEs
- Severe TEAEs
- TEAEs with preferred term that are experienced by at least 5% of the subjects in any treatment arm or by at least 5% of all subjects

Hypoglycaemic Episodes

Hypoglycaemic episodes were to be recorded by subjects in their trial diaries throughout the trial. The information collected was to include PG before treating the episode and whether the subject was able to treat him/herself. Information on last meal and dose was also collected. This information was used to classify an episode according to both the ADA definition (severe, documented symptomatic, asymptomatic, probable symptomatic and relative) and the additional definition of confirmed hypoglycaemic episodes as further detailed in Section [9.5.1.3](#)

A hypoglycaemic episode was defined as treatment emergent if the onset of the episode was on or after the first day of exposure to randomised treatment and no later than 7 days after the last day of randomised treatment.

The summaries of treatment emergent hypoglycaemic episodes were the following:

- the number of subjects with at least one episode
- the percentage of subjects with at least one episode
- the number of episodes and the episode rate per year
- separate summaries by severity:
 - all episodes

- nocturnal episodes using both the ADA and the additional minor category (refer to Section [9.5.1.3](#))

The nocturnal period was to be considered as the period between 00:00 and 05:59 a.m. (both included). A hypoglycaemic episode that has time of onset during this period was to be considered nocturnal; see also Section [9.8.2](#)

The number of hypoglycaemic episodes was to be analysed using a negative binomial regression model with a log-link function and the logarithm of the time period in which a hypoglycaemic episode is considered treatment emergent as offset. The analysis was based on the full analysis set. The model was to include treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age as covariate. To the extent where data allowed, separate analyses were to be performed for severe episodes, and severe or documented symptomatic episodes considering all episodes and nocturnal episodes separately.

Physical Examination

Physical examination was to include:

- Head, ears, eyes, nose, throat, neck
- Respiratory system
- Cardiovascular system
- Gastrointestinal system incl. mouth
- Musculoskeletal system
- Central and peripheral nervous system
- Skin

Changes from baseline in physical examination that were recorded as AEs were to be summarised separately in tables and listings.

Vital Signs

Vital signs include diastolic blood pressure, systolic blood pressure and pulse. The measurements and their change from baseline were to be summarised descriptively.

The measurements and their change from baseline at 26 weeks of treatment were to be summarised descriptively.

Laboratory assessments

The following laboratory assessments were to be performed:

- Haematology (haemoglobin, leucocytes, thrombocytes, erythrocytes, haematocrit, differential counts)

- Biochemistry (creatinine, total protein, ALAT/SGPT, AST/SGOT, AP, sodium, potassium, albumin, total bilirubin)
- Lipid profile (LDL, HDL, TG and total cholesterol)
- Blood pregnancy test was performed for females of childbearing potential. Additionally, at any time during the trial if a menstrual period is missed, a urine pregnancy test (stick) was to be performed locally
- Urinary albumin-to-creatinine ratio assessed in spot urine
- Urine by sticks (tests for blood, protein, glucose, ketones)
- Antibodies

Individual laboratory values were to be compared to their relevant reference range (when existing) and flagged as being below or above the range. Change from baseline at 26 weeks of treatment was to be summarised descriptively.

Change from baseline in lipid endpoints was to be analysed separately using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors and age and baseline value as covariates.

IDeg specific antibodies, IDet specific antibodies, IAsp specific antibodies, human insulin cross-reacting antibodies and the correlation to relevant efficacy (HbA_{1c}) and safety (insulin dose, hypoglycaemic episodes) variables were to be illustrated using descriptive statistics and graphs.

Fundoscopy/fundusphotography

Fundoscopy and fundusphotography findings were to be summarised descriptively including summaries of the change from baseline.

Changes from baseline in funduscopy / fundusphotography that were recorded as adverse events were to be summarised separately in tables and listings.

ECG

12-lead ECG findings were to be summarised descriptively including summaries of the change from baseline.

Changes from baseline in ECG that were recorded as AEs were to be summarised separately in tables and listings.

Body Weight

Body weight was to be assessed at the trial site. Change from baseline in body weight was to be analysed using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors and age and baseline body weight as covariates.

Insulin Dose and Time of Administration

Prescribed and actual insulin dose per day was to be recorded together with time of administration. The insulin dose was to be summarised descriptively according to regimen as dose in units, units/kg and nmol/kg. The summaries were also to include information on time of insulin administration in order to document the time of the day subjects injected their insulin and the degree to which subjects shifted injection times during the trial.

9.7.5 Interim Analyses

No interim analysis was planned for this trial.

9.7.6 Sequential Safety Analysis/Safety Monitoring

Not applicable.

9.7.7 Exploratory Statistical Analyses for Pharmacogenetics and Biomarkers

Not applicable.

9.7.8 PK and PD Modelling

Not applicable.

9.7.9 Health Economics and/or Patient Reported Outcomes

The following questionnaires were to be used to compare PRO and costs associated with hypoglycaemia between treatments:

- Diabetes Medication Satisfaction Questionnaire (DiabMedSat)
- Diabetes Productivity Measure Questionnaire (DPM)
- Short-Form 36 Health Survey Version 2 (SF-36, v2)
- Treatment Related Impact Measure – Diabetes (TRIM-D)
- Hypoglycaemia Questionnaire

The change from baseline in scores (total score if appropriate) was to be analysed separately using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors and age and the relevant baseline value as covariates.

9.7.10 Determination of Sample Size

The primary objective of this trial was to confirm efficacy of IDegAsp OD + IAsp in terms of glycaemic control.

This was to be done by showing that

IDegAsp OD + IAsp is non-inferior to IDet + IAsp

in terms of glucose lowering effect as assessed by mean change in HbA_{1c} from baseline at 26 weeks of treatment using a non-inferiority margin of 0.4% (absolute). Sample size was determined based on this primary objective.

Throughout this section of the protocol the term “investigational product” is used as a synonym for IDegAsp OD + IAsp for the remaining meals and the term “comparator” is used as a synonym for IDet + IAsp.

The non-inferiority margin of 0.4% (absolute) was chosen in accordance with the FDA guidance.³⁶ Let D be the treatment difference for HbA_{1c} (IDegAsp minus IDet). The null-hypothesis was to be tested against the alternative hypothesis of non-inferiority as given by

H₀: D > 0.4% against H_A: D ≤ 0.4%

Operationally the null-hypothesis was to be rejected and non-inferiority considered confirmed if the upper bound of the two-sided 95% CI was below or equal to 0.4%. This is equivalent to using a one-sided test of size 2.5%.

Sample size was determined using a t-statistic (t-test) under the assumption of a one-sided test of size 2.5% and a zero mean treatment difference (i.e. D=0%). Based on the experience from previous phase 3 trials in subjects with type 1 diabetes mellitus a conservative estimate for the standard deviation (SD) of 1.1% for HbA_{1c} was used in the sample size calculation. The sample size calculation was done using SAS 9.1.3.

Table 9–11 Specifications Assumed for Sample Size Calculation

Statistical test	One sided Significance Level	Non- inferiority Margin	SD	Mean Difference	Randomisation Scheme	Required Power
two-group t test	2.5%	0.4% (absolute)	1.1	0.0	2:1	95%

SD = standard deviation

Table 9–12 Sensitivity of Sample Size (Integers) to Variations in SD and Power

#subjects in total	SD=0.9	SD=1.0	SD=1.1	SD=1.2
Power = 80%	183	225	270	321
Power = 85%	207	255	309	366
Power = 90%	243	300	360	429
Power = 95%	300	369	447	531

SD = standard deviation

From [Table 9–12](#) it is seen that the minimum sample size required to meet the primary objective with at least 95% power was 447 with an assumed SD of 1.1%.

As this was a non-inferiority trial sample size was to be determined such that the anticipated power was at least 95% in the evaluation of the PP analysis set. In previous phase 3 trials in subjects with type 2 diabetes mellitus treated with insulin 5-25% of the randomised subjects were excluded from the PP analysis set. The number of excluded subjects was dependent on the trial design. In this trial an estimate of 15% was used and sample size was ceiled in the FAS to have integer sample size for each group that adhered exactly to the group allocation weights (2:1). Hence the total number of subject to be randomised was to be 528 subjects in order to have at least 95% power in the evaluation of the PP analysis set.

Table 9–13 Anticipated Number of Subjects in FAS and PP Analysis Set

	IDegAsp OD + IAsp	IDet + IAsp	Total
Number of subjects in the FAS	352	176	528
Number of subjects in the PP analysis set	298	149	447

IDegAsp = insulin degludec/insulin aspart; OD = once daily; IAsp = insulin aspart; IDet = insulin detemir; FAS = full analysis set; PP = per protocol

9.8 Changes in the Conduct of the Trial or Planned Analyses

9.8.1 Protocol Amendments and General Procedural Deviations

Protocol Amendments

There were 6 substantial amendments to the protocol (see [Table 9–14](#)). None of the substantial amendments were considered to have any serious implications for the subjects involved in this trial, nor on the overall results of this trial. The substantial amendments 1, 2 and 3 were implemented

before trial initiation (see [Table 9–14](#) for details). Amendment No. 2 included the removal of an exclusion criterion, which had no impact on the trial since the amendment was implemented before trial initiation. Substantial amendments No. 4, 5 and 6 were implemented after trial initiation. Refer to the protocol amendments ([Appendix 16.1.1](#)), for further details.

Table 9–14 Substantial Amendments

Amendment Type	Amendment No.	Date	Countries affected	Content change
Substantial	1_RO	25-Jun-2009	Romania	1 (one) additional site was selected for participation in the trial
Substantial	2	28-Jul-2009	Global	Constitution of Event Adjudication Committee and corrects some errors in protocol regarding: prescreening, exclusion criteria 5, source data verification, reporting of insulin doses, destruction of laboratory samples, collection of trial insulin doses in diary, recruitment period, measurements of lipids, directions for use of trial products, statistical models for analysing 9-point profile (SMPG) and subject Information/Informed Consent were updated.
Substantial	3_FR	16-Jul-2009	France	Collection of race and ethnicity was removed, as this was not authorised by French law
Substantial	4_PL	28-Aug-2009	Poland	List of key staff and relevant departments updated and addition of trial sites from participation in the trial
Substantial	05-UK	21-Oct-2009	U.K.	Removal of two trial sites from participation in the trial led to new version of List of Key Staff and Relevant Departments
Substantial	6_RO	23-Nov-2009	Romania	Principal Investigator at trial site ■■■ was changed.

SMPG = self-measured plasma glucose

General Procedural Deviations

There were no important protocol deviations at country level and trial level (see [Appendix 16.2.2](#), [Tables 16.2.2.1](#) and [16.2.2.2](#)). See Section [10.2](#) for important protocol deviations on trial site level and on subject level.

The naming of some of the PRO questionnaires has been updated in the CTR compared to the names stated in the protocol, to reflect the correct naming of the questionnaires used in the CRFs: 'Health Related Quality of Life questionnaire (SF-36)' is corrected to Short-Form 36 version 2 Health Survey (SF-36 v2), and 'Treatment satisfaction questionnaire' is corrected to 'Treatment Related Impact Measure – Diabetes'.

9.8.2 Changes to the Statistical Analysis Plan

No statistical analysis plan was created for this trial as the statistical analyses were specified with sufficient detail in the protocol. The text below refers to changes to the protocol.

All formal statistical analyses were based on the FAS. This was done to facilitate interpretability and ensure consistency within and between trials in the clinical development programme.

Hypoglycaemic episodes were considered to be treatment emergent if they had onset on or after first day of exposure to randomised treatment and no later than 7 days after the last day of exposure to randomised treatment when deriving HbA_{1c} responders without hypoglycaemic episodes. The text stated in the protocol: "no later than 5 days" was a misprint and a clarification to the protocol was included in the minutes from the database lock.

Hypoglycaemic episodes which had time of onset between 00:01 and 05:59 a.m. (both included) were considered to be nocturnal. This change was documented in the minutes from the database lock.

As stated in the protocol ([Appendix 16.1.1](#)) and Section [9.5.1.3](#), the further classification of pre-specified adverse events as medical events of special interest (MESI) was used as a tool to collect additional information on special adverse events. Summaries based on Standard MedDRA query (SMQ) searches will be presented for injection site reactions, immunogenicity, neoplasms and medication errors. These summaries will then form the basis for the presentation of these events in Section [12.2.2](#) and Section [12.3.3.4](#). The preferred terms or SOC's included in the SMQ searches are listed in [Appendix 16.2.7, Listing 16.2.7.4](#).

Instead of analysing the 9-P SMPG profiles using a mixed effect model it was analysed using a repeated measurements model with the same mean structure, but without the random subject effect, and with an unstructured residual covariance matrix. The reason for the change was to allow for varying variances at the different time points as well as varying correlations between the values of the profiles. The model also included the values from the 9-point SMPG profile at baseline as covariate as it was considered relevant to adjust for the values at baseline.

Only one survival endpoint was derived (time to meet the target for the first time) as the endpoint describing time until reaching and maintaining target was not considered to be clinically meaningful.

To the extent where data allowed, separate analyses were carried out for severe hypoglycaemic episodes, severe or minor hypoglycaemic episodes considering all episodes and nocturnal episodes separately. The text in the protocol stated “severe or documented symptomatic” episodes which was a misprint.

The insulin dose was not summarised and presented in nmol/kg as it was not considered relevant.

Correlation between antibodies and hypoglycaemic episodes was not investigated since scatter plots would not be suitable for visualising the relationship due to the number of hypoglycaemic episodes.

10 Trial Subjects

10.1 Disposition of Subjects

The overall withdrawal pattern was comparable between the two treatment groups and a similar proportion of subjects completed the trial in the two treatment arms; see [Table 10–1](#).

Of the 706 subjects screened, 158 were screening failures. Of the screening failures, 148 subjects failed to meet at least one of the specified inclusion or exclusion criteria, 8 subjects withdrew their informed consent, 1 was lost to follow-up and 1 was screened after randomisation was closed <(see [Appendix 16.2.1](#), [Table 16.2.1.1](#)).

Of the 548 randomised subjects, 6 were withdrawn before being exposed to trial product. In 3 of these cases, the underlying reason for withdrawal was related to violation of the inclusion/exclusion criteria or non-compliance.

Similar proportions of exposed subjects withdrew after randomisation in the IDegAsp and IDet treatment groups. The overall withdrawal pattern (reasons for withdrawal, time of withdrawal) was comparable between the two treatment groups and a similar proportion of subjects completed the trial in the two treatment arms; see [Table 10–1](#). In general, the subject withdrawals occurred throughout the trial period, with no apparent clustering of withdrawals at any specific time point during the trial; see [EOT Figure 14.1.3](#).

Table 10–1 Subject Disposition - Summary

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Screened			706
Screening Failures			158
Withdrawn before Randomisation			0
Randomised	366 (100.0)	182 (100.0)	548 (100.0)
Exposed	362 (98.9)	180 (98.9)	542 (98.9)
Withdrawn at/after Randomisation	46 (12.6)	26 (14.3)	72 (13.1)
Adverse Event	4 (1.1)	3 (1.6)	7 (1.3)
Ineffective Therapy	2 (0.5)	0 (0.0)	2 (0.4)
Non-Compliance With Protocol	8 (2.2)	6 (3.3)	14 (2.6)
Withdrawal Criteria	7 (1.9)	5 (2.7)	12 (2.2)
Other	25 (6.8)	12 (6.6)	37 (6.8)
Completed	320 (87.4)	156 (85.7)	476 (86.9)

N: Number of subjects

?: Proportion of randomised subjects

FUTURINS/NN5401/NN5401-3594/FREEZE_CTR_01

Cross-reference: [EOT Table 14.1.1](#)

The 548 subjects were randomised 2:1 to IDegAsp and IDet. In total, 72 subjects (13% of those randomised) were withdrawn from the trial after randomisation. The primary reason for withdrawal in both groups fell into the category of ‘other’ reasons. The reason most frequently stated in this category was withdrawal at the subjects’ own initiative. Some subjects stated as a cause that they believed the treatment to be ineffective (IDegAsp 7 and IDet 4 subjects), or found that the study protocol did not suit their lifestyle (7 subjects in the IDegAsp group). For others, the reason for withdrawal was unknown, or subjects were lost to follow-up. See [Appendix 16.2.1, Table 16.2.1.2](#) for details.

In total, 15 subjects were withdrawn because they met one of the withdrawal criteria (9 randomised to IDegAsp and 6 randomised to IDet). Of these, 3 were randomised in error, 4 were withdrawn due to hypoglycaemia posing a safety problem as judged by the investigator and 2 withdrew due to protocol deviations. In addition, 1 subject withdrew due to lack of treatment effect according to the criteria specified in the protocol. The subject () who withdrew due to lack of effect had low antibody levels at the time of withdrawal. Two (2) subjects withdrew because of pregnancy. For more detail about pregnancy during the trial, see Section [12.5.2.1](#). In addition, 3 subjects (, and) who were listed with the reason for withdrawal being ‘other’ were in fact withdrawn because they were randomised in error. Specific information about the subjects who withdrew from Week 12 and onwards can be found in [EOT Table 14.1.5](#).

Seven (7) subjects were withdrawn due to AEs, see Section [12.3.3.1](#).

Subject disposition by country is presented in [EOT Table 14.1.2](#). Information about individual subject disposition can be found in [Appendix 16.2.4, Table 16.2.4.1](#) and subject disposition by week is presented in [EOT Table 14.1.4](#). Information about withdrawals due to protocol deviations is presented in Section [10.2](#). The number of subjects allocated to each analysis set is shown in Section [11.1](#).

10.2 Protocol Deviations

10.2.1 Important Protocol Deviations

Protocol deviations (PDs) were reviewed and classified as important / not important by the study group prior to database lock. Important deviations were considered those that could affect the outcome of the trial by influencing key efficacy or safety parameters, those that could influence the safety of the subject, and those related to violations of GCP. Such deviations could lead to exclusion of a subject from the PP analysis set; see Section [11.1](#). A listing of all important protocol deviations reported in relation to this trial is included in [Appendix 16.2.2](#).

10.2.2 Important Deviations at Trial Site Level

A total of 29 important PDs were reported at the trial site level. Of these, 12 deviations were related to monitoring visits taking place outside the windows specified in the protocol. In addition, 4 important deviations were related to incorrect storage of trial products or incorrect temperature recording. In all 4 cases, trial product issued to subjects was assessed to be eligible for use. Two (2) deviations were related to site staff entering dates in the subject's diaries, and 2 deviations related to completion of informed consent forms. These and the remaining important deviations on trial site level are listed in [Appendix 16.2.2](#). None of the important protocol deviations were regarded as having a major effect on the trial outcome or safety of the subjects.

10.2.3 Important Deviations at Subject Level

A total of 131 important PDs were reported at the subject level, 86 for subjects in the IDegAsp group and 43 for subjects in the IDet group, corresponding to the 2:1 randomisation. In addition, 2 important PDs were recorded for subjects who were not randomised (i.e., screening failures).

The important PDs on subject level were divided into categories, corresponding to the relevant sections of the protocol. The number of deviations in each category by treatment group is shown in [Table 10–2](#).

Table 10–2 Important Protocol Deviations

Deviation	IDegAsp	IDet	Subject not Randomised
	N	N	
Selection Criteria	18	3	
– Randomisation despite not meeting inclusion criteria	3	0	
– Randomisation despite meeting exclusion criteria	15	3	
Informed Consent	3	0	2
Treatment Compliance	10	11	
– IDet taken in the morning instead of in the evening	0	3	
– Switch to twice-daily basal insulin in violation of protocol-defined criteria	0	5	
– Trial drug stopped, or replaced with commercially available insulin	5	1	
– Non-compliance with visit schedule or assessments	3	2	
– Wrong drug administration	1	0	
– Disallowed concomitant medication	1	0	
Trial Drug Handling	7	3	
– Trial product incorrectly dispensed and trial product used	5	2	
– Temperature not recorded in log	1	1	
– Insufficient instructions for use of trial product	1	0	
Assessment Deviations	16	7	
– Visit 28-29 safety measures not done or incomplete	5	3	
– Funduscopy/fundusphotography not done at Visit 28	4	1	
– Visit 28 pregnancy test incorrectly done, or not done	4	3	
– Procedural deviations at Visit 28	3	0	
Laboratory Sample Handling	8	4	
– Visit 28 pregnancy incorrectly done or not done	8	4	
Other	24	15	
– Diary entries done by trial site staff	2	2	
– Delayed reporting of AE/SAE/MESI	15	10	
– Missing visits	3	1	
– Insufficient instructions for use of trial product	2	1	
– Wrong needle used	1	0	
– Pregnancy discovered at Visit 28 – subject completed trial	1	0	
– Procedure deviation	0	1	
Total number of deviations	86	43	2

N: Number of deviations. Subjects were randomised 2:1 to IDegAsp:IDet

Inclusion and Exclusion Criteria

In total, 21 of the reported important deviations were related to violation of selection criteria. Of these, 10 deviations concerned subjects who were randomised although they did not have an ECG or funduscopy/fundusphotography performed according to the protocol, and in 9 of 10 cases, the subject in question was randomised to treatment with IDegAsp. With the exception of 2 subjects, subjects were not withdrawn from the trial due to this type of deviation. Other deviations in this category were mainly related to pretrial medication, see [Appendix 16.2.2](#).

Informed Consent

In total, 5 important deviations were related to informed consent. In 2 cases, ECG was performed before the informed consent form was signed. The remaining deviations were related to incorrect completion of the informed consent form. Two (2) of these 5 PDs were recorded for subjects who were recorded as screening failures and therefore were not randomised to trial treatment.

Treatment Compliance

A total of 21 important deviations were reported in the category of treatment compliance, evenly distributed between IDegAsp and IDet. Specific for the IDet group were deviations related to basal insulin injection in the morning instead of in the evening, and switch to twice-daily IDet in violation of the criteria defined in the protocol.

Trial Drug Handling

There were 10 important PDs related to trial drug handling, 7 in the IDegAsp group and 3 in the IDet group, corresponding to the 2:1 allocation of subjects. The deviations were mainly related to trial drug being manually dispensed instead of via the IV/WRS system or the wrong DUN being dispensed to subjects.

Two (2) subjects, one randomised to IDegAsp and one to IDet, were given trial drugs that were suspected to have been stored outside the allowed temperature range for a shorter period, as the continuous recording device on the refrigerator on one occasion had malfunctioned, and 2 important PDs were thus recorded. After database lock, the correct temperature information for the period in question was retrieved from the recording device, showing that no temperature deviation had actually occurred during this time, meaning that the recorded PDs should not have been rated as important. Nevertheless, these 2 PDs are still included in the total amount of important PDs for this category.

Assessment Deviations

There were 23 important PDs related to assessments, 16 in the IDegAsp and 7 in the IDet group. The deviations were all related to procedures to be performed at Visit 28 and Visit 29.

Handling of Laboratory Samples

There were 12 important PDs related to handling of laboratory samples, 8 in the IDegAsp and 4 in the IDet group. All of these deviations were related to subjects having a urine pregnancy test performed at Visit 28 instead of a serum pregnancy test as specified in the protocol.

Other Important Protocol Deviations

In total, 39 important PDs were recorded in the category of 'other'. Of these, 24 occurred in subjects randomised to IDegAsp, and 15 occurred in subjects randomised to IDet. The majority of

these cases (25 of 39) were related to the trial sites not reporting MESIs or SAEs within the timelines specified in the protocol.

11 Efficacy Evaluation

11.1 Data Sets Analysed

Assignment of Subjects to Analysis Sets

Before data were released for statistical analysis, a blinded review of the data was performed to identify protocol violations that could affect the results; see Section [9.7.3](#). Subjects who were exposed to trial products <12 weeks and who did not have a valid assessment of HbA_{1c} after randomisation were excluded from the PP analysis, as were subjects who violated the selection criteria in the trial, see Section [10.2](#). Individual subjects not included in the PP analysis set, including the reasons for their exclusion, are listed in [Appendix 16.2.3, Table 16.2.3.1](#).

All efficacy analyses, including analyses of patient reported outcome, and confirmatory analyses on confirmed hypoglycaemia and nocturnal confirmed hypoglycaemia, are based on the FAS. In addition, the analysis of the primary endpoint was repeated based on the PP analysis set and is considered as supportive evidence.

The number of subjects included in each analysis set is shown in [Table 11–1](#). For a definition of the analysis sets, see Section [9.7.3](#).

Table 11–1 Subject Disposition - Summary

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Full Analysis Set	366 (100.0)	182 (100.0)	548 (100.0)
PP Analysis Set	336 (91.8)	168 (92.3)	504 (92.0)
Safety Analysis Set	362 (98.9)	180 (98.9)	542 (98.9)

N: Number of subjects

?: Proportion of randomised subjects

Cross-reference: Modified from [EOT Table 14.1.1](#)

In total, 92 % of the randomised subjects were included in the PP analysis set. Of the 44 subjects excluded from the PP population, 3 were prematurely withdrawn from the trial and therefore exposed for less than the required 12 weeks, and 5 were withdrawn because they violated inclusion or exclusion criteria. The most frequent reason for subject exclusion from the PP analysis set was lack of a valid HbA_{1c} assessment after 12 weeks of exposure. A listing of subjects excluded from the efficacy analysis is presented in [Appendix 16.2.3, Table 16.2.3.1](#), and data points excluded from efficacy analysis are listed in [Appendix 16.2.3, Table 16.2.3.2](#).

The safety analysis set contained fewer subjects than the FAS because 6 subjects were withdrawn before being exposed. For 3 of these subjects, the underlying reason for withdrawal was related to violation of the selection criteria or non-compliance.

11.2 Demographic and Other Baseline Characteristics

The demographics and baseline characteristics in the two treatment groups were similar with only marginal differences between the treatment groups: the IDegAsp group had 3.0% subjects over 65 years of age and 48.1% females, while the IDet group had 7.7% subjects above 65 years and 54.9% females. The population consisted of male and female subjects with type 1 diabetes mellitus with a mean age of 41.3 years (ranging from 18 to 80 years), with a mean duration of diabetes of 17.4 years (ranging from 1 to 60 years), with a mean HbA_{1c} of 8.3 % and a mean BMI of 26.4 kg/m². The majority of the subjects (~90%) that reported their race were White and of non-Hispanic/Latino origin. The second-largest race group were Black or African-American subjects with 2.7% in the IDegAsp treatment group and 3.3% in the IDet group. The demographic and baseline characteristics of all randomised subjects are summarised descriptively in [Table 11-2](#) and [Table 11-3](#).

Table 11–2 Demographics and Baseline Characteristics - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
Age Group			
N	366 (100.0)	182 (100.0)	548 (100.0)
> 65 years	11 (3.0)	14 (7.7)	25 (4.6)
Adults (18-65 yrs)	355 (97.0)	168 (92.3)	523 (95.4)
Sex			
N	366 (100.0)	182 (100.0)	548 (100.0)
Female	176 (48.1)	100 (54.9)	276 (50.4)
Male	190 (51.9)	82 (45.1)	272 (49.6)
Country of Residence			
N	366 (100.0)	182 (100.0)	548 (100.0)
Australia	47 (12.8)	18 (9.9)	65 (11.9)
Denmark	16 (4.4)	15 (8.2)	31 (5.7)
France	17 (4.6)	8 (4.4)	25 (4.6)
Israel	22 (6.0)	11 (6.0)	33 (6.0)
Poland	37 (10.1)	15 (8.2)	52 (9.5)
Romania	49 (13.4)	21 (11.5)	70 (12.8)
Russian Federation	47 (12.8)	22 (12.1)	69 (12.6)
United Kingdom	24 (6.6)	12 (6.6)	36 (6.6)
United States	107 (29.2)	60 (33.0)	167 (30.5)
Ethnicity			
N	366 (100.0)	182 (100.0)	548 (100.0)
Hispanic or Latino	10 (2.7)	7 (3.8)	17 (3.1)
Not Hispanic or Latino	339 (92.6)	167 (91.8)	506 (92.3)
Not Applicable	17 (4.6)	8 (4.4)	25 (4.6)
Race			
N	366 (100.0)	182 (100.0)	548 (100.0)
White	333 (91.0)	162 (89.0)	495 (90.3)
Black or African American	10 (2.7)	6 (3.3)	16 (2.9)
Asian Indian	1 (0.3)	0 (0.0)	1 (0.2)
Asian non-Indian	3 (0.8)	3 (1.6)	6 (1.1)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	1 (0.3)	1 (0.5)	2 (0.4)
Not Applicable	17 (4.6)	8 (4.4)	25 (4.6)
Other	1 (0.3)	2 (1.1)	3 (0.5)

N = Number of Subjects
Subjects from France did not report race

Cross-reference: [EOT Table 14.1.6](#)

Table 11–3 Baseline and Diabetes Characteristics - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Age (years)			
N	366	182	548
Mean (SD)	40.7 (12.8)	42.6 (13.8)	41.3 (13.2)
Median	39.9	42.4	40.6
Min ; Max	18.3 ; 78.5	18.1 ; 80.2	18.1 ; 80.2
Height (m)			
N	366	182	548
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Median	1.7	1.7	1.7
Min ; Max	1.5 ; 2.0	1.1 ; 2.0	1.1 ; 2.0
Body Weight (kg)			
N	366	182	548
Mean (SD)	76.7 (14.6)	76.0 (14.0)	76.5 (14.4)
Median	75.0	76.0	75.3
Min ; Max	44.0 ; 123.4	42.9 ; 137.4	42.9 ; 137.4
BMI (kg/m ²)			
N	366	182	548
Mean (SD)	26.2 (4.0)	26.7 (3.9)	26.4 (4.0)
Median	25.9	26.3	26.0
Min ; Max	16.2 ; 35.6	18.7 ; 36.2	16.2 ; 36.2
Duration of Diabetes (year)			
N	366	181	547
Mean (SD)	17.2 (11.3)	17.9 (12.3)	17.4 (11.6)
Median	14.9	15.0	14.9
Min ; Max	1.1 ; 59.7	1.0 ; 56.6	1.0 ; 59.7
HbA _{1c} (%)			
N	366	182	548
Mean (SD)	8.3 (0.8)	8.3 (0.7)	8.3 (0.8)
Median	8.2	8.2	8.2
Min ; Max	6.8 ; 10.3	6.5 ; 10.4	6.5 ; 10.4
FPG (mmol/L)			
N	365	181	546
Mean (SD)	10.3 (4.7)	11.0 (4.8)	10.5 (4.8)
Median	9.6	10.3	9.9
Min ; Max	1.8 ; 30.2	2.9 ; 28.4	1.8 ; 30.2

BMI = Body Mass Index, N = Number of Subjects, SD = Standard Deviation

Cross-reference: [EOT Table 14.1.7](#)

The subjects were randomised based on measurements performed on Visit 1, and baseline values were recorded approximately 1 week later, at Visit 2. Since some subjects had an increase in body weight or HbA_{1c} from Visit 1 to Visit 2, the maximum values for HbA_{1c} and BMI displayed in [Table 11–3](#) are above the limits allowed in the inclusion criteria (see Section [9.3](#)).

Individual demographic data as well as baseline characteristics, diabetes complications at screening and anti-diabetic treatment at screening and are presented in [Appendix 16.2.4](#), [Tables 16.2.4.2](#) to [16.2.4.5](#).

Pretrial Antidiabetic Treatment Regimens

Eligible subjects at screening could have been treated with any of the following insulin regimens for ≥ 12 months prior to Visit 1:

- Basal-bolus regimen
- Premix insulin regimen
- Self-mix regimen

Subjects receiving either of the following pretrial anti-diabetic treatments were ineligible:

- Basal-bolus regimen with basal insulin injected twice daily
- Use within the last 3 months before Visit 1 of any other antidiabetic glucose-lowering drug than insulin

[Table 11–4](#) presents the anti-diabetic treatment regimens at screening. Basal-bolus insulin treatment was the most commonly used anti-diabetic treatment regimen (~90% of subjects). The different pretrial regimens were equally represented in the two treatment groups.

Table 11–4 Anti-diabetic Treatment Regimen at Screening - Full Analysis Set

	IDegAsp N	OD (%)	IDet N	IDet (%)	Total N	Total (%)
Number of Subjects	366		182		548	
Basal-Bolus	334	(91.3)	161	(88.5)	495	(90.3)
Basal-Bolus	334	(91.3)	161	(88.5)	495	(90.3)
Other	32	(8.7)	21	(11.5)	53	(9.7)
Basal + PreMix			1	(0.5)	1	(0.2)
Basal Only	1	(0.3)	1	(0.5)	2	(0.4)
PreMix + Bolus	11	(3.0)	7	(3.8)	18	(3.3)
PreMix Only	18	(4.9)	10	(5.5)	28	(5.1)
SelfMix	2	(0.5)	2	(1.1)	4	(0.7)

N: Number of Subjects
%: Proportion of Subjects

Cross-reference: [EOT Table 14.1.8](#)

According to [Table 11–4](#), 2 subjects were treated with basal insulin only at screening. These subjects, ([IDet] and [IDegAsp]) were randomised in error and were withdrawn from the trial without being exposed.

The antidiabetic treatment regimen at screening is shown in further detail in [EOT Table 14.1.9](#). Approximately 66% of all subjects used IGlax as basal insulin and IAsp was the most commonly used bolus insulin (used by 50% of subjects). A listing of antidiabetic treatment for individual subjects during the follow-up period is found in [Appendix 16.2.5, Table 16.2.5.4](#).

Diabetes Complications

Diabetes complications were grouped according to MedDRA high-level group terms. The proportion of subjects with diabetes complications at baseline was 32.5% for subjects in the IDegAsp group and 36.8% in the IDet group. In both groups, the most frequently reported diabetes complications were ophthalmic complications (diabetic retinopathy) and neurologic complications (diabetic neuropathy); see [Table 11-5](#).

Table 11–5 Diabetes Complications at Screening - Summary - Full Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Number of Subjects	366			182			548		
All Complications	119	(32.5)	217	67	(36.8)	102	186	(33.9)	319
Diabetic retinopathy	88	(24.0)	88	53	(29.1)	53	141	(25.7)	141
Diabetic neuropathy	70	(19.1)	70	24	(13.2)	24	94	(17.2)	94
Diabetic nephropathy	19	(5.2)	19	11	(6.0)	12	30	(5.5)	31
Microalbuminuria	10	(2.7)	10	5	(2.7)	5	15	(2.7)	15
Diabetic vascular disorder	12	(3.3)	12	2	(1.1)	2	14	(2.6)	14
Diabetic autonomic neuropathy	4	(1.1)	4	1	(0.5)	1	5	(0.9)	5
Retinopathy proliferative	2	(0.5)	2	2	(1.1)	2	4	(0.7)	4
Cardiac autonomic neuropathy	3	(0.8)	3				3	(0.5)	3
Diabetic encephalopathy	3	(0.8)	3				3	(0.5)	3
Cataract diabetic	2	(0.5)	2				2	(0.4)	2
Diabetic cheiropathy	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic gastroparesis	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic foot	1	(0.3)	1				1	(0.2)	1
Diabetic microangiopathy	1	(0.3)	1				1	(0.2)	1
Necrobiosis lipoidica diabetorum				1	(0.5)	1	1	(0.2)	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events

Cross-reference: [EOT Table 14.1.10](#)

Concomitant Illnesses and Medications

Clinically significant abnormal findings in vital signs, physical examinations, ECG and funduscopy/fundusphotography were to be recorded as concomitant illnesses at screening. In general, the pattern of concomitant illnesses was representative for a population with type 1 diabetes mellitus, and with the exception of a lower proportion of subjects with hypertension in the IDegAsp group compared with the IDet group, there were no apparent differences between groups with regards to concomitant illnesses. Vital signs, physical examinations, ECGs and funduscopies were similar between treatment groups at baseline.

In addition to diabetic complications, the concomitant illnesses most commonly reported fell in the system organ classes of vascular diseases, metabolism and nutrition disorders and endocrine disorders. Hypertension was the most common concomitant illness, reported by 30.9% of subjects in the IDegAsp group and by 39% of subjects in the IDet group (in addition essential hypertension was reported by 0.5% of subjects in the IDegAsp group, and renovascular hypertension by 0.5% of subjects in the IDet group). Hypercholesterolemia was reported by 10.9% of subjects in the IDegAsp group and 16.5% of subjects in the IDet group, hyperlipidemia by 12.8% in the IDegAsp group and 11.5% in the IDet group, dyslipidemia by 9.3% of subjects in the IDegAsp group and 12.1% in the IDet group and hypertriglyceridaemia by 0.3% of subjects in the IDegAsp group and 0.5% in the IDet group. Hypothyroidism was reported by 10.7% of subjects in the IDegAsp group and 9.9% in the IDet group.

Concomitant illness by treatment group are summarised in [EOT Table 14.1.11](#). A listing of the subjects individual concomitant medication is provided in [Appendix 16.2.4, Table 16.2.4.7](#).

Apart from insulin, the most common concomitant medications at screening were simvastatin (taken by 13.4% in the IDegAsp group and by 19.8% in the IDet group), acetylsalicylic acid (taken by 13.4 % in the IDegAsp group and by 14.3% in the IDet group) and levothyroxine sodium (taken by 10.7% of subjects in the IDegAsp group and by 8.2% of subjects in the IDet group); see [EOT Table 14.1.12](#). A listing of the subjects' individual concomitant medication is provided in [Appendix 16.2.4, Table 16.2.4.6](#).

11.3 Measurements of Treatment Compliance

Formal compliance with respect to trial products was not assessed because dosing was determined according to individual needs. However, at each visit/contact, the investigator reminded the subject to adhere to the trial procedures and treatment regimen described in the protocol, see [Section 9.4.8](#) for further details.

Drug accountability was performed at Visits 6, 8, 18, 28 and 29 (Weeks 4, 8, 16, 26 and 27).

The relationship between the actual mean daily basal insulin dose recorded by the subjects, the dose prescribed by the investigator and the dose recommended according to the dosing algorithm are evaluated and discussed in Section [12.1.2](#).

Tabulations were also made to evaluate the proportion of subjects achieving plasma glucose targets prebreakfast during the trial. See Section [11.4.1.6](#) for details.

11.4 Efficacy Results

11.4.1 Analysis of Efficacy

11.4.1.1 Summary of Confirmatory Testing

A hierarchical testing procedure was used to control the type I error rate. This procedure is described in detail in Section [9.7.2](#).

IDegAsp effectively improved long-term glycaemic control (non-inferior to IDet). As superiority of IDegAsp over IDet in terms of lowering FPG could not be confirmed (upper limit of 95% CI > 0%), the hierarchical testing procedure was stopped and thus superiority could not be confirmed for the two remaining confirmatory secondary efficacy and safety endpoints; See [Table 11–6](#).

Table 11–6 Confirmatory Statistical Analyses - Full Analysis Set

Endpoint	Estimate [95% CI]	p-value	Conclusion
PRIMARY			
Change in HbA1c after 26 Weeks of Treatment			
Treatment Contrast			
IDegAsp - IDet	-0.05 [-0.18; 0.08]	<0.001	Non-inferiority
CONFIRMATORY SECONDARY			
1) Change in FPG after 26 Weeks of Treatment			
Treatment Contrast			
IDegAsp - IDet	0.23 [-0.46; 0.91]	0.74	Inconclusive
2) HbA1c < 7.0% at End of Trial w/o Severe Hypoglycaemia			
Treatment Odds Ratio			
IDegAsp / IDet	1.24 [0.77; 2.02]		Testing Proc. Stopped
3) Number of Nocturnal Confirmed Hypoglycaemia			
Treatment Ratio			
IDegAsp / IDet	0.63 [0.49; 0.81]		Testing Proc. Stopped

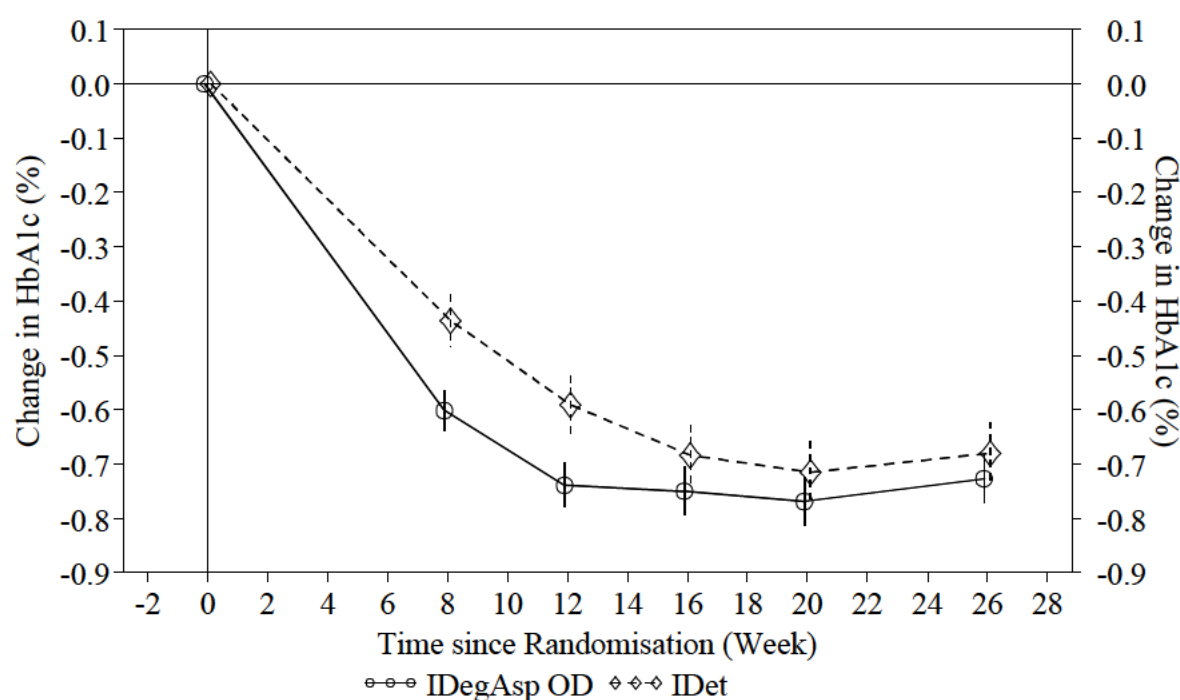
p-values are from the 1-sided test for non-inferiority and superiority respectively evaluated at the 2.5% level.

Cross-reference: [EOT Table 14.2.48](#)

Detailed descriptions of each of the confirmatory endpoints are provided in context with the associated supportive efficacy and safety analyses for the relevant assessment, i.e., analyses related to nocturnal confirmed hypoglycaemia are discussed in Section [12.4](#).

11.4.1.2 HbA_{1c} – Primary Endpoint

The primary objective of this trial was to confirm the efficacy of IDegAsp in controlling glycaemia with respect to change from baseline in HbA_{1c} after 26 weeks of treatment.



FAS; LOCF imputed data
Error bars: +-Standard Error(Mean)

FUTURINS/NN5401/NN5401-3594/FREEZE_CTR_01
13OCT2010:10:48:47 - fmean_numfind_v03.sas/e_hba1c_chb_mean_locf_fas.cgm

Cross-reference: EOT Figure 14.2.56

Figure 11–1 HbA_{1c} (%) by Treatment Week - Mean Plot - Full Analysis Set

Mean HbA_{1c} decreased during the trial in both treatment groups (Figure 11–1). After 26 weeks of treatment, the observed mean HbA_{1c} was 7.6 % with both IDegAsp and IDet (EOT Table 14.2.49). The observed mean change from baseline to end of trial was -0.73 %-points with IDegAsp and -0.68 %-point with IDet (EOT Table 14.2.50).

IDegAsp effectively improved glycaemic control, and IDegAsp was non-inferior to IDet in terms of lowering HbA_{1c}, as the upper limit of the 95% CI for the estimated mean treatment difference was > 0% and ≤0.4%; see Table 11–7.

Table 11–7 HbA1c (%) after 26 Weeks of Treatment - Primary Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	366	366	7.55	0.06	
IDet	182	182	7.60	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	366	366	-0.75	0.06	
IDet	182	182	-0.70	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.05		[-0.18 ; 0.08]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

Cross-reference: [EOT Table 14.2.51](#)

The estimated mean reduction in HbA_{1c} during the trial was 0.75 %-points with IDegAsp and 0.70 %-points with IDet, with an estimated mean difference of -0.05 %-points after 26 weeks of treatment.

Additional plots of HbA_{1c} over time are shown in [EOT Figures 14.2.57 to 14.2.60](#) and individual HbA_{1c} values are listed in [Appendix 16.2.6, Table 16.2.6.1](#). [EOT Table 14.2.52](#) shows the estimates for the parameters used as fixed factors and covariates on the observed scale.

The primary efficacy analysis was based on both the FAS and the PP analysis sets, where the PP analysis was considered as supportive evidence. The result of the analysis for the PP analysis set was in accordance with the result from the primary analysis ([Table 11–8](#)).

Table 11–8 HbA_{1c} (%) after 26 Weeks of Treatment - Statistical Sensitivity Analysis - PP Analysis Set

	PP	N	Estimate	SE	95% CI
HbA _{1c} (%)					
LSMeans					
IDegAsp OD	336	336	7.47	0.07	
IDet	168	168	7.53	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	336	336	-0.83	0.07	
IDet	168	168	-0.77	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.06		[-0.20 ; 0.08]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

Cross-reference: [EOT Table 14.2.53](#)

The primary analysis was further supported by two additional sensitivity analyses, one based on a simple model, including only HbA_{1c} at baseline as covariate, and one based on a repeated measurement model; see Section [9.7.1](#) for further details and [EOT Tables 14.2.54](#) and [14.2.55](#) for analysis results.

11.4.1.3 Responders for HbA_{1c}

Subjects Achieving HbA_{1c} Targets

At end of trial, the proportion of subjects who achieved the HbA_{1c} target of <7.0% was 24.6% with IDegAsp and 20.3% with IDet; see [Table 11–9](#).

Table 11–9 Responder for HbA_{1c} at End of Trial – Summary – Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
HbA _{1c} <7.0%			
Visit 28 (Week 26) (LOCF)			
N	366 (100.0)	182 (100.0)	548 (100.0)
Yes	90 (24.6)	37 (20.3)	127 (23.2)
No	276 (75.4)	145 (79.7)	421 (76.8)

N = Number of Subjects

Cross-reference: Modified from [EOT Table 14.2.61](#)

The estimated odds of achieving the target of HbA_{1c} < 7% was numerically higher (35%) with IDegAsp compared to IDet. No difference could be identified in the statistical analysis, as the lower limit of the 95% CI for the estimated odds ratio (IDegAsp/IDet) was ≤ 1; see [Table 11–10](#).

Table 11–10 Responder for HbA_{1c} at End of Trial - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
HbA _{1c} <7.0%				
LSMeans, Odds				
IDegAsp OD	366	366	0.33	
IDet	182	182	0.25	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.35	[0.85 ; 2.14]

N= Number of subjects contributing to analysis, CI= Confidence Interval The binary endpoint is analysed in a Logistic Regression Model using a logit link. The model includes treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and hbA_{1c} as covariates.

Missing data is imputed using last observation carried forward.

End of Trial means a subject's last end of trial visit excluding the follow-up visit

Cross-reference: [EOT Table 14.2.62](#)

Subjects Achieving HbA_{1c} Targets without Hypoglycaemia

In all, 4.5% of subjects treated with IDegAsp and 3.0% of subjects treated with IDet achieved the HbA_{1c} target < 7% without confirmed hypoglycaemic episodes during the last 12 weeks of treatment; see [Table 11–11](#).

The odds of achieving this target (HbA_{1c} < 7% without confirmed hypoglycaemia) was 53% higher with IDegAsp compared to IDet (estimated odds ratio (IDegAsp/IDet) 1.53 [0.54 ; 4.38]_{95%CI}). As

the lower limit of the 95% CI for the estimated odds ratio (IDegAsp/IDet) was ≤ 1 , this difference was not significant; see [EOT Table 14.2.66](#).

Table 11–11 Responder for HbA_{1c} at End of Trial Without Hypoglycaemia - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
HbA _{1c} <7.0% w/o Confirmed Hypo.			
Visit 28 (Week 26) (LOCF)			
N	337 (100.0)	169 (100.0)	506 (100.0)
Yes	15 (4.5)	5 (3.0)	20 (4.0)
No	322 (95.5)	164 (97.0)	486 (96.0)
HbA _{1c} <7.0% w/o Severe Hypo.			
Visit 28 (Week 26) (LOCF)			
N	337 (100.0)	169 (100.0)	506 (100.0)
Yes	82 (24.3)	35 (20.7)	117 (23.1)
No	255 (75.7)	134 (79.3)	389 (76.9)

N = Number of Subjects

Responder for HbA_{1c} without hypoglycaemia: subject meeting the HbA_{1c} target at end of trial without treatment emergent hypoglycaemia during the last 12 weeks of trt. Endpoint is only defined for subjects exposed for at least 12 trt. weeks. End of Trial: last end of trial visit of subject excluding follow-up visit. Confirmed hypoglycaemia: subject unable to treat self and/or have a recorded PG < 3.1 mmol/L (56mg/dL).

Cross-reference: Modified from [EOT Table 14.2.63](#)

The proportion of subjects achieving an HbA_{1c} < 7% without severe hypoglycaemia was defined as a confirmatory endpoint in this trial.

In total, 24.3% of subjects treated with IDegAsp and 20.7% of subjects treated with IDet achieved the HbA_{1c} target < 7% without severe hypoglycaemic episodes during the last 12 weeks of treatment; see [Table 11–11](#).

The estimated odds of achieving this target (HbA_{1c} <7% without severe hypoglycaemic episodes) were numerically higher (24%) with IDegAsp compared to IDet. As the lower limit of the 95% CI for the estimated odds ratio (IDegAsp/IDet) was ≤ 1 , this difference was not significant, and superiority of IDegAsp to IDet could not be confirmed; see [Table 11–12](#).

Table 11–12 HbA1c < 7.0% at End of Trial Without Severe Hypoglycaemia - Confirmatory Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
HbA1c<7.0 w/o S Hypo				
LSMeans, Odds				
IDegAsp OD	366	337	0.37	
IDet	182	169	0.30	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.24	[0.77 ; 2.02]

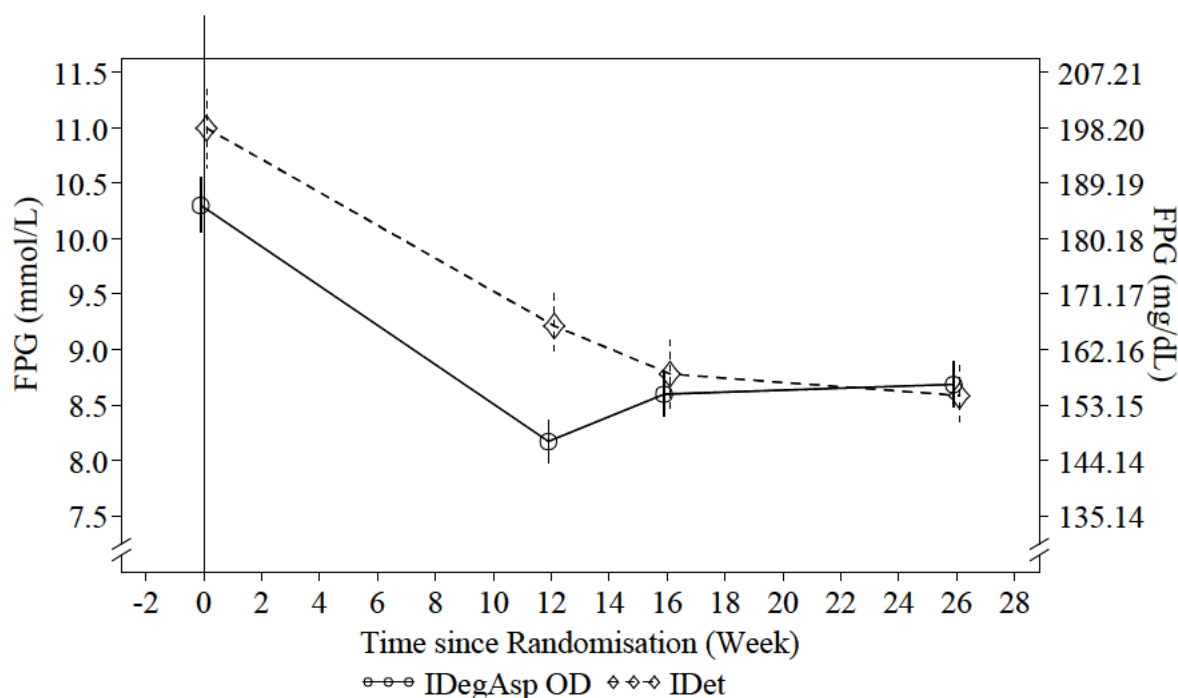
The endpoint is analysed in a Logistic Regression Model using a logit link, including treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and hba1c as covariates. Missing data is imputed using LOCF
HbA1c <7.0% w/o Hypo: A subject exposed for at least 12 weeks, who meets the HbA1c target w/o hypoglycaemia during the last 12 weeks of treatment or within 7 days from last randomised treatment. End of Trial: the last end of trial visit of a subject excluding the follow-up visit.

Cross-reference: [EOT Table 14.2.64](#)

[EOT Table 14.2.65](#) shows the estimated effects of the fixed effect parameters and covariates included in the logistic regression model. See [Appendix 16.2.6, Table 16.2.6.2](#) for responder data for individual subjects, and [Appendix 16.2.3, Table 16.2.3.4](#) for a listing of subjects not contributing data to this analysis.

11.4.1.4 Fasting Plasma Glucose

FPG decreased in both treatment groups during the trial; see [Figure 11–2](#). From baseline, mean FPG values of 10.3 mmol/L (IDegAsp) and 11.0 mmol/L (IDet), decreased by 1.6 mmol/L with IDegAsp and by 2.4 mmol/L with IDet, to similar observed mean FPG values at end of treatment (Week 26): 8.7 mmol/L with IDegAsp and 8.6 mmol/L with IDet.



FAS; LOCF imputed data
Error bars: +-Standard Error(Mean)

13OCT2010:10:52:41 - FUTURINS/NN5401/NN5401-3594/FREEZE_CTR_01
fmean_numfind_v03.sas/e_fpg_abs_mean_locf_fas.cgm

Cross-reference: [EOT Figure 14.2.71](#)

Figure 11–2 Fasting Plasma Glucose (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set

Change from baseline in FPG after 26 weeks of treatment was defined as a confirmatory endpoint in this trial. The estimated treatment difference (IDegAsp-IDet) was 0.23 mmol/L [-0.46; 0.91]_{95%CI}. Superiority could not be confirmed, as the upper limit of the 95% CI for the estimated mean treatment difference (IDegAsp minus IDet) was ≥ 0 ; see [Table 11–13](#). Consequently, the hierarchical testing procedure was stopped. Therefore, superiority could not be confirmed for the remaining two confirmatory secondary efficacy and safety endpoints; see [Table 11–6](#).

Table 11–13 Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment - Confirmatory Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
FPG (mmol/L)					
LSMeans					
IDegAsp OD	366	365	8.88	0.34	
IDet	182	181	8.65	0.39	
Change from Baseline					
LSMeans					
IDegAsp OD	366	365	-1.65	0.34	
IDet	182	181	-1.88	0.39	
Treatment Contrast					
IDegAsp OD - IDet			0.23		[-0.46 ; 0.91]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

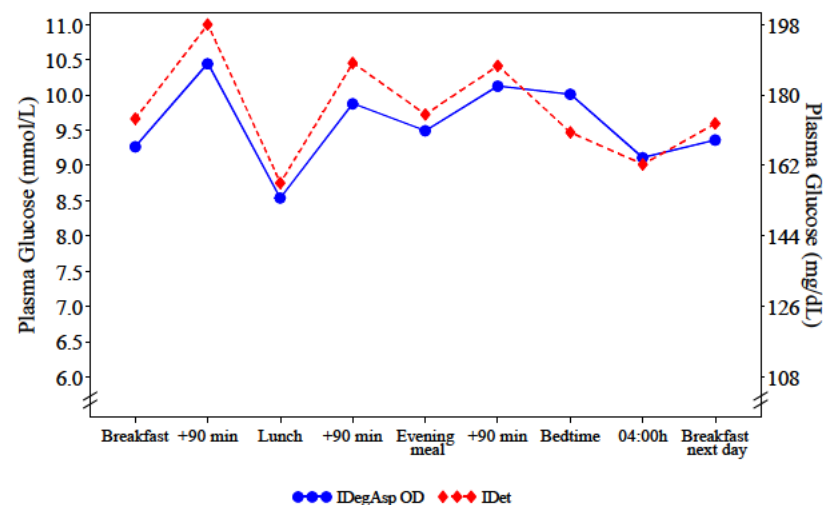
Missing data is imputed using last observation carried forward.

Cross-reference: [EOT Table 14.2.69](#)

FPG by treatment week is summarised in [EOT Tables 14.2.67](#) and [14.2.68](#), and change from baseline is plotted in [EOT Figure 14.2.72](#). [EOT Table 14.2.70](#) shows the estimated effects of the fixed effect parameters and covariates included in the ANOVA model. Empirical distribution plots are shown in [EOT Figure 14.2.73](#) and [14.2.74](#). Individual subject data for FPG are shown in [Appendix 16.2.6; Table 16.2.6.1](#), and a listing of subjects not contributing with information to this analysis is shown in [Appendix 16.2.3, Table 16.2.3.5](#).

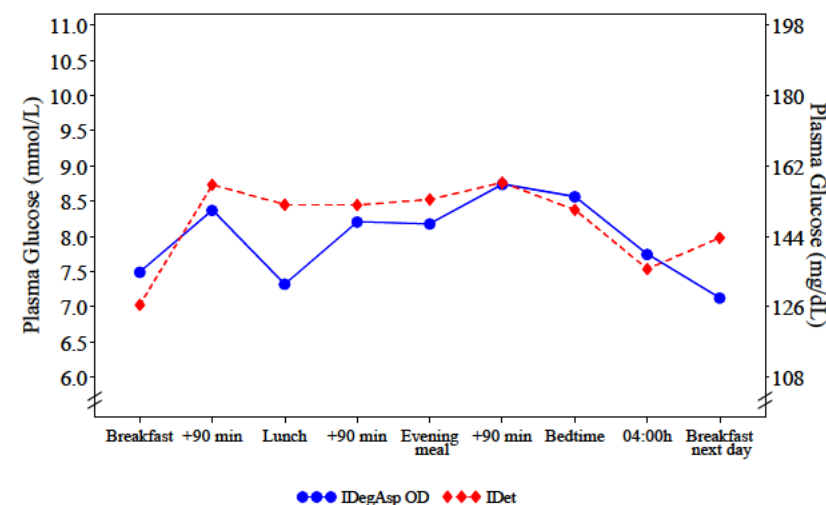
11.4.1.5 9-point Self-measured Plasma Glucose Profile

At baseline, the 9-point profiles appeared similar in the two treatment groups, and plasma glucose concentrations decreased in both treatment groups during the trial. Overall, the 9-point profiles were similar between IDegAsp and IDet after 26 weeks, except before lunch where the mean PG value was lower with IDegAsp than with IDet; see [Figure 11–3](#).



Missing profiles was imputed using LOCF

17NOV2010:15 53:25 - fplot_9PP/e_9pp_week0_abs_mean_locf_fas cgm



Missing profiles was imputed using LOCF

17NOV2010:15 56:33 - fplot_9PP/e_9pp_week26_abs_mean_locf_fas cgm

Cross-reference: [EOT Figure 14.2.79](#) and [14.2.82](#)

Figure 11–3 9-point Self Measured Plasma Glucose Profile (mmol/L) at Baseline (Left) and After 26 Weeks (Right) - LOCF - Mean Plot - Full Analysis Set

Descriptive statistics and results from the statistical analysis are shown in [EOT Tables 14.2.75](#) and [14.2.76](#) and plotted in [EOT Figures 14.2.77 to 14.2.82](#). Individual response data for SMPG is provided in [Appendix 16.2.6, Table 16.2.6.3](#).

Mean of 9-point SMPG Profiles

After 26 weeks of treatment, the estimated overall mean of the 9-point SMPG profile (defined as the area under the profile divided by measurement time), was 8.0 mmol/L and 8.4 mmol/L for subjects treated with IDegAsp and IDet, respectively. As the 95% CI for the estimated mean treatment difference (IDegAsp - IDet) contained 0, this difference was not significant; see [EOT Table 14.2.85](#). Descriptive data for the mean of the 9-point SMPG profile are shown in [EOT Tables 14.2.83](#) and [14.2.84](#). Mean plots are provided in [EOT Figure 14.2.86](#) and [14.2.87](#). Empirical distribution plots are shown in [EOT Figure 14.2.88](#) and [14.2.89](#).

Fluctuations in 9-point SMPG Profiles

Fluctuation in plasma glucose was assessed by the average distance in mmol/L from the individual mean plasma glucose level. After 26 weeks of treatment, the fluctuation was 1.3 mmol/L with IDegAsp and 1.5 mmol/L with IDet. The estimated treatment ratio was 0.84 [0.75; 0.94]_{95%CI}, meaning that fluctuation was 16% lower with IDegAsp. Hence, plasma glucose was more stable over a 24-hour period with IDegAsp than with IDet; see [Table 11–14](#).

Table 11–14 Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
Fluctuation (mmol/L)				
LSMeans				
IDegAsp OD	366	342	1.29	
IDet	182	176	1.53	
Treatment Ratio				
IDegAsp OD / IDet			0.84	[0.75 ; 0.94]

N= Number of subjects contributing to analysis, CI= Confidence Interval The log-transformed response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
Missing data is imputed using last observation carried forward.
Fluctuation is integrated abs. dist. from mean profile value divided by measurement time.

Cross-reference: [EOT Table 14.2.91](#)

Descriptive data related to fluctuations during the trial are shown in [EOT Table 14.2.90](#) and [EOT Figures 14.2.92 to 14.2.95](#).

Prandial PG Increment

Overall, the mean prandial increments appeared similar with IDegAsp and IDet after 26 weeks. In exception, the mean prandial increment at lunch was higher with IDegAsp (1.0 mmol/L) than with IDet (0.3 mmol/L) after 26 weeks (estimated difference IDegAsp-IDet: 0.92 [0.17; 1.68]_{95%CI}). Since the mean SMPG before lunch was 7.3 mmol/L with IDegAsp and 8.5 mmol/L with IDet, the

low prandial increment over lunch seen with IDet merely reflected a constantly high PG in this group, whereas the PG with IDegAsp clearly decreased from breakfast to lunch, as seen in the SMPG figures ([Figure 11–3](#) and [EOT Table 14.2.75](#)).

Statistical analysis of prandial increments at week 26 is shown in [EOT Table 14.2.98](#). Prandial increments (and change from baseline) are summarised separately for breakfast, lunch and dinner as well as for all meals in [EOT Table 14.2.96](#) and [14.2.97](#), while mean plots and distribution plots are shown in [EOT Figures 14.2.99 to 14.2.112](#). Listings for individual subjects are provided in [Appendix 16.2.6, Table 16.2.6.3](#).

Nocturnal SMPG Measurements

Change in nocturnal PG was assessed as the differences between SMPG levels measured at bedtime, at 04:00 a.m. and before breakfast the following day:

- Before-breakfast PG value minus 04:00 a.m. PG value
- Before-breakfast PG value minus before-bedtime PG value
- 04:00 a.m. PG value minus before-bedtime PG value

At baseline (Week 0) the mean change in nocturnal PG (bedtime to breakfast) was -0.7 mmol/L in the IDegAsp group and 0.1 mmol/L in the IDet group. After 26 weeks of treatment, the mean change in nocturnal PG (bedtime to breakfast) was -1.6 mmol/L with IDegAsp and -0.4 mmol/L with IDet. The change in nocturnal PG (bedtime to breakfast) was greater with IDegAsp after 26 weeks of treatment; estimated mean difference -1.01 mmol/L [-1.82; -0.19]_{95%CI}. This difference was driven by a difference in the period between 04:00 and breakfast; estimated mean difference between treatments of -0.87 mmol/L [-1.56; -0.17]_{95%CI}.

Change in nocturnal PG is summarised descriptively in [EOT Table 14.2.113](#) and [Table 14.2.114](#), and the statistical analysis is shown in [EOT Table 14.2.115](#). Mean plots and empirical distribution plots are shown in [EOT Figures 14.2.116 to 14.2.127](#).

11.4.1.6 SMPG Values Used for Dose Adjustment

Mean SMPG before Meals

The mean SMPG at breakfast, lunch, main evening meal and bedtime was reduced with both IDegAsp and IDet during the trial, the greatest changes occurred in the initial weeks of treatment. The mean prebreakfast SMPG was 7.4 mmol/L with IDegAsp and 7.3 mmol/L with IDet after 26 weeks of treatment; see [Table 11–15](#). Statistical analysis could not identify a difference at end of trial between the treatments ([EOT Table 14.2.129](#)).

Table 11–15 Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Before Breakfast (mmol/L)			
Visit 28 (Week 26) (LOCF)			
N	366	181	547
Mean (SD)	7.4 (2.5)	7.3 (2.5)	7.4 (2.5)
Median	6.9	6.9	6.9
Min ; Max	2.9 ; 16.2	2.1 ; 19.3	2.1 ; 19.3
Before Lunch (mmol/L)			
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	7.6 (2.6)	8.3 (3.0)	7.8 (2.8)
Median	7.1	7.9	7.3
Min ; Max	2.7 ; 18.9	2.9 ; 21.6	2.7 ; 21.6
Before Evening Meal (mmol/L)			
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	8.1 (2.8)	8.6 (3.4)	8.3 (3.0)
Median	7.6	7.9	7.7
Min ; Max	2.7 ; 19.6	2.4 ; 21.3	2.4 ; 21.3
Before Bedtime (mmol/L)			
Visit 28 (Week 26) (LOCF)			
N	361	181	542
Mean (SD)	8.4 (2.9)	8.5 (3.0)	8.4 (2.9)
Median	7.8	7.8	7.8
Min ; Max	2.9 ; 23.2	3.1 ; 22.1	2.9 ; 23.2

N = Number of Subjects, SD = Standard Deviation
Endpoint is calculated as the mean of the available SMPG values

Cross-reference: Modified from [EOT Table 14.2.128](#)

Descriptive statistics for the SMPG measurements used for dosing (before breakfast and before bedtime) are shown by treatment week in [EOT Table 14.2.128](#) and the statistical analysis is shown in [EOT Table 14.2.129](#). Mean plots of SMPG values before breakfast, lunch, main evening meal and bedtime are provided in [EOT Figures 14.2.130 to 14.2.133](#).

Within-subject variability in SMPG as measured by CV%

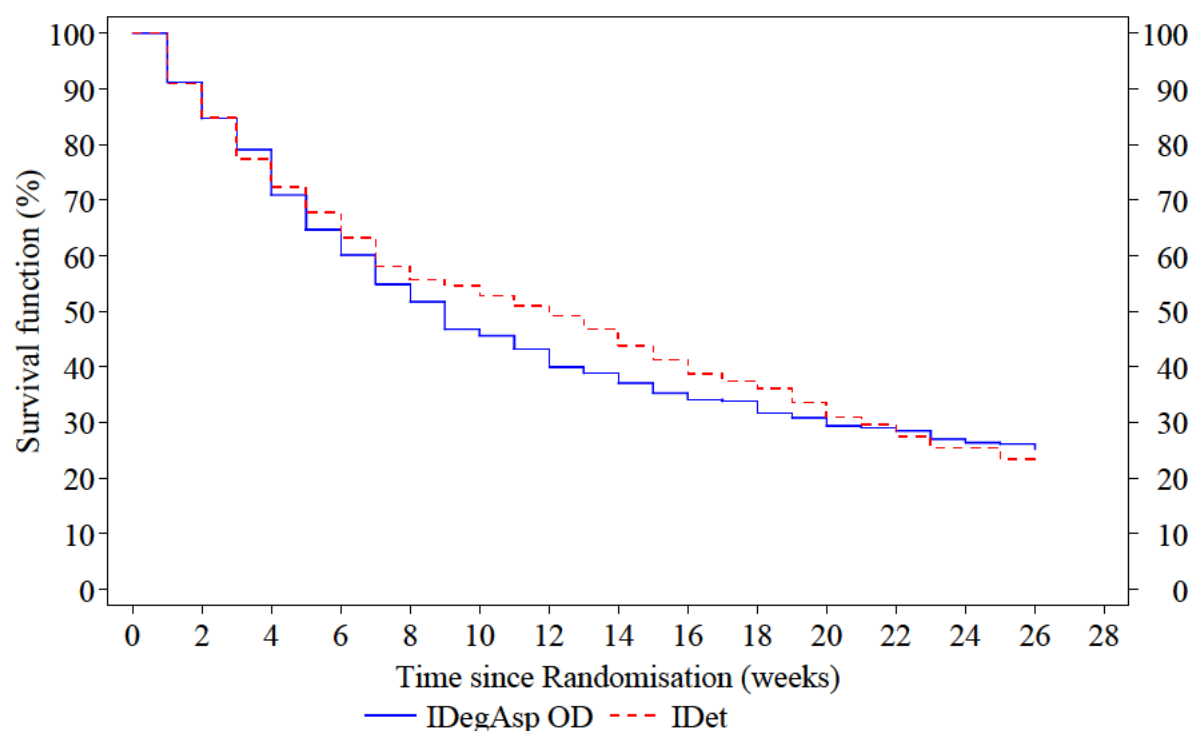
The estimated treatment ratio for the within-subject variability in SMPG was 0.91 [0.83; 1.00]_{95%CI}. As the CI for the estimated treatment ratio contained 1, this finding was not significant see [EOT Table 14.2.134](#).

Responder for SMPG Titration Target

At baseline, 7% of subjects revealed a prebreakfast SMPG below 5 mmol/L whereas approximately 17% achieved this target at end of treatment; see [EOT Table 14.2.135](#).

Time to Meet SMPG Titration Target

With IDegAsp, the median time to achieve the prebreakfast target of 5.0 mmol/L for the first time was 9 weeks, while for IDet the median time was 12 weeks; see [EOT Table 14.2.137](#), [Figure 11–4](#).



FAS; Observed data

17NOV2010:15:14:06 - fsurv_km_v01.sas/e_titrat_targ_bf_time_surv_fas.cgm
nn5401/pn5401-3594/freeze_ctr_Q4/stats

Cross-reference: [EOT Figure 14.2.136](#)

Figure 11–4 Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set

The hazard can be regarded as the probability of achieving the titration target for the first time within a given treatment week. Statistical analysis could not identify a significant difference between the treatment groups; estimated hazard ratio was 1.05 weeks [0.85; 1.30]_{95% CI}; see [EOT Table 14.2.138](#).

Individual subject data are listed in [Appendix 16.2.6, Table 16.2.6.4](#).

11.4.2 PK and PD Modelling

Not applicable.

11.4.3 Quality of Life Assessments

Aspects of Health Related Quality of Life was assessed by PRO questionnaires using a total of 4 questionnaires, which were completed by the trial subjects themselves at baseline and after 12 and 26 weeks of treatment. The changes in score from baseline to 26 weeks were analysed for each PRO questionnaire using an ANOVA model. A higher score (0-100) was related to a better perception of treatment, perception of satisfaction with medication or perception of productivity. Individual response data for PRO questionnaires are provided in [Appendix 16.2.6, Tables 16.2.6.5 to 16.2.6.9](#).

In addition, costs associated with hypoglycaemia were assessed by use of an interview-guided questionnaire completed at visits if the subject reported one or more hypoglycaemic episodes since last contact. Individual response data for the questionnaire are listed in [Appendix 16.2.6, Table 16.2.6.10](#).

Treatment Related Impact Measure - Diabetes (TRIM-D)

In general, a slightly better treatment related impact was seen in both treatment groups during the trial. After 26 weeks of treatment the total mean scores changed from 67.8 to 72.3 with IDegAsp and from 68.8 to 73.0 with IDet. Statistical analyses did not identify any differences in perception of treatment related impact between IDegAsp and IDet in any of the subcategories (domains). Summary tables for TRIM-D are found in [EOT Tables 14.2.150 and 14.2.151](#), and statistical analysis in [EOT Table 14.2.152](#).

Diabetes Medication Satisfaction Questionnaire (DiabMedSat)

The overall treatment satisfaction scores increased slightly in both treatment groups during the trial. After 26 weeks of treatment the mean scores changed from 69.8 to 71.0 with IDegAsp and from 69.4 to 70.2 with IDet. In contrast to the other domains, the score in the 'Symptoms' domain decreased slightly in both treatment groups, by 4.3 with IDegAsp and by 3.2 with IDet. Statistical analyses did not detect any statistically significant treatment differences between IDegAsp and IDet for any of the categories. Summary tables for DiabMedSat are found in [EOT Tables 14.2.144 and 14.2.145](#), and statistical analysis in [EOT Table 14.2.146](#).

Diabetes Productivity Measure (DPM)

In general, productivity scores increased slightly in both treatment groups during the trial. After 26 weeks of treatment the mean scores in the domain 'Life Productivity' changed from 72.1 to 73.8 with IDegAsp and from 72.2 to 73.2 with IDet. For the domain 'Life Productivity', statistical analyses did not detect any difference between the two treatment arms. The mean scores in the domain 'Work Productivity' changed from 82.3 to 84.4 with IDegAsp and from 85.4 to 83.6 with IDet. In the domain 'Work Productivity', the score was higher for IDegAsp compared to IDet, as

reflected in an estimated mean treatment difference of 2.9 [0.5; 5.2] $_{95\%CI}$. Summary tables for DPM are found in [EOT Tables 14.2.147 and 14.2.148](#), and statistical analysis in [EOT Table 14.2.149](#).

Short-Form 36 Version 2

In general, physical and mental scores changed marginally in both treatment groups during the trial. Mean physical scores changed by 0.1 with IDegAsp and by -0.3 with IDet, while mean mental scores changed by -0.1 with IDegAsp and 0.2 with IDet. Statistical analyses did not detect any differences between the two treatment arms. Summary tables for SF-36v2 are found in [EOT Tables 14.2.139 to 14.2.142](#), and statistical analysis in [EOT Table 14.2.143](#).

Hypoglycaemia Questionnaire (Interview)

The costs associated with hypoglycaemia were investigated based on subject interviews, which were performed at all site visits, in case a hypoglycaemic episode had occurred since the last visit or phone contact. No formal statistical analysis was carried out for these data, which were mainly generated to gain information relevant for health economic evaluation. Descriptive statistics for the Hypoglycaemia Questionnaire is shown in [EOT Tables 14.2.153 to 14.2.160](#), and the outcome from the interview for individual subjects is listed in [Appendix 16.2.6, Table 16.2.6.10](#).

11.4.4 Statistical/Analytical Issues

11.4.4.1 Handling of Dropouts or Missing Data

Refer to [Appendix 16.1.9](#) for detailed SAS output for statistical analyses.

Missing values were imputed by LOCF for all endpoints. To assess the sensitivity of the LOCF method on the conclusion from the analysis of the primary HbA_{1c} analysis, all observed HbA_{1c} values at scheduled measurement times were analysed using a repeated measurement model. The results from the sensitivity analysis are presented in [EOT Table 14.2.55](#), from which it can be seen that the conclusions from the analysis do not differ from the primary HbA_{1c} analysis.

11.4.5 Efficacy Conclusions

From the results of this 26-week trial of treatment with IDegAsp + IAsp at remaining meals or IDet + IAsp, the following can be concluded:

Primary Endpoint (HbA_{1c})

- HbA_{1c}:** IDegAsp effectively improved glycaemic control, and non-inferiority to IDet in terms of lowering HbA_{1c} was confirmed; estimated mean treatment difference (IDegAsp–IDet) -0.05% point [-0.18; 0.08] $_{95\%CI}$. The estimated mean change in HbA_{1c} was -0.75% points with IDegAsp and -0.70% points with IDet. After 26 weeks of treatment, the observed mean (SD) HbA_{1c} was 7.6 (0.9)% with IDegAsp and 7.6 (0.8)% with IDet.

Secondary Endpoints:

Confirmatory Endpoints

- **FPG:** FPG decreased during the trial to similar mean (SD) levels; 8.7 (4.0) mmol/L with IDegAsp and 8.6 (3.8) mmol/L with IDet. The estimated mean change in FPG was -1.65 mmol/L with IDegAsp and -1.88 mmol/L with IDet and the estimated mean treatment difference (IDegAsp-IDet) was 0.23 mmol/L [-0.46; 0.91]_{95%CI}. Superiority could not be confirmed and consequently, the hierarchical testing procedure was stopped. Therefore, superiority could not be confirmed for the remaining confirmatory secondary efficacy and safety endpoints.
- **Responders without severe hypoglycaemia:** The observed proportion of subjects achieving HbA_{1c} <7% without severe hypoglycaemic episodes was 24.3% with IDegAsp and 20.7% with IDet. The estimated odds of achieving this target were numerically higher (24%) with IDegAsp compared to IDet; odds ratio (IDegAsp/IDet) 1.24 [0.77; 2.02]_{95% CI}.
- **Nocturnal confirmed hypoglycaemia:** see conclusion in Section [12.7](#)

Supportive Efficacy Endpoints

- **Responders for HbA_{1c}:** A total of 24.6% of subjects treated with IDegAsp achieved HbA_{1c} <7% compared to the observed proportion of 20.3% for subjects treated with IDet. The odds of achieving this target were numerically higher (35%) with IDegAsp compared to IDet (estimated odds ratio (IDegAsp/IDet) 1.35 [0.85; 2.14]_{95% CI}).
- **Responders for HbA_{1c} without confirmed hypoglycaemia:** The observed proportion of subjects achieving HbA_{1c} <7% without confirmed hypoglycaemia was 4.5% with IDegAsp and 3.0% with IDet. The odds of achieving this target were numerically higher (53%) with IDegAsp compared to IDet (estimated odds ratio (IDegAsp/IDet) 1.53 [0.54; 4.38]_{95% CI}).
- **9-point SMPG profiles:** Fluctuation (mmol/L) in the 9-point profile was lower with IDegAsp than with IDet, with an estimated treatment ratio (IDegAsp/IDet) of 0.84 [0.75; 0.94]_{95% CI}. The change in nocturnal PG was greater with IDegAsp than with IDet from bedtime to breakfast and from 04:00 a.m. to breakfast; the estimated mean treatment difference (IDegAsp-IDet) was -1.01 mmol/L [-1.82; -0.19]_{95% CI}, and -0.87 mmol/L [-1.56; -0.17]_{95% CI}, respectively.
- **SMPG for dosing:** The estimated treatment ratio for within-subject variation (%CV) (IDegAsp/IDet) was 0.91 [0.83; 1.00]_{95% CI}, meaning that no statistically significant treatment difference was detected.
- **PRO:** The results related to PRO appeared similar between the two treatment groups, with only marginal changes over time. Work productivity score was higher with IDegAsp than with IDet, based on the DPM questionnaire: estimated treatment difference was 2.9 points [0.5 ; 5.2]_{95%CI}.

12 Safety Evaluation

12.1 Extent of Exposure

12.1.1 Exposure to Trial Products

All subjects who received at least one dose of trial product were included in the safety analysis set: 362 subjects in the IDegAsp group and 180 subjects in the IDet group.

The mean exposure time was equal in the treatment groups ([Table 12–1](#) and [EOT Table 14.2.1](#)), and the majority of subjects were exposed for 26 weeks ([EOT Figure 14.2.7](#) and [EOT Table 14.2.2](#)). The number of subject years of exposure was 169.3 in the IDegAsp group and 83.89 in the IDet group.

The proportions of men and women exposed to the trial products were equal in the treatment groups, and there was no difference between men and women in overall exposure or length of exposure in any of the treatment groups ([EOT Table 14.2.3](#)). The exposure by race and ethnicity was equal in the treatment groups ([EOT Table 14.2.4](#) and [14.2.5](#)). Approximately 90% of both adult and elderly subjects were exposed for 25-28 weeks ([EOT Table 14.2.6](#)).

Table 12–1 Exposure - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Total Exposure, yrs	169.3	83.89	253.2
Exposure (yrs)			
N	362	180	542
Mean (SD)	0.47 (0.10)	0.47 (0.11)	0.47 (0.10)
Median	0.50	0.50	0.50
Min ; Max	0.00 ; 0.55	0.01 ; 0.55	0.00 ; 0.55

N = Number of Subjects, SD = Standard Deviation

Cross-reference: [EOT Table 14.2.1](#)

12.1.2 Dosing During the Trial

12.1.2.1 Insulin Regimen and Dosing Time

A treat-to-target approach (prebreakfast SMPG target of < 5 mmol/L) and a frequent visit schedule was applied during the treatment period to ensure optimal titration of insulin based on SMPG values in order to improve glycaemic control (see [Section 9.4](#) for details). Guidance to insulin initiation and adjustment is described in [Section 9.4.4](#) and [Section 9.4.5](#).

IDegAsp is a combination product consisting of 70% ultra-long-acting basal insulin (IDeg) and 30% rapid-acting insulin (IAsp). Doses in the IDegAsp group are summarised both for the total daily insulin dose, the derived total basal insulin dose and the derived total bolus insulin dose ([Table 12–2](#)).

Table 12–2 Presentations of Insulin Doses in the IDegAsp group

	Definition	EOT Tables and Figures
Total daily insulin dose	IDegAsp OD dose plus separate injections of IAsp	Tables 14.2.28, 14.2.30 Figures 14.2.32, 14.2.34, 14.2.36, 14.2.38
Basal insulin dose	The IDeg part (70%) of the IDegAsp OD dose	Tables 14.2.18, 14.2.19 Figures 14.2.21, 14.2.23, 14.2.25, 14.2.27
Bolus insulin dose	The sum of injected IAsp doses plus the IAsp part (30%) of the IDegAsp OD dose	Tables 14.2.29, 14.2.31 Figures 14.2.33, 14.2.35, 14.2.37, 14.2.39

IDegAsp = insulin degludec/insulin aspart; OD = once daily; IAsp = insulin aspart; EOT = end of text

Subjects randomised to IDegAsp were instructed to administer IDegAsp OD with any meal of the day and furthermore, the dosing time of IDegAsp could be moved to a different meal at any time during the trial. IAsp was administered with the remaining meals. [Table 12–3](#) shows the distribution of IDegAsp injections among the three meals. Throughout the trial, injections of IDegAsp were distributed among all meals, indicating that subjects and investigators made use of the opportunity to individualise the treatment and choose a particular meal for the dosing of IDegAsp, though with an apparent preference for the main evening meal. The distribution of injections for the entire trial period can be seen in [EOT Table 14.2.42](#).

Table 12–3 IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set

Week	Breakfast		Lunch		Main Evening Meal	
	N	Mean	N	Mean	N	Mean
Visit 3 (Week 1)	52	35.46	73	34.22	243	36.72
Visit 28 (Week 26)	44	43.13	55	39.14	224	44.00

N: Number of Subjects
The descriptive statistics are based on recorded doses.

Cross-reference: Modified from [EOT Table 14.2.42](#)

Those subjects who were randomised to treatment with IDet + IAsp, injected IDet OD in the evening and IAsp with the meals. The investigator could consider adding a second dose of IDet after 8 weeks of treatment if a subject met the prespecified criteria for inadequate glycaemic control

listed in Section [9.4.5](#). [EOT Table 14.2.43](#) shows how the IDet injections were distributed between morning and evening in the IDet group from Week 1 to Week 26, as well as the mean dose in U per injection time. A few subjects started injecting a morning dose of IDet earlier than after 8 weeks of treatment. At Week 9, a total of 8 out of 166 subjects (approximately 5%) injected IDet in the morning at least once in the three days leading up to the visit. At Week 26, 42 out of 157 subjects (approximately 27%) recorded a morning dose of IDet at least once in the three days leading up to the visit. This indicated that the majority of subjects still injected IDet OD at end of trial. At Week 26, the mean morning IDet dose was 18 U and the mean evening dose was 33 U.

Each subject was instructed to start IDegAsp or IDet treatment with approximately the same number of basal units as they had received before randomisation; see Section [9.4.4](#). When transferring the subjects to treatment with IDegAsp, a table was used that provided information on the number of IDegAsp units to be used, corresponding to the exact amount of basal and bolus insulin taken at screening (see Appendix C of the Protocol in [Appendix 16.1.1](#)).

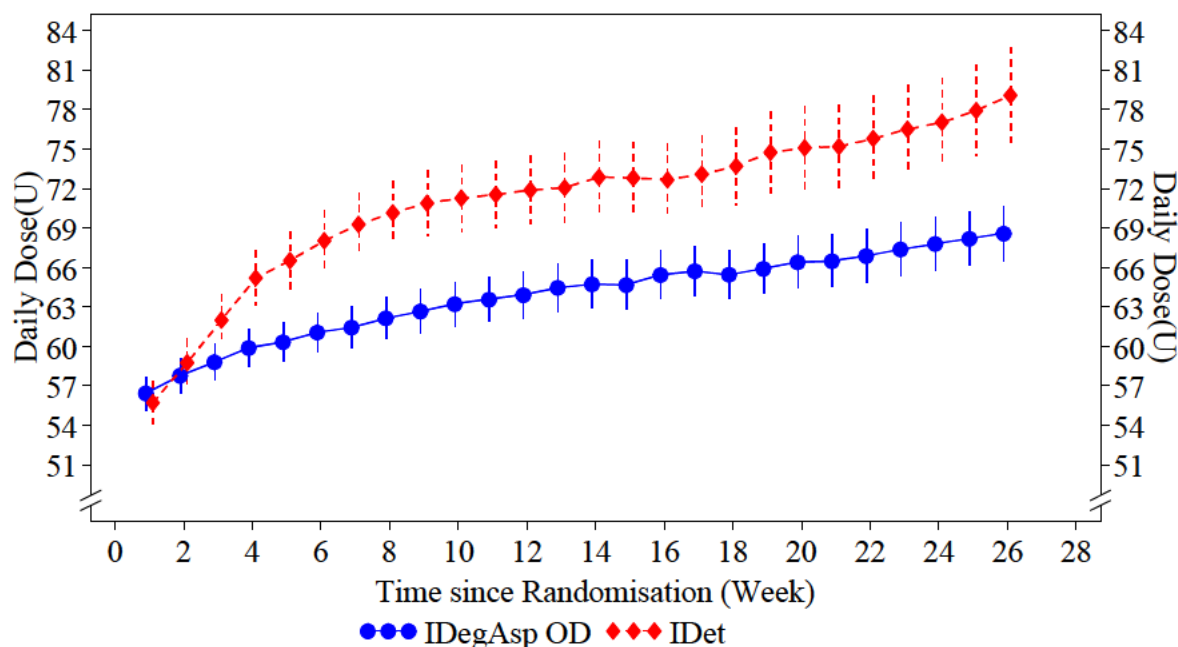
Increase of IDegAsp or IDet was done based on the mean prebreakfast plasma glucose from the preceding 3 days. The insulin dose adjustments were performed according to the titration guidelines in Section [9.4.5](#).

The direct comparison of IDegAsp doses with IDet doses must be interpreted with caution, as a bolus component is included in the IDegAsp dosage. The mean daily (non-derived) IDegAsp/IDet doses are summarised in [EOT Tables 14.2.8 to 14.2.10](#) and plotted in [EOT Figures 14.2.11 to 14.2.16](#). The mean daily actual (non-derived) bolus doses are summarised in [EOT Table 14.2.17](#) and plotted in [EOT Figures 14.2.20, 14.2.22, 14.2.24 and 14.2.26](#). Individual doses are listed by subject in [Appendix 16.2.5, Table 16.2.5.1 and 16.2.5.3](#).

12.1.2.2 Insulin Dose

Total IDegAsp/IDet Dose

At baseline (Week 1), the total daily insulin doses (basal and bolus) were similar in the IDegAsp group and the IDet group. After 26 weeks of treatment, the total insulin dose was numerically lower in the IDegAsp group compared with the IDet group ([Table 12–4](#) [U] and [Table 12–5](#) [U/kg]). In the IDegAsp group, the total daily insulin dose increased gradually throughout the course of the trial, while in the IDet group, the increase in total dose was steepest during the first weeks of treatment, as shown in [Figure 12–1](#) (U).



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

28APR2011:12:42:03 - fmean_numfind_v03.sas/e_tot_dose_d_act_u_mean_locf_sas.cgm

Cross-reference: [EOT Figure 14.2.32](#)

Figure 12–1 Total Daily Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set

Table 12–4 Total Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	Descriptive Statistics						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	362	360	56	24	51	16	184
		IDet	180	176	56	22	52	15	156
		Total	542	536	56	23	52	15	184
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp OD	362	360	69	40	57	13	266
		IDet	180	178	79	48	68	19	350
		Total	542	538	72	43	60	13	350

N = Number of Subjects, SD = Standard Deviation. The column SAFETY refers to the number of subjects in the safety analysis set.

Cross-reference: Modified from [EOT Table 14.2.28](#)

Table 12–5 Total Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	Descriptive Statistics						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	362	360	0.74	0.28	0.68	0.19	2.74
		IDet	180	176	0.73	0.25	0.69	0.27	2.11
		Total	542	536	0.73	0.27	0.69	0.19	2.74
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp OD	362	360	0.86	0.42	0.75	0.19	2.81
		IDet	180	178	1.00	0.57	0.88	0.32	4.51
		Total	542	538	0.91	0.48	0.79	0.19	4.51

N = Number of Subjects, SD = Standard Deviation. The column SAFETY refers to the number of subjects in the safety analysis set.

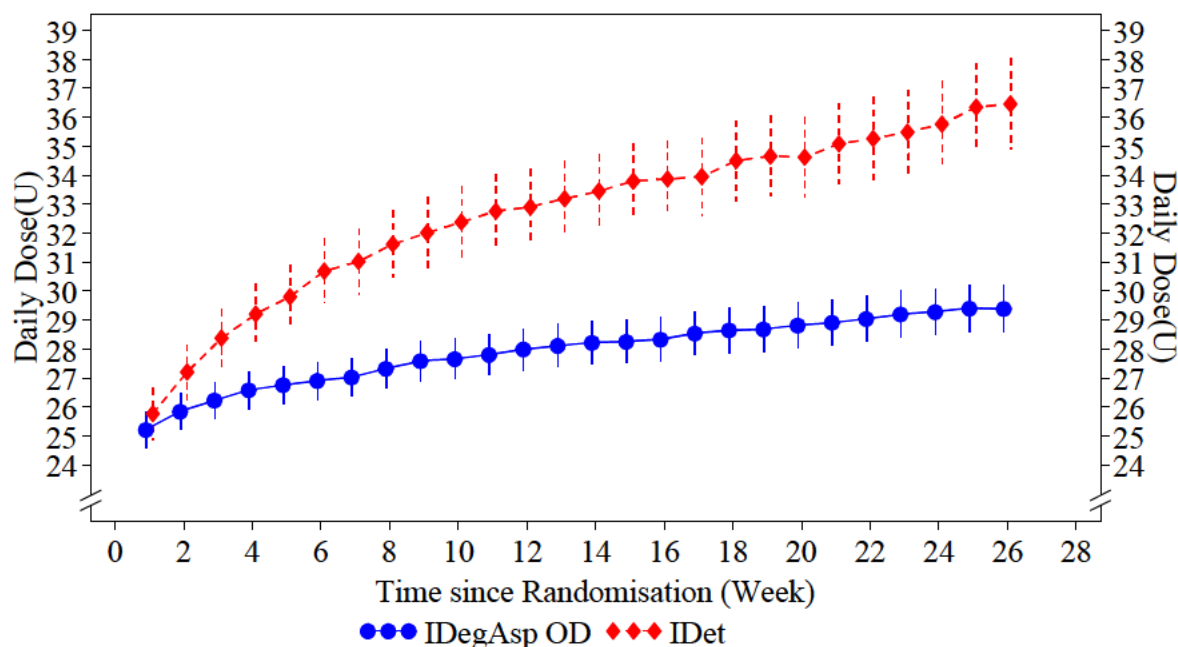
Cross-reference: Modified from [EOT Table 14.2.30](#)

A mean plot of total daily insulin dose (U/kg) is shown in [EOT Figure 14.2.34](#). The distribution of total daily insulin dose is shown in [EOT Figure 14.2.36](#) (U) and in [EOT Figure 14.2.38](#) (U/kg).

Basal Insulin Dose

The total basal insulin dose for subjects treated with IDegAsp was derived as seen in [Table 12–2](#) and compared to the mean daily basal dose for subjects treated with IDet.

The mean daily basal insulin doses were similar at baseline between the IDegAsp and the IDet groups. Throughout the trial, the basal insulin dose remained lower in the IDegAsp group compared with the IDet group, as shown in [Figure 12–2](#) (U). Derived basal insulin doses at baseline and at end of trial are shown in [Table 12–6](#) (U) and in [Table 12–7](#) (U/kg).



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

28APR2011:12:40:47 - fmean_numfind_v03.sas/e_basal_act_u_mean_locf_sas.cgm

Cross-reference: [EOT Figure 14.2.21](#)

Figure 12–2 Basal Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set

Table 12–6 Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	Descriptive Statistics						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	362	360	25	11	22	7	83
		IDet	180	176	26	12	24	7	77
		Total	542	536	25	12	24	7	83
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp OD	362	360	29	15	25	6	92
		IDet	180	178	36	21	34	6	111
		Total	542	538	32	18	28	6	111

N = Number of Subjects, SD = Standard Deviation. The column SAFETY refers to the number of subjects in the safety analysis set.

Cross-reference: Modified from [EOT Table 14.2.18](#)

Table 12–7 Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	Descriptive Statistics				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	362	360	0.33	0.13	0.30	0.09	0.88
		IDet	180	176	0.34	0.13	0.31	0.10	0.96
		Total	542	536	0.33	0.13	0.31	0.09	0.96
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp OD	362	360	0.37	0.16	0.33	0.11	1.02
		IDet	180	178	0.46	0.23	0.43	0.09	1.37
		Total	542	538	0.40	0.19	0.36	0.09	1.37

N = Number of Subjects, SD = Standard Deviation. The column SAFETY refers to the number of subjects in the safety analysis set.

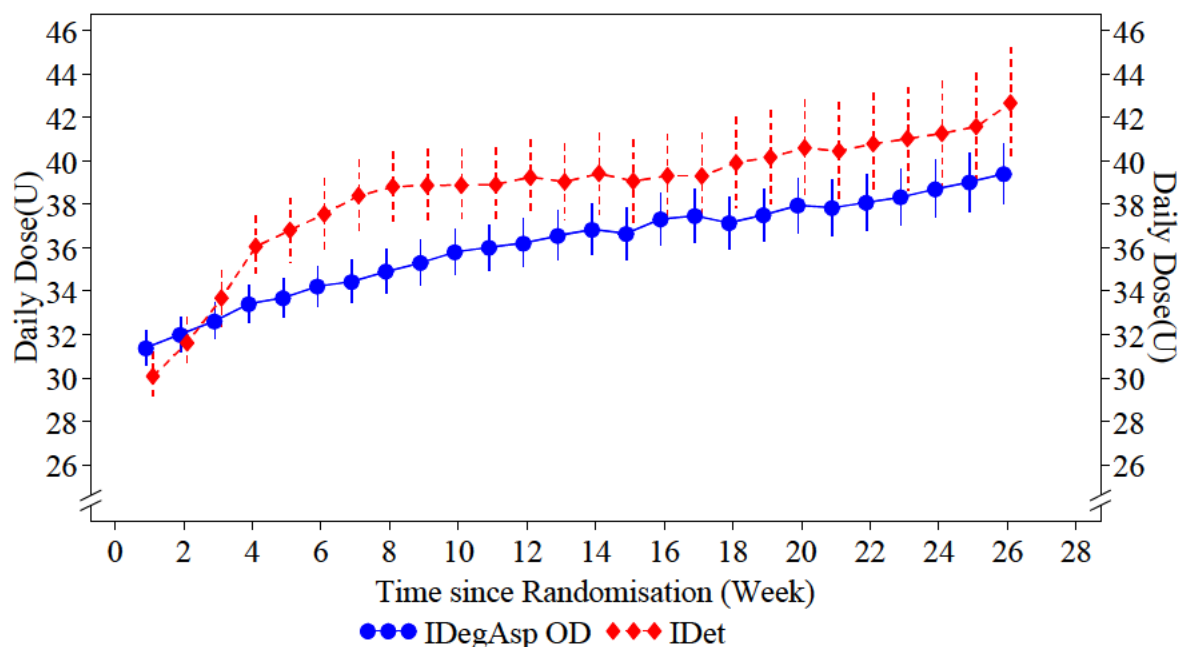
Cross-reference: Modified from [EOT Table 14.2.19](#)

A mean plot of derived daily basal insulin dose (U/kg) is shown in [EOT Figure 14.2.23](#). Distribution plots of derived daily basal insulin dose are shown in [EOT Figure 14.2.25 \(U\)](#) and [EOT Figure 14.2.27 \(U/kg\)](#).

Total Bolus Insulin Dose

The daily bolus insulin dose for subjects treated with IDegAsp was derived as seen in [Table 12–2](#) and compared to the total daily bolus insulin dose for subjects treated with IDet.

The mean daily bolus insulin doses were similar at baseline between the IDegAsp and the IDet group. During the first weeks of treatment, the increase in bolus dose was less in the IDegAsp group compared with the IDet group. Throughout the remainder of the trial, the total bolus insulin dose was slightly, but consistently lower in the IDegAsp group than in the IDet ([Figure 12–3 \[U\]](#) and [EOT Figure 14.2.35 \[U/kg\]](#)). This difference appeared to be driven by a few subjects in the IDet group who injected high doses of IAsp, as seen in the empirical distribution plots ([EOT Figure 14.2.37](#) and [14.2.39](#)). Derived bolus insulin doses at baseline and at end of trial are summarised in [Table 12–8 \(U\)](#) and [Table 12–9 \(U/kg\)](#).



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

28APR2011:12:42:10 - fmean_numfind_v03.sas/e_tot_b_d_act_u_mean_locf_sas.cgm

Cross-reference: EOT Figure 14.2.33

Figure 12-3 Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set

Table 12-8 Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	Descriptive Statistics						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	362	360	31	15	28	8	124
		IDet	180	176	30	15	28	5	130
		Total	542	536	31	15	28	5	130
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp OD	362	360	39	26	31	6	174
		IDet	180	178	43	34	33	4	244
		Total	542	538	40	29	32	4	244

N = Number of Subjects, SD = Standard Deviation. The column SAFETY refers to the number of subjects in the safety analysis set.

Cross-reference: Modified from EOT Table 14.2.29

Table 12–9 Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	Descriptive Statistics				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	362	360	0.41	0.19	0.37	0.09	1.93
		IDet	180	176	0.39	0.19	0.39	0.08	1.76
		Total	542	536	0.41	0.19	0.38	0.08	1.93
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp OD	362	360	0.49	0.29	0.41	0.12	1.88
		IDet	180	178	0.54	0.42	0.45	0.05	3.15
		Total	542	538	0.51	0.34	0.42	0.05	3.15

N = Number of Subjects, SD = Standard Deviation. The column SAFETY refers to the number of subjects in the safety analysis set.

Cross-reference: Modified from [EOT Table 14.2.31](#)

12.1.2.3 Insulin Dose Ratio at End of Trial

Insulin Dose Ratio between Treatment Groups

Overall, basal and bolus insulin doses appeared to be lower with IDegAsp than with IDet. After 26 weeks, the insulin dose ratio (IDegAsp/IDet) (U) was 0.87 for total daily insulin dose, hence 13% lower with IDegAsp. For the basal insulin dose and total bolus insulin dose, the insulin dose ratios were 0.81 and 0.92, hence mean basal and bolus doses were 19% and 8% lower with IDegAsp compared with IDet, respectively; see [Table 12–10](#).

Table 12–10 Insulin Dose Ratio after 26 Weeks of Treatment - Summary - Safety Analysis Set

Treatment Ratio	Mean Ratio (U)	Mean Ratio (U/kg)
Total Daily Insulin Dose		
IDegAsp / IDet	0.87	0.85
Derived Total Basal Insulin Dose		
IDegAsp / IDet	0.81	0.80
Derived Total Bolus Insulin Dose		
IDegAsp / IDet	0.92	0.91

Mean ratio is calculated as the ratio between mean doses at last scheduled treatment visit, where missing data have been imputed using last observation carried forward.
Derived total basal insulin dose:
IDegAsp = the IDeg part of the IDegAsp OD dose; IDet = the (sum of) injected IDet dose(s)
Derived total bolus insulin dose:
IDegAsp = the sum of injected IAsp doses plus the IAsp part of the IDegAsp OD dose;
IDet = the sum of injected IAsp doses.

Cross-reference: Modified from [EOT Table 14.2.40](#)

Insulin Dose Ratio between Basal and Bolus Insulin

After 26 weeks, the derived basal insulin component accounted for 43% of the total insulin dose in the IDegAsp group, and bolus insulin accounted for 57% of the total dose. With IDet, the split was 46% basal insulin and 54% bolus insulin at Week 26 ([Table 12–11](#)).

Table 12–11 Insulin Doses and Dose Ratio at Week 26

	Derived Total Basal Insulin Dose (U)	Derived Total Bolus Insulin Dose (U)	Total Daily Insulin Dose (U)	Basal: Bolus split
IDegAsp	29	39	69	43% : 57%
IDet	36	43	79	46% : 54%

Data from [EOT Tables 14.2.18, 14.2.29, 14.2.28](#)

Mean ratios for the basal: bolus insulin dose split in U and U/kg are shown in [EOT Table 14.2.41](#).

12.1.2.4 Difference between Titration Algorithm Dose and Prescribed Dose

The mean and median difference between the dose according to the titration algorithm and the prescribed dose was close to 0 U throughout the trial for both treatment groups indicating a close adherence to the titration algorithm. The differences are summarised descriptively in [EOT Table](#)

[14.2.45](#). Mean plots of prescribed, actual and algorithm doses are shown in [EOT Figures 14.2.46](#) and [14.2.47](#).

The prescribed insulin dose (IDegAsp/IDet) by treatment week is summarised in [EOT Table 14.2.9](#) (U) and shown in a mean plot in [EOT Figure 14.2.12](#) (U). The distribution of prescribed daily insulin dose in units is shown in [EOT Figure 14.2.15](#). Drug concentration data are listed by subject in [Appendix 16.2.5, Table 16.2.5.2](#).

12.1.2.5 Difference between Prescribed Dose and Actual Dose

The mean and median difference between the prescribed dose and the actual IDegAsp/IDet dose taken by the subject was close to 0 U throughout the trial for both treatment groups indicating a good subject compliance. The differences are summarised descriptively in [EOT Table 14.2.44](#). Plots of prescribed, actual and titration algorithm doses are shown in [EOT Figures 14.2.46](#) and [14.2.47](#). Drug concentration data are listed by subject in [Appendix 16.2.5, Table 16.2.5.2](#).

12.2 Adverse Events

12.2.1 Brief Summary of Adverse Events

The percentage of subjects reporting treatment emergent AEs (TEAES) and the rate of AEs per 100 patient years of exposure (PYE) was similar in the IDegAsp and the IDet treatment groups ([Table 12-12](#)). The most frequently reported AEs in both treatment groups were nasopharyngitis, hypoglycaemia, headache and upper respiratory tract infection, see [Table 12-13](#). The majority of AEs were mild or moderate in severity and only few of the AEs were severe. The rate of severe AEs was similar between the IDegAsp and IDet groups (37 and 45 events per 100 PYE, respectively). The rate of AEs possibly or probably related to investigational product was numerically lower with IDegAsp than with IDet (50 and 81 events per 100 PYE, respectively) ([Table 12-14](#)). The majority of subjects in both treatment groups recovered from the AEs at the end of trial.

No AEs were fatal (Section [12.3.1](#)). The rate of SAEs was similar between the IDegAsp and IDet groups (27 and 20 events per 100 PYE, respectively) (Section [12.3.2](#)). The most frequently reported SAEs were hypoglycaemia reported by approximately 3% of subjects in both treatment groups.

A similar proportion of subjects were withdrawn from the trial due to AEs in the IDegAsp group (5 subjects, 1.4%) and the IDet group (3 subjects, 1.7%) (Section [12.3.3.1](#)). The most frequently reported AEs leading to withdrawal were related to hypoglycaemia, see [EOT Listing 14.3.2.4](#).

Table 12–12 Adverse Events - Treatment Emergent – Summary – Safety Analysis Set

	IDegAsp N (%)	OD (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362				180			542		
Events	239 (66.0)		846	500	114 (63.3)	436	520	353 (65.1)	1282	506
Serious										
Yes	31 (8.6)		46	27	13 (7.2)	17	20	44 (8.1)	63	25
No	232 (64.1)		800	472	113 (62.8)	419	499	345 (63.7)	1219	481
Severity										
Severe	45 (12.4)		63	37	26 (14.4)	38	45	71 (13.1)	101	40
Moderate	104 (28.7)		183	108	40 (22.2)	81	97	144 (26.6)	264	104
Mild	191 (52.8)		600	354	102 (56.7)	317	378	293 (54.1)	917	362
Relationship to Investigational Product										
Probably	22 (6.1)		37	22	19 (10.6)	51	61	41 (7.6)	88	35
Possibly	36 (9.9)		47	28	14 (7.8)	17	20	50 (9.2)	64	25
Unlikely	220 (60.8)		757	447	107 (59.4)	364	434	327 (60.3)	1121	443
Missing	5 (1.4)		5	3	4 (2.2)	4	5	9 (1.7)	9	4
Relationship to Bolus Insulin										
Probably	22 (6.1)		36	21	16 (8.9)	25	30	38 (7.0)	61	24
Possibly	29 (8.0)		40	24	14 (7.8)	18	21	43 (7.9)	58	23
Unlikely	225 (62.2)		765	452	108 (60.0)	389	464	333 (61.4)	1154	456
Missing	5 (1.4)		5	3	4 (2.2)	4	5	9 (1.7)	9	4
Related to Device										
Yes	3 (0.8)		3	2	0 (0.0)	0	0	3 (0.6)	3	1
No	238 (65.7)		838	495	112 (62.2)	432	515	350 (64.6)	1270	502
Missing	5 (1.4)		5	3	4 (2.2)	4	5	9 (1.7)	9	4
Outcome										
Recovered	219 (60.5)		725	428	110 (61.1)	379	452	329 (60.7)	1104	436
Recovering	14 (3.9)		15	9	6 (3.3)	7	8	20 (3.7)	22	9
Recovered with Sequelae	2 (0.6)		2	1	1 (0.6)	1	1	3 (0.6)	3	1
Not Recovered	62 (17.1)		103	61	37 (20.6)	49	58	99 (18.3)	152	60
Unknown	1 (0.3)		1	1	0 (0.0)	0	0	1 (0.2)	1	0

N= Number of Subjects

%= Percentage of Subjects

E= Number of Events

R= Event Rate per 100 Patient Years of Exposure

Cross-reference: [EOT Table 14.3.1.1](#)

Table 12–13 Adverse Events by System Organ Class and Preferred Term - Most Frequent (>=5%) – Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Events	130	(35.9)	287	169	71	(39.4)	129	154	201	(37.1)	416	164
Infections and infestations												
Nasopharyngitis	78	(21.5)	111	66	32	(17.8)	44	52	110	(20.3)	155	61
Upper respiratory tract infection	24	(6.6)	33	19	16	(8.9)	26	31	40	(7.4)	59	23
Nervous system disorders												
Headache	27	(7.5)	83	49	15	(8.3)	18	21	42	(7.7)	101	40
Metabolism and nutrition disorders												
Hypoglycaemia	33	(9.1)	49	29	22	(12.2)	32	38	55	(10.1)	81	32
Gastrointestinal disorders												
Diarrhoea	10	(2.8)	11	6	9	(5.0)	9	11	19	(3.5)	20	8

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

Cross-reference: [EOT Table 14.3.1.3](#)

12.2.2 Analysis of Adverse Events

All Adverse Events

The observed rates of AEs were similar in the IDegAsp and the IDet treatment groups ([Table 12–12](#)). The most frequently reported AEs in both treatment groups were nasopharyngitis, hypoglycaemia, headache and upper respiratory tract infection ([Table 12–13](#)). See Section [12.3](#) for information on SAEs.

The observed rate of AEs was similar between treatment groups for most system organ classes (SOC) and preferred terms (PT) ([EOT Table 14.3.1.7](#)). There were few clinically relevant differences between treatment groups that are described here. The rate of ‘general disorders and administration site conditions’ was numerically lower with IDegAsp than with IDet (28 and 64 events per 100 PYE, respectively). This was primarily driven by injection site reactions in the IDet group. For details related to injection site reactions, see section below. For the remaining SOC and PTs, the rates were similar or only very few events were reported.

Clinically significant changes in vital signs, laboratory parameters, fundoscopy and other safety assessments were reported as AEs and are therefore included in these tables. A similar proportion of

subjects in each treatment group reported increased, decreased or abnormal clinical laboratory samples as AEs under the investigations SOC. See Section [12.5](#) and [12.6](#) for more details.

A total of 2 neoplasms, skin papilloma and benign neoplasm of thyroid gland (both in the IDet group) were reported in two subjects ([EOT Table 14.3.3](#)). [REDACTED]

[REDACTED] The event was assessed as unlikely related to trial drug and no changes to trial drug regimen were made. Subject [REDACTED]

[REDACTED] The event was considered not serious and of mild intensity. [REDACTED]

[REDACTED] the event was assessed as unlikely related to trial drug. No changes to trial drug conduct were made throughout the course of the event. Narratives are included in [Section 14.3.3](#).

After the end of this trial, one subject in the IDet group was diagnosed with bladder cancer. [REDACTED]

A listing of all TEAEs by subject is included in [Appendix 16.2.7, Listing 16.2.7.2](#). AEs with onset before treatment with trial products are listed by subject in [Appendix 16.2.7, Listing 16.2.7.3](#) as are AEs with onset after the defined treatment emergent period. AEs and SAEs reported by 1% or more of subjects are available in [EOT Tables 14.3.1.4 and 14.3.1.6](#), respectively.

Injection Site Reactions

The percentage of subjects with injection site disorders was low in each treatment group (IDegAsp: 1.4%; IDet: 4.4%). None of the injection site reactions were reported as SAEs. The rate of injection site reactions per 100 PYE was lower in the IDegAsp group (4) than in the IDet group (43) ([EOT Table 14.3.1.27](#) and [EOT Figure 14.3.1.28](#)). The difference was primarily driven by one subject in the IDet group that experienced 28 non-serious injection site related events ([Appendix 16.2.7, Listing 16.2.7.2](#)).

Immunogenicity Concerned Adverse Events

Two (2) AEs were reported as immunogenic AEs according to the SMQ list in [Appendix 16.2.7, Listing 16.2.7.4](#), eye swelling (IDegAsp) and Urticaria (IDet), [EOT Table 14.3.1.24](#).

In addition, 2 TEAEs were reported as immunogenicity by the Investigator, but not captured by the SMQ searches:

The rate of severe AEs considered possibly or probably related to IAsp by the investigator was similar between the two treatment groups (20 and 31 events per 100 PYE with IDegAsp and IDet, respectively) (EOT Table 14.3.1.17). Hypoglycaemia was the most frequently reported severe AE

considered possibly or probably related to IAsp, and was reported with similar rates across treatment groups.

Note that there was a considerable overlap between the hypoglycaemic episodes reported with possible/probable relationship to IDegAsp/IDet and IAsp.

Table 12–14 Adverse Events Possibly or Probably Related to IDegAsp or IDet by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	53 (14.6)		84	50	26 (14.4)		68	81	79 (14.6)		152	60
Metabolism and nutrition disorders	26 (7.2)		45	27	16 (8.9)		25	30	42 (7.7)		70	28
Hypoglycaemia	23 (6.4)		38	22	15 (8.3)		21	25	38 (7.0)		59	23
Hypoglycaemic unconsciousness	5 (1.4)		5	3	2 (1.1)		2	2	7 (1.3)		7	3
Hypoglycaemic seizure	1 (0.3)		1	1	1 (0.6)		1	1	2 (0.4)		2	1
Diabetic ketoacidosis					1 (0.6)		1	1	1 (0.2)		1	0
Hyperglycaemia	1 (0.3)		1	1					1 (0.2)		1	0
General disorders and administration site conditions	8 (2.2)		9	5	7 (3.9)		35	42	15 (2.8)		44	17
Injection site reaction	3 (0.8)		4	2	5 (2.8)		32	38	8 (1.5)		36	14
Injection site pain	2 (0.6)		2	1	1 (0.6)		1	1	3 (0.6)		3	1
Oedema peripheral	2 (0.6)		2	1					2 (0.4)		2	1
Asthenia					1 (0.6)		1	1	1 (0.2)		1	0
Hunger	1 (0.3)		1	1					1 (0.2)		1	0
Injection site papule					1 (0.6)		1	1	1 (0.2)		1	0
Injury, poisoning and procedural complications	5 (1.4)		5	3	2 (1.1)		2	2	7 (1.3)		7	3
Wrong drug administered	3 (0.8)		3	2	1 (0.6)		1	1	4 (0.7)		4	2
Medication error	1 (0.3)		1	1	1 (0.6)		1	1	2 (0.4)		2	1
Upper limb fracture	1 (0.3)		1	1					1 (0.2)		1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

Table continues on next page

Adverse Events Possibly or Probably Related to Investigational Medicinal Product by
System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Investigations	5	(1.4)	5	3	1	(0.6)	1	1	6	(1.1)	6	2
Weight increased	4	(1.1)	4	2					4	(0.7)	4	2
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	1					1	(0.2)	1	0
Nervous system disorders	6	(1.7)	9	5					6	(1.1)	9	4
Headache	4	(1.1)	7	4					4	(0.7)	7	3
Lethargy	1	(0.3)	1	1					1	(0.2)	1	0
Neurological symptom	1	(0.3)	1	1					1	(0.2)	1	0
Infections and infestations	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Abscess	1	(0.3)	1	1					1	(0.2)	1	0
Peritonsillar abscess					1	(0.6)	1	1	1	(0.2)	1	0
Sinusitis	1	(0.3)	1	1					1	(0.2)	1	0
Tracheobronchitis	1	(0.3)	1	1					1	(0.2)	1	0
Gastrointestinal disorders	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Nausea	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Vomiting	1	(0.3)	1	1					1	(0.2)	1	0
Musculoskeletal and connective tissue disorders	3	(0.8)	3	2					3	(0.6)	3	1
Arthralgia	2	(0.6)	2	1					2	(0.4)	2	1
Polyarthrititis	1	(0.3)	1	1					1	(0.2)	1	0
Skin and subcutaneous tissue disorders	1	(0.3)	1	1	2	(1.1)	3	4	3	(0.6)	4	2
Lipohypertrophy					1	(0.6)	2	2	1	(0.2)	2	1
Rash					1	(0.6)	1	1	1	(0.2)	1	0
Skin disorder	1	(0.3)	1	1					1	(0.2)	1	0
Eye disorders	1	(0.3)	1	1					1	(0.2)	1	0
Diabetic retinopathy	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

Cross-reference: [EOT Table 14.3.1.9](#)

12.2.2.3 Adverse Events by Relationship to the Insulin Delivery Device

The rate of AEs considered related to insulin delivery device by the investigator was similar in the two treatment groups (1 and 0 events per 100 PYE with IDegAsp and IDet, respectively) ([EOT Table 14.3.1.11](#)). Three (3) AEs of hyperglycaemia were reported with relation to the device: 2 to the IAsp insulin delivery device and 1 to the IDegAsp insulin delivery device ([Appendix 16.2.7, Listing 16.2.7.6](#)). None of the 3 events were severe ([EOT Table 14.3.1.18](#)) and none the AEs related to the insulin delivery device were associated with injection site disorders.

12.2.2.4 Adverse Events by Severity

The majority of AEs were mild or moderate. The rate of mild AEs was similar with IDegAsp and IDet (354 and 378 events per 100 PYE, respectively) ([Table 12–12](#) and [EOT Table 14.3.1.21](#)), as was the rate of moderate AEs (108 and 97 events per 100 PYE, respectively) ([EOT Table 14.3.1.20](#)). The majority of the AEs were recovered at the end of trial.

Few of the AEs were severe in either treatment group, and the rate of severe AEs was similar with IDegAsp and IDet (37 and 45 events per 100 PYE, respectively) ([Table 12–12](#) and [EOT Table 14.3.1.15](#)). The most frequently reported severe AEs were hypoglycaemia in both treatment groups (21 and 27 events per 100 PYE, in the IDegAsp and IDet group, respectively). For the remaining system organ classes and preferred terms, the rates were similar or only very few events were reported.

All but 4 subjects (Subjects [REDACTED], [REDACTED], [REDACTED], [REDACTED]) were completely recovered from severe AEs at the end of trial. None of these events were considered related to trial product or IAsp. See [Appendix 16.2.7, Listing 16.2.7.2](#) for individual data. SAEs are described in [Section 12.3](#).

AEs considered possibly or probably related to IDegAsp or IDet, IAsp or the insulin delivery device are described in [Sections 12.2.2.1, 12.2.2.2 and 12.2.2.3](#), respectively.

12.3 Deaths, Other Serious Adverse Events and Other Significant Adverse Events

12.3.1 Deaths

No deaths occurred during the trial. Hence the listings and narratives for deaths are empty ([EOT Listing 14.3.2.2](#) and [Section 14.3.3](#)).

12.3.2 Other Serious Adverse Events

The rate of SAEs was similar for IDegAsp and IDet (27 and 20 events per 100 PYE) ([Table 12–15](#)). The most frequently reported SAEs were hypoglycaemia in both treatment groups ([EOT Table 14.3.1.6](#)). Most subjects were recovered at the end of the trial.

Table 12–15 Serious Adverse Events – Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	31	(8.6)	46	27	13	(7.2)	17	20	44	(8.1)	63	25
Severity												
Severe	21	(5.8)	34	20	11	(6.1)	13	15	32	(5.9)	47	19
Moderate	11	(3.0)	11	6	2	(1.1)	3	4	13	(2.4)	14	6
Mild	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Relationship to Investigational Product												
Probably	13	(3.6)	20	12	5	(2.8)	6	7	18	(3.3)	26	10
Possibly	4	(1.1)	5	3	1	(0.6)	1	1	5	(0.9)	6	2
Unlikely	18	(5.0)	21	12	8	(4.4)	10	12	26	(4.8)	31	12
Relationship to Bolus Insulin												
Probably	10	(2.8)	16	9	6	(3.3)	8	10	16	(3.0)	24	9
Possibly	4	(1.1)	6	4	2	(1.1)	2	2	6	(1.1)	8	3
Unlikely	21	(5.8)	24	14	5	(2.8)	7	8	26	(4.8)	31	12
Related to Device												
No	31	(8.6)	46	27	13	(7.2)	17	20	44	(8.1)	63	25
Outcome												
Recovered	28	(7.7)	42	25	12	(6.7)	16	19	40	(7.4)	58	23
Recovering	1	(0.3)	1	1	0	(0.0)	0	0	1	(0.2)	1	0
Recovered with Sequelae	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Not Recovered	1	(0.3)	1	1	0	(0.0)	0	0	1	(0.2)	1	0

N: Number of subjects with adverse event

?: Proportion of subjects having adverse event

E: Number of adverse events

R= Event Rate per 100 Patient Years of Exposure

Cross-reference: [EOT Table 14.3.1.2](#)

The rate of SAEs considered possibly or probably related to IDegAsp or IDet by the investigator was 15 and 8 SAEs per 100 PYE, respectively ([Table 12–16](#)). The rate of SAEs considered possibly or probably related to IAsp by the investigator was similar between treatment groups (13 and 12 events per 100 PYE, with IDegAsp and IDet, respectively ([EOT Table 14.3.1.13](#)). The most frequently reported SAE considered possibly or probably related to IDegAsp, IDet and IAsp was hypoglycaemia in both treatment groups. Note that there was a considerable overlap between the hypoglycaemic episodes reported with possible/probable relationship to IDegAsp/IDet and IAsp.

There were two SAEs for which there was a discrepancy between the Investigator and the sponsor evaluated causality. For subject [REDACTED], the investigator evaluated the report of diabetic ketoacidosis ([REDACTED]) as unlikely related to IDet and IAsp, whereas the sponsor evaluated the SAE as possibly related to IDet and IAsp. For subject [REDACTED] (IDet), the investigator evaluated the report of suicidal ideation ([REDACTED]) as probably related to IAsp, whereas the sponsor evaluated the SAE as unlikely related to IAsp. [REDACTED]. Narratives for SAEs are included in [Section 14.3.3](#).

There were no SAEs considered related to device by the investigator in either treatment group ([EOT Table 14.3.1.14](#)). No injection site reactions were reported as SAEs.

Table 12–16 Serious Adverse Events Possibly or Probably Related to IDegAsp or Comparator by System Organ Class and Preferred Term -Treatment Emergent – Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	15	(4.1)	25	15	5	(2.8)	7	8	20	(3.7)	32	13
Metabolism and nutrition disorders	14	(3.9)	23	14	5	(2.8)	7	8	19	(3.5)	30	12
Hypoglycaemia	10	(2.8)	18	11	4	(2.2)	4	5	14	(2.6)	22	9
Hypoglycaemic unconsciousness	4	(1.1)	4	2	2	(1.1)	2	2	6	(1.1)	6	2
Hypoglycaemic seizure	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Injury, poisoning and procedural complications	2	(0.6)	2	1					2	(0.4)	2	1
Wrong drug administered	2	(0.6)	2	1					2	(0.4)	2	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

Cross-reference: EOT Table 14.3.1.12

The majority of SAEs were severe. The rate of severe SAEs was 20 and 15 events per 100 PYE in the IDegAsp and IDet group, respectively. See [EOT Table 14.3.1.19](#) for an overview of all severe SAEs.

SAEs leading to withdrawal are described in Section [12.3.3.1](#). A listing of all SAEs is included in [EOT Listing 14.3.2.1](#). Narratives for SAEs are included in [Section 14.3.3](#). Case report forms for subjects with SAEs are included in [Appendix 16.3.1](#).

Cardiovascular Events

An independent external Event Adjudication Committee (EAC) was constituted for the trial to perform ongoing adjudication, standardisation and assessment of cardiovascular events. Only 1 cardiovascular event qualified for adjudication during the trial. This event was evaluated not to be a major adverse cardiovascular event (MACE) by the EAC ([EOT Table 14.3.1.26](#)).

The cardiovascular event occurred in a [REDACTED] (Subject [REDACTED]) who had an SAE reported [REDACTED] days after randomisation to IDegAsp and IAsp. The SAE was diagnosed as pericardial effusion

[REDACTED] The causality was judged unlikely related to trial products by the investigator and sponsor. For details, see the narrative in [Section 14.3.3](#) and [Appendix 16.2.7, Listing 16.2.7.1](#).

12.3.3 Other Significant Adverse Events

12.3.3.1 Adverse Events leading to Withdrawal

A similar percentage of subjects withdrew from the trial due to AEs in the IDegAsp (1.4%) and the IDet (1.7%) group. Seven (7) subjects reported AEs as the primary reason leading to withdrawal in this trial: 4 subjects in the IDegAsp group (4 events) and 3 subjects in the IDet group (7 events) ([EOT Table 14.1.1](#)). In addition, 1 subject in the IDegAsp group (Subject [REDACTED]) was withdrawn due to a non-serious worsening of [REDACTED] but as this was recorded in the eCRF as withdrawal reason 'Other' instead of due to 'AE', this data is not in the AE withdrawal listing or table, but found in [Appendix 16.2.1](#). Considering the 2:1 randomisation and the low number of AEs leading to withdrawal, there was no difference between the treatment groups in the number of subjects with AEs leading to withdrawal. The AEs that led to withdrawal are listed in [Table 12–17](#), details are in [EOT Listing 14.3.2.4](#).

SAEs were reported as the reason for withdrawal in 4 of the 7 subjects who withdrew, 3 subjects in the IDegAsp group and 1 subject in the IDet group. All 4 subjects recovered from these severe SAEs. In the IDegAsp group, the 3 SAEs ([REDACTED] reported by Subjects [REDACTED], [REDACTED] and [REDACTED], respectively) were judged to have possible or probable relation to trial product by the investigator. In the IDet group, 1 SAE of [REDACTED] was reported for Subject [REDACTED] together with [REDACTED] other AEs. The investigator judged the [REDACTED] AEs from this subject to be unlikely related to trial products ([Appendix 16.2.7, Listing 16.2.7.2](#)).

Case report forms for subjects with SAEs and AEs leading to withdrawal are included in [Appendix 16.3.1](#).

Table 12–17 Subjects with Adverse Events leading to Withdrawal

Trial Insulin	Subject Number	Adverse Event	Investigator Causality (IDegAsp or IDet)/IAsp

12.3.3.2 Adverse Events leading to Dose Reduction

The rate of AEs leading to dose reduction was similar between treatment groups (24 and 31 events per 100 PYE in the IDegAsp and IDet group, respectively). Approximately 10% of subjects in each treatment group experienced AEs leading to dose reduction. A total of 55 subjects reported 67 TEAEs leading to a reduction in IDegAsp, IDet or IAsp during the trial: 37 subjects with 41 AEs in the IDegAsp group and 18 subjects with 26 AEs in the IDet group ([EOT Table 14.3.1.22](#)). In both treatment groups, approximately half of the AEs led to a reduction in the investigational product (IDegAsp or IDet) and half of the events led to a reduction in IAsp. One (1) AE led to a reduction in NPH insulin. The rate of SAEs leading to dose reduction was also similar between treatment groups (8 and 7 events per 100 PYE). All of the AEs leading to dose reduction were recovered except for 1 AE in each treatment group. The most frequent AE leading to a dose reduction was hypoglycaemia. The rate of hypoglycaemia leading to dose reduction was 12 and 19 events per 100 PYE in the IDegAsp and IDet group, respectively See [EOT Table 14.3.1.25](#). AEs leading to a decrease in IDegAsp or IDet dose are listed in [EOT Listing 14.3.2.3](#).

12.3.3.3 Adverse Events leading to Significant Additional Concomitant Medication

Concomitant medications started after screening are listed in [EOT Table 14.1.13](#). There was no apparent difference in the percent of subjects taking concomitant medications or in the type of concomitant medications taken between the treatment groups. A variety of concomitant medications were used. The most frequent concomitant medications initiated in both treatment groups were analgetics (paracetamol and ibuprofen: 13% and 10% of subjects, respectively), H1-N1 vaccine (6% of subjects) and influenza vaccine (5% of subjects). Information on concomitant medication for individual subjects is provided in [Appendix 16.2.4 Listing 16.2.4.6](#).

12.3.3.4 Medical Events of Special Interest

All AEs that, according to the protocol, were to be considered as medical events of special interest (Section [9.5.1.3](#)) and specified in the SMQ searches listed in [Appendix 16.2.7](#), [Listing 16.2.7.4](#) are summarised in [EOT Tables 14.3.1.23](#), [14.3.1.24](#), [14.3.1.26](#), [14.3.1.27](#) and [14.3.1.29](#). Narratives for these AEs are included in [Section 14.3.3](#).

Transmission of Infectious Agents via Trial Product

There were no reports of transmission of infectious agents via any of the trial products during this trial.

Medication Errors

A total of 23 medication errors (16 in IDegAsp and 7 in IDet group) were reported for 21 subjects ([EOT Table 14.3.1.29](#)). Based on the reasons described in the narratives, a total of 15 of the 23 medication errors were mix-ups between basal and bolus insulin. Of these, 10 were related to mix-ups between IDegAsp and IAsp (in 8 cases IAsp injected instead of IDegAsp and in 2 cases IDegAsp injected instead of IAsp) and 5 due to mix-ups between IDet and IAsp (4 cases of IAsp instead of IDet and 1 case of IDet instead of IAsp). Six (6) of the mix-ups occurred within the first month of treatment with trial product. One of the subjects with a mix-up was subsequently withdrawn from the trial (subject [REDACTED]).

In most cases, the subjects managed their own BG levels by adjusting their food or beverage intake and by monitoring their BG closely, thereby avoiding hypoglycaemic episodes. Seven (7) of the mix-ups led to a hypoglycaemic episode (6 were due to administration of IAsp and 1 where IDegAsp was administered instead of IAsp); one hypoglycaemic episode was reported as serious (subject [REDACTED]).

Two overdoses related to trial product (defined as 20% higher dose than prescribed) were reported in this trial, one in each treatment group. Both subjects experienced non-serious hypoglycaemic episodes (subjects [REDACTED] and [REDACTED]).

The remaining 6 cases concerned dosage errors related to bolus insulin (one of them was serious - subject [REDACTED]), [REDACTED].

Narratives for these events are presented in [Section 14.3.3](#).

12.4 Hypoglycaemia

12.4.1 Introduction to Hypoglycaemic Episodes

Confirmed hypoglycaemic episodes consisted of episodes of severe hypoglycaemia as well as minor hypoglycaemic episodes with a confirmed PG value of less than 3.1 mmol/L (56mg/dL).

Hypoglycaemic episodes were defined as nocturnal if the time of onset was between 00:01 and 05:59 (both included).

The descriptive safety data are based on the safety analysis set, while the statistical analyses of hypoglycaemia are based on the FAS (see Section [11.1](#)). Only treatment emergent hypoglycaemic episodes are described in this section. Hypoglycaemic episodes were categorised and analysed according to the definitions given in Sections [9.5.1.3](#) and [9.7.4.4](#).

Individual subject data for treatment emergent events of hypoglycaemia are listed in [Appendix 16.2.7, Listing 16.2.7.5](#). One (1) non-treatment emergent hypoglycaemic episode was reported and is listed with the non-treatment emergent AEs in [Appendix 16.2.7, Listing 16.2.7.3](#). Hypoglycaemic episodes reported as an SAE are listed in [EOT Listing 14.3.2.1](#).

12.4.2 Confirmed Hypoglycaemic Episodes

The percentage of subjects who experienced confirmed hypoglycaemic episodes during the treatment period was 94% with IDegAsp and 93% with IDet, while the rate of confirmed hypoglycaemic episodes per 100 PYE was 3917 with IDegAsp and 4434 with IDet ([Table 12–18](#)). Half (50%) of the subjects in both treatment groups reported less than 15 episodes during the trial ([EOT Figure 14.3.1.42](#)).

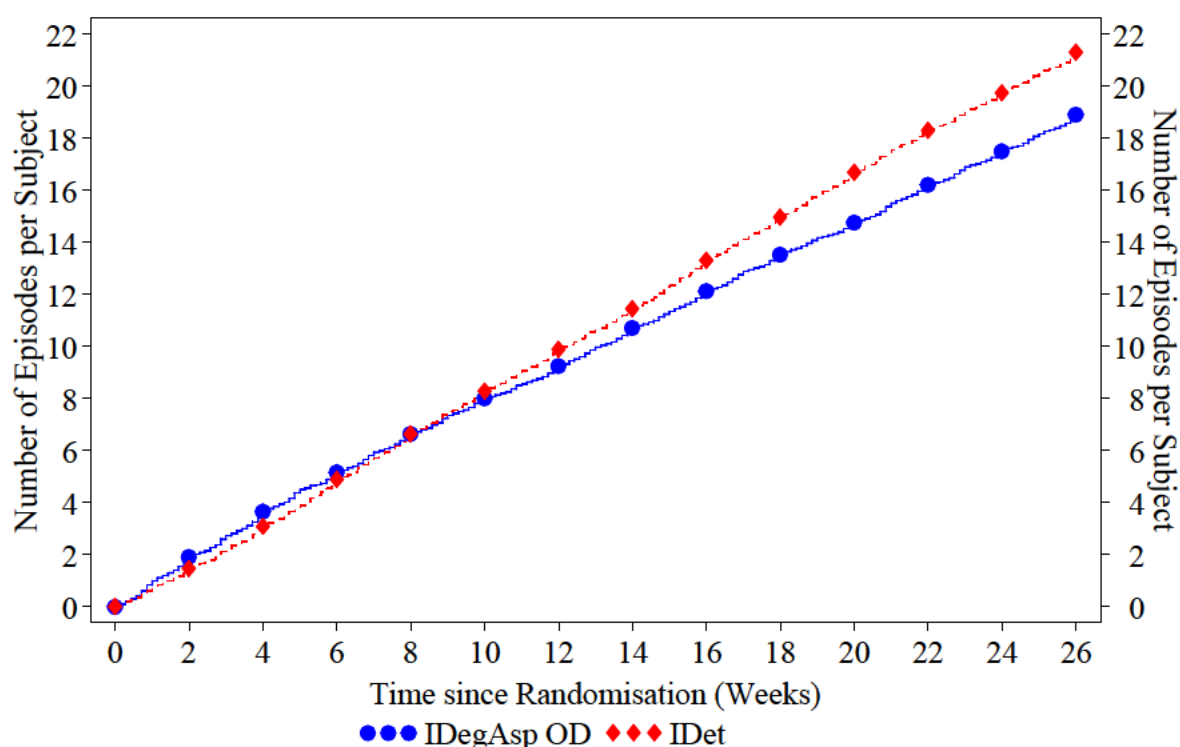
Table 12–18 Hypoglycaemic Episodes by Classification – Treatment Emergent – Summary - Safety Analysis Set

	IDegAsp				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Confirmed	341	(94.2)	6634	3917	168	(93.3)	3720	4434	509	(93.9)	10354	4089
ADA	352	(97.2)	14100	8326	172	(95.6)	7147	8519	524	(96.7)	21247	8390
Severe	35	(9.7)	56	33	22	(12.2)	35	42	57	(10.5)	91	36
Documented												
Sympt.	319	(88.1)	9670	5710	156	(86.7)	5126	6110	475	(87.6)	14796	5843
Asymptomatic	270	(74.6)	4032	2381	137	(76.1)	1804	2150	407	(75.1)	5836	2305
Probable Sympt.	71	(19.6)	234	138	40	(22.2)	149	178	111	(20.5)	383	151
Relative	42	(11.6)	108	64	17	(9.4)	33	39	59	(10.9)	141	56
ADA												
Unclassifiable	105	(29.0)	395	233	50	(27.8)	241	287	155	(28.6)	636	251

N: number of subjects; %: percentage of subjects; E: number of hypoglycaemic episodes; R: episode rate (calculated as number of episodes per 100 exposure years); Confirmed hypoglycaemia: subject unable to treat himself/herself and/or has a recorded PG < 3.1 mmol/L (56 mg/dL)

Cross-reference: [EOT Table 14.3.1.30](#)

The rate of confirmed hypoglycaemic events appeared similar between treatment groups during the first part of the trial, followed by a lower rate of hypoglycaemic episodes in the IDegAsp group than the IDet group during the last part of the trial ([Figure 12–4](#)). Note that the larger increase in the cumulative mean after 26 weeks is due to a lower number of subjects who are exposed at this time point compared to earlier in the trial, this implies that a single episode will contribute more to the cumulative mean in this time period compared to earlier time periods.



nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:57 - finean_cum_v01.sas/e_hypo_te_conf_mct_sas.cgm

Cross-reference: [EOT Figure 14.3.1.44](#)

Figure 12–4 Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set

The cumulative frequency of confirmed hypoglycaemic episodes over 24 hours was lower during the night (from 24:00 to around 6:00) as evaluated based on the slope, which then increased to a slightly higher but steady level during the day as evaluated by the straight line with a steeper slope from 6:00 to 24:00 in both treatment groups [EOT Figure 14.3.1.46](#).

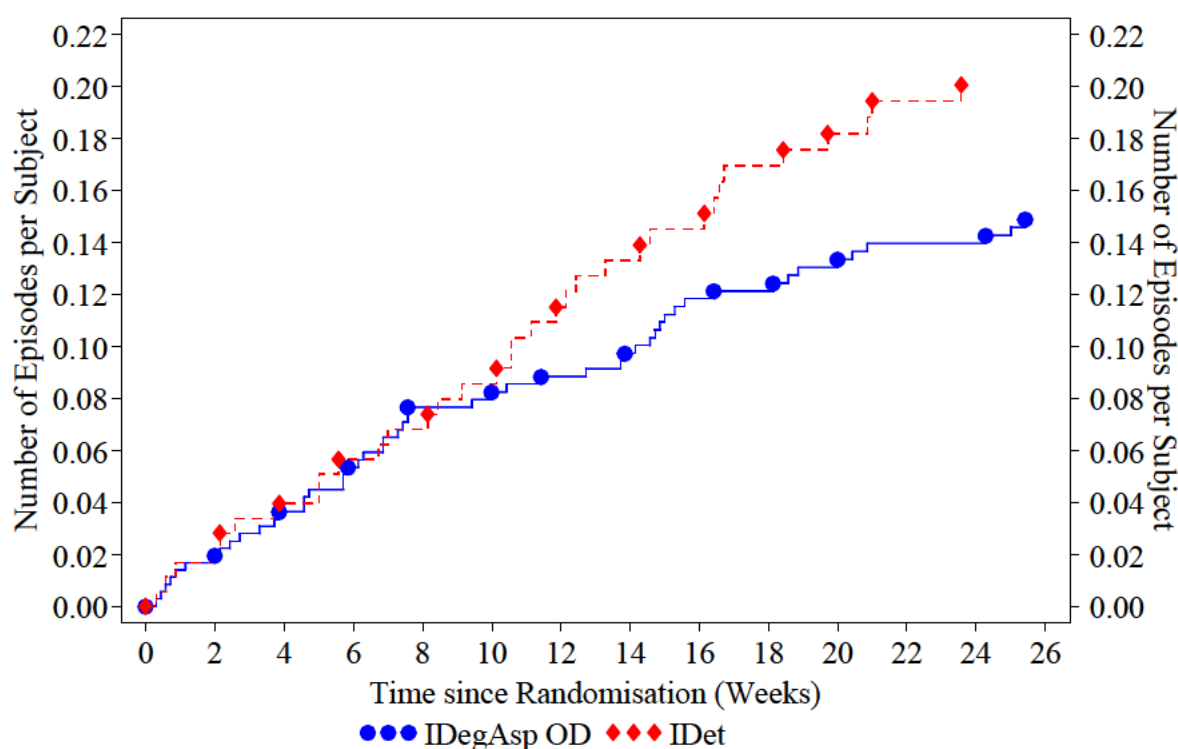
Statistical analysis did not reveal any difference in the rate of confirmed hypoglycaemic episodes between IDegAsp and IDet after 26 weeks of treatment. The estimated rate ratio for confirmed hypoglycaemia was 0.91 per 100 PYE [0.76; 1.09]_{95% CI}, [EOT Table 14.3.1.34](#).

12.4.3 Severe Hypoglycaemia

Severe Hypoglycaemia according to the ADA Classification

More than 85% of subjects in both treatment groups did not report any episodes of severe hypoglycaemia (EOT Figure 14.3.1.37). The percentage of subjects who experienced severe hypoglycaemia during the treatment period was 9.7% with IDegAsp and 12.2% with IDet. The rate of severe hypoglycaemia episodes per 100 PYE was 33 with IDegAsp and 42 with IDet (Table 12-18).

The rate of severe hypoglycaemia was constant in both treatment groups until Week 8 where after the rate appeared to become lower in the IDegAsp group, and remained constant in the IDet group (Figure 12-5).



nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:40 - fmean_cum_v01.sas/e_hypo_te_sev_mcf_sas.cgm

Cross-reference: EOT Figure 14.3.1.39

Figure 12-5 Severe Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set

The cumulative frequency of subjects experiencing severe hypoglycaemia over 24 hours in the IDegAsp group seemed to be lower in the early morning till noon (from 4:00 to 12:00) and higher in the afternoon to evening hours (from 14:00 to 22:00) than the IDet group, EOT Figure 14.3.1.41.

The statistical analysis did not reveal any difference in the rate of severe hypoglycaemia between IDegAsp and IDet after 26 weeks of treatment. The estimated rate ratio for severe hypoglycaemia was 1.19 per 100 PYE (IDegAsp: 26.6; IDet: 22.4) [0.58; 2.41]_{95% CI}, [EOT Table 14.3.1.34](#). The outcome of the statistical analysis was different than the observed rates because of a larger percentage of elderly and women in the IDet group (see [EOT Table 14.1.7](#)). As the rate of severe hypoglycaemia is influenced by age and sex, these between group differences are adjusted for in the statistical model when estimating the treatment difference. Narratives for episodes of severe hypoglycaemia reported as SAEs are included in [Section 14.3.3](#).

12.4.4 Nocturnal Hypoglycaemic Episodes

The percentage of subjects who experienced nocturnal confirmed hypoglycaemic episodes during the treatment period was 53% with IDegAsp and 69% with IDet, with rates of 371 and 572 nocturnal confirmed hypoglycaemic episodes per 100 PYE, respectively ([Table 12–19](#)). Half (50%) of subjects in both groups reported ≤ 2 episodes during the trial ([EOT Figure 14.3.1.43](#)).

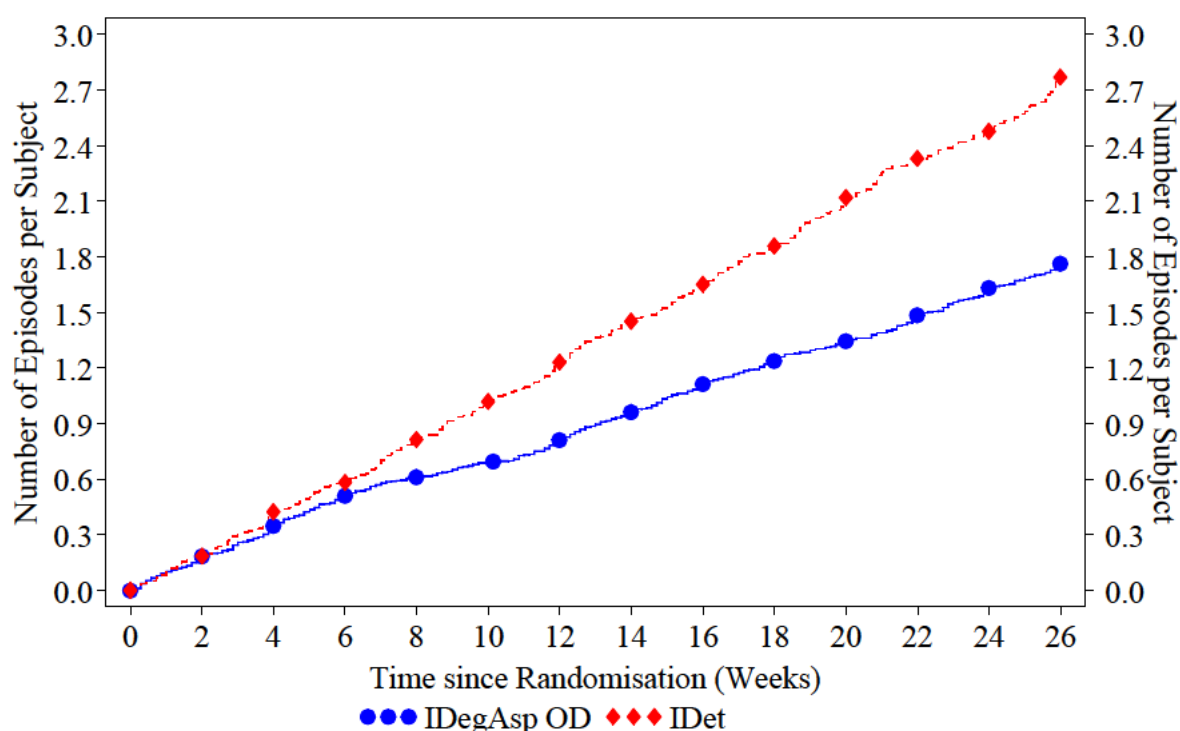
Table 12–19 Nocturnal Hypoglycaemic Episodes by Classification – Treatment Emergent – Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Confirmed	192	(53.0)	629	371	125	(69.4)	480	572	317	(58.5)	1109	438
ADA	232	(64.1)	1139	673	140	(77.8)	716	853	372	(68.6)	1855	733
Severe	10	(2.8)	11	6	10	(5.6)	14	17	20	(3.7)	25	10
Documented Sympt.	191	(52.8)	883	521	114	(63.3)	555	662	305	(56.3)	1438	568
Asymptomatic	86	(23.8)	201	119	45	(25.0)	111	132	131	(24.2)	312	123
Probable Sympt.	23	(6.4)	41	24	16	(8.9)	32	38	39	(7.2)	73	29
Relative	3	(0.8)	3	2	4	(2.2)	4	5	7	(1.3)	7	3
ADA Unclassified	7	(1.9)	8	5	8	(4.4)	15	18	15	(2.8)	23	9

N: number of subjects; %: percentage of subjects; E: number of hypoglycaemic episodes; R: episode rate (calculated as number of episodes per 100 exposure years); Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL) Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

Cross-reference: [EOT Table 14.3.1.31](#)

The number of nocturnal confirmed hypoglycaemic episodes over time was similar during the first part of the trial, followed by a lower rate of hypoglycaemic episodes in the IDegAsp group than the IDet group from week 6 ([Figure 12–6](#)).



Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:59 - fmean_cum_v01.sas/e_hypo_te_conf_noct_mcf_sas.cgm

Cross-reference: EOT Figure 14.3.1.45

Figure 12-6 Confirmed Nocturnal Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set

The nocturnal confirmed hypoglycaemic episodes reported during the 26 weeks of treatment were analysed using a negative binomial regression model as shown in [Table 12-20](#). For a description of the confirmatory testing procedure, see Section [11.4.1.1](#).

The rate of nocturnal confirmed hypoglycaemia episodes per 100 PYE was 37% lower with IDegAsp than with IDet. This difference was statistically significant as the upper limit of the 95% CI for the rate ratio (IDegAsp/IDet) was <1, 0.63 [0.49; 0.81]_{95% CI}, [Table 12-20](#). Superiority of IDegAsp over IDet could not be formally demonstrated as the hierarchical testing procedure was stopped prior to this analysis.

Table 12–20 Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent – Confirmatory Statistical Analysis – Full Analysis Set

	FAS	N	Estimate	95% CI
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	366	363	304.64	
IDet	182	180	484.94	
Treatment Ratio				
IDegAsp OD / IDet			0.63	[0.49 ; 0.81]

N: Number of subjects contributing to analysis, CI: Confidence Interval, PYE: Patient Years Exposure

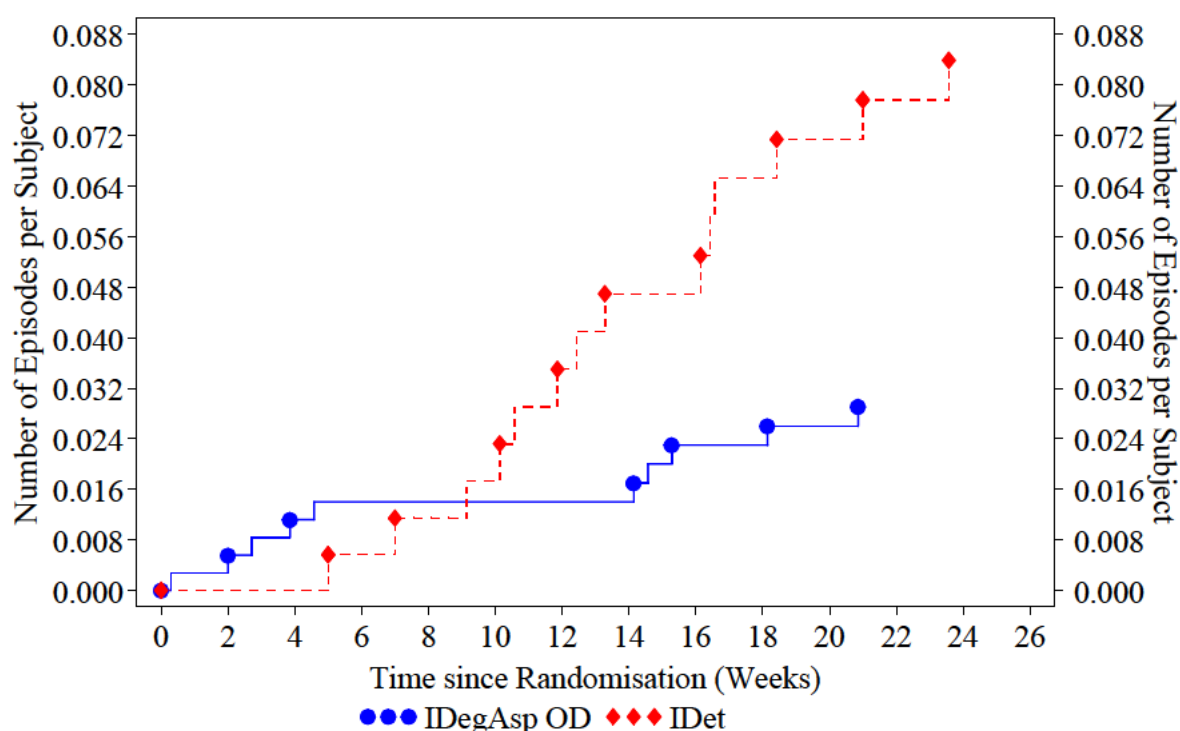
The number of events is analysed using a Negative Binomial Regression model using a log link and the logarithm of the exposure time (100 years) as offset. The model includes treatment, region, sex and antidiabetic treatment at screening as fixed effects and age as covariates. Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

Cross-reference: [EOT Table 14.3.1.35](#)

[EOT Table 14.3.1.36](#) shows the parameter estimates for the FAS.

12.4.4.1 Nocturnal Severe Hypoglycaemia

Few events of nocturnal severe hypoglycaemia were reported during the trial in either treatment group and approximately 95% or more of subjects in both treatment groups did not report any episodes of nocturnal severe hypoglycaemia ([Table 12–19](#) and [EOT Figure 14.3.1.38](#)). The observed rate of these events was lower with IDegAsp than with IDet (6 and 17 episodes per 100 PYE). The rate of nocturnal severe hypoglycaemia appeared lower in the IDegAsp group compared to the IDet group from Week 4 ([Figure 12–7](#)).



Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

28APR2011:12:57:42 - finean_cum_v01.sas/e_hypo_te_sev_noct_mcf_sas.cgm

Cross-reference: EOT Figure 14.3.1.40

Figure 12–7 Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function

12.4.5 ADA Classified Hypoglycaemic Episodes

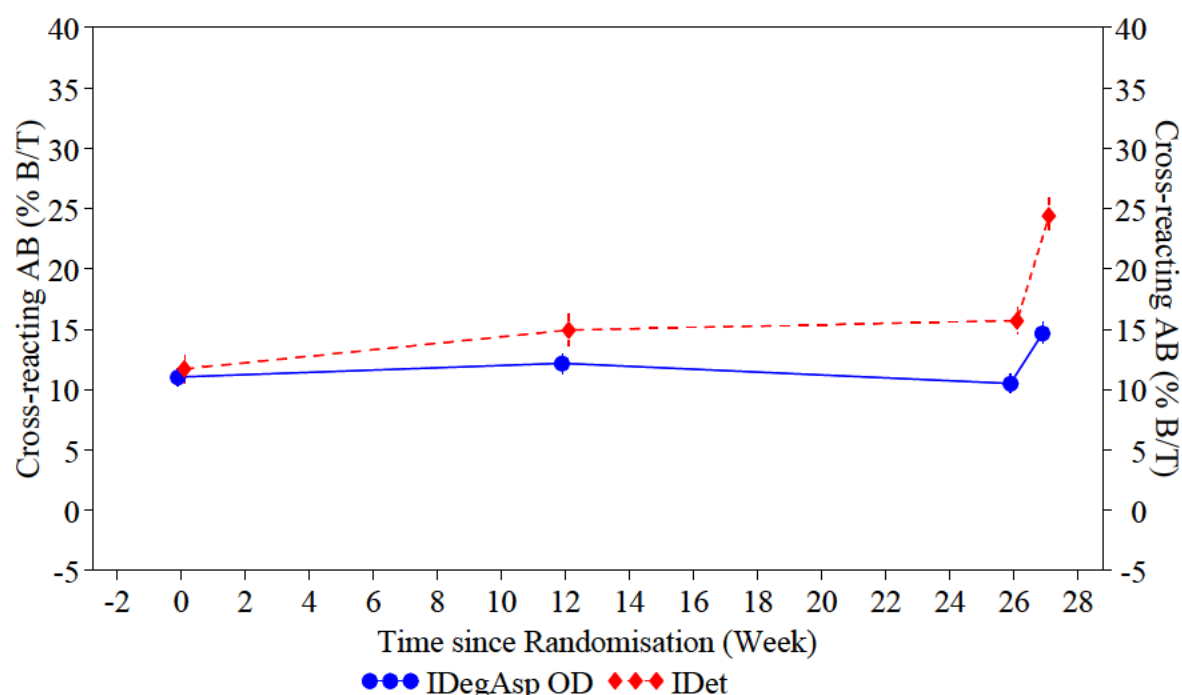
The rate of hypoglycaemic episodes according to the ADA classification was 8326 and 8519 episodes per 100 PYE with IDegAsp and IDet, respectively ([Table 12–18](#)). The majority of the ADA classified events were documented symptomatic or asymptomatic. The rate of nocturnal hypoglycaemic episodes according to the ADA classification was 673 and 853 episodes per 100 PYE with IDegAsp and IDet, respectively ([Table 12–19](#)). ADA classified hypoglycaemic episodes and nocturnal hypoglycaemic episodes over time are tabulated in [EOT Tables 14.3.1.32](#) and [14.3.1.33](#).

12.5 Clinical Laboratory Evaluation

12.5.1 Evaluation of Insulin Antibodies

12.5.1.1 Cross-reacting Insulin Antibodies

Insulin antibodies cross-reacting between insulin analogues and human insulin during the trial are shown in [Figure 12–8](#), [EOT Figure 14.3.6.35](#) and [EOT Table 14.3.6.28](#). The mean level of cross-reacting antibodies was low at baseline and remained low in the IDegAsp treatment group. In the IDet group, mean levels were low at baseline and increased slightly during the trial. At week 26 and 27, the change from baseline was smaller with IDegAsp than IDet. Individual insulin antibody data are presented in [EOT Listing 14.3.7.4](#).



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_04/stats
17NOV2010:15:49:49 - fmean_numfind_v03.sas/e_ab_cros_abs_mean_locf_sas.cgm

%B/T = Percent bound over total

Cross-reference: [EOT Table 14.3.6.34](#)

Figure 12–8 Cross-reacting Antibodies to Human Insulin (%B/T) – Mean Plot – Safety Analysis Set

No washout period was performed before antibody measurements at baseline and weeks 12 and 26. Consequently, the detection of cross-reacting insulin antibodies was lower at these time points. The observed differences in values at Week 26 and 27 (Visit 28 and 29) are related to improved insulin

antibody detection at Week 27 (Visit 29) enabled by the 1-week washout period where investigational product was discontinued and replaced with NPH insulin. NPH insulin causes less interference with the insulin antibody measurement due to its shorter half-life and lower plasma concentration. The washout period was included to get the best possible measurements of antibody levels for correlation to HbA_{1c} and insulin dose. For evaluation of antibody development over time, samples collected during treatment were used, as the degree of interference from trial product in these samples is comparable. See Section [9.5.1.3](#) for details regarding the insulin antibody detection methodology.

The descriptive statistics of the cross-reacting antibody levels are shown in [Table 12–21](#).

Table 12–21 Cross-reacting Antibodies to Human Insulin (%B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet
Number of Subjects	362	180
Human insulin reactive antibodies serum(% B/T)		
Visit 2 (Week 0)		
N	362	180
Mean (SD)	11.0 (13.9)	11.7 (15.6)
Median	5.0	5.0
Min ; Max	0.0 ; 76.0	0.0 ; 68.0
Visit 28 (Week 26) (LOCF)		
N	362	180
Mean (SD)	10.5 (13.8)	15.7 (15.5)
Median	5.0	10.0
Min ; Max	0.0 ; 76.0	0.0 ; 75.0
Visit 29 (Week 27)		
N	310	147
Mean (SD)	15.5 (17.3)	26.0 (19.4)
Median	8.0	23.0
Min ; Max	0.0 ; 78.0	0.0 ; 77.0

N = Number of Subjects, SD = Standard Deviation

Cross-reference: [EOT Table 14.3.6.28](#)

Insulin antibodies cross-reacting between IDeg, IDet and human insulin at Week 27 (follow-up) were plotted against HbA_{1c} ([EOT Figure 14.3.6.43](#)), change from baseline in HbA_{1c} ([EOT Figure 14.3.6.43](#)) and total insulin daily dose in U/kg ([EOT Figure 14.3.6.48](#)). The lines in the scatter plots are regression lines included to illustrate a potential linear relationship between the antibody binding and the variable on the x-axis for each treatment group. These plots did not indicate any correlation between cross-reacting antibody level and HbA_{1c} or total insulin dose.

12.5.1.2 Specific Insulin Antibodies

Insulin antibodies specific for IDeg, IAsp and IDet measured after 26 weeks of treatment are shown in [EOT Figures 14.3.6.30-33](#) and [EOT Table 14.3.6.25-27](#). The mean levels of IDeg, IDet and IAsp specific antibodies were low at baseline and remained low throughout the trial period.

Insulin antibodies specific for IDeg, IDet and IAsp measured at Week 27 (follow-up) were plotted against HbA_{1c} [EOT Figure 14.3.6.38](#) and [EOT Figure 14.3.6.39](#), change from baseline in HbA_{1c} ([EOT Figures 14.3.6.40](#) and [14.3.6.41](#)) and total insulin daily dose in U/kg ([EOT Figures 14.3.6.46](#) and [14.3.6.47](#)). These plots did not indicate any correlation between specific antibody level and HbA_{1c} or total insulin dose.

12.5.1.3 Total Insulin Antibodies

The mean and median total insulin antibody levels (sum of insulin-specific antibodies and cross-reacting antibodies = total insulin antibodies) were similar to the amount of cross-reacting antibodies due to the low level of insulin-specific antibodies against IDeg, IDet or IAsp ([EOT Table 14.3.6.29](#) and [EOT Figures 14.3.6.36](#) and [14.3.6.37](#)). Figures plotting total insulin antibody levels against HbA_{1c}, change in HbA_{1c} and total insulin dose indicated that there was no correlation between total insulin antibody levels and HbA_{1c} or total insulin dose ([EOT Figures 14.3.6.44](#), [14.3.6.45](#) and [14.3.6.49](#)).

12.5.2 Evaluation of Each Laboratory Parameter

12.5.2.1 Laboratory Values over Time

Mean haematology, biochemistry, lipids, and urine laboratory values remained stable during the trial, and there was no apparent difference between the two treatment groups in mean values or mean change in values during the trial ([EOT Tables 14.3.5.1 to 14.3.5.65](#)). The cumulative percentage of subjects having a given laboratory value showed that the majority of subjects' values remained within the reference ranges at baseline and at the end of trial. No difference was found in the change from baseline of any of the measured lipid parameters analysed separately using an ANOVA method ([EOT Table 14.3.5.49](#)). The reference ranges for all laboratory parameters are shown in [EOT Listing 14.3.4.1](#). All individual laboratory measurements are listed by subject in [Appendix 16.2.8](#), [Listings 16.2.8.2 to 16.2.8.8](#).

Pregnancy

Four (4) women became pregnant during the trial, 2 in the IDegAsp group (Subjects [REDACTED] and [REDACTED]) and 2 in the IDet group (Subject [REDACTED] and [REDACTED]).

[REDACTED] All of the pregnancies

were judged to be of unlikely or unknown relation to trial product. See [Appendix 16.2.8, Listing 16.2.8.8](#) for individual pregnancy lab data.

12.5.2.2 Individual Subject Changes

Most subjects had normal haematology, biochemistry, lipids and urinalysis laboratory value levels throughout the trial. Very few subjects had changes from normal to high or low values (or negative to positive urine tests) during the trial, and there was no difference between the treatment groups for any of the parameters ([EOT Tables 14.3.5.26, 14.3.5.4, 14.3.5.51, 14.3.5.63 and 14.3.5.67](#)). Individual laboratory values outside the reference range were flagged as high (H) or low (L) and presented in [EOT Listings 14.3.4.2 to 14.3.4.4](#).

12.5.2.3 Individual Clinically Significant Abnormalities

A clinical laboratory abnormality regarded as clinically significant was to be reported as an AE.

Haematology

Two (2) cases of clinically significant abnormalities in haematology parameters were reported in this trial for Subject [REDACTED] (1 decreased haemoglobin levels and 1 increased eosinophil count). Only the increase in eosinophils was considered possibly related to trial product by the investigator. See [EOT Listing 14.3.4.1](#), and [Appendix 16.2.7, Listing 16.2.7.2](#) for details.

Biochemistry

Five (5) cases of biochemistry related clinical laboratory AEs were reported during the trial ([EOT Table 14.3.1.7, EOT Listing 14.3.1.2](#)). All of the events were non-serious AEs and all but 1 ([REDACTED]: abnormal liver function, IDegAsp) were considered unlikely related to trial product. Four (4) of the 5 subjects with elevated biochemistry laboratory values were in the IDegAsp group ([REDACTED]: blood bilirubin; [REDACTED]: blood creatinine; [REDACTED]: hepatic enzymes; [REDACTED]: aspartate aminotransferase) and 1 was in the IDet group ([REDACTED]: urine albumin/creatinine levels).

Lipids

There were 7 reports of ‘hyperlipidaemia’ in the trial, 5 in the IDegAsp group and 2 in the IDet group ([Appendix 16.2.7, Listing 16.2.7.2](#)). In addition, 3 subjects in the IDegAsp group ([REDACTED], [REDACTED] and [REDACTED]) and 1 subject in the IDet group ([REDACTED]) had triglyceride levels of more than 2.5 times the upper reference range limit ([EOT Listing 14.3.4.3, EOT Figures 14.3.5.58 and 14.3.5.59](#)). Moreover, there were 2 (IDegAsp) reports of ‘worsening of hypercholesterolaemia’ (Subject [REDACTED], Day [REDACTED]) and hyperlipidaemia (Subject [REDACTED], Day [REDACTED]), respectively.

Urine Analyses

Few cases of clinically significant abnormalities in urine analyses were reported in this trial ([EOT Listing 14.3.4.4](#)). A case of ‘acute renal failure’ was reported in the IDegAsp group (Subject [REDACTED]). This subject had normal urine albumin/creatinine ratio at Visit [REDACTED] and [REDACTED], but positive urine tests for blood, ketones and protein at Visit [REDACTED]. The acute renal failure [REDACTED] and was judged to be mild and unlikely related to trial products by the investigator. This subject is also described

above in the biochemistry section in regards to ‘abnormal liver function’ reported as an AE. Individual urinalysis test results are available in [Appendix 16.2.8](#), [Listings 16.2.8.5](#) and [16.2.8.6](#).

12.6 Vital Signs, Physical Findings and Other Observations Related to Safety

12.6.1 Vital Signs

In both treatment groups, mean blood pressure (SBP/DBP) and pulse were approximately 124/75 mmHg and 74 beats/min at baseline, and 124/75 mmHg and 75 beats/min after 26 weeks of treatment ([EOT Tables 14.3.6.3](#) and [14.3.6.4](#)). Mean blood pressure and pulse data are plotted in [EOT Figures 14.3.6.5 to 14.3.6.13](#). Individual measurements of vital signs are listed in [EOT Listing 14.3.7.1](#).

12.6.2 Physical Examination

No clinically relevant differences in physical examinations were observed between treatment groups after 26 weeks of treatment ([EOT Tables 14.3.6.1](#) and [14.3.6.2](#)). Individual physical examination data are listed in [EOT Listing 14.3.7.5](#).

12.6.3 ECG

The majority of the ECG measurements were ‘normal’ or ‘abnormal, not clinically significant’ at baseline and Week 26 ([EOT Table 14.3.6.14](#) and [EOT Table 14.3.6.15](#)). Two (2) changes to ‘abnormal, clinically significant’ occurred during the trial, 1 in the IDegAsp group (bifascicular block) and 1 in the IDet group (atrial fibrillation) (see [Appendix 16.2.7](#), [Listing 16.2.7.2](#)). Individual ECG data are listed in [EOT Listing 14.3.7.2](#). None of the above AEs were qualified for adjudication.

12.6.4 Fundoscopy / Fundusphotography

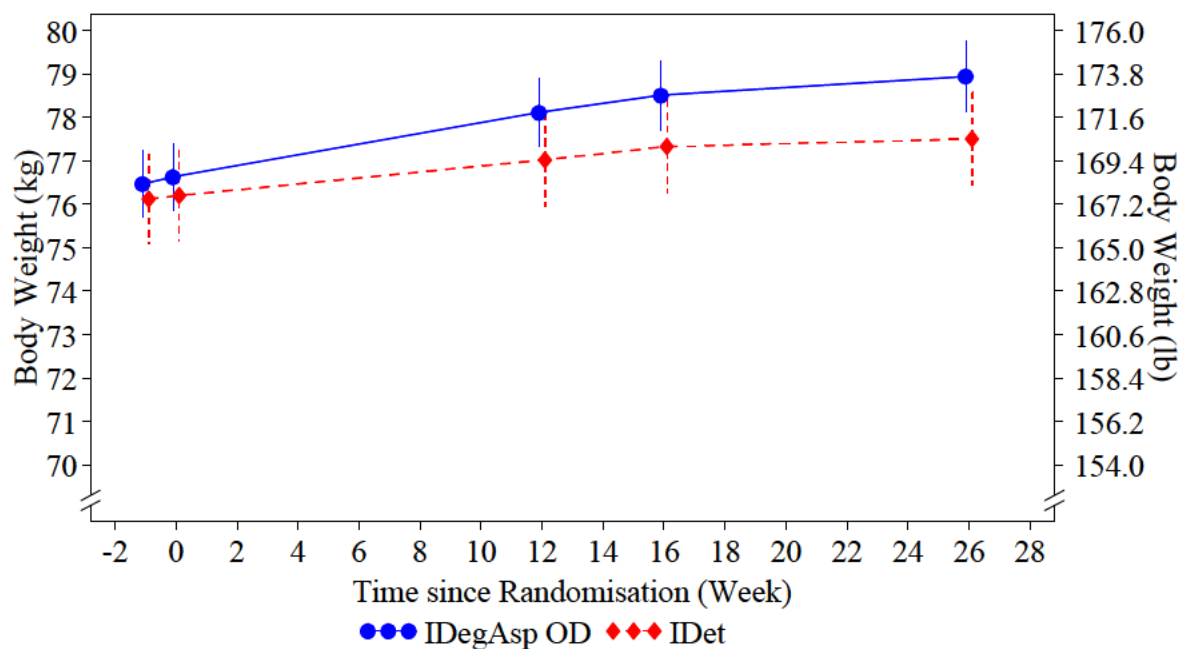
The majority of the fundoscopy measurements were ‘normal’ or ‘abnormal, not clinically significant’ at baseline and Week 26 in both treatment groups ([EOT Table 14.3.6.16](#) and [EOT Table 14.3.6.17](#)). A slightly higher percentage of subjects in the IDegAsp group had abnormal clinically significant findings at baseline than the IDet group. At the end of the trial, the percentage of subjects with abnormal clinically significant findings was slightly lower in both treatment groups than at baseline.

In total, 21 eye disorders were reported by 16 subjects: 12 subjects (3.3%) in the IDegAsp group reported 17 eye disorder AEs, and 4 subjects (2.2%) in the IDet group reported 4 eye disorder AEs. In addition, 4 eye related injuries were reported under the Injury, poisoning and procedural complications SOC: 2 in the IDegAsp group (1 eye injury, 1 corneal scar) and 2 in the IDet group (1 eye injury, 1 post procedural retinal haemorrhage). See [EOT Table 14.3.1.7](#) and [Appendix 16.2.7, Listing 16.2.7.2](#) for more information on eye disorders, injuries and procedural complications reported. Individual data are listed in [EOT Table 14.3.7.3](#).

12.6.5 Body Weight and Body Mass Index

Body weight and BMI are summarised in [EOT Table 14.3.6.18](#), while the change from baseline values are shown in [EOT Table 14.3.6.19](#). The mean body weight appeared to increase steadily throughout the trial for both treatment groups as shown in [Figure 12-9](#) and [EOT Figures 14.3.6.22-24](#). The mean weight gain was approximately 1 kg greater in the IDegAsp group (2.3 kg) than in the IDet group (1.3 kg) at the end of the trial ([EOT Table 14.3.6.19](#)). Individual data are listed in [EOT Listing 14.3.7.6](#)

IDegAsp was associated with more weight gain than IDet after 26 weeks of treatment as the lower limit of the 95% CI for the estimated treatment difference was > 0 (1.04 kg [0.38; 1.69]_{95% CI}), [EOT Table 14.3.6.20](#).



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

28APR2011:13:08:13 - fmean_numfind_v03.sas/e_bw_abs_mean_locf_sas.cgm

Cross-reference: [EOT Figure 14.3.6.21](#)

Figure 12–9 Body Weight – Mean Plot – Full Analysis Set

12.7 Safety Conclusions

From the results of this 26-week trial of treatment with IDegAsp + IAsp at remaining meals or IDet + IAsp, the following can be concluded:

Secondary Endpoints

Confirmatory Safety Endpoint

- **Hypoglycaemic episodes:** The observed rate of nocturnal confirmed hypoglycaemic episodes per 100 PYE was 371 episodes for IDegAsp and 572 episodes for IDet. The rate of nocturnal confirmed hypoglycaemia was 37% lower with IDegAsp than with IDet; estimated rate ratio (IDegAsp/IDet) was 0.63, [0.49; 0.81]_{95% CI}. The hierarchical testing was stopped prior to testing this endpoint for superiority.

Supportive Safety Endpoints

- **Hypoglycaemic episodes:** The observed rate of confirmed hypoglycaemic episodes, per 100 PYE was 3917 for IDegAsp and 4434 for IDet. The observed rates of severe and nocturnal severe hypoglycaemia per 100 PYE were 33 and 6 for IDegAsp and 42 and 17 for IDet, respectively. The estimated rate ratios (IDegAsp/IDet) for confirmed hypoglycaemia and severe hypoglycaemia were 0.91 [0.76; 1.09]_{95% CI} and 1.19 [0.58; 2.41]_{95% CI}, respectively.
- **Body weight:** IDegAsp was associated with more weight gain than IDet after 26 weeks of treatment as the lower limit of the 95% CI for the estimated treatment difference was > 0, 1.04 kg [0.38; 1.69]_{95% CI}. The mean (SD) body weight at baseline and at the end of the trial was 76.5 kg (14.4) and 78.9 kg (15.6) in the IDegAsp group and 76.1 kg (13.9) and 77.5 kg (14.4) in the IDet group, respectively.
- **Adverse events:** A similar percentage of subjects reported adverse events in the IDegAsp (66%) and IDet (63%) groups. The rates of all adverse events was numerically similar for the IDegAsp and IDet groups (500 vs. 520 events per 100 PYE) as were the rates of severe adverse events (37 vs. 45 events per 100 PYE). The rate of adverse events possibly or probably related to IDegAsp or IDet was numerically lower with IDegAsp than with IDet (50 vs. 81 events per 100 PYE). The most frequent adverse events in both treatment groups were nasopharyngitis, upper respiratory tract infection, hypoglycaemia and headache. The percentage of subjects with injection site disorders was low in both treatment groups: IDegAsp: 1.4% (7 events); IDet: 4.4% (36 events).
- **Deaths, serious adverse events and other significant adverse events:** No deaths were reported in this trial. A total of 31 (8.6%) and 13 (7.2%) subjects reported serious adverse events in the IDegAsp and IDet group, respectively. The rate of serious adverse events per 100 PYE was low in both treatment groups (IDegAsp: 27, IDet: 20) with hypoglycaemia as the most frequent serious adverse events in both groups. A similar percentage of subjects withdrew from the trial due to AEs in the IDegAsp (1.4%) and the IDet (1.7%) group.
- **Insulin antibodies:** The mean level of insulin antibodies cross-reacting between insulin degludec (respective comparator) and human insulin was low at baseline and remained low

with IDegAsp and increased only slightly with IDet after 26 weeks of treatment. Scatter plots did not indicate any correlation between antibody levels and HbA_{1c} or total insulin dose.

- **Vital signs, ECG, fundoscopy, physical examination and laboratory values:** No clinically relevant differences from baseline to end of treatment or between the two treatment groups were observed for vital signs, ECG, fundoscopy/fundusphotography, physical examination and laboratory values.
- **Insulin dose:** The mean daily total (basal and bolus) insulin dose after 26 weeks was numerically lower in the IDegAsp group compared with the IDet group: 69 U (0.86 U/kg) for IDegAsp and 79 U (1.00 U/kg) for IDet. The mean derived total daily basal insulin dose after 26 weeks was numerically lower in the IDegAsp group compared with the IDet group: 29 U (0.37 U/kg) for IDegAsp and 36 U (0.46 U/kg) for IDet. The mean derived total daily bolus insulin dose was lower in the IDegAsp group than in the IDet group: 39 U (0.49 U/kg) for IDegAsp and 43 U (0.54 U/kg) for IDet. The ratio of IDegAsp/IDet mean daily insulin dose (U) after 26 weeks was 0.87 for total insulin, 0.81 for derived total basal insulin and 0.92 for derived total bolus insulin, meaning that mean doses were lower in the IDegAsp group compared with the IDet group.

13 Discussion and Overall Conclusions

Background Information

Insulin analogues have been developed to more closely mimic the basal and mealtime components of endogenous insulin secretion and are now an established part of diabetes management. IDegAsp is the first soluble ready-to-use insulin that comprises both a basal insulin component (IDeg) and a bolus insulin component (IAsp). In the present trial, IDegAsp is investigated in subjects with type 1 diabetes mellitus who may benefit from a simplified basal-bolus regimen with IDegAsp once daily and IAsp at remaining meals.

The trial was conducted to confirm the efficacy and safety of IDegAsp OD + mealtime IAsp for the remaining meals in subjects with type 1 diabetes mellitus. The primary objective was to confirm efficacy in controlling glycaemia, with respect to change in HbA_{1c} with the IDegAsp + IAsp regimen compared to a conventional basal-bolus regimen with IDet as basal insulin (injected OD or BID) and IAsp injected at all meals. Baseline characteristics were similar in the two treatment regimens, and approximately 87% of subjects completed the trial.

As in any open-label trial, there may be a risk of an underlying reporting bias. In general, investigators are likely to be more alert when treating subjects with a new medical entity such as IDegAsp, and subjects may also be more hesitant towards a new treatment. This could influence the reporting of AEs, hypoglycaemia and PRO. Likewise, as investigators are less familiar with IDegAsp they may tend to be more cautious with regards to starting dose and dose adjustment of IDegAsp, which could compromise the titration and dose optimisation.

Glycaemic Control

The trial population had been treated with basal-bolus or premix insulin regimens for at least 12 months at trial entry. Still, both IDegAsp and IDet effectively improved long-term glycaemic control in terms of change in HbA_{1c} after 26 weeks of treatment (IDegAsp was non-inferior to IDet). The observed reduction in HbA_{1c} was approximately 0.7% points with both treatments after 26 weeks. After 26 weeks of treatment, mean HbA_{1c} was reduced to 7.6% in both the IDegAsp and the IDet groups. The level of glycaemic control achieved with IDet in this trial was comparable to that achieved in previous treat-to-target trials with a similar IDet treatment regimen.^{17,40}

While FPG was reduced in both groups to similar levels of 8.6 and 8.7 mmol/L, respectively, plasma glucose was more stable in the IDegAsp group as measured by less fluctuation in self-measured plasma glucose – in line with the flat and stable action profile of the insulin degludec component of IDegAsp.

Upon 26 weeks of treatment with IDegAsp, approximately 25% of subjects had achieved the HbA_{1c} target of < 7.0% compared to 20% of subjects in the comparator group. The estimated odds ratio indicated a numerically higher likelihood (35%) of achieving this treatment target when treated with

IDegAsp compared to IDet (not statistically significant). As would be expected for subjects with type 1 diabetes mellitus, the proportion of subjects reaching the HbA_{1c} target without any confirmed hypoglycaemic episodes was low in both treatment groups. Still, more than 20% of the subjects achieved the HbA_{1c} target without experiencing *severe* hypoglycaemic episodes during the 26 weeks of treatment, and the odds ratio indicated a numerically higher (24%) likelihood of achieving this target (HbA_{1c} < 7% without severe hypoglycaemic episodes) with IDegAsp compared to IDet (not statistically significant).

Overall, treatment with IDegAsp plus IAsp resulted in reductions in the 9-point SMPG profiles that were similar to those achieved with the IDet regimen. After 26 weeks of treatment, the mean SMPG was lower in the time from the 90-minutes postbreakfast measurement until lunchtime with IDegAsp, while the SMPG with IDet remained at a stable, but higher level during this time.

Insulin Doses and Titration

The total dose of insulin (basal + bolus) was similar in the IDegAsp and the IDet treatment groups at baseline (Week 1). Subjects in the IDegAsp group injected IDegAsp OD throughout the trial, while subjects in the IDet group could add a second dose of IDet if a pre-specified set of criteria were fulfilled. During the trial, the total dose of IDet + IAsp increased more than the total dose of IDegAsp + IAsp. The 14% higher total dose was primarily attributed to a larger increase in basal dose in the IDet group compared with the IDegAsp group.

The distribution of basal and bolus insulin in relation to the total insulin dose was similar at baseline, and remained similar throughout the trial with the two treatment regimens regardless of the differences in insulin dose. After 26 weeks of treatment, the basal:bolus split was 43%:57% in the IDegAsp group and 46%:54% in the IDet group.

In both treatment groups, there was no apparent difference between the dose recommended by the titration algorithm, the dose prescribed by the investigator, and the actual dose injected, suggesting good adherence to the titration algorithm and good subject compliance with both IDegAsp and IDet.

Subjects randomised to the IDegAsp regimen were instructed to administer IDegAsp once daily with the meal that ensured the most optimal coverage of both basal and bolus requirements for the prescribed IDegAsp dose. Throughout the trial, IDegAsp could be injected at any meal and furthermore, the injection could be moved to another meal in order to optimise glycaemic control. Throughout the trial, IDegAsp injections were distributed among all meals, with an apparent preference for the evening meal, indicating that indeed physicians made use of the opportunity for individualised insulin treatment by dosing IDegAsp at any meal of the day. Independent of dosing time, the IDegAsp dose was adjusted based on prebreakfast glucose measurement.

Hypoglycaemia

The rate of confirmed hypoglycaemic episodes and severe hypoglycaemia appeared similar during the first part of the trial, followed by a lower rate of hypoglycaemic episodes in the IDegAsp group than the IDet group during the last part of the trial. The rate of confirmed hypoglycaemic episodes for IDet in this trial (44 events per PYE) was similar to the results from a previous trial (NN304-1430) comparing IDet and IGlax in subjects with type 1 diabetes mellitus, where the rates of confirmed hypoglycaemic episodes (major plus minor) were 39 and 44 events PYE for IDet and IGlax, respectively.⁴⁰ Together these results indicate that switching from a basal bolus therapy to IDegAsp is safe in terms of the risk of hypoglycaemic episodes after the transition.

One of the greatest concerns for subjects with type 1 diabetes mellitus is the risk of hypoglycaemic episodes occurring during sleep. Subjects in the IDegAsp group experienced fewer nocturnal hypoglycaemic episodes and fewer severe nocturnal hypoglycaemic episodes than subjects in the IDet group. Hence the larger nocturnal decrement in BG observed with IDegAsp compared to IDet was not associated with increased nocturnal hypoglycaemia. The rate ratio (IDegAsp / IDet) for nocturnal hypoglycaemic episodes was 0.63, indicating that the rate of such episodes was 37% lower with IDegAsp, than with IDet. The lower rate of nocturnal hypoglycaemic episodes may be reflected in the trend towards fewer confirmed hypoglycaemic episodes in the IDegAsp group than the IDet group (39 versus 44 episodes per PYE in the IDegAsp and IDet groups, respectively). These findings could be related to the more stable and flat action profile of the basal component of IDegAsp, as shown by less fluctuation in SMPG levels during the day with IDegAsp compared to IDet. Together these results show that IDegAsp enables adjustment of insulin therapy to accomplish improved glycaemic control with fewer nocturnal confirmed hypoglycaemic episodes than with IDet.

Safety and Tolerability

In general, IDegAsp was well tolerated and the AE and SAE profiles were similar between the two treatment groups. The rates of AEs and SAEs per 100 exposure years were comparable in the IDegAsp and IDet group. There were no specific patterns or clustering of the AEs in the treatment groups. The vast majority of all events were mild or moderate in severity and were judged as having an unlikely relation to trial products. The SAEs judged to have a likely relation to trial products were primarily related to hypoglycaemia in both groups. As with any insulin therapy, injection site reactions may occur. The percentage of subjects experiencing injection site reactions was less than 2% in the IDegAsp arm. Administration of IDegAsp was not associated with any severe cardiovascular AEs recorded during the trial and no major adverse cardiovascular events were reported as evaluated by the independent event adjudication committee. The proportion of subjects with AEs leading to withdrawal was similar between treatment groups, as was the percent of subjects with medication errors.

Body weight increased slightly in both treatment groups as can be expected from an intensive basal bolus therapy. In the IDegAsp group, the change in body weight was 1 kg greater than in the IDet group. This is in line with previous reports on IDet, where IDet has been associated with an approximately 1 kg less body weight gain than other basal insulin products.¹⁷

After 26 weeks of treatment, the insulin antibody levels (cross-reacting and specific) increased slightly in both treatment groups, least in the IDegAsp group. There was no apparent correlation between insulin antibody levels and HbA_{1c}, or insulin dose in either treatment group. No clinically relevant differences were observed with respect to measurement of haematology, biochemistry, lipids, ECG, funduscopy or vital signs between the treatment groups.

Overall, treatment with IDegAsp dosed OD at any meal in combination with IAsp at the remaining meals, offered a safe and intensive treatment regimen with the convenience of fewer injections than a standard basal bolus regimen. Switching from other insulin regimens to IDegAsp + IAsp appeared safe and resulted in a similar AE and hypoglycaemia profile as IDet + IAsp, with the added benefits of less nocturnal hypoglycaemic episodes and the option of administering IDegAsp at any meal.

Overall Conclusions

This confirmatory, randomised, controlled, 26-week study investigated the efficacy and safety of treatment with IDegAsp taken once daily at any meal, together with IAsp taken at the remaining meals, compared to treatment with IDet in combination with IAsp at all meals in subjects with type 1 diabetes mellitus. The data support the following conclusions:

- IDegAsp effectively improves long-term glycaemic control as measured by HbA_{1c} (non-inferiority to IDet confirmed).
- FPG decreases to a similar level in both treatment groups. Plasma glucose is more stable during the day with IDegAsp compared to IDet as measured by less fluctuation in self-measured plasma glucose.
- For subjects achieving the treatment target (HbA_{1c} < 7%) without severe hypoglycaemia, superiority of IDegAsp compared to IDet can not be confirmed.
- Subjects treated with IDegAsp experience a lower rate of nocturnal confirmed hypoglycaemic episodes compared to subjects treated with IDet.
- The average total daily insulin dose is numerically lower in subjects treated with IDegAsp compared to those treated with IDet.
- In this trial, no safety issues are identified with IDegAsp; there is no apparent difference between IDegAsp and IDet with respect to AEs and standard safety parameters. Body weight increases slightly more in the IDegAsp treatment group compared to the IDet group. Antibody development is sparse and only a few injection site reactions are reported with IDegAsp.

In conclusion, these findings confirm the efficacy and safety of once-daily treatment with IDegAsp taken at any meal in combination with IAsp for the remaining meals in subjects with type 1 diabetes mellitus.

14 Tables, Figures and Graphs Referred to but not Included in the Text

14.1 Demographic Data

14.1.1: Subject Disposition - Summary

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Screened			706
Screening Failures			158
Withdrawn before Randomisation			0
Randomised	366 (100.0)	182 (100.0)	548 (100.0)
Exposed	362 (98.9)	180 (98.9)	542 (98.9)
Withdrawn at/after Randomisation	46 (12.6)	26 (14.3)	72 (13.1)
Adverse Event	4 (1.1)	3 (1.6)	7 (1.3)
Ineffective Therapy	2 (0.5)	0 (0.0)	2 (0.4)
Non-Compliance With Protocol	8 (2.2)	6 (3.3)	14 (2.6)
Withdrawal Criteria	7 (1.9)	5 (2.7)	12 (2.2)
Other	25 (6.8)	12 (6.6)	37 (6.8)
Completed	320 (87.4)	156 (85.7)	476 (86.9)
Full Analysis Set	366 (100.0)	182 (100.0)	548 (100.0)
PP Analysis Set	336 (91.8)	168 (92.3)	504 (92.0)
Safety Analysis Set	362 (98.9)	180 (98.9)	542 (98.9)

N: Number of subjects
 %: Proportion of randomised subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:38:32 - tsum_ds_v02.sas/t_dispos_sum.txt

14.1.2: Subject Disposition by Country – Summary - All Subjects

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Australia			
Screened			80
Randomised	47 (100.0)	18 (100.0)	65 (100.0)
Exposed	46 (97.9)	18 (100.0)	64 (98.5)
Completed	43 (91.5)	14 (77.8)	57 (87.7)
Full Analysis Set	47 (100.0)	18 (100.0)	65 (100.0)
PP Analysis Set	45 (95.7)	15 (83.3)	60 (92.3)
Safety Analysis Set	46 (97.9)	18 (100.0)	64 (98.5)
Denmark			
Screened			37
Randomised	16 (100.0)	15 (100.0)	31 (100.0)
Exposed	16 (100.0)	15 (100.0)	31 (100.0)
Completed	15 (93.8)	14 (93.3)	29 (93.5)
Full Analysis Set	16 (100.0)	15 (100.0)	31 (100.0)
PP Analysis Set	15 (93.8)	15 (100.0)	30 (96.8)
Safety Analysis Set	16 (100.0)	15 (100.0)	31 (100.0)
France			
Screened			28
Randomised	17 (100.0)	8 (100.0)	25 (100.0)
Exposed	15 (88.2)	8 (100.0)	23 (92.0)
Completed	14 (82.4)	6 (75.0)	20 (80.0)
Full Analysis Set	17 (100.0)	8 (100.0)	25 (100.0)
PP Analysis Set	13 (76.5)	7 (87.5)	20 (80.0)
Safety Analysis Set	15 (88.2)	8 (100.0)	23 (92.0)
Israel			
Screened			40
Randomised	22 (100.0)	11 (100.0)	33 (100.0)
Exposed	22 (100.0)	11 (100.0)	33 (100.0)
Completed	20 (90.9)	9 (81.8)	29 (87.9)
Full Analysis Set	22 (100.0)	11 (100.0)	33 (100.0)
PP Analysis Set	21 (95.5)	9 (81.8)	30 (90.9)
Safety Analysis Set	22 (100.0)	11 (100.0)	33 (100.0)
Poland			
Screened			66
Randomised	37 (100.0)	15 (100.0)	52 (100.0)
Exposed	37 (100.0)	15 (100.0)	52 (100.0)
Completed	32 (86.5)	14 (93.3)	46 (88.5)
Full Analysis Set	37 (100.0)	15 (100.0)	52 (100.0)
PP Analysis Set	32 (86.5)	14 (93.3)	46 (88.5)
Safety Analysis Set	37 (100.0)	15 (100.0)	52 (100.0)
Romania			
Screened			94
Randomised	49 (100.0)	21 (100.0)	70 (100.0)
Exposed	49 (100.0)	21 (100.0)	70 (100.0)
Completed	47 (95.9)	21 (100.0)	68 (97.1)
Full Analysis Set	49 (100.0)	21 (100.0)	70 (100.0)
PP Analysis Set	48 (98.0)	21 (100.0)	69 (98.6)
Safety Analysis Set	49 (100.0)	21 (100.0)	70 (100.0)

N: Number of subjects

?: Proportion of randomised subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:33 - tsum_ds_country_v01.sas/t_dispos_country_sum.txt

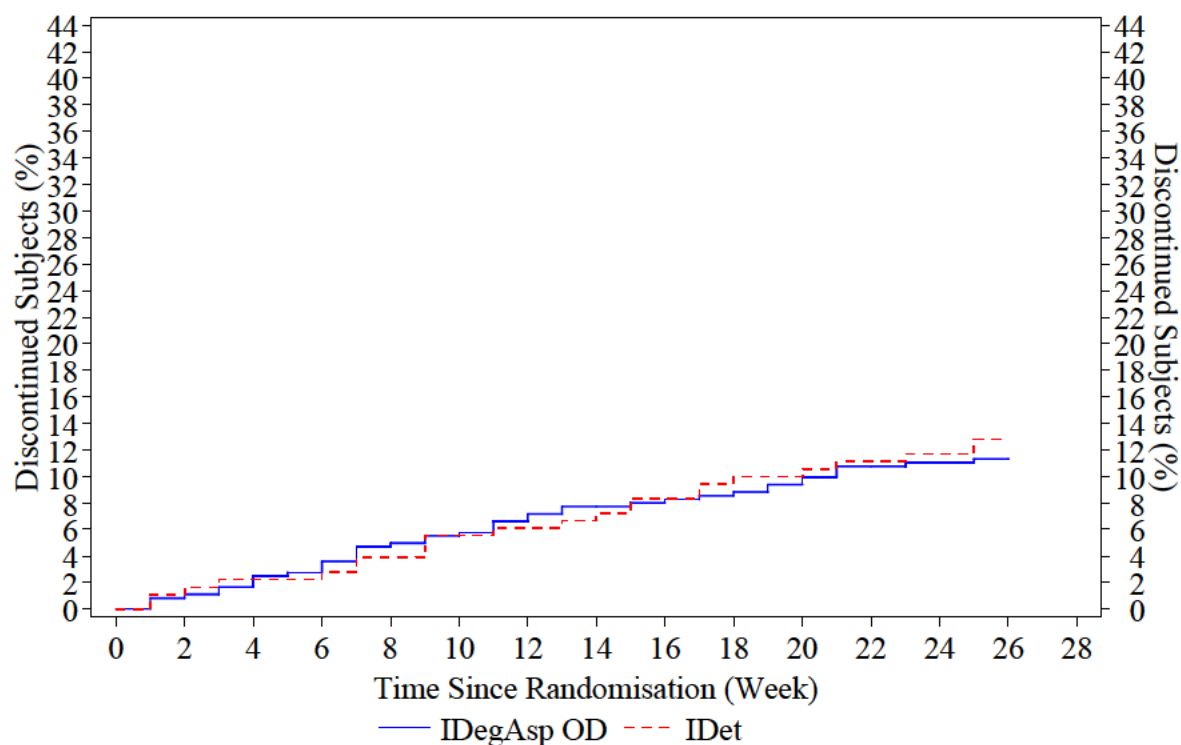
Subject Disposition by Country - Summary - All Subjects

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Russian Federation			
Screened			97
Randomised	47 (100.0)	22 (100.0)	69 (100.0)
Exposed	47 (100.0)	22 (100.0)	69 (100.0)
Completed	46 (97.9)	20 (90.9)	66 (95.7)
Full Analysis Set	47 (100.0)	22 (100.0)	69 (100.0)
PP Analysis Set	47 (100.0)	21 (95.5)	68 (98.6)
Safety Analysis Set	47 (100.0)	22 (100.0)	69 (100.0)
United Kingdom			
Screened			41
Randomised	24 (100.0)	12 (100.0)	36 (100.0)
Exposed	24 (100.0)	12 (100.0)	36 (100.0)
Completed	19 (79.2)	9 (75.0)	28 (77.8)
Full Analysis Set	24 (100.0)	12 (100.0)	36 (100.0)
PP Analysis Set	22 (91.7)	11 (91.7)	33 (91.7)
Safety Analysis Set	24 (100.0)	12 (100.0)	36 (100.0)
United States			
Screened			223
Randomised	107 (100.0)	60 (100.0)	167 (100.0)
Exposed	106 (99.1)	58 (96.7)	164 (98.2)
Completed	84 (78.5)	49 (81.7)	133 (79.6)
Full Analysis Set	107 (100.0)	60 (100.0)	167 (100.0)
PP Analysis Set	93 (86.9)	55 (91.7)	148 (88.6)
Safety Analysis Set	106 (99.1)	58 (96.7)	164 (98.2)

N: Number of subjects

?: Proportion of randomised subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:33 - tsum_ds_country_v01.sas/t_dispos_country_sum.txt



nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:38:56 - ID14100200_fplot_subj_disc.sas/e_dispos_fas.cgm

14.1.3: Time to Discontinuation - Full Analysis Set

14.1.4: Subject Disposition by Week - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
Attending			
Visit 1	366 (100.0)	182 (100.0)	548 (100.0)
Visit 2 (Week 0)	366 (100.0)	182 (100.0)	548 (100.0)
Visit 3 (Week 1)	360 (98.4)	179 (98.4)	539 (98.4)
Visit 4 (Week 2)	360 (98.4)	178 (97.8)	538 (98.2)
Visit 5 (Week 3)	357 (97.5)	176 (96.7)	533 (97.3)
Visit 6 (Week 4)	355 (97.0)	176 (96.7)	531 (96.9)
Visit 7 (Week 5)	352 (96.2)	175 (96.2)	527 (96.2)
Visit 8 (Week 6)	348 (95.1)	174 (95.6)	522 (95.3)
Visit 9 (Week 7)	345 (94.3)	174 (95.6)	519 (94.7)
Visit 10 (Week 8)	343 (93.7)	172 (94.5)	515 (94.0)
Visit 11 (Week 9)	342 (93.4)	170 (93.4)	512 (93.4)
Visit 12 (Week 10)	339 (92.6)	170 (93.4)	509 (92.9)
Visit 13 (Week 11)	337 (92.1)	170 (93.4)	507 (92.5)
Visit 14 (Week 12)	336 (91.8)	168 (92.3)	504 (92.0)
Visit 15 (Week 13)	334 (91.3)	166 (91.2)	500 (91.2)
Visit 16 (Week 14)	334 (91.3)	166 (91.2)	500 (91.2)
Visit 17 (Week 15)	333 (91.0)	164 (90.1)	497 (90.7)
Visit 18 (Week 16)	331 (90.4)	163 (89.6)	494 (90.1)
Visit 19 (Week 17)	331 (90.4)	163 (89.6)	494 (90.1)
Visit 20 (Week 18)	329 (89.9)	162 (89.0)	491 (89.6)
Visit 21 (Week 19)	328 (89.6)	162 (89.0)	490 (89.4)
Visit 22 (Week 20)	327 (89.3)	160 (87.9)	487 (88.9)
Visit 23 (Week 21)	324 (88.5)	159 (87.4)	483 (88.1)
Visit 24 (Week 22)	323 (88.3)	158 (86.8)	481 (87.8)
Visit 25 (Week 23)	323 (88.3)	158 (86.8)	481 (87.8)
Visit 26 (Week 24)	323 (88.3)	158 (86.8)	481 (87.8)
Visit 27 (Week 25)	322 (88.0)	158 (86.8)	480 (87.6)
Visit 28 (Week 26)	359 (98.1)	178 (97.8)	537 (98.0)
Visit 29 (Week 27)	348 (95.1)	169 (92.9)	517 (94.3)

N: Number of Subjects
 %: Percentages are based on N

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:38:36 - tsum_ds_week_v01.sas/t_dispos_week_fas.txt

14.1.5: Reasons for Discontinuation from Week 12 and onwards - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
Withdrawn	17 (4.6)	13 (7.1)	30 (5.5)
Adverse Event	2 (0.5)	3 (1.6)	5 (0.9)
Ineffective Therapy	0	0	0
Non-Compliance With Protocol	4 (1.1)	2 (1.1)	6 (1.1)
Withdrawal Criteria	4 (1.1)	2 (1.1)	6 (1.1)
Withdrawal Criteria 1	1 (0.3)	0	1 (0.2)
Withdrawal Criteria 2	1 (0.3)	0	1 (0.2)
Withdrawal Criteria 3	0	2 (1.1)	2 (0.4)
Withdrawal Criteria 4	1 (0.3)	0	1 (0.2)
Withdrawal Criteria 5	0	0	0
Withdrawal Criteria 6	0	0	0
Withdrawal Criteria 7	1 (0.3)	0	1 (0.2)
Other	7 (1.9)	6 (3.3)	13 (2.4)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:37 - t_withdraw_criteria.sas/t_withdraw_criteria_fas.txt

14.1.6: Demographics and Baseline Characteristics - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
Age Group			
N	366 (100.0)	182 (100.0)	548 (100.0)
> 65 years	11 (3.0)	14 (7.7)	25 (4.6)
Adults (18-65 yrs)	355 (97.0)	168 (92.3)	523 (95.4)
Sex			
N	366 (100.0)	182 (100.0)	548 (100.0)
Female	176 (48.1)	100 (54.9)	276 (50.4)
Male	190 (51.9)	82 (45.1)	272 (49.6)
Country of Residence			
N	366 (100.0)	182 (100.0)	548 (100.0)
Australia	47 (12.8)	18 (9.9)	65 (11.9)
Denmark	16 (4.4)	15 (8.2)	31 (5.7)
France	17 (4.6)	8 (4.4)	25 (4.6)
Israel	22 (6.0)	11 (6.0)	33 (6.0)
Poland	37 (10.1)	15 (8.2)	52 (9.5)
Romania	49 (13.4)	21 (11.5)	70 (12.8)
Russian Federation	47 (12.8)	22 (12.1)	69 (12.6)
United Kingdom	24 (6.6)	12 (6.6)	36 (6.6)
United States	107 (29.2)	60 (33.0)	167 (30.5)
Ethnicity			
N	366 (100.0)	182 (100.0)	548 (100.0)
Hispanic or Latino	10 (2.7)	7 (3.8)	17 (3.1)
Not Hispanic or Latino	339 (92.6)	167 (91.8)	506 (92.3)
Not Applicable	17 (4.6)	8 (4.4)	25 (4.6)
Race			
N	366 (100.0)	182 (100.0)	548 (100.0)
White	333 (91.0)	162 (89.0)	495 (90.3)
Black or African American	10 (2.7)	6 (3.3)	16 (2.9)
Asian Indian	1 (0.3)	0 (0.0)	1 (0.2)
Asian non-Indian	3 (0.8)	3 (1.6)	6 (1.1)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	1 (0.3)	1 (0.5)	2 (0.4)
Not Applicable	17 (4.6)	8 (4.4)	25 (4.6)
Other	1 (0.3)	2 (1.1)	3 (0.5)

N = Number of Subjects

Subjects from France did not report race

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:39 - tsum_sc_v01.sas/t_demog_basechar_fas.txt

14.1.7: Baseline and Diabetes Characteristics – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Age (years)			
N	366	182	548
Mean (SD)	40.7 (12.8)	42.6 (13.8)	41.3 (13.2)
Median	39.9	42.4	40.6
Min ; Max	18.3 ; 78.5	18.1 ; 80.2	18.1 ; 80.2
Height (m)			
N	366	182	548
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Median	1.7	1.7	1.7
Min ; Max	1.5 ; 2.0	1.1 ; 2.0	1.1 ; 2.0
Body Weight (kg)			
N	366	182	548
Mean (SD)	76.7 (14.6)	76.0 (14.0)	76.5 (14.4)
Median	75.0	76.0	75.3
Min ; Max	44.0 ; 123.4	42.9 ; 137.4	42.9 ; 137.4
BMI (kg/m^2)			
N	366	182	548
Mean (SD)	26.2 (4.0)	26.7 (3.9)	26.4 (4.0)
Median	25.9	26.3	26.0
Min ; Max	16.2 ; 35.6	18.7 ; 36.2	16.2 ; 36.2
Duration of Diabetes (year)			
N	366	181	547
Mean (SD)	17.2 (11.3)	17.9 (12.3)	17.4 (11.6)
Median	14.9	15.0	14.9
Min ; Max	1.1 ; 59.7	1.0 ; 56.6	1.0 ; 59.7
HbA1c (%)			
N	366	182	548
Mean (SD)	8.3 (0.8)	8.3 (0.7)	8.3 (0.8)
Median	8.2	8.2	8.2
Min ; Max	6.8 ; 10.3	6.5 ; 10.4	6.5 ; 10.4
FPG (mmol/L)			
N	365	181	546
Mean (SD)	10.3 (4.7)	11.0 (4.8)	10.5 (4.8)
Median	9.6	10.3	9.9
Min ; Max	1.8 ; 30.2	2.9 ; 28.4	1.8 ; 30.2

14.1.8: Anti-diabetic Treatment Regimen at Screening - Full Analysis Set

	IDegAsp N	OD (%)	IDet N	IDet (%)	Total N	Total (%)
Number of Subjects	366		182		548	
Basal-Bolus	334	(91.3)	161	(88.5)	495	(90.3)
Basal-Bolus	334	(91.3)	161	(88.5)	495	(90.3)
Other	32	(8.7)	21	(11.5)	53	(9.7)
Basal + PreMix			1	(0.5)	1	(0.2)
Basal Only	1	(0.3)	1	(0.5)	2	(0.4)
PreMix + Bolus	11	(3.0)	7	(3.8)	18	(3.3)
PreMix Only	18	(4.9)	10	(5.5)	28	(5.1)
SelfMix	2	(0.5)	2	(1.1)	4	(0.7)

N: Number of Subjects
 %: Proportion of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:38:46 - tscreen_regimen_sum_fas.sas/t_screen_regimen_sum_fas.txt

14.1.9: Insulin Type at Screening - Full Analysis Set

	IDegAsp OD		IDet		Total	
	N	(%)	N	(%)	N	(%)
Number of Subjects	366		182		548	
Basal	337	(92.1)	165	(90.7)	502	(91.6)
IDet	57	(15.6)	24	(13.2)	81	(14.8)
IGlar	237	(64.8)	125	(68.7)	362	(66.1)
NPH	43	(11.7)	16	(8.8)	59	(10.8)
Bolus	347	(94.8)	170	(93.4)	517	(94.3)
HI	33	(9.0)	19	(10.4)	52	(9.5)
IAsp	180	(49.2)	91	(50.0)	271	(49.5)
IGlu	22	(6.0)	13	(7.1)	35	(6.4)
ILis	108	(29.5)	50	(27.5)	158	(28.8)
Neutral	1	(0.3)	1	(0.5)	2	(0.4)
Porcine	4	(1.1)	1	(0.5)	5	(0.9)
PreMix	33	(9.0)	19	(10.4)	52	(9.5)
BHI	12	(3.3)	7	(3.8)	19	(3.5)
BIAsp	16	(4.4)	10	(5.5)	26	(4.7)
ILisMix	5	(1.4)	2	(1.1)	7	(1.3)

N: Number of Subjects

=: Proportion of Subjects

Subjects can use more than one type of insulin within each group

BHI: Biphasic Human Insulin, BIAsp: Biphasic Insulin Aspart, HI: Human Insulin

IAsp: Insulin Aspart, IDet: Insulin Detemir, IGlar: Insulin Glargine

IGlu: Insulin Glulisine, ILis: Insulin Lispro, ILisMix: Insulin Lispro Mix

NPH: Neutral Protamine Hagedorn

14.1.10: Diabetes Complications at Screening - Summary - Full Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Number of Subjects	366			182			548		
All Complications	119	(32.5)	217	67	(36.8)	102	186	(33.9)	319
Diabetic retinopathy	88	(24.0)	88	53	(29.1)	53	141	(25.7)	141
Diabetic neuropathy	70	(19.1)	70	24	(13.2)	24	94	(17.2)	94
Diabetic nephropathy	19	(5.2)	19	11	(6.0)	12	30	(5.5)	31
Microalbuminuria	10	(2.7)	10	5	(2.7)	5	15	(2.7)	15
Diabetic vascular disorder	12	(3.3)	12	2	(1.1)	2	14	(2.6)	14
Diabetic autonomic neuropathy	4	(1.1)	4	1	(0.5)	1	5	(0.9)	5
Retinopathy proliferative	2	(0.5)	2	2	(1.1)	2	4	(0.7)	4
Cardiac autonomic neuropathy	3	(0.8)	3				3	(0.5)	3
Diabetic encephalopathy	3	(0.8)	3				3	(0.5)	3
Cataract diabetic	2	(0.5)	2				2	(0.4)	2
Diabetic cheiropathy	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic gastroparesis	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic foot	1	(0.3)	1				1	(0.2)	1
Diabetic microangiopathy	1	(0.3)	1				1	(0.2)	1
Necrobiosis lipoidica diabetorum				1	(0.5)	1	1	(0.2)	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:48 - tsum_events_tpl_t030_v01.sas/t_screen_diabetes_comp_sum_fas.txt

14.1.11: Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp N	OD (%)	IDet N	(%)	Total N	(%)
Number of Subjects	366		182		548	
Metabolism and nutrition disorders	181	(49.5)	96	(52.7)	277	(50.5)
Type 1 diabetes mellitus	62	(16.9)	30	(16.5)	92	(16.8)
Hypercholesterolaemia	40	(10.9)	30	(16.5)	70	(12.8)
Hyperlipidaemia	47	(12.8)	21	(11.5)	68	(12.4)
Dyslipidaemia	34	(9.3)	22	(12.1)	56	(10.2)
Obesity	9	(2.5)	2	(1.1)	11	(2.0)
Diabetes mellitus	5	(1.4)	3	(1.6)	8	(1.5)
Vitamin B12 deficiency	4	(1.1)	1	(0.5)	5	(0.9)
Vitamin D deficiency	3	(0.8)	2	(1.1)	5	(0.9)
Gout	2	(0.5)	1	(0.5)	3	(0.5)
Overweight	2	(0.5)	1	(0.5)	3	(0.5)
Diabetic cheiropathy	1	(0.3)	1	(0.5)	2	(0.4)
Hypertriglyceridaemia	1	(0.3)	1	(0.5)	2	(0.4)
Iron deficiency	1	(0.3)	1	(0.5)	2	(0.4)
Diabetic foot	1	(0.3)			1	(0.2)
Fluid retention	1	(0.3)			1	(0.2)
Vascular disorders	131	(35.8)	77	(42.3)	208	(38.0)
Hypertension	113	(30.9)	71	(39.0)	184	(33.6)
Diabetic vascular disorder	12	(3.3)	2	(1.1)	14	(2.6)
Microangiopathy	1	(0.3)	4	(2.2)	5	(0.9)
Angiopathy	2	(0.5)	1	(0.5)	3	(0.5)
Peripheral vascular disorder	2	(0.5)	1	(0.5)	3	(0.5)
Venous insufficiency	1	(0.3)	2	(1.1)	3	(0.5)
Arterial disorder	2	(0.5)			2	(0.4)
Arteriosclerosis	2	(0.5)			2	(0.4)
Essential hypertension	2	(0.5)			2	(0.4)
Aneurysm			1	(0.5)	1	(0.2)
Aortic stenosis	1	(0.3)			1	(0.2)
Diabetic microangiopathy	1	(0.3)			1	(0.2)
Hot flush	1	(0.3)			1	(0.2)
Hypotension	1	(0.3)			1	(0.2)
Macroangiopathy	1	(0.3)			1	(0.2)
Renovascular hypertension			1	(0.5)	1	(0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Eye disorders	127 (34.7)	79 (43.4)	206 (37.6)
Diabetic retinopathy	88 (24.0)	53 (29.1)	141 (25.7)
Retinopathy	22 (6.0)	15 (8.2)	37 (6.8)
Cataract	19 (5.2)	7 (3.8)	26 (4.7)
Myopia	11 (3.0)	7 (3.8)	18 (3.3)
Glaucoma	5 (1.4)	6 (3.3)	11 (2.0)
Maculopathy	2 (0.5)	2 (1.1)	4 (0.7)
Retinopathy proliferative	2 (0.5)	2 (1.1)	4 (0.7)
Cataract diabetic	2 (0.5)		2 (0.4)
Astigmatism	1 (0.3)		1 (0.2)
Cataract nuclear		1 (0.5)	1 (0.2)
Conjunctivitis	1 (0.3)		1 (0.2)
Dry eye	1 (0.3)		1 (0.2)
Eyelid ptosis	1 (0.3)		1 (0.2)
Keratoconus	1 (0.3)		1 (0.2)
Lenticular opacities		1 (0.5)	1 (0.2)
Macular oedema	1 (0.3)		1 (0.2)
Ocular hypertension		1 (0.5)	1 (0.2)
Presbyopia		1 (0.5)	1 (0.2)
Retinal aneurysm	1 (0.3)		1 (0.2)
Retinal detachment		1 (0.5)	1 (0.2)
Retinal vascular disorder	1 (0.3)		1 (0.2)
Vision blurred		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Nervous system disorders	124 (33.9)	69 (37.9)	193 (35.2)
Diabetic neuropathy	70 (19.1)	24 (13.2)	94 (17.2)
Neuropathy peripheral	22 (6.0)	18 (9.9)	40 (7.3)
Headache	10 (2.7)	6 (3.3)	16 (2.9)
Polyneuropathy	5 (1.4)	8 (4.4)	13 (2.4)
Carpal tunnel syndrome	6 (1.6)	2 (1.1)	8 (1.5)
Migraine	4 (1.1)	3 (1.6)	7 (1.3)
Vascular encephalopathy	5 (1.4)	1 (0.5)	6 (1.1)
Diabetic autonomic neuropathy	4 (1.1)	1 (0.5)	5 (0.9)
Decreased vibratory sense	4 (1.1)		4 (0.7)
Cardiac autonomic neuropathy	3 (0.8)		3 (0.5)
Diabetic encephalopathy	3 (0.8)		3 (0.5)
Restless legs syndrome	1 (0.3)	2 (1.1)	3 (0.5)
Areflexia	1 (0.3)	1 (0.5)	2 (0.4)
Cerebral ischaemia	2 (0.5)		2 (0.4)
Encephalopathy	1 (0.3)	1 (0.5)	2 (0.4)
Epilepsy	1 (0.3)	1 (0.5)	2 (0.4)
Paraesthesia	1 (0.3)	1 (0.5)	2 (0.4)
Peripheral sensory neuropathy		2 (1.1)	2 (0.4)
Balance disorder	1 (0.3)		1 (0.2)
Carotid arteriosclerosis		1 (0.5)	1 (0.2)
Carotid artery stenosis	1 (0.3)		1 (0.2)
Cerebrovascular accident		1 (0.5)	1 (0.2)
Dizziness	1 (0.3)		1 (0.2)
Grand mal convulsion		1 (0.5)	1 (0.2)
Guillain-Barre syndrome	1 (0.3)		1 (0.2)
Hemicephalalgia		1 (0.5)	1 (0.2)
Hypoaesthesia	1 (0.3)		1 (0.2)
Migraine with aura		1 (0.5)	1 (0.2)
Myelopathy	1 (0.3)		1 (0.2)
Neuralgia		1 (0.5)	1 (0.2)
Radiculopathy	1 (0.3)		1 (0.2)
Sciatica	1 (0.3)		1 (0.2)
Syringomyelia	1 (0.3)		1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Musculoskeletal and connective tissue disorders	67 (18.3)	38 (20.9)	105 (19.2)
Osteoarthritis	10 (2.7)	6 (3.3)	16 (2.9)
Osteopenia	7 (1.9)	4 (2.2)	11 (2.0)
Back pain	4 (1.1)	6 (3.3)	10 (1.8)
Osteoporosis	4 (1.1)	6 (3.3)	10 (1.8)
Arthralgia	6 (1.6)	1 (0.5)	7 (1.3)
Arthritis	4 (1.1)	2 (1.1)	6 (1.1)
Osteochondrosis	4 (1.1)	2 (1.1)	6 (1.1)
Spinal osteoarthritis	4 (1.1)	2 (1.1)	6 (1.1)
Foot deformity	4 (1.1)	1 (0.5)	5 (0.9)
Muscle spasms	3 (0.8)	2 (1.1)	5 (0.9)
Periarthritis	2 (0.5)	3 (1.6)	5 (0.9)
Rheumatoid arthritis	4 (1.1)	1 (0.5)	5 (0.9)
Myalgia	2 (0.5)	2 (1.1)	4 (0.7)
Pain in extremity		4 (2.2)	4 (0.7)
Rotator cuff syndrome	3 (0.8)	1 (0.5)	4 (0.7)
Intervertebral disc degeneration	1 (0.3)	2 (1.1)	3 (0.5)
Intervertebral disc disorder	2 (0.5)	1 (0.5)	3 (0.5)
Intervertebral disc protrusion	2 (0.5)	1 (0.5)	3 (0.5)
Neck pain	3 (0.8)		3 (0.5)
Tendonitis	1 (0.3)	2 (1.1)	3 (0.5)
Arthropathy	2 (0.5)		2 (0.4)
Dupuytren's contracture	2 (0.5)		2 (0.4)
Exostosis	1 (0.3)	1 (0.5)	2 (0.4)
Fibromyalgia	2 (0.5)		2 (0.4)
Flank pain	2 (0.5)		2 (0.4)
Musculoskeletal pain	1 (0.3)	1 (0.5)	2 (0.4)
Polyarthritis	2 (0.5)		2 (0.4)
Trigger finger	2 (0.5)		2 (0.4)
Cervical spinal stenosis	1 (0.3)		1 (0.2)
Facet joint syndrome		1 (0.5)	1 (0.2)
Gouty arthritis	1 (0.3)		1 (0.2)
Hip deformity	1 (0.3)		1 (0.2)
Intervertebral disc compression	1 (0.3)		1 (0.2)
Joint stiffness	1 (0.3)		1 (0.2)
Muscle atrophy	1 (0.3)		1 (0.2)
Neuropathic arthropathy		1 (0.5)	1 (0.2)
Plantar fasciitis	1 (0.3)		1 (0.2)
Scoliosis	1 (0.3)		1 (0.2)
Sjogren's syndrome	1 (0.3)		1 (0.2)
Spondylitis		1 (0.5)	1 (0.2)
Spondylolisthesis	1 (0.3)		1 (0.2)
Systemic lupus erythematosus	1 (0.3)		1 (0.2)
Temporomandibular joint syndrome		1 (0.5)	1 (0.2)
Tenosynovitis		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Endocrine disorders	59 (16.1)	28 (15.4)	87 (15.9)
Hypothyroidism	39 (10.7)	18 (9.9)	57 (10.4)
Autoimmune thyroiditis	9 (2.5)	5 (2.7)	14 (2.6)
Goitre	6 (1.6)	4 (2.2)	10 (1.8)
Hypogonadism	3 (0.8)		3 (0.5)
Adrenal insufficiency	2 (0.5)		2 (0.4)
Myxoedema	1 (0.3)	1 (0.5)	2 (0.4)
Thyroiditis chronic	1 (0.3)	1 (0.5)	2 (0.4)
Androgen deficiency	1 (0.3)		1 (0.2)
Hyperparathyroidism	1 (0.3)		1 (0.2)
Hyperthyroidism		1 (0.5)	1 (0.2)
Postpartum hypopituitarism	1 (0.3)		1 (0.2)
Primary hypothyroidism	1 (0.3)		1 (0.2)
Thyroiditis	1 (0.3)		1 (0.2)
Gastrointestinal disorders	53 (14.5)	29 (15.9)	82 (15.0)
Gastrooesophageal reflux disease	13 (3.6)	10 (5.5)	23 (4.2)
Gastritis	8 (2.2)	3 (1.6)	11 (2.0)
Coeliac disease	8 (2.2)	2 (1.1)	10 (1.8)
Hiatus hernia	3 (0.8)	6 (3.3)	9 (1.6)
Constipation	5 (1.4)		5 (0.9)
Duodenal ulcer	5 (1.4)		5 (0.9)
Haemorrhoids	3 (0.8)	1 (0.5)	4 (0.7)
Impaired gastric emptying	2 (0.5)	2 (1.1)	4 (0.7)
Dyspepsia	2 (0.5)	1 (0.5)	3 (0.5)
Gastric ulcer	2 (0.5)	1 (0.5)	3 (0.5)
Gastroduodenitis	2 (0.5)	1 (0.5)	3 (0.5)
Colonic polyp	1 (0.3)	1 (0.5)	2 (0.4)
Diabetic gastroparesis	1 (0.3)	1 (0.5)	2 (0.4)
Irritable bowel syndrome	1 (0.3)	1 (0.5)	2 (0.4)
Pancreatitis	1 (0.3)	1 (0.5)	2 (0.4)
Reflux oesophagitis	2 (0.5)		2 (0.4)
Anal fissure	1 (0.3)		1 (0.2)
Colitis ulcerative	1 (0.3)		1 (0.2)
Diarrhoea		1 (0.5)	1 (0.2)
Diverticulum intestinal	1 (0.3)		1 (0.2)
Duodenitis	1 (0.3)		1 (0.2)
Gastritis atrophic		1 (0.5)	1 (0.2)
Gastrointestinal disorder	1 (0.3)		1 (0.2)
Gingival bleeding	1 (0.3)		1 (0.2)
Gingival swelling	1 (0.3)		1 (0.2)
Hyperchlorhydria	1 (0.3)		1 (0.2)
Oesophagitis	1 (0.3)		1 (0.2)
Pancreatitis chronic	1 (0.3)		1 (0.2)
Proctocolitis	1 (0.3)		1 (0.2)
Rectal polyp		1 (0.5)	1 (0.2)
Umbilical hernia	1 (0.3)		1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Psychiatric disorders	45 (12.3)	23 (12.6)	68 (12.4)
Depression	35 (9.6)	19 (10.4)	54 (9.9)
Anxiety	7 (1.9)	1 (0.5)	8 (1.5)
Attention deficit/hyperactivity disorder	3 (0.8)	3 (1.6)	6 (1.1)
Insomnia	3 (0.8)	2 (1.1)	5 (0.9)
Anxiety disorder	2 (0.5)		2 (0.4)
Bipolar disorder	1 (0.3)		1 (0.2)
Mood swings		1 (0.5)	1 (0.2)
Neurosis	1 (0.3)		1 (0.2)
Post-traumatic stress disorder	1 (0.3)		1 (0.2)
Schizophrenia	1 (0.3)		1 (0.2)
Tobacco abuse	1 (0.3)		1 (0.2)
Renal and urinary disorders	41 (11.2)	27 (14.8)	68 (12.4)
Diabetic nephropathy	19 (5.2)	11 (6.0)	30 (5.5)
Microalbuminuria	10 (2.7)	5 (2.7)	15 (2.7)
Nephropathy	4 (1.1)	4 (2.2)	8 (1.5)
Nephrolithiasis	3 (0.8)	2 (1.1)	5 (0.9)
Calculus urinary	3 (0.8)		3 (0.5)
Proteinuria	2 (0.5)	1 (0.5)	3 (0.5)
Nephroptosis	1 (0.3)	1 (0.5)	2 (0.4)
Urinary incontinence	1 (0.3)	1 (0.5)	2 (0.4)
Albuminuria		1 (0.5)	1 (0.2)
Dysuria	1 (0.3)		1 (0.2)
Glomerulonephritis chronic	1 (0.3)		1 (0.2)
Haematuria		1 (0.5)	1 (0.2)
Hypertonic bladder		1 (0.5)	1 (0.2)
Renal cyst		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Skin and subcutaneous tissue disorders	32 (8.7)	17 (9.3)	49 (8.9)
Lipodystrophy acquired	4 (1.1)	9 (4.9)	13 (2.4)
Acne	4 (1.1)	1 (0.5)	5 (0.9)
Eczema	3 (0.8)	1 (0.5)	4 (0.7)
Alopecia	3 (0.8)		3 (0.5)
Dry skin	2 (0.5)	1 (0.5)	3 (0.5)
Pruritus	3 (0.8)		3 (0.5)
Psoriasis	2 (0.5)	1 (0.5)	3 (0.5)
Urticaria	2 (0.5)	1 (0.5)	3 (0.5)
Vitiligo	3 (0.8)		3 (0.5)
Lipohypertrophy	1 (0.3)	1 (0.5)	2 (0.4)
Rash	1 (0.3)	1 (0.5)	2 (0.4)
Rosacea	1 (0.3)	1 (0.5)	2 (0.4)
Angioedema	1 (0.3)		1 (0.2)
Dermatitis	1 (0.3)		1 (0.2)
Dermatitis allergic	1 (0.3)		1 (0.2)
Dermatitis contact	1 (0.3)		1 (0.2)
Heat rash	1 (0.3)		1 (0.2)
Hyperhidrosis	1 (0.3)		1 (0.2)
Necrobiosis lipoidica diabetorum		1 (0.5)	1 (0.2)
Photodermatosis		1 (0.5)	1 (0.2)
Scar	1 (0.3)		1 (0.2)
Seborrhoeic dermatitis	1 (0.3)		1 (0.2)
Skin ulcer		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Infections and infestations	30 (8.2)	15 (8.2)	45 (8.2)
Pyelonephritis chronic	9 (2.5)	4 (2.2)	13 (2.4)
Sinusitis	3 (0.8)	2 (1.1)	5 (0.9)
Chronic tonsillitis	1 (0.3)	1 (0.5)	2 (0.4)
Folliculitis	2 (0.5)		2 (0.4)
Onychomycosis	1 (0.3)	1 (0.5)	2 (0.4)
Rhinitis		2 (1.1)	2 (0.4)
Bronchitis		1 (0.5)	1 (0.2)
Candidiasis	1 (0.3)		1 (0.2)
Cystitis		1 (0.5)	1 (0.2)
Cystitis bacterial		1 (0.5)	1 (0.2)
Fungal infection		1 (0.5)	1 (0.2)
Gastroenteritis		1 (0.5)	1 (0.2)
Genital candidiasis	1 (0.3)		1 (0.2)
Genital herpes		1 (0.5)	1 (0.2)
Helicobacter infection		1 (0.5)	1 (0.2)
Herpes simplex	1 (0.3)		1 (0.2)
Herpes virus infection		1 (0.5)	1 (0.2)
Infection		1 (0.5)	1 (0.2)
Kidney infection	1 (0.3)		1 (0.2)
Nasopharyngitis	1 (0.3)		1 (0.2)
Oral herpes	1 (0.3)		1 (0.2)
Otitis media	1 (0.3)		1 (0.2)
Pilonidal cyst	1 (0.3)		1 (0.2)
Pyelonephritis	1 (0.3)		1 (0.2)
Tinea pedis	1 (0.3)		1 (0.2)
Tuberculosis	1 (0.3)		1 (0.2)
Upper respiratory tract infection	1 (0.3)		1 (0.2)
Vaginal infection	1 (0.3)		1 (0.2)
Viral upper respiratory tract infection	1 (0.3)		1 (0.2)
Reproductive system and breast disorders	24 (6.6)	17 (9.3)	41 (7.5)
Erectile dysfunction	10 (2.7)	8 (4.4)	18 (3.3)
Dysmenorrhoea	4 (1.1)	4 (2.2)	8 (1.5)
Polycystic ovaries	3 (0.8)		3 (0.5)
Amenorrhoea	2 (0.5)		2 (0.4)
Benign prostatic hyperplasia	2 (0.5)		2 (0.4)
Fibrocystic breast disease	1 (0.3)	1 (0.5)	2 (0.4)
Ovarian cyst	1 (0.3)	1 (0.5)	2 (0.4)
Uterine polyp	1 (0.3)	1 (0.5)	2 (0.4)
Adenomyosis	1 (0.3)		1 (0.2)
Balanoposthitis		1 (0.5)	1 (0.2)
Menorrhagia	1 (0.3)		1 (0.2)
Peyronie's disease		1 (0.5)	1 (0.2)
Varicose veins pelvic		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Respiratory, thoracic and mediastinal disorders	27 (7.4)	12 (6.6)	39 (7.1)
Asthma	12 (3.3)	10 (5.5)	22 (4.0)
Sleep apnoea syndrome	7 (1.9)	1 (0.5)	8 (1.5)
Rhinitis allergic	3 (0.8)	2 (1.1)	5 (0.9)
Cough	2 (0.5)		2 (0.4)
Bronchitis chronic	1 (0.3)		1 (0.2)
Chronic obstructive pulmonary disease		1 (0.5)	1 (0.2)
Pulmonary granuloma	1 (0.3)		1 (0.2)
Sinus congestion	1 (0.3)		1 (0.2)
Upper-airway cough syndrome	1 (0.3)		1 (0.2)
Immune system disorders	29 (7.9)	8 (4.4)	37 (6.8)
Seasonal allergy	17 (4.6)	7 (3.8)	24 (4.4)
Drug hypersensitivity	8 (2.2)	2 (1.1)	10 (1.8)
Anaphylactic reaction	1 (0.3)		1 (0.2)
Atopy	1 (0.3)		1 (0.2)
Food allergy	1 (0.3)		1 (0.2)
Hypersensitivity	1 (0.3)		1 (0.2)
Multiple allergies	1 (0.3)		1 (0.2)
Cardiac disorders	24 (6.6)	11 (6.0)	35 (6.4)
Coronary artery disease	6 (1.6)	2 (1.1)	8 (1.5)
Myocardial ischaemia	6 (1.6)	2 (1.1)	8 (1.5)
Arteriosclerosis coronary artery	2 (0.5)	1 (0.5)	3 (0.5)
Atrial fibrillation	2 (0.5)	1 (0.5)	3 (0.5)
Angina pectoris	2 (0.5)		2 (0.4)
Bundle branch block left	2 (0.5)		2 (0.4)
Cardiomyopathy	1 (0.3)	1 (0.5)	2 (0.4)
Mitral valve prolapse	1 (0.3)	1 (0.5)	2 (0.4)
Sinus bradycardia	1 (0.3)	1 (0.5)	2 (0.4)
Sinus tachycardia	2 (0.5)		2 (0.4)
Tachycardia	2 (0.5)		2 (0.4)
Aortic valve incompetence		1 (0.5)	1 (0.2)
Bundle branch block right	1 (0.3)		1 (0.2)
Cardiac disorder		1 (0.5)	1 (0.2)
Diastolic dysfunction		1 (0.5)	1 (0.2)
Myocardial fibrosis	1 (0.3)		1 (0.2)
Postinfarction angina	1 (0.3)		1 (0.2)
Hepatobiliary disorders	18 (4.9)	8 (4.4)	26 (4.7)
Hepatic steatosis	12 (3.3)	2 (1.1)	14 (2.6)
Cholecystitis chronic	7 (1.9)	3 (1.6)	10 (1.8)
Liver disorder	2 (0.5)	1 (0.5)	3 (0.5)
Biliary dyskinesia	1 (0.3)		1 (0.2)
Gallbladder polyp		1 (0.5)	1 (0.2)
Hepatic cyst		1 (0.5)	1 (0.2)
Hyperbilirubinaemia neonatal		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
General disorders and administration site conditions	12 (3.3)	9 (4.9)	21 (3.8)
Fatigue	7 (1.9)	5 (2.7)	12 (2.2)
Application site nodule	1 (0.3)	1 (0.5)	2 (0.4)
Asthenia	2 (0.5)		2 (0.4)
Oedema peripheral		2 (1.1)	2 (0.4)
Nodule	1 (0.3)		1 (0.2)
Pain	1 (0.3)		1 (0.2)
Sensation of foreign body		1 (0.5)	1 (0.2)
Temperature intolerance	1 (0.3)		1 (0.2)
Investigations	11 (3.0)	6 (3.3)	17 (3.1)
Cardiac murmur	3 (0.8)	1 (0.5)	4 (0.7)
Vitamin D decreased	1 (0.3)	1 (0.5)	2 (0.4)
Arthroscopy		1 (0.5)	1 (0.2)
Blood alkaline phosphatase increased	1 (0.3)		1 (0.2)
Blood cholesterol increased		1 (0.5)	1 (0.2)
Blood pressure increased	1 (0.3)		1 (0.2)
Electrocardiogram T wave inversion	1 (0.3)		1 (0.2)
Heart rate irregular	1 (0.3)		1 (0.2)
Hepatic enzyme increased		1 (0.5)	1 (0.2)
QRS axis abnormal		1 (0.5)	1 (0.2)
Vibration test abnormal	1 (0.3)		1 (0.2)
Weight decreased	1 (0.3)		1 (0.2)
White blood cells urine	1 (0.3)		1 (0.2)
Social circumstances	12 (3.3)	5 (2.7)	17 (3.1)
Menopause	7 (1.9)	4 (2.2)	11 (2.0)
Postmenopause	4 (1.1)	1 (0.5)	5 (0.9)
Edentulous	1 (0.3)		1 (0.2)
Congenital, familial and genetic disorders	10 (2.7)	5 (2.7)	15 (2.7)
Albinism	2 (0.5)		2 (0.4)
Cataract congenital	1 (0.3)	1 (0.5)	2 (0.4)
Mixed hyperlipidaemia	2 (0.5)		2 (0.4)
Atrial septal defect	1 (0.3)		1 (0.2)
Benign familial haematuria	1 (0.3)		1 (0.2)
Congenital jaw malformation	1 (0.3)		1 (0.2)
Double ureter	1 (0.3)		1 (0.2)
Osteogenesis imperfecta		1 (0.5)	1 (0.2)
Phimosis		1 (0.5)	1 (0.2)
Strabismus congenital		1 (0.5)	1 (0.2)
Turner's syndrome	1 (0.3)		1 (0.2)
Ventricular septal defect		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp N (%)	OD (%)	IDet N (%)	Total N (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (2.2)		6 (3.3)	14 (2.6)
Thyroid neoplasm	3 (0.8)		1 (0.5)	4 (0.7)
Uterine leiomyoma	2 (0.5)		1 (0.5)	3 (0.5)
Eye naevus	1 (0.3)		1 (0.5)	2 (0.4)
Benign breast neoplasm			1 (0.5)	1 (0.2)
Benign neoplasm of thyroid gland	1 (0.3)			1 (0.2)
Breast adenoma			1 (0.5)	1 (0.2)
Breast fibroma	1 (0.3)			1 (0.2)
Morton's neuroma			1 (0.5)	1 (0.2)
Skin papilloma	1 (0.3)			1 (0.2)
Blood and lymphatic system disorders	7 (1.9)		6 (3.3)	13 (2.4)
Anaemia	1 (0.3)		6 (3.3)	7 (1.3)
Iron deficiency anaemia	3 (0.8)			3 (0.5)
Eosinophilia	1 (0.3)			1 (0.2)
Leukocytosis	1 (0.3)			1 (0.2)
Pernicious anaemia	1 (0.3)			1 (0.2)
Surgical and medical procedures	4 (1.1)		3 (1.6)	7 (1.3)
Female sterilisation	1 (0.3)		1 (0.5)	2 (0.4)
Appendicectomy			1 (0.5)	1 (0.2)
Finger amputation	1 (0.3)			1 (0.2)
Implantable defibrillator insertion	1 (0.3)			1 (0.2)
Nephrectomy			1 (0.5)	1 (0.2)
Thyroidectomy			1 (0.5)	1 (0.2)
Toe amputation	1 (0.3)			1 (0.2)
Injury, poisoning and procedural complications	5 (1.4)		1 (0.5)	6 (1.1)
Back injury	1 (0.3)			1 (0.2)
Foot fracture	1 (0.3)			1 (0.2)
Joint dislocation	1 (0.3)			1 (0.2)
Joint injury	1 (0.3)			1 (0.2)
Ligament rupture	1 (0.3)			1 (0.2)
Lumbar vertebral fracture	1 (0.3)			1 (0.2)
Post procedural hypothyroidism			1 (0.5)	1 (0.2)
Skeletal injury	1 (0.3)			1 (0.2)
Soft tissue injury	1 (0.3)			1 (0.2)
Ear and labyrinth disorders	4 (1.1)		1 (0.5)	5 (0.9)
Deafness bilateral	1 (0.3)			1 (0.2)
Deafness unilateral			1 (0.5)	1 (0.2)
Hypoacusis	1 (0.3)			1 (0.2)
Meniere's disease	1 (0.3)			1 (0.2)
Vertigo	1 (0.3)			1 (0.2)

N= Number of subjects

%= Percentage of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:50 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

14.1.12: Concomitant Medication at Screening – Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
INSULIN GLARGINE	237 (64.8)	125 (68.7)	362 (66.1)
INSULIN ASPART	182 (49.7)	95 (52.2)	277 (50.5)
INSULIN LISPRO	110 (30.1)	51 (28.0)	161 (29.4)
SIMVASTATIN	49 (13.4)	36 (19.8)	85 (15.5)
INSULIN DETEMIR	57 (15.6)	24 (13.2)	81 (14.8)
ACETYLSALICYLIC ACID	49 (13.4)	26 (14.3)	75 (13.7)
INSULIN HUMAN	44 (12.0)	23 (12.6)	67 (12.2)
LEVOTHYROXINE SODIUM	39 (10.7)	15 (8.2)	54 (9.9)
LISINOPRIL	26 (7.1)	16 (8.8)	42 (7.7)
RAMIPRIL	21 (5.7)	15 (8.2)	36 (6.6)
INSULIN GLULISINE	22 (6.0)	13 (7.1)	35 (6.4)
ATORVASTATIN CALCIUM	17 (4.6)	9 (4.9)	26 (4.7)
PARACETAMOL	12 (3.3)	8 (4.4)	20 (3.6)
INDAPAMIDE	11 (3.0)	6 (3.3)	17 (3.1)
ENALAPRIL	11 (3.0)	5 (2.7)	16 (2.9)
IBUPROFEN	9 (2.5)	7 (3.8)	16 (2.9)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
INSULIN HUMAN INJECTION, ISOPHANE	12 (3.3)	4 (2.2)	16 (2.9)
MULTIVITAMIN /	8 (2.2)	8 (4.4)	16 (2.9)
ROSUVASTATIN CALCIUM	8 (2.2)	8 (4.4)	16 (2.9)
AMLODIPINE BESILATE	9 (2.5)	6 (3.3)	15 (2.7)
ISOPHANE INSULIN	11 (3.0)	4 (2.2)	15 (2.7)
LEVOTHYROXINE	5 (1.4)	8 (4.4)	13 (2.4)
NOVOMIX /	8 (2.2)	5 (2.7)	13 (2.4)
HUMAN MIXTARD /	8 (2.2)	4 (2.2)	12 (2.2)
HYDROCHLOROTHIAZIDE	7 (1.9)	5 (2.7)	12 (2.2)
TELMISARTAN	9 (2.5)	3 (1.6)	12 (2.2)
ATORVASTATIN	6 (1.6)	4 (2.2)	10 (1.8)
CLOPIDOGREL	5 (1.4)	4 (2.2)	9 (1.6)
LOSARTAN POTASSIUM	7 (1.9)	2 (1.1)	9 (1.6)
SALBUTAMOL	5 (1.4)	4 (2.2)	9 (1.6)
AMLODIPINE	6 (1.6)	2 (1.1)	8 (1.5)
EUGYNON /	5 (1.4)	3 (1.6)	8 (1.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
FISH OIL	5 (1.4)	3 (1.6)	8 (1.5)
VITAMEDIN / [REDACTED]	4 (1.1)	4 (2.2)	8 (1.5)
VITAMIN D NOS	4 (1.1)	4 (2.2)	8 (1.5)
CALCIUM	3 (0.8)	4 (2.2)	7 (1.3)
DULOXETINE HYDROCHLORIDE	3 (0.8)	4 (2.2)	7 (1.3)
EZETIMIBE	6 (1.6)	1 (0.5)	7 (1.3)
METOPROLOL	6 (1.6)	1 (0.5)	7 (1.3)
OMEPRAZOLE	4 (1.1)	3 (1.6)	7 (1.3)
PERINDOPRIL ERBUMINE	2 (0.5)	5 (2.7)	7 (1.3)
PRAVASTATIN	6 (1.6)	1 (0.5)	7 (1.3)
ALBYL-ENTEROSOLUBILE	2 (0.5)	4 (2.2)	6 (1.1)
ASCORBIC ACID	4 (1.1)	2 (1.1)	6 (1.1)
BISOPROLOL	3 (0.8)	3 (1.6)	6 (1.1)
CARVEDILOL	5 (1.4)	1 (0.5)	6 (1.1)
CITALOPRAM	3 (0.8)	3 (1.6)	6 (1.1)
COLECALCIFEROL	3 (0.8)	3 (1.6)	6 (1.1)
ENALAPRIL MALEATE	1 (0.3)	5 (2.7)	6 (1.1)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
FENOFIBRATE	3 (0.8)	3 (1.6)	6 (1.1)
FUROSEMIDE	2 (0.5)	4 (2.2)	6 (1.1)
GABAPENTIN	4 (1.1)	2 (1.1)	6 (1.1)
LORATADINE	5 (1.4)	1 (0.5)	6 (1.1)
VALSARTAN	4 (1.1)	2 (1.1)	6 (1.1)
ESCITALOPRAM OXALATE	4 (1.1)	1 (0.5)	5 (0.9)
FEXOFENADINE HYDROCHLORIDE	2 (0.5)	3 (1.6)	5 (0.9)
INSULIN PORCINE	4 (1.1)	1 (0.5)	5 (0.9)
IRBESARTAN	1 (0.3)	4 (2.2)	5 (0.9)
METOPROLOL SUCCINATE	4 (1.1)	1 (0.5)	5 (0.9)
OBETROL [REDACTED]	/	2 (1.1)	5 (0.9)
PERINDOPRIL	2 (0.5)	3 (1.6)	5 (0.9)
THIOCTIC ACID	4 (1.1)	1 (0.5)	5 (0.9)
ALENDRONATE SODIUM	1 (0.3)	3 (1.6)	4 (0.7)
ATENOLOL	3 (0.8)	1 (0.5)	4 (0.7)
BUDESONIDE	3 (0.8)	1 (0.5)	4 (0.7)
CANDESARTAN CILEXETIL	2 (0.5)	2 (1.1)	4 (0.7)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CLONAZEPAM	2 (0.5)	2 (1.1)	4 (0.7)
ESOMEPRAZOLE MAGNESIUM	2 (0.5)	2 (1.1)	4 (0.7)
FERROUS SULFATE	1 (0.3)	3 (1.6)	4 (0.7)
HUMALOG MIX	3 (0.8)	1 (0.5)	4 (0.7)
INEGY	4 (1.1)		4 (0.7)
LOSARTAN	3 (0.8)	1 (0.5)	4 (0.7)
LOVASTATIN	2 (0.5)	2 (1.1)	4 (0.7)
MOXONIDINE	2 (0.5)	2 (1.1)	4 (0.7)
MULTIVITAMINS, COMBINATIONS	2 (0.5)	2 (1.1)	4 (0.7)
NIFEDIPINE	3 (0.8)	1 (0.5)	4 (0.7)
PANTOPRAZOLE SODIUM	2 (0.5)	2 (1.1)	4 (0.7)
SERTRALINE HYDROCHLORIDE	2 (0.5)	2 (1.1)	4 (0.7)
TADALAFIL	3 (0.8)	1 (0.5)	4 (0.7)
VITAMIN B12 NOS	2 (0.5)	2 (1.1)	4 (0.7)
ANOVLAR	3 (0.8)		3 (0.5)
BUPROPION	3 (0.8)		3 (0.5)
CALCIUM DOBESILATE	3 (0.8)		3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CANDESARTAN	1 (0.3)	2 (1.1)	3 (0.5)
CAPTOPRIL	1 (0.3)	2 (1.1)	3 (0.5)
CETIRIZINE HYDROCHLORIDE	1 (0.3)	2 (1.1)	3 (0.5)
CYCLOBENZAPRINE HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
DILTIAZEM	1 (0.3)	2 (1.1)	3 (0.5)
DILTIAZEM HYDROCHLORIDE		3 (1.6)	3 (0.5)
ESTROGENS CONJUGATED	1 (0.3)	2 (1.1)	3 (0.5)
FEMODENE	3 (0.8)		3 (0.5)
FLUOXETINE	2 (0.5)	1 (0.5)	3 (0.5)
FLUOXETINE HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
FOLIC ACID	1 (0.3)	2 (1.1)	3 (0.5)
GLUCOSAMINE	1 (0.3)	2 (1.1)	3 (0.5)
GLYCERYL TRINITRATE	3 (0.8)		3 (0.5)
INSULIN	2 (0.5)	1 (0.5)	3 (0.5)
LANSOPRAZOLE	3 (0.8)		3 (0.5)
LERCANIDIPINE HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
MONTELUKAST SODIUM	2 (0.5)	1 (0.5)	3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
NEBIVOLOL HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
OLMESARTAN MEDOXOMIL	2 (0.5)	1 (0.5)	3 (0.5)
PANTOPRAZOLE	1 (0.3)	2 (1.1)	3 (0.5)
POTASSIUM CHLORIDE		3 (1.6)	3 (0.5)
PREGABALIN	1 (0.3)	2 (1.1)	3 (0.5)
ROSUVASTATIN	2 (0.5)	1 (0.5)	3 (0.5)
SERETIDE	2 (0.5)	1 (0.5)	3 (0.5)
SERTRALINE	2 (0.5)	1 (0.5)	3 (0.5)
VALACICLOVIR HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
VARDENAFIL HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
VENLAFAXINE HYDROCHLORIDE	1 (0.3)	2 (1.1)	3 (0.5)
ACETYLSALICYLATE LYSINE		2 (1.1)	2 (0.4)
ALPRAZOLAM	1 (0.3)	1 (0.5)	2 (0.4)
AMOXICILLIN	2 (0.5)		2 (0.4)
ARIPIRAZOLE	2 (0.5)		2 (0.4)
BENDROFLUMETHIAZIDE		2 (1.1)	2 (0.4)
BI PREDONIUM	2 (0.5)		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
BISOPROLOL FUMARATE	2 (0.5)		2 (0.4)
BLOPRESS PLUS	2 (0.5)		2 (0.4)
BRIMONIDINE TARTRATE	1 (0.3)	1 (0.5)	2 (0.4)
BUDESONIDE W/FORMOTEROL FUMARATE		2 (1.1)	2 (0.4)
CALCIUM CARBONATE	1 (0.3)	1 (0.5)	2 (0.4)
CETIRIZINE	1 (0.3)	1 (0.5)	2 (0.4)
CILOSTAZOL	1 (0.3)	1 (0.5)	2 (0.4)
CITALOPRAM HYDROBROMIDE	1 (0.3)	1 (0.5)	2 (0.4)
CYANOCOBALAMIN	1 (0.3)	1 (0.5)	2 (0.4)
DIANE	2 (0.5)		2 (0.4)
DICLOFENAC	2 (0.5)		2 (0.4)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
DIPYRIDAMOLE	1 (0.3)	1 (0.5)	2 (0.4)
DOCUSATE SODIUM	1 (0.3)	1 (0.5)	2 (0.4)
ENALAPRILAT	1 (0.3)	1 (0.5)	2 (0.4)
ERGOCALCIFEROL	1 (0.3)	1 (0.5)	2 (0.4)
ESTRADIOL	2 (0.5)		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
FAMOTIDINE	1 (0.3)	1 (0.5)	2 (0.4)
FLUCONAZOLE	2 (0.5)		2 (0.4)
GENERAL NUTRIENTS	2 (0.5)		2 (0.4)
GINKGO BILOBA	1 (0.3)	1 (0.5)	2 (0.4)
HYDROCORTISONE	2 (0.5)		2 (0.4)
HYDROXYCHLOROQUINE	2 (0.5)		2 (0.4)
HYDROXYZINE	2 (0.5)		2 (0.4)
LACTOBACILLUS ACIDOPHILUS	1 (0.3)	1 (0.5)	2 (0.4)
LATANOPROST		2 (1.1)	2 (0.4)
MARVELON	1 (0.3)	1 (0.5)	2 (0.4)
MELOXICAM	2 (0.5)		2 (0.4)
METOCLOPRAMIDE	2 (0.5)		2 (0.4)
METRONIDAZOLE		2 (1.1)	2 (0.4)
MILGAMMA NA	2 (0.5)		2 (0.4)
MOMETASONE FUROATE	2 (0.5)		2 (0.4)
MULTIVITAMINS		2 (1.1)	2 (0.4)
MULTIVITAMINS, OTHER COMBINATIONS	2 (0.5)		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
NAPROXEN	2 (0.5)		2 (0.4)
NICOTINIC ACID	2 (0.5)		2 (0.4)
NORETHISTERONE	1 (0.3)	1 (0.5)	2 (0.4)
POTASSIUM	2 (0.5)		2 (0.4)
PRAVASTATIN SODIUM	2 (0.5)		2 (0.4)
PROVELLA-14	2 (0.5)		2 (0.4)
PSEUDOEPHEDRINE	1 (0.3)	1 (0.5)	2 (0.4)
RABEPRAZOLE SODIUM	1 (0.3)	1 (0.5)	2 (0.4)
SALBUTAMOL SULFATE	1 (0.3)	1 (0.5)	2 (0.4)
SALURES-K		2 (1.1)	2 (0.4)
SPIRONOLACTONE	1 (0.3)	1 (0.5)	2 (0.4)
SULFONAMIDES, PLAIN		2 (1.1)	2 (0.4)
TETRAZEPAM	2 (0.5)		2 (0.4)
TIMOLOL	1 (0.3)	1 (0.5)	2 (0.4)
TOCOPHEROL	1 (0.3)	1 (0.5)	2 (0.4)
TRAMADOL	1 (0.3)	1 (0.5)	2 (0.4)
TRAMADOL HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
TRIAMCINOLONE ACETONIDE	1 (0.3)	1 (0.5)	2 (0.4)
TRIMETAZIDINE	1 (0.3)	1 (0.5)	2 (0.4)
UBIDECARENONE	2 (0.5)		2 (0.4)
VALPROATE SODIUM	1 (0.3)	1 (0.5)	2 (0.4)
VENLAFAXINE	2 (0.5)		2 (0.4)
VITAMIN B-COMPLEX, PLAIN	1 (0.3)	1 (0.5)	2 (0.4)
ZOLPIDEM TARTRATE	1 (0.3)	1 (0.5)	2 (0.4)
ALANERV	1 (0.3)		1 (0.2)
ALEPSAL		1 (0.5)	1 (0.2)
ALFACALCIDOL	1 (0.3)		1 (0.2)
ALLIUM SATIVUM	1 (0.3)		1 (0.2)
ALLOPURINOL	1 (0.3)		1 (0.2)
ALPROSTADIL	1 (0.3)		1 (0.2)
AMILORIDE W/HYDROCHLOROTHIAZIDE	1 (0.3)		1 (0.2)
AMITRIPTYLINE		1 (0.5)	1 (0.2)
AMITRIPTYLINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
ASCRIPTIN	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ATOMOXETINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
BENAZEPRIL		1 (0.5)	1 (0.2)
BENAZEPRIL HYDROCHLORIDE	1 (0.3)		1 (0.2)
BENICAR HCT	1 (0.3)		1 (0.2)
BENZALKONIUM CHLORIDE	1 (0.3)		1 (0.2)
BETAHISTINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
BETAXOLOL	1 (0.3)		1 (0.2)
BETAXOLOL HYDROCHLORIDE	1 (0.3)		1 (0.2)
BIMATOPROST	1 (0.3)		1 (0.2)
BISELECT [REDACTED]	/	1 (0.3)	1 (0.2)
BRINZOLAMIDE	1 (0.3)		1 (0.2)
BROMAZEPAM	1 (0.3)		1 (0.2)
BUPROPION HYDROCHLORIDE	1 (0.3)		1 (0.2)
BUTALBITAL W/ASPIRIN/CAFFEINE	1 (0.3)		1 (0.2)
CADUET		1 (0.5)	1 (0.2)
CALCIUM W/MAGNESIUM	1 (0.3)		1 (0.2)
CALCIUM W/VITAMIN D NOS		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CAMELLIA SINENSIS	1 (0.3)		1 (0.2)
CARBAMAZEPINE	1 (0.3)		1 (0.2)
CARBIMAZOLE		1 (0.5)	1 (0.2)
CELECOXIB		1 (0.5)	1 (0.2)
CENTRUM SILVER [REDACTED]	/	1 (0.3)	1 (0.2)
CHLORHEXIDINE GLUCONATE	1 (0.3)		1 (0.2)
CHLORPHENAMINE MALEATE		1 (0.5)	1 (0.2)
CHONDROITIN		1 (0.5)	1 (0.2)
CICLOPIROX	1 (0.3)		1 (0.2)
CILAZAPRIL	1 (0.3)		1 (0.2)
CILEST	1 (0.3)		1 (0.2)
CIPROFLOXACIN	1 (0.3)		1 (0.2)
CITRACAL + D [REDACTED]	/	1 (0.3)	1 (0.2)
CLOMIPRAMINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
CLONIDINE	1 (0.3)		1 (0.2)
CLORAZEPATE DIPOTASSIUM	1 (0.3)		1 (0.2)
CO-DIOVAN	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
COD-LIVER OIL	1 (0.3)		1 (0.2)
COLESTYRAMINE		1 (0.5)	1 (0.2)
CREAM E45	1 (0.3)		1 (0.2)
DAILY MULTIVITAMIN		1 (0.5)	1 (0.2)
DECONAMINE	1 (0.3)		1 (0.2)
DESLORATADINE	1 (0.3)		1 (0.2)
DESOGESTREL		1 (0.5)	1 (0.2)
DESVENLAFAXINE	1 (0.3)		1 (0.2)
DIAZEPAM	1 (0.3)		1 (0.2)
DIFLORASONE DIACETATE	1 (0.3)		1 (0.2)
DIGOXIN	1 (0.3)		1 (0.2)
DIOVAN AMLO	1 (0.3)		1 (0.2)
DOMPERIDONE	1 (0.3)		1 (0.2)
DOSULEPIN HYDROCHLORIDE	1 (0.3)		1 (0.2)
DOZOL [REDACTED]	/		1 (0.2)
DROSPIRENONE W/ETHINYLESTRADIOL		1 (0.5)	1 (0.2)
DRUGS FOR PEPTIC ULCER AND GORD	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DUOTRAV		1 (0.5)	1 (0.2)
ELIDIUR	1 (0.3)		1 (0.2)
EPINEPHRINE	1 (0.3)		1 (0.2)
ERYTHROMYCIN		1 (0.5)	1 (0.2)
ESTRADIOL VALERATE	1 (0.3)		1 (0.2)
FEFOL /	1 (0.3)		1 (0.2)
FELODIPINE	1 (0.3)		1 (0.2)
FLUDROCORTISONE ACETATE	1 (0.3)		1 (0.2)
FLUTICASONE	1 (0.3)		1 (0.2)
FLUTICASONE FUROATE		1 (0.5)	1 (0.2)
FLUTICASONE PROPIONATE		1 (0.5)	1 (0.2)
FLUVASTATIN SODIUM		1 (0.5)	1 (0.2)
FOSAVANCE		1 (0.5)	1 (0.2)
FOSINOPRIL	1 (0.3)		1 (0.2)
GALENIC /FLUTICASONE/SALMETEROL/	1 (0.3)		1 (0.2)
GEMFIBROZIL	1 (0.3)		1 (0.2)
GERITOL /		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
GLUCOSAMINE W/CHONDROITIN SULFATE		1 (0.5)	1 (0.2)
GUAIFENESIN		1 (0.5)	1 (0.2)
HEDERA HELIX	1 (0.3)		1 (0.2)
HEXAQUINE	1 (0.3)		1 (0.2)
HYDROCODONE BITARTRATE		1 (0.5)	1 (0.2)
HYDROCORTISONE ACETATE	1 (0.3)		1 (0.2)
HYDROXOCOBALAMIN	1 (0.3)		1 (0.2)
HYDROXYZINE EMBONATE		1 (0.5)	1 (0.2)
IBANDRONATE SODIUM		1 (0.5)	1 (0.2)
ICAPS		1 (0.5)	1 (0.2)
INDOMETACIN	1 (0.3)		1 (0.2)
INFLUENZA VACCINE	1 (0.3)		1 (0.2)
INSULIN ISOPHANE BOVINE		1 (0.5)	1 (0.2)
INSULIN W/ISOPHANE INSULIN		1 (0.5)	1 (0.2)
INTRAUTERINE CONTRACEPTIVE DEVICE	1 (0.3)		1 (0.2)
IRON	1 (0.3)		1 (0.2)
ISOSORBIDE DINITRATE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
KARVEA HCT		1 (0.5)	1 (0.2)
KLIOGEST	1 (0.3)		1 (0.2)
LAMOTRIGINE	1 (0.3)		1 (0.2)
LERCANIDIPINE	1 (0.3)		1 (0.2)
LEVOCETIRIZINE DIHYDROCHLORIDE	1 (0.3)		1 (0.2)
LIOTHYRONINE SODIUM	1 (0.3)		1 (0.2)
LIPITAC		1 (0.5)	1 (0.2)
LISINOPRIL DIHYDRATE	1 (0.3)		1 (0.2)
LOMOTIL		1 (0.5)	1 (0.2)
LOPERAMIDE HYDROCHLORIDE		1 (0.5)	1 (0.2)
LYMECYCLINE	1 (0.3)		1 (0.2)
MAGNESIUM CHLORIDE ANHYDROUS	1 (0.3)		1 (0.2)
MEDROXYPROGESTERONE	1 (0.3)		1 (0.2)
MEDROXYPROGESTERONE ACETATE		1 (0.5)	1 (0.2)
MERSYNDOL [REDACTED]	/	1 (0.3)	1 (0.2)
METAXALONE		1 (0.5)	1 (0.2)
METFORMIN HYDROCHLORIDE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
METHADONE	1 (0.3)		1 (0.2)
METHYLDOPA	1 (0.3)		1 (0.2)
MIRTAZAPINE	1 (0.3)		1 (0.2)
MODURETIC	1 (0.3)		1 (0.2)
MORPHINE SULFATE		1 (0.5)	1 (0.2)
MOXIFLOXACIN HYDROCHLORIDE	1 (0.3)		1 (0.2)
MULTIVITAMINS W/MINERALS		1 (0.5)	1 (0.2)
NADOLOL		1 (0.5)	1 (0.2)
NARINE /	1 (0.3)		1 (0.2)
NEBIVOLOL	1 (0.3)		1 (0.2)
NICORANDIL	1 (0.3)		1 (0.2)
NITROFURANTOIN	1 (0.3)		1 (0.2)
NORLESTRIN FE	1 (0.3)		1 (0.2)
NORTRIPTYLINE		1 (0.5)	1 (0.2)
NORTRIPTYLINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
OMEGA-3 FATTY ACIDS	1 (0.3)		1 (0.2)
ONDANSETRON	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ONE-A-DAY MEN'S	1 (0.3)		1 (0.2)
OS-CAL /		1 (0.5)	1 (0.2)
OSCAL D /		1 (0.5)	1 (0.2)
OTHER COLD COMBINATION PREPARATIONS	1 (0.3)		1 (0.2)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.3)		1 (0.2)
OTHER RESPIRATORY SYSTEM PRODUCTS	1 (0.3)		1 (0.2)
OXCARBAZEPINE		1 (0.5)	1 (0.2)
OXYCODONE/APAP	1 (0.3)		1 (0.2)
PALIPERIDONE	1 (0.3)		1 (0.2)
PANCREATIN	1 (0.3)		1 (0.2)
PARA-SELTZER	1 (0.3)		1 (0.2)
PAROXETINE	1 (0.3)		1 (0.2)
PENICILLIN NOS	1 (0.3)		1 (0.2)
PHENOBARBITAL		1 (0.5)	1 (0.2)
PHENYLEPHRINE		1 (0.5)	1 (0.2)
POLYCARBOPHIL CALCIUM	1 (0.3)		1 (0.2)
PRAMIPEXOLE DIHYDROCHLORIDE		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
PRAZOSIN HYDROCHLORIDE		1 (0.5)	1 (0.2)
PREDNISONE	1 (0.3)		1 (0.2)
PRITORPLUS	1 (0.3)		1 (0.2)
PROCHLORPERAZINE	1 (0.3)		1 (0.2)
PROCTOFOAM /	1 (0.3)		1 (0.2)
PROGESTERONE	1 (0.3)		1 (0.2)
QUINAPRIL	1 (0.3)		1 (0.2)
QUINAPRIL HYDROCHLORIDE		1 (0.5)	1 (0.2)
RANITIDINE	1 (0.3)		1 (0.2)
RANITIDINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
RISEDRONATE SODIUM	1 (0.3)		1 (0.2)
RISPERIDONE	1 (0.3)		1 (0.2)
RONDEC TR	1 (0.3)		1 (0.2)
ROSIGLITAZONE	1 (0.3)		1 (0.2)
SALMETEROL XINAFOATE	1 (0.3)		1 (0.2)
SENNA ALEXANDRINA	1 (0.3)		1 (0.2)
SERENOA REPENS	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SILDENAFIL	1 (0.3)		1 (0.2)
SILDENAFIL CITRATE	1 (0.3)		1 (0.2)
SODIUM CHLORIDE	1 (0.3)		1 (0.2)
SORBITOL	1 (0.3)		1 (0.2)
SULFAMETHIZOLE		1 (0.5)	1 (0.2)
SULFASALAZINE		1 (0.5)	1 (0.2)
SULODEXIDE	1 (0.3)		1 (0.2)
TERBINAFINE		1 (0.5)	1 (0.2)
TESTOSTERONE	1 (0.3)		1 (0.2)
THOMAPYRIN N	1 (0.3)		1 (0.2)
THYROID	1 (0.3)		1 (0.2)
TIMOLOL MALEATE	1 (0.3)		1 (0.2)
TIOTROPIUM BROMIDE		1 (0.5)	1 (0.2)
TOBRADEX	1 (0.3)		1 (0.2)
TRANDOLAPRIL	1 (0.3)		1 (0.2)
TRAVOPROST		1 (0.5)	1 (0.2)
TRAZODONE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
TRIAMTERENE		1 (0.5)	1 (0.2)
TRIMETAZIDINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
TRIMETHOPRIM		1 (0.5)	1 (0.2)
TROPICAMIDE		1 (0.5)	1 (0.2)
UNSPECIFIED HERBAL	1 (0.3)		1 (0.2)
VALPROIC ACID	1 (0.3)		1 (0.2)
VALPROMIDE	1 (0.3)		1 (0.2)
VICODIN		1 (0.5)	1 (0.2)
VICON C	1 (0.3)		1 (0.2)
VINCENTS /	1 (0.3)		1 (0.2)
VITAMIN C WITH ZINC	1 (0.3)		1 (0.2)
VITAMINS /	1 (0.3)		1 (0.2)
WARFARIN SODIUM	1 (0.3)		1 (0.2)
XALACOM	1 (0.3)		1 (0.2)
ZINC SULFATE	1 (0.3)		1 (0.2)
ZOLEDRONIC ACID	1 (0.3)		1 (0.2)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:52 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

14.1.13: Concomitant Medication Started after Screening – Summary - Full Analysis Set

	IDegAsp N	OD (%)	IDet N	(%)	Total N	(%)
Number of Subjects	366		182		548	
PARACETAMOL	50	(13.7)	22	(12.1)	72	(13.1)
IBUPROFEN	33	(9.0)	24	(13.2)	57	(10.4)
INFLUENZA VIRUS VACCINE MONOVALENT	20	(5.5)	14	(7.7)	34	(6.2)
INFLUENZA VACCINE	19	(5.2)	10	(5.5)	29	(5.3)
AMOXICILLIN	20	(5.5)	4	(2.2)	24	(4.4)
ASCORUTIN	11	(3.0)	4	(2.2)	15	(2.7)
AZITHROMYCIN	10	(2.7)	5	(2.7)	15	(2.7)
GLUCOSE	9	(2.5)	5	(2.7)	14	(2.6)
ACETYLSALICYLIC ACID	10	(2.7)	3	(1.6)	13	(2.4)
ASCORBIC ACID	9	(2.5)	3	(1.6)	12	(2.2)
FERVEX	/					
	10	(2.7)	1	(0.5)	11	(2.0)
PANADEINE CO	8	(2.2)	2	(1.1)	10	(1.8)
MEDINITE	6	(1.6)	3	(1.6)	9	(1.6)
SIMVASTATIN	6	(1.6)	3	(1.6)	9	(1.6)
BENADRYL COLD AND FLU	4	(1.1)	3	(1.6)	7	(1.3)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CEFALEXIN	6 (1.6)	1 (0.5)	7 (1.3)
CITALOPRAM	4 (1.1)	3 (1.6)	7 (1.3)
DEXTROMETHORPHAN HYDROBROMIDE	6 (1.6)	1 (0.5)	7 (1.3)
GLUCAGON	4 (1.1)	3 (1.6)	7 (1.3)
LIDOCAINE	3 (0.8)	4 (2.2)	7 (1.3)
LISINOPRIL	5 (1.4)	2 (1.1)	7 (1.3)
TUSSIN DM	4 (1.1)	3 (1.6)	7 (1.3)
BACTRIM	5 (1.4)	1 (0.5)	6 (1.1)
BISMUTH SUBSALICYLATE	3 (0.8)	3 (1.6)	6 (1.1)
INSULIN GLARGINE	4 (1.1)	2 (1.1)	6 (1.1)
LEVOTHYROXINE SODIUM	6 (1.6)		6 (1.1)
OMEPRAZOLE	5 (1.4)	1 (0.5)	6 (1.1)
SODIUM CHLORIDE	4 (1.1)	2 (1.1)	6 (1.1)
VICKS FORMULA 44M	4 (1.1)	2 (1.1)	6 (1.1)
VICODIN	5 (1.4)	1 (0.5)	6 (1.1)
BENZYDAMINE HYDROCHLORIDE	4 (1.1)	1 (0.5)	5 (0.9)
CIPROFLOXACIN	3 (0.8)	2 (1.1)	5 (0.9)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DOXYCYCLINE	4 (1.1)	1 (0.5)	5 (0.9)
FLUCONAZOLE	3 (0.8)	2 (1.1)	5 (0.9)
INSULIN ASPART	3 (0.8)	2 (1.1)	5 (0.9)
INSULIN HUMAN	1 (0.3)	4 (2.2)	5 (0.9)
KETOPROFEN	4 (1.1)	1 (0.5)	5 (0.9)
METRONIDAZOLE	4 (1.1)	1 (0.5)	5 (0.9)
ROXITHROMYCIN	4 (1.1)	1 (0.5)	5 (0.9)
ACETYLCYSTEINE	3 (0.8)	1 (0.5)	4 (0.7)
ALUDROX	/		
		2 (0.5)	4 (0.7)
AMOXICILLIN TRIHYDRATE	2 (0.5)	2 (1.1)	4 (0.7)
ATORVASTATIN CALCIUM	3 (0.8)	1 (0.5)	4 (0.7)
CETIRIZINE HYDROCHLORIDE	4 (1.1)		4 (0.7)
CLARITHROMYCIN	3 (0.8)	1 (0.5)	4 (0.7)
COTYLENOL	3 (0.8)	1 (0.5)	4 (0.7)
DICLOFENAC	4 (1.1)		4 (0.7)
DIPHENHYDRAMINE HYDROCHLORIDE	2 (0.5)	2 (1.1)	4 (0.7)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DOMPERIDONE	4 (1.1)		4 (0.7)
LOPERAMIDE HYDROCHLORIDE	3 (0.8)	1 (0.5)	4 (0.7)
MELOXICAM	4 (1.1)		4 (0.7)
METOCLOPRAMIDE HYDROCHLORIDE	2 (0.5)	2 (1.1)	4 (0.7)
NIFUROXAZIDE	2 (0.5)	2 (1.1)	4 (0.7)
PYRIDOXINE HYDROCHLORIDE	3 (0.8)	1 (0.5)	4 (0.7)
SPEKTRAMOX	2 (0.5)	2 (1.1)	4 (0.7)
TIAPROFENIC ACID	4 (1.1)		4 (0.7)
TRIMETHOPRIM	1 (0.3)	3 (1.6)	4 (0.7)
VITAMIN D NOS	3 (0.8)	1 (0.5)	4 (0.7)
ALPRAZOLAM	2 (0.5)	1 (0.5)	3 (0.5)
AZELASTINE HYDROCHLORIDE		3 (1.6)	3 (0.5)
BUDESONIDE W/FORMOTEROL FUMARATE	1 (0.3)	2 (1.1)	3 (0.5)
CLINDAMYCIN	2 (0.5)	1 (0.5)	3 (0.5)
CLOTRIMAZOLE	3 (0.8)		3 (0.5)
CONJUNCTIN	2 (0.5)	1 (0.5)	3 (0.5)
COUGH AND COLD PREPARATIONS	3 (0.8)		3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DICLOFENAC SODIUM	2 (0.5)	1 (0.5)	3 (0.5)
DIPHENHYDRAMINE	2 (0.5)	1 (0.5)	3 (0.5)
DOLO MOBILAT [REDACTED]	/	3 (0.8)	3 (0.5)
DROSPIRENONE W/ETHINYLESTRADIOL	3 (0.8)		3 (0.5)
DRUGS FOR PEPTIC ULCER AND GORD	2 (0.5)	1 (0.5)	3 (0.5)
ESOMEPRAZOLE MAGNESIUM	2 (0.5)	1 (0.5)	3 (0.5)
FISH OIL	2 (0.5)	1 (0.5)	3 (0.5)
FLUTICASONE PROPIONATE	2 (0.5)	1 (0.5)	3 (0.5)
FUSAFUNGINE	2 (0.5)	1 (0.5)	3 (0.5)
HOT COLDREX	2 (0.5)	1 (0.5)	3 (0.5)
HYDROCODONE	3 (0.8)		3 (0.5)
HYDROCORTISONE	2 (0.5)	1 (0.5)	3 (0.5)
INDAPAMIDE	2 (0.5)	1 (0.5)	3 (0.5)
ISOPHANE INSULIN	3 (0.8)		3 (0.5)
LEVOTHYROXINE	3 (0.8)		3 (0.5)
LORATADINE	2 (0.5)	1 (0.5)	3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
METOCLOPRAMIDE	1 (0.3)	2 (1.1)	3 (0.5)
MOMETASONE FUROATE	3 (0.8)		3 (0.5)
MULTIVITAMIN / [REDACTED]	2 (0.5)	1 (0.5)	3 (0.5)
NAPROXEN SODIUM	2 (0.5)	1 (0.5)	3 (0.5)
NASAL DECONGESTANTS FOR SYSTEMIC USE	3 (0.8)		3 (0.5)
NEO-SYNEPHRINE COMPOUND COLD	3 (0.8)		3 (0.5)
NO-FLU F	1 (0.3)	2 (1.1)	3 (0.5)
OSELTAMIVIR PHOSPHATE	3 (0.8)		3 (0.5)
OXYCOCET	1 (0.3)	2 (1.1)	3 (0.5)
OXYMETAZOLINE HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
PANTOPRAZOLE	3 (0.8)		3 (0.5)
PHENOXYMETHYLPENICILLIN POTASSIUM	1 (0.3)	2 (1.1)	3 (0.5)
PHENYLEPHRINE HYDROCHLORIDE	3 (0.8)		3 (0.5)
PREDNISOLONE	1 (0.3)	2 (1.1)	3 (0.5)
PREDNISON	3 (0.8)		3 (0.5)
PROCET / [REDACTED]	3 (0.8)		3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
THOMAPYRIN N	3 (0.8)		3 (0.5)
TOLPERISONE HYDROCHLORIDE	3 (0.8)		3 (0.5)
TRAMADOL	2 (0.5)	1 (0.5)	3 (0.5)
ZOLPIDEM TARTRATE	2 (0.5)	1 (0.5)	3 (0.5)
A/H1N1 INFLUENZA PANDEMIC VACCINE	1 (0.3)	1 (0.5)	2 (0.4)
ALPHA-AMYLASE SWINE PANCREAS	2 (0.5)		2 (0.4)
AMBROXOL HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
AMPICILLIN SODIUM	1 (0.3)	1 (0.5)	2 (0.4)
ATORVASTATIN	1 (0.3)	1 (0.5)	2 (0.4)
BISACODYL	1 (0.3)	1 (0.5)	2 (0.4)
BUPROPION	2 (0.5)		2 (0.4)
CALCIUM	2 (0.5)		2 (0.4)
CALCIUM CARBONATE	2 (0.5)		2 (0.4)
CEFTRIAXONE	2 (0.5)		2 (0.4)
CEFUROXIME AXETIL	2 (0.5)		2 (0.4)
CELECOXIB	1 (0.3)	1 (0.5)	2 (0.4)
CHLORAMPHENICOL		2 (1.1)	2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CODRAL COLD & FLU	2 (0.5)		2 (0.4)
CORTISONE	2 (0.5)		2 (0.4)
DEXTROMETHORPHAN HBR W/DOXYLAM. SUCC/ PARACET.	1 (0.3)	1 (0.5)	2 (0.4)
DROTAVERINE	2 (0.5)		2 (0.4)
ESTROGENS CONJUGATED	1 (0.3)	1 (0.5)	2 (0.4)
EZETIMIBE	1 (0.3)	1 (0.5)	2 (0.4)
FENTANYL	1 (0.3)	1 (0.5)	2 (0.4)
FERROUS GLUCONATE	1 (0.3)	1 (0.5)	2 (0.4)
FERROUS SULFATE		2 (1.1)	2 (0.4)
FEXOFENADINE	2 (0.5)		2 (0.4)
FRUBIENZYM	2 (0.5)		2 (0.4)
GALENIC /ASCORBIC ACID/CALCIUM/	1 (0.3)	1 (0.5)	2 (0.4)
GALENIC /MAGNESIUM CARB/CALCIUM CARB/	1 (0.3)	1 (0.5)	2 (0.4)
GLUCAGON HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
GLUCOSAMINE	2 (0.5)		2 (0.4)
GUAIFENESIN		2 (1.1)	2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HEPATITIS A VACCINE	1 (0.3)	1 (0.5)	2 (0.4)
HYDROCHLOROTHIAZIDE	2 (0.5)		2 (0.4)
INFLUENZA VACCINE INACTIVATED	1 (0.3)	1 (0.5)	2 (0.4)
KETOROLAC TROMETHAMINE	1 (0.3)	1 (0.5)	2 (0.4)
LANSOPRAZOLE	1 (0.3)	1 (0.5)	2 (0.4)
LEVOCETIRIZINE DIHYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
LEVONORGESTREL	1 (0.3)	1 (0.5)	2 (0.4)
LORAZEPAM	1 (0.3)	1 (0.5)	2 (0.4)
LOSARTAN POTASSIUM	2 (0.5)		2 (0.4)
MAALOX [REDACTED]	/	2 (1.1)	2 (0.4)
METAMIZOLE SODIUM	1 (0.3)	1 (0.5)	2 (0.4)
METHYLPREDNISOLONE	2 (0.5)		2 (0.4)
MIDAZOLAM	1 (0.3)	1 (0.5)	2 (0.4)
NABUMETONE	2 (0.5)		2 (0.4)
NAPROXEN	1 (0.3)	1 (0.5)	2 (0.4)
NARINE [REDACTED]	/	1 (0.5)	2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
NIFLUMIC ACID	1 (0.3)	1 (0.5)	2 (0.4)
OXACILLIN	1 (0.3)	1 (0.5)	2 (0.4)
OXYCODONE HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
OXYMETAZOLINE	2 (0.5)		2 (0.4)
PARAMOL-118	2 (0.5)		2 (0.4)
PENICILLIN NOS	2 (0.5)		2 (0.4)
PHOLCODINE	1 (0.3)	1 (0.5)	2 (0.4)
POLYETHYL. GLYC. W/POTAS. CHLOR./SOD. BICARB.	1 (0.3)	1 (0.5)	2 (0.4)
PRAVASTATIN	1 (0.3)	1 (0.5)	2 (0.4)
PREGABALIN	2 (0.5)		2 (0.4)
PRISTINAMYCIN	1 (0.3)	1 (0.5)	2 (0.4)
PRONILIDE	1 (0.3)	1 (0.5)	2 (0.4)
PROPOFOL	1 (0.3)	1 (0.5)	2 (0.4)
PSEUDOEPHEDRINE		2 (1.1)	2 (0.4)
PSEUDOEPHEDRINE HYDROCHLORIDE	2 (0.5)		2 (0.4)
RAMIPRIL	2 (0.5)		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
RANITIDINE	2 (0.5)		2 (0.4)
RANITIDINE HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
RINOFLUIMUCIL [REDACTED]	/	2 (0.5)	2 (0.4)
SALBUTAMOL	1 (0.3)	1 (0.5)	2 (0.4)
SPASEFON [REDACTED]	/	1 (0.3)	1 (0.5)
SULFAMETHIZOLE	1 (0.3)	1 (0.5)	2 (0.4)
SULFAMETHOXAZOLE	2 (0.5)		2 (0.4)
TERBINAFINE HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
TETANUS VACCINE	1 (0.3)	1 (0.5)	2 (0.4)
TETRAZEPAM	2 (0.5)		2 (0.4)
THIOCTIC ACID	1 (0.3)	1 (0.5)	2 (0.4)
TOBRAMYCIN		2 (1.1)	2 (0.4)
VITAMIN B12 NOS	1 (0.3)	1 (0.5)	2 (0.4)
ZINC SULFATE	2 (0.5)		2 (0.4)
A.P.C. [REDACTED]	/	1 (0.5)	1 (0.2)
ACETAZOLAMIDE		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ACICLOVIR		1 (0.5)	1 (0.2)
ACTIFED [REDACTED]	/ 1 (0.3)		1 (0.2)
ADVIL PM [REDACTED]	/	1 (0.5)	1 (0.2)
AKRITOLIN	1 (0.3)		1 (0.2)
ALANERV	1 (0.3)		1 (0.2)
ALERNYL-B		1 (0.5)	1 (0.2)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.3)		1 (0.2)
ALOE FEROX EXTRACT	1 (0.3)		1 (0.2)
AMCAL DAY & NIGHT COLD & FLU		1 (0.5)	1 (0.2)
AMINOCAPROIC ACID	1 (0.3)		1 (0.2)
AMITRIPTYLINE	1 (0.3)		1 (0.2)
AMOXI-CLAVULANICO	1 (0.3)		1 (0.2)
AMPICILLIN	1 (0.3)		1 (0.2)
AMYLMETACRESOL	1 (0.3)		1 (0.2)
ANAESTHETICS, LOCAL	1 (0.3)		1 (0.2)
APOREX	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ARBIDOL		1 (0.5)	1 (0.2)
ASPIRIN PLUS C	1 (0.3)		1 (0.2)
ATROPINE SULFATE		1 (0.5)	1 (0.2)
AUGMENTIN [REDACTED]	/	1 (0.3)	1 (0.2)
BACICOLINE [REDACTED]	/	1 (0.5)	1 (0.2)
BECLOMETASONE DIPROPIONATE		1 (0.5)	1 (0.2)
BEECHAMS ALL-IN-ONE	1 (0.3)		1 (0.2)
BENZONATATE	1 (0.3)		1 (0.2)
BENZYL BENZOATE	1 (0.3)		1 (0.2)
BETAINE CITRATE		1 (0.5)	1 (0.2)
BETAMETHASONE		1 (0.5)	1 (0.2)
BIMATOPROST		1 (0.5)	1 (0.2)
BIOGESIC [REDACTED]	/	1 (0.5)	1 (0.2)
BIOGLAN MICELLE A PLUS E	1 (0.3)		1 (0.2)
BISOPROLOL		1 (0.5)	1 (0.2)
BROMHEXINE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
BROMHEXINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
BUPIVACAINE	1 (0.3)		1 (0.2)
CALCIUM LACTOGLUCONATE	1 (0.3)		1 (0.2)
CAPIVEN		1 (0.5)	1 (0.2)
CAPTOPRIL	1 (0.3)		1 (0.2)
CARBOCISTEINE	1 (0.3)		1 (0.2)
CARISOPRODOL	1 (0.3)		1 (0.2)
CARVEDILOL		1 (0.5)	1 (0.2)
CEFACLOR	1 (0.3)		1 (0.2)
CEFALEXIN SODIUM		1 (0.5)	1 (0.2)
CEFALOTIN	1 (0.3)		1 (0.2)
CEFAZOLIN	1 (0.3)		1 (0.2)
CEFAZOLIN SODIUM		1 (0.5)	1 (0.2)
CEFDINIR	1 (0.3)		1 (0.2)
CEFUROXIME	1 (0.3)		1 (0.2)
CETIRIZINE	1 (0.3)		1 (0.2)
CHARCOAL, ACTIVATED		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CHEMWORLD COLD & FLU RELIEF DAY & NIGHT	1 (0.3)		1 (0.2)
CHERACOL /	1 (0.3)		1 (0.2)
CHLORPHENAMINE W/PARACETAMOL/ PHENYLEPHRINE/	1 (0.3)		1 (0.2)
CICLOSPORIN	1 (0.3)		1 (0.2)
CITRAMON /	1 (0.3)		1 (0.2)
CLINDAMYCIN HYDROCHLORIDE	1 (0.3)		1 (0.2)
CLINDAMYCIN PHOSPHATE	1 (0.3)		1 (0.2)
CLONAZEPAM		1 (0.5)	1 (0.2)
CO-ADVIL	1 (0.3)		1 (0.2)
CO-TYLENOL /	1 (0.3)		1 (0.2)
CODAFEN /		1 (0.5)	1 (0.2)
CODEINE PHOSPHATE	1 (0.3)		1 (0.2)
CODRAL DAYTIME/NIGHTTIME	1 (0.3)		1 (0.2)
COLCHICINE	1 (0.3)		1 (0.2)
COLCHIMAX /		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

		IDegAsp OD N (%)	IDet N (%)	Total N (%)
COLDENIN	/	1 (0.3)		1 (0.2)
COLDREX NIGHT RELIEF			1 (0.5)	1 (0.2)
COLOXYL WITH SENNA		1 (0.3)		1 (0.2)
COMBINATIONS OF ANTIBACTERIALS		1 (0.3)		1 (0.2)
CORTICOSTEROIDS		1 (0.3)		1 (0.2)
CYCLOBENZAPRINE HYDROCHLORIDE			1 (0.5)	1 (0.2)
CYSTEX		1 (0.3)		1 (0.2)
D-MANNOSE		1 (0.3)		1 (0.2)
DALTEPARIN SODIUM		1 (0.3)		1 (0.2)
DAY & NIGHT COLD & FLU	/	1 (0.3)		1 (0.2)
DEMAZIN	/	1 (0.3)		1 (0.2)
DEMAZIN	/	1 (0.3)		1 (0.2)
DENOTIVIR			1 (0.5)	1 (0.2)
DERINOX	/	1 (0.3)		1 (0.2)
DESVENLAFAXINE SUCCINATE		1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DEXA POLYSPECTRAN N		1 (0.5)	1 (0.2)
DEXAMETHASONE	1 (0.3)		1 (0.2)
DEXAMETHASONE SODIUM PHOSPHATE		1 (0.5)	1 (0.2)
DEXPANTHENOL		1 (0.5)	1 (0.2)
DEXTROMETHORPHAN	1 (0.3)		1 (0.2)
DEXTROMETHORPHAN W/GUAIFENESIN/ PSEUDOEPHEDRIN		1 (0.5)	1 (0.2)
DIAZEPAM		1 (0.5)	1 (0.2)
DICLOFENAC EPOLAMINUM		1 (0.5)	1 (0.2)
DICLOFENAC POTASSIUM	1 (0.3)		1 (0.2)
DICLOXACILLIN SODIUM MONOHYDRATE		1 (0.5)	1 (0.2)
DIMETANE SANS SUCRE	1 (0.3)		1 (0.2)
DIPHENHYDRA. HCL W/PARACETAMOL/ PSEUDOEPH. HCL	1 (0.3)		1 (0.2)
DIPHThERIA AND TETANUS TOXOIDS AND PERTUSSIS	1 (0.3)		1 (0.2)
DIPHThERIA,TETANUS AND POLIOMYELITIS VAC	1 (0.3)		1 (0.2)
DIPROSPAN / [REDACTED]	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DOCOSANOL	1 (0.3)		1 (0.2)
DOXYCYCLINE HYCLATE		1 (0.5)	1 (0.2)
DOXYLAMINE	1 (0.3)		1 (0.2)
DOZOL [REDACTED]	/		1 (0.2)
DROTAVERINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
DULOXETINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
DURO-TUSS COUGH	1 (0.3)		1 (0.2)
EBASTINE	1 (0.3)		1 (0.2)
EMOXIPIN	1 (0.3)		1 (0.2)
ENALAPRIL	1 (0.3)		1 (0.2)
ENOXAPARIN	1 (0.3)		1 (0.2)
EPIPEVISON		1 (0.5)	1 (0.2)
ERDOSTEINE	1 (0.3)		1 (0.2)
ETAMSILATE	1 (0.3)		1 (0.2)
ETANERCEPT	1 (0.3)		1 (0.2)
EUCERIN [REDACTED]	/		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
EUGYNON [REDACTED]	/	1 (0.3)	1 (0.2)
FAMOTIDINE		1 (0.5)	1 (0.2)
FENSPIRIDE		1 (0.5)	1 (0.2)
FLUCLOXACILLIN	1 (0.3)		1 (0.2)
FLUOCINOLONE ACETONIDE	1 (0.3)		1 (0.2)
FLUOCINONIDE	1 (0.3)		1 (0.2)
FLURBIPROFEN	1 (0.3)		1 (0.2)
FLUTICASONE FUROATE	1 (0.3)		1 (0.2)
FOLIC ACID	1 (0.3)		1 (0.2)
FRENADOL [REDACTED]	/	1 (0.3)	1 (0.2)
FURAZOLIDONE	1 (0.3)		1 (0.2)
FUROSEMIDE	1 (0.3)		1 (0.2)
FUSIDIC ACID		1 (0.5)	1 (0.2)
GABAPENTIN	1 (0.3)		1 (0.2)
GALENIC /PARACETAMOL/CODEINE/		1 (0.5)	1 (0.2)
GASTROLIT [REDACTED]	/	1 (0.3)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
GAVISCON /	1 (0.3)		1 (0.2)
GLUCOCORTICIDS		1 (0.5)	1 (0.2)
GLUCOSAMINE W/CHONDROITIN SULFATE	1 (0.3)		1 (0.2)
GLUCOSE INJECTION	1 (0.3)		1 (0.2)
GLYCEROL MED OPIUM STAERKE		1 (0.5)	1 (0.2)
GLYCERYL TRINITRATE	1 (0.3)		1 (0.2)
GUAIFENESIN W/DEXTROMETHORPHAN	1 (0.3)		1 (0.2)
GUAJANAL		1 (0.5)	1 (0.2)
HALL'S MENTHO-LYPTUS		1 (0.5)	1 (0.2)
HALOPERIDOL	1 (0.3)		1 (0.2)
HEDERA HELIX		1 (0.5)	1 (0.2)
HEMO /	1 (0.3)		1 (0.2)
HEPARIN		1 (0.5)	1 (0.2)
HEPATITIS B VACCINE	1 (0.3)		1 (0.2)
HETASTARCH	1 (0.3)		1 (0.2)
HEXETIDINE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HEXYLRESORCINOL	1 (0.3)		1 (0.2)
HLD	1 (0.3)		1 (0.2)
HYDROCODONE W/HOMATROPINE	1 (0.3)		1 (0.2)
HYDROCORTISONE BUTYRATE		1 (0.5)	1 (0.2)
HYDROGEN PEROXIDE	1 (0.3)		1 (0.2)
HYDROMORPHONE HYDROCHLORIDE	1 (0.3)		1 (0.2)
HYDROXYCHLOROQUINE	1 (0.3)		1 (0.2)
HYPERTONIC SOLUTIONS	1 (0.3)		1 (0.2)
IDROCILAMIDE	1 (0.3)		1 (0.2)
INDOMETACIN	1 (0.3)		1 (0.2)
INFANRIX [REDACTED]	1 (0.3)		1 (0.2)
INFLUENZA VIRUS VACCINE POLYVALENT		1 (0.5)	1 (0.2)
INSULIN	1 (0.3)		1 (0.2)
INSULIN HUMAN INJECTION, ISOPHANE		1 (0.5)	1 (0.2)
IPRATROPIUM	1 (0.3)		1 (0.2)
IPRATROPIUM BROMIDE		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ISONIAZID	1 (0.3)		1 (0.2)
ISOTRETINOIN	1 (0.3)		1 (0.2)
JOX	1 (0.3)		1 (0.2)
KARVEA HCT	1 (0.3)		1 (0.2)
KETOCONAZOLE	1 (0.3)		1 (0.2)
LACTOBACILLUS ACIDOPHILUS	1 (0.3)		1 (0.2)
LERCANIDIPINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
LEVOFLOXACIN	1 (0.3)		1 (0.2)
LIOTHYRONINE SODIUM	1 (0.3)		1 (0.2)
LOTRISONE	1 (0.3)		1 (0.2)
LOVASTATIN	1 (0.3)		1 (0.2)
MACROGOL	1 (0.3)		1 (0.2)
MAGNECYL-KODEIN	1 (0.3)		1 (0.2)
MARVELON	1 (0.3)		1 (0.2)
MEBHYDROLIN	1 (0.3)		1 (0.2)
MECLOZINE	1 (0.3)		1 (0.2)
MEDIQUE MS.-AID		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
MENADIONE SODIUM BISULFITE	1 (0.3)		1 (0.2)
MESNA	1 (0.3)		1 (0.2)
METEOSPASMYL [REDACTED]	/	1 (0.5)	1 (0.2)
METHADONE		1 (0.5)	1 (0.2)
METHOTREXATE	1 (0.3)		1 (0.2)
METHYLPREDNISOLONE SODIUM SUCCINATE		1 (0.5)	1 (0.2)
METICILLIN	1 (0.3)		1 (0.2)
MICONAZOLE		1 (0.5)	1 (0.2)
MILGAMMA NA	1 (0.3)		1 (0.2)
MILNACIPRAN	1 (0.3)		1 (0.2)
MINERAL SUPPLEMENTS	1 (0.3)		1 (0.2)
MIRTAZAPINE	1 (0.3)		1 (0.2)
MONTELUKAST SODIUM		1 (0.5)	1 (0.2)
MOXIFLOXACIN HYDROCHLORIDE	1 (0.3)		1 (0.2)
NAPHAZOLINE	1 (0.3)		1 (0.2)
NAPHAZOLINE NITRATE		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
NEBIVOLOL HYDROCHLORIDE	1 (0.3)		1 (0.2)
NEO ANGIN N	1 (0.3)		1 (0.2)
NEUROTONIC		1 (0.5)	1 (0.2)
NICLOSAMIDE	1 (0.3)		1 (0.2)
NIMESULIDE		1 (0.5)	1 (0.2)
NITROFURAL	1 (0.3)		1 (0.2)
NITROFURANTOIN	1 (0.3)		1 (0.2)
NORFLOXACIN		1 (0.5)	1 (0.2)
OBETROL [REDACTED]	/	1 (0.5)	1 (0.2)
OLBAS [REDACTED]	/	1 (0.3)	1 (0.2)
OLOPATADINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
ONDANSETRON		1 (0.5)	1 (0.2)
ONE-A-DAY MEN'S	1 (0.3)		1 (0.2)
OTHER COLD COMBINATION PREPARATIONS	1 (0.3)		1 (0.2)
OTIDIN		1 (0.5)	1 (0.2)
OTOSPORIN	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
OXYCODONE		1 (0.5)	1 (0.2)
OXYTETRACYCLINE		1 (0.5)	1 (0.2)
PANCREATIN	1 (0.3)		1 (0.2)
PANTOPRAZOLE SODIUM	1 (0.3)		1 (0.2)
PAPAVERINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
PARA-SELTZER		1 (0.5)	1 (0.2)
PENTOXIFYLLINE	1 (0.3)		1 (0.2)
PHLEBODRIL /	1 (0.3)		1 (0.2)
PHOSPHOLIPIDS	1 (0.3)		1 (0.2)
PIRACETAM	1 (0.3)		1 (0.2)
PIROXICAM BETADEX	1 (0.3)		1 (0.2)
PIVMECILLINAM		1 (0.5)	1 (0.2)
PLATYPHYLLINE		1 (0.5)	1 (0.2)
PNEUMOCOCCAL VACCINE	1 (0.3)		1 (0.2)
POLYCARBOPHIL CALCIUM	1 (0.3)		1 (0.2)
POLYDEXA	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
POTASSIUM CHLORIDE	1 (0.3)		1 (0.2)
POVIDONE-IODINE		1 (0.5)	1 (0.2)
PRAMIPEXOLE		1 (0.5)	1 (0.2)
PRIMATENE		1 (0.5)	1 (0.2)
PROCAINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
PROCHLORPERAZINE	1 (0.3)		1 (0.2)
PROMETHAZINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
PROMETHAZINE W/CODEINE [REDACTED]	/	1 (0.3)	1 (0.2)
RESPAIRE-SR-120	1 (0.3)		1 (0.2)
RHODOGIL		1 (0.5)	1 (0.2)
RIFAMPICIN	1 (0.3)		1 (0.2)
RILMENIDINE PHOSPHATE	1 (0.3)		1 (0.2)
RIMANTADINE	1 (0.3)		1 (0.2)
RIVAROXABAN		1 (0.5)	1 (0.2)
ROBITUSSIN NIGHT-TIME COLD FORMULA	1 (0.3)		1 (0.2)
ROSUVASTATIN CALCIUM		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

		IDegAsp OD N (%)	IDet N (%)	Total N (%)
SACCHAROMYCES BOULARDII		1 (0.3)		1 (0.2)
SALONPAS	/		1 (0.5)	1 (0.2)
SCORBOLAMID			1 (0.5)	1 (0.2)
SEPTOLETE	/	1 (0.3)		1 (0.2)
SEPTOLETE	/		1 (0.5)	1 (0.2)
SERTRALINE			1 (0.5)	1 (0.2)
SERTRALINE HYDROCHLORIDE		1 (0.3)		1 (0.2)
SINE-OFF	/	1 (0.3)		1 (0.2)
SINGLET	/	1 (0.3)		1 (0.2)
SINUPRET	/	1 (0.3)		1 (0.2)
SMECTITE			1 (0.5)	1 (0.2)
SOFRACORT		1 (0.3)		1 (0.2)
SPIRONOLACTONE		1 (0.3)		1 (0.2)
SPIRULINA SPP.		1 (0.3)		1 (0.2)
SUCRALFATE		1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SULFARINOL	1 (0.3)		1 (0.2)
SULINDAC	1 (0.3)		1 (0.2)
SUMATRIPTAN	1 (0.3)		1 (0.2)
TADALAFIL	1 (0.3)		1 (0.2)
TAURINE	1 (0.3)		1 (0.2)
TETANUS TOXOID		1 (0.5)	1 (0.2)
TETANUS VACCINE ADSORBED	1 (0.3)		1 (0.2)
THENOIC ACID	1 (0.3)		1 (0.2)
THIOPCODIN /	1 (0.3)		1 (0.2)
TIMOLOL		1 (0.5)	1 (0.2)
TIZANIDINE	1 (0.3)		1 (0.2)
TIZANIDINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
TOPLEXIL /	1 (0.3)		1 (0.2)
TRACHISAN /	1 (0.3)		1 (0.2)
TRAMADOL HYDROCHLORIDE		1 (0.5)	1 (0.2)
TRAZODONE		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
TRETINOIN	1 (0.3)		1 (0.2)
TRIAMCINOLONE		1 (0.5)	1 (0.2)
TRIAMCINOLONE ACETONIDE	1 (0.3)		1 (0.2)
TYLENOL SINUS MEDICATION	1 (0.3)		1 (0.2)
TYPHOID VACCINE	1 (0.3)		1 (0.2)
ULTRACET	1 (0.3)		1 (0.2)
UROKINASE	1 (0.3)		1 (0.2)
VAGISIL		1 (0.5)	1 (0.2)
VARICELLA VIRUS VACCINE, LIVE		1 (0.5)	1 (0.2)
VASERETIC	1 (0.3)		1 (0.2)
VENLAFAXINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
VERAPAMIL HYDROCHLORIDE	1 (0.3)		1 (0.2)
VICKS FORMULA 44 [REDACTED]	/	1 (0.5)	1 (0.2)
WARFARIN		1 (0.5)	1 (0.2)
XYLOMETAZOLINE	1 (0.3)		1 (0.2)
YEAST	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ZALEPLON		1 (0.5)	1 (0.2)
ZANAMIVIR		1 (0.5)	1 (0.2)
ZINC		1 (0.5)	1 (0.2)
ZINGIBER OFFICINALE RHIZOME	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:55 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

14.2 Efficacy Data

14.2.1: Exposure - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Total Exposure, yrs	169.3	83.89	253.2
Exposure (yrs)			
N	362	180	542
Mean (SD)	0.47 (0.10)	0.47 (0.11)	0.47 (0.10)
Median	0.50	0.50	0.50
Min ; Max	0.00 ; 0.55	0.01 ; 0.55	0.00 ; 0.55

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:57 - tdesc_expo_tpl_t032_v01.sas/t_exposure_descp_sas.txt

14.2.2: Exposure by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposed , N (%)			
N	362 (100.0)	180 (100.0)	542 (100.0)
1 - 4 Weeks	9 (2.5)	4 (2.2)	13 (2.4)
5 - 8 Weeks	8 (2.2)	3 (1.7)	11 (2.0)
9 - 12 Weeks	8 (2.2)	5 (2.8)	13 (2.4)
13 - 16 Weeks	5 (1.4)	3 (1.7)	8 (1.5)
17 - 20 Weeks	5 (1.4)	4 (2.2)	9 (1.7)
21 - 24 Weeks	4 (1.1)	2 (1.1)	6 (1.1)
25 - 28 Weeks	320 (88.4)	157 (87.2)	477 (88.0)
29 - 32 Weeks	3 (0.8)	2 (1.1)	5 (0.9)

N = Number of Subjects
%: Percentage of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:59 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_w_descp_sas.txt

14.2.3: Exposure by Sex and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposure, yrs (%)			
Total	169.3 (100.0)	83.9 (100.0)	253.2 (100.0)
Female	79.4 (46.9)	44.4 (53.0)	123.8 (48.9)
Male	90.0 (53.1)	39.5 (47.0)	129.5 (51.1)
Exposed Female, N (%)			
N	173 (100.0)	98 (100.0)	271 (100.0)
1 - 4 Weeks	6 (3.5)	2 (2.0)	8 (3.0)
5 - 8 Weeks	4 (2.3)	3 (3.1)	7 (2.6)
9 - 12 Weeks	4 (2.3)	4 (4.1)	8 (3.0)
13 - 16 Weeks	4 (2.3)	3 (3.1)	7 (2.6)
17 - 20 Weeks	4 (2.3)	3 (3.1)	7 (2.6)
21 - 24 Weeks	3 (1.7)	1 (1.0)	4 (1.5)
25 - 28 Weeks	146 (84.4)	80 (81.6)	226 (83.4)
29 - 32 Weeks	2 (1.2)	2 (2.0)	4 (1.5)
Exposed Male, N (%)			
N	189 (100.0)	82 (100.0)	271 (100.0)
1 - 4 Weeks	3 (1.6)	2 (2.4)	5 (1.8)
5 - 8 Weeks	4 (2.1)	0 (0.0)	4 (1.5)
9 - 12 Weeks	4 (2.1)	1 (1.2)	5 (1.8)
13 - 16 Weeks	1 (0.5)	0 (0.0)	1 (0.4)
17 - 20 Weeks	1 (0.5)	1 (1.2)	2 (0.7)
21 - 24 Weeks	1 (0.5)	1 (1.2)	2 (0.7)
25 - 28 Weeks	174 (92.1)	77 (93.9)	251 (92.6)
29 - 32 Weeks	1 (0.5)	0 (0.0)	1 (0.4)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:01 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_sex_descp_sas.txt

14.2.4: Exposure by Race and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposure, yrs (%)			
Total	169.3 (100.0)	83.9 (100.0)	253.2 (100.0)
White	155.1 (91.6)	74.9 (89.3)	230.0 (90.8)
Black	4.3 (2.6)	2.6 (3.2)	7.0 (2.8)
Asian Indian	0.5 (0.3)	0.0 (0.0)	0.5 (0.2)
Asian non-Indian	1.3 (0.8)	1.3 (1.6)	2.6 (1.0)
American Indian	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Pacific Islander	0.5 (0.3)	0.5 (0.6)	1.0 (0.4)
Other	0.5 (0.3)	1.0 (1.2)	1.5 (0.6)
NA	7.1 (4.2)	3.5 (4.1)	10.6 (4.2)
Exposed White, N (%)			
N	331 (100.0)	160 (100.0)	491 (100.0)
1 - 4 Weeks	9 (2.7)	3 (1.9)	12 (2.4)
5 - 8 Weeks	6 (1.8)	3 (1.9)	9 (1.8)
9 - 12 Weeks	7 (2.1)	4 (2.5)	11 (2.2)
13 - 16 Weeks	4 (1.2)	3 (1.9)	7 (1.4)
17 - 20 Weeks	5 (1.5)	3 (1.9)	8 (1.6)
21 - 24 Weeks	4 (1.2)	2 (1.3)	6 (1.2)
25 - 28 Weeks	294 (88.8)	140 (87.5)	434 (88.4)
29 - 32 Weeks	2 (0.6)	2 (1.3)	4 (0.8)
Exposed Black, N (%)			
N	10 (100.0)	6 (100.0)	16 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	1 (10.0)	0 (0.0)	1 (6.3)
9 - 12 Weeks	1 (10.0)	1 (16.7)	2 (12.5)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	7 (70.0)	5 (83.3)	12 (75.0)
29 - 32 Weeks	1 (10.0)	0 (0.0)	1 (6.3)
Exposed Asian Indian, N (%)			
N	1 (100.0)	0 (0.0)	1 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	1 (100.0)	0 (0.0)	1 (100.0)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects
Subjects from France did not report race.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:02 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_race_descp_sas.txt

Exposure by Race and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Exposed Asian non-Indian, N (%)			
N	3 (100.0)	3 (100.0)	6 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	1 (33.3)	0 (0.0)	1 (16.7)
17 - 20 Weeks	0 (0.0)	1 (33.3)	1 (16.7)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	2 (66.7)	2 (66.7)	4 (66.7)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
Exposed American Indian, N (%)			
N	0 (0.0)	0 (0.0)	0 (0.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
Exposed Pacific Islander, N (%)			
N	1 (100.0)	1 (100.0)	2 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	1 (100.0)	1 (100.0)	2 (100.0)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
Exposed Other, N (%)			
N	1 (100.0)	2 (100.0)	3 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	1 (100.0)	2 (100.0)	3 (100.0)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
Exposed NA, N (%)			
N	15 (100.0)	8 (100.0)	23 (100.0)
1 - 4 Weeks	0 (0.0)	1 (12.5)	1 (4.3)
5 - 8 Weeks	1 (6.7)	0 (0.0)	1 (4.3)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	14 (93.3)	7 (87.5)	21 (91.3)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects

Subjects from France did not report race.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:02 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_race_descp_sas.txt

14.2.5: Exposure by Ethnicity and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposure, yrs (%)			
Total	169.3 (100.0)	83.9 (100.0)	253.2 (100.0)
Hispanic	4.4 (2.6)	2.4 (2.8)	6.8 (2.7)
Not Hispanic	157.8 (93.2)	78.0 (93.0)	235.9 (93.1)
NA	7.1 (4.2)	3.5 (4.1)	10.6 (4.2)
Exposed Hispanic, N (%)			
N	10 (100.0)	5 (100.0)	15 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	1 (10.0)	0 (0.0)	1 (6.7)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	1 (10.0)	0 (0.0)	1 (6.7)
17 - 20 Weeks	0 (0.0)	1 (20.0)	1 (6.7)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	8 (80.0)	4 (80.0)	12 (80.0)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
Exposed Not Hispanic, N (%)			
N	337 (100.0)	167 (100.0)	504 (100.0)
1 - 4 Weeks	9 (2.7)	3 (1.8)	12 (2.4)
5 - 8 Weeks	6 (1.8)	3 (1.8)	9 (1.8)
9 - 12 Weeks	8 (2.4)	5 (3.0)	13 (2.6)
13 - 16 Weeks	4 (1.2)	3 (1.8)	7 (1.4)
17 - 20 Weeks	5 (1.5)	3 (1.8)	8 (1.6)
21 - 24 Weeks	4 (1.2)	2 (1.2)	6 (1.2)
25 - 28 Weeks	298 (88.4)	146 (87.4)	444 (88.1)
29 - 32 Weeks	3 (0.9)	2 (1.2)	5 (1.0)
Exposed NA, N (%)			
N	15 (100.0)	8 (100.0)	23 (100.0)
1 - 4 Weeks	0 (0.0)	1 (12.5)	1 (4.3)
5 - 8 Weeks	1 (6.7)	0 (0.0)	1 (4.3)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	14 (93.3)	7 (87.5)	21 (91.3)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects
Subjects from France did not report race.

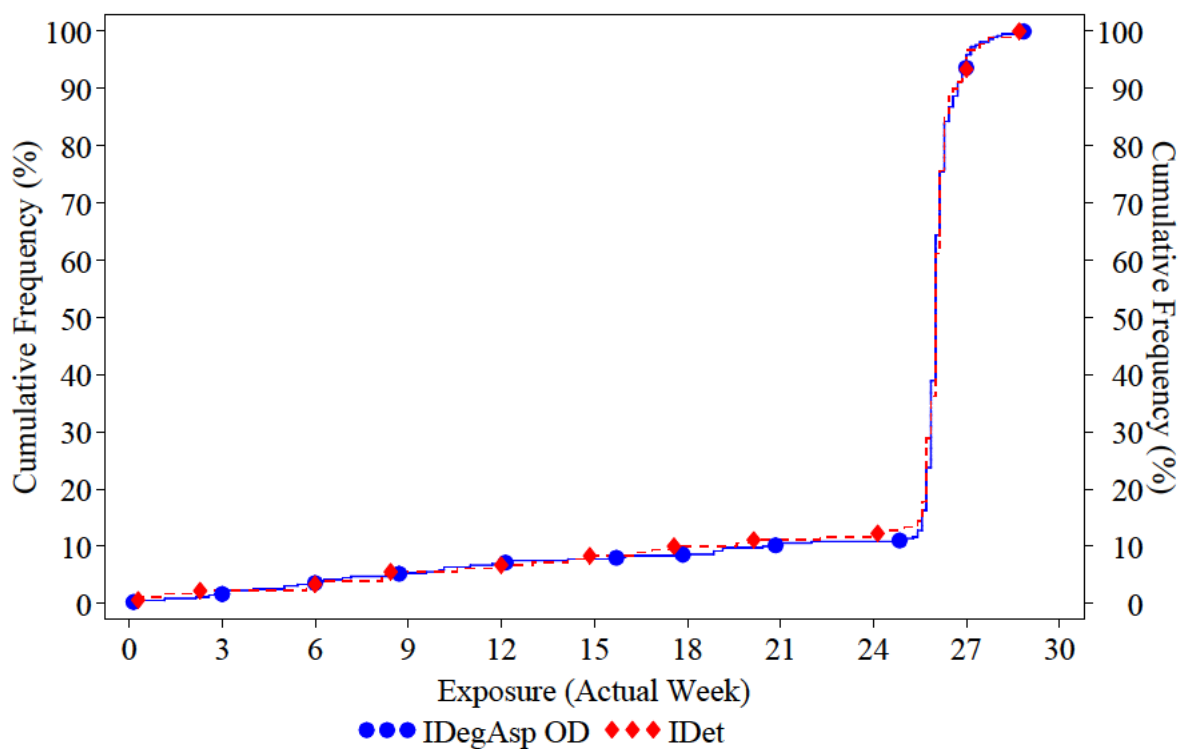
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:04 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_ethnicity_descp_sas.txt

14.2.6: Exposure by Age Group (Adults and Elderly) and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposure, yrs (%)			
Total	169.3 (100.0)	83.9 (100.0)	253.2 (100.0)
18-65 yrs	165.2 (97.5)	77.4 (92.3)	242.6 (95.8)
> 65 yrs	4.2 (2.5)	6.5 (7.7)	10.6 (4.2)
Exposed 18-65 yrs, N (%)			
N	353 (100.0)	166 (100.0)	519 (100.0)
1 - 4 Weeks	9 (2.5)	3 (1.8)	12 (2.3)
5 - 8 Weeks	7 (2.0)	3 (1.8)	10 (1.9)
9 - 12 Weeks	8 (2.3)	5 (3.0)	13 (2.5)
13 - 16 Weeks	5 (1.4)	3 (1.8)	8 (1.5)
17 - 20 Weeks	5 (1.4)	4 (2.4)	9 (1.7)
21 - 24 Weeks	4 (1.1)	2 (1.2)	6 (1.2)
25 - 28 Weeks	312 (88.4)	144 (86.7)	456 (87.9)
29 - 32 Weeks	3 (0.8)	2 (1.2)	5 (1.0)
Exposed > 65 yrs, N (%)			
N	9 (100.0)	14 (100.0)	23 (100.0)
1 - 4 Weeks	0 (0.0)	1 (7.1)	1 (4.3)
5 - 8 Weeks	1 (11.1)	0 (0.0)	1 (4.3)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	8 (88.9)	13 (92.9)	21 (91.3)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:06 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_age_descp_sas.txt



nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:08 - fedist_expo_v01.sas/e_exposure_cdf_sas.cgm

14.2.7: Exposure - Empirical Distribution Plot - Safety Analysis Set

14.2.8: IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	36	16	32	10	118
		OD							
		IDet	180	176	26	12	24	7	77
Visit 4 (Week 2)	Daily	Total	542	536	33	16	30	7	118
		IDegAsp	362	359	37	17	33	10	120
		OD							
Visit 5 (Week 3)	Daily	IDet	180	177	27	13	26	4	79
		Total	542	536	34	16	30	4	120
		IDegAsp	362	346	38	17	34	10	120
Visit 6 (Week 4)	Daily	OD							
		IDet	180	175	28	13	26	4	81
		Total	542	521	34	17	32	4	120
Visit 7 (Week 5)	Daily	IDegAsp	362	352	38	17	34	9	116
		OD							
		IDet	180	174	29	14	28	4	83
Visit 8 (Week 6)	Daily	Total	542	526	35	17	32	4	116
		IDegAsp	362	349	38	18	34	8	116
		OD							
Visit 9 (Week 7)	Daily	IDet	180	173	29	14	28	5	74
		Total	542	522	35	17	33	5	116
		IDegAsp	362	344	39	18	35	9	118
Visit 10 (Week 8)	Daily	OD							
		IDet	180	173	31	15	30	5	85
		Total	542	517	36	17	34	5	118
Visit 11 (Week 9)	Daily	IDegAsp	362	343	39	18	35	10	118
		OD							
		IDet	180	171	31	15	30	5	87
Visit 12 (Week 10)	Daily	Total	542	514	36	18	34	5	118
		IDegAsp	362	340	39	18	36	8	120
		OD							
Visit 13 (Week 11)	Daily	IDet	180	171	32	15	30	5	80
		Total	542	511	37	18	34	5	120
		IDegAsp	362	335	40	19	36	9	124
Visit 14 (Week 12)	Daily	OD							
		IDet	180	166	32	16	30	5	82
		Total	542	501	37	18	34	5	124
Visit 15 (Week 13)	Daily	IDegAsp	362	339	40	19	36	8	124
		OD							
		IDet	180	169	33	16	31	5	83
Visit 16 (Week 14)	Daily	Total	542	508	38	18	34	5	124
		IDegAsp	362	334	40	19	36	10	128
		OD							
Visit 17 (Week 15)	Daily	IDet	180	167	33	17	32	5	87
		Total	542	501	38	19	34	5	128
		IDegAsp	362	335	41	20	36	11	134
Visit 18 (Week 16)	Daily	OD							
		IDet	180	168	33	17	31	2	87
		Total	542	503	38	19	34	2	134

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:15 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics -
Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	324	41	20	36	10	134
		OD							
		IDet	180	162	34	17	32	2	92
Visit 16 (Week 14)	Daily	Total	542	486	38	20	34	2	134
		IDegAsp	362	332	41	20	36	8	130
		OD							
Visit 17 (Week 15)	Daily	IDet	180	166	34	17	32	4	94
		Total	542	498	39	20	34	4	130
		IDegAsp	362	327	41	21	36	9	124
Visit 18 (Week 16)	Daily	OD							
		IDet	180	164	34	17	32	5	100
		Total	542	491	39	20	34	5	124
Visit 19 (Week 17)	Daily	IDegAsp	362	330	41	21	36	6	128
		OD							
		IDet	180	164	34	17	32	4	102
Visit 20 (Week 18)	Daily	Total	542	494	39	20	34	4	128
		IDegAsp	362	322	42	21	37	10	130
		OD							
Visit 21 (Week 19)	Daily	IDet	180	162	34	18	32	4	104
		Total	542	484	39	20	35	4	130
		IDegAsp	362	321	42	21	37	8	126
Visit 22 (Week 20)	Daily	OD							
		IDet	180	158	35	18	34	5	108
		Total	542	479	40	20	36	5	126
Visit 23 (Week 21)	Daily	IDegAsp	362	319	42	21	38	9	124
		OD							
		IDet	180	162	35	18	34	4	101
Visit 24 (Week 22)	Daily	Total	542	481	40	20	36	4	124
		IDegAsp	362	322	42	22	37	10	130
		OD							
Visit 25 (Week 23)	Daily	IDet	180	158	35	18	33	4	100
		Total	542	480	40	21	36	4	130
		IDegAsp	362	320	42	21	37	9	132
Visit 26 (Week 24)	Daily	OD							
		IDet	180	157	36	19	33	4	104
		Total	542	477	40	21	36	4	132
Visit 27 (Week 25)	Daily	IDegAsp	362	318	43	22	38	9	132
		OD							
		IDet	180	156	36	19	33	5	98
Visit 28 (Week 26)	Daily	Total	542	474	40	21	36	5	132
		IDegAsp	362	320	43	22	37	8	132
		OD							
Visit 29 (Week 27)	Daily	IDet	180	151	36	19	34	6	102
		Total	542	471	41	22	36	6	132
		IDegAsp	362	319	43	22	37	9	132
Visit 30 (Week 28)	Daily	OD							
		IDet	180	158	37	20	34	6	106
		Total	542	477	41	22	36	6	132

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:15 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	43	22	37	9	134
		OD							
		IDet	180	155	37	20	34	6	110
		Total	542	473	41	22	36	6	134
Visit 28 (Week 26)	Daily	IDegAsp	362	320	43	23	37	9	132
		OD							
		IDet	180	157	37	21	34	6	111
		Total	542	477	41	22	36	6	132
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp	362	360	42	22	36	9	132
		OD							
		IDet	180	178	36	21	34	6	111
		Total	542	538	40	22	35	6	132

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:39:15 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_sas.txt

14.2.9: IDegAsp/Comparator Insulin Dose (Prescribed) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 2 (Week 0)	Daily	IDegAsp	362	362	37	16	34	10	118
		OD							
		IDet	180	180	26	12	24	7	77
		Total	542	542	33	16	30	7	118
		IDegAsp	362	360	37	17	33	12	124
		OD							
Visit 3 (Week 1)	Daily	IDet	180	177	27	13	27	6	79
		Total	542	537	34	16	30	6	124
		IDegAsp	362	359	38	17	34	10	124
Visit 4 (Week 2)	Daily	OD							
		IDet	180	175	28	13	28	4	81
		Total	542	534	35	17	32	4	124
Visit 5 (Week 3)	Daily	IDegAsp	362	348	38	17	34	9	116
		OD							
		IDet	180	175	29	14	28	0	83
		Total	542	523	35	17	32	0	116
		IDegAsp	362	351	39	18	34	6	116
		OD							
Visit 6 (Week 4)	Daily	IDet	180	175	30	14	29	5	85
		Total	542	526	36	17	33	5	116
		IDegAsp	362	349	39	18	35	0	118
Visit 7 (Week 5)	Daily	OD							
		IDet	180	172	30	14	30	5	76
		Total	542	521	36	17	34	0	118
Visit 8 (Week 6)	Daily	IDegAsp	362	342	39	18	35	10	118
		OD							
		IDet	180	173	31	15	30	5	87
		Total	542	515	36	18	34	5	118
		IDegAsp	362	340	40	18	36	8	120
		OD							
Visit 9 (Week 7)	Daily	IDet	180	171	32	16	30	5	89
		Total	542	511	37	18	34	5	120
		IDegAsp	362	341	40	19	36	9	124
Visit 10 (Week 8)	Daily	OD							
		IDet	180	171	32	16	30	5	82
		Total	542	512	37	18	34	5	124
Visit 11 (Week 9)	Daily	IDegAsp	362	334	40	19	36	0	124
		OD							
		IDet	180	166	33	16	32	5	84
		Total	542	500	38	19	34	0	124
		IDegAsp	362	337	40	19	36	9	128
		OD							
Visit 12 (Week 10)	Daily	IDet	180	169	33	17	32	5	87
		Total	542	506	38	19	34	5	128
		IDegAsp	362	333	41	20	36	11	134
Visit 13 (Week 11)	Daily	OD							
		IDet	180	167	33	17	31	2	87
		Total	542	500	38	19	34	2	134

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:23 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_prschr_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Prescribed) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 14 (Week 12) Daily		IDegAsp	362	333	41	20	36	10	136
		OD							
		IDet	180	167	34	17	32	2	92
Visit 15 (Week 13) Daily		Total	542	500	38	20	34	2	136
		IDegAsp	362	321	41	21	36	7	130
		OD							
Visit 16 (Week 14) Daily		IDet	180	161	34	17	33	4	96
		Total	542	482	39	20	34	4	130
		IDegAsp	362	332	41	21	36	0	130
Visit 17 (Week 15) Daily		OD							
		IDet	180	166	34	17	33	5	100
		Total	542	498	39	20	34	0	130
Visit 18 (Week 16) Daily		IDegAsp	362	324	41	21	36	0	128
		OD							
		IDet	180	163	35	18	32	4	102
Visit 19 (Week 17) Daily		Total	542	487	39	20	35	0	128
		IDegAsp	362	330	42	21	37	0	130
		OD							
Visit 20 (Week 18) Daily		IDet	180	163	35	18	32	4	104
		Total	542	493	39	20	35	0	130
		IDegAsp	362	321	42	22	37	0	134
Visit 21 (Week 19) Daily		OD							
		IDet	180	161	35	18	34	5	108
		Total	542	482	40	21	36	0	134
Visit 22 (Week 20) Daily		IDegAsp	362	319	42	21	37	0	130
		OD							
		IDet	180	157	36	18	34	5	101
Visit 23 (Week 21) Daily		Total	542	476	40	21	36	0	130
		IDegAsp	362	316	43	21	38	10	126
		OD							
Visit 24 (Week 22) Daily		IDet	180	161	36	18	34	4	100
		Total	542	477	40	20	36	4	126
		IDegAsp	362	322	42	22	38	9	132
Visit 25 (Week 23) Daily		OD							
		IDet	180	159	36	19	33	4	104
		Total	542	481	40	21	36	4	132
Visit 26 (Week 24) Daily		IDegAsp	362	315	43	22	37	9	132
		OD							
		IDet	180	156	36	19	34	5	98
Visit 27 (Week 25) Daily		Total	542	471	40	21	36	5	132
		IDegAsp	362	315	43	22	37	8	132
		OD							
Visit 28 (Week 26) Daily		IDet	180	156	36	19	34	6	102
		Total	542	471	41	22	36	6	132
		IDegAsp	362	316	43	22	38	9	132
Visit 29 (Week 27) Daily		OD							
		IDet	180	151	37	20	35	6	106
		Total	542	467	41	22	37	6	132

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:23 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_prscb_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Prescribed) in Units by Treatment Week - Descriptive Statistics -
Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 26 (Week 24)	Daily	IDegAsp	362	317	43	22	38	9	132
		OD							
		IDet	180	157	37	20	34	8	110
		Total	542	474	41	22	36	8	132
Visit 27 (Week 25)	Daily	IDegAsp	362	313	43	23	37	9	132
		OD							
		IDet	180	151	38	21	35	6	112
		Total	542	464	41	22	36	6	132

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:23 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_prscb_u_descp_sas.txt

14.2.10: IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.47	0.18	0.43	0.13	1.25
		OD							
		IDet	180	176	0.34	0.13	0.31	0.10	0.96
		Total	542	536	0.43	0.18	0.40	0.10	1.25
Visit 4 (Week 2)	Daily	IDegAsp	362	359	0.48	0.19	0.44	0.15	1.33
		OD							
		IDet	180	177	0.35	0.14	0.33	0.07	0.99
		Total	542	536	0.44	0.18	0.41	0.07	1.33
Visit 5 (Week 3)	Daily	IDegAsp	362	346	0.49	0.19	0.44	0.15	1.35
		OD							
		IDet	180	175	0.37	0.15	0.35	0.07	1.01
		Total	542	521	0.45	0.19	0.42	0.07	1.35
Visit 6 (Week 4)	Daily	IDegAsp	362	352	0.50	0.19	0.45	0.15	1.32
		OD							
		IDet	180	174	0.38	0.16	0.37	0.07	1.04
		Total	542	526	0.46	0.19	0.43	0.07	1.32
Visit 7 (Week 5)	Daily	IDegAsp	362	349	0.50	0.19	0.46	0.14	1.30
		OD							
		IDet	180	173	0.38	0.16	0.37	0.07	1.07
		Total	542	522	0.46	0.19	0.44	0.07	1.30
Visit 8 (Week 6)	Daily	IDegAsp	362	344	0.50	0.20	0.47	0.15	1.32
		OD							
		IDet	180	173	0.40	0.17	0.38	0.08	1.10
		Total	542	517	0.47	0.19	0.44	0.08	1.32
Visit 9 (Week 7)	Daily	IDegAsp	362	343	0.50	0.20	0.47	0.16	1.32
		OD							
		IDet	180	171	0.40	0.17	0.39	0.08	1.13
		Total	542	514	0.47	0.20	0.45	0.08	1.32
Visit 10 (Week 8)	Daily	IDegAsp	362	340	0.51	0.20	0.48	0.13	1.36
		OD							
		IDet	180	171	0.41	0.17	0.41	0.07	1.16
		Total	542	511	0.48	0.20	0.45	0.07	1.36
Visit 11 (Week 9)	Daily	IDegAsp	362	335	0.51	0.21	0.48	0.13	1.39
		OD							
		IDet	180	166	0.41	0.18	0.41	0.09	1.18
		Total	542	501	0.48	0.20	0.45	0.09	1.39
Visit 12 (Week 10)	Daily	IDegAsp	362	339	0.52	0.21	0.48	0.13	1.39
		OD							
		IDet	180	169	0.42	0.18	0.42	0.09	1.16
		Total	542	508	0.48	0.20	0.46	0.09	1.39
Visit 13 (Week 11)	Daily	IDegAsp	362	334	0.52	0.21	0.48	0.15	1.43
		OD							
		IDet	180	167	0.42	0.19	0.42	0.09	1.18
		Total	542	501	0.49	0.21	0.46	0.09	1.43
Visit 14 (Week 12)	Daily	IDegAsp	362	335	0.51	0.21	0.47	0.16	1.46
		OD							
		IDet	180	168	0.42	0.18	0.41	0.03	1.18
		Total	542	503	0.48	0.21	0.45	0.03	1.46

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:30 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	324	0.52	0.22	0.48	0.15	1.46
		OD							
		IDet	180	162	0.43	0.18	0.42	0.03	1.21
		Total	542	486	0.49	0.21	0.45	0.03	1.46
Visit 16 (Week 14)	Daily	IDegAsp	362	332	0.52	0.22	0.47	0.12	1.41
		OD							
		IDet	180	166	0.43	0.18	0.41	0.06	1.24
		Total	542	498	0.49	0.21	0.46	0.06	1.41
Visit 17 (Week 15)	Daily	IDegAsp	362	327	0.52	0.22	0.48	0.15	1.40
		OD							
		IDet	180	164	0.43	0.18	0.41	0.09	1.26
		Total	542	491	0.49	0.21	0.45	0.09	1.40
Visit 18 (Week 16)	Daily	IDegAsp	362	330	0.52	0.22	0.47	0.09	1.40
		OD							
		IDet	180	164	0.43	0.19	0.41	0.07	1.28
		Total	542	494	0.49	0.21	0.45	0.07	1.40
Visit 19 (Week 17)	Daily	IDegAsp	362	322	0.52	0.22	0.48	0.15	1.37
		OD							
		IDet	180	162	0.43	0.19	0.41	0.07	1.31
		Total	542	484	0.49	0.21	0.46	0.07	1.37
Visit 20 (Week 18)	Daily	IDegAsp	362	321	0.52	0.22	0.48	0.12	1.37
		OD							
		IDet	180	158	0.44	0.20	0.43	0.06	1.34
		Total	542	479	0.50	0.22	0.46	0.06	1.37
Visit 21 (Week 19)	Daily	IDegAsp	362	319	0.52	0.22	0.49	0.15	1.37
		OD							
		IDet	180	162	0.45	0.20	0.43	0.05	1.34
		Total	542	481	0.50	0.22	0.46	0.05	1.37
Visit 22 (Week 20)	Daily	IDegAsp	362	322	0.53	0.23	0.49	0.14	1.37
		OD							
		IDet	180	158	0.44	0.20	0.41	0.05	1.34
		Total	542	480	0.50	0.22	0.46	0.05	1.37
Visit 23 (Week 21)	Daily	IDegAsp	362	320	0.53	0.22	0.48	0.13	1.37
		OD							
		IDet	180	157	0.45	0.20	0.41	0.05	1.34
		Total	542	477	0.50	0.22	0.46	0.05	1.37
Visit 24 (Week 22)	Daily	IDegAsp	362	318	0.53	0.23	0.48	0.15	1.38
		OD							
		IDet	180	156	0.45	0.21	0.43	0.06	1.34
		Total	542	474	0.50	0.22	0.46	0.06	1.38
Visit 25 (Week 23)	Daily	IDegAsp	362	320	0.53	0.23	0.48	0.12	1.41
		OD							
		IDet	180	151	0.45	0.21	0.43	0.07	1.34
		Total	542	471	0.51	0.23	0.46	0.07	1.41
Visit 26 (Week 24)	Daily	IDegAsp	362	319	0.53	0.23	0.48	0.15	1.44
		OD							
		IDet	180	158	0.46	0.21	0.43	0.08	1.34
		Total	542	477	0.51	0.23	0.46	0.08	1.44

N = Number of Subjects, SD = Standard Deviation

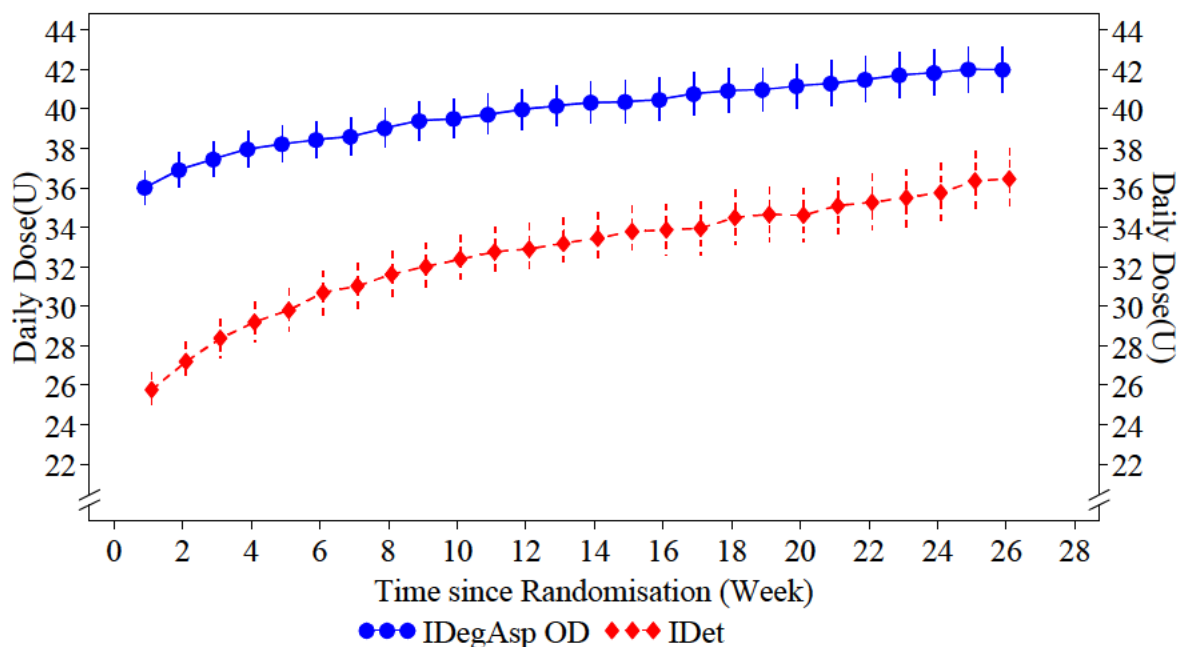
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:30 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics -
Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	0.54	0.23	0.49	0.15	1.44
		OD							
		IDet	180	155	0.47	0.22	0.43	0.09	1.34
		Total	542	473	0.51	0.23	0.47	0.09	1.44
Visit 28 (Week 26)	Daily	IDegAsp	362	320	0.53	0.23	0.49	0.15	1.46
		OD							
		IDet	180	157	0.47	0.23	0.43	0.09	1.37
		Total	542	477	0.51	0.23	0.47	0.09	1.46
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp	362	360	0.52	0.23	0.47	0.15	1.46
		OD							
		IDet	180	178	0.46	0.23	0.43	0.09	1.37
		Total	542	538	0.50	0.23	0.45	0.09	1.46

N = Number of Subjects, SD = Standard Deviation

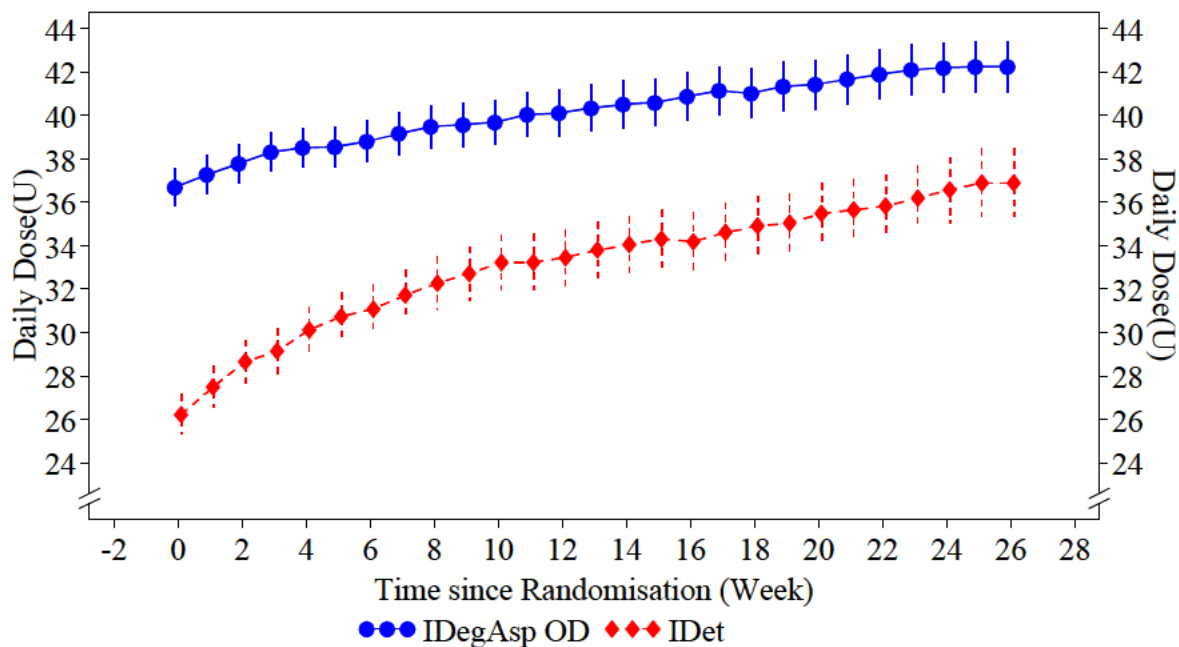
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:30 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_sas.txt



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:38 - finean_numfind_v03.sas/e_ins_dose_d_act_u_mean_locf_sas.cgm

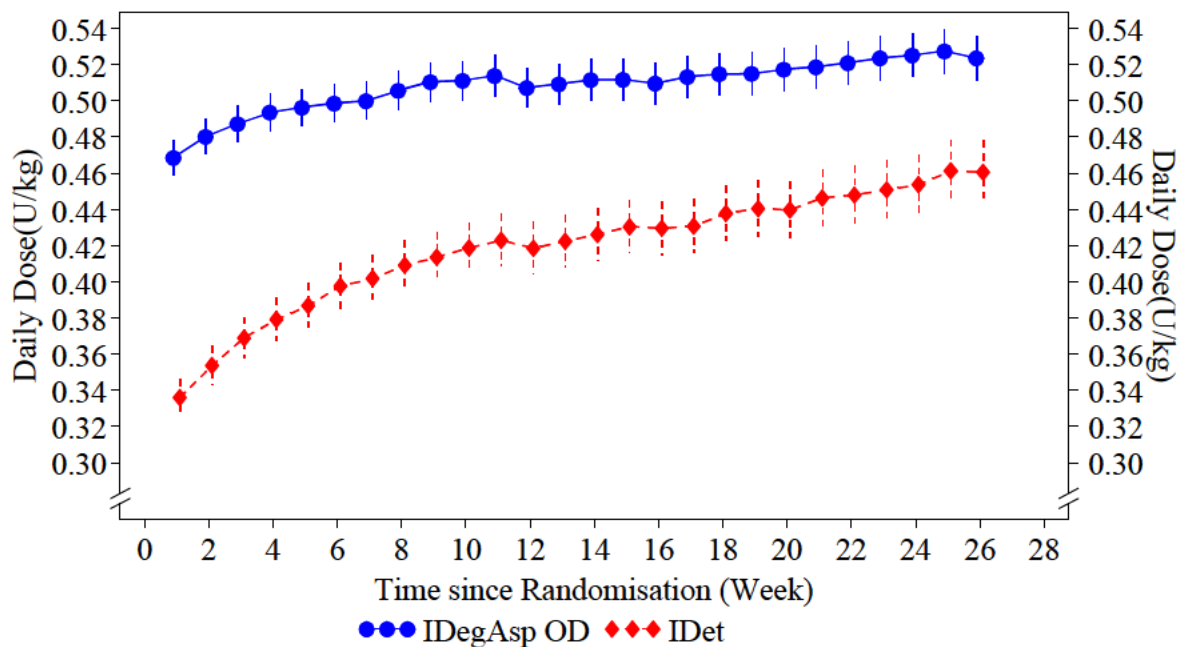
14.2.11: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:45 - fmean_numfind_v03.sas/e_ins_d_prscb_u_mean_locf_sas.cgm

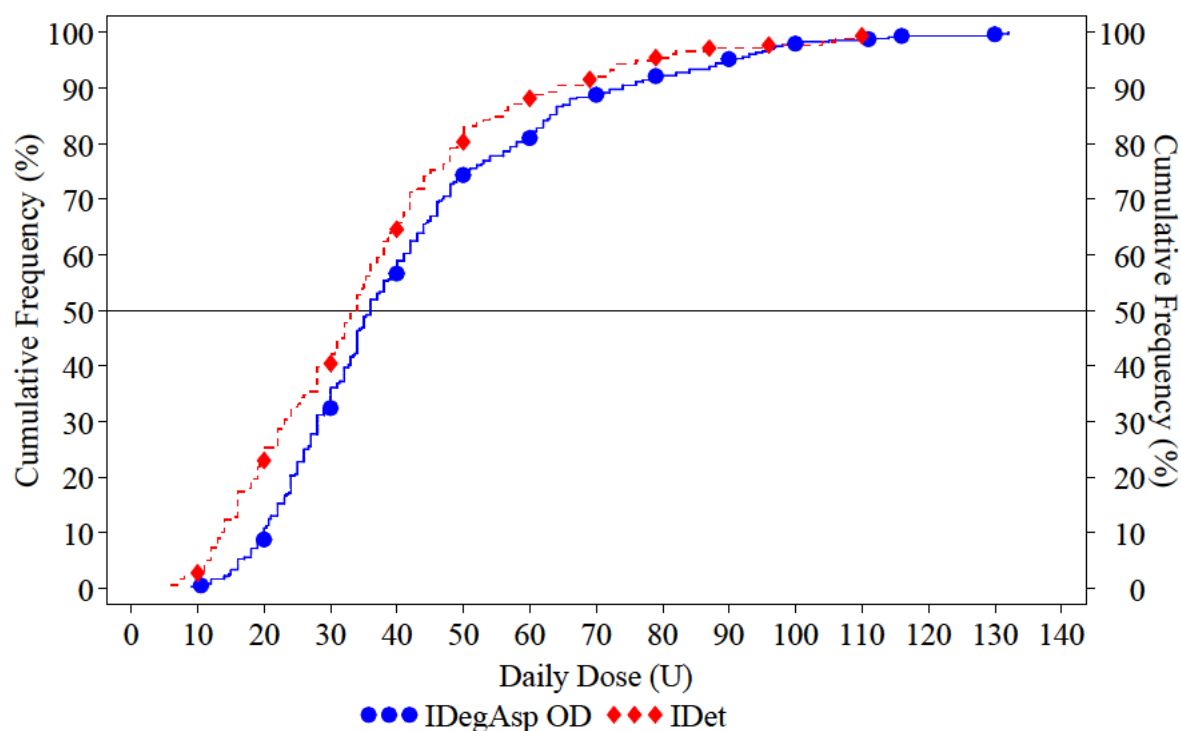
14.2.12: Daily IDegAsp/Comparator (Prescribed) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:52 - fmean_numfind_v03.sas/e_ins_d_act_ukg_mean_locf_sas.cgm

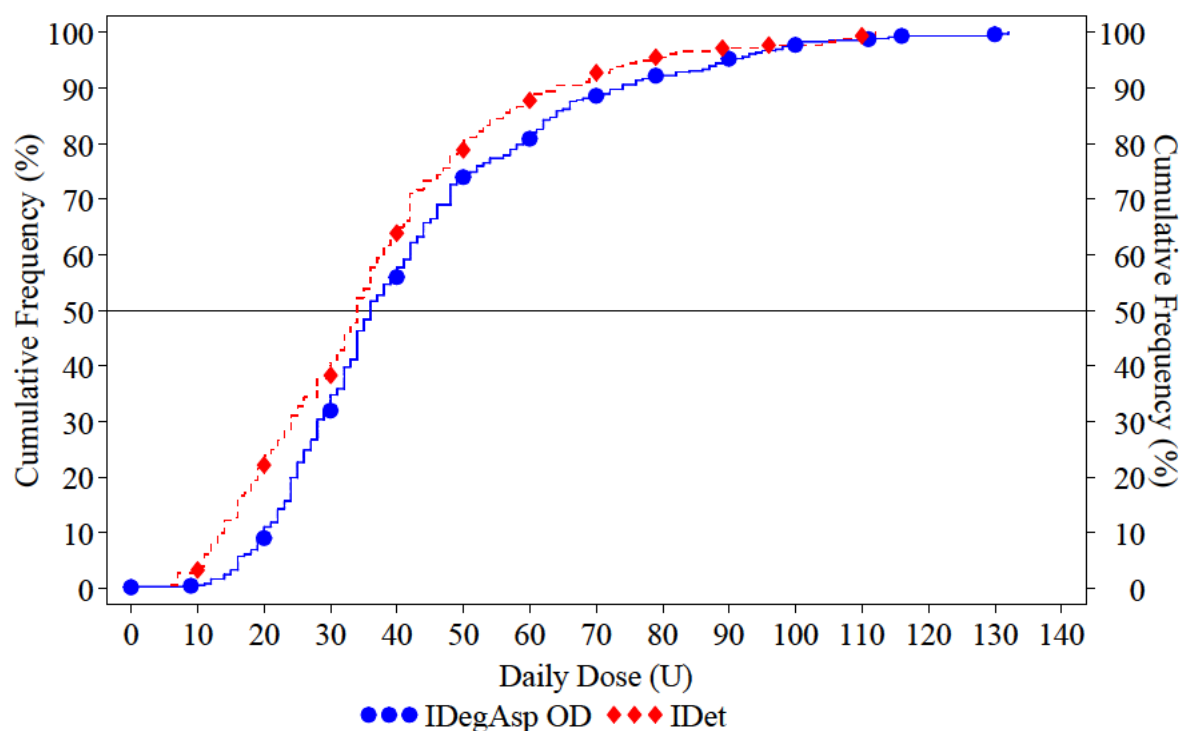
14.2.13: Daily IDegAsp/Comparator (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:39:58 - fedist_numfind_v01.sas/e_ins_dose_d_act_u_cdf_locf_sas.cgm

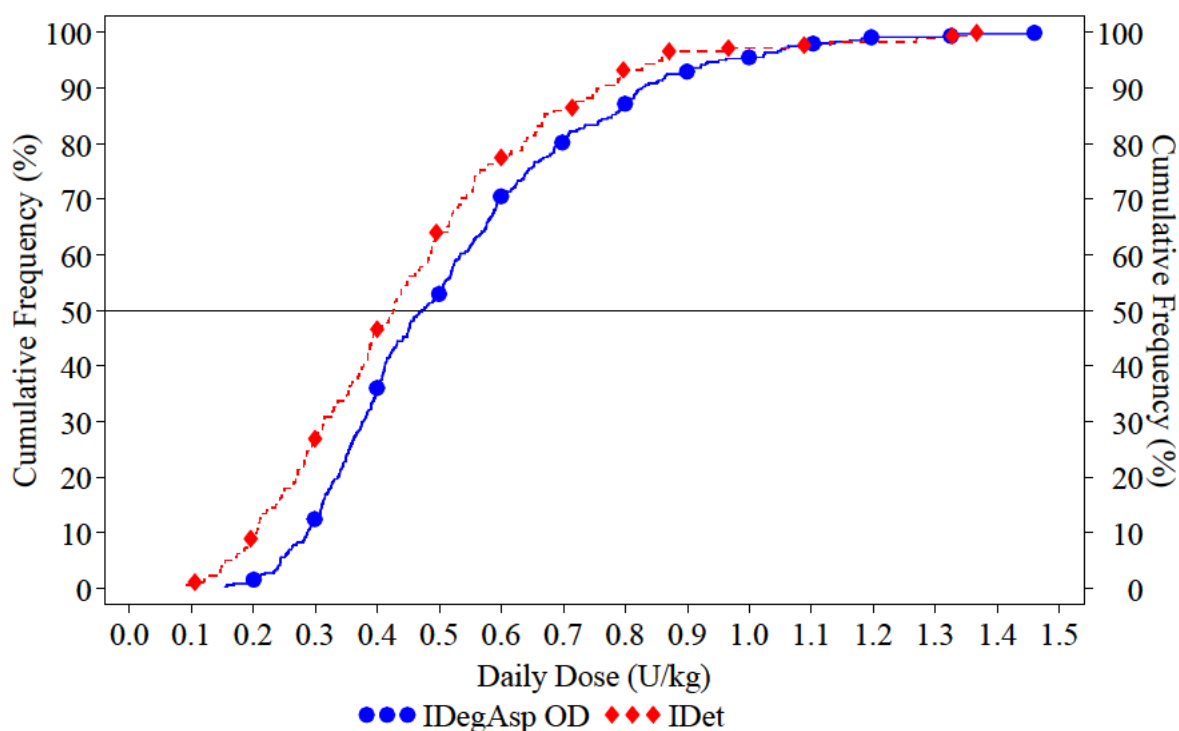
14.2.14: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:04 - fedist_numfind_v01.sas/e_ins_d_prscb_u_cdf_locf_sas.cgm

14.2.15: Daily IDegAsp/Comparator Insulin Dose (Prescribed) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:10 - fedist_numfind_v01.sas/e_ins_d_act_ukg_cdf_locf_sas.cgm

14.2.16: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.2.17: Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	21	13	18	2	100
		OD							
		IDet	180	176	30	15	28	5	130
Visit 4 (Week 2)	Daily	Total	542	536	24	14	20	2	130
		IDegAsp	362	359	21	13	19	1	110
		OD							
Visit 5 (Week 3)	Daily	IDet	180	177	32	16	29	8	132
		Total	542	536	24	15	21	1	132
		IDegAsp	362	346	22	13	19	0	108
Visit 6 (Week 4)	Daily	OD							
		IDet	180	175	34	17	30	6	138
		Total	542	521	26	16	23	0	138
Visit 7 (Week 5)	Daily	IDegAsp	362	352	22	14	19	2	115
		OD							
		IDet	180	174	36	19	32	9	142
Visit 8 (Week 6)	Daily	Total	542	526	27	17	24	2	142
		IDegAsp	362	349	22	14	19	0	113
		OD							
Visit 9 (Week 7)	Daily	IDet	180	173	37	20	33	5	158
		Total	542	522	27	17	24	0	158
		IDegAsp	362	344	23	14	19	1	115
Visit 10 (Week 8)	Daily	OD							
		IDet	180	173	37	22	32	6	158
		Total	542	517	28	18	24	1	158
Visit 11 (Week 9)	Daily	IDegAsp	362	343	23	15	18	0	115
		OD							
		IDet	180	171	38	22	34	5	158
Visit 12 (Week 10)	Daily	Total	542	514	28	19	23	0	158
		IDegAsp	362	340	23	16	19	2	120
		OD							
Visit 13 (Week 11)	Daily	IDet	180	171	39	22	36	5	130
		Total	542	511	29	19	24	2	130
		IDegAsp	362	336	24	16	20	2	120
Visit 14 (Week 12)	Daily	OD							
		IDet	180	166	39	23	34	7	140
		Total	542	502	29	20	24	2	140
Visit 15 (Week 13)	Daily	IDegAsp	362	340	24	16	19	3	120
		OD							
		IDet	180	169	39	23	34	7	146
Visit 16 (Week 14)	Daily	Total	542	509	29	20	24	3	146
		IDegAsp	362	335	25	16	20	2	105
		OD							
Visit 17 (Week 15)	Daily	IDet	180	167	39	23	34	8	153
		Total	542	502	29	20	25	2	153
		IDegAsp	362	336	25	17	19	4	124
Visit 18 (Week 16)	Daily	OD							
		IDet	180	168	39	23	34	7	163
		Total	542	504	30	20	25	4	163

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:18 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	325	25	18	19	3	124
		OD							
		IDet	180	161	40	24	34	8	170
		Total	542	486	30	21	24	3	170
Visit 16 (Week 14)	Daily	IDegAsp	362	333	25	18	19	4	126
		OD							
		IDet	180	166	40	25	33	6	177
		Total	542	499	30	22	25	4	177
Visit 17 (Week 15)	Daily	IDegAsp	362	328	25	18	19	3	132
		OD							
		IDet	180	164	40	26	33	5	182
		Total	542	492	30	22	25	3	182
Visit 18 (Week 16)	Daily	IDegAsp	362	331	26	19	20	3	138
		OD							
		IDet	180	164	40	26	34	4	181
		Total	542	495	30	22	26	3	181
Visit 19 (Week 17)	Daily	IDegAsp	362	324	26	19	20	3	132
		OD							
		IDet	180	161	40	27	35	6	187
		Total	542	485	31	23	25	3	187
Visit 20 (Week 18)	Daily	IDegAsp	362	323	25	19	20	3	120
		OD							
		IDet	180	157	41	28	34	5	203
		Total	542	480	30	23	25	3	203
Visit 21 (Week 19)	Daily	IDegAsp	362	321	26	19	20	2	120
		OD							
		IDet	180	162	41	30	34	3	201
		Total	542	483	31	24	25	2	201
Visit 22 (Week 20)	Daily	IDegAsp	362	324	26	20	21	2	139
		OD							
		IDet	180	158	41	31	33	6	207
		Total	542	482	31	25	24	2	207
Visit 23 (Week 21)	Daily	IDegAsp	362	321	26	20	20	3	139
		OD							
		IDet	180	156	41	31	34	3	204
		Total	542	477	31	25	24	3	204
Visit 24 (Week 22)	Daily	IDegAsp	362	319	27	20	20	3	139
		OD							
		IDet	180	156	41	32	34	3	213
		Total	542	475	31	25	25	3	213
Visit 25 (Week 23)	Daily	IDegAsp	362	320	27	20	20	2	132
		OD							
		IDet	180	151	42	33	34	4	220
		Total	542	471	32	26	25	2	220
Visit 26 (Week 24)	Daily	IDegAsp	362	319	27	21	21	3	132
		OD							
		IDet	180	158	42	33	34	6	224
		Total	542	477	32	27	25	3	224

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:18 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	27	21	21	3	134
		OD							
		IDet	180	155	42	34	35	3	234
		Total	542	473	32	27	25	3	234
Visit 28 (Week 26)	Daily	IDegAsp	362	320	28	21	21	4	134
		OD							
		IDet	180	157	43	35	34	4	244
		Total	542	477	33	28	26	4	244
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp	362	360	27	21	20	4	134
		OD							
		IDet	180	178	43	34	33	4	244
		Total	542	538	32	27	25	4	244

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:18 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

14.2.18: Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	362	360	25	11	22	7	83
		IDet	180	176	26	12	24	7	77
		Total	542	536	25	12	24	7	83
Visit 4 (Week 2)	Daily	IDegAsp OD	362	360	26	12	23	7	84
		IDet	180	178	27	13	26	4	79
		Total	542	538	26	12	24	4	84
Visit 5 (Week 3)	Daily	IDegAsp OD	362	360	26	12	24	7	84
		IDet	180	178	28	13	27	4	81
		Total	542	538	27	12	25	4	84
Visit 6 (Week 4)	Daily	IDegAsp OD	362	360	27	12	24	6	81
		IDet	180	178	29	14	28	4	83
		Total	542	538	27	13	25	4	83
Visit 7 (Week 5)	Daily	IDegAsp OD	362	360	27	12	24	6	81
		IDet	180	178	30	14	29	5	83
		Total	542	538	28	13	25	5	83
Visit 8 (Week 6)	Daily	IDegAsp OD	362	360	27	12	24	6	83
		IDet	180	178	31	15	30	5	85
		Total	542	538	28	13	26	5	85
Visit 9 (Week 7)	Daily	IDegAsp OD	362	360	27	13	25	7	83
		IDet	180	178	31	15	30	5	87
		Total	542	538	28	14	26	5	87
Visit 10 (Week 8)	Daily	IDegAsp OD	362	360	27	13	25	6	84
		IDet	180	178	32	16	30	5	87
		Total	542	538	29	14	26	5	87
Visit 11 (Week 9)	Daily	IDegAsp OD	362	360	28	13	25	6	87
		IDet	180	178	32	16	30	5	87
		Total	542	538	29	14	27	5	87
Visit 12 (Week 10)	Daily	IDegAsp OD	362	360	28	13	25	6	87
		IDet	180	178	32	16	31	5	87
		Total	542	538	29	14	27	5	87
Visit 13 (Week 11)	Daily	IDegAsp OD	362	360	28	13	25	7	90
		IDet	180	178	33	17	32	5	87
		Total	542	538	29	15	27	5	90
Visit 14 (Week 12)	Daily	IDegAsp OD	362	360	28	14	25	8	94
		IDet	180	178	33	17	30	2	87
		Total	542	538	30	15	27	2	94

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:25 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_u_descp_sas.txt

Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	360	28	14	25	7	94
		OD							
		IDet	180	178	33	17	32	2	92
		Total	542	538	30	15	27	2	94
Visit 16 (Week 14)	Daily	IDegAsp	362	360	28	14	25	6	91
		OD							
		IDet	180	178	33	17	32	4	94
		Total	542	538	30	15	27	4	94
Visit 17 (Week 15)	Daily	IDegAsp	362	360	28	14	25	6	87
		OD							
		IDet	180	178	34	17	32	5	100
		Total	542	538	30	15	27	5	100
Visit 18 (Week 16)	Daily	IDegAsp	362	360	28	14	25	4	90
		OD							
		IDet	180	178	34	18	32	4	102
		Total	542	538	30	16	27	4	102
Visit 19 (Week 17)	Daily	IDegAsp	362	360	29	14	25	7	91
		OD							
		IDet	180	178	34	18	32	4	104
		Total	542	538	30	16	27	4	104
Visit 20 (Week 18)	Daily	IDegAsp	362	360	29	15	25	6	88
		OD							
		IDet	180	178	35	18	32	5	108
		Total	542	538	31	16	27	5	108
Visit 21 (Week 19)	Daily	IDegAsp	362	360	29	15	25	6	88
		OD							
		IDet	180	178	35	18	33	4	101
		Total	542	538	31	16	27	4	101
Visit 22 (Week 20)	Daily	IDegAsp	362	360	29	15	25	7	91
		OD							
		IDet	180	178	35	18	32	4	100
		Total	542	538	31	16	27	4	100
Visit 23 (Week 21)	Daily	IDegAsp	362	360	29	15	25	6	92
		OD							
		IDet	180	178	35	19	32	4	104
		Total	542	538	31	17	27	4	104
Visit 24 (Week 22)	Daily	IDegAsp	362	360	29	15	25	6	92
		OD							
		IDet	180	178	35	19	33	5	98
		Total	542	538	31	17	27	5	98
Visit 25 (Week 23)	Daily	IDegAsp	362	360	29	15	25	6	92
		OD							
		IDet	180	178	35	19	33	6	102
		Total	542	538	31	17	27	6	102
Visit 26 (Week 24)	Daily	IDegAsp	362	360	29	15	25	6	92
		OD							
		IDet	180	178	36	20	33	6	106
		Total	542	538	31	17	28	6	106

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:25 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_u_descp_sas.txt

Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	360	29	15	25	6	94
		OD							
		IDet	180	178	36	20	34	6	110
		Total	542	538	32	17	28	6	110
Visit 28 (Week 26)	Daily	IDegAsp	362	360	29	15	25	6	92
		OD							
		IDet	180	178	36	21	34	6	111
		Total	542	538	32	18	28	6	111
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp	362	360	29	15	25	6	92
		OD							
		IDet	180	178	36	21	34	6	111
		Total	542	538	32	18	28	6	111

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:40:25 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_u_descp_sas.txt

14.2.19: Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.33	0.13	0.30	0.09	0.88
		OD							
		IDet	180	176	0.34	0.13	0.31	0.10	0.96
		Total	542	536	0.33	0.13	0.31	0.09	0.96
		IDegAsp	362	360	0.34	0.13	0.31	0.10	0.93
		OD							
Visit 4 (Week 2)	Daily	IDet	180	178	0.35	0.14	0.33	0.07	0.99
		Total	542	538	0.34	0.14	0.32	0.07	0.99
		IDegAsp	362	360	0.34	0.13	0.31	0.10	0.95
Visit 5 (Week 3)	Daily	OD							
		IDet	180	178	0.37	0.15	0.35	0.07	1.01
		Total	542	538	0.35	0.14	0.32	0.07	1.01
Visit 6 (Week 4)	Daily	IDegAsp	362	360	0.35	0.13	0.32	0.10	0.93
		OD							
		IDet	180	178	0.38	0.16	0.37	0.07	1.04
		Total	542	538	0.36	0.14	0.33	0.07	1.04
		IDegAsp	362	360	0.35	0.13	0.32	0.10	0.91
		OD							
Visit 7 (Week 5)	Daily	IDet	180	178	0.39	0.16	0.37	0.07	1.07
		Total	542	538	0.36	0.14	0.34	0.07	1.07
		IDegAsp	362	360	0.35	0.13	0.32	0.10	0.91
Visit 8 (Week 6)	Daily	OD							
		IDet	180	178	0.40	0.17	0.38	0.08	1.10
		Total	542	538	0.37	0.15	0.34	0.08	1.10
Visit 9 (Week 7)	Daily	IDegAsp	362	360	0.35	0.14	0.33	0.11	0.93
		OD							
		IDet	180	178	0.40	0.17	0.39	0.08	1.13
		Total	542	538	0.37	0.15	0.35	0.08	1.13
		IDegAsp	362	360	0.35	0.14	0.33	0.09	0.95
		OD							
Visit 10 (Week 8)	Daily	IDet	180	178	0.41	0.18	0.41	0.07	1.16
		Total	542	538	0.37	0.16	0.35	0.07	1.16
		IDegAsp	362	360	0.35	0.14	0.33	0.09	0.95
Visit 11 (Week 9)	Daily	OD							
		IDet	180	178	0.41	0.18	0.41	0.09	1.18
		Total	542	538	0.38	0.16	0.36	0.09	1.18
Visit 12 (Week 10)	Daily	IDegAsp	362	360	0.36	0.14	0.33	0.09	0.97
		OD							
		IDet	180	178	0.42	0.19	0.42	0.09	1.16
		Total	542	538	0.38	0.16	0.36	0.09	1.16
		IDegAsp	362	360	0.36	0.15	0.33	0.10	1.00
		OD							
Visit 13 (Week 11)	Daily	IDet	180	178	0.42	0.19	0.41	0.09	1.18
		Total	542	538	0.38	0.17	0.36	0.09	1.18
		IDegAsp	362	360	0.36	0.15	0.33	0.10	1.00
Visit 14 (Week 12)	Daily	OD							
		IDet	180	178	0.42	0.19	0.41	0.03	1.18
		Total	542	538	0.38	0.16	0.35	0.03	1.18

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:33 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_ukg_descp_sas.txt

Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	360	0.36	0.15	0.33	0.10	1.02
		OD							
		IDet	180	178	0.42	0.19	0.40	0.03	1.21
		Total	542	538	0.38	0.17	0.35	0.03	1.21
Visit 16 (Week 14)	Daily	IDegAsp	362	360	0.36	0.15	0.33	0.08	0.99
		OD							
		IDet	180	178	0.43	0.19	0.41	0.06	1.24
		Total	542	538	0.38	0.17	0.35	0.06	1.24
Visit 17 (Week 15)	Daily	IDegAsp	362	360	0.36	0.15	0.33	0.11	0.98
		OD							
		IDet	180	178	0.43	0.19	0.41	0.09	1.26
		Total	542	538	0.38	0.17	0.35	0.09	1.26
Visit 18 (Week 16)	Daily	IDegAsp	362	360	0.36	0.15	0.33	0.06	0.98
		OD							
		IDet	180	178	0.43	0.19	0.40	0.07	1.28
		Total	542	538	0.38	0.17	0.35	0.06	1.28
Visit 19 (Week 17)	Daily	IDegAsp	362	360	0.36	0.15	0.33	0.10	0.96
		OD							
		IDet	180	178	0.43	0.20	0.41	0.07	1.31
		Total	542	538	0.38	0.17	0.35	0.07	1.31
Visit 20 (Week 18)	Daily	IDegAsp	362	360	0.36	0.15	0.33	0.08	0.96
		OD							
		IDet	180	178	0.44	0.20	0.41	0.06	1.34
		Total	542	538	0.39	0.17	0.36	0.06	1.34
Visit 21 (Week 19)	Daily	IDegAsp	362	360	0.36	0.15	0.33	0.10	0.96
		OD							
		IDet	180	178	0.44	0.20	0.41	0.05	1.34
		Total	542	538	0.39	0.18	0.36	0.05	1.34
Visit 22 (Week 20)	Daily	IDegAsp	362	360	0.36	0.16	0.34	0.10	0.96
		OD							
		IDet	180	178	0.44	0.21	0.41	0.05	1.34
		Total	542	538	0.39	0.18	0.36	0.05	1.34
Visit 23 (Week 21)	Daily	IDegAsp	362	360	0.36	0.16	0.34	0.09	0.96
		OD							
		IDet	180	178	0.45	0.21	0.41	0.05	1.34
		Total	542	538	0.39	0.18	0.36	0.05	1.34
Visit 24 (Week 22)	Daily	IDegAsp	362	360	0.36	0.16	0.33	0.10	0.97
		OD							
		IDet	180	178	0.45	0.21	0.42	0.06	1.34
		Total	542	538	0.39	0.18	0.36	0.06	1.34
Visit 25 (Week 23)	Daily	IDegAsp	362	360	0.37	0.16	0.33	0.08	0.99
		OD							
		IDet	180	178	0.45	0.22	0.42	0.07	1.34
		Total	542	538	0.39	0.18	0.36	0.07	1.34
Visit 26 (Week 24)	Daily	IDegAsp	362	360	0.37	0.16	0.33	0.10	1.01
		OD							
		IDet	180	178	0.45	0.22	0.43	0.08	1.34
		Total	542	538	0.40	0.19	0.36	0.08	1.34

N = Number of Subjects, SD = Standard Deviation

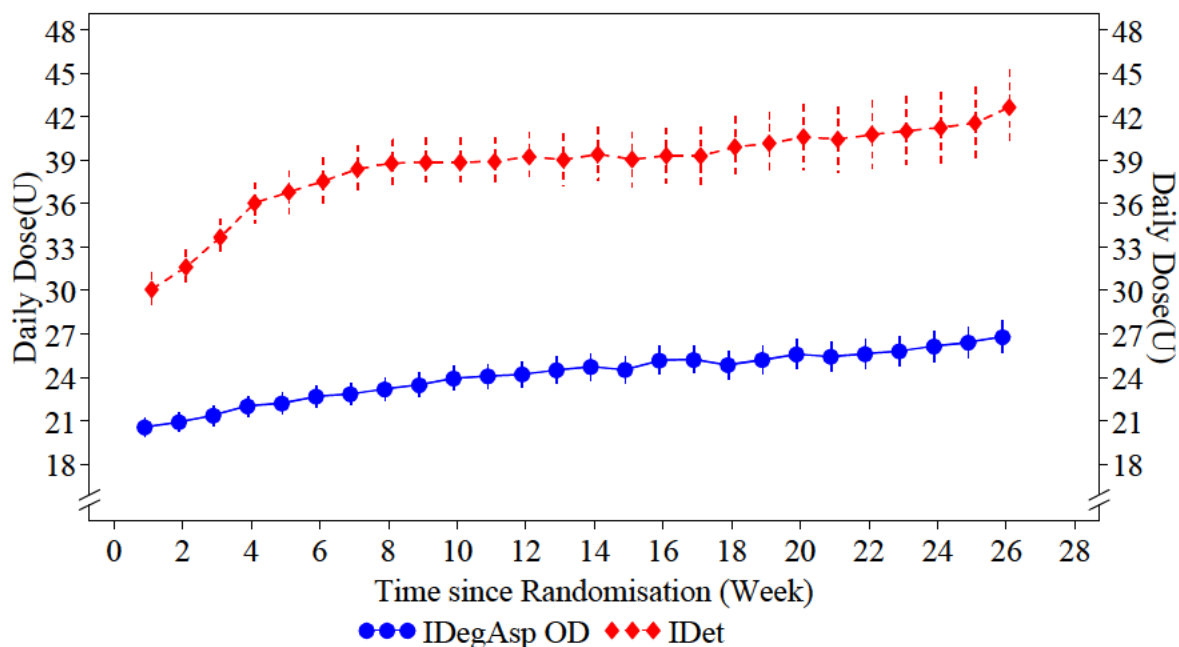
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:33 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_ukg_descp_sas.txt

Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	360	0.37	0.16	0.33	0.10	1.01
		OD							
		IDet	180	178	0.46	0.23	0.43	0.09	1.34
		Total	542	538	0.40	0.19	0.37	0.09	1.34
Visit 28 (Week 26)	Daily	IDegAsp	362	360	0.37	0.16	0.33	0.11	1.02
		OD							
		IDet	180	178	0.46	0.23	0.43	0.09	1.37
		Total	542	538	0.40	0.19	0.36	0.09	1.37
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp	362	360	0.37	0.16	0.33	0.11	1.02
		OD							
		IDet	180	178	0.46	0.23	0.43	0.09	1.37
		Total	542	538	0.40	0.19	0.36	0.09	1.37

N = Number of Subjects, SD = Standard Deviation

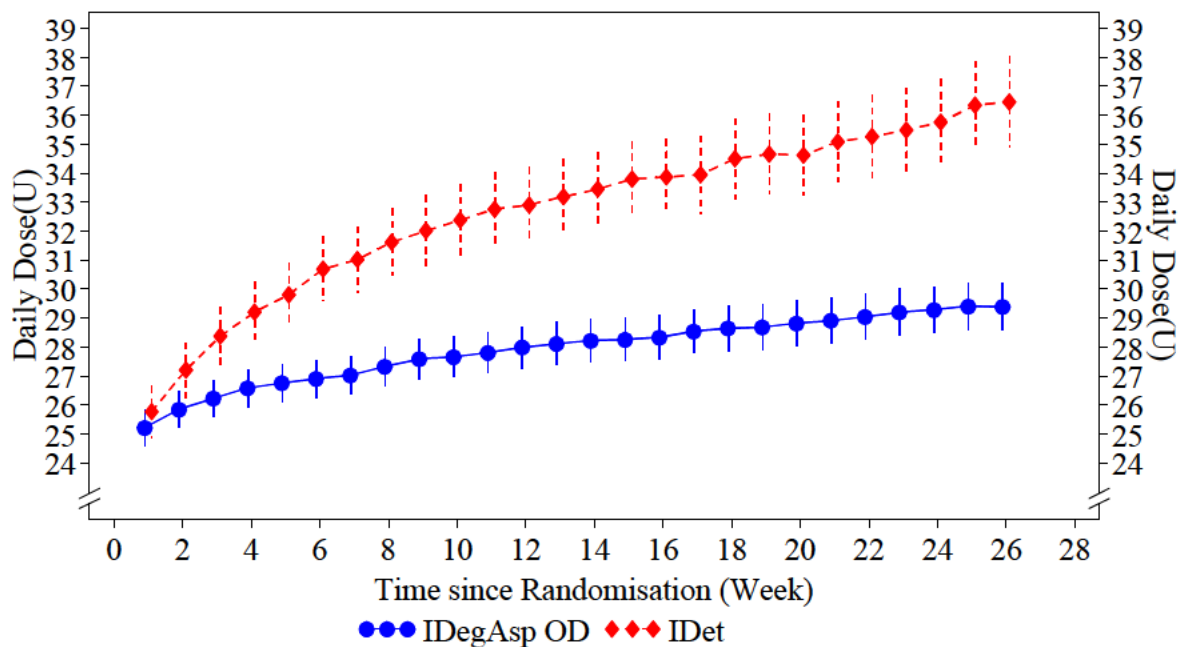
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:33 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_ukg_descp_sas.txt



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:40 - finean_numfind_v03.sas/e_b_dose_d_act_u_mean_locf_sas.cgm

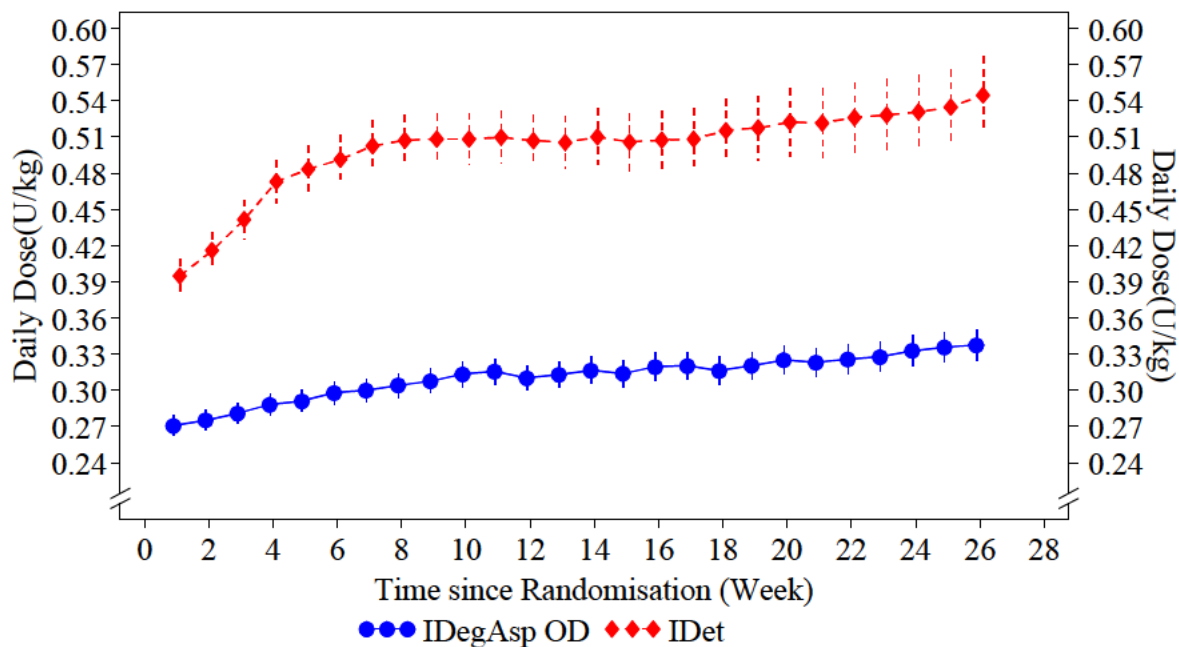
14.2.20: Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:40:47 - finean_numfind_v03.sas/e_basal_act_u_mean_locf_sas.cgm

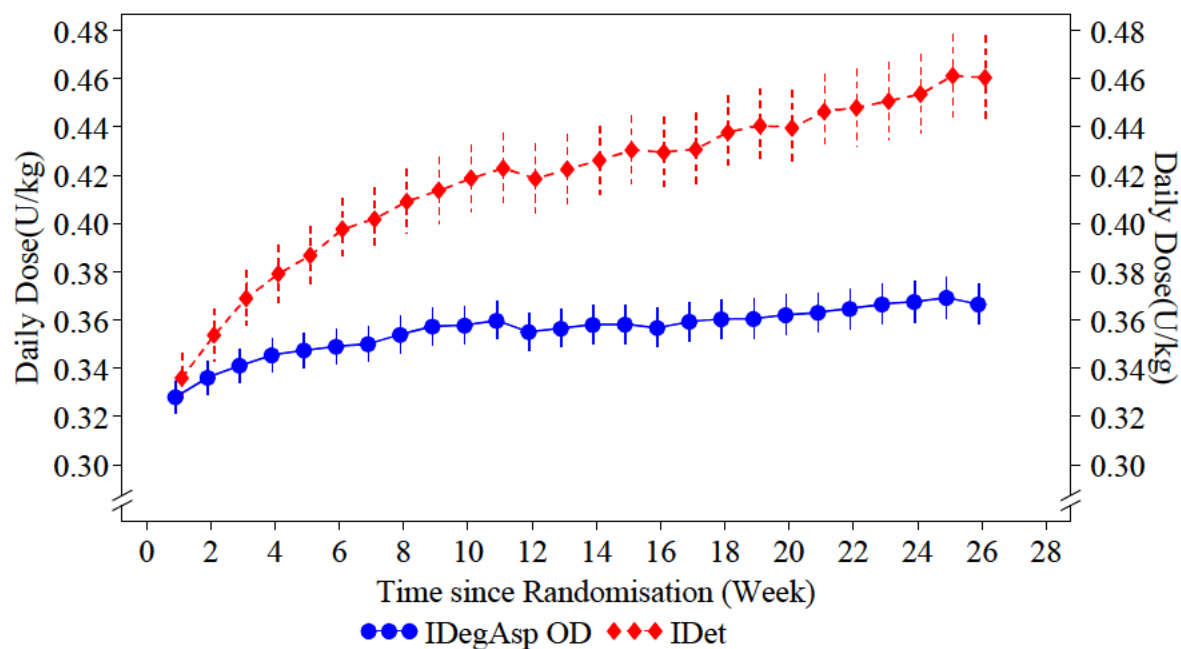
14.2.21: Basal Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

28APR2011:12:40:54 - fmean_numfind_v03.sas/e_b_dose_d_act_ukg_mean_locf_sas.cgm
nn5401/nn5401-3594/freeze_ctr_05/stats

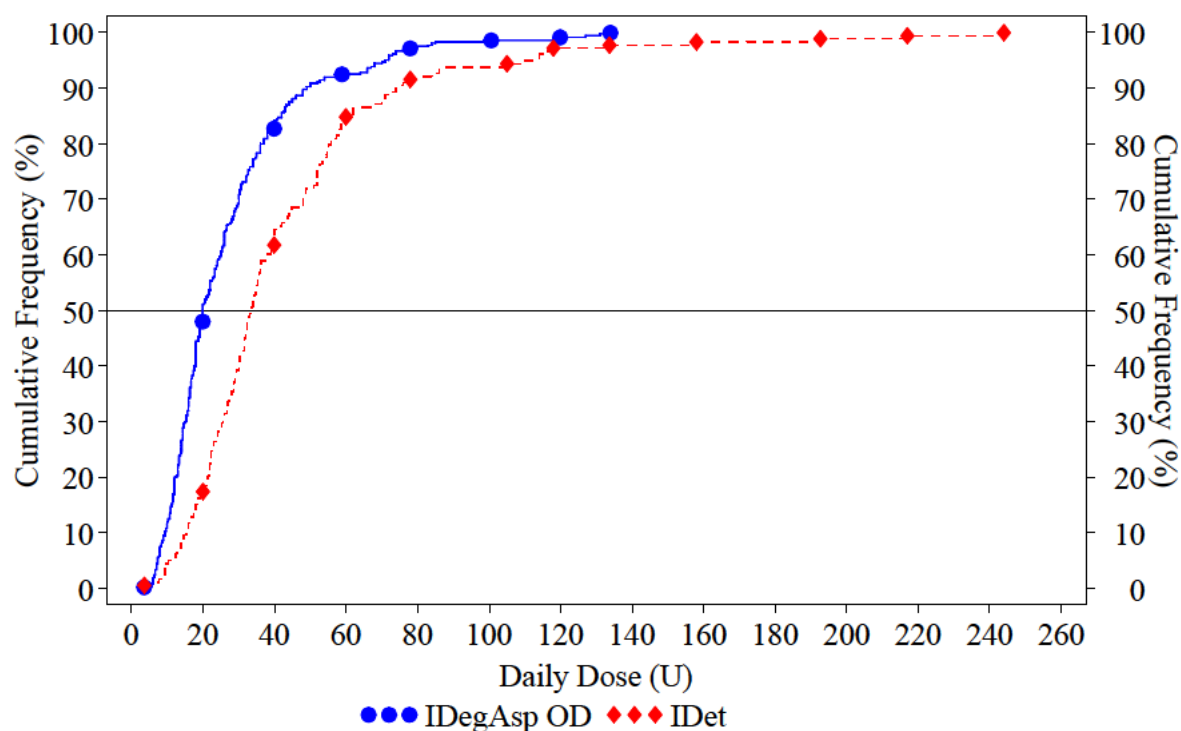
14.2.22: Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:01 - fmean_numfind_v03.sas/e_basal_act_ukg_mean_locf_sas.cgm

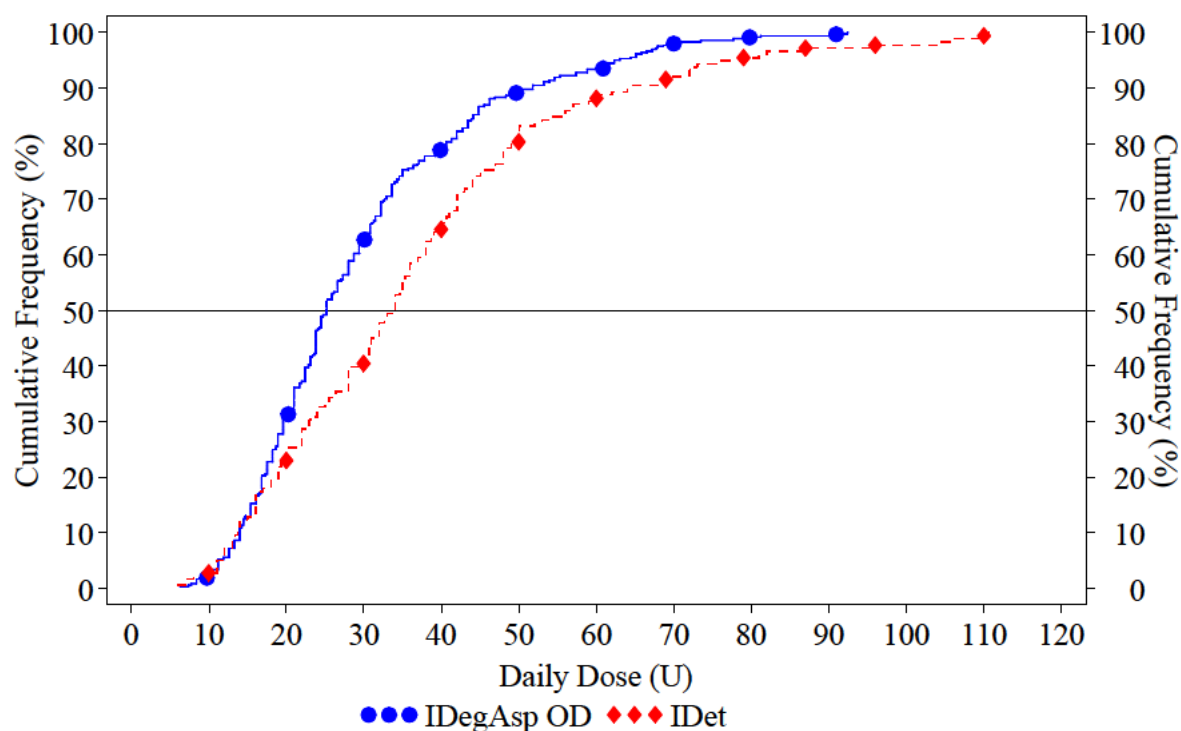
14.2.23: Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:07 - fedist_numfind_v01.sas/e_b_dose_d_act_u_cdf_locf_sas.cgm

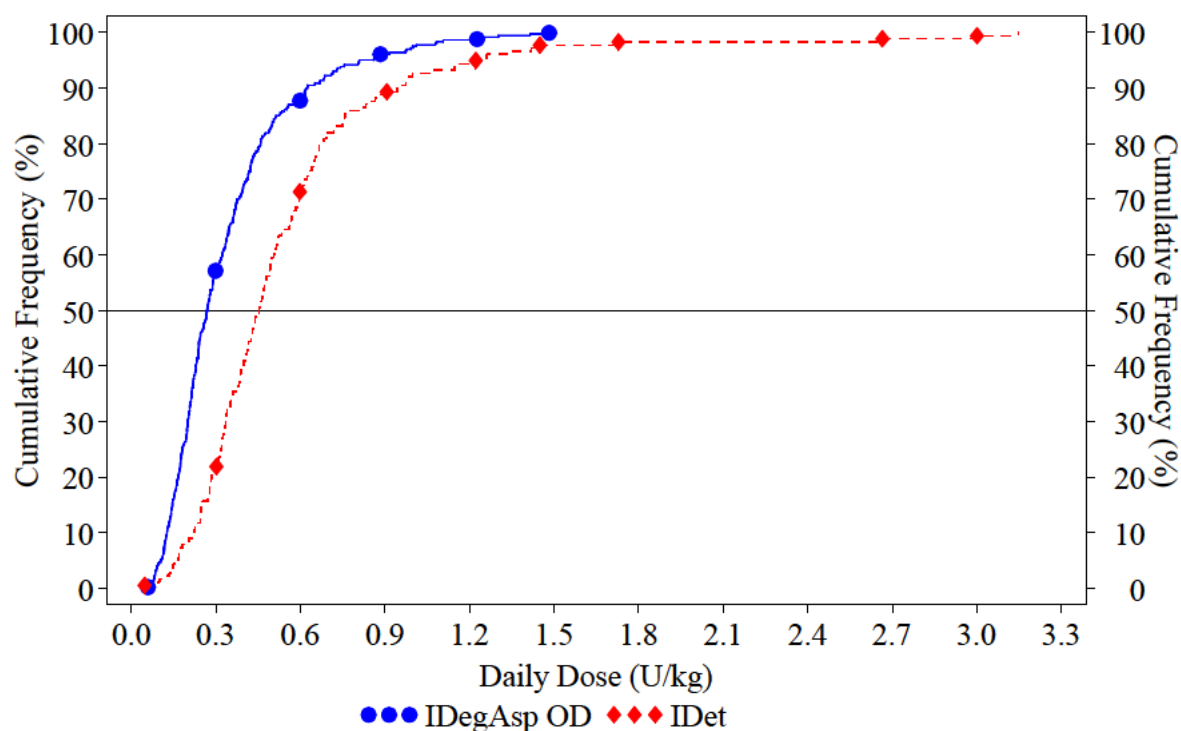
14.2.24: Daily Bolus Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:13 - fedist_numfind_v01.sas/e_basal_d_act_u_cdf_locf_sas.cgm

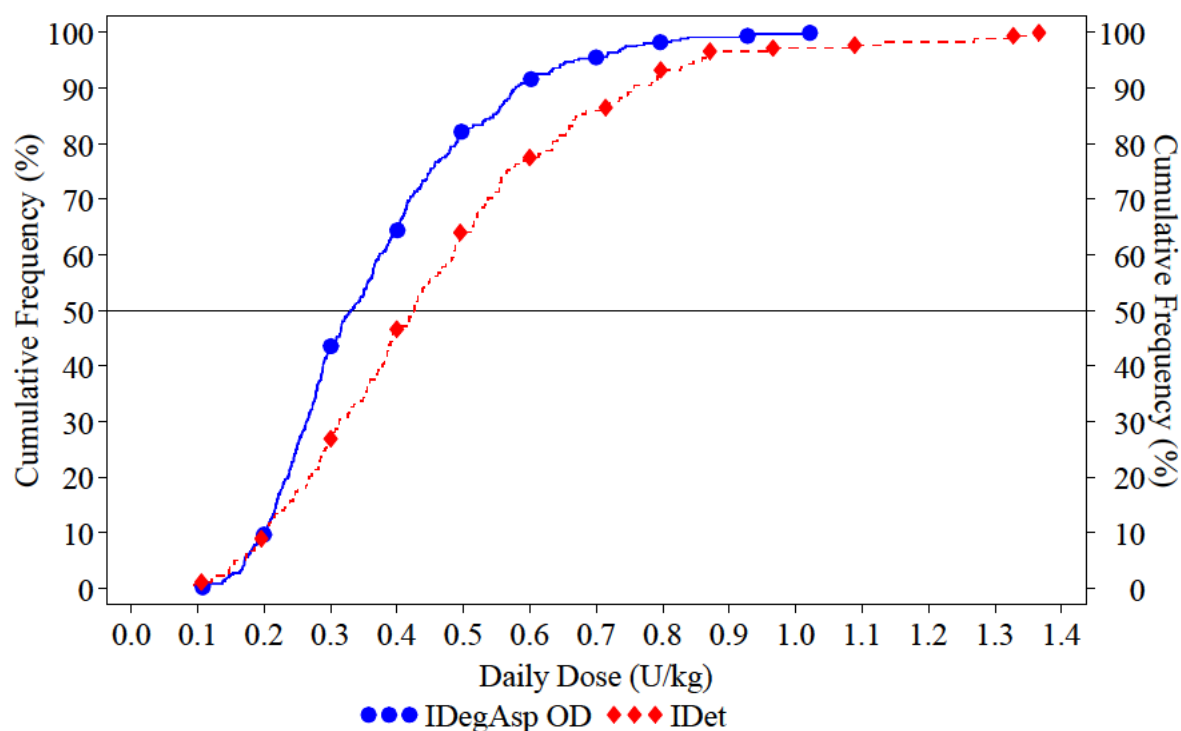
14.2.25: Basal Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:19 - fedist_numfind_v01.sas/e_b_dose_d_act_ukg_cdf_locf_sas.cgm

14.2.26: Daily Bolus Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:25 - fedist_numfind_v01.sas/e_basal_d_act_ukg_cdf_locf_sas.cgm

14.2.27: Basal Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.2.28: Total Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	56	24	51	16	184
		OD							
		IDet	180	176	56	22	52	15	156
		Total	542	536	56	23	52	15	184
		IDegAsp	362	359	58	25	52	14	202
		OD							
Visit 4 (Week 2)	Daily	IDet	180	177	59	23	54	12	160
		Total	542	536	58	25	53	12	202
		IDegAsp	362	346	59	26	53	15	204
Visit 5 (Week 3)	Daily	OD							
		IDet	180	175	62	26	58	12	168
		Total	542	521	60	26	55	12	204
Visit 6 (Week 4)	Daily	IDegAsp	362	352	60	27	54	14	221
		OD							
		IDet	180	174	65	28	61	14	174
		Total	542	526	62	27	56	14	221
		IDegAsp	362	349	61	28	54	15	221
		OD							
Visit 7 (Week 5)	Daily	IDet	180	173	66	29	62	16	192
		Total	542	522	62	28	56	15	221
		IDegAsp	362	344	62	29	54	14	227
Visit 8 (Week 6)	Daily	OD							
		IDet	180	173	68	31	63	16	194
		Total	542	517	64	29	58	14	227
Visit 9 (Week 7)	Daily	IDegAsp	362	343	62	29	54	14	231
		OD							
		IDet	180	171	69	32	65	17	194
		Total	542	514	64	30	57	14	231
		IDegAsp	362	340	63	31	54	13	238
		OD							
Visit 10 (Week 8)	Daily	IDet	180	171	70	32	66	17	195
		Total	542	511	65	31	58	13	238
		IDegAsp	362	336	64	32	56	15	242
Visit 11 (Week 9)	Daily	OD							
		IDet	180	166	71	33	67	17	203
		Total	542	502	66	32	59	15	242
Visit 12 (Week 10)	Daily	IDegAsp	362	340	64	32	55	13	241
		OD							
		IDet	180	169	72	33	67	17	207
		Total	542	509	67	33	60	13	241
		IDegAsp	362	335	65	32	56	13	200
		OD							
Visit 13 (Week 11)	Daily	IDet	180	167	72	34	67	17	215
		Total	542	502	67	33	59	13	215
		IDegAsp	362	336	65	34	56	12	246
Visit 14 (Week 12)	Daily	OD							
		IDet	180	168	72	34	64	16	227
		Total	542	504	67	34	59	12	246

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:33 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_u_descp_sas.txt

Total Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	325	66	35	57	9	246
		OD							
		IDet	180	162	73	35	66	16	236
		Total	542	487	68	35	60	9	246
Visit 16 (Week 14)	Daily	IDegAsp	362	333	66	35	58	11	248
		OD							
		IDet	180	166	73	36	67	16	245
		Total	542	499	69	36	60	11	248
Visit 17 (Week 15)	Daily	IDegAsp	362	328	66	36	57	15	256
		OD							
		IDet	180	164	74	37	67	17	252
		Total	542	492	69	36	60	15	256
Visit 18 (Week 16)	Daily	IDegAsp	362	331	67	36	57	14	266
		OD							
		IDet	180	164	73	37	68	16	255
		Total	542	495	69	37	61	14	266
Visit 19 (Week 17)	Daily	IDegAsp	362	324	68	37	58	13	262
		OD							
		IDet	180	162	74	39	68	18	263
		Total	542	486	70	38	61	13	263
Visit 20 (Week 18)	Daily	IDegAsp	362	323	67	36	57	9	244
		OD							
		IDet	180	158	76	40	69	17	279
		Total	542	481	70	38	61	9	279
Visit 21 (Week 19)	Daily	IDegAsp	362	321	67	36	58	11	244
		OD							
		IDet	180	162	76	42	68	17	277
		Total	542	483	70	38	61	11	277
Visit 22 (Week 20)	Daily	IDegAsp	362	324	68	38	58	12	269
		OD							
		IDet	180	158	76	43	67	18	285
		Total	542	482	71	40	62	12	285
Visit 23 (Week 21)	Daily	IDegAsp	362	321	68	38	56	10	271
		OD							
		IDet	180	157	76	43	66	19	289
		Total	542	478	71	40	59	10	289
Visit 24 (Week 22)	Daily	IDegAsp	362	319	69	39	58	9	271
		OD							
		IDet	180	156	77	44	68	18	297
		Total	542	475	72	41	62	9	297
Visit 25 (Week 23)	Daily	IDegAsp	362	320	70	39	58	11	264
		OD							
		IDet	180	151	78	46	68	17	306
		Total	542	471	72	41	60	11	306
Visit 26 (Week 24)	Daily	IDegAsp	362	319	70	40	59	13	264
		OD							
		IDet	180	158	79	46	69	17	312
		Total	542	477	73	42	63	13	312

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:33 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_u_descp_sas.txt

Total Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	70	40	58	12	268
		OD							
		IDet	180	155	80	48	68	18	334
		Total	542	473	73	43	62	12	334
Visit 28 (Week 26)	Daily	IDegAsp	362	320	71	41	58	13	266
		OD							
		IDet	180	157	81	50	70	19	350
		Total	542	477	74	44	62	13	350
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp	362	360	69	40	57	13	266
		OD							
		IDet	180	178	79	48	68	19	350
		Total	542	538	72	43	60	13	350

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:41:33 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_u_descp_sas.txt

14.2.29: Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	31	15	28	8	124
		OD							
		IDet	180	176	30	15	28	5	130
		Total	542	536	31	15	28	5	130
		IDegAsp	362	360	32	15	28	7	138
		OD							
Visit 4 (Week 2)	Daily	IDet	180	178	32	16	29	8	132
		Total	542	538	32	15	28	7	138
		IDegAsp	362	360	33	16	29	8	137
Visit 5 (Week 3)	Daily	OD							
		IDet	180	178	34	17	30	6	138
		Total	542	538	33	16	29	6	138
Visit 6 (Week 4)	Daily	IDegAsp	362	360	33	17	29	8	147
		OD							
		IDet	180	178	36	19	32	9	142
		Total	542	538	34	17	30	8	147
		IDegAsp	362	360	34	17	30	7	145
		OD							
Visit 7 (Week 5)	Daily	IDet	180	178	37	20	33	5	158
		Total	542	538	35	18	31	5	158
		IDegAsp	362	360	34	18	30	5	149
Visit 8 (Week 6)	Daily	OD							
		IDet	180	178	38	22	32	6	158
		Total	542	538	35	19	31	5	158
Visit 9 (Week 7)	Daily	IDegAsp	362	360	34	18	30	5	150
		OD							
		IDet	180	178	38	22	34	5	158
		Total	542	538	36	20	31	5	158
		IDegAsp	362	360	35	19	30	6	155
		OD							
Visit 10 (Week 8)	Daily	IDet	180	178	39	22	35	5	130
		Total	542	538	36	20	31	5	155
		IDegAsp	362	360	35	20	30	7	157
Visit 11 (Week 9)	Daily	OD							
		IDet	180	178	39	22	34	7	140
		Total	542	538	36	21	32	7	157
Visit 12 (Week 10)	Daily	IDegAsp	362	360	36	20	30	6	156
		OD							
		IDet	180	178	39	22	34	7	146
		Total	542	538	37	21	31	6	156
		IDegAsp	362	360	36	20	30	9	132
		OD							
Visit 13 (Week 11)	Daily	IDet	180	178	39	22	33	8	153
		Total	542	538	37	21	31	8	153
		IDegAsp	362	360	36	21	29	8	161
Visit 14 (Week 12)	Daily	OD							
		IDet	180	178	39	23	34	7	163
		Total	542	538	37	22	31	7	163

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:41 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_u_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	360	37	22	30	8	161
		OD							
		IDet	180	178	39	24	33	8	170
		Total	542	538	37	22	31	8	170
		IDegAsp	362	360	37	22	30	8	163
		OD							
Visit 16 (Week 14)	Daily	IDet	180	178	39	25	33	6	177
		Total	542	538	38	23	31	6	177
		IDegAsp	362	360	37	22	30	7	169
Visit 17 (Week 15)	Daily	OD							
		IDet	180	178	39	26	32	5	182
		Total	542	538	37	24	31	5	182
Visit 18 (Week 16)	Daily	IDegAsp	362	360	37	23	30	6	176
		OD							
		IDet	180	178	39	26	33	4	181
		Total	542	538	38	24	32	4	181
		IDegAsp	362	360	37	23	31	7	171
		OD							
Visit 19 (Week 17)	Daily	IDet	180	178	39	27	34	6	187
		Total	542	538	38	24	32	6	187
		IDegAsp	362	360	37	23	30	7	157
Visit 20 (Week 18)	Daily	OD							
		IDet	180	178	40	28	34	5	203
		Total	542	538	38	25	31	5	203
Visit 21 (Week 19)	Daily	IDegAsp	362	360	38	23	31	4	157
		OD							
		IDet	180	178	40	29	34	3	201
		Total	542	538	38	25	31	3	201
		IDegAsp	362	360	38	24	31	5	178
		OD							
Visit 22 (Week 20)	Daily	IDet	180	178	41	30	33	6	207
		Total	542	538	39	26	31	5	207
		IDegAsp	362	360	38	24	30	5	179
Visit 23 (Week 21)	Daily	OD							
		IDet	180	178	40	30	33	3	204
		Total	542	538	39	26	31	3	204
Visit 24 (Week 22)	Daily	IDegAsp	362	360	38	25	31	6	179
		OD							
		IDet	180	178	41	31	34	3	213
		Total	542	538	39	27	31	3	213
		IDegAsp	362	360	38	25	31	5	172
		OD							
Visit 25 (Week 23)	Daily	IDet	180	178	41	32	34	4	220
		Total	542	538	39	27	32	4	220
		IDegAsp	362	360	39	25	32	7	172
Visit 26 (Week 24)	Daily	OD							
		IDet	180	178	41	32	34	6	224
		Total	542	538	40	28	32	6	224

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:41 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_u_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	360	39	25	31	6	174
		OD							
		IDet	180	178	42	33	34	3	234
		Total	542	538	40	28	32	3	234
Visit 28 (Week 26)	Daily	IDegAsp	362	360	39	26	31	6	174
		OD							
		IDet	180	178	43	34	33	4	244
		Total	542	538	40	29	32	4	244
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp	362	360	39	26	31	6	174
		OD							
		IDet	180	178	43	34	33	4	244
		Total	542	538	40	29	32	4	244

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:41:41 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_u_descp_sas.txt

14.2.30: Total Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.74	0.28	0.68	0.19	2.74
		OD							
		IDet	180	176	0.73	0.25	0.69	0.27	2.11
		Total	542	536	0.73	0.27	0.69	0.19	2.74
Visit 4 (Week 2)	Daily	IDegAsp	362	359	0.76	0.29	0.71	0.21	2.79
		OD							
		IDet	180	177	0.77	0.27	0.72	0.21	2.16
		Total	542	536	0.76	0.28	0.71	0.21	2.79
Visit 5 (Week 3)	Daily	IDegAsp	362	346	0.77	0.30	0.71	0.22	2.75
		OD							
		IDet	180	175	0.81	0.31	0.76	0.22	2.27
		Total	542	521	0.78	0.30	0.73	0.22	2.75
Visit 6 (Week 4)	Daily	IDegAsp	362	352	0.78	0.31	0.73	0.25	2.85
		OD							
		IDet	180	174	0.85	0.32	0.79	0.26	2.35
		Total	542	526	0.81	0.31	0.76	0.25	2.85
Visit 7 (Week 5)	Daily	IDegAsp	362	349	0.79	0.31	0.75	0.24	2.83
		OD							
		IDet	180	173	0.86	0.34	0.82	0.29	2.60
		Total	542	522	0.81	0.33	0.76	0.24	2.83
Visit 8 (Week 6)	Daily	IDegAsp	362	344	0.80	0.33	0.74	0.19	2.84
		OD							
		IDet	180	173	0.88	0.36	0.83	0.30	2.62
		Total	542	517	0.83	0.34	0.78	0.19	2.84
Visit 9 (Week 7)	Daily	IDegAsp	362	343	0.80	0.34	0.75	0.19	2.85
		OD							
		IDet	180	171	0.90	0.38	0.85	0.30	2.69
		Total	542	514	0.84	0.35	0.79	0.19	2.85
Visit 10 (Week 8)	Daily	IDegAsp	362	340	0.82	0.35	0.75	0.18	2.93
		OD							
		IDet	180	171	0.91	0.38	0.87	0.31	2.82
		Total	542	511	0.85	0.36	0.80	0.18	2.93
Visit 11 (Week 9)	Daily	IDegAsp	362	336	0.82	0.36	0.75	0.20	3.02
		OD							
		IDet	180	166	0.92	0.39	0.87	0.31	2.93
		Total	542	502	0.86	0.37	0.80	0.20	3.02
Visit 12 (Week 10)	Daily	IDegAsp	362	340	0.83	0.37	0.76	0.17	3.09
		OD							
		IDet	180	169	0.93	0.40	0.86	0.31	2.99
		Total	542	509	0.86	0.38	0.80	0.17	3.09
Visit 13 (Week 11)	Daily	IDegAsp	362	335	0.84	0.37	0.76	0.22	3.08
		OD							
		IDet	180	167	0.94	0.41	0.86	0.31	3.11
		Total	542	502	0.87	0.39	0.81	0.22	3.11
Visit 14 (Week 12)	Daily	IDegAsp	362	336	0.82	0.37	0.74	0.19	2.90
		OD							
		IDet	180	168	0.92	0.39	0.83	0.30	3.13
		Total	542	504	0.86	0.38	0.79	0.19	3.13

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:49 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_ukg_descp_sas.txt

Total Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	325	0.83	0.39	0.75	0.15	3.03
		OD							
		IDet	180	162	0.93	0.40	0.86	0.29	3.24
		Total	542	487	0.87	0.39	0.79	0.15	3.24
Visit 16 (Week 14)	Daily	IDegAsp	362	333	0.84	0.39	0.75	0.18	2.98
		OD							
		IDet	180	166	0.94	0.41	0.85	0.29	3.36
		Total	542	499	0.87	0.40	0.80	0.18	3.36
Visit 17 (Week 15)	Daily	IDegAsp	362	328	0.84	0.39	0.75	0.25	2.99
		OD							
		IDet	180	164	0.94	0.43	0.85	0.29	3.47
		Total	542	492	0.87	0.41	0.79	0.25	3.47
Visit 18 (Week 16)	Daily	IDegAsp	362	331	0.84	0.39	0.74	0.25	2.99
		OD							
		IDet	180	164	0.94	0.43	0.86	0.28	3.56
		Total	542	495	0.87	0.41	0.78	0.25	3.56
Visit 19 (Week 17)	Daily	IDegAsp	362	324	0.85	0.40	0.75	0.18	2.93
		OD							
		IDet	180	162	0.95	0.46	0.84	0.30	3.67
		Total	542	486	0.88	0.42	0.80	0.18	3.67
Visit 20 (Week 18)	Daily	IDegAsp	362	323	0.84	0.40	0.74	0.13	2.90
		OD							
		IDet	180	158	0.96	0.47	0.88	0.29	3.78
		Total	542	481	0.88	0.43	0.79	0.13	3.78
Visit 21 (Week 19)	Daily	IDegAsp	362	321	0.85	0.40	0.75	0.17	2.90
		OD							
		IDet	180	162	0.97	0.49	0.87	0.28	3.87
		Total	542	483	0.89	0.43	0.80	0.17	3.87
Visit 22 (Week 20)	Daily	IDegAsp	362	324	0.85	0.41	0.76	0.17	2.90
		OD							
		IDet	180	158	0.96	0.50	0.88	0.30	3.95
		Total	542	482	0.89	0.45	0.80	0.17	3.95
Visit 23 (Week 21)	Daily	IDegAsp	362	321	0.85	0.42	0.74	0.14	2.90
		OD							
		IDet	180	157	0.97	0.50	0.88	0.30	4.04
		Total	542	478	0.89	0.45	0.81	0.14	4.04
Visit 24 (Week 22)	Daily	IDegAsp	362	319	0.87	0.42	0.76	0.13	2.90
		OD							
		IDet	180	156	0.97	0.52	0.88	0.29	4.12
		Total	542	475	0.90	0.46	0.81	0.13	4.12
Visit 25 (Week 23)	Daily	IDegAsp	362	320	0.87	0.42	0.76	0.20	2.90
		OD							
		IDet	180	151	0.99	0.53	0.88	0.31	4.20
		Total	542	471	0.91	0.46	0.80	0.20	4.20
Visit 26 (Week 24)	Daily	IDegAsp	362	319	0.88	0.43	0.76	0.23	2.90
		OD							
		IDet	180	158	1.00	0.54	0.87	0.31	4.29
		Total	542	477	0.92	0.47	0.81	0.23	4.29

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:49 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_ukg_descp_sas.txt

Total Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	0.88	0.44	0.77	0.22	2.94
		OD							
		IDet	180	155	1.01	0.56	0.86	0.29	4.29
		Total	542	473	0.92	0.48	0.81	0.22	4.29
Visit 28 (Week 26)	Daily	IDegAsp	362	320	0.88	0.43	0.77	0.24	2.81
		OD							
		IDet	180	157	1.02	0.58	0.88	0.32	4.51
		Total	542	477	0.92	0.49	0.80	0.24	4.51
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp	362	360	0.86	0.42	0.75	0.19	2.81
		OD							
		IDet	180	178	1.00	0.57	0.88	0.32	4.51
		Total	542	538	0.91	0.48	0.79	0.19	4.51

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:49 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_ukg_descp_sas.txt

14.2.31: Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.41	0.19	0.37	0.09	1.93
		OD							
		IDet	180	176	0.39	0.19	0.39	0.08	1.76
		Total	542	536	0.41	0.19	0.38	0.08	1.93
		IDegAsp	362	360	0.42	0.19	0.39	0.10	1.95
		OD							
Visit 4 (Week 2)	Daily	IDet	180	178	0.42	0.19	0.39	0.09	1.79
		Total	542	538	0.42	0.19	0.39	0.09	1.95
		IDegAsp	362	360	0.43	0.19	0.40	0.12	1.89
Visit 5 (Week 3)	Daily	OD							
		IDet	180	178	0.44	0.22	0.42	0.05	1.87
		Total	542	538	0.43	0.20	0.40	0.05	1.89
Visit 6 (Week 4)	Daily	IDegAsp	362	360	0.44	0.20	0.40	0.14	1.97
		OD							
		IDet	180	178	0.47	0.23	0.43	0.10	1.92
		Total	542	538	0.45	0.21	0.41	0.10	1.97
		IDegAsp	362	360	0.44	0.20	0.41	0.10	1.95
		OD							
Visit 7 (Week 5)	Daily	IDet	180	178	0.48	0.25	0.44	0.09	2.14
		Total	542	538	0.45	0.22	0.42	0.09	2.14
		IDegAsp	362	360	0.45	0.21	0.40	0.07	1.93
Visit 8 (Week 6)	Daily	OD							
		IDet	180	178	0.49	0.27	0.43	0.09	2.14
		Total	542	538	0.46	0.23	0.41	0.07	2.14
Visit 9 (Week 7)	Daily	IDegAsp	362	360	0.45	0.22	0.40	0.07	1.93
		OD							
		IDet	180	178	0.50	0.28	0.44	0.08	2.14
		Total	542	538	0.47	0.24	0.41	0.07	2.14
		IDegAsp	362	360	0.46	0.23	0.39	0.08	1.98
		OD							
Visit 10 (Week 8)	Daily	IDet	180	178	0.51	0.27	0.45	0.10	1.71
		Total	542	538	0.47	0.24	0.41	0.08	1.98
		IDegAsp	362	360	0.46	0.24	0.40	0.09	2.07
Visit 11 (Week 9)	Daily	OD							
		IDet	180	178	0.51	0.28	0.44	0.07	1.84
		Total	542	538	0.48	0.25	0.42	0.07	2.07
Visit 12 (Week 10)	Daily	IDegAsp	362	360	0.47	0.24	0.41	0.08	2.14
		OD							
		IDet	180	178	0.51	0.28	0.45	0.12	1.92
		Total	542	538	0.48	0.26	0.42	0.08	2.14
		IDegAsp	362	360	0.47	0.24	0.41	0.12	2.09
		OD							
Visit 13 (Week 11)	Daily	IDet	180	178	0.51	0.28	0.45	0.10	2.01
		Total	542	538	0.48	0.26	0.42	0.10	2.09
		IDegAsp	362	360	0.46	0.24	0.40	0.14	1.94
Visit 14 (Week 12)	Daily	OD							
		IDet	180	178	0.51	0.28	0.44	0.08	2.06
		Total	542	538	0.48	0.25	0.42	0.08	2.06

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:56 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_ukg_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	360	0.47	0.25	0.40	0.13	2.07
		OD							
		IDet	180	178	0.51	0.29	0.44	0.12	2.15
Visit 16 (Week 14)	Daily	Total	542	538	0.48	0.26	0.41	0.12	2.15
		IDegAsp	362	360	0.47	0.26	0.40	0.14	2.00
		OD							
Visit 17 (Week 15)	Daily	IDet	180	178	0.51	0.31	0.44	0.11	2.24
		Total	542	538	0.48	0.27	0.41	0.11	2.24
		IDegAsp	362	360	0.47	0.26	0.41	0.12	2.01
Visit 18 (Week 16)	Daily	OD							
		IDet	180	178	0.51	0.32	0.43	0.07	2.31
		Total	542	538	0.48	0.28	0.41	0.07	2.31
Visit 19 (Week 17)	Daily	IDegAsp	362	360	0.47	0.26	0.41	0.12	1.97
		OD							
		IDet	180	178	0.51	0.34	0.45	0.07	2.36
Visit 20 (Week 18)	Daily	Total	542	538	0.49	0.29	0.42	0.07	2.36
		IDegAsp	362	360	0.47	0.26	0.40	0.13	1.94
		OD							
Visit 21 (Week 19)	Daily	IDet	180	178	0.52	0.35	0.44	0.06	2.56
		Total	542	538	0.49	0.29	0.41	0.06	2.56
		IDegAsp	362	360	0.48	0.26	0.41	0.08	1.94
Visit 22 (Week 20)	Daily	OD							
		IDet	180	178	0.52	0.36	0.44	0.05	2.53
		Total	542	538	0.49	0.30	0.42	0.05	2.53
Visit 23 (Week 21)	Daily	IDegAsp	362	360	0.48	0.27	0.40	0.09	1.94
		OD							
		IDet	180	178	0.52	0.37	0.45	0.07	2.61
Visit 24 (Week 22)	Daily	Total	542	538	0.49	0.31	0.42	0.07	2.61
		IDegAsp	362	360	0.48	0.27	0.40	0.10	1.94
		OD							
Visit 25 (Week 23)	Daily	IDet	180	178	0.52	0.38	0.44	0.04	2.70
		Total	542	538	0.49	0.31	0.41	0.04	2.70
		IDegAsp	362	360	0.48	0.28	0.40	0.11	1.94
Visit 26 (Week 24)	Daily	OD							
		IDet	180	178	0.53	0.39	0.44	0.05	2.78
		Total	542	538	0.50	0.32	0.41	0.05	2.78
Visit 27 (Week 25)	Daily	IDegAsp	362	360	0.49	0.28	0.40	0.08	1.94
		OD							
		IDet	180	178	0.53	0.40	0.45	0.04	2.86
Visit 28 (Week 26)	Daily	Total	542	538	0.50	0.32	0.42	0.04	2.86
		IDegAsp	362	360	0.49	0.28	0.41	0.12	1.94
		OD							
Visit 29 (Week 27)	Daily	IDet	180	178	0.53	0.40	0.44	0.08	2.95
		Total	542	538	0.50	0.33	0.42	0.08	2.95
		IDegAsp	362	360	0.49	0.28	0.41	0.12	1.94

N = Number of Subjects, SD = Standard Deviation

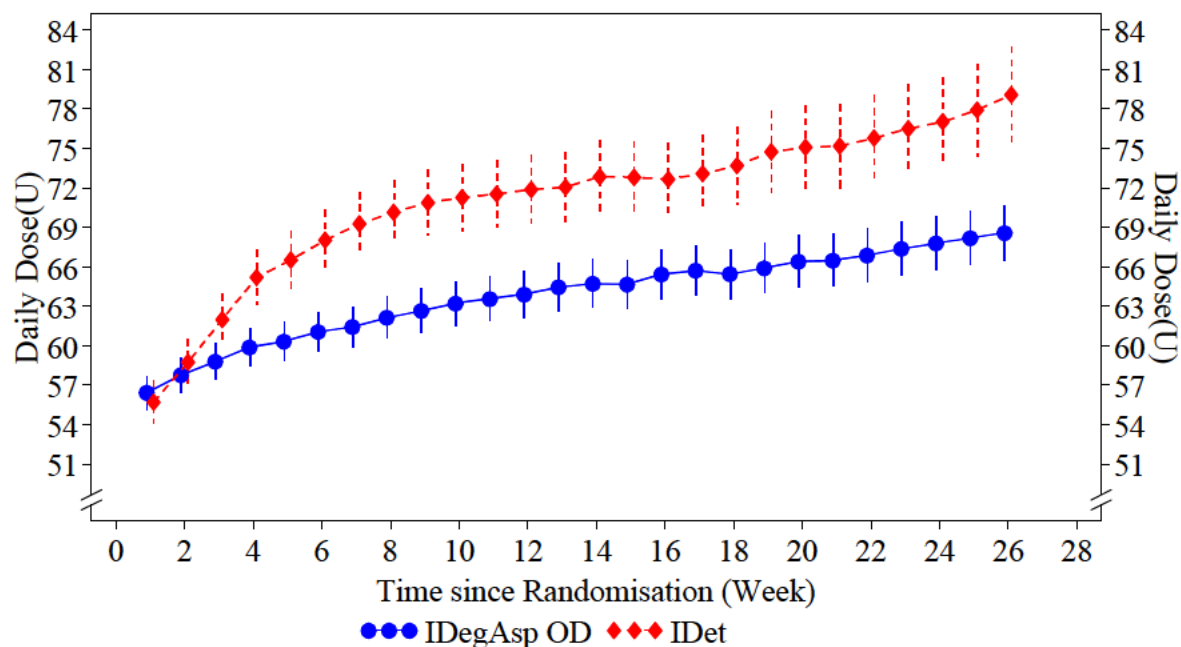
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:56 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_ukg_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	360	0.49	0.29	0.41	0.11	1.98
		OD							
		IDet	180	178	0.53	0.41	0.45	0.05	2.95
		Total	542	538	0.51	0.34	0.42	0.05	2.95
Visit 28 (Week 26)	Daily	IDegAsp	362	360	0.49	0.29	0.41	0.12	1.88
		OD							
		IDet	180	178	0.54	0.42	0.45	0.05	3.15
		Total	542	538	0.51	0.34	0.42	0.05	3.15
Visit 28 (Week 26) (LOCF)	Daily	IDegAsp	362	360	0.49	0.29	0.41	0.12	1.88
		OD							
		IDet	180	178	0.54	0.42	0.45	0.05	3.15
		Total	542	538	0.51	0.34	0.42	0.05	3.15

N = Number of Subjects, SD = Standard Deviation

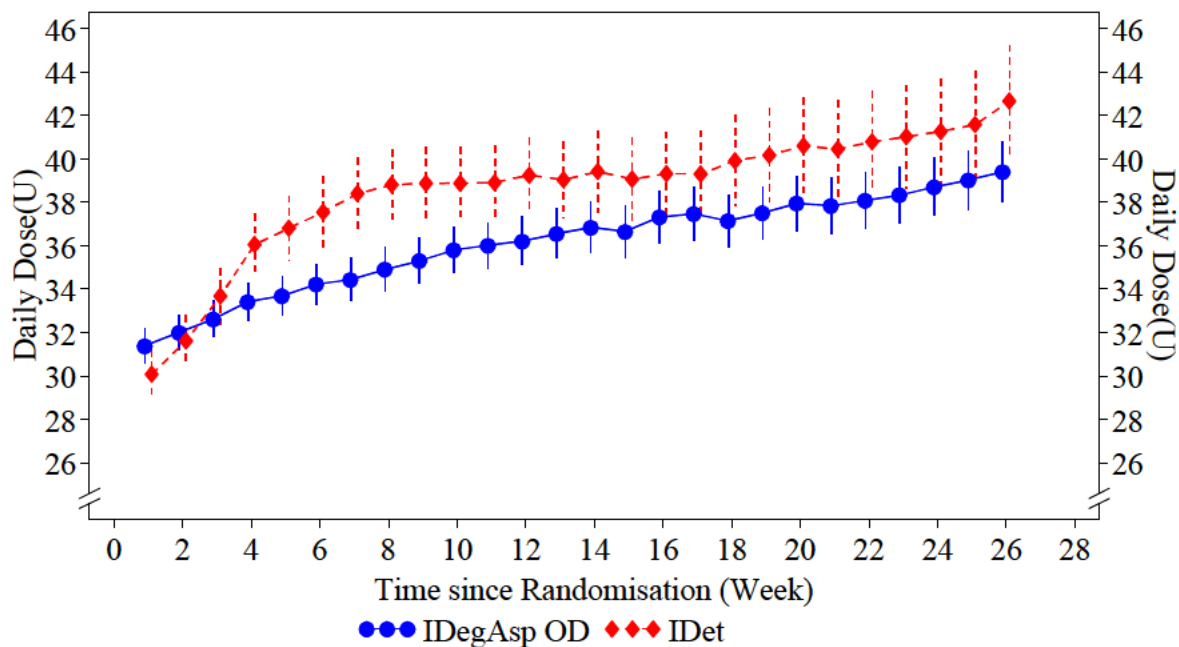
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:41:56 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_ukg_descp_sas.txt



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:03 - finean_numfind_v03.sas/e_tot_dose_d_act_u_mean_locf_sas.cgm

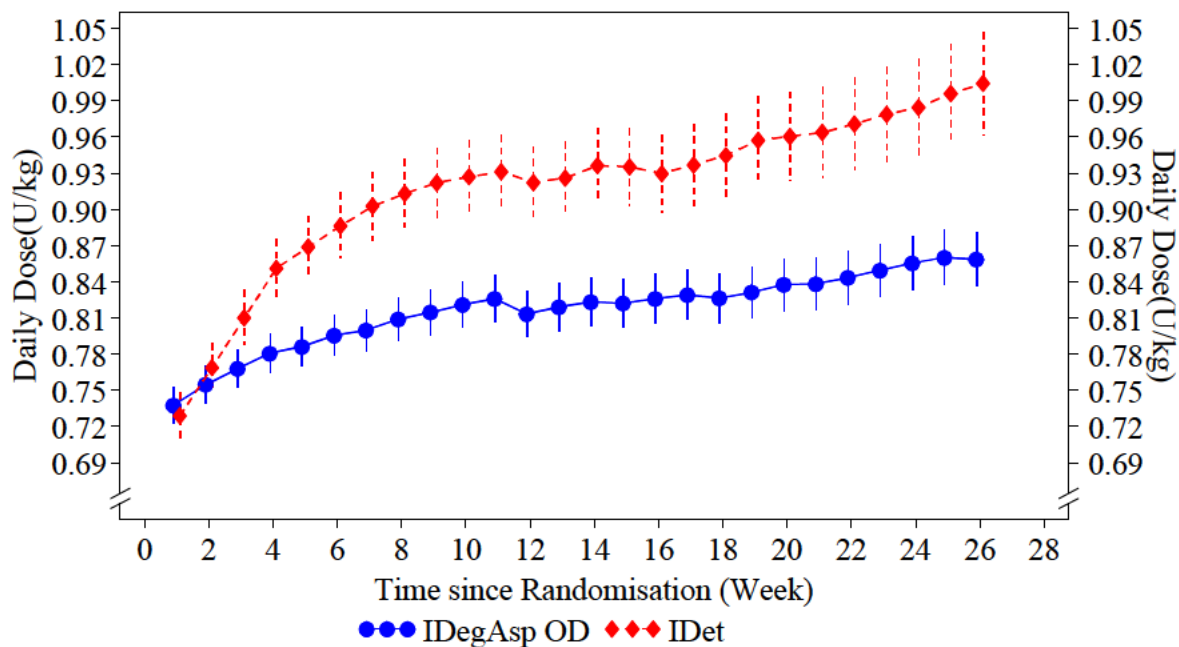
14.2.32: Total Daily Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:10 - fmean_numfind_v03.sas/e_tot_b_d_act_u_mean_locf_sas.cgm

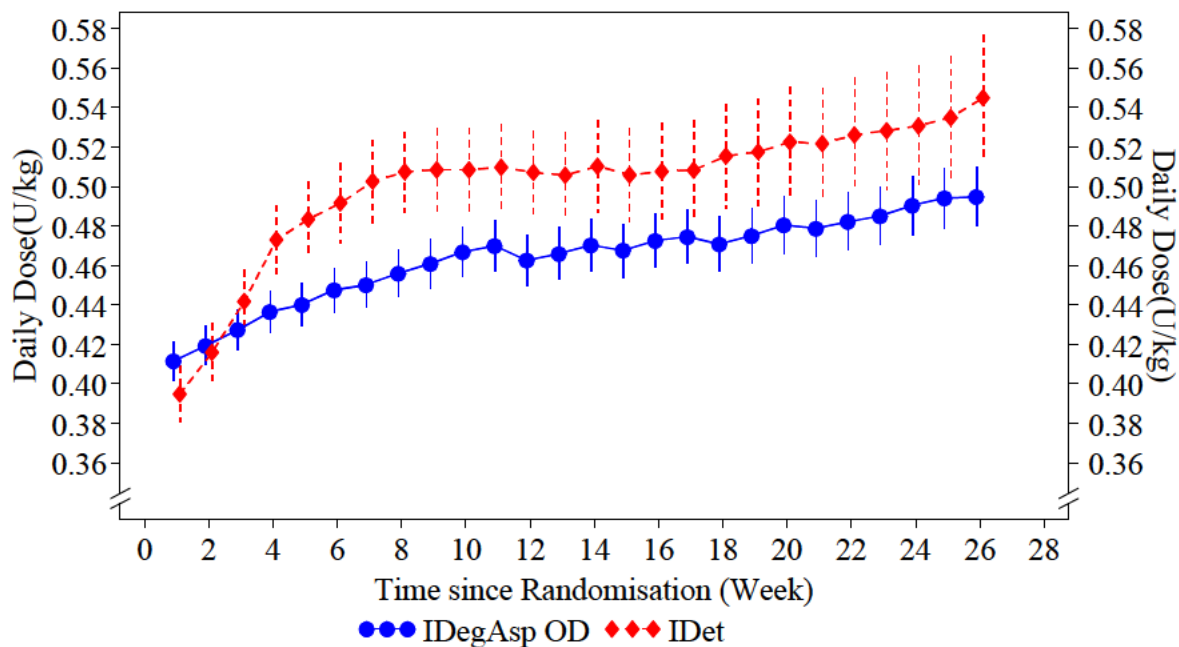
14.2.33: Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:17 - finean_numfind_v03.sas/e_t_dose_d_act_ukg_mean_locf_sas.cgm

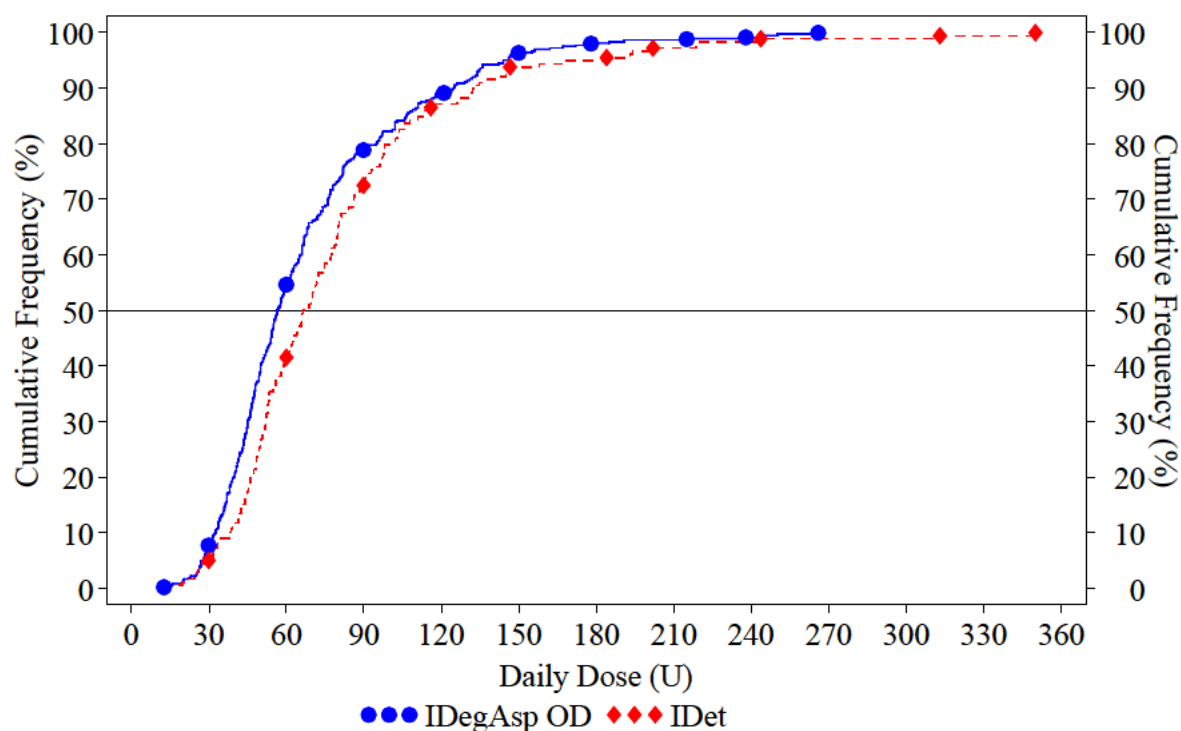
14.2.34: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:24 - fmean_numfind_v03.sas/e_tot_b_d_act_ukg_mean_locf_sas.cgm

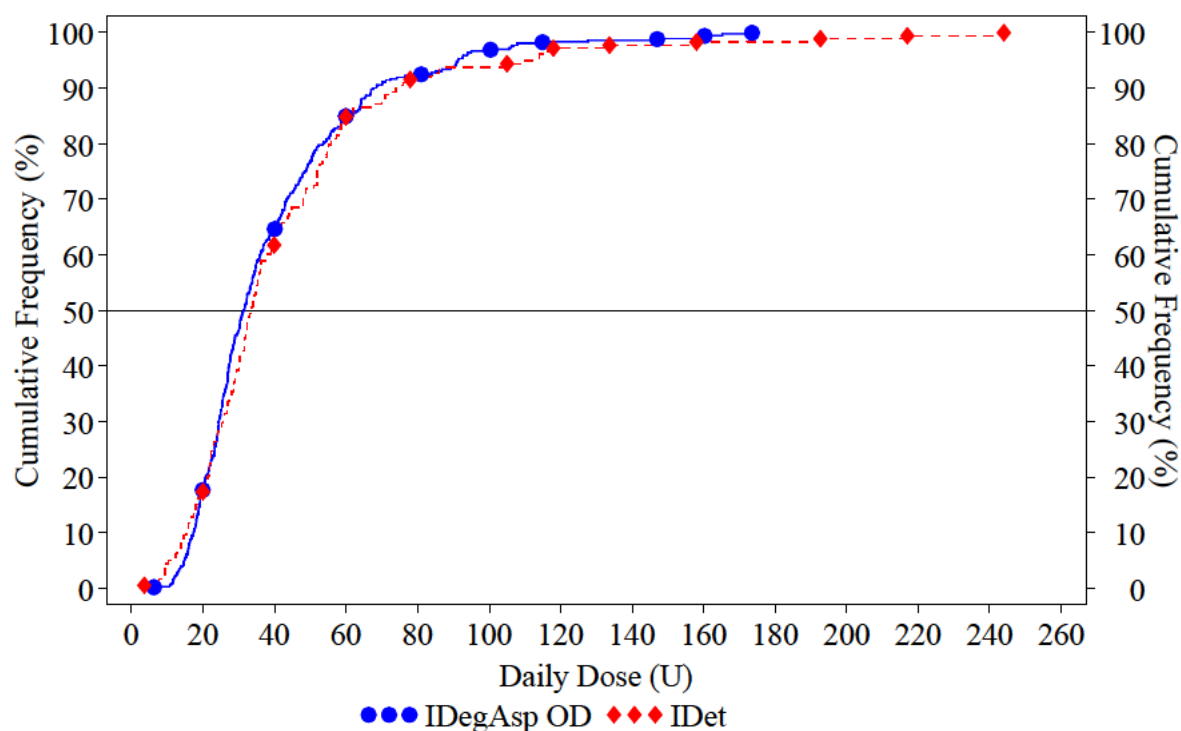
14.2.35: Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:30 - fedist_numfind_v01.sas/e_tot_dose_d_act_u_cdf_locf_sas.cgm

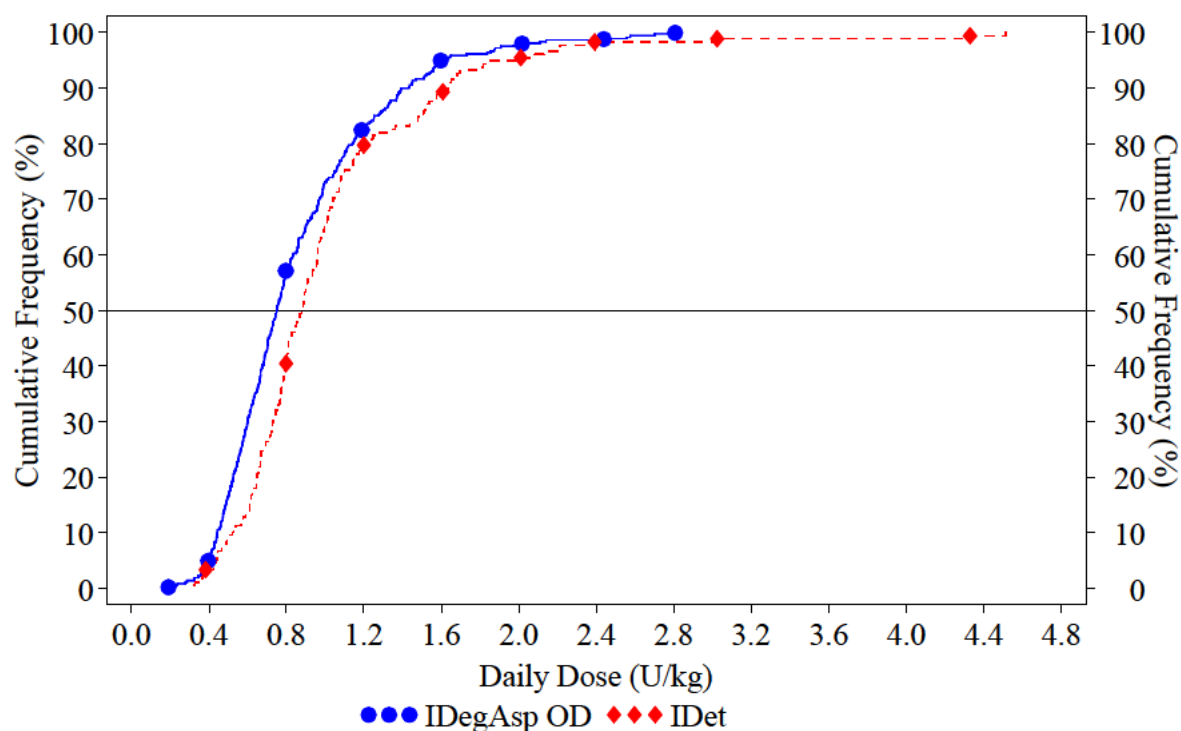
14.2.36: Total Daily Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:37 - fedist_numfind_v01.sas/e_tot_b_d_act_u_cdf_locf_sas.cgm

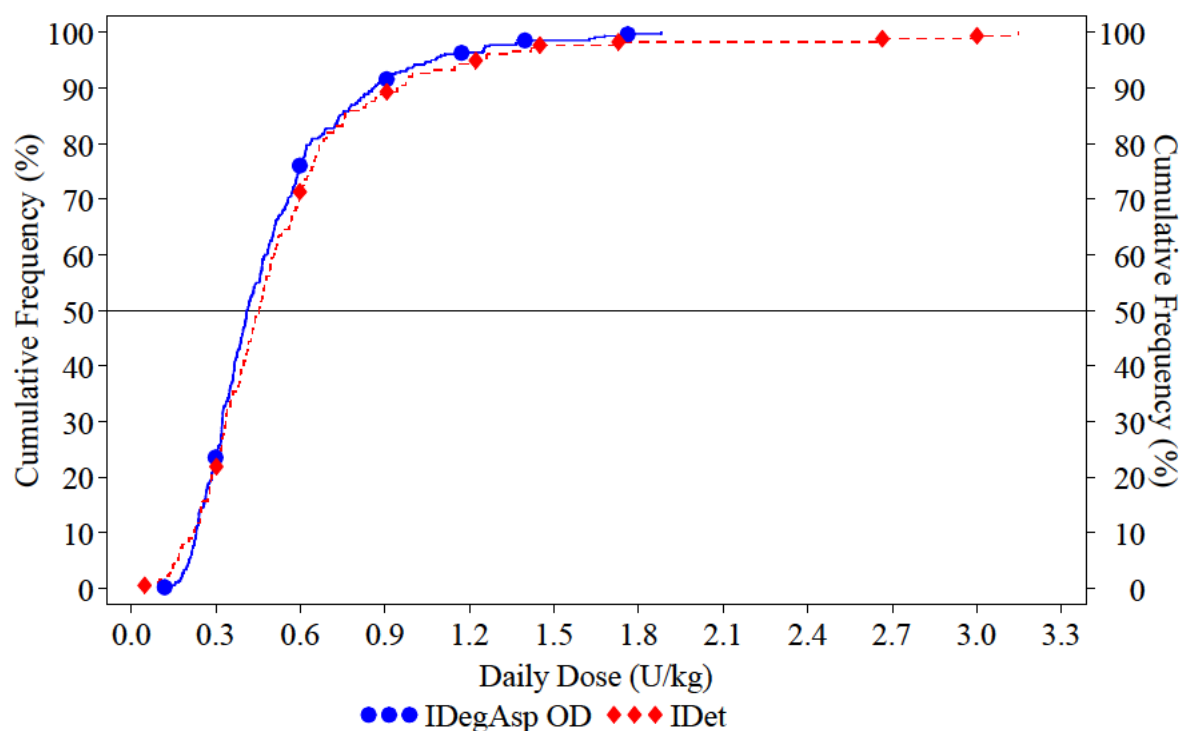
14.2.37: Total Daily Bolus Insulin Dose (Actual) in Units after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:43 - fedist_numfind_v01.sas/e_tot_d_act_ukg_cdf_locf_sas.cgm

14.2.38: Total Daily Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:49 - fedist_numfind_v01.sas/e_tot_b_d_act_ukg_cdf_locf_sas.cgm

14.2.39: Total Daily Bolus Insulin Dose (Actual) in Units/kg after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.2.40: Insulin Dose Ratio after 26 Weeks of Treatment - Summary - Safety Analysis Set

Treatment Ratio	Mean Ratio (U)	Mean Ratio (U/kg)
Total Daily Insulin Dose		
IDegAsp / IDet	0.87	0.85
Derived Total Basal Insulin Dose		
IDegAsp / IDet	0.81	0.80
Derived Total Bolus Insulin Dose		
IDegAsp / IDet	0.92	0.91
Bolus Insulin Dose (Separate IAsp doses)		
IDegAsp / IDet	0.63	0.62

Mean ratio is calculated as the ratio between mean doses at last scheduled treatment visit, where missing data have been imputed using last observation carried forward.
Derived total basal insulin dose:
IDegAsp = the IDeg part of the IDegAsp OD dose; IDet = the (sum of) injected IDet dose(s)
Derived total bolus insulin dose:
IDegAsp = the sum of injected IAsp doses plus the IAsp part of the IDegAsp OD dose;
IDet = the sum of injected IAsp doses.
Bolus insulin dose: 'separate' injections of IAsp.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:34 - tsum_dose_ratio.sas/t_ins_dose_ratio_locf_sas.txt

14.2.41: Basal-Bolus split after 26 Weeks of Treatment - Summary - Safety Analysis Set

Treatment Ratio	IDegAsp Mean Ratio (U)	IDet Mean Ratio (U)
Basal dose/Bolus dose	0.75	0.85

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:28 - tsum_bas_bol_dose.sas/t_basal_bolus_locf_sas.txt

14.2.42: IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set

Week	Breakfast		Lunch		Main Evening Meal		Other	
	N	Mean	N	Mean	N	Mean	N	Mean
Visit 3 (Week 1)	52	35.46	73	34.22	243	36.72		
Visit 4 (Week 2)	56	36.01	69	35.46	241	37.59	1	34.00
Visit 5 (Week 3)	59	37.01	60	36.26	228	38.12		
Visit 6 (Week 4)	58	37.17	67	35.66	233	38.97		
Visit 7 (Week 5)	54	37.07	71	35.82	231	39.53	1	33.00
Visit 8 (Week 6)	53	37.63	63	35.72	230	39.74		
Visit 9 (Week 7)	52	37.66	64	38.04	233	39.59		
Visit 10 (Week 8)	53	37.62	64	37.33	228	40.41		
Visit 11 (Week 9)	53	38.26	63	38.32	224	40.50	1	36.00
Visit 12 (Week 10)	52	38.19	64	39.05	226	40.75	1	23.00
Visit 13 (Week 11)	55	38.38	61	39.72	224	41.00	1	21.00
Visit 14 (Week 12)	54	38.86	62	40.45	224	41.00		
Visit 15 (Week 13)	48	38.62	66	39.28	215	41.75	1	74.00
Visit 16 (Week 14)	51	37.86	63	39.90	222	42.01	1	91.00
Visit 17 (Week 15)	52	38.99	60	39.64	219	42.15	1	24.00
Visit 18 (Week 16)	51	38.46	62	39.58	219	42.36		
Visit 19 (Week 17)	48	40.38	57	38.79	222	42.88		
Visit 20 (Week 18)	48	40.81	57	38.07	221	42.81		
Visit 21 (Week 19)	45	41.68	55	37.95	223	42.87		
Visit 22 (Week 20)	46	41.84	57	39.02	222	43.21		
Visit 23 (Week 21)	46	41.77	57	38.60	220	43.03	1	62.00
Visit 24 (Week 22)	44	42.31	57	38.42	219	43.75		
Visit 25 (Week 23)	44	43.70	57	38.68	223	43.70	1	36.00
Visit 26 (Week 24)	46	43.00	55	38.66	219	43.94		
Visit 27 (Week 25)	43	44.02	55	38.71	221	43.80	2	73.50
Visit 28 (Week 26)	44	43.13	55	39.14	224	44.00		

N: Number of Subjects

The descriptive statistics are based on recorded doses.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:34 - T_TRT_DOSE_MEAL.SAS/t_idegasp_dose_meal_descp_sas.txt

14.2.43: IDet Doses in Units per Injection Time by Treatment Week - Descriptive Statistics - Safety Analysis Set

Week	Morning		Evening	
	N	Mean	N	Mean
Visit 3 (Week 1)			169	25.72
Visit 4 (Week 2)			171	27.13
Visit 5 (Week 3)	1	30.00	170	28.22
Visit 6 (Week 4)	1	16.00	170	29.08
Visit 7 (Week 5)	1	12.00	169	29.12
Visit 8 (Week 6)	3	13.86	170	30.33
Visit 9 (Week 7)	1	18.00	167	31.01
Visit 10 (Week 8)	2	15.50	168	31.29
Visit 11 (Week 9)	8	13.50	163	31.14
Visit 12 (Week 10)	15	15.62	167	31.35
Visit 13 (Week 11)	24	15.76	162	31.38
Visit 14 (Week 12)	26	15.51	164	31.18
Visit 15 (Week 13)	27	13.79	160	31.55
Visit 16 (Week 14)	30	13.60	164	31.47
Visit 17 (Week 15)	34	13.82	160	31.62
Visit 18 (Week 16)	35	13.22	162	31.54
Visit 19 (Week 17)	35	13.83	160	31.63
Visit 20 (Week 18)	32	15.36	157	32.26
Visit 21 (Week 19)	32	15.52	161	32.19
Visit 22 (Week 20)	34	15.95	158	31.73
Visit 23 (Week 21)	37	16.85	157	31.59
Visit 24 (Week 22)	38	16.10	155	31.68
Visit 25 (Week 23)	36	16.77	151	32.00
Visit 26 (Week 24)	41	16.54	158	32.35
Visit 27 (Week 25)	42	17.57	153	32.72
Visit 28 (Week 26)	42	18.14	156	32.64

N: Number of Subjects

The descriptive statistics are based on recorded doses.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:36 - T_TRT_DOSE_MEAL.SAS/t_idet_dose_time_descp_sas.txt

14.2.44: Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Prescrib Compliance(U)			
Visit 3 (Week 1)			
N	359	176	535
Mean (SD)	0 (2)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 12	-4 ; 5	-7 ; 12
Visit 4 (Week 2)			
N	353	174	527
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 12	-4 ; 4	-6 ; 12
Visit 5 (Week 3)			
N	347	173	520
Mean (SD)	0 (1)	-0 (3)	0 (2)
Median	0	0	0
Min ; Max	-4 ; 10	-32 ; 5	-32 ; 10
Visit 6 (Week 4)			
N	350	175	525
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-4 ; 11	-12 ; 6	-12 ; 11
Visit 7 (Week 5)			
N	343	172	515
Mean (SD)	0 (1)	-0 (2)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 5	-18 ; 2	-18 ; 5
Visit 8 (Week 6)			
N	341	172	513
Mean (SD)	0 (1)	-0 (2)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 11	-18 ; 4	-18 ; 11
Visit 9 (Week 7)			
N	337	170	507
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 11	-18 ; 14	-18 ; 14
Visit 10 (Week 8)			
N	340	169	509
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-4 ; 8	-4 ; 9	-4 ; 9
Visit 11 (Week 9)			
N	333	166	499
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 12	-4 ; 8	-4 ; 12

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:55 - tdesc_numfind_tpl_t019_v01.sas/t_ins_prscb_act_diff_descp_sas.txt

Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week -
Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Prescrib Compliance(U)			
Visit 12 (Week 10)			
N	335	169	504
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 10	-5 ; 16	-5 ; 16
Visit 13 (Week 11)			
N	333	166	499
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 10	-2 ; 13	-7 ; 13
Visit 14 (Week 12)			
N	332	167	499
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-4 ; 7	-4 ; 5	-4 ; 7
Visit 15 (Week 13)			
N	321	160	481
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 14	-4 ; 8	-4 ; 14
Visit 16 (Week 14)			
N	331	164	495
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 13	-6 ; 7	-7 ; 13
Visit 17 (Week 15)			
N	323	163	486
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 11	-6 ; 13	-7 ; 13
Visit 18 (Week 16)			
N	328	163	491
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 10	-10 ; 4	-10 ; 10
Visit 19 (Week 17)			
N	318	160	478
Mean (SD)	0 (1)	-0 (1)	0 (1)
Median	0	0	0
Min ; Max	-5 ; 12	-7 ; 3	-7 ; 12
Visit 20 (Week 18)			
N	316	157	473
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 4	-3 ; 4	-3 ; 4
Visit 21 (Week 19)			
N	316	159	475
Mean (SD)	0 (1)	0 (2)	0 (2)
Median	0	0	0
Min ; Max	-3 ; 15	-6 ; 15	-6 ; 15

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:55 - tdesc_numfind_tpl_t019_v01.sas/t_ins_prscb_act_diff_descp_sas.txt

Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week -
Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Prescrib Compliance(U)			
Visit 22 (Week 20)			
N	321	157	478
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-10 ; 12	-4 ; 11	-10 ; 12
Visit 23 (Week 21)			
N	315	156	471
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 9	-4 ; 6	-4 ; 9
Visit 24 (Week 22)			
N	315	153	468
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-5 ; 16	-2 ; 7	-5 ; 16
Visit 25 (Week 23)			
N	315	151	466
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 14	-2 ; 6	-6 ; 14
Visit 26 (Week 24)			
N	316	157	473
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-2 ; 14	-8 ; 4	-8 ; 14
Visit 28 (Week 26) (LOCF)			
N	360	178	538
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 6	-8 ; 13	-8 ; 13

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:42:55 - tdesc_numfind_tpl_t019_v01.sas/t_ins_prscb_act_diff_descp_sas.txt

14.2.45: Prescribed minus Titration Algorithm Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Titration Compliance(U)			
Visit 3 (Week 1)			
N	358	174	532
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-13 ; 10	-8 ; 8	-13 ; 10
Visit 4 (Week 2)			
N	358	173	531
Mean (SD)	-1 (2)	-0 (2)	-1 (2)
Median	0	0	0
Min ; Max	-12 ; 20	-9 ; 4	-12 ; 20
Visit 5 (Week 3)			
N	344	170	514
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 6	-16 ; 4	-16 ; 6
Visit 6 (Week 4)			
N	348	173	521
Mean (SD)	-1 (3)	-0 (3)	-1 (3)
Median	0	0	0
Min ; Max	-8 ; 17	-10 ; 14	-10 ; 17
Visit 7 (Week 5)			
N	348	172	520
Mean (SD)	-1 (3)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-29 ; 12	-6 ; 10	-29 ; 12
Visit 8 (Week 6)			
N	340	171	511
Mean (SD)	-1 (2)	-0 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 6	-7 ; 4	-8 ; 6
Visit 9 (Week 7)			
N	338	168	506
Mean (SD)	-1 (3)	-1 (2)	-1 (3)
Median	0	0	0
Min ; Max	-8 ; 32	-6 ; 4	-8 ; 32
Visit 10 (Week 8)			
N	336	168	504
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-10 ; 10	-8 ; 5	-10 ; 10
Visit 11 (Week 9)			
N	330	165	495
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 6	-10 ; 6	-10 ; 6

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:43:02 - tdesc_numfind_tpl_t019_v01.sas/t_ins_ds_prscb_ttrt_diff_ds_c_sas.txt

Prescribed minus Titration Algorithm Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Titration Compliance(U)			
Visit 12 (Week 10)			
N	333	168	501
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-10 ; 5	-12 ; 10	-12 ; 10
Visit 13 (Week 11)			
N	332	164	496
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 8	-8 ; 8	-8 ; 8
Visit 14 (Week 12)			
N	331	165	496
Mean (SD)	-1 (3)	-1 (2)	-1 (2)
Median	-1	-2	-1
Min ; Max	-12 ; 24	-10 ; 4	-12 ; 24
Visit 15 (Week 13)			
N	319	159	478
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 10	-8 ; 6	-8 ; 10
Visit 16 (Week 14)			
N	330	165	495
Mean (SD)	-1 (2)	-0 (2)	-1 (2)
Median	0	0	0
Min ; Max	-20 ; 6	-10 ; 10	-20 ; 10
Visit 17 (Week 15)			
N	323	160	483
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-9 ; 5	-8 ; 6	-9 ; 6
Visit 18 (Week 16)			
N	327	162	489
Mean (SD)	-1 (2)	-1 (3)	-1 (3)
Median	0	0	0
Min ; Max	-14 ; 9	-8 ; 26	-14 ; 26
Visit 19 (Week 17)			
N	319	160	479
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-10 ; 4	-10 ; 6	-10 ; 6
Visit 20 (Week 18)			
N	313	156	469
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-9 ; 9	-12 ; 6	-12 ; 9
Visit 21 (Week 19)			
N	314	160	474
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-6 ; 4	-10 ; 5	-10 ; 5

N = Number of Subjects, SD = Standard Deviation

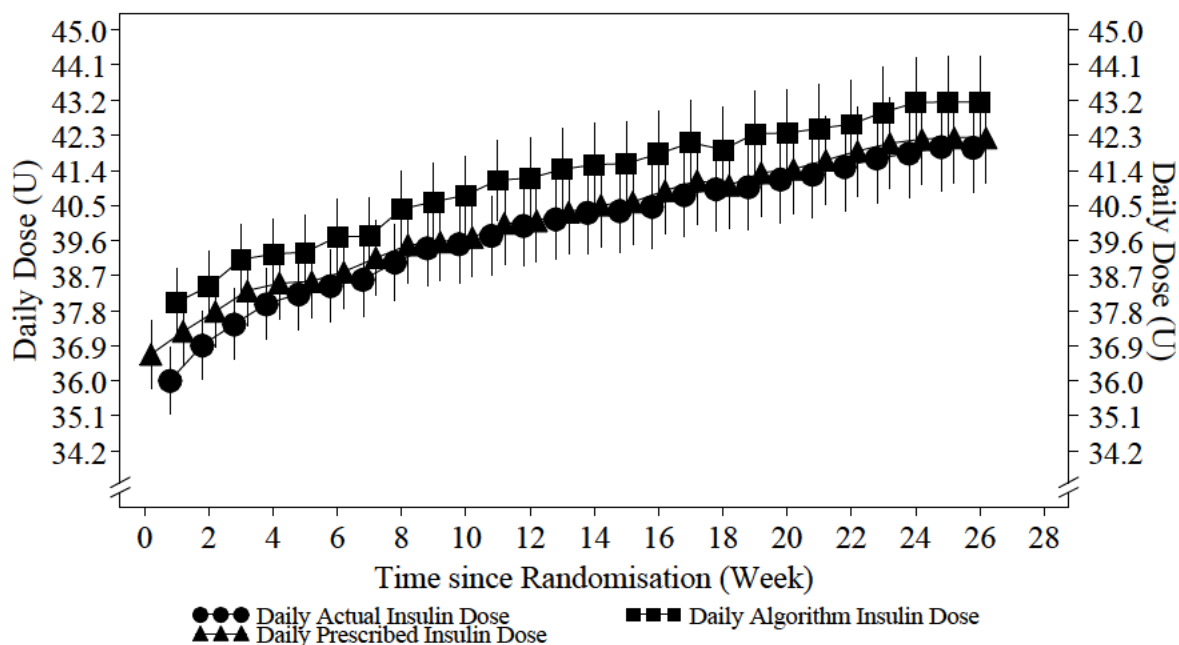
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:43:02 - tdesc_numfind_tpl_t019_v01.sas/t_ins_ds_prscb_ttrt_diff_dsc_sas.txt

Prescribed minus Titration Algorithm Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Titration Compliance(U)			
Visit 22 (Week 20)			
N	318	158	476
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 14	-9 ; 20	-9 ; 20
Visit 23 (Week 21)			
N	315	154	469
Mean (SD)	-1 (2)	-1 (3)	-1 (3)
Median	0	0	0
Min ; Max	-17 ; 22	-10 ; 28	-17 ; 28
Visit 24 (Week 22)			
N	313	156	469
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-6 ; 12	-8 ; 7	-8 ; 12
Visit 25 (Week 23)			
N	316	149	465
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-9 ; 6	-12 ; 22	-12 ; 22
Visit 26 (Week 24)			
N	317	157	474
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-10 ; 6	-10 ; 10	-10 ; 10
Visit 27 (Week 25)			
N	313	151	464
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-6 ; 6	-12 ; 7	-12 ; 7
Visit 28 (Week 26) (LOCF)			
N	360	178	538
Mean (SD)	-1 (2)	-1 (3)	-1 (3)
Median	0	0	0
Min ; Max	-29 ; 6	-12 ; 7	-29 ; 7

N = Number of Subjects, SD = Standard Deviation

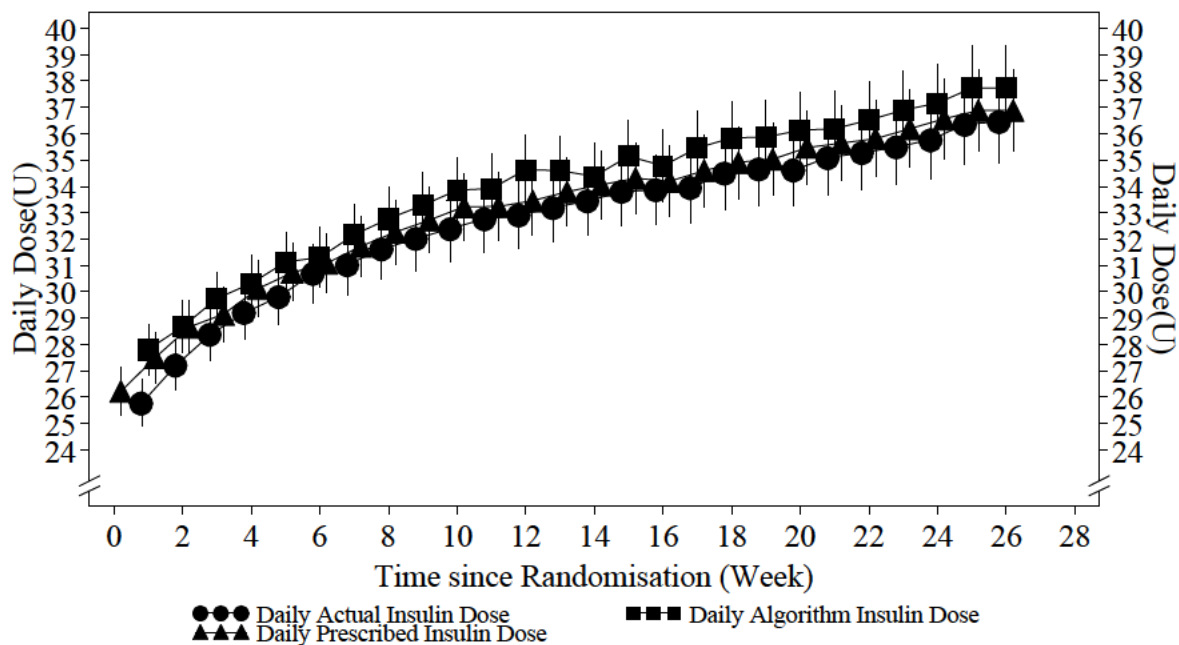
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:43:02 - tdesc_numfind_tpl_t019_v01.sas/t_ins_ds_prscb_ttrt_diff_dsc_sas.txt



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:43:19 - fmean_numfind_v03.sas/e_ins_comp_iv1_u_mean_locf_sas.cgm

14.2.46: Daily IDegAsp Dose in Units by Treatment Week - Prescribed, Actual and Titration Algorithm Dose - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:43:34 - finean_numfind_v03.sas/e_ins_comp_cm_u_mean_locf_sas.cgm

14.2.47: Daily IDet Insulin Dose in Units by Treatment Week - Prescribed, Actual and Titration Algorithm Dose – Mean Plot - Safety Analysis Set

14.2.48: Confirmatory Statistical Analyses - Full Analysis Set

Endpoint	Estimate [95% CI]	p-value	Conclusion
PRIMARY			
Change in HbA1c after 26 Weeks of Treatment			
Treatment Contrast			
IDegAsp - IDet	-0.05 [-0.18; 0.08]	<0.001	Non-inferiority
CONFIRMATORY SECONDARY			
1) Change in FPG after 26 Weeks of Treatment			
Treatment Contrast			
IDegAsp - IDet	0.23 [-0.46; 0.91]	0.74	Inconclusive
2) HbA1c < 7.0% at End of Trial w/o Severe Hypoglycaemia			
Treatment Odds Ratio			
IDegAsp / IDet	1.24 [0.77; 2.02]		Testing Proc. Stopped
3) Number of Nocturnal Confirmed Hypoglycaemia			
Treatment Ratio			
IDegAsp / IDet	0.63 [0.49; 0.81]		Testing Proc. Stopped

p-values are from the 1-sided test for non-inferiority and superiority respectively evaluated at the 2.5% level.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:13:17 - tstat_conf.sas/t_conclusion_sas.txt

14.2.49: HbA1c (%) by Treatment Week – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
HbA1c (%)			
Visit 1			
N	366	182	548
Mean (SD)	8.4 (0.8)	8.3 (0.8)	8.4 (0.8)
Median	8.3	8.3	8.3
Min ; Max	7.0 ; 10.3	7.0 ; 10.0	7.0 ; 10.3
Visit 2 (Week 0)			
N	366	182	548
Mean (SD)	8.3 (0.8)	8.3 (0.7)	8.3 (0.8)
Median	8.2	8.2	8.2
Min ; Max	6.8 ; 10.3	6.5 ; 10.4	6.5 ; 10.4
Visit 10 (Week 8)			
N	340	170	510
Mean (SD)	7.7 (0.9)	7.8 (0.8)	7.7 (0.9)
Median	7.6	7.8	7.7
Min ; Max	5.5 ; 11.3	6.1 ; 10.3	5.5 ; 11.3
Visit 14 (Week 12)			
N	336	167	503
Mean (SD)	7.5 (0.9)	7.7 (0.8)	7.6 (0.8)
Median	7.4	7.6	7.5
Min ; Max	5.9 ; 12.2	5.8 ; 9.8	5.8 ; 12.2
Visit 18 (Week 16)			
N	328	164	492
Mean (SD)	7.5 (0.9)	7.6 (0.8)	7.5 (0.8)
Median	7.3	7.6	7.4
Min ; Max	5.7 ; 11.5	5.8 ; 10.5	5.7 ; 11.5
Visit 22 (Week 20)			
N	322	160	482
Mean (SD)	7.4 (0.8)	7.5 (0.7)	7.5 (0.8)
Median	7.4	7.5	7.4
Min ; Max	5.5 ; 10.9	5.9 ; 9.4	5.5 ; 10.9
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	7.5 (0.8)	7.5 (0.8)	7.5 (0.8)
Median	7.4	7.5	7.5
Min ; Max	5.2 ; 11.0	5.3 ; 10.2	5.2 ; 11.0
Visit 28 (Week 26) (LOCF)			
N	366	182	548
Mean (SD)	7.6 (0.9)	7.6 (0.8)	7.6 (0.9)
Median	7.5	7.6	7.5
Min ; Max	5.2 ; 11.1	5.3 ; 11.1	5.2 ; 11.1

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:43:47 - tdesc_numfind_tpl_t019_v01.sas/t_hbA1c_abs_descp_fas.txt

14.2.50: HbA1c (%) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Change in HbA1c(%)			
Visit 10 (Week 8)			
N	340	170	510
Mean (SD)	-0.63 (0.71)	-0.46 (0.65)	-0.58 (0.69)
Median	-0.60	-0.50	-0.60
Min ; Max	-2.60 ; 3.30	-2.00 ; 1.30	-2.60 ; 3.30
Visit 14 (Week 12)			
N	336	167	503
Mean (SD)	-0.78 (0.78)	-0.65 (0.73)	-0.73 (0.76)
Median	-0.80	-0.70	-0.70
Min ; Max	-3.60 ; 2.90	-2.80 ; 1.30	-3.60 ; 2.90
Visit 18 (Week 16)			
N	328	164	492
Mean (SD)	-0.78 (0.85)	-0.75 (0.74)	-0.77 (0.81)
Median	-0.70	-0.80	-0.80
Min ; Max	-3.60 ; 2.10	-3.20 ; 0.90	-3.60 ; 2.10
Visit 22 (Week 20)			
N	322	160	482
Mean (SD)	-0.84 (0.84)	-0.79 (0.73)	-0.82 (0.80)
Median	-0.80	-0.80	-0.80
Min ; Max	-3.70 ; 1.60	-2.90 ; 1.20	-3.70 ; 1.60
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	-0.78 (0.84)	-0.76 (0.75)	-0.77 (0.81)
Median	-0.70	-0.80	-0.70
Min ; Max	-4.10 ; 1.80	-2.90 ; 1.70	-4.10 ; 1.80
Visit 28 (Week 26) (LOCF)			
N	366	182	548
Mean (SD)	-0.73 (0.83)	-0.68 (0.77)	-0.71 (0.81)
Median	-0.60	-0.70	-0.60
Min ; Max	-4.10 ; 1.80	-2.90 ; 1.70	-4.10 ; 1.80

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:43:59 - tdesc_numfind_tpl_t019_v01.sas/t_hba1c_chb_descp_fas.txt

14.2.51: HbA1c (%) after 26 Weeks of Treatment - Primary Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	366	366	7.55	0.06	
IDet	182	182	7.60	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	366	366	-0.75	0.06	
IDet	182	182	-0.70	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.05		[-0.18 ; 0.08]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:44:06 - tstat_find_tpl_t022.sas/t_hbA1c_conf_stat_locf_fas.txt

14.2.52: HbA1c (%) after 26 Weeks of Treatment - Parameter Estimates on Observed Scale - Full Analysis Set

	Estimate	DF	95% CI
HbA1c (%)			
Treatment			
IDegAsp OD	-0.05	540	[-0.18 ; 0.08]
IDet	0.00		
Region			
Australia	0.01	540	[-0.21 ; 0.22]
Europe	-0.13	540	[-0.27 ; 0.01]
North America	0.00		
Sex			
Female	0.00	540	[-0.12 ; 0.13]
Male	0.00		
Antidiabetic Treatment at Screening			
Basal-Bolus	0.13	540	[-0.08 ; 0.35]
Other	0.00		
Regression			
Age	-0.01	540	[-0.01 ; -0.00]
Baseline response	-0.43	540	[-0.51 ; -0.35]

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates. Estimates and Confidence intervals are based on change from baseline in the response. Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:44:06 - tstat_find_tpl_t022.sas/t_hba1c_conf_stat_parm_locf_fas.txt

14.2.53: HbA1c (%) after 26 Weeks of Treatment - Statistical Sensitivity Analysis - PP Analysis Set

	PP	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	336	336	7.47	0.07	
IDet	168	168	7.53	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	336	336	-0.83	0.07	
IDet	168	168	-0.77	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.06		[-0.20 ; 0.08]

N = Number of subjects contributing to analysis, CI = Confidence Interval, SE = Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:44:13 - tstat_find_tpl_t022.sas/t_hb1c_sens_stat_locf_pp.txt

14.2.54: HbA1c (%) after 26 Weeks of Treatment - Statistical Sensitivity Analysis - Simple Model - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	366	366	7.57	0.04	
IDet	182	182	7.61	0.05	
Change from Baseline					
LSMeans					
IDegAsp OD	366	366	-0.72	0.04	
IDet	182	182	-0.69	0.05	
Treatment Contrast					
IDegAsp OD - IDet			-0.04		[-0.17 ; 0.09]

N = Number of subjects contributing to analysis, CI = Confidence Interval, SE = Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment as fixed effect, and baseline response as covariate.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:44:19 - tstat_find_tpl_t022.sas/t_hba1c_sens_stat_smpl_locf_fas.txt

14.2.55: HbA1c (%) after 26 Weeks of Treatment - Statistical Sensitivity Analysis - Repeated Measurement Model - Full Analysis Set

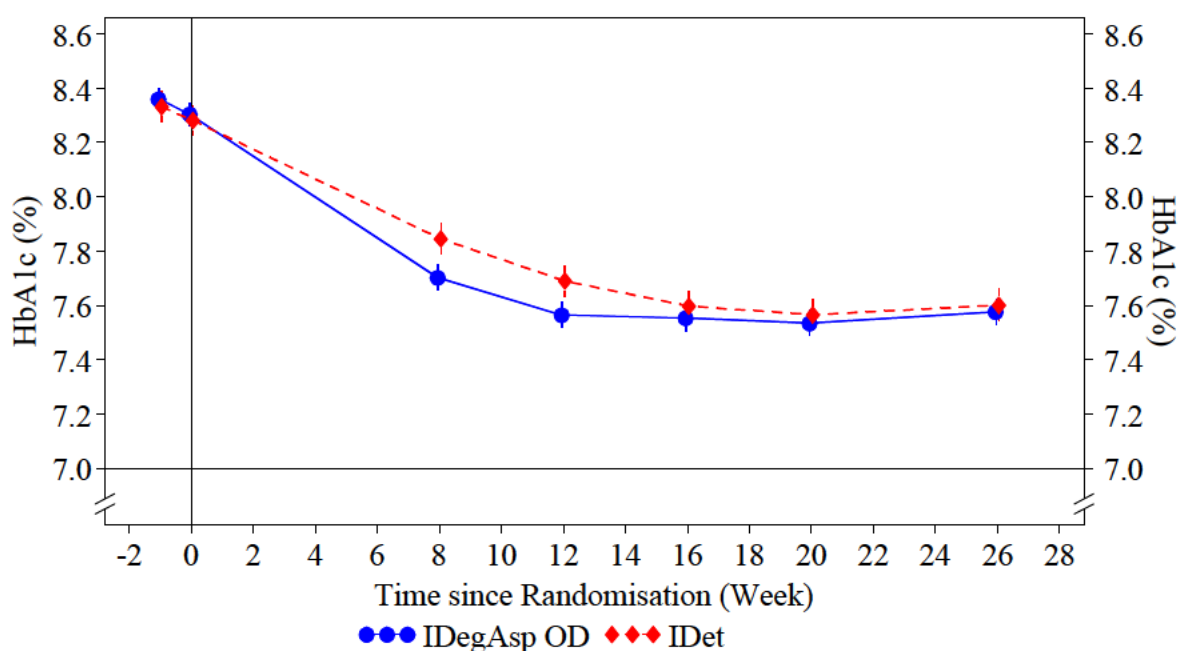
Value	FAS	N	Estimate	SE	95% CI
LSMeans					
IDegAsp OD	366	344	7.46	0.06	
IDet	182	173	7.52	0.07	
Treatment Contrast					
IDegAsp OD - IDet			-0.06		[-0.20 ; 0.08]

CI: Confidence Interval

SE: Standard Error of the Mean

HbA1c (%) records available at scheduled time points after randomisation are jointly analysed in a linear mixed model with an unstructured residual covariance matrix, and with treatment, time, interaction between treatment and time, region, anti-diabetic treatment at screening and sex as fixed effects and age and baseline HbA1c (%) as covariates.

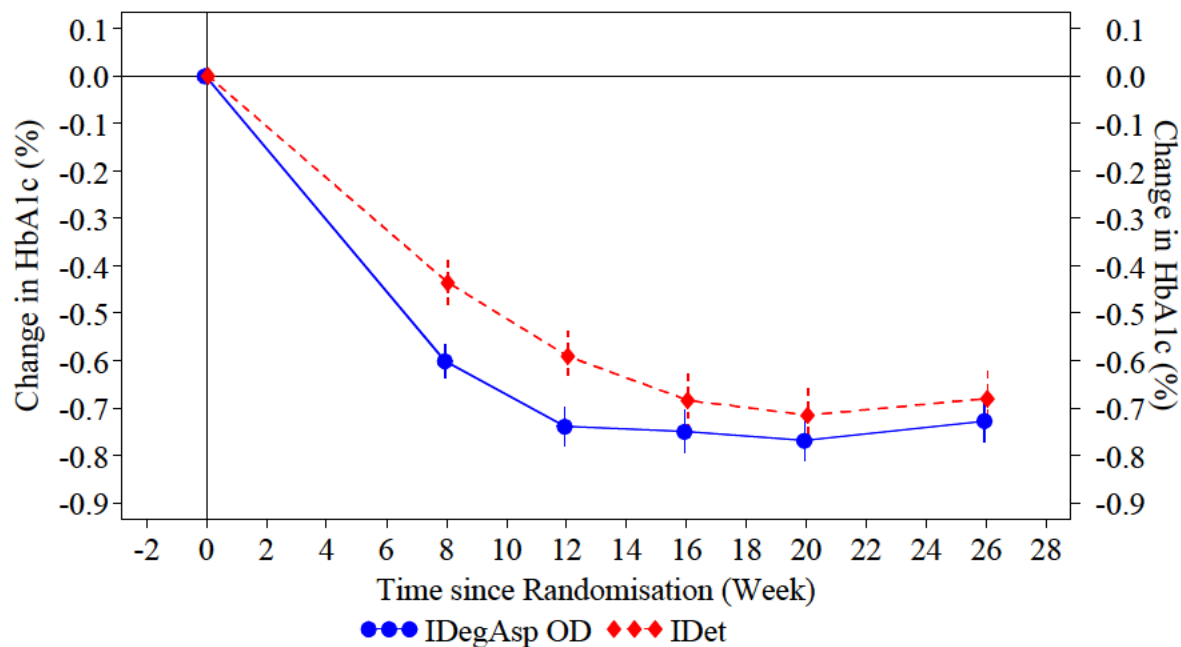
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:44:30 - tstat_hbA1c_after.sas/t_hbA1c_sens_stat_repeat_fas.txt



FAS: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:44:36 - fmean_numfind_v03.sas/e_hbA1c_abs_mean_locf_fas.cgm

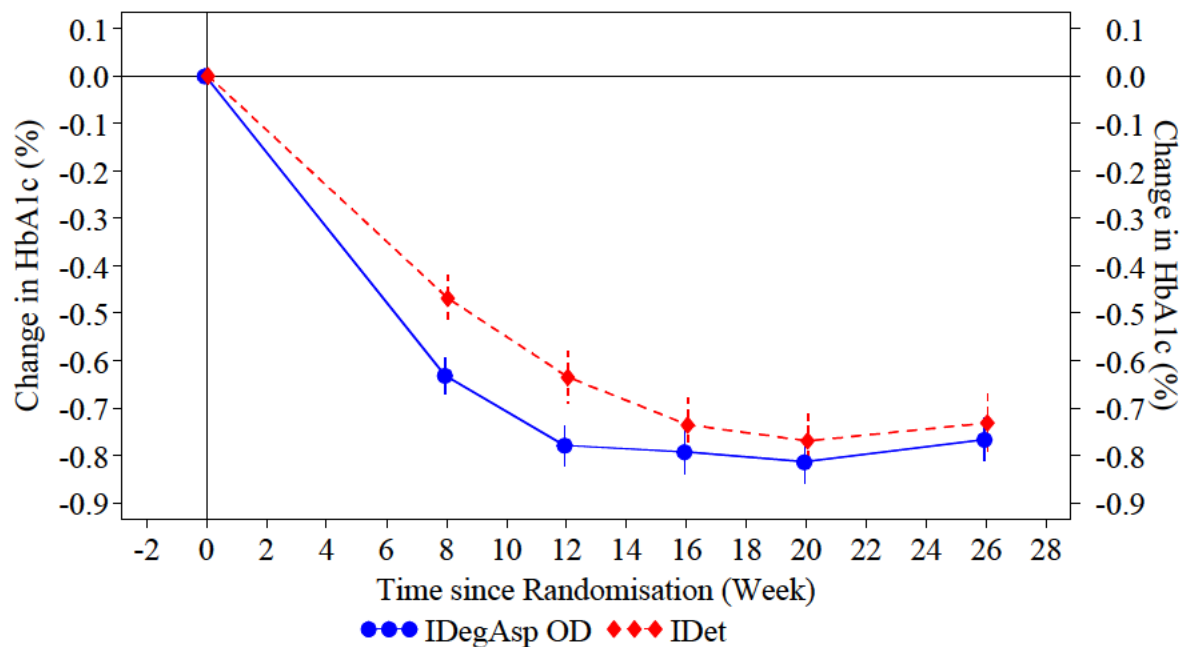
14.2.56: HbA1c (%) by Treatment Week – Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:44:42 - fmean_numfind_v03.sas/e_hb1c_chb_mean_locf_fas.cgm

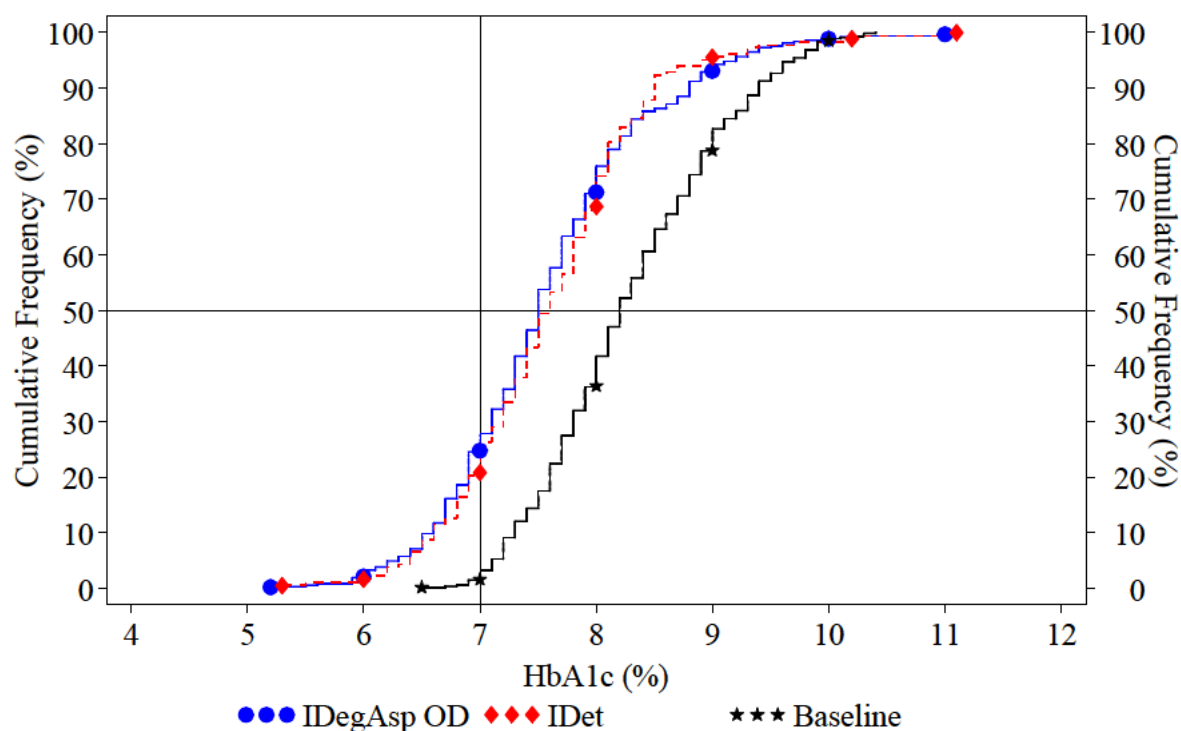
14.2.57: HbA1c (%) by Treatment Week – Change from Baseline – Mean Plot – Full Analysis Set



PP: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:44:48 - fmean_numfind_v03.sas/e_hba1c_chb_mean_locf_pp.cgm

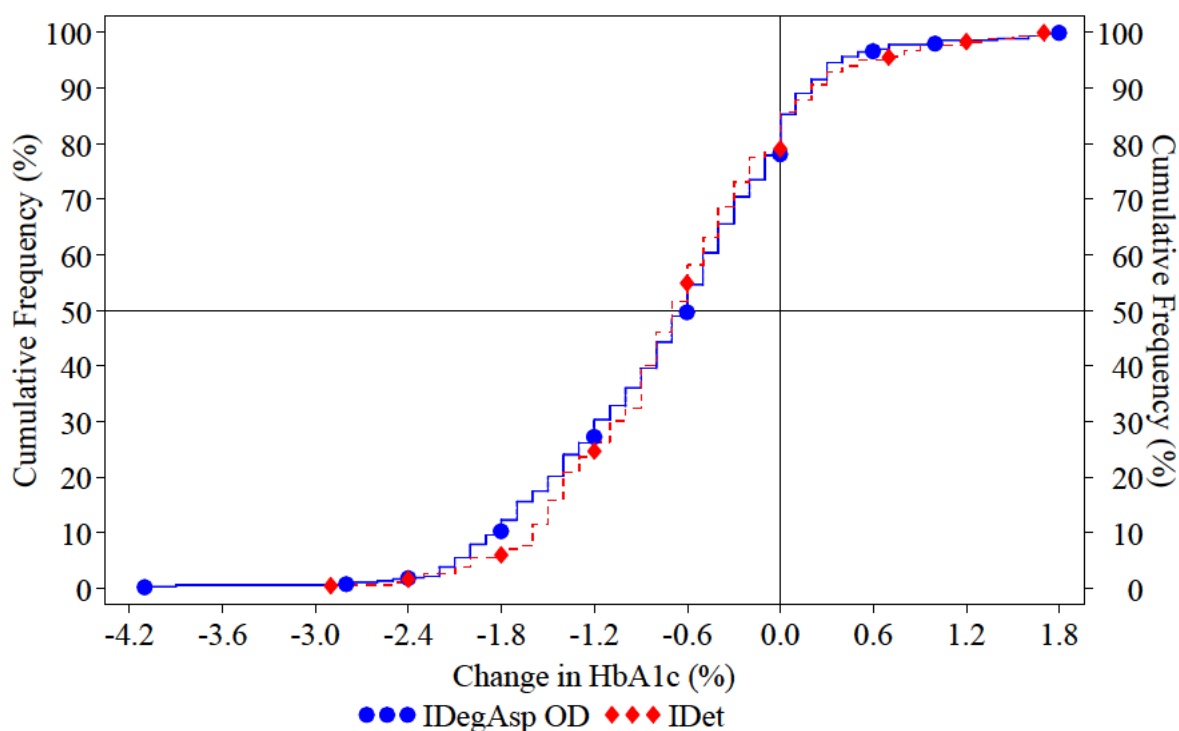
14.2.58: HbA1c (%) by Treatment Week – Change from Baseline – Mean Plot – PP Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:44:59 - fedist_numfind_v01.sas/e_hba1c_abs_cdf_locf_fas.cgm

14.2.59: HbA1c (%) after 26 Weeks of Treatment – Empirical Distribution Plot – Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:45:05 - fedist_numfind_v01.sas/e_hba1c_chb_cdf_locf_fas.cgm

14.2.60: HbA1c (%) after 26 Weeks of Treatment – Change from Baseline – Empirical Distribution Plot – Full Analysis Set

14.2.61: Responder for HbA1c by Treatment Week – Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
HbA1c <7.0% (ADA)			
Visit 1			
N	366 (100.0)	182 (100.0)	548 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	366 (100.0)	182 (100.0)	548 (100.0)
Visit 2 (Week 0)			
N	366 (100.0)	182 (100.0)	548 (100.0)
Yes	3 (0.8)	5 (2.7)	8 (1.5)
No	363 (99.2)	177 (97.3)	540 (98.5)
Visit 10 (Week 8)			
N	340 (100.0)	170 (100.0)	510 (100.0)
Yes	64 (18.8)	19 (11.2)	83 (16.3)
No	276 (81.2)	151 (88.8)	427 (83.7)
Visit 14 (Week 12)			
N	336 (100.0)	167 (100.0)	503 (100.0)
Yes	86 (25.6)	29 (17.4)	115 (22.9)
No	250 (74.4)	138 (82.6)	388 (77.1)
Visit 18 (Week 16)			
N	328 (100.0)	164 (100.0)	492 (100.0)
Yes	88 (26.8)	35 (21.3)	123 (25.0)
No	240 (73.2)	129 (78.7)	369 (75.0)
Visit 22 (Week 20)			
N	322 (100.0)	160 (100.0)	482 (100.0)
Yes	92 (28.6)	38 (23.8)	130 (27.0)
No	230 (71.4)	122 (76.3)	352 (73.0)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Yes	86 (26.9)	35 (22.3)	121 (25.4)
No	234 (73.1)	122 (77.7)	356 (74.6)
Visit 28 (Week 26) (LOCF)			
N	366 (100.0)	182 (100.0)	548 (100.0)
Yes	90 (24.6)	37 (20.3)	127 (23.2)
No	276 (75.4)	145 (79.7)	421 (76.8)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:45:08 - tsum_catgofind_tpl_t025_v01.sas/t_resp_hb1c_sum_locf_fas.txt

14.2.62: Responder for HbA1c at End of Trial - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
HbA1c<7.0%				
LSMeans, Odds				
IDegAsp OD	366	366	0.33	
IDet	182	182	0.25	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.35	[0.85 ; 2.14]

N= Number of subjects contributing to analysis, CI= Confidence Interval The binary endpoint is analysed in a Logistic Regression Model using a logit link. The model includes treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and hbalc as covariates.
Missing data is imputed using last observation carried forward.
End of Trial: the last end of trial visit of a subject excluding the follow-up visit
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:45:17 - tstat_find_tpl_t022.sas/t_resp_hbalc_stat_locf_fas.txt

14.2.63: Responder for HbA1c at End of Trial Without Hypoglycaemia – Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
HbA1c <7.0% w/o Confirmed Hypo.			
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Yes	15 (4.7)	5 (3.2)	20 (4.2)
No	305 (95.3)	152 (96.8)	457 (95.8)
Visit 28 (Week 26) (LOCF)			
N	337 (100.0)	169 (100.0)	506 (100.0)
Yes	15 (4.5)	5 (3.0)	20 (4.0)
No	322 (95.5)	164 (97.0)	486 (96.0)

N = Number of Subjects

Responder for HbA1c without hypoglycaemia: subject meeting the HbA1c target at end of trial without treatment emergent hypoglycaemia during the last 12 weeks of trt. Endpoint is only defined for subjects exposed for at least 12 trt. weeks. End of Trial: last end of trial visit of subject excluding follow-up visit.

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:45:20 - tsum_catgofind_tpl_t025_v01.sas/t_resp_hbA1c_hypO_sum_fas.txt

Responder for HbA1c at End of Trial Without Hypoglycaemia - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HbA1c <7.0% w/o Severe Hypo.			
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Yes	81 (25.3)	35 (22.3)	116 (24.3)
No	239 (74.7)	122 (77.7)	361 (75.7)
Visit 28 (Week 26) (LOCF)			
N	337 (100.0)	169 (100.0)	506 (100.0)
Yes	82 (24.3)	35 (20.7)	117 (23.1)
No	255 (75.7)	134 (79.3)	389 (76.9)

N = Number of Subjects

Responder for HbA1c without hypoglycaemia: subject meeting the HbA1c target at end of trial without treatment emergent hypoglycaemia during the last 12 weeks of trt. Endpoint is only defined for subjects exposed for at least 12 trt. weeks. End of Trial: last end of trial visit of subject excluding follow-up visit.

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:45:20 - tsum_catgofind_tpl_t025_v01.sas/t_resp_hb1c_hypo_sum_fas.txt

14.2.64: HbA1c < 7.0% at End of Trial Without Severe Hypoglycaemia - Confirmatory Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
HbA1c <7.0% w/o S Hypo				
LSMeans, Odds				
IDegAsp OD	366	337	0.37	
IDet	182	169	0.30	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.24	[0.77 ; 2.02]

N = Number of subjects contributing to analysis, CI = Confidence Interval
The endpoint is analysed in a Logistic Regression Model using a logit link, including treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and HbA1c as covariates. Missing data is imputed using LOCF.
HbA1c <7.0% w/o Hypo: A subject exposed for at least 12 weeks, who meets HbA1c target w/o hypoglycaemia during last 12 weeks treatment or within 7 days from last randomised treatment.
End of Trial: the last end of trial visit excluding follow-up visit.
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:14:42:19 - tstat_find_tpl_t022.sas/t_resp_hbA1c7_sh_cstat_locf_fas.txt

14.2.65: HbA1c < 7.0% at End of Trial Without Severe Hypoglycaemia - Parameter Estimates on Mean Scale - Full Analysis Set

	Estimate	DF	95% CI
HbA1c <7.0% w/o S Hypo			
Treatment			
IDegAsp OD	1.24	1	[0.77 ; 2.02]
IDet	1.00	0	[1.00 ; 1.00]
Region			
Australia	1.26	1	[0.56 ; 2.85]
Europe	1.48	1	[0.88 ; 2.50]
North America	1.00	0	[1.00 ; 1.00]
Sex			
Female	1.21	1	[0.77 ; 1.90]
Male	1.00	0	[1.00 ; 1.00]
Antidiabetic Treatment at Screening			
Basal-Bolus	0.35	1	[0.17 ; 0.72]
Other	1.00	0	[1.00 ; 1.00]
Regression			
HbA1c	0.29	1	[0.21 ; 0.41]
Age	1.00	1	[0.98 ; 1.02]

The binary endpoint is analysed in a Logistic Regression Model using a logit link. The model includes treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and hbA1c as covariates.

Estimates and Confidence intervals are odds ratios.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:14:42:20 - tstat_find_tpl_t022.sas/t_resp_hbA1c7_sh_cstat_p_fas.txt

14.2.66: Responder for HbA1c at End of Trial Without Hypoglycaemia - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
HbA1c < 7.0% w/o Confirmed Hypo				
LSMeans, Odds				
IDegAsp OD	366	337	0.03	
IDet	182	169	0.02	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.53	[0.54 ; 4.38]

The endpoint is analysed in a Logistic Regression Model using a logit link, including treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and hbalc as covariates. Missing data is imputed using LOCF.

HbA1c <7.0% w/o Hypo: A subject exposed for at least 12 weeks, who meets the HbA1c target w/o hypoglycaemia during the last 12 weeks of treatment or within 7 days from last randomised treatment. End of Trial: the last end of trial visit of a subject excluding the follow-up visit. Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL).

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:45:29 - tstat_find_tpl_t022.sas/t_resp_hbalc_hypo_stat_locf_fas.txt

14.2.67: Fasting Plasma Glucose (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
FPG (mmol/L)			
Visit 2 (Week 0)			
N	365	181	546
Mean (SD)	10.3 (4.7)	11.0 (4.8)	10.5 (4.8)
Median	9.6	10.3	9.9
Min ; Max	1.8 ; 30.2	2.9 ; 28.4	1.8 ; 30.2
Visit 14 (Week 12)			
N	332	167	499
Mean (SD)	8.0 (3.4)	9.0 (3.7)	8.3 (3.5)
Median	7.4	8.8	7.8
Min ; Max	1.7 ; 23.4	1.9 ; 22.9	1.7 ; 23.4
Visit 18 (Week 16)			
N	326	162	488
Mean (SD)	8.4 (3.6)	8.6 (4.2)	8.5 (3.8)
Median	8.0	7.5	7.9
Min ; Max	1.6 ; 26.6	1.8 ; 22.1	1.6 ; 26.6
Visit 28 (Week 26)			
N	321	156	477
Mean (SD)	8.4 (3.7)	8.3 (3.5)	8.4 (3.6)
Median	8.2	7.8	7.9
Min ; Max	1.9 ; 26.5	1.8 ; 19.3	1.8 ; 26.5
Visit 28 (Week 26) (LOCF)			
N	366	181	547
Mean (SD)	8.7 (4.0)	8.6 (3.8)	8.7 (3.9)
Median	8.2	7.9	8.2
Min ; Max	1.9 ; 26.5	1.8 ; 23.2	1.8 ; 26.5

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:45:41 - tdesc_numfind_tpl_t019_v01.sas/t_fpg_abs_descp_fas.txt

14.2.68: Fasting Plasma Glucose (mmol/L) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Change in FPG (mmol/L)			
Visit 14 (Week 12)			
N	331	167	498
Mean (SD)	-2.33 (5.33)	-2.04 (5.66)	-2.23 (5.44)
Median	-1.80	-2.00	-1.90
Min ; Max	-22.4 ; 14.00	-19.8 ; 15.10	-22.4 ; 15.10
Visit 18 (Week 16)			
N	325	162	487
Mean (SD)	-1.92 (5.59)	-2.32 (5.90)	-2.05 (5.69)
Median	-1.60	-2.10	-1.60
Min ; Max	-26.1 ; 12.60	-23.7 ; 14.10	-26.1 ; 14.10
Visit 28 (Week 26)			
N	320	156	476
Mean (SD)	-1.80 (5.37)	-2.61 (5.43)	-2.07 (5.40)
Median	-1.55	-1.90	-1.70
Min ; Max	-25.3 ; 12.50	-24.0 ; 14.20	-25.3 ; 14.20
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	-1.61 (5.38)	-2.41 (5.47)	-1.87 (5.42)
Median	-1.10	-1.60	-1.40
Min ; Max	-25.3 ; 12.50	-24.0 ; 14.20	-25.3 ; 14.20

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:45:54 - tdesc_numfind_tpl_t019_v01.sas/t_fpg_chb_descp_fas.txt

14.2.69: Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment - Confirmatory Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
FPG (mmol/L)					
LSMeans					
IDegAsp OD	366	365	8.88	0.34	
IDet	182	181	8.65	0.39	
Change from Baseline					
LSMeans					
IDegAsp OD	366	365	-1.65	0.34	
IDet	182	181	-1.88	0.39	
Treatment Contrast					
IDeg OD - IDet			0.23		[-0.46 ; 0.91]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
Missing data is imputed using last observation carried forward.

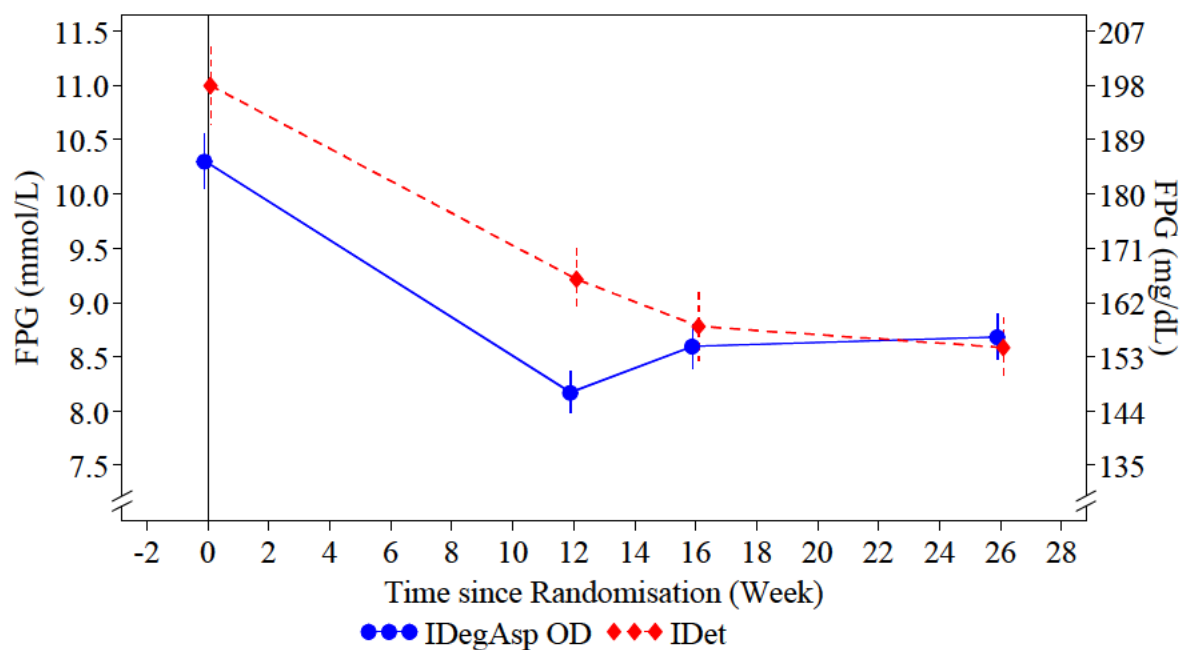
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:46:00 - tstat_find_tpl_t022.sas/t_fpg_conf_stat_locf_fas.txt

14.2.70: Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment - Parameter Estimates on Observed Scale - Full Analysis Set

	Estimate	DF	95% CI
FPG (mmol/L)			
Treatment			
IDegAsp OD	0.23	538	[-0.46 ; 0.91]
IDet	0.00		
Region			
Australia	0.18	538	[-0.93 ; 1.28]
Europe	0.11	538	[-0.61 ; 0.84]
North America	0.00		
Sex			
Female	0.07	538	[-0.57 ; 0.72]
Male	0.00		
Antidiabetic Treatment at Screening			
Basal-Bolus	-0.34	538	[-1.46 ; 0.77]
Other	0.00		
Regression			
Age	-0.01	538	[-0.03 ; 0.02]
Baseline response	-0.82	538	[-0.88 ; -0.75]

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates. Estimates and Confidence intervals are based on change from baseline in the response. Missing data is imputed using last observation carried forward.

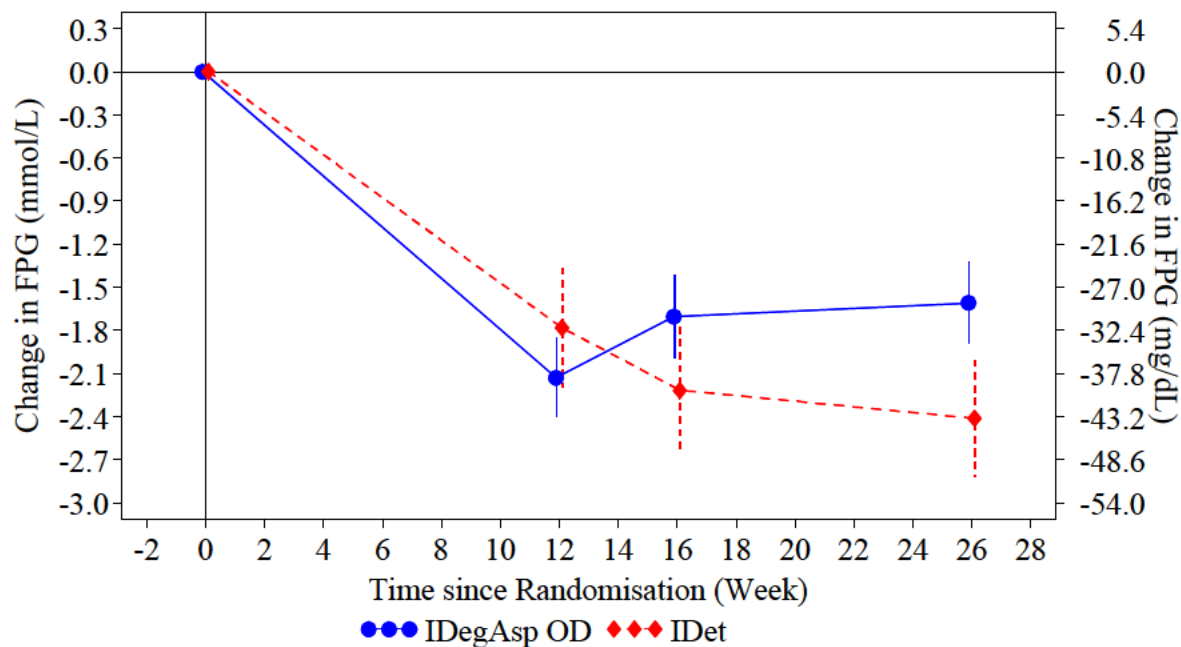
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:46:01 - tstat_find_tpl_t022.sas/t_fpg_conf_stat_parm_fas.txt



FAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:46:07 - fmean_numfind_v03.sas/e_fpg_abs_mean_locf_fas.cgm

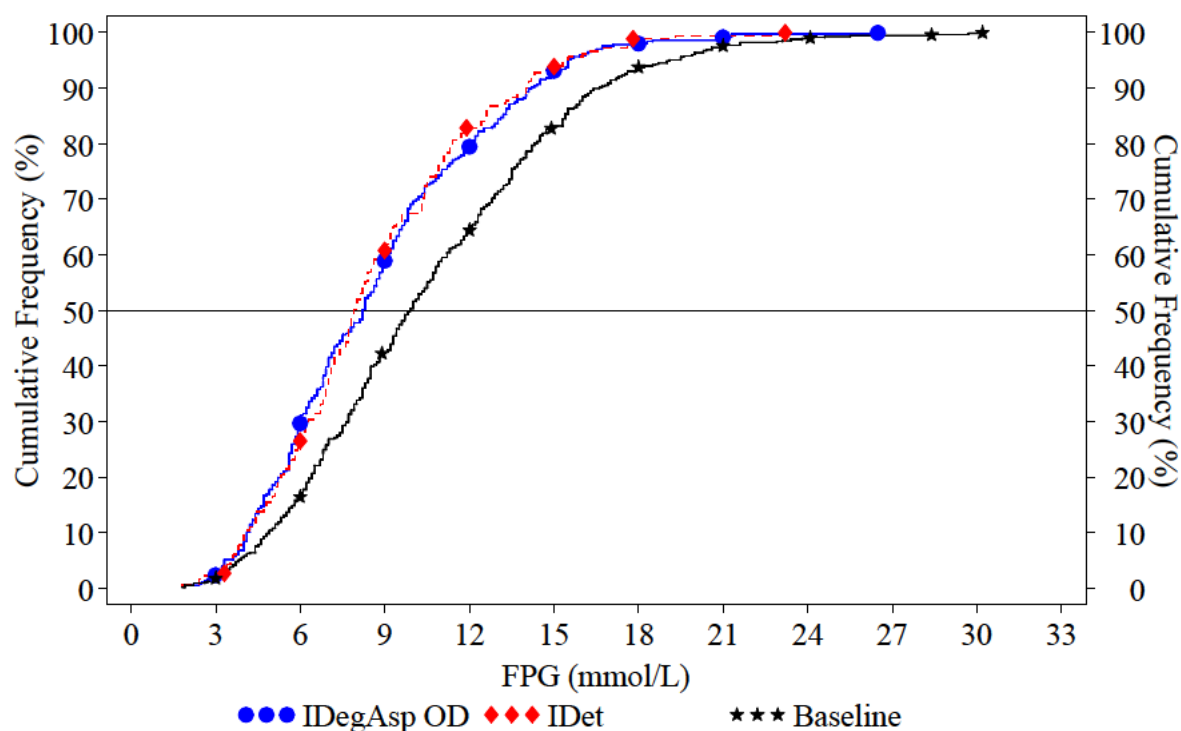
14.2.71: Fasting Plasma Glucose (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:46:14 - fmean_numfind_v03.sas/e_fpg_chb_mean_locf_fas.cgm

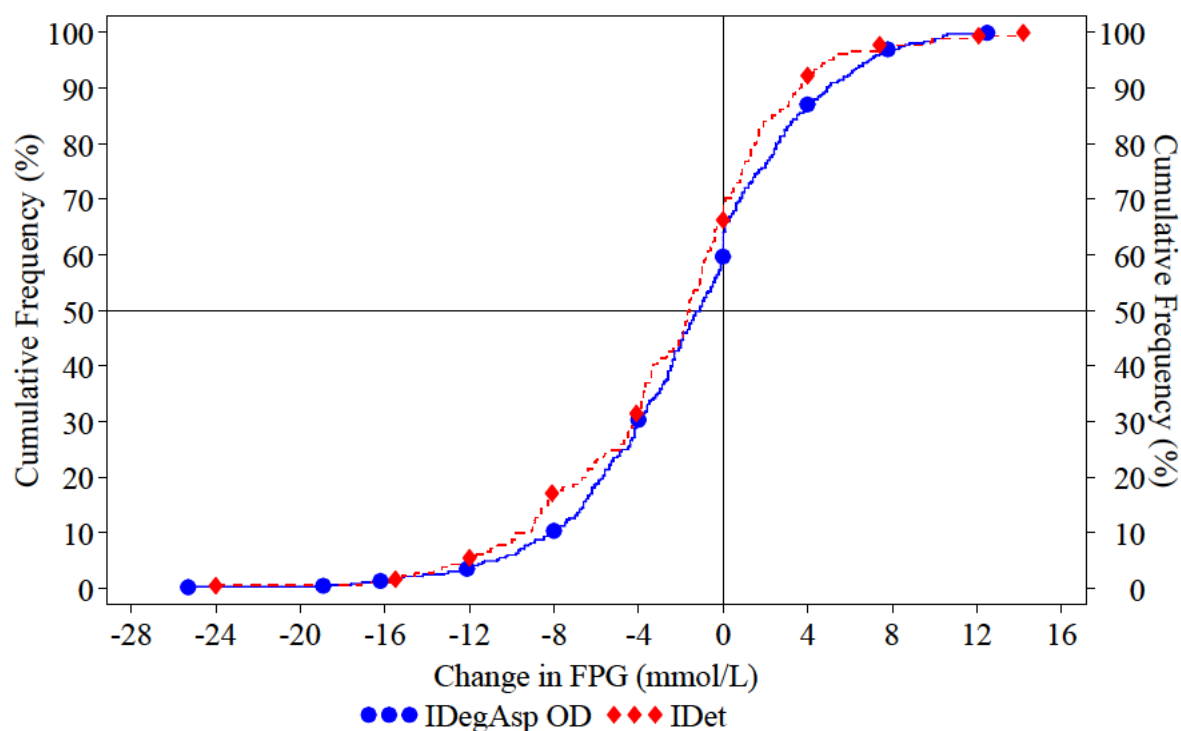
14.2.72: Fasting Plasma Glucose (mmol/L) by Treatment Week – Change from Baseline – Mean Plot – Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:46:24 - fedist_numfind_v01.sas/e_fpg_abs_mean_cdf_locf_fas.cgm

14.2.73: Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:46:30 - fedist_numfind_v01.sas/e_fpg_chb_cdf_locf_fas.cgm

14.2.74: Fasting Plasma Glucose (mmol/L) after 26 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set

14.2.75: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set

	N	IDegAsp Mean	OD SD	N	IDet Mean	SD	N	Total Mean	SD
Number Of Subjects	366			182			548		
SMPG (mmol/L)									
Visit 2 (Week 0)									
Before breakfast	360	9.3	4.5	180	9.7	4.3	540	9.4	4.4
90 minutes after start of breakfast	340	10.4	4.3	173	11.0	4.3	513	10.6	4.3
Before lunch	358	8.5	3.9	176	8.8	4.0	534	8.6	3.9
90 minutes after start of lunch	341	9.9	4.0	174	10.5	4.7	515	10.1	4.3
Before main evening meal	354	9.5	4.5	179	9.7	4.4	533	9.6	4.5
90 min after main evening meal	339	10.1	4.2	176	10.4	4.9	515	10.2	4.4
Before bedtime	345	10.0	4.3	170	9.5	4.4	515	9.8	4.4
At 04:00 A.M.	339	9.1	4.4	169	9.0	4.2	508	9.1	4.4
Before breakfast the following day	355	9.4	4.3	178	9.6	4.1	533	9.4	4.2
Visit 14 (Week 12)									
Before breakfast	331	7.4	3.1	167	7.4	3.4	498	7.4	3.2
90 minutes after start of breakfast	291	8.0	3.4	147	8.6	3.8	438	8.2	3.5
Before lunch	330	7.3	3.5	165	8.1	3.9	495	7.6	3.6
90 minutes after start of lunch	297	8.0	3.4	153	8.2	3.6	450	8.1	3.4
Before main evening meal	333	8.1	3.7	166	8.6	3.9	499	8.3	3.8
90 min after main evening meal	289	8.8	3.7	148	9.0	3.6	437	8.8	3.7
Before bedtime	291	8.6	4.2	156	8.9	3.8	447	8.7	4.1
At 04:00 A.M.	247	7.6	3.5	133	8.4	4.9	380	7.9	4.1
Before breakfast the following day	324	7.4	3.1	165	7.8	4.1	489	7.5	3.5
Visit 18 (Week 16)									
Before breakfast	326	7.4	3.4	162	6.8	3.1	488	7.2	3.3
90 minutes after start of breakfast	298	8.5	3.6	144	8.1	3.2	442	8.3	3.5
Before lunch	324	7.4	3.5	161	7.4	3.2	485	7.4	3.4
90 minutes after start of lunch	300	8.1	3.4	144	8.2	3.3	444	8.1	3.4
Before main evening meal	323	7.8	3.7	162	8.2	3.7	485	8.0	3.7
90 min after main evening meal	297	8.2	3.5	139	8.4	3.9	436	8.3	3.6
Before bedtime	306	8.2	3.4	157	8.7	4.4	463	8.4	3.8
At 04:00 A.M.	262	7.6	3.5	131	7.7	3.9	393	7.6	3.7
Before breakfast the following day	326	7.1	2.9	160	7.3	3.2	486	7.2	3.0
Visit 28 (Week 26)									
Before breakfast	317	7.2	3.1	154	6.9	3.4	471	7.1	3.2
90 minutes after start of breakfast	282	8.2	3.5	140	8.7	3.8	422	8.4	3.6
Before lunch	316	7.1	3.1	154	8.1	3.7	470	7.4	3.3
90 minutes after start of lunch	282	8.0	3.3	141	8.5	3.6	423	8.1	3.4
Before main evening meal	316	8.0	3.7	156	8.1	4.0	472	8.1	3.8
90 min after main evening meal	286	8.6	3.6	137	8.6	3.4	423	8.6	3.5
Before bedtime	297	8.4	3.4	149	7.9	3.5	446	8.2	3.4
At 04:00 A.M.	255	7.6	3.2	127	7.4	3.7	382	7.5	3.4
Before breakfast the following day	312	7.0	2.9	153	7.5	3.1	465	7.2	3.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:46:38 - tdesc_numfind_tpl_t020_v01.sas/t_9pp_abs_descp_fas.txt

9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week - Descriptive Statistics - Full Analysis Set

	N	IDegAsp Mean	OD SD	N	IDet Mean	SD	N	Total Mean	SD
SMPG (mmol/L)									
Visit 28 (Week 26) (LOCF)									
Before breakfast	363	7.5	3.5	178	7.0	3.5	541	7.3	3.5
90 minutes after start of breakfast	309	8.4	3.7	156	8.7	3.8	465	8.5	3.8
Before lunch	358	7.3	3.4	178	8.5	4.0	536	7.7	3.6
90 minutes after start of lunch	309	8.2	3.5	159	8.4	3.6	468	8.3	3.5
Before main evening meal	356	8.2	3.8	181	8.5	4.3	537	8.3	4.0
90 min after main evening meal	315	8.7	3.8	152	8.8	3.5	467	8.7	3.7
Before bedtime	339	8.6	3.5	170	8.4	4.1	509	8.5	3.7
At 04:00 A.M.	281	7.7	3.4	143	7.5	3.8	424	7.7	3.5
Before breakfast the following day	355	7.1	3.1	178	8.0	3.6	533	7.4	3.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:46:38 - tdesc_numfind_tpl_t020_v01.sas/t_9pp_abs_descp_fas.txt

14.2.76: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

Value	FAS	N	Estimate	SE	95% CI
Before Breakfast					
LSMeans					
IDegAsp OD	366	363	7.75	0.23	
IDet	182	178	7.26	0.30	
Treatment Contrast					
IDegAsp OD - IDet			0.48		[-0.13 ; 1.10]
90 Minutes After Start Of Breakfast					
LSMeans					
IDegAsp OD	366	309	8.57	0.26	
IDet	182	156	8.94	0.33	
Treatment Contrast					
IDegAsp OD - IDet			-0.37		[-1.07 ; 0.34]
Before Lunch					
LSMeans					
IDegAsp OD	366	358	7.70	0.24	
IDet	182	178	8.78	0.31	
Treatment Contrast					
IDegAsp OD - IDet			-1.08		[-1.73 ; -0.43]
90 Minutes After Start Of Lunch					
LSMeans					
IDegAsp OD	366	309	8.52	0.25	
IDet	182	159	8.65	0.32	
Treatment Contrast					
IDegAsp OD - IDet			-0.12		[-0.80 ; 0.55]
Before Main Evening Meal					
LSMeans					
IDegAsp OD	366	356	8.47	0.26	
IDet	182	181	8.75	0.33	
Treatment Contrast					
IDegAsp OD - IDet			-0.28		[-0.99 ; 0.43]

N: Number of subjects contributing to analysis

CI: Confidence Interval

SE: Standard Error of the Mean

9-point profile (SMPG) values after 26 weeks of treatment are analysed jointly using a linear mixed model with an unstructured residual covariance structure and with treatment, time-point and an interaction between treatment and time-point, anti-diabetic treatment at screening, region and sex as fixed effects, and age and baseline response per time-point as covariates. Missing profiles are imputed using last observation carried forward.

9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

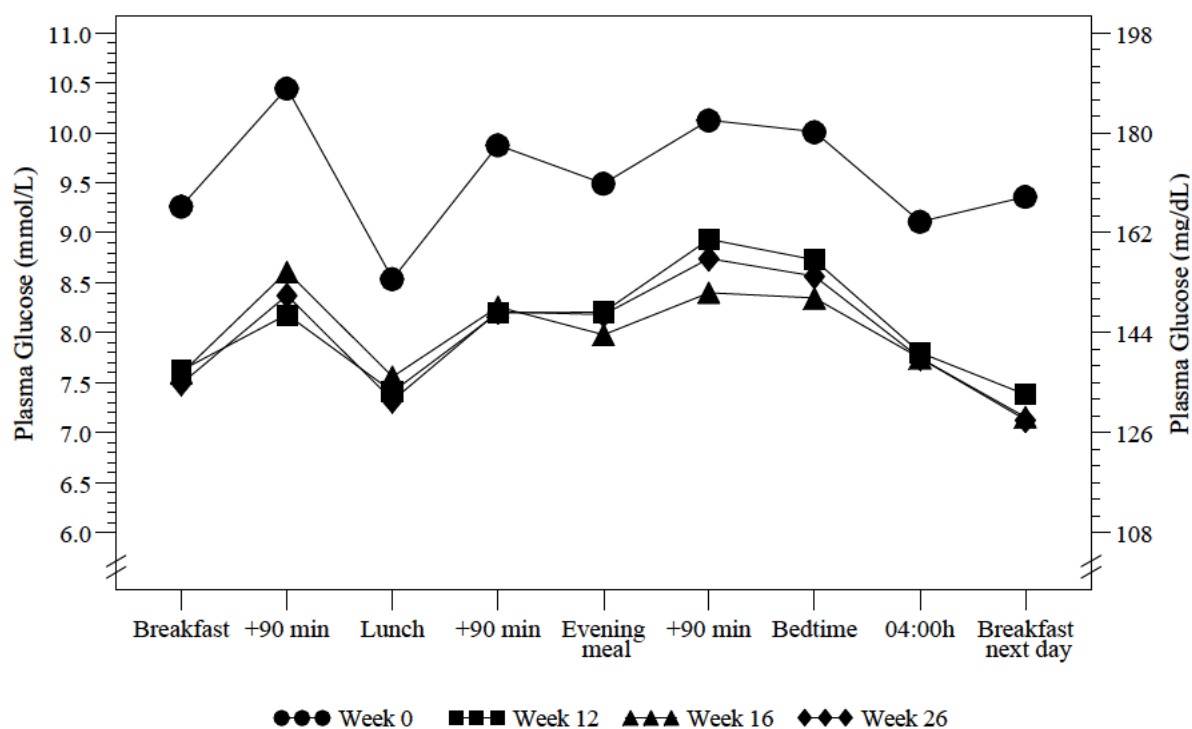
Value	FAS	N	Estimate	SE	95% CI
90 Minutes After The Start Of Main Evening Meal					
LSMeans					
IDegAsp OD	366	315	9.00	0.25	
IDet	182	152	9.06	0.32	
Treatment Contrast					
IDegAsp OD - IDet			-0.06		[-0.74 ; 0.63]
Before Bedtime					
LSMeans					
IDegAsp OD	366	339	8.76	0.24	
IDet	182	170	8.50	0.31	
Treatment Contrast					
IDegAsp OD - IDet			0.27		[-0.38 ; 0.91]
At 4:00 A.M.					
LSMeans					
IDegAsp OD	366	281	8.20	0.25	
IDet	182	143	8.00	0.32	
Treatment Contrast					
IDegAsp OD - IDet			0.20		[-0.49 ; 0.89]
Before Breakfast The Following Day					
LSMeans					
IDegAsp OD	366	355	7.42	0.22	
IDet	182	178	8.14	0.28	
Treatment Contrast					
IDegAsp OD - IDet			-0.72		[-1.28 ; -0.15]

N: Number of subjects contributing to analysis

CI: Confidence Interval

SE: Standard Error of the Mean

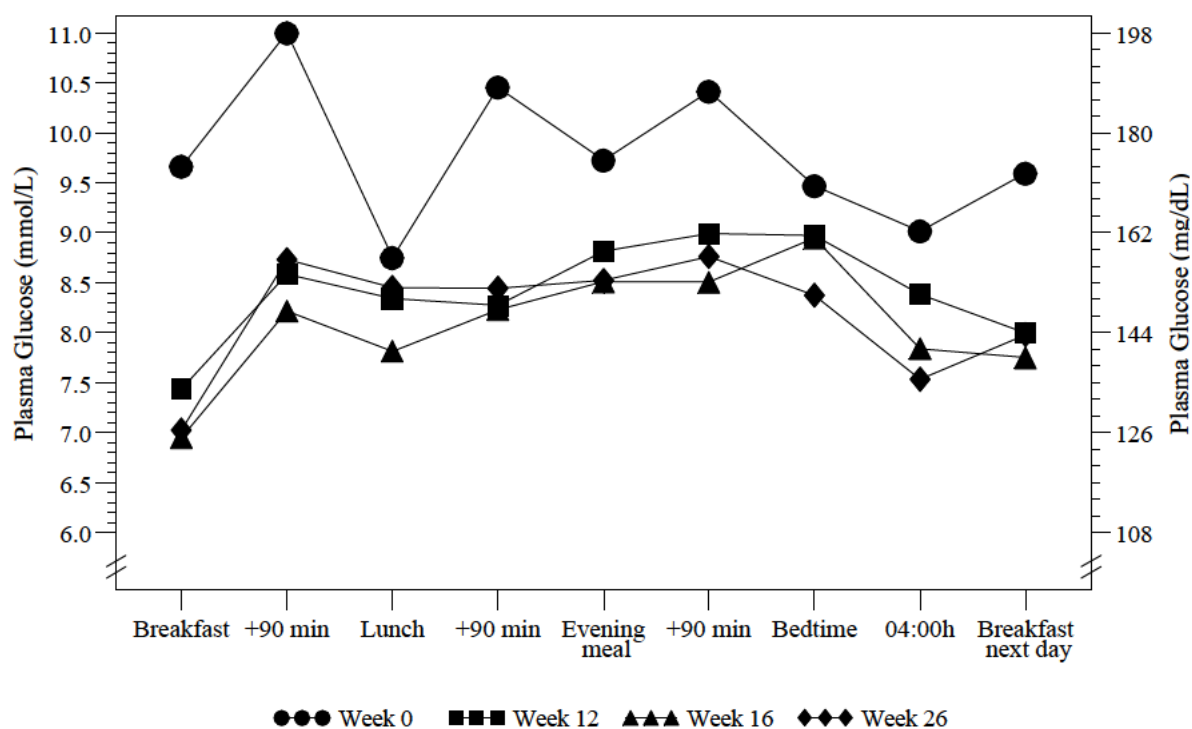
9-point profile (SMPG) values after 26 weeks of treatment are analysed jointly using a linear mixed model with an unstructured residual covariance structure and with treatment, time-point and an interaction between treatment and time-point, anti-diabetic treatment at screening, region and sex as fixed effects, and age and baseline response per time-point as covariates. Missing profiles are imputed using last observation carried forward.



Missing profiles was imputed using LOCF

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:08 - fplot_9PP/e_9pp_al_w_iv1_abs_mean_locf_fas.cgm

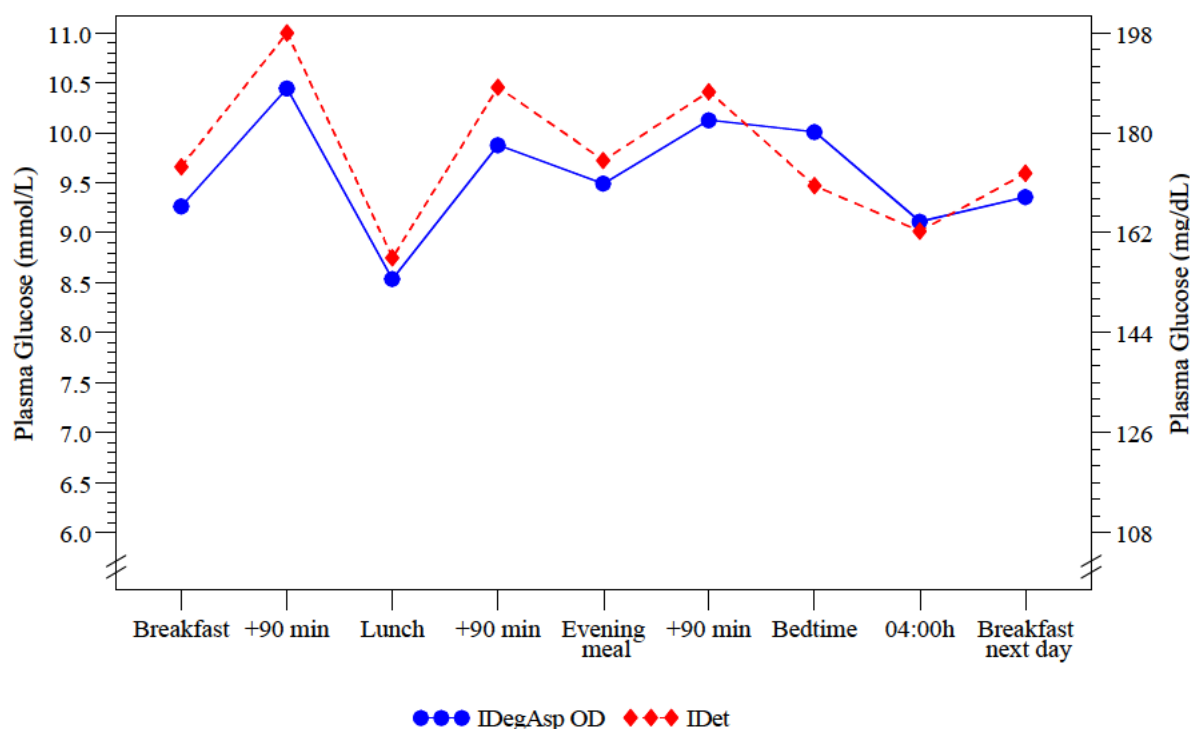
14.2.77: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Weeks - Mean Plot - IDegAsp OD - Full Analysis Set



Missing profiles was imputed using LOCF

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:12 - fplot_9PP/e_9pp_al_w_cm_abs_mean_locf_fas.cgm

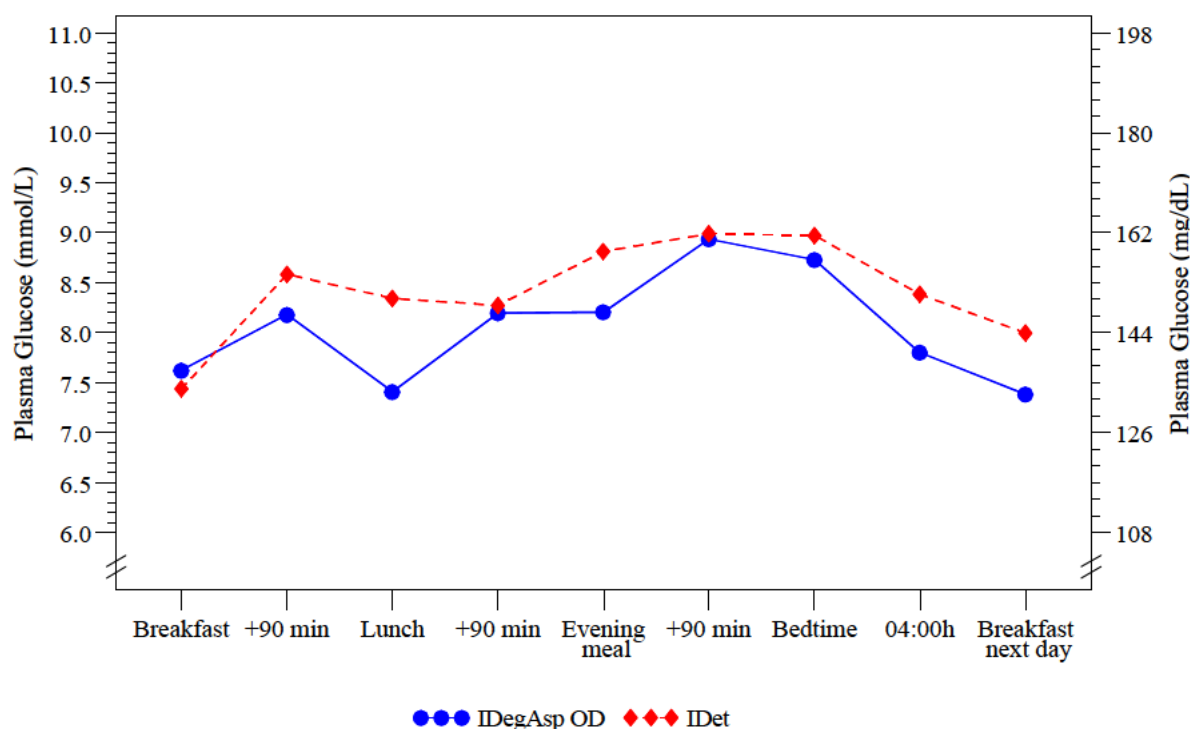
14.2.78: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Weeks - Mean Plot - IDet - Full Analysis Set



Missing profiles was imputed using LOCF

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:38:17 - fplot_9PP/e_9pp_week0_abs_mean_locf_fas.cgm

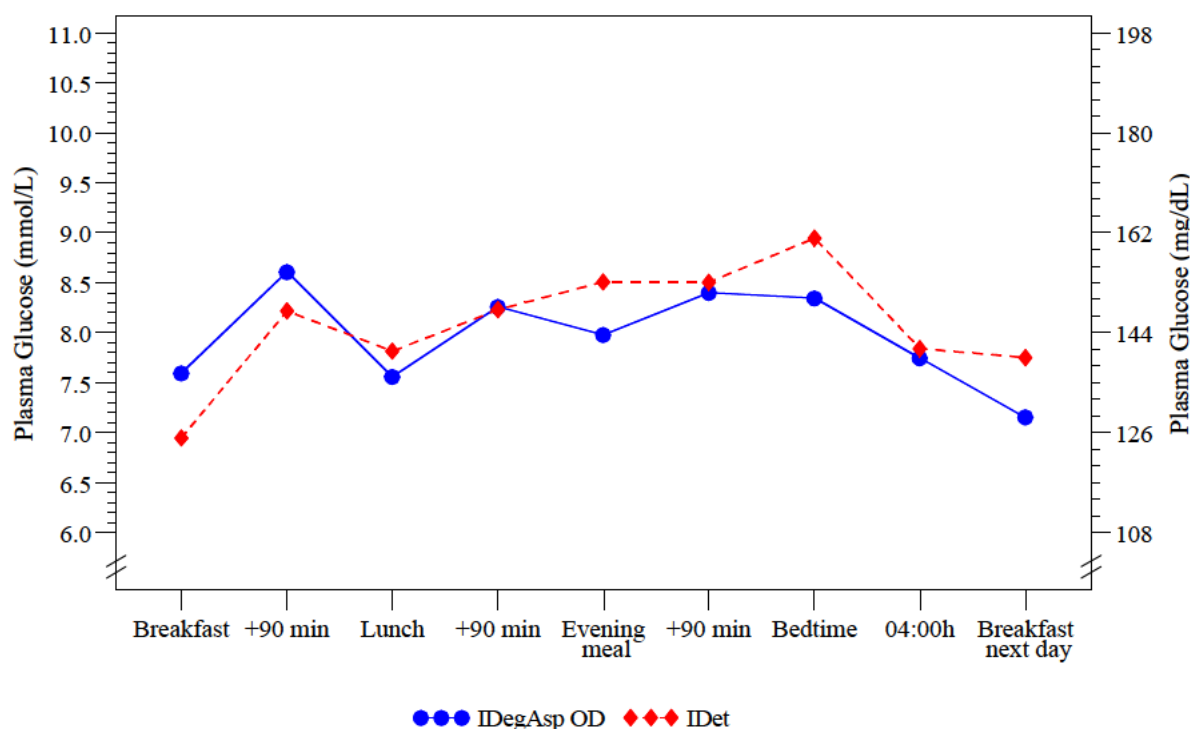
14.2.79: 9-point Self Measured Plasma Glucose Profile (mmol/L) at Baseline - Mean Plot - Full Analysis Set



Missing profiles was imputed using LOCF

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:21 - fplot_9PP/e_9pp_week12_abs_mean_locf_fas.cgm

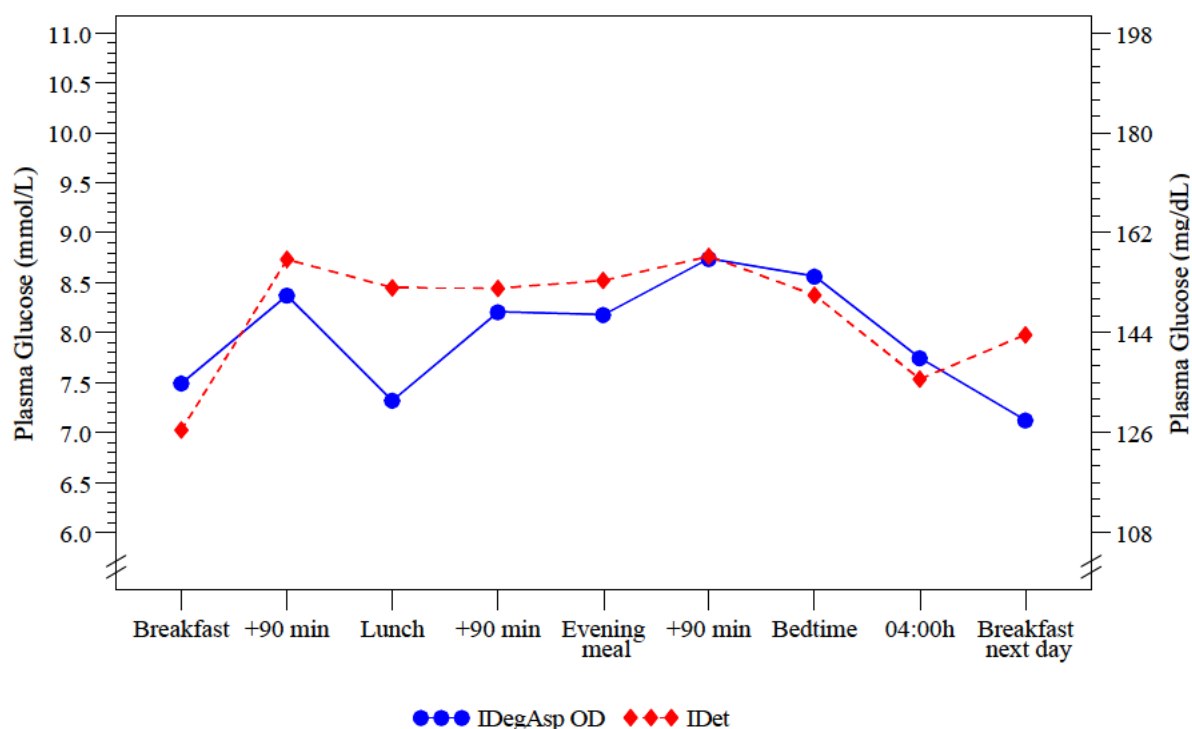
14.2.80: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 12 Weeks - Mean Plot - Full Analysis Set



Missing profiles was imputed using LOCF

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:38:26 - fplot_9PP/e_9pp_week16_abs_mean_locf_fas.cgm

14.2.81: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 16 Weeks - Mean Plot - Full Analysis Set



Missing profiles was imputed using LOCF

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:38:30 - fplot_9PP/e_9pp_week26_abs_mean_locf_fas.cgm

14.2.82: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks - Mean Plot - Full Analysis Set

14.2.83: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Mean PG (mmol/L)			
Visit 2 (Week 0)			
N	355	179	534
Mean (SD)	9.6 (2.2)	9.8 (2.3)	9.7 (2.2)
Median	9.4	9.4	9.4
Min ; Max	5.9 ; 16.7	5.2 ; 17.7	5.2 ; 17.7
Visit 14 (Week 12)			
N	325	164	489
Mean (SD)	8.0 (2.2)	8.4 (2.5)	8.2 (2.3)
Median	7.6	7.8	7.7
Min ; Max	4.4 ; 15.8	3.7 ; 19.6	3.7 ; 19.6
Visit 18 (Week 16)			
N	323	162	485
Mean (SD)	7.9 (2.0)	8.0 (2.0)	7.9 (2.0)
Median	7.6	7.6	7.6
Min ; Max	4.7 ; 15.2	4.5 ; 15.4	4.5 ; 15.4
Visit 28 (Week 26)			
N	310	153	463
Mean (SD)	7.9 (2.1)	8.1 (2.1)	7.9 (2.1)
Median	7.6	7.9	7.8
Min ; Max	4.5 ; 15.9	4.5 ; 14.8	4.5 ; 15.9
Visit 28 (Week 26) (LOCF)			
N	349	177	526
Mean (SD)	8.0 (2.2)	8.4 (2.5)	8.1 (2.3)
Median	7.8	8.1	7.9
Min ; Max	4.5 ; 15.9	4.5 ; 23.4	4.5 ; 23.4

N = Number of Subjects, SD = Standard Deviation

The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:47:25 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_mean_descp_fas.txt

14.2.84: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Change in Mean PG (mmol/L)			
Visit 14 (Week 12)			
N	319	164	483
Mean (SD)	-1.6 (2.7)	-1.4 (3.1)	-1.5 (2.9)
Median	-1.4	-1.5	-1.4
Min ; Max	-9.1 ; 7.6	-10.9 ; 7.4	-10.9 ; 7.6
Visit 18 (Week 16)			
N	316	162	478
Mean (SD)	-1.7 (2.6)	-1.8 (2.5)	-1.7 (2.5)
Median	-1.7	-1.7	-1.7
Min ; Max	-9.6 ; 6.1	-10.8 ; 6.1	-10.8 ; 6.1
Visit 28 (Week 26)			
N	303	153	456
Mean (SD)	-1.7 (2.6)	-1.7 (2.7)	-1.7 (2.6)
Median	-1.6	-1.6	-1.6
Min ; Max	-8.5 ; 5.5	-11.1 ; 6.5	-11.1 ; 6.5
Visit 28 (Week 26) (LOCF)			
N	342	176	518
Mean (SD)	-1.6 (2.6)	-1.4 (2.8)	-1.5 (2.7)
Median	-1.4	-1.3	-1.3
Min ; Max	-8.5 ; 5.5	-11.1 ; 7.4	-11.1 ; 7.4

N = Number of Subjects, SD = Standard Deviation

The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method

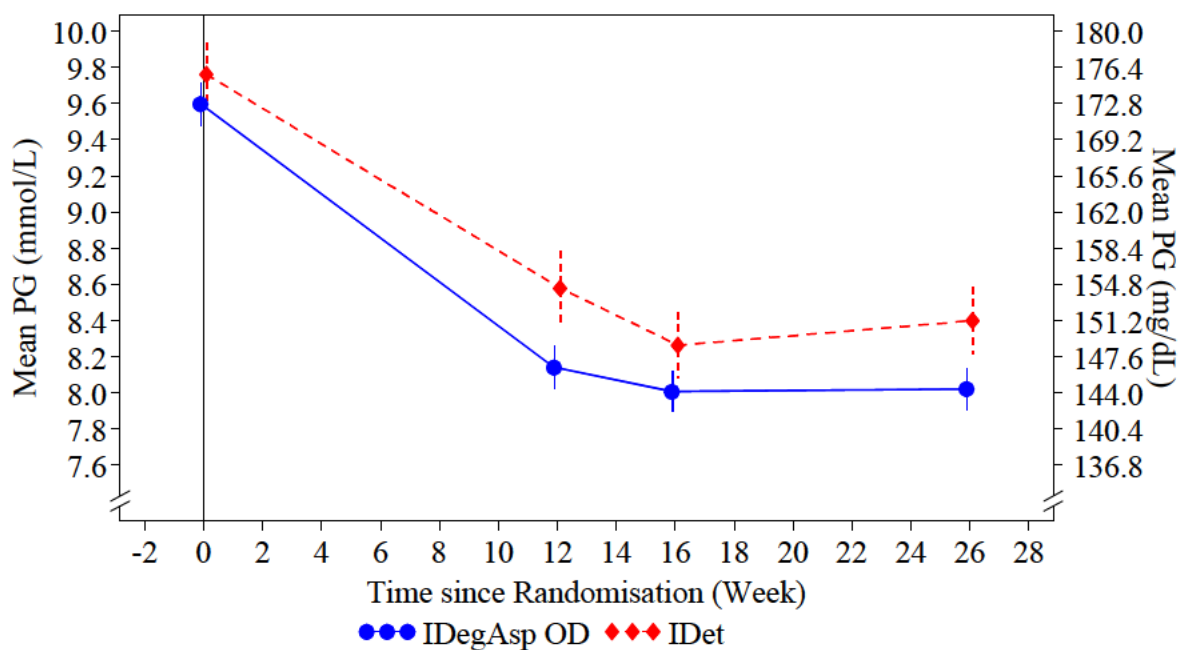
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:47:31 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_mean_descp_fas.txt

14.2.85: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Mean PG (mmol/L)					
LSMeans					
IDegAsp OD	366	342	8.14	0.19	
IDet	182	176	8.41	0.22	
Treatment Contrast					
IDegAsp OD - IDet			-0.27		[-0.65 ; 0.10]

The response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and mean profile at baseline as covariates. Missing data is imputed using LOCF. The mean profile is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

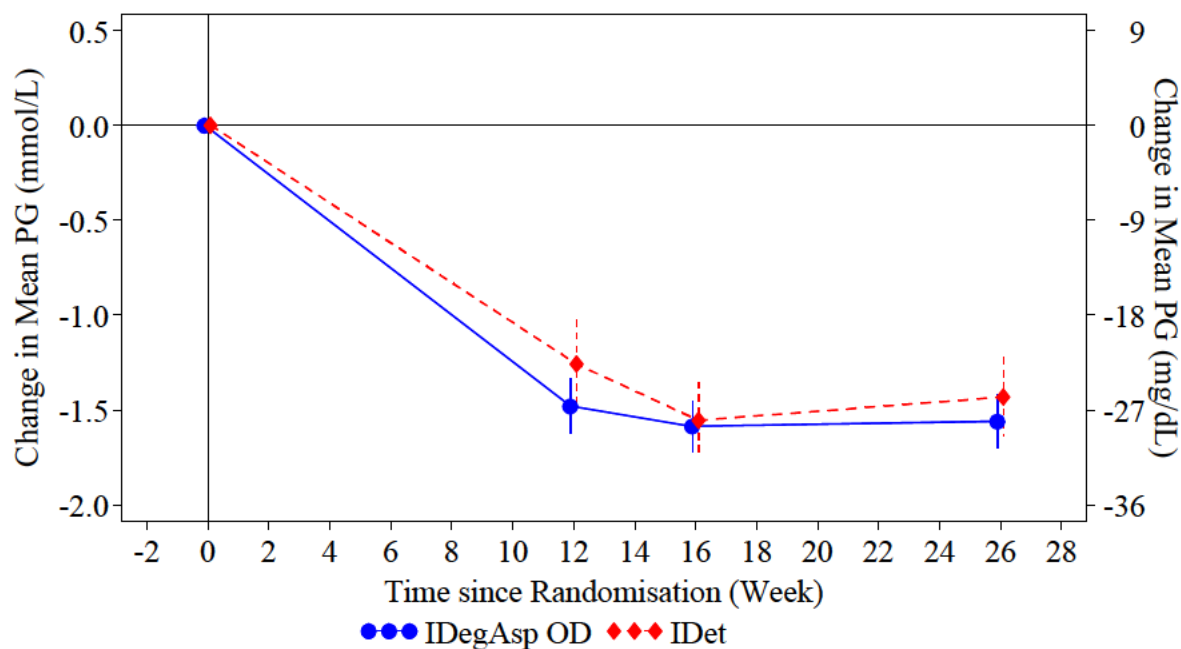
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:47:37 - tstat_find_tpl_t022.sas/t_9pp_mean_stat_locf_fas.txt



FAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:47:44 - finean_numfind_v03.sas/e_9pp_abs_mean_mean_locf_fas.cgm

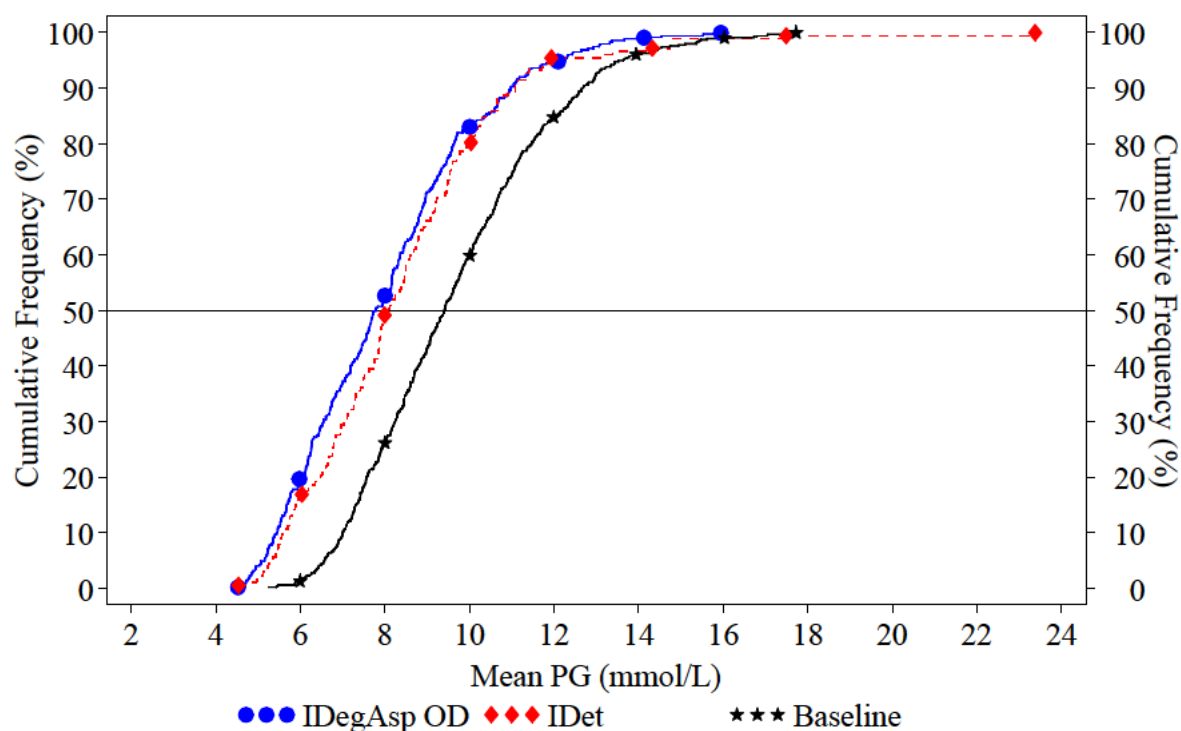
14.2.86: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:47:50 - fmean_numfind_v03.sas/e_9pp_chb_mean_mean_locf_fas.cgm

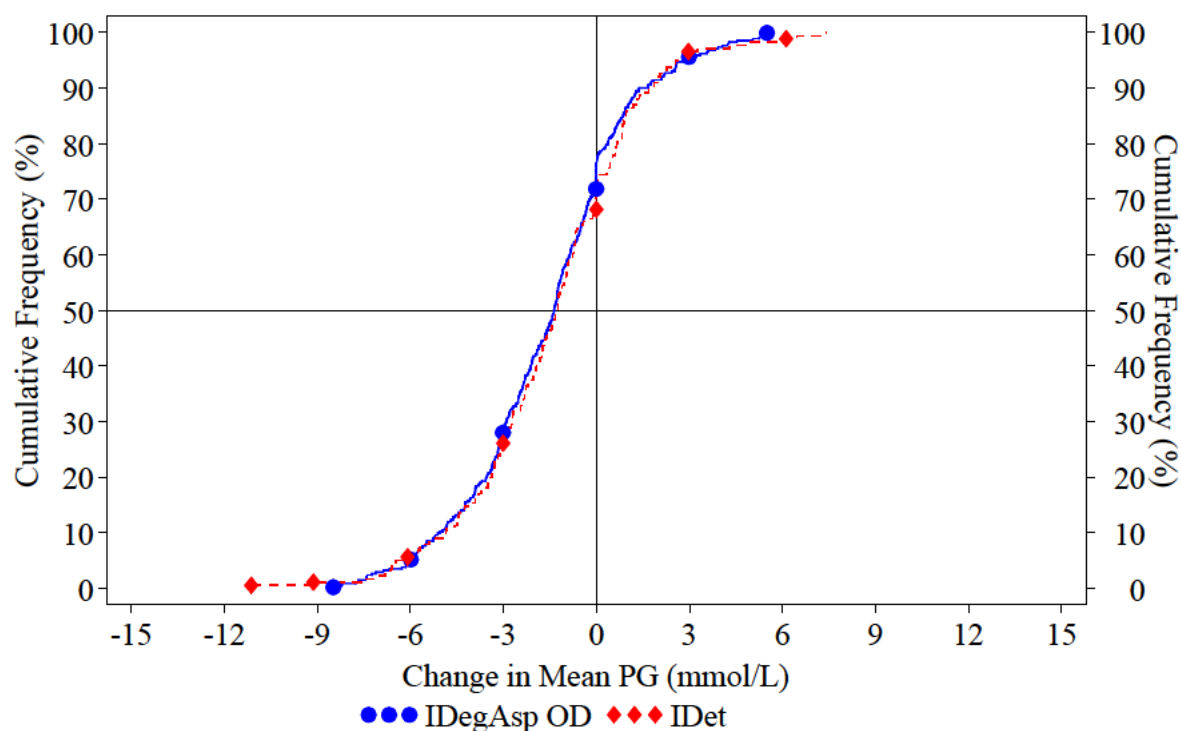
14.2.87: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:48:00 - fedist_numfind_v01.sas/e_9pp_abs_mean_cdf_locf_fas.cgm

14.2.88: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:48:06 - fedist_numfind_v01.sas/e_9pp_chb_mean_cdf_locf_fas.cgm

14.2.89: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set

14.2.90: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Fluctuation (mmol/L)			
Visit 2 (Week 0)			
N	355	179	534
Geometric Mean	2.1	2.1	2.1
CV	47.74	42.67	46.03
Median	2.1	2.2	2.1
Min ; Max	0.5 ; 6.9	0.4 ; 6.1	0.4 ; 6.9
Visit 14 (Week 12)			
N	325	164	489
Geometric Mean	1.3	1.5	1.4
CV	62.58	59.46	61.58
Median	1.4	1.7	1.6
Min ; Max	0.1 ; 5.8	0.2 ; 7.2	0.1 ; 7.2
Visit 18 (Week 16)			
N	323	162	485
Geometric Mean	1.3	1.5	1.4
CV	64.67	58.85	62.79
Median	1.4	1.8	1.5
Min ; Max	0.1 ; 7.2	0.1 ; 5.1	0.1 ; 7.2
Visit 28 (Week 26)			
N	310	153	463
Geometric Mean	1.2	1.5	1.3
CV	61.18	57.51	60.40
Median	1.4	1.7	1.5
Min ; Max	0.1 ; 5.5	0.2 ; 5.5	0.1 ; 5.5
Visit 28 (Week 26) (LOCF)			
N	349	177	526
Geometric Mean	1.3	1.5	1.4
CV	62.82	55.76	60.65
Median	1.4	1.7	1.5
Min ; Max	0.1 ; 5.7	0.2 ; 5.5	0.1 ; 5.7

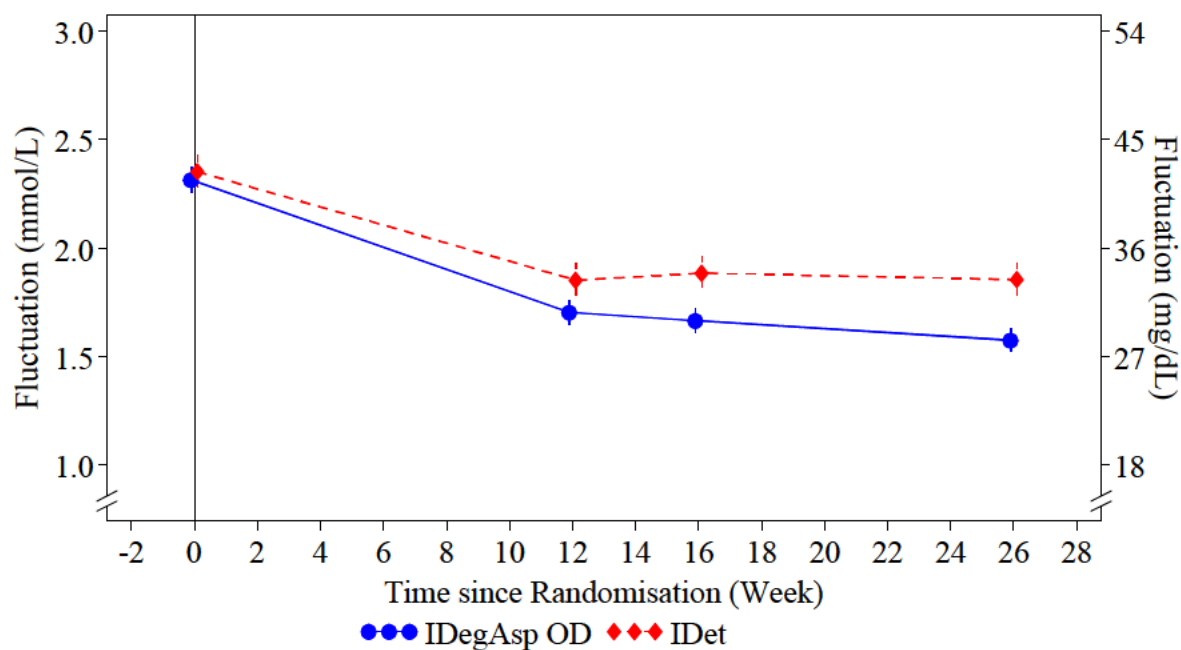
Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:48:19 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_fluc_descp_fas.txt

14.2.91: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
Fluctuation (mmol/L)				
LSMeans				
IDegAsp OD	366	342	1.29	
IDet	182	176	1.53	
Treatment Ratio				
IDegAsp OD / IDet			0.84	[0.75 ; 0.94]

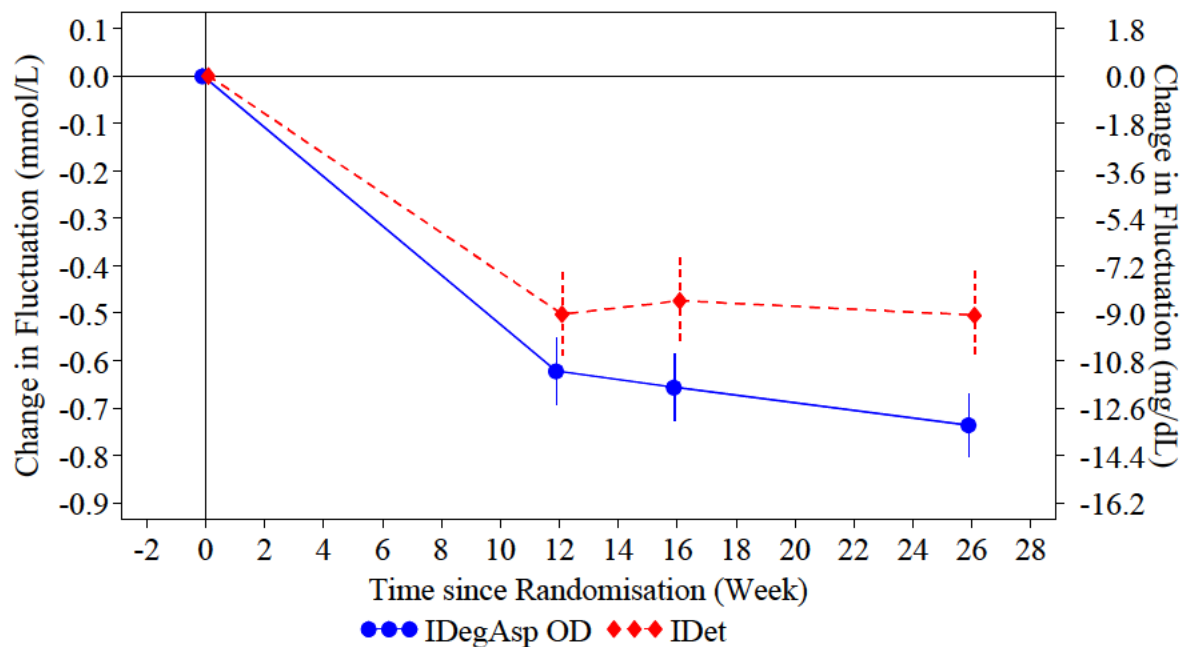
N = Number of subjects contributing to analysis, CI = Confidence Interval The log-transformed response after 26 weeks of treatment is analysed using an ANVOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
 Missing data is imputed using last observation carried forward.
 Fluctuation is integrated abs. dist. from mean profile value divided by measurement time.
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:48:25 - tstat_find_tpl_t022.sas/t_9pp_fluc_stat_locf_fas.txt



FAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:48:31 - fmean_numfind_v03.sas/e_9pp_abs_fluc_mean_locf_fas.cgm

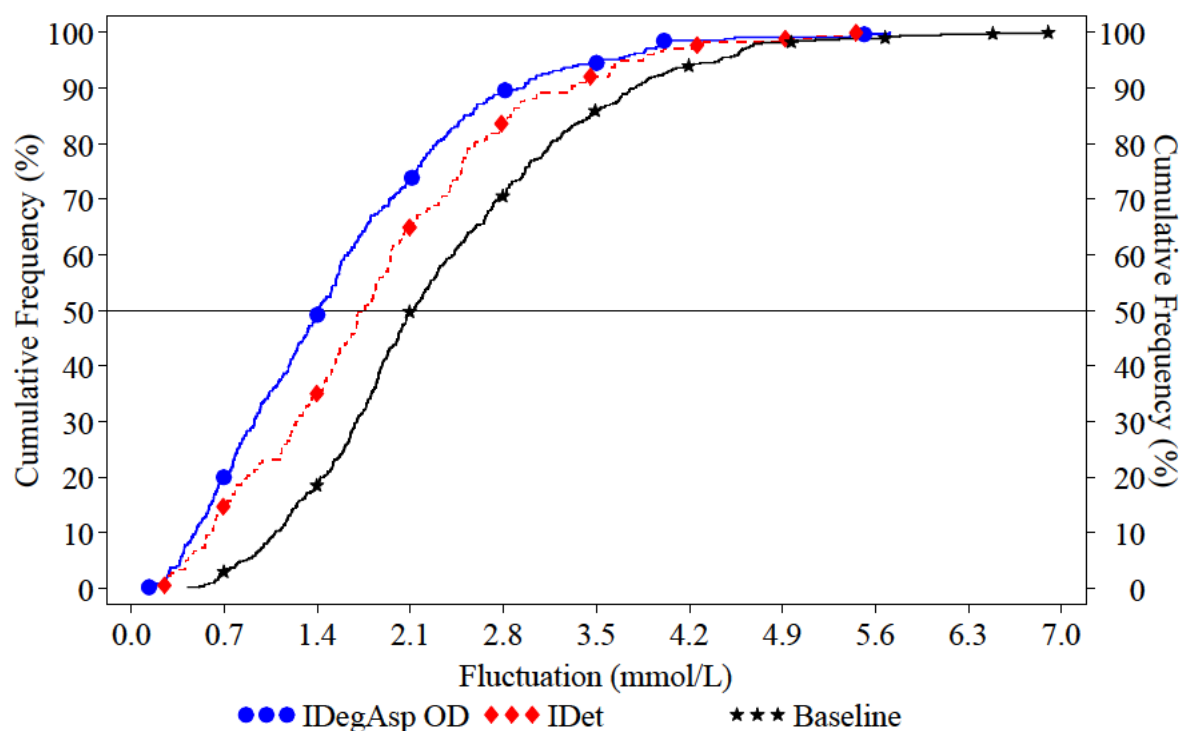
14.2.92: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:48:38 - fmean_numfind_v03.sas/e_9pp_chb_fluc_mean_locf_fas.cgm

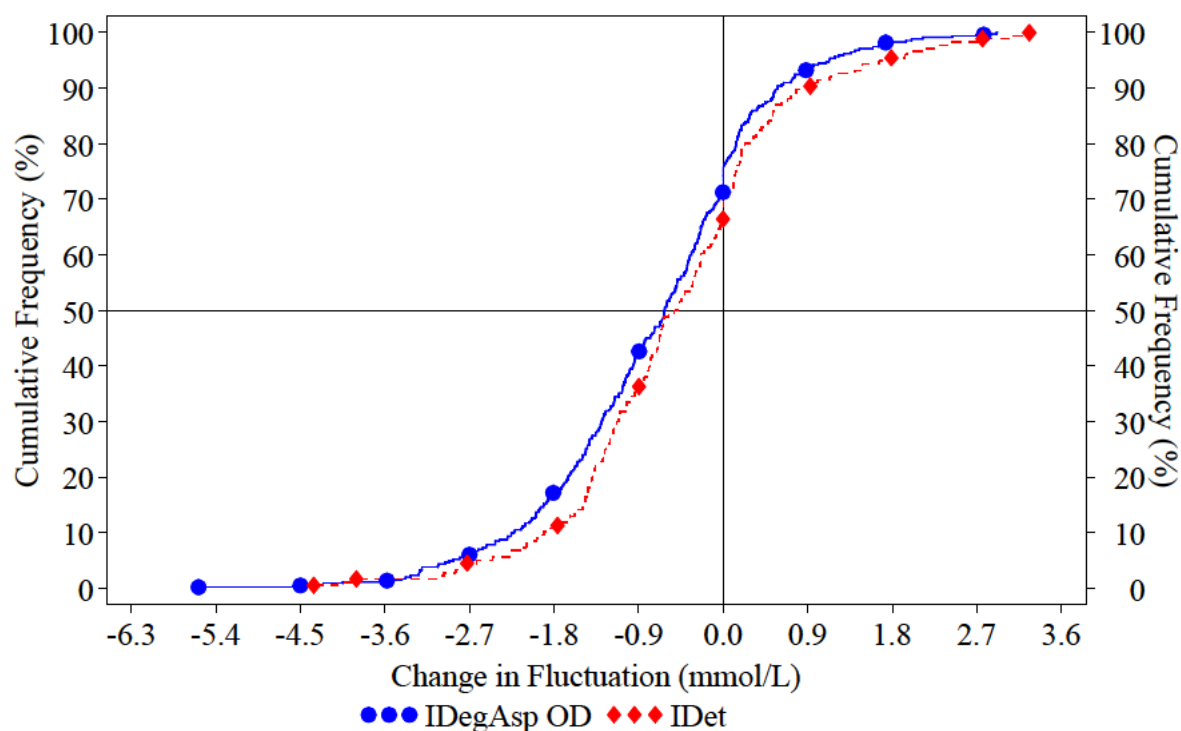
14.2.93: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:48:48 - fedist_numfind_v01.sas/e_9pp_abs_fluc_cdf_locf_fas.cgm

14.2.94: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:48:54 - fedist_numfind_v01.sas/e_9pp_chb_fluc_cdf_locf_fas.cgm

14.2.95: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set

14.2.96: Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
All Meals (mmol/L)			
Visit 2 (Week 0)			
N	349	180	529
Mean (SD)	1.0 (3.0)	1.2 (3.2)	1.1 (3.1)
Median	1.0	1.2	1.0
Min ; Max	-7.7 ; 10.0	-7.5 ; 11.0	-7.7 ; 11.0
Visit 14 (Week 12)			
N	303	154	457
Mean (SD)	0.8 (2.6)	0.7 (2.7)	0.8 (2.6)
Median	0.8	0.5	0.7
Min ; Max	-10.8 ; 10.5	-7.2 ; 13.0	-10.8 ; 13.0
Visit 18 (Week 16)			
N	310	151	461
Mean (SD)	0.8 (2.5)	0.9 (2.7)	0.8 (2.6)
Median	0.7	0.6	0.6
Min ; Max	-8.1 ; 11.8	-6.6 ; 9.3	-8.1 ; 11.8
Visit 28 (Week 26)			
N	293	146	439
Mean (SD)	0.9 (2.3)	1.0 (2.9)	0.9 (2.5)
Median	0.7	1.0	0.8
Min ; Max	-6.5 ; 9.3	-6.6 ; 8.4	-6.6 ; 9.3
Visit 28 (Week 26) (LOCF)			
N	322	165	487
Mean (SD)	1.0 (2.4)	0.8 (3.2)	0.9 (2.6)
Median	0.8	1.0	0.8
Min ; Max	-6.5 ; 9.3	-10.7 ; 8.8	-10.7 ; 9.3

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:01 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
(mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Breakfast (mmol/L)			
Visit 2 (Week 0)			
N	339	173	512
Mean (SD)	1.2 (5.1)	1.4 (4.9)	1.3 (5.1)
Median	1.4	1.7	1.4
Min ; Max	-13.0 ; 18.2	-10.8 ; 14.9	-13.0 ; 18.2
Visit 14 (Week 12)			
N	289	147	436
Mean (SD)	0.7 (3.5)	1.3 (3.7)	0.9 (3.6)
Median	0.7	0.7	0.7
Min ; Max	-14.7 ; 9.4	-9.2 ; 11.0	-14.7 ; 11.0
Visit 18 (Week 16)			
N	296	144	440
Mean (SD)	1.2 (3.9)	1.1 (3.6)	1.2 (3.8)
Median	1.0	1.0	1.0
Min ; Max	-12.5 ; 16.4	-8.7 ; 11.3	-12.5 ; 16.4
Visit 28 (Week 26)			
N	282	140	422
Mean (SD)	1.1 (3.7)	1.8 (4.7)	1.4 (4.0)
Median	1.1	1.4	1.2
Min ; Max	-9.4 ; 16.3	-12.0 ; 23.2	-12.0 ; 23.2
Visit 28 (Week 26) (LOCF)			
N	309	156	465
Mean (SD)	1.1 (3.7)	1.7 (4.7)	1.3 (4.1)
Median	1.1	1.2	1.1
Min ; Max	-10.8 ; 16.3	-12.0 ; 23.2	-12.0 ; 23.2

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:01 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
(mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Lunch (mmol/L)			
Visit 2 (Week 0)			
N	340	172	512
Mean (SD)	1.3 (4.5)	1.7 (5.4)	1.4 (4.8)
Median	1.5	1.4	1.4
Min ; Max	-18.4 ; 17.3	-14.5 ; 16.5	-18.4 ; 17.3
Visit 14 (Week 12)			
N	296	152	448
Mean (SD)	0.8 (3.9)	0.2 (3.8)	0.6 (3.9)
Median	0.8	0.3	0.6
Min ; Max	-16.9 ; 15.3	-14.4 ; 11.4	-16.9 ; 15.3
Visit 18 (Week 16)			
N	298	142	440
Mean (SD)	0.7 (4.0)	1.0 (3.9)	0.8 (3.9)
Median	0.6	0.9	0.8
Min ; Max	-19.9 ; 17.3	-9.7 ; 13.7	-19.9 ; 17.3
Visit 28 (Week 26)			
N	280	140	420
Mean (SD)	0.8 (3.5)	0.5 (4.1)	0.7 (3.7)
Median	0.7	0.6	0.6
Min ; Max	-12.2 ; 13.2	-10.3 ; 12.2	-12.2 ; 13.2
Visit 28 (Week 26) (LOCF)			
N	307	158	465
Mean (SD)	1.0 (3.6)	0.3 (4.5)	0.7 (3.9)
Median	0.8	0.6	0.7
Min ; Max	-12.2 ; 13.2	-14.5 ; 12.2	-14.5 ; 13.2

N = Number of Subjects, SD = Standard Deviation
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal
All Meals: Mean of all increments
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:01 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
(mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Main Evening Meal (mmol/L)			
Visit 2 (Week 0)			
N	334	174	508
Mean (SD)	0.6 (4.7)	0.5 (5.0)	0.6 (4.8)
Median	0.6	0.4	0.5
Min ; Max	-14.0 ; 19.0	-13.7 ; 13.4	-14.0 ; 19.0
Visit 14 (Week 12)			
N	289	147	436
Mean (SD)	0.7 (4.0)	0.6 (4.1)	0.7 (4.0)
Median	0.7	0.6	0.7
Min ; Max	-11.3 ; 19.9	-10.6 ; 13.0	-11.3 ; 19.9
Visit 18 (Week 16)			
N	294	139	433
Mean (SD)	0.4 (3.9)	0.3 (4.6)	0.4 (4.2)
Median	0.7	0.5	0.6
Min ; Max	-17.0 ; 12.1	-12.1 ; 18.6	-17.0 ; 18.6
Visit 28 (Week 26)			
N	284	137	421
Mean (SD)	0.7 (3.8)	0.8 (4.0)	0.7 (3.9)
Median	0.7	0.7	0.7
Min ; Max	-13.3 ; 12.6	-9.4 ; 13.0	-13.3 ; 13.0
Visit 28 (Week 26) (LOCF)			
N	312	152	464
Mean (SD)	0.7 (3.9)	0.7 (4.3)	0.7 (4.0)
Median	0.7	0.7	0.7
Min ; Max	-13.3 ; 12.6	-13.6 ; 13.4	-13.6 ; 13.4

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:01 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_prand_inc_descp_fas.txt

14.2.97: Prandial Increment by Treatment Week – Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
All Meals, Change (mmol/L)			
Visit 14 (Week 12)			
N	295	154	449
Mean (SD)	-0.1 (3.7)	-0.5 (3.6)	-0.2 (3.7)
Median	0.1	-0.6	-0.1
Min ; Max	-13.3 ; 11.7	-9.5 ; 11.0	-13.3 ; 11.7
Visit 18 (Week 16)			
N	300	151	451
Mean (SD)	-0.2 (3.5)	-0.3 (3.6)	-0.2 (3.6)
Median	-0.1	-0.4	-0.2
Min ; Max	-12.6 ; 11.7	-11.8 ; 13.5	-12.6 ; 13.5
Visit 28 (Week 26)			
N	283	146	429
Mean (SD)	0.1 (3.6)	-0.3 (4.0)	-0.1 (3.7)
Median	0.0	0.1	0.1
Min ; Max	-13.1 ; 14.8	-11.6 ; 9.5	-13.1 ; 14.8
Visit 28 (Week 26) (LOCF)			
N	312	165	477
Mean (SD)	0.0 (3.5)	-0.3 (4.1)	-0.1 (3.7)
Median	0.0	0.0	0.0
Min ; Max	-13.1 ; 14.8	-11.9 ; 13.5	-13.1 ; 14.8

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:14 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Breakfast, Change (mmol/L)			
Visit 14 (Week 12)			
N	277	145	422
Mean (SD)	-0.2 (5.9)	-0.1 (6.4)	-0.1 (6.1)
Median	-0.3	0.1	-0.2
Min ; Max	-19.1 ; 20.2	-18.6 ; 16.9	-19.1 ; 20.2
Visit 18 (Week 16)			
N	281	140	421
Mean (SD)	0.0 (6.2)	-0.3 (6.3)	-0.1 (6.2)
Median	0.0	-0.4	-0.2
Min ; Max	-20.2 ; 15.9	-20.2 ; 19.5	-20.2 ; 19.5
Visit 28 (Week 26)			
N	267	138	405
Mean (SD)	0.1 (5.8)	0.2 (6.1)	0.1 (5.9)
Median	-0.3	0.2	-0.2
Min ; Max	-17.3 ; 19.8	-19.4 ; 16.6	-19.4 ; 19.8
Visit 28 (Week 26) (LOCF)			
N	293	153	446
Mean (SD)	0.0 (5.6)	0.2 (6.0)	0.1 (5.8)
Median	-0.1	0.0	0.0
Min ; Max	-17.3 ; 19.8	-19.4 ; 16.6	-19.4 ; 19.8

N = Number of Subjects, SD = Standard Deviation
 Prandial increment is the difference between SMPG values after meal (90 min.) and before meal
 All Meals: Mean of all increments
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:49:14 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Lunch, Change (mmol/L)			
Visit 14 (Week 12)			
N	284	147	431
Mean (SD)	-0.4 (5.6)	-1.6 (6.3)	-0.8 (5.9)
Median	-0.4	-1.1	-0.7
Min ; Max	-16.6 ; 15.6	-24.4 ; 15.4	-24.4 ; 15.6
Visit 18 (Week 16)			
N	284	137	421
Mean (SD)	-0.6 (5.6)	-1.0 (6.0)	-0.7 (5.7)
Median	-0.5	-0.6	-0.5
Min ; Max	-23.1 ; 20.6	-17.4 ; 15.3	-23.1 ; 20.6
Visit 28 (Week 26)			
N	265	135	400
Mean (SD)	-0.4 (5.3)	-1.1 (6.5)	-0.7 (5.8)
Median	-0.6	-1.3	-0.8
Min ; Max	-18.0 ; 16.1	-23.1 ; 17.3	-23.1 ; 17.3
Visit 28 (Week 26) (LOCF)			
N	292	152	444
Mean (SD)	-0.2 (5.3)	-1.4 (6.4)	-0.6 (5.7)
Median	-0.2	-1.2	-0.4
Min ; Max	-18.0 ; 16.1	-23.1 ; 17.3	-23.1 ; 17.3

N = Number of Subjects, SD = Standard Deviation
 Prandial increment is the difference between SMPG values after meal (90 min.) and before meal
 All Meals: Mean of all increments
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:49:14 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change (mmol/L)			
Visit 14 (Week 12)			
N	273	144	417
Mean (SD)	0.3 (5.8)	-0.1 (6.2)	0.2 (5.9)
Median	0.2	-0.2	0.2
Min ; Max	-19.7 ; 16.8	-13.3 ; 15.9	-19.7 ; 16.8
Visit 18 (Week 16)			
N	277	136	413
Mean (SD)	-0.1 (5.8)	-0.2 (6.8)	-0.1 (6.1)
Median	0.0	-0.6	-0.2
Min ; Max	-21.2 ; 15.4	-14.9 ; 27.7	-21.2 ; 27.7
Visit 28 (Week 26)			
N	267	134	401
Mean (SD)	0.3 (6.2)	0.3 (6.6)	0.3 (6.3)
Median	0.4	0.1	0.4
Min ; Max	-22.4 ; 18.2	-16.2 ; 20.7	-22.4 ; 20.7
Visit 28 (Week 26) (LOCF)			
N	295	149	444
Mean (SD)	0.2 (5.9)	0.2 (6.4)	0.2 (6.1)
Median	0.1	0.0	0.0
Min ; Max	-22.4 ; 18.2	-16.2 ; 20.7	-22.4 ; 20.7

N = Number of Subjects, SD = Standard Deviation
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal
All Meals: Mean of all increments
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:14 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_prand_inc_descp_fas.txt

14.2.98: Prandial Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
All Meals (mmol/L)					
LSMeans					
IDegAsp OD	366	312	1.00	0.25	
IDet	182	165	0.77	0.29	
Treatment Contrast					
IDegAsp OD - IDet			0.24		[-0.27 ; 0.74]
Breakfast (mmol/L)					
LSMeans					
IDegAsp OD	366	293	1.08	0.38	
IDet	182	153	1.65	0.46	
Treatment Contrast					
IDegAsp OD - IDet			-0.57		[-1.37 ; 0.22]
Lunch (mmol/L)					
LSMeans					
IDegAsp OD	366	292	1.00	0.37	
IDet	182	152	0.07	0.43	
Treatment Contrast					
IDegAsp OD - IDet			0.92		[0.17 ; 1.68]
Main Evening Meal (mmol/L)					
LSMeans					
IDegAsp OD	366	295	0.65	0.38	
IDet	182	149	0.52	0.45	
Treatment Contrast					
IDegAsp OD - IDet			0.12		[-0.67 ; 0.92]

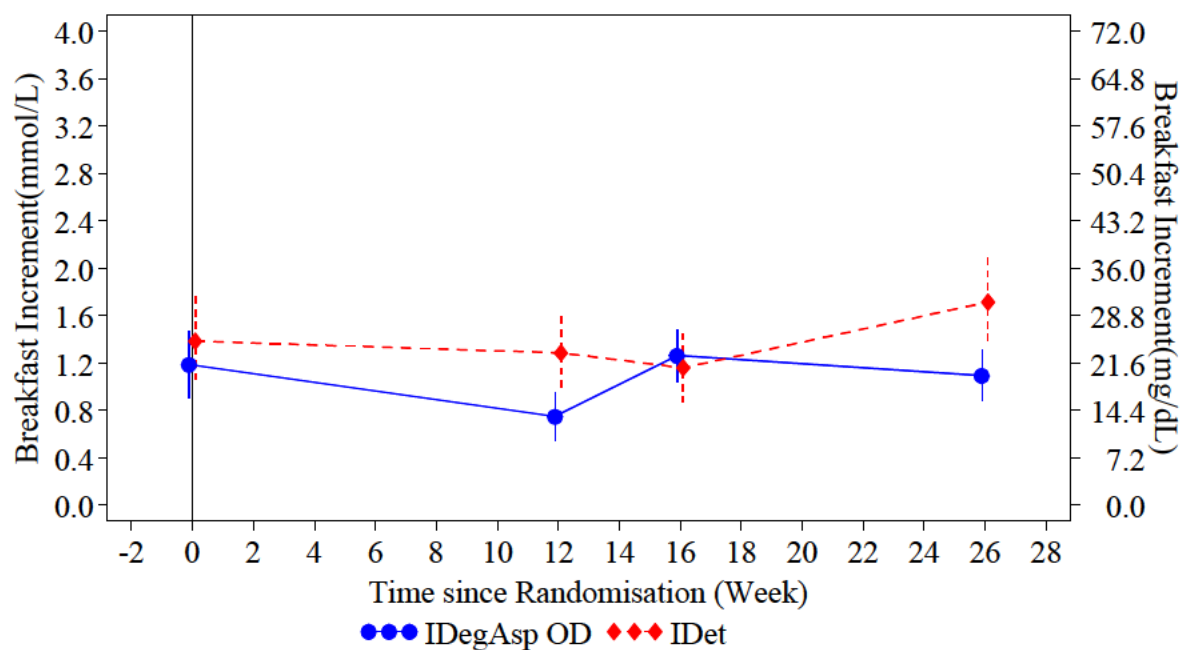
N = Number of subjects contributing to analysis, CI = Confidence Interval, SE = Standard Error of the Mean

The response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal. All Meals: Mean of all increments

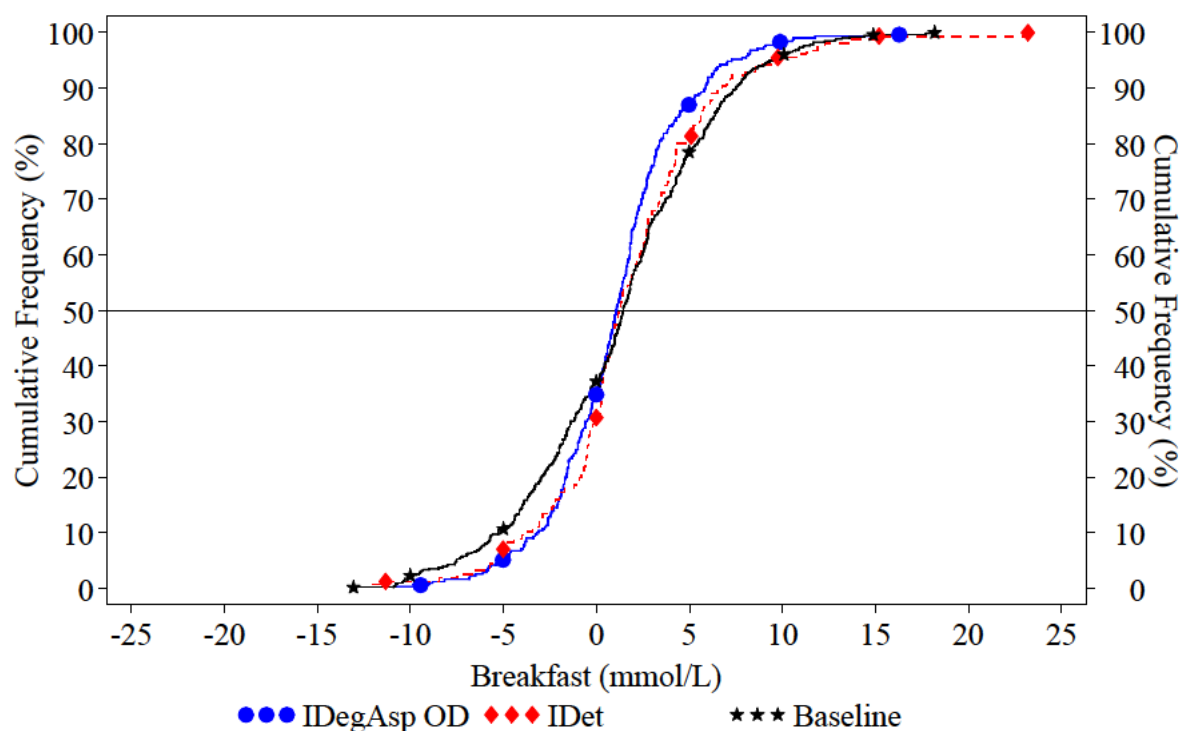
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:21 - tstat_find_tpl_t022.sas/t_9pp_prand_inc_stat_locf_fas.txt



FAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:27 - fmean_numfind_v03.sas/e_9pp_abs_bf_inc_mean_locf_fas.cgm

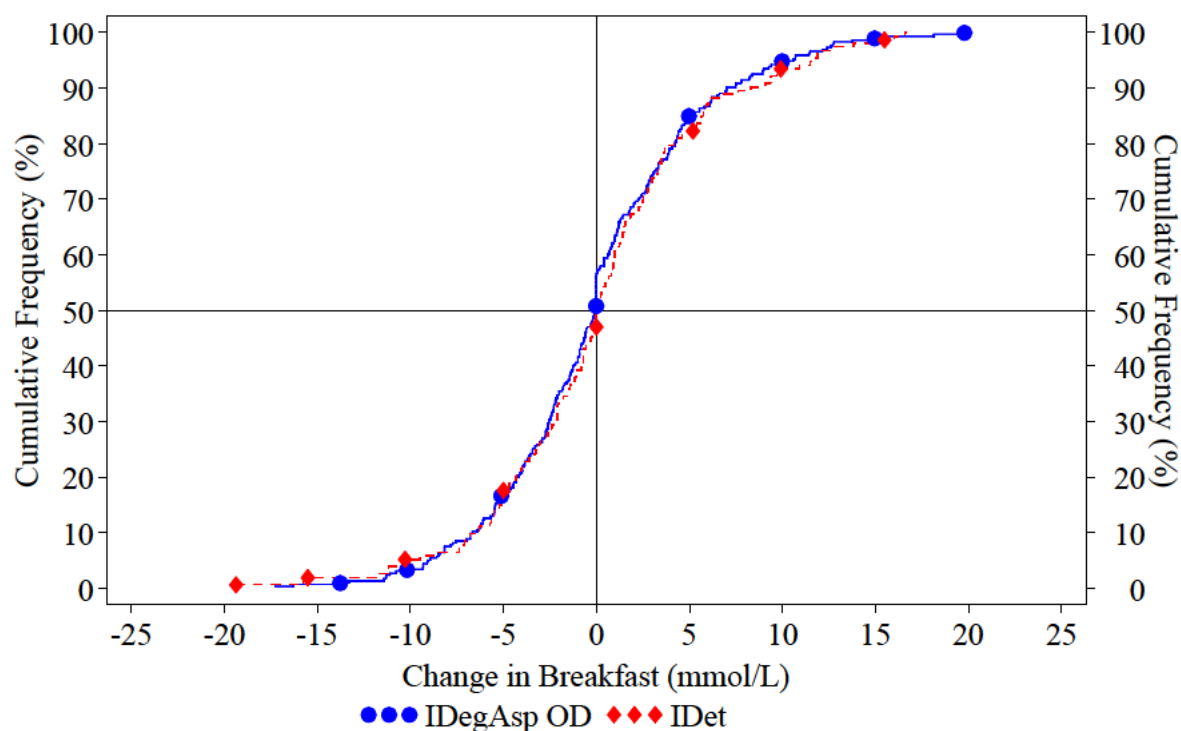
14.2.99: Breakfast Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:38 - fedist_numfind_v01.sas/e_9pp_abs_bf_inc_cdf_locf_fas.cgm

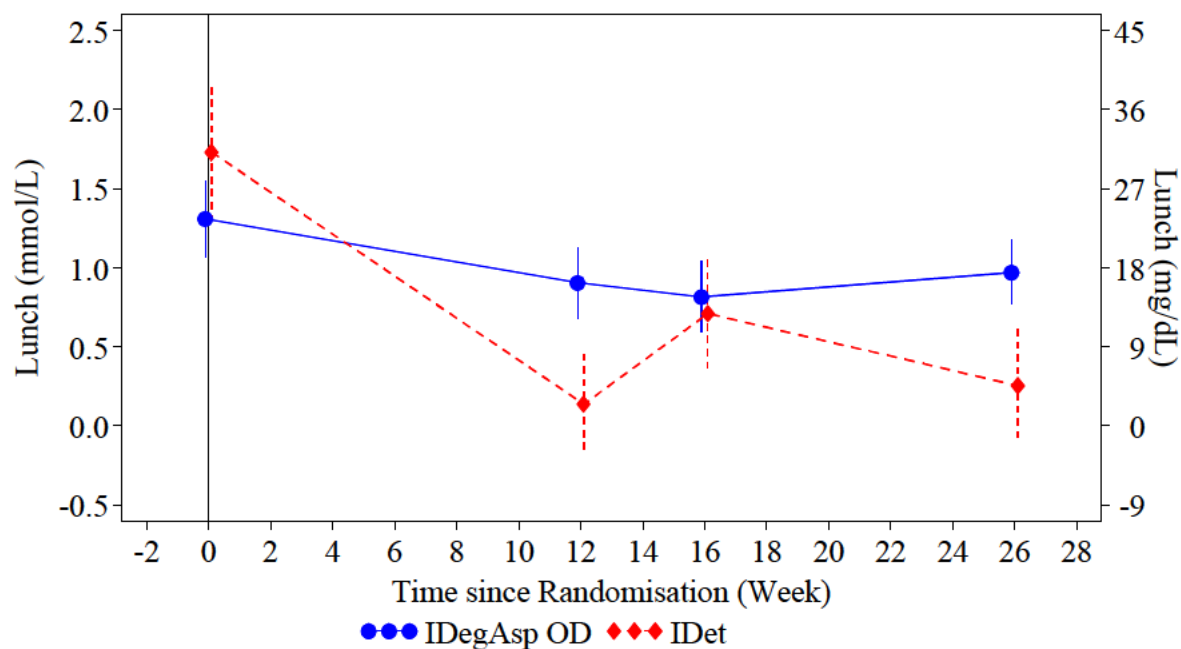
14.2.100: Breakfast Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:44 - fedist_numfind_v01.sas/e_9pp_chb_bf_inc_cdf_locf_fas.cgm

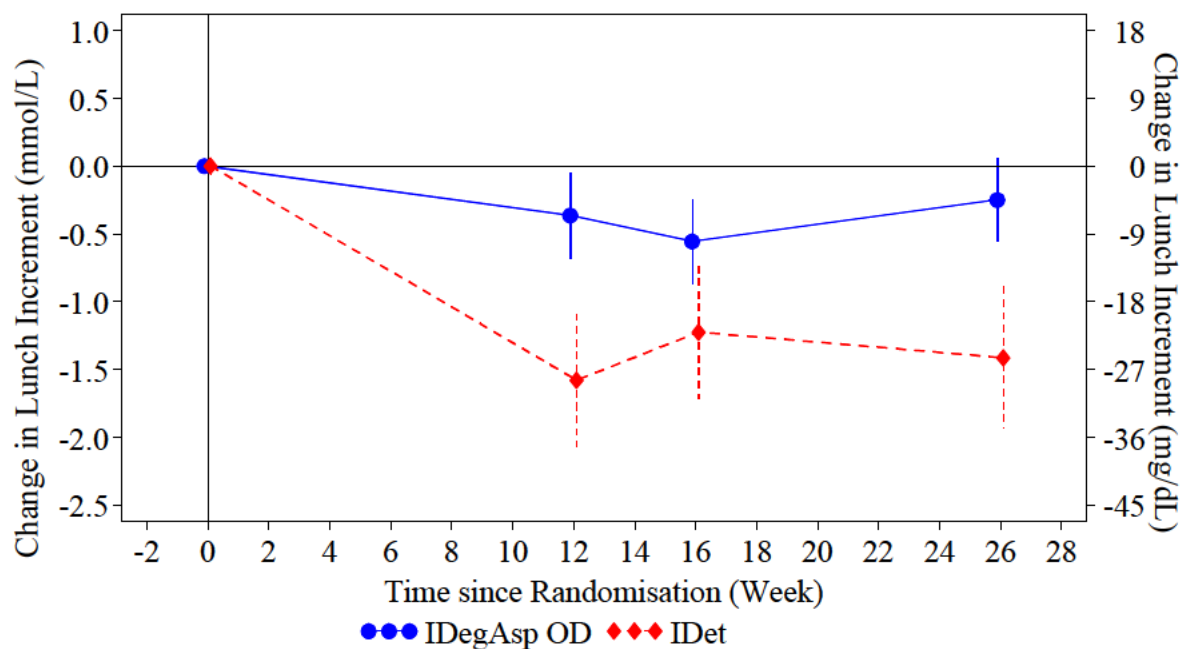
14.2.101: Breakfast Increment after 26 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:50 - fmean_numfind_v03.sas/e_9pp_abs_l_inc_mean_locf_fas.cgm

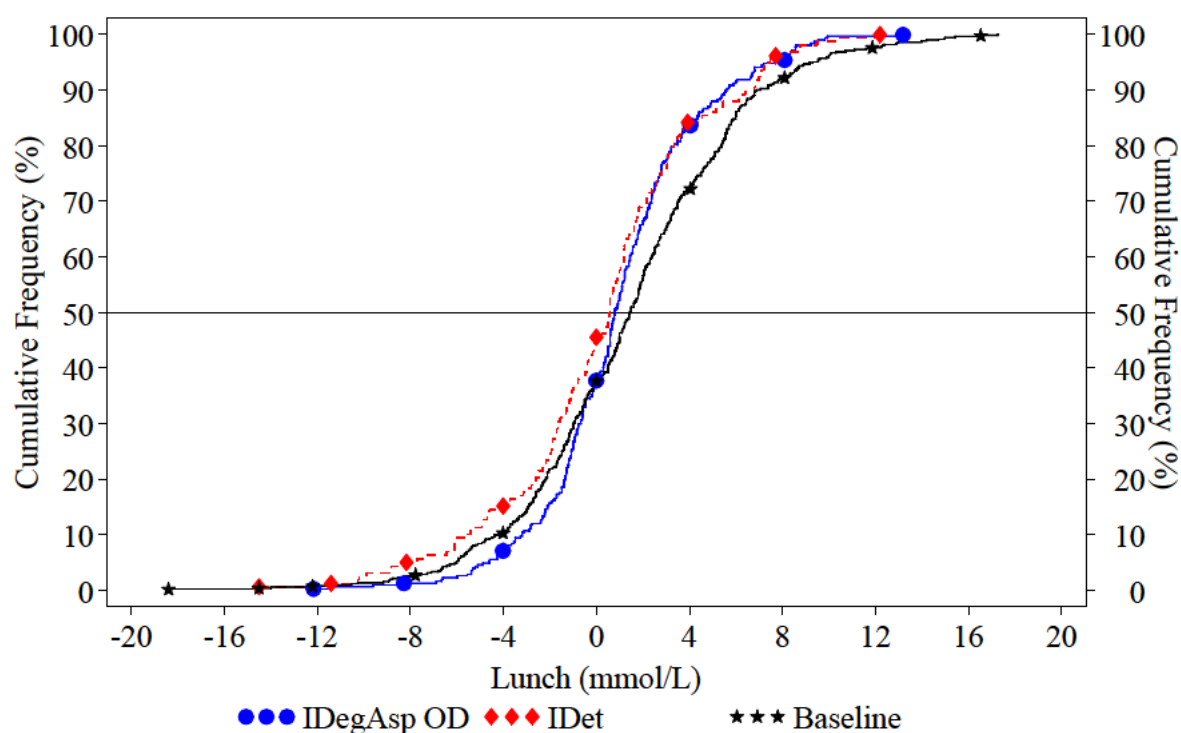
14.2.102: Lunch Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:49:56 - fmean_numfind_v03.sas/e_9pp_chb_1_inc_mean_locf_fas.cgm

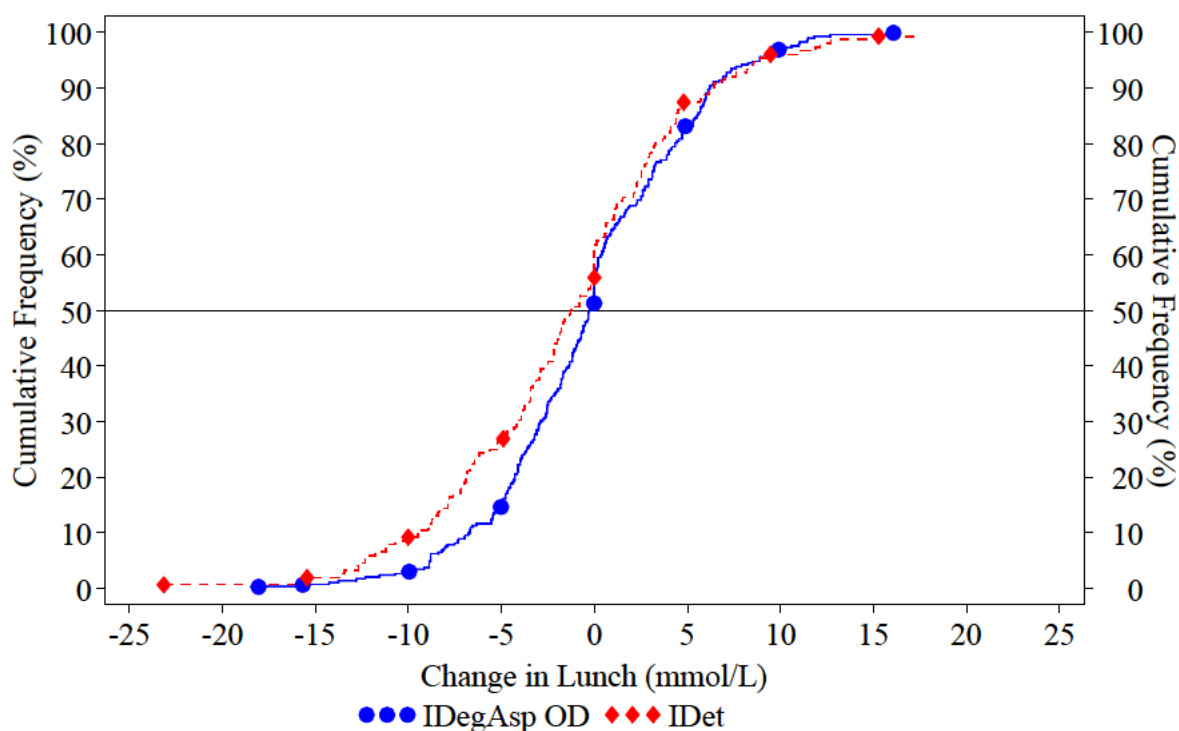
14.2.103: Lunch Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:50:07 - fedist_numfind_v01.sas/e_9pp_abs_l_inc_cdf_locf_fas.cgm

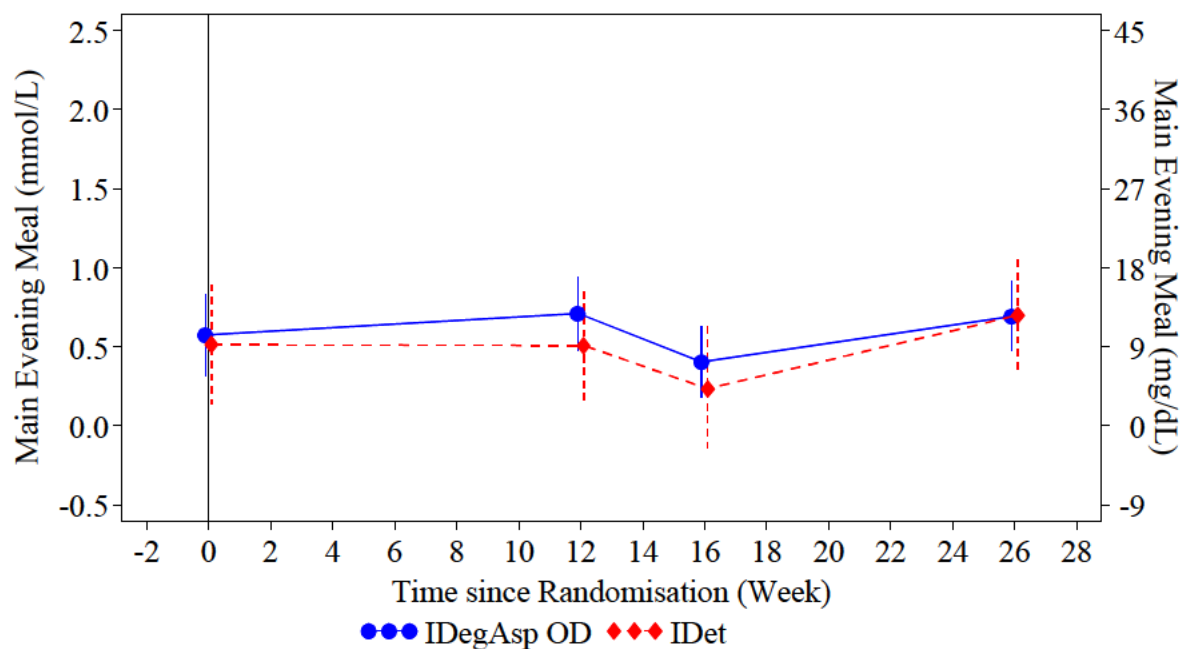
14.2.104: Lunch Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:50:13 - fedist_numfind_v01.sas/e_9pp_chb_l_inc_cdf_locf_fas.cgm

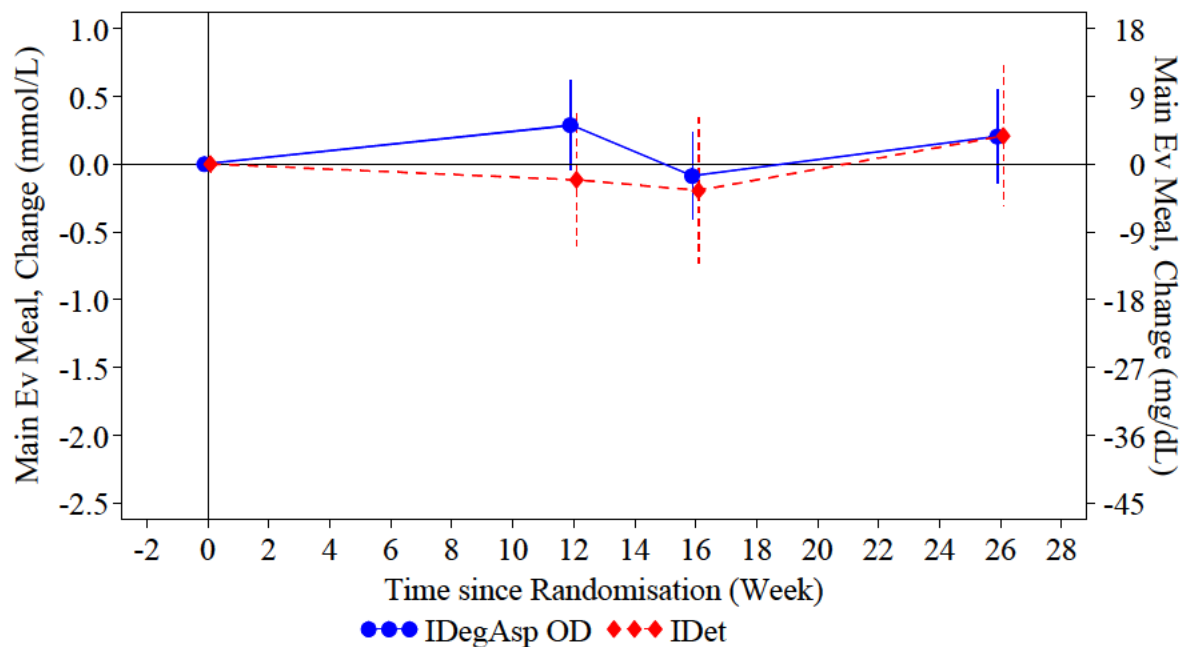
14.2.105: Lunch Increment after 26 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:50:19 - fmean_numfind_v03.sas/e_9pp_abs_ev_inc_mean_locf_fas.cgm

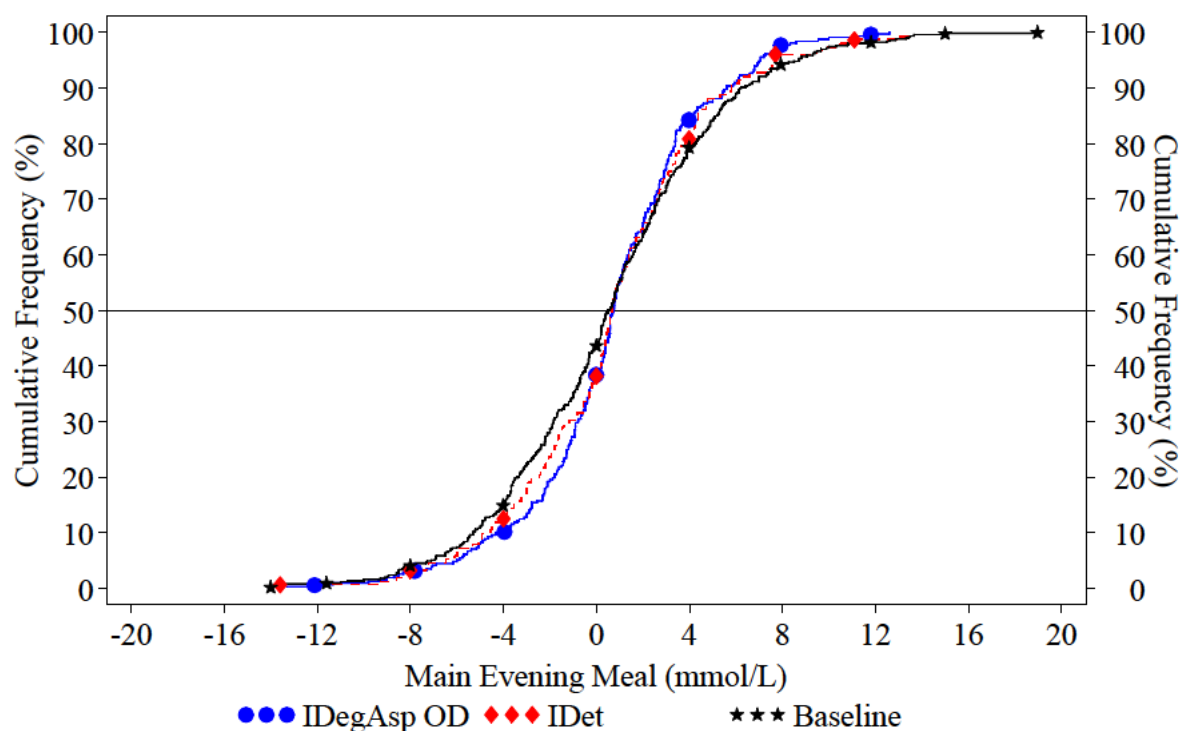
14.2.106: Main Evening Meal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:50:26 - fmean_numfind_v03.sas/e_9pp_chb_ev_inc_mean_locf_fas.cgm

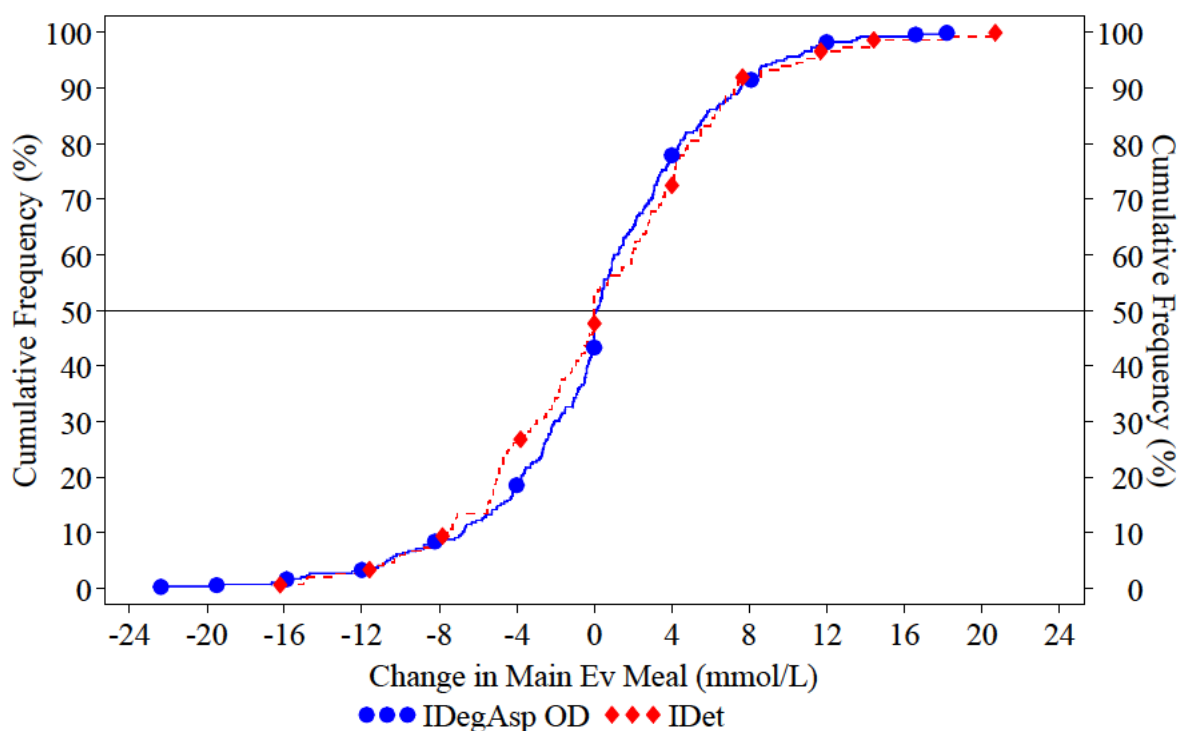
14.2.107: Main Evening Meal Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:50:36 - fedist_numfind_v01.sas/e_9pp_abs_ev_inc_cdf_locf_fas.cgm

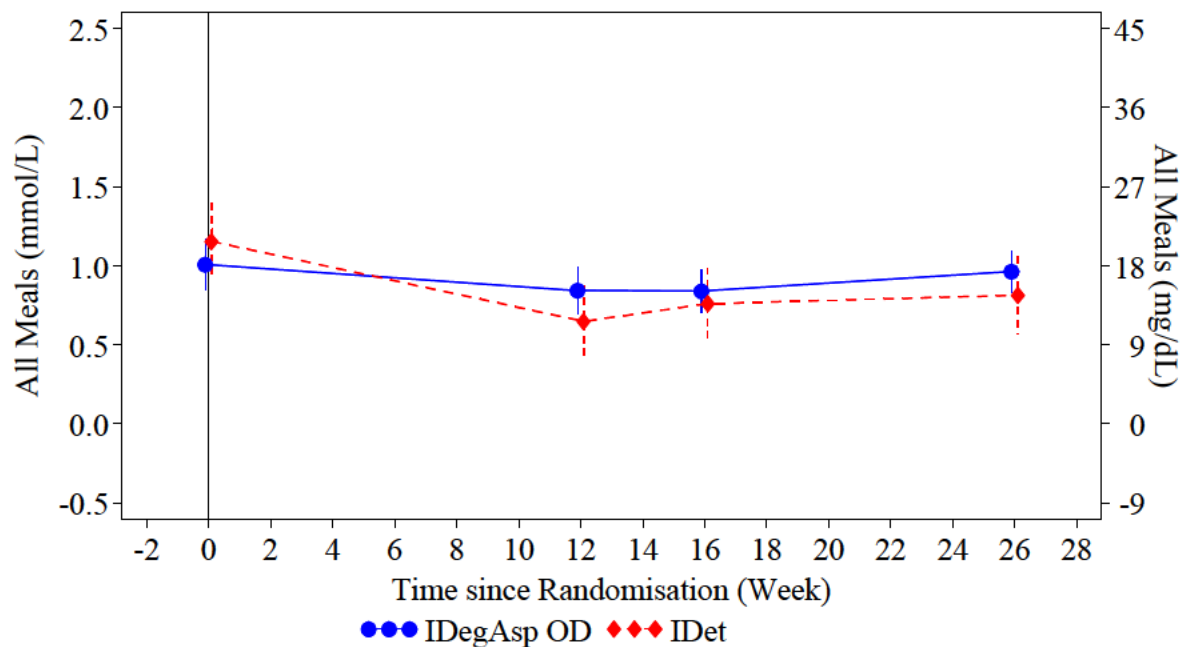
14.2.108: Main Evening Meal Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:50:42 - fedist_numfind_v01.sas/e_9pp_chb_ev_inc_cdf_locf_fas.cgm

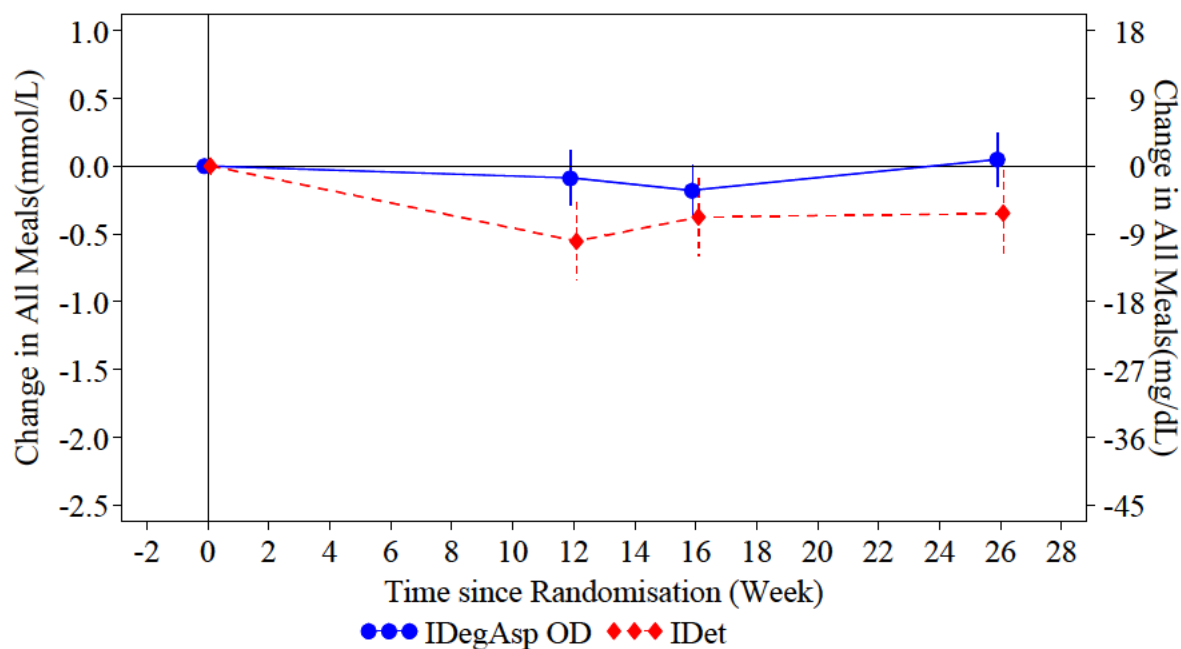
14.2.109: Main Evening Meal Increment after 26 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:50:49 - fmean_numfind_v03.sas/e_9pp_abs_pran_ic_mean_locf_fas.cgm

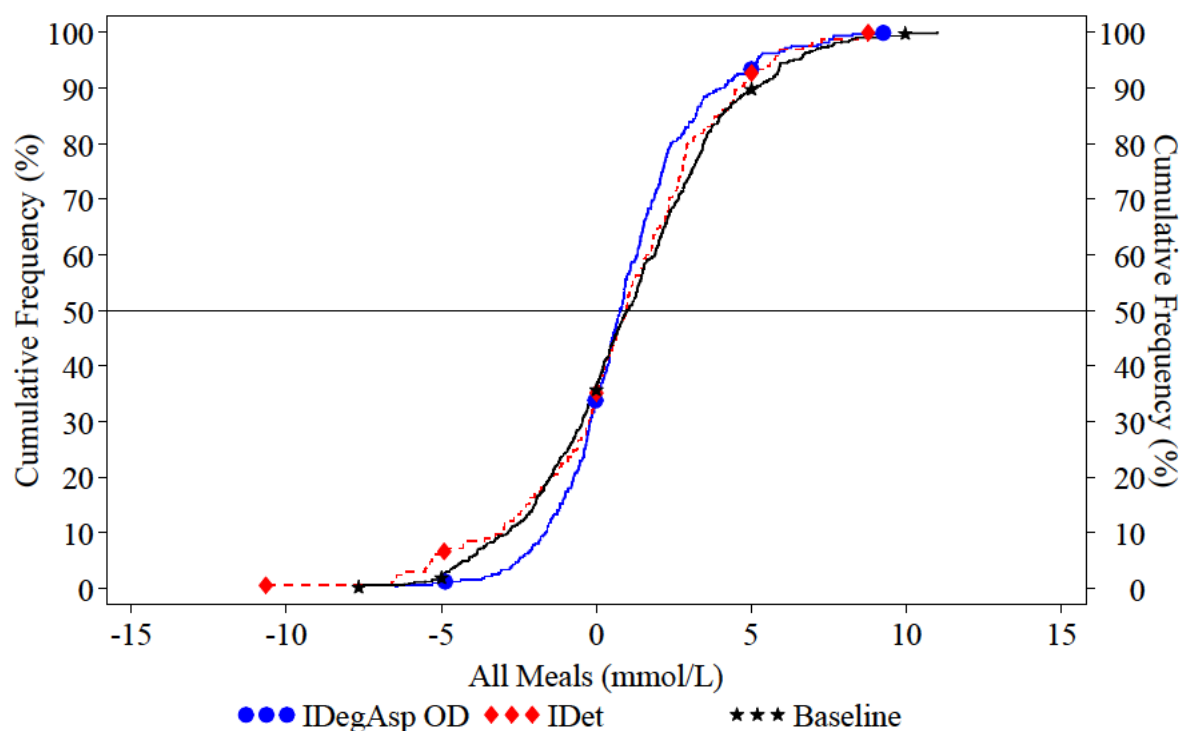
14.2.110: All Meals Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:50:55 - fmean_numfind_v03.sas/e_9pp_chb_pran_ic_mean_locf_fas.cgm

14.2.111: All Meals Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:51:06 - fedist_numfind_v01.sas/e_9pp_abs_prand_inc_cdf_locf_fas.cgm

14.2.112: All Meals Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set

14.2.113: Nocturnal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Bedtime to 04:00 (mmol/L)			
Visit 2 (Week 0)			
N	326	161	487
Mean (SD)	-0.9 (5.5)	-0.3 (6.1)	-0.7 (5.7)
Median	-0.8	-0.6	-0.8
Min ; Max	-19.1 ; 19.7	-14.7 ; 25.6	-19.1 ; 25.6
Visit 14 (Week 12)			
N	239	132	371
Mean (SD)	-1.0 (4.2)	-0.4 (4.7)	-0.8 (4.4)
Median	-0.5	-0.7	-0.6
Min ; Max	-19.0 ; 17.5	-13.8 ; 17.4	-19.0 ; 17.5
Visit 18 (Week 16)			
N	261	129	390
Mean (SD)	-0.6 (3.9)	-0.9 (5.0)	-0.7 (4.3)
Median	-0.6	-0.5	-0.6
Min ; Max	-15.8 ; 12.7	-17.0 ; 14.1	-17.0 ; 14.1
Visit 28 (Week 26)			
N	247	125	372
Mean (SD)	-0.9 (3.4)	-0.5 (4.5)	-0.8 (3.8)
Median	-1.0	-1.0	-1.0
Min ; Max	-13.8 ; 11.5	-13.3 ; 12.7	-13.8 ; 12.7
Visit 28 (Week 26) (LOCF)			
N	273	138	411
Mean (SD)	-0.9 (3.6)	-0.6 (4.5)	-0.8 (3.9)
Median	-0.9	-1.1	-0.9
Min ; Max	-15.4 ; 11.5	-13.3 ; 12.7	-15.4 ; 12.7

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:51:19 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_noct_inc_descp_fas.txt

Nocturnal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
 (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
04:00 to Breakfast (mmol/L)			
Visit 2 (Week 0)			
N	334	168	502
Mean (SD)	0.1 (4.5)	0.6 (4.0)	0.3 (4.3)
Median	0.0	0.3	0.1
Min ; Max	-14.9 ; 18.8	-16.4 ; 12.2	-16.4 ; 18.8
Visit 14 (Week 12)			
N	239	131	370
Mean (SD)	-0.4 (3.1)	-0.6 (4.5)	-0.5 (3.6)
Median	-0.3	-0.3	-0.3
Min ; Max	-11.7 ; 10.9	-17.9 ; 17.1	-17.9 ; 17.1
Visit 18 (Week 16)			
N	260	131	391
Mean (SD)	-0.7 (3.3)	-0.4 (4.0)	-0.6 (3.6)
Median	-0.4	-0.4	-0.4
Min ; Max	-13.2 ; 12.8	-15.4 ; 10.3	-15.4 ; 12.8
Visit 28 (Week 26)			
N	250	125	375
Mean (SD)	-0.8 (2.9)	0.1 (3.8)	-0.5 (3.2)
Median	-0.6	-0.1	-0.5
Min ; Max	-12.3 ; 9.1	-15.9 ; 11.3	-15.9 ; 11.3
Visit 28 (Week 26) (LOCF)			
N	276	141	417
Mean (SD)	-0.8 (3.1)	0.1 (3.8)	-0.5 (3.4)
Median	-0.6	-0.1	-0.4
Min ; Max	-12.3 ; 9.1	-15.9 ; 11.3	-15.9 ; 11.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:51:19 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_noct_inc_descp_fas.txt

Nocturnal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
(mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Bedtime to Breakfast (mmol/L)			
Visit 2 (Week 0)			
N	337	168	505
Mean (SD)	-0.7 (6.1)	0.1 (6.4)	-0.4 (6.2)
Median	-0.3	-0.2	-0.3
Min ; Max	-18.0 ; 16.4	-15.5 ; 17.2	-18.0 ; 17.2
Visit 14 (Week 12)			
N	281	153	434
Mean (SD)	-1.3 (4.5)	-1.3 (4.8)	-1.3 (4.6)
Median	-0.9	-1.1	-1.0
Min ; Max	-22.9 ; 12.5	-14.2 ; 17.0	-22.9 ; 17.0
Visit 18 (Week 16)			
N	304	155	459
Mean (SD)	-1.2 (4.1)	-1.4 (5.0)	-1.3 (4.4)
Median	-1.1	-0.9	-1.0
Min ; Max	-13.8 ; 18.0	-18.8 ; 14.2	-18.8 ; 18.0
Visit 28 (Week 26)			
N	292	146	438
Mean (SD)	-1.5 (3.9)	-0.4 (4.4)	-1.2 (4.1)
Median	-1.2	-0.3	-0.9
Min ; Max	-15.0 ; 13.6	-15.5 ; 12.7	-15.5 ; 13.6
Visit 28 (Week 26) (LOCF)			
N	333	167	500
Mean (SD)	-1.6 (4.2)	-0.4 (4.8)	-1.2 (4.5)
Median	-1.3	-0.3	-0.9
Min ; Max	-18.0 ; 13.6	-15.5 ; 17.8	-18.0 ; 17.8

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:51:19 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_noct_inc_descp_fas.txt

14.2.114: Nocturnal Increment by Treatment Week – Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Number of Subjects	366	182
Bedtime to 04:00, Ch(mmol/L)		
Visit 14 (Week 12)		
N	225	122
Mean (SD)	-0.3 (6.9)	0.2 (7.3)
Median	-0.3	0.0
Min ; Max	-25.5 ; 34.8	-25.2 ; 27.5
Visit 18 (Week 16)		
N	243	121
Mean (SD)	0.3 (6.0)	-1.0 (7.8)
Median	0.4	-0.1
Min ; Max	-17.3 ; 20.0	-23.9 ; 22.8
Visit 28 (Week 26)		
N	233	116
Mean (SD)	-0.2 (6.1)	0.0 (7.2)
Median	-0.1	-0.1
Min ; Max	-18.1 ; 20.3	-23.6 ; 20.2
Visit 28 (Week 26) (LOCF)		
N	259	129
Mean (SD)	-0.0 (5.9)	0.2 (7.0)
Median	0.0	0.0
Min ; Max	-18.1 ; 20.3	-23.6 ; 20.2

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:51:31 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_noct_inc_descp_fas.txt

Nocturnal Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
04:00 to Brkf, Ch(mmol/L)		
Visit 14 (Week 12)		
N	225	124
Mean (SD)	-0.5 (4.9)	-1.3 (5.1)
Median	-0.6	-1.5
Min ; Max	-13.6 ; 14.2	-15.2 ; 15.6
Visit 18 (Week 16)		
N	244	125
Mean (SD)	-0.8 (4.9)	-1.1 (5.0)
Median	-0.8	-0.9
Min ; Max	-18.6 ; 16.4	-16.1 ; 15.9
Visit 28 (Week 26)		
N	234	118
Mean (SD)	-0.8 (4.7)	-0.3 (5.3)
Median	-0.6	-0.8
Min ; Max	-14.8 ; 15.0	-16.6 ; 17.5
Visit 28 (Week 26) (LOCF)		
N	260	134
Mean (SD)	-0.7 (4.5)	-0.3 (5.1)
Median	-0.5	-0.6
Min ; Max	-14.8 ; 15.0	-16.6 ; 17.5

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:51:31 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_noct_inc_descp_fas.txt

Nocturnal Increment by Treatment Week - Change from Baseline - 9-point Self Measured
Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Bedtime to Brkf, Ch (mmol/L)		
Visit 14 (Week 12)		
N	263	146
Mean (SD)	-0.6 (7.5)	-1.3 (7.6)
Median	-0.7	-1.8
Min ; Max	-34.0 ; 22.4	-20.8 ; 21.2
Visit 18 (Week 16)		
N	282	147
Mean (SD)	-0.5 (6.8)	-1.6 (8.1)
Median	-0.9	-2.0
Min ; Max	-19.8 ; 21.2	-28.6 ; 19.5
Visit 28 (Week 26)		
N	273	137
Mean (SD)	-0.9 (6.8)	-0.5 (6.5)
Median	-0.7	-0.7
Min ; Max	-26.3 ; 19.7	-22.5 ; 16.0
Visit 28 (Week 26) (LOCF)		
N	311	157
Mean (SD)	-0.7 (6.6)	-0.3 (6.4)
Median	-0.2	-0.3
Min ; Max	-26.3 ; 19.7	-22.5 ; 20.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:51:31 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_noct_inc_descp_fas.txt

14.2.115: Nocturnal Increment after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Statistical Analysis - Full Analysis Set

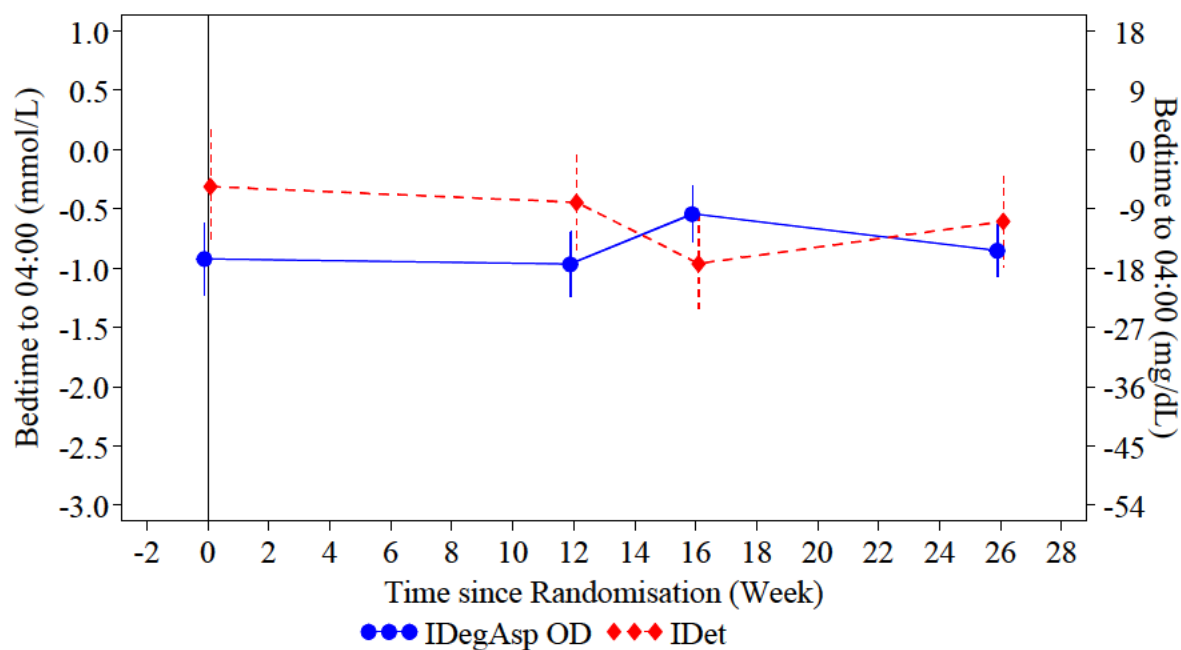
	FAS	N	Estimate	SE	95% CI
Bedtime to Breakfast (mmol/L)					
LSMeans					
IDegAsp OD	366	311	-1.41	0.41	
IDet	182	157	-0.40	0.47	
Treatment Contrast					
IDegAsp OD - IDet			-1.01		[-1.82 ; -0.19]
Bedtime to 04:00 (mmol/L)					
LSMeans					
IDegAsp OD	366	259	-0.71	0.40	
IDet	182	129	-0.38	0.48	
Treatment Contrast					
IDegAsp OD - IDet			-0.33		[-1.16 ; 0.50]
04:00 to Breakfast (mmol/L)					
LSMeans					
IDegAsp OD	366	260	-0.89	0.33	
IDet	182	134	-0.02	0.40	
Treatment Contrast					
IDegAsp OD - IDet			-0.87		[-1.56 ; -0.17]

N = Number of subjects contributing to analysis, CI = Confidence Interval, SE = Standard Error of the Mean

The response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

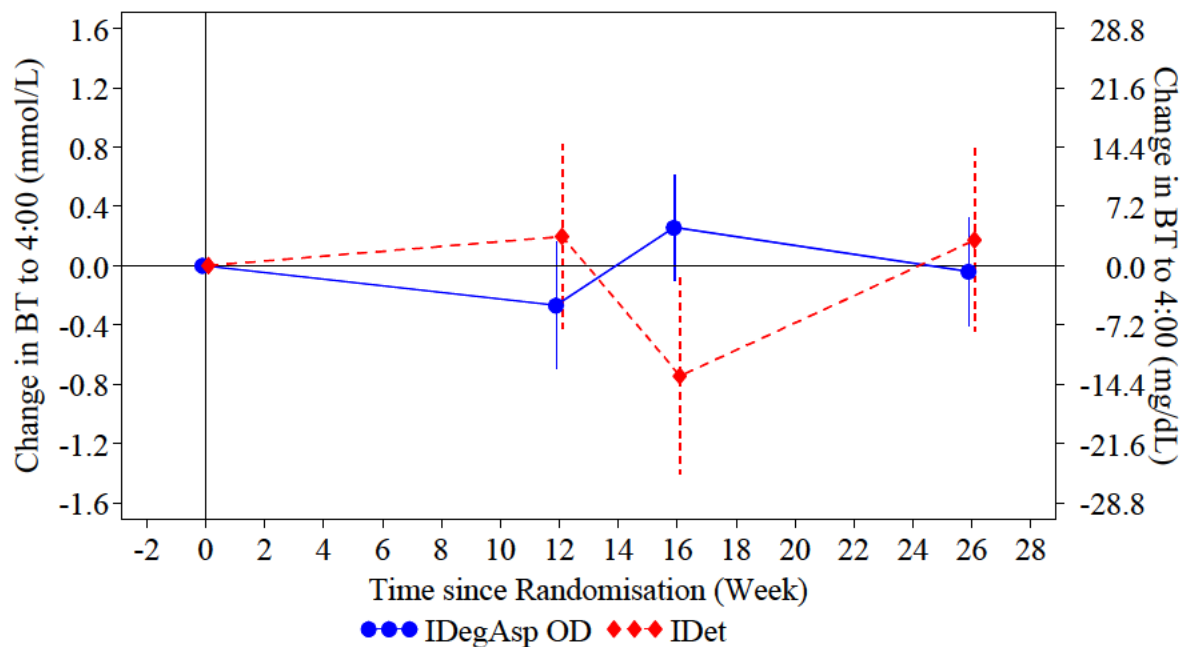
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:51:38 - tstat_find_tpl_t022.sas/t_9pp_noct_inc_stat_locf_fas.txt



FAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:51:44 - fmean_numfind_v03.sas/e_9pp_abs_bt_4_inc_mean_locf_fas.cgm

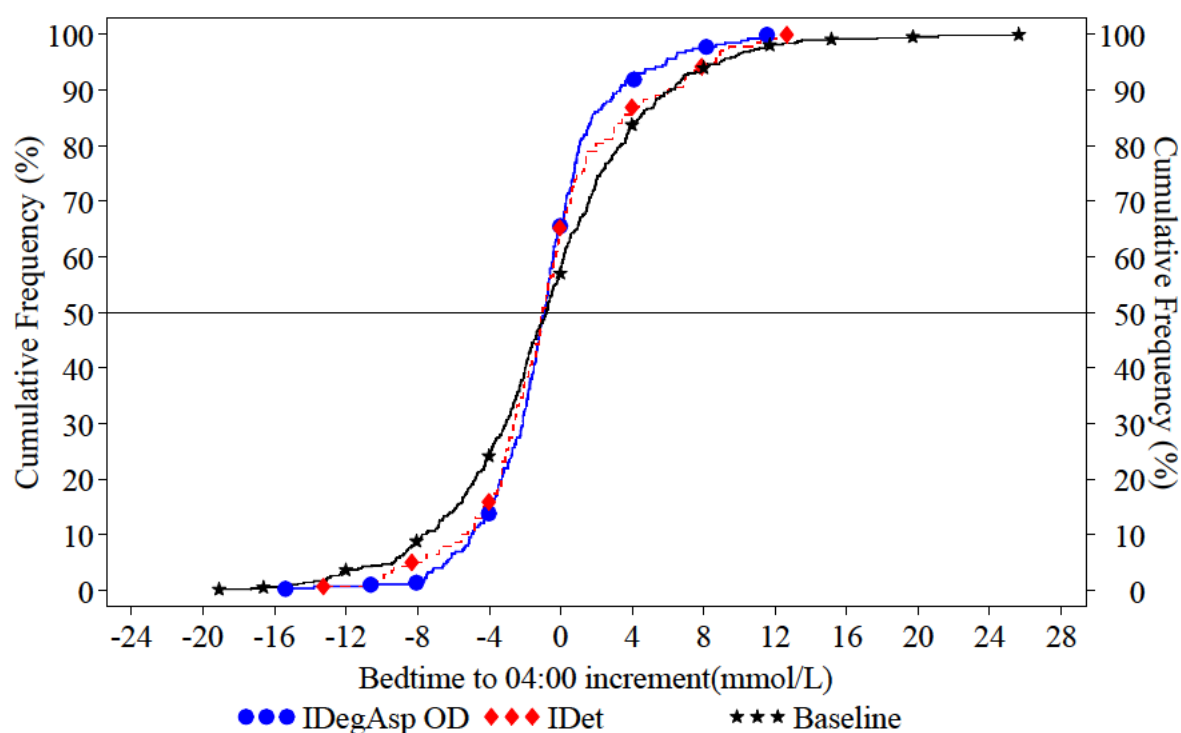
14.2.116: Nocturnal Increment (Bedtime to 04:00) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) -Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:51:50 - fmean_numfind_v03.sas/e_9pp_chb_bt_4_inc_mean_locf_fas.cgm

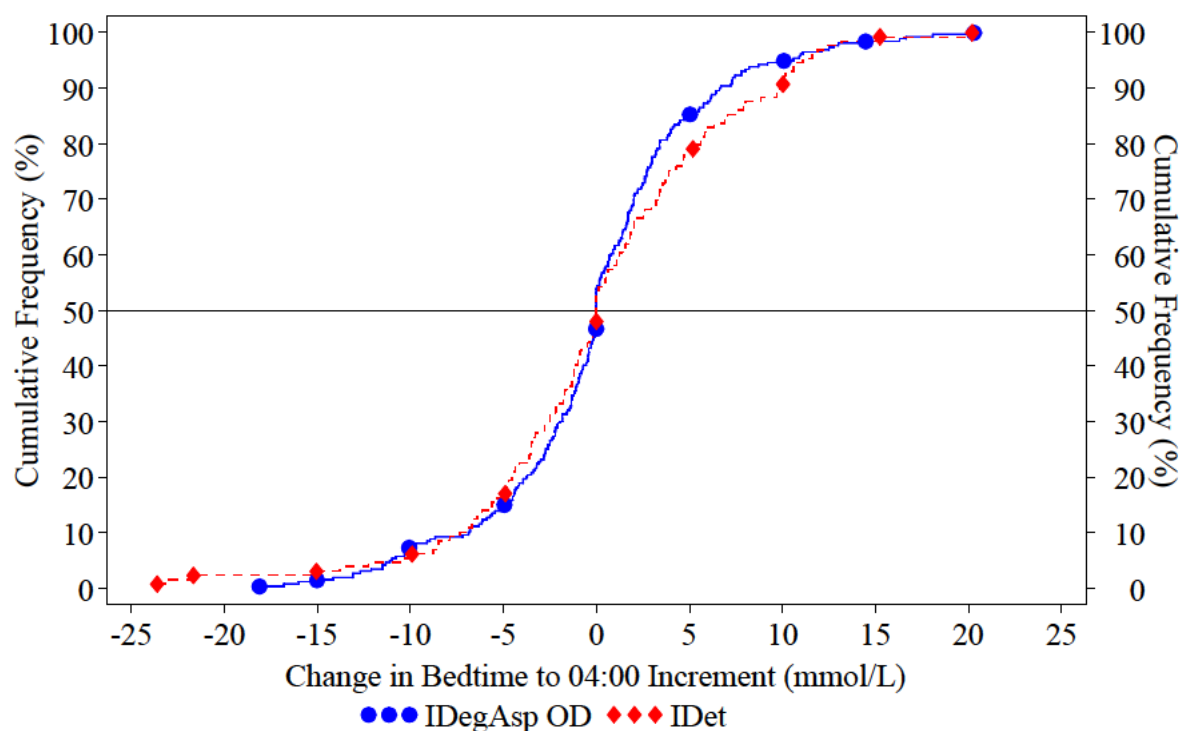
14.2.117: Nocturnal Increment (Bedtime to 04:00) by Treatment Week - Change from Baseline – 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:52:01 - fedist_numfind_v01.sas/e_9pp_abs_bt_4_inc_cdf_locf_fas.cgm

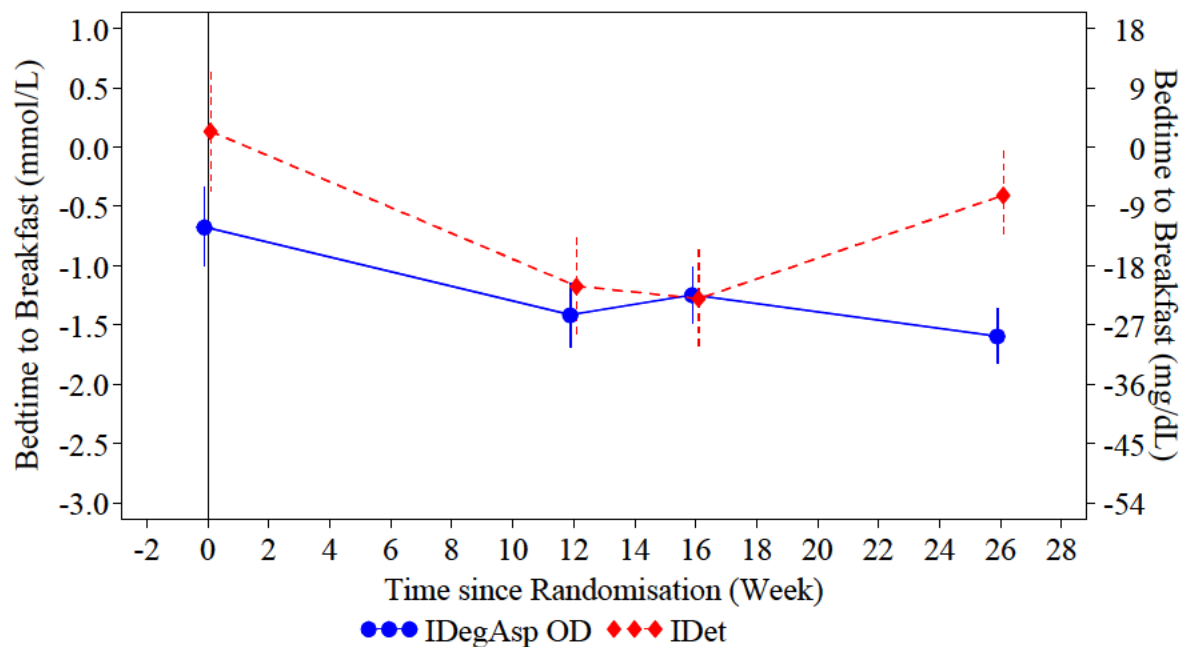
14.2.118: Nocturnal Increment (Bedtime to 04:00) after 26 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:52:07 - fedist_numfind_v01.sas/e_9pp_chb_bt_4_inc_cdf_locf_fas.cgm

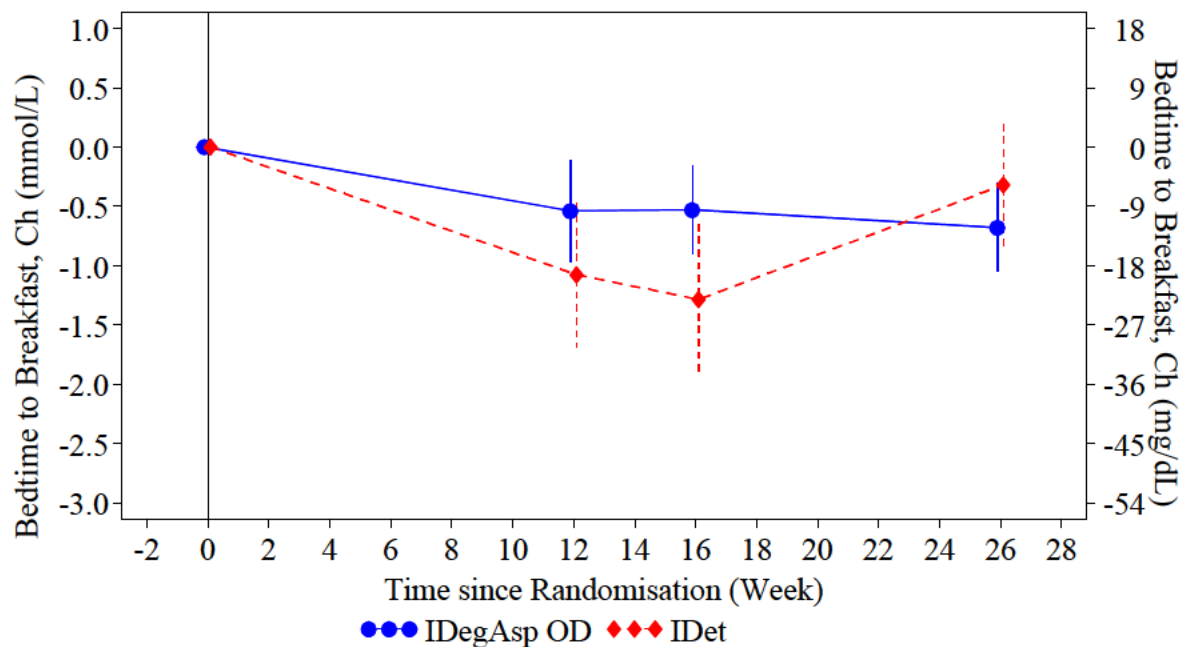
14.2.119: Nocturnal Increment (Bedtime to 04:00) after 26 Weeks of Treatment– Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:52:13 - fmean_numfind_v03.sas/e_9pp_abs_bt_bf_ic_mean_locf_fas.cgm

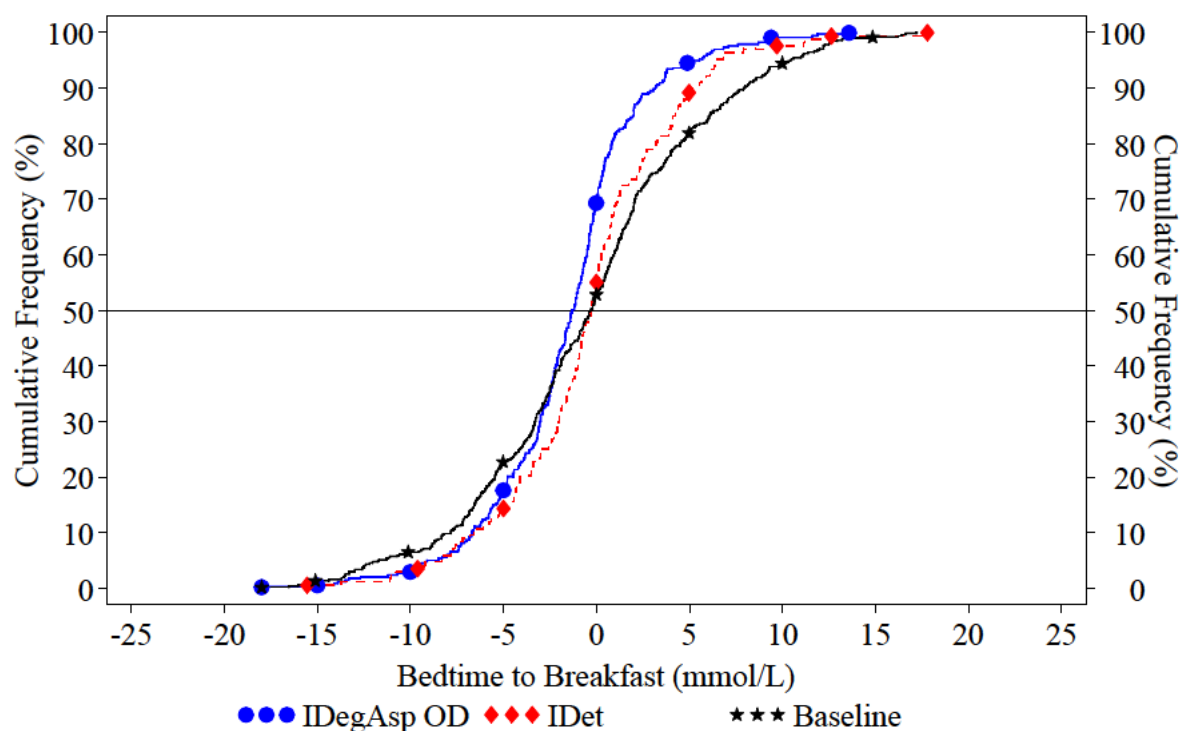
14.2.120: Nocturnal Increment (Bedtime to Breakfast) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:52:19 - fmean_numfind_v03.sas/e_9pp_chb_bt_bf_ic_mean_locf_fas.cgm

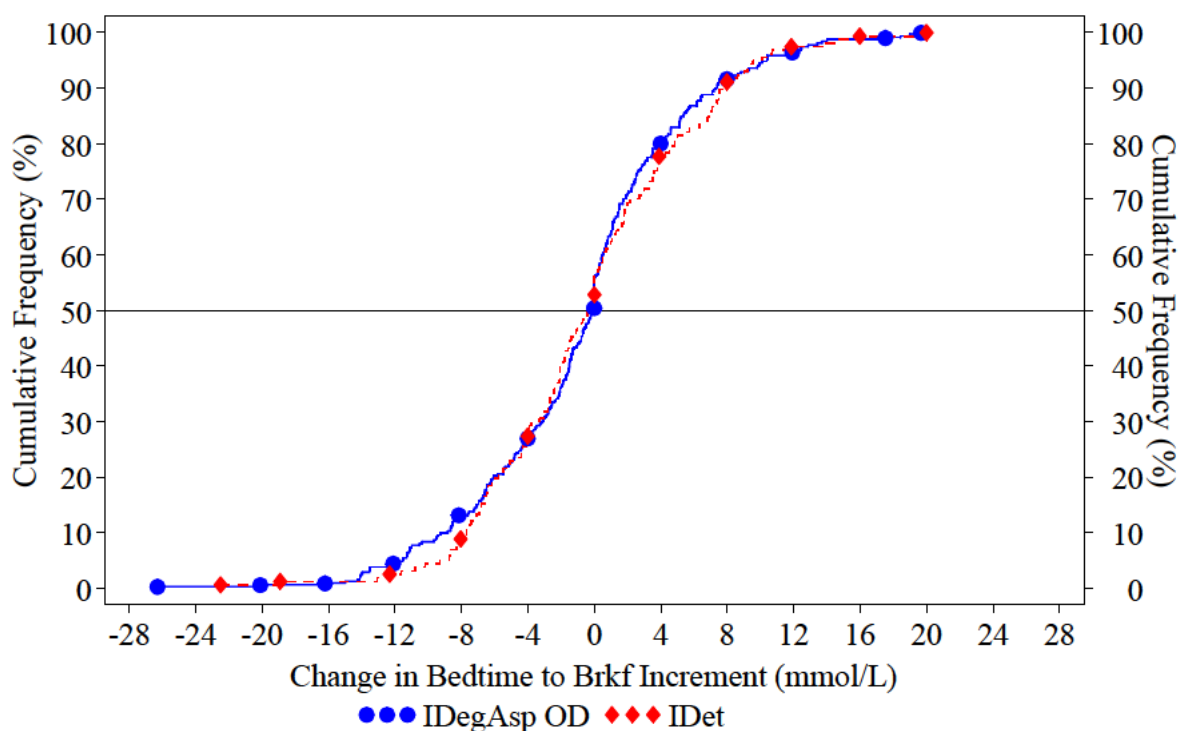
14.2.121: Nocturnal Increment (Bedtime to Breakfast) by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:52:30 - fedist_numfind_v01.sas/e_9pp_abs_bt_bf_inc_cdf_locf_fas.cgm

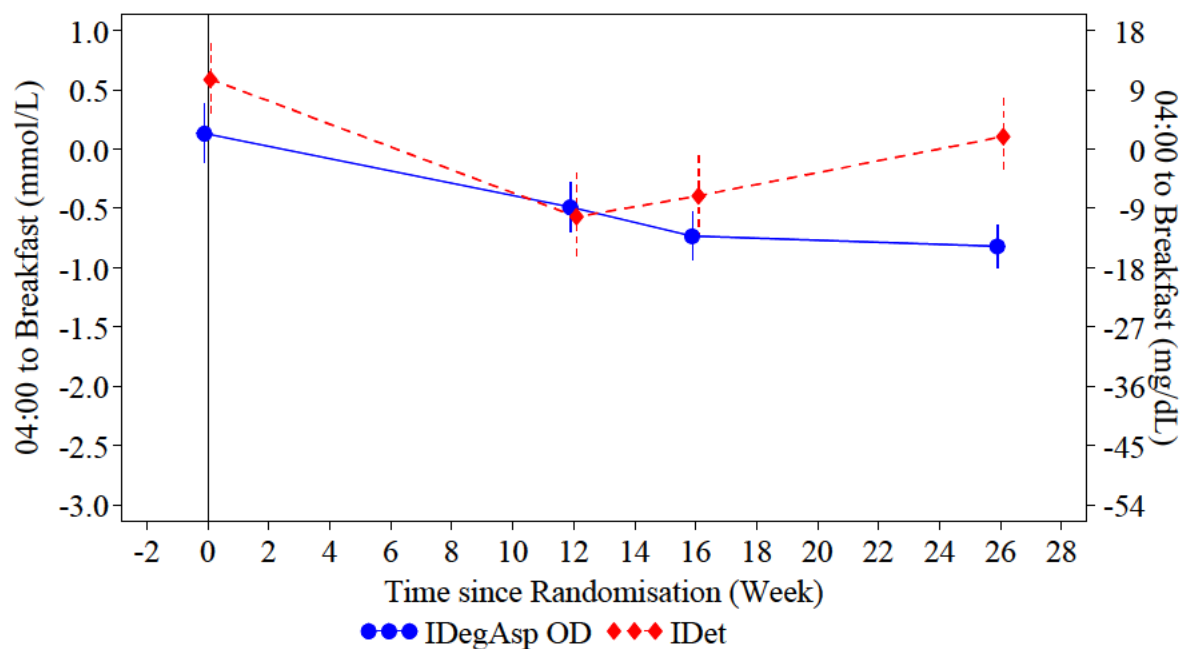
14.2.122: Nocturnal Increment (Bedtime to Breakfast) after 26 Weeks of Treatment -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:52:36 - fedist_numfind_v01.sas/e_9pp_chb_bt_bf_inc_cdf_locf_fas.cgm

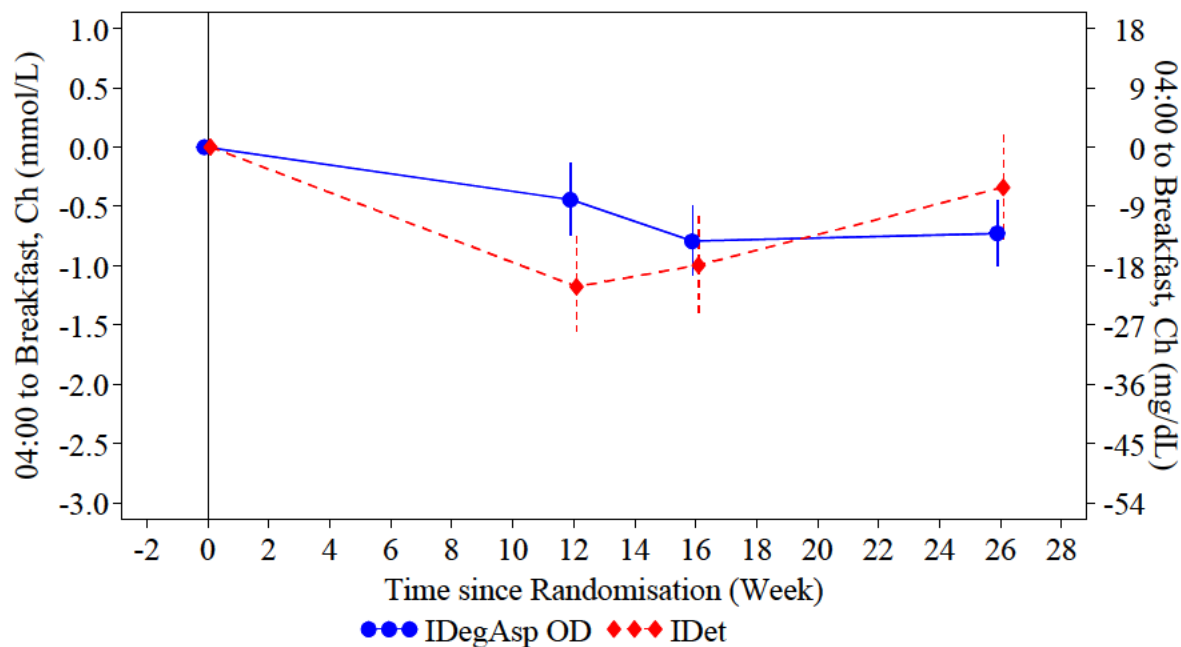
14.2.123: Nocturnal Increment (Bedtime to Breakfast) after 26 Weeks of Treatment – Change from Baseline -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:52:42 - finean_numfind_v03.sas/e_9pp_abs_4_bf_inc_mean_locf_fas.cgm

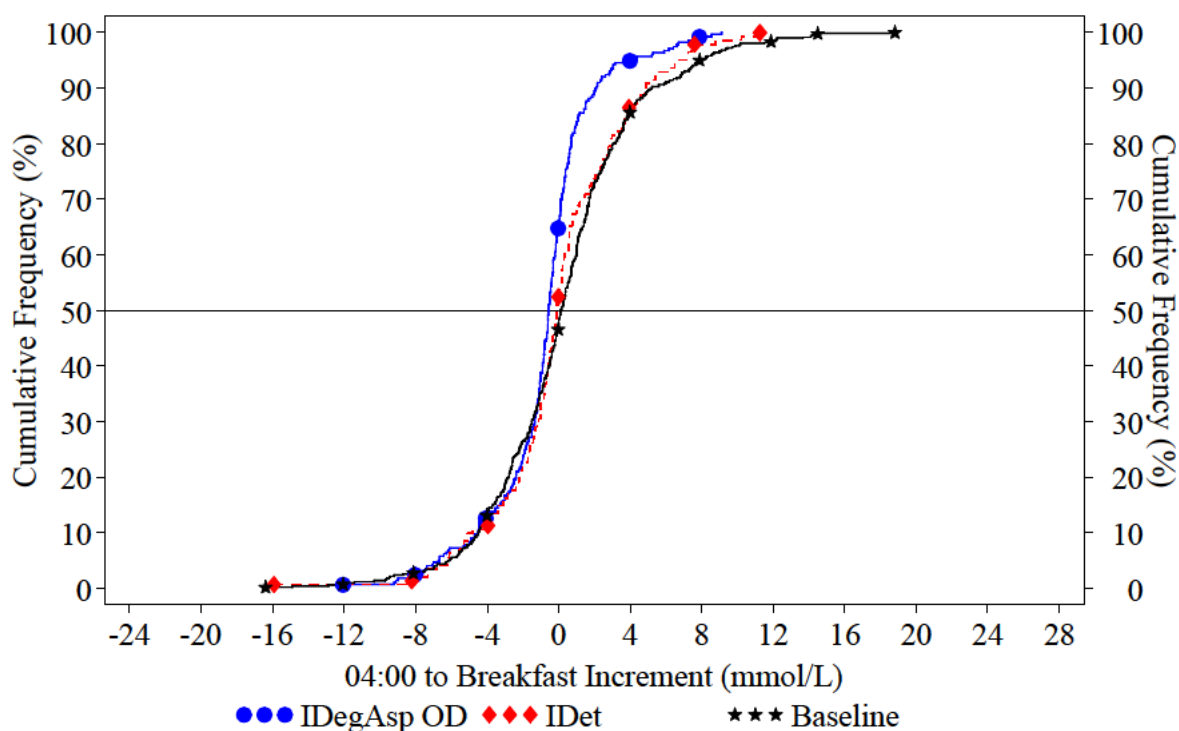
14.2.124: Nocturnal Increment (04:00 to Breakfast) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) – Mean Plot – Full Analysis Set



FAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:52:48 - fmean_numfind_v03.sas/e_9pp_chb_4_bf_inc_mean_locf_fas.cgm

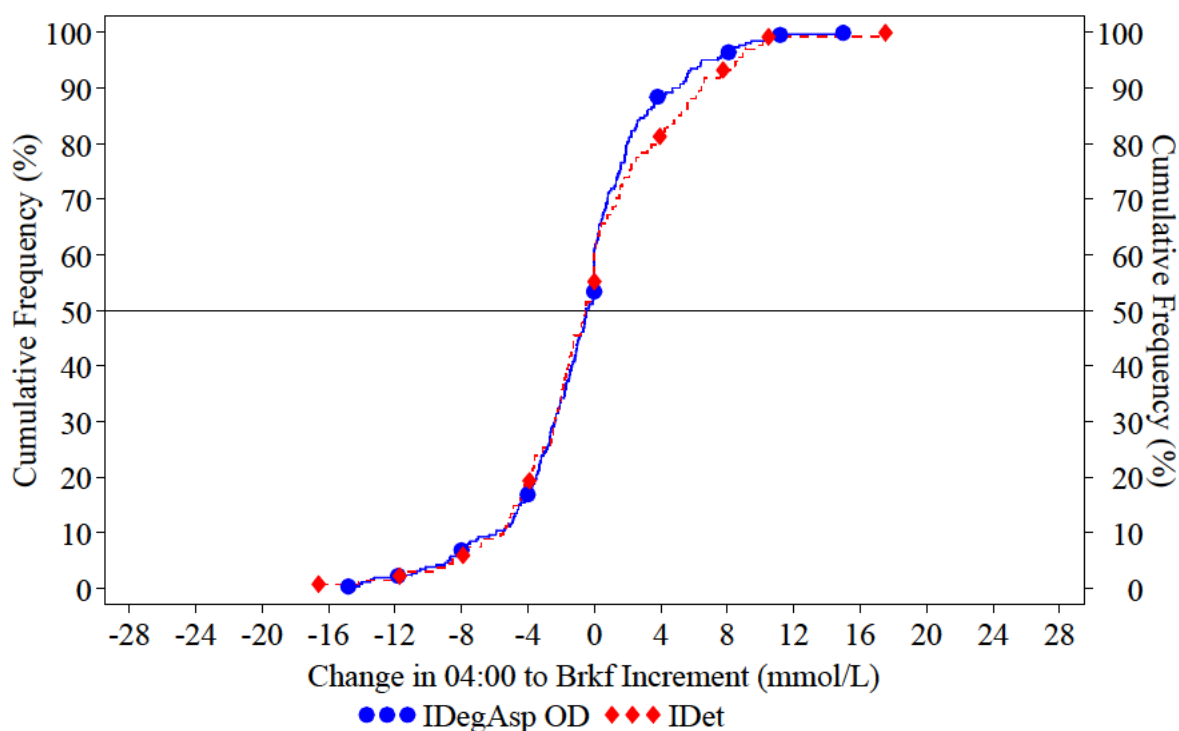
14.2.125: Nocturnal Increment (04:00 to Breakfast) by Treatment Week - Change from Baseline – 9-point Self Measured Plasma Glucose Profile (mmol/L) – Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:52:59 - fedist_numfind_v01.sas/e_9pp_abs_4_bf_inc_cdf_locf_fas.cgm

14.2.126: Nocturnal Increment (04:00 to Breakfast) after 26 Weeks of Treatment -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:05 - fedist_numfind_v01.sas/e_9pp_chb_4_bf_inc_cdf_locf_fas.cgm

14.2.127: Nocturnal Increment (04:00 to Breakfast) after 26 Weeks of Treatment – Change from Baseline -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set

14.2.128: Self Measured Plasma Glucose for Dose Adjustment (mmol/L) – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Before Breakfast (mmol/L)			
Visit 2 (Week 0)			
N	365	181	546
Mean (SD)	9.3 (3.4)	9.7 (3.1)	9.4 (3.3)
Median	8.6	9.3	8.9
Min ; Max	2.3 ; 19.5	2.6 ; 17.6	2.3 ; 19.5
Visit 3 (Week 1)			
N	360	176	536
Mean (SD)	9.0 (3.1)	9.3 (3.6)	9.1 (3.3)
Median	8.6	8.7	8.6
Min ; Max	2.3 ; 19.4	2.8 ; 24.4	2.3 ; 24.4
Visit 4 (Week 2)			
N	359	176	535
Mean (SD)	8.3 (2.8)	8.7 (3.2)	8.4 (3.0)
Median	7.8	8.2	7.9
Min ; Max	2.8 ; 19.1	2.5 ; 21.3	2.5 ; 21.3
Visit 5 (Week 3)			
N	346	174	520
Mean (SD)	8.1 (2.7)	8.3 (3.0)	8.1 (2.8)
Median	7.6	7.9	7.7
Min ; Max	3.1 ; 17.5	2.5 ; 18.8	2.5 ; 18.8
Visit 6 (Week 4)			
N	351	174	525
Mean (SD)	7.9 (2.8)	7.9 (2.8)	7.9 (2.8)
Median	7.4	7.3	7.4
Min ; Max	2.5 ; 20.4	2.4 ; 19.5	2.4 ; 20.4
Visit 7 (Week 5)			
N	349	173	522
Mean (SD)	7.6 (2.5)	7.9 (2.7)	7.7 (2.6)
Median	7.2	7.5	7.3
Min ; Max	2.6 ; 17.4	2.6 ; 17.2	2.6 ; 17.4
Visit 8 (Week 6)			
N	344	174	518
Mean (SD)	7.7 (2.6)	7.5 (2.4)	7.6 (2.5)
Median	7.3	7.1	7.2
Min ; Max	3.2 ; 18.6	2.9 ; 15.6	2.9 ; 18.6
Visit 9 (Week 7)			
N	343	170	513
Mean (SD)	7.4 (2.4)	7.9 (3.0)	7.5 (2.7)
Median	7.0	7.1	7.0
Min ; Max	2.7 ; 16.4	2.7 ; 21.7	2.7 ; 21.7

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Breakfast (mmol/L)			
Visit 10 (Week 8)			
N	339	171	510
Mean (SD)	7.5 (2.6)	7.8 (2.6)	7.6 (2.6)
Median	7.1	7.3	7.1
Min ; Max	2.7 ; 16.4	3.1 ; 16.3	2.7 ; 16.4
Visit 11 (Week 9)			
N	335	165	500
Mean (SD)	7.1 (2.2)	7.8 (2.6)	7.4 (2.3)
Median	6.9	7.4	7.0
Min ; Max	2.9 ; 14.6	2.8 ; 17.0	2.8 ; 17.0
Visit 12 (Week 10)			
N	338	168	506
Mean (SD)	7.4 (2.4)	7.4 (2.5)	7.4 (2.4)
Median	6.8	7.0	6.9
Min ; Max	3.3 ; 16.8	2.6 ; 16.7	2.6 ; 16.8
Visit 13 (Week 11)			
N	334	165	499
Mean (SD)	7.4 (2.5)	7.6 (2.6)	7.5 (2.5)
Median	6.8	6.9	6.8
Min ; Max	4.0 ; 19.7	3.3 ; 17.9	3.3 ; 19.7
Visit 14 (Week 12)			
N	335	168	503
Mean (SD)	7.4 (2.4)	7.6 (2.5)	7.5 (2.5)
Median	7.1	7.0	7.0
Min ; Max	2.4 ; 15.7	4.0 ; 19.1	2.4 ; 19.1
Visit 15 (Week 13)			
N	324	161	485
Mean (SD)	7.3 (2.4)	7.7 (2.7)	7.4 (2.5)
Median	7.0	7.2	7.0
Min ; Max	3.2 ; 18.0	3.1 ; 17.4	3.1 ; 18.0
Visit 16 (Week 14)			
N	332	166	498
Mean (SD)	7.2 (2.4)	7.3 (2.4)	7.3 (2.4)
Median	6.9	6.9	6.9
Min ; Max	3.0 ; 17.3	3.1 ; 18.4	3.0 ; 18.4
Visit 17 (Week 15)			
N	328	163	491
Mean (SD)	7.2 (2.4)	7.3 (2.8)	7.2 (2.5)
Median	6.8	6.6	6.7
Min ; Max	3.3 ; 16.2	2.1 ; 26.9	2.1 ; 26.9

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Breakfast (mmol/L)			
Visit 18 (Week 16)			
N	329	163	492
Mean (SD)	7.4 (2.5)	7.1 (2.3)	7.3 (2.4)
Median	6.8	6.6	6.7
Min ; Max	2.9 ; 17.6	3.4 ; 13.7	2.9 ; 17.6
Visit 19 (Week 17)			
N	324	161	485
Mean (SD)	7.2 (2.3)	7.3 (2.3)	7.3 (2.3)
Median	6.8	7.0	6.9
Min ; Max	2.4 ; 15.5	2.5 ; 16.1	2.4 ; 16.1
Visit 20 (Week 18)			
N	321	158	479
Mean (SD)	7.1 (2.4)	7.2 (2.3)	7.1 (2.4)
Median	6.7	6.8	6.7
Min ; Max	2.2 ; 16.8	2.7 ; 13.9	2.2 ; 16.8
Visit 21 (Week 19)			
N	321	161	482
Mean (SD)	7.0 (2.1)	7.3 (2.5)	7.1 (2.3)
Median	6.5	6.5	6.5
Min ; Max	3.4 ; 14.5	3.9 ; 15.4	3.4 ; 15.4
Visit 22 (Week 20)			
N	324	158	482
Mean (SD)	7.0 (2.3)	7.2 (2.5)	7.1 (2.4)
Median	6.6	6.7	6.7
Min ; Max	3.1 ; 17.7	3.3 ; 18.3	3.1 ; 18.3
Visit 23 (Week 21)			
N	322	156	478
Mean (SD)	7.1 (2.3)	6.9 (2.5)	7.0 (2.3)
Median	6.6	6.1	6.4
Min ; Max	3.1 ; 15.5	2.7 ; 15.8	2.7 ; 15.8
Visit 24 (Week 22)			
N	319	156	475
Mean (SD)	7.0 (2.2)	7.2 (2.5)	7.0 (2.3)
Median	6.5	6.5	6.5
Min ; Max	3.1 ; 15.2	3.4 ; 14.9	3.1 ; 15.2
Visit 25 (Week 23)			
N	320	151	471
Mean (SD)	7.0 (2.2)	7.0 (2.3)	7.0 (2.2)
Median	6.6	6.7	6.6
Min ; Max	2.6 ; 12.9	2.5 ; 14.6	2.5 ; 14.6

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Breakfast (mmol/L)			
Visit 26 (Week 24)			
N	319	158	477
Mean (SD)	7.0 (2.5)	6.9 (2.2)	7.0 (2.4)
Median	6.3	6.5	6.4
Min ; Max	2.8 ; 22.2	3.4 ; 13.7	2.8 ; 22.2
Visit 27 (Week 25)			
N	318	155	473
Mean (SD)	7.1 (2.4)	7.1 (2.6)	7.1 (2.4)
Median	6.6	6.4	6.5
Min ; Max	3.1 ; 16.5	3.1 ; 16.5	3.1 ; 16.5
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	7.2 (2.3)	7.1 (2.5)	7.2 (2.4)
Median	6.8	6.4	6.7
Min ; Max	2.9 ; 14.3	2.1 ; 19.3	2.1 ; 19.3
Visit 28 (Week 26) (LOCF)			
N	366	181	547
Mean (SD)	7.4 (2.5)	7.3 (2.5)	7.4 (2.5)
Median	6.9	6.9	6.9
Min ; Max	2.9 ; 16.2	2.1 ; 19.3	2.1 ; 19.3

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 2 (Week 0)			
N	364	181	545
Mean (SD)	8.8 (2.8)	9.1 (3.4)	8.9 (3.0)
Median	8.5	9.1	8.6
Min ; Max	3.2 ; 20.8	3.4 ; 20.4	3.2 ; 20.8
Visit 3 (Week 1)			
N	360	176	536
Mean (SD)	8.8 (2.9)	9.8 (3.6)	9.1 (3.2)
Median	8.4	9.3	8.6
Min ; Max	2.5 ; 18.7	3.1 ; 20.2	2.5 ; 20.2
Visit 4 (Week 2)			
N	357	177	534
Mean (SD)	8.0 (2.8)	9.5 (3.5)	8.5 (3.1)
Median	7.6	9.1	7.9
Min ; Max	2.5 ; 18.3	2.8 ; 23.5	2.5 ; 23.5
Visit 5 (Week 3)			
N	346	175	521
Mean (SD)	7.7 (2.6)	8.8 (3.1)	8.1 (2.8)
Median	7.3	8.3	7.6
Min ; Max	2.8 ; 19.9	2.7 ; 17.9	2.7 ; 19.9
Visit 6 (Week 4)			
N	352	174	526
Mean (SD)	7.7 (2.7)	8.3 (2.9)	7.9 (2.8)
Median	7.4	7.8	7.4
Min ; Max	2.5 ; 21.6	3.2 ; 18.5	2.5 ; 21.6
Visit 7 (Week 5)			
N	349	173	522
Mean (SD)	7.7 (2.9)	8.4 (2.7)	8.0 (2.8)
Median	7.2	7.9	7.4
Min ; Max	2.9 ; 24.1	3.4 ; 17.0	2.9 ; 24.1
Visit 8 (Week 6)			
N	345	174	519
Mean (SD)	7.7 (2.8)	8.2 (3.0)	7.9 (2.9)
Median	7.2	7.7	7.3
Min ; Max	3.0 ; 25.2	2.4 ; 17.4	2.4 ; 25.2
Visit 9 (Week 7)			
N	343	171	514
Mean (SD)	7.5 (2.5)	8.2 (2.9)	7.7 (2.6)
Median	6.9	7.6	7.1
Min ; Max	2.9 ; 15.9	3.0 ; 19.3	2.9 ; 19.3

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 10 (Week 8)			
N	340	171	511
Mean (SD)	7.5 (2.5)	8.1 (2.7)	7.7 (2.6)
Median	7.2	7.8	7.4
Min ; Max	3.0 ; 16.4	2.9 ; 17.6	2.9 ; 17.6
Visit 11 (Week 9)			
N	334	166	500
Mean (SD)	7.4 (2.5)	8.1 (2.8)	7.7 (2.6)
Median	6.9	7.4	7.1
Min ; Max	2.9 ; 19.2	3.1 ; 17.5	2.9 ; 19.2
Visit 12 (Week 10)			
N	339	169	508
Mean (SD)	7.6 (2.6)	7.9 (2.5)	7.7 (2.6)
Median	7.0	7.4	7.1
Min ; Max	3.2 ; 18.1	3.2 ; 14.6	3.2 ; 18.1
Visit 13 (Week 11)			
N	334	166	500
Mean (SD)	7.6 (2.6)	8.0 (2.7)	7.7 (2.7)
Median	7.0	7.4	7.2
Min ; Max	3.3 ; 17.0	4.0 ; 21.1	3.3 ; 21.1
Visit 14 (Week 12)			
N	335	168	503
Mean (SD)	7.6 (2.6)	8.0 (2.7)	7.7 (2.6)
Median	6.9	7.4	7.1
Min ; Max	3.2 ; 18.9	3.4 ; 17.6	3.2 ; 18.9
Visit 15 (Week 13)			
N	325	161	486
Mean (SD)	7.5 (2.7)	7.9 (2.7)	7.6 (2.7)
Median	7.0	7.3	7.1
Min ; Max	3.2 ; 23.4	2.8 ; 22.5	2.8 ; 23.4
Visit 16 (Week 14)			
N	333	166	499
Mean (SD)	7.3 (2.6)	8.3 (3.0)	7.7 (2.8)
Median	6.8	7.8	7.0
Min ; Max	3.0 ; 18.4	2.9 ; 22.4	2.9 ; 22.4
Visit 17 (Week 15)			
N	328	164	492
Mean (SD)	7.2 (2.4)	7.7 (2.4)	7.3 (2.4)
Median	6.7	7.2	6.9
Min ; Max	2.9 ; 20.3	2.7 ; 18.1	2.7 ; 20.3

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 18 (Week 16)			
N	329	163	492
Mean (SD)	7.5 (2.5)	7.5 (2.3)	7.5 (2.4)
Median	6.9	7.0	6.9
Min ; Max	3.2 ; 17.3	2.0 ; 16.3	2.0 ; 17.3
Visit 19 (Week 17)			
N	324	160	484
Mean (SD)	7.2 (2.3)	7.7 (2.5)	7.4 (2.4)
Median	6.6	7.2	6.9
Min ; Max	3.3 ; 17.1	2.4 ; 16.7	2.4 ; 17.1
Visit 20 (Week 18)			
N	322	158	480
Mean (SD)	7.3 (2.4)	7.4 (2.7)	7.3 (2.5)
Median	6.8	6.9	6.8
Min ; Max	3.4 ; 18.2	2.4 ; 16.6	2.4 ; 18.2
Visit 21 (Week 19)			
N	321	161	482
Mean (SD)	7.1 (2.4)	7.7 (2.7)	7.3 (2.5)
Median	6.7	6.9	6.8
Min ; Max	2.2 ; 15.5	3.7 ; 15.6	2.2 ; 15.6
Visit 22 (Week 20)			
N	324	158	482
Mean (SD)	7.2 (2.4)	7.3 (2.4)	7.3 (2.4)
Median	6.7	7.1	6.8
Min ; Max	3.2 ; 16.0	2.4 ; 15.9	2.4 ; 16.0
Visit 23 (Week 21)			
N	322	156	478
Mean (SD)	7.0 (2.2)	7.7 (2.5)	7.2 (2.3)
Median	6.7	7.1	6.8
Min ; Max	2.4 ; 15.8	3.8 ; 16.7	2.4 ; 16.7
Visit 24 (Week 22)			
N	319	155	474
Mean (SD)	7.2 (2.4)	7.6 (2.6)	7.3 (2.5)
Median	6.7	6.9	6.8
Min ; Max	2.6 ; 18.9	2.8 ; 16.7	2.6 ; 18.9
Visit 25 (Week 23)			
N	319	151	470
Mean (SD)	7.2 (2.4)	7.5 (2.3)	7.3 (2.4)
Median	6.7	7.1	6.8
Min ; Max	2.4 ; 16.9	3.9 ; 14.7	2.4 ; 16.9

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 26 (Week 24)			
N	319	158	477
Mean (SD)	7.2 (2.6)	7.6 (2.6)	7.3 (2.6)
Median	6.5	7.1	6.8
Min ; Max	2.4 ; 18.2	3.0 ; 20.4	2.4 ; 20.4
Visit 27 (Week 25)			
N	318	155	473
Mean (SD)	7.1 (2.4)	7.6 (2.6)	7.2 (2.5)
Median	6.7	7.0	6.8
Min ; Max	2.4 ; 20.6	4.1 ; 22.9	2.4 ; 22.9
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	7.5 (2.6)	8.1 (2.8)	7.7 (2.7)
Median	7.0	7.7	7.1
Min ; Max	2.7 ; 17.1	3.8 ; 19.4	2.7 ; 19.4
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	7.6 (2.6)	8.3 (3.0)	7.8 (2.8)
Median	7.1	7.9	7.3
Min ; Max	2.7 ; 18.9	2.9 ; 21.6	2.7 ; 21.6

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 2 (Week 0)			
N	364	181	545
Mean (SD)	9.6 (3.3)	10.2 (3.5)	9.8 (3.4)
Median	9.0	9.7	9.2
Min ; Max	2.3 ; 22.0	3.5 ; 22.1	2.3 ; 22.1
Visit 3 (Week 1)			
N	360	176	536
Mean (SD)	9.7 (3.3)	11.0 (4.2)	10.1 (3.6)
Median	9.3	9.9	9.6
Min ; Max	2.8 ; 22.3	5.0 ; 23.2	2.8 ; 23.2
Visit 4 (Week 2)			
N	359	177	536
Mean (SD)	9.1 (3.1)	10.3 (3.9)	9.5 (3.4)
Median	8.5	9.5	8.8
Min ; Max	2.6 ; 19.6	4.1 ; 25.5	2.6 ; 25.5
Visit 5 (Week 3)			
N	346	175	521
Mean (SD)	8.6 (3.2)	9.5 (3.2)	8.9 (3.2)
Median	8.0	8.8	8.2
Min ; Max	3.2 ; 19.7	4.3 ; 19.0	3.2 ; 19.7
Visit 6 (Week 4)			
N	352	174	526
Mean (SD)	8.4 (3.0)	9.7 (3.4)	8.8 (3.2)
Median	7.9	9.1	8.3
Min ; Max	3.1 ; 20.2	4.4 ; 20.8	3.1 ; 20.8
Visit 7 (Week 5)			
N	349	173	522
Mean (SD)	8.5 (3.1)	9.3 (3.4)	8.8 (3.2)
Median	8.0	8.9	8.3
Min ; Max	2.6 ; 20.3	2.5 ; 19.0	2.5 ; 20.3
Visit 8 (Week 6)			
N	343	174	517
Mean (SD)	8.4 (3.1)	9.1 (3.3)	8.7 (3.2)
Median	7.9	8.7	8.1
Min ; Max	2.8 ; 21.9	3.5 ; 21.3	2.8 ; 21.9
Visit 9 (Week 7)			
N	343	171	514
Mean (SD)	8.1 (2.6)	9.0 (3.3)	8.4 (2.9)
Median	7.7	8.3	7.9
Min ; Max	3.1 ; 19.1	3.7 ; 20.6	3.1 ; 20.6

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 10 (Week 8)			
N	340	171	511
Mean (SD)	8.3 (2.9)	8.9 (3.4)	8.5 (3.1)
Median	7.5	8.3	7.7
Min ; Max	3.1 ; 19.8	3.5 ; 25.0	3.1 ; 25.0
Visit 11 (Week 9)			
N	335	166	501
Mean (SD)	8.1 (2.8)	9.0 (3.2)	8.4 (3.0)
Median	7.6	8.3	7.8
Min ; Max	3.3 ; 20.5	3.3 ; 19.8	3.3 ; 20.5
Visit 12 (Week 10)			
N	338	169	507
Mean (SD)	8.3 (2.8)	8.4 (2.8)	8.3 (2.8)
Median	7.9	7.8	7.9
Min ; Max	2.7 ; 19.8	4.0 ; 18.8	2.7 ; 19.8
Visit 13 (Week 11)			
N	334	166	500
Mean (SD)	8.2 (2.8)	8.9 (3.1)	8.4 (2.9)
Median	7.6	8.2	7.9
Min ; Max	2.7 ; 22.2	3.6 ; 22.0	2.7 ; 22.2
Visit 14 (Week 12)			
N	335	168	503
Mean (SD)	8.2 (2.9)	8.5 (2.9)	8.3 (2.9)
Median	7.7	8.2	7.8
Min ; Max	2.4 ; 21.4	4.2 ; 19.6	2.4 ; 21.4
Visit 15 (Week 13)			
N	325	161	486
Mean (SD)	8.1 (3.0)	8.6 (2.9)	8.3 (3.0)
Median	7.5	8.2	7.7
Min ; Max	2.4 ; 23.0	3.8 ; 17.6	2.4 ; 23.0
Visit 16 (Week 14)			
N	332	166	498
Mean (SD)	8.0 (2.8)	8.5 (3.0)	8.1 (2.9)
Median	7.2	8.0	7.5
Min ; Max	3.7 ; 19.3	3.3 ; 21.9	3.3 ; 21.9
Visit 17 (Week 15)			
N	328	164	492
Mean (SD)	7.7 (2.5)	8.4 (2.7)	7.9 (2.6)
Median	7.1	7.9	7.4
Min ; Max	3.0 ; 16.9	3.7 ; 17.2	3.0 ; 17.2

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 18 (Week 16)			
N	329	163	492
Mean (SD)	8.0 (2.8)	8.5 (2.7)	8.2 (2.8)
Median	7.4	8.0	7.6
Min ; Max	2.5 ; 18.8	4.2 ; 17.5	2.5 ; 18.8
Visit 19 (Week 17)			
N	324	161	485
Mean (SD)	7.9 (2.6)	8.3 (3.0)	8.0 (2.7)
Median	7.2	7.8	7.4
Min ; Max	3.0 ; 19.6	3.1 ; 19.1	3.0 ; 19.6
Visit 20 (Week 18)			
N	322	158	480
Mean (SD)	7.8 (2.6)	8.6 (3.2)	8.1 (2.8)
Median	7.3	8.1	7.4
Min ; Max	3.2 ; 19.0	3.6 ; 19.4	3.2 ; 19.4
Visit 21 (Week 19)			
N	320	161	481
Mean (SD)	7.6 (2.6)	8.4 (3.4)	7.9 (2.9)
Median	7.0	7.6	7.3
Min ; Max	2.5 ; 16.7	3.3 ; 23.7	2.5 ; 23.7
Visit 22 (Week 20)			
N	324	158	482
Mean (SD)	7.8 (2.8)	8.6 (2.9)	8.0 (2.8)
Median	7.2	7.9	7.4
Min ; Max	3.4 ; 18.4	3.6 ; 17.9	3.4 ; 18.4
Visit 23 (Week 21)			
N	322	156	478
Mean (SD)	7.8 (2.8)	8.3 (3.2)	8.0 (2.9)
Median	7.1	7.5	7.3
Min ; Max	2.9 ; 18.3	3.6 ; 21.9	2.9 ; 21.9
Visit 24 (Week 22)			
N	319	156	475
Mean (SD)	7.8 (2.6)	8.0 (2.9)	7.9 (2.7)
Median	7.5	7.4	7.4
Min ; Max	3.3 ; 17.2	3.6 ; 21.4	3.3 ; 21.4
Visit 25 (Week 23)			
N	320	151	471
Mean (SD)	7.8 (2.8)	8.2 (3.0)	7.9 (2.9)
Median	7.3	7.8	7.5
Min ; Max	2.9 ; 17.8	3.0 ; 23.1	2.9 ; 23.1

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 26 (Week 24)			
N	319	158	477
Mean (SD)	7.6 (2.7)	8.2 (2.8)	7.8 (2.8)
Median	7.1	7.6	7.3
Min ; Max	3.2 ; 18.4	4.3 ; 20.0	3.2 ; 20.0
Visit 27 (Week 25)			
N	318	155	473
Mean (SD)	7.6 (2.6)	8.0 (2.8)	7.8 (2.7)
Median	6.9	7.2	7.1
Min ; Max	3.2 ; 16.7	3.8 ; 17.5	3.2 ; 17.5
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	8.0 (2.7)	8.2 (3.0)	8.0 (2.8)
Median	7.5	7.6	7.5
Min ; Max	2.7 ; 19.6	2.4 ; 21.3	2.4 ; 21.3
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	8.1 (2.8)	8.6 (3.4)	8.3 (3.0)
Median	7.6	7.9	7.7
Min ; Max	2.7 ; 19.6	2.4 ; 21.3	2.4 ; 21.3

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 2 (Week 0)			
N	359	180	539
Mean (SD)	10.2 (3.2)	10.0 (3.3)	10.1 (3.3)
Median	9.7	9.5	9.7
Min ; Max	3.3 ; 20.5	3.4 ; 21.3	3.3 ; 21.3
Visit 3 (Week 1)			
N	358	175	533
Mean (SD)	9.7 (3.5)	11.4 (3.9)	10.3 (3.8)
Median	9.2	11.1	9.8
Min ; Max	2.6 ; 21.4	4.5 ; 26.1	2.6 ; 26.1
Visit 4 (Week 2)			
N	356	176	532
Mean (SD)	9.6 (3.5)	10.7 (3.9)	9.9 (3.7)
Median	9.0	9.8	9.3
Min ; Max	2.4 ; 23.4	3.5 ; 22.1	2.4 ; 23.4
Visit 5 (Week 3)			
N	342	175	517
Mean (SD)	9.3 (3.5)	10.2 (3.4)	9.6 (3.5)
Median	8.7	9.9	9.1
Min ; Max	2.9 ; 23.1	3.9 ; 20.0	2.9 ; 23.1
Visit 6 (Week 4)			
N	350	174	524
Mean (SD)	9.1 (3.5)	9.6 (3.3)	9.3 (3.5)
Median	8.5	8.8	8.6
Min ; Max	2.2 ; 24.2	4.1 ; 19.6	2.2 ; 24.2
Visit 7 (Week 5)			
N	347	173	520
Mean (SD)	8.8 (3.1)	9.1 (3.4)	8.9 (3.2)
Median	8.3	8.2	8.2
Min ; Max	3.3 ; 19.0	3.2 ; 19.1	3.2 ; 19.1
Visit 8 (Week 6)			
N	338	173	511
Mean (SD)	8.7 (3.0)	9.1 (3.5)	8.8 (3.2)
Median	8.1	8.4	8.3
Min ; Max	3.3 ; 20.4	2.8 ; 23.4	2.8 ; 23.4
Visit 9 (Week 7)			
N	338	171	509
Mean (SD)	8.5 (3.0)	9.0 (3.1)	8.7 (3.1)
Median	8.0	8.5	8.0
Min ; Max	1.6 ; 20.8	4.3 ; 18.4	1.6 ; 20.8

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 10 (Week 8)			
N	338	171	509
Mean (SD)	8.4 (2.6)	9.2 (3.5)	8.7 (3.0)
Median	7.9	8.6	8.1
Min ; Max	3.3 ; 19.0	4.2 ; 22.1	3.3 ; 22.1
Visit 11 (Week 9)			
N	330	166	496
Mean (SD)	8.5 (3.1)	8.9 (3.2)	8.6 (3.1)
Median	7.9	8.1	7.9
Min ; Max	2.0 ; 19.8	2.5 ; 18.8	2.0 ; 19.8
Visit 12 (Week 10)			
N	337	169	506
Mean (SD)	8.5 (2.9)	8.7 (2.7)	8.6 (2.9)
Median	7.8	8.4	8.1
Min ; Max	2.9 ; 21.9	3.9 ; 19.8	2.9 ; 21.9
Visit 13 (Week 11)			
N	331	166	497
Mean (SD)	8.6 (3.0)	8.7 (3.1)	8.6 (3.0)
Median	8.0	8.3	8.0
Min ; Max	3.3 ; 19.7	4.1 ; 25.6	3.3 ; 25.6
Visit 14 (Week 12)			
N	334	168	502
Mean (SD)	8.5 (3.0)	8.8 (3.1)	8.6 (3.0)
Median	8.0	8.1	8.0
Min ; Max	2.6 ; 19.4	3.9 ; 20.3	2.6 ; 20.3
Visit 15 (Week 13)			
N	323	161	484
Mean (SD)	8.7 (3.2)	8.7 (3.0)	8.7 (3.2)
Median	8.0	8.1	8.0
Min ; Max	2.4 ; 22.2	3.0 ; 19.3	2.4 ; 22.2
Visit 16 (Week 14)			
N	331	166	497
Mean (SD)	8.4 (3.0)	8.6 (3.0)	8.5 (3.0)
Median	7.6	8.3	7.8
Min ; Max	3.5 ; 19.9	4.1 ; 19.9	3.5 ; 19.9
Visit 17 (Week 15)			
N	324	164	488
Mean (SD)	8.1 (2.6)	8.5 (2.9)	8.2 (2.7)
Median	7.6	8.2	7.7
Min ; Max	3.1 ; 17.7	2.6 ; 18.1	2.6 ; 18.1

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 18 (Week 16)			
N	328	163	491
Mean (SD)	8.3 (2.8)	8.7 (3.1)	8.4 (2.9)
Median	7.6	8.2	7.8
Min ; Max	2.1 ; 24.0	4.4 ; 19.0	2.1 ; 24.0
Visit 19 (Week 17)			
N	323	161	484
Mean (SD)	8.3 (2.8)	8.6 (2.9)	8.4 (2.8)
Median	7.7	8.0	7.8
Min ; Max	3.9 ; 18.8	4.3 ; 21.0	3.9 ; 21.0
Visit 20 (Week 18)			
N	320	158	478
Mean (SD)	8.3 (3.1)	8.6 (2.9)	8.4 (3.0)
Median	7.7	8.1	7.8
Min ; Max	2.6 ; 19.2	4.4 ; 21.4	2.6 ; 21.4
Visit 21 (Week 19)			
N	320	161	481
Mean (SD)	8.0 (2.6)	8.7 (3.3)	8.2 (2.8)
Median	7.7	7.9	7.8
Min ; Max	3.4 ; 17.1	2.6 ; 20.5	2.6 ; 20.5
Visit 22 (Week 20)			
N	320	158	478
Mean (SD)	8.3 (2.9)	8.3 (2.6)	8.3 (2.8)
Median	7.6	7.8	7.7
Min ; Max	2.8 ; 18.9	3.7 ; 16.6	2.8 ; 18.9
Visit 23 (Week 21)			
N	319	156	475
Mean (SD)	8.2 (3.0)	8.3 (3.2)	8.2 (3.1)
Median	7.4	7.6	7.4
Min ; Max	2.6 ; 23.0	3.2 ; 25.5	2.6 ; 25.5
Visit 24 (Week 22)			
N	317	156	473
Mean (SD)	8.1 (2.7)	8.3 (3.0)	8.2 (2.8)
Median	7.8	7.7	7.8
Min ; Max	2.6 ; 22.5	3.5 ; 21.9	2.6 ; 22.5
Visit 25 (Week 23)			
N	315	151	466
Mean (SD)	8.0 (2.9)	8.6 (3.0)	8.2 (2.9)
Median	7.5	8.0	7.5
Min ; Max	3.1 ; 18.6	3.4 ; 17.9	3.1 ; 18.6

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 26 (Week 24)			
N	315	158	473
Mean (SD)	8.3 (3.0)	8.4 (3.1)	8.3 (3.0)
Median	7.6	7.7	7.6
Min ; Max	3.2 ; 19.2	3.8 ; 18.2	3.2 ; 19.2
Visit 27 (Week 25)			
N	317	154	471
Mean (SD)	8.2 (2.8)	8.4 (2.8)	8.3 (2.8)
Median	7.7	7.9	7.7
Min ; Max	3.0 ; 18.8	4.1 ; 18.3	3.0 ; 18.8
Visit 28 (Week 26)			
N	317	157	474
Mean (SD)	8.2 (2.7)	8.3 (2.9)	8.3 (2.7)
Median	7.7	7.8	7.7
Min ; Max	2.9 ; 18.4	3.1 ; 18.7	2.9 ; 18.7
Visit 28 (Week 26) (LOCF)			
N	361	181	542
Mean (SD)	8.4 (2.9)	8.5 (3.0)	8.4 (2.9)
Median	7.8	7.8	7.8
Min ; Max	2.9 ; 23.2	3.1 ; 22.1	2.9 ; 23.2

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:26 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

14.2.129: Self Measured Plasma Glucose for Dose Adjustment after 26 Treatment Weeks - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Before Breakfast (mmol/L)					
LSMeans					
IDegAsp OD	366	365	7.85	0.21	
IDet	182	181	7.70	0.24	
Treatment Contrast					
IDegAsp OD - IDet			0.15		[-0.27 ; 0.58]

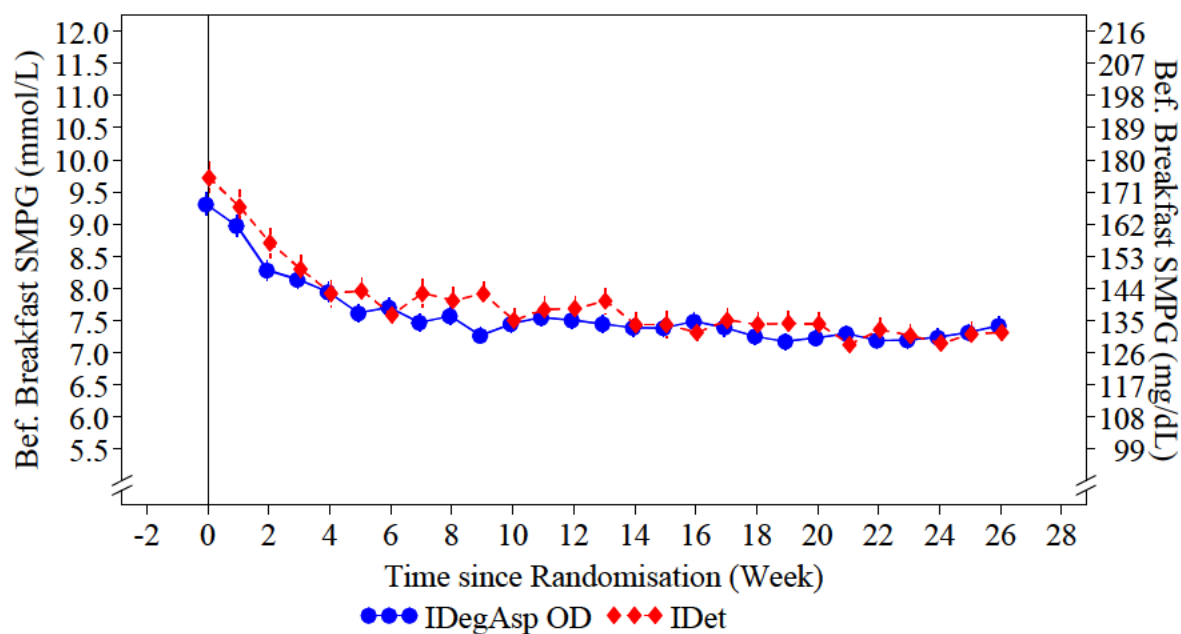
N=Number of subjects contributing to analysis, CI=Confidence Interval, SE=Standard Error of the Mean

The response after 26 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

Endpoint is calculated as mean of the available SMPG values.

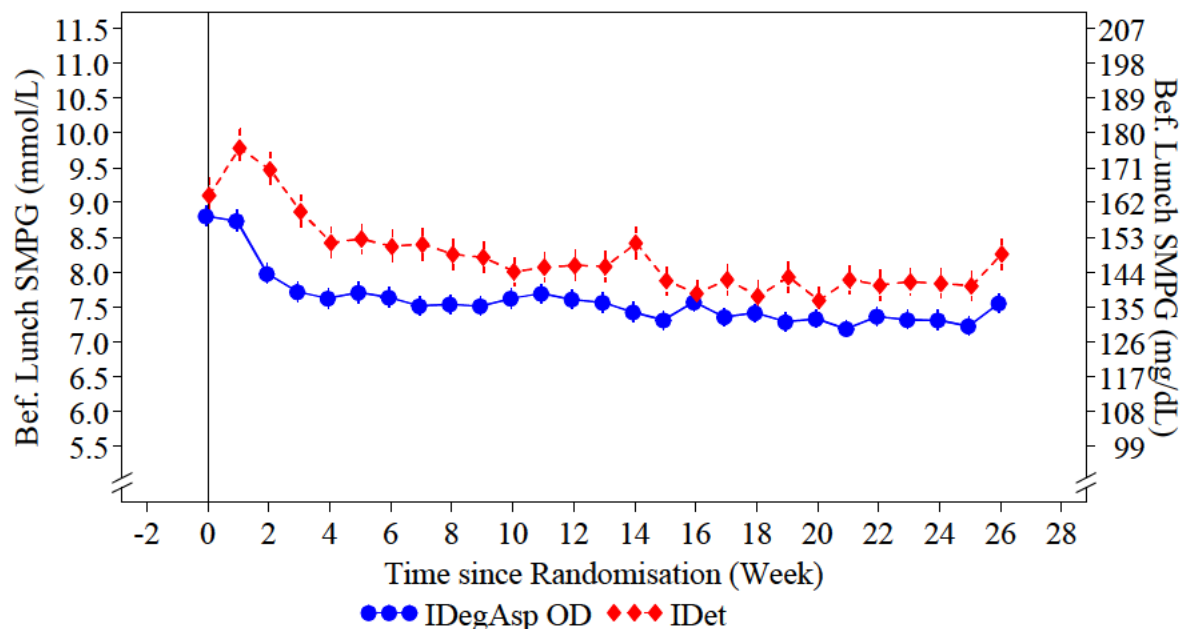
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:32 - tstat_find_tpl_t022.sas/t_smpg_stat_locf_fas.txt



FAS: LOCF imputed data
Endpoint is calculated as the mean of the available SMPG values,
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:39 - fmean_numfind_v03.sas/e_smpg_abs_bf_mean_locf_fas.cgm

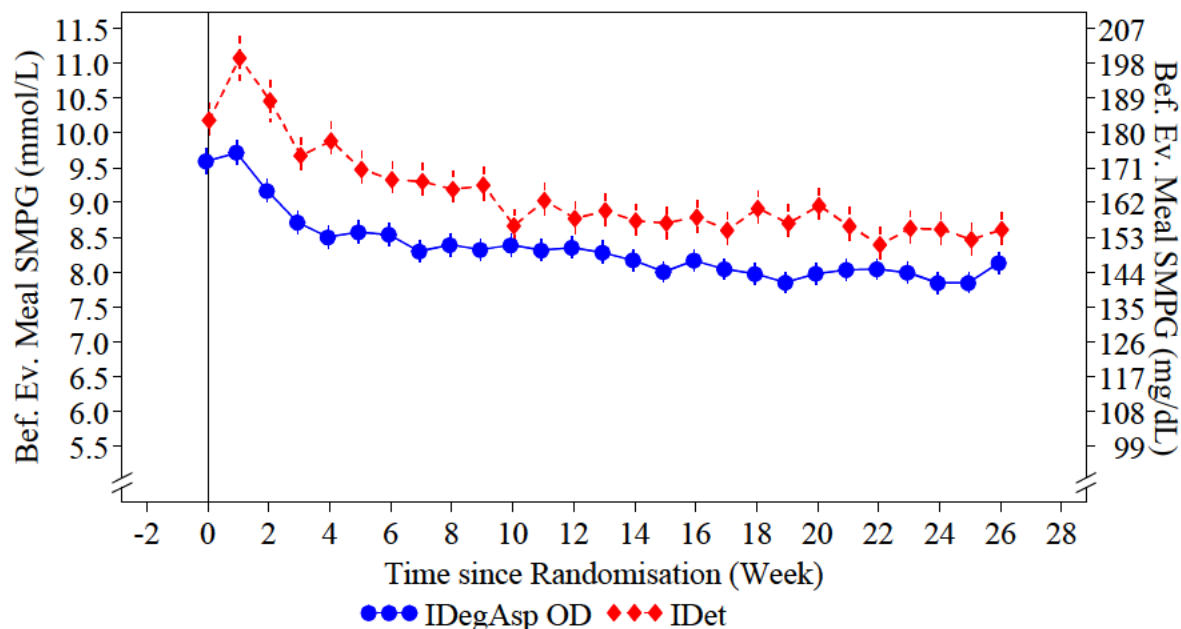
14.2.130: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set



FAS; LOCF imputed data
Endpoint is calculated as the mean of the available SMPG values,
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:47 - finean_numfind_v03.sas/e_smpg_abs_1_mean_locf_fas.cgm

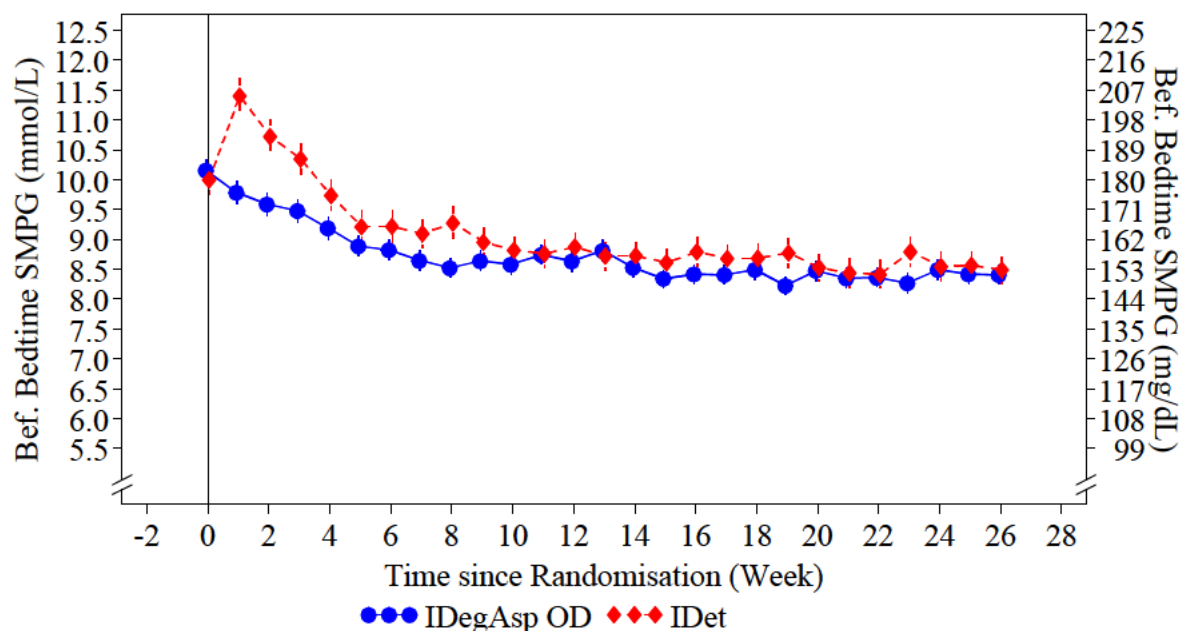
14.2.131: Mean Before Lunch Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set



FAS; LOCF imputed data
Endpoint is calculated as the mean of the available SMPG values,
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:53:54 - finean_numfind_v03.sas/e_smpg_abs_ev_mean_locf_fas.cgm

14.2.132: Mean Before Main Evening Meal Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set



FAS; LOCF imputed data
Endpoint is calculated as the mean of the available SMPG values,
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:01 - fmean_numfind_v03.sas/e_smpg_abs_bt_mean_locf_fas.cgm

14.2.133: Mean Before Bedtime Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set

14.2.134: Within-Subject Variation in Self Measured Plasma Glucose for Dose Adjustment after 26 Treatment Weeks - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
Before Breakfast				
Within-Subject CV (%)				
IDegAsp OD	366	366	35.08	
IDet	182	181	38.35	
Treatment Ratio				
IDegAsp OD / IDet			0.91	[0.83; 1.00]

N: Number of subjects contributing to analysis

CI: Confidence Interval

CV: Coefficient of Variation

Log-transformed self measured plasma glucose values after 26 treatment weeks are analysed as repeated measures in a mixed linear model with treatment, anti-diabetic treatment at screening, region and sex as fixed effects, age as covariate and subject as random effect. The model assumes independent within and between subject variances with variances depending on treatment. In case all SMPG values are missing then last observation carried forward will be used to impute missing values. The NLmixed procedure in SAS is applied.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:17 - t_stat_within_smpg_var.sas/t_smpg_within_var_stat_locf_fas.txt

14.2.135: Before Breakfast Titration Target (SMPG < 5 mmol/L) by Treatment Week – Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
SMPG <5.0 mmol/L (Breakfast)			
Visit 2 (Week 0)			
N	365 (100.0)	181 (100.0)	546 (100.0)
Yes	26 (7.1)	11 (6.1)	37 (6.8)
No	339 (92.9)	170 (93.9)	509 (93.2)
Visit 3 (Week 1)			
N	360 (100.0)	176 (100.0)	536 (100.0)
Yes	32 (8.9)	16 (9.1)	48 (9.0)
No	328 (91.1)	160 (90.9)	488 (91.0)
Visit 4 (Week 2)			
N	359 (100.0)	176 (100.0)	535 (100.0)
Yes	31 (8.6)	14 (8.0)	45 (8.4)
No	328 (91.4)	162 (92.0)	490 (91.6)
Visit 5 (Week 3)			
N	346 (100.0)	174 (100.0)	520 (100.0)
Yes	37 (10.7)	21 (12.1)	58 (11.2)
No	309 (89.3)	153 (87.9)	462 (88.8)
Visit 6 (Week 4)			
N	351 (100.0)	174 (100.0)	525 (100.0)
Yes	51 (14.5)	19 (10.9)	70 (13.3)
No	300 (85.5)	155 (89.1)	455 (86.7)
Visit 7 (Week 5)			
N	349 (100.0)	173 (100.0)	522 (100.0)
Yes	55 (15.8)	17 (9.8)	72 (13.8)
No	294 (84.2)	156 (90.2)	450 (86.2)
Visit 8 (Week 6)			
N	344 (100.0)	174 (100.0)	518 (100.0)
Yes	44 (12.8)	17 (9.8)	61 (11.8)
No	300 (87.2)	157 (90.2)	457 (88.2)
Visit 9 (Week 7)			
N	343 (100.0)	170 (100.0)	513 (100.0)
Yes	52 (15.2)	27 (15.9)	79 (15.4)
No	291 (84.8)	143 (84.1)	434 (84.6)
Visit 10 (Week 8)			
N	339 (100.0)	171 (100.0)	510 (100.0)
Yes	52 (15.3)	24 (14.0)	76 (14.9)
No	287 (84.7)	147 (86.0)	434 (85.1)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:26 - tsum_catgofind_tpl_t025_v01.sas/t_titrat_targ_bf_sum_fas.txt

Before Breakfast Titration Target (SMPG < 5 mmol/L) by Treatment Week - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SMPG <5.0 mmol/L (Breakfast)			
Visit 11 (Week 9)			
N	335 (100.0)	165 (100.0)	500 (100.0)
Yes	60 (17.9)	19 (11.5)	79 (15.8)
No	275 (82.1)	146 (88.5)	421 (84.2)
Visit 12 (Week 10)			
N	338 (100.0)	168 (100.0)	506 (100.0)
Yes	51 (15.1)	28 (16.7)	79 (15.6)
No	287 (84.9)	140 (83.3)	427 (84.4)
Visit 13 (Week 11)			
N	334 (100.0)	165 (100.0)	499 (100.0)
Yes	55 (16.5)	16 (9.7)	71 (14.2)
No	279 (83.5)	149 (90.3)	428 (85.8)
Visit 14 (Week 12)			
N	335 (100.0)	168 (100.0)	503 (100.0)
Yes	53 (15.8)	15 (8.9)	68 (13.5)
No	282 (84.2)	153 (91.1)	435 (86.5)
Visit 15 (Week 13)			
N	324 (100.0)	161 (100.0)	485 (100.0)
Yes	53 (16.4)	18 (11.2)	71 (14.6)
No	271 (83.6)	143 (88.8)	414 (85.4)
Visit 16 (Week 14)			
N	332 (100.0)	166 (100.0)	498 (100.0)
Yes	48 (14.5)	26 (15.7)	74 (14.9)
No	284 (85.5)	140 (84.3)	424 (85.1)
Visit 17 (Week 15)			
N	328 (100.0)	163 (100.0)	491 (100.0)
Yes	60 (18.3)	21 (12.9)	81 (16.5)
No	268 (81.7)	142 (87.1)	410 (83.5)
Visit 18 (Week 16)			
N	329 (100.0)	163 (100.0)	492 (100.0)
Yes	55 (16.7)	29 (17.8)	84 (17.1)
No	274 (83.3)	134 (82.2)	408 (82.9)
Visit 19 (Week 17)			
N	324 (100.0)	161 (100.0)	485 (100.0)
Yes	48 (14.8)	20 (12.4)	68 (14.0)
No	276 (85.2)	141 (87.6)	417 (86.0)
Visit 20 (Week 18)			
N	321 (100.0)	158 (100.0)	479 (100.0)
Yes	63 (19.6)	27 (17.1)	90 (18.8)
No	258 (80.4)	131 (82.9)	389 (81.2)

N = Number of Subjects

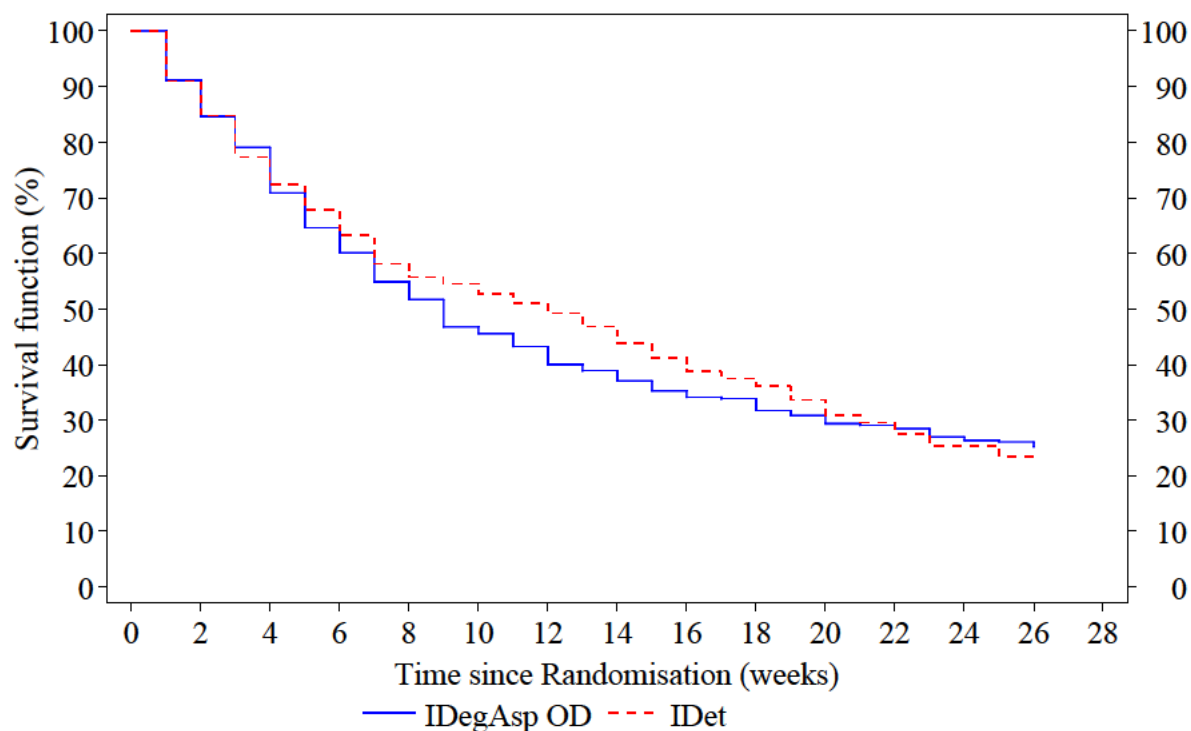
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:26 - tsum_catgofind_tpl_t025_v01.sas/t_titrat_targ_bf_sum_fas.txt

Before Breakfast Titration Target (SMPG < 5 mmol/L) by Treatment Week - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SMPG <5.0 mmol/L (Breakfast)			
Visit 21 (Week 19)			
N	321 (100.0)	161 (100.0)	482 (100.0)
Yes	66 (20.6)	30 (18.6)	96 (19.9)
No	255 (79.4)	131 (81.4)	386 (80.1)
Visit 22 (Week 20)			
N	324 (100.0)	158 (100.0)	482 (100.0)
Yes	58 (17.9)	26 (16.5)	84 (17.4)
No	266 (82.1)	132 (83.5)	398 (82.6)
Visit 23 (Week 21)			
N	322 (100.0)	156 (100.0)	478 (100.0)
Yes	60 (18.6)	31 (19.9)	91 (19.0)
No	262 (81.4)	125 (80.1)	387 (81.0)
Visit 24 (Week 22)			
N	319 (100.0)	156 (100.0)	475 (100.0)
Yes	65 (20.4)	34 (21.8)	99 (20.8)
No	254 (79.6)	122 (78.2)	376 (79.2)
Visit 25 (Week 23)			
N	320 (100.0)	151 (100.0)	471 (100.0)
Yes	57 (17.8)	29 (19.2)	86 (18.3)
No	263 (82.2)	122 (80.8)	385 (81.7)
Visit 26 (Week 24)			
N	319 (100.0)	158 (100.0)	477 (100.0)
Yes	67 (21.0)	31 (19.6)	98 (20.5)
No	252 (79.0)	127 (80.4)	379 (79.5)
Visit 27 (Week 25)			
N	318 (100.0)	155 (100.0)	473 (100.0)
Yes	62 (19.5)	37 (23.9)	99 (20.9)
No	256 (80.5)	118 (76.1)	374 (79.1)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Yes	56 (17.5)	29 (18.5)	85 (17.8)
No	264 (82.5)	128 (81.5)	392 (82.2)
Visit 28 (Week 26) (LOCF)			
N	366 (100.0)	181 (100.0)	547 (100.0)
Yes	62 (16.9)	29 (16.0)	91 (16.6)
No	304 (83.1)	152 (84.0)	456 (83.4)
Visit 29 (Week 27)			
N	326 (100.0)	154 (100.0)	480 (100.0)
Yes	26 (8.0)	10 (6.5)	36 (7.5)
No	300 (92.0)	144 (93.5)	444 (92.5)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:26 - tsum_catgofind_tpl_t025_v01.sas/t_titrat_targ_bf_sum_fas.txt



FAS; Observed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:36 - fsurv_km_v01.sas/e_titrat_targ_bf_time_surv_fas.cgm

14.2.136: Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set

14.2.137: Time to Titration Target is Met for the First Time (Treatment Week) – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Number of Subjects	366	182
Time to SMPG<5.0 mmol/L (Breakfast) (Week)		
25% percentile	4.0	4.0
Median	9.0	12.0
75% percentile		25.0

25%, median (50%) and 75% percentiles for the cumulative distribution function are obtained from the Kaplan-Meier survival function.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:42 - tdesc_surv_tpl_t023_v01.sas/t_titrat_targ_time_descp_fas.txt

14.2.138: Time to Titration Target is Met for the First Time (Treatment Week) - Statistical Analysis - Full Analysis Set

	Estimate	95% CI
Time to SMPG <5.0 mmol/L (Breakfast)		
Hazard Ratio IDegAsp OD / IDet	1.05	[0.85 ; 1.30]

Time to event is analysed using Cox Proportional Hazards model with treatment, anti-diabetic treatment at screening, region and sex as fixed effects, and age as covariate.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:20 - stat_time_to_treat_week.sas/t_titrat_targ_time_stat_locf_fas.txt

14.2.139: Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Number of Subjects	366	182
Physical Score()		
Visit 2 (Week 0)		
N	365	181
Mean (SD)	50.9 (7.7)	50.3 (7.9)
Median	52.4	52.1
Min ; Max	13.2 ; 63.7	19.9 ; 65.3
Visit 14 (Week 12)		
N	337	168
Mean (SD)	51.3 (7.1)	50.5 (7.7)
Median	53.1	52.4
Min ; Max	17.7 ; 64.1	22.1 ; 61.5
Visit 28 (Week 26)		
N	316	157
Mean (SD)	51.3 (7.1)	50.6 (7.7)
Median	53.1	52.5
Min ; Max	25.7 ; 65.8	18.4 ; 62.8
Visit 28 (Week 26) (LOCF)		
N	366	181
Mean (SD)	51.0 (7.5)	50.1 (7.8)
Median	53.0	52.1
Min ; Max	17.7 ; 65.8	18.4 ; 62.8

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:48 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_abs_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health -
 Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Physical Functioning()		
Visit 2 (Week 0)		
N	363	180
Mean (SD)	51.7 (7.4)	51.2 (8.4)
Median	54.9	54.9
Min ; Max	23.4 ; 57.0	23.4 ; 57.0
Visit 14 (Week 12)		
N	333	165
Mean (SD)	51.9 (7.3)	51.5 (8.1)
Median	54.9	54.9
Min ; Max	17.0 ; 57.0	19.2 ; 57.0
Visit 28 (Week 26)		
N	312	156
Mean (SD)	51.9 (7.2)	51.2 (7.9)
Median	54.9	54.9
Min ; Max	14.9 ; 57.0	19.2 ; 57.0
Visit 28 (Week 26) (LOCF)		
N	366	181
Mean (SD)	51.7 (7.5)	50.8 (8.4)
Median	54.9	54.9
Min ; Max	14.9 ; 57.0	19.2 ; 57.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:54:48 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_abs_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Role-Physical()		
Visit 2 (Week 0)		
N	361	179
Mean (SD)	50.5 (8.0)	50.3 (8.3)
Median	54.4	54.4
Min ; Max	22.6 ; 56.9	25.0 ; 56.9
Visit 14 (Week 12)		
N	334	168
Mean (SD)	50.7 (7.2)	50.1 (7.7)
Median	54.4	52.0
Min ; Max	17.7 ; 56.9	20.1 ; 56.9
Visit 28 (Week 26)		
N	313	155
Mean (SD)	50.8 (7.0)	50.1 (8.2)
Median	54.4	54.4
Min ; Max	22.6 ; 56.9	17.7 ; 56.9
Visit 28 (Week 26) (LOCF)		
N	366	181
Mean (SD)	50.3 (7.3)	49.6 (8.5)
Median	52.0	54.4
Min ; Max	22.6 ; 56.9	17.7 ; 56.9

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:48 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_abs_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Bodily Pain()		
Visit 2 (Week 0)		
N	362	180
Mean (SD)	52.2 (10.2)	51.6 (10.2)
Median	55.4	55.4
Min ; Max	19.9 ; 62.1	24.1 ; 62.1
Visit 14 (Week 12)		
N	334	166
Mean (SD)	53.1 (9.9)	52.4 (9.9)
Median	55.4	55.4
Min ; Max	19.9 ; 62.1	24.1 ; 62.1
Visit 28 (Week 26)		
N	314	157
Mean (SD)	52.9 (10.0)	52.7 (10.2)
Median	55.4	55.4
Min ; Max	19.9 ; 62.1	24.1 ; 62.1
Visit 28 (Week 26) (LOCF)		
N	366	181
Mean (SD)	52.3 (10.4)	52.0 (10.4)
Median	55.4	55.4
Min ; Max	19.9 ; 62.1	24.1 ; 62.1

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:48 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_abs_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
General Health()		
Visit 2 (Week 0)		
N	364	181
Mean (SD)	45.2 (9.7)	45.9 (9.7)
Median	45.8	46.0
Min ; Max	18.6 ; 63.9	21.0 ; 63.9
Visit 14 (Week 12)		
N	333	166
Mean (SD)	45.5 (9.5)	45.6 (9.4)
Median	45.8	45.8
Min ; Max	18.6 ; 63.9	18.6 ; 63.9
Visit 28 (Week 26)		
N	313	154
Mean (SD)	46.2 (9.5)	45.9 (10.6)
Median	45.8	46.5
Min ; Max	18.6 ; 63.9	18.6 ; 63.9
Visit 28 (Week 26) (LOCF)		
N	366	181
Mean (SD)	45.7 (9.6)	45.3 (10.4)
Median	45.8	45.8
Min ; Max	18.6 ; 63.9	18.6 ; 63.9

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:48 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_abs_descp_fas.txt

14.2.140: Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Number of Subjects	366	182
Mental Score()		
Visit 2 (Week 0)		
N	365	181
Mean (SD)	49.1 (10.0)	49.9 (9.0)
Median	52.0	51.6
Min ; Max	12.9 ; 68.6	20.4 ; 63.9
Visit 14 (Week 12)		
N	337	168
Mean (SD)	49.2 (9.9)	49.7 (9.1)
Median	52.1	51.6
Min ; Max	4.6 ; 65.4	17.7 ; 66.4
Visit 28 (Week 26)		
N	316	157
Mean (SD)	49.6 (9.3)	49.9 (10.5)
Median	51.5	53.2
Min ; Max	8.9 ; 71.2	11.0 ; 65.5
Visit 28 (Week 26) (LOCF)		
N	366	181
Mean (SD)	48.9 (9.9)	49.3 (10.5)
Median	51.3	51.9
Min ; Max	8.9 ; 71.2	11.0 ; 65.5

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:55 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_abs_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Vitality()		
Visit 2 (Week 0)		
N	361	181
Mean (SD)	52.4 (9.2)	52.3 (9.5)
Median	55.2	52.1
Min ; Max	20.9 ; 70.8	20.9 ; 70.8
Visit 14 (Week 12)		
N	334	164
Mean (SD)	52.4 (8.8)	51.9 (9.9)
Median	55.2	52.1
Min ; Max	20.9 ; 70.8	20.9 ; 70.8
Visit 28 (Week 26)		
N	313	156
Mean (SD)	52.5 (9.1)	52.4 (10.4)
Median	55.2	53.1
Min ; Max	20.9 ; 70.8	20.9 ; 70.8
Visit 28 (Week 26) (LOCF)		
N	366	181
Mean (SD)	51.7 (9.4)	51.5 (10.5)
Median	53.1	52.1
Min ; Max	20.9 ; 70.8	20.9 ; 70.8

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:55 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_abs_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Social Functioning()		
Visit 2 (Week 0)		
N	363	181
Mean (SD)	50.1 (9.0)	50.6 (8.6)
Median	56.8	56.8
Min ; Max	18.7 ; 56.8	18.7 ; 56.8
Visit 14 (Week 12)		
N	337	167
Mean (SD)	50.3 (8.9)	50.2 (7.9)
Median	56.8	51.4
Min ; Max	13.2 ; 56.8	18.7 ; 56.8
Visit 28 (Week 26)		
N	316	157
Mean (SD)	50.7 (8.0)	50.2 (9.0)
Median	56.8	56.8
Min ; Max	13.2 ; 56.8	13.2 ; 56.8
Visit 28 (Week 26) (LOCF)		
N	365	181
Mean (SD)	49.9 (8.7)	49.9 (9.1)
Median	51.4	56.8
Min ; Max	13.2 ; 56.8	13.2 ; 56.8

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:55 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_abs_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Role-Emotional()		
Visit 2 (Week 0)		
N	359	178
Mean (SD)	48.8 (9.8)	49.0 (9.1)
Median	55.9	52.0
Min ; Max	9.2 ; 55.9	20.9 ; 55.9
Visit 14 (Week 12)		
N	333	167
Mean (SD)	49.5 (8.9)	49.5 (9.1)
Median	55.9	55.9
Min ; Max	9.2 ; 55.9	9.2 ; 55.9
Visit 28 (Week 26)		
N	314	156
Mean (SD)	49.7 (8.8)	49.4 (9.4)
Median	55.9	55.9
Min ; Max	9.2 ; 55.9	9.2 ; 55.9
Visit 28 (Week 26) (LOCF)		
N	365	181
Mean (SD)	49.1 (9.2)	49.1 (9.3)
Median	52.0	55.9
Min ; Max	9.2 ; 55.9	9.2 ; 55.9

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:55 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_abs_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Mental Health()		
Visit 2 (Week 0)		
N	361	181
Mean (SD)	49.2 (10.1)	50.1 (8.9)
Median	52.8	50.0
Min ; Max	16.2 ; 64.1	19.0 ; 64.1
Visit 14 (Week 12)		
N	334	164
Mean (SD)	49.0 (10.1)	49.8 (9.3)
Median	50.0	50.0
Min ; Max	7.8 ; 64.1	19.0 ; 64.1
Visit 28 (Week 26)		
N	313	156
Mean (SD)	49.6 (9.5)	50.0 (10.3)
Median	50.0	52.8
Min ; Max	10.6 ; 64.1	13.4 ; 64.1
Visit 28 (Week 26) (LOCF)		
N	366	181
Mean (SD)	48.8 (10.0)	49.2 (10.5)
Median	50.0	52.8
Min ; Max	7.8 ; 64.1	13.4 ; 64.1

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:54:55 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_abs_descp_fas.txt

14.2.141: Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Number of Subjects	366	182
Physical Score ch()		
Visit 14 (Week 12)		
N	336	168
Mean (SD)	0.2 (6.2)	0.0 (5.9)
Median	0.1	0.0
Min ; Max	-32.8 ; 32.0	-20.6 ; 15.5
Visit 28 (Week 26)		
N	315	157
Mean (SD)	0.1 (5.7)	-0.1 (5.0)
Median	-0.3	-0.0
Min ; Max	-20.8 ; 21.5	-11.3 ; 17.7
Visit 28 (Week 26) (LOCF)		
N	365	181
Mean (SD)	0.1 (5.9)	-0.3 (4.9)
Median	-0.1	-0.0
Min ; Max	-20.8 ; 32.0	-12.1 ; 17.7

N = Number of Subjects, SD = Standard Deviation
 ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:55:02 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_chb_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health -
 Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Phys Functioning ch()		
Visit 14 (Week 12)		
N	330	164
Mean (SD)	0.2 (5.9)	0.2 (5.7)
Median	0.0	0.0
Min ; Max	-40.0 ; 31.6	-23.1 ; 29.5
Visit 28 (Week 26)		
N	309	156
Mean (SD)	-0.1 (6.2)	-0.3 (4.9)
Median	0.0	0.0
Min ; Max	-42.1 ; 21.0	-21.0 ; 16.8
Visit 28 (Week 26) (LOCF)		
N	363	180
Mean (SD)	0.0 (6.2)	-0.5 (5.0)
Median	0.0	0.0
Min ; Max	-42.1 ; 31.6	-23.1 ; 16.8

N = Number of Subjects, SD = Standard Deviation
 ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:55:02 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_chb_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health -
Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Role-Physical ch()		
Visit 14 (Week 12)		
N	330	166
Mean (SD)	-0.2 (6.7)	-0.5 (6.7)
Median	0.0	0.0
Min ; Max	-34.3 ; 29.4	-29.4 ; 19.6
Visit 28 (Week 26)		
N	308	153
Mean (SD)	-0.2 (6.3)	-0.4 (7.7)
Median	0.0	0.0
Min ; Max	-19.6 ; 29.4	-36.7 ; 17.1
Visit 28 (Week 26) (LOCF)		
N	361	179
Mean (SD)	-0.2 (6.5)	-0.7 (7.4)
Median	0.0	0.0
Min ; Max	-26.9 ; 29.4	-36.7 ; 17.1

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:02 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_chb_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health -
Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Bodily Pain ch()		
Visit 14 (Week 12)		
N	330	165
Mean (SD)	0.6 (9.6)	0.7 (9.4)
Median	0.0	0.0
Min ; Max	-42.3 ; 42.3	-24.9 ; 33.4
Visit 28 (Week 26)		
N	310	157
Mean (SD)	0.2 (9.0)	0.4 (9.1)
Median	0.0	0.0
Min ; Max	-26.2 ; 29.2	-29.2 ; 33.4
Visit 28 (Week 26) (LOCF)		
N	362	180
Mean (SD)	0.2 (9.3)	0.4 (9.0)
Median	0.0	0.0
Min ; Max	-33.0 ; 42.3	-29.2 ; 33.4

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:02 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_chb_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Physical Health -
Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
General Health ch()		
Visit 14 (Week 12)		
N	331	166
Mean (SD)	0.2 (6.7)	-0.2 (6.0)
Median	0.0	0.0
Min ; Max	-19.1 ; 23.8	-17.6 ; 14.3
Visit 28 (Week 26)		
N	311	154
Mean (SD)	0.8 (7.3)	-0.1 (6.3)
Median	0.0	0.0
Min ; Max	-26.2 ; 22.4	-22.4 ; 16.9
Visit 28 (Week 26) (LOCF)		
N	364	181
Mean (SD)	0.4 (7.1)	-0.6 (6.2)
Median	0.0	0.0
Min ; Max	-26.2 ; 22.4	-22.4 ; 16.9

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:02 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_ph_chb_descp_fas.txt

14.2.142: Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Number of Subjects	366	182
Mental Score ch()		
Visit 14 (Week 12)		
N	336	168
Mean (SD)	-0.3 (8.0)	-0.4 (8.0)
Median	0.1	0.3
Min ; Max	-49.7 ; 30.8	-38.3 ; 26.0
Visit 28 (Week 26)		
N	315	157
Mean (SD)	0.2 (9.3)	-0.4 (9.3)
Median	-0.1	0.1
Min ; Max	-25.9 ; 40.2	-45.0 ; 33.2
Visit 28 (Week 26) (LOCF)		
N	365	181
Mean (SD)	-0.2 (9.3)	-0.6 (9.0)
Median	-0.1	0.0
Min ; Max	-26.7 ; 40.2	-45.0 ; 33.2

N = Number of Subjects, SD = Standard Deviation
 ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:55:08 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_chb_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Vitality ch()		
Visit 14 (Week 12)		
N	330	164
Mean (SD)	-0.3 (7.7)	-0.4 (7.7)
Median	0.0	0.0
Min ; Max	-37.5 ; 28.1	-34.3 ; 21.9
Visit 28 (Week 26)		
N	308	156
Mean (SD)	-0.4 (8.1)	-0.4 (7.7)
Median	0.0	0.0
Min ; Max	-25.0 ; 31.2	-34.3 ; 31.2
Visit 28 (Week 26) (LOCF)		
N	361	181
Mean (SD)	-0.6 (8.0)	-0.8 (7.8)
Median	0.0	0.0
Min ; Max	-25.0 ; 31.2	-34.3 ; 31.2

N = Number of Subjects, SD = Standard Deviation
 ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:55:08 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_chb_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Social Funct. ch()		
Visit 14 (Week 12)		
N	335	167
Mean (SD)	-0.1 (8.2)	-0.5 (7.4)
Median	0.0	0.0
Min ; Max	-43.6 ; 27.3	-21.8 ; 21.8
Visit 28 (Week 26)		
N	314	157
Mean (SD)	0.2 (8.4)	-0.7 (9.7)
Median	0.0	0.0
Min ; Max	-32.7 ; 32.7	-43.6 ; 32.7
Visit 28 (Week 26) (LOCF)		
N	363	181
Mean (SD)	-0.2 (8.7)	-0.7 (9.3)
Median	0.0	0.0
Min ; Max	-32.7 ; 32.7	-43.6 ; 32.7

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:08 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_chb_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Role-Emotional ch()		
Visit 14 (Week 12)		
N	328	164
Mean (SD)	0.2 (7.4)	0.3 (9.1)
Median	0.0	0.0
Min ; Max	-31.1 ; 27.2	-46.6 ; 27.2
Visit 28 (Week 26)		
N	308	153
Mean (SD)	0.4 (9.1)	0.3 (9.4)
Median	0.0	0.0
Min ; Max	-27.2 ; 35.0	-46.6 ; 27.2
Visit 28 (Week 26) (LOCF)		
N	359	178
Mean (SD)	0.4 (8.9)	0.1 (9.1)
Median	0.0	0.0
Min ; Max	-27.2 ; 35.0	-46.6 ; 27.2

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:08 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_chb_descp_fas.txt

Health Related Quality of Life (SF-36) Scores by Treatment Week - Mental Health - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Mental Health ch()		
Visit 14 (Week 12)		
N	330	164
Mean (SD)	-0.4 (7.9)	-0.3 (7.3)
Median	0.0	0.0
Min ; Max	-36.6 ; 31.0	-22.5 ; 22.5
Visit 28 (Week 26)		
N	308	156
Mean (SD)	0.4 (9.4)	-0.7 (7.9)
Median	0.0	0.0
Min ; Max	-25.3 ; 41.3	-28.2 ; 25.3
Visit 28 (Week 26) (LOCF)		
N	361	181
Mean (SD)	-0.3 (9.4)	-0.9 (7.7)
Median	0.0	0.0
Min ; Max	-25.3 ; 41.3	-28.2 ; 25.3

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:08 - tdesc_numfind_tpl_t019_v01.sas/t_sf36_mh_chb_descp_fas.txt

14.2.143: Health Related Quality of Life (SF-36) Scores after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Physical Score					
LSMeans					
IDegAsp OD	366	365	50.3	0.4	
IDet	182	181	50.0	0.5	
Change from Baseline					
LSMeans					
IDegAsp OD	366	365	-0.4	0.4	
IDet	182	181	-0.7	0.5	
Treatment Contrast					
IDegAsp OD - IDet			0.3		[-0.6 ; 1.3]
Mental Score					
LSMeans					
IDegAsp OD	366	365	49.3	0.7	
IDet	182	181	49.5	0.8	
Change from Baseline					
LSMeans					
IDegAsp OD	366	365	-0.0	0.7	
IDet	182	181	0.1	0.8	
Treatment Contrast					
IDegAsp OD - IDet			-0.1		[-1.6 ; 1.3]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates. Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:15 - tstat_find_tpl_t022.sas/t_sf36_stat_locf_fas.txt

14.2.144: Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Overall Score()			
Visit 2 (Week 0)			
N	362	181	543
Mean (SD)	69.8 (13.4)	69.4 (13.3)	69.7 (13.4)
Median	71.3	69.9	70.8
Min ; Max	24.3 ; 96.4	23.2 ; 98.9	23.2 ; 98.9
Visit 14 (Week 12)			
N	332	166	498
Mean (SD)	71.5 (12.5)	72.1 (13.0)	71.7 (12.7)
Median	73.5	73.3	73.4
Min ; Max	24.2 ; 97.8	39.0 ; 97.8	24.2 ; 97.8
Visit 28 (Week 26)			
N	315	155	470
Mean (SD)	72.2 (12.5)	71.8 (14.6)	72.1 (13.2)
Median	73.5	75.1	74.1
Min ; Max	28.2 ; 100.0	18.5 ; 97.3	18.5 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	366	181	547
Mean (SD)	71.0 (13.1)	70.2 (15.2)	70.7 (13.8)
Median	72.1	72.2	72.2
Min ; Max	28.2 ; 100.0	18.5 ; 97.3	18.5 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:21 - tdesc_numfind_tpl_t019_v01.sas/t_diabmedsat_abs_descp_fas.txt

Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Burden()			
Visit 2 (Week 0)			
N	358	179	537
Mean (SD)	78.1 (15.6)	77.6 (14.6)	77.9 (15.3)
Median	81.1	79.5	80.3
Min ; Max	15.9 ; 100.0	28.8 ; 100.0	15.9 ; 100.0
Visit 14 (Week 12)			
N	323	164	487
Mean (SD)	79.9 (14.0)	79.1 (14.2)	79.6 (14.1)
Median	81.1	81.4	81.1
Min ; Max	36.4 ; 100.0	35.6 ; 100.0	35.6 ; 100.0
Visit 28 (Week 26)			
N	310	151	461
Mean (SD)	80.3 (14.2)	80.4 (14.9)	80.3 (14.4)
Median	82.6	84.8	83.3
Min ; Max	20.5 ; 100.0	34.8 ; 100.0	20.5 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	366	181	547
Mean (SD)	79.4 (14.9)	78.3 (16.1)	79.0 (15.3)
Median	81.4	80.3	81.1
Min ; Max	20.5 ; 100.0	28.8 ; 100.0	20.5 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:55:21 - tdesc_numfind_tpl_t019_v01.sas/t_diabmedsat_abs_descp_fas.txt

Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Efficacy()			
Visit 2 (Week 0)			
N	350	180	530
Mean (SD)	58.8 (19.3)	58.3 (19.0)	58.6 (19.2)
Median	60.0	56.7	58.3
Min ; Max	0.0 ; 100.0	8.3 ; 100.0	0.0 ; 100.0
Visit 14 (Week 12)			
N	330	165	495
Mean (SD)	66.0 (17.7)	65.9 (18.9)	66.0 (18.1)
Median	66.7	66.7	66.7
Min ; Max	13.3 ; 100.0	13.3 ; 100.0	13.3 ; 100.0
Visit 28 (Week 26)			
N	311	153	464
Mean (SD)	67.9 (17.2)	66.4 (19.8)	67.4 (18.1)
Median	68.3	68.3	68.3
Min ; Max	0.0 ; 100.0	15.0 ; 100.0	0.0 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	366	180	546
Mean (SD)	65.4 (19.0)	64.4 (20.8)	65.1 (19.6)
Median	66.7	68.3	66.7
Min ; Max	0.0 ; 100.0	15.0 ; 100.0	0.0 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:21 - tdesc_numfind_tpl_t019_v01.sas/t_diabmedsat_abs_descp_fas.txt

Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Symptoms ()			
Visit 2 (Week 0)			
N	355	178	533
Mean (SD)	72.2 (16.0)	72.4 (15.9)	72.3 (15.9)
Median	72.0	72.0	72.0
Min ; Max	0.0 ; 100.0	15.0 ; 100.0	0.0 ; 100.0
Visit 14 (Week 12)			
N	332	161	493
Mean (SD)	69.1 (15.3)	71.2 (16.0)	69.8 (15.6)
Median	72.0	72.0	72.0
Min ; Max	0.0 ; 100.0	24.0 ; 100.0	0.0 ; 100.0
Visit 28 (Week 26)			
N	313	153	466
Mean (SD)	68.4 (15.2)	69.3 (16.9)	68.7 (15.7)
Median	72.0	72.0	72.0
Min ; Max	4.0 ; 100.0	12.0 ; 100.0	4.0 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	366	180	546
Mean (SD)	68.1 (15.3)	69.0 (17.1)	68.4 (15.9)
Median	72.0	72.0	72.0
Min ; Max	4.0 ; 100.0	12.0 ; 100.0	4.0 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:21 - tdesc_numfind_tpl_t019_v01.sas/t_diabmedsat_abs_descp_fas.txt

14.2.145: Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Number of Subjects	366	182
Overall Score ch()		
Visit 14 (Week 12)		
N	328	166
Mean (SD)	1.3 (12.2)	2.3 (10.6)
Median	1.2	1.9
Min ; Max	-43.2 ; 44.0	-19.9 ; 40.2
Visit 28 (Week 26)		
N	311	155
Mean (SD)	1.9 (12.5)	1.6 (12.7)
Median	1.3	1.7
Min ; Max	-35.5 ; 44.6	-39.4 ; 40.0
Visit 28 (Week 26) (LOCF)		
N	362	181
Mean (SD)	1.0 (12.5)	0.8 (12.6)
Median	0.2	0.3
Min ; Max	-35.5 ; 44.6	-39.4 ; 40.0

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:27 - tdesc_numfind_tpl_t019_v01.sas/t_diabmedsat_chb_descp_fas.txt

Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Burden ch()		
Visit 14 (Week 12)		
N	316	162
Mean (SD)	1.5 (13.0)	0.7 (13.4)
Median	0.8	0.4
Min ; Max	-40.2 ; 51.5	-32.0 ; 34.8
Visit 28 (Week 26)		
N	302	149
Mean (SD)	1.6 (13.8)	1.2 (12.8)
Median	2.3	0.8
Min ; Max	-43.9 ; 49.2	-37.9 ; 40.9
Visit 28 (Week 26) (LOCF)		
N	358	179
Mean (SD)	1.2 (13.6)	0.6 (13.1)
Median	0.8	0.0
Min ; Max	-43.9 ; 49.2	-50.0 ; 40.9

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:27 - tdesc_numfind_tpl_t019_v01.sas/t_diabmedsat_chb_descp_fas.txt

Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Efficacy ch()		
Visit 14 (Week 12)		
N	315	165
Mean (SD)	6.6 (21.2)	7.3 (19.2)
Median	5.0	6.7
Min ; Max	-73.3 ; 71.7	-36.7 ; 73.3
Visit 28 (Week 26)		
N	297	153
Mean (SD)	8.2 (19.6)	8.0 (20.8)
Median	8.3	5.0
Min ; Max	-61.7 ; 71.7	-63.3 ; 76.7
Visit 28 (Week 26) (LOCF)		
N	350	180
Mean (SD)	6.6 (20.0)	6.0 (21.6)
Median	6.7	3.3
Min ; Max	-61.7 ; 71.7	-63.3 ; 76.7

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:27 - tdesc_numfind_tpl_t019_v01.sas/t_diabmedsat_chb_descp_fas.txt

Diabetes Medication Satisfaction (DiabMedSat) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Symptoms ch()		
Visit 14 (Week 12)		
N	321	159
Mean (SD)	-3.3 (15.4)	-1.2 (14.1)
Median	-4.0	0.0
Min ; Max	-44.0 ; 48.0	-36.0 ; 37.0
Visit 28 (Week 26)		
N	303	152
Mean (SD)	-4.2 (16.3)	-3.7 (15.1)
Median	-4.0	0.0
Min ; Max	-64.0 ; 52.0	-48.0 ; 28.0
Visit 28 (Week 26) (LOCF)		
N	355	178
Mean (SD)	-4.3 (15.8)	-3.2 (14.9)
Median	-4.0	0.0
Min ; Max	-64.0 ; 52.0	-48.0 ; 37.0

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:27 - tdesc_numfind_tpl_t019_v01.sas/t_diabmedsat_chb_descp_fas.txt

14.2.146: Diabetes Medication Satisfaction (DiabMedSat) Scores after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Overall Score					
LSMeans					
IDegAsp OD	366	362	70.1	1.0	
IDet	182	181	70.1	1.2	
Change from Baseline					
LSMeans					
IDegAsp OD	366	362	0.5	1.0	
IDet	182	181	0.4	1.2	
Treatment Contrast					
IDegAsp OD - IDet			0.1		[-2.0 ; 2.1]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates. Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:34 - tstat_find_tpl_t022.sas/t_diabmedsat_stat_locf_fas.txt

14.2.147: Diabetes Productivity Measure (DPM) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Life Productivity()			
Visit 2 (Week 0)			
N	356	181	537
Mean (SD)	72.1 (17.8)	72.2 (20.0)	72.1 (18.6)
Median	75.0	75.0	75.0
Min ; Max	19.4 ; 100.0	16.7 ; 100.0	16.7 ; 100.0
Visit 14 (Week 12)			
N	326	165	491
Mean (SD)	74.8 (17.0)	74.1 (19.1)	74.6 (17.7)
Median	76.4	77.8	77.8
Min ; Max	25.0 ; 100.0	5.6 ; 100.0	5.6 ; 100.0
Visit 28 (Week 26)			
N	313	152	465
Mean (SD)	75.2 (18.1)	74.2 (19.3)	74.9 (18.5)
Median	77.8	76.4	77.8
Min ; Max	19.4 ; 100.0	19.4 ; 100.0	19.4 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	366	181	547
Mean (SD)	73.8 (18.4)	73.2 (19.9)	73.6 (18.9)
Median	75.0	75.0	75.0
Min ; Max	19.4 ; 100.0	19.4 ; 100.0	19.4 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:40 - tdesc_numfind_tpl_t019_v01.sas/t_dpm_abs_descp_fas.txt

Diabetes Productivity Measure (DPM) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Work Productivity()			
Visit 2 (Week 0)			
N	299	147	446
Mean (SD)	82.3 (15.5)	85.4 (14.9)	83.4 (15.3)
Median	85.0	90.0	85.0
Min ; Max	15.0 ; 100.0	25.0 ; 100.0	15.0 ; 100.0
Visit 14 (Week 12)			
N	265	133	398
Mean (SD)	84.9 (13.9)	86.9 (13.0)	85.6 (13.6)
Median	90.0	90.0	90.0
Min ; Max	30.0 ; 100.0	50.0 ; 100.0	30.0 ; 100.0
Visit 28 (Week 26)			
N	246	121	367
Mean (SD)	85.5 (14.0)	83.5 (16.2)	84.8 (14.7)
Median	90.0	85.0	90.0
Min ; Max	30.0 ; 100.0	37.5 ; 100.0	30.0 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	319	155	474
Mean (SD)	84.4 (14.6)	83.6 (17.1)	84.1 (15.5)
Median	85.0	90.0	88.8
Min ; Max	30.0 ; 100.0	25.0 ; 100.0	25.0 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:55:40 - tdesc_numfind_tpl_t019_v01.sas/t_dpm_abs_descp_fas.txt

14.2.148: Diabetes Productivity Measure (DPM) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Number of Subjects	366	182
Life Productivity ch()		
Visit 14 (Week 12)		
N	316	165
Mean (SD)	1.8 (13.5)	1.9 (13.5)
Median	0.0	0.0
Min ; Max	-38.9 ; 52.8	-38.9 ; 52.8
Visit 28 (Week 26)		
N	305	152
Mean (SD)	2.4 (14.4)	1.3 (13.4)
Median	0.0	0.0
Min ; Max	-36.1 ; 66.7	-38.9 ; 38.9
Visit 28 (Week 26) (LOCF)		
N	356	181
Mean (SD)	1.6 (14.1)	1.0 (14.0)
Median	0.0	0.0
Min ; Max	-36.1 ; 66.7	-55.6 ; 38.9

N = Number of Subjects, SD = Standard Deviation
 ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:55:47 - tdesc_numfind_tpl_t019_v01.sas/t_dpm_chb_descp_fas.txt

Diabetes Productivity Measure (DPM) Scores by Treatment Week - Change from Baseline -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Work Productivity ch()		
Visit 14 (Week 12)		
N	249	127
Mean (SD)	2.9 (12.7)	1.3 (12.1)
Median	0.0	0.0
Min ; Max	-30.0 ; 50.0	-30.0 ; 35.0
Visit 28 (Week 26)		
N	231	115
Mean (SD)	3.5 (13.8)	-1.0 (12.6)
Median	0.0	0.0
Min ; Max	-45.0 ; 75.0	-40.0 ; 25.0
Visit 28 (Week 26) (LOCF)		
N	299	147
Mean (SD)	2.3 (13.0)	-1.7 (12.8)
Median	0.0	0.0
Min ; Max	-45.0 ; 75.0	-55.0 ; 25.0

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:47 - tdesc_numfind_tpl_t019_v01.sas/t_dpm_chb_descp_fas.txt

14.2.149: Diabetes Productivity Measure (DPM) Scores after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Life Productivity					
LSMeans					
IDegAsp OD	366	356	73.9	1.2	
IDet	182	181	73.7	1.4	
Change from Baseline					
LSMeans					
IDegAsp OD	366	356	1.8	1.2	
IDet	182	181	1.6	1.4	
Treatment Contrast					
IDegAsp OD - IDet			0.2		[-2.1 ; 2.6]
Work Productivity					
LSMeans					
IDegAsp OD	366	299	84.3	1.2	
IDet	182	147	81.4	1.4	
Change from Baseline					
LSMeans					
IDegAsp OD	366	299	0.9	1.2	
IDet	182	147	-2.0	1.4	
Treatment Contrast					
IDegAsp OD - IDet			2.9		[0.5 ; 5.2]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates. Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:55:53 - tstat_find_tpl_t022.sas/t_dpm_stat_locf_fas.txt

14.2.150: Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Compliance()			
Visit 2 (Week 0)			
N	345	177	522
Mean (SD)	74.4 (17.6)	77.0 (16.4)	75.3 (17.2)
Median	75.0	81.3	75.0
Min ; Max	6.3 ; 100.0	37.5 ; 100.0	6.3 ; 100.0
Visit 14 (Week 12)			
N	332	166	498
Mean (SD)	81.6 (15.9)	82.6 (14.5)	81.9 (15.4)
Median	87.5	87.5	87.5
Min ; Max	0.0 ; 100.0	37.5 ; 100.0	0.0 ; 100.0
Visit 28 (Week 26)			
N	314	153	467
Mean (SD)	81.8 (13.1)	83.2 (15.0)	82.3 (13.7)
Median	81.3	87.5	81.3
Min ; Max	31.3 ; 100.0	31.3 ; 100.0	31.3 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	80.8 (14.3)	82.7 (15.2)	81.5 (14.6)
Median	81.3	87.5	81.3
Min ; Max	18.8 ; 100.0	31.3 ; 100.0	18.8 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:00 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_abs_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Daily Life()			
Visit 2 (Week 0)			
N	344	177	521
Mean (SD)	75.0 (18.0)	76.8 (19.1)	75.6 (18.4)
Median	75.0	80.0	80.0
Min ; Max	20.0 ; 100.0	20.0 ; 100.0	20.0 ; 100.0
Visit 14 (Week 12)			
N	332	166	498
Mean (SD)	78.7 (17.6)	79.4 (17.4)	79.0 (17.5)
Median	80.0	80.0	80.0
Min ; Max	20.0 ; 100.0	35.0 ; 100.0	20.0 ; 100.0
Visit 28 (Week 26)			
N	313	153	466
Mean (SD)	78.1 (17.5)	79.2 (19.0)	78.5 (18.0)
Median	80.0	80.0	80.0
Min ; Max	10.0 ; 100.0	30.0 ; 100.0	10.0 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	77.2 (18.0)	78.9 (19.1)	77.8 (18.4)
Median	80.0	80.0	80.0
Min ; Max	10.0 ; 100.0	30.0 ; 100.0	10.0 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:00 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_abs_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week -
 Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Diabetes Management()			
Visit 2 (Week 0)			
N	345	177	522
Mean (SD)	51.3 (19.2)	50.6 (20.3)	51.1 (19.6)
Median	50.0	50.0	50.0
Min ; Max	0.0 ; 100.0	5.0 ; 100.0	0.0 ; 100.0
Visit 14 (Week 12)			
N	332	166	498
Mean (SD)	56.9 (19.2)	55.2 (21.4)	56.3 (19.9)
Median	55.0	55.6	55.0
Min ; Max	0.0 ; 100.0	0.0 ; 100.0	0.0 ; 100.0
Visit 28 (Week 26)			
N	314	153	467
Mean (SD)	57.2 (19.3)	58.1 (22.2)	57.5 (20.3)
Median	60.0	60.0	60.0
Min ; Max	5.0 ; 100.0	0.0 ; 100.0	0.0 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	55.0 (20.5)	56.0 (23.3)	55.4 (21.5)
Median	60.0	55.0	60.0
Min ; Max	0.0 ; 100.0	0.0 ; 100.0	0.0 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:00 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_abs_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Psychological Health()			
Visit 2 (Week 0)			
N	343	177	520
Mean (SD)	77.9 (18.1)	79.4 (16.9)	78.4 (17.7)
Median	81.3	81.3	81.3
Min ; Max	6.3 ; 100.0	0.0 ; 100.0	0.0 ; 100.0
Visit 14 (Week 12)			
N	328	165	493
Mean (SD)	83.2 (17.0)	82.9 (16.0)	83.1 (16.6)
Median	87.5	87.5	87.5
Min ; Max	25.0 ; 100.0	12.5 ; 100.0	12.5 ; 100.0
Visit 28 (Week 26)			
N	310	153	463
Mean (SD)	82.5 (17.8)	82.7 (16.3)	82.5 (17.3)
Median	87.5	87.5	87.5
Min ; Max	9.4 ; 100.0	21.9 ; 100.0	9.4 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	81.3 (18.4)	81.2 (16.9)	81.3 (17.9)
Median	84.4	84.4	84.4
Min ; Max	9.4 ; 100.0	21.9 ; 100.0	9.4 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:00 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_abs_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
TRIM-D Total()			
Visit 2 (Week 0)			
N	346	177	523
Mean (SD)	67.8 (13.9)	68.9 (13.5)	68.2 (13.7)
Median	68.0	68.8	68.8
Min ; Max	24.1 ; 99.1	35.2 ; 100.0	24.1 ; 100.0
Visit 14 (Week 12)			
N	333	166	499
Mean (SD)	73.7 (13.3)	73.3 (13.6)	73.6 (13.3)
Median	75.0	75.0	75.0
Min ; Max	27.7 ; 99.1	30.4 ; 99.1	27.7 ; 99.1
Visit 28 (Week 26)			
N	313	153	466
Mean (SD)	73.6 (13.3)	74.1 (14.6)	73.7 (13.7)
Median	75.0	75.0	75.0
Min ; Max	18.8 ; 100.0	31.3 ; 100.0	18.8 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	72.3 (13.7)	73.0 (14.7)	72.5 (14.0)
Median	73.2	73.2	73.2
Min ; Max	18.8 ; 100.0	31.3 ; 100.0	18.8 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:00 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_abs_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week -
 Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Treatment Burden()			
Visit 2 (Week 0)			
N	346	176	522
Mean (SD)	57.8 (20.5)	58.1 (20.6)	57.9 (20.5)
Median	58.3	56.3	58.3
Min ; Max	4.2 ; 100.0	0.0 ; 100.0	0.0 ; 100.0
Visit 14 (Week 12)			
N	331	164	495
Mean (SD)	65.8 (17.9)	64.4 (20.8)	65.3 (18.9)
Median	66.7	66.7	66.7
Min ; Max	16.7 ; 100.0	0.0 ; 100.0	0.0 ; 100.0
Visit 28 (Week 26)			
N	312	153	465
Mean (SD)	65.9 (18.6)	66.0 (20.3)	65.9 (19.2)
Median	66.7	70.8	70.0
Min ; Max	0.0 ; 100.0	8.3 ; 100.0	0.0 ; 100.0
Visit 28 (Week 26) (LOCF)			
N	365	181	546
Mean (SD)	65.1 (18.7)	64.9 (20.6)	65.0 (19.3)
Median	66.7	66.7	66.7
Min ; Max	0.0 ; 100.0	0.0 ; 100.0	0.0 ; 100.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:00 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_abs_descp_fas.txt

**14.2.151: Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week -
Change from Baseline - Descriptive Statistics - Full Analysis Set**

	IDegAsp OD	IDet
Number of Subjects	366	182
Compliance ch()		
Visit 14 (Week 12)		
N	312	163
Mean (SD)	6.6 (18.2)	5.1 (15.1)
Median	6.3	0.0
Min ; Max	-100 ; 68.8	-25.0 ; 62.5
Visit 28 (Week 26)		
N	295	151
Mean (SD)	6.5 (15.7)	6.1 (16.7)
Median	6.3	6.3
Min ; Max	-37.5 ; 68.8	-50.0 ; 56.3
Visit 28 (Week 26) (LOCF)		
N	345	177
Mean (SD)	6.2 (15.6)	5.4 (15.9)
Median	6.3	6.3
Min ; Max	-37.5 ; 68.8	-50.0 ; 56.3

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:07 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_chb_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Daily Life ch()		
Visit 14 (Week 12)		
N	311	163
Mean (SD)	3.2 (15.6)	2.2 (15.1)
Median	0.0	0.0
Min ; Max	-60.0 ; 50.0	-45.0 ; 65.0
Visit 28 (Week 26)		
N	293	151
Mean (SD)	2.6 (15.7)	2.4 (15.9)
Median	0.0	0.0
Min ; Max	-50.0 ; 50.0	-35.0 ; 80.0
Visit 28 (Week 26) (LOCF)		
N	344	177
Mean (SD)	2.1 (15.2)	1.8 (15.7)
Median	0.0	0.0
Min ; Max	-50.0 ; 50.0	-45.0 ; 80.0

N = Number of Subjects, SD = Standard Deviation
 ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:07 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_chb_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Diab. Management ch()		
Visit 14 (Week 12)		
N	312	163
Mean (SD)	4.6 (20.6)	4.3 (19.0)
Median	5.0	0.0
Min ; Max	-70.0 ; 65.0	-45.0 ; 50.0
Visit 28 (Week 26)		
N	295	151
Mean (SD)	5.0 (21.1)	7.1 (19.2)
Median	5.0	5.0
Min ; Max	-80.0 ; 80.0	-40.0 ; 70.0
Visit 28 (Week 26) (LOCF)		
N	345	177
Mean (SD)	3.7 (21.3)	5.3 (20.3)
Median	0.0	5.0
Min ; Max	-80.0 ; 80.0	-60.0 ; 70.0

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:07 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_chb_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Psych. Health ch()		
Visit 14 (Week 12)		
N	306	162
Mean (SD)	4.5 (14.8)	2.6 (15.2)
Median	3.1	0.0
Min ; Max	-53.1 ; 84.4	-68.8 ; 100.0
Visit 28 (Week 26)		
N	290	151
Mean (SD)	4.2 (15.6)	2.4 (16.6)
Median	3.1	0.0
Min ; Max	-43.8 ; 87.5	-46.9 ; 100.0
Visit 28 (Week 26) (LOCF)		
N	343	177
Mean (SD)	3.1 (15.7)	1.5 (16.3)
Median	0.0	0.0
Min ; Max	-59.4 ; 87.5	-46.9 ; 100.0

N = Number of Subjects, SD = Standard Deviation
ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:07 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_chb_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
TRIM-D Total ch()		
Visit 14 (Week 12)		
N	314	163
Mean (SD)	5.1 (11.4)	3.8 (10.1)
Median	4.8	2.7
Min ; Max	-43.8 ; 37.5	-25.9 ; 48.2
Visit 28 (Week 26)		
N	296	151
Mean (SD)	5.1 (11.7)	4.9 (12.2)
Median	3.6	2.7
Min ; Max	-34.8 ; 52.7	-25.0 ; 55.4
Visit 28 (Week 26) (LOCF)		
N	346	177
Mean (SD)	4.3 (11.7)	3.8 (12.4)
Median	2.7	1.8
Min ; Max	-34.8 ; 52.7	-37.5 ; 55.4

N = Number of Subjects, SD = Standard Deviation
 ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:07 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_chb_descp_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) Scores by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Treatment Burden ch()		
Visit 14 (Week 12)		
N	312	160
Mean (SD)	6.7 (18.4)	5.8 (18.1)
Median	4.2	4.2
Min ; Max	-58.3 ; 66.7	-50.0 ; 66.7
Visit 28 (Week 26)		
N	295	150
Mean (SD)	7.1 (20.0)	7.8 (20.3)
Median	6.7	4.2
Min ; Max	-75.0 ; 95.8	-41.7 ; 70.8
Visit 28 (Week 26) (LOCF)		
N	346	176
Mean (SD)	6.9 (19.9)	6.5 (20.1)
Median	4.2	4.2
Min ; Max	-75.0 ; 95.8	-41.7 ; 70.8

N = Number of Subjects, SD = Standard Deviation
 ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:07 - tdesc_numfind_tpl_t019_v01.sas/t_trim_d_chb_descp_fas.txt

14.2.152: Treatment Related Impact Measures - Diabetes (TRIM-D) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Compliance					
LSMeans					
IDegAsp OD	366	345	79.2	1.1	
IDet	182	177	80.2	1.3	
Change from Baseline					
LSMeans					
IDegAsp OD	366	345	3.9	1.1	
IDet	182	177	4.9	1.3	
Treatment Contrast					
IDegAsp OD - IDet			-0.9		[-3.2 ; 1.4]
Daily Life					
LSMeans					
IDegAsp OD	366	344	77.1	1.3	
IDet	182	177	77.5	1.5	
Change from Baseline					
LSMeans					
IDegAsp OD	366	344	1.6	1.3	
IDet	182	177	1.9	1.5	
Treatment Contrast					
IDegAsp OD - IDet			-0.3		[-2.9 ; 2.2]
Diabetes Management					
LSMeans					
IDegAsp OD	366	345	56.7	1.7	
IDet	182	177	58.2	2.0	
Change from Baseline					
LSMeans					
IDegAsp OD	366	345	5.7	1.7	
IDet	182	177	7.1	2.0	
Treatment Contrast					
IDegAsp OD - IDet			-1.4		[-4.9 ; 2.0]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:14 - tstat_find_tpl_t022.sas/t_trim_d_stat_locf_fas.txt

Treatment Related Impact Measures - Diabetes (TRIM-D) after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Psychological Health					
LSMeans					
IDegAsp OD	366	343	81.1	1.3	
IDet	182	177	80.3	1.5	
Change from Baseline					
LSMeans					
IDegAsp OD	366	343	2.7	1.3	
IDet	182	177	1.8	1.5	
Treatment Contrast					
IDegAsp OD - IDet			0.8		[-1.8 ; 3.5]
TRIM-D Total					
LSMeans					
IDegAsp OD	366	346	72.7	1.0	
IDet	182	177	72.6	1.1	
Change from Baseline					
LSMeans					
IDegAsp OD	366	346	4.5	1.0	
IDet	182	177	4.4	1.1	
Treatment Contrast					
IDegAsp OD - IDet			0.1		[-1.9 ; 2.1]
Treatment Burden					
LSMeans					
IDegAsp OD	366	346	66.4	1.5	
IDet	182	176	66.1	1.8	
Change from Baseline					
LSMeans					
IDegAsp OD	366	346	8.5	1.5	
IDet	182	176	8.2	1.8	
Treatment Contrast					
IDegAsp OD - IDet			0.3		[-2.8 ; 3.4]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:14 - tstat_find_tpl_t022.sas/t_trim_d_stat_locf_fas.txt

14.2.153: Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Number of Subjects	366	182
What Were You Doing When This Hypo Occurred?		
Visit 2 (Week 0)		
At school	0	2 (1.1)
At work	31 (8.5)	14 (7.7)
Being social, doing sports or recreational activities	7 (1.9)	2 (1.1)
Doing household jobs (cleaning, cooking) or running errands (shopping)	30 (8.2)	15 (8.2)
Driving	2 (0.5)	1 (0.5)
Eating	2 (0.5)	3 (1.6)
Relaxing (watching tv, reading)	55 (15.0)	29 (15.9)
Sleeping	49 (13.4)	27 (14.8)
Other	31 (8.5)	12 (6.6)
Unk	5 (1.4)	0
Visit 3 (Week 1)		
At school	0	2 (1.1)
At work	47 (12.8)	8 (4.4)
Being social, doing sports or recreational activities	10 (2.7)	5 (2.7)
Doing household jobs (cleaning, cooking) or running errands (shopping)	33 (9.0)	14 (7.7)
Driving	4 (1.1)	2 (1.1)
Eating	2 (0.5)	1 (0.5)
Relaxing (watching tv, reading)	69 (18.9)	37 (20.3)
Sleeping	32 (8.7)	23 (12.6)
Other	31 (8.5)	13 (7.1)
Unk	4 (1.1)	1 (0.5)
Visit 4 (Week 2)		
At school	1 (0.3)	0
At work	49 (13.4)	15 (8.2)
Being social, doing sports or recreational activities	13 (3.6)	1 (0.5)
Doing household jobs (cleaning, cooking) or running errands (shopping)	32 (8.7)	14 (7.7)
Driving	3 (0.8)	3 (1.6)
Eating	3 (0.8)	1 (0.5)
Relaxing (watching tv, reading)	57 (15.6)	32 (17.6)
Sleeping	33 (9.0)	16 (8.8)
Other	27 (7.4)	17 (9.3)
Unk	3 (0.8)	1 (0.5)
Visit 6 (Week 4)		
At school	1 (0.3)	0
At work	45 (12.3)	15 (8.2)
Being social, doing sports or recreational activities	10 (2.7)	6 (3.3)

A patient can have checked more than one
 Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Were You Doing When This Hypo Occurred?		
Visit 6 (Week 4)		
Doing household jobs (cleaning, cooking) or running errands (shopping)	32 (8.7)	22 (12.1)
Driving	3 (0.8)	2 (1.1)
Eating	5 (1.4)	1 (0.5)
Relaxing (watching tv, reading)	58 (15.8)	30 (16.5)
Sleeping	27 (7.4)	24 (13.2)
Other	35 (9.6)	9 (4.9)
Unk	4 (1.1)	1 (0.5)
Visit 8 (Week 6)		
At school	2 (0.5)	2 (1.1)
At work	35 (9.6)	13 (7.1)
Being social, doing sports or recreational activities	9 (2.5)	4 (2.2)
Doing household jobs (cleaning, cooking) or running errands (shopping)	32 (8.7)	17 (9.3)
Driving	3 (0.8)	3 (1.6)
Eating	4 (1.1)	2 (1.1)
Relaxing (watching tv, reading)	76 (20.8)	27 (14.8)
Sleeping	31 (8.5)	26 (14.3)
Other	35 (9.6)	11 (6.0)
Unk	4 (1.1)	0
Visit 10 (Week 8)		
At school	1 (0.3)	2 (1.1)
At work	31 (8.5)	16 (8.8)
Being social, doing sports or recreational activities	11 (3.0)	2 (1.1)
Doing household jobs (cleaning, cooking) or running errands (shopping)	40 (10.9)	19 (10.4)
Driving	9 (2.5)	2 (1.1)
Eating	4 (1.1)	1 (0.5)
Relaxing (watching tv, reading)	49 (13.4)	33 (18.1)
Sleeping	26 (7.1)	14 (7.7)
Other	29 (7.9)	17 (9.3)
Unk	2 (0.5)	1 (0.5)
Visit 12 (Week 10)		
At school	0	1 (0.5)
At work	25 (6.8)	13 (7.1)
Being social, doing sports or recreational activities	14 (3.8)	4 (2.2)
Doing household jobs (cleaning, cooking) or running errands (shopping)	36 (9.8)	10 (5.5)
Driving	2 (0.5)	2 (1.1)

A patient can have checked more than one
Unk = Unknown

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
 - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Were You Doing When This Hypo Occurred?		
Visit 12 (Week 10)		
Eating	3 (0.8)	3 (1.6)
Relaxing (watching tv, reading)	60 (16.4)	35 (19.2)
Sleeping	21 (5.7)	19 (10.4)
Other	33 (9.0)	15 (8.2)
Unk	2 (0.5)	1 (0.5)
Visit 14 (Week 12)		
At school	1 (0.3)	0
At work	28 (7.7)	17 (9.3)
Being social, doing sports or recreational activities	11 (3.0)	2 (1.1)
Doing household jobs (cleaning, cooking) or running errands (shopping)	35 (9.6)	17 (9.3)
Driving	1 (0.3)	0
Relaxing (watching tv, reading)	60 (16.4)	34 (18.7)
Sleeping	32 (8.7)	26 (14.3)
Other	27 (7.4)	10 (5.5)
Unk	2 (0.5)	1 (0.5)
Visit 16 (Week 14)		
At school	1 (0.3)	1 (0.5)
At work	27 (7.4)	18 (9.9)
Being social, doing sports or recreational activities	9 (2.5)	4 (2.2)
Doing household jobs (cleaning, cooking) or running errands (shopping)	40 (10.9)	13 (7.1)
Driving	1 (0.3)	0
Eating	1 (0.3)	0
Relaxing (watching tv, reading)	64 (17.5)	39 (21.4)
Sleeping	25 (6.8)	15 (8.2)
Other	20 (5.5)	16 (8.8)
Unk	1 (0.3)	1 (0.5)
Visit 18 (Week 16)		
At school	1 (0.3)	1 (0.5)
At work	38 (10.4)	16 (8.8)
Being social, doing sports or recreational activities	10 (2.7)	3 (1.6)
Doing household jobs (cleaning, cooking) or running errands (shopping)	46 (12.6)	20 (11.0)
Driving	5 (1.4)	1 (0.5)
Eating	1 (0.3)	0
Relaxing (watching tv, reading)	48 (13.1)	27 (14.8)
Sleeping	25 (6.8)	22 (12.1)

A patient can have checked more than one
 Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Were You Doing When This Hypo Occurred?		
Visit 18 (Week 16)		
Other	25 (6.8)	10 (5.5)
Unk	8 (2.2)	3 (1.6)
Visit 22 (Week 20)		
At school	1 (0.3)	0
At work	40 (10.9)	16 (8.8)
Being social, doing sports or recreational activities	10 (2.7)	5 (2.7)
Doing household jobs (cleaning, cooking) or running errands (shopping)	33 (9.0)	19 (10.4)
Driving	2 (0.5)	0
Eating	4 (1.1)	1 (0.5)
Relaxing (watching tv, reading)	57 (15.6)	23 (12.6)
Sleeping	27 (7.4)	14 (7.7)
Other	21 (5.7)	16 (8.8)
Unk	7 (1.9)	1 (0.5)
Visit 26 (Week 24)		
At school	1 (0.3)	1 (0.5)
At work	25 (6.8)	7 (3.8)
Being social, doing sports or recreational activities	13 (3.6)	5 (2.7)
Doing household jobs (cleaning, cooking) or running errands (shopping)	31 (8.5)	22 (12.1)
Driving	2 (0.5)	3 (1.6)
Eating	0	1 (0.5)
Relaxing (watching tv, reading)	53 (14.5)	27 (14.8)
Sleeping	28 (7.7)	15 (8.2)
Other	23 (6.3)	7 (3.8)
Unk	8 (2.2)	3 (1.6)
Visit 28 (Week 26)		
At work	33 (9.0)	12 (6.6)
Being social, doing sports or recreational activities	5 (1.4)	4 (2.2)
Doing household jobs (cleaning, cooking) or running errands (shopping)	29 (7.9)	17 (9.3)
Driving	3 (0.8)	4 (2.2)
Eating	1 (0.3)	1 (0.5)
Relaxing (watching tv, reading)	60 (16.4)	29 (15.9)
Sleeping	29 (7.9)	31 (17.0)
Other	14 (3.8)	7 (3.8)
Unk	9 (2.5)	1 (0.5)
Visit 29 (Week 27)		
At school	1 (0.3)	1 (0.5)

A patient can have checked more than one
Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Were You Doing When This Hypo Occurred?		
Visit 29 (Week 27)		
At work	27 (7.4)	9 (4.9)
Being social, doing sports or recreational activities	6 (1.6)	7 (3.8)
Doing household jobs (cleaning, cooking) or running errands (shopping)	34 (9.3)	17 (9.3)
Driving	2 (0.5)	2 (1.1)
Eating	1 (0.3)	0
Relaxing (watching tv, reading)	52 (14.2)	26 (14.3)
Sleeping	14 (3.8)	12 (6.6)
Other	12 (3.3)	11 (6.0)
Unk	5 (1.4)	1 (0.5)
What Do You Think Was The Cause Of This Hypo?		
Visit 2 (Week 0)		
Alcohol	1 (0.3)	0
General poor glucose control	6 (1.6)	1 (0.5)
Irregular or insufficient food intake or poor diet	78 (21.3)	36 (19.8)
Miscalculation of insulin doses	55 (15.0)	36 (19.8)
On purpose - to get my blood sugar down or keep it low	7 (1.9)	0
Physical exercise/overexertion	42 (11.5)	27 (14.8)
Stress	6 (1.6)	3 (1.6)
Other	15 (4.1)	4 (2.2)
Unk	26 (7.1)	18 (9.9)
Visit 3 (Week 1)		
Alcohol	2 (0.5)	0
General poor glucose control	3 (0.8)	3 (1.6)
Irregular or insufficient food intake or poor diet	80 (21.9)	28 (15.4)
Miscalculation of insulin doses	61 (16.7)	31 (17.0)
On purpose - to get my blood sugar down or keep it low	0	4 (2.2)
Physical exercise/overexertion	50 (13.7)	24 (13.2)
Stress	6 (1.6)	0
Other	18 (4.9)	9 (4.9)
Unk	42 (11.5)	19 (10.4)
Visit 4 (Week 2)		
General poor glucose control	5 (1.4)	1 (0.5)
Irregular or insufficient food intake or poor diet	81 (22.1)	42 (23.1)
Miscalculation of insulin doses	47 (12.8)	25 (13.7)
On purpose - to get my blood sugar down or keep it low	1 (0.3)	4 (2.2)
Physical exercise/overexertion	45 (12.3)	17 (9.3)

A patient can have checked more than one
Unk = Unknown

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Do You Think Was The Cause Of This Hypo?		
Visit 4 (Week 2)		
Stress	5 (1.4)	4 (2.2)
Other	15 (4.1)	4 (2.2)
Unk	40 (10.9)	15 (8.2)
Visit 6 (Week 4)		
General poor glucose control	7 (1.9)	2 (1.1)
Irregular or insufficient food intake	79 (21.6)	39 (21.4)
or poor diet		
Miscalculation of insulin doses	46 (12.6)	30 (16.5)
On purpose - to get my blood sugar	4 (1.1)	1 (0.5)
down or keep it low		
Physical exercise/overexertion	51 (13.9)	19 (10.4)
Stress	8 (2.2)	3 (1.6)
Other	14 (3.8)	8 (4.4)
Unk	42 (11.5)	18 (9.9)
Visit 8 (Week 6)		
Alcohol	3 (0.8)	0
General poor glucose control	5 (1.4)	2 (1.1)
Irregular or insufficient food intake	91 (24.9)	39 (21.4)
or poor diet		
Miscalculation of insulin doses	40 (10.9)	28 (15.4)
On purpose - to get my blood sugar	1 (0.3)	1 (0.5)
down or keep it low		
Physical exercise/overexertion	43 (11.7)	18 (9.9)
Stress	5 (1.4)	1 (0.5)
Other	13 (3.6)	4 (2.2)
Unk	49 (13.4)	19 (10.4)
Visit 10 (Week 8)		
Alcohol	2 (0.5)	1 (0.5)
Irregular or insufficient food intake	80 (21.9)	43 (23.6)
or poor diet		
Miscalculation of insulin doses	46 (12.6)	27 (14.8)
On purpose - to get my blood sugar	5 (1.4)	0
down or keep it low		
Physical exercise/overexertion	47 (12.8)	22 (12.1)
Stress	5 (1.4)	2 (1.1)
Other	6 (1.6)	1 (0.5)
Unk	30 (8.2)	24 (13.2)
Visit 12 (Week 10)		
General poor glucose control	2 (0.5)	3 (1.6)
Irregular or insufficient food intake	78 (21.3)	29 (15.9)
or poor diet		
Miscalculation of insulin doses	37 (10.1)	30 (16.5)
On purpose - to get my blood sugar	3 (0.8)	1 (0.5)
down or keep it low		

A patient can have checked more than one
Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Do You Think Was The Cause Of This Hypo?		
Visit 12 (Week 10)		
Physical exercise/overexertion	41 (11.2)	17 (9.3)
Stress	6 (1.6)	0
Other	3 (0.8)	3 (1.6)
Unk	37 (10.1)	27 (14.8)
Visit 14 (Week 12)		
General poor glucose control	0	1 (0.5)
Irregular or insufficient food intake or poor diet	74 (20.2)	44 (24.2)
Miscalculation of insulin doses	41 (11.2)	33 (18.1)
Physical exercise/overexertion	43 (11.7)	17 (9.3)
Stress	5 (1.4)	2 (1.1)
Other	8 (2.2)	4 (2.2)
Unk	41 (11.2)	20 (11.0)
Visit 16 (Week 14)		
Alcohol	0	2 (1.1)
Irregular or insufficient food intake or poor diet	77 (21.0)	43 (23.6)
Miscalculation of insulin doses	43 (11.7)	27 (14.8)
On purpose - to get my blood sugar down or keep it low	2 (0.5)	1 (0.5)
Physical exercise/overexertion	37 (10.1)	17 (9.3)
Stress	4 (1.1)	2 (1.1)
Other	6 (1.6)	4 (2.2)
Unk	42 (11.5)	29 (15.9)
Visit 18 (Week 16)		
General poor glucose control	4 (1.1)	0
Irregular or insufficient food intake or poor diet	78 (21.3)	35 (19.2)
Miscalculation of insulin doses	43 (11.7)	32 (17.6)
On purpose - to get my blood sugar down or keep it low	4 (1.1)	0
Physical exercise/overexertion	52 (14.2)	21 (11.5)
Stress	2 (0.5)	2 (1.1)
Other	8 (2.2)	6 (3.3)
Unk	38 (10.4)	18 (9.9)
Visit 22 (Week 20)		
Alcohol	0	2 (1.1)
General poor glucose control	1 (0.3)	1 (0.5)
Irregular or insufficient food intake or poor diet	82 (22.4)	35 (19.2)
Miscalculation of insulin doses	44 (12.0)	33 (18.1)
On purpose - to get my blood sugar down or keep it low	4 (1.1)	0

A patient can have checked more than one
Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Do You Think Was The Cause Of This Hypo?		
Visit 22 (Week 20)		
Physical exercise/overexertion	50 (13.7)	18 (9.9)
Stress	7 (1.9)	2 (1.1)
Other	3 (0.8)	5 (2.7)
Unk	33 (9.0)	14 (7.7)
Visit 26 (Week 24)		
General poor glucose control	2 (0.5)	1 (0.5)
Irregular or insufficient food intake or poor diet	60 (16.4)	31 (17.0)
Miscalculation of insulin doses	36 (9.8)	30 (16.5)
On purpose - to get my blood sugar down or keep it low	3 (0.8)	1 (0.5)
Physical exercise/overexertion	44 (12.0)	19 (10.4)
Stress	4 (1.1)	1 (0.5)
Other	7 (1.9)	2 (1.1)
Unk	43 (11.7)	18 (9.9)
Visit 28 (Week 26)		
Alcohol	1 (0.3)	0
General poor glucose control	2 (0.5)	2 (1.1)
Irregular or insufficient food intake or poor diet	63 (17.2)	38 (20.9)
Miscalculation of insulin doses	41 (11.2)	31 (17.0)
On purpose - to get my blood sugar down or keep it low	4 (1.1)	0
Physical exercise/overexertion	32 (8.7)	14 (7.7)
Stress	9 (2.5)	1 (0.5)
Other	7 (1.9)	7 (3.8)
Unk	43 (11.7)	27 (14.8)
Visit 29 (Week 27)		
Alcohol	1 (0.3)	0
General poor glucose control	4 (1.1)	0
Irregular or insufficient food intake or poor diet	56 (15.3)	40 (22.0)
Miscalculation of insulin doses	35 (9.6)	23 (12.6)
On purpose - to get my blood sugar down or keep it low	2 (0.5)	0
Physical exercise/overexertion	35 (9.6)	14 (7.7)
Stress	5 (1.4)	1 (0.5)
Other	11 (3.0)	4 (2.2)
Unk	23 (6.3)	10 (5.5)
What Did You, Or Some Helping You, Take To Recover From This Hypo?		
Visit 2 (Week 0)		
Candy, sweets, cake or biscuit/cookie	63 (17.2)	29 (15.9)
Full meal (breakfast, lunch or dinner)	41 (11.2)	23 (12.6)

A patient can have checked more than one
Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Did You, Or Some Helping You, Take To Recover From This Hypo?		
Visit 2 (Week 0)		
Glucose tablets	12 (3.3)	6 (3.3)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	71 (19.4)	40 (22.0)
Sandwich, light meal or snack	45 (12.3)	16 (8.8)
Sugar packages	11 (3.0)	4 (2.2)
Other	9 (2.5)	3 (1.6)
Visit 3 (Week 1)		
Candy, sweets, cake or biscuit/cookie	64 (17.5)	22 (12.1)
Full meal (breakfast, lunch or dinner)	49 (13.4)	27 (14.8)
Glucagon injection	1 (0.3)	0
Glucose gel	1 (0.3)	0
Glucose tablets	13 (3.6)	7 (3.8)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	66 (18.0)	36 (19.8)
Sandwich, light meal or snack	51 (13.9)	23 (12.6)
Sugar packages	17 (4.6)	3 (1.6)
Other	12 (3.3)	3 (1.6)
Visit 4 (Week 2)		
Candy, sweets, cake or biscuit/cookie	59 (16.1)	26 (14.3)
Full meal (breakfast, lunch or dinner)	57 (15.6)	25 (13.7)
Glucose gel	1 (0.3)	3 (1.6)
Glucose tablets	12 (3.3)	4 (2.2)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	76 (20.8)	32 (17.6)
Sandwich, light meal or snack	40 (10.9)	22 (12.1)
Sugar packages	11 (3.0)	6 (3.3)
Other	5 (1.4)	4 (2.2)
Unk	2 (0.5)	1 (0.5)
Visit 6 (Week 4)		
Candy, sweets, cake or biscuit/cookie	61 (16.7)	28 (15.4)
Full meal (breakfast, lunch or dinner)	57 (15.6)	28 (15.4)
Glucose gel	2 (0.5)	1 (0.5)
Glucose tablets	13 (3.6)	1 (0.5)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	66 (18.0)	36 (19.8)
Sandwich, light meal or snack	50 (13.7)	27 (14.8)
Sugar packages	14 (3.8)	4 (2.2)
Other	6 (1.6)	4 (2.2)
Unk	2 (0.5)	0

A patient can have checked more than one
Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp N (%)	OD N (%)	IDet N (%)
What Did You, Or Some Helping You, Take To Recover From This Hypo?			
Visit 8 (Week 6)			
Candy, sweets, cake or biscuit/cookie	52 (14.2)		24 (13.2)
Full meal (breakfast, lunch or dinner)	63 (17.2)		25 (13.7)
Glucose gel	1 (0.3)		1 (0.5)
Glucose tablets	10 (2.7)		3 (1.6)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	71 (19.4)		36 (19.8)
Sandwich, light meal or snack	50 (13.7)		28 (15.4)
Sugar packages	16 (4.4)		6 (3.3)
Other	8 (2.2)		2 (1.1)
Unk	1 (0.3)		0
Visit 10 (Week 8)			
Candy, sweets, cake or biscuit/cookie	46 (12.6)		26 (14.3)
Full meal (breakfast, lunch or dinner)	58 (15.8)		23 (12.6)
Glucose tablets	9 (2.5)		3 (1.6)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	58 (15.8)		32 (17.6)
Sandwich, light meal or snack	42 (11.5)		34 (18.7)
Sugar packages	15 (4.1)		6 (3.3)
Other	5 (1.4)		4 (2.2)
Unk	1 (0.3)		0
Visit 12 (Week 10)			
Candy, sweets, cake or biscuit/cookie	38 (10.4)		30 (16.5)
Full meal (breakfast, lunch or dinner)	56 (15.3)		34 (18.7)
Glucose gel	2 (0.5)		0
Glucose tablets	5 (1.4)		5 (2.7)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	63 (17.2)		25 (13.7)
Sandwich, light meal or snack	41 (11.2)		17 (9.3)
Sugar packages	15 (4.1)		5 (2.7)
Other	5 (1.4)		3 (1.6)
Unk	1 (0.3)		0
Visit 14 (Week 12)			
Candy, sweets, cake or biscuit/cookie	56 (15.3)		22 (12.1)
Full meal (breakfast, lunch or dinner)	46 (12.6)		25 (13.7)
Glucagon injection	0		1 (0.5)
Glucose gel	1 (0.3)		0
Glucose tablets	12 (3.3)		5 (2.7)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	57 (15.6)		37 (20.3)

A patient can have checked more than one
Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Did You, Or Some Helping You, Take To Recover From This Hypo?		
Visit 14 (Week 12)		
Sandwich, light meal or snack	30 (8.2)	20 (11.0)
Sugar packages	17 (4.6)	11 (6.0)
Other	5 (1.4)	3 (1.6)
Unk	3 (0.8)	0
Visit 16 (Week 14)		
Candy, sweets, cake or biscuit/cookie	43 (11.7)	24 (13.2)
Full meal (breakfast, lunch or dinner)	57 (15.6)	34 (18.7)
Glucagon injection	0	1 (0.5)
Glucose gel	1 (0.3)	0
Glucose tablets	6 (1.6)	3 (1.6)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	57 (15.6)	30 (16.5)
Sandwich, light meal or snack	41 (11.2)	18 (9.9)
Sugar packages	14 (3.8)	5 (2.7)
Other	6 (1.6)	5 (2.7)
Unk	0	1 (0.5)
Visit 18 (Week 16)		
Candy, sweets, cake or biscuit/cookie	51 (13.9)	22 (12.1)
Full meal (breakfast, lunch or dinner)	49 (13.4)	28 (15.4)
Glucagon injection	0	1 (0.5)
Glucose gel	3 (0.8)	0
Glucose tablets	10 (2.7)	4 (2.2)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	70 (19.1)	35 (19.2)
Sandwich, light meal or snack	36 (9.8)	15 (8.2)
Sugar packages	16 (4.4)	3 (1.6)
Other	1 (0.3)	5 (2.7)
Unk	4 (1.1)	2 (1.1)
Visit 22 (Week 20)		
Candy, sweets, cake or biscuit/cookie	46 (12.6)	14 (7.7)
Full meal (breakfast, lunch or dinner)	58 (15.8)	33 (18.1)
Glucose gel	1 (0.3)	0
Glucose tablets	9 (2.5)	1 (0.5)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	55 (15.0)	29 (15.9)
Sandwich, light meal or snack	40 (10.9)	21 (11.5)
Sugar packages	18 (4.9)	7 (3.8)
Other	7 (1.9)	1 (0.5)

A patient can have checked more than one
Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

Hypoglycaemic Questionnaire - Question 1 to 3 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
What Did You, Or Some Helping You, Take To Recover From This Hypo?		
Visit 22 (Week 20)		
Unk	2 (0.5)	0
Visit 26 (Week 24)		
Candy, sweets, cake or biscuit/cookie	43 (11.7)	17 (9.3)
Full meal (breakfast, lunch or dinner)	59 (16.1)	23 (12.6)
Glucose tablets	6 (1.6)	2 (1.1)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	57 (15.6)	37 (20.3)
Sandwich, light meal or snack	28 (7.7)	21 (11.5)
Sugar packages	13 (3.6)	3 (1.6)
Other	2 (0.5)	1 (0.5)
Unk	5 (1.4)	1 (0.5)
Visit 28 (Week 26)		
Candy, sweets, cake or biscuit/cookie	29 (7.9)	19 (10.4)
Full meal (breakfast, lunch or dinner)	58 (15.8)	33 (18.1)
Glucagon injection	1 (0.3)	0
Glucose gel	1 (0.3)	0
Glucose tablets	8 (2.2)	6 (3.3)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	59 (16.1)	35 (19.2)
Sandwich, light meal or snack	30 (8.2)	19 (10.4)
Sugar packages	14 (3.8)	4 (2.2)
Other	6 (1.6)	5 (2.7)
Unk	4 (1.1)	1 (0.5)
Visit 29 (Week 27)		
Candy, sweets, cake or biscuit/cookie	30 (8.2)	14 (7.7)
Full meal (breakfast, lunch or dinner)	50 (13.7)	25 (13.7)
Glucagon injection	1 (0.3)	0
Glucose gel	1 (0.3)	0
Glucose tablets	8 (2.2)	3 (1.6)
Nutritional or sweet drink (e.g. soda, juice, sweet tea or milk)	42 (11.5)	29 (15.9)
Sandwich, light meal or snack	31 (8.5)	23 (12.6)
Sugar packages	14 (3.8)	5 (2.7)
Other	4 (1.1)	2 (1.1)
Unk	3 (0.8)	0

A patient can have checked more than one
Unk = Unknown

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:47 - t_hypoquest_1to3_descp.sas/t_hypoquest_1to3_descp_fas.txt

14.2.154: Hypoglycaemic Questionnaire - Question 4 to 7 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet
Number of Subjects	366	182
Lasting of the hypoglycaem. episode (hr)		
Visit 2 (Week 0)		
N	195	101
Mean (SD)	0.28 (0.23)	0.32 (0.32)
Median	0.25	0.25
Min ; Max	0.00 ; 2.00	0.00 ; 2.00
Visit 3 (Week 1)		
N	218	99
Mean (SD)	0.28 (0.25)	0.34 (0.45)
Median	0.25	0.25
Min ; Max	0.00 ; 2.00	0.00 ; 4.00
Visit 4 (Week 2)		
N	213	94
Mean (SD)	0.31 (0.28)	0.28 (0.24)
Median	0.25	0.21
Min ; Max	0.00 ; 2.50	0.00 ; 1.00
Visit 6 (Week 4)		
N	214	103
Mean (SD)	0.44 (2.07)	0.35 (0.46)
Median	0.25	0.25
Min ; Max	0.00 ; 30.02	0.02 ; 4.00
Visit 8 (Week 6)		
N	217	99
Mean (SD)	0.34 (0.77)	0.25 (0.21)
Median	0.25	0.20
Min ; Max	0.00 ; 9.00	0.02 ; 1.00
Visit 10 (Week 8)		
N	195	103
Mean (SD)	0.28 (0.27)	0.29 (0.26)
Median	0.25	0.17
Min ; Max	0.00 ; 2.00	0.00 ; 1.50
Visit 12 (Week 10)		
N	188	102
Mean (SD)	0.31 (0.49)	0.31 (0.22)
Median	0.25	0.25
Min ; Max	0.00 ; 5.00	0.02 ; 1.00

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:52 - t_hypoquest_4to7_descp.sas/t_hypoquest_4to7_descp_fas.txt

Hypoglycaemic Questionnaire - Question 4 to 7 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD	IDet
Lasting of the hypoglycaem. episode (hr)		
Visit 14 (Week 12)		
N	190	105
Mean (SD)	0.31 (0.38)	0.34 (0.38)
Median	0.25	0.25
Min ; Max	0.00 ; 3.00	0.00 ; 2.00
Visit 16 (Week 14)		
N	183	98
Mean (SD)	0.27 (0.27)	0.29 (0.29)
Median	0.25	0.25
Min ; Max	0.00 ; 2.00	0.00 ; 2.00
Visit 18 (Week 16)		
N	199	94
Mean (SD)	0.29 (0.37)	0.27 (0.24)
Median	0.25	0.17
Min ; Max	0.00 ; 4.50	0.02 ; 1.25
Visit 22 (Week 20)		
N	192	90
Mean (SD)	0.27 (0.24)	0.27 (0.26)
Median	0.25	0.17
Min ; Max	0.00 ; 2.00	0.00 ; 2.00
Visit 26 (Week 24)		
N	174	86
Mean (SD)	0.28 (0.24)	0.30 (0.25)
Median	0.25	0.25
Min ; Max	0.00 ; 2.00	0.00 ; 1.50
Visit 28 (Week 26)		
N	177	102
Mean (SD)	0.28 (0.29)	0.24 (0.18)
Median	0.25	0.21
Min ; Max	0.00 ; 2.00	0.00 ; 1.00
Visit 29 (Week 27)		
N	150	85
Mean (SD)	0.31 (0.31)	0.28 (0.20)
Median	0.25	0.25
Min ; Max	0.00 ; 2.00	0.00 ; 1.00

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:52 - t_hypoquest_4to7_descp.sas/t_hypoquest_4to7_descp_fas.txt

Hypoglycaemic Questionnaire - Question 4 to 7 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD	IDet
Time to real. of the hypo. episode (hr)		
Visit 2 (Week 0)		
N	189	99
Mean (SD)	0.08 (0.09)	0.10 (0.17)
Median	0.05	0.03
Min ; Max	0.00 ; 0.50	0.00 ; 1.00
Visit 3 (Week 1)		
N	220	98
Mean (SD)	0.09 (0.16)	0.12 (0.20)
Median	0.05	0.08
Min ; Max	0.00 ; 1.83	0.00 ; 1.50
Visit 4 (Week 2)		
N	207	93
Mean (SD)	0.10 (0.12)	0.09 (0.11)
Median	0.07	0.05
Min ; Max	0.00 ; 0.75	0.00 ; 0.50
Visit 6 (Week 4)		
N	213	99
Mean (SD)	0.10 (0.15)	0.15 (0.42)
Median	0.05	0.08
Min ; Max	0.00 ; 1.50	0.02 ; 4.00
Visit 8 (Week 6)		
N	217	97
Mean (SD)	0.10 (0.13)	0.15 (0.26)
Median	0.05	0.08
Min ; Max	0.00 ; 0.75	0.00 ; 2.00
Visit 10 (Week 8)		
N	188	99
Mean (SD)	0.09 (0.12)	0.09 (0.11)
Median	0.05	0.03
Min ; Max	0.00 ; 1.00	0.00 ; 0.50
Visit 12 (Week 10)		
N	186	98
Mean (SD)	0.11 (0.15)	0.10 (0.13)
Median	0.05	0.07
Min ; Max	0.00 ; 1.00	0.00 ; 1.00

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:52 - t_hypoquest_4to7_descp.sas/t_hypoquest_4to7_descp_fas.txt

Hypoglycaemic Questionnaire - Question 4 to 7 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD	IDet
Time to real. of the hypo. episode (hr)		
Visit 14 (Week 12)		
N	190	103
Mean (SD)	0.09 (0.10)	0.12 (0.22)
Median	0.08	0.05
Min ; Max	0.00 ; 0.75	0.00 ; 2.00
Visit 16 (Week 14)		
N	181	101
Mean (SD)	0.10 (0.14)	0.10 (0.13)
Median	0.07	0.08
Min ; Max	0.00 ; 1.17	0.00 ; 1.00
Visit 18 (Week 16)		
N	193	94
Mean (SD)	0.10 (0.14)	0.09 (0.10)
Median	0.08	0.03
Min ; Max	0.00 ; 1.00	0.00 ; 0.50
Visit 22 (Week 20)		
N	190	93
Mean (SD)	0.09 (0.11)	0.09 (0.10)
Median	0.08	0.05
Min ; Max	0.00 ; 1.00	0.00 ; 0.50
Visit 26 (Week 24)		
N	175	85
Mean (SD)	0.09 (0.11)	0.11 (0.13)
Median	0.08	0.08
Min ; Max	0.00 ; 0.75	0.00 ; 0.50
Visit 28 (Week 26)		
N	176	103
Mean (SD)	0.09 (0.11)	0.09 (0.13)
Median	0.08	0.05
Min ; Max	0.00 ; 1.00	0.00 ; 1.00
Visit 29 (Week 27)		
N	149	83
Mean (SD)	0.09 (0.09)	0.09 (0.09)
Median	0.08	0.08
Min ; Max	0.00 ; 0.50	0.00 ; 0.50

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:52 - t_hypoquest_4to7_descp.sas/t_hypoquest_4to7_descp_fas.txt

Hypoglycaemic Questionnaire - Question 4 to 7 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD	IDet
Time bef. doing someth. about hypo (hr)		
Visit 2 (Week 0)		
N	199	104
Mean (SD)	0.19 (0.23)	0.19 (0.28)
Median	0.12	0.08
Min ; Max	0.00 ; 2.00	0.00 ; 2.00
Visit 3 (Week 1)		
N	225	100
Mean (SD)	0.21 (0.32)	0.32 (0.90)
Median	0.12	0.08
Min ; Max	0.00 ; 3.00	0.00 ; 8.00
Visit 4 (Week 2)		
N	213	94
Mean (SD)	0.24 (0.50)	0.16 (0.20)
Median	0.17	0.08
Min ; Max	0.00 ; 6.00	0.00 ; 1.00
Visit 6 (Week 4)		
N	219	107
Mean (SD)	0.22 (0.42)	0.21 (0.24)
Median	0.13	0.08
Min ; Max	0.00 ; 5.00	0.02 ; 1.00
Visit 8 (Week 6)		
N	221	98
Mean (SD)	0.23 (0.63)	0.17 (0.20)
Median	0.17	0.08
Min ; Max	0.00 ; 9.00	0.00 ; 1.00
Visit 10 (Week 8)		
N	195	103
Mean (SD)	0.21 (0.27)	0.19 (0.22)
Median	0.17	0.08
Min ; Max	0.00 ; 2.00	0.00 ; 1.50
Visit 12 (Week 10)		
N	186	100
Mean (SD)	0.20 (0.29)	0.19 (0.17)
Median	0.17	0.17
Min ; Max	0.00 ; 3.00	0.02 ; 0.75

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:52 - t_hypoquest_4to7_descp.sas/t_hypoquest_4to7_descp_fas.txt

Hypoglycaemic Questionnaire - Question 4 to 7 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD	IDet
Time bef. doing someth. about hypo (hr)		
Visit 14 (Week 12)		
N	192	104
Mean (SD)	0.17 (0.21)	0.25 (0.39)
Median	0.08	0.17
Min ; Max	0.00 ; 2.00	0.02 ; 3.00
Visit 16 (Week 14)		
N	185	101
Mean (SD)	0.17 (0.18)	0.17 (0.20)
Median	0.08	0.08
Min ; Max	0.00 ; 1.33	0.00 ; 1.50
Visit 18 (Week 16)		
N	201	100
Mean (SD)	0.19 (0.37)	0.19 (0.20)
Median	0.08	0.17
Min ; Max	0.00 ; 4.50	0.02 ; 1.50
Visit 22 (Week 20)		
N	191	93
Mean (SD)	0.17 (0.18)	0.20 (0.25)
Median	0.08	0.17
Min ; Max	0.00 ; 1.00	0.02 ; 2.00
Visit 26 (Week 24)		
N	175	86
Mean (SD)	0.18 (0.23)	0.25 (0.55)
Median	0.08	0.17
Min ; Max	0.00 ; 2.00	0.00 ; 5.00
Visit 28 (Week 26)		
N	179	99
Mean (SD)	0.31 (1.79)	0.16 (0.16)
Median	0.08	0.08
Min ; Max	0.00 ; 24.00	0.00 ; 1.00
Visit 29 (Week 27)		
N	151	85
Mean (SD)	0.18 (0.20)	0.20 (0.20)
Median	0.08	0.13
Min ; Max	0.00 ; 1.50	0.02 ; 1.00

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:52 - t_hypoquest_4to7_descp.sas/t_hypoquest_4to7_descp_fas.txt

Hypoglycaemic Questionnaire - Question 4 to 7 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD	IDet
Time to recover from the hypo. (hr)		
Visit 2 (Week 0)		
N	196	100
Mean (SD)	0.34 (0.88)	0.68 (2.93)
Median	0.25	0.17
Min ; Max	0.00 ; 12.00	0.00 ; 25.00
Visit 3 (Week 1)		
N	223	97
Mean (SD)	0.45 (2.03)	1.09 (7.30)
Median	0.25	0.25
Min ; Max	0.00 ; 30.00	0.00 ; 72.00
Visit 4 (Week 2)		
N	212	94
Mean (SD)	0.35 (0.87)	0.45 (1.33)
Median	0.25	0.17
Min ; Max	0.00 ; 12.00	0.00 ; 12.00
Visit 6 (Week 4)		
N	218	105
Mean (SD)	0.34 (0.85)	0.52 (2.34)
Median	0.25	0.17
Min ; Max	0.00 ; 12.00	0.00 ; 24.00
Visit 8 (Week 6)		
N	218	97
Mean (SD)	0.40 (1.66)	0.58 (3.03)
Median	0.20	0.17
Min ; Max	0.00 ; 24.00	0.00 ; 30.02
Visit 10 (Week 8)		
N	193	102
Mean (SD)	0.31 (0.40)	0.31 (0.39)
Median	0.17	0.17
Min ; Max	0.00 ; 3.00	0.00 ; 2.00
Visit 12 (Week 10)		
N	187	100
Mean (SD)	0.34 (0.65)	0.27 (0.24)
Median	0.17	0.17
Min ; Max	0.00 ; 6.00	0.02 ; 1.33

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:52 - t_hypoquest_4to7_descp.sas/t_hypoquest_4to7_descp_fas.txt

Hypoglycaemic Questionnaire - Question 4 to 7 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD	IDet
Time to recover from the hypo. (hr)		
Visit 14 (Week 12)		
N	188	105
Mean (SD)	0.41 (1.76)	0.33 (0.42)
Median	0.17	0.17
Min ; Max	0.00 ; 24.00	0.00 ; 2.25
Visit 16 (Week 14)		
N	183	98
Mean (SD)	0.43 (1.92)	0.28 (0.35)
Median	0.17	0.17
Min ; Max	0.00 ; 25.50	0.00 ; 2.00
Visit 18 (Week 16)		
N	200	92
Mean (SD)	0.43 (1.74)	0.35 (0.67)
Median	0.17	0.17
Min ; Max	0.00 ; 24.00	0.00 ; 6.00
Visit 22 (Week 20)		
N	193	92
Mean (SD)	0.27 (0.26)	0.38 (0.77)
Median	0.17	0.17
Min ; Max	0.00 ; 2.00	0.00 ; 6.00
Visit 26 (Week 24)		
N	173	85
Mean (SD)	0.24 (0.21)	0.80 (3.46)
Median	0.17	0.25
Min ; Max	0.00 ; 1.50	0.00 ; 30.00
Visit 28 (Week 26)		
N	177	101
Mean (SD)	0.52 (3.60)	0.36 (1.03)
Median	0.17	0.17
Min ; Max	0.00 ; 48.00	0.00 ; 10.00
Visit 29 (Week 27)		
N	149	85
Mean (SD)	0.52 (2.12)	0.27 (0.23)
Median	0.17	0.17
Min ; Max	0.00 ; 24.00	0.00 ; 1.00

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:52 - t_hypoquest_4to7_descp.sas/t_hypoquest_4to7_descp_fas.txt

14.2.155: Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Number of Subjects	366	182
Number of extra blood sugar tests		
Visit 2 (Week 0)		
The 1st Day		
1	59 (16.1)	30 (16.5)
2	32 (8.7)	11 (6.0)
3	13 (3.6)	6 (3.3)
4	6 (1.6)	3 (1.6)
>=5	1 (0.3)	2 (1.1)
The 2nd Day		
1	4 (1.1)	0
2	3 (0.8)	1 (0.5)
3	1 (0.3)	4 (2.2)
4	2 (0.5)	0
>=5	0	2 (1.1)
The 3rd Day		
1	2 (0.5)	0
2	1 (0.3)	1 (0.5)
3	1 (0.3)	1 (0.5)
4	1 (0.3)	0
>=5	0	0
The 4th Day		
1	1 (0.3)	0
2	0	0
3	2 (0.5)	0
4	1 (0.3)	0
>=5	0	0
The 5th Day		
1	2 (0.5)	0
2	1 (0.3)	0
3	0	0
4	1 (0.3)	0
>=5	0	0
The 6th Day		
1	1 (0.3)	0
2	1 (0.3)	0
3	0	0
4	1 (0.3)	0
>=5	0	0
The 7th Day		
1	2 (0.5)	0
2	1 (0.3)	0
3	0	0
4	1 (0.3)	0
>=5	0	0

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 3 (Week 1)		
The 1st Day		
1	66 (18.0)	25 (13.7)
2	41 (11.2)	18 (9.9)
3	12 (3.3)	2 (1.1)
4	11 (3.0)	4 (2.2)
>=5	2 (0.5)	3 (1.6)
The 2nd Day		
1	4 (1.1)	2 (1.1)
2	11 (3.0)	1 (0.5)
3	2 (0.5)	0
4	3 (0.8)	0
>=5	0	2 (1.1)
The 3rd Day		
1	2 (0.5)	0
2	3 (0.8)	0
3	2 (0.5)	0
4	0	0
>=5	0	1 (0.5)
The 4th Day		
1	1 (0.3)	0
2	1 (0.3)	0
3	0	0
4	0	0
>=5	0	0
The 5th Day		
1	1 (0.3)	0
2	2 (0.5)	0
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	2 (0.5)	0
2	0	0
3	1 (0.3)	0
4	0	0
>=5	0	0
The 7th Day		
1	2 (0.5)	0
2	0	0
3	2 (0.5)	0
4	0	0
>=5	0	0
Visit 4 (Week 2)		
The 1st Day		
1	65 (17.8)	22 (12.1)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 4 (Week 2)		
The 1st Day		
2	28 (7.7)	13 (7.1)
3	19 (5.2)	5 (2.7)
4	4 (1.1)	4 (2.2)
>=5	5 (1.4)	4 (2.2)
The 2nd Day		
1	3 (0.8)	1 (0.5)
2	2 (0.5)	2 (1.1)
3	6 (1.6)	0
4	2 (0.5)	0
>=5	0	2 (1.1)
The 3rd Day		
1	1 (0.3)	0
2	3 (0.8)	1 (0.5)
3	1 (0.3)	1 (0.5)
4	0	0
>=5	0	1 (0.5)
The 4th Day		
1	0	1 (0.5)
2	3 (0.8)	0
3	0	0
4	0	1 (0.5)
>=5	0	0
The 5th Day		
1	3 (0.8)	1 (0.5)
2	0	0
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	3 (0.8)	1 (0.5)
2	0	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	3 (0.8)	1 (0.5)
2	0	0
3	1 (0.3)	0
4	0	0
>=5	0	0
Visit 6 (Week 4)		
The 1st Day		
1	57 (15.6)	26 (14.3)
2	28 (7.7)	12 (6.6)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 6 (Week 4)		
The 1st Day		
3	13 (3.6)	7 (3.8)
4	9 (2.5)	4 (2.2)
>=5	2 (0.5)	3 (1.6)
The 2nd Day		
1	2 (0.5)	0
2	1 (0.3)	0
3	6 (1.6)	2 (1.1)
4	3 (0.8)	1 (0.5)
>=5	0	0
The 3rd Day		
1	0	0
2	3 (0.8)	1 (0.5)
3	2 (0.5)	0
4	1 (0.3)	1 (0.5)
>=5	0	0
The 4th Day		
1	0	0
2	4 (1.1)	1 (0.5)
3	1 (0.3)	0
4	0	0
>=5	0	0
The 5th Day		
1	2 (0.5)	1 (0.5)
2	2 (0.5)	0
3	1 (0.3)	0
4	0	0
>=5	0	0
The 6th Day		
1	4 (1.1)	1 (0.5)
2	1 (0.3)	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	5 (1.4)	1 (0.5)
2	0	0
3	0	0
4	0	0
>=5	0	0
Visit 8 (Week 6)		
The 1st Day		
1	53 (14.5)	27 (14.8)
2	31 (8.5)	9 (4.9)
3	16 (4.4)	5 (2.7)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 8 (Week 6)		
The 1st Day		
4	9 (2.5)	3 (1.6)
>=5	4 (1.1)	1 (0.5)
The 2nd Day		
1	2 (0.5)	2 (1.1)
2	5 (1.4)	2 (1.1)
3	4 (1.1)	0
4	2 (0.5)	1 (0.5)
>=5	0	0
The 3rd Day		
1	1 (0.3)	0
2	4 (1.1)	1 (0.5)
3	3 (0.8)	0
4	0	0
>=5	0	0
The 4th Day		
1	1 (0.3)	0
2	3 (0.8)	1 (0.5)
3	1 (0.3)	0
4	0	0
>=5	0	0
The 5th Day		
1	3 (0.8)	1 (0.5)
2	2 (0.5)	0
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	4 (1.1)	1 (0.5)
2	1 (0.3)	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	4 (1.1)	1 (0.5)
2	1 (0.3)	0
3	0	0
4	0	0
>=5	1 (0.3)	0
Visit 10 (Week 8)		
The 1st Day		
1	42 (11.5)	24 (13.2)
2	30 (8.2)	17 (9.3)
3	16 (4.4)	6 (3.3)
4	6 (1.6)	5 (2.7)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 10 (Week 8)		
The 1st Day		
>=5	4 (1.1)	3 (1.6)
The 2nd Day		
1	1 (0.3)	0
2	5 (1.4)	0
3	2 (0.5)	5 (2.7)
4	0	0
>=5	0	1 (0.5)
The 3rd Day		
1	0	0
2	4 (1.1)	3 (1.6)
3	0	0
4	0	0
>=5	0	0
The 4th Day		
1	2 (0.5)	0
2	1 (0.3)	2 (1.1)
3	0	0
4	0	0
>=5	0	0
The 5th Day		
1	2 (0.5)	2 (1.1)
2	1 (0.3)	0
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	3 (0.8)	2 (1.1)
2	0	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	3 (0.8)	2 (1.1)
2	0	0
3	0	0
4	0	0
>=5	0	0
Visit 12 (Week 10)		
The 1st Day		
1	48 (13.1)	28 (15.4)
2	25 (6.8)	8 (4.4)
3	7 (1.9)	7 (3.8)
4	6 (1.6)	2 (1.1)
>=5	5 (1.4)	2 (1.1)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 12 (Week 10)		
The 2nd Day		
1	2 (0.5)	1 (0.5)
2	4 (1.1)	3 (1.6)
3	2 (0.5)	4 (2.2)
4	1 (0.3)	0
>=5	1 (0.3)	0
The 3rd Day		
1	2 (0.5)	0
2	2 (0.5)	2 (1.1)
3	1 (0.3)	3 (1.6)
4	0	0
>=5	0	0
The 4th Day		
1	2 (0.5)	2 (1.1)
2	2 (0.5)	0
3	0	0
4	0	0
>=5	0	0
The 5th Day		
1	3 (0.8)	1 (0.5)
2	1 (0.3)	1 (0.5)
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	4 (1.1)	2 (1.1)
2	0	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	4 (1.1)	2 (1.1)
2	0	0
3	0	0
4	0	0
>=5	0	0
Visit 14 (Week 12)		
The 1st Day		
1	53 (14.5)	23 (12.6)
2	21 (5.7)	12 (6.6)
3	18 (4.9)	8 (4.4)
4	5 (1.4)	2 (1.1)
>=5	2 (0.5)	2 (1.1)
The 2nd Day		
1	0	2 (1.1)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 14 (Week 12)		
The 2nd Day		
2	3 (0.8)	2 (1.1)
3	3 (0.8)	2 (1.1)
4	1 (0.3)	0
>=5	0	0
The 3rd Day		
1	1 (0.3)	0
2	2 (0.5)	2 (1.1)
3	1 (0.3)	1 (0.5)
4	0	0
>=5	0	0
The 4th Day		
1	1 (0.3)	0
2	2 (0.5)	0
3	0	0
4	0	0
>=5	0	0
The 5th Day		
1	1 (0.3)	0
2	2 (0.5)	0
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	3 (0.8)	0
2	0	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	3 (0.8)	0
2	0	0
3	0	0
4	0	0
>=5	0	0
Visit 16 (Week 14)		
The 1st Day		
1	40 (10.9)	22 (12.1)
2	27 (7.4)	15 (8.2)
3	15 (4.1)	5 (2.7)
4	5 (1.4)	3 (1.6)
>=5	3 (0.8)	1 (0.5)
The 2nd Day		
1	5 (1.4)	2 (1.1)
2	1 (0.3)	3 (1.6)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 16 (Week 14)		
The 2nd Day		
3	6 (1.6)	1 (0.5)
4	2 (0.5)	0
>=5	0	0
The 3rd Day		
1	0	1 (0.5)
2	5 (1.4)	3 (1.6)
3	1 (0.3)	0
4	0	0
>=5	0	0
The 4th Day		
1	1 (0.3)	1 (0.5)
2	4 (1.1)	1 (0.5)
3	1 (0.3)	0
4	0	0
>=5	0	0
The 5th Day		
1	4 (1.1)	1 (0.5)
2	2 (0.5)	1 (0.5)
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	4 (1.1)	1 (0.5)
2	2 (0.5)	1 (0.5)
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	4 (1.1)	1 (0.5)
2	2 (0.5)	1 (0.5)
3	0	0
4	0	0
>=5	0	0
Visit 18 (Week 16)		
The 1st Day		
1	51 (13.9)	28 (15.4)
2	31 (8.5)	13 (7.1)
3	11 (3.0)	6 (3.3)
4	9 (2.5)	0
>=5	4 (1.1)	3 (1.6)
The 2nd Day		
1	2 (0.5)	3 (1.6)
2	3 (0.8)	4 (2.2)
3	2 (0.5)	1 (0.5)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 18 (Week 16)		
The 2nd Day		
4	3 (0.8)	0
>=5	0	0
The 3rd Day		
1	1 (0.3)	1 (0.5)
2	3 (0.8)	1 (0.5)
3	3 (0.8)	0
4	0	0
>=5	0	0
The 4th Day		
1	2 (0.5)	1 (0.5)
2	3 (0.8)	0
3	0	0
4	0	0
>=5	0	0
The 5th Day		
1	3 (0.8)	1 (0.5)
2	1 (0.3)	0
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	3 (0.8)	1 (0.5)
2	1 (0.3)	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	4 (1.1)	0
2	0	0
3	0	0
4	0	0
>=5	0	0
Visit 22 (Week 20)		
The 1st Day		
1	53 (14.5)	18 (9.9)
2	29 (7.9)	15 (8.2)
3	12 (3.3)	1 (0.5)
4	6 (1.6)	3 (1.6)
>=5	2 (0.5)	2 (1.1)
The 2nd Day		
1	6 (1.6)	2 (1.1)
2	5 (1.4)	4 (2.2)
3	1 (0.3)	0
4	1 (0.3)	0

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 22 (Week 20)		
The 2nd Day		
>=5	0	1 (0.5)
The 3rd Day		
1	5 (1.4)	3 (1.6)
2	3 (0.8)	0
3	1 (0.3)	0
4	0	0
>=5	0	0
The 4th Day		
1	3 (0.8)	0
2	2 (0.5)	0
3	1 (0.3)	0
4	0	0
>=5	0	0
The 5th Day		
1	1 (0.3)	0
2	3 (0.8)	0
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	2 (0.5)	0
2	2 (0.5)	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	2 (0.5)	0
2	2 (0.5)	0
3	0	0
4	0	0
>=5	0	0
Visit 26 (Week 24)		
The 1st Day		
1	46 (12.6)	21 (11.5)
2	30 (8.2)	13 (7.1)
3	8 (2.2)	5 (2.7)
4	2 (0.5)	1 (0.5)
>=5	0	1 (0.5)
The 2nd Day		
1	3 (0.8)	2 (1.1)
2	3 (0.8)	2 (1.1)
3	0	2 (1.1)
4	0	0
>=5	0	0

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
- Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 26 (Week 24)		
The 3rd Day		
1	1 (0.3)	1 (0.5)
2	1 (0.3)	1 (0.5)
3	0	1 (0.5)
4	0	0
>=5	0	0
The 4th Day		
1	1 (0.3)	0
2	0	0
3	0	1 (0.5)
4	0	0
>=5	0	0
The 5th Day		
1	1 (0.3)	0
2	0	1 (0.5)
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	0	1 (0.5)
2	0	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	0	1 (0.5)
2	0	0
3	0	0
4	0	0
>=5	0	0
Visit 28 (Week 26)		
The 1st Day		
1	39 (10.7)	18 (9.9)
2	22 (6.0)	15 (8.2)
3	10 (2.7)	4 (2.2)
4	2 (0.5)	5 (2.7)
>=5	5 (1.4)	2 (1.1)
The 2nd Day		
1	5 (1.4)	0
2	2 (0.5)	3 (1.6)
3	2 (0.5)	0
4	2 (0.5)	1 (0.5)
>=5	0	0
The 3rd Day		
1	1 (0.3)	0

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
 - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 28 (Week 26)		
The 3rd Day		
2	2 (0.5)	1 (0.5)
3	2 (0.5)	0
4	0	0
>=5	0	1 (0.5)
The 4th Day		
1	1 (0.3)	1 (0.5)
2	1 (0.3)	0
3	0	0
4	0	1 (0.5)
>=5	0	0
The 5th Day		
1	0	0
2	1 (0.3)	0
3	0	0
4	0	0
>=5	0	0
The 6th Day		
1	0	0
2	1 (0.3)	0
3	0	0
4	0	0
>=5	0	0
The 7th Day		
1	0	0
2	1 (0.3)	0
3	0	0
4	0	0
>=5	0	0
Visit 29 (Week 27)		
The 1st Day		
1	43 (11.7)	30 (16.5)
2	19 (5.2)	14 (7.7)
3	10 (2.7)	4 (2.2)
4	3 (0.8)	0
>=5	0	1 (0.5)
The 2nd Day		
1	3 (0.8)	2 (1.1)
2	4 (1.1)	0
3	0	0
4	1 (0.3)	0
>=5	1 (0.3)	0
The 3rd Day		
1	2 (0.5)	1 (0.5)
2	0	0

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

Hypoglycaemic Questionnaire - Question 8 by Treatment Week - Descriptive Statistics
 - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 29 (Week 27)		
The 3rd Day		
3	0	0
4	1 (0.3)	0
>=5	0	0
The 4th Day		
1	1 (0.3)	0
2	0	0
3	0	0
4	1 (0.3)	0
>=5	0	0
The 5th Day		
1	0	0
2	0	0
3	1 (0.3)	0
4	0	0
>=5	0	0
The 6th Day		
1	0	0
2	0	0
3	1 (0.3)	0
4	0	0
>=5	0	0
The 7th Day		
1	1 (0.3)	0
2	0	0
3	0	0
4	0	0
>=5	0	0

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:17:54 - t_hypoquest_8_descp.sas/t_hypoquest_8_descp_fas.txt

14.2.156: Hypoglycaemic Questionnaire - Question 9 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Number of Subjects	366	182
Contact to HC Prof after hypo		
Visit 2 (Week 0)		
No, I Did Not Contact Any Health Care Professionals	206 (56.3)	102 (56.0)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	0	1 (0.5)
Yes, Other Health Care Professional	0	1 (0.5)
Visit 3 (Week 1)		
No, I Did Not Contact Any Health Care Professionals	221 (60.4)	95 (52.2)
Yes, The Hospital Or Diabetes Clinic	3 (0.8)	3 (1.6)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	3 (0.8)	3 (1.6)
Yes, Other Health Care Professional	3 (0.8)	1 (0.5)
Visit 4 (Week 2)		
No, I Did Not Contact Any Health Care Professionals	218 (59.6)	97 (53.3)
Yes, The Hospital Or Diabetes Clinic	3 (0.8)	1 (0.5)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	1 (0.3)	1 (0.5)
Yes, Other Health Care Professional	1 (0.3)	1 (0.5)
Visit 6 (Week 4)		
No, I Did Not Contact Any Health Care Professionals	214 (58.5)	107 (58.8)
Yes, The Hospital Or Diabetes Clinic	4 (1.1)	0
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	2 (0.5)	1 (0.5)
Yes, Other Health Care Professional	3 (0.8)	0
Visit 8 (Week 6)		
No, I Did Not Contact Any Health Care Professionals	224 (61.2)	99 (54.4)
Yes, The Hospital Or Diabetes Clinic	1 (0.3)	1 (0.5)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	1 (0.3)	0
Yes, Other Health Care Professional	1 (0.3)	1 (0.5)
Visit 10 (Week 8)		
No, I Did Not Contact Any Health Care Professionals	200 (54.6)	102 (56.0)
Yes, The Hospital Or Diabetes Clinic	1 (0.3)	1 (0.5)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	2 (0.5)	2 (1.1)
Yes, Other Health Care Professional	0	1 (0.5)
Visit 12 (Week 10)		
No, I Did Not Contact Any Health Care Professionals	189 (51.6)	99 (54.4)
Yes, The Hospital Or Diabetes Clinic	0	1 (0.5)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	1 (0.3)	2 (1.1)
Yes, Other Health Care Professional	1 (0.3)	0
Visit 14 (Week 12)		
No, I Did Not Contact Any Health Care Professionals	191 (52.2)	106 (58.2)
Yes, The Hospital Or Diabetes Clinic	1 (0.3)	0
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	2 (0.5)	0
Visit 16 (Week 14)		
No, I Did Not Contact Any Health Care Professionals	187 (51.1)	103 (56.6)
Yes, The Hospital Or Diabetes Clinic	1 (0.3)	0

Hypoglycaemic Questionnaire - Question 9 by Treatment Week
- Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 16 (Week 14)		
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	1 (0.3)	2 (1.1)
Yes, Other Health Care Professional	1 (0.3)	0
Visit 18 (Week 16)		
No, I Did Not Contact Any Health Care Professionals	200 (54.6)	100 (54.9)
Yes, The Hospital Or Diabetes Clinic	1 (0.3)	1 (0.5)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	1 (0.3)	0
Yes, Other Health Care Professional	1 (0.3)	0
Visit 22 (Week 20)		
No, I Did Not Contact Any Health Care Professionals	197 (53.8)	92 (50.5)
Yes, The Hospital Or Diabetes Clinic	2 (0.5)	2 (1.1)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	1 (0.3)	1 (0.5)
Visit 26 (Week 24)		
No, I Did Not Contact Any Health Care Professionals	180 (49.2)	86 (47.3)
Yes, The Hospital Or Diabetes Clinic	0	1 (0.5)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	1 (0.3)	0
Visit 28 (Week 26)		
No, I Did Not Contact Any Health Care Professionals	179 (48.9)	104 (57.1)
Yes, The Hospital Or Diabetes Clinic	1 (0.3)	1 (0.5)
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	1 (0.3)	0
Yes, Other Health Care Professional	1 (0.3)	0
Visit 29 (Week 27)		
No, I Did Not Contact Any Health Care Professionals	151 (41.3)	84 (46.2)
Yes, The Hospital Or Diabetes Clinic	2 (0.5)	0
Yes, My Primary Care Doctor (E.G. GP, Family Physician)	1 (0.3)	0
Yes, Other Health Care Professional	0	1 (0.5)

14.2.157: Hypoglycaemic Questionnaire - Question 10 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Number of Subjects	366	182
Impact to carry out usual activities		
Visit 2 (Week 0)		
0	115 (31.4)	50 (27.5)
1	36 (9.8)	15 (8.2)
2	19 (5.2)	14 (7.7)
3	13 (3.6)	11 (6.0)
4	7 (1.9)	5 (2.7)
5	4 (1.1)	2 (1.1)
6	1 (0.3)	3 (1.6)
7	3 (0.8)	2 (1.1)
8	6 (1.6)	1 (0.5)
9	2 (0.5)	0
10	0	1 (0.5)
Visit 3 (Week 1)		
0	101 (27.6)	49 (26.9)
1	50 (13.7)	15 (8.2)
2	29 (7.9)	11 (6.0)
3	14 (3.8)	8 (4.4)
4	13 (3.6)	6 (3.3)
5	10 (2.7)	3 (1.6)
6	3 (0.8)	1 (0.5)
7	3 (0.8)	4 (2.2)
8	5 (1.4)	3 (1.6)
9	2 (0.5)	1 (0.5)
10	2 (0.5)	3 (1.6)
Visit 4 (Week 2)		
0	96 (26.2)	55 (30.2)
1	40 (10.9)	16 (8.8)
2	37 (10.1)	4 (2.2)
3	12 (3.3)	5 (2.7)
4	10 (2.7)	8 (4.4)
5	6 (1.6)	5 (2.7)
6	6 (1.6)	0
7	3 (0.8)	4 (2.2)
8	8 (2.2)	2 (1.1)
9	0	1 (0.5)
10	4 (1.1)	0
Visit 5 (Week 3)		
0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0

N: Number of Subjects, %: Percentage of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:45 - t_hypoquest_13_14_descp/t_hypoquest_10_descp_fas.txt

Hypoglycaemic Questionnaire - Question 10 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
8	0	0
9	0	0
10	0	0
Visit 6 (Week 4)		
0	101 (27.6)	56 (30.8)
1	54 (14.8)	17 (9.3)
2	21 (5.7)	7 (3.8)
3	17 (4.6)	14 (7.7)
4	5 (1.4)	4 (2.2)
5	10 (2.7)	4 (2.2)
6	4 (1.1)	2 (1.1)
7	2 (0.5)	1 (0.5)
8	3 (0.8)	3 (1.6)
9	2 (0.5)	0
10	5 (1.4)	0
Visit 7 (Week 5)		
0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 8 (Week 6)		
0	112 (30.6)	57 (31.3)
1	45 (12.3)	19 (10.4)
2	35 (9.6)	5 (2.7)
3	13 (3.6)	4 (2.2)
4	10 (2.7)	3 (1.6)
5	3 (0.8)	8 (4.4)
6	5 (1.4)	4 (2.2)
7	3 (0.8)	1 (0.5)
8	3 (0.8)	2 (1.1)
9	0	0
10	0	0
Visit 9 (Week 7)		
0	0	0
1	1 (0.3)	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	1 (0.3)	0

N: Number of Subjects, %: Percentage of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:45 - t_hypoquest_13_14_descp/t_hypoquest_10_descp_fas.txt

Hypoglycaemic Questionnaire - Question 10 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
10	0	0
Visit 10 (Week 8)		
0	89 (24.3)	55 (30.2)
1	38 (10.4)	17 (9.3)
2	28 (7.7)	12 (6.6)
3	16 (4.4)	7 (3.8)
4	12 (3.3)	2 (1.1)
5	13 (3.6)	10 (5.5)
6	3 (0.8)	3 (1.6)
7	0	0
8	2 (0.5)	0
9	2 (0.5)	0
10	0	0
Visit 11 (Week 9)		
0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 12 (Week 10)		
0	78 (21.3)	55 (30.2)
1	47 (12.8)	16 (8.8)
2	22 (6.0)	10 (5.5)
3	14 (3.8)	7 (3.8)
4	10 (2.7)	7 (3.8)
5	7 (1.9)	3 (1.6)
6	3 (0.8)	2 (1.1)
7	5 (1.4)	2 (1.1)
8	1 (0.3)	1 (0.5)
9	2 (0.5)	0
10	3 (0.8)	0
Visit 13 (Week 11)		
0	1 (0.3)	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0

N: Number of Subjects, %: Percentage of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:45 - t_hypoquest_13_14_descp/t_hypoquest_10_descp_fas.txt

Hypoglycaemic Questionnaire - Question 10 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Visit 14 (Week 12)		
0	93 (25.4)	49 (26.9)
1	42 (11.5)	25 (13.7)
2	19 (5.2)	9 (4.9)
3	6 (1.6)	8 (4.4)
4	13 (3.6)	4 (2.2)
5	9 (2.5)	5 (2.7)
6	3 (0.8)	2 (1.1)
7	4 (1.1)	1 (0.5)
8	6 (1.6)	2 (1.1)
9	1 (0.3)	0
10	1 (0.3)	2 (1.1)
Visit 15 (Week 13)		
0	0	1 (0.5)
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 16 (Week 14)		
0	80 (21.9)	53 (29.1)
1	42 (11.5)	22 (12.1)
2	27 (7.4)	15 (8.2)
3	16 (4.4)	6 (3.3)
4	9 (2.5)	1 (0.5)
5	8 (2.2)	4 (2.2)
6	2 (0.5)	3 (1.6)
7	0	1 (0.5)
8	2 (0.5)	1 (0.5)
9	2 (0.5)	0
10	1 (0.3)	0
Visit 17 (Week 15)		
0	0	0
1	0	1 (0.5)
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 18 (Week 16)		
0	103 (28.1)	53 (29.1)

N: Number of Subjects, %: Percentage of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:45 - t_hypoquest_13_14_descp/t_hypoquest_10_descp_fas.txt

Hypoglycaemic Questionnaire - Question 10 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
1	41 (11.2)	16 (8.8)
2	27 (7.4)	14 (7.7)
3	14 (3.8)	9 (4.9)
4	6 (1.6)	1 (0.5)
5	5 (1.4)	3 (1.6)
6	7 (1.9)	2 (1.1)
7	2 (0.5)	1 (0.5)
8	3 (0.8)	0
9	0	1 (0.5)
10	1 (0.3)	0
Visit 19 (Week 17)		
0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 20 (Week 18)		
0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 21 (Week 19)		
0	0	0
1	0	0
2	0	1 (0.5)
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	1 (0.3)	0
Visit 22 (Week 20)		
0	77 (21.0)	44 (24.2)
1	52 (14.2)	22 (12.1)
2	29 (7.9)	12 (6.6)

N: Number of Subjects, %: Percentage of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:45 - t_hypoquest_13_14_descp/t_hypoquest_10_descp_fas.txt

Hypoglycaemic Questionnaire - Question 10 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
3	19 (5.2)	6 (3.3)
4	6 (1.6)	2 (1.1)
5	6 (1.6)	4 (2.2)
6	1 (0.3)	3 (1.6)
7	6 (1.6)	1 (0.5)
8	2 (0.5)	0
9	1 (0.3)	1 (0.5)
10	1 (0.3)	1 (0.5)
Visit 23 (Week 21)		
0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 24 (Week 22)		
0	0	0
1	0	0
2	0	1 (0.5)
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 25 (Week 23)		
0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 26 (Week 24)		
0	76 (20.8)	41 (22.5)
1	45 (12.3)	17 (9.3)
2	28 (7.7)	10 (5.5)
3	10 (2.7)	6 (3.3)
4	10 (2.7)	6 (3.3)

N: Number of Subjects, %: Percentage of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:45 - t_hypoquest_13_14_descp/t_hypoquest_10_descp_fas.txt

Hypoglycaemic Questionnaire - Question 10 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
5	6 (1.6)	3 (1.6)
6	3 (0.8)	3 (1.6)
7	3 (0.8)	0
8	0	1 (0.5)
9	0	1 (0.5)
10	0	0
Visit 27 (Week 25)		
0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Visit 28 (Week 26)		
0	90 (24.6)	45 (24.7)
1	34 (9.3)	26 (14.3)
2	14 (3.8)	11 (6.0)
3	15 (4.1)	7 (3.8)
4	5 (1.4)	3 (1.6)
5	3 (0.8)	3 (1.6)
6	3 (0.8)	0
7	4 (1.1)	1 (0.5)
8	2 (0.5)	0
9	0	0
10	1 (0.3)	1 (0.5)
Visit 29 (Week 27)		
0	69 (18.9)	37 (20.3)
1	38 (10.4)	21 (11.5)
2	20 (5.5)	6 (3.3)
3	11 (3.0)	8 (4.4)
4	2 (0.5)	5 (2.7)
5	4 (1.1)	3 (1.6)
6	2 (0.5)	2 (1.1)
7	2 (0.5)	1 (0.5)
8	2 (0.5)	2 (1.1)
9	0	0
10	2 (0.5)	0

N: Number of Subjects, %: Percentage of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:17:45 - t_hypoquest_13_14_descp/t_hypoquest_10_descp_fas.txt

14.2.158: Hypoglycaemic Questionnaire - Question 11 to 12 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Number of Subjects	366	182
Visit 2 (Week 0)		
Late to work or leave early due to hypo		
Yes	4 (2.8)	1 (1.4)
No	114 (79.2)	52 (74.3)
NA	26 (18.1)	17 (24.3)
Amount work time loss due to hypo. (hr)		
N	6	0
Mean (SD)	0.5 (0.6)	
Median	0.2	
Min ; Max	0.0 ; 1.5	
Miss meeting or work appointment		
Yes	3 (2.1)	1 (1.4)
No	116 (80.0)	52 (74.3)
NA	26 (17.9)	17 (24.3)
Amount app. time loss due to hypo (hr)		
N	2	0
Mean (SD)	27.0 (4.2)	
Median	27.0	
Min ; Max	24.0 ; 30.0	
Visit 3 (Week 1)		
Late to work or leave early due to hypo		
Yes	5 (3.1)	1 (1.4)
No	126 (79.2)	45 (65.2)
NA	28 (17.6)	23 (33.3)
Amount work time loss due to hypo. (hr)		
N	3	1
Mean (SD)	0.4 (0.1)	5.0 ()
Median	0.5	5.0
Min ; Max	0.3 ; 0.5	5.0 ; 5.0
Miss meeting or work appointment		
Yes	6 (3.7)	2 (2.9)
No	123 (76.4)	43 (63.2)
NA	32 (19.9)	23 (33.8)
Amount app. time loss due to hypo (hr)		
N	4	1
Mean (SD)	0.6 (0.3)	0.3 ()
Median	0.5	0.3
Min ; Max	0.5 ; 1.0	0.3 ; 0.3
Visit 4 (Week 2)		
Late to work or leave early due to hypo		

NA: Not relevant (e.g. during weekend).

The denominator for the percentage calculations are the sum of Yes, No and NA.

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:13:17:39 - t_hypoquest_11to12_descp_fas.sas/t_hypoquest_11to12_descp_fas.txt

Hypoglycaemic Questionnaire - Question 11 to 12 by Treatment Week
- Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Yes	2 (1.3)	0
No	129 (81.6)	49 (71.0)
NA	27 (17.1)	20 (29.0)
Amount work time loss due to hypo. (hr)		
N	2	0
Mean (SD)	12.5 (16.3)	
Median	12.5	
Min ; Max	1.0 ; 24.0	
Miss meeting or work appointment		
Yes	5 (3.2)	1 (1.4)
No	129 (81.6)	49 (71.0)
NA	24 (15.2)	19 (27.5)
Amount app. time loss due to hypo (hr)		
N	5	1
Mean (SD)	15.9 (20.4)	2.0 ()
Median	6.0	2.0
Min ; Max	0.3 ; 48.0	2.0 ; 2.0
Visit 6 (Week 4)		
Late to work or leave early due to hypo		
Yes	3 (2.0)	1 (1.4)
No	114 (76.5)	53 (73.6)
NA	32 (21.5)	18 (25.0)
Amount work time loss due to hypo. (hr)		
N	3	0
Mean (SD)	1.8 (0.6)	
Median	1.5	
Min ; Max	1.5 ; 2.5	
Miss meeting or work appointment		
Yes	4 (2.6)	0
No	116 (75.8)	53 (74.6)
NA	33 (21.6)	18 (25.4)
Amount app. time loss due to hypo (hr)		
N	3	0
Mean (SD)	32.8 (54.8)	
Median	1.5	
Min ; Max	0.8 ; 96.0	
Visit 8 (Week 6)		
Late to work or leave early due to hypo		
Yes	2 (1.3)	3 (4.2)
No	118 (75.6)	45 (62.5)
NA	36 (23.1)	24 (33.3)
Amount work time loss due to hypo. (hr)		
N	1	2

NA: Not relevant (e.g. during weekend).

The denominator for the percentage calculations are the sum of Yes, No and NA.

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:13:17:39 - t_hypoquest_11to12_descp_fas.sas/t_hypoquest_11to12_descp_fas.txt

Hypoglycaemic Questionnaire - Question 11 to 12 by Treatment Week
- Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Mean (SD)	4.0 ()	0.3 (0.1)
Median	4.0	0.3
Min ; Max	4.0 ; 4.0	0.3 ; 0.3
Miss meeting or work appointment		
Yes	2 (1.3)	0
No	119 (76.3)	48 (66.7)
NA	35 (22.4)	24 (33.3)
Amount app. time loss due to hypo (hr)		
N	2	0
Mean (SD)	2.3 (2.5)	
Median	2.3	
Min ; Max	0.5 ; 4.0	
Visit 10 (Week 8)		
Late to work or leave early due to hypo		
Yes	1 (0.7)	0
No	112 (78.9)	48 (65.8)
NA	29 (20.4)	25 (34.2)
Amount work time loss due to hypo. (hr)		
N	1	0
Mean (SD)	0.5 ()	
Median	0.5	
Min ; Max	0.5 ; 0.5	
Miss meeting or work appointment		
Yes	1 (0.7)	1 (1.4)
No	111 (78.7)	47 (65.3)
NA	29 (20.6)	24 (33.3)
Amount app. time loss due to hypo (hr)		
N	1	2
Mean (SD)	1.0 ()	0.4 (0.2)
Median	1.0	0.4
Min ; Max	1.0 ; 1.0	0.3 ; 0.6
Visit 12 (Week 10)		
Late to work or leave early due to hypo		
Yes	7 (5.4)	3 (3.8)
No	95 (73.1)	53 (67.9)
NA	28 (21.5)	22 (28.2)
Amount work time loss due to hypo. (hr)		
N	4	2
Mean (SD)	1.0 (1.4)	0.4 (0.1)
Median	0.4	0.4
Min ; Max	0.2 ; 3.0	0.3 ; 0.5
Miss meeting or work appointment		
Yes	6 (4.7)	2 (2.6)

NA: Not relevant (e.g. during weekend).

The denominator for the percentage calculations are the sum of Yes, No and NA.

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:13:17:39 - t_hypoquest_11to12_descp_fas.sas/t_hypoquest_11to12_descp_fas.txt

Hypoglycaemic Questionnaire - Question 11 to 12 by Treatment Week
- Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
No	94 (74.0)	52 (67.5)
NA	27 (21.3)	23 (29.9)
Amount app. time loss due to hypo (hr)		
N	3	1
Mean (SD)	0.4 (0.1)	0.3 ()
Median	0.5	0.3
Min ; Max	0.3 ; 0.5	0.3 ; 0.3
Visit 14 (Week 12)		
Late to work or leave early due to hypo		
Yes	2 (1.5)	6 (7.5)
No	110 (81.5)	50 (62.5)
NA	23 (17.0)	24 (30.0)
Amount work time loss due to hypo. (hr)		
N	1	5
Mean (SD)	0.3 ()	14.8 (21.1)
Median	0.3	1.0
Min ; Max	0.3 ; 0.3	0.3 ; 48.0
Miss meeting or work appointment		
Yes	3 (2.2)	2 (2.5)
No	109 (80.1)	55 (68.8)
NA	24 (17.6)	23 (28.8)
Amount app. time loss due to hypo (hr)		
N	2	2
Mean (SD)	19.0 (15.6)	36.0 (17.0)
Median	19.0	36.0
Min ; Max	8.0 ; 30.0	24.0 ; 48.0
Visit 16 (Week 14)		
Late to work or leave early due to hypo		
Yes	2 (1.6)	2 (2.9)
No	91 (70.5)	53 (75.7)
NA	36 (27.9)	15 (21.4)
Amount work time loss due to hypo. (hr)		
N	0	0
Mean (SD)		
Median		
Min ; Max		
Miss meeting or work appointment		
Yes	4 (3.1)	3 (4.3)
No	92 (71.9)	51 (72.9)
NA	32 (25.0)	16 (22.9)
Amount app. time loss due to hypo (hr)		
N	2	2
Mean (SD)	15.3 (20.9)	0.4 (0.1)

NA: Not relevant (e.g. during weekend).

The denominator for the percentage calculations are the sum of Yes, No and NA.

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:13:17:39 - t_hypoquest_11to12_descp_fas.sas/t_hypoquest_11to12_descp_fas.txt

Hypoglycaemic Questionnaire - Question 11 to 12 by Treatment Week
- Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Median	15.3	0.4
Min ; Max	0.5 ; 30.0	0.3 ; 0.5
Visit 18 (Week 16)		
Late to work or leave early due to hypo		
Yes	2 (1.4)	3 (3.8)
No	112 (77.2)	58 (74.4)
NA	31 (21.4)	17 (21.8)
Amount work time loss due to hypo. (hr)		
N	3	2
Mean (SD)	3.2 (4.2)	0.4 (0.1)
Median	1.0	0.4
Min ; Max	0.5 ; 8.0	0.3 ; 0.5
Miss meeting or work appointment		
Yes	5 (3.4)	2 (2.6)
No	110 (75.9)	59 (76.6)
NA	30 (20.7)	16 (20.8)
Amount app. time loss due to hypo (hr)		
N	5	1
Mean (SD)	3.5 (6.4)	0.5 ()
Median	0.5	0.5
Min ; Max	0.5 ; 15.0	0.5 ; 0.5
Visit 22 (Week 20)		
Late to work or leave early due to hypo		
Yes	1 (0.7)	1 (1.5)
No	112 (81.8)	45 (66.2)
NA	24 (17.5)	22 (32.4)
Amount work time loss due to hypo. (hr)		
N	1	1
Mean (SD)	1.5 ()	1.0 ()
Median	1.5	1.0
Min ; Max	1.5 ; 1.5	1.0 ; 1.0
Miss meeting or work appointment		
Yes	1 (0.7)	1 (1.5)
No	112 (81.8)	45 (66.2)
NA	24 (17.5)	22 (32.4)
Amount app. time loss due to hypo (hr)		
N	1	1
Mean (SD)	0.5 ()	0.3 ()
Median	0.5	0.3
Min ; Max	0.5 ; 0.5	0.3 ; 0.3
Visit 26 (Week 24)		
Late to work or leave early due to hypo		
Yes	1 (0.9)	0

NA: Not relevant (e.g. during weekend).

The denominator for the percentage calculations are the sum of Yes, No and NA.

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:13:17:39 - t_hypoquest_11to12_descp_fas.sas/t_hypoquest_11to12_descp_fas.txt

Hypoglycaemic Questionnaire - Question 11 to 12 by Treatment Week
- Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
No	84 (73.7)	43 (67.2)
NA	29 (25.4)	21 (32.8)
Amount work time loss due to hypo. (hr)		
N	2	0
Mean (SD)	1.0 (1.4)	
Median	1.0	
Min ; Max	0.0 ; 2.0	
Miss meeting or work appointment		
Yes	2 (1.7)	1 (1.6)
No	83 (72.2)	42 (65.6)
NA	30 (26.1)	21 (32.8)
Amount app. time loss due to hypo (hr)		
N	3	0
Mean (SD)	8.1 (13.8)	
Median	0.2	
Min ; Max	0.0 ; 24.0	
Visit 28 (Week 26)		
Late to work or leave early due to hypo		
Yes	4 (3.3)	3 (3.9)
No	87 (71.3)	50 (65.8)
NA	31 (25.4)	23 (30.3)
Amount work time loss due to hypo. (hr)		
N	4	3
Mean (SD)	42.4 (83.7)	2.1 (2.6)
Median	0.8	1.0
Min ; Max	0.3 ; 168.0	0.3 ; 5.0
Miss meeting or work appointment		
Yes	3 (2.5)	2 (2.6)
No	88 (72.1)	52 (68.4)
NA	31 (25.4)	22 (28.9)
Amount app. time loss due to hypo (hr)		
N	2	2
Mean (SD)	15.5 (20.5)	5.0 (0.0)
Median	15.5	5.0
Min ; Max	1.0 ; 30.0	5.0 ; 5.0
Visit 29 (Week 27)		
Late to work or leave early due to hypo		
No	82 (75.2)	43 (70.5)
NA	27 (24.8)	18 (29.5)
Amount work time loss due to hypo. (hr)		
N	0	0
Mean (SD)		
Median		

NA: Not relevant (e.g. during weekend).

The denominator for the percentage calculations are the sum of Yes, No and NA.

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:13:17:39 - t_hypoquest_11to12_descp_fas.sas/t_hypoquest_11to12_descp_fas.txt

Hypoglycaemic Questionnaire - Question 11 to 12 by Treatment Week
 - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Min ; Max		
Miss meeting or work appointment		
Yes	1 (0.9)	1 (1.6)
No	82 (75.2)	43 (70.5)
NA	26 (23.9)	17 (27.9)
Amount app. time loss due to hypo (hr)		
N	1	1
Mean (SD)	1.5 ()	0.5 ()
Median	1.5	0.5
Min ; Max	1.5 ; 1.5	0.5 ; 0.5

NA: Not relevant (e.g. during weekend).

The denominator for the percentage calculations are the sum of Yes, No and NA.

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:13:17:39 - t_hypoquest_11to12_descp_fas.sas/t_hypoquest_11to12_descp_fas.txt

14.2.159: Hypoglycaemic Questionnaire - Question 13 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Number of Subjects	267	132
To What Extent Did This Hypo Affect Your Productivity At Work		
Visit 2 (Week 0)		
0	81 (30.3)	37 (28.0)
1	29 (10.9)	11 (8.3)
2	8 (3.0)	7 (5.3)
3	8 (3.0)	4 (3.0)
4	2 (0.7)	0
5	3 (1.1)	0
6	0	0
7	0	1 (0.8)
8	1 (0.4)	0
9	1 (0.4)	0
10	0	0
NA	0	0
Visit 3 (Week 1)		
0	87 (32.6)	36 (27.3)
1	29 (10.9)	11 (8.3)
2	14 (5.2)	4 (3.0)
3	4 (1.5)	1 (0.8)
4	5 (1.9)	0
5	2 (0.7)	0
6	2 (0.7)	0
7	3 (1.1)	2 (1.5)
8	0	0
9	0	0
10	2 (0.7)	0
NA	0	0
Visit 4 (Week 2)		
0	68 (25.5)	36 (27.3)
1	39 (14.6)	13 (9.8)
2	11 (4.1)	1 (0.8)
3	8 (3.0)	4 (3.0)
4	3 (1.1)	1 (0.8)
5	5 (1.9)	1 (0.8)
6	1 (0.4)	0
7	3 (1.1)	1 (0.8)
8	3 (1.1)	0
9	0	0
10	3 (1.1)	0
NA	1 (0.4)	0
Visit 6 (Week 4)		
0	66 (24.7)	31 (23.5)
1	29 (10.9)	15 (11.4)
2	12 (4.5)	6 (4.5)

N: Number of Subjects, %: Percentage of Subjects, NA: Not Applicable
 Number of Subjects are those with responses as only a subgroup has been asked
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:17:42 - t_hypoquest_13_14_descp/t_hypoquest_13_descp_fas.txt

Hypoglycaemic Questionnaire - Question 13 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
3	8 (3.0)	1 (0.8)
4	4 (1.5)	5 (3.8)
5	4 (1.5)	1 (0.8)
6	0	0
7	1 (0.4)	0
8	3 (1.1)	1 (0.8)
9	0	0
10	1 (0.4)	0
NA	0	0
Visit 8 (Week 6)		
0	76 (28.5)	33 (25.0)
1	30 (11.2)	12 (9.1)
2	10 (3.7)	3 (2.3)
3	3 (1.1)	2 (1.5)
4	5 (1.9)	0
5	4 (1.5)	4 (3.0)
6	2 (0.7)	1 (0.8)
7	1 (0.4)	0
8	1 (0.4)	0
9	1 (0.4)	0
10	0	0
NA	0	0
Visit 10 (Week 8)		
0	58 (21.7)	23 (17.4)
1	30 (11.2)	16 (12.1)
2	15 (5.6)	7 (5.3)
3	9 (3.4)	2 (1.5)
4	4 (1.5)	0
5	3 (1.1)	2 (1.5)
6	2 (0.7)	1 (0.8)
7	1 (0.4)	1 (0.8)
8	2 (0.7)	0
9	0	0
10	0	0
NA	0	0
Visit 12 (Week 10)		
0	56 (21.0)	33 (25.0)
1	31 (11.6)	19 (14.4)
2	7 (2.6)	5 (3.8)
3	7 (2.6)	1 (0.8)
4	2 (0.7)	2 (1.5)
5	0	2 (1.5)
6	0	1 (0.8)
7	1 (0.4)	0
8	1 (0.4)	0
9	1 (0.4)	0
10	2 (0.7)	0
NA	0	0
Visit 14 (Week 12)		

N: Number of Subjects, %: Percentage of Subjects, NA: Not Applicable

Number of Subjects are those with responses as only a subgroup has been asked

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:42 - t_hypoquest_13_14_descp/t_hypoquest_13_descp_fas.txt

Hypoglycaemic Questionnaire - Question 13 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
0	70 (26.2)	31 (23.5)
1	24 (9.0)	14 (10.6)
2	10 (3.7)	6 (4.5)
3	4 (1.5)	6 (4.5)
4	1 (0.4)	0
5	6 (2.2)	2 (1.5)
6	3 (1.1)	0
7	1 (0.4)	1 (0.8)
8	0	0
9	0	0
10	2 (0.7)	2 (1.5)
NA	0	0
Visit 16 (Week 14)		
0	62 (23.2)	32 (24.2)
1	23 (8.6)	17 (12.9)
2	7 (2.6)	5 (3.8)
3	4 (1.5)	0
4	7 (2.6)	2 (1.5)
5	1 (0.4)	1 (0.8)
6	0	0
7	1 (0.4)	0
8	1 (0.4)	1 (0.8)
9	0	0
10	1 (0.4)	1 (0.8)
NA	0	0
Visit 18 (Week 16)		
0	62 (23.2)	37 (28.0)
1	35 (13.1)	13 (9.8)
2	10 (3.7)	4 (3.0)
3	5 (1.9)	5 (3.8)
4	1 (0.4)	0
5	4 (1.5)	2 (1.5)
6	2 (0.7)	0
7	1 (0.4)	1 (0.8)
8	1 (0.4)	1 (0.8)
9	0	0
10	1 (0.4)	0
NA	0	0
Visit 22 (Week 20)		
0	59 (22.1)	34 (25.8)
1	31 (11.6)	12 (9.1)
2	13 (4.9)	3 (2.3)
3	5 (1.9)	1 (0.8)
4	5 (1.9)	2 (1.5)
5	1 (0.4)	1 (0.8)
6	2 (0.7)	0
7	2 (0.7)	0
8	1 (0.4)	0
9	0	0
10	0	0

N: Number of Subjects, %: Percentage of Subjects, NA: Not Applicable

Number of Subjects are those with responses as only a subgroup has been asked

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:13:17:42 - t_hypoquest_13_14_descp/t_hypoquest_13_descp_fas.txt

Hypoglycaemic Questionnaire - Question 13 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
NA	0	0
Visit 26 (Week 24)		
0	59 (22.1)	34 (25.8)
1	23 (8.6)	7 (5.3)
2	7 (2.6)	4 (3.0)
3	2 (0.7)	3 (2.3)
4	3 (1.1)	2 (1.5)
5	2 (0.7)	0
6	0	0
7	1 (0.4)	0
8	0	0
9	0	0
10	0	0
NA	0	0
Visit 28 (Week 26)		
0	52 (19.5)	33 (25.0)
1	23 (8.6)	13 (9.8)
2	9 (3.4)	4 (3.0)
3	4 (1.5)	5 (3.8)
4	2 (0.7)	0
5	1 (0.4)	1 (0.8)
6	1 (0.4)	0
7	2 (0.7)	0
8	1 (0.4)	0
9	1 (0.4)	0
10	1 (0.4)	1 (0.8)
NA	0	0
Visit 29 (Week 27)		
0	57 (21.3)	24 (18.2)
1	22 (8.2)	12 (9.1)
2	6 (2.2)	5 (3.8)
3	3 (1.1)	2 (1.5)
4	1 (0.4)	0
5	1 (0.4)	2 (1.5)
6	1 (0.4)	0
7	0	1 (0.8)
8	1 (0.4)	1 (0.8)
9	0	0
10	0	0
NA	0	0

N: Number of Subjects, %: Percentage of Subjects, NA: Not Applicable
 Number of Subjects are those with responses as only a subgroup has been asked
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:17:42 - t_hypoquest_13_14_descp/t_hypoquest_13_descp_fas.txt

14.2.160: Hypoglycaemic Questionnaire - Question 14 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Number of Subjects	194	112
How Much Did This Nocturnal Hypo Impact Your Sleep Quality		
Visit 2 (Week 0)		
0	19 (9.8)	8 (7.1)
1	12 (6.2)	4 (3.6)
2	8 (4.1)	3 (2.7)
3	1 (0.5)	1 (0.9)
4	1 (0.5)	3 (2.7)
5	2 (1.0)	1 (0.9)
6	2 (1.0)	0
7	5 (2.6)	2 (1.8)
8	1 (0.5)	1 (0.9)
9	0	0
10	0	1 (0.9)
NA	0	0
Visit 3 (Week 1)		
0	13 (6.7)	7 (6.3)
1	6 (3.1)	1 (0.9)
2	5 (2.6)	2 (1.8)
3	2 (1.0)	1 (0.9)
4	5 (2.6)	5 (4.5)
5	2 (1.0)	2 (1.8)
6	1 (0.5)	0
7	1 (0.5)	3 (2.7)
8	2 (1.0)	2 (1.8)
9	0	1 (0.9)
10	0	0
NA	1 (0.5)	0
Visit 4 (Week 2)		
0	9 (4.6)	6 (5.4)
1	5 (2.6)	6 (5.4)
2	3 (1.5)	1 (0.9)
3	2 (1.0)	1 (0.9)
4	6 (3.1)	1 (0.9)
5	2 (1.0)	3 (2.7)
6	2 (1.0)	1 (0.9)
7	4 (2.1)	2 (1.8)
8	1 (0.5)	1 (0.9)
9	1 (0.5)	0
10	1 (0.5)	0
NA	1 (0.5)	0
Visit 6 (Week 4)		
0	14 (7.2)	9 (8.0)
1	4 (2.1)	6 (5.4)
2	3 (1.5)	2 (1.8)

N: Number of Subjects, %: Percentage of Subjects, NA: Not Applicable
 Number of Subjects are those with responses as only a subgroup has been asked
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:17:43 - t_hypoquest_13_14_descp/t_hypoquest_14_descp_fas.txt

Hypoglycaemic Questionnaire - Question 14 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
3	5 (2.6)	3 (2.7)
4	3 (1.5)	1 (0.9)
5	2 (1.0)	3 (2.7)
6	2 (1.0)	0
7	2 (1.0)	1 (0.9)
8	0	0
9	0	0
10	1 (0.5)	0
NA	0	0
Visit 8 (Week 6)		
0	9 (4.6)	6 (5.4)
1	5 (2.6)	5 (4.5)
2	6 (3.1)	0
3	0	1 (0.9)
4	6 (3.1)	2 (1.8)
5	3 (1.5)	2 (1.8)
6	2 (1.0)	2 (1.8)
7	2 (1.0)	1 (0.9)
8	1 (0.5)	1 (0.9)
9	0	0
10	1 (0.5)	0
NA	0	0
Visit 10 (Week 8)		
0	11 (5.7)	6 (5.4)
1	3 (1.5)	2 (1.8)
2	2 (1.0)	1 (0.9)
3	3 (1.5)	1 (0.9)
4	1 (0.5)	2 (1.8)
5	1 (0.5)	3 (2.7)
6	4 (2.1)	0
7	0	0
8	0	0
9	1 (0.5)	0
10	3 (1.5)	1 (0.9)
NA	0	0
Visit 12 (Week 10)		
0	6 (3.1)	13 (11.6)
1	2 (1.0)	3 (2.7)
2	1 (0.5)	0
3	4 (2.1)	2 (1.8)
4	1 (0.5)	1 (0.9)
5	2 (1.0)	1 (0.9)
6	1 (0.5)	2 (1.8)
7	1 (0.5)	1 (0.9)
8	0	0
9	0	0
10	1 (0.5)	0
NA	0	0
Visit 14 (Week 12)		

N: Number of Subjects, %: Percentage of Subjects, NA: Not Applicable

Number of Subjects are those with responses as only a subgroup has been asked

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:43 - t_hypoquest_13_14_descp/t_hypoquest_14_descp_fas.txt

Hypoglycaemic Questionnaire - Question 14 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
0	11 (5.7)	6 (5.4)
1	3 (1.5)	6 (5.4)
2	6 (3.1)	3 (2.7)
3	2 (1.0)	5 (4.5)
4	4 (2.1)	1 (0.9)
5	4 (2.1)	2 (1.8)
6	1 (0.5)	2 (1.8)
7	2 (1.0)	1 (0.9)
8	1 (0.5)	0
9	1 (0.5)	0
10	1 (0.5)	1 (0.9)
NA	0	0
Visit 16 (Week 14)		
0	13 (6.7)	5 (4.5)
1	1 (0.5)	6 (5.4)
2	4 (2.1)	0
3	4 (2.1)	1 (0.9)
4	2 (1.0)	0
5	1 (0.5)	1 (0.9)
6	0	0
7	0	1 (0.9)
8	1 (0.5)	1 (0.9)
9	2 (1.0)	0
10	0	0
NA	0	0
Visit 18 (Week 16)		
0	9 (4.6)	6 (5.4)
1	1 (0.5)	5 (4.5)
2	3 (1.5)	3 (2.7)
3	7 (3.6)	5 (4.5)
4	3 (1.5)	0
5	0	1 (0.9)
6	1 (0.5)	0
7	0	2 (1.8)
8	1 (0.5)	0
9	1 (0.5)	0
10	0	1 (0.9)
NA	0	0
Visit 22 (Week 20)		
0	6 (3.1)	5 (4.5)
1	6 (3.1)	1 (0.9)
2	2 (1.0)	1 (0.9)
3	3 (1.5)	1 (0.9)
4	4 (2.1)	4 (3.6)
5	2 (1.0)	2 (1.8)
6	0	2 (1.8)
7	3 (1.5)	0
8	0	0
9	0	0
10	0	0

N: Number of Subjects, %: Percentage of Subjects, NA: Not Applicable

Number of Subjects are those with responses as only a subgroup has been asked

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:43 - t_hypoquest_13_14_descp/t_hypoquest_14_descp_fas.txt

Hypoglycaemic Questionnaire - Question 14 by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)
NA	0	0
Visit 26 (Week 24)		
0	13 (6.7)	5 (4.5)
1	3 (1.5)	2 (1.8)
2	5 (2.6)	0
3	3 (1.5)	3 (2.7)
4	0	2 (1.8)
5	2 (1.0)	0
6	0	2 (1.8)
7	0	0
8	0	0
9	0	2 (1.8)
10	0	0
NA	0	0
Visit 28 (Week 26)		
0	8 (4.1)	9 (8.0)
1	6 (3.1)	6 (5.4)
2	2 (1.0)	5 (4.5)
3	5 (2.6)	7 (6.3)
4	1 (0.5)	2 (1.8)
5	1 (0.5)	1 (0.9)
6	1 (0.5)	1 (0.9)
7	1 (0.5)	1 (0.9)
8	0	1 (0.9)
9	2 (1.0)	0
10	0	0
NA	0	0
Visit 29 (Week 27)		
0	4 (2.1)	2 (1.8)
1	1 (0.5)	2 (1.8)
2	4 (2.1)	3 (2.7)
3	1 (0.5)	2 (1.8)
4	1 (0.5)	1 (0.9)
5	2 (1.0)	1 (0.9)
6	1 (0.5)	0
7	1 (0.5)	1 (0.9)
8	0	2 (1.8)
9	0	0
10	0	0
NA	0	0

N: Number of Subjects, %: Percentage of Subjects, NA: Not Applicable
 Number of Subjects are those with responses as only a subgroup has been asked
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:17:43 - t_hypoquest_13_14_descp/t_hypoquest_14_descp_fas.txt

14.3 Safety Data

14.3.1 Displays of Adverse Events

14.3.1.1: Adverse Events - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	239 (66.0)	846	500	114 (63.3)	436	520	353 (65.1)	1282	506
Serious									
Yes	31 (8.6)	46	27	13 (7.2)	17	20	44 (8.1)	63	25
No	232 (64.1)	800	472	113 (62.8)	419	499	345 (63.7)	1219	481
Severity									
Severe	45 (12.4)	63	37	26 (14.4)	38	45	71 (13.1)	101	40
Moderate	104 (28.7)	183	108	40 (22.2)	81	97	144 (26.6)	264	104
Mild	191 (52.8)	600	354	102 (56.7)	317	378	293 (54.1)	917	362
Related to Investigational Product									
Probably	22 (6.1)	37	22	19 (10.6)	51	61	41 (7.6)	88	35
Possibly	36 (9.9)	47	28	14 (7.8)	17	20	50 (9.2)	64	25
Unlikely	220 (60.8)	757	447	107 (59.4)	364	434	327 (60.3)	1121	443
Missing	5 (1.4)	5	3	4 (2.2)	4	5	9 (1.7)	9	4
Related to Bolus Insulin									
Probably	22 (6.1)	36	21	16 (8.9)	25	30	38 (7.0)	61	24
Possibly	29 (8.0)	40	24	14 (7.8)	18	21	43 (7.9)	58	23
Unlikely	225 (62.2)	765	452	108 (60.0)	389	464	333 (61.4)	1154	456
Missing	5 (1.4)	5	3	4 (2.2)	4	5	9 (1.7)	9	4
Related to Device									
Yes	3 (0.8)	3	2	0 (0.0)	0	0	3 (0.6)	3	1
No	238 (65.7)	838	495	112 (62.2)	432	515	350 (64.6)	1270	502
Missing	5 (1.4)	5	3	4 (2.2)	4	5	9 (1.7)	9	4
Outcome									
Recovered	219 (60.5)	725	428	110 (61.1)	379	452	329 (60.7)	1104	436
Recovering	14 (3.9)	15	9	6 (3.3)	7	8	20 (3.7)	22	9
Recovered with Sequelae	2 (0.6)	2	1	1 (0.6)	1	1	3 (0.6)	3	1
Not Recovered	62 (17.1)	103	61	37 (20.6)	49	58	99 (18.3)	152	60
Unknown	1 (0.3)	1	1	0 (0.0)	0	0	1 (0.2)	1	0

N= Number of Subjects

%= Percentage of Subjects

E= Number of Events

R= Event Rate per 100 Patient Years of Exposure

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:17 - tsum_ae_tpl_t024_v01.sas/t_ae_te_sum_sas.txt

14.3.1.2: Serious Adverse Events – Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	31	(8.6)	46	27	13	(7.2)	17	20	44	(8.1)	63	25
Severity												
Severe	21	(5.8)	34	20	11	(6.1)	13	15	32	(5.9)	47	19
Moderate	11	(3.0)	11	6	2	(1.1)	3	4	13	(2.4)	14	6
Mild	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Related to Investigational Product												
Probably	13	(3.6)	20	12	5	(2.8)	6	7	18	(3.3)	26	10
Possibly	4	(1.1)	5	3	1	(0.6)	1	1	5	(0.9)	6	2
Unlikely	18	(5.0)	21	12	8	(4.4)	10	12	26	(4.8)	31	12
Related to Bolus Insulin												
Probably	10	(2.8)	16	9	6	(3.3)	8	10	16	(3.0)	24	9
Possibly	4	(1.1)	6	4	2	(1.1)	2	2	6	(1.1)	8	3
Unlikely	21	(5.8)	24	14	5	(2.8)	7	8	26	(4.8)	31	12
Related to Device												
No	31	(8.6)	46	27	13	(7.2)	17	20	44	(8.1)	63	25
Outcome												
Recovered	28	(7.7)	42	25	12	(6.7)	16	19	40	(7.4)	58	23
Recovering	1	(0.3)	1	1	0	(0.0)	0	0	1	(0.2)	1	0
Recovered with Sequelae	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Not Recovered	1	(0.3)	1	1	0	(0.0)	0	0	1	(0.2)	1	0

N= Number of Subjects

%= Percentage of Subjects

E= Number of Events

R= Event Rate per 100 Patient Years of Exposure

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:19 - tsum_ae_tpl_t024_v01.sas/t_sae_tē_sum_sas.txt

14.3.1.3: Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 5\%$]- Treatment Emergent - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	N	Total (%)	E	R
Number of Subjects	362				180				542			
Events	130	(35.9)	287	169	71	(39.4)	129	154	201	(37.1)	416	164
Infections and infestations												
Nasopharyngitis	78	(21.5)	111	66	32	(17.8)	44	52	110	(20.3)	155	61
Upper respiratory tract infection	24	(6.6)	33	19	16	(8.9)	26	31	40	(7.4)	59	23
Nervous system disorders												
Headache	27	(7.5)	83	49	15	(8.3)	18	21	42	(7.7)	101	40
Metabolism and nutrition disorders												
Hypoglycaemia	33	(9.1)	49	29	22	(12.2)	32	38	55	(10.1)	81	32
Gastrointestinal disorders												
Diarrhoea	10	(2.8)	11	6	9	(5.0)	9	11	19	(3.5)	20	8

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:22 - tsum_ae_soc.sas/t_ae_te_soc_pf_most_freq_sum_sas.txt

14.3.1.4: Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$]- Treatment Emergent - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	N	Total (%)	E	R
Number of Subjects	362				180				542			
Events	201	(55.5)	604	357	103	(57.2)	334	398	304	(56.1)	938	370
Infections and infestations												
Acute tonsillitis	4	(1.1)	6	4	1	(0.6)	1	1	5	(0.9)	7	3
Bronchitis	8	(2.2)	8	5	1	(0.6)	1	1	9	(1.7)	9	4
Eye infection					2	(1.1)	2	2	2	(0.4)	2	1
Gastroenteritis	10	(2.8)	10	6	6	(3.3)	6	7	16	(3.0)	16	6
Gastroenteritis viral	5	(1.4)	5	3	2	(1.1)	2	2	7	(1.3)	7	3
Influenza	18	(5.0)	18	11	6	(3.3)	8	10	24	(4.4)	26	10
Localised infection	4	(1.1)	4	2	2	(1.1)	2	2	6	(1.1)	6	2
Nasopharyngitis	78	(21.5)	111	66	32	(17.8)	44	52	110	(20.3)	155	61
Pharyngitis	4	(1.1)	6	4					4	(0.7)	6	2
Respiratory tract infection					3	(1.7)	3	4	3	(0.6)	3	1
Sinusitis	9	(2.5)	10	6	3	(1.7)	3	4	12	(2.2)	13	5
Tooth abscess	5	(1.4)	6	4	2	(1.1)	2	2	7	(1.3)	8	3
Tooth infection	4	(1.1)	4	2	1	(0.6)	1	1	5	(0.9)	5	2
Upper respiratory tract infection	24	(6.6)	33	19	16	(8.9)	26	31	40	(7.4)	59	23
Urinary tract infection	2	(0.6)	3	2	3	(1.7)	3	4	5	(0.9)	6	2
Viral infection	7	(1.9)	7	4	5	(2.8)	5	6	12	(2.2)	12	5
Metabolism and nutrition disorders												
Diabetic ketoacidosis	1	(0.3)	2	1	3	(1.7)	3	4	4	(0.7)	5	2
Hypercholesterolaemia	4	(1.1)	4	2	2	(1.1)	2	2	6	(1.1)	6	2
Hyperglycaemia	4	(1.1)	4	2					4	(0.7)	4	2
Hyperlipidaemia	5	(1.4)	5	3	2	(1.1)	2	2	7	(1.3)	7	3
Hypoglycaemia	33	(9.1)	49	29	22	(12.2)	32	38	55	(10.1)	81	32

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:23 - tsum_ae_soc.sas/t_ae_te_soc_pf_one_freq_sum_sas.txt

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
542 of 1733

Novo Nordisk

Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$] - Treatment Emergent - Summary
- Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Hypoglycaemic unconsciousness	6	(1.7)	6	4	4	(2.2)	4	5	10	(1.8)	10	4
Nervous system disorders												
Headache	27	(7.5)	83	49	15	(8.3)	18	21	42	(7.7)	101	40
Migraine	6	(1.7)	6	4	1	(0.6)	1	1	7	(1.3)	7	3
Gastrointestinal disorders												
Abdominal discomfort	5	(1.4)	7	4	4	(2.2)	5	6	9	(1.7)	12	5
Abdominal pain	5	(1.4)	6	4	1	(0.6)	1	1	6	(1.1)	7	3
Abdominal pain upper	5	(1.4)	6	4	3	(1.7)	3	4	8	(1.5)	9	4
Diarrhoea	10	(2.8)	11	6	9	(5.0)	9	11	19	(3.5)	20	8
Dyspepsia	3	(0.8)	3	2	4	(2.2)	4	5	7	(1.3)	7	3
Nausea	10	(2.8)	11	6	7	(3.9)	8	10	17	(3.1)	19	8
Toothache	2	(0.6)	2	1	2	(1.1)	2	2	4	(0.7)	4	2
Vomiting	11	(3.0)	12	7	5	(2.8)	5	6	16	(3.0)	17	7
General disorders and administration site conditions												
Discomfort					2	(1.1)	2	2	2	(0.4)	2	1
Fatigue	3	(0.8)	3	2	4	(2.2)	4	5	7	(1.3)	7	3
Influenza like illness	9	(2.5)	10	6	2	(1.1)	2	2	11	(2.0)	12	5
Injection site reaction	3	(0.8)	5	3	6	(3.3)	33	39	9	(1.7)	38	15
Malaise	4	(1.1)	4	2					4	(0.7)	4	2
Oedema peripheral	7	(1.9)	9	5					7	(1.3)	9	4
Pyrexia	7	(1.9)	7	4	5	(2.8)	5	6	12	(2.2)	12	5
Musculoskeletal and connective tissue disorders												
Arthralgia	7	(1.9)	8	5	5	(2.8)	5	6	12	(2.2)	13	5

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:23 - tsum_ae_soc.sas/t_ae_te_soc_pf_one_freq_sum_sas.txt

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
543 of 1733

Novo Nordisk

Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$] - Treatment Emergent - Summary
- Safety Analysis Set

	IDegAsp OD			IDet			Total		
	N	(%)	E R	N	(%)	E R	N	(%)	E R
Back pain	6	(1.7)	7 4	5	(2.8)	6 7	11	(2.0)	13 5
Musculoskeletal chest pain				2	(1.1)	2 2	2	(0.4)	2 1
Musculoskeletal pain	3	(0.8)	3 2	4	(2.2)	4 5	7	(1.3)	7 3
Myalgia	3	(0.8)	3 2	2	(1.1)	2 2	5	(0.9)	5 2
Neck pain	6	(1.7)	7 4	2	(1.1)	2 2	8	(1.5)	9 4
Pain in extremity	6	(1.7)	8 5	3	(1.7)	4 5	9	(1.7)	12 5
Periarthritis	1	(0.3)	1 1	2	(1.1)	2 2	3	(0.6)	3 1
Respiratory, thoracic and mediastinal disorders									
Cough	5	(1.4)	7 4	2	(1.1)	2 2	7	(1.3)	9 4
Dyspnoea	4	(1.1)	4 2	1	(0.6)	1 1	5	(0.9)	5 2
Oropharyngeal pain	12	(3.3)	14 8	4	(2.2)	4 5	16	(3.0)	18 7
Sinus congestion	1	(0.3)	2 1	2	(1.1)	2 2	3	(0.6)	4 2
Injury, poisoning and procedural complications									
Medication error	1	(0.3)	1 1	2	(1.1)	2 2	3	(0.6)	3 1
Procedural pain				2	(1.1)	2 2	2	(0.4)	2 1
Vaccination complication	4	(1.1)	5 3	3	(1.7)	3 4	7	(1.3)	8 3
Wrong drug administered	10	(2.8)	12 7	5	(2.8)	5 6	15	(2.8)	17 7
Psychiatric disorders									
Depression	7	(1.9)	7 4	3	(1.7)	3 4	10	(1.8)	10 4
Insomnia	3	(0.8)	3 2	4	(2.2)	4 5	7	(1.3)	7 3
Stress	1	(0.3)	1 1	4	(2.2)	4 5	5	(0.9)	5 2
Skin and subcutaneous tissue disorders									
Lipodystrophy acquired	1	(0.3)	1 1	2	(1.1)	3 4	3	(0.6)	4 2

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:23 - tsum_ae_soc.sas/t_ae_te_soc_pf_one_freq_sum_sas.txt

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
544 of 1733

Novo Nordisk

Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$] - Treatment Emergent - Summary
- Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	N	Total (%)	E	R
Lipohypertrophy	1	(0.3)	1	1	2	(1.1)	3	4	3	(0.6)	4	2
Rash	1	(0.3)	1	1	5	(2.8)	5	6	6	(1.1)	6	2
Vascular disorders												
Hypertension	8	(2.2)	8	5	2	(1.1)	2	2	10	(1.8)	10	4
Reproductive system and breast disorders												
Dysmenorrhoea	4	(1.1)	5	3	2	(1.1)	2	2	6	(1.1)	7	3
Immune system disorders												
Seasonal allergy	3	(0.8)	3	2	2	(1.1)	2	2	5	(0.9)	5	2
Ear and labyrinth disorders												
Ear pain	2	(0.6)	2	1	2	(1.1)	2	2	4	(0.7)	4	2
Investigations												
Weight increased	4	(1.1)	4	2					4	(0.7)	4	2
Eye disorders												
Conjunctivitis					2	(1.1)	2	2	2	(0.4)	2	1

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:23 - tsum_ae_soc.sas/t_ae_te_soc_pf_one_freq_sum_sas.txt

14.3.1.5: Serious Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 5\%$]- Treatment Emergent - Summary - Safety Analysis Set

There is no data for this table

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:23 - tsum_ae_soc.sas/t_ae_te_s_soc_pf_mst_frq_sum_sas.txt

14.3.1.6: Serious Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$]- Treatment Emergent - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	N	Total (%)	E	R
Number of Subjects	362				180				542			
Events	16	(4.4)	26	15	9	(5.0)	10	12	25	(4.6)	36	14
Metabolism and nutrition disorders												
Diabetic ketoacidosis	1	(0.3)	2	1	2	(1.1)	2	2	3	(0.6)	4	2
Hypoglycaemia	11	(3.0)	19	11	5	(2.8)	5	6	16	(3.0)	24	9
Hypoglycaemic unconsciousness	5	(1.4)	5	3	3	(1.7)	3	4	8	(1.5)	8	3

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:23 - tsum_ae_soc.sas/t_ae_te_s_soc_pf_one_frq_sum_sas.txt

14.3.1.7: Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	239	(66.0)	846		500	114 (63.3)	436		520	353 (65.1)	1282	506
Infections and infestations	150	(41.4)	290		171	71 (39.4)	125		149	221 (40.8)	415	164
Nasopharyngitis	78	(21.5)	111		66	32 (17.8)	44		52	110 (20.3)	155	61
Upper respiratory tract infection	24	(6.6)	33		19	16 (8.9)	26		31	40 (7.4)	59	23
Influenza	18	(5.0)	18		11	6 (3.3)	8		10	24 (4.4)	26	10
Gastroenteritis	10	(2.8)	10		6	6 (3.3)	6		7	16 (3.0)	16	6
Sinusitis	9	(2.5)	10		6	3 (1.7)	3		4	12 (2.2)	13	5
Viral infection	7	(1.9)	7		4	5 (2.8)	5		6	12 (2.2)	12	5
Bronchitis	8	(2.2)	8		5	1 (0.6)	1		1	9 (1.7)	9	4
Gastroenteritis viral	5	(1.4)	5		3	2 (1.1)	2		2	7 (1.3)	7	3
Tooth abscess	5	(1.4)	6		4	2 (1.1)	2		2	7 (1.3)	8	3
Localised infection	4	(1.1)	4		2	2 (1.1)	2		2	6 (1.1)	6	2
Acute tonsillitis	4	(1.1)	6		4	1 (0.6)	1		1	5 (0.9)	7	3
Tooth infection	4	(1.1)	4		2	1 (0.6)	1		1	5 (0.9)	5	2
Urinary tract infection	2	(0.6)	3		2	3 (1.7)	3		4	5 (0.9)	6	2
Cellulitis	3	(0.8)	3		2	1 (0.6)	1		1	4 (0.7)	4	2
Infection	3	(0.8)	3		2	1 (0.6)	1		1	4 (0.7)	4	2
Pharyngitis	4	(1.1)	6		4					4 (0.7)	6	2
Ear infection	3	(0.8)	3		2					3 (0.6)	3	1
Respiratory tract infection						3 (1.7)	3		4	3 (0.6)	3	1
Staphylococcal skin infection	2	(0.6)	2		1	1 (0.6)	1		1	3 (0.6)	3	1
Viral upper respiratory tract infection	3	(0.8)	3		2					3 (0.6)	3	1
Vulvovaginal candidiasis	2	(0.6)	3		2	1 (0.6)	1		1	3 (0.6)	4	2
Abscess limb	2	(0.6)	3		2					2 (0.4)	3	1
Acute sinusitis	2	(0.6)	2		1					2 (0.4)	2	1
Eye infection					2	(1.1)	2		2	2 (0.4)	2	1
Fungal infection	1	(0.3)	1		1	(0.6)	1		1	2 (0.4)	2	1
Gingival abscess	1	(0.3)	1		1	(0.6)	1		1	2 (0.4)	2	1
H1N1 influenza	1	(0.3)	1		1	(0.6)	1		1	2 (0.4)	2	1
Oral herpes	1	(0.3)	1		1	(0.6)	1		1	2 (0.4)	2	1
Pharyngitis streptococcal	2	(0.6)	2		1					2 (0.4)	2	1
Pneumonia	1	(0.3)	1		1	(0.6)	1		1	2 (0.4)	2	1
Abscess	1	(0.3)	1		1					1 (0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Blister infected	1	(0.3)	1	1					1	(0.2)	1	0
Cystitis	1	(0.3)	1	1					1	(0.2)	1	0
Erysipelas	1	(0.3)	1	1					1	(0.2)	1	0
Genital candidiasis	1	(0.3)	1	1					1	(0.2)	1	0
Groin abscess	1	(0.3)	1	1					1	(0.2)	1	0
Herpes simplex					1	(0.6)	1	1	1	(0.2)	1	0
Intrauterine infection					1	(0.6)	1	1	1	(0.2)	1	0
Labyrinthitis	1	(0.3)	1	1					1	(0.2)	1	0
Laryngitis	1	(0.3)	1	1					1	(0.2)	1	0
Lower respiratory tract infection	1	(0.3)	1	1					1	(0.2)	1	0
Mastitis					1	(0.6)	1	1	1	(0.2)	1	0
Onychomycosis	1	(0.3)	1	1					1	(0.2)	1	0
Oral fungal infection					1	(0.6)	1	1	1	(0.2)	1	0
Peritonsillar abscess					1	(0.6)	1	1	1	(0.2)	1	0
Pilonidal cyst	1	(0.3)	1	1					1	(0.2)	1	0
Postoperative wound infection	1	(0.3)	2	1					1	(0.2)	2	1
Pulmonary tuberculosis	1	(0.3)	1	1					1	(0.2)	1	0
Respiratory tract infection viral	1	(0.3)	1	1					1	(0.2)	1	0
Rhinitis	1	(0.3)	1	1					1	(0.2)	1	0
Rotavirus infection	1	(0.3)	1	1					1	(0.2)	1	0
Skin infection	1	(0.3)	1	1					1	(0.2)	1	0
Staphylococcal infection	1	(0.3)	1	1					1	(0.2)	1	0
Subcutaneous abscess	1	(0.3)	4	2					1	(0.2)	4	2
Superinfection	1	(0.3)	1	1					1	(0.2)	1	0
Taeniasis	1	(0.3)	1	1					1	(0.2)	1	0
Tinea infection					1	(0.6)	1	1	1	(0.2)	1	0
Tonsillitis	1	(0.3)	1	1					1	(0.2)	1	0
Tracheobronchitis	1	(0.3)	1	1					1	(0.2)	1	0
Vaginal infection					1	(0.6)	1	1	1	(0.2)	1	0
Viral pharyngitis	1	(0.3)	1	1					1	(0.2)	1	0
Vulvovaginal mycotic infection	1	(0.3)	1	1					1	(0.2)	1	0
Wound infection	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Metabolism and nutrition disorders	52	(14.4)	79	47	30	(16.7)	47	56	82	(15.1)	126	50
Hypoglycaemia	33	(9.1)	49	29	22	(12.2)	32	38	55	(10.1)	81	32
Hypoglycaemic unconsciousness	6	(1.7)	6	4	4	(2.2)	4	5	10	(1.8)	10	4
Hyperlipidaemia	5	(1.4)	5	3	2	(1.1)	2	2	7	(1.3)	7	3
Hypercholesterolaemia	4	(1.1)	4	2	2	(1.1)	2	2	6	(1.1)	6	2
Diabetic ketoacidosis	1	(0.3)	2	1	3	(1.7)	3	4	4	(0.7)	5	2
Hyperglycaemia	4	(1.1)	4	2					4	(0.7)	4	2
Decreased appetite	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Dehydration	2	(0.6)	2	1					2	(0.4)	2	1
Hypoglycaemic seizure	1	(0.3)	2	1	1	(0.6)	1	1	2	(0.4)	3	1
Vitamin D deficiency	2	(0.6)	2	1					2	(0.4)	2	1
Gout	1	(0.3)	1	1					1	(0.2)	1	0
Hypertriglyceridaemia	1	(0.3)	1	1					1	(0.2)	1	0
Hypokalaemia					1	(0.6)	1	1	1	(0.2)	1	0
Hypovolaemia					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Gastrointestinal disorders	47	(13.0)	77	45	27	(15.0)	47	56	74	(13.7)	124	49
Diarrhoea	10	(2.8)	11	6	9	(5.0)	9	11	19	(3.5)	20	8
Nausea	10	(2.8)	11	6	7	(3.9)	8	10	17	(3.1)	19	8
Vomiting	11	(3.0)	12	7	5	(2.8)	5	6	16	(3.0)	17	7
Abdominal discomfort	5	(1.4)	7	4	4	(2.2)	5	6	9	(1.7)	12	5
Abdominal pain upper	5	(1.4)	6	4	3	(1.7)	3	4	8	(1.5)	9	4
Dyspepsia	3	(0.8)	3	2	4	(2.2)	4	5	7	(1.3)	7	3
Abdominal pain	5	(1.4)	6	4	1	(0.6)	1	1	6	(1.1)	7	3
Toothache	2	(0.6)	2	1	2	(1.1)	2	2	4	(0.7)	4	2
Food poisoning	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Gastritis	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Gastrooesophageal reflux disease	2	(0.6)	7	4					2	(0.4)	7	3
Hiatus hernia	2	(0.6)	2	1					2	(0.4)	2	1
Rectal haemorrhage	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Abdominal distension	1	(0.3)	1	1					1	(0.2)	1	0
Colitis					1	(0.6)	1	1	1	(0.2)	1	0
Constipation	1	(0.3)	1	1					1	(0.2)	1	0
Flatulence					1	(0.6)	1	1	1	(0.2)	1	0
Haemorrhoids					1	(0.6)	1	1	1	(0.2)	1	0
Mouth ulceration	1	(0.3)	2	1					1	(0.2)	2	1
Oesophagitis					1	(0.6)	1	1	1	(0.2)	1	0
Pancreatitis	1	(0.3)	1	1					1	(0.2)	1	0
Pancreatitis acute					1	(0.6)	1	1	1	(0.2)	1	0
Pancreatitis chronic					1	(0.6)	1	1	1	(0.2)	1	0
Periodontitis	1	(0.3)	1	1					1	(0.2)	1	0
Umbilical hernia					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
General disorders and administration site conditions	39	(10.8)	47	28	22	(12.2)	54	64	61	(11.3)	101	40
Pyrexia	7	(1.9)	7	4	5	(2.8)	5	6	12	(2.2)	12	5
Influenza like illness	9	(2.5)	10	6	2	(1.1)	2	2	11	(2.0)	12	5
Injection site reaction	3	(0.8)	5	3	6	(3.3)	33	39	9	(1.7)	38	15
Fatigue	3	(0.8)	3	2	4	(2.2)	4	5	7	(1.3)	7	3
Oedema peripheral	7	(1.9)	9	5					7	(1.3)	9	4
Malaise	4	(1.1)	4	2					4	(0.7)	4	2
Hunger	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Injection site pain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Asthenia	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Discomfort					2	(1.1)	2	2	2	(0.4)	2	1
Pain	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Chest pain	1	(0.3)	1	1					1	(0.2)	1	0
Cyst	1	(0.3)	1	1					1	(0.2)	1	0
Feeling cold					1	(0.6)	1	1	1	(0.2)	1	0
Injection site haematoma					1	(0.6)	1	1	1	(0.2)	1	0
Injection site hypertrophy					1	(0.6)	1	1	1	(0.2)	1	0
Injection site papule					1	(0.6)	1	1	1	(0.2)	1	0
Non-cardiac chest pain	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Injury, poisoning and procedural complications	37	(10.2)	50	30	22	(12.2)	25	30	59	(10.9)	75	30
Wrong drug administered	10	(2.8)	12	7	5	(2.8)	5	6	15	(2.8)	17	7
Vaccination complication	4	(1.1)	5	3	3	(1.7)	3	4	7	(1.3)	8	3
Foot fracture	3	(0.8)	3	2					3	(0.6)	3	1
Joint sprain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Medication error	1	(0.3)	1	1	2	(1.1)	2	2	3	(0.6)	3	1
Muscle strain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Skin laceration	3	(0.8)	4	2					3	(0.6)	4	2
Ankle fracture	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Contusion	2	(0.6)	3	2					2	(0.4)	3	1
Eye injury	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Fall	2	(0.6)	2	1					2	(0.4)	2	1
Incorrect dose administered	2	(0.6)	2	1					2	(0.4)	2	1
Limb injury	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Procedural pain					2	(1.1)	2	2	2	(0.4)	2	1
Rib fracture	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Concussion	1	(0.3)	1	1					1	(0.2)	1	0
Corneal scar	1	(0.3)	1	1					1	(0.2)	1	0
Epicondylitis	1	(0.3)	1	1					1	(0.2)	1	0
Face injury	1	(0.3)	1	1					1	(0.2)	1	0
Foreign body					1	(0.6)	1	1	1	(0.2)	1	0
Hand fracture					1	(0.6)	1	1	1	(0.2)	1	0
Injury corneal					1	(0.6)	1	1	1	(0.2)	1	0
Joint dislocation	1	(0.3)	1	1					1	(0.2)	1	0
Limb traumatic amputation					1	(0.6)	1	1	1	(0.2)	1	0
Overdose	1	(0.3)	1	1					1	(0.2)	1	0
Post procedural haemorrhage					1	(0.6)	1	1	1	(0.2)	1	0
Post-traumatic pain					1	(0.6)	1	1	1	(0.2)	1	0
Road traffic accident					1	(0.6)	1	1	1	(0.2)	1	0
Soft tissue injury	1	(0.3)	1	1					1	(0.2)	1	0
Tooth fracture	1	(0.3)	2	1					1	(0.2)	2	1
Upper limb fracture	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Musculoskeletal and connective tissue disorders	35	(9.7)	55	32	24	(13.3)	36	43	59	(10.9)	91	36
Arthralgia	7	(1.9)	8	5	5	(2.8)	5	6	12	(2.2)	13	5
Back pain	6	(1.7)	7	4	5	(2.8)	6	7	11	(2.0)	13	5
Pain in extremity	6	(1.7)	8	5	3	(1.7)	4	5	9	(1.7)	12	5
Neck pain	6	(1.7)	7	4	2	(1.1)	2	2	8	(1.5)	9	4
Musculoskeletal pain	3	(0.8)	3	2	4	(2.2)	4	5	7	(1.3)	7	3
Myalgia	3	(0.8)	3	2	2	(1.1)	2	2	5	(0.9)	5	2
Muscle spasms	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Osteoarthritis	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Periarthritis	1	(0.3)	1	1	2	(1.1)	2	2	3	(0.6)	3	1
Intervertebral disc protrusion	2	(0.6)	2	1					2	(0.4)	2	1
Joint swelling	1	(0.3)	2	1	1	(0.6)	1	1	2	(0.4)	3	1
Musculoskeletal chest pain					2	(1.1)	2	2	2	(0.4)	2	1
Arthritis	1	(0.3)	1	1					1	(0.2)	1	0
Bunion	1	(0.3)	1	1					1	(0.2)	1	0
Costochondritis	1	(0.3)	1	1					1	(0.2)	1	0
Dupuytren's contracture	1	(0.3)	1	1					1	(0.2)	1	0
Foot deformity	1	(0.3)	1	1					1	(0.2)	1	0
Intervertebral disc degeneration					1	(0.6)	1	1	1	(0.2)	1	0
Intervertebral disc disorder	1	(0.3)	1	1					1	(0.2)	1	0
Myositis					1	(0.6)	2	2	1	(0.2)	2	1
Osteopenia					1	(0.6)	1	1	1	(0.2)	1	0
Osteoporosis	1	(0.3)	1	1					1	(0.2)	1	0
Plantar fasciitis					1	(0.6)	1	1	1	(0.2)	1	0
Polyarthritis	1	(0.3)	1	1					1	(0.2)	1	0
Rotator cuff syndrome	1	(0.3)	1	1					1	(0.2)	1	0
Systemic lupus erythematosus	1	(0.3)	1	1					1	(0.2)	1	0
Trigger finger					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Nervous system disorders	42	(11.6)	105		62	17 (9.4)	22	26	59	(10.9)	127	50
Headache	27	(7.5)	83		49	15 (8.3)	18	21	42	(7.7)	101	40
Migraine	6	(1.7)	6		4	1 (0.6)	1	1	7	(1.3)	7	3
Dizziness	3	(0.8)	3		2	1 (0.6)	1	1	4	(0.7)	4	2
Lethargy	3	(0.8)	3		2				3	(0.6)	3	1
Sinus headache	2	(0.6)	2		1	1 (0.6)	1	1	3	(0.6)	3	1
Aphonia	1	(0.3)	1		1				1	(0.2)	1	0
Areflexia	1	(0.3)	1		1				1	(0.2)	1	0
Carpal tunnel syndrome	1	(0.3)	1		1				1	(0.2)	1	0
Hypoaesthesia	1	(0.3)	1		1				1	(0.2)	1	0
Neurological symptom	1	(0.3)	1		1				1	(0.2)	1	0
Neuropathy peripheral					1	(0.6)	1	1	1	(0.2)	1	0
Paraesthesia	1	(0.3)	1		1				1	(0.2)	1	0
Phantom pain	1	(0.3)	1		1				1	(0.2)	1	0
Sensory loss	1	(0.3)	1		1				1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Respiratory, thoracic and mediastinal disorders	28	(7.7)	42	25	12	(6.7)	14	17	40	(7.4)	56	22
Oropharyngeal pain	12	(3.3)	14	8	4	(2.2)	4	5	16	(3.0)	18	7
Cough	5	(1.4)	7	4	2	(1.1)	2	2	7	(1.3)	9	4
Dyspnoea	4	(1.1)	4	2	1	(0.6)	1	1	5	(0.9)	5	2
Sinus congestion	1	(0.3)	2	1	2	(1.1)	2	2	3	(0.6)	4	2
Asthma	1	(0.3)	1	1	1	(0.6)	2	2	2	(0.4)	3	1
Epistaxis	2	(0.6)	3	2					2	(0.4)	3	1
Respiratory disorder	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Bronchospasm					1	(0.6)	1	1	1	(0.2)	1	0
Dysphonia					1	(0.6)	1	1	1	(0.2)	1	0
Dyspnoea exertional	1	(0.3)	1	1					1	(0.2)	1	0
Emphysema	1	(0.3)	1	1					1	(0.2)	1	0
Paranasal sinus hypersecretion	1	(0.3)	1	1					1	(0.2)	1	0
Pulmonary congestion	1	(0.3)	1	1					1	(0.2)	1	0
Pulmonary fibrosis	1	(0.3)	1	1					1	(0.2)	1	0
Rhinitis allergic	1	(0.3)	1	1					1	(0.2)	1	0
Rhinorrhoea	1	(0.3)	1	1					1	(0.2)	1	0
Throat irritation	1	(0.3)	1	1					1	(0.2)	1	0
Upper respiratory tract congestion	1	(0.3)	1	1					1	(0.2)	1	0
Vocal cord disorder	1	(0.3)	1	1					1	(0.2)	1	0
Psychiatric disorders	15	(4.1)	17	10	11	(6.1)	13	15	26	(4.8)	30	12
Depression	7	(1.9)	7	4	3	(1.7)	3	4	10	(1.8)	10	4
Insomnia	3	(0.8)	3	2	4	(2.2)	4	5	7	(1.3)	7	3
Stress	1	(0.3)	1	1	4	(2.2)	4	5	5	(0.9)	5	2
Anxiety	2	(0.6)	3	2	1	(0.6)	1	1	3	(0.6)	4	2
Suicidal ideation	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Drug abuse	1	(0.3)	1	1					1	(0.2)	1	0
Sleep disorder	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Skin and subcutaneous tissue disorders	11	(3.0)	15	9	13	(7.2)	15	18	24	(4.4)	30	12
Rash	1	(0.3)	1	1	5	(2.8)	5	6	6	(1.1)	6	2
Lipodystrophy acquired	1	(0.3)	1	1	2	(1.1)	3	4	3	(0.6)	4	2
Lipohypertrophy	1	(0.3)	1	1	2	(1.1)	3	4	3	(0.6)	4	2
Dry skin	2	(0.6)	2	1					2	(0.4)	2	1
Pruritus	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Rash pruritic	2	(0.6)	2	1					2	(0.4)	2	1
Acne	1	(0.3)	1	1					1	(0.2)	1	0
Alopecia	1	(0.3)	1	1					1	(0.2)	1	0
Eczema	1	(0.3)	1	1					1	(0.2)	1	0
Erythema	1	(0.3)	1	1					1	(0.2)	1	0
Heat rash					1	(0.6)	1	1	1	(0.2)	1	0
Hyperhidrosis					1	(0.6)	1	1	1	(0.2)	1	0
Hyperkeratosis	1	(0.3)	1	1					1	(0.2)	1	0
Hyperkeratosis follicularis et parafo	1	(0.3)	1	1					1	(0.2)	1	0
llicularis s	1	(0.3)	1	1					1	(0.2)	1	0
Skin disorder	1	(0.3)	1	1					1	(0.2)	1	0
Urticaria					1	(0.6)	1	1	1	(0.2)	1	0
Eye disorders	12	(3.3)	17	10	4	(2.2)	4	5	16	(3.0)	21	8
Diabetic retinopathy	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Cataract	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Conjunctivitis					2	(1.1)	2	2	2	(0.4)	2	1
Myopia	2	(0.6)	2	1					2	(0.4)	2	1
Cataract diabetic	1	(0.3)	1	1					1	(0.2)	1	0
Conjunctivitis allergic	1	(0.3)	1	1					1	(0.2)	1	0
Dry eye	1	(0.3)	1	1					1	(0.2)	1	0
Eye haemorrhage	1	(0.3)	1	1					1	(0.2)	1	0
Eye swelling	1	(0.3)	1	1					1	(0.2)	1	0
Maculopathy	1	(0.3)	1	1					1	(0.2)	1	0
Retinal aneurysm	1	(0.3)	1	1					1	(0.2)	1	0
Retinal vascular disorder	1	(0.3)	1	1					1	(0.2)	1	0
Retinopathy proliferative	1	(0.3)	1	1					1	(0.2)	1	0
Vitreous fibrin	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Reproductive system and breast disorders	8	(2.2)	9	5	6	(3.3)	7	8	14	(2.6)	16	6
Dysmenorrhoea	4	(1.1)	5	3	2	(1.1)	2	2	6	(1.1)	7	3
Premenstrual syndrome	2	(0.6)	2	1					2	(0.4)	2	1
Breast cyst					1	(0.6)	1	1	1	(0.2)	1	0
Endometriosis	1	(0.3)	1	1					1	(0.2)	1	0
Metrorrhagia					1	(0.6)	1	1	1	(0.2)	1	0
Prostatitis					1	(0.6)	1	1	1	(0.2)	1	0
Uterine polyp	1	(0.3)	1	1					1	(0.2)	1	0
Vulvovaginal pruritus					1	(0.6)	2	2	1	(0.2)	2	1
Investigations	12	(3.3)	12	7	1	(0.6)	3	4	13	(2.4)	15	6
Weight increased	4	(1.1)	4	2					4	(0.7)	4	2
Arthroscopy	1	(0.3)	1	1					1	(0.2)	1	0
Blood bilirubin increased	1	(0.3)	1	1					1	(0.2)	1	0
Blood creatinine increased	1	(0.3)	1	1					1	(0.2)	1	0
Blood pressure increased	1	(0.3)	1	1					1	(0.2)	1	0
Cardiac murmur	1	(0.3)	1	1					1	(0.2)	1	0
Electrocardiogram QT prolonged	1	(0.3)	1	1					1	(0.2)	1	0
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Haemoglobin decreased					1	(0.6)	1	1	1	(0.2)	1	0
Hepatic enzyme increased	1	(0.3)	1	1					1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	1					1	(0.2)	1	0
Urine albumin/creatinine ratio increased					1	(0.6)	1	1	1	(0.2)	1	0
Vascular disorders	9	(2.5)	10	6	4	(2.2)	4	5	13	(2.4)	14	6
Hypertension	8	(2.2)	8	5	2	(1.1)	2	2	10	(1.8)	10	4
Haematoma	1	(0.3)	1	1					1	(0.2)	1	0
Hot flush					1	(0.6)	1	1	1	(0.2)	1	0
Hypotension					1	(0.6)	1	1	1	(0.2)	1	0
Varicose vein	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Immune system disorders	6	(1.7)	6	4	2	(1.1)	2	2	8	(1.5)	8	3
Seasonal allergy	3	(0.8)	3	2	2	(1.1)	2	2	5	(0.9)	5	2
Hypersensitivity	2	(0.6)	2	1					2	(0.4)	2	1
Allergy to animal	1	(0.3)	1	1					1	(0.2)	1	0
Cardiac disorders	4	(1.1)	4	2	3	(1.7)	3	4	7	(1.3)	7	3
Palpitations	2	(0.6)	2	1					2	(0.4)	2	1
Atrial fibrillation					1	(0.6)	1	1	1	(0.2)	1	0
Bifascicular block	1	(0.3)	1	1					1	(0.2)	1	0
Pericardial effusion	1	(0.3)	1	1					1	(0.2)	1	0
Tachyarrhythmia					1	(0.6)	1	1	1	(0.2)	1	0
Tachycardia					1	(0.6)	1	1	1	(0.2)	1	0
Ear and labyrinth disorders	3	(0.8)	3	2	4	(2.2)	5	6	7	(1.3)	8	3
Ear pain	2	(0.6)	2	1	2	(1.1)	2	2	4	(0.7)	4	2
Vertigo	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Middle ear effusion					1	(0.6)	1	1	1	(0.2)	1	0
Tympanic membrane disorder					1	(0.6)	1	1	1	(0.2)	1	0
Renal and urinary disorders	2	(0.6)	2	1	3	(1.7)	3	4	5	(0.9)	5	2
Cystitis												
noninfective	1	(0.3)	1	1					1	(0.2)	1	0
Haematuria					1	(0.6)	1	1	1	(0.2)	1	0
Ketonuria					1	(0.6)	1	1	1	(0.2)	1	0
Renal failure acute	1	(0.3)	1	1					1	(0.2)	1	0
Urinary incontinence					1	(0.6)	1	1	1	(0.2)	1	0
Blood and lymphatic system disorders	1	(0.3)	4	2	3	(1.7)	3	4	4	(0.7)	7	3
Anaemia	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Leukocytosis					1	(0.6)	1	1	1	(0.2)	1	0
Lymphadenitis					1	(0.6)	1	1	1	(0.2)	1	0
Lymphadenopathy	1	(0.3)	3	2					1	(0.2)	3	1

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Hepatobiliary disorders	1 (0.3)	1	1	1 (0.6)	1	1	2 (0.4)	2	1
Hepatic steatosis	1 (0.3)	1	1				1 (0.2)	1	0
Hepatitis toxic				1 (0.6)	1	1	1 (0.2)	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				2 (1.1)	2	2	2 (0.4)	2	1
Benign neoplasm of thyroid gland				1 (0.6)	1	1	1 (0.2)	1	0
Skin papilloma				1 (0.6)	1	1	1 (0.2)	1	0
Endocrine disorders	1 (0.3)	1	1				1 (0.2)	1	0
Hypothyroidism	1 (0.3)	1	1				1 (0.2)	1	0
Surgical and medical procedures				1 (0.6)	1	1	1 (0.2)	1	0
Tooth extraction				1 (0.6)	1	1	1 (0.2)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:22 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

14.3.1.8: Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	31	(8.6)	46	27	13	(7.2)	17	20	44	(8.1)	63	25
Metabolism and nutrition disorders	17	(4.7)	28	17	9	(5.0)	11	13	26	(4.8)	39	15
Hypoglycaemia	11	(3.0)	19	11	5	(2.8)	5	6	16	(3.0)	24	9
Hypoglycaemic unconsciousness	5	(1.4)	5	3	3	(1.7)	3	4	8	(1.5)	8	3
Diabetic ketoacidosis	1	(0.3)	2	1	2	(1.1)	2	2	3	(0.6)	4	2
Hypoglycaemic seizure	1	(0.3)	2	1	1	(0.6)	1	1	2	(0.4)	3	1
Musculoskeletal and connective tissue disorders	4	(1.1)	4	2	2	(1.1)	2	2	6	(1.1)	6	2
Osteoarthritis	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Arthralgia	1	(0.3)	1	1					1	(0.2)	1	0
Intervertebral disc degeneration					1	(0.6)	1	1	1	(0.2)	1	0
Intervertebral disc disorder	1	(0.3)	1	1					1	(0.2)	1	0
Intervertebral disc protrusion	1	(0.3)	1	1					1	(0.2)	1	0
Injury, poisoning and procedural complications	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Ankle fracture	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Wrong drug administered	2	(0.6)	2	1					2	(0.4)	2	1
Psychiatric disorders	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Depression	2	(0.6)	2	1					2	(0.4)	2	1
Suicidal ideation	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:24 - tsum_events_tpl_t030_v01.sas/t_sae_te_soc_pf_sum_sas.txt

Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Gastrointestinal disorders	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Hiatus hernia	2	(0.6)	2	1					2	(0.4)	2	1
Pancreatitis acute					1	(0.6)	1	1	1	(0.2)	1	0
Infections and infestations	3	(0.8)	3	2					3	(0.6)	3	1
Abscess limb	1	(0.3)	1	1					1	(0.2)	1	0
Pulmonary tuberculosis	1	(0.3)	1	1					1	(0.2)	1	0
Wound infection	1	(0.3)	1	1					1	(0.2)	1	0
Cardiac disorders	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Pericardial effusion	1	(0.3)	1	1					1	(0.2)	1	0
Tachyarrhythmia					1	(0.6)	1	1	1	(0.2)	1	0
Eye disorders	1	(0.3)	1	1					1	(0.2)	1	0
Eye haemorrhage	1	(0.3)	1	1					1	(0.2)	1	0
Immune system disorders	1	(0.3)	1	1					1	(0.2)	1	0
Hypersensitivity	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:24 - tsum_events_tpl_t030_v01.sas/t_sae_te_soc_pf_sum_sas.txt

14.3.1.9: Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	53 (14.6)	84	50	26 (14.4)	68	81	79 (14.6)	152	60
Metabolism and nutrition disorders	26 (7.2)	45	27	16 (8.9)	25	30	42 (7.7)	70	28
Hypoglycaemia	23 (6.4)	38	22	15 (8.3)	21	25	38 (7.0)	59	23
Hypoglycaemic unconsciousness	5 (1.4)	5	3	2 (1.1)	2	2	7 (1.3)	7	3
Hypoglycaemic seizure	1 (0.3)	1	1	1 (0.6)	1	1	2 (0.4)	2	1
Diabetic ketoacidosis				1 (0.6)	1	1	1 (0.2)	1	0
Hyperglycaemia	1 (0.3)	1	1				1 (0.2)	1	0
General disorders and administration site conditions	8 (2.2)	9	5	7 (3.9)	35	42	15 (2.8)	44	17
Injection site reaction	3 (0.8)	4	2	5 (2.8)	32	38	8 (1.5)	36	14
Injection site pain	2 (0.6)	2	1	1 (0.6)	1	1	3 (0.6)	3	1
Oedema peripheral	2 (0.6)	2	1				2 (0.4)	2	1
Asthenia				1 (0.6)	1	1	1 (0.2)	1	0
Hunger	1 (0.3)	1	1				1 (0.2)	1	0
Injection site papule				1 (0.6)	1	1	1 (0.2)	1	0
Injury, poisoning and procedural complications	5 (1.4)	5	3	2 (1.1)	2	2	7 (1.3)	7	3
Wrong drug administered	3 (0.8)	3	2	1 (0.6)	1	1	4 (0.7)	4	2
Medication error	1 (0.3)	1	1	1 (0.6)	1	1	2 (0.4)	2	1
Upper limb fracture	1 (0.3)	1	1				1 (0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:26 - tsum_events_tpl_t030_v01.sas/t_ae_te_relatt_insum_sas.txt

Adverse Events Possibly or Probably Related to Investigational Medicinal Product by
System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Investigations	5	(1.4)	5	3	1	(0.6)	1	1	6	(1.1)	6	2
Weight increased	4	(1.1)	4	2					4	(0.7)	4	2
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	1					1	(0.2)	1	0
Nervous system disorders	6	(1.7)	9	5					6	(1.1)	9	4
Headache	4	(1.1)	7	4					4	(0.7)	7	3
Lethargy	1	(0.3)	1	1					1	(0.2)	1	0
Neurological symptom	1	(0.3)	1	1					1	(0.2)	1	0
Infections and infestations	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Abscess	1	(0.3)	1	1					1	(0.2)	1	0
Peritonsillar abscess					1	(0.6)	1	1	1	(0.2)	1	0
Sinusitis	1	(0.3)	1	1					1	(0.2)	1	0
Tracheobronchitis	1	(0.3)	1	1					1	(0.2)	1	0
Gastrointestinal disorders	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Nausea	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Vomiting	1	(0.3)	1	1					1	(0.2)	1	0
Musculoskeletal and connective tissue disorders	3	(0.8)	3	2					3	(0.6)	3	1
Arthralgia	2	(0.6)	2	1					2	(0.4)	2	1
Polyarthrititis	1	(0.3)	1	1					1	(0.2)	1	0
Skin and subcutaneous tissue disorders	1	(0.3)	1	1	2	(1.1)	3	4	3	(0.6)	4	2
Lipohypertrophy					1	(0.6)	2	2	1	(0.2)	2	1
Rash					1	(0.6)	1	1	1	(0.2)	1	0
Skin disorder	1	(0.3)	1	1					1	(0.2)	1	0
Eye disorders	1	(0.3)	1	1					1	(0.2)	1	0
Diabetic retinopathy	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:26 - tsum_events_tpl_t030_v01.sas/t_ae_te_relat_ins_sum_sas.txt

Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Vascular disorders	1	(0.3)	1	1					1	(0.2)	1	0
Hypertension	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:26 - tsum_events_tpl_t030_v01.sas/t_ae_te_relatt_ins_sum_sas.txt

14.3.1.10: Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	47 (13.0)	76	45	26 (14.4)	43	51	73 (13.5)	119	47
Metabolism and nutrition disorders	26 (7.2)	44	26	19 (10.6)	28	33	45 (8.3)	72	28
Hypoglycaemia	22 (6.1)	36	21	16 (8.9)	22	26	38 (7.0)	58	23
Hypoglycaemic unconsciousness	6 (1.7)	6	4	4 (2.2)	4	5	10 (1.8)	10	4
Hypoglycaemic seizure	1 (0.3)	1	1	1 (0.6)	1	1	2 (0.4)	2	1
Diabetic ketoacidosis				1 (0.6)	1	1	1 (0.2)	1	0
Hyperglycaemia	1 (0.3)	1	1				1 (0.2)	1	0
General disorders and administration site conditions	6 (1.7)	8	5	3 (1.7)	4	5	9 (1.7)	12	5
Injection site reaction	2 (0.6)	4	2	2 (1.1)	2	2	4 (0.7)	6	2
Injection site pain	1 (0.3)	1	1	1 (0.6)	1	1	2 (0.4)	2	1
Oedema peripheral	2 (0.6)	2	1				2 (0.4)	2	1
Hunger	1 (0.3)	1	1				1 (0.2)	1	0
Injection site papule				1 (0.6)	1	1	1 (0.2)	1	0
Injury, poisoning and procedural complications	5 (1.4)	5	3	3 (1.7)	3	4	8 (1.5)	8	3
Wrong drug administered	2 (0.6)	2	1	2 (1.1)	2	2	4 (0.7)	4	2
Incorrect dose administered	1 (0.3)	1	1				1 (0.2)	1	0
Medication error				1 (0.6)	1	1	1 (0.2)	1	0
Overdose	1 (0.3)	1	1				1 (0.2)	1	0
Upper limb fracture	1 (0.3)	1	1				1 (0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:28 - tsum_events_tpl_t030_v01.sas/t_ae_te_relatabolu_sum_sas.txt

Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Investigations	4	(1.1)	4	2	1	(0.6)	1	1	5	(0.9)	5	2
Weight increased	3	(0.8)	3	2					3	(0.6)	3	1
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	1					1	(0.2)	1	0
Nervous system disorders	5	(1.4)	8	5					5	(0.9)	8	3
Headache	4	(1.1)	7	4					4	(0.7)	7	3
Neurological symptom	1	(0.3)	1	1					1	(0.2)	1	0
Infections and infestations	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Abscess	1	(0.3)	1	1					1	(0.2)	1	0
Peritonsillar abscess					1	(0.6)	1	1	1	(0.2)	1	0
Sinusitis	1	(0.3)	1	1					1	(0.2)	1	0
Tracheobronchitis	1	(0.3)	1	1					1	(0.2)	1	0
Skin and subcutaneous tissue disorders	1	(0.3)	1	1	2	(1.1)	3	4	3	(0.6)	4	2
Lipohypertrophy					1	(0.6)	2	2	1	(0.2)	2	1
Rash					1	(0.6)	1	1	1	(0.2)	1	0
Skin disorder	1	(0.3)	1	1					1	(0.2)	1	0
Gastrointestinal disorders	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Nausea	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Cardiac disorders					1	(0.6)	1	1	1	(0.2)	1	0
Atrial fibrillation					1	(0.6)	1	1	1	(0.2)	1	0
Eye disorders	1	(0.3)	1	1					1	(0.2)	1	0
Diabetic retinopathy	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:28 - tsum_events_tpl_t030_v01.sas/t_ae_te_relatabolus_sum_sas.txt

Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Psychiatric disorders				1 (0.6)	1	1	1 (0.2)	1	0
Suicidal ideation				1 (0.6)	1	1	1 (0.2)	1	0
Vascular disorders	1 (0.3)	1	1				1 (0.2)	1	0
Hypertension	1 (0.3)	1	1				1 (0.2)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:28 - tsum_events_tpl_t030_v01.sas/t_ae_te_relata_bolus_sum_sas.txt

14.3.1.11: Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	3	(0.8)	3	2					3	(0.6)	3	1
Metabolism and nutrition disorders	3	(0.8)	3	2					3	(0.6)	3	1
Hyperglycaemia	3	(0.8)	3	2					3	(0.6)	3	1

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:30 - tsum_events_tpl_t030_v01.sas/t_ae_te_relat_devis_e_sum_sas.txt

14.3.1.12: Serious Adverse Events Possibly or Probably Related Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	15	(4.1)	25	15	5	(2.8)	7	8	20	(3.7)	32	13
Metabolism and nutrition disorders	14	(3.9)	23	14	5	(2.8)	7	8	19	(3.5)	30	12
Hypoglycaemia	10	(2.8)	18	11	4	(2.2)	4	5	14	(2.6)	22	9
Hypoglycaemic unconsciousness	4	(1.1)	4	2	2	(1.1)	2	2	6	(1.1)	6	2
Hypoglycaemic seizure	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Injury, poisoning and procedural complications	2	(0.6)	2	1					2	(0.4)	2	1
Wrong drug administered	2	(0.6)	2	1					2	(0.4)	2	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:32 - tsum_events_tpl_t030_v01.sas/t_sae_te_relat_ins_sum_sas.txt

14.3.1.13: Serious Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Events	12	(3.3)	22	13	8	(4.4)	10	12	20	(3.7)	32	13
Metabolism and nutrition disorders	12	(3.3)	21	12	7	(3.9)	9	11	19	(3.5)	30	12
Hypoglycaemia	7	(1.9)	15	9	5	(2.8)	5	6	12	(2.2)	20	8
Hypoglycaemic unconsciousness	5	(1.4)	5	3	3	(1.7)	3	4	8	(1.5)	8	3
Hypoglycaemic seizure	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Injury, poisoning and procedural complications	1	(0.3)	1	1					1	(0.2)	1	0
Wrong drug administered	1	(0.3)	1	1					1	(0.2)	1	0
Psychiatric disorders					1	(0.6)	1	1	1	(0.2)	1	0
Suicidal ideation					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:34 - tsum_events_tpl_t030_v01.sas/t_sae_te_relatabolusum_sas.txt

14.3.1.14: Serious Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

There is no data for this Table

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:14:16:57 - tsum_events_tpl_t030/t_sae_te_relat_devis_e_sum_sas.txt

14.3.1.15: Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	45 (12.4)		63	37	26 (14.4)		38	45	71 (13.1)		101	40
Metabolism and nutrition disorders	32 (8.8)		44	26	20 (11.1)		29	35	52 (9.6)		73	29
Hypoglycaemia	25 (6.9)		35	21	18 (10.0)		23	27	43 (7.9)		58	23
Hypoglycaemic unconsciousness	6 (1.7)		6	4	3 (1.7)		3	4	9 (1.7)		9	4
Diabetic ketoacidosis	1 (0.3)		1	1	2 (1.1)		2	2	3 (0.6)		3	1
Hypoglycaemic seizure	1 (0.3)		2	1	1 (0.6)		1	1	2 (0.4)		3	1
Gastrointestinal disorders	4 (1.1)		5	3	1 (0.6)		1	1	5 (0.9)		6	2
Nausea	1 (0.3)		1	1	1 (0.6)		1	1	2 (0.4)		2	1
Abdominal pain	1 (0.3)		1	1					1 (0.2)		1	0
Constipation	1 (0.3)		1	1					1 (0.2)		1	0
Hiatus hernia	1 (0.3)		1	1					1 (0.2)		1	0
Vomiting	1 (0.3)		1	1					1 (0.2)		1	0
Musculoskeletal and connective tissue disorders	2 (0.6)		3	2	3 (1.7)		3	4	5 (0.9)		6	2
Arthralgia	1 (0.3)		1	1					1 (0.2)		1	0
Intervertebral disc degeneration					1 (0.6)		1	1	1 (0.2)		1	0
Intervertebral disc disorder	1 (0.3)		1	1					1 (0.2)		1	0
Myalgia					1 (0.6)		1	1	1 (0.2)		1	0
Osteoarthritis					1 (0.6)		1	1	1 (0.2)		1	0
Systemic lupus erythematosus	1 (0.3)		1	1					1 (0.2)		1	0
Injury, poisoning and procedural complications	2 (0.6)		2	1	2 (1.1)		2	2	4 (0.7)		4	2
Medication error	1 (0.3)		1	1	1 (0.6)		1	1	2 (0.4)		2	1
Skin laceration	1 (0.3)		1	1					1 (0.2)		1	0
Wrong drug administered					1 (0.6)		1	1	1 (0.2)		1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:36 - tsum_events_tpl_t030_v01.sas/t_ae_te_sev_soc_pf_sum_sas.txt

Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Infections and infestations	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Abscess limb	1	(0.3)	1	1					1	(0.2)	1	0
Gastroenteritis					1	(0.6)	1	1	1	(0.2)	1	0
Pulmonary tuberculosis	1	(0.3)	1	1					1	(0.2)	1	0
Psychiatric disorders	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Suicidal ideation	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Depression	1	(0.3)	1	1					1	(0.2)	1	0
Nervous system disorders	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Headache					1	(0.6)	1	1	1	(0.2)	1	0
Neurological symptom	1	(0.3)	1	1					1	(0.2)	1	0
Eye disorders	1	(0.3)	1	1					1	(0.2)	1	0
Eye haemorrhage	1	(0.3)	1	1					1	(0.2)	1	0
General disorders and administration site conditions	1	(0.3)	1	1					1	(0.2)	1	0
Influenza like illness	1	(0.3)	1	1					1	(0.2)	1	0
Immune system disorders	1	(0.3)	1	1					1	(0.2)	1	0
Hypersensitivity	1	(0.3)	1	1					1	(0.2)	1	0
Skin and subcutaneous tissue disorders	1	(0.3)	1	1					1	(0.2)	1	0
Rash	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:36 - tsum_events_tpl_t030_v01.sas/t_ae_te_sev_soc_pf_sum_sas.txt

14.3.1.16: Severe Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	26	(7.2)	37	22	15	(8.3)	21	25	41	(7.6)	58	23
Metabolism and nutrition disorders	24	(6.6)	35	21	14	(7.8)	19	23	38	(7.0)	54	21
Hypoglycaemia	19	(5.2)	29	17	13	(7.2)	15	18	32	(5.9)	44	17
Hypoglycaemic unconsciousness	5	(1.4)	5	3	2	(1.1)	2	2	7	(1.3)	7	3
Hypoglycaemic seizure	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Diabetic ketoacidosis					1	(0.6)	1	1	1	(0.2)	1	0
Injury, poisoning and procedural complications	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Medication error	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Gastrointestinal disorders					1	(0.6)	1	1	1	(0.2)	1	0
Nausea					1	(0.6)	1	1	1	(0.2)	1	0
Nervous system disorders	1	(0.3)	1	1					1	(0.2)	1	0
Neurological symptom	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:38 - tsum_events_tpl_t030_v01.sas/t_ae_te_sev_relat_ins_sum_sas.txt

14.3.1.17: Severe Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term – Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Events	23	(6.4)	34	20	17	(9.4)	26	31	40	(7.4)	60	24
Metabolism and nutrition disorders	22	(6.1)	33	19	15	(8.3)	23	27	37	(6.8)	56	22
Hypoglycaemia	16	(4.4)	26	15	13	(7.2)	18	21	29	(5.4)	44	17
Hypoglycaemic unconsciousness	6	(1.7)	6	4	3	(1.7)	3	4	9	(1.7)	9	4
Hypoglycaemic seizure	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Diabetic ketoacidosis					1	(0.6)	1	1	1	(0.2)	1	0
Gastrointestinal disorders					1	(0.6)	1	1	1	(0.2)	1	0
Nausea					1	(0.6)	1	1	1	(0.2)	1	0
Injury, poisoning and procedural complications					1	(0.6)	1	1	1	(0.2)	1	0
Wrong drug administered					1	(0.6)	1	1	1	(0.2)	1	0
Nervous system disorders	1	(0.3)	1	1					1	(0.2)	1	0
Neurological symptom	1	(0.3)	1	1					1	(0.2)	1	0
Psychiatric disorders					1	(0.6)	1	1	1	(0.2)	1	0
Suicidal ideation					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:40 - tsum_events_tpl_t030_v01.sas/t_ae_te_sev_relat_bolus_sum_sas.txt

14.3.1.18: Severe Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

There is no data for this Table

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:14:16:58 - tsum_events_tpl_t030/t_ae_te_sev_relat_device_sum_sas.txt

14.3.1.19: Serious Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Events	21	(5.8)	34	20	11	(6.1)	13	15	32	(5.9)	47	19
Metabolism and nutrition disorders	16	(4.4)	26	15	8	(4.4)	10	12	24	(4.4)	36	14
Hypoglycaemia	10	(2.8)	18	11	5	(2.8)	5	6	15	(2.8)	23	9
Hypoglycaemic unconsciousness	5	(1.4)	5	3	3	(1.7)	3	4	8	(1.5)	8	3
Diabetic ketoacidosis	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Hypoglycaemic seizure	1	(0.3)	2	1	1	(0.6)	1	1	2	(0.4)	3	1
Musculoskeletal and connective tissue disorders	1	(0.3)	1	1	2	(1.1)	2	2	3	(0.6)	3	1
Intervertebral disc degeneration					1	(0.6)	1	1	1	(0.2)	1	0
Intervertebral disc disorder	1	(0.3)	1	1					1	(0.2)	1	0
Osteoarthritis					1	(0.6)	1	1	1	(0.2)	1	0
Psychiatric disorders	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Suicidal ideation	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Depression	1	(0.3)	1	1					1	(0.2)	1	0
Infections and infestations	2	(0.6)	2	1					2	(0.4)	2	1
Abscess limb	1	(0.3)	1	1					1	(0.2)	1	0
Pulmonary tuberculosis	1	(0.3)	1	1					1	(0.2)	1	0
Eye disorders	1	(0.3)	1	1					1	(0.2)	1	0
Eye haemorrhage	1	(0.3)	1	1					1	(0.2)	1	0
Gastrointestinal disorders	1	(0.3)	1	1					1	(0.2)	1	0
Hiatus hernia	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:42 - tsum_events_tpl_t030_v01.sas/t_sae_te_sev_soc_pf_sum_sas.txt

Serious Severe Adverse Events by System Organ Class and Preferred Term - Treatment
 Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Immune system disorders	1	(0.3)	1	1					1	(0.2)	1	0
Hypersensitivity	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:42 - tsum_events_tpl_t030_v01.sas/t_sae_te_sev_soc_pf_sum_sas.txt

14.3.1.20: Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	104 (28.7)	183	108	40 (22.2)	81	97	144 (26.6)	264	104
Infections and infestations	60 (16.6)	72	43	17 (9.4)	23	27	77 (14.2)	95	38
Nasopharyngitis	14 (3.9)	14	8	3 (1.7)	4	5	17 (3.1)	18	7
Influenza	8 (2.2)	8	5	2 (1.1)	2	2	10 (1.8)	10	4
Gastroenteritis	5 (1.4)	5	3	3 (1.7)	3	4	8 (1.5)	8	3
Sinusitis	6 (1.7)	7	4	2 (1.1)	2	2	8 (1.5)	9	4
Upper respiratory tract infection	4 (1.1)	5	3	2 (1.1)	4	5	6 (1.1)	9	4
Tooth abscess	4 (1.1)	4	2	1 (0.6)	1	1	5 (0.9)	5	2
Cellulitis	3 (0.8)	3	2	1 (0.6)	1	1	4 (0.7)	4	2
Infection	3 (0.8)	3	2	1 (0.6)	1	1	4 (0.7)	4	2
Bronchitis	3 (0.8)	3	2				3 (0.6)	3	1
Gastroenteritis viral	2 (0.6)	2	1	1 (0.6)	1	1	3 (0.6)	3	1
Viral infection	1 (0.3)	1	1	2 (1.1)	2	2	3 (0.6)	3	1
H1N1 influenza	1 (0.3)	1	1	1 (0.6)	1	1	2 (0.4)	2	1
Tooth infection	2 (0.6)	2	1				2 (0.4)	2	1
Urinary tract infection	1 (0.3)	1	1	1 (0.6)	1	1	2 (0.4)	2	1
Abscess	1 (0.3)	1	1				1 (0.2)	1	0
Acute sinusitis	1 (0.3)	1	1				1 (0.2)	1	0
Cystitis	1 (0.3)	1	1				1 (0.2)	1	0
Fungal infection	1 (0.3)	1	1				1 (0.2)	1	0
Gingival abscess	1 (0.3)	1	1				1 (0.2)	1	0
Labyrinthitis	1 (0.3)	1	1				1 (0.2)	1	0
Localised infection	1 (0.3)	1	1				1 (0.2)	1	0
Pneumonia	1 (0.3)	1	1				1 (0.2)	1	0
Respiratory tract infection viral	1 (0.3)	1	1				1 (0.2)	1	0
Staphylococcal infection	1 (0.3)	1	1				1 (0.2)	1	0
Staphylococcal skin infection	1 (0.3)	1	1				1 (0.2)	1	0
Tracheobronchitis	1 (0.3)	1	1				1 (0.2)	1	0
Wound infection	1 (0.3)	1	1				1 (0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:45 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Metabolism and nutrition disorders	15	(4.1)	20	12	8	(4.4)	11	13	23	(4.2)	31	12
Hypoglycaemia	9	(2.5)	12	7	5	(2.8)	7	8	14	(2.6)	19	8
Dehydration	2	(0.6)	2	1					2	(0.4)	2	1
Diabetic ketoacidosis	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Vitamin D deficiency	2	(0.6)	2	1					2	(0.4)	2	1
Gout	1	(0.3)	1	1					1	(0.2)	1	0
Hypercholesterolaemia	1	(0.3)	1	1					1	(0.2)	1	0
Hyperglycaemia	1	(0.3)	1	1					1	(0.2)	1	0
Hypoglycaemic unconsciousness					1	(0.6)	1	1	1	(0.2)	1	0
Hypokalaemia					1	(0.6)	1	1	1	(0.2)	1	0
Hypovolaemia					1	(0.6)	1	1	1	(0.2)	1	0
Injury, poisoning and procedural complications	16	(4.4)	18	11	6	(3.3)	7	8	22	(4.1)	25	10
Wrong drug administered	6	(1.7)	6	4	1	(0.6)	1	1	7	(1.3)	7	3
Ankle fracture	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Fall	2	(0.6)	2	1					2	(0.4)	2	1
Rib fracture	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Concussion	1	(0.3)	1	1					1	(0.2)	1	0
Corneal scar	1	(0.3)	1	1					1	(0.2)	1	0
Foot fracture	1	(0.3)	1	1					1	(0.2)	1	0
Injury corneal					1	(0.6)	1	1	1	(0.2)	1	0
Joint dislocation	1	(0.3)	1	1					1	(0.2)	1	0
Medication error					1	(0.6)	1	1	1	(0.2)	1	0
Muscle strain	1	(0.3)	1	1					1	(0.2)	1	0
Post procedural haemorrhage					1	(0.6)	1	1	1	(0.2)	1	0
Procedural pain					1	(0.6)	1	1	1	(0.2)	1	0
Skin laceration	1	(0.3)	1	1					1	(0.2)	1	0
Soft tissue injury	1	(0.3)	1	1					1	(0.2)	1	0
Upper limb fracture	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:45 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Musculoskeletal and connective tissue disorders	13	(3.6)	14	8	9	(5.0)	11	13	22	(4.1)	25	10
Back pain	1	(0.3)	1	1	3	(1.7)	3	4	4	(0.7)	4	2
Arthralgia	3	(0.8)	3	2					3	(0.6)	3	1
Myalgia	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Osteoarthritis	2	(0.6)	2	1					2	(0.4)	2	1
Pain in extremity	1	(0.3)	1	1	1	(0.6)	2	2	2	(0.4)	3	1
Intervertebral disc protrusion	1	(0.3)	1	1					1	(0.2)	1	0
Joint swelling					1	(0.6)	1	1	1	(0.2)	1	0
Muscle spasms	1	(0.3)	1	1					1	(0.2)	1	0
Musculoskeletal pain	1	(0.3)	1	1					1	(0.2)	1	0
Neck pain					1	(0.6)	1	1	1	(0.2)	1	0
Osteopenia					1	(0.6)	1	1	1	(0.2)	1	0
Periarthritis					1	(0.6)	1	1	1	(0.2)	1	0
Plantar fasciitis					1	(0.6)	1	1	1	(0.2)	1	0
Polyarthrititis	1	(0.3)	1	1					1	(0.2)	1	0
Rotator cuff syndrome	1	(0.3)	1	1					1	(0.2)	1	0
Gastrointestinal disorders	9	(2.5)	14	8	6	(3.3)	7	8	15	(2.8)	21	8
Vomiting	4	(1.1)	4	2					4	(0.7)	4	2
Diarrhoea	1	(0.3)	2	1	2	(1.1)	2	2	3	(0.6)	4	2
Nausea	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Toothache	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Abdominal pain upper	1	(0.3)	1	1					1	(0.2)	1	0
Gastrooesophageal reflux disease	1	(0.3)	2	1					1	(0.2)	2	1
Haemorrhoids					1	(0.6)	1	1	1	(0.2)	1	0
Hiatus hernia	1	(0.3)	1	1					1	(0.2)	1	0
Pancreatitis	1	(0.3)	1	1					1	(0.2)	1	0
Pancreatitis acute					1	(0.6)	1	1	1	(0.2)	1	0
Umbilical hernia					1	(0.6)	1	1	1	(0.2)	1	0
Psychiatric disorders	7	(1.9)	7	4	4	(2.2)	5	6	11	(2.0)	12	5
Depression	6	(1.7)	6	4	2	(1.1)	2	2	8	(1.5)	8	3
Anxiety	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Insomnia					2	(1.1)	2	2	2	(0.4)	2	1

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:45 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
General disorders and administration site conditions	7	(1.9)	7	4	3	(1.7)	3	4	10	(1.8)	10	4
Influenza like illness	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Injection site reaction	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Pyrexia	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Chest pain	1	(0.3)	1	1					1	(0.2)	1	0
Oedema peripheral	1	(0.3)	1	1					1	(0.2)	1	0
Pain	1	(0.3)	1	1					1	(0.2)	1	0
Respiratory, thoracic and mediastinal disorders	8	(2.2)	9	5	2	(1.1)	2	2	10	(1.8)	11	4
Oropharyngeal pain	3	(0.8)	3	2					3	(0.6)	3	1
Asthma	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Cough	2	(0.6)	3	2					2	(0.4)	3	1
Dyspnoea					1	(0.6)	1	1	1	(0.2)	1	0
Emphysema	1	(0.3)	1	1					1	(0.2)	1	0
Vocal cord disorder	1	(0.3)	1	1					1	(0.2)	1	0
Nervous system disorders	6	(1.7)	6	4	2	(1.1)	3	4	8	(1.5)	9	4
Headache	3	(0.8)	3	2	1	(0.6)	2	2	4	(0.7)	5	2
Dizziness	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Lethargy	1	(0.3)	1	1					1	(0.2)	1	0
Migraine	1	(0.3)	1	1					1	(0.2)	1	0
Vascular disorders	5	(1.4)	5	3					5	(0.9)	5	2
Hypertension	4	(1.1)	4	2					4	(0.7)	4	2
Varicose vein	1	(0.3)	1	1					1	(0.2)	1	0
Investigations	4	(1.1)	4	2					4	(0.7)	4	2
Blood creatinine increased	1	(0.3)	1	1					1	(0.2)	1	0
Blood pressure increased	1	(0.3)	1	1					1	(0.2)	1	0
Hepatic enzyme increased	1	(0.3)	1	1					1	(0.2)	1	0
Weight increased	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:45 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Skin and subcutaneous tissue disorders	2	(0.6)	2	1	2	(1.1)	2	2	4	(0.7)	4	2
Lipodystrophy acquired					1	(0.6)	1	1	1	(0.2)	1	0
Lipohypertrophy					1	(0.6)	1	1	1	(0.2)	1	0
Pruritus	1	(0.3)	1	1					1	(0.2)	1	0
Skin disorder	1	(0.3)	1	1					1	(0.2)	1	0
Cardiac disorders	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Pericardial effusion	1	(0.3)	1	1					1	(0.2)	1	0
Tachycardia					1	(0.6)	1	1	1	(0.2)	1	0
Ear and labyrinth disorders					2	(1.1)	2	2	2	(0.4)	2	1
Ear pain					1	(0.6)	1	1	1	(0.2)	1	0
Vertigo					1	(0.6)	1	1	1	(0.2)	1	0
Eye disorders	2	(0.6)	2	1					2	(0.4)	2	1
Maculopathy	1	(0.3)	1	1					1	(0.2)	1	0
Retinal vascular disorder	1	(0.3)	1	1					1	(0.2)	1	0
Immune system disorders	2	(0.6)	2	1					2	(0.4)	2	1
Hypersensitivity	1	(0.3)	1	1					1	(0.2)	1	0
Seasonal allergy	1	(0.3)	1	1					1	(0.2)	1	0
Blood and lymphatic system disorders					1	(0.6)	1	1	1	(0.2)	1	0
Leukocytosis					1	(0.6)	1	1	1	(0.2)	1	0
Hepatobiliary disorders					1	(0.6)	1	1	1	(0.2)	1	0
Hepatitis toxic					1	(0.6)	1	1	1	(0.2)	1	0
Renal and urinary disorders					1	(0.6)	1	1	1	(0.2)	1	0
Urinary incontinence					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:45 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent -
Summary - Safety Analysis Set

	IDegAsp	OD			IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders					1	(0.6)	1	1	1	(0.2)	1	0
Vulvovaginal pruritus					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:45 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

14.3.1.21: Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	191	(52.8)	600	354	102	(56.7)	317	378	293	(54.1)	917	362
Infections and infestations	115	(31.8)	216	128	63	(35.0)	101	120	178	(32.8)	317	125
Nasopharyngitis	68	(18.8)	97	57	29	(16.1)	40	48	97	(17.9)	137	54
Upper respiratory tract infection	21	(5.8)	28	17	15	(8.3)	22	26	36	(6.6)	50	20
Influenza	10	(2.8)	10	6	5	(2.8)	6	7	15	(2.8)	16	6
Viral infection	6	(1.7)	6	4	3	(1.7)	3	4	9	(1.7)	9	4
Gastroenteritis	5	(1.4)	5	3	2	(1.1)	2	2	7	(1.3)	7	3
Bronchitis	5	(1.4)	5	3	1	(0.6)	1	1	6	(1.1)	6	2
Acute tonsillitis	4	(1.1)	6	4	1	(0.6)	1	1	5	(0.9)	7	3
Localised infection	3	(0.8)	3	2	2	(1.1)	2	2	5	(0.9)	5	2
Gastroenteritis viral	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Pharyngitis	4	(1.1)	6	4					4	(0.7)	6	2
Sinusitis	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Ear infection	3	(0.8)	3	2					3	(0.6)	3	1
Respiratory tract infection					3	(1.7)	3	4	3	(0.6)	3	1
Tooth abscess	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Tooth infection	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Urinary tract infection	1	(0.3)	2	1	2	(1.1)	2	2	3	(0.6)	4	2
Viral upper respiratory tract infection	3	(0.8)	3	2					3	(0.6)	3	1
Vulvovaginal candidiasis	2	(0.6)	3	2	1	(0.6)	1	1	3	(0.6)	4	2
Eye infection					2	(1.1)	2	2	2	(0.4)	2	1
Oral herpes	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Pharyngitis streptococcal	2	(0.6)	2	1					2	(0.4)	2	1
Staphylococcal skin infection	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Abscess limb	1	(0.3)	2	1					1	(0.2)	2	1
Acute sinusitis	1	(0.3)	1	1					1	(0.2)	1	0
Blister infected	1	(0.3)	1	1					1	(0.2)	1	0
Erysipelas	1	(0.3)	1	1					1	(0.2)	1	0
Fungal infection					1	(0.6)	1	1	1	(0.2)	1	0
Genital candidiasis	1	(0.3)	1	1					1	(0.2)	1	0
Gingival abscess					1	(0.6)	1	1	1	(0.2)	1	0
Groin abscess	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent -
 Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Herpes simplex				1 (0.6)	1	1	1 (0.2)	1	0
Intrauterine infection				1 (0.6)	1	1	1 (0.2)	1	0
Laryngitis	1 (0.3)	1	1				1 (0.2)	1	0
Lower respiratory tract infection	1 (0.3)	1	1				1 (0.2)	1	0
Mastitis				1 (0.6)	1	1	1 (0.2)	1	0
Onychomycosis	1 (0.3)	1	1				1 (0.2)	1	0
Oral fungal infection				1 (0.6)	1	1	1 (0.2)	1	0
Peritonsillar abscess				1 (0.6)	1	1	1 (0.2)	1	0
Pilonidal cyst	1 (0.3)	1	1				1 (0.2)	1	0
Pneumonia				1 (0.6)	1	1	1 (0.2)	1	0
Postoperative wound infection	1 (0.3)	2	1				1 (0.2)	2	1
Rhinitis	1 (0.3)	1	1				1 (0.2)	1	0
Rotavirus infection	1 (0.3)	1	1				1 (0.2)	1	0
Skin infection	1 (0.3)	1	1				1 (0.2)	1	0
Subcutaneous abscess	1 (0.3)	4	2				1 (0.2)	4	2
Superinfection	1 (0.3)	1	1				1 (0.2)	1	0
Taeniasis	1 (0.3)	1	1				1 (0.2)	1	0
Tinea infection				1 (0.6)	1	1	1 (0.2)	1	0
Tonsillitis	1 (0.3)	1	1				1 (0.2)	1	0
Vaginal infection				1 (0.6)	1	1	1 (0.2)	1	0
Viral pharyngitis	1 (0.3)	1	1				1 (0.2)	1	0
Vulvovaginal mycotic infection	1 (0.3)	1	1				1 (0.2)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Gastrointestinal disorders	41	(11.3)	58	34	22	(12.2)	39	46	63	(11.6)	97	38
Diarrhoea	9	(2.5)	9	5	7	(3.9)	7	8	16	(3.0)	16	6
Nausea	8	(2.2)	8	5	5	(2.8)	6	7	13	(2.4)	14	6
Vomiting	6	(1.7)	7	4	5	(2.8)	5	6	11	(2.0)	12	5
Abdominal discomfort	5	(1.4)	7	4	4	(2.2)	5	6	9	(1.7)	12	5
Abdominal pain upper	5	(1.4)	5	3	3	(1.7)	3	4	8	(1.5)	8	3
Dyspepsia	3	(0.8)	3	2	4	(2.2)	4	5	7	(1.3)	7	3
Abdominal pain	4	(1.1)	5	3	1	(0.6)	1	1	5	(0.9)	6	2
Food poisoning	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Gastritis	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Gastrooesophageal reflux disease	2	(0.6)	5	3					2	(0.4)	5	2
Rectal haemorrhage	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Toothache	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Abdominal distension	1	(0.3)	1	1					1	(0.2)	1	0
Colitis					1	(0.6)	1	1	1	(0.2)	1	0
Flatulence					1	(0.6)	1	1	1	(0.2)	1	0
Mouth ulceration	1	(0.3)	2	1					1	(0.2)	2	1
Oesophagitis					1	(0.6)	1	1	1	(0.2)	1	0
Pancreatitis chronic					1	(0.6)	1	1	1	(0.2)	1	0
Periodontitis	1	(0.3)	1	1					1	(0.2)	1	0
Nervous system disorders	38	(10.5)	98	58	15	(8.3)	18	21	53	(9.8)	116	46
Headache	26	(7.2)	80	47	13	(7.2)	15	18	39	(7.2)	95	38
Migraine	5	(1.4)	5	3	1	(0.6)	1	1	6	(1.1)	6	2
Sinus headache	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Dizziness	2	(0.6)	2	1					2	(0.4)	2	1
Lethargy	2	(0.6)	2	1					2	(0.4)	2	1
Aphonia	1	(0.3)	1	1					1	(0.2)	1	0
Areflexia	1	(0.3)	1	1					1	(0.2)	1	0
Carpal tunnel syndrome	1	(0.3)	1	1					1	(0.2)	1	0
Hypoaesthesia	1	(0.3)	1	1					1	(0.2)	1	0
Neuropathy peripheral					1	(0.6)	1	1	1	(0.2)	1	0
Paraesthesia	1	(0.3)	1	1					1	(0.2)	1	0
Phantom pain	1	(0.3)	1	1					1	(0.2)	1	0
Sensory loss	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent -
Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
General disorders and administration site conditions	32	(8.8)	39	23	20	(11.1)	51	61	52	(9.6)	90	36
Pyrexia	6	(1.7)	6	4	4	(2.2)	4	5	10	(1.8)	10	4
Injection site reaction	3	(0.8)	4	2	5	(2.8)	32	38	8	(1.5)	36	14
Fatigue	3	(0.8)	3	2	4	(2.2)	4	5	7	(1.3)	7	3
Influenza like illness	6	(1.7)	7	4	1	(0.6)	1	1	7	(1.3)	8	3
Oedema peripheral	6	(1.7)	8	5					6	(1.1)	8	3
Malaise	4	(1.1)	4	2					4	(0.7)	4	2
Hunger	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Injection site pain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Asthenia	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Discomfort					2	(1.1)	2	2	2	(0.4)	2	1
Cyst	1	(0.3)	1	1					1	(0.2)	1	0
Feeling cold					1	(0.6)	1	1	1	(0.2)	1	0
Injection site haematoma					1	(0.6)	1	1	1	(0.2)	1	0
Injection site hypertrophy					1	(0.6)	1	1	1	(0.2)	1	0
Injection site papule					1	(0.6)	1	1	1	(0.2)	1	0
Non-cardiac chest pain	1	(0.3)	1	1					1	(0.2)	1	0
Pain					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Musculoskeletal and connective tissue disorders	25	(6.9)	38	22	16	(8.9)	22	26	41	(7.6)	60	24
Arthralgia	4	(1.1)	4	2	5	(2.8)	5	6	9	(1.7)	9	4
Pain in extremity	6	(1.7)	7	4	2	(1.1)	2	2	8	(1.5)	9	4
Back pain	5	(1.4)	6	4	2	(1.1)	3	4	7	(1.3)	9	4
Neck pain	6	(1.7)	7	4	1	(0.6)	1	1	7	(1.3)	8	3
Musculoskeletal pain	2	(0.6)	2	1	4	(2.2)	4	5	6	(1.1)	6	2
Muscle spasms	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Musculoskeletal chest pain					2	(1.1)	2	2	2	(0.4)	2	1
Periarthritis	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Arthritis	1	(0.3)	1	1					1	(0.2)	1	0
Bunion	1	(0.3)	1	1					1	(0.2)	1	0
Costochondritis	1	(0.3)	1	1					1	(0.2)	1	0
Dupuytren's contracture	1	(0.3)	1	1					1	(0.2)	1	0
Foot deformity	1	(0.3)	1	1					1	(0.2)	1	0
Intervertebral disc protrusion	1	(0.3)	1	1					1	(0.2)	1	0
Joint swelling	1	(0.3)	2	1					1	(0.2)	2	1
Myalgia	1	(0.3)	1	1					1	(0.2)	1	0
Myositis					1	(0.6)	2	2	1	(0.2)	2	1
Osteoporosis	1	(0.3)	1	1					1	(0.2)	1	0
Trigger finger					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent -
Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Injury, poisoning and procedural complications	21	(5.8)	30	18	14	(7.8)	16	19	35	(6.5)	46	18
Wrong drug administered	5	(1.4)	6	4	3	(1.7)	3	4	8	(1.5)	9	4
Vaccination complication	4	(1.1)	5	3	3	(1.7)	3	4	7	(1.3)	8	3
Joint sprain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Contusion	2	(0.6)	3	2					2	(0.4)	3	1
Eye injury	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Foot fracture	2	(0.6)	2	1					2	(0.4)	2	1
Incorrect dose administered	2	(0.6)	2	1					2	(0.4)	2	1
Limb injury	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Muscle strain	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Epicondylitis	1	(0.3)	1	1					1	(0.2)	1	0
Face injury	1	(0.3)	1	1					1	(0.2)	1	0
Foreign body					1	(0.6)	1	1	1	(0.2)	1	0
Hand fracture					1	(0.6)	1	1	1	(0.2)	1	0
Limb traumatic amputation					1	(0.6)	1	1	1	(0.2)	1	0
Overdose	1	(0.3)	1	1					1	(0.2)	1	0
Post-traumatic pain					1	(0.6)	1	1	1	(0.2)	1	0
Procedural pain					1	(0.6)	1	1	1	(0.2)	1	0
Road traffic accident					1	(0.6)	1	1	1	(0.2)	1	0
Skin laceration	1	(0.3)	2	1					1	(0.2)	2	1
Tooth fracture	1	(0.3)	2	1					1	(0.2)	2	1

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Respiratory, thoracic and mediastinal disorders	20	(5.5)	33	19	11	(6.1)	12	14	31	(5.7)	45	18
Oropharyngeal pain	9	(2.5)	11	6	4	(2.2)	4	5	13	(2.4)	15	6
Cough	3	(0.8)	4	2	2	(1.1)	2	2	5	(0.9)	6	2
Dyspnoea	4	(1.1)	4	2					4	(0.7)	4	2
Sinus congestion	1	(0.3)	2	1	2	(1.1)	2	2	3	(0.6)	4	2
Epistaxis	2	(0.6)	3	2					2	(0.4)	3	1
Respiratory disorder	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Asthma					1	(0.6)	1	1	1	(0.2)	1	0
Bronchospasm					1	(0.6)	1	1	1	(0.2)	1	0
Dysphonia					1	(0.6)	1	1	1	(0.2)	1	0
Dyspnoea exertional	1	(0.3)	1	1					1	(0.2)	1	0
Paranasal sinus hypersecretion	1	(0.3)	1	1					1	(0.2)	1	0
Pulmonary congestion	1	(0.3)	1	1					1	(0.2)	1	0
Pulmonary fibrosis	1	(0.3)	1	1					1	(0.2)	1	0
Rhinitis allergic	1	(0.3)	1	1					1	(0.2)	1	0
Rhinorrhoea	1	(0.3)	1	1					1	(0.2)	1	0
Throat irritation	1	(0.3)	1	1					1	(0.2)	1	0
Upper respiratory tract congestion	1	(0.3)	1	1					1	(0.2)	1	0
Metabolism and nutrition disorders	15	(4.1)	15	9	7	(3.9)	7	8	22	(4.1)	22	9
Hyperlipidaemia	5	(1.4)	5	3	2	(1.1)	2	2	7	(1.3)	7	3
Hypercholesterolaemia	3	(0.8)	3	2	2	(1.1)	2	2	5	(0.9)	5	2
Hypoglycaemia	2	(0.6)	2	1	2	(1.1)	2	2	4	(0.7)	4	2
Hyperglycaemia	3	(0.8)	3	2					3	(0.6)	3	1
Decreased appetite	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Hypertriglyceridaemia	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Skin and subcutaneous tissue disorders	9	(2.5)	12	7	12	(6.7)	13	15	21	(3.9)	25	10
Rash					5	(2.8)	5	6	5	(0.9)	5	2
Lipodystrophy acquired	1	(0.3)	1	1	2	(1.1)	2	2	3	(0.6)	3	1
Dry skin	2	(0.6)	2	1					2	(0.4)	2	1
Lipohypertrophy	1	(0.3)	1	1	1	(0.6)	2	2	2	(0.4)	3	1
Rash pruritic	2	(0.6)	2	1					2	(0.4)	2	1
Acne	1	(0.3)	1	1					1	(0.2)	1	0
Alopecia	1	(0.3)	1	1					1	(0.2)	1	0
Eczema	1	(0.3)	1	1					1	(0.2)	1	0
Erythema	1	(0.3)	1	1					1	(0.2)	1	0
Heat rash					1	(0.6)	1	1	1	(0.2)	1	0
Hyperhidrosis					1	(0.6)	1	1	1	(0.2)	1	0
Hyperkeratosis	1	(0.3)	1	1					1	(0.2)	1	0
Hyperkeratosis follicularis et parafollicularis	1	(0.3)	1	1					1	(0.2)	1	0
Pruritus					1	(0.6)	1	1	1	(0.2)	1	0
Urticaria					1	(0.6)	1	1	1	(0.2)	1	0
Eye disorders	11	(3.0)	14	8	4	(2.2)	4	5	15	(2.8)	18	7
Diabetic retinopathy	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Cataract	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Conjunctivitis					2	(1.1)	2	2	2	(0.4)	2	1
Myopia	2	(0.6)	2	1					2	(0.4)	2	1
Cataract diabetic	1	(0.3)	1	1					1	(0.2)	1	0
Conjunctivitis allergic	1	(0.3)	1	1					1	(0.2)	1	0
Dry eye	1	(0.3)	1	1					1	(0.2)	1	0
Eye swelling	1	(0.3)	1	1					1	(0.2)	1	0
Retinal aneurysm	1	(0.3)	1	1					1	(0.2)	1	0
Retinopathy proliferative	1	(0.3)	1	1					1	(0.2)	1	0
Vitreous fibrin	1	(0.3)	1	1					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Reproductive system and breast disorders	8	(2.2)	9	5	6	(3.3)	6	7	14	(2.6)	15	6
Dysmenorrhoea	4	(1.1)	5	3	2	(1.1)	2	2	6	(1.1)	7	3
Premenstrual syndrome	2	(0.6)	2	1					2	(0.4)	2	1
Breast cyst					1	(0.6)	1	1	1	(0.2)	1	0
Endometriosis	1	(0.3)	1	1					1	(0.2)	1	0
Metrorrhagia					1	(0.6)	1	1	1	(0.2)	1	0
Prostatitis					1	(0.6)	1	1	1	(0.2)	1	0
Uterine polyp	1	(0.3)	1	1					1	(0.2)	1	0
Vulvovaginal pruritus					1	(0.6)	1	1	1	(0.2)	1	0
Psychiatric disorders	6	(1.7)	8	5	7	(3.9)	7	8	13	(2.4)	15	6
Insomnia	3	(0.8)	3	2	2	(1.1)	2	2	5	(0.9)	5	2
Stress	1	(0.3)	1	1	4	(2.2)	4	5	5	(0.9)	5	2
Anxiety	1	(0.3)	2	1					1	(0.2)	2	1
Depression					1	(0.6)	1	1	1	(0.2)	1	0
Drug abuse	1	(0.3)	1	1					1	(0.2)	1	0
Sleep disorder	1	(0.3)	1	1					1	(0.2)	1	0
Investigations	8	(2.2)	8	5	1	(0.6)	3	4	9	(1.7)	11	4
Weight increased	3	(0.8)	3	2					3	(0.6)	3	1
Arthroscopy	1	(0.3)	1	1					1	(0.2)	1	0
Blood bilirubin increased	1	(0.3)	1	1					1	(0.2)	1	0
Cardiac murmur	1	(0.3)	1	1					1	(0.2)	1	0
Electrocardiogram QT prolonged	1	(0.3)	1	1					1	(0.2)	1	0
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Haemoglobin decreased					1	(0.6)	1	1	1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	1					1	(0.2)	1	0
Urine albumin/creatinine ratio increased					1	(0.6)	1	1	1	(0.2)	1	0
Vascular disorders	4	(1.1)	5	3	4	(2.2)	4	5	8	(1.5)	9	4
Hypertension	4	(1.1)	4	2	2	(1.1)	2	2	6	(1.1)	6	2
Haematoma	1	(0.3)	1	1					1	(0.2)	1	0
Hot flush					1	(0.6)	1	1	1	(0.2)	1	0
Hypotension					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Ear and labyrinth disorders	3	(0.8)	3	2	3	(1.7)	3	4	6	(1.1)	6	2
Ear pain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Middle ear effusion					1	(0.6)	1	1	1	(0.2)	1	0
Tympanic membrane disorder					1	(0.6)	1	1	1	(0.2)	1	0
Vertigo	1	(0.3)	1	1					1	(0.2)	1	0
Cardiac disorders	3	(0.8)	3	2	2	(1.1)	2	2	5	(0.9)	5	2
Palpitations	2	(0.6)	2	1					2	(0.4)	2	1
Atrial fibrillation					1	(0.6)	1	1	1	(0.2)	1	0
Bifascicular block	1	(0.3)	1	1					1	(0.2)	1	0
Tachyarrhythmia					1	(0.6)	1	1	1	(0.2)	1	0
Immune system disorders	3	(0.8)	3	2	2	(1.1)	2	2	5	(0.9)	5	2
Seasonal allergy	2	(0.6)	2	1	2	(1.1)	2	2	4	(0.7)	4	2
Allergy to animal	1	(0.3)	1	1					1	(0.2)	1	0
Renal and urinary disorders	2	(0.6)	2	1	2	(1.1)	2	2	4	(0.7)	4	2
Cystitis												
noninfective	1	(0.3)	1	1					1	(0.2)	1	0
Haematuria					1	(0.6)	1	1	1	(0.2)	1	0
Ketonuria					1	(0.6)	1	1	1	(0.2)	1	0
Renal failure acute	1	(0.3)	1	1					1	(0.2)	1	0
Blood and lymphatic system disorders	1	(0.3)	4	2	2	(1.1)	2	2	3	(0.6)	6	2
Anaemia	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Lymphadenitis					1	(0.6)	1	1	1	(0.2)	1	0
Lymphadenopathy	1	(0.3)	3	2					1	(0.2)	3	1

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent -
 Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					2	(1.1)	2	2	2	(0.4)	2	1
Benign neoplasm of thyroid gland					1	(0.6)	1	1	1	(0.2)	1	0
Skin papilloma					1	(0.6)	1	1	1	(0.2)	1	0
Endocrine disorders	1	(0.3)	1	1					1	(0.2)	1	0
Hypothyroidism	1	(0.3)	1	1					1	(0.2)	1	0
Hepatobiliary disorders	1	(0.3)	1	1					1	(0.2)	1	0
Hepatic steatosis	1	(0.3)	1	1					1	(0.2)	1	0
Surgical and medical procedures					1	(0.6)	1	1	1	(0.2)	1	0
Tooth extraction					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:47 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

14.3.1.22: Adverse Events Leading To Dose Reduction - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N (%)	OD E R	IDet N (%)	E R	Total N (%)	E R
Number of Subjects	362		180		542	
Events	37 (10.2)	41 24	18 (10.0)	26 31	55 (10.1)	67 26
Serious						
Yes	12 (3.3)	14 8	5 (2.8)	6 7	17 (3.1)	20 8
No	25 (6.9)	27 16	14 (7.8)	20 24	39 (7.2)	47 19
Severity						
Severe	18 (5.0)	21 12	13 (7.2)	20 24	31 (5.7)	41 16
Moderate	6 (1.7)	7 4	4 (2.2)	4 5	10 (1.8)	11 4
Mild	13 (3.6)	13 8	2 (1.1)	2 2	15 (2.8)	15 6
Relationship to Investigational Product						
Probable	8 (2.2)	9 5	9 (5.0)	9 11	17 (3.1)	18 7
Possible	5 (1.4)	5 3	3 (1.7)	3 4	8 (1.5)	8 3
Unlikely	10 (2.8)	10 6	3 (1.7)	4 5	13 (2.4)	14 6
Relationship to Bolus Insulin						
Probable	11 (3.0)	12 7	7 (3.9)	8 10	18 (3.3)	20 8
Possible	6 (1.7)	6 4	5 (2.8)	5 6	11 (2.0)	11 4
Unlikely	7 (1.9)	7 4	5 (2.8)	5 6	12 (2.2)	12 5
Dose Reduction	37 (10.2)	41 24	18 (10.0)	26 31	55 (10.1)	67 26
IDegAsp/Comparator	23 (6.4)	24 14	13 (7.2)	16 19	36 (6.6)	40 16
Insulin Aspart	23 (6.4)	25 15	15 (8.3)	18 21	38 (7.0)	43 17
NPH	1 (0.3)	1 1	0		1 (0.2)	1 0
Outcome						
Recovered	36 (9.9)	40 24	17 (9.4)	25 30	53 (9.8)	65 26
Recovering	0		0		0	
Recovered With Sequelae	0		0		0	
Not Recovered	1 (0.3)	1 1	1 (0.6)	1 1	2 (0.4)	2 1
Fatal	0		0		0	
Unknown	0		0		0	

N: Number of Subjects, %: Percentage of subjects, E: Number of Events

A single adverse event can lead to the dose reduction of multiple trial products

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:21 - tsum_ae_dose_red/t_ae_dos_red_te_sum_sas.txt

14.3.1.23: Neoplasms by System Organ Class and Preferred Term - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	Total N	(%)	E	R
Number Of Subjects	362				180				542			
Events					2 (1.1)		2	2	2 (0.4)		2	1
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)												
Benign Neoplasm Of Thyroid Gland					1 (0.6)		1	1	1 (0.2)		1	0
Skin Papilloma					1 (0.6)		1	1	1 (0.2)		1	0

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events,
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:30 - t_teae_allergy_neoplasm.sas/t_ae_te_neoplasms.txt

14.3.1.24: Allergic Reaction (Immunogenicity) by System Organ Class and Preferred Term - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	Total N	(%)	E	R
Number Of Subjects	362				180				542			
Events	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Eye Disorders												
Eye Swelling	1	(0.3)	1	1					1	(0.2)	1	0
Skin And Subcutaneous Tissue Disorders												
Urticaria					1	(0.6)	1	1	1	(0.2)	1	0

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events,
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:29 - t_teae_allergy_neoplasm.sas/t_ae_te_allergy.txt

14.3.1.25: Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	37 (10.2)	41	24	18 (10.0)	26	31	55 (10.1)	67	26
Metabolism and nutrition disorders	22 (6.1)	26	15	16 (8.9)	21	25	38 (7.0)	47	19
Hypoglycaemia	17 (4.7)	21	12	13 (7.2)	16	19	30 (5.5)	37	15
Hypoglycaemic unconsciousness	5 (1.4)	5	3	3 (1.7)	3	4	8 (1.5)	8	3
Diabetic ketoacidosis				1 (0.6)	1	1	1 (0.2)	1	0
Hypoglycaemic seizure				1 (0.6)	1	1	1 (0.2)	1	0
Infections and infestations	6 (1.7)	6	4	1 (0.6)	1	1	7 (1.3)	7	3
Acute tonsillitis	1 (0.3)	1	1				1 (0.2)	1	0
Gastroenteritis	1 (0.3)	1	1				1 (0.2)	1	0
Gastroenteritis viral				1 (0.6)	1	1	1 (0.2)	1	0
H1N1 influenza	1 (0.3)	1	1				1 (0.2)	1	0
Pharyngitis	1 (0.3)	1	1				1 (0.2)	1	0
Rotavirus infection	1 (0.3)	1	1				1 (0.2)	1	0
Upper respiratory tract infection	1 (0.3)	1	1				1 (0.2)	1	0
Gastrointestinal disorders	2 (0.6)	2	1	2 (1.1)	2	2	4 (0.7)	4	2
Abdominal discomfort	1 (0.3)	1	1				1 (0.2)	1	0
Food poisoning	1 (0.3)	1	1				1 (0.2)	1	0
Nausea				1 (0.6)	1	1	1 (0.2)	1	0
Pancreatitis chronic				1 (0.6)	1	1	1 (0.2)	1	0
Injury, poisoning and procedural complications	3 (0.8)	3	2	1 (0.6)	1	1	4 (0.7)	4	2
Wrong drug administered	2 (0.6)	2	1				2 (0.4)	2	1
Medication error				1 (0.6)	1	1	1 (0.2)	1	0
Overdose	1 (0.3)	1	1				1 (0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:49 - tsum_events_tpl_t030_v01.sas/t_ae_te_dose_red_soc_pf_sum_sas.txt

Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term -
 Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Nervous system disorders	2	(0.6)	2	1					2	(0.4)	2	1
Headache	2	(0.6)	2	1					2	(0.4)	2	1
Skin and subcutaneous tissue disorders	2	(0.6)	2	1					2	(0.4)	2	1
Lipodystrophy												
acquired	1	(0.3)	1	1					1	(0.2)	1	0
Lipohypertrophy	1	(0.3)	1	1					1	(0.2)	1	0
General disorders and administration site conditions					1	(0.6)	1	1	1	(0.2)	1	0
Injection site reaction					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:56:49 - tsum_events_tpl_t030_v01.sas/t_ae_te_dose_red_soc_pf_sum_sas.txt

14.3.1.26: Adjudicated Cardiovascular Events - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180			
EAC Evaluated Events	1	(0.3)	1	1	0	(0.0)	0	0
Non MACE	1	(0.3)	1	1	0	(0.0)	0	0
MACE	0	(0.0)	0	0	0	(0.0)	0	0
Acute coronary syndrome	0	(0.0)	0	0	0	(0.0)	0	0
Unstable Angina pectoris	0	(0.0)	0	0	0	(0.0)	0	0
Myocardial Infarction	0	(0.0)	0	0	0	(0.0)	0	0
STEMI	0	(0.0)	0	0	0	(0.0)	0	0
NSTEMI	0	(0.0)	0	0	0	(0.0)	0	0
Stroke	0	(0.0)	0	0	0	(0.0)	0	0
Cardiovascular Death	0	(0.0)	0	0	0	(0.0)	0	0

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
 R: Event Rate per 100 Exposure Years, EAC:(external) Event Adjudication Committee,
 MACE: Major Adverse Cardiovascular Events, NSTEMI: Non-ST-elevation Myocardial Infarction
 STEMI: ST-elevation Myocardial Infarction.

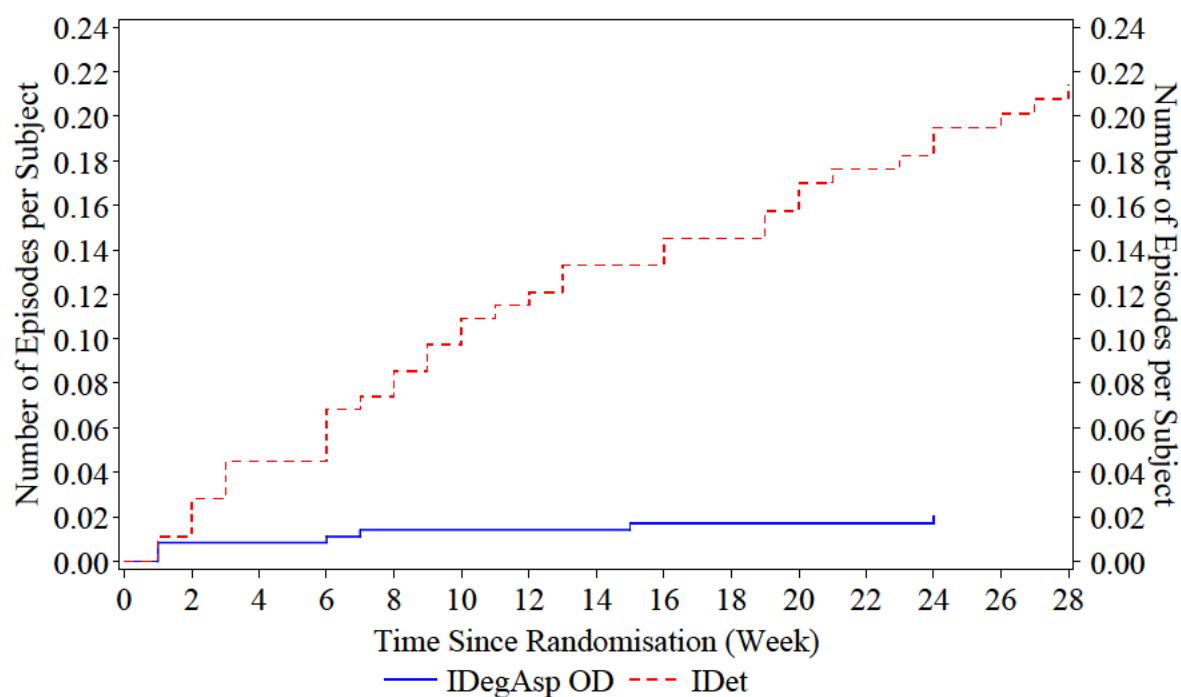
nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:19:21 - tsum_adj_cardio_teae.sas/t_eac_te_sum_sas.txt

14.3.1.27: Injection Site Reaction by System Organ Class and Preferred Term - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	Total N	(%)	E	R
Number Of Subjects	362				180				542			
Events	5 (1.4)		7	4	8 (4.4)		36	43	13 (2.4)		43	17
General Disorders And Administration Site Conditions												
Injection Site Haematoma					1 (0.6)		1	1	1 (0.2)		1	0
Injection Site Pain	2 (0.6)		2	1	1 (0.6)		1	1	3 (0.6)		3	1
Injection Site Papule					1 (0.6)		1	1	1 (0.2)		1	0
Injection Site Reaction	3 (0.8)		5	3	6 (3.3)		33	39	9 (1.7)		38	15

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events,
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:31 - t_teae_allergy_neoplasm.sas/t_ae_te_injec_sit_react.txt



SAFETY;
Observed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:13:17 - fmean_inj_react.sas/e_inject_site_react_mcf_sas.cgm

14.3.1.28: Injection Site Reactions - Mean Cumulative Function - Safety Analysis Set

14.3.1.29: Medication Errors - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Total Events	14	(3.9)	16	9	7	(3.9)	7	8	21	(3.9)	23	9
Serious												
Yes	2	(0.6)	2	1	0	(0.0)	0	0	2	(0.4)	2	1
No	12	(3.3)	14	8	7	(3.9)	7	8	19	(3.5)	21	8
Severity												
Severe	1	(0.3)	1	1	2	(1.1)	2	2	3	(0.6)	3	1
Moderate	6	(1.7)	6	4	2	(1.1)	2	2	8	(1.5)	8	3
Mild	8	(2.2)	9	5	3	(1.7)	3	4	11	(2.0)	12	5
Relationship to IDegAsp/Comparator												
Probable/Possible	4	(1.1)	4	2	2	(1.1)	2	2	6	(1.1)	6	2
Relationship to Insulin Aspart												
Probable/Possible	4	(1.1)	4	2	3	(1.7)	3	4	7	(1.3)	7	3
Outcome												
Recovered	14	(3.9)	16	9	7	(3.9)	7	8	21	(3.9)	23	9
Recovering	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Recovered With Sequelae	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Not Recovered	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Unknown	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Incorrect dose administered	2	(0.6)	2	1	0	(0.0)	0	0	2	(0.4)	2	1
Serious	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relationship to IDegAsp/Comparator												
Probable/Possible	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relationship to Insulin Aspart												
Probable/Possible	1	(0.3)	1	1	0	(0.0)	0	0	1	(0.2)	1	0
Medication error	1	(0.3)	1	1	2	(1.1)	2	2	3	(0.6)	3	1
Serious	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relationship to IDegAsp/Comparator												
Probable/Possible	1	(0.3)	1	1	1	(0.6)	1	1	2	(0.4)	2	1
Relationship to Insulin Aspart												
Probable/Possible	0	(0.0)	0	0	1	(0.6)	1	1	1	(0.2)	1	0
Overdose	1	(0.3)	1	1	0	(0.0)	0	0	1	(0.2)	1	0
Serious	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relationship to IDegAsp/Comparator												
Probable/Possible	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relationship to Insulin Aspart												
Probable/Possible	1	(0.3)	1	1	0	(0.0)	0	0	1	(0.2)	1	0
Wrong drug administered	10	(2.8)	12	7	5	(2.8)	5	6	15	(2.8)	17	7
Serious	2	(0.6)	2	1	0	(0.0)	0	0	2	(0.4)	2	1
Relationship to IDegAsp/Comparator												
Probable/Possible	3	(0.8)	3	2	1	(0.6)	1	1	4	(0.7)	4	2
Relationship to Insulin Aspart												
Probable/Possible	2	(0.6)	2	1	2	(1.1)	2	2	4	(0.7)	4	2

N: Number of Subjects, %: Percentage of subjects, E: Number of Events,
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:20:00 - tsum_teae_med_err.sas/tsum_teae_med_err_sas.txt

14.3.1.30: Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Confirmed	341 (94.2)	6634	3917	168 (93.3)	3720	4434	509 (93.9)	10354	4089
ADA	352 (97.2)	14100	8326	172 (95.6)	7147	8519	524 (96.7)	21247	8390
Severe	35 (9.7)	56	33	22 (12.2)	35	42	57 (10.5)	91	36
Documented Sympt.	319 (88.1)	9670	5710	156 (86.7)	5126	6110	475 (87.6)	14796	5843
Asymptomatic	270 (74.6)	4032	2381	137 (76.1)	1804	2150	407 (75.1)	5836	2305
Probable Sympt.	71 (19.6)	234	138	40 (22.2)	149	178	111 (20.5)	383	151
Relative	42 (11.6)	108	64	17 (9.4)	33	39	59 (10.9)	141	56
ADA Unclassifiable	105 (29.0)	395	233	50 (27.8)	241	287	155 (28.6)	636	251

N: Number of Subjects

?: Percentage of Subjects with the Event

E: Number of Events

R: Event Rate per 100 Patient Year(s) of Exposure

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:56:55 - tsum_hypo_class_tpl_t027_v01.sas/t_hypo_te_sum_sas.txt

14.3.1.31: Nocturnal Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Confirmed	192 (53.0)	629	371	125 (69.4)	480	572	317 (58.5)	1109	438
ADA	232 (64.1)	1139	673	140 (77.8)	716	853	372 (68.6)	1855	733
Severe	10 (2.8)	11	6	10 (5.6)	14	17	20 (3.7)	25	10
Documented Sympt.	191 (52.8)	883	521	114 (63.3)	555	662	305 (56.3)	1438	568
Asymptomatic	86 (23.8)	201	119	45 (25.0)	111	132	131 (24.2)	312	123
Probable Sympt.	23 (6.4)	41	24	16 (8.9)	32	38	39 (7.2)	73	29
Relative	3 (0.8)	3	2	4 (2.2)	4	5	7 (1.3)	7	3
ADA Unclassified	7 (1.9)	8	5	8 (4.4)	15	18	15 (2.8)	23	9

N: Number of Subjects

%: Percentage of Subjects with the Event

E: Number of Events

R: Event Rate per 100 Patient Year(s) of Exposure

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:02 - tsum_hypo_class_tpl_t027_v01.sas/t_hypo_te_noct_sum_sas.txt

14.3.1.32: Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp	OD		IDet		Total	
	N	(%)	E	N	(%)	N	(%)
Number of Subjects	362			180		542	
Confirmed	341 (94.2)	6634		168 (93.3)	3720	509 (93.9)	10354
1 - 4 Weeks	277 (76.5)	1307		134 (74.4)	546	411 (75.8)	1853
5 - 8 Weeks	262 (72.4)	1045		125 (69.4)	618	387 (71.4)	1663
9 - 12 Weeks	231 (63.8)	888		129 (71.7)	553	360 (66.4)	1441
13 - 16 Weeks	235 (64.9)	965		120 (66.7)	568	355 (65.5)	1533
17 - 20 Weeks	226 (62.4)	868		112 (62.2)	551	338 (62.4)	1419
21 - 24 Weeks	230 (63.5)	890		111 (61.7)	488	341 (62.9)	1378
25 - 28 Weeks	196 (54.1)	659		107 (59.4)	391	303 (55.9)	1050
> 28 Weeks	4 (1.1)	12		3 (1.7)	5	7 (1.3)	17
ADA	352 (97.2)	14100		172 (95.6)	7147	524 (96.7)	21247
1 - 4 Weeks	316 (87.3)	2586		157 (87.2)	1094	473 (87.3)	3680
5 - 8 Weeks	306 (84.5)	2229		150 (83.3)	1200	456 (84.1)	3429
9 - 12 Weeks	282 (77.9)	1960		149 (82.8)	1066	431 (79.5)	3026
13 - 16 Weeks	283 (78.2)	2051		140 (77.8)	1070	423 (78.0)	3121
17 - 20 Weeks	278 (76.8)	1931		139 (77.2)	987	417 (76.9)	2918
21 - 24 Weeks	265 (73.2)	1941		136 (75.6)	972	401 (74.0)	2913
25 - 28 Weeks	246 (68.0)	1387		129 (71.7)	751	375 (69.2)	2138
> 28 Weeks	4 (1.1)	15		4 (2.2)	7	8 (1.5)	22
Severe	35 (9.7)	56		22 (12.2)	35	57 (10.5)	91
1 - 4 Weeks	9 (2.5)	13		6 (3.3)	7	15 (2.8)	20
5 - 8 Weeks	11 (3.0)	14		5 (2.8)	5	16 (3.0)	19
9 - 12 Weeks	4 (1.1)	4		7 (3.9)	8	11 (2.0)	12
13 - 16 Weeks	8 (2.2)	10		5 (2.8)	5	13 (2.4)	15
17 - 20 Weeks	4 (1.1)	5		6 (3.3)	6	10 (1.8)	11
21 - 24 Weeks	2 (0.6)	2		3 (1.7)	3	5 (0.9)	5
25 - 28 Weeks	6 (1.7)	8		1 (0.6)	1	7 (1.3)	9
> 28 Weeks	0 (0.0)	0		0 (0.0)	0	0 (0.0)	0
Doc. Symptomatic	319 (88.1)	9670		156 (86.7)	5126	475 (87.6)	14796
1 - 4 Weeks	273 (75.4)	1824		128 (71.1)	754	401 (74.0)	2578
5 - 8 Weeks	258 (71.3)	1566		130 (72.2)	881	388 (71.6)	2447
9 - 12 Weeks	236 (65.2)	1316		125 (69.4)	786	361 (66.6)	2102
13 - 16 Weeks	237 (65.5)	1372		109 (60.6)	763	346 (63.8)	2135
17 - 20 Weeks	234 (64.6)	1285		114 (63.3)	720	348 (64.2)	2005
21 - 24 Weeks	221 (61.0)	1345		114 (63.3)	694	335 (61.8)	2039
25 - 28 Weeks	197 (54.4)	955		106 (58.9)	524	303 (55.9)	1479
> 28 Weeks	3 (0.8)	7		3 (1.7)	4	6 (1.1)	11

N: Number of Subjects

#: Percentage of Subjects

E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:07 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_sas.txt

Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Asymptomatic	270	(74.6)	4032	137	(76.1)	1804	407	(75.1)	5836
1 - 4 Weeks	174	(48.1)	651	85	(47.2)	285	259	(47.8)	936
5 - 8 Weeks	164	(45.3)	599	73	(40.6)	281	237	(43.7)	880
9 - 12 Weeks	158	(43.6)	592	70	(38.9)	247	228	(42.1)	839
13 - 16 Weeks	160	(44.2)	632	72	(40.0)	279	232	(42.8)	911
17 - 20 Weeks	144	(39.8)	607	67	(37.2)	250	211	(38.9)	857
21 - 24 Weeks	129	(35.6)	553	66	(36.7)	248	195	(36.0)	801
25 - 28 Weeks	120	(33.1)	390	57	(31.7)	211	177	(32.7)	601
> 28 Weeks	2	(0.6)	8	1	(0.6)	3	3	(0.6)	11
Prob. Symptomatic	71	(19.6)	234	40	(22.2)	149	111	(20.5)	383
1 - 4 Weeks	40	(11.0)	70	15	(8.3)	37	55	(10.1)	107
5 - 8 Weeks	23	(6.4)	34	16	(8.9)	24	39	(7.2)	58
9 - 12 Weeks	21	(5.8)	32	14	(7.8)	23	35	(6.5)	55
13 - 16 Weeks	21	(5.8)	29	11	(6.1)	21	32	(5.9)	50
17 - 20 Weeks	12	(3.3)	18	6	(3.3)	10	18	(3.3)	28
21 - 24 Weeks	12	(3.3)	24	14	(7.8)	23	26	(4.8)	47
25 - 28 Weeks	15	(4.1)	27	8	(4.4)	11	23	(4.2)	38
> 28 Weeks	0	(0.0)	0	0	(0.0)	0	0	(0.0)	0
Relative	42	(11.6)	108	17	(9.4)	33	59	(10.9)	141
1 - 4 Weeks	15	(4.1)	28	7	(3.9)	11	22	(4.1)	39
5 - 8 Weeks	10	(2.8)	16	6	(3.3)	9	16	(3.0)	25
9 - 12 Weeks	9	(2.5)	16	2	(1.1)	2	11	(2.0)	18
13 - 16 Weeks	6	(1.7)	8	1	(0.6)	2	7	(1.3)	10
17 - 20 Weeks	11	(3.0)	16	1	(0.6)	1	12	(2.2)	17
21 - 24 Weeks	9	(2.5)	17	2	(1.1)	4	11	(2.0)	21
25 - 28 Weeks	5	(1.4)	7	3	(1.7)	4	8	(1.5)	11
> 28 Weeks	0	(0.0)	0	0	(0.0)	0	0	(0.0)	0
ADA Unclassifiable	105	(29.0)	395	50	(27.8)	241	155	(28.6)	636
1 - 4 Weeks	43	(11.9)	62	5	(2.8)	6	48	(8.9)	68
5 - 8 Weeks	32	(8.8)	66	23	(12.8)	38	55	(10.1)	104
9 - 12 Weeks	34	(9.4)	48	14	(7.8)	36	48	(8.9)	84
13 - 16 Weeks	25	(6.9)	50	16	(8.9)	40	41	(7.6)	90
17 - 20 Weeks	32	(8.8)	75	20	(11.1)	57	52	(9.6)	132
21 - 24 Weeks	29	(8.0)	58	15	(8.3)	49	44	(8.1)	107
25 - 28 Weeks	22	(6.1)	36	9	(5.0)	15	31	(5.7)	51
> 28 Weeks	0	(0.0)	0	0	(0.0)	0	0	(0.0)	0

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:07 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_sas.txt

14.3.1.33: Nocturnal Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp	OD		IDet		Total	
	N	(%)	E	N	(%)	N	(%)
Number of Subjects	362			180		542	
Confirmed	192	(53.0)	629	125	(69.4)	480	317 (58.5)
1 - 4 Weeks	74	(20.4)	125	48	(26.7)	75	122 (22.5)
5 - 8 Weeks	66	(18.2)	92	48	(26.7)	68	114 (21.0)
9 - 12 Weeks	54	(14.9)	68	45	(25.0)	71	99 (18.3)
13 - 16 Weeks	63	(17.4)	101	47	(26.1)	70	110 (20.3)
17 - 20 Weeks	58	(16.0)	77	44	(24.4)	76	102 (18.8)
21 - 24 Weeks	59	(16.3)	93	32	(17.8)	57	91 (16.8)
25 - 28 Weeks	49	(13.5)	72	44	(24.4)	63	93 (17.2)
> 28 Weeks	1	(0.3)	1	0	(0.0)	0	1 (0.2)
ADA	232	(64.1)	1139	140	(77.8)	716	372 (68.6)
1 - 4 Weeks	117	(32.3)	229	64	(35.6)	117	181 (33.4)
5 - 8 Weeks	92	(25.4)	154	64	(35.6)	112	156 (28.8)
9 - 12 Weeks	83	(22.9)	131	59	(32.8)	96	142 (26.2)
13 - 16 Weeks	103	(28.5)	195	60	(33.3)	105	163 (30.1)
17 - 20 Weeks	82	(22.7)	146	58	(32.2)	102	140 (25.8)
21 - 24 Weeks	85	(23.5)	166	46	(25.6)	92	131 (24.2)
25 - 28 Weeks	65	(18.0)	115	59	(32.8)	91	124 (22.9)
> 28 Weeks	3	(0.8)	3	1	(0.6)	1	4 (0.7)
Severe	10	(2.8)	11	10	(5.6)	14	20 (3.7)
1 - 4 Weeks	4	(1.1)	4	0	(0.0)	0	4 (0.7)
5 - 8 Weeks	1	(0.3)	1	2	(1.1)	2	3 (0.6)
9 - 12 Weeks	0	(0.0)	0	4	(2.2)	4	4 (0.7)
13 - 16 Weeks	3	(0.8)	3	2	(1.1)	2	5 (0.9)
17 - 20 Weeks	1	(0.3)	1	4	(2.2)	4	5 (0.9)
21 - 24 Weeks	1	(0.3)	1	2	(1.1)	2	3 (0.6)
25 - 28 Weeks	1	(0.3)	1	0	(0.0)	0	1 (0.2)
> 28 Weeks	0	(0.0)	0	0	(0.0)	0	0 (0.0)
Doc. Symptomatic	191	(52.8)	883	114	(63.3)	555	305 (56.3)
1 - 4 Weeks	94	(26.0)	177	51	(28.3)	96	145 (26.8)
5 - 8 Weeks	76	(21.0)	131	53	(29.4)	88	129 (23.8)
9 - 12 Weeks	67	(18.5)	99	49	(27.2)	79	116 (21.4)
13 - 16 Weeks	76	(21.0)	146	47	(26.1)	77	123 (22.7)
17 - 20 Weeks	54	(14.9)	104	45	(25.0)	81	99 (18.3)
21 - 24 Weeks	70	(19.3)	131	34	(18.9)	67	104 (19.2)
25 - 28 Weeks	53	(14.6)	92	46	(25.6)	66	99 (18.3)
> 28 Weeks	3	(0.8)	3	1	(0.6)	1	4 (0.7)

N: Number of Subjects

?: Percentage of Subjects

E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:12:57:10 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_noct_week_sum_sas.txt

Nocturnal Hypoglycaemic Episodes by Classification and Time - Treatment Emergent -
Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	IDet N (%)	E	Total N (%)	E
Asymptomatic	86 (23.8)	201	45 (25.0)	111	131 (24.2)	312
1 - 4 Weeks	20 (5.5)	33	12 (6.7)	13	32 (5.9)	46
5 - 8 Weeks	17 (4.7)	19	9 (5.0)	11	26 (4.8)	30
9 - 12 Weeks	21 (5.8)	28	6 (3.3)	8	27 (5.0)	36
13 - 16 Weeks	29 (8.0)	39	14 (7.8)	23	43 (7.9)	62
17 - 20 Weeks	28 (7.7)	35	14 (7.8)	15	42 (7.7)	50
21 - 24 Weeks	20 (5.5)	29	10 (5.6)	18	30 (5.5)	47
25 - 28 Weeks	14 (3.9)	18	15 (8.3)	23	29 (5.4)	41
> 28 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
Prob. Symptomatic	23 (6.4)	41	16 (8.9)	32	39 (7.2)	73
1 - 4 Weeks	12 (3.3)	14	6 (3.3)	7	18 (3.3)	21
5 - 8 Weeks	3 (0.8)	3	5 (2.8)	9	8 (1.5)	12
9 - 12 Weeks	4 (1.1)	4	5 (2.8)	5	9 (1.7)	9
13 - 16 Weeks	6 (1.7)	6	3 (1.7)	3	9 (1.7)	9
17 - 20 Weeks	6 (1.7)	6	2 (1.1)	2	8 (1.5)	8
21 - 24 Weeks	3 (0.8)	4	4 (2.2)	4	7 (1.3)	8
25 - 28 Weeks	3 (0.8)	4	2 (1.1)	2	5 (0.9)	6
> 28 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
Relative	3 (0.8)	3	4 (2.2)	4	7 (1.3)	7
1 - 4 Weeks	1 (0.3)	1	1 (0.6)	1	2 (0.4)	2
5 - 8 Weeks	0 (0.0)	0	2 (1.1)	2	2 (0.4)	2
9 - 12 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
13 - 16 Weeks	1 (0.3)	1	0 (0.0)	0	1 (0.2)	1
17 - 20 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
21 - 24 Weeks	1 (0.3)	1	1 (0.6)	1	2 (0.4)	2
25 - 28 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
> 28 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
ADA Unclassifiable	7 (1.9)	8	8 (4.4)	15	15 (2.8)	23
1 - 4 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
5 - 8 Weeks	2 (0.6)	2	1 (0.6)	1	3 (0.6)	3
9 - 12 Weeks	1 (0.3)	1	2 (1.1)	2	3 (0.6)	3
13 - 16 Weeks	1 (0.3)	1	2 (1.1)	2	3 (0.6)	3
17 - 20 Weeks	2 (0.6)	2	3 (1.7)	6	5 (0.9)	8
21 - 24 Weeks	0 (0.0)	0	2 (1.1)	2	2 (0.4)	2
25 - 28 Weeks	2 (0.6)	2	1 (0.6)	2	3 (0.6)	4
> 28 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0

N: Number of Subjects

%: Percentage of Subjects

E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded
PG < 3.1 mmol/L (56mg/dL)

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594/freeze_ctr_05/stats

28APR2011:12:57:10 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_noct_week_sum_sas.txt

14.3.1.34: Hypoglycaemic Episodes - Treatment Emergent - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
Severe				
LSMeans, Events per 100 PYE				
IDegAsp OD	366	363	26.55	
IDet	182	180	22.36	
Treatment Ratio				
IDegAsp OD / IDet			1.19	[0.58 ; 2.41]
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	366	363	3984.11	
IDet	182	180	4377.80	
Treatment Ratio				
IDegAsp OD / IDet			0.91	[0.76 ; 1.09]

N= Number of subjects contributing to analysis, CI= Confidence Interval, PYE= Patient Years Exposure

The number of events is analysed using a Negative Binomial Regression model using a log link and the logarithm of the exposure time (100 years) as offset. The model includes treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age as covariate.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:16 - tstat_find_tpl_t022.sas/t_hypo_te_stat_fas.txt

14.3.1.35: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent – Confirmatory Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	366	363	304.64	
IDet	182	180	484.94	
Treatment Ratio				
IDegAsp OD / IDet			0.63	[0.49 ; 0.81]

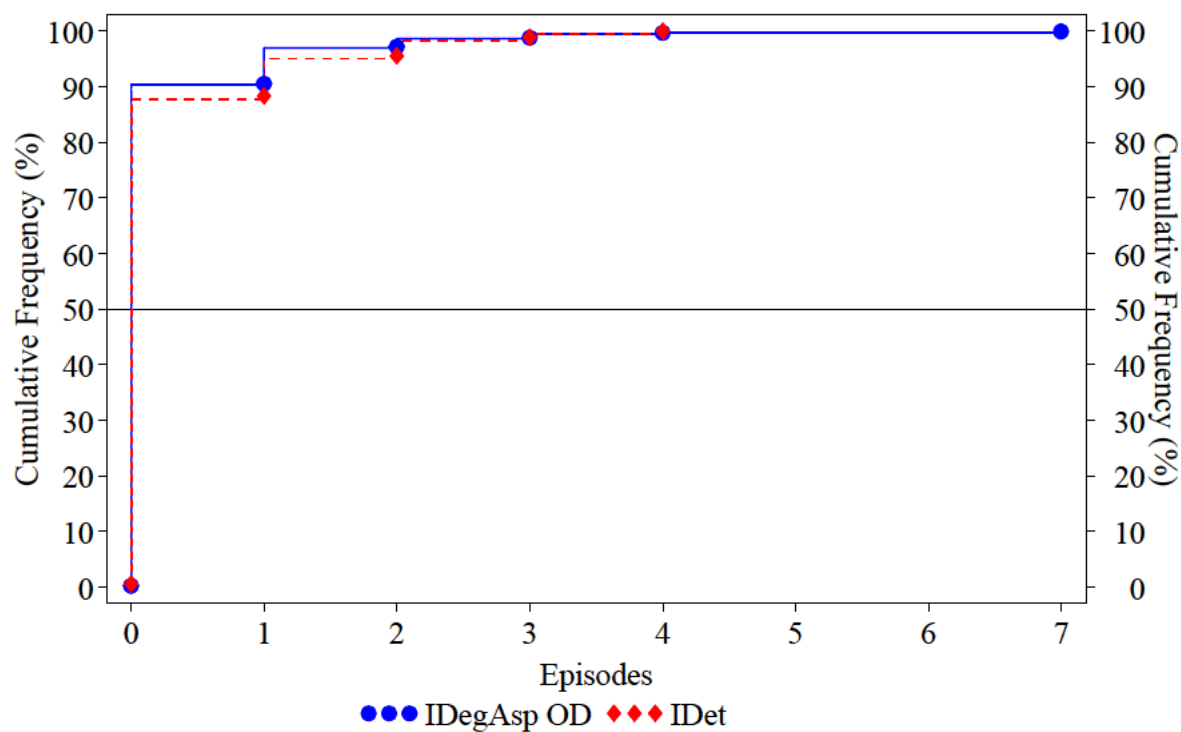
N= Number of subjects contributing to analysis, CI= Confidence Interval, PYE= Patient Years Exposure
 The number of events is analysed using a Negative Binomial Regression model using a log link and the logarithm of the exposure time (100 years) as offset. The model includes treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age as covariate.
 Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:57:22 - tstat_find_tpl_t022.sas/t_hypo_te_c_noct_cstat_fas.txt

14.3.1.36: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Parameter Estimates on Mean Scale - Full Analysis Set

	Estimate	DF	95% CI
Confirmed			
Treatment			
IDegAsp OD	0.63	1	[0.49 ; 0.81]
IDet	1.00	0	[1.00 ; 1.00]
Region			
Australia	1.18	1	[0.78 ; 1.76]
Europe	0.78	1	[0.59 ; 1.02]
North America	1.00	0	[1.00 ; 1.00]
Sex			
Female	1.47	1	[1.15 ; 1.87]
Male	1.00	0	[1.00 ; 1.00]
Antidiabetic Treatment at Screening			
Basal-Bolus	1.69	1	[1.07 ; 2.67]
Other	1.00	0	[1.00 ; 1.00]
Regression			
Age	1.00	1	[0.99 ; 1.01]
Dispersion	1.50	1	[1.21 ; 1.78]

The number of events is analysed using a Negative Binomial Regression model using a log link and the logarithm of the exposure time (100 years) as offset. The model includes treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age as covariate. Estimates and Confidence intervals are rate ratios.

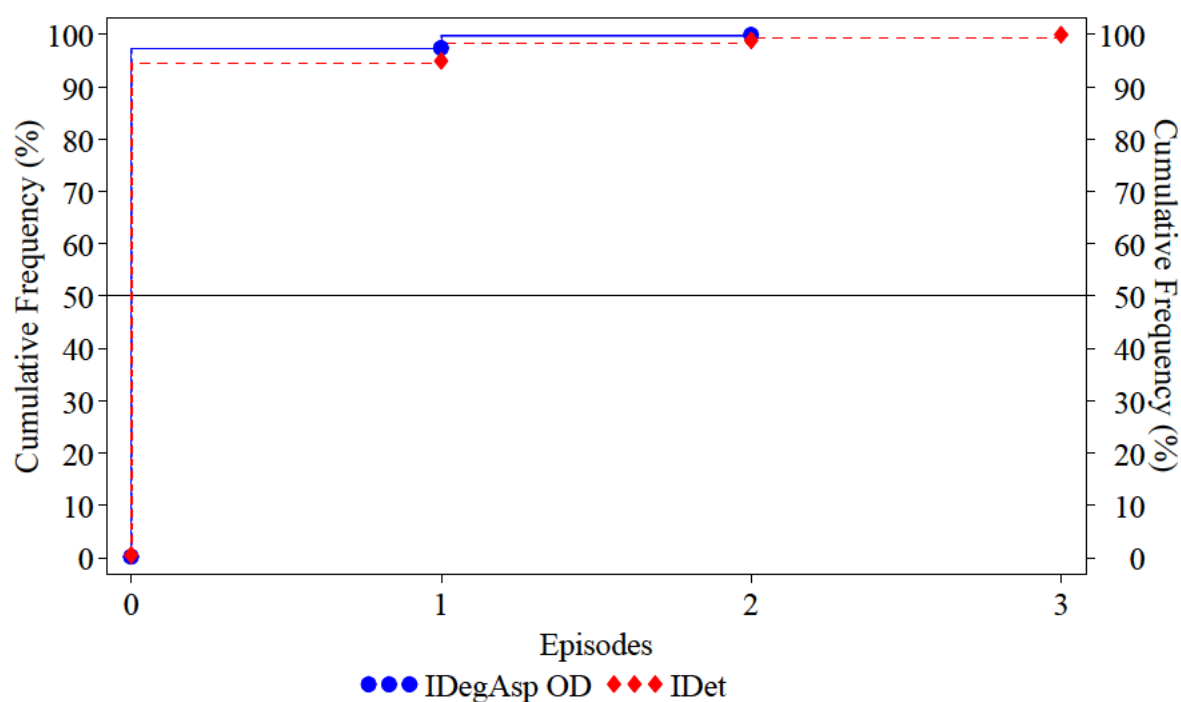
nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:57:23 - tstat_find_tpl_t022.sas/t_hypo_te_c_noct_cstat_parm_fas.txt



SAFETY; Observed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:29 - fedist_numfind_v01.sas/e_hypo_te_sev_cdf_sas.cgm

14.3.1.37: Severe Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set

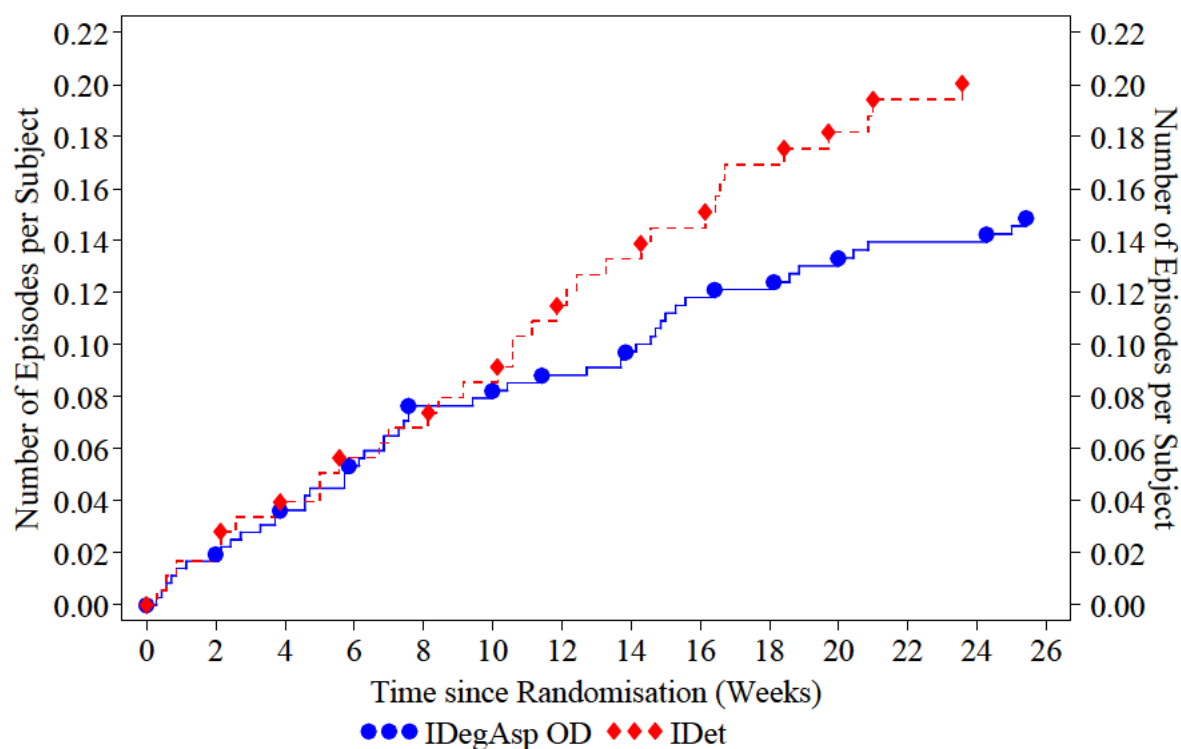


SAFETY: Observed data

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

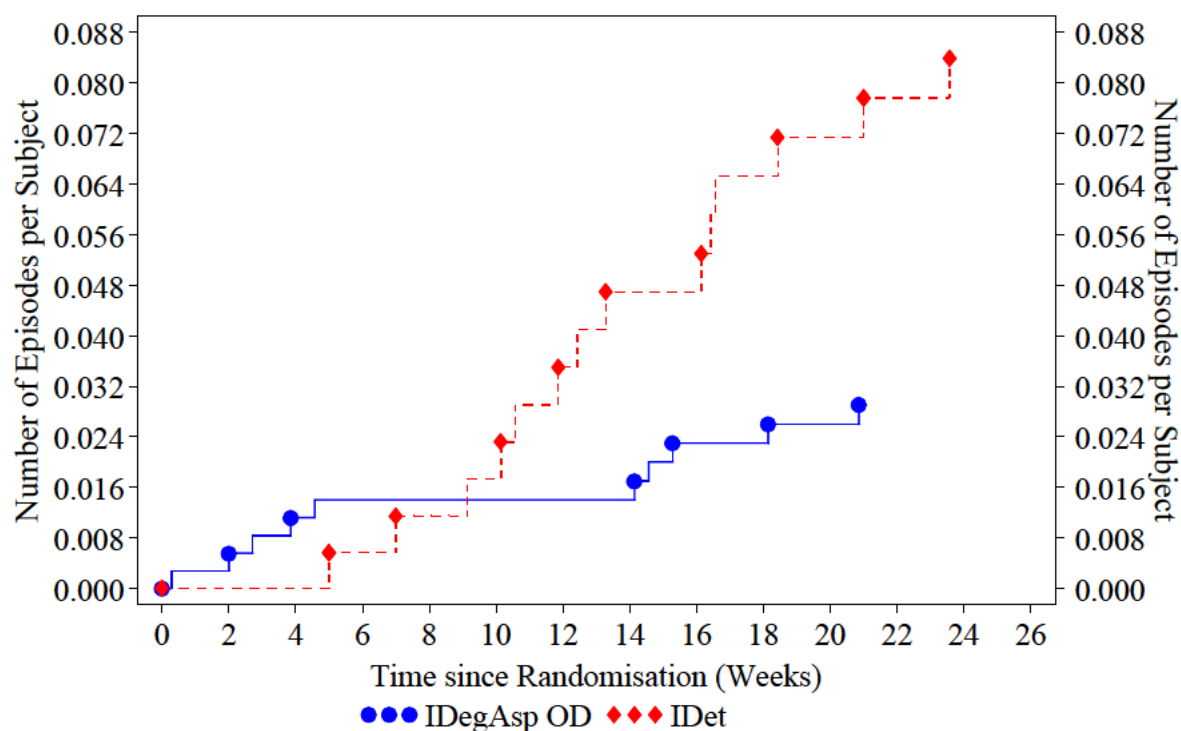
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:35 - fedist_numfind_v01.sas/e_hypo_te_sev_noct_cdf_sas.cgm

14.3.1.38: Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent – Empirical Distribution Plot – Safety Analysis Set



nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:57:40 - fmean_cum_v01.sas/e_hypo_te_sev_mcf_sas.cgm

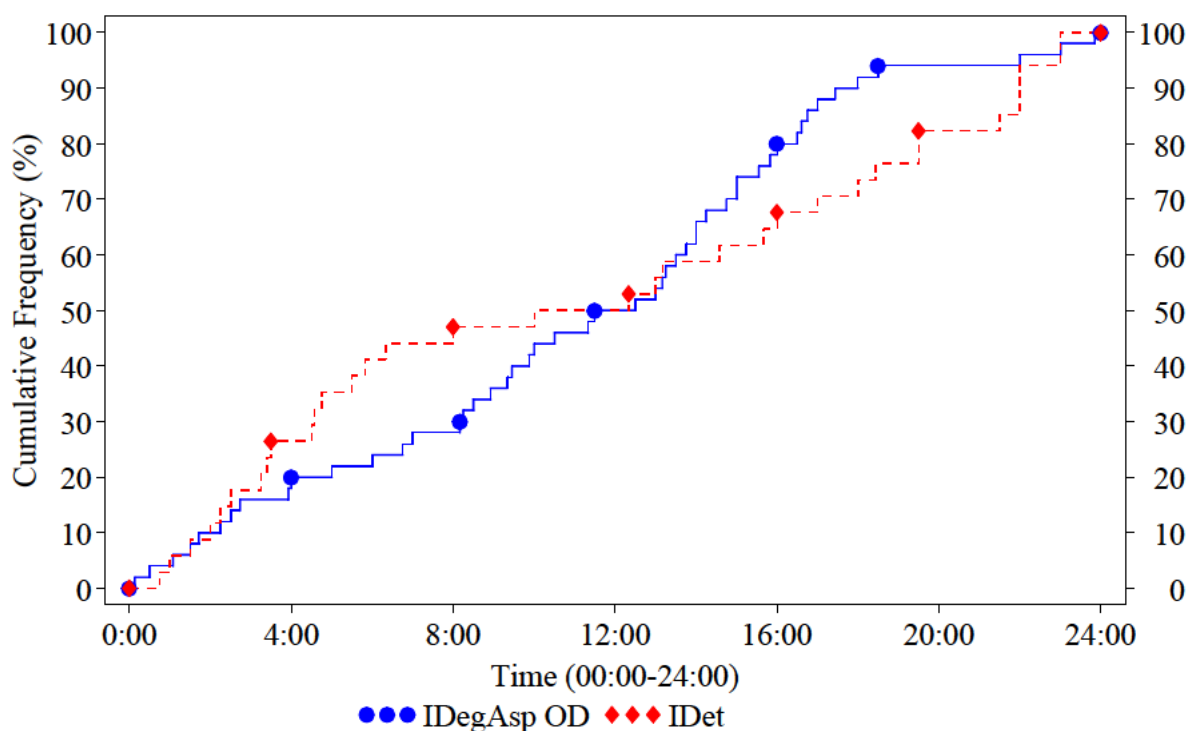
14.3.1.39: Severe Hypoglycaemic Episodes - Treatment Emergent - Mean Cumulative Function - Safety Analysis Set



Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:42 - fmean_cum_v01.sas/e_hypo_te_sev_noct_mcf_sas.cgm

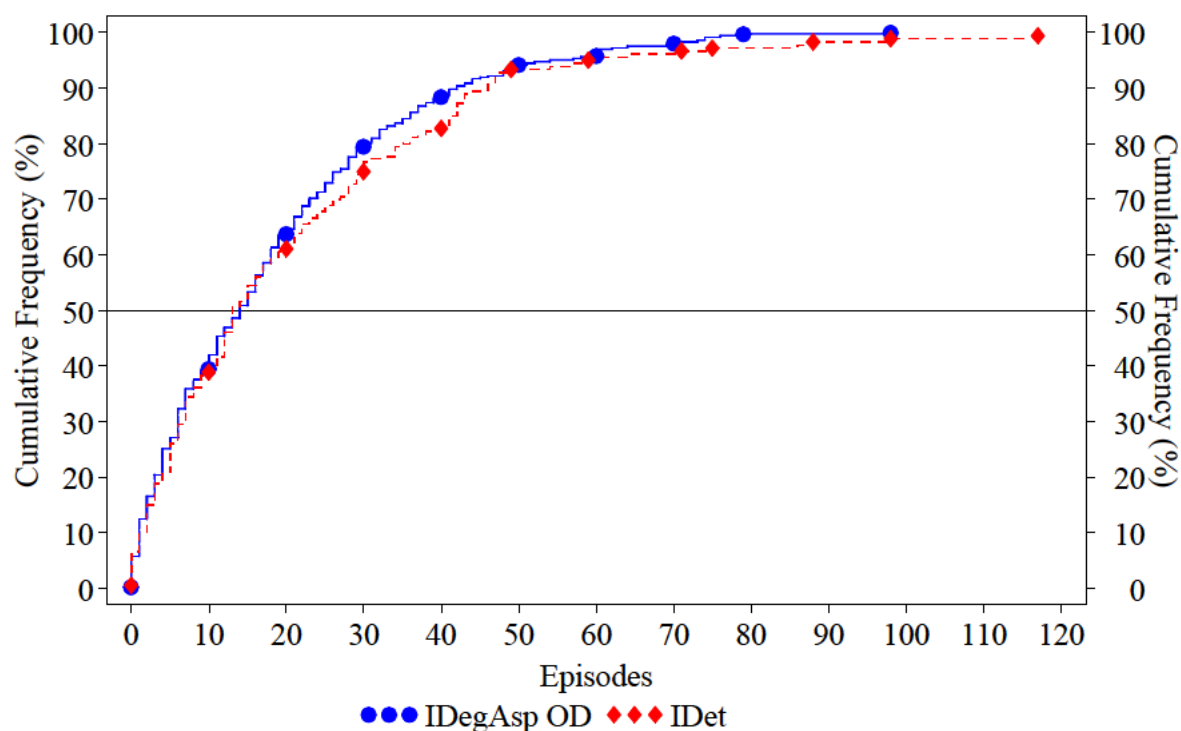
14.3.1.40: Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent – Mean Cumulative Function – Safety Analysis Set



SAFETY

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:43 - fcum_time_v01.sas/e_hypo_te_sev_cf_day_sas.cgm

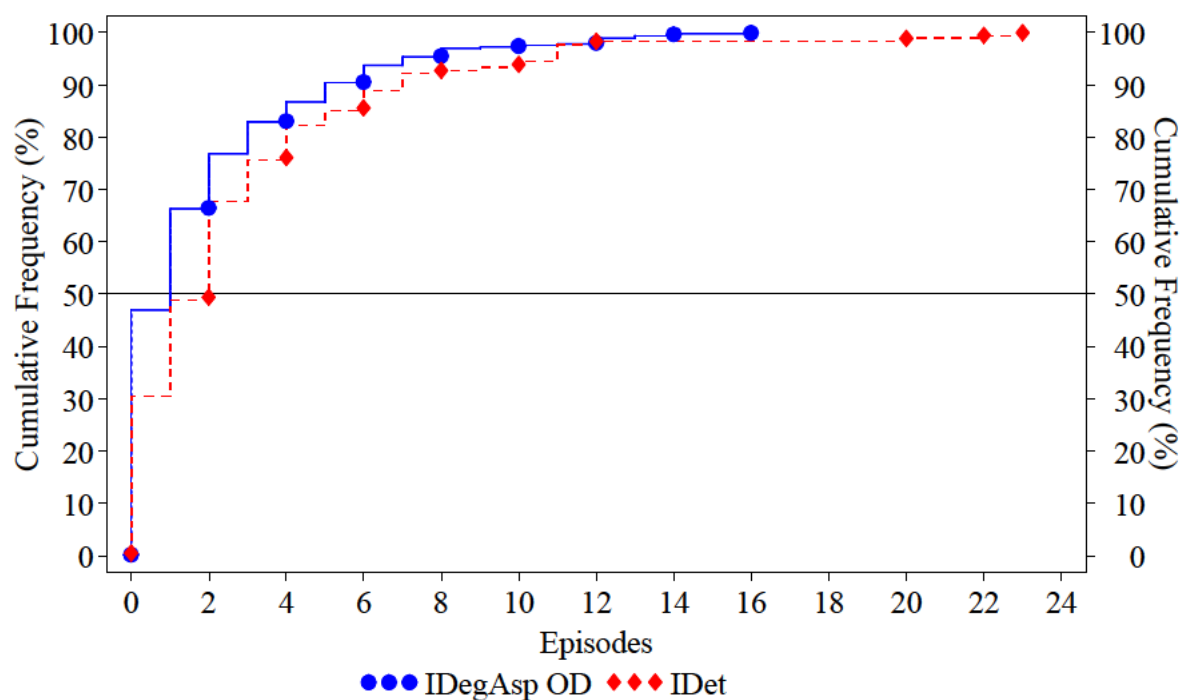
14.3.1.41: Severe Hypoglycaemic Episodes – Treatment Emergent - Cumulative Frequency over Day - Safety Analysis Set



SAFETY; Observed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:49 - fedist_numfind_v01.sas/e_hypo_te_conf_cdf_sas.cgm

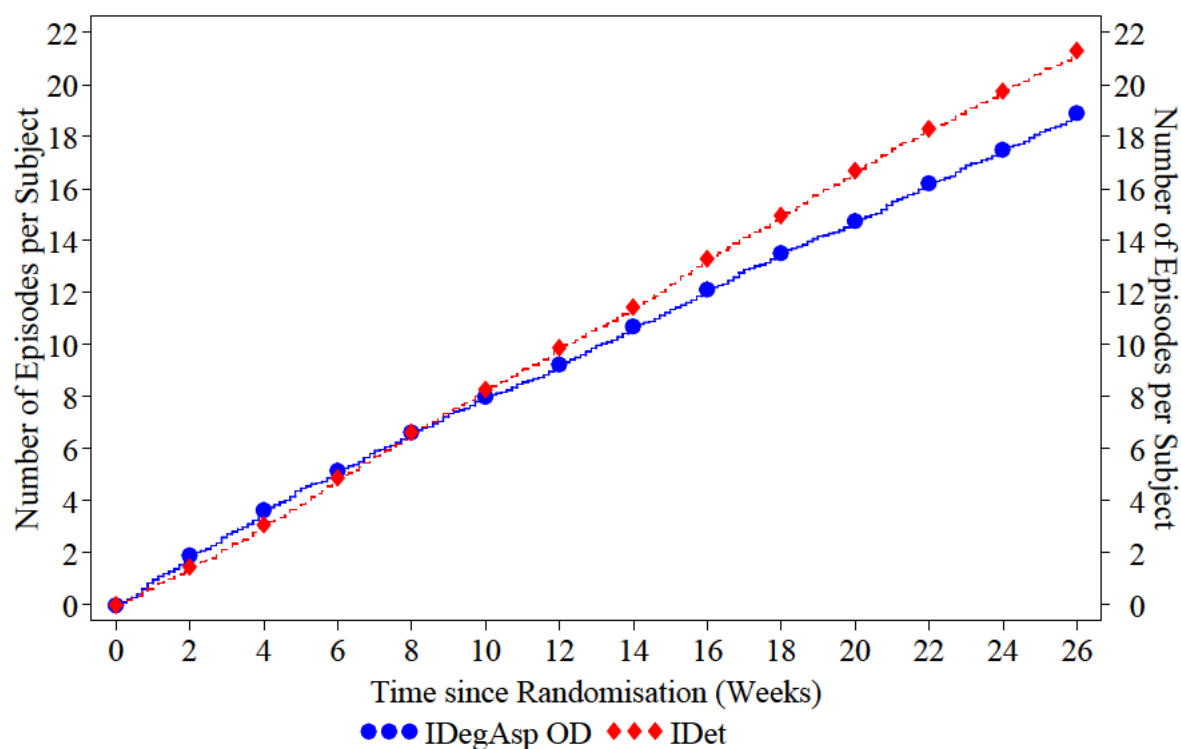
14.3.1.42: Confirmed Hypoglycaemic Episodes – Treatment Emergent – Empirical Distribution Plot – Safety Analysis Set



SAFETY: Observed data
Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

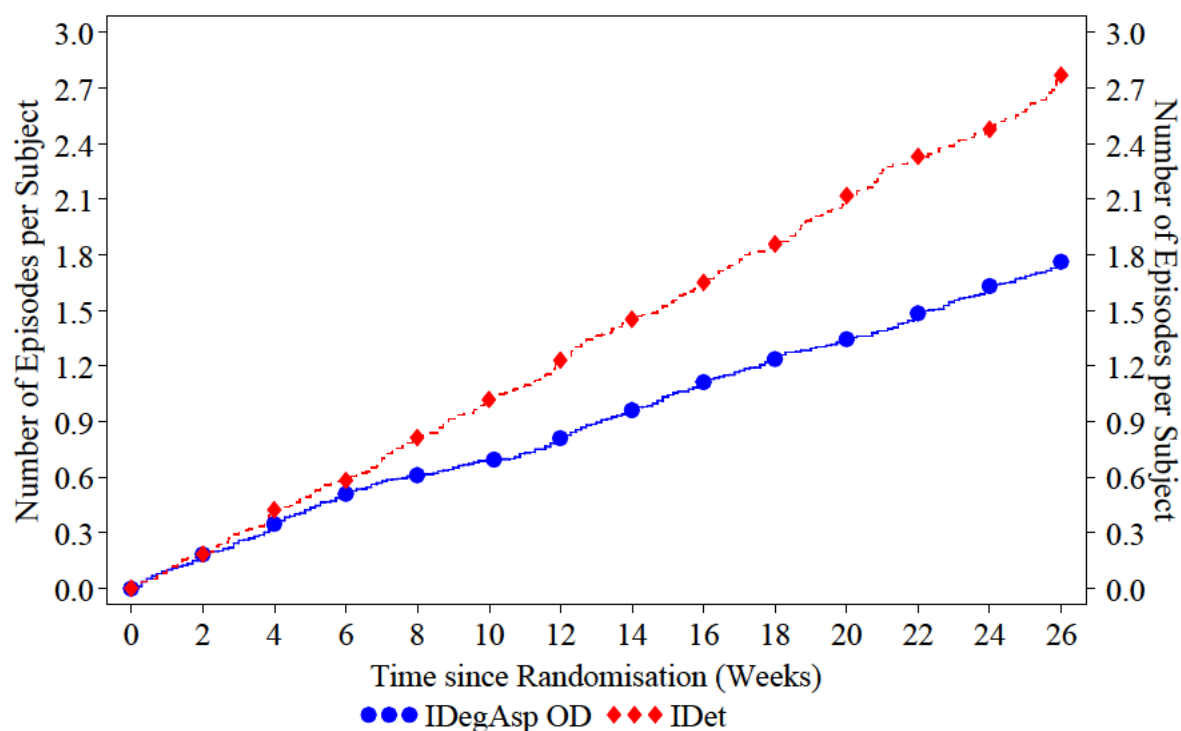
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:55 - fedist_numfind_v01.sas/e_hypo_te_conf_noct_cdf_sas.cgm

14.3.1.43: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set



nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:57:57 - fmean_cum_v01.sas/e_hypo_te_conf_mcf_sas.cgm

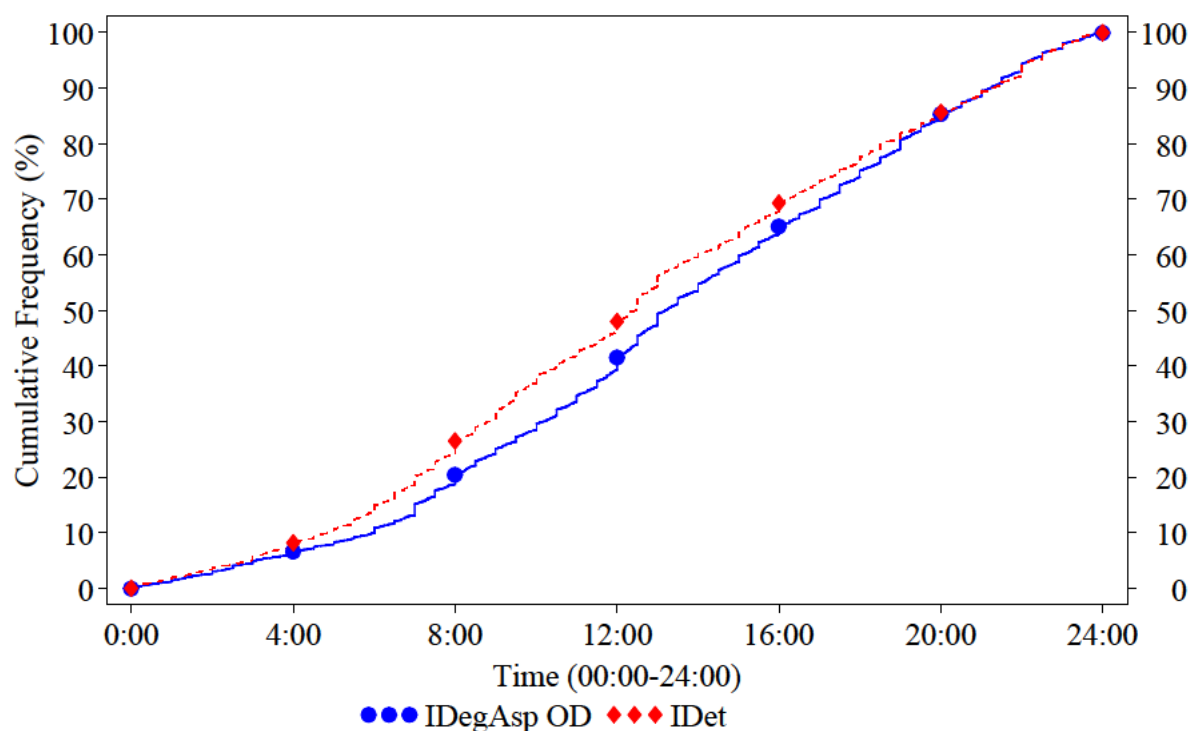
14.3.1.44: Confirmed Hypoglycaemic Episodes – Treatment Emergent – Mean Cumulative Function – Safety Analysis Set



Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:57:59 - fmean_cum_v01.sas/e_hypo_te_conf_noct_mcf_sas.cgm

14.3.1.45: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function – Safety Analysis Set



SAFETY

28APR2011:12:58:01 - fcum_time_v01.sas/e_hypo_te_conf_cf_day_sas.cgm
nn5401/nn5401-3594/freeze_ctr_05/stats

14.3.1.46: Confirmed Hypoglycaemic Episodes – Treatment Emergent – Cumulative Frequency over Day – Safety Analysis Set

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

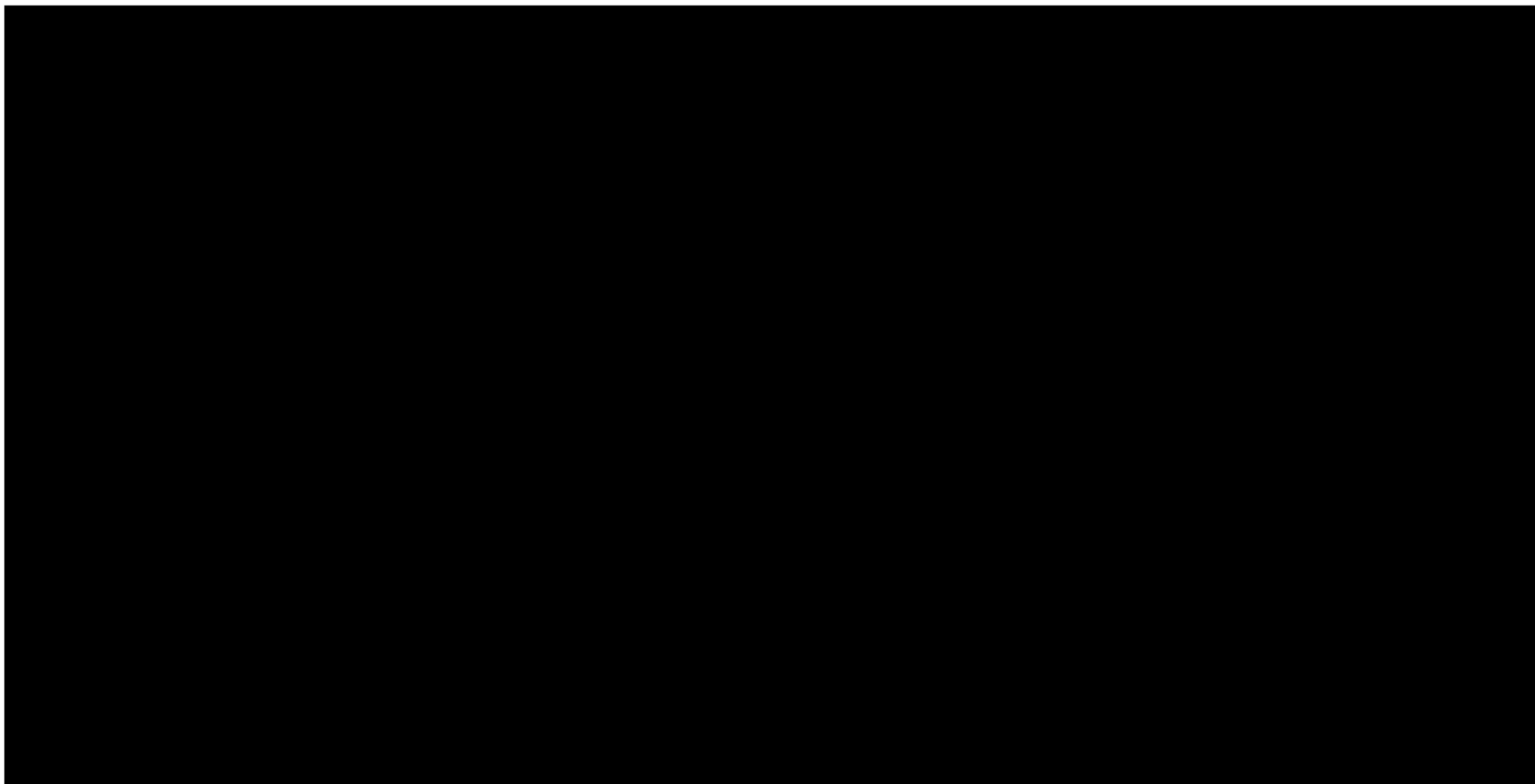
14 June 2011
3.0 | Status:
Page:

Final
624 of 1733 | **Novo Nordisk**

14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

14.3.2.1: Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	--------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
625 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
626 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
627 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
628 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
629 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
630 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
631 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
632 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
633 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

</										

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
634 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
635 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
636 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

</										

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
637 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

</										

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
638 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
639 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
640 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
641 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
642 of 1733

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
643 of 1733

Novo Nordisk

14.3.2.2: Treatment Emergent Adverse Events with Fatal Outcome - Safety Analysis Set

There is no data for this Listing

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:17:31 - lis_teae.sas/l_teae_fatal_sas.txt

14.3.2.3: Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

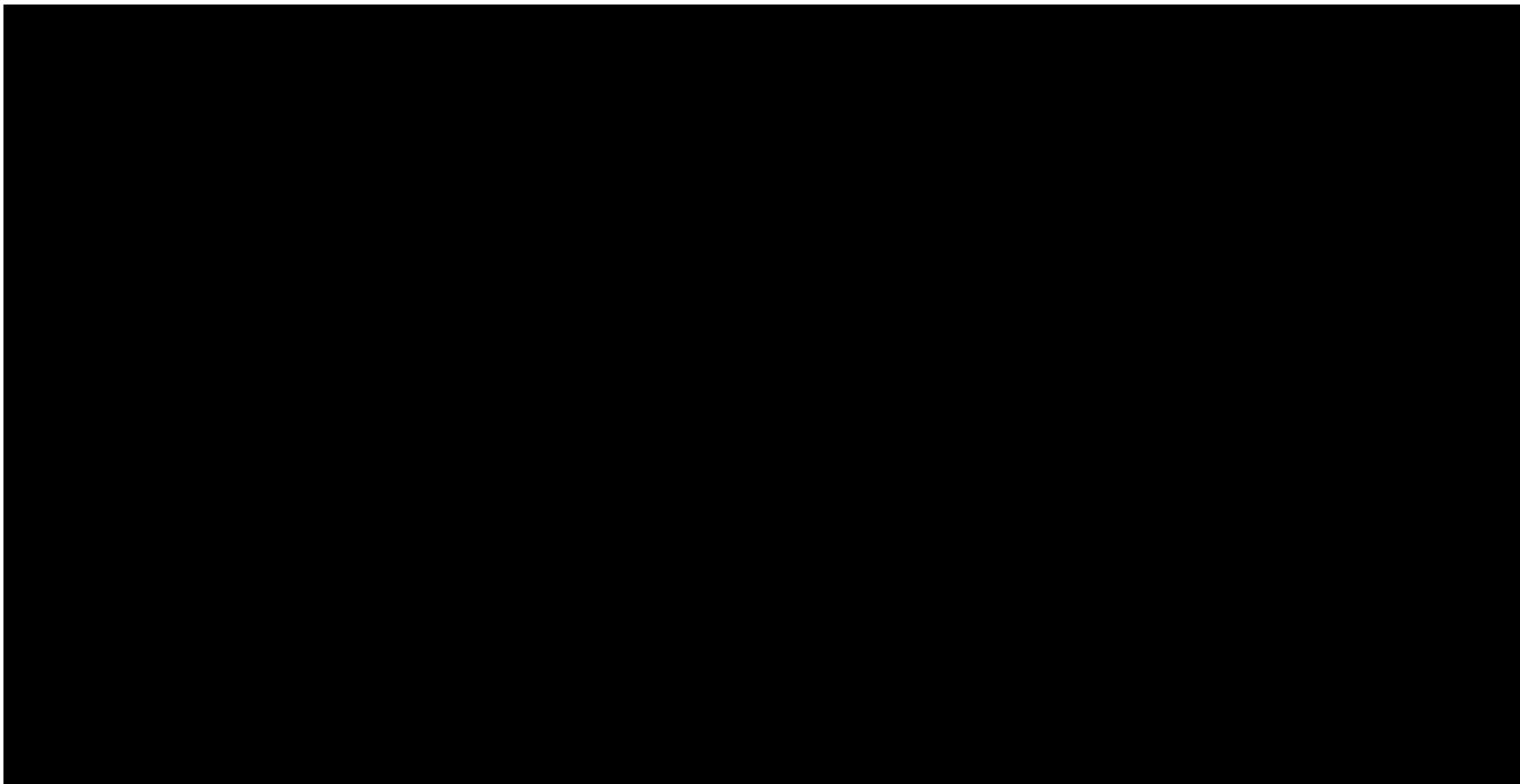
Status:
Page:

Final
645 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
646 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

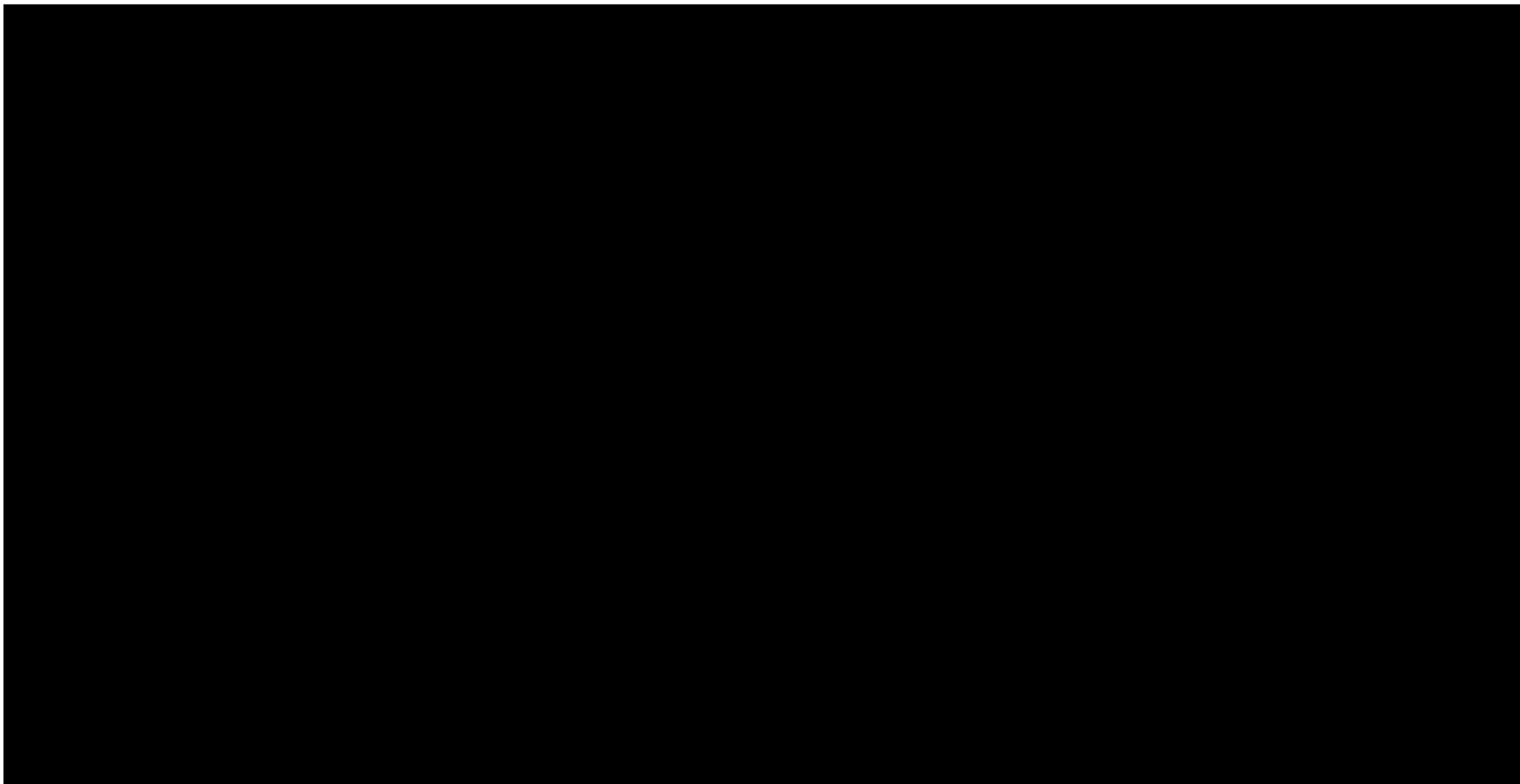
Status:
Page:

Final
647 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

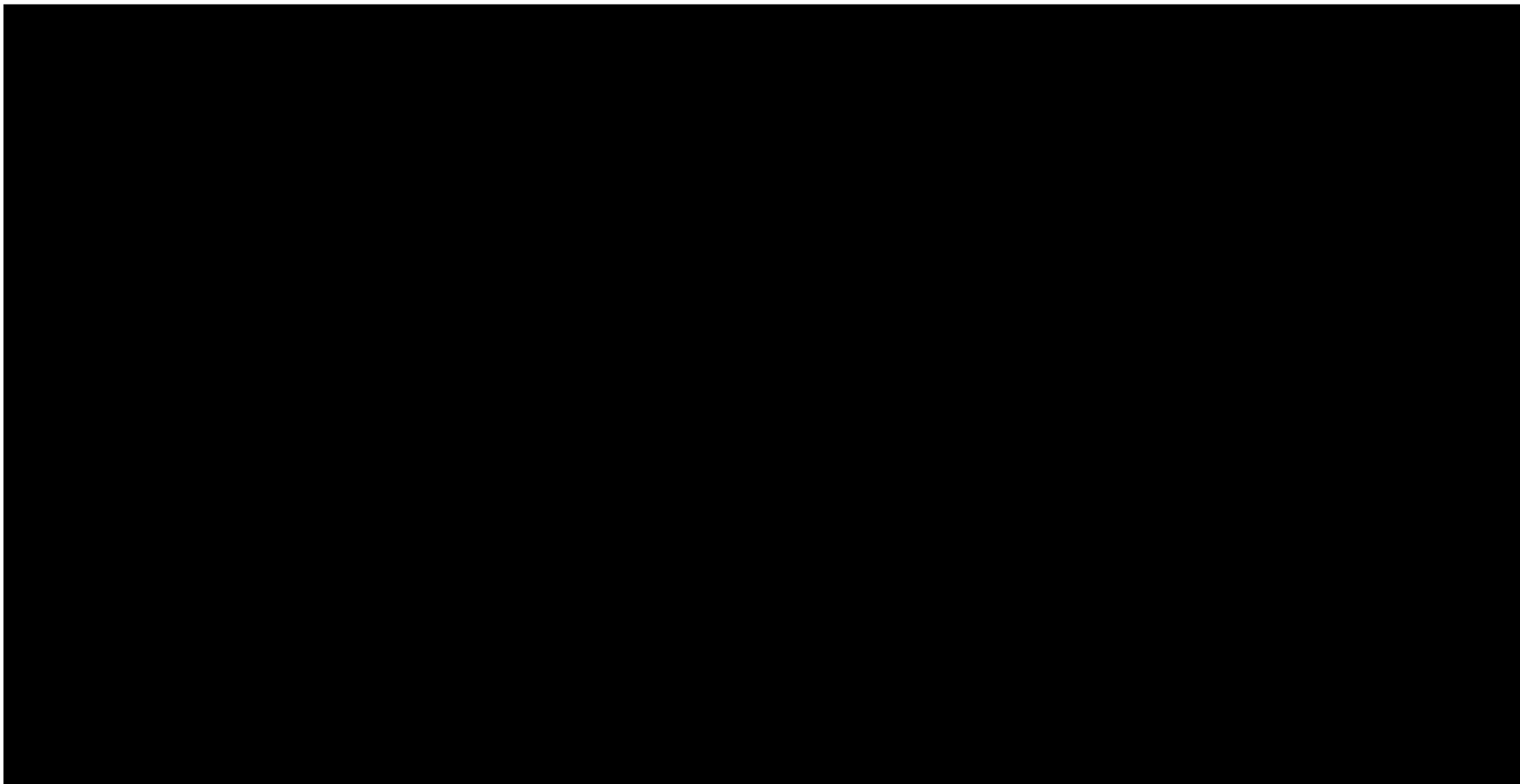
Status:
Page:

Final
648 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

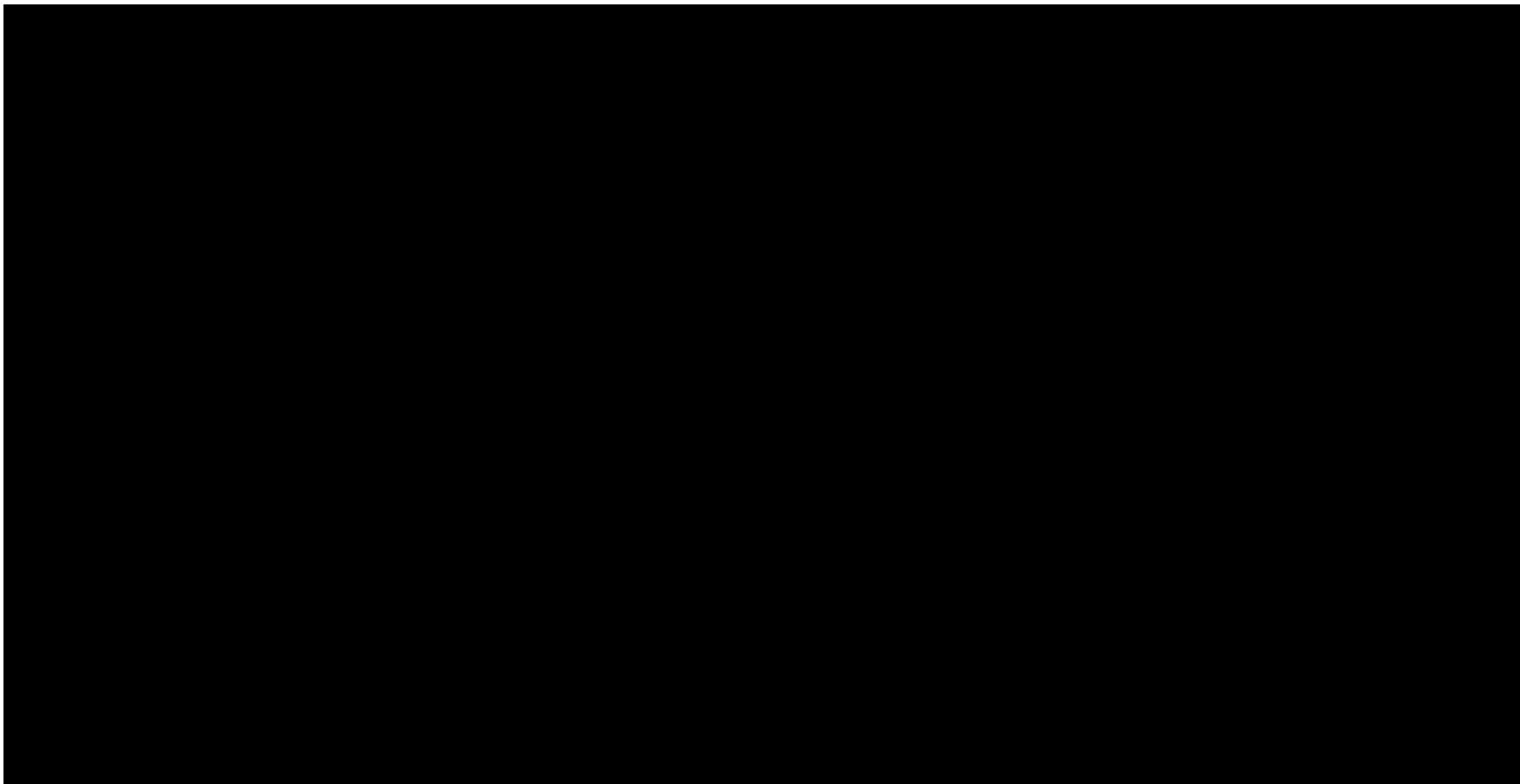
Status:
Page:

Final
649 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

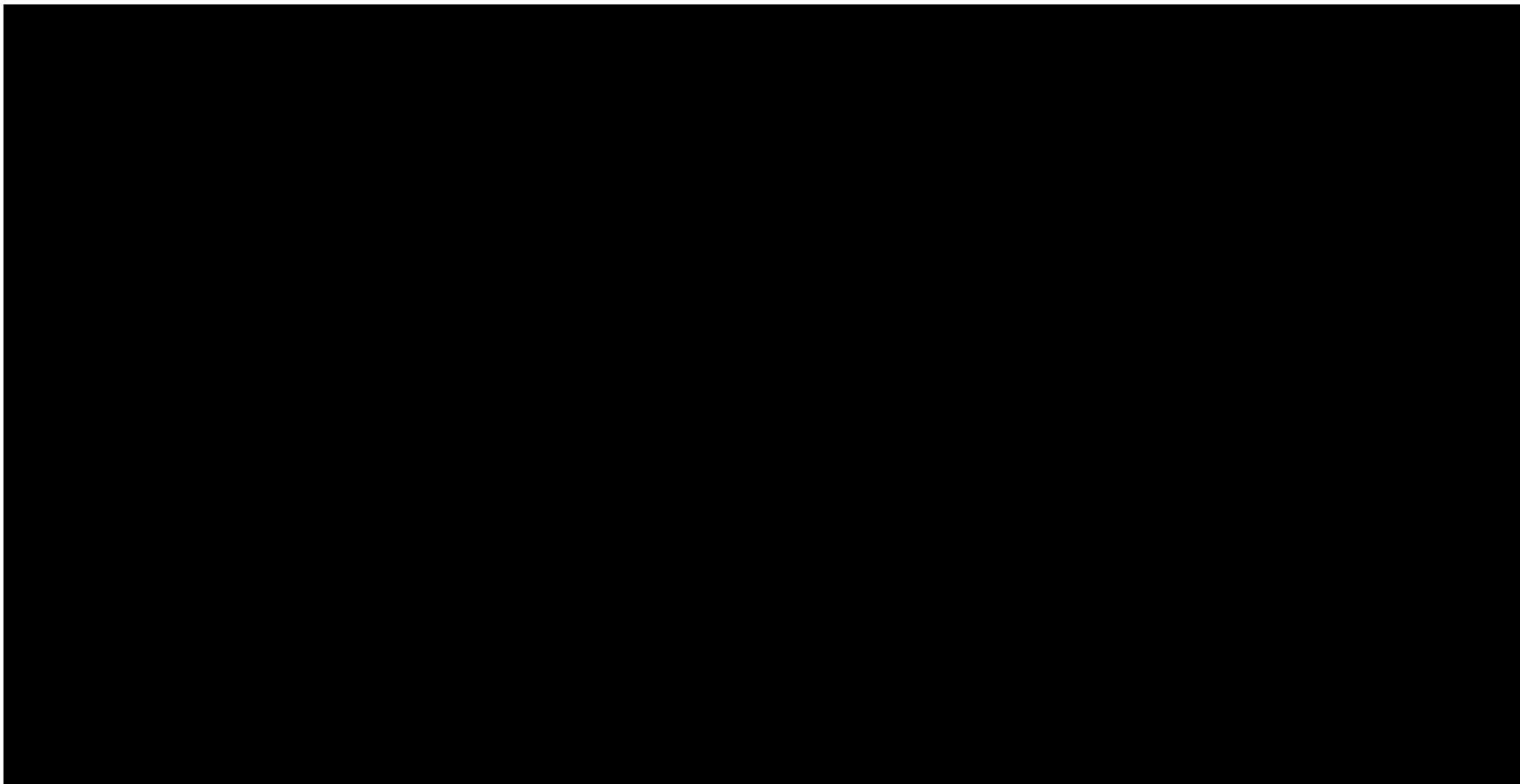
Status:
Page:

Final
650 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

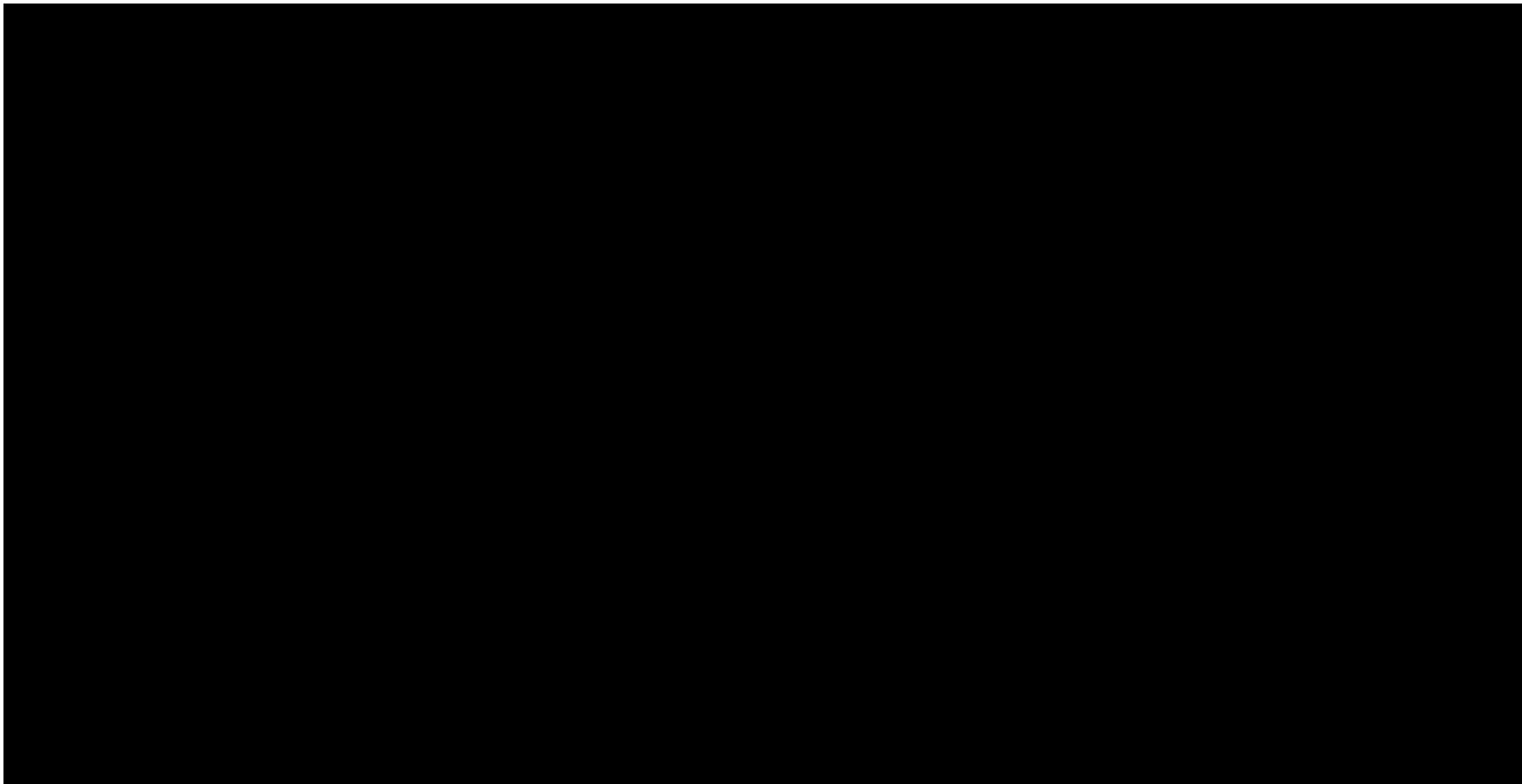
Status:
Page:

Final
651 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

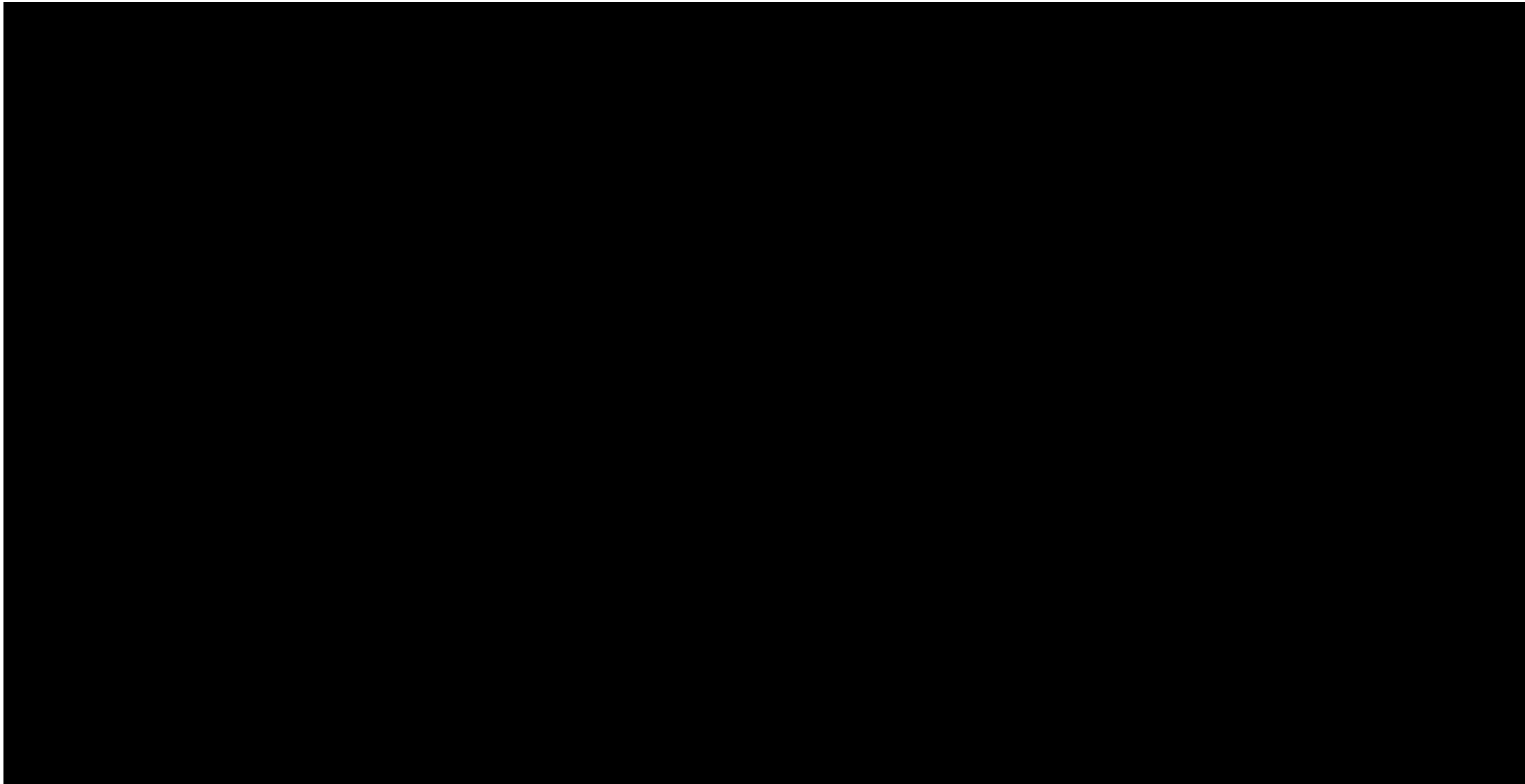
Status:
Page:

Final
652 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

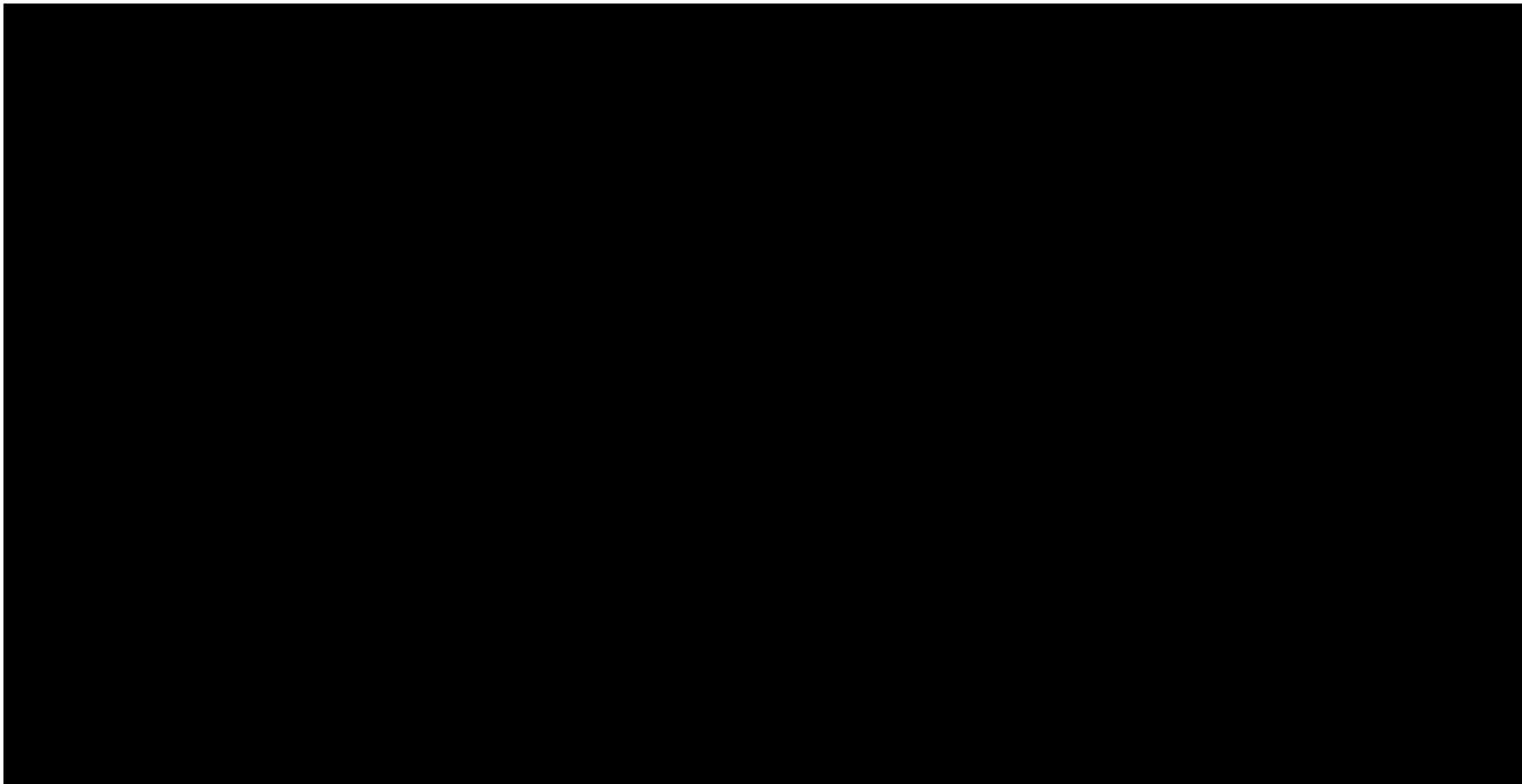
Status:
Page:

Final
653 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

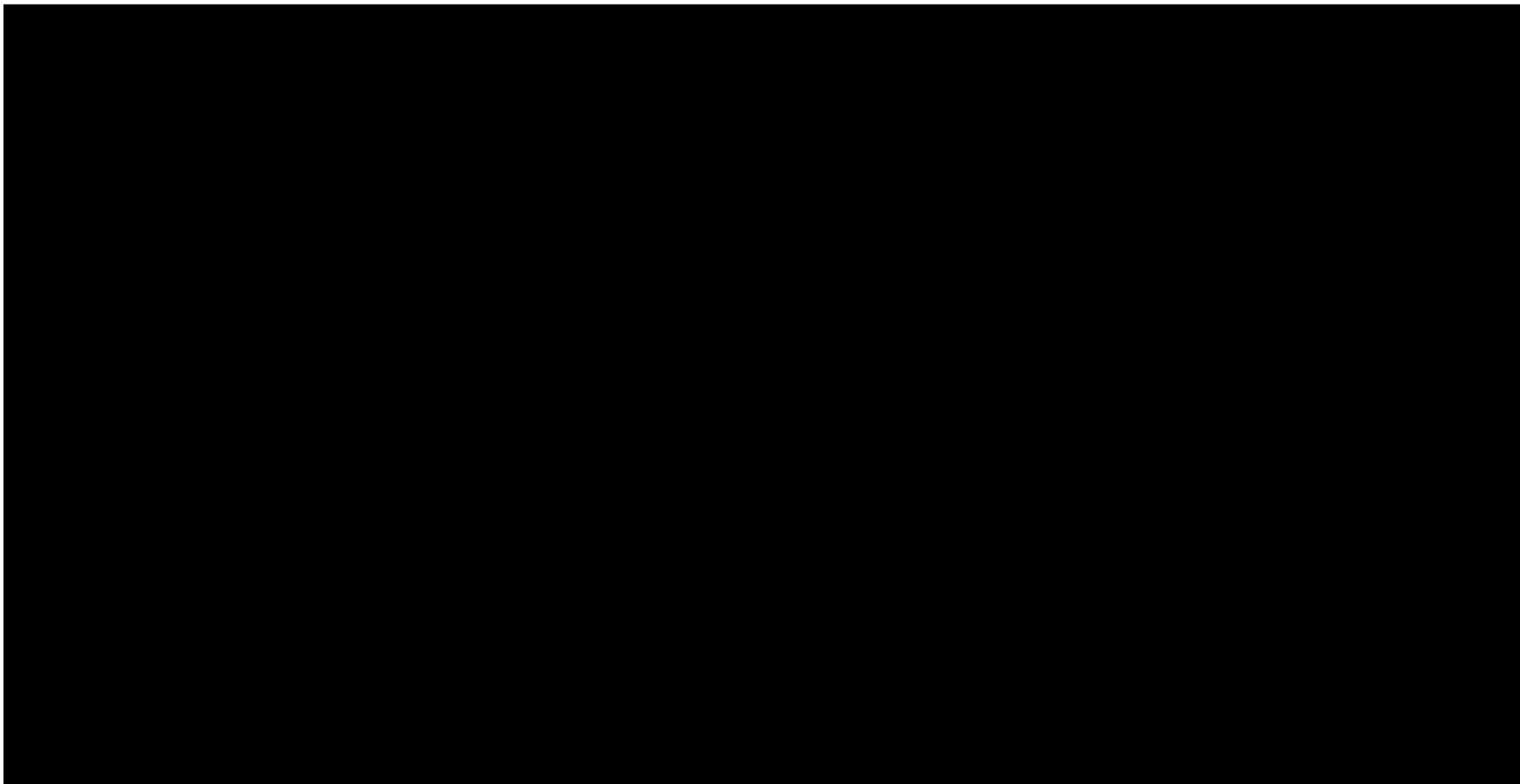
Status:
Page:

Final
654 of 1733

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

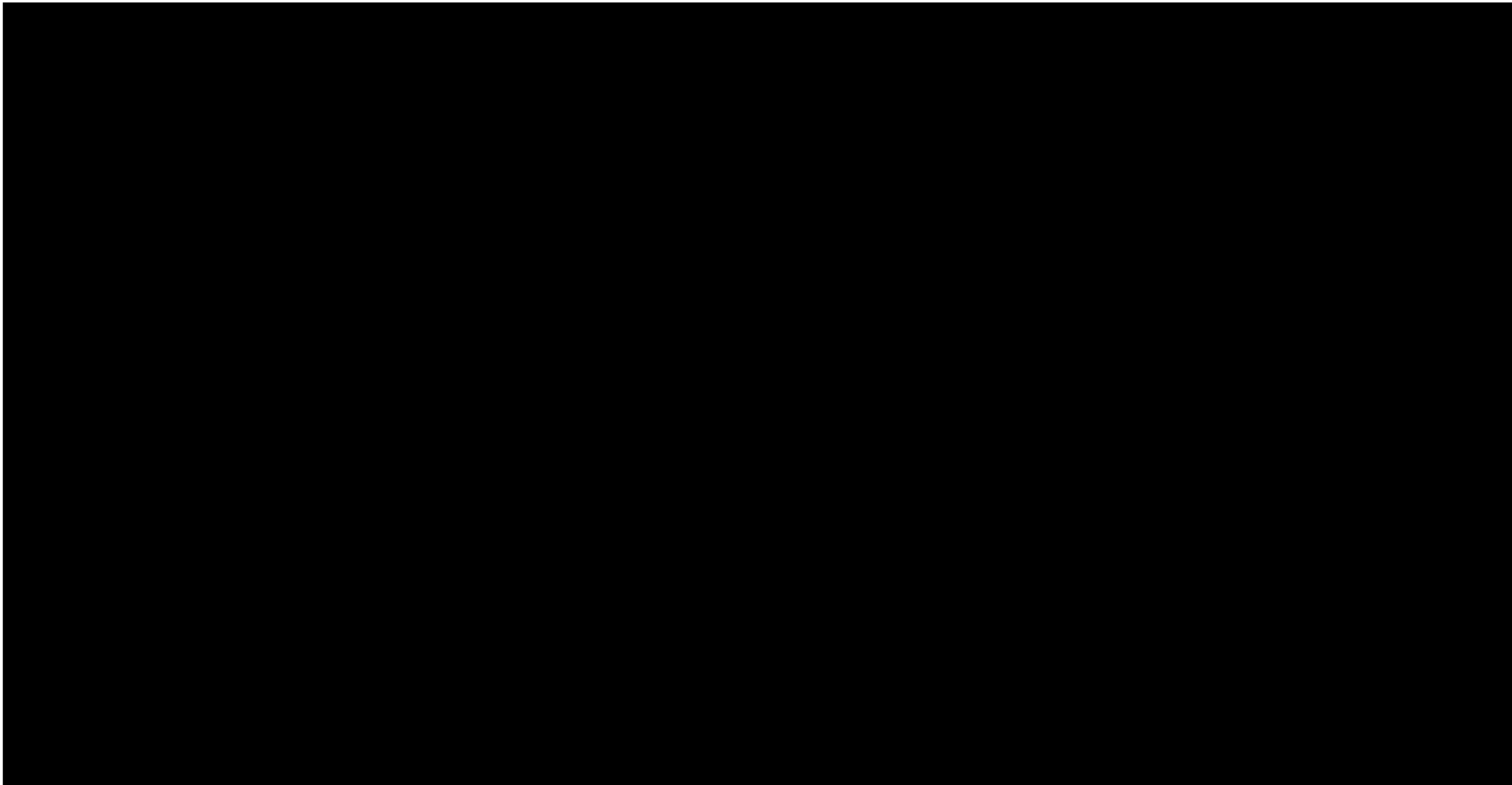
Status:
Page:

Final
655 of 1733

Novo Nordisk

14.3.2.4: Adverse Events Leading to Withdrawal - Full Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

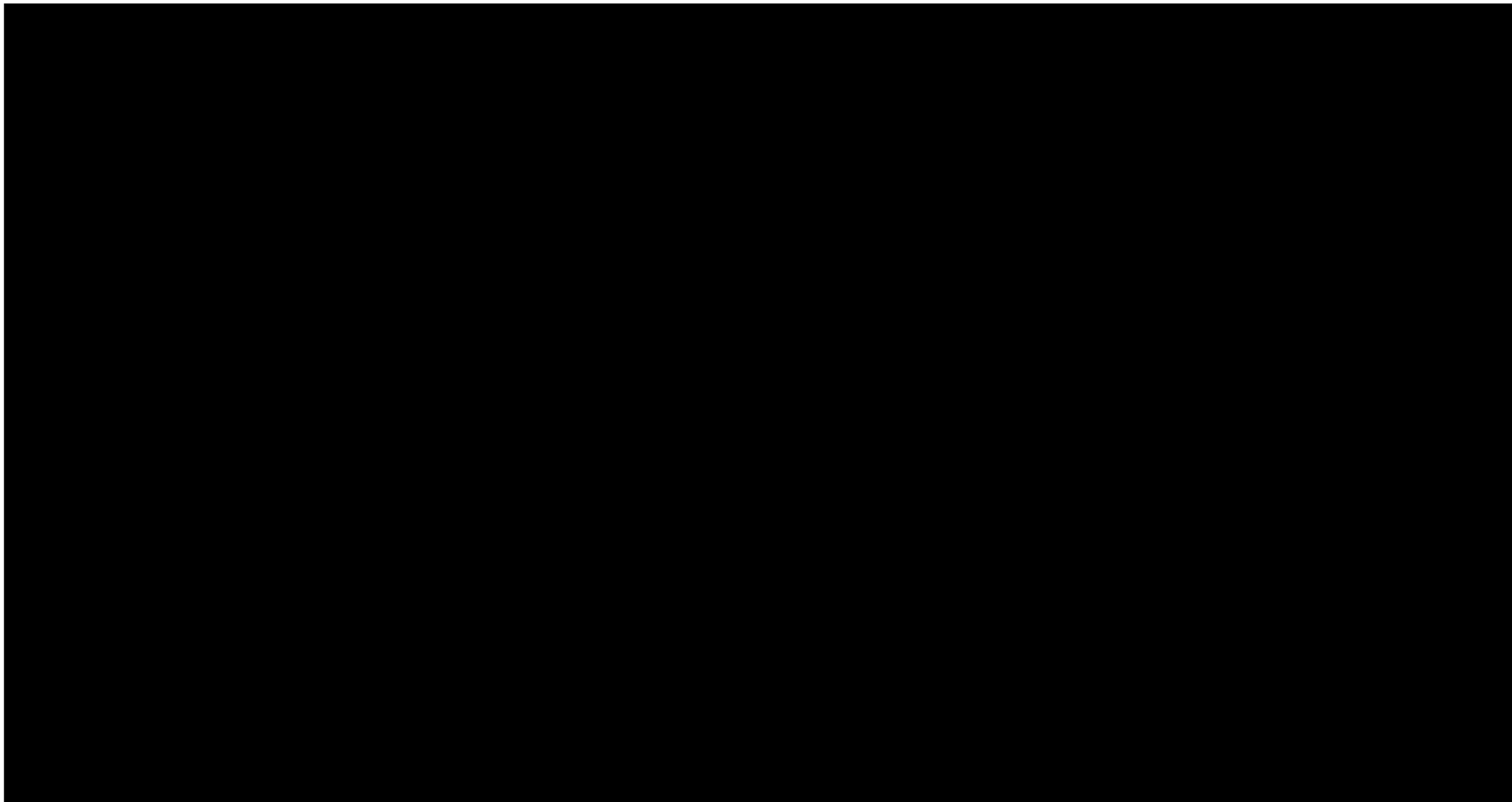
Status:
Page:

Final
656 of 1733

Novo Nordisk

Adverse Events Leading to Withdrawal - Full Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------	------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
657 of 1733

Novo Nordisk

Adverse Events Leading to Withdrawal - Full Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE No.	Diag (Y/N)/ Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------	------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

Abbreviation Statement

Please note the definition of the following abbreviation:

SIAC: Soluble Insulin Analogue Combination, NN5401. Synonym previously used for IDegAsp

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

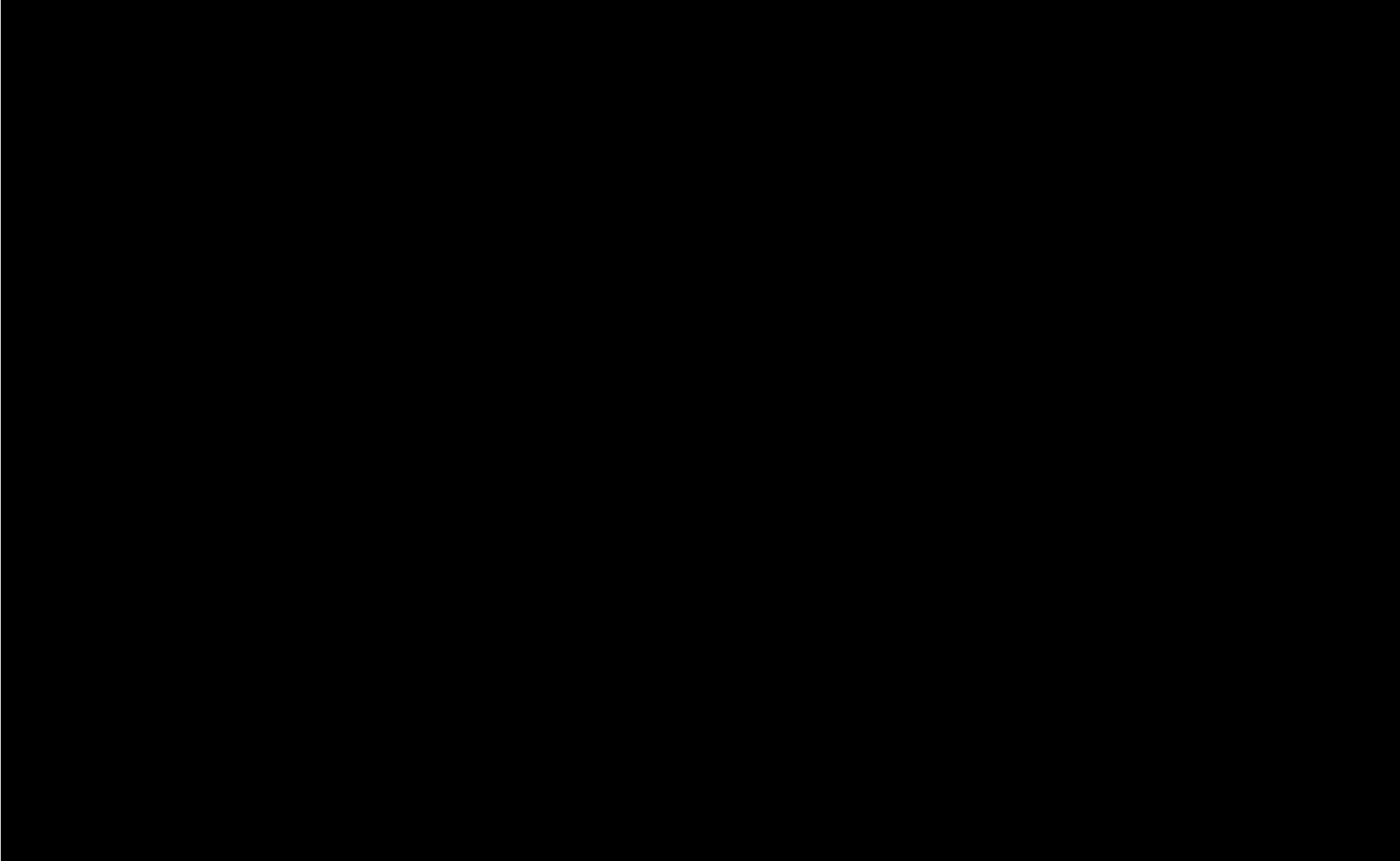
14 June 2011
3.0

Status:
Page:

Final
659 of 1733

Novo Nordisk

Period: 01-Jan-1900 Through 22-Jun-2010



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

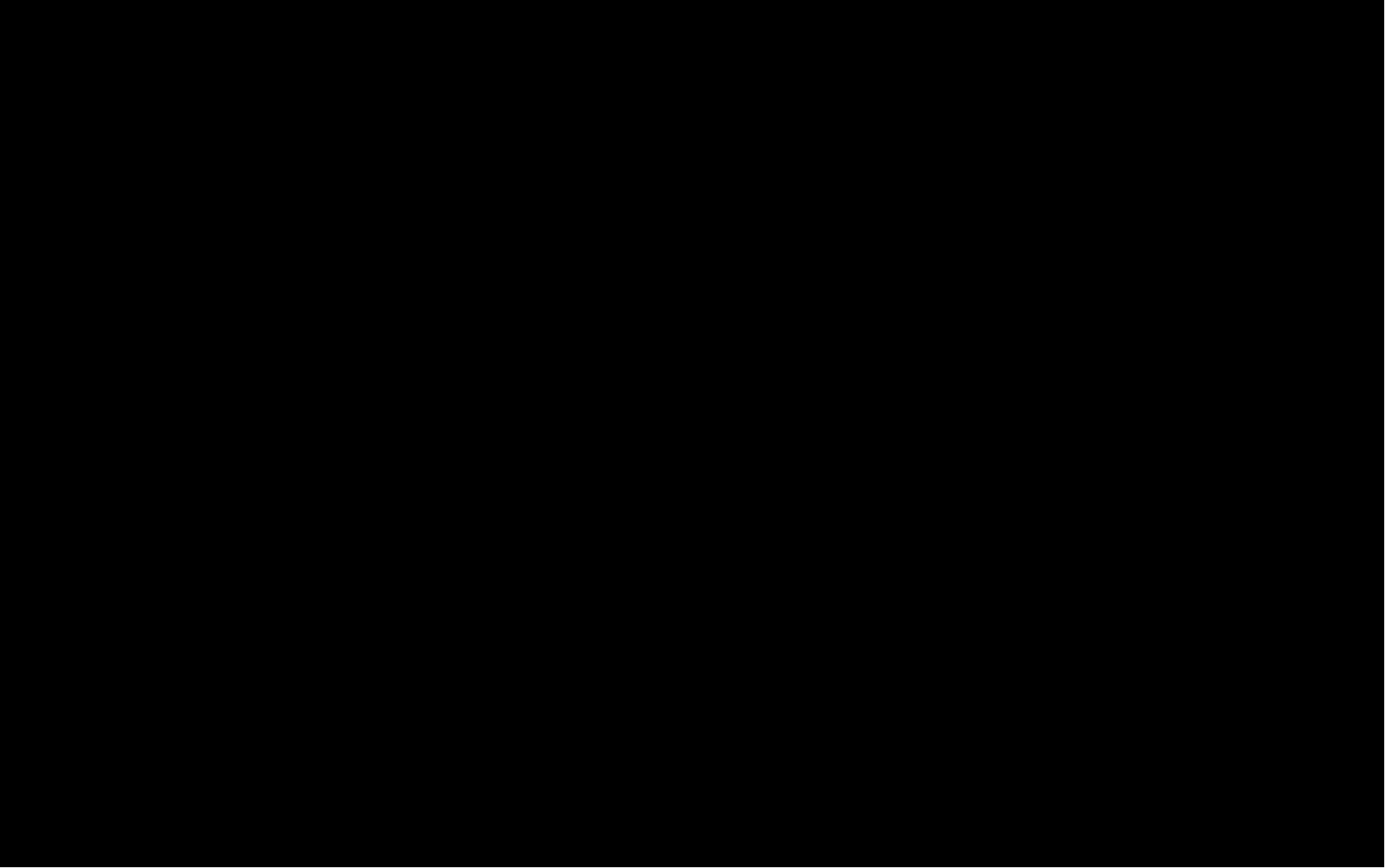
14 June 2011
3.0

Status:
Page:

Final
660 of 1733

Novo Nordisk

Period: 01-Jan-1900 Through 22-Jun-2010



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

Status: Final
Page: 661 of 1733

Novo Nordisk

Report #: **NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final** Date: 10-May-2011 19:32:38
Period: 01-Jan-1900 Through 22-Jun-2010

Ingredient		Insulin Degludec															
										</							

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Patient Outcome
			Daily Dose [Dose Frequency]	Route			

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
-------------	----------------	---------	---	-------	--	-----------------------------------	------------------	-----------------

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

Status: Final
Page: 675 of 1733

Novo Nordisk

Report #: **NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final** Date: 10-May-2011 19:32:38
Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Date: 10-May-2011 19:32:38

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
-------------	----------------	---------	---	-------	--	-----------------------------------	------------------	-----------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

Status: Final
Page: 683 of 1733

Novo Nordisk

Report #: **NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final** Date: 10-May-2011 19:32:38
Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Report #:

NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final

Date: 10-May-2011 19:32:38

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
-------------	----------------	---------	---	-------	--	-----------------------------------	------------------	-----------------

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Date: 10-May-2011 19:32:38

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Novo Nordisk

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
-------------	----------------	---------	---	-------	--	-----------------------------------	------------------	-----------------

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Report #:

NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final

Date: 10-May-2011 19:32:38

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
-------------	----------------	---------	---	-------	--	-----------------------------------	------------------	-----------------

Novo Nordisk

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Novo Nordisk

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

Status: Final
Page: 728 of 1733

Novo Nordisk

Report #: **NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final** Date: 10-May-2011 19:32:38
Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Patient Outcome
			Daily Dose [Dose Frequency]	Route			

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Novo Nordisk

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

Status: Final
Page: 738 of 1733

Novo Nordisk

Report #: **NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final** Date: 10-May-2011 19:32:38
Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Patient Outcome
			Daily Dose [Dose Frequency]	Route			

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Report #:

NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final

Date: 10-May-2011 19:32:38

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
-------------	----------------	---------	---	-------	--	-----------------------------------	------------------	-----------------

Report #:

NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final

Date: 10-May-2011 19:32:38

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
-------------	----------------	---------	---	-------	--	-----------------------------------	------------------	-----------------

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Novo Nordisk

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Patient Outcome
			Daily Dose [Dose Frequency]	Route			

Report #:

NN5401-3594 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases -- Final

Date: 10-May-2011 19:32:38

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
-------------	----------------	---------	---	-------	--	-----------------------------------	------------------	-----------------

Novo Nordisk

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Novo Nordisk

Period: 01-Jan-1900 Through 22-Jun-2010

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401-3594

Study ID: NN5401-3594

IDet

Skin Papilloma

[REDACTED] The event was assessed as non serious and of mild intensity. [REDACTED]
[REDACTED]. The event was assessed as unlikely related to trial drug and no changes to trial drug regimen were made.

Study ID: NN5401-3594

IDet

Benign neoplasm of thyroid gland

[REDACTED] The event was considered not serious and of mild intensity. [REDACTED]
[REDACTED] the event was assessed as unlikely related to trial drug. No changes to trial drug conduct were made throughout the course of the event.

NN5401-3594 Narratives for non-serious Adverse Events leading to withdrawal

Subject [REDACTED] (IDet), [REDACTED]
[REDACTED], experienced wrong drug administration on trial day [REDACTED]
[REDACTED]

Subject [REDACTED] (IDet), [REDACTED]
[REDACTED] diabetic ketoacidosis (serious, severe in severity) on trial day [REDACTED] and was
subsequently withdrawn from the trial. All events were evaluated to be unlikely related to trial product
[REDACTED]

Subject [REDACTED] (IDegAsp OD), [REDACTED]
[REDACTED] experienced worsening of depression on trial day [REDACTED] (non-
serious, moderate in severity) and was subsequently withdrawn from the trial. The causality was
assessed as unlikely related to trial product [REDACTED].

Subject [REDACTED] (IDet), [REDACTED]
[REDACTED], experienced an injection site reaction (non-serious, moderate in severity) on trial day [REDACTED]
and was subsequently withdrawn from the trial. The causality was assessed as probably related to
[REDACTED]

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

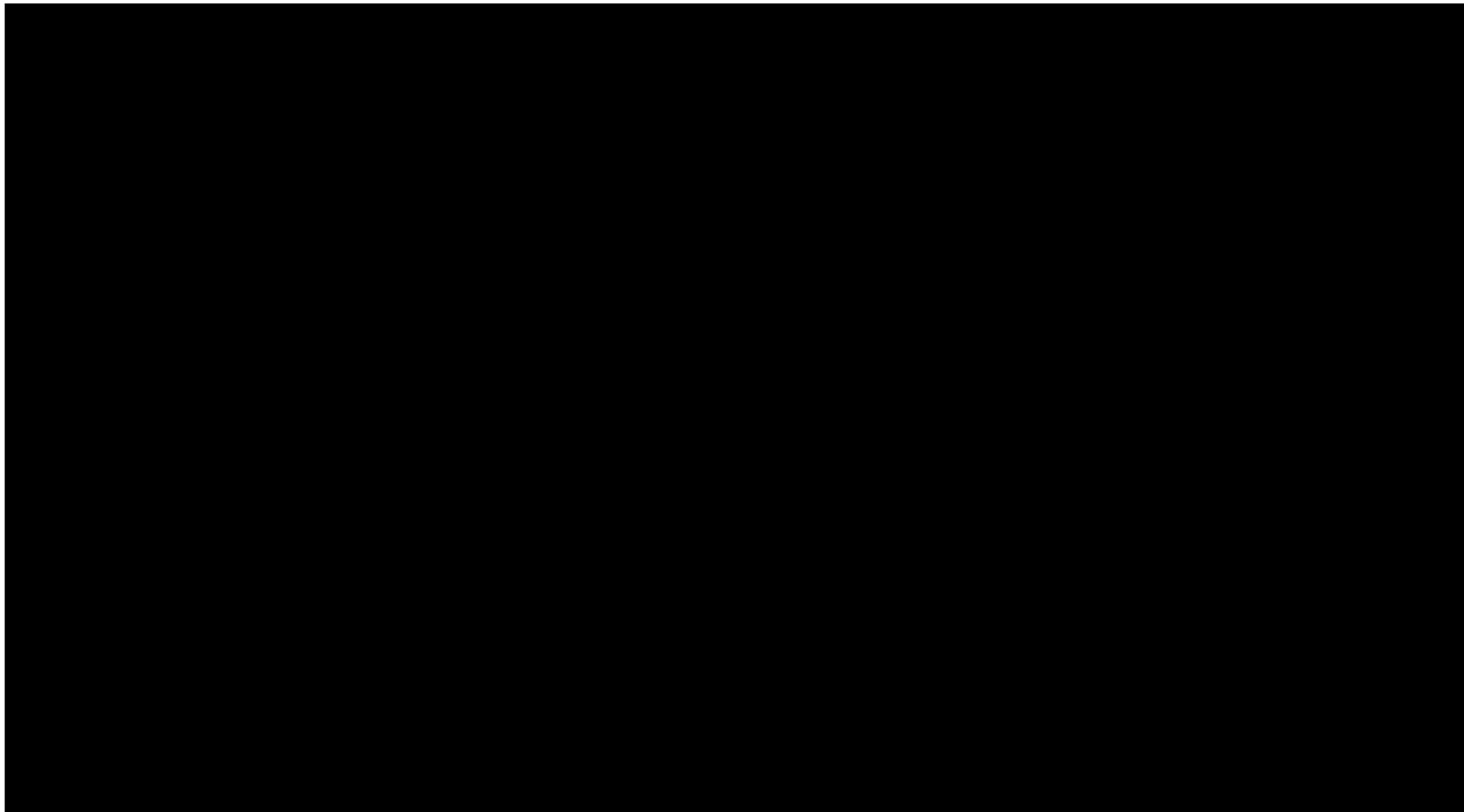
Status:
Page:

Final
766 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

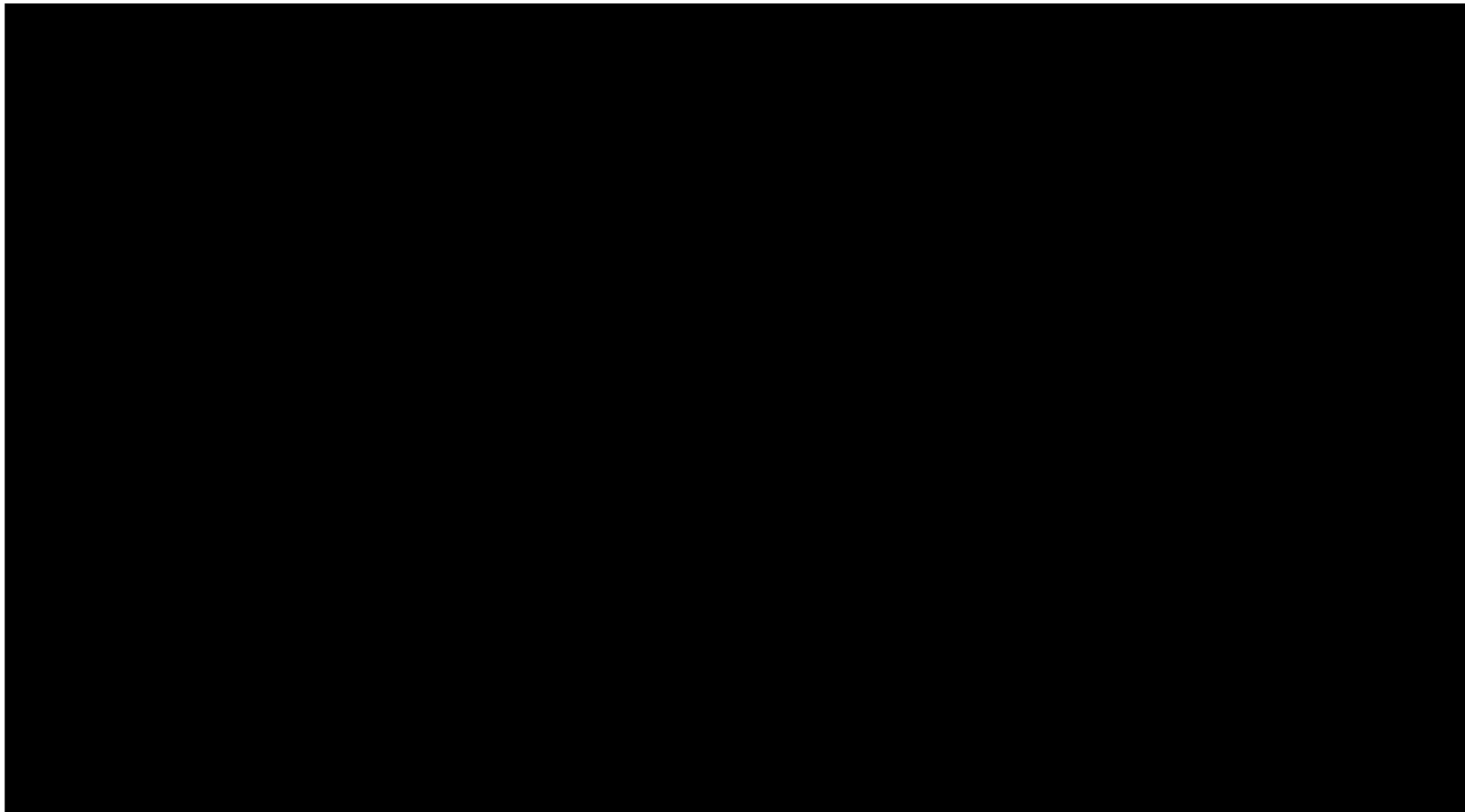
Status:
Page:

Final
767 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

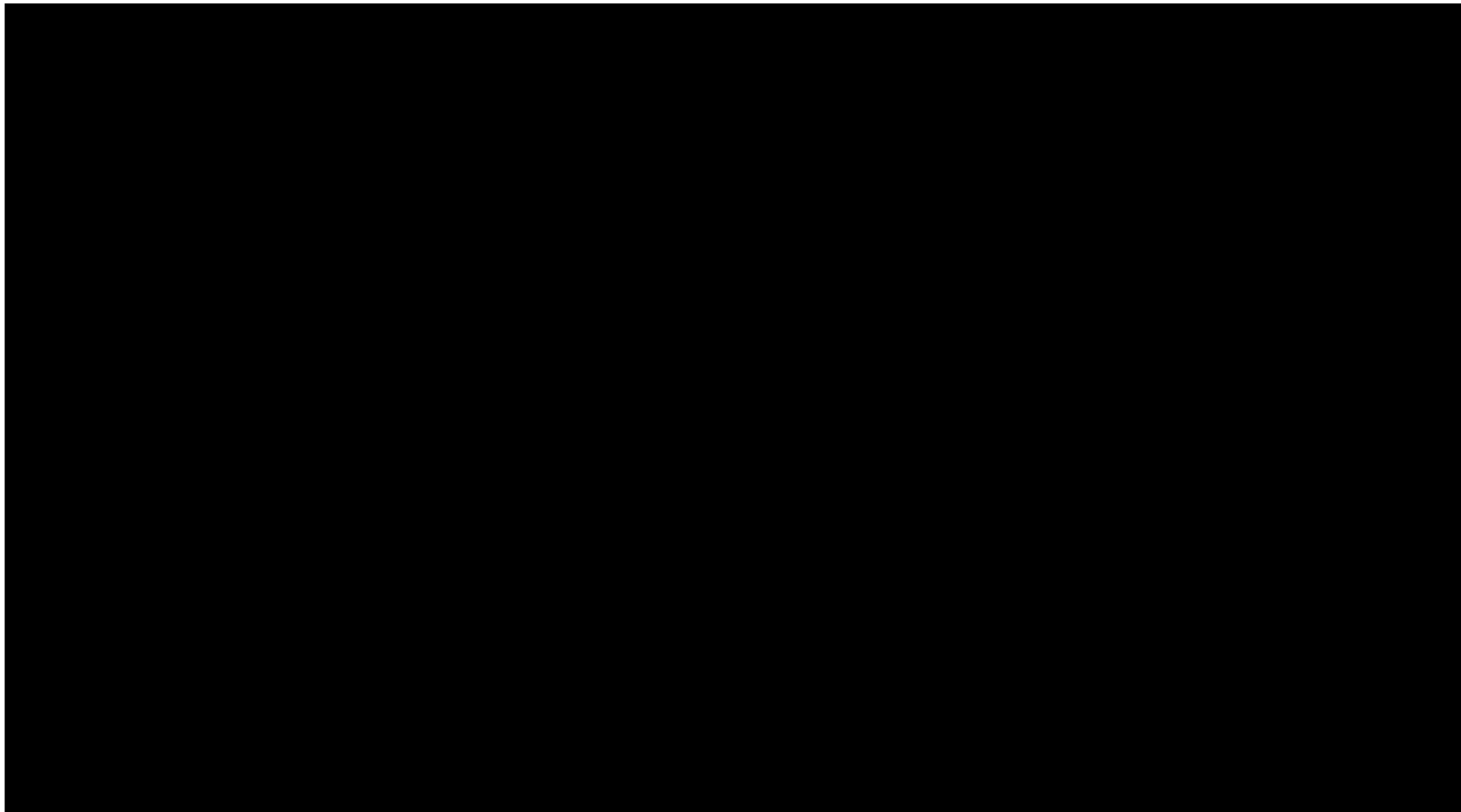
Status:
Page:

Final
768 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

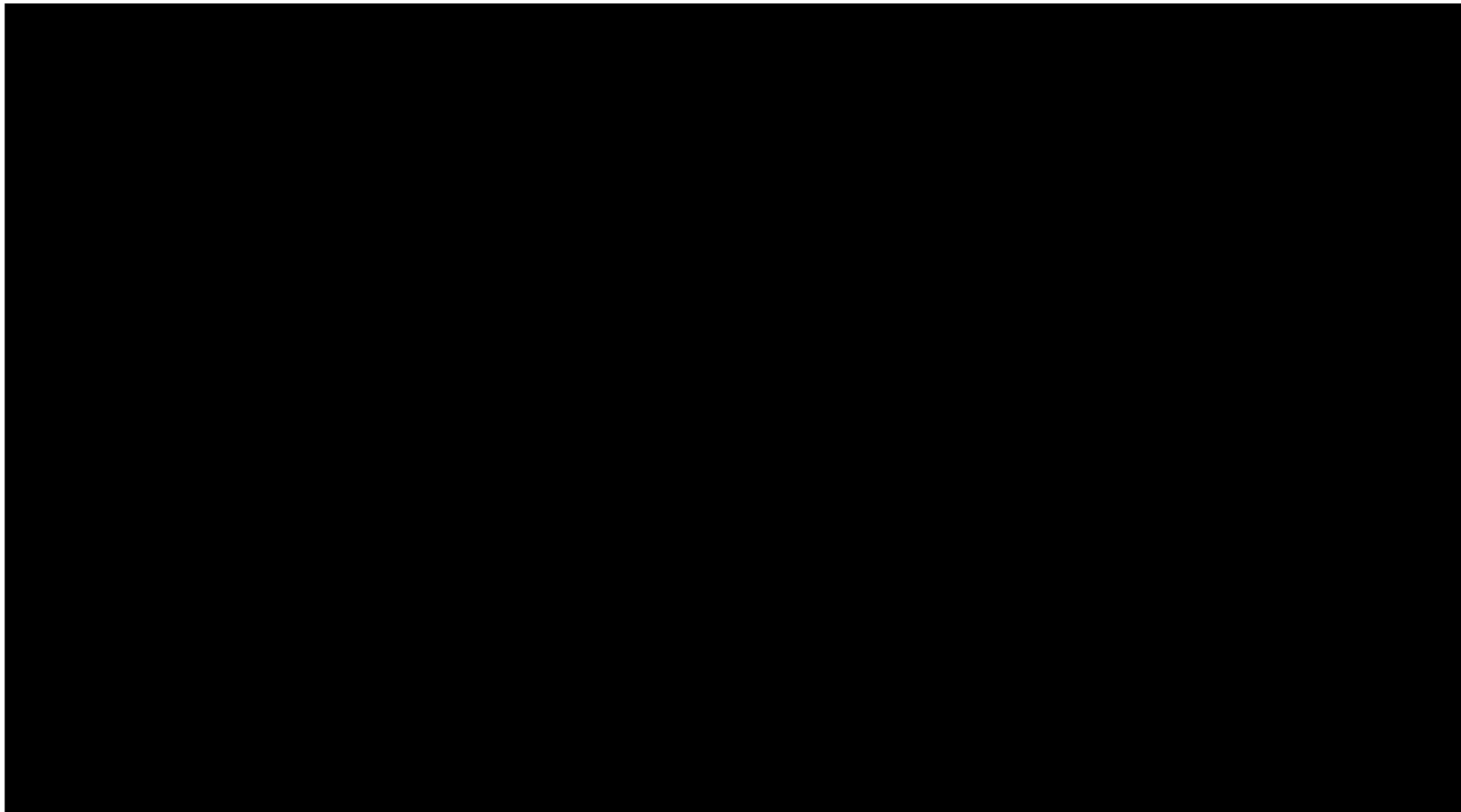
Status:
Page:

Final
769 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

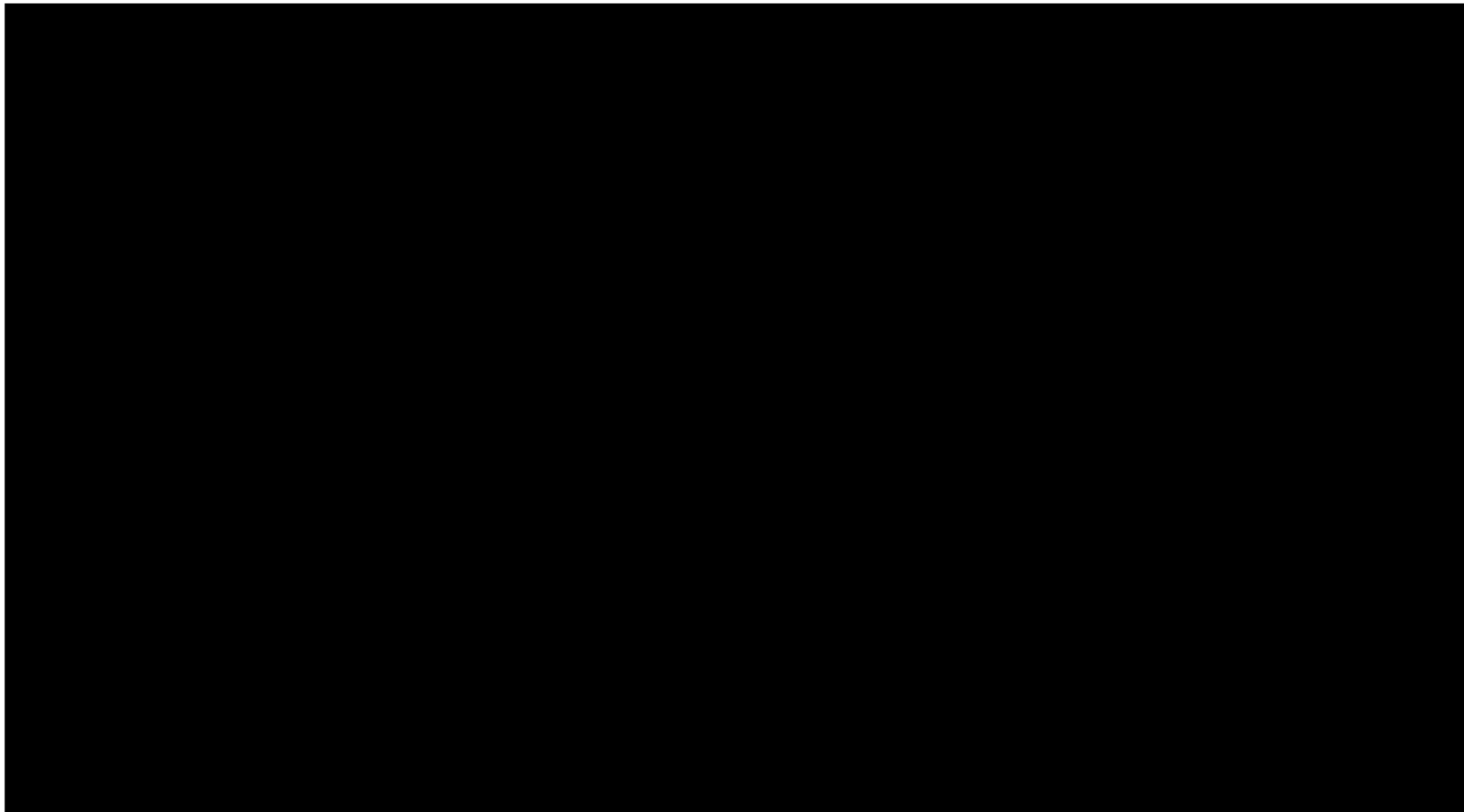
Status:
Page:

Final
771 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

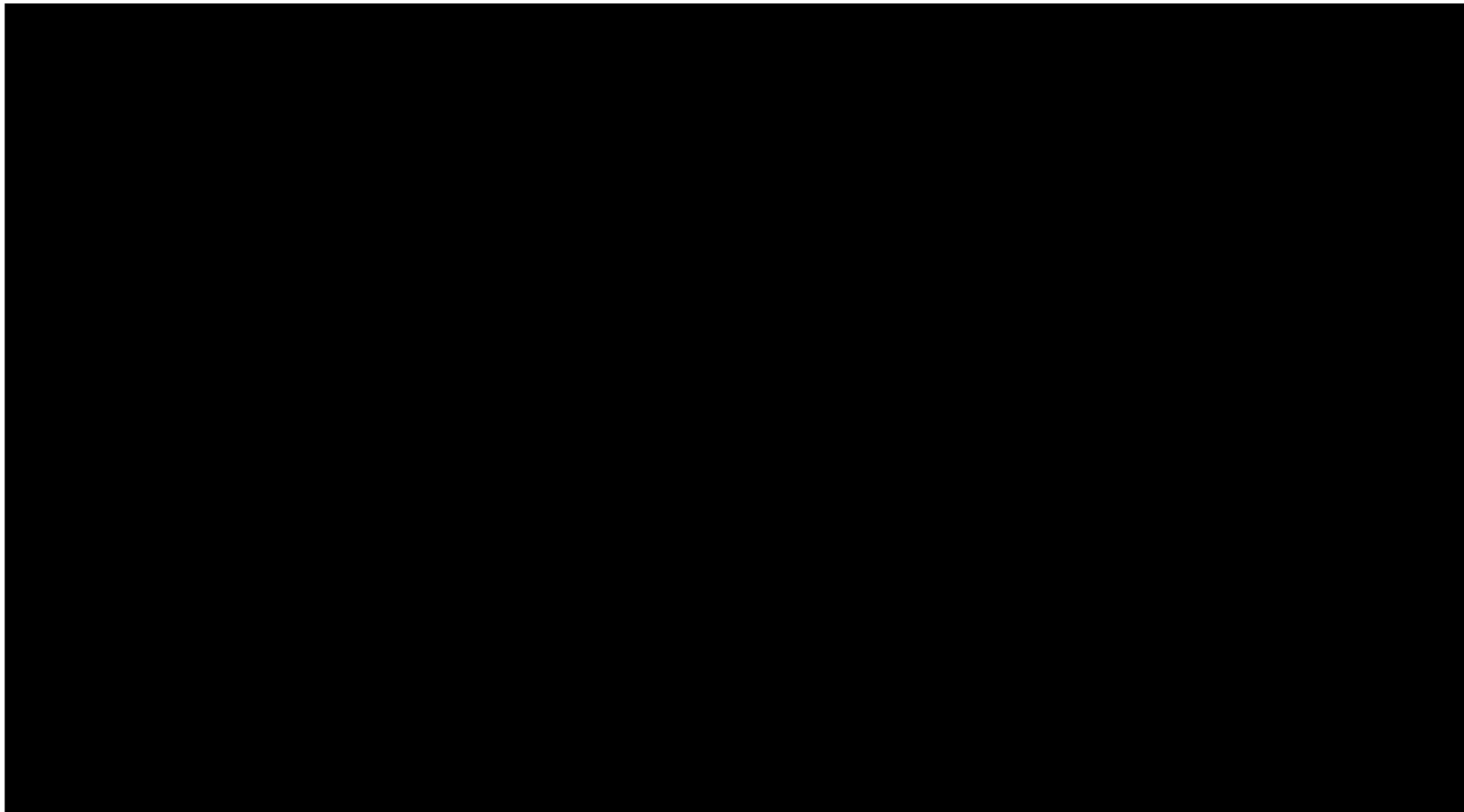
Status:
Page:

Final
772 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

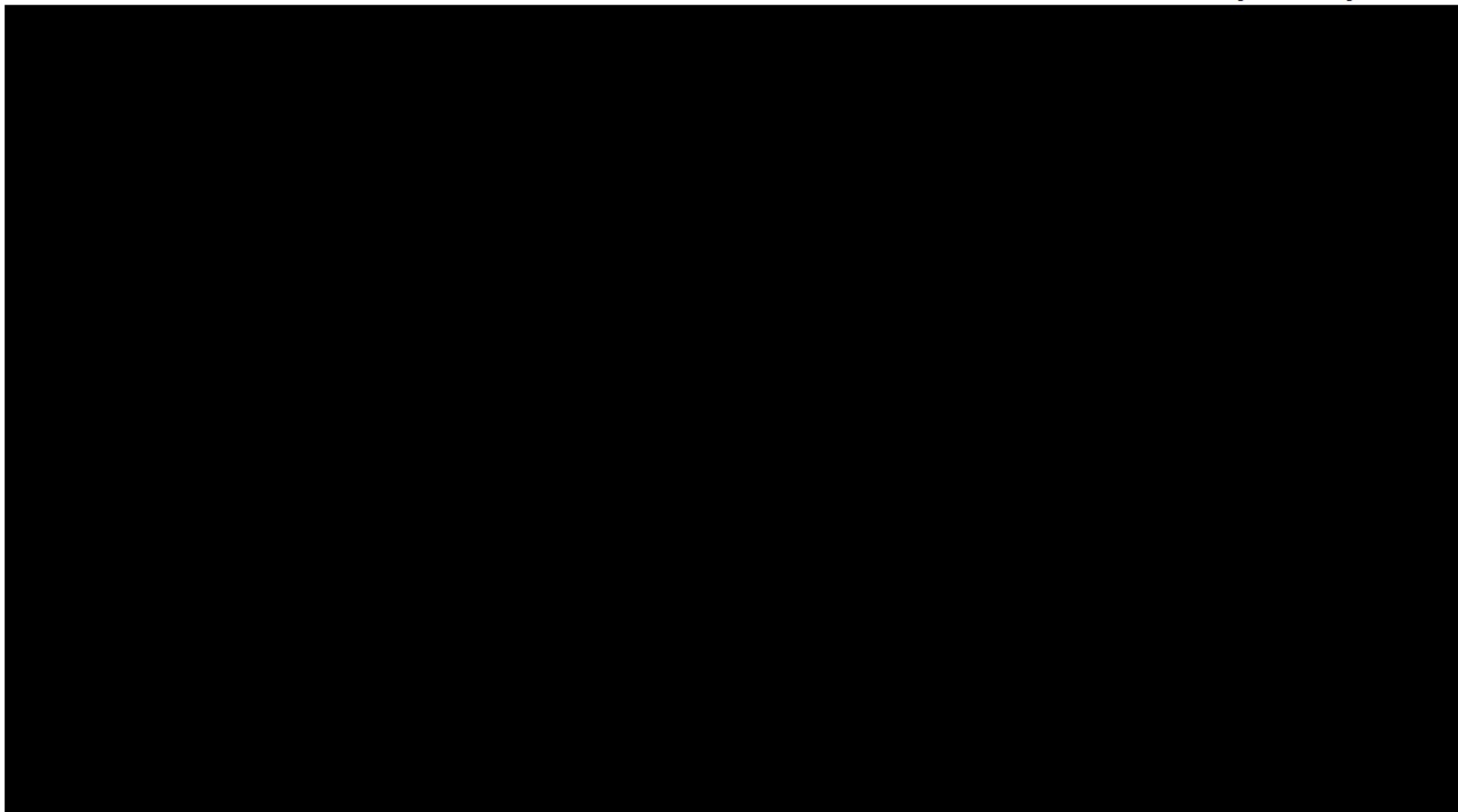
Status:
Page:

Final
773 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

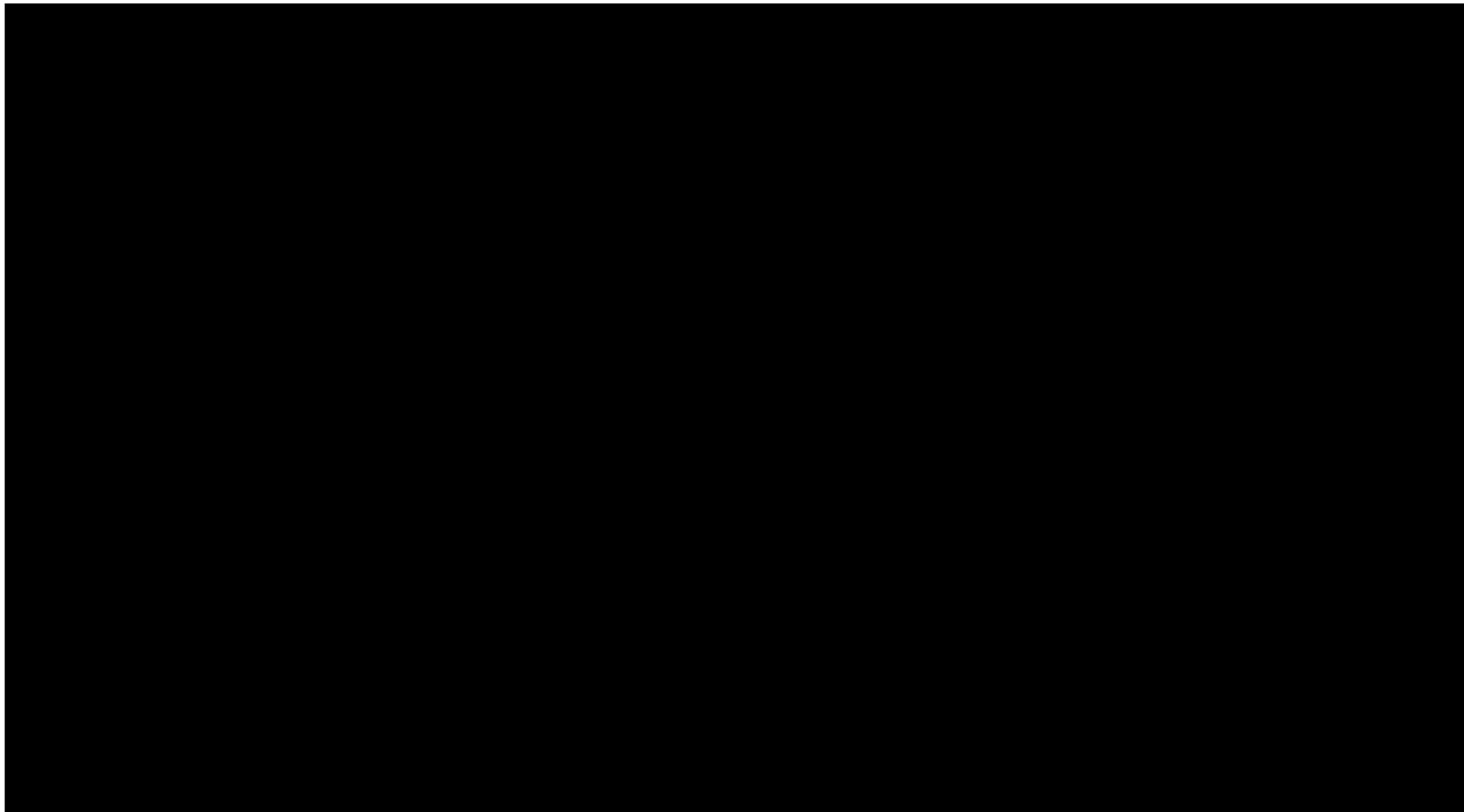
Status:
Page:

Final
774 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

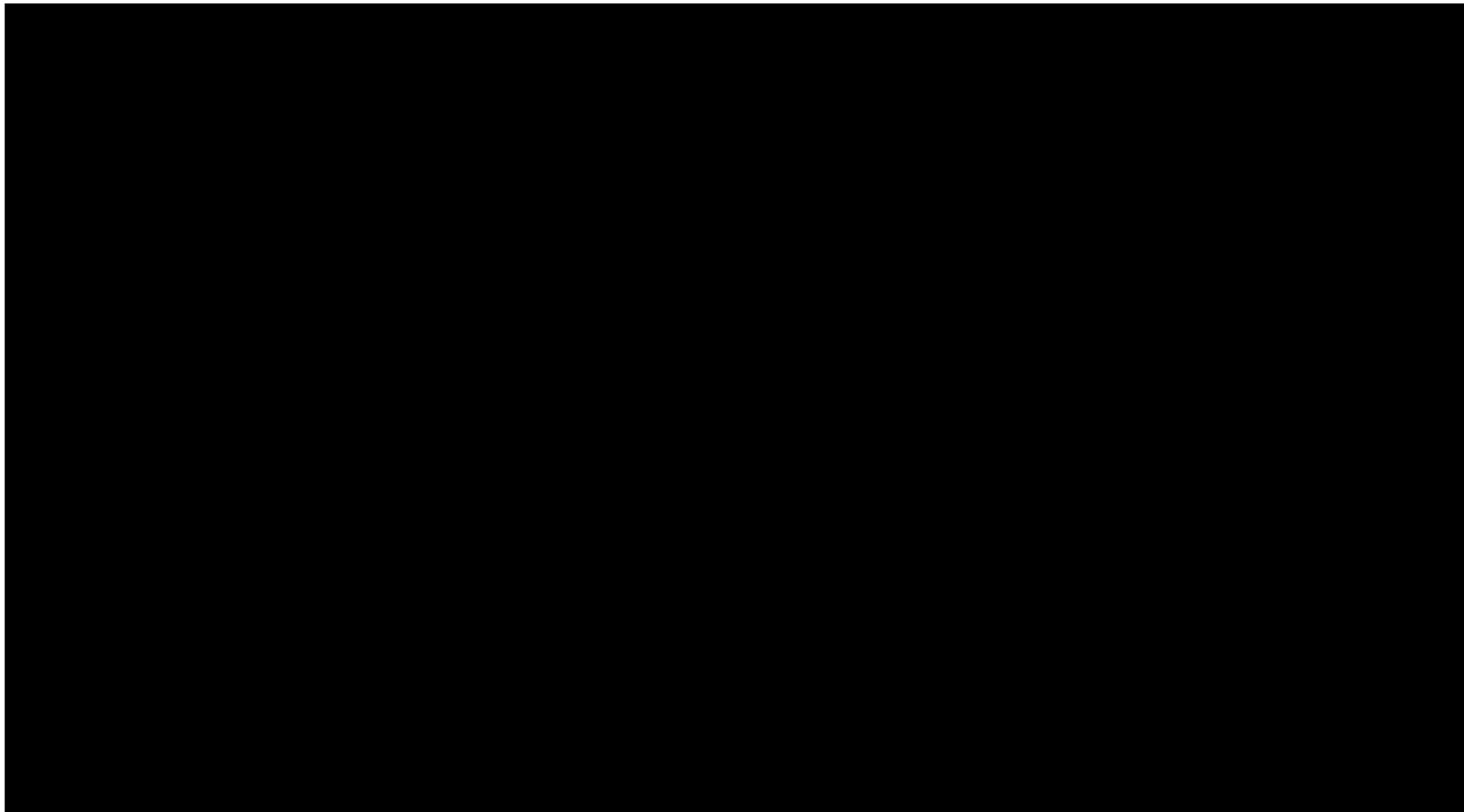
Status:
Page:

Final
775 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

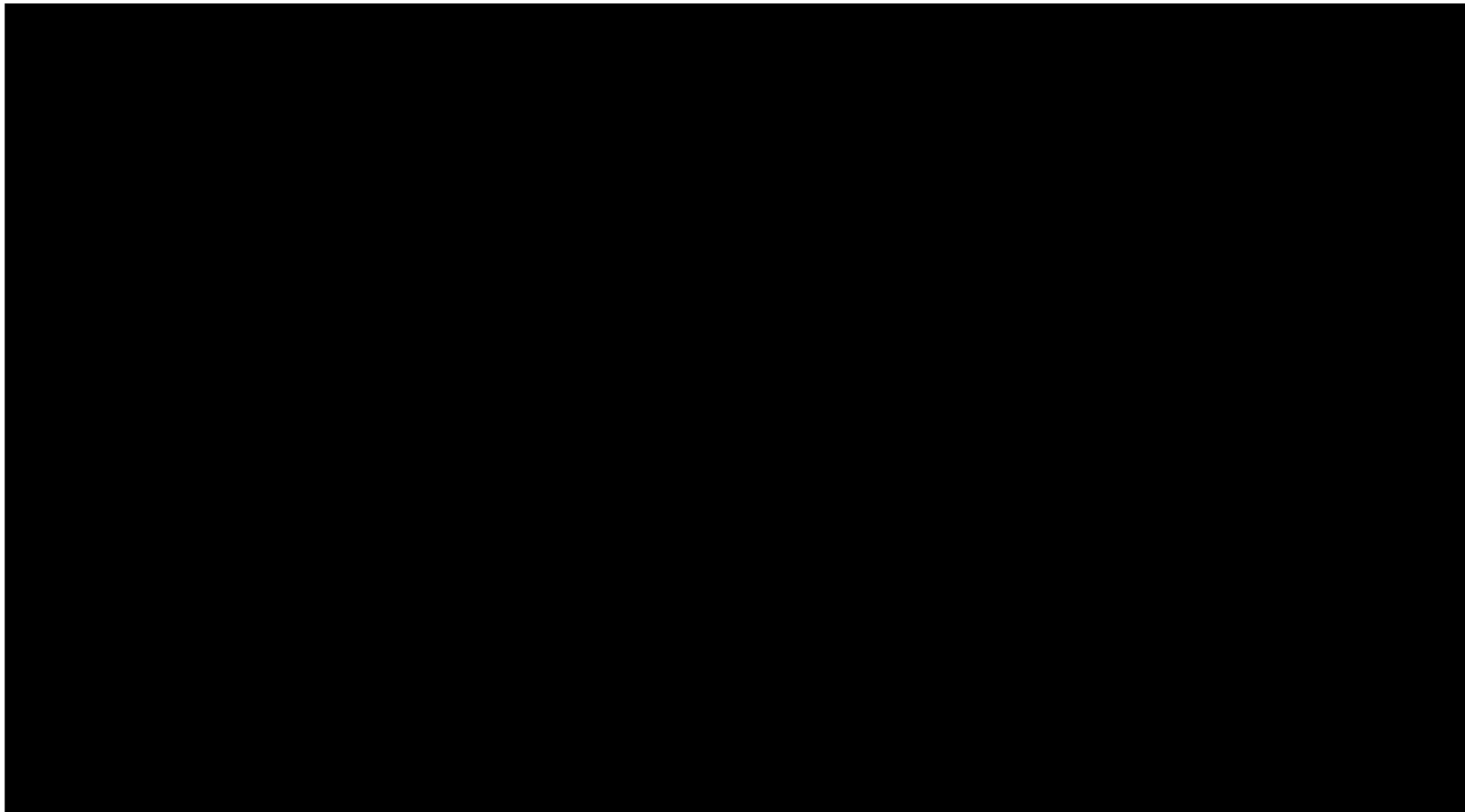
Status:
Page:

Final
776 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

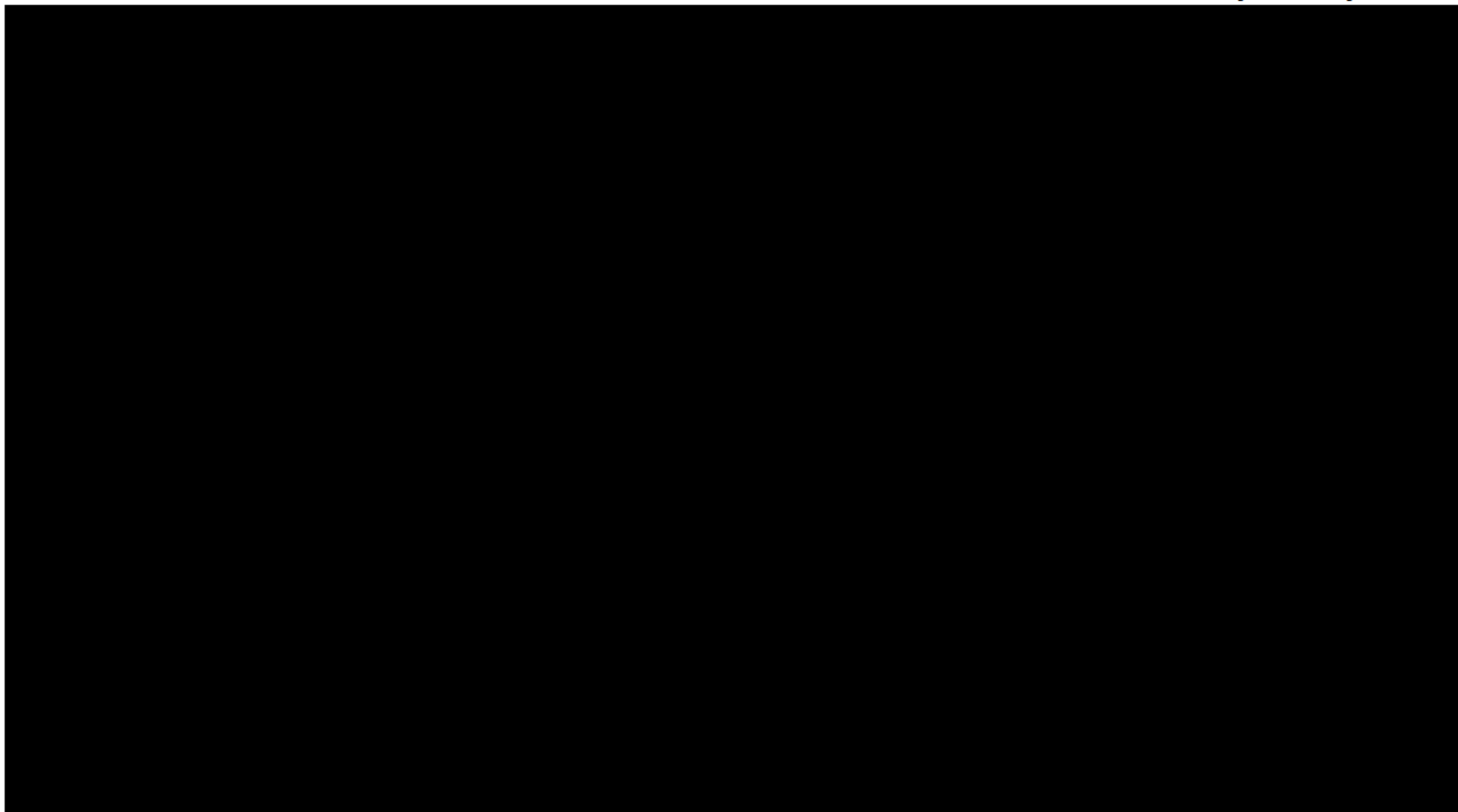
Status:
Page:

Final
777 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

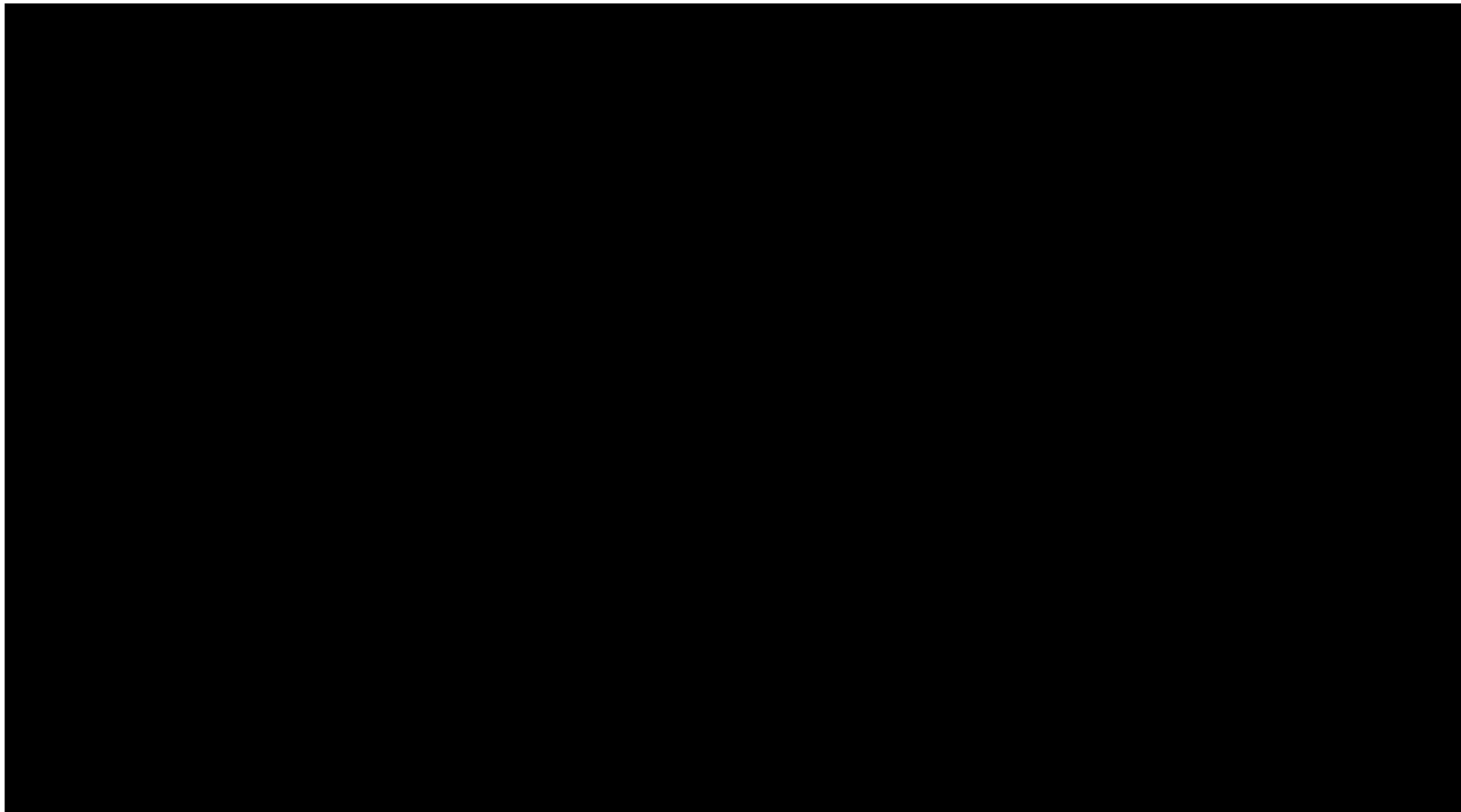
Status:
Page:

Final
778 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

Status:
Page:

Final
779 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

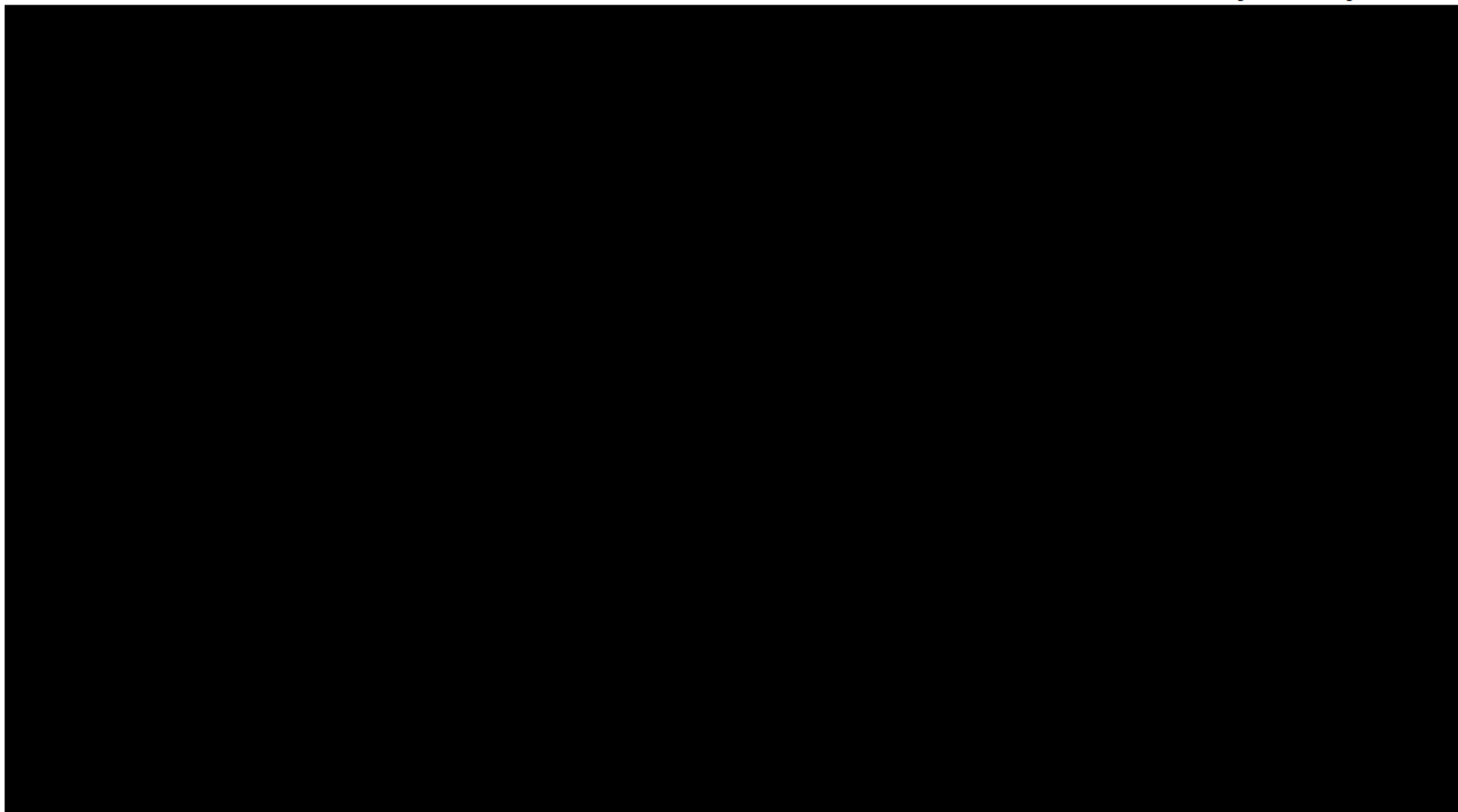


Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children and the number of children in the household. The rows represent different levels of the 'Number of children' variable (1, 2, 3) and the columns represent different levels of the 'Number of children in the household' variable (1, 2, 3). Each plot shows a positive correlation between the two variables.

The plots are arranged as follows:

- Row 1: Number of children = 1
- Row 2: Number of children = 2
- Row 3: Number of children = 3
- Column 1: Number of children in the household = 1
- Column 2: Number of children in the household = 2
- Column 3: Number of children in the household = 3

Each plot shows a positive correlation between the number of children and the number of children in the household. The plots are arranged in a 3x3 grid, with the number of children on the x-axis and the number of children in the household on the y-axis.

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

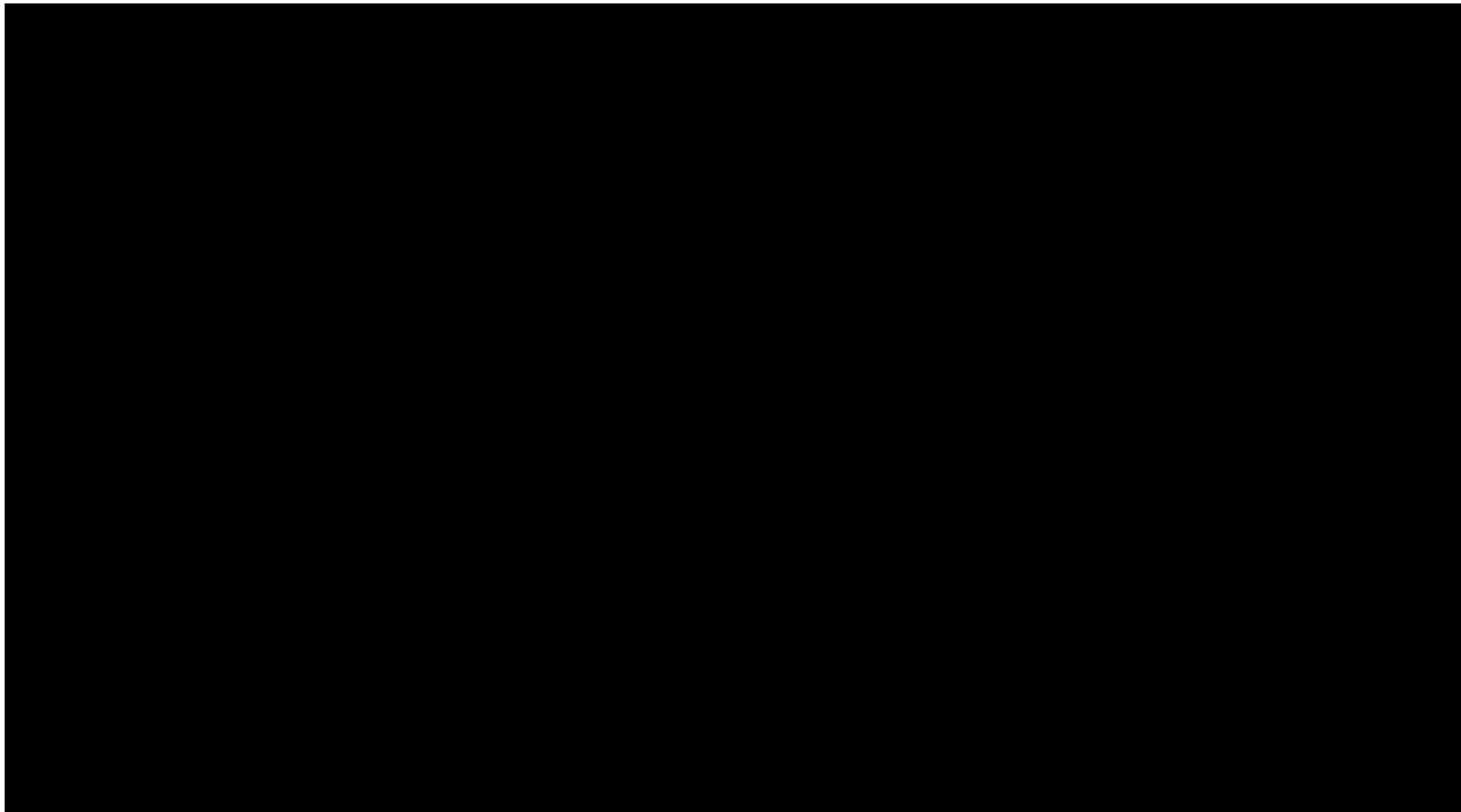
Status:
Page:

Final
781 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

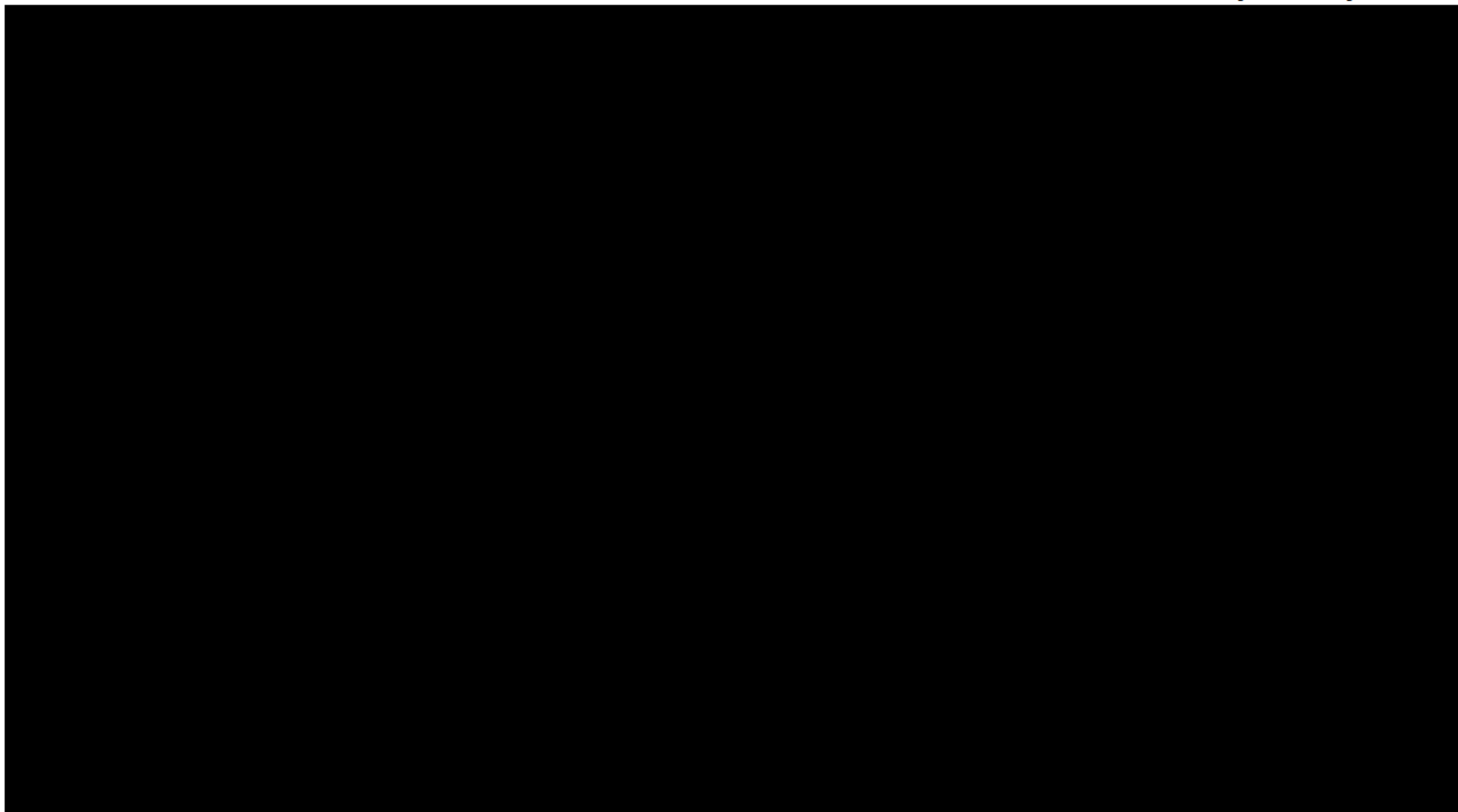
Status:
Page:

Final
782 of 1733

Novo Nordisk

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

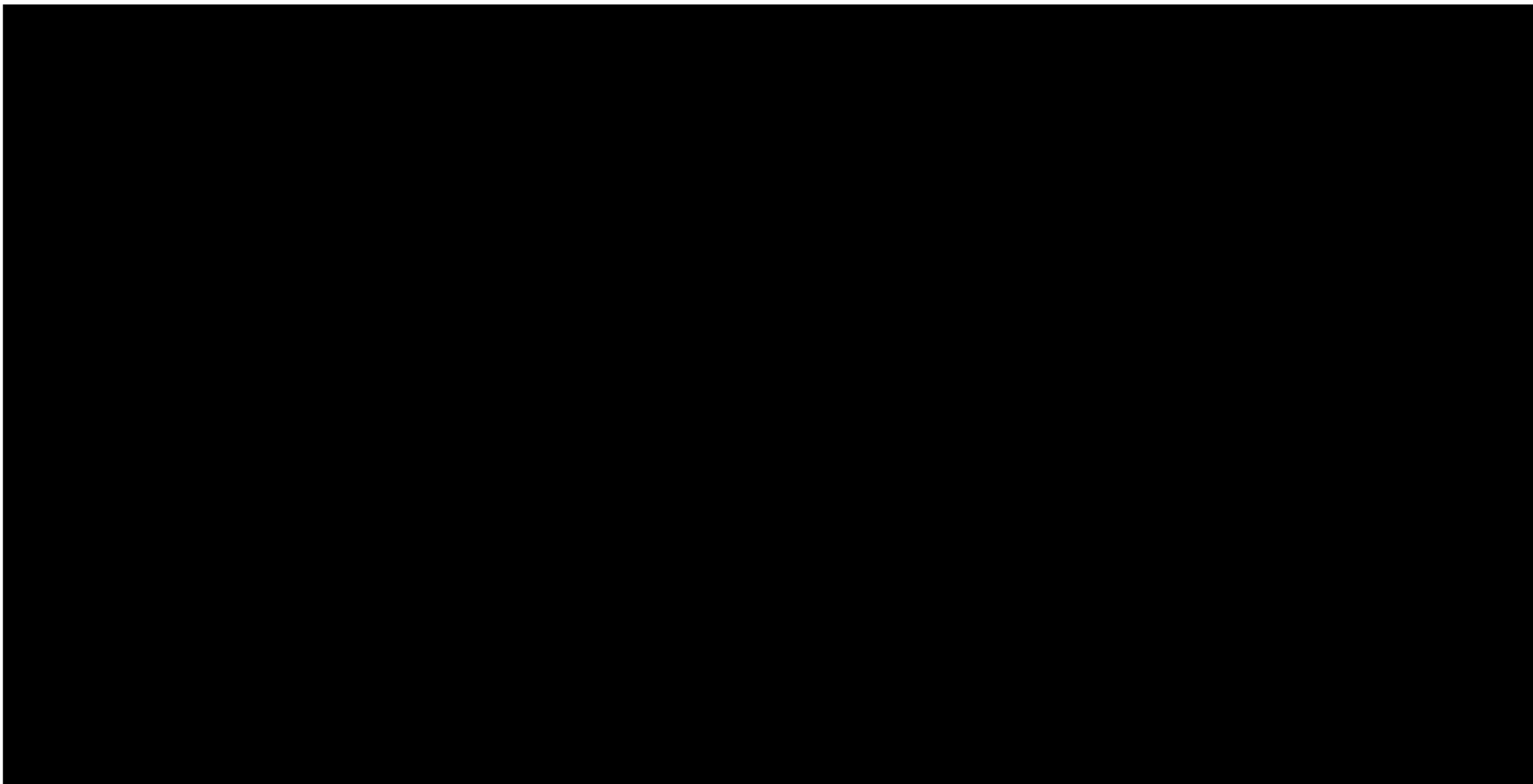
Status:
Page:

Final
783 of 1733

Novo Nordisk

14.3.4.2: Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

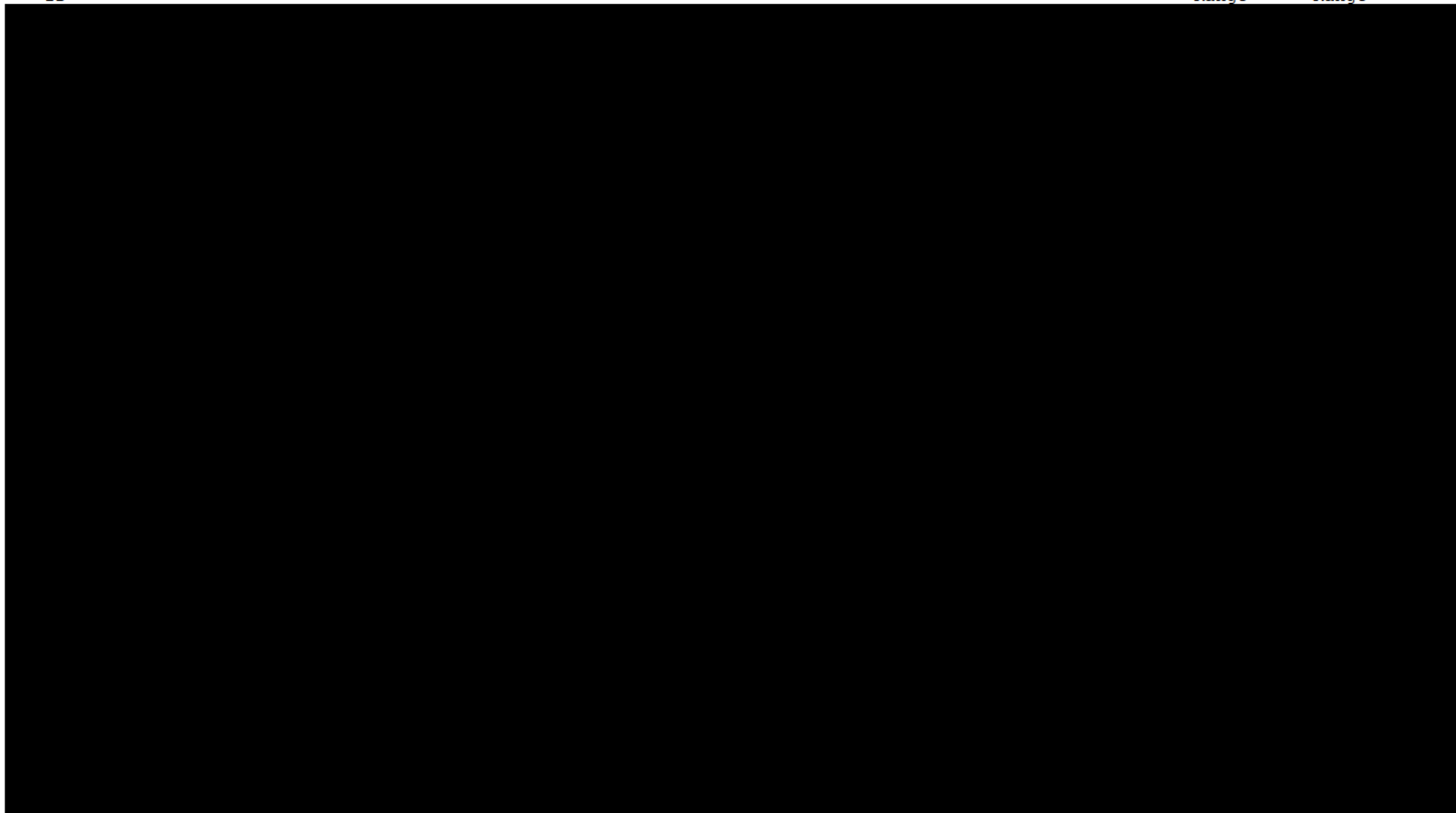
Status:
Page:

Final
784 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

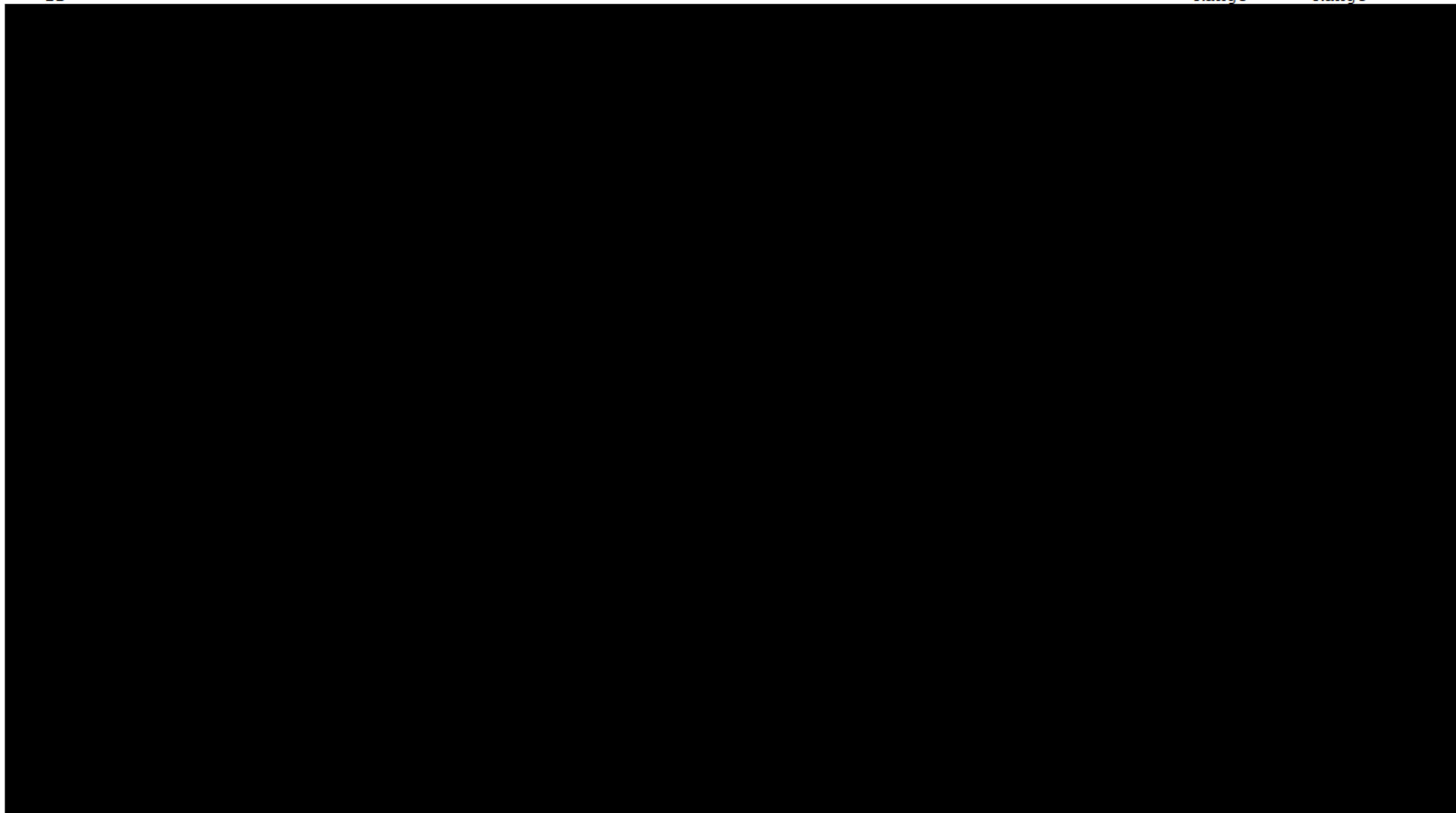
Status:
Page:

Final
785 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

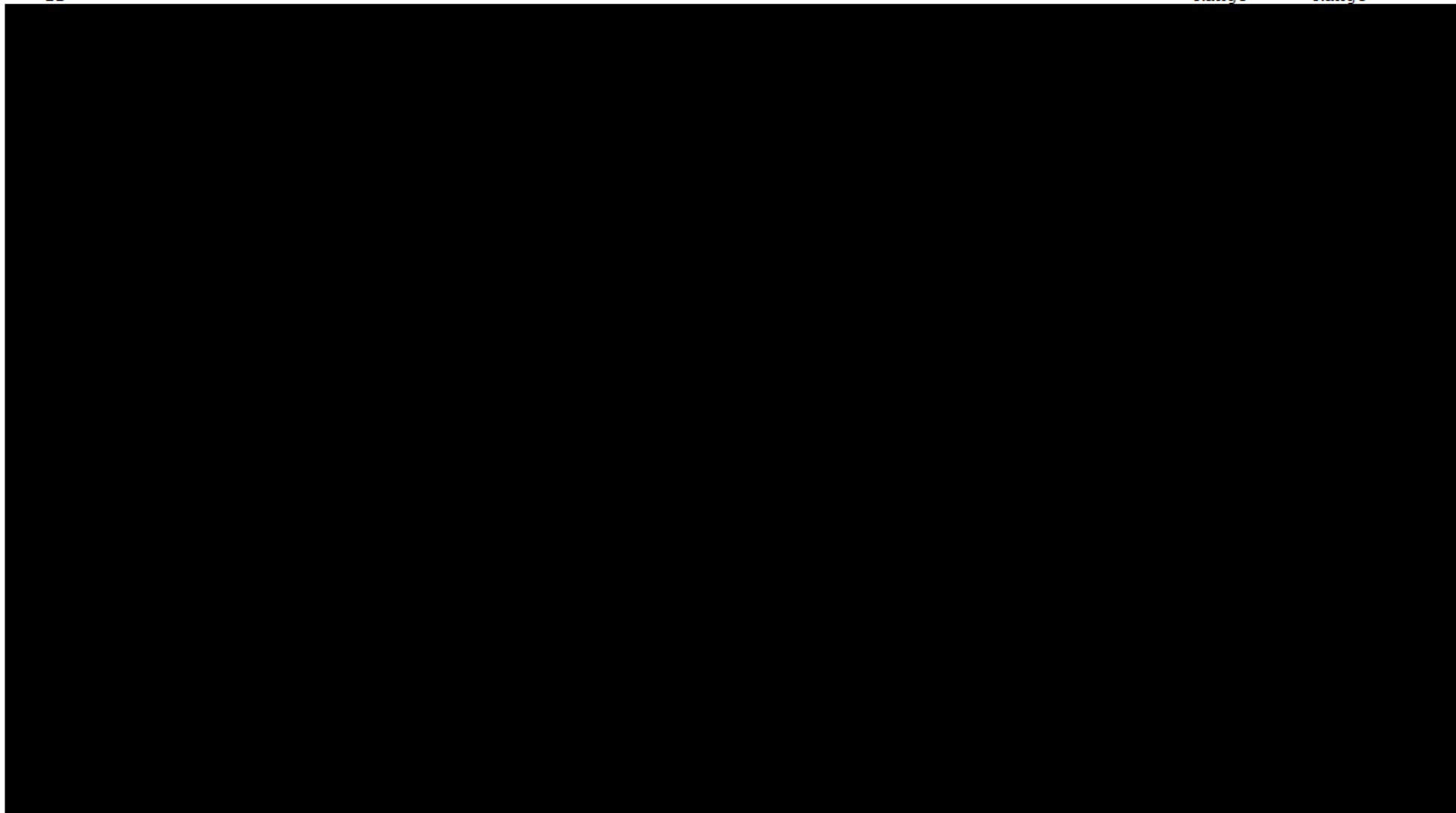
Status:
Page:

Final
786 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

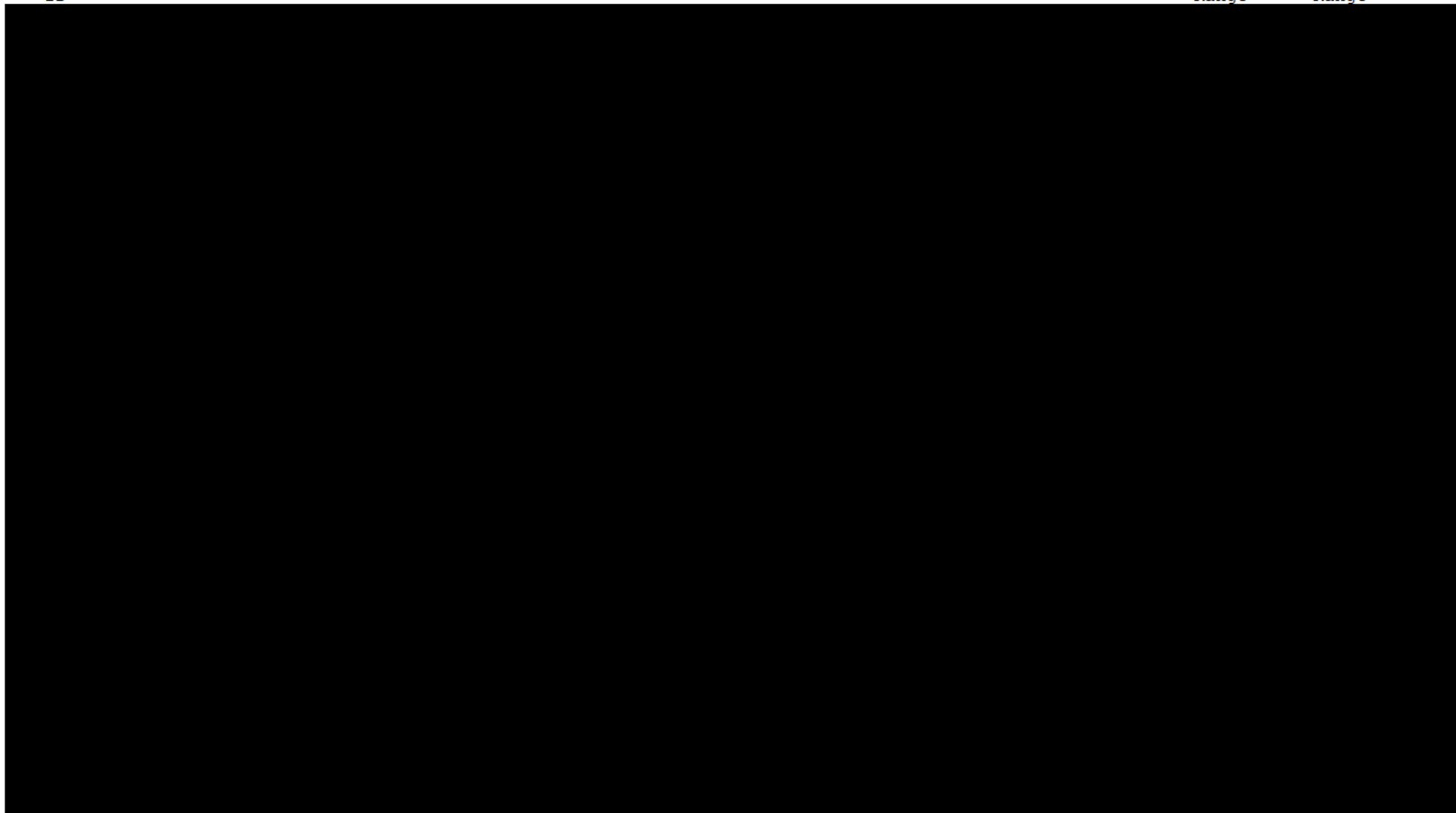
Status:
Page:

Final
787 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

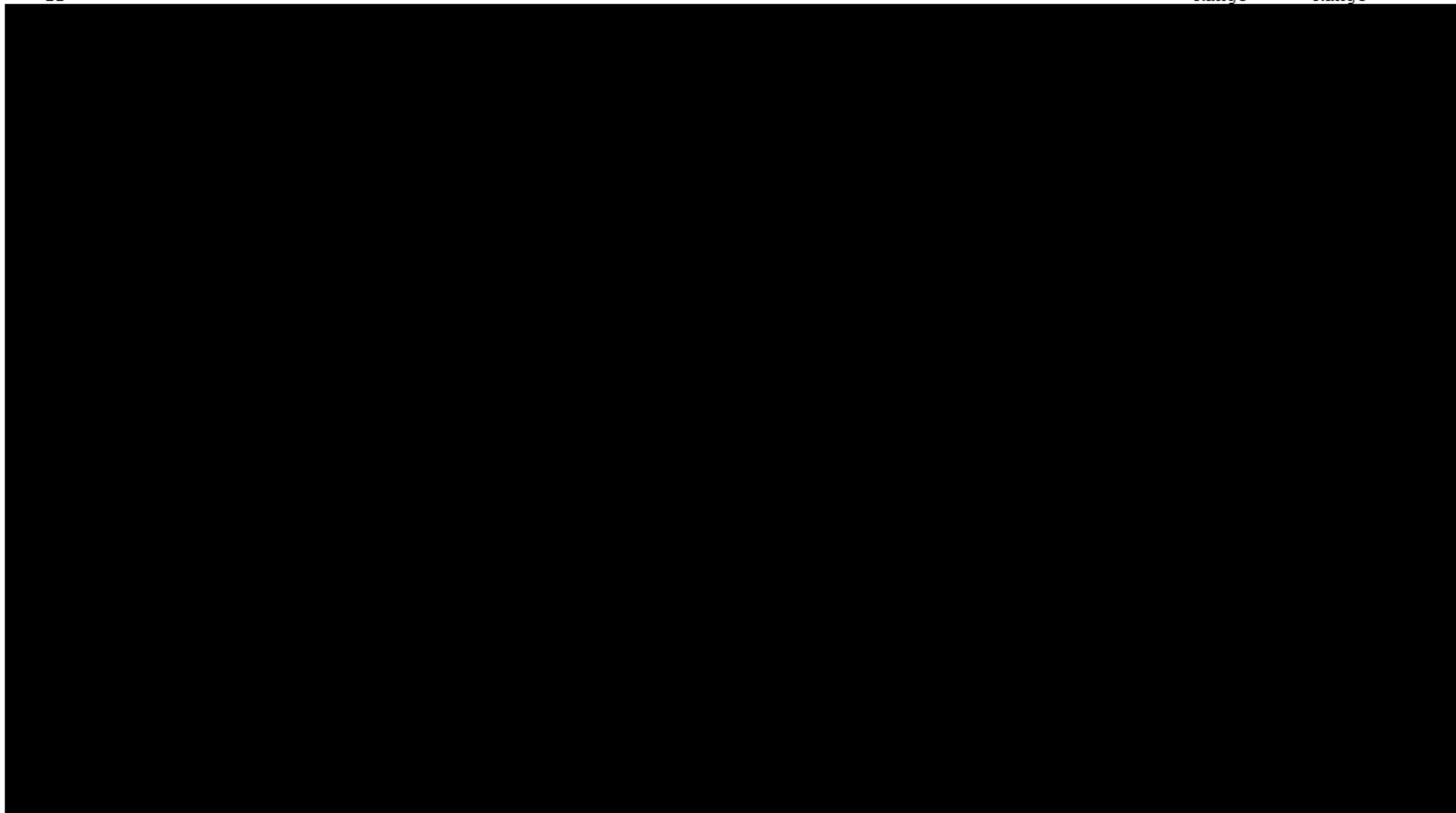
Status:
Page:

Final
788 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

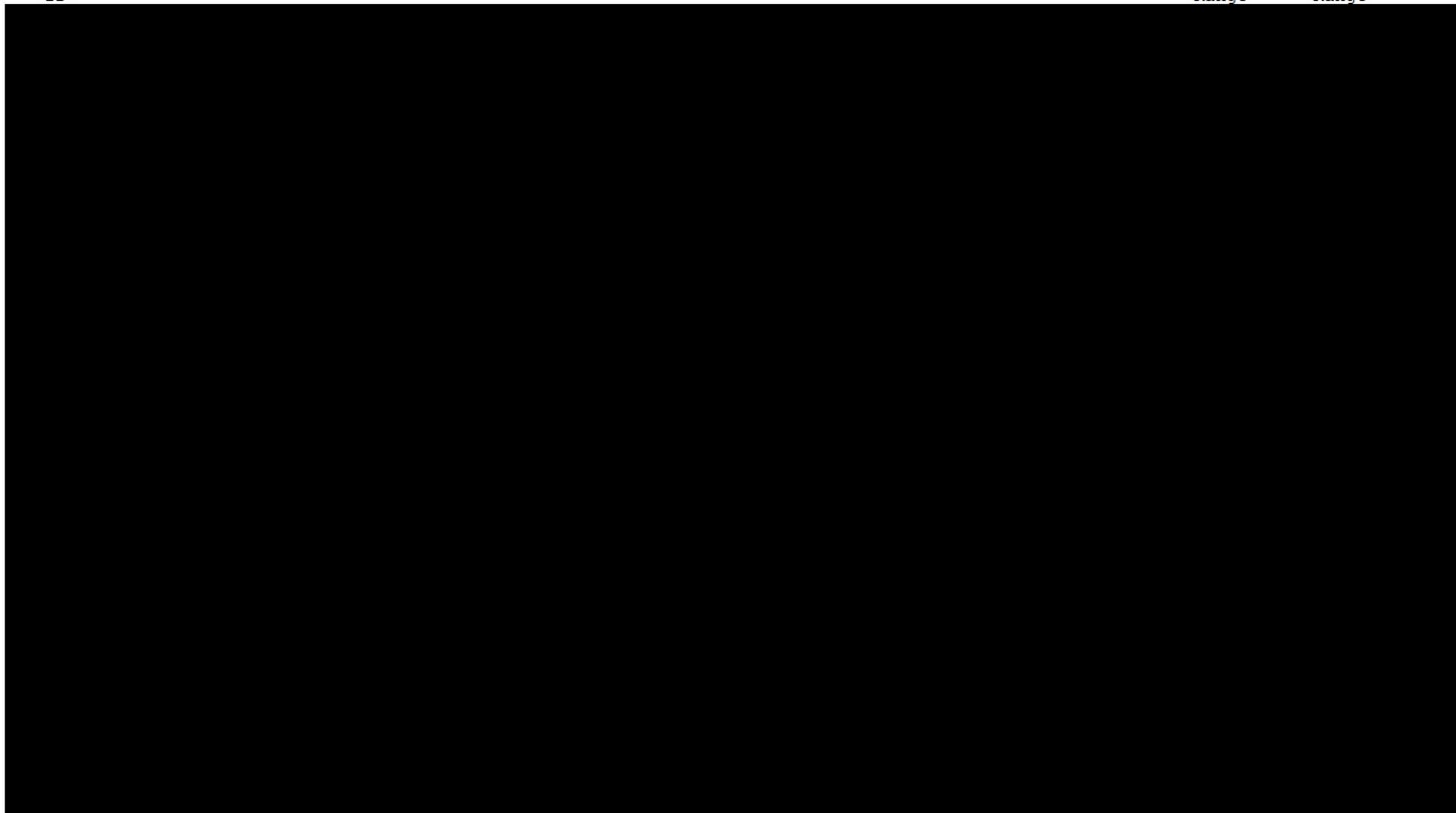
Status:
Page:

Final
789 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

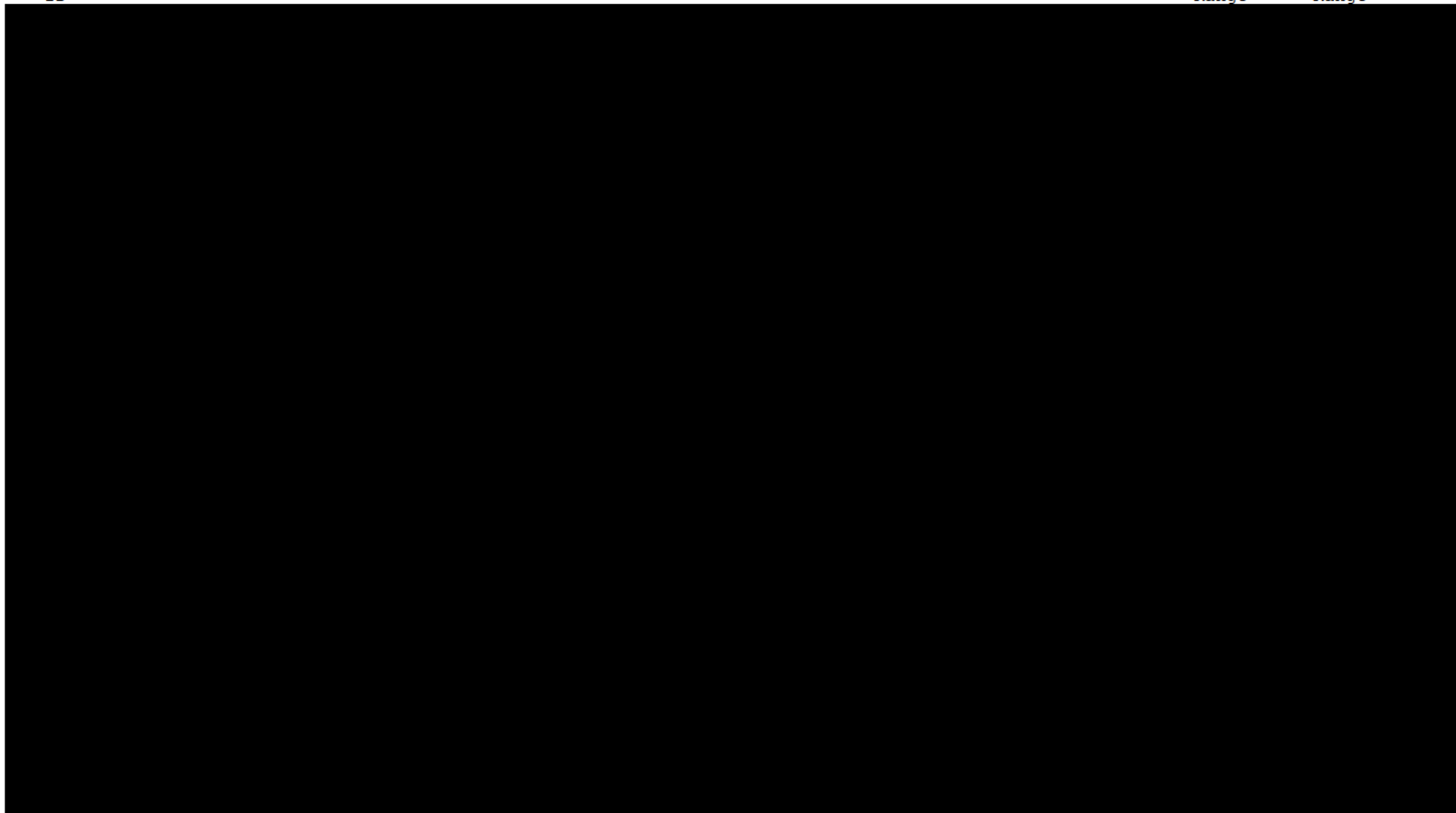
Status:
Page:

Final
790 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

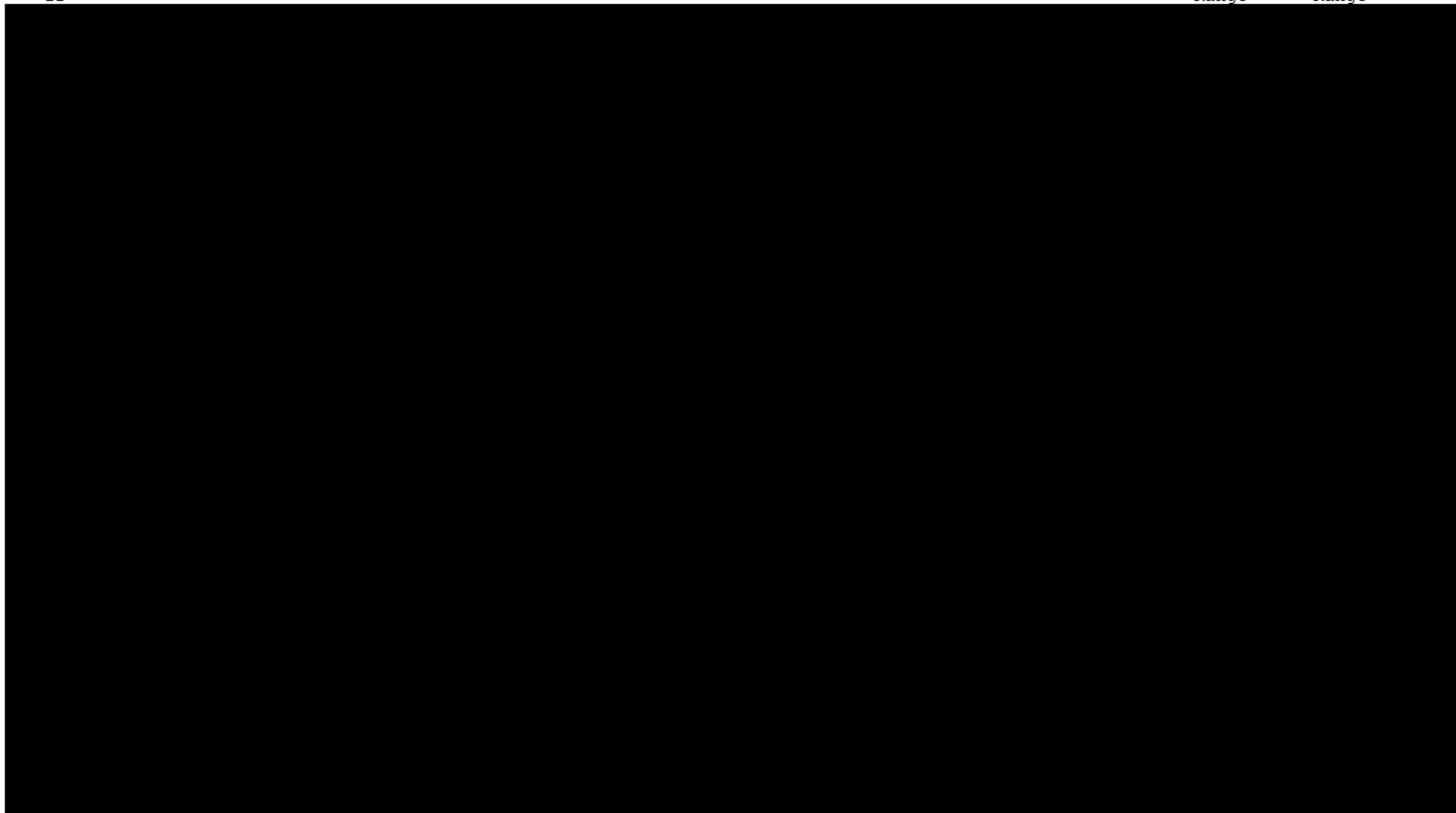
Status:
Page:

Final
791 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

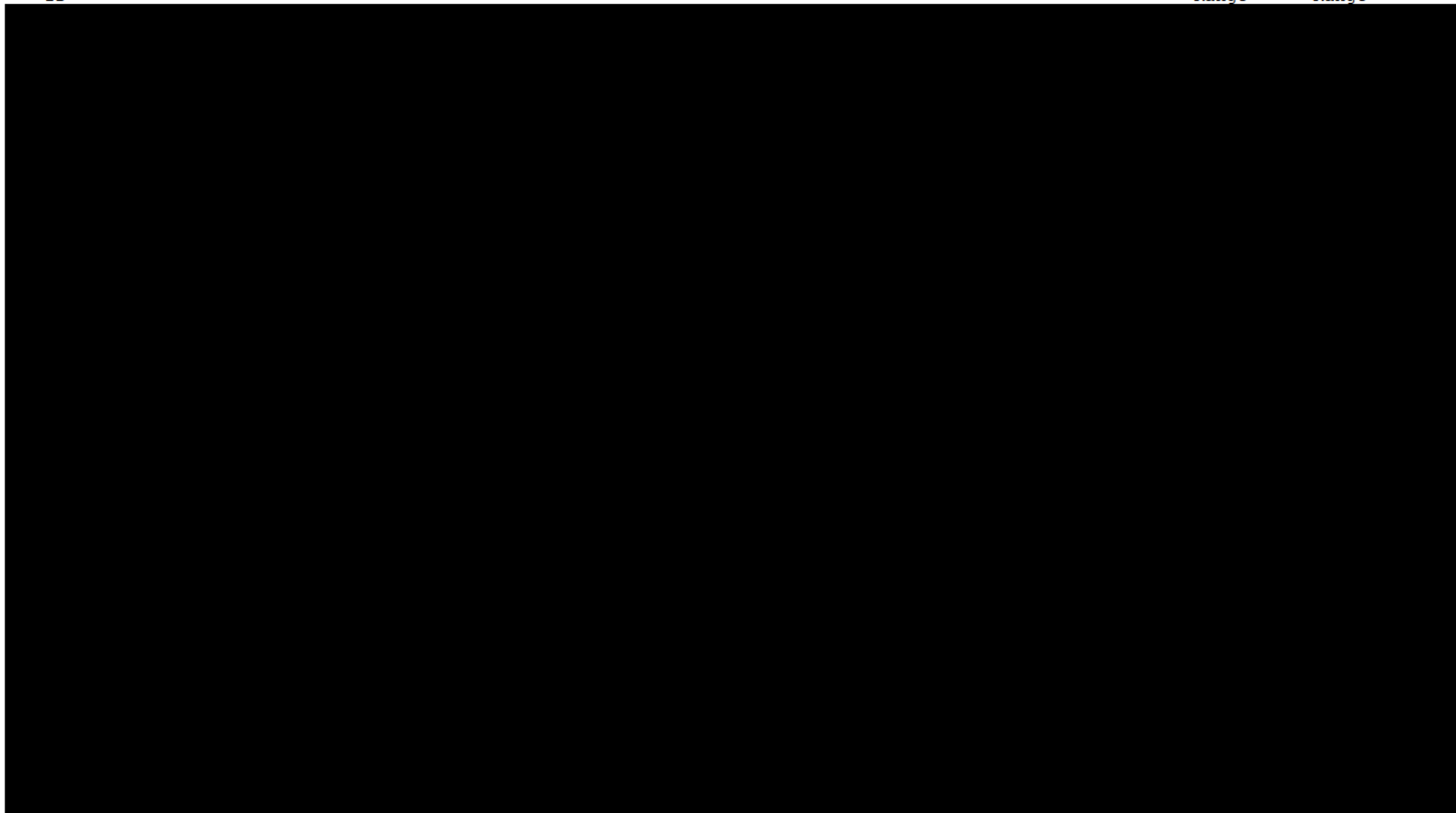
Status:
Page:

Final
792 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

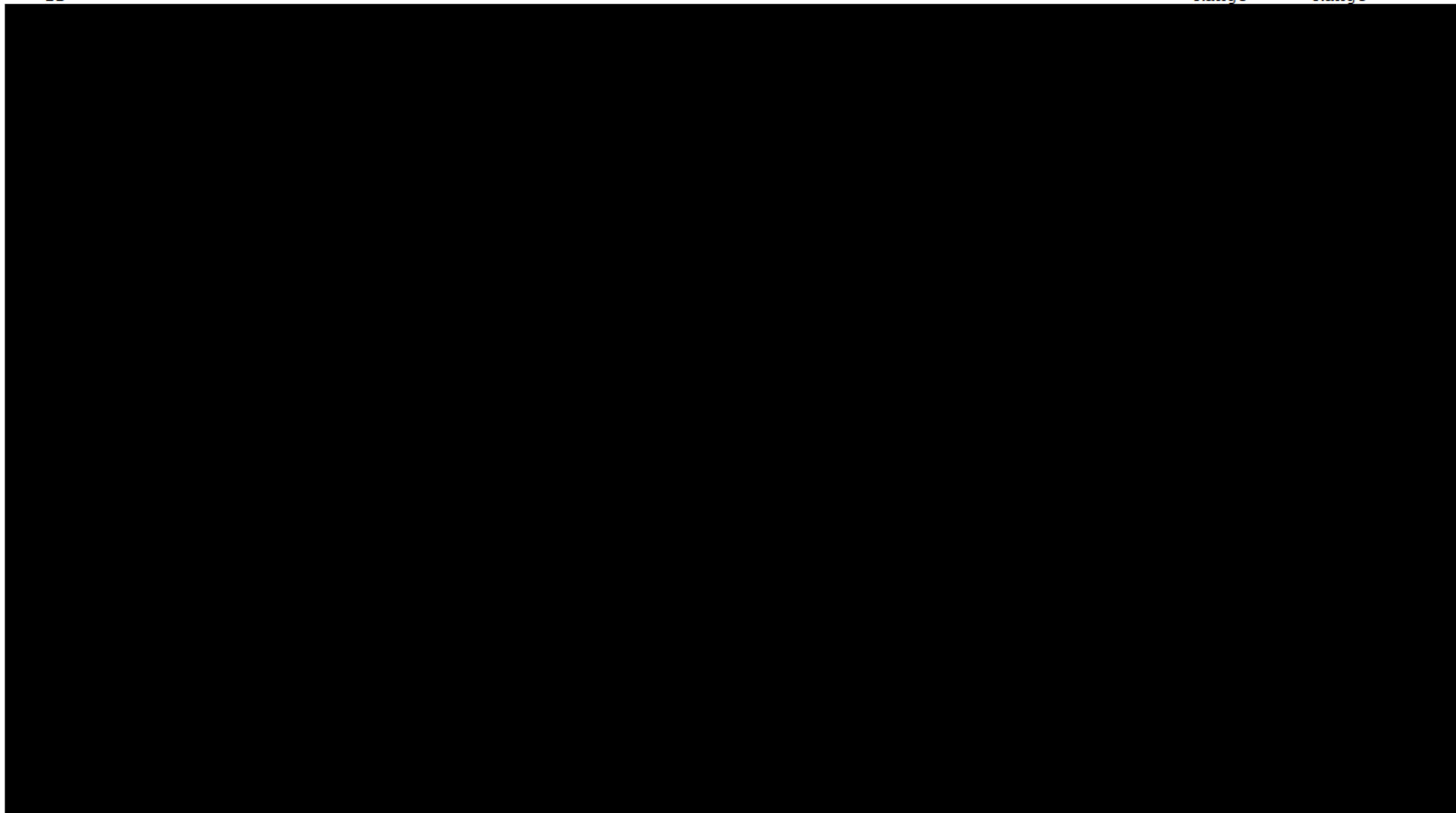
Status:
Page:

Final
793 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

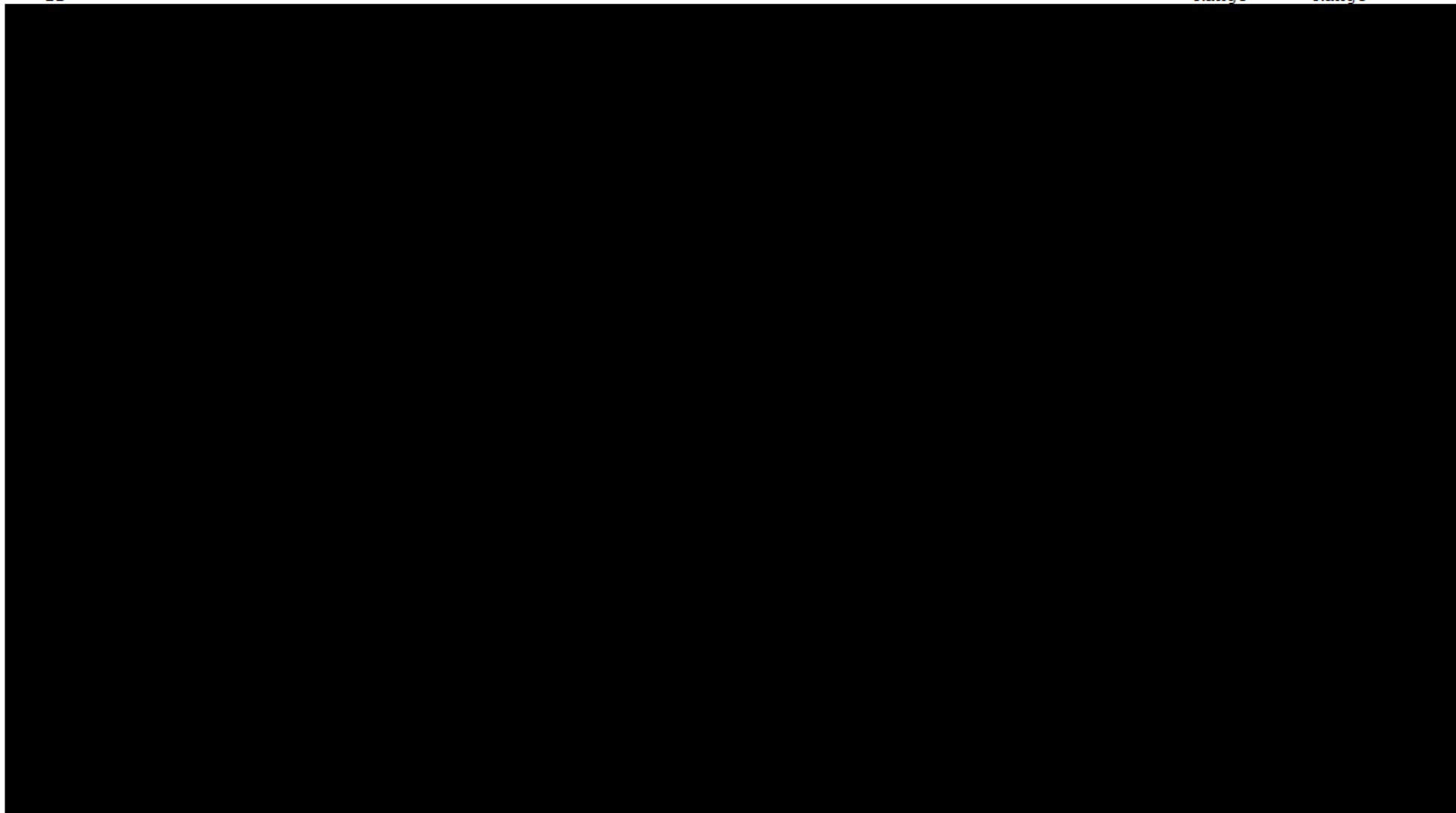
Status:
Page:

Final
794 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

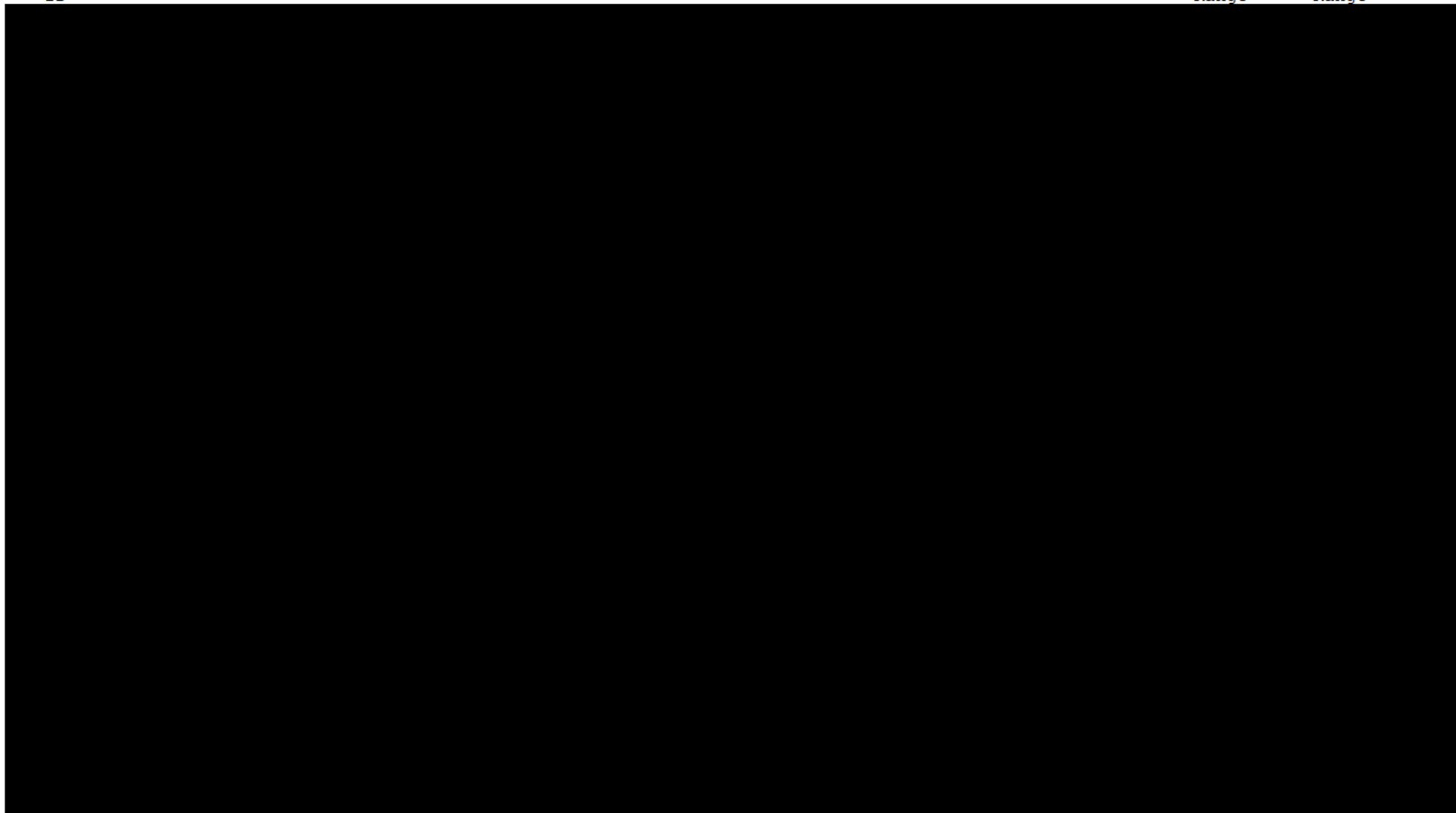
Status:
Page:

Final
795 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

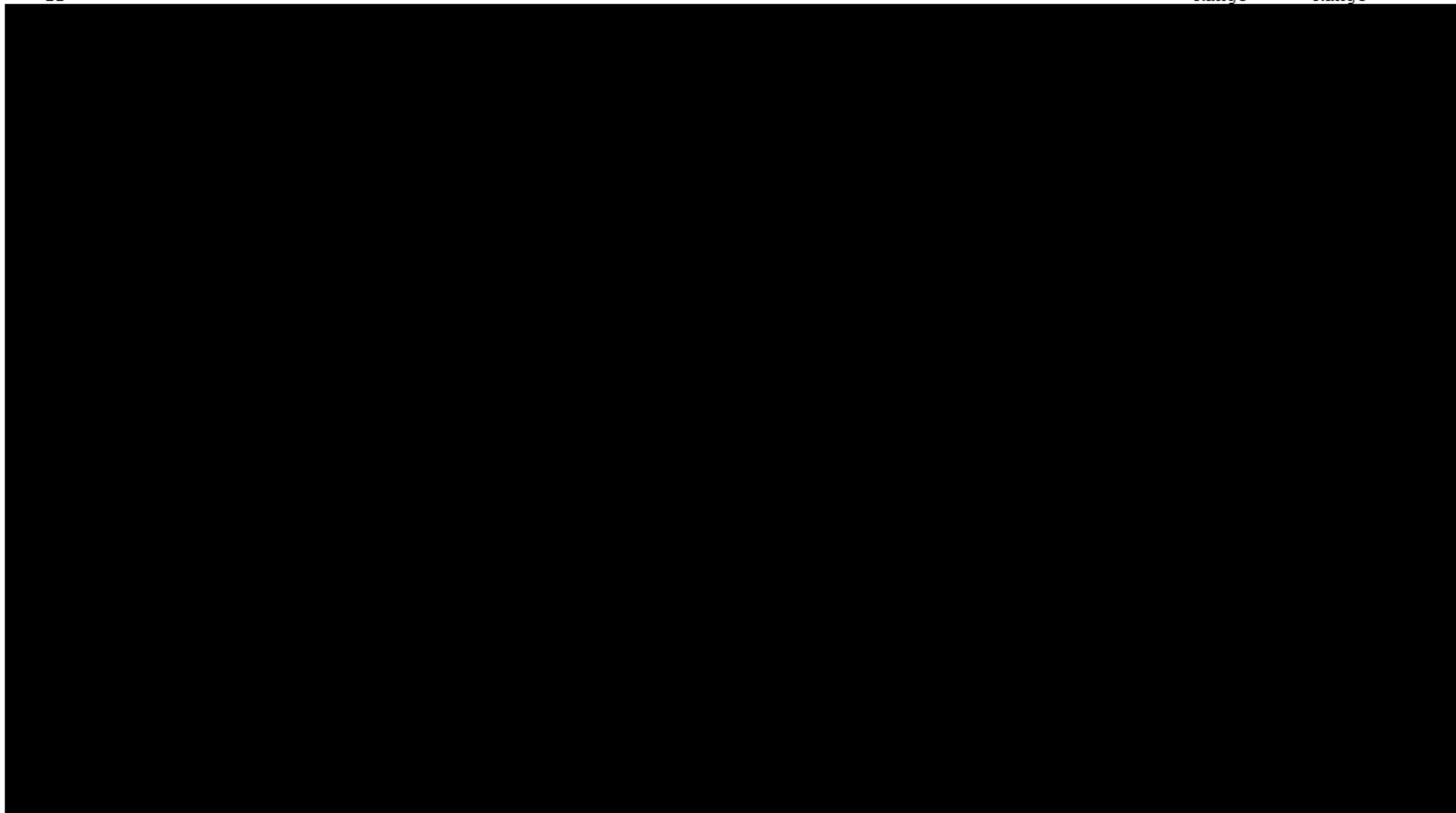
Status:
Page:

Final
796 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

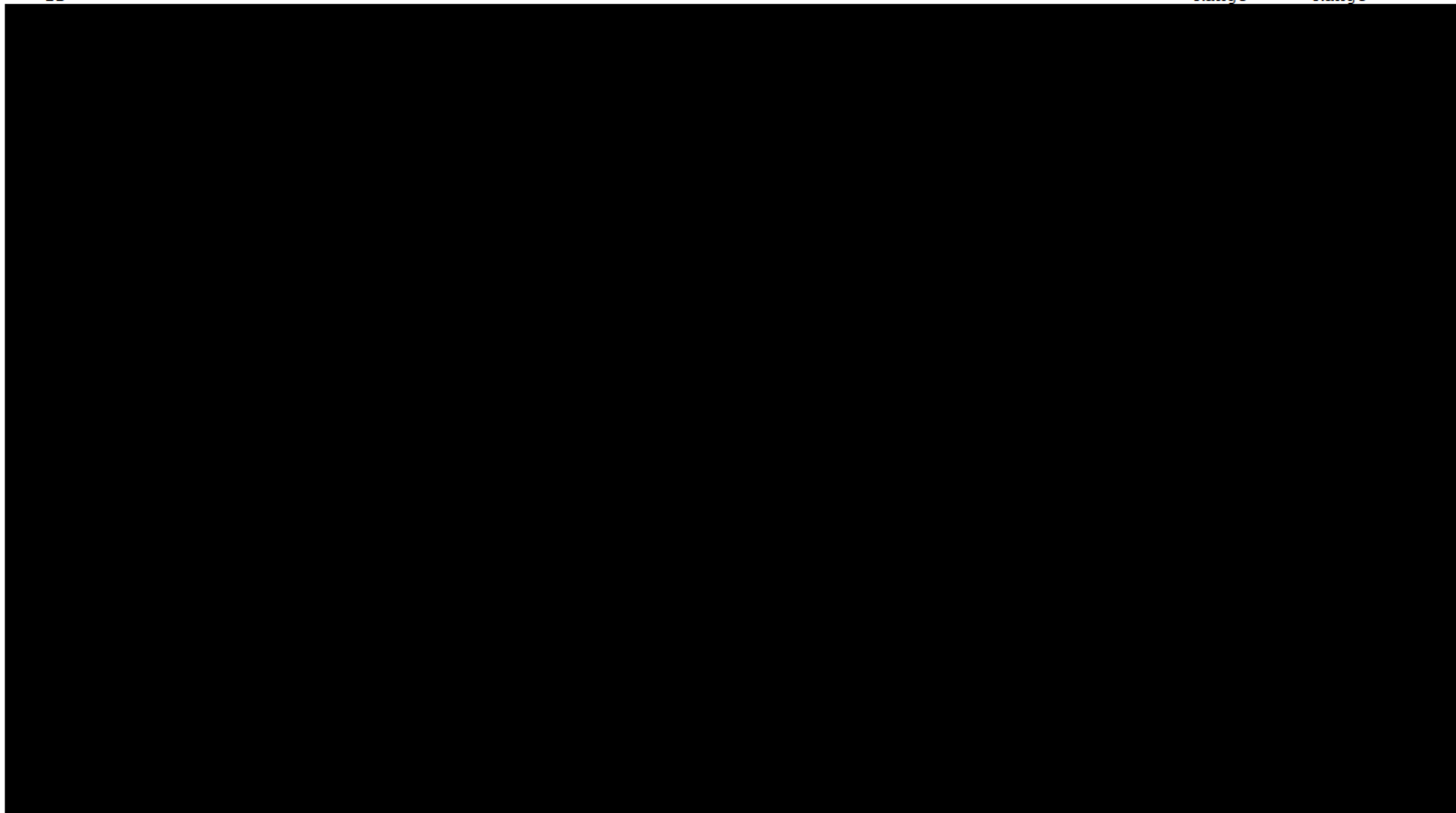
Date: 14 June 2011
Version: 3.0

Status: Final
Page: 797 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

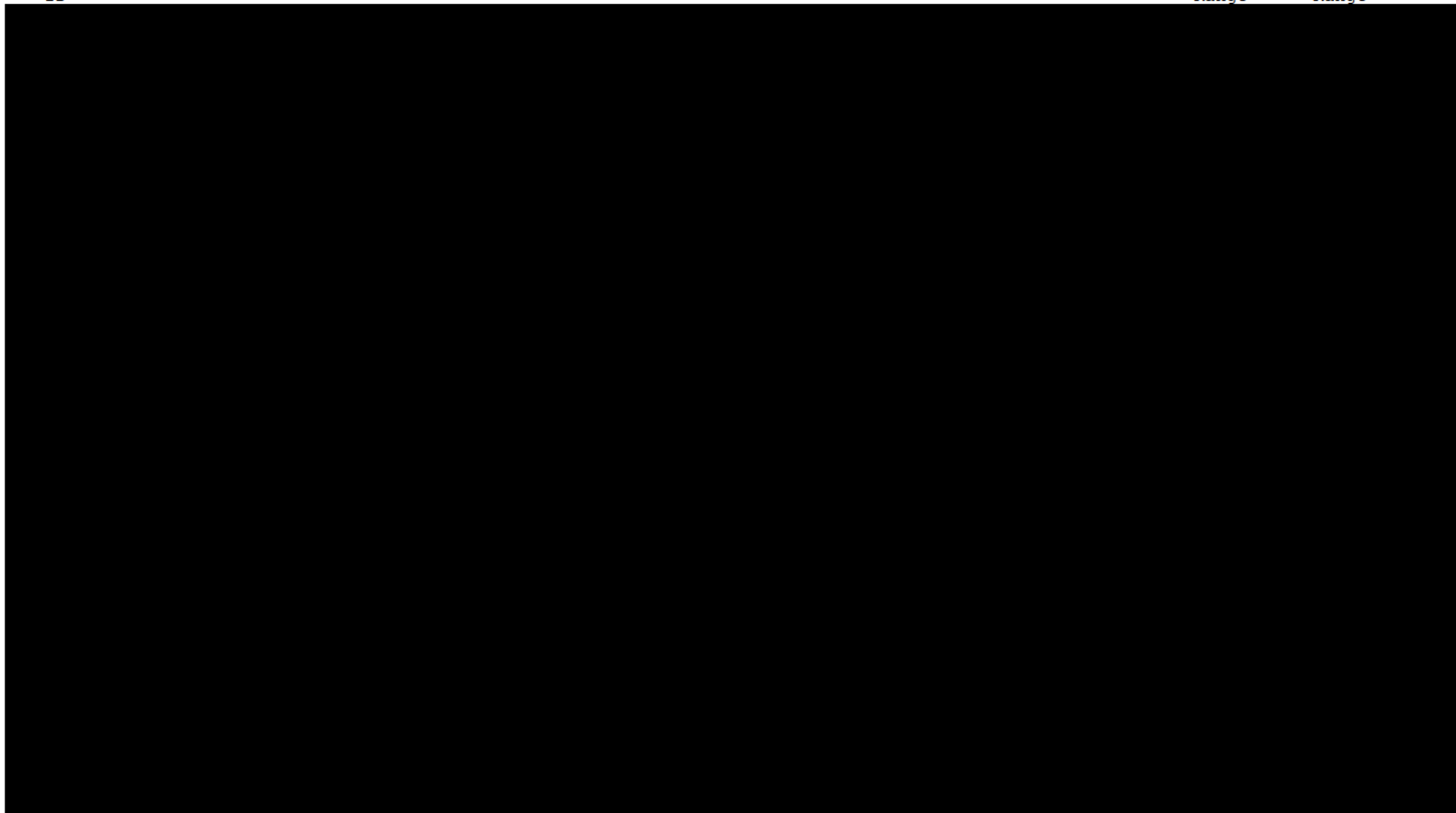
Status:
Page:

Final
798 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

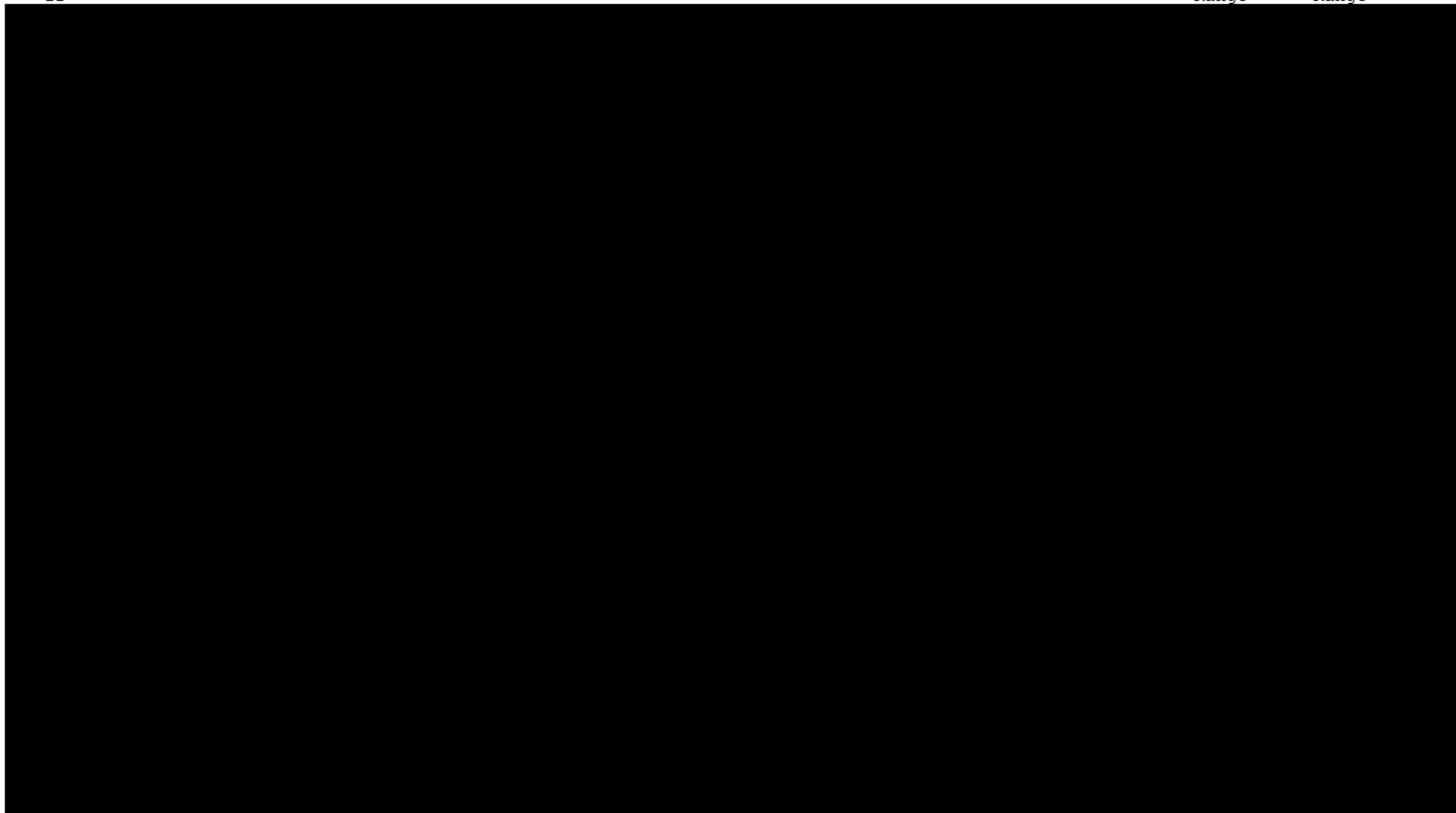
Status:
Page:

Final
799 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

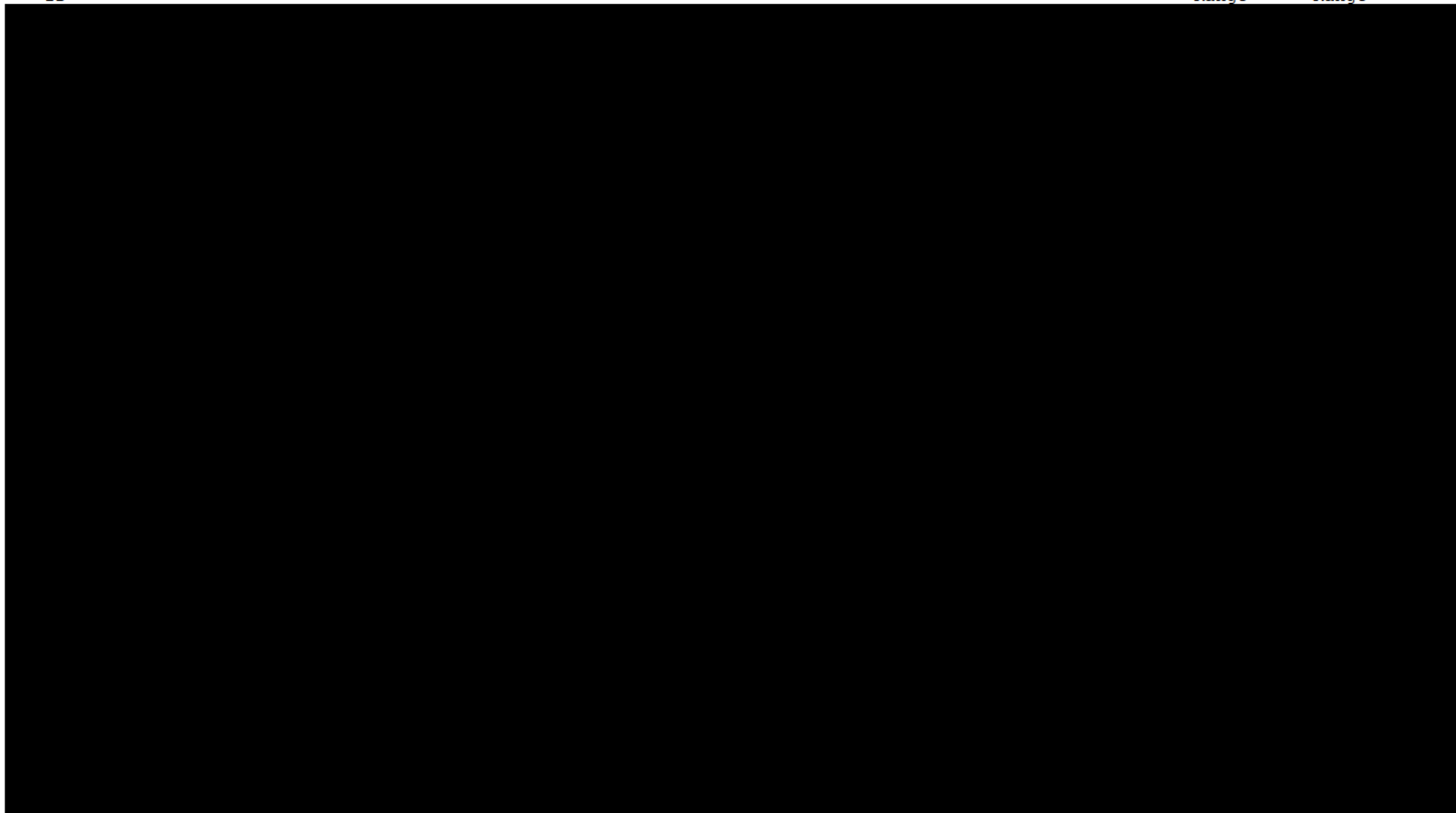
Status:
Page:

Final
800 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

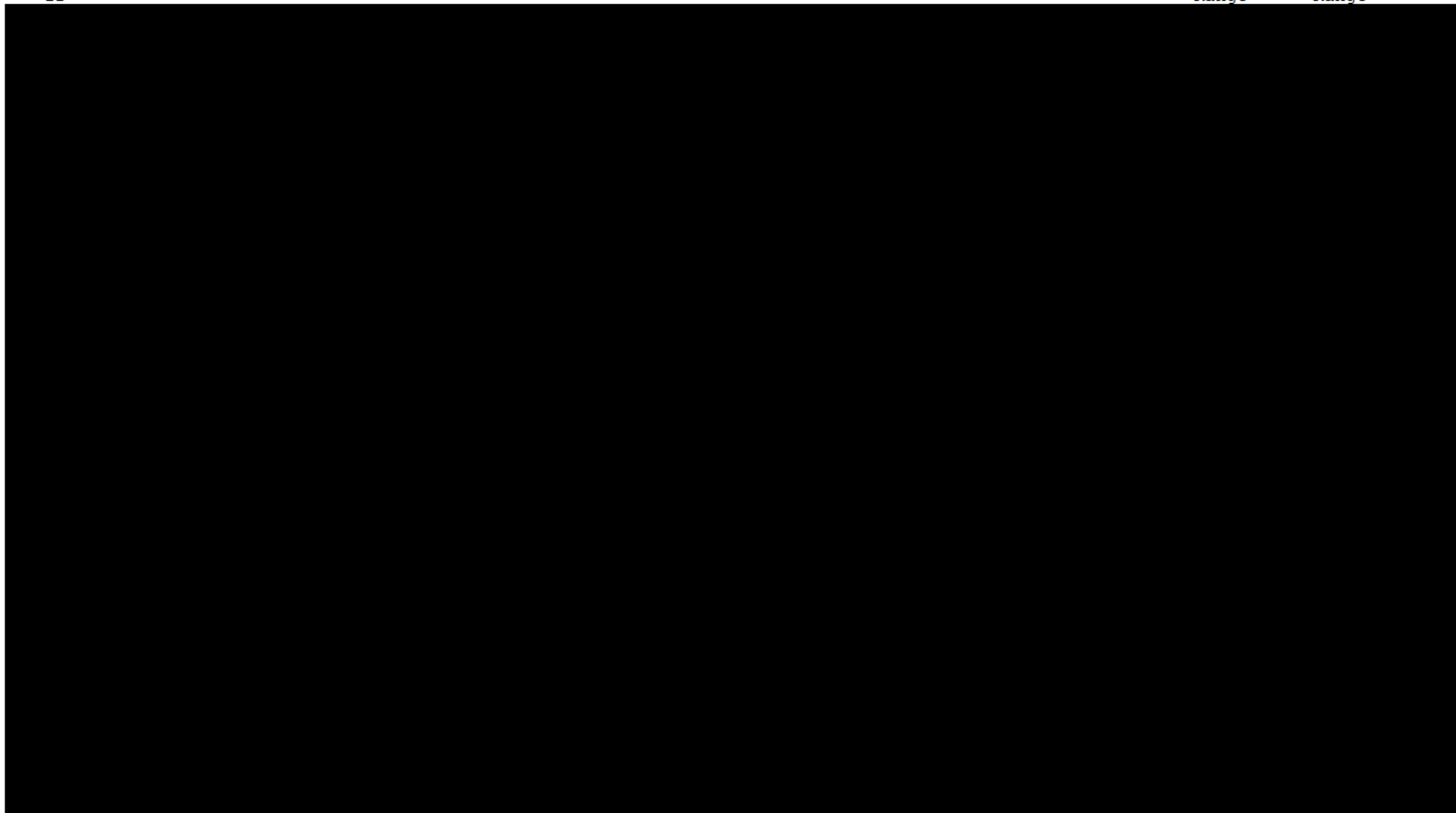
Date: 14 June 2011
Version: 3.0

Status: Final
Page: 801 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

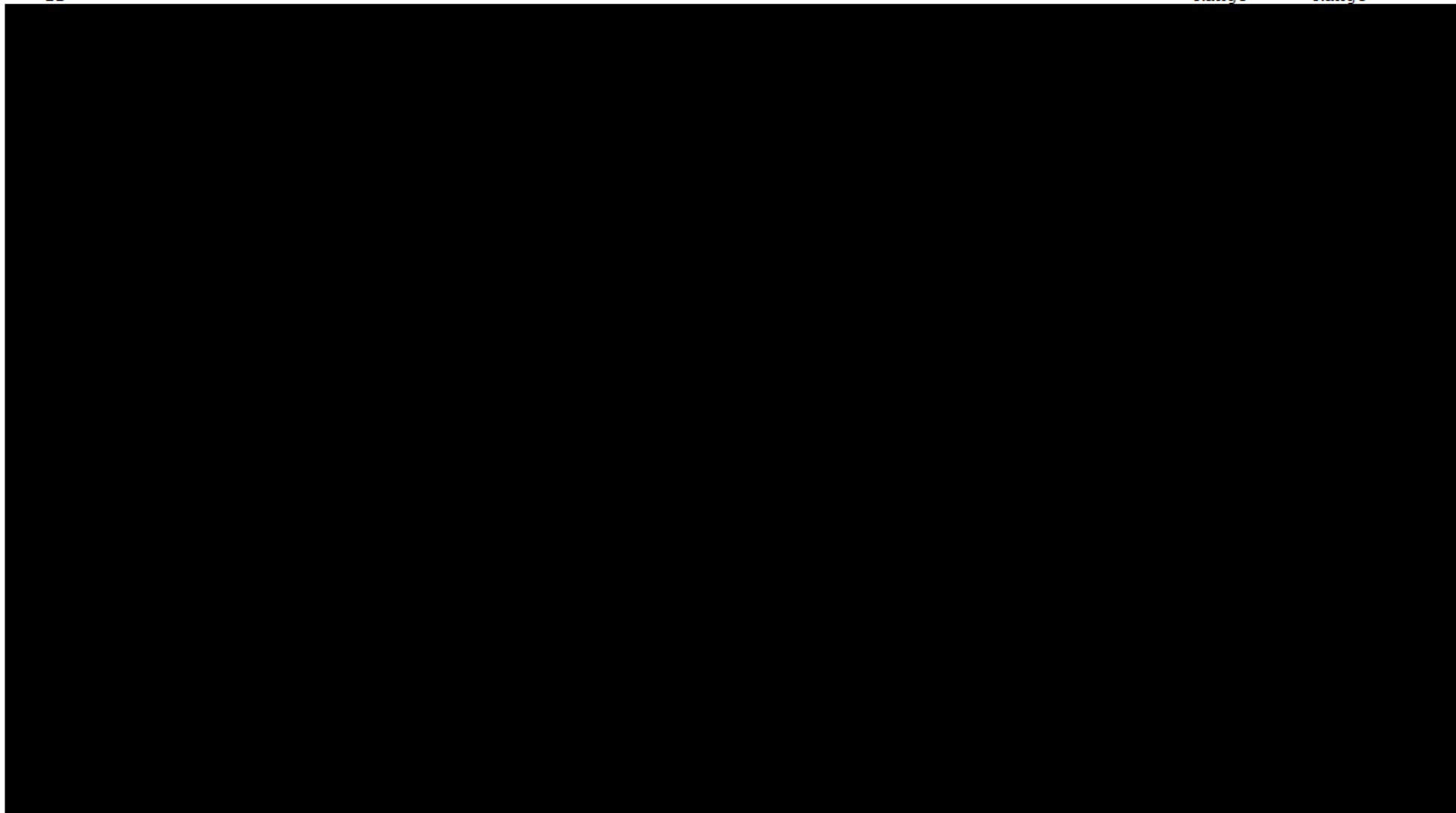
Status:
Page:

Final
802 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

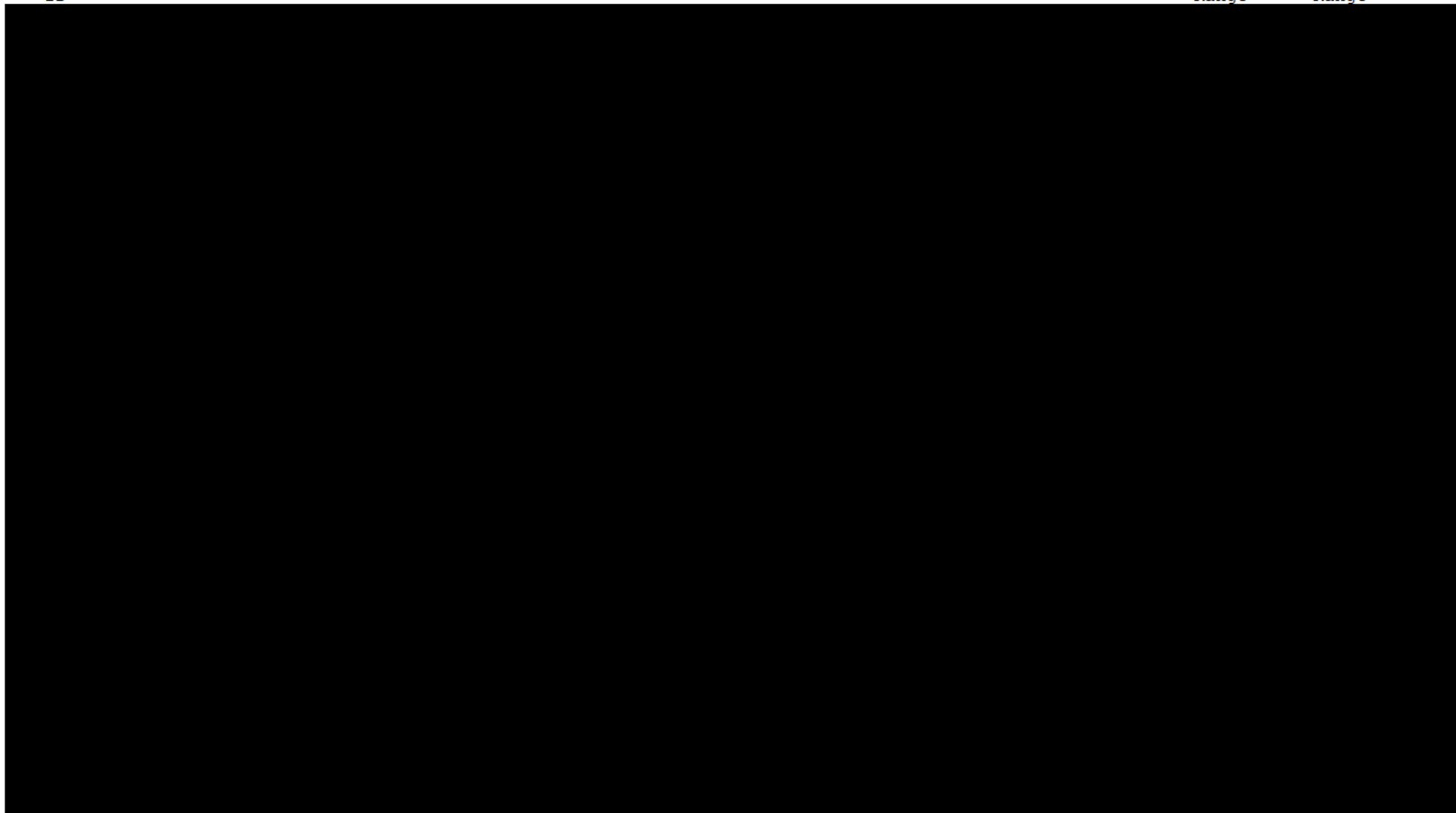
Status:
Page:

Final
803 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

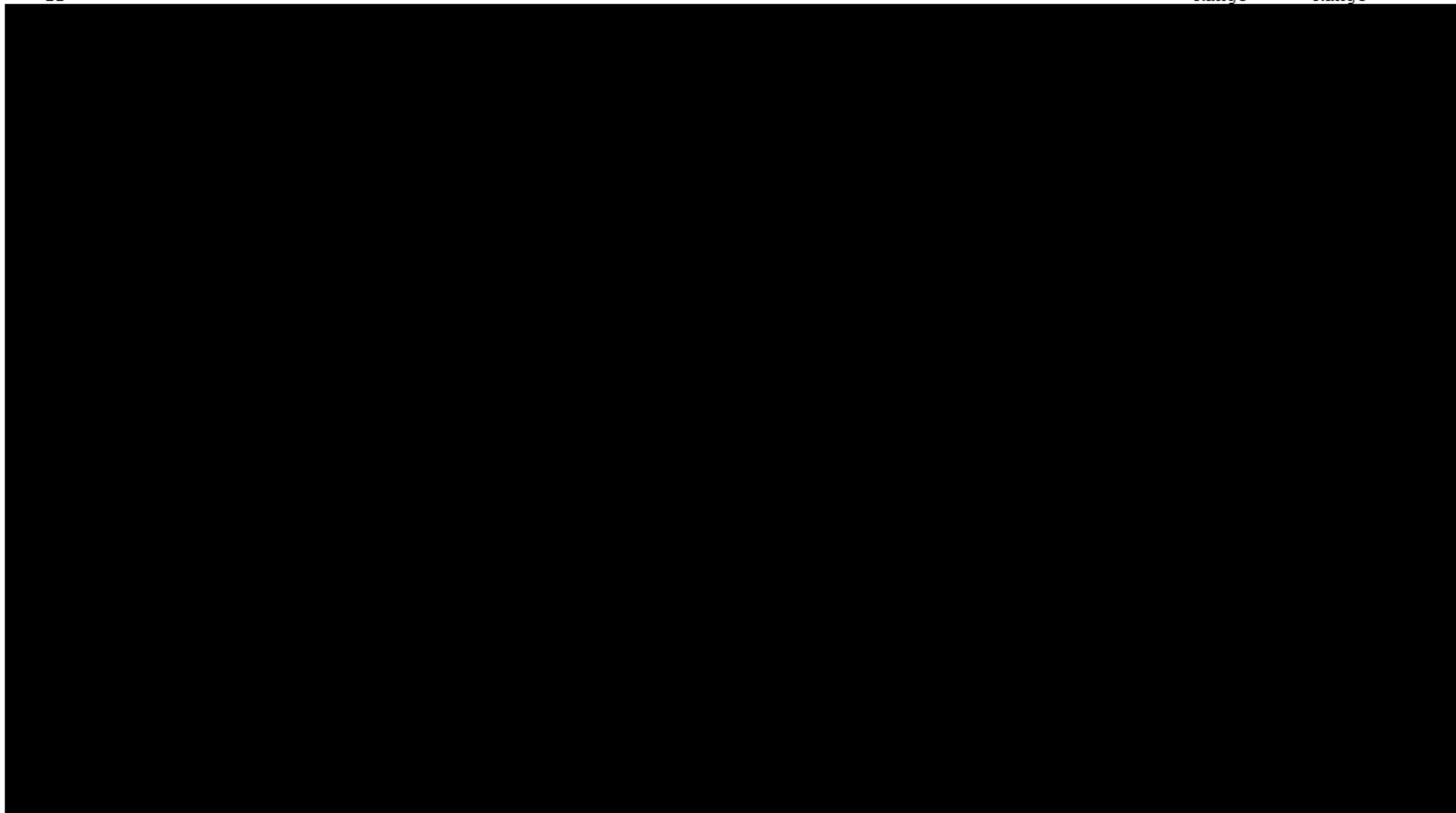
Status:
Page:

Final
804 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date: 14 June 2011
Version: 3.0

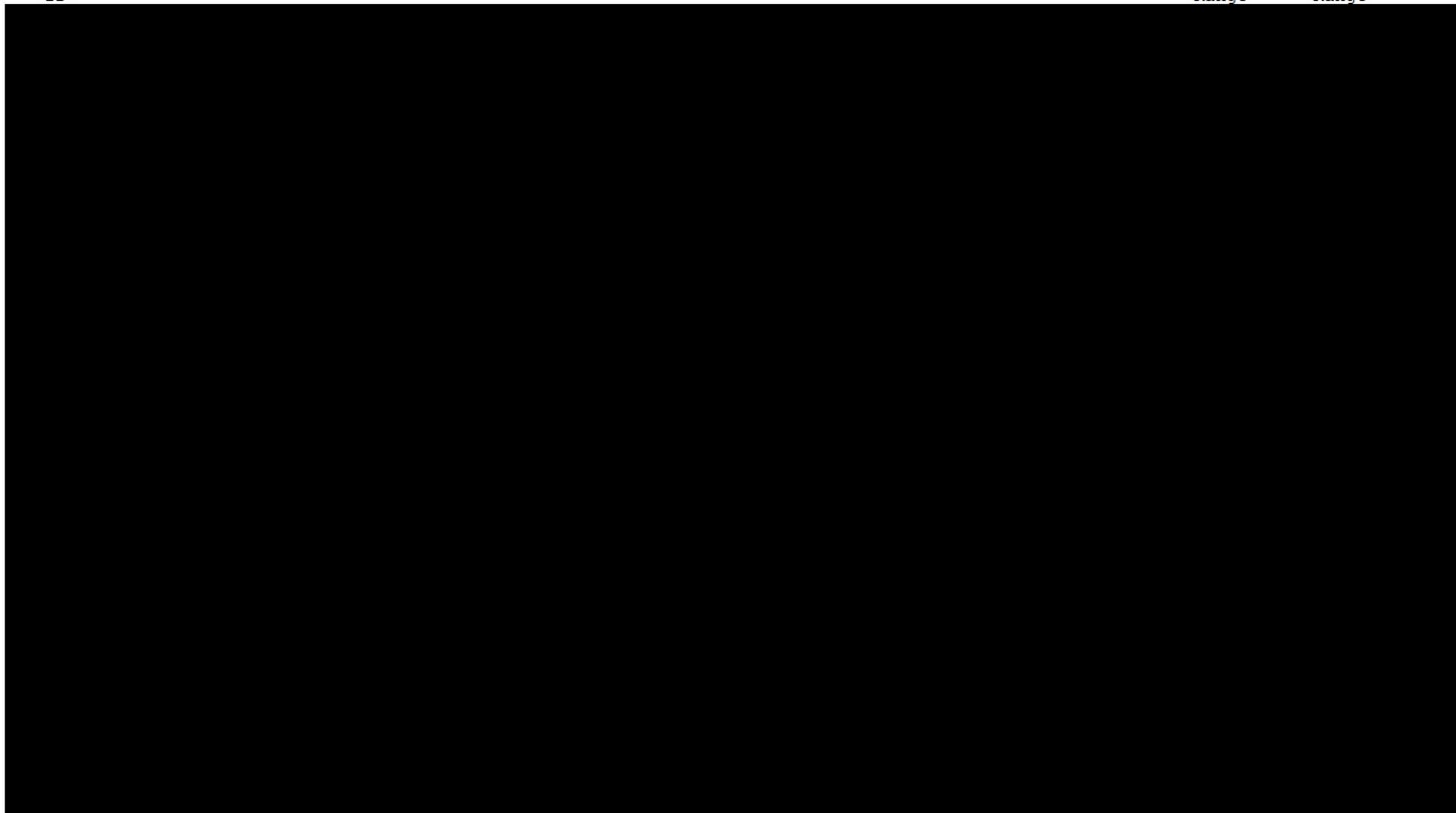
Status:
Page:

Final
805 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

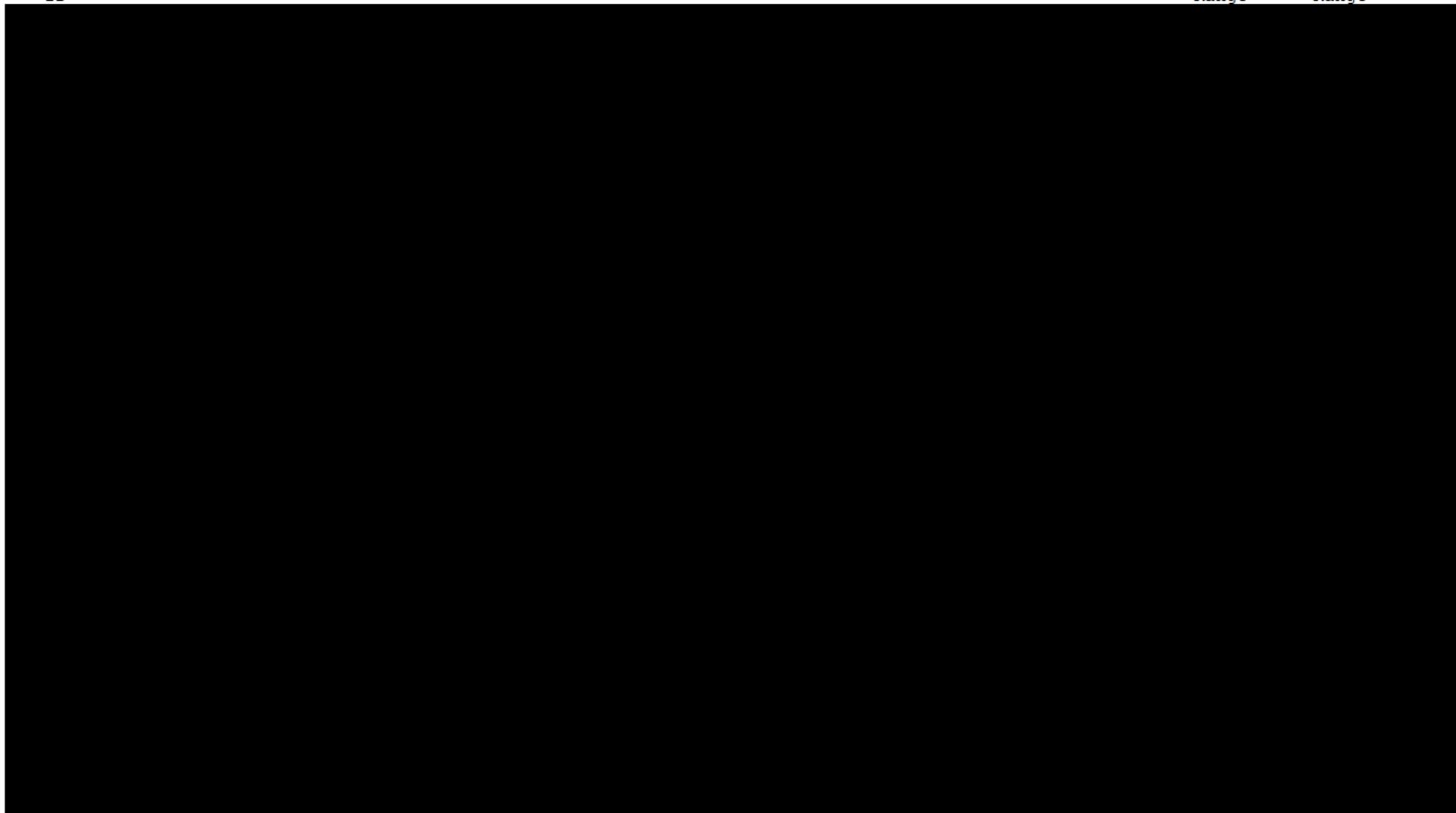
Date: 14 June 2011
Version: 3.0

Status: Final
Page: 806 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

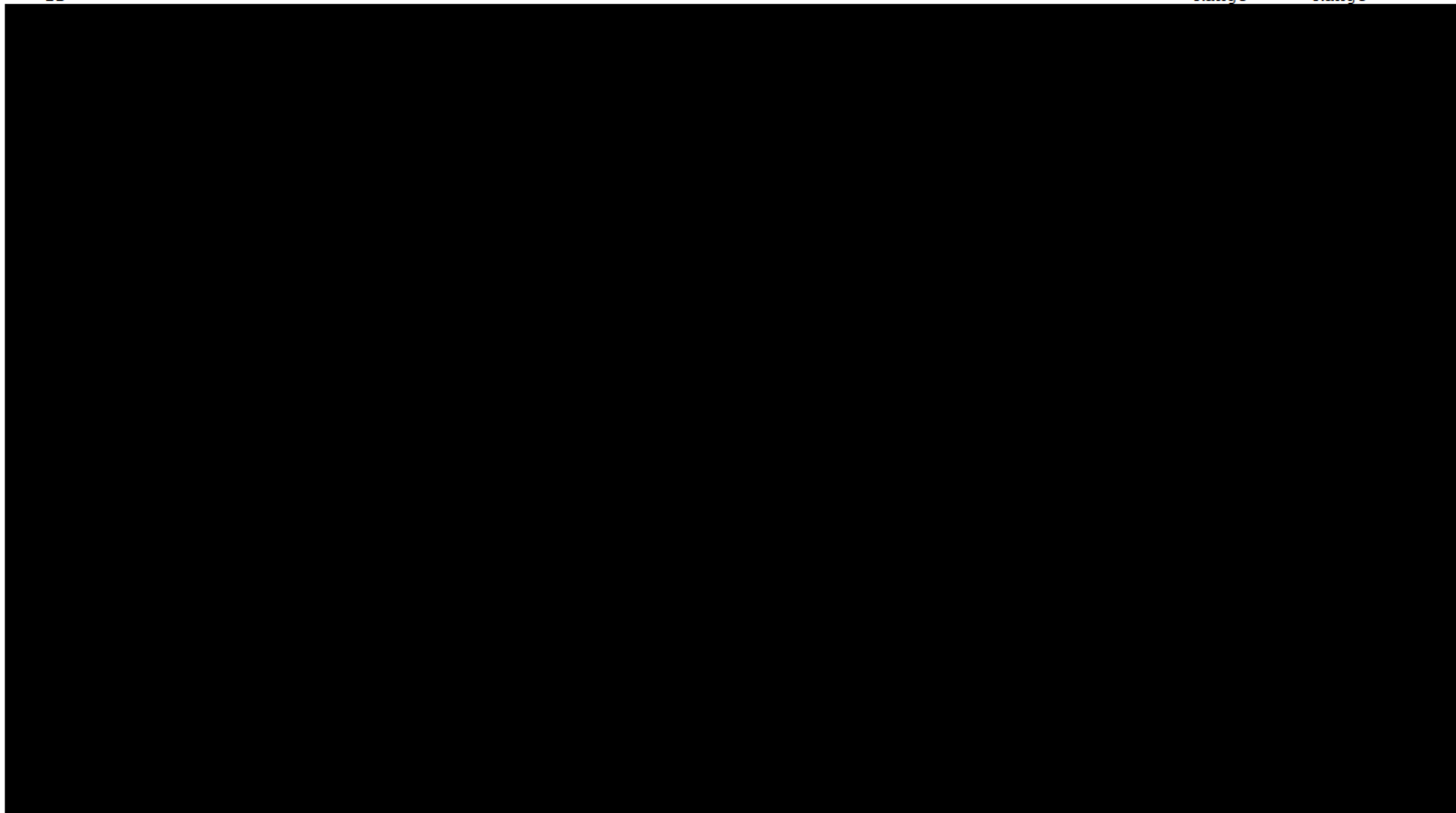
Date: 14 June 2011
Version: 3.0

Status: Final
Page: 807 of 1733

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



14.3.4.3: Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color.

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

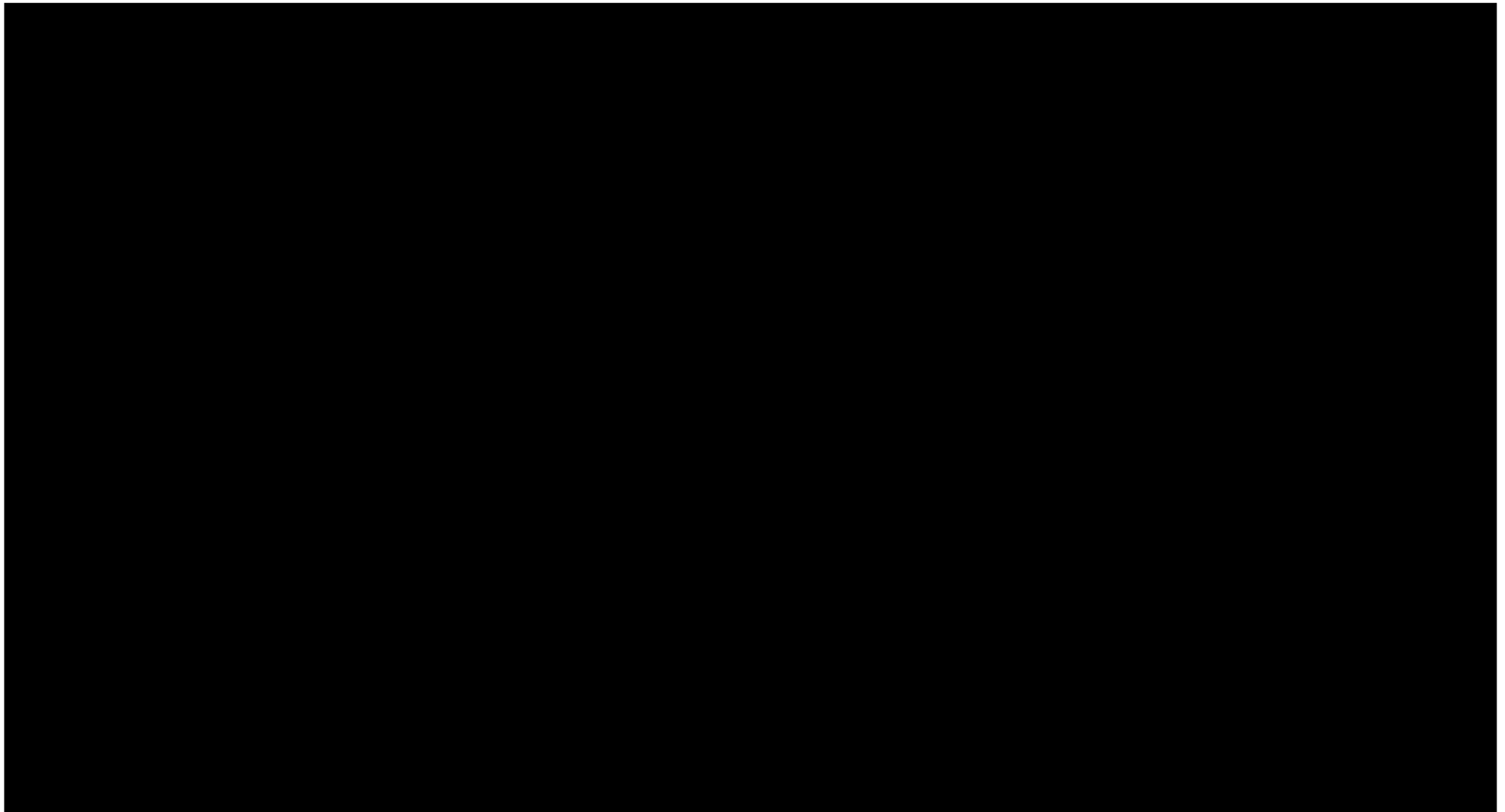
Status:
Page:

Final
811 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

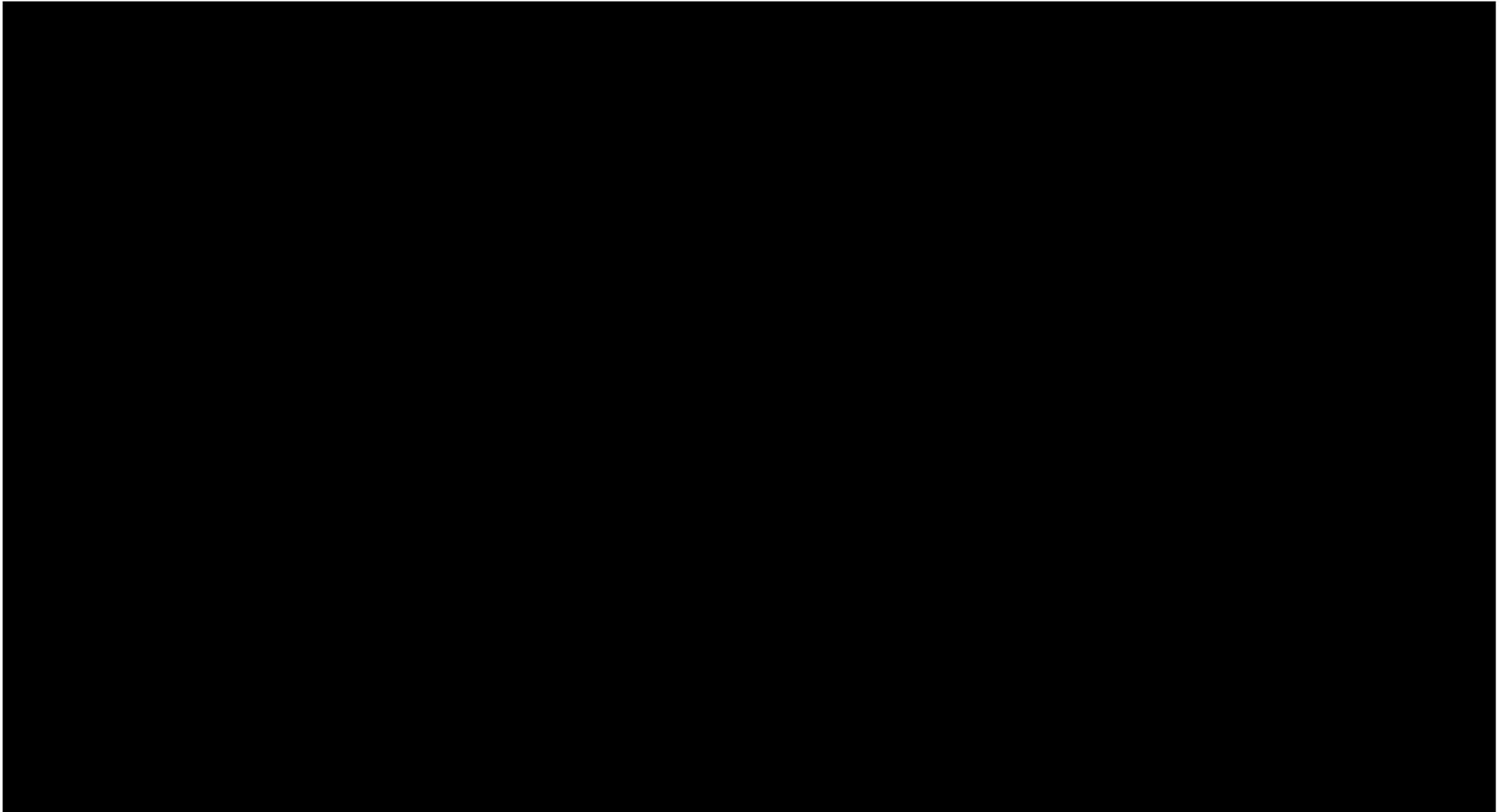
Status:
Page:

Final
812 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

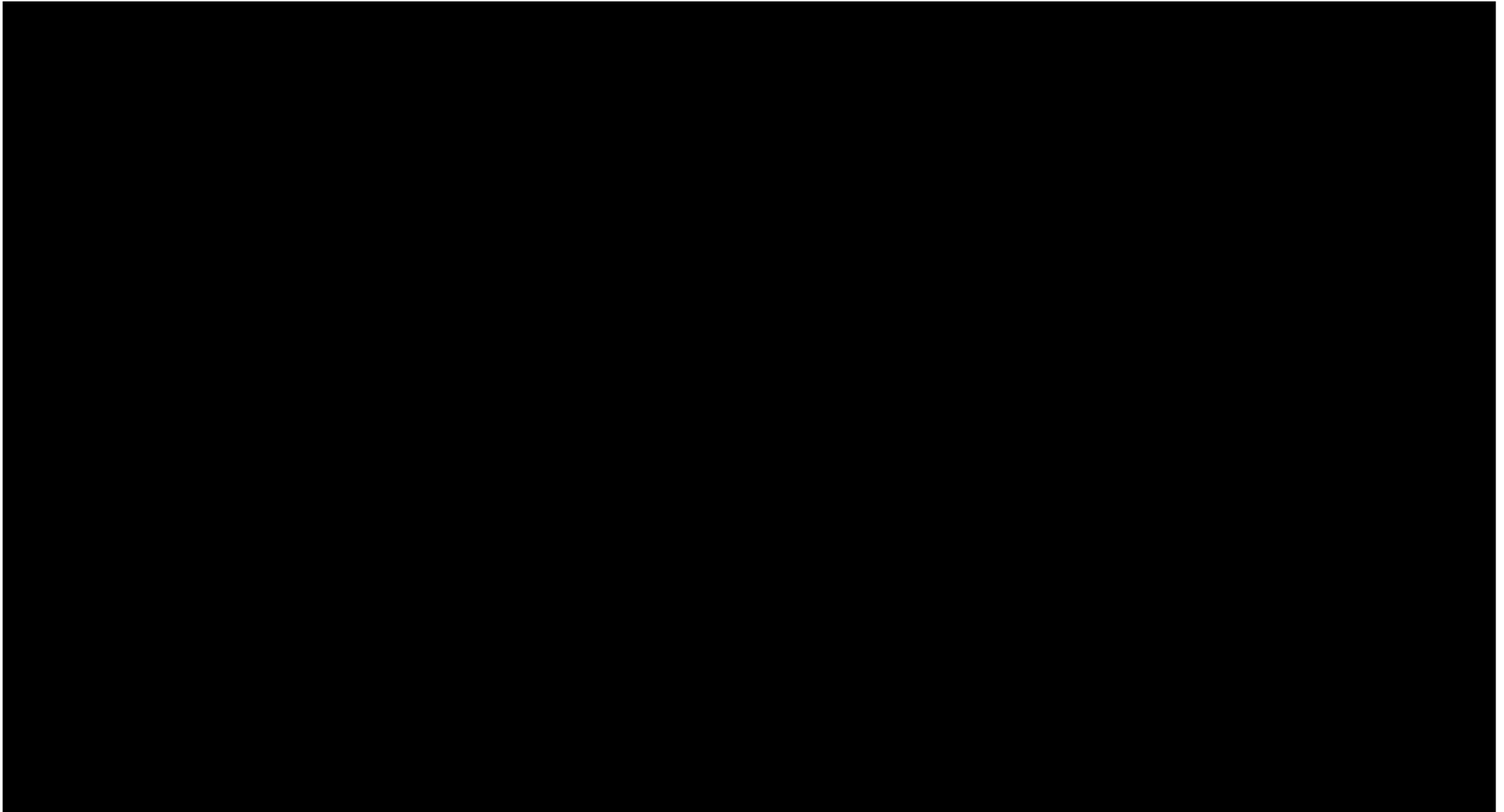
Status:
Page:

Final
813 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

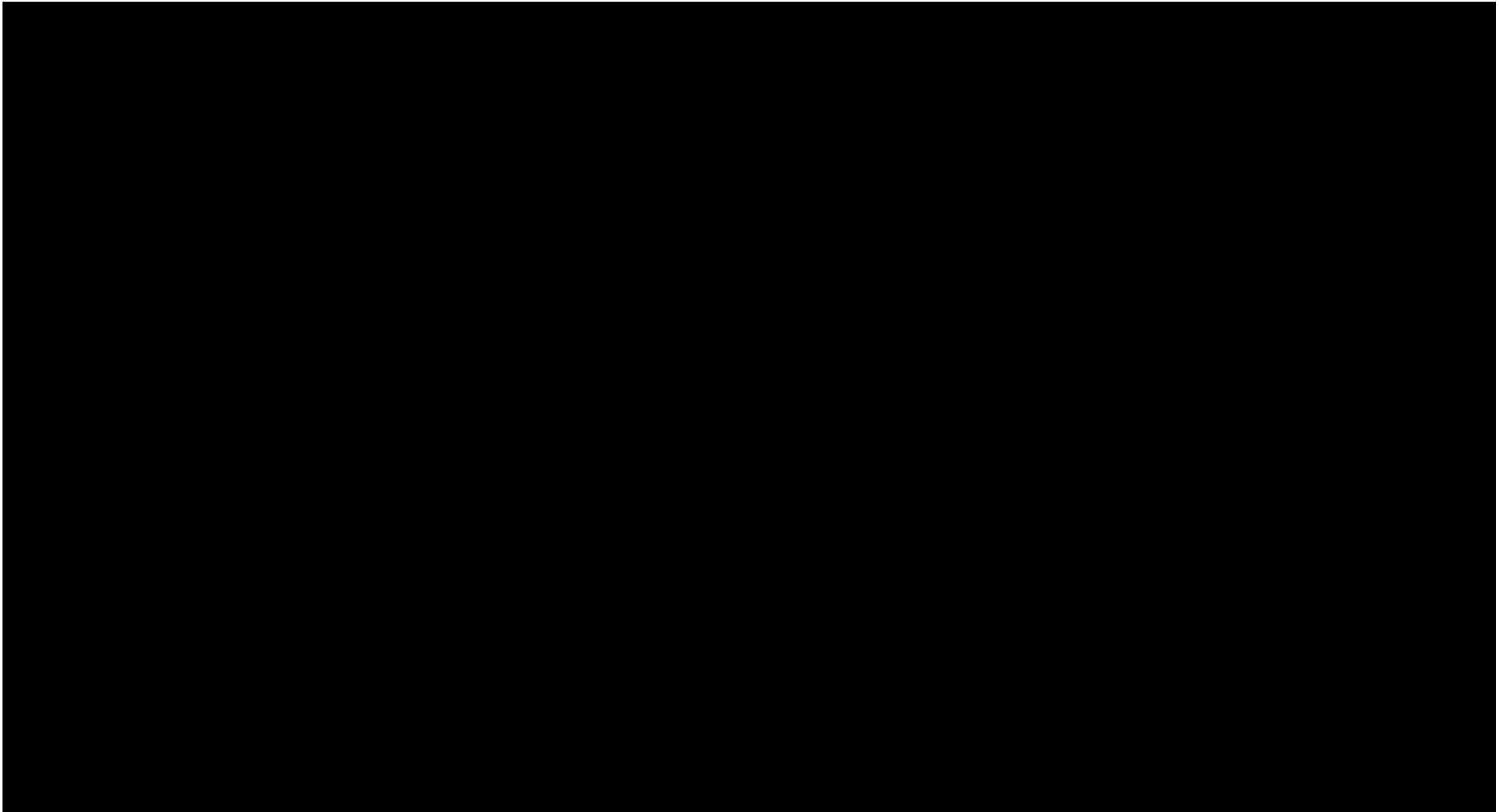
Status:
Page:

Final
816 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

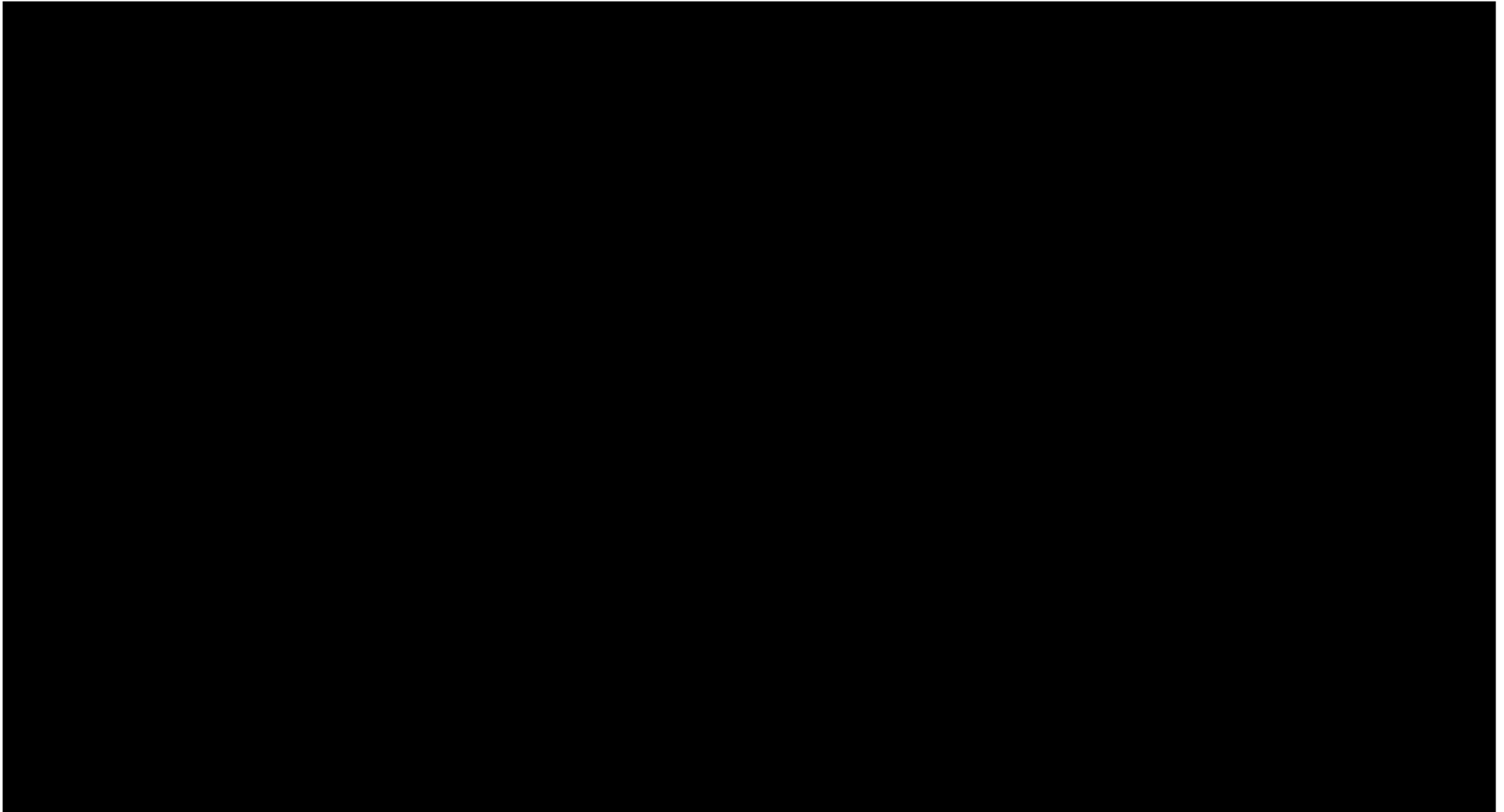
Status:
Page:

Final
817 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

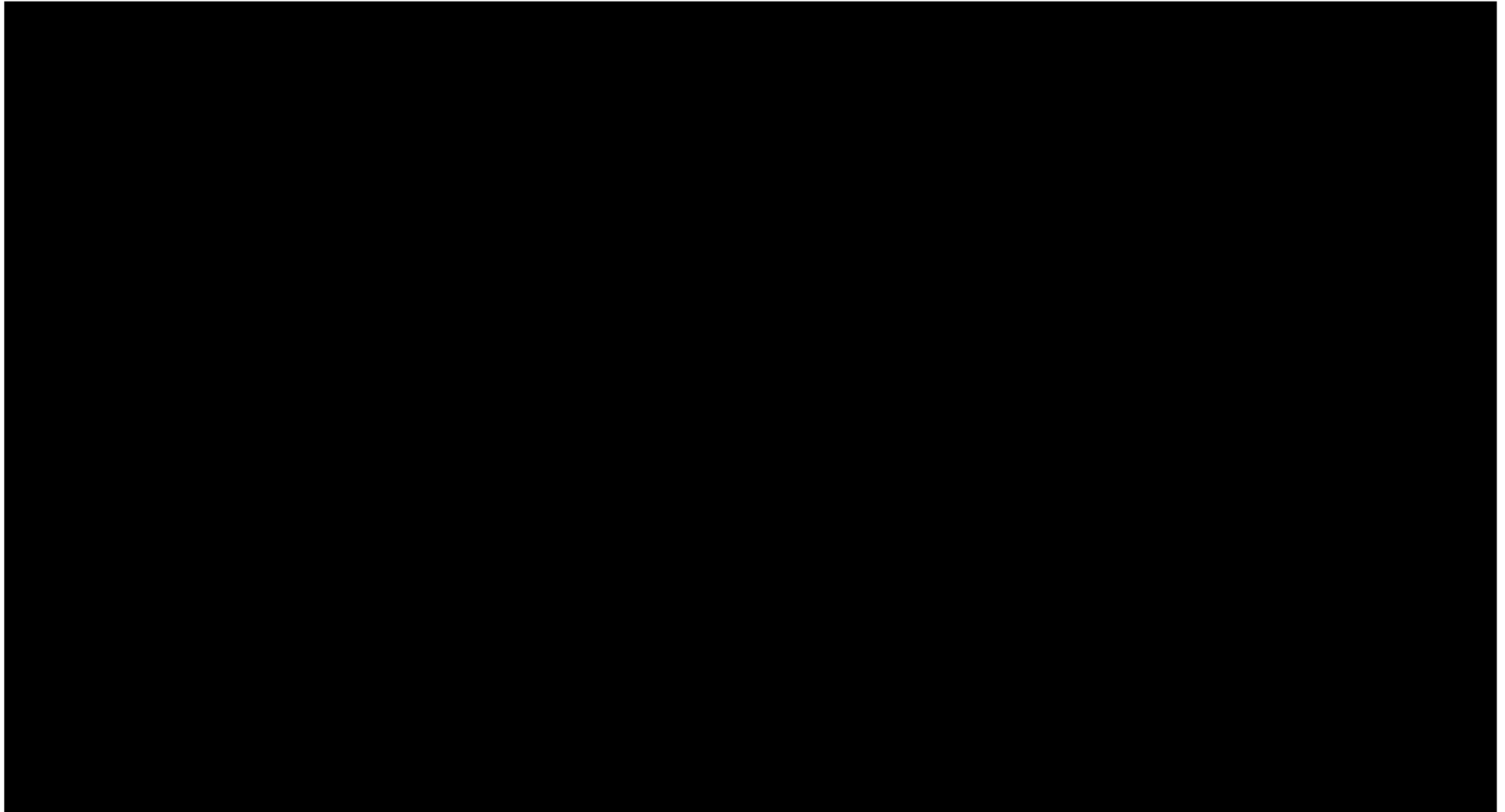
Status:
Page:

Final
821 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

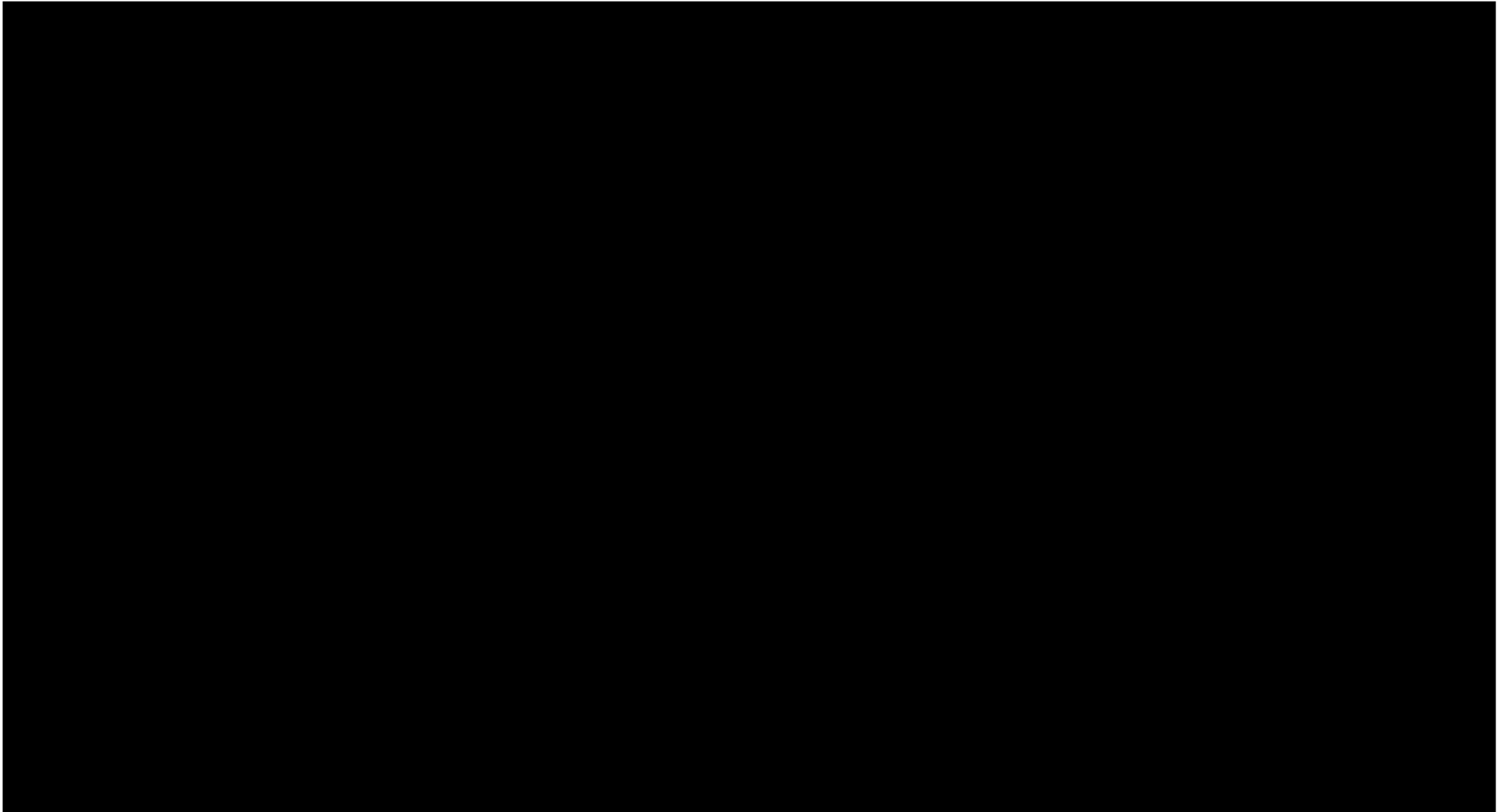
Status:
Page:

Final
823 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

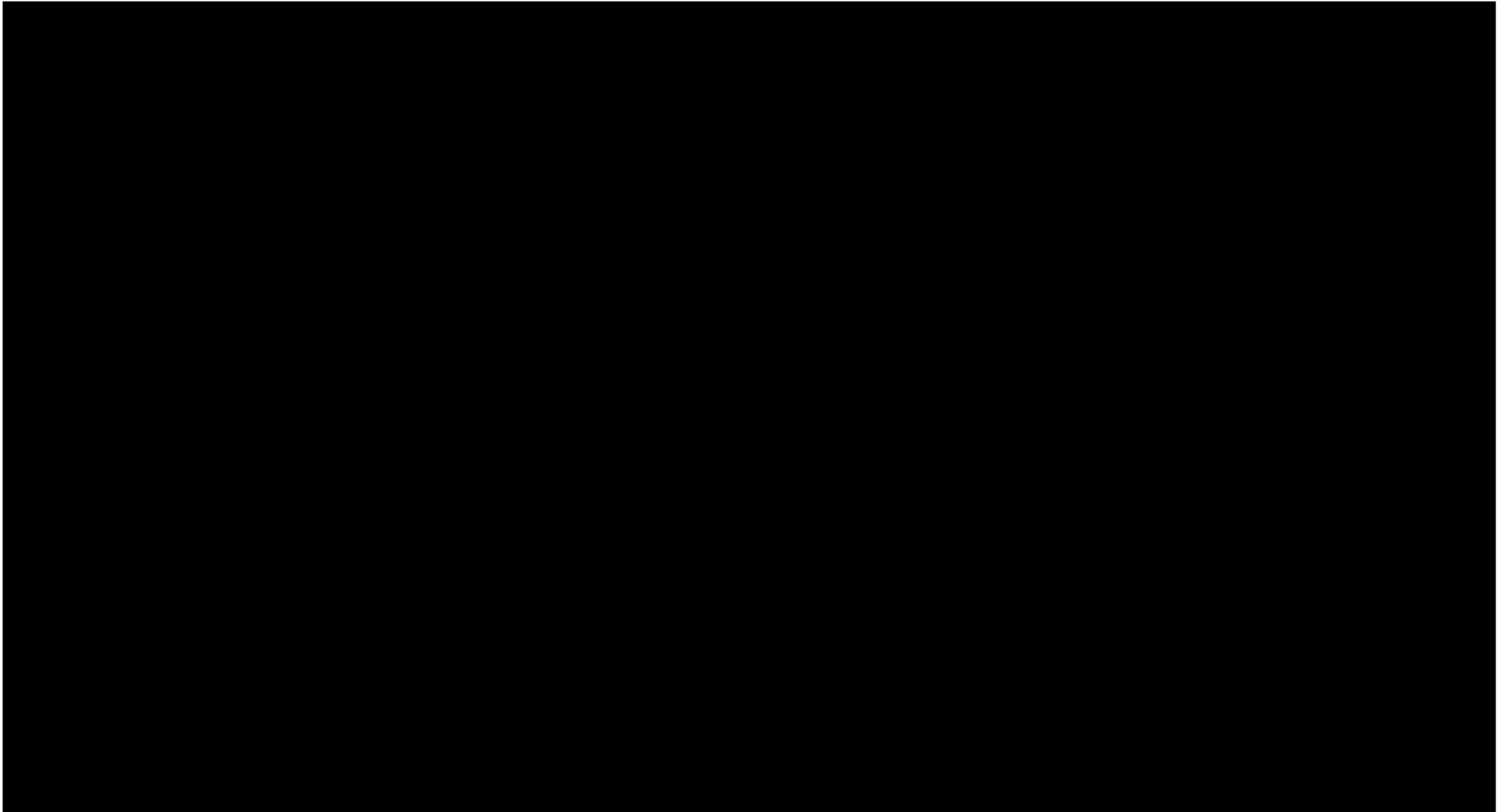
Status:
Page:

Final
826 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

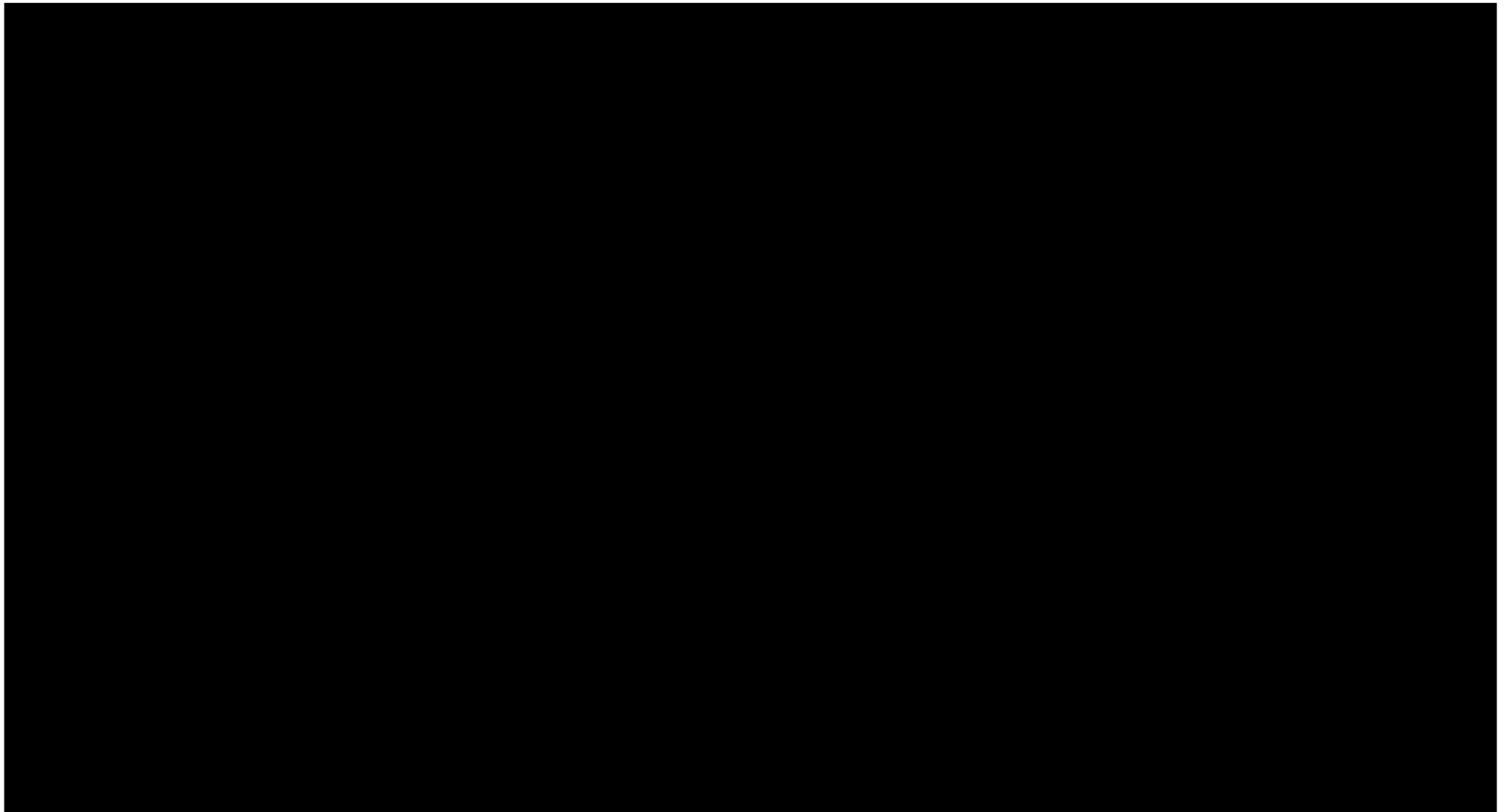
Status:
Page:

Final
828 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

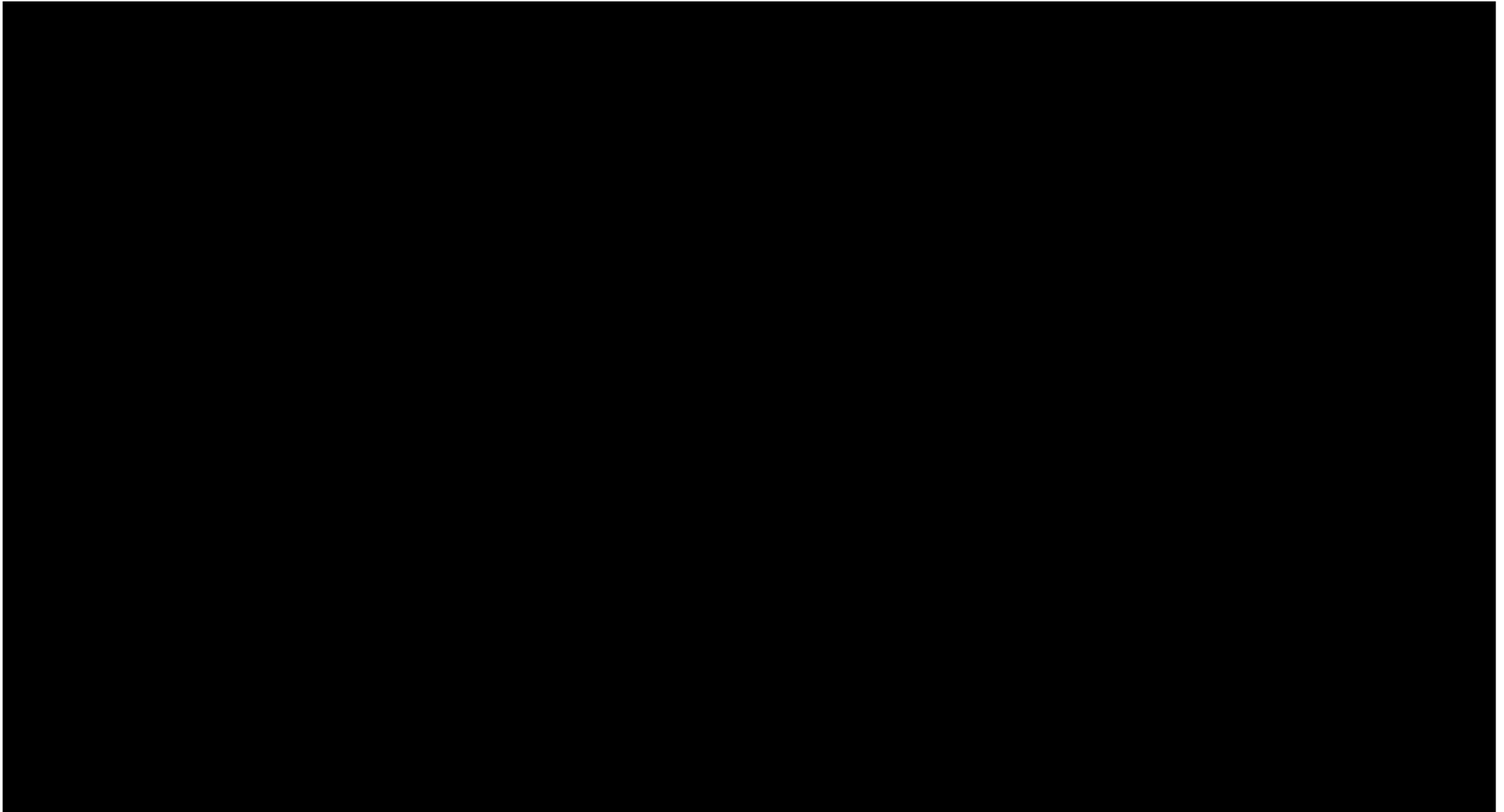
Status:
Page:

Final
829 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

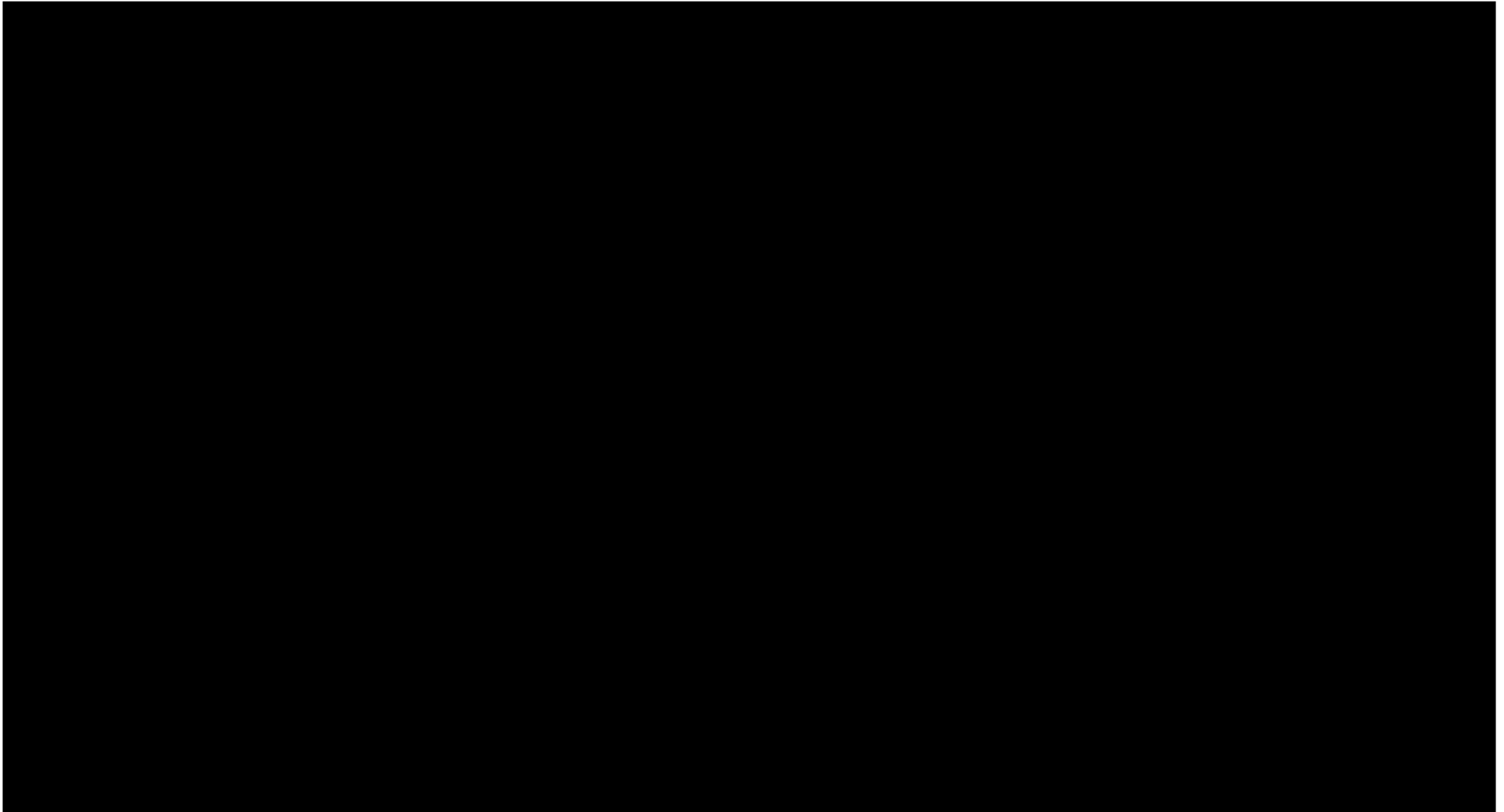
Status:
Page:

Final
830 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

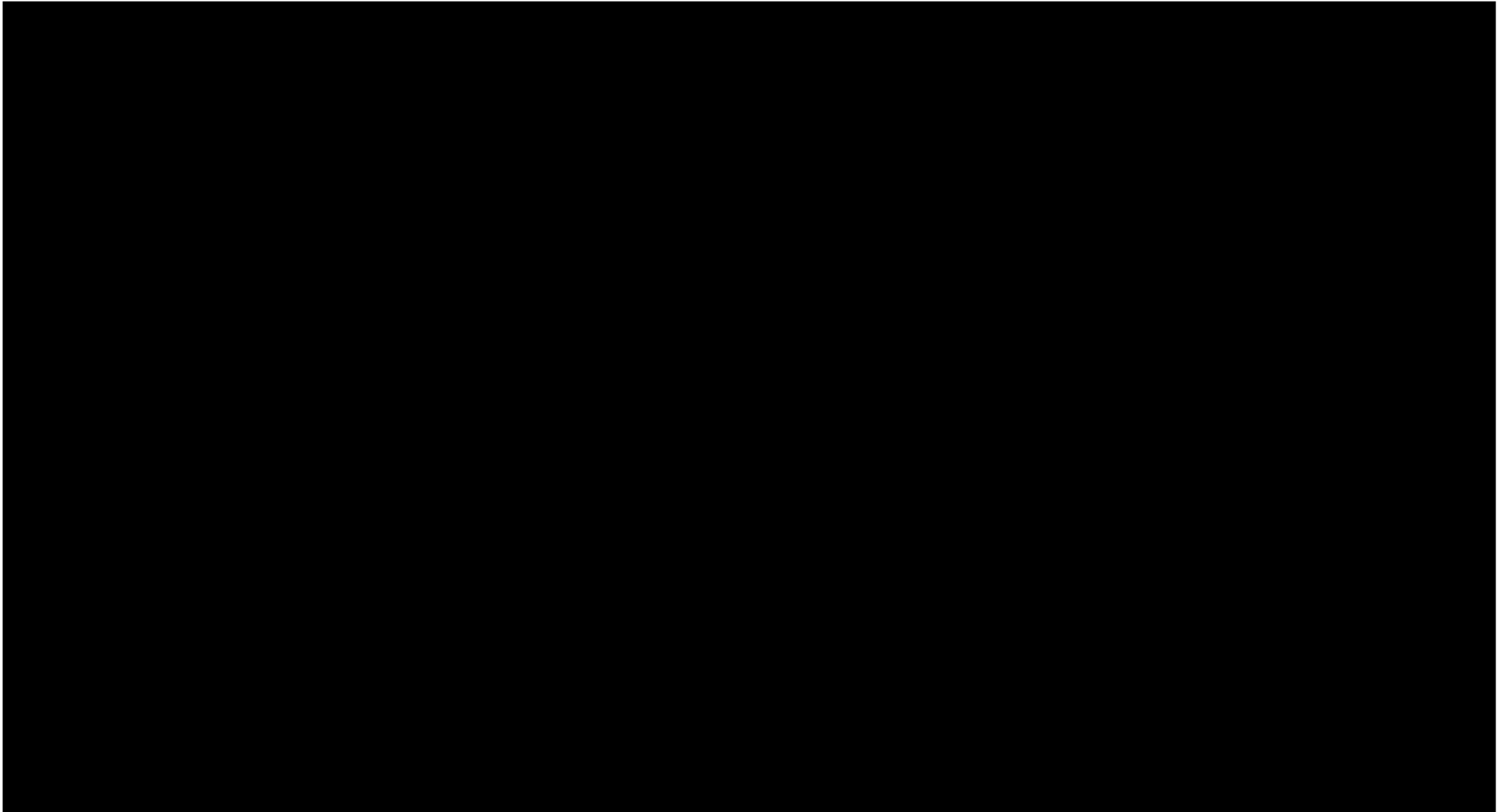
Status:
Page:

Final
831 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Figure 1**

12. **Figure 2**

13. **Figure 3**

14. **Figure 4**

15. **Figure 5**

16. **Figure 6**

17. **Figure 7**

18. **Figure 8**

19. **Figure 9**

20. **Figure 10**

21. **Figure 11**

22. **Figure 12**

23. **Figure 13**

24. **Figure 14**

25. **Figure 15**

26. **Figure 16**

27. **Figure 17**

28. **Figure 18**

29. **Figure 19**

30. **Figure 20**

31. **Figure 21**

32. **Figure 22**

33. **Figure 23**

34. **Figure 24**

35. **Figure 25**

36. **Figure 26**

37. **Figure 27**

38. **Figure 28**

39. **Figure 29**

40. **Figure 30**

41. **Figure 31**

42. **Figure 32**

43. **Figure 33**

44. **Figure 34**

45. **Figure 35**

46. **Figure 36**

47. **Figure 37**

48. **Figure 38**

49. **Figure 39**

50. **Figure 40**

51. **Figure 41**

52. **Figure 42**

53. **Figure 43**

54. **Figure 44**

55. **Figure 45**

56. **Figure 46**

57. **Figure 47**

58. **Figure 48**

59. **Figure 49**

60. **Figure 50**

61. **Figure 51**

62. **Figure 52**

63. **Figure 53**

64. **Figure 54**

65. **Figure 55**

66. **Figure 56**

67. **Figure 57**

68. **Figure 58**

69. **Figure 59**

70. **Figure 60**

71. **Figure 61**

72. **Figure 62**

73. **Figure 63**

74. **Figure 64**

75. **Figure 65**

76. **Figure 66**

77. **Figure 67**

78. **Figure 68**

79. **Figure 69**

80. **Figure 70**

81. **Figure 71**

82. **Figure 72**

83. **Figure 73**

84. **Figure 74**

85. **Figure 75**

86. **Figure 76**

87. **Figure 77**

88. **Figure 78**

89. **Figure 79**

90. **Figure 80**

91. **Figure 81**

92. **Figure 82**

93. **Figure 83**

94. **Figure 84**

95. **Figure 85**

96. **Figure 86**

97. **Figure 87**

98. **Figure 88**

99. **Figure 89**

100. **Figure 90**

101. **Figure 91**

102. **Figure 92**

103. **Figure 93**

104. **Figure 94**

105. **Figure 95**

106. **Figure 96**

107. **Figure 97**

108. **Figure 98**

109. **Figure 99**

110. **Figure 100**

111. **Figure 101**

112. **Figure 102**

113. **Figure 103**

114. **Figure 104**

115. **Figure 105**

116. **Figure 106**

117. **Figure 107**

118. **Figure 108**

119. **Figure 109**

120. **Figure 110**

121. **Figure 111**

122. **Figure 112**

123. **Figure 113**

124. **Figure 114**

125. **Figure 115**

126. **Figure 116**

127. **Figure 117**

128. **Figure 118**

129. **Figure 119**

130. **Figure 120**

131. **Figure 121**

132. **Figure 122**

133. **Figure 123**

134. **Figure 124**

135. **Figure 125**

136. **Figure 126**

137. **Figure 127**

138. **Figure 128**

139. **Figure 129**

140. **Figure 130**

141. **Figure 131**

142. **Figure 132**

143. **Figure 133**

144. **Figure 134**

145. **Figure 135**

146. **Figure 136**

147. **Figure 137**

148. **Figure 138**

149. **Figure 139**

150. **Figure 140**

151. **Figure 141**

152. **Figure 142**

153. **Figure 143**

154. **Figure 144**

155. **Figure 145**

156. **Figure 146**

157. **Figure 147**

158. **Figure 148**

159. **Figure 149**

160. **Figure 150**

161. **Figure 151**

162. **Figure 152**

163. **Figure 153**

164. **Figure 154**

165. **Figure 155**

166. **Figure 156**

167. **Figure 157**

168. **Figure 158**

169. **Figure 159**

170. **Figure 160**

171. **Figure 161**

172. **Figure 162**

173. **Figure 163**

174. **Figure 164**

175. **Figure 165**

176. **Figure 166**

177. **Figure 167**

178. **Figure 168**

179. **Figure 169**

180. **Figure 170**

181. **Figure 171**

182. **Figure 172**

183. **Figure 173**

184. **Figure 174**

185. **Figure 175**

186. **Figure 176**

187. **Figure 177**

188. **Figure 178**

189. **Figure 179**

190. **Figure 180**

191. **Figure 181**

192. **Figure 182**

193. **Figure 183**

194. **Figure 184**

195. **Figure 185**

196. **Figure 186**

197. **Figure 187**

198. **Figure 188**

199. **Figure 189**

200. **Figure 190**

201. **Figure 191**

202. **Figure 192**

203. **Figure 193**

204. **Figure 194**

205. **Figure 195**

206. **Figure 196**

207. **Figure 197**

208. **Figure 198**

209. **Figure 199**

210. **Figure 200**

211. **Figure 201**

212. **Figure 202**

213. **Figure 203**

214. **Figure 204**

215. **Figure 205**

216. **Figure 206**

217. **Figure 207**

218. **Figure 208**

219. **Figure 209**

220. **Figure 210**

221. **Figure 211**

222. **Figure 212**

223. **Figure 213**

224. **Figure 214**

225. **Figure 215**

226. **Figure 216**

227. **Figure 217**

228.

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

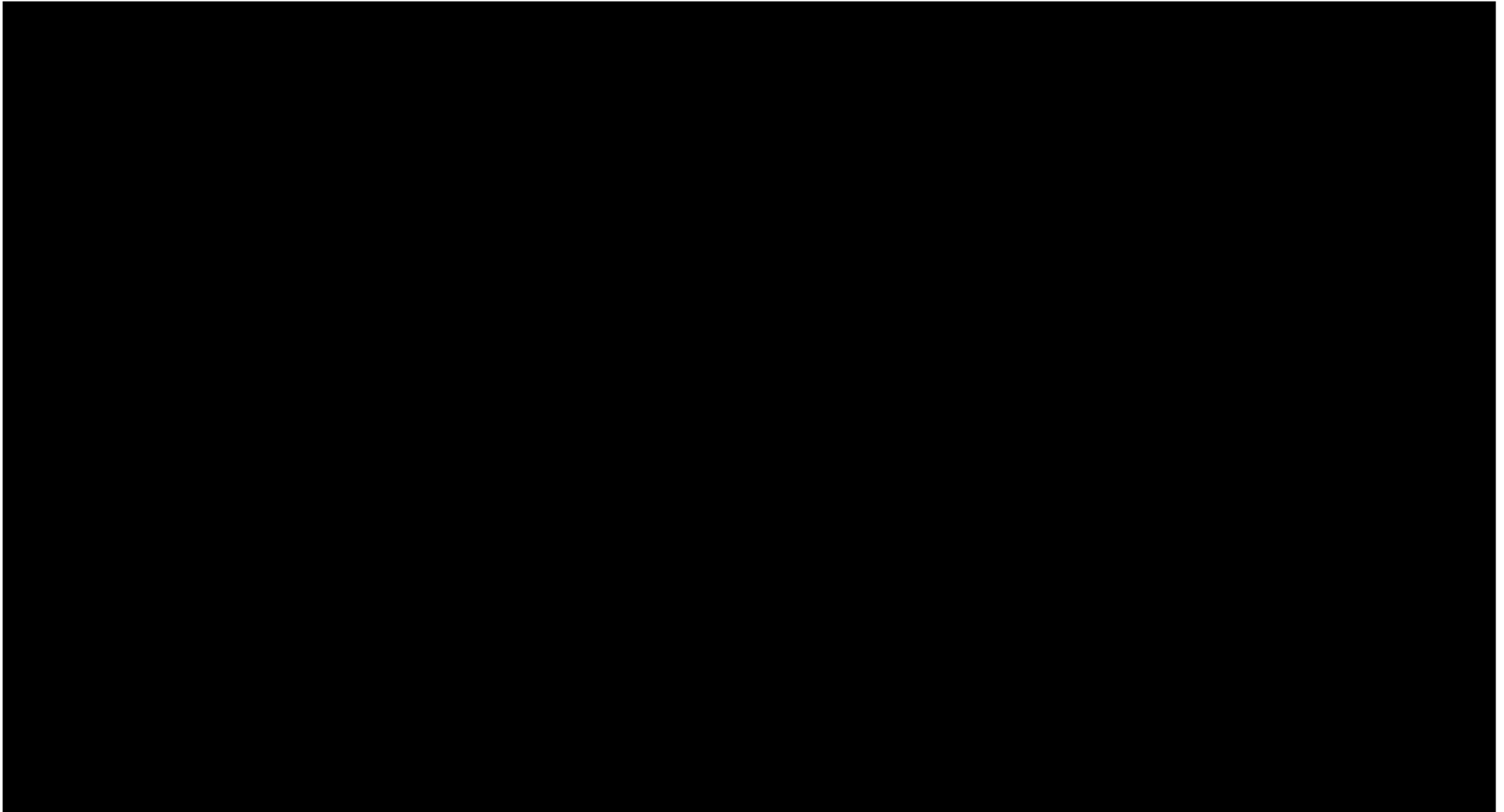
Status:
Page:

Final
833 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

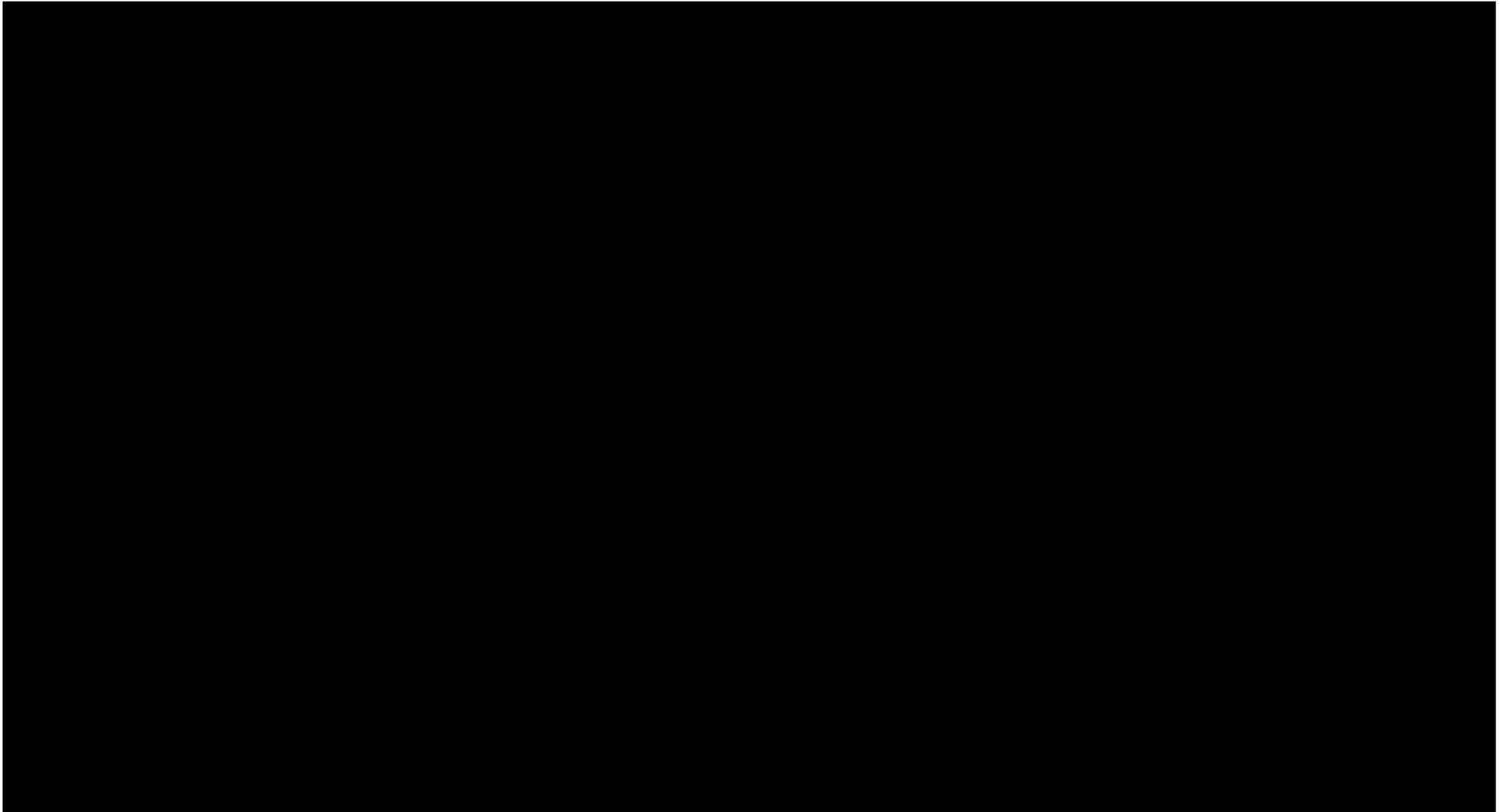
Status:
Page:

Final
835 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

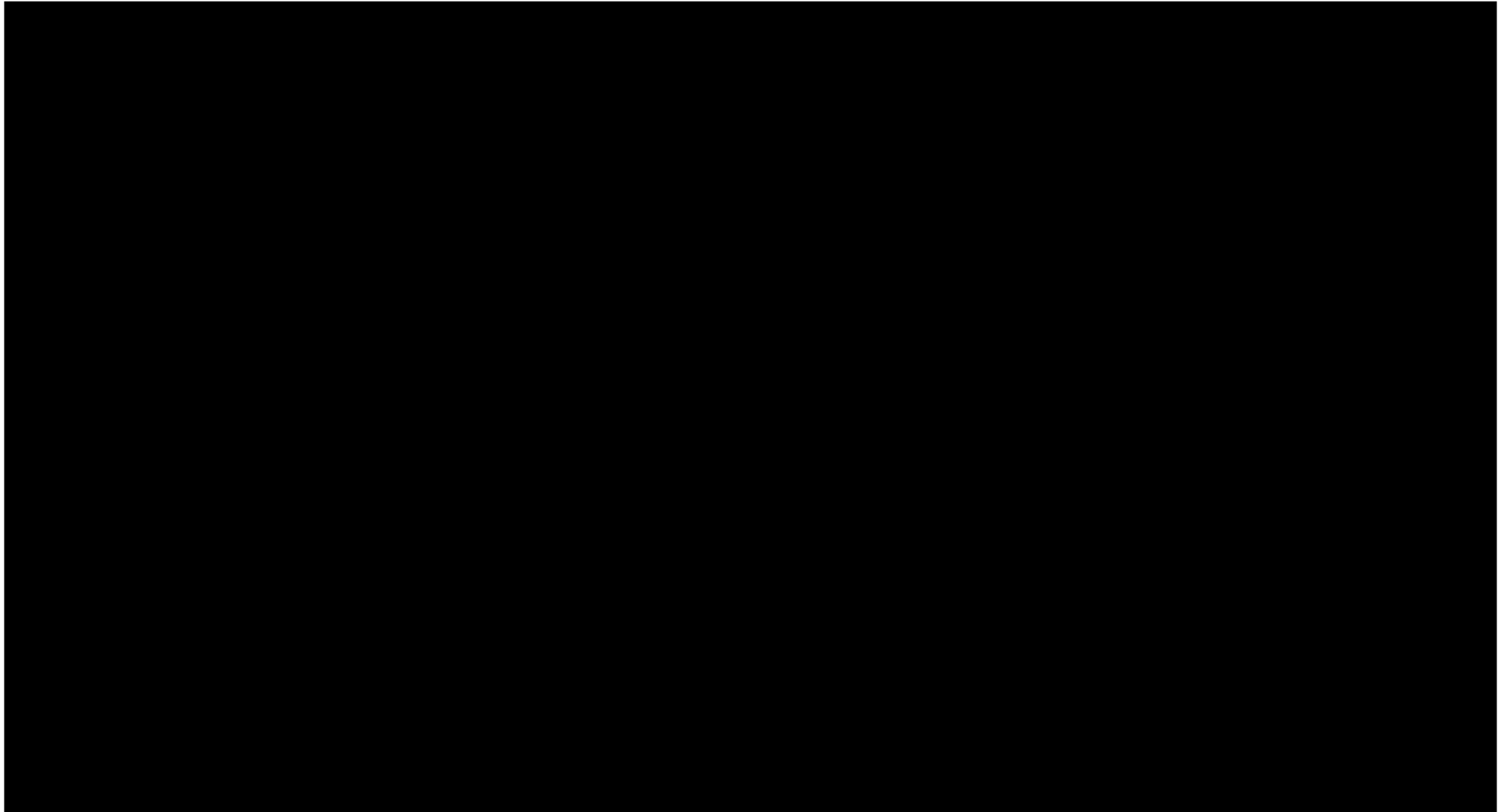
Status:
Page:

Final
836 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

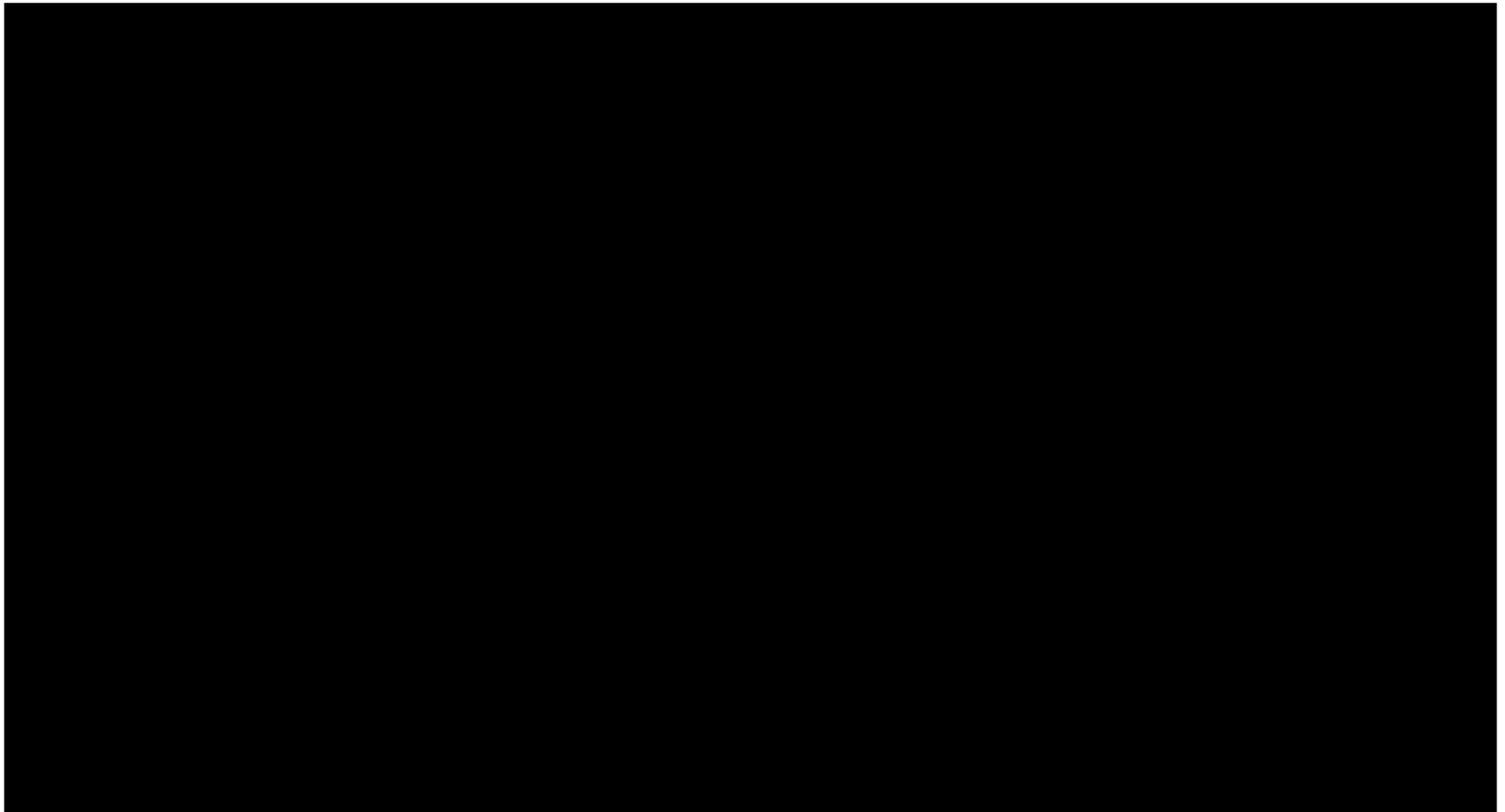
Status:
Page:

Final
837 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

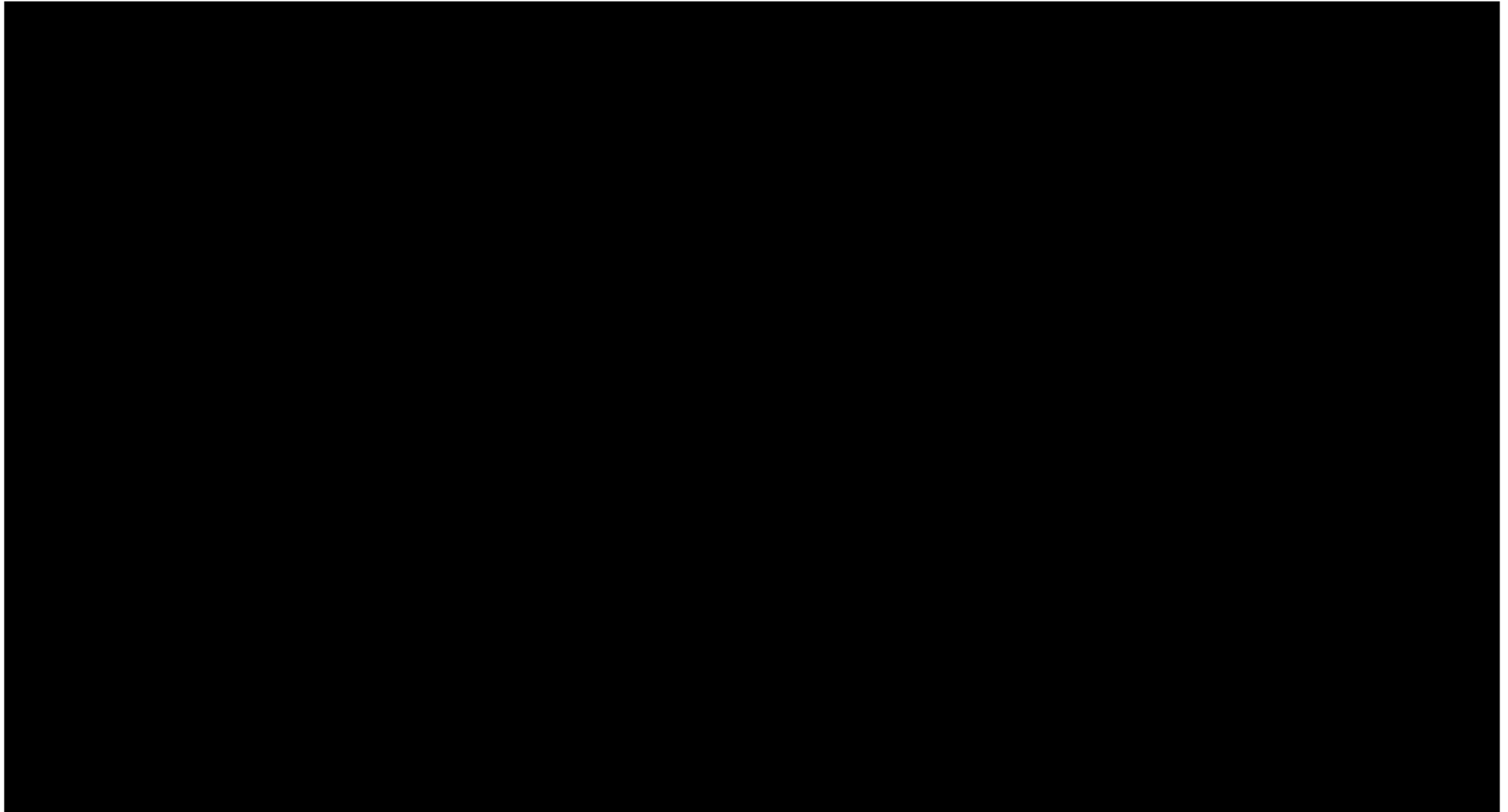
Status:
Page:

Final
840 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

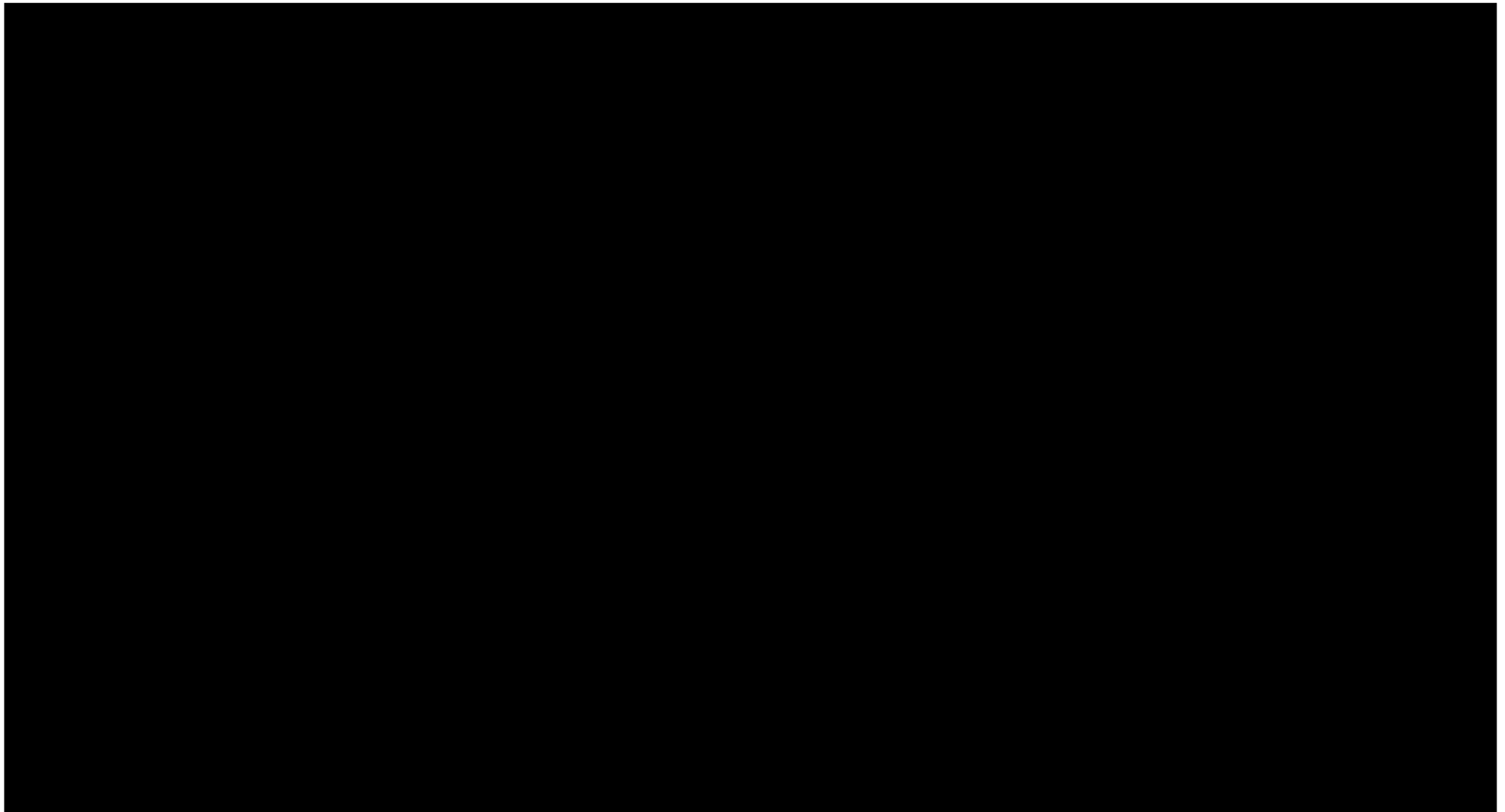
Status:
Page:

Final
843 of 1733

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

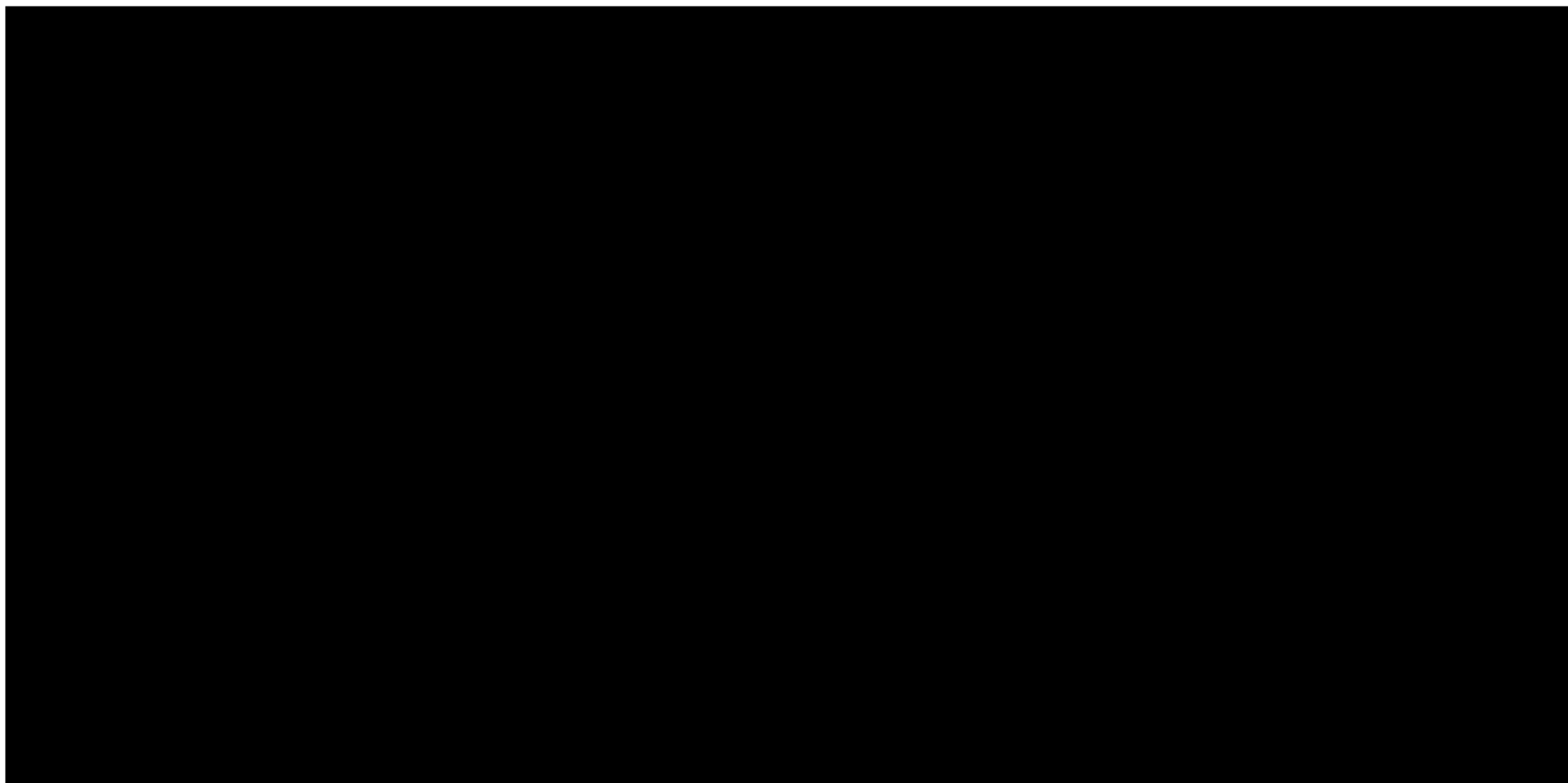
Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

14.3.4.4: Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

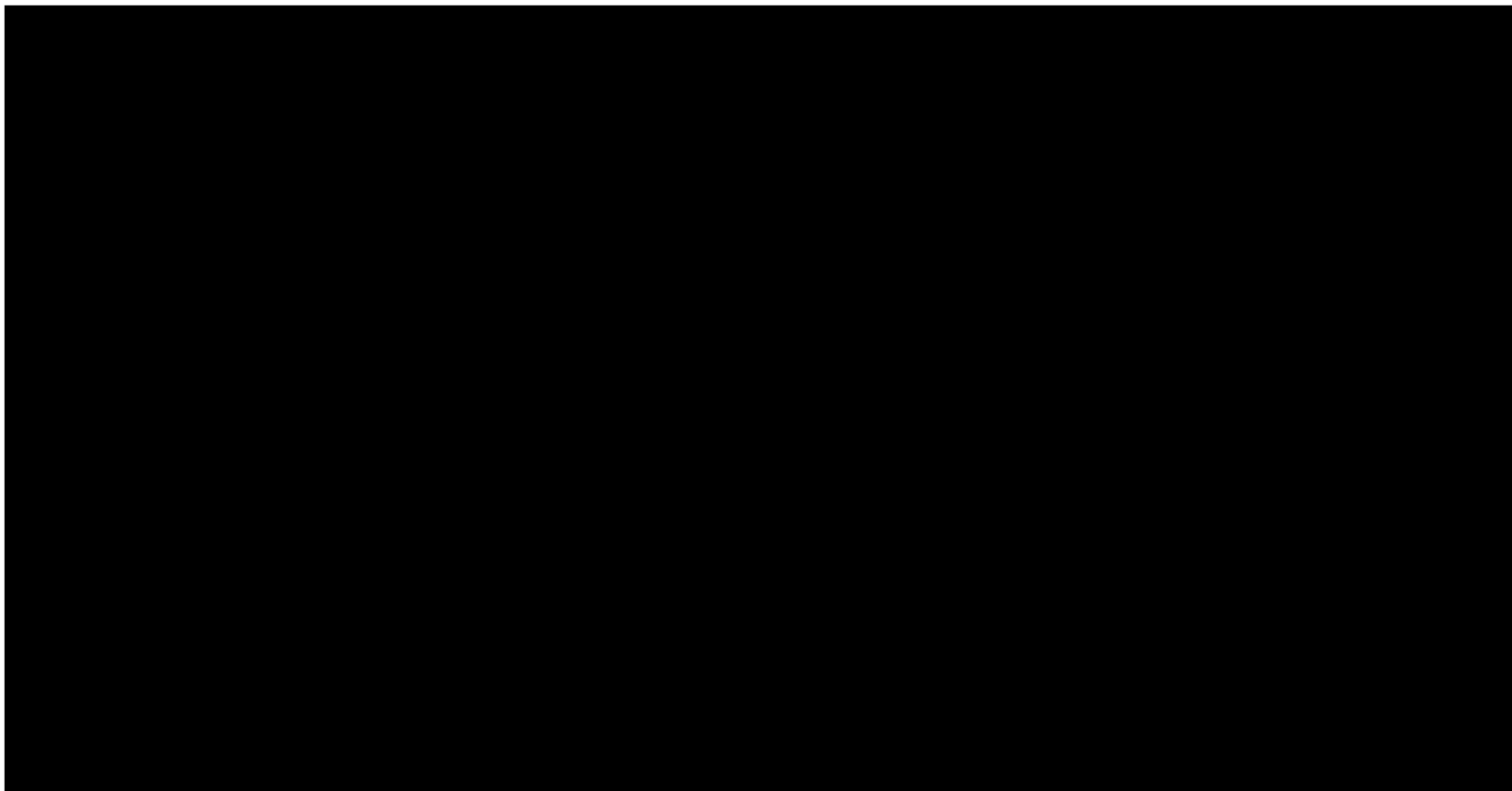
Status:
Page:

Final
847 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

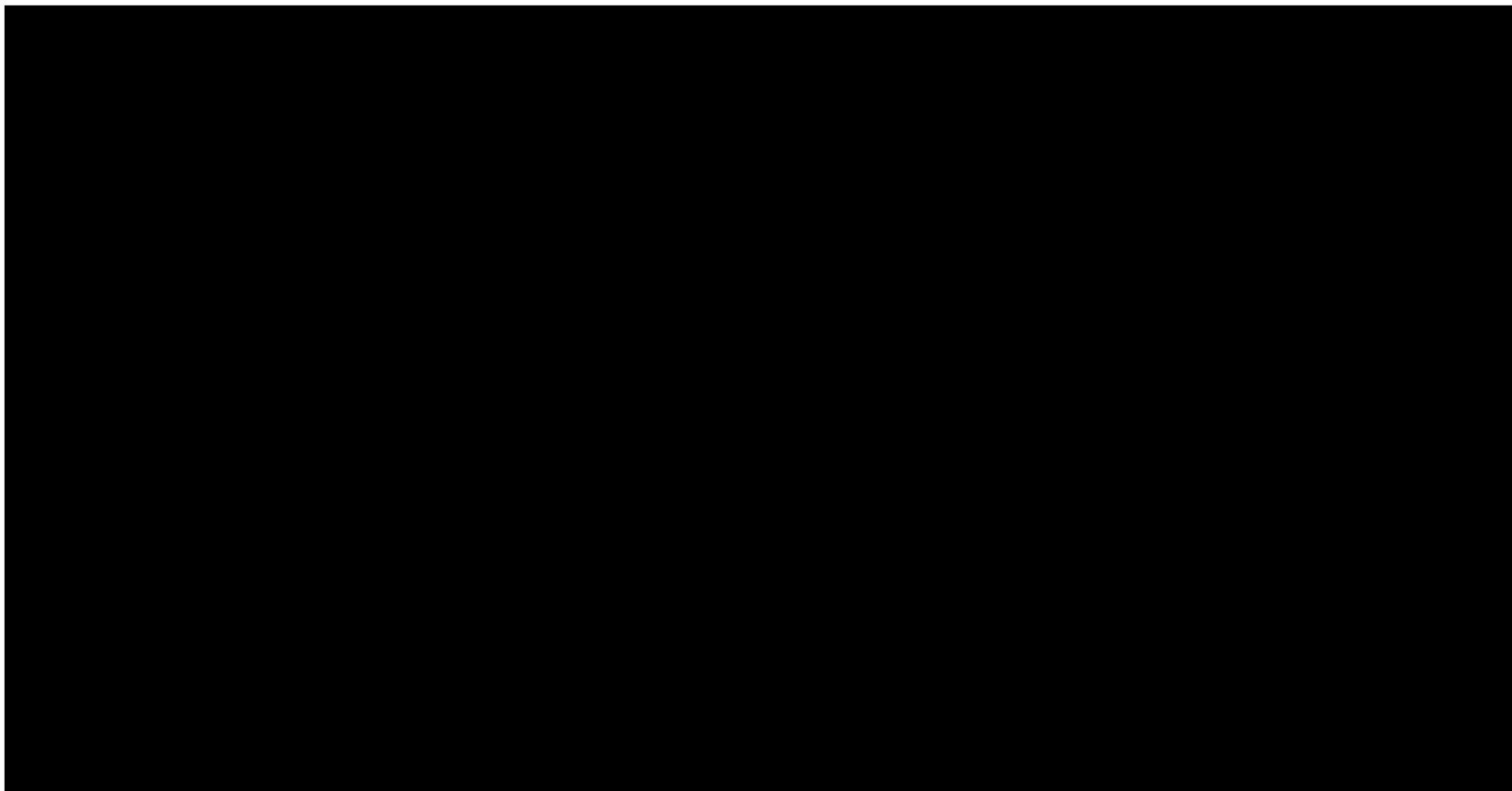
Status:
Page:

Final
848 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

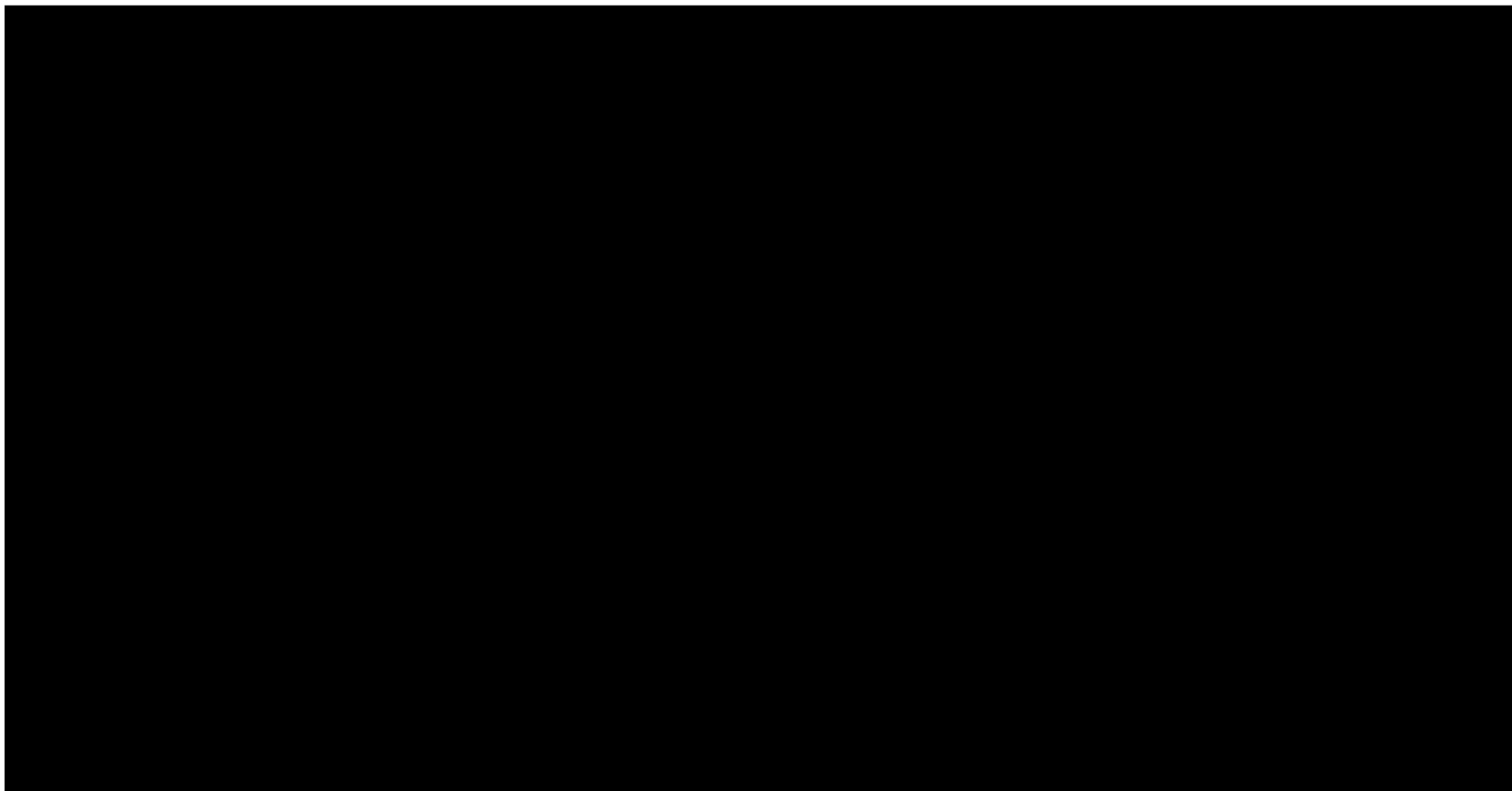
Status:
Page:

Final
849 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

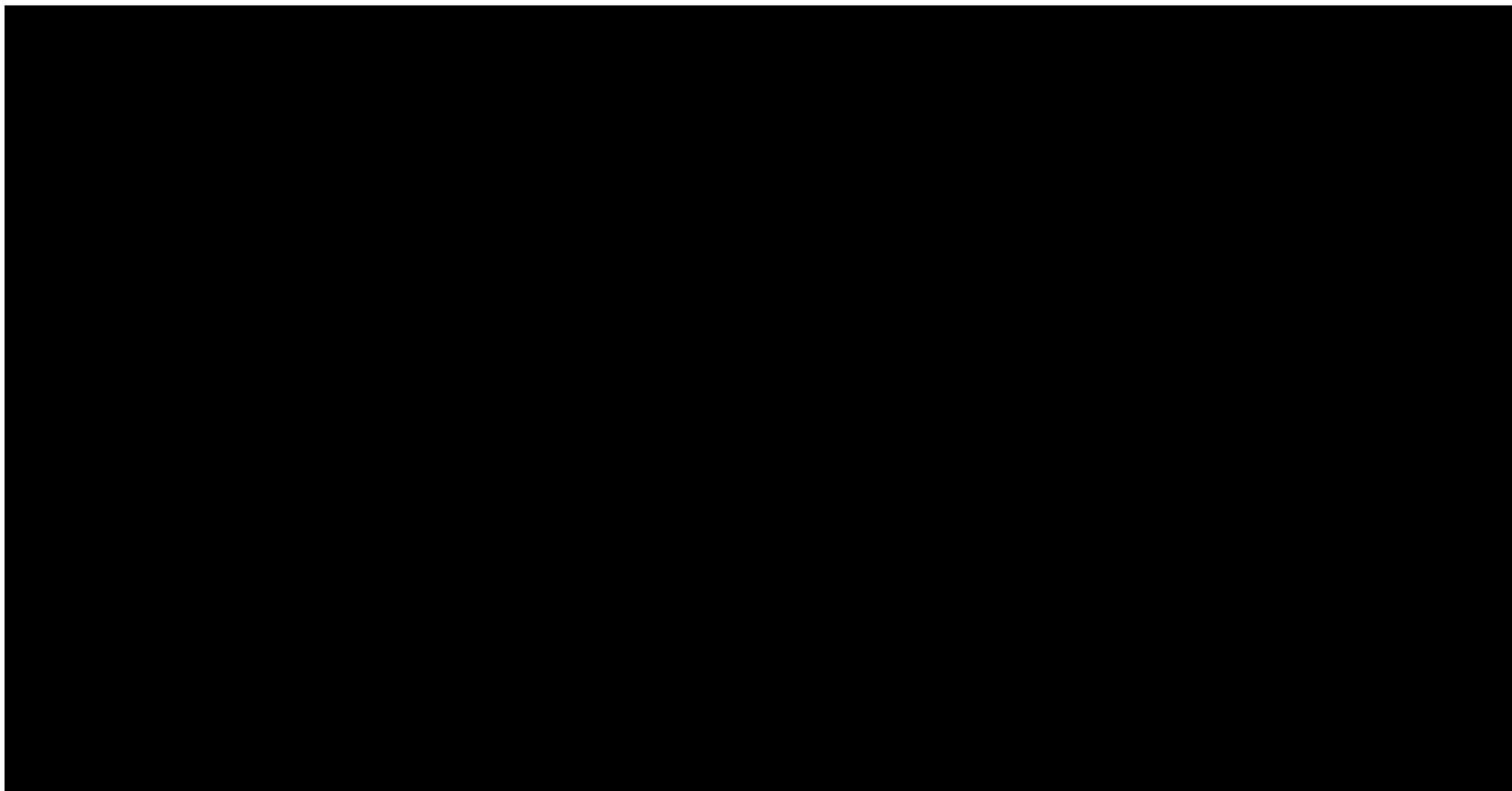
Status:
Page:

Final
850 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

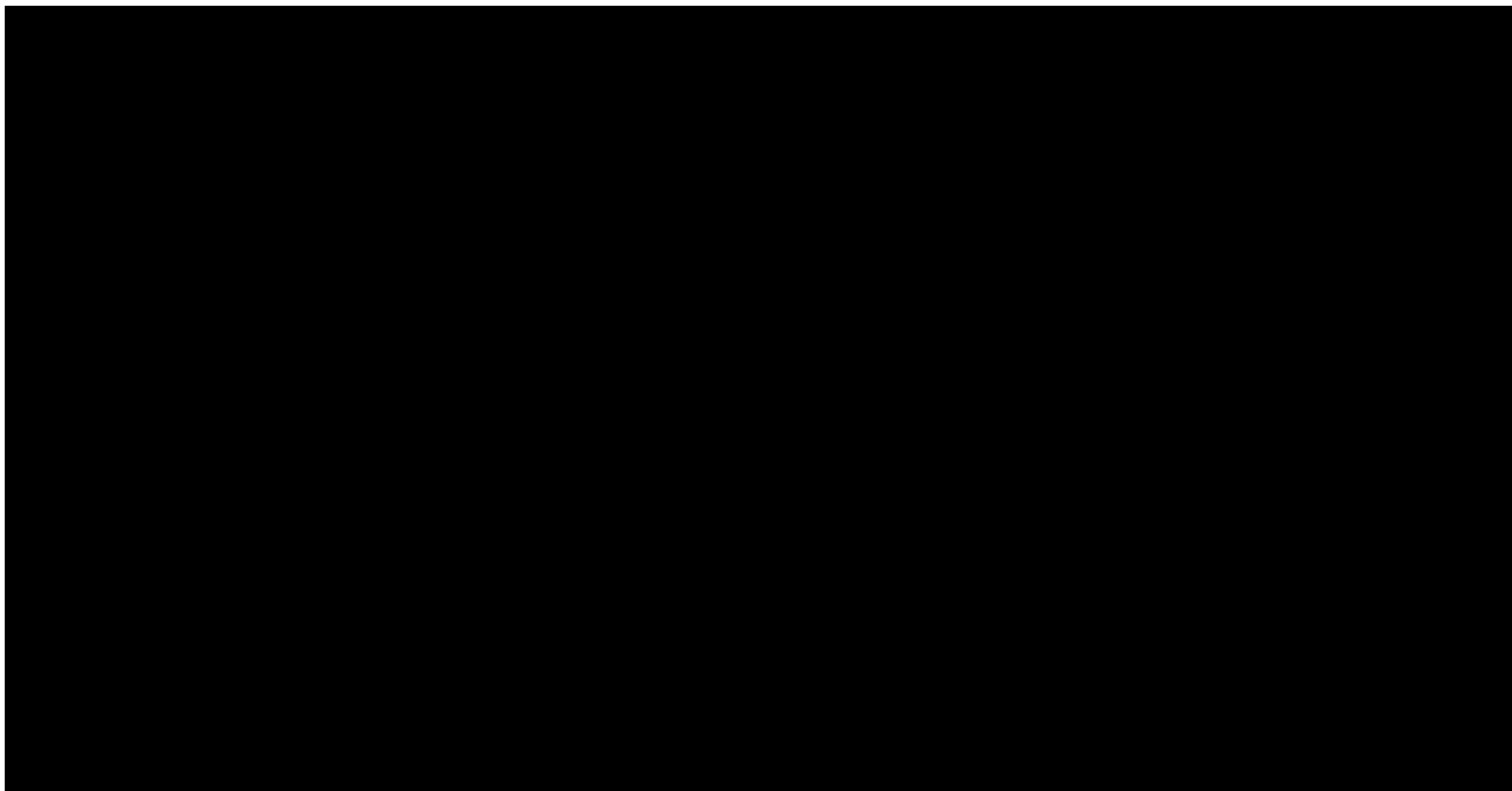
Status:
Page:

Final
851 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

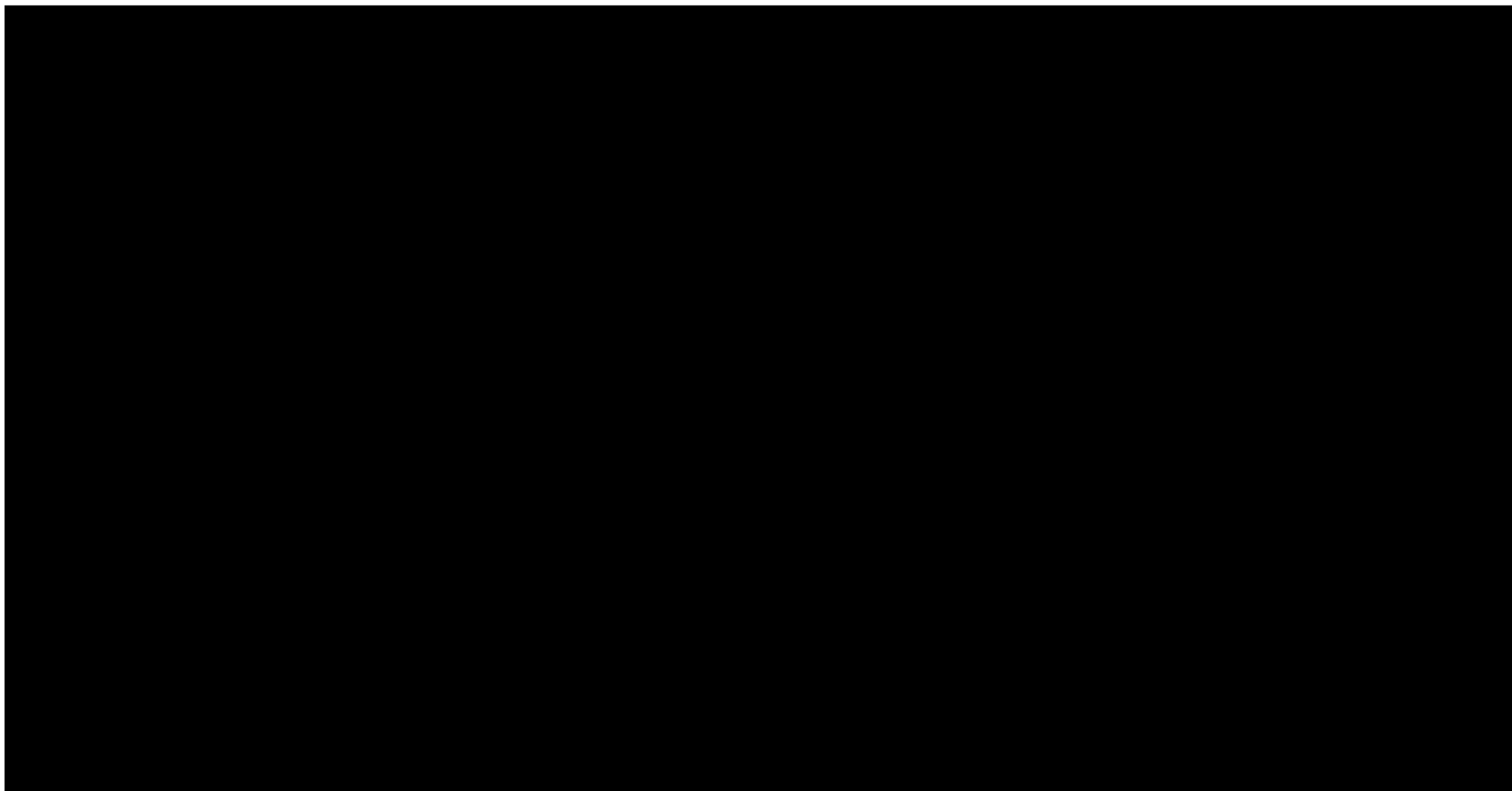
Status:
Page:

Final
852 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

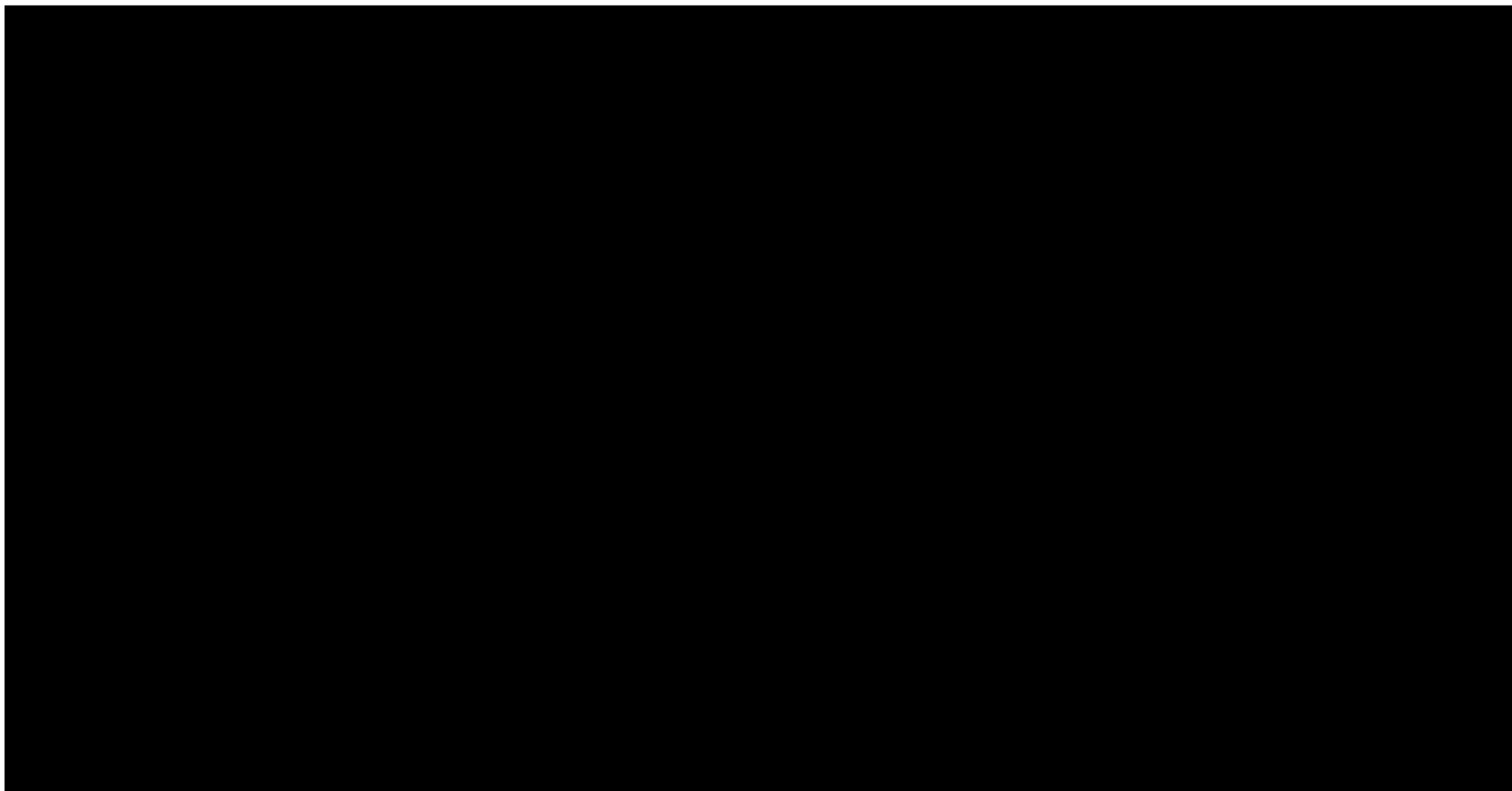
Status:
Page:

Final
853 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

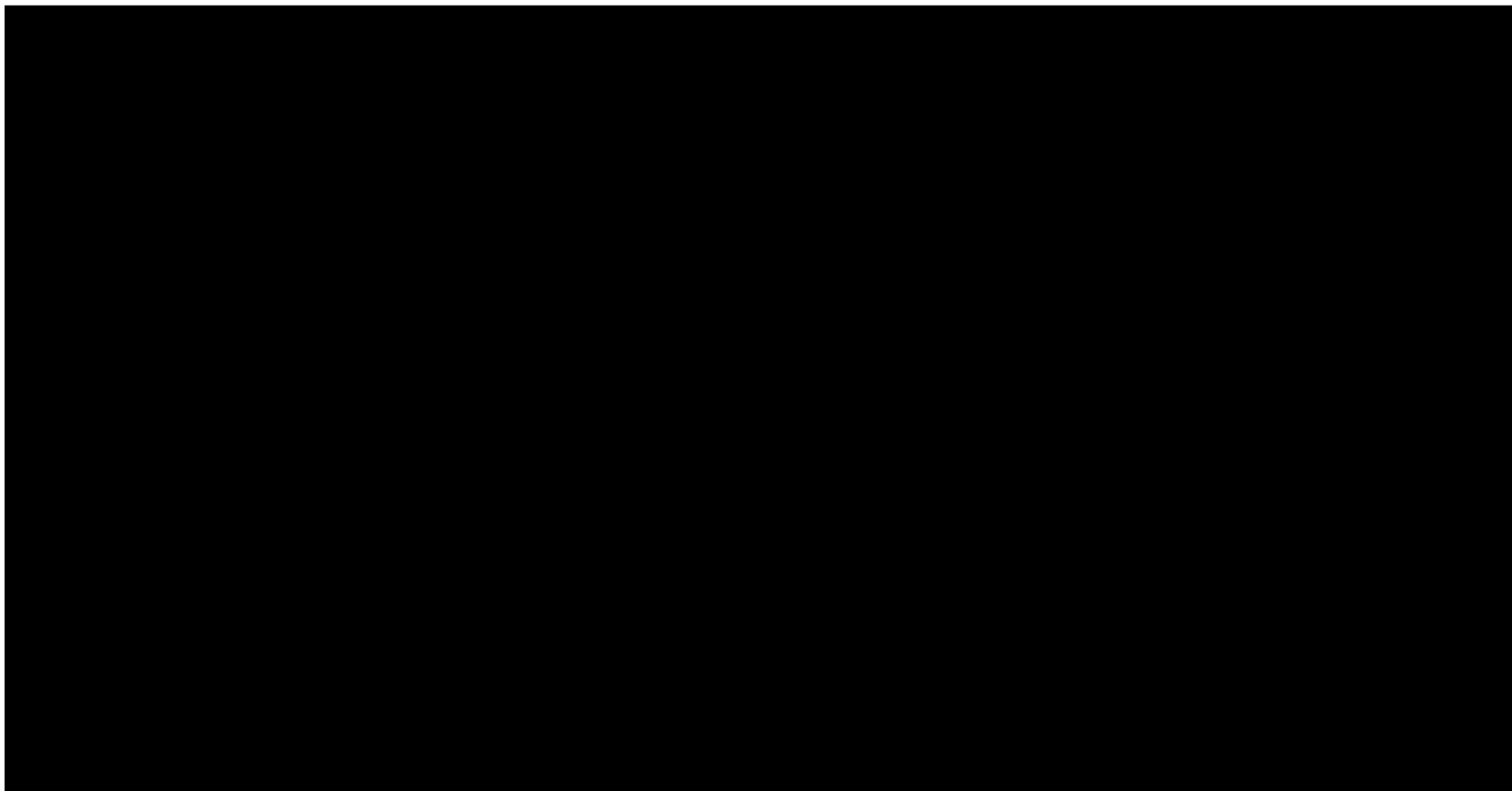
Status:
Page:

Final
854 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

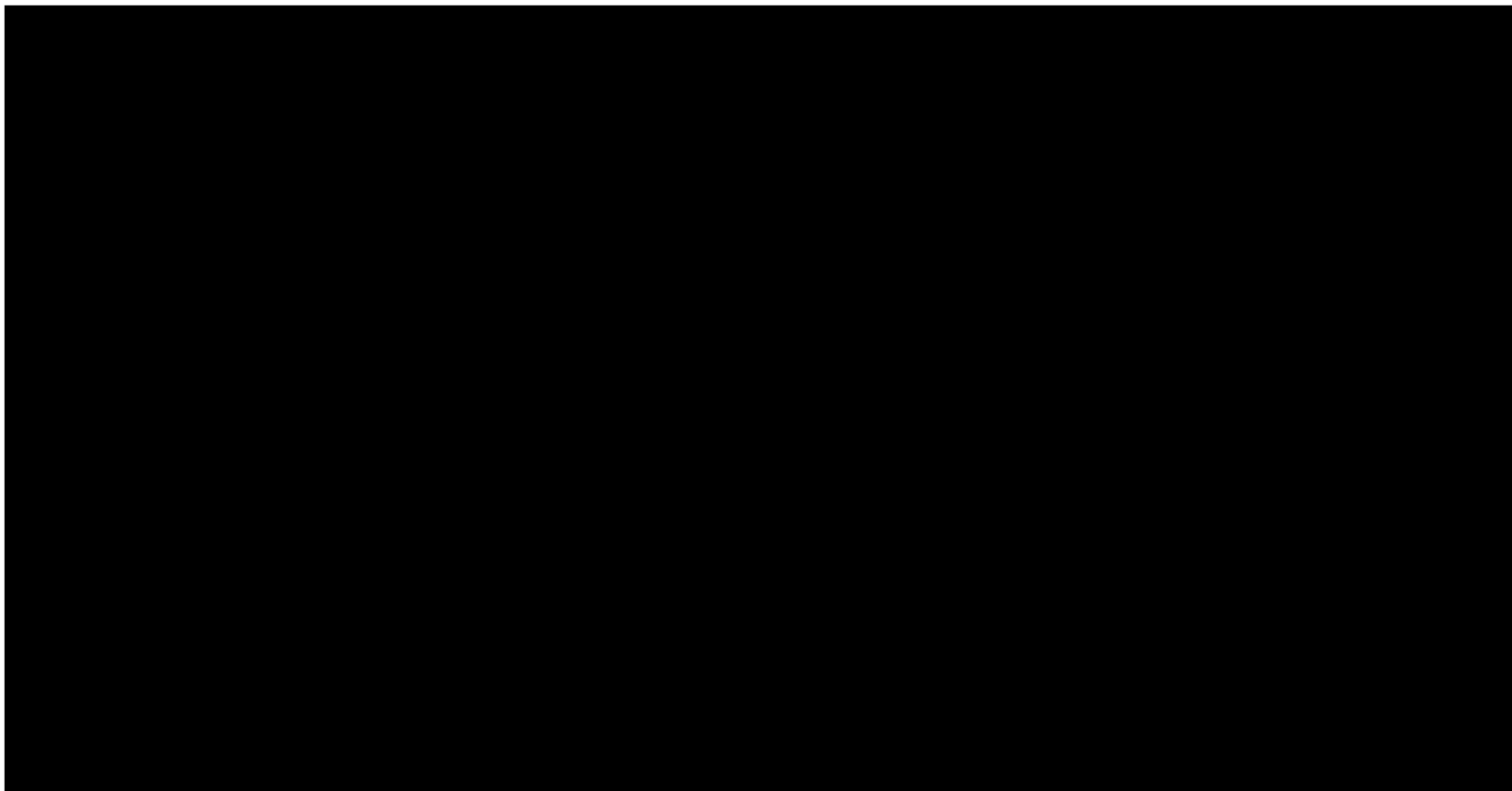
Status:
Page:

Final
855 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

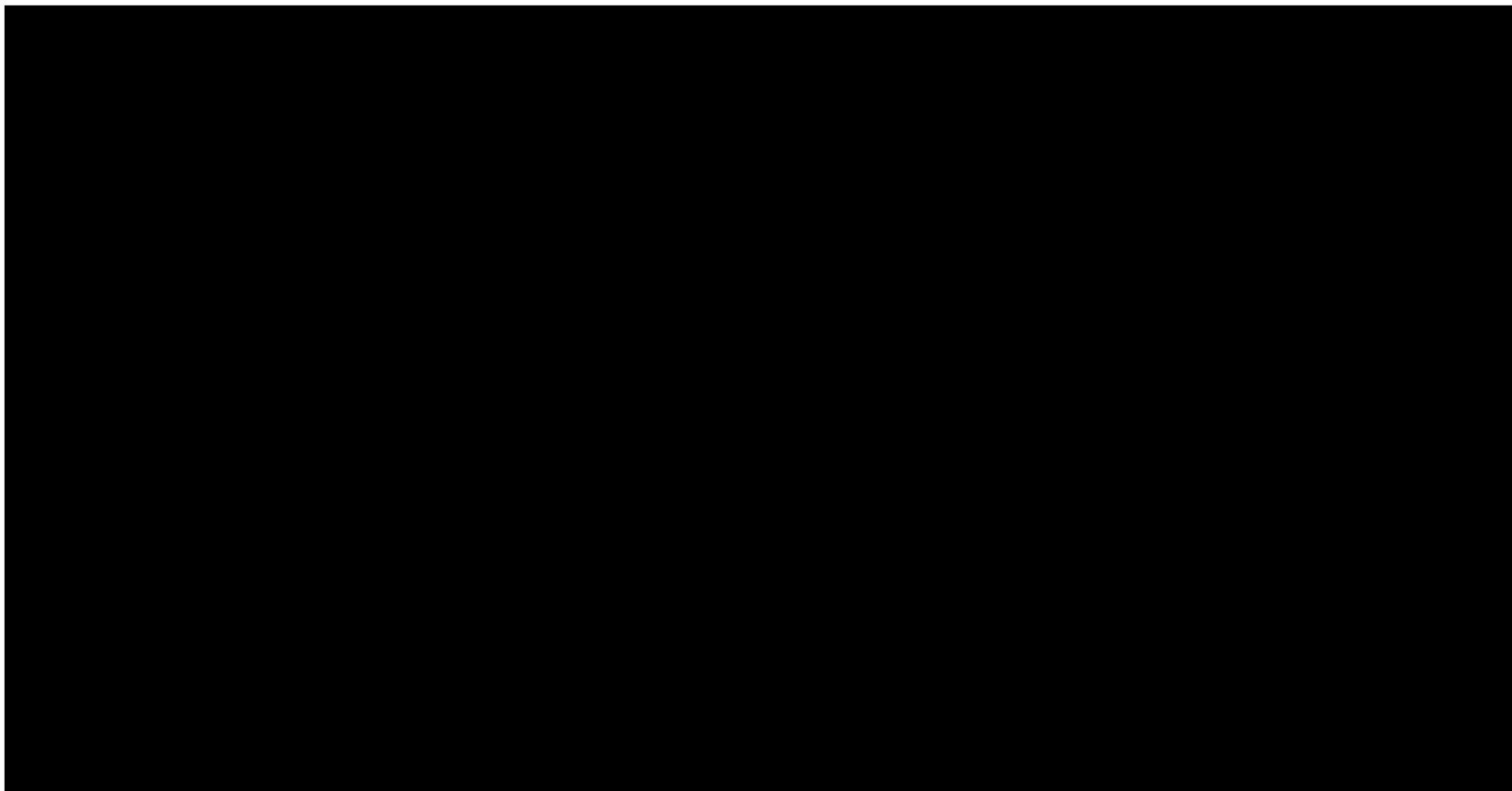
Status:
Page:

Final
856 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

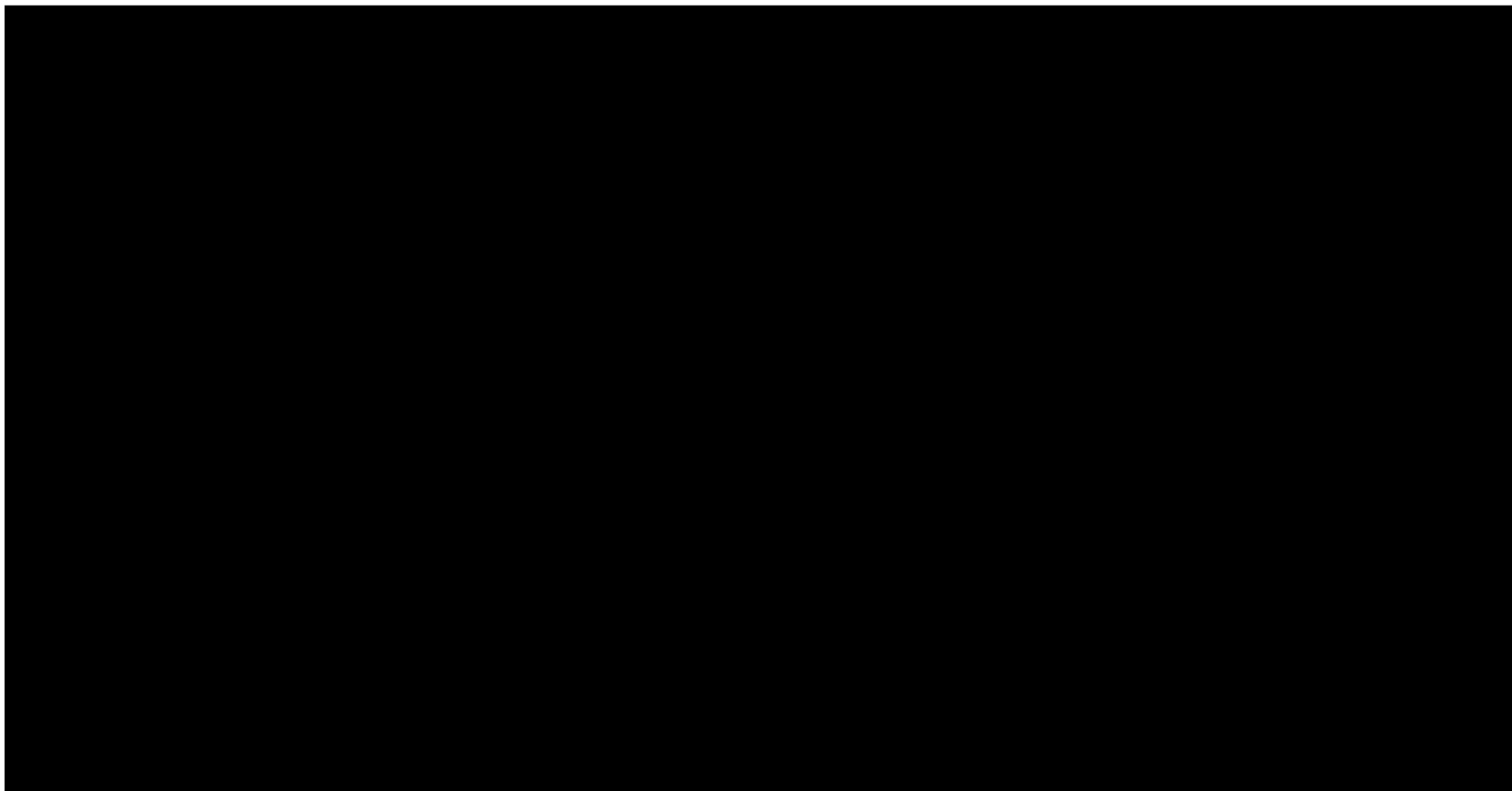
Status:
Page:

Final
857 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

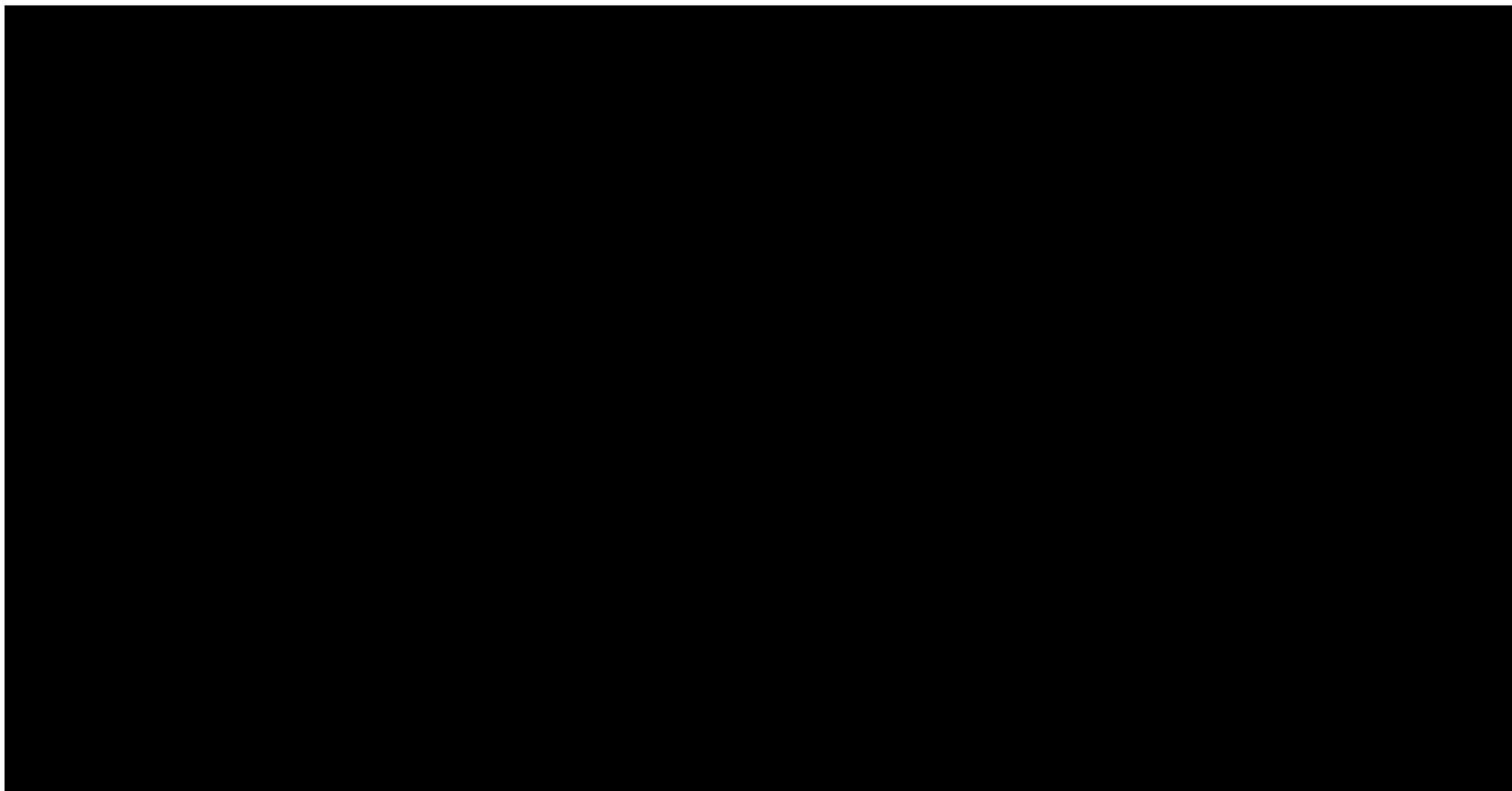
Status:
Page:

Final
858 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

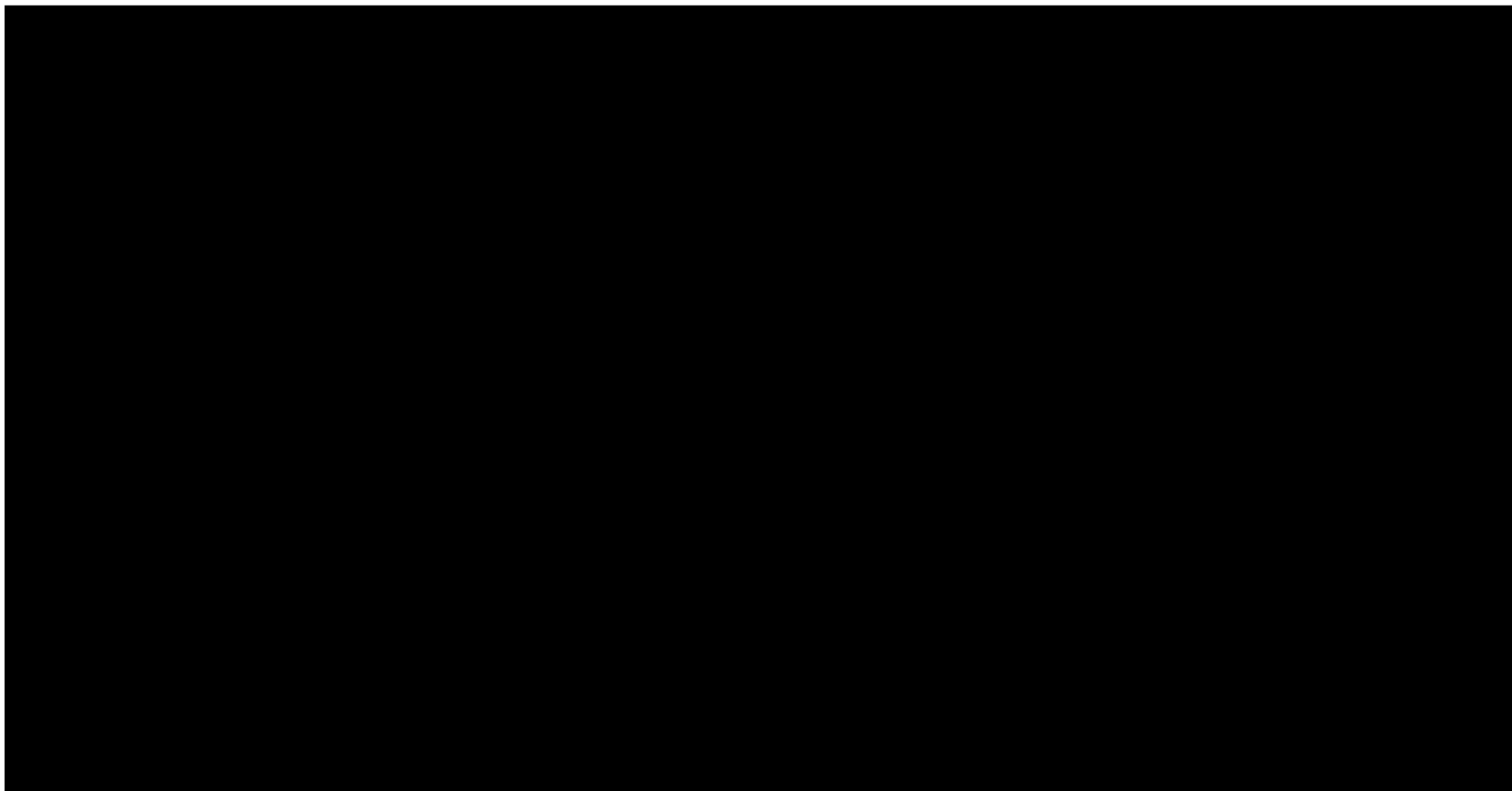
Status:
Page:

Final
859 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

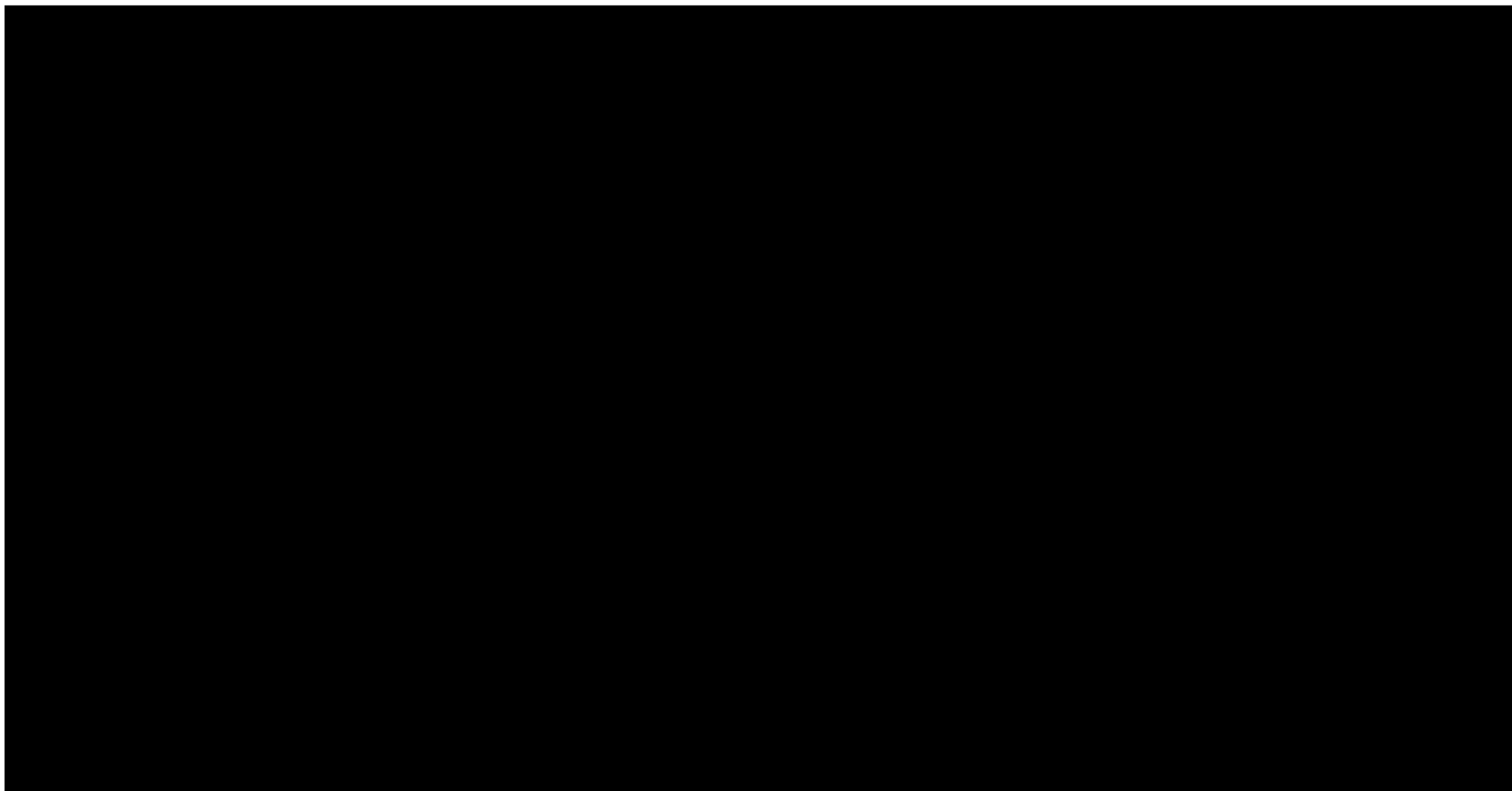
Status:
Page:

Final
860 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

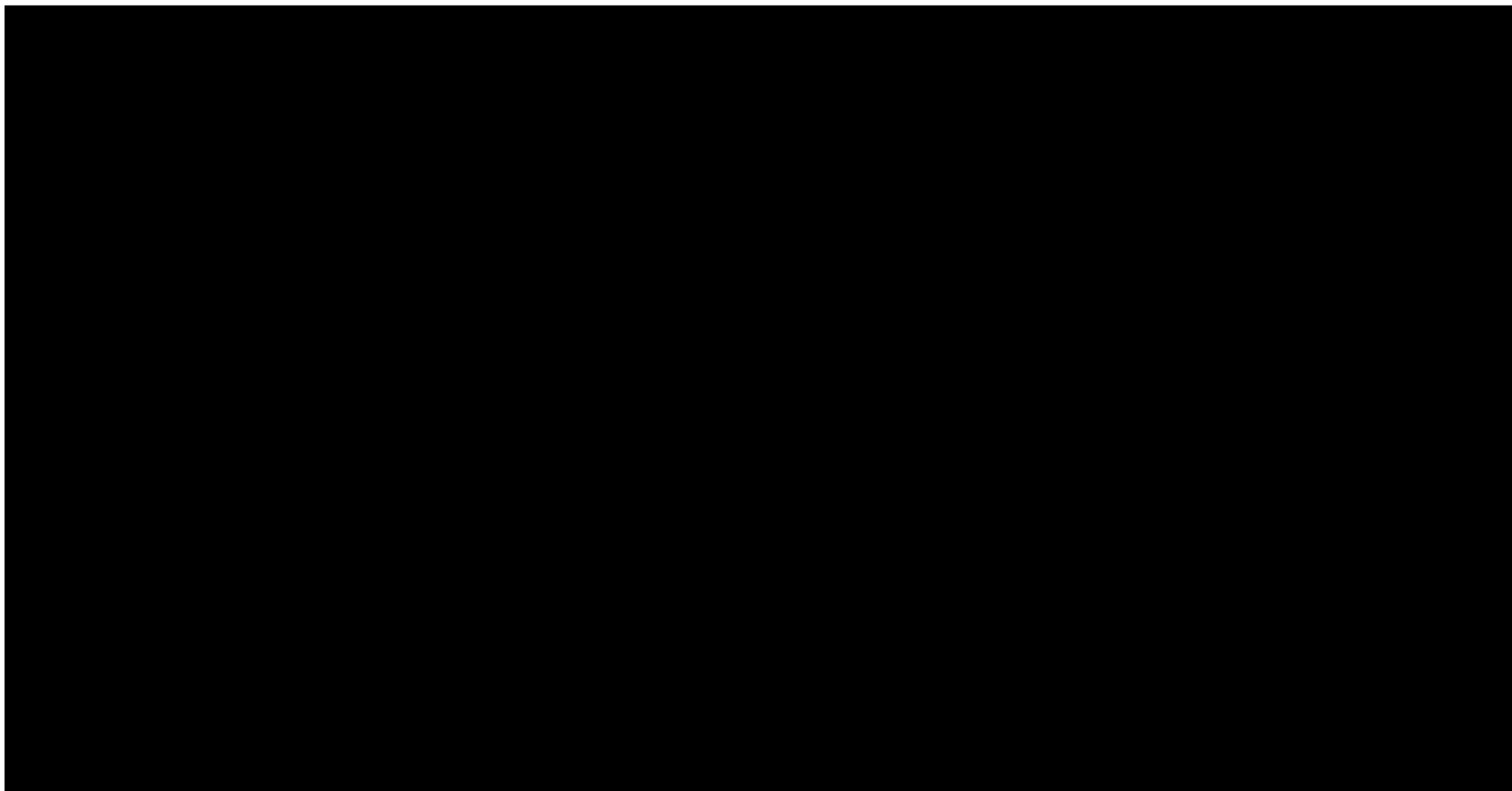
Status:
Page:

Final
861 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

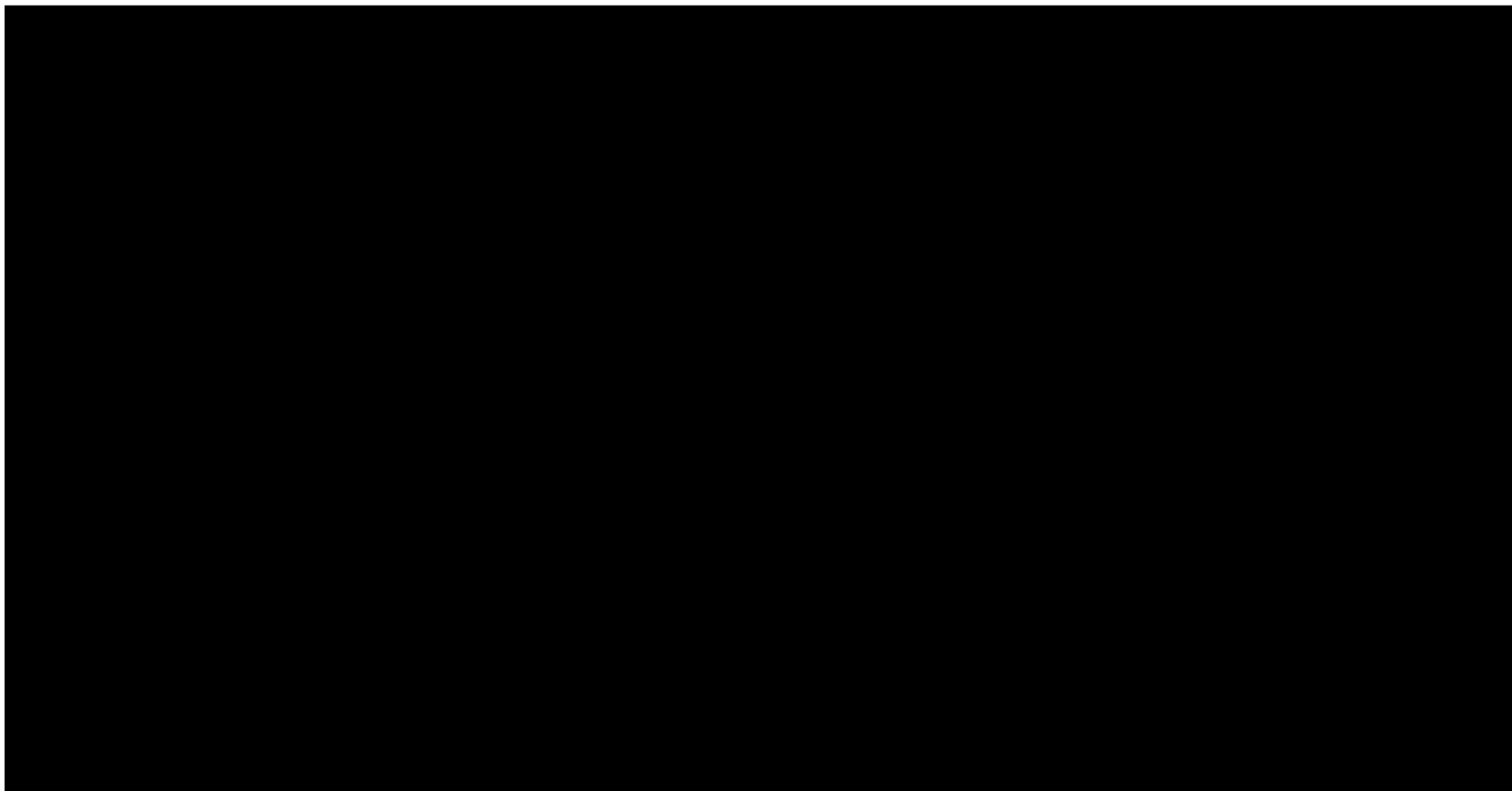
Status:
Page:

Final
862 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

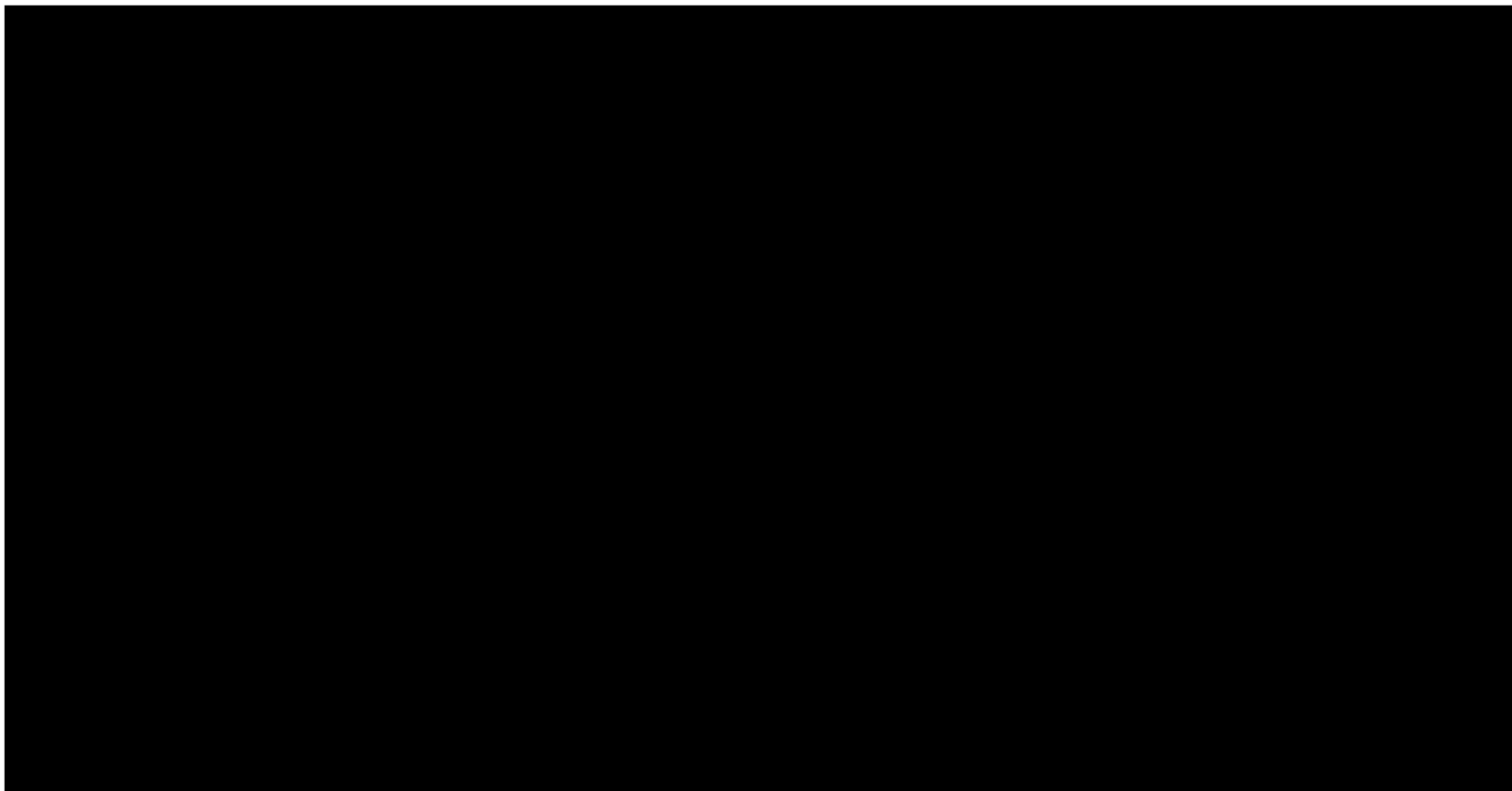
Status:
Page:

Final
863 of 1733

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



14.3.5 Displays of Laboratory Values

14.3.5.1: Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Albumin serum(g/dL)			
Visit 1			
N	362	180	542
Mean (SD)	4.4 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.7 ; 5.3	3.7 ; 5.1	3.7 ; 5.3
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	4.4 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.5 ; 5.2	3.6 ; 5.0	3.5 ; 5.2
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	4.4 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.5 ; 5.2	3.6 ; 5.0	3.5 ; 5.2

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:29 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Alanine aminotransferase serum(U/L)			
Visit 1			
N	362	180	542
Mean (SD)	23 (14)	23 (13)	23 (13)
Median	19	19	19
Min ; Max	5 ; 117	6 ; 92	5 ; 117
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	23 (15)	23 (12)	23 (14)
Median	18	20	19
Min ; Max	6 ; 134	6 ; 74	6 ; 134
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	23 (15)	24 (20)	23 (17)
Median	18	20	19
Min ; Max	6 ; 134	6 ; 234	6 ; 234

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:29 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Alkaline phosphatase serum(U/L)			
Visit 1			
N	362	180	542
Mean (SD)	78 (26)	78 (26)	78 (26)
Median	75	72	74
Min ; Max	28 ; 296	38 ; 194	28 ; 296
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	77 (26)	79 (25)	78 (25)
Median	73	75	74
Min ; Max	29 ; 231	34 ; 185	29 ; 231
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	77 (25)	79 (25)	78 (25)
Median	72	75	73
Min ; Max	29 ; 231	33 ; 185	29 ; 231

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:29 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Creatinine serum(umol/L)			
Visit 1			
N	362	180	542
Mean (SD)	78 (16)	78 (18)	78 (17)
Median	77	76	77
Min ; Max	46 ; 176	25 ; 156	25 ; 176
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	77 (15)	77 (17)	77 (16)
Median	76	75	76
Min ; Max	34 ; 168	43 ; 130	34 ; 168
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	77 (16)	78 (19)	77 (17)
Median	75	76	75
Min ; Max	34 ; 168	43 ; 177	34 ; 177

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:29 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Potassium serum (mmol/L)			
Visit 1			
N	362	180	542
Mean (SD)	4.5 (0.4)	4.5 (0.4)	4.5 (0.4)
Median	4.4	4.5	4.4
Min ; Max	3.4 ; 6.0	3.5 ; 5.7	3.4 ; 6.0
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	4.5 (0.5)	4.5 (0.4)	4.5 (0.4)
Median	4.5	4.4	4.4
Min ; Max	2.9 ; 7.0	3.4 ; 6.3	2.9 ; 7.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	4.5 (0.5)	4.5 (0.4)	4.5 (0.4)
Median	4.5	4.4	4.4
Min ; Max	2.9 ; 7.0	3.4 ; 6.3	2.9 ; 7.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:29 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Aspartate aminotransferase serum(U/L)			
Visit 1			
N	362	180	542
Mean (SD)	22 (9)	22 (11)	22 (10)
Median	20	20	20
Min ; Max	10 ; 97	9 ; 113	9 ; 113
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	22 (12)	22 (9)	22 (11)
Median	19	21	19
Min ; Max	11 ; 152	9 ; 60	9 ; 152
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	22 (12)	22 (8)	22 (11)
Median	19	20	19
Min ; Max	11 ; 152	9 ; 60	9 ; 152

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:29 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Sodium serum (mmol/L)			
Visit 1			
N	362	180	542
Mean (SD)	140 (3)	140 (3)	140 (3)
Median	140	139	139
Min ; Max	129 ; 151	131 ; 148	129 ; 151
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	141 (3)	141 (3)	141 (3)
Median	141	141	141
Min ; Max	132 ; 156	129 ; 152	129 ; 156
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	141 (3)	140 (3)	141 (3)
Median	141	141	141
Min ; Max	132 ; 156	129 ; 152	129 ; 156

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:29 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Total Protein serum(g/dL)			
Visit 1			
N	362	180	542
Mean (SD)	7.1 (0.4)	7.1 (0.4)	7.1 (0.4)
Median	7.1	7.1	7.1
Min ; Max	5.9 ; 8.6	6.1 ; 8.1	5.9 ; 8.6
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	7.0 (0.4)	7.0 (0.4)	7.0 (0.4)
Median	7.0	7.0	7.0
Min ; Max	6.0 ; 9.5	6.0 ; 8.1	6.0 ; 9.5
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	7.0 (0.4)	7.0 (0.4)	7.0 (0.4)
Median	7.0	7.0	7.0
Min ; Max	6.0 ; 9.5	6.0 ; 8.1	6.0 ; 9.5

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:29 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Total Bilirubin serum(umol/L)			
Visit 1			
N	362	179	541
Mean (SD)	9.0 (5.6)	7.9 (3.7)	8.7 (5.1)
Median	7.0	7.0	7.0
Min ; Max	2.0 ; 39.0	2.0 ; 29.0	2.0 ; 39.0
Visit 28 (Week 26)			
N	319	157	476
Mean (SD)	8.2 (4.0)	7.8 (3.7)	8.1 (3.9)
Median	7.0	7.0	7.0
Min ; Max	2.0 ; 27.0	3.0 ; 32.0	2.0 ; 32.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	8.4 (4.6)	7.7 (3.6)	8.2 (4.3)
Median	7.0	7.0	7.0
Min ; Max	2.0 ; 43.0	3.0 ; 32.0	2.0 ; 43.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:29 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

14.3.5.2: Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Albumin Serum(g/dL)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	-0.0 (0.2)	-0.0 (0.2)	-0.0 (0.2)
Median	0.0	0.0	0.0
Min ; Max	-0.8 ; 0.7	-0.7 ; 0.7	-0.8 ; 0.7
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	-0.0 (0.2)	-0.0 (0.2)	-0.0 (0.2)
Median	0.0	0.0	0.0
Min ; Max	-0.8 ; 0.7	-0.7 ; 0.7	-0.8 ; 0.7

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:35 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Alanine aminotransferase Serum(U/L)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	-0.2 (14.3)	-0.2 (9.8)	-0.2 (13.0)
Median	0.0	0.0	0.0
Min ; Max	-97.0 ; 96.0	-51.0 ; 35.0	-97.0 ; 96.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	-0.2 (13.9)	0.8 (18.9)	0.1 (15.7)
Median	0.0	0.0	0.0
Min ; Max	-97.0 ; 96.0	-51.0 ; 220.0	-97.0 ; 220.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:35 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Alkaline Phosphatase Serum(U/L)			
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	-1.2 (15.4)	0.1 (16.6)	-0.8 (15.8)
Median	-1.0	1.0	-1.0
Min ; Max	-65.0 ; 70.0	-68.0 ; 49.0	-68.0 ; 70.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	-1.4 (15.2)	0.5 (16.0)	-0.7 (15.5)
Median	-1.0	1.0	0.0
Min ; Max	-65.0 ; 70.0	-68.0 ; 49.0	-68.0 ; 70.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:35 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Creatinine Serum(umol/L)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	-1.2 (7.3)	-0.5 (8.7)	-0.9 (7.8)
Median	-1.0	0.0	-1.0
Min ; Max	-27.0 ; 20.0	-37.0 ; 18.0	-37.0 ; 20.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	-1.0 (7.1)	0.0 (9.8)	-0.7 (8.1)
Median	0.0	0.0	0.0
Min ; Max	-27.0 ; 20.0	-37.0 ; 59.0	-37.0 ; 59.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:35 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Potassium Serum(mmol/L)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	0.0 (0.5)	-0.0 (0.5)	0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-1.6 ; 2.6	-1.7 ; 1.8	-1.7 ; 2.6
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	0.0 (0.5)	-0.0 (0.5)	0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-1.6 ; 2.6	-1.7 ; 1.8	-1.7 ; 2.6

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:35 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Aspartate aminotransferase Serum(U/L)			
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	0.4 (11.7)	-0.4 (10.6)	0.1 (11.3)
Median	0.0	0.0	0.0
Min ; Max	-71.0 ; 99.0	-98.0 ; 43.0	-98.0 ; 99.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	0.3 (11.2)	-0.5 (10.1)	0.0 (10.9)
Median	0.0	0.0	0.0
Min ; Max	-71.0 ; 99.0	-98.0 ; 43.0	-98.0 ; 99.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:35 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Sodium Serum(umol/L)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	1.6 (3.4)	1.2 (3.1)	1.5 (3.3)
Median	2.0	1.0	1.0
Min ; Max	-9.0 ; 17.0	-13.0 ; 14.0	-13.0 ; 17.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	1.4 (3.4)	0.9 (3.2)	1.3 (3.3)
Median	1.0	1.0	1.0
Min ; Max	-9.0 ; 17.0	-13.0 ; 14.0	-13.0 ; 17.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:35 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Total Protein Serum(g/dL)			
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	-0.1 (0.4)	-0.1 (0.4)	-0.1 (0.4)
Median	-0.1	-0.2	-0.1
Min ; Max	-1.3 ; 1.3	-1.3 ; 0.9	-1.3 ; 1.3
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	-0.1 (0.4)	-0.1 (0.4)	-0.1 (0.4)
Median	-0.1	-0.1	-0.1
Min ; Max	-1.3 ; 1.3	-1.3 ; 0.9	-1.3 ; 1.3

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:35 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Bilirubin Serum (mmol/L)			
Visit 28 (Week 26)			
N	319	156	475
Mean (SD)	-0.8 (3.8)	-0.3 (3.7)	-0.6 (3.7)
Median	0.0	0.0	0.0
Min ; Max	-21.0 ; 9.0	-16.0 ; 12.0	-21.0 ; 12.0
Visit 28 (Week 26) (LOCF)			
N	362	179	541
Mean (SD)	-0.6 (3.7)	-0.1 (3.6)	-0.5 (3.7)
Median	0.0	0.0	0.0
Min ; Max	-21.0 ; 12.0	-16.0 ; 12.0	-21.0 ; 12.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:35 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

14.3.5.3: Biochemistry by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Alanine aminotransferase serum (U/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	2 (0.6)	0	2 (0.4)
Normal	337 (93.1)	167 (92.8)	504 (93.0)
High	23 (6.4)	13 (7.2)	36 (6.6)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	298 (92.8)	148 (94.3)	446 (93.3)
High	23 (7.2)	9 (5.7)	32 (6.7)
Visit 28 Week 26(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	336 (92.8)	169 (93.9)	505 (93.2)
High	26 (7.2)	11 (6.1)	37 (6.8)
Albumin serum (g/dL)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	360 (99.4)	180 (100.0)	540 (99.6)
High	2 (0.6)	0	2 (0.4)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	320 (99.7)	157 (100.0)	477 (99.8)
High	1 (0.3)	0	1 (0.2)
Visit 28 Week 26(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	361 (99.7)	180 (100.0)	541 (99.8)
High	1 (0.3)	0	1 (0.2)
Alkaline phosphatase serum (U/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	5 (1.4)	2 (1.1)	7 (1.3)
Normal	329 (90.9)	160 (88.9)	489 (90.2)
High	28 (7.7)	18 (10.0)	46 (8.5)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Low	10 (3.1)	5 (3.2)	15 (3.1)
Normal	284 (88.8)	137 (87.3)	421 (88.3)
High	26 (8.1)	15 (9.6)	41 (8.6)
Visit 28 Week 26(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)

N = Number of Subjects

Biochemistry by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Low	10 (2.8)	6 (3.3)	16 (3.0)
Normal	323 (89.2)	156 (86.7)	479 (88.4)
High	29 (8.0)	18 (10.0)	47 (8.7)
Aspartate aminotransferase serum (U/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	0	2 (1.1)	2 (0.4)
Normal	350 (96.7)	171 (95.0)	521 (96.1)
High	12 (3.3)	7 (3.9)	19 (3.5)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Low	0	1 (0.6)	1 (0.2)
Normal	309 (96.6)	150 (95.5)	459 (96.2)
High	11 (3.4)	6 (3.8)	17 (3.6)
Visit 28 Week 26(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	0	1 (0.6)	1 (0.2)
Normal	348 (96.1)	173 (96.1)	521 (96.1)
High	14 (3.9)	6 (3.3)	20 (3.7)
Creatinine serum (umol/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	0	1 (0.6)	1 (0.2)
Normal	353 (97.5)	169 (93.9)	522 (96.3)
High	9 (2.5)	10 (5.6)	19 (3.5)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	314 (97.8)	154 (98.1)	468 (97.9)
High	6 (1.9)	3 (1.9)	9 (1.9)
Visit 28 Week 26(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	354 (97.8)	174 (96.7)	528 (97.4)
High	7 (1.9)	6 (3.3)	13 (2.4)
Potassium serum (mmol/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	1 (0.6)	2 (0.4)
Normal	355 (98.1)	177 (98.3)	532 (98.2)
High	6 (1.7)	2 (1.1)	8 (1.5)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	1 (0.3)	2 (1.3)	3 (0.6)
Normal	311 (96.9)	153 (97.5)	464 (97.1)

N = Number of Subjects

Biochemistry by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
High	9 (2.8)	2 (1.3)	11 (2.3)
Visit 28 Week 26(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	2 (1.1)	3 (0.6)
Normal	352 (97.2)	175 (97.2)	527 (97.2)
High	9 (2.5)	3 (1.7)	12 (2.2)
Sodium serum (mmol/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	4 (1.1)	1 (0.6)	5 (0.9)
Normal	355 (98.1)	177 (98.3)	532 (98.2)
High	3 (0.8)	2 (1.1)	5 (0.9)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	0	2 (1.3)	2 (0.4)
Normal	312 (97.2)	154 (98.1)	466 (97.5)
High	9 (2.8)	1 (0.6)	10 (2.1)
Visit 28 Week 26(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	0	2 (1.1)	2 (0.4)
Normal	353 (97.5)	177 (98.3)	530 (97.8)
High	9 (2.5)	1 (0.6)	10 (1.8)
Total Bilirubin serum (umol/L)			
Visit 1			
N	362 (100.0)	179 (100.0)	541 (100.0)
Low	1 (0.3)	3 (1.7)	4 (0.7)
Normal	345 (95.3)	175 (97.8)	520 (96.1)
High	16 (4.4)	1 (0.6)	17 (3.1)
Visit 28 (Week 26)			
N	319 (100.0)	157 (100.0)	476 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	314 (98.4)	156 (99.4)	470 (98.7)
High	4 (1.3)	1 (0.6)	5 (1.1)
Visit 28 Week 26(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	353 (97.5)	179 (99.4)	532 (98.2)
High	8 (2.2)	1 (0.6)	9 (1.7)
Total Protein serum (g/dL)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	360 (99.4)	180 (100.0)	540 (99.6)
High	1 (0.3)	0	1 (0.2)

N = Number of Subjects

Biochemistry by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Normal	318 (99.4)	157 (100.0)	475 (99.6)
High	2 (0.6)	0	2 (0.4)
Visit 28 Week 26 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	360 (99.4)	180 (100.0)	540 (99.6)
High	2 (0.6)	0	2 (0.4)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:19:40 - tsum_lab_summary.sas/t_biochem_sum_sas.txt

14.3.5.4: Biochemistry – Shift Table – Baseline to Week 26 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 28 (Week 26)								
Alanine aminotransferase serum (U/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	2 (0.6)	282 (77.9)	14 (3.9)	0 (0.0)	0 (0.0)	142 (78.9)	6 (3.3)	0 (0.0)
High	0 (0.0)	17 (4.7)	6 (1.7)	0 (0.0)	0 (0.0)	4 (2.2)	5 (2.8)	0 (0.0)
Missing	0 (0.0)	38 (10.5)	3 (0.8)	0 (0.0)	0 (0.0)	21 (11.7)	2 (1.1)	0 (0.0)
Albumin serum (g/dL)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	319 (88.1)	1 (0.3)	0 (0.0)	0 (0.0)	157 (87.2)	0 (0.0)	0 (0.0)
High	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	41 (11.3)	0 (0.0)	0 (0.0)	0 (0.0)	23 (12.8)	0 (0.0)	0 (0.0)
Alkaline phosphatase serum (U/L)								
Low	3 (0.8)	7 (1.9)	0 (0.0)	0 (0.0)	1 (0.6)	4 (2.2)	0 (0.0)	0 (0.0)
Normal	2 (0.6)	274 (75.7)	8 (2.2)	0 (0.0)	0 (0.0)	131 (72.8)	6 (3.3)	0 (0.0)
High	0 (0.0)	10 (2.8)	16 (4.4)	0 (0.0)	0 (0.0)	5 (2.8)	10 (5.6)	0 (0.0)
Missing	0 (0.0)	38 (10.5)	4 (1.1)	0 (0.0)	1 (0.6)	20 (11.1)	2 (1.1)	0 (0.0)
Aspartate aminotransferase serum (U/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	302 (83.4)	7 (1.9)	0 (0.0)	1 (0.6)	144 (80.0)	5 (2.8)	0 (0.0)
High	0 (0.0)	8 (2.2)	3 (0.8)	0 (0.0)	0 (0.0)	4 (2.2)	2 (1.1)	0 (0.0)
Missing	0 (0.0)	40 (11.0)	2 (0.6)	0 (0.0)	0 (0.0)	23 (12.8)	0 (0.0)	0 (0.0)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:03 - t_lab_shift.sas/t_biochem_shift_w26_sas.txt

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
888 of 1733

Novo Nordisk

Biochemistry - Shift Table - Baseline to Week 26 - Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 28 (Week 26)								
Creatinine serum (umol/L)								
Low	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	311 (85.9)	3 (0.8)	0 (0.0)	0 (0.0)	149 (82.8)	5 (2.8)	0 (0.0)
High	0 (0.0)	1 (0.3)	5 (1.4)	0 (0.0)	0 (0.0)	1 (0.6)	2 (1.1)	0 (0.0)
Missing	0 (0.0)	40 (11.0)	1 (0.3)	0 (0.0)	1 (0.6)	19 (10.6)	3 (1.7)	0 (0.0)
Potassium serum (mmol/L)								
Low	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)
Normal	1 (0.3)	306 (84.5)	4 (1.1)	0 (0.0)	1 (0.6)	150 (83.3)	2 (1.1)	0 (0.0)
High	0 (0.0)	8 (2.2)	1 (0.3)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	40 (11.0)	1 (0.3)	0 (0.0)	0 (0.0)	23 (12.8)	0 (0.0)	0 (0.0)
Sodium serum (mmol/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)
Normal	3 (0.8)	306 (84.5)	3 (0.8)	0 (0.0)	1 (0.6)	153 (85.0)	0 (0.0)	0 (0.0)
High	0 (0.0)	9 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Missing	1 (0.3)	40 (11.0)	0 (0.0)	0 (0.0)	0 (0.0)	21 (11.7)	2 (1.1)	0 (0.0)
Total Bilirubin serum (umol/L)								
Low	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	305 (84.3)	9 (2.5)	0 (0.0)	2 (1.1)	153 (85.0)	0 (0.0)	1 (0.6)
High	0 (0.0)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Missing	0 (0.0)	40 (11.0)	3 (0.8)	0 (0.0)	1 (0.6)	22 (12.2)	0 (0.0)	0 (0.0)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:03 - t_lab_shift.sas/t_biochem_shift_w26_sas.txt

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0 | Status:
Page:

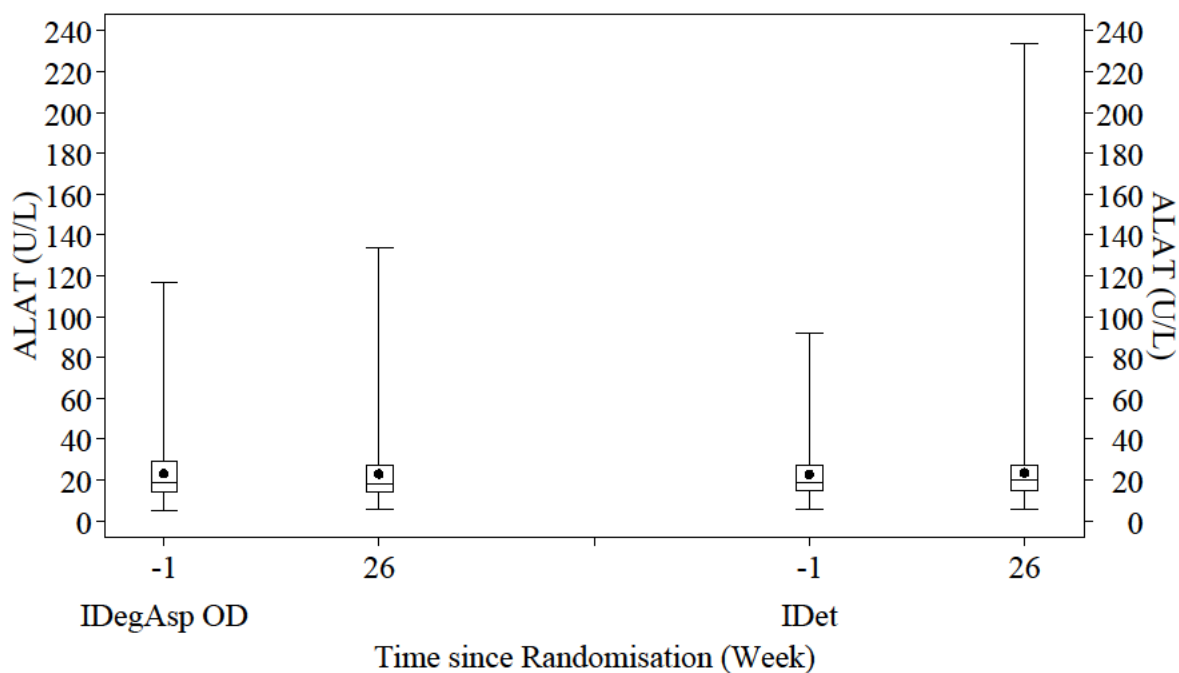
Final
889 of 1733 | **Novo Nordisk**

Biochemistry - Shift Table - Baseline to Week 26 - Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 28 (Week 26)								
Total Protein serum (g/dL)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	1 (0.3)	316 (87.3)	1 (0.3)	0 (0.0)	0 (0.0)	157 (87.2)	0 (0.0)	0 (0.0)
High	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	42 (11.6)	0 (0.0)	0 (0.0)	0 (0.0)	23 (12.8)	0 (0.0)	0 (0.0)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:03 - t_lab_shift.sas/t_biochem_shift_w26_sas.txt



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

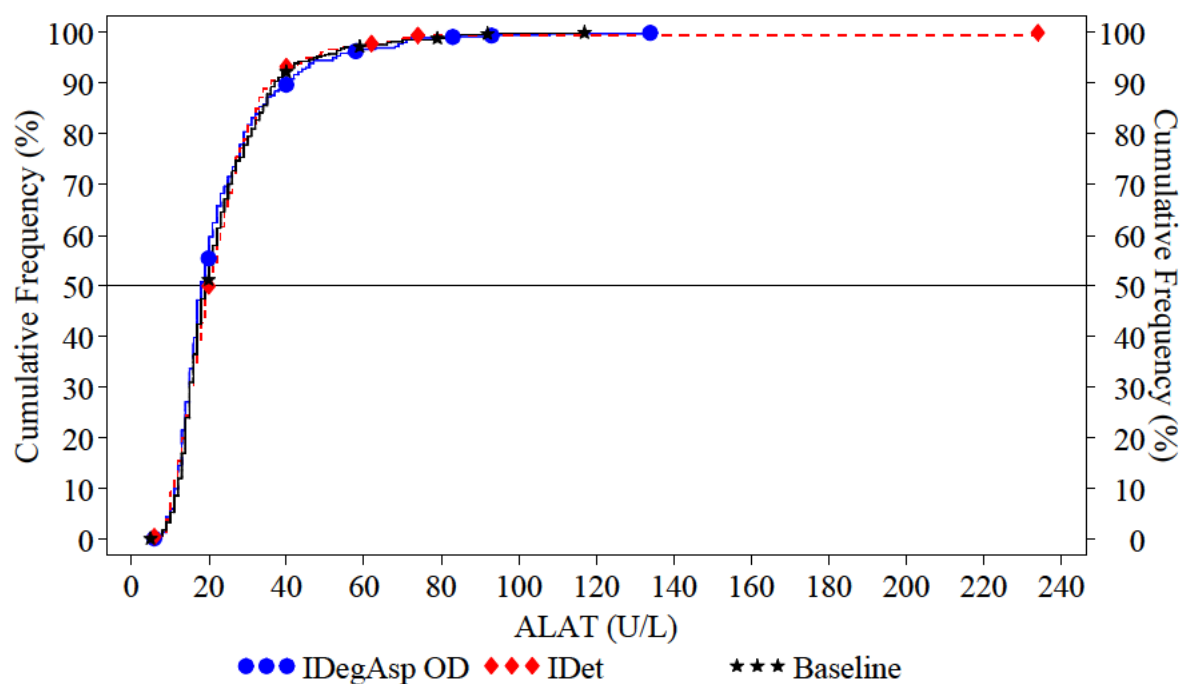
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-91)[6]; Female, Age(18-91)[6]

Upper ref.: Male, Age(18-91)[48]; Female, Age(18-91)[37]

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:58:42 - fbox_numfind_v01.sas/e_ala_amino_s_abs_box_locf_sas.cgm

14.3.5.5: Biochemistry - Alanine Amino Serum - Box Plot - Safety Analysis Set



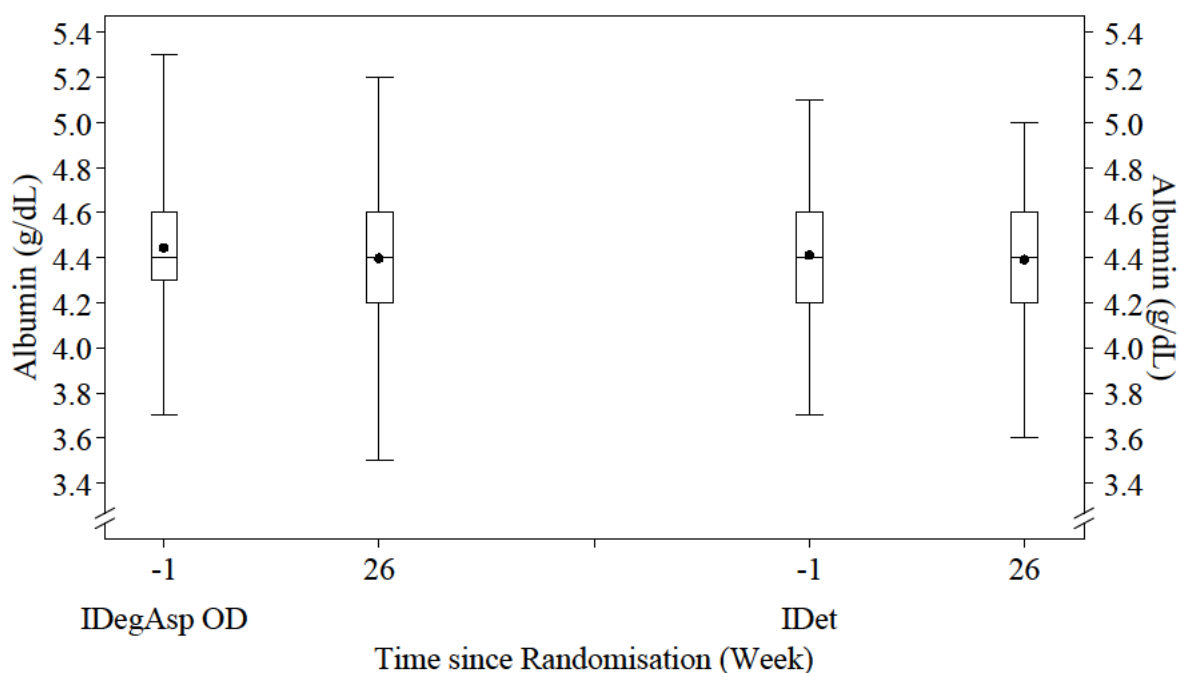
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-91)[6]; Female, Age(18-91)[6]

Upper ref.: Male, Age(18-91)[48]; Female, Age(18-91)[37]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:58:52 - fedist_numfind_v01.sas/e_ala_amino_s_abs_cdf_locf_sas.cgm

14.3.5.6: Biochemistry - Alanine Amino Serum after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

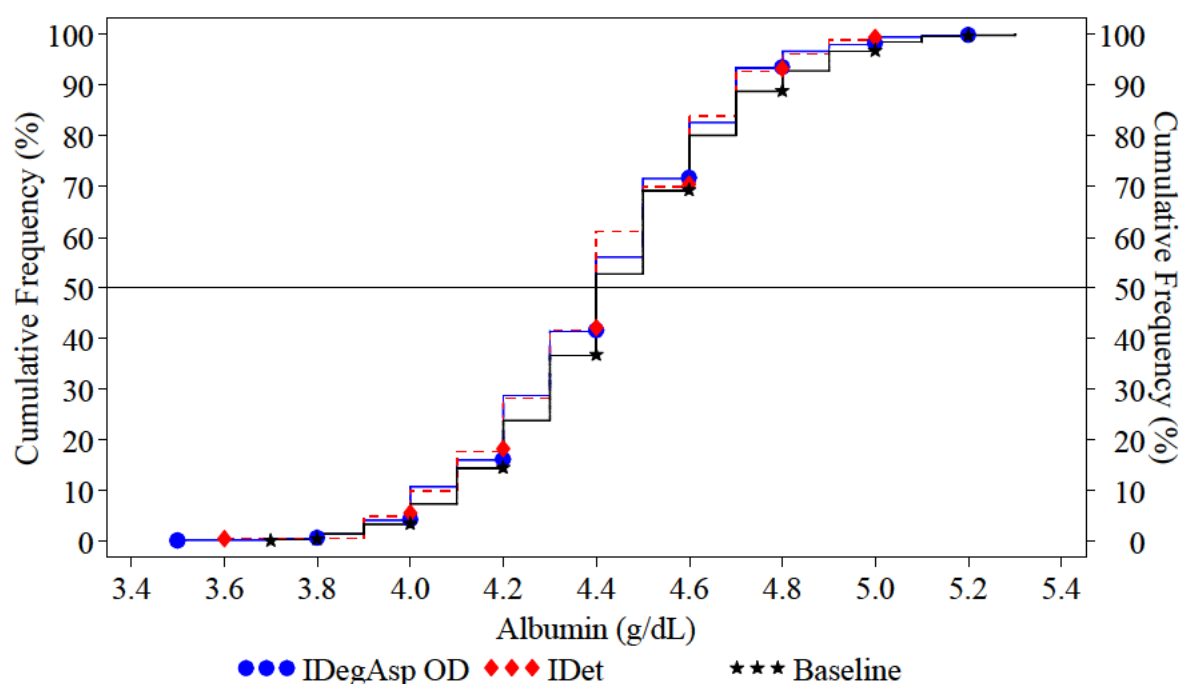
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[3.5], Age(66-91)[3.2]; Female, Age(18-66)[3.5], Age(66-91)[3.2]

Upper ref.: Male, Age(18-66)[5.3], Age(66-91)[4.6]; Female, Age(18-66)[5.3], Age(66-91)[4.6]

28APR2011:12:58:58 - fbox_numfind_v01.sas/e_albu_s_abs_box_locf_sas.cgm
nn5401/nn5401-3594/freeze_ctr_05/stats

14.3.5.7: Biochemistry - Albumin Serum - Box Plot - Safety Analysis Set



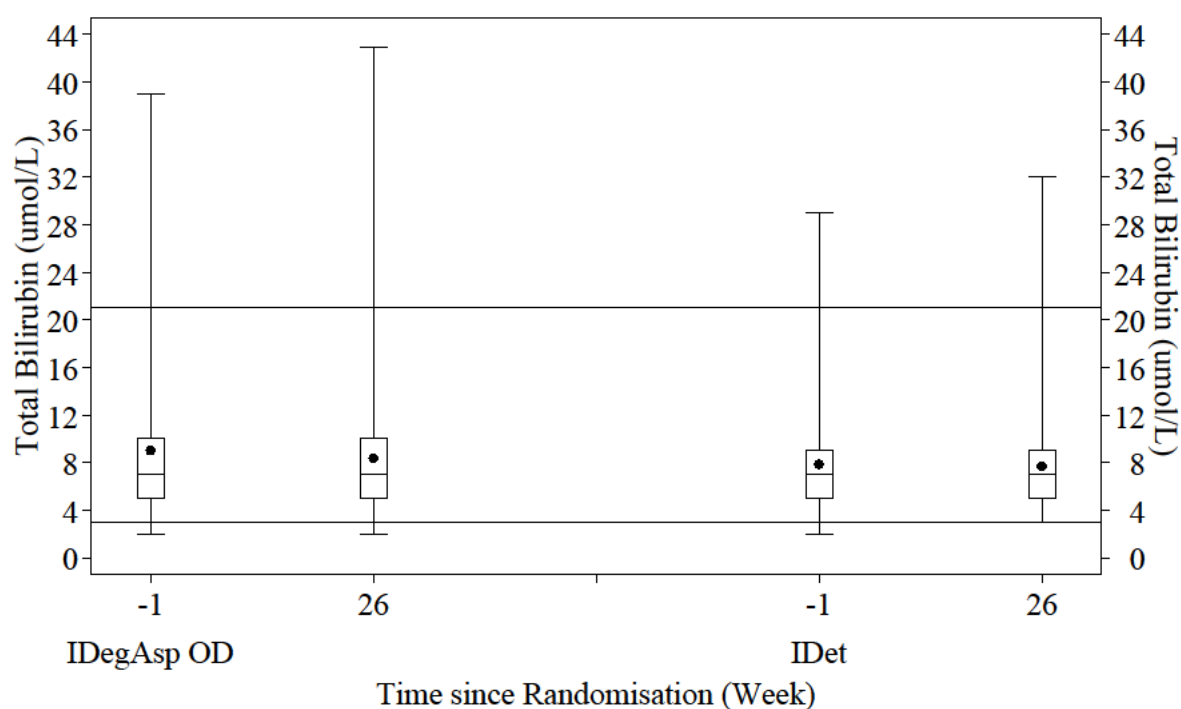
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[3.5], Age(66-91)[3.2]; Female, Age(18-66)[3.5], Age(66-91)[3.2]

Upper ref.: Male, Age(18-66)[5.3], Age(66-91)[4.6]; Female, Age(18-66)[5.3], Age(66-91)[4.6]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:59:09 - fedist_numfind_v01.sas/e_albu_s_abs_cdf_locf_sas.cgm

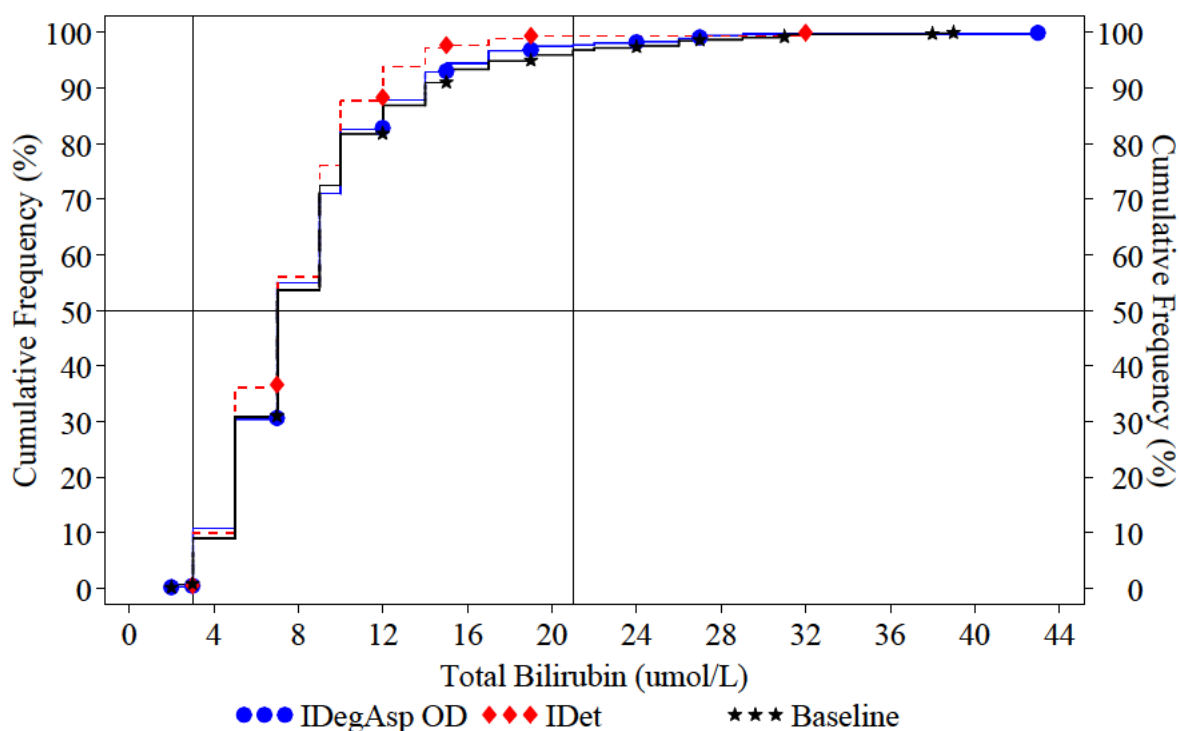
14.3.5.8: Biochemistry - Albumin Serum after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:12:59:15 - fbox_numfind_v01.sas/e_t_bilirubin_abs_box_locf_sas.cgm

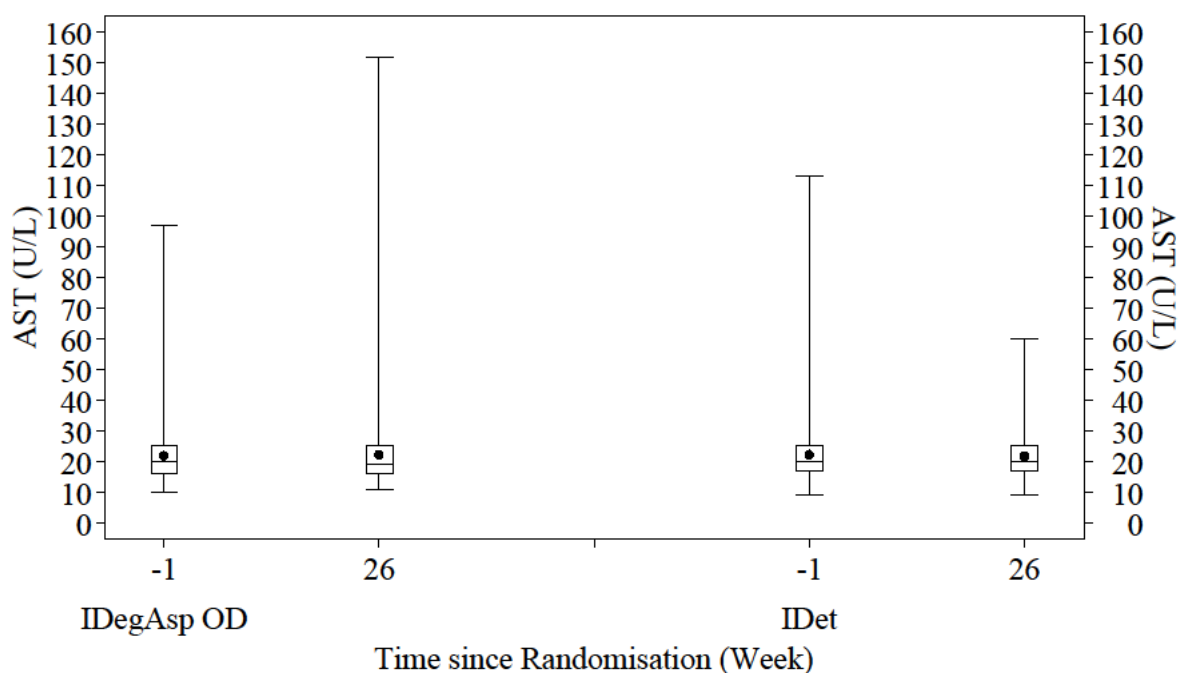
14.3.5.9: Biochemistry - Total Bilirubin - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:59:25 - fedist_numfind_v01.sas/e_t_bilirubin_abs_cdf_locf_sas.cgm

14.3.5.10: Biochemistry - Total Bilirubin after 26 Weeks of Treatment – Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

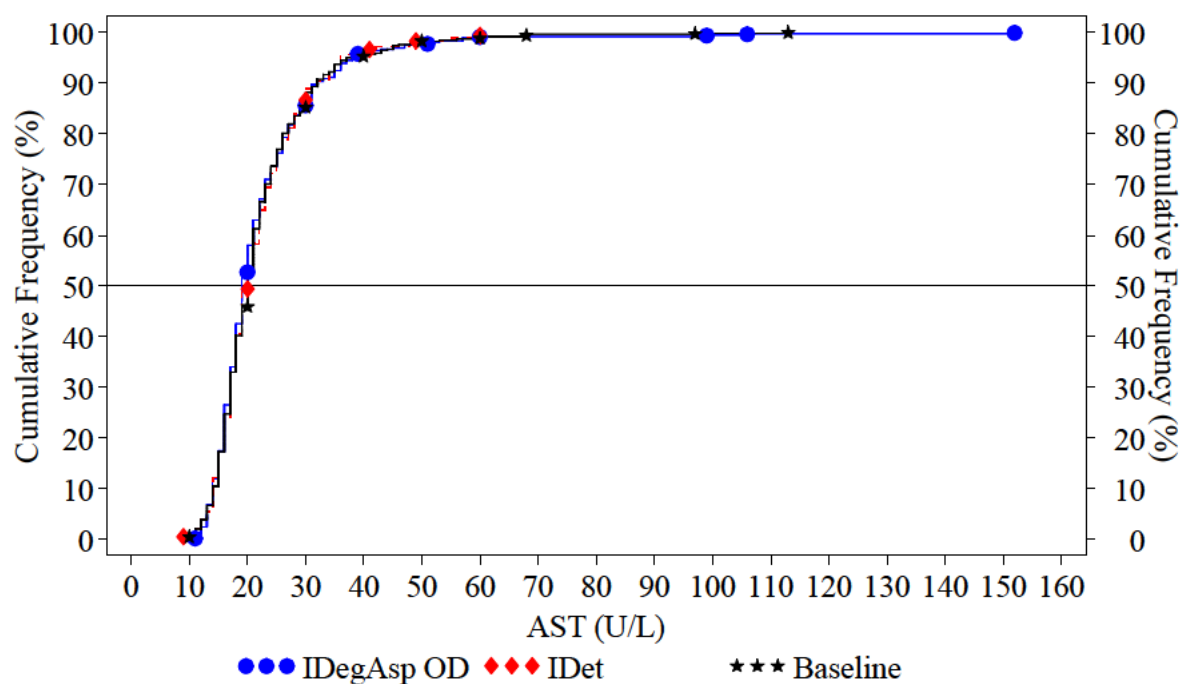
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-91)[10]; Female, Age(18-91)[10]

Upper ref.: Male, Age(18-91)[45]; Female, Age(18-91)[36]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:59:31 - fbox_numfind_v01.sas/e_ast_abs_box_locf_sas.cgm

14.3.5.11: Biochemistry - AST - Box Plot - Safety Analysis Set



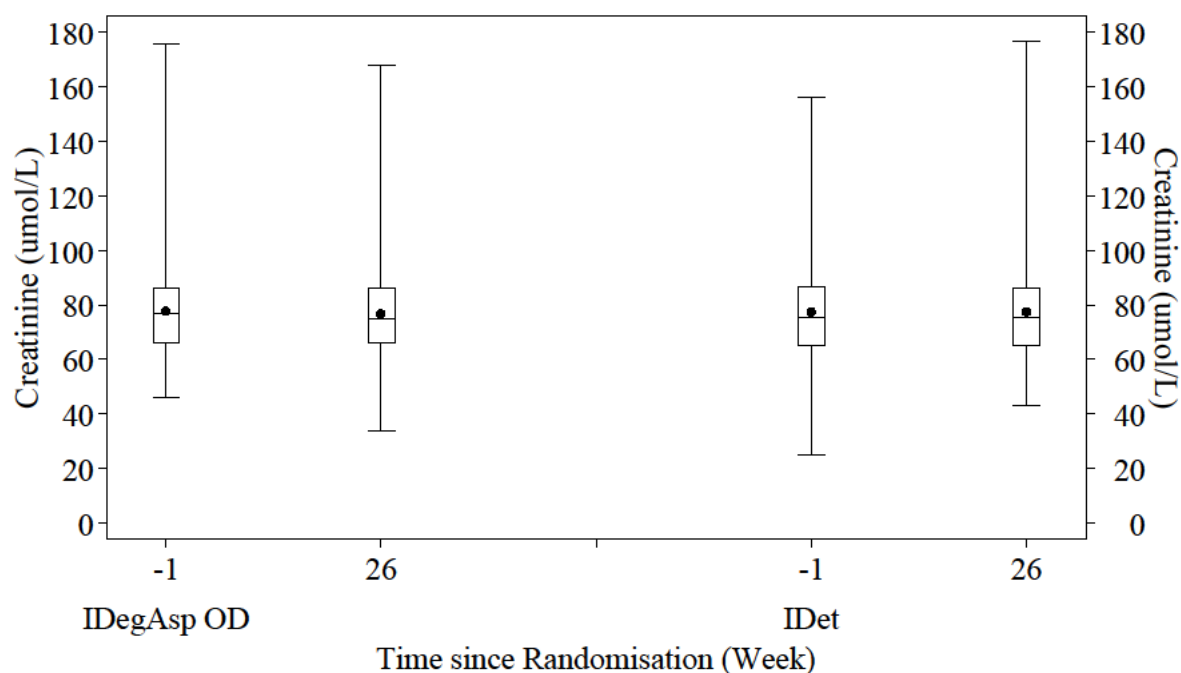
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-91)[10]; Female, Age(18-91)[10]

Upper ref.: Male, Age(18-91)[45]; Female, Age(18-91)[36]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:59:42 - fedist_numfind_v01.sas/e_ast_abs_cdf_locf_sas.cgm

14.3.5.12: Biochemistry - AST after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

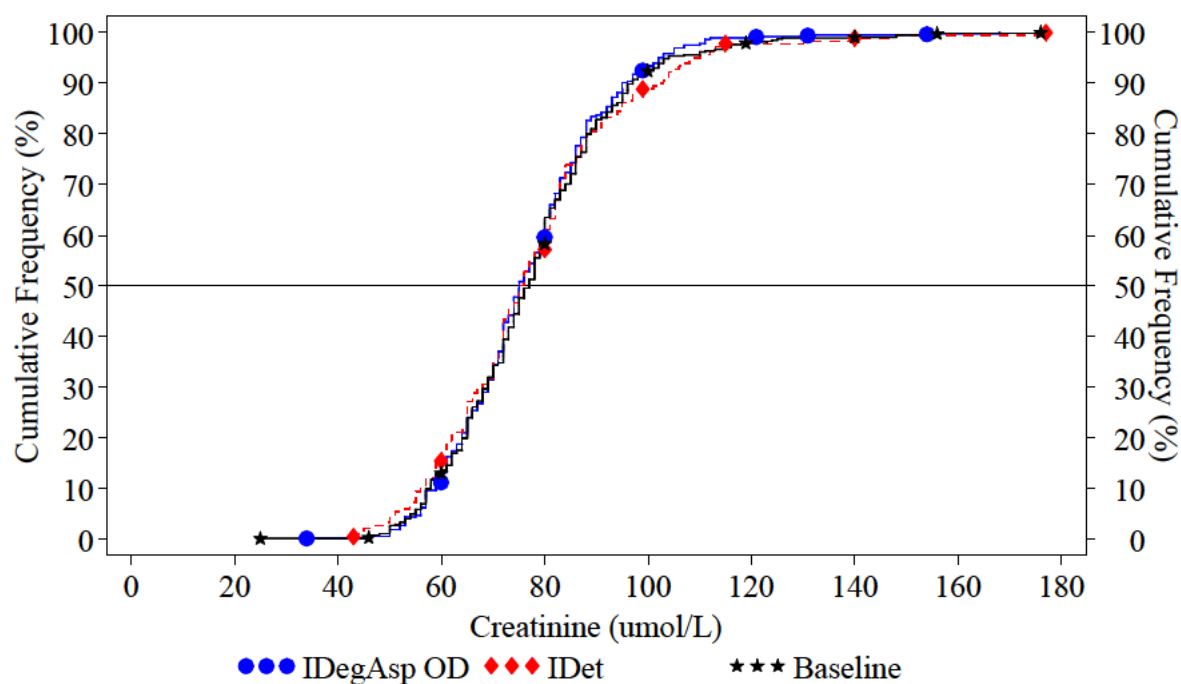
SAFETY: LOCF imputed data

Lower ref.: Male, Age(13-110)[44]; Female, Age(13-110)[35]

Upper ref.: Male, Age(13-110)[115]; Female, Age(13-110)[106]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:59:48 - fbox_numfind_v01.sas/e_crea_abs_box_locf_sas.cgm

14.3.5.13: Biochemistry - Creatinine - Box Plot - Safety Analysis Set



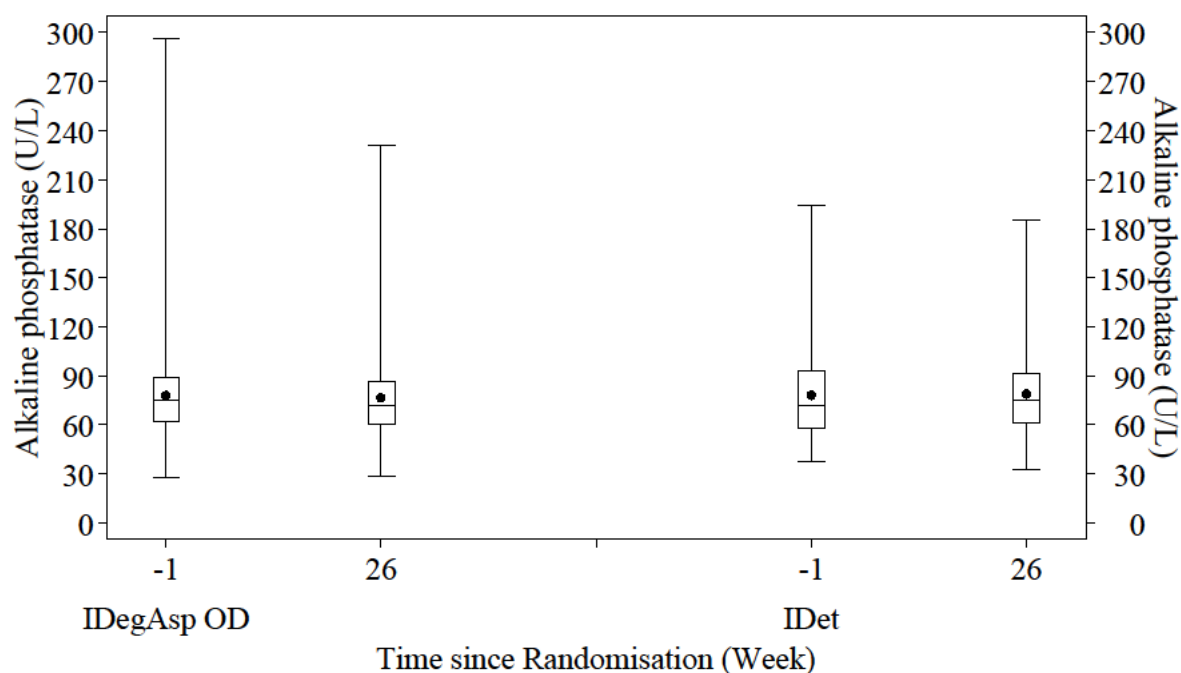
SAFETY; LOCF imputed data

Lower ref.: Male, Age (13-110) [44]; Female, Age (13-110) [35]

Upper ref.: Male, Age (13-110) [115]; Female, Age (13-110) [106]

np5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:12:59:58 - fedist_numfind_v01.sas/e_crea_abs_cdf_locf_sas.cgm

14.3.5.14: Biochemistry - Creatinine after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

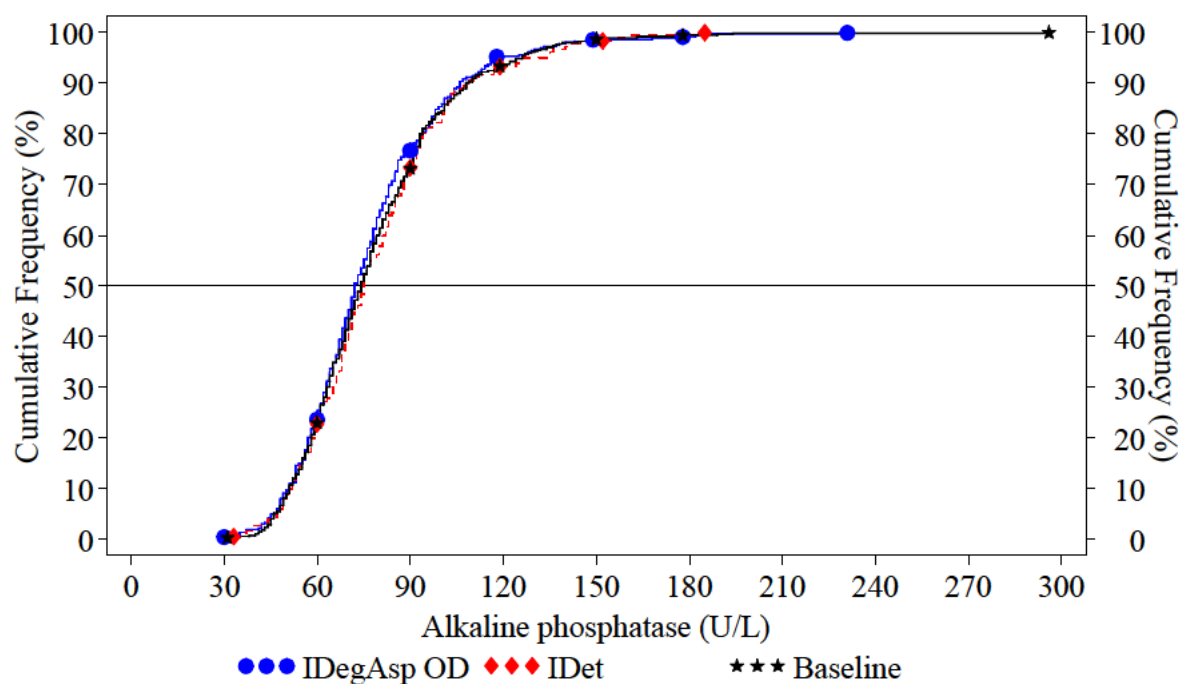
SAFETY: LOCF imputed data

Lower ref.: Male, Age (16-111) [45]; Female, Age (16-111) [40]

Upper ref.: Male, Age (16-111) [145]; Female, Age (16-111) [100]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:00:05 - fbox_numfind_v01.sas/e_alka_phosph_abs_box_locf_sas.cgm

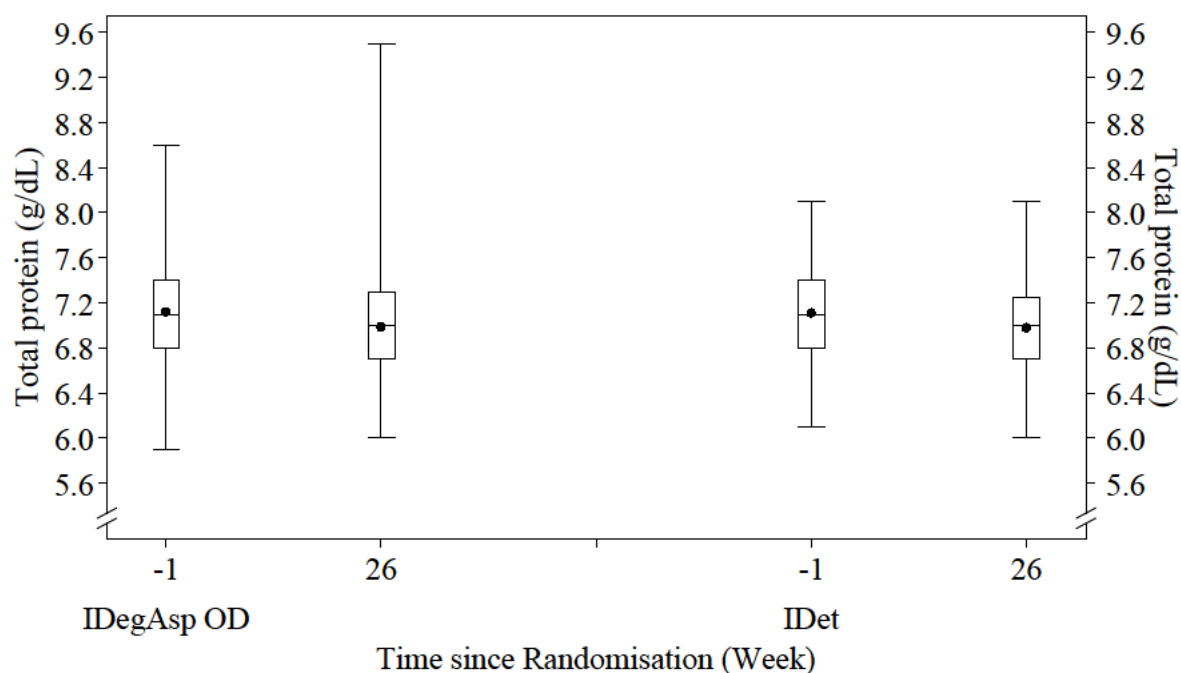
14.3.5.15: Biochemistry - Alkaline phosphatase - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data
Lower ref.: Male, Age (16-111) [45]; Female, Age (16-111) [40]
Upper ref.: Male, Age (16-111) [145]; Female, Age (16-111) [100]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:00:15 - fedist_numfind_v01.sas/e_alka_phosph_abs_cdf_locf_sas.cgm

14.3.5.16: Biochemistry - Alkaline phosphatase after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

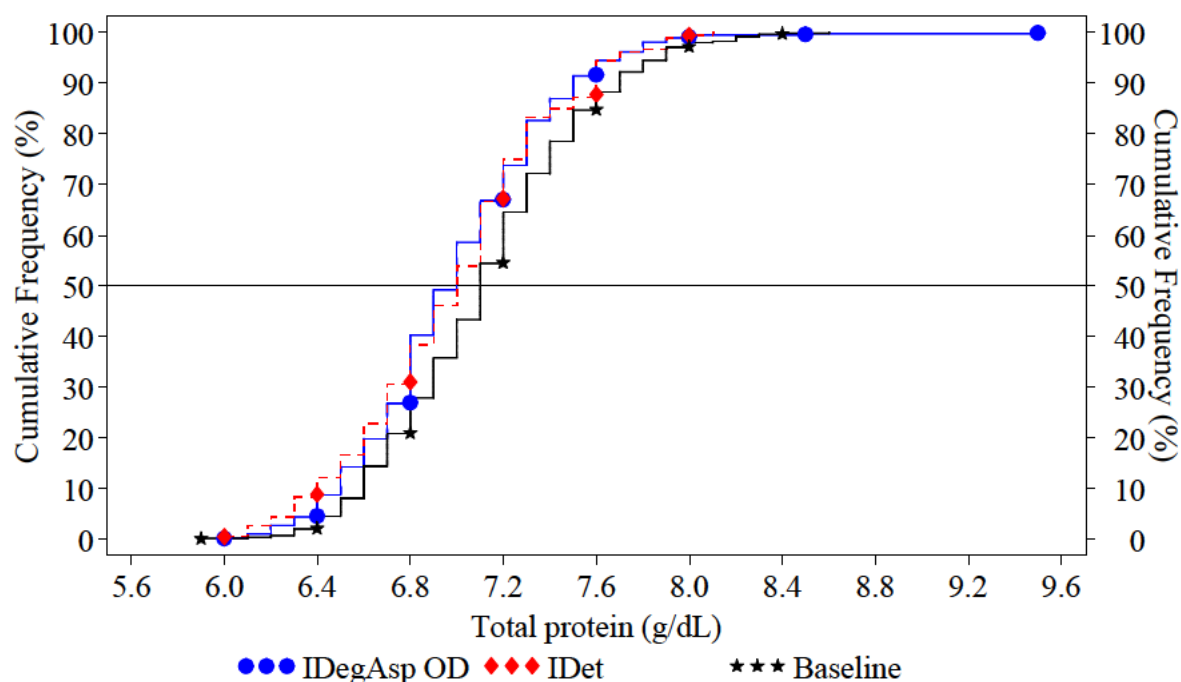
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[6], Age(66-91)[6]; Female, Age(18-66)[6], Age(66-91)[6]

Upper ref.: Male, Age(18-66)[8.4], Age(66-91)[8.3]; Female, Age(18-66)[8.4], Age(66-91)[8.3]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:00:21 - fbox_numfind_v01.sas/e_tot_prot_abs_box_locf_sas.cgm

14.3.5.17: Biochemistry - Total Protein - Box Plot - Safety Analysis Set



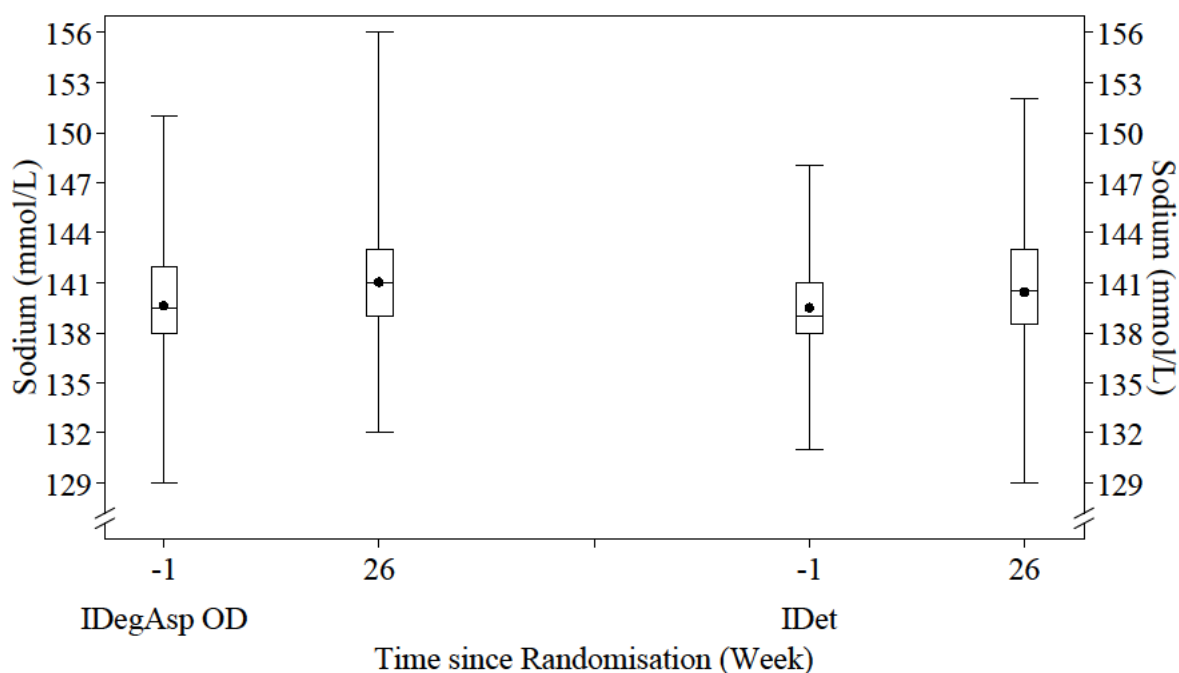
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[6], Age(66-91)[6]; Female, Age(18-66)[6], Age(66-91)[6]

Upper ref.: Male, Age(18-66)[8.4], Age(66-91)[8.3]; Female, Age(18-66)[8.4], Age(66-91)[8.3]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:00:32 - fedist_numfind_v01.sas/e_tot_prot_abs_cdf_locf_sas.cgm

14.3.5.18: Biochemistry - Total Protein after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

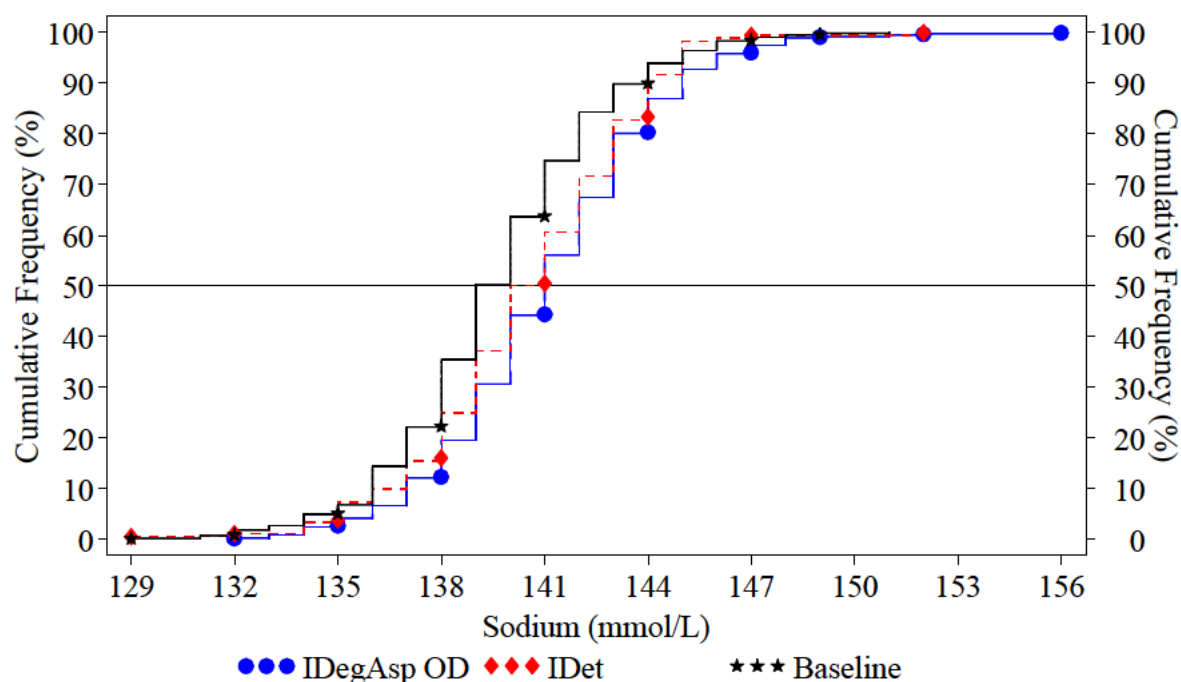
SAFETY: LOCF imputed data

Lower ref.: Male, Age(0-66)[132], Age(66-91)[135]; Female, Age(0-66)[132], Age(66-91)[135]

Upper ref.: Male, Age(0-66)[147], Age(66-91)[148]; Female, Age(0-66)[147], Age(66-91)[148]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:00:38 - fbox_numfind_v01.sas/e_sodium_abs_box_locf_sas.cgm

14.3.5.19: Biochemistry - Sodium - Box Plot - Safety Analysis Set



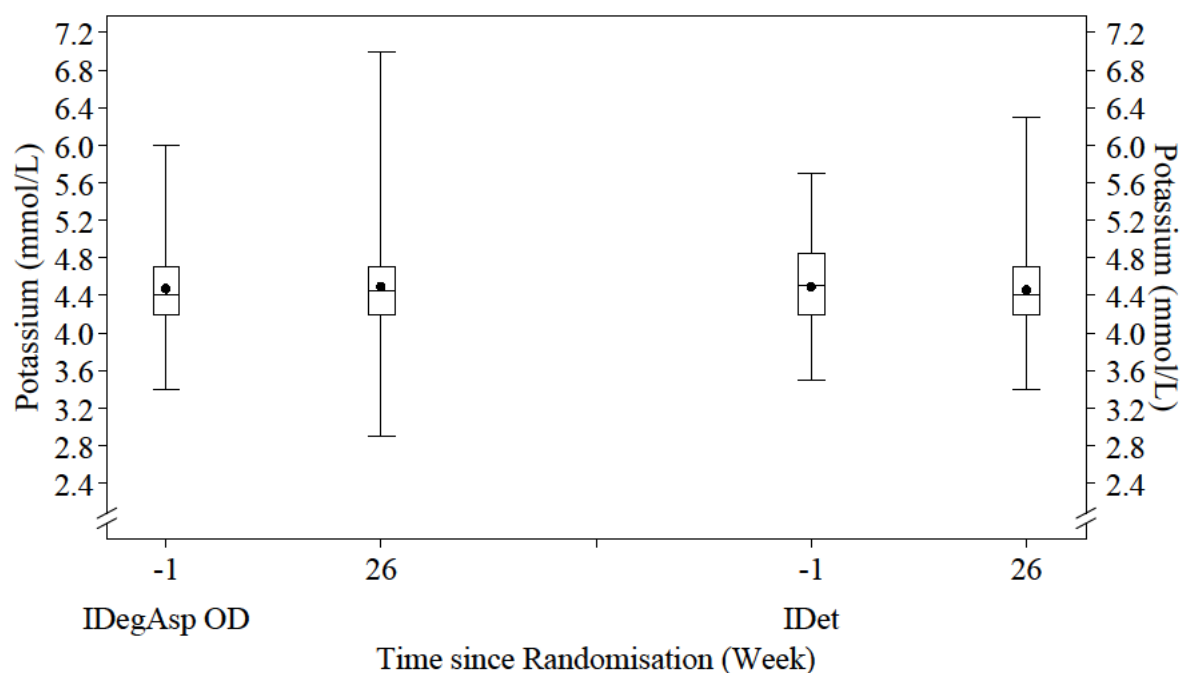
SAFETY: LOCF imputed data

Lower ref.: Male, Age(0-66)[132]; Age(66-91)[135]; Female, Age(0-66)[132]; Age(66-91)[135]

Upper ref.: Male, Age(0-66)[147]; Age(66-91)[148]; Female, Age(0-66)[147]; Age(66-91)[148]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:00:48 - fedist_numfind_v01.sas/e_sodium_abs_cdf_locf_sas.cgm

14.3.5.20: Biochemistry - Sodium after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

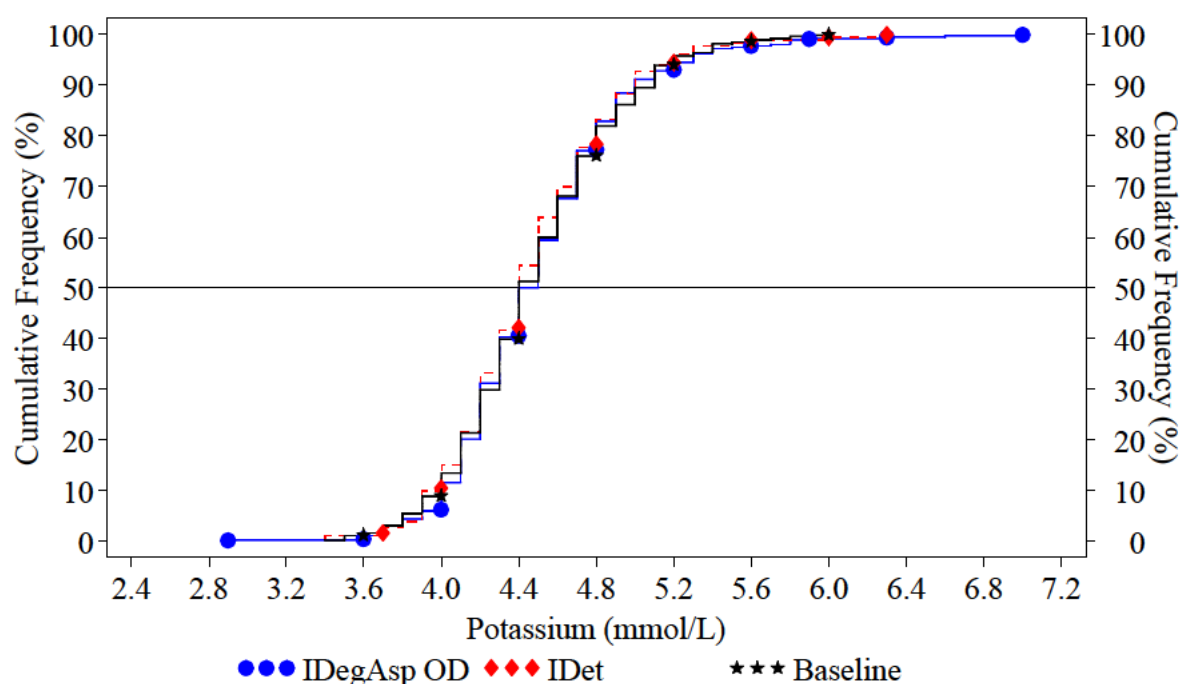
SAFETY: LOCF imputed data

Lower ref.: Male, Age(0-66)[3.5], Age(66-110)[3.6]; Female, Age(0-66)[3.5], Age(66-110)[3.6]

Upper ref.: Male, Age(0-66)[5.5], Age(66-110)[5.5]; Female, Age(0-66)[5.5], Age(66-110)[5.5]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:00:54 - fbox_numfind_v01.sas/e_potas_abs_box_locf_sas.cgm

14.3.5.21: Biochemistry - Potassium - Box Plot - Safety Analysis Set



SAFETY: LOCF imputed data

Lower ref.: Male, Age(0-66)[3.5], Age(66-110)[3.6]; Female, Age(0-66)[3.5], Age(66-110)[3.6]

Upper ref.: Male, Age(0-66)[5.5], Age(66-110)[5.5]; Female, Age(0-66)[5.5], Age(66-110)[5.5]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:05 - fedist_numfind_v01.sas/e_potas_abs_cdf_locf_sas.cgm

14.3.5.22: Biochemistry - Potassium after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.3.5.23: Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Basophils(%)			
Visit 1			
N	359	179	538
Mean (SD)	0.40 (0.24)	0.42 (0.26)	0.41 (0.25)
Median	0.40	0.40	0.40
Min ; Max	0.00 ; 1.80	0.00 ; 1.50	0.00 ; 1.80
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	0.40 (0.23)	0.40 (0.27)	0.40 (0.25)
Median	0.40	0.40	0.40
Min ; Max	0.00 ; 1.90	0.00 ; 1.90	0.00 ; 1.90
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	0.41 (0.24)	0.41 (0.27)	0.41 (0.25)
Median	0.40	0.40	0.40
Min ; Max	0.00 ; 1.90	0.00 ; 1.90	0.00 ; 1.90

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Eosinophils(%)			
Visit 1			
N	359	179	538
Mean (SD)	2.4 (2.1)	2.6 (2.1)	2.5 (2.1)
Median	1.9	2.1	1.9
Min ; Max	0.1 ; 27.0	0.0 ; 12.3	0.0 ; 27.0
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	2.7 (1.9)	2.9 (2.3)	2.7 (2.0)
Median	2.2	2.3	2.3
Min ; Max	0.1 ; 10.9	0.0 ; 15.3	0.0 ; 15.3
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	2.7 (1.9)	2.9 (2.3)	2.8 (2.1)
Median	2.2	2.3	2.2
Min ; Max	0.1 ; 10.9	0.0 ; 15.3	0.0 ; 15.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Haematocrit(%)			
Visit 1			
N	357	176	533
Mean (SD)	42 (4)	41 (4)	42 (4)
Median	42	42	42
Min ; Max	28 ; 52	29 ; 53	28 ; 53
Visit 28 (Week 26)			
N	299	152	451
Mean (SD)	42 (4)	41 (4)	42 (4)
Median	43	42	42
Min ; Max	30 ; 51	28 ; 52	28 ; 52
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	42 (4)	41 (4)	42 (4)
Median	43	41	42
Min ; Max	28 ; 51	28 ; 52	28 ; 52

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Haemoglobin (mmol/L)			
Visit 1			
N	361	180	541
Mean (SD)	8.8 (0.8)	8.5 (0.9)	8.7 (0.9)
Median	8.8	8.6	8.7
Min ; Max	5.8 ; 10.6	5.8 ; 10.8	5.8 ; 10.8
Visit 28 (Week 26)			
N	317	157	474
Mean (SD)	8.8 (0.9)	8.6 (0.9)	8.7 (0.9)
Median	8.9	8.7	8.7
Min ; Max	5.9 ; 11.0	5.0 ; 10.7	5.0 ; 11.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	8.8 (0.9)	8.5 (0.9)	8.7 (0.9)
Median	8.8	8.6	8.7
Min ; Max	5.8 ; 11.0	5.0 ; 10.7	5.0 ; 11.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Lymphocytes blood(%)			
Visit 1			
N	359	179	538
Mean (SD)	29.3 (8.1)	28.3 (8.1)	28.9 (8.1)
Median	29.3	27.7	28.5
Min ; Max	8.1 ; 53.2	12.2 ; 53.0	8.1 ; 53.2
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	30.3 (7.8)	29.4 (8.4)	30.0 (8.0)
Median	30.0	28.7	29.5
Min ; Max	8.9 ; 52.5	12.3 ; 48.1	8.9 ; 52.5
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	30.1 (7.9)	29.4 (8.4)	29.9 (8.1)
Median	29.8	28.7	29.3
Min ; Max	8.9 ; 57.4	12.3 ; 48.1	8.9 ; 57.4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Monocytes blood(%)			
Visit 1			
N	359	179	538
Mean (SD)	6.0 (2.2)	5.9 (2.1)	6.0 (2.2)
Median	5.9	6.0	5.9
Min ; Max	0.5 ; 13.3	0.2 ; 13.2	0.2 ; 13.3
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	6.2 (2.2)	6.4 (2.3)	6.2 (2.2)
Median	6.0	6.2	6.1
Min ; Max	1.5 ; 14.4	0.5 ; 12.6	0.5 ; 14.4
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	6.2 (2.2)	6.2 (2.3)	6.2 (2.2)
Median	6.0	6.0	6.0
Min ; Max	1.5 ; 14.4	0.3 ; 12.6	0.3 ; 14.4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Neutrophils blood(%)			
Visit 1			
N	359	179	538
Mean (SD)	61.9 (9.4)	62.9 (9.3)	62.2 (9.4)
Median	62.0	64.2	62.3
Min ; Max	36.1 ; 88.2	26.2 ; 84.6	26.2 ; 88.2
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	60.5 (8.8)	60.9 (9.7)	60.6 (9.1)
Median	60.6	61.2	60.7
Min ; Max	31.8 ; 83.4	38.8 ; 82.1	31.8 ; 83.4
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	60.6 (9.1)	61.0 (9.7)	60.7 (9.3)
Median	60.7	61.4	60.9
Min ; Max	31.8 ; 83.4	38.8 ; 82.3	31.8 ; 83.4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Thrombocytes (10 ⁹ /L)			
Visit 1			
N	359	180	539
Mean (SD)	247 (58)	252 (59)	249 (59)
Median	242	241	242
Min ; Max	133 ; 532	158 ; 490	133 ; 532
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	241 (55)	244 (61)	242 (57)
Median	234	231	233
Min ; Max	129 ; 454	128 ; 437	128 ; 454
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	239 (55)	245 (61)	241 (57)
Median	232	232	232
Min ; Max	129 ; 454	128 ; 437	128 ; 454

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Leukocytes (10 ⁹ /L)			
Visit 1			
N	361	180	541
Mean (SD)	6.8 (2.0)	6.6 (1.8)	6.8 (1.9)
Median	6.5	6.3	6.4
Min ; Max	3.1 ; 13.9	3.3 ; 12.6	3.1 ; 13.9
Visit 28 (Week 26)			
N	316	157	473
Mean (SD)	6.5 (1.8)	6.3 (1.6)	6.5 (1.7)
Median	6.2	6.1	6.2
Min ; Max	3.5 ; 13.8	3.4 ; 14.4	3.4 ; 14.4
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	6.6 (1.8)	6.3 (1.6)	6.5 (1.7)
Median	6.2	6.1	6.2
Min ; Max	3.5 ; 13.8	3.4 ; 14.4	3.4 ; 14.4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Erythrocytes (10 ¹² /L)			
Visit 1			
N	361	180	541
Mean (SD)	4.6 (0.4)	4.6 (0.5)	4.6 (0.4)
Median	4.6	4.5	4.6
Min ; Max	3.2 ; 6.4	3.1 ; 6.2	3.1 ; 6.4
Visit 28 (Week 26)			
N	317	157	474
Mean (SD)	4.7 (0.4)	4.6 (0.5)	4.6 (0.5)
Median	4.6	4.5	4.6
Min ; Max	3.2 ; 6.2	3.1 ; 6.6	3.1 ; 6.6
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	4.6 (0.4)	4.5 (0.5)	4.6 (0.5)
Median	4.6	4.5	4.6
Min ; Max	3.2 ; 6.2	3.1 ; 6.6	3.1 ; 6.6

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:12 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

14.3.5.24: Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Basophils Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	-0.0 (0.3)	-0.0 (0.3)	-0.0 (0.3)
Median	0.0	0.0	0.0
Min ; Max	-1.5 ; 1.1	-1.2 ; 1.4	-1.5 ; 1.4
Visit 28 (Week 26) (LOCF)			
N	359	179	538
Mean (SD)	0.0 (0.3)	-0.0 (0.3)	-0.0 (0.3)
Median	0.0	0.0	0.0
Min ; Max	-1.5 ; 1.1	-1.2 ; 1.4	-1.5 ; 1.4

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Eosinophils Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	0.3 (2.1)	0.3 (1.8)	0.3 (2.0)
Median	0.3	0.2	0.2
Min ; Max	-17.4 ; 9.2	-6.4 ; 6.7	-17.4 ; 9.2
Visit 28 (Week 26) (LOCF)			
N	359	179	538
Mean (SD)	0.3 (2.0)	0.3 (1.7)	0.3 (1.9)
Median	0.2	0.2	0.2
Min ; Max	-17.4 ; 9.2	-6.4 ; 6.7	-17.4 ; 9.2

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Haematocrit Blood(%)			
Visit 28 (Week 26)			
N	294	149	443
Mean (SD)	0.2 (2.2)	-0.1 (2.2)	0.1 (2.2)
Median	0.3	0.0	0.2
Min ; Max	-6.8 ; 8.5	-6.1 ; 6.7	-6.8 ; 8.5
Visit 28 (Week 26) (LOCF)			
N	357	176	533
Mean (SD)	0.1 (2.1)	-0.1 (2.2)	0.0 (2.1)
Median	0.0	0.0	0.0
Min ; Max	-6.8 ; 8.5	-6.1 ; 7.9	-6.8 ; 8.5

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Haemoglobin Blood (mmol/L)			
Visit 28 (Week 26)			
N	316	157	473
Mean (SD)	0.0 (0.5)	-0.0 (0.4)	0.0 (0.5)
Median	0.1	0.0	0.1
Min ; Max	-1.6 ; 2.0	-1.1 ; 1.2	-1.6 ; 2.0
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	0.0 (0.5)	-0.0 (0.4)	0.0 (0.4)
Median	0.1	0.0	0.0
Min ; Max	-1.6 ; 2.0	-1.1 ; 1.4	-1.6 ; 2.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Lymphocytes Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	1.1 (8.0)	1.0 (8.0)	1.1 (8.0)
Median	0.8	1.5	1.1
Min ; Max	-28.0 ; 40.7	-20.5 ; 28.3	-28.0 ; 40.7
Visit 28 (Week 26) (LOCF)			
N	359	179	538
Mean (SD)	0.9 (7.8)	1.0 (7.6)	0.9 (7.8)
Median	0.0	1.4	0.4
Min ; Max	-28.0 ; 40.7	-20.5 ; 28.3	-28.0 ; 40.7

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Monocytes Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	0.2 (2.1)	0.4 (2.3)	0.3 (2.1)
Median	0.1	0.4	0.2
Min ; Max	-7.7 ; 9.0	-7.8 ; 9.8	-7.8 ; 9.8
Visit 28 (Week 26) (LOCF)			
N	359	179	538
Mean (SD)	0.2 (2.0)	0.4 (2.2)	0.3 (2.1)
Median	0.1	0.3	0.1
Min ; Max	-7.7 ; 9.0	-7.8 ; 9.8	-7.8 ; 9.8

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Neutrophils Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	-1.6 (9.3)	-1.7 (9.6)	-1.6 (9.4)
Median	-0.8	-1.9	-1.3
Min ; Max	-47.6 ; 31.3	-32.4 ; 22.1	-47.6 ; 31.3
Visit 28 (Week 26) (LOCF)			
N	359	179	538
Mean (SD)	-1.3 (9.2)	-1.7 (9.1)	-1.5 (9.2)
Median	-0.3	-1.4	-0.7
Min ; Max	-47.6 ; 31.3	-32.4 ; 22.1	-47.6 ; 31.3

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Thrombocytes Blood($10^9/L$)			
Visit 28 (Week 26)			
N	312	157	469
Mean (SD)	-7.6 (35.7)	-9.9 (34.8)	-8.4 (35.4)
Median	-7.0	-14.0	-8.0
Min ; Max	-224 ; 92.0	-91.0 ; 170.0	-224 ; 170.0
Visit 28 (Week 26) (LOCF)			
N	359	180	539
Mean (SD)	-7.8 (34.5)	-7.7 (34.4)	-7.7 (34.4)
Median	-5.0	-8.0	-5.0
Min ; Max	-224 ; 92.0	-91.0 ; 170.0	-224 ; 170.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Leukocytes Blood(10 ⁹ /L)			
Visit 28 (Week 26)			
N	315	157	472
Mean (SD)	-0.3 (1.7)	-0.3 (1.6)	-0.3 (1.7)
Median	-0.3	-0.1	-0.2
Min ; Max	-7.6 ; 5.3	-6.2 ; 5.2	-7.6 ; 5.3
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	-0.3 (1.7)	-0.3 (1.5)	-0.3 (1.6)
Median	-0.2	-0.1	-0.2
Min ; Max	-7.6 ; 5.3	-6.2 ; 5.2	-7.6 ; 5.3

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Erythrocytes Blood($10^{12}/L$)			
Visit 28 (Week 26)			
N	316	157	473
Mean (SD)	0.0 (0.2)	-0.0 (0.2)	-0.0 (0.2)
Median	0.0	0.0	0.0
Min ; Max	-0.8 ; 0.9	-0.7 ; 0.7	-0.8 ; 0.9
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	0.0 (0.2)	-0.0 (0.2)	-0.0 (0.2)
Median	0.0	0.0	0.0
Min ; Max	-0.8 ; 0.9	-0.7 ; 0.9	-0.8 ; 0.9

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:19 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

14.3.5.25: Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Basophils (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Normal	359 (100.0)	179 (100.0)	538 (100.0)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Normal	314 (100.0)	157 (100.0)	471 (100.0)
Visit 28 Week 26 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Normal	361 (100.0)	180 (100.0)	541 (100.0)
Eosinophils (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Normal	341 (95.0)	170 (95.0)	511 (95.0)
High	18 (5.0)	9 (5.0)	27 (5.0)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Normal	296 (94.3)	144 (91.7)	440 (93.4)
High	18 (5.7)	13 (8.3)	31 (6.6)
Visit 28 Week 26 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Normal	339 (93.9)	165 (91.7)	504 (93.2)
High	22 (6.1)	15 (8.3)	37 (6.8)
Erythrocytes (10 ¹² /L)			
Visit 1			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	11 (3.0)	6 (3.3)	17 (3.1)
Normal	349 (96.7)	171 (95.0)	520 (96.1)
High	1 (0.3)	3 (1.7)	4 (0.7)
Visit 28 (Week 26)			
N	317 (100.0)	157 (100.0)	474 (100.0)
Low	7 (2.2)	5 (3.2)	12 (2.5)
Normal	309 (97.5)	150 (95.5)	459 (96.8)
High	1 (0.3)	2 (1.3)	3 (0.6)
Visit 28 Week 26 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	8 (2.2)	7 (3.9)	15 (2.8)
Normal	353 (97.5)	171 (95.0)	524 (96.7)
High	1 (0.3)	2 (1.1)	3 (0.6)

N = Number of Subjects

Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Haematocrit (%)			
Visit 1			
N	357 (100.0)	176 (100.0)	533 (100.0)
Low	23 (6.4)	20 (11.4)	43 (8.1)
Normal	332 (93.0)	155 (88.1)	487 (91.4)
High	2 (0.6)	1 (0.6)	3 (0.6)
Visit 28 (Week 26)			
N	299 (100.0)	152 (100.0)	451 (100.0)
Low	17 (5.7)	9 (5.9)	26 (5.8)
Normal	282 (94.3)	143 (94.1)	425 (94.2)
Visit 28 Week 26 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	22 (6.1)	14 (7.8)	36 (6.6)
Normal	340 (93.9)	166 (92.2)	506 (93.4)
Haemoglobin (mmol/L)			
Visit 1			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	14 (3.9)	14 (7.8)	28 (5.2)
Normal	346 (95.8)	166 (92.2)	512 (94.6)
High	1 (0.3)	0	1 (0.2)
Visit 28 (Week 26)			
N	317 (100.0)	157 (100.0)	474 (100.0)
Low	16 (5.0)	14 (8.9)	30 (6.3)
Normal	300 (94.6)	143 (91.1)	443 (93.5)
High	1 (0.3)	0	1 (0.2)
Visit 28 Week 26 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	18 (5.0)	18 (10.0)	36 (6.6)
Normal	343 (94.8)	162 (90.0)	505 (93.2)
High	1 (0.3)	0	1 (0.2)
Leukocytes (10 ⁹ /L)			
Visit 1			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	12 (3.3)	8 (4.4)	20 (3.7)
Normal	343 (95.0)	171 (95.0)	514 (95.0)
High	6 (1.7)	1 (0.6)	7 (1.3)
Visit 28 (Week 26)			
N	316 (100.0)	157 (100.0)	473 (100.0)
Low	12 (3.8)	9 (5.7)	21 (4.4)
Normal	302 (95.6)	147 (93.6)	449 (94.9)
High	2 (0.6)	1 (0.6)	3 (0.6)
Visit 28 Week 26 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	13 (3.6)	9 (5.0)	22 (4.1)
Normal	345 (95.3)	170 (94.4)	515 (95.0)

N = Number of Subjects

Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
High	4 (1.1)	1 (0.6)	5 (0.9)
Lymphocytes blood (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Low	16 (4.5)	6 (3.4)	22 (4.1)
Normal	335 (93.3)	168 (93.9)	503 (93.5)
High	8 (2.2)	5 (2.8)	13 (2.4)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Low	7 (2.2)	7 (4.5)	14 (3.0)
Normal	301 (95.9)	147 (93.6)	448 (95.1)
High	6 (1.9)	3 (1.9)	9 (1.9)
Visit 28 Week 26(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	8 (2.2)	8 (4.4)	16 (3.0)
Normal	346 (95.8)	169 (93.9)	515 (95.2)
High	7 (1.9)	3 (1.7)	10 (1.8)
Monocytes blood (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Low	30 (8.4)	15 (8.4)	45 (8.4)
Normal	326 (90.8)	163 (91.1)	489 (90.9)
High	3 (0.8)	1 (0.6)	4 (0.7)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Low	20 (6.4)	8 (5.1)	28 (5.9)
Normal	291 (92.7)	148 (94.3)	439 (93.2)
High	3 (1.0)	1 (0.6)	4 (0.8)
Visit 28 Week 26(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	22 (6.1)	11 (6.1)	33 (6.1)
Normal	336 (93.1)	168 (93.3)	504 (93.2)
High	3 (0.8)	1 (0.6)	4 (0.7)
Neutrophils blood (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Low	5 (1.4)	3 (1.7)	8 (1.5)
Normal	334 (93.0)	167 (93.3)	501 (93.1)
High	20 (5.6)	9 (5.0)	29 (5.4)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Low	7 (2.2)	4 (2.5)	11 (2.3)
Normal	299 (95.2)	146 (93.0)	445 (94.5)
High	8 (2.5)	7 (4.5)	15 (3.2)

N = Number of Subjects

Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Visit 28 Week 26(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	9 (2.5)	5 (2.8)	14 (2.6)
Normal	343 (95.0)	167 (92.8)	510 (94.3)
High	9 (2.5)	8 (4.4)	17 (3.1)
Thrombocytes (10 ⁹ /L)			
Visit 1			
N	359 (100.0)	180 (100.0)	539 (100.0)
Low	4 (1.1)	0	4 (0.7)
Normal	352 (98.1)	179 (99.4)	531 (98.5)
High	3 (0.8)	1 (0.6)	4 (0.7)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Low	3 (1.0)	1 (0.6)	4 (0.8)
Normal	310 (98.7)	156 (99.4)	466 (98.9)
High	1 (0.3)	0	1 (0.2)
Visit 28 Week 26(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	4 (1.1)	1 (0.6)	5 (0.9)
Normal	356 (98.6)	179 (99.4)	535 (98.9)
High	1 (0.3)	0	1 (0.2)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:45 - tsum_lab_summary.sas/t_haem_sum_sas.txt

14.3.5.26: Haematology – Shift Table – Baseline to Week 26 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 28 (Week 26)								
Basophils (%)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	312 (86.2)	0 (0.0)	2 (0.6)	0 (0.0)	156 (86.7)	0 (0.0)	1 (0.6)
High	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	47 (13.0)	0 (0.0)	1 (0.3)	0 (0.0)	23 (12.8)	0 (0.0)	0 (0.0)
Eosinophils (%)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	285 (78.7)	9 (2.5)	2 (0.6)	0 (0.0)	140 (77.8)	3 (1.7)	1 (0.6)
High	0 (0.0)	11 (3.0)	7 (1.9)	0 (0.0)	0 (0.0)	9 (5.0)	4 (2.2)	0 (0.0)
Missing	0 (0.0)	45 (12.4)	2 (0.6)	1 (0.3)	0 (0.0)	21 (11.7)	2 (1.1)	0 (0.0)
Erythrocytes (10 ¹² /L)								
Low	5 (1.4)	2 (0.6)	0 (0.0)	0 (0.0)	3 (1.7)	2 (1.1)	0 (0.0)	0 (0.0)
Normal	4 (1.1)	304 (84.0)	0 (0.0)	1 (0.3)	3 (1.7)	146 (81.1)	1 (0.6)	0 (0.0)
High	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)
Missing	2 (0.6)	43 (11.9)	0 (0.0)	0 (0.0)	0 (0.0)	23 (12.8)	0 (0.0)	0 (0.0)
Haematocrit (%)								
Low	9 (2.5)	7 (1.9)	0 (0.0)	1 (0.3)	6 (3.3)	3 (1.7)	0 (0.0)	0 (0.0)
Normal	10 (2.8)	268 (74.0)	0 (0.0)	4 (1.1)	9 (5.0)	130 (72.2)	1 (0.6)	3 (1.7)
High	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	4 (1.1)	57 (15.7)	2 (0.6)	0 (0.0)	5 (2.8)	22 (12.2)	0 (0.0)	1 (0.6)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:11 - t_lab_shift.sas/t_haem_shift_w26_sas.txt

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
933 of 1733

Novo Nordisk

Haematology - Shift Table - Baseline to Week 26 - Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 28 (Week 26)								
Haemoglobin (mmol/L)								
Low	8 (2.2)	8 (2.2)	0 (0.0)	0 (0.0)	10 (5.6)	4 (2.2)	0 (0.0)	0 (0.0)
Normal	4 (1.1)	295 (81.5)	0 (0.0)	1 (0.3)	1 (0.6)	142 (78.9)	0 (0.0)	0 (0.0)
High	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	2 (0.6)	42 (11.6)	1 (0.3)	0 (0.0)	3 (1.7)	20 (11.1)	0 (0.0)	0 (0.0)
Leukocytes (10 ⁹ /L)								
Low	3 (0.8)	9 (2.5)	0 (0.0)	0 (0.0)	5 (2.8)	4 (2.2)	0 (0.0)	0 (0.0)
Normal	7 (1.9)	290 (80.1)	4 (1.1)	1 (0.3)	3 (1.7)	143 (79.4)	1 (0.6)	0 (0.0)
High	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Missing	2 (0.6)	43 (11.9)	1 (0.3)	0 (0.0)	0 (0.0)	23 (12.8)	0 (0.0)	0 (0.0)
Lymphocytes blood (%)								
Low	2 (0.6)	5 (1.4)	0 (0.0)	0 (0.0)	1 (0.6)	6 (3.3)	0 (0.0)	0 (0.0)
Normal	12 (3.3)	283 (78.2)	4 (1.1)	2 (0.6)	3 (1.7)	139 (77.2)	4 (2.2)	1 (0.6)
High	1 (0.3)	4 (1.1)	1 (0.3)	0 (0.0)	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
Missing	1 (0.3)	43 (11.9)	3 (0.8)	1 (0.3)	2 (1.1)	20 (11.1)	1 (0.6)	0 (0.0)
Monocytes blood (%)								
Low	6 (1.7)	14 (3.9)	0 (0.0)	0 (0.0)	0 (0.0)	8 (4.4)	0 (0.0)	0 (0.0)
Normal	22 (6.1)	265 (73.2)	2 (0.6)	2 (0.6)	10 (5.6)	136 (75.6)	1 (0.6)	1 (0.6)
High	0 (0.0)	2 (0.6)	1 (0.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	2 (0.6)	45 (12.4)	0 (0.0)	1 (0.3)	4 (2.2)	19 (10.6)	0 (0.0)	0 (0.0)

N: Number of subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:11 - t_lab_shift.sas/t_haem_shift_w26_sas.txt

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
934 of 1733

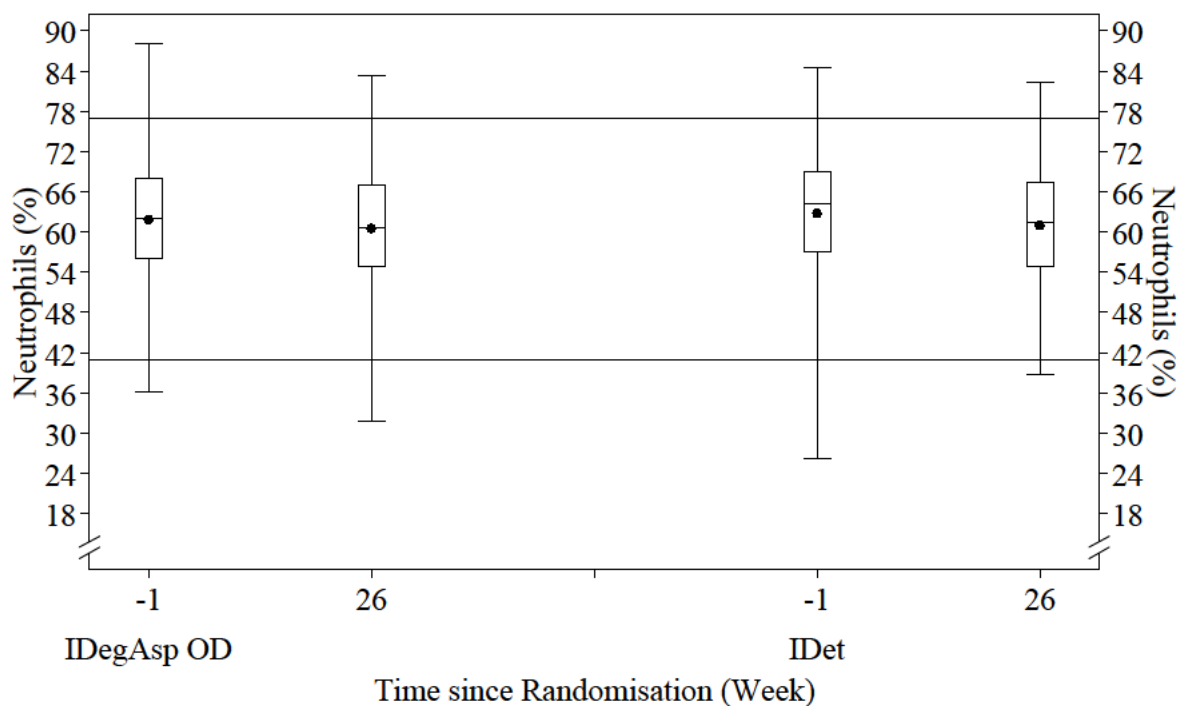
Novo Nordisk

Haematology - Shift Table - Baseline to Week 26 - Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 28 (Week 26)								
Neutrophils blood (%)								
Low	2 (0.6)	4 (1.1)	1 (0.3)	0 (0.0)	0 (0.0)	4 (2.2)	0 (0.0)	0 (0.0)
Normal	3 (0.8)	278 (76.8)	16 (4.4)	2 (0.6)	2 (1.1)	136 (75.6)	7 (3.9)	1 (0.6)
High	0 (0.0)	6 (1.7)	2 (0.6)	0 (0.0)	0 (0.0)	7 (3.9)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	46 (12.7)	1 (0.3)	1 (0.3)	1 (0.6)	20 (11.1)	2 (1.1)	0 (0.0)
Thrombocytes (10 ⁹ /L)								
Low	1 (0.3)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Normal	3 (0.8)	303 (83.7)	2 (0.6)	2 (0.6)	0 (0.0)	155 (86.1)	1 (0.6)	0 (0.0)
High	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	47 (13.0)	0 (0.0)	1 (0.3)	0 (0.0)	23 (12.8)	0 (0.0)	0 (0.0)

N: Number of subjects

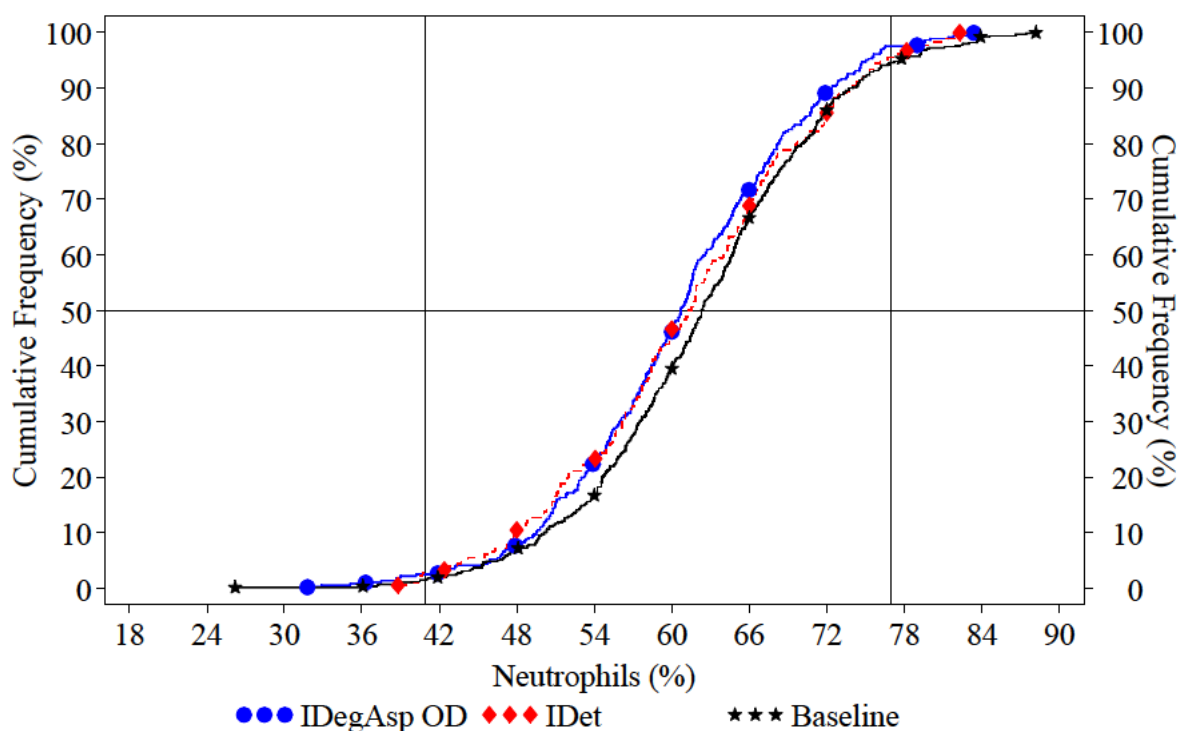
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:11 - t_lab_shift.sas/t_haem_shift_w26_sas.txt



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:25 - fbox_numfind_v01.sas/e_neutrophils_abs_box_locf_sas.cgm

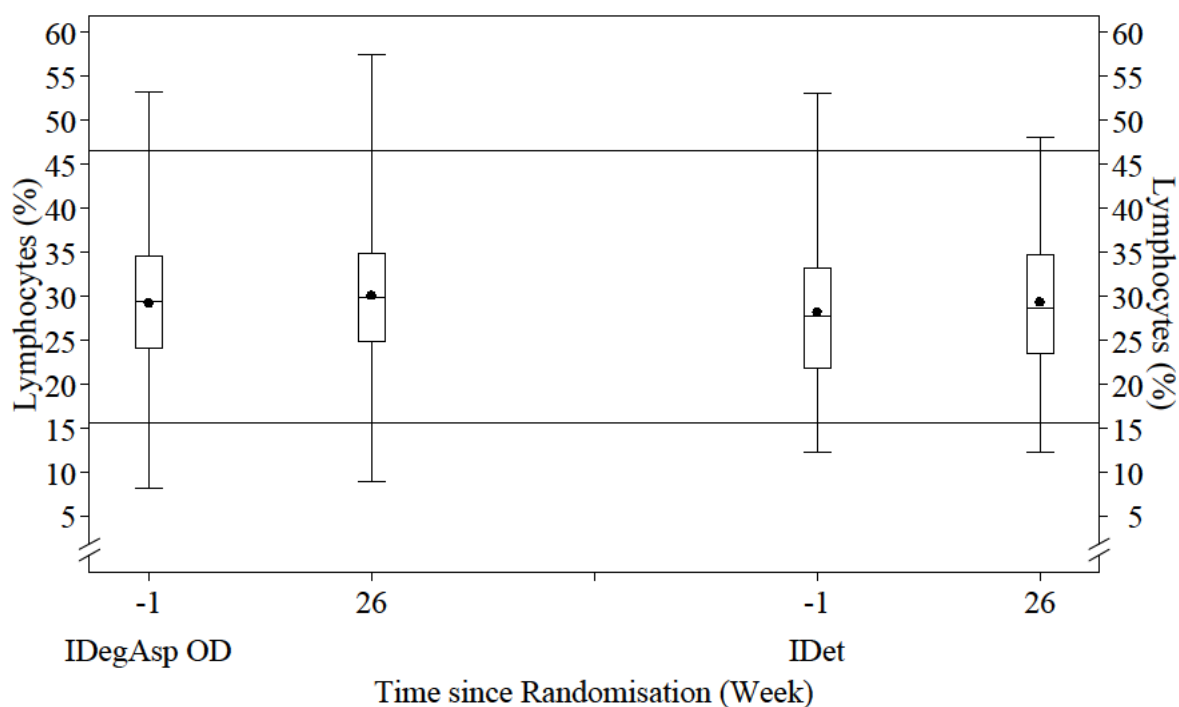
14.3.5.27: Haematology - Neutrophils - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:35 - fedist_numfind_v01.sas/e_neutrophils_abs_cdf_locf_sas.cgm

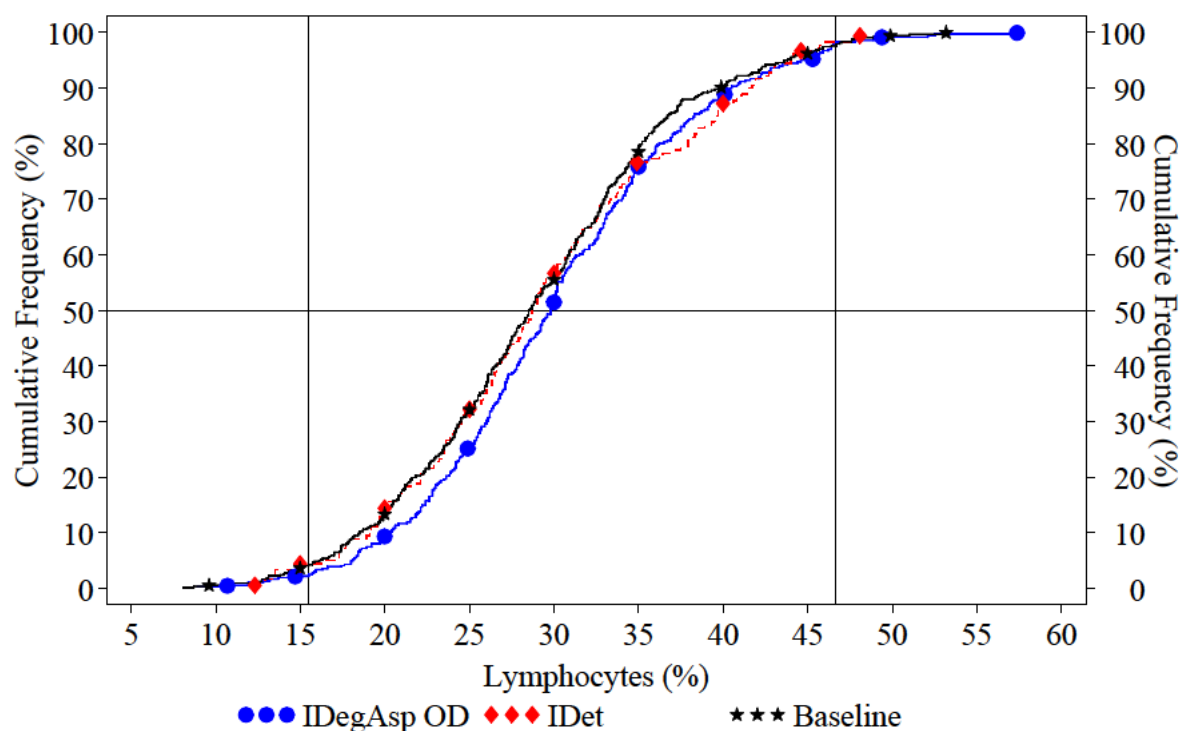
14.3.5.28: Haematology - Neutrophils after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:41 - fbox_numfind_v01.sas/e_lymphocytes_abs_box_locf_sas.cgm

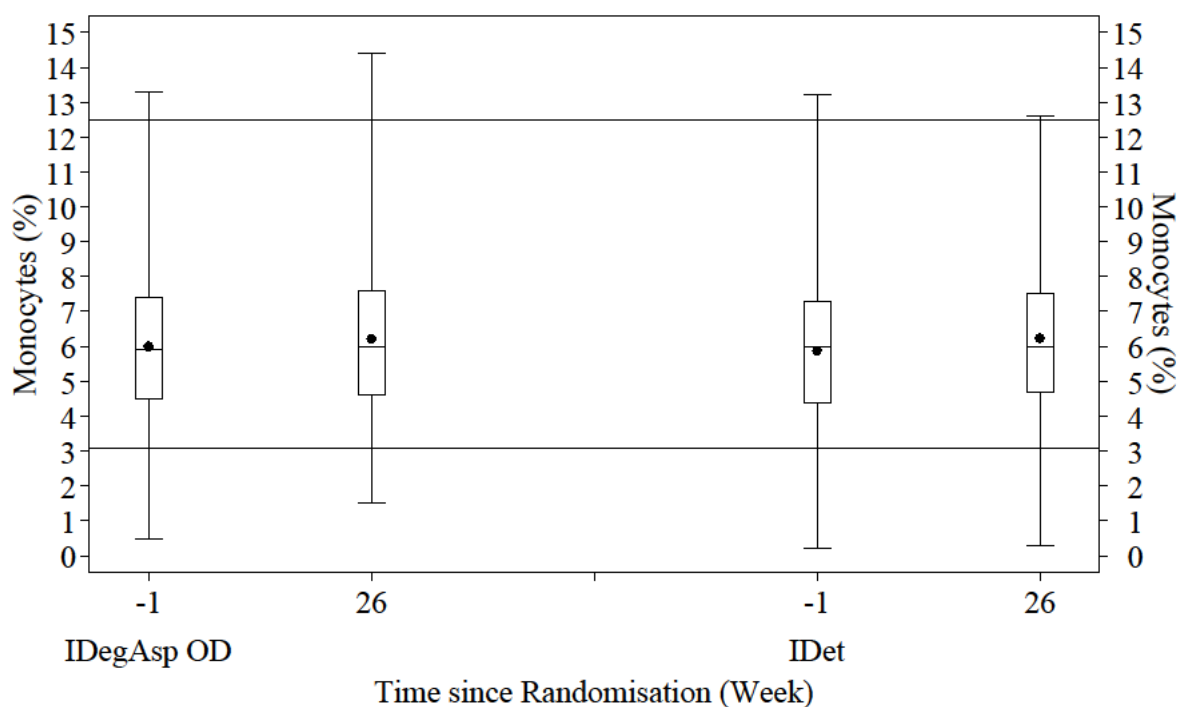
14.3.5.29: Haematology - Lymphocytes - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:01:52 - fedist_numfind_v01.sas/e_lymphocytes_abs_cdf_locf_sas.cgm

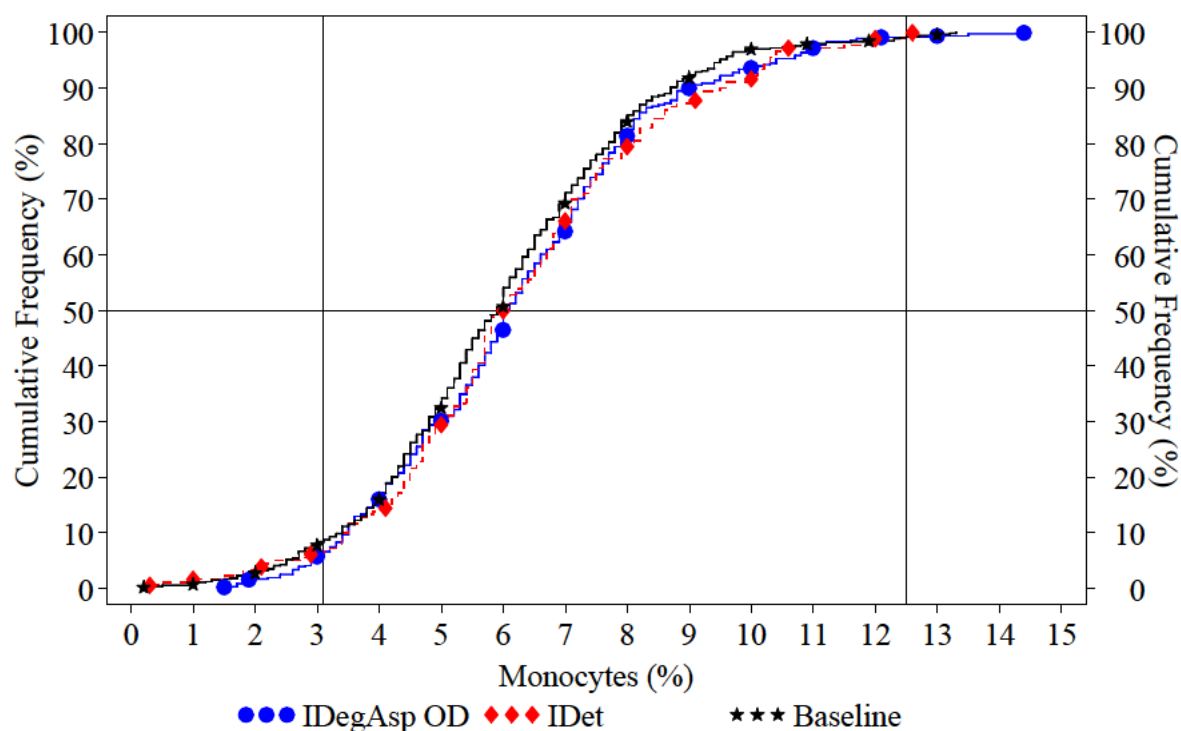
14.3.5.30: Haematology - Lymphocytes after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:01:58 - fbox_numfind_v01.sas/e_monocytes_abs_box_locf_sas.cgm

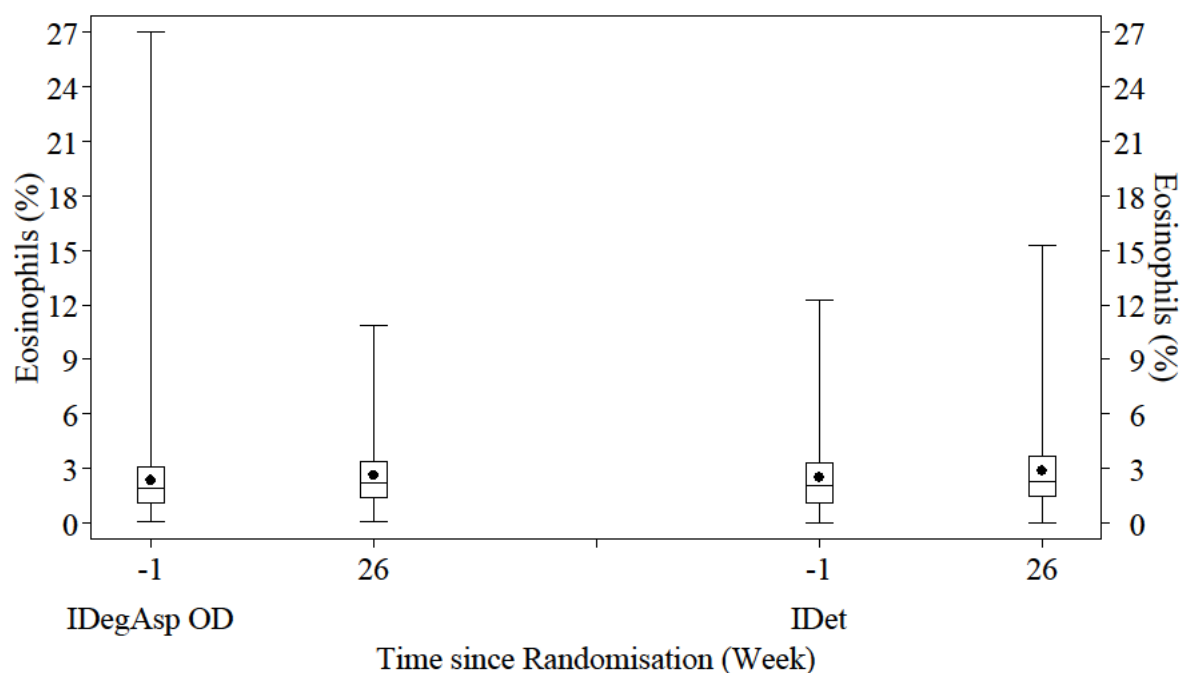
14.3.5.31: Haematology - Monocytes - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:02:08 - fedist_numfind_v01.sas/e_monocytes_abs_cdf_locf_sas.cgm

14.3.5.32: Haematology - Monocytes after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

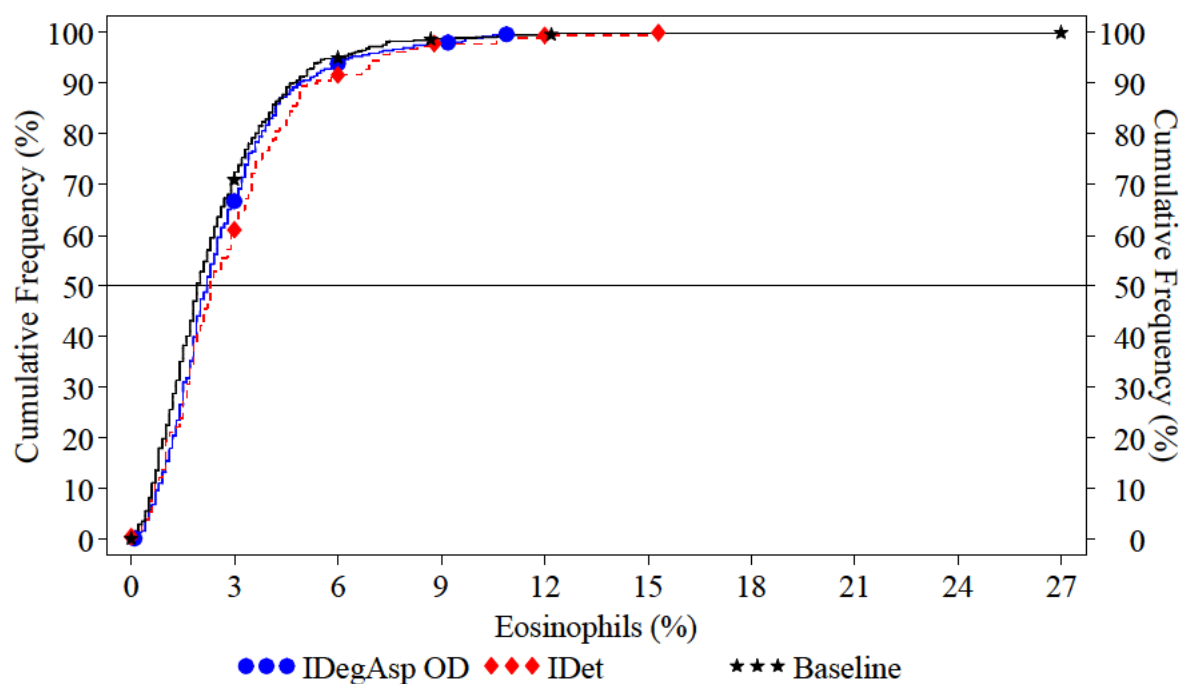
SAFETY: LOCF imputed data

Lower ref.: Male, Age(1-19)[0], Age(19-111)[0]; Female, Age(1-19)[0], Age(19-111)[0]

Upper ref.: Male, Age(1-19)[4.8], Age(19-111)[6]; Female, Age(1-19)[4.8], Age(19-111)[6]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:02:14 - fbox_numfind_v01.sas/e_eosinophils_abs_box_locf_sas.cgm

14.3.5.33: Haematology - Eosinophils - Box Plot - Safety Analysis Set

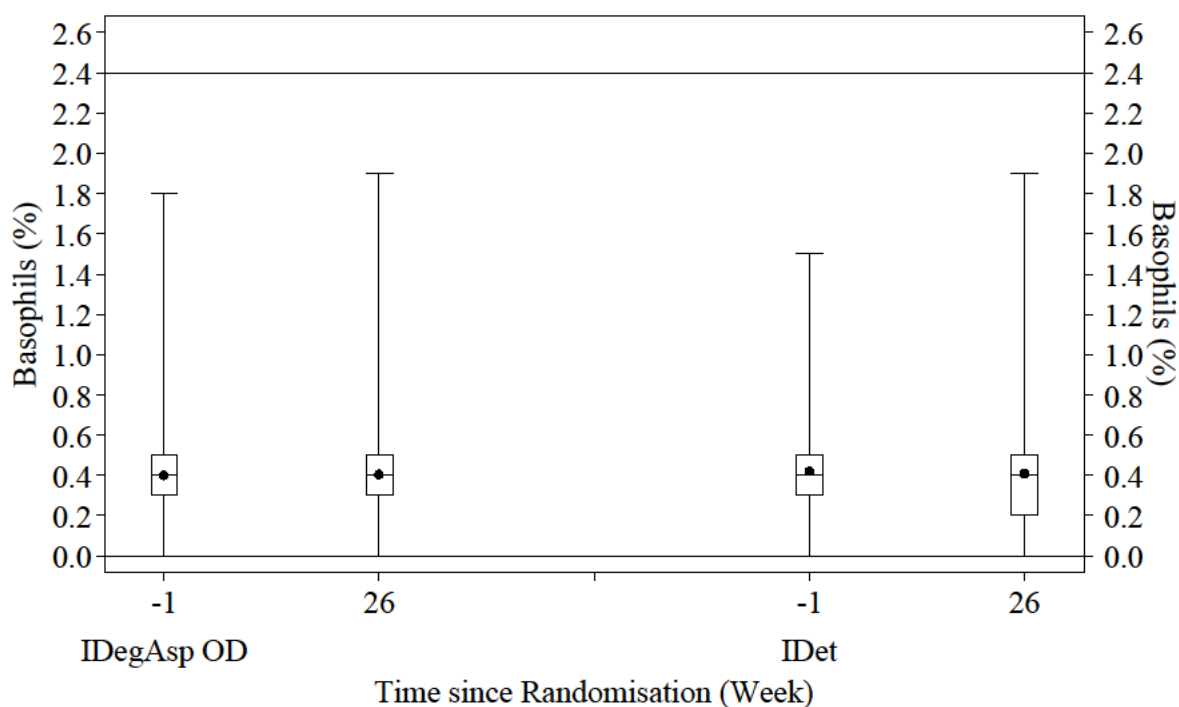


SAFETY; LOCF imputed data

Lower ref.: Male, Age(1-19)[0], Age(19-111)[0]; Female, Age(1-19)[0], Age(19-111)[0]
Upper ref.: Male, Age(1-19)[4.8], Age(19-111)[6]; Female, Age(1-19)[4.8], Age(19-111)[6]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:02:24 - fedist_numfind_v01.sas/e_eosinophils_abs_cdf_locf_sas.cgm

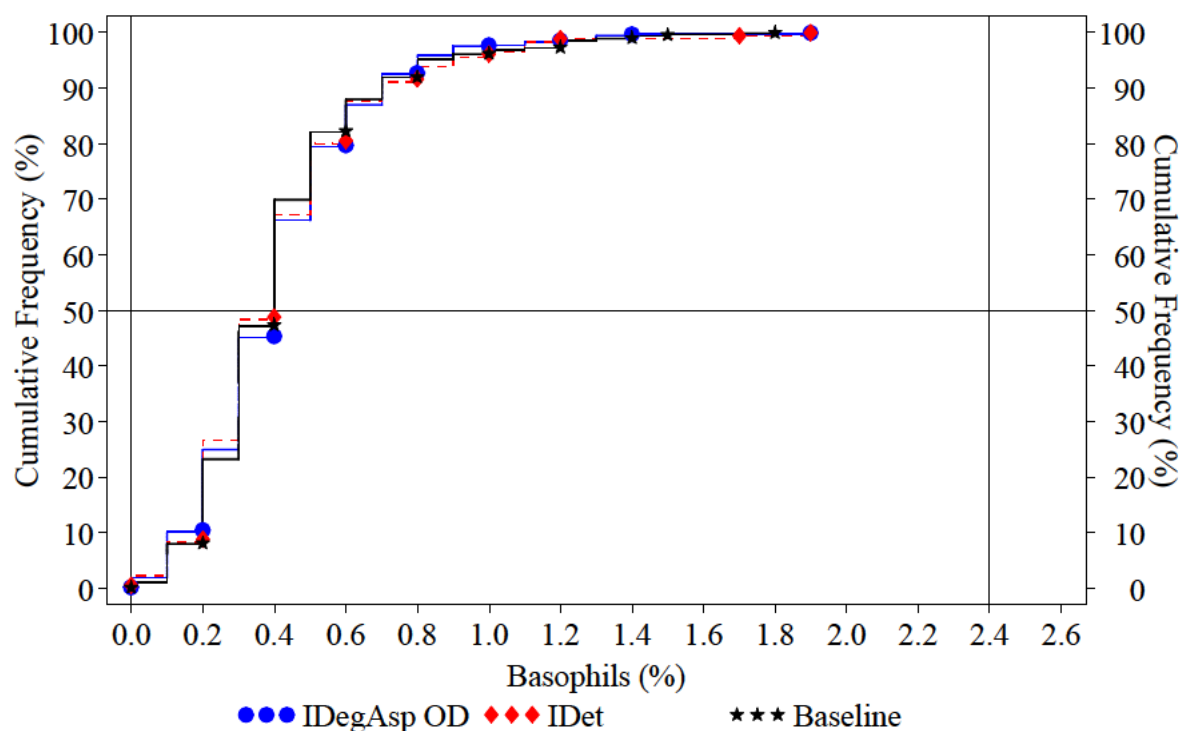
14.3.5.34: Haematology - Eosinophils after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:02:30 - fbox_numfind_v01.sas/e_basophils_abs_box_locf_sas.cgm

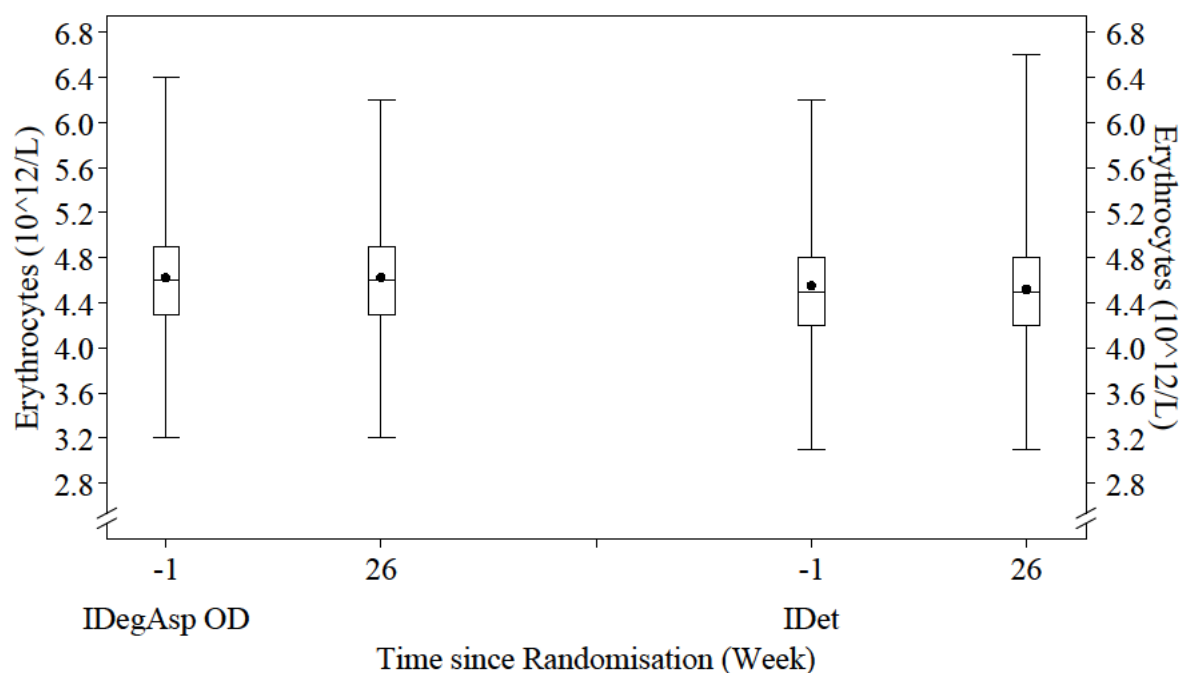
14.3.5.35: Haematology - Basophils - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:02:40 - fedist_numfind_v01.sas/e_basophils_abs_cdf_locf_sas.cgm

14.3.5.36: Haematology - Basophils after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

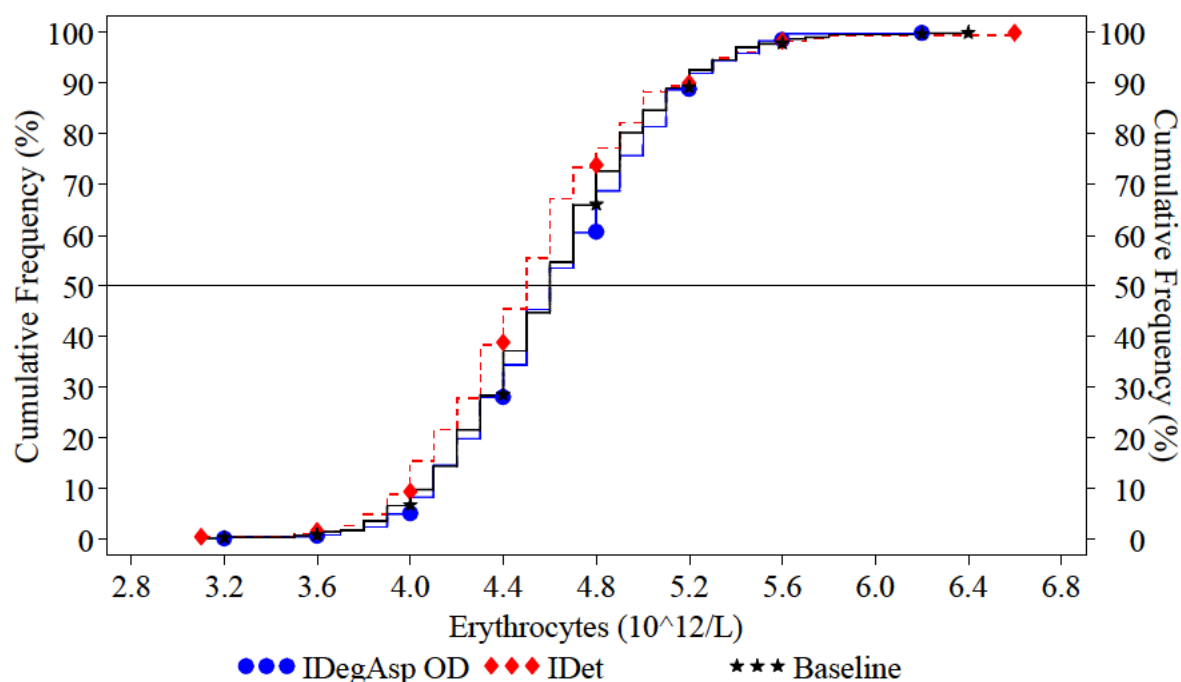
SAFETY: LOCF imputed data

Lower ref.: Male, Age(12-66)[4.1], Age(66-111)[4]; Female, Age(12-66)[3.8], Age(66-111)[3.8]

Upper ref.: Male, Age(12-66)[5.9], Age(66-111)[5.8]; Female, Age(12-66)[5.5], Age(66-91)[5.4]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:02:46 - fbox_numfind_v01.sas/e_erythrocyt_abs_box_locf_sas.cgm

14.3.5.37: Haematology - Erythrocytes - Box Plot - Safety Analysis Set



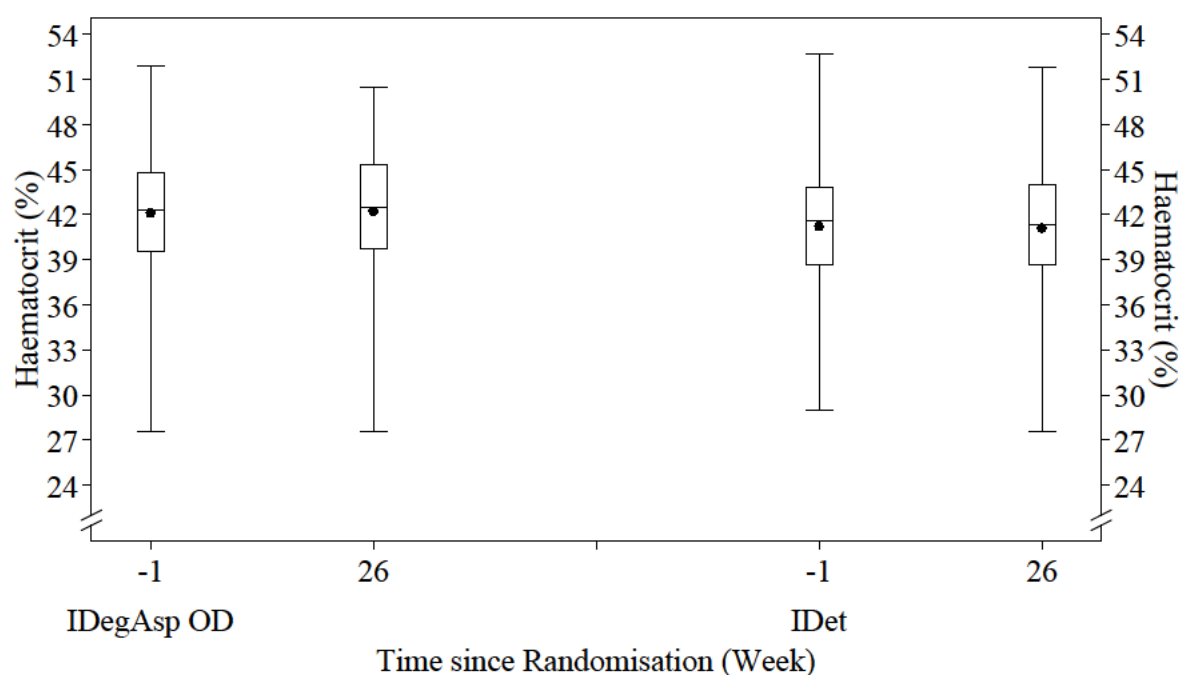
SAFETY: LOCF imputed data

Lower ref.: Male, Age(12-66)[4.1], Age(66-111)[4]; Female, Age(12-66)[3.8], Age(66-111)[3.8]

Upper ref.: Male, Age(12-66)[5.9], Age(66-111)[5.8]; Female, Age(12-66)[5.5], Age(66-111)[5.4]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:02:57 - fedist_numfind_v01.sas/e_erythrocyt_abs_cdf_locf_sas.cgm

14.3.5.38: Haematology - Erythrocytes after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

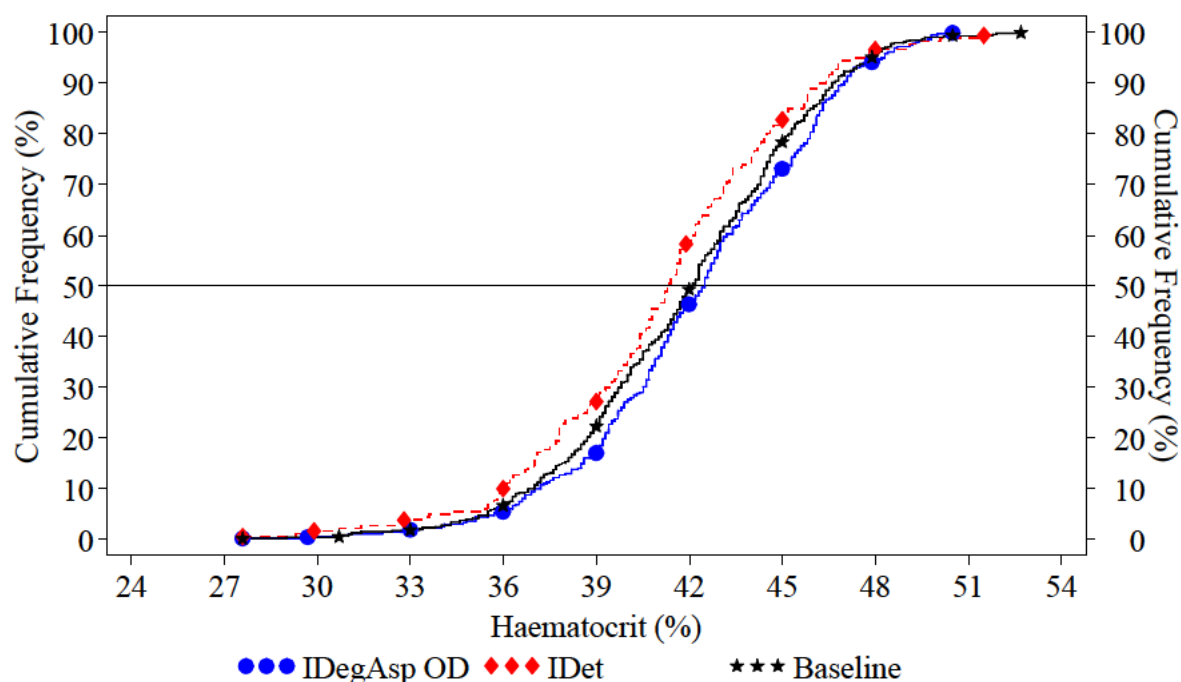
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[40], Age(66-111)[37]; Female, Age(12-66)[35], Age(66-111)[33]

Upper ref.: Male, Age(18-66)[52], Age(66-111)[50]; Female, Age(12-66)[47], Age(66-111)[46]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:03:03 - fbox_numfind_v01.sas/e_haematocr_abs_box_locf_sas.cgm

14.3.5.39: Haematology - Haematocrit - Box Plot - Safety Analysis Set



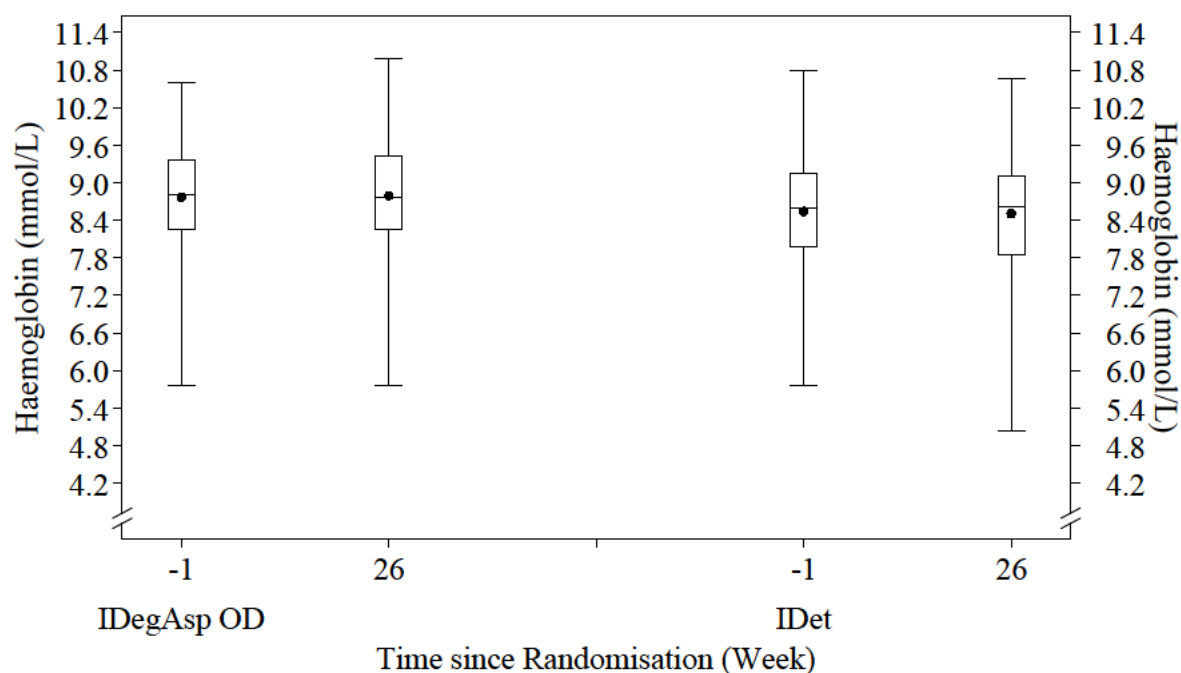
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[40], Age(66-111)[37]; Female, Age(12-66)[35], Age(66-111)[33]

Upper ref.: Male, Age(18-66)[52], Age(66-111)[50]; Female, Age(12-66)[47], Age(66-111)[46]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:03:13 - fedist_numfind_v01.sas/e_haematocr_abs_cdf_locf_sas.cgm

14.3.5.40: Haematology - Haematocrit after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

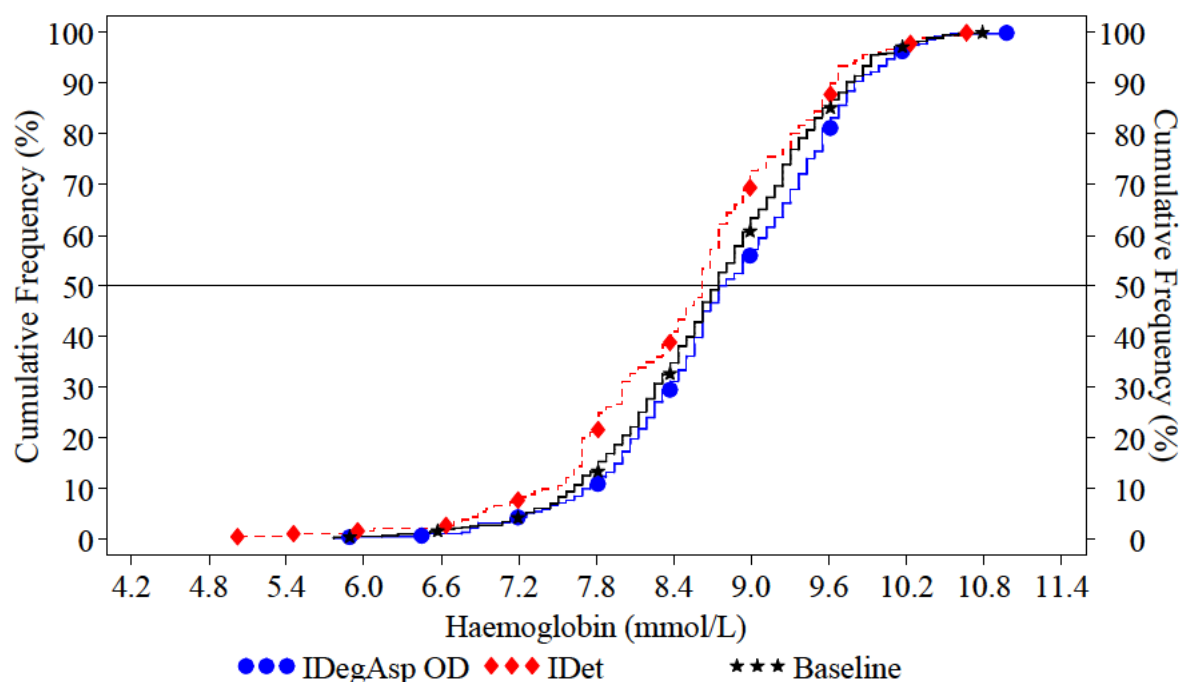
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[8.1], Age(66-111)[7.8]; Female, Age(12-66)[7.2], Age(66-111)[6.8]

Upper ref.: Male, Age(18-66)[10.9], Age(66-111)[11]; Female, Age(12-66)[10], Age(66-111)[10]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:03:20 - fbox_numfind_v01.sas/e_haemoglob_abs_box_locf_sas.cgm

14.3.5.41: Haematology - Haemoglobin - Box Plot - Safety Analysis Set



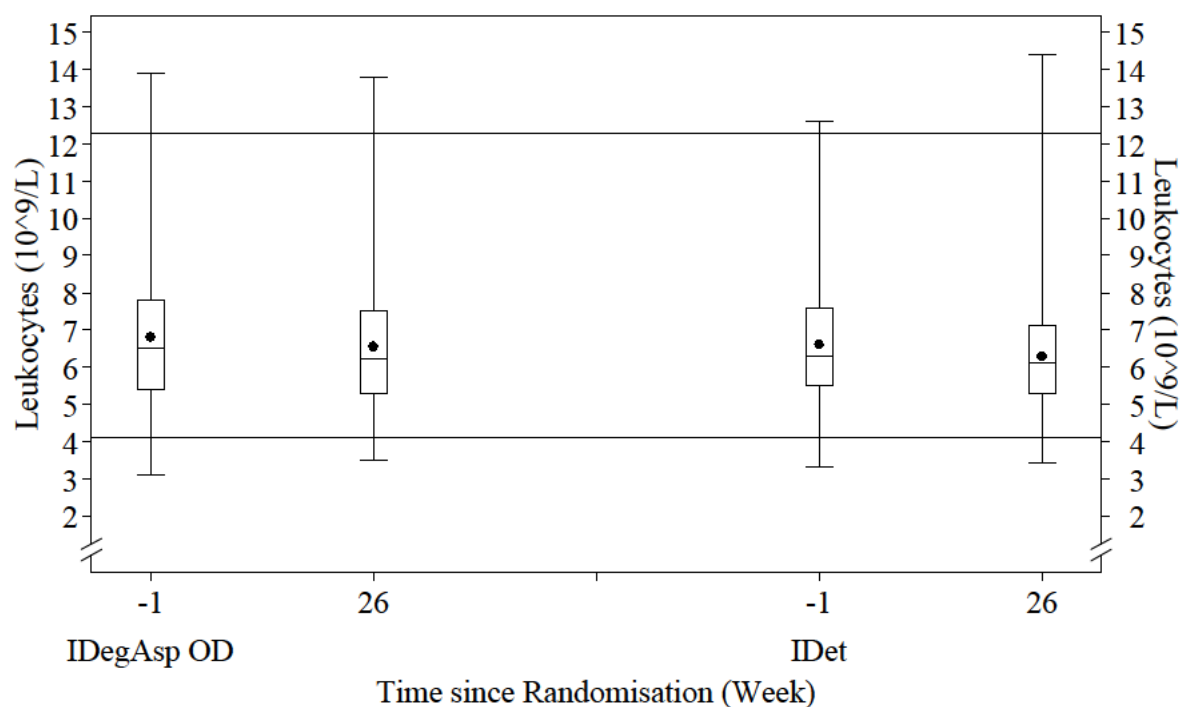
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[8.1], Age(66-111)[7.8]; Female, Age(12-66)[7.2], Age(66-111)[6.8]

Upper ref.: Male, Age(18-66)[10.9], Age(66-111)[11]; Female, Age(12-66)[10], Age(66-111)[10]

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:03:30 - fedist_numfind_v01.sas/e_haemoglob_abs_cdf_locf_sas.cgm

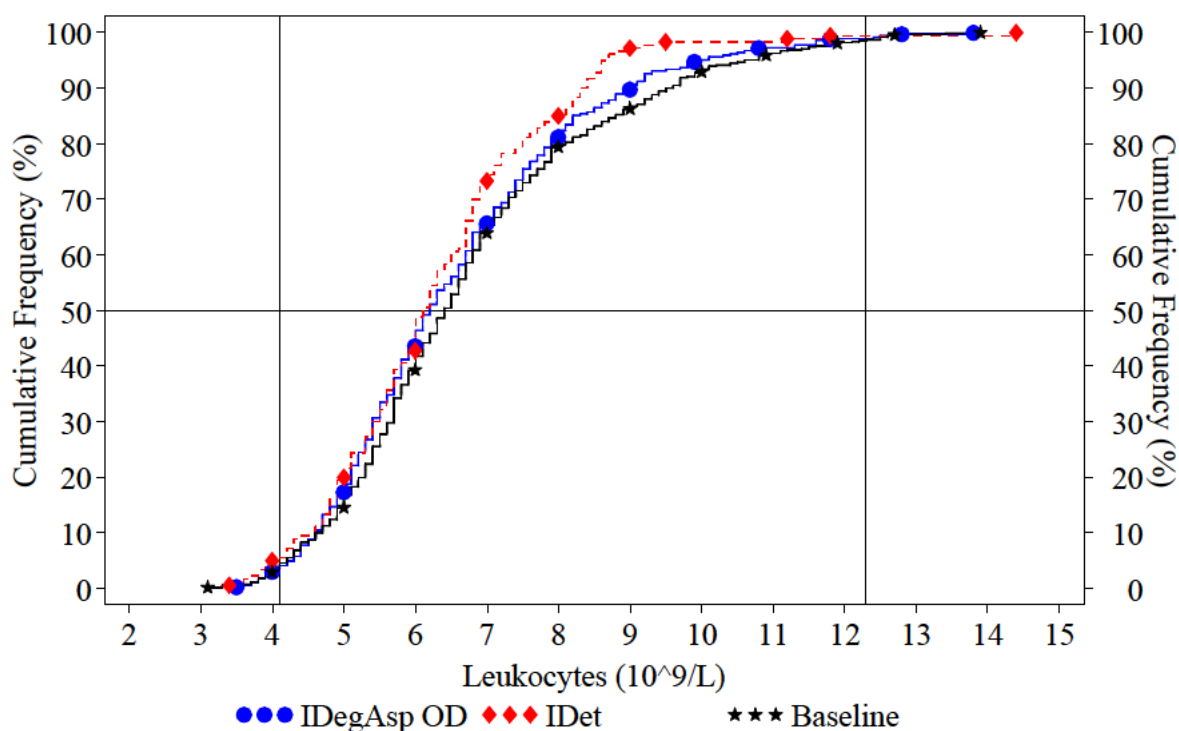
14.3.5.42: Haematology - Haemoglobin after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:03:36 - fbox_numfind_v01.sas/e_leukocyt_abs_box_locf_sas.cgm

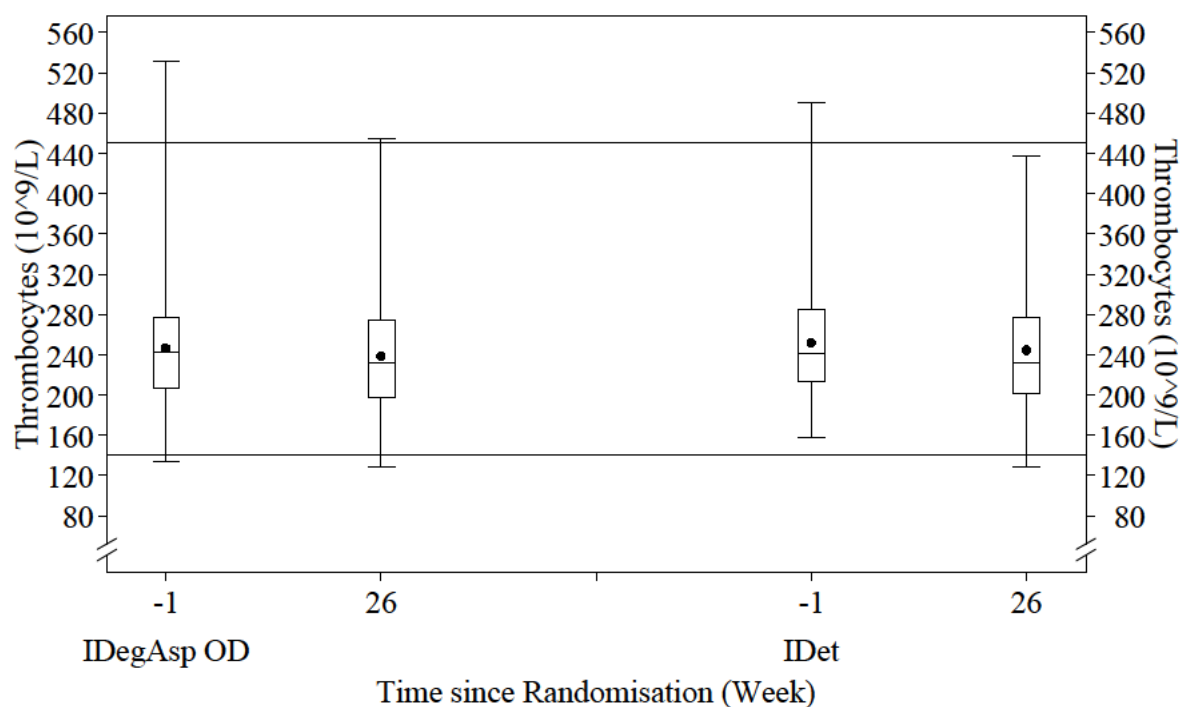
14.3.5.43: Haematology - Leukocytes - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:03:46 - fedist_numfind_v01.sas/e_leukocyt_abs_cdf_locf_sas.cgm

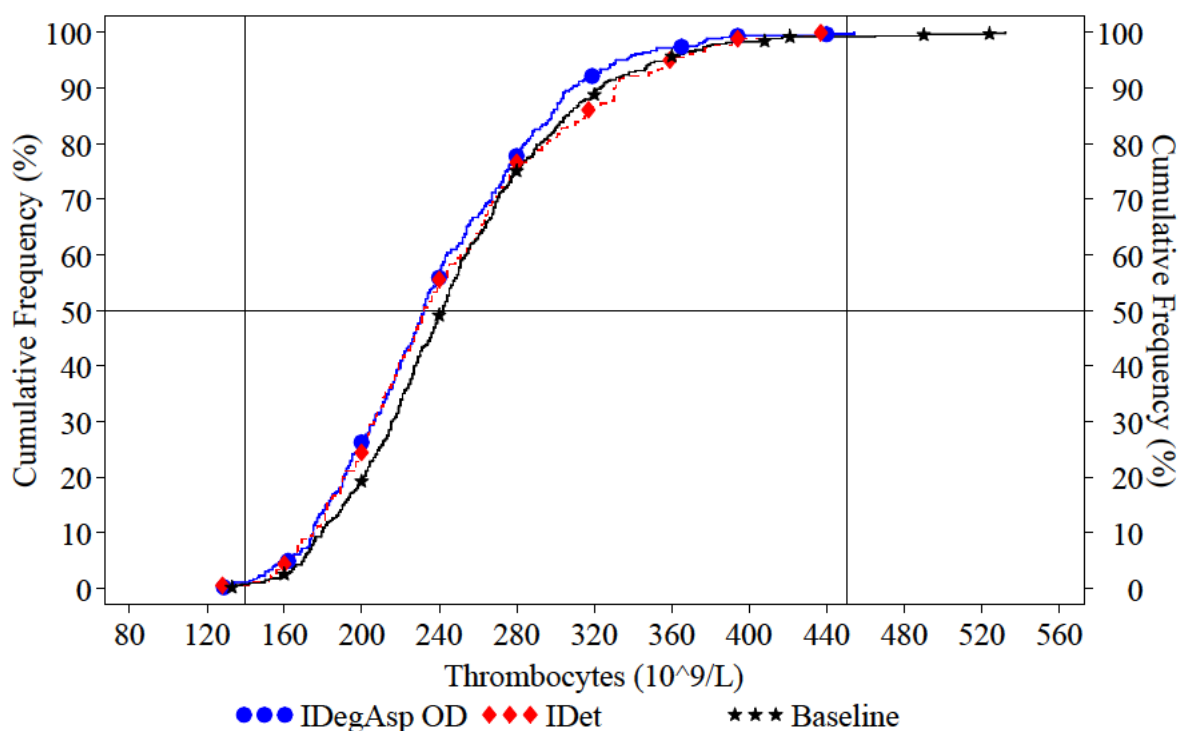
14.3.5.44: Haematology - Leukocytes after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:03:53 - fbox_numfind_v01.sas/e_thrombocyt_abs_box_locf_sas.cgm

14.3.5.45: Haematology - Thrombocytes - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:04:03 - fedist_numfind_v01.sas/e_thrombocyt_abs_cdf_locf_sas.cgm

14.3.5.46: Haematology - Thrombocytes after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.3.5.47: Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
HDL Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	1.56 (0.41)	1.61 (0.46)	1.57 (0.43)
Median	1.53	1.55	1.53
Min ; Max	0.65 ; 3.13	0.65 ; 3.39	0.65 ; 3.39
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	1.52 (0.40)	1.59 (0.45)	1.54 (0.42)
Median	1.48	1.53	1.50
Min ; Max	0.65 ; 3.26	0.80 ; 3.34	0.65 ; 3.34
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	1.54 (0.41)	1.62 (0.45)	1.57 (0.43)
Median	1.48	1.57	1.53
Min ; Max	0.65 ; 3.26	0.80 ; 3.34	0.65 ; 3.34

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:10 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_abs_descp_sas.txt

Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
LDL Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	2.69 (0.84)	2.59 (0.74)	2.65 (0.81)
Median	2.62	2.51	2.56
Min ; Max	0.73 ; 6.27	1.01 ; 5.10	0.73 ; 6.27
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	2.74 (0.88)	2.67 (0.76)	2.71 (0.85)
Median	2.63	2.59	2.59
Min ; Max	0.73 ; 6.16	0.88 ; 5.23	0.73 ; 6.16
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	2.71 (0.87)	2.67 (0.76)	2.70 (0.84)
Median	2.59	2.59	2.59
Min ; Max	0.73 ; 6.16	0.88 ; 5.23	0.73 ; 6.16

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:10 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_abs_descp_sas.txt

Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Total Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	4.77 (1.00)	4.68 (0.87)	4.74 (0.96)
Median	4.69	4.51	4.66
Min ; Max	2.25 ; 9.09	3.11 ; 8.16	2.25 ; 9.09
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	4.78 (1.08)	4.75 (0.84)	4.77 (1.00)
Median	4.63	4.64	4.64
Min ; Max	2.12 ; 9.01	2.67 ; 7.02	2.12 ; 9.01
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	4.78 (1.05)	4.77 (0.86)	4.78 (0.99)
Median	4.64	4.66	4.64
Min ; Max	2.12 ; 9.01	2.67 ; 7.23	2.12 ; 9.01

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:10 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_abs_descp_sas.txt

Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Triglycerides serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	1.15 (0.88)	1.08 (1.32)	1.13 (1.04)
Median	0.95	0.87	0.92
Min ; Max	0.36 ; 10.29	0.42 ; 17.62	0.36 ; 17.62
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	1.19 (1.23)	1.06 (0.57)	1.15 (1.06)
Median	0.90	0.93	0.90
Min ; Max	0.33 ; 13.62	0.45 ; 5.24	0.33 ; 13.62
Visit 28 (Week 26) (LOCF)			
N	361	180	541
Mean (SD)	1.17 (1.16)	1.08 (0.61)	1.14 (1.01)
Median	0.90	0.91	0.90
Min ; Max	0.33 ; 13.62	0.45 ; 5.24	0.33 ; 13.62

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:10 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_abs_descp_sas.txt

14.3.5.48: Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. HDL Cholesterol Serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Median	0.0	0.0	0.0
Min ; Max	0.0 ; 0.0	0.0 ; 0.0	0.0 ; 0.0
Visit 28 (Week 26)			
N	320	156	476
Mean (SD)	-0.0 (0.3)	0.0 (0.3)	-0.0 (0.3)
Median	-0.0	0.0	-0.0
Min ; Max	-0.8 ; 1.4	-0.7 ; 0.7	-0.8 ; 1.4
Visit 28 (Week 26) (LOCF)			
N	360	179	539
Mean (SD)	-0.0 (0.3)	0.0 (0.3)	-0.0 (0.3)
Median	-0.0	0.0	0.0
Min ; Max	-0.8 ; 1.4	-0.7 ; 1.1	-0.8 ; 1.4

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:16 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_chb_descp_sas.txt

Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. LDL Cholesterol Serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Median	0.0	0.0	0.0
Min ; Max	0.0 ; 0.0	0.0 ; 0.0	0.0 ; 0.0
Visit 28 (Week 26)			
N	319	156	475
Mean (SD)	0.0 (0.6)	0.1 (0.6)	0.0 (0.6)
Median	0.0	0.0	0.0
Min ; Max	-2.9 ; 3.8	-2.1 ; 2.5	-2.9 ; 3.8
Visit 28 (Week 26) (LOCF)			
N	360	179	539
Mean (SD)	0.0 (0.6)	0.1 (0.7)	0.0 (0.6)
Median	0.0	0.0	0.0
Min ; Max	-2.9 ; 3.8	-2.1 ; 2.8	-2.9 ; 3.8

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:16 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_chb_descp_sas.txt

Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Triglycerides Serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Median	0.0	0.0	0.0
Min ; Max	0.0 ; 0.0	0.0 ; 0.0	0.0 ; 0.0
Visit 28 (Week 26)			
N	320	156	476
Mean (SD)	0.0 (1.0)	0.1 (0.4)	0.0 (0.9)
Median	0.0	0.0	0.0
Min ; Max	-9.0 ; 10.0	-1.5 ; 2.0	-9.0 ; 10.0
Visit 28 (Week 26) (LOCF)			
N	360	179	539
Mean (SD)	0.0 (1.0)	-0.0 (1.1)	0.0 (1.0)
Median	0.0	0.0	0.0
Min ; Max	-9.0 ; 10.0	-13.9 ; 2.0	-13.9 ; 10.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:04:16 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_chb_descp_sas.txt

Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Total Cholesterol Serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Median	0.0	0.0	0.0
Min ; Max	0.0 ; 0.0	0.0 ; 0.0	0.0 ; 0.0
Visit 28 (Week 26)			
N	319	156	475
Mean (SD)	0.0 (0.8)	0.1 (0.7)	0.0 (0.8)
Median	-0.0	0.1	0.0
Min ; Max	-3.8 ; 4.2	-2.2 ; 2.8	-3.8 ; 4.2
Visit 28 (Week 26) (LOCF)			
N	360	179	539
Mean (SD)	0.0 (0.8)	0.1 (0.7)	0.0 (0.8)
Median	-0.0	0.0	0.0
Min ; Max	-3.8 ; 4.2	-2.2 ; 2.8	-3.8 ; 4.2

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:16 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_chb_descp_sas.txt

14.3.5.49: Lipids after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Total Cholesterol (mmol/L)					
LSMeans					
IDegAsp OD	366	364	4.74	0.06	
IDet	182	180	4.82	0.07	
Change from Baseline					
LSMeans					
IDegAsp OD	366	364	0.01	0.06	
IDet	182	180	0.09	0.07	
Treatment Contrast					
IDegAsp OD - IDet			-0.08		[-0.20 ; 0.05]
HDL Cholesterol (mmol/L)					
LSMeans					
IDegAsp OD	366	364	1.52	0.02	
IDet	182	180	1.55	0.03	
Change from Baseline					
LSMeans					
IDegAsp OD	366	364	-0.05	0.02	
IDet	182	180	-0.02	0.03	
Treatment Contrast					
IDegAsp OD - IDet			-0.03		[-0.07 ; 0.02]
LDL Cholesterol (mmol/L)					
LSMeans					
IDegAsp OD	366	364	2.68	0.05	
IDet	182	180	2.73	0.06	
Change from Baseline					
LSMeans					
IDegAsp OD	366	364	0.03	0.05	
IDet	182	180	0.08	0.06	
Treatment Contrast					
IDegAsp OD - IDet			-0.05		[-0.15 ; 0.06]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:04:23 - tstat_find_tpl_t022.sas/t_lipid_stat_locf_fas.txt

Lipids after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Triglycerides (mmol/L)					
LSMeans					
IDegAsp OD	366	364	1.24	0.08	
IDet	182	180	1.19	0.09	
Change from Baseline					
LSMeans					
IDegAsp OD	366	364	0.11	0.08	
IDet	182	180	0.06	0.09	
Treatment Contrast					
IDegAsp OD - IDet			0.05		[-0.10 ; 0.21]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean
 The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
 Missing data is imputed using last observation carried forward.
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:23 - tstat_find_tpl_t022.sas/t_lipid_stat_locf_fas.txt

14.3.5.50: Lipids by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
HDL Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360 (100.0)	179 (100.0)	539 (100.0)
Low	30 (8.3)	17 (9.5)	47 (8.7)
Normal	293 (81.4)	144 (80.4)	437 (81.1)
High	37 (10.3)	18 (10.1)	55 (10.2)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	26 (8.1)	8 (5.1)	34 (7.1)
Normal	265 (82.6)	130 (82.8)	395 (82.6)
High	30 (9.3)	19 (12.1)	49 (10.3)
Visit 28 Week 26 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	27 (7.5)	9 (5.0)	36 (6.7)
Normal	296 (82.0)	147 (81.7)	443 (81.9)
High	38 (10.5)	24 (13.3)	62 (11.5)
LDL Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360 (100.0)	179 (100.0)	539 (100.0)
Normal	296 (82.2)	154 (86.0)	450 (83.5)
High	64 (17.8)	25 (14.0)	89 (16.5)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Normal	254 (79.4)	132 (84.1)	386 (80.9)
High	66 (20.6)	25 (15.9)	91 (19.1)
Visit 28 Week 26 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Normal	290 (80.3)	151 (83.9)	441 (81.5)
High	71 (19.7)	29 (16.1)	100 (18.5)
Total Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360 (100.0)	179 (100.0)	539 (100.0)
Low	25 (6.9)	7 (3.9)	32 (5.9)
Normal	223 (61.9)	127 (70.9)	350 (64.9)
High	112 (31.1)	45 (25.1)	157 (29.1)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Low	22 (6.9)	6 (3.8)	28 (5.9)
Normal	202 (63.1)	109 (69.4)	311 (65.2)
High	96 (30.0)	42 (26.8)	138 (28.9)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:50 - tsum_lab_summary.sas/t_lipid_sum_sas.txt

Lipids by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Visit 28 Week 26(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	25 (6.9)	6 (3.3)	31 (5.7)
Normal	227 (62.9)	124 (68.9)	351 (64.9)
High	109 (30.2)	50 (27.8)	159 (29.4)
Triglycerides serum (mmol/L)			
Visit 2 (Week 0)			
N	360 (100.0)	179 (100.0)	539 (100.0)
Low	20 (5.6)	7 (3.9)	27 (5.0)
Normal	327 (90.8)	170 (95.0)	497 (92.2)
High	13 (3.6)	2 (1.1)	15 (2.8)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	16 (5.0)	3 (1.9)	19 (4.0)
Normal	296 (92.2)	152 (96.8)	448 (93.7)
High	9 (2.8)	2 (1.3)	11 (2.3)
Visit 28 Week 26(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	17 (4.7)	4 (2.2)	21 (3.9)
Normal	335 (92.8)	173 (96.1)	508 (93.9)
High	9 (2.5)	3 (1.7)	12 (2.2)

N = Number of Subjects

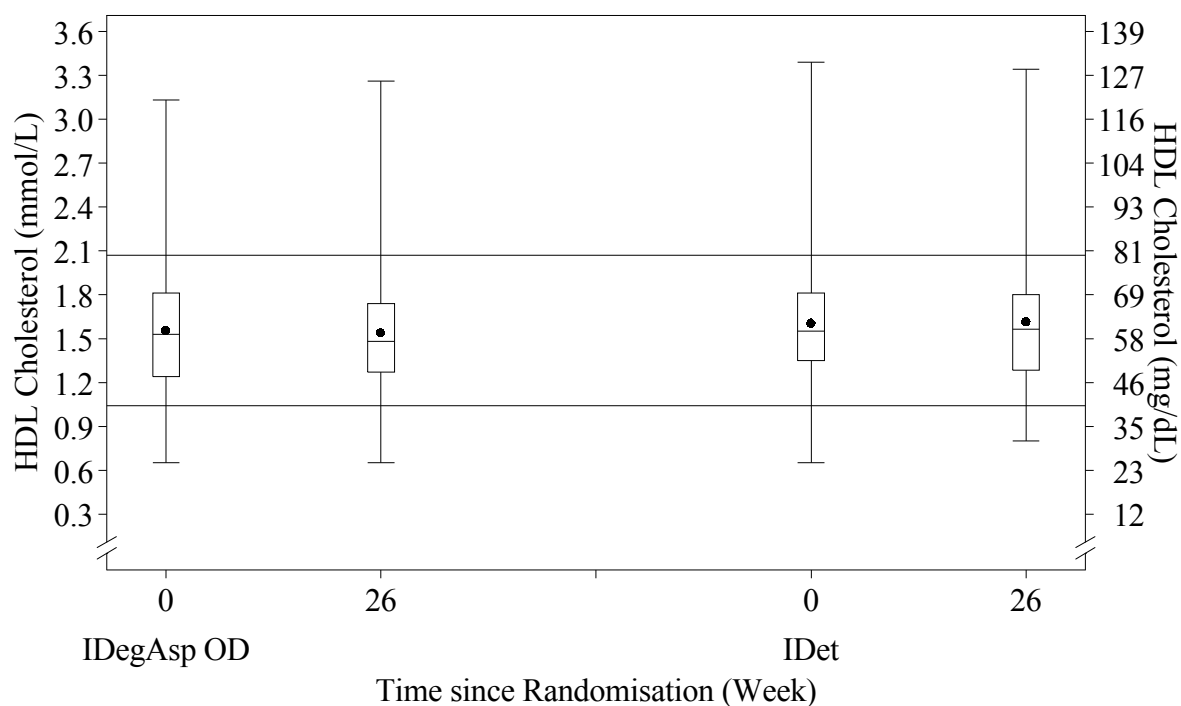
nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:19:50 - tsum_lab_summary.sas/t_lipid_sum_sas.txt

14.3.5.51: Lipids – Shift Table – Baseline to Week 26 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 28 (Week 26)								
HDL Cholesterol serum (mmol/L)								
Low	17 (4.7)	9 (2.5)	0 (0.0)	0 (0.0)	6 (3.3)	2 (1.1)	0 (0.0)	0 (0.0)
Normal	10 (2.8)	239 (66.0)	15 (4.1)	1 (0.3)	10 (5.6)	117 (65.0)	2 (1.1)	1 (0.6)
High	0 (0.0)	17 (4.7)	13 (3.6)	0 (0.0)	0 (0.0)	6 (3.3)	13 (7.2)	0 (0.0)
Missing	3 (0.8)	28 (7.7)	9 (2.5)	1 (0.3)	1 (0.6)	19 (10.6)	3 (1.7)	0 (0.0)
LDL Cholesterol serum (mmol/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	240 (66.3)	13 (3.6)	1 (0.3)	0 (0.0)	121 (67.2)	10 (5.6)	1 (0.6)
High	0 (0.0)	24 (6.6)	42 (11.6)	0 (0.0)	0 (0.0)	11 (6.1)	14 (7.8)	0 (0.0)
Missing	0 (0.0)	32 (8.8)	9 (2.5)	1 (0.3)	0 (0.0)	22 (12.2)	1 (0.6)	0 (0.0)
Total Cholesterol serum (mmol/L)								
Low	10 (2.8)	12 (3.3)	0 (0.0)	0 (0.0)	2 (1.1)	4 (2.2)	0 (0.0)	0 (0.0)
Normal	12 (3.3)	168 (46.4)	22 (6.1)	0 (0.0)	5 (2.8)	85 (47.2)	18 (10.0)	1 (0.6)
High	0 (0.0)	23 (6.4)	72 (19.9)	1 (0.3)	0 (0.0)	20 (11.1)	22 (12.2)	0 (0.0)
Missing	3 (0.8)	20 (5.5)	18 (5.0)	1 (0.3)	0 (0.0)	18 (10.0)	5 (2.8)	0 (0.0)
Triglycerides serum (mmol/L)								
Low	6 (1.7)	9 (2.5)	1 (0.3)	0 (0.0)	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
Normal	11 (3.0)	278 (76.8)	6 (1.7)	1 (0.3)	7 (3.9)	144 (80.0)	0 (0.0)	1 (0.6)
High	0 (0.0)	3 (0.8)	6 (1.7)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)	0 (0.0)
Missing	3 (0.8)	37 (10.2)	0 (0.0)	1 (0.3)	0 (0.0)	22 (12.2)	1 (0.6)	0 (0.0)

N: Number of subjects

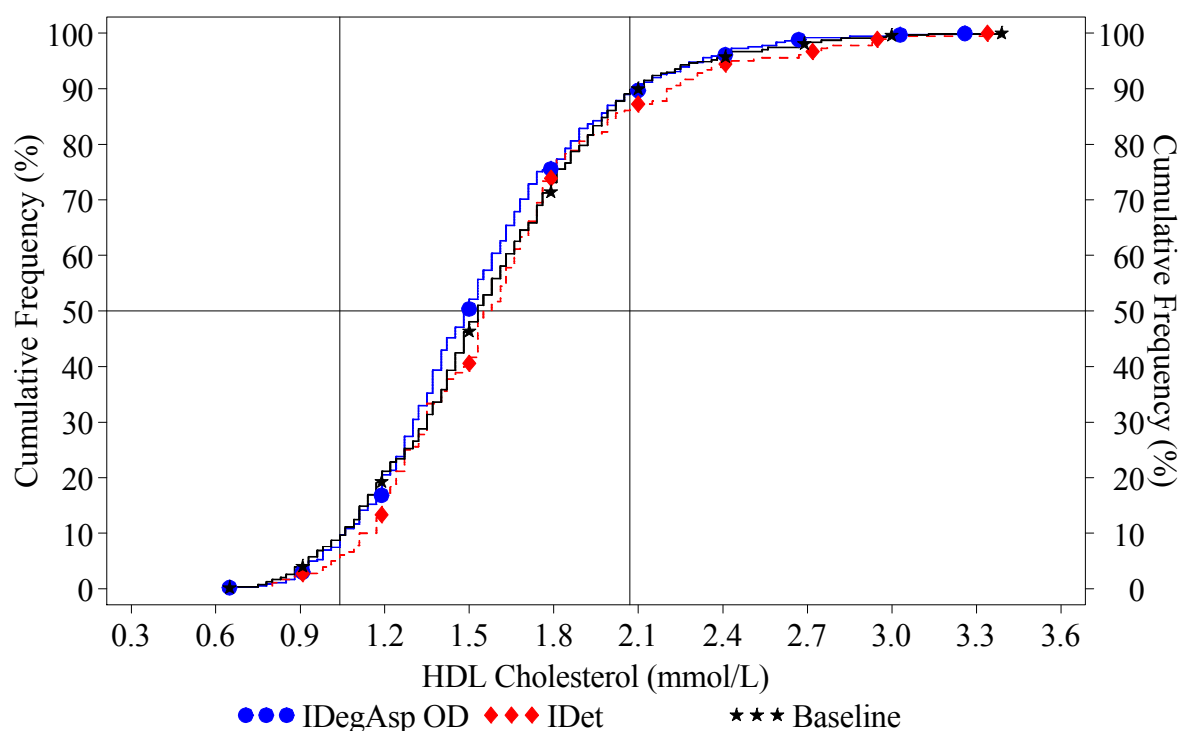
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:18 - t_lab_shift.sas/t_lipid_shift_w26_sas.txt



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:29 - fbox_numfind_v01.sas/e_hdl_abs_box_locf_sas.cgm

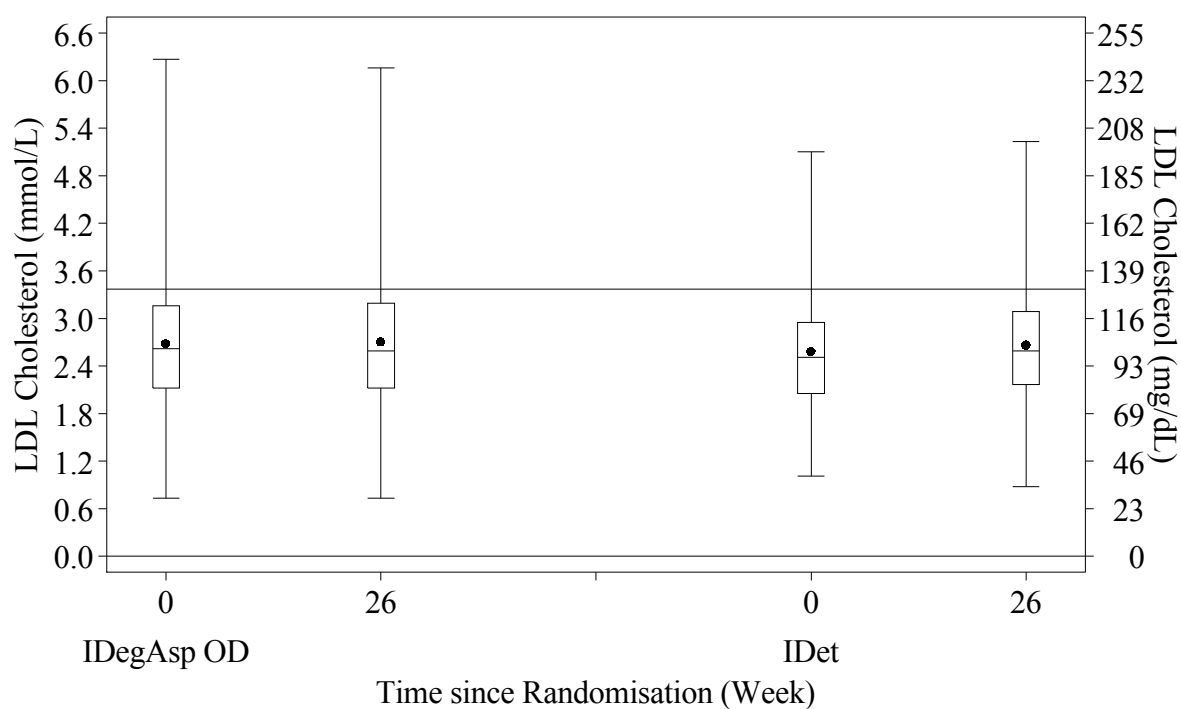
14.3.5.52: Lipid - HDL Cholesterol - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:40 - fedist_numfind_v01.sas/e_hdl_abs_cdf_locf_sas.cgm

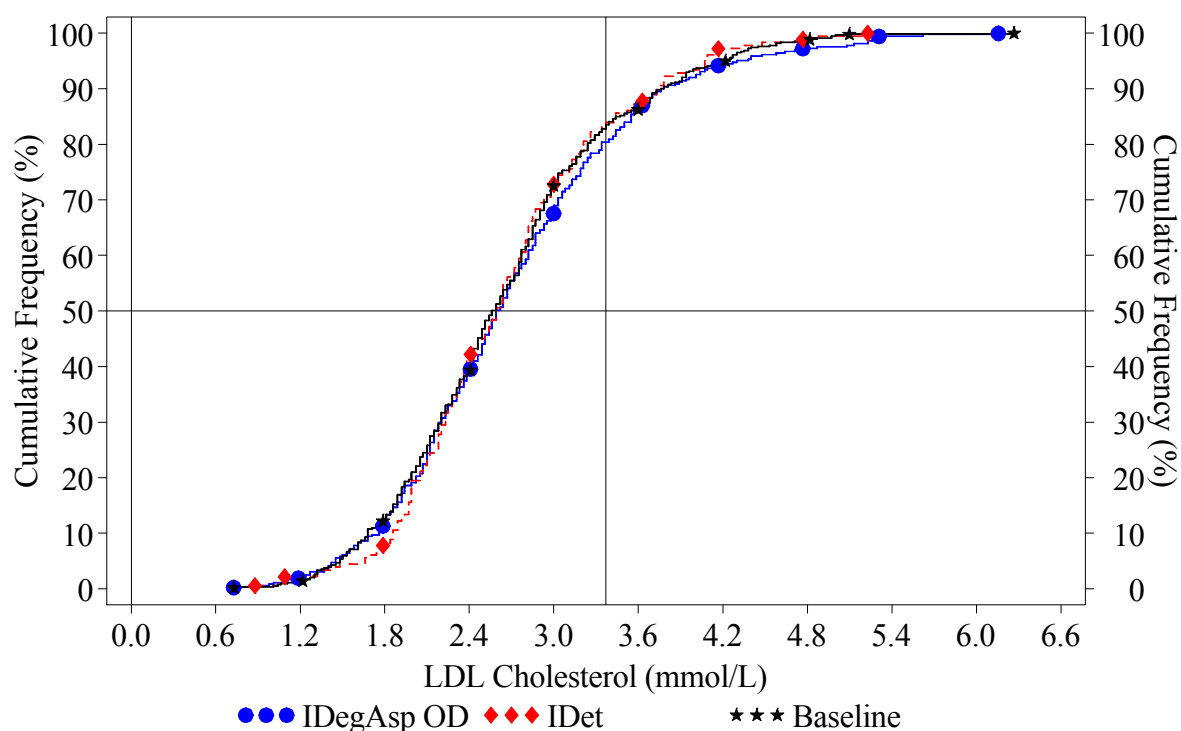
14.3.5.53: Lipid - HDL Cholesterol after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:04:46 - fbox_numfind_v01.sas/e_ldl_abs_box_locf_sas.cgm

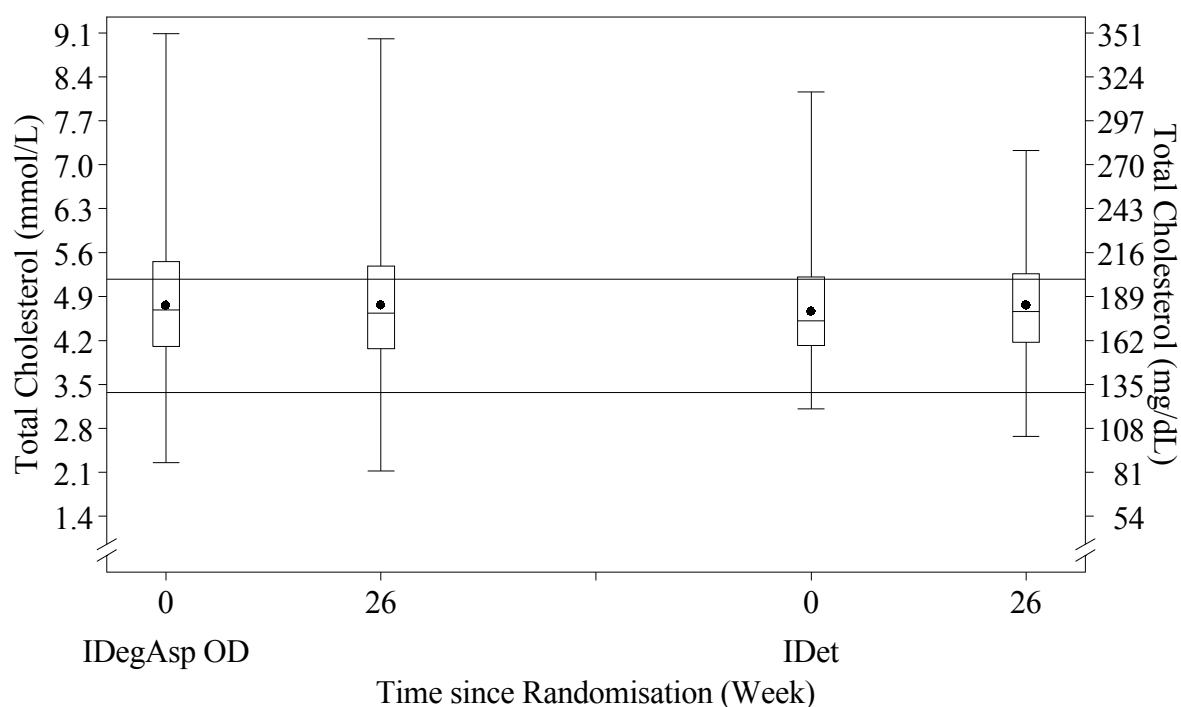
14.3.5.54: Lipid - LDL Cholesterol - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:04:57 - fedist_numfind_v01.sas/e_ldl_abs_cdf_locf_sas.cgm

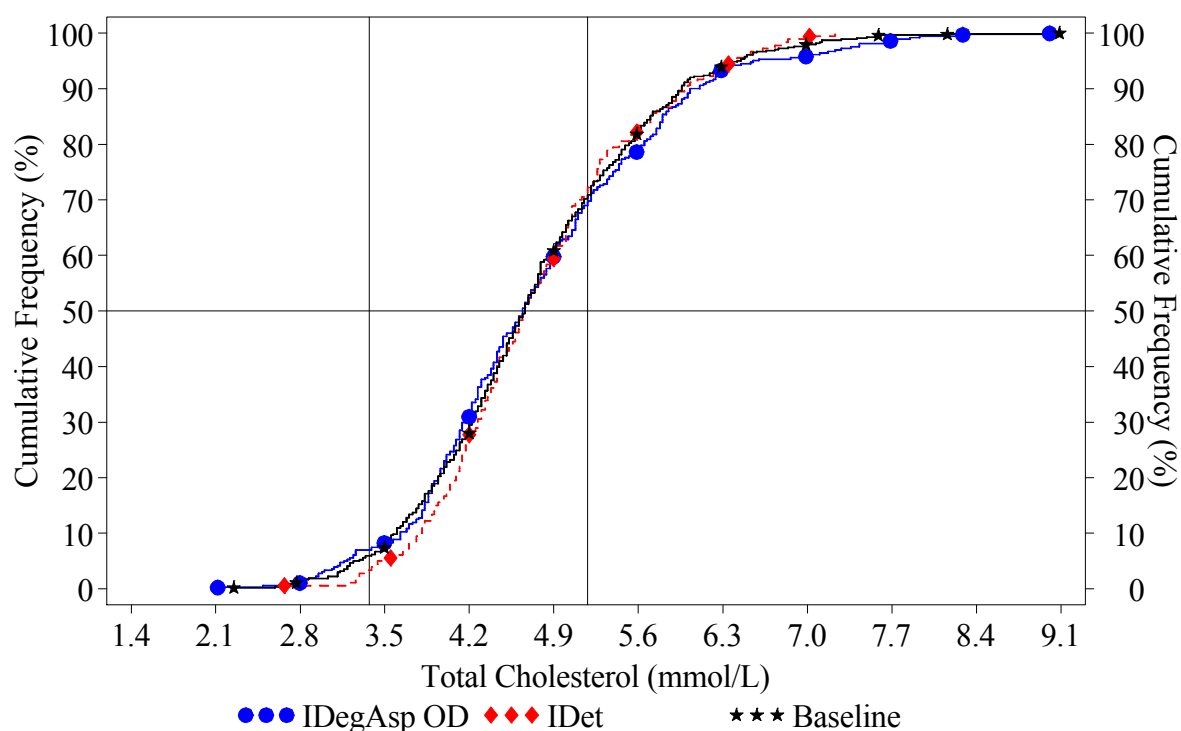
14.3.5.55: Lipid - LDL Cholesterol after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:05:03 - fbox_numfind_v01.sas/e_t_chol_abs_box_locf_sas.cgm

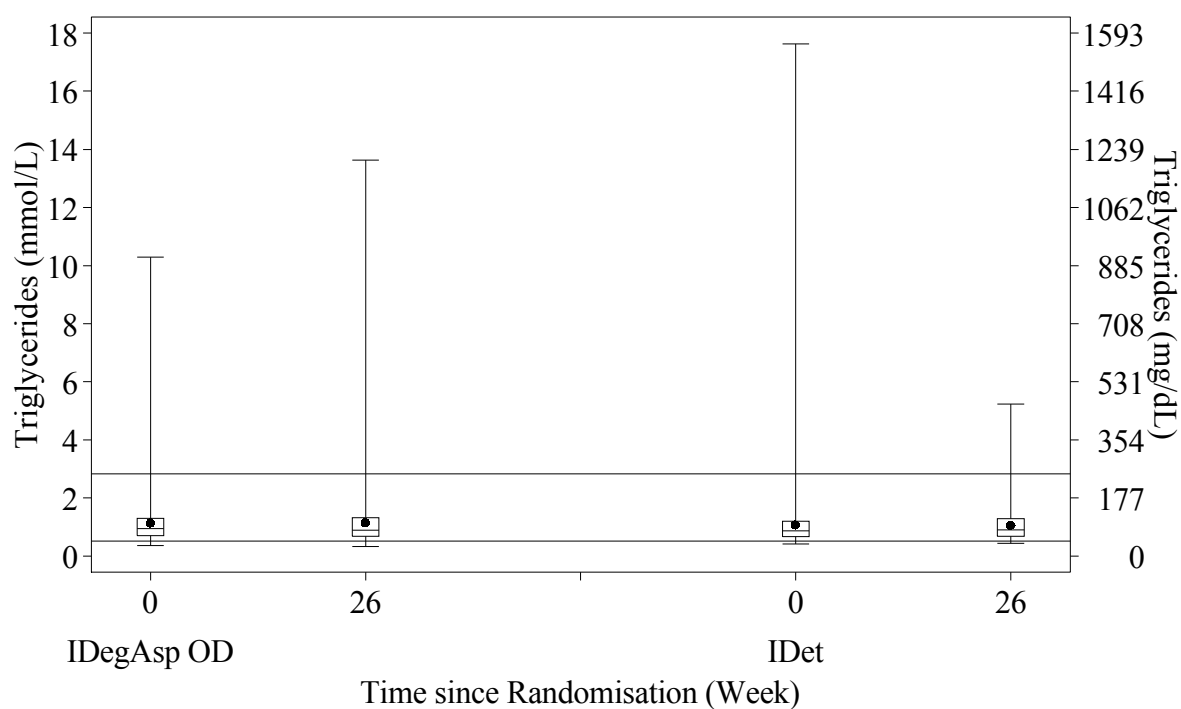
14.3.5.56: Lipid - Tot. Chol. Serum - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:05:13 - fedist_numfind_v01.sas/e_t_chol_abs_cdf_locf_sas.cgm

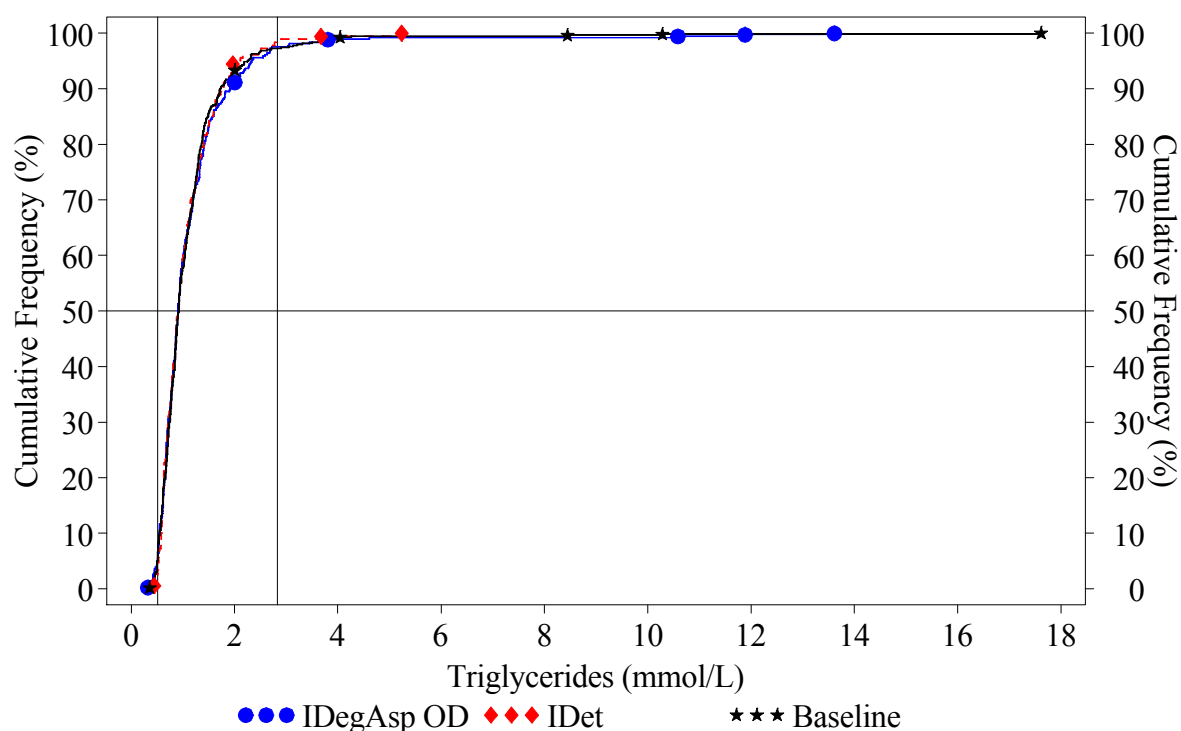
14.3.5.57: Lipid - Tot. Chol. Serum after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:05:19 - fbox_numfind_v01.sas/e_triglyc_abs_box_locf_sas.cgm

14.3.5.58: Lipid - Triglycerides Serum - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:05:29 - fedist_numfind_v01.sas/e_triglyc_abs_cdf_locf_sas.cgm

14.3.5.59: Lipid - Triglycerides Serum after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.3.5.60: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Albumin/Creatinine Ratio (mg/mmol)			
Visit 2 (Week 0)			
N	358	178	536
Mean (SD)	3.8 (15.1)	4.2 (18.2)	3.9 (16.2)
Median	0.6	0.6	0.6
Min ; Max	0.1 ; 217.6	0.1 ; 200.9	0.1 ; 217.6
Visit 28 (Week 26)			
N	317	154	471
Mean (SD)	4.2 (16.1)	4.8 (21.5)	4.4 (18.0)
Median	0.6	0.6	0.6
Min ; Max	0.1 ; 181.3	0.1 ; 237.5	0.1 ; 237.5
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	4.8 (19.6)	5.6 (23.7)	5.1 (21.0)
Median	0.6	0.6	0.6
Min ; Max	0.1 ; 217.6	0.1 ; 237.5	0.1 ; 237.5

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:05:36 - tdesc_numfind_tpl_t019_v01.sas/t_urinary_ratio_abs_descp_sas.txt

14.3.5.61: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Albumin / Creatinine Ratio (mg/mmol)			
Visit 2 (Week 0)			
N	358	178	536
Mean (SD)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Median	0.0	0.0	0.0
Min ; Max	0.0 ; 0.0	0.0 ; 0.0	0.0 ; 0.0
Visit 28 (Week 26)			
N	313	152	465
Mean (SD)	1.0 (11.0)	1.2 (8.3)	1.1 (10.2)
Median	0.0	0.0	0.0
Min ; Max	-59.0 ; 103.3	-22.1 ; 75.3	-59.0 ; 103.3
Visit 28 (Week 26) (LOCF)			
N	358	178	536
Mean (SD)	1.1 (10.6)	1.4 (9.2)	1.2 (10.2)
Median	0.0	0.0	0.0
Min ; Max	-59.0 ; 103.3	-22.1 ; 75.3	-59.0 ; 103.3

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:05:42 - tdesc_numfind_tpl_t019_v01.sas/t_urinary_ratio_chb_descp_sas.txt

14.3.5.62: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Albumin/Creatinine Ratio (mg/mmol)			
Visit 2 (Week 0)			
N	358 (100.0)	178 (100.0)	536 (100.0)
Normal	312 (87.2)	156 (87.6)	468 (87.3)
High	46 (12.8)	22 (12.4)	68 (12.7)
Visit 28 (Week 26)			
N	317 (100.0)	154 (100.0)	471 (100.0)
Normal	275 (86.8)	133 (86.4)	408 (86.6)
High	42 (13.2)	21 (13.6)	63 (13.4)
Visit 28 Week 26 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	316 (87.3)	154 (85.6)	470 (86.7)
High	46 (12.7)	26 (14.4)	72 (13.3)

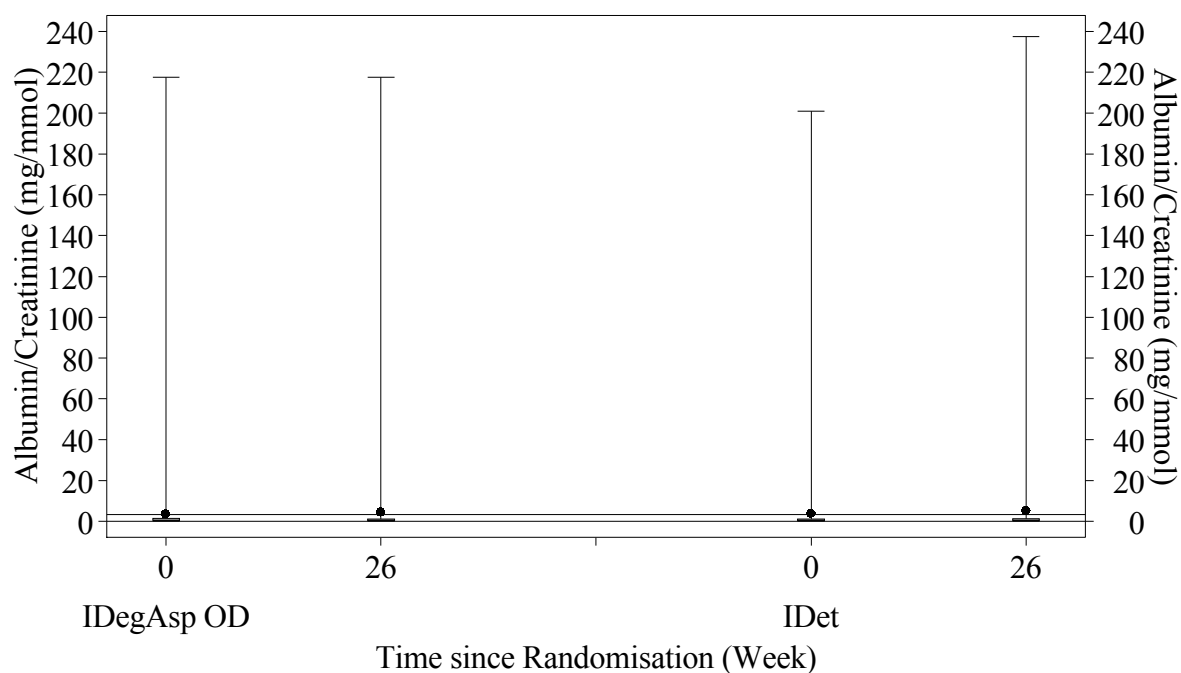
N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:19:55 - tsum_lab_summary.sas/t_urinary_ratio_sum_sas.txt

14.3.5.63: Urinary Albumin-to-Creatinine Ratio – Shift Table – Baseline to Week 26 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 28 (Week 26)								
Albumin/Creatinine Ratio (mg/mmol)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	262 (72.4)	9 (2.5)	4 (1.1)	0 (0.0)	127 (70.6)	5 (2.8)	1 (0.6)
High	0 (0.0)	10 (2.8)	32 (8.8)	0 (0.0)	0 (0.0)	6 (3.3)	14 (7.8)	1 (0.6)
Missing	0 (0.0)	40 (11.0)	5 (1.4)	0 (0.0)	0 (0.0)	23 (12.8)	3 (1.7)	0 (0.0)

N: Number of subjects



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

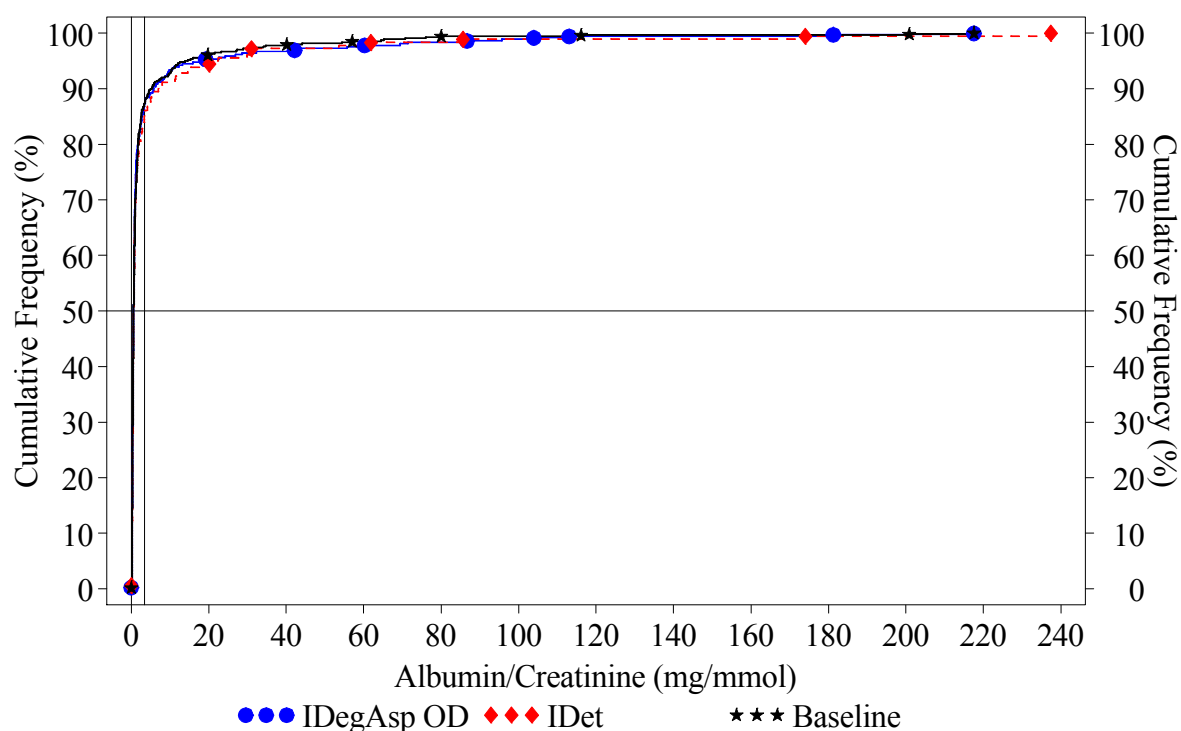
SAFETY: LOCF imputed data

Lower ref.: Male, Age(13-110)[0]; Female, Age(13-110)[0];

Upper ref.: Male, Age(13-110)[3.4]; Female, Age(13-110)[3.4]

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:05:48 - fbox_numfind_v01.sas/e_urinary_ratio_abs_box_locf_sas.cgm

14.3.5.64: Urinary Albumin-to-Creatinine Ratio - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:05:58 - fedist_numfind_v01.sas/e_urinary_ratio_abs_cdf_locf_sas.cgm

14.3.5.65: Urinary Albumin-to-Creatinine Ratio after 26 Weeks of Treatment – Empirical Distribution Plot - Safety Analysis Set

14.3.5.66: Urine by Sticks - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
ERCS Urine			
Visit 1			
N	360 (100.0)	178 (100.0)	538 (100.0)
Negative	324 (90.0)	167 (93.8)	491 (91.3)
Positive	36 (10.0)	11 (6.2)	47 (8.7)
Visit 28 (Week 26)			
N	313 (100.0)	153 (100.0)	466 (100.0)
Negative	297 (94.9)	137 (89.5)	434 (93.1)
Positive	16 (5.1)	16 (10.5)	32 (6.9)
Visit 28 Week 26(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Negative	340 (94.2)	163 (90.6)	503 (93.0)
Positive	21 (5.8)	17 (9.4)	38 (7.0)
Ketones			
Visit 1			
N	360 (100.0)	178 (100.0)	538 (100.0)
Negative	298 (82.8)	161 (90.4)	459 (85.3)
Positive	62 (17.2)	17 (9.6)	79 (14.7)
Visit 28 (Week 26)			
N	313 (100.0)	153 (100.0)	466 (100.0)
Negative	290 (92.7)	133 (86.9)	423 (90.8)
Positive	23 (7.3)	20 (13.1)	43 (9.2)
Visit 28 Week 26(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Negative	330 (91.4)	153 (85.0)	483 (89.3)
Positive	31 (8.6)	27 (15.0)	58 (10.7)
Protein-sticks			
Visit 1			
N	360 (100.0)	178 (100.0)	538 (100.0)
Negative	261 (72.5)	137 (77.0)	398 (74.0)
Positive	99 (27.5)	41 (23.0)	140 (26.0)
Visit 28 (Week 26)			
N	313 (100.0)	153 (100.0)	466 (100.0)
Negative	184 (58.8)	107 (69.9)	291 (62.4)
Positive	129 (41.2)	46 (30.1)	175 (37.6)
Visit 28 Week 26(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Negative	217 (60.1)	122 (67.8)	339 (62.7)
Positive	144 (39.9)	58 (32.2)	202 (37.3)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:19:58 - tsum_lab_summary.sas/t_urine_sticks_sum_sas.txt

14.3.5.67: Urine by Sticks – Shift Table – Baseline to Week 26 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Positive N (%)	Negative N (%)	Trace N (%)	Unknown N (%)	Positive N (%)	Negative N (%)	Trace N (%)	Unknown N (%)
Visit 28 (Week 26)								
ERCS Urine								
Positive	6 (1.7)	9 (2.5)	0 (0.0)	1 (0.3)	2 (1.1)	14 (7.8)	0 (0.0)	0 (0.0)
Negative	23 (6.4)	274 (75.7)	0 (0.0)	0 (0.0)	8 (4.4)	128 (71.1)	0 (0.0)	1 (0.6)
Trace	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Unknown	7 (1.9)	41 (11.3)	0 (0.0)	1 (0.3)	1 (0.6)	25 (13.9)	0 (0.0)	1 (0.6)
Ketones Urine Stick								
Positive	2 (0.6)	20 (5.5)	0 (0.0)	1 (0.3)	3 (1.7)	17 (9.4)	0 (0.0)	0 (0.0)
Negative	54 (14.9)	236 (65.2)	0 (0.0)	0 (0.0)	12 (6.7)	120 (66.7)	0 (0.0)	1 (0.6)
Trace	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Unknown	6 (1.7)	42 (11.6)	0 (0.0)	1 (0.3)	2 (1.1)	24 (13.3)	0 (0.0)	1 (0.6)
Urine Protein-sticks								
Positive	48 (13.3)	80 (22.1)	0 (0.0)	1 (0.3)	20 (11.1)	25 (13.9)	0 (0.0)	1 (0.6)
Negative	36 (9.9)	148 (40.9)	0 (0.0)	0 (0.0)	12 (6.7)	95 (52.8)	0 (0.0)	0 (0.0)
Trace	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Unknown	15 (4.1)	33 (9.1)	0 (0.0)	1 (0.3)	9 (5.0)	17 (9.4)	0 (0.0)	1 (0.6)

N: Number of subjects, ERCS Urine: Erythrocytes urine

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:18:28 - t_lab_shift.sas/t_urine_sticks_shift_w26_sas.txt

14.3.6 Displays of Vital Signs, Physical Findings and Other Observations Related to Safety

14.3.6.1: Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Cardiovascular System			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	344 (95.0)	166 (92.2)	510 (94.1)
Abnormal, Not Clinically Significant	16 (4.4)	12 (6.7)	28 (5.2)
Abnormal, Clinically Significant	2 (0.6)	2 (1.1)	4 (0.7)
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	300 (93.5)	143 (91.1)	443 (92.7)
Abnormal, Not Clinically Significant	18 (5.6)	7 (4.5)	25 (5.2)
Abnormal, Clinically Significant	1 (0.3)	3 (1.9)	4 (0.8)
UNKNOWN	2 (0.6)	4 (2.5)	6 (1.3)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	337 (93.1)	163 (90.6)	500 (92.3)
Abnormal, Not Clinically Significant	19 (5.2)	8 (4.4)	27 (5.0)
Abnormal, Clinically Significant	2 (0.6)	3 (1.7)	5 (0.9)
UNKNOWN	4 (1.1)	6 (3.3)	10 (1.8)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:06:03 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Central and Peripheral Nervous System			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	275 (76.0)	133 (73.9)	408 (75.3)
Abnormal, Not Clinically Significant	74 (20.4)	43 (23.9)	117 (21.6)
Abnormal, Clinically Significant	13 (3.6)	4 (2.2)	17 (3.1)
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	256 (79.8)	119 (75.8)	375 (78.5)
Abnormal, Not Clinically Significant	57 (17.8)	32 (20.4)	89 (18.6)
Abnormal, Clinically Significant	6 (1.9)	2 (1.3)	8 (1.7)
UNKNOWN	2 (0.6)	4 (2.5)	6 (1.3)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	292 (80.7)	137 (76.1)	429 (79.2)
Abnormal, Not Clinically Significant	59 (16.3)	35 (19.4)	94 (17.3)
Abnormal, Clinically Significant	7 (1.9)	2 (1.1)	9 (1.7)
UNKNOWN	4 (1.1)	6 (3.3)	10 (1.8)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:06:03 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Head, Ears, Eyes, Nose, Throat, Neck			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	312 (86.2)	164 (91.1)	476 (87.8)
Abnormal, Not Clinically Significant	45 (12.4)	15 (8.3)	60 (11.1)
Abnormal, Clinically Significant	5 (1.4)	1 (0.6)	6 (1.1)
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	284 (88.5)	142 (90.4)	426 (89.1)
Abnormal, Not Clinically Significant	32 (10.0)	11 (7.0)	43 (9.0)
Abnormal, Clinically Significant	3 (0.9)	0 (0.0)	3 (0.6)
UNKNOWN	2 (0.6)	4 (2.5)	6 (1.3)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	320 (88.4)	160 (88.9)	480 (88.6)
Abnormal, Not Clinically Significant	35 (9.7)	14 (7.8)	49 (9.0)
Abnormal, Clinically Significant	3 (0.8)	0 (0.0)	3 (0.6)
UNKNOWN	4 (1.1)	6 (3.3)	10 (1.8)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:06:03 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Musculoskeletal System			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	345 (95.3)	169 (93.9)	514 (94.8)
Abnormal, Not Clinically Significant	15 (4.1)	10 (5.6)	25 (4.6)
Abnormal, Clinically Significant	2 (0.6)	1 (0.6)	3 (0.6)
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	309 (96.3)	145 (92.4)	454 (95.0)
Abnormal, Not Clinically Significant	9 (2.8)	7 (4.5)	16 (3.3)
Abnormal, Clinically Significant	1 (0.3)	1 (0.6)	2 (0.4)
UNKNOWN	2 (0.6)	4 (2.5)	6 (1.3)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	347 (95.9)	164 (91.1)	511 (94.3)
Abnormal, Not Clinically Significant	10 (2.8)	9 (5.0)	19 (3.5)
Abnormal, Clinically Significant	1 (0.3)	1 (0.6)	2 (0.4)
UNKNOWN	4 (1.1)	6 (3.3)	10 (1.8)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:06:03 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Respiratory System			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	359 (99.2)	177 (98.3)	536 (98.9)
Abnormal, Not Clinically Significant	3 (0.8)	3 (1.7)	6 (1.1)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	316 (98.4)	150 (95.5)	466 (97.5)
Abnormal, Not Clinically Significant	3 (0.9)	3 (1.9)	6 (1.3)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
UNKNOWN	2 (0.6)	4 (2.5)	6 (1.3)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	355 (98.1)	171 (95.0)	526 (97.0)
Abnormal, Not Clinically Significant	3 (0.8)	3 (1.7)	6 (1.1)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
UNKNOWN	4 (1.1)	6 (3.3)	10 (1.8)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:06:03 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Skin			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	329 (90.9)	163 (90.6)	492 (90.8)
Abnormal, Not Clinically Significant	29 (8.0)	16 (8.9)	45 (8.3)
Abnormal, Clinically Significant	4 (1.1)	1 (0.6)	5 (0.9)
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	291 (90.7)	133 (84.7)	424 (88.7)
Abnormal, Not Clinically Significant	25 (7.8)	20 (12.7)	45 (9.4)
Abnormal, Clinically Significant	3 (0.9)	0 (0.0)	3 (0.6)
UNKNOWN	2 (0.6)	4 (2.5)	6 (1.3)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	327 (90.3)	153 (85.0)	480 (88.6)
Abnormal, Not Clinically Significant	28 (7.7)	21 (11.7)	49 (9.0)
Abnormal, Clinically Significant	3 (0.8)	0 (0.0)	3 (0.6)
UNKNOWN	4 (1.1)	6 (3.3)	10 (1.8)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:06:03 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Gastrointestinal System incl. Mouth			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	355 (98.1)	173 (96.1)	528 (97.4)
Abnormal, Not Clinically Significant	6 (1.7)	7 (3.9)	13 (2.4)
Abnormal, Clinically Significant	1 (0.3)	0 (0.0)	1 (0.2)
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	315 (98.1)	152 (96.8)	467 (97.7)
Abnormal, Not Clinically Significant	3 (0.9)	1 (0.6)	4 (0.8)
Abnormal, Clinically Significant	1 (0.3)	0 (0.0)	1 (0.2)
UNKNOWN	2 (0.6)	4 (2.5)	6 (1.3)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	353 (97.5)	172 (95.6)	525 (96.9)
Abnormal, Not Clinically Significant	4 (1.1)	2 (1.1)	6 (1.1)
Abnormal, Clinically Significant	1 (0.3)	0 (0.0)	1 (0.2)
UNKNOWN	4 (1.1)	6 (3.3)	10 (1.8)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:06:03 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

14.3.6.2: Physical Examination - Shift Table - Baseline to Week 26 - Safety Analysis Set

IDegAsp OD				IDet		
Number of Subjects	362			180		
	Visit 28 (Week 26)					
	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
Visit 1	N	N	N	N	N	N
Cardiovascular System						
Normal	294	8	1	140	1	1
Abnormal, NCS	5	10	0	2	6	1
Abnormal, CS	1	0	0	1	0	1
Central and Peripheral Nervous System						
Normal	235	2	0	110	2	0
Abnormal, NCS	16	53	1	7	30	0
Abnormal, CS	5	2	5	2	0	2
Gastrointestinal System incl. Mouth						
Normal	310	2	1	149	0	0
Abnormal, NCS	4	1	0	3	1	0
Abnormal, CS	1	0	0	0	0	0
Head, Ears, Eyes, Nose, Throat, Neck						
Normal	268	7	1	139	2	0
Abnormal, NCS	12	24	2	3	8	0
Abnormal, CS	4	1	0	0	1	0
Musculoskeletal System						
Normal	303	3	0	144	1	0
Abnormal, NCS	5	6	0	1	6	0
Abnormal, CS	1	0	1	0	0	1

N = Number of Subjects, NCS = Not Clinically Significant, CS = Clinically Significant.
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:06:07 - tshift_catgofind_tpl_t026_v01.sas/t_phys_exam_shift_w26_sas.txt

Physical Examination - Shift Table - Baseline to Week 26 - Safety Analysis Set

IDegAsp OD				IDet		
Number of Subjects						
362				180		
				Visit 28 (Week 26)		
Visit 1	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
	N	N	N	N	N	N
Respiratory System						
Normal	316	1	0	149	1	0
Abnormal, NCS	0	2	0	1	2	0
Abnormal, CS	0	0	0	0	0	0
Skin						
Normal	282	6	2	131	8	0
Abnormal, NCS	7	18	0	1	12	0
Abnormal, CS	2	1	1	1	0	0

14.3.6.3: Vital Signs by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Pulse (beats/min)			
Visit 1			
N	362	180	542
Mean (SD)	74.6 (10.4)	74.3 (10.4)	74.5 (10.4)
Median	74.0	74.0	74.0
Min ; Max	47.0 ; 112.0	50.0 ; 102.0	47.0 ; 112.0
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	74.8 (10.3)	75.5 (10.8)	75.1 (10.5)
Median	74.0	74.0	74.0
Min ; Max	45.0 ; 110.0	52.0 ; 108.0	45.0 ; 110.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	74.9 (10.3)	75.7 (10.6)	75.1 (10.4)
Median	74.0	75.5	75.0
Min ; Max	45.0 ; 110.0	52.0 ; 108.0	45.0 ; 110.0

Vital Signs by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Mean Diastolic BP (mmHg)			
Visit 1			
N	357	177	534
Mean (SD)	75.8 (8.8)	74.8 (8.2)	75.5 (8.6)
Median	77.0	74.0	75.0
Min ; Max	40.0 ; 103.0	50.0 ; 97.0	40.0 ; 103.0
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	75.0 (8.9)	74.5 (9.4)	74.9 (9.1)
Median	75.0	75.0	75.0
Min ; Max	40.0 ; 96.0	51.0 ; 99.0	40.0 ; 99.0
Visit 28 (Week 26) (LOCF)			
N	362	179	541
Mean (SD)	74.9 (8.8)	74.6 (9.1)	74.8 (8.9)
Median	75.0	75.0	75.0
Min ; Max	40.0 ; 96.0	51.0 ; 99.0	40.0 ; 99.0

Vital Signs by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Mean Systolic BP (mmHg)			
Visit 1			
N	357	177	534
Mean (SD)	123.9 (13.9)	123.5 (13.6)	123.8 (13.8)
Median	123.0	122.0	122.5
Min ; Max	91.0 ; 178.0	89.0 ; 166.0	89.0 ; 178.0
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	123.6 (13.5)	123.4 (15.1)	123.5 (14.0)
Median	123.0	122.0	123.0
Min ; Max	83.0 ; 180.0	87.0 ; 180.0	83.0 ; 180.0
Visit 28 (Week 26) (LOCF)			
N	362	179	541
Mean (SD)	123.6 (13.8)	123.6 (14.8)	123.6 (14.2)
Median	123.0	122.0	123.0
Min ; Max	83.0 ; 180.0	87.0 ; 180.0	83.0 ; 180.0

14.3.6.4: Vital Signs by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

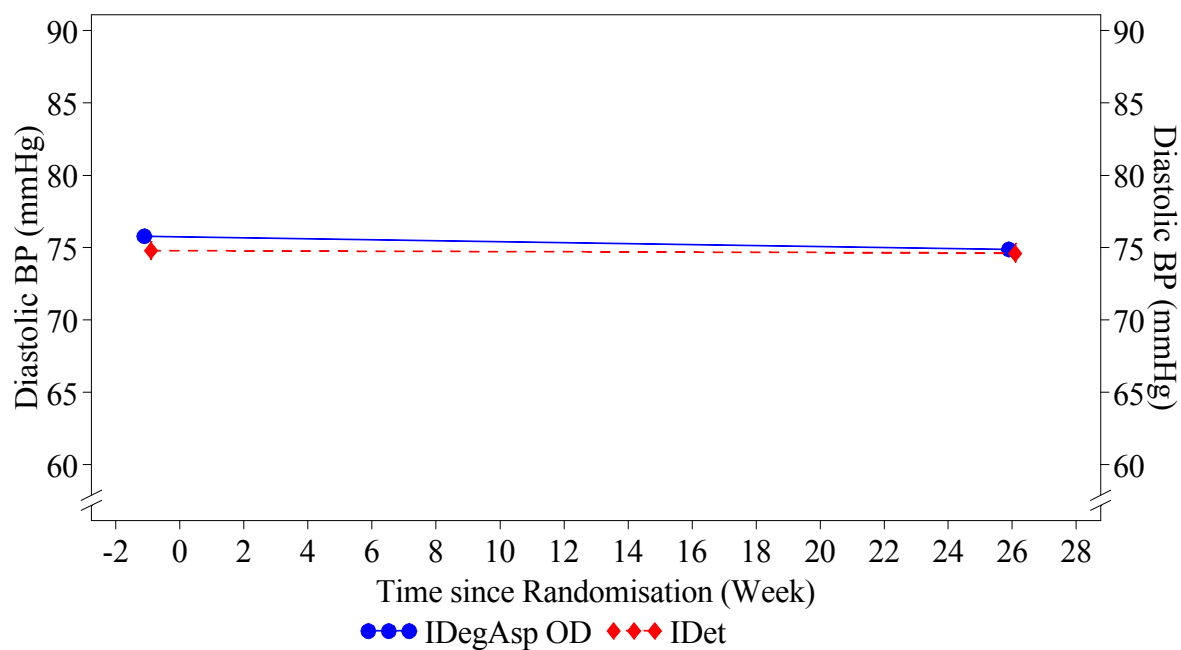
	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Systolic Blood Pressure (mmHg)			
Visit 28 (Week 26)			
N	315	156	471
Mean (SD)	-0.3 (12.7)	-0.0 (14.0)	-0.2 (13.1)
Median	-1.0	-1.0	-1.0
Min ; Max	-44.0 ; 67.0	-54.0 ; 36.0	-54.0 ; 67.0
Visit 28 (Week 26) (LOCF)			
N	357	177	534
Mean (SD)	-0.4 (12.2)	0.1 (13.6)	-0.3 (12.6)
Median	0.0	0.0	0.0
Min ; Max	-44.0 ; 67.0	-54.0 ; 36.0	-54.0 ; 67.0

Vital Signs by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Diastolic Blood Pressure (mmHg)			
Visit 28 (Week 26)			
N	315	156	471
Mean (SD)	-0.9 (9.0)	-0.2 (9.4)	-0.7 (9.2)
Median	-1.0	-1.0	-1.0
Min ; Max	-38.0 ; 35.0	-27.0 ; 37.0	-38.0 ; 37.0
Visit 28 (Week 26) (LOCF)			
N	357	177	534
Mean (SD)	-0.8 (8.9)	-0.1 (9.2)	-0.6 (9.0)
Median	-1.0	0.0	0.0
Min ; Max	-38.0 ; 35.0	-27.0 ; 37.0	-38.0 ; 37.0

Vital Signs by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

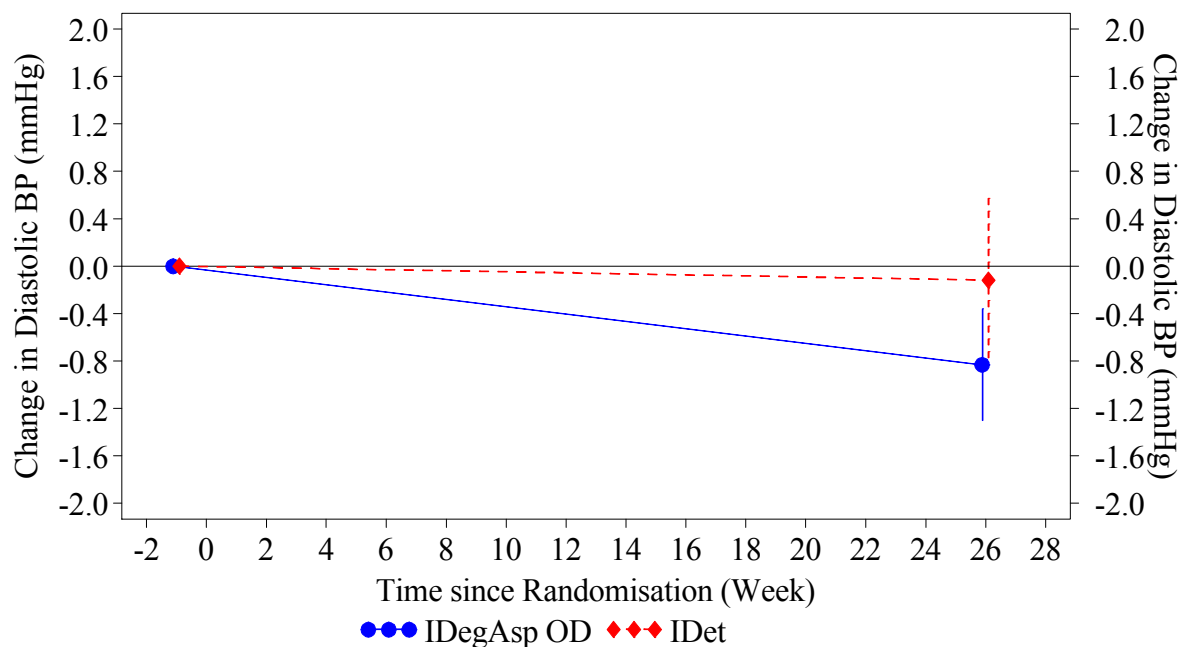
	IDegAsp OD	IDet	Total
Ch. Pulse (beats/min)			
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	0.2 (10.6)	1.1 (9.4)	0.5 (10.2)
Median	0.0	0.0	0.0
Min ; Max	-38.0 ; 45.0	-30.0 ; 34.0	-38.0 ; 45.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	0.3 (10.4)	1.4 (9.0)	0.6 (10.0)
Median	0.0	0.0	0.0
Min ; Max	-38.0 ; 45.0	-30.0 ; 34.0	-38.0 ; 45.0



SAFETY; LOCF imputed data
 Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:06:27 - fmean_numfind_v03.sas/e_vital_diasto_abs_mean_locf_sas.cgm

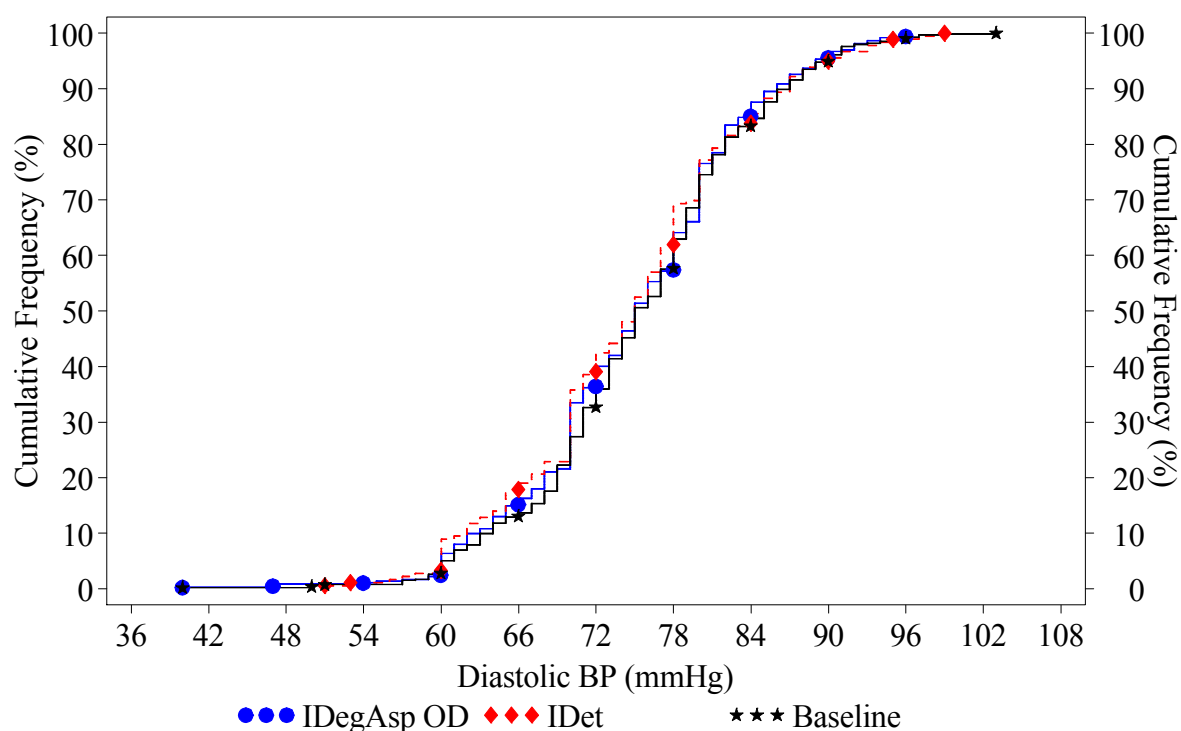
14.3.6.5: Diastolic Blood Pressure - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: $\pm$ Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:06:33 - fmean_numfind_v03.sas/e_vital_diasto_chb_mean_locf_sas.cgm

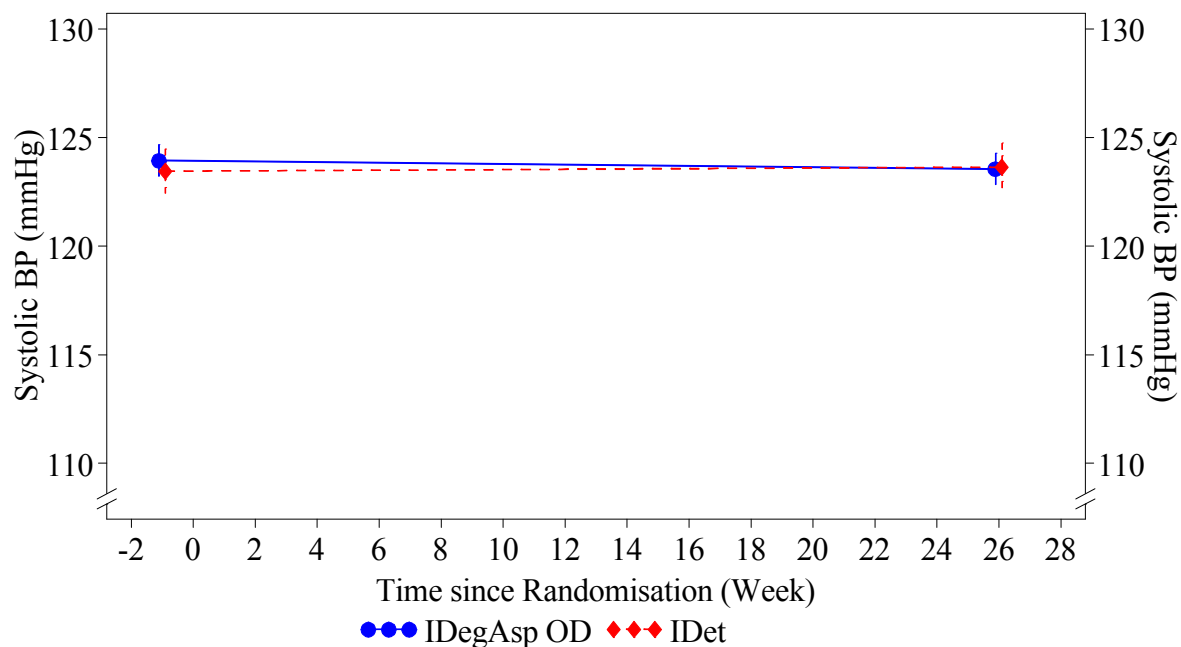
14.3.6.6: Diastolic Blood Pressure - Change from Baseline - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:06:44 - fedist_numfind_v01.sas/e_vital_diasto_abs_cdf_locf_sas.cgm

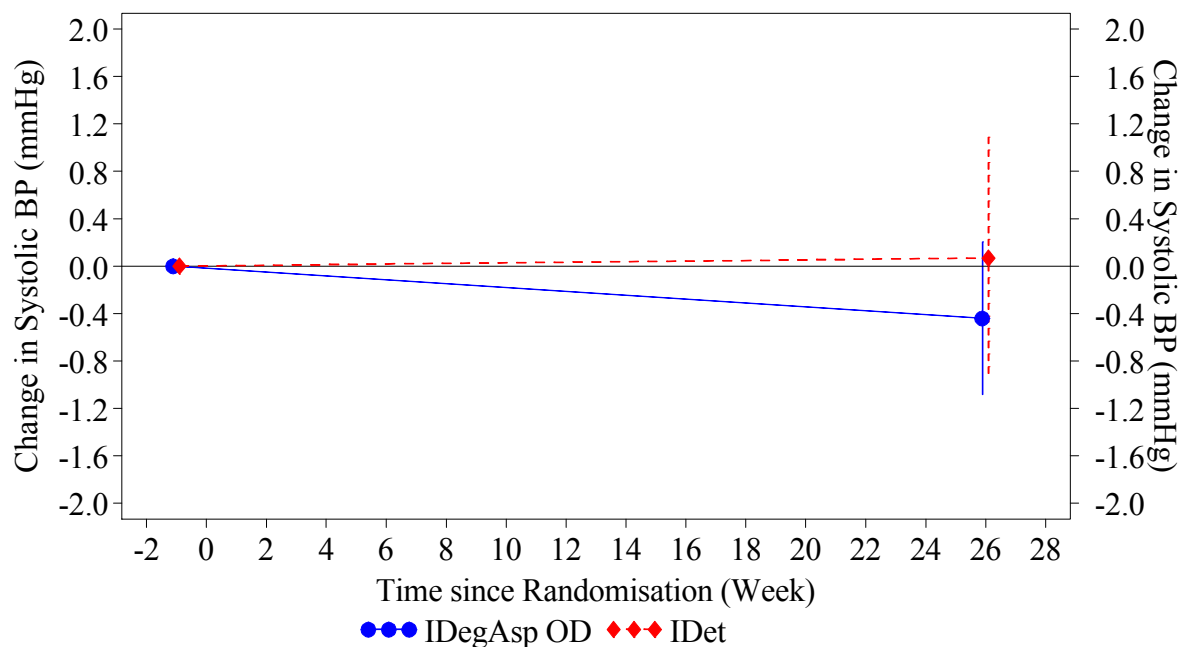
14.3.6.7: Diastolic Blood Pressure after 26 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:06:51 - fmean_numfind_v03.sas/e_vital_systo_abs_mean_locf_sas.cgm

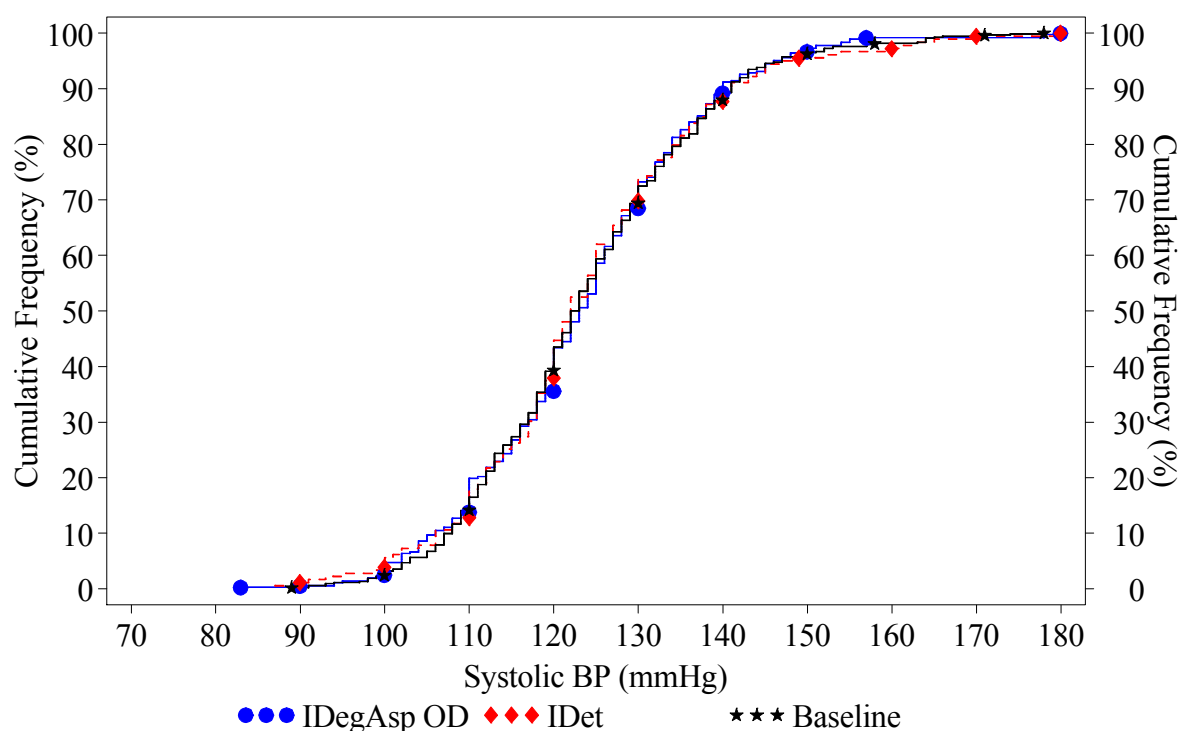
14.3.6.8: Systolic Blood Pressure - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:06:57 - fmean_numfind_v03.sas/e_vital_systo_chb_mean_locf_sas.cgm

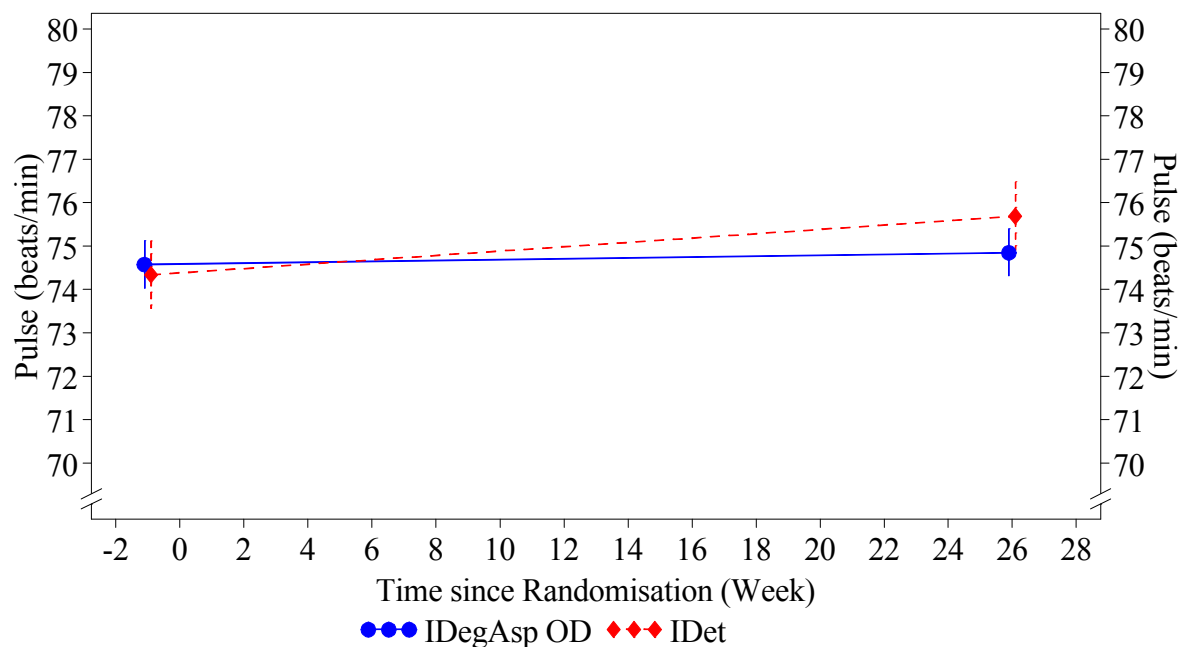
14.3.6.9: Systolic Blood Pressure - Change from Baseline - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:07:08 - fedist_numfind_v01.sas/e_vital_systo_abs_cdf_locf_sas.cgm

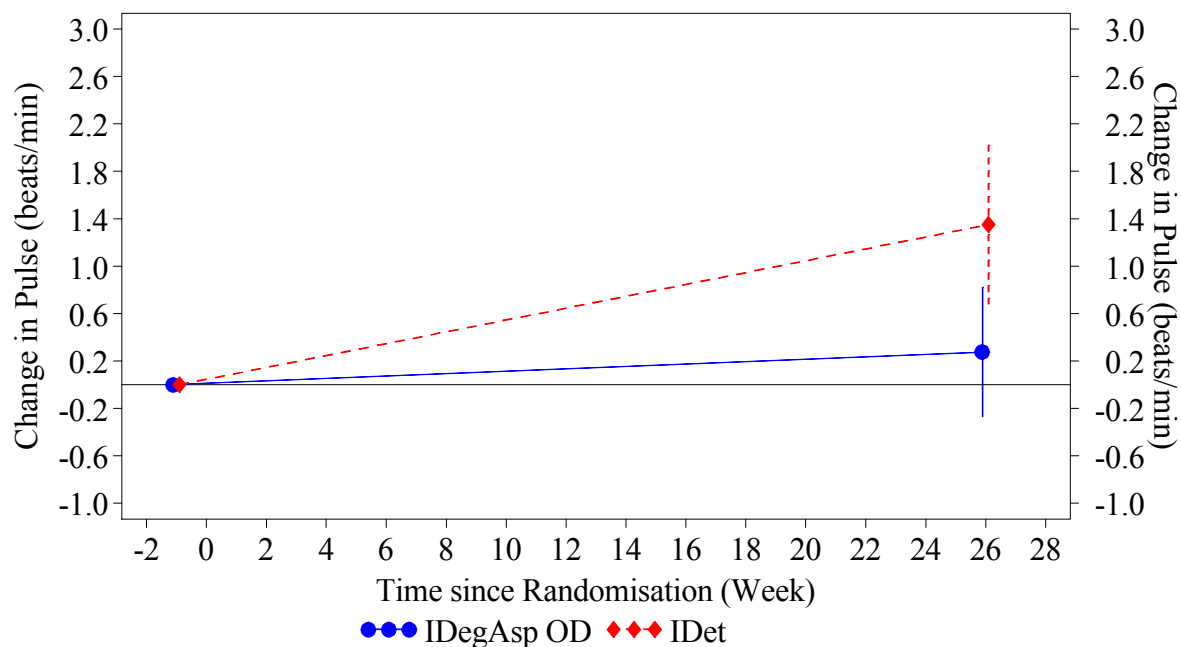
14.3.6.10: Systolic Blood Pressure after 26 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set



SAFETY: LOCF imputed data
 Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:07:14 - fmean_numfind_v03.sas/e_vital_pulse_abs_mean_locf_sas.cgm

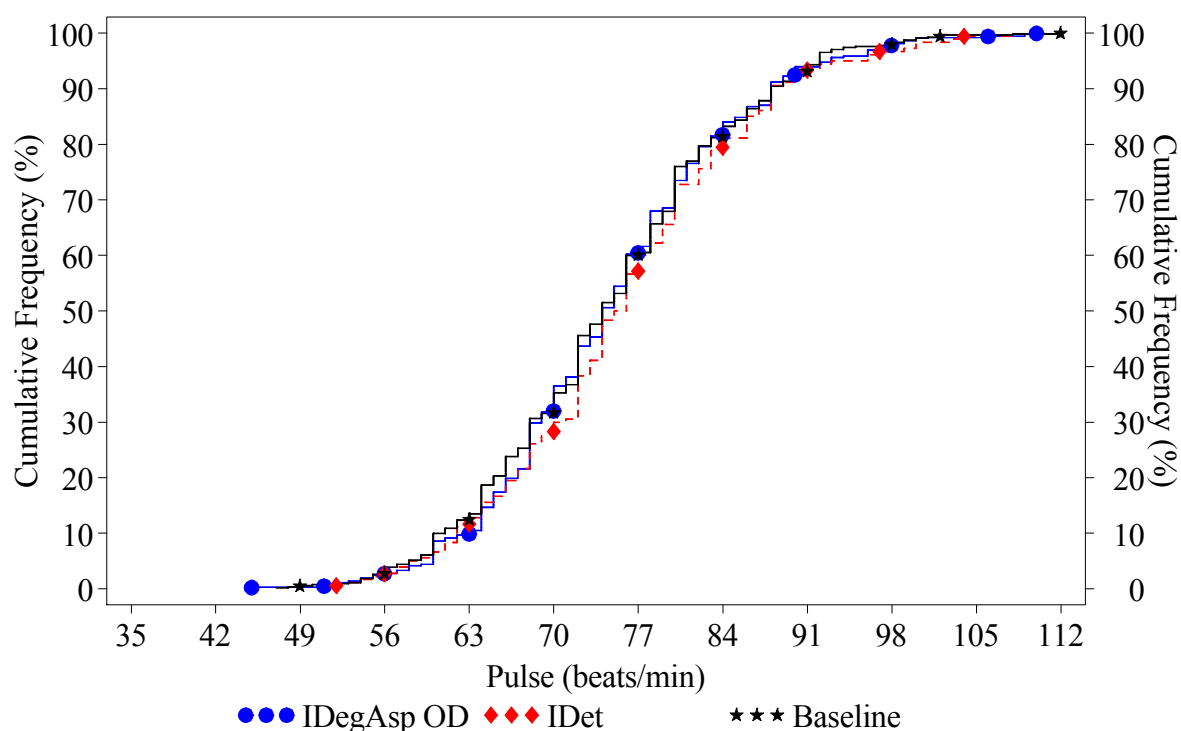
14.3.6.11: Pulse - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:07:21 - fmean_numfind_v03.sas/e_vital_pulse_chb_mean_locf_sas.cgm

14.3.6.12: Pulse - Change from Baseline - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:07:31 - fedist_numfind_v01.sas/e_vital_pulse_abs_cdf_locf_sas.cgm

14.3.6.13: Pulse after 26 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set

14.3.6.14: ECG by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
ECG			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	292 (80.7)	150 (83.3)	442 (81.5)
Abnormal, Not Clinically Significant	68 (18.8)	29 (16.1)	97 (17.9)
Abnormal, Clinically Significant	2 (0.6)	1 (0.6)	3 (0.6)
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	250 (77.9)	134 (85.4)	384 (80.3)
Abnormal, Not Clinically Significant	65 (20.2)	21 (13.4)	86 (18.0)
Abnormal, Clinically Significant	2 (0.6)	1 (0.6)	3 (0.6)
UNKNOWN	4 (1.2)	1 (0.6)	5 (1.0)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	278 (76.8)	150 (83.3)	428 (79.0)
Abnormal, Not Clinically Significant	77 (21.3)	26 (14.4)	103 (19.0)
Abnormal, Clinically Significant	2 (0.6)	1 (0.6)	3 (0.6)
UNKNOWN	5 (1.4)	3 (1.7)	8 (1.5)

ECG = Electrocardiogram, N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:07:35 - tsum_catgofind_tpl_t025_v01.sas/t_ecg_sum_sas.txt

14.3.6.15: ECG - Shift Table - Baseline to Week 26 - Safety Analysis Set

IDegAsp OD						IDet					
Number of Subjects		362					180				
		Visit 28 (Week 26)									
	Normal	Abnormal, NCS	Abnormal, CS	UNKNOWN	Missing	Normal	Abnormal, NCS	Abnormal, CS	UNKNOWN	Missing	
Visit 1	N	N	N	N	N	N	N	N	N	N	
ECG											
Normal	233	25	1	2	31	122	7	1	1	19	
Abnormal, NCS	17	39	0	2	10	12	13	0	0	4	
Abnormal, CS	0	1	1	0	0	0	1	0	0	0	
UNKNOWN	0	0	0	0	0	0	0	0	0	0	
Missing	0	0	0	0	0	0	0	0	0	0	

N = Number of Subjects, NCS = Not Clinically Significant, CS = Clinically Significant

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:07:39 - tshift_catgofind_tpl_t026_v01.sas/t_ecg_shift_w26_sas.txt

14.3.6.16: Funduscopy / Fundusphotography by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Left eye exam			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	219 (60.5)	103 (57.2)	322 (59.4)
Abnormal, Not Clinically Significant	122 (33.7)	74 (41.1)	196 (36.2)
Abnormal, Clinically Significant	21 (5.8)	3 (1.7)	24 (4.4)
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Normal	197 (61.6)	90 (57.3)	287 (60.2)
Abnormal, Not Clinically Significant	106 (33.1)	61 (38.9)	167 (35.0)
Abnormal, Clinically Significant	15 (4.7)	2 (1.3)	17 (3.6)
UNKNOWN	2 (0.6)	4 (2.5)	6 (1.3)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	220 (60.8)	104 (57.8)	324 (59.8)
Abnormal, Not Clinically Significant	113 (31.2)	67 (37.2)	180 (33.2)
Abnormal, Clinically Significant	16 (4.4)	2 (1.1)	18 (3.3)
UNKNOWN	13 (3.6)	7 (3.9)	20 (3.7)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:07:43 - tsum_catgofind_tpl_t025_v01.sas/t_fundusum_sas.txt

Funduscopy / Fundusphotography by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Right eye exam			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	225 (62.2)	101 (56.1)	326 (60.1)
Abnormal, Not Clinically Significant	119 (32.9)	75 (41.7)	194 (35.8)
Abnormal, Clinically Significant	17 (4.7)	4 (2.2)	21 (3.9)
UNKNOWN	1 (0.3)	0 (0.0)	1 (0.2)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	198 (61.7)	89 (56.7)	287 (60.0)
Abnormal, Not Clinically Significant	106 (33.0)	61 (38.9)	167 (34.9)
Abnormal, Clinically Significant	15 (4.7)	2 (1.3)	17 (3.6)
UNKNOWN	2 (0.6)	5 (3.2)	7 (1.5)
Visit 28 (Week 26) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	222 (61.3)	99 (55.0)	321 (59.2)
Abnormal, Not Clinically Significant	111 (30.7)	71 (39.4)	182 (33.6)
Abnormal, Clinically Significant	16 (4.4)	2 (1.1)	18 (3.3)
UNKNOWN	13 (3.6)	8 (4.4)	21 (3.9)

N = Number of Subjects

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:07:43 - tsum_catgofind_tpl_t025_v01.sas/t_fundusum_sas.txt

14.3.6.17: Funduscopy / Fundusphotography - Shift Table - Baseline to Week 26 - Safety Analysis Set

IDegAsp OD						IDet				
Number of Subjects						180				
						Visit 28 (Week 26)				
		Normal	Abnormal, NCS	Abnormal, CS	UNKNOWN	Missing	Normal	Abnormal, NCS	Abnormal, CS	UNKNOWN
Visit 1		N	N	N	N	N	N	N	N	N
Left eye exam										
Normal		179	6	2	2	30	82	6	0	2
Abnormal, NCS		18	93	3	0	8	8	54	0	2
Abnormal, CS		0	7	10	0	4	0	1	2	0
UNKNOWN		0	0	0	0	0	0	0	0	0
Missing		0	0	0	0	0	0	0	0	0
Right eye exam										
Normal		180	8	3	2	32	81	6	0	2
Abnormal, NCS		18	92	3	0	6	8	53	0	3
Abnormal, CS		0	6	8	0	3	0	2	2	0
UNKNOWN		0	0	1	0	0	0	0	0	0
Missing		0	0	0	0	0	0	0	0	0

N = Number of Subjects, NCS = Not Clinically Significant, CS = Clinically Significant.

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:07:47 - tshift_catgofind_tpl_t026_v01.sas/t_fundu_shift_w26_sas.txt

14.3.6.18: Body Weight and BMI by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Body Weight (kg)			
Visit 1			
N	362	180	542
Mean (SD)	76.5 (14.4)	76.1 (13.9)	76.4 (14.2)
Median	75.0	75.5	75.2
Min ; Max	44.8 ; 122.9	41.7 ; 135.0	41.7 ; 135.0
Visit 2 (Week 0)			
N	362	180	542
Mean (SD)	76.6 (14.5)	76.2 (14.0)	76.5 (14.3)
Median	75.0	76.0	75.3
Min ; Max	44.0 ; 123.4	42.9 ; 137.4	42.9 ; 137.4
Visit 14 (Week 12)			
N	335	167	502
Mean (SD)	78.3 (14.9)	77.3 (14.6)	78.0 (14.8)
Median	77.0	77.7	77.1
Min ; Max	42.8 ; 125.2	41.7 ; 141.1	41.7 ; 141.1
Visit 18 (Week 16)			
N	331	161	492
Mean (SD)	79.0 (15.1)	77.8 (14.7)	78.6 (15.0)
Median	77.4	78.0	77.5
Min ; Max	43.0 ; 127.9	42.8 ; 142.9	42.8 ; 142.9
Visit 28 (Week 26)			
N	318	156	474
Mean (SD)	79.4 (15.7)	78.2 (14.9)	79.0 (15.4)
Median	77.1	78.5	77.6
Min ; Max	44.2 ; 132.0	45.5 ; 147.4	44.2 ; 147.4
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	78.9 (15.6)	77.5 (14.4)	78.5 (15.2)
Median	76.4	77.2	76.7
Min ; Max	44.2 ; 132.0	45.5 ; 147.4	44.2 ; 147.4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:07:53 - tdesc_numfind_tpl_t019_v01.sas/t_bw_bmi_abs_descp_sas.txt

Body Weight and BMI by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
BMI (kg/m ²)			
Visit 1			
N	362	180	542
Mean (SD)	26.2 (3.9)	26.6 (3.8)	26.3 (3.9)
Median	25.7	26.2	25.9
Min ; Max	16.2 ; 35.0	18.6 ; 35.0	16.2 ; 35.0
Visit 2 (Week 0)			
N	362	180	542
Mean (SD)	26.2 (4.0)	26.7 (3.9)	26.4 (3.9)
Median	25.9	26.4	26.0
Min ; Max	16.2 ; 35.6	18.7 ; 36.2	16.2 ; 36.2
Visit 14 (Week 12)			
N	335	167	502
Mean (SD)	26.8 (4.1)	27.0 (4.0)	26.9 (4.1)
Median	26.2	26.6	26.4
Min ; Max	16.9 ; 40.3	18.7 ; 36.1	16.9 ; 40.3
Visit 18 (Week 16)			
N	331	161	492
Mean (SD)	26.9 (4.2)	27.1 (4.1)	27.0 (4.2)
Median	26.4	27.0	26.5
Min ; Max	17.0 ; 40.0	19.0 ; 36.4	17.0 ; 40.0
Visit 28 (Week 26)			
N	318	156	474
Mean (SD)	27.1 (4.3)	27.2 (4.0)	27.1 (4.2)
Median	26.6	26.8	26.7
Min ; Max	17.5 ; 42.0	18.4 ; 38.2	17.5 ; 42.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	27.0 (4.4)	27.1 (4.1)	27.0 (4.3)
Median	26.5	26.8	26.7
Min ; Max	16.2 ; 42.0	18.4 ; 38.2	16.2 ; 42.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:07:53 - tdesc_numfind_tpl_t019_v01.sas/t_bw_bmi_abs_descp_sas.txt

14.3.6.19: Body Weight and BMI by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Body Weight(kg)			
Visit 14 (Week 12)			
N	335	167	502
Mean (SD)	1.5 (3.0)	0.9 (2.3)	1.3 (2.8)
Median	1.3	0.5	1.0
Min ; Max	-14.8 ; 17.2	-5.0 ; 8.2	-14.8 ; 17.2
Visit 18 (Week 16)			
N	331	161	492
Mean (SD)	2.0 (3.3)	1.2 (2.8)	1.7 (3.1)
Median	1.9	0.9	1.5
Min ; Max	-13.7 ; 18.0	-7.3 ; 9.5	-13.7 ; 18.0
Visit 28 (Week 26)			
N	318	156	474
Mean (SD)	2.4 (4.0)	1.4 (3.5)	2.1 (3.9)
Median	2.0	1.1	1.8
Min ; Max	-13.7 ; 20.4	-13.4 ; 11.9	-13.7 ; 20.4
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	2.3 (3.9)	1.3 (3.4)	2.0 (3.8)
Median	1.9	1.0	1.6
Min ; Max	-13.7 ; 20.4	-13.4 ; 11.9	-13.7 ; 20.4

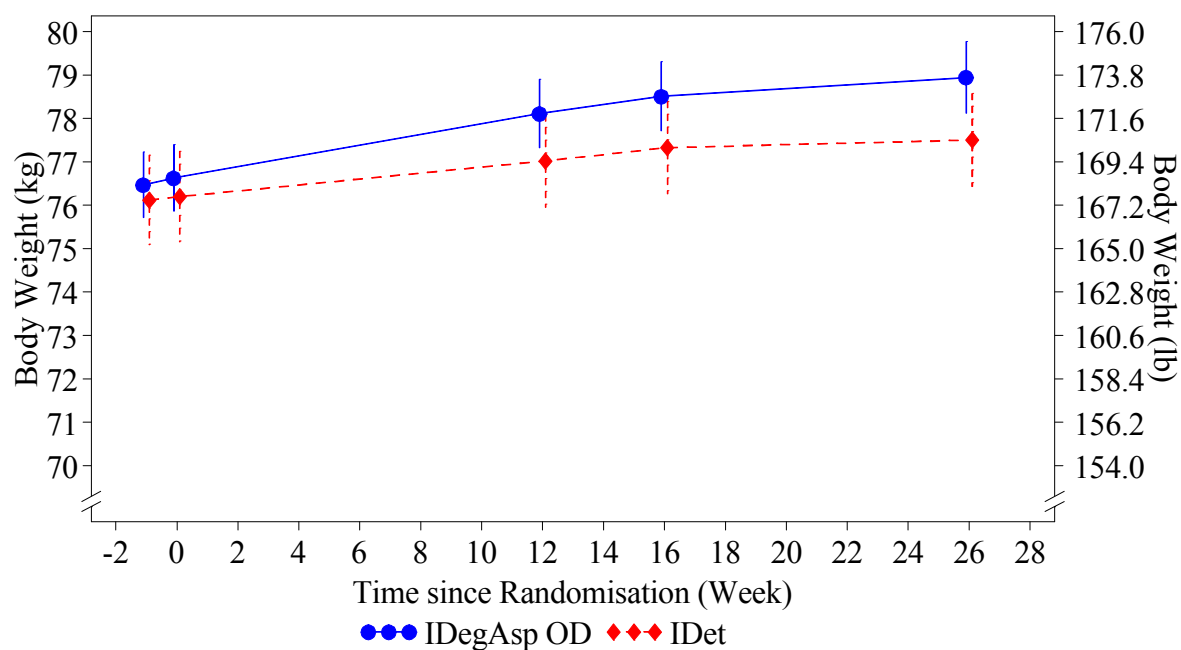
Body Weight and BMI by Treatment Week - Change from Baseline - Descriptive Statistics -
 Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Derived Body Mass Index(kg/m ²)			
Visit 14 (Week 12)			
N	335	167	502
Mean (SD)	0.5 (1.0)	0.3 (0.8)	0.5 (1.0)
Median	0.5	0.2	0.4
Min ; Max	-4.7 ; 6.1	-1.5 ; 3.1	-4.7 ; 6.1
Visit 18 (Week 16)			
N	331	161	492
Mean (SD)	0.7 (1.1)	0.4 (1.0)	0.6 (1.1)
Median	0.7	0.3	0.5
Min ; Max	-5.0 ; 6.4	-2.6 ; 3.6	-5.0 ; 6.4
Visit 28 (Week 26)			
N	318	156	474
Mean (SD)	0.8 (1.4)	0.5 (1.2)	0.7 (1.3)
Median	0.7	0.4	0.6
Min ; Max	-5.0 ; 7.3	-5.3 ; 4.5	-5.3 ; 7.3
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	0.8 (1.3)	0.5 (1.2)	0.7 (1.3)
Median	0.6	0.3	0.5
Min ; Max	-5.0 ; 7.3	-5.3 ; 4.5	-5.3 ; 7.3

14.3.6.20: Body Weight after 26 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Body Weight (kg)					
LSMeans					
IDegAsp OD	366	366	79.20	0.32	
IDet	182	182	78.16	0.37	
Change from Baseline					
LSMeans					
IDegAsp OD	366	366	2.73	0.32	
IDet	182	182	1.70	0.37	
Treatment Contrast					
IDegAsp OD - IDet			1.04		[0.38 ; 1.69]

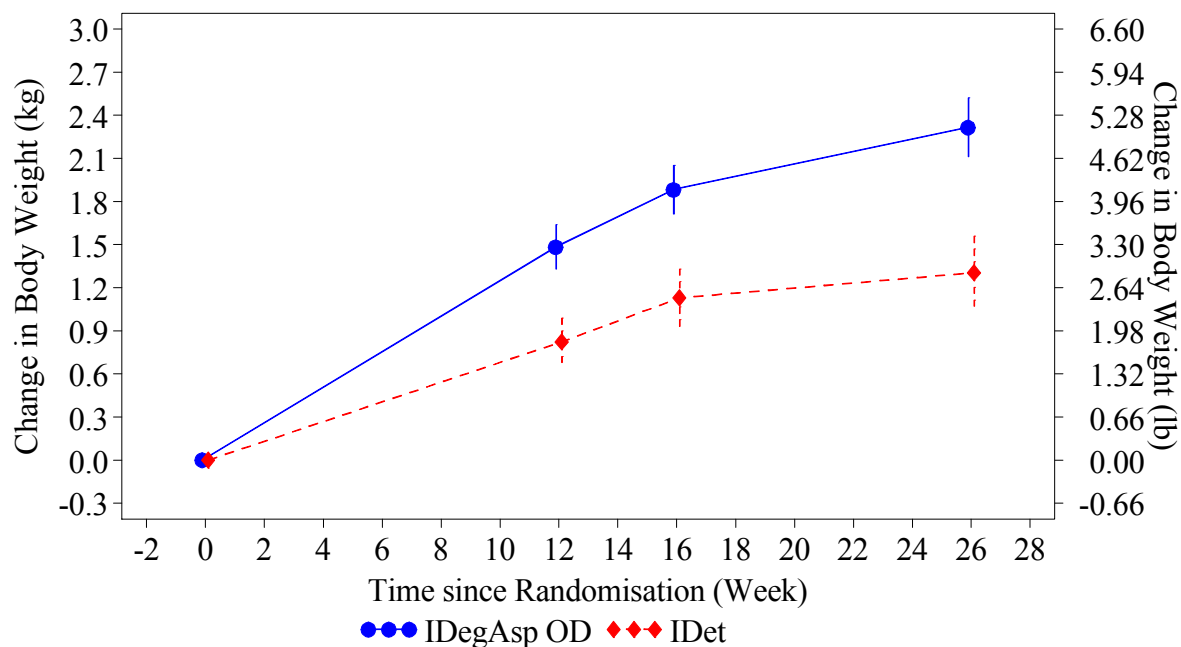
N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean
 The response and change from baseline in the response after 26 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
 Missing data is imputed using last observation carried forward.
 nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:08:06 - tstat_find_tpl_t022.sas/t_bw_stat_fas.txt



SAFETY; LOCF imputed data
 Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:08:13 - fmean_numfind_v03.sas/e_bw_abs_mean_locf_sas.cgm

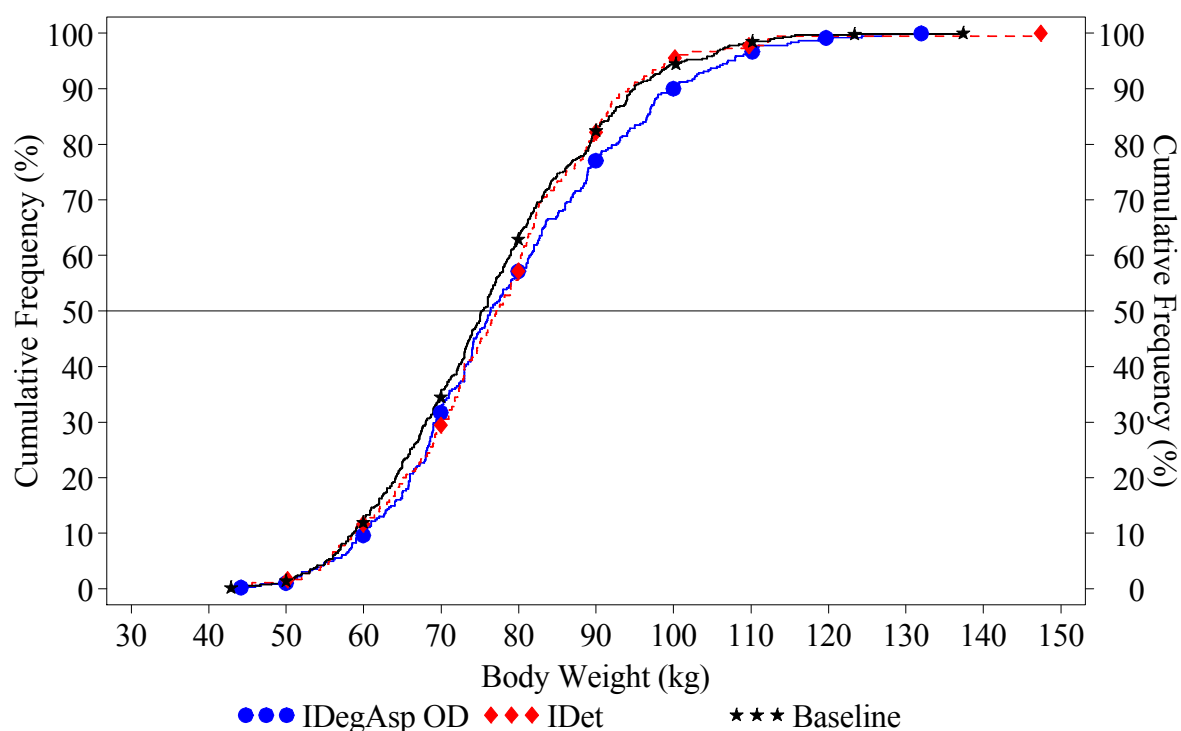
14.3.6.21: Body Weight - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:08:19 - fmean_numfind_v03.sas/e_bw_chb_mean_locf_sas.cgm

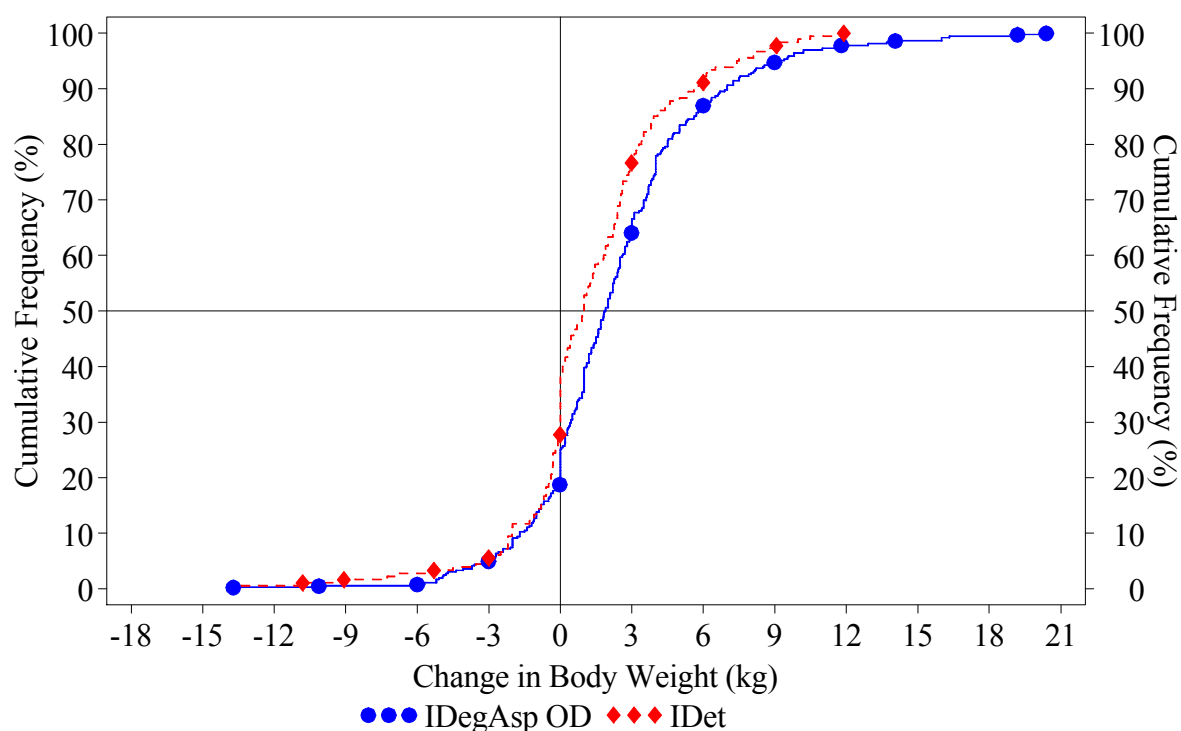
14.3.6.22: Body Weight – Change from Baseline - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:08:30 - fedist_numfind_v01.sas/e_bw_abs_cdf_locf_sas.cgm

14.3.6.23: Body weight after 26 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:08:36 - fedist_numfind_v01.sas/e_bw_chb_cdf_locf_sas.cgm

14.3.6.24: Body weight after 26 Weeks of Treatment - Change from Baseline Empirical Distribution Plot - Safety Analysis Set

14.3.6.25: Specific Antibodies (%B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Insulin Aspart Specific Antibodies(% B/T)			
Visit 2 (Week 0)			
N	362	180	542
Mean (SD)	1.0 (2.9)	0.9 (3.0)	1.0 (2.9)
Median	0.0	0.0	0.0
Min ; Max	-1.0 ; 34.0	-1.0 ; 30.0	-1.0 ; 34.0
Visit 14 (Week 12)			
N	333	165	498
Mean (SD)	1.1 (2.6)	1.4 (4.2)	1.2 (3.2)
Median	0.0	0.0	0.0
Min ; Max	-1.0 ; 20.0	-1.0 ; 31.0	-1.0 ; 31.0
Visit 28 (Week 26)			
N	319	155	474
Mean (SD)	1.1 (2.4)	1.7 (5.5)	1.3 (3.7)
Median	0.0	1.0	0.0
Min ; Max	-1.0 ; 19.0	0.0 ; 44.0	-1.0 ; 44.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	1.3 (3.1)	1.6 (5.1)	1.4 (3.9)
Median	0.0	0.0	0.0
Min ; Max	-1.0 ; 35.0	0.0 ; 44.0	-1.0 ; 44.0
Visit 29 (Week 27)			
N	309	148	457
Mean (SD)	1.3 (2.6)	1.4 (3.8)	1.3 (3.0)
Median	0.0	1.0	1.0
Min ; Max	0.0 ; 19.0	0.0 ; 41.0	0.0 ; 41.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:08:48 - tdesc_numfind_tpl_t019_v01.sas/t_ab_specific_abs_descp_sas.txt

14.3.6.26: Insulin Degludec Specific Antibodies (%B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp	OD
Number of Subjects	362	
Insulin Degludec Specific Antibodies(% B/T)		
Visit 2 (Week 0)		
N	362	
Mean (SD)	0.1 (0.5)	
Median	0.0	
Min ; Max	-6.0 ; 4.0	
Visit 14 (Week 12)		
N	332	
Mean (SD)	0.0 (0.4)	
Median	0.0	
Min ; Max	-5.0 ; 2.0	
Visit 28 (Week 26)		
N	316	
Mean (SD)	0.0 (0.2)	
Median	0.0	
Min ; Max	-1.0 ; 2.0	
Visit 28 (Week 26) (LOCF)		
N	362	
Mean (SD)	0.0 (0.2)	
Median	0.0	
Min ; Max	-1.0 ; 2.0	
Visit 29 (Week 27)		
N	308	
Mean (SD)	0.1 (0.4)	
Median	0.0	
Min ; Max	-1.0 ; 3.0	

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:08:55 - tdesc_numfind_tpl_t019_v01.sas/t_ideg_ab_specific_abs_descp_sas.txt

14.3.6.27: IDet Specific Antibodies (%B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

		IDet
Number of Subjects		180
Insulin Detemir Specific Antibodies(% B/T)		
Visit 2 (Week 0)		
N		179
Mean (SD)		2.0 (2.0)
Median		2.0
Min ; Max		-1.0 ; 16.0
Visit 14 (Week 12)		
N		165
Mean (SD)		2.6 (2.2)
Median		2.0
Min ; Max		0.0 ; 11.0
Visit 28 (Week 26)		
N		155
Mean (SD)		3.4 (4.0)
Median		2.0
Min ; Max		0.0 ; 29.0
Visit 28 (Week 26) (LOCF)		
N		180
Mean (SD)		3.4 (3.9)
Median		2.0
Min ; Max		0.0 ; 29.0
Visit 29 (Week 27)		
N		148
Mean (SD)		6.5 (7.5)
Median		3.0
Min ; Max		0.0 ; 41.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:09:01 - tdesc_numfind_tpl_t019_v01.sas/t_idet_ab_specific_abs_descp_sas.txt

14.3.6.28: Cross-reacting Antibodies to Human Insulin (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Human insulin reactive antibodies serum(% B/T)			
Visit 2 (Week 0)			
N	362	180	542
Mean (SD)	11.0 (13.9)	11.7 (15.6)	11.3 (14.4)
Median	5.0	5.0	5.0
Min ; Max	0.0 ; 76.0	0.0 ; 68.0	0.0 ; 76.0
Visit 14 (Week 12)			
N	332	165	497
Mean (SD)	12.0 (15.2)	14.2 (16.6)	12.7 (15.7)
Median	6.0	8.0	7.0
Min ; Max	0.0 ; 82.0	0.0 ; 81.0	0.0 ; 82.0
Visit 28 (Week 26)			
N	319	155	474
Mean (SD)	10.7 (14.0)	15.4 (14.6)	12.2 (14.3)
Median	5.0	10.0	7.0
Min ; Max	0.0 ; 76.0	0.0 ; 75.0	0.0 ; 76.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	10.5 (13.8)	15.7 (15.5)	12.2 (14.6)
Median	5.0	10.0	7.0
Min ; Max	0.0 ; 76.0	0.0 ; 75.0	0.0 ; 76.0
Visit 29 (Week 27)			
N	310	147	457
Mean (SD)	15.5 (17.3)	26.0 (19.4)	18.9 (18.6)
Median	8.0	23.0	12.0
Min ; Max	0.0 ; 78.0	0.0 ; 77.0	0.0 ; 78.0

N = Number of Subjects, SD = Standard Deviation

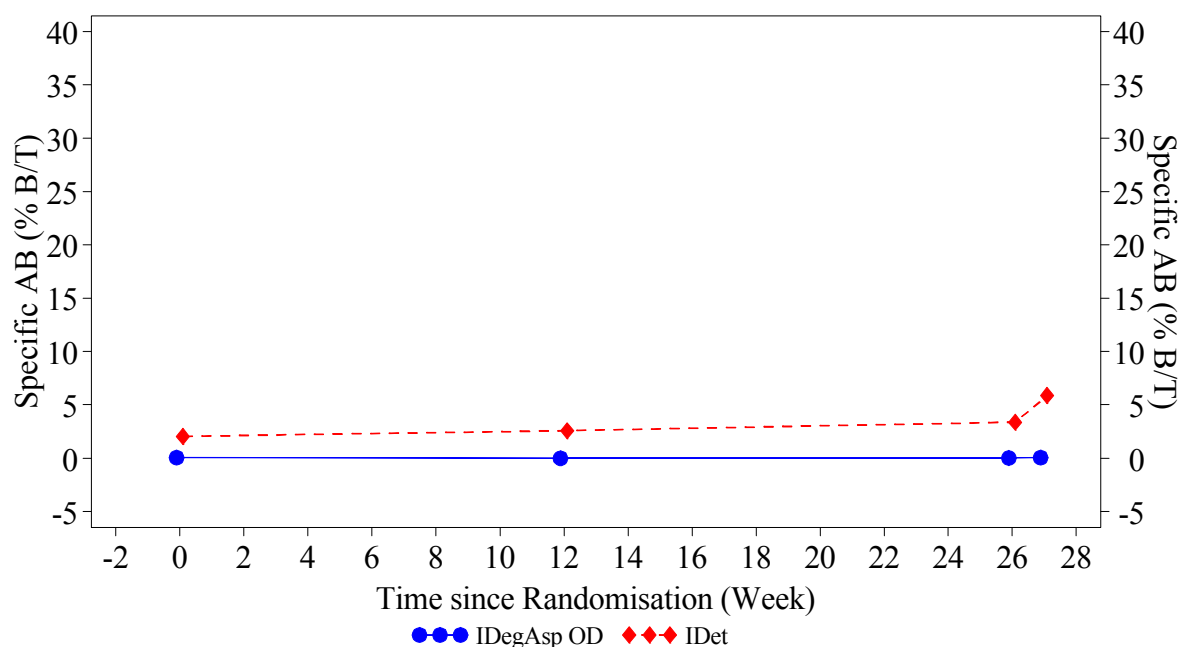
nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:09:07 - tdesc_numfind_tpl_t019_v01.sas/t_ab_cros_abs_descp_sas.txt

14.3.6.29: Total Antibodies (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Total Insulin Antibodies(% B/T)			
Visit 2 (Week 0)			
N	361	179	540
Mean (SD)	12.2 (14.2)	14.7 (16.9)	13.0 (15.2)
Median	7.0	8.0	7.0
Min ; Max	-1.0 ; 77.0	0.0 ; 88.0	-1.0 ; 88.0
Visit 14 (Week 12)			
N	331	165	496
Mean (SD)	13.2 (15.9)	18.1 (18.8)	14.8 (17.1)
Median	7.0	12.0	9.0
Min ; Max	0.0 ; 84.0	0.0 ; 93.0	0.0 ; 93.0
Visit 28 (Week 26)			
N	317	154	471
Mean (SD)	11.8 (14.7)	20.6 (18.6)	14.7 (16.6)
Median	6.0	15.0	9.0
Min ; Max	0.0 ; 79.0	0.0 ; 101.0	0.0 ; 101.0
Visit 28 (Week 26) (LOCF)			
N	362	180	542
Mean (SD)	11.8 (14.6)	20.5 (19.0)	14.7 (16.7)
Median	6.0	14.0	9.0
Min ; Max	0.0 ; 79.0	0.0 ; 101.0	0.0 ; 101.0
Visit 29 (Week 27)			
N	306	147	453
Mean (SD)	16.7 (18.1)	33.9 (25.8)	22.3 (22.3)
Median	10.0	27.0	15.0
Min ; Max	0.0 ; 88.0	0.0 ; 133.0	0.0 ; 133.0

N = Number of Subjects, SD = Standard Deviation

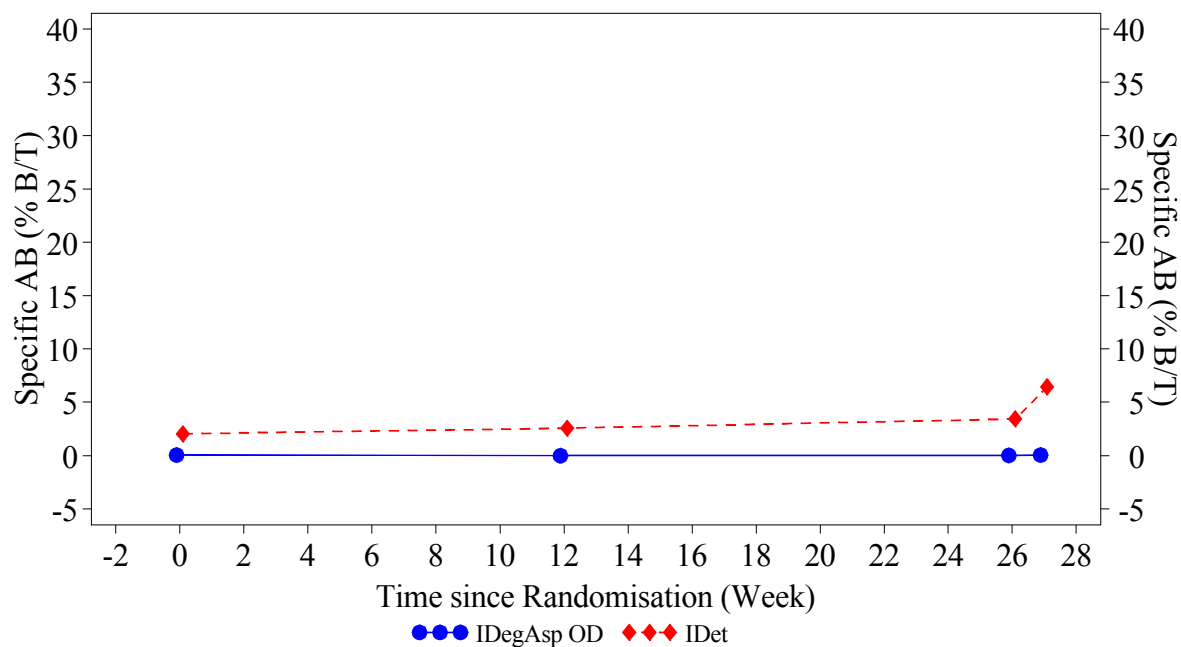
nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:09:13 - tdesc_numfind_tpl_t019_v01.sas/t_ab_tot_abs_descp_sas.txt



SAFETY; LOCF imputed data
 Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:09:24 - fmean_numfind_v03.sas/e_ab_spe_imp_abs_mean_locf_sas.cgm

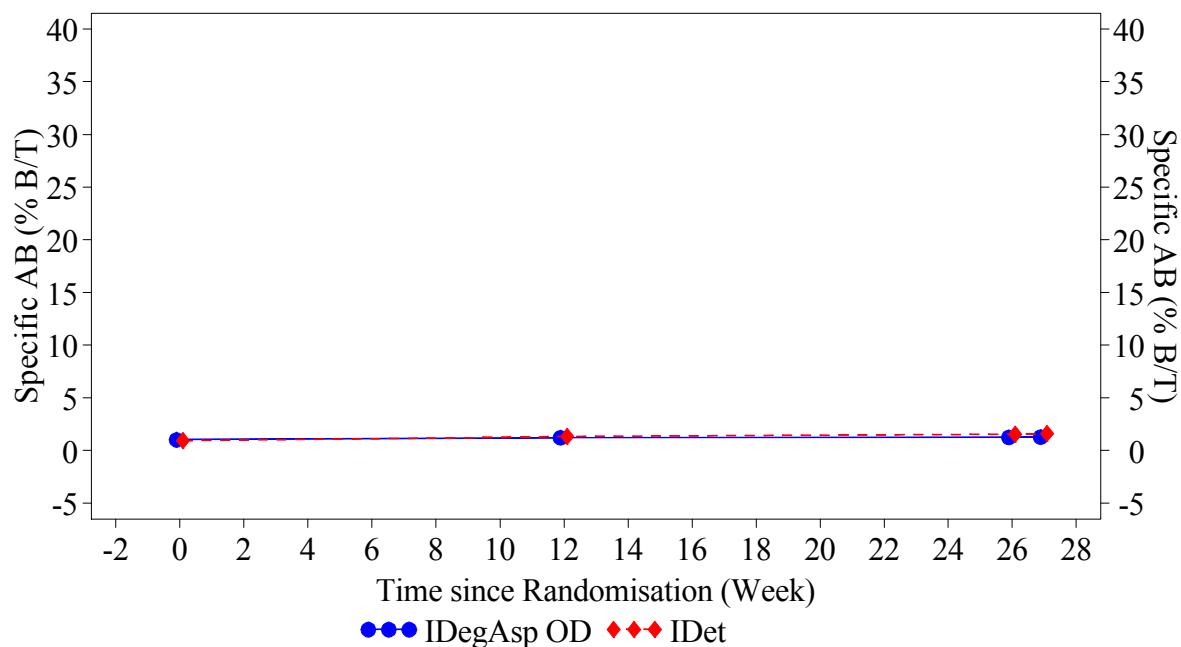
14.3.6.30: Insulin 454 / Comparator Specific Antibodies (% B/T) - Mean Plot - Safety Analysis Set



SAFETY: Observed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:09:35 - fmean_numfind_v03.sas/e_ab_spe_imp_abs_mean_obs_sas.cgm

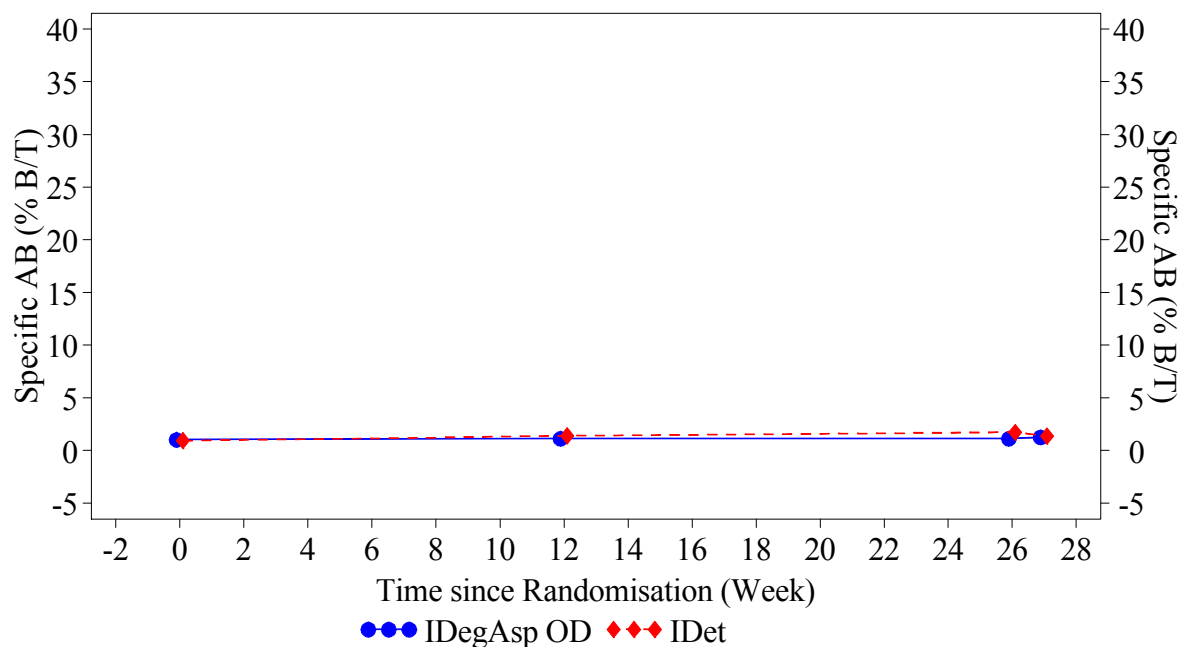
14.3.6.31: Insulin 454 / Comparator Specific Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:09:42 - fmean_numfind_v03.sas/e_ab_spe_iasp_abs_mean_locf_sas.cgm

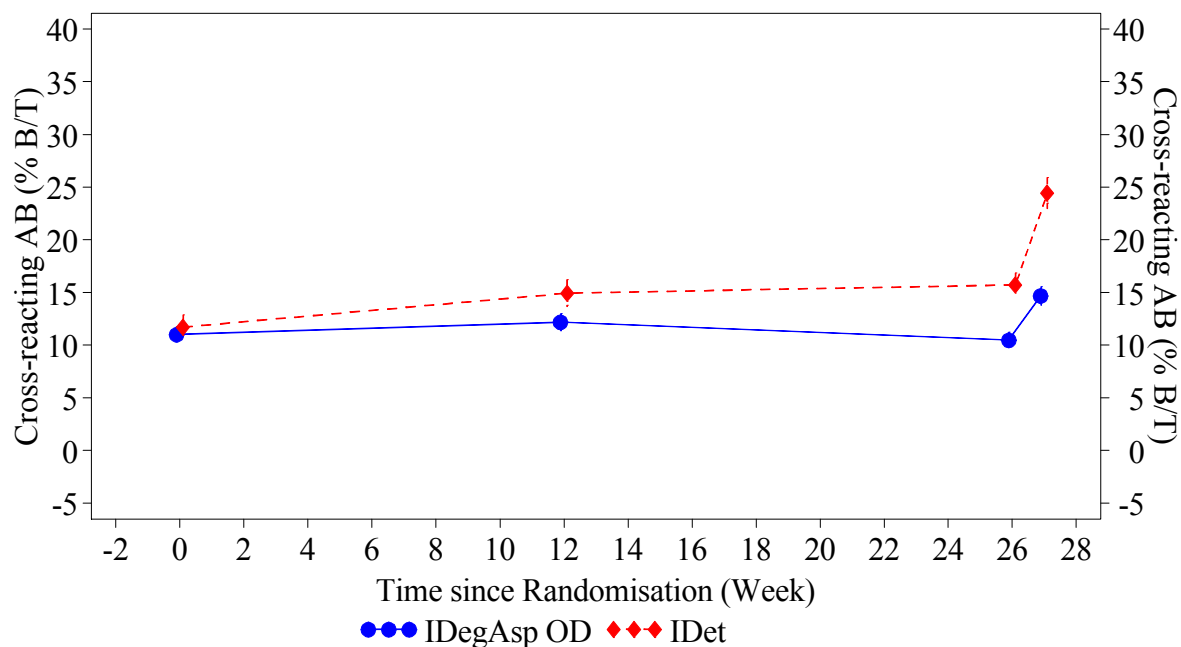
14.3.6.32: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Safety Analysis Set



SAFETY: Observed data
 Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:09:48 - fmean_numfind_v03.sas/e_ab_spe_iasp_abs_mean_obs_sas.cgm

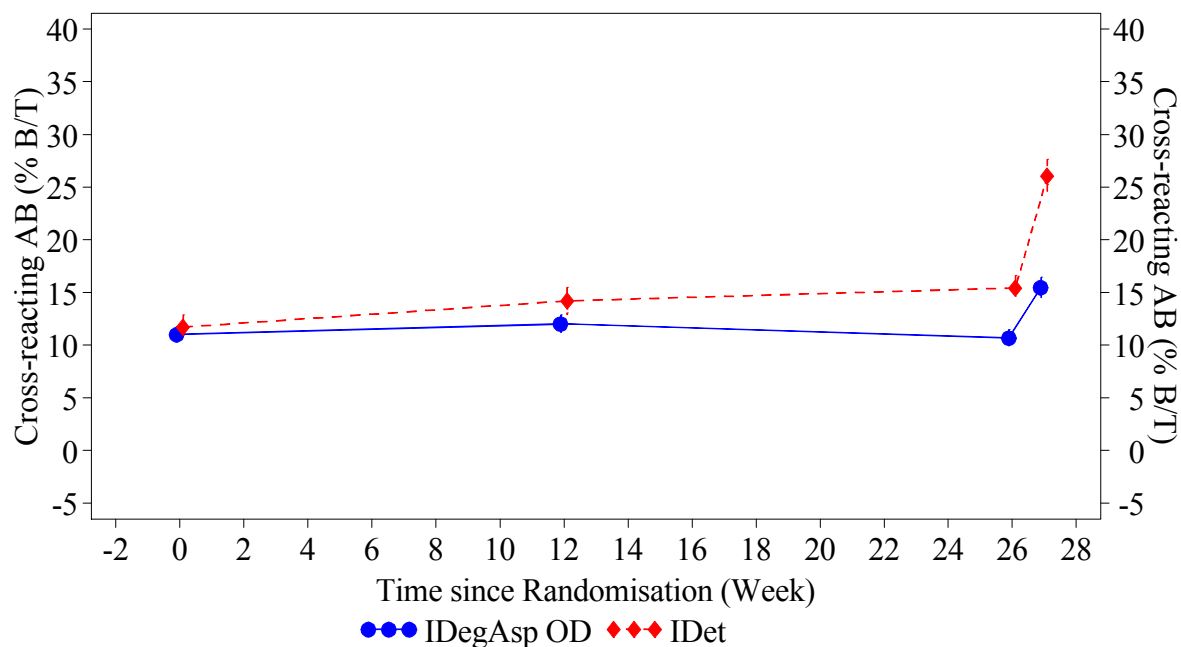
14.3.6.33: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:09:55 - fmean_numfind_v03.sas/e_ab_cros_abs_mean_locf_sas.cgm

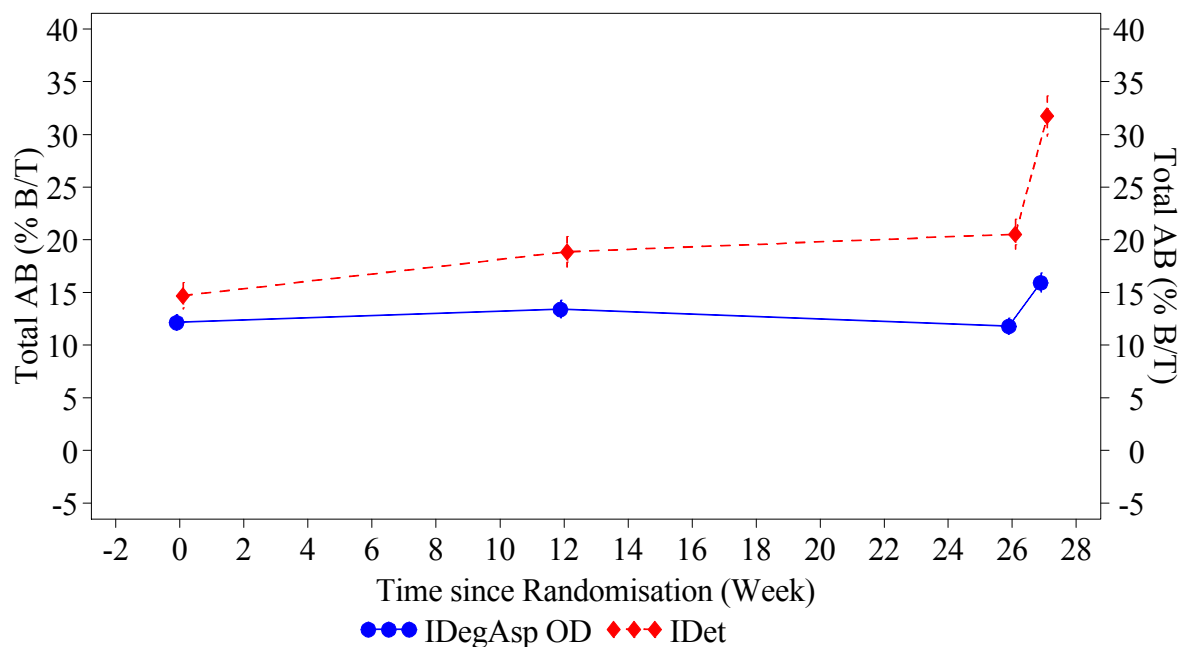
14.3.6.34: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Safety Analysis Set



SAFETY: Observed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:10:01 - fmean_numfind_v03.sas/e_ab_cros_abs_mean_obs_sas.cgm

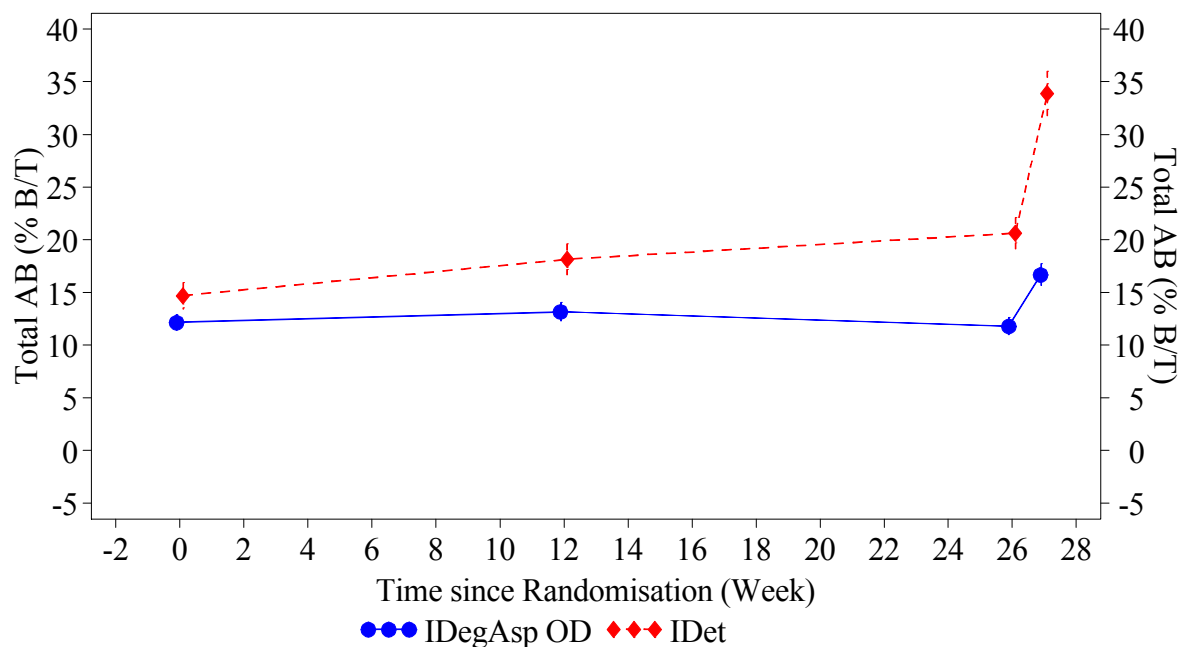
14.3.6.35: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Observed Values - Safety Analysis Set



SAFETY: LOCF imputed data
 Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594/freeze_ctr_05/stats
 28APR2011:13:10:07 - fmean_numfind_v03.sas/e_ab_tot_abs_mean_locf_sas.cgm

14.3.6.36: Total Antibodies (% B/T) - Mean Plot - Safety Analysis Set

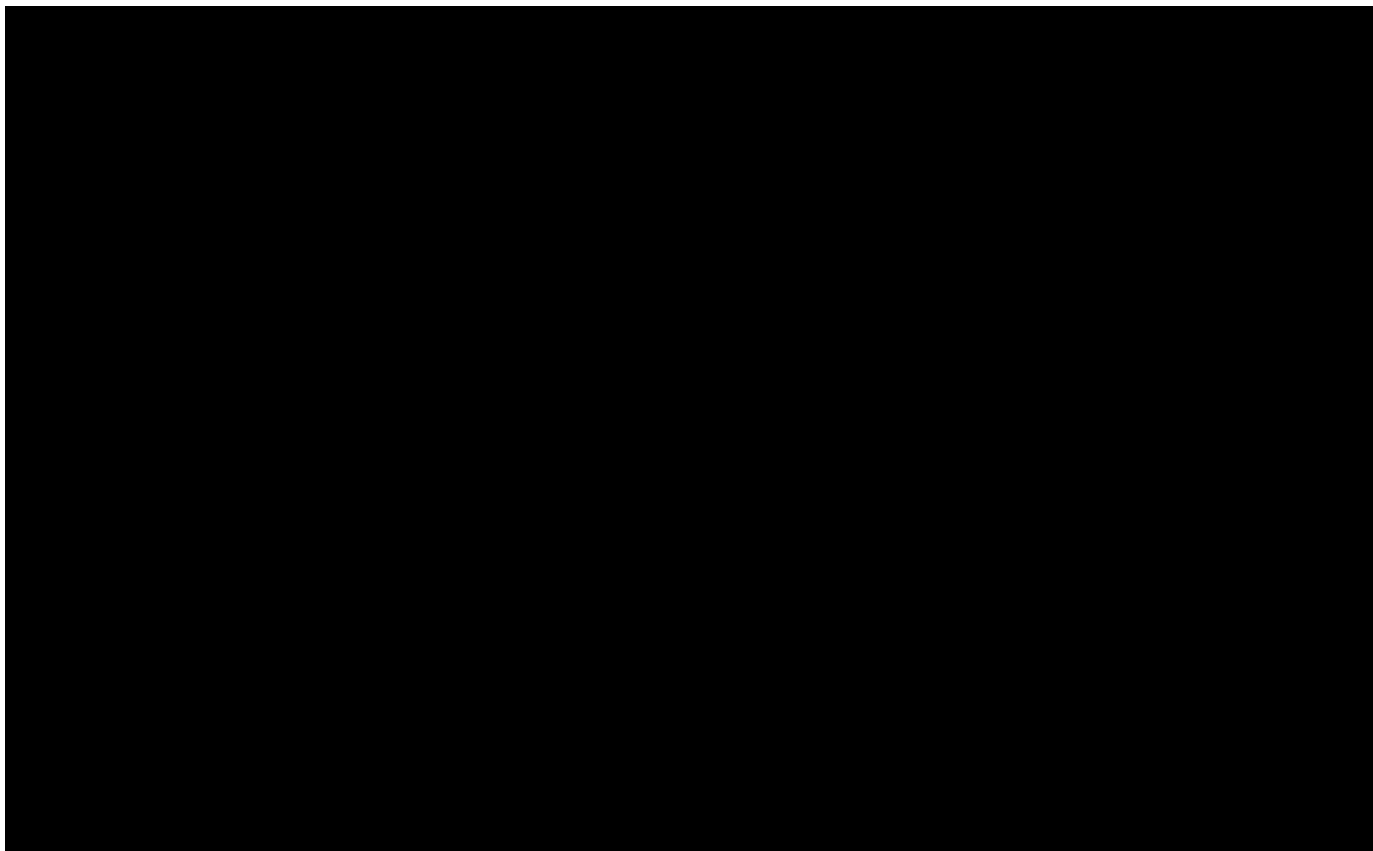


SAFETY: Observed data
Error bars: +-Standard Error(Mean)

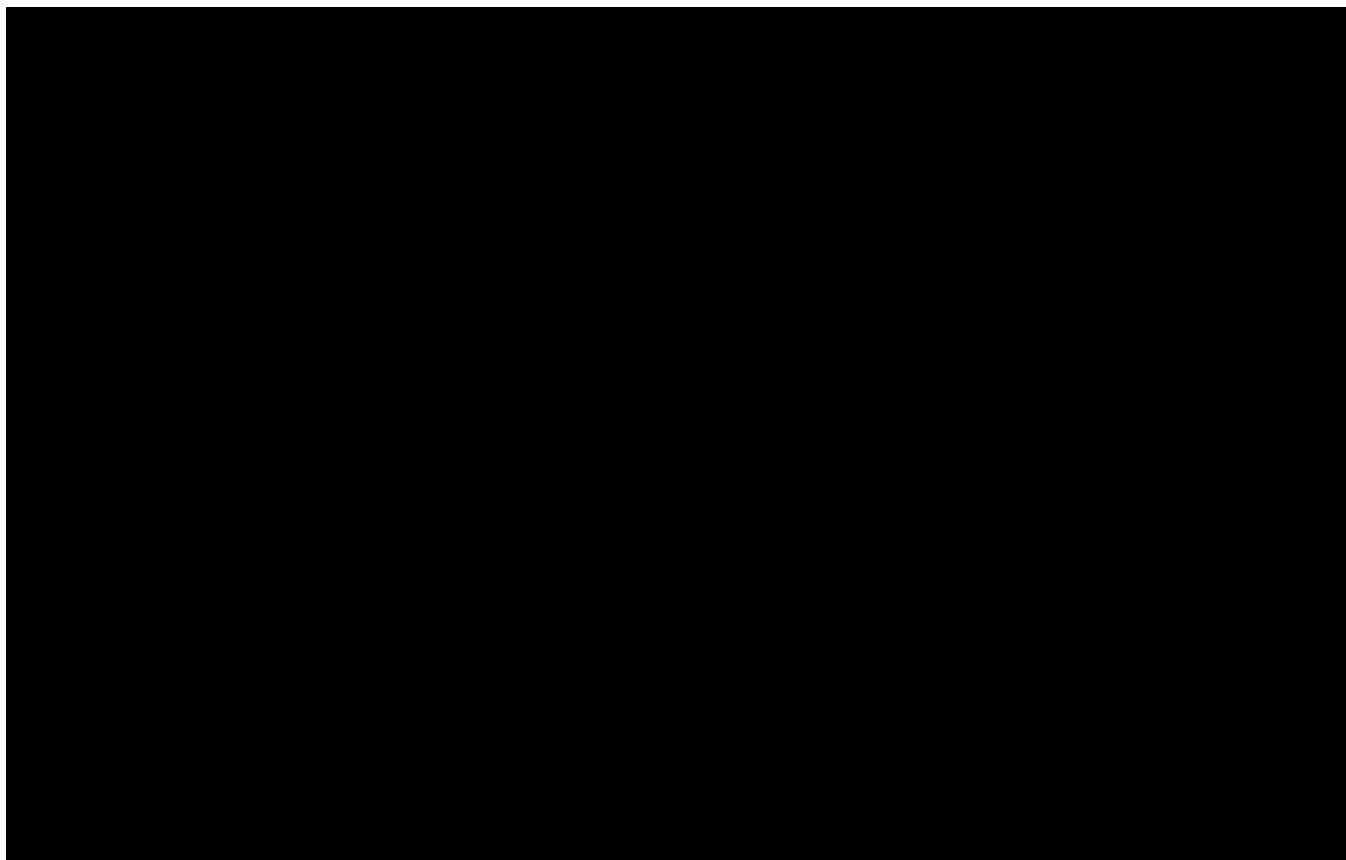
nn5401/nn5401-3594/freeze_ctr_05/stats
28APR2011:13:10:14 - fmean_numfind_v03.sas/e_ab_tot_abs_mean_obs_sas.cgm

14.3.6.37: Total Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set

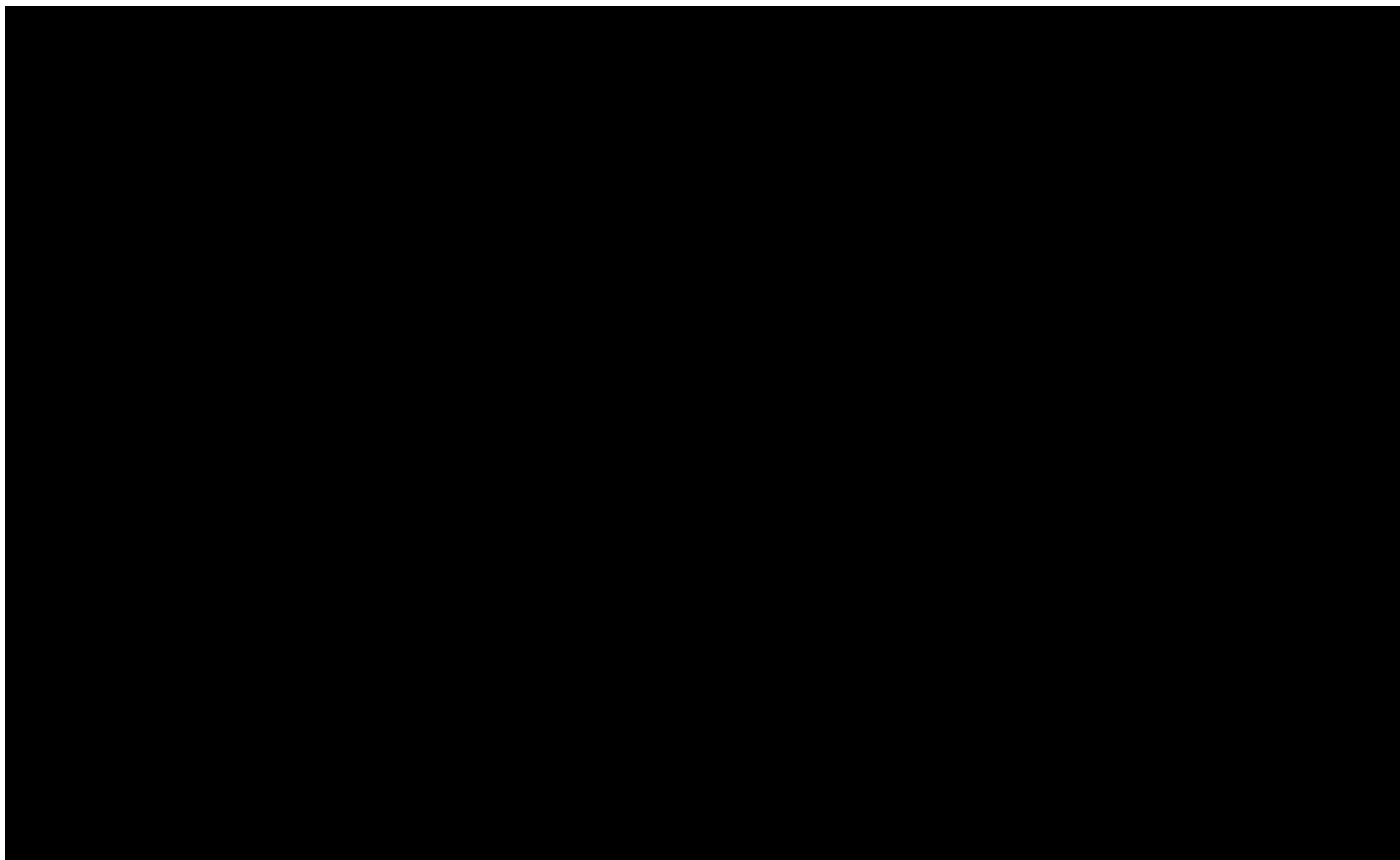
14.3.6.38: Insulin Degludec /Comparator Specific Antibodies (% B/T) against HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set



14.3.6.39: Insulin Aspart Specific Antibodies (% B/T) against HbA1c (%) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set



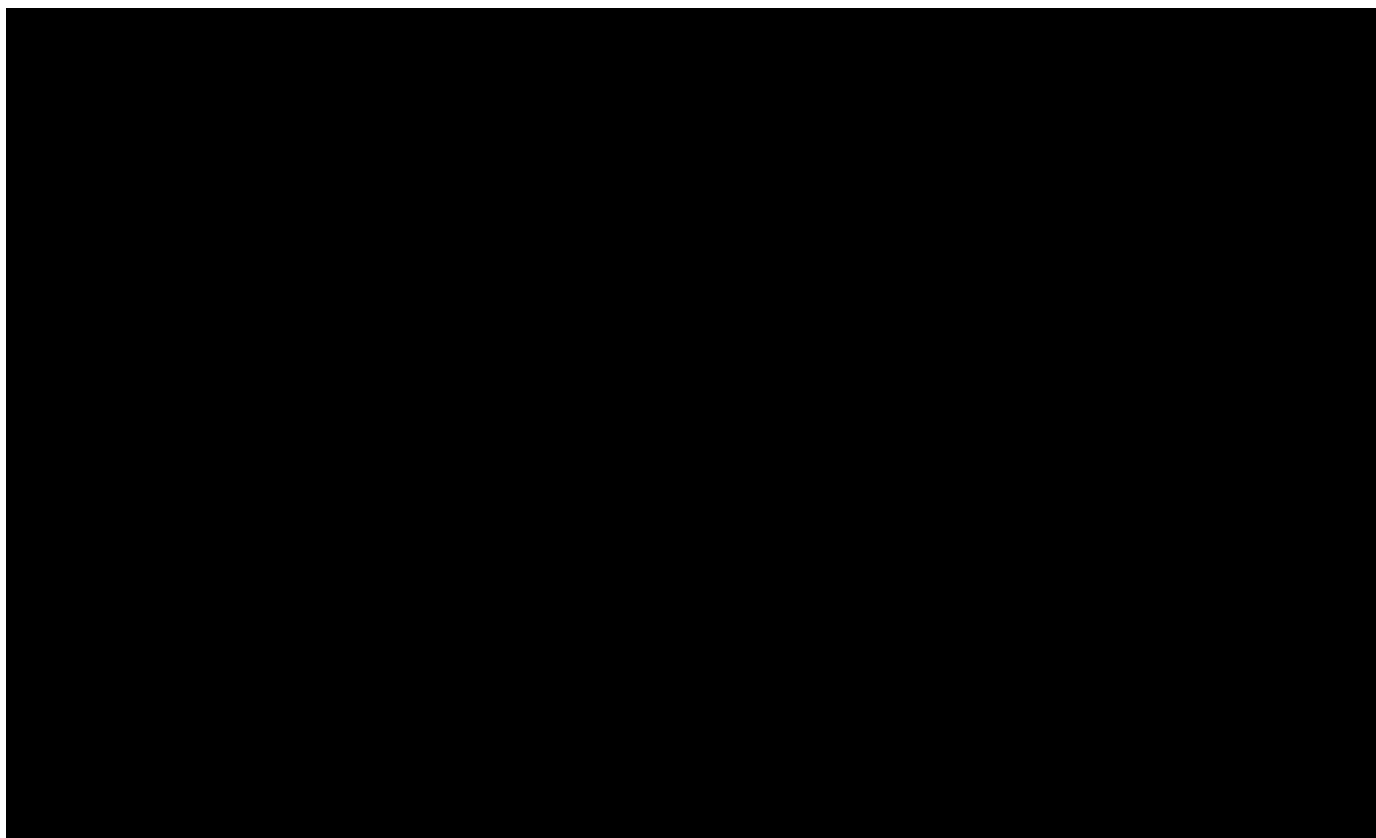
14.3.6.40: Insulin Degludec / Comparator Specific Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set



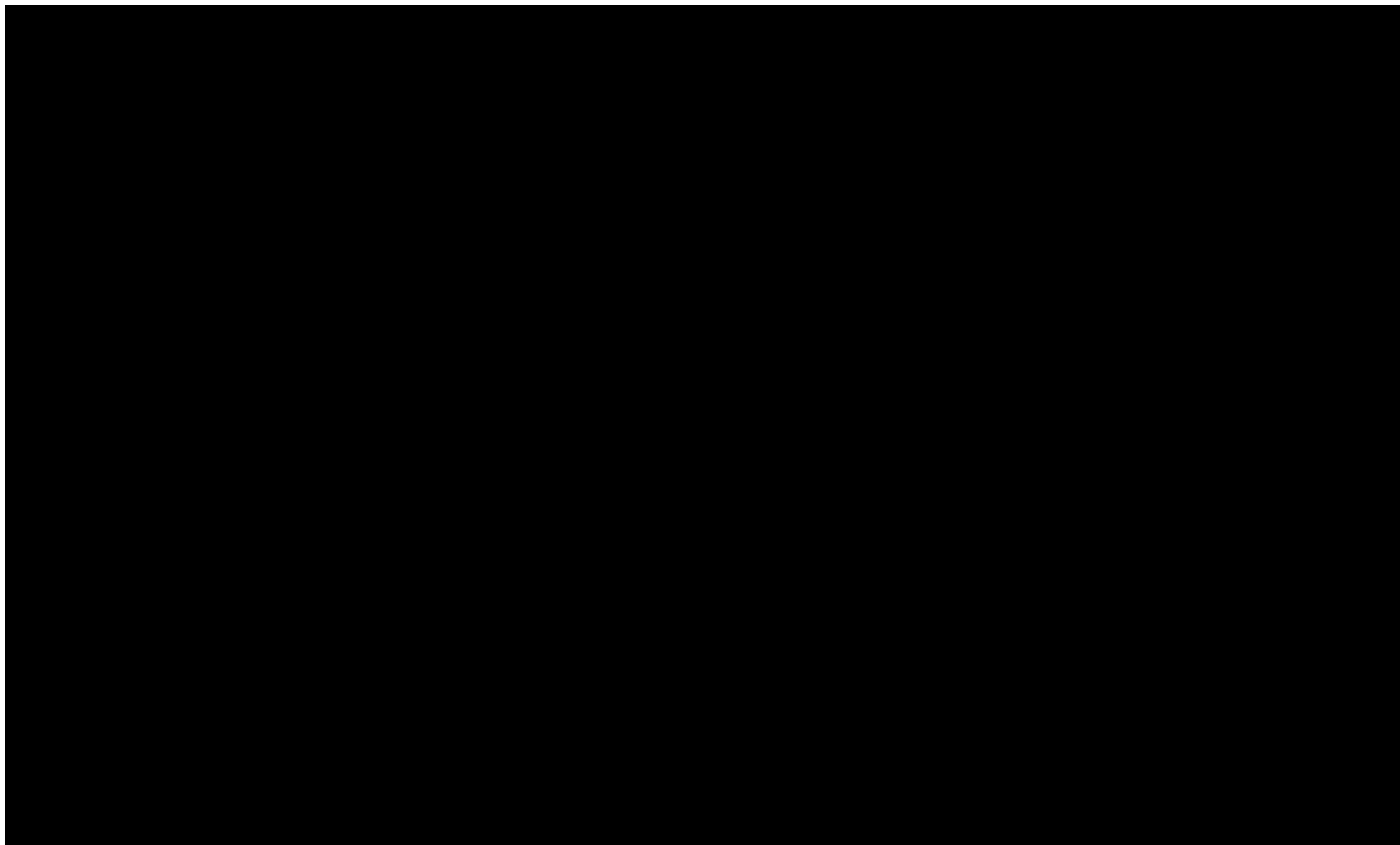
**14.3.6.41: Insulin Aspart Specific Antibodies (% B/T) against Change from Baseline in HbA1c (%))
after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set**

14.3.6.42: Cross-reacting Antibodies to Human Insulin (% B/T) against HbA1c (%) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set

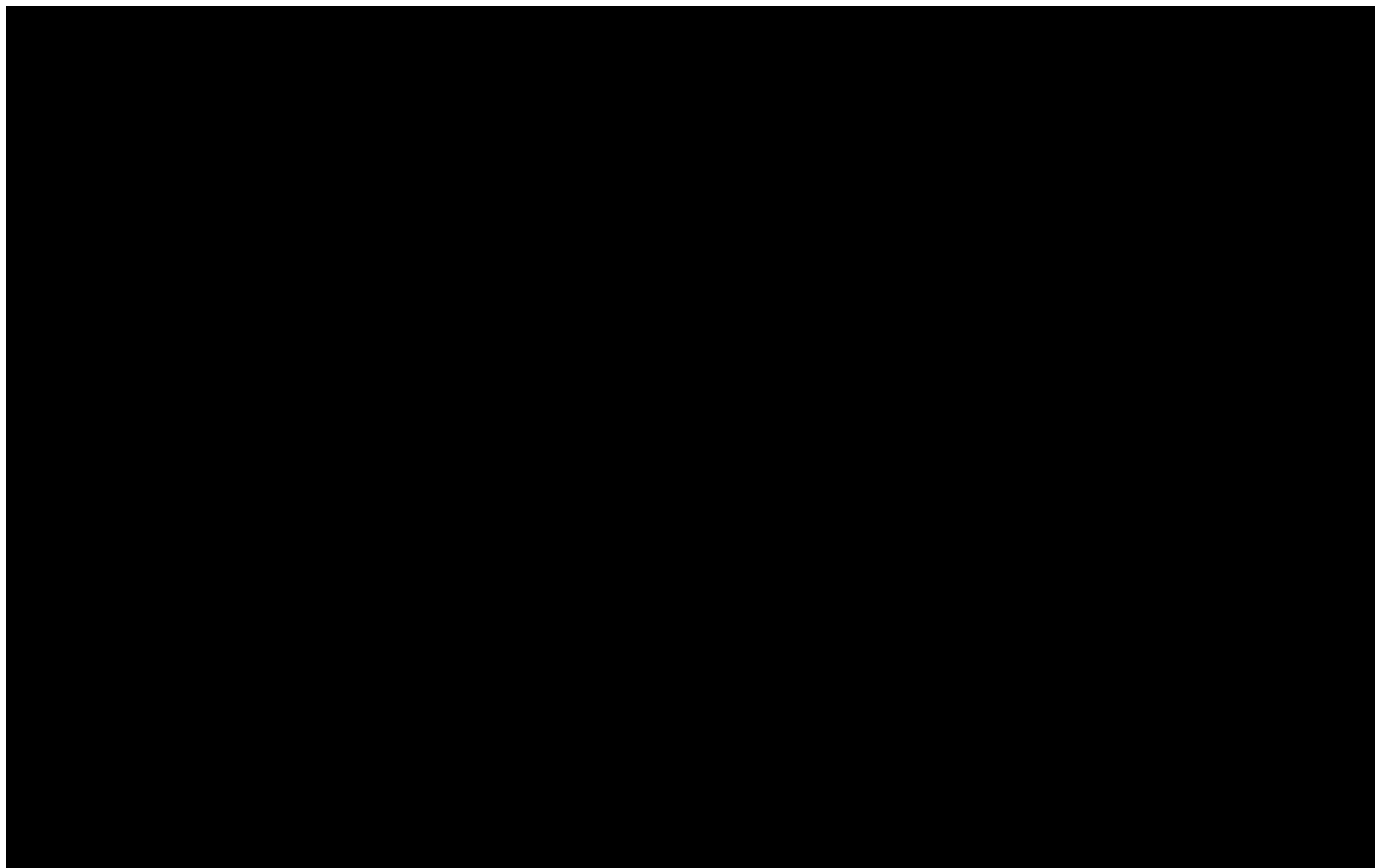
14.3.6.43: Cross-reacting Antibodies to Human Insulin (% B/T) against Change from Baseline in HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set



14.3.6.44: Total Antibodies (% B/T) against HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set



14.3.6.45: Total Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 26 Weeks of Treatment - Scatter Plot - Safety Analysis Set



14.3.6.46: Insulin Degludec / Comparator Specific Antibodies (% B/T) against Total Insulin Dose (U/kg) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set

14.3.6.47: Insulin Aspart Specific Antibodies (% B/T) against Total Insulin Dose (U/kg) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set

14.3.6.48: Cross-reacting Antibodies to Human Insulin (% B/T) against Total Insulin Dose (U/kg) after 26 Weeks of Treatment - Scatter Plot -Safety Analysis Set

**14.3.6.49: Total Antibodies (% B/T) against Total Insulin Dose (U/kg) after 26 Weeks of Treatment -
Scatter Plot -Safety Analysis Set**

14.3.7 Listings of Vital Signs, Physical Findings and Other Observations Related to Safety

14.3.7.1: Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

</								

[illegible]

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	25	M	22.5	1	120	80	75
2	1	30	F	25.0	1	115	75	70
3	1	35	M	27.5	1	130	85	78
4	1	40	F	30.0	1	140	90	80
5	1	45	M	32.5	1	150	95	82
6	1	50	F	35.0	1	160	100	85
7	1	55	M	37.5	1	170	105	88
8	1	60	F	40.0	1	180	110	90
9	1	65	M	42.5	1	190	115	92
10	1	70	F	45.0	1	200	120	95
11	2	25	M	22.5	2	125	82	76
12	2	30	F	25.0	2	120	78	72
13	2	35	M	27.5	2	135	88	80
14	2	40	F	30.0	2	145	92	85
15	2	45	M	32.5	2	155	98	88
16	2	50	F	35.0	2	165	102	90
17	2	55	M	37.5	2	175	108	95
18	2	60	F	40.0	2	185	112	98
19	2	65	M	42.5	2	195	118	100
20	2	70	F	45.0	2	205	122	102

[illegible]

[illegible]

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

[illegible]

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	25	M	22.5	1	120	80	75
2	1	30	F	25.0	1	115	75	70
3	1	35	M	27.5	1	130	85	78
4	1	40	F	30.0	1	140	90	80
5	1	45	M	32.5	1	150	95	82
6	1	50	F	35.0	1	160	100	85
7	1	55	M	37.5	1	170	105	88
8	1	60	F	40.0	1	180	110	90
9	1	65	M	42.5	1	190	115	92
10	1	70	F	45.0	1	200	120	95
11	2	25	M	22.5	1	120	80	75
12	2	30	F	25.0	1	115	75	70
13	2	35	M	27.5	1	130	85	78
14	2	40	F	30.0	1	140	90	80
15	2	45	M	32.5	1	150	95	82
16	2	50	F	35.0	1	160	100	85
17	2	55	M	37.5	1	170	105	88
18	2	60	F	40.0	1	180	110	90
19	2	65	M	42.5	1	190	115	92
20	2	70	F	45.0	1	200	120	95
21	2	25	M	22.5	2	110	75	70
22	2	30	F	25.0	2	105	70	65
23	2	35	M	27.5	2	115	78	72
24	2	40	F	30.0	2	125	80	75
25	2	45	M	32.5	2	135	85	78
26	2	50	F	35.0	2	145	90	80
27	2	55	M	37.5	2	155	95	82
28	2	60	F	40.0	2	165	100	85
29	2	65	M	42.5	2	175	105	88
30	2	70	F	45.0	2	185	110	90
31	3	25	M	22.5	1	120	80	75
32	3	30	F	25.0	1	115	75	70
33	3	35	M	27.5	1	130	85	78
34	3	40	F	30.0	1	140	90	80
35	3	45	M	32.5	1	150	95	82
36	3	50	F	35.0	1	160	100	85
37	3	55	M	37.5	1	170	105	88
38	3	60	F	40.0	1	180	110	90
39	3	65	M	42.5	1	190	115	92
40	3	70	F	45.0	1	200	120	95
41	3	25	M	22.5	2	110	75	70
42	3	30	F	25.0	2	105	70	65
43	3	35	M	27.5	2	115	78	72
44	3	40	F	30.0	2	125	80	75
45	3	45	M	32.5	2	135	85	78
46	3	50	F	35.0	2	145	90	80
47	3	55	M	37.5	2	155	95	82
48	3	60	F	40.0	2	165	100	85
49	3	65	M	42.5	2	175	105	88
50	3	70	F	45.0	2	185	110	90
51	3	25	M	22.5	3	100	70	6

[illegible]

[illegible]

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	55	M	25.2	1	120	80	72
2	1	62	F	28.5	1	115	75	68
3	1	58	M	22.1	1	118	78	70
4	1	65	F	30.1	1	125	82	75
5	1	52	M	20.5	1	112	72	65
6	1	60	F	27.8	1	122	80	73
7	1	57	M	23.5	1	116	76	69
8	1	63	F	29.2	1	124	81	74
9	1	54	M	21.8	1	114	74	67
10	1	61	F	28.9	1	121	79	72
11	2	55	M	25.2	2	118	78	70
12	2	62	F	28.5	2	115	75	68
13	2	58	M	22.1	2	112	72	65
14	2	65	F	30.1	2	120	80	72
15	2	52	M	20.5	2	110	70	63
16	2	60	F	27.8	2	118	78	69
17	2	57	M	23.5	2	116	76	69
18	2	63	F	29.2	2	122	80	73
19	2	54	M	21.8	2	114	74	67
20	2	61	F	28.9	2	121	79	72

[illegible]

[illegible]

[illegible]

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

[illegible]

[illegible]

[illegible]

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

[illegible]

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

Novo Nordisk

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

[illegible]

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

[illegible]

14.3.7.2: ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

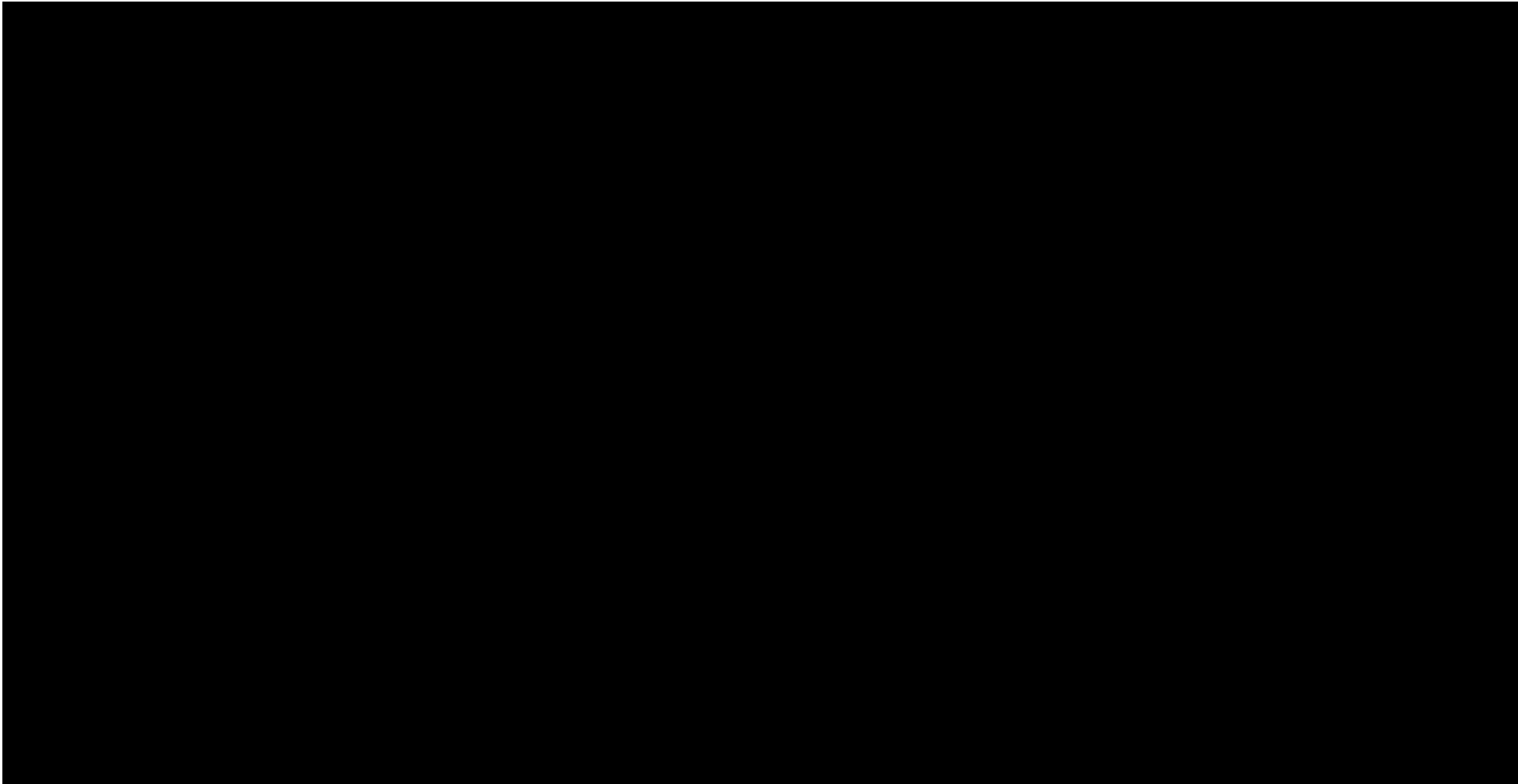
Status:
Page:

Final
1086 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

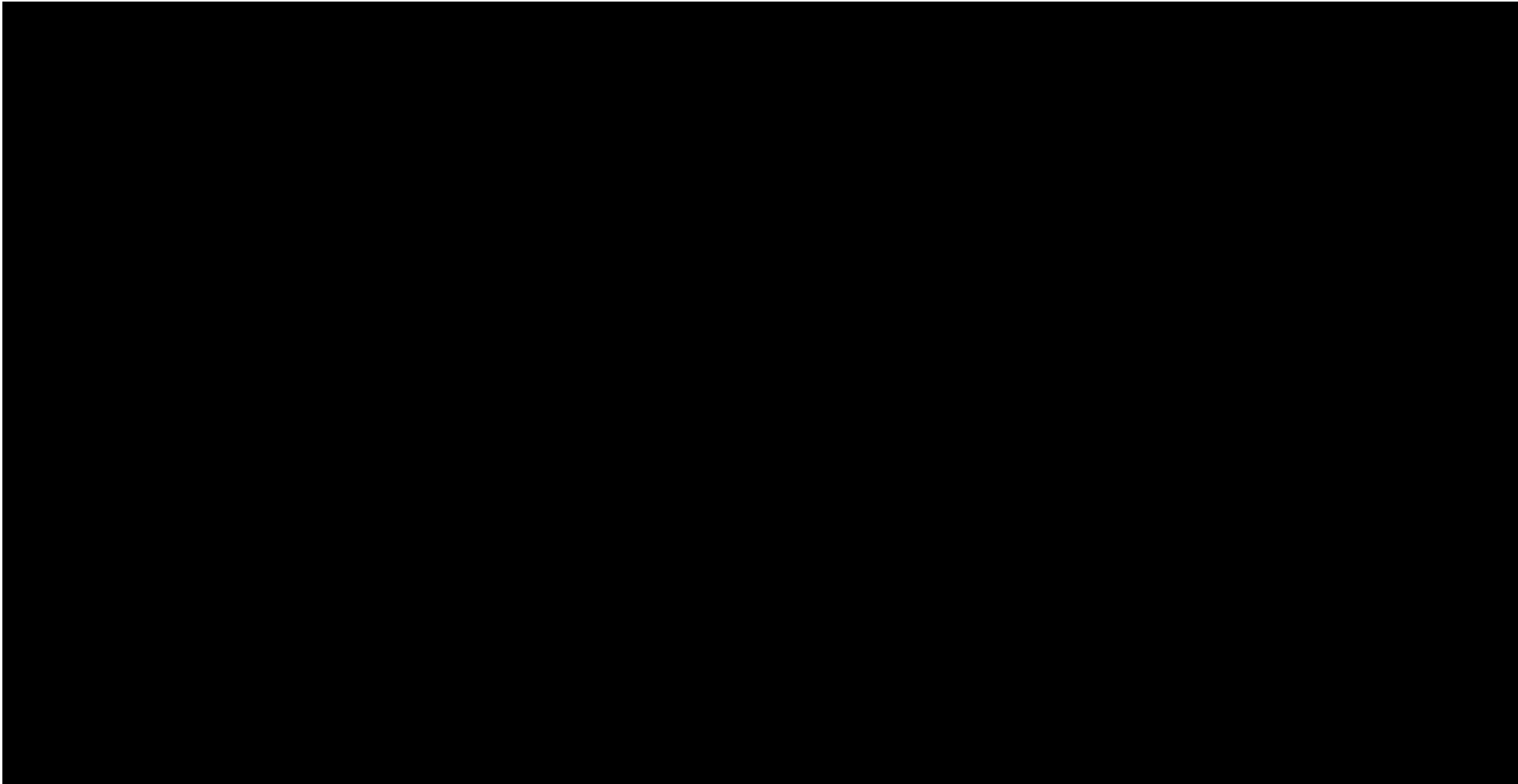
Status:
Page:

Final
1087 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

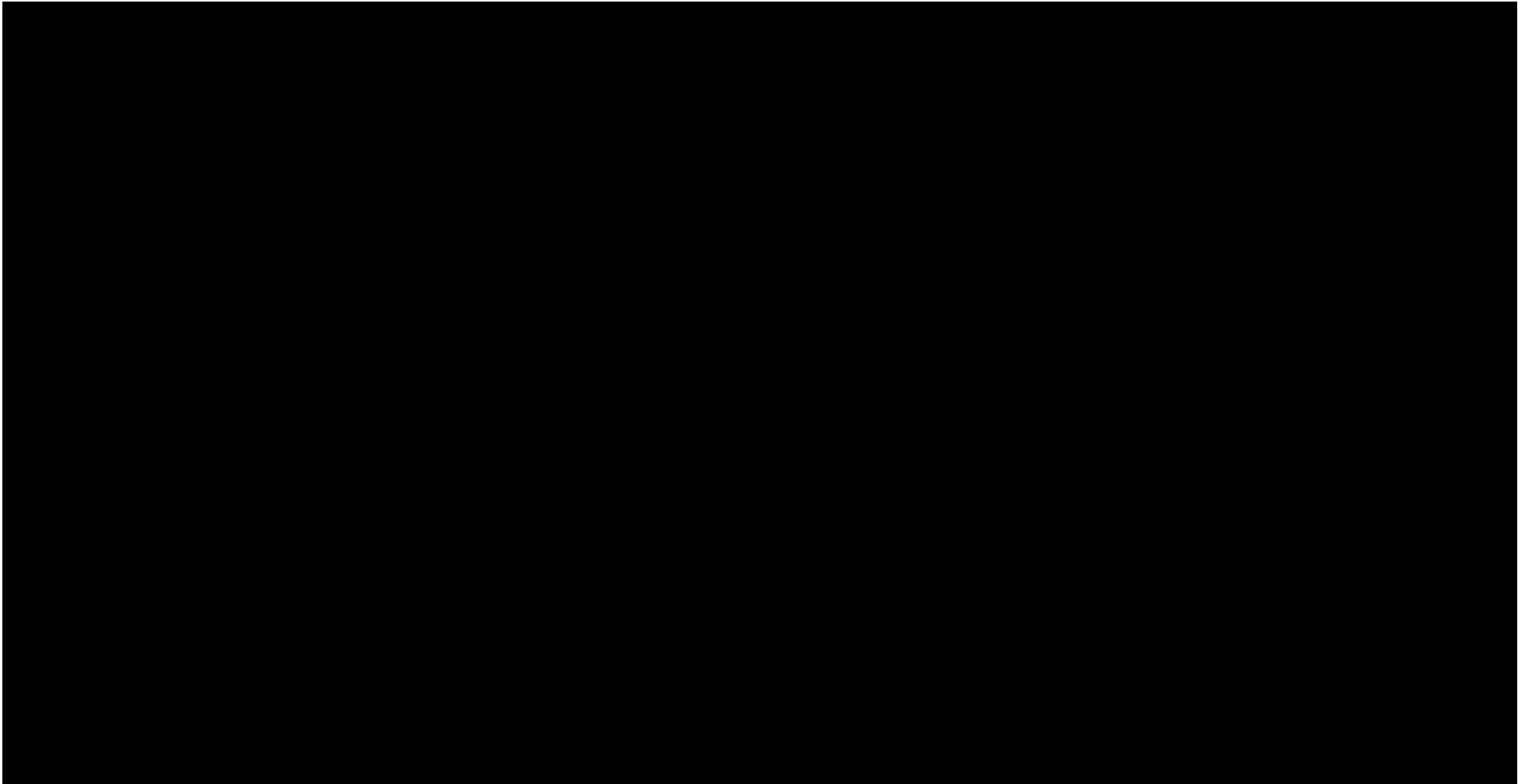
Status:
Page:

Final
1089 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

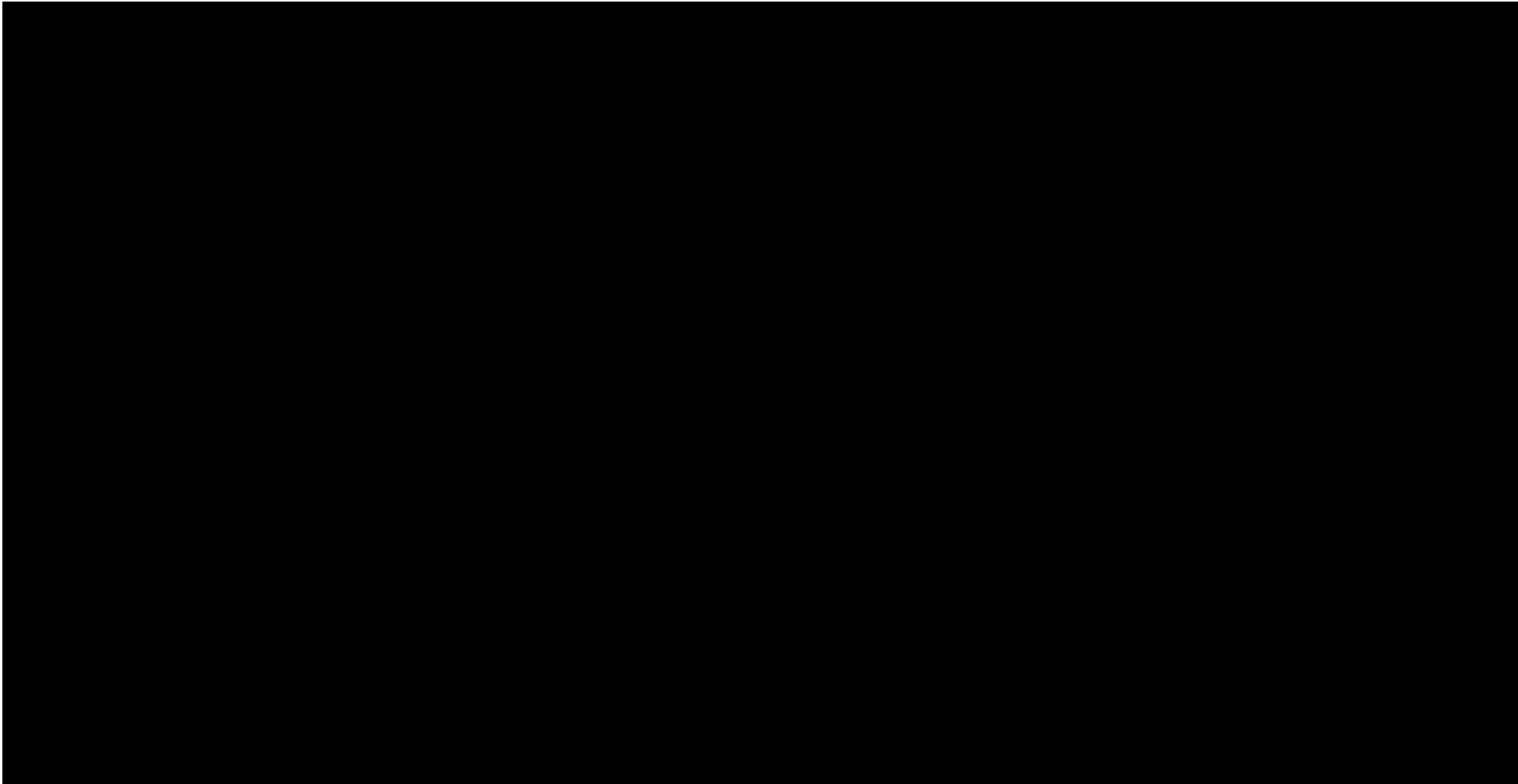
Status:
Page:

Final
1090 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

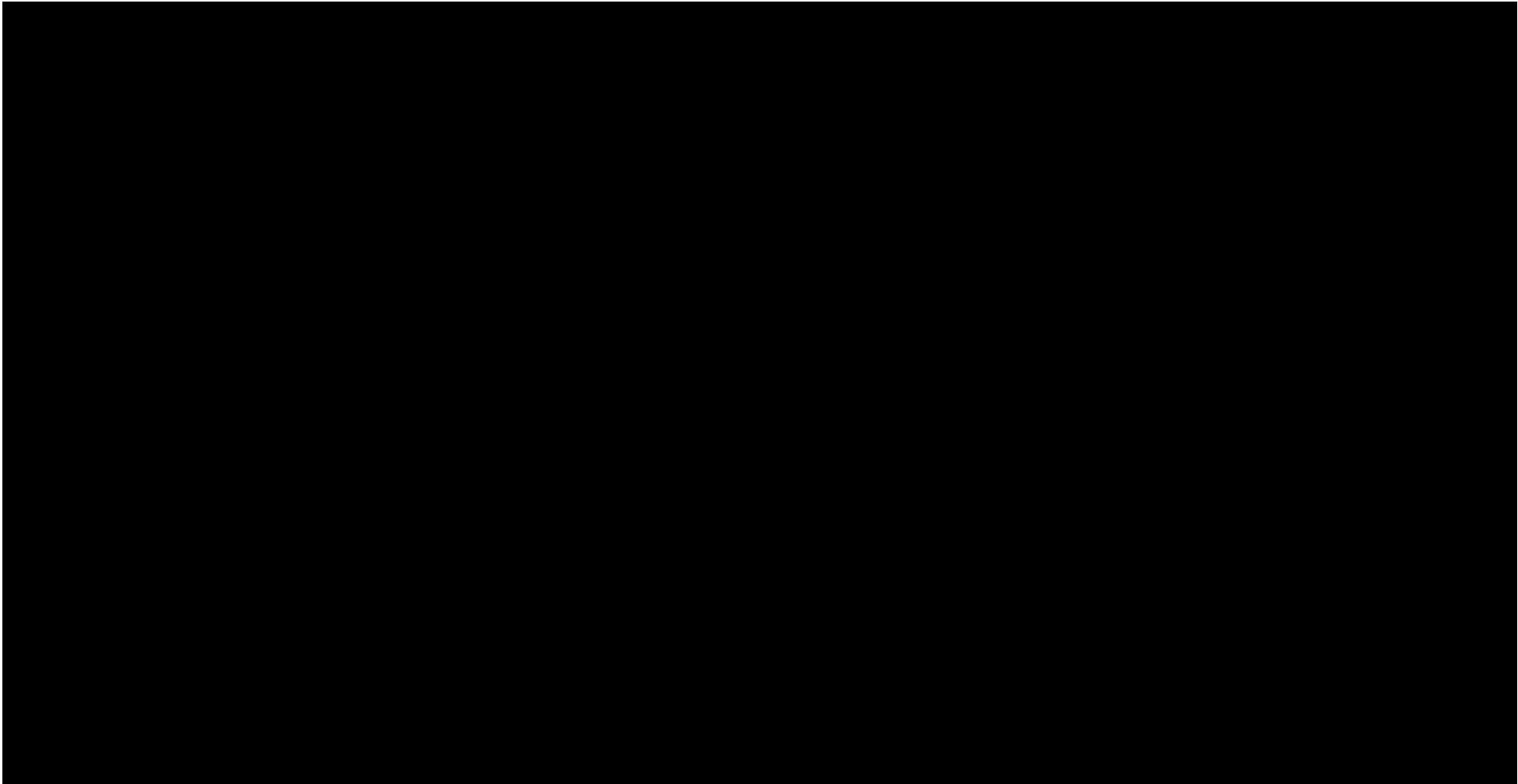
Status:
Page:

Final
1091 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

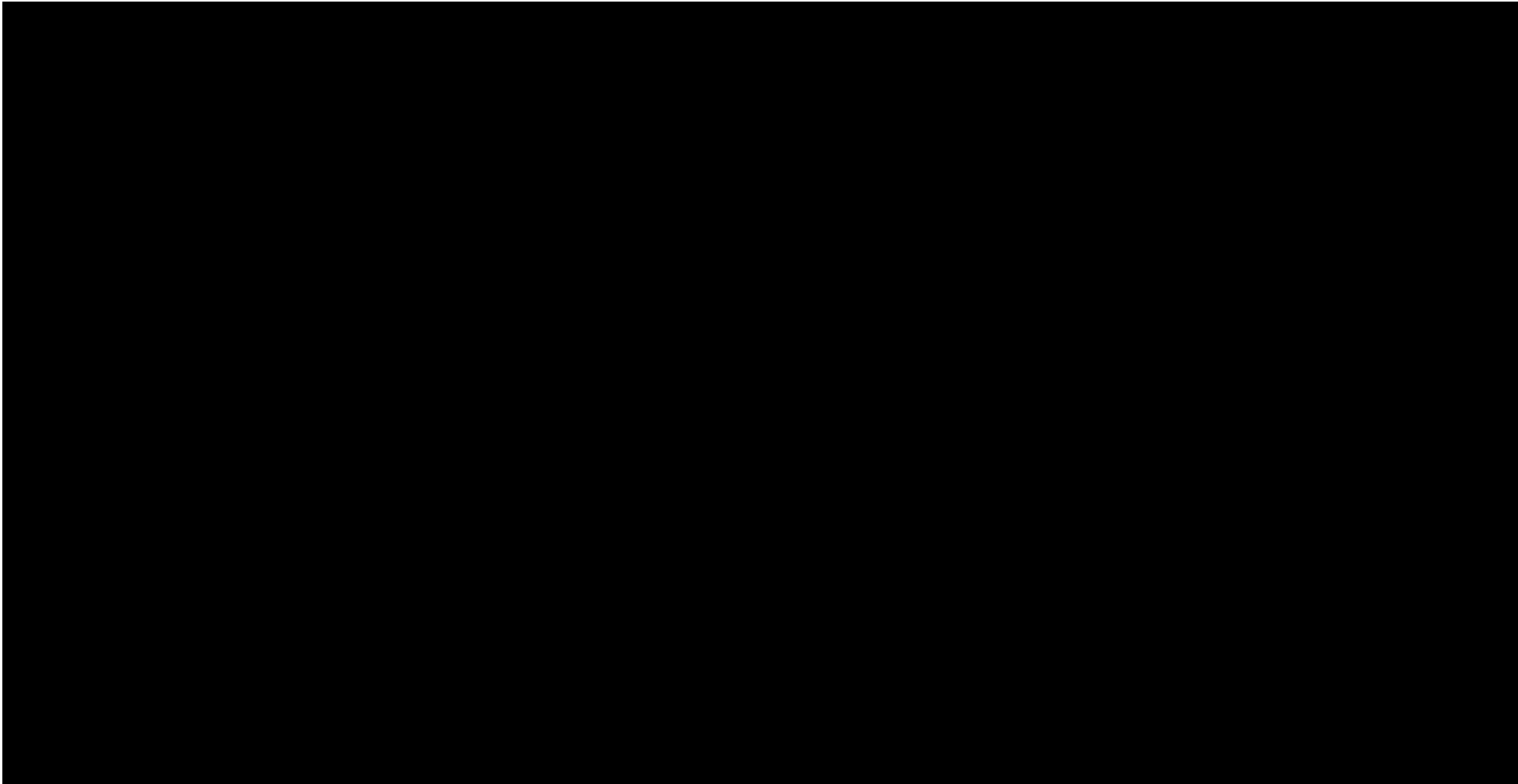
Status:
Page:

Final
1093 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

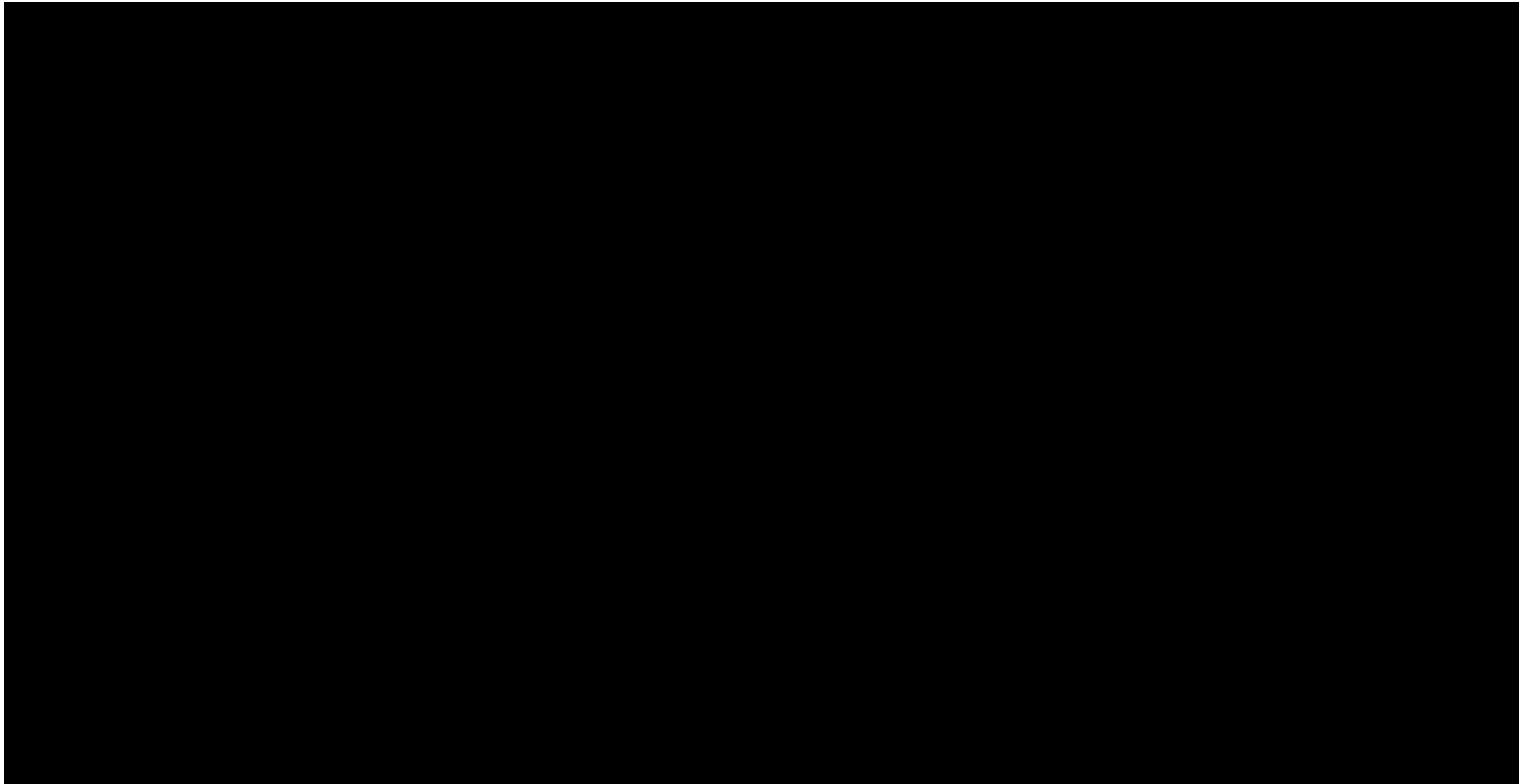
Status:
Page:

Final
1097 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

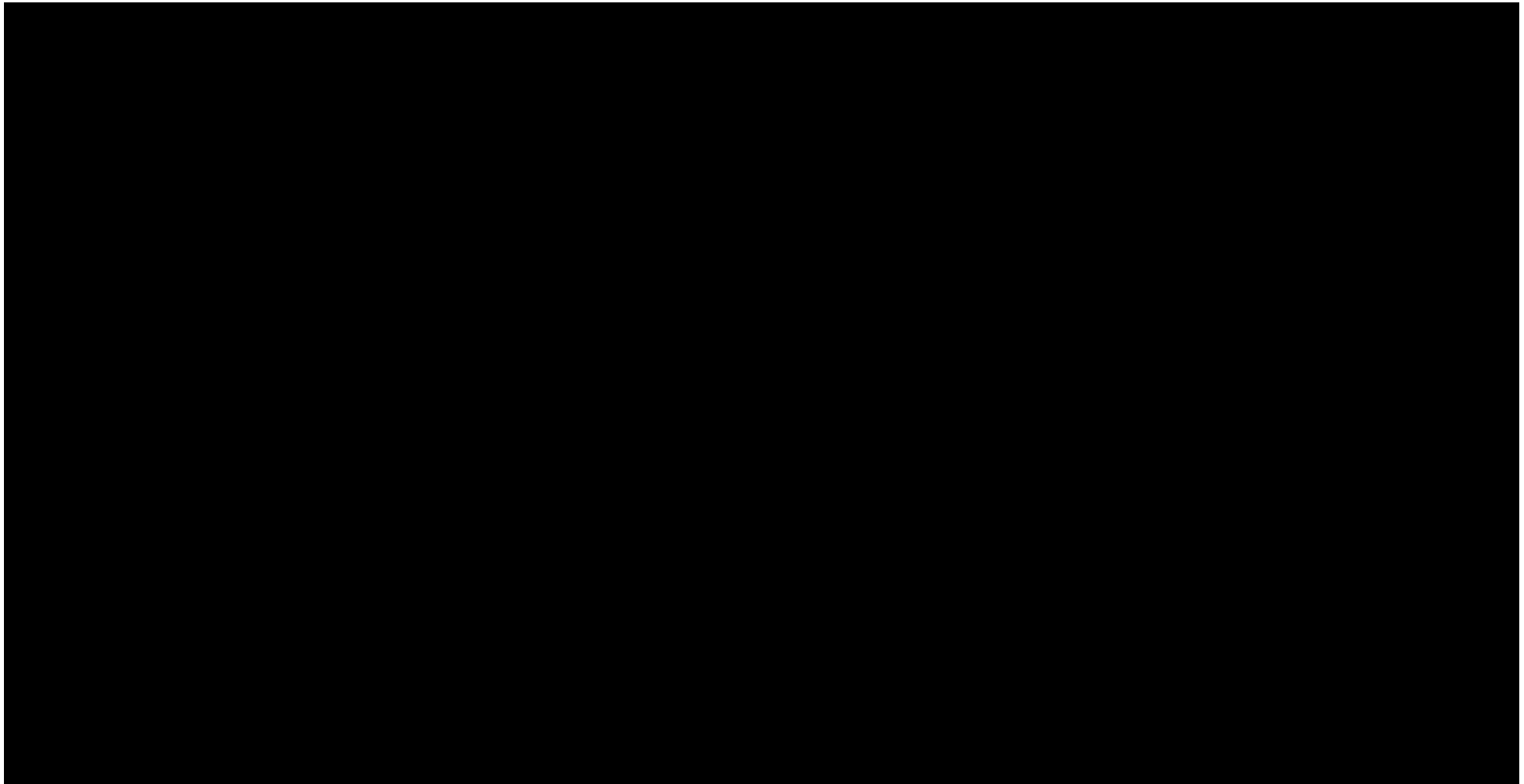
Status:
Page:

Final
1099 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

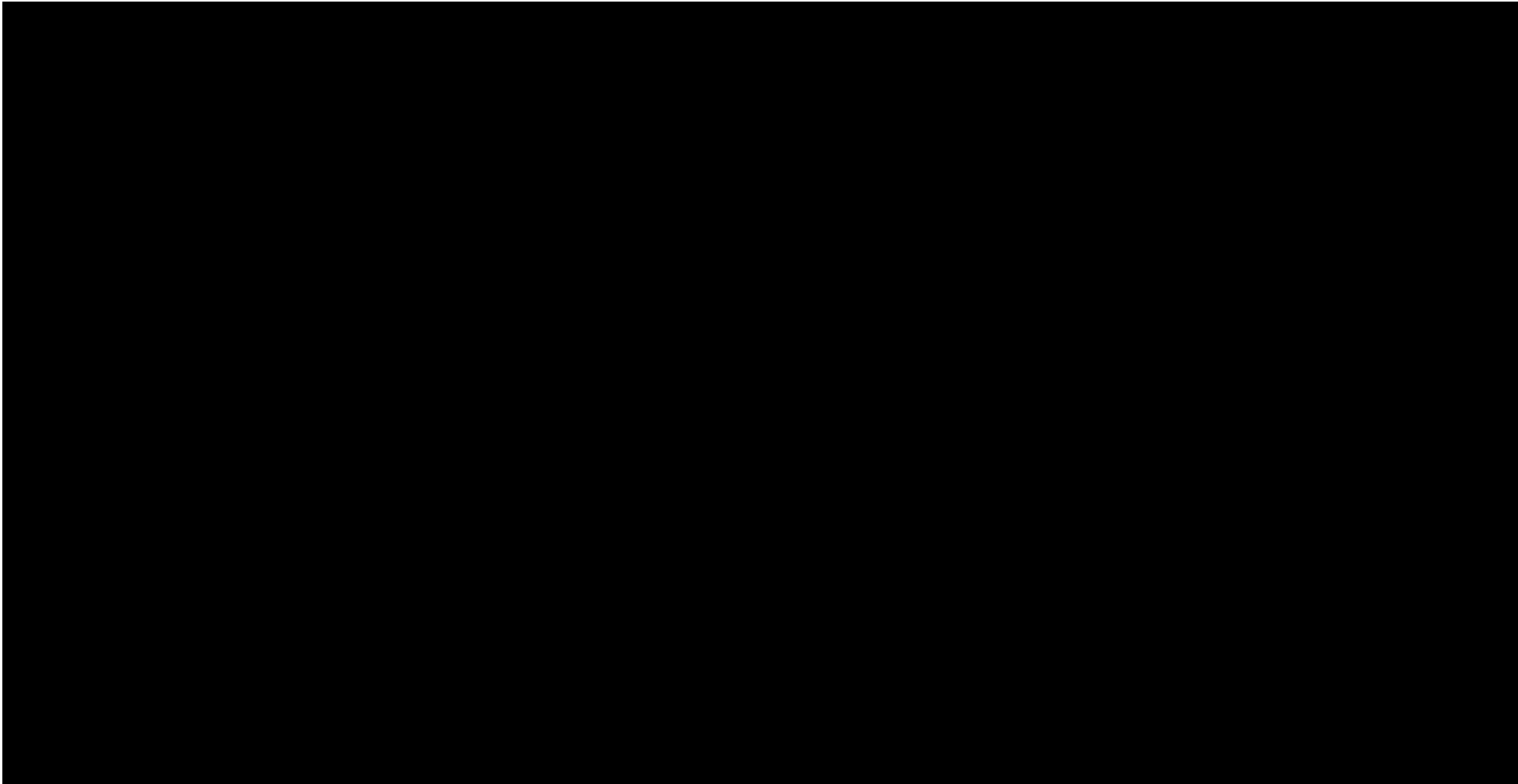
Status:
Page:

Final
1101 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

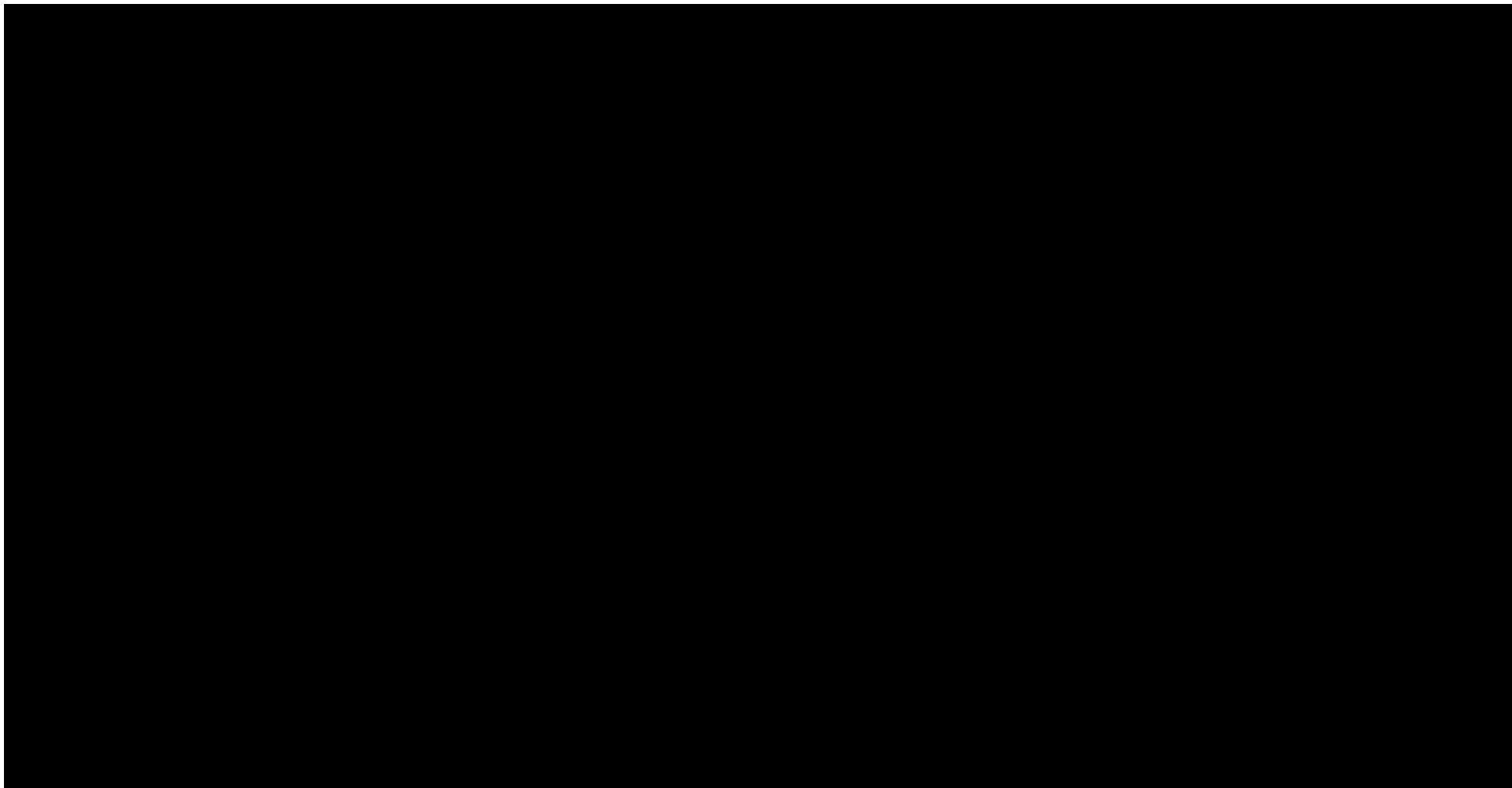
Status:
Page:

Final
1103 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

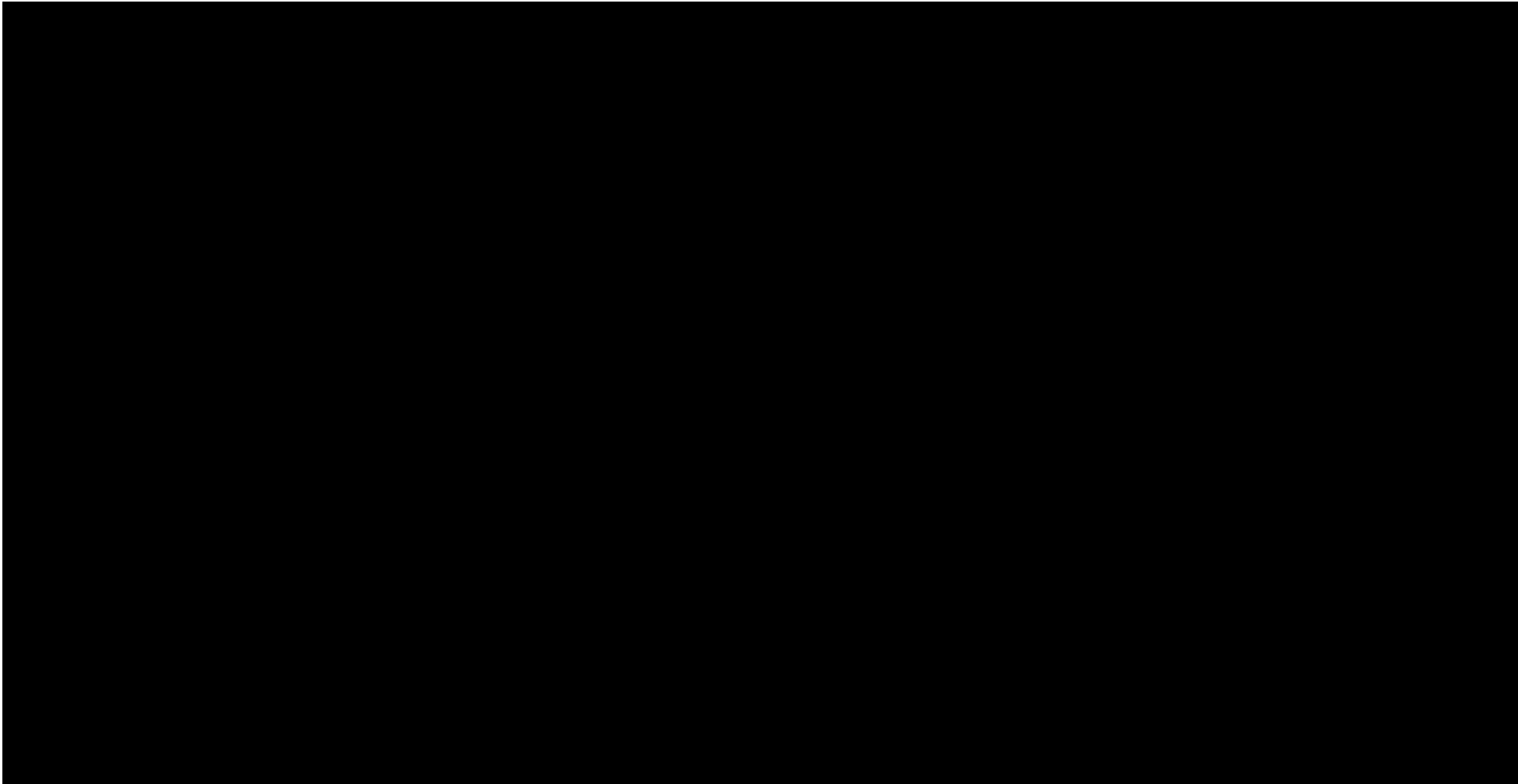
Status:
Page:

Final
1104 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

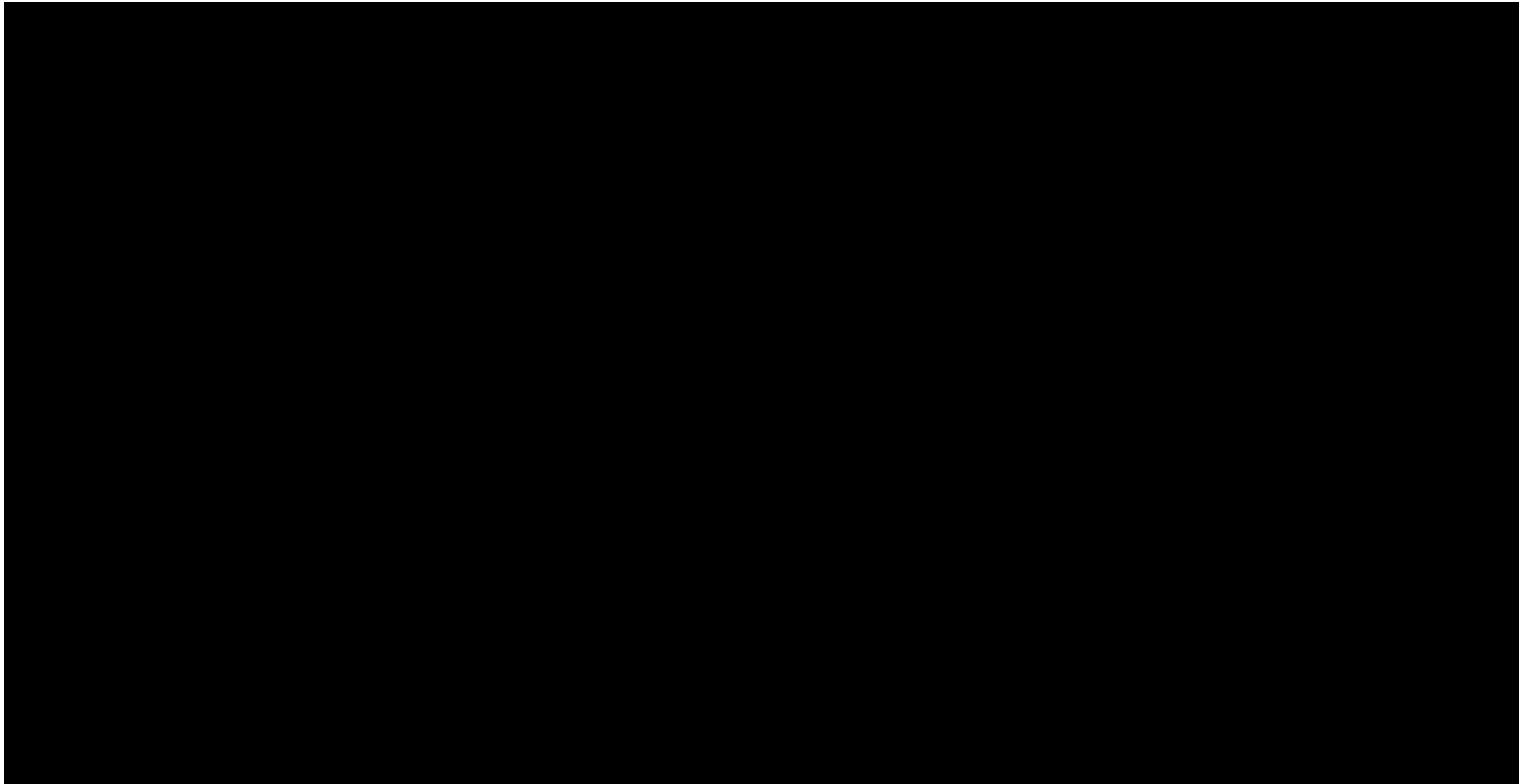
Status:
Page:

Final
1105 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

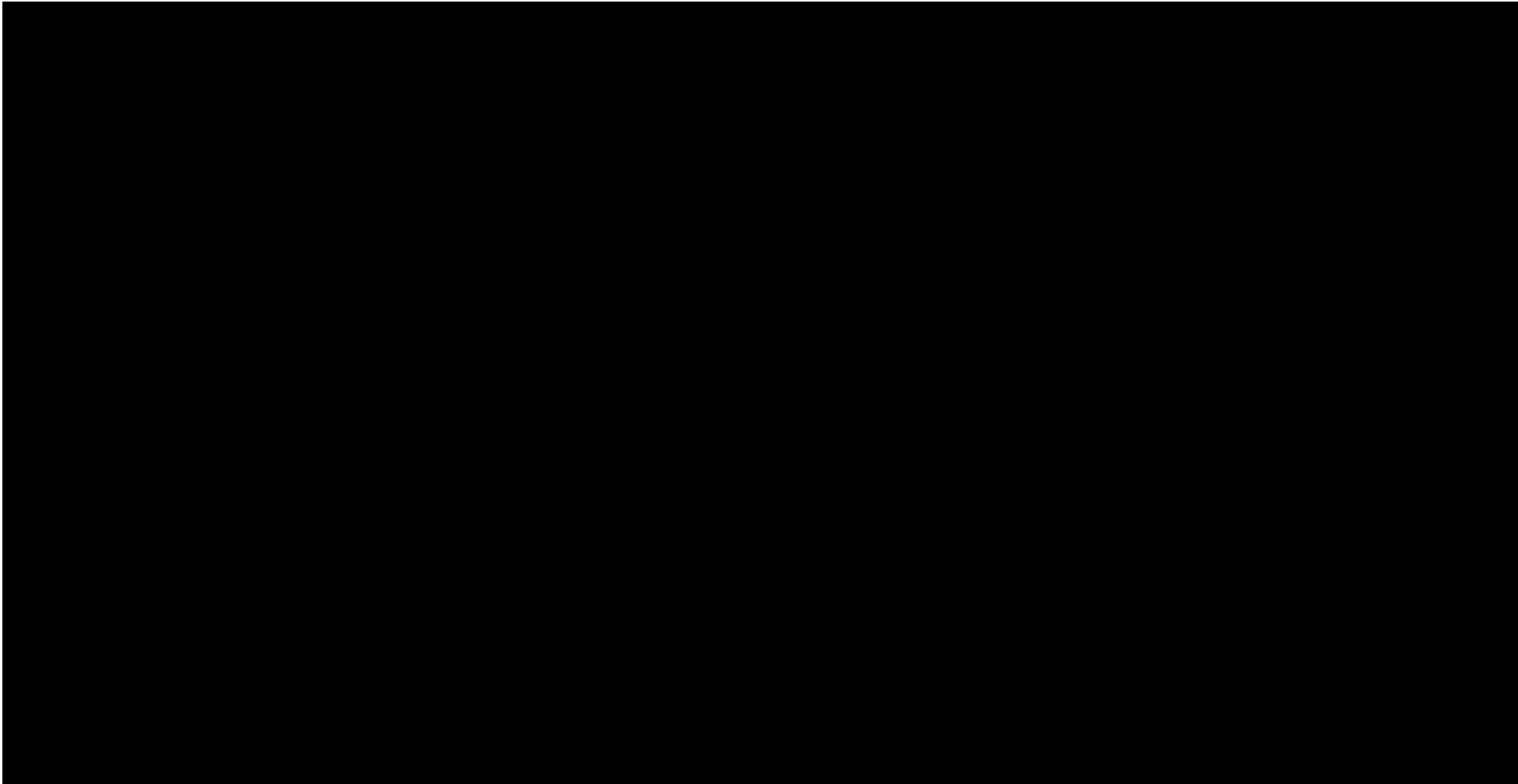
Status:
Page:

Final
1106 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

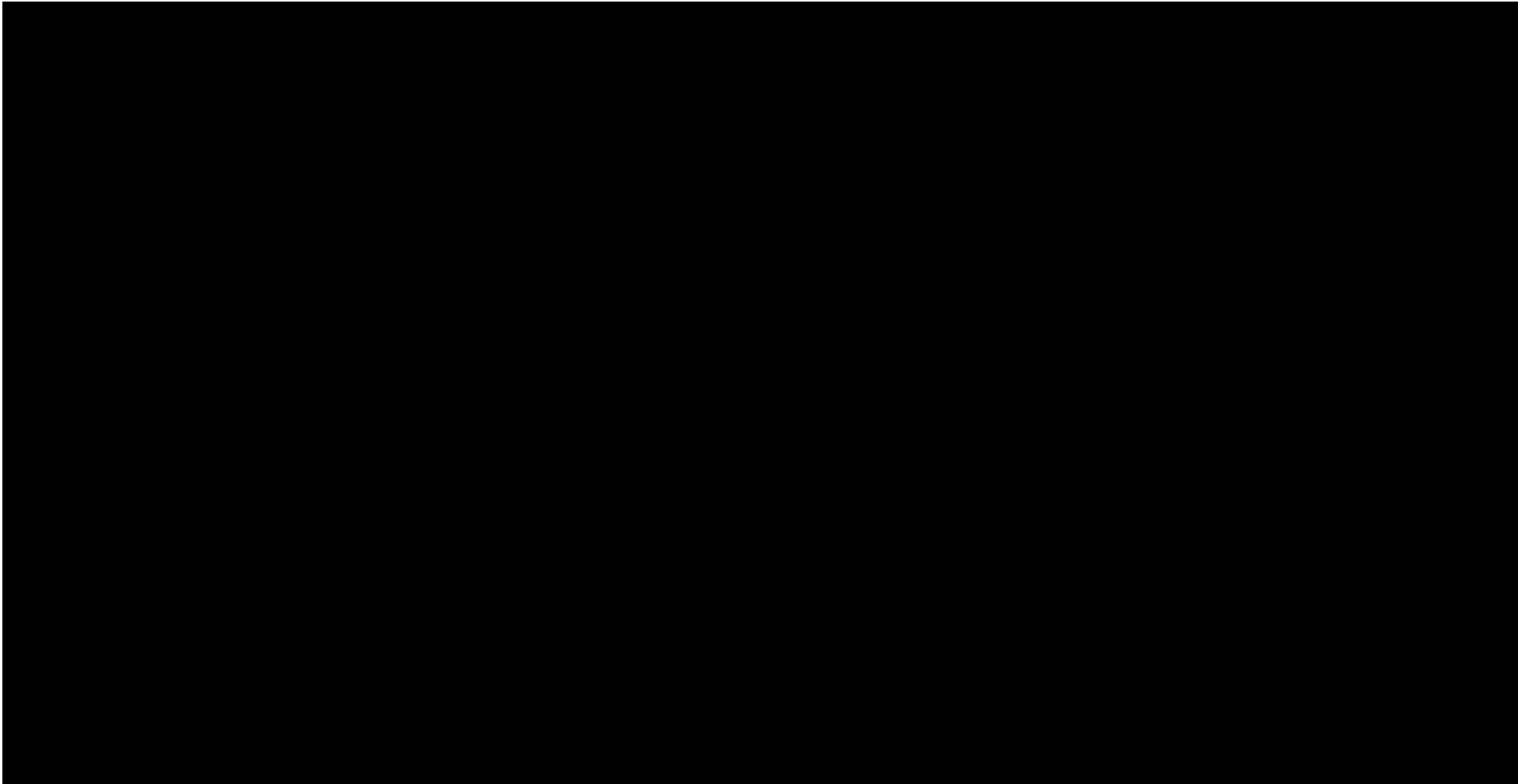
Status:
Page:

Final
1107 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

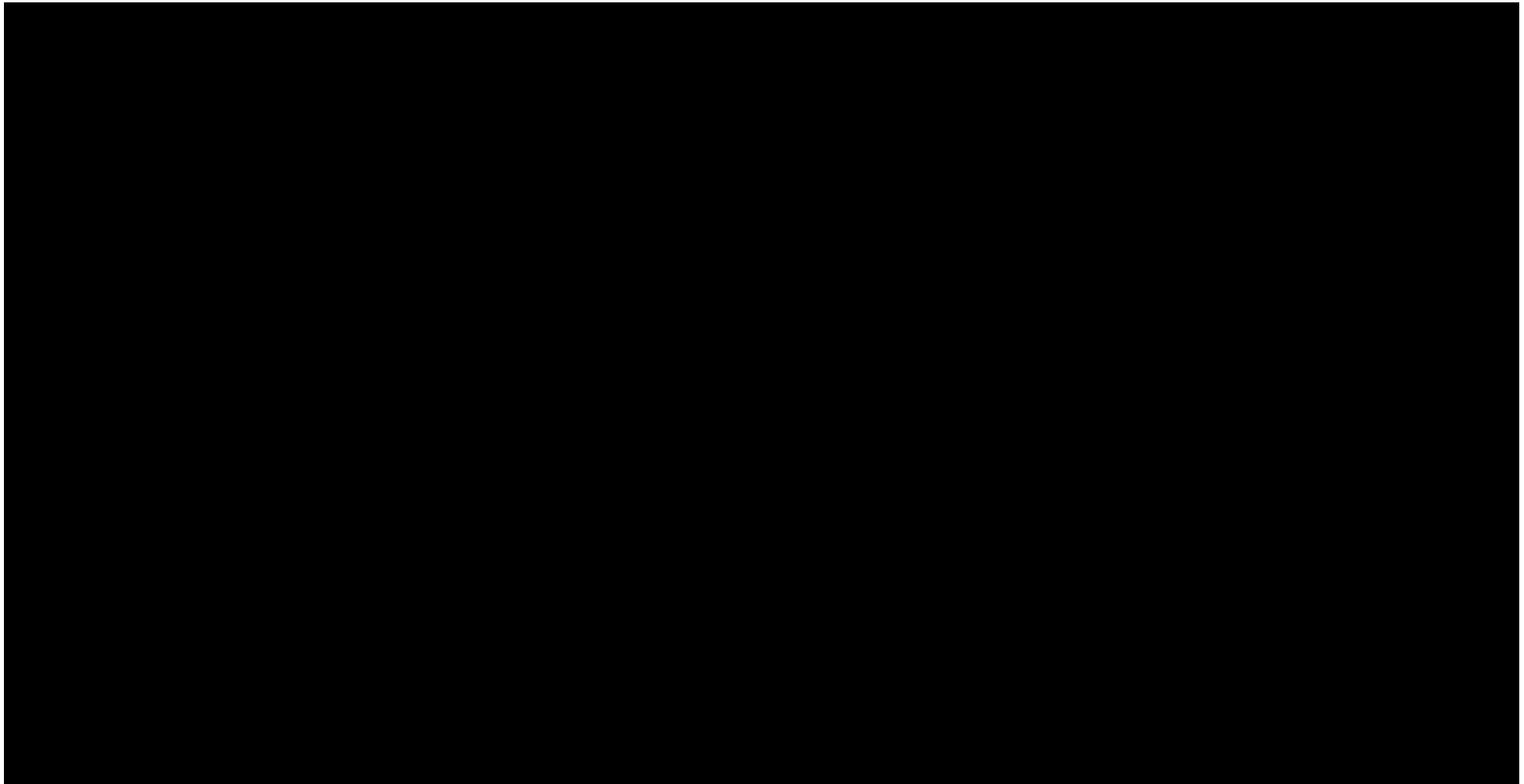
Status:
Page:

Final
1108 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

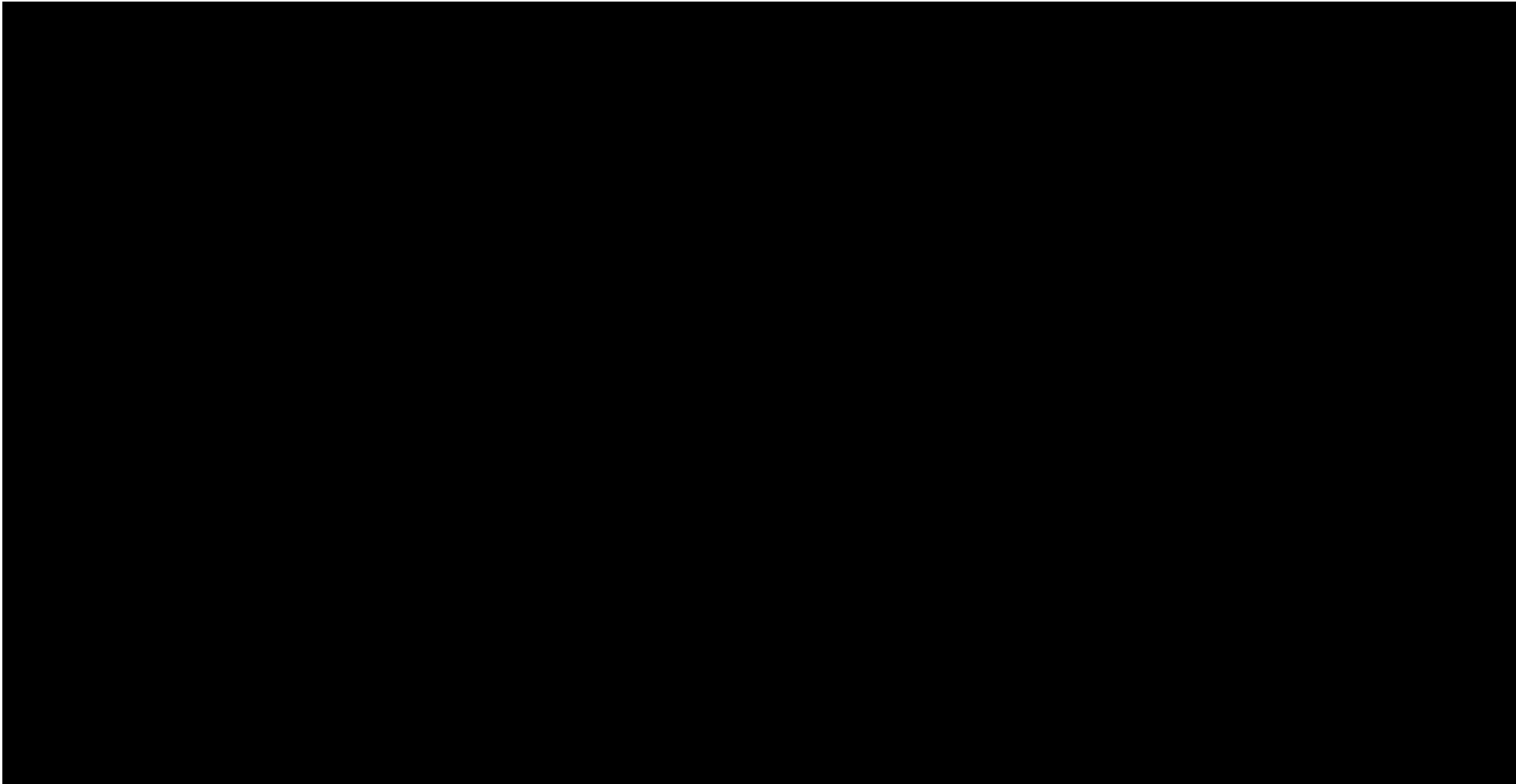
Status:
Page:

Final
1109 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

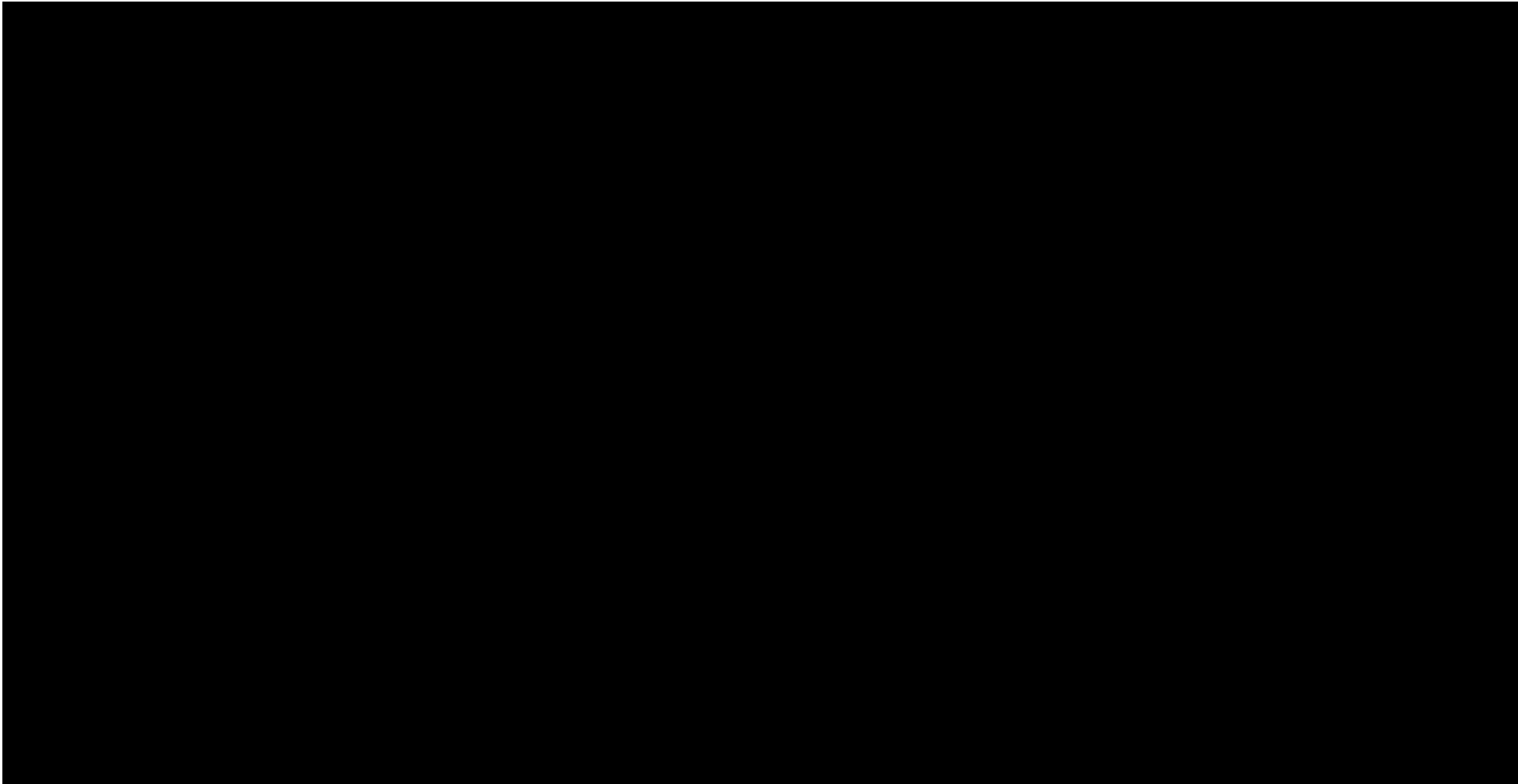
Status:
Page:

Final
1110 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

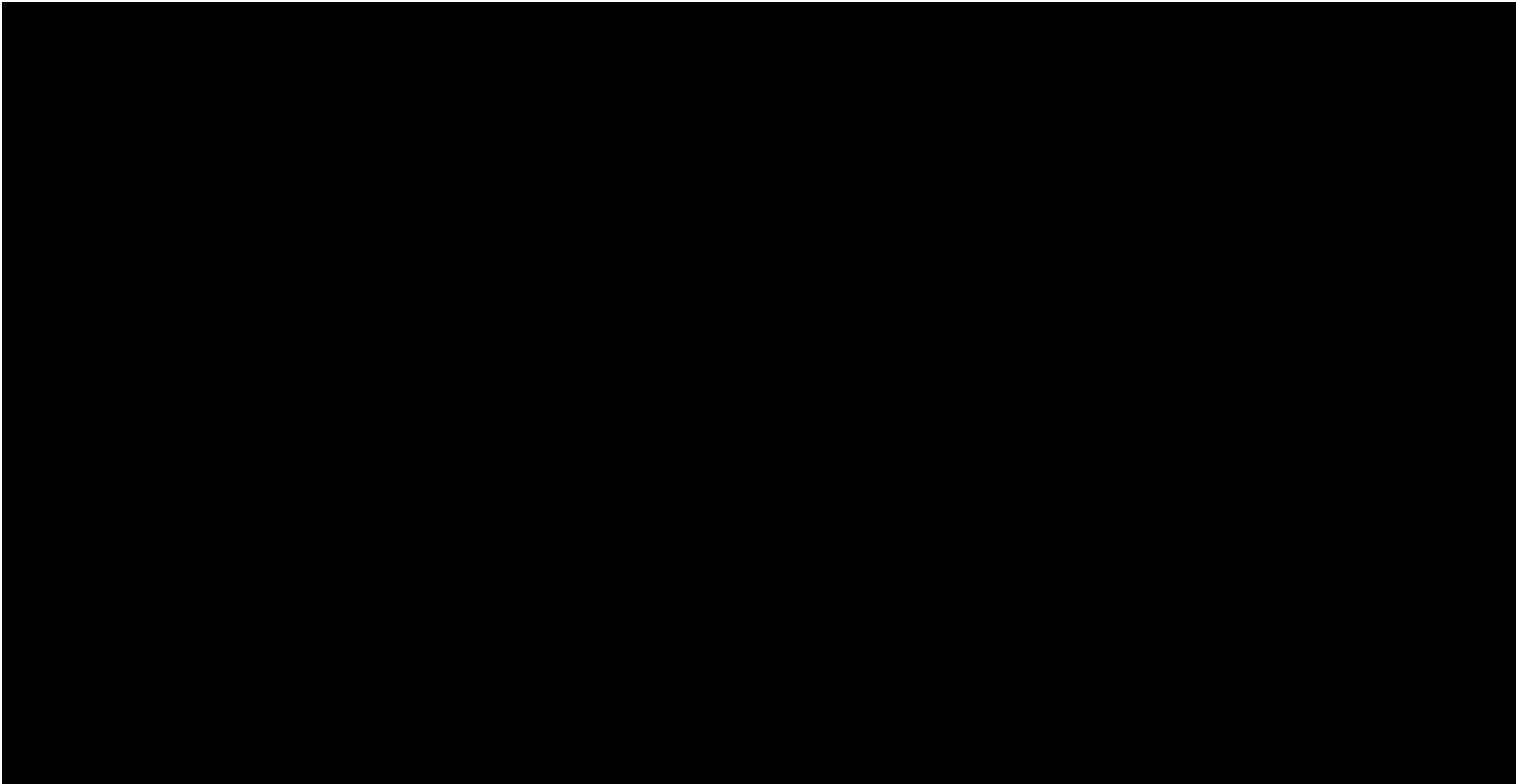
Status:
Page:

Final
1111 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

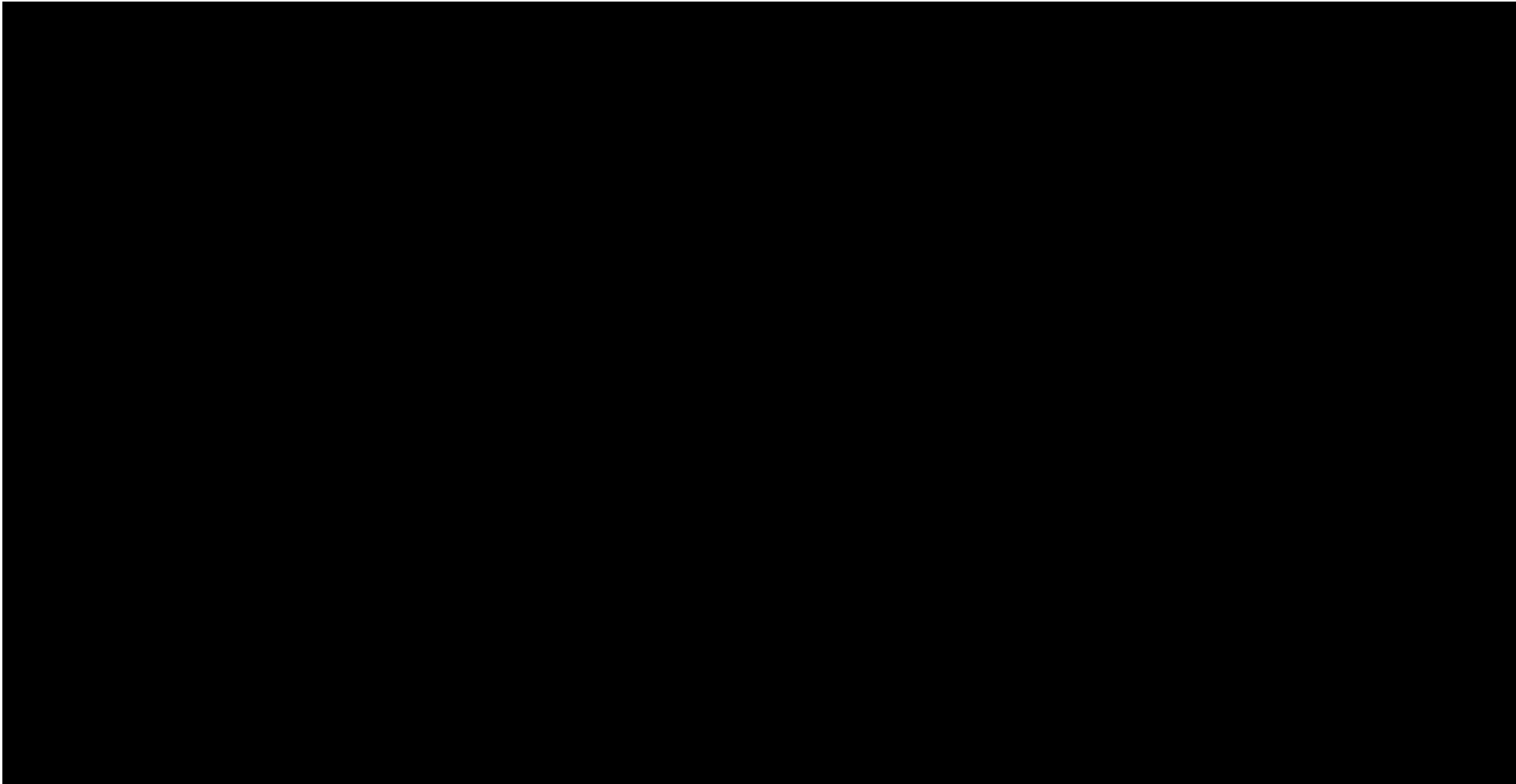
Status:
Page:

Final
1112 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

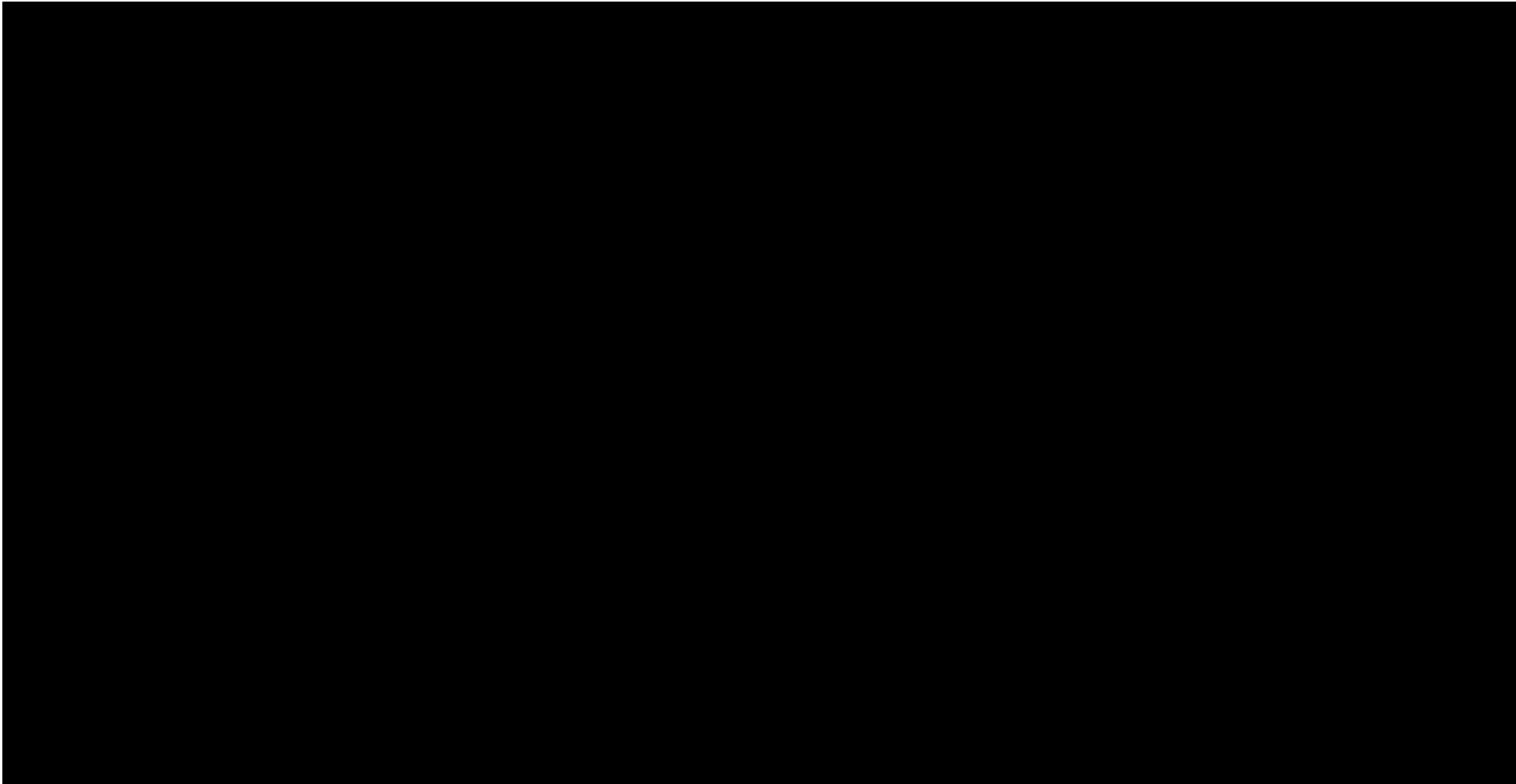
Status:
Page:

Final
1113 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

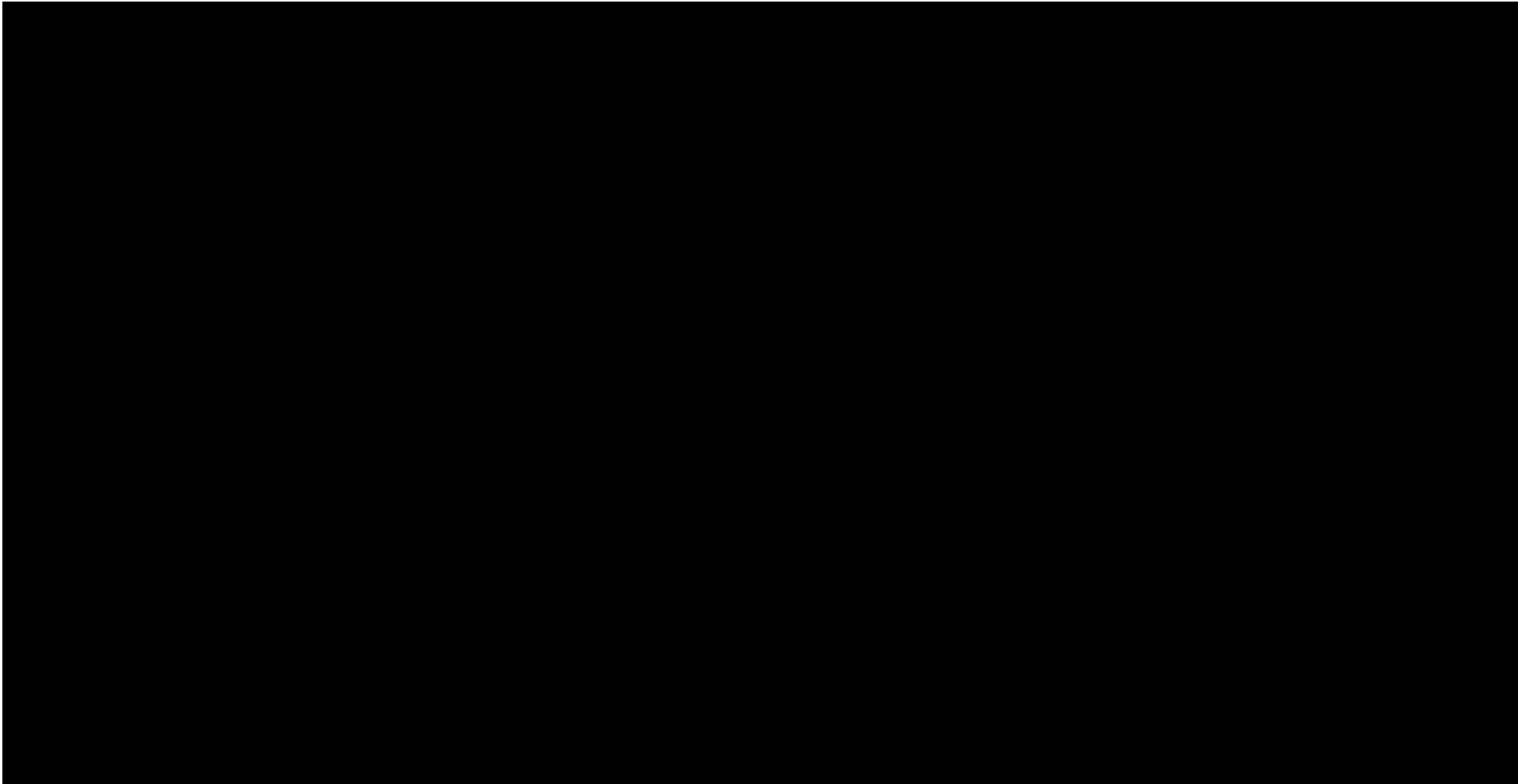
Status:
Page:

Final
1115 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

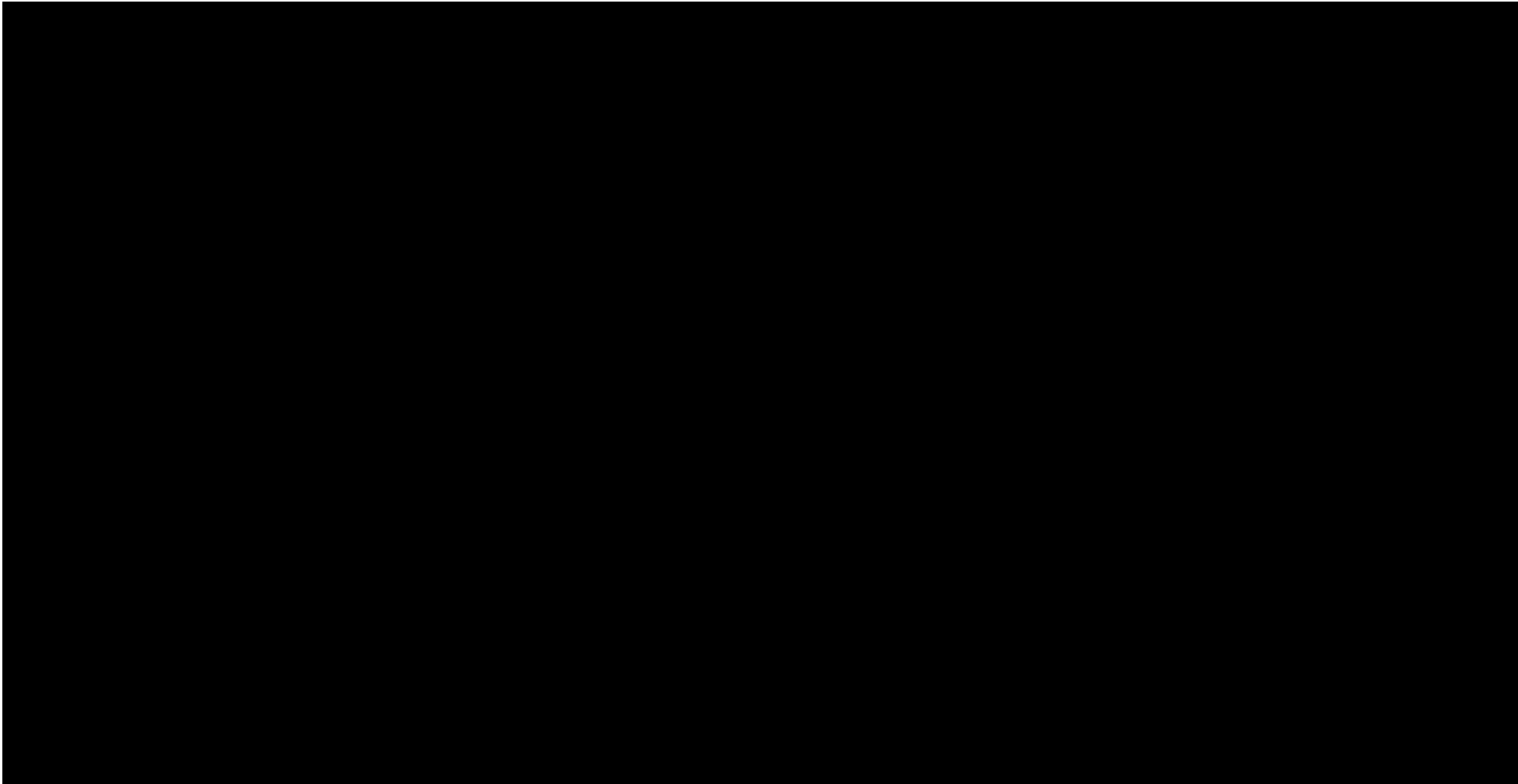
Status:
Page:

Final
1116 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

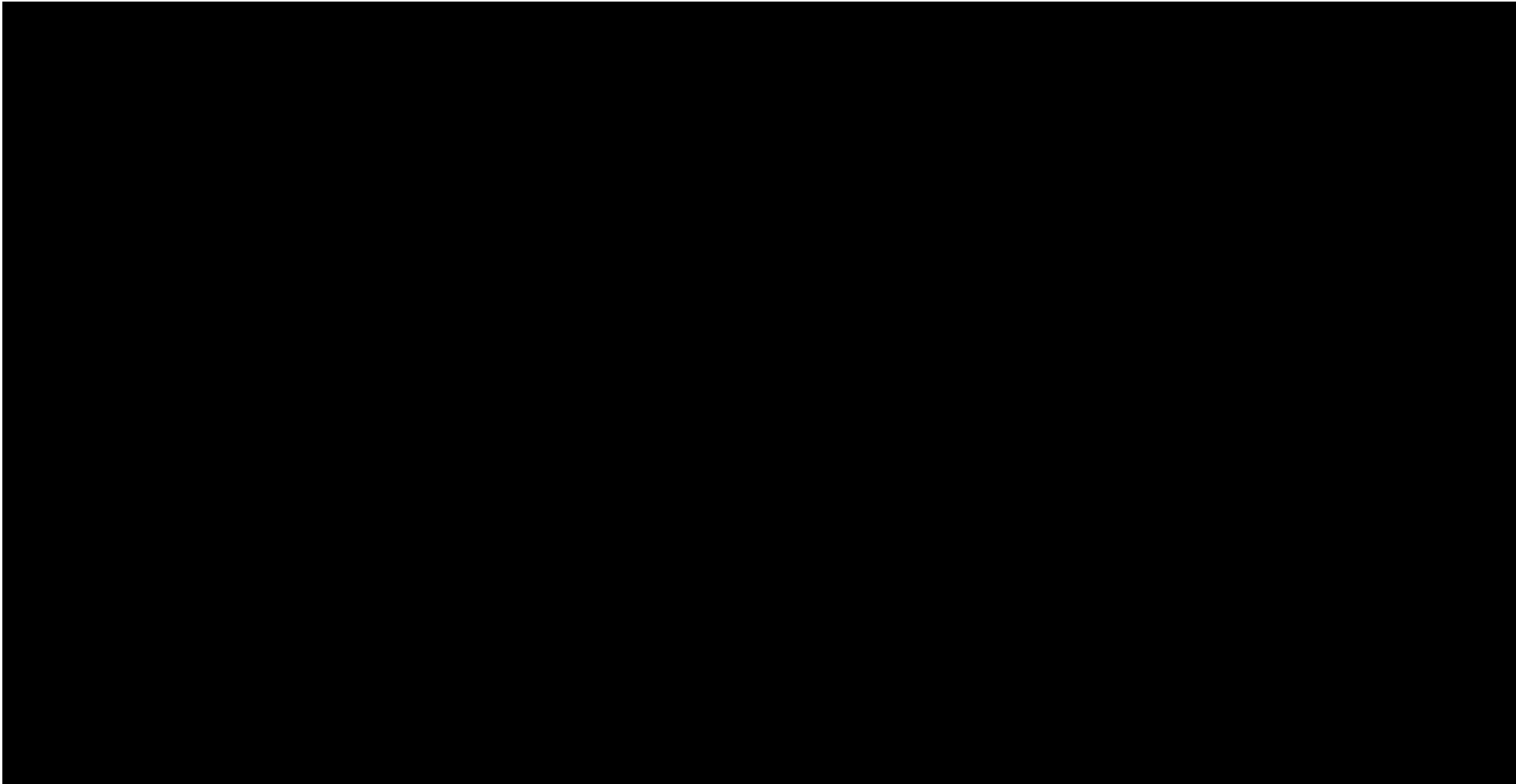
Status:
Page:

Final
1117 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

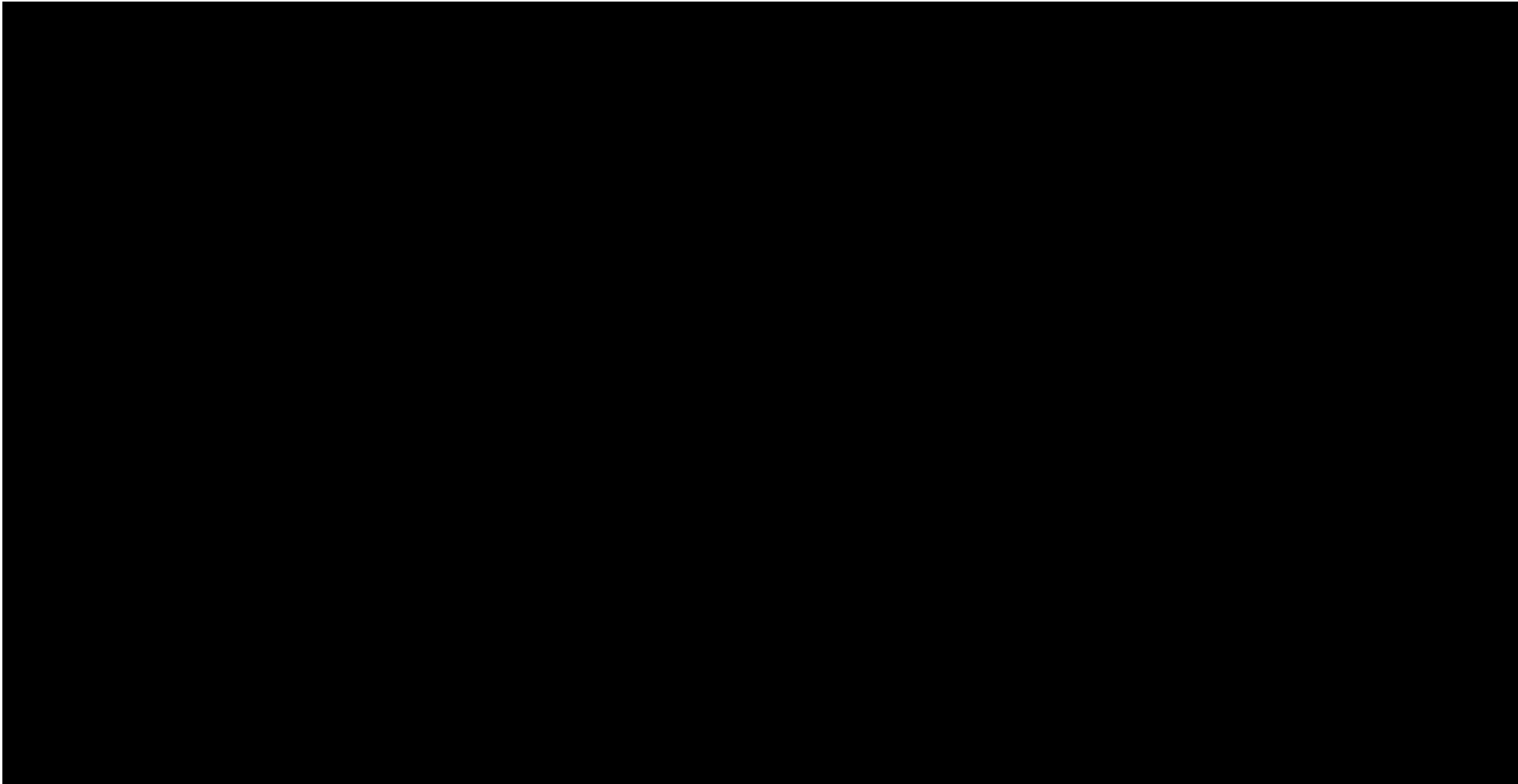
Status:
Page:

Final
1119 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

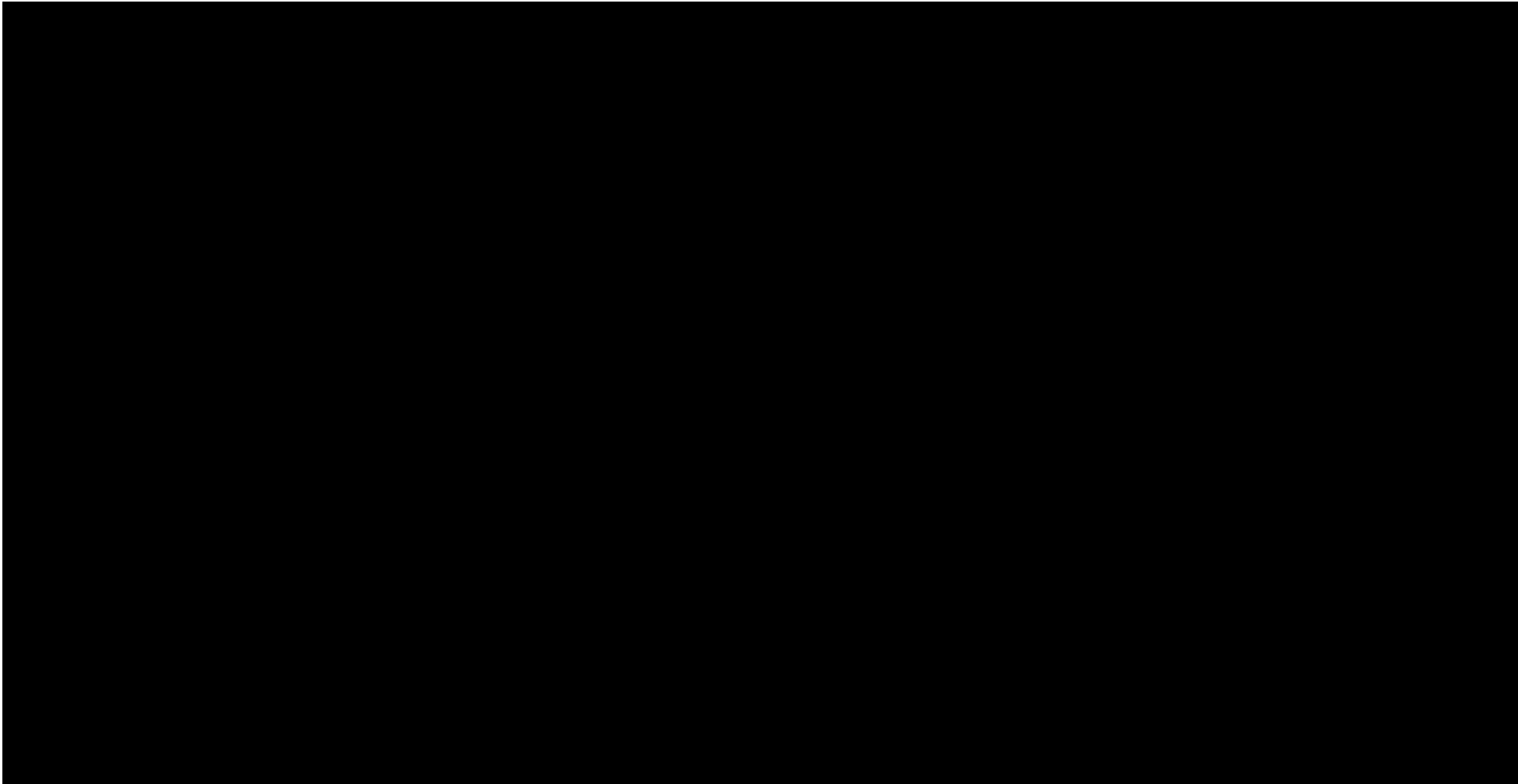
Status:
Page:

Final
1120 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

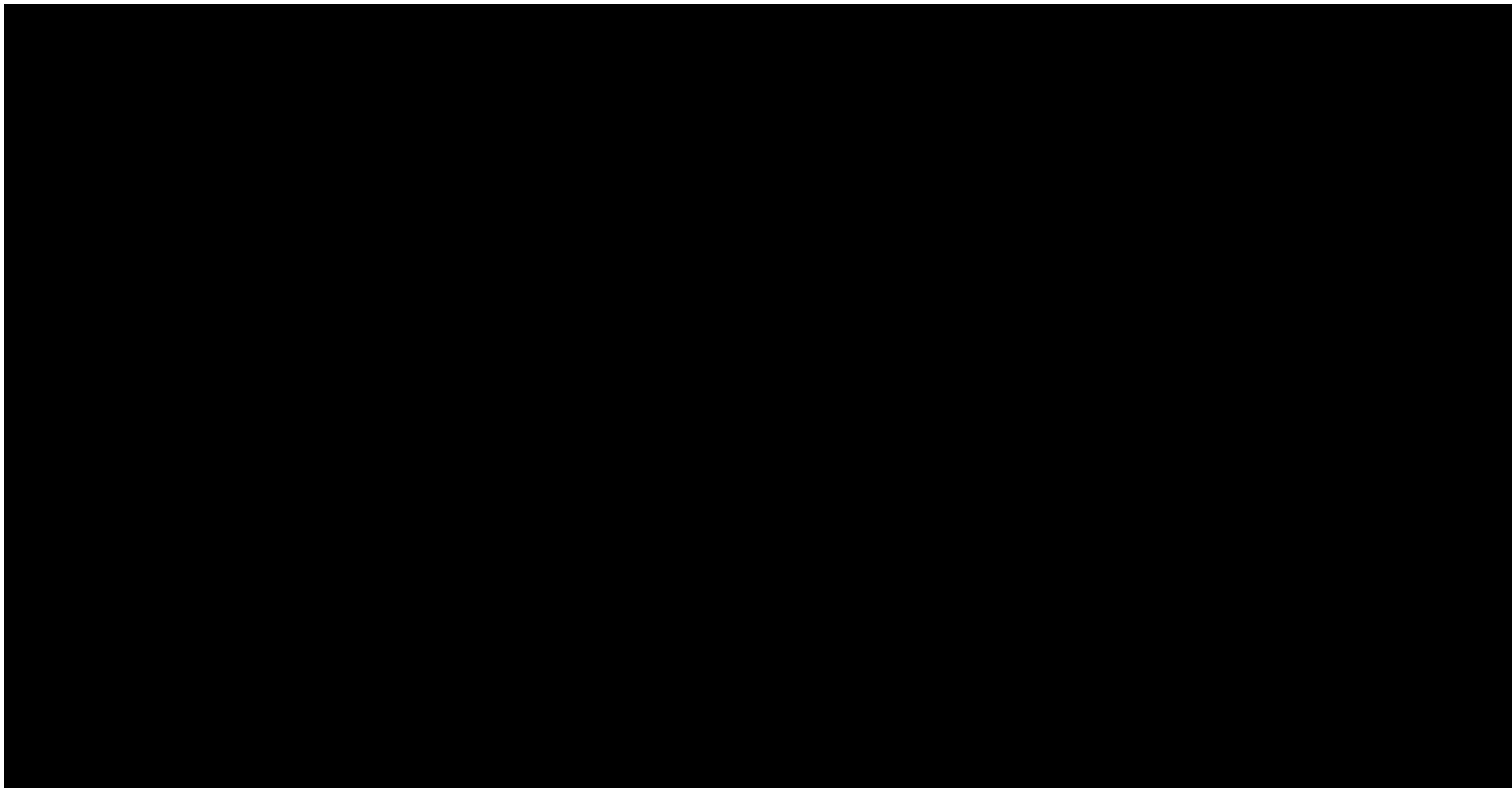
Status:
Page:

Final
1121 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

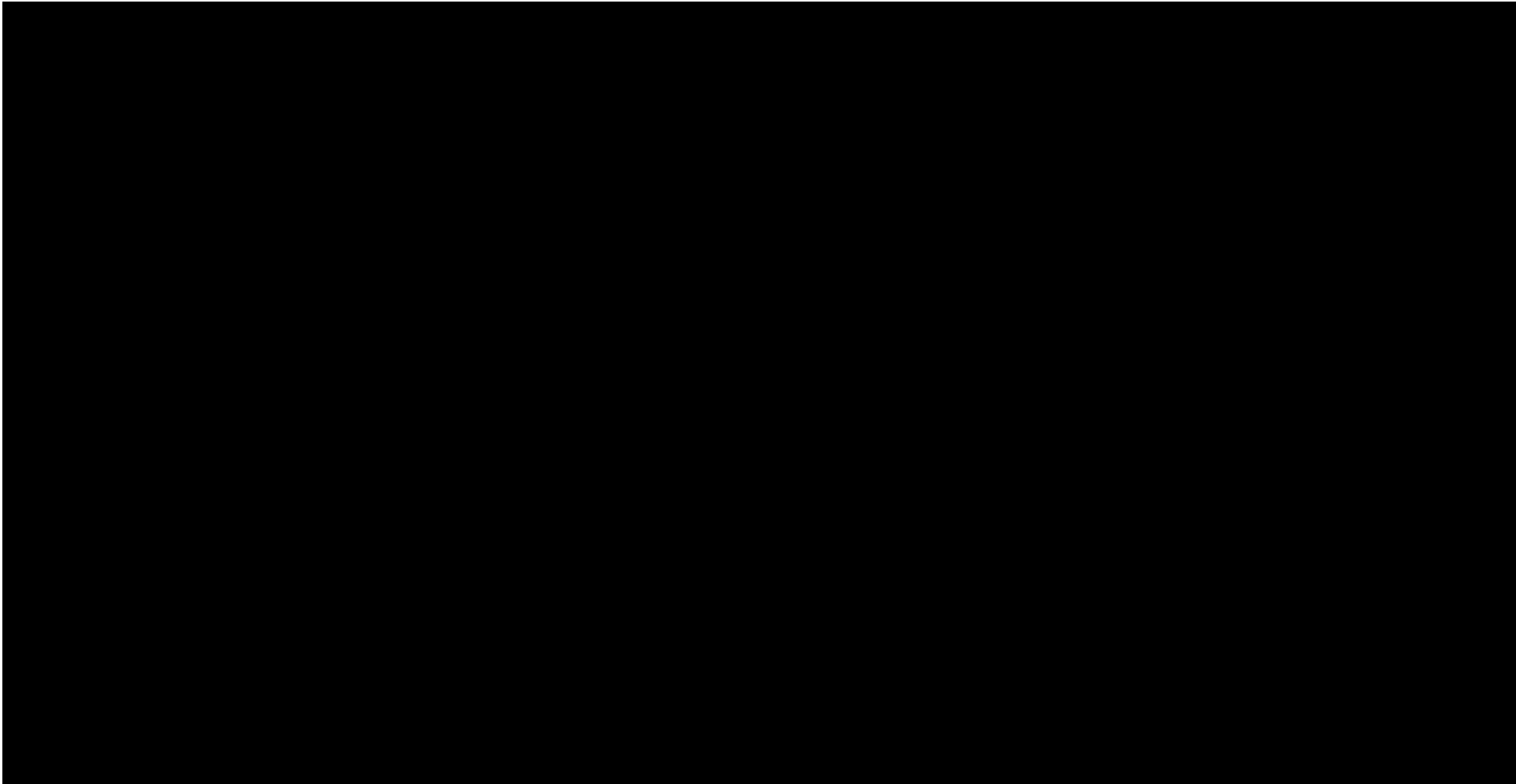
Status:
Page:

Final
1122 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

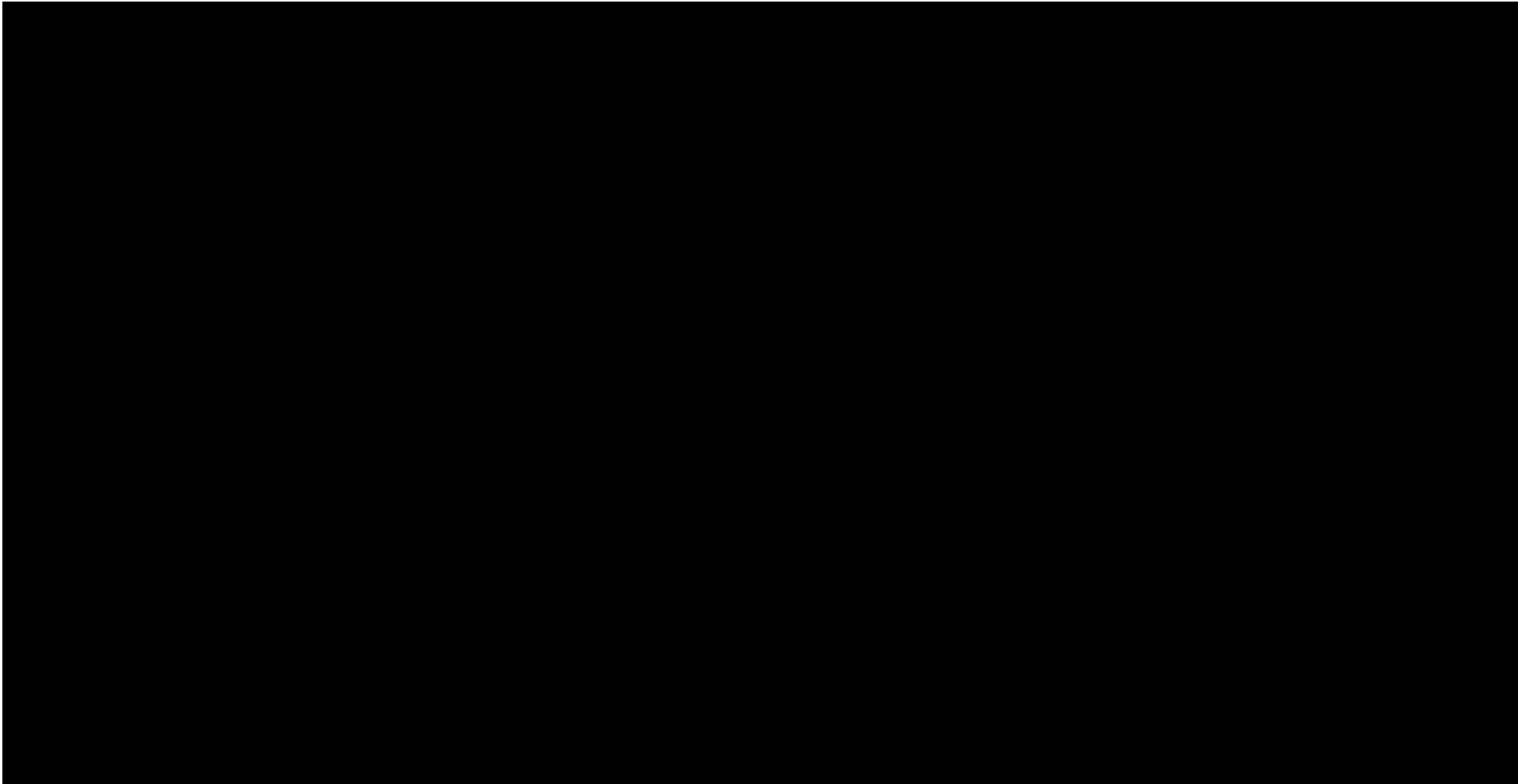
Status:
Page:

Final
1123 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

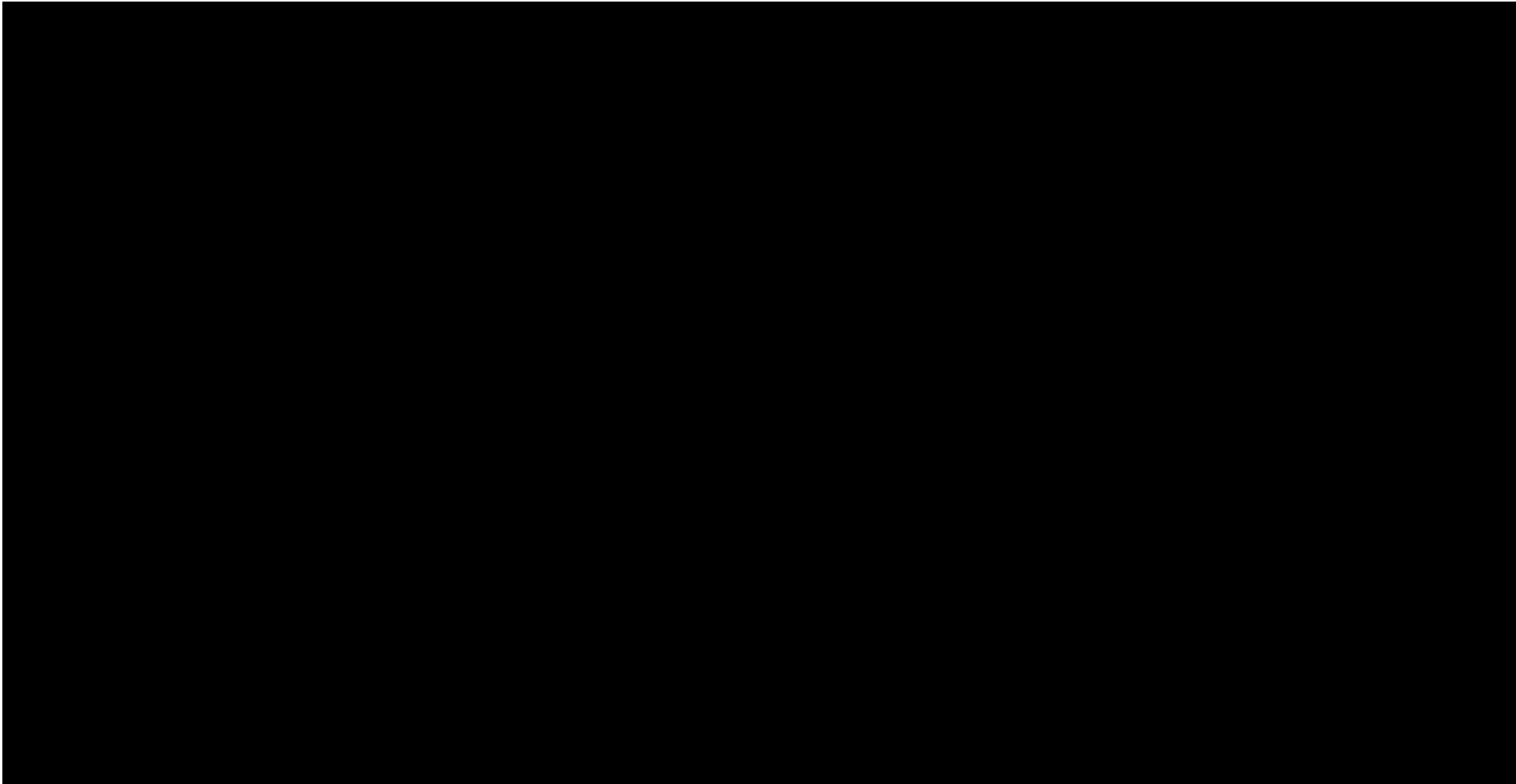
Status:
Page:

Final
1124 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

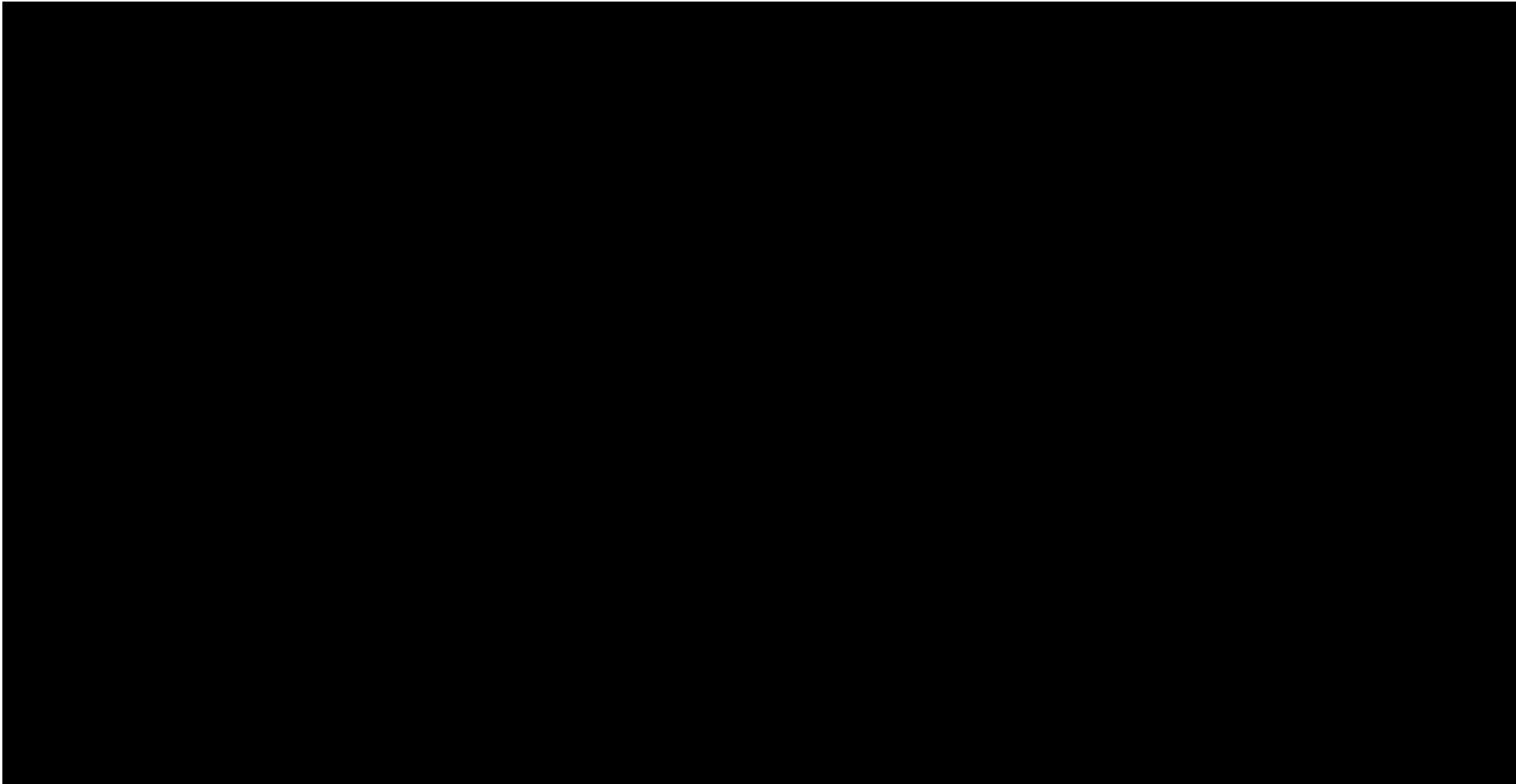
Status:
Page:

Final
1126 of 1733

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	--------	---------



14.3.7.3: Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

14.3.7.4: Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1216 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1217 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1218 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1219 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1221 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

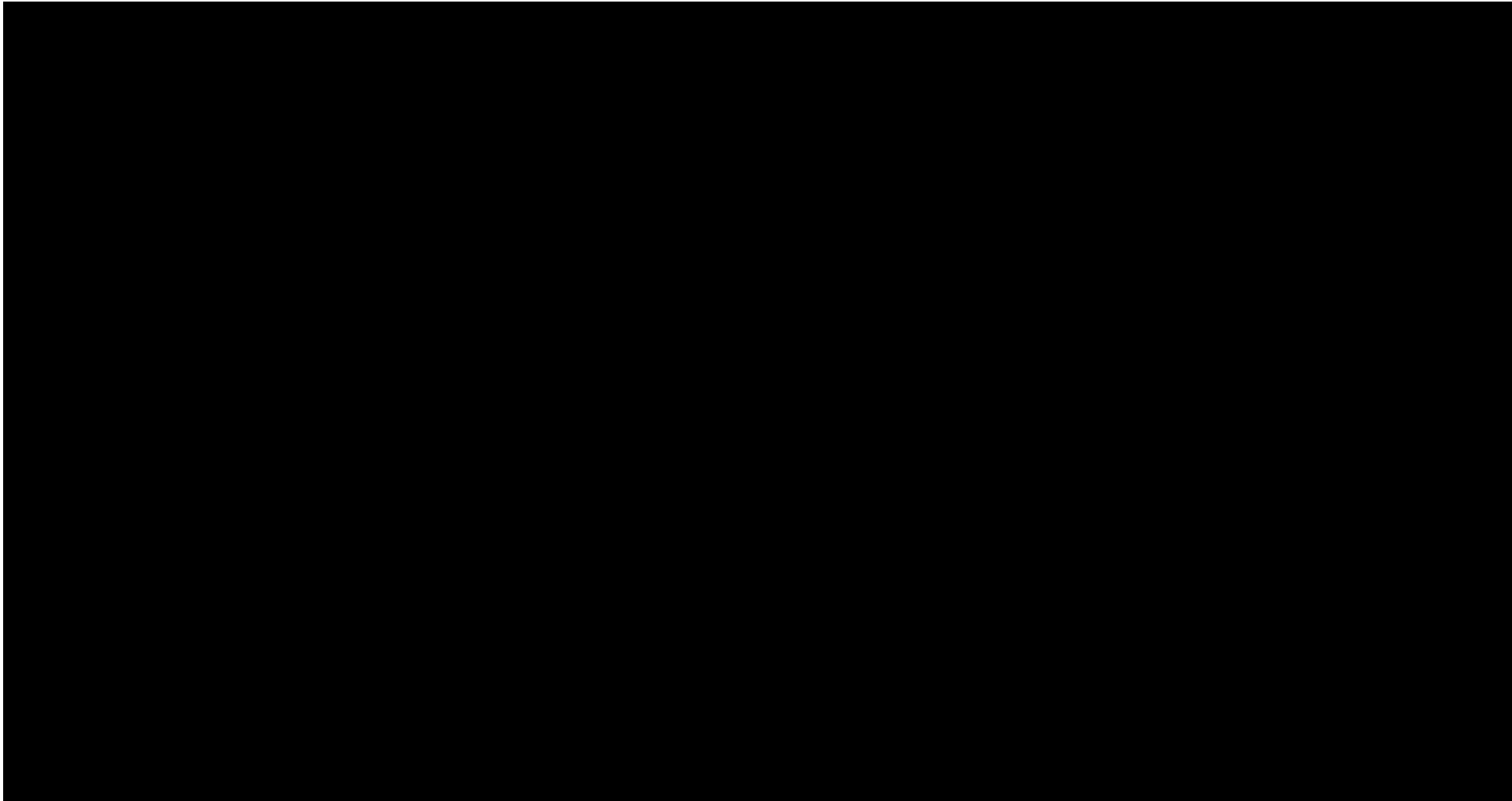
Status:
Page:

Final
1222 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1223 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1225 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1226 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1227 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1228 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

</								

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1232 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1233 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1234 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1237 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

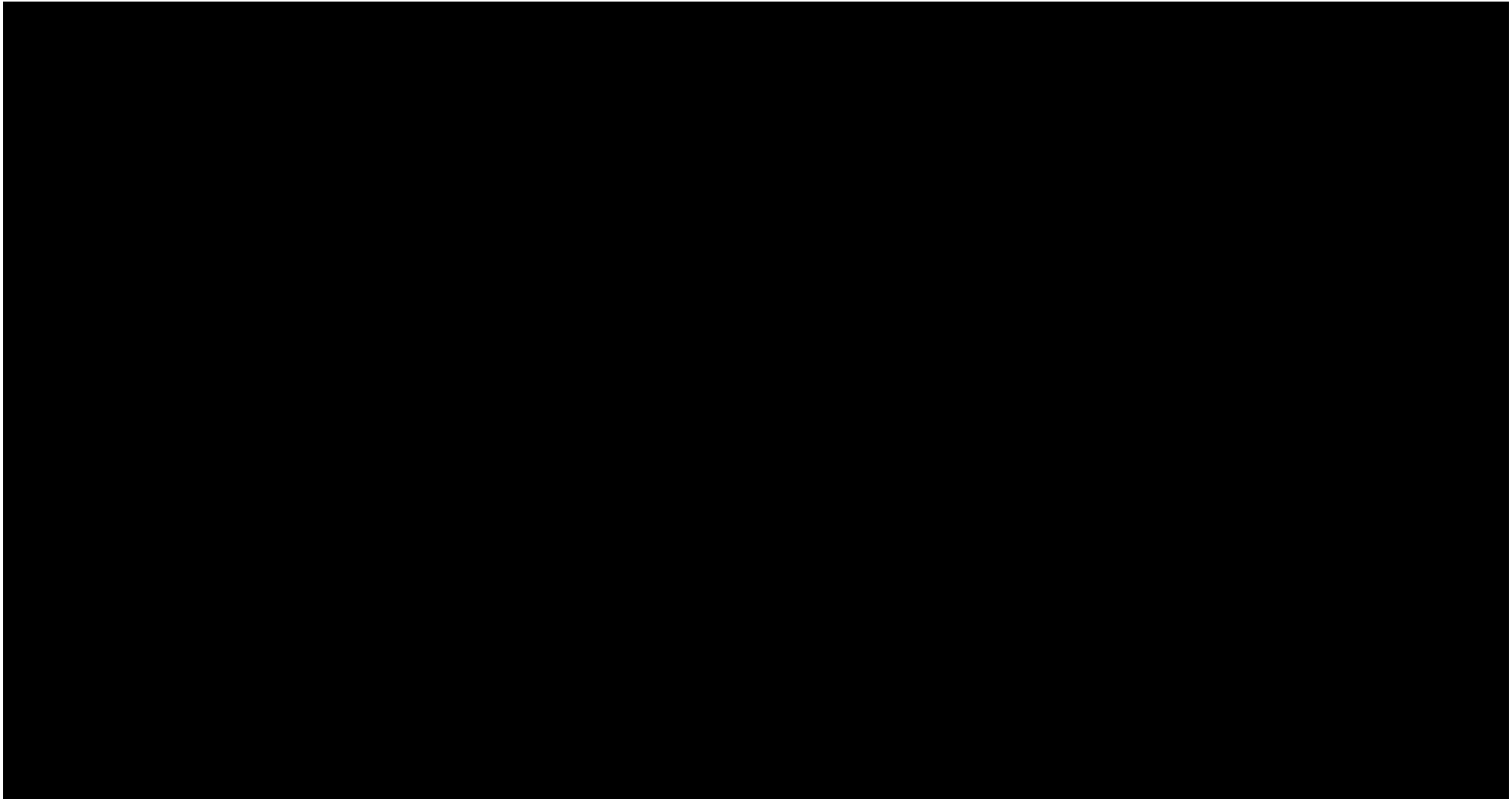
Status:
Page:

Final
1238 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1239 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1240 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1241 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

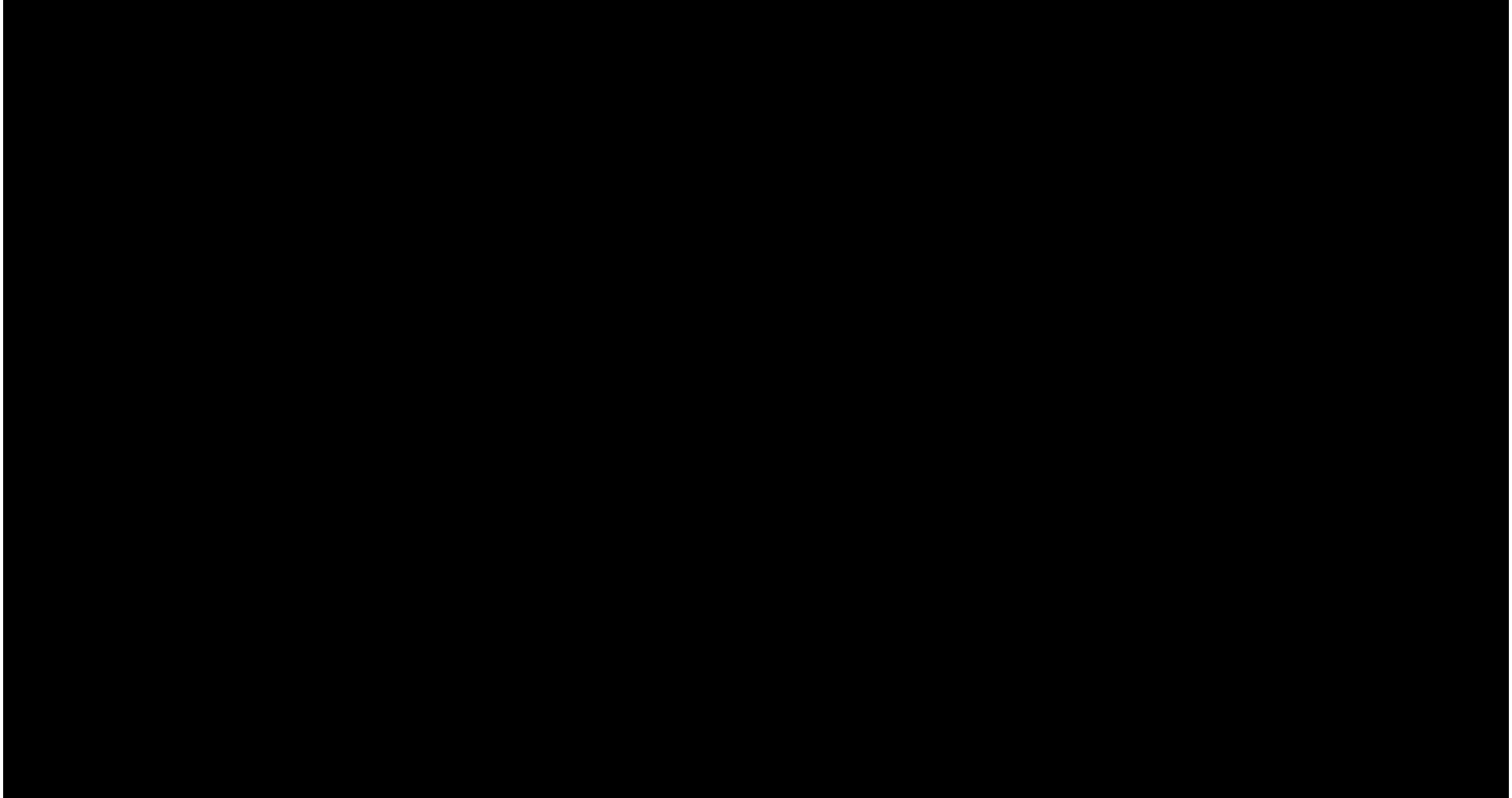
Status:
Page:

Final
1244 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1248 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1250 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1251 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1253 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1255 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1258 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1262 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject
ID

Treatment

Age

Sex

BMI

Parameter

Visit

Value

Unit

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1266 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1267 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1268 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

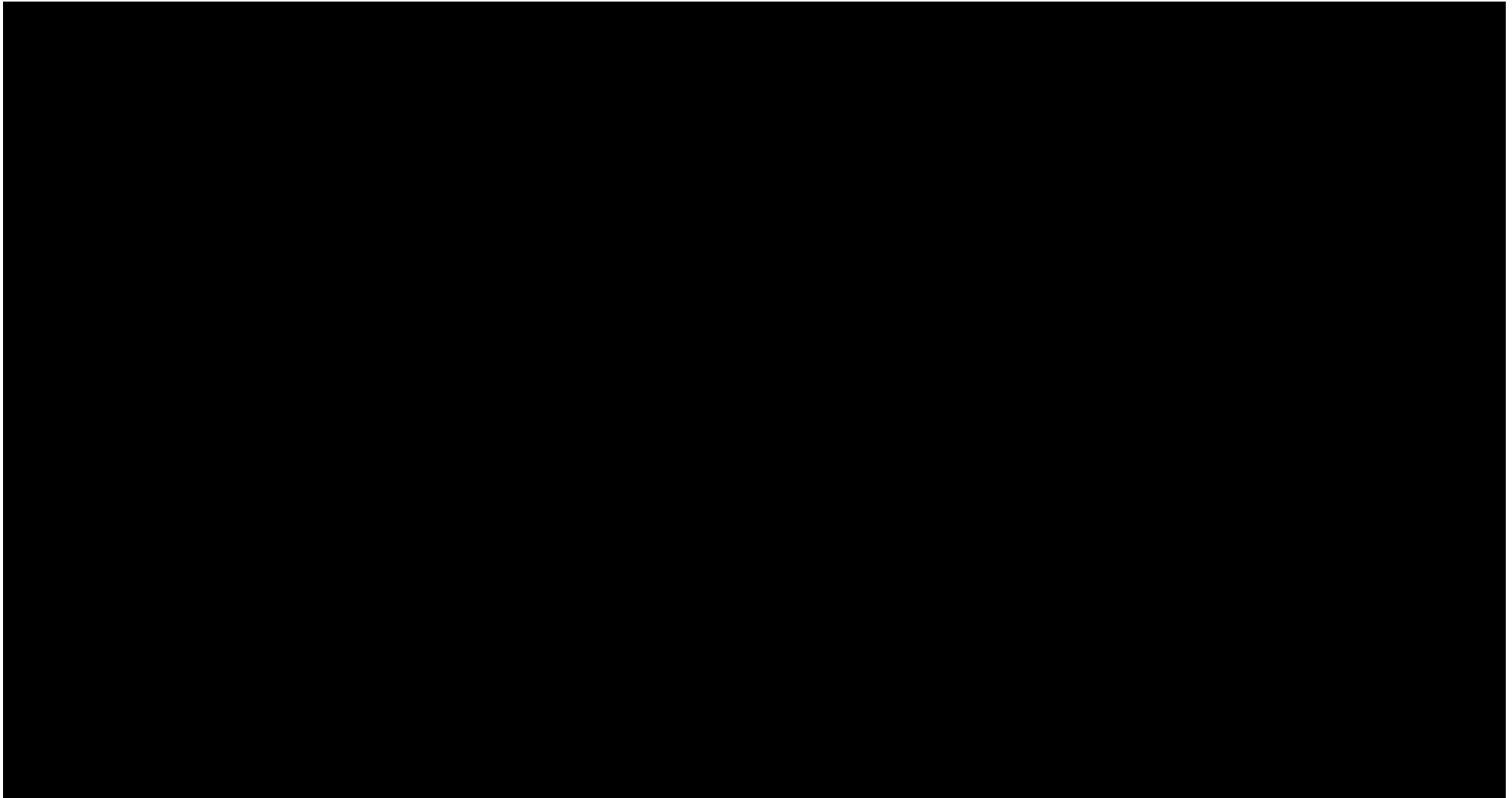
Status:
Page:

Final
1270 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1271 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1272 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1273 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1275 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

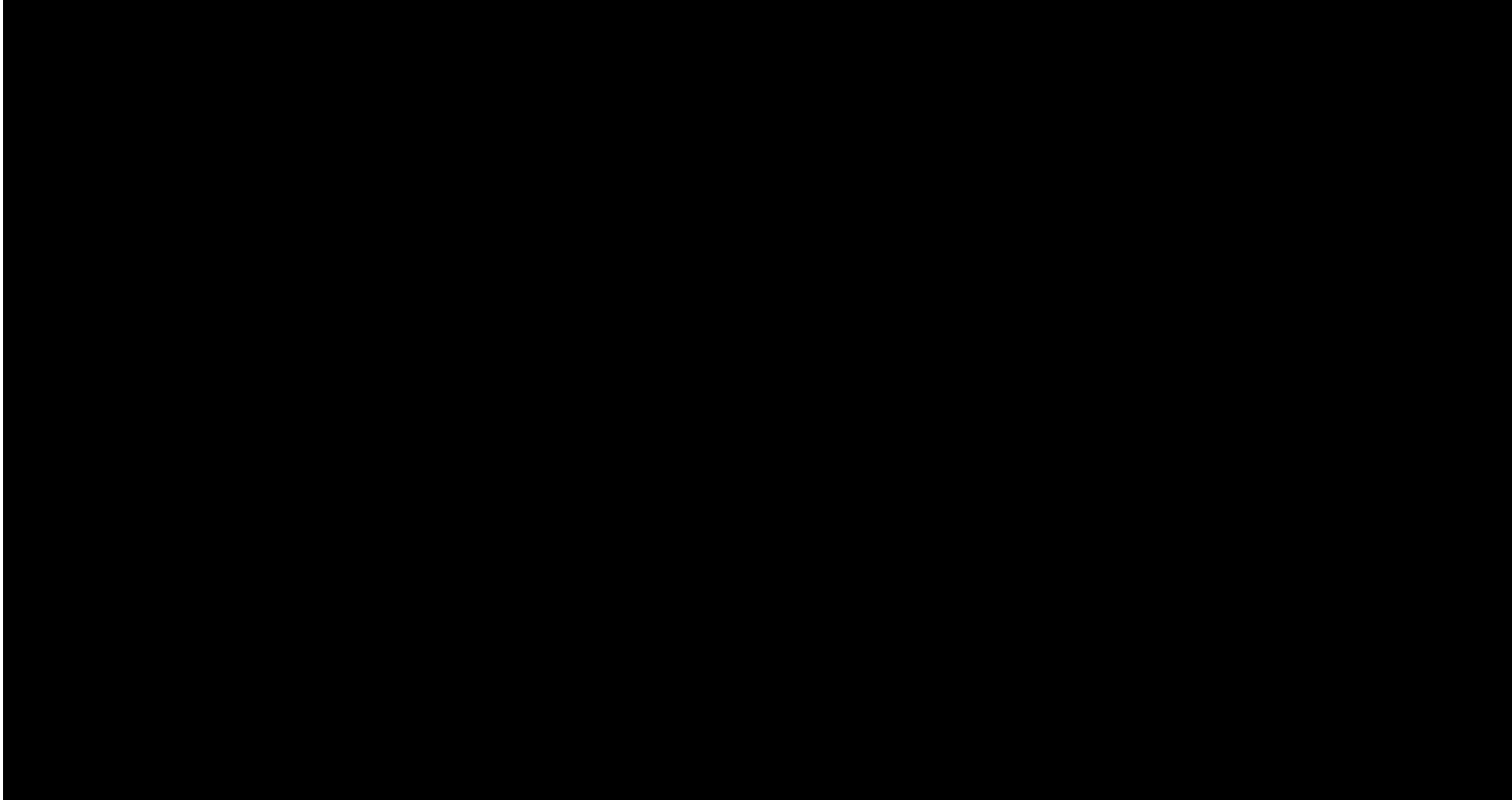
Status:
Page:

Final
1276 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1278 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1280 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1282 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1283 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1284 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1285 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1286 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1291 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1292 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1293 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

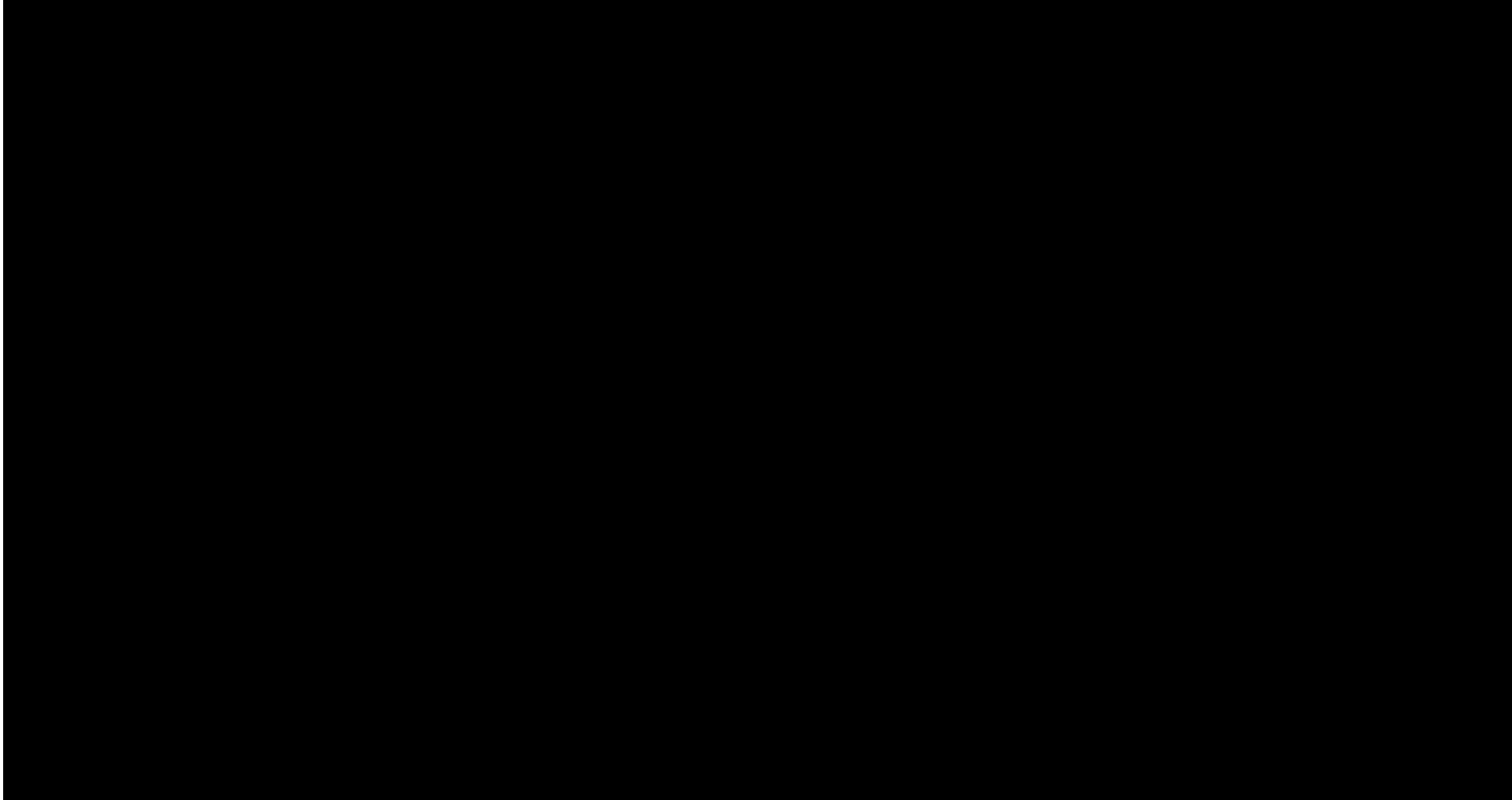
Status:
Page:

Final
1296 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1297 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1298 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1299 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1301 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

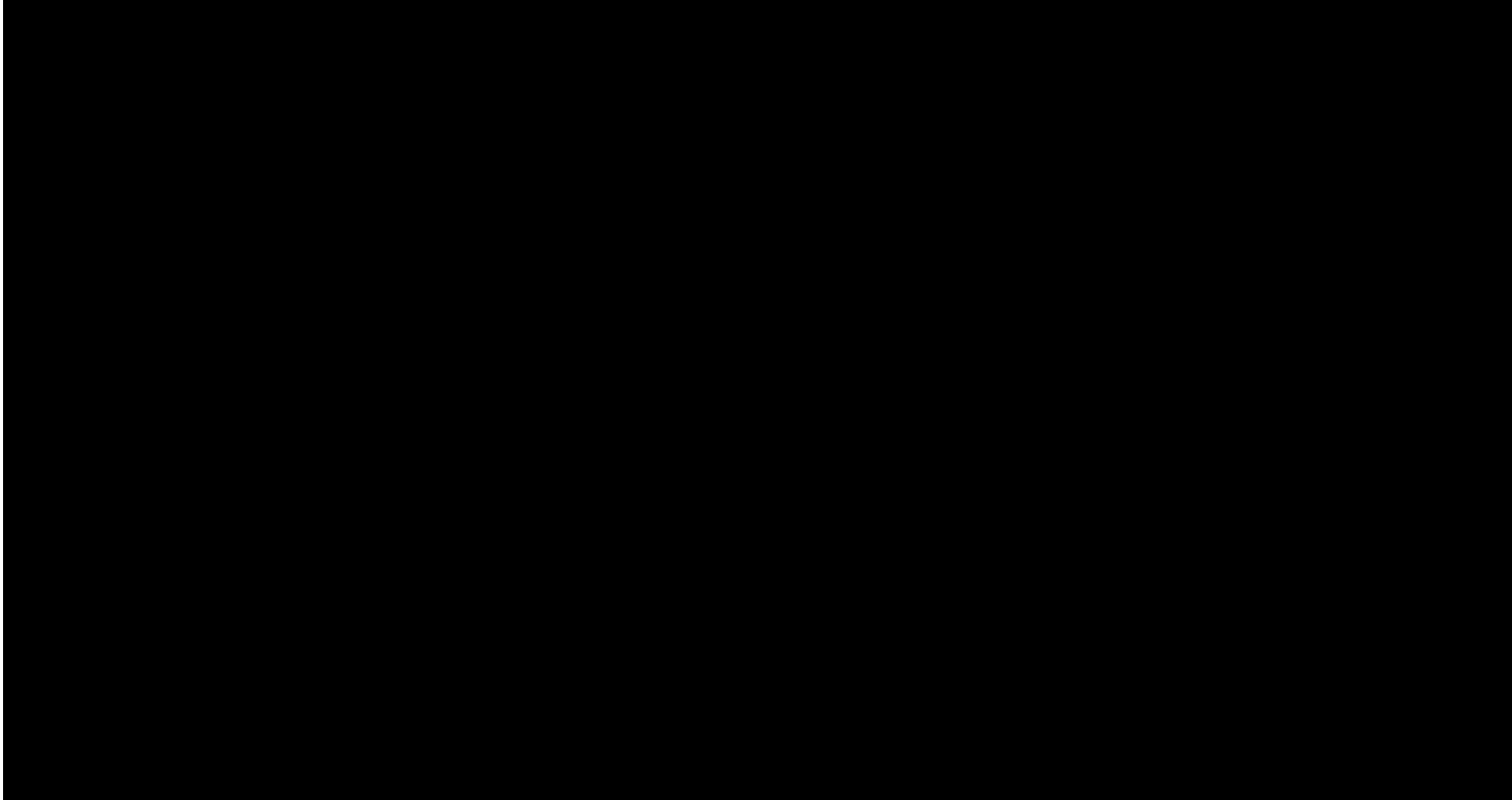
Status:
Page:

Final
1302 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1304 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1307 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1308 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1309 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1311 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1313 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1315 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1316 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1317 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1319 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1320 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1321 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1322 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1323 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1325 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject
ID

Treatment

Age

Sex

BMI

Parameter

Visit

Value

Unit

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1327 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1333 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1334 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1335 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1337 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1338 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1339 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1343 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1345 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1346 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1347 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1348 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1350 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1351 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
 Version:

14 June 2011
3.0

Status:
Page:

Final
1352 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1353 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1354 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

</								

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1356 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1358 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1360 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1362 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1363 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1366 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject
ID

Treatment

Age

Sex

BMI

Parameter

Visit

Value

Unit

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1367 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1370 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1371 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

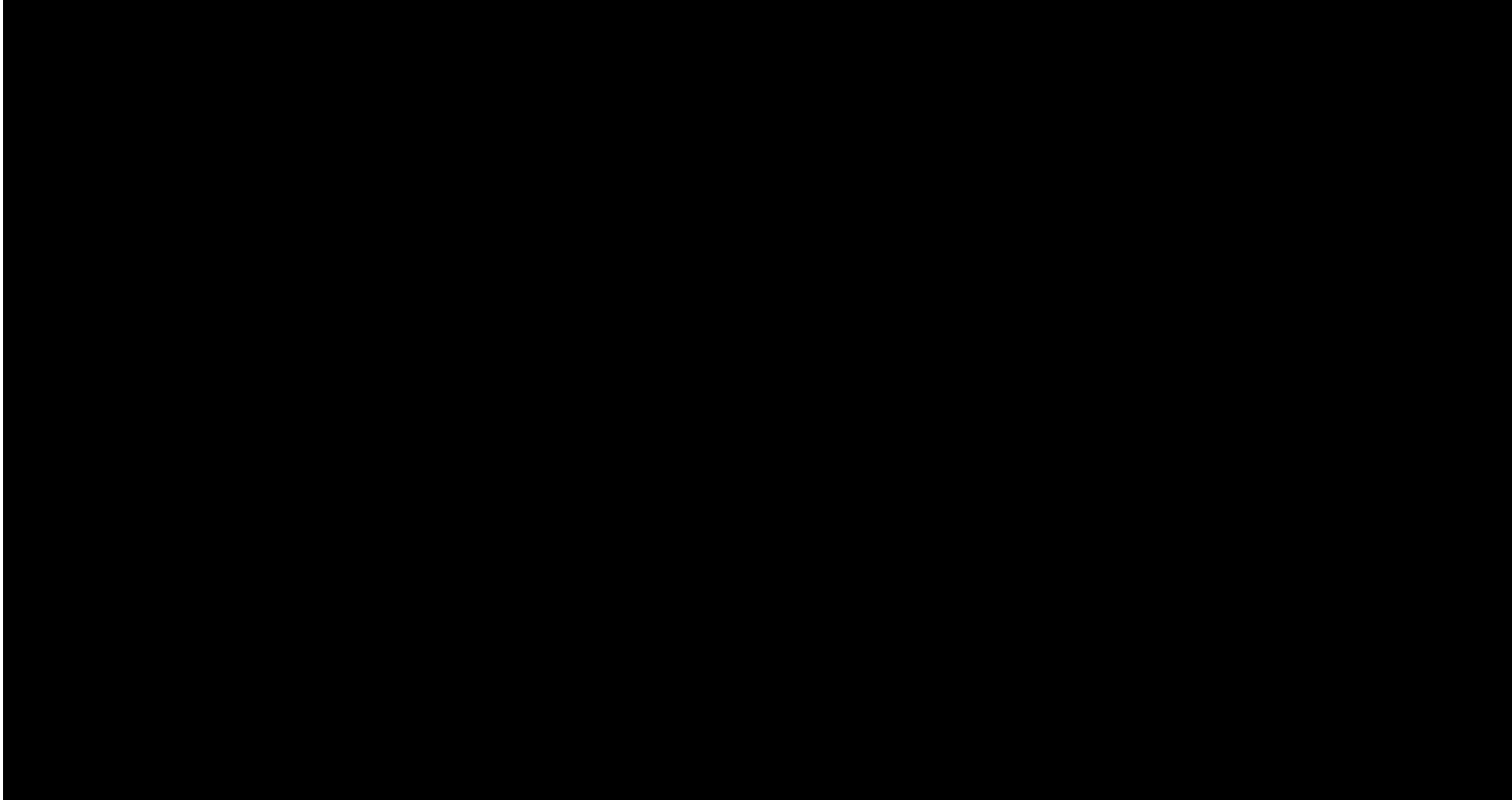
Status:
Page:

Final
1372 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1375 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1376 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1381 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1384 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1385 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1386 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1387 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1389 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1390 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

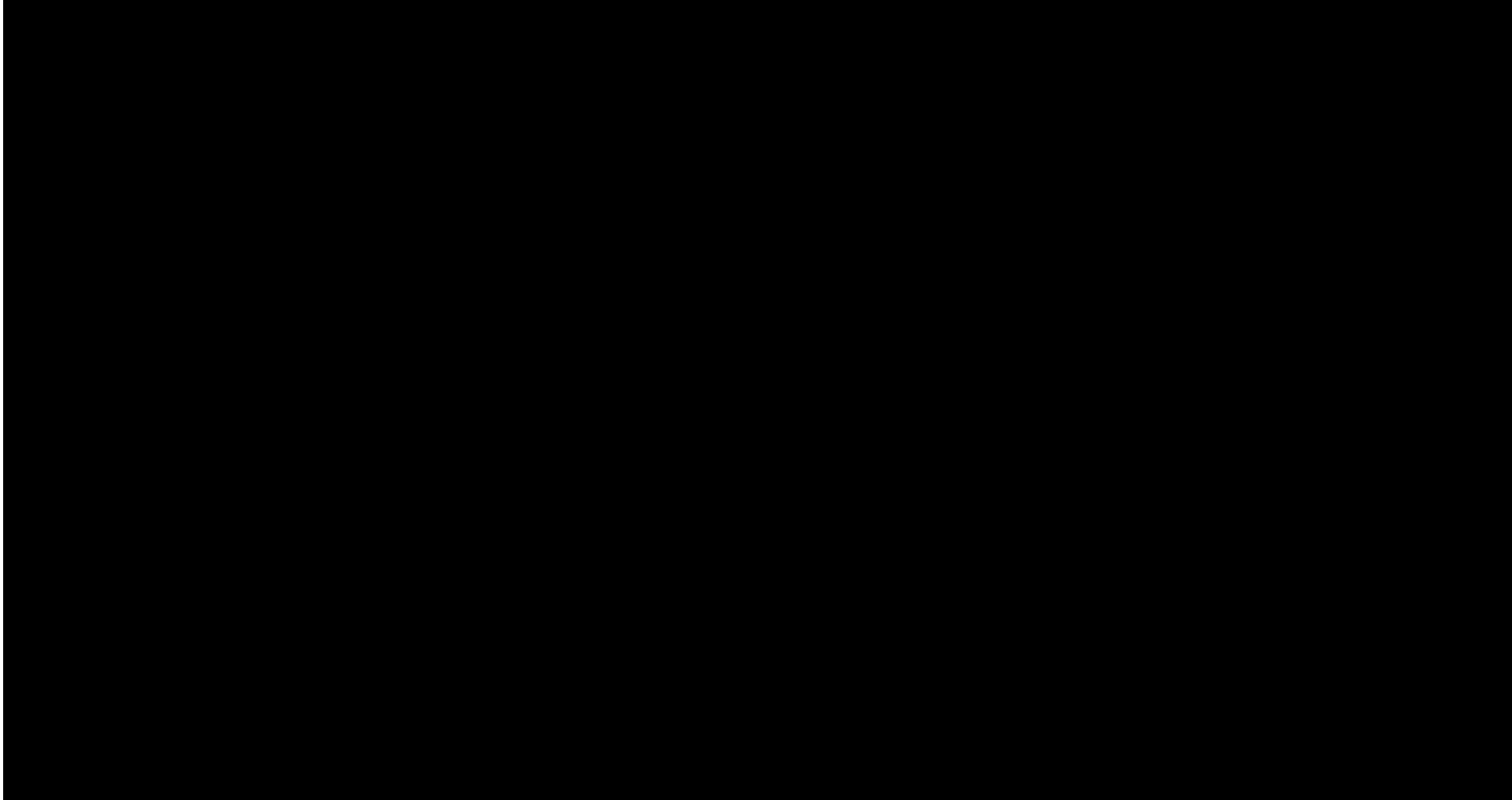
Status:
Page:

Final
1392 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1398 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1399 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1400 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1401 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1402 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1403 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1405 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1407 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1409 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1410 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject
ID

Treatment

Age

Sex

BMI

Parameter

Visit

Value

Unit

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1412 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1413 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

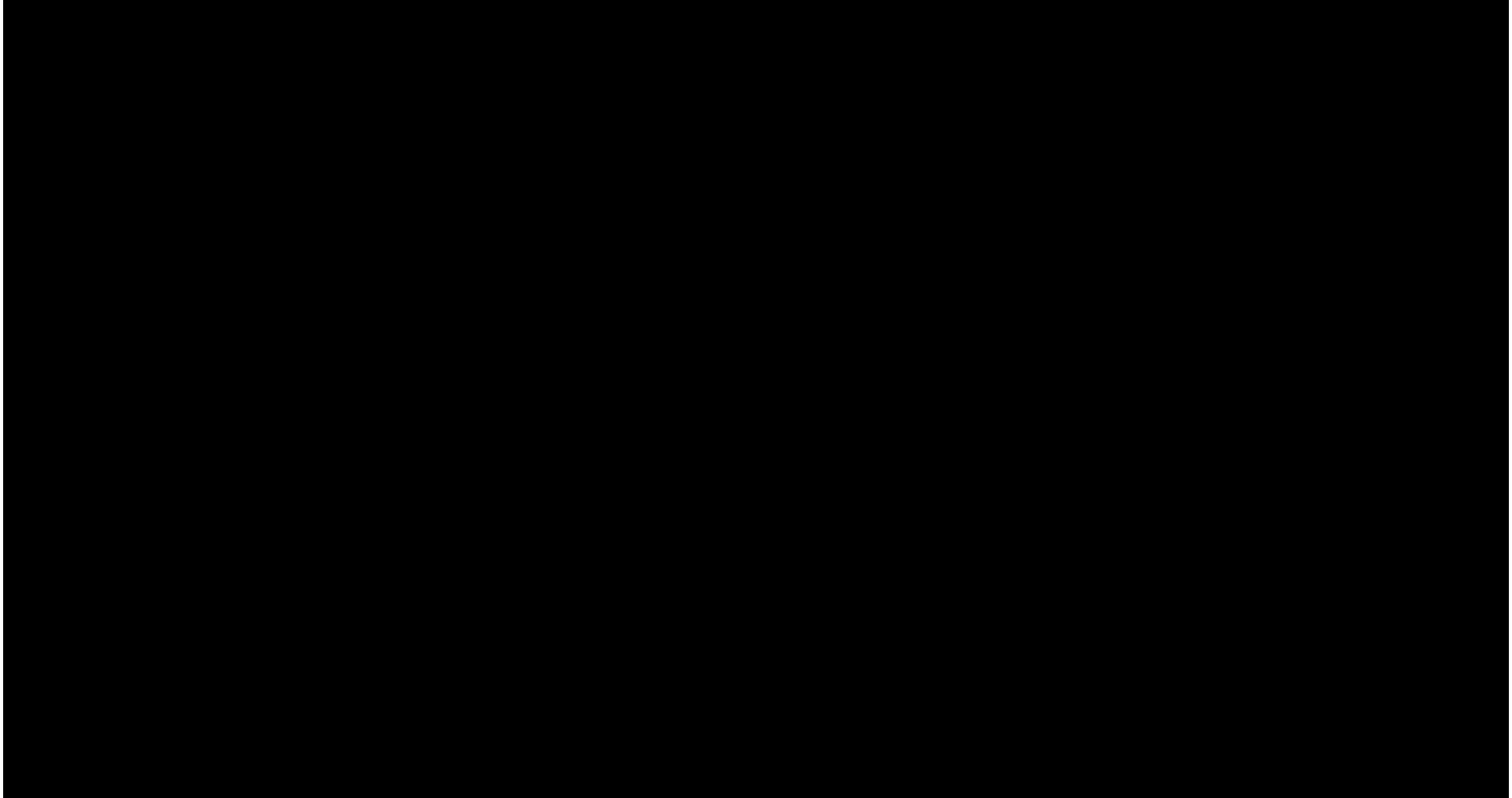
Status:
Page:

Final
1414 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1415 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

</								

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1418 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1419 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1420 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date: _____

Version: _____

14 June 2011
3.0

Status:
Page:

Final
1423 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1425 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

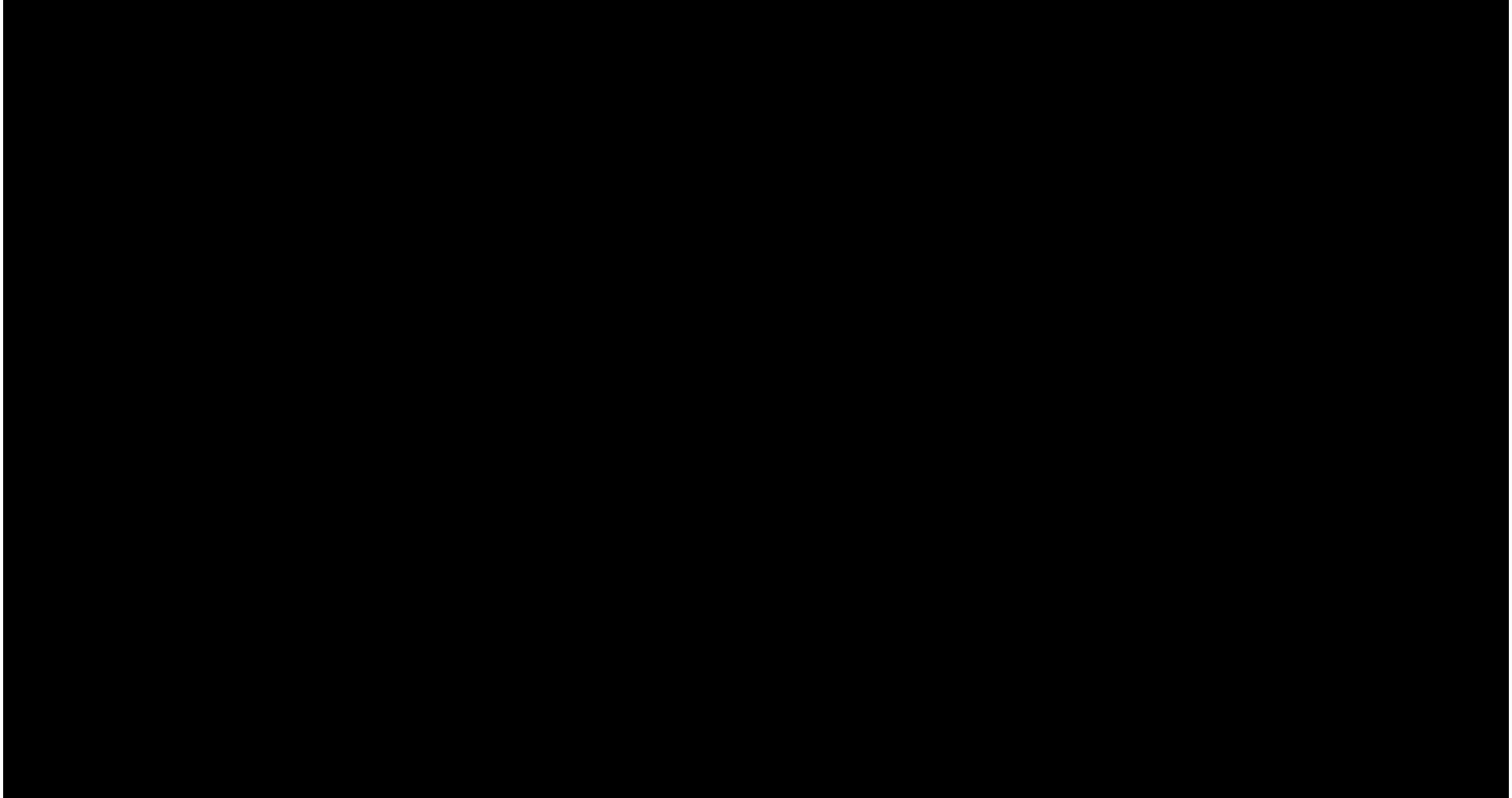
Status:
Page:

Final
1426 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1427 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

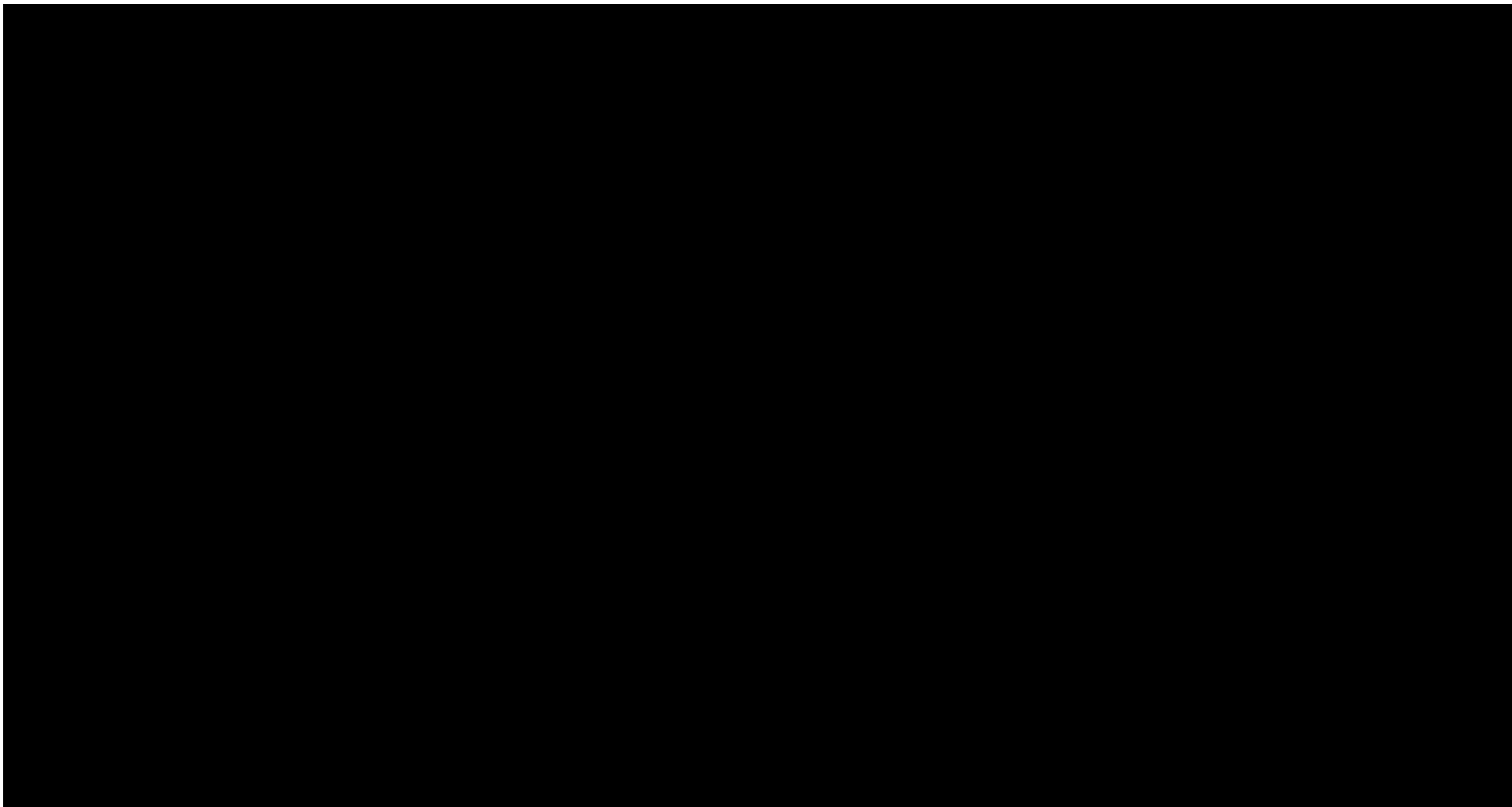
Status:
Page:

Final
1429 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1430 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1431 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1433 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1435 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1436 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1439 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1440 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1442 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1443 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1445 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1447 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1449 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:

Version:

14 June 2011
3.0

Status:
Page:

Final
1450 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1451 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1452 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1453 of 1733

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

14.3.7.5: Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1468 of 1733

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image is a uniform, featureless black rectangle. There are no visible elements, text, or patterns.

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

[illegible]

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

[illegible]

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

[illegible]

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1581 of 1733

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle. There are no discernible features, patterns, or variations in color or texture throughout the entire frame.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

[illegible]

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image is a uniform, featureless black rectangle. There are no visible elements, text, or patterns.

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1634 of 1733

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

[illegible]

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

[illegible]

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

[illegible]

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

[illegible]

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report

Report Body

Date:
Version:

14 June 2011
3.0

Status:
Page:

Final
1665 of 1733

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

[illegible]

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image is entirely black and contains no visible content.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

The image is a uniform, featureless black rectangle. There are no discernible objects, patterns, or textures present.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

14.3.7.6: Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

[illegible]

[illegible]

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

The image is entirely black and contains no visible content.

[illegible]

The image is entirely black and contains no visible content.

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid black color.

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

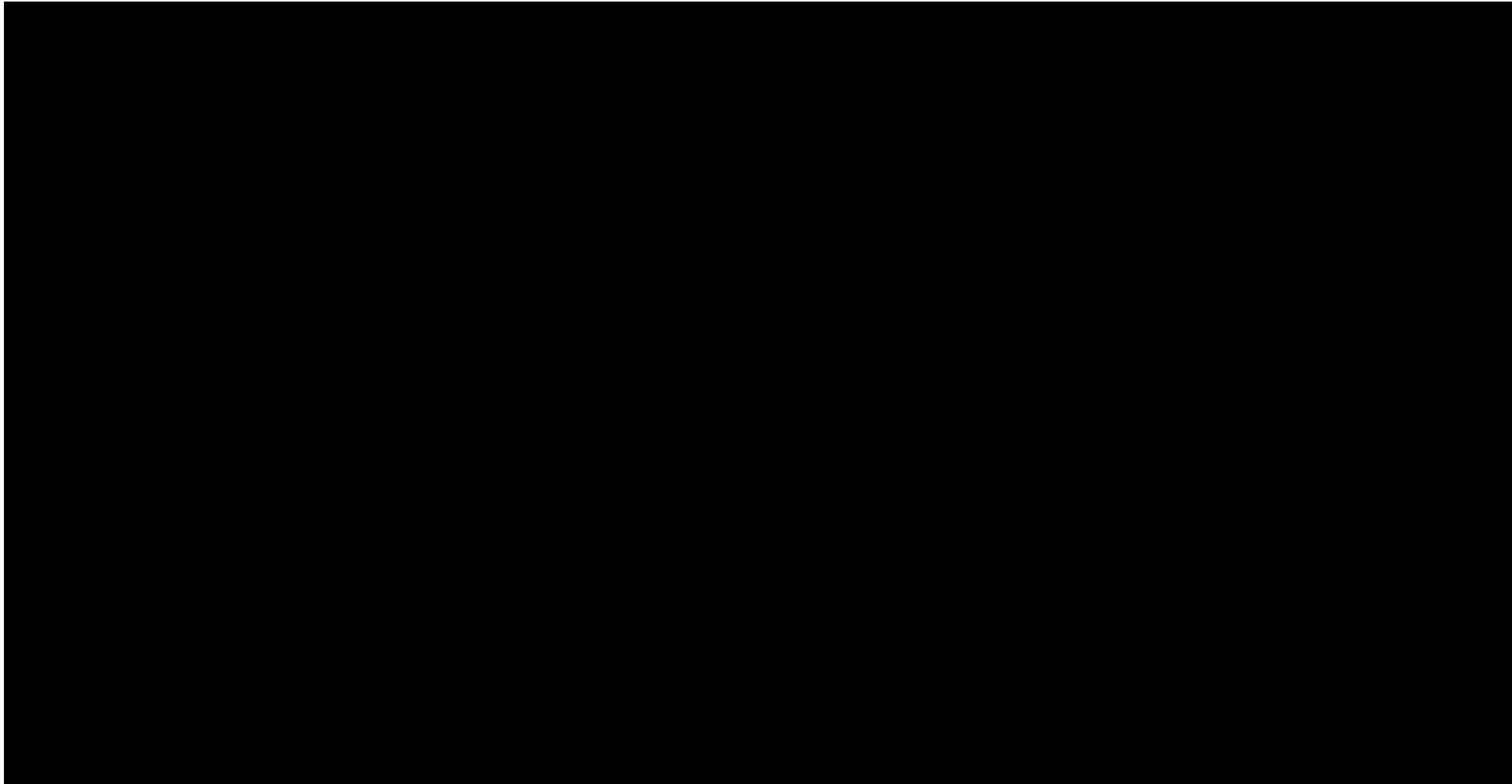
Status:
Page:

Final
1715 of 1733

Novo Nordisk

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m ²)
---------------	-----------	--------------	--------------	-------	---------------	---------------------	-----------------------------



Novo Nordisk

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Novo Nordisk

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid black color.

NN5401 IDegAsp
Trial ID: NN5401-3594

Clinical Trial Report
Report Body

Date:
Version:

14 June 2011
3.0

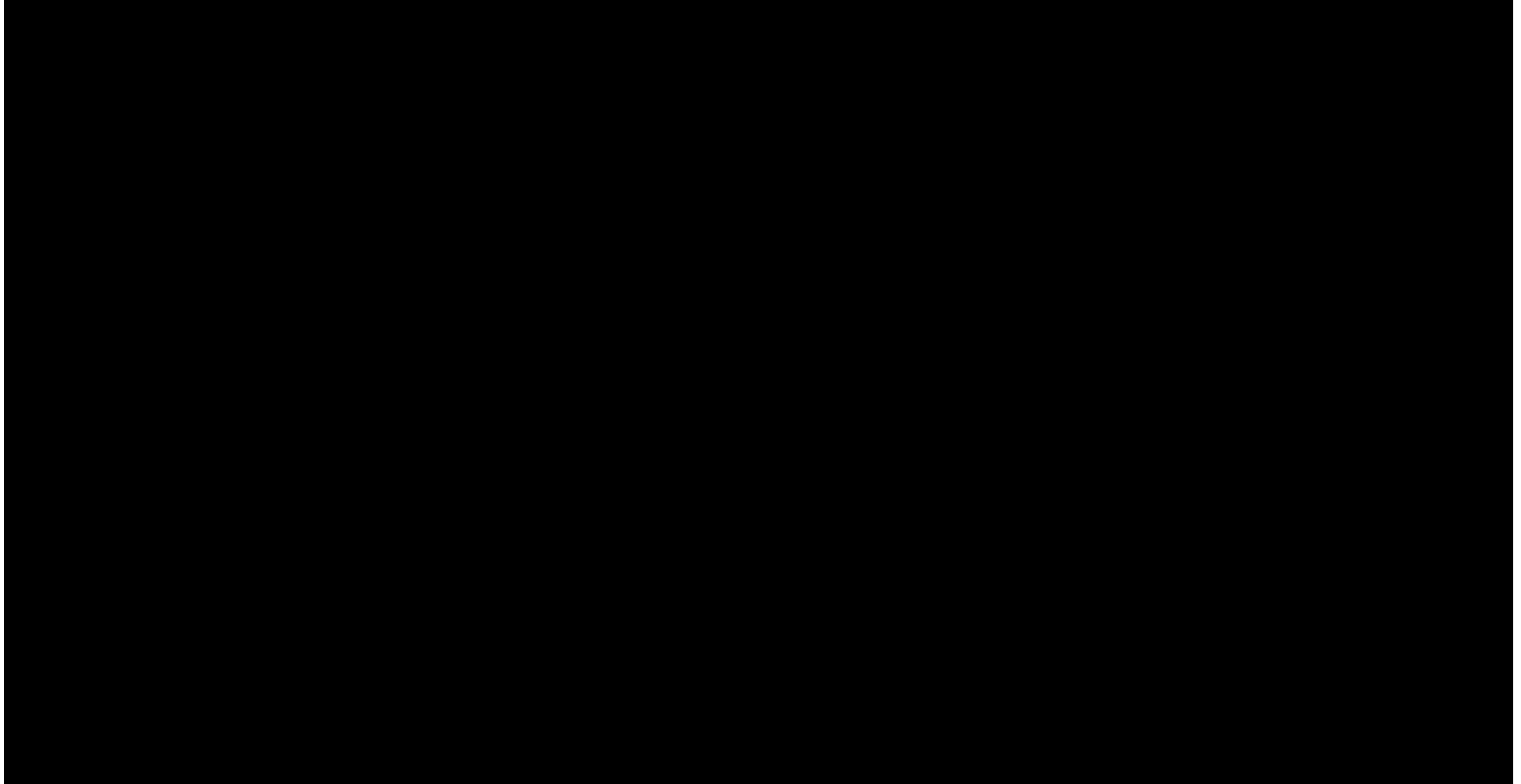
Status:
Page:

Final
1727 of 1733

Novo Nordisk

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m ²)
---------------	-----------	--------------	--------------	-------	---------------	---------------------	-----------------------------



The image is entirely black and contains no visible content.

15 Reference List

- 1 World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects - Last amended by the 59th WMA General Assembly, Seoul 2008.
<http://www.wma.net/en/30publications/10policies/b3/index.html>. 2008.
- 2 ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6 (R1), Step 4.
<http://www.ich.org/LOB/media/MEDIA482.pdf>. 10-Jun-1996.
- 3 The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New Engl J Med* 1993; 329(14):977-986.
- 4 The effect of intensive diabetes treatment on the progression of diabetic retinopathy in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial. *Arch Ophthalmol* 1995; 113:36-51.
- 5 Effect of intensive therapy on the development and progression of diabetic nephropathy in the Diabetes Control and Complications Trial. The Diabetes Control and Complications (DCCT) Research Group. *Kidney Int* 1995; 47(6):1703-1720.
- 6 Effect of intensive diabetes management on macrovascular events and risk factors in the Diabetes Control and Complications Trial. *Am J Cardiol* 1995; 75(14):894-903.
- 7 Nathan DM, Buse JB, Davidson MB, Ferrannini E, Holman RR, Sherwin R et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care* 2009; 32(1):193-203.
- 8 Levemir - U.S. Label Information.
http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021536s015lbl.pdf. 2007.
- 9 Levemir - Summary of Product Characteristics.
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000528/WC500036662.pdf. 2010.
- 10 Lantus - U.S. Label information.
http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021081s034lbl.pdf. 2009.
- 11 Lantus - Summary of Product Characteristics.
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000284/WC500036082.pdf. 2010.
- 12 Novo Nordisk A/S. Investigator's Brochure, SIAC (4th Edition). SIAC. 23-3-2009.
- 13 Heise T, Hermanski L, Nosek L, Feldmann A, Rasmussen S, Stryhn TK et al. Insulin degludec: less pharmacodynamic variability than insulin glargine under steady state conditions. *Diabetologia* 53 (Suppl1), S387. 2010.

- 14 Kurtzhals P, Havelund S, Jonassen I, Kiehr B, Larsen UD, Ribel U et al. Albumin binding of insulins acylated with fatty acids: characterization of the ligand-protein interaction and correlation between binding affinity and timing of the insulin effect in vivo. *Biochem J* 1995; 312(Pt 3):725-731.
- 15 Philis-Tsimikas A, Charpentier G, Clauson P, Ravn GM, Roberts VL, Thorsteinsson B. Comparison of once-daily insulin detemir with NPH insulin added to a regimen of oral antidiabetic drugs in poorly controlled type 2 diabetes. *Clin Ther* 2006; 28(10):1569-1581.
- 16 Heise T, Nosek L, Ronn BB, Endahl L, Heinemann L, Kapitza C et al. Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in people with type 1 diabetes. *Diabetes* 2004; 53(6):1614-1620.
- 17 Bartley PC, Bogoev M, Larsen J, Philotheou A. Long-term efficacy and safety of insulin detemir compared to Neutral Protamine Hagedorn insulin in patients with Type 1 diabetes using a treat-to-target basal-bolus regimen with insulin aspart at meals: a 2-year, randomized, controlled trial. *Diabet Med* 2008; 25(4):442-449.
- 18 Home PD, Lindholm A, Riis A. Insulin aspart vs. human insulin in the management of long-term blood glucose control in Type 1 diabetes mellitus: a randomized controlled trial. *Diabet Med* 2000; 17(11):762-770.
- 19 Lindholm A, McEwen J, Riis AP. Improved postprandial glycemic control with insulin aspart. A randomized double-blind cross-over trial in type 1 diabetes. *Diabetes Care* 1999; 22(5):801-805.
- 20 Raskin P, Guthrie RA, Leiter L, Riis A, Jovanovic L. Use of insulin aspart, a fast-acting insulin analog, as the mealtime insulin in the management of patients with type 1 diabetes. *Diabetes Care* 2000; 23(5):583-588.
- 21 Bretzel RG, Arnolds S, Medding J, Linn T. A direct efficacy and safety comparison of insulin aspart, human soluble insulin, and human premix insulin (70/30) in patients with type 2 diabetes. *Diabetes Care* 2004; 27(5):1023-1027.
- 22 Gallagher A, Home PD. The effect of improved post-prandial blood glucose control on post-prandial metabolism and markers of vascular risk in people with Type 2 diabetes. *Diabetes Res Clin Pract* 2005; 67(3):196-203.
- 23 Perriello G, Pampanelli S, Porcellati F, Avogaro A, Bosi E, Petrella G et al. Insulin aspart improves meal time glycaemic control in patients with Type 2 diabetes: a randomized, stratified, double-blind and cross-over trial. *Diabet Med* 2005; 22(5):606-611.
- 24 NovoRapid - Summary of Product Characteristics.
<http://www.emea.europa.eu/humandocs/Humans/EPAR/novorapid/novorapid.htm>. 23-Apr-2008.
- 25 NovoLog - U.S. Label information.
<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&searchTerm=020986&SearchType=BasicSearch>. 28-Nov-2008.

- 26 Boston MLB&C. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. NYHA - New York Heart Association 1994;(9th Ed.):253-256.
- 27 Brod M, Skovlund SE, Wittrup-Jensen KU. Measuring the impact of diabetes through patient report of treatment satisfaction, productivity and symptom experience. Qual Life Res 2006; 15(3):481-491.
- 28 Turner-Bowker DM, Bartley PJ, Ware JE Jr. SF-36 Health Survey and "SF" Bibliography. Lincoln,RI: QualityMetric, Incorporated 1998;(3rd. Ed).
- 29 Ware JE, Kosinski M, Dewey JE. How to Score Version Two of the SF-36 Health Survey. Lincoln,RI:QualityMetric, Incorporated 2002.
- 30 Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992; 30(6):473-483.
- 31 CCDS Insulatard. Novo Nordisk A/S. 15-Jan-2007.
- 32 CCDS - Levemir. Novo Nordisk A/S. Apr-2008.
- 33 CCDS - NovoRapid. Novo Nordisk A/S. 6-Mar-2008.
- 34 ADA - American Diabetes Association. Defining and reporting hypoglycemia in diabetes: a report from the American Diabetes Association Workgroup on Hypoglycemia. Diabetes Care 2005; 28(5):1245-1249.
- 35 EMEA-Committee for Proprietary Medicinal Products. EMEA/CPMP/EWP/1080/00 - Note for guidance on clinical investigations of medicinal products in the treatment of diabetes mellitus. 2002.
- 36 Food and Drug Administration, Code of Federal Regulations, Guidance for Industry, Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention. Draft Guidance. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071624.pdf>. Feb-2008.
- 37 CPMP/EWP/482/99 - Points to consider on switching between superiority and non-inferiority. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003658.pdf. 27-Feb-2000.
- 38 ICH Harmonised Tripartite Guideline. Statistical principles for clinical trials E9. International Conference on Harmonisation E9 Expert Working Group. <http://www.ich.org/LOB/media/MEDIA485.pdf>. 5-Feb-1998.
- 39 Rubin D.B. Inference and missing data. Biometrika 1976; 63(3):581-592.
- 40 Heller S, Koenen C, Bode B. Comparison of insulin detemir and insulin glargine in a basal-bolus regimen, with insulin aspart as the mealtime insulin, in patients with type 1 diabetes: a 52-week, multinational, randomized, open-label, parallel-group, treat-to-target noninferiority trial. Clin Ther 2009; 31(10):2086-2097.

Clinical Trial Report

Trial ID: NN5401-3645

BOOST™: T1

An Extension Trial Comparing Safety and Efficacy of NN5401 Plus Meal-time Insulin Aspart for the Remaining Meals with Insulin Detemir Plus Meal-time Insulin Aspart in Type 1 Diabetes

A 26-week, multinational, multi-centre, open-labelled, two-arm, parallel, treat-to-target extension trial comparing safety and efficacy of NN5401 once daily (OD) plus meal-time insulin aspart for the remaining meals vs. basal-bolus treatment with insulin detemir plus meal-time insulin aspart in subjects with type 1 diabetes

This report contains the results after 52 weeks treatment (26 weeks in the main trial NN5401-3594 and 26 weeks in the present extension trial NN5401-3645)

~~This confidential document is the property of Novo Nordisk. No unpublished information contained herein may be disclosed without prior written approval from Novo Nordisk. Access to this document must be restricted to relevant parties.~~

1 Title Page

Title of Trial	A 26-week, multinational, multi-centre, open-labelled, two-arm, parallel, treat-to-target extension trial comparing safety and efficacy of NN5401 once daily (OD) plus meal-time insulin aspart for the remaining meals vs. basal-bolus treatment with insulin detemir plus meal-time insulin aspart in subjects with type 1 diabetes
Trial ID	NN5401-3645
Development Phase	Phase 3a
Trial Registration ID no.	NCT01087606
IND Number (US only)	IND 73,198
EudraCT Number	2009-013412-13
Japanese Trial Number	Not Applicable
Generic Name	Insulin degludec/insulin aspart (IDegAsp)
Indication	Diabetes mellitus
Investigator(s)	There were 71 principal investigators. [REDACTED] MD was appointed signatory investigator: [REDACTED]
Trial Site(s)	The trial was conducted at 71 sites in 9 countries: Denmark (3 sites), Poland (6 sites), Romania (7 sites), France (2 sites), United Kingdom (6 sites), Russian Federation (10 sites), Israel (4 sites), Australia (7 sites), and United States (26 sites)
Trial Initiated	15 March 2010
Trial Completed	02 December 2010
Sponsor	Novo Nordisk A/S, Denmark
International Medical Directors	[REDACTED] Novo Nordisk A/S [REDACTED] Novo Nordisk A/S, [REDACTED] Novo Nordisk Inc.
International Trial Manager	[REDACTED] Novo Nordisk A/S
Local Trial Manager(s)	FR: [REDACTED] PL: [REDACTED], AU: [REDACTED], DK: [REDACTED] [REDACTED], RU: [REDACTED], UK: [REDACTED], IL: [REDACTED] [REDACTED], US: [REDACTED], RO: [REDACTED], all Novo Nordisk A/S
Trial Statistician	[REDACTED] Novo Nordisk A/S
Trial Medical Writer	[REDACTED] Novo Nordisk A/S
Report Date(s)	03 June 2011

The trial was conducted in accordance with the Declaration of Helsinki¹ and ICH Good Clinical Practice²

2 Synopsis

Please refer to separate document.

3 Table of Contents for the Individual Clinical Study

	Page
1 Title Page.....	2
2 Synopsis	3
3 Table of Contents for the Individual Clinical Study Report	4
4 List of Abbreviations and Definition of Terms	27
5 Ethics	30
5.1 Independent Ethics Committee (IEC) or Institutional Review Board (IRB)	30
5.2 Ethical Conduct of the Trial.....	30
5.3 Subject Information and Consent.....	30
6 Investigators and Trial Administrative Structure.....	31
7 Introduction	35
7.1 Therapeutic area.....	35
7.2 IDegAsp	35
7.3 IDet	36
7.4 IAsp.....	36
7.5 Rationale for the Trial.....	37
8 Trial Objectives	38
9 Investigational Plan	39
9.1 Overall Trial Design and Plan: Description.....	39
9.2 Discussion of Trial Design, Including the Choice of Control Groups	41
9.3 Selection of Trial Population	42
9.3.1 Inclusion Criteria	42
Inclusion Criteria in the Main Trial	42
Inclusion Criteria in the Extension Trial.....	43
Rationale for Inclusion Criteria in the Extension Trial.....	43
9.3.2 Exclusion Criteria	43
Exclusion Criteria in the Main Trial	43
Exclusion Criteria in the Extension Trial.....	45
Rationale for Exclusion Criteria in the Extension Trial.....	46
9.3.3 Removal of Subjects from Therapy and Assessment	46
9.4 Treatments.....	48
9.4.1 Treatments Administered	48
9.4.2 Identity of Investigational Products.....	49
9.4.3 Method of Assigning Subjects to Treatment Groups	50
9.4.4 Selection of Doses in the Trial	51
9.4.5 Selection and Timing of Dose for Each Subject.....	52
Titration of Basal Insulin (IDegAsp or IDet).....	52
Titration of second dose of IDet (Morning dose)	53
Titration of Bolus Insulin (IAsp)	54
9.4.6 Blinding	55
9.4.7 Prior and Concomitant Therapy	55
9.4.8 Treatment Compliance	56

9.5 Efficacy and Safety Variables.....	56
9.5.1 Efficacy and Safety Measurements Assessed and Flow Chart.....	56
9.5.1.1 Flow Chart	56
9.5.1.2 Efficacy Assessments.....	65
9.5.1.3 Safety Assessments.....	67
9.5.1.4 Assessments of Demographic and other Baseline Characteristics.....	77
9.5.2 Appropriateness of Measurements	78
9.5.3 Primary Efficacy Variable(s).....	78
9.6 Data Quality Assurance	78
9.7 Statistical Methods and Determination of Sample Size.....	79
9.7.1 General Considerations.....	79
9.7.2 Endpoints in Relation to the Objectives and Hypotheses	79
9.7.3 Definition of Analysis Sets.....	80
9.7.4 Statistical Analyses.....	81
9.7.4.1 Primary Endpoints	81
9.7.4.2 Secondary Endpoints	85
9.7.5 Interim Analyses.....	88
9.7.6 Sequential Safety Analysis/Safety Monitoring.....	88
9.7.7 Exploratory Statistical Analyses for Pharmacogenetics and Biomarkers.....	88
9.7.8 PK and PD Modelling.....	88
9.7.9 Health Economics and/or Patient Reported Outcomes.....	88
9.7.10 Determination of Sample Size.....	88
9.8 Changes in the Conduct of the Study or Planned Analyses.....	89
9.8.1 Protocol Amendments and General Procedural Deviations	89
9.8.2 Changes to the Statistical Analyses Planned in the Protocol.....	89
10 Trial Subjects.....	91
10.1 Disposition of Subjects	91
10.2 Protocol Deviations.....	94
10.2.1 Important Protocol Deviations.....	94
10.2.2 Important Deviations at Trial Site Level	94
10.2.2.1 Important Deviations at Trial Site Level- Main Trial	94
10.2.2.2 Important Deviations at Trial Site Level- Main Trial, after the Final of CTR.....	94
10.2.2.3 Important Deviations at Trial Site Level- Extension Trial.....	94
10.2.3 Important Deviations at Subject Level	95
10.2.3.1 Important Deviations at Subject Level- Main Trial	95
10.2.3.2 Important Deviations at Subject Level- Main Trial, after the Final of CTR.....	98
10.2.3.3 Important Deviations at Subject Level- Extension Trial.....	98
11 Efficacy Evaluation	101
11.1 Data Sets Analysed	101
11.2 Demographic and Other Baseline Characteristics.....	102
11.3 Measurements of Treatment Compliance	108
11.4 Efficacy Results	108
11.4.1 Analysis of Efficacy	108
11.4.1.1 HbA1c.....	108
11.4.1.2 Responders for HbA1c.....	112

11.4.1.3 Fasting Plasma Glucose	115
11.4.1.4 9-point Self-measured Plasma Glucose Profiles	117
11.4.1.5 SMPG Values used for Dose Adjustments	120
11.4.2 PK and PD Modelling	124
11.4.3 Statistical/Analytical Issues	124
11.4.3.1 Handling of Dropouts or Missing Data	124
11.4.4 Efficacy Conclusions	124
12 Safety Evaluation	126
12.1 Extent of Exposure	126
12.1.1 Exposure to Trial Products	126
12.1.2 Dosing During the Trial	127
12.1.2.1 Insulin Regimen and Dosing Time	127
12.1.2.2 Insulin Dose	129
12.1.2.3 Insulin Dose Ratio at End of Trial	134
12.1.2.4 Difference between Titration Algorithm Dose and Prescribed Dose	135
12.1.2.5 Difference between Prescribed Dose and Actual Dose	136
12.2 Adverse Events	136
12.2.1 Brief Summary of Adverse Events	136
12.2.2 Analysis of Adverse Events	139
12.2.2.1 All Adverse Events	139
12.2.2.2 Adverse Events by Relationship to Investigational Product (IDegAsp or IDet)	142
12.2.2.3 Adverse Events by Relationship to Bolus Insulin (IAsp)	145
12.2.2.4 Adverse Events by Relationship to Insulin Delivery Device	145
12.2.2.5 Adverse Events by Severity	145
12.3 Deaths, Other Serious Adverse Events and Other Significant Adverse Events	146
12.3.1 Deaths	146
12.3.2 Other Serious Adverse Events	146
12.3.2.1 All Serious Adverse Events	146
12.3.2.2 Serious Adverse Events by Relationship	149
12.3.3 Other Significant Adverse Events	151
12.3.3.1 Adverse Events leading to Withdrawal	151
12.3.3.2 Adverse Events Leading to Dose Reduction in Investigational Product	152
12.3.3.3 Medical Events of Special Interest	152
12.4 Hypoglycaemia	153
12.4.1 Introduction to Hypoglycaemic Episodes	153
12.4.2 Confirmed Hypoglycaemic Episodes	154
12.4.3 Severe Hypoglycaemia	157
12.4.4 Nocturnal Hypoglycaemic Episodes	158
12.4.4.1 Nocturnal Confirmed Hypoglycaemic Episodes	158
12.4.4.2 Nocturnal Severe Hypoglycaemic Episodes	160
12.4.5 Hypoglycaemic Episodes according to the ADA Classification	161
12.5 Clinical Laboratory Evaluation	162
12.5.1 Evaluation of Insulin Antibodies	162
12.5.1.1 Cross-reacting Insulin Antibodies	162
12.5.1.2 Specific Insulin Antibodies	165

12.5.1.3 Total Insulin Antibodies	165
12.5.2 Evaluation of Each Laboratory Parameter.....	165
12.5.2.1 Laboratory Values over Time	165
12.5.2.2 Individual Subject Changes	166
12.5.2.3 Individual Clinically Significant Abnormalities	166
12.6 Vital Signs, Physical Findings and Other Observations Related to Safety	167
12.6.1 Vital Signs	167
12.6.2 Physical Examination	168
12.6.3 ECG	168
12.6.4 Fundoscopy / Fundusphotography.....	168
12.6.5 Body Weight and Body Mass Index	169
12.7 Safety Conclusions.....	170
13 Discussion and Overall Conclusions	172
14 Tables, Figures and Graph Referred to but not Included in the Text.....	177
14.1 Demographic Data	177
14.1.1: Subject disposition - Summary	177
14.1.2: Subject disposition by Country - Summary.....	179
14.1.3: Time to Discontinuation - Full Analysis Set	183
14.1.4: Time to Discontinuation (Weeks) – All Non-Completers - Full Analysis Set	184
14.1.5: Subject Disposition by Week - Summary - Full Analysis Set.....	185
14.1.6: Reasons for Discontinuation from Week 12 and onwards - Full Analysis Set.....	186
14.1.7: Demographics and Baseline Characteristics - Summary - Full Analysis Set.....	187
14.1.8: Demographics and Baseline Characteristics - Summary - Extension Trial Set.....	188
14.1.9: Baseline and Diabetes Characteristics – Descriptive Statistics - Full Analysis Set	189
14.1.10: Baseline and Diabetes Characteristics - Descriptive Statistics - Extension Trial Set	190
14.1.11: Anti-diabetic Treatment Regimen at Screening - Full Analysis Set.....	191
14.1.12: Insulin Type at Screening - Full Analysis Set.....	192
14.1.13: Diabetes Complications at Screening - Summary - Full Analysis Set	193
14.1.14: Concomitant Illness at Screening - Summary - Full Analysis Set.....	194
14.1.15: Concomitant Medication at Screening – Summary - Full Analysis Set	205
14.1.16: Concomitant Medication Started after Screening – Summary - Full Analysis Set	227
14.2 Efficacy Data	265
14.2.1: Exposure - Descriptive Statistics - Safety Analysis Set	266
14.2.2: Exposure – Descriptive Statistics - Extension Trial Set.....	267
14.2.3: Exposure by Treatment Week - Summary - Safety Analysis Set.....	268
14.2.4: Exposure by Treatment Week - Summary - Extension Trial Set	269
14.2.5: Exposure by Sex and Treatment Week - Summary - Safety Analysis Set	270
14.2.6: Exposure by Race and Treatment Week - Summary - Safety Analysis Set	271
14.2.7: Exposure by Ethnicity and Treatment Week - Summary - Safety Analysis Set.....	275
14.2.8: Exposure by Age Group (Adults and Elderly) and Treatment Week - Summary - Safety Analysis Set	277
14.2.9: Exposure - Empirical Distribution Plot - Safety Analysis Set.....	278
14.2.10: IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	279

14.2.11: IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Extension Trial Set.....	283
14.2.12: IDegAsp/Comparator Insulin Dose (Prescribed) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	287
14.2.13: IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	291
14.2.14: IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Extension Trial Set.....	295
14.2.15: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	299
14.2.16: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Extension Trial Set	300
14.2.17: Daily IDegAsp/Comparator (Prescribed) in Units by Treatment Week - Mean Plot - Safety Analysis Set.....	301
14.2.18: Daily IDegAsp/Comparator (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set	302
14.2.19: Daily IDegAsp/Comparator (Actual) in Units/kg by Treatment Week - Mean Plot - Extension Trial Set	303
14.2.20: Daily IDegAsp OD Dose (Actual) in Units/kg by Treatment Week - Box Plot - Safety Analysis Set	304
14.2.21: Daily IDet Dose (Actual) in Units/kg by Treatment Week - Box Plot - Safety Analysis Set	305
14.2.22: Daily IDegAsp OD Dose (Prescribed) in Units by Treatment Week - Box Plot - Safety Analysis Set	306
14.2.23: Daily IDet Dose (Prescribed) in Units by Treatment Week - Box Plot - Safety Analysis Set	307
14.2.24: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	308
14.2.25: Daily IDegAsp/Comparator Insulin Dose (Prescribed) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	309
14.2.26: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	310
14.2.27: Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	311
14.2.28: Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	329
14.2.29: Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	333
14.2.30: Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	337
14.2.31: Basal Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	338
14.2.32: Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set	339
14.2.33: Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set	340
14.2.34: Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - IDegAsp OD - Box Plot - Safety Analysis Set.....	341

14.2.35: Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - IDet - Box Plot - Safety Analysis Set.....	342
14.2.36: Daily Bolus Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	343
14.2.37: Basal Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	344
14.2.38: Daily Bolus Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	345
14.2.39: Basal Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	346
14.2.40: Total Daily Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	347
14.2.41: Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	351
14.2.42: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	355
14.2.43: Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	359
14.2.44: Total Daily Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	363
14.2.45: Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set.....	364
14.2.46: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set	365
14.2.47: Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set.....	366
14.2.48: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - IDegAsp OD - Box Plot - Safety Analysis Set.....	367
14.2.49: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - IDet - Box Plot - Safety Analysis Set.....	368
14.2.50: Total Daily Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	369
14.2.51: Total Daily Bolus Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	370
14.2.52: Total Daily Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	371
14.2.53: Total Daily Bolus Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	372
14.2.54: IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set	373
14.2.55: IDet Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set	376
14.2.56: Insulin Dose Ratio after 52 Weeks of Treatment - Summary - Safety Analysis Set...	378
14.2.57: Basal - Bolus Split of Total Daily Insulin Dose (U/kg) - Summary - Safety Analysis Set	379
14.2.58: Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	380
14.2.59: Prescribed minus Titration Algorithm Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	385

14.2.60: Daily IDegAsp OD Insulin Dose in Units by Treatment Week - Prescribed, Actual and Titration Algorithm Dose - Mean Plot - Safety Analysis Set	389
14.2.61: Daily IDet Insulin Dose in Units by Treatment Week - Prescribed, Actual and Titration Algorithm Dose – Mean Plot - Safety Analysis Set.....	390
14.2.62: HbA1c (%) by Treatment Week – Descriptive Statistics - Full Analysis Set	391
14.2.63: HbA1c (%) by Treatment Week – Descriptive Statistics - Extension Trial Set	393
14.2.64: HbA1c (%) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set	395
14.2.65: HbA1c (%) by Treatment Week – Change from Baseline - Descriptive Statistics - Extension Trial Set.....	397
14.2.66: HbA1c (%) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set...	399
14.2.67: HbA1c (%) after 52 Weeks of Treatment - Statistical Analysis - Extension Trial Set	400
14.2.68: HbA1c (%) after 52 Weeks of Treatment - Parameter Estimates on Observed Scale - Full Analysis Set	401
14.2.69: HbA1c (%) after 52 Weeks of Treatment - Statistical Sensitivity Analysis - PP Analysis Set	402
14.2.70: HbA1c (%) after 52 Weeks of Treatment - Statistical Sensitivity Analysis - Simple Model - Full Analysis Set.....	403
14.2.71: HbA1c (%) after 52 Weeks of Treatment - Statistical Sensitivity Analysis - Repeated Measurement Model - Full Analysis Set.....	404
14.2.72: HbA1c (%) by Treatment Week – Mean Plot - Full Analysis Set.....	404
14.2.73: HbA1c (%) by Treatment Week - Mean Plot - Extension Trial Set.....	405
14.2.74: HbA1c (%) by Treatment Week – Change from Baseline - Mean Plot - Full Analysis Set	406
14.2.75: HbA1c (%) by Treatment Week – Change from Baseline - Mean Plot - Extension Trial Set.....	407
14.2.76: HbA1c (%) by Treatment Week – Change from Baseline - Mean Plot - PP Analysis Set	408
14.2.77: HbA1c (%) by Treatment Week – Box Plot - Full Analysis Set.....	409
14.2.78: HbA1c (%) after 52 Weeks of Treatment – Empirical Distribution Plot - Full Analysis Set	410
14.2.79: HbA1c (%) after 52 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set.....	411
14.2.80: Responder for HbA1c by Treatment Week – Summary - Full Analysis Set.....	412
14.2.81: Responder for HbA1c at End of Trial - Statistical Analysis - Full Analysis Set.....	414
14.2.82: Responder for HbA1c at End of Trial Without Hypoglycaemia – Summary - Full Analysis Set	415
14.2.83: Responder for HbA1c at End of Trial Without Hypoglycaemia - Statistical Analysis - Full Analysis Set.....	417
14.2.84: Fasting Plasma Glucose (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set.....	418
14.2.85: Fasting Plasma Glucose (mmol/L) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set.....	419
14.2.86: Fasting Plasma Glucose (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set.....	420
14.2.87: Fasting Plasma Glucose (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set	421

14.2.88: Fasting Plasma Glucose (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set	422
14.2.89: Fasting Plasma Glucose (mmol/L) by Treatment Week - Box Plot - Full Analysis Set	423
14.2.90: Fasting Plasma Glucose (mmol/L) after 52 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set	424
14.2.91: Fasting Plasma Glucose (mmol/L) after 52 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set	425
14.2.92: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set	426
14.2.93: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set	428
14.2.94: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Weeks - Mean Plot - IDegAsp OD - Full Analysis Set	430
14.2.95: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Weeks - Mean Plot - IDet - Full Analysis Set	431
14.2.96: 9-point Self Measured Plasma Glucose Profile (mmol/L) at Baseline - Mean Plot - Full Analysis Set	432
14.2.97: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 12 Weeks - Mean Plot - Full Analysis Set	433
14.2.98: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 16 Weeks - Mean Plot - Full Analysis Set	434
14.2.99: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks - Mean Plot - Full Analysis Set	435
14.2.100: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 39 Weeks - Mean Plot - Full Analysis Set	436
14.2.101: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks - Mean Plot - Full Analysis Set	437
14.2.102: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set	438
14.2.103: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set	439
14.2.104: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set	440
14.2.105: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set	441
14.2.106: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set	442
14.2.107: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set	443
14.2.108: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set	444
14.2.109: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week - Descriptive Statistics - Full Analysis Set	445
14.2.110: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set	447
14.2.111: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set	448

14.2.112: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set.....	449
14.2.113: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set.....	450
14.2.114: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set	451
14.2.115: Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) – Descriptive Statistics - Full Analysis Set.....	452
14.2.116: Prandial Increment by Treatment Week – Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set	456
14.2.117: Prandial Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Statistical Analysis - Full Analysis Set	460
14.2.118: Breakfast Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set.....	461
14.2.119: Breakfast Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set	462
14.2.120: Breakfast Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	463
14.2.121: Breakfast Increment after 52 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	464
14.2.122: Lunch Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set.....	465
14.2.123: Lunch Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set	466
14.2.124: Lunch Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	467
14.2.125: Lunch Increment after 52 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	468
14.2.126: Main Evening Meal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set	469
14.2.127: Main Evening Meal Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set...	470
14.2.128: Main Evening Meal Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	471
14.2.129: Main Evening Meal Increment after 52 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	472
14.2.130: All Meals Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set.....	473
14.2.131: All Meals Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set	474
14.2.132: All Meals Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	475

14.2.133: All Meals Increment after 52 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	476
14.2.134: Nocturnal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) – Descriptive Statistics - Full Analysis Set.....	477
14.2.135: Nocturnal Increment by Treatment Week – Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set	480
14.2.136: Nocturnal Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Statistical Analysis - Full Analysis Set.....	483
14.2.137: Nocturnal Increment (Bedtime to 04:00) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) -Mean Plot - Full Analysis Set	484
14.2.138: Nocturnal Increment (Bedtime to 04:00) by Treatment Week - Change from Baseline – 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set	485
14.2.139: Nocturnal Increment (Bedtime to 04:00) after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	486
14.2.140: Nocturnal Increment (Bedtime to 04:00) after 52 Weeks of Treatment– Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	487
14.2.141: Nocturnal Increment (Bedtime to Breakfast) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set	488
14.2.142: Nocturnal Increment (Bedtime to Breakfast) by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set	489
14.2.143: Nocturnal Increment (Bedtime to Breakfast) after 52 Weeks of Treatment -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set.....	490
14.2.144: Nocturnal Increment (Bedtime to Breakfast) after 52 Weeks of Treatment – Change from Baseline -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	491
14.2.145: Nocturnal Increment (04:00 to Breakfast) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) – Mean Plot - Full Analysis Set.....	492
14.2.146: Nocturnal Increment (04:00 to Breakfast) by Treatment Week - Change from Baseline – 9-point Self Measured Plasma Glucose Profile (mmol/L) – Mean Plot - Full Analysis Set.....	493
14.2.147: Nocturnal Increment (04:00 to Breakfast) after 52 Weeks of Treatment -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	494
14.2.148: Nocturnal Increment (04:00 to Breakfast) after 52 Weeks of Treatment – Change from Baseline -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set	495
14.2.149: Self Measured Plasma Glucose for Dose Adjustment (mmol/L) – Descriptive Statistics - Full Analysis Set	496
14.2.150: Self Measured Plasma Glucose for Dose Adjustment after 52 Treatment Weeks - Statistical Analysis - Full Analysis Set.....	520
14.2.151: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set.....	521

14.2.152: Mean Before Lunch Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set.....	522
14.2.153: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDegAsp OD - Box Plot - Full Analysis Set.....	523
14.2.154: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDet - Box Plot - Full Analysis Set.....	524
14.2.155: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDegAsp OD - Box Plot - Full Analysis Set.....	525
14.2.156: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDet - Box Plot - Full Analysis Set.....	526
14.2.157: Mean Before Main Evening Meal Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set.....	527
14.2.158: Mean Before Main Evening Meal Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDegAsp OD - Box Plot - Full Analysis Set	528
14.2.159: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDet - Box Plot - Full Analysis Set.....	529
14.2.160: Mean Before Bedtime Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set.....	530
14.2.161: Mean Before Bedtime Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDegAsp OD - Box Plot - Full Analysis Set.....	531
14.2.162: Mean Before Bedtime Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDet - Box Plot - Full Analysis Set.....	532
14.2.163: Within-Subject Variation in Self Measured Plasma Glucose for Dose Adjustment after 52 Treatment Weeks - Statistical Analysis - Full Analysis Set.....	533
14.2.164: Before Breakfast Titration Target (SMPG<5 mmol/L) by Treatment Week – Summary - Full Analysis Set	534
14.2.165: Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set.....	539
14.2.166: Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set.....	540
14.2.167: Time to All Titration Targets are Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set.....	541
14.2.168: Time to Titration Target is Met for the First Time (Treatment Week) – Descriptive Statistics - Full Analysis Set.....	542
14.2.169: Time to Titration Target is Met for the First Time (Treatment Week) - Statistical Analysis - Full Analysis Set.....	543
14.3 Safety Data.....	544
14.3.1 Displays of Adverse Events.....	544
14.3.1.1: Adverse Events - Treatment Emergent - Summary - Safety Analysis Set.....	545
14.3.1.2: Serious Adverse Events – Treatment Emergent - Summary - Safety Analysis Set.....	546
14.3.1.3: Serious Adverse Events – Treatment Emergent - Summary - Extension Trial Set.....	547
14.3.1.4: Adverse Events by System Organ Class and Preferred Term - Most Frequent [≥5%]- Treatment Emergent - Summary - Safety Analysis Set.....	548
14.3.1.5: Adverse Events by System Organ Class and Preferred Term - Most Frequent [≥1%]- Treatment Emergent - Summary - Safety Analysis Set.....	549

14.3.1.6: Serious Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 5\%$]- Treatment Emergent - Summary - Safety Analysis Set.....	554
14.3.1.7: Serious Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$]- Treatment Emergent - Summary - Safety Analysis Set.....	555
14.3.1.8: Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	556
14.3.1.9: Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	571
14.3.1.10: Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Extension Trial Set.....	574
14.3.1.11: Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set.....	577
14.3.1.12: Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set.....	580
14.3.1.13: Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	583
14.3.1.14: Serious Adverse Events Possibly or Probably Related Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	584
14.3.1.15: Serious Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set.....	585
14.3.1.16: Serious Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	586
14.3.1.17: Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	587
14.3.1.18: Severe Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	590
14.3.1.19: Severe Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term – Treatment Emergent - Summary - Safety Analysis Set.....	591
14.3.1.20: Severe Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	592
14.3.1.21: Serious Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	593
14.3.1.22: Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	596
14.3.1.23: Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	603
14.3.1.24: Adverse Events Leading To Dose Reduction - Treatment Emergent - Summary - Safety Analysis Set.....	616
14.3.1.25: Neoplasms by System Organ Class and Preferred Term - Summary - Safety Analysis Set.....	617
14.3.1.26: Allergic Reaction (Immunogenicity) by System Organ Class and Preferred Term - Summary - Safety Analysis Set.....	618

14.3.1.27: Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	619
14.3.1.28: Adjudicated Cardiovascular Events - Treatment Emergent - Summary - Safety Analysis Set.....	621
14.3.1.29: Injection Site Reaction by System Organ Class and Preferred Term - Summary - Safety Analysis Set.....	622
14.3.1.30: Injection Site Reactions - Mean Cumulative Function - Safety Analysis Set.....	623
14.3.1.31: Medication Errors - Treatment Emergent - Summary - Safety Analysis Set.....	624
14.3.1.32: Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set.....	626
14.3.1.33: Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Extension Trial Set	627
14.3.1.34: Nocturnal Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set	628
14.3.1.35: Nocturnal Hypoglycaemic Episodes by Classification – Treatment Emergent - Summary - Extension Trial Set.....	629
14.3.1.36: Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set.....	630
14.3.1.37: Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Extension Trial Set	634
14.3.1.38: Nocturnal Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set.....	638
14.3.1.39: Hypoglycaemic Episodes - Treatment Emergent - Statistical Analysis - Full Analysis Set.....	642
14.3.1.40: Hypoglycaemic Episodes - Treatment Emergent - Statistical Analysis - Extension Trial Set.....	643
14.3.1.41: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent– Statistical Analysis - Full Analysis Set	644
14.3.1.42: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent – Statistical Analysis - Extension Trial Set.....	645
14.3.1.43: Severe Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set.....	646
14.3.1.44: Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set.....	647
14.3.1.45: Severe Hypoglycaemic Episodes - Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	648
14.3.1.46: Severe Hypoglycaemic Episodes - Treatment Emergent - Mean Cumulative Function - Extension Trial Set.....	649
14.3.1.47: Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	650
14.3.1.48: Severe Hypoglycaemic Episodes – Treatment Emergent - Cumulative Frequency over Day - Safety Analysis Set.....	651
14.3.1.49: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set.....	652
14.3.1.50: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set.....	653
14.3.1.51: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	654

14.3.1.52: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Extension Trial Set	655
14.3.1.53: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set	656
14.3.1.54: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Extension Trial Set	657
14.3.1.55: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Cumulative Frequency over Day - Safety Analysis Set	658
14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events	659
14.3.2.1: Treatment Emergent Serious Adverse Events - Safety Analysis Set	659
14.3.2.2: Treatment Emergent Adverse Events with Fatal Outcome - Safety Analysis Set	687
14.3.2.3: Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set	688
14.3.2.4: Adverse Events Leading to Withdrawal - Full Analysis Set	705
14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events	710
Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events Abbreviation Statement	710
14.3.4 Abnormal Laboratory Value Listing (each patient)	868
14.3.4.1: Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set	868
14.3.4.2: Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set	890
14.3.4.3: Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set	922
14.3.4.4: Urinalysis With Positive Test Results - Safety Analysis Set	971
14.3.5 Laboratory Displays	988
14.3.5.1: Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set	990
14.3.5.2: Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set	999
14.3.5.3: Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set	1008
14.3.5.4: Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Extension Trial Set	1017
14.3.5.5: Biochemistry by Treatment Week - Summary - Safety Analysis Set	1026
14.3.5.6: Biochemistry by Treatment Week - Summary - Extension Trial Set	1031
14.3.5.7: Biochemistry – Shift Table – Baseline to Week 53 – Safety Analysis Set	1033
14.3.5.8: Biochemistry – Shift Table – Baseline to Week 53 – Extension Trial Set	1036
14.3.5.9: Biochemistry - Alanine Amino Serum - Box Plot - Safety Analysis Set	1037
14.3.5.10: Biochemistry - Alanine Amino Serum after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1038
14.3.5.11: Biochemistry - Albumin Serum - Box Plot - Safety Analysis Set	1039
14.3.5.12: Biochemistry - Albumin Serum after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1040
14.3.5.13: Biochemistry - Total Bilirubin - Box Plot - Safety Analysis Set	1041
14.3.5.14: Biochemistry - Total Bilirubin after 52 Weeks of Treatment – Empirical Distribution Plot - Safety Analysis Set	1042

14.3.5.15: Biochemistry - AST - Box Plot - Safety Analysis Set	1043
14.3.5.16: Biochemistry - AST after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1044
14.3.5.17: Biochemistry - Creatinine - Box Plot - Safety Analysis Set	1045
14.3.5.18: Biochemistry - Creatinine after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1046
14.3.5.19: Biochemistry - Alkaline phosphatase - Box Plot - Safety Analysis Set	1047
14.3.5.20: Biochemistry - Alkaline phosphatase after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1048
14.3.5.21: Biochemistry - Total Protein - Box Plot - Safety Analysis Set	1049
14.3.5.22: Biochemistry - Total Protein after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1050
14.3.5.23: Biochemistry - Sodium - Box Plot - Safety Analysis Set	1051
14.3.5.24: Biochemistry - Sodium after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1052
14.3.5.25: Biochemistry - Potassium - Box Plot - Safety Analysis Set	1053
14.3.5.26: Biochemistry - Potassium after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1054
14.3.5.27: Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set	1055
14.3.5.28: Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set	1065
14.3.5.29: Haematology by Treatment Week - Summary - Safety Analysis Set	1075
14.3.5.30: Haematology – Shift Table – Baseline to Week 53 – Safety Analysis Set	1081
14.3.5.31: Haematology - Neutrophils - Box Plot - Safety Analysis Set	1084
14.3.5.32: Haematology - Neutrophils after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1085
14.3.5.33: Haematology - Lymphocytes - Box Plot - Safety Analysis Set	1086
14.3.5.34: Haematology - Lymphocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1087
14.3.5.35: Haematology - Monocytes - Box Plot - Safety Analysis Set	1088
14.3.5.36: Haematology - Monocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1089
14.3.5.37: Haematology - Eosinophils - Box Plot - Safety Analysis Set	1090
14.3.5.38: Haematology - Eosinophils after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1091
14.3.5.39: Haematology - Basophils - Box Plot - Safety Analysis Set	1092
14.3.5.40: Haematology - Basophils after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1093
14.3.5.41: Haematology - Erythrocytes - Box Plot - Safety Analysis Set	1094
14.3.5.42: Haematology - Erythrocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1095
14.3.5.43: Haematology - Haematocrit - Box Plot - Safety Analysis Set	1096
14.3.5.44: Haematology - Haematocrit after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set	1097
14.3.5.45: Haematology - Haemoglobin - Box Plot - Safety Analysis Set	1098

14.3.5.46: Haematology - Haemoglobin after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	1099
14.3.5.47: Haematology - Leukocytes - Box Plot - Safety Analysis Set	1100
14.3.5.48: Haematology - Leukocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	1101
14.3.5.49: Haematology - Thrombocytes - Box Plot - Safety Analysis Set.....	1102
14.3.5.50: Haematology - Thrombocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	1103
14.3.5.51: Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1104
14.3.5.52: Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set.....	1108
14.3.5.53: Lipids after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set.....	1112
14.3.5.54: Lipids after 52 Weeks of Treatment - Statistical Analysis - Extension Trial Set.....	1114
14.3.5.55: Lipids by Treatment Week - Summary - Safety Analysis Set	1116
14.3.5.56: Lipids – Shift Table – Baseline to Week 53 – Safety Analysis Set	1119
14.3.5.57: Lipid - HDL Cholesterol - Box Plot - Safety Analysis Set.....	1120
14.3.5.58: Lipid - HDL Cholesterol after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	1121
14.3.5.59: Lipid - LDL Cholesterol - Box Plot - Safety Analysis Set	1122
14.3.5.60: Lipid - LDL Cholesterol after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	1123
14.3.5.61: Lipid - Tot. Chol. Serum - Box Plot - Safety Analysis Set.....	1124
14.3.5.62: Lipid - Tot. Chol. Serum after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	1125
14.3.5.63: Lipid - Triglycerides Serum - Box Plot - Safety Analysis Set.....	1126
14.3.5.64: Lipid - Triglycerides Serum after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	1127
14.3.5.65: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1128
14.3.5.66: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set	1129
14.3.5.67: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Summary - Safety AnalysisSet.....	1130
14.3.5.68: Urinary Albumin-to-Creatinine Ratio – Shift Table – Baseline to Week 53 – Safety Analysis Set.....	1131
14.3.5.69: Urinary Albumin-to-Creatinine Ratio - Box Plot - Safety Analysis Set.....	1132
14.3.5.70: Urinary Albumin-to-Creatinine Ratio after 52 Weeks of Treatment – Empirical Distribution Plot - Safety Analysis Set.....	1133
14.3.5.71: Urine by Sticks - Summary - Safety Analysis Set	1134
14.3.5.72: Urine by Sticks – Shift Table – Baseline to Week 53 – Safety Analysis Set	1136
14.3.6 Other Safety Observations Displays.....	1137
14.3.6.1: Physical Examination by Treatment Week - Summary - Safety Analysis Set	1138
14.3.6.2: Physical Examination - Shift Table - Baseline to Week 52 - Safety Analysis Set.....	1145
14.3.6.3: Vital Signs by Treatment Week - Descriptive Statistics - Safety Analysis Set	1147

14.3.6.4: Vital Signs by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set.....	1150
14.3.6.5: Diastolic Blood Pressure - Mean Plot - Safety Analysis Set	1153
14.3.6.6: Diastolic Blood Pressure - Change from Baseline - Mean Plot - Safety Analysis Set.....	1154
14.3.6.7: Diastolic Blood Pressure after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set.....	1155
14.3.6.8: Systolic Blood Pressure - Mean Plot - Safety Analysis Set.....	1156
14.3.6.9: Systolic Blood Pressure - Change from Baseline - Mean Plot - Safety Analysis Set.....	1157
14.3.6.10: Systolic Blood Pressure after 52 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set.....	1158
14.3.6.11: Pulse - Mean Plot - Safety Analysis Set	1159
14.3.6.12: Pulse - Change from Baseline - Mean Plot - Safety Analysis Set	1160
14.3.6.13: Pulse after 52 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set.....	1161
14.3.6.14: ECG by Treatment Week - Summary - Safety Analysis Set	1162
14.3.6.15: ECG - Shift Table - Baseline to Week 52 - Safety Analysis Set	1163
14.3.6.16: Funduscopy / Fundusphotography by Treatment Week - Summary - Safety Analysis Set.....	1164
14.3.6.17: Funduscopy / Fundusphotography - Shift Table - Baseline to Week 52 - Safety Analysis Set.....	1166
14.3.6.18: Body Weight and BMI by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1167
14.3.6.19: Body Weight and BMI by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set.....	1171
14.3.6.20: Body Weight (kg) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set.....	1173
14.3.6.21: Body Weight - Mean Plot - Safety Analysis Set.....	1174
14.3.6.22: Body Weight – Change from Baseline - Mean Plot - Safety Analysis Set	1175
14.3.6.23: Body Weight by Treatment week - Box Plot - Safety Analysis Set	1176
14.3.6.24: Body weight after 52 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set.....	1177
14.3.6.25: Body weight after 52 Weeks of Treatment - Change from Baseline Empirical Distribution Plot - Safety Analysis Set.....	1178
14.3.6.26: Insulin Degludec Specific Antibodies (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1179
14.3.6.27: Insulin Aspart Specific Antibodies (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1180
14.3.6.28: Cross-reacting Antibodies to Human Insulin (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1181
14.3.6.29: Total Antibodies (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	1182
14.3.6.30: IDegAsp / Comparator Specific Antibodies (% B/T) - Mean Plot - Safety Analysis Set.....	1183
14.3.6.31: IDegAsp / Comparator Specific Antibodies (% B/T) - Mean Plot - Extension Trial Set.....	1184

14.3.6.32: IDegAsp / Comparator Specific Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set	1185
14.3.6.33: IDegAsp / Comparator Specific Antibodies (% B/T) - Mean Plot - Observed Values - Extension Trial Set.....	1186
14.3.6.34: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Safety Analysis Set.....	1187
14.3.6.35: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Extension Trial Set.....	1188
14.3.6.36: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set.....	1189
14.3.6.37: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Observed Values - Extension Trial Set	1190
14.3.6.38: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Safety Analysis Set.....	1191
14.3.6.39: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Extension Trial Set	1192
14.3.6.40: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Observed Values - Safety Analysis Set	1193
14.3.6.41: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Observed Values - Extension Trial Set.....	1194
14.3.6.42: Total Antibodies (% B/T) - Mean Plot - Safety Analysis Set.....	1195
14.3.6.43: Total Antibodies (% B/T) - Mean Plot - Extension Trial Set	1196
14.3.6.44: Total Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set.....	1197
14.3.6.45: Total Antibodies (% B/T) - Mean Plot - Observed Values - Extension Trial Set.....	1198
14.3.6.46: Degludec specific Antibodies (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set.....	1199
14.3.6.47: Degludec specific Antibodies (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot – Extension Trial Set.....	1200
14.3.6.48: Degludec specific Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set	1201
14.3.6.49: Degludec specific Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set.....	1202
14.3.6.50: Cross-reacting Antibodies to Human Insulin (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set.....	1203
14.3.6.51: Cross-reacting Antibodies to Human Insulin (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set	1204
14.3.6.52: Cross-reacting Antibodies to Human Insulin (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set.....	1205
14.3.6.53: Cross-reacting Antibodies to Human Insulin (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set.....	1206
14.3.6.54: Total Antibodies (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set.....	1207
14.3.6.55: Total Antibodies (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set	1208

14.3.6.56: Total Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set	1209
14.3.6.57: Total Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set	1210
14.3.6.58: Degludec specific Antibodies (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set	1211
14.3.6.59: Degludec specific Antibodies (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set.....	1212
14.3.6.60: Cross-reacting Antibodies to Human Insulin (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set.....	1213
14.3.6.61: Cross-reacting Antibodies to Human Insulin (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Extension trial Set....	1214
14.3.6.62: Total Antibodies (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set	1215
14.3.6.63: Total Antibodies (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set	1216
14.3.7 Other Safety Observations Lists	1217
14.3.7.1: Vital Signs - Safety Analysis Set	1217
14.3.7.2: ECG Findings - Safety Analysis Set.....	1289
14.3.7.3: Fundoscopy / Fundusphotography Findings - Safety Analysis Set	1345
14.3.7.4: Antibodies - Safety Analysis Set	1461
14.3.7.5: Physical Examination Findings - Safety Analysis Set.....	1826
14.3.7.6: Body Measurements - Safety Analysis Set.....	2151
15 Reference List	2237

List of In-Text Figures

	Page
Figure 9–1 Trial Design.....	40
Figure 9–2 Classification of hypoglycaemia according to ADA	73
Figure 11–1 HbA1c (%) by Treatment Week – Mean Plot – Full Analysis Set.....	109
Figure 11–2 Fasting Plasma Glucose (mmol/L) by Treatment Week – Mean Plot – Full Analysis Set.....	116
Figure 11–3 9-point Self Measured Plasma Glucose Profile (mmol/L) at Baseline (Left) and After 52 Weeks (Right) - LOCF - Mean Plot - Full Analysis Set.....	118
Figure 11–4 Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set.....	123
Figure 12–1 Total Daily Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set	130
Figure 12–2 Basal Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set.....	131
Figure 12–3 Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set.....	133
Figure 12–4 Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	156
Figure 12–5 Severe Hypoglycaemic Episodes - Treatment Emergent - Mean Cumulative Function - Safety Analysis Set	157
Figure 12–6 Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	159
Figure 12–7 Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set.....	161
Figure 12–8 Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Safety Analysis Set.....	162
Figure 12–9 Body Weight - Mean Plot - Safety Analysis Set.....	169

List of In-Text Tables

	Page
Table 6–1 Contract Research Organisations	33
Table 9–1 Trial Products	49
Table 9–2 Start Dose of IDet.....	52
Table 9–3 Increase of IDegAsp or Evening IDet	53
Table 9–4 Reduction of IDegAsp or Evening IDet	53
Table 9–5 Increase of Morning IDet.....	54
Table 9–6 Reduction of Morning IDet.....	54
Table 9–7 Titration of Meal time IAsp	54
Table 9–8 Trial Flow Chart- Main Trial.....	57
Table 9–9 Trial Flow Chart- Extension Trial	60
Table 9–10 9-point profile (SMPG) (✓) with additional 4-point profiles (SMPG) (X)	67
Table 9–11 Substantial Protocol Amendments	89
Table 10–1 Subject Disposition - Summary	93
Table 10–2 Important Protocol Deviations- Main Trial	96
Table 10–3 Summary of Important Protocol Deviations- Extension Trial	100
Table 11–1 Analysis Sets	101
Table 11–2 Demographics and Baseline Characterises - Summary - Full Analysis Set.....	103
Table 11–3 Baseline and Diabetes Characteristics – Descriptive Statistics - Full Analysis Set.....	104
Table 11–4 Anti-diabetic Treatment Regimen at Screening - Full Analysis Set.....	105
Table 11–5 Diabetes Complications at Screening – Summary – Full Analysis Set.....	107
Table 11–6 HbA1c (%) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set.....	110
Table 11–7 HbA1c (%) after 52 Weeks of Treatment - Statistical Analysis - Extension Trial Set.....	111
Table 11–8 HbA1c (%) after 52 Weeks of Treatment - Statistical Sensitivity Analysis - PP Analysis Set.....	111
Table 11–9 Responder for HbA1c by Treatment Week – Summary – Full Analysis Set	112
Table 11–10 Responder for HbA1c at End of Trial - Statistical Analysis - Full Analysis Set....	113
Table 11–11 Responder for HbA1c at End of Trial Without Hypoglycaemia – Summary – Full Analysis Set.....	114
Table 11–12 Responder for HbA1c at End of Trial Without Hypoglycaemia - Statistical Analysis - Full Analysis Set.....	115
Table 11–13 Fasting Plasma Glucose (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set.....	117
Table 11–14 Self Measured Plasma Glucose for Dose Adjustment (mmol/L) – Descriptive Statistics – Full Analysis Set.....	121
Table 11–15 Self Measured Plasma Glucose for Dose Adjustment after 52 Treatment Weeks - Statistical Analysis - Full Analysis Set.....	122
Table 12–1 Exposure - Descriptive Statistics - Safety Analysis Set.....	126
Table 12–2 Presentations of Insulin Doses in the IDegAsp group.....	127
Table 12–3 IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	128

Table 12–4 Total Daily Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	129
Table 12–5 Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	129
Table 12–6 Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set.....	131
Table 12–7 Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	132
Table 12–8 Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set	133
Table 12–9 Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set	134
Table 12–10 Insulin Dose Ratio after 52 Weeks of Treatment - Summary - Safety Analysis Set	135
Table 12–11 Insulin Doses and Dose Ratio after 52 Week of treatment.....	135
Table 12–12 Adverse Events - Treatment Emergent - Summary - Safety Analysis Set.....	137
Table 12–13 Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 5\%$]- Treatment Emergent - Summary - Safety Analysis Set	138
Table 12–14 Neoplasms Events Safety Analysis Set.....	141
Table 12–15 Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set.....	143
Table 12–16 Serious Adverse Events – Treatment Emergent - Summary - Safety Analysis Set.....	147
Table 12–17 Adjudicated Cardiovascular Events - Treatment Emergent - Summary - Safety Analysis Set.....	148
Table 12–18 Serious Adverse Events Possibly or Probably Related Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set.....	150
Table 12–19 Subjects with Adverse Events leading to Withdrawal.....	151
Table 12–20 Hypoglycaemic Episodes by Classification – Treatment Emergent – Summary - Safety Analysis Set.....	155
Table 12–21 Nocturnal Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set.....	158
Table 12–22 Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent – Statistical Analysis - Full Analysis Set	160
Table 12–23 Cross-reacting Antibodies to Human Insulin (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set	164

List of Appendices

16.1 Study Information

- 16.1.1 Protocol and Protocol Amendments
- 16.1.2 Sample Case Report Forms
- 16.1.3 List of Independent Ethics Committees or Institutional Review Boards
- 16.1.4 List and Description of Investigators and Other Important Participants in the Study
- 16.1.5 Signatures of Principal or Coordinating Investigator(s)
- 16.1.6 Listing of Patients Receiving Test Drug(s)/Investigational Product(s) from Specific Batches
- 16.1.7 Randomisation Scheme and Codes
- 16.1.8 Audit Certificates
- 16.1.9 Documentation of Statistical Methods
- 16.1.10 Documentation of Inter-laboratory Standardisation Methods and Quality Assurance Procedures
- 16.1.11 Publications based on the Study
- 16.1.12 Important Publications Referenced in the Report

16.2 Patient Data Listings

- 16.2.1 Discontinued Patients
- 16.2.2 Protocol Deviations
- 16.2.3 Patients Excluded from the Efficacy Analysis
- 16.2.4 Demographic Data
- 16.2.5 Compliance and/or Drug Concentration Data
- 16.2.6 Individual Efficacy Response Data
- 16.2.7 Adverse Event Listings (Each Patient)
- 16.2.8 Listing of Individual Laboratory Measurements by Patient

16.3 Case Report Forms

- 16.3.1 CRFs for Deaths, other Serious Adverse Events, and Withdrawals for AE
- 16.3.2 Other CRFs submitted

16.4 Individual Patient Data Listings (US Archival Listings)

4 List of Abbreviations and Definition of Terms

Abbreviations

ACS	acute coronary syndrome
ADA	American Diabetes Association
AE	adverse event
ALAT	alanine aminotransferase
ANOVA	analysis of variance
a.m.	ante meridiem (latin for before noon)
AP	alkaline phosphatase
ASAT	aspartate aminotransferase
BB	basal bolus
BID	twice daily
BMI	body mass index
CCC	Customer Complaint Centre
CCDS	Company Core Data Sheet
CFR	Code of Federal Regulation
CNS	central nervous system
CPMP	Committee for Proprietary Medicinal Products
CRF	case report form
CRO	contract research organisation
CTA	Clinical Trial Application
CTR	clinical trial report
CV	cardiovascular
CV%	coefficient of variation
DUN	dispensing unit number
EAC	Event Adjudication Committee
ECG	electrocardiogram
eCRF	electronic case report form
EDC	electronic data capture
EMA	European Medicines Agency
EOT	end of trial
ETS	extension trial set
FAS	full analysis set
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act
FPFT	first patient first treatment
FPFV	first patient first visit
FPG	fasting plasma glucose
GCP	good clinical practice
HbA _{1c}	glycosylated haemoglobin
HDL	high density lipoprotein
IB	Investigator's Brochure
ICH	International Conference on Harmonisation

ICMJE	International Committee of Medical Journal Editors
ID	identification
IDeg	insulin degludec
IDegAsp	insulin degludec/insulin aspart
IDet	insulin detemir
IEC	independent ethics committee
IgE	immunoglobulin E
IND	Investigational New Drug
IRB	institutional review board
ITT	intention to treat
i.v.	intravenous
IV/WRS	interactive voice/web response system
LDL	low density lipoprotein
LOCF	last observation carried forward
LPFV	last patient first visit
LPLV	last patient last visit
MAO	monoamine oxidase
MedDRA	Medical Dictionary for Regulatory Activities
MESI	medical event of special interest
NPH	neutral protamine Hagedorn
OD	once daily
PG	plasma glucose
PP	per protocol
SAE	serious adverse event
SAP	statistical analysis plan
SAS	safety analysis set
SD	standard deviation
SGOT	serum glutamic oxaloacetic transaminase
SGPT	serum glutamic pyruvic transaminase
SMPG	self measured plasma glucose
SMQ	standard MedDRA query
SPC	summary of product characteristics
TEAE	treatment emergent adverse events
TG	triglycerides
TMF	trial master file
TMM	trial material manual
T-T-T	treat-to-target
TVP	trial validation plan
U	unit

Definition of Terms

IDegAsp (F): The IDegAsp drug product consists of two drug substances (70 volume% IDeg + 30 volume% IAsp) 100 U/mL

Insulin 454: Synonym previously used for IDeg drug substance

SIAC: Soluble Insulin Analogue Combination, NN5401. Synonym previously used for IDegAsp

5 Ethics

5.1 Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

The protocol, the protocol amendments ([Appendix 16.1.1](#)), the consent form, and the subject information sheet were reviewed and approved by appropriate authorities according to local regulations, and by local IECs and ITBs ([Appendix 16.1.3](#)), prior to trial initiation.

5.2 Ethical Conduct of the Trial

The trial was performed in accordance with the "Declaration of Helsinki"¹ and its amendments in force at the initiation of the trial. The subjects were informed of the risks and benefits of the trial.

The trial also followed International Conference on Harmonisation (ICH) Good Clinical Practice (GCP)³

The trial followed the Code of Federal Regulations, Title 21, parts 312, 50 and 56.

5.3 Subject Information and Consent

The subjects were informed verbally and in writing that they could withdraw from the trial at any time for any reason. Consent was to be obtained in writing prior to any trial-related activities and the investigators were to retain the consent forms. The consent forms were available to Novo Nordisk A/S for inspection. The master subject information sheet and consent form are in [Appendix 16.1.3](#).

Separated protocols, subject information and informed consent forms were prepared for both main trial and extension trial. Verbal and written information was provided to the subjects and the informed consent form was signed by the subject and the investigator.

The subjects were covered by the sponsor's insurance according to local legal requirements.

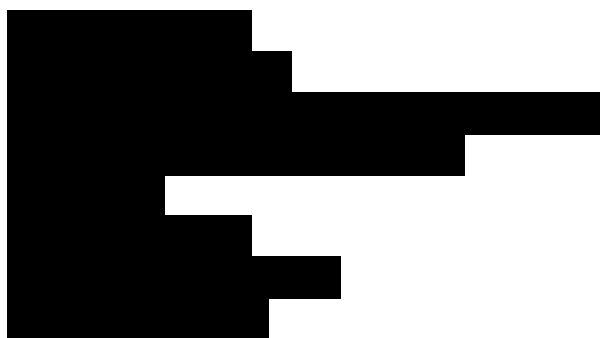
6 Investigators and Trial Administrative Structure

Trial Sites

The trial was conducted at 71 sites in 9 countries: Denmark (3 sites), Poland (6 sites), Romania (7 sites), France (2 sites), United Kingdom (6 sites), Russian Federation (10 sites), Israel (4 sites), Australia (7 sites), and United States (26 sites).

One principal investigator was appointed for each trial site. A list of the principal investigators, sub investigators and other important persons who were involved in the conduct of the trial, and their curricula vitae are provided in [Appendix 16.1.4](#).

The following investigator has been designated signatory investigators for the trial (see [Appendix 16.1.5](#)):



Sponsor

Novo Nordisk A/S was responsible for the protocol, electronic case report form (eCRF), interactive voice/web response system (IV/WRS) supply of trial products and auxiliary supplies, monitoring, data management, statistics and the clinical trial report (CTR). Novo Nordisk A/S also provided a system for electronic data capture (EDC). The system and support services were provided by [REDACTED]. Sample CRFs are found in [Appendix 16.1.2](#).

Novo Nordisk A/S has constituted an internal safety committee to perform ongoing safety surveillance. The safety committee was blinded to the treatment but could recommend unblinding of the data to be assessed by an independent ad hoc group if appropriate.

An independent external event adjudication committee (EAC) (see [Appendix 16.1.4](#)) was constituted for the trial to perform ongoing adjudication, standardisation and assessment of cardiovascular events in accordance with predefined classifications. The following events were to be evaluated and adjudicated by the EAC in an independent and blinded manner:

- Acute Coronary Syndrome (including myocardial infarction)
- Stroke

- Cardiovascular death

The titration of insulin doses was monitored by [REDACTED] and reviewed by an internal titration committee composed of members from Novo Nordisk A/S, and any significant changes from the titration algorithm were addressed.

Contract Research Organisations

The following contract research organisations (CROs) were used ([Table 6–1](#))

Table 6–1 Contract Research Organisations

Name	Address	Responsibility
Central Laboratories		
		All laboratory analyses for Denmark, France, Israel, Poland, Romania, Russian Federation and U.K. with exception of insulin antibody
		All laboratory analyses for Australia with exception of insulin antibody
		All laboratory analyses for U.S. with exception of insulin antibody
Titration Surveillance		
		Titration surveillance Australia
		Titration surveillance U.S.
		Titration surveillance Denmark, France, Israel, Poland, Romania, Russian Federation, U.K.
		All laboratory insulin antibody analyses for all countries

Name	Address	Responsibility
Cardiovascular Event Adjudication		
		Management of Cardiovascular Event Adjudication
EDC		
		eCRF
IV/WRS		
		IV/WRS
Data management		
		Data management

All laboratories used identical, standardised analysis methods and reference ranges; see [Appendix 16.1.10](#). Laboratories were responsible for sending the data electronically to Novo Nordisk A/S.

7 Introduction

7.1 Therapeutic area

Diabetes mellitus is characterised by chronic hyperglycaemia and encompasses various metabolic disorders. It is generally classified according to aetiological factors, where type 1 and type 2 diabetes mellitus constitute the vast majority of cases.

The natural pattern of endogenous insulin secretion can be divided into two components: basal secretion and meal-related secretion. Subjects with type 1 diabetes are lacking insulin secretion entirely and therefore need complete exogenous insulin replacement to cover basal as well as meal-related (bolus) insulin requirements.

A number of landmark studies have demonstrated the importance of maintaining tight glycaemic control to reduce the risk of long-term complications associated with type 1 diabetes.^{4,5} In general, it is recommended to aim for an $HbA_{1c} < 7.0\%$, without significant hypoglycaemia.⁶

Insulin analogues have been developed to more closely mimic endogenous insulin secretion as compared with human insulin preparations and are now an established part of diabetes management. Currently, insulin detemir (IDet) and insulin glargine (IGlar) cannot be mixed with any rapid-acting insulin analogues due to formulation issues.⁷⁻¹⁰ This has prompted the development of insulin degludec (IDeg), an ultra-long-acting insulin that is intended for use as a basal insulin as well as in a co-formulation with insulin aspart (IAsp).

7.2 IDegAsp

Insulin degludec/insulin aspart (IDegAsp) is an insulin combination product of ultra-long-acting IDeg with rapid-acting IAsp, formulated to maintain the ability of IDeg to form multi-hexamers at the injection site without interfering with the rapid release of IAsp monomers into the circulation. IDegAsp is formulated such that IDeg exists as di-hexamers and IAsp as hexamers. After subcutaneous injection, IDeg di-hexamers assemble to form soluble and stable multi-hexamers, creating a depot of insulin in the subcutaneous tissue, while IAsp hexamers promptly separate into monomers that rapidly enter the circulation. IDeg monomers gradually separate from the multi-hexamers, resulting in a slow and continuous delivery of IDeg into the circulation.

IDegAsp will provide main meal coverage as well as at least 24-hour basal coverage for people with diabetes mellitus when used once daily, and will therefore offer distinct advantages (i.e., greater ease of use and compliance, and reduced hypoglycaemia) over existing insulin therapies. As IDegAsp is soluble, the product can be injected immediately, without any mixing.

IDeg differs from human insulin in that the threonine in position B30 has been omitted, and a side-chain consisting of a glutamic acid spacer with a fatty acid attached to position B29.

IAsp is homologous to human insulin, except that proline is substituted with aspartic acid at position B28. The rapid action of IAsp is related to a weakened tendency of the insulin molecules to self-associate because of this modification, leading to faster absorption as compared with human insulin.

IDegAsp is designed to result in similar or improved glycaemic control compared to treatment with currently available insulin products. The basal component of IDegAsp, IDeg, is even longer-acting than currently available basal insulin analogues.¹¹ This is believed to result in an even more stable and predictable insulin profile with lower day-to-day variation in fasting plasma glucose (FPG) than those attained with the currently available insulin analogues. A significantly (four times) lower within-subject variability in glucose-lowering activity compared with IGlax has recently been demonstrated.¹²

7.3 IDet

IDet (Levemir[®]) is a long-acting soluble insulin analogue, indicated for treatment of diabetes mellitus in combination with oral antidiabetic agents and as part of a basal-bolus insulin regimen.

In IDet, the threonine at position B30 of the human insulin molecule has been omitted, and a C14 fatty-acid side-chain has been attached directly to position B29.¹³

The protracted action of IDet (up to 24 h) is mediated by strong self-association of IDet molecules at the injection site and albumin binding via the fatty-acid side-chain. These combined mechanisms of protraction provide a more reproducible absorption and action profile of IDet with less pronounced peak effect and lower within-subject variation, compared to Neutral Protamine Hagedorn (NPH) insulin, thus providing lower mean and day-to-day variability in FPG, lower risk of nocturnal hypoglycaemia and less body-weight gain.¹⁴⁻¹⁶

For further details, refer to the current versions of summary of product characteristics (SmPC) for IDet and the U.S. Label Information and any updates of these documents.^{17,18}

7.4 IAsp

IAsp (NovoRapid[®], NovoLog[®]) is a rapid-acting analogue indicated for the treatment of diabetes mellitus. IAsp is also one of the active substances in IDegAsp (see above).

Compared with human insulin, IAsp has a faster onset and a shorter duration of action, resulting in superior postprandial glycaemic control by means of lowering total glucose excursion following a meal, both in subjects with type 1 diabetes mellitus,¹⁹⁻²¹ and in subjects with type 2 diabetes

mellitus.²²⁻²⁴ This also allows IAsp to be injected immediately before (or even soon after) a meal, in contrast to soluble human insulin products.

For further details, refer to the current version of the SmPC²⁵ and the U.S. Label Information²⁶ and any updates of these documents.

7.5 Rationale for the Trial

Standard care in type 1 diabetes mellitus is the basal-bolus (BB) therapy, where short-acting insulin is injected prior to each meal and long-acting insulin is injected once daily (OD) or twice daily (BID) to cover the basal insulin requirements. This regimen has proven to be successful in reducing the incidence of late diabetic complications as shown in the Diabetes Control and Complication Trial.⁵ However, low and relatively constant basal insulin levels are difficult to obtain with the currently available long-acting insulin preparations. IDegAsp represents a new class of soluble insulin combination products comprising the ultra-long-acting basal insulin, IDeg, and the rapid-acting insulin, IAsp. Treatment with IDegAsp OD provides prandial coverage of the main meal on top of a stable, ultra-long-acting basal coverage in subjects with type 2 diabetes mellitus. Thus, treatment with IDegAsp OD plus IAsp for the additional meals is expected to offer a safe and intensive treatment regimen with the convenience of fewer injections than the current BB regimens.

The purpose of this trial was to investigate long-term safety and efficacy after 52 weeks of treatment (26 weeks in the main trial NN5401-3594 plus 26 weeks in the present extension trial) with the treatment regimen of IDegAsp OD plus IAsp for the additional meals, in subjects with type 1 diabetes.

8 Trial Objectives

As stated in the protocol (included in [Appendix 16.1.1](#)), the objectives of the trial were as follows:

Primary Objective:

The primary objective was to investigate the long-term safety and tolerability of IDegAsp OD + meal-time IAsp for the remaining meals. This was done by comparing the difference between IDegAsp OD + meal-time IAsp for the remaining meals and IDet + meal-time IAsp treatment (26 weeks of treatment in the main trial NN5401-3594 plus 26 weeks of treatment in the present extension trial) in terms of the listed safety assessments:

- Adverse events
- Hypoglycaemic episodes
- Clinical evaluations
- Central laboratory assessments including lipid profile and insulin antibodies
- Body weight
- Insulin dose

Secondary Objective:

The secondary objective was to compare the efficacy between IDegAsp OD + meal-time IAsp for the remaining meals and IDet + meal-time IAsp after 52 weeks of treatment in terms of the listed assessments:

- HbA_{1c}
- Fasting plasma glucose (FPG)
- 9-point self measured plasma glucose profile (9-point profile (SMPG))
- Self measured plasma glucose (SMPG) for dose adjustments

9 Investigational Plan

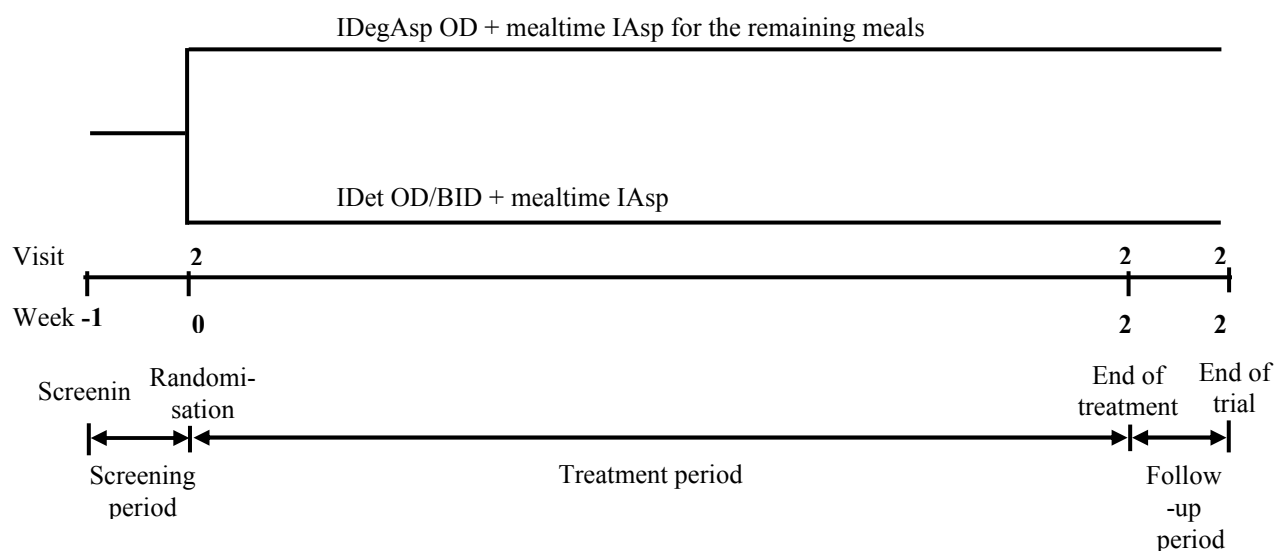
9.1 Overall Trial Design and Plan: Description

The main trial (NN5401-3594) was a 26-week, 2:1 randomised, parallel group trial comparing two active treatment groups in subjects with type 1 diabetes: IDegAsp OD + IAsp for the remaining meals and IDet + meal-time IAsp, and the present 26-week extension trial was with the same treatment regimen to ensure the most optimal coverage of both basal and bolus requirements. Subjects who consented to participate in the extension trial continually received treatment with either IDegAsp OD + meal-time IAsp or IDet + meal-time IAsp as previously randomly allocated in the main trial NN5401-3594. The randomisation was carried out in a 2:1 manner to IDegAsp OD (at any meal) and IAsp at the remaining meals or IDet and meal-time IAsp.

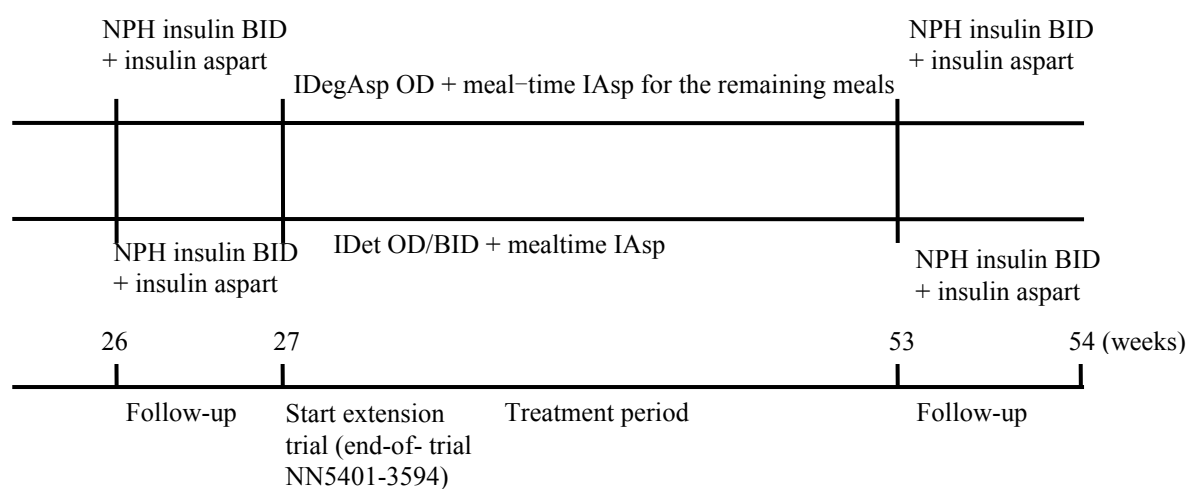
The main trial included a screening visit and a randomisation visit. The subjects were required to attend further visits and phone contacts during the 26 weeks of treatment, followed by a follow-up visit of one week. The extension trial included a screening visit to assess eligibility on the same day as the follow-up visit in the main trial. The subjects were required to attend further 7 visits and 7 phone contacts during the 26 weeks of treatment, followed by a follow-up visit of one week after discontinuing the trial treatment. The total duration of each subject's participation in the extension trial was approximately 28 weeks ([Figure 9-1](#)).

The trial population constituted a population with type 1 diabetes mellitus who would benefit from intensified therapy, applying a treat-to-target concept. The planned number of subjects to be screened and complete the main trial was 754 and 447 respectively. The planned number of subjects to be screened (335) and complete the current extension trial (285) was based on the sample size determination method outlined in Section [9.7.10](#). All subjects enrolled in the extension trial had previously been participating in the 26-week main trial (NN5401-3594) and received maximum of 52 weeks of treatment in total.

Trial design – Main trial



Trial design –Extension trial



IDegAsp = insulin degludec/insulin aspart; IDet = insulin detemir; OD = once daily

Figure 9–1 Trial Design

No interim analyses were performed in this trial.

An internal Novo Nordisk A/S safety committee performed ongoing safety surveillance during the trial.

The titration of insulin doses was monitored by [REDACTED] and reviewed by an internal titration committee composed of members from Novo Nordisk A/S, and any significant changes from the titration algorithm were addressed.

9.2 Discussion of Trial Design, Including the Choice of Control Groups

Control Groups

Basal- Bolus regimen is currently the standard of care in type 1 diabetes. Therefore, the present extension trial had an active comparator group (IDet + IAsp at insulin-requiring meals) which was the same as for the main trial NN5401-3594. Addition of a second dose of IDet was described in the Insulin Titration Guideline in case of inadequate glycaemic control in subjects.

Trial Design

This extension trial had the same trial design as the main trial NN5401-3594, i.e. a parallel, open-labelled and multinational trial design.

An open trial design was chosen as the two treatment regimens required different number of daily injections.

The multinational approach was to ensure that the results were applicable for subjects with different ethnic/racial characteristics.

The total treatment period of 52 weeks (including 26 weeks of treatment in the main trial NN5401-3594 and 26 weeks of treatment in the present extension trial) was expected to be sufficient to confirm the long-term safety of treatment with IDegAsp. Each treatment period of the main trial and the extension trial had a follow-up period of at least seven days to ensure that all IDegAsp was washed out when measuring insulin antibodies.

The visit schedule with visits/phone contacts weekly in the main trial and every second week in the extension trial was chosen to ensure:

- Optimal treatment with continued dose adjustment (based on SMPG values) to achieve and maintain glycaemic targets
- Optimisation of compliance

Assignment and Blinding

An open-label trial design was chosen as the two treatment regimens required a different number of daily injections. The subjects were randomised in a 2:1 ratio using an IV/WRS at the beginning of the main trial and there was no further randomisation in the extension trial period. The unequal randomisation was performed in order to ensure an adequate number of subjects exposed to IDegAsp in the entire clinical programme. After completion of the main trial, eligible subjects continued with the same treatment regimen as in the main trial (NN5401-3594).

9.3 Selection of Trial Population

9.3.1 Inclusion Criteria

Inclusion Criteria in the Main Trial

1. Informed consent obtained before any trial-related activities. (Trial related activities were defined as any procedure that would not have been performed during normal management of the subject)
2. Male or female ≥ 18 years of age
3. Type 1 diabetes mellitus (diagnosed clinically) for ≥ 12 months
4. Ongoing daily treatment with insulin (in a BB regimen, premix insulin regimen, self-mix regimen) for at least 12 months prior to Visit 1
5. HbA_{1c} 7.0-10.0% (both inclusive) by central laboratory analysis
6. Body mass index (BMI) ≤ 35.0 kg/m²
7. Ability and willingness to adhere to the protocol including performance of SMPG profiles according to the protocol
8. Subject was likely to comply with the investigators instruction.

Rationale for Inclusion Criteria in the Main Trial

The bullet numbers correspond to the numbering of the inclusion criteria.

1. In accordance with the Helsinki Declaration, human subjects had to consent participation in a clinical trial
2. As adolescents are not the focus in the current stage of the development program, the inclusion of adolescents are not warranted in accordance with the Helsinki Declaration and ICH guidelines
3. To assure certainty of type 1 diabetes mellitus diagnosis
4. All subjects required insulin and were used to inject themselves with insulin and perform SMPG
5. In order to assure that the subjects were able to control the disease to a certain degree, an upper limit of HbA_{1c} was included. An HbA_{1c} of < 7.0 % is the identified goal for good glycaemic control by the ADA. Subjects optimised on current anti-diabetic therapy with an HbA_{1c} ≥ 7.0 % are considered in focus for additional antidiabetic therapy.

6. To include a wide distribution of subjects while limiting participation of individuals with severe insulin resistance
7. Self-explanatory
8. Self-explanatory

Inclusion Criteria in the Extension Trial

1. Informed consent obtained before any trial-related activities. (Trial related activities were defined as any procedure that would not have been performed during normal management of the subject)
2. The subject must have completed the 26-week treatment period (Visit 28) in trial NN5401-3594

Rationale for Inclusion Criteria in the Extension Trial

The bullet numbers correspond to the numbering of the inclusion criteria.

1. In accordance with the Declaration of Helsinki, human subjects must consent to participate in a clinical trial.
2. To investigate the long-term safety and efficacy of IDegAsp + meal-time IAsp

9.3.2 Exclusion Criteria

Exclusion Criteria in the Main Trial

1. Treatment with other insulin regimens than those listed in inclusion criterion number 4 within 3 months prior to Visit 1
2. BB regimen with basal insulin injected BID
3. Use within the last 3 months prior to Visit 1 of any other antidiabetic glucose lowering drug than insulin
4. Anticipated change in concomitant medication known to interfere significantly with glucose metabolism, such as systemic corticosteroids, beta-blockers, monoaminoxidase (MAO) inhibitors
5. Anticipated significant lifestyle changes during the trial, shift work (including permanent night/evening shift workers), as well as highly variable eating habits
6. Cardiovascular disease, within the last 6 months prior to Visit 1, defined as: stroke; decompensated heart failure New York Heart Association (NYHA)²⁷ class III or IV; myocardial infarction; unstable angina pectoris; or coronary arterial bypass graft or angioplasty
7. Uncontrolled treated/untreated severe hypertension (systolic blood pressure $\geq$ 180 millimetre [mm] mercury [Hg] and/or diastolic blood pressure $\geq$ 100 mmHg)
8. Impaired liver function, defined as alanine aminotransferase (ALAT) $\geq$ 2.5 times upper limit of normal (1 retest analysed at the central laboratory within a week of receipt of the results was permitted with the result of the last sample being conclusive)

9. Impaired renal function defined as serum-creatinine $\geq 180 \mu\text{mol/L}$ ($\geq 2 \text{ mg/dL}$). One (1) retest analysed at the central laboratory within a week of receipt of the results was permitted with the result of the last sample being conclusive
10. Recurrent severe hypoglycaemia (more than 1 severe hypoglycaemic event during the last 12 months) or hypoglycaemic unawareness as judged by the investigator or hospitalisation for diabetic ketoacidosis during the previous 6 months
11. Proliferative retinopathy or maculopathy requiring treatment according to the investigator
12. Pregnancy, breast-feeding, the intention of becoming pregnant or not using adequate contraceptive measures according to local requirements (for Germany: implants, injectables, combined oral contraceptives, hormonal intrauterine device, sexual abstinence or vasectomised partner; for U.K.: Adequate contraceptive measures were defined as established use of oral, injected or implanted hormonal methods of contraception, sterilisation, intrauterine device or intrauterine system, or consistent use of barrier methods)
13. Cancer and medical history of cancer (except basal cell skin cancer or squamous cell skin cancer)
14. Any clinically significant disease or disorder, which in the investigator's opinion could have interfered with the results of the trial
15. Mental incapacity, psychiatric disorder, unwillingness or language barriers precluding adequate understanding or co-operation, including subject not able to read or write
16. Previous participation in this trial. Participation was defined as randomised. Re-screening of screening failures was allowed only once within the limits of the recruitment period.
17. Known or suspected allergy to any of the trial products or related products
18. Receipt of any investigational drug within 1 month prior Visit 1
19. Donation of blood or participation in other trials within 1 month prior to Visit 1.
20. Known or suspected abuse of alcohol, narcotics or illicit drugs

Subjects randomised in error (not fulfilling the inclusion and/or exclusion criteria) were to be withdrawn immediately from the trial.

Rationale for Exclusion Criteria in the Main Trial

The bullet numbers correspond to the numbering of the exclusion criteria.

1. Only subjects treated with an insulin regimen typical for type 1 diabetes mellitus (as listed in inclusion criteria number.4) were included in this trial
2. For safety reasons all subjects were to start the trial on basal insulin OD
3. To minimise confounding factors in assessment of IDegAsp effect on HbA_{1c}
4. Changes in dose of drugs interfering significantly with the glucose levels were not allowed as they could have influenced HbA_{1c} (the primary endpoint)
5. For safety reasons since IDegAsp has a prandial insulin component
6. Including subjects with serious and recently active heart conditions, as the ones listed, in a treat-to-target trial could have created a higher risk than benefit

7. Including subjects with severe uncontrolled hypertension in a treat-to-target trial would have created a higher risk than benefit
8. Including subjects with liver enzyme values indicating impaired liver function was a safety issue
9. Including subjects with advanced renal disease in a treat-to-target trial could have created a higher risk than benefit
10. Including subjects with recurrent severe hypoglycaemia or hypoglycaemic unawareness in a treat-to-target trial could have created a higher risk than benefit
11. Including subjects with proliferative retinopathy or maculopathy requiring treatment in a treat-to-target trial could have created a higher risk than benefit due to the risk of worsening of the condition
12. Standard requirement for participation in clinical trials with new chemical or biological entities
13. Cancer is a severe condition associated with increased mortality. It may affect different organs with a variety of types, and be at different stages. Since it was impossible to be specific for each of the types/stages, subjects with known cancer were not included in the trial due to increased mortality risk due to cancer. In addition, participation in a trial could have been an additional burden for the subject on top of the treatment and diagnostic procedures related to their cancer. Subjects with history of any cancer were not included for the same reasons, as to exclude the possibility of its recurrence or actual presence even in the cases of 5-year (or longer) survival. Subjects with basal cell skin cancer or squamous cell skin cancer were allowed as these cancers were not associated with high mortality risk
14. These conditions could have confounded trial results
15. To avoid inclusion of subjects that could not have been able to adhere to trial treatment and procedures
16. Standard requirement for participation in clinical trials
17. To avoid risk of allergic reactions as they could have put the subjects at risk
18. Standard requirement for participation in clinical trials
19. Donating blood could have lowered HbA_{1c} and thus could have influenced key inclusion criteria
20. Subjects abusing alcohol, narcotics or illicit drugs could be unable to adhere to trial treatment and procedures

Exclusion Criteria in the Extension Trial

1. Anticipated change in concomitant medication known to interfere significantly with glucose metabolism, such as systemic corticosteroids, beta-blockers, monoamine oxidase (MAO) inhibitors
2. Anticipated significant lifestyle changes during the trial, e.g. shift work (including permanent night/evening shift workers), as well as highly variable eating habits
3. Pregnancy, breast-feeding, the intention of becoming pregnant or not using adequate contraceptive measures according to local requirements (for Germany: implants, injectables, combined oral contraceptives, hormonal intrauterine devices, sexual abstinence or vasectomised

partner; for United Kingdom (GB): Adequate contraceptive measures are defined as established use of oral, injected or implanted hormonal methods of contraception, sterilisation, intrauterine device or intrauterine system, or consistent use of barrier methods)

4. Known or suspected allergy to any of the trial products or related products

Rationale for Exclusion Criteria in the Extension Trial

The bullet numbers correspond to the numbering of the exclusion criteria.

1. Changes in dose of drugs interfering significantly with the glucose levels were not allowed as they could have influenced HbA_{1c} (the secondary endpoint)
2. For safety reasons since IDegAsp has a prandial insulin component
3. Standard requirement for participation in clinical trials with new chemical or biological entities
4. To avoid risk of allergic reactions as they could have put the subjects at risk

9.3.3 Removal of Subjects from Therapy and Assessment

The subject could withdraw from the trial at will at any time.

The subject could be withdrawn from the trial at the discretion of the investigator due to safety concerns or if judged non-compliant with trial procedures.

Withdrawal Criteria in the Main Trial

A subject was to be withdrawn in the main trial if the following applied:

1. Pregnancy or intention of becoming pregnant
2. Hypoglycaemia during the treatment period posing a safety problem as judged by the investigator
3. Protocol deviation having influence on efficacy or safety data as judged by the investigator
4. Subjects randomised in error (not fulfilling the inclusion and/or exclusion criteria)
5. Initiation or significant change of any systemic treatment which in the investigator's opinion could have interfered with glucose metabolism (inhaled corticosteroids were allowed)
6. Donation of blood or participation in other trials throughout the trial
7. Lack of effect: After Week 12, if the subject had not had reduction in HbA_{1c} and had a prebreakfast SMPG reading > 13.3 mmol/L (240 mg/dL) on 3 consecutive days despite appropriate dose adjustments. The subject contacted the investigator and came in for an unscheduled visit as soon as possible (within 1 week). The next scheduled visit was not awaited. An FPG was obtained and analysed by the central laboratory. If this FPG exceeded 13.3 mmol/L (>240 mg/dL) and no treatable intercurrent cause for the hyperglycaemia was diagnosed, the subject was withdrawn.

Rationales for Withdrawal Criteria in the Main Trial

The bullet numbers correspond to the numbering of the withdrawal criteria.

1. Standard requirement for clinical trials with new chemical or biological entities

2. Safety issue
3. Important protocol deviations had to be considered by the investigator if they had influenced on efficacy and safety
4. Self-explanatory
5. Changes in dose of drugs interfering significantly with the glucose levels were not allowed as they could have influenced HbA_{1c} (the primary endpoint)
6. Donating blood could have lowered HbA_{1c} and thus influenced key efficacy criteria. It is a standard requirement that participation in another trial was not allowed
7. Subjects could not be exposed for a long time to ineffective treatment. Twelve (12) weeks reflected clinical practice to allow adequate titration and obtain a valid HbA_{1c} measurement

Withdrawal Criteria in the extension Trial

A subject was to be withdrawn in the extension trial if the following applied:

1. Pregnancy or intention of becoming pregnant
2. Hypoglycaemia during the treatment period posing a safety problem as judged by the investigator
3. Major protocol deviation having influence on efficacy or safety data as judged by the investigator
4. Initiation of or significant change to any systemic treatment which in the investigator's opinion could interfere with glucose metabolism (inhaled corticosteroids were allowed)
5. Donation of blood or participation in other trials throughout the trial
6. Lack of effect: not in acceptable glycaemic control when the maximum effects of the treatment regimens were seen, at the discretion of the investigator
7. Lack of effect: after week 12 of the extension trial and at any time point thereafter, if the subject has not had reduction in HbA_{1c} and has a pre-breakfast SMPG reading > 13.3 mmol/L (240 mg/dL) on three consecutive days despite appropriate dose adjustments. The subject should contact the investigator and come in for an unscheduled visit as soon as possible (within one week). The next scheduled visit should not be awaited. An FPG should be obtained and analysed by the central laboratory. If this FPG exceeded 13.3 mmol/L (>240 mg/dL) and no treatable intercurrent cause for the hyperglycaemia had been diagnosed, the subject had to be withdrawn.

Rationales for Withdrawal Criteria in the Extension Trial

The bullet numbers correspond to the numbering of the withdrawal criteria.

1. Standard requirement for clinical trials with new chemical or biological entities
2. Safety issue
3. Important protocol deviations had to be considered by the investigator if they had influence on efficacy and safety
4. Changes in dose of drugs interfering significantly with the glucose levels were not allowed as they could have influenced HbA_{1c}

5. Donating blood could have lowered HbA_{1c} and thus influenced key efficacy criteria. It is a standard requirement that participation in another trial was not allowed
6. Subjects should not be exposed for a long time to ineffective treatment. Twelve (12) weeks reflected clinical practice to allow adequate titration and obtain a valid HbA_{1c} measurement
7. Subjects could not expose for a long time to ineffective treatment. Twelve (12) weeks reflected clinical practice to allow adequate titration and obtain a valid HbA_{1c} measurement

If a subject was prematurely withdrawn from the trial the investigator had to ensure that the procedures for Visit 44 (end-of-treatment visit) and Visit 45 (follow-up visit) were undertaken, if possible. The same procedure also applied for subjects withdrawn during the main trial.

Withdrawn subjects were not replaced. Predicted withdrawal rate was 15%; see Section [9.7.10](#).

9.4 Treatments

9.4.1 Treatments Administered

During the main trial, all subjects randomised to IDegAsp were to be instructed to administer IDegAsp OD at any main meal. IAsp was used for bolus administration at the remaining main meals and was to be injected with the meals.

During the main trial, all subjects randomised to IDet were to be instructed to initiate IDet OD. IDet was to be dosed at the evening meal or at bedtime according to local practice. IAsp was used for bolus administration and was to be injected with each main meal. In case of inadequate glycaemic control at Visit 10 or later (i.e., after at least 8 weeks of treatment and optimisation of dosing), the investigator was to consider adding a second dose of IDet in the morning, based on the fulfilment of specific criteria.

At Visit 28 (end of treatment) in the main trial, subjects were instructed to switch basal insulin treatment to the intermediate-acting NPH insulin injected BID + mealtime IAsp until the follow-up visit (Visit 29).

All subjects who completed the main trial NN5401-3594 (Visit 28) and found eligible for the present extension trial (Visit 30) were encouraged to participate. The antidiabetic treatment (NPH insulin + IAsp) that subjects received during the follow up period of the main trial was discontinued when entering the extension trial and subjects were instructed to restart treatment with either IDegAsp + IAsp or IDet + IAsp according to what they were randomised to in the main trial (NN5401-3594). Subjects were instructed to re-start treatment with their respective trial insulin products preferably at the same dose levels as reported at end of treatment in the main trial. The dose of insulin was adjusted according to the current dose levels, the treatment response and most recent SMPG measurements obtained. The insulin dose adjustments were to follow the titration

guidelines stated in the protocol. A central titration committee at Novo Nordisk A/S followed up on repeated deviation from the titration algorithm.

At Visit 44 (end of treatment), subjects were instructed to switch basal insulin treatment to the intermediate-acting NPH insulin injected BID + mealtime IAsp during the follow-up period before measurement of antibodies. All insulin products used in this trial were injected in the abdomen, upper arm (deltoid region) or thighs. Rotation of injection sites within a given region was recommended.

9.4.2 Identity of Investigational Products

The trial products during the treatment were as follows:

- IDegAsp 100 U/mL, 3 mL FlexPen®
- IDet (Levemir®) 100 U/mL, 3 mL FlexPen®
- IAsp (NovoRapid®, NovoLog®) 100 U/mL, 3 mL FlexPen®
- NPH insulin (Insulatard®, Protaphane®, Novolin N™) 100 U/mL, 3 mL FlexPen®

Novo Nordisk A/S, Denmark, provided the trial products. Details of the preparations including batch numbers are shown in [Table 9–1](#). For batch numbers of each subject, refer to [Appendix 16.1.6](#).

Table 9–1 Trial Products

Trial Product	Dose	Batch Number	Expiry Date
IDegAsp (F) 100 U/mL, 3 mL FlexPen®	Individual	XP 50558,	07 January 2011
		EU: XP 51553,	19 February 2011
		US, EU, IO: XP 52373	18 February 2011
IDet (Levemir®) 100 U/mL, 3 mL FlexPen®	Individual	US: XP 50990	28 February 2011
		EU, IO, AU: XP 51112	19 February 2011
		US: XP 52645	16 January 2011
IAsp (NovoRapid®, NovoLog®) 100 U/mL, 3 mL FlexPen®	Individual	EU: YP 50152	29 March 2012
		EU, IO, AU: XP 50716	15 July 2011
		US: XP 51084	12 September 2011
NPH insulin (Insulatard®, Protaphane®, Novolin N™) 100 U/mL, 3 mL FlexPen®	Individual	EU: XP 52291	15 March 2012
		XP 51117,	19 April 2011,

AU = Australia; EU = European Union ; IO = International Operations (Israel, Russian Federation); U.S. = United States. IDegAsp = insulin degludec/insulin aspart; IDet = insulin detemir; IAsp = insulin aspart; NPH = Neutral Protamine Hagedorn;

Cross-reference: [Appendix 16.1.6](#)

All insulin products were administered via the FlexPen[®] insulin delivery device and were stored between 2°C and 8°C and were not allowed to freeze. The investigator was to ensure the availability of proper storage conditions and keep a temperature log to document the right temperature interval. The temperatures during storage were to be monitored by a calibrated, stationary and continuously recording system. In case of storage outside the temperature range the investigator was to contact the monitor. Trial products stored outside the temperature range were not to be used and were to be stored separately within allowed temperature ranges until after evaluation of the deviation by Novo Nordisk A/S. Fifteen (15) minutes outside the indicated range was considered negligible and allowed, and were not to be recorded as a deviation. Returned trial products (partly used or unused including empty packaging material) was to be stored separately from non-allocated trial products.

Once opened (i.e., during use), IAsp, IDet and NPH insulin were to be stored according to approved labelling. IDegAsp was to be kept at a temperature below 30°C and was not to be refrigerated. Insulin preparations (both not in-use and in-use) were not exposed to excessive heat or direct sunlight. The product was not used if it did not appear clear and colourless.

Trial products were packaged and labelled by Novo Nordisk A/S, Denmark. Labelling was in accordance with local law and trial requirements. Each investigational site was supplied with sufficient trial products for the trial on an ongoing basis controlled by the IV/WRS. Dispensing units were prepared and distributed to the sites according to enrolment and randomisation. Note that the trial product labelling was different from the labelling of the marketed or to be marketed products.

The subjects were provided with directions for the use of IDegAsp, IAsp, IDet and NPH insulin. These were distributed separately by the investigator according to the flow charts (see [Table 9–8](#) and [Table 9–9](#)). The distribution was documented in the subject notes.

None of the insulin products were used after the expiry date.

Auxiliary Supply

The following were also supplied by Novo Nordisk A/S:

- Needles for insulin pens
- Blood glucose meters, including lancets, plasma-calibrated test strips and control solutions

9.4.3 Method of Assigning Subjects to Treatment Groups

During the main trial, subjects enrolled at Visit 1 were to be provided with a Subject Participation Card stating that the subject was participating in the trial and contact details (site address, investigator name and telephone number). Eligible subjects were to be randomised in a 2:1 manner using an IV/WRS to 1 of the following 2 treatment groups:

- IDegAsp OD + IAsp

● IDet OD + IAsp

This unequal randomisation was performed in order to ensure an adequate number of subjects were exposed to IDegAsp during the clinical development program.

Randomisation was stratified with respect to previous insulin regimen with the categories:

- BB regimen or
- Other insulin regimen

There was no further randomisation in the extension trial. Subjects participating in this extension trial were instructed to re-start the same treatment regimen to which they were allocated in the main trial

9.4.4 Selection of Doses in the Trial

Initiation of IDegAsp + IAsp

Subjects Currently on Basal-Bolus Therapy

In the main trial, subjects were to be initiated on the same number of basal units as the subject received prior to randomisation.

Subjects Currently on Premix/Self-mix Therapy

Subjects were to initiate the IDegAsp regimen with an approximately 1:1 ratio between basal and bolus insulin. Current total daily insulin dose (before randomisation) was to be calculated, and 70% of the total daily insulin dose was to be prescribed as IDegAsp OD, while 30% of the total daily insulin dose was to be split and given as IAsp at the remaining main meals.

Initiation of IDet + IAsp

For subjects randomised to IDet + IAsp the starting dose of IDet should be determined according to [Table 9-2](#).

Table 9–2 Start Dose of IDet

Prior treatment	Start dose of IDet once daily
NPH or other basal insulin	Prescribe the same number of units once daily at the evening meal or at bedtime.
Premixed or self-mixed insulin	Calculate the total daily basal insulin component and prescribe the same total daily basal dose as IDet given once daily at the evening meal or at bedtime. If prior basal insulin component was taken more than once daily, dose reduction should be considered according to the investigator's discretion.

IDet: insulin detemir; NPH: Neutral Protamine Hagedorn

Similarly, the subjects were to continue the same doses of IAsp at mealtime as taken prior to randomisation.

In the extension trial, subjects were instructed to re-start treatment with respective trial insulin products preferably at the same dose levels (same number of units) as reported at end of treatment (Visit 28) in trial NN5401-3594. There was possibility for dose adjustment at the discretion of the investigator taking into consideration the dose levels, treatment response and most recent SMPG measurements obtained during treatment with NPH insulin + IAsp in the follow-up period.

9.4.5 Selection and Timing of Dose for Each Subject

In general, the same treatment algorithms as specified were applied to both the main trial and the extension trial regarding the titration of trial insulin products. Furthermore, subjects were allowed to adjust insulin doses in between visits according to individual requirements. No maximum dose of any insulin was specified.

Titration of Basal Insulin (IDegAsp or IDet)

IDegAsp was injected OD at any of the main meals and the injection of IDegAsp could be moved to another main meal during both the main and the extension trial. IDet was injected at the evening meal or at bed time. Increase in IDegAsp or IDet evening dose was based on the mean prebreakfast plasma glucose (PG) from the preceding three days. The insulin dose adjustments were performed according to the titration guidelines shown in [Table 9–3](#) and [Table 9–4](#) (see [Appendix C](#) of the Protocol in [Appendix 16.1.1](#)).

Table 9–3 Increase of IDegAsp or Evening IDet

Mean prebreakfast PG		Adjustment of IDegAsp or IDet U
mmol/L	mg/dL	
< 5.0	< 90	No adjustment
< 10.0	< 180	+ 2
< 15.0	< 270	+ 4
≥ 15.0	≥ 270	+ 6

PG = Plasma Glucose; IDegAsp = Insulin degludec/insulin aspart; IDet = insulin detemir

If one or more low PG values occurred without any obvious explanation, the IDegAsp or IDet dose was reduced according to the lowest SMPG value, see [Table 9–4](#).

Table 9–4 Reduction of IDegAsp or Evening IDet

Prebreakfast PG		Adjustment of IDegAsp or IDet U
mmol/L	mg/dL	
< 3.1	< 56	- 4 (for a dose of >45 U, suggest a dose reduction of 10%)
≤ 3.9	≤ 70	- 2 (for a dose of >45 U, suggest a dose reduction of 5%)

PG = Plasma glucose; IDegAsp = Insulin degludec/insulin aspart; IDet = insulin detemir

If subject only measured PG values on two of the last three days prior to the contact, insulin dose titration was based on these values. If PG measurements were only available for one day, these were used to assess the need for insulin dose adjustment at the discretion of the investigator.

Titration of second dose of IDet (Morning dose)

Subjects treated with IDet OD in the main trial and the extension trial had the option of switching to twice daily dosing of IDet in case the subjects met all of the following three criteria for inadequate glycaemic control (and met no withdrawal criteria, please refer to Section [9.3.3](#)):

1. Lack of improvement in glycaemic control, i.e.
 - For subjects with main trial NN5401-3594 baseline (Visit 1) HbA_{1c} < 8.0%: any deterioration of HbA_{1c} or
 - For subjects with main trial NN5401-3594 baseline (Visit 1) HbA_{1c} between 8.0% and 10%: (both inclusive): improvement in HbA_{1c} which was less than 0.5 percentage point.
2. Mean pre-dinner PG > 6.0 mmol/L (108 mg/dL).
3. No treatable concurrent disease causing hyperglycaemia has been diagnosed.

The starting dose for the second dose of IDet was 4U prescribed at breakfast. Increase of the morning IDet dose was based on the mean predinner PG from the preceding 3 days using the titration algorithm in [Table 9–5](#).

Table 9–5 Increase of Morning IDet

Mean predinner PG		Adjustment of IDet U
mmol/L	mg/dL	
< 5.0	< 90	No adjustment
< 10.0	< 180	+ 2
< 15.0	< 270	+ 4
≥ 15.0	≥ 270	+ 6

PG = plasma glucose; IDet = insulin detemir

If one or more low PG values occurred without any obvious explanation, the dose of IDet was reduced according to the lowest SMPG value, see [Table 9–6](#).

Table 9–6 Reduction of Morning IDet

Predinner PG		Adjustment of IDet U
mmol/L	mg/dL	
< 3.1	< 56	- 4 (for a dose of >45 U, suggest a dose reduction of 10%)
≤ 3.9	≤ 70	- 2 (for a dose of >45 U, suggest a dose reduction of 5%)

PG = plasma glucose; IDet = insulin detemir

Titration of Bolus Insulin (IAsp)

Any increase of the IAsp was based on the mean pre-prandial PG using the titration algorithm shown in [Table 9–7](#). If subject only measured PG values on two of the last three days prior to the contact, insulin dose titration was based on these values. If PG measurements were only available for one day, these were used to assess the need for insulin dose adjustment at the discretion of the investigator.

Table 9–7 Titration of Meal-time IAsp

Mean premeal PG		Adjustment of IAsp U
mmol/L	mg/dL	
< 5.0	< 90	No adjustment
< 8.0	< 144	+2
< 10.0	< 180	+3
≥ 10.0	≥ 180	+4

PG = plasma glucose; IAsp = insulin aspart

The prebreakfast IAsp dose was titrated according to the mean prelunch PG. The prelunch IAsp dose was titrated according to the mean predinner PG. The predinner IAsp dose was titrated

according to the mean bedtime PG. The subject was allowed to inject an additional bolus dose of IAsp in order to cover an additional main meal.

Treatment with NPH Insulin During Follow-up

At Visit 28 and Visit 44, subjects in both treatment groups were instructed to switch to treatment with NPH insulin for the 1-week follow-up period. Since NPH insulin is an intermediate-acting insulin, it was to be administered BID. Subjects randomised to IDet + IAsp were to reduce their total daily basal dose at end of treatment by 20% and divide by two to be administered morning and evening. Subjects randomised to IDegAsp + IAsp were to determine their total daily basal dose at end of treatment, reduce it by 20% and divide by 2 to be administered morning and evening. IAsp was used for bolus administration and was to be injected with each main meal.

9.4.6 Blinding

This was an open-label trial and there was no blinding of investigators and subjects due to different number of daily injections required by the two treatment regimens.

See Section [9.2](#) for further details regarding assignment and blinding of trial products.

9.4.7 Prior and Concomitant Therapy

Concomitant illness

Concomitant illness was defined as any illness that was present at the start of the trial (i.e. at the first visit).

Concomitant medication

Concomitant medication was defined as any medication other than the trial product(s) that was taken during the trial, including the screening periods.

Details of all concomitant illnesses, medical history and concomitant medication in the main trial were to be recorded at trial entry (i.e., at Visit 1). Details of all concomitant illnesses and medication were recorded at extension trial entry (at Visit 30). Adverse events that were not yet recovered by the end of the main trial NN5401-3594 were not regarded as concomitant illnesses in the extension trial. Concomitant medication recorded during trial NN5401-3594 which was still taken at start of the extension trial was transcribed to a concomitant medication form for the extension trial by the investigator. Any changes in concomitant medication were recorded at each visit. If the change influenced the subject's eligibility to continue in the trial, the sponsor was informed. Concomitant illnesses and medication recorded at main trial screening visit were used as baseline.

Details of all medical history and allergy towards medication and or food, pollen or other types of allergies were recorded at trial entry.

9.4.8 Treatment Compliance

At each visit the investigator emphasised the necessity for the subject to adhere to trial procedures in order to encourage subject compliance. During extension trial period, the subject compliance was assessed by monitoring of drug accountability at Visits 6, 10, 18, 28 and 29 in the main trial, and Visits 37, 44 and 45 in the extension trial (please see Section [9.5.1.1](#)). The unused amount of trial product was assessed against the dispensed amount and, in case of discrepancies, the subject was asked for clarification. Substantial failure to comply with the prescribed insulin dosage regimen led to withdrawal of subject.

In addition, the investigator assessed the compliance of the subject at each visit based on a review of glycaemic control, adherence of the visit schedule, completion of the subject's diary including the SMPG profiles. If a subject was discovered to be non-compliant, the investigator was to inform the subject of the importance of taking trial products as directed.

9.5 Efficacy and Safety Variables

9.5.1 Efficacy and Safety Measurements Assessed and Flow Chart

9.5.1.1 Flow Chart

The main trial consisted of a screening visit (Visit 1), a randomisation visit (Visit 2), a 26-week treatment period (Visit 3 to Visit 28) after which a follow-up visit (Visit 29) was to be performed.

Procedures for the scheduled visits and phone contacts are described in the section below and in the flowcharts [Table 9–8](#).

Table 9–8 Trial Flow Chart- Main Trial

Trial NN5401-3594 Type 1	Screen	Rand	0-26 weeks Visit window ± 3 days													FU
			V3	V4	V6	V8	V10	V12	V14	V16	V18	V22	V26	V28	V29	
Phone Contact number (P) ¹ (For details see separate flowchart below)			P5 P7 P9 P11 P13 P15 P17 P19 P23 P27 P20 P24 P21 P25													
Time of visit ⁴ (weeks)	-1 ²	0	1	2	4	6	8	10	12	14	16	20	24	26	27 ³	
Visit window (days)			± 3	± 3	± 3	± 3	± 3	± 3	± 3	± 3	± 3	± 3	± 3	-3	+5	
SUBJECT RELATED INFO/ASSESSMENTS																
Informed consent	x															
In/Exclusion criteria	x	X														
Randomisation		x ⁵														
Withdrawal criteria			x	x	x	x	x	x	x	x	x	x	x	x	x	
Demography	x															
Diagnosis of diabetes	x															
Concomitant illness/Medical history	x															
Concomitant medication	x	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Height	x															
Body weight	x	x ⁶							x ⁶		x ⁶				x ⁶	
EFFICACY																
Fasting plasma glucose ⁶		X							x		x				x	
HbA _{1c}	x	X					x		x		x	x			x	
4-point profile ⁷		X	x	x	x	x	x	x	x	x	x	x	x	x	x	x
9-point profile ⁸		X							x		x				x	
SAFETY																
Adverse events	x	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Insulin antibodies ⁶		X							x						x	x
Biochemistry	x														x	
Haematology	x														x	
Lipids ⁶		X													x	
Urinalysis	x														x	
Pregnancy test ⁹	x														x	
Urine Albumin/creatinine ratio		X													x	
ECG – 12 lead	x ¹⁰														x	
Eye examination (fundoscopy/fundusphotography)	x ¹⁰														x ¹¹	
Hypoglycaemic episodes		X	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Hypo event questionnaire ¹²		X	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Physical examination	x														x	
Vital signs	x														x	
OTHER ASSESSMENTS																
PRO questionnaires ¹³		X							x						x	
End of trial																x
TRIAL MATERIAL																
IV/WRS call	x	X			x		x				x				x	x
Drug accountability (IV/WRS)					x		x				x				x	x
Dispensing visit		X			x		x				x				x	

Trial NN5401-3594 Type 1	Screen	Rand	0-26 weeks Visit window ±3 days													FU
Visit Number (V)	V1	V2	V3	V4	V6	V8	V10	V12	V14	V16	V18	V22	V26	V28	V29	
 Phone Contact number (P) ¹ (For details see separate flowchart below)	P5 P7 P9 P11 P13 P15 P17 P19 P23 P27 P20 P24 P21 P25															
Time of visit ⁴ (weeks)	-1 ²	0	1	2	4	6	8	10	12	14	16	20	24	26	27 ³	
Visit window (days)			±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	-3	+5	
Dispense directions for use		X			x		x				x			x		
First date and dose on trial insulin (IDegAsp or IDet)			x													
Date, dose and time (time point) of trial insulin, on 3 days before visit			x	x	x	x	x	x	x	x	x	x	x	x	x ¹⁴	
New (prescribed) dose of trial insulin		X	x	x	x	x	x	x	x	x	x	x	x	x		
Last date and dose on trial insulin (IDegAsp or IDet)														x		
Date and dose of NPH insulin ¹⁵															x	
REMINDERS																
Attend visit fasting		X							x		x			x	x	
Make appointment for Eye examination at end of trial										x						
Handling/training of product/device ¹⁶		X	x											x		
Instruction//handout of glucose meter	x															
Hand-out/instruction diary	x	X	x	x	x	x	x	x	x	x	x	x	x	x		
Sign off case book			x												x	

FU = follow-up; IDegAsp = insulin degludec/insulin aspart; IDet = insulin detemir; ECG = electrocardiogram; PRO = patient reported outcome; IV/WRS = interactive voice/web response system

1. A phone contact was converted to a visit if for instance, further titration attention was needed.
2. Screening took place approximately 1 week prior to randomisation.
3. Follow-up visit was not to be performed earlier than 7 days after Visit 28/end-of-treatment.
4. Time of visit was always to be calculated in relation to the actual date of the randomisation visit.
5. In case of retesting of laboratory samples, randomisation was not to be performed before the results of the retest were obtained and the investigator had confirmed that the subject complied with the inclusion/exclusion criteria. The retesting was to be performed within the screening period of approximately 1 week.
6. Fasting visits: The subjects had to attend Visits 2, 14, 18, 28 and 29 fasting, having consumed only water since midnight, for measurement of lipids (Visits 2 and 28), weight and fasting plasma glucose (Visits 2, 14, 18, and 28) and insulin antibodies (Visits 2, 14, 28 and 29). No diabetes medication was allowed on the day of the visit before the blood sample was drawn. If the subjects attended the trial site in a non-fasting condition, the visit was to be re-scheduled within the next two working days.
7. 4-point profiles (self-measured plasma glucose [SMPG]) were preferably to be taken on the 3 consecutive days just before Visits 2-29. Measurements, in both treatments arms, were to be taken before breakfast, lunch, main evening meal and bedtime.

8. 9-point profiles (SMPG) were to be started in the morning 2 days before Visits 2, 14, 18 and 28. Measurements were to be performed before and after (90 minutes after the start of the meal) breakfast, lunch, main evening meal, before bedtime, at 4 a.m. and before breakfast on the following day. Note that the 9-point profile was overlapping with the 4-point profile.

9. Pregnancy test: At Visits 1 and 28, a blood pregnancy test was to be performed in women of child bearing potential. During the trial, a urine pregnancy test was to be performed if a menstrual period was missed or whenever pregnancy was suspected. If at phone contacts, subjects report missed menstrual period, the subject was to attend the site for a urine pregnancy test.

10. Electrocardiogram and fundoscopy/fundusphotography performed within 8 weeks before Visit 2 were acceptable if results were available at the visit.

11. Fundoscopy/fundusphotography performed within a period of 2 weeks before Visit 28 was acceptable, if results were available at the visit.

12. A hypoglycaemic event questionnaire was to be used at all visits, but only if a subject reported to have experienced 1 or more hypoglycaemic events (symptomatic or asymptomatic) since last visit or phone contact.

13. Patient reported outcome (PRO) questionnaires; a battery of several PRO questionnaires evaluated health related quality of life, treatment satisfaction and preferences. The PRO questionnaires were to be filled in by the subject at the visits, preferably before any other trial related procedures, in a confidential manner.

14. Only the total dose of IAsp was to be recorded and only on the last day before Visit 29

15. Dose of insulin neutral protamine Hagedorn during Days 1, 3 and 5 after Visit 28 (last treatment visit) and on the day just before Visit 29.

16. Instruction was to be done in the start of the trial and if required.

The extension trial consisted of a screening visit (Visit 30), a 26-week treatment period (Visit 31 to Visit 44) after which a follow-up visit (Visit 45) was to be performed. The screening visit of extension trial was took place on the same day as the follow-up visit in the main trial NN5401-3594. Procedures for the scheduled visits and phone contacts in extension trial period were described in the section below and in the flow chart (see [Table 9-9](#)).

If a planned phone contact for some reason was not performed according to the visit schedule, the investigator was to ensure that the phone contact was performed within visit window of the originally planned phone contact.

[illegible]

Trial NN5401-3645 (extension trial) Type 1	Screen	1-26 weeks Visits														FU
Visit number (V)  Phone Contact number (P) ¹	V30 ²	P31	P32	V33	P34	V35	P36	V37	P38	V39	P40	V41	P42	V43	V44	V45
Time of visit ³ (weeks)	27 ²	28	29	31	33	35	37	39	41	43	45	47	49	51	53	54 ⁴
Visit window (days)		±3	±3	±3	±6	±6	±6	±6	±6	±6	±6	±6	±6	±6	-3	+5
Date, dose and time (time point) of trial insulin, on 3 days before visit		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x ¹⁹
New (prescribed) dose of trial insulin	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Last date and dose on trial insulin (IDegAsp and NPH insulin or IDet and NPH insulin)															x	X
Date and dose of NPH insulin ²⁰																X
REMINDERS																
Attend visit fasting	x ²¹							x							x	X
Make appointment for Eye examination at EOT (V 44)								x								
Handling/training of product/device ²²	X														x	
Instruction/handout of glucose meter ²³	X															
Hand-out/instruction diary	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Sign off case book																X

1. A phone contact might be converted to a visit if for instance further titration attention was needed.
2. Start of extension trial screening visit (Visit 30) was same time as trial NN5401-3594 follow-up visit (Visit 29).
3. Time of visit was always calculated in relation to the actual date of the screening visit (Visit 30).
4. Follow-up visit (Visit 45) was not performed earlier than seven days after end-of-treatment (Visit 44).
5. The informed consent process including obtaining informed consent was preferably take place during trial NN5401-3594 and at the latest at the screening visit (Visit 30) before any trial-related activities took place.
6. Demography, diagnosis of diabetes and height were transferred from trial NN5401-3594 screening visit (Visit 1) to extension trial screening visit (Visit 30) and were not performed by the investigator again.
7. Adverse events that were not yet recovered by the end of trial NN5401-3594 were not regarded as concomitant illnesses in extension trial.
8. Concomitant medication recorded during trial NN5401-3594 which was still being taken at start of extension trial (Visit 30) was transcribed by the investigator to a concomitant medication form for extension trial at screening visit (Visit 30).
9. Fasting visits: The subjects must attend Visits 30, 37, 44 and 45 fasting, having consumed only water since midnight for measurement of lipids (Visits 30 and 44), weight and fasting plasma glucose (Visits 30, 37 and 44) and insulin antibodies (Visits 30, 37, 44 and 45). No diabetes medication was allowed on the day of the visit before the blood sample had been drawn. If the subjects attended the site in a non-fasting condition the visit was re-scheduled within the next two working days.
10. 4-point profiles (SMPG) was preferably performed on the three consecutive days just before Phone Contact 31-Visit 45. Measurements, in both treatments arms, were to be taken before breakfast, lunch, main evening meal and bedtime.
11. 9-point profiles (SMPG) was started in the morning two days before Visits 37 and 44. Measurements were to be performed before and after (90 min after the start of the meal) breakfast, lunch, main evening meal, before bedtime, at 4 a.m. and before breakfast on the following day. Please note that the 9-point profile was overlapping with the 4-point profile.

12. Adverse events were not linked between trial NN5401-3594 and extension trial. Adverse events that were not yet recovered by the end of trial NN5401-3594 were to be followed up on NN5401-3594 AE follow-up forms.
13. Adverse events were collected from the time the first trial-related procedure had taken place at extension trial screening visit (Visit 30) and not from the time of informed consent.
14. This measurement of Insulin antibodies was required both in accordance with trial NN5401-3594 follow-up visit (Visit 29) and extension trial screening visit (Visit 30). The result from trial NN5401-3594 Visit 29 was transferred to extension trial Visit 30 and the assessment was only performed at extension trial Visit 30 if not done at trial NN5401-3594 Visit 29.
15. These measurements of biochemistry, haematology, lipids, urinalysis, urine albumin/creatinine ratio, physical examination, ECG and funduscopy/fundusphotography were required both in accordance with trial NN5401-3594 end-of-treatment visit (Visit 28) and extension trial screening visit (Visit 30). The results from trial NN5401-3594 Visit 28 were transferred to extension trial Visit 30 and the assessments were only performed at extension trial Visit 30 if not done at trial NN5401-3594 Visit 28.
16. Pregnancy test: at Visit 30 a urine pregnancy test and at Visit 44 a blood pregnancy test were performed in women of childbearing potential. During the trial a urine pregnancy test was performed if a menstrual period was missed or whenever pregnancy was suspected. If at phone contacts, subjects reported missed menstrual period, the subject was had to attend the site for a urine pregnancy test.
17. Funduscopy/fundusphotography performed within a period of three weeks before end-of-treatment visit (Visit 44) was acceptable if results were available at the visit.
18. If a subject was discontinued in extension trial due to an ongoing adverse event from trial NN5401-3594, the primary reason for discontinuation was entered under 'Other' in the End of Trial form.
19. Only the total daily dose and date of insulin aspart were recorded and only on the last day before follow-up visit (Visit 45).
20. Total daily dose and date of NPH insulin during days 1, 3, and 5 after Visit 44 (end-of-treatment Visit) and on the day just before Visit 45 (follow-up Visit).
21. Subjects were fasting according to trial NN5401-3594 follow-up visit (Visit 29) schedule.
22. Instruction was done at the start of the trial, before the follow-up period and if required.
23. Was only supplied if the blood glucose meter from trial NN5401-3594 can not be re-used.

Screening Visit in Main Trial(Visit 1)

Screening took place approximately 1 week prior to randomisation. Before screening took place, subjects were to be provided with written information about the trial and the procedures involved, in accordance with local requirements. Subjects were to be fully informed, orally and in writing, of their responsibilities and rights while participating in the trial, as well as of possible advantages/disadvantages when being treated with the trial medication (IDegAsp + IAsp or IDet + IAsp). Subjects were to be given the opportunity to ask questions, and to have ample time to consider participation. The informed consent process was to take place before the screening visit (Visit 1). Subjects who participated in the trial were to sign and date the informed consent form before any trial-related procedures.

All subjects were to be provided with a copy of their own signed and dated informed consent forms.

If the investigator was not the subject's primary physician, the investigator was to notify the primary physician about the subject's trial participation. If required, permission from the subject was to be requested.

Subjects were to continue on their current diabetes treatment until the randomisation visit (Visit 2), and they were not to be supplied with any trial medication until then.

At screening, the subjects were assigned unique subject identification (ID) which remained the same throughout the trial. The subject ID consisted of 6 digits (the first 3 digits indicating site number and the last 3 digits indicating subject number).

The following were to be performed and/or recorded in the eCRF in addition to what was already described in the flowcharts (see [Table 9–8](#)):

- Signed informed consent form(s), date and time
- Demography:
 - Date of birth
 - Sex
 - Race[#]
 - Ethnicity[#]
- Diagnosis of diabetes:
 - Date of diagnosis of diabetes
- Diabetes treatment history (concomitant medication):
 - Current diabetes treatment (prior to the screening visit (Visit 1) and until randomisation)
 - Dose of current diabetes treatment
 - Start date of current diabetes treatment

[#] Collection of race and ethnicity was not performed in France, as this was not authorised by the French law.

Randomisation Visit (Visit 2) to Main Trial Follow-up Visit

For randomisation visit (Visit 2) to follow-up visit (Visit 29), see [Table 9–8](#).

After end of IDegAsp + IAsp or IDet + IAsp treatment or if the trial insulin treatment was discontinued earlier than expected, the investigator was to ensure that the procedures for Visit 28 (end-of-treatment visit), the follow-up period and Visit 29 (follow-up visit) were undertaken.

After the follow-up visit, or if the subject did not wish to complete the follow-up period, the subject was to be transferred to a suitable marketed product as recommended by the investigator. If transferred to another insulin product after treatment with IDegAsp, careful titration of the subsequent antidiabetic treatment was to be carried out based on glucose measurements (SMPGs) due to the long effect and half-life of IDegAsp (IDeg component).

All subjects were offered to participate in an extension trial (NN5401-3645) following the 1-week follow-up period. A separate protocol, subject information and informed consent form was prepared for the extension trial. Verbal and written information was provided to the subjects and the informed consent form was signed by the subject and the investigator.

Screening Visit in Extension Trial (Visit 30)

Before screening took place (Visit 30), subjects were provided with written information about the trial and the procedures involved, in accordance with local requirements. Subjects were fully informed, orally and in writing, of their responsibilities and rights while participating in the trial, as well as of the possible advantages/disadvantages of being treated with the trial medication (IDegAsp + IAsp or IDet + IAsp). Subjects had the opportunity to ask questions, and had ample time to consider participation. Subjects who wished to participate in the trial then signed, dated and recorded the clock time on the informed consent for the trial before any trial-related procedures took place. The informed consent process including obtaining informed consent may preferably take place during trial NN5401-3594 and at the latest at the screening visit (Visit 30) before any trial-related procedures took place.

All subjects were provided with a copy of their own signed and dated informed consent form.

If the investigator was not the subject's primary physician, the investigator was to preferably notify the primary physician about the subject's trial participation. If required, permission was given by the subject.

Subjects were identified by the same subject number given in trial NN5401-3594. At screening, the subjects were re-assigned the same unique subject identification (ID) which remained the same throughout the trial. The subject ID consisted of six digits (the first three digits indicating site number and the last three digits indicating subject number).

Screening Visit (Visit 30) to Follow-up Visit (Visit 45) in Extension Trial

From extension trial screening visit (Visit 30) to follow-up visit (Visit 45), refer to [Table 9–9](#) for further detailed procedure. During the treatment period there were mandatory visits to the clinic at week 27, 31, 35, 39, 47, 51, 53 and 54. In addition there was a visit in the form of a telephone contact at week 28, 29, 33, 37, 41, 45 and 49. Further unscheduled visits could be performed at the discretion of the investigator. At Phone Contact 31 on week 28, information on first date and dose on trial product (IDegAsp or IDet) in extension trial was recorded.

Information on demography, diagnosis of diabetes and height were transferred from trial NN5401-3594 screening visit (Visit 1) to extension trial screening visit (Visit 30).

Insulin antibodies results from trial NN5401-3594 follow-up visit (Visit 29) were transferred to extension trial screening visit (Visit 30) and the assessment was only performed at extension trial screening visit (Visit 30) if not done at trial NN5401-3594 follow-up visit (Visit 29).

The results of biochemistry, haematology, lipids, urinalysis, urine albumin/creatinine ratio, physical examination, ECG and funduscopy/fundusphotography from trial NN5401-3594 end-of-treatment visit (Visit 28) were transferred to extension trial screening visit (Visit 30) and the assessments

were only performed at extension trial screening visit (Visit 30) if not done at trial NN5401-3594 end-of-treatment visit (Visit 28).

At Visit 44 (end-of-treatment) information on last date and dose on trial products (IDegAsp or IDet) was recorded.

At visit 44 (end-of-treatment) subjects were instructed to switch basal insulin treatment to the intermediate acting NPH insulin and meal time IAsp until the follow-up visit (Visit 45).

Visit 45 (follow-up visit) was not performed any earlier than seven days after the end-of-treatment visit. All subjects attended the follow-up visit fasting and without having taken any insulin (neither NPH insulin nor insulin aspart) on the morning of the day of the follow-up visit.

At Visit 45 (follow-up visit) information on date and dose of first and last injection of NPH insulin was recorded. In addition information on date and total daily dose of NPH insulin on days 1, 3 and 5 after Visit 44 (end-of-treatment visit) and on the day just before Visit 45 (follow-up visit) was recorded.

If a subject was prematurely withdrawn from the trial, the investigator was to ensure that the procedures for Visit 44 (end-of-treatment visit) and Visit 45 (follow-up visit) were undertaken. Subjects were switched to NPH insulin + meal-time IAsp at the end-of-treatment visit until the follow-up visit (if these were done on different days).

9.5.1.2 Efficacy Assessments

The following efficacy variables were assessed in both the main trial and the extension trial:

. HbA_{1c}

. FPG

. SMPG

- 4-point profiles (SMPG)
- 9-point profile (SMPG) with additional 4-point profiles (SMPG)

The following efficacy variable was only assessed in the main trial:

PRO questionnaires

- Treatment Related Impact Measure - Diabetes (TRIM-D)
- Diabetes Medication Satisfaction Questionnaire (DiabMedSat)
- Diabetes Productivity Measure Questionnaire (DPM)
- Short-form 36 version 2 Health Survey (SF-36 v2)

The timing of assessments is outlined in the trial flow charts. Descriptions of assay methods and reference ranges are provided in [Appendix 16.1.10](#).

HbA_{1c}

Blood samples for HbA_{1c} were to be collected and analysed at Visits 1, 2, 10, 14, 18, 22 and 28 in the main trial and at Visits 30, 33, 35, 37, 39, 41, 43 and 44 in extension trial. The assay method used was a National Glycohaemoglobin Standardization Program certified method, refer to [Appendix 16.1.10](#).

FPG

FPG samples were to be collected at Visits 2, 14, 18 and 28 in the main trial and at Visits 30, 37 and 44 in the extension trial. The subjects had to attend these visits fasting.

Self-Measured Plasma Glucose

At Visit 1 in the main trial and Visit 30 in the extension trial, subjects were supplied with a glucose meter and instructions on use of the device including regular calibration according to the manufacturer's instructions ([Appendix 16.1.1](#)).

Subjects were instructed in how to record the results of the SMPG values in the diaries provided and only recorded the plasma glucose values based on glucose meter measurements. The record of each plasma glucose measurement included date and plasma glucose value.

4-point profiles (SMPG)

Subjects were asked to perform SMPG measurements at four different time points, before breakfast, lunch, main evening meal and bedtime. Measurements were preferably to be performed on three consecutive days just before each scheduled visit or phone contact using the glucose meter provided. SMPG measurements before breakfast were preferably performed after having consumed only water since midnight, and before insulin injection. SMPG measurements before lunch, main evening meal and bedtime were performed before insulin injection. These measurements were required for optimal insulin dose adjustment and maintenance as described in the Insulin Titration Guideline, Protocol [Appendix C](#) ([Appendix 16.1.1](#)).

It is important that SMPG measurements were recorded on the same days as the insulin doses were recorded.

9-point profile (SMPG) with additional 4-point profiles (SMPG)

Subjects were instructed to perform a 9-point profile (SMPG) with additional 4-point profiles (SMPG) on the three days immediately before Visits 2, 14, 18 and 28 in the main trial and before Visits 37 and 44 in the extension trial.

The plasma glucose levels were measured and recorded in the diary at the following time points, always starting with the measurement before breakfast on Day 1 (three days before site visit). The 9-point profile (SMPG) included the measurement before breakfast on Day 3. Each plasma glucose

measurement for the 9-point profile (SMPG) included date, time point, actual clock time and plasma glucose value.

The timing of SMPG measurements is summarised in [Table 9–10](#).

Table 9–10 9-point profile (SMPG) (√) with additional 4-point profiles (SMPG) (X)

Time point	Day 1	Day 2	Day 3
Before breakfast	X	√	√
90 min. after the start of breakfast		√	
Before lunch	X	√	X
90 min. after the start of lunch		√	
Before main evening meal	X	√	X
90 min. after the start of main evening meal		√	
Before bedtime	X	√	X
At 04:00 am		√	

Patient Reported Outcome Questionnaires

Patient Reported Outcomes (PROs) were to be assessed by a PRO battery consisting of 4 questionnaires only during the main trial

- Diabetes Medication Satisfaction Questionnaire (DiabMedSat)
- Diabetes Productivity Measure (DPM)
- Short-Form 36 Health Survey, Version 2 (SF-36, v2)

Hypoglycaemia Questionnaire

A hypoglycaemia questionnaire was to be used at all visits in the main trial, but only if a subject reported to have experienced symptoms of one or more hypoglycaemic episodes (symptomatic or asymptomatic) since last visit or phone contact. The investigator or a trial coordinator completed the questionnaire in an interview.

9.5.1.3 Safety Assessments

Adverse Events

Adverse Events (AEs) were recorded by the subjects in the diaries at each visit and were to be transcribed from the diaries to the eCRF. Any clinically significant worsening since baseline of a previous finding was reported as an AE.

Adverse Event Definitions:

An AE is defined as any unfavourable and unintended sign, symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. This included events from the first trial related activity after the subject had signed the IC.

The following were not recorded as AEs:

- Pre-planned procedures unless the condition for which the procedure was planned has worsened from the first trial related activity at Visit 30 after the subject has signed the informed consent.
- Pre-existing conditions found as a result of screening procedures. These were recorded as medical history/concomitant illness.

An AE can also be a clinical laboratory abnormality regarded as clinically significant i.e. an abnormality that suggests a disease and/or organ toxicity and was of a severity which requires active management (i.e. change of dose, discontinuation of trial product, more frequent follow-up or diagnostic investigation).

Serious adverse event (SAE)

A SAE is an experience that at any dose results in any of the following:

- Death
- A life-threatening^{*} experience
- In-subject hospitalisation^{**} or prolongation of existing hospitalisation
- A persistent or significant disability/incapacity^{***}
- A congenital anomaly/birth defect
- Important medical events^{****} that may not result in death, be life-threatening^{*}, or require hospitalisation^{**} may be considered an SAE when, based upon appropriate medical judgement, they may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

^{*} The term “life-threatening” in the definition of SAE refers to an event in which the subject was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it was more severe.

^{**} The term “hospitalisation” describes a period of at least 24 hours. Over-night stay for observation, treatment at emergency room or treatment on an out-subject-basis does not constitute a hospitalisation. However, medical judgement must always be exercised and when in doubt the case should be considered serious.

Hospitalisations for administrative, trial related and social purposes do not constitute hospitalisations as defined by the seriousness criteria for SAEs and should therefore not be

reported as such. Likewise, hospital admissions for surgical procedures planned prior to trial inclusion are not considered adverse events.

*** The term “disability/incapacity” means that following the event the subject or clinical investigation subject has significant, persistent or permanent change, impairment, damage or disruption in his body function or structure, physical activity and/or quality of life.

**** The term “important medical events” means events which may jeopardise the subject or require intervention to prevent a seriousness criterion. It can be AEs which suggest a significant hazard or puts the subject or clinical investigation subject at risk, such as drug-interactions, contra-indications or precautions, occurrence of malignancies or development of drug dependency or drug abuse.

Non-serious adverse event

A non-serious AE is any AE which does not fulfil the definition of a SAE.

Medical Events of Special Interest

Medical events of special interest (MESI) were used as a tool to collect additional information on special adverse events. Events such as medication errors (e.g., wrong drug administration or wrong route of administration) and suspected transmission of an infectious agent via a trial product were always considered as MESI.

MESI were always to be reported to the department responsible for global product safety using both the AE form and the safety information form, irrespective of seriousness. MESI were to be reported within the same timelines as for SAEs. In the event that the investigator chose not to report the above specified AEs as MESI, there could be discrepancies between the protocol-defined MESI and the actually reported MESI.

In addition to the above, the following were also considered to be medical events of special interest for this trial: severe hypoglycaemia (see below for definition), immunogenicity, neoplasms and cardiovascular events.

- **Severe Hypoglycaemia**

Any episode of hypoglycaemia, which fulfils the American Diabetes Association (ADA) definition for a severe hypoglycaemia, i.e. an episode requiring assistance of another person to actively administer carbohydrate, glucagons, or other resuscitative actions, was to be reported always to the department responsible for global product safety on an AE form and safety information form irrespective of seriousness.

- **Cardiovascular Events**

Cardiovascular events which were suspected as related to Acute Coronary Syndrome (ACS), stroke or cardiovascular death were to be reported always to the department responsible for

global product safety on an AE form and safety information form irrespective of seriousness. Please see [Appendix D](#) of Protocol ([Appendix 16.1.1](#)) for definitions of cardiovascular events.

- **Neoplasms**

All types of neoplasm events, i.e. benign, malignant and unspecified (including cysts and polyps) were always reported to the department responsible for global product safety on an adverse event form and safety information form irrespective of seriousness. Medical history and important follow-up data included information about malignancy versus non-malignancy, preferably histologically verified.

- **Immunogenicity**

Events which in the opinion of the investigator were causally related to immune mechanisms to trial product, for example acute immunoglobulin E (IgE) mediated reactions (clinical signs may include anaphylactic reactions, angioedema and urticaria) and delayed type hypersensitivity (clinical signs may include various types of skin rashes), were always reported to the department responsible for global product safety on an adverse event form and safety information form irrespective of seriousness.

For further information regarding MESIs, see [Appendix D](#) to the protocol ([Appendix 16.1.1](#)).

Severity:

- Mild – No or transient symptoms, no interference with the subject's daily activities.
- Moderate - Marked symptoms, moderate interference with the subject's daily activities.
- Severe - Considerable interference with the subject's daily activities, unacceptable.

Relation to trial product:

- Probable: good reasons and sufficient documentation to assume a causal relationship
 - Possible: a causal relationship is conceivable and cannot be dismissed
 - Unlikely: the event is most likely related to an aetiology other than the trial product
- * IDegAsp, IAsp, IDet and NPH insulin must be included in the relationship assessment.

Relation to device:

Any device related issues were to be reported by the investigator to Novo Nordisk A/S.

Technical complaints are reported as part Novo Nordisk's continuous aggregated surveillance of device complaints. The technical complaint data are entered into the Novo Nordisk complaint handling system (COCPIT), whereafter they are investigated further. The results of the investigations are reported to the Novo Nordisk department responsible for safety surveillance on an ongoing basis. All adverse events related to technical complaints are reported in the clinical trial report, Section [12.2.2.4](#).

Outcome:

- Recovered - Fully recovered, or by medical or surgical treatment the condition has returned to the level observed at the first trial related activity at Visit 30 after the subject signed the informed consent.
- Recovering - The condition is improving and the subject is expected to recover from the event. This term should only be used when the subject has completed the trial.
- Recovered with sequelae - As a result of the AE, the subject suffered persistent and significant disability/incapacity (e.g. became blind, deaf, paralysed). Any AE recovered with sequelae should be rated as an SAE.
- Not recovered.
- Death.
- Unknown - This term should only be used in cases where the subject is lost to follow-up.

Reporting of Adverse Events

All adverse events either observed by the investigator or reported spontaneously by the subjects were recorded by the investigator and evaluated.

At each contact with the trial site (visit or telephone, excluding safety visits, where the subject was not seeing the investigator or his staff), the subject was to be asked about AEs.

The subject was asked about AEs (mentioned as 'Medical problems' in the diary) in the following way: "Have you experienced any medical problems since the last contact?"

All AEs either observed by the investigator or reported spontaneously by the subjects were recorded by the investigator and evaluated. All AEs were to be recorded by the investigator on the AE form in the electronic data capture (EDC) application.

The investigator was required to report SAE to Novo Nordisk A/S within 24h. The investigator was to complete the AE form in the EDC application and the safety information form on the paper CRFs and forward to Novo Nordisk A/S within five calendar days.

Coding of Adverse Events

All the serious adverse events were coded using the most recent version of Medical Dictionary for Regulatory Activities (MedDRA) coding (version 13.0). Non-serious adverse events were coded locally by Novo Nordisk A/S personnel or a CRO using the semi-automated Thesaurus Management System (TMS). Serious adverse events were coded by medically qualified staff at International Product Safety, Novo Nordisk A/S. All adverse events were presented based on system organ class and preferred terms.

Treatment and Follow-up of Adverse Events

Any adverse events that occurred during the trial were treated by established standards of care. All serious adverse events and any non-serious adverse events that were severe or probably or possibly related to the trial product were followed up until the subject recovered, stabilised, recovered with sequelae, or died. However, cases of chronic conditions were closed with an outcome of “recovering” or “not recovered”.

All other non-serious AEs were followed until the outcome of the event is “recovering” (for chronic conditions), or “recovered” or until the end of the post-treatment follow-up stated in the protocol, whichever comes first, and until all queries related to these AEs were resolved.

The investigator ensured that the worst case severity and seriousness was kept consistent.

Queries or follow-up requests from Novo Nordisk A/S were responded to within 14 calendar days, unless otherwise specified. The investigator recorded follow-up information on non-serious adverse events by updating the adverse event form in the eCRF.

The investigator forwarded follow-up information on serious adverse events **within 5 calendar days** of obtaining the information. This was done by updating the adverse event form in the eCRF and/or completing the safety information form on paper CRF and forwarding these to Novo Nordisk A/S.

All SAEs were followed until the outcome of the event was recovered, recovered with sequelae or fatal and until all queries were resolved. For cases of chronic conditions and cancer **or if the subject dies from another event** follow-up until the outcome categories were “recovered”, “recovered with sequelae” or “fatal” was not required, as these cases were closed with an outcome of “recovering” or “not recovered”.

After access to update the AE form in the eCRF was removed the investigator recorded any SAE follow-up information, if required, on the paper CRFs provided at study closure.

Hypoglycaemic Episodes

Hypoglycaemic episodes were defined and classified according to the following:

ADA Hypoglycaemic Episode Definition- Classification²⁸

ADA definitions and classification of hypoglycaemia were used for the statistical analyses. According to the ADA, the definition of a hypoglycaemic episode (refer to [Figure 9–2](#)) is categorised as:

Severe hypoglycaemia: an episode requiring assistance of another person to actively administer carbohydrate, glucagons, or other resuscitative actions

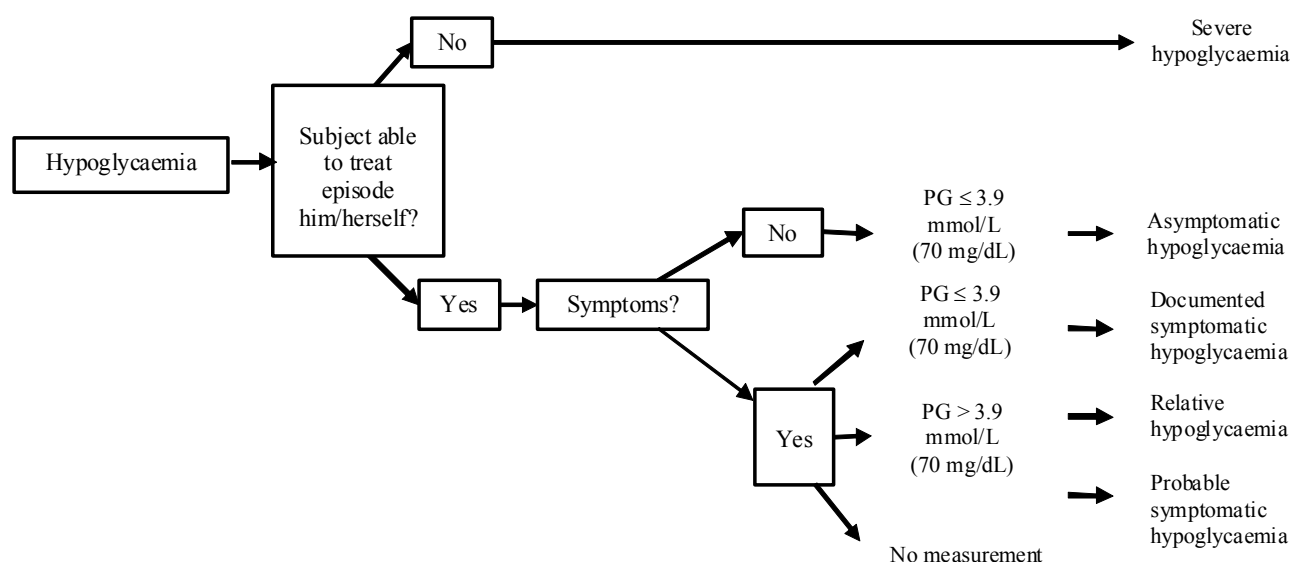
Documented symptomatic hypoglycaemia: an episode during which typical symptoms of hypoglycaemia are accompanied by a measured plasma glucose concentration ≤ 3.9 mmol/l (70 mg/dl)

Asymptomatic hypoglycaemia: an episode not accompanied by typical symptoms of hypoglycaemia, but with a measured plasma glucose concentration ≤ 3.9 mmol/l (70 mg/dl)

Probable symptomatic hypoglycaemia: an episode during which symptoms of hypoglycaemia are not accompanied by a plasma glucose determination (but that was presumably caused by a plasma glucose concentration ≤ 3.9 mmol/l (70 mg/dl).

Relative hypoglycaemia: an episode during which the person with diabetes reports any of the typical symptoms of hypoglycaemia, and interprets those as indicative of hypoglycaemia, but with a measured plasma glucose concentration > 3.9 mmol/l (70 mg/dl).

Unclassifiable: In case a hypoglycaemic episode could not be allocated into any of the above groups it is listed as unclassifiable.



PG = plasma glucose

Figure 9–2 Classification of hypoglycaemia according to ADA

Additional Definition of Confirmed Hypoglycaemic Episodes

The pool of severe and minor hypoglycaemic episodes is referred to as confirmed hypoglycaemic episodes (See also [9.8.2](#)). In normal physiology hypoglycaemia symptoms occur at a blood glucose level of approximately < 2.8 mmol/l (50 mg/dl) / plasma glucose level glucose < 3.1 mmol/l (56 mg/dl). Therefore Novo Nordisk A/S used this cut-off value to define minor hypoglycaemia. Minor hypoglycaemic episode is defined as:

- An episode with symptoms consistent with hypoglycaemia with confirmation by plasma glucose < 3.1 mmol/l (56 mg/dl) or full blood glucose < 2.8 mmol/l (50 mg/dl) and which is handled by the subject himself/herself.
- Or any asymptomatic plasma glucose value < 3.1 mmol/l (56 mg/dl) or full blood glucose value < 2.8 mmol/l (50 mg/dl)

Hypoglycaemic episodes were only recorded as adverse events if they fulfilled the definition of an SAE or if reported as a MESI case of severe hypoglycaemia.

Insulin dose

During both main and extension extension trial (starting at the Visit 2 and Visit 30), subjects were instructed to report the date, time point and insulin dose in the diary on preferably three consecutive days before each visit. The days where the insulin doses were recorded were to be the same days as when the SMPGs were recorded. The recommended insulin doses were calculated automatically in the eCRF based on recommendations from the Insulin Titration Guideline.

Physical examination

Physical examination was carried out at Visits 1 and 28 in the main trial and at Visit 30 and Visit 44 in the extension trial and included:

- Head, ears, eyes, nose, throat, neck
- Respiratory system
- Cardiovascular system
- Gastrointestinal system including mouth
- Musculoskeletal system
- Central and peripheral nervous system
- Skin

The physical examination results from trial NN5401-3594 end-of treatment visit (Visit 28) were transferred to extension trial screening visit (Visit 30) and the assessment was only performed at extension trial screening visit (Visit 30) if not done at trial NN5401-3594 end-of treatment visit (Visit 28).

If any clinically significant worsening from trial NN5401-3594 baseline (Visit 1) occurred, the investigator was to comment in the subject notes and, report this as an AE in trial NN5401-3594.

Any clinically significant worsening from from baseline in the main and extension trial was reported as an AE.

Vital signs

Diastolic and systolic blood pressures and pulse were measured at Visits 1 and 28 in the main trial and at Visit 30 and Visit 44 in extension trial. Diastolic blood pressure, systolic blood pressure and pulse were assessed while the subject was sitting. Measurements were performed after resting for five minutes. Any clinically significant worsening from baseline was to be reported as an AE.

Body weight

Body weight was measured at at Visits 1 and 28 in the main trial and at Visit 30, Visit 37 and Visit 44 in the extension trial. Body weight was measured in kilograms (kg) or pounds (lb) without coat and shoes and wearing only light clothing. Body weight was recorded to one decimal place. The subjects were to be attend these visits fasting (i.e. only intake of water since midnight is allowed).

Eye examination

Eye examination was carried out at Visits 1 and 28 in the main trial and at Vist 30 and Visit 44 in the extension trial. Fundoscopy/fundusphotography was performed by the investigator, a local ophthalmologist or an optometrist according to local practice. Result of the fundoscopy/fundusphotography was interpreted locally by the investigator in relation to the trial. Fundoscopy/fundusphotography performed within 8 weeks before Visit 2 and 2 weeks before Visit 28 in the main trial or within three weeks before end-of-treatment visit (Visit 44) was acceptable. The results of the examination were to be signed and dated by the investigator and evaluated following the categories:

- “Normal”
- “Abnormal, not clinically significant”
- “Abnormal, clinically significant”

Any clinically significant worsening of the fundoscopy/fundusphotography result from baseline in both main and extension trial was to be reported as an AE.

Electrocardiogram (ECG) – 12 lead

A 12-lead ECG was performed at Visits 1 and 28 in the main trial and at Visit 30 and Visit 44 in the extension trial. It was interpreted locally by the investigator in relation to the trial according to the following categories:

- “Normal”

- “Abnormal, not clinically significant”
- “Abnormal, clinically significant”

12-lead ECG was required both in accordance with trial NN5401-3594 end-of-treatment visit (Visit 28) and extension trial screening visit (Visit 30). The results from trial NN5401-3594 end-of-treatment visit (Visit 28) were transferred to extension trial screening visit (Visit 30) and the assessment was only performed at extension trial screening visit (Visit 30) if not done at trial NN5401-3594 end-of-treatment visit (Visit 28).

Any clinically significant worsening from trial NN5401-3594 baseline (Visit 1) was commented in the subject notes and reported as an AE by the investigator in trial NN5401-3594. Any clinically significant worsening of the ECG result from baseline (Visit 30) must be reported as an AE.

Clinical Laboratory Tests

For laboratory analysis of safety and efficacy parameters a total of approximately 120 mL blood could be drawn during the main trial and approximately 80 ml blood was drawn during the extension trial. The laboratory analyses were performed by a central laboratory unless otherwise specified. Descriptions of assay methods, laboratory supplies and procedures for obtaining samples, handling and storage of samples are provided in [Appendix 16.1.10](#).

Laboratory samples (including HbA_{1c}, FPG and pregnancy test) could be drawn on a day other than the day of the actual visit as long as it was within the visit window (e.g., if the subject was not fasting). For measurement of insulin antibodies, serum samples were mixed with radio labelled IDeg, IAsp, IDet or human insulin and incubated overnight. Antigen/ Antibody complexes were precipitated using polyethyleneglycol and bound radioactivity in the precipitate was used to express antibody binding (% bound/ total radioactivity: % B/T).

The following clinical laboratory tests were performed during the trial:

- Haematology and biochemistry (erythrocytes, haematocrit, haemoglobin, leucocytes, thrombocytes and differential count)
- Insulin antibodies (antibodies determination for IDeg specific, IDet specific, IAsp specific and antibodies cross-reacting to human insulin)
- Biochemistry (creatinine, total protein, alanine amino transferase /serum glutamic pyruvic transaminase [ALAT/SGPT], aspartate amino transferase/serum glutamic oxaloacetic transaminase [ASAT/SGOT], alkaline phosphatase [AP], sodium, potassium, albumin and total bilirubin)
- Lipid profile (total cholesterol, high density lipoproteins [HDL cholesterol], low density lipoproteins [LDL cholesterol] and triglycerides [TG])
- Urinary albumin-to-creatinine ratio assessed in spot urine
- Urine by sticks (tests for blood, protein, ketones)

For some of the samples drawn during the trial it was required for the sensitivity of the analysis that the subject was fasting.

Samples were coded in order to keep subject identity anonymous.

Laboratory results were sent by the central laboratory to the investigator on an ongoing basis. Data from the analysis were included in the CTR and the clinical trial database. The antibody data were also included in an analytical report. All laboratory printouts were dated and signed by the investigator on the day of evaluation. If a result is outside the normal range, the investigator judged whether the abnormality is clinically significant. Any clinically significant was reported as an AE.

All samples were destroyed on an ongoing basis after analysis except for insulin antibody samples which were destroyed after approval of IDegAsp.

Pregnancy

Subjects were to notify the investigator immediately if they became pregnant. The investigator was to report any pregnancy reported during the trial to Novo Nordisk A/S, except for pregnancies occurring in the screening period. On enrolment, subjects were to give consent to the investigator reporting any pregnancy during the trial to Novo Nordisk A/S and to provide information about pregnancy, delivery and the health of the infant until age one month.

The investigator was to report information on pregnancy and follow-up within 14 calendar days of obtaining the information. If the pregnancy resulted in an abnormal outcome, such as congenital abnormalities, foetal death, spontaneous abortion, or serious AEs in the neonate, this information was to be forwarded to the department responsible for global product safety within 72 hours from receipt.

For pregnancies in partners of trial subjects, in case of an AE (with a causal relationship evaluated as possible or probable by the investigator) in the foetus, newborn infant(s) or infant(s)/toddler(s) of a trial subject's partner, who was potentially exposed to the trial product via the trial subject, the pregnancy and the AE was to be reported on the same forms as for a subject in the trial.

9.5.1.4 Assessments of Demographic and other Baseline Characteristics

The following baseline characteristics were to be recorded at Visit 1 in the main trial:

- Demography (date of birth, gender, race[#], ethnicity[#])
- Diabetes data (history, complications and current therapy)
- Medical history, concomitant illnesses (also recorded at Visit 30 in the extension trial)

[#] Collection of race and ethnicity was not performed in France, as this was not authorised by French law.

Height

At screening visit (Visit 1), height (without shoes) was to be measured in inches or metres and recorded with two decimal places.

Body mass index

BMI was calculated using the eCRF. BMI calculation: $\text{BMI kg/m}^2 = \text{Body weight (kg)} / (\text{Height (m)} \times \text{Height (m)})$ ($\text{kg/m}^2 = [\text{lb/in}^2 \times 703]$).

Body weight

Body weight was to be measured in kilogram (kg) or pounds (lb) without coat and shoes. Body weight was to be recorded to 1 decimal place. The subjects were to attend these visits fasting (i.e., only intake of water since midnight was allowed) except for screening visit (Visit 1).

Demography, diagnosis of diabetes, height and medical history were transferred from trial NN5401-3594 screening visit (Visit 1) to extension trial screening visit (Visit 30). Baseline was defined at the time of randomisation in the main trial.

Concomitant medication recorded during trial NN5401-3594 which was still taken at start of extension trial were transcribed by the investigator to a concomitant medication form for extension trial at screening visit.

9.5.2 Appropriateness of Measurements

Both efficacy and safety assessments were standard for this type of trial.

9.5.3 Primary Efficacy Variable(s)

Since the primary objective of the present extension trial was to investigate the long-term safety and tolerability of IDegAsp, safety variables including adverse events, hypoglycaemic episodes, clinical evaluations, central laboratory assessments, body weight and insulin dose were the primary endpoints. There were no primary efficacy variables in this trial.

9.6 Data Quality Assurance

The trial was conducted in accordance with Declaration of Helsinki¹ and ICH Good Clinical Practice²⁹.

The trial was monitored by the sponsor by means of on-site visits, telephone calls, and regular inspection of the case report forms (CRFs) with sufficient frequency to verify the following: Subject enrolment; compliance with the protocol; the completeness and accuracy of data entered in the CRFs by verification against original source documents; compliance in the use of trial product; drug accountability; and recording of adverse events.

9.7 Statistical Methods and Determination of Sample Size

9.7.1 General Considerations

The statistical section described the planned statistical analyses as described in the trial protocol ([Appendix 16.1.1](#)). Any changes from the planned analyses were described in Section [9.8.2](#).

9.7.2 Endpoints in Relation to the Objectives and Hypotheses

The primary objective was to investigate the long-term safety and tolerability of IDegAsp. This was done by comparing IDegAsp to IDet after 52 weeks of treatment in terms of safety assessments. The secondary objective was to compare the efficacy between IDegAsp and IDet after 52 weeks of treatment.

Baseline was defined as the time of randomisation in the main trial. Unless otherwise specified missing values including intermittent missing values and values missing in both main trial and extension trial were imputed using the Last Observation Carried Forward (LOCF) method as recommended for its transparency in the FDA guidance.³⁰ In the following section “end of trial” means a subject’s last end of trial visit excluding the follow-up visit in the extension trial.

All endpoints were summarised descriptively at each scheduled visit by treatment and in total using observed data. After 52 weeks of treatment descriptive statistics were presented based on both observed and LOCF imputed data.

LOCF imputed data were used as the basis for plotting data if not otherwise specified. For survival endpoints, Kaplan-Meier plots were presented by treatment.

Only endpoints derived after 52 weeks of treatment were analysed statistically if not otherwise stated. Except for possible exploratory analyses, the statistical models were specified to always include antidiabetic therapy at screening, sex and region (Australia, Europe or North America) as fixed factors, and age as a covariate. The antidiabetic therapy at screening was a factor with two levels according to the stratification in the main trial (BB regimen and other insulin regimen).

Endpoints that were analysed untransformed and endpoints that were not formally analysed were summarised by the arithmetic mean, standard deviation (SD), median, and minimum and maximum value. Endpoints that were analysed log-transformed were summarised by the geometric mean, CV, median, minimum and maximum value.

Presentation of results from statistical analyses included the estimated mean treatment effects (LSMeans) for absolute values and change from baseline if applicable. Estimated mean treatment differences (or ratios) were presented together with two-sided 95% confidence intervals for all endpoints analysed statistically. No p-values were presented as all analyses were considered explorative.

Safety endpoints were summarised and analysed using the Safety Analysis Set. Efficacy endpoints were summarised and analysed using the Full Analysis Set (FAS). The analysis of secondary endpoint, HbA_{1c}, was repeated on the per protocol (PP) analysis set in accordance with the Committee for Proprietary Medicinal Products (CPMP) Points to Consider (CPMP/EWP/482/99).³¹

Analyses were repeated for serious treatment emergent AE's, number of severe and minor treatment emergent hypoglycaemic episodes, anti-bodies, central laboratory parameters (ALAT/SGPT, ASAT/SGOT) and HbA_{1c} using the Extension Trial Set (ETS) to assess the stability of key results.

The impact of protocol deviations and outliers were to be investigated further in sensitivity analyses if deemed relevant.

9.7.3 Definition of Analysis Sets

The following analysis sets were defined in accordance with the ICH-E9 guidance as stated in the main trial (NN5401-3594) protocol.³²

- Full analysis set (FAS): included all randomised subjects. In exceptional cases subjects from the FAS could be eliminated. In such cases the elimination was to be justified and documented. The statistical evaluation of the FAS was to follow the intention-to treat (ITT) principle and subjects were to contribute to the evaluation “as randomised”.
- Per Protocol (PP) analysis set: included subjects without any major protocol violations that may have affected the primary endpoint. Moreover, subjects must have been exposed to the investigational product or its comparator for more than 12 weeks and must have had a valid assessment necessary for deriving the primary endpoint. Subjects in the PP set were to contribute to the evaluation “as treated”.
- Safety Analysis Set: included all subjects receiving at least one dose of the investigational product or its comparator. Subjects in the safety set were to contribute to the evaluation “as treated”.
- Extension Trial Set: included subjects receiving at least one dose of the investigational product or its comparator in the extension trial.

The analysis sets (FAS, PP and Safety analysis set) were defined in the main trial and the assignment of subjects to these analysis sets in the extension trial was following the definition in the main trial.

Randomised subjects who were lost to follow up and where no exposure information of the investigational product or its comparator was available after randomisation were to be handled as unexposed.

Before data were released for statistical analysis, a blinded review of all data was to take place to identify protocol deviations that may potentially have affected the results. This review was to be performed without revealing which trial product the subjects were assigned to. The blinding of the trial products was to be maintained for everyone involved in defining the analysis sets until data were released for statistical analysis. Furthermore, extreme values and outliers were to be identified by the statistician during programming and data review according to ICH-E9, using a fake randomisation.

The decision to exclude any subject or observation from the statistical analysis was the joint responsibility of the study group. The subjects or observations to be excluded and the reason for their exclusion were to be documented and signed by all parties, prior to release of the clinical trial database. The documentation was to be stored together with the remaining trial documentation.

9.7.4 Statistical Analyses

9.7.4.1 Primary Endpoints

The following primary safety endpoints were assessed:

- Adverse events
 - Number of events by medical event of special interest (MESI), system organ class and preferred term, seriousness, severity, relation to trial drug and device, and withdrawal due to AEs and outcome
- Hypoglycaemic episodes
 - Number of episodes by severity (classified according to the American Diabetes Association (ADA) classification and the additional definition for minor episodes)
 - Number of nocturnal episodes by severity (classified according to the ADA classification and the additional definition for minor episodes)
- Clinical evaluations
 - Physical examination
 - Fundoscopy/fundusphotography
 - 12-lead electrocardiogram (ECG)
 - Vital signs
- Central laboratory
 - Haematology (haemoglobin, leucocytes, thrombocytes, haematocrit, differential counts and erythrocytes)
 - Biochemistry (creatinine, total protein, alanine aminotransferase (ALAT), aspartate aminotransferase (ASAT), alkaline phosphatase (AP), sodium, potassium, albumin, and total bilirubin)
 - Lipid profile (low density lipoproteins (LDL), high density lipoproteins (HDL), triglyceride (TG) and total cholesterol)
 - Urinary albumin-to-creatinine ratio assessed in spot urine

- Urine by sticks (central tests for blood, protein and ketones)
- Insulin antibodies (IDeg-, IDet- and IAsp- specific antibodies in the corresponding treatment arms, human insulin cross-reacting antibodies in both arms)
- Body weight
- Insulin dose and time of administration

The timing of each endpoint was defined in the trial flow chart in both the main trial and this extension trial protocol.

Adverse events

Adverse Events were to be coded using the most recent version of Medical Dictionary for Regulatory Activities (MedDRA) coding. All adverse events were presented based on system organ class and preferred terms.

When reporting the trial results the EAC evaluation was employed. All discrepancies between EAC and the investigators' classification of the cardiovascular events were listed by event.

A Treatment Emergent Adverse Event (TEAE) was defined as an event that had onset date on or after the first day of exposure to randomised treatment in the main trial and no later than seven days after the last day of randomised treatment. All AEs occurring in the follow-up period of the main trial for subjects continuing in the extension trial were considered treatment emergent independently of the length of the follow-up period.

TEAEs were summarised descriptively whereas AEs not defined as treatment emergent were presented in listings. The summaries of TEAEs were made displaying the number of subjects with at least one event, the percentage of subjects with at least one event, the number of events and the event rate per 100 years. These summaries were done by seriousness, severity, relation to insulin treatment, relation to device, withdrawal due to AEs and outcome.

Furthermore summary tables based on system organ class and preferred terms were made for:

- All TEAEs
- Serious TEAEs
- Possibly or probably related TEAEs
- Severe TEAEs
- TEAEs with preferred term that are experienced by at least 5% of the subjects in any treatment arm or by at least 5% of all subjects.

Hypoglycaemic episodes

Hypoglycaemic episodes were recorded by subjects in their trial diaries throughout the trial. The information collected was used to classify an episode according to both the ADA definition (severe, documented symptomatic, asymptomatic, probable symptomatic and relative) and the additional classification for minor hypoglycaemic episodes.

A hypoglycaemic episode was defined as treatment emergent if the onset of the episode was on or after the first day of exposure to randomised treatment and no later than seven days after the last day of randomised treatment. All episodes occurring in the follow-up period of the main trial for subjects continuing in the extension trial were considered treatment emergent independent of the length of the follow-up period.

The summaries of treatment emergent hypoglycaemic episodes were the following:

the number of subjects with at least one episode
the percentage of subjects with at least one episode,
the number of episode and the episode rate per 100 years.

separate summaries by severity:

- all episodes
- nocturnal episodes using both the ADA and the additional minor category (refer to Section [9.5.1.3](#))

The nocturnal period was considered as the period between 00:01 and 05:59 a.m. (both included). A hypoglycaemic episode that has time of onset during this period was to be considered nocturnal.

The number of hypoglycaemic episodes was analysed using a negative binomial regression model with a log-link function and the logarithm of the time period in which a hypoglycaemic episode was considered treatment emergent as offset. The model included treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age as covariate. To the extent where data allow, separate analyses were performed for severe episodes, and severe or documented symptomatic episodes considering all episodes and nocturnal episodes separately.

Physical examination

Physical examination included:

- Head, ears, eyes, nose, throat, neck
- Respiratory system
- Cardiovascular system
- Gastrointestinal system including mouth
- Musculoskeletal system
- Central and peripheral nervous system
- Skin

The physical examination measurements and their change from baseline were summarised descriptively.

Vital Signs

Vital signs included diastolic blood pressure, systolic blood pressure and pulse. The measurements and their change from baseline were summarised descriptively.

Laboratory safety parameters

The following laboratory assessments were performed:

- Haematology (haemoglobin, leucocytes, thrombocytes, erythrocytes, haematocrit, differential counts)
- Biochemistry (creatinine, total protein, ALAT/SGPT, ASAT/SGOT, AP, sodium, potassium, albumin, total bilirubin)
- Lipid profile (LDL, HDL, TG and total cholesterol)
- Urinary albumin-to-creatinine ratio assessed in spot urine
- Urine by sticks (tests for blood, protein and ketones)
- Insulin antibodies

Individual laboratory values were compared to their relevant reference range (when existing) and flagged as being below or above the range. Change from baseline was summarised descriptively.

Change from baseline (baseline in the main trial) in lipid endpoints was analysed separately using an Analysis of Variance (ANOVA) method with treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age and baseline value as covariates.

IDeg specific antibodies, IDet specific antibodies, IAsp specific antibodies and cross-reacting antibodies and the correlation to other relevant variables such as, for example, insulin dose and HbA_{1c} were illustrated using descriptive statistics and graphs.

Funduscopy / fundusphotography

Funduscopy and fundusphotography findings were summarised descriptively including summaries of the change from baseline.

ECG

ECG 12-lead findings were summarised descriptively including summaries of the change from baseline.

Body weight

Body weight was assessed at the trial site. Change from baseline in body weight was analysed using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age and baseline body weight as covariates.

Insulin dose and time of administration

Prescribed and actual insulin dose were recorded together with time of administration. Both the basal and bolus insulin dose were summarised descriptively according to regimen as dose in units, units/kg and units/kg per week. The summaries also included information on time of insulin administration in order to document the time of the day patients inject their insulin and the degree to which patient shift injection times during the trial.

9.7.4.2 Secondary Endpoints

Efficacy was addressed in terms of the following list of assessments from which endpoints were calculated, analysed and presented:

- HbA_{1c}
- FPG
- 9-point profile (SMPG)
- SMPG for dose adjustments

HbA_{1c}

The endpoints from the HbA_{1c} assessments were:

- Change from baseline in HbA_{1c} after 52 weeks of treatment
- Responder for HbA_{1c} (< 7.0%)
- Responder for HbA_{1c} at end of trial (< 7.0%) without hypoglycaemic episodes

Change from baseline in HbA_{1c} after 52 weeks of treatments

This endpoint was analysed using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age and baseline HbA_{1c} as covariates.

As sensitivity analyses all observed HbA_{1c} measurements available post randomisation at scheduled measurement times were also analysed in a linear mixed model using an unstructured residual covariance matrix (if possible) as done in the main trial. Any marked difference concerning treatment differences between the different analyses methods was commented upon in the clinical trial report.

Change in HbA_{1c} from baseline was also analysed using a model with only treatment as fixed factor and baseline HbA_{1c} as covariate to assess the sensitivity of the results to inclusion/exclusion of fixed factors and covariates.

Responder endpoints

A dichotomous endpoint (responder/non-responder) was defined based on whether a subject has met the American Diabetes Association (ADA) HbA_{1c} target (HbA_{1c} < 7.0%).

Additional dichotomous endpoints were defined based on whether this treatment target at end of trial was achieved without hypoglycaemic episodes in the last 12 weeks of treatment considering

severe episodes only, and severe and minor episodes together. The endpoints were only defined for subjects that have been exposed for at least 12 weeks in the main trial.

The responder endpoints were analysed separately based on a logistic regression model using treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age and baseline HbA_{1c} as covariates.

Fasting plasma glucose

Change from baseline in FPG after 52 weeks of treatment was analysed using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age and baseline FPG as covariates.

Self measured plasma glucose

Self-measured plasma glucose was measured in terms of the 9-point profile (SMPG) and glucose measurements used for insulin dose adjustments.

9-point profile (SMPG)

A 9-point profile (SMPG) was included measurements before and 90 minutes after start of breakfast, lunch and main evening meal, measurements prior to bedtime and at 4 a.m., and one before breakfast the following day.

The endpoints from a 9-point profile (SMPG) were:

- Mean of the 9-point profile (SMPG)
- Fluctuation in 9-point profile (SMPG)
- Prandial PG increment
- Differences between nocturnal SMPG measurements

The mean of 9-point profile (SMPG) was defined as the area under the profile divided by the measurement time and was calculated using the trapezoidal method. The fluctuation in the 9-point profile (SMPG) was defined as

$$\frac{1}{T} \int_0^T |PG(t) - \overline{PG}| dt$$

where T , $PG(t)$ and, $\overline{PG}$ denotes the length of the profile, the PG value at time t and the mean of the profile, respectively.

Prandial PG increment for each meal was derived from the 9-point profile (SMPG) as the difference between PG values available 90 minutes after meal and before meal. Mean prandial PG increment over all meals was derived as the mean of all available meal increments.

Change in nocturnal PG was assessed by considering the differences between PG values available prior bedtime, at 4 a.m. and the before breakfast value the following day: (4 a.m. PG value minus prior bedtime PG value), (before breakfast PG value minus prior bedtime PG value) and (before breakfast PG value minus 4 a.m. PG value).

A mixed effect model was fitted to the 9-point profile (SMPG) data. The model included treatment, time, interaction between treatment and time, antidiabetic therapy at screening, sex and region as fixed factors, age as covariate and subject as random effect. From the model the mean profile by treatment and relevant treatment differences were estimated and explored.

Mean and fluctuation in the 9-point profile (SMPG), prandial PG increment and nocturnal PG endpoints were analysed separately using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age and the relevant baseline value as covariates. Fluctuation in the 9-point profile (SMPG) was logarithm transformed before analysed.

SMPG values used for dose adjustment

The SMPG values used for dose adjustment were collected and recorded by the subjects for three consecutive days prior to visits and included measurements before main meals (2-4 times daily). Dose adjustment of basal insulin was based on the subjects before breakfast value, and this value was always obtained even if a subject did not eat breakfast. The titration algorithm including information on adjustment of bolus insulin was detailed in the Insulin Titration Guideline, Appendix C.

The endpoints from SMPG measurements obtained throughout the trial for dose adjustment were:

- Mean PG before meal
- Responder for PG titration target
- Time from randomisation (measured in weeks) to achieve titration target
- Within-subject variability as measured by CV%

The mean PG before meal was calculated at each visit using the available data and separately for each meal where data was available.

The mean of before breakfast PG values was analysed using an ANOVA method with treatment, antidiabetic therapy at screening, sex and region as fixed factors, and age and the corresponding mean PG at baseline as covariates.

From the mean before breakfast PG value a dichotomous endpoint (responder/non-responder) was derived showing if a subject has achieved the titration target at each visit.

Two survival endpoints were derived as the time from randomisation to the date a subject met the titration target for the first time, and the time to a subject met the titration target and stayed on the target for the remaining treatment period.

The survival endpoints were analysed separately in a Cox proportional hazards model including treatment, antidiabetic therapy at screening, sex and region as fixed factors and age as covariate. Subjects that were lost for follow-up without meeting the target and subjects that never met the target during treatment were censored at the last day of treatment.

The logarithm transformed SMPG values available before breakfast were analysed as repeated measures in a linear mixed model with treatment, antidiabetic therapy at screening, sex and region as fixed factors and age as covariate and subject as random factor. The model assumed independent within- and between-subject errors with variances depending on treatment. Within-subject variability as measured by CV% for a treatment was calculated from the corresponding residual variance σ^2 as $CV\% = 100\sqrt{(\exp(\sigma^2) - 1)}$. The confidence interval for the CV ratio between treatments was calculated using the delta method.

9.7.5 Interim Analyses

No interim analysis was planned for this trial.

9.7.6 Sequential Safety Analysis/Safety Monitoring

Not applicable.

9.7.7 Exploratory Statistical Analyses for Pharmacogenetics and Biomarkers

Not applicable.

9.7.8 PK and PD Modelling

Not applicable.

9.7.9 Health Economics and/or Patient Reported Outcomes

Not applicable.

9.7.10 Determination of Sample Size

Sample size in this extension trial was determined by the number of subjects continuing from the main trial. At the first visit in the extension trial (Visit 30) subjects were discontinued the regimen of NPH insulin+ IAsp received in the follow-up period of the main trial and restart the same treatment regimen as in the main trial (NN5401-3594) with either IDegAsp OD + IAsp or IDet + IAsp.

It was assumed that 75% of the completers in the main trial would continue in the extension trial from which at least 85% were expected to complete the extension trial.

9.8 Changes in the Conduct of the Study or Planned Analyses

9.8.1 Protocol Amendments and General Procedural Deviations

Protocol Amendments

There were 3 substantial amendments to the protocol (see [Table 9–11](#)). None of the substantial amendments was considered to have any serious implications for the subjects involved in this trial, nor on the overall results of this trial. The substantial amendment 1 was implemented before trial initiation (see [Table 9–11](#) for details). Substantial amendment 2 and 3 were implemented after trial initiation. Refer to the protocol amendments ([Appendix 16.1.1](#)), for further details.

Table 9–11 Substantial Protocol Amendments

Amendment Type	Amendment No.	Date	Countries affected	Content change
Substantial	1_RO	07-Feb-2010	Romania	1 (one) additional site was selected for participation in the trial
Substantial	2_RO	25-Mar-2010	Romania	1 (one) additional site was selected for participation in the trial
Substantial	3_RO	01-Jun-2010	Romania	The wording describing requirement for male contraception and reporting of subject partner pregnancy have been changed due to inconsistencies between trial protocol version 2.0 dated 30-Sep-2009 and the subject information version 2.0 dated 20-Oct-2009.

General Procedural Deviations

There were no important protocol deviations at country level and trial level (see [Appendix 16.2.2](#)). See Section [10.2](#) for important protocol deviations on trial site level and on subject level.

9.8.2 Changes to the Statistical Analyses Planned in the Protocol

No statistical analysis plan was created for this trial as the statistical analyses were specified with sufficient detail in the protocol. The text below refers to changes to the protocol. All changes were made before data base lock.

All formal statistical analyses (including Statistical analysis on hypoglycaemic episodes, body weight and lipids) were based on the FAS. This was done to facilitate interpretability and ensure consistency within and between trials in the clinical development programme. Hypoglycaemic episodes which had time of onset between 00:01 and 05:59 a.m. (both included) were classified to be nocturnal. This change was documented in the minutes from the database lock in the main trial. The demographic and baseline characteristics of subjects who participating the extension trial were analysed using extension trial set.

Only one survival endpoint was derived (time to meet the target for the first time) as the endpoint describing time until reaching and maintaining target was not considered to be clinically meaningful.

As stated in the protocol ([Appendix 16.1.1](#)) and Section [9.5.1.3](#), the further classification of pre-specified adverse events as medical events of special interest (MESI) was used as a tool to collect additional information on special adverse events. Summaries based on standard MedDRA query (SMQ) searches will be presented for injection site reactions, immunogenicity, neoplasms and medication errors. These summaries will then form the basis for the presentation of these events in Section [12.2.2](#) and Section [12.3.3.3](#). The preferred terms and/or SOCs included in the SMQ searches are listed in [Appendix 16.2.7](#), [Listing 16.2.7.4](#).

10 Trial Subjects

10.1 Disposition of Subjects

In total 706 subjects were screened and 548 subjects were randomised in the main trial. The 548 subjects were randomised 2:1 to IDegAsp and IDet. In total, 72 subjects (13% of those randomised) were withdrawn from the trial after randomisation.

Out of the 476 subjects who completed the main trial, 100 subjects did not continue into the screening visit for the extension trial. Of these 100 subjects, 66 subjects were treated with IDegAsp and 34 were treated with IDet (corresponding to the 2:1 randomisation). A total of 377 subjects were screened and enrolled for the extension trial (254 subjects in the IDegAsp group and 122 subjects in the IDet group) and none of them were screening failures.

In total, 346 subjects completed the extension trial (233 subjects in the IDegAsp group and 113 subjects in the IDet group, corresponding to the 2:1 randomisation). In total 30 subjects (5.5% of those participated in) were withdrawals from the extension trial. Similar proportions of exposed subjects withdrew during the extension trial in the IDegAsp (21 subjects) and IDet (9 subjects) treatment groups. The overall withdrawal pattern (reasons for withdrawal, time of withdrawal) was comparable between the two treatment groups and a similar proportion of subjects completed the trial in the two treatment arms; see [Table 10–1](#). In general, the subject withdrawals occurred throughout the trial period, with no apparent clustering of withdrawals at any specific time point during the trial; see [EOT Figure 14.1.3](#).

The primary reason for withdrawal in both groups fell into the category of ‘other’ reasons, i.e. unable to continue visits (8 subjects), withdrawal of consent (5 subjects), lost to follow-up (3 subjects), refusal of continuation of the trial due to personal reason (1 subjects), hypoglycaemia (1 subject) and 1 subject had thyroidectomy during the trial.

The number of withdrawals due to non-compliance was 5 (4 in the IDegAsp group and 1 in the IDet group).

Three (3) subjects were withdrawn due to adverse events in the extension trial. See [Appendix 16.2.1](#) for detail.

In total, 3 subjects were withdrawn because they met one of the withdrawal criteria (2 in the IDegAsp group and 1 in the IDet group). Of these, 1 subject (in the IDet group) was withdrawn due to hypoglycaemia posing a safety problem as judged by the investigator and 1 subject (in IDegAsp group) withdrew due to lack of treatment effect according to the criteria specified in the protocol. In addition, 1 subject (in IDegAsp group) withdrew because of pregnancy. For more detail about pregnancy during the trial, see Section [12.3.3.1](#)

Subject disposition by country is presented in [EOT Table 14.1.2](#). Information about individual subject disposition is in [Appendix 16.2.4](#), [Table 16.2.4.1](#) and subject disposition by week is presented in [EOT Table 14.1.4](#) and [EOT Table 14.1.5](#). Reasons for withdrawn are summarised in [EOT Table 14.1.6](#). Information about withdrawals due to protocol deviations is presented in Section [10.2](#). The number of subjects allocated to each analysis set is shown in Section [11.1](#).

Table 10–1 Subject Disposition - Summary

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Screened			706
Screening Failures			158
Withdrawn before Randomisation			0
Randomised	366 (100.0)	182 (100.0)	548 (100.0)
Exposed	362 (98.9)	180 (98.9)	542 (98.9)
Completed Main Trial	320 (87.4)	156 (85.7)	476 (86.9)
Withdrawn at/after Randomisation and Before extension	46 (12.6)	26 (14.3)	72 (13.1)
Adverse Event	4 (1.1)	3 (1.6)	7 (1.3)
Ineffective Therapy	2 (0.5)		2 (0.4)
Non-Compliance	8 (2.2)	6 (3.3)	14 (2.6)
Withdrawal Criteria	7 (1.9)	5 (2.7)	12 (2.2)
Other	25 (6.8)	12 (6.6)	37 (6.8)
Completed Main Trial Not screened for extension	66 (18.0)	34 (18.7)	100 (18.2)
Completed Main Trial screening failure in extension	0 (0.0)	0 (0.0)	0 (0.0)
Included in Extension	254 (69.4)	122 (67.0)	376 (68.6)
Withdrawn during extension	21 (5.7)	9 (4.9)	30 (5.5)
Adverse Event	3 (0.8)		3 (0.5)
Ineffective Therapy	0 (0.0)	0 (0.0)	0 (0.0)
Non-Compliance	4 (1.1)	1 (0.5)	5 (0.9)
Withdrawal Criteria	2 (0.5)	1 (0.5)	3 (0.5)
Other	12 (3.3)	7 (3.8)	19 (3.5)
Completed Extension	233 (63.7)	113 (62.1)	346 (63.1)

10.2 Protocol Deviations

10.2.1 Important Protocol Deviations

Protocol deviations (PDs) were reviewed and classified as important / not important by the study group prior to database lock. Important deviations were considered those which could affect the outcome of the trial by influencing key efficacy or safety parameters, those that could influence the safety of the subject as well as those related to violations of GCP. Such deviations could potentially lead to exclusion of a subject from the PP analysis set; see Section [9.7.3](#) and Section [11.1](#). A log of all important protocol deviations reported in relation to this trial is included in [Appendix 16.2.2](#).

10.2.2 Important Deviations at Trial Site Level

10.2.2.1 Important Deviations at Trial Site Level- Main Trial

A total of 29 important PDs were reported at the trial site level. Of these, 12 deviations were related to monitoring visits taking place outside the windows specified in the protocol. In addition, 4 important deviations were related to incorrect storage of trial products or incorrect temperature recording. In all 4 cases, trial product issued to subjects was assessed to be eligible for use. Two (2) deviations were related to site staff entering dates in the subject's diaries, and 2 deviations related to completion of informed consent forms. These and the remaining important deviations on trial site level are listed in [Appendix 16.2.2](#). None of the important protocol deviations were regarded as having a major effect on the trial outcome or safety of the subjects.

10.2.2.2 Important Deviations at Trial Site Level- Main Trial, after the Final of CTR

In total, 2 new important PDs were reported at the trial site level after the final of the main trial CTR. One (1) deviation was related to incorrect temperature of trial products storage and the other one was related to the completion of informed consent forms. One (1) important PD previously reported was deleted after the final of main trial CTR. It was related to the trial site did not send the safety information form within timeline. None of the important protocol deviations were regarded as having a major effect on the trial outcome or safety of the subjects.

10.2.2.3 Important Deviations at Trial Site Level- Extension Trial

A total of 21 important PDs were reported at trial site level. Of these, 9 deviations were related to monitoring visits taking place outside the windows specified in the protocol and 2 deviations were related IWSR registration performed before actual time of visit. Another 6 deviations were related to the incorrect completion of informed consent forms. In addition, 2 important deviations were related to incorrect storage of trial products or incorrect temperature recording. In both 2 cases, trial product issued to subjects was assessed to be eligible for use. Two (2) deviations were related to site staff not performing important assessments as specified in the protocol. These important

deviations on trial site level are listed in [Appendix 16.2.2](#). None of the deviations were regarded as having a major effect on the trial outcome or on the safety of the subjects.

10.2.3 Important Deviations at Subject Level

10.2.3.1 Important Deviations at Subject Level- Main Trial

A total of 131 important PDs were reported at the subject level, 86 for subjects in the IDegAsp group and 43 for subjects in the IDet group, corresponding to the 2:1 randomisation. In addition, 2 important PDs were recorded for subjects who were not randomised (i.e., screening failures).

The important PDs on subject level were divided into categories, corresponding to the relevant sections of the protocol. The number of deviations in each category by treatment group is shown in [Table 10-2](#).

Table 10–2 Important Protocol Deviations- Main Trial

Deviation	IDegAsp	IDet	Subject not Randomised
	N	N	
Selection Criteria	18	3	
– Randomisation despite not meeting inclusion criteria	3	0	
– Randomisation despite meeting exclusion criteria	15	3	
Informed Consent	3	0	2
Treatment Compliance	10	11	
– IDet taken in the morning instead of in the evening	0	3	
– Switch to twice-daily basal insulin in violation of protocol-defined criteria	0	5	
– Trial drug stopped, or replaced with commercially available insulin	5	1	
– Non-compliance with visit schedule or assessments	3	2	
– Wrong drug administration	1	0	
– Disallowed concomitant medication	1	0	
Trial Drug Handling	7	3	
– Trial product incorrectly dispensed and trial product used	5	2	
– Temperature not recorded in log	1	1	
– Insufficient instructions for use of trial product	1	0	
Assessment Deviations	16	7	
– Visit 28-29 safety measures not done or incomplete	5	3	
– Funduscopy/fundusphotography not done at Visit 28	4	1	
– Visit 28 pregnancy test incorrectly done, or not done	4	3	
– Procedural deviations at Visit 28	3	0	
Laboratory Sample Handling	8	4	
– Visit 28 pregnancy incorrectly done or not done	8	4	
Other	24	15	
– Diary entries done by trial site staff	2	2	
– Delayed reporting of AE/SAE/MESI	15	10	
– Missing visits	3	1	
– Insufficient instructions for use of trial product	2	1	
– Wrong needle used	1	0	
– Pregnancy discovered at Visit 28 – subject completed trial	1	0	
– Procedure deviation	0	1	
Total number of deviations	86	43	2

N: Number of deviations. Subjects were randomised 2:1 to IDegAsp:IDet

Inclusion and Exclusion Criteria

In total, 21 of the reported important deviations were related to violation of selection criteria. Of these, 10 deviations concerned subjects who were randomised although they did not have an ECG or funduscopy/fundusphotography performed according to the protocol, and in 9 of 10 cases, the subject in question was randomised to treatment with IDegAsp. With the exception of 2 subjects, subjects were not withdrawn from the trial due to this type of deviation. Other deviations in this category were mainly related to pretrial medication, see [Appendix 16.2.2](#).

Informed Consent

In total, 5 important deviations were related to informed consent. In 2 cases, ECG was performed before the informed consent form was signed. The remaining deviations were related to incorrect completion of the informed consent form. Two (2) of these 5 PDs were recorded for subjects who were recorded as screening failures and therefore were not randomised to trial treatment.

Treatment Compliance

A total of 21 important deviations were reported in the category of treatment compliance, evenly distributed between IDegAsp and IDet. Specific for the IDet group were deviations related to basal insulin injection in the morning instead of in the evening, and switch to twice-daily IDet in violation of the criteria defined in the protocol.

Trial Drug Handling

There were 10 important PDs related to trial drug handling, 7 in the IDegAsp group and 3 in the IDet group, corresponding to the 2:1 allocation of subjects. The deviations were mainly related to trial drug being manually dispensed instead of via the IV/WRS system or the wrong DUN being dispensed to subjects.

Two (2) subjects, one randomised to IDegAsp and one to IDet, were given trial drugs that were suspected to have been stored outside the allowed temperature range for a shorter period, as the continuous recording device on the refrigerator on one occasion had malfunctioned, and 2 important PDs were thus recorded. After database lock, the correct temperature information for the period in question was retrieved from the recording device, showing that no temperature deviation had actually occurred during this time, meaning that the recorded PDs should not have been rated as important. Nevertheless, these 2 PDs are still included in the total amount of important PDs for this category.

Assessment Deviations

There were 23 important PDs related to assessments, 16 in the IDegAsp and 7 in the IDet group. The deviations were all related to procedures to be performed at Visit 28 and Visit 29.

Handling of Laboratory Samples

There were 12 important PDs related to handling of laboratory samples, 8 in the IDegAsp and 4 in the IDet group. All of these deviations were related to subjects having a urine pregnancy test performed at Visit 28 instead of a serum pregnancy test as specified in the protocol.

Other Important Protocol Deviations

In total, 39 important PDs were recorded in the category of 'other'. Of these, 24 occurred in subjects randomised to IDegAsp, and 15 occurred in subjects randomised to IDet. The majority of

these cases (25 of 39) were related to the trial sites not reporting MESIs or SAEs within the timelines specified in the protocol.

10.2.3.2 Important Deviations at Subject Level- Main Trial, after the Final of CTR

In total, 4 new important PDs were reported at the subject level after the final of the main trial CTR. Among all of them, 1 deviation was related to incorrect completion of the informed consent form, 1 deviation was about uncorrected reporting of hypoglycaemic episode and the other 2 deviations were recorded in the category of 'assessments deviations' and both related to serum pregnancy test not performed at V28.

10.2.3.3 Important Deviations at Subject Level- Extension Trial

A total of 96 important PDs were reported on subject level; 57 for subjects in the IDegAsp treatment group and 39 for subjects in the IDet treatment group. The deviations were divided into categories, corresponding to the relevant trial procedures described in the protocol. The number of deviations is shown by treatment and category in [Table 10-3](#).

Inclusion and Exclusion Criteria

In total, 9 of the reported important deviations were related to violation of selection criteria. All of the 9 deviations concerned subjects who did not have a pregnancy test performed according to the protocol, and in 7 of 9 cases, the subjects in question were randomised to treatment with IDegAsp.

Informed Consent

In total, 10 important deviations were related to informed consent. In 1 case, lab sample was drawn before the informed consent form was signed. The remaining 9 deviations were related to incorrect completion of the informed consent form.

Treatment Compliance

A total of 14 important deviations were reported in the category of treatment compliance, among them 8 cases were in IDegAsp treatment group.

Trial Drug Handling

There were 5 important PDs related to trial drug handling, and all in the IDegAsp group. The deviations were mainly related to trial drug being manually dispensed instead of via the IV/WRS system or the wrong DUN being dispensed to subjects.

One (1) subject, in the IDegAsp treatment group, was given trial drugs that were stored outside the allowed temperature range for a short period of time. The temperature deviations occurred during the main trial (NN5401-3594), however the trial products affected by the deviations were dispensed in this extension trial.

Assessment Deviations

There were 29 important PDs related to assessments, 18 in the IDegAsp and 11 in the IDet group. There were 12 deviations related to incomplete assessments at Visit 30 and 8 deviations related to funduscopy test not performed at Visit 44. The other deviations were mainly related to diary missing, incorrect assessment and procedural deviations.

Handling of Laboratory Samples

There were 9 important PDs related to handling of laboratory samples, 7 in the IDegAsp and 2 in the IDet group. In 6 of 9 cases, the deviations were related to subjects having a urine pregnancy test performed at Visit 44 instead of a serum pregnancy test as specified in the protocol.

Other Important Protocol Deviations

In total, 20 important PDs were recorded in the category of 'other'. Of these, 10 occurred in subjects randomised to IDegAsp, and 10 occurred in subjects randomised to IDet. Many of these cases (12 of 20) were related to the trial sites not reporting MESIs or SAEs within the timelines specified in the protocol. There were 6 deviations related to the loss of visits.

Table 10–3 Summary of Important Protocol Deviations- Extension Trial

Deviation	IDegAsp	IDet
	N	N
Selection Criteria	7	2
– Urine pregnancy test was not done on V30	7	2
Informed Consent	2	8
Treatment Compliance	8	6
– Trial drug stopped, or replaced with commercially available insulin	3	3
– Non-compliance with visit schedule or assessments	1	2
– Non-compliance with prescribed dose of trial drug	4	0
– Disallowed concomitant medication	0	1
Trial Drug Handling	5	0
– Trial product incorrectly dispensed and trial product used	4	0
– Temperature deviations for drug storage	1	0
Assessment Deviations	18	11
– Visit 30 HbA _{1c} / FPG assesement not done or incomplete	9	3
– Funduscopy/fundusphotography not done at Visit 44	6	2
– Diary lost or not return	0	3
– Visit 39, 43, 44 assessments incorrectly done, or not done	2	1
– Procedural deviations	1	2
Laboratory Sample Handling	7	2
– Visit 44 pregnancy test incorrectly done	4	2
– Final page of laboratory report signed incorrectly	1	0
– Visit 44 lab assessments not done	2	0
Other	10	10
– Information lost from diary	0	2
– Delayed/incorrectly reporting of AE/SAE/MESI	7	5
– Missing/partially performed visits	3	3
Total number of deviations	57	39

N: Number of deviations. Subjects were randomised 2:1 to IDegAsp:IDet in the main trial NN5401-3594.

11 Efficacy Evaluation

11.1 Data Sets Analysed

Assignment of Subjects to Analysis Set

Before data were released for statistical analysis in the main trial, a blinded review of the data was performed to identify protocol violations that could affect the results; see Section 9.7.3. Subjects who were exposed to trial products <12 weeks and who did not have a valid assessment of HbA_{1c} after randomisation in the main trial were excluded from the PP analysis, as were subjects who violated the selection criteria in the trial, see Section 10.2. Individual subjects not included in the PP analysis set, including the reasons for their exclusion are listed in Appendix 16.2.3, Listing 16.2.3.1. Individual subjects not included in the PP analysis set in the extension trial are listed in Appendix 16.2.3, Listing 16.2.3.2.

All formal statistical analyses (including statistical analysis on hypoglycaemic episodes, body weight and lipids) are based on the FAS. Other safety endpoints are summarised and analysed using the Safety Analysis Set. The analyses of HbA_{1c} are repeated on the PP Analysis Set. Analyses are repeated for serious treatment emergent AEs, number of confirmed hypoglycaemic episodes, anti-bodies, central laboratory parameters (ALAT/SGPT, ASAT/SGOT) and HbA_{1c} using the Extension Trial Set to assess the stability of key results.

The number of subjects included in each analysis set is shown in Table 11–1. For a definition of the analysis sets, please see Section 9.7.3.

Table 11–1 Analysis Sets

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Full Analysis Set	366 (100.0)	182 (100.0)	548 (100.0)
PP Analysis Set	336 (91.8)	168 (92.3)	504 (92.0)
Safety Analysis Set	362 (98.9)	180 (98.9)	542 (98.9)
Extension Trial Set	254 (69.4)	122 (67.0)	376 (68.6)

N: Number of subjects

#: Proportion of randomised subjects

Cross-reference: EOT Table 14.1.1

In total, 92 % of the randomised subjects were included in the PP analysis set. Of the 44 subjects excluded from the PP population, 3 were prematurely withdrawn from the trial and therefore exposed for less than the required 12 weeks, and 5 were withdrawn because they violated inclusion or exclusion criteria. The most frequent reason for subject exclusion from the PP analysis set was lack of a valid HbA_{1c} assessment after 12 weeks of exposure. A listing of subjects excluded from

the efficacy analysis in both main and extension trial is presented in [Appendix 16.2.3](#), [Table 16.2.3.1](#).

The Safety Analysis Set contained fewer subjects than the FAS because 6 subjects were randomised but withdrawn before being exposed. For 3 of these subjects, the underlying reason for withdrawal was related to violation of the selection criteria or non-compliance.

Among all 476 subjects who completed the main trial, 100 subjects did not continue into the extension trial. The Extension Trial Set contained 376 subjects (254 with IDegAsp treatment and 122 with IDet treatment). All subjects exposed in extension trial were included in Extension Trial Set.

11.2 Demographic and Other Baseline Characteristics

The demographics and baseline characteristics were similar with only marginal differences between the treatment groups: the IDegAsp group had 3.0% subjects over 65 years of age and 48.1% females, while the IDet group had 7.7% subjects above 65 years and 54.9% females. The population consisted of male and female subjects with type 1 diabetes mellitus with a mean age of 41.3 years (ranging from 18 to 80 years), with a mean duration of diabetes mellitus of 17.4 years (ranging from 1 to 60 years), with a mean HbA_{1c} of 8.3 % and a mean BMI of 26.4 kg/m². The majority of the subjects (~90%) that reported their race were White and of non-Hispanic/Latino origin. The second-largest race group consisted of Black or African-American subjects with 2.7% in the IDegAsp treatment group and 3.3% in the IDet group. The demographic and baseline characteristics of subjects who participating the extension trial were evaluated using extension trial set and results were in accordance with the analysis based on FAS, see [EOT Tables 14.1.8](#) and [14.1.10](#). The demographic and baseline characteristics of all randomised subjects are summarised descriptively in [Table 11-2](#) and [Table 11-3](#).

Table 11–2 Demographics and Baseline Characterises - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
Age Group			
N	366 (100.0)	182 (100.0)	548 (100.0)
> 65 years	11 (3.0)	14 (7.7)	25 (4.6)
Adults (18-65 yrs)	355 (97.0)	168 (92.3)	523 (95.4)
Sex			
N	366 (100.0)	182 (100.0)	548 (100.0)
Female	176 (48.1)	100 (54.9)	276 (50.4)
Male	190 (51.9)	82 (45.1)	272 (49.6)
Country of Residence			
N	366 (100.0)	182 (100.0)	548 (100.0)
Australia	47 (12.8)	18 (9.9)	65 (11.9)
Denmark	16 (4.4)	15 (8.2)	31 (5.7)
France	17 (4.6)	8 (4.4)	25 (4.6)
Israel	22 (6.0)	11 (6.0)	33 (6.0)
Poland	37 (10.1)	15 (8.2)	52 (9.5)
Romania	49 (13.4)	21 (11.5)	70 (12.8)
Russian Federation	47 (12.8)	22 (12.1)	69 (12.6)
United Kingdom	24 (6.6)	12 (6.6)	36 (6.6)
United States	107 (29.2)	60 (33.0)	167 (30.5)
Ethnicity			
N	366 (100.0)	182 (100.0)	548 (100.0)
Hispanic or Latino	10 (2.7)	7 (3.8)	17 (3.1)
Not Hispanic or Latino	339 (92.6)	167 (91.8)	506 (92.3)
Not Applicable	17 (4.6)	8 (4.4)	25 (4.6)
Race			
N	366 (100.0)	182 (100.0)	548 (100.0)
White	333 (91.0)	162 (89.0)	495 (90.3)
Black or African American	10 (2.7)	6 (3.3)	16 (2.9)
Asian Indian	1 (0.3)	0 (0.0)	1 (0.2)
Asian non-Indian	3 (0.8)	3 (1.6)	6 (1.1)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	1 (0.3)	1 (0.5)	2 (0.4)
Not Applicable	17 (4.6)	8 (4.4)	25 (4.6)
Other	1 (0.3)	2 (1.1)	3 (0.5)

N = Number of Subjects

Subjects from France did not report race

Cross-reference: [EOT Table 14.1.7](#)

Table 11–3 Baseline and Diabetes Characteristics – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Age (years)			
N	366	182	548
Mean (SD)	40.7 (12.8)	42.6 (13.8)	41.3 (13.2)
Median	39.9	42.4	40.6
Min ; Max	18.3 ; 78.5	18.1 ; 80.2	18.1 ; 80.2
Height (m)			
N	366	182	548
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Median	1.7	1.7	1.7
Min ; Max	1.5 ; 2.0	1.1 ; 2.0	1.1 ; 2.0
Body Weight (kg)			
N	366	182	548
Mean (SD)	76.7 (14.6)	76.0 (14.0)	76.5 (14.4)
Median	75.0	76.0	75.3
Min ; Max	44.0 ; 123.4	42.9 ; 137.4	42.9 ; 137.4
BMI (kg/m ²)			
N	366	182	548
Mean (SD)	26.2 (4.0)	26.7 (3.9)	26.4 (4.0)
Median	25.9	26.3	26.0
Min ; Max	16.2 ; 35.6	18.7 ; 36.2	16.2 ; 36.2
Duration of Diabetes (years)			
N	366	181	547
Mean (SD)	17.2 (11.3)	17.9 (12.3)	17.4 (11.6)
Median	14.9	15.0	14.9
Min ; Max	1.1 ; 59.7	1.0 ; 56.6	1.0 ; 59.7
HbA _{1c} (%)			
N	366	182	548
Mean (SD)	8.3 (0.8)	8.3 (0.7)	8.3 (0.8)
Median	8.2	8.2	8.2
Min ; Max	6.8 ; 10.3	6.5 ; 10.4	6.5 ; 10.4
FPG (mmol/L)			
N	365	181	546
Mean (SD)	10.3 (4.7)	11.0 (4.8)	10.5 (4.8)
Median	9.6	10.3	9.9
Min ; Max	1.8 ; 30.2	2.9 ; 28.4	1.8 ; 30.2

BMI = Body Mass Index, N = Number of Subjects, SD = Standard Deviation

Cross-reference: [EOT Table 14.1.9](#)

The subjects were randomised based on measurements performed on Visit 1, and baseline values were recorded approximately 1 week later, at Visit 2. Since some subjects had an increase in body weight or HbA_{1c} from Visit 1 to Visit 2, the maximum values for HbA_{1c} and BMI displayed in [Table 11–3](#) are above the limits allowed in the inclusion criteria (see Section [9.3](#)).

Individual demographic data as well as baseline characteristics, diabetes complications at screening and anti-diabetic treatment at screening are presented in [Appendix 16.2.4](#), [Tables 16.2.4.2](#) to [16.2.4.5](#).

Pretrial Antidiabetic Treatment Regimens

Eligible subjects at screening could have been treated with any of the following regimens for ≥ 12 months prior to Visit 1:

- Basal-bolus regimen
- Premix insulin regimen
- Self-mix regimen

Subjects receiving either of the following pretrial anti-diabetic treatments were ineligible:

- Basal-bolus regimen with basal insulin injected twice daily
- Use within the last 3 months before Visit 1 of any other antidiabetic glucose-lowering drug than insulin

[Table 11–4](#) presents the anti-diabetic treatment regimens at screening. Basal-bolus insulin treatment was the most commonly used anti-diabetic treatment regimen (~90% of subjects). The different pretrial regimens were equally represented in the two treatment groups.

Table 11–4 Anti-diabetic Treatment Regimen at Screening - Full Analysis Set

	IDegAsp OD		IDet		Total	
	N	(%)	N	(%)	N	(%)
Number of Subjects	366		182		548	
Basal-Bolus	334	(91.3)	161	(88.5)	495	(90.3)
Basal-Bolus	334	(91.3)	161	(88.5)	495	(90.3)
Other	32	(8.7)	21	(11.5)	53	(9.7)
Basal + PreMix			1	(0.5)	1	(0.2)
Basal Only	1	(0.3)	1	(0.5)	2	(0.4)
PreMix + Bolus	11	(3.0)	7	(3.8)	18	(3.3)
PreMix Only	18	(4.9)	10	(5.5)	28	(5.1)
SelfMix	2	(0.5)	2	(1.1)	4	(0.7)

N: Number of Subjects

?: Proportion of Subjects

Cross-reference: [EOT Table 14.1.11](#)

According to [Table 11–4](#), two (2) subjects were treated with basal insulin only at screening. These subjects, ([IDet] and [IDegAsp]) were randomised in error and were withdrawn from the trial without being exposed.

The antidiabetic treatment regimen at screening is shown in further detail in [EOT Table 14.1.12](#). Approximately 66% of all subjects used IGlax as basal insulin and IAsp was the most commonly used bolus insulin (used by 50% of subjects). The insulin type at screening is shown in detail in [EOT Table 14.1.12](#). A listing of antidiabetic treatment for individual subjects during the follow-up period is found in [Appendix 16.2.5, Table 16.2.5.4](#).

Diabetic Complications

Diabetic complications were coded in MedDRA and grouped based on preferred terms. The proportion of subjects with diabetes complications at baseline was 32.5% for subjects in the IDegAsp group and 36.8% in the IDet group. In both groups, the most frequently reported diabetes complications were ophthalmic complications (diabetic retinopathy) and neurologic complications (diabetic neuropathy); see [Table 11-5](#).

Concomitant Illnesses and Medications

Clinically significant abnormal findings in vital signs, physical examinations, ECG and fundoscopy/fundusphotography were to be recorded as concomitant illnesses at screening. In general, the pattern of concomitant illnesses was representative for a population with type 1 diabetes mellitus, and with the exception of a lower proportion of subjects with hypertension in the IDegAsp group compared with the IDet group, there were no apparent differences between groups concerning concomitant illnesses. Vital signs, physical examinations, ECGs and fundoscopies were similar between treatment groups at baseline.

In addition to diabetic complications, the concomitant illnesses most commonly reported fell in the system organ classes of metabolism and nutrition disorders, vascular diseases and eye disorders. Hypertension was the most common concomitant illness, reported by 30.9% of subjects in the IDegAsp group and by 39.0% of subjects in the IDet group. Diabetic retinopathy was reported by 24.0% of subjects in the IDegAsp group and 29.1% of subjects in the IDet group. Diabetic neuropathy was reported by 19.1% of subjects in the IDegAsp group and 13.2% of subjects in the IDet group. Hypercholesterolemia was reported by 10.9% of subjects in the IDegAsp group and 16.5% of subjects in the IDet group, hyperlipidemia by 12.8% in the IDegAsp group and 11.5% in the IDet group and dyslipidemia by 9.3% of subjects in the IDegAsp group and 12.1% in the IDet group.

Concomitant illness by treatment group are summarised in [EOT Table 14.1.14](#). A listing of the subjects individual concomitant illness is provided in [Appendix 16.2.4, Table 16.2.4.7](#).

Apart from insulin, the most common concomitant medications at screening were simvastatin (taken by 13.4% in the IDegAsp group and by 19.8% in the IDet group), acetylsalicylic acid (taken by 13.4 % in the IDegAsp group and by 14.3% in the IDet group) and levothyroxine sodium (taken by 10.7% of subjects in the IDegAsp group and by 8.2% of subjects in the IDet group); see [EOT Table 14.1.15](#). Concomitant medication started after the screening is summarised in

[EOT Table 14.1.16](#). A listing of the subjects' individual concomitant medication is provided in [Appendix 16.2.4](#), [Table 16.2.4.6](#).

Table 11–5 Diabetes Complications at Screening – Summary – Full Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Number of Subjects	366			182			548		
All Complications	119	(32.5)	217	67	(36.8)	102	186	(33.9)	319
Ophthalmic complications	90	(24.6)	92	55	(30.2)	55	145	(26.5)	147
Diabetic retinopathy	88	(24.0)	88	53	(29.1)	53	141	(25.7)	141
Retinopathy proliferative	2	(0.5)	2	2	(1.1)	2	4	(0.7)	4
Cataract diabetic	2	(0.5)	2				2	(0.4)	2
Neurological complications	71	(19.4)	77	24	(13.2)	25	95	(17.3)	102
Diabetic neuropathy	70	(19.1)	70	24	(13.2)	24	94	(17.2)	94
Diabetic autonomic neuropathy	4	(1.1)	4	1	(0.5)	1	5	(0.9)	5
Diabetic encephalopathy	3	(0.8)	3				3	(0.5)	3
Renal complications	29	(7.9)	29	16	(8.8)	17	45	(8.2)	46
Diabetic nephropathy	19	(5.2)	19	11	(6.0)	12	30	(5.5)	31
Microalbuminuria	10	(2.7)	10	5	(2.7)	5	15	(2.7)	15
Cardiovascular complications	14	(3.8)	16	2	(1.1)	2	16	(2.9)	18
Diabetic vascular disorder	12	(3.3)	12	2	(1.1)	2	14	(2.6)	14
Cardiac autonomic neuropathy	3	(0.8)	3				3	(0.5)	3
Diabetic microangiopathy	1	(0.3)	1				1	(0.2)	1
Dermal complications	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic foot	1	(0.3)	1				1	(0.2)	1
Necrobiosis lipoidica diabetorum				1	(0.5)	1	1	(0.2)	1
Gastrointestinal complications	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic gastroparesis	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Other complications	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic cheirography	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2

N= Number of subjects
%= Percentage of subjects
E= Number of Events

Cross-reference: [EOT Table 14.1.13](#)

11.3 Measurements of Treatment Compliance

Formal compliance with respect to trial products was not assessed because dosing was determined according to individual needs. However, at each visit/contact, the investigator reminded the subject to adhere to the trial procedures and treatment regimen described in the protocol, see Section [9.4.8](#) for further details.

Drug accountability was performed at Visits 6, 8, 18, 28 and 29 (Weeks 4, 8, 16, 26 and 27) in the main trial and at Visits 37, 44 and 45 (Week 39, 53 and 54) in the extension trial.

The relationship between the actual mean daily basal insulin dose recorded by the subjects, the dose prescribed by the investigator and the dose recommended according to the dosing algorithm are evaluated and discussed in Section [12.1.2](#).

Tabulations were also made to evaluate the proportion of subjects achieving plasma glucose targets prebreakfast (and predinner) during the trial. See Section [11.4.1.5](#) for details.

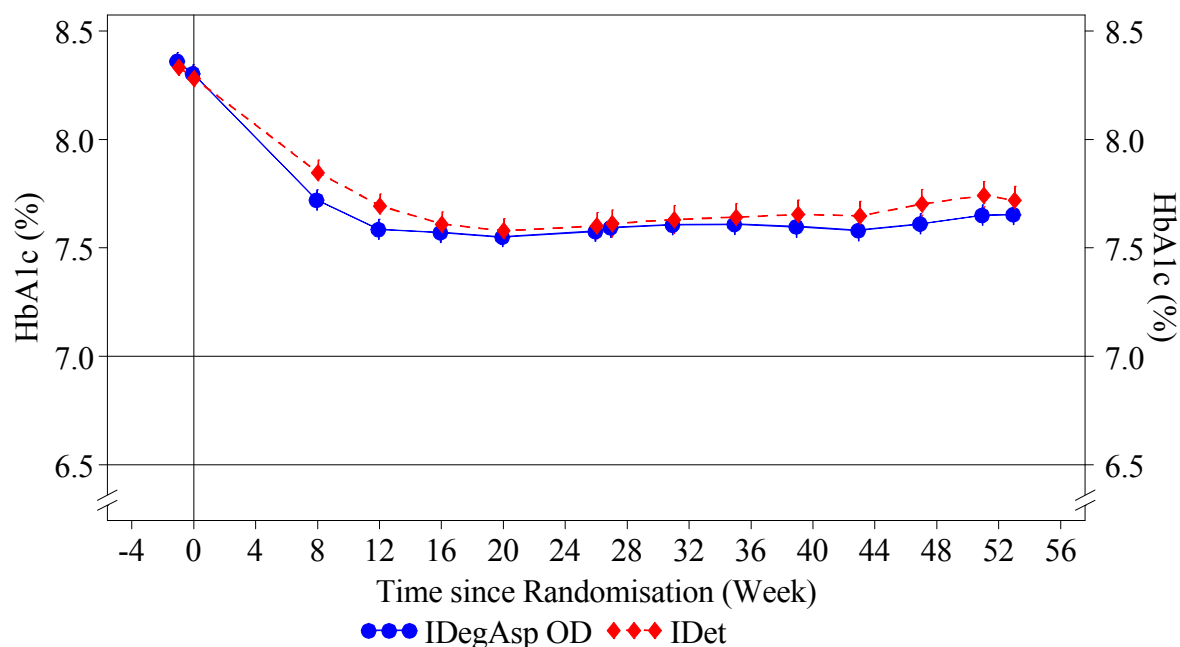
11.4 Efficacy Results

11.4.1 Analysis of Efficacy

11.4.1.1 HbA_{1c}

The secondary objective of this trial was to compare the efficacy between IDegAsp OD + meal-time IAsp for the remaining meals and IDet + meal-time IAsp after 52 weeks of treatment.

Mean HbA_{1c} decreased during the first 4 months and remained stable for rest of the trial duration in both treatment groups; see [Figure 11-1](#). After 52 weeks of treatment, the observed mean (SD) HbA_{1c} was 7.7 (0.9) % with IDegAsp and 7.7 (0.9) % with IDet ([EOT Table 14.2.62](#)). The observed mean change from baseline to end of trial was -0.65 %-points with IDegAsp and -0.56 %-point with IDet ([EOT Table 14.2.64](#)).



FAS; LOCF imputed data
Error bars: $\pm$ Standard Error(Mean)

Cross-reference: [EOT Figure 14.2.72](#)

Figure 11–1 HbA_{1c} (%) by Treatment Week – Mean Plot – Full Analysis Set

The estimated mean reduction in HbA_{1c} during the trial was numerically larger with IDegAsp (0.67 %-points) compared to IDet (0.57 %-points), with an estimated mean difference of -0.10 %-points [-0.24; 0.03] _{95%CI} after 52 weeks of treatment. There was no statistically significant difference between the two treatment groups at the end of the trial; see [Table 11–6](#).

Table 11–6 HbA_{1c} (%) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
HbA _{1c} (%)					
LSMeans					
IDegAsp OD	366	366	7.62	0.07	
IDet	182	182	7.73	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	366	366	-0.67	0.07	
IDet	182	182	-0.57	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.10		[-0.24 ; 0.03]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates. Missing data is imputed using last observation carried forward.

Cross-reference: [EOT Table 14.2.66](#)

The efficacy analysis was based on FAS, ETS and PP analysis sets. The results of analysis for ETS and PP analysis set were in accordance with the results obtained from the analysis based on FAS, see [Table 11–7](#) and [Table 11–8](#).

The results of the efficacy analysis was also supported by two additional sensitivity analyses, one based on a simple model, including only HbA_{1c} at baseline as covariate, and one based on a repeated measurement model; see Section [9.7.4.1](#) for further details and [EOT Tables 14.2.70](#) and [14.2.71](#) for analysis results.

Additional plots of HbA_{1c} over time are shown in [EOT Figures 14.2.73](#) to [14.2.79](#) and individual HbA_{1c} values are listed in [Appendix 16.2.6](#), [Table 16.2.6.1](#). [EOT Table 14.2.68](#) shows the estimates for the parameters used as fixed factors and covariates on the observed scale.

Table 11–7 HbA_{1c} (%) after 52 Weeks of Treatment - Statistical Analysis - Extension Trial Set

	EXT	N	Estimate	SE	95% CI
HbA _{1c} (%)					
LSMeans					
IDegAsp OD	254	254	7.53	0.08	
IDet	122	122	7.63	0.10	
Change from Baseline					
LSMeans					
IDegAsp OD	254	254	-0.79	0.08	
IDet	122	122	-0.68	0.10	
Treatment Contrast					
IDegAsp OD - IDet			-0.11		[-0.27 ; 0.06]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean
The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
Missing data is imputed using last observation carried forward.
nn5401/nn5401-3594-3645/freeze_ctr_01/stats
08FEB2011:10:01:55 - tstat_find_tpl_t022.sas/t_hba1c_stat_locf_ets.txt

Cross-reference: [EOT Table 14.2.67](#)

Table 11–8 HbA_{1c} (%) after 52 Weeks of Treatment - Statistical Sensitivity Analysis - PP Analysis Set

	PP	N	Estimate	SE	95% CI
HbA _{1c} (%)					
LSMeans					
IDegAsp OD	336	336	7.55	0.07	
IDet	168	168	7.67	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	336	336	-0.75	0.07	
IDet	168	168	-0.63	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.12		[-0.26 ; 0.02]

N = Number of subjects contributing to analysis, CI = Confidence Interval, SE = Standard Error of the Mean
The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
Missing data is imputed using last observation carried forward.

Cross-reference: [EOT Table 4.2.69](#)

11.4.1.2 Responders for HbA_{1c}

Subjects Achieving HbA_{1c} Targets

At end of trial, the proportion of subjects who achieved the HbA_{1c} target of <7.0 % was 22.4 % with IDegAsp and 17.0 % with IDet; see [Table 11–9](#).

Table 11–9 Responder for HbA_{1c} by Treatment Week – Summary – Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
HbA _{1c} <7.0% (ADA)			
Visit 44 (Week 53) (LOCF)			
N	366 (100.0)	182 (100.0)	548 (100.0)
Yes	82 (22.4)	31 (17.0)	113 (20.6)
No	284 (77.6)	151 (83.0)	435 (79.4)

N = Number of Subjects

Cross-reference: [EOT Table 14.2.80](#)

The estimated odds of achieving the target of HbA_{1c} < 7% was numerically higher (56%) with IDegAsp compared to IDet. The estimated odds ratio (IDegAsp/IDet) is 1.56 [0.94; 2.59]_{95% CI}. There was no statistically significant difference between the two treatment groups at the end of the trial; see [Table 11–10](#).

Table 11–10 Responder for HbA_{1c} at End of Trial - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
HbA _{1c} <7.0%				
LSMeans, Odds				
IDegAsp OD	366	366	0.19	
IDet	182	182	0.12	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.56	[0.94 ; 2.59]

N= Number of subjects contributing to analysis, CI= Confidence Interval The binary endpoint is analysed in a Logistic Regression Model using a logit link. The model includes treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and hbA_{1c} as covariates.
Missing data is imputed using last observation carried forward.
End of Trial: the last end of trial visit of a subject excluding the follow-up visit

Cross-reference: [EOT Table 14.2.81](#)

Subjects Achieving HbA_{1c} Targets without Hypoglycaemia

In all, 5.3% of subjects treated with IDegAsp and 3.6% of subjects treated with IDet achieved the HbA_{1c} target < 7% without confirmed hypoglycaemic episodes during the last 12 weeks of treatment; see [Table 11–11](#).

In total, 22.0% of subjects treated with IDegAsp and 16.6% of subjects treated with IDet achieved the HbA_{1c} target < 7% without severe hypoglycaemic episodes during the last 12 weeks of treatment; see [Table 11–11](#).

Table 11–11 Responder for HbA_{1c} at End of Trial Without Hypoglycaemia – Summary – Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
HbA _{1c} <7.0% w/o Confirmed Hypo.			
Visit 44 (Week 53) (LOCF)			
N	337 (100.0)	169 (100.0)	506 (100.0)
Yes	18 (5.3)	6 (3.6)	24 (4.7)
No	319 (94.7)	163 (96.4)	482 (95.3)
HbA _{1c} <7.0% w/o Severe Hypo.			
Visit 44 (Week 53) (LOCF)			
N	337 (100.0)	169 (100.0)	506 (100.0)
Yes	74 (22.0)	28 (16.6)	102 (20.2)
No	263 (78.0)	141 (83.4)	404 (79.8)

Responder for HbA_{1c} without hypoglycaemia: subject meeting the HbA_{1c} target at end of trial without treatment emergent hypoglycaemia during the last 12 weeks of trt. Endpoint is only defined for subjects exposed for at least 12 trt. weeks. End of Trial: last end of trial visit of subject excluding follow-up visit.
Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Cross-reference: [EOT Table 14.2.82](#)

The odds of achieving this target (HbA_{1c} < 7% without confirmed hypoglycaemia) was numerically higher (50%) with IDegAsp compared to IDet. The estimated odds ratio (IDegAsp/IDet) is 1.50 [0.57; 3.97]_{95%CI}. There was no statistically significant difference between the two treatment groups at the end of the trial; see [Table 11–12](#).

The odds of achieving this target (HbA_{1c} < 7% without severe hypoglycaemia) was numerically higher (54%) with IDegAsp compared to IDet. The estimated odds ratio (IDegAsp/IDet) is 1.54 [0.90; 2.63]_{95%CI}. There was no statistically significant difference between the two treatment groups at the end of the trial; see [Table 11–12](#).

See [Appendix 16.2.6](#), [Table 16.2.6.2](#) for responder data for individual subjects.

Table 11–12 Responder for HbA_{1c} at End of Trial Without Hypoglycaemia - Statistical Analysis - Full Analysis Set

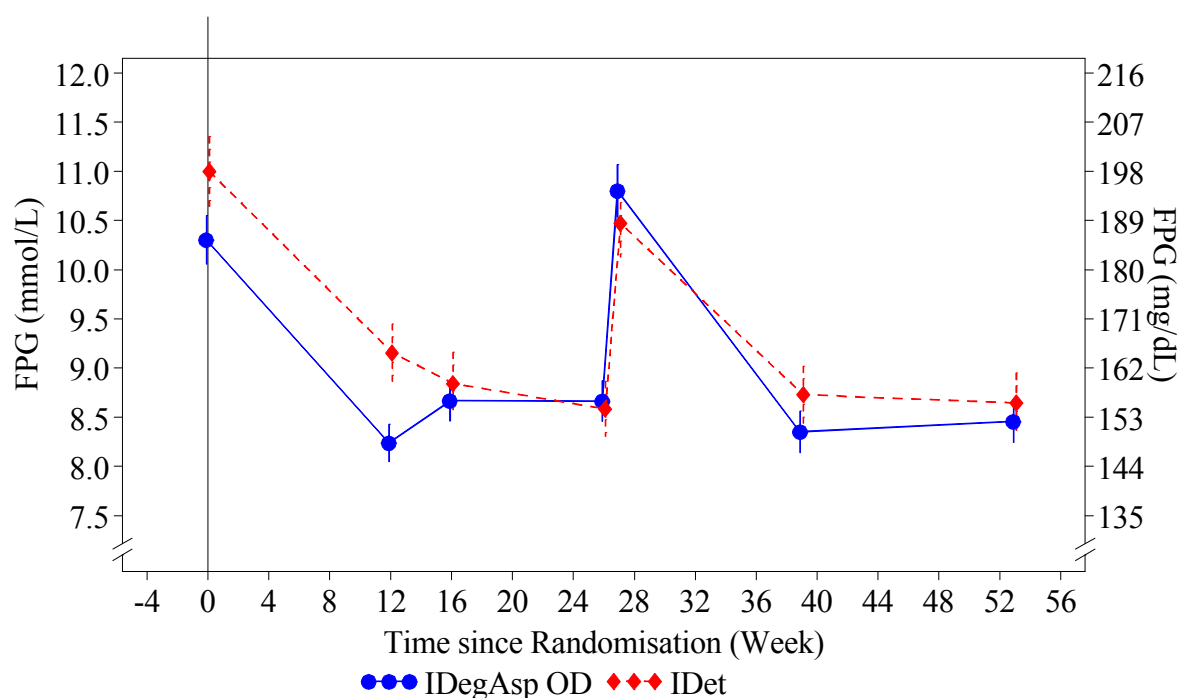
	FAS	N	Estimate	95% CI
HbA _{1c} < 7.0% w/o Confirmed Hypo				
LSMeans, Odds				
IDegAsp OD	366	337	0.00	
IDet	182	169	0.00	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.50	[0.57 ; 3.97]
HbA _{1c} < 7.0% w/o Severe Hypo				
LSMeans, Odds				
IDegAsp OD	366	337	0.21	
IDet	182	169	0.14	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.54	[0.90 ; 2.63]

The endpoint is analysed in a Logistic Regression Model using a logit link, including treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and hba1c as covariates. Missing data is imputed using LOCF.
HbA_{1c} <7.0% w/o Hypo: A subject exposed for at least 12 weeks, who meets the HbA_{1c} target w/o hypoglycaemia during the last 12 weeks of treatment or within 7 days from last randomised treatment. End of Trial: the last end of trial visit of a subject excluding the follow-up visit. Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL).

Cross-reference: [EOT Table 14.2.83](#)

11.4.1.3 Fasting Plasma Glucose

FPG decreased in both treatment groups during the trial; see [Figure 11–2](#). The observed mean FPG values at baseline were 10.3 mmol/L (IDegAsp) and 11.0 mmol/L (IDet), and changed to 8.5 mmol/L with IDegAsp and 8.6 mmol/L with IDet at the end of treatment (week 53). The FPG reduction after 52 weeks of treatment was 1.83 mmol/L with IDegAsp and 2.40 mmol/L with IDet respectively, see [EOT tables 14.2.84](#) and [14.2.85](#).



FAS; LOCF imputed data
Error Bars: $\pm$ Standard Error(Mean)

Cross-reference: [EOT Figure 14.2.87](#)

Figure 11–2 Fasting Plasma Glucose (mmol/L) by Treatment Week – Mean Plot – Full Analysis Set

FPG increased after week 26 and then decreased after week 28. This appeared to be driven by that at week 26, during the transition between the end of the main trial and the beginning of the extension trial, subjects were transferred from IDegAsp/IDet treatment to NPH insulin with reduction of insulin dose to 80% of their previous total daily basal dose of IDegAsp/IDet. Treatment with NPH insulin was discontinued at the end of Week 27 when the treatment in the extension trial resumed with the same dose of IDegAsp/IDet as at the end of the main trial.

The estimated mean reduction from baseline in FPG during this trial was numerically higher with IDegAsp (2.08 mmol/L) compare to IDet (2.01 mmol/L), and the estimated mean difference was -0.07 mmol/L [-0.79; 0.66]_{95%CI} after 52 weeks of treatment. There was no statistically significant difference between the two treatment groups at the end of the trial; see [Table 11–13](#).

FPG by treatment week is summarised in [EOT Tables 14.2.84, 14.2.85](#) and [EOT Figure 14.2.89](#), and change from baseline is plotted in [EOT Figure 14.2.88](#). Empirical distribution plots are shown in [EOT Figures 14.2.90](#) and [14.2.91](#).

Table 11–13 Fasting Plasma Glucose (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

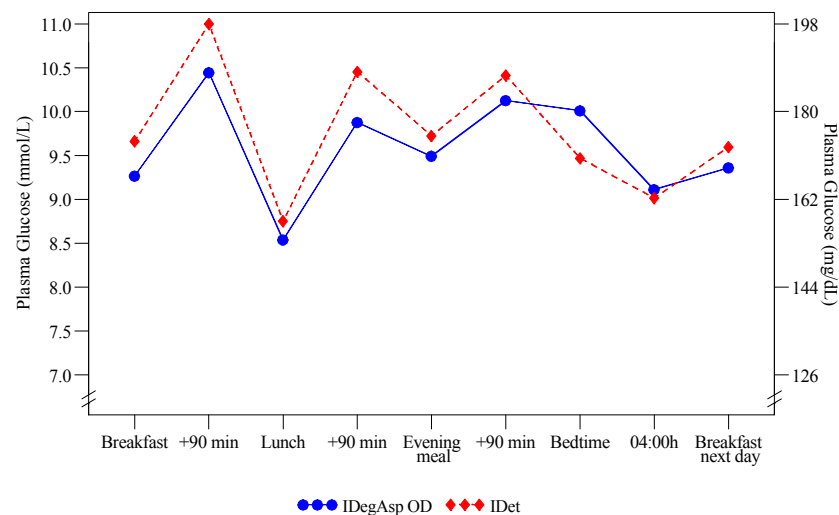
	FAS	N	Estimate	SE	95% CI
FPG (mmol/L)					
LSMeans					
IDegAsp OD	366	365	8.45	0.35	
IDet	182	181	8.52	0.41	
Change from Baseline					
LSMeans					
IDegAsp OD	366	365	-2.08	0.35	
IDet	182	181	-2.01	0.41	
Treatment Contrast					
IDegAsp OD - IDet			-0.07		[-0.79 ; 0.66]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean
The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
Missing data is imputed using last observation carried forward.

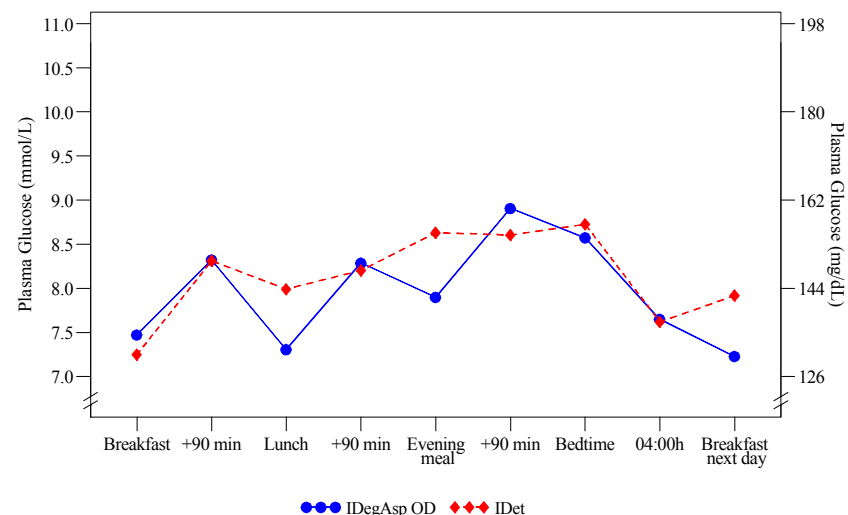
Cross-reference: [EOT Table 14.2.86](#)

11.4.1.4 9-point Self-measured Plasma Glucose Profiles

The 9-point SMPG profiles appeared similar between the two treatment groups at baseline and plasma glucose generally decreased in both groups during the trial. After 52 weeks of treatment, subjects treated with IDegAsp appeared to have lower mean plasma glucose levels before lunch, main evening meal and breakfast in the following day compared to subjects treated with IDet, while no apparent difference in postprandial plasma glucose levels were observed between treatments; see [Figure 11–3](#).



FAS; LOCF imputed data



FAS; LOCF imputed data

Cross-reference: [EOT Figure 14.2.96](#) and [14.2.101](#)

Figure 11–3 9-point Self Measured Plasma Glucose Profile (mmol/L) at Baseline (Left) and After 52 Weeks (Right) - LOCF - Mean Plot - Full Analysis Set

The mean SMPG level was lower for IDegAsp compared to IDet before lunch (estimated difference: -0.70 mmol/L [-1.35; -0.06]_{95% CI}), before main evening meal (estimated difference: -0.75 mmol/L [-1.41; -0.10]_{95% CI}); and before breakfast the following day (estimated difference: -0.59 mmol/L [-1.16; -0.02]_{95% CI}), see [EOT Table 14.2.93](#).

Descriptive statistics and results from the statistical analysis are shown in [EOT Tables 14.2.92 and 14.2.93](#) and plotted in [EOT Figures 14.2.94 to 14.2.101](#). Individual response data for SMPG is provided in [Appendix 16.2.6, Table 16.2.6.3](#).

Mean of 9-point SMPG Profiles

After 52 weeks of treatment, the estimated overall mean of the 9-point SMPG profile (defined as the area under the profile divided by measurement time), was 8.05 mmol/L and 8.26 mmol/L for subjects treated with IDegAsp and IDet, respectively. There was no statistically significant difference between the two treatment groups at the end of the trial; see [EOT Table 14.2.104](#). Descriptive data for the mean of the 9-point SMPG profile are shown in [EOT Table 14.2.102](#), [EOT Figure 14.2.105](#) and [EOT Figure 14.2.107](#). Change from baseline in the mean SMPG profiles is shown in [EOT Table 14.2.103](#), [EOT Figures 14.2.106 and 14.2.108](#).

Fluctuations in 9-point SMPG Profiles

Fluctuation in SMPG was assessed by the average distance in mmol/L from the individual mean plasma glucose level. After 52 weeks of treatment, the fluctuation in 9-point SMPG was 1.36 mmol/L with IDegAsp and 1.36 mmol/L with IDet. The estimated treatment ratio was 1.00 [0.89; 1.13]_{95% CI}. There was no statistically significant difference between the two treatment groups at the end of the trial; see [EOT Table 14.2.110](#).

Descriptive data related to fluctuations during the trial are shown in [EOT Table 14.2.109](#) and [EOT Figures 14.2.111-114](#).

Prandial PG Increment

The estimated mean increment across all meals was 1.03 mmol/L with IDegAsp and 0.40 mmol/L with IDet; (estimated difference IDegAsp-IDet: 0.64 [0.14; 1.14]_{95% CI}); see [EOT Table 14.2.117](#). The mean prandial increment at lunch was 1.04 mmol/L with IDegAsp and 0.05 mmol/L with IDet after 52 weeks treatment (estimated difference IDegAsp-IDet: 0.98 [0.25; 1.72]_{95% CI}). The mean prandial increment at main evening meal was 0.80 mmol/L with IDegAsp and 0.01 mmol/L with IDet after 52 weeks treatment (estimated difference IDegAsp-IDet: 0.80 [0.06; 1.54]_{95% CI}), see [EOT Table 14.2.117](#) and [Figures 14.2.122 to 14.2.129](#). However, the low prandial increment over lunch and evening meal seen with IDet reflected a constantly high PG in this group, whereas the PG with IDegAsp decreased from breakfast to lunch and from lunch to evening meal, as seen in the SMPG figures [Figure 11-3](#).

Statistical analysis of prandial increments at week 52 is shown in [EOT Table 14.2.117](#). Prandial increments (and change from baseline) are summarised separately for breakfast, lunch and main evening meal as well as for all meals in [EOT Tables 14.2.115](#) and [14.2.116](#), while mean plots and distribution plots are shown in [EOT Figures 14.2.118 to 14.2.133](#). Listings for individual subjects are provided in [Appendix 16.2.6](#), [Table 16.2.6.3](#).

Nocturnal SMPG Measurements

Changes in nocturnal PG levels were assessed as the differences between SMPG levels measured at bedtime, at 04:00 a.m. and before breakfast the following day:

- Bedtime to 04:00: (04:00 am PG value minus prior bedtime PG value)
- 04:00 to breakfast: (before breakfast PG value minus 04:00 am PG value)
- Bedtime to breakfast: (before breakfast PG value minus prior bedtime PG value)

At baseline (Week 0) the mean change in nocturnal PG (bedtime to breakfast) was -0.7 mmol/L in the IDegAsp group and 0.1 mmol/L in the IDet group. After 52 weeks of treatment, the observed mean change in nocturnal PG (bedtime to breakfast) was -1.4 mmol/L with IDegAsp and -0.9 mmol/L with IDet, see [EOT table 14.2.134](#). The change in nocturnal PG (bedtime to breakfast) was numerically higher with IDegAsp after 52 weeks of treatment; estimated mean difference -0.48 mmol/L [-1.23; 0.27]_{95%CI}. There was no statistically significant difference between the two treatment groups at the end of the trial, see [EOT Table 14.2.136](#).

Change in nocturnal PG is summarised descriptively in [EOT Table 14.2.134](#) and [Table 14.2.135](#), and the statistical analysis is shown in [EOT Table 14.2.136](#). Mean plots and empirical distribution plots are shown in [EOT Figures 14.2.137 to 14.2.148](#).

11.4.1.5 SMPG Values used for Dose Adjustments

Mean SMPG before Meals

The mean SMPG before breakfast, lunch, main evening meal and bedtime was reduced with both IDegAsp and IDet during the trial, the greatest changes occurred in the initial weeks of the trial. The mean prebreakfast SMPG was 7.7 mmol/L with both the IDegAsp and the IDet group after 52 weeks of treatment; see [Table 11-14](#).

Table 11–14 Self Measured Plasma Glucose for Dose Adjustment (mmol/L) – Descriptive Statistics – Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Before Breakfast (mmol/L)			
Visit 44 (Week 53) (LOCF)			
N	366	181	547
Mean (SD)	7.7 (3.0)	7.7 (2.9)	7.7 (3.0)
Median	6.9	7.2	6.9
Min ; Max	2.9 ; 21.8	2.8 ; 19.3	2.8 ; 21.8
Before Lunch (mmol/L)			
Visit 44 (Week 53) (LOCF)			
N	365	181	546
Mean (SD)	7.4 (2.6)	8.1 (2.8)	7.6 (2.7)
Median	6.9	7.5	7.1
Min ; Max	3.0 ; 18.9	2.9 ; 21.6	2.9 ; 21.6
Before Evening Meal (mmol/L)			
Visit 44 (Week 53) (LOCF)			
N	364	181	545
Mean (SD)	8.1 (2.8)	8.4 (3.1)	8.2 (2.9)
Median	7.5	7.6	7.5
Min ; Max	3.7 ; 17.6	3.3 ; 20.2	3.3 ; 20.2
Before Bedtime (mmol/L)			
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	8.7 (3.1)	8.5 (3.0)	8.6 (3.0)
Median	8.2	7.9	8.0
Min ; Max	1.9 ; 24.3	4.1 ; 22.1	1.9 ; 24.3

N = Number of Subjects, SD = Standard Deviation
Endpoint is calculated as the mean of the available SMPG values

Cross-reference: [EOT Table 14.2.149](#)

The SMPG profiles appeared to be similar for the two treatments before breakfast as well as before evening meal. The estimated mean SMPG value before lunch was lower with IDegAsp (7.3 mmol/L) compare to IDet (8.0 mmol/L) after 52 weeks of treatments, and the estimated mean difference was -0.7 mmol/L $[-1.1; -0.2]_{95\%CI}$. No other statistically significant differences were detected with respect to the mean SMPG values before the other meals; see [Table 11–15](#).

**Table 11–15 Self Measured Plasma Glucose for Dose Adjustment after 52 Treatment Weeks
- Statistical Analysis - Full Analysis Set**

	FAS	N	Estimate	SE	95% CI
Before Breakfast (mmol/L)					
LSMeans					
IDegAsp OD	366	365	7.77	0.26	
IDet	182	181	7.62	0.30	
Treatment Contrast					
IDegAsp OD - IDet			0.15		[-0.37 ; 0.67]
Before Lunch (mmol/L)					
LSMeans					
IDegAsp OD	366	363	7.3	0.2	
IDet	182	181	8.0	0.3	
Treatment Contrast					
IDegAsp OD - IDet			-0.7		[-1.1 ; -0.2]
Before Evening Meal (mmol/L)					
LSMeans					
IDegAsp OD	366	362	8.1	0.2	
IDet	182	181	8.3	0.3	
Treatment Contrast					
IDegAsp OD - IDet			-0.2		[-0.7 ; 0.3]
Before Bedtime (mmol/L)					
LSMeans					
IDegAsp OD	366	356	8.8	0.3	
IDet	182	179	8.7	0.3	
Treatment Contrast					
IDegAsp OD - IDet			0.1		[-0.4 ; 0.6]

N=Number of subjects contributing to analysis, CI=Confidence Interval, SE=Standard Error of the Mean

The response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

Endpoint is calculated as mean of the available SMPG values.

Cross-reference: [EOT Table 14.2.150](#)

Descriptive statistics for the SMPG values used for dosing are shown by treatment week in [EOT Table 14.2.149](#). Plots of SMPG values before breakfast, lunch, main evening meal and bedtime are provided in [EOT Figures 14.2.151 to 14.2.162](#).

Within-subject variability in SMPG as measured by CV%

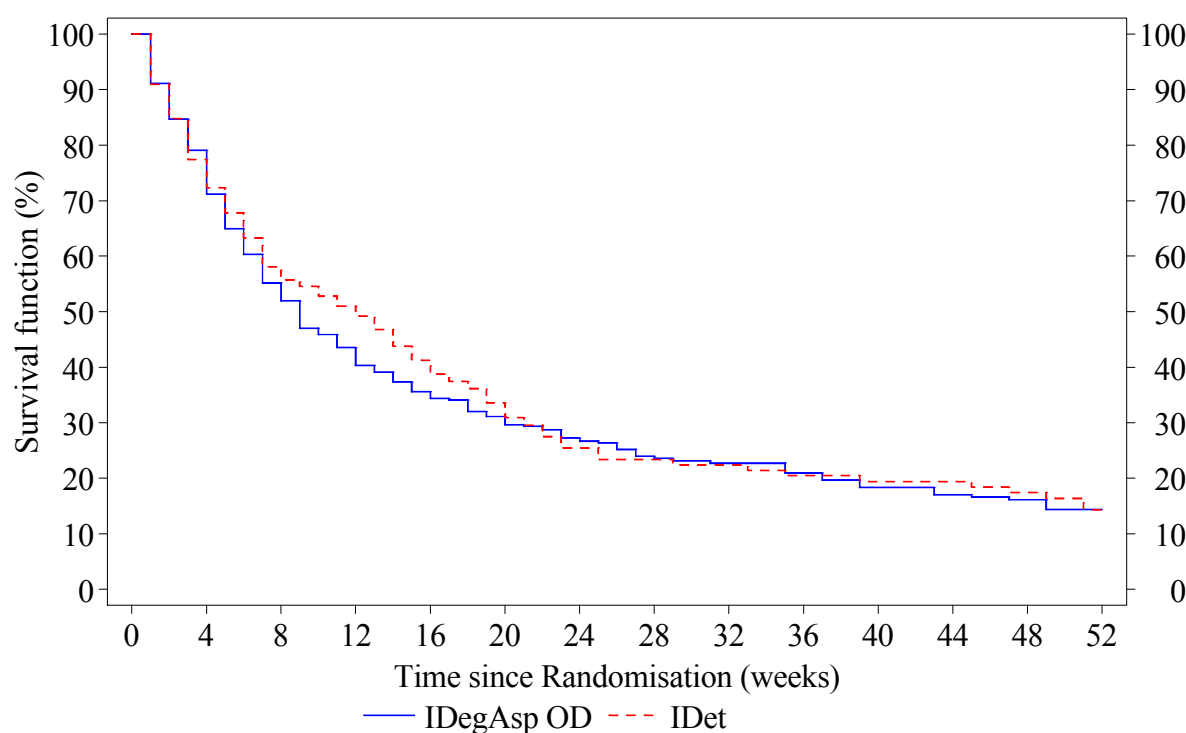
The estimated treatment ratio for the within-subject variability in SMPG was 0.97 [0.88; 1.06]_{95%CI}. There was no statistically significant difference between the two treatment groups at the end of the trial, see [EOT Table 14.2.163](#).

Responder for SMPG Titration Target(s)

At baseline, 6.8% of subjects had a prebreakfast SMPG value < 5 mmol/L (90 mg/dL). The proportion of subjects who met the pre-specified prebreakfast SMPG titration target of <5 mmol/L after 52 weeks of treatment was 15.0% with IDegAsp and 17.7% with IDet, see [EOT Table 14.2.164](#).

Time to Meet SMPG Titration Target(s)

With IDegAsp, the median time to achieve the prebreakfast target of 5.0 mmol/L for the first time was 9 weeks, while for IDet the median time was 12 weeks; see [EOT Table 14.2.168](#), [Figure 11–4](#).



FAS; Observed data

Cross-reference: [EOT Figure 14.2.165](#)

Figure 11–4 Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set

There was no statistical significant difference between groups in the probability of achieving the titration target for the first time within a given treatment week; estimated hazard ratio was 1.08 [0.87; 1.33]_{95% CI}; see [EOT Table 14.2.169](#).

Plots of titration target met for the first time are presented in [EOT Figures 14.2.165 to 14.2.167](#). Individual subject data are listed in [Appendix 16.2.6, Table 16.2.6.4](#).

11.4.2 PK and PD Modelling

Not applicable

11.4.3 Statistical/Analytical Issues

11.4.3.1 Handling of Dropouts or Missing Data

Refer to [Appendix 16.1.9](#) for detailed SAS output for statistical analyses.

Missing values were imputed by LOCF for all endpoints. To assess the sensitivity of the LOCF method on the conclusion from the analysis of the HbA_{1c} analysis, all observed HbA_{1c} values at scheduled measurement times were analysed using a repeated measurement model. The repeated measurement model, addressed whether the inclusion of the HbA_{1c} values at all scheduled visits in the model would provide different results than the approach in the primary analysis were included.

The PP analysis, addressed whether LOCF from subjects withdrawing early in the trial (before the HbA_{1c} measurement had stabilised) or subjects randomised in error (not necessarily fulfilling all inclusion and exclusion criteria) influenced the conclusion. The results from these sensitivity analyses are presented in [EOT Tables 14.2.69 and 14.2.76](#) from which it can be seen that the conclusions from these analyses were similar and resulted in the same conclusion.

11.4.4 Efficacy Conclusions

After 52 weeks of treatment with IDegAsp + meal-time IAsp at remaining meals or IDet + meal-time IAsp, the following was concluded:

Secondary Endpoints

- **HbA_{1c}:** IDegAsp effectively improved long-term glycaemic control, as measured by HbA_{1c}. The estimated mean reduction in HbA_{1c} during the trial was numerically larger (0.67 %-points) with IDegAsp compared to IDet (0.57 %-points), and the estimated mean difference was -0.10 %-points [-0.24; 0.03] _{95%CI}. After 52 weeks of treatment, the observed mean (SD) HbA_{1c} was 7.7 (0.9) % with IDegAsp and 7.7 (0.9) % with IDet.
- **Responders for HbA_{1c}:** A total of 22.4% of subjects treated with IDegAsp achieved HbA_{1c} <7% compared to the observed proportion of 17.0% for subjects treated with IDet. The estimated odds

of achieving this target were numerically higher (56%) with IDegAsp compared to IDet [estimated odds ratio (IDegAsp/IDet) 1.56 (0.94; 2.59)_{95% CI}].

- **Responders for HbA_{1c} without hypoglycaemia:** The observed proportion of subjects achieving HbA_{1c} <7% without confirmed hypoglycaemia was 5.3% with IDegAsp and 3.6% with IDet. The estimated odds of achieving this target were numerically higher (50%) with IDegAsp compared to IDet (estimated odds ratio [IDegAsp/IDet] 1.50 [0.57; 3.97]_{95% CI}). The observed proportion of subjects achieving HbA_{1c} <7% without severe hypoglycaemic episodes was 22.0% with IDegAsp and 16.6% with IDet. The estimated odds of achieving this target were numerically higher (54%) with IDegAsp compared to IDet (odds ratio [IDegAsp/IDet] 1.54 [0.90; 2.63]_{95% CI}).
- **FPG:** FPG decreased during the trial to similar observed mean levels; 8.5 mmol/L with IDegAsp and 8.6 mmol/L with IDet. The estimated mean reduction from baseline in FPG during this trial was numerically higher with IDegAsp (2.08 mmol/L) compared to IDet (2.01 mmol/L), with an estimated mean difference (IDegAsp-IDet) of -0.07 mmol/L [-0.79; 0.66]_{95% CI}.
- **9-point SMPG profiles:** Estimated mean SMPG values before lunch, before main evening meal and before breakfast the following day were lower with IDegAsp compared to IDet, the estimated mean treatment difference (IDegAsp-IDet) was -0.70 mmol/L [-1.35; -0.06]_{95% CI}, -0.75 mmol/L [-1.41; -0.10]_{95% CI} and -0.59 mmol/L [-1.16; -0.02]_{95% CI}, respectively. There was no difference in the fluctuation in PG based on the 9-point SMPG profile, estimated treatment ratio (IDegAsp/IDet) of 1.00 [0.89; 1.13]_{95% CI}. The estimated mean change in nocturnal PG (bedtime to breakfast) was numerically higher with IDegAsp after 52 weeks of treatment; estimated mean difference -0.48 mmol/L [-1.23; 0.27]_{95% CI}.
- **SMPG for dosing:** Mean SMPG before breakfast, lunch, main evening meal and bedtime was reduced with both IDegAsp and IDet during the trial. The estimated mean SMPG value before lunch was lower with IDegAsp (estimated mean difference -0.7 mmol/L [-1.1; -0.2]_{95% CI}). After 52 weeks of treatment, 15.0% and 17.7% of subjects in IDegAsp and IDet treatment groups achieved the prebreakfast SMPG target < 5 mmol/L. There was no statistically significant difference the within-subject variation (CV%) in pre-breakfast SMPG with IDegAsp compared to IDet (estimated treatment ratio [IDegAsp/IDet] 0.97 [0.88; 1.06]_{95% CI}). There was no statistical significant difference regarding the time to meet the prebreakfast PG titration target between treatment groups.

12 Safety Evaluation

12.1 Extent of Exposure

12.1.1 Exposure to Trial Products

All subjects who were exposed to at least one dose of trial product were included in the safety analysis set: 362 subjects in the IDegAsp group and 180 subjects in the IDet group.

The mean exposure time was equal in the treatment groups ([Table 12–1](#) and [EOT Table 14.2.1](#)), and the majority of subjects were exposed for 53-56 weeks ([EOT Figure 14.2.9](#), [EOT Table 14.2.3](#)). The number of subject years of exposure was 296.9 in the IDegAsp group and 145.5 in the IDet group.

The proportions of men and women exposed to the trial products were equal in the treatment groups, and there was no difference between men and women in overall exposure or length of exposure in any of the treatment groups ([EOT Table 14.2.5](#)). The exposure by race and ethnicity was equal in the treatment groups ([EOT Tables 14.2.6](#) and [14.2.7](#)) and the majority of exposed subjects were White (91.3%) followed by Black (2.9%) and Asian (1.2%). The proportion of adult (18-65 years), geriatric (> 65 years) subjects exposed to the trial products was similar in the treatment groups ([EOT Table 14.2.8](#)). A total of 47.8% of geriatric subjects and 62.4% of adult subjects were exposed for 53-56 weeks ([EOT Table 14.2.8](#)) respectively.

Table 12–1 Exposure - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Total Exposure, yrs	296.9	145.5	442.3
Exposure (yrs)			
N	362	180	542
Mean (SD)	0.82 (0.30)	0.81 (0.31)	0.82 (0.30)
Median	1.01	1.01	1.01
Min ; Max	0.00 ; 1.09	0.01 ; 1.10	0.00 ; 1.10

N = Number of Subjects, SD = Standard Deviation
Exposure for Extension trial only derived for subjects included in extension trial.
Period where subjects on NPH before extension not included as part of exposure.

Cross-reference: [EOT Table 14.2.1](#)

The analysis of exposure was repeated using extension trial set and results was in accordance with FAS, see [EOT Tables 14.2.2](#) and [14.2.4](#).

12.1.2 Dosing During the Trial

A treat-to-target approach (prebreakfast SMPG target of < 5 mmol/L) and a very tight and frequent visit schedule was applied during the treatment period to ensure optimal titration of insulin based on SMPG values in order to improve glycaemic control (see Section 9.4 for details). Guidance to insulin initiation and adjustment is described in Section 9.4.4 and Section 9.4.5.

12.1.2.1 Insulin Regimen and Dosing Time

IDegAsp is a combination product consisting of 70% ultra-long-acting basal insulin (IDeg) and 30% rapid-acting insulin (IAsp). Doses in the IDegAsp group are summarised both for the total daily insulin dose, the derived total basal insulin dose and the derived total bolus insulin dose (Table 12–2).

Table 12–2 Presentations of Insulin Doses in the IDegAsp group

	Definition	EOT Tables and Figures
Total daily insulin dose	IDegAsp OD dose plus separate injections of IAsp	Tables 14.2.40, 14.2.42 Figures 14.2.44, 14.2.46, 14.2.48, 14.2.49, 14.2.50, 14.2.52
Basal insulin dose	The IDeg part (70%) of the IDegAsp OD dose	Tables 14.2.28, 14.2.29 Figures 14.2.31, 14.2.33, 14.2.37, 14.2.39
Bolus insulin dose	The sum of injected IAsp doses plus the IAsp part (30%) of the IDegAsp OD dose	Tables 14.2.41, 14.2.43 Figures 14.2.45, 14.2.47, 14.2.51, 14.2.53

IDegAsp = insulin degludec/insulin aspart; OD = once daily; IAsp = insulin aspart; EOT = end of text

At screening visit (Visit 30) in the extension trial, subjects were instructed to re-start treatment with IDegAsp or IDet as previously randomised in main trial NN5401-3594. It was preferably at the same dose levels as reported at end of treatment in the main trial NN5401-3594 with a possibility for adjustment at the discretion of the investigator.

IDegAsp OD was administrated with any meal of the day and furthermore, the dosing time of IDegAsp could be moved to a different meal at any time during the trial. IAsp was administered with the remaining meals. Table 12–3 shows the distribution of IDegAsp injections and the mean IDegAsp dose among the three meals. Throughout the trial, injections of IDegAsp were distributed among all meals, indicating that subjects and investigators made use of the opportunity to individualise the treatment and choose a particular meal for the dosing of IDegAsp, though with an apparent preference for the main evening meal. The distribution of injections for the entire trial period can be seen in EOT Table 14.2.54.

Table 12–3 IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set

Week	Breakfast		Lunch		Main Evening Meal	
	N (%)	Mean	N (%)	Mean	N (%)	Mean
Visit 3 (Week 1)	52 (14.4)	35.46	73 (20.2)	34.22	243 (67.1)	36.72
Visit 31 (Week 28)	31 (8.56)	42.74	45 (12.4)	39.09	179 (49.4)	42.91
Visit 44 (Week 53)	31 (8.56)	43.23	38 (10.5)	43.66	168 (46.4)	46.44

N: Number of Subjects

The descriptive statistics are based on recorded doses.

Cross-reference: [EOT Table 14.2.54](#)

Those subjects who were randomised to treatment with IDet + IAsp were instructed to re-start IDet once or twice daily, depending on previous regimen in the main trial NN5401-3594. For subjects treated with IDet once daily, IDet was dosed at the evening meal or at bedtime according to local practice. The investigator could consider adding a second dose of IDet if a subject met the prespecified criteria for inadequate glycaemic control listed in Section [9.4.5](#). For subjects optimised to IDet twice daily, IDet was dosed at the morning meal and either the evening meal or bedtime. IAsp was administrated as bolus insulin and injected with each main meal.

[EOT Table 14.2.55](#) shows how the IDet injections were distributed between morning and evening in the IDet group from Week 1 to Week 53, as well as the mean dose in U per injection time. At Week 53, 36 out of 148 subjects (approximately 20%) recorded a morning dose of IDet at least once in the three days leading up to the visit. This indicated that the majority of subjects still injected IDet OD at end of trial. At Week 53, the mean morning IDet dose was 23.02 U and the mean evening dose was 34.15 U.

Dose adjustment of IDegAsp and IDet was done based on the mean prebreakfast plasma glucose from the preceding 3 days. The insulin dose adjustments were performed according to the titration guidelines in Section [9.4.5](#).

The direct comparison of IDegAsp doses with IDet doses must be interpreted with caution, as a bolus component is included in the IDegAsp dose. The mean daily (non-derived) IDegAsp/IDet doses are summarised in [EOT Tables 14.2.10 to 14.2.14](#) (using both safety analysis set and extension trial set) and plotted in [EOT Figures 14.2.15 to 14.2.26](#). The mean daily actual (non-derived) bolus doses are summarised in [EOT Table 14.2.27](#) and plotted in [EOT Figures 14.2.30, 14.2.32, 14.2.34, 14.2.35 and 14.2.38](#). Individual doses are listed by subject in [Appendix 16.2.5, Tables 16.2.5.1 and 16.2.5.3](#).

12.1.2.2 Insulin Dose

Total Daily Insulin Dose

At baseline (Week 1), the total daily insulin doses (basal and bolus) were similar in the IDegAsp group (56 U) and the IDet group (56 U). After 52 weeks of treatment, the total insulin dose was numerically lower in the IDegAsp treatment group (72 U) compared with the IDet treatment group (82 U) ([Table 12–4](#) [U] and [Table 12–5](#) [U/kg]). In the IDegAsp group, the total daily insulin dose increased gradually throughout the course of the trial, while in the IDet group, the increase in total dose was steepest during the first weeks of treatment, as shown in [Figure 12–1](#) (U).

Table 12–4 Total Daily Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	56	24	51	16	184
		OD							
		IDet	180	176	56	22	52	15	156
		Total	542	536	56	23	52	15	184
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	72	46	57	7	324
		OD							
		IDet	180	178	82	53	69	19	400
		Total	542	538	75	49	61	7	400

N = Number of Subjects, SD = Standard Deviation

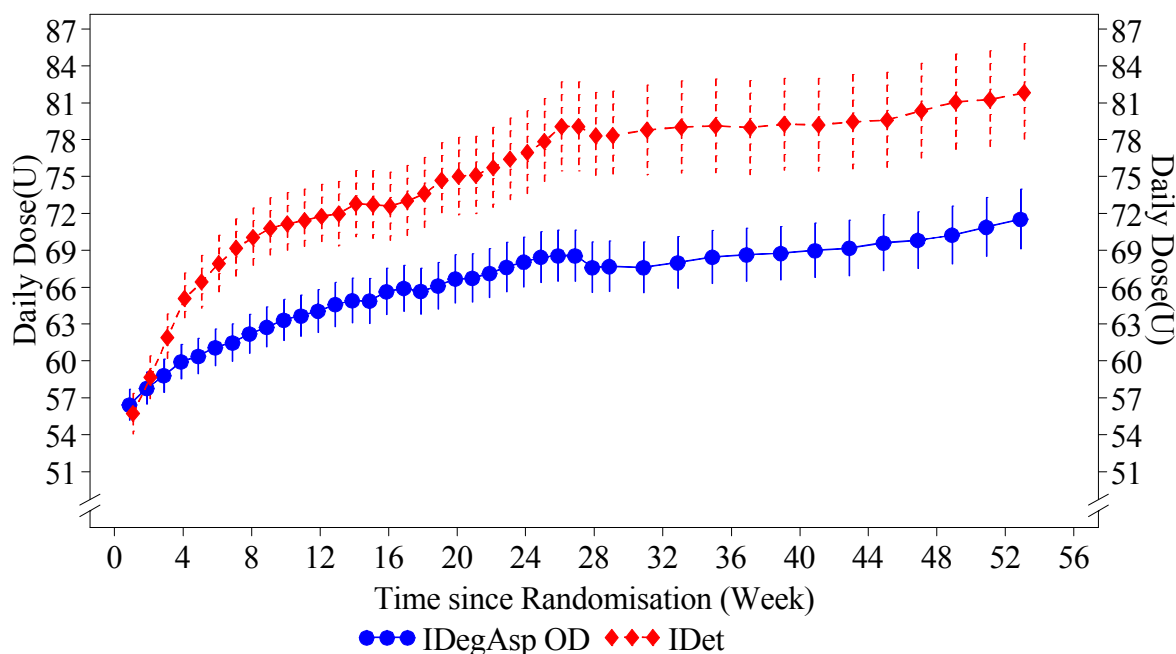
Cross-reference: [EOT Table 14.2.40](#)

Table 12–5 Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.74	0.28	0.68	0.19	2.74
		OD							
		IDet	180	176	0.73	0.25	0.69	0.27	2.11
		Total	542	536	0.73	0.27	0.69	0.19	2.74
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	0.89	0.49	0.75	0.08	3.42
		OD							
		IDet	180	178	1.04	0.65	0.88	0.30	5.80
		Total	542	538	0.94	0.55	0.80	0.08	5.80

N = Number of Subjects, SD = Standard Deviation

Cross-reference: [EOT Table 14. 2. 42](#)



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

Cross-reference: [EOT Figure 14.2.44](#)

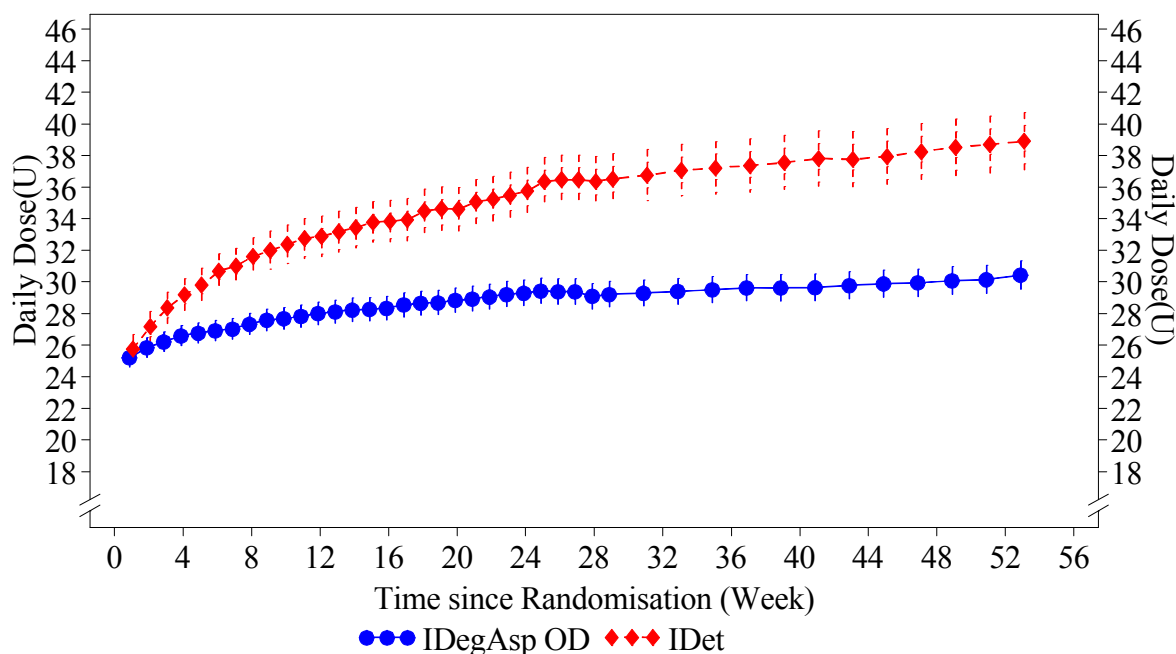
Figure 12–1 Total Daily Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set

A mean plot of total daily insulin dose (U/kg) is shown in [EOT Figure 14.2.46](#). The distribution of total daily insulin dose is shown in [EOT Figures 14.2.44 and 14.2.50 \(U\)](#) and in [EOT Figures 14.2.48, 14.2.49 and 14.2.52 \(U/kg\)](#).

Basal Insulin Dose

The total basal insulin dose for subjects treated with IDegAsp was derived (70% of IDegAsp dose) as seen in [Table 12–2](#) and compared to the mean daily basal dose for subjects treated with IDet.

The mean daily basal insulin doses were similar at baseline between the IDegAsp (25 U) and the IDet groups (26 U). Throughout the trial, the basal insulin dose remained numerically lower in the IDegAsp group compared with the IDet group, as shown in [Figure 12–2 \(U\)](#). Derived basal insulin doses at baseline and at end of trial are shown in [Table 12–6 \(U\)](#) and in [Table 12–7 \(U/kg\)](#).



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

Cross-reference: [EOT Figure 14.2.31](#)

Figure 12–2 Basal Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set

Table 12–6 Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	Descriptive Statistics						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	25	11	22	7	83
		OD							
		IDet	180	176	26	12	24	7	77
		Total	542	536	25	12	24	7	83
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	30	17	26	6	109
		OD							
		IDet	180	178	39	24	34	6	134
		Total	542	538	33	20	28	6	134

N = Number of Subjects, SD = Standard Deviation

Cross-reference: [EOT Table 14.2.28](#)

Table 12–7 Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.33	0.13	0.30	0.09	0.88
		OD							
		IDet	180	176	0.34	0.13	0.31	0.10	0.96
		Total	542	536	0.33	0.13	0.31	0.09	0.96
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	0.38	0.18	0.34	0.10	1.12
		OD							
		IDet	180	178	0.49	0.26	0.44	0.09	1.60
		Total	542	538	0.41	0.22	0.36	0.09	1.60

N = Number of Subjects, SD = Standard Deviation

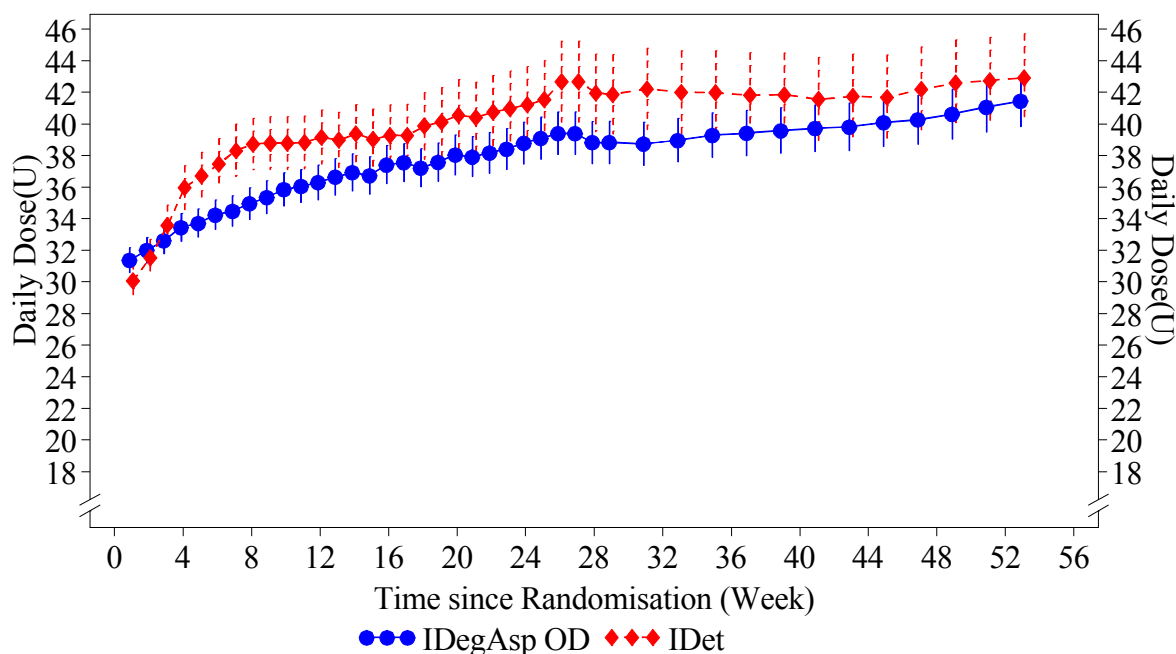
Cross-reference: [EOT Table 14.2.29](#)

A mean plot of derived daily basal insulin dose (U/kg) is shown in [EOT Figure 14.2.33](#). Distribution plots of derived daily basal insulin dose are shown in [EOT Figure 14.2.37](#) (U) and [EOT Figure 14.2.39](#) (U/kg).

Total Bolus Insulin Dose

The daily bolus insulin dose for subjects treated with IDegAsp was derived (the sum of injected IAsp doses plus 30% of the IDegAsp dose) as seen in [Table 12–2](#) and compared to the total daily bolus insulin dose for subjects treated with IDet.

The mean daily bolus insulin doses were similar at baseline between the IDegAsp (31 U) and the IDet group (30 U). During the first weeks of treatment, the increase in bolus dose was numerically lower in the IDegAsp group compared with the IDet group. Throughout the remainder of the trial, the total bolus insulin dose was slightly, but consistently lower in the IDegAsp group than in the IDet and at the end of the trial the doses were 41 U and 43 U, respectively ([Figure 12–3](#) [U] and [EOT Figure 14.2.47](#) [U/kg]). Derived bolus insulin doses at baseline and at end of trial are summarised in [Table 12–8](#) (U) and [Table 12–9](#) (U/kg). The empirical distribution plots of daily bolus insulin doses are presented in [EOT Figures 14.2.51](#) and [14.2.53](#).



SAFETY; LOCF imputed data
Error bars: +/-Standard Error(Mean)

Cross-reference: [EOT Figure 14.2.45](#)

Figure 12–3 Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set

Table 12–8 Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	362	360	31	15	28	8	124
		IDet	180	176	30	15	28	5	130
		Total	542	536	31	15	28	5	130
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp OD	362	360	41	31	30	10	225
		IDet	180	178	43	37	33	2	290
		Total	542	538	42	33	32	2	290

N = Number of Subjects, SD = Standard Deviation

Cross-reference: [EOT Table 14.2.41](#)

Table 12–9 Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.41	0.19	0.37	0.09	1.93
		OD							
		IDet	180	176	0.39	0.19	0.39	0.08	1.76
		Total	542	536	0.41	0.19	0.38	0.08	1.93
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	0.52	0.34	0.41	0.11	2.38
		OD							
		IDet	180	178	0.55	0.48	0.44	0.03	4.21
		Total	542	538	0.53	0.39	0.42	0.03	4.21

N = Number of Subjects, SD = Standard Deviation

Cross-reference: [EOT Table 14.2.43](#)

12.1.2.3 Insulin Dose Ratio at End of Trial

Insulin Dose Ratio between Treatment Groups

Overall, basal and bolus insulin doses appeared to be lower with IDegAsp than with IDet. After 52 weeks of treatment, the insulin dose ratio (IDegAsp/IDet) (U) was 0.87 for total daily insulin dose, hence 13% lower with IDegAsp. For the derived total basal insulin dose and derived total bolus insulin dose (IAsp), the insulin dose ratios (IDegAsp/IDet) (U) were 0.78 and 0.97, hence mean basal and bolus doses were 22% and 3% lower with IDegAsp compared with IDet, respectively, see [Table 12–10](#).

Table 12–10 Insulin Dose Ratio after 52 Weeks of Treatment - Summary - Safety Analysis Set

Treatment Ratio	Mean Ratio (U)	Mean Ratio (U/kg)
Total Daily Insulin Dose		
IDegAsp / IDet	0.87	0.85
Derived Total Basal Insulin Dose		
IDegAsp / IDet	0.78	0.77
Derived Total Bolus Insulin Dose		
IDegAsp / IDet	0.97	0.93

Mean ratio is calculated as the ratio between mean doses at last scheduled treatment visit, where missing data have been imputed using last observation carried forward.
Derived total basal insulin dose:
IDegAsp = the IDeg part of the IDegAsp OD dose; IDet = the (sum of) injected IDet dose(s)
Derived total bolus insulin dose:
IDegAsp = the sum of injected IAsp doses plus the IAsp part of the IDegAsp OD dose;
IDet = the sum of injected IAsp doses.
Bolus insulin dose: 'separate' injections of IAsp.

Cross-reference: [EOT Table 14.2.56](#)

Insulin Dose Ratio between Basal and Bolus Insulin

After 52 weeks of treatment, the derived basal insulin component accounted for 42% of the total insulin dose in the IDegAsp group, and bolus insulin accounted for 58% of the total dose. With IDet, the basal: bolus split was 47% basal insulin and 53% bolus insulin after 52 weeks of treatment ([Table 12–11](#)).

Table 12–11 Insulin Doses and Dose Ratio after 52 Week of treatment

	Derived Total Basal Insulin Dose (U)	Derived Total Bolus Insulin Dose (U)	Total Daily Insulin Dose (U)	Basal: Bolus split
IDegAsp	30	41	72	42% : 58%
IDet	39	43	82	47% : 53%

Data from [EOT Tables 14.2.28, 14.2.40, 14.2.41, 14.2.57](#)

Mean ratios for the basal: bolus insulin dose split in U and U/kg are shown in [EOT Table 14.2.57](#).

12.1.2.4 Difference between Titration Algorithm Dose and Prescribed Dose

The mean and median difference between the dose according to the titration algorithm and the prescribed dose was close to zero (0) U throughout the trial for both treatment groups indicating a

close adherence to the titration algorithm, see [EOT Table 14.2.59](#). The differences are summarised descriptively in [EOT Table 14.2.59](#). Mean plots of prescribed, actual and algorithm doses are shown in [EOT Figures 14.2.60](#) and [14.2.61](#).

The prescribed insulin dose (IDegAsp/IDet) by treatment week is summarised in [EOT Table 14.2.12 \(U\)](#) and shown in a mean plot in [EOT Figure 14.2.17 \(U\)](#). The distribution of prescribed daily insulin dose in units is shown in [EOT Figures 14.2.22](#), [14.2.23](#) and [14.2.25](#). Compliance to titration guideline data are listed by subject in [Appendix 16.2.5](#), [Table 16.2.5.2](#).

12.1.2.5 Difference between Prescribed Dose and Actual Dose

The mean and median difference between the prescribed dose and the actual IDegAsp/IDet dose taken by the subject was close to zero (0) U throughout the trial for both treatment groups indicating a good subject compliance. The differences are summarised descriptively in [EOT Table 14.2.58](#). Plots of prescribed, actual and titration algorithm doses are shown in [EOT Figures 14.2.60](#) and [14.2.61](#). Compliance to titration guideline data are listed by subject in [Appendix 16.2.5](#), [Table 16.2.5.2](#).

12.2 Adverse Events

12.2.1 Brief Summary of Adverse Events

The percentage of subjects reporting treatment emergent AEs (TEAES) and the rate of AEs per 100 patient years of exposure (PYE) was similar in the IDegAsp and the IDet treatment groups, see [Table 12–12](#). The most frequently reported AEs in both treatment groups were nasopharyngitis, hypoglycaemia, upper respiratory tract infection and headache, see [Table 12–13](#). The majority of AEs were mild or moderate in severity and only few of the AEs were severe. The rate of severe AEs was numerically lower with IDegAsp than with IDet (33 and 48 events per 100 PYE, respectively). The rate of AEs possibly or probably related to investigational product was numerically lower with IDegAsp than with IDet (37 and 69 events per 100 PYE, respectively) ([Table 12–15](#)). The majority of subjects in both treatment groups recovered from the AEs at the end of trial.

No AEs were fatal (Section [12.3.1](#)). The rate of SAEs was similar between the IDegAsp and IDet groups (24 and 19 events per 100 PYE, respectively) (Section [12.3.2](#)). The most frequently reported SAEs were hypoglycaemia reported by 4.1% and 5.0% of subjects in IDegAsp and IDet treatment groups, see [EOT Table 14.3.1.6](#). The analysis of SAE was also repeated using ETS and the results was in accordance with the results based on SAS, see [EOT Table 14.3.1.3](#).

A similar proportion of subjects were withdrawn from the trial due to AEs in the IDegAsp group (7 subjects) and the IDet group (3 subjects) corresponding to the 2:1 randomisation (Section [12.3.3.1](#)). The most frequently reported AEs leading to withdrawal were related to hypoglycaemia, see [EOT Listing 14.3.2.4](#).

Table 12–12 Adverse Events - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N (%)	OD E R	IDet N (%)	E R	Total N (%)	E R
Number of Subjects	362		180		542	
Events	267 (73.8)	1210 408	127 (70.6)	643 442	394 (72.7)	1853 419
Serious						
Yes	46 (12.7)	72 24	20 (11.1)	28 19	66 (12.2)	100 23
No	262 (72.4)	1138 383	126 (70.0)	615 423	388 (71.6)	1753 396
Severity						
Severe	64 (17.7)	98 33	34 (18.9)	70 48	98 (18.1)	168 38
Moderate	131 (36.2)	276 93	55 (30.6)	121 83	186 (34.3)	397 90
Mild	220 (60.8)	836 282	115 (63.9)	452 311	335 (61.8)	1288 291
Related to Investigational Product						
Probably	30 (8.3)	50 17	24 (13.3)	65 45	54 (10.0)	115 26
Possibly	48 (13.3)	61 21	24 (13.3)	35 24	72 (13.3)	96 22
Unlikely	252 (69.6)	1094 369	121 (67.2)	539 371	373 (68.8)	1633 369
Missing	5 (1.4)	5 2	4 (2.2)	4 3	9 (1.7)	9 2
Related to Bolus Insulin						
Probably	32 (8.8)	55 19	23 (12.8)	35 24	55 (10.1)	90 20
Possibly	39 (10.8)	52 18	21 (11.7)	35 24	60 (11.1)	87 20
Unlikely	254 (70.2)	1098 370	122 (67.8)	569 391	376 (69.4)	1667 377
Missing	5 (1.4)	5 2	4 (2.2)	4 3	9 (1.7)	9 2
Related to Device						
Yes	4 (1.1)	4 1	0 (0.0)	0 0	4 (0.7)	4 1
No	266 (73.5)	1201 405	125 (69.4)	639 439	391 (72.1)	1840 416
Missing	5 (1.4)	5 2	4 (2.2)	4 3	9 (1.7)	9 2
Outcome						
Recovered	246 (68.0)	1023 345	121 (67.2)	532 366	367 (67.7)	1555 352
Recovering	17 (4.7)	19 6	7 (3.9)	8 5	24 (4.4)	27 6
Recovered with Sequelae	2 (0.6)	2 1	1 (0.6)	1 1	3 (0.6)	3 1
Not Recovered	92 (25.4)	165 56	51 (28.3)	102 70	143 (26.4)	267 60
Unknown	1 (0.3)	1 0	0 (0.0)	0 0	1 (0.2)	1 0

N= Number of Subjects
%= Percentage of Subjects
E= Number of Events
R= Event Rate per 100 Patient Years of Exposure

Cross-reference: [EOT Table 14.3.1.1](#)

Table 12–13 Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 5\%$]- Treatment Emergent - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	N	Total (%)	E	R
Number of Subjects	362				180				542			
Events	172	(47.5)	441	149	92	(51.1)	253	174	264	(48.7)	694	157
Infections and infestations												
Gastroenteritis	15	(4.1)	16	5	9	(5.0)	10	7	24	(4.4)	26	6
Influenza	25	(6.9)	25	8	9	(5.0)	12	8	34	(6.3)	37	8
Nasopharyngitis	89	(24.6)	139	47	38	(21.1)	62	43	127	(23.4)	201	45
Upper respiratory tract infection	33	(9.1)	48	16	20	(11.1)	30	21	53	(9.8)	78	18
Metabolism and nutrition disorders												
Hypoglycaemia	41	(11.3)	65	22	31	(17.2)	59	41	72	(13.3)	124	28
Nervous system disorders												
Headache	35	(9.7)	102	34	16	(8.9)	22	15	51	(9.4)	124	28
Gastrointestinal disorders												
Diarrhoea	13	(3.6)	14	5	12	(6.7)	12	8	25	(4.6)	26	6
Nausea	14	(3.9)	24	8	9	(5.0)	10	7	23	(4.2)	34	8
General disorders and administration site conditions												
Injection site reaction	5	(1.4)	8	3	9	(5.0)	36	25	14	(2.6)	44	10

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

Cross-reference: [EOT Table 14.3.1.4](#)

12.2.2 Analysis of Adverse Events

12.2.2.1 All Adverse Events

The observed rates of AEs were similar in the IDegAsp and the IDet treatment groups, 408 and 442 events per 100 PYE, respectively ([Table 12–12](#)). The most frequently reported AEs in both treatment groups were nasopharyngitis, hypoglycaemia, upper respiratory tract infection and headache, see [Table 12–13](#). See Section [12.3](#) for information on SAEs.

The observed rate of AEs was similar between treatment groups for most system organ classes (SOC) and preferred terms (PT) ([EOT Table 14.3.1.8](#)). No clustering of terms was noted. There were few clinically relevant differences between treatment groups that are described here. The rate of ‘general disorders and administration site conditions’ was numerically lower with IDegAsp than with IDet (21 and 48 events per 100 PYE, respectively). This was primarily driven by injection site reactions in the IDet group. For details related to injection site reactions, see section below. For the remaining SOC and PTs, the rates were similar or only very few events were reported.

Clinically significant changes in vital signs, laboratory parameters, fundoscopy, ECG and other safety assessments were reported as AEs and are therefore included in these tables. Hypoglycaemic episodes were only reported as AEs if they fulfilled the criteria of SAEs or the definition of severe hypoglycaemia. Hypoglycaemic episodes are described in Section [12.4](#). A similar proportion of subjects in each treatment group reported increased, decreased or abnormal clinical laboratory samples as AEs under the investigations SOC. See Section [12.5](#) and [12.6](#) for more details.

A listing of all treatment emergent AEs by subject is included in [Appendix 16.2.7, Listings 16.2.7.1 and 16.2.7.2](#). AEs with onset prior to treatment with trial products are also listed by subject in [Appendix 16.2.7, Listing 16.2.7.3](#), as are AEs with onset after the defined treatment emergent period. AEs and SAEs reported by 1% or more of subjects are available in [EOT Tables 14.3.1.5 and 14.3.1.7](#), respectively.

Injection Site Reactions

Injection site reactions were reported more frequently in the IDet group (6.7%) than in the IDegAsp group (1.9%). None of the injection site reactions were reported as SAEs. The rate of injection site reactions per 100 PYE was numerically lower in the IDegAsp group (3) than in the IDet group (28) ([EOT Table 14.3.1.29](#) and [EOT Figure 14.3.1.30](#)). The difference was primarily driven by one subject in the IDet group who experienced ■ non-serious injection site related events.

Immunogenicity Concerned Adverse Events (Allergic Reactions)

Three (3) AEs were identified as immunogenicity related events (allergic reactions) according to the SMQ list in [Appendix 16.2.7, Listing 16.2.7.4](#), two (2) in the IDet treatment group (eye swelling and urticaria) and one (1) in the IDegAsp treatment group (eye swelling), [EOT Table 14.3.1.26](#).

Two (2) of these immunogenicity concerned AEs were reported in the main trial NN5401-3594. The narratives are provided in [EOT Listing 14.3.3](#).

The following TEAE was not captured in the above classification but was reported as an allergic reaction by the investigator (PT:hypersensitivity):

Briefly, subject [REDACTED] (IDegAsp) had a severe SAE, (hypersensitivity), [REDACTED]

[REDACTED]

The following TEAE is included in [EOT Table 14.3.1.29](#) (injection site reactions):

Subject [REDACTED] (IDet), had a moderate non-serious injection site reaction [REDACTED]

[REDACTED]

For detail, refer to [EOT Narratives 14.3.3](#).

Neoplasm

In total 11 AEs were identified as neoplasms (IDegAsp:4 and IDet: 7). One event reported by Subject [REDACTED] was not assessed as being neoplasms by medical review. Of these, four (4) were serious neoplasm AEs (all in the IDet group) and seven (7) non-serious AEs. Two of the neoplasms were reported during the main trial [REDACTED] [PT: skin papilloma]), whereas the remaining neoplasms were reported during the extension trial. All neoplasms were considered unlikely related to the trial product, see [12.3.2](#) for detail. Please see [Table 12–14](#) for an overview.

Subject ID	Treatment arm	System Organ Class	Preferred Term/ Reported Term	Study Day	Serious/Severity / Relationship	Outcome
██████	IDegAsp	Neoplasms benign,malignant and unspecified (inclcysts and polyps)	Lipoma/ ██████████	██████████	N/Mild /Unlikely	██████████
██████	IDegAsp	Gastrointestinal disorders	Colonic polyp ██████████		N/Moderate/ Unlikely	
██████	IDegAsp	Gastrointestinal disorders	Gastric polyps ██████████		Y/Moderate/ Unlikely	
██████	IDegAsp	Infections and infestations	Helicobacter gastritis ██████████		N/Moderate/ Unlikely	
██████	IDet	Neoplasms benign,malignant and unspecified (inclcysts and polyps)	Squamous cell carcinoma of skin/ ██████████		Y/ Moderate /Unlikely	
██████	IDet	Neoplasms benign,malignant and unspecified (inclcysts and polyps)/	Uterine leiomyoma/ ██████████		Y/ Severe/ Unlikely	
██████	IDet	Neoplasms benign,malignant and unspecified (inclcysts and polyps)/	Uterine leiomyoma/ ██████████		N/Mild/ Unlikely	
██████	IDet	Neoplasms benign,malignant and unspecified (inclcysts and polyps)	Skin papilloma/ ██████████		N/Mild/ Unlikely	
██████	IDet	Neoplasms benign,malignant and unspecified (inclcysts and polyps)	Thyroid neoplasm/ ██████████		N/Mild/ Unlikely	

Subject ID	Treatment arm	System Organ Class	Preferred Term/ Reported Term	Study Day	Serious/Severity / Relationship	Outcome
██████	IDet	Neoplasms benign,malignant and unspecified (inclcysts and polyps)	Benign neoplasma of thyroid gland/██████	██████	N/Mild/ Unlikely	██████
██████	IDet	Neoplasms benign,malignant and unspecified (inclcysts and polyps)	Bladder cancer/██████		Y/ Severe /Unlikely	

ID = identification; IDegAsp = insulin degludec/insulin aspart; IDet = insulin detemir

Cross-reference: [EOT Table 14.3.1.25](#) and [Narratives 14.3.3](#)

12.2.2.2 Adverse Events by Relationship to Investigational Product (IDegAsp or IDet)

The percentage of subjects with AEs considered possibly or probably related to investigational product (IDegAsp or IDet) by the investigator was similar in the two treatment groups (18.5% with IDegAsp and 22.2% with IDet). The rate of AEs considered possibly or probably related to IDegAsp or IDet by the investigator was numerically lower in the IDegAsp group than the IDet group (37 and 69 events per 100 PYE, respectively) ([Table 12–15](#)). Of the AEs considered possibly or probably related to investigational product, hypoglycaemia and injection site reactions were reported with the highest rates. The rates of both hypoglycaemia and injection site reactions were numerically lower with the IDegAsp group than the IDet group (rate of hypoglycaemia: 17 and 29 events per 100 PYE; rate of injection site reactions: 2 and 24 events per 100 PYE respectively), refer to Section [12.4](#).

Table 12–15 Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	67	(18.5)	111	37	40	(22.2)	100	69	107	(19.7)	211	48
Metabolism and nutrition disorders	36	(9.9)	60	20	23	(12.8)	47	32	59	(10.9)	107	24
Hypoglycaemia	30	(8.3)	49	17	22	(12.2)	42	29	52	(9.6)	91	21
Hypoglycaemic unconsciousness	7	(1.9)	7	2	3	(1.7)	3	2	10	(1.8)	10	2
Hypoglycaemic seizure	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Hyperglycaemia	2	(0.6)	2	1					2	(0.4)	2	0
Diabetic ketoacidosis					1	(0.6)	1	1	1	(0.2)	1	0
General disorders and administration site conditions	9	(2.5)	11	4	10	(5.6)	39	27	19	(3.5)	50	11
Injection site reaction	4	(1.1)	6	2	8	(4.4)	35	24	12	(2.2)	41	9
Injection site pain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Oedema peripheral	2	(0.6)	2	1					2	(0.4)	2	0
Asthenia					1	(0.6)	1	1	1	(0.2)	1	0
Hunger	1	(0.3)	1	0					1	(0.2)	1	0
Injection site erythema					1	(0.6)	1	1	1	(0.2)	1	0
Injection site papule					1	(0.6)	1	1	1	(0.2)	1	0
Injury, poisoning and procedural complications	7	(1.9)	7	2	3	(1.7)	3	2	10	(1.8)	10	2
Wrong drug administered	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Medication error	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Incorrect dose administered	1	(0.3)	1	0					1	(0.2)	1	0
Intentional overdose	1	(0.3)	1	0					1	(0.2)	1	0
Upper limb fracture	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

Adverse Events Possibly or Probably Related to Investigational Medicinal Product by
System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Investigations	7	(1.9)	7	2	2	(1.1)	2	1	9	(1.7)	9	2
Weight increased	5	(1.4)	5	2	1	(0.6)	1	1	6	(1.1)	6	1
Blood glucose increased	1	(0.3)	1	0					1	(0.2)	1	0
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	0					1	(0.2)	1	0
Nervous system disorders	8	(2.2)	11	4					8	(1.5)	11	2
Headache	5	(1.4)	8	3					5	(0.9)	8	2
Hypoglycaemic coma	1	(0.3)	1	0					1	(0.2)	1	0
Lethargy	1	(0.3)	1	0					1	(0.2)	1	0
Neurological symptom	1	(0.3)	1	0					1	(0.2)	1	0
Gastrointestinal disorders	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Nausea	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Vomiting	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Abdominal discomfort	1	(0.3)	1	0					1	(0.2)	1	0
Infections and infestations	3	(0.8)	3	1	1	(0.6)	1	1	4	(0.7)	4	1
Abscess	1	(0.3)	1	0					1	(0.2)	1	0
Peritonsillar abscess					1	(0.6)	1	1	1	(0.2)	1	0
Sinusitis	1	(0.3)	1	0					1	(0.2)	1	0
Tracheobronchitis	1	(0.3)	1	0					1	(0.2)	1	0
Skin and subcutaneous tissue disorders	1	(0.3)	1	0	3	(1.7)	4	3	4	(0.7)	5	1
Lipodystrophy acquired					1	(0.6)	1	1	1	(0.2)	1	0
Lipohypertrophy					1	(0.6)	2	1	1	(0.2)	2	0
Rash					1	(0.6)	1	1	1	(0.2)	1	0
Skin disorder	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

Cross-reference: [EOT Table 14.3.1.11](#)

The rate of severe AEs considered possibly or probably related to IDegAsp or IDet by the investigator was numerically lower with IDegAsp (18 and 28 events per 100 PYE with IDegAsp and IDet treatments groups, respectively) ([EOT Table 14.3.1.18](#)). Hypoglycaemia was the most frequently reported severe AE considered possibly or probably related to IDegAsp or IDet and was reported with 13 and 23 events per 100 PYE with IDegAsp and IDet treatment groups, respectively.

12.2.2.3 Adverse Events by Relationship to Bolus Insulin (IAsp)

The rate of AEs considered possibly or probably related to IAsp by the investigator was numerically lower in IDegAsp treatment group (36 and 48 events per 100 PYE with IDegAsp and IDet, respectively) ([EOT Table 14.3.1.12](#)). Hypoglycaemia was the most frequently reported AE considered possibly or probably related to IAsp with a numerically lower rate with IDegAsp (17 and 29 events per 100 PYE with IDegAsp and IDet, respectively), see Section [12.4](#).

The rate of severe AEs considered possibly or probably related to IAsp by the investigator was numerically lower in IDegAsp treatment group (19 and 32 events per 100 PYE with IDegAsp and IDet, respectively) ([EOT Table 14.3.1.19](#)). Hypoglycaemia was the most frequently reported severe AE considered possibly or probably related to IAsp, and was reported with a numerically lower rate with IDegAsp (13 and 25 events per 100 PYE with IDegAsp and IDet, respectively), see Section [12.4](#).

Note that there was a considerable overlap between the hypoglycaemic episodes reported with possible/probable relationship to IDegAsp/IDet and IAsp.

12.2.2.4 Adverse Events by Relationship to Insulin Delivery Device

The rate of AEs considered related to insulin delivery device by the investigator was low in both treatment groups (1 and 0 events per 100 PYE with IDegAsp and IDet, respectively) ([EOT Table 14.3.1.13](#)). In total four (4) AEs related to insulin delivery device were reported, including three (3) hyperglycaemia in the main trial and one (1) blood glucose increase in the extension trial. Two (2) of these AEs were related to the IAsp insulin delivery device, one (1) to the IDegAsp insulin delivery device and one (1) to both IDegAsp and IAsp insulin delivery device ([Appendix 16.2.7](#), [EOT Listings 16.2.7.2](#) and [16.2.7.6](#)). Technical complaints to the insulin delivery device with relation to an AE are listed in [Appendix 16.2.7, Listing 16.2.7.6](#). None of the four (4) events were severe ([EOT Table 14.3.1.20](#)) and none of the AEs related to the insulin delivery device were associated with injection site disorders.

12.2.2.5 Adverse Events by Severity

The majority of AEs were mild or moderate. The rate of mild AEs was similar with IDegAsp and IDet (282 and 311 events per 100 PYE, respectively) ([Table 12-12](#) and [EOT Table 14.3.1.23](#)), as was the rate of moderate AEs (93 and 83 events per 100 PYE, respectively) ([EOT Table 14.3.1.22](#)). The majority of the AEs were recovered at the end of trial.

Few of the AEs were severe in either treatment group, and the rate of severe AEs was numerically lower with IDegAsp group (33 and 48 events per 100 PYE, with IDegAsp and IDet respectively) ([Table 12–12](#) and [EOT Table 14.3.1.17](#)). The majority of subjects with severe AEs were recovered or recovering at the end of the trial. The most frequently reported severe AE was hypoglycaemia in both treatment groups (17 and 33 events per 100 PYE, in the IDegAsp and IDet group, respectively), see [EOT Table 14.3.1.17](#). For the remaining system organ classes and preferred terms, the rates were similar or only very few events were reported.

Severe AEs considered possibly or probably related to investigational product are described in Section [12.2.2.2](#), severe AEs considered possibly or probably related to bolus insulin are described in Section [12.2.2.3](#) and severe AEs considered related to device are described in Section [12.2.2.4](#).

12.3 Deaths, Other Serious Adverse Events and Other Significant Adverse Events

12.3.1 Deaths

No deaths occurred during the trial. Hence the listing and narratives for deaths are empty ([EOT Listing 14.3.2.2](#) and [EOT Listing 14.3.3](#)).

12.3.2 Other Serious Adverse Events

12.3.2.1 All Serious Adverse Events

The rate of SAEs was similar for IDegAsp and IDet (24 and 19 events per 100 PYE) ([Table 12–16](#)). The most frequently reported SAEs were hypoglycaemia (4.4%) in both treatment groups, with rates of 8 and 6 events per 100 PYE with IDegAsp and IDet, respectively ([EOT Tables 14.3.1.6](#) and [14.3.1.7](#)). All but 2 subjects (Subject [REDACTED] and [REDACTED], both in the IDegAsp group) were recovered at the end of the trial. The analysis of SAE was also repeated on ETS analysis set, and the result was in accordance with those from SAS, see [EOT Table 14.3.1.3](#). Narratives of all SAEs are available in [EOT Narratives 14.3.3](#). SAE by system organ classes (SOC) and preferred terms (PT) are summarised in [EOT Tables 14.3.1.9](#) and [14.3.1.10](#).

Table 12–16 Serious Adverse Events – Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	46 (12.7)	72	24	20 (11.1)	28	19	66 (12.2)	100	23
Severity									
Severe	34 (9.4)	55	19	18 (10.0)	22	15	52 (9.6)	77	17
Moderate	15 (4.1)	16	5	3 (1.7)	5	3	18 (3.3)	21	5
Mild	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Related to Investigational Product									
Probably	16 (4.4)	27	9	7 (3.9)	8	5	23 (4.2)	35	8
Possibly	8 (2.2)	9	3	2 (1.1)	2	1	10 (1.8)	11	2
Unlikely	29 (8.0)	36	12	15 (8.3)	18	12	44 (8.1)	54	12
Related to Bolus Insulin									
Probably	14 (3.9)	27	9	9 (5.0)	11	8	23 (4.2)	38	9
Possibly	7 (1.9)	9	3	2 (1.1)	2	1	9 (1.7)	11	2
Unlikely	31 (8.6)	36	12	12 (6.7)	15	10	43 (7.9)	51	12
Related to Device									
No	46 (12.7)	72	24	20 (11.1)	28	19	66 (12.2)	100	23
Outcome									
Recovered	42 (11.6)	67	23	19 (10.6)	27	19	61 (11.3)	94	21
Recovering	1 (0.3)	1	0	0 (0.0)	0	0	1 (0.2)	1	0
Recovered with Sequelae	2 (0.6)	2	1	1 (0.6)	1	1	3 (0.6)	3	1
Not Recovered	2 (0.6)	2	1	0 (0.0)	0	0	2 (0.4)	2	0

N= Number of Subjects
%= Percentage of Subjects
E= Number of Events
R= Event Rate per 100 Patient Years of Exposure

Cross-reference: [EOT Table 14.3.1.2](#)

Cardiovascular Events Suspected Related to Acute Coronary Syndrome, Stroke or Cardiovascular Death

An independent external Event Adjudication Committee (EAC) was constituted for the trial to perform ongoing adjudication, standardisation and assessment of cardiovascular events. A total of 3 (0.8%) subjects experienced 3 cardiovascular events in the IDegAsp group and 1 (0.6%) subject experienced 1 cardiovascular event in the IDet group that qualified for adjudication by the event adjudication committee (EAC). None of these cardiovascular events was evaluated to be major adverse cardiovascular events (MACE) by the EAC, see [Table 12–17](#).

Table 12–17 Adjudicated Cardiovascular Events - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp				IDet			
	N	(%)	OD E	R	N	(%)	E	R
Number of Subjects	362				180			
EAC Evaluated Events	3	(0.8)	3	1	1	(0.6)	1	1
Non MACE	3	(0.8)	3	1	1	(0.6)	1	1
MACE	0	(0.0)	0	0	0	(0.0)	0	0
Acute coronary syndrome	0	(0.0)	0	0	0	(0.0)	0	0
Unstable Angina pectoris	0	(0.0)	0	0	0	(0.0)	0	0
Myocardial Infarction	0	(0.0)	0	0	0	(0.0)	0	0
STEMI	0	(0.0)	0	0	0	(0.0)	0	0
NSTEMI	0	(0.0)	0	0	0	(0.0)	0	0
Stroke	0	(0.0)	0	0	0	(0.0)	0	0
Cardiovascular Death	0	(0.0)	0	0	0	(0.0)	0	0

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years, EAC:(external) Event Adjudication Committee,
MACE: Major Adverse Cardiovascular Events, NSTEMI: Non-ST-elevation Myocardial Infarction
STEMI: ST-elevation Myocardial Infarction.

Cross-reference: [EOT Table 14.3.1.28](#)

A cardiovascular event occurred in a [REDACTED] Subject [REDACTED] in the IDegAsp group) [REDACTED]
[REDACTED]
[REDACTED] The causality was judged unlikely related to trial products by the investigator and sponsor. The cardiovascular event occurred in a [REDACTED] Subject ID: [REDACTED] in the IDegAsp group) [REDACTED]
[REDACTED]
[REDACTED] The causality was judged unlikely related to trial products by the investigator and sponsor. Another two (2) subjects (subject ID: [REDACTED] in the IDet group and [REDACTED] in the IDegAsp group, both in extension trial) [REDACTED]
[REDACTED] were evaluated to be non-related to cardiovascular event. The causality was judged unlikely related to trial products by the investigator for both events. For detail, see [Appendix 16.2.8, Listing 16.2.8.1](#).

Neoplasms

A total of 11 AEs were identified as neoplasms (IDegAsp:4 and IDet: 7). Of these, four (4) were serious neoplasm AEs (3 in the IDet treatment group and 1 in the IDegAsp treatment group) and seven (7) non-serious AEs. Two of the neoplasms were reported during the main trial. All neoplasms were considered unlikely related to the trial product. Please see [Table 12–14](#) for an

overview. Four (4) subjects reported neoplasm as SAEs. One event was reported by an [REDACTED]

In addition, two (2) events were reported as neoplasms by the investigator, but not captured by the SMQ searches. These two events covered [REDACTED] (Subject ID: [REDACTED]) and one [REDACTED] (Subject ID: [REDACTED]).

12.3.2.2 Serious Adverse Events by Relationship

The rate of SAEs considered possibly or probably related to IDegAsp or IDet by the investigator was 12 and 7 SAEs per 100 PYE, respectively ([Table 12–18](#)). The rate of SAEs considered possibly or probably related to IAsp by the investigator was similar between treatment groups (12 and 9 events per 100 PYE, with IDegAsp and IDet, respectively, [EOT Table 14.3.1.15](#)). The most frequently reported SAE considered possibly or probably related to IDegAsp, IDet and IAsp was hypoglycaemia in both treatment groups. Note that there was a considerable overlap between the hypoglycaemic episodes reported with possible/probable relationship to IDegAsp/IDet and IAsp.

There were two SAEs reported in the main trial for which there was a discrepancy between the Investigator and the sponsor regarding the evaluation of causality. For subject [REDACTED], the investigator evaluated the report of diabetic ketoacidosis [REDACTED] as unlikely related to IDet and IAsp, whereas the sponsor evaluated the SAE as possibly related to IDet and IAsp. For subject [REDACTED] (IDet), the investigator evaluated the report of suicidal ideation [REDACTED] as probably related to IAsp, whereas the sponsor evaluated the SAE as unlikely related to IAsp.

Table 12–18 Serious Adverse Events Possibly or Probably Related Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp	OD			IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Events	21	(5.8)	36	12	8	(4.4)	10	7	29	(5.4)	46	10
Metabolism and nutrition disorders	18	(5.0)	30	10	8	(4.4)	10	7	26	(4.8)	40	9
Hypoglycaemia	13	(3.6)	23	8	6	(3.3)	6	4	19	(3.5)	29	7
Hypoglycaemic unconsciousness	5	(1.4)	5	2	3	(1.7)	3	2	8	(1.5)	8	2
Hypoglycaemic seizure	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Injury, poisoning and procedural complications	3	(0.8)	3	1					3	(0.6)	3	1
Wrong drug administered	2	(0.6)	2	1					2	(0.4)	2	0
Intentional overdose	1	(0.3)	1	0					1	(0.2)	1	0
Musculoskeletal and connective tissue disorders	1	(0.3)	1	0					1	(0.2)	1	0
Arthralgia	1	(0.3)	1	0					1	(0.2)	1	0
Nervous system disorders	1	(0.3)	1	0					1	(0.2)	1	0
Hypoglycaemic coma	1	(0.3)	1	0					1	(0.2)	1	0
Psychiatric disorders	1	(0.3)	1	0					1	(0.2)	1	0
Suicide attempt	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

Cross-reference: [EOT Table 14.3.1.14](#)

There were no SAEs considered related to device by the investigator in either treatment group ([EOT Table 14.3.1.16](#)). No injection site reactions were reported as SAEs.

The majority of SAEs were severe. The rate of severe SAEs was 19 and 15 events per 100 PYE in the IDegAsp and IDet group, respectively. See [EOT Table 14.3.1.21](#) for an overview of all severe SAEs.

SAEs leading to withdrawal are described in Section [12.3.3.1](#). A listing of all SAEs is included in [EOT Listing 14.3.2.1](#). Narratives for SAEs are included in [EOT Listing 14.3.3](#). Case report forms for subjects with SAEs are included in [Appendix 16.3.1](#).

12.3.3 Other Significant Adverse Events

12.3.3.1 Adverse Events leading to Withdrawal

A total of 7 (1.3%) subjects withdrew from the main trial (NN5401-3594) due to AEs: 4 (1.1%) in the IDegAsp group and 3 (1.6%) in the IDet group ([EOT Table 14.1.1](#)). A total of 3 (0.5%) subjects withdrew from the extension trial due to AEs: 3 (0.8%) in the IDegAsp group and 0 (0%) in the IDet group. In addition, one (1) subject in the IDegAsp group (Subject [REDACTED]) was withdrawn due to a non-serious worsening of [REDACTED]. However, the withdrawal reason recorded in the eCRF was 'Other' instead of 'AE', relevant data are not included in the AE withdrawal listing or table but located in [Appendix 16.2.1](#). Considering the 2:1 randomisation and the low number of AEs leading to withdrawal, there was no difference between the treatment groups in the number of subjects with AEs leading to withdrawal. The AEs that led to withdrawal are listed in [Table 12–19](#), details are in [EOT Listing 14.3.2.4](#).

Table 12–19 Subjects with Adverse Events leading to Withdrawal

Trial Insulin	Subject Number	Adverse Event	Withdrawals time	Investigator Causality (IDegAsp or IDet)/IAsp
IDegAsp	[REDACTED]	Severe Hypoglycaemia	Main trial	Probable/Probable
IDegAsp	[REDACTED]	Unconsciousness Hypoglycaemia	Main trial	Probable/Probable
IDegAsp	[REDACTED]	Hypoglycaemic Seizure	Main trial	Possible/Possible
IDegAsp	[REDACTED]	Worsening of Depression	Main trial	Unlikely/Unlikely
IDegAsp	[REDACTED]	Generalised Arthralgias	Extension trial	Probable/Unlikely
IDegAsp	[REDACTED]	Hypoglycemic Unconsciousness	Extension trial	Unlikely/Probable
IDegAsp	[REDACTED]	Hypoglycaemic coma, Suicide Attempt, Intentional Overdose	Extension trial	Unlikely/Probable
IDegAsp	[REDACTED]	Worsening of systemic lupus and Arthralgia	Main trial	- ^a
IDet	[REDACTED]	Wrong Drug Administered	Main trial	Unlikely/Probable
IDet	[REDACTED]	Diabetic Ketoacidosis, Leukocytosis, Intravascular Volume Depletion, Probable Viral Syndrome, and Hypokalemia	Main trial	Unlikely/Unlikely
IDet	[REDACTED]	Injection Site Reaction-Immunogenicity	Main trial	Probable/Possible

^a Primary reason for withdrawal of Subject [REDACTED] was listed as 'Other' and not AE. [REDACTED] there is therefore no causality evaluation for these 2 events.

SAEs were reported as the reason for withdrawal in 7 of the 10 subjects who withdrew because of an AE, 6 subjects in the IDegAsp group and 1 subject in the IDet group. All of the subjects recovered from these SAEs. In the IDegAsp group, the 4 SAEs (severe hypoglycaemia, unconsciousness Hypoglycaemia, hypoglycaemic seizure, generalised arthralgias, reported by Subjects [REDACTED], [REDACTED], [REDACTED] and [REDACTED] respectively) were judged to have possible or probable relation to trial product by the investigator. In the IDet group, one (1) SAE of diabetic ketoacidosis was reported for Subject [REDACTED] together with 4 other AEs. The investigator judged the 5 AEs from this subject to be unlikely related to trial products ([Appendix Listing 16.2.7.2](#)).

All AEs leading to withdrawal are listed in [EOT Listing 14.3.2.4](#). Case report forms for subjects with AEs leading to withdrawal are included in [Appendix 16.3.1](#). Narratives for AEs leading to withdrawal are included in [EOT Listing 14.3.3](#).

12.3.3.2 Adverse Events Leading to Dose Reduction in Investigational Product

A total of 71 subjects reported 101 AEs leading to a reduction in IDegAsp, IDet or IAsp during the trial: 49 subjects with 62 AEs in the IDegAsp group and 22 subjects with 39 AEs in the IDet group ([EOT Table 14.3.1.24](#)). Among all of them, 67 AEs leading to investigational product dose reduction were reported by 55 subjects in the main trial. The rate of AEs leading to dose reduction was similar between treatment groups (21 and 27 events per 100 PYE in the IDegAsp and IDet group, respectively). Approximately 13% of subjects in each treatment group experienced AEs leading to dose reduction. In both treatment groups, more than half of the AEs led to a reduction in the investigational product (IDegAsp or IDet). The rate of SAEs leading to dose reduction was also similar between treatment groups (6 and 5 events per 100 PYE in the IDegAsp and IDet group, respectively) ([EOT Table 14.3.1.24](#)). All of the AEs leading to dose reduction were recovered except for two (2) AEs (one in each treatment group). The most frequent AE leading to a dose reduction was hypoglycaemia. The rate of hypoglycaemia leading to dose reduction was 10 and 18 events per 100 PYE in the IDegAsp and IDet groups, respectively. See [EOT Table 14.3.1.26](#). AEs leading to a decrease in IDegAsp or IDet dose are listed in [EOT Listing 14.3.2.3](#).

12.3.3.3 Medical Events of Special Interest

Protocol predefined medical events of special interest (MESI) are described in Section [9.5.1.3](#). All AEs that, according to the protocol, were to be considered as medical events of special interest (Section [9.5.1.3](#)) and specified in the SMQ searches listed in [Appendix 16.2.7](#), [Listing 16.2.7.4](#) are summarised in [EOT Tables 14.3.1.25](#), [14.3.1.26](#), [14.3.1.28](#), [14.3.1.29](#) and [14.3.1.30](#). Narratives for these AEs are included in [EOT Listing 14.3.3](#).

Medication Errors

A total of 28 medication errors (20 in IDegAsp and 8 in IDet group) were reported for 24 subjects ([EOT Table 14.3.1.31](#)). Based on the reasons described in the narratives, a total of 16 of the 28

medication errors were mix-ups between basal and bolus insulin whereof 10 were related to mix-ups between IDegAsp and Iasp (in 8 cases IAsp injected instead of IDegAsp and in 2 cases IDegAsp injected instead of IAsp) and 6 due to mix-ups between IDet and Iasp (5 IAsp instead of IDet and 1 IDet instead of Iasp). Six (6) of the mix-ups occurred within the first month of treatment with trial product. One of the subjects with mix-up was subsequently withdrawn from the trial (subject [REDACTED]).

In most cases, the subjects managed their own BG levels by adjusting their food or beverage intake and by monitoring their BG closely, thereby avoiding hypoglycaemic episodes. Eight (8) of the mix-ups led to a hypoglycaemic episode (seven of them were due to administration of IAsp and one where IDegAsp was administered instead of IAsp); one of them was reported as serious (subject [REDACTED] required assistance from his wife).

Five overdoses related to IDegAsp or IDet (defined as 20% higher dose than prescribed) were reported by 4 subjects in this trial, four in IDegAsp group and 1 in IDet group. Subject [REDACTED] reported two episodes of [REDACTED]. The subject was subsequently withdrawn from the trial. Two subjects experienced non-serious hypoglycaemic episodes (subjects [REDACTED] and [REDACTED]).

The remaining 7 cases concerned dosage errors related to bolus insulin (one of them was serious - subject [REDACTED]), dispensing errors, missed dose and administration of insulin from patient's own supply.

Narratives for these events are presented in [EOT Listing 14.3.3](#).

Transmission of Infectious Agents via Trial Product

There was no report of transmission of infectious agents via trial product.

12.4 Hypoglycaemia

12.4.1 Introduction to Hypoglycaemic Episodes

Confirmed hypoglycaemic episodes consisted of episodes of severe hypoglycaemia as well as minor hypoglycaemic episodes with a confirmed PG value of less than 3.1 mmol/L (56 mg/dL). Hypoglycaemic episodes were defined as nocturnal if the time of onset was between 00:01 and 05:59 (both included).

The descriptive safety data and statistical analyses are based on the safety analysis set, while the statistical analyses of hypoglycaemia are based on the FAS (see Section [11.1](#)). Only treatment emergent hypoglycaemic episodes are described in this section. Hypoglycaemic episodes were categorised and analysed according to the definitions given in Sections [9.5.1.3](#) and [9.7.4.1](#).

Individual subject data for episodes of severe hypoglycaemia are included in [EOT Listing 14.3.3](#). Treatment emergent events of severe hypoglycaemia are listed in [Appendix 16.2.7](#), [Listing 16.2.7.5](#). Hypoglycaemic episodes reported as an SAE are listed in [EOT Listing 14.3.2.1](#).

12.4.2 Confirmed Hypoglycaemic Episodes

The percentage of subjects who experienced confirmed hypoglycaemic episodes during the treatment period was similar in IDegAsp and IDet group (95% and 93.9%, respectively). The rate of confirmed hypoglycaemic episodes per 100 PYE was similar with IDegAsp and IDet (3183 and 3673 episodes per 100 PYE, respectively), see [Table 12–20](#). Half (50%) of the subjects in both treatment groups reported less than 20 confirmed hypoglycaemic episodes during the trial ([EOT Figure 14.3.1.49](#)).

Table 12–20 Hypoglycaemic Episodes by Classification – Treatment Emergent – Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Confirmed	344 (95.0)		9450	3183	169 (93.9)		5342	3673	513 (94.6)		14792	3344
ADA	355 (98.1)		20460	6892	173 (96.1)		10536	7243	528 (97.4)		30996	7007
Severe	48 (13.3)		79	27	33 (18.3)		65	45	81 (14.9)		144	33
Documented Sympt.	330 (91.2)		14038	4729	162 (90.0)		7611	5232	492 (90.8)		21649	4894
Asymptomatic	283 (78.2)		5879	1980	141 (78.3)		2575	1770	424 (78.2)		8454	1911
Probable Sympt.	84 (23.2)		323	109	48 (26.7)		245	168	132 (24.4)		568	128
Relative	50 (13.8)		141	47	21 (11.7)		40	27	71 (13.1)		181	41
ADA Unclassifiable	119 (32.9)		507	171	57 (31.7)		296	203	176 (32.5)		803	182

N: Number of Subjects

#: Percentage of Subjects with the Event

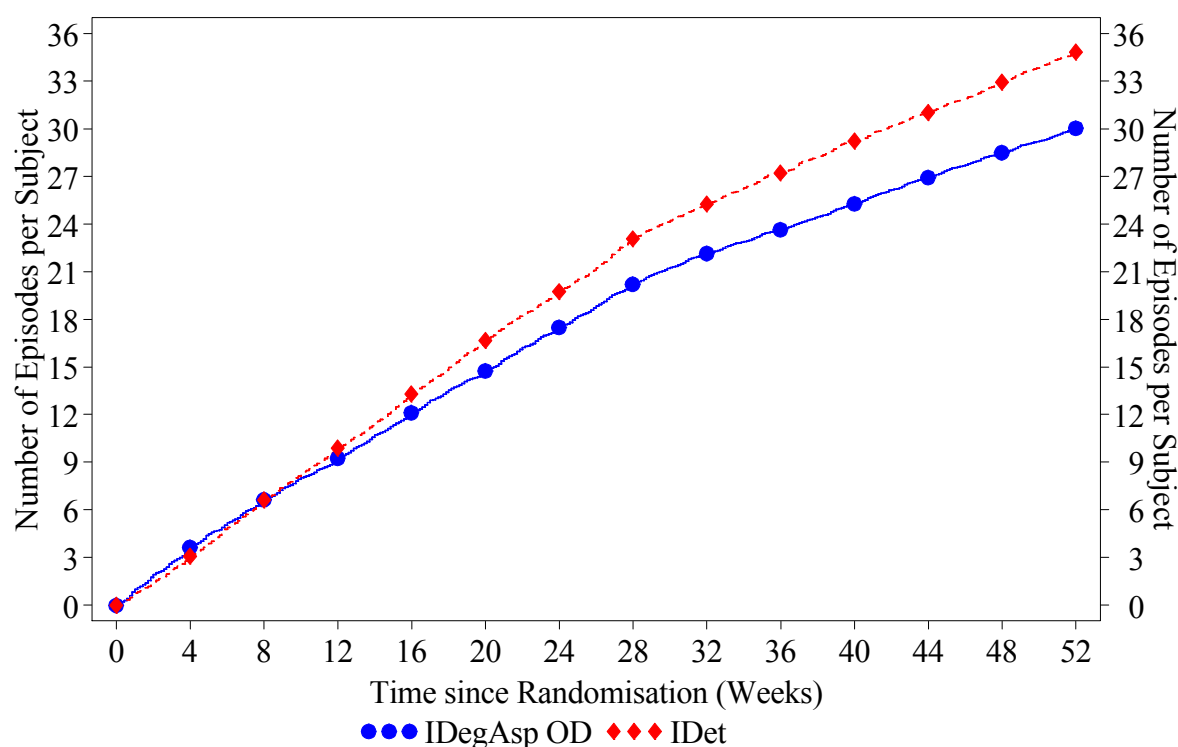
E: Number of Events

R: Event Rate per 100 Patient Year(s) of Exposure

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Cross-reference: [EOT Table 14.3.1.32](#)

The rate of confirmed hypoglycaemic events appeared similar between treatment groups during the first part of the trial (approximately before 8 weeks of treatment), followed by a numerically lower rate of hypoglycaemic episodes in the IDegAsp group than the IDet group during the last part of the trial ([Figure 12–4](#)).



Cross-reference: [EOT Figure 14.3.1.51](#)

Figure 12–4 Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set

The cumulative frequency of confirmed hypoglycaemic episodes over 24 hours was lower during the night (from 24:00 to around 6:00) as evaluated based on the slope, which then increased to a slightly higher but steady level during the day as evaluated by the straight line with a steeper slope from 6:00 to 24:00 in both treatment groups [EOT Figure 14.3.1.55](#).

There was no statistical significant difference in the rate of confirmed hypoglycaemic episodes between IDegAsp and IDet after 52 weeks of treatment. The estimated rate ratio for confirmed hypoglycaemia was 0.95 [0.79; 1.14]_{95% CI}, [EOT Table 14.3.1.39](#). The confirmed hypoglycaemic episodes was also analysed on ETS analysis set, and result was in accordance with those from FAS, see [EOT Tables 14.3.1.33](#), [14.3.1.40](#) and [EOT Figure 14.3.1.52](#).

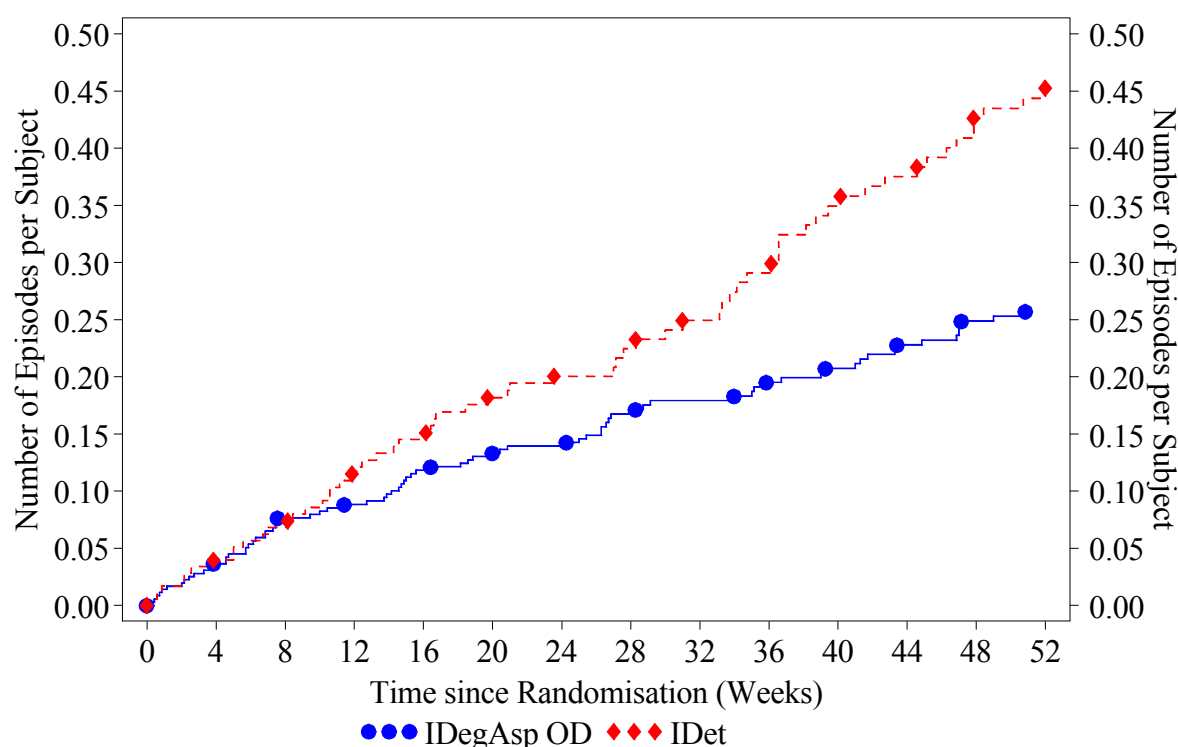
The number of subjects achieving HbA_{1c} targets without confirmed hypoglycaemia was analysed in Section [11.4.1.2](#).

12.4.3 Severe Hypoglycaemia

The percentage of subjects who experienced severe hypoglycaemia during the treatment period was 13.3% with IDegAsp and 18.3% with IDet. The rate of severe hypoglycaemia episodes per 100 PYE was 27 with IDegAsp and 45 with IDet ([Table 12-20](#)). More than 80% of subjects in both treatment groups did not report any episodes of severe hypoglycaemia ([EOT Table 14.3.1.32](#) and [EOT Figure 14.3.1.43](#)).

The rate of severe hypoglycaemia was lower in the IDegAsp treatment group than in the IDet treatment group ([Figure 12-5](#)).

The cumulative frequency of severe hypoglycaemia over 24 hours was low during the night (from 24:00 to around 6:00) and then increased to a slightly higher but steady level during the day (from 6:00 to 24:00) in both treatment groups. The cumulative frequency of severe hypoglycaemia in the IDet group displayed an increased rate from around 2:00 to 6:00 as seen from the steeper slope during this period compared to the IDegAsp group which displayed a more constant rate throughout the 24 hours ([EOT Figure 14.3.1.48](#)).



Cross-reference: [EOT Figure 14.3.1.45](#)

Figure 12-5 Severe Hypoglycaemic Episodes - Treatment Emergent - Mean Cumulative Function - Safety Analysis Set

There was no statistical significant difference in the rate of severe hypoglycaemic episodes between IDegAsp and IDet after 52 weeks of treatment. The estimated rate ratios (IDegAsp/IDet) for severe hypoglycaemia were 0.98 [0.54; 1.79]_{95% CI}. The severe hypoglycaemic episodes was also analysed on ETS analysis set, and result was in accordance with those from FAS, see [EOT Table 14.3.1.40](#) and [EOT Figure 14.3.1.46](#). Narratives for episodes of severe hypoglycaemia reported as SAEs are included in [EOT Listing 14.3.3](#).

12.4.4 Nocturnal Hypoglycaemic Episodes

12.4.4.1 Nocturnal Confirmed Hypoglycaemic Episodes

The percentage of subjects who experienced nocturnal confirmed hypoglycaemic episodes during the treatment period was 61% with IDegAsp and 75% with IDet, with rates of 309 and 541 nocturnal confirmed hypoglycaemic episodes per 100 PYE, respectively ([Table 12–21](#)). Half (50%) of subjects in the IDegAsp group reported less than 2 episodes per PYE and 50% of subjects in the IDet group reported less than 4 episodes per PYE ([EOT Figure 14.3.1.50](#)).

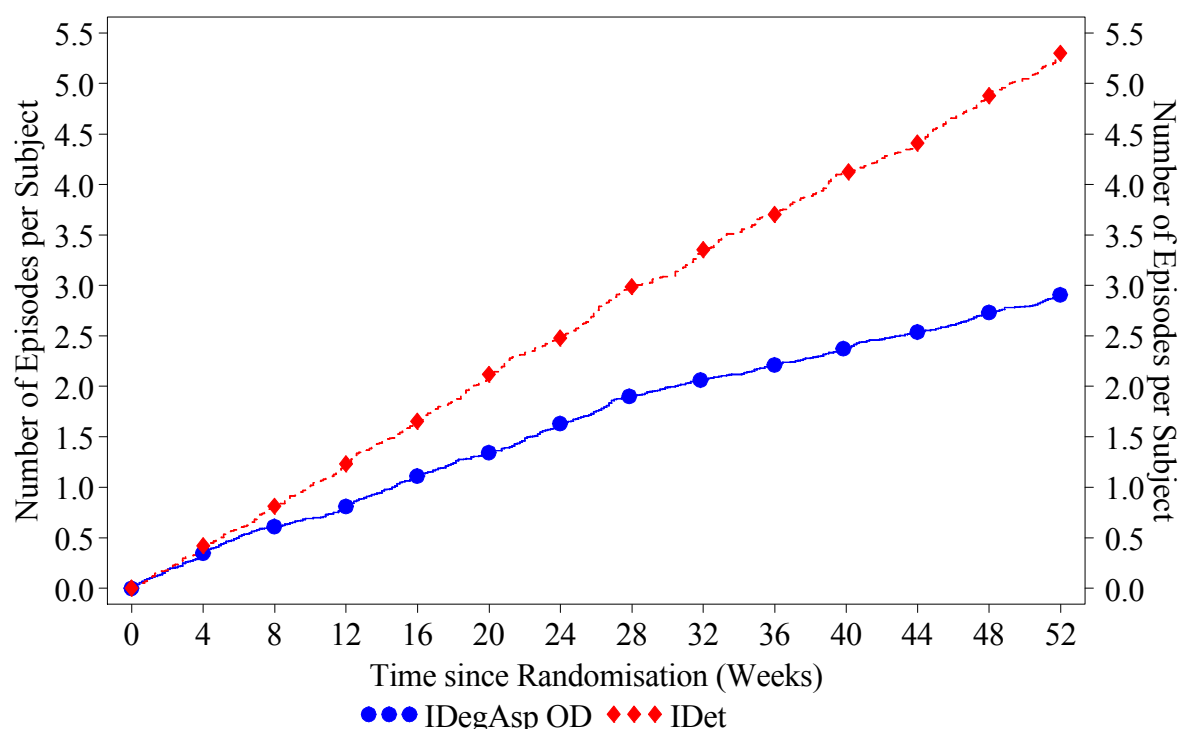
Table 12–21 Nocturnal Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	N	Total (%)	E	R
Number of Subjects	362			180			542			
Confirmed	221 (61.0)	918	309	135 (75.0)	787	541	356 (65.7)	1705	385	
ADA	256 (70.7)	1654	557	147 (81.7)	1171	805	403 (74.4)	2825	639	
Severe	13 (3.6)	14	5	14 (7.8)	28	19	27 (5.0)	42	9	
Documented Sympt.	224 (61.9)	1275	429	119 (66.1)	904	621	343 (63.3)	2179	493	
Asymptomatic	98 (27.1)	303	102	58 (32.2)	176	121	156 (28.8)	479	108	
Probable Sympt.	28 (7.7)	56	19	24 (13.3)	58	40	52 (9.6)	114	26	
Relative	4 (1.1)	6	2	5 (2.8)	5	3	9 (1.7)	11	2	
ADA Unclassified	12 (3.3)	13	4	8 (4.4)	22	15	20 (3.7)	35	8	

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure

Cross-reference: [EOT Table 14.3.1.34](#)

The rate of nocturnal confirmed hypoglycaemic episodes was lower in the IDegAsp group than the IDet group throughout the trial ([Figure 12–6](#)).



Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

Cross-reference: [EOT Figure 14.3.1.53](#)

Figure 12–6 Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set

The nocturnal confirmed hypoglycaemic episodes reported during the 52 weeks of treatment were analysed using a negative binomial regression model as shown in [Table 12–22](#). The rate of nocturnal confirmed hypoglycaemia episodes per 100 PYE was 38% lower with IDegAsp than with IDet (treatment ratio 0.62 [0.48; 0.79]_{95% CI}, [Table 12–22](#)). The nocturnal confirmed hypoglycaemic episodes were also analysed on ETS analysis set, and the result was in accordance with those from FAS, see [EOT Table 14.3.1.42](#) and [EOT Figure 14.3.1.54](#).

Table 12–22 Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent – Statistical Analysis - Full Analysis Set

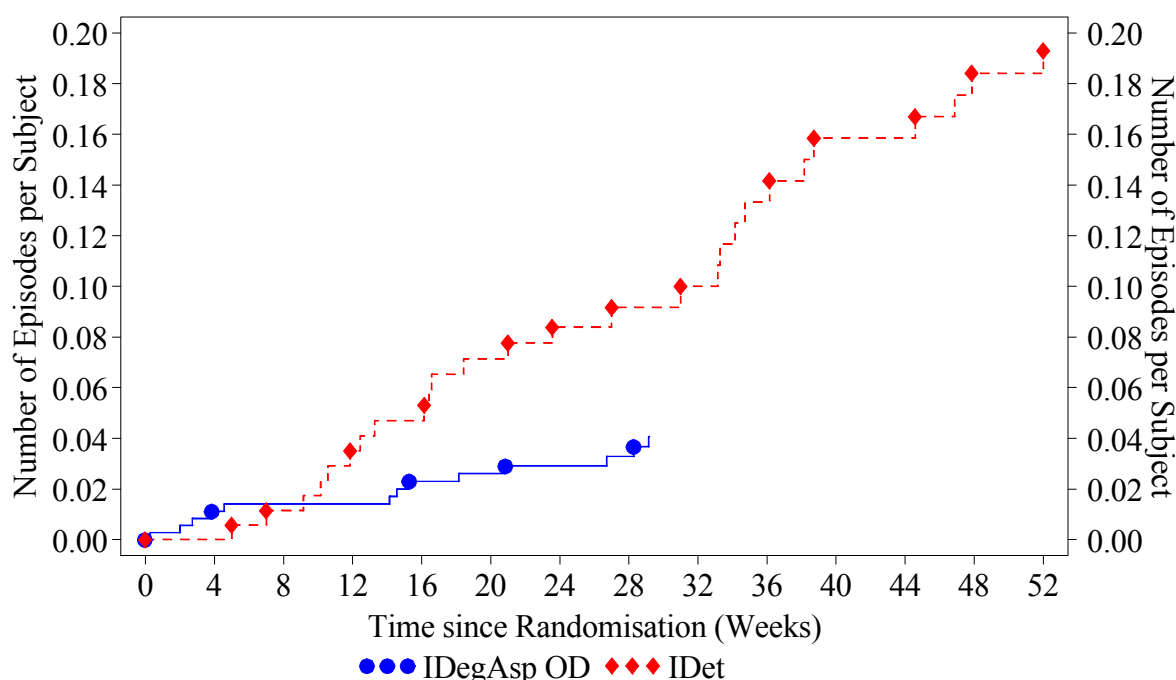
	FAS	N	Estimate	95% CI
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	366	363	261.54	
IDet	182	180	423.39	
Treatment Ratio				
IDegAsp OD / IDet			0.62	[0.48 ; 0.79]

N= Number of subjects contributing to analysis, CI= Confidence Interval, PYE= Patient Years Exposure
The number of events is analysed using a Negative Binomial Regression model using a log link and the logarithm of the exposure time (100 years) as offset. The model includes treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age as covariate.
Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

Cross-reference: [EOT Table 14.3.1.41](#)

12.4.4.2 Nocturnal Severe Hypoglycaemic Episodes

Few episodes of nocturnal severe hypoglycaemia were reported during the trial in either treatment group and more than 90% of subjects in both treatment groups did not report any episodes of nocturnal severe hypoglycaemia ([Table 12–21](#) and [EOT Figures 14.3.1.35](#) and [14.3.1.44](#)). The observed rate of nocturnal severe hypoglycaemic episodes according to the ADA classification was 5 and 19 episodes per 100 PYE with IDegAsp and IDet group, respectively ([Table 12–21](#)). The rate of nocturnal severe hypoglycaemic episodes over time was similar in the two treatment groups during the first 8 weeks of the trial, followed by numerically lower rate in the IDegAsp group compared to the IDet group from Week 8 ([Figure 12–7](#)). There was no nocturnal severe hypoglycaemic episode reported in the IDegAsp group in the period between Week 30 and the end of trial.



Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).
No events occurred in the IDegAsp OD arm after 28 weeks,
hence the cumulative function is not shown after this time point.

Cross-reference: [EOT Figure 14.3.1.47](#)

Figure 12–7 Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set

12.4.5 Hypoglycaemic Episodes according to the ADA Classification

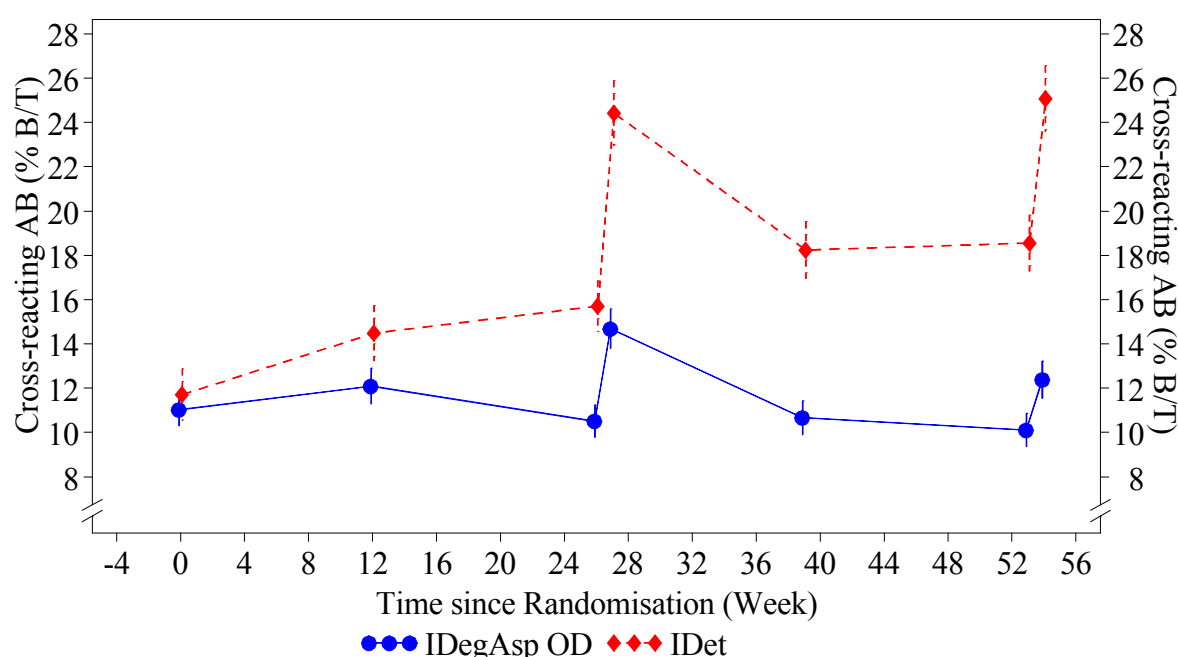
The rate of hypoglycaemic episodes according to the ADA classification was 6892 and 7243 episodes per 100 PYE with IDegAsp and IDet, respectively ([Table 12–20](#)). The majority of the ADA classified events were documented symptomatic or asymptomatic. The rate of nocturnal hypoglycaemic episodes according to the ADA classification was 557 and 805 episodes per 100 PYE with IDegAsp and IDet, respectively ([Table 12–21](#)). ADA classified hypoglycaemic episodes and nocturnal hypoglycaemic episodes over time are tabulated in [EOT Tables 14.3.1.32](#) and [14.3.1.34](#) based on FAS, and in [EOT Tables 14.3.1.33](#) and [14.3.1.35](#) based on ETS.

12.5 Clinical Laboratory Evaluation

12.5.1 Evaluation of Insulin Antibodies

12.5.1.1 Cross-reacting Insulin Antibodies

Insulin antibodies cross-reacting between insulin analogues and human insulin during the trial are shown in [Figure 12–8](#), [EOT Figure 14.3.6.38](#) and [EOT Table 14.3.6.28](#). The mean level of cross-reacting antibodies was low at baseline and remained low in the IDegAsp treatment group. In the IDet group, mean levels were low at baseline and increased slightly during the trial. A modest increase in cross-reacting insulin antibody levels was detected in the IDegAsp and IDet treatment groups from baseline to Week 54. At both week 27 to 28 and week 53 to 54, the change from baseline was smaller with IDegAsp than IDet.



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

Cross-reference: [EOT Figure 14.3.6.38](#)

Figure 12–8 Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Safety Analysis Set

No washout period was performed before antibody measurements at baseline, Weeks 12, 26, 39 and 53. Consequently, the detection of cross-reacting insulin antibodies was numerically lower at these time points. The observed differences in values at Week 26 and 27 (Visit 28 and 29) and Week 53 and 54 (Visit 44 and 45) are related to improved insulin antibody detection at Week 27 (Visit 29)

and Week 54 (Visit 45) enabled by the one-week washout period where investigational product was discontinued and replaced with NPH insulin. NPH insulin causes less interference with the insulin antibody measurement due to its shorter half-life. For evaluation of antibody development over time, samples collected during treatment were used, as the degree of interference from trial product in these samples is comparable. See Section [9.5.1.3](#) for details regarding the insulin antibody detection methodology.

The descriptive statistics of the cross-reacting antibody levels are shown in [Table 12–23](#) or [EOT Tables 14.3.6.28, 14.3.6.40](#). The cross-reacting insulin antibody was also plotted based on ETS, see [EOT Figures 14.3.6.39, 14.3.6.41](#). Individual insulin antibody data are presented in [EOT Tables 14.3.7.4](#).

Table 12–23 Cross-reacting Antibodies to Human Insulin (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet
Number of Subjects	362	180
Human insulin reactive antibodies serum(% B/T)		
Visit 2 (Week 0)		
N	362	180
Mean (SD)	11.0 (13.9)	11.7 (15.6)
Median	5.0	5.0
Min ; Max	0.0 ; 76.0	0.0 ; 68.0
Visit 28 (Week 26)		
N	348	172
Mean (SD)	10.6 (13.9)	15.8 (15.6)
Median	5.0	10.0
Min ; Max	0.0 ; 76.0	0.0 ; 75.0
Visit 29 (Week 27)		
N	310	147
Mean (SD)	15.5 (17.3)	26.0 (19.4)
Median	8.0	23.0
Min ; Max	0.0 ; 78.0	0.0 ; 77.0
Visit 44 (Week 53)		
N	197	101
Mean (SD)	7.4 (10.9)	16.8 (13.1)
Median	3.0	13.0
Min ; Max	0.0 ; 70.0	0.0 ; 59.0
Visit 44 (Week 53) (LOCF)		
N	362	180
Mean (SD)	10.1 (14.2)	18.6 (17.1)
Median	4.0	12.0
Min ; Max	0.0 ; 78.0	0.0 ; 71.0
Visit 45 (Week 54)		
N	236	111
Mean (SD)	11.4 (14.6)	27.5 (18.6)
Median	5.0	24.0
Min ; Max	0.0 ; 68.0	1.0 ; 69.0

N = Number of Subjects, SD = Standard Deviation

Cross-reference: [EOT Table 14.3.6.28](#)

Insulin antibodies cross-reacting between IAsp, IDeg, IDet and human insulin after 52 weeks of treatment were plotted against HbA_{1c} ([EOT Figure 14.3.6.50](#) on SAS and [EOT Figure 14.3.6.51](#) on ETS), change from baseline in HbA_{1c} ([EOT Figure 14.3.6.52](#) on SAS and [EOT Figure 14.3.6.53](#) on ETS) and total insulin dose in U/kg ([EOT Figure 14.3.6.60](#) on SAS and [EOT Figure 14.3.6.61](#) on ETS).

12.5.1.2 Specific Insulin Antibodies

Insulin antibodies specific for IDeg, IAsp and IDet after 52 weeks of treatment are shown in [EOT Figures 14.3.6.30-37](#) and [EOT Tables 14.3.6.26 and 27](#). The mean level of IDeg, IDet and IAsp specific antibodies was low at baseline and remained low throughout the treatment periods. Individual insulin antibody data are presented in [EOT Tables 14.3.7.4](#). The analysis of insulin antibodies specific for IDeg, IAsp and IDet after 52 weeks of treatment was also repeated based on ETS and the results were in accordance with the results from the analysis based on SAS, see [EOT Figures 14.3.6.31, 14.3.6.33, 14.3.6.35 and 14.3.6.37](#).

Insulin antibodies specific for IDeg after 52 weeks of treatment were plotted against HbA_{1c} ([EOT Figure 14.3.6.46](#)), change from baseline in HbA_{1c} ([EOT Figure 14.3.6.48](#)) and total insulin dose in U/kg ([EOT Figure 14.3.6.58](#)). The plot of insulin antibodies specific for IDeg after 52 weeks of treatment against HbA_{1c}, change from baseline in HbA_{1c} and total insulin dose in U/kg was also repeated based on ETS, see [EOT Figures 14.3.6.47, 14.3.6.49 and 14.3.6.59](#).

12.5.1.3 Total Insulin Antibodies

The mean and median total insulin antibody levels (sum of insulin-specific antibodies and cross-reacting antibodies = total insulin antibodies) reflected to the amount of cross-reacting antibodies due to the low level of insulin-specific antibodies against IDeg, IDet or IAsp ([EOT Table 14.3.6.29](#) and [EOT Figures 14.3.6.42 and 14.3.6.44](#)). Figures plotting total insulin antibody levels against HbA_{1c}, change in HbA_{1c} and total insulin dose are presented in [EOT Figures 14.3.6.54, 14.3.6.56 and 14.3.6.62](#). Individual total insulin antibody data are presented in [EOT Tables 14.3.7.4](#). The analysis of total insulin antibodies after 52 weeks of treatment was repeated based on ETS and the results were in accordance with the results from the analysis based on SAS, see [EOT Figures 14.3.6.43 and 14.3.45](#). The plot of total insulin antibodies against HbA_{1c}, change from baseline in HbA_{1c} and total insulin dose in U/kg was also repeated based on ETS, see [EOT Figures 14.3.6.55, 14.3.6.57 and 14.3.6.63](#).

12.5.2 Evaluation of Each Laboratory Parameter

12.5.2.1 Laboratory Values over Time

Mean haematology, biochemistry, lipids, and urine laboratory values remained stable during the trial, and there was no apparent difference between the two treatment groups in mean values or mean change in values during the trial ([EOT Tables 14.3.5.1 to 14.3.5.72](#)). The cumulative percentage of subjects having a given laboratory value showed that the majority of subjects' values remained within the reference ranges at baseline and at the end of trial. There were no statistical significant differences in the change from baseline of any of the measured lipid parameters analysed separately using an ANOVA method ([EOT Table 14.3.5.53](#) and [EOT Table 14.3.5.54](#)). The reference ranges for all laboratory parameters are shown in [EOT Listing 14.3.4.1 to 14.3.4.4](#). All

individual laboratory measurements are listed by subject in [Appendix 16.2.8](#), [Listings 16.2.8.2 to 16.2.8.9](#).

Pregnancy

Five (5) women became pregnant during the trial, three (3) in the IDegAsp group (Subjects [REDACTED], [REDACTED] and [REDACTED]) and two (2) in the IDet group (Subject [REDACTED] and [REDACTED]). Four (4) of the 5 pregnancies were reported in the main trial, 2 in the IDegAsp group (Subjects [REDACTED] and [REDACTED]) and 2 in the IDet group (Subject [REDACTED] and [REDACTED]). Two (2) of the women reported pregnancy during [REDACTED]

See [Appendix 16.2.8](#), [Listing 16.2.8.8](#) and [16.2.8.9](#) for individual pregnancy lab data for extension trial.

12.5.2.2 Individual Subject Changes

Most subjects had normal haematology, biochemistry, lipids and urinalysis laboratory value levels throughout the trial. Very few subjects had changes from normal to high or low values (or negative to positive urine tests) during the trial, and there was no difference between the treatment groups for any of the parameters ([EOT Tables 14.3.5.30](#), [14.3.5.7](#), [14.3.5.56](#) and [14.3.5.72](#)). Individual laboratory values outside the reference range were flagged as high (H) or low (L) and presented in [EOT Listings 14.3.4.1 to 14.3.4.4](#).

12.5.2.3 Individual Clinically Significant Abnormalities

A clinical laboratory abnormality regarded as clinically significant was to be reported as an AE. Abnormal laboratory values for haematology, biochemistry, lipids, cardiovascular risk markers and urine are listed by subject in [EOT Listings 14.3.4.1 to 14.3.4.4](#).

Haematology

Two (2) cases of clinically significant abnormalities in haematology parameters were reported in the main trial for Subject [REDACTED] (1 decreased haemoglobin levels and 1 increased eosinophil count). Only the increase in eosinophils was considered possibly related to trial product by the investigator. Both cases were reported during the main trial. See [EOT Listing 14.3.4.2](#), and [Appendix 16.2.7](#), [Listing 16.2.7.2](#) for details.

Biochemistry

Six (6) cases of biochemistry related clinical laboratory AEs were reported by 6 subjects during the trial, and five (5) were reported in the main trial ([EOT Table 14.3.4.1](#) and [EOT Listing 16.2.7.2](#)).

All of the events were non-serious AEs and all were considered unlikely related to trial product. Four (4) of the 6 subjects with elevated biochemistry laboratory values were in the IDegAsp group (██████: blood bilirubin; ██████: blood creatinine; ██████: hepatic enzymes; ██████: aspartate aminotransferase) and 2 were in the IDet group (██████: urine albumin/creatinine levels, ██████: hepatic enzymes).

Lipids

There were 10 reports of ‘hyperlipidaemia’ in the trial, and seven (7) of them were reported during the main trial. In total seven (7) hyperlipidaemia were reported by IDegAsp group (subject ██████, ██████, ██████, ██████, ██████ and ██████) and three (3) by IDet group (subject ██████, ██████ and ██████) ([Appendix 16.2.7, Listing 16.2.7.2](#)). In addition, four (4) subjects in the IDegAsp group (██████, ██████, ██████ and ██████) and 1 subject in the IDet group (██████) had triglyceride levels of more than ██████ the upper reference range limit, and among all of them, only subject ██████ reported the abnormality during the extension trial ([EOT Listing 14.3.4.3, EOT Figures 14.3.5.57-64](#)). Moreover, there was one (1) report of ‘worsening of hypercholesterolaemia’ in the IDegAsp group (Subject ██████, Day ██████) and two (2) reports of ‘worsening of hyperlipidaemia’ (Subject ██████: IDegAsp group, Day ██████; Subject ██████: IDet group, Day ██████), respectively.

Urine Analyses

Very few cases of clinically significant abnormalities in urine analyses were reported in this trial ([EOT Listing 14.3.4.4](#)). A case of ‘acute renal failure’ was reported in the IDegAsp group in the main trial (Subject ██████). This subject had normal urine albumin/creatinine ratio at Visit ██████ and ██████, but positive urine tests for blood, ketones and protein at Visit ██████. The acute renal failure ██████ and was judged to be mild and unlikely related to trial products by the investigator. ██████

Individual urinalysis test results are available in [Appendix 16.2.8, Listings 16.2.8.5 and 16.2.8.6](#).

12.6 Vital Signs, Physical Findings and Other Observations Related to Safety

12.6.1 Vital Signs

In both treatment groups, mean blood pressure (SBP/DBP) and pulse were approximately 124/75 mmHg and 74 beats/min at baseline, and 124/75 mmHg and 75 beats/min after 52 weeks of treatment ([EOT Tables 14.3.6.3 and 14.3.6.4](#)). Mean blood pressure and pulse data are plotted in [EOT Figures 14.3.6.5 to 14.3.6.13](#). Individual measurements of vital signs are listed in [EOT Listing 14.3.7.1](#). There were no clinically relevant findings during the trial.

12.6.2 Physical Examination

No clinically relevant differences in physical examination were observed between treatment groups after 52 weeks of treatment ([EOT Tables 14.3.6.1](#) and [14.3.6.2](#)). Individual physical examination data are listed in [EOT Listing 14.3.7.5](#). Any new findings or deterioration of previous findings observed during the trial were recorded as adverse events and are presented in Section [12.2](#).

12.6.3 ECG

ECG measurements are summarised in [EOT Table 14.3.6.14](#) and a shift table with changes from baseline to week 52 is presented in [EOT Table 14.3.6.15](#).

The majority of the ECG measurements were 'normal' or 'abnormal, not clinically significant' at baseline and Week 53 ([EOT Table 14.3.6.14](#) and [EOT Table 14.3.6.15](#)). Two (2) changed to 'abnormal, clinically significant' occurred during the main trial, one (1) in the IDegAsp group (Subject ID: [REDACTED]) and one (1) in IDet group (Subject ID: [REDACTED]) (see [Appendix 16.2.7, Listing 16.2.7.2](#)). These changes were reported as AEs, and were considered as unlikely related to IDegAsp and IDet, but the AE reported by Subject [REDACTED] was considered as possibly related to IAsp (see [Appendix 16.2.7, Listing 16.2.7.2](#)). Individual ECG data are listed in [EOT Listing 14.3.7.2](#). The above AE was not qualified for adjudication.

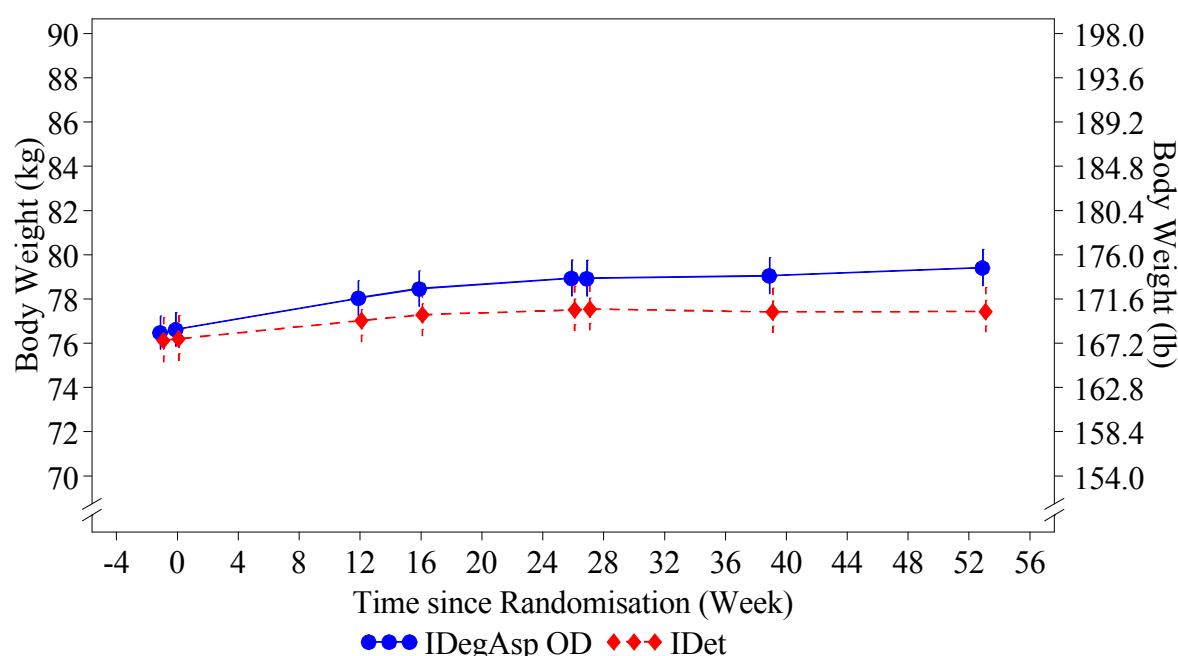
12.6.4 Fundoscopy / Fundusphotography

Fundoscopy/fundusphotography measurements are summarised in [EOT Table 14.3.6.16](#) and a shift table with changes from baseline to week 52 is presented in [EOT Table 14.3.6.17](#). The majority of the fundoscopy measurements were 'normal' or 'abnormal, not clinically significant' at baseline and at Visit 44 (Week 53) in both treatment groups ([EOT Table 14.3.6.16](#) and [EOT Table 14.3.6.17](#)). A slightly higher percentage of subjects in the IDegAsp group had abnormal clinically significant findings at baseline than the IDet group. At the end of the trial, the percentage of subjects with abnormal clinically significant findings in both treatment groups remained similar with baseline. There were 14 subjects in the IDegAsp group (Subject ID: [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], and [REDACTED]), and four (4) subjects in the IDet group (Subject ID: [REDACTED], [REDACTED], [REDACTED], and [REDACTED]) had changes to 'abnormal, clinically significant' during the trial, see [EOT table 14.3.7.3](#). These changes were reported as AEs; all were considered as unlikely related to trial product ([Appendix 16.2.7, Listing 16.2.7.2](#)).

In total, 61 eye disorders were reported by 41 subjects (21 eye disorders from 16 subjects were reported in the main trial): 25 subjects (6.9%) in the IDegAsp group reported 35 eye disorder AEs, and 16 subjects (8.9%) in the IDet group reported 26 eye disorder AEs. The majority of the events were mild or moderate. Please see individual fundoscopy and AE data, and in [EOT Listing 14.3.7.3](#) and [Appendix 16.2.7, Listing 16.2.7.2](#).

12.6.5 Body Weight and Body Mass Index

Body weight and BMI are summarised in [EOT Table 14.3.6.18](#), while the change from baseline values are shown in [EOT Table 14.3.6.19](#). The mean body weight appeared to increase steadily throughout the trial in the IDegAsp group whereas the mean body weight increased slightly in the first 16 weeks in the IDet group and then remained stable, as shown in [Figure 12–9](#) and [EOT Figures 14.3.6.21–25](#). The mean (SD) body weight at baseline and at the end of the trial was 76.5 kg (14.4) and 79.4 kg (15.6) in the IDegAsp group and 76.1 kg (13.9) and 77.4 kg (14.3) in the IDet group, respectively. IDegAsp was associated with more weight gain than IDet after 52 weeks of treatment (the estimated treatment difference was 1.64 kg [0.89; 2.38]_{95% CI}), see [EOT Table 14.3.6.20](#). Individual data are listed in [EOT Listing 14.3.7.6](#).



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

21JAN2011:11:30:22 - fmean_numfind_v03.sas/e_bw_abs_mean_locf_fas.cgm
nn5401/nn5401-3594-3645/current/stats

Cross-reference: [EOT Figure 14.3.6.21](#)

Figure 12–9 Body Weight - Mean Plot - Safety Analysis Set

12.7 Safety Conclusions

After 52 weeks of treatment with IDegAsp + IAsp at remaining meals or IDet + IAsp, the following was concluded:

Primary Endpoints

- **Adverse events:** There was no clinically relevant difference between the treatment groups in the reporting of AEs. A similar percentage of subjects reported adverse events in the IDegAsp and IDet groups (73.8% and 70.6%, respectively). The rate of all adverse events was similar for the IDegAsp and IDet groups (408 and 442 events per 100 PYE, respectively). The rate of severe adverse events was numerically lower with IDegAsp than with IDet (33 and 48 events per 100 PYE, respectively). The rate of adverse events possibly or probably related to investigational product was numerically lower with IDegAsp than IDet (37 and 69 events per 100 PYE, respectively). The most frequently reported adverse events in both treatment groups were nasopharyngitis, hypoglycaemia, upper respiratory tract infection and headache. Injection site reactions were reported more frequently in the IDet group (6.7%) than in the IDegAsp group (1.9%). The majority of subjects in both treatment groups recovered from the AEs at the end of trial.
- **Deaths, serious adverse events and other significant adverse events:** No death was reported in this trial. A total of 46 (12.7%) and 20 (11.1%) subjects reported 100 serious adverse events in IDegAsp (72 events) and IDet group (28 events), respectively. The rate of serious adverse events per 100 PYE was low in both treatment groups (IDegAsp: 24, IDet: 19) with hypoglycaemia (4.4%) as the most frequent serious adverse events in both groups. A similar percentage of subjects withdrew from the trial due to AEs: 4 (1.1%) in the IDegAsp group and 3 (1.6%) in the IDet group in main trial and 3 (0.8%) in the IDegAsp group and 0 (0%) in the IDet group in the extension trial treatment.
- **Hypoglycaemic episodes:** The observed rate of confirmed and nocturnal confirmed hypoglycaemic episodes, per 100 PYE was 3183 and 309 for IDegAsp and 3673 and 541 for IDet. The estimated rate ratios (IDegAsp/IDet) for confirmed hypoglycaemic episodes was 0.95 [0.79; 1.14]_{95% CI}, whereas the estimated rate of nocturnal confirmed hypoglycaemia was 38% lower with IDegAsp than with IDet; estimated rate ratio (IDegAsp/IDet) was 0.62, [0.48; 0.79]_{95% CI}. The observed rates of severe and nocturnal severe hypoglycaemia per 100 PYE were 27 and 5 for IDegAsp and 45 and 19 for IDet, respectively. The estimated rate ratios (IDegAsp/IDet) for severe hypoglycaemia were 0.98 [0.54; 1.79]_{95% CI}.
- **Insulin dose:** The mean total daily (basal and bolus) insulin dose after 52 weeks was numerically lower in the IDegAsp group compared with the IDet group: 72 U (0.89 U/kg) for IDegAsp and 82 U (1.04 U/kg) for IDet. The mean derived total daily basal insulin dose after 52 weeks was numerically lower in the IDegAsp group compared with the IDet group: 30 U (0.38 U/kg) for IDegAsp and 39 U (0.49 U/kg) for IDet. The mean derived total daily bolus insulin dose was numerically lower in the IDegAsp group than in the IDet group: 41 U

(0.52 U/kg) for IDegAsp and 43 U (0.55 U/kg) for IDet. The ratio of IDegAsp/IDet mean daily insulin dose (U) after 52 weeks was 0.87 for total insulin, 0.78 for derived total basal insulin and 0.97 for derived total bolus insulin, meaning that mean doses were numerically lower in the IDegAsp group compared with the IDet group.

- **Vital signs, ECG, fundoscopy, physical examination and laboratory values:** No clinically relevant differences from baseline to end of treatment or between the two treatment groups were observed for vital signs, ECG, fundoscopy/fundusphotography, physical examination and laboratory values.
- **Insulin antibodies:** The mean level of insulin antibodies cross-reacting between IDegAsp, IDet and human insulin was low at baseline and remained low with IDegAsp and increased only slightly with IDet after 52 weeks of treatment. The mean level of IDeg, IDet and IAsp specific antibodies was very low at baseline and remained low throughout the treatment periods.
- **Body weight:** IDegAsp was associated with more weight gain than IDet after 52 weeks of treatment, and the estimated treatment difference (IDegAsp–IDet) was 1.64 kg [0.89; 2.38]_{95% CI}. The mean (SD) body weight at baseline and at the end of the trial was 76.5 (14.4) kg and 79.4 (15.6) kg in the IDegAsp group and 76.1 (13.9) kg and 77.4 (14.3) kg in the IDet group, respectively.

13 Discussion and Overall Conclusions

Background Information

Insulin analogues have been developed to more closely mimic the basal and mealtime components of endogenous insulin secretion and are now an established part of diabetes management. IDegAsp is the first soluble ready-to-use insulin that comprises both a basal insulin component (IDeg) and a bolus insulin component (IAsp). In the present trial, IDegAsp is investigated in subjects with type 1 diabetes mellitus who may benefit from a simplified basal-bolus regimen with IDegAsp once daily and IAsp at remaining meals.

The present extension trial was conducted to confirm the safety and efficacy of IDegAsp OD + mealtime IAsp for the remaining meals in subjects with type 1 diabetes mellitus. The primary objective was to investigate the long-term safety and tolerability of IDegAsp, with respect to adverse events, hypoglycaemic episodes, clinical evaluations, central laboratory assessments, body weight and insulin dose compared to a conventional basal-bolus regimen with IDet as basal insulin (injected OD or BID) and IAsp injected at all meals. Baseline characteristics were similar in the two treatment regimens. Approximately 63% of the randomised subjects completed the 52-week trial (with 87% of randomised subjects completing the main trial and 92% of subjects screened for extension trial completing the extension trial).

As in any open-label trial, there may be a risk of an underlying reporting bias. In general, investigators are likely to be more attentive when treating subjects with a new medical entity such as IDegAsp, and subjects may also be more hesitant towards a new treatment. This could influence the reporting of AEs and hypoglycaemia. Likewise, as investigators are less familiar with IDegAsp they may tend to be more cautious with regards to starting dose and dose adjustment of IDegAsp, which could compromise the titration and dose optimisation.

The titration of insulin doses was monitored and reviewed by a titration committee in a blinded fashion. Significant deviations from the titration algorithm were discussed with the trial site in a blinded manner and handled at the discretion of the investigator.

Glycaemic Control

The trial population had been treated with basal-bolus or premix insulin regimens for at least 12 months at trial entry. Still, both IDegAsp and IDet effectively improved long-term glycaemic control in terms of change in HbA_{1c} after 52 weeks of treatment. The observed reduction in HbA_{1c} was 0.65 %-points with IDegAsp and 0.56 %-point with IDet. After 52 weeks of treatment, mean HbA_{1c} was reduced to 7.7 % with IDegAsp and 7.7 % with IDet. The level of glycaemic control achieved with IDet in this trial was comparable to that achieved in previous treat-to-target trials with a similar IDet treatment regimen.^{33,34}

FPG was reduced in both groups to similar levels of 8.5 and 8.6 mmol/L, respectively, and there was no statistical significant difference detected between the treatment groups with regards to fluctuation in self-measured plasma glucose.

Upon 52 weeks of treatment with IDegAsp, approximately 22% of subjects had achieved the HbA_{1c} target of < 7.0% compared to 17% of subjects in the IDet group. The estimated odds ratio indicated a numerically higher odds (56%) of achieving this treatment target when treated with IDegAsp compared to IDet (not statistically significant). As would be expected for subjects with type 1 diabetes mellitus, the proportion of subjects reaching the HbA_{1c} target without any confirmed hypoglycaemic episodes was low in both treatment groups. Still, more than 22% of the subjects achieved the HbA_{1c} target without experiencing severe hypoglycaemic episodes during the 52 weeks of IDegAsp treatment, and the odds of achieving this target (HbA_{1c} < 7% without severe hypoglycaemic episodes) was numerically higher (54%) with IDegAsp compared to IDet (not statistically significant).

Overall, treatment with IDegAsp plus IAsp resulted in larger improvements in the 9-point SMPG profiles than those achieved with the IDet regimen. After 52 weeks of treatment, estimated mean SMPG values before lunch, before main evening meal and before breakfast the following day were lower with IDegAsp compared to IDet, while the SMPG with IDet remained at higher level during this time.

The mean prandial increment was higher in IDegAsp group, which may be explained by an observed lower mean SMPG before lunch and main evening meal with IDegAsp (7.3 mmol/L and 7.9 mmol/L, respectively) than IDet (8.0 mmol/L and 8.6 mmol/L, respectively). Hence the low prandial increments over lunch and main evening meal seen with IDet merely reflected a constantly high PG in this group, whereas the PG with IDegAsp clearly decreased from breakfast to lunch and from lunch to main evening meal, as seen in the SMPG figures.

Insulin Doses and Titration

The total dose of insulin (basal + bolus) was similar in the IDegAsp and the IDet treatment groups at baseline (Week 1). Subjects in the IDegAsp group injected IDegAsp OD throughout the trial, while subjects in the IDet group could add a second dose of IDet if a pre-specified set of criteria were fulfilled. The majority of subjects in IDet group were still on OD after 52 weeks of treatment. During the trial, the total dose of IDet + IAsp increased slightly more than the total dose of IDegAsp + IAsp. The 13% higher total dose was primarily attributed to a larger increase in basal dose in the IDet group compared with the IDegAsp group.

The distribution of basal and bolus insulin in relation to the total insulin dose was similar at baseline, and remained similar throughout the trial with the two treatment regimens regardless of the differences in insulin dose. After 52 weeks of treatment, the basal:bolus split was 42%:58% in the IDegAsp group and 47%:53% in the IDet group.

In both treatment groups, there was no apparent difference between the dose recommended by the titration algorithm, the dose prescribed by the investigator, and the actual dose injected, suggesting good adherence to the titration algorithm and good subject compliance with both IDegAsp and IDet.

Subjects randomised to the IDegAsp regimen were instructed to administer IDegAsp once daily with the meal that ensured the most optimal coverage of both basal and bolus requirements for the prescribed IDegAsp dose. IDegAsp should be dosed once-daily with a meal; the ultra-long duration of action and consistent absorption profile allow the patient to administer IDegAsp with a different meal from day to day. Throughout the trial, IDegAsp could be injected at any meal and furthermore, the injection could be moved to another meal in order to optimise glycaemic control. Throughout the trial, IDegAsp injections were distributed among all meals, with an apparent preference for the evening meal, indicating that indeed physicians made use of the opportunity for individualised insulin treatment by dosing IDegAsp at any meal of the day. Independent of dosing time, the IDegAsp dose was adjusted based on prebreakfast glucose measurement.

Hypoglycaemia

The rate of confirmed hypoglycaemic episodes and severe hypoglycaemia appeared similar in the two treatment groups during the trial. The rate of nocturnal confirmed hypoglycaemia episodes was lower in the IDegAsp group compared to the IDet group. Together these results indicate that switching from a basal bolus therapy to IDegAsp is safe in terms of the risk of hypoglycaemic episodes after the transition.

One of the greatest concerns for subjects with type 1 diabetes mellitus is the risk of hypoglycaemic episodes occurring during sleep. Subjects in the IDegAsp group experienced fewer nocturnal confirmed hypoglycaemic episodes and fewer severe nocturnal hypoglycaemic episodes than subjects in the IDet group. The rate ratio (IDegAsp / IDet) for nocturnal confirmed hypoglycaemic episodes was 0.62, indicating that the rate of such episodes was 38% lower with IDegAsp, than with IDet. The lower rate of nocturnal hypoglycaemic episodes may be reflected in the trend towards fewer confirmed hypoglycaemic episodes in the IDegAsp group than the IDet group (3183 versus 3673 episodes per 100 PYE in the IDegAsp and IDet groups, respectively). These findings could be related to the more flat and ultra-long-acting profile of the basal component of IDegAsp. Together these results show that IDegAsp enables adjustment of insulin therapy to accomplish improved glycaemic control with fewer nocturnal confirmed hypoglycaemic episodes than with IDet.

Safety and Tolerability

IDegAsp was well tolerated and the AE and SAE profiles were similar between the two treatment groups. The rates of AEs and SAEs were comparable in the IDegAsp and IDet group. There were no specific patterns or clustering of the AEs in the treatment groups. The vast majority of all events were mild or moderate in severity and were judged as having an unlikely relation to trial products. The SAEs judged to have a likely relation to trial products were primarily related to hypoglycaemia in both groups. As with any insulin therapy, injection site reactions may occur. The percentage of

subjects experiencing injection site reactions was approximately 2% in the IDegAsp arm. Administration of IDegAsp was not associated with any severe cardiovascular AEs recorded during the trial and no major adverse cardiovascular events were reported as evaluated by the independent event adjudication committee. The proportion of subjects with AEs leading to withdrawal was similar between treatment groups, as was the percent of subjects with medication errors.

Body weight increased slightly in both treatment groups as can be expected from an intensive basal bolus therapy. The mean body weight gain was 2.8 kg in the IDegAsp group and 1.2 Kg in the IDet group. The difference in body weight gain was statistically significant. This is in line with previous reports on IDet, where IDet has been associated with an approximately 1 kg less body weight gain than other basal insulin products.³⁵

The mean level of insulin antibodies cross-reacting between IDegAsp, IDet and human insulin was low at baseline and remained low with IDegAsp and increased only slightly with IDet after 52 weeks of treatment. No clinically relevant differences were observed with respect to measurement of haematology, biochemistry, lipids, ECG, funduscopy or vital signs between the treatment groups.

Overall, the findings presented in this report after 52-week treatment period were similar to the findings after 26-week treatment. Treatment with IDegAsp dosed OD at any meal in combination with IAsp at the remaining meals, offered a safe and intensive treatment regimen with fewer injections than a standard basal bolus regimen. Switching from other insulin regimens to IDegAsp + IAsp appeared safe and resulted in a similar AE and hypoglycaemia profile as IDet + IAsp, with less nocturnal confirmed hypoglycaemic episodes and the option of administering IDegAsp at any meal.

Overall Conclusions

This confirmatory, randomised, controlled, 52-week trial investigated the long-term safety and efficacy of treatment with IDegAsp administered once daily at any meal, together with IAsp administered at the remaining meals, compared to treatment with IDet in combination with IAsp at all meals in subjects with type 1 diabetes mellitus. The data support the following conclusions:

- In this trial, no safety issues are identified with IDegAsp + IAsp after 52 weeks of treatment.
- There is no apparent difference between IDegAsp + IAsp and IDet + IAsp with respect to AEs and standard safety parameters with the exception of body weight, which increases more with the IDegAsp regimen compared to the IDet regimen.
- The rates of severe and confirmed hypoglycaemic episodes are numerically lower with IDegAsp + IAsp than with IDet + IAsp.
- Subjects treated with IDegAsp + IAsp experience a lower rate of nocturnal confirmed hypoglycaemic episodes compared to subjects treated with IDet + IAsp.

- Antibody development is sparse for both treatment regimens and only a few injection site reactions are reported with IDegAsp + IAsp.
- The average total daily insulin dose is numerically lower in subjects treated with IDegAsp + IAsp compared to subjects treated with IDet + IAsp.
- Treatment with IDegAsp + IAsp effectively improves long-term glycaemic control (as measured by HbA_{1c}). Improvements in HbA_{1c} and FPG are similar with both regimens after 52 weeks of treatment.

In conclusion, these findings confirm the safety and efficacy of once-daily treatment with IDegAsp administered once daily at any meal, together with IAsp administered at the remaining meals in subjects with type 1 diabetes mellitus.

14 Tables, Figures and Graphs Referred to but not Included in the Text

14.1 Demographic Data

14.1.1: Subject disposition - Summary

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Screened			706
Screening Failures			158
Withdrawn before Randomisation			0
Randomised	366 (100.0)	182 (100.0)	548 (100.0)
Exposed	362 (98.9)	180 (98.9)	542 (98.9)
Completed Main Trial	320 (87.4)	156 (85.7)	476 (86.9)
Withdrawn at/after Randomisation and Before extension	46 (12.6)	26 (14.3)	72 (13.1)
Adverse Event	4 (1.1)	3 (1.6)	7 (1.3)
Ineffective Therapy	2 (0.5)		2 (0.4)
Non-Compliance	8 (2.2)	6 (3.3)	14 (2.6)
Withdrawal Criteria	7 (1.9)	5 (2.7)	12 (2.2)
Other	25 (6.8)	12 (6.6)	37 (6.8)
Completed Main Trial Not screened for extension	66 (18.0)	34 (18.7)	100 (18.2)
Completed Main Trial screening failure in extension	0 (0.0)	0 (0.0)	0 (0.0)
Included in Extension	254 (69.4)	122 (67.0)	376 (68.6)
Withdrawn during extension	21 (5.7)	9 (4.9)	30 (5.5)
Adverse Event	3 (0.8)		3 (0.5)
Ineffective Therapy	0 (0.0)	0 (0.0)	0 (0.0)
Non-Compliance	4 (1.1)	1 (0.5)	5 (0.9)
Withdrawal Criteria	2 (0.5)	1 (0.5)	3 (0.5)
Other	12 (3.3)	7 (3.8)	19 (3.5)
Completed Extension	233 (63.7)	113 (62.1)	346 (63.1)

Subject disposition - Summary

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Full Analysis Set	366 (100.0)	182 (100.0)	548 (100.0)
PP Analysis Set	336 (91.8)	168 (92.3)	504 (92.0)
Safety Analysis Set	362 (98.9)	180 (98.9)	542 (98.9)
Extension Trial Set	254 (69.4)	122 (67.0)	376 (68.6)

14.1.2: Subject disposition by Country - Summary

	IDegAsp N	OD (%)	IDet N	IDet (%)	Total N	Total (%)	N
Australia							
Screened							80
Randomised	47	(100.0)	18	(100.0)	65	(100.0)	
Exposed	46	(97.9)	18	(100.0)	64	(98.5)	
Completed Main Trial	43	(91.5)	14	(77.8)	57	(87.7)	
Full Analysis Set	47	(100.0)	18	(100.0)	65	(100.0)	
PP Analysis Set	45	(95.7)	15	(83.3)	60	(92.3)	
Safety Analysis Set	46	(97.9)	18	(100.0)	64	(98.5)	
Included in Extension	32	(68.1)	11	(61.1)	43	(66.2)	
Completed Extension	27	(57.4)	11	(61.1)	38	(58.5)	
Extension Trial Set	32	(68.1)	11	(61.1)	43	(66.2)	
Denmark							
Screened							37
Randomised	16	(100.0)	15	(100.0)	31	(100.0)	
Exposed	16	(100.0)	15	(100.0)	31	(100.0)	
Completed Main Trial	15	(93.8)	14	(93.3)	29	(93.5)	
Full Analysis Set	16	(100.0)	15	(100.0)	31	(100.0)	
PP Analysis Set	15	(93.8)	15	(100.0)	30	(96.8)	
Safety Analysis Set	16	(100.0)	15	(100.0)	31	(100.0)	
Included in Extension	12	(75.0)	9	(60.0)	21	(67.7)	
Completed Extension	12	(75.0)	9	(60.0)	21	(67.7)	
Extension Trial Set	12	(75.0)	9	(60.0)	21	(67.7)	
France							
Screened							28
Randomised	17	(100.0)	8	(100.0)	25	(100.0)	

N: Number of Subjects

?: Proportion of Subjects

Subject disposition by Country - Summary

	IDegAsp OD		IDet		Total		
	N	(%)	N	(%)	N	(%)	N
Exposed	15	(88.2)	8	(100.0)	23	(92.0)	
Completed Main Trial	14	(82.4)	6	(75.0)	20	(80.0)	
Full Analysis Set	17	(100.0)	8	(100.0)	25	(100.0)	
PP Analysis Set	13	(76.5)	7	(87.5)	20	(80.0)	
Safety Analysis Set	15	(88.2)	8	(100.0)	23	(92.0)	
Included in Extension	8	(47.1)	4	(50.0)	12	(48.0)	
Completed Extension	5	(29.4)	4	(50.0)	9	(36.0)	
Extension Trial Set	8	(47.1)	4	(50.0)	12	(48.0)	
Israel							40
Screened							
Randomised	22	(100.0)	11	(100.0)	33	(100.0)	
Exposed	22	(100.0)	11	(100.0)	33	(100.0)	
Completed Main Trial	20	(90.9)	9	(81.8)	29	(87.9)	
Full Analysis Set	22	(100.0)	11	(100.0)	33	(100.0)	
PP Analysis Set	21	(95.5)	9	(81.8)	30	(90.9)	
Safety Analysis Set	22	(100.0)	11	(100.0)	33	(100.0)	
Included in Extension	15	(68.2)	8	(72.7)	23	(69.7)	
Completed Extension	12	(54.5)	8	(72.7)	20	(60.6)	
Extension Trial Set	15	(68.2)	8	(72.7)	23	(69.7)	
Poland							66
Screened							
Randomised	37	(100.0)	15	(100.0)	52	(100.0)	
Exposed	37	(100.0)	15	(100.0)	52	(100.0)	
Completed Main Trial	32	(86.5)	14	(93.3)	46	(88.5)	
Full Analysis Set	37	(100.0)	15	(100.0)	52	(100.0)	
PP Analysis Set	32	(86.5)	14	(93.3)	46	(88.5)	

N: Number of Subjects

?: Proportion of Subjects

Subject disposition by Country - Summary

	IDegAsp OD		IDet		Total		
	N	(%)	N	(%)	N	(%)	N
Safety Analysis Set	37	(100.0)	15	(100.0)	52	(100.0)	
Included in Extension	31	(83.8)	10	(66.7)	41	(78.8)	
Completed Extension	30	(81.1)	10	(66.7)	40	(76.9)	
Extension Trial Set	31	(83.8)	10	(66.7)	41	(78.8)	
Romania							
Screened							94
Randomised	49	(100.0)	21	(100.0)	70	(100.0)	
Exposed	49	(100.0)	21	(100.0)	70	(100.0)	
Completed Main Trial	47	(95.9)	21	(100.0)	68	(97.1)	
Full Analysis Set	49	(100.0)	21	(100.0)	70	(100.0)	
PP Analysis Set	48	(98.0)	21	(100.0)	69	(98.6)	
Safety Analysis Set	49	(100.0)	21	(100.0)	70	(100.0)	
Included in Extension	33	(67.3)	15	(71.4)	48	(68.6)	
Completed Extension	33	(67.3)	13	(61.9)	46	(65.7)	
Extension Trial Set	33	(67.3)	15	(71.4)	48	(68.6)	
Russian Federation							
Screened							97
Randomised	47	(100.0)	22	(100.0)	69	(100.0)	
Exposed	47	(100.0)	22	(100.0)	69	(100.0)	
Completed Main Trial	46	(97.9)	20	(90.9)	66	(95.7)	
Full Analysis Set	47	(100.0)	22	(100.0)	69	(100.0)	
PP Analysis Set	47	(100.0)	21	(95.5)	68	(98.6)	
Safety Analysis Set	47	(100.0)	22	(100.0)	69	(100.0)	
Included in Extension	38	(80.9)	16	(72.7)	54	(78.3)	
Completed Extension	38	(80.9)	14	(63.6)	52	(75.4)	

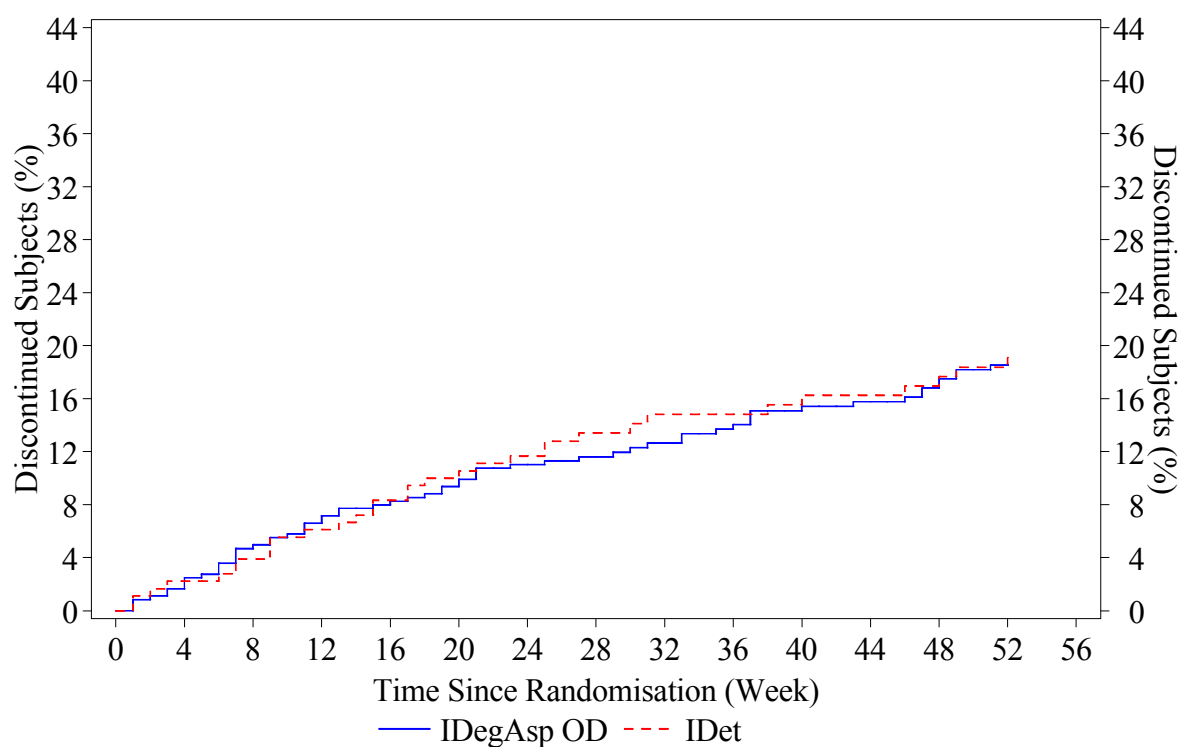
N: Number of Subjects

?: Proportion of Subjects

Subject disposition by Country - Summary

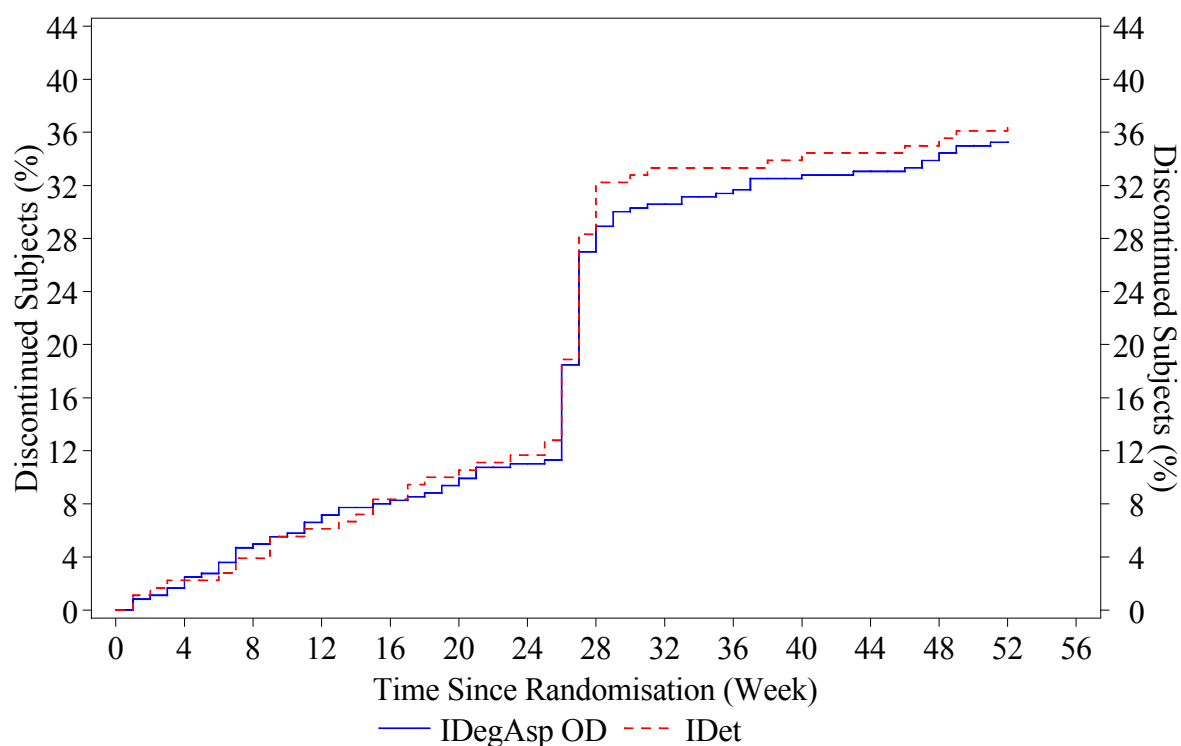
	IDegAsp OD		IDet		Total		
	N	(%)	N	(%)	N	(%)	N
Extension Trial Set	38	(80.9)	16	(72.7)	54	(78.3)	
United Kingdom							41
Screened							
Randomised	24	(100.0)	12	(100.0)	36	(100.0)	
Exposed	24	(100.0)	12	(100.0)	36	(100.0)	
Completed Main Trial	19	(79.2)	9	(75.0)	28	(77.8)	
Full Analysis Set	24	(100.0)	12	(100.0)	36	(100.0)	
PP Analysis Set	22	(91.7)	11	(91.7)	33	(91.7)	
Safety Analysis Set	24	(100.0)	12	(100.0)	36	(100.0)	
Included in Extension	15	(62.5)	6	(50.0)	21	(58.3)	
Completed Extension	15	(62.5)	6	(50.0)	21	(58.3)	
Extension Trial Set	15	(62.5)	6	(50.0)	21	(58.3)	
United States							223
Screened							
Randomised	107	(100.0)	60	(100.0)	167	(100.0)	
Exposed	106	(99.1)	58	(96.7)	164	(98.2)	
Completed Main Trial	84	(78.5)	49	(81.7)	133	(79.6)	
Full Analysis Set	107	(100.0)	60	(100.0)	167	(100.0)	
PP Analysis Set	93	(86.9)	55	(91.7)	148	(88.6)	
Safety Analysis Set	106	(99.1)	58	(96.7)	164	(98.2)	
Included in Extension	70	(65.4)	43	(71.7)	113	(67.7)	
Completed Extension	61	(57.0)	38	(63.3)	99	(59.3)	
Extension Trial Set	70	(65.4)	43	(71.7)	113	(67.7)	

N: Number of Subjects
%: Proportion of Subjects



nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:29 - ID14100200_fplot_subj_disc.sas/e_dispos_fas.cgm

14.1.3: Time to Discontinuation - Full Analysis Set



nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:31 - ID14100250_fplot_subj_disc.sas/e_dispos_all_non_compl_fas.cgm

14.1.4: Time to Discontinuation (Weeks) – All Non-Completers - Full Analysis Set

14.1.5: Subject Disposition by Week - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
Attending			
Visit 2 (Week 0)	366 (100.0)	182 (100.0)	548 (100.0)
Visit 3 (Week 1)	360 (98.4)	179 (98.4)	539 (98.4)
Visit 4 (Week 2)	360 (98.4)	178 (97.8)	538 (98.2)
Visit 5 (Week 3)	357 (97.5)	176 (96.7)	533 (97.3)
Visit 6 (Week 4)	355 (97.0)	176 (96.7)	531 (96.9)
Visit 7 (Week 5)	352 (96.2)	175 (96.2)	527 (96.2)
Visit 8 (Week 6)	348 (95.1)	174 (95.6)	522 (95.3)
Visit 9 (Week 7)	345 (94.3)	174 (95.6)	519 (94.7)
Visit 10 (Week 8)	343 (93.7)	172 (94.5)	515 (94.0)
Visit 11 (Week 9)	342 (93.4)	170 (93.4)	512 (93.4)
Visit 12 (Week 10)	339 (92.6)	170 (93.4)	509 (92.9)
Visit 13 (Week 11)	337 (92.1)	170 (93.4)	507 (92.5)
Visit 14 (Week 12)	336 (91.8)	168 (92.3)	504 (92.0)
Visit 15 (Week 13)	334 (91.3)	166 (91.2)	500 (91.2)
Visit 16 (Week 14)	334 (91.3)	166 (91.2)	500 (91.2)
Visit 17 (Week 15)	333 (91.0)	164 (90.1)	497 (90.7)
Visit 18 (Week 16)	331 (90.4)	163 (89.6)	494 (90.1)
Visit 19 (Week 17)	331 (90.4)	163 (89.6)	494 (90.1)
Visit 20 (Week 18)	329 (89.9)	162 (89.0)	491 (89.6)
Visit 21 (Week 19)	328 (89.6)	162 (89.0)	490 (89.4)
Visit 22 (Week 20)	327 (89.3)	160 (87.9)	487 (88.9)
Visit 23 (Week 21)	324 (88.5)	159 (87.4)	483 (88.1)
Visit 24 (Week 22)	323 (88.3)	158 (86.8)	481 (87.8)
Visit 25 (Week 23)	323 (88.3)	158 (86.8)	481 (87.8)
Visit 26 (Week 24)	323 (88.3)	158 (86.8)	481 (87.8)
Visit 27 (Week 25)	322 (88.0)	158 (86.8)	480 (87.6)
Visit 28 (Week 26)	359 (98.1)	178 (97.8)	537 (98.0)
Visit 29 (Week 27)	348 (95.1)	169 (92.9)	517 (94.3)
Visit 30 (Week 27)	254 (69.4)	122 (67.0)	376 (68.6)
Visit 31 (Week 28)	253 (69.1)	121 (66.5)	374 (68.2)
Visit 32 (Week 29)	254 (69.4)	122 (67.0)	376 (68.6)
Visit 33 (Week 31)	251 (68.6)	122 (67.0)	373 (68.1)
Visit 34 (Week 33)	249 (68.0)	120 (65.9)	369 (67.3)
Visit 35 (Week 35)	247 (67.5)	120 (65.9)	367 (67.0)
Visit 36 (Week 37)	246 (67.2)	119 (65.4)	365 (66.6)
Visit 37 (Week 39)	244 (66.7)	118 (64.8)	362 (66.1)
Visit 38 (Week 41)	241 (65.8)	118 (64.8)	359 (65.5)
Visit 39 (Week 43)	243 (66.4)	118 (64.8)	361 (65.9)
Visit 40 (Week 45)	241 (65.8)	118 (64.8)	359 (65.5)
Visit 41 (Week 47)	237 (64.8)	116 (63.7)	353 (64.4)
Visit 42 (Week 49)	236 (64.5)	115 (63.2)	351 (64.1)
Visit 43 (Week 51)	235 (64.2)	115 (63.2)	350 (63.9)
Visit 44 (Week 53)	253 (69.1)	121 (66.5)	374 (68.2)
Visit 45 (Week 54)	250 (68.3)	119 (65.4)	369 (67.3)

N: Number of Subjects

?: Percentages are based on N

Main trial: visit 2 (week 0) - visit 29 (week 27)

Extension trial: visit 30 (visit 27) - visit 45 (week 54)

This table will be made in a new version that fulfills the req. in SPS for section 14.1
nn5401/nn5401-3594-3645/freeze_ctr 02/stats
07MAY2011:13:28:33 - tsum_ds_week_v01.sas/t_dispos_week_fas.txt

14.1.6: Reasons for Discontinuation from Week 12 and onwards - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
Withdrawn Main Trial (12 - 26 weeks)	17 (4.6)	13 (7.1)	30 (5.5)
Adverse Event	2 (0.5)	3 (1.6)	5 (0.9)
Ineffective Therapy	0	0	0
Non-Compliance With Protocol	4 (1.1)	2 (1.1)	6 (1.1)
Withdrawal Criteria	4 (1.1)	2 (1.1)	6 (1.1)
Withdrawal Criteria 1	1 (0.3)	0	1 (0.2)
Withdrawal Criteria 2	1 (0.3)	0	1 (0.2)
Withdrawal Criteria 3	0	2 (1.1)	2 (0.4)
Withdrawal Criteria 4	1 (0.3)	0	1 (0.2)
Withdrawal Criteria 5	0	0	0
Withdrawal Criteria 6	0	0	0
Withdrawal Criteria 7	1 (0.3)	0	1 (0.2)
Other	7 (1.9)	6 (3.3)	13 (2.4)
Withdrawn during Extension Trial	21 (5.7)	9 (4.9)	30 (5.5)
Adverse Event	3 (0.8)	0	3 (0.5)
Ineffective Therapy	0	0	0
Non-Compliance With Protocol	4 (1.1)	1 (0.5)	5 (0.9)
Withdrawal Criteria	2 (0.5)	1 (0.5)	3 (0.5)
Withdrawal Criteria 1	1 (0.3)	0	1 (0.2)
Withdrawal Criteria 2	0	1 (0.5)	1 (0.2)
Withdrawal Criteria 3	0	0	0
Withdrawal Criteria 4	0	0	0
Withdrawal Criteria 5	0	0	0
Withdrawal Criteria 6	1 (0.3)	0	1 (0.2)
Withdrawal Criteria 7	0	0	0
Other	12 (3.3)	7 (3.8)	19 (3.5)

14.1.7: Demographics and Baseline Characteristics - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
Age Group			
N	366 (100.0)	182 (100.0)	548 (100.0)
> 65 years	11 (3.0)	14 (7.7)	25 (4.6)
Adults (18-65 yrs)	355 (97.0)	168 (92.3)	523 (95.4)
Sex			
N	366 (100.0)	182 (100.0)	548 (100.0)
Female	176 (48.1)	100 (54.9)	276 (50.4)
Male	190 (51.9)	82 (45.1)	272 (49.6)
Country of Residence			
N	366 (100.0)	182 (100.0)	548 (100.0)
Australia	47 (12.8)	18 (9.9)	65 (11.9)
Denmark	16 (4.4)	15 (8.2)	31 (5.7)
France	17 (4.6)	8 (4.4)	25 (4.6)
Israel	22 (6.0)	11 (6.0)	33 (6.0)
Poland	37 (10.1)	15 (8.2)	52 (9.5)
Romania	49 (13.4)	21 (11.5)	70 (12.8)
Russian Federation	47 (12.8)	22 (12.1)	69 (12.6)
United Kingdom	24 (6.6)	12 (6.6)	36 (6.6)
United States	107 (29.2)	60 (33.0)	167 (30.5)
Ethnicity			
N	366 (100.0)	182 (100.0)	548 (100.0)
Hispanic or Latino	10 (2.7)	7 (3.8)	17 (3.1)
Not Hispanic or Latino	339 (92.6)	167 (91.8)	506 (92.3)
Not Applicable	17 (4.6)	8 (4.4)	25 (4.6)
Race			
N	366 (100.0)	182 (100.0)	548 (100.0)
White	333 (91.0)	162 (89.0)	495 (90.3)
Black or African American	10 (2.7)	6 (3.3)	16 (2.9)
Asian Indian	1 (0.3)	0 (0.0)	1 (0.2)
Asian non-Indian	3 (0.8)	3 (1.6)	6 (1.1)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	1 (0.3)	1 (0.5)	2 (0.4)
Not Applicable	17 (4.6)	8 (4.4)	25 (4.6)
Other	1 (0.3)	2 (1.1)	3 (0.5)

N = Number of Subjects
Subjects from France did not report race

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:37 - tsum_sc_v01.sas/t_demog_basechar_fas.txt

14.1.8: Demographics and Baseline Characteristics - Summary - Extension Trial Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	254	122	376
Age Group			
N	254 (100.0)	122 (100.0)	376 (100.0)
> 65 years	6 (2.4)	9 (7.4)	15 (4.0)
Adults (18-65 yrs)	248 (97.6)	113 (92.6)	361 (96.0)
Sex			
N	254 (100.0)	122 (100.0)	376 (100.0)
Female	111 (43.7)	61 (50.0)	172 (45.7)
Male	143 (56.3)	61 (50.0)	204 (54.3)
Country of Residence			
N	254 (100.0)	122 (100.0)	376 (100.0)
Australia	32 (12.6)	11 (9.0)	43 (11.4)
Denmark	12 (4.7)	9 (7.4)	21 (5.6)
France	8 (3.1)	4 (3.3)	12 (3.2)
Israel	15 (5.9)	8 (6.6)	23 (6.1)
Poland	31 (12.2)	10 (8.2)	41 (10.9)
Romania	33 (13.0)	15 (12.3)	48 (12.8)
Russian Federation	38 (15.0)	16 (13.1)	54 (14.4)
United Kingdom	15 (5.9)	6 (4.9)	21 (5.6)
United States	70 (27.6)	43 (35.2)	113 (30.1)
Ethnicity			
N	254 (100.0)	122 (100.0)	376 (100.0)
Hispanic or Latino	6 (2.4)	2 (1.6)	8 (2.1)
Not Hispanic or Latino	240 (94.5)	116 (95.1)	356 (94.7)
Not Applicable	8 (3.1)	4 (3.3)	12 (3.2)
Race			
N	254 (100.0)	122 (100.0)	376 (100.0)
White	235 (92.5)	109 (89.3)	344 (91.5)
Black or African American	7 (2.8)	4 (3.3)	11 (2.9)
Asian Indian	1 (0.4)	0 (0.0)	1 (0.3)
Asian non-Indian	1 (0.4)	2 (1.6)	3 (0.8)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	1 (0.4)	1 (0.8)	2 (0.5)
Not Applicable	8 (3.1)	4 (3.3)	12 (3.2)
Other	1 (0.4)	2 (1.6)	3 (0.8)

N = Number of Subjects
Subjects from France did not report race

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:39 - tsum_sc_v01.sas/t_demog_basechar_ets.txt

14.1.9: Baseline and Diabetes Characteristics – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Age (years)			
N	366	182	548
Mean (SD)	40.7 (12.8)	42.6 (13.8)	41.3 (13.2)
Median	39.9	42.4	40.6
Min ; Max	18.3 ; 78.5	18.1 ; 80.2	18.1 ; 80.2
Height (m)			
N	366	182	548
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Median	1.7	1.7	1.7
Min ; Max	1.5 ; 2.0	1.1 ; 2.0	1.1 ; 2.0
Body Weight (kg)			
N	366	182	548
Mean (SD)	76.7 (14.6)	76.0 (14.0)	76.5 (14.4)
Median	75.0	76.0	75.3
Min ; Max	44.0 ; 123.4	42.9 ; 137.4	42.9 ; 137.4
BMI (kg/m ²)			
N	366	182	548
Mean (SD)	26.2 (4.0)	26.7 (3.9)	26.4 (4.0)
Median	25.9	26.3	26.0
Min ; Max	16.2 ; 35.6	18.7 ; 36.2	16.2 ; 36.2
Duration of Diabetes (years)			
N	366	181	547
Mean (SD)	17.2 (11.3)	17.9 (12.3)	17.4 (11.6)
Median	14.9	15.0	14.9
Min ; Max	1.1 ; 59.7	1.0 ; 56.6	1.0 ; 59.7
HbA1c (%)			
N	366	182	548
Mean (SD)	8.3 (0.8)	8.3 (0.7)	8.3 (0.8)
Median	8.2	8.2	8.2
Min ; Max	6.8 ; 10.3	6.5 ; 10.4	6.5 ; 10.4
FPG (mmol/L)			
N	365	181	546
Mean (SD)	10.3 (4.7)	11.0 (4.8)	10.5 (4.8)
Median	9.6	10.3	9.9
Min ; Max	1.8 ; 30.2	2.9 ; 28.4	1.8 ; 30.2

14.1.10: Baseline and Diabetes Characteristics - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Number of Subjects	254	122	376
Age (years)			
N	254	122	376
Mean (StD)	40.1 (12.7)	42.7 (13.7)	40.9 (13.1)
Median	39.4	42.2	40.2
Min ; Max	18.3 ; 78.5	18.1 ; 80.2	18.1 ; 80.2
Height (m)			
N	254	122	376
Mean (StD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Median	1.7	1.7	1.7
Min ; Max	1.5 ; 2.0	1.1 ; 2.0	1.1 ; 2.0
Body Weight (kg)			
N	254	122	376
Mean (StD)	77.3 (14.9)	77.9 (15.1)	77.5 (15.0)
Median	76.0	78.0	76.5
Min ; Max	44.0 ; 115.7	42.9 ; 137.4	42.9 ; 137.4
BMI (kg/m^2)			
N	254	122	376
Mean (StD)	26.3 (4.0)	26.9 (3.9)	26.5 (4.0)
Median	25.9	26.5	26.2
Min ; Max	17.6 ; 35.6	18.9 ; 36.2	17.6 ; 36.2
HbA1c (%)			
N	254	122	376
Mean (StD)	8.3 (0.8)	8.3 (0.8)	8.3 (0.8)
Median	8.3	8.4	8.3
Min ; Max	6.8 ; 10.3	6.5 ; 10.4	6.5 ; 10.4
FPG (mmol/L)			
N	253	122	375
Mean (StD)	10.3 (4.7)	10.9 (4.5)	10.5 (4.6)
Median	9.8	10.2	9.9
Min ; Max	1.9 ; 30.2	2.9 ; 22.9	1.9 ; 30.2
Duration of Diabetes (years)			
N	254	122	376
Mean (StD)	16.6 (11.5)	15.4 (10.2)	16.2 (11.1)
Median	14.3	13.3	14.2
Min ; Max	1.1 ; 59.7	1.0 ; 50.3	1.0 ; 59.7

BMI = Body Mass Index, N = Number of Subjects, StD = Standard Deviation
 nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:38:54 - tsum_sc_v01.sas/t_baseline_diabetes_sum_ets.txt

14.1.11: Anti-diabetic Treatment Regimen at Screening - Full Analysis Set

	IDegAsp OD		IDet		Total	
	N	(%)	N	(%)	N	(%)
Number of Subjects	366		182		548	
Basal-Bolus	334	(91.3)	161	(88.5)	495	(90.3)
Basal-Bolus	334	(91.3)	161	(88.5)	495	(90.3)
Other	32	(8.7)	21	(11.5)	53	(9.7)
Basal + PreMix			1	(0.5)	1	(0.2)
Basal Only	1	(0.3)	1	(0.5)	2	(0.4)
PreMix + Bolus	11	(3.0)	7	(3.8)	18	(3.3)
PreMix Only	18	(4.9)	10	(5.5)	28	(5.1)
SelfMix	2	(0.5)	2	(1.1)	4	(0.7)

N: Number of Subjects
%: Proportion of Subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:49 - tscreen_regimen_sum_fas.sas/t_screen_regimen_sum_fas.txt

14.1.12: Insulin Type at Screening - Full Analysis Set

	IDegAsp OD		IDet		Total	
	N	(%)	N	(%)	N	(%)
Number of Subjects	366		182		548	
Basal	337	(92.1)	165	(90.7)	502	(91.6)
IDet	57	(15.6)	24	(13.2)	81	(14.8)
IGlar	238	(65.0)	125	(68.7)	363	(66.2)
NPH	44	(12.0)	17	(9.3)	61	(11.1)
Bolus	347	(94.8)	170	(93.4)	517	(94.3)
HI	33	(9.0)	19	(10.4)	52	(9.5)
IAsp	180	(49.2)	91	(50.0)	271	(49.5)
IGlu	22	(6.0)	13	(7.1)	35	(6.4)
ILis	108	(29.5)	50	(27.5)	158	(28.8)
Neutral	1	(0.3)	1	(0.5)	2	(0.4)
Porcine	4	(1.1)	1	(0.5)	5	(0.9)
PreMix	33	(9.0)	19	(10.4)	52	(9.5)
BHI	12	(3.3)	7	(3.8)	19	(3.5)
BIAsp	16	(4.4)	10	(5.5)	26	(4.7)
ILisMix	5	(1.4)	2	(1.1)	7	(1.3)

N: Number of Subjects

?: Proportion of Subjects

Subjects can use more than one type of insulin within each group

BHI: Biphasic Human Insulin, BIAsp: Biphasic Insulin Aspart, HI: Human Insulin

IAsp: Insulin Aspart, IDet: Insulin Detemir, IGlar: Insulin Glargine

IGlu: Insulin Glulisine, ILis: Insulin Lispro, ILisMix: Insulin Lispro Mix

NPH: Neutral Protamine Hagedorn

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:49 - t_screen_insulin_sum_fas.sas/t_screen_insulin_sum_fas.txt

14.1.13: Diabetes Complications at Screening - Summary - Full Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Number of Subjects	366			182			548		
All Complications	119	(32.5)	217	67	(36.8)	102	186	(33.9)	319
Ophthalmic complications	90	(24.6)	92	55	(30.2)	55	145	(26.5)	147
Diabetic retinopathy	88	(24.0)	88	53	(29.1)	53	141	(25.7)	141
Retinopathy proliferative	2	(0.5)	2	2	(1.1)	2	4	(0.7)	4
Cataract diabetic	2	(0.5)	2				2	(0.4)	2
Neurological complications	71	(19.4)	77	24	(13.2)	25	95	(17.3)	102
Diabetic neuropathy	70	(19.1)	70	24	(13.2)	24	94	(17.2)	94
Diabetic autonomic neuropathy	4	(1.1)	4	1	(0.5)	1	5	(0.9)	5
Diabetic encephalopathy	3	(0.8)	3				3	(0.5)	3
Renal complications	29	(7.9)	29	16	(8.8)	17	45	(8.2)	46
Diabetic nephropathy	19	(5.2)	19	11	(6.0)	12	30	(5.5)	31
Microalbuminuria	10	(2.7)	10	5	(2.7)	5	15	(2.7)	15
Cardiovascular complications	14	(3.8)	16	2	(1.1)	2	16	(2.9)	18
Diabetic vascular disorder	12	(3.3)	12	2	(1.1)	2	14	(2.6)	14
Cardiac autonomic neuropathy	3	(0.8)	3				3	(0.5)	3
Diabetic microangiopathy	1	(0.3)	1				1	(0.2)	1
Dermal complications	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic foot	1	(0.3)	1				1	(0.2)	1
Necrobiosis lipoidica diabetorum				1	(0.5)	1	1	(0.2)	1
Gastrointestinal complications	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic gastroparesis	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Other complications	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2
Diabetic cheiropathy	1	(0.3)	1	1	(0.5)	1	2	(0.4)	2

N= Number of subjects
%= Percentage of subjects
E= Number of Events

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:51 - tsum_events_tpl_t030_v01.sas/t_screen_diabetes_comp_sum_fas.txt

14.1.14: Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp N	OD (%)	IDet N	(%)	Total N	(%)
Number of Subjects	366		182		548	
Metabolism and nutrition disorders	181	(49.5)	96	(52.7)	277	(50.5)
Type 1 diabetes mellitus	62	(16.9)	30	(16.5)	92	(16.8)
Hypercholesterolaemia	40	(10.9)	30	(16.5)	70	(12.8)
Hyperlipidaemia	47	(12.8)	21	(11.5)	68	(12.4)
Dyslipidaemia	34	(9.3)	22	(12.1)	56	(10.2)
Obesity	9	(2.5)	2	(1.1)	11	(2.0)
Diabetes mellitus	5	(1.4)	3	(1.6)	8	(1.5)
Vitamin B12 deficiency	4	(1.1)	1	(0.5)	5	(0.9)
Vitamin D deficiency	3	(0.8)	2	(1.1)	5	(0.9)
Gout	2	(0.5)	1	(0.5)	3	(0.5)
Overweight	2	(0.5)	1	(0.5)	3	(0.5)
Diabetic cheiropathy	1	(0.3)	1	(0.5)	2	(0.4)
Hypertriglyceridaemia	1	(0.3)	1	(0.5)	2	(0.4)
Iron deficiency	1	(0.3)	1	(0.5)	2	(0.4)
Diabetic foot	1	(0.3)			1	(0.2)
Fluid retention	1	(0.3)			1	(0.2)
Vascular disorders	131	(35.8)	77	(42.3)	208	(38.0)
Hypertension	113	(30.9)	71	(39.0)	184	(33.6)
Diabetic vascular disorder	12	(3.3)	2	(1.1)	14	(2.6)
Microangiopathy	1	(0.3)	4	(2.2)	5	(0.9)
Angiopathy	2	(0.5)	1	(0.5)	3	(0.5)
Peripheral vascular disorder	2	(0.5)	1	(0.5)	3	(0.5)
Venous insufficiency	1	(0.3)	2	(1.1)	3	(0.5)
Arterial disorder	2	(0.5)			2	(0.4)
Arteriosclerosis	2	(0.5)			2	(0.4)
Essential hypertension	2	(0.5)			2	(0.4)
Aneurysm			1	(0.5)	1	(0.2)
Aortic stenosis	1	(0.3)			1	(0.2)
Diabetic microangiopathy	1	(0.3)			1	(0.2)
Hot flush	1	(0.3)			1	(0.2)
Hypotension	1	(0.3)			1	(0.2)
Macroangiopathy	1	(0.3)			1	(0.2)
Renovascular hypertension			1	(0.5)	1	(0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Eye disorders	127 (34.7)	79 (43.4)	206 (37.6)
Diabetic retinopathy	88 (24.0)	53 (29.1)	141 (25.7)
Retinopathy	22 (6.0)	15 (8.2)	37 (6.8)
Cataract	19 (5.2)	7 (3.8)	26 (4.7)
Myopia	11 (3.0)	7 (3.8)	18 (3.3)
Glaucoma	5 (1.4)	6 (3.3)	11 (2.0)
Maculopathy	2 (0.5)	2 (1.1)	4 (0.7)
Retinopathy proliferative	2 (0.5)	2 (1.1)	4 (0.7)
Cataract diabetic	2 (0.5)		2 (0.4)
Astigmatism	1 (0.3)		1 (0.2)
Cataract nuclear		1 (0.5)	1 (0.2)
Conjunctivitis	1 (0.3)		1 (0.2)
Dry eye	1 (0.3)		1 (0.2)
Eyelid ptosis	1 (0.3)		1 (0.2)
Keratoconus	1 (0.3)		1 (0.2)
Lenticular opacities		1 (0.5)	1 (0.2)
Macular oedema	1 (0.3)		1 (0.2)
Ocular hypertension		1 (0.5)	1 (0.2)
Presbyopia		1 (0.5)	1 (0.2)
Retinal aneurysm	1 (0.3)		1 (0.2)
Retinal detachment		1 (0.5)	1 (0.2)
Retinal vascular disorder	1 (0.3)		1 (0.2)
Vision blurred		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Nervous system disorders	124 (33.9)	69 (37.9)	193 (35.2)
Diabetic neuropathy	70 (19.1)	24 (13.2)	94 (17.2)
Neuropathy peripheral	22 (6.0)	18 (9.9)	40 (7.3)
Headache	10 (2.7)	6 (3.3)	16 (2.9)
Polyneuropathy	5 (1.4)	8 (4.4)	13 (2.4)
Carpal tunnel syndrome	6 (1.6)	2 (1.1)	8 (1.5)
Migraine	4 (1.1)	3 (1.6)	7 (1.3)
Vascular encephalopathy	5 (1.4)	1 (0.5)	6 (1.1)
Diabetic autonomic neuropathy	4 (1.1)	1 (0.5)	5 (0.9)
Decreased vibratory sense	4 (1.1)		4 (0.7)
Cardiac autonomic neuropathy	3 (0.8)		3 (0.5)
Diabetic encephalopathy	3 (0.8)		3 (0.5)
Restless legs syndrome	1 (0.3)	2 (1.1)	3 (0.5)
Areflexia	1 (0.3)	1 (0.5)	2 (0.4)
Cerebral ischaemia	2 (0.5)		2 (0.4)
Encephalopathy	1 (0.3)	1 (0.5)	2 (0.4)
Epilepsy	1 (0.3)	1 (0.5)	2 (0.4)
Paraesthesia	1 (0.3)	1 (0.5)	2 (0.4)
Peripheral sensory neuropathy		2 (1.1)	2 (0.4)
Balance disorder	1 (0.3)		1 (0.2)
Carotid arteriosclerosis		1 (0.5)	1 (0.2)
Carotid artery stenosis	1 (0.3)		1 (0.2)
Cerebrovascular accident		1 (0.5)	1 (0.2)
Dizziness	1 (0.3)		1 (0.2)
Grand mal convulsion		1 (0.5)	1 (0.2)
Guillain-Barre syndrome	1 (0.3)		1 (0.2)
Hemicephalalgia		1 (0.5)	1 (0.2)
Hypoaesthesia	1 (0.3)		1 (0.2)
Migraine with aura		1 (0.5)	1 (0.2)
Myelopathy	1 (0.3)		1 (0.2)
Neuralgia		1 (0.5)	1 (0.2)
Radiculopathy	1 (0.3)		1 (0.2)
Sciatica	1 (0.3)		1 (0.2)
Syringomyelia	1 (0.3)		1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Musculoskeletal and connective tissue disorders	67 (18.3)	38 (20.9)	105 (19.2)
Osteoarthritis	10 (2.7)	6 (3.3)	16 (2.9)
Osteopenia	7 (1.9)	4 (2.2)	11 (2.0)
Back pain	4 (1.1)	6 (3.3)	10 (1.8)
Osteoporosis	4 (1.1)	6 (3.3)	10 (1.8)
Arthralgia	6 (1.6)	1 (0.5)	7 (1.3)
Arthritis	4 (1.1)	2 (1.1)	6 (1.1)
Osteochondrosis	4 (1.1)	2 (1.1)	6 (1.1)
Spinal osteoarthritis	4 (1.1)	2 (1.1)	6 (1.1)
Foot deformity	4 (1.1)	1 (0.5)	5 (0.9)
Muscle spasms	3 (0.8)	2 (1.1)	5 (0.9)
Periarthritis	2 (0.5)	3 (1.6)	5 (0.9)
Rheumatoid arthritis	4 (1.1)	1 (0.5)	5 (0.9)
Myalgia	2 (0.5)	2 (1.1)	4 (0.7)
Pain in extremity		4 (2.2)	4 (0.7)
Rotator cuff syndrome	3 (0.8)	1 (0.5)	4 (0.7)
Intervertebral disc degeneration	1 (0.3)	2 (1.1)	3 (0.5)
Intervertebral disc disorder	2 (0.5)	1 (0.5)	3 (0.5)
Intervertebral disc protrusion	2 (0.5)	1 (0.5)	3 (0.5)
Neck pain	3 (0.8)		3 (0.5)
Tendonitis	1 (0.3)	2 (1.1)	3 (0.5)
Arthropathy	2 (0.5)		2 (0.4)
Dupuytren's contracture	2 (0.5)		2 (0.4)
Exostosis	1 (0.3)	1 (0.5)	2 (0.4)
Fibromyalgia	2 (0.5)		2 (0.4)
Flank pain	2 (0.5)		2 (0.4)
Musculoskeletal pain	1 (0.3)	1 (0.5)	2 (0.4)
Polyarthritis	2 (0.5)		2 (0.4)
Trigger finger	2 (0.5)		2 (0.4)
Cervical spinal stenosis	1 (0.3)		1 (0.2)
Facet joint syndrome		1 (0.5)	1 (0.2)
Gouty arthritis	1 (0.3)		1 (0.2)
Hip deformity	1 (0.3)		1 (0.2)
Intervertebral disc compression	1 (0.3)		1 (0.2)
Joint stiffness	1 (0.3)		1 (0.2)
Muscle atrophy	1 (0.3)		1 (0.2)
Neuropathic arthropathy		1 (0.5)	1 (0.2)
Plantar fasciitis	1 (0.3)		1 (0.2)
Scoliosis	1 (0.3)		1 (0.2)
Sjogren's syndrome	1 (0.3)		1 (0.2)
Spondylitis		1 (0.5)	1 (0.2)
Spondylolisthesis	1 (0.3)		1 (0.2)
Systemic lupus erythematosus	1 (0.3)		1 (0.2)
Temporomandibular joint syndrome		1 (0.5)	1 (0.2)
Tenosynovitis		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Endocrine disorders	59 (16.1)	28 (15.4)	87 (15.9)
Hypothyroidism	39 (10.7)	18 (9.9)	57 (10.4)
Autoimmune thyroiditis	9 (2.5)	5 (2.7)	14 (2.6)
Goitre	6 (1.6)	4 (2.2)	10 (1.8)
Hypogonadism	3 (0.8)		3 (0.5)
Adrenal insufficiency	2 (0.5)		2 (0.4)
Myxoedema	1 (0.3)	1 (0.5)	2 (0.4)
Thyroiditis chronic	1 (0.3)	1 (0.5)	2 (0.4)
Androgen deficiency	1 (0.3)		1 (0.2)
Hyperparathyroidism	1 (0.3)		1 (0.2)
Hyperthyroidism		1 (0.5)	1 (0.2)
Postpartum hypopituitarism	1 (0.3)		1 (0.2)
Primary hypothyroidism	1 (0.3)		1 (0.2)
Thyroiditis	1 (0.3)		1 (0.2)
Gastrointestinal disorders	53 (14.5)	29 (15.9)	82 (15.0)
Gastrooesophageal reflux disease	13 (3.6)	10 (5.5)	23 (4.2)
Gastritis	8 (2.2)	3 (1.6)	11 (2.0)
Coeliac disease	8 (2.2)	2 (1.1)	10 (1.8)
Hiatus hernia	3 (0.8)	6 (3.3)	9 (1.6)
Constipation	5 (1.4)		5 (0.9)
Duodenal ulcer	5 (1.4)		5 (0.9)
Haemorrhoids	3 (0.8)	1 (0.5)	4 (0.7)
Impaired gastric emptying	2 (0.5)	2 (1.1)	4 (0.7)
Dyspepsia	2 (0.5)	1 (0.5)	3 (0.5)
Gastric ulcer	2 (0.5)	1 (0.5)	3 (0.5)
Gastroduodenitis	2 (0.5)	1 (0.5)	3 (0.5)
Colonic polyp	1 (0.3)	1 (0.5)	2 (0.4)
Diabetic gastroparesis	1 (0.3)	1 (0.5)	2 (0.4)
Irritable bowel syndrome	1 (0.3)	1 (0.5)	2 (0.4)
Pancreatitis	1 (0.3)	1 (0.5)	2 (0.4)
Reflux oesophagitis	2 (0.5)		2 (0.4)
Anal fissure	1 (0.3)		1 (0.2)
Colitis ulcerative	1 (0.3)		1 (0.2)
Diarrhoea		1 (0.5)	1 (0.2)
Diverticulum intestinal	1 (0.3)		1 (0.2)
Duodenitis	1 (0.3)		1 (0.2)
Gastritis atrophic		1 (0.5)	1 (0.2)
Gastrointestinal disorder	1 (0.3)		1 (0.2)
Gingival bleeding	1 (0.3)		1 (0.2)
Gingival swelling	1 (0.3)		1 (0.2)
Hyperchlorhydria	1 (0.3)		1 (0.2)
Oesophagitis	1 (0.3)		1 (0.2)
Pancreatitis chronic	1 (0.3)		1 (0.2)
Proctocolitis	1 (0.3)		1 (0.2)
Rectal polyp		1 (0.5)	1 (0.2)
Umbilical hernia	1 (0.3)		1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Psychiatric disorders	45 (12.3)	23 (12.6)	68 (12.4)
Depression	35 (9.6)	19 (10.4)	54 (9.9)
Anxiety	7 (1.9)	1 (0.5)	8 (1.5)
Attention deficit/hyperactivity disorder	3 (0.8)	3 (1.6)	6 (1.1)
Insomnia	3 (0.8)	2 (1.1)	5 (0.9)
Anxiety disorder	2 (0.5)		2 (0.4)
Bipolar disorder	1 (0.3)		1 (0.2)
Mood swings		1 (0.5)	1 (0.2)
Neurosis	1 (0.3)		1 (0.2)
Post-traumatic stress disorder	1 (0.3)		1 (0.2)
Schizophrenia	1 (0.3)		1 (0.2)
Tobacco abuse	1 (0.3)		1 (0.2)
Renal and urinary disorders	41 (11.2)	27 (14.8)	68 (12.4)
Diabetic nephropathy	19 (5.2)	11 (6.0)	30 (5.5)
Microalbuminuria	10 (2.7)	5 (2.7)	15 (2.7)
Nephropathy	4 (1.1)	4 (2.2)	8 (1.5)
Nephrolithiasis	3 (0.8)	2 (1.1)	5 (0.9)
Calculus urinary	3 (0.8)		3 (0.5)
Proteinuria	2 (0.5)	1 (0.5)	3 (0.5)
Nephroptosis	1 (0.3)	1 (0.5)	2 (0.4)
Urinary incontinence	1 (0.3)	1 (0.5)	2 (0.4)
Albuminuria		1 (0.5)	1 (0.2)
Dysuria	1 (0.3)		1 (0.2)
Glomerulonephritis chronic	1 (0.3)		1 (0.2)
Haematuria		1 (0.5)	1 (0.2)
Hypertonic bladder		1 (0.5)	1 (0.2)
Renal cyst		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Skin and subcutaneous tissue disorders	32 (8.7)	17 (9.3)	49 (8.9)
Lipodystrophy acquired	4 (1.1)	9 (4.9)	13 (2.4)
Acne	4 (1.1)	1 (0.5)	5 (0.9)
Eczema	3 (0.8)	1 (0.5)	4 (0.7)
Alopecia	3 (0.8)		3 (0.5)
Dry skin	2 (0.5)	1 (0.5)	3 (0.5)
Pruritus	3 (0.8)		3 (0.5)
Psoriasis	2 (0.5)	1 (0.5)	3 (0.5)
Urticaria	2 (0.5)	1 (0.5)	3 (0.5)
Vitiligo	3 (0.8)		3 (0.5)
Lipohypertrophy	1 (0.3)	1 (0.5)	2 (0.4)
Rash	1 (0.3)	1 (0.5)	2 (0.4)
Rosacea	1 (0.3)	1 (0.5)	2 (0.4)
Angioedema	1 (0.3)		1 (0.2)
Dermatitis	1 (0.3)		1 (0.2)
Dermatitis allergic	1 (0.3)		1 (0.2)
Dermatitis contact	1 (0.3)		1 (0.2)
Heat rash	1 (0.3)		1 (0.2)
Hyperhidrosis	1 (0.3)		1 (0.2)
Necrobiosis lipoidica diabetorum		1 (0.5)	1 (0.2)
Photodermatosis		1 (0.5)	1 (0.2)
Scar	1 (0.3)		1 (0.2)
Seborrhoeic dermatitis	1 (0.3)		1 (0.2)
Skin ulcer		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Infections and infestations	30 (8.2)	15 (8.2)	45 (8.2)
Pyelonephritis chronic	9 (2.5)	4 (2.2)	13 (2.4)
Sinusitis	3 (0.8)	2 (1.1)	5 (0.9)
Chronic tonsillitis	1 (0.3)	1 (0.5)	2 (0.4)
Folliculitis	2 (0.5)		2 (0.4)
Onychomycosis	1 (0.3)	1 (0.5)	2 (0.4)
Rhinitis		2 (1.1)	2 (0.4)
Bronchitis		1 (0.5)	1 (0.2)
Candidiasis	1 (0.3)		1 (0.2)
Cystitis		1 (0.5)	1 (0.2)
Cystitis bacterial		1 (0.5)	1 (0.2)
Fungal infection		1 (0.5)	1 (0.2)
Gastroenteritis		1 (0.5)	1 (0.2)
Genital candidiasis	1 (0.3)		1 (0.2)
Genital herpes		1 (0.5)	1 (0.2)
Helicobacter infection		1 (0.5)	1 (0.2)
Herpes simplex	1 (0.3)		1 (0.2)
Herpes virus infection		1 (0.5)	1 (0.2)
Infection		1 (0.5)	1 (0.2)
Kidney infection	1 (0.3)		1 (0.2)
Nasopharyngitis	1 (0.3)		1 (0.2)
Oral herpes	1 (0.3)		1 (0.2)
Otitis media	1 (0.3)		1 (0.2)
Pilonidal cyst	1 (0.3)		1 (0.2)
Pyelonephritis	1 (0.3)		1 (0.2)
Tinea pedis	1 (0.3)		1 (0.2)
Tuberculosis	1 (0.3)		1 (0.2)
Upper respiratory tract infection	1 (0.3)		1 (0.2)
Vaginal infection	1 (0.3)		1 (0.2)
Viral upper respiratory tract infection	1 (0.3)		1 (0.2)
Reproductive system and breast disorders	24 (6.6)	17 (9.3)	41 (7.5)
Erectile dysfunction	10 (2.7)	8 (4.4)	18 (3.3)
Dysmenorrhoea	4 (1.1)	4 (2.2)	8 (1.5)
Polycystic ovaries	3 (0.8)		3 (0.5)
Amenorrhoea	2 (0.5)		2 (0.4)
Benign prostatic hyperplasia	2 (0.5)		2 (0.4)
Fibrocystic breast disease	1 (0.3)	1 (0.5)	2 (0.4)
Ovarian cyst	1 (0.3)	1 (0.5)	2 (0.4)
Uterine polyp	1 (0.3)	1 (0.5)	2 (0.4)
Adenomyosis	1 (0.3)		1 (0.2)
Balanoposthitis		1 (0.5)	1 (0.2)
Menorrhagia	1 (0.3)		1 (0.2)
Peyronie's disease		1 (0.5)	1 (0.2)
Varicose veins pelvic		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Respiratory, thoracic and mediastinal disorders	27 (7.4)	12 (6.6)	39 (7.1)
Asthma	12 (3.3)	10 (5.5)	22 (4.0)
Sleep apnoea syndrome	7 (1.9)	1 (0.5)	8 (1.5)
Rhinitis allergic	3 (0.8)	2 (1.1)	5 (0.9)
Cough	2 (0.5)		2 (0.4)
Bronchitis chronic	1 (0.3)		1 (0.2)
Chronic obstructive pulmonary disease		1 (0.5)	1 (0.2)
Pulmonary granuloma	1 (0.3)		1 (0.2)
Sinus congestion	1 (0.3)		1 (0.2)
Upper-airway cough syndrome	1 (0.3)		1 (0.2)
Immune system disorders	29 (7.9)	8 (4.4)	37 (6.8)
Seasonal allergy	17 (4.6)	7 (3.8)	24 (4.4)
Drug hypersensitivity	8 (2.2)	2 (1.1)	10 (1.8)
Anaphylactic reaction	1 (0.3)		1 (0.2)
Atopy	1 (0.3)		1 (0.2)
Food allergy	1 (0.3)		1 (0.2)
Hypersensitivity	1 (0.3)		1 (0.2)
Multiple allergies	1 (0.3)		1 (0.2)
Cardiac disorders	24 (6.6)	11 (6.0)	35 (6.4)
Coronary artery disease	6 (1.6)	2 (1.1)	8 (1.5)
Myocardial ischaemia	6 (1.6)	2 (1.1)	8 (1.5)
Arteriosclerosis coronary artery	2 (0.5)	1 (0.5)	3 (0.5)
Atrial fibrillation	2 (0.5)	1 (0.5)	3 (0.5)
Angina pectoris	2 (0.5)		2 (0.4)
Bundle branch block left	2 (0.5)		2 (0.4)
Cardiomyopathy	1 (0.3)	1 (0.5)	2 (0.4)
Mitral valve prolapse	1 (0.3)	1 (0.5)	2 (0.4)
Sinus bradycardia	1 (0.3)	1 (0.5)	2 (0.4)
Sinus tachycardia	2 (0.5)		2 (0.4)
Tachycardia	2 (0.5)		2 (0.4)
Aortic valve incompetence		1 (0.5)	1 (0.2)
Bundle branch block right	1 (0.3)		1 (0.2)
Cardiac disorder		1 (0.5)	1 (0.2)
Diastolic dysfunction		1 (0.5)	1 (0.2)
Myocardial fibrosis	1 (0.3)		1 (0.2)
Postinfarction angina	1 (0.3)		1 (0.2)
Hepatobiliary disorders	18 (4.9)	8 (4.4)	26 (4.7)
Hepatic steatosis	12 (3.3)	2 (1.1)	14 (2.6)
Cholecystitis chronic	7 (1.9)	3 (1.6)	10 (1.8)
Liver disorder	2 (0.5)	1 (0.5)	3 (0.5)
Biliary dyskinesia	1 (0.3)		1 (0.2)
Gallbladder polyp		1 (0.5)	1 (0.2)
Hepatic cyst		1 (0.5)	1 (0.2)
Hyperbilirubinaemia neonatal		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
General disorders and administration site conditions	12 (3.3)	9 (4.9)	21 (3.8)
Fatigue	7 (1.9)	5 (2.7)	12 (2.2)
Application site nodule	1 (0.3)	1 (0.5)	2 (0.4)
Asthenia	2 (0.5)		2 (0.4)
Oedema peripheral		2 (1.1)	2 (0.4)
Nodule	1 (0.3)		1 (0.2)
Pain	1 (0.3)		1 (0.2)
Sensation of foreign body		1 (0.5)	1 (0.2)
Temperature intolerance	1 (0.3)		1 (0.2)
Investigations	11 (3.0)	6 (3.3)	17 (3.1)
Cardiac murmur	3 (0.8)	1 (0.5)	4 (0.7)
Vitamin D decreased	1 (0.3)	1 (0.5)	2 (0.4)
Arthroscopy		1 (0.5)	1 (0.2)
Blood alkaline phosphatase increased	1 (0.3)		1 (0.2)
Blood cholesterol increased		1 (0.5)	1 (0.2)
Blood pressure increased	1 (0.3)		1 (0.2)
Electrocardiogram T wave inversion	1 (0.3)		1 (0.2)
Heart rate irregular	1 (0.3)		1 (0.2)
Hepatic enzyme increased		1 (0.5)	1 (0.2)
QRS axis abnormal		1 (0.5)	1 (0.2)
Vibration test abnormal	1 (0.3)		1 (0.2)
Weight decreased	1 (0.3)		1 (0.2)
White blood cells urine	1 (0.3)		1 (0.2)
Social circumstances	12 (3.3)	5 (2.7)	17 (3.1)
Menopause	7 (1.9)	4 (2.2)	11 (2.0)
Postmenopause	4 (1.1)	1 (0.5)	5 (0.9)
Edentulous	1 (0.3)		1 (0.2)
Congenital, familial and genetic disorders	10 (2.7)	5 (2.7)	15 (2.7)
Albinism	2 (0.5)		2 (0.4)
Cataract congenital	1 (0.3)	1 (0.5)	2 (0.4)
Mixed hyperlipidaemia	2 (0.5)		2 (0.4)
Atrial septal defect	1 (0.3)		1 (0.2)
Benign familial haematuria	1 (0.3)		1 (0.2)
Congenital jaw malformation	1 (0.3)		1 (0.2)
Double ureter	1 (0.3)		1 (0.2)
Osteogenesis imperfecta		1 (0.5)	1 (0.2)
Phimosis		1 (0.5)	1 (0.2)
Strabismus congenital		1 (0.5)	1 (0.2)
Turner's syndrome	1 (0.3)		1 (0.2)
Ventricular septal defect		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

Concomitant Illness at Screening - Summary - Full Analysis Set

	IDegAsp N (%)	OD (%)	IDet N (%)	Total N (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (2.2)		6 (3.3)	14 (2.6)
Thyroid neoplasm	3 (0.8)		1 (0.5)	4 (0.7)
Uterine leiomyoma	2 (0.5)		1 (0.5)	3 (0.5)
Eye naevus	1 (0.3)		1 (0.5)	2 (0.4)
Benign breast neoplasm			1 (0.5)	1 (0.2)
Benign neoplasm of thyroid gland	1 (0.3)			1 (0.2)
Breast adenoma			1 (0.5)	1 (0.2)
Breast fibroma	1 (0.3)			1 (0.2)
Morton's neuroma			1 (0.5)	1 (0.2)
Skin papilloma	1 (0.3)			1 (0.2)
Blood and lymphatic system disorders	7 (1.9)		6 (3.3)	13 (2.4)
Anaemia	1 (0.3)		6 (3.3)	7 (1.3)
Iron deficiency anaemia	3 (0.8)			3 (0.5)
Eosinophilia	1 (0.3)			1 (0.2)
Leukocytosis	1 (0.3)			1 (0.2)
Pernicious anaemia	1 (0.3)			1 (0.2)
Surgical and medical procedures	4 (1.1)		3 (1.6)	7 (1.3)
Female sterilisation	1 (0.3)		1 (0.5)	2 (0.4)
Appendicectomy			1 (0.5)	1 (0.2)
Finger amputation	1 (0.3)			1 (0.2)
Implantable defibrillator insertion	1 (0.3)			1 (0.2)
Nephrectomy			1 (0.5)	1 (0.2)
Thyroidectomy			1 (0.5)	1 (0.2)
Toe amputation	1 (0.3)			1 (0.2)
Injury, poisoning and procedural complications	5 (1.4)		1 (0.5)	6 (1.1)
Back injury	1 (0.3)			1 (0.2)
Foot fracture	1 (0.3)			1 (0.2)
Joint dislocation	1 (0.3)			1 (0.2)
Joint injury	1 (0.3)			1 (0.2)
Ligament rupture	1 (0.3)			1 (0.2)
Lumbar vertebral fracture	1 (0.3)			1 (0.2)
Post procedural hypothyroidism			1 (0.5)	1 (0.2)
Skeletal injury	1 (0.3)			1 (0.2)
Soft tissue injury	1 (0.3)			1 (0.2)
Ear and labyrinth disorders	4 (1.1)		1 (0.5)	5 (0.9)
Deafness bilateral	1 (0.3)			1 (0.2)
Deafness unilateral			1 (0.5)	1 (0.2)
Hypoacusis	1 (0.3)			1 (0.2)
Meniere's disease	1 (0.3)			1 (0.2)
Vertigo	1 (0.3)			1 (0.2)

N= Number of subjects

%= Percentage of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:53 - tsum_events_tpl_t030_v01.sas/t_screen_con_ill_sum_fas.txt

14.1.15: Concomitant Medication at Screening – Summary - Full Analysis Set

	IDegAsp N	OD (%)	IDet N	(%)	Total N	(%)
Number of Subjects	366		182		548	
INSULIN GLARGINE	237	(64.8)	125	(68.7)	362	(66.1)
INSULIN ASPART	182	(49.7)	95	(52.2)	277	(50.5)
INSULIN LISPRO	110	(30.1)	51	(28.0)	161	(29.4)
SIMVASTATIN	49	(13.4)	36	(19.8)	85	(15.5)
INSULIN DETEMIR	57	(15.6)	24	(13.2)	81	(14.8)
ACETYLSALICYLIC ACID	49	(13.4)	26	(14.3)	75	(13.7)
INSULIN HUMAN	44	(12.0)	23	(12.6)	67	(12.2)
LEVOTHYROXINE SODIUM	39	(10.7)	15	(8.2)	54	(9.9)
LISINOPRIL	26	(7.1)	16	(8.8)	42	(7.7)
RAMIPRIL	21	(5.7)	15	(8.2)	36	(6.6)
INSULIN GLULISINE	22	(6.0)	13	(7.1)	35	(6.4)
ATORVASTATIN CALCIUM	17	(4.6)	9	(4.9)	26	(4.7)
PARACETAMOL	12	(3.3)	8	(4.4)	20	(3.6)
INDAPAMIDE	11	(3.0)	6	(3.3)	17	(3.1)
ENALAPRIL	11	(3.0)	5	(2.7)	16	(2.9)
IBUPROFEN	9	(2.5)	7	(3.8)	16	(2.9)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
INSULIN HUMAN INJECTION, ISOPHANE	12 (3.3)	4 (2.2)	16 (2.9)
MULTIVITAMIN / [REDACTED]	8 (2.2)	8 (4.4)	16 (2.9)
ROSUVASTATIN CALCIUM	8 (2.2)	8 (4.4)	16 (2.9)
AMLODIPINE BESILATE	9 (2.5)	6 (3.3)	15 (2.7)
ISOPHANE INSULIN	11 (3.0)	4 (2.2)	15 (2.7)
LEVOTHYROXINE	5 (1.4)	8 (4.4)	13 (2.4)
NOVOMIX / [REDACTED]	8 (2.2)	5 (2.7)	13 (2.4)
HUMAN MIXTARD / [REDACTED]	8 (2.2)	4 (2.2)	12 (2.2)
HYDROCHLOROTHIAZIDE	7 (1.9)	5 (2.7)	12 (2.2)
TELMISARTAN	9 (2.5)	3 (1.6)	12 (2.2)
ATORVASTATIN	6 (1.6)	4 (2.2)	10 (1.8)
CLOPIDOGREL	5 (1.4)	4 (2.2)	9 (1.6)
LOSARTAN POTASSIUM	7 (1.9)	2 (1.1)	9 (1.6)
SALBUTAMOL	5 (1.4)	4 (2.2)	9 (1.6)
AMLODIPINE	6 (1.6)	2 (1.1)	8 (1.5)
EUGYNON / [REDACTED]	5 (1.4)	3 (1.6)	8 (1.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
FISH OIL	5 (1.4)	3 (1.6)	8 (1.5)
VITAMEDIN / [REDACTED]	4 (1.1)	4 (2.2)	8 (1.5)
VITAMIN D NOS	4 (1.1)	4 (2.2)	8 (1.5)
CALCIUM	3 (0.8)	4 (2.2)	7 (1.3)
DULOXETINE HYDROCHLORIDE	3 (0.8)	4 (2.2)	7 (1.3)
EZETIMIBE	6 (1.6)	1 (0.5)	7 (1.3)
METOPROLOL	6 (1.6)	1 (0.5)	7 (1.3)
OMEPRAZOLE	4 (1.1)	3 (1.6)	7 (1.3)
PERINDOPRIL ERBUMINE	2 (0.5)	5 (2.7)	7 (1.3)
PRAVASTATIN	6 (1.6)	1 (0.5)	7 (1.3)
ALBYL-ENTEROSOLUBILE	2 (0.5)	4 (2.2)	6 (1.1)
ASCORBIC ACID	4 (1.1)	2 (1.1)	6 (1.1)
BISOPROLOL	3 (0.8)	3 (1.6)	6 (1.1)
CARVEDILOL	5 (1.4)	1 (0.5)	6 (1.1)
CITALOPRAM	3 (0.8)	3 (1.6)	6 (1.1)
COLECALCIFEROL	3 (0.8)	3 (1.6)	6 (1.1)
ENALAPRIL MALEATE	1 (0.3)	5 (2.7)	6 (1.1)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
FENOFIBRATE	3 (0.8)	3 (1.6)	6 (1.1)
FUROSEMIDE	2 (0.5)	4 (2.2)	6 (1.1)
GABAPENTIN	4 (1.1)	2 (1.1)	6 (1.1)
LORATADINE	5 (1.4)	1 (0.5)	6 (1.1)
VALSARTAN	4 (1.1)	2 (1.1)	6 (1.1)
ESCITALOPRAM OXALATE	4 (1.1)	1 (0.5)	5 (0.9)
FEXOFENADINE HYDROCHLORIDE	2 (0.5)	3 (1.6)	5 (0.9)
INSULIN PORCINE	4 (1.1)	1 (0.5)	5 (0.9)
IRBESARTAN	1 (0.3)	4 (2.2)	5 (0.9)
METOPROLOL SUCCINATE	4 (1.1)	1 (0.5)	5 (0.9)
OBETROL [REDACTED]	/	2 (1.1)	5 (0.9)
PERINDOPRIL	2 (0.5)	3 (1.6)	5 (0.9)
THIOCTIC ACID	4 (1.1)	1 (0.5)	5 (0.9)
ALENDRONATE SODIUM	1 (0.3)	3 (1.6)	4 (0.7)
ATENOLOL	3 (0.8)	1 (0.5)	4 (0.7)
BUDESONIDE	3 (0.8)	1 (0.5)	4 (0.7)
CANDESARTAN CILEXETIL	2 (0.5)	2 (1.1)	4 (0.7)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CLONAZEPAM	2 (0.5)	2 (1.1)	4 (0.7)
ESOMEPRAZOLE MAGNESIUM	2 (0.5)	2 (1.1)	4 (0.7)
FERROUS SULFATE	1 (0.3)	3 (1.6)	4 (0.7)
HUMALOG MIX	3 (0.8)	1 (0.5)	4 (0.7)
INEGY	4 (1.1)		4 (0.7)
LOSARTAN	3 (0.8)	1 (0.5)	4 (0.7)
LOVASTATIN	2 (0.5)	2 (1.1)	4 (0.7)
MOXONIDINE	2 (0.5)	2 (1.1)	4 (0.7)
MULTIVITAMINS, COMBINATIONS	2 (0.5)	2 (1.1)	4 (0.7)
NIFEDIPINE	3 (0.8)	1 (0.5)	4 (0.7)
PANTOPRAZOLE SODIUM	2 (0.5)	2 (1.1)	4 (0.7)
SERTRALINE HYDROCHLORIDE	2 (0.5)	2 (1.1)	4 (0.7)
TADALAFIL	3 (0.8)	1 (0.5)	4 (0.7)
VITAMIN B12 NOS	2 (0.5)	2 (1.1)	4 (0.7)
ANOVLAR	3 (0.8)		3 (0.5)
BUPROPION	3 (0.8)		3 (0.5)
CALCIUM DOBESILATE	3 (0.8)		3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CANDESARTAN	1 (0.3)	2 (1.1)	3 (0.5)
CAPTOPRIL	1 (0.3)	2 (1.1)	3 (0.5)
CETIRIZINE HYDROCHLORIDE	1 (0.3)	2 (1.1)	3 (0.5)
CYCLOBENZAPRINE HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
DILTIAZEM	1 (0.3)	2 (1.1)	3 (0.5)
DILTIAZEM HYDROCHLORIDE		3 (1.6)	3 (0.5)
ESTROGENS CONJUGATED	1 (0.3)	2 (1.1)	3 (0.5)
FEMODENE	3 (0.8)		3 (0.5)
FLUOXETINE	2 (0.5)	1 (0.5)	3 (0.5)
FLUOXETINE HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
FOLIC ACID	1 (0.3)	2 (1.1)	3 (0.5)
GLUCOSAMINE	1 (0.3)	2 (1.1)	3 (0.5)
GLYCERYL TRINITRATE	3 (0.8)		3 (0.5)
INSULIN	2 (0.5)	1 (0.5)	3 (0.5)
LANSOPRAZOLE	3 (0.8)		3 (0.5)
LERCANIDIPINE HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
MONTELUKAST SODIUM	2 (0.5)	1 (0.5)	3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
NEBIVOLOL HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
OLMESARTAN MEDOXOMIL	2 (0.5)	1 (0.5)	3 (0.5)
PANTOPRAZOLE	1 (0.3)	2 (1.1)	3 (0.5)
POTASSIUM CHLORIDE		3 (1.6)	3 (0.5)
PREGABALIN	1 (0.3)	2 (1.1)	3 (0.5)
ROSUVASTATIN	2 (0.5)	1 (0.5)	3 (0.5)
SERETIDE	2 (0.5)	1 (0.5)	3 (0.5)
SERTRALINE	2 (0.5)	1 (0.5)	3 (0.5)
VALACICLOVIR HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
VARDENAFIL HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
VENLAFAXINE HYDROCHLORIDE	1 (0.3)	2 (1.1)	3 (0.5)
ACETYLSALICYLATE LYSINE		2 (1.1)	2 (0.4)
ALPRAZOLAM	1 (0.3)	1 (0.5)	2 (0.4)
AMOXICILLIN	2 (0.5)		2 (0.4)
ARIPIRAZOLE	2 (0.5)		2 (0.4)
BENDROFLUMETHIAZIDE		2 (1.1)	2 (0.4)
BI PREDONIUM	2 (0.5)		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
BISOPROLOL FUMARATE	2 (0.5)		2 (0.4)
BLOPRESS PLUS	2 (0.5)		2 (0.4)
BRIMONIDINE TARTRATE	1 (0.3)	1 (0.5)	2 (0.4)
BUDESONIDE W/FORMOTEROL FUMARATE		2 (1.1)	2 (0.4)
CALCIUM CARBONATE	1 (0.3)	1 (0.5)	2 (0.4)
CETIRIZINE	1 (0.3)	1 (0.5)	2 (0.4)
CILOSTAZOL	1 (0.3)	1 (0.5)	2 (0.4)
CITALOPRAM HYDROBROMIDE	1 (0.3)	1 (0.5)	2 (0.4)
CYANOCOBALAMIN	1 (0.3)	1 (0.5)	2 (0.4)
DIANE	2 (0.5)		2 (0.4)
DICLOFENAC	2 (0.5)		2 (0.4)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
DIPYRIDAMOLE	1 (0.3)	1 (0.5)	2 (0.4)
DOCUSATE SODIUM	1 (0.3)	1 (0.5)	2 (0.4)
ENALAPRILAT	1 (0.3)	1 (0.5)	2 (0.4)
ERGOCALCIFEROL	1 (0.3)	1 (0.5)	2 (0.4)
ESTRADIOL	2 (0.5)		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
FAMOTIDINE	1 (0.3)	1 (0.5)	2 (0.4)
FLUCONAZOLE	2 (0.5)		2 (0.4)
GENERAL NUTRIENTS	2 (0.5)		2 (0.4)
GINKGO BILOBA	1 (0.3)	1 (0.5)	2 (0.4)
HYDROCORTISONE	2 (0.5)		2 (0.4)
HYDROXYCHLOROQUINE	2 (0.5)		2 (0.4)
HYDROXYZINE	2 (0.5)		2 (0.4)
LACTOBACILLUS ACIDOPHILUS	1 (0.3)	1 (0.5)	2 (0.4)
LATANOPROST		2 (1.1)	2 (0.4)
MARVELON	1 (0.3)	1 (0.5)	2 (0.4)
MELOXICAM	2 (0.5)		2 (0.4)
METOCLOPRAMIDE	2 (0.5)		2 (0.4)
METRONIDAZOLE		2 (1.1)	2 (0.4)
MILGAMMA NA	2 (0.5)		2 (0.4)
MOMETASONE FUROATE	2 (0.5)		2 (0.4)
MULTIVITAMINS		2 (1.1)	2 (0.4)
MULTIVITAMINS, OTHER COMBINATIONS	2 (0.5)		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
NAPROXEN	2 (0.5)		2 (0.4)
NICOTINIC ACID	2 (0.5)		2 (0.4)
NORETHISTERONE	1 (0.3)	1 (0.5)	2 (0.4)
POTASSIUM	2 (0.5)		2 (0.4)
PRAVASTATIN SODIUM	2 (0.5)		2 (0.4)
PROVELLA-14	2 (0.5)		2 (0.4)
PSEUDOEPHEDRINE	1 (0.3)	1 (0.5)	2 (0.4)
RABEPRAZOLE SODIUM	1 (0.3)	1 (0.5)	2 (0.4)
SALBUTAMOL SULFATE	1 (0.3)	1 (0.5)	2 (0.4)
SALURES-K		2 (1.1)	2 (0.4)
SPIRONOLACTONE	1 (0.3)	1 (0.5)	2 (0.4)
SULFONAMIDES, PLAIN		2 (1.1)	2 (0.4)
TETRAZEPAM	2 (0.5)		2 (0.4)
TIMOLOL	1 (0.3)	1 (0.5)	2 (0.4)
TOCOPHEROL	1 (0.3)	1 (0.5)	2 (0.4)
TRAMADOL	1 (0.3)	1 (0.5)	2 (0.4)
TRAMADOL HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
TRIAMCINOLONE ACETONIDE	1 (0.3)	1 (0.5)	2 (0.4)
TRIMETAZIDINE	1 (0.3)	1 (0.5)	2 (0.4)
UBIDECARENONE	2 (0.5)		2 (0.4)
VALPROATE SODIUM	1 (0.3)	1 (0.5)	2 (0.4)
VENLAFAXINE	2 (0.5)		2 (0.4)
VITAMIN B-COMPLEX, PLAIN	1 (0.3)	1 (0.5)	2 (0.4)
ZOLPIDEM TARTRATE	1 (0.3)	1 (0.5)	2 (0.4)
ALANERV	1 (0.3)		1 (0.2)
ALEPSAL		1 (0.5)	1 (0.2)
ALFACALCIDOL	1 (0.3)		1 (0.2)
ALLIUM SATIVUM	1 (0.3)		1 (0.2)
ALLOPURINOL	1 (0.3)		1 (0.2)
ALPROSTADIL	1 (0.3)		1 (0.2)
AMILORIDE W/HYDROCHLOROTHIAZIDE	1 (0.3)		1 (0.2)
AMITRIPTYLINE		1 (0.5)	1 (0.2)
AMITRIPTYLINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
ASCRIPTIN	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ATOMOXETINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
BENAZEPRIL		1 (0.5)	1 (0.2)
BENAZEPRIL HYDROCHLORIDE	1 (0.3)		1 (0.2)
BENICAR HCT	1 (0.3)		1 (0.2)
BENZALKONIUM CHLORIDE	1 (0.3)		1 (0.2)
BETAHISTINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
BETAXOLOL	1 (0.3)		1 (0.2)
BETAXOLOL HYDROCHLORIDE	1 (0.3)		1 (0.2)
BIMATOPROST	1 (0.3)		1 (0.2)
BISELECT [REDACTED]	/	1 (0.3)	1 (0.2)
BRINZOLAMIDE	1 (0.3)		1 (0.2)
BROMAZEPAM	1 (0.3)		1 (0.2)
BUPROPION HYDROCHLORIDE	1 (0.3)		1 (0.2)
BUTALBITAL W/ASPIRIN/CAFFEINE	1 (0.3)		1 (0.2)
CADUET		1 (0.5)	1 (0.2)
CALCIUM W/MAGNESIUM	1 (0.3)		1 (0.2)
CALCIUM W/VITAMIN D NOS		1 (0.5)	1 (0.2)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CAMELLIA SINENSIS	1 (0.3)		1 (0.2)
CARBAMAZEPINE	1 (0.3)		1 (0.2)
CARBIMAZOLE		1 (0.5)	1 (0.2)
CELECOXIB		1 (0.5)	1 (0.2)
CENTRUM SILVER [REDACTED]	/	1 (0.3)	1 (0.2)
CHLORHEXIDINE GLUCONATE	1 (0.3)		1 (0.2)
CHLORPHENAMINE MALEATE		1 (0.5)	1 (0.2)
CHONDROITIN		1 (0.5)	1 (0.2)
CICLOPIROX	1 (0.3)		1 (0.2)
CILAZAPRIL	1 (0.3)		1 (0.2)
CILEST	1 (0.3)		1 (0.2)
CIPROFLOXACIN	1 (0.3)		1 (0.2)
CITRACAL + D [REDACTED]	/	1 (0.3)	1 (0.2)
CLOMIPRAMINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
CLONIDINE	1 (0.3)		1 (0.2)
CLORAZEPATE DIPOTASSIUM	1 (0.3)		1 (0.2)
CO-DIOVAN	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
COD-LIVER OIL	1 (0.3)		1 (0.2)
COLESTYRAMINE		1 (0.5)	1 (0.2)
CREAM E45	1 (0.3)		1 (0.2)
DAILY MULTIVITAMIN		1 (0.5)	1 (0.2)
DECONAMINE	1 (0.3)		1 (0.2)
DESLORATADINE	1 (0.3)		1 (0.2)
DESOGESTREL		1 (0.5)	1 (0.2)
DESVENLAFAXINE	1 (0.3)		1 (0.2)
DIAZEPAM	1 (0.3)		1 (0.2)
DIFLORASONE DIACETATE	1 (0.3)		1 (0.2)
DIGOXIN	1 (0.3)		1 (0.2)
DIOVAN AMLO	1 (0.3)		1 (0.2)
DOMPERIDONE	1 (0.3)		1 (0.2)
DOSULEPIN HYDROCHLORIDE	1 (0.3)		1 (0.2)
DOZOL [REDACTED]	/	1 (0.3)	1 (0.2)
DROSPIRENONE W/ETHINYLESTRADIOL		1 (0.5)	1 (0.2)
DRUGS FOR PEPTIC ULCER AND GORD	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DUOTRAV		1 (0.5)	1 (0.2)
ELIDIUR	1 (0.3)		1 (0.2)
EPINEPHRINE	1 (0.3)		1 (0.2)
ERYTHROMYCIN		1 (0.5)	1 (0.2)
ESTRADIOL VALERATE	1 (0.3)		1 (0.2)
FEFOL / [REDACTED]	1 (0.3)		1 (0.2)
FELODIPINE	1 (0.3)		1 (0.2)
FLUDROCORTISONE ACETATE	1 (0.3)		1 (0.2)
FLUTICASONE	1 (0.3)		1 (0.2)
FLUTICASONE FUROATE		1 (0.5)	1 (0.2)
FLUTICASONE PROPIONATE		1 (0.5)	1 (0.2)
FLUVASTATIN SODIUM		1 (0.5)	1 (0.2)
FOSAVANCE		1 (0.5)	1 (0.2)
FOSINOPRIL	1 (0.3)		1 (0.2)
GALENIC /FLUTICASONE/SALMETEROL/	1 (0.3)		1 (0.2)
GEMFIBROZIL	1 (0.3)		1 (0.2)
GERITOL / [REDACTED]		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
GLUCOSAMINE W/CHONDROITIN SULFATE		1 (0.5)	1 (0.2)
GUAIFENESIN		1 (0.5)	1 (0.2)
HEDERA HELIX	1 (0.3)		1 (0.2)
HEXAQUINE	1 (0.3)		1 (0.2)
HYDROCODONE BITARTRATE		1 (0.5)	1 (0.2)
HYDROCORTISONE ACETATE	1 (0.3)		1 (0.2)
HYDROXOCOBALAMIN	1 (0.3)		1 (0.2)
HYDROXYZINE EMBONATE		1 (0.5)	1 (0.2)
IBANDRONATE SODIUM		1 (0.5)	1 (0.2)
ICAPS		1 (0.5)	1 (0.2)
INDOMETACIN	1 (0.3)		1 (0.2)
INFLUENZA VACCINE	1 (0.3)		1 (0.2)
INSULIN ISOPHANE BOVINE		1 (0.5)	1 (0.2)
INSULIN W/ISOPHANE INSULIN		1 (0.5)	1 (0.2)
INTRAUTERINE CONTRACEPTIVE DEVICE	1 (0.3)		1 (0.2)
IRON	1 (0.3)		1 (0.2)
ISOSORBIDE DINITRATE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
KARVEA HCT		1 (0.5)	1 (0.2)
KLIOGEST	1 (0.3)		1 (0.2)
LAMOTRIGINE	1 (0.3)		1 (0.2)
LERCANIDIPINE	1 (0.3)		1 (0.2)
LEVOCETIRIZINE DIHYDROCHLORIDE	1 (0.3)		1 (0.2)
LIOTHYRONINE SODIUM	1 (0.3)		1 (0.2)
LIPITAC		1 (0.5)	1 (0.2)
LISINOPRIL DIHYDRATE	1 (0.3)		1 (0.2)
LOMOTIL		1 (0.5)	1 (0.2)
LOPERAMIDE HYDROCHLORIDE		1 (0.5)	1 (0.2)
LYMECYCLINE	1 (0.3)		1 (0.2)
MAGNESIUM CHLORIDE ANHYDROUS	1 (0.3)		1 (0.2)
MEDROXYPROGESTERONE	1 (0.3)		1 (0.2)
MEDROXYPROGESTERONE ACETATE		1 (0.5)	1 (0.2)
MERSYNDOL [REDACTED]	/	1 (0.3)	1 (0.2)
METAXALONE		1 (0.5)	1 (0.2)
METFORMIN HYDROCHLORIDE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
METHADONE	1 (0.3)		1 (0.2)
METHYLDOPA	1 (0.3)		1 (0.2)
MIRTAZAPINE	1 (0.3)		1 (0.2)
MODURETIC	1 (0.3)		1 (0.2)
MORPHINE SULFATE		1 (0.5)	1 (0.2)
MOXIFLOXACIN HYDROCHLORIDE	1 (0.3)		1 (0.2)
MULTIVITAMINS W/MINERALS		1 (0.5)	1 (0.2)
NADOLOL		1 (0.5)	1 (0.2)
NARINE /	1 (0.3)		1 (0.2)
NEBIVOLOL	1 (0.3)		1 (0.2)
NICORANDIL	1 (0.3)		1 (0.2)
NITROFURANTOIN	1 (0.3)		1 (0.2)
NORLESTRIN FE	1 (0.3)		1 (0.2)
NORTRIPTYLINE		1 (0.5)	1 (0.2)
NORTRIPTYLINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
OMEGA-3 FATTY ACIDS	1 (0.3)		1 (0.2)
ONDANSETRON	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ONE-A-DAY MEN'S	1 (0.3)		1 (0.2)
OS-CAL /		1 (0.5)	1 (0.2)
OSCAL D /		1 (0.5)	1 (0.2)
OTHER COLD COMBINATION PREPARATIONS	1 (0.3)		1 (0.2)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.3)		1 (0.2)
OTHER RESPIRATORY SYSTEM PRODUCTS	1 (0.3)		1 (0.2)
OXCARBAZEPINE		1 (0.5)	1 (0.2)
OXYCODONE/APAP	1 (0.3)		1 (0.2)
PALIPERIDONE	1 (0.3)		1 (0.2)
PANCREATIN	1 (0.3)		1 (0.2)
PARA-SELTZER	1 (0.3)		1 (0.2)
PAROXETINE	1 (0.3)		1 (0.2)
PENICILLIN NOS	1 (0.3)		1 (0.2)
PHENOBARBITAL		1 (0.5)	1 (0.2)
PHENYLEPHRINE		1 (0.5)	1 (0.2)
POLYCARBOPHIL CALCIUM	1 (0.3)		1 (0.2)
PRAMIPEXOLE DIHYDROCHLORIDE		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
PRAZOSIN HYDROCHLORIDE		1 (0.5)	1 (0.2)
PREDNISONE	1 (0.3)		1 (0.2)
PRITORPLUS	1 (0.3)		1 (0.2)
PROCHLORPERAZINE	1 (0.3)		1 (0.2)
PROCTOFOAM /	1 (0.3)		1 (0.2)
PROGESTERONE	1 (0.3)		1 (0.2)
QUINAPRIL	1 (0.3)		1 (0.2)
QUINAPRIL HYDROCHLORIDE		1 (0.5)	1 (0.2)
RANITIDINE	1 (0.3)		1 (0.2)
RANITIDINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
RISEDRONATE SODIUM	1 (0.3)		1 (0.2)
RISPERIDONE	1 (0.3)		1 (0.2)
RONDEC TR	1 (0.3)		1 (0.2)
ROSIGLITAZONE	1 (0.3)		1 (0.2)
SALMETEROL XINAFOATE	1 (0.3)		1 (0.2)
SENNA ALEXANDRINA	1 (0.3)		1 (0.2)
SERENOA REPENS	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SILDENAFIL	1 (0.3)		1 (0.2)
SILDENAFIL CITRATE	1 (0.3)		1 (0.2)
SODIUM CHLORIDE	1 (0.3)		1 (0.2)
SORBITOL	1 (0.3)		1 (0.2)
SULFAMETHIZOLE		1 (0.5)	1 (0.2)
SULFASALAZINE		1 (0.5)	1 (0.2)
SULODEXIDE	1 (0.3)		1 (0.2)
TERBINAFINE		1 (0.5)	1 (0.2)
TESTOSTERONE	1 (0.3)		1 (0.2)
THOMAPYRIN N	1 (0.3)		1 (0.2)
THYROID	1 (0.3)		1 (0.2)
TIMOLOL MALEATE	1 (0.3)		1 (0.2)
TIOTROPIUM BROMIDE		1 (0.5)	1 (0.2)
TOBRADEX	1 (0.3)		1 (0.2)
TRANDOLAPRIL	1 (0.3)		1 (0.2)
TRAVOPROST		1 (0.5)	1 (0.2)
TRAZODONE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

Concomitant Medication at Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
TRIAMTERENE		1 (0.5)	1 (0.2)
TRIMETAZIDINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
TRIMETHOPRIM		1 (0.5)	1 (0.2)
TROPICAMIDE		1 (0.5)	1 (0.2)
UNSPECIFIED HERBAL	1 (0.3)		1 (0.2)
VALPROIC ACID	1 (0.3)		1 (0.2)
VALPROMIDE	1 (0.3)		1 (0.2)
VICODIN		1 (0.5)	1 (0.2)
VICON C	1 (0.3)		1 (0.2)
VINCENTS [REDACTED]	/	1 (0.3)	1 (0.2)
VITAMIN C WITH ZINC	1 (0.3)		1 (0.2)
VITAMINS [REDACTED]	/	1 (0.3)	1 (0.2)
WARFARIN SODIUM	1 (0.3)		1 (0.2)
XALACOM	1 (0.3)		1 (0.2)
ZINC SULFATE	1 (0.3)		1 (0.2)
ZOLEDRONIC ACID	1 (0.3)		1 (0.2)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:55 - tsum_events_tpl_t030_v01.sas/t_screen_con_med_sum_fas.txt

14.1.16: Concomitant Medication Started after Screening – Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
PARACETAMOL	62 (16.9)	27 (14.8)	89 (16.2)
IBUPROFEN	37 (10.1)	25 (13.7)	62 (11.3)
AMOXICILLIN	33 (9.0)	7 (3.8)	40 (7.3)
INFLUENZA VACCINE	21 (5.7)	15 (8.2)	36 (6.6)
INFLUENZA VIRUS VACCINE MONOVALENT	20 (5.5)	14 (7.7)	34 (6.2)
GLUCOSE	13 (3.6)	7 (3.8)	20 (3.6)
ACETYLSALICYLIC ACID	13 (3.6)	4 (2.2)	17 (3.1)
ASCORUTIN	13 (3.6)	4 (2.2)	17 (3.1)
AZITHROMYCIN	10 (2.7)	7 (3.8)	17 (3.1)
PANADEINE CO	11 (3.0)	2 (1.1)	13 (2.4)
ASCORBIC ACID	9 (2.5)	3 (1.6)	12 (2.2)
CEFALEXIN	10 (2.7)	2 (1.1)	12 (2.2)
FERVEX [REDACTED]	/	11 (3.0)	1 (0.5)
SIMVASTATIN	7 (1.9)	5 (2.7)	12 (2.2)
OMEPRAZOLE	8 (2.2)	3 (1.6)	11 (2.0)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DICLOFENAC	7 (1.9)	3 (1.6)	10 (1.8)
DOXYCYCLINE	6 (1.6)	4 (2.2)	10 (1.8)
GLUCAGON	6 (1.6)	4 (2.2)	10 (1.8)
SODIUM CHLORIDE	6 (1.6)	4 (2.2)	10 (1.8)
AMOXICILLIN TRIHYDRATE	6 (1.6)	3 (1.6)	9 (1.6)
CITALOPRAM	5 (1.4)	4 (2.2)	9 (1.6)
LORATADINE	7 (1.9)	2 (1.1)	9 (1.6)
MEDINITE	6 (1.6)	3 (1.6)	9 (1.6)
TUSSIN DM	5 (1.4)	4 (2.2)	9 (1.6)
BISMUTH SUBSALICYLATE	5 (1.4)	3 (1.6)	8 (1.5)
CLARITHROMYCIN	5 (1.4)	3 (1.6)	8 (1.5)
DEXTROMETHORPHAN HYDROBROMIDE	6 (1.6)	2 (1.1)	8 (1.5)
FLUCONAZOLE	5 (1.4)	3 (1.6)	8 (1.5)
INSULIN GLARGINE	5 (1.4)	3 (1.6)	8 (1.5)
LEVOTHYROXINE SODIUM	7 (1.9)	1 (0.5)	8 (1.5)
LISINOPRIL	5 (1.4)	3 (1.6)	8 (1.5)
METRONIDAZOLE	6 (1.6)	2 (1.1)	8 (1.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
VICODIN	5 (1.4)	3 (1.6)	8 (1.5)
BACTRIM	5 (1.4)	2 (1.1)	7 (1.3)
BENADRYL COLD AND FLU	4 (1.1)	3 (1.6)	7 (1.3)
CETIRIZINE HYDROCHLORIDE	7 (1.9)		7 (1.3)
CIPROFLOXACIN	3 (0.8)	4 (2.2)	7 (1.3)
INSULIN ASPART	3 (0.8)	4 (2.2)	7 (1.3)
LIDOCAINE	3 (0.8)	4 (2.2)	7 (1.3)
METOCLOPRAMIDE	4 (1.1)	3 (1.6)	7 (1.3)
VICKS FORMULA 44M	5 (1.4)	2 (1.1)	7 (1.3)
ACETYLCYSTEINE	5 (1.4)	1 (0.5)	6 (1.1)
AMBROXOL HYDROCHLORIDE	4 (1.1)	2 (1.1)	6 (1.1)
ATORVASTATIN CALCIUM	5 (1.4)	1 (0.5)	6 (1.1)
CLINDAMYCIN	5 (1.4)	1 (0.5)	6 (1.1)
COUGH AND COLD PREPARATIONS	4 (1.1)	2 (1.1)	6 (1.1)
KETOPROFEN	5 (1.4)	1 (0.5)	6 (1.1)
LOPERAMIDE HYDROCHLORIDE	4 (1.1)	2 (1.1)	6 (1.1)
MELOXICAM	6 (1.6)		6 (1.1)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
METAMIZOLE SODIUM	4 (1.1)	2 (1.1)	6 (1.1)
MOMETASONE FUROATE	6 (1.6)		6 (1.1)
NASAL DECONGESTANTS FOR SYSTEMIC USE	5 (1.4)	1 (0.5)	6 (1.1)
OFLOXACIN	4 (1.1)	2 (1.1)	6 (1.1)
PREDNISONE	4 (1.1)	2 (1.1)	6 (1.1)
BENZYLAMINE HYDROCHLORIDE	4 (1.1)	1 (0.5)	5 (0.9)
CETIRIZINE	4 (1.1)	1 (0.5)	5 (0.9)
CHLORAMPHENICOL	3 (0.8)	2 (1.1)	5 (0.9)
CLOTRIMAZOLE	4 (1.1)	1 (0.5)	5 (0.9)
DICLOFENAC SODIUM	3 (0.8)	2 (1.1)	5 (0.9)
DIPHENHYDRAMINE HYDROCHLORIDE	3 (0.8)	2 (1.1)	5 (0.9)
DOMPERIDONE	4 (1.1)	1 (0.5)	5 (0.9)
DROSPIRENONE W/ETHINYLESTRADIOL	5 (1.4)		5 (0.9)
INDAPAMIDE	3 (0.8)	2 (1.1)	5 (0.9)
INSULIN HUMAN	1 (0.3)	4 (2.2)	5 (0.9)
MIDAZOLAM	4 (1.1)	1 (0.5)	5 (0.9)
OXYCOCET	2 (0.5)	3 (1.6)	5 (0.9)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
PANTOPRAZOLE	4 (1.1)	1 (0.5)	5 (0.9)
ROXITHROMYCIN	4 (1.1)	1 (0.5)	5 (0.9)
SPEKTRAMOX	3 (0.8)	2 (1.1)	5 (0.9)
VITAMIN D NOS	4 (1.1)	1 (0.5)	5 (0.9)
ALUDROX /	2 (0.5)	2 (1.1)	4 (0.7)
AMPICILLIN SODIUM	3 (0.8)	1 (0.5)	4 (0.7)
CODRAL COLD & FLU	4 (1.1)		4 (0.7)
COTYLENOL	3 (0.8)	1 (0.5)	4 (0.7)
EZETIMIBE	3 (0.8)	1 (0.5)	4 (0.7)
FENTANYL	3 (0.8)	1 (0.5)	4 (0.7)
FLUTICASONE PROPIONATE	2 (0.5)	2 (1.1)	4 (0.7)
GLUCOSE INJECTION	3 (0.8)	1 (0.5)	4 (0.7)
HOT COLDREX	2 (0.5)	2 (1.1)	4 (0.7)
INSULIN DETEMIR	1 (0.3)	3 (1.6)	4 (0.7)
METOCLOPRAMIDE HYDROCHLORIDE	2 (0.5)	2 (1.1)	4 (0.7)
NAPROXEN	3 (0.8)	1 (0.5)	4 (0.7)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
NIFUROXAZIDE	2 (0.5)	2 (1.1)	4 (0.7)
OXYCODONE HYDROCHLORIDE	3 (0.8)	1 (0.5)	4 (0.7)
PHENOXYMETHYLPENICILLIN POTASSIUM	2 (0.5)	2 (1.1)	4 (0.7)
PREDNISOLONE	2 (0.5)	2 (1.1)	4 (0.7)
PYRIDOXINE HYDROCHLORIDE	3 (0.8)	1 (0.5)	4 (0.7)
RANITIDINE HYDROCHLORIDE	1 (0.3)	3 (1.6)	4 (0.7)
SALBUTAMOL	2 (0.5)	2 (1.1)	4 (0.7)
THOMAPYRIN N	4 (1.1)		4 (0.7)
TIAPROFENIC ACID	4 (1.1)		4 (0.7)
TRIMETHOPRIM	1 (0.3)	3 (1.6)	4 (0.7)
VITAMIN B12 NOS	3 (0.8)	1 (0.5)	4 (0.7)
ALPRAZOLAM	2 (0.5)	1 (0.5)	3 (0.5)
ATORVASTATIN	2 (0.5)	1 (0.5)	3 (0.5)
AZELASTINE HYDROCHLORIDE		3 (1.6)	3 (0.5)
BISACODYL	1 (0.3)	2 (1.1)	3 (0.5)
BUDESONIDE W/FORMOTEROL FUMARATE	1 (0.3)	2 (1.1)	3 (0.5)
CALCIUM CARBONATE	3 (0.8)		3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CEFTRIAXONE	3 (0.8)		3 (0.5)
CEFUROXIME AXETIL	2 (0.5)	1 (0.5)	3 (0.5)
CONJUNCTIN	2 (0.5)	1 (0.5)	3 (0.5)
CORTISONE	3 (0.8)		3 (0.5)
DEXAMETHASONE SODIUM PHOSPHATE	2 (0.5)	1 (0.5)	3 (0.5)
DIPHENHYDRAMINE	2 (0.5)	1 (0.5)	3 (0.5)
DOLO MOBILAT /	3 (0.8)		3 (0.5)
DRUGS FOR PEPTIC ULCER AND GORD	2 (0.5)	1 (0.5)	3 (0.5)
ENALAPRIL	3 (0.8)		3 (0.5)
ESOMEPRAZOLE MAGNESIUM	2 (0.5)	1 (0.5)	3 (0.5)
FERROUS SULFATE		3 (1.6)	3 (0.5)
FEXOFENADINE	3 (0.8)		3 (0.5)
FEXOFENADINE HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
FISH OIL	2 (0.5)	1 (0.5)	3 (0.5)
FUSAFUNGINE	2 (0.5)	1 (0.5)	3 (0.5)
GUAIFENESIN	1 (0.3)	2 (1.1)	3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HYDROCHLOROTHIAZIDE	3 (0.8)		3 (0.5)
HYDROCODONE	3 (0.8)		3 (0.5)
HYDROCORTISONE	2 (0.5)	1 (0.5)	3 (0.5)
ISOPHANE INSULIN	3 (0.8)		3 (0.5)
KETOROLAC TROMETHAMINE	2 (0.5)	1 (0.5)	3 (0.5)
LEVOTHYROXINE	3 (0.8)		3 (0.5)
METHYLPREDNISOLONE	2 (0.5)	1 (0.5)	3 (0.5)
MOXIFLOXACIN HYDROCHLORIDE	1 (0.3)	2 (1.1)	3 (0.5)
MULTIVITAMIN [REDACTED]	/	2 (0.5)	3 (0.5)
NAPROXEN SODIUM	2 (0.5)	1 (0.5)	3 (0.5)
NEO-SYNEPHRINE COMPOUND COLD	3 (0.8)		3 (0.5)
NO-FLU F	1 (0.3)	2 (1.1)	3 (0.5)
NORFLOXACIN		3 (1.6)	3 (0.5)
ONDANSETRON	1 (0.3)	2 (1.1)	3 (0.5)
OSELTAMIVIR PHOSPHATE	3 (0.8)		3 (0.5)
OTIDIN	2 (0.5)	1 (0.5)	3 (0.5)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
OXYMETAZOLINE HYDROCHLORIDE	2 (0.5)	1 (0.5)	3 (0.5)
PHENYLEPHRINE HYDROCHLORIDE	3 (0.8)		3 (0.5)
PROCTET [REDACTED]	/	3 (0.8)	3 (0.5)
PROPOFOL	2 (0.5)	1 (0.5)	3 (0.5)
ROSUVASTATIN CALCIUM	2 (0.5)	1 (0.5)	3 (0.5)
SULFAMETHIZOLE	2 (0.5)	1 (0.5)	3 (0.5)
TETANUS VACCINE	1 (0.3)	2 (1.1)	3 (0.5)
THIOPCODIN [REDACTED]	/	2 (0.5)	3 (0.5)
THIOCTIC ACID	2 (0.5)	1 (0.5)	3 (0.5)
TOBRAMYCIN	1 (0.3)	2 (1.1)	3 (0.5)
TOLPERISONE HYDROCHLORIDE	3 (0.8)		3 (0.5)
TRAMADOL	2 (0.5)	1 (0.5)	3 (0.5)
ZOLPIDEM TARTRATE	2 (0.5)	1 (0.5)	3 (0.5)
A/H1N1 INFLUENZA PANDEMIC VACCINE	1 (0.3)	1 (0.5)	2 (0.4)
ACICLOVIR		2 (1.1)	2 (0.4)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.3)	1 (0.5)	2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ALPHA-AMYLASE SWINE PANCREAS	2 (0.5)		2 (0.4)
AMOXI-CLAVULANICO	2 (0.5)		2 (0.4)
ANAESTHETICS, LOCAL	2 (0.5)		2 (0.4)
BECLOMETASONE DIPROPIONATE	1 (0.3)	1 (0.5)	2 (0.4)
BIOGLAN MICELLE A PLUS E	2 (0.5)		2 (0.4)
BROMHEXINE HYDROCHLORIDE		2 (1.1)	2 (0.4)
BUDESONIDE	2 (0.5)		2 (0.4)
BUPIVACAINE	2 (0.5)		2 (0.4)
BUPROPION	2 (0.5)		2 (0.4)
CALCIUM	2 (0.5)		2 (0.4)
CAPIVEN		2 (1.1)	2 (0.4)
CARBOCISTEINE	2 (0.5)		2 (0.4)
CEFALEXIN SODIUM		2 (1.1)	2 (0.4)
CELECOXIB	1 (0.3)	1 (0.5)	2 (0.4)
CHARCOAL, ACTIVATED	1 (0.3)	1 (0.5)	2 (0.4)
CITALOPRAM HYDROBROMIDE	1 (0.3)	1 (0.5)	2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CODAFEN [REDACTED] /		2 (1.1)	2 (0.4)
CORTICOSTEROIDS	2 (0.5)		2 (0.4)
CYCLOBENZAPRINE HYDROCHLORIDE		2 (1.1)	2 (0.4)
DALTEPARIN SODIUM	1 (0.3)	1 (0.5)	2 (0.4)
DAY & NIGHT COLD & FLU [REDACTED] /	2 (0.5)		2 (0.4)
DESLORATADINE	2 (0.5)		2 (0.4)
DEXTROMETHORPHAN HBR W/DOXYLAM. SUCC/ PARACET.	1 (0.3)	1 (0.5)	2 (0.4)
DIAZEPAM	1 (0.3)	1 (0.5)	2 (0.4)
DICLOFENAC POTASSIUM	1 (0.3)	1 (0.5)	2 (0.4)
DOZOL [REDACTED] /	2 (0.5)		2 (0.4)
DROTAVERINE	2 (0.5)		2 (0.4)
DULOXETINE HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
ERDOSTEINE	2 (0.5)		2 (0.4)
ESTROGENS CONJUGATED	1 (0.3)	1 (0.5)	2 (0.4)
EUGYNON [REDACTED] /	1 (0.3)	1 (0.5)	2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
FERROUS GLUCONATE	1 (0.3)	1 (0.5)	2 (0.4)
FLUCLOXACILLIN	2 (0.5)		2 (0.4)
FLUTICASONE FUROATE	2 (0.5)		2 (0.4)
FOLIC ACID	2 (0.5)		2 (0.4)
FRENADOL / [REDACTED]	2 (0.5)		2 (0.4)
FRUBIENZYM	2 (0.5)		2 (0.4)
FUROSEMIDE	2 (0.5)		2 (0.4)
GALENIC /ASCORBIC ACID/CALCIUM/	1 (0.3)	1 (0.5)	2 (0.4)
GALENIC /MAGNESIUM CARB/CALCIUM CARB/	1 (0.3)	1 (0.5)	2 (0.4)
GENERAL NUTRIENTS	1 (0.3)	1 (0.5)	2 (0.4)
GLUCAGON HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
GLUCOSAMINE	2 (0.5)		2 (0.4)
GLYCERYL TRINITRATE	2 (0.5)		2 (0.4)
HALL'S MENTHO-LYPTUS		2 (1.1)	2 (0.4)
HEPATITIS A VACCINE	1 (0.3)	1 (0.5)	2 (0.4)
HEPATITIS B VACCINE	2 (0.5)		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HYDROMORPHONE HYDROCHLORIDE	2 (0.5)		2 (0.4)
INDOMETACIN	2 (0.5)		2 (0.4)
INFLUENZA VACCINE INACTIVATED	1 (0.3)	1 (0.5)	2 (0.4)
INSULIN	2 (0.5)		2 (0.4)
KARVEA HCT	1 (0.3)	1 (0.5)	2 (0.4)
LACTOBACILLUS ACIDOPHILUS	1 (0.3)	1 (0.5)	2 (0.4)
LANSOPRAZOLE	1 (0.3)	1 (0.5)	2 (0.4)
LEVOCETIRIZINE DIHYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
LEVOFLOXACIN	2 (0.5)		2 (0.4)
LEVONORGESTREL	1 (0.3)	1 (0.5)	2 (0.4)
LINUM USITATISSIMUM SEED OIL		2 (1.1)	2 (0.4)
LORAZEPAM	1 (0.3)	1 (0.5)	2 (0.4)
LOSARTAN POTASSIUM	2 (0.5)		2 (0.4)
MAALOX /		2 (1.1)	2 (0.4)
MAGNECYL-KODEIN	1 (0.3)	1 (0.5)	2 (0.4)
METHOTREXATE	2 (0.5)		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
MICONAZOLE		2 (1.1)	2 (0.4)
MORPHINE	1 (0.3)	1 (0.5)	2 (0.4)
NABUMETONE	2 (0.5)		2 (0.4)
NAPHAZOLINE	1 (0.3)	1 (0.5)	2 (0.4)
NARINE /	1 (0.3)	1 (0.5)	2 (0.4)
NEBIVOLOL HYDROCHLORIDE	2 (0.5)		2 (0.4)
NEODECADRON	1 (0.3)	1 (0.5)	2 (0.4)
NIFLUMIC ACID	1 (0.3)	1 (0.5)	2 (0.4)
NIMESULIDE	1 (0.3)	1 (0.5)	2 (0.4)
OXACILLIN	1 (0.3)	1 (0.5)	2 (0.4)
OXYMETAZOLINE	2 (0.5)		2 (0.4)
OXYTETRACYCLINE		2 (1.1)	2 (0.4)
PARAMOL-118	2 (0.5)		2 (0.4)
PENICILLIN NOS	2 (0.5)		2 (0.4)
PHENOXYMETHYLPENICILLIN	1 (0.3)	1 (0.5)	2 (0.4)
PHOLCODINE	1 (0.3)	1 (0.5)	2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
PIRACETAM	2 (0.5)		2 (0.4)
PIROXICAM BETADEX	2 (0.5)		2 (0.4)
PIVMECILLINAM	1 (0.3)	1 (0.5)	2 (0.4)
PNEUMOCOCCAL VACCINE	2 (0.5)		2 (0.4)
POLYETHYL. GLYC. W/POTAS. CHLOR./SOD. BICARB.	1 (0.3)	1 (0.5)	2 (0.4)
PRAVASTATIN	1 (0.3)	1 (0.5)	2 (0.4)
PREDNISOLONE ACETATE	1 (0.3)	1 (0.5)	2 (0.4)
PREGABALIN	2 (0.5)		2 (0.4)
PRISTINAMYCIN	1 (0.3)	1 (0.5)	2 (0.4)
PROCHLORPERAZINE	1 (0.3)	1 (0.5)	2 (0.4)
PRONILIDE	1 (0.3)	1 (0.5)	2 (0.4)
PSEUDOEPHEDRINE		2 (1.1)	2 (0.4)
PSEUDOEPHEDRINE HYDROCHLORIDE	2 (0.5)		2 (0.4)
RAMIPRIL	2 (0.5)		2 (0.4)
RANITIDINE	2 (0.5)		2 (0.4)
RINOFLUIMUCIL [REDACTED]	/		2 (0.4)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SCORBOLAMID	1 (0.3)	1 (0.5)	2 (0.4)
SEPTOLETE [REDACTED]	/	1 (0.5)	2 (0.4)
SILYBUM MARIANUM	2 (0.5)		2 (0.4)
SPASFON [REDACTED]	/	1 (0.5)	2 (0.4)
SULFAMETHOXAZOLE	2 (0.5)		2 (0.4)
TERBINAFINE		2 (1.1)	2 (0.4)
TERBINAFINE HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
TETRAZEPAM	2 (0.5)		2 (0.4)
TRILAC	2 (0.5)		2 (0.4)
TYLENOL SINUS MEDICATION	2 (0.5)		2 (0.4)
TYPHOID VACCINE	2 (0.5)		2 (0.4)
UNSPECIFIED HERBAL	2 (0.5)		2 (0.4)
VERAPAMIL HYDROCHLORIDE	1 (0.3)	1 (0.5)	2 (0.4)
ZINC SULFATE	2 (0.5)		2 (0.4)
A.P.C. [REDACTED]	/	1 (0.5)	1 (0.2)
ACETAZOLAMIDE		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ACETORPHAN		1 (0.5)	1 (0.2)
ACTIFED [REDACTED]	/ 1 (0.3)		1 (0.2)
ADVIL PM [REDACTED]	/	1 (0.5)	1 (0.2)
AKRITOLIN	1 (0.3)		1 (0.2)
AKTIFERRIN [REDACTED]	/	1 (0.5)	1 (0.2)
ALANERV	1 (0.3)		1 (0.2)
ALBENDAZOLE	1 (0.3)		1 (0.2)
ALERNYL-B		1 (0.5)	1 (0.2)
ALOE FEROX EXTRACT	1 (0.3)		1 (0.2)
AMCAL DAY & NIGHT COLD & FLU		1 (0.5)	1 (0.2)
AMINOCAPROIC ACID	1 (0.3)		1 (0.2)
AMITRIPTYLINE	1 (0.3)		1 (0.2)
AMOXICILLIN W/CLAVULANATE POTASSIUM		1 (0.5)	1 (0.2)
AMPICILLIN	1 (0.3)		1 (0.2)
AMYLMETACRESOL	1 (0.3)		1 (0.2)
APOREX	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ARBIDOL		1 (0.5)	1 (0.2)
ARTIFICIAL TEARS [REDACTED]	/	1 (0.5)	1 (0.2)
ASASANTIN		1 (0.5)	1 (0.2)
ASPIRIN PLUS C	1 (0.3)		1 (0.2)
ATROPINE	1 (0.3)		1 (0.2)
ATROPINE SULFATE		1 (0.5)	1 (0.2)
AUGMENTIN [REDACTED]	/	1 (0.3)	1 (0.2)
BACICOLINE [REDACTED]	/	1 (0.5)	1 (0.2)
BEECHAMS ALL-IN-ONE	1 (0.3)		1 (0.2)
BENZONATATE	1 (0.3)		1 (0.2)
BENZYL BENZOATE	1 (0.3)		1 (0.2)
BENZYL PENICILLIN	1 (0.3)		1 (0.2)
BETAINE CITRATE		1 (0.5)	1 (0.2)
BETAMETHASONE		1 (0.5)	1 (0.2)
BETAMETHASONE SODIUM PHOSPHATE	1 (0.3)		1 (0.2)
BETAMETHASONE VALERATE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
BI PREDONIUM	1 (0.3)		1 (0.2)
BIMATOPROST		1 (0.5)	1 (0.2)
BIOGESIC /		1 (0.5)	1 (0.2)
BISOPROLOL		1 (0.5)	1 (0.2)
BLOOD, CALF, DEPROT., LMW PORTION	1 (0.3)		1 (0.2)
BRIMONIDINE TARTRATE	1 (0.3)		1 (0.2)
BRINZOLAMIDE	1 (0.3)		1 (0.2)
BROMHEXINE	1 (0.3)		1 (0.2)
BUPROPION HYDROCHLORIDE	1 (0.3)		1 (0.2)
CALCIUM LACTOGLUCONATE	1 (0.3)		1 (0.2)
CALGEL	1 (0.3)		1 (0.2)
CAMELLIA SINENSIS	1 (0.3)		1 (0.2)
CANDESARTAN CILEXETIL	1 (0.3)		1 (0.2)
CANESTEN-HC		1 (0.5)	1 (0.2)
CAPTOPRIL	1 (0.3)		1 (0.2)
CARISOPRODOL	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CARVEDILOL		1 (0.5)	1 (0.2)
CEFACLOX	1 (0.3)		1 (0.2)
CEFALEXIN MONOHYDRATE	1 (0.3)		1 (0.2)
CEFALOTIN	1 (0.3)		1 (0.2)
CEFAZOLIN	1 (0.3)		1 (0.2)
CEFAZOLIN SODIUM		1 (0.5)	1 (0.2)
CEFDINIR	1 (0.3)		1 (0.2)
CEFUROXIME	1 (0.3)		1 (0.2)
CHEMWORLD COLD & FLU RELIEF DAY & NIGHT	1 (0.3)		1 (0.2)
CHERACOL / [REDACTED]	1 (0.3)		1 (0.2)
CHLORPHENAMINE	1 (0.3)		1 (0.2)
CHLORPHENAMINE W/PARACETAMOL/ PHENYLEPHRINE/	1 (0.3)		1 (0.2)
CHOLINE SALICYLATE	1 (0.3)		1 (0.2)
CICLESONIDE	1 (0.3)		1 (0.2)
CICLOSPORIN	1 (0.3)		1 (0.2)
CILEST		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CIPROFLOXACIN HYDROCHLORIDE		1 (0.5)	1 (0.2)
CIRRUS	1 (0.3)		1 (0.2)
CITRAMON [REDACTED]	/	1 (0.3)	1 (0.2)
CLINDAMYCIN HYDROCHLORIDE	1 (0.3)		1 (0.2)
CLINDAMYCIN PHOSPHATE	1 (0.3)		1 (0.2)
CLOBETASOL PROPIONATE		1 (0.5)	1 (0.2)
CLONAZEPAM		1 (0.5)	1 (0.2)
CO-ADVIL	1 (0.3)		1 (0.2)
CO-TRIMOXAZOLE	1 (0.3)		1 (0.2)
CO-TYLENOL [REDACTED]	/	1 (0.3)	1 (0.2)
CODEINE PHOSPHATE	1 (0.3)		1 (0.2)
CODRAL DAYTIME/NIGHTTIME	1 (0.3)		1 (0.2)
COLCHICINE	1 (0.3)		1 (0.2)
COLCHIMAX [REDACTED]	/	1 (0.5)	1 (0.2)
COLDENIN [REDACTED]	/	1 (0.3)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
COLDREX NIGHT RELIEF		1 (0.5)	1 (0.2)
COLESTYRAMINE		1 (0.5)	1 (0.2)
COLOXYL WITH SENNA	1 (0.3)		1 (0.2)
COMBINATIONS OF ANTIBACTERIALS	1 (0.3)		1 (0.2)
CORTISONE ACETATE	1 (0.3)		1 (0.2)
CORTIVAZOL	1 (0.3)		1 (0.2)
COVERAM	1 (0.3)		1 (0.2)
CROMOGLICATE SODIUM	1 (0.3)		1 (0.2)
CYSTEX	1 (0.3)		1 (0.2)
D-MANNOSE	1 (0.3)		1 (0.2)
DAY NURSE [REDACTED]	/	1 (0.5)	1 (0.2)
DEMAZIN [REDACTED]	/	1 (0.3)	1 (0.2)
DEMAZIN [REDACTED]	/	1 (0.3)	1 (0.2)
DENOTIVIR		1 (0.5)	1 (0.2)
DERINOX [REDACTED]	/	1 (0.3)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DESVENLAFAXINE SUCCINATE	1 (0.3)		1 (0.2)
DEXA POLYSPECTRAN N		1 (0.5)	1 (0.2)
DEXAMETHASONE	1 (0.3)		1 (0.2)
DEXPANTHENOL		1 (0.5)	1 (0.2)
DEXTROMETHORPHAN	1 (0.3)		1 (0.2)
DEXTROMETHORPHAN W/GUAIFENESIN/ PSEUDOEPHEDRIN		1 (0.5)	1 (0.2)
DIAGNOSTIC RADIOPHARMACEUTICALS	1 (0.3)		1 (0.2)
DICLOFENAC EPOLAMINUM		1 (0.5)	1 (0.2)
DICLOXACILLIN	1 (0.3)		1 (0.2)
DICLOXACILLIN SODIUM MONOHYDRATE		1 (0.5)	1 (0.2)
DIMETANE SANS SUCRE	1 (0.3)		1 (0.2)
DIOVAN AMLO	1 (0.3)		1 (0.2)
DIPHENHYDRA. HCL W/PARACETAMOL/ PSEUDOEPH. HCL	1 (0.3)		1 (0.2)
DIPHThERIA AND TETANUS TOXOIDS AND PERTUSSIS	1 (0.3)		1 (0.2)
DIPHThERIA,TETANUS AND POLIOMYELITIS VAC	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DIPROSPAN [REDACTED]	1 (0.3)		1 (0.2)
DIPYRIDAMOLE	1 (0.3)		1 (0.2)
DOCOSANOL	1 (0.3)		1 (0.2)
DOCUSATE SODIUM		1 (0.5)	1 (0.2)
DOXYCYCLINE HYCLATE		1 (0.5)	1 (0.2)
DOXYCYCLINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
DOXYCYCLINE MONOHYDRATE	1 (0.3)		1 (0.2)
DOXYLAMINE	1 (0.3)		1 (0.2)
DROTAVERINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
DURO-TUSS COUGH	1 (0.3)		1 (0.2)
DYAZIDE	1 (0.3)		1 (0.2)
EBASTINE	1 (0.3)		1 (0.2)
ELECTROLYTE SOLUTIONS	1 (0.3)		1 (0.2)
EMOXIPIN	1 (0.3)		1 (0.2)
ENOXAPARIN	1 (0.3)		1 (0.2)
ENOXAPARIN SODIUM		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
EPIPEVISONONE		1 (0.5)	1 (0.2)
ETAMSILATE	1 (0.3)		1 (0.2)
ETANERCEPT	1 (0.3)		1 (0.2)
ETODOLAC	1 (0.3)		1 (0.2)
ETORICOXIB	1 (0.3)		1 (0.2)
EUCERIN [REDACTED]	/	1 (0.3)	1 (0.2)
FAMOTIDINE		1 (0.5)	1 (0.2)
FENOTEROL HYDROBROMIDE	1 (0.3)		1 (0.2)
FENSPIRIDE		1 (0.5)	1 (0.2)
FERRIC HYDROXIDE POLYMALTOSE COMPLEX	1 (0.3)		1 (0.2)
FLECAINIDE		1 (0.5)	1 (0.2)
FLUOCINOLONE ACETONIDE	1 (0.3)		1 (0.2)
FLUOCINONIDE	1 (0.3)		1 (0.2)
FLUOROURACIL	1 (0.3)		1 (0.2)
FLUOXETINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
FLURBIPROFEN	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
FURAZOLIDONE	1 (0.3)		1 (0.2)
FUSIDIC ACID		1 (0.5)	1 (0.2)
GABAPENTIN	1 (0.3)		1 (0.2)
GALENIC /CHLORPHENAMINE/PARACETAMOL/ PSEUDOEPH	1 (0.3)		1 (0.2)
GALENIC /PARACETAMOL/CODEINE/		1 (0.5)	1 (0.2)
GASTROLIT / [REDACTED]	1 (0.3)		1 (0.2)
GATIFLOXACIN	1 (0.3)		1 (0.2)
GAVISCON / [REDACTED]	1 (0.3)		1 (0.2)
GENTAMICIN	1 (0.3)		1 (0.2)
GLUCOCORTICIDS		1 (0.5)	1 (0.2)
GLUCOSAMINE W/CHONDROITIN SULFATE	1 (0.3)		1 (0.2)
GLYCEROL MED OPIUM STAERKE		1 (0.5)	1 (0.2)
GLYCINE	1 (0.3)		1 (0.2)
GUAIFENESIN W/DEXTROMETHORPHAN	1 (0.3)		1 (0.2)
GUAJANAL		1 (0.5)	1 (0.2)
HALOPERIDOL	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HEDERA HELIX		1 (0.5)	1 (0.2)
HEMO [REDACTED]	/ 1 (0.3)		1 (0.2)
HEPARIN		1 (0.5)	1 (0.2)
HETASTARCH	1 (0.3)		1 (0.2)
HEXETIDINE	1 (0.3)		1 (0.2)
HEXYLRESORCINOL	1 (0.3)		1 (0.2)
HLD	1 (0.3)		1 (0.2)
HYDROCODONE W/HOMATROPINE	1 (0.3)		1 (0.2)
HYDROCORTISONE BUTYRATE		1 (0.5)	1 (0.2)
HYDROCORTISONE VALERATE		1 (0.5)	1 (0.2)
HYDROGEN PEROXIDE	1 (0.3)		1 (0.2)
HYDROXYCHLOROQUINE	1 (0.3)		1 (0.2)
HYOSCINE BUTYLBROMIDE	1 (0.3)		1 (0.2)
HYPERTONIC SOLUTIONS	1 (0.3)		1 (0.2)
IDROCILAMIDE	1 (0.3)		1 (0.2)
INEGY	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
INFANRIX [REDACTED] /	1 (0.3)		1 (0.2)
INFLUENZA VIRUS VACCINE POLYVALENT		1 (0.5)	1 (0.2)
INSULIN HUMAN INJECTION, ISOPHANE		1 (0.5)	1 (0.2)
IPRATROPIUM	1 (0.3)		1 (0.2)
IPRATROPIUM BROMIDE		1 (0.5)	1 (0.2)
IRBESARTAN		1 (0.5)	1 (0.2)
ISONIAZID	1 (0.3)		1 (0.2)
ISOTRETINOIN	1 (0.3)		1 (0.2)
JOX	1 (0.3)		1 (0.2)
KALMS [REDACTED] /	1 (0.3)		1 (0.2)
KETOCONAZOLE	1 (0.3)		1 (0.2)
LEMSIP [REDACTED] /		1 (0.5)	1 (0.2)
LERCANIDIPINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
LIOTHYRONINE SODIUM	1 (0.3)		1 (0.2)
LOPERAMIDE	1 (0.3)		1 (0.2)
LOSARTAN	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
LOTRISONE	1 (0.3)		1 (0.2)
LOVASTATIN	1 (0.3)		1 (0.2)
LYMECYCLINE		1 (0.5)	1 (0.2)
MACROGOL	1 (0.3)		1 (0.2)
MALARIA VACCINE	1 (0.3)		1 (0.2)
MANNITOL	1 (0.3)		1 (0.2)
MARCAINE WITH EPINEPHRINE [REDACTED]	1 (0.3)		1 (0.2)
MARVELON	1 (0.3)		1 (0.2)
MAXITROL		1 (0.5)	1 (0.2)
MEASLES, MUMPS AND RUBELLA VACCINE	1 (0.3)		1 (0.2)
MEBENDAZOLE	1 (0.3)		1 (0.2)
MEBHYDROLIN	1 (0.3)		1 (0.2)
MECLOZINE	1 (0.3)		1 (0.2)
MEDIQUE MS.-AID		1 (0.5)	1 (0.2)
MENADIONE SODIUM BISULFITE	1 (0.3)		1 (0.2)
MESNA	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
METAMIZOLE	1 (0.3)		1 (0.2)
METEOSPASMYL [REDACTED]	/	1 (0.5)	1 (0.2)
METHADONE		1 (0.5)	1 (0.2)
METHYLPHENIDATE HYDROCHLORIDE	1 (0.3)		1 (0.2)
METHYLPREDNISOLONE ACETATE	1 (0.3)		1 (0.2)
METHYLPREDNISOLONE SODIUM SUCCINATE		1 (0.5)	1 (0.2)
METICILLIN	1 (0.3)		1 (0.2)
MILGAMMA NA	1 (0.3)		1 (0.2)
MILNACIPRAN	1 (0.3)		1 (0.2)
MINERAL SUPPLEMENTS	1 (0.3)		1 (0.2)
MIRTAZAPINE	1 (0.3)		1 (0.2)
MIZOLASTINE		1 (0.5)	1 (0.2)
MOMETASONE	1 (0.3)		1 (0.2)
MONTELUKAST SODIUM		1 (0.5)	1 (0.2)
MOXONIDINE	1 (0.3)		1 (0.2)
MYCOLOG	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
NAPHAZOLINE NITRATE		1 (0.5)	1 (0.2)
NAPROXEN SODIUM W/PSEUDOEPHEDRINE HCL	1 (0.3)		1 (0.2)
NEO ANGIN N	1 (0.3)		1 (0.2)
NEO CITRAN [REDACTED] /	1 (0.3)		1 (0.2)
NEPAFENAC		1 (0.5)	1 (0.2)
NEUROTONIC		1 (0.5)	1 (0.2)
NICLOSAMIDE	1 (0.3)		1 (0.2)
NITROFURAL	1 (0.3)		1 (0.2)
NITROFURANTOIN	1 (0.3)		1 (0.2)
NUVARING	1 (0.3)		1 (0.2)
OBETROL [REDACTED] /		1 (0.5)	1 (0.2)
OCTOCAINE WITH EPINEPHRINE	1 (0.3)		1 (0.2)
OLBAS [REDACTED] /	1 (0.3)		1 (0.2)
OLOPATADINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
ONE-A-DAY MEN'S	1 (0.3)		1 (0.2)
OPIUM ALKALOIDS AND DERIVATIVES	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	1 (0.3)		1 (0.2)
OTHER COLD COMBINATION PREPARATIONS	1 (0.3)		1 (0.2)
OTIPAX /	1 (0.3)		1 (0.2)
OTOMIZE	1 (0.3)		1 (0.2)
OTOSPORIN	1 (0.3)		1 (0.2)
OXACILLIN SODIUM	1 (0.3)		1 (0.2)
OXYCODONE		1 (0.5)	1 (0.2)
PANCREATIN	1 (0.3)		1 (0.2)
PANTOPRAZOLE SODIUM	1 (0.3)		1 (0.2)
PAPAVERINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
PARA-SELTZER		1 (0.5)	1 (0.2)
PENTOXIFYLLINE	1 (0.3)		1 (0.2)
PEPTAC /	1 (0.3)		1 (0.2)
PERINDOPRIL	1 (0.3)		1 (0.2)
PERINDOPRIL ERBUMINE	1 (0.3)		1 (0.2)
PHLEBODRIL /	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
PHLOROGLUCINOL		1 (0.5)	1 (0.2)
PHOSPHOLIPIDS	1 (0.3)		1 (0.2)
PLATYPHYLLINE		1 (0.5)	1 (0.2)
PNEUMOCOCCAL VACCINE POLYVALENT		1 (0.5)	1 (0.2)
POLYCARBOPHIL CALCIUM	1 (0.3)		1 (0.2)
POLYDEXA	1 (0.3)		1 (0.2)
POTASSIUM CHLORIDE	1 (0.3)		1 (0.2)
POVIDONE-IODINE		1 (0.5)	1 (0.2)
PRAMIPEXOLE		1 (0.5)	1 (0.2)
PRAZOSIN HYDROCHLORIDE	1 (0.3)		1 (0.2)
PREDNEFRIN [REDACTED]	/	1 (0.3)	1 (0.2)
PRIMATENE		1 (0.5)	1 (0.2)
PROCAINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
PROMETHAZINE HYDROCHLORIDE		1 (0.5)	1 (0.2)
PROMETHAZINE W/CODEINE [REDACTED]	/	1 (0.3)	1 (0.2)
PSYLLIUM HYDROPHILIC MUCILLOID	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
PYCNOGENOL		1 (0.5)	1 (0.2)
RENICOL-P	1 (0.3)		1 (0.2)
RESPAIRE-SR-120	1 (0.3)		1 (0.2)
RHODOGIL		1 (0.5)	1 (0.2)
RIFAMPICIN	1 (0.3)		1 (0.2)
RILMENIDINE PHOSPHATE	1 (0.3)		1 (0.2)
RIMANTADINE	1 (0.3)		1 (0.2)
RIVAROXABAN		1 (0.5)	1 (0.2)
ROBITUSSIN NIGHT-TIME COLD FORMULA	1 (0.3)		1 (0.2)
ROPIVACAINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
SACCHAROMYCES BOULARDII	1 (0.3)		1 (0.2)
SALONPAS /		1 (0.5)	1 (0.2)
SEPTOLETE /		1 (0.5)	1 (0.2)
SERTRALINE		1 (0.5)	1 (0.2)
SERTRALINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
SIMECO /	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

		IDegAsp OD N (%)	IDet N (%)	Total N (%)
SINE-OFF	/	1 (0.3)		1 (0.2)
SINGLET	/	1 (0.3)		1 (0.2)
SINUPRET	/	1 (0.3)		1 (0.2)
SMECTITE			1 (0.5)	1 (0.2)
SOFRACORT		1 (0.3)		1 (0.2)
SOLPADEINE	/		1 (0.5)	1 (0.2)
SPIRONOLACTONE		1 (0.3)		1 (0.2)
SPIRULINA SPP.		1 (0.3)		1 (0.2)
SUCRALFATE		1 (0.3)		1 (0.2)
SULFACETAMIDE			1 (0.5)	1 (0.2)
SULFACETAMIDE SODIUM		1 (0.3)		1 (0.2)
SULFARINOL		1 (0.3)		1 (0.2)
SULINDAC		1 (0.3)		1 (0.2)
SUMATRIPTAN		1 (0.3)		1 (0.2)
TADALAFIL		1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
TAMSULOSIN HYDROCHLORIDE	1 (0.3)		1 (0.2)
TAURINE	1 (0.3)		1 (0.2)
TESTOSTERONE		1 (0.5)	1 (0.2)
TETANUS TOXOID		1 (0.5)	1 (0.2)
TETANUS VACCINE ADSORBED	1 (0.3)		1 (0.2)
TETRACYCLINE	1 (0.3)		1 (0.2)
THENOIC ACID	1 (0.3)		1 (0.2)
THYROID	1 (0.3)		1 (0.2)
TILOPHONE	1 (0.3)		1 (0.2)
TIMOLOL		1 (0.5)	1 (0.2)
TIZANIDINE	1 (0.3)		1 (0.2)
TIZANIDINE HYDROCHLORIDE	1 (0.3)		1 (0.2)
TONICS	1 (0.3)		1 (0.2)
TOPILEXIL [REDACTED]	/	1 (0.3)	1 (0.2)
TRACHISAN [REDACTED]	/	1 (0.3)	1 (0.2)
TRAMADOL HYDROCHLORIDE		1 (0.5)	1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
TRANEXAMIC ACID		1 (0.5)	1 (0.2)
TRAZODONE		1 (0.5)	1 (0.2)
TRETINOIN	1 (0.3)		1 (0.2)
TRIAMCINOLONE		1 (0.5)	1 (0.2)
TRIAMCINOLONE ACETONIDE	1 (0.3)		1 (0.2)
TRIMEBUTINE		1 (0.5)	1 (0.2)
TROPHICARD	1 (0.3)		1 (0.2)
TUBERCULIN PPD		1 (0.5)	1 (0.2)
TWINRIX [REDACTED]	/	1 (0.3)	1 (0.2)
ULTRACET	1 (0.3)		1 (0.2)
UROKINASE	1 (0.3)		1 (0.2)
VAGISIL		1 (0.5)	1 (0.2)
VALACICLOVIR HYDROCHLORIDE	1 (0.3)		1 (0.2)
VARICELLA VIRUS VACCINE, LIVE		1 (0.5)	1 (0.2)
VASERETIC	1 (0.3)		1 (0.2)
VENLAFAXINE HYDROCHLORIDE	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

Concomitant Medication Started after Screening - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
VERAPAMIL	1 (0.3)		1 (0.2)
VICKS FORMULA 44 [REDACTED]	/	1 (0.5)	1 (0.2)
VINPOCETINE	1 (0.3)		1 (0.2)
VITAMINS, OTHER COMBINATIONS		1 (0.5)	1 (0.2)
WARFARIN		1 (0.5)	1 (0.2)
XYLOMETAZOLINE	1 (0.3)		1 (0.2)
YEAST	1 (0.3)		1 (0.2)
ZALEPLON		1 (0.5)	1 (0.2)
ZANAMIVIR		1 (0.5)	1 (0.2)
ZINC		1 (0.5)	1 (0.2)
ZINC GLUCONATE		1 (0.5)	1 (0.2)
ZINGIBER OFFICINALE RHIZOME	1 (0.3)		1 (0.2)

N= Number of subjects

%= Percentage of subjects

Generic names of the drugs are presented.

Prescribed marketed insulin treatments and changes in OAD during the follow up period have been included.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:58 - tsum_events_tpl_t030_v01.sas/t_screen_after_con_med_sum_fas.txt

14.2 Efficacy Data

14.2.1: Exposure - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Total Exposure, yrs	296.9	145.5	442.3
Exposure (yrs)			
N	362	180	542
Mean (SD)	0.82 (0.30)	0.81 (0.31)	0.82 (0.30)
Median	1.01	1.01	1.01
Min ; Max	0.00 ; 1.09	0.01 ; 1.10	0.00 ; 1.10

N = Number of Subjects, SD = Standard Deviation
Exposure for Extension trial only derived for subjects included in extension trial.
Period where subjects on NPH before extension not included as part of exposure.
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:28:59 - tdesc_expo_tpl_t032_v01.sas/t_exposure_descp_sas.txt

14.2.2: Exposure – Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Number of Subjects	254	122	376
Total Exposure, yrs	254.6	122.6	377.3
Exposure (yrs)			
N	254	122	376
Mean (SD)	1.00 (0.08)	1.01 (0.07)	1.00 (0.08)
Median	1.02	1.02	1.02
Min ; Max	0.56 ; 1.09	0.57 ; 1.10	0.56 ; 1.10

N = Number of Subjects, SD = Standard Deviation
Exposure for Extension trial only derived for subjects included in extension trial.
Period where subjects on NPH before extension not included as part of exposure.
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:01 - tdesc_expo_tpl_t032_v01.sas/t_exposure_descp_ets.txt

14.2.3: Exposure by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposed , N (%)			
N	362 (100.0)	180 (100.0)	542 (100.0)
1 - 4 Weeks	9 (2.5)	4 (2.2)	13 (2.4)
5 - 8 Weeks	8 (2.2)	3 (1.7)	11 (2.0)
9 - 12 Weeks	8 (2.2)	5 (2.8)	13 (2.4)
13 - 16 Weeks	5 (1.4)	3 (1.7)	8 (1.5)
17 - 20 Weeks	5 (1.4)	4 (2.2)	9 (1.7)
21 - 24 Weeks	4 (1.1)	2 (1.1)	6 (1.1)
25 - 28 Weeks	66 (18.2)	37 (20.6)	103 (19.0)
29 - 32 Weeks	6 (1.7)	2 (1.1)	8 (1.5)
33 - 36 Weeks	3 (0.8)	0 (0.0)	3 (0.6)
37 - 40 Weeks	4 (1.1)	2 (1.1)	6 (1.1)
41 - 44 Weeks	1 (0.3)	0 (0.0)	1 (0.2)
45 - 48 Weeks	5 (1.4)	2 (1.1)	7 (1.3)
49 - 52 Weeks	9 (2.5)	7 (3.9)	16 (3.0)
53 - 56 Weeks	228 (63.0)	107 (59.4)	335 (61.8)
57 - 60 Weeks	1 (0.3)	2 (1.1)	3 (0.6)

N = Number of Subjects

%: Percentage of Subjects

Each subject only appears in one interval. Exposure for main trial does not include subjects who continue into extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:03 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_w_descp_sas.txt

14.2.4: Exposure by Treatment Week - Summary - Extension Trial Set

	IDegAsp OD	IDet	Total
Number of Subjects	254	122	376
Exposed , N (%)			
N	254 (100.0)	122 (100.0)	376 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
29 - 32 Weeks	3 (1.2)	2 (1.6)	5 (1.3)
33 - 36 Weeks	3 (1.2)	0 (0.0)	3 (0.8)
37 - 40 Weeks	4 (1.6)	2 (1.6)	6 (1.6)
41 - 44 Weeks	1 (0.4)	0 (0.0)	1 (0.3)
45 - 48 Weeks	5 (2.0)	2 (1.6)	7 (1.9)
49 - 52 Weeks	9 (3.5)	7 (5.7)	16 (4.3)
53 - 56 Weeks	228 (89.8)	107 (87.7)	335 (89.1)
57 - 60 Weeks	1 (0.4)	2 (1.6)	3 (0.8)

N = Number of Subjects

%: Percentage of Subjects

Each subject only appears in one interval. Exposure for main trial does not include subjects who continue into extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats

07MAY2011:13:29:04 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_w_descp_ets.txt

14.2.5: Exposure by Sex and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposure, yrs (%)			
Total	296.9 (100.0)	145.5 (100.0)	442.3 (100.0)
Female	135.6 (45.7)	75.1 (51.6)	210.7 (47.6)
Male	161.3 (54.3)	70.3 (48.4)	231.6 (52.4)
Exposed Female, N (%)			
N	173 (100.0)	98 (100.0)	271 (100.0)
1 - 4 Weeks	6 (3.5)	2 (2.0)	8 (3.0)
5 - 8 Weeks	4 (2.3)	3 (3.1)	7 (2.6)
9 - 12 Weeks	4 (2.3)	4 (4.1)	8 (3.0)
13 - 16 Weeks	4 (2.3)	3 (3.1)	7 (2.6)
17 - 20 Weeks	4 (2.3)	3 (3.1)	7 (2.6)
21 - 24 Weeks	3 (1.7)	1 (1.0)	4 (1.5)
25 - 28 Weeks	35 (20.2)	21 (21.4)	56 (20.7)
29 - 32 Weeks	3 (1.7)	1 (1.0)	4 (1.5)
33 - 36 Weeks	1 (0.6)	0 (0.0)	1 (0.4)
37 - 40 Weeks	1 (0.6)	2 (2.0)	3 (1.1)
41 - 44 Weeks	1 (0.6)	0 (0.0)	1 (0.4)
45 - 48 Weeks	3 (1.7)	0 (0.0)	3 (1.1)
49 - 52 Weeks	3 (1.7)	2 (2.0)	5 (1.8)
53 - 56 Weeks	101 (58.4)	54 (55.1)	155 (57.2)
57 - 60 Weeks	0 (0.0)	2 (2.0)	2 (0.7)
Exposed Male, N (%)			
N	189 (100.0)	82 (100.0)	271 (100.0)
1 - 4 Weeks	3 (1.6)	2 (2.4)	5 (1.8)
5 - 8 Weeks	4 (2.1)	0 (0.0)	4 (1.5)
9 - 12 Weeks	4 (2.1)	1 (1.2)	5 (1.8)
13 - 16 Weeks	1 (0.5)	0 (0.0)	1 (0.4)
17 - 20 Weeks	1 (0.5)	1 (1.2)	2 (0.7)
21 - 24 Weeks	1 (0.5)	1 (1.2)	2 (0.7)
25 - 28 Weeks	31 (16.4)	16 (19.5)	47 (17.3)
29 - 32 Weeks	3 (1.6)	1 (1.2)	4 (1.5)
33 - 36 Weeks	2 (1.1)	0 (0.0)	2 (0.7)
37 - 40 Weeks	3 (1.6)	0 (0.0)	3 (1.1)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	2 (1.1)	2 (2.4)	4 (1.5)
49 - 52 Weeks	6 (3.2)	5 (6.1)	11 (4.1)
53 - 56 Weeks	127 (67.2)	53 (64.6)	180 (66.4)
57 - 60 Weeks	1 (0.5)	0 (0.0)	1 (0.4)

N = Number of Subjects

Each subject only appears in one interval. Exposure for Extension trial only derived for subjects included in extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:06 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_sex_descp_sas.txt

14.2.6: Exposure by Race and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposure, yrs (%)			
Total	296.9 (100.0)	145.5 (100.0)	442.3 (100.0)
White	273.9 (92.3)	129.9 (89.3)	403.8 (91.3)
Black	8.0 (2.7)	4.7 (3.2)	12.6 (2.9)
Asian Indian	1.1 (0.4)	0.0 (0.0)	1.1 (0.2)
Asian non-Indian	1.8 (0.6)	2.4 (1.6)	4.2 (1.0)
American Indian	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Pacific Islander	0.6 (0.2)	1.0 (0.7)	1.6 (0.4)
Other	1.0 (0.3)	2.0 (1.4)	3.0 (0.7)
NA	10.5 (3.5)	5.5 (3.8)	16.0 (3.6)
Exposed White, N (%)			
N	331 (100.0)	160 (100.0)	491 (100.0)
1 - 4 Weeks	9 (2.7)	3 (1.9)	12 (2.4)
5 - 8 Weeks	6 (1.8)	3 (1.9)	9 (1.8)
9 - 12 Weeks	7 (2.1)	4 (2.5)	11 (2.2)
13 - 16 Weeks	4 (1.2)	3 (1.9)	7 (1.4)
17 - 20 Weeks	5 (1.5)	3 (1.9)	8 (1.6)
21 - 24 Weeks	4 (1.2)	2 (1.3)	6 (1.2)
25 - 28 Weeks	59 (17.8)	33 (20.6)	92 (18.7)
29 - 32 Weeks	4 (1.2)	2 (1.3)	6 (1.2)
33 - 36 Weeks	2 (0.6)	0 (0.0)	2 (0.4)
37 - 40 Weeks	3 (0.9)	2 (1.3)	5 (1.0)
41 - 44 Weeks	1 (0.3)	0 (0.0)	1 (0.2)
45 - 48 Weeks	5 (1.5)	2 (1.3)	7 (1.4)
49 - 52 Weeks	8 (2.4)	4 (2.5)	12 (2.4)
53 - 56 Weeks	213 (64.4)	97 (60.6)	310 (63.1)
57 - 60 Weeks	1 (0.3)	2 (1.3)	3 (0.6)
Exposed Black, N (%)			
N	10 (100.0)	6 (100.0)	16 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	1 (10.0)	0 (0.0)	1 (6.3)
9 - 12 Weeks	1 (10.0)	1 (16.7)	2 (12.5)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	0 (0.0)	1 (16.7)	1 (6.3)
29 - 32 Weeks	1 (10.0)	0 (0.0)	1 (6.3)
33 - 36 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
37 - 40 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	0 (0.0)	1 (16.7)	1 (6.3)
53 - 56 Weeks	7 (70.0)	3 (50.0)	10 (62.5)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects

#: Percentage of Subjects

Subjects from France did not report race.

Each subject only appears in one interval. Exposure for main trial does not include subjects who continue into extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:07 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_race_descp_sas.txt

Exposure by Race and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Exposed Asian Indian, N (%)			
N	1 (100.0)	0 (0.0)	1 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
33 - 36 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
37 - 40 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
53 - 56 Weeks	1 (100.0)	0 (0.0)	1 (100.0)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
Exposed Asian non-Indian, N (%)			
N	3 (100.0)	3 (100.0)	6 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	1 (33.3)	0 (0.0)	1 (16.7)
17 - 20 Weeks	0 (0.0)	1 (33.3)	1 (16.7)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	1 (33.3)	0 (0.0)	1 (16.7)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
33 - 36 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
37 - 40 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
53 - 56 Weeks	1 (33.3)	2 (66.7)	3 (50.0)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects

#: Percentage of Subjects

Subjects from France did not report race.

Each subject only appears in one interval. Exposure for main trial does not include subjects who continue into extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:07 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_race_descp_sas.txt

Exposure by Race and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Exposed American Indian, N (%)			
N	0 (0.0)	0 (0.0)	0 (0.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
33 - 36 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
37 - 40 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
53 - 56 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
Exposed Pacific Islander, N (%)			
N	1 (100.0)	1 (100.0)	2 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
29 - 32 Weeks	1 (100.0)	0 (0.0)	1 (50.0)
33 - 36 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
37 - 40 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
53 - 56 Weeks	0 (0.0)	1 (100.0)	1 (50.0)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects

#: Percentage of Subjects

Subjects from France did not report race.

Each subject only appears in one interval. Exposure for main trial does not include subjects who continue into extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:07 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_race_descp_sas.txt

Exposure by Race and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Exposed Other, N (%)			
N	1 (100.0)	2 (100.0)	3 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
33 - 36 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
37 - 40 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	0 (0.0)	1 (50.0)	1 (33.3)
53 - 56 Weeks	1 (100.0)	1 (50.0)	2 (66.7)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
Exposed NA, N (%)			
N	15 (100.0)	8 (100.0)	23 (100.0)
1 - 4 Weeks	0 (0.0)	1 (12.5)	1 (4.3)
5 - 8 Weeks	1 (6.7)	0 (0.0)	1 (4.3)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	6 (40.0)	3 (37.5)	9 (39.1)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
33 - 36 Weeks	1 (6.7)	0 (0.0)	1 (4.3)
37 - 40 Weeks	1 (6.7)	0 (0.0)	1 (4.3)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	1 (6.7)	1 (12.5)	2 (8.7)
53 - 56 Weeks	5 (33.3)	3 (37.5)	8 (34.8)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects

#: Percentage of Subjects

Subjects from France did not report race.

Each subject only appears in one interval. Exposure for main trial does not include subjects who continue into extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:07 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_race_descp_sas.txt

14.2.7: Exposure by Ethnicity and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposure, yrs (%)			
Total	296.9 (100.0)	145.5 (100.0)	442.3 (100.0)
Hispanic	7.6 (2.5)	3.4 (2.4)	11.0 (2.5)
Not Hispanic	278.8 (93.9)	136.6 (93.9)	415.3 (93.9)
NA	10.5 (3.5)	5.5 (3.8)	16.0 (3.6)
Exposed Hispanic, N (%)			
N	10 (100.0)	5 (100.0)	15 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	1 (10.0)	0 (0.0)	1 (6.7)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	1 (10.0)	0 (0.0)	1 (6.7)
17 - 20 Weeks	0 (0.0)	1 (20.0)	1 (6.7)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	2 (20.0)	2 (40.0)	4 (26.7)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
33 - 36 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
37 - 40 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
53 - 56 Weeks	6 (60.0)	2 (40.0)	8 (53.3)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
Exposed Not Hispanic, N (%)			
N	337 (100.0)	167 (100.0)	504 (100.0)
1 - 4 Weeks	9 (2.7)	3 (1.8)	12 (2.4)
5 - 8 Weeks	6 (1.8)	3 (1.8)	9 (1.8)
9 - 12 Weeks	8 (2.4)	5 (3.0)	13 (2.6)
13 - 16 Weeks	4 (1.2)	3 (1.8)	7 (1.4)
17 - 20 Weeks	5 (1.5)	3 (1.8)	8 (1.6)
21 - 24 Weeks	4 (1.2)	2 (1.2)	6 (1.2)
25 - 28 Weeks	58 (17.2)	32 (19.2)	90 (17.9)
29 - 32 Weeks	6 (1.8)	2 (1.2)	8 (1.6)
33 - 36 Weeks	2 (0.6)	0 (0.0)	2 (0.4)
37 - 40 Weeks	3 (0.9)	2 (1.2)	5 (1.0)
41 - 44 Weeks	1 (0.3)	0 (0.0)	1 (0.2)
45 - 48 Weeks	5 (1.5)	2 (1.2)	7 (1.4)
49 - 52 Weeks	8 (2.4)	6 (3.6)	14 (2.8)
53 - 56 Weeks	217 (64.4)	102 (61.1)	319 (63.3)
57 - 60 Weeks	1 (0.3)	2 (1.2)	3 (0.6)

N = Number of Subjects

%: Percentage of Subjects

Each subject only appears in one interval. Exposure for main trial does not include subjects who continue into extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:09 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_ethnicity_descp_sas.txt

Exposure by Ethnicity and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Exposed NA, N (%)			
N	15 (100.0)	8 (100.0)	23 (100.0)
1 - 4 Weeks	0 (0.0)	1 (12.5)	1 (4.3)
5 - 8 Weeks	1 (6.7)	0 (0.0)	1 (4.3)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	6 (40.0)	3 (37.5)	9 (39.1)
29 - 32 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
33 - 36 Weeks	1 (6.7)	0 (0.0)	1 (4.3)
37 - 40 Weeks	1 (6.7)	0 (0.0)	1 (4.3)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	1 (6.7)	1 (12.5)	2 (8.7)
53 - 56 Weeks	5 (33.3)	3 (37.5)	8 (34.8)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects

#: Percentage of Subjects

Each subject only appears in one interval. Exposure for main trial does not include subjects who continue into extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:29:09 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_ethnicity_descp_sas.txt

14.2.8: Exposure by Age Group (Adults and Elderly) and Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Exposure, yrs (%)			
Total	296.9 (100.0)	145.5 (100.0)	442.3 (100.0)
18-65 yrs	290.3 (97.8)	134.8 (92.6)	425.1 (96.1)
> 65 yrs	6.6 (2.2)	10.7 (7.4)	17.2 (3.9)
Exposed 18-65 yrs, N (%)			
N	353 (100.0)	166 (100.0)	519 (100.0)
1 - 4 Weeks	9 (2.5)	3 (1.8)	12 (2.3)
5 - 8 Weeks	7 (2.0)	3 (1.8)	10 (1.9)
9 - 12 Weeks	8 (2.3)	5 (3.0)	13 (2.5)
13 - 16 Weeks	5 (1.4)	3 (1.8)	8 (1.5)
17 - 20 Weeks	5 (1.4)	4 (2.4)	9 (1.7)
21 - 24 Weeks	4 (1.1)	2 (1.2)	6 (1.2)
25 - 28 Weeks	64 (18.1)	33 (19.9)	97 (18.7)
29 - 32 Weeks	5 (1.4)	1 (0.6)	6 (1.2)
33 - 36 Weeks	2 (0.6)	0 (0.0)	2 (0.4)
37 - 40 Weeks	4 (1.1)	2 (1.2)	6 (1.2)
41 - 44 Weeks	1 (0.3)	0 (0.0)	1 (0.2)
45 - 48 Weeks	5 (1.4)	2 (1.2)	7 (1.3)
49 - 52 Weeks	9 (2.5)	6 (3.6)	15 (2.9)
53 - 56 Weeks	224 (63.5)	100 (60.2)	324 (62.4)
57 - 60 Weeks	1 (0.3)	2 (1.2)	3 (0.6)
Exposed > 65 yrs, N (%)			
N	9 (100.0)	14 (100.0)	23 (100.0)
1 - 4 Weeks	0 (0.0)	1 (7.1)	1 (4.3)
5 - 8 Weeks	1 (11.1)	0 (0.0)	1 (4.3)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
17 - 20 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
21 - 24 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
25 - 28 Weeks	2 (22.2)	4 (28.6)	6 (26.1)
29 - 32 Weeks	1 (11.1)	1 (7.1)	2 (8.7)
33 - 36 Weeks	1 (11.1)	0 (0.0)	1 (4.3)
37 - 40 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
41 - 44 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
45 - 48 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
49 - 52 Weeks	0 (0.0)	1 (7.1)	1 (4.3)
53 - 56 Weeks	4 (44.4)	7 (50.0)	11 (47.8)
57 - 60 Weeks	0 (0.0)	0 (0.0)	0 (0.0)

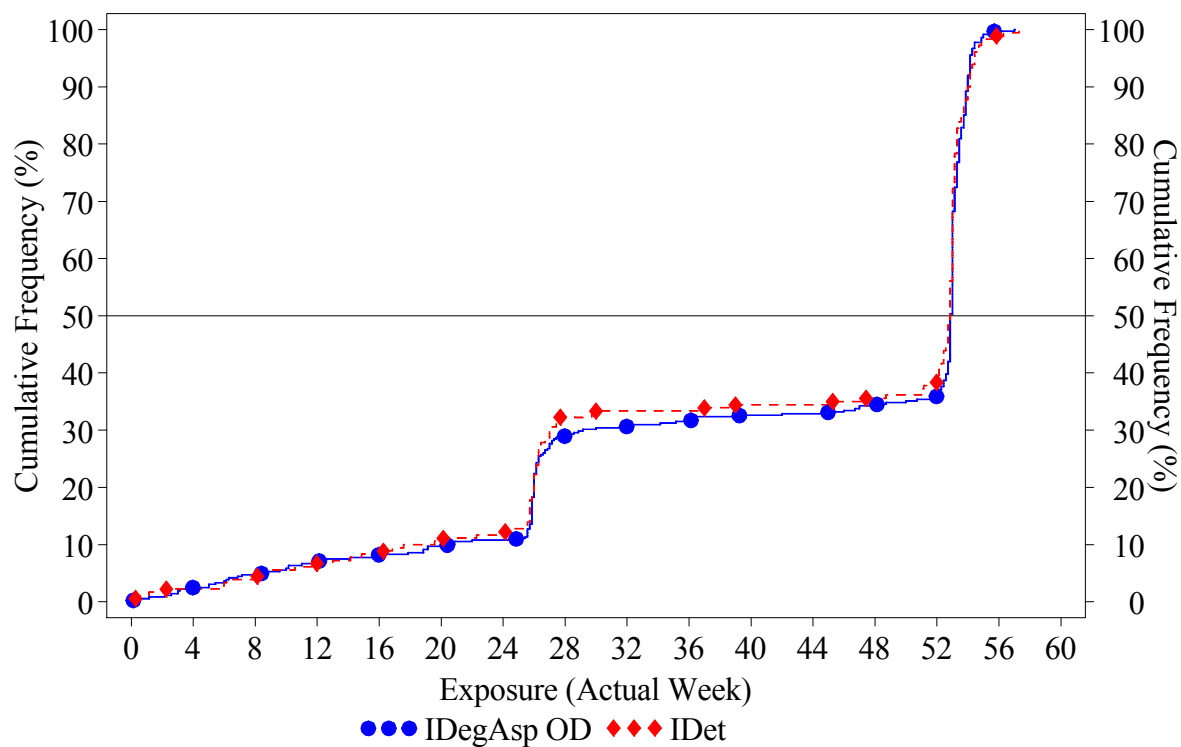
N = Number of Subjects

#: Percentage of Subjects.

Each subject only appears in one interval. Exposure for main trial does not include subjects who continue into extension trial.

Period where subjects on NPH before extension not included as part of exposure.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:11 - tsum_expo_cat_tpl_t033_v01.sas/t_exposure_age_descp_sas.txt



np5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:13 - fedist_expo_v01.sas/e_exposure_cdf_sas.cgm

14.2.9: Exposure - Empirical Distribution Plot - Safety Analysis Set

14.2.10: IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	36	16	32	10	118
		OD							
		IDet	180	176	26	12	24	7	77
Visit 4 (Week 2)	Daily	Total	542	536	33	16	30	7	118
		IDegAsp	362	359	37	17	33	10	120
		OD							
Visit 5 (Week 3)	Daily	IDet	180	176	27	13	26	4	79
		Total	542	535	34	16	30	4	120
		IDegAsp	362	346	38	17	34	10	120
Visit 6 (Week 4)	Daily	OD							
		IDet	180	175	28	13	26	4	81
		Total	542	521	34	17	32	4	120
Visit 7 (Week 5)	Daily	IDegAsp	362	351	38	17	34	9	116
		OD							
		IDet	180	174	29	14	28	4	83
Visit 8 (Week 6)	Daily	Total	542	525	35	17	32	4	116
		IDegAsp	362	349	38	18	34	8	116
		OD							
Visit 9 (Week 7)	Daily	IDet	180	173	29	14	28	5	74
		Total	542	522	35	17	33	5	116
		IDegAsp	362	343	39	18	35	9	118
Visit 10 (Week 8)	Daily	OD							
		IDet	180	172	31	15	30	5	85
		Total	542	515	36	17	34	5	118
Visit 11 (Week 9)	Daily	IDegAsp	362	342	39	18	35	10	118
		OD							
		IDet	180	171	31	15	30	5	87
Visit 12 (Week 10)	Daily	Total	542	513	36	18	34	5	118
		IDegAsp	362	340	39	18	36	8	120
		OD							
Visit 13 (Week 11)	Daily	IDet	180	171	32	15	30	5	80
		Total	542	511	37	18	34	5	120
		IDegAsp	362	334	40	19	36	9	124
Visit 14 (Week 12)	Daily	OD							
		IDet	180	166	32	16	30	5	82
		Total	542	500	37	18	34	5	124
Visit 15 (Week 13)	Daily	IDegAsp	362	337	40	19	36	8	124
		OD							
		IDet	180	169	33	16	31	5	83
Visit 16 (Week 14)	Daily	Total	542	506	38	18	34	5	124
		IDegAsp	362	334	40	19	36	10	128
		OD							
Visit 17 (Week 15)	Daily	IDet	180	167	33	17	32	5	87
		Total	542	501	38	19	34	5	128
		IDegAsp	362	333	41	20	36	11	134
Visit 18 (Week 16)	Daily	OD							
		IDet	180	167	33	17	31	2	87
		Total	542	500	38	19	34	2	134

N = Number of Subjects, SD = Standard Deviation
Exposure for Extension trial only derived for subjects included in extension trial.
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:27 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	324	41	20	36	10	134
		OD							
		IDet	180	161	34	17	32	2	92
Visit 16 (Week 14)	Daily	Total	542	485	39	20	34	2	134
		IDegAsp	362	331	41	20	36	8	130
		OD							
Visit 17 (Week 15)	Daily	IDet	180	165	34	17	32	4	94
		Total	542	496	39	20	34	4	130
		IDegAsp	362	327	41	21	36	9	124
Visit 18 (Week 16)	Daily	OD							
		IDet	180	164	34	17	32	5	100
		Total	542	491	39	20	34	5	124
Visit 19 (Week 17)	Daily	IDegAsp	362	329	41	21	36	6	128
		OD							
		IDet	180	163	34	17	32	4	102
Visit 20 (Week 18)	Daily	Total	542	492	39	20	34	4	128
		IDegAsp	362	322	42	21	37	10	130
		OD							
Visit 21 (Week 19)	Daily	IDet	180	162	34	18	32	4	104
		Total	542	484	39	20	35	4	130
		IDegAsp	362	319	42	21	37	8	126
Visit 22 (Week 20)	Daily	OD							
		IDet	180	158	35	18	34	5	108
		Total	542	477	40	20	36	5	126
Visit 23 (Week 21)	Daily	IDegAsp	362	319	42	21	37	9	124
		OD							
		IDet	180	162	35	18	34	4	101
Visit 24 (Week 22)	Daily	Total	542	481	40	20	36	4	124
		IDegAsp	362	322	42	22	37	10	130
		OD							
Visit 25 (Week 23)	Daily	IDet	180	158	35	18	33	4	100
		Total	542	480	40	21	36	4	130
		IDegAsp	362	319	42	21	37	9	132
Visit 26 (Week 24)	Daily	OD							
		IDet	180	157	36	19	33	4	104
		Total	542	476	40	21	36	4	132
Visit 27 (Week 25)	Daily	IDegAsp	362	318	43	22	38	9	132
		OD							
		IDet	180	156	36	19	33	5	98
Visit 28 (Week 26)	Daily	Total	542	474	40	21	36	5	132
		IDegAsp	362	320	43	22	37	8	132
		OD							
Visit 29 (Week 27)	Daily	IDet	180	151	36	19	34	6	102
		Total	542	471	41	22	36	6	132
		IDegAsp	362	318	43	22	37	9	132
Visit 30 (Week 28)	Daily	OD							
		IDet	180	157	36	20	34	6	106
		Total	542	475	41	22	36	6	132

N = Number of Subjects, SD = Standard Deviation

Exposure for Extension trial only derived for subjects included in extension trial.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:27 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	43	22	37	9	134
		OD							
		IDet	180	155	37	20	34	6	110
		Total	542	473	41	22	36	6	134
Visit 28 (Week 26)	Daily	IDegAsp	362	339	42	22	36	9	132
		OD							
		IDet	180	165	37	21	34	6	111
		Total	542	504	41	22	35	6	132
Visit 31 (Week 28)	Daily	IDegAsp	362	250	42	22	36	10	134
		OD							
		IDet	180	121	37	21	36	6	112
		Total	542	371	41	22	36	6	134
Visit 32 (Week 29)	Daily	IDegAsp	362	251	43	23	36	9	136
		OD							
		IDet	180	122	38	21	36	6	116
		Total	542	373	41	23	36	6	136
Visit 33 (Week 31)	Daily	IDegAsp	362	251	43	23	36	10	140
		OD							
		IDet	180	121	38	22	36	6	118
		Total	542	372	41	23	36	6	140
Visit 34 (Week 33)	Daily	IDegAsp	362	245	43	23	36	11	140
		OD							
		IDet	180	120	39	22	36	7	122
		Total	542	365	42	23	36	7	140
Visit 35 (Week 35)	Daily	IDegAsp	362	247	43	24	36	10	142
		OD							
		IDet	180	120	39	23	36	7	126
		Total	542	367	42	23	36	7	142
Visit 36 (Week 37)	Daily	IDegAsp	362	242	44	24	38	10	144
		OD							
		IDet	180	118	39	23	36	7	130
		Total	542	360	42	24	37	7	144
Visit 37 (Week 39)	Daily	IDegAsp	362	245	44	24	38	10	146
		OD							
		IDet	180	118	39	23	36	6	134
		Total	542	363	42	24	37	6	146
Visit 38 (Week 41)	Daily	IDegAsp	362	237	44	25	37	10	148
		OD							
		IDet	180	118	40	24	37	6	138
		Total	542	355	42	24	37	6	148
Visit 39 (Week 43)	Daily	IDegAsp	362	241	44	24	38	9	150
		OD							
		IDet	180	118	40	24	37	7	135
		Total	542	359	42	24	38	7	150
Visit 40 (Week 45)	Daily	IDegAsp	362	237	44	25	40	9	150
		OD							
		IDet	180	116	40	25	36	6	139
		Total	542	353	43	25	38	6	150

N = Number of Subjects, SD = Standard Deviation

Exposure for Extension trial only derived for subjects included in extension trial.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:27 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics -
Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	362	240	44	25	38	6	150
		OD							
		IDet	180	116	40	24	37	8	136
		Total	542	356	43	25	38	6	150
Visit 42 (Week 49)	Daily	IDegAsp	362	234	45	26	38	4	152
		OD							
		IDet	180	113	41	25	38	8	134
		Total	542	347	43	26	38	4	152
Visit 43 (Week 51)	Daily	IDegAsp	362	232	45	26	38	6	152
		OD							
		IDet	180	112	41	25	38	8	132
		Total	542	344	44	26	38	6	152
Visit 44 (Week 53)	Daily	IDegAsp	362	236	46	27	38	8	156
		OD							
		IDet	180	113	41	25	38	7	134
		Total	542	349	44	26	38	7	156
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	43	25	38	8	156
		OD							
		IDet	180	178	39	24	34	6	134
		Total	542	538	42	24	36	6	156

N = Number of Subjects, SD = Standard Deviation

Exposure for Extension trial only derived for subjects included in extension trial.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:27 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_sas.txt

14.2.11: IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Extension Trial Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			EXT	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	254	254	37	17	34	10	118
		OD							
		IDet	122	121	26	11	25	7	70
		Total	376	375	33	16	30	7	118
Visit 4 (Week 2)	Daily	IDegAsp	254	254	38	18	34	10	120
		OD							
		IDet	122	122	28	12	27	4	70
		Total	376	376	34	17	31	4	120
Visit 5 (Week 3)	Daily	IDegAsp	254	250	38	18	34	10	120
		OD							
		IDet	122	121	29	13	28	4	70
		Total	376	371	35	17	32	4	120
Visit 6 (Week 4)	Daily	IDegAsp	254	254	39	18	35	10	116
		OD							
		IDet	122	121	30	14	28	4	72
		Total	376	375	36	17	33	4	116
Visit 7 (Week 5)	Daily	IDegAsp	254	253	39	18	35	8	116
		OD							
		IDet	122	120	30	14	29	5	74
		Total	376	373	36	18	34	5	116
Visit 8 (Week 6)	Daily	IDegAsp	254	252	40	19	36	9	118
		OD							
		IDet	122	121	31	15	31	5	76
		Total	376	373	37	18	34	5	118
Visit 9 (Week 7)	Daily	IDegAsp	254	253	40	19	36	10	118
		OD							
		IDet	122	121	32	15	31	5	78
		Total	376	374	37	18	34	5	118
Visit 10 (Week 8)	Daily	IDegAsp	254	254	40	19	37	8	120
		OD							
		IDet	122	121	32	16	32	5	80
		Total	376	375	38	19	35	5	120
Visit 11 (Week 9)	Daily	IDegAsp	254	250	41	20	37	9	124
		OD							
		IDet	122	121	33	16	32	5	82
		Total	376	371	38	19	35	5	124
Visit 12 (Week 10)	Daily	IDegAsp	254	254	41	20	37	8	124
		OD							
		IDet	122	121	33	17	32	5	83
		Total	376	375	38	19	35	5	124
Visit 13 (Week 11)	Daily	IDegAsp	254	252	41	20	37	10	128
		OD							
		IDet	122	120	33	17	32	5	87
		Total	376	372	39	20	35	5	128
Visit 14 (Week 12)	Daily	IDegAsp	254	253	41	21	37	11	134
		OD							
		IDet	122	122	34	17	32	2	87
		Total	376	375	39	20	35	2	134

N = Number of Subjects, SD = Standard Deviation
Exposure for Extension trial only derived for subjects included in extension trial.
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:38 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_ets.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics -
Extension Trial Set

Visit	Endpoint	Treatment	EXT	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	254	249	42	21	36	10	134
		OD							
		IDet	122	119	34	17	32	2	92
Visit 16 (Week 14)	Daily	Total	376	368	39	20	35	2	134
		IDegAsp	254	254	42	21	37	8	130
		OD							
Visit 17 (Week 15)	Daily	IDet	122	122	34	17	32	4	94
		Total	376	376	39	20	35	4	130
		IDegAsp	254	250	42	22	36	9	124
Visit 18 (Week 16)	Daily	OD							
		IDet	122	122	35	18	33	5	100
		Total	376	372	40	21	34	5	124
Visit 19 (Week 17)	Daily	IDegAsp	254	254	42	22	36	6	128
		OD							
		IDet	122	122	35	18	33	4	102
Visit 20 (Week 18)	Daily	Total	376	376	40	21	34	4	128
		IDegAsp	254	247	42	22	36	10	130
		OD							
Visit 21 (Week 19)	Daily	IDet	122	121	35	18	33	4	104
		Total	376	368	40	21	35	4	130
		IDegAsp	254	249	42	22	36	8	126
Visit 22 (Week 20)	Daily	OD							
		IDet	122	119	36	19	34	5	108
		Total	376	368	40	21	36	5	126
Visit 23 (Week 21)	Daily	IDegAsp	254	248	42	21	37	9	124
		OD							
		IDet	122	122	35	19	34	4	101
Visit 24 (Week 22)	Daily	Total	376	370	40	21	36	4	124
		IDegAsp	254	252	43	22	37	10	130
		OD							
Visit 25 (Week 23)	Daily	IDet	122	120	35	19	34	4	100
		Total	376	372	40	21	36	4	130
		IDegAsp	254	249	43	22	36	9	132
Visit 26 (Week 24)	Daily	OD							
		IDet	122	122	36	19	35	4	104
		Total	376	371	40	21	36	4	132
Visit 27 (Week 25)	Daily	IDegAsp	254	249	43	23	37	9	132
		OD							
		IDet	122	121	36	19	35	5	98
Visit 28 (Week 26)	Daily	Total	376	370	41	22	36	5	132
		IDegAsp	254	252	43	23	37	8	132
		OD							
Visit 29 (Week 27)	Daily	IDet	122	116	36	19	35	6	102
		Total	376	368	41	22	36	6	132
		IDegAsp	254	251	43	23	37	9	132
Visit 30 (Week 28)	Daily	OD							
		IDet	122	122	37	20	36	6	106
		Total	376	373	41	22	36	6	132

N = Number of Subjects, SD = Standard Deviation

Exposure for Extension trial only derived for subjects included in extension trial.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:38 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_ets.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Extension Trial Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			EXT	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	254	252	43	23	37	9	134
		OD							
		IDet	122	121	37	20	36	6	110
Visit 28 (Week 26)	Daily	Total	376	373	41	22	36	6	134
		IDegAsp	254	254	43	23	36	9	132
		OD							
Visit 31 (Week 28)	Daily	IDet	122	122	37	21	35	6	111
		Total	376	376	41	23	36	6	132
Visit 32 (Week 29)	Daily	IDegAsp	254	250	42	22	36	10	134
		OD							
		IDet	122	121	37	21	36	6	112
Visit 33 (Week 31)	Daily	Total	376	371	41	22	36	6	134
		IDegAsp	254	251	43	23	36	9	136
		OD							
Visit 34 (Week 33)	Daily	IDet	122	122	38	21	36	6	116
		Total	376	373	41	23	36	6	136
Visit 35 (Week 35)	Daily	IDegAsp	254	245	43	23	36	11	140
		OD							
		IDet	122	120	39	22	36	7	122
Visit 36 (Week 37)	Daily	Total	376	365	42	23	36	7	140
		IDegAsp	254	247	43	24	36	10	142
		OD							
Visit 37 (Week 39)	Daily	IDet	122	120	39	23	36	7	126
		Total	376	367	42	23	36	7	142
Visit 38 (Week 41)	Daily	IDegAsp	254	242	44	24	38	10	144
		OD							
		IDet	122	118	39	23	36	7	130
Visit 39 (Week 43)	Daily	Total	376	360	42	24	37	7	144
		IDegAsp	254	245	44	24	38	10	146
		OD							
Visit 40 (Week 45)	Daily	IDet	122	118	39	23	36	6	134
		Total	376	363	42	24	37	6	146
Visit 41 (Week 47)	Daily	IDegAsp	254	237	44	25	37	10	148
		OD							
		IDet	122	118	40	24	37	6	138
Visit 42 (Week 49)	Daily	Total	376	355	42	24	37	6	148
		IDegAsp	254	241	44	24	38	9	150
		OD							
Visit 43 (Week 51)	Daily	IDet	122	118	40	24	37	7	135
		Total	376	359	42	24	38	7	150
Visit 44 (Week 53)	Daily	IDegAsp	254	237	44	25	40	9	150
		OD							
		IDet	122	116	40	25	36	6	139
Visit 45 (Week 55)	Daily	Total	376	353	43	25	38	6	150
		IDegAsp	254	237	44	25	40	9	150
		OD							

N = Number of Subjects, SD = Standard Deviation

Exposure for Extension trial only derived for subjects included in extension trial.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:38 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_ets.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics -
Extension Trial Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			EXT	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	254	240	44	25	38	6	150
		OD							
		IDet	122	116	40	24	37	8	136
		Total	376	356	43	25	38	6	150
Visit 42 (Week 49)	Daily	IDegAsp	254	234	45	26	38	4	152
		OD							
		IDet	122	113	41	25	38	8	134
		Total	376	347	43	26	38	4	152
Visit 43 (Week 51)	Daily	IDegAsp	254	232	45	26	38	6	152
		OD							
		IDet	122	112	41	25	38	8	132
		Total	376	344	44	26	38	6	152
Visit 44 (Week 53)	Daily	IDegAsp	254	236	46	27	38	8	156
		OD							
		IDet	122	113	41	25	38	7	134
		Total	376	349	44	26	38	7	156
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	254	254	45	26	38	8	156
		OD							
		IDet	122	122	41	25	38	6	134
		Total	376	376	44	26	38	6	156

N = Number of Subjects, SD = Standard Deviation

Exposure for Extension trial only derived for subjects included in extension trial.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:38 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_u_descp_ets.txt

14.2.12: IDegAsp/Comparator Insulin Dose (Prescribed) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 2 (Week 0)	Daily	IDegAsp	362	362	37	16	34	10	118
		OD							
		IDet	180	180	26	12	24	7	77
		Total	542	542	33	16	30	7	118
Visit 3 (Week 1)	Daily	IDegAsp	362	360	37	17	33	12	124
		OD							
		IDet	180	177	27	13	27	6	79
		Total	542	537	34	16	30	6	124
Visit 4 (Week 2)	Daily	IDegAsp	362	359	38	17	34	10	124
		OD							
		IDet	180	175	28	13	28	4	81
		Total	542	534	35	17	32	4	124
Visit 5 (Week 3)	Daily	IDegAsp	362	348	38	17	34	9	116
		OD							
		IDet	180	175	29	14	28	0	83
		Total	542	523	35	17	32	0	116
Visit 6 (Week 4)	Daily	IDegAsp	362	351	39	18	34	6	116
		OD							
		IDet	180	175	30	14	29	5	85
		Total	542	526	36	17	33	5	116
Visit 7 (Week 5)	Daily	IDegAsp	362	349	39	18	35	0	118
		OD							
		IDet	180	173	30	14	30	5	76
		Total	542	522	36	17	34	0	118
Visit 8 (Week 6)	Daily	IDegAsp	362	343	39	18	35	10	118
		OD							
		IDet	180	173	31	15	30	5	87
		Total	542	516	36	18	34	5	118
Visit 9 (Week 7)	Daily	IDegAsp	362	341	40	18	36	8	120
		OD							
		IDet	180	171	32	16	30	5	89
		Total	542	512	37	18	34	5	120
Visit 10 (Week 8)	Daily	IDegAsp	362	341	40	19	36	9	124
		OD							
		IDet	180	171	32	16	30	5	82
		Total	542	512	37	18	34	5	124
Visit 11 (Week 9)	Daily	IDegAsp	362	334	40	19	36	0	124
		OD							
		IDet	180	166	33	16	32	5	84
		Total	542	500	38	19	34	0	124
Visit 12 (Week 10)	Daily	IDegAsp	362	337	40	19	36	9	128
		OD							
		IDet	180	169	33	17	32	5	87
		Total	542	506	38	19	34	5	128
Visit 13 (Week 11)	Daily	IDegAsp	362	333	41	20	36	11	134
		OD							
		IDet	180	167	33	17	31	2	87
		Total	542	500	38	19	34	2	134

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:49 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_prscb_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Prescribed) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 14 (Week 12)	Daily	IDegAsp	362	333	41	20	36	10	136
		OD							
		IDet	180	167	34	17	32	2	92
Visit 15 (Week 13)	Daily	Total	542	500	38	20	34	2	136
		IDegAsp	362	321	41	21	36	7	130
		OD							
Visit 16 (Week 14)	Daily	IDet	180	161	34	17	33	4	96
		Total	542	482	39	20	34	4	130
		IDegAsp	362	332	41	21	36	0	130
Visit 17 (Week 15)	Daily	OD							
		IDet	180	166	34	17	33	5	100
		Total	542	498	39	20	34	0	130
Visit 18 (Week 16)	Daily	IDegAsp	362	324	41	21	36	0	128
		OD							
		IDet	180	163	35	18	32	4	102
Visit 19 (Week 17)	Daily	Total	542	487	39	20	35	0	128
		IDegAsp	362	330	42	21	37	0	130
		OD							
Visit 20 (Week 18)	Daily	IDet	180	163	35	18	32	4	104
		Total	542	493	39	20	35	0	130
		IDegAsp	362	322	42	21	37	0	134
Visit 21 (Week 19)	Daily	OD							
		IDet	180	161	35	18	34	5	108
		Total	542	483	40	21	36	0	134
Visit 22 (Week 20)	Daily	IDegAsp	362	319	42	21	37	0	130
		OD							
		IDet	180	157	36	18	34	5	101
Visit 23 (Week 21)	Daily	Total	542	476	40	21	36	0	130
		IDegAsp	362	316	43	21	38	10	126
		OD							
Visit 24 (Week 22)	Daily	IDet	180	161	36	18	34	4	100
		Total	542	477	40	20	36	4	126
		IDegAsp	362	322	42	22	38	9	132
Visit 25 (Week 23)	Daily	OD							
		IDet	180	159	36	19	33	4	104
		Total	542	481	40	21	36	4	132
Visit 26 (Week 24)	Daily	IDegAsp	362	316	43	22	38	9	132
		OD							
		IDet	180	156	36	19	34	5	98
Visit 27 (Week 25)	Daily	Total	542	472	40	21	36	5	132
		IDegAsp	362	315	43	22	37	8	132
		OD							
Visit 28 (Week 26)	Daily	IDet	180	156	36	19	34	6	102
		Total	542	471	41	22	36	6	132
		IDegAsp	362	316	43	22	38	9	132
Visit 29 (Week 27)	Daily	OD							
		IDet	180	151	37	20	35	6	106
		Total	542	467	41	22	37	6	132

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:49 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_prscb_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Prescribed) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 26 (Week 24)	Daily	IDegAsp	362	317	43	22	38	9	132
		OD							
		IDet	180	157	37	20	34	8	110
		Total	542	474	41	22	36	8	132
Visit 27 (Week 25)	Daily	IDegAsp	362	313	43	23	37	9	132
		OD							
		IDet	180	151	38	21	35	6	112
		Total	542	464	41	22	36	6	132
Visit 30 (Week 27)	Daily	IDegAsp	362	254	43	23	36	10	132
		OD							
		IDet	180	122	37	21	36	6	112
		Total	542	376	41	22	36	6	132
Visit 31 (Week 28)	Daily	IDegAsp	362	249	43	23	36	9	136
		OD							
		IDet	180	120	38	21	36	6	116
		Total	542	369	41	22	36	6	136
Visit 32 (Week 29)	Daily	IDegAsp	362	248	43	23	37	10	140
		OD							
		IDet	180	120	38	22	36	6	118
		Total	542	368	42	23	36	6	140
Visit 33 (Week 31)	Daily	IDegAsp	362	251	43	23	36	9	140
		OD							
		IDet	180	120	39	22	36	7	122
		Total	542	371	42	23	36	7	140
Visit 34 (Week 33)	Daily	IDegAsp	362	243	43	24	36	10	142
		OD							
		IDet	180	120	39	22	36	7	126
		Total	542	363	42	23	36	7	142
Visit 35 (Week 35)	Daily	IDegAsp	362	246	44	24	38	10	144
		OD							
		IDet	180	120	39	23	36	7	130
		Total	542	366	42	24	37	7	144
Visit 36 (Week 37)	Daily	IDegAsp	362	241	44	24	38	10	146
		OD							
		IDet	180	115	40	24	37	6	134
		Total	542	356	43	24	38	6	146
Visit 37 (Week 39)	Daily	IDegAsp	362	244	44	24	38	10	148
		OD							
		IDet	180	118	40	24	37	6	138
		Total	542	362	43	24	38	6	148
Visit 38 (Week 41)	Daily	IDegAsp	362	234	44	25	38	9	150
		OD							
		IDet	180	118	40	24	37	7	135
		Total	542	352	43	25	38	7	150
Visit 39 (Week 43)	Daily	IDegAsp	362	241	44	25	40	9	150
		OD							
		IDet	180	118	40	25	37	6	139
		Total	542	359	43	25	38	6	150

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:49 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_prscb_u_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Prescribed) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 40 (Week 45)	Daily	IDegAsp	362	235	45	26	40	8	150
		OD							
		IDet	180	115	41	25	38	8	136
		Total	542	350	43	25	38	8	150
Visit 41 (Week 47)	Daily	IDegAsp	362	236	45	26	39	4	152
		OD							
		IDet	180	116	40	24	37	8	134
		Total	542	352	43	25	38	4	152
Visit 42 (Week 49)	Daily	IDegAsp	362	230	45	26	39	6	152
		OD							
		IDet	180	113	41	25	38	8	132
		Total	542	343	44	26	38	6	152
Visit 43 (Week 51)	Daily	IDegAsp	362	232	46	27	38	8	156
		OD							
		IDet	180	112	42	25	38	8	134
		Total	542	344	44	26	38	8	156
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	362	44	25	37	0	156
		OD							
		IDet	180	180	39	24	35	6	134
		Total	542	542	42	24	36	0	156

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:49 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_prscb_u_descp_sas.txt

14.2.13: IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.47	0.18	0.43	0.13	1.25
		OD							
		IDet	180	176	0.34	0.13	0.31	0.10	0.96
		Total	542	536	0.43	0.18	0.40	0.10	1.25
Visit 4 (Week 2)	Daily	IDegAsp	362	359	0.48	0.19	0.44	0.15	1.33
		OD							
		IDet	180	176	0.35	0.14	0.33	0.07	0.99
		Total	542	535	0.44	0.18	0.41	0.07	1.33
Visit 5 (Week 3)	Daily	IDegAsp	362	346	0.49	0.19	0.44	0.15	1.35
		OD							
		IDet	180	175	0.37	0.15	0.35	0.07	1.01
		Total	542	521	0.45	0.19	0.42	0.07	1.35
Visit 6 (Week 4)	Daily	IDegAsp	362	351	0.50	0.19	0.45	0.15	1.32
		OD							
		IDet	180	174	0.38	0.16	0.37	0.07	1.04
		Total	542	525	0.46	0.19	0.43	0.07	1.32
Visit 7 (Week 5)	Daily	IDegAsp	362	349	0.50	0.19	0.46	0.14	1.30
		OD							
		IDet	180	173	0.38	0.16	0.37	0.07	1.07
		Total	542	522	0.46	0.19	0.44	0.07	1.30
Visit 8 (Week 6)	Daily	IDegAsp	362	343	0.50	0.20	0.47	0.15	1.32
		OD							
		IDet	180	172	0.40	0.17	0.39	0.08	1.10
		Total	542	515	0.47	0.19	0.44	0.08	1.32
Visit 9 (Week 7)	Daily	IDegAsp	362	342	0.50	0.20	0.47	0.16	1.32
		OD							
		IDet	180	171	0.40	0.17	0.39	0.08	1.13
		Total	542	513	0.47	0.20	0.45	0.08	1.32
Visit 10 (Week 8)	Daily	IDegAsp	362	340	0.51	0.20	0.48	0.13	1.36
		OD							
		IDet	180	171	0.41	0.17	0.41	0.07	1.16
		Total	542	511	0.48	0.20	0.45	0.07	1.36
Visit 11 (Week 9)	Daily	IDegAsp	362	334	0.51	0.21	0.48	0.13	1.39
		OD							
		IDet	180	166	0.41	0.18	0.41	0.09	1.18
		Total	542	500	0.48	0.20	0.45	0.09	1.39
Visit 12 (Week 10)	Daily	IDegAsp	362	337	0.52	0.21	0.48	0.13	1.39
		OD							
		IDet	180	169	0.42	0.18	0.42	0.09	1.16
		Total	542	506	0.48	0.20	0.46	0.09	1.39
Visit 13 (Week 11)	Daily	IDegAsp	362	334	0.52	0.21	0.48	0.15	1.43
		OD							
		IDet	180	167	0.42	0.19	0.42	0.09	1.18
		Total	542	501	0.49	0.21	0.46	0.09	1.43
Visit 14 (Week 12)	Daily	IDegAsp	362	333	0.51	0.21	0.47	0.16	1.46
		OD							
		IDet	180	167	0.42	0.18	0.41	0.03	1.18
		Total	542	500	0.48	0.21	0.45	0.03	1.46

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:59 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	324	0.52	0.22	0.48	0.15	1.46
		OD							
		IDet	180	161	0.43	0.18	0.41	0.03	1.21
		Total	542	485	0.49	0.21	0.45	0.03	1.46
Visit 16 (Week 14)	Daily	IDegAsp	362	331	0.52	0.22	0.47	0.12	1.41
		OD							
		IDet	180	165	0.43	0.18	0.41	0.06	1.24
		Total	542	496	0.49	0.21	0.46	0.06	1.41
Visit 17 (Week 15)	Daily	IDegAsp	362	327	0.52	0.22	0.48	0.15	1.40
		OD							
		IDet	180	164	0.43	0.18	0.41	0.09	1.26
		Total	542	491	0.49	0.21	0.45	0.09	1.40
Visit 18 (Week 16)	Daily	IDegAsp	362	329	0.52	0.22	0.48	0.09	1.40
		OD							
		IDet	180	163	0.43	0.19	0.41	0.07	1.28
		Total	542	492	0.49	0.21	0.45	0.07	1.40
Visit 19 (Week 17)	Daily	IDegAsp	362	322	0.52	0.22	0.48	0.15	1.37
		OD							
		IDet	180	162	0.43	0.19	0.41	0.07	1.31
		Total	542	484	0.49	0.21	0.46	0.07	1.37
Visit 20 (Week 18)	Daily	IDegAsp	362	319	0.52	0.22	0.48	0.12	1.37
		OD							
		IDet	180	158	0.44	0.20	0.43	0.06	1.34
		Total	542	477	0.50	0.22	0.46	0.06	1.37
Visit 21 (Week 19)	Daily	IDegAsp	362	319	0.52	0.22	0.49	0.15	1.37
		OD							
		IDet	180	162	0.45	0.20	0.43	0.05	1.34
		Total	542	481	0.50	0.22	0.46	0.05	1.37
Visit 22 (Week 20)	Daily	IDegAsp	362	322	0.53	0.23	0.49	0.14	1.37
		OD							
		IDet	180	158	0.44	0.20	0.41	0.05	1.34
		Total	542	480	0.50	0.22	0.46	0.05	1.37
Visit 23 (Week 21)	Daily	IDegAsp	362	319	0.53	0.22	0.49	0.13	1.37
		OD							
		IDet	180	157	0.45	0.20	0.41	0.05	1.34
		Total	542	476	0.50	0.22	0.46	0.05	1.37
Visit 24 (Week 22)	Daily	IDegAsp	362	318	0.53	0.23	0.48	0.15	1.38
		OD							
		IDet	180	156	0.45	0.21	0.43	0.06	1.34
		Total	542	474	0.50	0.22	0.46	0.06	1.38
Visit 25 (Week 23)	Daily	IDegAsp	362	320	0.53	0.23	0.48	0.12	1.41
		OD							
		IDet	180	151	0.45	0.21	0.43	0.07	1.34
		Total	542	471	0.51	0.23	0.46	0.07	1.41
Visit 26 (Week 24)	Daily	IDegAsp	362	318	0.53	0.23	0.49	0.15	1.44
		OD							
		IDet	180	157	0.46	0.21	0.43	0.08	1.34
		Total	542	475	0.51	0.23	0.46	0.08	1.44

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:59 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25) Daily		IDegAsp	362	318	0.54	0.23	0.49	0.15	1.44
		OD							
		IDet	180	155	0.47	0.22	0.43	0.09	1.34
Visit 28 (Week 26) Daily		Total	542	473	0.51	0.23	0.47	0.09	1.44
		IDegAsp	362	339	0.53	0.23	0.48	0.15	1.46
		OD							
Visit 31 (Week 28) Daily		IDet	180	165	0.46	0.23	0.43	0.09	1.37
		Total	542	504	0.51	0.23	0.46	0.09	1.46
		IDegAsp	362	250	0.52	0.23	0.47	0.16	1.45
Visit 32 (Week 29) Daily		OD							
		IDet	180	122	0.46	0.23	0.43	0.09	1.32
		Total	542	371	0.50	0.23	0.45	0.09	1.45
Visit 33 (Week 31) Daily		IDegAsp	362	251	0.53	0.24	0.47	0.13	1.48
		OD							
		IDet	180	122	0.46	0.23	0.44	0.09	1.35
Visit 34 (Week 33) Daily		Total	542	373	0.51	0.24	0.46	0.09	1.48
		IDegAsp	362	245	0.53	0.24	0.47	0.16	1.51
		OD							
Visit 35 (Week 35) Daily		IDet	180	120	0.47	0.23	0.44	0.08	1.40
		Total	542	365	0.51	0.24	0.46	0.08	1.51
		IDegAsp	362	247	0.53	0.24	0.48	0.15	1.51
Visit 36 (Week 37) Daily		OD							
		IDet	180	120	0.48	0.24	0.43	0.08	1.43
		Total	542	367	0.51	0.24	0.46	0.08	1.51
Visit 37 (Week 39) Daily		IDegAsp	362	242	0.54	0.25	0.49	0.15	1.51
		OD							
		IDet	180	118	0.48	0.24	0.44	0.08	1.46
Visit 38 (Week 41) Daily		Total	542	360	0.52	0.25	0.47	0.08	1.51
		IDegAsp	362	245	0.54	0.25	0.47	0.15	1.52
		OD							
Visit 39 (Week 43) Daily		IDet	180	118	0.48	0.24	0.43	0.07	1.49
		Total	542	363	0.52	0.25	0.46	0.07	1.52
		IDegAsp	362	237	0.54	0.25	0.47	0.15	1.55
Visit 40 (Week 45) Daily		OD							
		IDet	180	118	0.49	0.25	0.46	0.07	1.52
		Total	542	355	0.52	0.25	0.46	0.07	1.55
Visit 39 (Week 43) Daily		IDegAsp	362	241	0.54	0.25	0.48	0.13	1.55
		OD							
		IDet	180	118	0.49	0.25	0.46	0.08	1.55
Visit 40 (Week 45) Daily		Total	542	359	0.52	0.25	0.46	0.08	1.55
		IDegAsp	362	237	0.54	0.26	0.49	0.13	1.53
		OD							
Visit 40 (Week 45) Daily		IDet	180	116	0.49	0.26	0.45	0.07	1.55
		Total	542	353	0.53	0.26	0.47	0.07	1.55
		IDegAsp	362	237	0.54	0.26	0.49	0.13	1.53

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:59 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_sas.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	362	240	0.55	0.26	0.49	0.12	1.56
		OD							
		IDet	180	116	0.49	0.26	0.46	0.09	1.55
		Total	542	356	0.53	0.26	0.47	0.09	1.56
Visit 42 (Week 49)	Daily	IDegAsp	362	234	0.55	0.26	0.49	0.07	1.59
		OD							
		IDet	180	113	0.50	0.26	0.46	0.09	1.49
		Total	542	347	0.53	0.26	0.48	0.07	1.59
Visit 43 (Week 51)	Daily	IDegAsp	362	232	0.55	0.27	0.49	0.11	1.62
		OD							
		IDet	180	112	0.50	0.26	0.46	0.09	1.52
		Total	542	344	0.54	0.27	0.48	0.09	1.62
Visit 44 (Week 53)	Daily	IDegAsp	362	236	0.55	0.27	0.50	0.15	1.60
		OD							
		IDet	180	113	0.51	0.26	0.46	0.09	1.60
		Total	542	349	0.54	0.27	0.48	0.09	1.60
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	0.54	0.25	0.48	0.15	1.60
		OD							
		IDet	180	178	0.49	0.26	0.44	0.09	1.60
		Total	542	538	0.52	0.26	0.46	0.09	1.60

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:29:59 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_sas.txt

14.2.14: IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Extension Trial Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			EXT	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	254	254	0.47	0.19	0.44	0.13	1.19
		OD							
		IDet	122	121	0.34	0.12	0.32	0.10	0.87
		Total	376	375	0.43	0.18	0.39	0.10	1.19
Visit 4 (Week 2)	Daily	IDegAsp	254	254	0.49	0.19	0.44	0.15	1.21
		OD							
		IDet	122	122	0.36	0.14	0.33	0.07	0.90
		Total	376	376	0.44	0.19	0.41	0.07	1.21
Visit 5 (Week 3)	Daily	IDegAsp	254	250	0.50	0.19	0.45	0.15	1.23
		OD							
		IDet	122	121	0.37	0.14	0.36	0.07	0.95
		Total	376	371	0.45	0.19	0.42	0.07	1.23
Visit 6 (Week 4)	Daily	IDegAsp	254	254	0.50	0.19	0.47	0.15	1.26
		OD							
		IDet	122	121	0.38	0.15	0.38	0.07	1.01
		Total	376	375	0.46	0.19	0.44	0.07	1.26
Visit 7 (Week 5)	Daily	IDegAsp	254	253	0.51	0.20	0.48	0.14	1.30
		OD							
		IDet	122	120	0.39	0.15	0.37	0.07	1.07
		Total	376	373	0.47	0.19	0.44	0.07	1.30
Visit 8 (Week 6)	Daily	IDegAsp	254	252	0.51	0.20	0.48	0.15	1.32
		OD							
		IDet	122	121	0.40	0.16	0.39	0.08	1.10
		Total	376	373	0.47	0.19	0.45	0.08	1.32
Visit 9 (Week 7)	Daily	IDegAsp	254	253	0.51	0.20	0.48	0.16	1.32
		OD							
		IDet	122	121	0.40	0.17	0.39	0.08	1.13
		Total	376	374	0.48	0.20	0.46	0.08	1.32
Visit 10 (Week 8)	Daily	IDegAsp	254	254	0.52	0.21	0.49	0.13	1.36
		OD							
		IDet	122	121	0.41	0.17	0.41	0.07	1.16
		Total	376	375	0.48	0.20	0.45	0.07	1.36
Visit 11 (Week 9)	Daily	IDegAsp	254	250	0.52	0.21	0.49	0.13	1.39
		OD							
		IDet	122	121	0.41	0.18	0.40	0.09	1.18
		Total	376	371	0.49	0.21	0.46	0.09	1.39
Visit 12 (Week 10)	Daily	IDegAsp	254	254	0.52	0.21	0.50	0.13	1.39
		OD							
		IDet	122	121	0.42	0.18	0.42	0.09	1.16
		Total	376	375	0.49	0.21	0.47	0.09	1.39
Visit 13 (Week 11)	Daily	IDegAsp	254	252	0.53	0.22	0.50	0.15	1.43
		OD							
		IDet	122	120	0.42	0.19	0.41	0.09	1.18
		Total	376	372	0.49	0.22	0.46	0.09	1.43
Visit 14 (Week 12)	Daily	IDegAsp	254	253	0.52	0.22	0.48	0.16	1.46
		OD							
		IDet	122	122	0.42	0.18	0.41	0.03	1.18
		Total	376	375	0.49	0.21	0.46	0.03	1.46

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:30:09 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_ets.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Extension Trial Set

Visit	Endpoint	Treatment	EXT	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	254	249	0.52	0.22	0.49	0.15	1.46
		OD							
		IDet	122	119	0.42	0.18	0.41	0.03	1.21
		Total	376	368	0.49	0.22	0.46	0.03	1.46
Visit 16 (Week 14)	Daily	IDegAsp	254	254	0.52	0.23	0.48	0.12	1.41
		OD							
		IDet	122	122	0.43	0.18	0.41	0.06	1.24
		Total	376	376	0.49	0.22	0.46	0.06	1.41
Visit 17 (Week 15)	Daily	IDegAsp	254	250	0.53	0.23	0.48	0.15	1.40
		OD							
		IDet	122	122	0.43	0.18	0.42	0.09	1.26
		Total	376	372	0.50	0.22	0.45	0.09	1.40
Visit 18 (Week 16)	Daily	IDegAsp	254	254	0.52	0.23	0.47	0.09	1.40
		OD							
		IDet	122	122	0.43	0.19	0.41	0.07	1.28
		Total	376	376	0.49	0.22	0.45	0.07	1.40
Visit 19 (Week 17)	Daily	IDegAsp	254	247	0.53	0.23	0.48	0.15	1.37
		OD							
		IDet	122	121	0.43	0.19	0.42	0.07	1.31
		Total	376	368	0.50	0.22	0.46	0.07	1.37
Visit 20 (Week 18)	Daily	IDegAsp	254	249	0.53	0.23	0.47	0.12	1.37
		OD							
		IDet	122	119	0.44	0.20	0.42	0.06	1.34
		Total	376	368	0.50	0.22	0.46	0.06	1.37
Visit 21 (Week 19)	Daily	IDegAsp	254	248	0.53	0.23	0.48	0.15	1.37
		OD							
		IDet	122	122	0.44	0.20	0.43	0.05	1.34
		Total	376	370	0.50	0.22	0.46	0.05	1.37
Visit 22 (Week 20)	Daily	IDegAsp	254	252	0.53	0.23	0.49	0.15	1.37
		OD							
		IDet	122	120	0.44	0.20	0.41	0.05	1.34
		Total	376	372	0.50	0.23	0.45	0.05	1.37
Visit 23 (Week 21)	Daily	IDegAsp	254	249	0.53	0.23	0.48	0.13	1.37
		OD							
		IDet	122	122	0.45	0.20	0.43	0.05	1.34
		Total	376	371	0.50	0.22	0.46	0.05	1.37
Visit 24 (Week 22)	Daily	IDegAsp	254	249	0.54	0.24	0.48	0.15	1.38
		OD							
		IDet	122	121	0.45	0.20	0.43	0.06	1.34
		Total	376	370	0.51	0.23	0.46	0.06	1.38
Visit 25 (Week 23)	Daily	IDegAsp	254	252	0.53	0.24	0.48	0.12	1.41
		OD							
		IDet	122	116	0.45	0.21	0.43	0.07	1.34
		Total	376	368	0.51	0.23	0.46	0.07	1.41
Visit 26 (Week 24)	Daily	IDegAsp	254	251	0.53	0.24	0.48	0.15	1.44
		OD							
		IDet	122	122	0.46	0.21	0.43	0.08	1.34
		Total	376	373	0.51	0.23	0.46	0.08	1.44

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:30:09 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_ets.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Extension Trial Set

Visit	Endpoint	Treatment	EXT	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	254	252	0.54	0.24	0.49	0.15	1.44
		OD							
		IDet	122	121	0.46	0.22	0.44	0.09	1.34
Visit 28 (Week 26)	Daily	Total	376	373	0.51	0.23	0.46	0.09	1.44
		IDegAsp	254	254	0.53	0.24	0.49	0.15	1.46
		OD							
Visit 31 (Week 28)	Daily	IDet	122	122	0.46	0.22	0.44	0.09	1.33
		Total	376	376	0.51	0.23	0.46	0.09	1.46
Visit 32 (Week 29)	Daily	IDegAsp	254	250	0.52	0.23	0.47	0.16	1.45
		OD							
		IDet	122	121	0.46	0.22	0.43	0.09	1.32
Visit 33 (Week 31)	Daily	Total	376	371	0.50	0.23	0.45	0.09	1.45
		IDegAsp	254	251	0.53	0.24	0.47	0.13	1.48
		OD							
Visit 34 (Week 33)	Daily	IDet	122	122	0.46	0.23	0.44	0.09	1.35
		Total	376	373	0.51	0.24	0.46	0.09	1.48
Visit 35 (Week 35)	Daily	IDegAsp	254	245	0.53	0.24	0.47	0.16	1.51
		OD							
		IDet	122	120	0.47	0.23	0.44	0.08	1.40
Visit 36 (Week 37)	Daily	Total	376	365	0.51	0.24	0.46	0.08	1.51
		IDegAsp	254	247	0.53	0.24	0.48	0.15	1.51
		OD							
Visit 37 (Week 39)	Daily	IDet	122	120	0.48	0.24	0.43	0.08	1.43
		Total	376	367	0.51	0.24	0.46	0.08	1.51
		IDegAsp	254	242	0.54	0.25	0.49	0.15	1.51
Visit 38 (Week 41)	Daily	OD							
		IDet	122	118	0.48	0.24	0.44	0.08	1.46
		Total	376	360	0.52	0.25	0.47	0.08	1.51
Visit 39 (Week 43)	Daily	IDegAsp	254	245	0.54	0.25	0.47	0.15	1.52
		OD							
		IDet	122	118	0.48	0.24	0.43	0.07	1.49
Visit 40 (Week 45)	Daily	Total	376	363	0.52	0.25	0.46	0.07	1.52
		IDegAsp	254	237	0.54	0.25	0.47	0.15	1.55
		OD							
Visit 39 (Week 43)	Daily	IDet	122	118	0.49	0.25	0.46	0.07	1.52
		Total	376	355	0.52	0.25	0.46	0.07	1.55
		IDegAsp	254	241	0.54	0.25	0.48	0.13	1.55
Visit 40 (Week 45)	Daily	OD							
		IDet	122	116	0.49	0.26	0.45	0.07	1.55
		Total	376	353	0.53	0.26	0.47	0.07	1.55

N = Number of Subjects, SD = Standard Deviation

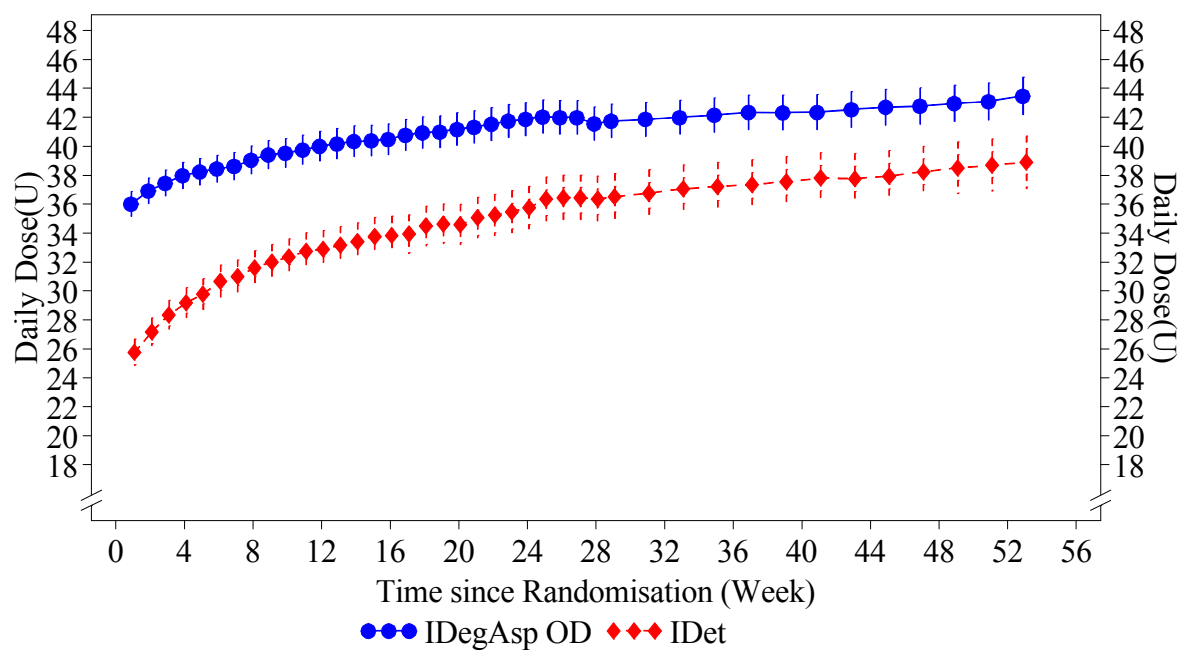
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:30:09 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_ets.txt

IDegAsp/Comparator Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Extension Trial Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			EXT	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	254	240	0.55	0.26	0.49	0.12	1.56
		OD							
		IDet	122	116	0.49	0.26	0.46	0.09	1.55
		Total	376	356	0.53	0.26	0.47	0.09	1.56
Visit 42 (Week 49)	Daily	IDegAsp	254	234	0.55	0.26	0.49	0.07	1.59
		OD							
		IDet	122	113	0.50	0.26	0.46	0.09	1.49
		Total	376	347	0.53	0.26	0.48	0.07	1.59
Visit 43 (Week 51)	Daily	IDegAsp	254	232	0.55	0.27	0.49	0.11	1.62
		OD							
		IDet	122	112	0.50	0.26	0.46	0.09	1.52
		Total	376	344	0.54	0.27	0.48	0.09	1.62
Visit 44 (Week 53)	Daily	IDegAsp	254	236	0.55	0.27	0.50	0.15	1.60
		OD							
		IDet	122	113	0.51	0.26	0.46	0.09	1.60
		Total	376	349	0.54	0.27	0.48	0.09	1.60
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	254	254	0.55	0.27	0.50	0.15	1.60
		OD							
		IDet	122	122	0.51	0.27	0.46	0.09	1.60
		Total	376	376	0.54	0.27	0.48	0.09	1.60

N = Number of Subjects, SD = Standard Deviation

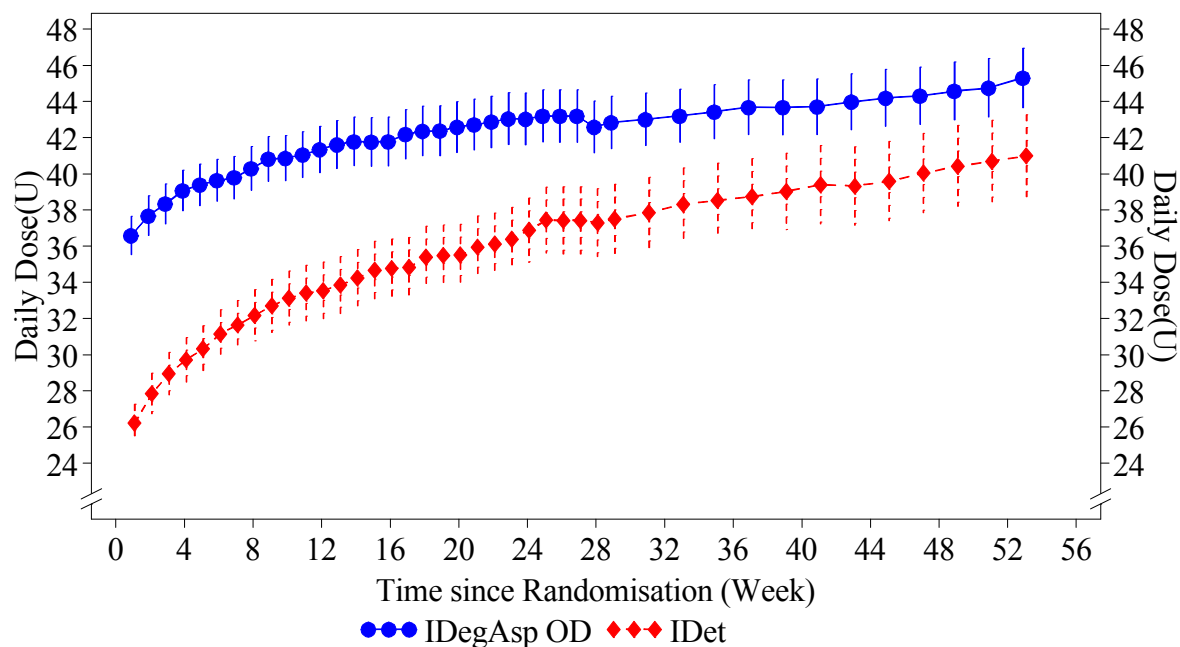
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:30:09 - tdesc_numfind_tpl_t021_v01.sas/t_ins_dose_act_ukg_descp_ets.txt



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:30:20 - fmean_numfind_v03.sas/e_ins_dose_d_act_u_mean_locf_sas.cgm

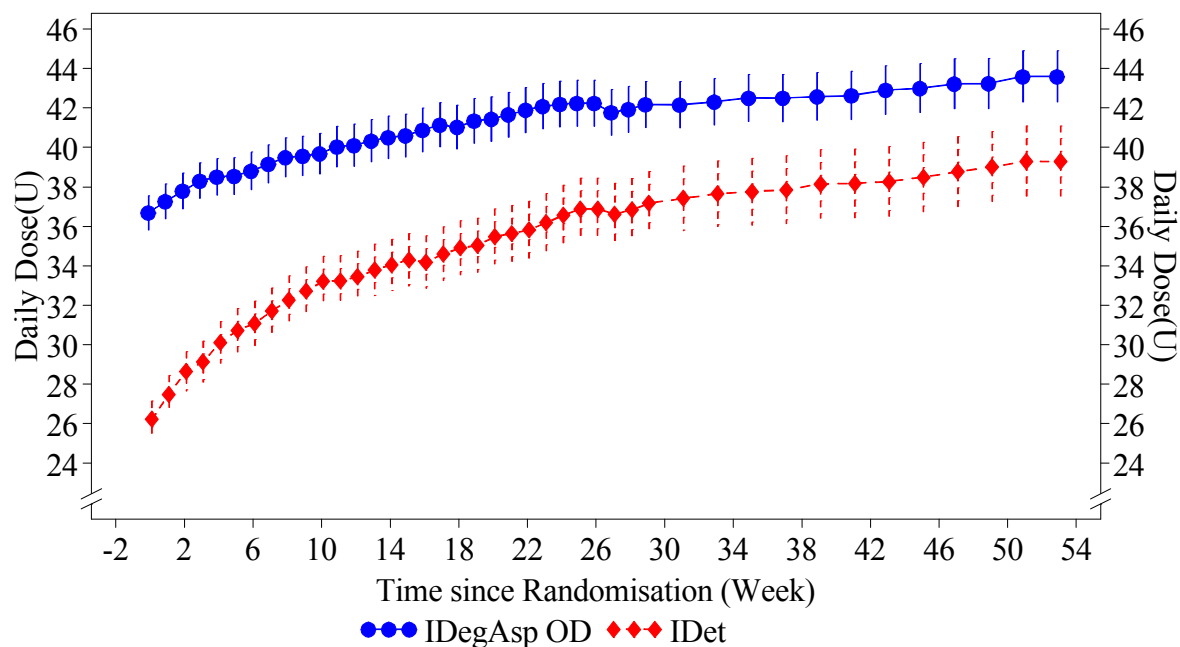
14.2.15: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



EXT: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:30:29 - fmean_numfind_v03.sas/e_ins_dose_d_act_u_mean_locf_ets.cgm

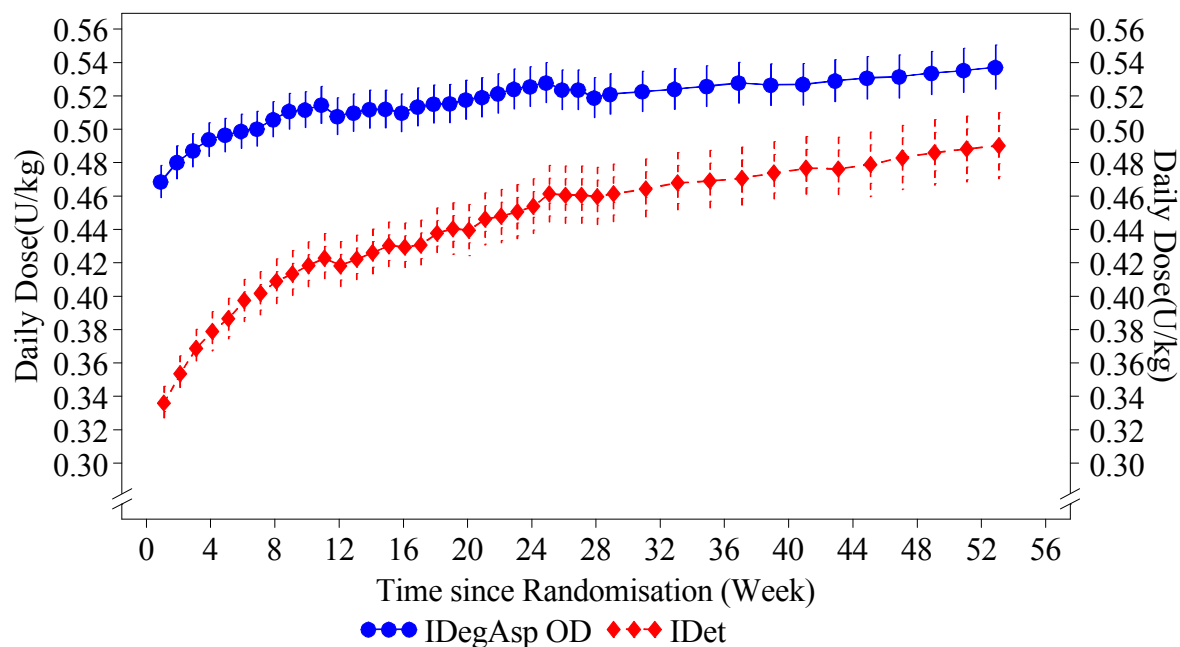
14.2.16: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Extension Trial Set



SAFETY: LOCF imputed data
Error bars: +/-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:30:39 - fmean_numfind_v03.sas/e_ins_d_prscb_u_mean_locf_sas.cgm

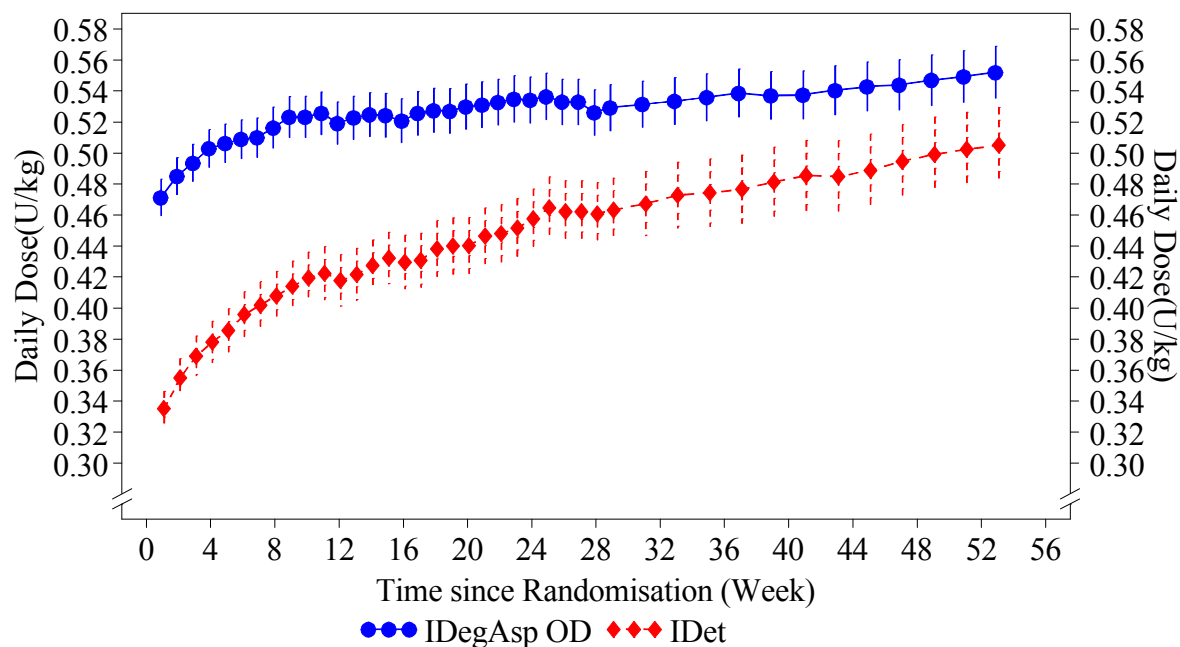
14.2.17: Daily IDegAsp/Comparator (Prescribed) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:30:49 - fmean_numfind_v03.sas/e_ins_d_act_ukg_mean_locf_sas.cgm

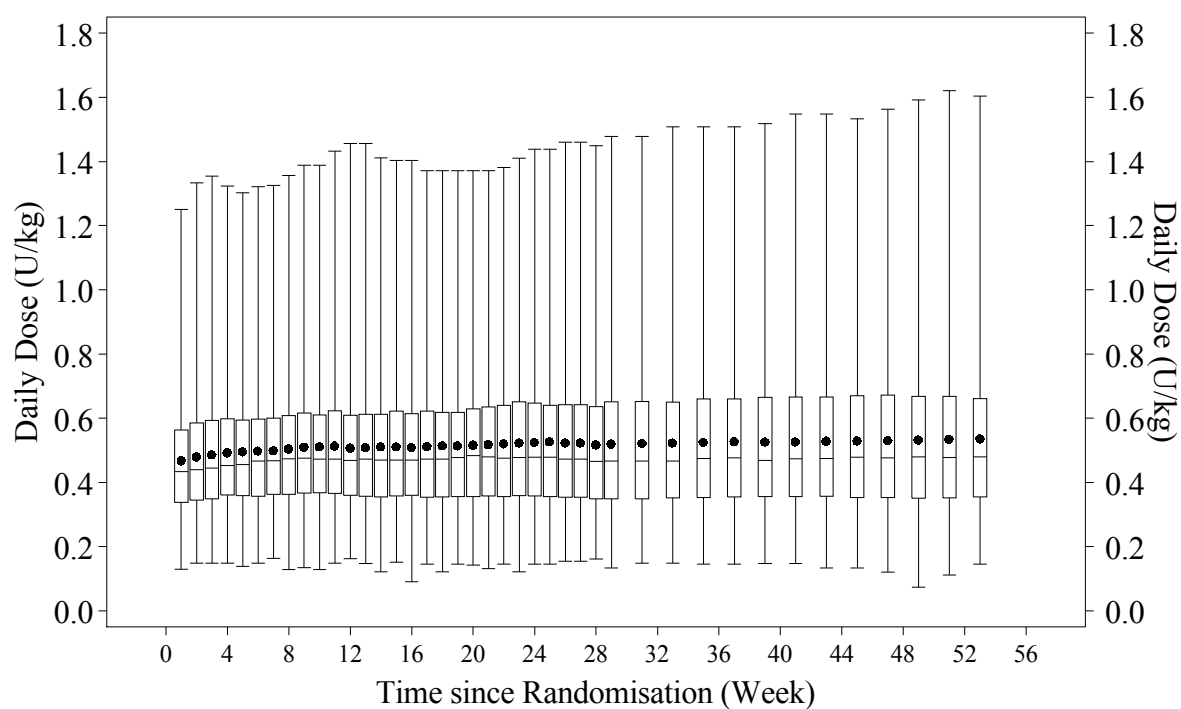
14.2.18: Daily IDegAsp/Comparator (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



EXT: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:30:59 - fmean_numfind_v03.sas/e_ins_d_act_ukg_mean_locf_ets.cgm

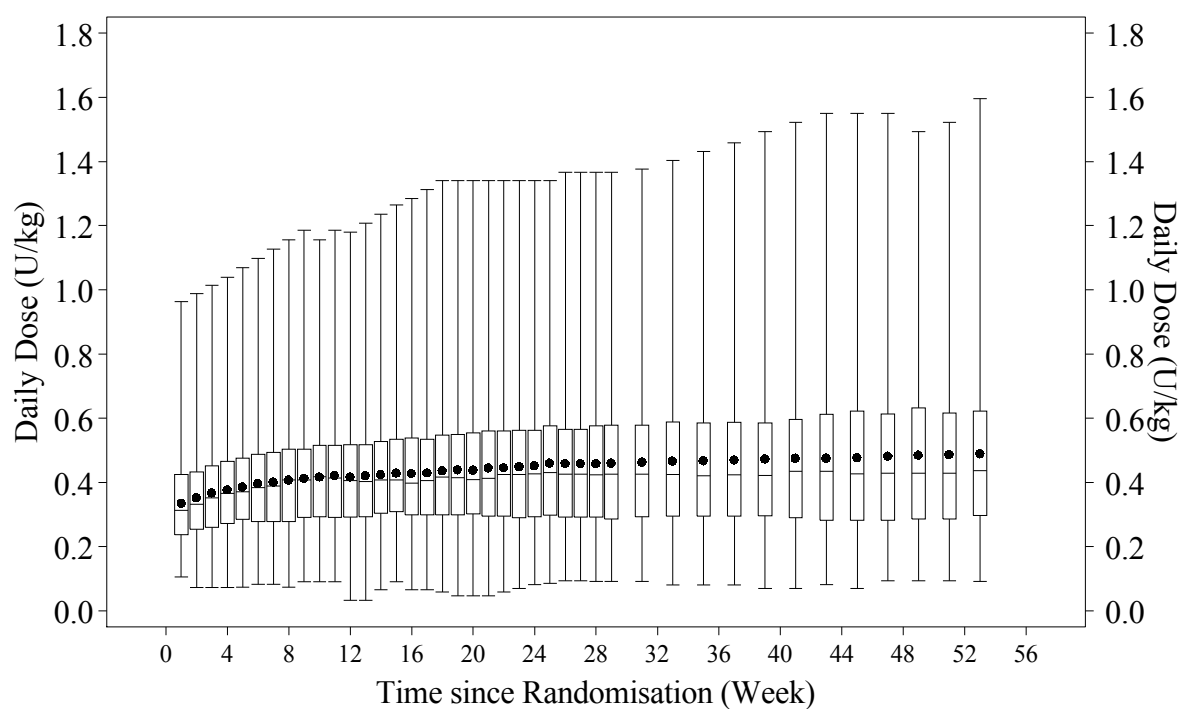
14.2.19: Daily IDegAsp/Comparator (Actual) in Units/kg by Treatment Week - Mean Plot - Extension Trial Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:31:09 - fbox_numfind_v01.sas/e_ins_d_iv1_act_ukg_box_locf_sas.cgm

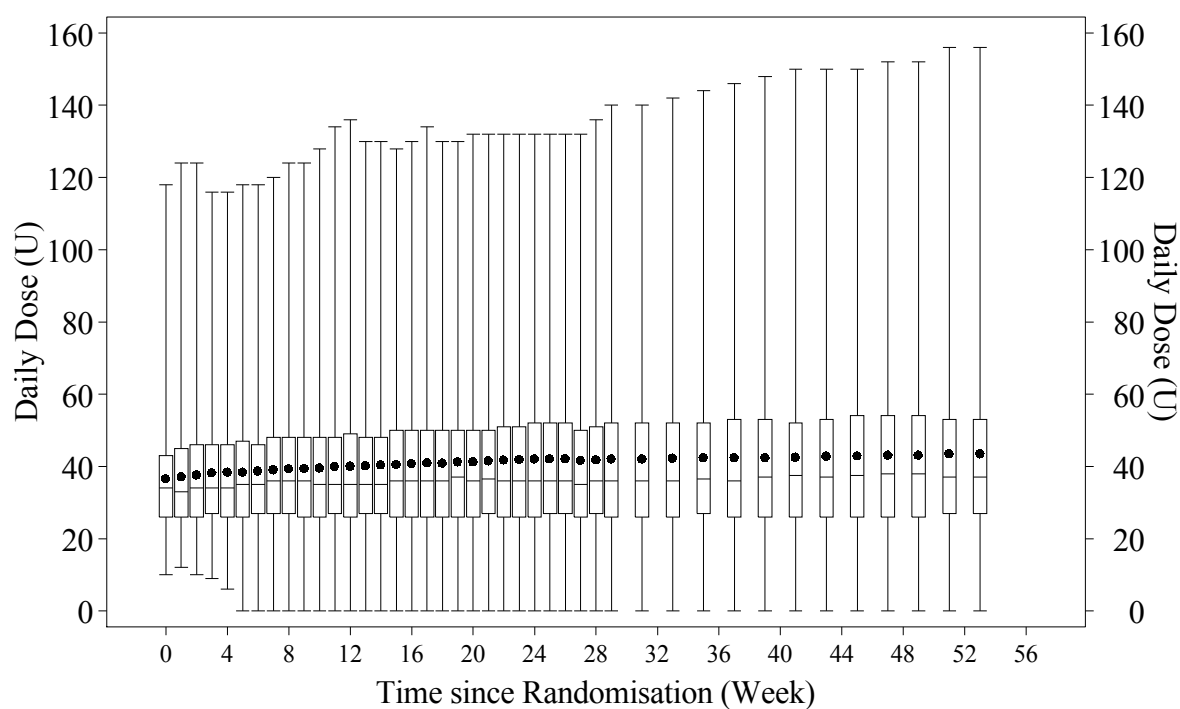
14.2.20: Daily IDegAsp OD Dose (Actual) in Units/kg by Treatment Week - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

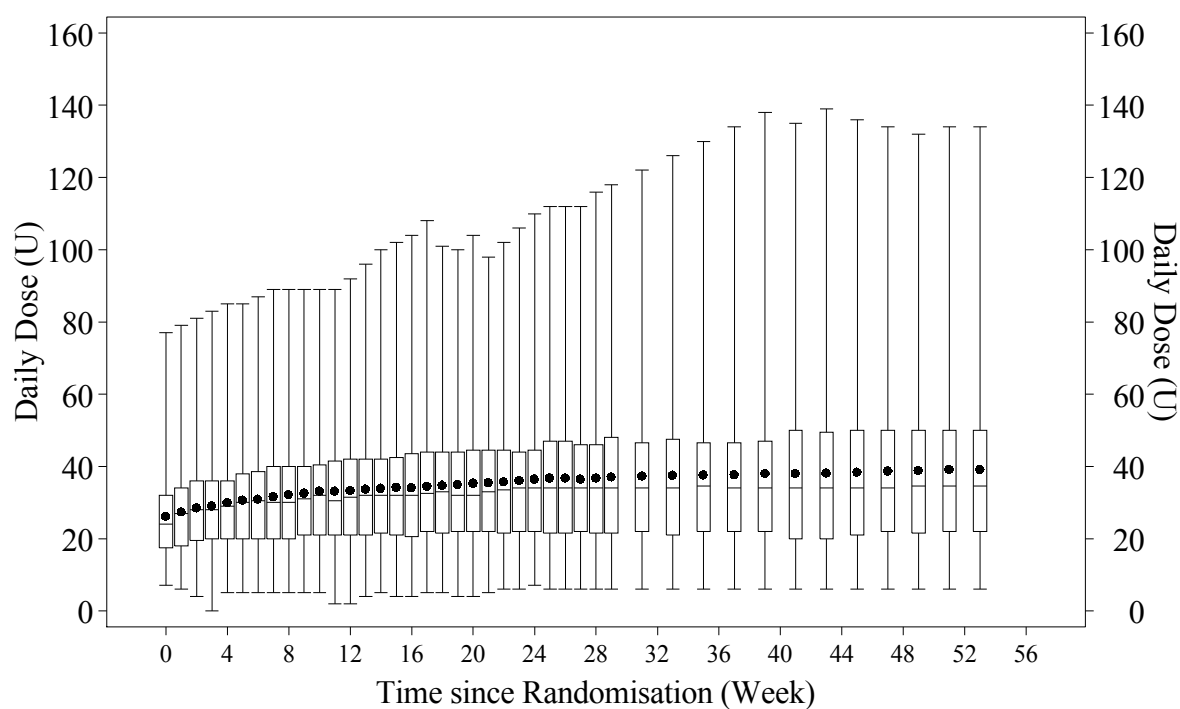
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:31:18 - fbox_numfind_v01.sas/e_ins_d_com_act_ukg_box_locf_sas.cgm

14.2.21: Daily IDet Dose (Actual) in Units/kg by Treatment Week - Box Plot - Safety Analysis Set



nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:31:28 - fbox_numfind_v01.sas/e_ins_d_iv1_prscl_u_box_locl_sas.cgm

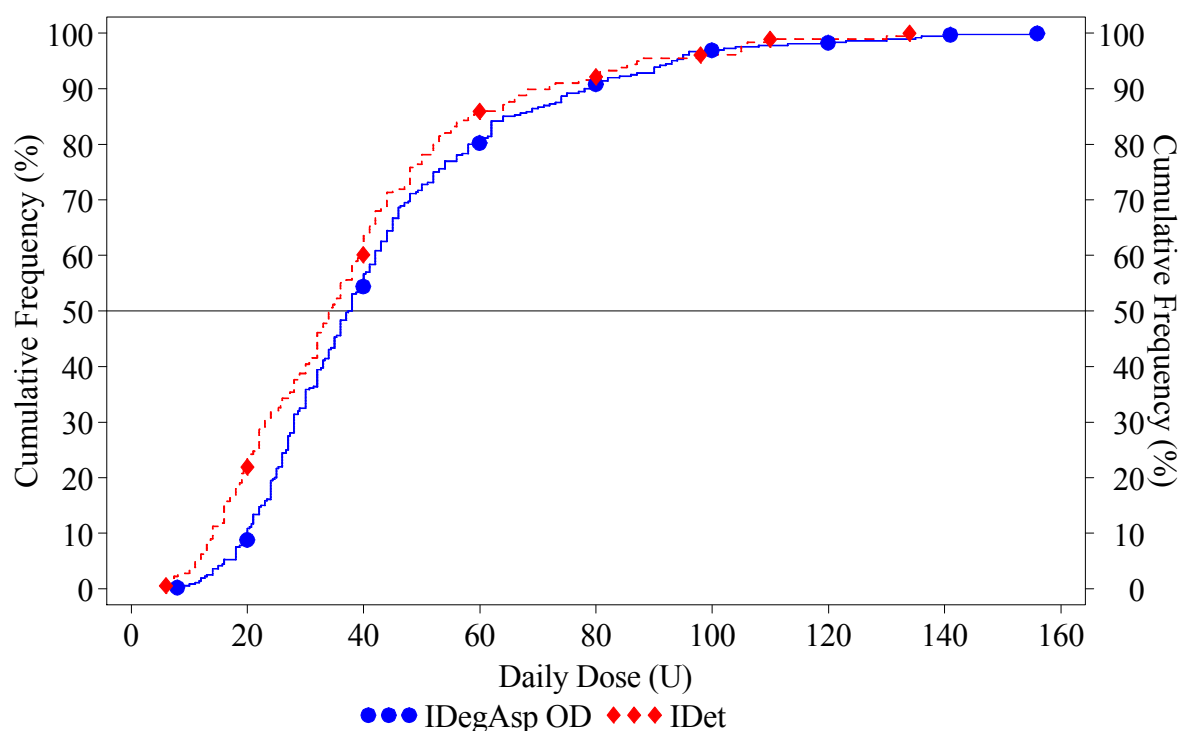
14.2.22: Daily IDegAsp OD Dose (Prescribed) in Units by Treatment Week - Box Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:31:37 - fbox_numfind_v01.sas/e_ins_d_com_prscl_u_box_locl_sas.cgm

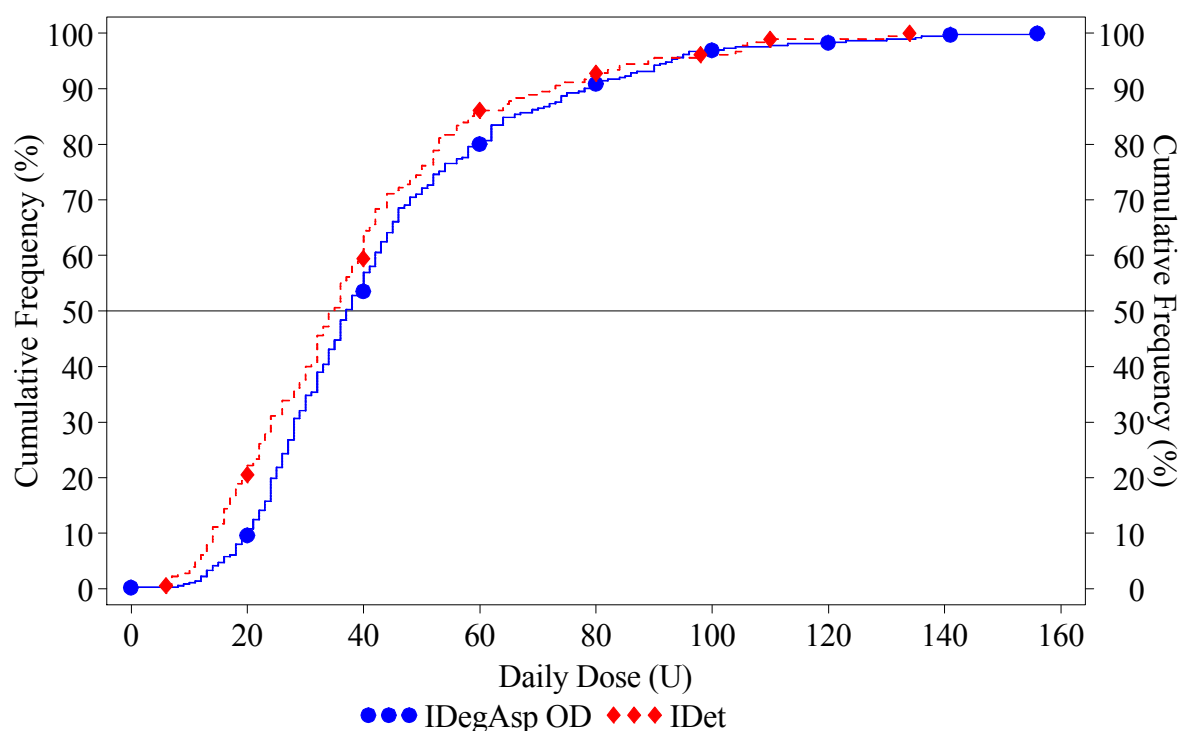
14.2.23: Daily IDet Dose (Prescribed) in Units by Treatment Week - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:31:46 - fedist_numfind_v01.sas/e_ins_dose_d_act_u_cdf_locf_sas.cgm

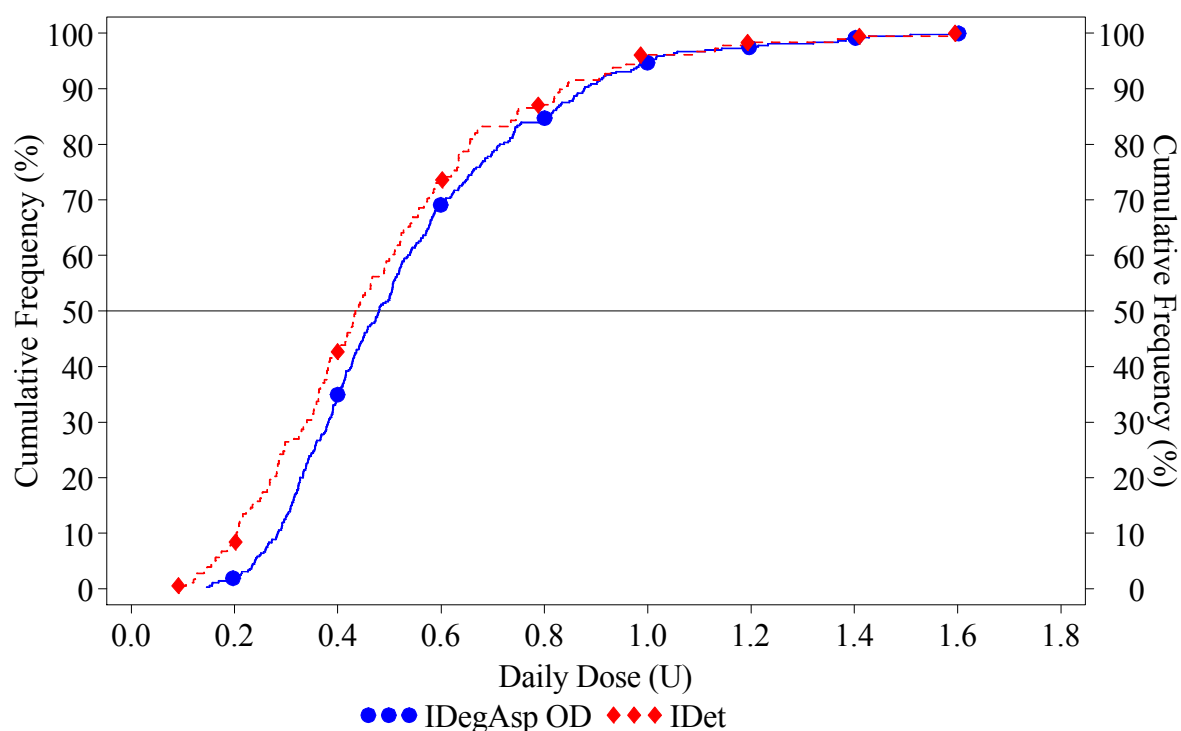
14.2.24: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:31:55 - fedist_numfind_v01.sas/e_ins_d_prscb_u_cdf_locf_sas.cgm

14.2.25: Daily IDegAsp/Comparator Insulin Dose (Prescribed) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:03 - fedist_numfind_v01.sas/e_ins_d_act_ukg_cdf_locf_sas.cgm

14.2.26: Daily IDegAsp/Comparator Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.2.27: Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	362	360	21	13	18	2	100
		IDet	180	176	30	15	28	5	130
		Total	542	536	24	14	20	2	130
	Breakfast	IDegAsp OD	362	307	10	6	8	2	48
		IDet	180	172	9	5	8	0	30
		Total	542	479	9	6	8	0	48
	Lunch	IDegAsp OD	362	299	10	6	9	2	53
		IDet	180	176	9	5	9	0	40
		Total	542	475	10	5	9	0	53
	Main Evening Meal	IDegAsp OD	362	145	9	7	8	0	48
		IDet	180	173	11	6	10	2	60
		Total	542	318	10	7	9	0	60
	Other	IDegAsp OD	362	108	6	5	5	0	30
		IDet	180	78	7	5	6	0	24
		Total	542	186	6	5	5	0	30
Visit 4 (Week 2)	Daily	IDegAsp OD	362	359	21	13	19	1	110
		IDet	180	176	32	16	29	8	132
		Total	542	535	24	14	21	1	132
	Breakfast	IDegAsp OD	362	301	10	6	9	0	50
		IDet	180	172	9	5	8	0	32
		Total	542	473	10	6	9	0	50
	Lunch	IDegAsp OD	362	297	10	6	9	0	60
		IDet	180	176	10	5	9	0	40
		Total	542	473	10	6	9	0	60
	Main Evening Meal	IDegAsp OD	362	142	9	7	8	0	48
		IDet	180	175	11	6	10	2	60
		Total	542	317	10	6	10	0	60
	Other	IDegAsp OD	362	86	5	4	4	0	24
		IDet	180	68	6	4	5	0	20
		Total	542	154	6	4	5	0	24
Visit 5 (Week 3)	Daily	IDegAsp OD	362	346	22	13	19	0	108
		IDet	180	175	34	17	30	6	138
		Total	542	521	26	16	23	0	138
	Breakfast	IDegAsp OD	362	293	10	7	8	0	53
		IDet	180	170	10	6	10	1	36
		Total	542	463	10	7	9	0	53

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 5 (Week 3)	Lunch	IDegAsp OD	362	286	11	6	10	0	55
		IDet	180	175	11	6	10	0	40
		Total	542	461	11	6	10	0	55
	Main Evening Meal	IDegAsp OD	362	140	9	6	7	0	48
		IDet	180	174	12	7	11	2	62
		Total	542	314	10	7	10	0	62
	Other	IDegAsp OD	362	91	5	4	4	0	22
		IDet	180	55	6	4	5	1	16
		Total	542	146	5	4	4	0	22
Visit 6 (Week 4)	Daily	IDegAsp OD	362	351	22	14	19	2	115
		IDet	180	174	36	19	32	9	142
		Total	542	525	27	17	24	2	142
	Breakfast	IDegAsp OD	362	300	10	7	8	1	50
		IDet	180	171	11	6	10	0	40
		Total	542	471	10	7	9	0	50
	Lunch	IDegAsp OD	362	288	11	7	10	0	55
		IDet	180	174	12	6	10	1	40
		Total	542	462	11	6	10	0	55
	Main Evening Meal	IDegAsp OD	362	144	9	7	8	0	48
		IDet	180	174	13	7	12	3	62
		Total	542	318	11	7	10	0	62
	Other	IDegAsp OD	362	87	5	4	4	0	30
		IDet	180	59	6	4	5	0	22
		Total	542	146	6	4	4	0	30
Visit 7 (Week 5)	Daily	IDegAsp OD	362	349	22	14	19	0	113
		IDet	180	173	37	20	33	5	158
		Total	542	522	27	17	24	0	158
	Breakfast	IDegAsp OD	362	293	11	7	8	0	58
		IDet	180	172	11	7	10	0	48
		Total	542	465	11	7	9	0	58
	Lunch	IDegAsp OD	362	285	11	7	10	0	55
		IDet	180	173	12	7	10	1	44
		Total	542	458	12	7	10	0	55

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 7 (Week 5)	Main Evening Meal	IDegAsp OD	362	140	9	7	8	0	48
		IDet	180	173	13	8	12	3	66
		Total	542	313	11	7	10	0	66
	Other	IDegAsp OD	362	85	4	3	4	0	11
		IDet	180	53	6	4	5	1	20
		Total	542	138	5	3	4	0	20
Visit 8 (Week 6)	Daily	IDegAsp OD	362	343	23	14	19	1	115
		IDet	180	172	37	22	32	6	158
		Total	542	515	28	18	24	1	158
	Breakfast	IDegAsp OD	362	292	11	8	9	0	60
		IDet	180	170	11	7	9	0	48
		Total	542	462	11	8	9	0	60
	Lunch	IDegAsp OD	362	282	12	7	10	1	55
		IDet	180	172	12	7	10	1	44
		Total	542	454	12	7	10	1	55
	Main Evening Meal	IDegAsp OD	362	139	9	7	8	0	48
		IDet	180	172	14	8	12	3	66
		Total	542	311	12	8	10	0	66
	Other	IDegAsp OD	362	78	4	3	4	0	12
		IDet	180	59	6	4	5	2	24
		Total	542	137	5	4	4	0	24
Visit 9 (Week 7)	Daily	IDegAsp OD	362	342	23	15	18	0	115
		IDet	180	171	38	22	34	5	158
		Total	542	513	28	19	23	0	158
	Breakfast	IDegAsp OD	362	292	11	8	8	0	60
		IDet	180	168	11	8	10	0	48
		Total	542	460	11	8	9	0	60
	Lunch	IDegAsp OD	362	282	12	8	10	0	55
		IDet	180	170	13	7	11	1	44
		Total	542	452	12	8	10	0	55
	Main Evening Meal	IDegAsp OD	362	134	9	7	8	0	48
		IDet	180	170	14	8	12	3	66
		Total	542	304	12	8	10	0	66

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 9 (Week 7)	Other	IDegAsp OD	362	79	4	3	4	0	14
		IDet	180	48	6	5	5	1	30
		Total	542	127	5	4	4	0	30
Visit 10 (Week 8)	Daily	IDegAsp OD	362	340	23	16	19	2	120
		IDet	180	171	39	22	36	5	130
		Total	542	511	29	19	24	2	130
	Breakfast	IDegAsp OD	362	289	11	8	8	1	60
		IDet	180	170	12	7	10	0	42
		Total	542	459	11	8	9	0	60
	Lunch	IDegAsp OD	362	277	12	8	10	1	60
		IDet	180	171	13	7	12	1	44
		Total	542	448	12	8	11	1	60
	Main Evening Meal	IDegAsp OD	362	139	10	7	8	0	48
		IDet	180	171	14	9	12	2	80
		Total	542	310	12	9	11	0	80
	Other	IDegAsp OD	362	83	5	3	4	0	12
		IDet	180	56	6	6	5	0	36
		Total	542	139	5	5	4	0	36
Visit 11 (Week 9)	Daily	IDegAsp OD	362	335	24	16	20	2	120
		IDet	180	166	39	23	34	7	140
		Total	542	501	29	20	24	2	140
	Breakfast	IDegAsp OD	362	282	11	8	8	1	60
		IDet	180	165	11	8	10	1	44
		Total	542	447	11	8	9	1	60
	Lunch	IDegAsp OD	362	272	13	8	11	2	60
		IDet	180	164	13	8	11	2	48
		Total	542	436	13	8	11	2	60
	Main Evening Meal	IDegAsp OD	362	137	10	7	8	0	50
		IDet	180	166	14	9	12	2	60
		Total	542	303	12	8	11	0	60
	Other	IDegAsp OD	362	86	4	3	4	0	14
		IDet	180	41	6	5	5	2	24
		Total	542	127	5	4	4	0	24
Visit 12 (Week 10)	Daily	IDegAsp OD	362	338	24	16	19	3	120
		IDet	180	169	39	23	34	7	146
		Total	542	507	29	20	24	3	146

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 12 (Week 10)	Breakfast	IDegAsp OD	362	286	11	8	9	1	60
		IDet	180	167	11	8	10	0	46
		Total	542	453	11	8	9	0	60
	Lunch	IDegAsp OD	362	275	13	8	10	2	60
		IDet	180	169	13	8	11	2	50
		Total	542	444	13	8	10	2	60
	Main Evening Meal	IDegAsp OD	362	138	10	7	8	0	50
		IDet	180	169	14	9	12	2	70
		Total	542	307	12	8	10	0	70
	Other	IDegAsp OD	362	90	5	3	4	0	14
		IDet	180	52	6	5	4	1	30
		Total	542	142	5	4	4	0	30
Visit 13 (Week 11)	Daily	IDegAsp OD	362	335	25	16	20	2	105
		IDet	180	167	39	23	34	8	153
		Total	542	502	29	20	25	2	153
	Breakfast	IDegAsp OD	362	281	11	8	8	1	50
		IDet	180	166	12	8	9	0	50
		Total	542	447	11	8	9	0	50
	Lunch	IDegAsp OD	362	276	13	8	10	1	48
		IDet	180	167	13	8	11	2	50
		Total	542	443	13	8	10	1	50
	Main Evening Meal	IDegAsp OD	362	140	10	8	8	0	50
		IDet	180	167	14	9	13	2	57
		Total	542	307	12	8	10	0	57
	Other	IDegAsp OD	362	82	5	3	4	0	14
		IDet	180	45	6	4	5	0	24
		Total	542	127	5	3	4	0	24
Visit 14 (Week 12)	Daily	IDegAsp OD	362	334	25	17	19	4	124
		IDet	180	167	40	23	34	7	163
		Total	542	501	30	20	25	4	163
	Breakfast	IDegAsp OD	362	283	11	9	8	0	62
		IDet	180	167	11	8	10	0	54
		Total	542	450	11	9	9	0	62
	Lunch	IDegAsp OD	362	275	13	9	10	1	62
		IDet	180	166	13	8	11	0	53
		Total	542	441	13	9	10	0	62

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 14 (Week 12)	Main Evening Meal	IDegAsp OD	362	135	10	8	8	0	50
		IDet	180	166	14	8	12	3	56
		Total	542	301	13	8	11	0	56
	Other	IDegAsp OD	362	82	5	3	4	0	12
		IDet	180	55	5	3	4	0	11
		Total	542	137	5	3	4	0	12
Visit 15 (Week 13)	Daily	IDegAsp OD	362	325	25	18	19	3	124
		IDet	180	160	40	24	34	8	170
		Total	542	485	30	21	24	3	170
	Breakfast	IDegAsp OD	362	276	12	9	8	2	62
		IDet	180	159	12	9	10	0	57
		Total	542	435	12	9	9	0	62
	Lunch	IDegAsp OD	362	263	13	9	10	0	62
		IDet	180	160	13	8	11	2	55
		Total	542	423	13	9	11	0	62
	Main Evening Meal	IDegAsp OD	362	135	10	8	8	0	50
		IDet	180	160	14	9	13	1	58
		Total	542	295	12	9	11	0	58
	Other	IDegAsp OD	362	75	4	3	4	0	15
		IDet	180	48	5	4	5	0	26
		Total	542	123	5	4	4	0	26
Visit 16 (Week 14)	Daily	IDegAsp OD	362	332	25	18	19	4	126
		IDet	180	165	40	25	34	6	177
		Total	542	497	30	22	25	4	177
	Breakfast	IDegAsp OD	362	279	12	9	9	2	64
		IDet	180	165	12	9	10	1	60
		Total	542	444	12	9	9	1	64
	Lunch	IDegAsp OD	362	272	13	10	10	2	62
		IDet	180	164	13	9	11	1	55
		Total	542	436	13	9	10	1	62
	Main Evening Meal	IDegAsp OD	362	139	10	8	8	0	50
		IDet	180	165	14	9	12	2	62
		Total	542	304	12	9	10	0	62

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 16 (Week 14)	Other	IDegAsp OD	362	81	5	3	4	0	15
		IDet	180	53	5	4	4	0	18
		Total	542	134	5	3	4	0	18
Visit 17 (Week 15)	Daily	IDegAsp OD	362	328	25	18	19	3	132
		IDet	180	164	40	26	33	5	182
		Total	542	492	30	22	25	3	182
	Breakfast	IDegAsp OD	362	276	12	9	9	1	68
		IDet	180	162	12	9	10	0	60
		Total	542	438	12	9	9	0	68
	Lunch	IDegAsp OD	362	270	13	10	10	1	64
		IDet	180	163	13	9	11	0	57
		Total	542	433	13	9	10	0	64
	Main Evening Meal	IDegAsp OD	362	133	10	8	8	0	50
		IDet	180	162	14	9	12	2	65
		Total	542	295	12	9	10	0	65
	Other	IDegAsp OD	362	70	5	3	4	0	18
		IDet	180	51	5	3	4	0	15
		Total	542	121	5	3	4	0	18
Visit 18 (Week 16)	Daily	IDegAsp OD	362	330	26	19	20	3	138
		IDet	180	163	40	26	34	4	181
		Total	542	493	30	22	26	3	181
	Breakfast	IDegAsp OD	362	280	12	10	8	0	70
		IDet	180	163	12	9	10	1	60
		Total	542	443	12	9	9	0	70
	Lunch	IDegAsp OD	362	273	13	10	10	1	68
		IDet	180	162	13	9	11	1	59
		Total	542	435	13	10	10	1	68
	Main Evening Meal	IDegAsp OD	362	139	10	8	8	0	50
		IDet	180	163	14	9	12	1	62
		Total	542	302	12	9	10	0	62
	Other	IDegAsp OD	362	80	5	4	4	0	33
		IDet	180	48	6	4	4	0	20
		Total	542	128	5	4	4	0	33
Visit 19 (Week 17)	Daily	IDegAsp OD	362	324	26	19	20	3	132
		IDet	180	161	40	27	35	6	187
		Total	542	485	31	23	25	3	187

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 19 (Week 17)	Breakfast	IDegAsp OD	362	274	12	10	9	1	67
		IDet	180	161	12	10	10	0	62
		Total	542	435	12	10	9	0	67
	Lunch	IDegAsp OD	362	270	14	10	10	2	65
		IDet	180	160	13	9	11	1	61
		Total	542	430	13	10	11	1	65
	Main Evening Meal	IDegAsp OD	362	129	11	9	8	0	52
		IDet	180	161	14	9	12	2	64
		Total	542	290	13	9	11	0	64
	Other	IDegAsp OD	362	75	4	3	4	0	14
		IDet	180	53	5	3	4	0	16
		Total	542	128	4	3	4	0	16
Visit 20 (Week 18)	Daily	IDegAsp OD	362	321	25	19	20	3	120
		IDet	180	157	41	28	34	5	203
		Total	542	478	30	23	25	3	203
	Breakfast	IDegAsp OD	362	275	12	10	8	0	70
		IDet	180	156	12	10	10	1	74
		Total	542	431	12	10	9	0	74
	Lunch	IDegAsp OD	362	266	13	10	10	0	60
		IDet	180	156	13	10	11	1	63
		Total	542	422	13	10	10	0	63
	Main Evening Meal	IDegAsp OD	362	131	11	9	8	0	54
		IDet	180	157	15	10	12	2	66
		Total	542	288	13	10	11	0	66
	Other	IDegAsp OD	362	63	5	3	4	0	14
		IDet	180	44	4	3	4	0	15
		Total	542	107	5	3	4	0	15
Visit 21 (Week 19)	Daily	IDegAsp OD	362	321	26	19	20	2	120
		IDet	180	162	41	30	34	3	201
		Total	542	483	31	24	25	2	201
	Breakfast	IDegAsp OD	362	277	12	9	8	1	60
		IDet	180	160	12	10	9	1	67
		Total	542	437	12	10	9	1	67
	Lunch	IDegAsp OD	362	271	13	10	10	1	60
		IDet	180	160	13	10	11	1	66
		Total	542	431	13	10	10	1	66

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 21 (Week 19)	Main Evening Meal	IDegAsp OD	362	129	10	9	8	0	57
		IDet	180	161	15	10	12	2	68
		Total	542	290	13	10	11	0	68
	Other	IDegAsp OD	362	69	4	3	4	0	16
		IDet	180	46	5	4	5	0	28
		Total	542	115	4	4	4	0	28
Visit 22 (Week 20)	Daily	IDegAsp OD	362	324	26	20	21	2	139
		IDet	180	158	41	31	33	6	207
		Total	542	482	31	25	24	2	207
	Breakfast	IDegAsp OD	362	275	12	10	9	0	70
		IDet	180	155	12	11	9	0	69
		Total	542	430	12	10	9	0	70
	Lunch	IDegAsp OD	362	271	14	11	10	1	69
		IDet	180	156	14	10	11	1	68
		Total	542	427	14	11	10	1	69
	Main Evening Meal	IDegAsp OD	362	128	11	9	8	0	59
		IDet	180	157	15	11	12	2	70
		Total	542	285	13	10	10	0	70
	Other	IDegAsp OD	362	83	4	3	4	0	16
		IDet	180	44	5	4	4	0	15
		Total	542	127	5	3	4	0	16
Visit 23 (Week 21)	Daily	IDegAsp OD	362	320	26	20	20	3	139
		IDet	180	156	41	31	34	3	204
		Total	542	476	31	25	24	3	204
	Breakfast	IDegAsp OD	362	275	12	10	9	1	70
		IDet	180	154	12	11	10	0	68
		Total	542	429	12	10	9	0	70
	Lunch	IDegAsp OD	362	270	14	11	10	1	69
		IDet	180	154	14	11	11	1	72
		Total	542	424	14	11	10	1	72
	Main Evening Meal	IDegAsp OD	362	124	11	9	8	0	61
		IDet	180	155	15	10	12	1	67
		Total	542	279	13	10	10	0	67

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 23 (Week 21)	Other	IDegAsp OD	362	76	4	3	4	0	14
		IDet	180	48	4	3	3	0	18
		Total	542	124	4	3	4	0	18
Visit 24 (Week 22)	Daily	IDegAsp OD	362	319	27	20	20	3	139
		IDet	180	156	41	32	34	3	213
		Total	542	475	31	25	25	3	213
	Breakfast	IDegAsp OD	362	274	12	10	9	1	70
		IDet	180	155	12	11	10	0	71
		Total	542	429	12	10	9	0	71
	Lunch	IDegAsp OD	362	264	14	11	10	2	69
		IDet	180	156	14	11	11	0	75
		Total	542	420	14	11	10	0	75
	Main Evening Meal	IDegAsp OD	362	126	11	9	8	0	61
		IDet	180	156	15	11	12	2	69
		Total	542	282	13	10	10	0	69
	Other	IDegAsp OD	362	71	5	3	4	0	14
		IDet	180	45	4	3	4	0	12
		Total	542	116	4	3	4	0	14
Visit 25 (Week 23)	Daily	IDegAsp OD	362	320	27	20	20	2	132
		IDet	180	151	42	33	34	4	220
		Total	542	471	32	26	25	2	220
	Breakfast	IDegAsp OD	362	279	12	10	9	0	72
		IDet	180	150	13	11	10	0	73
		Total	542	429	12	11	9	0	73
	Lunch	IDegAsp OD	362	266	14	11	10	0	61
		IDet	180	149	14	11	12	1	77
		Total	542	415	14	11	11	0	77
	Main Evening Meal	IDegAsp OD	362	129	11	10	8	0	63
		IDet	180	149	15	11	13	2	71
		Total	542	278	13	11	10	0	71
	Other	IDegAsp OD	362	73	4	3	4	0	14
		IDet	180	45	5	4	4	0	20
		Total	542	118	4	3	4	0	20
Visit 26 (Week 24)	Daily	IDegAsp OD	362	318	27	21	21	3	132
		IDet	180	157	42	33	34	6	224
		Total	542	475	32	26	25	3	224

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 26 (Week 24)	Breakfast	IDegAsp OD	362	271	13	10	9	0	72
		IDet	180	155	13	11	10	0	70
		Total	542	426	13	11	10	0	72
	Lunch	IDegAsp OD	362	266	14	11	11	1	63
		IDet	180	156	14	11	12	2	80
		Total	542	422	14	11	11	1	80
	Main Evening Meal	IDegAsp OD	362	122	11	10	8	0	65
		IDet	180	156	15	12	12	2	74
		Total	542	278	13	11	10	0	74
	Other	IDegAsp OD	362	76	5	3	4	0	17
		IDet	180	43	5	4	4	0	27
		Total	542	119	5	4	4	0	27
Visit 27 (Week 25)	Daily	IDegAsp OD	362	318	27	21	21	3	134
		IDet	180	155	42	34	35	3	234
		Total	542	473	32	27	25	3	234
	Breakfast	IDegAsp OD	362	276	12	10	9	0	74
		IDet	180	152	13	11	10	0	72
		Total	542	428	12	11	9	0	74
	Lunch	IDegAsp OD	362	266	14	11	10	0	65
		IDet	180	154	14	12	11	0	84
		Total	542	420	14	11	11	0	84
	Main Evening Meal	IDegAsp OD	362	125	11	10	8	0	65
		IDet	180	155	15	12	12	1	78
		Total	542	280	13	11	11	0	78
	Other	IDegAsp OD	362	67	4	3	4	0	16
		IDet	180	42	4	3	4	0	13
		Total	542	109	4	3	4	0	16
Visit 28 (Week 26)	Daily	IDegAsp OD	362	340	27	21	20	4	134
		IDet	180	165	43	35	33	4	244
		Total	542	505	32	27	25	4	244
	Breakfast	IDegAsp OD	362	290	12	10	9	0	74
		IDet	180	164	13	12	10	0	74
		Total	542	454	12	11	9	0	74
	Lunch	IDegAsp OD	362	285	14	11	10	1	67
		IDet	180	164	14	12	11	1	88
		Total	542	449	14	12	10	1	88

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 28 (Week 26)	Main Evening Meal	IDegAsp OD	362	136	11	10	8	1	67
		IDet	180	165	15	12	12	1	82
		Total	542	301	13	11	10	1	82
	Other	IDegAsp OD	362	89	4	3	4	0	20
		IDet	180	52	5	3	4	2	19
		Total	542	141	5	3	4	0	20
Visit 31 (Week 28)	Daily	IDegAsp OD	362	250	27	21	21	3	135
		IDet	180	121	43	31	35	5	217
		Total	542	371	32	26	26	3	217
	Breakfast	IDegAsp OD	362	218	13	10	10	2	75
		IDet	180	119	13	11	10	0	69
		Total	542	337	13	10	10	0	75
	Lunch	IDegAsp OD	362	210	14	11	10	2	67
		IDet	180	119	14	11	12	1	73
		Total	542	329	14	11	10	1	73
	Main Evening Meal	IDegAsp OD	362	93	11	11	8	1	67
		IDet	180	121	15	11	13	2	75
		Total	542	214	14	11	10	1	75
	Other	IDegAsp OD	362	51	5	5	4	0	28
		IDet	180	34	4	2	4	0	10
		Total	542	85	5	4	4	0	28
Visit 32 (Week 29)	Daily	IDegAsp OD	362	251	28	22	20	1	138
		IDet	180	122	42	33	34	3	224
		Total	542	373	32	27	25	1	224
	Breakfast	IDegAsp OD	362	219	13	11	9	2	78
		IDet	180	120	13	11	10	0	72
		Total	542	339	13	11	10	0	78
	Lunch	IDegAsp OD	362	211	14	11	10	0	67
		IDet	180	121	14	11	11	1	75
		Total	542	332	14	11	10	0	75
	Main Evening Meal	IDegAsp OD	362	92	11	11	8	1	67
		IDet	180	122	15	11	12	1	77
		Total	542	214	13	11	10	1	77

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 32 (Week 29)	Other	IDegAsp OD	362	55	4	3	4	0	16
		IDet	180	31	4	2	4	0	10
		Total	542	86	4	2	4	0	16
Visit 33 (Week 31)	Daily	IDegAsp OD	362	251	27	22	20	2	137
		IDet	180	121	42	33	34	4	230
		Total	542	372	32	27	25	2	230
	Breakfast	IDegAsp OD	362	216	13	11	10	1	74
		IDet	180	120	13	11	10	0	74
		Total	542	336	13	11	10	0	74
	Lunch	IDegAsp OD	362	205	14	12	10	1	69
		IDet	180	120	14	12	12	1	77
		Total	542	325	14	12	10	1	77
	Main Evening Meal	IDegAsp OD	362	96	11	12	8	0	69
		IDet	180	121	15	12	12	2	79
		Total	542	217	14	12	10	0	79
	Other	IDegAsp OD	362	56	4	3	3	0	12
		IDet	180	35	4	3	4	0	14
		Total	542	91	4	3	4	0	14
Visit 34 (Week 33)	Daily	IDegAsp OD	362	245	28	23	21	3	141
		IDet	180	119	43	35	34	4	236
		Total	542	364	33	28	25	3	236
	Breakfast	IDegAsp OD	362	212	13	11	9	1	76
		IDet	180	118	13	12	10	1	76
		Total	542	330	13	11	10	1	76
	Lunch	IDegAsp OD	362	203	14	12	10	0	70
		IDet	180	118	14	12	12	1	79
		Total	542	321	14	12	10	0	79
	Main Evening Meal	IDegAsp OD	362	90	12	12	8	2	71
		IDet	180	119	15	12	12	1	81
		Total	542	209	14	12	10	1	81
	Other	IDegAsp OD	362	57	4	2	4	0	10
		IDet	180	28	5	3	4	2	10
		Total	542	85	4	2	4	0	10
Visit 35 (Week 35)	Daily	IDegAsp OD	362	247	28	23	20	3	145
		IDet	180	120	42	35	34	5	242
		Total	542	367	33	29	25	3	242

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 35 (Week 35)	Breakfast	IDegAsp OD	362	216	13	11	9	1	76
		IDet	180	119	13	12	10	0	78
		Total	542	335	13	12	9	0	78
	Lunch	IDegAsp OD	362	209	15	12	10	1	72
		IDet	180	119	14	12	11	1	81
		Total	542	328	14	12	10	1	81
	Main Evening Meal	IDegAsp OD	362	91	12	12	7	2	73
		IDet	180	120	15	12	12	2	83
		Total	542	211	14	12	11	2	83
	Other	IDegAsp OD	362	56	5	3	4	0	10
		IDet	180	40	5	3	4	0	14
		Total	542	96	5	3	4	0	14
Visit 36 (Week 37)	Daily	IDegAsp OD	362	242	29	24	21	1	150
		IDet	180	118	42	36	33	5	248
		Total	542	360	33	29	24	1	248
	Breakfast	IDegAsp OD	362	213	13	11	9	2	72
		IDet	180	115	13	12	9	1	80
		Total	542	328	13	12	9	1	80
	Lunch	IDegAsp OD	362	204	15	13	10	0	74
		IDet	180	114	15	13	12	2	83
		Total	542	318	15	13	10	0	83
	Main Evening Meal	IDegAsp OD	362	85	12	12	8	1	76
		IDet	180	117	15	12	12	2	85
		Total	542	202	14	12	11	1	85
	Other	IDegAsp OD	362	48	5	4	4	0	22
		IDet	180	29	5	3	4	0	10
		Total	542	77	5	4	4	0	22
Visit 37 (Week 39)	Daily	IDegAsp OD	362	245	29	24	20	2	155
		IDet	180	118	42	35	34	5	254
		Total	542	363	33	29	26	2	254
	Breakfast	IDegAsp OD	362	214	13	12	8	2	74
		IDet	180	117	12	12	9	0	82
		Total	542	331	13	12	9	0	82
	Lunch	IDegAsp OD	362	206	15	13	10	1	77
		IDet	180	118	14	12	11	0	85
		Total	542	324	14	12	10	0	85

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 37 (Week 39)	Main Evening Meal	IDegAsp OD	362	92	12	12	8	2	78
		IDet	180	118	15	12	12	2	87
		Total	542	210	14	12	10	2	87
	Other	IDegAsp OD	362	52	5	2	4	2	11
		IDet	180	47	4	5	4	0	27
		Total	542	99	5	4	4	0	27
Visit 38 (Week 41)	Daily	IDegAsp OD	362	237	29	25	21	3	159
		IDet	180	118	42	35	33	1	260
		Total	542	355	33	29	26	1	260
	Breakfast	IDegAsp OD	362	204	13	12	9	1	76
		IDet	180	117	13	12	10	0	84
		Total	542	321	13	12	9	0	84
	Lunch	IDegAsp OD	362	203	15	13	10	1	79
		IDet	180	118	14	12	11	0	87
		Total	542	321	15	13	10	0	87
	Main Evening Meal	IDegAsp OD	362	86	12	13	8	0	80
		IDet	180	118	15	12	12	0	89
		Total	542	204	14	12	10	0	89
	Other	IDegAsp OD	362	48	5	3	4	0	10
		IDet	180	36	5	3	4	0	15
		Total	542	84	5	3	4	0	15
Visit 39 (Week 43)	Daily	IDegAsp OD	362	241	28	25	20	1	163
		IDet	180	118	42	36	33	2	266
		Total	542	359	33	30	24	1	266
	Breakfast	IDegAsp OD	362	210	13	12	9	1	76
		IDet	180	117	12	12	9	0	86
		Total	542	327	13	12	9	0	86
	Lunch	IDegAsp OD	362	204	15	14	10	1	81
		IDet	180	118	14	13	11	1	89
		Total	542	322	15	13	10	1	89
	Main Evening Meal	IDegAsp OD	362	87	11	12	8	0	82
		IDet	180	118	15	12	12	1	91
		Total	542	205	13	12	10	0	91

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 39 (Week 43)	Other	IDegAsp OD	362	47	4	3	4	0	18
		IDet	180	35	5	4	4	0	22
		Total	542	82	5	4	4	0	22
Visit 40 (Week 45)	Daily	IDegAsp OD	362	237	29	26	20	2	167
		IDet	180	116	42	37	33	2	272
		Total	542	353	33	30	25	2	272
	Breakfast	IDegAsp OD	362	208	13	12	9	0	77
		IDet	180	115	13	13	9	0	88
		Total	542	323	13	12	9	0	88
	Lunch	IDegAsp OD	362	197	15	14	10	2	83
		IDet	180	116	14	13	11	0	91
		Total	542	313	15	14	10	0	91
	Main Evening Meal	IDegAsp OD	362	89	12	13	9	1	84
		IDet	180	116	15	12	12	1	93
		Total	542	205	14	13	10	1	93
	Other	IDegAsp OD	362	52	5	3	4	0	12
		IDet	180	34	5	4	4	0	22
		Total	542	86	5	4	4	0	22
Visit 41 (Week 47)	Daily	IDegAsp OD	362	240	29	27	21	3	171
		IDet	180	116	42	35	33	2	272
		Total	542	356	34	30	25	2	272
	Breakfast	IDegAsp OD	362	209	14	13	9	1	78
		IDet	180	115	13	13	10	0	88
		Total	542	324	13	13	9	0	88
	Lunch	IDegAsp OD	362	201	15	14	10	2	85
		IDet	180	116	14	12	11	0	91
		Total	542	317	15	14	10	0	91
	Main Evening Meal	IDegAsp OD	362	88	12	13	8	0	86
		IDet	180	116	15	12	12	1	93
		Total	542	204	14	13	10	0	93
	Other	IDegAsp OD	362	45	5	3	4	0	10
		IDet	180	35	5	4	4	0	21
		Total	542	80	5	3	4	0	21
Visit 42 (Week 49)	Daily	IDegAsp OD	362	233	30	28	21	3	175
		IDet	180	113	43	36	34	2	278
		Total	542	346	34	31	24	2	278

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 42 (Week 49)	Breakfast	IDegAsp OD	362	205	14	13	9	1	79
		IDet	180	112	13	13	10	0	90
		Total	542	317	14	13	9	0	90
	Lunch	IDegAsp OD	362	194	16	15	10	0	87
		IDet	180	111	15	13	12	1	93
		Total	542	305	15	14	11	0	93
	Main Evening Meal	IDegAsp OD	362	84	12	14	8	0	88
		IDet	180	113	15	12	12	1	95
		Total	542	197	14	13	10	0	95
	Other	IDegAsp OD	362	44	4	3	4	0	12
		IDet	180	38	4	3	3	0	14
		Total	542	82	4	3	4	0	14
Visit 43 (Week 51)	Daily	IDegAsp OD	362	232	31	28	21	3	179
		IDet	180	111	43	37	36	1	284
		Total	542	343	35	32	26	1	284
	Breakfast	IDegAsp OD	362	202	14	13	9	1	82
		IDet	180	111	13	13	10	0	92
		Total	542	313	14	13	9	0	92
	Lunch	IDegAsp OD	362	191	16	15	10	0	89
		IDet	180	111	14	13	11	0	95
		Total	542	302	15	14	11	0	95
	Main Evening Meal	IDegAsp OD	362	89	12	14	8	2	90
		IDet	180	111	16	13	12	0	97
		Total	542	200	14	13	11	0	97
	Other	IDegAsp OD	362	58	5	3	4	0	12
		IDet	180	38	4	4	4	0	20
		Total	542	96	5	3	4	0	20
Visit 44 (Week 53)	Daily	IDegAsp OD	362	236	31	29	21	4	183
		IDet	180	113	43	38	35	2	290
		Total	542	349	35	32	26	2	290
	Breakfast	IDegAsp OD	362	206	14	14	9	1	84
		IDet	180	112	13	13	10	0	94
		Total	542	318	14	14	9	0	94
	Lunch	IDegAsp OD	362	195	16	15	10	0	91
		IDet	180	112	15	13	11	1	97
		Total	542	307	16	14	11	0	97

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 44 (Week 53)	Main Evening Meal	IDegAsp OD	362	88	12	14	8	2	92
		IDet	180	113	16	13	12	1	99
		Total	542	201	14	14	10	1	99
	Other	IDegAsp OD	362	58	5	3	4	0	12
		IDet	180	36	4	4	3	0	22
		Total	542	94	5	3	4	0	22
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp OD	362	360	28	25	20	4	183
		IDet	180	178	43	37	33	2	290
		Total	542	538	33	30	25	2	290
	Breakfast	IDegAsp OD	362	336	12	12	8	0	84
		IDet	180	177	13	13	10	0	94
		Total	542	513	12	12	9	0	94
	Lunch	IDegAsp OD	362	337	14	13	10	0	91
		IDet	180	178	15	13	11	0	97
		Total	542	515	14	13	10	0	97
	Main Evening Meal	IDegAsp OD	362	247	10	11	8	0	92
		IDet	180	178	15	13	12	1	99
		Total	542	425	12	12	10	0	99
	Other	IDegAsp OD	362	217	5	4	4	0	30
		IDet	180	129	5	5	4	0	27
		Total	542	346	5	4	4	0	30

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:19 - tdesc_numfind_tpl_t021_v01.sas/t_b_dose_act_u_descp_sas.txt

14.2.28: Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	25	11	22	7	83
		OD							
		IDet	180	176	26	12	24	7	77
Visit 4 (Week 2)	Daily	Total	542	536	25	12	24	7	83
		IDegAsp	362	359	26	12	23	7	84
		OD							
Visit 5 (Week 3)	Daily	IDet	180	176	27	13	26	4	79
		Total	542	535	26	12	24	4	84
		IDegAsp	362	346	26	12	24	7	84
Visit 6 (Week 4)	Daily	IDet	180	175	28	13	26	4	81
		Total	542	521	27	12	25	4	84
		IDegAsp	362	351	27	12	24	6	81
Visit 7 (Week 5)	Daily	IDet	180	174	29	14	28	4	83
		Total	542	525	28	13	25	4	83
		IDegAsp	362	349	27	12	24	6	81
Visit 8 (Week 6)	Daily	IDet	180	173	29	14	28	5	74
		Total	542	522	28	13	25	5	81
		IDegAsp	362	343	27	13	25	6	83
Visit 9 (Week 7)	Daily	IDet	180	172	31	15	30	5	85
		Total	542	515	28	13	26	5	85
		IDegAsp	362	342	27	13	25	7	83
Visit 10 (Week 8)	Daily	IDet	180	171	31	15	30	5	87
		Total	542	513	29	14	26	5	87
		IDegAsp	362	340	28	13	25	6	84
Visit 11 (Week 9)	Daily	IDet	180	171	32	15	30	5	80
		Total	542	511	29	14	27	5	84
		IDegAsp	362	334	28	13	25	6	87
Visit 12 (Week 10)	Daily	IDet	180	166	32	16	30	5	82
		Total	542	500	29	14	27	5	87
		IDegAsp	362	337	28	13	25	6	87
Visit 13 (Week 11)	Daily	IDet	180	169	33	16	31	5	83
		Total	542	506	30	14	27	5	87
		IDegAsp	362	334	28	14	25	7	90
Visit 14 (Week 12)	Daily	IDet	180	167	33	17	32	5	87
		Total	542	501	30	15	27	5	90
		IDegAsp	362	333	28	14	25	8	94

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:30 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_u_descp_sas.txt

Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	324	29	14	25	7	94
		OD							
		IDet	180	161	34	17	32	2	92
		Total	542	485	30	15	28	2	94
Visit 16 (Week 14)	Daily	IDegAsp	362	331	29	14	25	6	91
		OD							
		IDet	180	165	34	17	32	4	94
		Total	542	496	30	15	28	4	94
Visit 17 (Week 15)	Daily	IDegAsp	362	327	29	14	25	6	87
		OD							
		IDet	180	164	34	17	32	5	100
		Total	542	491	31	16	28	5	100
Visit 18 (Week 16)	Daily	IDegAsp	362	329	29	14	25	4	90
		OD							
		IDet	180	163	34	17	32	4	102
		Total	542	492	31	16	28	4	102
Visit 19 (Week 17)	Daily	IDegAsp	362	322	29	15	26	7	91
		OD							
		IDet	180	162	34	18	32	4	104
		Total	542	484	31	16	28	4	104
Visit 20 (Week 18)	Daily	IDegAsp	362	319	29	15	26	6	88
		OD							
		IDet	180	158	35	18	34	5	108
		Total	542	477	31	16	28	5	108
Visit 21 (Week 19)	Daily	IDegAsp	362	319	29	15	27	6	87
		OD							
		IDet	180	162	35	18	34	4	101
		Total	542	481	31	16	28	4	101
Visit 22 (Week 20)	Daily	IDegAsp	362	322	30	15	26	7	91
		OD							
		IDet	180	158	35	18	33	4	100
		Total	542	480	31	16	28	4	100
Visit 23 (Week 21)	Daily	IDegAsp	362	319	29	15	26	6	92
		OD							
		IDet	180	157	36	19	33	4	104
		Total	542	476	31	17	28	4	104
Visit 24 (Week 22)	Daily	IDegAsp	362	318	30	15	27	6	92
		OD							
		IDet	180	156	36	19	33	5	98
		Total	542	474	32	17	28	5	98
Visit 25 (Week 23)	Daily	IDegAsp	362	320	30	15	26	6	92
		OD							
		IDet	180	151	36	19	34	6	102
		Total	542	471	32	17	28	6	102
Visit 26 (Week 24)	Daily	IDegAsp	362	318	30	16	26	6	92
		OD							
		IDet	180	157	36	20	34	6	106
		Total	542	475	32	17	28	6	106

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:30 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_u_descp_sas.txt

Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	30	16	26	6	94
		OD							
		IDet	180	155	37	20	34	6	110
Visit 28 (Week 26)	Daily	Total	542	473	32	18	29	6	110
		IDegAsp	362	339	30	16	25	6	92
		OD							
Visit 31 (Week 28)	Daily	IDet	180	165	37	21	34	6	111
		Total	542	504	32	18	28	6	111
		IDegAsp	362	250	30	16	25	7	94
Visit 32 (Week 29)	Daily	OD							
		IDet	180	121	37	21	36	6	112
		Total	542	371	32	18	28	6	112
Visit 33 (Week 31)	Daily	IDegAsp	362	251	30	16	25	7	98
		OD							
		IDet	180	121	38	22	36	6	118
Visit 34 (Week 33)	Daily	Total	542	372	32	18	28	6	118
		IDegAsp	362	245	30	16	25	8	98
		OD							
Visit 35 (Week 35)	Daily	IDet	180	120	39	22	36	7	122
		Total	542	365	33	19	28	7	122
		IDegAsp	362	247	30	17	25	7	99
Visit 36 (Week 37)	Daily	OD							
		IDet	180	120	39	23	36	7	126
		Total	542	367	33	19	28	7	126
Visit 37 (Week 39)	Daily	IDegAsp	362	242	31	17	26	7	101
		OD							
		IDet	180	118	39	23	36	7	130
Visit 38 (Week 41)	Daily	Total	542	360	33	19	28	7	130
		IDegAsp	362	245	31	17	27	7	102
		OD							
Visit 39 (Week 43)	Daily	IDet	180	118	39	23	36	6	134
		Total	542	363	33	20	28	6	134
		IDegAsp	362	237	31	17	26	7	104
Visit 40 (Week 45)	Daily	OD							
		IDet	180	118	40	24	37	6	138
		Total	542	355	34	20	28	6	138
Visit 39 (Week 43)	Daily	IDegAsp	362	241	31	17	27	6	105
		OD							
		IDet	180	118	40	24	37	7	135
Visit 40 (Week 45)	Daily	Total	542	359	34	20	28	6	135
		IDegAsp	362	237	31	18	28	6	105
		OD							
Visit 40 (Week 45)	Daily	IDet	180	116	40	25	36	6	139
		Total	542	353	34	21	29	6	139
		IDegAsp	362	237	31	18	28	6	105

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:30 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_u_descp_sas.txt

Basal Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	362	240	31	18	27	4	105
		OD							
		IDet	180	116	40	24	37	8	136
		Total	542	356	34	20	29	4	136
Visit 42 (Week 49)	Daily	IDegAsp	362	234	31	18	27	3	106
		OD							
		IDet	180	113	41	25	38	8	134
		Total	542	347	34	21	29	3	134
Visit 43 (Week 51)	Daily	IDegAsp	362	232	32	18	27	4	106
		OD							
		IDet	180	112	41	25	38	8	132
		Total	542	344	35	21	29	4	132
Visit 44 (Week 53)	Daily	IDegAsp	362	236	32	19	27	6	109
		OD							
		IDet	180	113	41	25	38	7	134
		Total	542	349	35	21	29	6	134
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	30	17	26	6	109
		OD							
		IDet	180	178	39	24	34	6	134
		Total	542	538	33	20	28	6	134

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:30 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_u_descp_sas.txt

14.2.29: Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.33	0.13	0.30	0.09	0.88
		OD							
		IDet	180	176	0.34	0.13	0.31	0.10	0.96
		Total	542	536	0.33	0.13	0.31	0.09	0.96
Visit 4 (Week 2)	Daily	IDegAsp	362	359	0.34	0.13	0.31	0.10	0.93
		OD							
		IDet	180	176	0.35	0.14	0.33	0.07	0.99
		Total	542	535	0.34	0.14	0.32	0.07	0.99
Visit 5 (Week 3)	Daily	IDegAsp	362	346	0.34	0.13	0.31	0.10	0.95
		OD							
		IDet	180	175	0.37	0.15	0.35	0.07	1.01
		Total	542	521	0.35	0.14	0.32	0.07	1.01
Visit 6 (Week 4)	Daily	IDegAsp	362	351	0.35	0.13	0.32	0.10	0.93
		OD							
		IDet	180	174	0.38	0.16	0.37	0.07	1.04
		Total	542	525	0.36	0.14	0.33	0.07	1.04
Visit 7 (Week 5)	Daily	IDegAsp	362	349	0.35	0.13	0.32	0.10	0.91
		OD							
		IDet	180	173	0.38	0.16	0.37	0.07	1.07
		Total	542	522	0.36	0.14	0.34	0.07	1.07
Visit 8 (Week 6)	Daily	IDegAsp	362	343	0.35	0.14	0.33	0.10	0.92
		OD							
		IDet	180	172	0.40	0.17	0.39	0.08	1.10
		Total	542	515	0.37	0.15	0.34	0.08	1.10
Visit 9 (Week 7)	Daily	IDegAsp	362	342	0.35	0.14	0.33	0.11	0.93
		OD							
		IDet	180	171	0.40	0.17	0.39	0.08	1.13
		Total	542	513	0.37	0.15	0.35	0.08	1.13
Visit 10 (Week 8)	Daily	IDegAsp	362	340	0.36	0.14	0.34	0.09	0.95
		OD							
		IDet	180	171	0.41	0.17	0.41	0.07	1.16
		Total	542	511	0.37	0.15	0.35	0.07	1.16
Visit 11 (Week 9)	Daily	IDegAsp	362	334	0.36	0.14	0.33	0.09	0.97
		OD							
		IDet	180	166	0.41	0.18	0.41	0.09	1.18
		Total	542	500	0.38	0.16	0.36	0.09	1.18
Visit 12 (Week 10)	Daily	IDegAsp	362	337	0.36	0.15	0.33	0.09	0.97
		OD							
		IDet	180	169	0.42	0.18	0.42	0.09	1.16
		Total	542	506	0.38	0.16	0.36	0.09	1.16
Visit 13 (Week 11)	Daily	IDegAsp	362	334	0.36	0.15	0.33	0.10	1.00
		OD							
		IDet	180	167	0.42	0.19	0.42	0.09	1.18
		Total	542	501	0.38	0.17	0.36	0.09	1.18
Visit 14 (Week 12)	Daily	IDegAsp	362	333	0.36	0.15	0.33	0.11	1.02
		OD							
		IDet	180	167	0.42	0.18	0.41	0.03	1.18
		Total	542	500	0.38	0.16	0.35	0.03	1.18

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:40 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_ukg_descp_sas.txt

Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	324	0.36	0.15	0.33	0.10	1.02
		OD							
		IDet	180	161	0.43	0.18	0.41	0.03	1.21
		Total	542	485	0.38	0.17	0.36	0.03	1.21
Visit 16 (Week 14)	Daily	IDegAsp	362	331	0.36	0.15	0.33	0.08	0.99
		OD							
		IDet	180	165	0.43	0.18	0.41	0.06	1.24
		Total	542	496	0.38	0.17	0.35	0.06	1.24
Visit 17 (Week 15)	Daily	IDegAsp	362	327	0.36	0.15	0.33	0.11	0.98
		OD							
		IDet	180	164	0.43	0.18	0.41	0.09	1.26
		Total	542	491	0.39	0.17	0.36	0.09	1.26
Visit 18 (Week 16)	Daily	IDegAsp	362	329	0.36	0.15	0.33	0.06	0.98
		OD							
		IDet	180	163	0.43	0.19	0.41	0.07	1.28
		Total	542	492	0.38	0.17	0.35	0.06	1.28
Visit 19 (Week 17)	Daily	IDegAsp	362	322	0.37	0.15	0.33	0.10	0.96
		OD							
		IDet	180	162	0.43	0.19	0.41	0.07	1.31
		Total	542	484	0.39	0.17	0.36	0.07	1.31
Visit 20 (Week 18)	Daily	IDegAsp	362	319	0.37	0.15	0.34	0.08	0.96
		OD							
		IDet	180	158	0.44	0.20	0.43	0.06	1.34
		Total	542	477	0.39	0.17	0.36	0.06	1.34
Visit 21 (Week 19)	Daily	IDegAsp	362	319	0.37	0.15	0.34	0.10	0.96
		OD							
		IDet	180	162	0.45	0.20	0.43	0.05	1.34
		Total	542	481	0.39	0.18	0.36	0.05	1.34
Visit 22 (Week 20)	Daily	IDegAsp	362	322	0.37	0.16	0.34	0.10	0.96
		OD							
		IDet	180	158	0.44	0.20	0.41	0.05	1.34
		Total	542	480	0.39	0.18	0.36	0.05	1.34
Visit 23 (Week 21)	Daily	IDegAsp	362	319	0.37	0.16	0.34	0.09	0.96
		OD							
		IDet	180	157	0.45	0.20	0.41	0.05	1.34
		Total	542	476	0.39	0.18	0.36	0.05	1.34
Visit 24 (Week 22)	Daily	IDegAsp	362	318	0.37	0.16	0.34	0.10	0.97
		OD							
		IDet	180	156	0.45	0.21	0.43	0.06	1.34
		Total	542	474	0.40	0.18	0.37	0.06	1.34
Visit 25 (Week 23)	Daily	IDegAsp	362	320	0.37	0.16	0.34	0.08	0.99
		OD							
		IDet	180	151	0.45	0.21	0.43	0.07	1.34
		Total	542	471	0.40	0.18	0.37	0.07	1.34
Visit 26 (Week 24)	Daily	IDegAsp	362	318	0.37	0.16	0.34	0.10	1.01
		OD							
		IDet	180	157	0.46	0.21	0.43	0.08	1.34
		Total	542	475	0.40	0.18	0.37	0.08	1.34

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:40 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_ukg_descp_sas.txt

Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	0.38	0.16	0.34	0.10	1.01
		OD							
		IDet	180	155	0.47	0.22	0.43	0.09	1.34
		Total	542	473	0.41	0.19	0.37	0.09	1.34
Visit 28 (Week 26)	Daily	IDegAsp	362	339	0.37	0.16	0.34	0.11	1.02
		OD							
		IDet	180	165	0.46	0.23	0.43	0.09	1.37
		Total	542	504	0.40	0.19	0.36	0.09	1.37
Visit 31 (Week 28)	Daily	IDegAsp	362	250	0.37	0.16	0.33	0.11	1.01
		OD							
		IDet	180	121	0.46	0.22	0.43	0.09	1.32
		Total	542	371	0.40	0.19	0.36	0.09	1.32
Visit 32 (Week 29)	Daily	IDegAsp	362	251	0.37	0.17	0.33	0.09	1.03
		OD							
		IDet	180	122	0.46	0.23	0.44	0.09	1.35
		Total	542	373	0.40	0.19	0.36	0.09	1.35
Visit 33 (Week 31)	Daily	IDegAsp	362	251	0.37	0.17	0.33	0.10	1.03
		OD							
		IDet	180	121	0.47	0.23	0.44	0.09	1.38
		Total	542	372	0.40	0.19	0.36	0.09	1.38
Visit 34 (Week 33)	Daily	IDegAsp	362	245	0.37	0.17	0.33	0.11	1.06
		OD							
		IDet	180	120	0.47	0.23	0.44	0.08	1.40
		Total	542	365	0.41	0.20	0.37	0.08	1.40
Visit 35 (Week 35)	Daily	IDegAsp	362	247	0.37	0.17	0.33	0.10	1.06
		OD							
		IDet	180	120	0.48	0.24	0.43	0.08	1.43
		Total	542	367	0.41	0.20	0.36	0.08	1.43
Visit 36 (Week 37)	Daily	IDegAsp	362	242	0.38	0.17	0.34	0.10	1.06
		OD							
		IDet	180	118	0.48	0.24	0.44	0.08	1.46
		Total	542	360	0.41	0.20	0.38	0.08	1.46
Visit 37 (Week 39)	Daily	IDegAsp	362	245	0.38	0.17	0.33	0.10	1.06
		OD							
		IDet	180	118	0.48	0.24	0.43	0.07	1.49
		Total	542	363	0.41	0.20	0.37	0.07	1.49
Visit 38 (Week 41)	Daily	IDegAsp	362	237	0.38	0.18	0.33	0.10	1.08
		OD							
		IDet	180	118	0.49	0.25	0.46	0.07	1.52
		Total	542	355	0.41	0.21	0.37	0.07	1.52
Visit 39 (Week 43)	Daily	IDegAsp	362	241	0.38	0.17	0.33	0.09	1.08
		OD							
		IDet	180	118	0.49	0.25	0.46	0.08	1.55
		Total	542	359	0.41	0.21	0.36	0.08	1.55
Visit 40 (Week 45)	Daily	IDegAsp	362	237	0.38	0.18	0.34	0.09	1.07
		OD							
		IDet	180	116	0.49	0.26	0.45	0.07	1.55
		Total	542	353	0.42	0.21	0.37	0.07	1.55

N = Number of Subjects, SD = Standard Deviation

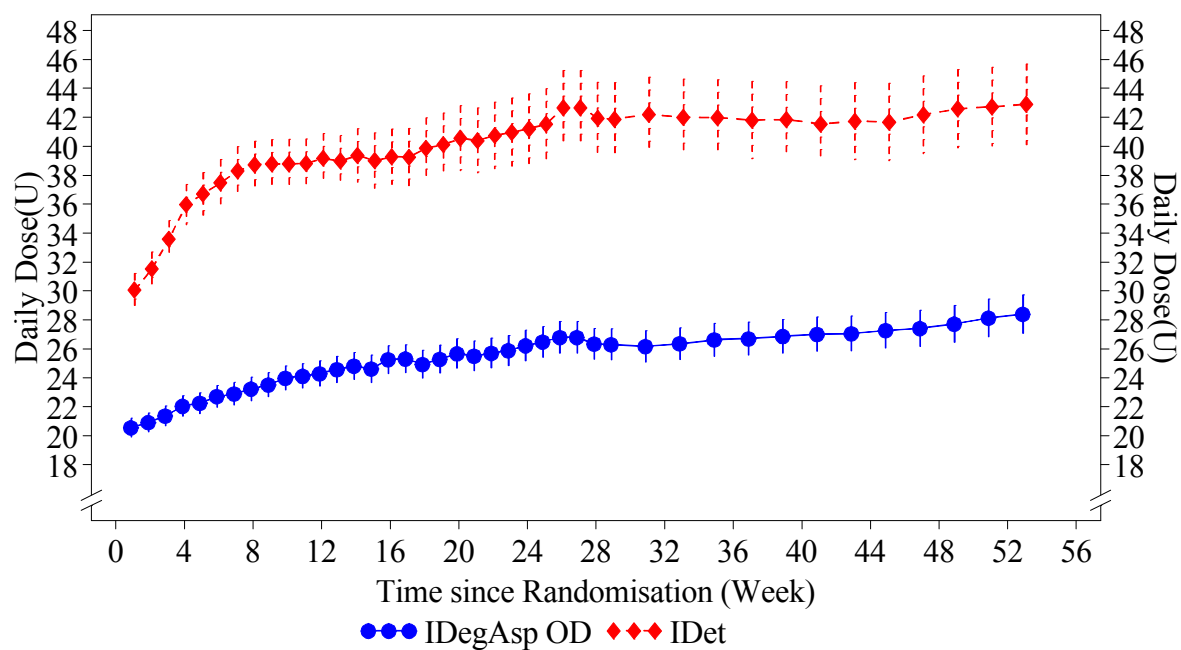
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:40 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_ukg_descp_sas.txt

Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	362	240	0.38	0.18	0.34	0.08	1.09
		OD							
		IDet	180	116	0.49	0.26	0.46	0.09	1.55
		Total	542	356	0.42	0.22	0.37	0.08	1.55
Visit 42 (Week 49)	Daily	IDegAsp	362	234	0.38	0.19	0.34	0.05	1.11
		OD							
		IDet	180	113	0.50	0.26	0.46	0.09	1.49
		Total	542	347	0.42	0.22	0.37	0.05	1.49
Visit 43 (Week 51)	Daily	IDegAsp	362	232	0.39	0.19	0.34	0.08	1.13
		OD							
		IDet	180	112	0.50	0.26	0.46	0.09	1.52
		Total	542	344	0.43	0.22	0.37	0.08	1.52
Visit 44 (Week 53)	Daily	IDegAsp	362	236	0.39	0.19	0.35	0.10	1.12
		OD							
		IDet	180	113	0.51	0.26	0.46	0.09	1.60
		Total	542	349	0.43	0.22	0.37	0.09	1.60
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	0.38	0.18	0.34	0.10	1.12
		OD							
		IDet	180	178	0.49	0.26	0.44	0.09	1.60
		Total	542	538	0.41	0.22	0.36	0.09	1.60

N = Number of Subjects, SD = Standard Deviation

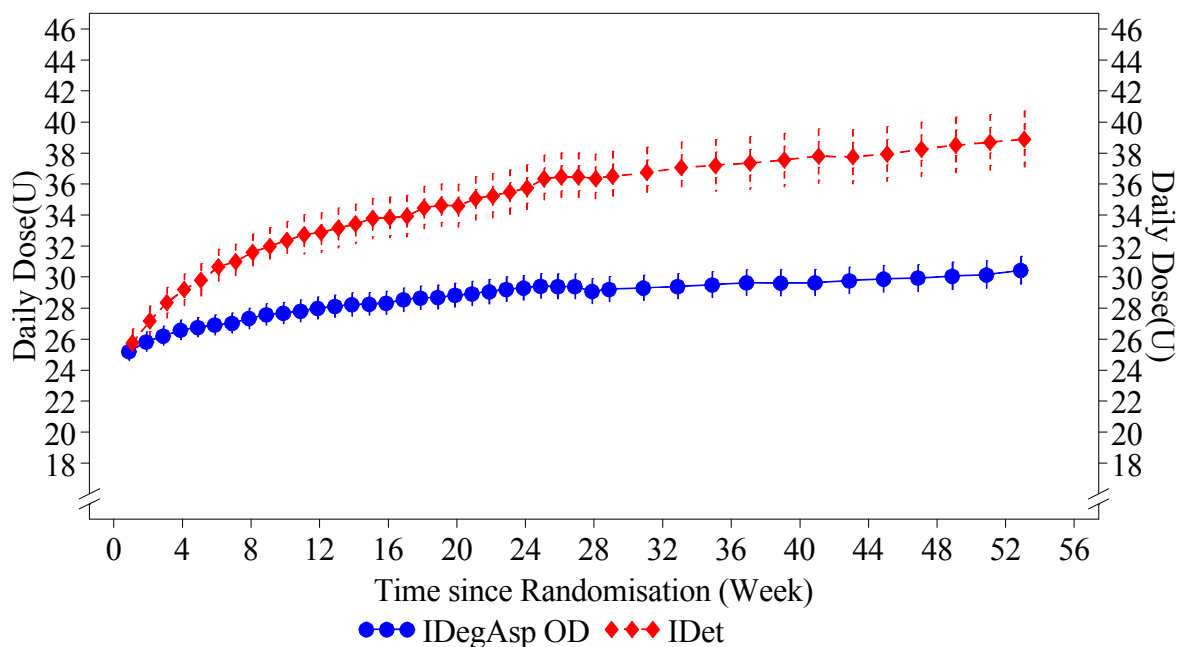
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:40 - tdesc_numfind_tpl_t021_v01.sas/t_basal_dose_act_ukg_descp_sas.txt



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:32:51 - fmean_numfind_v03.sas/e_b_dose_d_act_u_mean_locf_sas.cgm

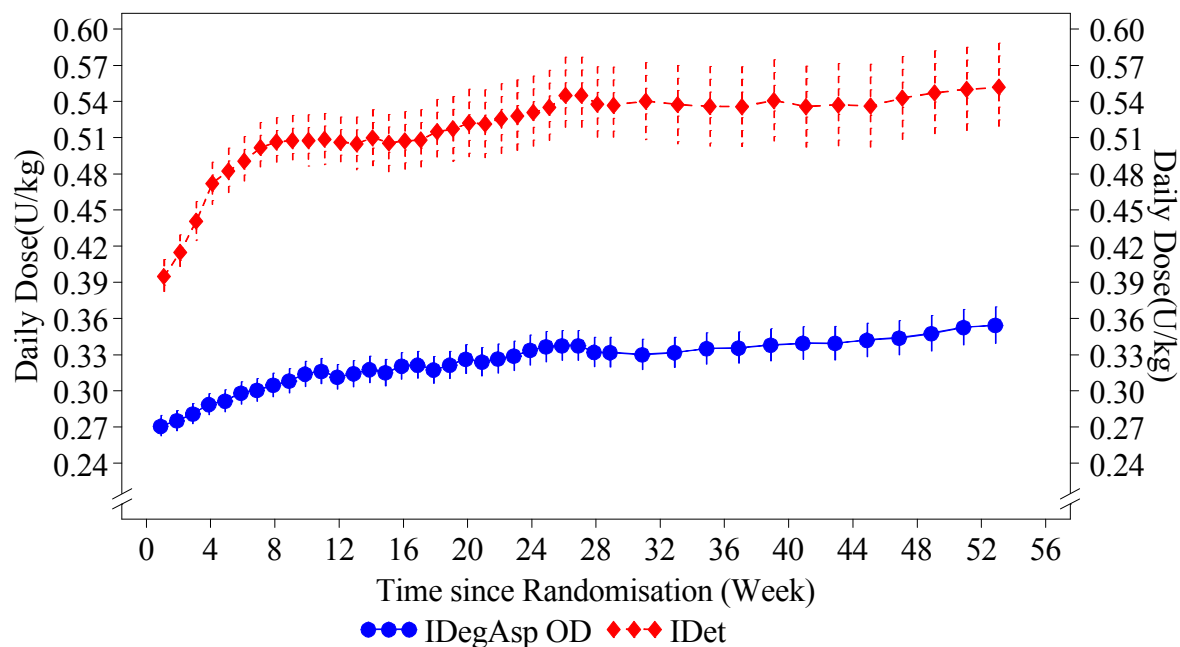
14.2.30: Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:33:01 - fmean_numfind_v03.sas/e_basal_act_u_mean_locf_sas.cgm

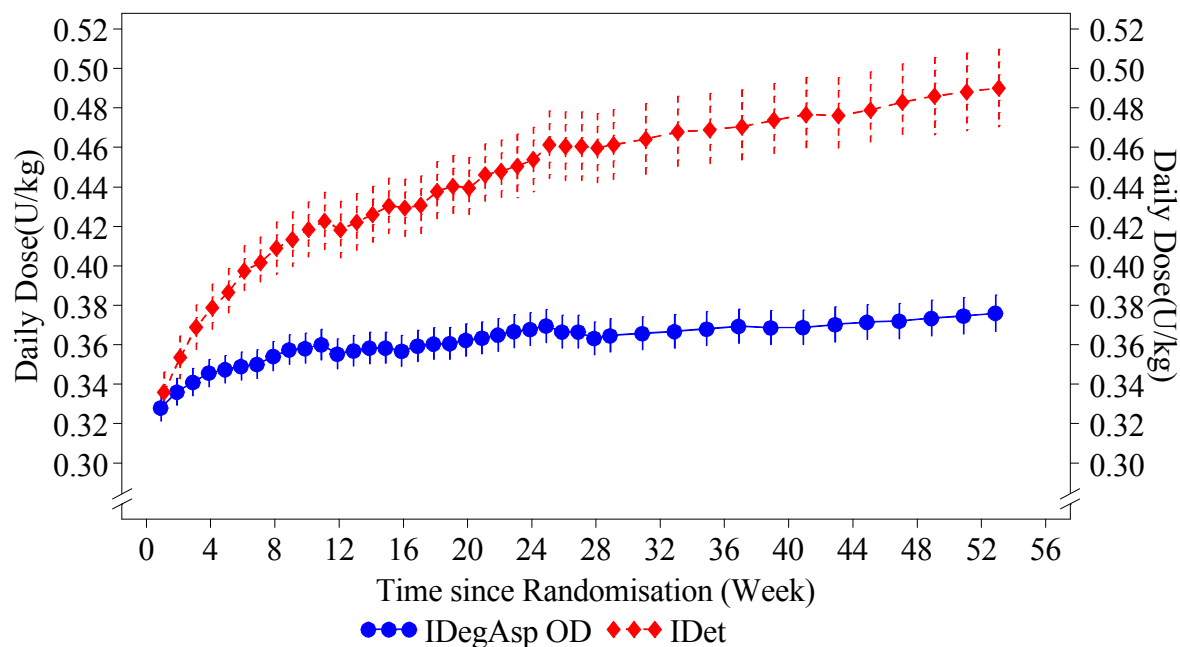
14.2.31: Basal Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:33:10 - fmean_numfind_v03.sas/e_b_dose_d_act_ukg_mean_locf_sas.cgm

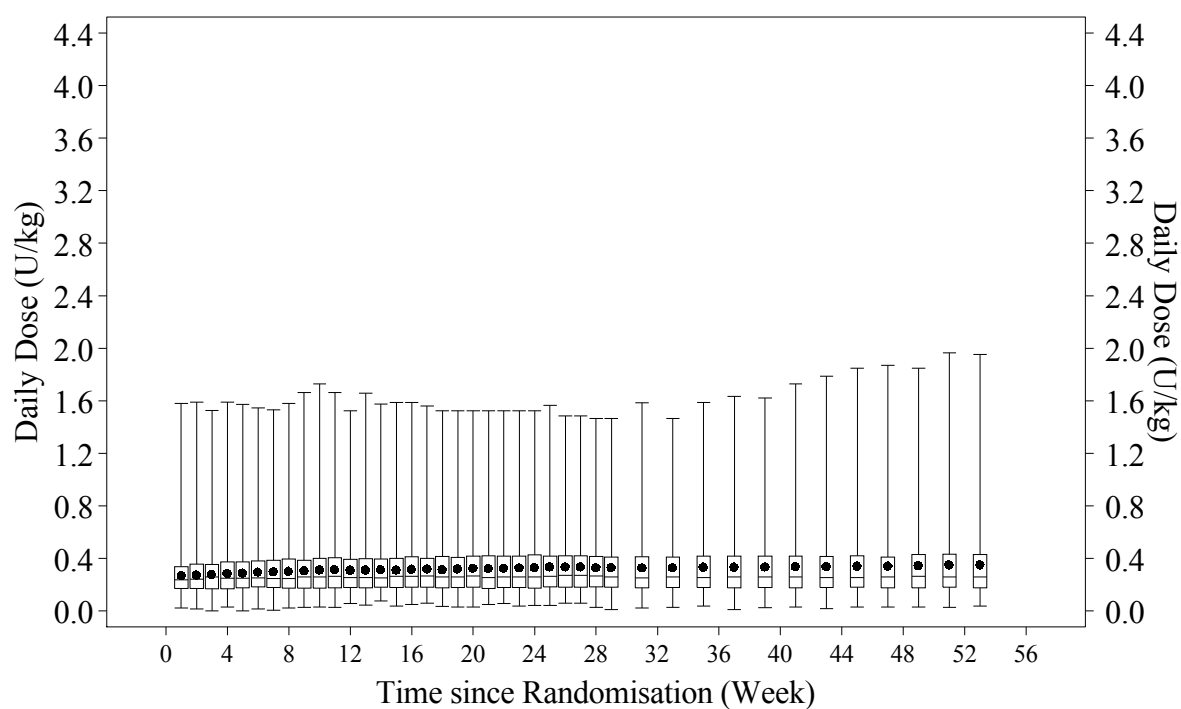
14.2.32: Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:33:21 - fmean_numfind_v03.sas/e_basal_act_ukg_mean_locf_sas.cgm

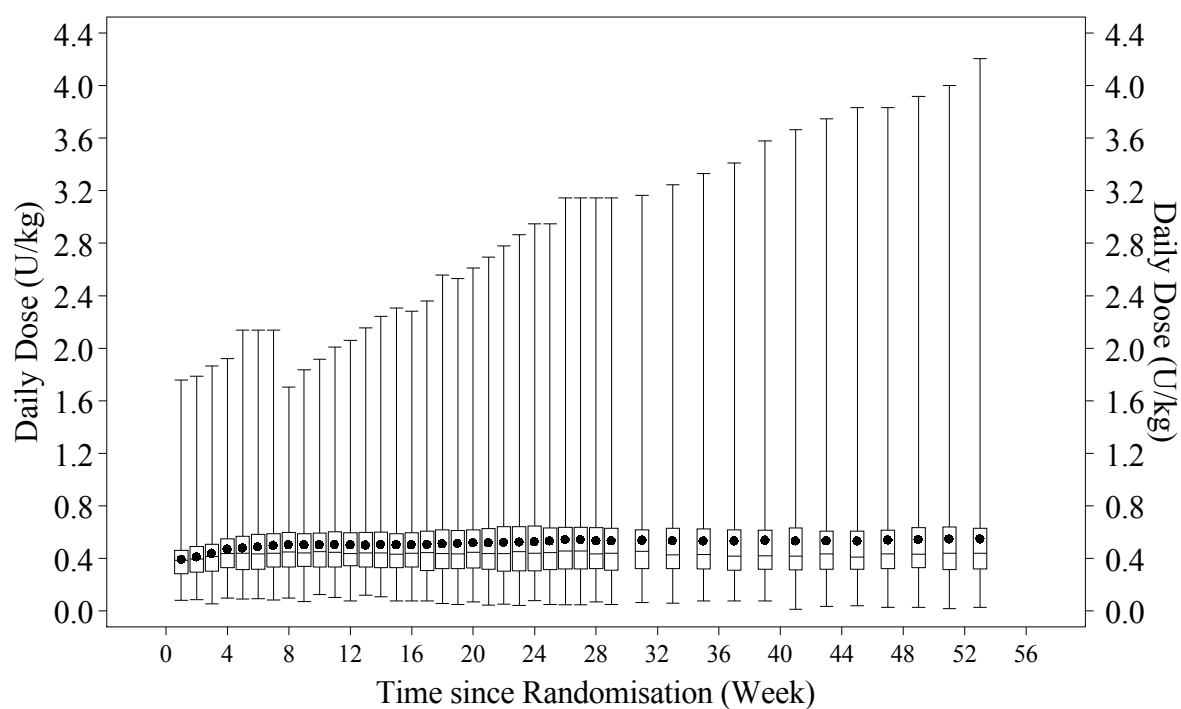
14.2.33: Basal Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:33:31 - fbox_numfind_v01.sas/e_b_d_inv1_act_ukg_box_locf_sas.cgm

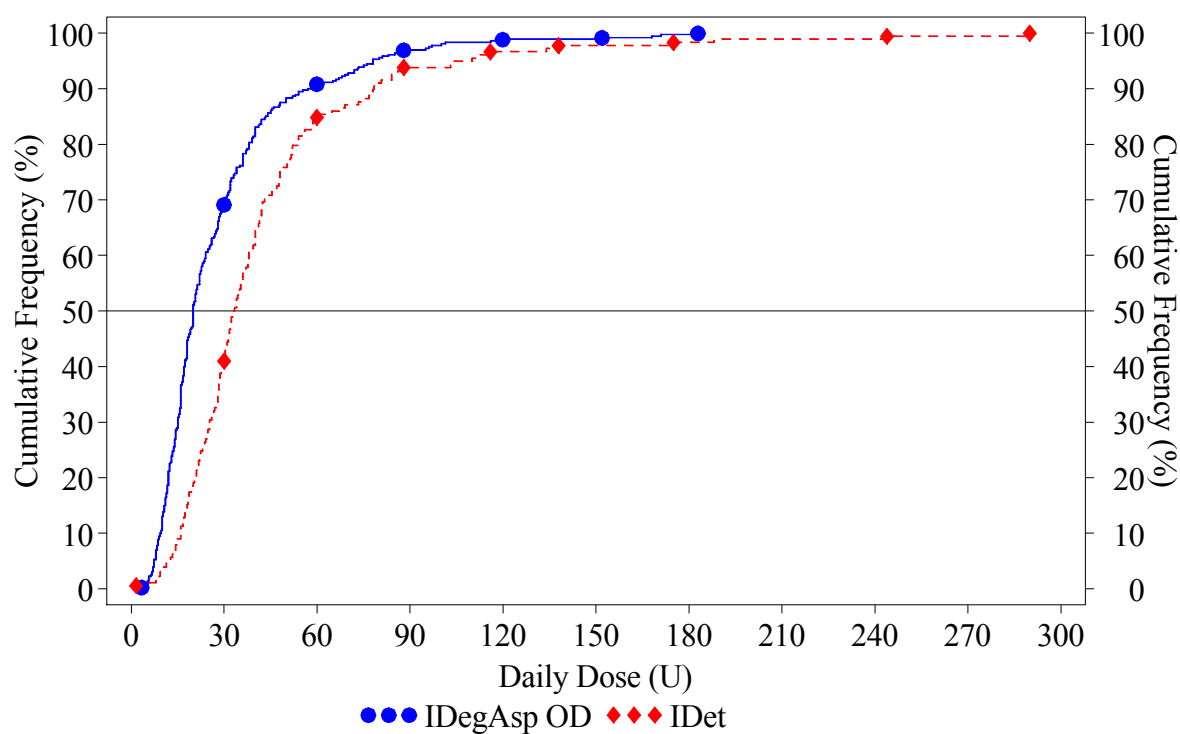
14.2.34: Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - IDegAsp OD - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:33:40 - fbox_numfind_v01.sas/e_b_d_com_act_ukg_box_locf_sas.cgm

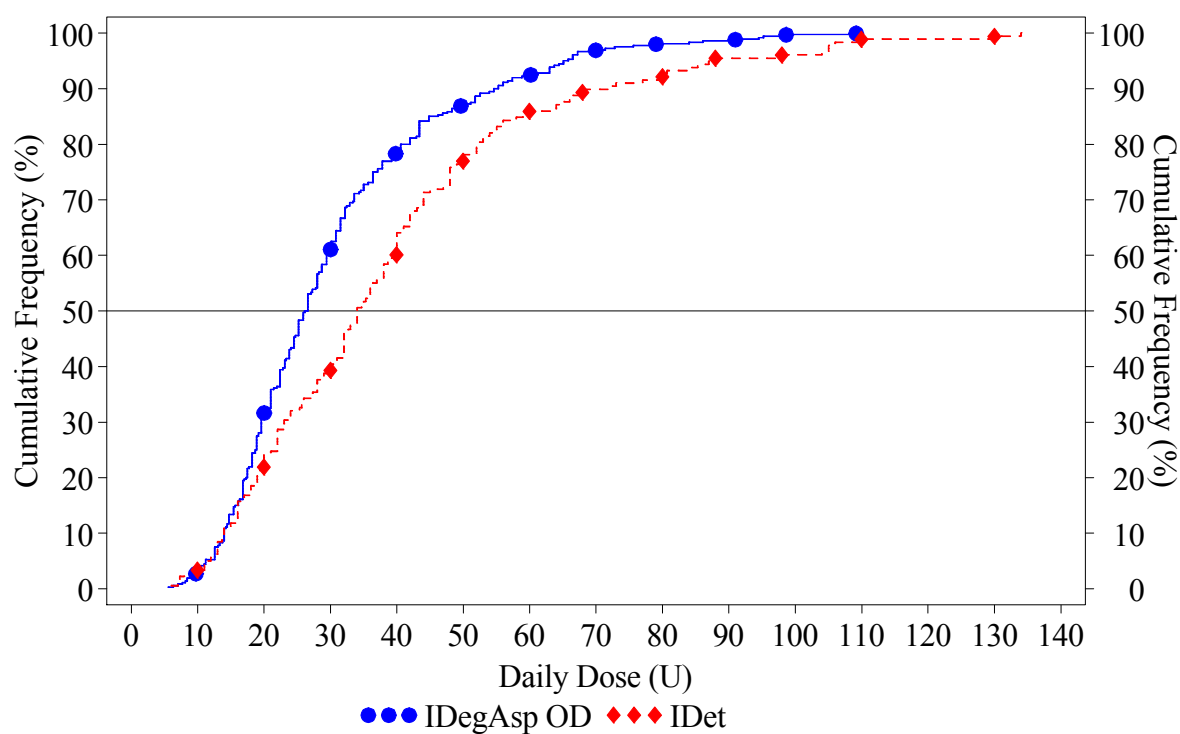
14.2.35: Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - IDet - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:33:49 - fedist_numfind_v01.sas/e_b_dose_d_act_u_cdf_locf_sas.cgm

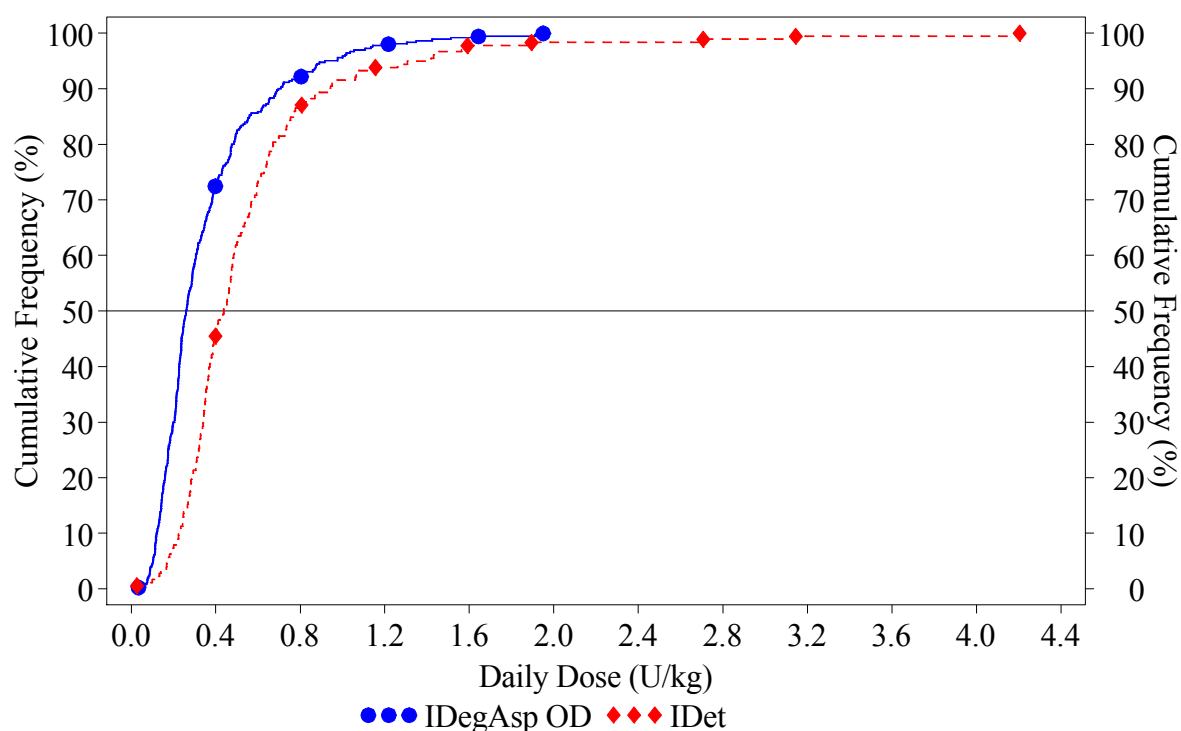
14.2.36: Daily Bolus Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:33:57 - fedist_numfind_v01.sas/e_basal_d_act_u_cdf_locf_sas.cgm

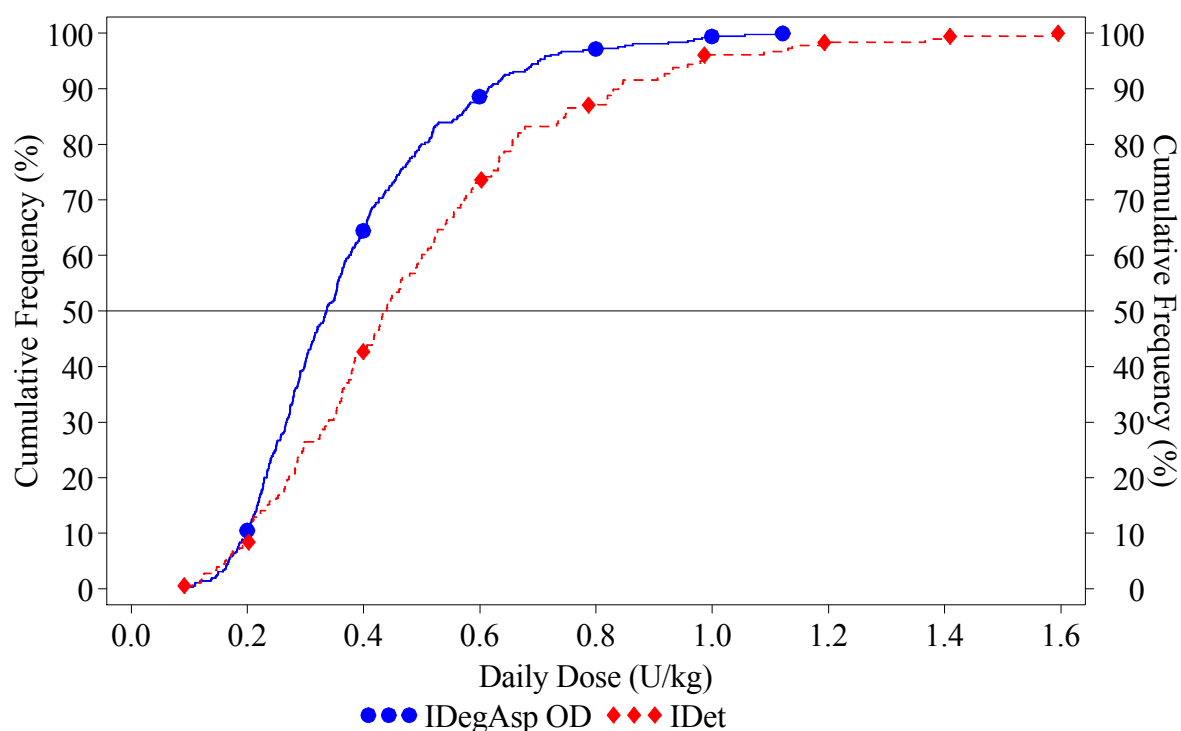
14.2.37: Basal Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:06 - fedist_numfind_v01.sas/e_b_dose_d_act_ukg_cdf_locf_sas.cgm

14.2.38: Daily Bolus Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:14 - fedist_numfind_v01.sas/e_basal_d_act_ukg_cdf_locf_sas.cgm

14.2.39: Basal Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.2.40: Total Daily Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	SAFETY	N	--Descriptive Statistics--				
					Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	56	24	51	16	184
		OD							
		IDet	180	176	56	22	52	15	156
Visit 4 (Week 2)	Daily	Total	542	536	56	23	52	15	184
		IDegAsp	362	359	58	25	52	14	202
		OD							
Visit 5 (Week 3)	Daily	IDet	180	176	59	23	54	12	160
		Total	542	535	58	25	53	12	202
		IDegAsp	362	346	59	26	53	15	204
Visit 6 (Week 4)	Daily	OD							
		IDet	180	175	62	26	58	12	168
		Total	542	521	60	26	55	12	204
Visit 7 (Week 5)	Daily	IDegAsp	362	351	60	27	54	14	221
		OD							
		IDet	180	174	65	28	61	14	174
Visit 8 (Week 6)	Daily	Total	542	525	62	27	56	14	221
		IDegAsp	362	349	61	28	54	15	221
		OD							
Visit 9 (Week 7)	Daily	IDet	180	173	66	29	62	16	192
		Total	542	522	62	28	56	15	221
		IDegAsp	362	343	62	29	54	14	227
Visit 10 (Week 8)	Daily	OD							
		IDet	180	172	68	31	64	16	194
		Total	542	515	64	29	58	14	227
Visit 11 (Week 9)	Daily	IDegAsp	362	342	62	29	54	14	231
		OD							
		IDet	180	171	69	32	65	17	194
Visit 12 (Week 10)	Daily	Total	542	513	65	30	57	14	231
		IDegAsp	362	340	63	31	54	13	238
		OD							
Visit 13 (Week 11)	Daily	IDet	180	171	70	32	66	17	195
		Total	542	511	65	31	58	13	238
		IDegAsp	362	335	64	32	56	15	242
Visit 14 (Week 12)	Daily	OD							
		IDet	180	166	71	33	67	17	203
		Total	542	501	66	32	59	15	242
Visit 15 (Week 13)	Daily	IDegAsp	362	338	64	32	55	13	241
		OD							
		IDet	180	169	72	33	67	17	207
Visit 16 (Week 14)	Daily	Total	542	507	67	33	60	13	241
		IDegAsp	362	335	65	32	56	13	200
		OD							
Visit 17 (Week 15)	Daily	IDet	180	167	72	34	67	17	215
		Total	542	502	67	33	59	13	215
		IDegAsp	362	334	65	34	56	12	246
Visit 18 (Week 16)	Daily	OD							
		IDet	180	167	72	34	64	16	227
		Total	542	501	68	34	59	12	246

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:24 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_u_descp_sas.txt

Total Daily Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	325	66	35	57	9	246
		OD							
		IDet	180	161	73	35	66	16	236
Visit 16 (Week 14)	Daily	Total	542	486	68	35	60	9	246
		IDegAsp	362	332	66	35	58	11	248
		OD							
Visit 17 (Week 15)	Daily	IDet	180	165	74	36	67	16	245
		Total	542	497	69	36	60	11	248
		IDegAsp	362	328	66	36	57	15	256
Visit 18 (Week 16)	Daily	OD							
		IDet	180	164	74	37	67	17	252
		Total	542	492	69	36	60	15	256
Visit 19 (Week 17)	Daily	IDegAsp	362	330	67	36	58	14	266
		OD							
		IDet	180	163	74	37	69	16	255
Visit 20 (Week 18)	Daily	Total	542	493	69	37	61	14	266
		IDegAsp	362	324	68	37	58	13	262
		OD							
Visit 21 (Week 19)	Daily	IDet	180	162	74	39	68	18	263
		Total	542	486	70	38	61	13	263
		IDegAsp	362	321	67	36	58	9	244
Visit 22 (Week 20)	Daily	OD							
		IDet	180	158	76	40	69	17	279
		Total	542	479	70	38	61	9	279
Visit 23 (Week 21)	Daily	IDegAsp	362	321	67	36	58	11	244
		OD							
		IDet	180	162	76	42	68	17	277
Visit 24 (Week 22)	Daily	Total	542	483	70	38	61	11	277
		IDegAsp	362	324	68	38	58	12	269
		OD							
Visit 25 (Week 23)	Daily	IDet	180	158	76	43	67	18	285
		Total	542	482	71	40	62	12	285
		IDegAsp	362	320	68	38	56	10	271
Visit 26 (Week 24)	Daily	OD							
		IDet	180	157	76	43	66	19	289
		Total	542	477	71	40	59	10	289
Visit 27 (Week 25)	Daily	IDegAsp	362	319	69	39	58	9	271
		OD							
		IDet	180	156	77	44	68	18	297
Visit 28 (Week 26)	Daily	Total	542	475	72	41	62	9	297
		IDegAsp	362	320	70	39	58	11	264
		OD							
Visit 29 (Week 27)	Daily	IDet	180	151	78	46	68	17	306
		Total	542	471	72	41	60	11	306
		IDegAsp	362	318	70	40	59	13	264
Visit 30 (Week 28)	Daily	OD							
		IDet	180	157	78	46	69	17	312
		Total	542	475	73	42	63	13	312

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:24 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_u_descp_sas.txt

Total Daily Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	70	40	58	12	268
		OD							
		IDet	180	155	80	48	68	18	334
Visit 28 (Week 26)	Daily	Total	542	473	73	43	62	12	334
		IDegAsp	362	340	69	40	57	7	266
		OD							
Visit 31 (Week 28)	Daily	IDet	180	165	80	49	69	19	350
		Total	542	505	73	44	60	7	350
Visit 32 (Week 29)	Daily	IDegAsp	362	250	70	40	58	14	269
		OD							
		IDet	180	121	80	44	70	18	313
Visit 33 (Week 31)	Daily	Total	542	371	73	41	63	14	313
		IDegAsp	362	251	70	41	58	13	274
		OD							
Visit 34 (Week 33)	Daily	IDet	180	122	80	46	70	19	322
		Total	542	373	73	43	62	13	322
Visit 35 (Week 35)	Daily	IDegAsp	362	245	71	43	57	16	278
		OD							
		IDet	180	120	81	48	68	22	338
Visit 36 (Week 37)	Daily	Total	542	365	74	45	64	16	338
		IDegAsp	362	247	71	44	57	14	280
		OD							
Visit 37 (Week 39)	Daily	IDet	180	120	81	50	67	20	346
		Total	542	367	74	46	63	14	346
Visit 38 (Week 41)	Daily	IDegAsp	362	242	72	44	60	18	278
		OD							
		IDet	180	118	81	51	68	23	354
Visit 39 (Week 43)	Daily	Total	542	360	75	47	63	18	354
		IDegAsp	362	245	72	45	58	17	283
		OD							
Visit 40 (Week 45)	Daily	IDet	180	118	81	48	69	26	360
		Total	542	363	75	46	63	17	360
Visit 38 (Week 41)	Daily	IDegAsp	362	237	72	46	57	15	289
		OD							
		IDet	180	118	81	49	69	23	368
Visit 39 (Week 43)	Daily	Total	542	355	75	47	62	15	368
		IDegAsp	362	241	72	46	58	15	294
		OD							
Visit 40 (Week 45)	Daily	IDet	180	118	82	50	71	23	376
		Total	542	359	75	48	62	15	376
Visit 40 (Week 45)	Daily	IDegAsp	362	237	74	48	60	14	300
		OD							
		IDet	180	116	82	52	69	24	382
Visit 40 (Week 45)	Daily	Total	542	353	76	49	63	14	382

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:24 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_u_descp_sas.txt

Total Daily Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	362	240	74	48	60	12	306
		OD							
		IDet	180	116	82	50	72	24	382
		Total	542	356	76	49	63	12	382
Visit 42 (Week 49)	Daily	IDegAsp	362	234	75	50	59	16	312
		OD							
		IDet	180	113	84	51	70	24	384
		Total	542	347	78	50	65	16	384
Visit 43 (Week 51)	Daily	IDegAsp	362	232	76	51	59	17	318
		OD							
		IDet	180	112	84	52	72	25	392
		Total	542	344	79	51	64	17	392
Visit 44 (Week 53)	Daily	IDegAsp	362	236	76	51	59	17	324
		OD							
		IDet	180	113	84	53	71	24	400
		Total	542	349	79	52	65	17	400
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	72	46	57	7	324
		OD							
		IDet	180	178	82	53	69	19	400
		Total	542	538	75	49	61	7	400

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:24 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_u_descp_sas.txt

14.2.41: Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	31	15	28	8	124
		OD							
		IDet	180	176	30	15	28	5	130
		Total	542	536	31	15	28	5	130
		IDegAsp	362	359	32	15	29	7	138
		OD							
Visit 4 (Week 2)	Daily	IDet	180	176	32	16	29	8	132
		Total	542	535	32	15	29	7	138
		IDegAsp	362	346	33	16	29	8	137
Visit 5 (Week 3)	Daily	OD							
		IDet	180	175	34	17	30	6	138
		Total	542	521	33	16	29	6	138
Visit 6 (Week 4)	Daily	IDegAsp	362	351	34	17	29	8	147
		OD							
		IDet	180	174	36	19	32	9	142
		Total	542	525	34	18	30	8	147
		IDegAsp	362	349	34	17	30	7	145
		OD							
Visit 7 (Week 5)	Daily	IDet	180	173	37	20	33	5	158
		Total	542	522	35	18	31	5	158
		IDegAsp	362	343	34	18	30	5	149
Visit 8 (Week 6)	Daily	OD							
		IDet	180	172	37	22	32	6	158
		Total	542	515	35	19	31	5	158
Visit 9 (Week 7)	Daily	IDegAsp	362	342	35	19	30	5	150
		OD							
		IDet	180	171	38	22	34	5	158
		Total	542	513	36	20	31	5	158
		IDegAsp	362	340	35	19	30	6	155
		OD							
Visit 10 (Week 8)	Daily	IDet	180	171	39	22	36	5	130
		Total	542	511	37	20	32	5	155
		IDegAsp	362	334	36	20	31	7	157
Visit 11 (Week 9)	Daily	OD							
		IDet	180	166	39	23	34	7	140
		Total	542	500	37	21	32	7	157
Visit 12 (Week 10)	Daily	IDegAsp	362	337	36	20	31	6	156
		OD							
		IDet	180	169	39	23	34	7	146
		Total	542	506	37	21	32	6	156
		IDegAsp	362	334	37	20	30	9	132
		OD							
Visit 13 (Week 11)	Daily	IDet	180	167	39	23	34	8	153
		Total	542	501	38	21	32	8	153
		IDegAsp	362	333	37	21	30	8	161
Visit 14 (Week 12)	Daily	OD							
		IDet	180	167	40	23	34	7	163
		Total	542	500	38	22	32	7	163

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:35 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_u_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	324	37	22	31	8	161
		OD							
		IDet	180	160	40	24	34	8	170
Visit 16 (Week 14)	Daily	Total	542	484	38	23	32	8	170
		IDegAsp	362	331	38	23	31	8	163
		OD							
Visit 17 (Week 15)	Daily	IDet	180	165	40	25	34	6	177
		Total	542	496	38	23	31	6	177
Visit 18 (Week 16)	Daily	IDegAsp	362	327	38	23	30	7	169
		OD							
		IDet	180	164	40	26	33	5	182
Visit 19 (Week 17)	Daily	Total	542	491	38	24	32	5	182
		IDegAsp	362	329	38	23	31	6	176
		OD							
Visit 20 (Week 18)	Daily	IDet	180	163	40	26	34	4	181
		Total	542	492	39	24	33	4	181
Visit 21 (Week 19)	Daily	IDegAsp	362	322	39	24	32	7	171
		OD							
		IDet	180	161	40	27	35	6	187
Visit 22 (Week 20)	Daily	Total	542	483	39	25	33	6	187
		IDegAsp	362	319	38	23	31	7	157
		OD							
Visit 23 (Week 21)	Daily	IDet	180	157	41	28	34	5	203
		Total	542	476	39	25	32	5	203
Visit 24 (Week 22)	Daily	IDegAsp	362	319	39	23	32	4	157
		OD							
		IDet	180	162	41	30	34	3	201
Visit 25 (Week 23)	Daily	Total	542	481	39	26	32	3	201
		IDegAsp	362	322	39	25	32	5	178
		OD							
Visit 26 (Week 24)	Daily	IDet	180	158	41	31	33	6	207
		Total	542	480	40	27	32	5	207
Visit 27 (Week 25)	Daily	IDegAsp	362	319	39	25	31	5	179
		OD							
		IDet	180	156	41	31	34	3	204
Visit 28 (Week 26)	Daily	Total	542	475	40	27	31	3	204
		IDegAsp	362	318	40	25	32	6	179
		OD							
Visit 29 (Week 27)	Daily	IDet	180	156	41	32	34	3	213
		Total	542	474	40	28	32	3	213
Visit 30 (Week 28)	Daily	IDegAsp	362	320	40	25	32	5	172
		OD							
		IDet	180	151	42	33	34	4	220
Visit 31 (Week 29)	Daily	Total	542	471	40	28	33	4	220
		IDegAsp	362	318	40	26	32	7	172
		OD							
Visit 32 (Week 30)	Daily	IDet	180	157	42	33	34	6	224
		Total	542	475	41	28	33	6	224
		IDegAsp	362	318	40	26	32	7	172

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:35 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_u_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	40	26	32	6	174
		OD							
		IDet	180	155	42	34	35	3	234
Visit 28 (Week 26)	Daily	Total	542	473	41	29	33	3	234
		IDegAsp	362	339	40	26	32	6	174
		OD							
Visit 31 (Week 28)	Daily	IDet	180	165	43	35	33	4	244
		Total	542	504	41	29	32	4	244
Visit 32 (Week 29)	Daily	IDegAsp	362	250	40	26	32	7	175
		OD							
		IDet	180	121	43	31	35	5	217
Visit 33 (Week 31)	Daily	Total	542	371	41	28	33	5	217
		IDegAsp	362	251	41	27	32	6	179
		OD							
Visit 34 (Week 33)	Daily	IDet	180	122	42	33	34	3	224
		Total	542	373	41	29	32	3	224
Visit 35 (Week 35)	Daily	IDegAsp	362	251	40	28	31	7	178
		OD							
		IDet	180	121	42	33	34	4	230
Visit 36 (Week 37)	Daily	Total	542	372	41	30	32	4	230
		IDegAsp	362	245	41	28	32	8	180
		OD							
Visit 37 (Week 39)	Daily	IDet	180	119	43	35	34	4	236
		Total	542	364	41	30	32	4	236
Visit 38 (Week 41)	Daily	IDegAsp	362	247	41	29	31	6	182
		OD							
		IDet	180	120	42	35	34	5	242
Visit 39 (Week 43)	Daily	Total	542	367	41	31	32	5	242
		IDegAsp	362	242	42	30	32	6	187
		OD							
Visit 40 (Week 45)	Daily	IDet	180	118	42	36	33	5	248
		Total	542	360	42	32	33	5	248
Visit 41 (Week 47)	Daily	IDegAsp	362	245	42	30	31	9	193
		OD							
		IDet	180	118	42	35	34	5	254
Visit 42 (Week 49)	Daily	Total	542	363	42	31	32	5	254
		IDegAsp	362	237	42	31	32	7	198
		OD							
Visit 43 (Week 51)	Daily	IDet	180	118	42	35	33	1	260
		Total	542	355	42	32	33	1	260
Visit 44 (Week 53)	Daily	IDegAsp	362	241	41	31	32	6	202
		OD							
		IDet	180	118	42	36	33	2	266
Visit 45 (Week 55)	Daily	Total	542	359	42	33	32	2	266
		IDegAsp	362	237	43	32	33	6	207
		OD							
Visit 46 (Week 57)	Daily	IDet	180	116	42	37	33	2	272
		Total	542	353	42	33	33	2	272
		IDegAsp							

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:35 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_u_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	362	240	43	33	32	8	212
		OD							
		IDet	180	116	42	35	33	2	272
		Total	542	356	43	34	32	2	272
Visit 42 (Week 49)	Daily	IDegAsp	362	233	44	34	32	8	216
		OD							
		IDet	180	113	43	36	34	2	278
		Total	542	346	43	35	33	2	278
Visit 43 (Week 51)	Daily	IDegAsp	362	232	44	34	32	8	221
		OD							
		IDet	180	111	43	37	36	1	284
		Total	542	343	44	35	33	1	284
Visit 44 (Week 53)	Daily	IDegAsp	362	236	45	35	31	10	225
		OD							
		IDet	180	113	43	38	35	2	290
		Total	542	349	44	36	33	2	290
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	41	31	30	10	225
		OD							
		IDet	180	178	43	37	33	2	290
		Total	542	538	42	33	32	2	290

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:35 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_u_descp_sas.txt

14.2.42: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.74	0.28	0.68	0.19	2.74
		OD							
		IDet	180	176	0.73	0.25	0.69	0.27	2.11
		Total	542	536	0.73	0.27	0.69	0.19	2.74
Visit 4 (Week 2)	Daily	IDegAsp	362	359	0.76	0.29	0.71	0.21	2.79
		OD							
		IDet	180	176	0.77	0.27	0.72	0.21	2.16
		Total	542	535	0.76	0.28	0.71	0.21	2.79
Visit 5 (Week 3)	Daily	IDegAsp	362	346	0.77	0.30	0.71	0.22	2.75
		OD							
		IDet	180	175	0.81	0.31	0.76	0.22	2.27
		Total	542	521	0.78	0.30	0.73	0.22	2.75
Visit 6 (Week 4)	Daily	IDegAsp	362	351	0.78	0.31	0.73	0.25	2.85
		OD							
		IDet	180	174	0.85	0.32	0.79	0.26	2.35
		Total	542	525	0.81	0.31	0.76	0.25	2.85
Visit 7 (Week 5)	Daily	IDegAsp	362	349	0.79	0.31	0.75	0.24	2.83
		OD							
		IDet	180	173	0.86	0.34	0.82	0.29	2.60
		Total	542	522	0.81	0.33	0.76	0.24	2.83
Visit 8 (Week 6)	Daily	IDegAsp	362	343	0.80	0.33	0.74	0.19	2.84
		OD							
		IDet	180	172	0.89	0.36	0.83	0.30	2.62
		Total	542	515	0.83	0.34	0.78	0.19	2.84
Visit 9 (Week 7)	Daily	IDegAsp	362	342	0.81	0.34	0.75	0.19	2.85
		OD							
		IDet	180	171	0.90	0.38	0.85	0.30	2.69
		Total	542	513	0.84	0.35	0.79	0.19	2.85
Visit 10 (Week 8)	Daily	IDegAsp	362	340	0.82	0.35	0.75	0.18	2.93
		OD							
		IDet	180	171	0.91	0.38	0.87	0.31	2.82
		Total	542	511	0.85	0.36	0.80	0.18	2.93
Visit 11 (Week 9)	Daily	IDegAsp	362	335	0.83	0.36	0.75	0.20	3.02
		OD							
		IDet	180	166	0.92	0.39	0.87	0.31	2.93
		Total	542	501	0.86	0.37	0.80	0.20	3.02
Visit 12 (Week 10)	Daily	IDegAsp	362	338	0.83	0.37	0.77	0.17	3.09
		OD							
		IDet	180	169	0.93	0.40	0.86	0.31	2.99
		Total	542	507	0.87	0.38	0.80	0.17	3.09
Visit 13 (Week 11)	Daily	IDegAsp	362	335	0.84	0.37	0.76	0.22	3.08
		OD							
		IDet	180	167	0.94	0.41	0.86	0.31	3.11
		Total	542	502	0.87	0.39	0.81	0.22	3.11
Visit 14 (Week 12)	Daily	IDegAsp	362	334	0.83	0.37	0.74	0.19	2.90
		OD							
		IDet	180	167	0.93	0.39	0.84	0.30	3.13
		Total	542	501	0.86	0.38	0.79	0.19	3.13

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:46 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_ukg_descp_sas.txt

Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	325	0.83	0.39	0.75	0.15	3.03
		OD							
		IDet	180	161	0.93	0.40	0.87	0.29	3.24
		Total	542	486	0.87	0.40	0.79	0.15	3.24
Visit 16 (Week 14)	Daily	IDegAsp	362	332	0.84	0.39	0.75	0.18	2.98
		OD							
		IDet	180	165	0.94	0.41	0.85	0.29	3.36
		Total	542	497	0.87	0.40	0.80	0.18	3.36
Visit 17 (Week 15)	Daily	IDegAsp	362	328	0.84	0.39	0.75	0.25	2.99
		OD							
		IDet	180	164	0.94	0.43	0.85	0.29	3.47
		Total	542	492	0.87	0.41	0.79	0.25	3.47
Visit 18 (Week 16)	Daily	IDegAsp	362	330	0.84	0.39	0.74	0.25	2.99
		OD							
		IDet	180	163	0.94	0.43	0.87	0.28	3.56
		Total	542	493	0.87	0.41	0.78	0.25	3.56
Visit 19 (Week 17)	Daily	IDegAsp	362	324	0.85	0.40	0.75	0.18	2.93
		OD							
		IDet	180	162	0.95	0.46	0.84	0.30	3.67
		Total	542	486	0.88	0.42	0.80	0.18	3.67
Visit 20 (Week 18)	Daily	IDegAsp	362	321	0.84	0.40	0.74	0.13	2.90
		OD							
		IDet	180	158	0.96	0.47	0.88	0.29	3.78
		Total	542	479	0.88	0.43	0.79	0.13	3.78
Visit 21 (Week 19)	Daily	IDegAsp	362	321	0.85	0.40	0.75	0.17	2.90
		OD							
		IDet	180	162	0.97	0.49	0.87	0.28	3.87
		Total	542	483	0.89	0.43	0.80	0.17	3.87
Visit 22 (Week 20)	Daily	IDegAsp	362	324	0.86	0.41	0.76	0.17	2.90
		OD							
		IDet	180	158	0.96	0.50	0.88	0.30	3.95
		Total	542	482	0.89	0.44	0.80	0.17	3.95
Visit 23 (Week 21)	Daily	IDegAsp	362	320	0.86	0.42	0.74	0.14	2.90
		OD							
		IDet	180	157	0.97	0.50	0.88	0.30	4.04
		Total	542	477	0.89	0.45	0.81	0.14	4.04
Visit 24 (Week 22)	Daily	IDegAsp	362	319	0.87	0.42	0.76	0.13	2.90
		OD							
		IDet	180	156	0.97	0.52	0.88	0.29	4.12
		Total	542	475	0.90	0.46	0.81	0.13	4.12
Visit 25 (Week 23)	Daily	IDegAsp	362	320	0.87	0.42	0.76	0.20	2.90
		OD							
		IDet	180	151	0.99	0.53	0.88	0.31	4.20
		Total	542	471	0.91	0.46	0.80	0.20	4.20
Visit 26 (Week 24)	Daily	IDegAsp	362	318	0.88	0.43	0.76	0.23	2.90
		OD							
		IDet	180	157	0.99	0.54	0.87	0.31	4.29
		Total	542	475	0.92	0.47	0.81	0.23	4.29

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:46 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_ukg_descp_sas.txt

Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25) Daily		IDegAsp	362	318	0.88	0.44	0.77	0.22	2.94
		OD							
		IDet	180	155	1.01	0.56	0.86	0.29	4.29
Visit 28 (Week 26) Daily		Total	542	473	0.92	0.48	0.81	0.22	4.29
		IDegAsp	362	340	0.87	0.43	0.76	0.08	2.81
		OD							
Visit 31 (Week 28) Daily		IDet	180	165	1.01	0.58	0.88	0.32	4.51
		Total	542	505	0.91	0.49	0.79	0.08	4.51
		IDegAsp	362	250	0.86	0.42	0.76	0.25	2.79
Visit 32 (Week 29) Daily		OD							
		IDet	180	121	0.99	0.51	0.88	0.32	4.31
		Total	542	371	0.91	0.46	0.80	0.25	4.31
Visit 33 (Week 31) Daily		IDegAsp	362	251	0.87	0.44	0.76	0.24	2.79
		OD							
		IDet	180	122	0.99	0.53	0.87	0.33	4.43
Visit 34 (Week 33) Daily		Total	542	373	0.91	0.47	0.79	0.24	4.43
		IDegAsp	362	251	0.87	0.45	0.76	0.24	2.93
		OD							
Visit 35 (Week 35) Daily		IDet	180	121	0.99	0.54	0.86	0.33	4.54
		Total	542	372	0.91	0.48	0.78	0.24	4.54
		IDegAsp	362	245	0.88	0.46	0.77	0.25	2.83
Visit 36 (Week 37) Daily		OD							
		IDet	180	120	1.00	0.56	0.84	0.30	4.65
		Total	542	365	0.92	0.49	0.79	0.25	4.65
Visit 37 (Week 39) Daily		IDegAsp	362	247	0.88	0.47	0.77	0.26	2.84
		OD							
		IDet	180	120	1.00	0.57	0.85	0.30	4.76
Visit 38 (Week 41) Daily		Total	542	367	0.92	0.51	0.79	0.26	4.76
		IDegAsp	362	242	0.89	0.47	0.76	0.28	2.91
		OD							
Visit 39 (Week 43) Daily		IDet	180	118	1.01	0.58	0.85	0.30	4.87
		Total	542	360	0.93	0.51	0.80	0.28	4.87
		IDegAsp	362	245	0.89	0.48	0.75	0.26	2.92
Visit 40 (Week 45) Daily		OD							
		IDet	180	118	1.01	0.58	0.87	0.31	5.07
		Total	542	363	0.93	0.52	0.80	0.26	5.07
Visit 39 (Week 43) Daily		IDegAsp	362	237	0.90	0.49	0.75	0.27	3.04
		OD							
		IDet	180	118	1.01	0.59	0.88	0.30	5.18
Visit 40 (Week 45) Daily		Total	542	355	0.93	0.53	0.80	0.27	5.18
		IDegAsp	362	241	0.89	0.48	0.76	0.26	3.12
		OD							
Visit 40 (Week 45) Daily		IDet	180	118	1.01	0.60	0.87	0.33	5.30
		Total	542	359	0.93	0.53	0.79	0.26	5.30
		IDegAsp	362	237	0.91	0.50	0.78	0.25	3.21
Visit 40 (Week 45) Daily		OD							
		IDet	180	116	1.02	0.62	0.86	0.31	5.38
		Total	542	353	0.94	0.55	0.80	0.25	5.38

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:46 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_ukg_descp_sas.txt

Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	362	240	0.91	0.52	0.77	0.24	3.25
		OD							
		IDet	180	116	1.02	0.60	0.88	0.33	5.38
		Total	542	356	0.95	0.55	0.80	0.24	5.38
Visit 42 (Week 49)	Daily	IDegAsp	362	234	0.92	0.53	0.77	0.27	3.21
		OD							
		IDet	180	113	1.04	0.62	0.88	0.30	5.41
		Total	542	347	0.96	0.56	0.81	0.27	5.41
Visit 43 (Week 51)	Daily	IDegAsp	362	232	0.94	0.54	0.78	0.27	3.40
		OD							
		IDet	180	112	1.05	0.63	0.89	0.30	5.52
		Total	542	344	0.97	0.57	0.81	0.27	5.52
Visit 44 (Week 53)	Daily	IDegAsp	362	236	0.94	0.55	0.77	0.25	3.42
		OD							
		IDet	180	113	1.05	0.65	0.91	0.30	5.80
		Total	542	349	0.97	0.58	0.82	0.25	5.80
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	0.89	0.49	0.76	0.08	3.42
		OD							
		IDet	180	178	1.04	0.65	0.88	0.30	5.80
		Total	542	538	0.94	0.55	0.80	0.08	5.80

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:46 - tdesc_numfind_tpl_t021_v01.sas/t_tot_dose_act_ukg_descp_sas.txt

14.2.43: Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp	362	360	0.41	0.19	0.37	0.09	1.93
		OD							
		IDet	180	176	0.39	0.19	0.39	0.08	1.76
		Total	542	536	0.41	0.19	0.38	0.08	1.93
		IDegAsp	362	359	0.42	0.19	0.39	0.10	1.95
		OD							
Visit 4 (Week 2)	Daily	IDet	180	176	0.41	0.20	0.39	0.09	1.79
		Total	542	535	0.42	0.19	0.39	0.09	1.95
		IDegAsp	362	346	0.43	0.19	0.40	0.12	1.89
Visit 5 (Week 3)	Daily	OD							
		IDet	180	175	0.44	0.22	0.42	0.05	1.87
		Total	542	521	0.43	0.20	0.40	0.05	1.89
Visit 6 (Week 4)	Daily	IDegAsp	362	351	0.44	0.20	0.40	0.14	1.97
		OD							
		IDet	180	174	0.47	0.24	0.43	0.10	1.92
		Total	542	525	0.45	0.21	0.41	0.10	1.97
		IDegAsp	362	349	0.44	0.21	0.41	0.10	1.95
		OD							
Visit 7 (Week 5)	Daily	IDet	180	173	0.48	0.25	0.44	0.09	2.14
		Total	542	522	0.46	0.22	0.42	0.09	2.14
		IDegAsp	362	343	0.45	0.22	0.40	0.07	1.93
Visit 8 (Week 6)	Daily	OD							
		IDet	180	172	0.49	0.27	0.43	0.09	2.14
		Total	542	515	0.46	0.24	0.41	0.07	2.14
Visit 9 (Week 7)	Daily	IDegAsp	362	342	0.45	0.22	0.40	0.07	1.93
		OD							
		IDet	180	171	0.50	0.28	0.45	0.08	2.14
		Total	542	513	0.47	0.24	0.41	0.07	2.14
		IDegAsp	362	340	0.46	0.23	0.39	0.08	1.98
		OD							
Visit 10 (Week 8)	Daily	IDet	180	171	0.51	0.27	0.46	0.10	1.71
		Total	542	511	0.48	0.25	0.42	0.08	1.98
		IDegAsp	362	334	0.47	0.24	0.41	0.09	2.07
Visit 11 (Week 9)	Daily	OD							
		IDet	180	166	0.51	0.28	0.45	0.07	1.84
		Total	542	500	0.48	0.26	0.42	0.07	2.07
Visit 12 (Week 10)	Daily	IDegAsp	362	337	0.47	0.24	0.41	0.08	2.14
		OD							
		IDet	180	169	0.51	0.29	0.45	0.12	1.92
		Total	542	506	0.49	0.26	0.42	0.08	2.14
		IDegAsp	362	334	0.48	0.25	0.41	0.12	2.09
		OD							
Visit 13 (Week 11)	Daily	IDet	180	167	0.51	0.29	0.45	0.10	2.01
		Total	542	501	0.49	0.26	0.42	0.10	2.09
		IDegAsp	362	333	0.47	0.25	0.40	0.14	1.94
Visit 14 (Week 12)	Daily	OD							
		IDet	180	167	0.51	0.28	0.44	0.08	2.06
		Total	542	500	0.48	0.26	0.43	0.08	2.06

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:56 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_ukg_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp	362	324	0.47	0.26	0.40	0.13	2.07
		OD							
		IDet	180	160	0.51	0.30	0.45	0.12	2.15
Visit 16 (Week 14)	Daily	Total	542	484	0.49	0.27	0.42	0.12	2.15
		IDegAsp	362	331	0.48	0.26	0.40	0.14	2.00
		OD							
Visit 17 (Week 15)	Daily	IDet	180	165	0.51	0.31	0.45	0.11	2.24
		Total	542	496	0.49	0.28	0.42	0.11	2.24
		IDegAsp	362	327	0.48	0.26	0.41	0.12	2.01
Visit 18 (Week 16)	Daily	OD							
		IDet	180	164	0.51	0.32	0.44	0.07	2.31
		Total	542	491	0.49	0.28	0.42	0.07	2.31
Visit 19 (Week 17)	Daily	IDegAsp	362	329	0.48	0.26	0.40	0.11	2.01
		OD							
		IDet	180	163	0.51	0.33	0.45	0.07	2.28
Visit 20 (Week 18)	Daily	Total	542	492	0.49	0.29	0.41	0.07	2.28
		IDegAsp	362	322	0.49	0.27	0.41	0.12	1.97
		OD							
Visit 21 (Week 19)	Daily	IDet	180	161	0.52	0.34	0.45	0.08	2.36
		Total	542	483	0.50	0.29	0.42	0.08	2.36
		IDegAsp	362	319	0.48	0.27	0.40	0.13	1.94
Visit 22 (Week 20)	Daily	OD							
		IDet	180	157	0.52	0.36	0.44	0.06	2.56
		Total	542	476	0.49	0.30	0.41	0.06	2.56
Visit 23 (Week 21)	Daily	IDegAsp	362	319	0.49	0.27	0.42	0.08	1.94
		OD							
		IDet	180	162	0.52	0.37	0.44	0.05	2.53
Visit 24 (Week 22)	Daily	Total	542	481	0.50	0.31	0.42	0.05	2.53
		IDegAsp	362	322	0.49	0.28	0.41	0.09	1.94
		OD							
Visit 25 (Week 23)	Daily	IDet	180	158	0.52	0.38	0.45	0.07	2.61
		Total	542	480	0.50	0.32	0.42	0.07	2.61
		IDegAsp	362	319	0.49	0.28	0.41	0.10	1.94
Visit 26 (Week 24)	Daily	OD							
		IDet	180	156	0.52	0.39	0.44	0.04	2.70
		Total	542	475	0.50	0.32	0.42	0.04	2.70
Visit 27 (Week 25)	Daily	IDegAsp	362	318	0.50	0.28	0.41	0.11	1.94
		OD							
		IDet	180	156	0.53	0.40	0.45	0.05	2.78
Visit 28 (Week 26)	Daily	Total	542	474	0.51	0.33	0.42	0.05	2.78
		IDegAsp	362	320	0.50	0.29	0.41	0.08	1.94
		OD							
Visit 29 (Week 27)	Daily	IDet	180	151	0.54	0.41	0.46	0.04	2.86
		Total	542	471	0.51	0.33	0.43	0.04	2.86
		IDegAsp	362	318	0.50	0.29	0.42	0.12	1.94
Visit 30 (Week 28)	Daily	OD							
		IDet	180	157	0.53	0.41	0.45	0.08	2.95
		Total	542	475	0.51	0.34	0.42	0.08	2.95

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:56 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_ukg_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 27 (Week 25)	Daily	IDegAsp	362	318	0.51	0.30	0.42	0.11	1.98
		OD							
		IDet	180	155	0.54	0.43	0.45	0.05	2.95
		Total	542	473	0.52	0.34	0.43	0.05	2.95
Visit 28 (Week 26)	Daily	IDegAsp	362	339	0.50	0.29	0.42	0.12	1.88
		OD							
		IDet	180	165	0.55	0.44	0.46	0.05	3.15
		Total	542	504	0.52	0.34	0.43	0.05	3.15
Visit 31 (Week 28)	Daily	IDegAsp	362	250	0.50	0.29	0.42	0.09	1.86
		OD							
		IDet	180	121	0.53	0.39	0.43	0.07	2.98
		Total	542	371	0.51	0.32	0.42	0.07	2.98
Visit 32 (Week 29)	Daily	IDegAsp	362	251	0.50	0.30	0.42	0.09	1.86
		OD							
		IDet	180	122	0.53	0.41	0.43	0.05	3.08
		Total	542	373	0.51	0.34	0.42	0.05	3.08
Visit 33 (Week 31)	Daily	IDegAsp	362	251	0.50	0.31	0.41	0.09	1.99
		OD							
		IDet	180	121	0.53	0.42	0.46	0.07	3.16
		Total	542	372	0.51	0.35	0.42	0.07	3.16
Visit 34 (Week 33)	Daily	IDegAsp	362	245	0.51	0.31	0.42	0.09	1.88
		OD							
		IDet	180	119	0.53	0.43	0.42	0.06	3.25
		Total	542	364	0.52	0.35	0.42	0.06	3.25
Visit 35 (Week 35)	Daily	IDegAsp	362	247	0.51	0.32	0.41	0.11	1.96
		OD							
		IDet	180	120	0.53	0.44	0.43	0.08	3.33
		Total	542	367	0.52	0.36	0.42	0.08	3.33
Visit 36 (Week 37)	Daily	IDegAsp	362	242	0.52	0.33	0.42	0.09	2.02
		OD							
		IDet	180	118	0.53	0.44	0.42	0.07	3.41
		Total	542	360	0.52	0.37	0.42	0.07	3.41
Visit 37 (Week 39)	Daily	IDegAsp	362	245	0.52	0.33	0.41	0.11	2.01
		OD							
		IDet	180	118	0.54	0.45	0.42	0.08	3.58
		Total	542	363	0.52	0.37	0.41	0.08	3.58
Visit 38 (Week 41)	Daily	IDegAsp	362	237	0.52	0.34	0.41	0.11	2.12
		OD							
		IDet	180	118	0.53	0.46	0.42	0.01	3.66
		Total	542	355	0.52	0.38	0.41	0.01	3.66
Visit 39 (Week 43)	Daily	IDegAsp	362	241	0.51	0.33	0.41	0.10	2.19
		OD							
		IDet	180	118	0.53	0.47	0.43	0.03	3.75
		Total	542	359	0.52	0.38	0.41	0.03	3.75
Visit 40 (Week 45)	Daily	IDegAsp	362	237	0.53	0.35	0.42	0.11	2.25
		OD							
		IDet	180	116	0.53	0.47	0.40	0.04	3.83
		Total	542	353	0.53	0.39	0.41	0.04	3.83

N = Number of Subjects, SD = Standard Deviation

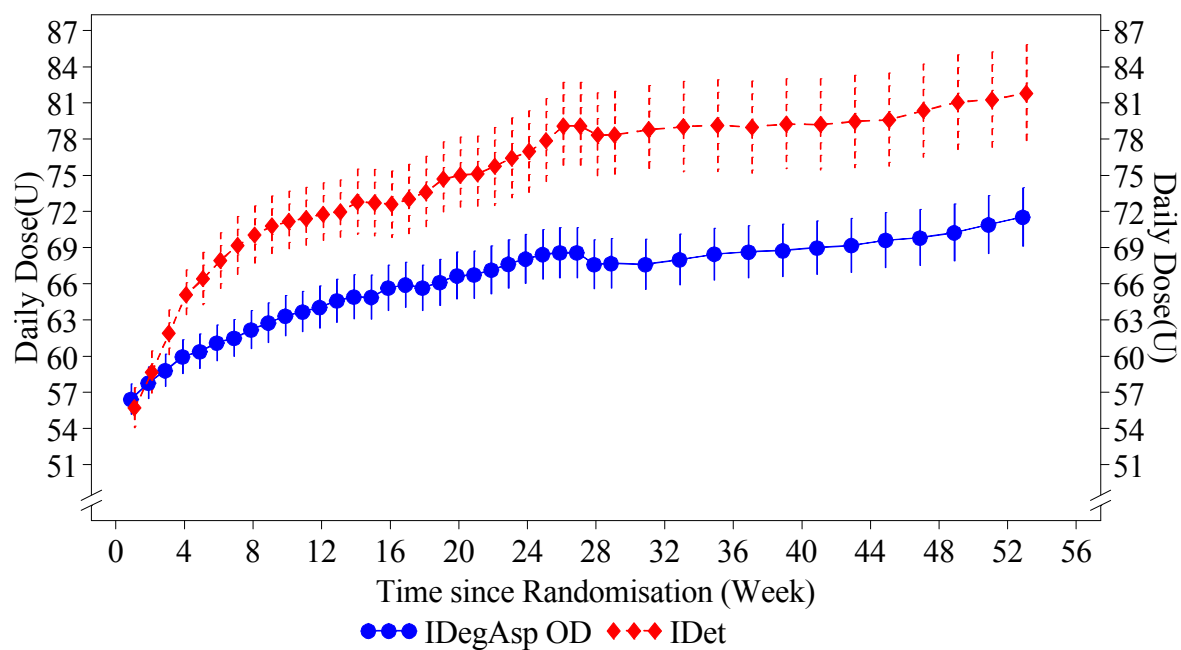
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:34:56 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_ukg_descp_sas.txt

Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Descriptive Statistics - Safety Analysis Set

Visit	Endpoint	Treatment	--Descriptive Statistics--						
			SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 41 (Week 47)	Daily	IDegAsp	362	240	0.53	0.36	0.42	0.10	2.29
		OD							
		IDet	180	116	0.53	0.46	0.42	0.03	3.83
		Total	542	356	0.53	0.40	0.42	0.03	3.83
Visit 42 (Week 49)	Daily	IDegAsp	362	233	0.54	0.37	0.42	0.10	2.25
		OD							
		IDet	180	113	0.54	0.48	0.43	0.03	3.92
		Total	542	346	0.54	0.41	0.42	0.03	3.92
Visit 43 (Week 51)	Daily	IDegAsp	362	232	0.55	0.38	0.43	0.10	2.39
		OD							
		IDet	180	111	0.55	0.49	0.44	0.02	4.00
		Total	542	343	0.55	0.42	0.44	0.02	4.00
Visit 44 (Week 53)	Daily	IDegAsp	362	236	0.55	0.38	0.42	0.11	2.38
		OD							
		IDet	180	113	0.55	0.51	0.43	0.03	4.21
		Total	542	349	0.55	0.43	0.42	0.03	4.21
Visit 44 (Week 53) (LOCF)	Daily	IDegAsp	362	360	0.52	0.34	0.41	0.11	2.38
		OD							
		IDet	180	178	0.55	0.48	0.44	0.03	4.21
		Total	542	538	0.53	0.39	0.42	0.03	4.21

N = Number of Subjects, SD = Standard Deviation

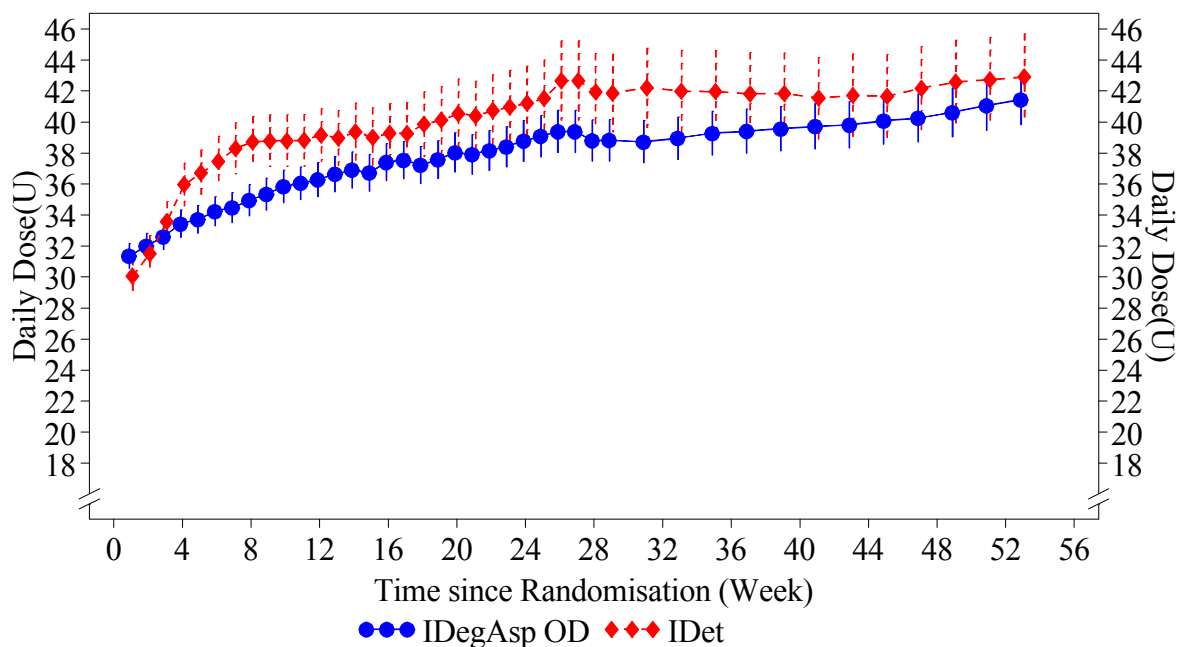
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:34:56 - tdesc_numfind_tpl_t021_v01.sas/t_tot_b_dose_act_ukg_descp_sas.txt



SAFETY; LOCF imputed data
 Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:35:06 - fmean_numfind_v03.sas/e_tot_dose_d_act_u_mean_locf_sas.cgm

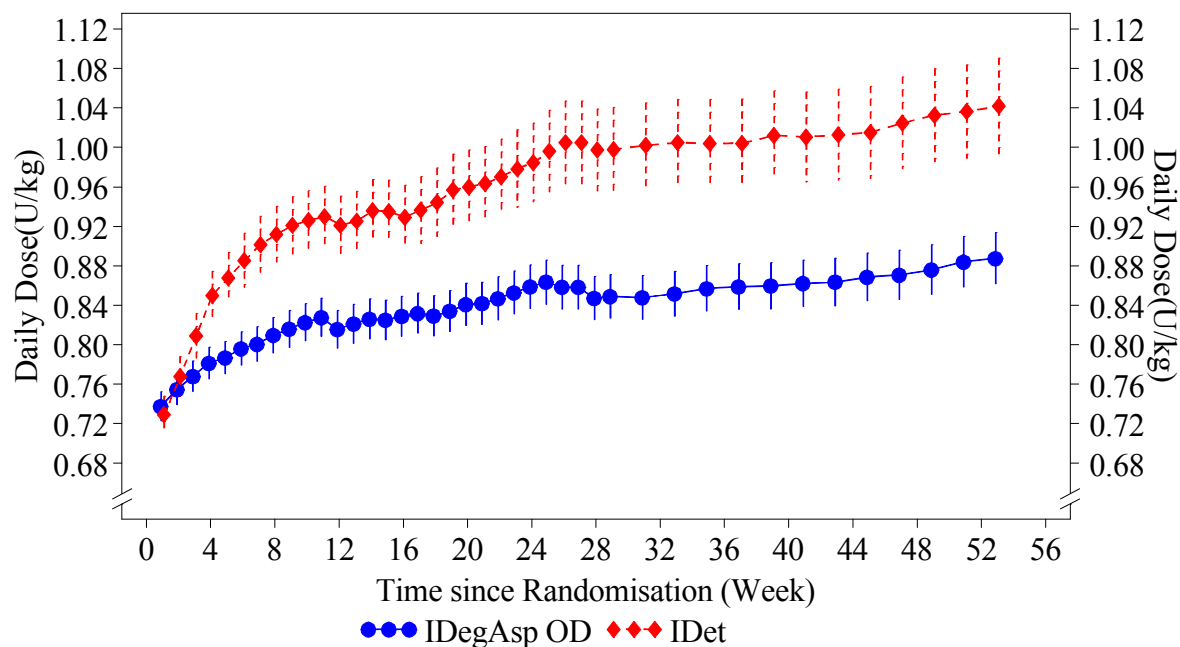
14.2.44: Total Daily Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:35:16 - fmean_numfind_v03.sas/e_tot_b_d_act_u_mean_locf_sas.cgm

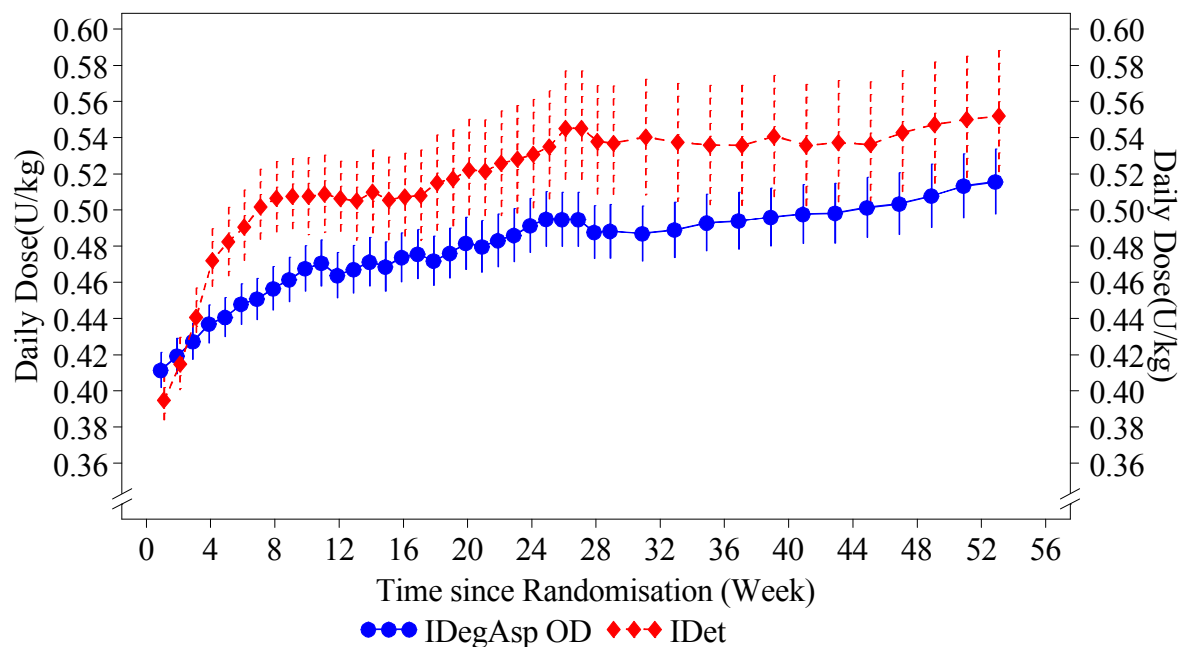
14.2.45: Total Daily Bolus Insulin Dose (Actual) in Units by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:35:26 - fmean_numfind_v03.sas/e_t_dose_d_act_ukg_mean_locf_sas.cgm

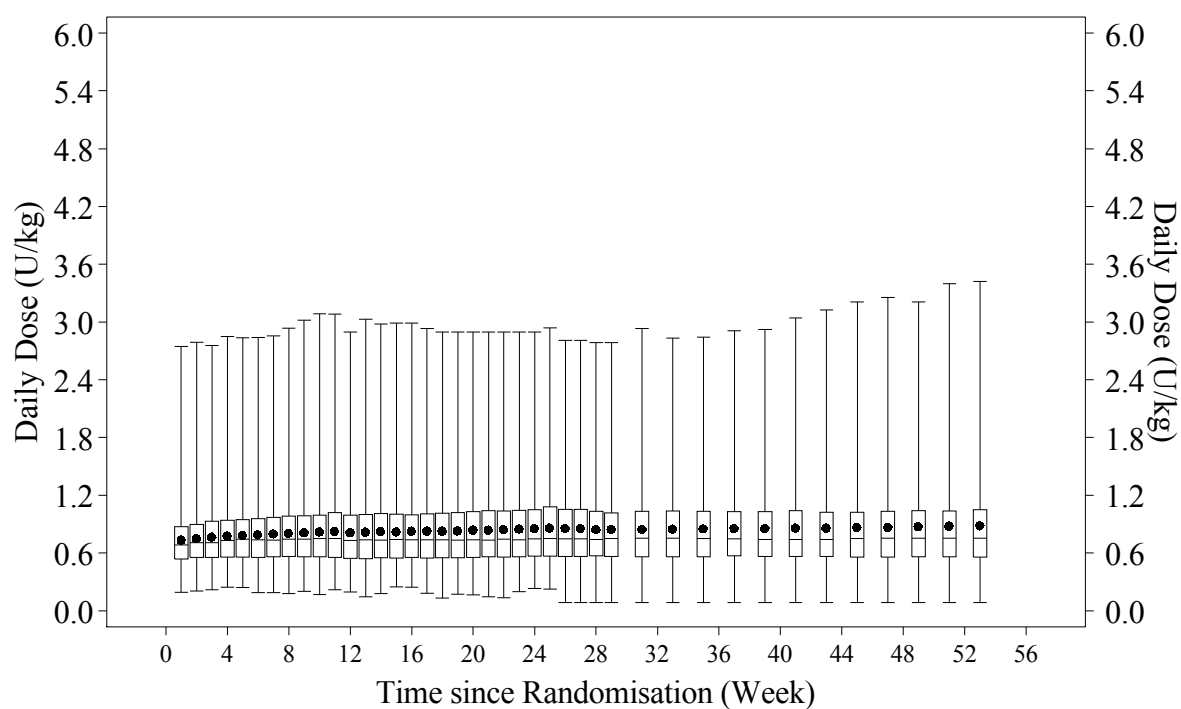
14.2.46: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:35:36 - fmean_numfind_v03.sas/e_tot_b_d_act_ukg_mean_locf_sas.cgm

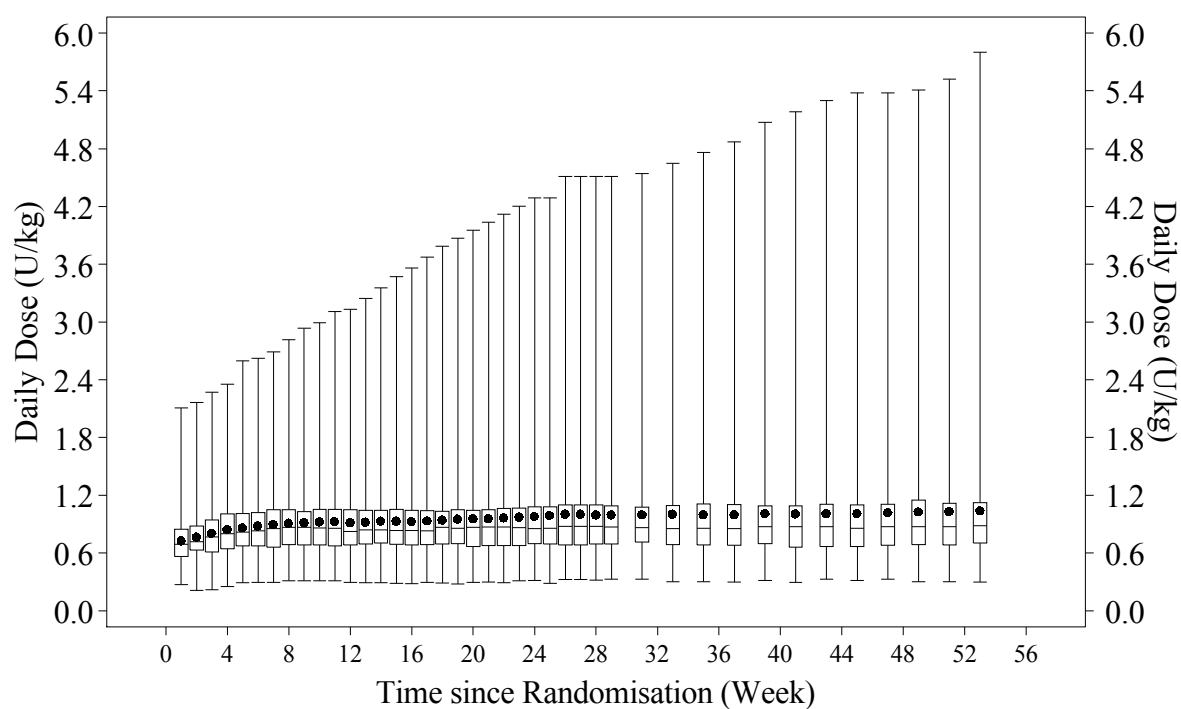
14.2.47: Total Daily Bolus Insulin Dose (Actual) in Units/kg by Treatment Week - Mean Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:35:46 - fbox_numfind_v01.sas/e_tot_d_iv1_act_ukg_box_locf_sas.cgm

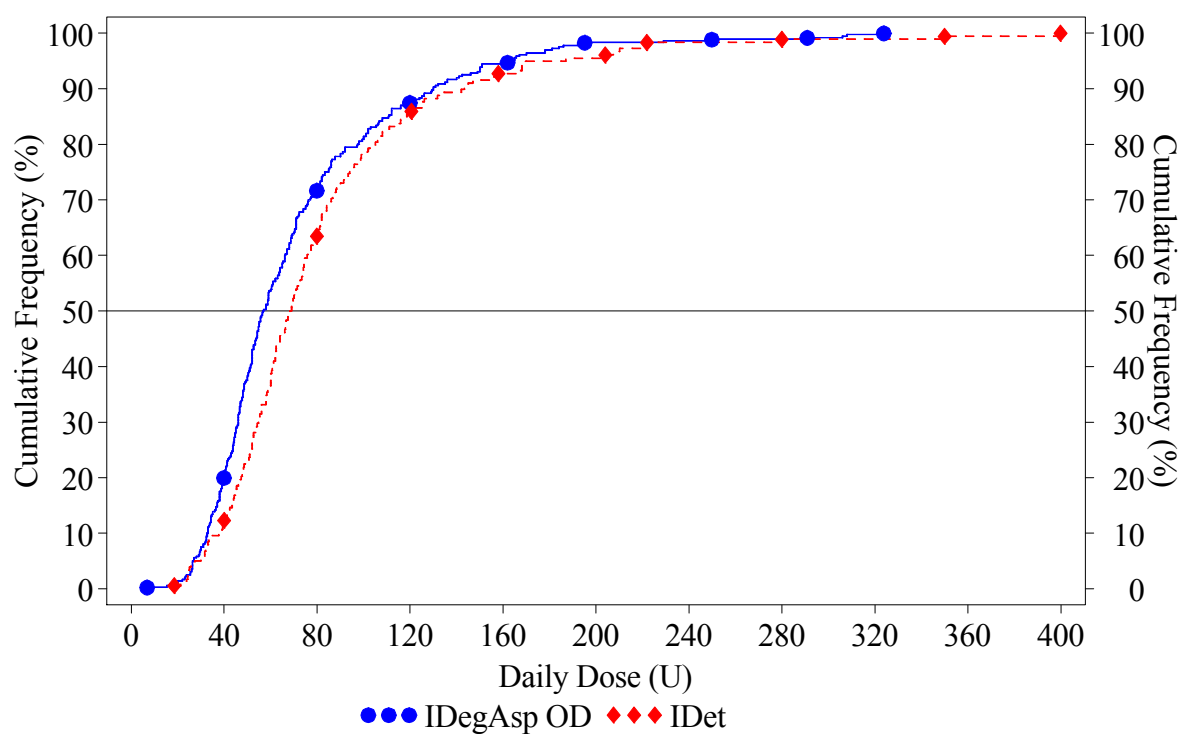
14.2.48: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - IDegAsp OD - Box Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:35:56 - fbox_numfind_v01.sas/e_tot_d_cm_act_ukg_box_locf_sas.cgm

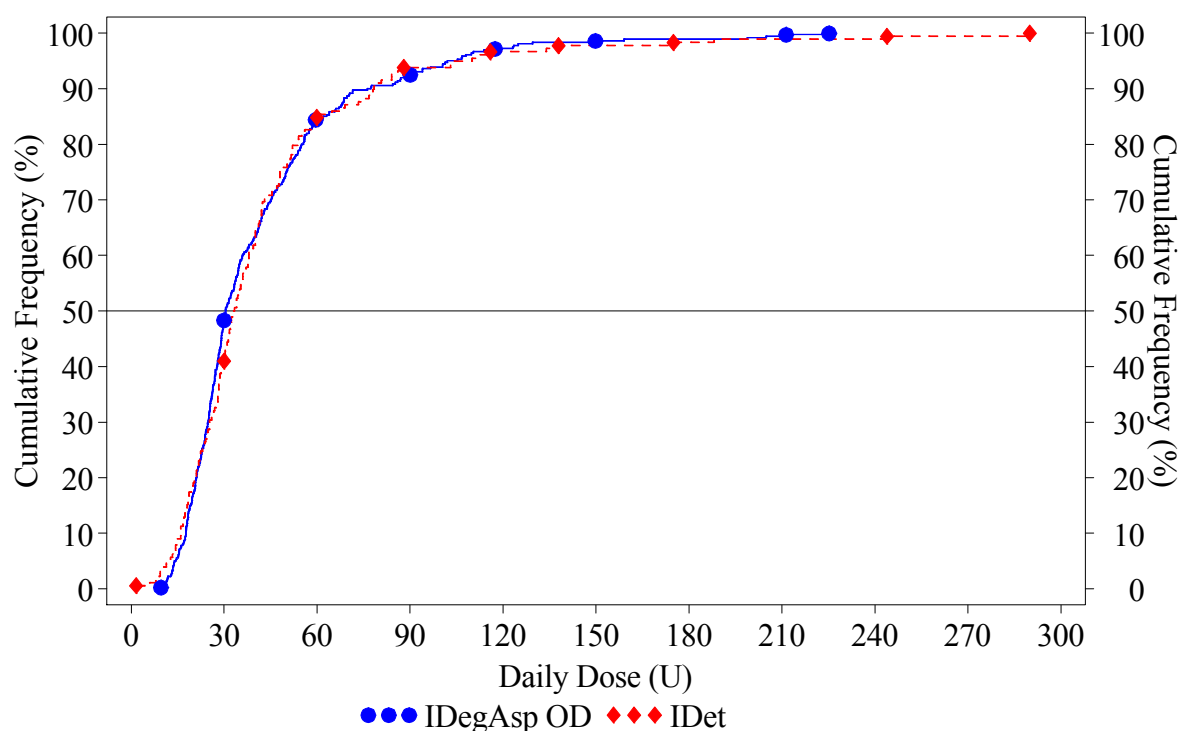
14.2.49: Total Daily Insulin Dose (Actual) in Units/kg by Treatment Week - IDet - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:04 - fedist_numfind_v01.sas/e_tot_dose_d_act_u_cdf_locf_sas.cgm

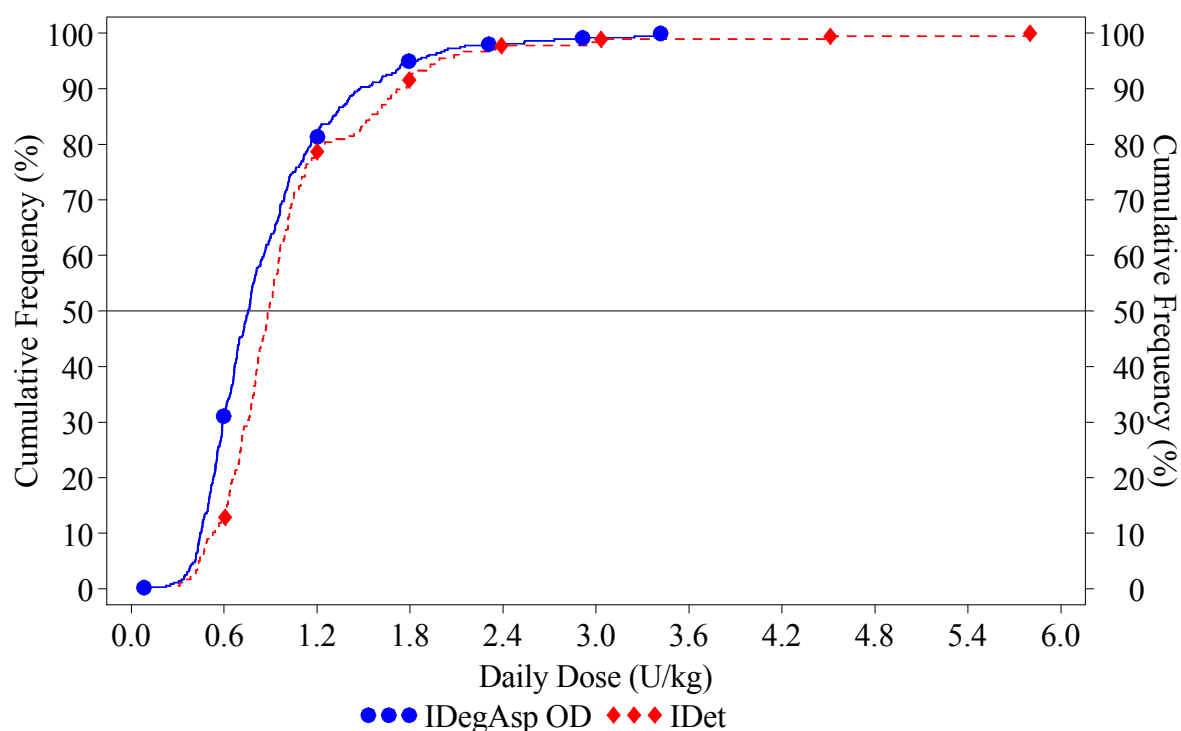
14.2.50: Total Daily Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:13 - fedist_numfind_v01.sas/e_tot_b_d_act_u_cdf_locf_sas.cgm

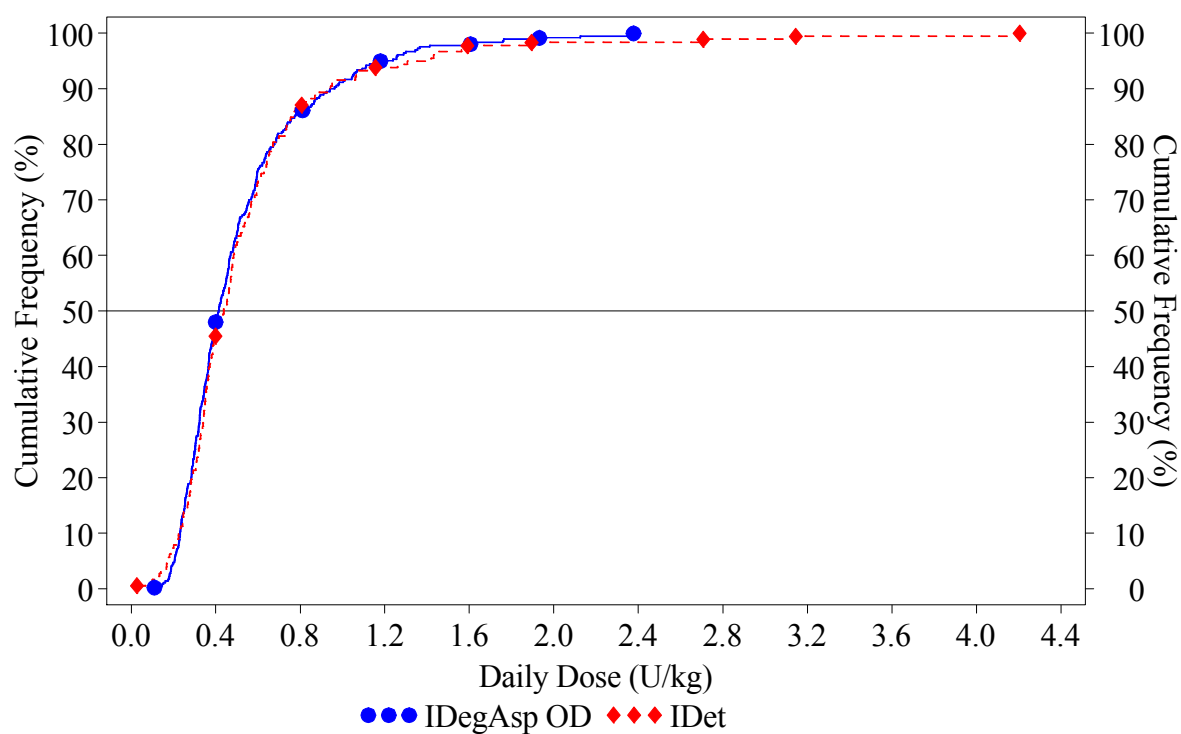
14.2.51: Total Daily Bolus Insulin Dose (Actual) in Units after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:21 - fedist_numfind_v01.sas/e_tot_d_act_ukg_cdf_locf_sas.cgm

14.2.52: Total Daily Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:29 - fedist_numfind_v01.sas/e_tot_b_d_act_ukg_cdf_locf_sas.cgm

14.2.53: Total Daily Bolus Insulin Dose (Actual) in Units/kg after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.2.54: IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set

Week	Breakfast N (%)	Mean	Lunch N (%)	Mean	Main Evening Meal N (%)	Mean	Other N (%)	Mean
Visit 3 (Week 1)	52 (14.4)	35.46	73 (20.2)	34.22	243 (67.1)	36.72		
Visit 4 (Week 2)	56 (15.5)	36.01	69 (19.1)	35.46	241 (66.6)	37.59	1 (0.28)	34.00
Visit 5 (Week 3)	59 (16.3)	37.01	60 (16.6)	36.26	228 (63.0)	38.12		
Visit 6 (Week 4)	58 (16.0)	37.17	67 (18.5)	35.66	232 (64.1)	39.05		
Visit 7 (Week 5)	54 (14.9)	37.07	71 (19.6)	35.82	231 (63.8)	39.53	1 (0.28)	33.00
Visit 8 (Week 6)	53 (14.6)	37.63	62 (17.1)	35.62	230 (63.5)	39.73		
Visit 9 (Week 7)	51 (14.1)	37.81	64 (17.7)	38.04	233 (64.4)	39.55		
Visit 10 (Week 8)	53 (14.6)	37.62	64 (17.7)	37.33	228 (63.0)	40.41		
Visit 11 (Week 9)	53 (14.6)	38.26	63 (17.4)	38.32	223 (61.6)	40.53	1 (0.28)	36.00
Visit 12 (Week 10)	52 (14.4)	38.19	63 (17.4)	39.36	225 (62.2)	40.82	1 (0.28)	23.00
Visit 13 (Week 11)	55 (15.2)	38.38	61 (16.9)	39.72	224 (61.9)	41.00	1 (0.28)	21.00
Visit 14 (Week 12)	53 (14.6)	39.07	62 (17.1)	40.45	223 (61.6)	41.06		
Visit 15 (Week 13)	48 (13.3)	38.62	66 (18.2)	39.28	215 (59.4)	41.75	1 (0.28)	74.00
Visit 16 (Week 14)	51 (14.1)	37.86	62 (17.1)	39.52	222 (61.3)	42.01	1 (0.28)	91.00
Visit 17 (Week 15)	52 (14.4)	38.99	60 (16.6)	39.64	219 (60.5)	42.15	1 (0.28)	24.00

N: Number of Subjects

The descriptive statistics are based on recorded doses.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:46 - T_TRT_DOSE_MEAL.SAS/t_idegasp_dose_meal_descp_sas.txt

IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics
- Safety Analysis Set

Week	Breakfast N (%)	Mean	Lunch N (%)	Mean	Main Evening Meal N (%)	Mean	Other N (%)	Mean
Visit 18 (Week 16)	50 (13.8)	38.99	62 (17.1)	39.58	219 (60.5)	42.36		
Visit 19 (Week 17)	48 (13.3)	40.34	57 (15.7)	38.79	222 (61.3)	42.88		
Visit 20 (Week 18)	47 (13.0)	41.16	57 (15.7)	38.07	220 (60.8)	42.92		
Visit 21 (Week 19)	45 (12.4)	41.68	55 (15.2)	37.95	223 (61.6)	42.87		
Visit 22 (Week 20)	46 (12.7)	41.84	57 (15.7)	39.02	222 (61.3)	43.21		
Visit 23 (Week 21)	46 (12.7)	41.77	56 (15.5)	38.72	220 (60.8)	43.04	1 (0.28)	62.00
Visit 24 (Week 22)	44 (12.2)	42.31	57 (15.7)	38.42	219 (60.5)	43.75		
Visit 25 (Week 23)	44 (12.2)	43.70	57 (15.7)	38.68	223 (61.6)	43.70	1 (0.28)	36.00
Visit 26 (Week 24)	45 (12.4)	43.25	55 (15.2)	38.66	219 (60.5)	43.94		
Visit 27 (Week 25)	43 (11.9)	44.02	55 (15.2)	38.71	221 (61.0)	43.80	2 (0.55)	73.50
Visit 28 (Week 26)	50 (13.8)	41.41	59 (16.3)	39.14	233 (64.4)	43.65		
Visit 31 (Week 28)	31 (8.56)	42.74	45 (12.4)	39.09	179 (49.4)	42.91		
Visit 32 (Week 29)	31 (8.56)	42.83	46 (12.7)	39.20	178 (49.2)	43.83	2 (0.55)	44.00
Visit 33 (Week 31)	33 (9.12)	42.44	47 (13.0)	38.63	172 (47.5)	43.58		
Visit 34 (Week 33)	31 (8.56)	42.23	41 (11.3)	40.17	173 (47.8)	43.94		

N: Number of Subjects

The descriptive statistics are based on recorded doses.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:46 - T_TRT_DOSE_MEAL.SAS/t_idegasp_dose_meal_descp_sas.txt

IDegAsp Doses in Units per Meal by Treatment Week - Descriptive Statistics
- Safety Analysis Set

Week	Breakfast N (%)	Mean	Lunch N (%)	Mean	Main Evening Meal N (%)	Mean	Other N (%)	Mean
Visit 35 (Week 35)	32 (8.84)	42.10	40 (11.0)	40.12	177 (48.9)	43.92	1 (0.28)	15.00
Visit 36 (Week 37)	30 (8.29)	43.03	39 (10.8)	42.83	178 (49.2)	44.16		
Visit 37 (Week 39)	32 (8.84)	42.84	39 (10.8)	43.25	176 (48.6)	43.88	1 (0.28)	75.00
Visit 38 (Week 41)	31 (8.56)	43.15	37 (10.2)	43.03	170 (47.0)	43.96		
Visit 39 (Week 43)	31 (8.56)	42.73	37 (10.2)	42.22	174 (48.1)	44.21		
Visit 40 (Week 45)	31 (8.56)	43.37	40 (11.0)	43.23	169 (46.7)	44.84		
Visit 41 (Week 47)	31 (8.56)	43.63	40 (11.0)	43.59	172 (47.5)	44.99		
Visit 42 (Week 49)	28 (7.73)	44.45	39 (10.8)	42.83	168 (46.4)	45.14	1 (0.28)	48.00
Visit 43 (Week 51)	31 (8.56)	42.47	38 (10.5)	43.22	163 (45.0)	45.95	1 (0.28)	27.00
Visit 44 (Week 53)	31 (8.56)	43.23	38 (10.5)	43.66	168 (46.4)	46.44		

N: Number of Subjects

The descriptive statistics are based on recorded doses.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:46 - T_TRT_DOSE_MEAL.SAS/t_idegasp_dose_meal_descp_sas.txt

14.2.55: IDet Doses in Units per Meal by Treatment Week - Descriptive Statistics - Safety Analysis Set

Week	Morning N (%)	Mean	Evening N (%)	Mean
Visit 3 (Week 1)			169 (93.9)	25.72
Visit 4 (Week 2)			170 (94.4)	27.09
Visit 5 (Week 3)	1 (0.56)	30.00	170 (94.4)	28.22
Visit 6 (Week 4)	1 (0.56)	16.00	170 (94.4)	29.08
Visit 7 (Week 5)	1 (0.56)	12.00	169 (93.9)	29.12
Visit 8 (Week 6)	2 (1.11)	19.00	169 (93.9)	30.47
Visit 9 (Week 7)	1 (0.56)	18.00	167 (92.8)	31.01
Visit 10 (Week 8)	2 (1.11)	15.50	168 (93.3)	31.29
Visit 11 (Week 9)	8 (4.44)	13.50	163 (90.6)	31.14
Visit 12 (Week 10)	15 (8.33)	15.62	167 (92.8)	31.35
Visit 13 (Week 11)	24 (13.3)	15.76	162 (90.0)	31.38
Visit 14 (Week 12)	26 (14.4)	15.51	163 (90.6)	31.22
Visit 15 (Week 13)	26 (14.4)	14.17	159 (88.3)	31.59
Visit 16 (Week 14)	30 (16.7)	13.60	163 (90.6)	31.49
Visit 17 (Week 15)	34 (18.9)	13.82	160 (88.9)	31.62
Visit 18 (Week 16)	35 (19.4)	13.22	161 (89.4)	31.65
Visit 19 (Week 17)	35 (19.4)	13.83	160 (88.9)	31.63
Visit 20 (Week 18)	32 (17.8)	15.36	157 (87.2)	32.26
Visit 21 (Week 19)	32 (17.8)	15.52	161 (89.4)	32.19
Visit 22 (Week 20)	34 (18.9)	15.95	158 (87.8)	31.73
Visit 23 (Week 21)	37 (20.6)	16.85	157 (87.2)	31.59
Visit 24 (Week 22)	38 (21.1)	16.10	155 (86.1)	31.68
Visit 25 (Week 23)	36 (20.0)	16.77	151 (83.9)	32.00
Visit 26 (Week 24)	41 (22.8)	16.54	157 (87.2)	32.25
Visit 27 (Week 25)	42 (23.3)	17.57	153 (85.0)	32.72
Visit 28 (Week 26)	44 (24.4)	17.56	164 (91.1)	32.19

N: Number of Subjects

The descriptive statistics are based on recorded doses.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:49 - T_TRT_DOSE_MEAL.SAS/t_idet_dose_meal_descp_sas.txt

IDet Doses in Units per Meal by Treatment Week - Descriptive Statistics
 - Safety Analysis Set

Week	Morning N (%)	Mean	Evening N (%)	Mean
Visit 31 (Week 28)	30 (16.7)	17.24	121 (67.2)	33.22
Visit 32 (Week 29)	31 (17.2)	17.71	122 (67.8)	33.13
Visit 33 (Week 31)	33 (18.3)	18.01	121 (67.2)	33.24
Visit 34 (Week 33)	34 (18.9)	18.21	120 (66.7)	33.34
Visit 35 (Week 35)	35 (19.4)	18.17	119 (66.1)	33.64
Visit 36 (Week 37)	33 (18.3)	18.75	118 (65.6)	33.59
Visit 37 (Week 39)	35 (19.4)	18.93	118 (65.6)	33.67
Visit 38 (Week 41)	35 (19.4)	19.89	118 (65.6)	33.84
Visit 39 (Week 43)	34 (18.9)	20.41	117 (65.0)	33.99
Visit 40 (Week 45)	34 (18.9)	20.56	116 (64.4)	33.99
Visit 41 (Week 47)	35 (19.4)	21.45	115 (63.9)	33.91
Visit 42 (Week 49)	35 (19.4)	21.71	112 (62.2)	34.44
Visit 43 (Week 51)	35 (19.4)	22.75	111 (61.7)	34.41
Visit 44 (Week 53)	36 (20.0)	23.02	112 (62.2)	34.15

N: Number of Subjects

The descriptive statistics are based on recorded doses.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:37:49 - T_TRT_DOSE_MEAL.SAS/t_idet_dose_meal_descp_sas.txt

14.2.56: Insulin Dose Ratio after 52 Weeks of Treatment - Summary - Safety Analysis Set

Treatment Ratio	Mean Ratio (U)	Mean Ratio (U/kg)
Total Daily Insulin Dose		
IDegAsp / IDet	0.87	0.85
Derived Total Basal Insulin Dose		
IDegAsp / IDet	0.78	0.77
Derived Total Bolus Insulin Dose		
IDegAsp / IDet	0.97	0.93
Bolus Insulin Dose (Separate IAsp doses)		
IDegAsp / IDet	0.66	0.64

Mean ratio is calculated as the ratio between mean doses at last scheduled treatment visit, where missing data have been imputed using last observation carried forward.

Derived total basal insulin dose:
IDegAsp = the IDeg part of the IDegAsp OD dose; IDet = the (sum of) injected IDet dose(s)

Derived total bolus insulin dose:
IDegAsp = the sum of injected IAsp doses plus the IAsp part of the IDegAsp OD dose;
IDet = the sum of injected IAsp doses.

Bolus insulin dose: 'separate' injections of IAsp.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:38:02 - tsum_dose_ratio.sas/t_ins_dose_ratio_locf_sas.txt

14.2.57: Basal - Bolus Split of Total Daily Insulin Dose (U/kg) - Summary - Safety Analysis Set

	IDegAsp Basal / Bolus	IDet Basal / Bolus
Visit 3 (Week 1)	44 / 56	46 / 54
Visit 44 (Week 53)	42 / 58	47 / 53

Basal: Percentage Basal Insulin, Bolus; Percentage Bolus Insulin
Basal-Bolus Split is derived from Mean Doses Computed from LOCF imputed data.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:36:41 - t_basal_bolus_ratio.sas/t_basal_bolus_ratio_locf_sas.txt

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:36:41 - t_basal_bolus_ratio.sas/t_basal_bolus_ratio_locf_sas.txt

14.2.58: Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Prescrib Compliance(U)			
Visit 2 (Week 0)			
N	360	177	537
Mean (SD)	1 (3)	0 (1)	0 (2)
Median	0	0	0
Min ; Max	-14 ; 23	-6 ; 12	-14 ; 23
Visit 3 (Week 1)			
N	359	176	535
Mean (SD)	0 (2)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 12	-4 ; 5	-7 ; 12
Visit 4 (Week 2)			
N	353	174	527
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 12	-4 ; 4	-6 ; 12
Visit 5 (Week 3)			
N	347	173	520
Mean (SD)	0 (1)	-0 (3)	0 (2)
Median	0	0	0
Min ; Max	-4 ; 10	-32 ; 5	-32 ; 10
Visit 6 (Week 4)			
N	350	175	525
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-4 ; 11	-12 ; 6	-12 ; 11
Visit 7 (Week 5)			
N	343	173	516
Mean (SD)	0 (1)	-0 (2)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 5	-18 ; 2	-18 ; 5
Visit 8 (Week 6)			
N	342	172	514
Mean (SD)	0 (1)	-0 (2)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 11	-18 ; 4	-18 ; 11
Visit 9 (Week 7)			
N	338	170	508
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 11	-18 ; 14	-18 ; 14
Visit 10 (Week 8)			
N	340	169	509
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-4 ; 8	-4 ; 9	-4 ; 9

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:39 - tdesc_numfind_tpl_t019_v01.sas/t_ins_prscb_act_diff_descp_sas.txt

Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week -
Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Prescrib Compliance(U)			
Visit 11 (Week 9)			
N	333	166	499
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 12	-4 ; 8	-4 ; 12
Visit 12 (Week 10)			
N	335	169	504
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 10	-5 ; 16	-5 ; 16
Visit 13 (Week 11)			
N	333	166	499
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 10	-2 ; 13	-7 ; 13
Visit 14 (Week 12)			
N	332	167	499
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-4 ; 7	-4 ; 5	-4 ; 7
Visit 15 (Week 13)			
N	321	160	481
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 14	-4 ; 8	-4 ; 14
Visit 16 (Week 14)			
N	331	164	495
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 13	-6 ; 7	-7 ; 13
Visit 17 (Week 15)			
N	323	163	486
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-7 ; 11	-6 ; 13	-7 ; 13
Visit 18 (Week 16)			
N	328	163	491
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 10	-10 ; 4	-10 ; 10
Visit 19 (Week 17)			
N	319	160	479
Mean (SD)	0 (1)	-0 (1)	0 (1)
Median	0	0	0
Min ; Max	-5 ; 12	-7 ; 3	-7 ; 12
Visit 20 (Week 18)			
N	316	157	473
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 4	-3 ; 4	-3 ; 4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:39 - tdesc_numfind_tpl_t019_v01.sas/t_ins_prscb_act_diff_descp_sas.txt

Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week -
Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Prescrib Compliance(U)			
Visit 21 (Week 19)			
N	316	159	475
Mean (SD)	0 (1)	0 (2)	0 (2)
Median	0	0	0
Min ; Max	-3 ; 15	-6 ; 15	-6 ; 15
Visit 22 (Week 20)			
N	321	157	478
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-10 ; 12	-4 ; 11	-10 ; 12
Visit 23 (Week 21)			
N	316	156	472
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 9	-4 ; 6	-4 ; 9
Visit 24 (Week 22)			
N	315	153	468
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-5 ; 16	-2 ; 7	-5 ; 16
Visit 25 (Week 23)			
N	314	151	465
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 14	-2 ; 6	-6 ; 14
Visit 26 (Week 24)			
N	310	153	463
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-2 ; 14	-8 ; 4	-8 ; 14
Visit 27 (Week 25)			
N	66	33	99
Mean (SD)	0 (1)	0 (2)	0 (2)
Median	0	0	0
Min ; Max	-1 ; 6	-8 ; 8	-8 ; 8
Visit 31 (Week 28)			
N	249	120	369
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 4	-5 ; 7	-5 ; 7
Visit 32 (Week 29)			
N	246	120	366
Mean (SD)	0 (2)	0 (1)	0 (2)
Median	0	0	0
Min ; Max	-7 ; 18	-2 ; 9	-7 ; 18
Visit 33 (Week 31)			
N	250	120	370
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-9 ; 7	-7 ; 7	-9 ; 7

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:39 - tdesc_numfind_tpl_t019_v01.sas/t_ins_prscb_act_diff_descp_sas.txt

Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week -
Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Prescrib Compliance(U)			
Visit 34 (Week 33)			
N	243	120	363
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-9 ; 6	-4 ; 14	-9 ; 14
Visit 35 (Week 35)			
N	244	120	364
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-5 ; 8	-4 ; 8	-5 ; 8
Visit 36 (Week 37)			
N	241	114	355
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-2 ; 9	-2 ; 3	-2 ; 9
Visit 37 (Week 39)			
N	244	118	362
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-3 ; 6	-10 ; 4	-10 ; 6
Visit 38 (Week 41)			
N	234	118	352
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 5	-4 ; 6	-6 ; 6
Visit 39 (Week 43)			
N	240	117	357
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 7	-2 ; 6	-6 ; 7
Visit 40 (Week 45)			
N	235	114	349
Mean (SD)	0 (2)	0 (2)	0 (2)
Median	0	0	0
Min ; Max	-13 ; 12	-13 ; 12	-13 ; 12
Visit 41 (Week 47)			
N	235	114	349
Mean (SD)	0 (1)	-0 (1)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 10	-4 ; 4	-6 ; 10
Visit 42 (Week 49)			
N	229	112	341
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-4 ; 5	-5 ; 13	-5 ; 13
Visit 43 (Week 51)			
N	232	111	343
Mean (SD)	0 (1)	0 (1)	0 (1)
Median	0	0	0
Min ; Max	-4 ; 6	-3 ; 8	-4 ; 8

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:39 - tdesc_numfind_tpl_t019_v01.sas/t_ins_prscb_act_diff_descp_sas.txt

Prescribed minus Actual Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week -
Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Prescrib Compliance(U)			
Visit 44 (Week 53) (LOCF)			
N	360	178	538
Mean (SD)	0 (1)	0 (2)	0 (1)
Median	0	0	0
Min ; Max	-6 ; 6	-8 ; 8	-8 ; 8

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:39 - tdesc_numfind_tpl_t019_v01.sas/t_ins_prscb_act_diff_descp_sas.txt

14.2.59: Prescribed minus Titration Algorithm Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Titration Compliance(U)			
Visit 3 (Week 1)			
N	358	174	532
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-13 ; 10	-8 ; 8	-13 ; 10
Visit 4 (Week 2)			
N	358	173	531
Mean (SD)	-1 (2)	-0 (2)	-1 (2)
Median	0	0	0
Min ; Max	-12 ; 20	-9 ; 4	-12 ; 20
Visit 5 (Week 3)			
N	344	170	514
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 6	-16 ; 4	-16 ; 6
Visit 6 (Week 4)			
N	348	173	521
Mean (SD)	-1 (3)	-0 (3)	-1 (3)
Median	0	0	0
Min ; Max	-8 ; 17	-10 ; 14	-10 ; 17
Visit 7 (Week 5)			
N	348	173	521
Mean (SD)	-1 (3)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-29 ; 12	-6 ; 10	-29 ; 12
Visit 8 (Week 6)			
N	341	171	512
Mean (SD)	-1 (2)	-0 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 6	-7 ; 4	-8 ; 6
Visit 9 (Week 7)			
N	339	168	507
Mean (SD)	-1 (3)	-1 (2)	-1 (3)
Median	0	0	0
Min ; Max	-8 ; 32	-6 ; 4	-8 ; 32
Visit 10 (Week 8)			
N	336	168	504
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-10 ; 10	-8 ; 5	-10 ; 10
Visit 11 (Week 9)			
N	330	165	495
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 6	-10 ; 6	-10 ; 6

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:49 - tdesc_numfind_tpl_t019_v01.sas/t_ins_ds_prscb_ttrt_diff_ds_c_sas.txt

Prescribed minus Titration Algorithm Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Titration Compliance(U)			
Visit 12 (Week 10)			
N	333	168	501
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-10 ; 5	-12 ; 10	-12 ; 10
Visit 13 (Week 11)			
N	332	164	496
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 8	-8 ; 8	-8 ; 8
Visit 14 (Week 12)			
N	331	165	496
Mean (SD)	-1 (3)	-1 (2)	-1 (2)
Median	-1	-2	-1
Min ; Max	-12 ; 24	-10 ; 4	-12 ; 24
Visit 15 (Week 13)			
N	319	159	478
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 10	-8 ; 6	-8 ; 10
Visit 16 (Week 14)			
N	330	165	495
Mean (SD)	-1 (2)	-0 (2)	-1 (2)
Median	0	0	0
Min ; Max	-20 ; 6	-10 ; 10	-20 ; 10
Visit 17 (Week 15)			
N	323	160	483
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-9 ; 5	-8 ; 6	-9 ; 6
Visit 18 (Week 16)			
N	327	162	489
Mean (SD)	-1 (2)	-1 (3)	-1 (3)
Median	0	0	0
Min ; Max	-14 ; 9	-8 ; 26	-14 ; 26
Visit 19 (Week 17)			
N	320	160	480
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-10 ; 4	-10 ; 6	-10 ; 6
Visit 20 (Week 18)			
N	313	156	469
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-9 ; 9	-12 ; 6	-12 ; 9
Visit 21 (Week 19)			
N	314	160	474
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-6 ; 4	-10 ; 5	-10 ; 5

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:49 - tdesc_numfind_tpl_t019_v01.sas/t_ins_ds_prscb_ttrt_diff_dsc_sas.txt

Prescribed minus Titration Algorithm Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Titration Compliance(U)			
Visit 22 (Week 20)			
N	318	158	476
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-8 ; 14	-9 ; 20	-9 ; 20
Visit 23 (Week 21)			
N	316	154	470
Mean (SD)	-1 (2)	-1 (3)	-1 (3)
Median	0	0	0
Min ; Max	-17 ; 22	-10 ; 28	-17 ; 28
Visit 24 (Week 22)			
N	313	156	469
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-6 ; 12	-8 ; 7	-8 ; 12
Visit 25 (Week 23)			
N	316	149	465
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-9 ; 6	-12 ; 22	-12 ; 22
Visit 26 (Week 24)			
N	317	157	474
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-10 ; 6	-10 ; 10	-10 ; 10
Visit 27 (Week 25)			
N	313	151	464
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-6 ; 6	-12 ; 7	-12 ; 7
Visit 31 (Week 28)			
N	249	120	369
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	-2	0
Min ; Max	-10 ; 11	-9 ; 4	-10 ; 11
Visit 32 (Week 29)			
N	248	120	368
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	0	0
Min ; Max	-12 ; 5	-8 ; 5	-12 ; 5
Visit 33 (Week 31)			
N	249	120	369
Mean (SD)	-1 (2)	-2 (3)	-1 (2)
Median	0	-2	0
Min ; Max	-8 ; 5	-11 ; 2	-11 ; 5
Visit 34 (Week 33)			
N	243	119	362
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-6 ; 6	-8 ; 12	-8 ; 12

N = Number of Subjects, SD = Standard Deviation

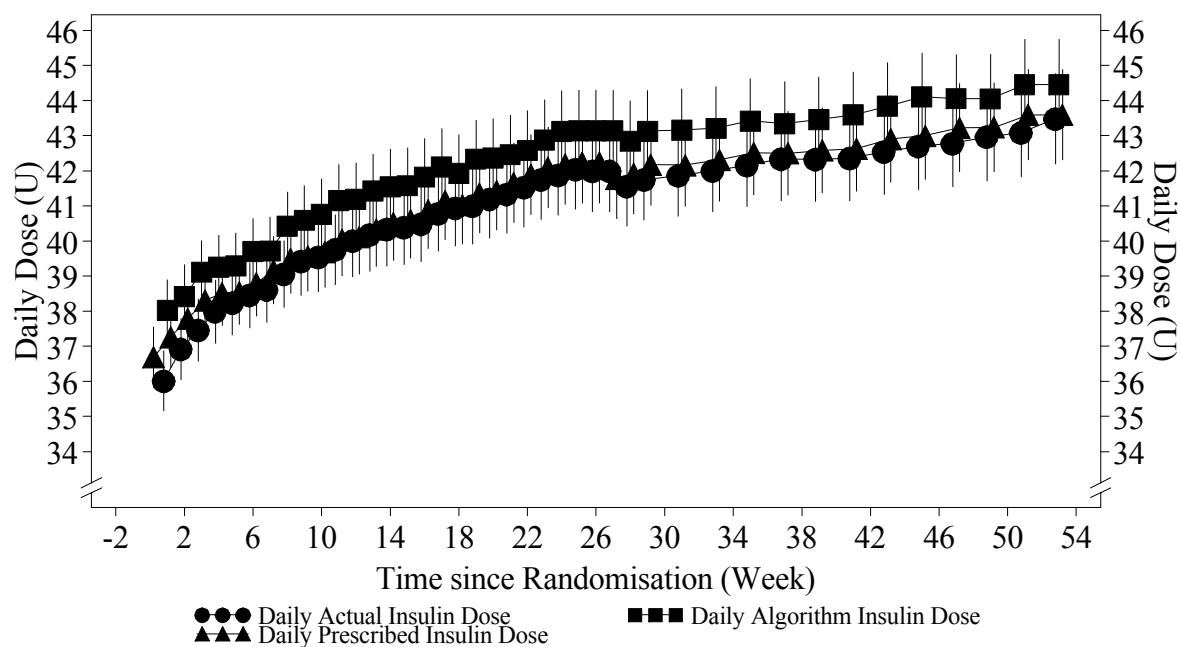
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:49 - tdesc_numfind_tpl_t019_v01.sas/t_ins_ds_prscb_ttrt_diff_dsc_sas.txt

Prescribed minus Titration Algorithm Daily IDegAsp/Comparator Insulin Dose in Units by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Titration Compliance(U)			
Visit 35 (Week 35)			
N	246	120	366
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	-1	0
Min ; Max	-6 ; 6	-13 ; 10	-13 ; 10
Visit 36 (Week 37)			
N	240	115	355
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	-1	0
Min ; Max	-9 ; 7	-8 ; 8	-9 ; 8
Visit 37 (Week 39)			
N	244	118	362
Mean (SD)	-1 (2)	-2 (3)	-1 (2)
Median	0	-2	0
Min ; Max	-10 ; 8	-9 ; 8	-10 ; 8
Visit 38 (Week 41)			
N	234	118	352
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-6 ; 4	-20 ; 4	-20 ; 4
Visit 39 (Week 43)			
N	240	117	357
Mean (SD)	-1 (2)	-2 (3)	-1 (2)
Median	0	-1	0
Min ; Max	-6 ; 6	-8 ; 5	-8 ; 6
Visit 40 (Week 45)			
N	235	115	350
Mean (SD)	-1 (2)	-1 (2)	-1 (2)
Median	0	-1	0
Min ; Max	-12 ; 4	-10 ; 6	-12 ; 6
Visit 41 (Week 47)			
N	236	116	352
Mean (SD)	-0 (2)	-1 (4)	-1 (3)
Median	0	0	0
Min ; Max	-9 ; 7	-25 ; 18	-25 ; 18
Visit 42 (Week 49)			
N	228	113	341
Mean (SD)	-0 (2)	-2 (4)	-1 (3)
Median	0	-2	0
Min ; Max	-6 ; 8	-25 ; 4	-25 ; 8
Visit 43 (Week 51)			
N	232	112	344
Mean (SD)	-1 (2)	-1 (3)	-1 (2)
Median	0	0	0
Min ; Max	-4 ; 6	-10 ; 8	-10 ; 8
Visit 44 (Week 53) (LOCF)			
N	360	178	538
Mean (SD)	-1 (2)	-1 (3)	-1 (3)
Median	0	0	0
Min ; Max	-29 ; 6	-10 ; 8	-29 ; 8

N = Number of Subjects, SD = Standard Deviation

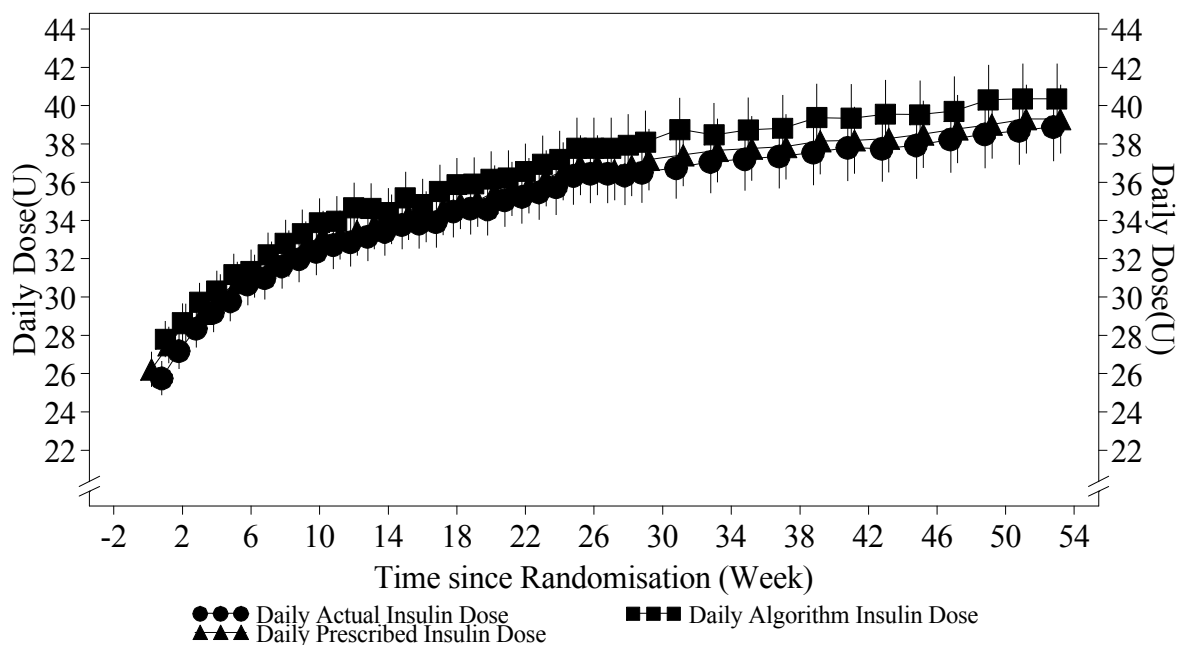
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:36:49 - tdesc_numfind_tpl_t019_v01.sas/t_ins_ds_prscb_ttrt_diff_dsc_sas.txt



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:37:13 - fmean_numfind_v03.sas/e_ins_comp_iv1_u_mean_locf_sas.cgm

14.2.60: Daily IDegAsp OD Insulin Dose in Units by Treatment Week - Prescribed, Actual and Titration Algorithm Dose - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:37:37 - fmean_numfind_v03.sas/e_ins_comp_cm_u_mean_locf_sas.cgm

14.2.61: Daily IDet Insulin Dose in Units by Treatment Week - Prescribed, Actual and Titration Algorithm Dose – Mean Plot - Safety Analysis Set

14.2.62: HbA1c (%) by Treatment Week – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
HbA1c (%)			
Visit 1			
N	366	182	548
Mean (SD)	8.4 (0.8)	8.3 (0.8)	8.4 (0.8)
Median	8.3	8.3	8.3
Min ; Max	7.0 ; 10.3	7.0 ; 10.0	7.0 ; 10.3
Visit 2 (Week 0)			
N	366	182	548
Mean (SD)	8.3 (0.8)	8.3 (0.7)	8.3 (0.8)
Median	8.2	8.2	8.2
Min ; Max	6.8 ; 10.3	6.5 ; 10.4	6.5 ; 10.4
Visit 10 (Week 8)			
N	340	170	510
Mean (SD)	7.7 (0.9)	7.8 (0.8)	7.7 (0.9)
Median	7.6	7.8	7.7
Min ; Max	5.5 ; 11.3	6.1 ; 10.3	5.5 ; 11.3
Visit 14 (Week 12)			
N	336	167	503
Mean (SD)	7.5 (0.9)	7.7 (0.8)	7.6 (0.8)
Median	7.4	7.6	7.5
Min ; Max	5.9 ; 12.2	5.8 ; 9.8	5.8 ; 12.2
Visit 18 (Week 16)			
N	328	164	492
Mean (SD)	7.5 (0.9)	7.6 (0.8)	7.5 (0.8)
Median	7.3	7.6	7.4
Min ; Max	5.7 ; 11.5	5.8 ; 10.5	5.7 ; 11.5
Visit 22 (Week 20)			
N	322	160	482
Mean (SD)	7.4 (0.8)	7.5 (0.7)	7.5 (0.8)
Median	7.4	7.5	7.4
Min ; Max	5.5 ; 10.9	5.9 ; 9.4	5.5 ; 10.9
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	7.5 (0.8)	7.5 (0.8)	7.5 (0.8)
Median	7.4	7.5	7.5
Min ; Max	5.2 ; 11.0	5.3 ; 10.2	5.2 ; 11.0
Visit 30 (Week 27)			
N	238	118	356
Mean (SD)	7.5 (0.9)	7.5 (0.8)	7.5 (0.8)
Median	7.4	7.5	7.4
Min ; Max	5.3 ; 11.7	5.3 ; 10.0	5.3 ; 11.7

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:37:46 - tdesc_numfind_tpl_t019_v01.sas/t_hbA1c_abs_descp_fas.txt

HbA1c (%) by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
HbA1c (%)			
Visit 33 (Week 31)			
N	250	118	368
Mean (SD)	7.5 (0.9)	7.5 (0.8)	7.5 (0.9)
Median	7.4	7.6	7.5
Min ; Max	5.4 ; 12.9	5.3 ; 9.4	5.3 ; 12.9
Visit 35 (Week 35)			
N	245	119	364
Mean (SD)	7.5 (0.9)	7.6 (0.8)	7.5 (0.9)
Median	7.4	7.6	7.5
Min ; Max	5.5 ; 12.4	5.6 ; 9.7	5.5 ; 12.4
Visit 37 (Week 39)			
N	245	118	363
Mean (SD)	7.5 (0.9)	7.6 (0.8)	7.5 (0.9)
Median	7.4	7.6	7.5
Min ; Max	4.4 ; 10.5	5.4 ; 9.9	4.4 ; 10.5
Visit 39 (Week 43)			
N	236	117	353
Mean (SD)	7.4 (0.9)	7.6 (0.8)	7.5 (0.9)
Median	7.4	7.6	7.5
Min ; Max	4.6 ; 10.7	5.2 ; 10.0	4.6 ; 10.7
Visit 41 (Week 47)			
N	237	115	352
Mean (SD)	7.5 (0.8)	7.7 (0.8)	7.5 (0.8)
Median	7.4	7.7	7.5
Min ; Max	5.3 ; 9.6	5.6 ; 9.8	5.3 ; 9.8
Visit 43 (Week 51)			
N	228	110	338
Mean (SD)	7.5 (0.8)	7.7 (0.8)	7.6 (0.8)
Median	7.5	7.7	7.6
Min ; Max	5.3 ; 10.1	5.8 ; 9.9	5.3 ; 10.1
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	7.5 (0.8)	7.7 (0.8)	7.6 (0.8)
Median	7.5	7.7	7.5
Min ; Max	5.4 ; 10.3	4.7 ; 9.6	4.7 ; 10.3
Visit 44 (Week 53) (LOCF)			
N	366	182	548
Mean (SD)	7.7 (0.9)	7.7 (0.9)	7.7 (0.9)
Median	7.6	7.7	7.6
Min ; Max	5.4 ; 11.1	4.7 ; 11.1	4.7 ; 11.1

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:37:46 - tdesc_numfind_tpl_t019_v01.sas/t_hba1c_abs_descp_fas.txt

14.2.63: HbA1c (%) by Treatment Week – Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Number of Subjects	254	122	376
HbA1c (%)			
Visit 1			
N	254	122	376
Mean (SD)	8.4 (0.8)	8.4 (0.8)	8.4 (0.8)
Median	8.3	8.3	8.3
Min ; Max	7.0 ; 10.0	7.0 ; 10.0	7.0 ; 10.0
Visit 2 (Week 0)			
N	254	122	376
Mean (SD)	8.3 (0.8)	8.3 (0.8)	8.3 (0.8)
Median	8.3	8.4	8.3
Min ; Max	6.8 ; 10.3	6.5 ; 10.4	6.5 ; 10.4
Visit 10 (Week 8)			
N	253	121	374
Mean (SD)	7.6 (0.9)	7.8 (0.8)	7.7 (0.8)
Median	7.5	7.7	7.6
Min ; Max	5.5 ; 11.3	6.1 ; 10.2	5.5 ; 11.3
Visit 14 (Week 12)			
N	253	122	375
Mean (SD)	7.5 (0.9)	7.6 (0.7)	7.5 (0.8)
Median	7.4	7.6	7.4
Min ; Max	5.9 ; 12.2	5.8 ; 9.8	5.8 ; 12.2
Visit 18 (Week 16)			
N	252	122	374
Mean (SD)	7.4 (0.8)	7.5 (0.7)	7.5 (0.8)
Median	7.3	7.6	7.4
Min ; Max	5.7 ; 10.9	5.8 ; 9.4	5.7 ; 10.9
Visit 22 (Week 20)			
N	252	122	374
Mean (SD)	7.4 (0.8)	7.5 (0.7)	7.4 (0.8)
Median	7.4	7.5	7.4
Min ; Max	5.5 ; 10.9	5.9 ; 9.1	5.5 ; 10.9
Visit 28 (Week 26)			
N	253	122	375
Mean (SD)	7.5 (0.8)	7.5 (0.7)	7.5 (0.8)
Median	7.4	7.5	7.4
Min ; Max	5.2 ; 11.0	5.3 ; 9.7	5.2 ; 11.0
Visit 30 (Week 27)			
N	238	118	356
Mean (SD)	7.5 (0.9)	7.5 (0.8)	7.5 (0.8)
Median	7.4	7.5	7.4
Min ; Max	5.3 ; 11.7	5.3 ; 10.0	5.3 ; 11.7

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:37:55 - tdesc_numfind_tpl_t019_v01.sas/t_hbA1c_abs_descp_ets.txt

HbA1c (%) by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
HbA1c (%)			
Visit 33 (Week 31)			
N	250	118	368
Mean (SD)	7.5 (0.9)	7.5 (0.8)	7.5 (0.9)
Median	7.4	7.6	7.5
Min ; Max	5.4 ; 12.9	5.3 ; 9.4	5.3 ; 12.9
Visit 35 (Week 35)			
N	245	119	364
Mean (SD)	7.5 (0.9)	7.6 (0.8)	7.5 (0.9)
Median	7.4	7.6	7.5
Min ; Max	5.5 ; 12.4	5.6 ; 9.7	5.5 ; 12.4
Visit 37 (Week 39)			
N	245	118	363
Mean (SD)	7.5 (0.9)	7.6 (0.8)	7.5 (0.9)
Median	7.4	7.6	7.5
Min ; Max	4.4 ; 10.5	5.4 ; 9.9	4.4 ; 10.5
Visit 39 (Week 43)			
N	236	117	353
Mean (SD)	7.4 (0.9)	7.6 (0.8)	7.5 (0.9)
Median	7.4	7.6	7.5
Min ; Max	4.6 ; 10.7	5.2 ; 10.0	4.6 ; 10.7
Visit 41 (Week 47)			
N	237	115	352
Mean (SD)	7.5 (0.8)	7.7 (0.8)	7.5 (0.8)
Median	7.4	7.7	7.5
Min ; Max	5.3 ; 9.6	5.6 ; 9.8	5.3 ; 9.8
Visit 43 (Week 51)			
N	228	110	338
Mean (SD)	7.5 (0.8)	7.7 (0.8)	7.6 (0.8)
Median	7.5	7.7	7.6
Min ; Max	5.3 ; 10.1	5.8 ; 9.9	5.3 ; 10.1
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	7.5 (0.8)	7.7 (0.8)	7.6 (0.8)
Median	7.5	7.7	7.5
Min ; Max	5.4 ; 10.3	4.7 ; 9.6	4.7 ; 10.3
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	7.6 (0.9)	7.7 (0.8)	7.6 (0.9)
Median	7.5	7.7	7.6
Min ; Max	5.4 ; 10.9	4.7 ; 9.6	4.7 ; 10.9

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:37:55 - tdesc_numfind_tpl_t019_v01.sas/t_hba1c_abs_descp_ets.txt

14.2.64: HbA1c (%) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Change in HbA1c(%)			
Visit 10 (Week 8)			
N	340	170	510
Mean (SD)	-0.63 (0.71)	-0.46 (0.65)	-0.58 (0.69)
Median	-0.60	-0.50	-0.60
Min ; Max	-2.60 ; 3.30	-2.00 ; 1.30	-2.60 ; 3.30
Visit 14 (Week 12)			
N	336	167	503
Mean (SD)	-0.78 (0.78)	-0.65 (0.73)	-0.73 (0.76)
Median	-0.80	-0.70	-0.70
Min ; Max	-3.60 ; 2.90	-2.80 ; 1.30	-3.60 ; 2.90
Visit 18 (Week 16)			
N	328	164	492
Mean (SD)	-0.78 (0.85)	-0.75 (0.74)	-0.77 (0.81)
Median	-0.70	-0.80	-0.80
Min ; Max	-3.60 ; 2.10	-3.20 ; 0.90	-3.60 ; 2.10
Visit 22 (Week 20)			
N	322	160	482
Mean (SD)	-0.84 (0.84)	-0.79 (0.73)	-0.82 (0.80)
Median	-0.80	-0.80	-0.80
Min ; Max	-3.70 ; 1.60	-2.90 ; 1.20	-3.70 ; 1.60
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	-0.78 (0.84)	-0.76 (0.75)	-0.77 (0.81)
Median	-0.70	-0.80	-0.70
Min ; Max	-4.10 ; 1.80	-2.90 ; 1.70	-4.10 ; 1.80
Visit 30 (Week 27)			
N	238	118	356
Mean (SD)	-0.85 (0.88)	-0.84 (0.74)	-0.85 (0.84)
Median	-0.70	-0.85	-0.80
Min ; Max	-4.10 ; 2.40	-3.00 ; 1.60	-4.10 ; 2.40
Visit 33 (Week 31)			
N	250	118	368
Mean (SD)	-0.81 (0.88)	-0.79 (0.81)	-0.80 (0.86)
Median	-0.65	-0.75	-0.70
Min ; Max	-4.40 ; 3.60	-3.10 ; 1.30	-4.40 ; 3.60
Visit 35 (Week 35)			
N	245	119	364
Mean (SD)	-0.80 (0.87)	-0.76 (0.85)	-0.79 (0.86)
Median	-0.80	-0.80	-0.80
Min ; Max	-4.20 ; 3.10	-3.40 ; 1.30	-4.20 ; 3.10

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:38:03 - tdesc_numfind_tpl_t019_v01.sas/t_hbA1c_chb_descp_fas.txt

HbA1c (%) by Treatment Week - Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Change in HbA1c(%)			
Visit 37 (Week 39)			
N	245	118	363
Mean (SD)	-0.82 (0.94)	-0.74 (0.82)	-0.79 (0.91)
Median	-0.80	-0.70	-0.80
Min ; Max	-4.80 ; 2.20	-3.00 ; 1.30	-4.80 ; 2.20
Visit 39 (Week 43)			
N	236	117	353
Mean (SD)	-0.84 (0.89)	-0.74 (0.83)	-0.81 (0.87)
Median	-0.80	-0.70	-0.80
Min ; Max	-4.40 ; 1.70	-3.20 ; 1.20	-4.40 ; 1.70
Visit 41 (Week 47)			
N	237	115	352
Mean (SD)	-0.83 (0.80)	-0.67 (0.85)	-0.78 (0.82)
Median	-0.80	-0.60	-0.80
Min ; Max	-3.50 ; 1.30	-2.80 ; 1.70	-3.50 ; 1.70
Visit 43 (Week 51)			
N	228	110	338
Mean (SD)	-0.75 (0.80)	-0.57 (0.77)	-0.69 (0.79)
Median	-0.70	-0.50	-0.60
Min ; Max	-3.60 ; 1.90	-2.60 ; 1.80	-3.60 ; 1.90
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	-0.76 (0.84)	-0.62 (0.78)	-0.71 (0.82)
Median	-0.70	-0.50	-0.70
Min ; Max	-3.60 ; 1.90	-2.60 ; 1.50	-3.60 ; 1.90
Visit 44 (Week 53) (LOCF)			
N	366	182	548
Mean (SD)	-0.65 (0.81)	-0.56 (0.80)	-0.62 (0.81)
Median	-0.60	-0.50	-0.60
Min ; Max	-3.60 ; 1.90	-2.60 ; 1.70	-3.60 ; 1.90

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:38:03 - tdesc_numfind_tpl_t019_v01.sas/t_hba1c_chb_descp_fas.txt

14.2.65: HbA1c (%) by Treatment Week – Change from Baseline - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Number of Subjects	254	122	376
Change in HbA1c(%)			
Visit 10 (Week 8)			
N	253	121	374
Mean (SD)	-0.70 (0.74)	-0.50 (0.63)	-0.63 (0.71)
Median	-0.70	-0.50	-0.70
Min ; Max	-2.60 ; 3.30	-2.00 ; 0.90	-2.60 ; 3.30
Visit 14 (Week 12)			
N	253	122	375
Mean (SD)	-0.85 (0.78)	-0.69 (0.73)	-0.79 (0.76)
Median	-0.90	-0.75	-0.80
Min ; Max	-3.60 ; 2.90	-2.80 ; 1.30	-3.60 ; 2.90
Visit 18 (Week 16)			
N	252	122	374
Mean (SD)	-0.87 (0.85)	-0.79 (0.75)	-0.85 (0.82)
Median	-0.85	-0.80	-0.80
Min ; Max	-3.60 ; 1.60	-3.20 ; 0.90	-3.60 ; 1.60
Visit 22 (Week 20)			
N	252	122	374
Mean (SD)	-0.92 (0.86)	-0.84 (0.76)	-0.89 (0.82)
Median	-0.80	-0.95	-0.90
Min ; Max	-3.70 ; 1.60	-2.90 ; 1.20	-3.70 ; 1.60
Visit 28 (Week 26)			
N	253	122	375
Mean (SD)	-0.85 (0.86)	-0.85 (0.73)	-0.85 (0.81)
Median	-0.70	-0.80	-0.80
Min ; Max	-4.10 ; 1.80	-2.90 ; 1.30	-4.10 ; 1.80
Visit 30 (Week 27)			
N	238	118	356
Mean (SD)	-0.85 (0.88)	-0.84 (0.74)	-0.85 (0.84)
Median	-0.70	-0.85	-0.80
Min ; Max	-4.10 ; 2.40	-3.00 ; 1.60	-4.10 ; 2.40
Visit 33 (Week 31)			
N	250	118	368
Mean (SD)	-0.81 (0.88)	-0.79 (0.81)	-0.80 (0.86)
Median	-0.65	-0.75	-0.70
Min ; Max	-4.40 ; 3.60	-3.10 ; 1.30	-4.40 ; 3.60
Visit 35 (Week 35)			
N	245	119	364
Mean (SD)	-0.80 (0.87)	-0.76 (0.85)	-0.79 (0.86)
Median	-0.80	-0.80	-0.80
Min ; Max	-4.20 ; 3.10	-3.40 ; 1.30	-4.20 ; 3.10

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:38:12 - tdesc_numfind_tpl_t019_v01.sas/t_hbA1c_chb_descp_ets.txt

HbA1c (%) by Treatment Week - Change from Baseline - Descriptive Statistics - Extension
Trial Set

	IDegAsp OD	IDet	Total
Change in HbA1c(%)			
Visit 37 (Week 39)			
N	245	118	363
Mean (SD)	-0.82 (0.94)	-0.74 (0.82)	-0.79 (0.91)
Median	-0.80	-0.70	-0.80
Min ; Max	-4.80 ; 2.20	-3.00 ; 1.30	-4.80 ; 2.20
Visit 39 (Week 43)			
N	236	117	353
Mean (SD)	-0.84 (0.89)	-0.74 (0.83)	-0.81 (0.87)
Median	-0.80	-0.70	-0.80
Min ; Max	-4.40 ; 1.70	-3.20 ; 1.20	-4.40 ; 1.70
Visit 41 (Week 47)			
N	237	115	352
Mean (SD)	-0.83 (0.80)	-0.67 (0.85)	-0.78 (0.82)
Median	-0.80	-0.60	-0.80
Min ; Max	-3.50 ; 1.30	-2.80 ; 1.70	-3.50 ; 1.70
Visit 43 (Week 51)			
N	228	110	338
Mean (SD)	-0.75 (0.80)	-0.57 (0.77)	-0.69 (0.79)
Median	-0.70	-0.50	-0.60
Min ; Max	-3.60 ; 1.90	-2.60 ; 1.80	-3.60 ; 1.90
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	-0.76 (0.84)	-0.62 (0.78)	-0.71 (0.82)
Median	-0.70	-0.50	-0.70
Min ; Max	-3.60 ; 1.90	-2.60 ; 1.50	-3.60 ; 1.90
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	-0.74 (0.84)	-0.67 (0.80)	-0.72 (0.83)
Median	-0.70	-0.50	-0.70
Min ; Max	-3.60 ; 1.90	-2.60 ; 1.50	-3.60 ; 1.90

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:38:12 - tdesc_numfind_tpl_t019_v01.sas/t_hb1c_chb_descp_ets.txt

14.2.66: HbA1c (%) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	366	366	7.63	0.07	
IDet	182	182	7.73	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	366	366	-0.67	0.07	
IDet	182	182	-0.57	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.10		[-0.24 ; 0.03]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:38:21 - tstat_find_tpl_t022.sas/t_hbA1c_stat_locf_fas.txt

14.2.67: HbA1c (%) after 52 Weeks of Treatment - Statistical Analysis - Extension Trial Set

	EXT	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	254	254	7.53	0.08	
IDet	122	122	7.63	0.10	
Change from Baseline					
LSMeans					
IDegAsp OD	254	254	-0.79	0.08	
IDet	122	122	-0.68	0.10	
Treatment Contrast					
IDegAsp OD - IDet			-0.11		[-0.27 ; 0.06]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:38:30 - tstat_find_tpl_t022.sas/t_hbA1c_stat_locf_ets.txt

14.2.68: HbA1c (%) after 52 Weeks of Treatment - Parameter Estimates on Observed Scale - Full Analysis Set

	Estimate	DF	95% CI
HbA1c (%)			
Treatment			
IDegAsp OD	-0.10	540	[-0.24 ; 0.03]
IDet	0.00		
Region			
Australia	0.22	540	[0.01 ; 0.44]
Europe	-0.05	540	[-0.19 ; 0.09]
North America	0.00		
Sex			
Female	-0.04	540	[-0.17 ; 0.08]
Male	0.00		
Antidiabetic Treatment at Screening			
Basal-Bolus	0.19	540	[-0.03 ; 0.40]
Other	0.00		
Regression			
Age	-0.00	540	[-0.01 ; 0.00]
Baseline response	-0.38	540	[-0.46 ; -0.30]

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates. Estimates and Confidence intervals are based on change from baseline in the response. Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:38:22 - tstat_find_tpl_t022.sas/t_hba1c_conf_stat_parm_locf_fas.txt

14.2.69: HbA1c (%) after 52 Weeks of Treatment - Statistical Sensitivity Analysis - PP Analysis Set

	PP	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	336	336	7.55	0.07	
IDet	168	168	7.67	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	336	336	-0.75	0.07	
IDet	168	168	-0.63	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.12		[-0.26 ; 0.02]

N = Number of subjects contributing to analysis, CI = Confidence Interval, SE = Standard Error of the Mean

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:38:39 - tstat_find_tpl_t022.sas/t_hb1c_sens_stat_locf_pp.txt

14.2.70: HbA1c (%) after 52 Weeks of Treatment - Statistical Sensitivity Analysis - Simple Model - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	366	366	7.65	0.04	
IDet	182	182	7.73	0.06	
Change from Baseline					
LSMeans					
IDegAsp OD	366	366	-0.65	0.04	
IDet	182	182	-0.57	0.06	
Treatment Contrast					
IDegAsp OD - IDet			-0.08		[-0.21 ; 0.06]

N = Number of subjects contributing to analysis, CI = Confidence Interval, SE = Standard Error of the Mean

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment as fixed effects, and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:38:48 - tstat_find_tpl_t022.sas/t_hba1c_sens_stat_smpl_locf_fas.txt

14.2.71: HbA1c (%) after 52 Weeks of Treatment - Statistical Sensitivity Analysis - Repeated Measurement Model - Full Analysis Set

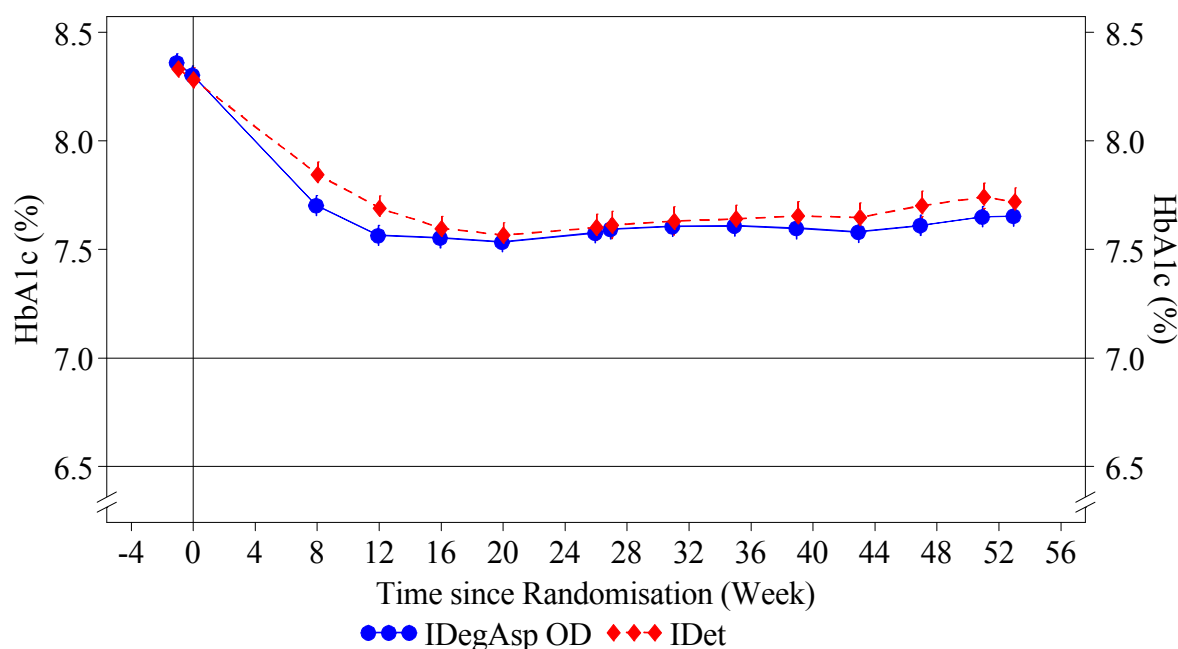
Value	FAS	N	Estimate	SE	95% CI
LSMeans					
IDegAsp OD	366	344	7.56	0.06	
IDet	182	173	7.69	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.14		[-0.29 ; 0.02]

CI: Confidence Interval

SE: Standard Error of the Mean

HbA1c (%) records available at scheduled time points after randomisation are jointly analysed in a linear mixed model with an unstructured residual covariance matrix, and with treatment, time, interaction between treatment and time, region, anti-diabetic treatment at screening and sex as fixed effects and age and baseline HbA1c (%) as covariates.

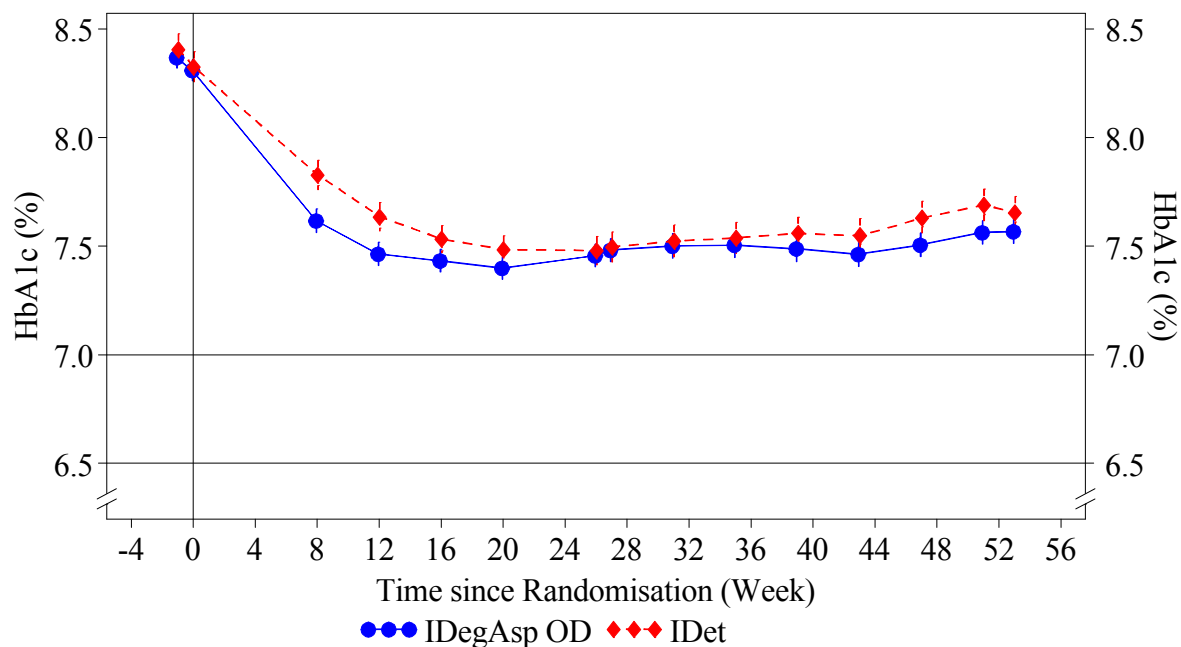
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:42:41 - tstat_hbabc_after.sas/t_hbabc_sens_stat_repeat_fas.txt



FAS: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:42:50 - fmean_numfind_v03.sas/e_hbabc_abs_mean_locf_fas.cgm

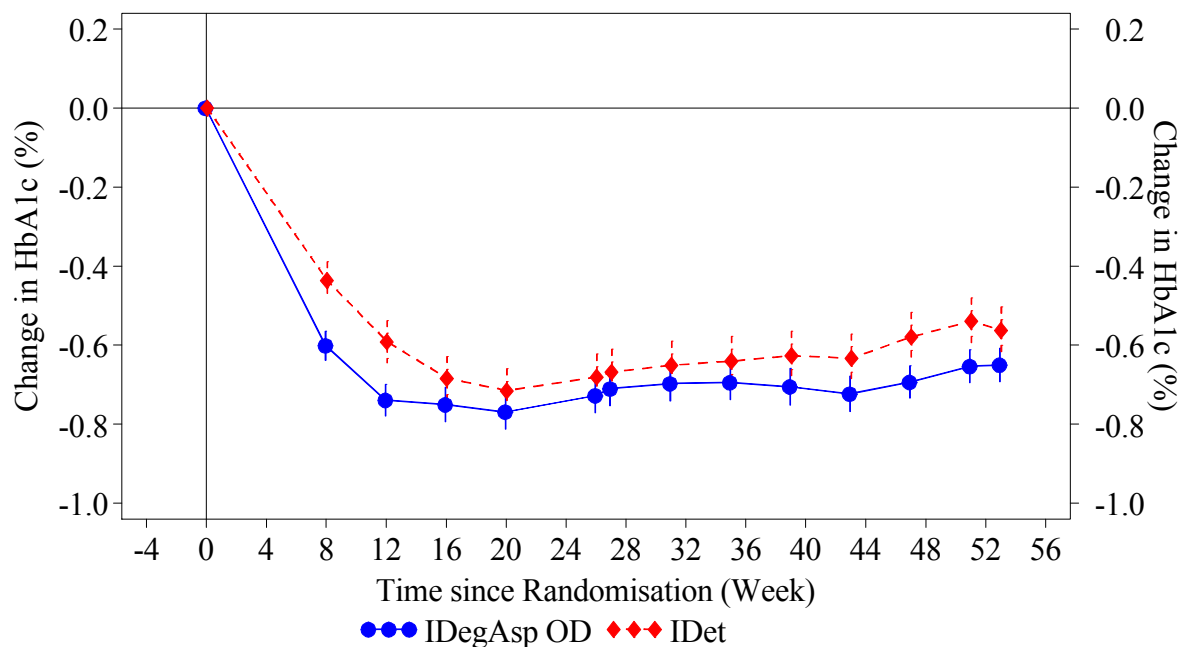
14.2.72: HbA1c (%) by Treatment Week – Mean Plot - Full Analysis Set



EXT: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:42:59 - fmean_numfind_v03.sas/e_hbA1c_abs_mean_locf_ets.cgm

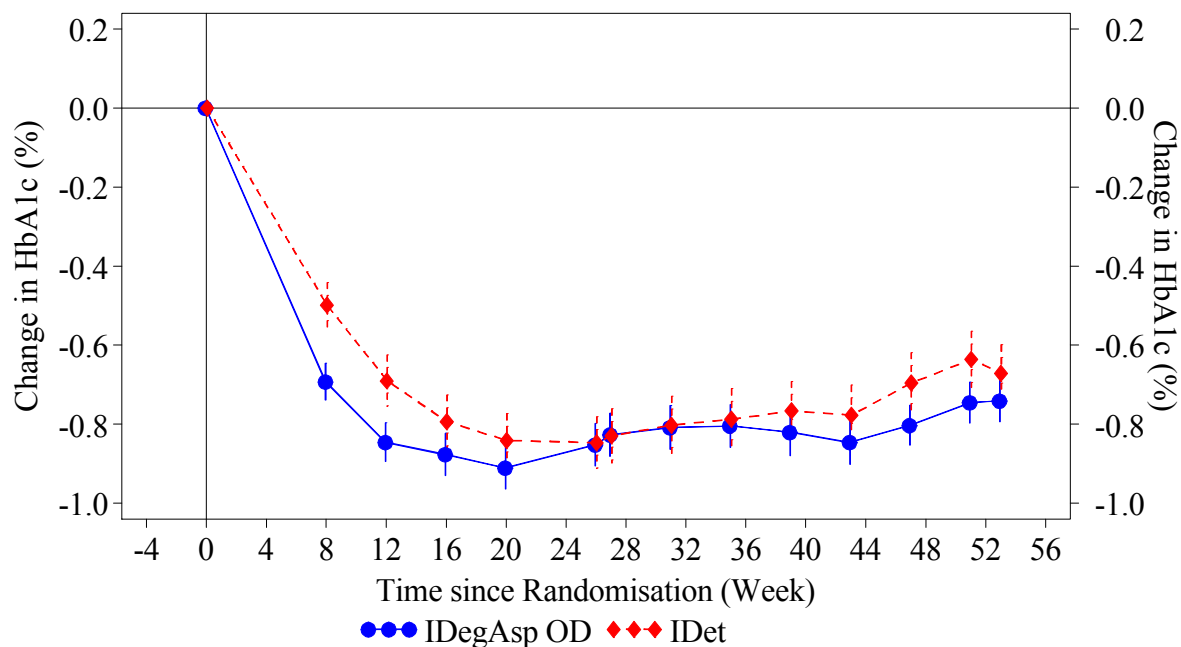
14.2.73: HbA1c (%) by Treatment Week - Mean Plot - Extension Trial Set



FAS; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:43:08 - fmean_numfind_v03.sas/e_hbA1c_chb_mean_locf_fas.cgm

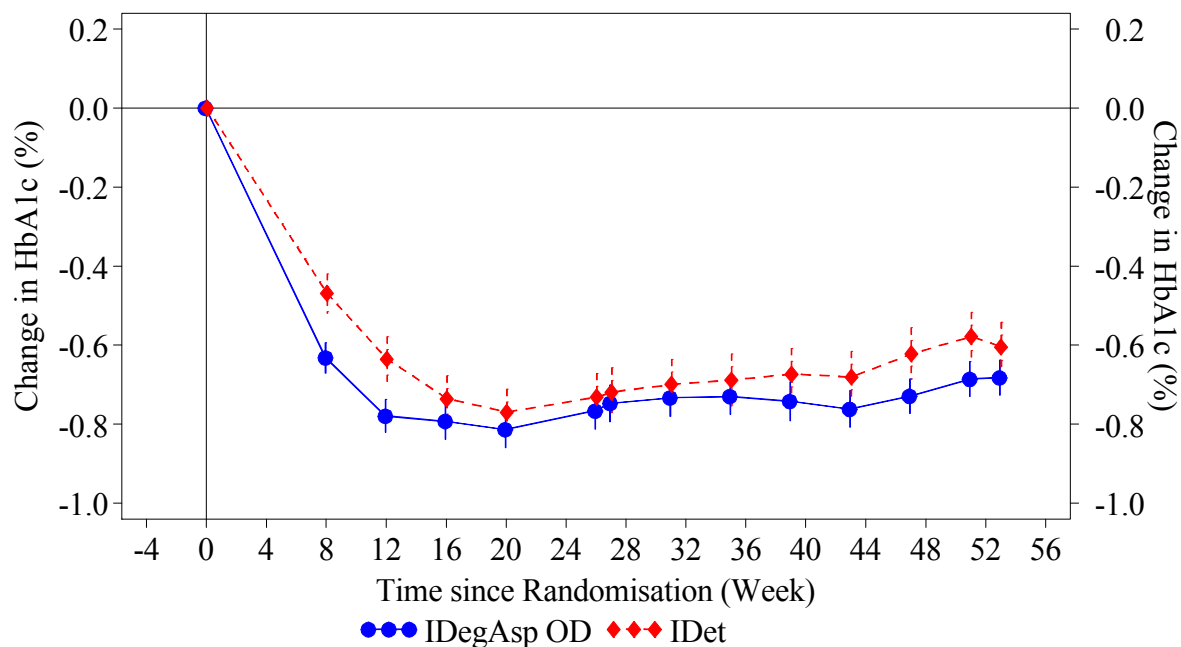
14.2.74: HbA1c (%) by Treatment Week – Change from Baseline - Mean Plot - Full Analysis Set



EXT: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:43:17 - fmean_numfind_v03.sas/e_hba1c_chb_mean_locf_ets.cgm

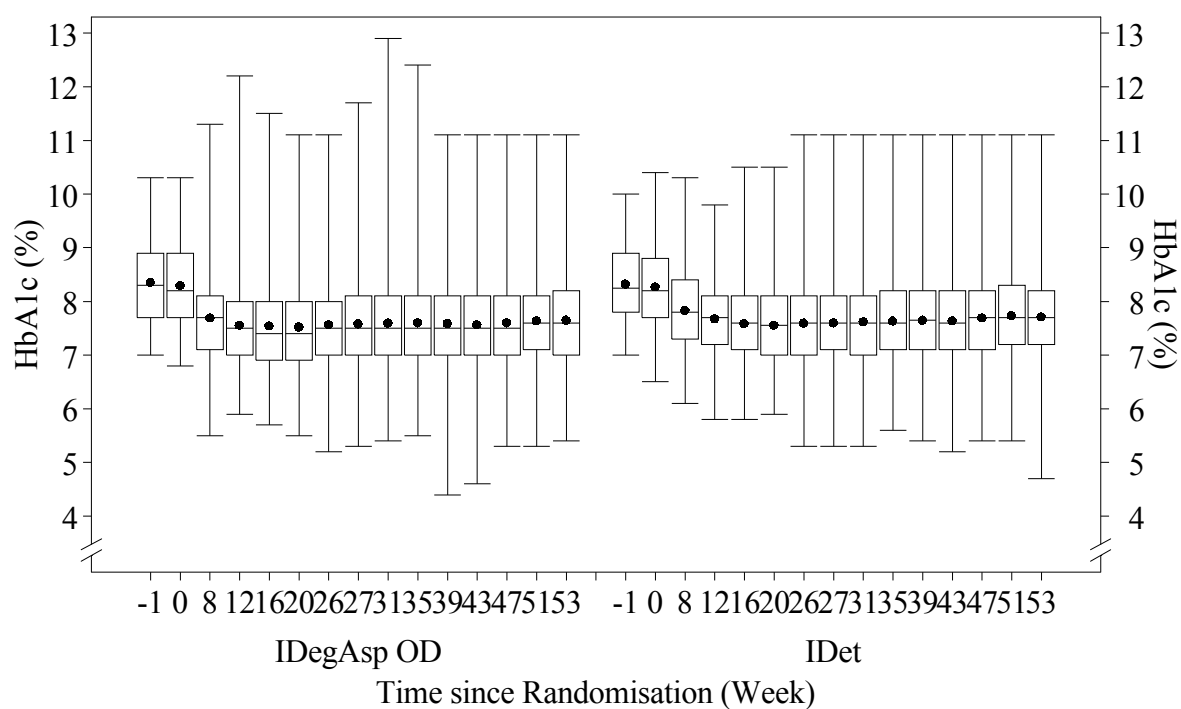
14.2.75: HbA1c (%) by Treatment Week – Change from Baseline - Mean Plot - Extension Trial Set



PP: LOCF imputed data
Error bars: +-Standard Error(Mean)

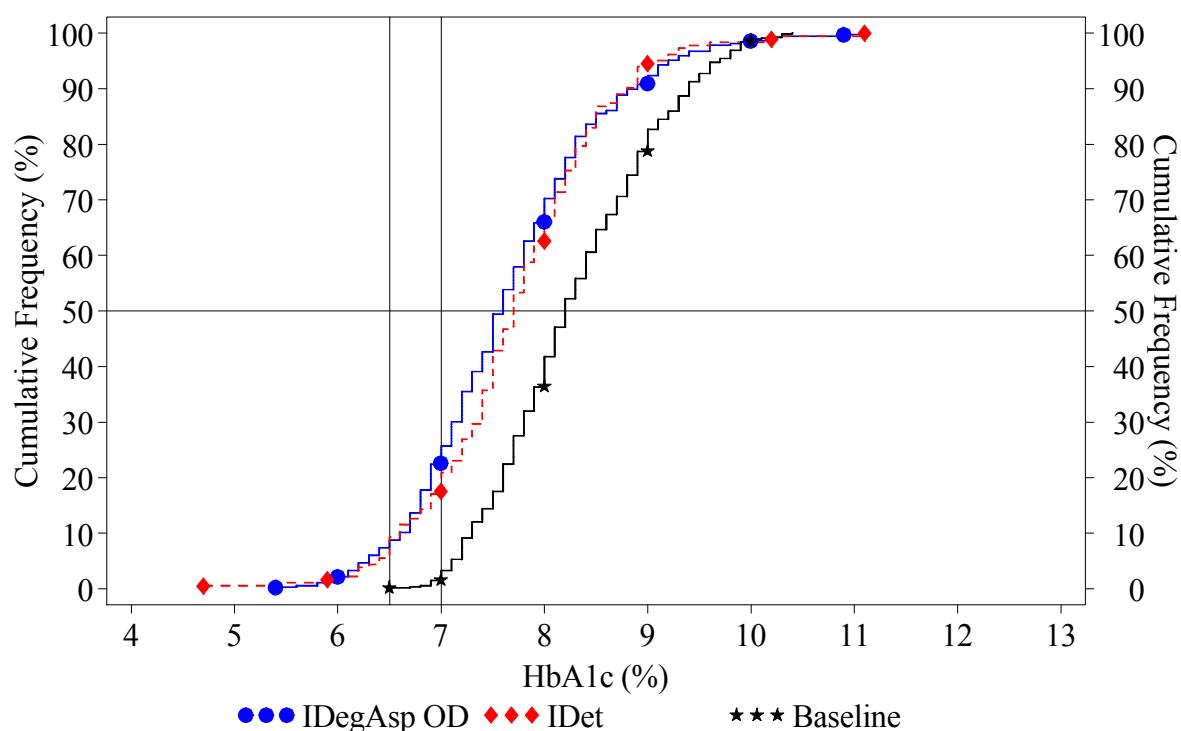
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:43:26 - fmean_numfind_v03.sas/e_hbA1c_chb_mean_locf_pp.cgm

14.2.76: HbA1c (%) by Treatment Week – Change from Baseline - Mean Plot - PP Analysis Set



nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:43:36 - fbox_numfind_v01.sas/e_hba1c_abs_box_locf_fas.cgm

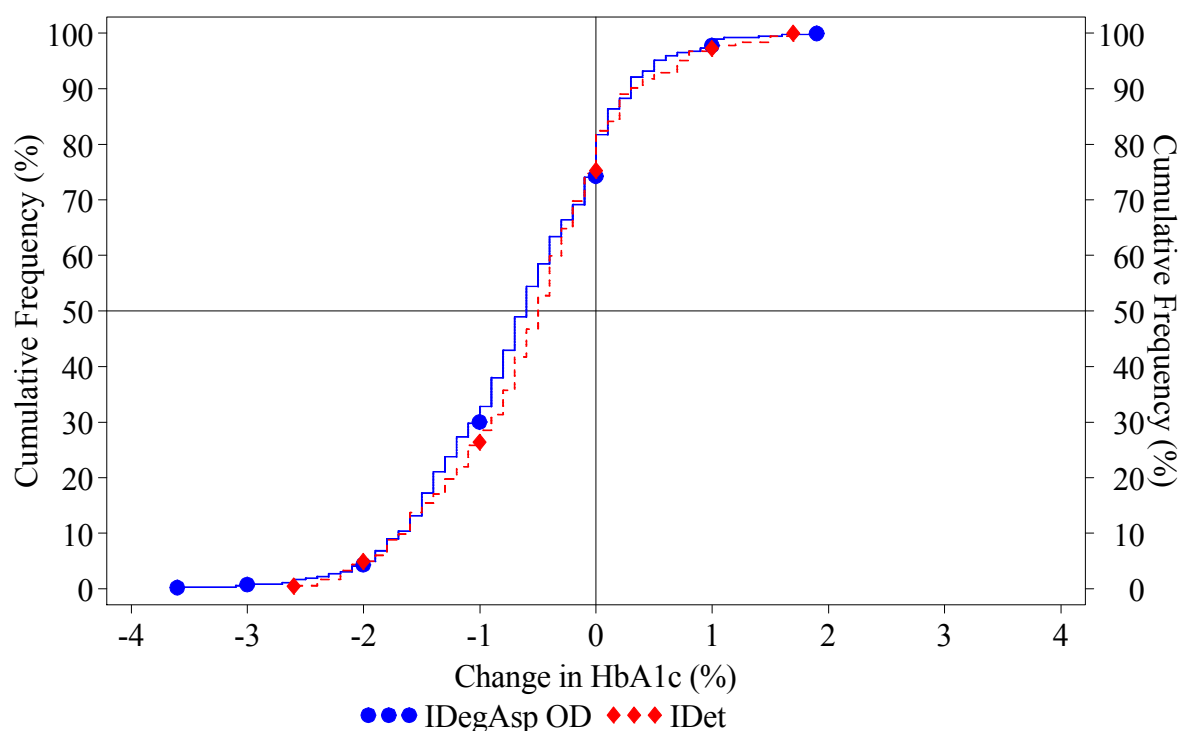
14.2.77: HbA1c (%) by Treatment Week – Box Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:43:51 - fedist_numfind_v01.sas/e_hba1c_abs_cdf_locf_fas.cgm

14.2.78: HbA1c (%) after 52 Weeks of Treatment – Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:44:00 - fedist_numfind_v01.sas/e_hba1c_chb_cdf_locf_fas.cgm

14.2.79: HbA1c (%) after 52 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set

14.2.80: Responder for HbA1c by Treatment Week – Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
HbA1c <7.0% (ADA)			
Visit 1			
N	366 (100.0)	182 (100.0)	548 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	366 (100.0)	182 (100.0)	548 (100.0)
Visit 2 (Week 0)			
N	366 (100.0)	182 (100.0)	548 (100.0)
Yes	3 (0.8)	5 (2.7)	8 (1.5)
No	363 (99.2)	177 (97.3)	540 (98.5)
Visit 10 (Week 8)			
N	340 (100.0)	170 (100.0)	510 (100.0)
Yes	64 (18.8)	19 (11.2)	83 (16.3)
No	276 (81.2)	151 (88.8)	427 (83.7)
Visit 14 (Week 12)			
N	336 (100.0)	167 (100.0)	503 (100.0)
Yes	86 (25.6)	29 (17.4)	115 (22.9)
No	250 (74.4)	138 (82.6)	388 (77.1)
Visit 18 (Week 16)			
N	328 (100.0)	164 (100.0)	492 (100.0)
Yes	88 (26.8)	35 (21.3)	123 (25.0)
No	240 (73.2)	129 (78.7)	369 (75.0)
Visit 22 (Week 20)			
N	322 (100.0)	160 (100.0)	482 (100.0)
Yes	92 (28.6)	38 (23.8)	130 (27.0)
No	230 (71.4)	122 (76.3)	352 (73.0)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Yes	86 (26.9)	35 (22.3)	121 (25.4)
No	234 (73.1)	122 (77.7)	356 (74.6)
Visit 30 (Week 27)			
N	238 (100.0)	118 (100.0)	356 (100.0)
Yes	63 (26.5)	28 (23.7)	91 (25.6)
No	175 (73.5)	90 (76.3)	265 (74.4)
Visit 33 (Week 31)			
N	250 (100.0)	118 (100.0)	368 (100.0)
Yes	67 (26.8)	24 (20.3)	91 (24.7)
No	183 (73.2)	94 (79.7)	277 (75.3)
Visit 35 (Week 35)			
N	245 (100.0)	119 (100.0)	364 (100.0)
Yes	68 (27.8)	24 (20.2)	92 (25.3)
No	177 (72.2)	95 (79.8)	272 (74.7)

Responder for HbA1c by Treatment Week - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HbA1c <7.0% (ADA)			
Visit 37 (Week 39)			
N	245 (100.0)	118 (100.0)	363 (100.0)
Yes	68 (27.8)	24 (20.3)	92 (25.3)
No	177 (72.2)	94 (79.7)	271 (74.7)
Visit 39 (Week 43)			
N	236 (100.0)	117 (100.0)	353 (100.0)
Yes	68 (28.8)	22 (18.8)	90 (25.5)
No	168 (71.2)	95 (81.2)	263 (74.5)
Visit 41 (Week 47)			
N	237 (100.0)	115 (100.0)	352 (100.0)
Yes	62 (26.2)	20 (17.4)	82 (23.3)
No	175 (73.8)	95 (82.6)	270 (76.7)
Visit 43 (Week 51)			
N	228 (100.0)	110 (100.0)	338 (100.0)
Yes	56 (24.6)	16 (14.5)	72 (21.3)
No	172 (75.4)	94 (85.5)	266 (78.7)
Visit 44 (Week 53)			
N	235 (100.0)	114 (100.0)	349 (100.0)
Yes	63 (26.8)	18 (15.8)	81 (23.2)
No	172 (73.2)	96 (84.2)	268 (76.8)
Visit 44 (Week 53) (LOCF)			
N	366 (100.0)	182 (100.0)	548 (100.0)
Yes	82 (22.4)	31 (17.0)	113 (20.6)
No	284 (77.6)	151 (83.0)	435 (79.4)

14.2.81: Responder for HbA1c at End of Trial - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
HbA1c<7.0%				
LSMeans, Odds				
IDegAsp OD	366	366	0.19	
IDet	182	182	0.12	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.56	[0.94 ; 2.59]

N= Number of subjects contributing to analysis, CI= Confidence Interval The binary endpoint is analysed in a Logistic Regression Model using a logit link. The model includes treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and hbalc as covariates.
 Missing data is imputed using last observation carried forward.
 End of Trial: the last end of trial visit of a subject excluding the follow-up visit
 nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:44:15 - tstat_find_tpl_t022.sas/t_resp_hbalc_stat_locf_fas.txt

14.2.82: Responder for HbA1c at End of Trial Without Hypoglycaemia – Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
HbA1c <7.0% w/o Confirmed Hypo.			
Visit 44 (Week 53)			
N	235 (100.0)	114 (100.0)	349 (100.0)
Yes	18 (7.7)	3 (2.6)	21 (6.0)
No	217 (92.3)	111 (97.4)	328 (94.0)
Visit 44 (Week 53) (LOCF)			
N	337 (100.0)	169 (100.0)	506 (100.0)
Yes	18 (5.3)	6 (3.6)	24 (4.7)
No	319 (94.7)	163 (96.4)	482 (95.3)

Responder for HbA1c without hypoglycaemia: subject meeting the HbA1c target at end of trial without treatment emergent hypoglycaemia during the last 12 weeks of trt. Endpoint is only defined for subjects exposed for at least 12 trt. weeks. End of Trial: last end of trial visit of subject excluding follow-up visit.
Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:44:19 - tsum_catgofind_tpl_t025_v01.sas/t_resp_hbA1c_hypo_sum_fas.txt

Responder for HbA1c at End of Trial Without Hypoglycaemia - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HbA1c <7.0% w/o Severe Hypo.			
Visit 44 (Week 53)			
N	235 (100.0)	114 (100.0)	349 (100.0)
Yes	60 (25.5)	17 (14.9)	77 (22.1)
No	175 (74.5)	97 (85.1)	272 (77.9)
Visit 44 (Week 53) (LOCF)			
N	337 (100.0)	169 (100.0)	506 (100.0)
Yes	74 (22.0)	28 (16.6)	102 (20.2)
No	263 (78.0)	141 (83.4)	404 (79.8)

Responder for HbA1c without hypoglycaemia: subject meeting the HbA1c target at end of trial without treatment emergent hypoglycaemia during the last 12 weeks of trt. Endpoint is only defined for subjects exposed for at least 12 trt. weeks. End of Trial: last end of trial visit of subject excluding follow-up visit.
Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:44:19 - tsum_catgofind_tpl_t025_v01.sas/t_resp_hb1c_hypo_sum_fas.txt

14.2.83: Responder for HbA1c at End of Trial Without Hypoglycaemia - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
HbA1c < 7.0% w/o Confirmed Hypo				
LSMeans, Odds				
IDegAsp OD	366	337	0.00	
IDet	182	169	0.00	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.50	[0.57 ; 3.97]
HbA1c < 7.0% w/o Severe Hypo				
LSMeans, Odds				
IDegAsp OD	366	337	0.21	
IDet	182	169	0.14	
Treatment Odds Ratio				
IDegAsp OD / IDet			1.54	[0.90 ; 2.63]

The endpoint is analysed in a Logistic Regression Model using a logit link, including treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and hba1c as covariates. Missing data is imputed using LOCF.
HbA1c <7.0% w/o Hypo: A subject exposed for at least 12 weeks, who meets the HbA1c target w/o hypoglycaemia during the last 12 weeks of treatment or within 7 days from last randomised treatment. End of Trial: the last end of trial visit of a subject excluding the follow-up visit. Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL).

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:44:30 - tstat_find_tpl_t022.sas/t_resp_hba1c_hypo_stat_locf_fas.txt

14.2.84: Fasting Plasma Glucose (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
FPG (mmol/L)			
Visit 2 (Week 0)			
N	365	181	546
Mean (SD)	10.3 (4.7)	11.0 (4.8)	10.5 (4.8)
Median	9.6	10.3	9.9
Min ; Max	1.8 ; 30.2	2.9 ; 28.4	1.8 ; 30.2
Visit 14 (Week 12)			
N	332	167	499
Mean (SD)	8.0 (3.4)	9.0 (3.7)	8.3 (3.5)
Median	7.4	8.8	7.8
Min ; Max	1.7 ; 23.4	1.9 ; 22.9	1.7 ; 23.4
Visit 18 (Week 16)			
N	326	162	488
Mean (SD)	8.4 (3.6)	8.6 (4.2)	8.5 (3.8)
Median	8.0	7.5	7.9
Min ; Max	1.6 ; 26.6	1.8 ; 22.1	1.6 ; 26.6
Visit 28 (Week 26)			
N	321	156	477
Mean (SD)	8.4 (3.7)	8.3 (3.5)	8.4 (3.6)
Median	8.2	7.8	7.9
Min ; Max	1.9 ; 26.5	1.8 ; 19.3	1.8 ; 26.5
Visit 30 (Week 27)			
N	234	112	346
Mean (SD)	11.5 (5.2)	11.3 (4.7)	11.5 (5.0)
Median	11.2	10.8	11.0
Min ; Max	2.2 ; 32.3	1.9 ; 22.6	1.9 ; 32.3
Visit 37 (Week 39)			
N	245	118	363
Mean (SD)	7.7 (3.6)	8.4 (3.6)	8.0 (3.6)
Median	6.9	7.9	7.2
Min ; Max	1.8 ; 21.3	1.9 ; 18.3	1.8 ; 21.3
Visit 44 (Week 53)			
N	230	114	344
Mean (SD)	7.8 (3.5)	8.1 (3.8)	7.9 (3.6)
Median	7.2	7.4	7.3
Min ; Max	1.7 ; 23.0	1.9 ; 22.0	1.7 ; 23.0
Visit 44 (Week 53) (LOCF)			
N	366	181	547
Mean (SD)	8.5 (4.0)	8.6 (4.1)	8.5 (4.1)
Median	7.7	7.7	7.7
Min ; Max	1.7 ; 23.0	1.9 ; 23.2	1.7 ; 23.2

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:44:39 - tdesc_numfind_tpl_t019_v01.sas/t_fpg_abs_descp_fas.txt

14.2.85: Fasting Plasma Glucose (mmol/L) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Change in FPG(mmol/L)			
Visit 14 (Week 12)			
N	331	167	498
Mean (SD)	-2.32 (5.34)	-2.04 (5.66)	-2.23 (5.44)
Median	-1.80	-2.00	-1.90
Min ; Max	-22.4 ; 14.00	-19.8 ; 15.10	-22.4 ; 15.10
Visit 18 (Week 16)			
N	325	162	487
Mean (SD)	-1.92 (5.59)	-2.32 (5.90)	-2.05 (5.69)
Median	-1.60	-2.10	-1.60
Min ; Max	-26.1 ; 12.60	-23.7 ; 14.10	-26.1 ; 14.10
Visit 28 (Week 26)			
N	320	156	476
Mean (SD)	-1.80 (5.37)	-2.61 (5.43)	-2.07 (5.40)
Median	-1.55	-1.90	-1.70
Min ; Max	-25.3 ; 12.50	-24.0 ; 14.20	-25.3 ; 14.20
Visit 30 (Week 27)			
N	233	112	345
Mean (SD)	1.02 (6.55)	0.27 (5.83)	0.78 (6.33)
Median	0.20	-0.15	0.10
Min ; Max	-17.6 ; 18.90	-19.3 ; 16.70	-19.3 ; 18.90
Visit 37 (Week 39)			
N	244	118	362
Mean (SD)	-2.47 (5.57)	-2.43 (5.60)	-2.45 (5.57)
Median	-2.30	-2.40	-2.35
Min ; Max	-20.8 ; 15.70	-15.9 ; 10.70	-20.8 ; 15.70
Visit 44 (Week 53)			
N	230	114	344
Mean (SD)	-2.32 (5.39)	-2.70 (5.87)	-2.45 (5.55)
Median	-1.90	-2.55	-2.05
Min ; Max	-23.5 ; 13.30	-17.7 ; 18.60	-23.5 ; 18.60
Visit 44 (Week 53) (LOCF)			
N	365	181	546
Mean (SD)	-1.83 (5.69)	-2.40 (5.86)	-2.02 (5.75)
Median	-1.50	-1.70	-1.50
Min ; Max	-26.6 ; 13.30	-23.1 ; 18.60	-26.6 ; 18.60

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:44:48 - tdesc_numfind_tpl_t019_v01.sas/t_fpg_chb_descp_fas.txt

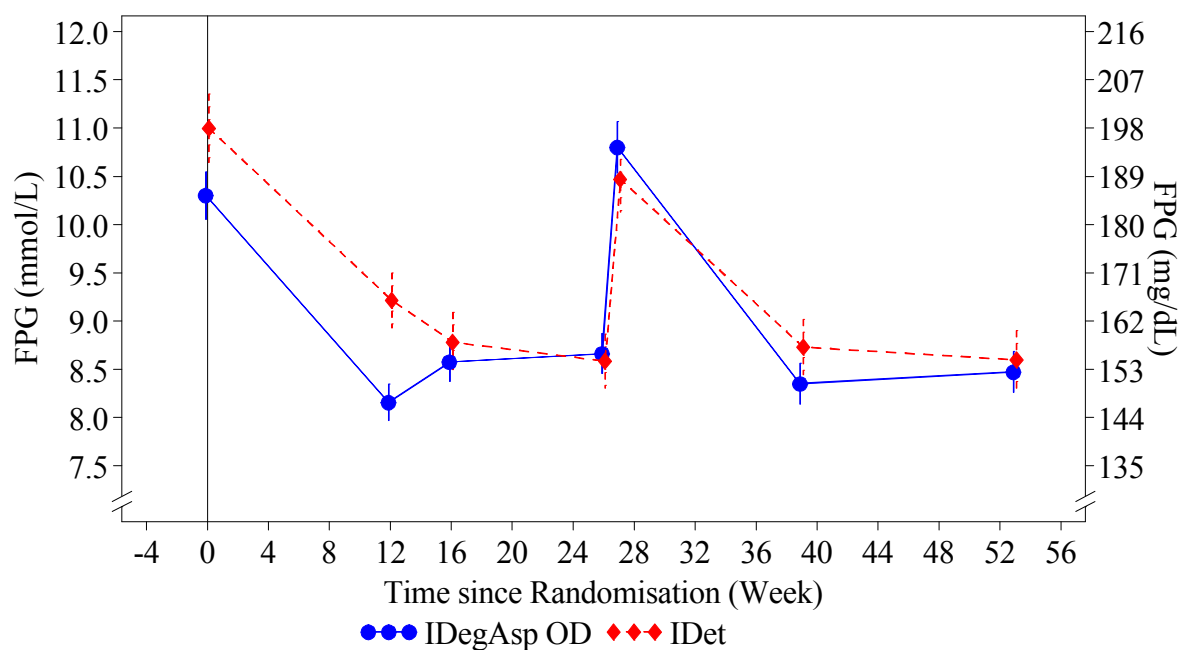
14.2.86: Fasting Plasma Glucose (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
FPG (mmol/L)					
LSMeans					
IDegAsp OD	366	365	8.45	0.35	
IDet	182	181	8.52	0.41	
Change from Baseline					
LSMeans					
IDegAsp OD	366	365	-2.08	0.35	
IDet	182	181	-2.01	0.41	
Treatment Contrast					
IDegAsp OD - IDet			-0.07		[-0.79 ; 0.66]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates. Missing data is imputed using last observation carried forward.

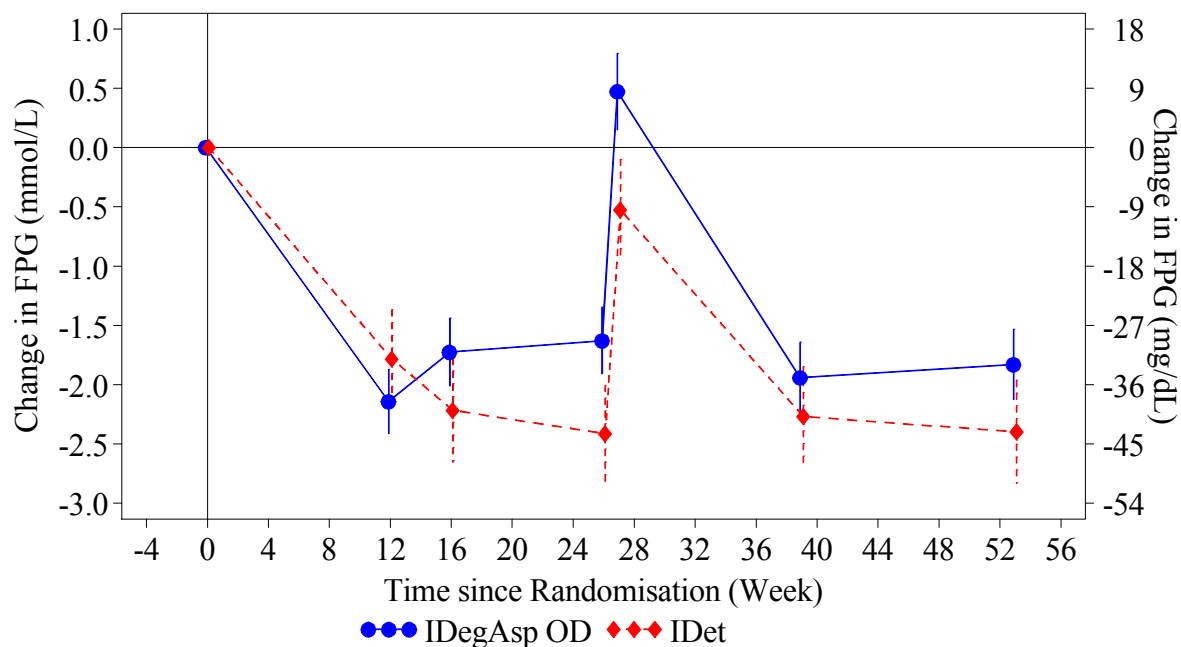
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:44:56 - tstat_find_tpl_t022.sas/t_fpg_stat_locf_fas.txt



FAS; LOCF imputed data
 Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:45:05 - fmean_numfind_v03.sas/e_fpg_abs_mean_locf_fas.cgm

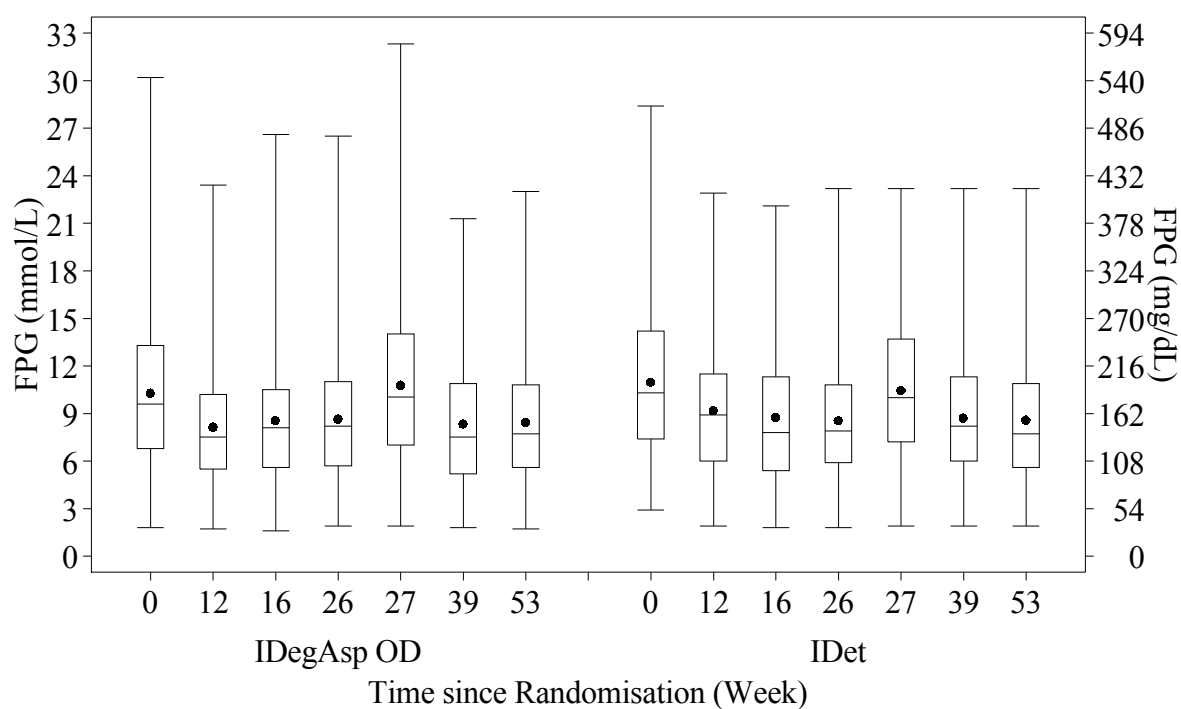
14.2.87: Fasting Plasma Glucose (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:45:14 - fmean_numfind_v03.sas/e_fpg_chb_mean_locf_fas.cgm

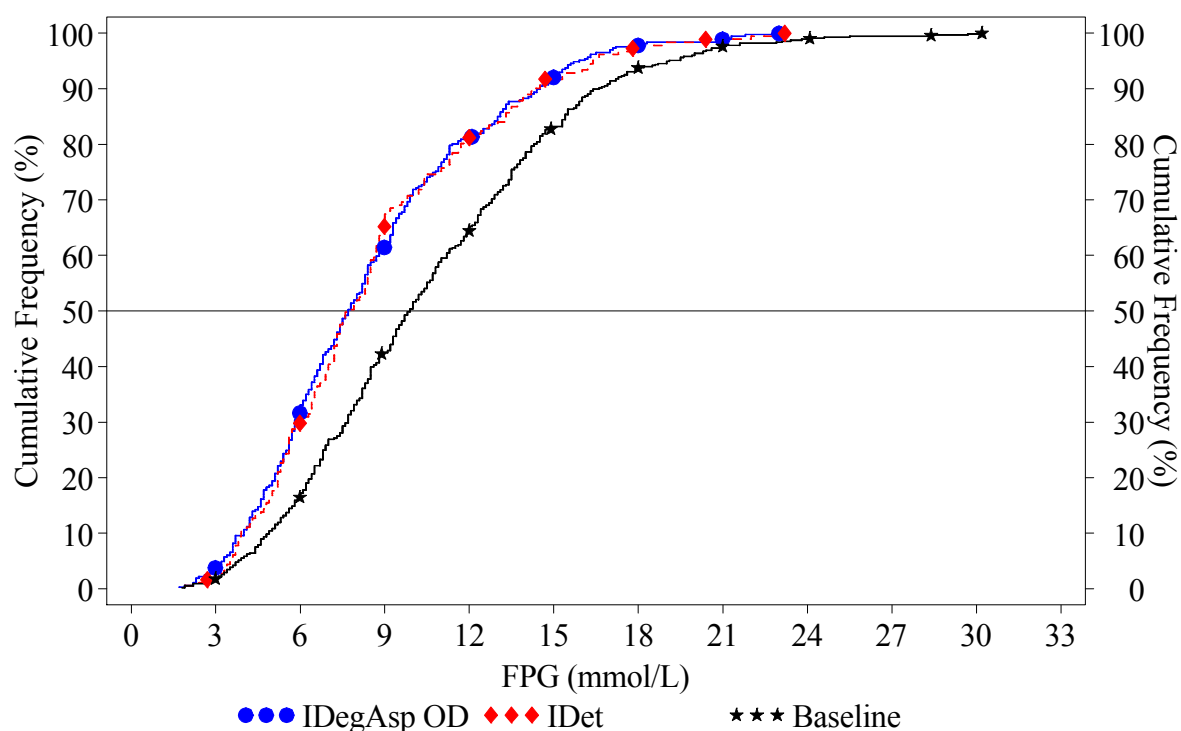
14.2.88: Fasting Plasma Glucose (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS, LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:45:23 - fbox_numfind_v01.sas/e_fpg_abs_box_locf_fas.cgm

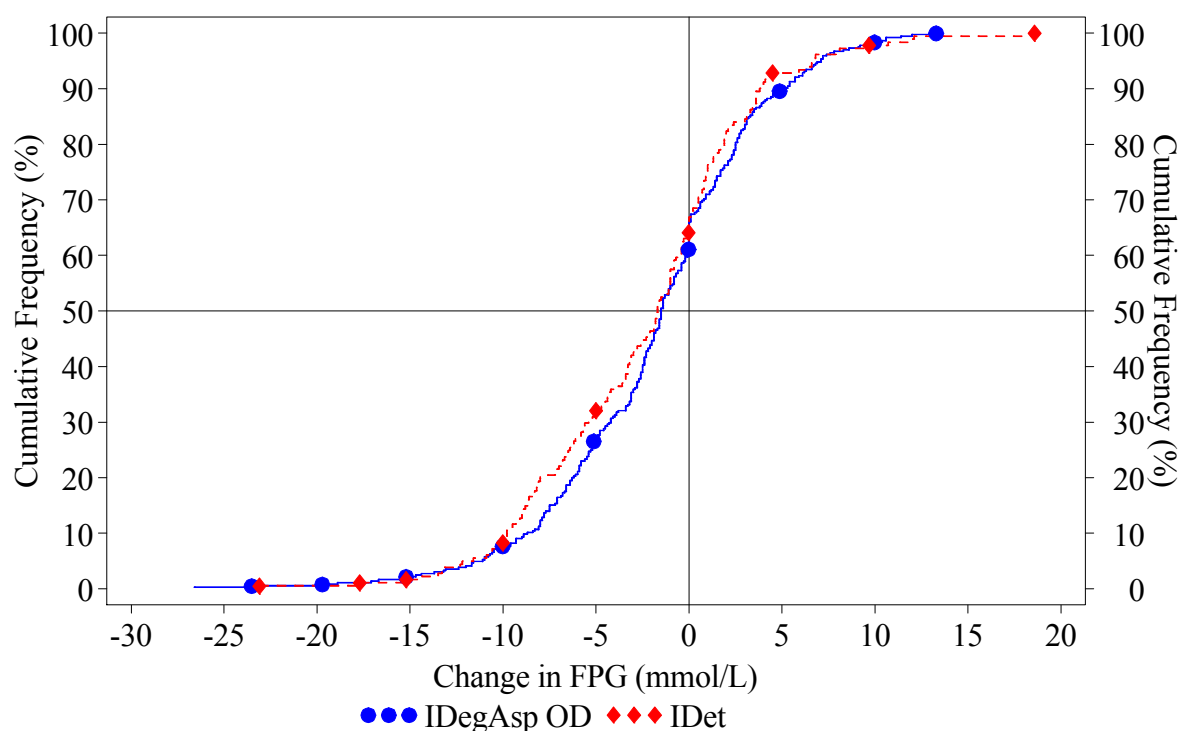
14.2.89: Fasting Plasma Glucose (mmol/L) by Treatment Week - Box Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:45:38 - fedist_numfind_v01.sas/e_fpg_abs_mean_cdf_locf_fas.cgm

14.2.90: Fasting Plasma Glucose (mmol/L) after 52 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:45:46 - fedist_numfind_v01.sas/e_fpg_chb_cdf_locf_fas.cgm

14.2.91: Fasting Plasma Glucose (mmol/L) after 52 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set

14.2.92: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set

	N	IDegAsp Mean	OD SD	N	IDet Mean	SD
Number Of Subjects	366			182		
SMPG (mmol/L)						
Visit 2 (Week 0)						
Before breakfast	360	9.3	4.5	180	9.7	4.3
90 minutes after start of breakfast	340	10.4	4.3	173	11.0	4.3
Before lunch	358	8.5	3.9	176	8.8	4.0
90 minutes after start of lunch	341	9.9	4.0	174	10.5	4.7
Before main evening meal	354	9.5	4.5	179	9.7	4.4
90 min after main evening meal	339	10.1	4.2	176	10.4	4.9
Before bedtime	345	10.0	4.3	170	9.5	4.4
At 04:00 A.M.	339	9.1	4.4	169	9.0	4.2
Before breakfast the following day	355	9.4	4.3	178	9.6	4.1
Visit 14 (Week 12)						
Before breakfast	329	7.4	3.1	165	7.5	3.4
90 minutes after start of breakfast	289	8.0	3.3	145	8.5	3.8
Before lunch	329	7.3	3.5	163	8.1	3.9
90 minutes after start of lunch	296	8.0	3.4	151	8.2	3.6
Before main evening meal	331	8.1	3.7	164	8.6	3.7
90 min after main evening meal	287	8.8	3.7	146	9.0	3.6
Before bedtime	290	8.6	4.2	154	8.9	3.8
At 04:00 A.M.	246	7.6	3.5	131	8.5	4.9
Before breakfast the following day	322	7.4	3.1	163	7.7	4.1
Visit 18 (Week 16)						
Before breakfast	325	7.4	3.4	162	6.8	3.1
90 minutes after start of breakfast	297	8.4	3.6	144	8.1	3.2
Before lunch	323	7.4	3.4	161	7.4	3.2
90 minutes after start of lunch	299	8.1	3.4	144	8.2	3.3
Before main evening meal	322	7.8	3.7	162	8.2	3.7
90 min after main evening meal	296	8.2	3.5	139	8.4	3.9
Before bedtime	305	8.2	3.4	157	8.7	4.4
At 04:00 A.M.	261	7.6	3.5	131	7.7	3.9
Before breakfast the following day	325	7.0	2.8	160	7.3	3.2
Visit 28 (Week 26)						
Before breakfast	336	7.4	3.3	162	6.9	3.4
90 minutes after start of breakfast	287	8.3	3.6	143	8.7	3.8
Before lunch	333	7.3	3.2	162	8.3	3.8
90 minutes after start of lunch	286	8.0	3.4	145	8.3	3.6
Before main evening meal	333	8.1	3.6	164	8.4	4.3
90 min after main evening meal	291	8.5	3.6	140	8.6	3.4
Before bedtime	314	8.4	3.4	157	8.1	4.0
At 04:00 A.M.	258	7.6	3.2	130	7.4	3.7
Before breakfast the following day	329	7.1	3.0	161	7.8	3.6

9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week - Descriptive Statistics - Full Analysis Set

	N	IDegAsp Mean	OD SD	N	IDet Mean	SD
SMPG (mmol/L)						
Visit 37 (Week 39)						
Before breakfast	241	6.8	3.2	118	7.2	3.7
90 minutes after start of breakfast	226	8.1	3.1	106	8.6	3.5
Before lunch	244	7.0	3.1	118	7.3	3.4
90 minutes after start of lunch	226	7.9	3.1	110	8.6	4.0
Before main evening meal	242	7.5	3.6	117	8.8	4.3
90 min after main evening meal	222	8.3	3.5	106	8.8	3.8
Before bedtime	230	8.0	3.5	114	8.5	3.6
At 04:00 A.M.	216	6.9	3.0	104	7.2	3.8
Before breakfast the following day	243	6.8	2.8	117	7.3	3.6
Visit 44 (Week 53)						
Before breakfast	233	6.8	2.6	110	6.9	3.0
90 minutes after start of breakfast	224	7.9	3.1	100	8.3	3.3
Before lunch	231	6.9	3.0	111	7.2	2.7
90 minutes after start of lunch	219	7.9	3.2	102	7.8	2.9
Before main evening meal	231	7.6	3.1	111	8.0	3.5
90 min after main evening meal	221	8.6	3.1	102	8.1	3.3
Before bedtime	229	8.3	3.6	110	8.2	3.3
At 04:00 A.M.	207	7.2	3.2	97	7.4	3.4
Before breakfast the following day	233	6.9	2.5	112	7.2	3.4
Visit 44 (Week 53) (LOCF)						
Before breakfast	363	7.5	3.4	177	7.2	3.4
90 minutes after start of breakfast	318	8.3	3.5	154	8.3	3.6
Before lunch	356	7.3	3.5	177	8.0	3.7
90 minutes after start of lunch	310	8.3	3.4	161	8.2	3.3
Before main evening meal	355	7.9	3.5	179	8.6	4.0
90 min after main evening meal	320	8.9	3.5	156	8.6	3.5
Before bedtime	343	8.6	3.7	170	8.7	4.1
At 04:00 A.M.	289	7.7	3.5	146	7.6	3.6
Before breakfast the following day	357	7.2	2.9	179	7.9	4.0

14.2.93: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

Value	FAS	N	Estimate	SE	95% CI
Before Breakfast					
LSMeans					
IDegAsp OD	366	363	7.50	0.23	
IDet	182	177	7.26	0.29	
Treatment Contrast					
IDegAsp OD - IDet			0.23		[-0.38 ; 0.85]
90 Minutes After Start Of Breakfast					
LSMeans					
IDegAsp OD	366	318	8.26	0.25	
IDet	182	154	8.27	0.32	
Treatment Contrast					
IDegAsp OD - IDet			-0.01		[-0.68 ; 0.67]
Before Lunch					
LSMeans					
IDegAsp OD	366	356	7.48	0.24	
IDet	182	177	8.18	0.31	
Treatment Contrast					
IDegAsp OD - IDet			-0.70		[-1.35 ; -0.06]
90 Minutes After Start Of Lunch					
LSMeans					
IDegAsp OD	366	310	8.41	0.24	
IDet	182	161	8.22	0.30	
Treatment Contrast					
IDegAsp OD - IDet			0.20		[-0.45 ; 0.84]
Before Main Evening Meal					
LSMeans					
IDegAsp OD	366	355	7.89	0.24	
IDet	182	179	8.64	0.31	
Treatment Contrast					
IDegAsp OD - IDet			-0.75		[-1.41 ; -0.10]

N: Number of subjects contributing to analysis

CI: Confidence Interval

SE: Standard Error of the Mean

9-point profile (SMPG) values after 52 weeks of treatment are analysed jointly using a linear mixed model with an unstructured residual covariance structure and with treatment, time-point and an interaction between treatment and time-point, anti-diabetic treatment at screening, region and sex as fixed effects, and age and baseline response per time-point as covariates. Missing profiles are imputed using last observation carried forward.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:46:42 - tstat_9pp_after.sas/t_9pp_stat_joint_locf_fas.txt

9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

Value	FAS	N	Estimate	SE	95% CI
90 Minutes After The Start Of Main Evening Meal					
LSMeans					
IDegAsp OD	366	320	8.97	0.25	
IDet	182	156	8.63	0.31	
Treatment Contrast					
IDegAsp OD - IDet			0.34		[-0.32 ; 1.00]
Before Bedtime					
LSMeans					
IDegAsp OD	366	343	8.60	0.25	
IDet	182	170	8.59	0.32	
Treatment Contrast					
IDegAsp OD - IDet			0.01		[-0.65 ; 0.68]
At 4:00 A.M.					
LSMeans					
IDegAsp OD	366	289	7.84	0.25	
IDet	182	146	8.02	0.32	
Treatment Contrast					
IDegAsp OD - IDet			-0.18		[-0.85 ; 0.49]
Before Breakfast The Following Day					
LSMeans					
IDegAsp OD	366	357	7.30	0.22	
IDet	182	179	7.89	0.28	
Treatment Contrast					
IDegAsp OD - IDet			-0.59		[-1.16 ; -0.02]

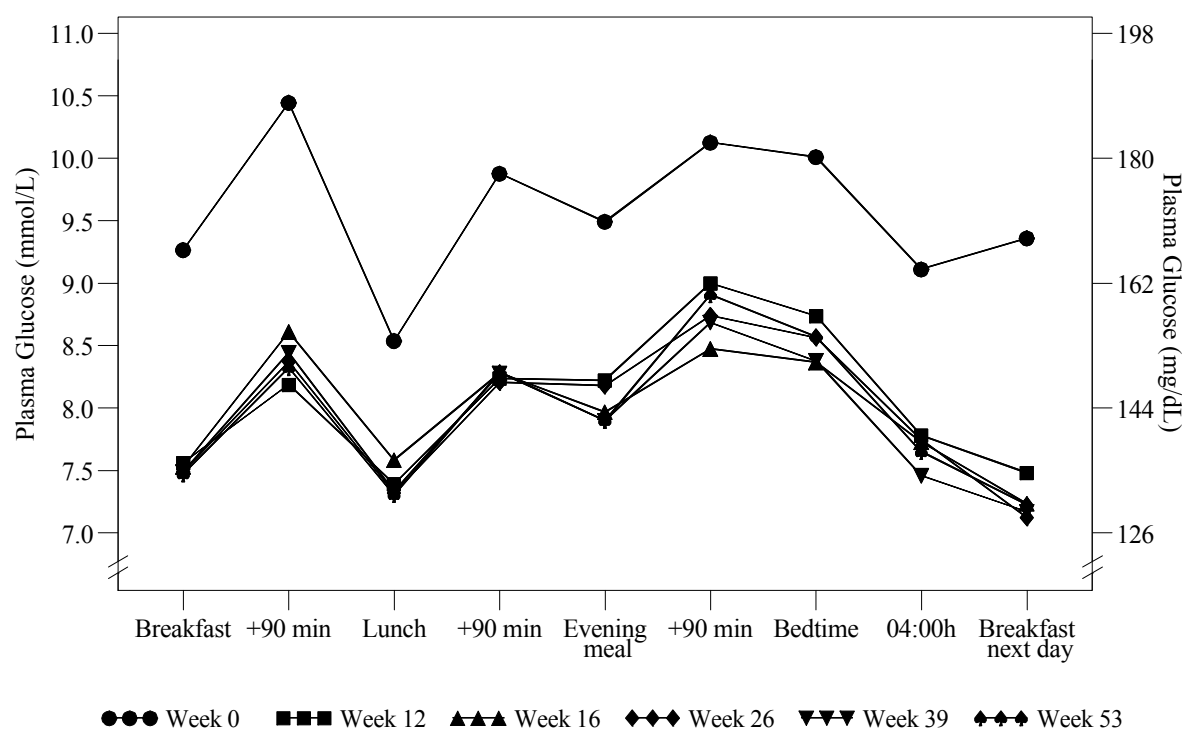
N: Number of subjects contributing to analysis

CI: Confidence Interval

SE: Standard Error of the Mean

9-point profile (SMPG) values after 52 weeks of treatment are analysed jointly using a linear mixed model with an unstructured residual covariance structure and with treatment, time-point and an interaction between treatment and time-point, anti-diabetic treatment at screening, region and sex as fixed effects, and age and baseline response per time-point as covariates. Missing profiles are imputed using last observation carried forward.

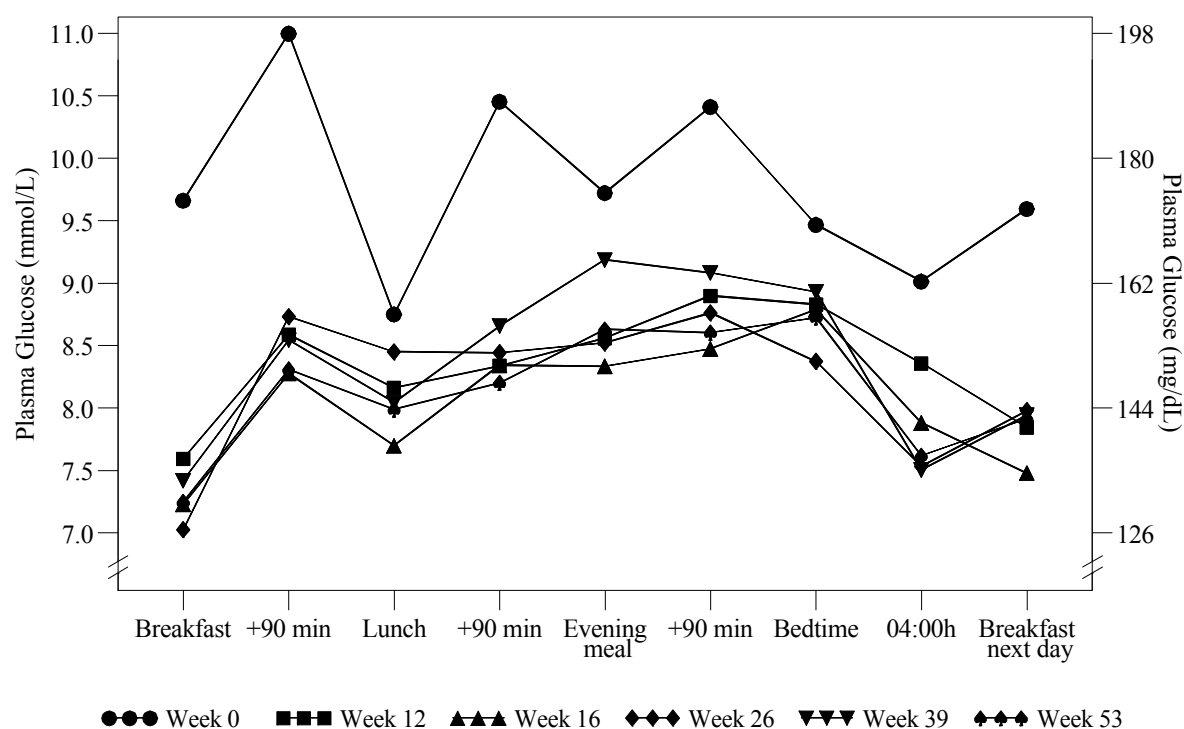
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:46:42 - tstat_9pp_after.sas/t_9pp_stat_joint_locf_fas.txt



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:26:28 - fplot_9PP/e_9pp_al_w_iv1_abs_mean_locf_fas.cgm

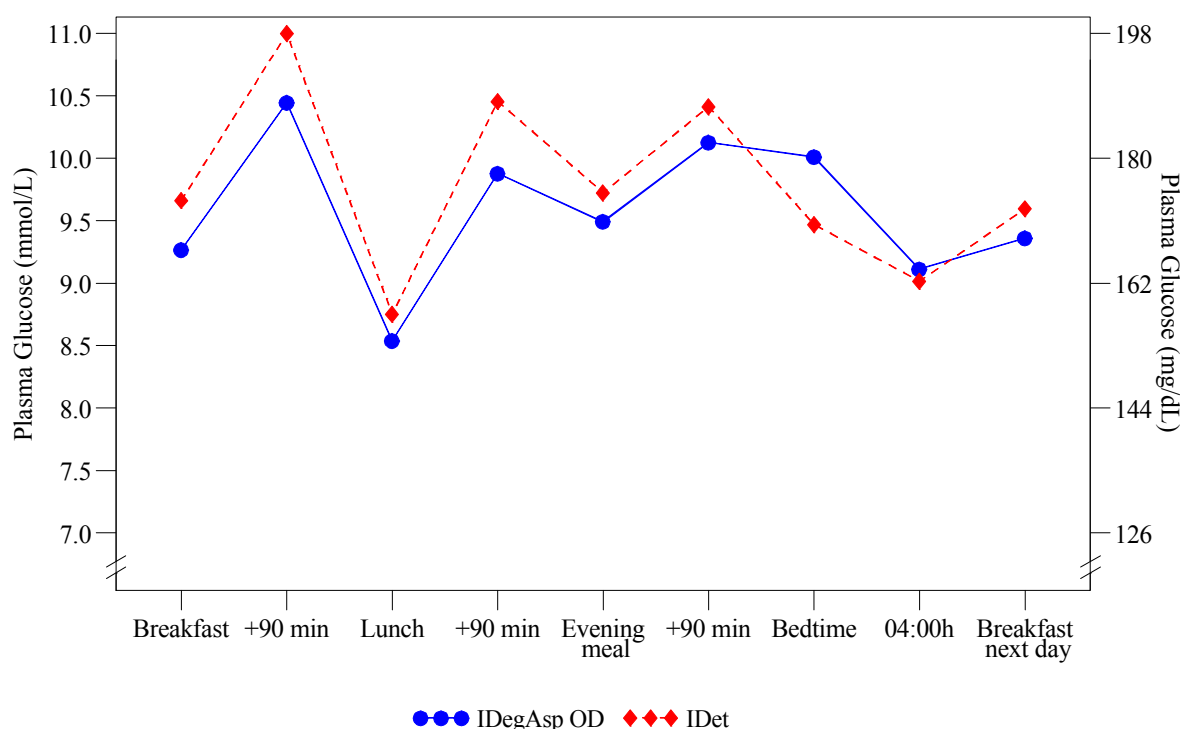
14.2.94: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Weeks - Mean Plot - IDegAsp OD - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:26:48 - fplot_9PP/e_9pp_al_w_cm_abs_mean_locf_fas.cgm

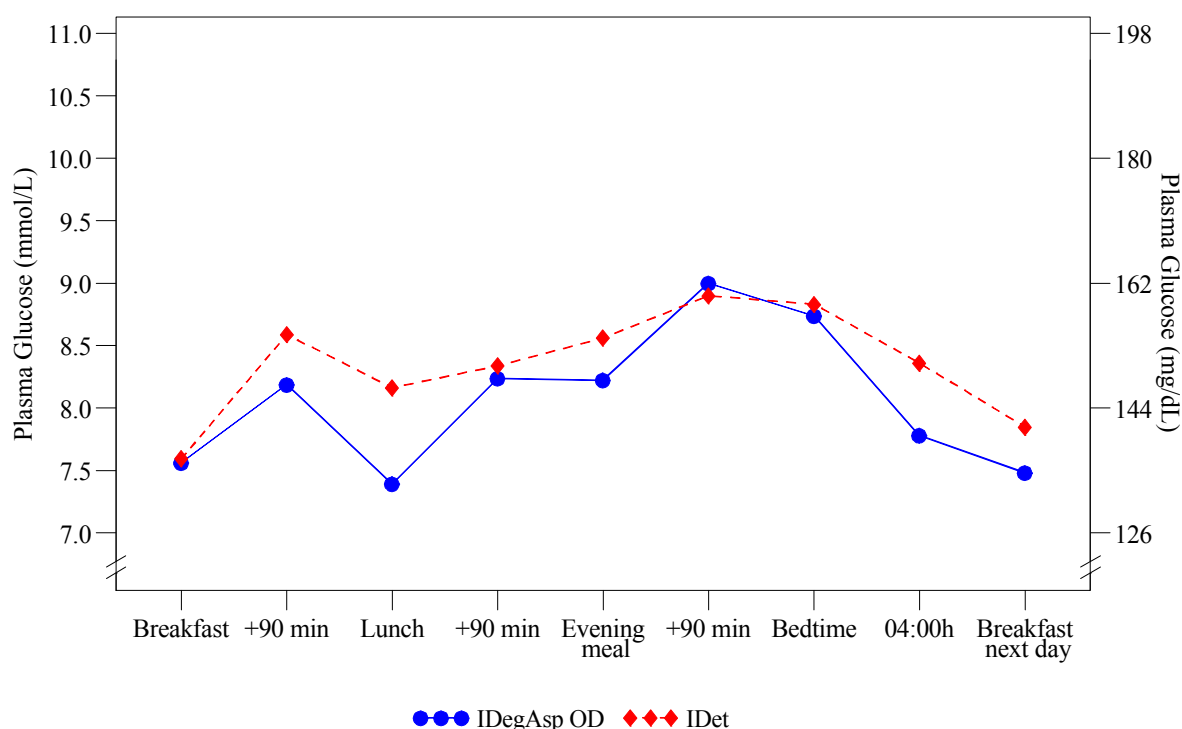
14.2.95: 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Weeks - Mean Plot - IDet - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:24:26 - fplot_9PP/e_9pp_week0_abs_mean_locf_fas.cgm

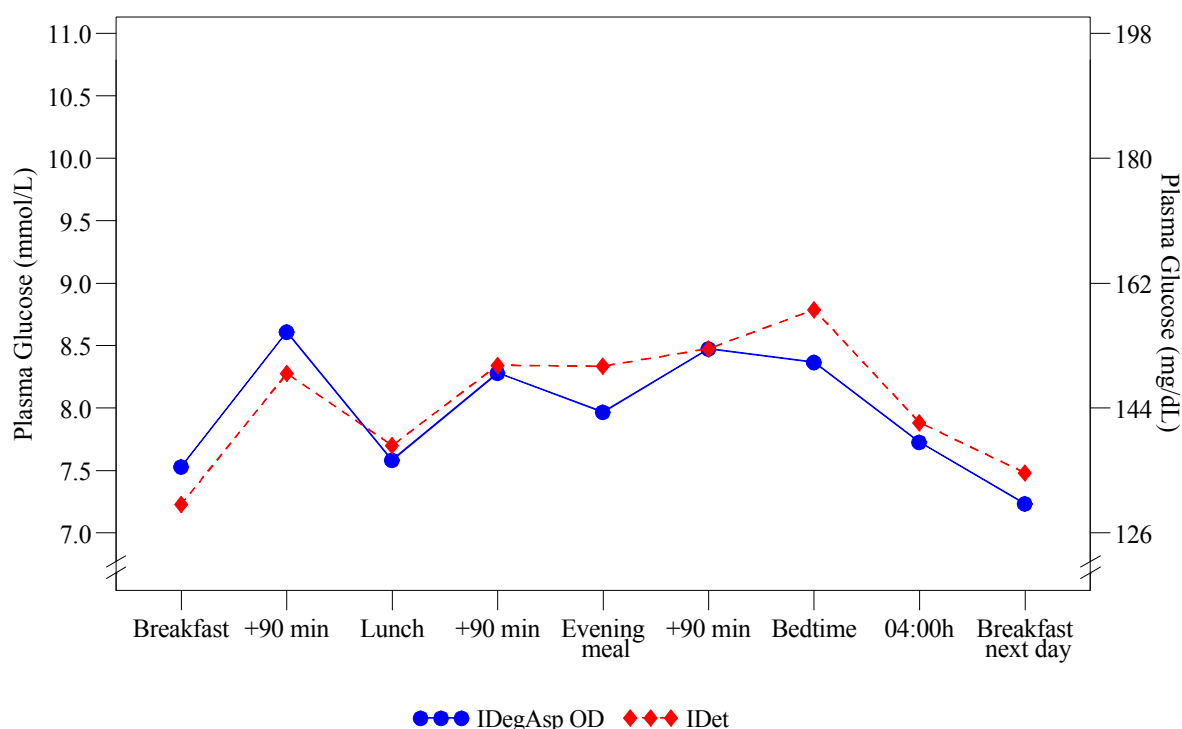
14.2.96: 9-point Self Measured Plasma Glucose Profile (mmol/L) at Baseline - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:24:47 - fplot_9PP/e_9pp_week12_abs_mean_locf_fas.cgm

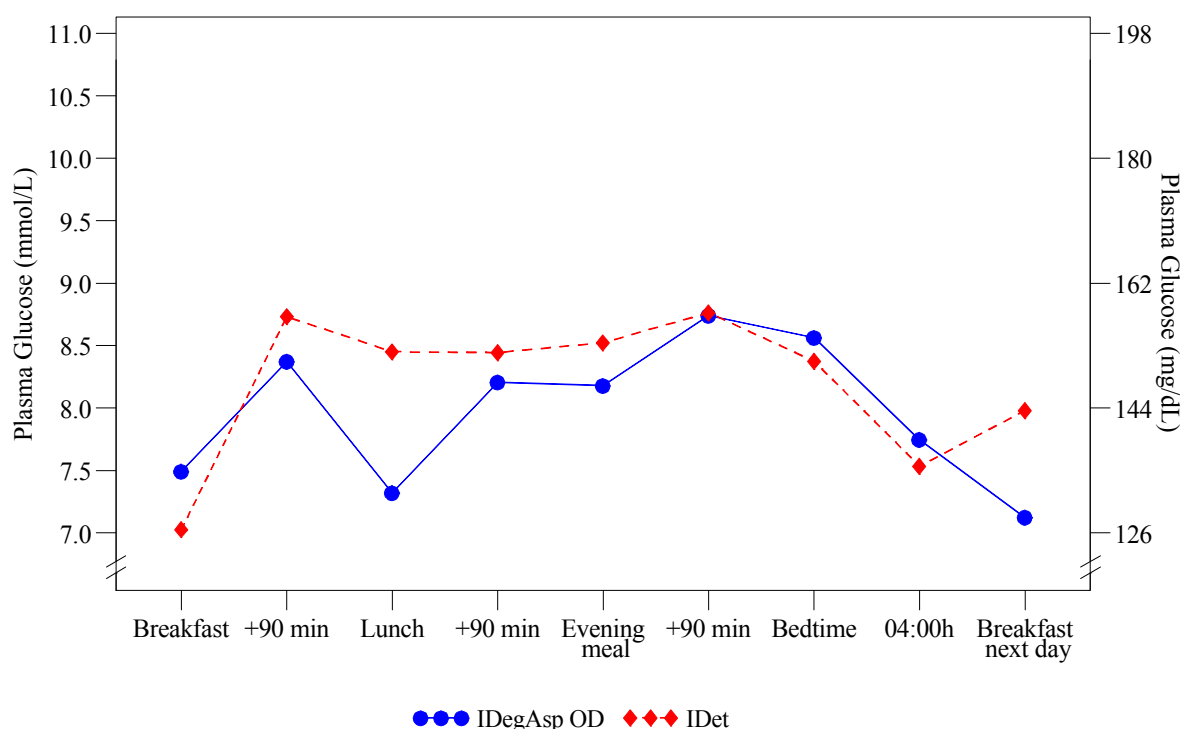
14.2.97: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 12 Weeks - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:25:07 - fplot_9PP/e_9pp_week16_abs_mean_locf_fas.cgm

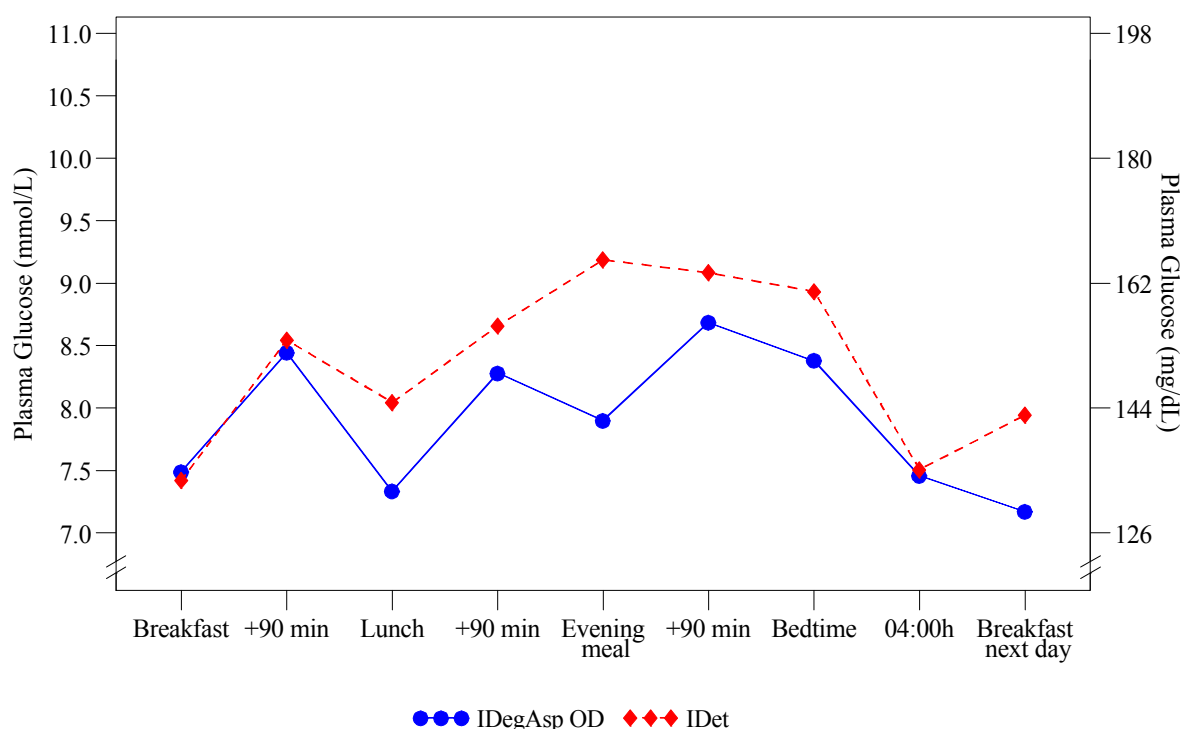
14.2.98: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 16 Weeks - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:25:28 - fplot_9PP/e_9pp_week26_abs_mean_locf_fas.cgm

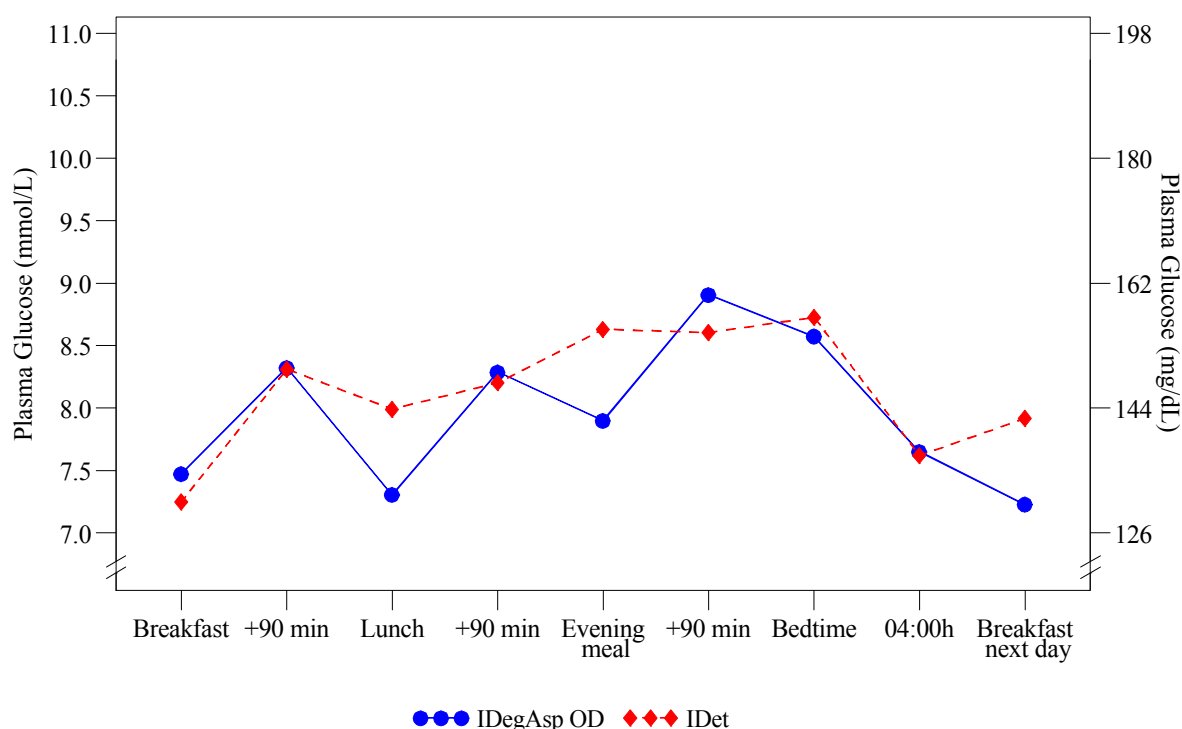
14.2.99: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 26 Weeks - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:25:48 - fplot_9PP/e_9pp_week39_abs_mean_locf_fas.cgm

14.2.100: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 39 Weeks - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:26:08 - fplot_9PP/e_9pp_week52_abs_mean_locf_fas.cgm

14.2.101: 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks - Mean Plot - Full Analysis Set

14.2.102: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Mean PG (mmol/L)			
Visit 2 (Week 0)			
N	355	179	534
Mean (SD)	9.6 (2.2)	9.8 (2.3)	9.7 (2.2)
Median	9.4	9.4	9.4
Min ; Max	5.9 ; 16.7	5.2 ; 17.7	5.2 ; 17.7
Visit 14 (Week 12)			
N	323	162	485
Mean (SD)	8.0 (2.2)	8.4 (2.5)	8.2 (2.3)
Median	7.6	7.8	7.7
Min ; Max	4.4 ; 15.8	3.7 ; 19.6	3.7 ; 19.6
Visit 18 (Week 16)			
N	322	162	484
Mean (SD)	7.9 (2.0)	8.0 (2.0)	7.9 (2.0)
Median	7.6	7.6	7.6
Min ; Max	4.7 ; 15.2	4.5 ; 15.4	4.5 ; 15.4
Visit 28 (Week 26)			
N	326	161	487
Mean (SD)	7.9 (2.1)	8.3 (2.4)	8.0 (2.2)
Median	7.7	7.9	7.9
Min ; Max	4.5 ; 15.9	4.5 ; 23.4	4.5 ; 23.4
Visit 37 (Week 39)			
N	241	118	359
Mean (SD)	7.6 (1.9)	8.2 (2.3)	7.8 (2.1)
Median	7.2	7.7	7.3
Min ; Max	4.5 ; 14.5	4.6 ; 15.2	4.5 ; 15.2
Visit 44 (Week 53)			
N	231	111	342
Mean (SD)	7.6 (1.9)	7.8 (2.3)	7.7 (2.0)
Median	7.4	7.4	7.4
Min ; Max	4.6 ; 16.8	4.2 ; 19.6	4.2 ; 19.6
Visit 44 (Week 53) (LOCF)			
N	350	177	527
Mean (SD)	8.0 (2.1)	8.3 (2.6)	8.1 (2.3)
Median	7.7	7.9	7.7
Min ; Max	4.5 ; 16.8	4.2 ; 23.4	4.2 ; 23.4

N = Number of Subjects, SD = Standard Deviation

The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:46:50 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_mean_descp_fas.txt

14.2.103: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Change in Mean PG (mmol/L)			
Visit 14 (Week 12)			
N	317	162	479
Mean (SD)	-1.6 (2.7)	-1.4 (3.1)	-1.5 (2.8)
Median	-1.4	-1.5	-1.5
Min ; Max	-9.1 ; 7.6	-10.9 ; 7.4	-10.9 ; 7.6
Visit 18 (Week 16)			
N	315	162	477
Mean (SD)	-1.7 (2.5)	-1.8 (2.5)	-1.7 (2.5)
Median	-1.7	-1.7	-1.7
Min ; Max	-9.6 ; 6.1	-10.8 ; 6.1	-10.8 ; 6.1
Visit 28 (Week 26)			
N	319	160	479
Mean (SD)	-1.6 (2.7)	-1.6 (2.7)	-1.6 (2.7)
Median	-1.5	-1.4	-1.5
Min ; Max	-8.5 ; 5.5	-11.1 ; 6.5	-11.1 ; 6.5
Visit 37 (Week 39)			
N	237	118	355
Mean (SD)	-1.9 (2.6)	-1.6 (2.8)	-1.8 (2.7)
Median	-1.9	-1.4	-1.8
Min ; Max	-9.9 ; 6.3	-10.7 ; 6.7	-10.7 ; 6.7
Visit 44 (Week 53)			
N	227	111	338
Mean (SD)	-1.8 (2.8)	-1.9 (2.8)	-1.9 (2.8)
Median	-1.8	-1.8	-1.8
Min ; Max	-9.0 ; 8.9	-10.0 ; 8.6	-10.0 ; 8.9
Visit 44 (Week 53) (LOCF)			
N	343	176	519
Mean (SD)	-1.6 (2.8)	-1.5 (2.8)	-1.6 (2.8)
Median	-1.4	-1.4	-1.4
Min ; Max	-9.0 ; 8.9	-10.0 ; 8.6	-10.0 ; 8.9

N = Number of Subjects, SD = Standard Deviation

The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method

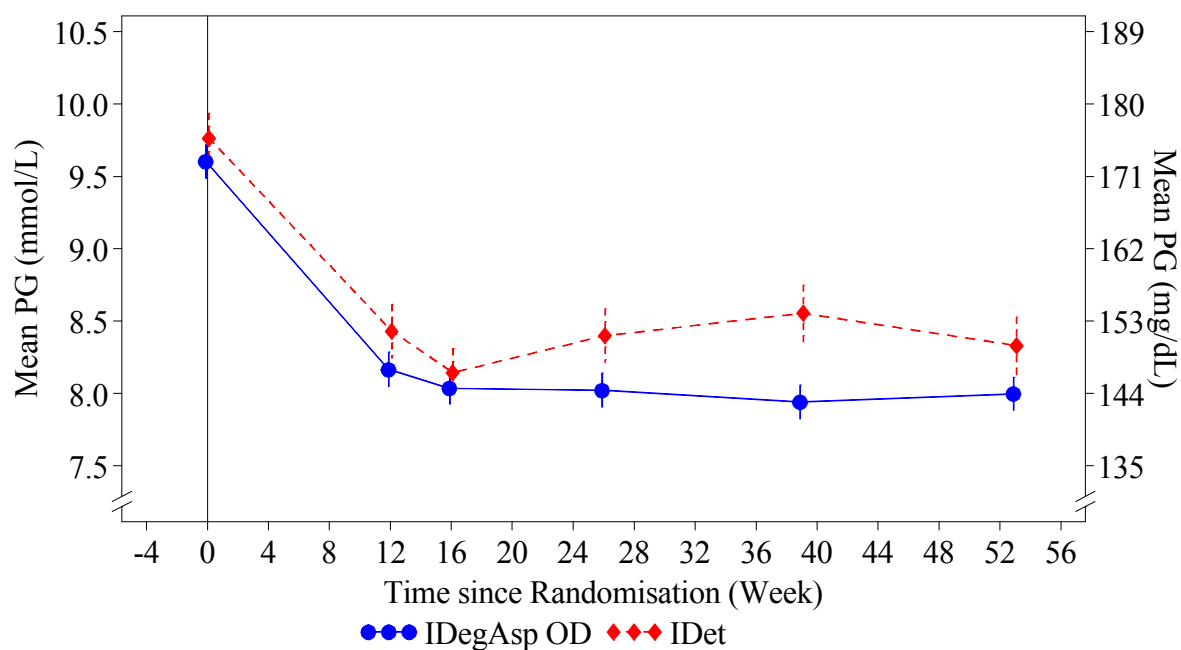
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:46:59 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_mean_descp_fas.txt

14.2.104: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Mean PG (mmol/L)					
LSMeans					
IDegAsp OD	366	343	8.05	0.19	
IDet	182	176	8.26	0.22	
Treatment Contrast					
IDegAsp OD - IDet			-0.20		[-0.59 ; 0.18]

The response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and mean profile at baseline as covariates. Missing data is imputed using LOCF. The mean profile is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

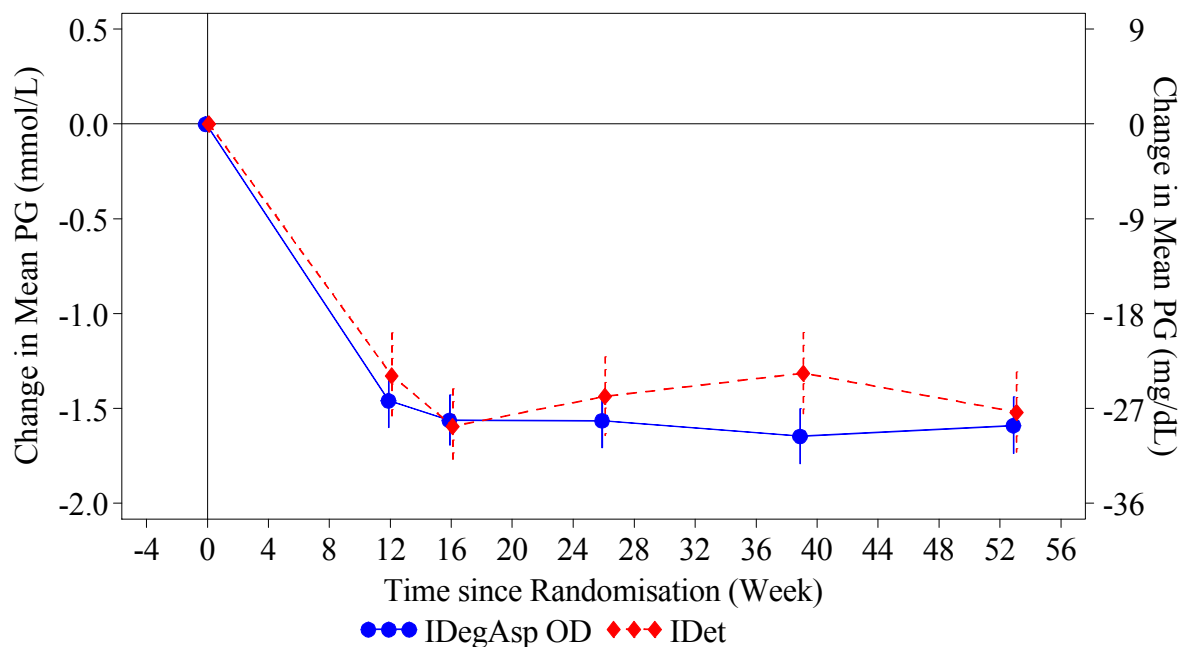
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:47:07 - tstat_find_tpl_t022.sas/t_9pp_mean_stat_locf_fas.txt



FAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:47:16 - fmean_numfind_v03.sas/e_9pp_abs_mean_mean_locf_fas.cgm

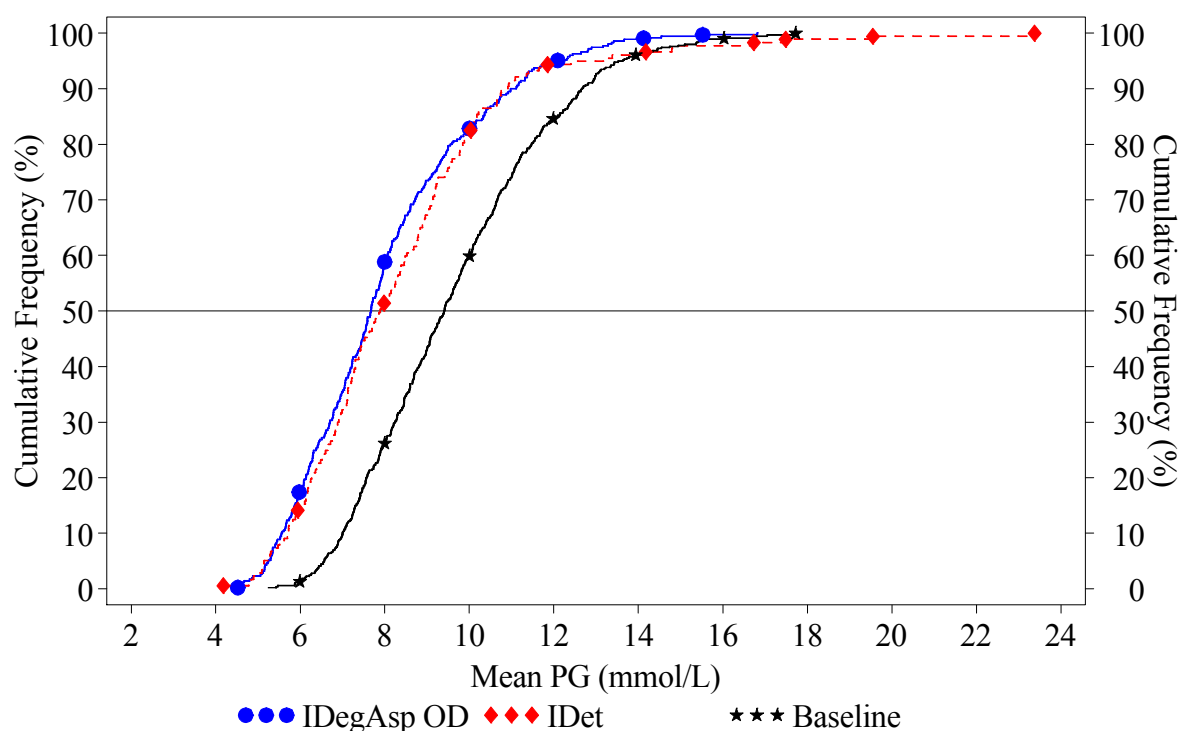
14.2.105: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set



FAS; LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:47:25 - fmean_numfind_v03.sas/e_9pp_chb_mean_mean_locf_fas.cgm

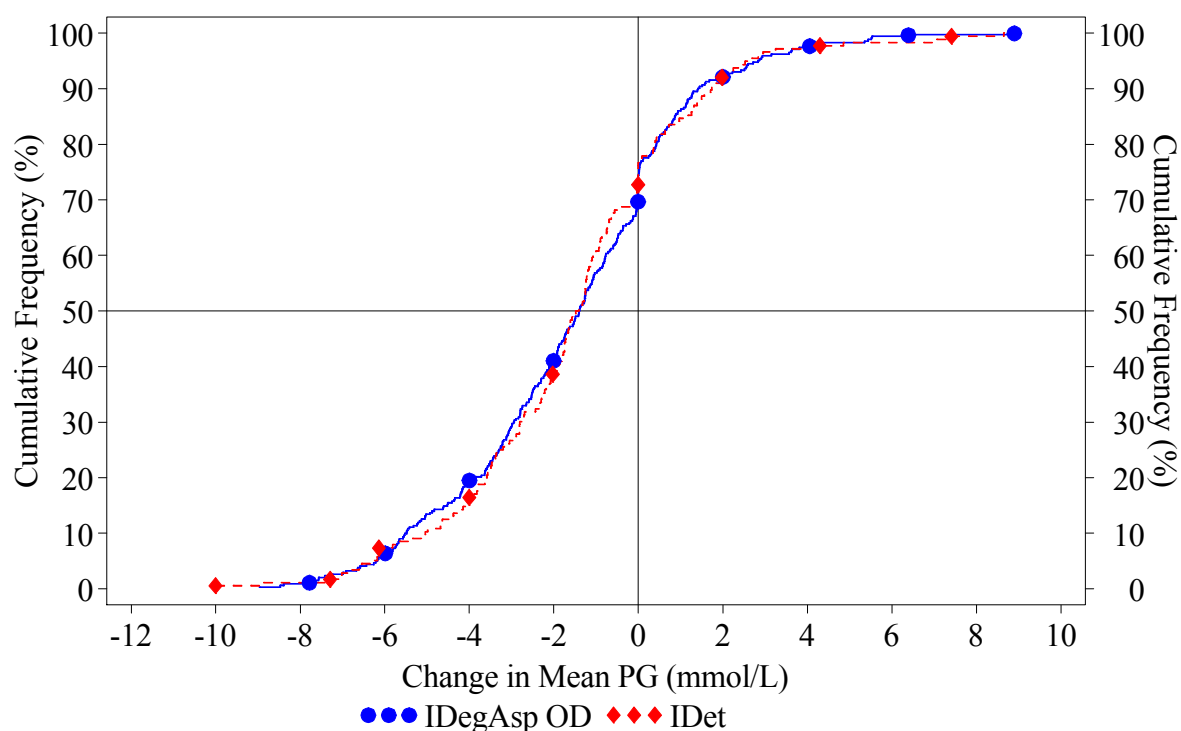
14.2.106: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:47:40 - fedist_numfind_v01.sas/e_9pp_abs_mean_cdf_locf_fas.cgm

14.2.107: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:47:49 - fedist_numfind_v01.sas/e_9pp_chb_mean_cdf_locf_fas.cgm

14.2.108: Mean of 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set

14.2.109: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Fluctuation (mmol/L)			
Visit 2 (Week 0)			
N	355	179	534
Geometric Mean	2.1	2.1	2.1
CV	47.80	42.54	46.03
Median	2.1	2.2	2.1
Min ; Max	0.5 ; 6.9	0.4 ; 6.1	0.4 ; 6.9
Visit 14 (Week 12)			
N	323	162	485
Geometric Mean	1.3	1.5	1.4
CV	62.55	60.11	61.80
Median	1.4	1.7	1.6
Min ; Max	0.1 ; 5.8	0.2 ; 7.2	0.1 ; 7.2
Visit 18 (Week 16)			
N	322	162	484
Geometric Mean	1.3	1.5	1.4
CV	64.83	58.85	62.89
Median	1.4	1.8	1.5
Min ; Max	0.1 ; 7.2	0.1 ; 5.1	0.1 ; 7.2
Visit 28 (Week 26)			
N	326	161	487
Geometric Mean	1.2	1.5	1.3
CV	60.67	56.75	59.92
Median	1.4	1.7	1.5
Min ; Max	0.1 ; 5.5	0.2 ; 5.5	0.1 ; 5.5
Visit 37 (Week 39)			
N	241	118	359
Geometric Mean	1.2	1.4	1.3
CV	65.37	59.68	63.56
Median	1.4	1.6	1.4
Min ; Max	0.1 ; 5.9	0.2 ; 5.4	0.1 ; 5.9
Visit 44 (Week 53)			
N	231	111	342
Geometric Mean	1.2	1.2	1.2
CV	65.55	56.68	63.09
Median	1.3	1.3	1.3
Min ; Max	0.2 ; 5.5	0.2 ; 3.8	0.2 ; 5.5

CV = Coefficient of Variation, N = Number of Subjects
Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:47:58 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_fluc_descp_fas.txt

Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week -
Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Fluctuation (mmol/L)			
Visit 44 (Week 53) (LOCF)			
N	350	177	527
Geometric Mean	1.3	1.3	1.3
CV	63.21	58.14	61.49
Median	1.4	1.5	1.5
Min ; Max	0.2 ; 5.7	0.2 ; 4.9	0.2 ; 5.7

CV = Coefficient of Variation, N = Number of Subjects

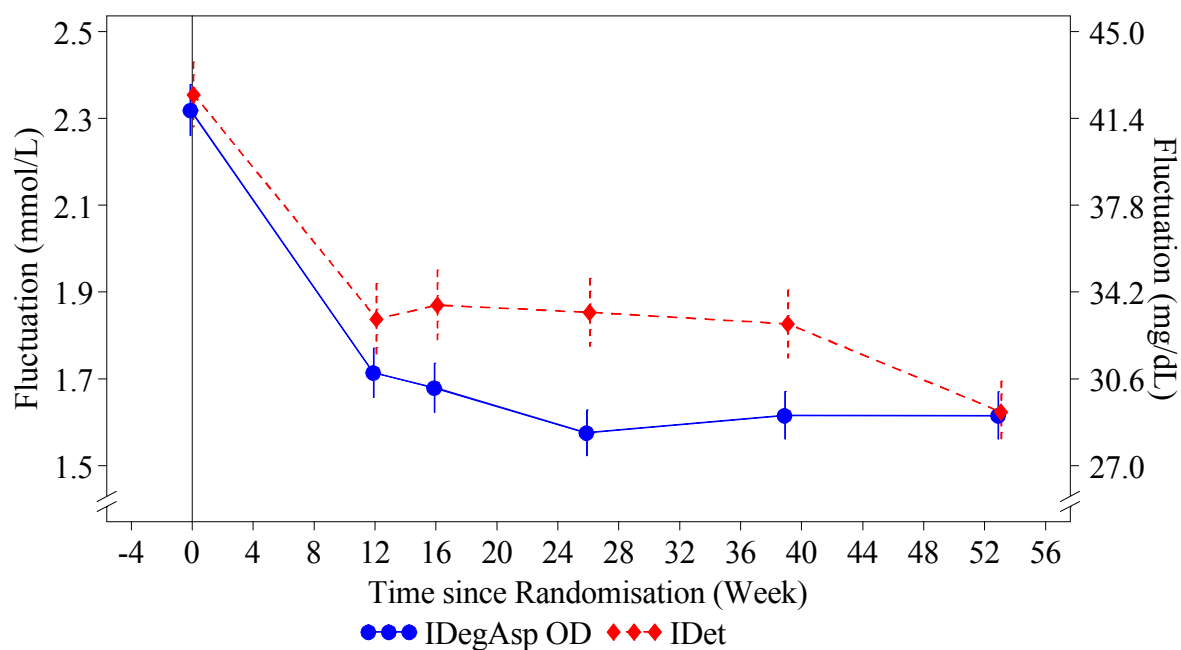
Fluctuation is defined as the integrated absolute distance from mean profile value
divided by measurement time

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:47:58 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_fluc_descp_fas.txt

14.2.110: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
Fluctuation (mmol/L)				
LSMeans				
IDegAsp OD	366	343	1.36	
IDet	182	176	1.36	
Treatment Ratio				
IDegAsp OD / IDet			1.00	[0.89 ; 1.13]

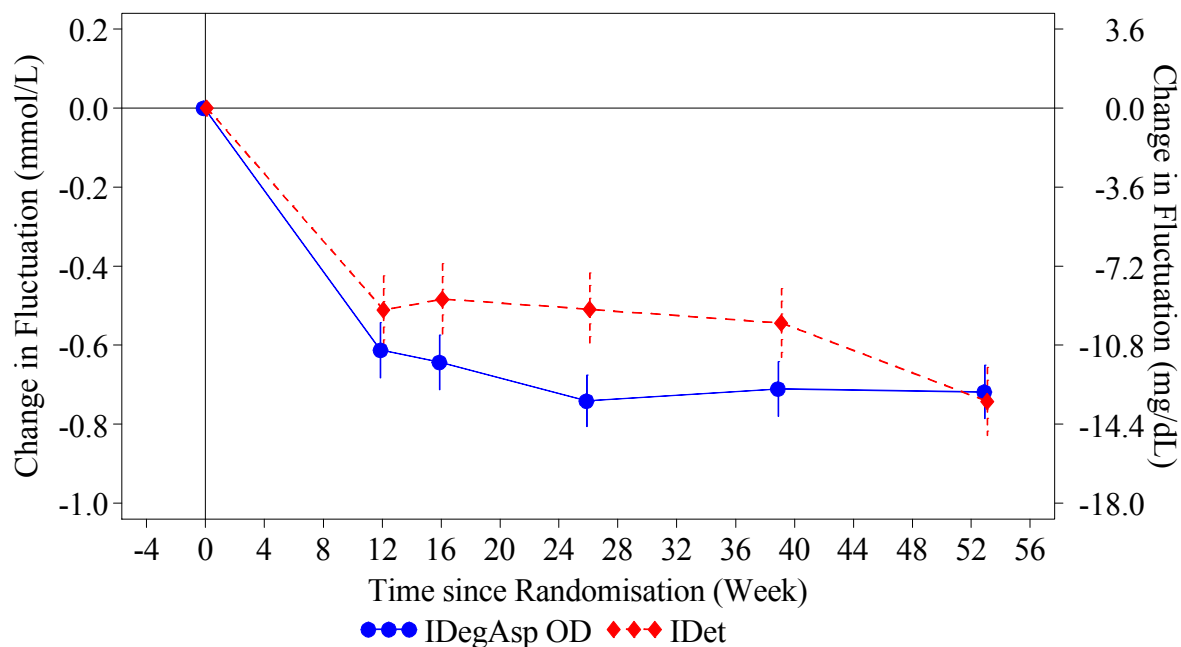
N = Number of subjects contributing to analysis, CI = Confidence Interval The log-transformed response after 52 weeks of treatment is analysed using an ANVOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
Missing data is imputed using last observation carried forward.
Fluctuation is integrated abs. dist. from mean profile value divided by measurement time.
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:48:06 - tstat_find_tpl_t022.sas/t_9pp_fluc_stat_locf_fas.txt



FAS; LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:48:15 - fmean_numfind_v03.sas/e_9pp_abs_fluc_mean_locf_fas.cgm

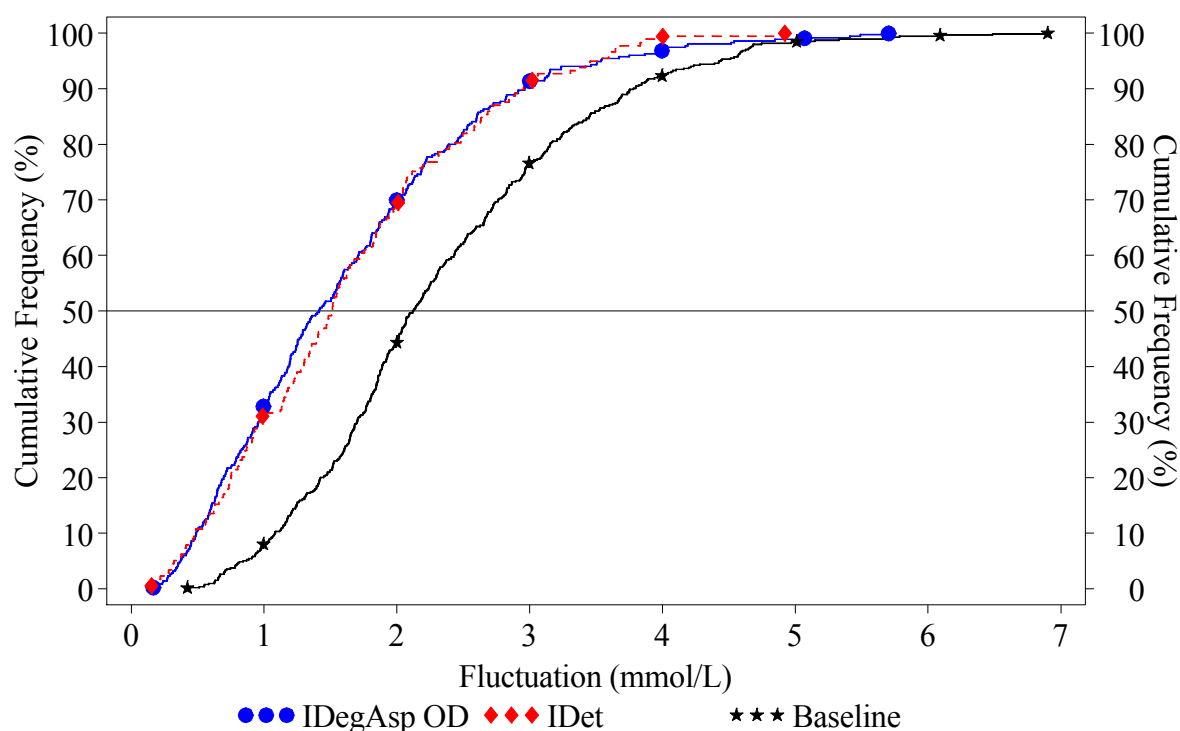
14.2.111: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Mean Plot - Full Analysis Set



EAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:48:24 - fmean_numfind_v03.sas/e_9pp_chb_fluc_mean_locf_fas.cgm

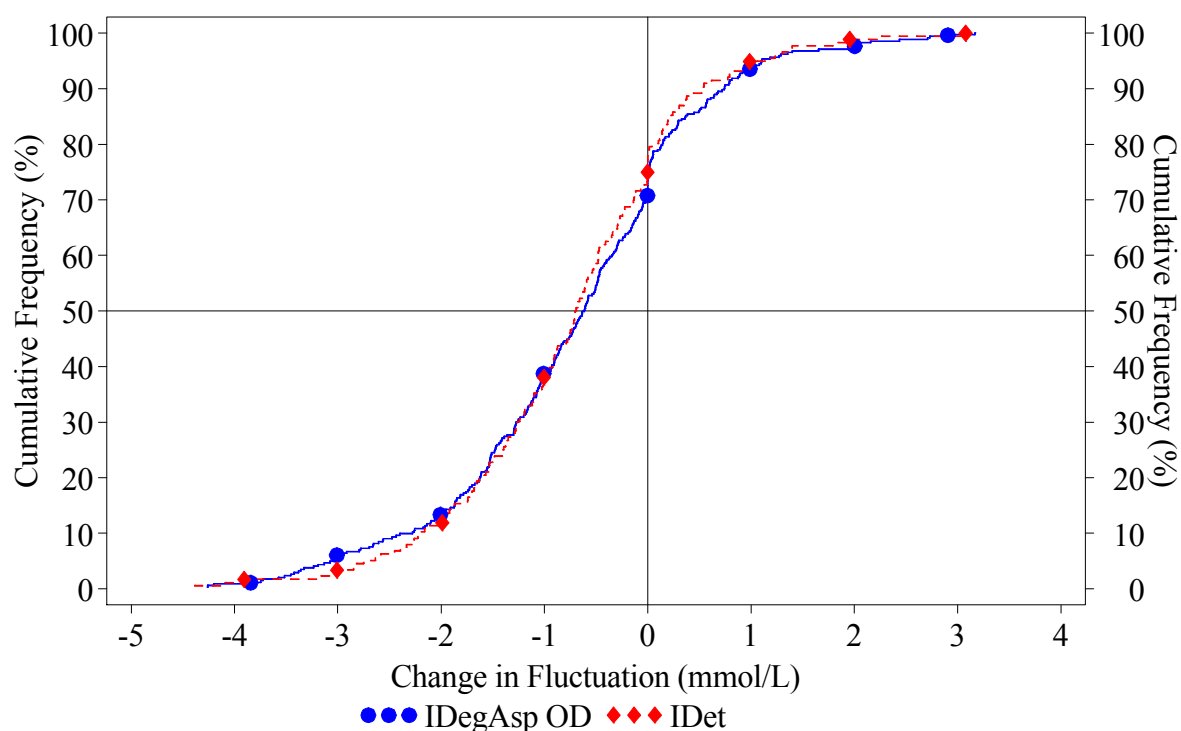
14.2.112: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) by Treatment Week – Change from Baseline – Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:48:39 - fedist_numfind_v01.sas/e_9pp_abs_fluc_cdf_locf_fas.cgm

14.2.113: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:48:48 - fedist_numfind_v01.sas/e_9pp_chb_fluc_cdf_locf_fas.cgm

14.2.114: Fluctuation in 9-point Self Measured Plasma Glucose Profile (mmol/L) after 52 Weeks of Treatment – Change from Baseline - Empirical Distribution Plot - Full Analysis Set

14.2.115: Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
All Meals (mmol/L)			
Visit 2 (Week 0)			
N	349	180	529
Mean (SD)	1.0 (3.0)	1.2 (3.2)	1.1 (3.1)
Median	1.0	1.2	1.0
Min ; Max	-7.7 ; 10.0	-7.5 ; 11.0	-7.7 ; 11.0
Visit 14 (Week 12)			
N	301	152	453
Mean (SD)	0.8 (2.6)	0.7 (2.7)	0.8 (2.6)
Median	0.8	0.5	0.7
Min ; Max	-10.8 ; 10.5	-7.2 ; 13.0	-10.8 ; 13.0
Visit 18 (Week 16)			
N	309	151	460
Mean (SD)	0.8 (2.5)	0.9 (2.7)	0.8 (2.6)
Median	0.7	0.6	0.7
Min ; Max	-8.1 ; 11.8	-6.6 ; 9.3	-8.1 ; 11.8
Visit 28 (Week 26)			
N	298	150	448
Mean (SD)	0.9 (2.3)	0.9 (3.0)	0.9 (2.5)
Median	0.7	1.0	0.8
Min ; Max	-6.5 ; 9.3	-10.7 ; 8.4	-10.7 ; 9.3
Visit 37 (Week 39)			
N	232	113	345
Mean (SD)	1.0 (2.2)	0.9 (2.9)	1.0 (2.4)
Median	0.9	0.7	0.9
Min ; Max	-7.0 ; 7.2	-6.7 ; 11.0	-7.0 ; 11.0
Visit 44 (Week 53)			
N	225	104	329
Mean (SD)	1.1 (2.4)	0.8 (2.4)	1.0 (2.4)
Median	1.0	0.8	1.0
Min ; Max	-11.7 ; 9.8	-8.7 ; 8.8	-11.7 ; 9.8
Visit 44 (Week 53) (LOCF)			
N	326	164	490
Mean (SD)	1.1 (2.5)	0.5 (2.9)	0.9 (2.7)
Median	1.0	0.7	0.9
Min ; Max	-11.7 ; 9.8	-10.7 ; 8.8	-11.7 ; 9.8

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:48:57 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
(mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Breakfast (mmol/L)			
Visit 2 (Week 0)			
N	339	173	512
Mean (SD)	1.2 (5.1)	1.4 (4.9)	1.3 (5.1)
Median	1.4	1.7	1.4
Min ; Max	-13.0 ; 18.2	-10.8 ; 14.9	-13.0 ; 18.2
Visit 14 (Week 12)			
N	287	145	432
Mean (SD)	0.7 (3.5)	1.2 (3.6)	0.8 (3.6)
Median	0.7	0.7	0.7
Min ; Max	-14.7 ; 9.4	-9.2 ; 10.5	-14.7 ; 10.5
Visit 18 (Week 16)			
N	295	144	439
Mean (SD)	1.2 (3.9)	1.1 (3.6)	1.2 (3.8)
Median	1.0	1.0	1.0
Min ; Max	-12.5 ; 16.4	-8.7 ; 11.3	-12.5 ; 16.4
Visit 28 (Week 26)			
N	287	143	430
Mean (SD)	1.1 (3.7)	1.9 (4.7)	1.4 (4.1)
Median	1.1	1.4	1.2
Min ; Max	-9.4 ; 16.3	-12.0 ; 23.2	-12.0 ; 23.2
Visit 37 (Week 39)			
N	225	106	331
Mean (SD)	1.3 (3.4)	1.4 (4.4)	1.3 (3.8)
Median	1.2	1.2	1.2
Min ; Max	-12.2 ; 14.5	-12.7 ; 13.3	-12.7 ; 14.5
Visit 44 (Week 53)			
N	224	99	323
Mean (SD)	1.3 (3.7)	1.4 (3.9)	1.3 (3.7)
Median	1.3	1.6	1.3
Min ; Max	-11.7 ; 15.1	-10.4 ; 13.5	-11.7 ; 15.1
Visit 44 (Week 53) (LOCF)			
N	318	153	471
Mean (SD)	1.1 (3.9)	1.1 (4.2)	1.1 (4.0)
Median	1.1	1.0	1.1
Min ; Max	-11.7 ; 15.1	-11.3 ; 15.2	-11.7 ; 15.2

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:48:57 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
(mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Lunch (mmol/L)			
Visit 2 (Week 0)			
N	340	172	512
Mean (SD)	1.3 (4.5)	1.7 (5.4)	1.4 (4.8)
Median	1.5	1.4	1.4
Min ; Max	-18.4 ; 17.3	-14.5 ; 16.5	-18.4 ; 17.3
Visit 14 (Week 12)			
N	295	150	445
Mean (SD)	0.8 (3.9)	0.2 (3.8)	0.6 (3.9)
Median	0.8	0.3	0.6
Min ; Max	-16.9 ; 15.3	-14.4 ; 11.4	-16.9 ; 15.3
Visit 18 (Week 16)			
N	297	142	439
Mean (SD)	0.7 (4.0)	1.0 (3.9)	0.8 (3.9)
Median	0.6	0.9	0.7
Min ; Max	-19.9 ; 17.3	-9.7 ; 13.7	-19.9 ; 17.3
Visit 28 (Week 26)			
N	284	144	428
Mean (SD)	0.8 (3.5)	0.4 (4.2)	0.7 (3.7)
Median	0.7	0.6	0.6
Min ; Max	-12.2 ; 13.2	-10.3 ; 12.2	-12.2 ; 13.2
Visit 37 (Week 39)			
N	226	110	336
Mean (SD)	1.0 (3.4)	1.3 (3.9)	1.1 (3.6)
Median	0.9	0.8	0.9
Min ; Max	-12.2 ; 11.2	-6.7 ; 16.9	-12.2 ; 16.9
Visit 44 (Week 53)			
N	219	101	320
Mean (SD)	1.0 (3.7)	0.7 (2.7)	0.9 (3.4)
Median	1.2	0.5	0.9
Min ; Max	-10.0 ; 15.4	-6.6 ; 6.7	-10.0 ; 15.4
Visit 44 (Week 53) (LOCF)			
N	309	160	469
Mean (SD)	1.1 (3.8)	0.4 (3.8)	0.8 (3.8)
Median	1.2	0.5	0.9
Min ; Max	-12.2 ; 15.4	-14.5 ; 9.5	-14.5 ; 15.4

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:48:57 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
(mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Main Evening Meal (mmol/L)			
Visit 2 (Week 0)			
N	334	174	508
Mean (SD)	0.6 (4.7)	0.5 (5.0)	0.6 (4.8)
Median	0.6	0.4	0.5
Min ; Max	-14.0 ; 19.0	-13.7 ; 13.4	-14.0 ; 19.0
Visit 14 (Week 12)			
N	287	145	432
Mean (SD)	0.7 (4.0)	0.7 (4.0)	0.7 (4.0)
Median	0.7	0.6	0.7
Min ; Max	-11.3 ; 19.9	-10.6 ; 13.0	-11.3 ; 19.9
Visit 18 (Week 16)			
N	293	139	432
Mean (SD)	0.4 (3.9)	0.3 (4.6)	0.4 (4.2)
Median	0.7	0.5	0.6
Min ; Max	-17.0 ; 12.1	-12.1 ; 18.6	-17.0 ; 18.6
Visit 28 (Week 26)			
N	289	140	429
Mean (SD)	0.6 (3.8)	0.6 (4.2)	0.6 (3.9)
Median	0.6	0.7	0.6
Min ; Max	-13.3 ; 12.6	-13.6 ; 13.0	-13.6 ; 13.0
Visit 37 (Week 39)			
N	221	105	326
Mean (SD)	0.8 (3.6)	0.1 (4.1)	0.6 (3.8)
Median	0.7	0.4	0.6
Min ; Max	-12.3 ; 18.3	-16.5 ; 11.0	-16.5 ; 18.3
Visit 44 (Week 53)			
N	219	101	320
Mean (SD)	1.1 (3.5)	0.4 (3.6)	0.9 (3.5)
Median	0.8	0.5	0.7
Min ; Max	-11.1 ; 19.0	-11.8 ; 8.1	-11.8 ; 19.0
Visit 44 (Week 53) (LOCF)			
N	317	155	472
Mean (SD)	1.0 (3.7)	0.3 (4.0)	0.8 (3.8)
Median	0.8	0.5	0.7
Min ; Max	-11.1 ; 19.0	-13.6 ; 13.4	-13.6 ; 19.0

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:48:57 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_prand_inc_descp_fas.txt

14.2.116: Prandial Increment by Treatment Week – Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
All Meals, Change (mmol/L)			
Visit 14 (Week 12)			
N	293	152	445
Mean (SD)	-0.1 (3.7)	-0.5 (3.6)	-0.2 (3.7)
Median	0.1	-0.7	-0.2
Min ; Max	-13.3 ; 11.7	-9.5 ; 11.0	-13.3 ; 11.7
Visit 18 (Week 16)			
N	299	151	450
Mean (SD)	-0.2 (3.5)	-0.3 (3.6)	-0.2 (3.6)
Median	-0.1	-0.4	-0.2
Min ; Max	-12.6 ; 11.7	-11.8 ; 13.5	-12.6 ; 13.5
Visit 28 (Week 26)			
N	288	150	438
Mean (SD)	0.1 (3.6)	-0.4 (4.1)	-0.1 (3.8)
Median	0.0	0.1	0.0
Min ; Max	-13.1 ; 14.8	-11.9 ; 9.5	-13.1 ; 14.8
Visit 37 (Week 39)			
N	223	113	336
Mean (SD)	0.2 (3.5)	-0.2 (3.7)	0.1 (3.6)
Median	0.2	0.0	0.1
Min ; Max	-13.6 ; 8.7	-8.7 ; 11.7	-13.6 ; 11.7
Visit 44 (Week 53)			
N	217	104	321
Mean (SD)	0.3 (3.8)	-0.3 (3.3)	0.1 (3.6)
Median	0.2	-0.2	-0.1
Min ; Max	-17.6 ; 10.8	-10.7 ; 8.5	-17.6 ; 10.8
Visit 44 (Week 53) (LOCF)			
N	315	164	479
Mean (SD)	0.2 (3.7)	-0.5 (3.8)	-0.1 (3.7)
Median	0.0	-0.2	0.0
Min ; Max	-17.6 ; 10.8	-11.9 ; 13.5	-17.6 ; 13.5

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:49:07 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Breakfast, Change (mmol/L)			
Visit 14 (Week 12)			
N	275	143	418
Mean (SD)	-0.2 (5.9)	-0.3 (6.3)	-0.2 (6.0)
Median	-0.3	0.0	-0.3
Min ; Max	-19.1 ; 20.2	-18.6 ; 16.9	-19.1 ; 20.2
Visit 18 (Week 16)			
N	280	140	420
Mean (SD)	0.0 (6.2)	-0.3 (6.3)	-0.1 (6.2)
Median	0.0	-0.4	-0.1
Min ; Max	-20.2 ; 15.9	-20.2 ; 19.5	-20.2 ; 19.5
Visit 28 (Week 26)			
N	272	141	413
Mean (SD)	0.0 (5.8)	0.3 (6.2)	0.1 (5.9)
Median	-0.4	0.3	-0.2
Min ; Max	-17.3 ; 19.8	-19.4 ; 16.6	-19.4 ; 19.8
Visit 37 (Week 39)			
N	212	104	316
Mean (SD)	0.5 (5.4)	0.4 (6.5)	0.5 (5.8)
Median	0.3	0.4	0.3
Min ; Max	-12.9 ; 16.1	-17.8 ; 14.8	-17.8 ; 16.1
Visit 44 (Week 53)			
N	211	97	308
Mean (SD)	0.3 (5.7)	0.3 (6.0)	0.3 (5.8)
Median	-0.1	0.4	0.1
Min ; Max	-13.3 ; 18.6	-14.4 ; 16.1	-14.4 ; 18.6
Visit 44 (Week 53) (LOCF)			
N	300	150	450
Mean (SD)	-0.0 (5.7)	-0.3 (6.1)	-0.1 (5.8)
Median	-0.0	0.0	0.0
Min ; Max	-17.3 ; 18.6	-17.8 ; 16.1	-17.8 ; 18.6

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:49:07 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Lunch, Change (mmol/L)			
Visit 14 (Week 12)			
N	283	145	428
Mean (SD)	-0.4 (5.6)	-1.6 (6.3)	-0.8 (5.9)
Median	-0.4	-1.1	-0.7
Min ; Max	-16.6 ; 15.6	-24.4 ; 15.4	-24.4 ; 15.6
Visit 18 (Week 16)			
N	283	137	420
Mean (SD)	-0.6 (5.6)	-1.0 (6.0)	-0.7 (5.7)
Median	-0.5	-0.6	-0.5
Min ; Max	-23.1 ; 20.6	-17.4 ; 15.3	-23.1 ; 20.6
Visit 28 (Week 26)			
N	269	139	408
Mean (SD)	-0.4 (5.4)	-1.3 (6.6)	-0.7 (5.8)
Median	-0.6	-1.6	-0.8
Min ; Max	-18.0 ; 16.1	-23.1 ; 17.3	-23.1 ; 17.3
Visit 37 (Week 39)			
N	211	107	318
Mean (SD)	-0.4 (5.3)	-0.2 (6.1)	-0.3 (5.6)
Median	-0.4	0.1	-0.3
Min ; Max	-17.4 ; 13.6	-15.9 ; 20.0	-17.4 ; 20.0
Visit 44 (Week 53)			
N	206	98	304
Mean (SD)	-0.1 (6.0)	-1.0 (4.9)	-0.4 (5.7)
Median	-0.3	-0.1	-0.2
Min ; Max	-21.0 ; 18.8	-19.4 ; 9.3	-21.0 ; 18.8
Visit 44 (Week 53) (LOCF)			
N	293	155	448
Mean (SD)	-0.1 (5.7)	-1.3 (5.4)	-0.6 (5.7)
Median	-0.0	-0.3	-0.2
Min ; Max	-21.0 ; 18.8	-19.4 ; 17.3	-21.0 ; 18.8

N = Number of Subjects, SD = Standard Deviation

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:49:07 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_prand_inc_descp_fas.txt

Prandial Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change (mmol/L)			
Visit 14 (Week 12)			
N	271	142	413
Mean (SD)	0.3 (5.8)	-0.0 (6.2)	0.2 (6.0)
Median	0.2	-0.2	0.2
Min ; Max	-19.7 ; 16.8	-13.3 ; 15.9	-19.7 ; 16.8
Visit 18 (Week 16)			
N	276	136	412
Mean (SD)	-0.1 (5.8)	-0.2 (6.8)	-0.1 (6.1)
Median	0.0	-0.6	-0.2
Min ; Max	-21.2 ; 15.4	-14.9 ; 27.7	-21.2 ; 27.7
Visit 28 (Week 26)			
N	272	137	409
Mean (SD)	0.2 (6.2)	0.2 (6.6)	0.2 (6.3)
Median	0.4	0.0	0.4
Min ; Max	-22.4 ; 18.2	-16.2 ; 20.7	-22.4 ; 20.7
Visit 37 (Week 39)			
N	208	102	310
Mean (SD)	0.3 (5.5)	-0.0 (6.1)	0.2 (5.7)
Median	0.2	0.1	0.2
Min ; Max	-22.7 ; 16.1	-15.8 ; 14.8	-22.7 ; 16.1
Visit 44 (Week 53)			
N	205	100	305
Mean (SD)	0.6 (5.8)	-0.0 (5.8)	0.4 (5.8)
Median	0.8	0.2	0.6
Min ; Max	-20.1 ; 20.9	-16.0 ; 12.9	-20.1 ; 20.9
Visit 44 (Week 53) (LOCF)			
N	298	153	451
Mean (SD)	0.6 (5.7)	-0.2 (5.9)	0.3 (5.8)
Median	0.5	0.0	0.3
Min ; Max	-20.1 ; 20.9	-16.2 ; 18.3	-20.1 ; 20.9

N = Number of Subjects, SD = Standard Deviation
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal

All Meals: Mean of all increments

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:49:07 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_prand_inc_descp_fas.txt

14.2.117: Prandial Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
All Meals (mmol/L)					
LSMeans					
IDegAsp OD	366	315	1.03	0.24	
IDet	182	164	0.40	0.28	
Treatment Contrast					
IDegAsp OD - IDet			0.64		[0.14 ; 1.14]
Breakfast (mmol/L)					
LSMeans					
IDegAsp OD	366	300	0.98	0.37	
IDet	182	150	0.96	0.44	
Treatment Contrast					
IDegAsp OD - IDet			0.02		[-0.74 ; 0.78]
Lunch (mmol/L)					
LSMeans					
IDegAsp OD	366	293	1.04	0.36	
IDet	182	155	0.05	0.42	
Treatment Contrast					
IDegAsp OD - IDet			0.98		[0.25 ; 1.72]
Main Evening Meal (mmol/L)					
LSMeans					
IDegAsp OD	366	298	0.80	0.36	
IDet	182	153	0.01	0.42	
Treatment Contrast					
IDegAsp OD - IDet			0.80		[0.06 ; 1.54]

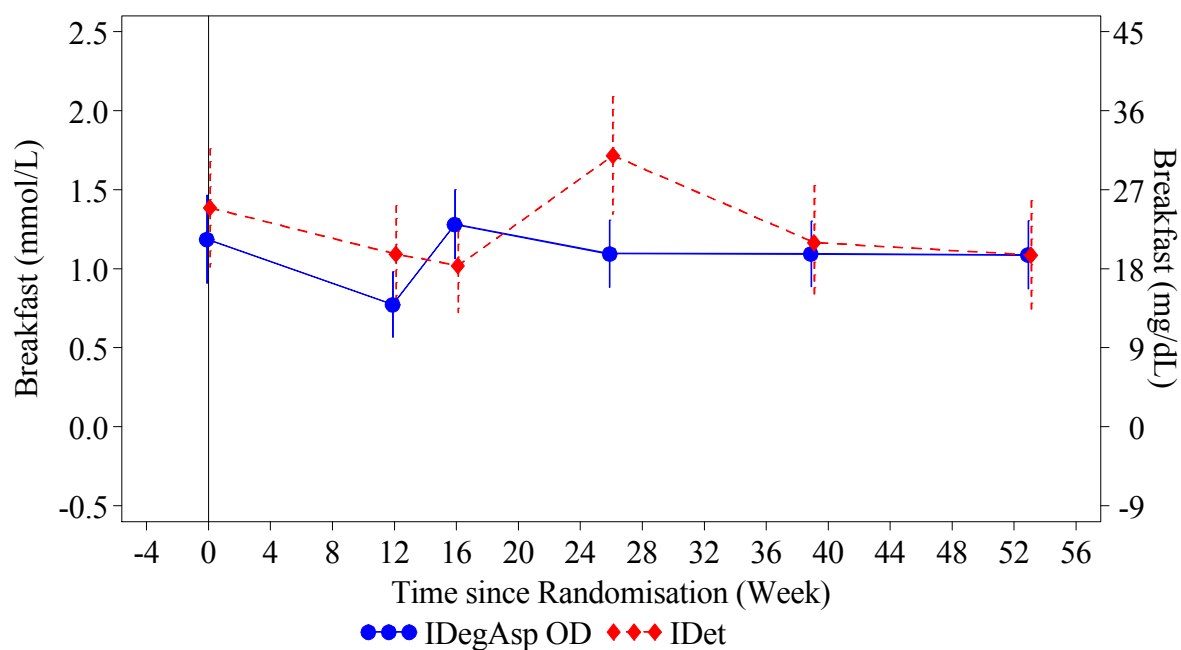
N = Number of subjects contributing to analysis, CI = Confidence Interval, SE = Standard Error of the Mean

The response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

Prandial increment is the difference between SMPG values after meal (90 min.) and before meal. All Meals: Mean of all increments

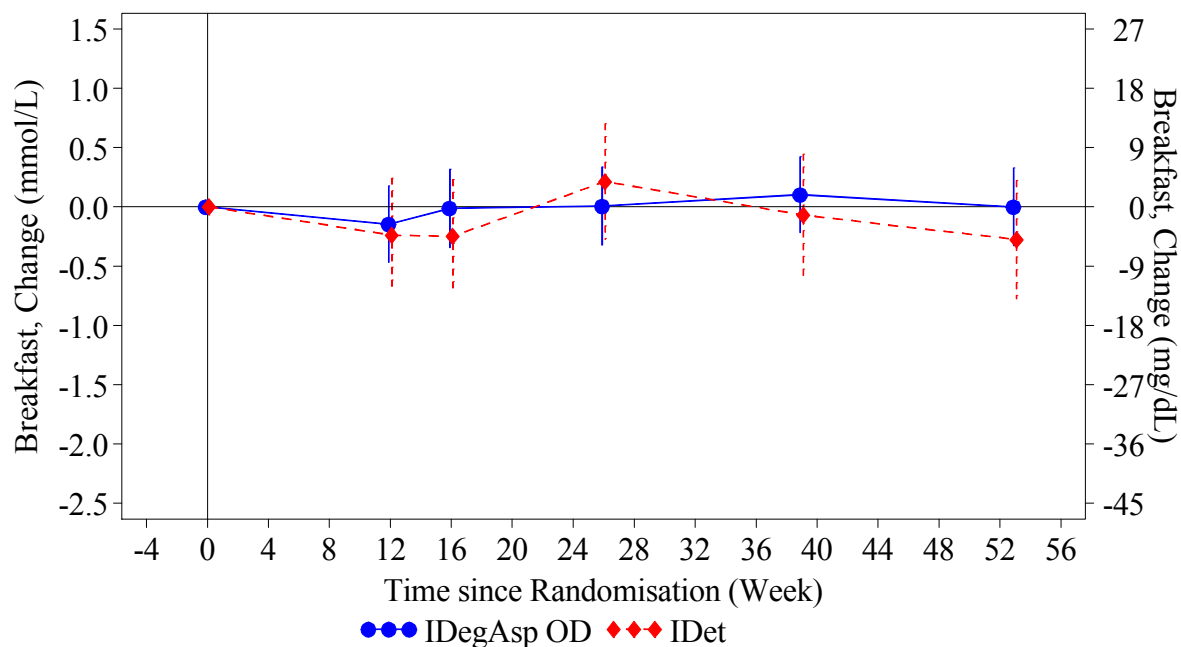
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:49:16 - tstat_find_tpl_t022.sas/t_9pp_prand_inc_stat_locf_fas.txt



FAS; LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:49:25 - fmean_numfind_v03.sas/e_9pp_abs_bf_inc_mean_locf_fas.cgm

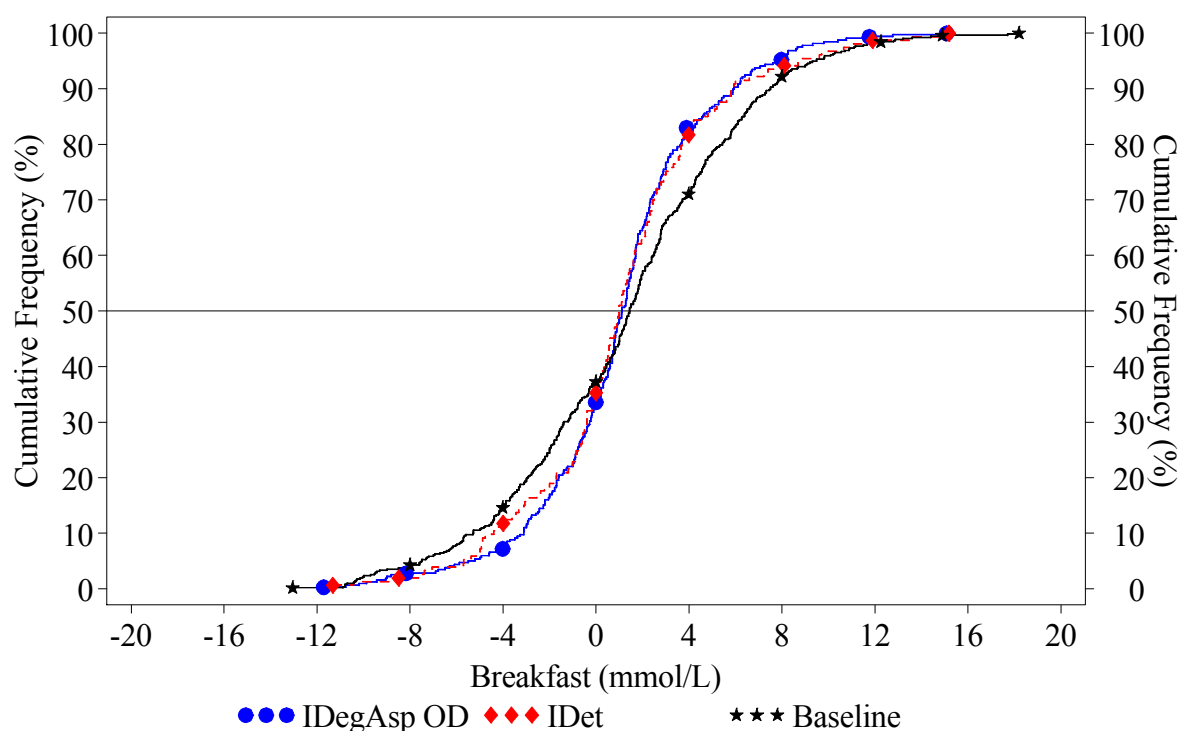
14.2.118: Breakfast Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set



EAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:49:33 - fmean_numfind_v03.sas/e_9pp_chb_bf_inc_mean_locf_fas.cgm

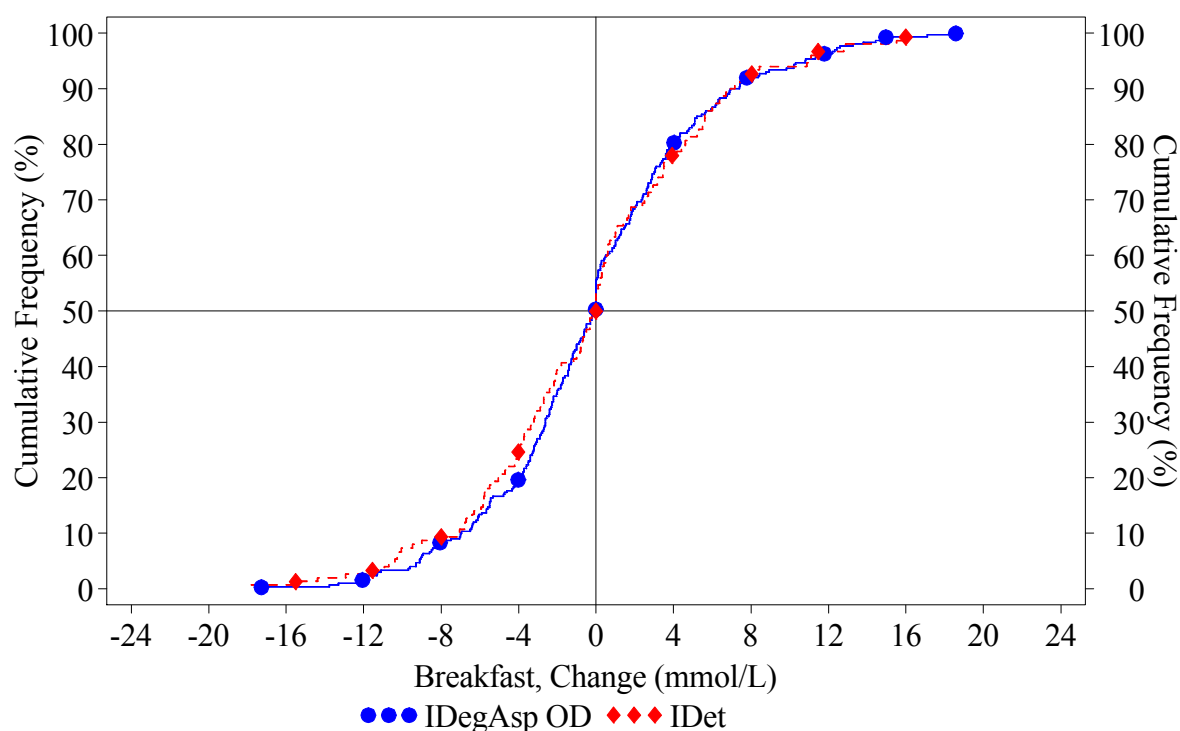
14.2.119: Breakfast Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:49:49 - fedist_numfind_v01.sas/e_9pp_abs_bf_inc_cdf_locf_fas.cgm

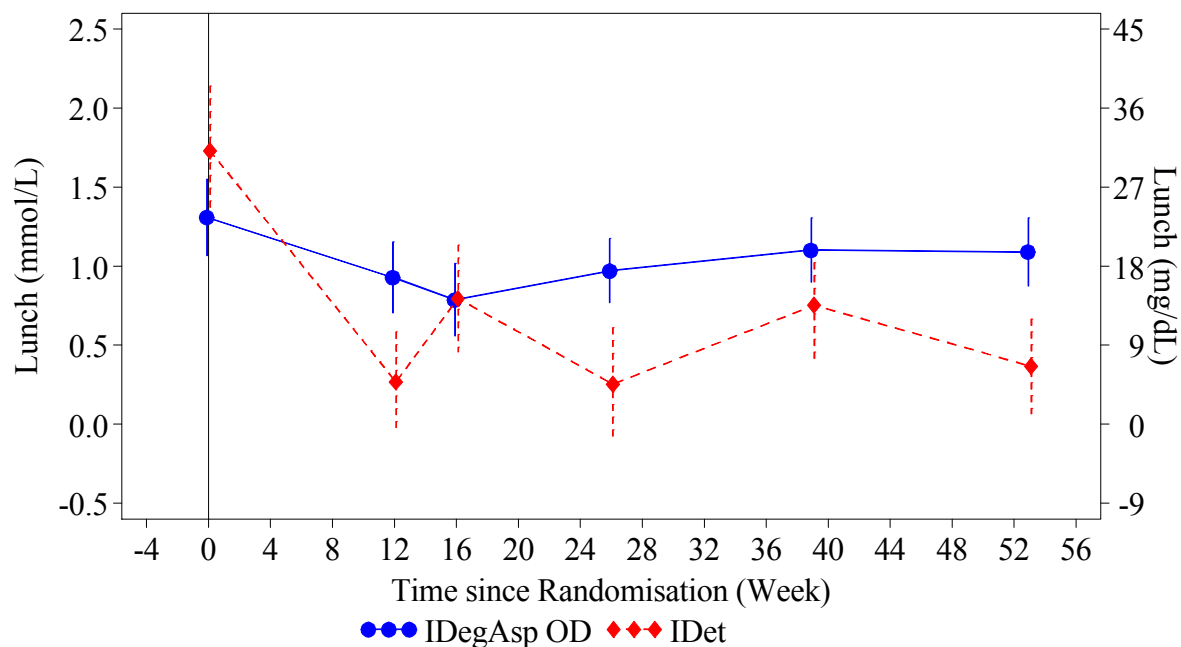
14.2.120: Breakfast Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:49:57 - fedist_numfind_v01.sas/e_9pp_chb_bf_inc_cdf_locf_fas.cgm

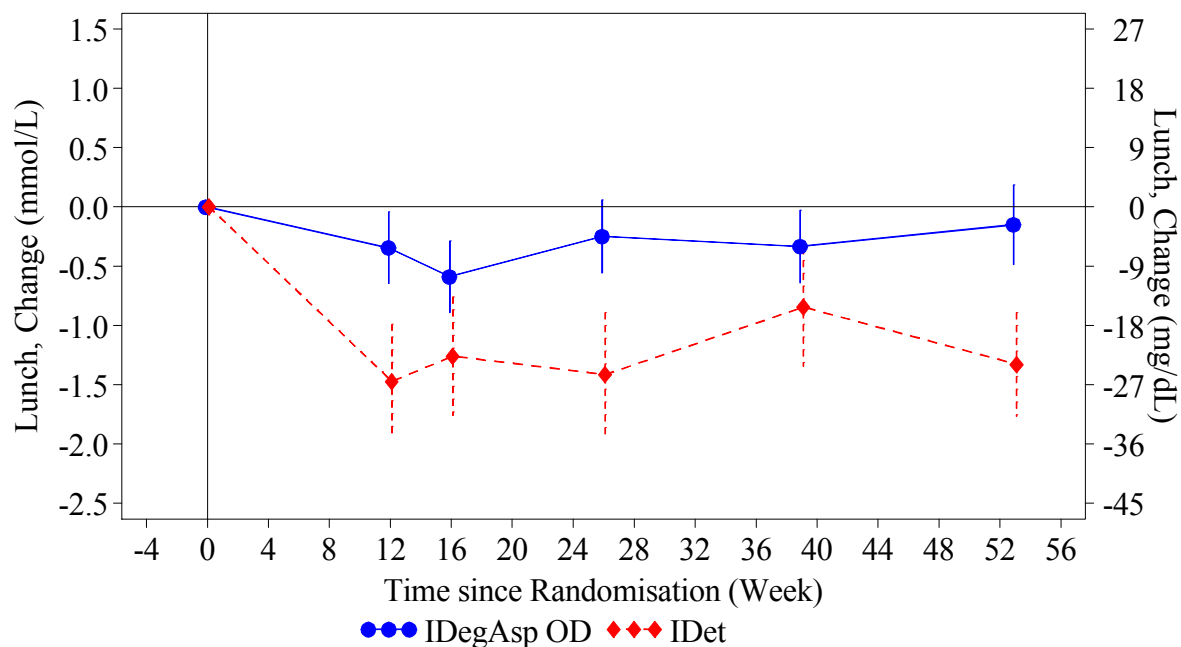
14.2.121: Breakfast Increment after 52 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



EAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:50:06 - fmean_numfind_v03.sas/e_9pp_abs_l_inc_mean_locf_fas.cgm

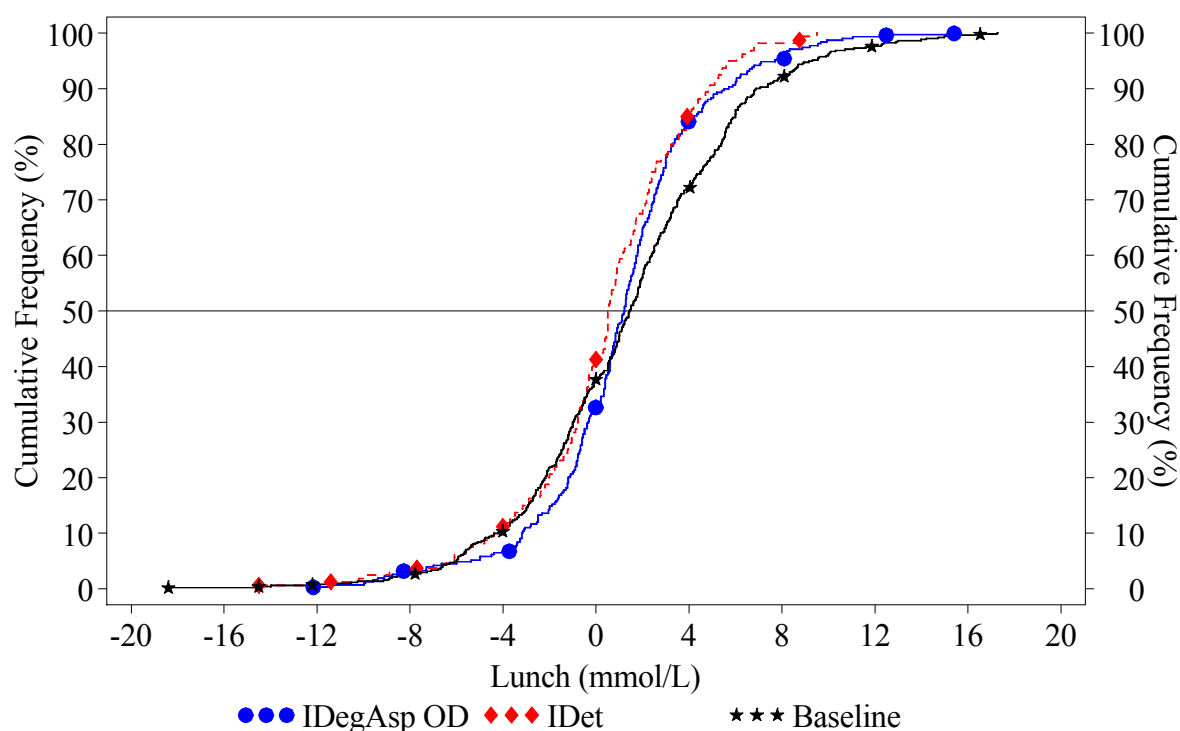
14.2.122: Lunch Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



EAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:50:15 - fmean_numfind_v03.sas/e_9pp_chb_l_inc_mean_locf_fas.cgm

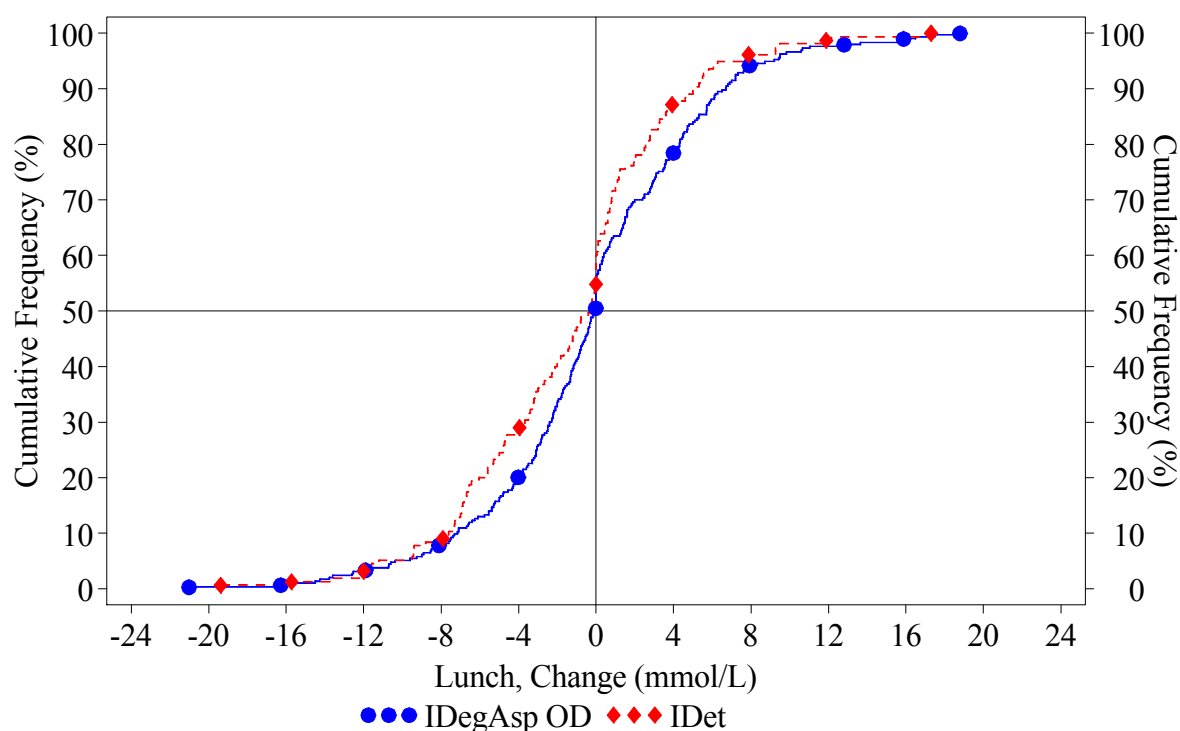
14.2.123: Lunch Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:50:30 - fedist_numfind_v01.sas/e_9pp_abs_l_inc_cdf_locf_fas.cgm

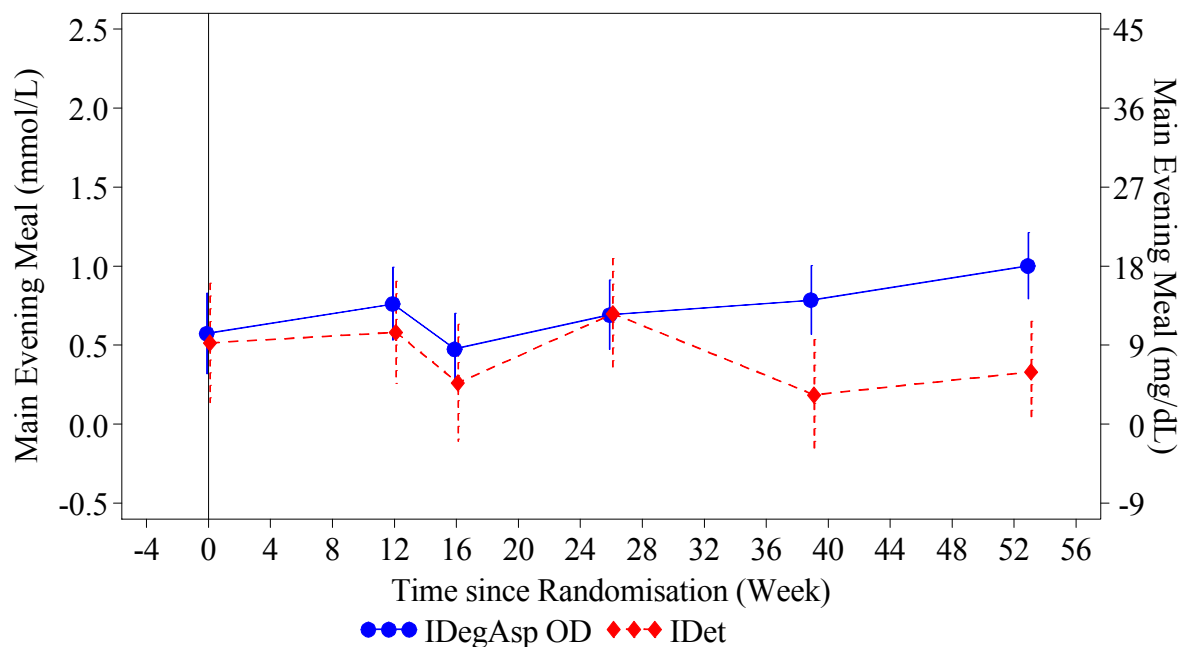
14.2.124: Lunch Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:50:39 - fedist_numfind_v01.sas/e_9pp_chb_l_inc_cdf_locf_fas.cgm

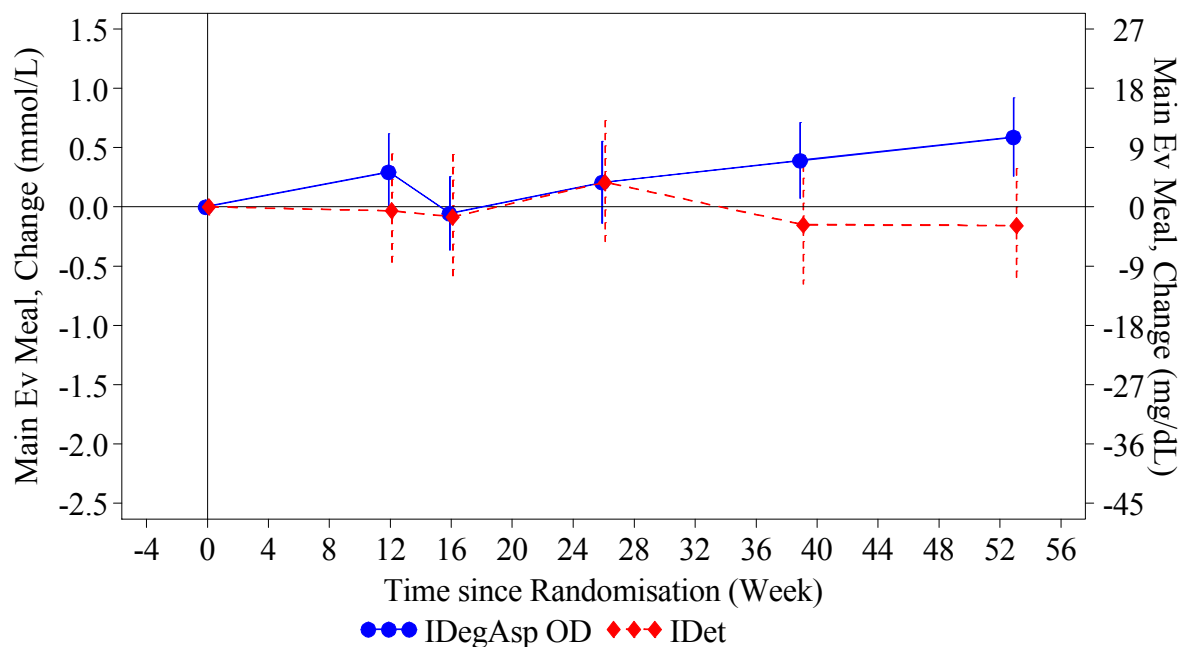
14.2.125: Lunch Increment after 52 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS: LOCF imputed data
 Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:50:47 - fmean_numfind_v03.sas/e_9pp_abs_ev_inc_mean_locf_fas.cgm

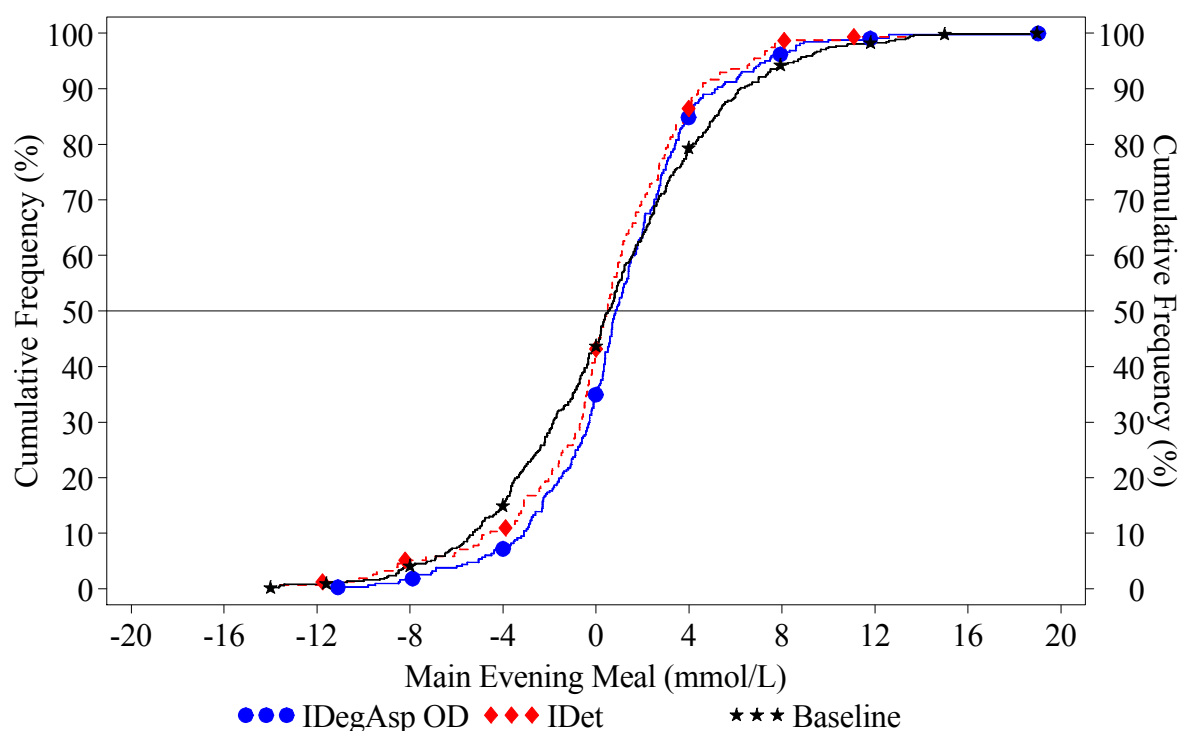
14.2.126: Main Evening Meal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set



FAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:50:56 - fmean_numfind_v03.sas/e_9pp_chb_ev_inc_mean_locf_fas.cgm

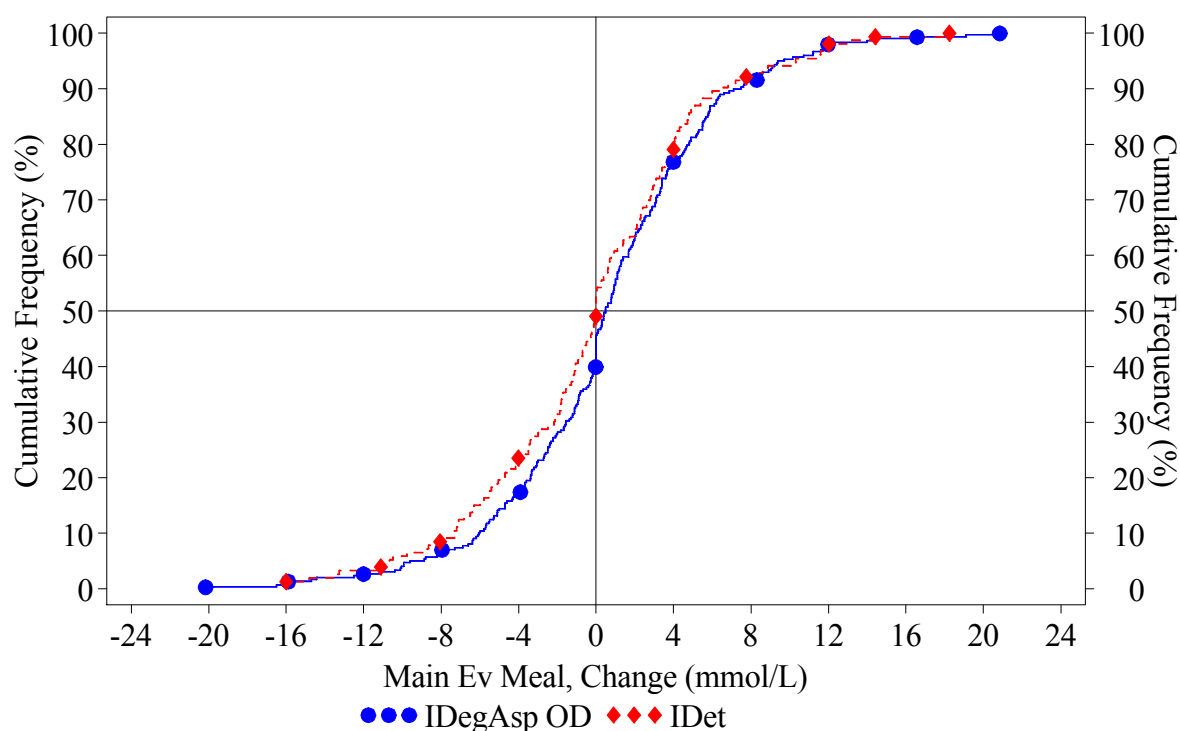
14.2.127: Main Evening Meal Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:51:11 - fedist_numfind_v01.sas/e_9pp_abs_ev_inc_cdf_locf_fas.cgm

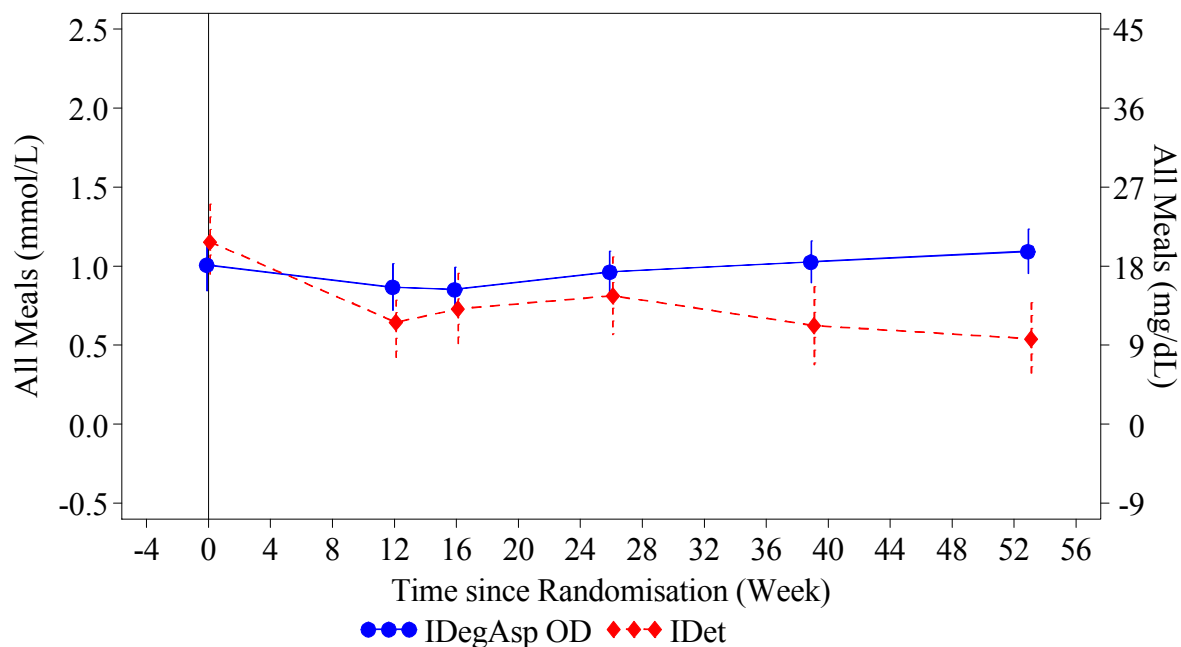
14.2.128: Main Evening Meal Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:51:20 - fedist_numfind_v01.sas/e_9pp_chb_ev_inc_cdf_locf_fas.cgm

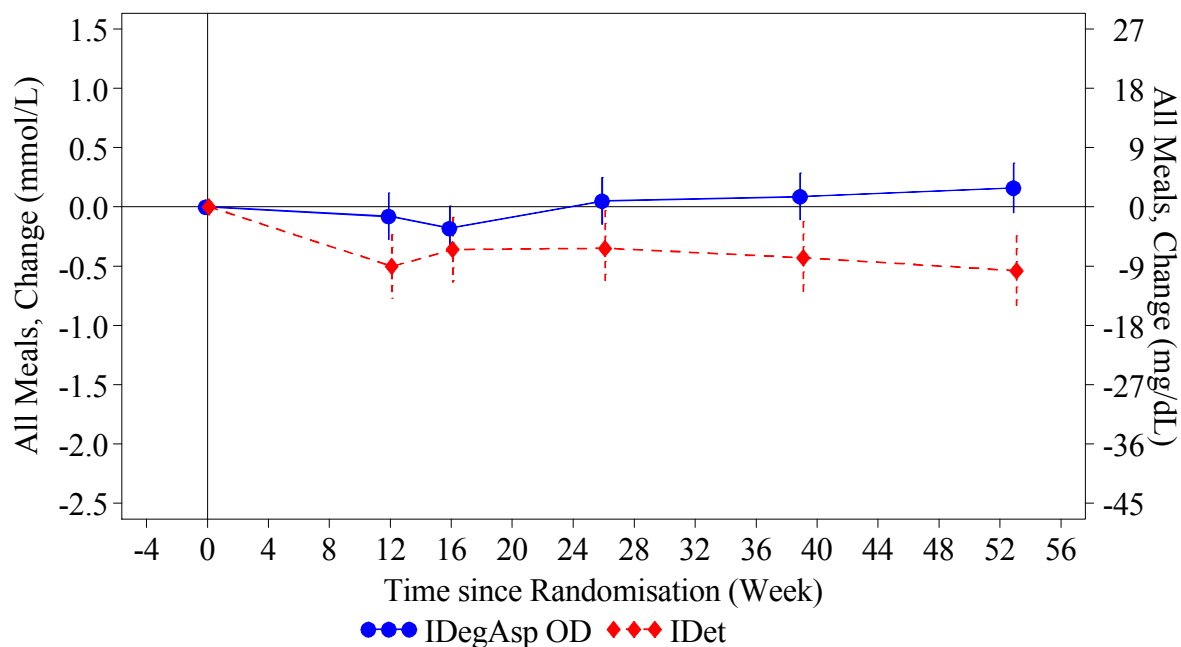
14.2.129: Main Evening Meal Increment after 52 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:51:29 - fmean_numfind_v03.sas/e_9pp_abs_pran_ic_mean_locf_fas.cgm

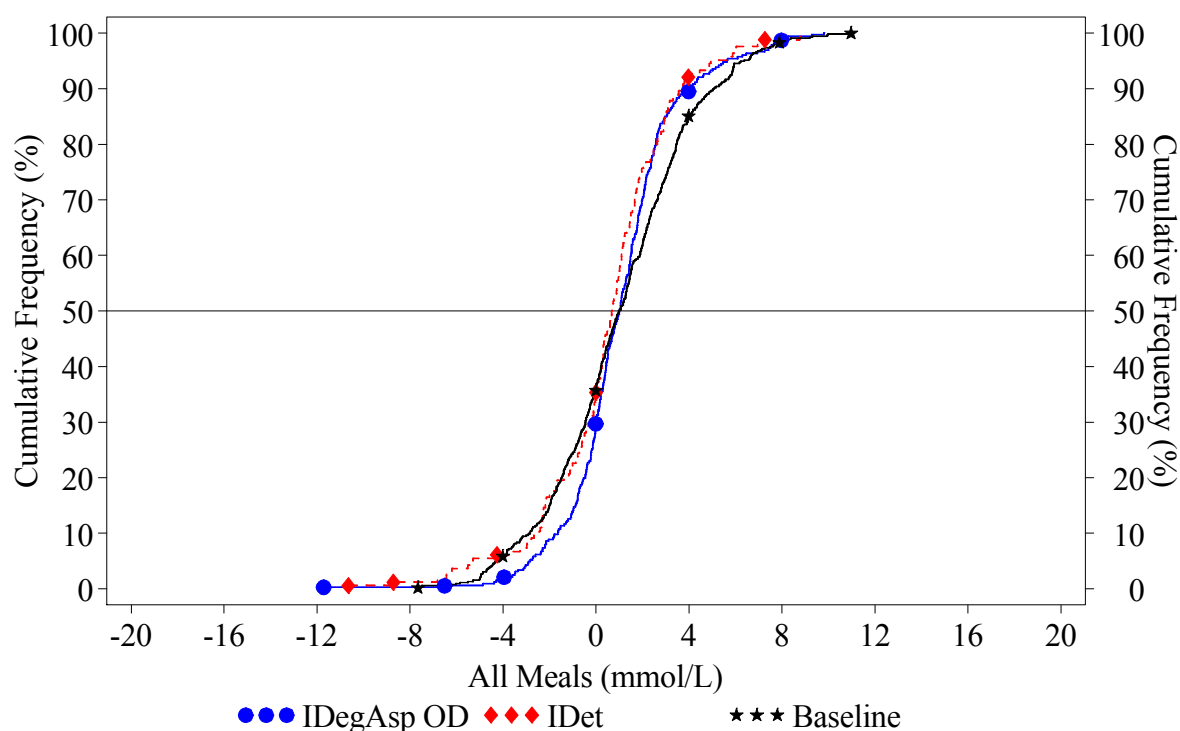
14.2.130: All Meals Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L)– Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:51:37 - fmean_numfind_v03.sas/e_9pp_chb_pran_ic_mean_locf_fas.cgm

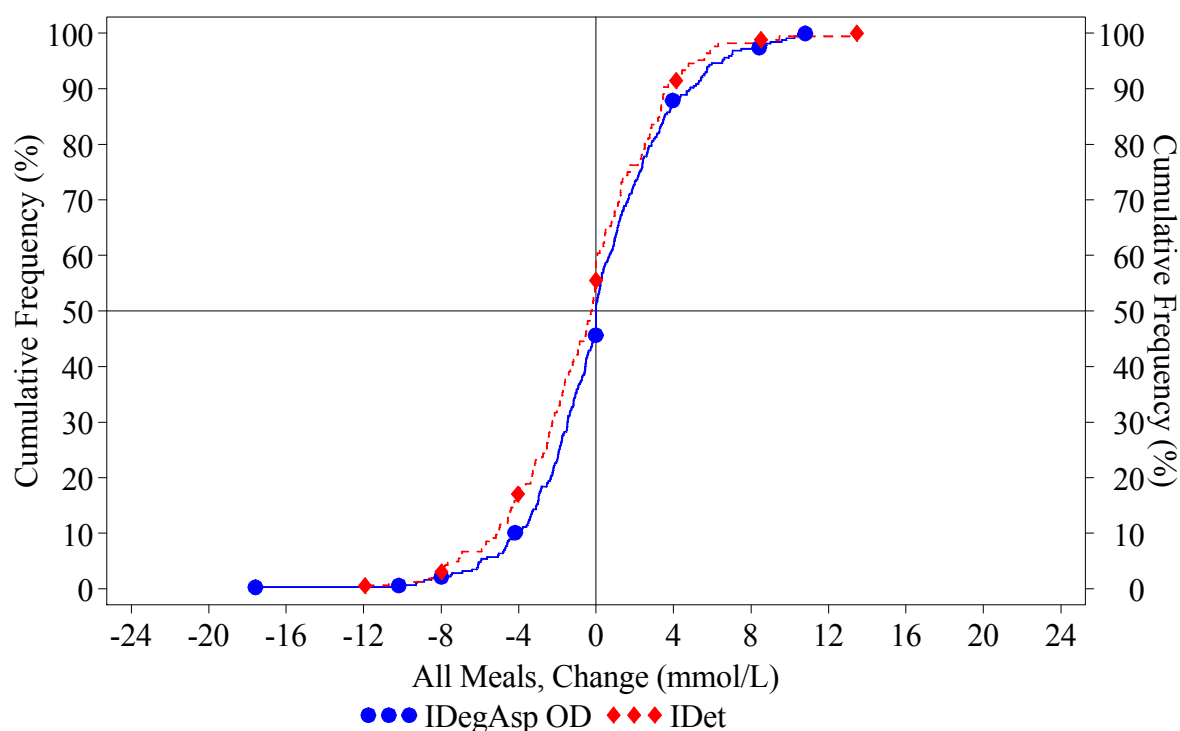
14.2.131: All Meals Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L)- Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:51:53 - fedist_numfind_v01.sas/e_9pp_abs_prand_inc_cdf_locf_fas.cgm

14.2.132: All Meals Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:52:01 - fedist_numfind_v01.sas/e_9pp_chb_prand_inc_cdf_locf_fas.cgm

14.2.133: All Meals Increment after 52 Weeks of Treatment - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set

14.2.134: Nocturnal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile (mmol/L) – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Bedtime to 04:00 (mmol/L)			
Visit 2 (Week 0)			
N	326	161	487
Mean (SD)	-0.9 (5.5)	-0.3 (6.1)	-0.7 (5.7)
Median	-0.8	-0.6	-0.8
Min ; Max	-19.1 ; 19.7	-14.7 ; 25.6	-19.1 ; 25.6
Visit 14 (Week 12)			
N	238	130	368
Mean (SD)	-1.0 (4.2)	-0.3 (4.7)	-0.8 (4.4)
Median	-0.5	-0.6	-0.6
Min ; Max	-19.0 ; 17.5	-13.8 ; 17.4	-19.0 ; 17.5
Visit 18 (Week 16)			
N	260	129	389
Mean (SD)	-0.6 (3.9)	-0.9 (5.0)	-0.7 (4.3)
Median	-0.6	-0.5	-0.6
Min ; Max	-15.8 ; 12.7	-17.0 ; 14.1	-17.0 ; 14.1
Visit 28 (Week 26)			
N	250	128	378
Mean (SD)	-0.9 (3.4)	-0.6 (4.5)	-0.8 (3.8)
Median	-0.9	-1.1	-1.0
Min ; Max	-13.8 ; 11.5	-13.3 ; 12.7	-13.8 ; 12.7
Visit 37 (Week 39)			
N	210	101	311
Mean (SD)	-1.0 (3.4)	-1.0 (4.1)	-1.0 (3.6)
Median	-0.7	-1.1	-0.8
Min ; Max	-14.1 ; 12.9	-14.7 ; 11.4	-14.7 ; 12.9
Visit 44 (Week 53)			
N	207	96	303
Mean (SD)	-1.0 (3.2)	-0.4 (3.4)	-0.8 (3.3)
Median	-0.9	-0.7	-0.8
Min ; Max	-9.9 ; 14.7	-12.6 ; 8.5	-12.6 ; 14.7
Visit 44 (Week 53) (LOCF)			
N	285	141	426
Mean (SD)	-0.9 (3.5)	-0.7 (3.8)	-0.8 (3.6)
Median	-0.9	-0.7	-0.8
Min ; Max	-15.4 ; 14.7	-12.6 ; 12.7	-15.4 ; 14.7

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:52:10 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_noct_inc_descp_fas.txt

Nocturnal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
(mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
04:00 to Breakfast (mmol/L)			
Visit 2 (Week 0)			
N	334	168	502
Mean (SD)	0.1 (4.5)	0.6 (4.0)	0.3 (4.3)
Median	0.0	0.3	0.1
Min ; Max	-14.9 ; 18.8	-16.4 ; 12.2	-16.4 ; 18.8
Visit 14 (Week 12)			
N	238	129	367
Mean (SD)	-0.4 (3.1)	-0.7 (4.5)	-0.5 (3.6)
Median	-0.3	-0.4	-0.3
Min ; Max	-11.7 ; 10.9	-17.9 ; 17.1	-17.9 ; 17.1
Visit 18 (Week 16)			
N	259	131	390
Mean (SD)	-0.7 (3.3)	-0.4 (4.0)	-0.6 (3.6)
Median	-0.4	-0.4	-0.4
Min ; Max	-13.2 ; 12.8	-15.4 ; 10.3	-15.4 ; 12.8
Visit 28 (Week 26)			
N	253	128	381
Mean (SD)	-0.7 (2.9)	0.1 (3.9)	-0.5 (3.2)
Median	-0.6	-0.1	-0.5
Min ; Max	-12.3 ; 9.1	-15.9 ; 11.3	-15.9 ; 11.3
Visit 37 (Week 39)			
N	214	104	318
Mean (SD)	-0.3 (2.8)	-0.0 (4.2)	-0.2 (3.3)
Median	-0.3	-0.3	-0.3
Min ; Max	-9.5 ; 8.9	-12.0 ; 17.8	-12.0 ; 17.8
Visit 44 (Week 53)			
N	206	96	302
Mean (SD)	-0.4 (2.8)	-0.8 (2.9)	-0.5 (2.8)
Median	-0.4	-0.5	-0.4
Min ; Max	-11.4 ; 13.9	-7.2 ; 10.7	-11.4 ; 13.9
Visit 44 (Week 53) (LOCF)			
N	285	145	430
Mean (SD)	-0.5 (3.0)	-0.3 (3.5)	-0.4 (3.2)
Median	-0.4	-0.3	-0.4
Min ; Max	-12.0 ; 13.9	-8.2 ; 17.8	-12.0 ; 17.8

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:52:10 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_noct_inc_descp_fas.txt

Nocturnal Increment by Treatment Week - 9-point Self Measured Plasma Glucose Profile
(mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Bedtime to Breakfast (mmol/L)			
Visit 2 (Week 0)			
N	337	168	505
Mean (SD)	-0.7 (6.1)	0.1 (6.4)	-0.4 (6.2)
Median	-0.3	-0.2	-0.3
Min ; Max	-18.0 ; 16.4	-15.5 ; 17.2	-18.0 ; 17.2
Visit 14 (Week 12)			
N	280	151	431
Mean (SD)	-1.3 (4.6)	-1.3 (4.9)	-1.3 (4.7)
Median	-1.0	-1.1	-1.1
Min ; Max	-22.9 ; 12.5	-14.2 ; 17.0	-22.9 ; 17.0
Visit 18 (Week 16)			
N	303	155	458
Mean (SD)	-1.2 (4.1)	-1.4 (5.0)	-1.3 (4.4)
Median	-1.1	-0.9	-1.0
Min ; Max	-13.8 ; 18.0	-18.8 ; 14.2	-18.8 ; 18.0
Visit 28 (Week 26)			
N	308	154	462
Mean (SD)	-1.5 (4.0)	-0.3 (4.8)	-1.1 (4.3)
Median	-1.2	-0.2	-0.8
Min ; Max	-15.0 ; 13.6	-15.5 ; 17.8	-15.5 ; 17.8
Visit 37 (Week 39)			
N	228	113	341
Mean (SD)	-1.2 (3.6)	-1.1 (4.6)	-1.2 (4.0)
Median	-0.9	-0.8	-0.8
Min ; Max	-14.2 ; 11.7	-13.6 ; 13.6	-14.2 ; 13.6
Visit 44 (Week 53)			
N	228	109	337
Mean (SD)	-1.4 (3.4)	-1.2 (3.1)	-1.3 (3.3)
Median	-1.1	-0.9	-1.0
Min ; Max	-12.2 ; 11.5	-9.5 ; 10.2	-12.2 ; 11.5
Visit 44 (Week 53) (LOCF)			
N	339	168	507
Mean (SD)	-1.4 (4.0)	-0.9 (4.2)	-1.2 (4.1)
Median	-1.1	-0.8	-1.0
Min ; Max	-18.0 ; 11.9	-13.7 ; 17.8	-18.0 ; 17.8

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:52:10 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_abs_noct_inc_descp_fas.txt

14.2.135: Nocturnal Increment by Treatment Week – Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Bedtime to 04:00, Ch(mmol/L)			
Visit 14 (Week 12)			
N	224	120	344
Mean (SD)	-0.3 (6.9)	0.3 (7.3)	-0.1 (7.1)
Median	-0.2	0.3	-0.2
Min ; Max	-25.5 ; 34.8	-25.2 ; 27.5	-25.5 ; 34.8
Visit 18 (Week 16)			
N	242	121	363
Mean (SD)	0.3 (6.0)	-1.0 (7.8)	-0.1 (6.7)
Median	0.4	-0.1	0.2
Min ; Max	-17.3 ; 20.0	-23.9 ; 22.8	-23.9 ; 22.8
Visit 28 (Week 26)			
N	236	119	355
Mean (SD)	-0.2 (6.1)	-0.0 (7.2)	-0.1 (6.5)
Median	-0.0	-0.2	-0.1
Min ; Max	-18.1 ; 20.3	-23.6 ; 20.2	-23.6 ; 20.3
Visit 37 (Week 39)			
N	195	94	289
Mean (SD)	-0.1 (5.9)	-0.3 (7.5)	-0.1 (6.5)
Median	0.2	-0.4	0.1
Min ; Max	-18.3 ; 19.1	-21.6 ; 16.6	-21.6 ; 19.1
Visit 44 (Week 53)			
N	192	89	281
Mean (SD)	-0.0 (5.9)	0.5 (6.0)	0.2 (5.9)
Median	0.3	0.6	0.4
Min ; Max	-16.7 ; 18.3	-15.1 ; 13.7	-16.7 ; 18.3
Visit 44 (Week 53) (LOCF)			
N	268	132	400
Mean (SD)	-0.0 (5.8)	0.1 (6.8)	-0.0 (6.1)
Median	0.0	0.0	0.0
Min ; Max	-16.8 ; 18.3	-23.6 ; 13.7	-23.6 ; 18.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:52:20 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_noct_inc_descp_fas.txt

Nocturnal Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
04:00 to Brkf, Ch (mmol/L)			
Visit 14 (Week 12)			
N	224	122	346
Mean (SD)	-0.5 (4.9)	-1.3 (5.1)	-0.8 (5.0)
Median	-0.5	-1.5	-0.9
Min ; Max	-13.6 ; 14.2	-15.2 ; 15.6	-15.2 ; 15.6
Visit 18 (Week 16)			
N	243	125	368
Mean (SD)	-0.8 (4.9)	-1.1 (5.0)	-0.9 (4.9)
Median	-0.8	-0.9	-0.9
Min ; Max	-18.6 ; 16.4	-16.1 ; 15.9	-18.6 ; 16.4
Visit 28 (Week 26)			
N	237	121	358
Mean (SD)	-0.8 (4.7)	-0.3 (5.3)	-0.6 (4.9)
Median	-0.6	-0.8	-0.7
Min ; Max	-14.8 ; 15.0	-16.6 ; 17.5	-16.6 ; 17.5
Visit 37 (Week 39)			
N	199	99	298
Mean (SD)	-0.4 (4.6)	-0.8 (5.3)	-0.5 (4.8)
Median	-0.4	-0.4	-0.4
Min ; Max	-16.7 ; 15.1	-13.8 ; 18.4	-16.7 ; 18.4
Visit 44 (Week 53)			
N	193	91	284
Mean (SD)	-0.5 (4.6)	-1.7 (4.2)	-0.9 (4.5)
Median	-0.7	-0.7	-0.7
Min ; Max	-18.4 ; 15.3	-11.6 ; 5.7	-18.4 ; 15.3
Visit 44 (Week 53) (LOCF)			
N	267	138	405
Mean (SD)	-0.5 (4.5)	-0.9 (4.6)	-0.6 (4.5)
Median	-0.4	-0.2	-0.4
Min ; Max	-18.4 ; 15.3	-11.6 ; 18.4	-18.4 ; 18.4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:52:20 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_noct_inc_descp_fas.txt

Nocturnal Increment by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Bedtime to Brkf, Ch (mmol/L)			
Visit 14 (Week 12)			
N	262	144	406
Mean (SD)	-0.5 (7.5)	-1.2 (7.6)	-0.8 (7.5)
Median	-0.6	-1.8	-1.1
Min ; Max	-34.0 ; 22.4	-20.8 ; 21.2	-34.0 ; 22.4
Visit 18 (Week 16)			
N	281	147	428
Mean (SD)	-0.6 (6.8)	-1.6 (8.1)	-0.9 (7.3)
Median	-0.9	-2.0	-1.1
Min ; Max	-19.8 ; 21.2	-28.6 ; 19.5	-28.6 ; 21.2
Visit 28 (Week 26)			
N	286	144	430
Mean (SD)	-0.9 (6.7)	-0.5 (6.6)	-0.7 (6.7)
Median	-0.7	-0.7	-0.7
Min ; Max	-26.3 ; 19.7	-22.5 ; 20.0	-26.3 ; 20.0
Visit 37 (Week 39)			
N	216	107	323
Mean (SD)	-0.4 (6.4)	-1.1 (8.1)	-0.6 (7.0)
Median	-0.9	-0.7	-0.9
Min ; Max	-17.4 ; 19.1	-24.7 ; 17.4	-24.7 ; 19.1
Visit 44 (Week 53)			
N	215	104	319
Mean (SD)	-0.6 (6.5)	-1.1 (6.5)	-0.8 (6.5)
Median	-1.1	-2.1	-1.5
Min ; Max	-16.6 ; 23.6	-16.1 ; 13.3	-16.6 ; 23.6
Visit 44 (Week 53) (LOCF)			
N	318	161	479
Mean (SD)	-0.7 (6.4)	-0.9 (6.8)	-0.7 (6.5)
Median	-0.4	-0.6	-0.5
Min ; Max	-16.6 ; 23.6	-22.5 ; 20.0	-22.5 ; 23.6

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:52:20 - tdesc_numfind_tpl_t019_v01.sas/t_9pp_chb_noct_inc_descp_fas.txt

14.2.136: Nocturnal Increment after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Statistical Analysis - Full Analysis Set

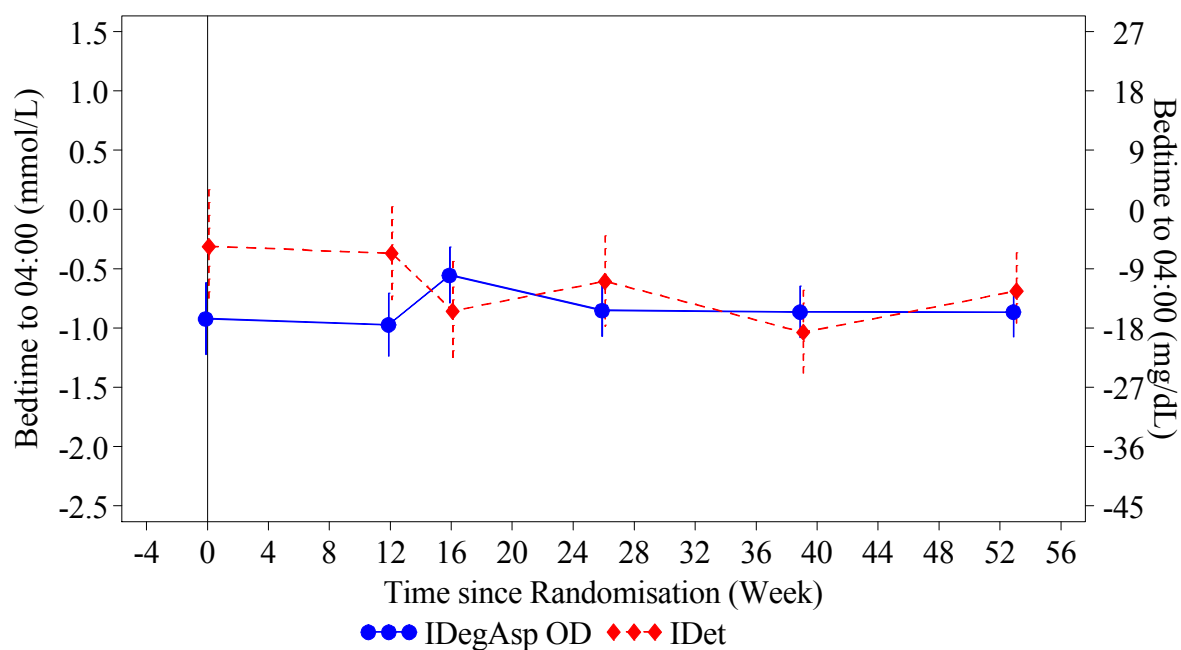
	FAS	N	Estimate	SE	95% CI
Bedtime to Breakfast (mmol/L)					
LSMeans					
IDegAsp OD	366	318	-1.51	0.37	
IDet	182	161	-1.03	0.43	
Treatment Contrast					
IDegAsp OD - IDet			-0.48		[-1.23 ; 0.27]
Bedtime to 04:00 (mmol/L)					
LSMeans					
IDegAsp OD	366	268	-0.73	0.36	
IDet	182	132	-0.51	0.43	
Treatment Contrast					
IDegAsp OD - IDet			-0.22		[-0.96 ; 0.53]
04:00 to Breakfast (mmol/L)					
LSMeans					
IDegAsp OD	366	267	-0.80	0.31	
IDet	182	138	-0.69	0.36	
Treatment Contrast					
IDegAsp OD - IDet			-0.11		[-0.75 ; 0.54]

N = Number of subjects contributing to analysis, CI = Confidence Interval, SE = Standard Error of the Mean

The response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

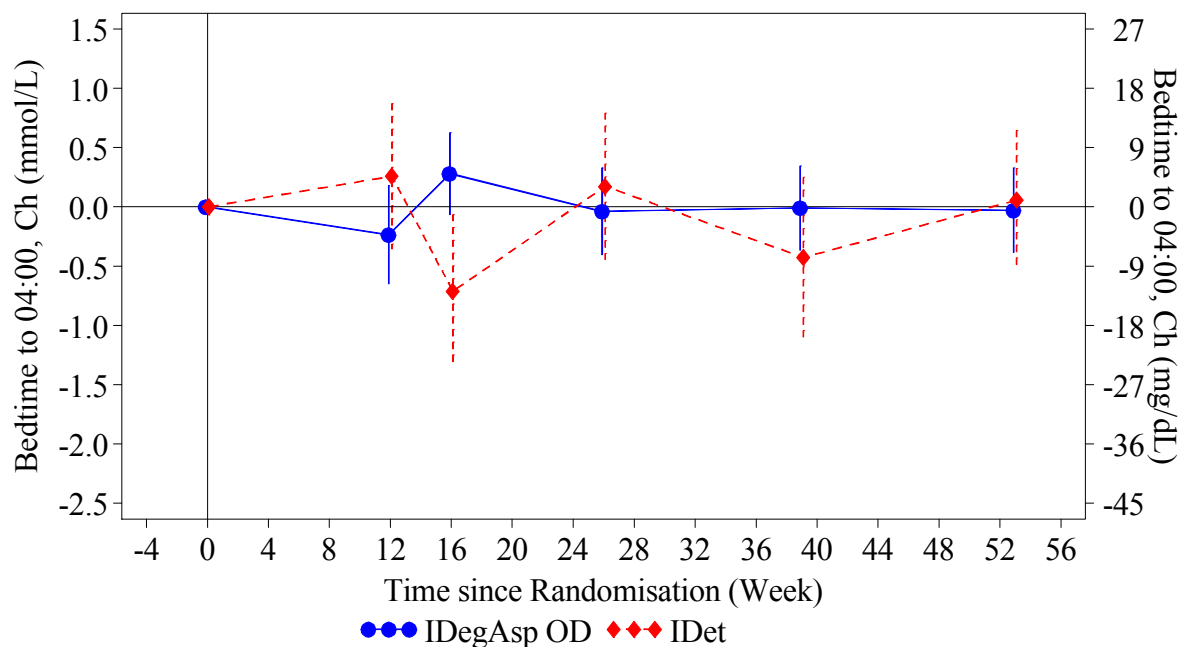
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:52:29 - tstat_find_tpl_t022.sas/t_9pp_noct_inc_stat_locf_fas.txt



FAS; LOCF imputed data
 Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:52:37 - fmean_numfind_v03.sas/e_9pp_abs_bt_4_inc_mean_locf_fas.cgm

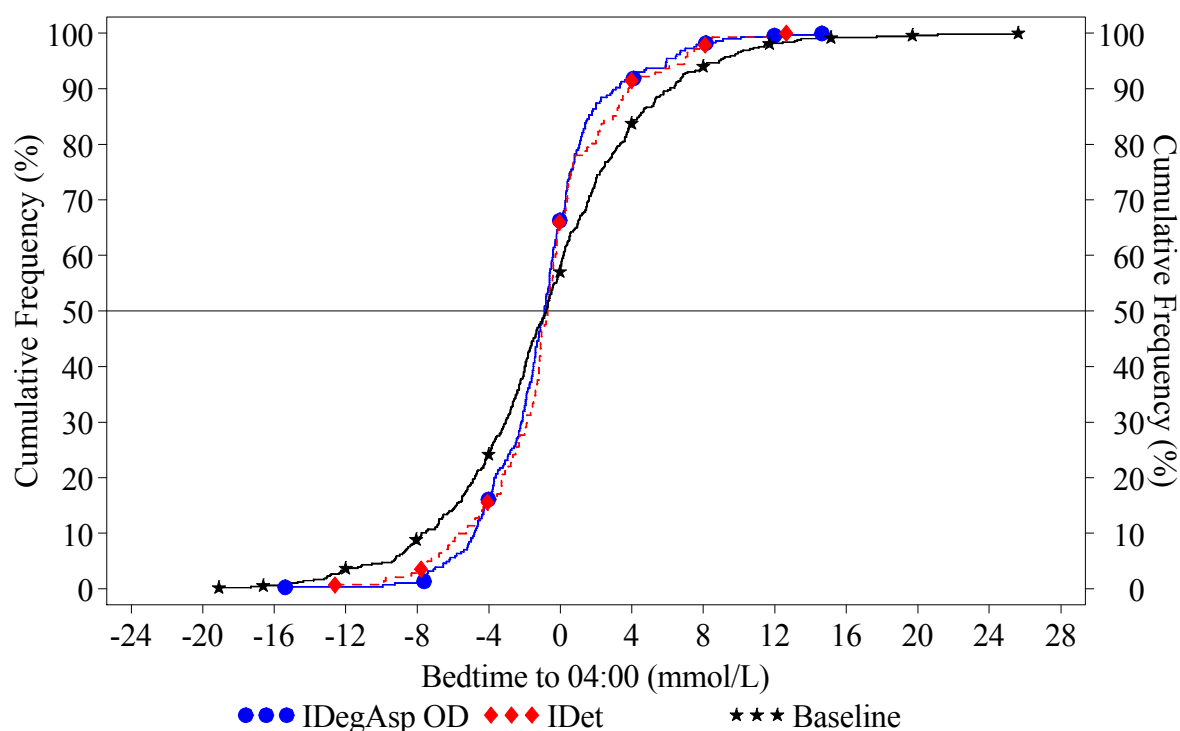
14.2.137: Nocturnal Increment (Bedtime to 04:00) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) -Mean Plot - Full Analysis Set



EAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:52:46 - fmean_numfind_v03.sas/e_9pp_chb_bt_4_inc_mean_locf_fas.cgm

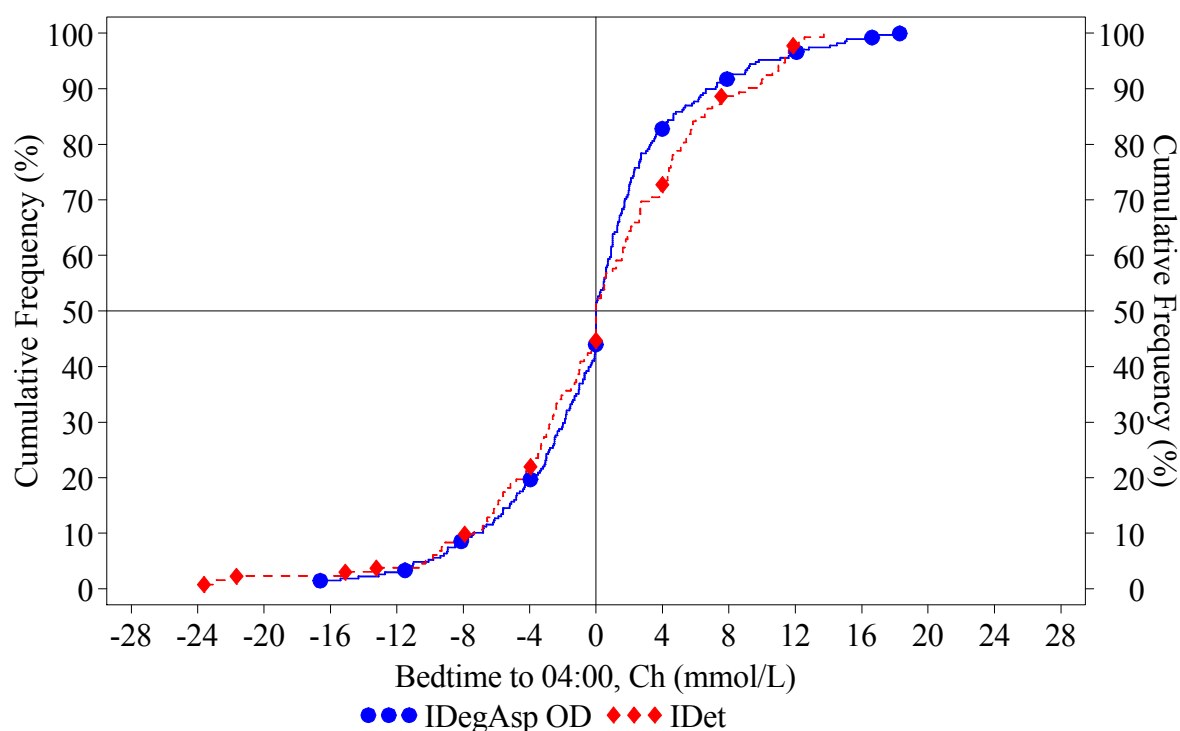
14.2.138: Nocturnal Increment (Bedtime to 04:00) by Treatment Week - Change from Baseline – 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:53:01 - fedist_numfind_v01.sas/e_9pp_abs_bt_4_inc_cdf_locf_fas.cgm

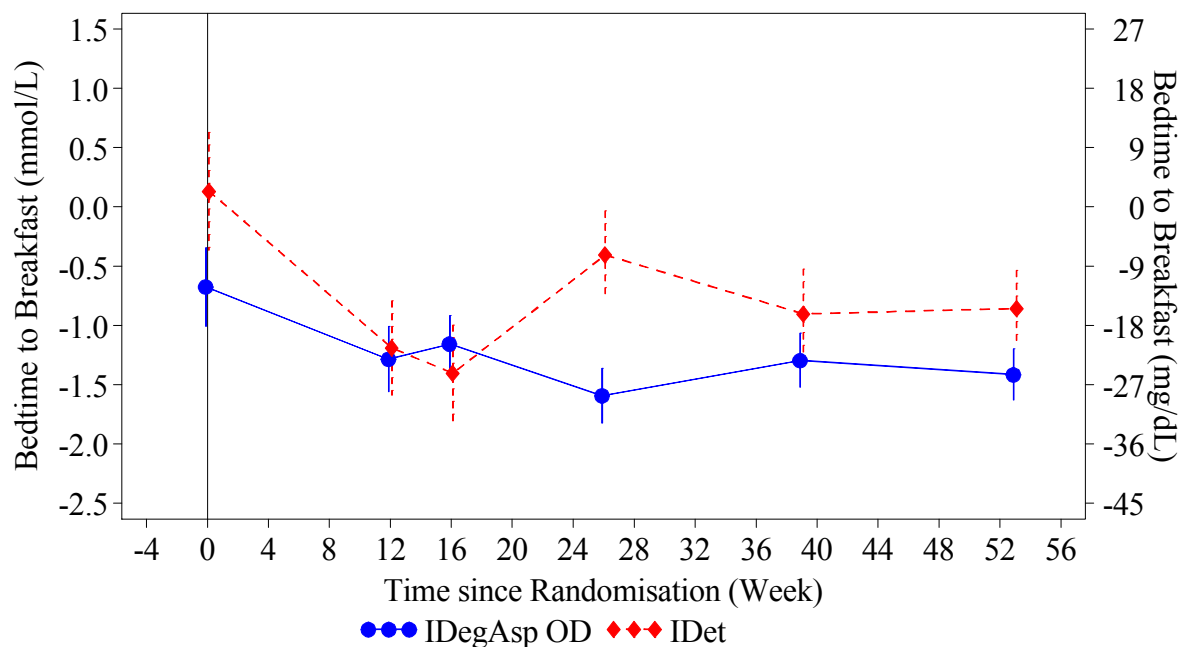
14.2.139: Nocturnal Increment (Bedtime to 04:00) after 52 Weeks of Treatment - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:53:10 - fedist_numfind_v01.sas/e_9pp_chb_bt_4_inc_cdf_locf_fas.cgm

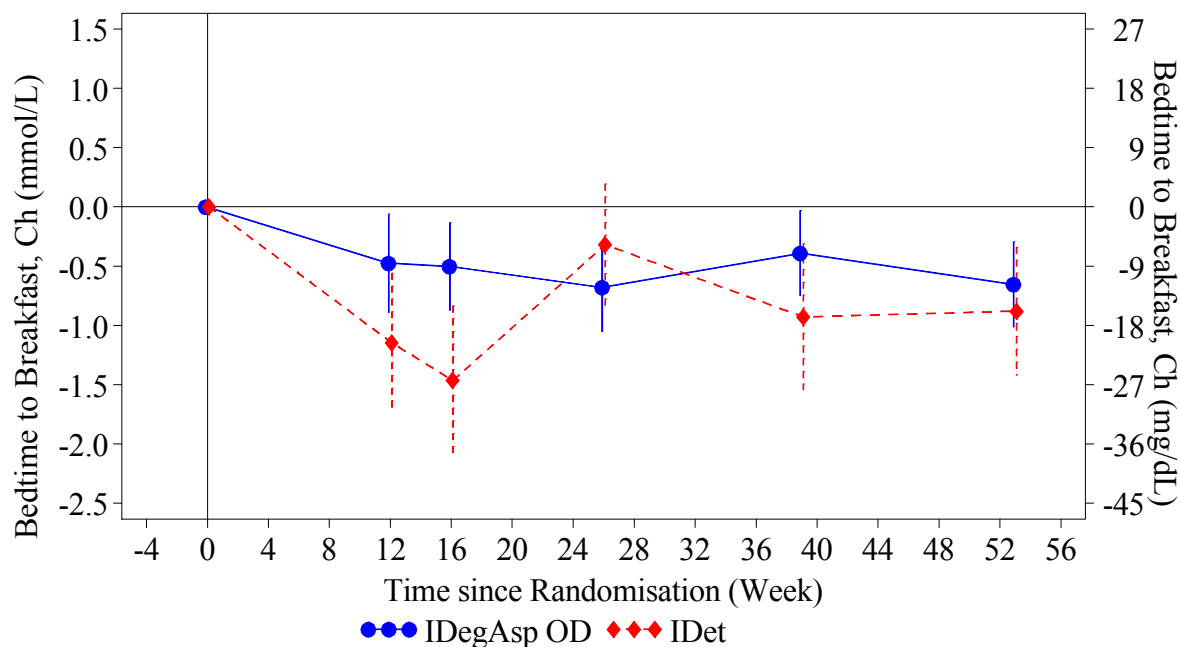
14.2.140: Nocturnal Increment (Bedtime to 04:00) after 52 Weeks of Treatment– Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:53:18 - fmean_numfind_v03.sas/e_9pp_abs_bt_bf_ic_mean_locf_fas.cgm

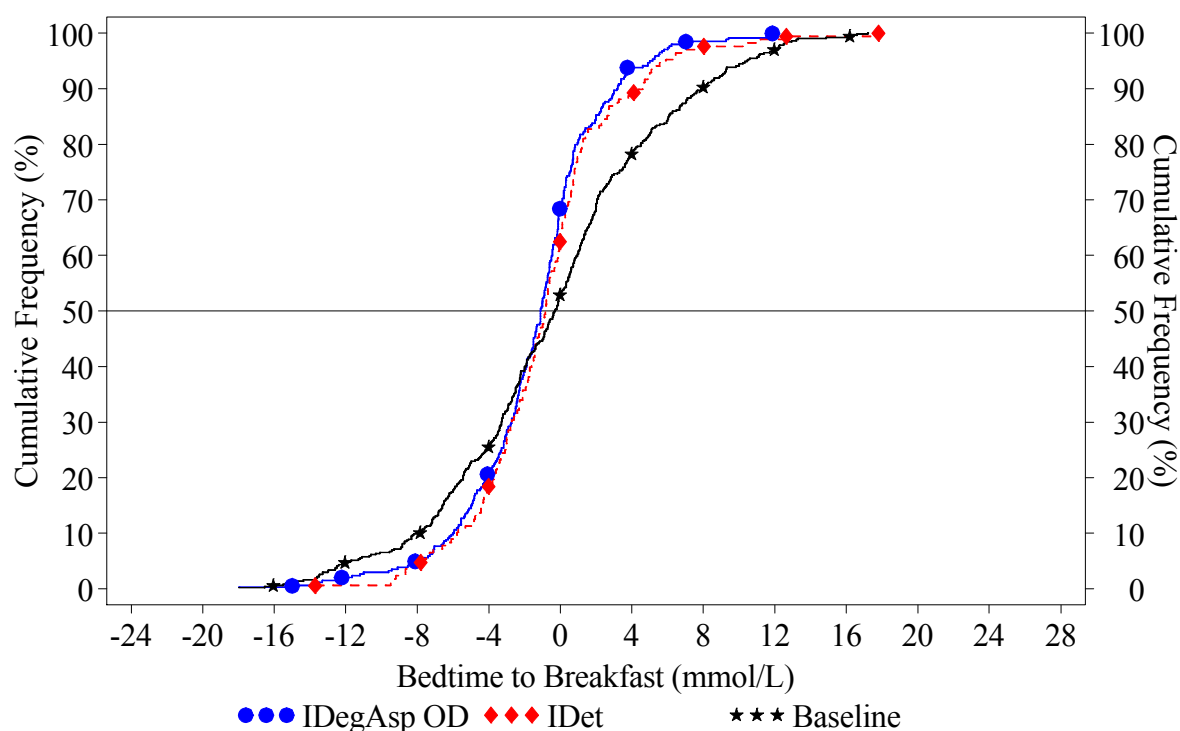
14.2.141: Nocturnal Increment (Bedtime to Breakfast) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



FAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:53:27 - finean_numfind_v03.sas/e_9pp_chb_bt_bf_ic_mean_locf_fas.cgm

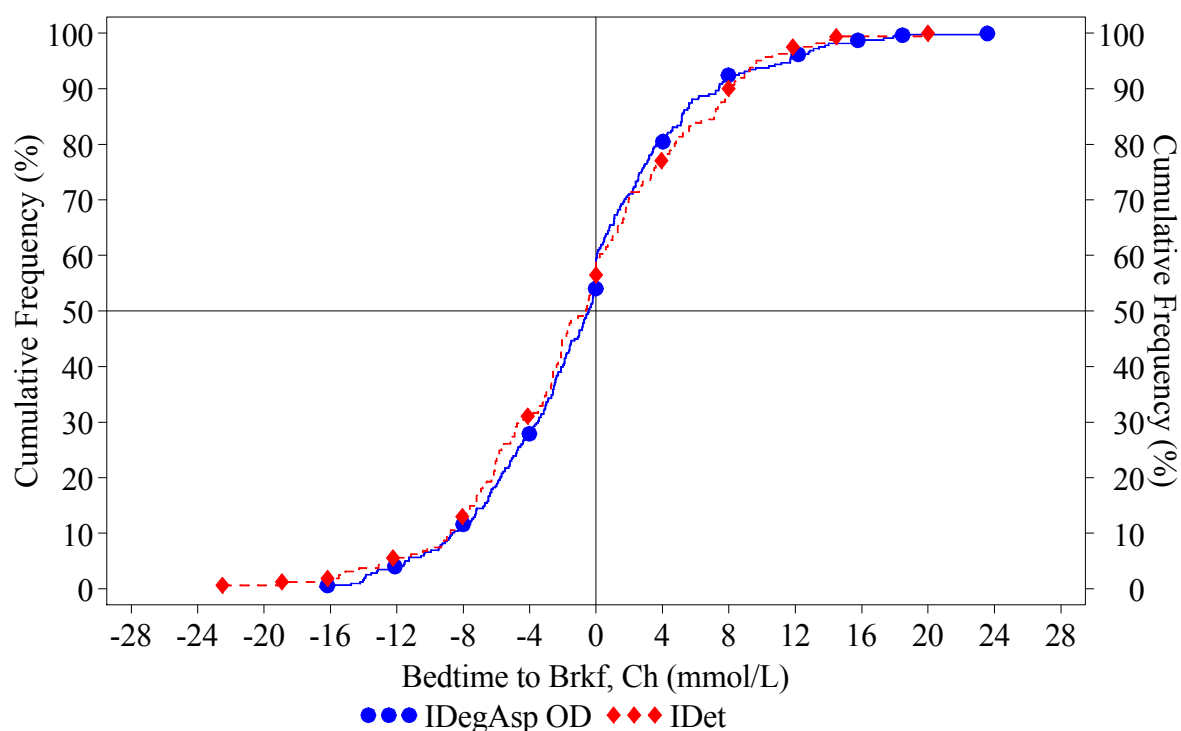
14.2.142: Nocturnal Increment (Bedtime to Breakfast) by Treatment Week - Change from Baseline - 9-point Self Measured Plasma Glucose Profile (mmol/L) - Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:53:42 - fedist_numfind_v01.sas/e_9pp_abs_bt_bf_inc_cdf_locf_fas.cgm

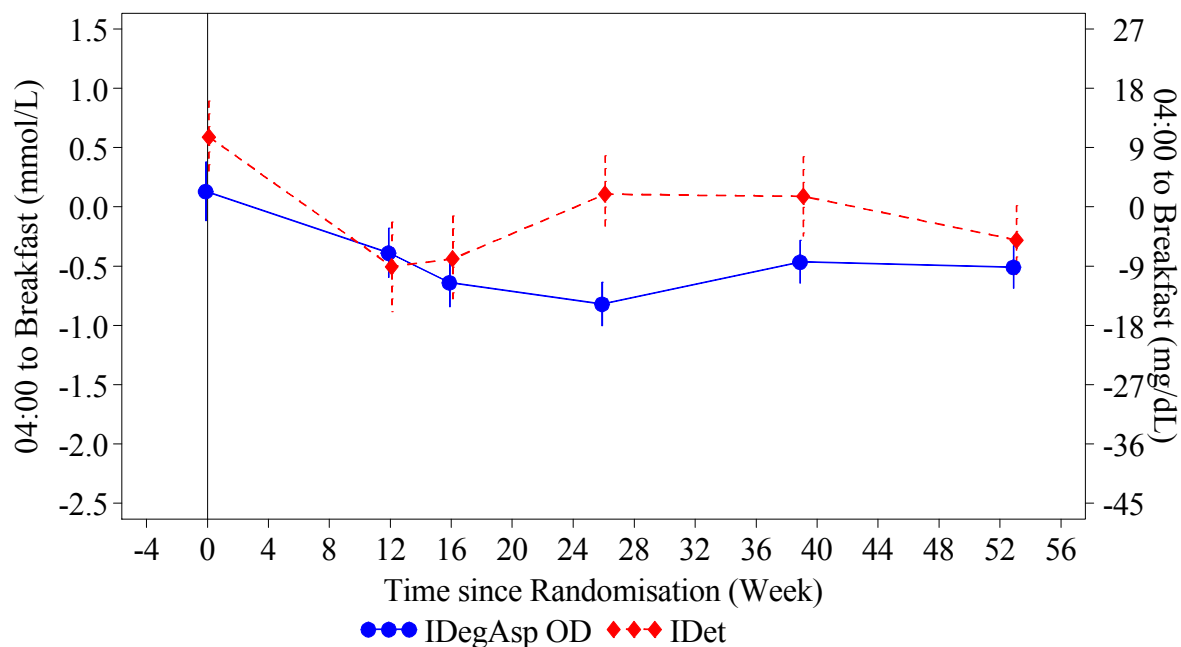
14.2.143: Nocturnal Increment (Bedtime to Breakfast) after 52 Weeks of Treatment -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:53:51 - fedist_numfind_v01.sas/e_9pp_chb_bt_bf_inc_cdf_locf_fas.cgm

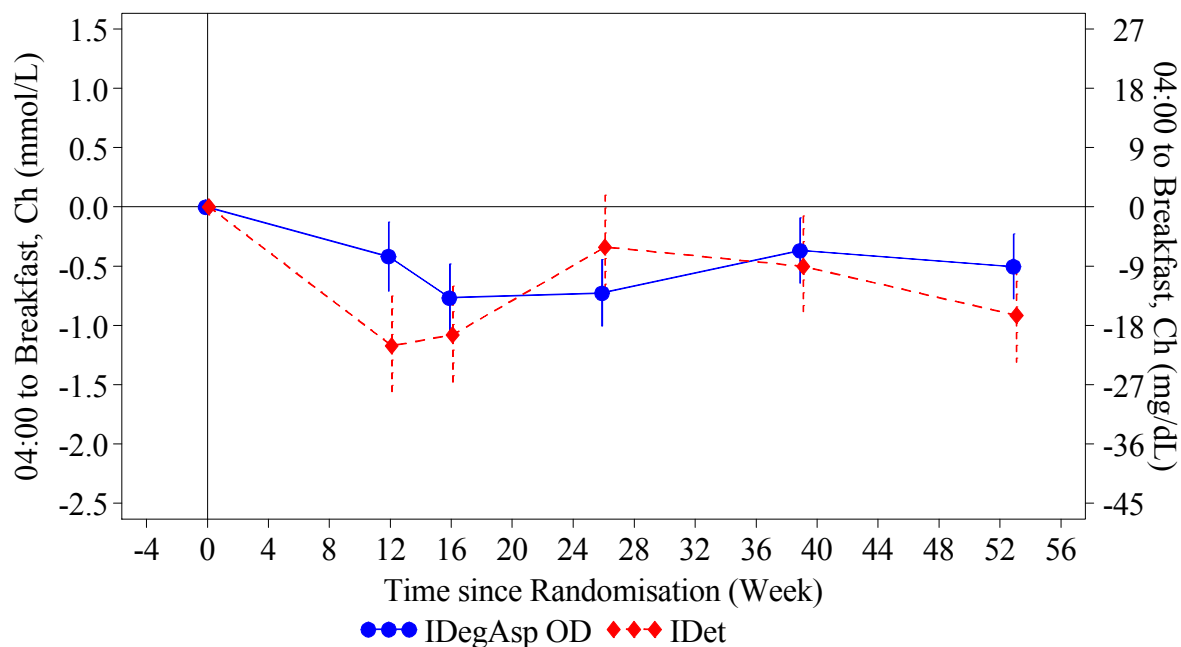
14.2.144: Nocturnal Increment (Bedtime to Breakfast) after 52 Weeks of Treatment – Change from Baseline -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



EAS: LOCF imputed data
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:53:59 - fmean_numfind_v03.sas/e_9pp_abs_4_bf_inc_mean_locf_fas.cgm

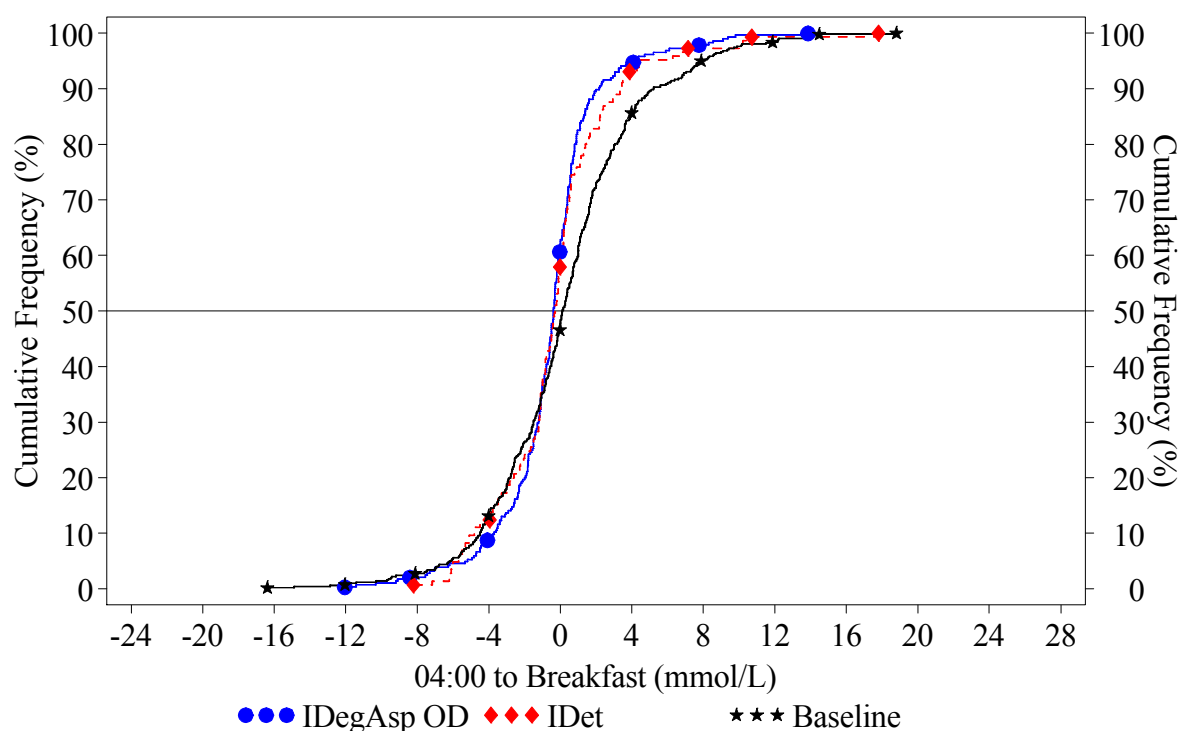
14.2.145: Nocturnal Increment (04:00 to Breakfast) by Treatment Week – 9-point Self Measured Plasma Glucose Profile (mmol/L) – Mean Plot - Full Analysis Set



EAS: LOCF imputed data
Error Bars: +- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:08 - fmean_numfind_v03.sas/e_9pp_chb_4_bf_inc_mean_locf_fas.cgm

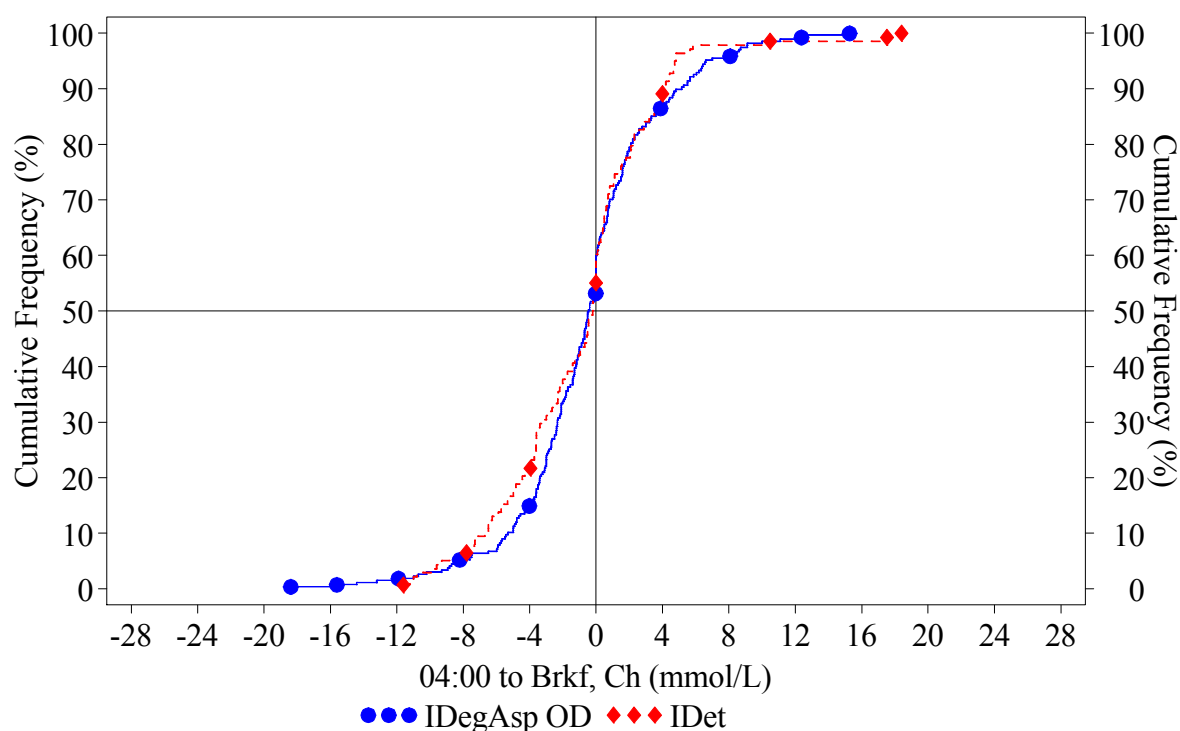
14.2.146: Nocturnal Increment (04:00 to Breakfast) by Treatment Week - Change from Baseline – 9-point Self Measured Plasma Glucose Profile (mmol/L) – Mean Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:23 - fedist_numfind_v01.sas/e_9pp_abs_4_bf_inc_cdf_locf_fas.cgm

14.2.147: Nocturnal Increment (04:00 to Breakfast) after 52 Weeks of Treatment -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set



FAS; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:32 - fedist_numfind_v01.sas/e_9pp_chb_4_bf_inc_cdf_locf_fas.cgm

14.2.148: Nocturnal Increment (04:00 to Breakfast) after 52 Weeks of Treatment – Change from Baseline -9-point Self Measured Plasma Glucose Profile (mmol/L) - Empirical Distribution Plot - Full Analysis Set

14.2.149: Self Measured Plasma Glucose for Dose Adjustment (mmol/L) – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Before Breakfast (mmol/L)			
Visit 2 (Week 0)			
N	365	181	546
Mean (SD)	9.3 (3.4)	9.7 (3.1)	9.4 (3.3)
Median	8.6	9.3	8.9
Min ; Max	2.3 ; 19.5	2.6 ; 17.6	2.3 ; 19.5
Visit 3 (Week 1)			
N	360	176	536
Mean (SD)	9.0 (3.1)	9.3 (3.6)	9.1 (3.3)
Median	8.6	8.7	8.6
Min ; Max	2.3 ; 19.4	2.8 ; 24.4	2.3 ; 24.4
Visit 4 (Week 2)			
N	359	175	534
Mean (SD)	8.3 (2.8)	8.7 (3.2)	8.4 (3.0)
Median	7.8	8.2	7.9
Min ; Max	2.8 ; 19.1	2.5 ; 21.3	2.5 ; 21.3
Visit 5 (Week 3)			
N	346	174	520
Mean (SD)	8.1 (2.7)	8.3 (3.0)	8.1 (2.8)
Median	7.6	7.9	7.7
Min ; Max	3.1 ; 17.5	2.5 ; 18.8	2.5 ; 18.8
Visit 6 (Week 4)			
N	350	174	524
Mean (SD)	7.9 (2.8)	7.9 (2.8)	7.9 (2.8)
Median	7.4	7.3	7.4
Min ; Max	2.5 ; 20.4	2.4 ; 19.5	2.4 ; 20.4
Visit 7 (Week 5)			
N	349	173	522
Mean (SD)	7.6 (2.5)	7.9 (2.7)	7.7 (2.6)
Median	7.2	7.5	7.3
Min ; Max	2.6 ; 17.4	2.6 ; 17.2	2.6 ; 17.4
Visit 8 (Week 6)			
N	343	173	516
Mean (SD)	7.7 (2.6)	7.5 (2.3)	7.6 (2.5)
Median	7.3	7.0	7.2
Min ; Max	3.2 ; 18.6	2.9 ; 15.6	2.9 ; 18.6
Visit 9 (Week 7)			
N	342	170	512
Mean (SD)	7.4 (2.4)	7.9 (3.0)	7.5 (2.7)
Median	7.0	7.1	7.0
Min ; Max	2.7 ; 16.4	2.7 ; 21.7	2.7 ; 21.7

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Breakfast (mmol/L)			
Visit 10 (Week 8)			
N	339	171	510
Mean (SD)	7.5 (2.6)	7.8 (2.6)	7.6 (2.6)
Median	7.1	7.3	7.1
Min ; Max	2.7 ; 16.4	3.1 ; 16.3	2.7 ; 16.4
Visit 11 (Week 9)			
N	334	165	499
Mean (SD)	7.1 (2.2)	7.8 (2.6)	7.4 (2.3)
Median	6.9	7.4	7.0
Min ; Max	2.9 ; 14.6	2.8 ; 17.0	2.8 ; 17.0
Visit 12 (Week 10)			
N	336	168	504
Mean (SD)	7.4 (2.4)	7.4 (2.5)	7.4 (2.4)
Median	6.8	7.0	6.9
Min ; Max	3.3 ; 16.8	2.6 ; 16.7	2.6 ; 16.8
Visit 13 (Week 11)			
N	334	165	499
Mean (SD)	7.4 (2.5)	7.6 (2.6)	7.5 (2.5)
Median	6.8	6.9	6.8
Min ; Max	4.0 ; 19.7	3.3 ; 17.9	3.3 ; 19.7
Visit 14 (Week 12)			
N	333	166	499
Mean (SD)	7.4 (2.4)	7.6 (2.5)	7.5 (2.4)
Median	7.0	7.0	7.0
Min ; Max	2.4 ; 15.7	4.0 ; 19.1	2.4 ; 19.1
Visit 15 (Week 13)			
N	324	160	484
Mean (SD)	7.3 (2.4)	7.7 (2.7)	7.4 (2.5)
Median	7.0	7.1	7.0
Min ; Max	3.2 ; 18.0	3.1 ; 17.4	3.1 ; 18.0
Visit 16 (Week 14)			
N	331	165	496
Mean (SD)	7.2 (2.3)	7.3 (2.4)	7.2 (2.3)
Median	6.8	6.9	6.8
Min ; Max	3.0 ; 17.3	3.1 ; 18.4	3.0 ; 18.4
Visit 17 (Week 15)			
N	328	163	491
Mean (SD)	7.2 (2.4)	7.3 (2.8)	7.2 (2.5)
Median	6.8	6.6	6.7
Min ; Max	3.3 ; 16.2	2.1 ; 26.9	2.1 ; 26.9

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Breakfast (mmol/L)			
Visit 18 (Week 16)			
N	328	163	491
Mean (SD)	7.3 (2.5)	7.1 (2.3)	7.3 (2.4)
Median	6.8	6.6	6.7
Min ; Max	2.9 ; 17.6	3.4 ; 13.7	2.9 ; 17.6
Visit 19 (Week 17)			
N	324	161	485
Mean (SD)	7.2 (2.3)	7.3 (2.3)	7.3 (2.3)
Median	6.8	7.0	6.9
Min ; Max	2.4 ; 15.5	2.5 ; 16.1	2.4 ; 16.1
Visit 20 (Week 18)			
N	319	158	477
Mean (SD)	7.1 (2.4)	7.2 (2.3)	7.1 (2.4)
Median	6.7	6.8	6.7
Min ; Max	2.2 ; 16.8	2.7 ; 13.9	2.2 ; 16.8
Visit 21 (Week 19)			
N	321	161	482
Mean (SD)	7.0 (2.1)	7.3 (2.5)	7.1 (2.3)
Median	6.5	6.5	6.5
Min ; Max	3.4 ; 14.5	3.9 ; 15.4	3.4 ; 15.4
Visit 22 (Week 20)			
N	324	158	482
Mean (SD)	7.0 (2.3)	7.2 (2.5)	7.1 (2.4)
Median	6.6	6.7	6.7
Min ; Max	3.1 ; 17.7	3.3 ; 18.3	3.1 ; 18.3
Visit 23 (Week 21)			
N	321	156	477
Mean (SD)	7.1 (2.3)	6.9 (2.5)	7.0 (2.3)
Median	6.6	6.1	6.4
Min ; Max	3.1 ; 15.5	2.7 ; 15.8	2.7 ; 15.8
Visit 24 (Week 22)			
N	319	156	475
Mean (SD)	7.0 (2.2)	7.2 (2.5)	7.0 (2.3)
Median	6.5	6.5	6.5
Min ; Max	3.1 ; 15.2	3.4 ; 14.9	3.1 ; 15.2
Visit 25 (Week 23)			
N	320	151	471
Mean (SD)	7.0 (2.2)	7.0 (2.3)	7.0 (2.2)
Median	6.6	6.7	6.6
Min ; Max	2.6 ; 12.9	2.5 ; 14.6	2.5 ; 14.6

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Breakfast (mmol/L)			
Visit 26 (Week 24)			
N	318	157	475
Mean (SD)	7.0 (2.5)	6.9 (2.2)	7.0 (2.4)
Median	6.3	6.5	6.4
Min ; Max	2.8 ; 22.2	3.4 ; 13.7	2.8 ; 22.2
Visit 27 (Week 25)			
N	318	155	473
Mean (SD)	7.1 (2.4)	7.1 (2.6)	7.1 (2.4)
Median	6.6	6.4	6.5
Min ; Max	3.1 ; 16.5	3.1 ; 16.5	3.1 ; 16.5
Visit 28 (Week 26)			
N	339	165	504
Mean (SD)	7.3 (2.4)	7.2 (2.6)	7.3 (2.5)
Median	6.8	6.6	6.8
Min ; Max	2.9 ; 16.2	2.1 ; 19.3	2.1 ; 19.3
Visit 29 (Week 27)			
N	326	154	480
Mean (SD)	9.8 (3.7)	9.3 (3.3)	9.6 (3.6)
Median	9.6	9.3	9.5
Min ; Max	2.9 ; 21.9	3.4 ; 19.5	2.9 ; 21.9
Visit 31 (Week 28)			
N	250	121	371
Mean (SD)	7.3 (2.5)	7.2 (2.3)	7.3 (2.4)
Median	7.0	6.5	6.8
Min ; Max	3.8 ; 17.6	3.7 ; 15.4	3.7 ; 17.6
Visit 32 (Week 29)			
N	251	122	373
Mean (SD)	6.9 (2.1)	7.4 (2.7)	7.0 (2.3)
Median	6.5	6.7	6.5
Min ; Max	3.5 ; 15.2	3.6 ; 17.2	3.5 ; 17.2
Visit 33 (Week 31)			
N	249	121	370
Mean (SD)	6.9 (2.3)	7.4 (2.6)	7.1 (2.4)
Median	6.5	6.5	6.5
Min ; Max	2.4 ; 16.7	3.9 ; 16.6	2.4 ; 16.7
Visit 34 (Week 33)			
N	244	119	363
Mean (SD)	7.0 (2.3)	7.1 (2.4)	7.0 (2.3)
Median	6.6	6.7	6.6
Min ; Max	2.5 ; 19.0	3.0 ; 13.9	2.5 ; 19.0

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Breakfast (mmol/L)			
Visit 35 (Week 35)			
N	247	120	367
Mean (SD)	6.8 (2.0)	7.0 (2.3)	6.9 (2.1)
Median	6.4	6.6	6.5
Min ; Max	3.0 ; 14.8	3.2 ; 15.5	3.0 ; 15.5
Visit 36 (Week 37)			
N	241	118	359
Mean (SD)	6.8 (2.4)	7.4 (2.8)	7.0 (2.6)
Median	6.2	6.7	6.4
Min ; Max	2.9 ; 18.0	3.1 ; 19.6	2.9 ; 19.6
Visit 37 (Week 39)			
N	245	118	363
Mean (SD)	6.8 (2.1)	7.3 (2.6)	7.0 (2.3)
Median	6.5	6.6	6.6
Min ; Max	3.4 ; 14.5	2.8 ; 15.1	2.8 ; 15.1
Visit 38 (Week 41)			
N	237	118	355
Mean (SD)	6.7 (2.2)	6.9 (2.5)	6.8 (2.3)
Median	6.0	6.3	6.1
Min ; Max	2.8 ; 15.8	3.5 ; 16.8	2.8 ; 16.8
Visit 39 (Week 43)			
N	241	117	358
Mean (SD)	6.9 (2.4)	6.9 (2.2)	6.9 (2.3)
Median	6.3	6.3	6.3
Min ; Max	3.4 ; 17.5	3.2 ; 13.2	3.2 ; 17.5
Visit 40 (Week 45)			
N	237	116	353
Mean (SD)	6.6 (2.1)	7.0 (2.3)	6.8 (2.2)
Median	6.0	6.4	6.1
Min ; Max	3.5 ; 14.0	2.7 ; 14.3	2.7 ; 14.3
Visit 41 (Week 47)			
N	239	116	355
Mean (SD)	6.8 (2.3)	7.0 (2.4)	6.8 (2.3)
Median	6.3	6.3	6.3
Min ; Max	3.3 ; 17.2	3.1 ; 20.0	3.1 ; 20.0
Visit 42 (Week 49)			
N	234	113	347
Mean (SD)	6.6 (2.1)	6.9 (2.3)	6.7 (2.2)
Median	6.3	6.3	6.3
Min ; Max	2.9 ; 13.8	3.3 ; 17.3	2.9 ; 17.3

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Breakfast (mmol/L)			
Visit 43 (Week 51)			
N	233	112	345
Mean (SD)	6.8 (2.2)	7.2 (2.4)	6.9 (2.3)
Median	6.5	6.5	6.5
Min ; Max	2.9 ; 14.6	3.5 ; 15.9	2.9 ; 15.9
Visit 44 (Week 53)			
N	235	113	348
Mean (SD)	6.8 (2.1)	7.0 (2.6)	6.9 (2.3)
Median	6.3	6.4	6.4
Min ; Max	3.3 ; 16.1	2.8 ; 18.8	2.8 ; 18.8
Visit 44 (Week 53) (LOCF)			
N	366	181	547
Mean (SD)	7.7 (3.0)	7.7 (2.9)	7.7 (3.0)
Median	6.9	7.2	6.9
Min ; Max	2.9 ; 21.8	2.8 ; 19.3	2.8 ; 21.8

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 2 (Week 0)			
N	364	181	545
Mean (SD)	8.8 (2.8)	9.1 (3.4)	8.9 (3.0)
Median	8.5	9.1	8.6
Min ; Max	3.2 ; 20.8	3.4 ; 20.4	3.2 ; 20.8
Visit 3 (Week 1)			
N	360	176	536
Mean (SD)	8.8 (2.9)	9.8 (3.6)	9.1 (3.2)
Median	8.4	9.3	8.6
Min ; Max	2.5 ; 18.7	3.1 ; 20.2	2.5 ; 20.2
Visit 4 (Week 2)			
N	357	176	533
Mean (SD)	8.0 (2.8)	9.4 (3.3)	8.5 (3.0)
Median	7.6	9.1	7.9
Min ; Max	2.5 ; 18.3	2.8 ; 23.5	2.5 ; 23.5
Visit 5 (Week 3)			
N	346	175	521
Mean (SD)	7.7 (2.6)	8.8 (3.1)	8.1 (2.8)
Median	7.3	8.3	7.6
Min ; Max	2.8 ; 19.9	2.7 ; 17.9	2.7 ; 19.9
Visit 6 (Week 4)			
N	351	174	525
Mean (SD)	7.7 (2.7)	8.3 (2.9)	7.9 (2.8)
Median	7.4	7.8	7.4
Min ; Max	2.5 ; 21.6	3.2 ; 18.5	2.5 ; 21.6
Visit 7 (Week 5)			
N	349	173	522
Mean (SD)	7.7 (2.9)	8.4 (2.7)	8.0 (2.8)
Median	7.2	7.9	7.4
Min ; Max	2.9 ; 24.1	3.4 ; 17.0	2.9 ; 24.1
Visit 8 (Week 6)			
N	344	173	517
Mean (SD)	7.6 (2.8)	8.2 (3.0)	7.8 (2.9)
Median	7.2	7.7	7.3
Min ; Max	3.0 ; 25.2	2.4 ; 17.4	2.4 ; 25.2
Visit 9 (Week 7)			
N	342	171	513
Mean (SD)	7.5 (2.5)	8.2 (2.9)	7.7 (2.6)
Median	6.9	7.6	7.1
Min ; Max	2.9 ; 15.9	3.0 ; 19.3	2.9 ; 19.3

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 10 (Week 8)			
N	340	171	511
Mean (SD)	7.5 (2.5)	8.1 (2.7)	7.7 (2.6)
Median	7.2	7.8	7.4
Min ; Max	3.0 ; 16.4	2.9 ; 17.6	2.9 ; 17.6
Visit 11 (Week 9)			
N	333	166	499
Mean (SD)	7.4 (2.5)	8.1 (2.8)	7.6 (2.6)
Median	6.9	7.4	7.1
Min ; Max	2.9 ; 19.2	3.1 ; 17.5	2.9 ; 19.2
Visit 12 (Week 10)			
N	337	169	506
Mean (SD)	7.6 (2.6)	7.9 (2.5)	7.7 (2.6)
Median	6.9	7.4	7.1
Min ; Max	3.2 ; 18.1	3.2 ; 14.6	3.2 ; 18.1
Visit 13 (Week 11)			
N	334	166	500
Mean (SD)	7.6 (2.6)	8.0 (2.7)	7.7 (2.7)
Median	7.0	7.4	7.2
Min ; Max	3.3 ; 17.0	4.0 ; 21.1	3.3 ; 21.1
Visit 14 (Week 12)			
N	333	166	499
Mean (SD)	7.6 (2.6)	8.0 (2.7)	7.7 (2.7)
Median	6.9	7.4	7.1
Min ; Max	3.2 ; 18.9	3.4 ; 17.6	3.2 ; 18.9
Visit 15 (Week 13)			
N	325	160	485
Mean (SD)	7.5 (2.7)	7.9 (2.7)	7.6 (2.7)
Median	7.0	7.3	7.1
Min ; Max	3.2 ; 23.4	2.8 ; 22.5	2.8 ; 23.4
Visit 16 (Week 14)			
N	332	165	497
Mean (SD)	7.3 (2.5)	8.3 (3.0)	7.6 (2.7)
Median	6.8	7.8	7.0
Min ; Max	3.0 ; 18.4	2.9 ; 22.4	2.9 ; 22.4
Visit 17 (Week 15)			
N	328	164	492
Mean (SD)	7.2 (2.4)	7.7 (2.4)	7.3 (2.4)
Median	6.7	7.2	6.9
Min ; Max	2.9 ; 20.3	2.7 ; 18.1	2.7 ; 20.3

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 18 (Week 16)			
N	328	163	491
Mean (SD)	7.5 (2.5)	7.5 (2.3)	7.5 (2.4)
Median	6.9	7.0	6.9
Min ; Max	3.2 ; 17.3	2.0 ; 16.3	2.0 ; 17.3
Visit 19 (Week 17)			
N	324	160	484
Mean (SD)	7.2 (2.3)	7.7 (2.5)	7.4 (2.4)
Median	6.6	7.2	6.9
Min ; Max	3.3 ; 17.1	2.4 ; 16.7	2.4 ; 17.1
Visit 20 (Week 18)			
N	320	158	478
Mean (SD)	7.3 (2.4)	7.4 (2.7)	7.3 (2.5)
Median	6.8	6.9	6.8
Min ; Max	3.4 ; 18.2	2.4 ; 16.6	2.4 ; 18.2
Visit 21 (Week 19)			
N	321	161	482
Mean (SD)	7.1 (2.4)	7.7 (2.7)	7.3 (2.5)
Median	6.7	6.9	6.8
Min ; Max	2.2 ; 15.5	3.7 ; 15.6	2.2 ; 15.6
Visit 22 (Week 20)			
N	324	158	482
Mean (SD)	7.2 (2.4)	7.3 (2.4)	7.3 (2.4)
Median	6.7	7.1	6.8
Min ; Max	3.2 ; 16.0	2.4 ; 15.9	2.4 ; 16.0
Visit 23 (Week 21)			
N	321	156	477
Mean (SD)	7.0 (2.2)	7.7 (2.5)	7.2 (2.3)
Median	6.7	7.1	6.8
Min ; Max	2.4 ; 15.8	3.8 ; 16.7	2.4 ; 16.7
Visit 24 (Week 22)			
N	319	155	474
Mean (SD)	7.2 (2.4)	7.6 (2.6)	7.3 (2.5)
Median	6.7	6.9	6.8
Min ; Max	2.6 ; 18.9	2.8 ; 16.7	2.6 ; 18.9
Visit 25 (Week 23)			
N	319	151	470
Mean (SD)	7.2 (2.4)	7.5 (2.3)	7.3 (2.4)
Median	6.7	7.1	6.8
Min ; Max	2.4 ; 16.9	3.9 ; 14.7	2.4 ; 16.9

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 26 (Week 24)			
N	318	157	475
Mean (SD)	7.2 (2.6)	7.6 (2.6)	7.3 (2.6)
Median	6.5	7.1	6.7
Min ; Max	2.4 ; 18.2	3.0 ; 20.4	2.4 ; 20.4
Visit 27 (Week 25)			
N	318	155	473
Mean (SD)	7.1 (2.4)	7.6 (2.6)	7.2 (2.5)
Median	6.7	7.0	6.8
Min ; Max	2.4 ; 20.6	4.1 ; 22.9	2.4 ; 22.9
Visit 28 (Week 26)			
N	339	165	504
Mean (SD)	7.5 (2.6)	8.3 (3.0)	7.8 (2.8)
Median	7.1	7.7	7.3
Min ; Max	2.7 ; 17.1	3.8 ; 21.6	2.7 ; 21.6
Visit 29 (Week 27)			
N	326	154	480
Mean (SD)	8.6 (3.2)	7.9 (2.5)	8.4 (3.0)
Median	8.0	7.4	7.8
Min ; Max	2.0 ; 21.7	3.0 ; 16.8	2.0 ; 21.7
Visit 31 (Week 28)			
N	249	121	370
Mean (SD)	7.1 (2.3)	7.7 (2.5)	7.3 (2.4)
Median	6.8	7.2	6.9
Min ; Max	2.9 ; 18.2	3.7 ; 14.2	2.9 ; 18.2
Visit 32 (Week 29)			
N	251	122	373
Mean (SD)	6.9 (2.2)	7.7 (2.5)	7.2 (2.3)
Median	6.7	7.3	6.9
Min ; Max	1.6 ; 13.8	3.8 ; 15.4	1.6 ; 15.4
Visit 33 (Week 31)			
N	250	121	371
Mean (SD)	7.1 (2.4)	7.8 (2.9)	7.3 (2.6)
Median	6.5	7.1	6.8
Min ; Max	2.6 ; 15.9	3.3 ; 18.1	2.6 ; 18.1
Visit 34 (Week 33)			
N	244	119	363
Mean (SD)	7.0 (2.4)	7.7 (2.8)	7.3 (2.5)
Median	6.6	6.8	6.6
Min ; Max	2.7 ; 17.1	3.3 ; 16.6	2.7 ; 17.1

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 35 (Week 35)			
N	247	120	367
Mean (SD)	7.1 (2.1)	7.6 (2.5)	7.3 (2.2)
Median	6.7	7.0	6.8
Min ; Max	3.0 ; 13.9	4.2 ; 17.6	3.0 ; 17.6
Visit 36 (Week 37)			
N	241	118	359
Mean (SD)	7.2 (2.3)	7.9 (3.1)	7.4 (2.6)
Median	6.8	7.3	6.9
Min ; Max	2.9 ; 15.3	2.9 ; 19.7	2.9 ; 19.7
Visit 37 (Week 39)			
N	245	118	363
Mean (SD)	7.2 (2.3)	7.7 (2.5)	7.4 (2.3)
Median	6.8	7.2	7.0
Min ; Max	3.8 ; 15.0	4.1 ; 16.4	3.8 ; 16.4
Visit 38 (Week 41)			
N	237	117	354
Mean (SD)	7.3 (2.3)	7.4 (2.2)	7.4 (2.3)
Median	6.8	6.8	6.8
Min ; Max	3.7 ; 16.4	4.1 ; 14.6	3.7 ; 16.4
Visit 39 (Week 43)			
N	241	116	357
Mean (SD)	7.1 (2.2)	7.6 (2.5)	7.2 (2.3)
Median	6.5	7.1	6.7
Min ; Max	3.4 ; 15.4	3.4 ; 15.5	3.4 ; 15.5
Visit 40 (Week 45)			
N	237	116	353
Mean (SD)	7.1 (2.2)	7.7 (2.5)	7.3 (2.3)
Median	6.5	7.0	6.7
Min ; Max	2.5 ; 17.1	3.4 ; 15.0	2.5 ; 17.1
Visit 41 (Week 47)			
N	239	116	355
Mean (SD)	7.2 (2.2)	7.9 (2.7)	7.4 (2.4)
Median	6.8	7.3	6.9
Min ; Max	3.1 ; 16.6	4.3 ; 17.8	3.1 ; 17.8
Visit 42 (Week 49)			
N	234	113	347
Mean (SD)	7.0 (2.1)	7.5 (2.6)	7.2 (2.3)
Median	6.7	6.8	6.7
Min ; Max	3.2 ; 14.5	3.6 ; 17.1	3.2 ; 17.1

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Lunch (mmol/L)			
Visit 43 (Week 51)			
N	232	112	344
Mean (SD)	7.0 (2.2)	7.4 (2.2)	7.1 (2.2)
Median	6.5	7.2	6.7
Min ; Max	3.4 ; 15.6	3.9 ; 14.0	3.4 ; 15.6
Visit 44 (Week 53)			
N	235	113	348
Mean (SD)	6.8 (2.0)	7.9 (2.5)	7.2 (2.2)
Median	6.4	7.2	6.8
Min ; Max	3.1 ; 15.6	4.4 ; 14.5	3.1 ; 15.6
Visit 44 (Week 53) (LOCF)			
N	365	181	546
Mean (SD)	7.4 (2.6)	8.1 (2.8)	7.6 (2.7)
Median	6.9	7.5	7.1
Min ; Max	3.0 ; 18.9	2.9 ; 21.6	2.9 ; 21.6

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 2 (Week 0)			
N	364	181	545
Mean (SD)	9.6 (3.3)	10.2 (3.5)	9.8 (3.4)
Median	9.0	9.7	9.2
Min ; Max	2.3 ; 22.0	3.5 ; 22.1	2.3 ; 22.1
Visit 3 (Week 1)			
N	360	176	536
Mean (SD)	9.7 (3.3)	11.0 (4.2)	10.1 (3.6)
Median	9.3	9.9	9.6
Min ; Max	2.8 ; 22.3	5.0 ; 23.2	2.8 ; 23.2
Visit 4 (Week 2)			
N	359	176	535
Mean (SD)	9.1 (3.1)	10.3 (3.8)	9.5 (3.4)
Median	8.5	9.5	8.8
Min ; Max	2.6 ; 19.6	4.1 ; 25.5	2.6 ; 25.5
Visit 5 (Week 3)			
N	346	175	521
Mean (SD)	8.6 (3.2)	9.5 (3.2)	8.9 (3.2)
Median	8.0	8.8	8.2
Min ; Max	3.2 ; 19.7	4.3 ; 19.0	3.2 ; 19.7
Visit 6 (Week 4)			
N	351	174	525
Mean (SD)	8.4 (3.0)	9.7 (3.4)	8.8 (3.2)
Median	8.0	9.1	8.3
Min ; Max	3.1 ; 20.2	4.4 ; 20.8	3.1 ; 20.8
Visit 7 (Week 5)			
N	349	173	522
Mean (SD)	8.5 (3.1)	9.2 (3.4)	8.7 (3.2)
Median	8.0	8.9	8.2
Min ; Max	2.6 ; 20.3	2.5 ; 19.0	2.5 ; 20.3
Visit 8 (Week 6)			
N	343	173	516
Mean (SD)	8.5 (3.1)	9.1 (3.3)	8.7 (3.2)
Median	7.9	8.7	8.1
Min ; Max	2.8 ; 21.9	3.5 ; 21.3	2.8 ; 21.9
Visit 9 (Week 7)			
N	342	171	513
Mean (SD)	8.1 (2.6)	9.0 (3.3)	8.4 (2.9)
Median	7.7	8.3	7.9
Min ; Max	3.1 ; 19.1	3.7 ; 20.6	3.1 ; 20.6

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 10 (Week 8)			
N	340	171	511
Mean (SD)	8.3 (2.9)	8.9 (3.4)	8.5 (3.1)
Median	7.5	8.3	7.7
Min ; Max	3.1 ; 19.8	3.5 ; 25.0	3.1 ; 25.0
Visit 11 (Week 9)			
N	334	166	500
Mean (SD)	8.1 (2.8)	9.0 (3.2)	8.4 (3.0)
Median	7.6	8.3	7.8
Min ; Max	3.3 ; 20.5	3.3 ; 19.8	3.3 ; 20.5
Visit 12 (Week 10)			
N	336	169	505
Mean (SD)	8.3 (2.8)	8.4 (2.8)	8.3 (2.8)
Median	7.9	7.8	7.9
Min ; Max	2.7 ; 19.8	4.0 ; 18.8	2.7 ; 19.8
Visit 13 (Week 11)			
N	334	166	500
Mean (SD)	8.2 (2.8)	8.9 (3.1)	8.4 (2.9)
Median	7.6	8.2	7.9
Min ; Max	2.7 ; 22.2	3.6 ; 22.0	2.7 ; 22.2
Visit 14 (Week 12)			
N	333	166	499
Mean (SD)	8.2 (2.9)	8.5 (2.8)	8.3 (2.8)
Median	7.7	8.2	7.8
Min ; Max	2.4 ; 21.4	4.2 ; 19.6	2.4 ; 21.4
Visit 15 (Week 13)			
N	325	160	485
Mean (SD)	8.1 (3.0)	8.6 (2.9)	8.3 (3.0)
Median	7.5	8.2	7.7
Min ; Max	2.4 ; 23.0	3.8 ; 17.6	2.4 ; 23.0
Visit 16 (Week 14)			
N	331	165	496
Mean (SD)	8.0 (2.8)	8.4 (2.9)	8.1 (2.9)
Median	7.2	8.0	7.5
Min ; Max	3.7 ; 19.3	3.3 ; 21.9	3.3 ; 21.9
Visit 17 (Week 15)			
N	328	164	492
Mean (SD)	7.7 (2.5)	8.4 (2.7)	7.9 (2.6)
Median	7.1	7.9	7.4
Min ; Max	3.0 ; 16.9	3.7 ; 17.2	3.0 ; 17.2

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 18 (Week 16)			
N	328	163	491
Mean (SD)	8.0 (2.8)	8.5 (2.7)	8.2 (2.8)
Median	7.4	8.0	7.6
Min ; Max	2.5 ; 18.8	4.2 ; 17.5	2.5 ; 18.8
Visit 19 (Week 17)			
N	324	161	485
Mean (SD)	7.9 (2.6)	8.3 (3.0)	8.0 (2.7)
Median	7.2	7.8	7.4
Min ; Max	3.0 ; 19.6	3.1 ; 19.1	3.0 ; 19.6
Visit 20 (Week 18)			
N	320	158	478
Mean (SD)	7.8 (2.6)	8.6 (3.2)	8.1 (2.8)
Median	7.3	8.1	7.4
Min ; Max	3.2 ; 19.0	3.6 ; 19.4	3.2 ; 19.4
Visit 21 (Week 19)			
N	320	161	481
Mean (SD)	7.6 (2.6)	8.4 (3.4)	7.9 (2.9)
Median	7.0	7.6	7.3
Min ; Max	2.5 ; 16.7	3.3 ; 23.7	2.5 ; 23.7
Visit 22 (Week 20)			
N	324	158	482
Mean (SD)	7.8 (2.8)	8.6 (2.9)	8.0 (2.8)
Median	7.2	7.9	7.4
Min ; Max	3.4 ; 18.4	3.6 ; 17.9	3.4 ; 18.4
Visit 23 (Week 21)			
N	321	156	477
Mean (SD)	7.8 (2.8)	8.3 (3.2)	8.0 (2.9)
Median	7.1	7.5	7.3
Min ; Max	2.9 ; 18.3	3.6 ; 21.9	2.9 ; 21.9
Visit 24 (Week 22)			
N	319	156	475
Mean (SD)	7.8 (2.6)	8.0 (2.9)	7.9 (2.7)
Median	7.5	7.4	7.4
Min ; Max	3.3 ; 17.2	3.6 ; 21.4	3.3 ; 21.4
Visit 25 (Week 23)			
N	320	151	471
Mean (SD)	7.8 (2.8)	8.2 (3.0)	7.9 (2.9)
Median	7.3	7.8	7.5
Min ; Max	2.9 ; 17.8	3.0 ; 23.1	2.9 ; 23.1

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 26 (Week 24)			
N	318	157	475
Mean (SD)	7.6 (2.7)	8.2 (2.8)	7.8 (2.8)
Median	7.1	7.6	7.3
Min ; Max	3.2 ; 18.4	4.3 ; 20.0	3.2 ; 20.0
Visit 27 (Week 25)			
N	318	155	473
Mean (SD)	7.6 (2.6)	8.0 (2.8)	7.8 (2.7)
Median	6.9	7.2	7.1
Min ; Max	3.2 ; 16.7	3.8 ; 17.5	3.2 ; 17.5
Visit 28 (Week 26)			
N	338	165	503
Mean (SD)	8.0 (2.7)	8.4 (3.2)	8.1 (2.9)
Median	7.6	7.7	7.6
Min ; Max	2.7 ; 19.6	2.4 ; 21.3	2.4 ; 21.3
Visit 29 (Week 27)			
N	326	154	480
Mean (SD)	9.0 (3.2)	8.2 (2.9)	8.7 (3.1)
Median	8.5	7.6	8.1
Min ; Max	2.2 ; 19.8	2.8 ; 20.3	2.2 ; 20.3
Visit 31 (Week 28)			
N	250	121	371
Mean (SD)	7.8 (2.6)	8.2 (2.5)	7.9 (2.6)
Median	7.5	7.7	7.5
Min ; Max	3.4 ; 19.8	3.8 ; 16.1	3.4 ; 19.8
Visit 32 (Week 29)			
N	250	122	372
Mean (SD)	7.6 (2.5)	8.3 (2.9)	7.8 (2.7)
Median	7.0	7.7	7.2
Min ; Max	3.5 ; 15.9	3.9 ; 19.6	3.5 ; 19.6
Visit 33 (Week 31)			
N	249	121	370
Mean (SD)	7.8 (2.7)	8.2 (2.8)	7.9 (2.7)
Median	7.2	7.7	7.5
Min ; Max	3.1 ; 21.0	3.3 ; 17.6	3.1 ; 21.0
Visit 34 (Week 33)			
N	244	119	363
Mean (SD)	7.7 (2.8)	8.3 (3.1)	7.9 (2.9)
Median	7.2	7.5	7.2
Min ; Max	3.2 ; 19.2	4.0 ; 19.3	3.2 ; 19.3

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 35 (Week 35)			
N	247	120	367
Mean (SD)	7.6 (2.7)	8.3 (2.9)	7.8 (2.8)
Median	6.8	7.6	7.2
Min ; Max	3.5 ; 18.6	4.6 ; 19.5	3.5 ; 19.5
Visit 36 (Week 37)			
N	241	118	359
Mean (SD)	7.5 (2.6)	8.3 (3.3)	7.7 (2.9)
Median	7.1	7.5	7.2
Min ; Max	3.0 ; 19.1	2.9 ; 21.8	2.9 ; 21.8
Visit 37 (Week 39)			
N	244	118	362
Mean (SD)	7.6 (2.7)	8.6 (3.3)	7.9 (2.9)
Median	7.0	7.5	7.2
Min ; Max	3.3 ; 19.8	3.9 ; 20.4	3.3 ; 20.4
Visit 38 (Week 41)			
N	237	118	355
Mean (SD)	7.7 (2.7)	8.2 (2.9)	7.8 (2.7)
Median	7.0	7.6	7.3
Min ; Max	3.5 ; 18.2	3.8 ; 16.2	3.5 ; 18.2
Visit 39 (Week 43)			
N	241	117	358
Mean (SD)	7.6 (2.5)	8.4 (2.9)	7.9 (2.7)
Median	7.0	7.8	7.3
Min ; Max	2.7 ; 17.3	4.5 ; 16.9	2.7 ; 17.3
Visit 40 (Week 45)			
N	237	116	353
Mean (SD)	7.5 (2.7)	8.4 (2.8)	7.8 (2.7)
Median	7.1	8.0	7.4
Min ; Max	2.8 ; 17.7	4.1 ; 18.8	2.8 ; 18.8
Visit 41 (Week 47)			
N	238	116	354
Mean (SD)	7.4 (2.4)	8.5 (2.9)	7.8 (2.6)
Median	6.9	8.1	7.2
Min ; Max	3.7 ; 17.6	4.6 ; 19.7	3.7 ; 19.7
Visit 42 (Week 49)			
N	234	113	347
Mean (SD)	7.3 (2.4)	8.4 (2.8)	7.7 (2.6)
Median	7.0	7.9	7.2
Min ; Max	2.9 ; 16.7	4.2 ; 17.1	2.9 ; 17.1

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Evening Meal (mmol/L)			
Visit 43 (Week 51)			
N	233	112	345
Mean (SD)	7.6 (2.4)	7.9 (2.5)	7.7 (2.4)
Median	7.0	7.6	7.1
Min ; Max	3.2 ; 18.1	3.1 ; 14.1	3.1 ; 18.1
Visit 44 (Week 53)			
N	235	113	348
Mean (SD)	7.5 (2.3)	7.9 (2.5)	7.6 (2.4)
Median	7.1	7.4	7.2
Min ; Max	3.9 ; 15.6	4.4 ; 17.8	3.9 ; 17.8
Visit 44 (Week 53) (LOCF)			
N	364	181	545
Mean (SD)	8.1 (2.8)	8.4 (3.1)	8.2 (2.9)
Median	7.5	7.6	7.5
Min ; Max	3.7 ; 17.6	3.3 ; 20.2	3.3 ; 20.2

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 2 (Week 0)			
N	359	180	539
Mean (SD)	10.2 (3.2)	10.0 (3.3)	10.1 (3.3)
Median	9.7	9.5	9.7
Min ; Max	3.3 ; 20.5	3.4 ; 21.3	3.3 ; 21.3
Visit 3 (Week 1)			
N	358	175	533
Mean (SD)	9.7 (3.5)	11.4 (3.9)	10.3 (3.8)
Median	9.2	11.1	9.8
Min ; Max	2.6 ; 21.4	4.5 ; 26.1	2.6 ; 26.1
Visit 4 (Week 2)			
N	356	175	531
Mean (SD)	9.6 (3.5)	10.6 (3.8)	9.9 (3.6)
Median	9.0	9.7	9.3
Min ; Max	2.4 ; 23.4	3.5 ; 21.7	2.4 ; 23.4
Visit 5 (Week 3)			
N	342	175	517
Mean (SD)	9.3 (3.5)	10.2 (3.4)	9.6 (3.5)
Median	8.7	9.9	9.1
Min ; Max	2.9 ; 23.1	3.9 ; 20.0	2.9 ; 23.1
Visit 6 (Week 4)			
N	349	174	523
Mean (SD)	9.1 (3.5)	9.6 (3.3)	9.3 (3.5)
Median	8.5	8.8	8.6
Min ; Max	2.2 ; 24.2	4.1 ; 19.6	2.2 ; 24.2
Visit 7 (Week 5)			
N	347	173	520
Mean (SD)	8.8 (3.1)	9.1 (3.4)	8.9 (3.2)
Median	8.3	8.2	8.2
Min ; Max	3.3 ; 19.0	3.2 ; 19.1	3.2 ; 19.1
Visit 8 (Week 6)			
N	338	172	510
Mean (SD)	8.7 (3.1)	9.1 (3.5)	8.9 (3.2)
Median	8.1	8.5	8.3
Min ; Max	3.3 ; 20.4	2.8 ; 23.4	2.8 ; 23.4
Visit 9 (Week 7)			
N	337	171	508
Mean (SD)	8.5 (3.1)	9.0 (3.1)	8.7 (3.1)
Median	8.0	8.5	8.1
Min ; Max	1.6 ; 20.8	4.3 ; 18.4	1.6 ; 20.8

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 10 (Week 8)			
N	338	171	509
Mean (SD)	8.4 (2.6)	9.2 (3.5)	8.7 (3.0)
Median	7.9	8.6	8.1
Min ; Max	3.3 ; 19.0	4.2 ; 22.1	3.3 ; 22.1
Visit 11 (Week 9)			
N	329	166	495
Mean (SD)	8.5 (3.1)	8.9 (3.2)	8.7 (3.1)
Median	7.8	8.1	7.9
Min ; Max	2.0 ; 19.8	2.5 ; 18.8	2.0 ; 19.8
Visit 12 (Week 10)			
N	335	169	504
Mean (SD)	8.5 (2.9)	8.7 (2.7)	8.5 (2.9)
Median	7.8	8.4	8.1
Min ; Max	2.9 ; 21.9	3.9 ; 19.8	2.9 ; 21.9
Visit 13 (Week 11)			
N	331	166	497
Mean (SD)	8.6 (3.0)	8.7 (3.1)	8.6 (3.0)
Median	8.0	8.3	8.0
Min ; Max	3.3 ; 19.7	4.1 ; 25.6	3.3 ; 25.6
Visit 14 (Week 12)			
N	332	166	498
Mean (SD)	8.5 (3.0)	8.8 (3.1)	8.6 (3.1)
Median	8.0	8.2	8.0
Min ; Max	2.6 ; 19.4	3.9 ; 20.3	2.6 ; 20.3
Visit 15 (Week 13)			
N	323	160	483
Mean (SD)	8.7 (3.2)	8.6 (3.0)	8.7 (3.2)
Median	8.0	8.1	8.0
Min ; Max	2.4 ; 22.2	3.0 ; 19.3	2.4 ; 22.2
Visit 16 (Week 14)			
N	330	165	495
Mean (SD)	8.4 (3.0)	8.6 (2.9)	8.4 (3.0)
Median	7.6	8.3	7.8
Min ; Max	3.5 ; 19.9	4.1 ; 19.9	3.5 ; 19.9
Visit 17 (Week 15)			
N	324	164	488
Mean (SD)	8.1 (2.6)	8.5 (2.9)	8.2 (2.7)
Median	7.6	8.2	7.7
Min ; Max	3.1 ; 17.7	2.6 ; 18.1	2.6 ; 18.1

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 18 (Week 16)			
N	327	163	490
Mean (SD)	8.3 (2.8)	8.7 (3.1)	8.4 (2.9)
Median	7.6	8.2	7.8
Min ; Max	2.1 ; 24.0	4.4 ; 19.0	2.1 ; 24.0
Visit 19 (Week 17)			
N	323	161	484
Mean (SD)	8.3 (2.8)	8.6 (2.9)	8.4 (2.8)
Median	7.7	8.0	7.8
Min ; Max	3.9 ; 18.8	4.3 ; 21.0	3.9 ; 21.0
Visit 20 (Week 18)			
N	318	158	476
Mean (SD)	8.3 (3.0)	8.6 (2.9)	8.4 (3.0)
Median	7.7	8.1	7.8
Min ; Max	2.6 ; 19.2	4.4 ; 21.4	2.6 ; 21.4
Visit 21 (Week 19)			
N	320	161	481
Mean (SD)	8.0 (2.6)	8.7 (3.3)	8.2 (2.8)
Median	7.7	7.9	7.8
Min ; Max	3.4 ; 17.1	2.6 ; 20.5	2.6 ; 20.5
Visit 22 (Week 20)			
N	320	158	478
Mean (SD)	8.3 (2.9)	8.3 (2.6)	8.3 (2.8)
Median	7.6	7.8	7.7
Min ; Max	2.8 ; 18.9	3.7 ; 16.6	2.8 ; 18.9
Visit 23 (Week 21)			
N	318	156	474
Mean (SD)	8.1 (3.0)	8.3 (3.2)	8.2 (3.0)
Median	7.4	7.6	7.4
Min ; Max	2.6 ; 23.0	3.2 ; 25.5	2.6 ; 25.5
Visit 24 (Week 22)			
N	317	156	473
Mean (SD)	8.1 (2.7)	8.3 (3.0)	8.2 (2.8)
Median	7.8	7.7	7.8
Min ; Max	2.6 ; 22.5	3.5 ; 21.9	2.6 ; 22.5
Visit 25 (Week 23)			
N	315	151	466
Mean (SD)	8.0 (2.9)	8.6 (3.0)	8.2 (2.9)
Median	7.5	8.0	7.5
Min ; Max	3.1 ; 18.6	3.4 ; 17.9	3.1 ; 18.6

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 26 (Week 24)			
N	314	157	471
Mean (SD)	8.3 (3.0)	8.4 (3.1)	8.3 (3.0)
Median	7.6	7.7	7.6
Min ; Max	3.2 ; 19.2	3.8 ; 18.2	3.2 ; 19.2
Visit 27 (Week 25)			
N	317	154	471
Mean (SD)	8.2 (2.8)	8.4 (2.8)	8.3 (2.8)
Median	7.7	7.9	7.7
Min ; Max	3.0 ; 18.8	4.1 ; 18.3	3.0 ; 18.8
Visit 28 (Week 26)			
N	335	165	500
Mean (SD)	8.3 (2.7)	8.4 (3.0)	8.3 (2.8)
Median	7.7	7.8	7.8
Min ; Max	2.9 ; 18.4	3.1 ; 22.1	2.9 ; 22.1
Visit 29 (Week 27)			
N	325	154	479
Mean (SD)	9.4 (3.4)	8.7 (3.1)	9.1 (3.3)
Median	9.0	8.0	8.6
Min ; Max	1.9 ; 24.3	3.0 ; 18.3	1.9 ; 24.3
Visit 31 (Week 28)			
N	249	121	370
Mean (SD)	8.1 (2.9)	8.0 (2.6)	8.0 (2.8)
Median	7.4	7.5	7.5
Min ; Max	3.5 ; 19.8	3.4 ; 16.1	3.4 ; 19.8
Visit 32 (Week 29)			
N	251	122	373
Mean (SD)	8.1 (2.7)	8.4 (2.9)	8.2 (2.7)
Median	7.6	7.8	7.7
Min ; Max	3.1 ; 16.8	2.9 ; 17.4	2.9 ; 17.4
Visit 33 (Week 31)			
N	245	121	366
Mean (SD)	8.1 (2.7)	8.5 (3.0)	8.2 (2.8)
Median	7.7	8.0	7.8
Min ; Max	3.9 ; 17.7	3.2 ; 20.3	3.2 ; 20.3
Visit 34 (Week 33)			
N	242	119	361
Mean (SD)	8.0 (2.9)	8.5 (2.9)	8.2 (2.9)
Median	7.4	7.7	7.5
Min ; Max	3.0 ; 17.5	3.0 ; 18.0	3.0 ; 18.0

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 35 (Week 35)			
N	246	120	366
Mean (SD)	8.1 (2.7)	8.5 (3.4)	8.2 (3.0)
Median	7.4	7.7	7.5
Min ; Max	4.3 ; 22.0	4.3 ; 21.7	4.3 ; 22.0
Visit 36 (Week 37)			
N	241	118	359
Mean (SD)	7.7 (2.7)	8.4 (2.7)	8.0 (2.7)
Median	7.4	8.2	7.6
Min ; Max	2.6 ; 17.7	3.6 ; 17.7	2.6 ; 17.7
Visit 37 (Week 39)			
N	242	118	360
Mean (SD)	8.0 (2.8)	8.6 (3.2)	8.2 (2.9)
Median	7.4	7.9	7.6
Min ; Max	3.0 ; 19.3	2.6 ; 21.0	2.6 ; 21.0
Visit 38 (Week 41)			
N	235	118	353
Mean (SD)	8.0 (2.6)	8.5 (3.1)	8.2 (2.8)
Median	7.5	7.9	7.6
Min ; Max	3.7 ; 18.6	4.2 ; 19.2	3.7 ; 19.2
Visit 39 (Week 43)			
N	238	116	354
Mean (SD)	8.3 (2.9)	8.7 (3.3)	8.4 (3.0)
Median	7.7	7.9	7.8
Min ; Max	3.3 ; 19.6	4.7 ; 22.2	3.3 ; 22.2
Visit 40 (Week 45)			
N	237	115	352
Mean (SD)	8.1 (2.8)	8.3 (3.0)	8.1 (2.8)
Median	7.4	7.5	7.4
Min ; Max	4.3 ; 17.5	3.3 ; 17.6	3.3 ; 17.6
Visit 41 (Week 47)			
N	236	116	352
Mean (SD)	8.3 (2.8)	8.8 (3.3)	8.5 (3.0)
Median	7.9	7.7	7.8
Min ; Max	2.2 ; 17.4	4.5 ; 19.2	2.2 ; 19.2
Visit 42 (Week 49)			
N	233	111	344
Mean (SD)	7.6 (2.5)	8.6 (3.1)	7.9 (2.8)
Median	7.3	7.7	7.5
Min ; Max	3.3 ; 20.5	4.3 ; 23.5	3.3 ; 23.5

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

Self Measured Plasma Glucose for Dose Adjustment (mmol/L) - Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Before Bedtime (mmol/L)			
Visit 43 (Week 51)			
N	231	112	343
Mean (SD)	7.8 (2.6)	8.3 (2.9)	8.0 (2.7)
Median	7.2	7.3	7.2
Min ; Max	3.8 ; 17.2	4.6 ; 21.2	3.8 ; 21.2
Visit 44 (Week 53)			
N	234	112	346
Mean (SD)	8.2 (2.6)	8.3 (2.7)	8.2 (2.6)
Median	7.8	7.7	7.7
Min ; Max	2.6 ; 18.7	4.3 ; 19.9	2.6 ; 19.9
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	8.7 (3.1)	8.5 (3.0)	8.6 (3.0)
Median	8.2	7.9	8.0
Min ; Max	1.9 ; 24.3	4.1 ; 22.1	1.9 ; 24.3

N = Number of Subjects, SD = Standard Deviation

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:54:46 - tdesc_numfind_tpl_t019_v01.sas/t_smpg_abs_descp_fas.txt

14.2.150: Self Measured Plasma Glucose for Dose Adjustment after 52 Treatment Weeks - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Before Breakfast (mmol/L)					
LSMeans					
IDegAsp OD	366	365	7.77	0.26	
IDet	182	181	7.62	0.30	
Treatment Contrast					
IDegAsp OD - IDet			0.15		[-0.37 ; 0.67]
Before Lunch (mmol/L)					
LSMeans					
IDegAsp OD	366	363	7.3	0.2	
IDet	182	181	8.0	0.3	
Treatment Contrast					
IDegAsp OD - IDet			-0.7		[-1.1 ; -0.2]
Before Evening Meal (mmol/L)					
LSMeans					
IDegAsp OD	366	362	8.1	0.2	
IDet	182	181	8.3	0.3	
Treatment Contrast					
IDegAsp OD - IDet			-0.2		[-0.7 ; 0.3]
Before Bedtime (mmol/L)					
LSMeans					
IDegAsp OD	366	356	8.8	0.3	
IDet	182	179	8.7	0.3	
Treatment Contrast					
IDegAsp OD - IDet			0.1		[-0.4 ; 0.6]

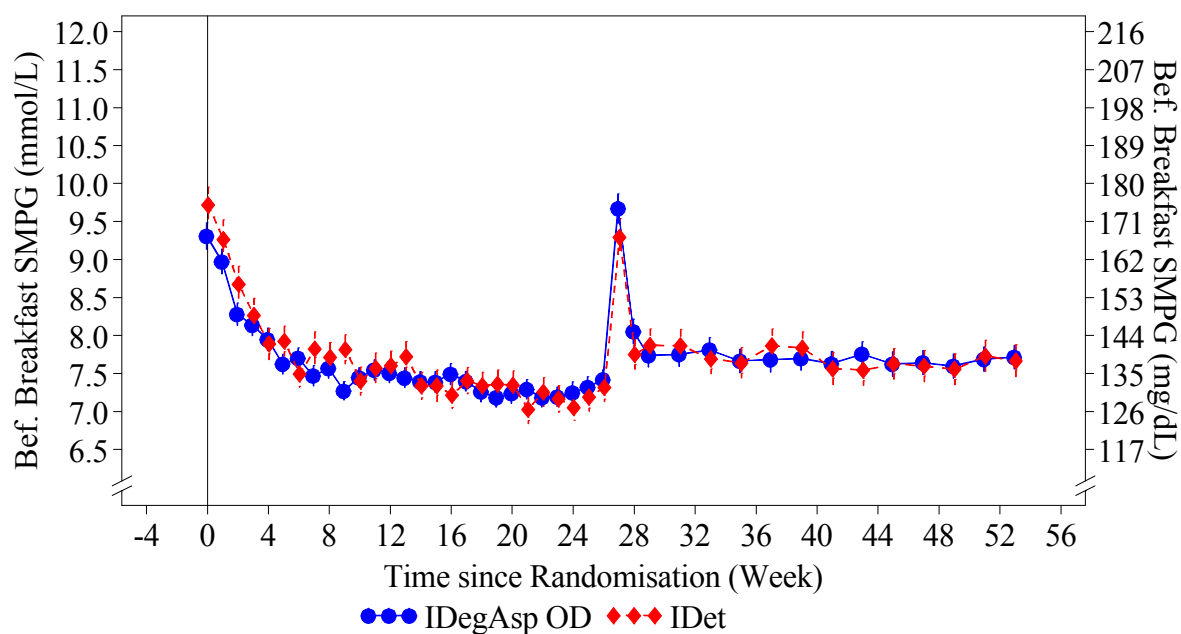
N=Number of subjects contributing to analysis, CI=Confidence Interval, SE=Standard Error of the Mean

The response after 52 weeks of treatment is analysed using an ANOVA method with treatment, region, sex and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

Endpoint is calculated as mean of the available SMPG values.

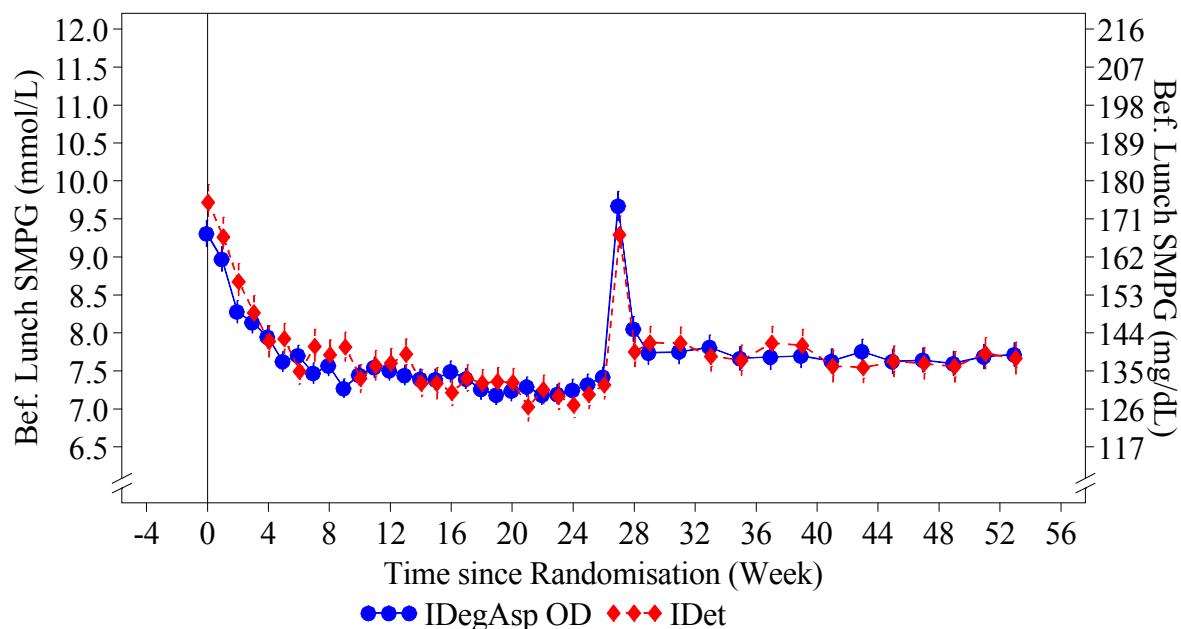
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:54:56 - tstat_find_tpl_t022.sas/t_smpg_stat_locf_fas.txt



FAS: LOCF imputed data
Endpoint is calculated as the mean of the available SMPG values,
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:55:06 - fmean_numfind_v03.sas/e_smpg_abs_bf_mean_locf_fas.cgm

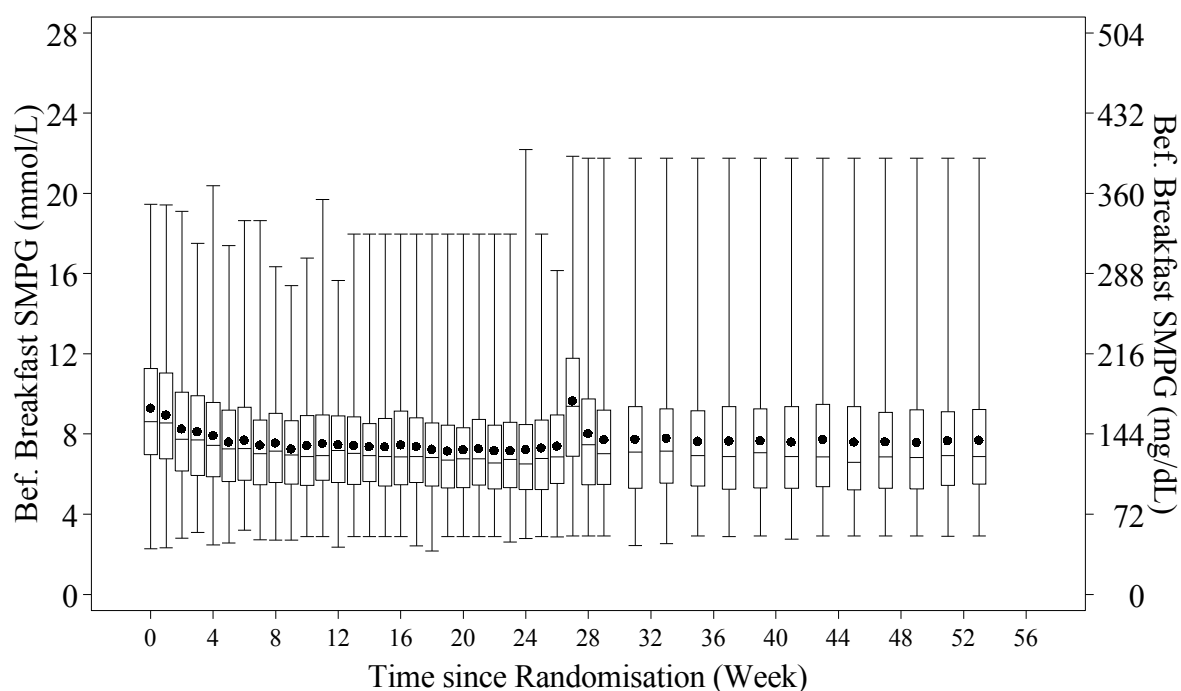
14.2.151: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set



FAS; LOCF imputed data
Endpoint is calculated as the mean of the available SMPG values,
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:55:35 - fmean_numfind_v03.sas/e_smpg_abs_l_mean_locf_fas.cgm

14.2.152: Mean Before Lunch Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set



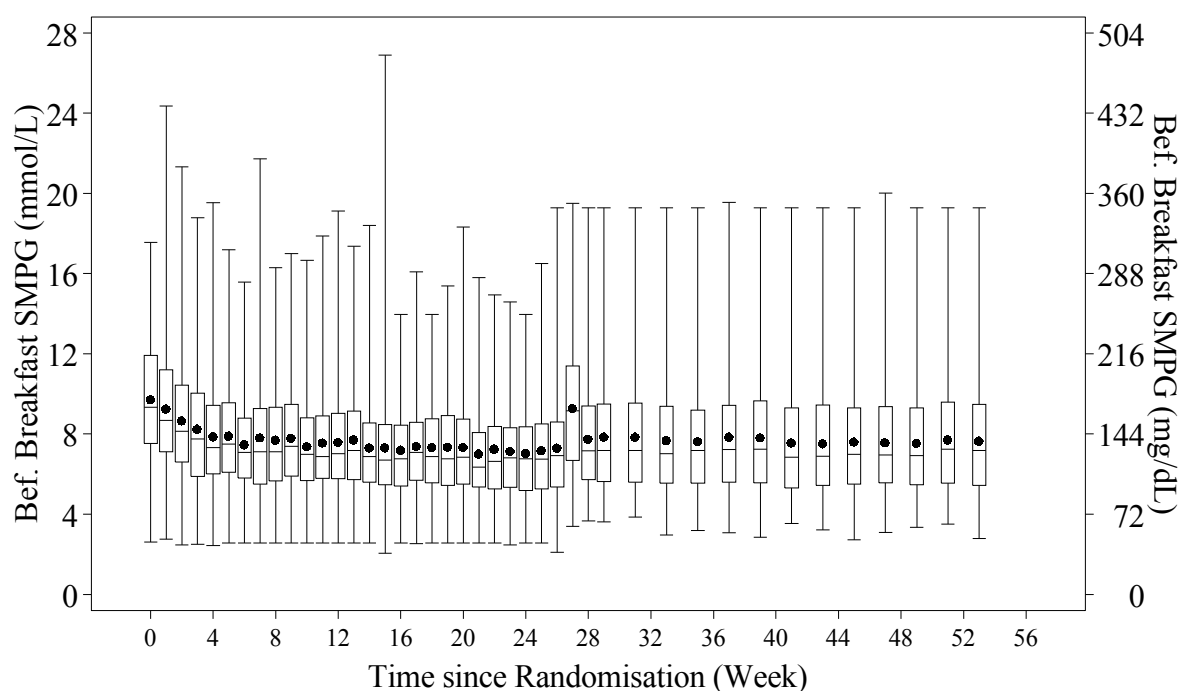
Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

FAS: LOCF imputed data

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:55:16 - fbox_numfind_v01.sas/e_smpg_inv1_abs_bf_box_locf_fas.cgm

14.2.153: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDegAsp OD - Box Plot - Full Analysis Set



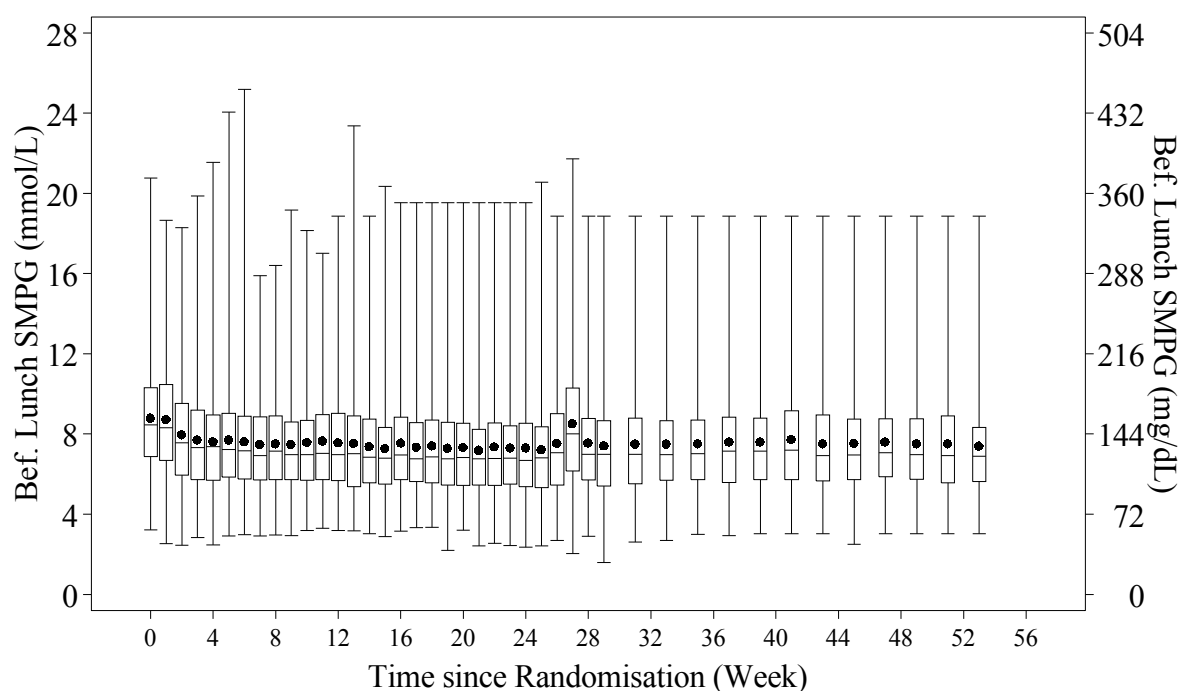
Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

EAS; LOCF imputed data

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:55:25 - fbox_numfind_v01.sas/e_smpg_com_abs_bf_box_locf_fas.cgm

14.2.154: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDet - Box Plot - Full Analysis Set



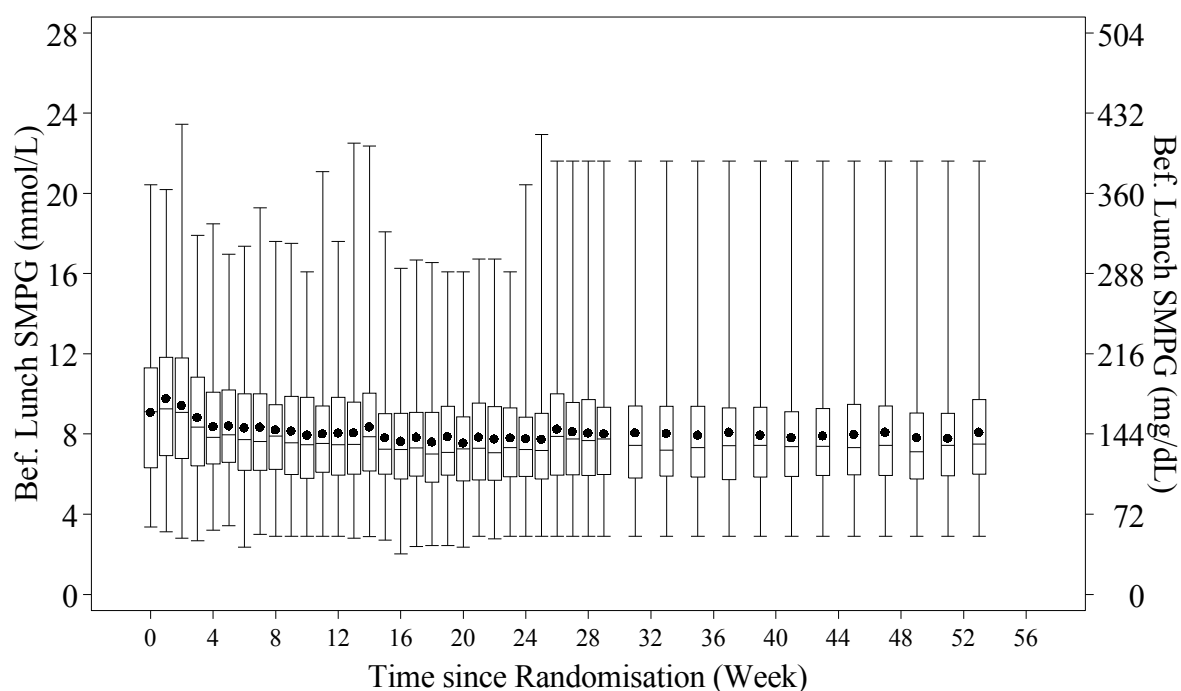
Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

FAS: LOCF imputed data

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:55:46 - fbox_numfind_v01.sas/e_smpg_inv1_abs_1_box_locf_fas.cgm

14.2.155: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDegAsp OD - Box Plot - Full Analysis Set



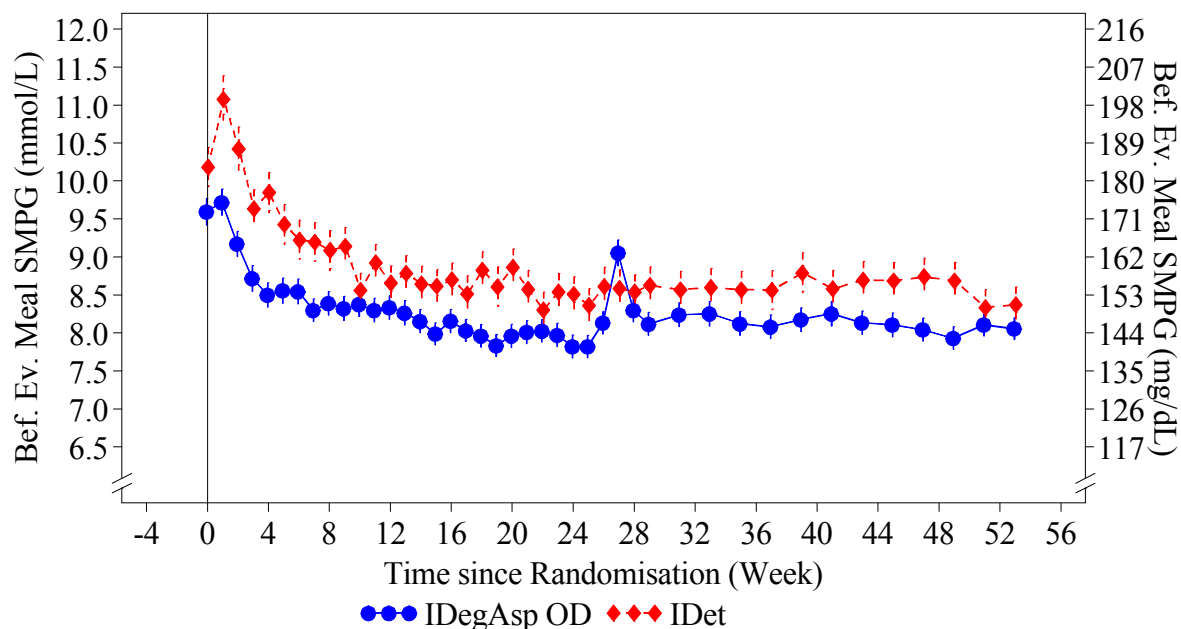
Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

FAS: LOCF imputed data

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:55:55 - fbox_numfind_v01.sas/e_smpg_com_abs_l_box_locf_fas.cgm

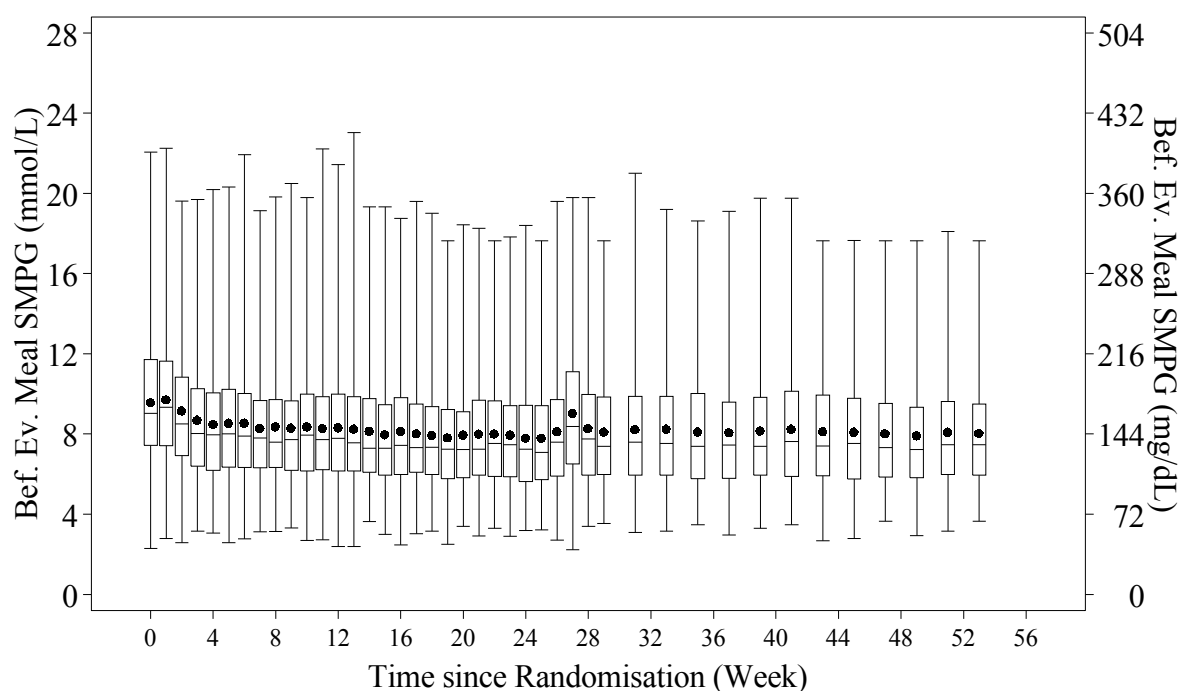
14.2.156: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDet - Box Plot - Full Analysis Set



FAS; LOCF imputed data
Endpoint is calculated as the mean of the available SMPG values,
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:56:06 - fmean_numfind_v03.sas/e_smpg_abs_ev_mean_locf_fas.cgm

14.2.157: Mean Before Main Evening Meal Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set



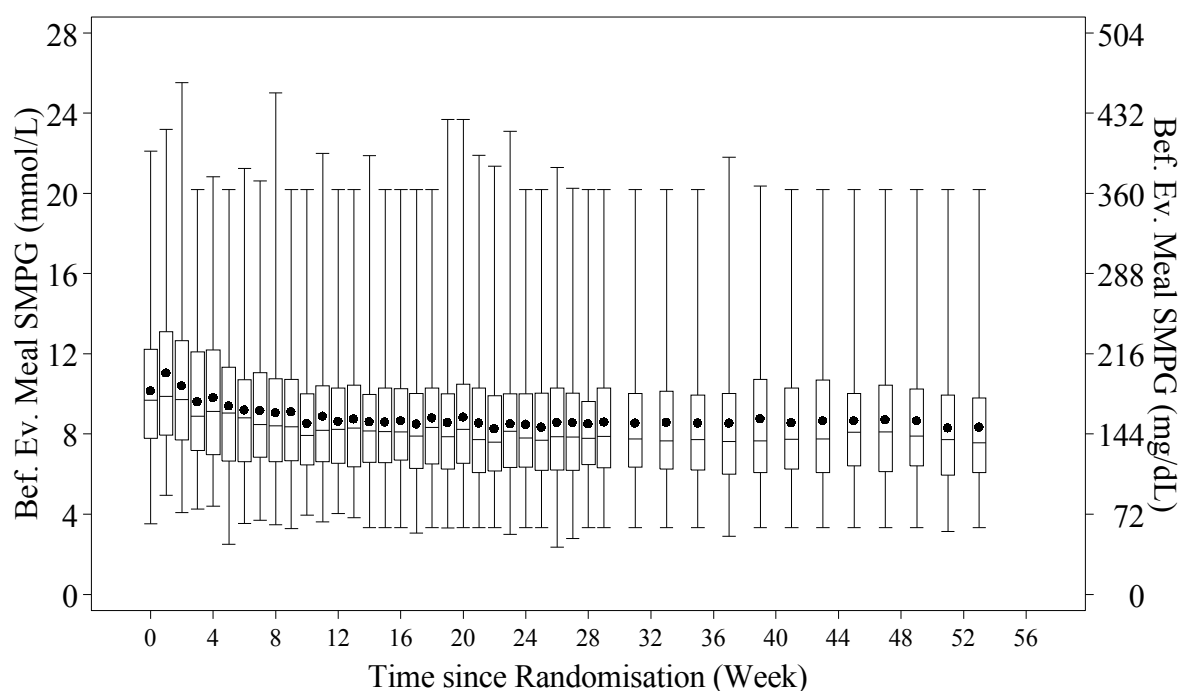
Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

EAS: LOCF imputed data

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:56:16 - fbox_numfind_v01.sas/e_smpg_invl_abs_ev_box_locf_fas.cgm

14.2.158: Mean Before Main Evening Meal Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDegAsp OD - Box Plot - Full Analysis Set



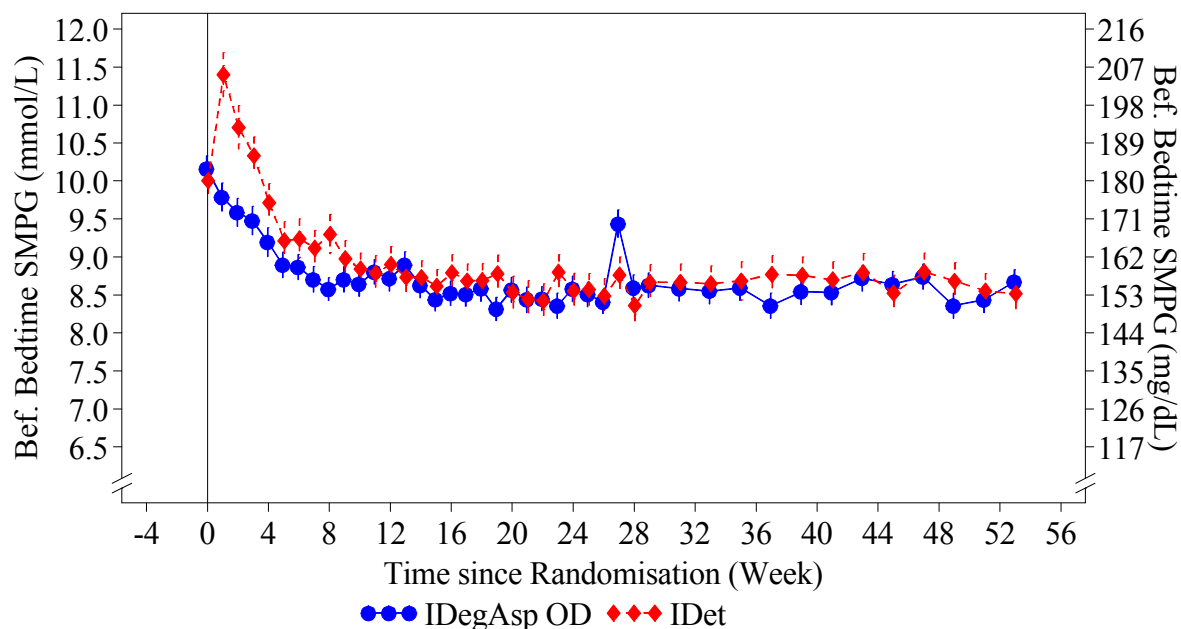
Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

FAS: LOCF imputed data

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:56:25 - fbox_numfind_v01.sas/e_smpg_com_abs_ev_box_locf_fas.cgm

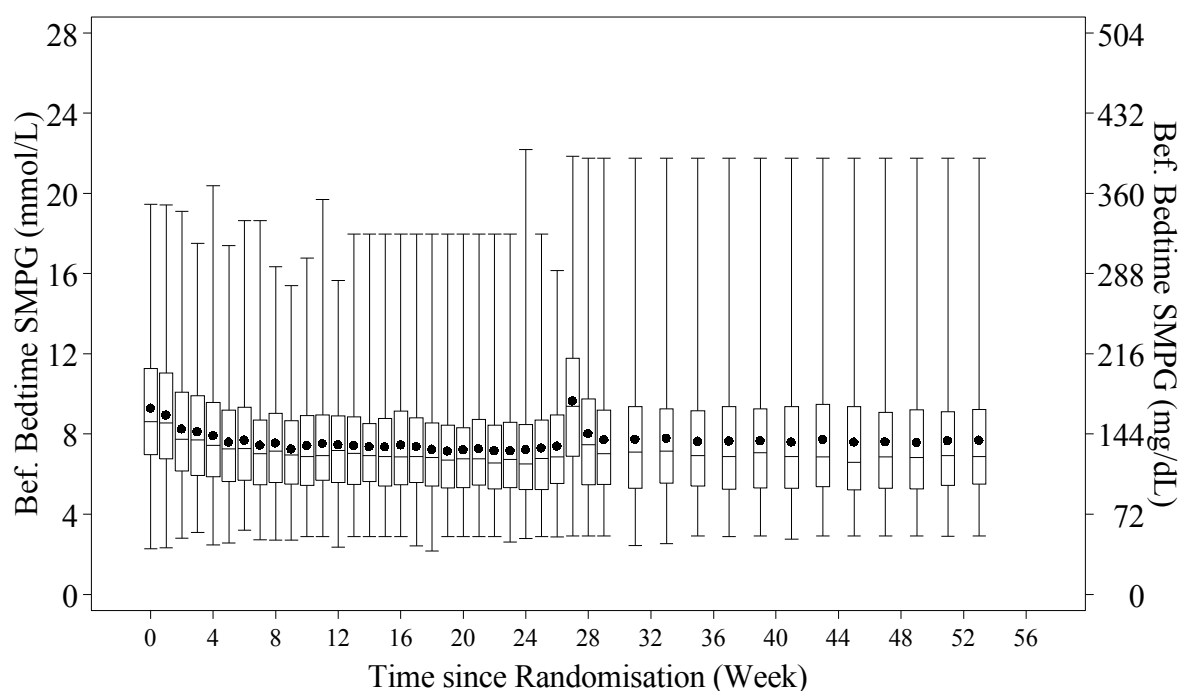
14.2.159: Mean Before Breakfast Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDet - Box Plot - Full Analysis Set



FAS; LOCF imputed data
Endpoint is calculated as the mean of the available SMPG values,
Error Bars: +/- Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:56:35 - fmean_numfind_v03.sas/e_smpg_abs_bt_mean_locf_fas.cgm

14.2.160: Mean Before Bedtime Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - Mean Plot - Full Analysis Set



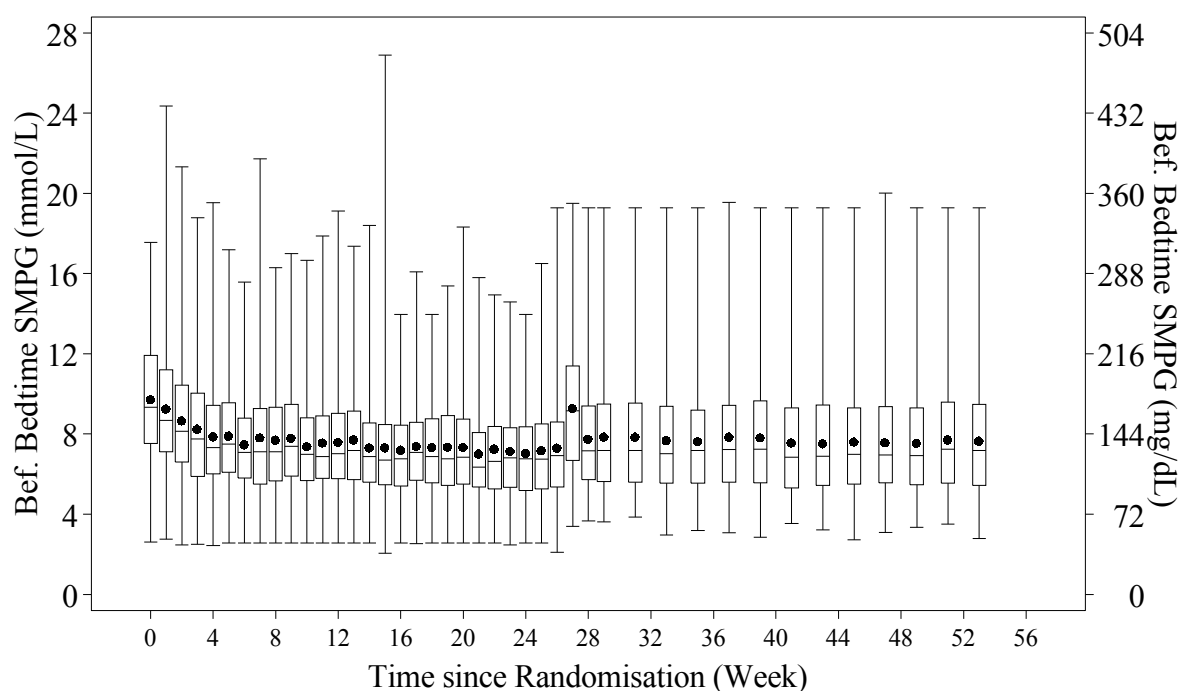
Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

EAS: LOCF imputed data

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:56:46 - fbox_numfind_v01.sas/e_smpg_inv1_abs_bt_box_focf_fas.cgm

14.2.161: Mean Before Bedtime Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDegAsp OD - Box Plot - Full Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

FAS: LOCF imputed data

Endpoint is calculated as the mean of the available SMPG values

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:56:55 - fbox_numfind_v01.sas/e_smpg_com_abs_bt_box_locf_fas.cgm

14.2.162: Mean Before Bedtime Self Measured Plasma Glucose for Dose Adjustment (mmol/L) by Treatment Week - IDet - Box Plot - Full Analysis Set

14.2.163: Within-Subject Variation in Self Measured Plasma Glucose for Dose Adjustment after 52 Treatment Weeks - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
Before Breakfast				
Within-Subject CV (%)				
IDegAsp OD	366	366	33.91	
IDet	182	181	35.00	
Treatment Ratio				
IDegAsp OD / IDet			0.97	[0.88; 1.06]

N: Number of subjects contributing to analysis

CI: Confidence Interval

CV: Coefficient of Variation

Log-transformed self measured plasma glucose values after 52 treatment weeks are analysed as repeated measures in a mixed linear model with treatment, anti-diabetic treatment at screening, region and sex as fixed effects, age as covariate and subject as random effect. The model assumes independent within and between subject variances with variances depending on treatment. In case all SMPG values are missing then last observation carried forward will be used to impute missing values. The NLmixed procedure in SAS is applied.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:57:17 - t_stat_within_smpg_var.sas/t_smpg_within_var_stat_locf_fas.txt

14.2.164: Before Breakfast Titration Target (SMPG < 5 mmol/L) by Treatment Week – Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	366	182	548
SMPG <5.0 mmol/L (Breakfast)			
Visit 2 (Week 0)			
N	365 (100.0)	181 (100.0)	546 (100.0)
Yes	26 (7.1)	11 (6.1)	37 (6.8)
No	339 (92.9)	170 (93.9)	509 (93.2)
Visit 3 (Week 1)			
N	360 (100.0)	176 (100.0)	536 (100.0)
Yes	32 (8.9)	16 (9.1)	48 (9.0)
No	328 (91.1)	160 (90.9)	488 (91.0)
Visit 4 (Week 2)			
N	359 (100.0)	175 (100.0)	534 (100.0)
Yes	31 (8.6)	14 (8.0)	45 (8.4)
No	328 (91.4)	161 (92.0)	489 (91.6)
Visit 5 (Week 3)			
N	346 (100.0)	174 (100.0)	520 (100.0)
Yes	37 (10.7)	21 (12.1)	58 (11.2)
No	309 (89.3)	153 (87.9)	462 (88.8)
Visit 6 (Week 4)			
N	350 (100.0)	174 (100.0)	524 (100.0)
Yes	50 (14.3)	19 (10.9)	69 (13.2)
No	300 (85.7)	155 (89.1)	455 (86.8)
Visit 7 (Week 5)			
N	349 (100.0)	173 (100.0)	522 (100.0)
Yes	55 (15.8)	17 (9.8)	72 (13.8)
No	294 (84.2)	156 (90.2)	450 (86.2)
Visit 8 (Week 6)			
N	343 (100.0)	173 (100.0)	516 (100.0)
Yes	44 (12.8)	17 (9.8)	61 (11.8)
No	299 (87.2)	156 (90.2)	455 (88.2)
Visit 9 (Week 7)			
N	342 (100.0)	170 (100.0)	512 (100.0)
Yes	51 (14.9)	27 (15.9)	78 (15.2)
No	291 (85.1)	143 (84.1)	434 (84.8)
Visit 10 (Week 8)			
N	339 (100.0)	171 (100.0)	510 (100.0)
Yes	52 (15.3)	24 (14.0)	76 (14.9)
No	287 (84.7)	147 (86.0)	434 (85.1)

Before Breakfast Titration Target (SMPG < 5 mmol/L) by Treatment Week - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SMPG <5.0 mmol/L (Breakfast)			
Visit 11 (Week 9)			
N	334 (100.0)	165 (100.0)	499 (100.0)
Yes	60 (18.0)	19 (11.5)	79 (15.8)
No	274 (82.0)	146 (88.5)	420 (84.2)
Visit 12 (Week 10)			
N	336 (100.0)	168 (100.0)	504 (100.0)
Yes	51 (15.2)	28 (16.7)	79 (15.7)
No	285 (84.8)	140 (83.3)	425 (84.3)
Visit 13 (Week 11)			
N	334 (100.0)	165 (100.0)	499 (100.0)
Yes	55 (16.5)	16 (9.7)	71 (14.2)
No	279 (83.5)	149 (90.3)	428 (85.8)
Visit 14 (Week 12)			
N	333 (100.0)	166 (100.0)	499 (100.0)
Yes	53 (15.9)	15 (9.0)	68 (13.6)
No	280 (84.1)	151 (91.0)	431 (86.4)
Visit 15 (Week 13)			
N	324 (100.0)	160 (100.0)	484 (100.0)
Yes	53 (16.4)	18 (11.3)	71 (14.7)
No	271 (83.6)	142 (88.8)	413 (85.3)
Visit 16 (Week 14)			
N	331 (100.0)	165 (100.0)	496 (100.0)
Yes	48 (14.5)	26 (15.8)	74 (14.9)
No	283 (85.5)	139 (84.2)	422 (85.1)
Visit 17 (Week 15)			
N	328 (100.0)	163 (100.0)	491 (100.0)
Yes	60 (18.3)	21 (12.9)	81 (16.5)
No	268 (81.7)	142 (87.1)	410 (83.5)
Visit 18 (Week 16)			
N	328 (100.0)	163 (100.0)	491 (100.0)
Yes	55 (16.8)	29 (17.8)	84 (17.1)
No	273 (83.2)	134 (82.2)	407 (82.9)
Visit 19 (Week 17)			
N	324 (100.0)	161 (100.0)	485 (100.0)
Yes	48 (14.8)	20 (12.4)	68 (14.0)
No	276 (85.2)	141 (87.6)	417 (86.0)
Visit 20 (Week 18)			
N	319 (100.0)	158 (100.0)	477 (100.0)
Yes	63 (19.7)	27 (17.1)	90 (18.9)
No	256 (80.3)	131 (82.9)	387 (81.1)

Before Breakfast Titration Target (SMPG < 5 mmol/L) by Treatment Week - Summary - Full Analysis Set

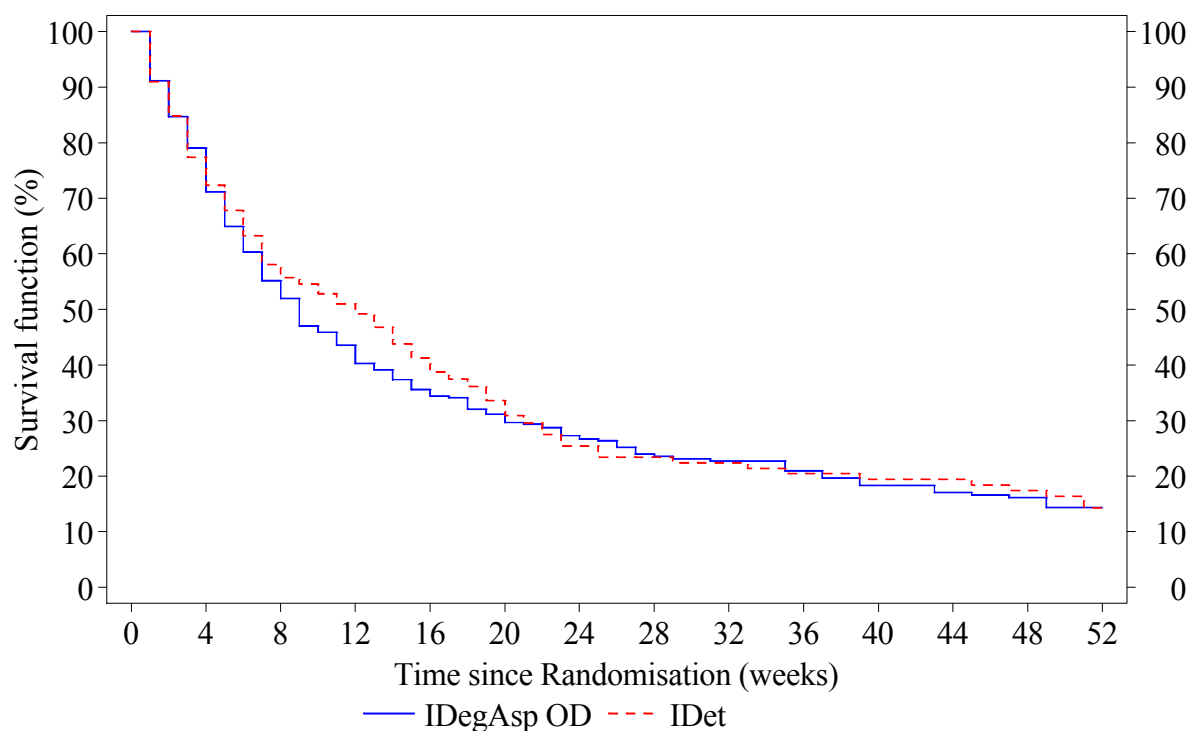
	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SMPG <5.0 mmol/L (Breakfast)			
Visit 21 (Week 19)			
N	321 (100.0)	161 (100.0)	482 (100.0)
Yes	66 (20.6)	30 (18.6)	96 (19.9)
No	255 (79.4)	131 (81.4)	386 (80.1)
Visit 22 (Week 20)			
N	324 (100.0)	158 (100.0)	482 (100.0)
Yes	58 (17.9)	26 (16.5)	84 (17.4)
No	266 (82.1)	132 (83.5)	398 (82.6)
Visit 23 (Week 21)			
N	321 (100.0)	156 (100.0)	477 (100.0)
Yes	60 (18.7)	31 (19.9)	91 (19.1)
No	261 (81.3)	125 (80.1)	386 (80.9)
Visit 24 (Week 22)			
N	319 (100.0)	156 (100.0)	475 (100.0)
Yes	65 (20.4)	34 (21.8)	99 (20.8)
No	254 (79.6)	122 (78.2)	376 (79.2)
Visit 25 (Week 23)			
N	320 (100.0)	151 (100.0)	471 (100.0)
Yes	57 (17.8)	29 (19.2)	86 (18.3)
No	263 (82.2)	122 (80.8)	385 (81.7)
Visit 26 (Week 24)			
N	318 (100.0)	157 (100.0)	475 (100.0)
Yes	67 (21.1)	31 (19.7)	98 (20.6)
No	251 (78.9)	126 (80.3)	377 (79.4)
Visit 27 (Week 25)			
N	318 (100.0)	155 (100.0)	473 (100.0)
Yes	62 (19.5)	37 (23.9)	99 (20.9)
No	256 (80.5)	118 (76.1)	374 (79.1)
Visit 28 (Week 26)			
N	339 (100.0)	165 (100.0)	504 (100.0)
Yes	58 (17.1)	29 (17.6)	87 (17.3)
No	281 (82.9)	136 (82.4)	417 (82.7)
Visit 29 (Week 27)			
N	326 (100.0)	154 (100.0)	480 (100.0)
Yes	26 (8.0)	10 (6.5)	36 (7.5)
No	300 (92.0)	144 (93.5)	444 (92.5)
Visit 31 (Week 28)			
N	250 (100.0)	121 (100.0)	371 (100.0)
Yes	52 (20.8)	16 (13.2)	68 (18.3)
No	198 (79.2)	105 (86.8)	303 (81.7)

Before Breakfast Titration Target (SMPG < 5 mmol/L) by Treatment Week - Summary - Full Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SMPG <5.0 mmol/L (Breakfast)			
Visit 32 (Week 29)			
N	251 (100.0)	122 (100.0)	373 (100.0)
Yes	48 (19.1)	22 (18.0)	70 (18.8)
No	203 (80.9)	100 (82.0)	303 (81.2)
Visit 33 (Week 31)			
N	249 (100.0)	121 (100.0)	370 (100.0)
Yes	54 (21.7)	17 (14.0)	71 (19.2)
No	195 (78.3)	104 (86.0)	299 (80.8)
Visit 34 (Week 33)			
N	244 (100.0)	119 (100.0)	363 (100.0)
Yes	47 (19.3)	22 (18.5)	69 (19.0)
No	197 (80.7)	97 (81.5)	294 (81.0)
Visit 35 (Week 35)			
N	247 (100.0)	120 (100.0)	367 (100.0)
Yes	50 (20.2)	20 (16.7)	70 (19.1)
No	197 (79.8)	100 (83.3)	297 (80.9)
Visit 36 (Week 37)			
N	241 (100.0)	118 (100.0)	359 (100.0)
Yes	63 (26.1)	18 (15.3)	81 (22.6)
No	178 (73.9)	100 (84.7)	278 (77.4)
Visit 37 (Week 39)			
N	245 (100.0)	118 (100.0)	363 (100.0)
Yes	54 (22.0)	23 (19.5)	77 (21.2)
No	191 (78.0)	95 (80.5)	286 (78.8)
Visit 38 (Week 41)			
N	237 (100.0)	118 (100.0)	355 (100.0)
Yes	56 (23.6)	25 (21.2)	81 (22.8)
No	181 (76.4)	93 (78.8)	274 (77.2)
Visit 39 (Week 43)			
N	241 (100.0)	117 (100.0)	358 (100.0)
Yes	51 (21.2)	23 (19.7)	74 (20.7)
No	190 (78.8)	94 (80.3)	284 (79.3)
Visit 40 (Week 45)			
N	237 (100.0)	116 (100.0)	353 (100.0)
Yes	54 (22.8)	20 (17.2)	74 (21.0)
No	183 (77.2)	96 (82.8)	279 (79.0)
Visit 41 (Week 47)			
N	239 (100.0)	116 (100.0)	355 (100.0)
Yes	58 (24.3)	22 (19.0)	80 (22.5)
No	181 (75.7)	94 (81.0)	275 (77.5)

Before Breakfast Titration Target (SMPG < 5 mmol/L) by Treatment Week - Summary - Full Analysis Set

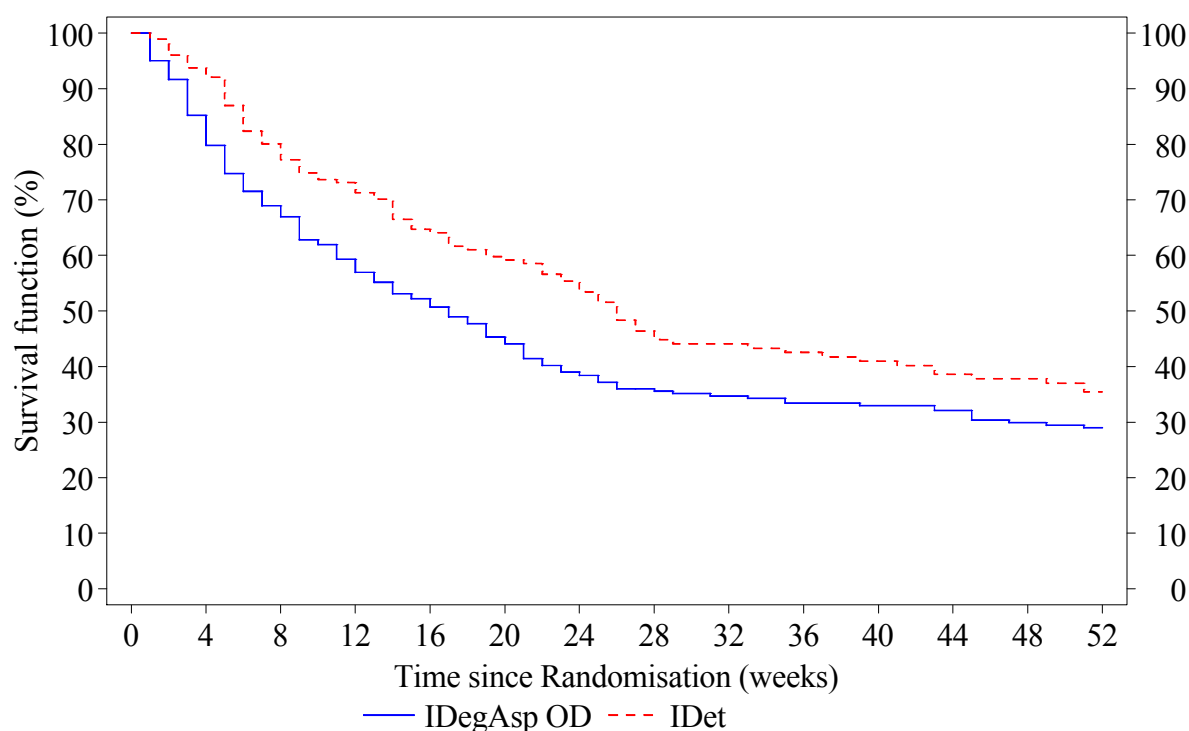
	IDegAsp OD N (%)	IDet N (%)	Total N (%)
SMPG <5.0 mmol/L (Breakfast)			
Visit 42 (Week 49)			
N	234 (100.0)	113 (100.0)	347 (100.0)
Yes	63 (26.9)	25 (22.1)	88 (25.4)
No	171 (73.1)	88 (77.9)	259 (74.6)
Visit 43 (Week 51)			
N	233 (100.0)	112 (100.0)	345 (100.0)
Yes	43 (18.5)	21 (18.8)	64 (18.6)
No	190 (81.5)	91 (81.3)	281 (81.4)
Visit 44 (Week 53)			
N	235 (100.0)	113 (100.0)	348 (100.0)
Yes	41 (17.4)	25 (22.1)	66 (19.0)
No	194 (82.6)	88 (77.9)	282 (81.0)
Visit 44 (Week 53) (LOCF)			
N	366 (100.0)	181 (100.0)	547 (100.0)
Yes	55 (15.0)	32 (17.7)	87 (15.9)
No	311 (85.0)	149 (82.3)	460 (84.1)



FAS; Observed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:57:38 - fsurv_km_v01.sas/e_titrat_targ_bf_time_surv_fas.cgm

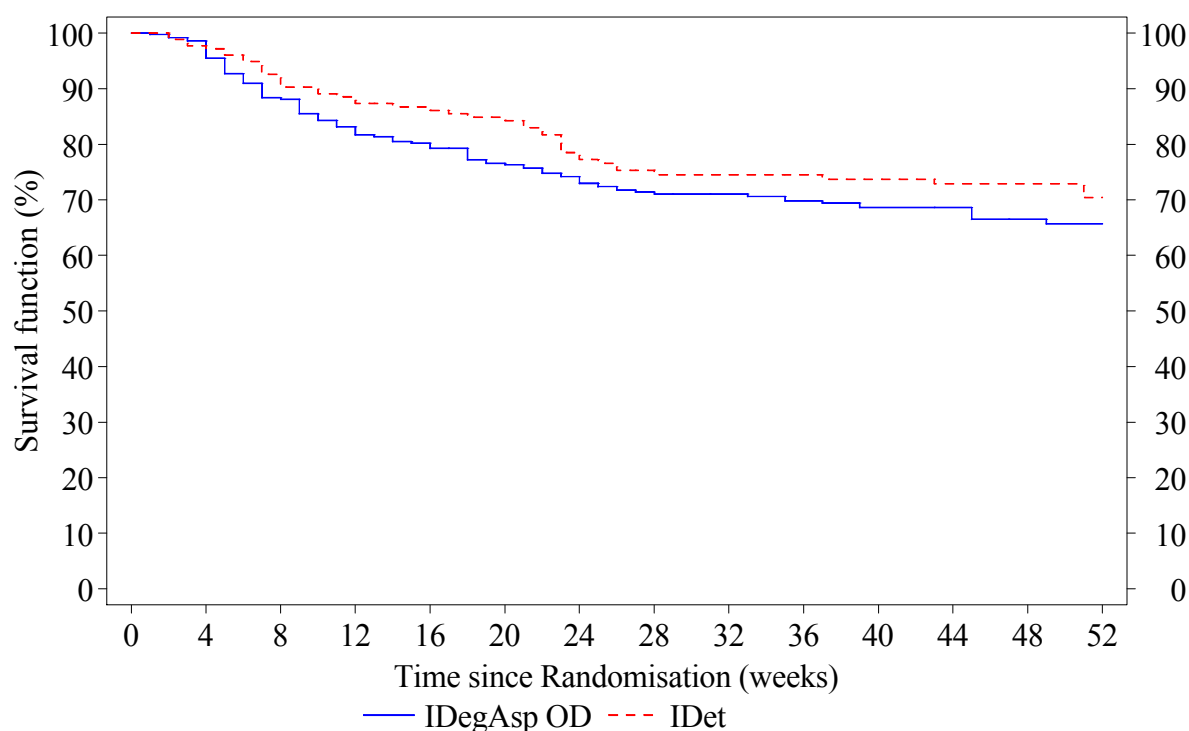
14.2.165: Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set



FAS; Observed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:57:53 - fsurv_km_v01.sas/e_titrat_targ_ev_time_surv_fas.cgm

14.2.166: Time to Before Breakfast Titration Target is Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set



FAS; Observed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:58:08 - fsurv_km_v01.sas/e_titrat_targ_all_time_surv_fas.cgm

14.2.167: Time to All Titration Targets are Met for the First Time (Treatment Week) - Kaplan-Meier Plot - Full Analysis Set

14.2.168: Time to Titration Target is Met for the First Time (Treatment Week) – Descriptive Statistics - Full Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	366	182	548
Time to SMPG<5.0 mmol/L (Breakfast) (Week)			
25% percentile	4.0	4.0	4.0
Median	9.0	12.0	9.0
75% percentile	27.0	25.0	26.0
Time to SMPG<5.0 mmol/L (Evening Meal) (Week)			
25% percentile	5.0	9.0	7.0
Median	17.0	26.0	20.0
75% percentile			
Time to SMPG<5.0 mmol/L (All Targets) (Week)			
25% percentile	22.0	28.0	24.0
Median			
75% percentile			

25%, median (50%) and 75% percentiles for the cumulative distribution function are obtained from the Kaplan-Meier survival function.

This table is based on the filter: Deletion flag value(s): (" ")

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:58:17 - tdesc_surv_tpl_t023_v01.sas/t_titrat_targ_time_descp_fas.txt

14.2.169: Time to Titration Target is Met for the First Time (Treatment Week) - Statistical Analysis - Full Analysis Set

	Estimate	95% CI
Time to SMPG <5.0 mmol/L (All Targets)		
Hazard Ratio IDegAsp OD / IDet	1.24	[0.87 ; 1.77]
Time to SMPG <5.0 mmol/L (Breakfast)		
Hazard Ratio IDegAsp OD / IDet	1.08	[0.87 ; 1.33]
Time to SMPG <5.0 mmol/L (Evening Meal)		
Hazard Ratio IDegAsp OD / IDet	1.36	[1.06 ; 1.73]

CI = Confidence Interval

Time to event is analysed using Cox Proportional Hazards model with treatment, anti-diabetic treatment at screening, region and sex as fixed effects, and age as a covariate.

Meet all targets means meet both before breakfast and main evening meal targets.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:26 - tstat_time_to_treat_week.sas/t_titrat_targ_time_stat_locf_fas.txt

14.3 Safety Data

14.3.1 Displays of Adverse Events

14.3.1.1: Adverse Events - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	267 (73.8)		1210	408	127 (70.6)		643	442	394 (72.7)		1853	419
Serious												
Yes	46 (12.7)		72	24	20 (11.1)		28	19	66 (12.2)		100	23
No	262 (72.4)		1138	383	126 (70.0)		615	423	388 (71.6)		1753	396
Severity												
Severe	64 (17.7)		98	33	34 (18.9)		70	48	98 (18.1)		168	38
Moderate	131 (36.2)		276	93	55 (30.6)		121	83	186 (34.3)		397	90
Mild	220 (60.8)		836	282	115 (63.9)		452	311	335 (61.8)		1288	291
Related to Investigational Product												
Probably	30 (8.3)		50	17	24 (13.3)		65	45	54 (10.0)		115	26
Possibly	48 (13.3)		61	21	24 (13.3)		35	24	72 (13.3)		96	22
Unlikely	252 (69.6)		1094	369	121 (67.2)		539	371	373 (68.8)		1633	369
Missing	5 (1.4)		5	2	4 (2.2)		4	3	9 (1.7)		9	2
Related to Bolus Insulin												
Probably	32 (8.8)		55	19	23 (12.8)		35	24	55 (10.1)		90	20
Possibly	39 (10.8)		52	18	21 (11.7)		35	24	60 (11.1)		87	20
Unlikely	254 (70.2)		1098	370	122 (67.8)		569	391	376 (69.4)		1667	377
Missing	5 (1.4)		5	2	4 (2.2)		4	3	9 (1.7)		9	2
Related to Device												
Yes	4 (1.1)		4	1	0 (0.0)		0	0	4 (0.7)		4	1
No	266 (73.5)		1201	405	125 (69.4)		639	439	391 (72.1)		1840	416
Missing	5 (1.4)		5	2	4 (2.2)		4	3	9 (1.7)		9	2
Outcome												
Recovered	246 (68.0)		1023	345	121 (67.2)		532	366	367 (67.7)		1555	352
Recovering	17 (4.7)		19	6	7 (3.9)		8	5	24 (4.4)		27	6
Recovered with Sequelae	2 (0.6)		2	1	1 (0.6)		1	1	3 (0.6)		3	1
Not Recovered	92 (25.4)		165	56	51 (28.3)		102	70	143 (26.4)		267	60
Unknown	1 (0.3)		1	0	0 (0.0)		0	0	1 (0.2)		1	0

N= Number of Subjects

%= Percentage of Subjects

E= Number of Events

R= Event Rate per 100 Patient Years of Exposure

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:30 - tsum_ae_tpl_t024_v01.sas/t_ae_te_sum_sas.txt

14.3.1.2: Serious Adverse Events – Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	46 (12.7)	72	24	20 (11.1)	28	19	66 (12.2)	100	23
Severity									
Severe	34 (9.4)	55	19	18 (10.0)	22	15	52 (9.6)	77	17
Moderate	15 (4.1)	16	5	3 (1.7)	5	3	18 (3.3)	21	5
Mild	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Related to Investigational Product									
Probably	16 (4.4)	27	9	7 (3.9)	8	5	23 (4.2)	35	8
Possibly	8 (2.2)	9	3	2 (1.1)	2	1	10 (1.8)	11	2
Unlikely	29 (8.0)	36	12	15 (8.3)	18	12	44 (8.1)	54	12
Related to Bolus Insulin									
Probably	14 (3.9)	27	9	9 (5.0)	11	8	23 (4.2)	38	9
Possibly	7 (1.9)	9	3	2 (1.1)	2	1	9 (1.7)	11	2
Unlikely	31 (8.6)	36	12	12 (6.7)	15	10	43 (7.9)	51	12
Related to Device									
No	46 (12.7)	72	24	20 (11.1)	28	19	66 (12.2)	100	23
Outcome									
Recovered	42 (11.6)	67	23	19 (10.6)	27	19	61 (11.3)	94	21
Recovering	1 (0.3)	1	0	0 (0.0)	0	0	1 (0.2)	1	0
Recovered with Sequelae	2 (0.6)	2	1	1 (0.6)	1	1	3 (0.6)	3	1
Not Recovered	2 (0.6)	2	1	0 (0.0)	0	0	2 (0.4)	2	0

N= Number of Subjects

%= Percentage of Subjects

E= Number of Events

R= Event Rate per 100 Patient Years of Exposure

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:32 - tsum_ae_tpl_t024_v01.sas/t_sae_te_sum_sas.txt

14.3.1.3: Serious Adverse Events – Treatment Emergent - Summary - Extension Trial Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	254				122				376			
Events	31	(12.2)	48	19	16	(13.1)	23	19	47	(12.5)	71	19
Severity												
Severe	22	(8.7)	36	14	14	(11.5)	17	14	36	(9.6)	53	14
Moderate	11	(4.3)	12	5	3	(2.5)	5	4	14	(3.7)	17	5
Mild	0	(0.0)	0	0	1	(0.8)	1	1	1	(0.3)	1	0
Related to Investigational Product												
Probably	10	(3.9)	19	7	5	(4.1)	6	5	15	(4.0)	25	7
Possibly	5	(2.0)	5	2	1	(0.8)	1	1	6	(1.6)	6	2
Unlikely	20	(7.9)	24	9	13	(10.7)	16	13	33	(8.8)	40	11
Related to Bolus Insulin												
Probably	9	(3.5)	21	8	7	(5.7)	8	7	16	(4.3)	29	8
Possibly	4	(1.6)	4	2	2	(1.6)	2	2	6	(1.6)	6	2
Unlikely	21	(8.3)	23	9	10	(8.2)	13	11	31	(8.2)	36	10
Related to Device												
No	31	(12.2)	48	19	16	(13.1)	23	19	47	(12.5)	71	19
Outcome												
Recovered	29	(11.4)	46	18	16	(13.1)	23	19	45	(12.0)	69	18
Recovered with Sequelae	1	(0.4)	1	0	0	(0.0)	0	0	1	(0.3)	1	0
Not Recovered	1	(0.4)	1	0	0	(0.0)	0	0	1	(0.3)	1	0

N= Number of Subjects

%= Percentage of Subjects

E= Number of Events

R= Event Rate per 100 Patient Years of Exposure

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:35 - tsum_ae_tpl_t024_v01.sas/t_sae_te_sum_ets.txt

14.3.1.4: Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 5\%$]- Treatment Emergent - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	N	Total (%)	E	R
Number of Subjects	362				180				542			
Events	172	(47.5)	441	149	92	(51.1)	253	174	264	(48.7)	694	157
Infections and infestations												
Gastroenteritis	15	(4.1)	16	5	9	(5.0)	10	7	24	(4.4)	26	6
Influenza	25	(6.9)	25	8	9	(5.0)	12	8	34	(6.3)	37	8
Nasopharyngitis	89	(24.6)	139	47	38	(21.1)	62	43	127	(23.4)	201	45
Upper respiratory tract infection	33	(9.1)	48	16	20	(11.1)	30	21	53	(9.8)	78	18
Metabolism and nutrition disorders												
Hypoglycaemia	41	(11.3)	65	22	31	(17.2)	59	41	72	(13.3)	124	28
Nervous system disorders												
Headache	35	(9.7)	102	34	16	(8.9)	22	15	51	(9.4)	124	28
Gastrointestinal disorders												
Diarrhoea	13	(3.6)	14	5	12	(6.7)	12	8	25	(4.6)	26	6
Nausea	14	(3.9)	24	8	9	(5.0)	10	7	23	(4.2)	34	8
General disorders and administration site conditions												
Injection site reaction	5	(1.4)	8	3	9	(5.0)	36	25	14	(2.6)	44	10

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events

R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:52 - tsum_ae_soc.sas/t_ae_te_soc_pf_most_freq_sum_sas.txt

14.3.1.5: Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$]- Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Events	240	(66.3)	901	303	123	(68.3)	506	348	363	(67.0)	1407	318
Infections and infestations												
Acute tonsillitis	4	(1.1)	6	2	1	(0.6)	1	1	5	(0.9)	7	2
Bronchitis	9	(2.5)	9	3	6	(3.3)	6	4	15	(2.8)	15	3
Ear infection	4	(1.1)	4	1					4	(0.7)	4	1
Eye infection	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Gastroenteritis	15	(4.1)	16	5	9	(5.0)	10	7	24	(4.4)	26	6
Gastroenteritis viral	5	(1.4)	6	2	2	(1.1)	2	1	7	(1.3)	8	2
Infection	5	(1.4)	5	2	1	(0.6)	1	1	6	(1.1)	6	1
Influenza	25	(6.9)	25	8	9	(5.0)	12	8	34	(6.3)	37	8
Localised infection	5	(1.4)	5	2	3	(1.7)	3	2	8	(1.5)	8	2
Nasopharyngitis	89	(24.6)	139	47	38	(21.1)	62	43	127	(23.4)	201	45
Oral herpes	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Pharyngitis	8	(2.2)	11	4	1	(0.6)	1	1	9	(1.7)	12	3
Pneumonia	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Respiratory tract infection	1	(0.3)	1	0	4	(2.2)	5	3	5	(0.9)	6	1
Sinusitis	14	(3.9)	18	6	5	(2.8)	5	3	19	(3.5)	23	5
Tinea infection					2	(1.1)	2	1	2	(0.4)	2	0
Tonsillitis	4	(1.1)	4	1					4	(0.7)	4	1
Tooth abscess	6	(1.7)	8	3	2	(1.1)	2	1	8	(1.5)	10	2
Tooth infection	7	(1.9)	7	2	1	(0.6)	1	1	8	(1.5)	8	2
Upper respiratory tract infection	33	(9.1)	48	16	20	(11.1)	30	21	53	(9.8)	78	18
Urinary tract infection	5	(1.4)	6	2	7	(3.9)	7	5	12	(2.2)	13	3
Viral infection	9	(2.5)	9	3	5	(2.8)	5	3	14	(2.6)	14	3
Viral upper respiratory tract infection	4	(1.1)	5	2	1	(0.6)	1	1	5	(0.9)	6	1

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:53 - tsum_ae_soc.sas/t_ae_te_soc_pf_one_freq_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$] - Treatment Emergent - Summary
- Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders												
Diabetic ketoacidosis	1	(0.3)	2	1	4	(2.2)	4	3	5	(0.9)	6	1
Hypercholesterolaemia	4	(1.1)	4	1	2	(1.1)	2	1	6	(1.1)	6	1
Hyperglycaemia	5	(1.4)	5	2					5	(0.9)	5	1
Hyperlipidaemia	7	(1.9)	7	2	3	(1.7)	3	2	10	(1.8)	10	2
Hypoglycaemia	41	(11.3)	65	22	31	(17.2)	59	41	72	(13.3)	124	28
Hypoglycaemic unconsciousness	9	(2.5)	9	3	7	(3.9)	7	5	16	(3.0)	16	4
Gastrointestinal disorders												
Abdominal discomfort	6	(1.7)	8	3	5	(2.8)	6	4	11	(2.0)	14	3
Abdominal distension	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Abdominal pain	6	(1.7)	7	2	3	(1.7)	3	2	9	(1.7)	10	2
Abdominal pain upper	7	(1.9)	9	3	4	(2.2)	4	3	11	(2.0)	13	3
Diarrhoea	13	(3.6)	14	5	12	(6.7)	12	8	25	(4.6)	26	6
Dyspepsia	5	(1.4)	5	2	4	(2.2)	5	3	9	(1.7)	10	2
Food poisoning	4	(1.1)	5	2	1	(0.6)	1	1	5	(0.9)	6	1
Gastritis	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Nausea	14	(3.9)	24	8	9	(5.0)	10	7	23	(4.2)	34	8
Toothache	4	(1.1)	4	1	3	(1.7)	3	2	7	(1.3)	7	2
Vomiting	15	(4.1)	16	5	6	(3.3)	7	5	21	(3.9)	23	5
Nervous system disorders												
Dizziness	6	(1.7)	6	2	1	(0.6)	1	1	7	(1.3)	7	2
Headache	35	(9.7)	102	34	16	(8.9)	22	15	51	(9.4)	124	28
Migraine	6	(1.7)	7	2	3	(1.7)	3	2	9	(1.7)	10	2
Neuropathy peripheral	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:53 - tsum_ae_soc.sas/t_ae_te_soc_pf_one_freq_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$] - Treatment Emergent - Summary
- Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
General disorders and administration site conditions												
Asthenia	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Discomfort					2	(1.1)	2	1	2	(0.4)	2	0
Fatigue	3	(0.8)	3	1	6	(3.3)	6	4	9	(1.7)	9	2
Influenza like illness	9	(2.5)	11	4	5	(2.8)	6	4	14	(2.6)	17	4
Injection site haematoma					2	(1.1)	2	1	2	(0.4)	2	0
Injection site reaction	5	(1.4)	8	3	9	(5.0)	36	25	14	(2.6)	44	10
Malaise	4	(1.1)	4	1					4	(0.7)	4	1
Oedema peripheral	8	(2.2)	12	4					8	(1.5)	12	3
Pain	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Pyrexia	10	(2.8)	11	4	7	(3.9)	8	5	17	(3.1)	19	4
Musculoskeletal and connective tissue disorders												
Arthralgia	8	(2.2)	10	3	5	(2.8)	5	3	13	(2.4)	15	3
Back pain	10	(2.8)	12	4	6	(3.3)	7	5	16	(3.0)	19	4
Musculoskeletal chest pain	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Musculoskeletal pain	5	(1.4)	5	2	7	(3.9)	7	5	12	(2.2)	12	3
Myalgia	5	(1.4)	5	2	2	(1.1)	2	1	7	(1.3)	7	2
Neck pain	7	(1.9)	8	3	3	(1.7)	4	3	10	(1.8)	12	3
Pain in extremity	11	(3.0)	13	4	3	(1.7)	4	3	14	(2.6)	17	4
Periarthritis	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Tendonitis	4	(1.1)	5	2					4	(0.7)	5	1
Respiratory, thoracic and mediastinal disorders												
Cough	9	(2.5)	11	4	2	(1.1)	2	1	11	(2.0)	13	3
Dyspnoea	7	(1.9)	7	2	2	(1.1)	2	1	9	(1.7)	9	2
Oropharyngeal pain	16	(4.4)	18	6	6	(3.3)	7	5	22	(4.1)	25	6

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:53 - tsum_ae_soc.sas/t_ae_te_soc_pf_one_freq_sum_sas.txt

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 552 of 2239

Novo Nordisk

Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$] - Treatment Emergent - Summary
- Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Sinus congestion	1	(0.3)	2	1	2	(1.1)	2	1	3	(0.6)	4	1
Injury, poisoning and procedural complications												
Epicondylitis	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Joint sprain	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Limb injury	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Medication error	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Procedural pain					2	(1.1)	2	1	2	(0.4)	2	0
Skin laceration	4	(1.1)	5	2	1	(0.6)	1	1	5	(0.9)	6	1
Vaccination complication	4	(1.1)	5	2	3	(1.7)	3	2	7	(1.3)	8	2
Wrong drug administered	10	(2.8)	12	4	6	(3.3)	6	4	16	(3.0)	18	4
Eye disorders												
Cataract	4	(1.1)	5	2	4	(2.2)	4	3	8	(1.5)	9	2
Conjunctivitis	2	(0.6)	2	1	4	(2.2)	4	3	6	(1.1)	6	1
Diabetic retinopathy	12	(3.3)	13	4	8	(4.4)	8	5	20	(3.7)	21	5
Maculopathy	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Psychiatric disorders												
Depression	8	(2.2)	8	3	3	(1.7)	3	2	11	(2.0)	11	2
Insomnia	4	(1.1)	5	2	4	(2.2)	4	3	8	(1.5)	9	2
Stress	3	(0.8)	3	1	4	(2.2)	4	3	7	(1.3)	7	2
Immune system disorders												
Hypersensitivity	5	(1.4)	6	2	2	(1.1)	2	1	7	(1.3)	8	2
Seasonal allergy	9	(2.5)	9	3	2	(1.1)	2	1	11	(2.0)	11	2
Skin and subcutaneous tissue disorders												

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:53 - tsum_ae_soc.sas/t_ae_te_soc_pf_one_freq_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$] - Treatment Emergent - Summary
- Safety Analysis Set

	IDegAsp OD			IDet			Total		
	N	(%)	E R	N	(%)	E R	N	(%)	E R
Lipodystrophy acquired	1	(0.3)	1 0	3	(1.7)	4 3	4	(0.7)	5 1
Lipohypertrophy	1	(0.3)	1 0	2	(1.1)	3 2	3	(0.6)	4 1
Rash	3	(0.8)	3 1	5	(2.8)	5 3	8	(1.5)	8 2
Vascular disorders									
Hypertension	9	(2.5)	9 3	3	(1.7)	3 2	12	(2.2)	12 3
Reproductive system and breast disorders									
Dysmenorrhoea	5	(1.4)	7 2	2	(1.1)	2 1	7	(1.3)	9 2
Ear and labyrinth disorders									
Ear pain	3	(0.8)	4 1	3	(1.7)	3 2	6	(1.1)	7 2
Investigations									
Weight increased	5	(1.4)	5 2	1	(0.6)	1 1	6	(1.1)	6 1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Uterine leiomyoma				2	(1.1)	2 1	2	(0.4)	2 0

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:53 - tsum_ae_soc.sas/t_ae_te_soc_pf_one_freq_sum_sas.txt

14.3.1.6: Serious Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 5\%$]- Treatment Emergent - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	N	Total (%)	E	R
Number of Subjects	362				180				542			
Events	15	(4.1)	25	8	9	(5.0)	9	6	24	(4.4)	34	8
Metabolism and nutrition disorders												
Hypoglycaemia	15	(4.1)	25	8	9	(5.0)	9	6	24	(4.4)	34	8

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:53 - tsum_ae_soc.sas/t_ae_te_s_soc_pf_mst_frq_sum_sas.txt

14.3.1.7: Serious Adverse Events by System Organ Class and Preferred Term - Most Frequent [$\geq 1\%$]- Treatment Emergent - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	N	Total (%)	E	R
Number of Subjects	362				180				542			
Events	21	(5.8)	34	11	15	(8.3)	16	11	36	(6.6)	50	11
Metabolism and nutrition disorders												
Diabetic ketoacidosis	1	(0.3)	2	1	3	(1.7)	3	2	4	(0.7)	5	1
Hypoglycaemia	15	(4.1)	25	8	9	(5.0)	9	6	24	(4.4)	34	8
Hypoglycaemic unconsciousness	7	(1.9)	7	2	4	(2.2)	4	3	11	(2.0)	11	2

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:53 - tsum_ae_soc.sas/t_ae_te_s_soc_pf_one_frq_sum_sas.txt

14.3.1.8: Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	267 (73.8)	1210	408	127 (70.6)	643	442	394 (72.7)	1853	419
Infections and infestations	178 (49.2)	403	136	93 (51.7)	183	126	271 (50.0)	586	132
Nasopharyngitis	89 (24.6)	139	47	38 (21.1)	62	43	127 (23.4)	201	45
Upper respiratory tract infection	33 (9.1)	48	16	20 (11.1)	30	21	53 (9.8)	78	18
Influenza	25 (6.9)	25	8	9 (5.0)	12	8	34 (6.3)	37	8
Gastroenteritis	15 (4.1)	16	5	9 (5.0)	10	7	24 (4.4)	26	6
Sinusitis	14 (3.9)	18	6	5 (2.8)	5	3	19 (3.5)	23	5
Bronchitis	9 (2.5)	9	3	6 (3.3)	6	4	15 (2.8)	15	3
Viral infection	9 (2.5)	9	3	5 (2.8)	5	3	14 (2.6)	14	3
Urinary tract infection	5 (1.4)	6	2	7 (3.9)	7	5	12 (2.2)	13	3
Pharyngitis	8 (2.2)	11	4	1 (0.6)	1	1	9 (1.7)	12	3
Localised infection	5 (1.4)	5	2	3 (1.7)	3	2	8 (1.5)	8	2
Tooth abscess	6 (1.7)	8	3	2 (1.1)	2	1	8 (1.5)	10	2
Tooth infection	7 (1.9)	7	2	1 (0.6)	1	1	8 (1.5)	8	2
Gastroenteritis viral	5 (1.4)	6	2	2 (1.1)	2	1	7 (1.3)	8	2
Infection	5 (1.4)	5	2	1 (0.6)	1	1	6 (1.1)	6	1
Acute tonsillitis	4 (1.1)	6	2	1 (0.6)	1	1	5 (0.9)	7	2
Respiratory tract infection	1 (0.3)	1	0	4 (2.2)	5	3	5 (0.9)	6	1
Viral upper respiratory tract infection	4 (1.1)	5	2	1 (0.6)	1	1	5 (0.9)	6	1
Cellulitis	3 (0.8)	3	1	1 (0.6)	1	1	4 (0.7)	4	1
Ear infection	4 (1.1)	4	1				4 (0.7)	4	1
Tonsillitis	4 (1.1)	4	1				4 (0.7)	4	1
Eye infection	1 (0.3)	1	0	2 (1.1)	2	1	3 (0.6)	3	1
Laryngitis	3 (0.8)	3	1				3 (0.6)	3	1
Oral herpes	1 (0.3)	1	0	2 (1.1)	2	1	3 (0.6)	3	1
Pneumonia	1 (0.3)	1	0	2 (1.1)	2	1	3 (0.6)	3	1
Staphylococcal skin infection	2 (0.6)	2	1	1 (0.6)	1	1	3 (0.6)	3	1
Vulvovaginal candidiasis	2 (0.6)	4	1	1 (0.6)	1	1	3 (0.6)	5	1
Abscess limb	2 (0.6)	3	1				2 (0.4)	3	1
Acute sinusitis	2 (0.6)	2	1				2 (0.4)	2	0
Candidiasis	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Fungal infection	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Gingival abscess	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Groin abscess	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
H1N1 influenza	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Pharyngitis												
streptococcal	2	(0.6)	2	1					2	(0.4)	2	0
Respiratory tract												
infection viral	2	(0.6)	2	1					2	(0.4)	2	0
Rhinitis	1	(0.3)	2	1	1	(0.6)	1	1	2	(0.4)	3	1
Tinea infection					2	(1.1)	2	1	2	(0.4)	2	0
Wound infection	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Abscess	1	(0.3)	1	0					1	(0.2)	1	0
Ascariasis	1	(0.3)	1	0					1	(0.2)	1	0
Bacterial												
infection	1	(0.3)	1	0					1	(0.2)	1	0
Blister infected	1	(0.3)	1	0					1	(0.2)	1	0
Conjunctivitis												
infective	1	(0.3)	1	0					1	(0.2)	1	0
Cystitis	1	(0.3)	1	0					1	(0.2)	1	0
Enterovirus												
infection	1	(0.3)	1	0					1	(0.2)	1	0
Erysipelas	1	(0.3)	1	0					1	(0.2)	1	0
Furuncle					1	(0.6)	1	1	1	(0.2)	1	0
Genital												
candidiasis	1	(0.3)	1	0					1	(0.2)	1	0
Helicobacter												
gastritis	1	(0.3)	1	0					1	(0.2)	1	0
Herpes simplex					1	(0.6)	1	1	1	(0.2)	1	0
Herpes zoster	1	(0.3)	1	0					1	(0.2)	1	0
Hordeolum					1	(0.6)	1	1	1	(0.2)	1	0
Intrauterine												
infection					1	(0.6)	1	1	1	(0.2)	1	0
Labyrinthitis	1	(0.3)	1	0					1	(0.2)	1	0
Lower respiratory												
tract infection	1	(0.3)	1	0					1	(0.2)	1	0
Lyme disease	1	(0.3)	1	0					1	(0.2)	1	0
Mastitis					1	(0.6)	1	1	1	(0.2)	1	0
Meningitis	1	(0.3)	1	0					1	(0.2)	1	0
Nail infection					1	(0.6)	1	1	1	(0.2)	1	0
Onychomycosis	1	(0.3)	1	0					1	(0.2)	1	0
Oral candidiasis	1	(0.3)	1	0					1	(0.2)	1	0
Oral fungal												
infection					1	(0.6)	1	1	1	(0.2)	1	0
Otitis media acute	1	(0.3)	1	0					1	(0.2)	1	0
Paronychia	1	(0.3)	1	0					1	(0.2)	1	0
Peritonsillar												
abscess					1	(0.6)	1	1	1	(0.2)	1	0
Pilonidal cyst	1	(0.3)	2	1					1	(0.2)	2	0
Pneumonia viral	1	(0.3)	1	0					1	(0.2)	1	0
Postoperative												
wound infection	1	(0.3)	2	1					1	(0.2)	2	0
Pulmonary												
tuberculosis	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Rotavirus infection	1	(0.3)	1	0					1	(0.2)	1	0
Skin infection	1	(0.3)	1	0					1	(0.2)	1	0
Staphylococcal infection	1	(0.3)	1	0					1	(0.2)	1	0
Subcutaneous abscess	1	(0.3)	4	1					1	(0.2)	4	1
Superinfection	1	(0.3)	1	0					1	(0.2)	1	0
Taeniasis	1	(0.3)	1	0					1	(0.2)	1	0
Tinea pedis					1	(0.6)	1	1	1	(0.2)	1	0
Tracheobronchitis	1	(0.3)	1	0					1	(0.2)	1	0
Vaginal infection					1	(0.6)	1	1	1	(0.2)	1	0
Vaginitis												
bacterial	1	(0.3)	1	0					1	(0.2)	1	0
Viral pharyngitis	1	(0.3)	1	0					1	(0.2)	1	0
Vulval abscess	1	(0.3)	1	0					1	(0.2)	1	0
Vulvovaginal mycotic infection	1	(0.3)	1	0					1	(0.2)	1	0
Vulvovaginitis					1	(0.6)	1	1	1	(0.2)	1	0
Metabolism and nutrition disorders	66	(18.2)	103	35	43	(23.9)	80	55	109	(20.1)	183	41
Hypoglycaemia	41	(11.3)	65	22	31	(17.2)	59	41	72	(13.3)	124	28
Hypoglycaemic unconsciousness	9	(2.5)	9	3	7	(3.9)	7	5	16	(3.0)	16	4
Hyperlipidaemia	7	(1.9)	7	2	3	(1.7)	3	2	10	(1.8)	10	2
Hypercholesterolaemia	4	(1.1)	4	1	2	(1.1)	2	1	6	(1.1)	6	1
Diabetic ketoacidosis	1	(0.3)	2	1	4	(2.2)	4	3	5	(0.9)	6	1
Hyperglycaemia	5	(1.4)	5	2					5	(0.9)	5	1
Decreased appetite	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Hypoglycaemic seizure	2	(0.6)	3	1	1	(0.6)	1	1	3	(0.6)	4	1
Dehydration	2	(0.6)	2	1					2	(0.4)	2	0
Vitamin D deficiency	2	(0.6)	2	1					2	(0.4)	2	0
Dyslipidaemia					1	(0.6)	1	1	1	(0.2)	1	0
Gout	1	(0.3)	1	0					1	(0.2)	1	0
Hypertriglyceridaemia	1	(0.3)	1	0					1	(0.2)	1	0
Hypokalaemia					1	(0.6)	1	1	1	(0.2)	1	0
Hypovolaemia					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Gastrointestinal disorders	63	(17.4)	115	39	37	(20.6)	68	47	100	(18.5)	183	41
Diarrhoea	13	(3.6)	14	5	12	(6.7)	12	8	25	(4.6)	26	6
Nausea	14	(3.9)	24	8	9	(5.0)	10	7	23	(4.2)	34	8
Vomiting	15	(4.1)	16	5	6	(3.3)	7	5	21	(3.9)	23	5
Abdominal discomfort	6	(1.7)	8	3	5	(2.8)	6	4	11	(2.0)	14	3
Abdominal pain upper	7	(1.9)	9	3	4	(2.2)	4	3	11	(2.0)	13	3
Abdominal pain	6	(1.7)	7	2	3	(1.7)	3	2	9	(1.7)	10	2
Dyspepsia	5	(1.4)	5	2	4	(2.2)	5	3	9	(1.7)	10	2
Toothache	4	(1.1)	4	1	3	(1.7)	3	2	7	(1.3)	7	2
Food poisoning	4	(1.1)	5	2	1	(0.6)	1	1	5	(0.9)	6	1
Gastritis	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Gastrooesophageal reflux disease	3	(0.8)	9	3	1	(0.6)	1	1	4	(0.7)	10	2
Abdominal distension	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Hiatus hernia	3	(0.8)	3	1					3	(0.6)	3	1
Periodontitis	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Rectal haemorrhage	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Colitis					1	(0.6)	1	1	1	(0.2)	1	0
Colonic polyp	1	(0.3)	1	0					1	(0.2)	1	0
Constipation	1	(0.3)	1	0					1	(0.2)	1	0
Enterocolitis					1	(0.6)	1	1	1	(0.2)	1	0
Flatulence					1	(0.6)	1	1	1	(0.2)	1	0
Gastric polyps	1	(0.3)	1	0					1	(0.2)	1	0
Haemorrhoids					1	(0.6)	1	1	1	(0.2)	1	0
Mouth ulceration	1	(0.3)	2	1					1	(0.2)	2	0
Oesophagitis					1	(0.6)	1	1	1	(0.2)	1	0
Pancreatitis	1	(0.3)	1	0					1	(0.2)	1	0
Pancreatitis acute					1	(0.6)	1	1	1	(0.2)	1	0
Pancreatitis chronic					1	(0.6)	1	1	1	(0.2)	1	0
Salivary gland enlargement					1	(0.6)	1	1	1	(0.2)	1	0
Small intestinal obstruction					1	(0.6)	1	1	1	(0.2)	1	0
Umbilical hernia					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Musculoskeletal and connective tissue disorders	55	(15.2)	87	29	27	(15.0)	43	30	82	(15.1)	130	29
Back pain	10	(2.8)	12	4	6	(3.3)	7	5	16	(3.0)	19	4
Pain in extremity	11	(3.0)	13	4	3	(1.7)	4	3	14	(2.6)	17	4
Arthralgia	8	(2.2)	10	3	5	(2.8)	5	3	13	(2.4)	15	3
Musculoskeletal pain	5	(1.4)	5	2	7	(3.9)	7	5	12	(2.2)	12	3
Neck pain	7	(1.9)	8	3	3	(1.7)	4	3	10	(1.8)	12	3
Myalgia	5	(1.4)	5	2	2	(1.1)	2	1	7	(1.3)	7	2
Muscle spasms	3	(0.8)	3	1	1	(0.6)	1	1	4	(0.7)	4	1
Musculoskeletal chest pain	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Periarthritis	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Tendonitis	4	(1.1)	5	2					4	(0.7)	5	1
Osteoarthritis	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Intervertebral disc protrusion	2	(0.6)	2	1					2	(0.4)	2	0
Joint swelling	1	(0.3)	2	1	1	(0.6)	1	1	2	(0.4)	3	1
Rheumatoid arthritis	2	(0.6)	2	1					2	(0.4)	2	0
Rotator cuff syndrome	2	(0.6)	2	1					2	(0.4)	2	0
Arthritis	1	(0.3)	1	0					1	(0.2)	1	0
Bunion	1	(0.3)	1	0					1	(0.2)	1	0
Costochondritis	1	(0.3)	1	0					1	(0.2)	1	0
Dupuytren's contracture	1	(0.3)	1	0					1	(0.2)	1	0
Exostosis					1	(0.6)	1	1	1	(0.2)	1	0
Foot deformity	1	(0.3)	1	0					1	(0.2)	1	0
Intervertebral disc degeneration					1	(0.6)	1	1	1	(0.2)	1	0
Intervertebral disc disorder	1	(0.3)	1	0					1	(0.2)	1	0
Joint effusion	1	(0.3)	1	0					1	(0.2)	1	0
Myositis					1	(0.6)	2	1	1	(0.2)	2	0
Osteopenia					1	(0.6)	1	1	1	(0.2)	1	0
Osteoporosis	1	(0.3)	1	0					1	(0.2)	1	0
Plantar fasciitis					1	(0.6)	1	1	1	(0.2)	1	0
Polyarthritis	1	(0.3)	1	0					1	(0.2)	1	0
Systemic lupus erythematosus	1	(0.3)	1	0					1	(0.2)	1	0
Tendon disorder	1	(0.3)	2	1					1	(0.2)	2	0
Trigger finger					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Injury, poisoning and procedural complications	50	(13.8)	68	23	29	(16.1)	37	25	79	(14.6)	105	24
Wrong drug administered	10	(2.8)	12	4	6	(3.3)	6	4	16	(3.0)	18	4
Vaccination complication	4	(1.1)	5	2	3	(1.7)	3	2	7	(1.3)	8	2
Skin laceration	4	(1.1)	5	2	1	(0.6)	1	1	5	(0.9)	6	1
Contusion	3	(0.8)	4	1	1	(0.6)	1	1	4	(0.7)	5	1
Joint sprain	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Medication error	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Muscle strain	3	(0.8)	3	1	1	(0.6)	1	1	4	(0.7)	4	1
Epicondylitis	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Fall	3	(0.8)	3	1					3	(0.6)	3	1
Foot fracture	3	(0.8)	3	1					3	(0.6)	3	1
Incorrect dose administered	3	(0.8)	3	1					3	(0.6)	3	1
Limb injury	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Tooth fracture	3	(0.8)	4	1					3	(0.6)	4	1
Ankle fracture	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Arthropod bite	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Eye injury	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Procedural pain					2	(1.1)	2	1	2	(0.4)	2	0
Rib fracture	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Road traffic accident	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Wound	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Cartilage injury					1	(0.6)	1	1	1	(0.2)	1	0
Cataract traumatic	1	(0.3)	1	0					1	(0.2)	1	0
Concussion	1	(0.3)	1	0					1	(0.2)	1	0
Corneal scar	1	(0.3)	1	0					1	(0.2)	1	0
Face injury	1	(0.3)	1	0					1	(0.2)	1	0
Foreign body					1	(0.6)	1	1	1	(0.2)	1	0
Hand fracture					1	(0.6)	1	1	1	(0.2)	1	0
Head injury	1	(0.3)	1	0					1	(0.2)	1	0
Injury corneal					1	(0.6)	1	1	1	(0.2)	1	0
Intentional overdose	1	(0.3)	2	1					1	(0.2)	2	0
Joint dislocation	1	(0.3)	1	0					1	(0.2)	1	0
Joint injury	1	(0.3)	1	0					1	(0.2)	1	0
Ligament rupture					1	(0.6)	1	1	1	(0.2)	1	0
Limb traumatic amputation					1	(0.6)	1	1	1	(0.2)	1	0
Overdose	1	(0.3)	1	0					1	(0.2)	1	0
Post procedural haemorrhage					1	(0.6)	1	1	1	(0.2)	1	0
Post-traumatic pain					1	(0.6)	1	1	1	(0.2)	1	0
Radius fracture	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Skull fracture	1	(0.3)	1	0					1	(0.2)	1	0
Soft tissue injury	1	(0.3)	1	0					1	(0.2)	1	0
Traumatic haematoma					1	(0.6)	1	1	1	(0.2)	1	0
Upper limb fracture	1	(0.3)	1	0					1	(0.2)	1	0
Nervous system disorders	54	(14.9)	135	45	23	(12.8)	33	23	77	(14.2)	168	38
Headache	35	(9.7)	102	34	16	(8.9)	22	15	51	(9.4)	124	28
Migraine	6	(1.7)	7	2	3	(1.7)	3	2	9	(1.7)	10	2
Dizziness	6	(1.7)	6	2	1	(0.6)	1	1	7	(1.3)	7	2
Lethargy	3	(0.8)	3	1					3	(0.6)	3	1
Neuropathy peripheral	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Sinus headache	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Hypoaesthesia	2	(0.6)	2	1					2	(0.4)	2	0
Paraesthesia	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Aphonia	1	(0.3)	1	0					1	(0.2)	1	0
Areflexia	1	(0.3)	1	0					1	(0.2)	1	0
Carpal tunnel syndrome	1	(0.3)	1	0					1	(0.2)	1	0
Cerebral atrophy					1	(0.6)	1	1	1	(0.2)	1	0
Hypoglycaemic coma	1	(0.3)	2	1					1	(0.2)	2	0
Memory impairment					1	(0.6)	1	1	1	(0.2)	1	0
Multiple sclerosis	1	(0.3)	1	0					1	(0.2)	1	0
Neuralgia	1	(0.3)	1	0					1	(0.2)	1	0
Neurological symptom	1	(0.3)	1	0					1	(0.2)	1	0
Phantom pain	1	(0.3)	1	0					1	(0.2)	1	0
Restless legs syndrome					1	(0.6)	1	1	1	(0.2)	1	0
Sensory loss	1	(0.3)	1	0					1	(0.2)	1	0
Syncope	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
General disorders and administration site conditions	45	(12.4)	63	21	31	(17.2)	70	48	76	(14.0)	133	30
Pyrexia	10	(2.8)	11	4	7	(3.9)	8	5	17	(3.1)	19	4
Influenza like illness	9	(2.5)	11	4	5	(2.8)	6	4	14	(2.6)	17	4
Injection site reaction	5	(1.4)	8	3	9	(5.0)	36	25	14	(2.6)	44	10
Fatigue	3	(0.8)	3	1	6	(3.3)	6	4	9	(1.7)	9	2
Oedema peripheral	8	(2.2)	12	4					8	(1.5)	12	3
Asthenia	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Malaise	4	(1.1)	4	1					4	(0.7)	4	1
Hunger	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Injection site pain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Pain	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Discomfort					2	(1.1)	2	1	2	(0.4)	2	0
Injection site haematoma					2	(1.1)	2	1	2	(0.4)	2	0
Non-cardiac chest pain	2	(0.6)	3	1					2	(0.4)	3	1
Chest discomfort	1	(0.3)	1	0					1	(0.2)	1	0
Chest pain	1	(0.3)	1	0					1	(0.2)	1	0
Cyst	1	(0.3)	1	0					1	(0.2)	1	0
Feeling cold					1	(0.6)	1	1	1	(0.2)	1	0
Injection site erythema					1	(0.6)	1	1	1	(0.2)	1	0
Injection site hypertrophy					1	(0.6)	1	1	1	(0.2)	1	0
Injection site papule					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Respiratory, thoracic and mediastinal disorders	40	(11.0)	59	20	15	(8.3)	18	12	55	(10.1)	77	17
Oropharyngeal pain	16	(4.4)	18	6	6	(3.3)	7	5	22	(4.1)	25	6
Cough	9	(2.5)	11	4	2	(1.1)	2	1	11	(2.0)	13	3
Dyspnoea	7	(1.9)	7	2	2	(1.1)	2	1	9	(1.7)	9	2
Respiratory disorder	3	(0.8)	3	1	1	(0.6)	1	1	4	(0.7)	4	1
Asthma	2	(0.6)	2	1	1	(0.6)	2	1	3	(0.6)	4	1
Sinus congestion	1	(0.3)	2	1	2	(1.1)	2	1	3	(0.6)	4	1
Epistaxis	2	(0.6)	4	1					2	(0.4)	4	1
Bronchospasm					1	(0.6)	1	1	1	(0.2)	1	0
Chronic obstructive pulmonary disease	1	(0.3)	1	0					1	(0.2)	1	0
Dysphonia					1	(0.6)	1	1	1	(0.2)	1	0
Dyspnoea exertional	1	(0.3)	1	0					1	(0.2)	1	0
Emphysema	1	(0.3)	1	0					1	(0.2)	1	0
Paranasal sinus hypersecretion	1	(0.3)	1	0					1	(0.2)	1	0
Pulmonary congestion	1	(0.3)	1	0					1	(0.2)	1	0
Pulmonary fibrosis	1	(0.3)	1	0					1	(0.2)	1	0
Respiratory tract congestion	1	(0.3)	1	0					1	(0.2)	1	0
Rhinitis allergic	1	(0.3)	1	0					1	(0.2)	1	0
Rhinorrhoea	1	(0.3)	1	0					1	(0.2)	1	0
Throat irritation	1	(0.3)	1	0					1	(0.2)	1	0
Upper respiratory tract congestion	1	(0.3)	1	0					1	(0.2)	1	0
Vocal cord disorder	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Eye disorders	25	(6.9)	35	12	16	(8.9)	26	18	41	(7.6)	61	14
Diabetic retinopathy	12	(3.3)	13	4	8	(4.4)	8	5	20	(3.7)	21	5
Cataract	4	(1.1)	5	2	4	(2.2)	4	3	8	(1.5)	9	2
Conjunctivitis	2	(0.6)	2	1	4	(2.2)	4	3	6	(1.1)	6	1
Maculopathy	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Dry eye	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Eye swelling	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Myopia	2	(0.6)	2	1					2	(0.4)	2	0
Retinal degeneration	2	(0.6)	2	1					2	(0.4)	2	0
Cataract diabetic	1	(0.3)	1	0					1	(0.2)	1	0
Conjunctivitis allergic	1	(0.3)	1	0					1	(0.2)	1	0
Eye haemorrhage	1	(0.3)	1	0					1	(0.2)	1	0
Retinal aneurysm	1	(0.3)	1	0					1	(0.2)	1	0
Retinal detachment	1	(0.3)	1	0					1	(0.2)	1	0
Retinal haemorrhage					1	(0.6)	1	1	1	(0.2)	1	0
Retinal vascular disorder	1	(0.3)	1	0					1	(0.2)	1	0
Retinopathy proliferative	1	(0.3)	1	0					1	(0.2)	1	0
Vision blurred					1	(0.6)	2	1	1	(0.2)	2	0
Visual acuity reduced					1	(0.6)	1	1	1	(0.2)	1	0
Visual impairment					1	(0.6)	1	1	1	(0.2)	1	0
Vitreous detachment					1	(0.6)	1	1	1	(0.2)	1	0
Vitreous fibrin	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Skin and subcutaneous tissue disorders	17	(4.7)	23	8	17	(9.4)	19	13	34	(6.3)	42	9
Rash	3	(0.8)	3	1	5	(2.8)	5	3	8	(1.5)	8	2
Lipodystrophy acquired	1	(0.3)	1	0	3	(1.7)	4	3	4	(0.7)	5	1
Lipohypertrophy	1	(0.3)	1	0	2	(1.1)	3	2	3	(0.6)	4	1
Pruritus	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Acne	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Dry skin	2	(0.6)	2	1					2	(0.4)	2	0
Hyperkeratosis	2	(0.6)	2	1					2	(0.4)	2	0
Rash pruritic	2	(0.6)	2	1					2	(0.4)	2	0
Alopecia	1	(0.3)	1	0					1	(0.2)	1	0
Blister	1	(0.3)	1	0					1	(0.2)	1	0
Dermatitis	1	(0.3)	1	0					1	(0.2)	1	0
Dermatitis allergic					1	(0.6)	1	1	1	(0.2)	1	0
Eczema	1	(0.3)	1	0					1	(0.2)	1	0
Erythema	1	(0.3)	1	0					1	(0.2)	1	0
Heat rash					1	(0.6)	1	1	1	(0.2)	1	0
Hyperhidrosis					1	(0.6)	1	1	1	(0.2)	1	0
Hyperkeratosis follicularis et parafollicularis	1	(0.3)	1	0					1	(0.2)	1	0
Photosensitivity allergic reaction	1	(0.3)	1	0					1	(0.2)	1	0
Photosensitivity reaction					1	(0.6)	1	1	1	(0.2)	1	0
Skin disorder	1	(0.3)	1	0					1	(0.2)	1	0
Skin irritation	1	(0.3)	1	0					1	(0.2)	1	0
Urticaria					1	(0.6)	1	1	1	(0.2)	1	0
Psychiatric disorders	20	(5.5)	26	9	11	(6.1)	13	9	31	(5.7)	39	9
Depression	8	(2.2)	8	3	3	(1.7)	3	2	11	(2.0)	11	2
Insomnia	4	(1.1)	5	2	4	(2.2)	4	3	8	(1.5)	9	2
Stress	3	(0.8)	3	1	4	(2.2)	4	3	7	(1.3)	7	2
Anxiety	3	(0.8)	4	1	1	(0.6)	1	1	4	(0.7)	5	1
Suicidal ideation	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Drug abuse	1	(0.3)	1	0					1	(0.2)	1	0
Mood altered	1	(0.3)	1	0					1	(0.2)	1	0
Sleep disorder	1	(0.3)	1	0					1	(0.2)	1	0
Suicide attempt	1	(0.3)	2	1					1	(0.2)	2	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Investigations	18	(5.0)	18	6	6	(3.3)	8	5	24	(4.4)	26	6
Weight increased	5	(1.4)	5	2	1	(0.6)	1	1	6	(1.1)	6	1
Blood pressure increased	3	(0.8)	3	1					3	(0.6)	3	1
Blood glucose increased	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Cardiac murmur	2	(0.6)	2	1					2	(0.4)	2	0
Hepatic enzyme increased	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Arthroscopy	1	(0.3)	1	0					1	(0.2)	1	0
Blood bilirubin increased	1	(0.3)	1	0					1	(0.2)	1	0
Blood cholesterol increased	1	(0.3)	1	0					1	(0.2)	1	0
Blood creatinine increased	1	(0.3)	1	0					1	(0.2)	1	0
Electrocardiogram QT prolonged	1	(0.3)	1	0					1	(0.2)	1	0
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Exercise test abnormal					1	(0.6)	1	1	1	(0.2)	1	0
Haemoglobin decreased					1	(0.6)	1	1	1	(0.2)	1	0
Intraocular pressure increased					1	(0.6)	1	1	1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	0					1	(0.2)	1	0
Urine albumin/creatinine ratio increased					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Reproductive system and breast disorders	13	(3.6)	16	5	7	(3.9)	8	5	20	(3.7)	24	5
Dysmenorrhoea	5	(1.4)	7	2	2	(1.1)	2	1	7	(1.3)	9	2
Premenstrual syndrome	2	(0.6)	2	1					2	(0.4)	2	0
Benign prostatic hyperplasia	1	(0.3)	1	0					1	(0.2)	1	0
Breast cyst					1	(0.6)	1	1	1	(0.2)	1	0
Ectropion of cervix	1	(0.3)	1	0					1	(0.2)	1	0
Endometriosis	1	(0.3)	1	0					1	(0.2)	1	0
Erectile dysfunction					1	(0.6)	1	1	1	(0.2)	1	0
Haemospermia	1	(0.3)	1	0					1	(0.2)	1	0
Metrorrhagia					1	(0.6)	1	1	1	(0.2)	1	0
Ovarian cyst	1	(0.3)	1	0					1	(0.2)	1	0
Prostatitis					1	(0.6)	1	1	1	(0.2)	1	0
Prostatomegaly	1	(0.3)	1	0					1	(0.2)	1	0
Uterine polyp	1	(0.3)	1	0					1	(0.2)	1	0
Vulvovaginal pruritus					1	(0.6)	2	1	1	(0.2)	2	0
Immune system disorders	15	(4.1)	16	5	4	(2.2)	4	3	19	(3.5)	20	5
Seasonal allergy	9	(2.5)	9	3	2	(1.1)	2	1	11	(2.0)	11	2
Hypersensitivity	5	(1.4)	6	2	2	(1.1)	2	1	7	(1.3)	8	2
Allergy to animal	1	(0.3)	1	0					1	(0.2)	1	0
Vascular disorders	12	(3.3)	14	5	6	(3.3)	6	4	18	(3.3)	20	5
Hypertension	9	(2.5)	9	3	3	(1.7)	3	2	12	(2.2)	12	3
Varicose vein	3	(0.8)	3	1	1	(0.6)	1	1	4	(0.7)	4	1
Haematoma	1	(0.3)	2	1					1	(0.2)	2	0
Hot flush					1	(0.6)	1	1	1	(0.2)	1	0
Hypotension					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Cardiac disorders	6	(1.7)	6	2	4	(2.2)	4	3	10	(1.8)	10	2
Palpitations	2	(0.6)	2	1					2	(0.4)	2	0
Angina pectoris	1	(0.3)	1	0					1	(0.2)	1	0
Atrial fibrillation					1	(0.6)	1	1	1	(0.2)	1	0
Bifascicular block	1	(0.3)	1	0					1	(0.2)	1	0
Bundle branch block right					1	(0.6)	1	1	1	(0.2)	1	0
Left ventricular dysfunction	1	(0.3)	1	0					1	(0.2)	1	0
Pericardial effusion	1	(0.3)	1	0					1	(0.2)	1	0
Tachyarrhythmia					1	(0.6)	1	1	1	(0.2)	1	0
Tachycardia					1	(0.6)	1	1	1	(0.2)	1	0
Ear and labyrinth disorders	5	(1.4)	6	2	5	(2.8)	6	4	10	(1.8)	12	3
Ear pain	3	(0.8)	4	1	3	(1.7)	3	2	6	(1.1)	7	2
Vertigo	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Middle ear effusion					1	(0.6)	1	1	1	(0.2)	1	0
Tinnitus	1	(0.3)	1	0					1	(0.2)	1	0
Tympanic membrane disorder					1	(0.6)	1	1	1	(0.2)	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	(0.3)	1	0	7	(3.9)	7	5	8	(1.5)	8	2
Uterine leiomyoma					2	(1.1)	2	1	2	(0.4)	2	0
Benign neoplasm of thyroid gland					1	(0.6)	1	1	1	(0.2)	1	0
Bladder cancer					1	(0.6)	1	1	1	(0.2)	1	0
Lipoma	1	(0.3)	1	0					1	(0.2)	1	0
Skin papilloma					1	(0.6)	1	1	1	(0.2)	1	0
Squamous cell carcinoma of skin					1	(0.6)	1	1	1	(0.2)	1	0
Thyroid neoplasm					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Renal and urinary disorders	5 (1.4)	5	2	3 (1.7)	3	2	8 (1.5)	8	2
Bladder irritation	1 (0.3)	1	0				1 (0.2)	1	0
Cystitis noninfective	1 (0.3)	1	0				1 (0.2)	1	0
Haematuria				1 (0.6)	1	1	1 (0.2)	1	0
Hydronephrosis	1 (0.3)	1	0				1 (0.2)	1	0
Ketonuria				1 (0.6)	1	1	1 (0.2)	1	0
Nephrolithiasis	1 (0.3)	1	0				1 (0.2)	1	0
Renal failure acute	1 (0.3)	1	0				1 (0.2)	1	0
Urinary incontinence				1 (0.6)	1	1	1 (0.2)	1	0
Blood and lymphatic system disorders	2 (0.6)	5	2	3 (1.7)	3	2	5 (0.9)	8	2
Anaemia	2 (0.6)	2	1	1 (0.6)	1	1	3 (0.6)	3	1
Leukocytosis				1 (0.6)	1	1	1 (0.2)	1	0
Lymphadenitis				1 (0.6)	1	1	1 (0.2)	1	0
Lymphadenopathy	1 (0.3)	3	1				1 (0.2)	3	1
Hepatobiliary disorders	1 (0.3)	1	0	2 (1.1)	2	1	3 (0.6)	3	1
Cholelithiasis				1 (0.6)	1	1	1 (0.2)	1	0
Hepatic steatosis	1 (0.3)	1	0				1 (0.2)	1	0
Hepatitis toxic				1 (0.6)	1	1	1 (0.2)	1	0
Surgical and medical procedures	2 (0.6)	3	1	1 (0.6)	1	1	3 (0.6)	4	1
Tooth extraction	1 (0.3)	2	1	1 (0.6)	1	1	2 (0.4)	3	1
Intraocular lens implant	1 (0.3)	1	0				1 (0.2)	1	0
Endocrine disorders	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Hypogonadism				1 (0.6)	1	1	1 (0.2)	1	0
Hypothyroidism	1 (0.3)	1	0				1 (0.2)	1	0
Social circumstances	1 (0.3)	1	0				1 (0.2)	1	0
Victim of crime	1 (0.3)	1	0				1 (0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:37 - tsum_events_tpl_t030_v01.sas/t_ae_te_soc_pf_sum_sas.txt

14.3.1.9: Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	46 (12.7)		72	24	20 (11.1)		28	19	66 (12.2)		100	23
Metabolism and nutrition disorders	23 (6.4)		37	12	15 (8.3)		17	12	38 (7.0)		54	12
Hypoglycaemia	15 (4.1)		25	8	9 (5.0)		9	6	24 (4.4)		34	8
Hypoglycaemic unconsciousness	7 (1.9)		7	2	4 (2.2)		4	3	11 (2.0)		11	2
Diabetic ketoacidosis	1 (0.3)		2	1	3 (1.7)		3	2	4 (0.7)		5	1
Hypoglycaemic seizure	2 (0.6)		3	1	1 (0.6)		1	1	3 (0.6)		4	1
Musculoskeletal and connective tissue disorders	6 (1.7)		6	2	2 (1.1)		2	1	8 (1.5)		8	2
Arthralgia	2 (0.6)		2	1					2 (0.4)		2	0
Osteoarthritis	1 (0.3)		1	0	1 (0.6)		1	1	2 (0.4)		2	0
Intervertebral disc degeneration					1 (0.6)		1	1	1 (0.2)		1	0
Intervertebral disc disorder	1 (0.3)		1	0					1 (0.2)		1	0
Intervertebral disc protrusion	1 (0.3)		1	0					1 (0.2)		1	0
Rotator cuff syndrome	1 (0.3)		1	0					1 (0.2)		1	0
Gastrointestinal disorders	5 (1.4)		5	2	2 (1.1)		2	1	7 (1.3)		7	2
Hiatus hernia	2 (0.6)		2	1					2 (0.4)		2	0
Abdominal pain	1 (0.3)		1	0					1 (0.2)		1	0
Food poisoning	1 (0.3)		1	0					1 (0.2)		1	0
Gastric polyps	1 (0.3)		1	0					1 (0.2)		1	0
Pancreatitis acute					1 (0.6)		1	1	1 (0.2)		1	0
Small intestinal obstruction					1 (0.6)		1	1	1 (0.2)		1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:39 - tsum_events_tpl_t030_v01.sas/t_sae_te_soc_pf_sum_sas.txt

Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Infections and infestations	5	(1.4)	5	2					5	(0.9)	5	1
Abscess limb	1	(0.3)	1	0					1	(0.2)	1	0
Gastroenteritis	1	(0.3)	1	0					1	(0.2)	1	0
Meningitis	1	(0.3)	1	0					1	(0.2)	1	0
Pulmonary tuberculosis	1	(0.3)	1	0					1	(0.2)	1	0
Wound infection	1	(0.3)	1	0					1	(0.2)	1	0
Injury, poisoning and procedural complications	4	(1.1)	5	2	1	(0.6)	1	1	5	(0.9)	6	1
Ankle fracture	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Wrong drug administered	2	(0.6)	2	1					2	(0.4)	2	0
Intentional overdose	1	(0.3)	2	1					1	(0.2)	2	0
Psychiatric disorders	3	(0.8)	5	2	1	(0.6)	1	1	4	(0.7)	6	1
Depression	2	(0.6)	2	1					2	(0.4)	2	0
Suicidal ideation	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Suicide attempt	1	(0.3)	2	1					1	(0.2)	2	0
Cardiac disorders	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Angina pectoris	1	(0.3)	1	0					1	(0.2)	1	0
Pericardial effusion	1	(0.3)	1	0					1	(0.2)	1	0
Tachyarrhythmia					1	(0.6)	1	1	1	(0.2)	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					3	(1.7)	3	2	3	(0.6)	3	1
Bladder cancer					1	(0.6)	1	1	1	(0.2)	1	0
Squamous cell carcinoma of skin					1	(0.6)	1	1	1	(0.2)	1	0
Uterine leiomyoma					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:39 - tsum_events_tpl_t030_v01.sas/t_sae_te_soc_pf_sum_sas.txt

Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Nervous system disorders	2	(0.6)	3	1					2	(0.4)	3	1
Hypoglycaemic coma	1	(0.3)	2	1					1	(0.2)	2	0
Migraine	1	(0.3)	1	0					1	(0.2)	1	0
Eye disorders	1	(0.3)	1	0					1	(0.2)	1	0
Eye haemorrhage	1	(0.3)	1	0					1	(0.2)	1	0
Immune system disorders	1	(0.3)	1	0					1	(0.2)	1	0
Hypersensitivity	1	(0.3)	1	0					1	(0.2)	1	0
Reproductive system and breast disorders	1	(0.3)	1	0					1	(0.2)	1	0
Benign prostatic hyperplasia	1	(0.3)	1	0					1	(0.2)	1	0
Respiratory, thoracic and mediastinal disorders					1	(0.6)	1	1	1	(0.2)	1	0
Dyspnoea					1	(0.6)	1	1	1	(0.2)	1	0
Social circumstances	1	(0.3)	1	0					1	(0.2)	1	0
Victim of crime	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:39 - tsum_events_tpl_t030_v01.sas/t_sae_te_soc_pf_sum_sas.txt

14.3.1.10: Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Extension Trial Set

	IDegAsp	OD			IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	254				122				376			
Events	31	(12.2)	48	19	16	(13.1)	23	19	47	(12.5)	71	19
Metabolism and nutrition disorders	13	(5.1)	22	9	12	(9.8)	13	11	25	(6.6)	35	9
Hypoglycaemia	8	(3.1)	16	6	7	(5.7)	7	6	15	(4.0)	23	6
Hypoglycaemic unconsciousness	5	(2.0)	5	2	3	(2.5)	3	2	8	(2.1)	8	2
Diabetic ketoacidosis					2	(1.6)	2	2	2	(0.5)	2	1
Hypoglycaemic seizure	1	(0.4)	1	0	1	(0.8)	1	1	2	(0.5)	2	1
Musculoskeletal and connective tissue disorders	5	(2.0)	5	2	1	(0.8)	1	1	6	(1.6)	6	2
Arthralgia	2	(0.8)	2	1					2	(0.5)	2	1
Intervertebral disc degeneration					1	(0.8)	1	1	1	(0.3)	1	0
Intervertebral disc disorder	1	(0.4)	1	0					1	(0.3)	1	0
Intervertebral disc protrusion	1	(0.4)	1	0					1	(0.3)	1	0
Rotator cuff syndrome	1	(0.4)	1	0					1	(0.3)	1	0
Gastrointestinal disorders	3	(1.2)	3	1	2	(1.6)	2	2	5	(1.3)	5	1
Abdominal pain	1	(0.4)	1	0					1	(0.3)	1	0
Food poisoning	1	(0.4)	1	0					1	(0.3)	1	0
Gastric polyps	1	(0.4)	1	0					1	(0.3)	1	0
Pancreatitis acute					1	(0.8)	1	1	1	(0.3)	1	0
Small intestinal obstruction					1	(0.8)	1	1	1	(0.3)	1	0
Infections and infestations	4	(1.6)	4	2					4	(1.1)	4	1
Abscess limb	1	(0.4)	1	0					1	(0.3)	1	0
Gastroenteritis	1	(0.4)	1	0					1	(0.3)	1	0
Meningitis	1	(0.4)	1	0					1	(0.3)	1	0
Wound infection	1	(0.4)	1	0					1	(0.3)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:41 - tsum_events_tpl_t030_v01.sas/t_sae_te_soc_pf_sum_ets.txt

Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Extension Trial Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Injury, poisoning and procedural complications	3	(1.2)	4	2	1	(0.8)	1	1	4	(1.1)	5	1
Ankle fracture	1	(0.4)	1	0	1	(0.8)	1	1	2	(0.5)	2	1
Intentional overdose	1	(0.4)	2	1					1	(0.3)	2	1
Wrong drug administered	1	(0.4)	1	0					1	(0.3)	1	0
Cardiac disorders	2	(0.8)	2	1	1	(0.8)	1	1	3	(0.8)	3	1
Angina pectoris	1	(0.4)	1	0					1	(0.3)	1	0
Pericardial effusion	1	(0.4)	1	0					1	(0.3)	1	0
Tachyarrhythmia					1	(0.8)	1	1	1	(0.3)	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					3	(2.5)	3	2	3	(0.8)	3	1
Bladder cancer					1	(0.8)	1	1	1	(0.3)	1	0
Squamous cell carcinoma of skin					1	(0.8)	1	1	1	(0.3)	1	0
Uterine leiomyoma					1	(0.8)	1	1	1	(0.3)	1	0
Nervous system disorders	2	(0.8)	3	1					2	(0.5)	3	1
Hypoglycaemic coma	1	(0.4)	2	1					1	(0.3)	2	1
Migraine	1	(0.4)	1	0					1	(0.3)	1	0
Psychiatric disorders	1	(0.4)	3	1	1	(0.8)	1	1	2	(0.5)	4	1
Depression	1	(0.4)	1	0					1	(0.3)	1	0
Suicidal ideation					1	(0.8)	1	1	1	(0.3)	1	0
Suicide attempt	1	(0.4)	2	1					1	(0.3)	2	1
Reproductive system and breast disorders	1	(0.4)	1	0					1	(0.3)	1	0
Benign prostatic hyperplasia	1	(0.4)	1	0					1	(0.3)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:41 - tsum_events_tpl_t030_v01.sas/t_sae_te_soc_pf_sum_ets.txt

Serious Adverse Events by System Organ Class and Preferred Term - Treatment Emergent -
 Summary - Extension Trial Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Respiratory, thoracic and mediastinal disorders					1	(0.8)	1	1	1	(0.3)	1	0
Dyspnoea					1	(0.8)	1	1	1	(0.3)	1	0
Social circumstances	1	(0.4)	1	0					1	(0.3)	1	0
Victim of crime	1	(0.4)	1	0					1	(0.3)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:13:59:41 - tsum_events_tpl_t030_v01.sas/t_sae_te_soc_pf_sum_ets.txt

14.3.1.11: Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	67	(18.5)	111	37	40	(22.2)	100	69	107	(19.7)	211	48
Metabolism and nutrition disorders	36	(9.9)	60	20	23	(12.8)	47	32	59	(10.9)	107	24
Hypoglycaemia	30	(8.3)	49	17	22	(12.2)	42	29	52	(9.6)	91	21
Hypoglycaemic unconsciousness	7	(1.9)	7	2	3	(1.7)	3	2	10	(1.8)	10	2
Hypoglycaemic seizure	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Hyperglycaemia	2	(0.6)	2	1					2	(0.4)	2	0
Diabetic ketoacidosis					1	(0.6)	1	1	1	(0.2)	1	0
General disorders and administration site conditions	9	(2.5)	11	4	10	(5.6)	39	27	19	(3.5)	50	11
Injection site reaction	4	(1.1)	6	2	8	(4.4)	35	24	12	(2.2)	41	9
Injection site pain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Oedema peripheral	2	(0.6)	2	1					2	(0.4)	2	0
Asthenia					1	(0.6)	1	1	1	(0.2)	1	0
Hunger	1	(0.3)	1	0					1	(0.2)	1	0
Injection site erythema					1	(0.6)	1	1	1	(0.2)	1	0
Injection site papule					1	(0.6)	1	1	1	(0.2)	1	0
Injury, poisoning and procedural complications	7	(1.9)	7	2	3	(1.7)	3	2	10	(1.8)	10	2
Wrong drug administered	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Medication error	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Incorrect dose administered	1	(0.3)	1	0					1	(0.2)	1	0
Intentional overdose	1	(0.3)	1	0					1	(0.2)	1	0
Upper limb fracture	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:44 - tsum_events_tpl_t030_v01.sas/t_ae_te_relatt_insum_sas.txt

Adverse Events Possibly or Probably Related to Investigational Medicinal Product by
System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Investigations	7	(1.9)	7	2	2	(1.1)	2	1	9	(1.7)	9	2
Weight increased	5	(1.4)	5	2	1	(0.6)	1	1	6	(1.1)	6	1
Blood glucose increased	1	(0.3)	1	0					1	(0.2)	1	0
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	0					1	(0.2)	1	0
Nervous system disorders	8	(2.2)	11	4					8	(1.5)	11	2
Headache	5	(1.4)	8	3					5	(0.9)	8	2
Hypoglycaemic coma	1	(0.3)	1	0					1	(0.2)	1	0
Lethargy	1	(0.3)	1	0					1	(0.2)	1	0
Neurological symptom	1	(0.3)	1	0					1	(0.2)	1	0
Gastrointestinal disorders	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Nausea	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Vomiting	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Abdominal discomfort	1	(0.3)	1	0					1	(0.2)	1	0
Infections and infestations	3	(0.8)	3	1	1	(0.6)	1	1	4	(0.7)	4	1
Abscess	1	(0.3)	1	0					1	(0.2)	1	0
Peritonsillar abscess					1	(0.6)	1	1	1	(0.2)	1	0
Sinusitis	1	(0.3)	1	0					1	(0.2)	1	0
Tracheobronchitis	1	(0.3)	1	0					1	(0.2)	1	0
Skin and subcutaneous tissue disorders	1	(0.3)	1	0	3	(1.7)	4	3	4	(0.7)	5	1
Lipodystrophy acquired					1	(0.6)	1	1	1	(0.2)	1	0
Lipohypertrophy					1	(0.6)	2	1	1	(0.2)	2	0
Rash					1	(0.6)	1	1	1	(0.2)	1	0
Skin disorder	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:44 - tsum_events_tpl_t030_v01.sas/t_ae_te_relatt_ins_sum_sas.txt

Adverse Events Possibly or Probably Related to Investigational Medicinal Product by
System Organ Class and Preferred Term - Treatment Emergent - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Musculoskeletal and connective tissue disorders	3	(0.8)	4	1					3	(0.6)	4	1
Arthralgia	2	(0.6)	3	1					2	(0.4)	3	1
Polyarthrititis	1	(0.3)	1	0					1	(0.2)	1	0
Eye disorders	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Diabetic retinopathy	1	(0.3)	1	0					1	(0.2)	1	0
Maculopathy					1	(0.6)	1	1	1	(0.2)	1	0
Vascular disorders	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Hypertension	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Psychiatric disorders	1	(0.3)	1	0					1	(0.2)	1	0
Suicide attempt	1	(0.3)	1	0					1	(0.2)	1	0
Respiratory, thoracic and mediastinal disorders	1	(0.3)	1	0					1	(0.2)	1	0
Dyspnoea	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:44 - tsum_events_tpl_t030_v01.sas/t_ae_te_relat_ins_sum_sas.txt

14.3.1.12: Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	62	(17.1)	107	36	39	(21.7)	70	48	101	(18.6)	177	40
Metabolism and nutrition disorders	36	(9.9)	61	21	27	(15.0)	50	34	63	(11.6)	111	25
Hypoglycaemia	30	(8.3)	50	17	23	(12.8)	42	29	53	(9.8)	92	21
Hypoglycaemic unconsciousness	8	(2.2)	8	3	6	(3.3)	6	4	14	(2.6)	14	3
Hyperglycaemia	2	(0.6)	2	1					2	(0.4)	2	0
Hypoglycaemic seizure	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Diabetic ketoacidosis					1	(0.6)	1	1	1	(0.2)	1	0
General disorders and administration site conditions	7	(1.9)	10	3	4	(2.2)	5	3	11	(2.0)	15	3
Injection site reaction	3	(0.8)	6	2	3	(1.7)	3	2	6	(1.1)	9	2
Injection site pain	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Oedema peripheral	2	(0.6)	2	1					2	(0.4)	2	0
Hunger	1	(0.3)	1	0					1	(0.2)	1	0
Injection site papule					1	(0.6)	1	1	1	(0.2)	1	0
Injury, poisoning and procedural complications	7	(1.9)	8	3	4	(2.2)	4	3	11	(2.0)	12	3
Wrong drug administered	2	(0.6)	2	1	3	(1.7)	3	2	5	(0.9)	5	1
Incorrect dose administered	2	(0.6)	2	1					2	(0.4)	2	0
Intentional overdose	1	(0.3)	2	1					1	(0.2)	2	0
Medication error					1	(0.6)	1	1	1	(0.2)	1	0
Overdose	1	(0.3)	1	0					1	(0.2)	1	0
Upper limb fracture	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:46 - tsum_events_tpl_t030_v01.sas/t_ae_te_relatabolu_sum_sas.txt

Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Investigations	6	(1.7)	6	2	2	(1.1)	2	1	8	(1.5)	8	2
Weight increased	4	(1.1)	4	1	1	(0.6)	1	1	5	(0.9)	5	1
Blood glucose increased	1	(0.3)	1	0					1	(0.2)	1	0
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	0					1	(0.2)	1	0
Nervous system disorders	7	(1.9)	11	4					7	(1.3)	11	2
Headache	5	(1.4)	8	3					5	(0.9)	8	2
Hypoglycaemic coma	1	(0.3)	2	1					1	(0.2)	2	0
Neurological symptom	1	(0.3)	1	0					1	(0.2)	1	0
Gastrointestinal disorders	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Nausea	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Abdominal discomfort	1	(0.3)	1	0					1	(0.2)	1	0
Vomiting					1	(0.6)	1	1	1	(0.2)	1	0
Infections and infestations	3	(0.8)	3	1	1	(0.6)	1	1	4	(0.7)	4	1
Abscess	1	(0.3)	1	0					1	(0.2)	1	0
Peritonsillar abscess					1	(0.6)	1	1	1	(0.2)	1	0
Sinusitis	1	(0.3)	1	0					1	(0.2)	1	0
Tracheobronchitis	1	(0.3)	1	0					1	(0.2)	1	0
Skin and subcutaneous tissue disorders	1	(0.3)	1	0	2	(1.1)	3	2	3	(0.6)	4	1
Lipohypertrophy					1	(0.6)	2	1	1	(0.2)	2	0
Rash					1	(0.6)	1	1	1	(0.2)	1	0
Skin disorder	1	(0.3)	1	0					1	(0.2)	1	0
Eye disorders	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Diabetic retinopathy	1	(0.3)	1	0					1	(0.2)	1	0
Maculopathy					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:46 - tsum_events_tpl_t030_v01.sas/t_ae_te_relata_bolus_sum_sas.txt

Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Psychiatric disorders	1 (0.3)	2	1	1 (0.6)	1	1	2 (0.4)	3	1
Suicidal ideation				1 (0.6)	1	1	1 (0.2)	1	0
Suicide attempt	1 (0.3)	2	1				1 (0.2)	2	0
Cardiac disorders				1 (0.6)	1	1	1 (0.2)	1	0
Atrial fibrillation				1 (0.6)	1	1	1 (0.2)	1	0
Musculoskeletal and connective tissue disorders	1 (0.3)	1	0				1 (0.2)	1	0
Tendonitis	1 (0.3)	1	0				1 (0.2)	1	0
Vascular disorders	1 (0.3)	1	0				1 (0.2)	1	0
Hypertension	1 (0.3)	1	0				1 (0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:46 - tsum_events_tpl_t030_v01.sas/t_ae_te_relatabolus_sum_sas.txt

14.3.1.13: Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	4	(1.1)	4	1					4	(0.7)	4	1
Metabolism and nutrition disorders	3	(0.8)	3	1					3	(0.6)	3	1
Hyperglycaemia	3	(0.8)	3	1					3	(0.6)	3	1
Investigations	1	(0.3)	1	0					1	(0.2)	1	0
Blood glucose increased	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:48 - tsum_events_tpl_t030_v01.sas/t_ae_te_relat_devis_e_sum_sas.txt

14.3.1.14: Serious Adverse Events Possibly or Probably Related Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Events	21	(5.8)	36	12	8	(4.4)	10	7	29	(5.4)	46	10
Metabolism and nutrition disorders	18	(5.0)	30	10	8	(4.4)	10	7	26	(4.8)	40	9
Hypoglycaemia	13	(3.6)	23	8	6	(3.3)	6	4	19	(3.5)	29	7
Hypoglycaemic unconsciousness	5	(1.4)	5	2	3	(1.7)	3	2	8	(1.5)	8	2
Hypoglycaemic seizure	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Injury, poisoning and procedural complications	3	(0.8)	3	1					3	(0.6)	3	1
Wrong drug administered	2	(0.6)	2	1					2	(0.4)	2	0
Intentional overdose	1	(0.3)	1	0					1	(0.2)	1	0
Musculoskeletal and connective tissue disorders	1	(0.3)	1	0					1	(0.2)	1	0
Arthralgia	1	(0.3)	1	0					1	(0.2)	1	0
Nervous system disorders	1	(0.3)	1	0					1	(0.2)	1	0
Hypoglycaemic coma	1	(0.3)	1	0					1	(0.2)	1	0
Psychiatric disorders	1	(0.3)	1	0					1	(0.2)	1	0
Suicide attempt	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:50 - tsum_events_tpl_t030_v01.sas/t_sae_te_relatt_insum_sas.txt

14.3.1.15: Serious Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term - Treatment Emergent – Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	19	(5.2)	36	12	11	(6.1)	13	9	30	(5.5)	49	11
Metabolism and nutrition disorders	18	(5.0)	29	10	10	(5.6)	12	8	28	(5.2)	41	9
Hypoglycaemia	12	(3.3)	21	7	7	(3.9)	7	5	19	(3.5)	28	6
Hypoglycaemic unconsciousness	7	(1.9)	7	2	4	(2.2)	4	3	11	(2.0)	11	2
Hypoglycaemic seizure	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Injury, poisoning and procedural complications	2	(0.6)	3	1					2	(0.4)	3	1
Intentional overdose	1	(0.3)	2	1					1	(0.2)	2	0
Wrong drug administered	1	(0.3)	1	0					1	(0.2)	1	0
Psychiatric disorders	1	(0.3)	2	1	1	(0.6)	1	1	2	(0.4)	3	1
Suicidal ideation					1	(0.6)	1	1	1	(0.2)	1	0
Suicide attempt	1	(0.3)	2	1					1	(0.2)	2	0
Nervous system disorders	1	(0.3)	2	1					1	(0.2)	2	0
Hypoglycaemic coma	1	(0.3)	2	1					1	(0.2)	2	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:52 - tsum_events_tpl_t030_v01.sas/t_sae_te_relat_bolus_sum_sas.txt

14.3.1.16: Serious Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

There is no data for this Table

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:50 - tsum_events_tpl_t030/t_sae_te_relat_devis_e_sum_sas.txt

14.3.1.17: Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	64 (17.7)		98	33	34 (18.9)		70	48	98 (18.1)		168	38
Metabolism and nutrition disorders	42 (11.6)		63	21	28 (15.6)		56	38	70 (12.9)		119	27
Hypoglycaemia	33 (9.1)		51	17	25 (13.9)		48	33	58 (10.7)		99	22
Hypoglycaemic unconsciousness	8 (2.2)		8	3	5 (2.8)		5	3	13 (2.4)		13	3
Diabetic ketoacidosis	1 (0.3)		1	0	2 (1.1)		2	1	3 (0.6)		3	1
Hypoglycaemic seizure	2 (0.6)		3	1	1 (0.6)		1	1	3 (0.6)		4	1
Gastrointestinal disorders	8 (2.2)		9	3	2 (1.1)		2	1	10 (1.8)		11	2
Abdominal pain	2 (0.6)		2	1					2 (0.4)		2	0
Nausea	1 (0.3)		1	0	1 (0.6)		1	1	2 (0.4)		2	0
Vomiting	2 (0.6)		2	1					2 (0.4)		2	0
Constipation	1 (0.3)		1	0					1 (0.2)		1	0
Food poisoning	1 (0.3)		1	0					1 (0.2)		1	0
Hiatus hernia	1 (0.3)		1	0					1 (0.2)		1	0
Small intestinal obstruction					1 (0.6)		1	1	1 (0.2)		1	0
Toothache	1 (0.3)		1	0					1 (0.2)		1	0
Infections and infestations	4 (1.1)		4	1	2 (1.1)		2	1	6 (1.1)		6	1
Gastroenteritis	1 (0.3)		1	0	1 (0.6)		1	1	2 (0.4)		2	0
Abscess limb	1 (0.3)		1	0					1 (0.2)		1	0
Bronchitis					1 (0.6)		1	1	1 (0.2)		1	0
Meningitis	1 (0.3)		1	0					1 (0.2)		1	0
Pulmonary tuberculosis	1 (0.3)		1	0					1 (0.2)		1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:54 - tsum_events_tpl_t030_v01.sas/t_ae_te_sev_soc_pf_sum_sas.txt

Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Injury, poisoning and procedural complications	3	(0.8)	4	1	2	(1.1)	2	1	5	(0.9)	6	1
Medication error	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Intentional overdose	1	(0.3)	2	1					1	(0.2)	2	0
Skin laceration	1	(0.3)	1	0					1	(0.2)	1	0
Wrong drug administered					1	(0.6)	1	1	1	(0.2)	1	0
Musculoskeletal and connective tissue disorders	2	(0.6)	3	1	3	(1.7)	3	2	5	(0.9)	6	1
Arthralgia	1	(0.3)	1	0					1	(0.2)	1	0
Intervertebral disc degeneration					1	(0.6)	1	1	1	(0.2)	1	0
Intervertebral disc disorder	1	(0.3)	1	0					1	(0.2)	1	0
Myalgia					1	(0.6)	1	1	1	(0.2)	1	0
Osteoarthritis					1	(0.6)	1	1	1	(0.2)	1	0
Systemic lupus erythematosus	1	(0.3)	1	0					1	(0.2)	1	0
Psychiatric disorders	4	(1.1)	5	2	1	(0.6)	1	1	5	(0.9)	6	1
Suicidal ideation	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Anxiety	1	(0.3)	1	0					1	(0.2)	1	0
Depression	1	(0.3)	1	0					1	(0.2)	1	0
Suicide attempt	1	(0.3)	2	1					1	(0.2)	2	0
Nervous system disorders	2	(0.6)	3	1	1	(0.6)	1	1	3	(0.6)	4	1
Headache					1	(0.6)	1	1	1	(0.2)	1	0
Hypoglycaemic coma	1	(0.3)	2	1					1	(0.2)	2	0
Neurological symptom	1	(0.3)	1	0					1	(0.2)	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					2	(1.1)	2	1	2	(0.4)	2	0
Bladder cancer					1	(0.6)	1	1	1	(0.2)	1	0
Uterine leiomyoma					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:54 - tsum_events_tpl_t030_v01.sas/t_ae_te_sev_soc_pf_sum_sas.txt

Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Ear and labyrinth disorders	1	(0.3)	1	0					1	(0.2)	1	0
Ear pain	1	(0.3)	1	0					1	(0.2)	1	0
Eye disorders	1	(0.3)	1	0					1	(0.2)	1	0
Eye haemorrhage	1	(0.3)	1	0					1	(0.2)	1	0
General disorders and administration site conditions	1	(0.3)	1	0					1	(0.2)	1	0
Influenza like illness	1	(0.3)	1	0					1	(0.2)	1	0
Immune system disorders	1	(0.3)	1	0					1	(0.2)	1	0
Hypersensitivity	1	(0.3)	1	0					1	(0.2)	1	0
Reproductive system and breast disorders	1	(0.3)	1	0					1	(0.2)	1	0
Benign prostatic hyperplasia	1	(0.3)	1	0					1	(0.2)	1	0
Respiratory, thoracic and mediastinal disorders					1	(0.6)	1	1	1	(0.2)	1	0
Dyspnoea					1	(0.6)	1	1	1	(0.2)	1	0
Skin and subcutaneous tissue disorders	1	(0.3)	1	0					1	(0.2)	1	0
Rash	1	(0.3)	1	0					1	(0.2)	1	0
Social circumstances	1	(0.3)	1	0					1	(0.2)	1	0
Victim of crime	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:54 - tsum_events_tpl_t030_v01.sas/t_ae_te_sev_soc_pf_sum_sas.txt

14.3.1.18: Severe Adverse Events Possibly or Probably Related to Investigational Medicinal Product by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	35	(9.7)	53	18	20	(11.1)	41	28	55	(10.1)	94	21
Metabolism and nutrition disorders	32	(8.8)	48	16	19	(10.6)	39	27	51	(9.4)	87	20
Hypoglycaemia	26	(7.2)	40	13	18	(10.0)	34	23	44	(8.1)	74	17
Hypoglycaemic unconsciousness	6	(1.7)	6	2	3	(1.7)	3	2	9	(1.7)	9	2
Hypoglycaemic seizure	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Diabetic ketoacidosis					1	(0.6)	1	1	1	(0.2)	1	0
Injury, poisoning and procedural complications	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Medication error	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Intentional overdose	1	(0.3)	1	0					1	(0.2)	1	0
Nervous system disorders	2	(0.6)	2	1					2	(0.4)	2	0
Hypoglycaemic coma	1	(0.3)	1	0					1	(0.2)	1	0
Neurological symptom	1	(0.3)	1	0					1	(0.2)	1	0
Gastrointestinal disorders					1	(0.6)	1	1	1	(0.2)	1	0
Nausea					1	(0.6)	1	1	1	(0.2)	1	0
Psychiatric disorders	1	(0.3)	1	0					1	(0.2)	1	0
Suicide attempt	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:56 - tsum_events_tpl_t030_v01.sas/t_ae_te_sev_relat_ins_sum_sas.txt

14.3.1.19: Severe Adverse Events Possibly or Probably Related to Bolus Insulin by System Organ Class and Preferred Term – Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	33 (9.1)		56	19	23 (12.8)		46	32	56 (10.3)		102	23
Metabolism and nutrition disorders	31 (8.6)		49	17	21 (11.7)		43	30	52 (9.6)		92	21
Hypoglycaemia	24 (6.6)		40	13	19 (10.6)		37	25	43 (7.9)		77	17
Hypoglycaemic unconsciousness	8 (2.2)		8	3	4 (2.2)		4	3	12 (2.2)		12	3
Hypoglycaemic seizure	1 (0.3)		1	0	1 (0.6)		1	1	2 (0.4)		2	0
Diabetic ketoacidosis					1 (0.6)		1	1	1 (0.2)		1	0
Injury, poisoning and procedural complications	1 (0.3)		2	1	1 (0.6)		1	1	2 (0.4)		3	1
Intentional overdose	1 (0.3)		2	1					1 (0.2)		2	0
Wrong drug administered					1 (0.6)		1	1	1 (0.2)		1	0
Nervous system disorders	2 (0.6)		3	1					2 (0.4)		3	1
Hypoglycaemic coma	1 (0.3)		2	1					1 (0.2)		2	0
Neurological symptom	1 (0.3)		1	0					1 (0.2)		1	0
Psychiatric disorders	1 (0.3)		2	1	1 (0.6)		1	1	2 (0.4)		3	1
Suicidal ideation					1 (0.6)		1	1	1 (0.2)		1	0
Suicide attempt	1 (0.3)		2	1					1 (0.2)		2	0
Gastrointestinal disorders					1 (0.6)		1	1	1 (0.2)		1	0
Nausea					1 (0.6)		1	1	1 (0.2)		1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:13:59:58 - tsum_events_tpl_t030_v01.sas/t_ae_te_sev_relat_bolus_sum_sas.txt

14.3.1.20: Severe Adverse Events Related to Device by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

There is no data for this Table

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:50 - tsum_events_tpl_t030/t_ae_te_sev_relat_device_sum_sas.txt

14.3.1.21: Serious Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	362				180				542			
Events	34	(9.4)	55	19	18	(10.0)	22	15	52	(9.6)	77	17
Metabolism and nutrition disorders	22	(6.1)	35	12	13	(7.2)	15	10	35	(6.5)	50	11
Hypoglycaemia	14	(3.9)	24	8	9	(5.0)	9	6	23	(4.2)	33	7
Hypoglycaemic unconsciousness	7	(1.9)	7	2	4	(2.2)	4	3	11	(2.0)	11	2
Hypoglycaemic seizure	2	(0.6)	3	1	1	(0.6)	1	1	3	(0.6)	4	1
Diabetic ketoacidosis	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Gastrointestinal disorders	3	(0.8)	3	1	1	(0.6)	1	1	4	(0.7)	4	1
Abdominal pain	1	(0.3)	1	0					1	(0.2)	1	0
Food poisoning	1	(0.3)	1	0					1	(0.2)	1	0
Hiatus hernia	1	(0.3)	1	0					1	(0.2)	1	0
Small intestinal obstruction					1	(0.6)	1	1	1	(0.2)	1	0
Infections and infestations	4	(1.1)	4	1					4	(0.7)	4	1
Abscess limb	1	(0.3)	1	0					1	(0.2)	1	0
Gastroenteritis	1	(0.3)	1	0					1	(0.2)	1	0
Meningitis	1	(0.3)	1	0					1	(0.2)	1	0
Pulmonary tuberculosis	1	(0.3)	1	0					1	(0.2)	1	0
Psychiatric disorders	3	(0.8)	4	1	1	(0.6)	1	1	4	(0.7)	5	1
Suicidal ideation	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Depression	1	(0.3)	1	0					1	(0.2)	1	0
Suicide attempt	1	(0.3)	2	1					1	(0.2)	2	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:00 - tsum_events_tpl_t030_v01.sas/t_sae_te_sev_soc_pf_sum_sas.txt

Serious Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Musculoskeletal and connective tissue disorders	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Intervertebral disc degeneration					1	(0.6)	1	1	1	(0.2)	1	0
Intervertebral disc disorder	1	(0.3)	1	0					1	(0.2)	1	0
Osteoarthritis					1	(0.6)	1	1	1	(0.2)	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					2	(1.1)	2	1	2	(0.4)	2	0
Bladder cancer					1	(0.6)	1	1	1	(0.2)	1	0
Uterine leiomyoma					1	(0.6)	1	1	1	(0.2)	1	0
Eye disorders	1	(0.3)	1	0					1	(0.2)	1	0
Eye haemorrhage	1	(0.3)	1	0					1	(0.2)	1	0
Immune system disorders	1	(0.3)	1	0					1	(0.2)	1	0
Hypersensitivity	1	(0.3)	1	0					1	(0.2)	1	0
Injury, poisoning and procedural complications	1	(0.3)	2	1					1	(0.2)	2	0
Intentional overdose	1	(0.3)	2	1					1	(0.2)	2	0
Nervous system disorders	1	(0.3)	2	1					1	(0.2)	2	0
Hypoglycaemic coma	1	(0.3)	2	1					1	(0.2)	2	0
Reproductive system and breast disorders	1	(0.3)	1	0					1	(0.2)	1	0
Benign prostatic hyperplasia	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:00 - tsum_events_tpl_t030_v01.sas/t_sae_te_sev_soc_pf_sum_sas.txt

Serious Severe Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Respiratory, thoracic and mediastinal disorders					1	(0.6)	1	1	1	(0.2)	1	0
Dyspnoea					1	(0.6)	1	1	1	(0.2)	1	0
Social circumstances	1	(0.3)	1	0					1	(0.2)	1	0
Victim of crime	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
 %= Percentage of subjects
 E= Number of Events
 R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:00:00 - tsum_events_tpl_t030_v01.sas/t_sae_te_sev_soc_pf_sum_sas.txt

14.3.1.22: Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	131 (36.2)	276	93	55 (30.6)	121	83	186 (34.3)	397	90
Infections and infestations	76 (21.0)	108	36	25 (13.9)	34	23	101 (18.6)	142	32
Nasopharyngitis	17 (4.7)	18	6	4 (2.2)	5	3	21 (3.9)	23	5
Influenza	10 (2.8)	10	3	2 (1.1)	3	2	12 (2.2)	13	3
Upper respiratory tract infection	8 (2.2)	10	3	4 (2.2)	6	4	12 (2.2)	16	4
Gastroenteritis	8 (2.2)	8	3	3 (1.7)	4	3	11 (2.0)	12	3
Sinusitis	8 (2.2)	11	4	2 (1.1)	2	1	10 (1.8)	13	3
Tooth abscess	5 (1.4)	6	2	1 (0.6)	1	1	6 (1.1)	7	2
Bronchitis	4 (1.1)	4	1	1 (0.6)	1	1	5 (0.9)	5	1
Infection	4 (1.1)	4	1	1 (0.6)	1	1	5 (0.9)	5	1
Cellulitis	3 (0.8)	3	1	1 (0.6)	1	1	4 (0.7)	4	1
Gastroenteritis viral	2 (0.6)	3	1	1 (0.6)	1	1	3 (0.6)	4	1
Tooth infection	3 (0.8)	3	1				3 (0.6)	3	1
Urinary tract infection	1 (0.3)	1	0	2 (1.1)	2	1	3 (0.6)	3	1
Viral infection	1 (0.3)	1	0	2 (1.1)	2	1	3 (0.6)	3	1
H1N1 influenza	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Localised infection	2 (0.6)	2	1				2 (0.4)	2	0
Pneumonia	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Abscess	1 (0.3)	1	0				1 (0.2)	1	0
Acute sinusitis	1 (0.3)	1	0				1 (0.2)	1	0
Bacterial infection	1 (0.3)	1	0				1 (0.2)	1	0
Conjunctivitis infective	1 (0.3)	1	0				1 (0.2)	1	0
Cystitis	1 (0.3)	1	0				1 (0.2)	1	0
Fungal infection	1 (0.3)	1	0				1 (0.2)	1	0
Gingival abscess	1 (0.3)	1	0				1 (0.2)	1	0
Groin abscess				1 (0.6)	1	1	1 (0.2)	1	0
Helicobacter gastritis	1 (0.3)	1	0				1 (0.2)	1	0
Labyrinthitis	1 (0.3)	1	0				1 (0.2)	1	0
Laryngitis	1 (0.3)	1	0				1 (0.2)	1	0
Lyme disease	1 (0.3)	1	0				1 (0.2)	1	0
Oral herpes				1 (0.6)	1	1	1 (0.2)	1	0
Otitis media acute	1 (0.3)	1	0				1 (0.2)	1	0
Pharyngitis	1 (0.3)	1	0				1 (0.2)	1	0
Pneumonia viral	1 (0.3)	1	0				1 (0.2)	1	0
Respiratory tract infection viral	1 (0.3)	1	0				1 (0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:02 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Rhinitis	1	(0.3)	1	0					1	(0.2)	1	0
Staphylococcal infection	1	(0.3)	1	0					1	(0.2)	1	0
Staphylococcal skin infection	1	(0.3)	1	0					1	(0.2)	1	0
Tinea pedis					1	(0.6)	1	1	1	(0.2)	1	0
Tonsillitis	1	(0.3)	1	0					1	(0.2)	1	0
Tracheobronchitis	1	(0.3)	1	0					1	(0.2)	1	0
Vulval abscess	1	(0.3)	1	0					1	(0.2)	1	0
Wound infection	1	(0.3)	1	0					1	(0.2)	1	0
Injury, poisoning and procedural complications	22	(6.1)	25	8	10	(5.6)	11	8	32	(5.9)	36	8
Wrong drug administered	6	(1.7)	6	2	2	(1.1)	2	1	8	(1.5)	8	2
Fall	3	(0.8)	3	1					3	(0.6)	3	1
Skin laceration	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Ankle fracture	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Rib fracture	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Cataract traumatic	1	(0.3)	1	0					1	(0.2)	1	0
Concussion	1	(0.3)	1	0					1	(0.2)	1	0
Contusion					1	(0.6)	1	1	1	(0.2)	1	0
Corneal scar	1	(0.3)	1	0					1	(0.2)	1	0
Foot fracture	1	(0.3)	1	0					1	(0.2)	1	0
Injury corneal					1	(0.6)	1	1	1	(0.2)	1	0
Joint dislocation	1	(0.3)	1	0					1	(0.2)	1	0
Joint injury	1	(0.3)	1	0					1	(0.2)	1	0
Ligament rupture					1	(0.6)	1	1	1	(0.2)	1	0
Medication error					1	(0.6)	1	1	1	(0.2)	1	0
Muscle strain	1	(0.3)	1	0					1	(0.2)	1	0
Post procedural haemorrhage					1	(0.6)	1	1	1	(0.2)	1	0
Procedural pain					1	(0.6)	1	1	1	(0.2)	1	0
Radius fracture	1	(0.3)	1	0					1	(0.2)	1	0
Skull fracture	1	(0.3)	1	0					1	(0.2)	1	0
Soft tissue injury	1	(0.3)	1	0					1	(0.2)	1	0
Upper limb fracture	1	(0.3)	1	0					1	(0.2)	1	0
Wound	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:02 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Musculoskeletal and connective tissue disorders	20	(5.5)	23	8	10	(5.6)	13	9	30	(5.5)	36	8
Back pain	2	(0.6)	2	1	3	(1.7)	3	2	5	(0.9)	5	1
Arthralgia	3	(0.8)	4	1					3	(0.6)	4	1
Myalgia	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Pain in extremity	2	(0.6)	2	1	1	(0.6)	2	1	3	(0.6)	4	1
Musculoskeletal pain	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Osteoarthritis	2	(0.6)	2	1					2	(0.4)	2	0
Periarthritis	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Rotator cuff syndrome	2	(0.6)	2	1					2	(0.4)	2	0
Tendonitis	2	(0.6)	2	1					2	(0.4)	2	0
Intervertebral disc protrusion	1	(0.3)	1	0					1	(0.2)	1	0
Joint effusion	1	(0.3)	1	0					1	(0.2)	1	0
Joint swelling					1	(0.6)	1	1	1	(0.2)	1	0
Muscle spasms	1	(0.3)	1	0					1	(0.2)	1	0
Neck pain					1	(0.6)	2	1	1	(0.2)	2	0
Osteopenia					1	(0.6)	1	1	1	(0.2)	1	0
Plantar fasciitis					1	(0.6)	1	1	1	(0.2)	1	0
Polyarthrititis	1	(0.3)	1	0					1	(0.2)	1	0
Rheumatoid arthritis	1	(0.3)	1	0					1	(0.2)	1	0
Metabolism and nutrition disorders	17	(4.7)	22	7	12	(6.7)	15	10	29	(5.4)	37	8
Hypoglycaemia	9	(2.5)	12	4	7	(3.9)	9	6	16	(3.0)	21	5
Diabetic ketoacidosis	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Hypoglycaemic unconsciousness	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Dehydration	2	(0.6)	2	1					2	(0.4)	2	0
Vitamin D deficiency	2	(0.6)	2	1					2	(0.4)	2	0
Decreased appetite	1	(0.3)	1	0					1	(0.2)	1	0
Gout	1	(0.3)	1	0					1	(0.2)	1	0
Hypercholesterolaemia	1	(0.3)	1	0					1	(0.2)	1	0
Hyperglycaemia	1	(0.3)	1	0					1	(0.2)	1	0
Hypokalaemia					1	(0.6)	1	1	1	(0.2)	1	0
Hypovolaemia					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:02 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Gastrointestinal disorders	14	(3.9)	22	7	12	(6.7)	13	9	26	(4.8)	35	8
Vomiting	5	(1.4)	5	2	1	(0.6)	1	1	6	(1.1)	6	1
Nausea	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Diarrhoea	2	(0.6)	3	1	2	(1.1)	2	1	4	(0.7)	5	1
Toothache	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Abdominal discomfort	1	(0.3)	1	0					1	(0.2)	1	0
Abdominal distension					1	(0.6)	1	1	1	(0.2)	1	0
Abdominal pain					1	(0.6)	1	1	1	(0.2)	1	0
Abdominal pain upper	1	(0.3)	1	0					1	(0.2)	1	0
Colonic polyp	1	(0.3)	1	0					1	(0.2)	1	0
Dyspepsia	1	(0.3)	1	0					1	(0.2)	1	0
Gastric polyps	1	(0.3)	1	0					1	(0.2)	1	0
Gastritis					1	(0.6)	1	1	1	(0.2)	1	0
Gastrooesophageal reflux disease	1	(0.3)	2	1					1	(0.2)	2	0
Haemorrhoids					1	(0.6)	1	1	1	(0.2)	1	0
Hiatus hernia	1	(0.3)	1	0					1	(0.2)	1	0
Pancreatitis	1	(0.3)	1	0					1	(0.2)	1	0
Pancreatitis acute					1	(0.6)	1	1	1	(0.2)	1	0
Periodontitis					1	(0.6)	1	1	1	(0.2)	1	0
Umbilical hernia					1	(0.6)	1	1	1	(0.2)	1	0
Nervous system disorders	10	(2.8)	10	3	5	(2.8)	6	4	15	(2.8)	16	4
Headache	5	(1.4)	5	2	1	(0.6)	2	1	6	(1.1)	7	2
Dizziness	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Migraine	2	(0.6)	2	1					2	(0.4)	2	0
Cerebral atrophy					1	(0.6)	1	1	1	(0.2)	1	0
Lethargy	1	(0.3)	1	0					1	(0.2)	1	0
Memory impairment					1	(0.6)	1	1	1	(0.2)	1	0
Multiple sclerosis	1	(0.3)	1	0					1	(0.2)	1	0
Restless legs syndrome					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:02 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Respiratory, thoracic and mediastinal disorders	12	(3.3)	13	4	2	(1.1)	2	1	14	(2.6)	15	3
Asthma	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Oropharyngeal pain	3	(0.8)	3	1					3	(0.6)	3	1
Cough	2	(0.6)	3	1					2	(0.4)	3	1
Dyspnoea	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Emphysema	1	(0.3)	1	0					1	(0.2)	1	0
Respiratory disorder	1	(0.3)	1	0					1	(0.2)	1	0
Respiratory tract congestion	1	(0.3)	1	0					1	(0.2)	1	0
Vocal cord disorder	1	(0.3)	1	0					1	(0.2)	1	0
Eye disorders	8	(2.2)	9	3	5	(2.8)	6	4	13	(2.4)	15	3
Diabetic retinopathy	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Conjunctivitis	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Cataract	1	(0.3)	2	1	1	(0.6)	1	1	2	(0.4)	3	1
Maculopathy	1	(0.3)	1	0					1	(0.2)	1	0
Retinal detachment	1	(0.3)	1	0					1	(0.2)	1	0
Retinal haemorrhage					1	(0.6)	1	1	1	(0.2)	1	0
Retinal vascular disorder	1	(0.3)	1	0					1	(0.2)	1	0
General disorders and administration site conditions	9	(2.5)	9	3	4	(2.2)	4	3	13	(2.4)	13	3
Pyrexia	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Influenza like illness	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Injection site reaction	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Chest pain	1	(0.3)	1	0					1	(0.2)	1	0
Non-cardiac chest pain	1	(0.3)	1	0					1	(0.2)	1	0
Oedema peripheral	1	(0.3)	1	0					1	(0.2)	1	0
Pain	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:02 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Psychiatric disorders	9	(2.5)	10	3	4	(2.2)	5	3	13	(2.4)	15	3
Depression	7	(1.9)	7	2	2	(1.1)	2	1	9	(1.7)	9	2
Insomnia	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Anxiety	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Investigations	4	(1.1)	4	1	2	(1.1)	2	1	6	(1.1)	6	1
Hepatic enzyme increased	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Blood creatinine increased	1	(0.3)	1	0					1	(0.2)	1	0
Blood pressure increased	1	(0.3)	1	0					1	(0.2)	1	0
Exercise test abnormal					1	(0.6)	1	1	1	(0.2)	1	0
Weight increased	1	(0.3)	1	0					1	(0.2)	1	0
Vascular disorders	6	(1.7)	6	2					6	(1.1)	6	1
Hypertension	4	(1.1)	4	1					4	(0.7)	4	1
Varicose vein	2	(0.6)	2	1					2	(0.4)	2	0
Immune system disorders	5	(1.4)	5	2					5	(0.9)	5	1
Seasonal allergy	4	(1.1)	4	1					4	(0.7)	4	1
Hypersensitivity	1	(0.3)	1	0					1	(0.2)	1	0
Skin and subcutaneous tissue disorders	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Lipodystrophy acquired					1	(0.6)	1	1	1	(0.2)	1	0
Lipohypertrophy					1	(0.6)	1	1	1	(0.2)	1	0
Photosensitivity allergic reaction	1	(0.3)	1	0					1	(0.2)	1	0
Pruritus	1	(0.3)	1	0					1	(0.2)	1	0
Skin disorder	1	(0.3)	1	0					1	(0.2)	1	0
Cardiac disorders	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Angina pectoris	1	(0.3)	1	0					1	(0.2)	1	0
Pericardial effusion	1	(0.3)	1	0					1	(0.2)	1	0
Tachycardia					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:02 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

Moderate Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Ear and labyrinth disorders	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Ear pain	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Vertigo					1	(0.6)	1	1	1	(0.2)	1	0
Renal and urinary disorders	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Hydronephrosis	1	(0.3)	1	0					1	(0.2)	1	0
Nephrolithiasis	1	(0.3)	1	0					1	(0.2)	1	0
Urinary incontinence					1	(0.6)	1	1	1	(0.2)	1	0
Blood and lymphatic system disorders	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Anaemia	1	(0.3)	1	0					1	(0.2)	1	0
Leukocytosis					1	(0.6)	1	1	1	(0.2)	1	0
Reproductive system and breast disorders	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Prostatomegaly	1	(0.3)	1	0					1	(0.2)	1	0
Vulvovaginal pruritus					1	(0.6)	1	1	1	(0.2)	1	0
Hepatobiliary disorders					1	(0.6)	1	1	1	(0.2)	1	0
Hepatitis toxic					1	(0.6)	1	1	1	(0.2)	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					1	(0.6)	1	1	1	(0.2)	1	0
Squamous cell carcinoma of skin					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:02 - tsum_events_tpl_t030_v01.sas/t_ae_te_mod_soc_pf_sum_sas.txt

14.3.1.23: Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	220 (60.8)	836	282	115 (63.9)	452	311	335 (61.8)	1288	291
Infections and infestations	136 (37.6)	291	98	80 (44.4)	147	101	216 (39.9)	438	99
Nasopharyngitis	78 (21.5)	121	41	35 (19.4)	57	39	113 (20.8)	178	40
Upper respiratory tract infection	28 (7.7)	38	13	17 (9.4)	24	16	45 (8.3)	62	14
Influenza	15 (4.1)	15	5	8 (4.4)	9	6	23 (4.2)	24	5
Gastroenteritis	6 (1.7)	7	2	5 (2.8)	5	3	11 (2.0)	12	3
Viral infection	8 (2.2)	8	3	3 (1.7)	3	2	11 (2.0)	11	2
Bronchitis	5 (1.4)	5	2	4 (2.2)	4	3	9 (1.7)	9	2
Sinusitis	6 (1.7)	7	2	3 (1.7)	3	2	9 (1.7)	10	2
Urinary tract infection	4 (1.1)	5	2	5 (2.8)	5	3	9 (1.7)	10	2
Pharyngitis	7 (1.9)	10	3	1 (0.6)	1	1	8 (1.5)	11	2
Localised infection	3 (0.8)	3	1	3 (1.7)	3	2	6 (1.1)	6	1
Acute tonsillitis	4 (1.1)	6	2	1 (0.6)	1	1	5 (0.9)	7	2
Respiratory tract infection	1 (0.3)	1	0	4 (2.2)	5	3	5 (0.9)	6	1
Tooth infection	4 (1.1)	4	1	1 (0.6)	1	1	5 (0.9)	5	1
Viral upper respiratory tract infection	4 (1.1)	5	2	1 (0.6)	1	1	5 (0.9)	6	1
Ear infection	4 (1.1)	4	1				4 (0.7)	4	1
Gastroenteritis viral	3 (0.8)	3	1	1 (0.6)	1	1	4 (0.7)	4	1
Eye infection	1 (0.3)	1	0	2 (1.1)	2	1	3 (0.6)	3	1
Tonsillitis	3 (0.8)	3	1				3 (0.6)	3	1
Tooth abscess	2 (0.6)	2	1	1 (0.6)	1	1	3 (0.6)	3	1
Vulvovaginal candidiasis	2 (0.6)	4	1	1 (0.6)	1	1	3 (0.6)	5	1
Candidiasis	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Laryngitis	2 (0.6)	2	1				2 (0.4)	2	0
Oral herpes	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Pharyngitis streptococcal	2 (0.6)	2	1				2 (0.4)	2	0
Rhinitis	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Staphylococcal skin infection	1 (0.3)	1	0	1 (0.6)	1	1	2 (0.4)	2	0
Tinea infection				2 (1.1)	2	1	2 (0.4)	2	0
Abscess limb	1 (0.3)	2	1				1 (0.2)	2	0
Acute sinusitis	1 (0.3)	1	0				1 (0.2)	1	0
Ascariasis	1 (0.3)	1	0				1 (0.2)	1	0
Blister infected	1 (0.3)	1	0				1 (0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Enterovirus infection	1 (0.3)	1	0				1 (0.2)	1	0
Erysipelas	1 (0.3)	1	0				1 (0.2)	1	0
Fungal infection				1 (0.6)	1	1	1 (0.2)	1	0
Furuncle				1 (0.6)	1	1	1 (0.2)	1	0
Genital candidiasis	1 (0.3)	1	0				1 (0.2)	1	0
Gingival abscess				1 (0.6)	1	1	1 (0.2)	1	0
Groin abscess	1 (0.3)	1	0				1 (0.2)	1	0
Herpes simplex				1 (0.6)	1	1	1 (0.2)	1	0
Herpes zoster	1 (0.3)	1	0				1 (0.2)	1	0
Hordeolum				1 (0.6)	1	1	1 (0.2)	1	0
Infection	1 (0.3)	1	0				1 (0.2)	1	0
Intrauterine infection				1 (0.6)	1	1	1 (0.2)	1	0
Lower respiratory tract infection	1 (0.3)	1	0				1 (0.2)	1	0
Mastitis				1 (0.6)	1	1	1 (0.2)	1	0
Nail infection				1 (0.6)	1	1	1 (0.2)	1	0
Onychomycosis	1 (0.3)	1	0				1 (0.2)	1	0
Oral candidiasis	1 (0.3)	1	0				1 (0.2)	1	0
Oral fungal infection				1 (0.6)	1	1	1 (0.2)	1	0
Paronychia	1 (0.3)	1	0				1 (0.2)	1	0
Peritonsillar abscess				1 (0.6)	1	1	1 (0.2)	1	0
Pilonidal cyst	1 (0.3)	2	1				1 (0.2)	2	0
Pneumonia				1 (0.6)	1	1	1 (0.2)	1	0
Postoperative wound infection	1 (0.3)	2	1				1 (0.2)	2	0
Respiratory tract infection viral	1 (0.3)	1	0				1 (0.2)	1	0
Rotavirus infection	1 (0.3)	1	0				1 (0.2)	1	0
Skin infection	1 (0.3)	1	0				1 (0.2)	1	0
Subcutaneous abscess	1 (0.3)	4	1				1 (0.2)	4	1
Superinfection	1 (0.3)	1	0				1 (0.2)	1	0
Taeniasis	1 (0.3)	1	0				1 (0.2)	1	0
Vaginal infection				1 (0.6)	1	1	1 (0.2)	1	0
Vaginitis bacterial	1 (0.3)	1	0				1 (0.2)	1	0
Viral pharyngitis	1 (0.3)	1	0				1 (0.2)	1	0
Vulvovaginal mycotic infection	1 (0.3)	1	0				1 (0.2)	1	0
Vulvovaginitis				1 (0.6)	1	1	1 (0.2)	1	0
Wound infection				1 (0.6)	1	1	1 (0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Gastrointestinal disorders	51	(14.1)	84	28	28	(15.6)	53	36	79	(14.6)	137	31
Diarrhoea	11	(3.0)	11	4	10	(5.6)	10	7	21	(3.9)	21	5
Nausea	11	(3.0)	20	7	6	(3.3)	7	5	17	(3.1)	27	6
Vomiting	8	(2.2)	9	3	5	(2.8)	6	4	13	(2.4)	15	3
Abdominal pain upper	7	(1.9)	8	3	4	(2.2)	4	3	11	(2.0)	12	3
Abdominal discomfort	5	(1.4)	7	2	5	(2.8)	6	4	10	(1.8)	13	3
Dyspepsia	4	(1.1)	4	1	4	(2.2)	5	3	8	(1.5)	9	2
Abdominal pain	4	(1.1)	5	2	2	(1.1)	2	1	6	(1.1)	7	2
Food poisoning	3	(0.8)	4	1	1	(0.6)	1	1	4	(0.7)	5	1
Gastrooesophageal reflux disease	3	(0.8)	7	2	1	(0.6)	1	1	4	(0.7)	8	2
Gastritis	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Toothache	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Abdominal distension	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Rectal haemorrhage	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Colitis					1	(0.6)	1	1	1	(0.2)	1	0
Enterocolitis					1	(0.6)	1	1	1	(0.2)	1	0
Flatulence					1	(0.6)	1	1	1	(0.2)	1	0
Hiatus hernia	1	(0.3)	1	0					1	(0.2)	1	0
Mouth ulceration	1	(0.3)	2	1					1	(0.2)	2	0
Oesophagitis					1	(0.6)	1	1	1	(0.2)	1	0
Pancreatitis chronic					1	(0.6)	1	1	1	(0.2)	1	0
Periodontitis	1	(0.3)	1	0					1	(0.2)	1	0
Salivary gland enlargement					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
General disorders and administration site conditions	37	(10.2)	53	18	28	(15.6)	66	45	65	(12.0)	119	27
Injection site reaction	5	(1.4)	7	2	8	(4.4)	35	24	13	(2.4)	42	9
Pyrexia	8	(2.2)	9	3	5	(2.8)	6	4	13	(2.4)	15	3
Influenza like illness	6	(1.7)	8	3	4	(2.2)	5	3	10	(1.8)	13	3
Fatigue	3	(0.8)	3	1	6	(3.3)	6	4	9	(1.7)	9	2
Oedema peripheral	7	(1.9)	11	4					7	(1.3)	11	2
Asthenia	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Malaise	4	(1.1)	4	1					4	(0.7)	4	1
Hunger	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Injection site pain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Discomfort					2	(1.1)	2	1	2	(0.4)	2	0
Injection site haematoma					2	(1.1)	2	1	2	(0.4)	2	0
Pain					2	(1.1)	2	1	2	(0.4)	2	0
Chest discomfort	1	(0.3)	1	0					1	(0.2)	1	0
Cyst	1	(0.3)	1	0					1	(0.2)	1	0
Feeling cold					1	(0.6)	1	1	1	(0.2)	1	0
Injection site erythema					1	(0.6)	1	1	1	(0.2)	1	0
Injection site hypertrophy					1	(0.6)	1	1	1	(0.2)	1	0
Injection site papule					1	(0.6)	1	1	1	(0.2)	1	0
Non-cardiac chest pain	1	(0.3)	2	1					1	(0.2)	2	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Nervous system disorders	46 (12.7)	122		41 19 (10.6)	26	18	65 (12.0)	148	33
Headache	32 (8.8)	97		33 14 (7.8)	19	13	46 (8.5)	116	26
Migraine	5 (1.4)	5		2 3 (1.7)	3	2	8 (1.5)	8	2
Dizziness	5 (1.4)	5		2			5 (0.9)	5	1
Neuropathy peripheral	1 (0.3)	1		2 (1.1)	2	1	3 (0.6)	3	1
Sinus headache	2 (0.6)	2		1 (0.6)	1	1	3 (0.6)	3	1
Hypoaesthesia	2 (0.6)	2		1			2 (0.4)	2	0
Lethargy	2 (0.6)	2		1			2 (0.4)	2	0
Paraesthesia	1 (0.3)	1		0 1 (0.6)	1	1	2 (0.4)	2	0
Aphonia	1 (0.3)	1		0			1 (0.2)	1	0
Areflexia	1 (0.3)	1		0			1 (0.2)	1	0
Carpal tunnel syndrome	1 (0.3)	1		0			1 (0.2)	1	0
Neuralgia	1 (0.3)	1		0			1 (0.2)	1	0
Phantom pain	1 (0.3)	1		0			1 (0.2)	1	0
Sensory loss	1 (0.3)	1		0			1 (0.2)	1	0
Syncope	1 (0.3)	1		0			1 (0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Musculoskeletal and connective tissue disorders	40	(11.0)	61	21	18	(10.0)	27	19	58	(10.7)	88	20
Pain in extremity	10	(2.8)	11	4	2	(1.1)	2	1	12	(2.2)	13	3
Back pain	8	(2.2)	10	3	3	(1.7)	4	3	11	(2.0)	14	3
Arthralgia	5	(1.4)	5	2	5	(2.8)	5	3	10	(1.8)	10	2
Musculoskeletal pain	4	(1.1)	4	1	6	(3.3)	6	4	10	(1.8)	10	2
Neck pain	7	(1.9)	8	3	2	(1.1)	2	1	9	(1.7)	10	2
Musculoskeletal chest pain	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Muscle spasms	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Myalgia	3	(0.8)	3	1					3	(0.6)	3	1
Periarthritis	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Tendonitis	2	(0.6)	3	1					2	(0.4)	3	1
Arthritis	1	(0.3)	1	0					1	(0.2)	1	0
Bunion	1	(0.3)	1	0					1	(0.2)	1	0
Costochondritis	1	(0.3)	1	0					1	(0.2)	1	0
Dupuytren's contracture	1	(0.3)	1	0					1	(0.2)	1	0
Exostosis					1	(0.6)	1	1	1	(0.2)	1	0
Foot deformity	1	(0.3)	1	0					1	(0.2)	1	0
Intervertebral disc protrusion	1	(0.3)	1	0					1	(0.2)	1	0
Joint swelling	1	(0.3)	2	1					1	(0.2)	2	0
Myositis					1	(0.6)	2	1	1	(0.2)	2	0
Osteoporosis	1	(0.3)	1	0					1	(0.2)	1	0
Rheumatoid arthritis	1	(0.3)	1	0					1	(0.2)	1	0
Tendon disorder	1	(0.3)	2	1					1	(0.2)	2	0
Trigger finger					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Injury, poisoning and procedural complications	30	(8.3)	39	13	18	(10.0)	24	16	48	(8.9)	63	14
Wrong drug administered	5	(1.4)	6	2	3	(1.7)	3	2	8	(1.5)	9	2
Vaccination complication	4	(1.1)	5	2	3	(1.7)	3	2	7	(1.3)	8	2
Joint sprain	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Contusion	3	(0.8)	4	1					3	(0.6)	4	1
Epicondylitis	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Incorrect dose administered	3	(0.8)	3	1					3	(0.6)	3	1
Limb injury	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Muscle strain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Tooth fracture	3	(0.8)	4	1					3	(0.6)	4	1
Arthropod bite	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Eye injury	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Foot fracture	2	(0.6)	2	1					2	(0.4)	2	0
Road traffic accident	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Cartilage injury					1	(0.6)	1	1	1	(0.2)	1	0
Face injury	1	(0.3)	1	0					1	(0.2)	1	0
Foreign body					1	(0.6)	1	1	1	(0.2)	1	0
Hand fracture					1	(0.6)	1	1	1	(0.2)	1	0
Head injury	1	(0.3)	1	0					1	(0.2)	1	0
Limb traumatic amputation					1	(0.6)	1	1	1	(0.2)	1	0
Medication error	1	(0.3)	1	0					1	(0.2)	1	0
Overdose	1	(0.3)	1	0					1	(0.2)	1	0
Post-traumatic pain					1	(0.6)	1	1	1	(0.2)	1	0
Procedural pain					1	(0.6)	1	1	1	(0.2)	1	0
Skin laceration	1	(0.3)	2	1					1	(0.2)	2	0
Traumatic haematoma					1	(0.6)	1	1	1	(0.2)	1	0
Wound					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Respiratory, thoracic and mediastinal disorders	29	(8.0)	46	15	13	(7.2)	15	10	42	(7.7)	61	14
Oropharyngeal pain	13	(3.6)	15	5	6	(3.3)	7	5	19	(3.5)	22	5
Cough	7	(1.9)	8	3	2	(1.1)	2	1	9	(1.7)	10	2
Dyspnoea	6	(1.7)	6	2					6	(1.1)	6	1
Respiratory disorder	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Sinus congestion	1	(0.3)	2	1	2	(1.1)	2	1	3	(0.6)	4	1
Epistaxis	2	(0.6)	4	1					2	(0.4)	4	1
Asthma					1	(0.6)	1	1	1	(0.2)	1	0
Bronchospasm					1	(0.6)	1	1	1	(0.2)	1	0
Chronic obstructive pulmonary disease	1	(0.3)	1	0					1	(0.2)	1	0
Dysphonia					1	(0.6)	1	1	1	(0.2)	1	0
Dyspnoea exertional	1	(0.3)	1	0					1	(0.2)	1	0
Paranasal sinus hypersecretion	1	(0.3)	1	0					1	(0.2)	1	0
Pulmonary congestion	1	(0.3)	1	0					1	(0.2)	1	0
Pulmonary fibrosis	1	(0.3)	1	0					1	(0.2)	1	0
Rhinitis allergic	1	(0.3)	1	0					1	(0.2)	1	0
Rhinorrhoea	1	(0.3)	1	0					1	(0.2)	1	0
Throat irritation	1	(0.3)	1	0					1	(0.2)	1	0
Upper respiratory tract congestion	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Eye disorders	21	(5.8)	25	8	12	(6.7)	20	14	33	(6.1)	45	10
Diabetic retinopathy	10	(2.8)	10	3	6	(3.3)	6	4	16	(3.0)	16	4
Cataract	3	(0.8)	3	1	3	(1.7)	3	2	6	(1.1)	6	1
Conjunctivitis	1	(0.3)	1	0	2	(1.1)	2	1	3	(0.6)	3	1
Dry eye	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Eye swelling	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Maculopathy					2	(1.1)	2	1	2	(0.4)	2	0
Myopia	2	(0.6)	2	1					2	(0.4)	2	0
Retinal degeneration	2	(0.6)	2	1					2	(0.4)	2	0
Cataract diabetic	1	(0.3)	1	0					1	(0.2)	1	0
Conjunctivitis allergic	1	(0.3)	1	0					1	(0.2)	1	0
Retinal aneurysm	1	(0.3)	1	0					1	(0.2)	1	0
Retinopathy proliferative	1	(0.3)	1	0					1	(0.2)	1	0
Vision blurred					1	(0.6)	2	1	1	(0.2)	2	0
Visual acuity reduced					1	(0.6)	1	1	1	(0.2)	1	0
Visual impairment					1	(0.6)	1	1	1	(0.2)	1	0
Vitreous detachment					1	(0.6)	1	1	1	(0.2)	1	0
Vitreous fibrin	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Skin and subcutaneous tissue disorders	14	(3.9)	19	6	16	(8.9)	17	12	30	(5.5)	36	8
Rash	2	(0.6)	2	1	5	(2.8)	5	3	7	(1.3)	7	2
Lipodystrophy acquired	1	(0.3)	1	0	3	(1.7)	3	2	4	(0.7)	4	1
Acne	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Dry skin	2	(0.6)	2	1					2	(0.4)	2	0
Hyperkeratosis	2	(0.6)	2	1					2	(0.4)	2	0
Lipohypertrophy	1	(0.3)	1	0	1	(0.6)	2	1	2	(0.4)	3	1
Pruritus	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Rash pruritic	2	(0.6)	2	1					2	(0.4)	2	0
Alopecia	1	(0.3)	1	0					1	(0.2)	1	0
Blister	1	(0.3)	1	0					1	(0.2)	1	0
Dermatitis	1	(0.3)	1	0					1	(0.2)	1	0
Dermatitis allergic					1	(0.6)	1	1	1	(0.2)	1	0
Eczema	1	(0.3)	1	0					1	(0.2)	1	0
Erythema	1	(0.3)	1	0					1	(0.2)	1	0
Heat rash					1	(0.6)	1	1	1	(0.2)	1	0
Hyperhidrosis					1	(0.6)	1	1	1	(0.2)	1	0
Hyperkeratosis follicularis et parafollicularis	1	(0.3)	1	0					1	(0.2)	1	0
Photosensitivity reaction					1	(0.6)	1	1	1	(0.2)	1	0
Skin irritation	1	(0.3)	1	0					1	(0.2)	1	0
Urticaria					1	(0.6)	1	1	1	(0.2)	1	0
Metabolism and nutrition disorders	18	(5.0)	18	6	9	(5.0)	9	6	27	(5.0)	27	6
Hyperlipidaemia	7	(1.9)	7	2	3	(1.7)	3	2	10	(1.8)	10	2
Hypercholesterolaemia	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Hyperglycaemia	4	(1.1)	4	1					4	(0.7)	4	1
Hypoglycaemia	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Decreased appetite	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Dyslipidaemia					1	(0.6)	1	1	1	(0.2)	1	0
Hypertriglyceridaemia	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Investigations	14	(3.9)	14	5	4	(2.2)	6	4	18	(3.3)	20	5
Weight increased	4	(1.1)	4	1	1	(0.6)	1	1	5	(0.9)	5	1
Blood glucose increased	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Blood pressure increased	2	(0.6)	2	1					2	(0.4)	2	0
Cardiac murmur	2	(0.6)	2	1					2	(0.4)	2	0
Arthroscopy	1	(0.3)	1	0					1	(0.2)	1	0
Blood bilirubin increased	1	(0.3)	1	0					1	(0.2)	1	0
Blood cholesterol increased	1	(0.3)	1	0					1	(0.2)	1	0
Electrocardiogram QT prolonged	1	(0.3)	1	0					1	(0.2)	1	0
Eosinophil count increased					1	(0.6)	1	1	1	(0.2)	1	0
Haemoglobin decreased					1	(0.6)	1	1	1	(0.2)	1	0
Intraocular pressure increased					1	(0.6)	1	1	1	(0.2)	1	0
Liver function test abnormal	1	(0.3)	1	0					1	(0.2)	1	0
Urine albumin/creatinine ratio increased					1	(0.6)	1	1	1	(0.2)	1	0
Reproductive system and breast disorders	11	(3.0)	14	5	7	(3.9)	7	5	18	(3.3)	21	5
Dysmenorrhoea	5	(1.4)	7	2	2	(1.1)	2	1	7	(1.3)	9	2
Premenstrual syndrome	2	(0.6)	2	1					2	(0.4)	2	0
Breast cyst					1	(0.6)	1	1	1	(0.2)	1	0
Ectropion of cervix	1	(0.3)	1	0					1	(0.2)	1	0
Endometriosis	1	(0.3)	1	0					1	(0.2)	1	0
Erectile dysfunction					1	(0.6)	1	1	1	(0.2)	1	0
Haematospermia	1	(0.3)	1	0					1	(0.2)	1	0
Metrorrhagia					1	(0.6)	1	1	1	(0.2)	1	0
Ovarian cyst	1	(0.3)	1	0					1	(0.2)	1	0
Prostatitis					1	(0.6)	1	1	1	(0.2)	1	0
Uterine polyp	1	(0.3)	1	0					1	(0.2)	1	0
Vulvovaginal pruritus					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Psychiatric disorders	9	(2.5)	11	4	7	(3.9)	7	5	16	(3.0)	18	4
Stress	3	(0.8)	3	1	4	(2.2)	4	3	7	(1.3)	7	2
Insomnia	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Anxiety	1	(0.3)	2	1					1	(0.2)	2	0
Depression					1	(0.6)	1	1	1	(0.2)	1	0
Drug abuse	1	(0.3)	1	0					1	(0.2)	1	0
Mood altered	1	(0.3)	1	0					1	(0.2)	1	0
Sleep disorder	1	(0.3)	1	0					1	(0.2)	1	0
Immune system disorders	9	(2.5)	10	3	4	(2.2)	4	3	13	(2.4)	14	3
Seasonal allergy	5	(1.4)	5	2	2	(1.1)	2	1	7	(1.3)	7	2
Hypersensitivity	3	(0.8)	4	1	2	(1.1)	2	1	5	(0.9)	6	1
Allergy to animal	1	(0.3)	1	0					1	(0.2)	1	0
Vascular disorders	6	(1.7)	8	3	6	(3.3)	6	4	12	(2.2)	14	3
Hypertension	5	(1.4)	5	2	3	(1.7)	3	2	8	(1.5)	8	2
Varicose vein	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Haematoma	1	(0.3)	2	1					1	(0.2)	2	0
Hot flush					1	(0.6)	1	1	1	(0.2)	1	0
Hypotension					1	(0.6)	1	1	1	(0.2)	1	0
Ear and labyrinth disorders	4	(1.1)	4	1	4	(2.2)	4	3	8	(1.5)	8	2
Ear pain	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Middle ear effusion					1	(0.6)	1	1	1	(0.2)	1	0
Tinnitus	1	(0.3)	1	0					1	(0.2)	1	0
Tympanic membrane disorder					1	(0.6)	1	1	1	(0.2)	1	0
Vertigo	1	(0.3)	1	0					1	(0.2)	1	0
Cardiac disorders	4	(1.1)	4	1	3	(1.7)	3	2	7	(1.3)	7	2
Palpitations	2	(0.6)	2	1					2	(0.4)	2	0
Atrial fibrillation					1	(0.6)	1	1	1	(0.2)	1	0
Bifascicular block	1	(0.3)	1	0					1	(0.2)	1	0
Bundle branch block right					1	(0.6)	1	1	1	(0.2)	1	0
Left ventricular dysfunction	1	(0.3)	1	0					1	(0.2)	1	0
Tachyarrhythmia					1	(0.6)	1	1	1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

Mild Adverse Events by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	(0.3)	1	0	4	(2.2)	4	3	5	(0.9)	5	1
Benign neoplasm of thyroid gland					1	(0.6)	1	1	1	(0.2)	1	0
Lipoma	1	(0.3)	1	0					1	(0.2)	1	0
Skin papilloma					1	(0.6)	1	1	1	(0.2)	1	0
Thyroid neoplasm					1	(0.6)	1	1	1	(0.2)	1	0
Uterine leiomyoma					1	(0.6)	1	1	1	(0.2)	1	0
Renal and urinary disorders	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Bladder irritation	1	(0.3)	1	0					1	(0.2)	1	0
Cystitis noninfective	1	(0.3)	1	0					1	(0.2)	1	0
Haematuria					1	(0.6)	1	1	1	(0.2)	1	0
Ketonuria					1	(0.6)	1	1	1	(0.2)	1	0
Renal failure acute	1	(0.3)	1	0					1	(0.2)	1	0
Blood and lymphatic system disorders	1	(0.3)	4	1	2	(1.1)	2	1	3	(0.6)	6	1
Anaemia	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Lymphadenitis					1	(0.6)	1	1	1	(0.2)	1	0
Lymphadenopathy	1	(0.3)	3	1					1	(0.2)	3	1
Surgical and medical procedures	2	(0.6)	3	1	1	(0.6)	1	1	3	(0.6)	4	1
Tooth extraction	1	(0.3)	2	1	1	(0.6)	1	1	2	(0.4)	3	1
Intraocular lens implant	1	(0.3)	1	0					1	(0.2)	1	0
Endocrine disorders	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Hypogonadism					1	(0.6)	1	1	1	(0.2)	1	0
Hypothyroidism	1	(0.3)	1	0					1	(0.2)	1	0
Hepatobiliary disorders	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Cholelithiasis					1	(0.6)	1	1	1	(0.2)	1	0
Hepatic steatosis	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:05 - tsum_events_tpl_t030_v01.sas/t_ae_te_mild_soc_pf_sum_sas.txt

14.3.1.24: Adverse Events Leading To Dose Reduction - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N (%)	OD E R	IDet N (%)	E R	Total N (%)	E R
Number of Subjects	362		180		542	
Events	49 (13.5)	62 21	22 (12.2)	39 27	71 (13.1)	101 23
Serious						
Yes	16 (4.4)	19 6	6 (3.3)	7 5	22 (4.1)	26 6
No	33 (9.1)	43 14	19 (10.6)	32 22	52 (9.6)	75 17
Severity						
Severe	25 (6.9)	32 11	16 (8.9)	31 21	41 (7.6)	63 14
Moderate	10 (2.8)	12 4	5 (2.8)	5 3	15 (2.8)	17 4
Mild	16 (4.4)	18 6	3 (1.7)	3 2	19 (3.5)	21 5
Relationship to Investigational Product						
Probable	11 (3.0)	13 4	10 (5.6)	11 8	21 (3.9)	24 5
Possible	8 (2.2)	8 3	6 (3.3)	7 5	14 (2.6)	15 3
Unlikely	15 (4.1)	20 7	3 (1.7)	5 3	18 (3.3)	25 6
Relationship to Bolus Insulin						
Probable	17 (4.7)	19 6	8 (4.4)	11 8	25 (4.6)	30 7
Possible	8 (2.2)	8 3	8 (4.4)	8 5	16 (3.0)	16 4
Unlikely	14 (3.9)	17 6	5 (2.8)	6 4	19 (3.5)	23 5
Dose Reduction	49 (13.5)	62 21	22 (12.2)	39 27	71 (13.1)	101 23
IDegAsp/Comparator	31 (8.6)	41 14	16 (8.9)	23 16	47 (8.7)	64 14
Insulin Aspart	36 (9.9)	44 15	16 (8.9)	25 17	52 (9.6)	69 16
NPH	1 (0.3)	1 0	0		1 (0.2)	1 0
Outcome						
Recovered	48 (13.3)	61 21	21 (11.7)	38 26	69 (12.7)	99 22
Recovering	0		0		0	
Recovered With Sequelae	0		0		0	
Not Recovered	1 (0.3)	1 0	1 (0.6)	1 1	2 (0.4)	2 0
Fatal	0		0		0	
Unknown	0		0		0	

N: Number of Subjects, %: Percentage of subjects, E: Number of Events
A single adverse event can lead to the dose reduction of multiple trial products
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:51 - tsum_ae_dose_red/t_ae_dos_red_te_sum_sas.txt

14.3.1.25: Neoplasms by System Organ Class and Preferred Term - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	Total N	(%)	E	R
Number Of Subjects	362				180				542			
Events	4 (1.1)	4	1		7 (3.9)	7	5		11 (2.0)	11	2	
Gastrointestinal Disorders												
Colonic Polyp	1 (0.3)	1	0						1 (0.2)	1	0	
Gastric Polyps	1 (0.3)	1	0						1 (0.2)	1	0	
Infections And Infestations												
Helicobacter Gastritis	1 (0.3)	1	0						1 (0.2)	1	0	
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)												
Benign Neoplasm Of Thyroid Gland					1 (0.6)	1	1		1 (0.2)	1	0	
Bladder Cancer					1 (0.6)	1	1		1 (0.2)	1	0	
Lipoma	1 (0.3)	1	0						1 (0.2)	1	0	
Skin Papilloma					1 (0.6)	1	1		1 (0.2)	1	0	
Squamous Cell Carcinoma Of Skin					1 (0.6)	1	1		1 (0.2)	1	0	
Thyroid Neoplasm					1 (0.6)	1	1		1 (0.2)	1	0	
Uterine Leiomyoma					2 (1.1)	2	1		2 (0.4)	2	0	

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events,
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:41 - t_teae_allergy_neoplasm.sas/t_ae_te_neoplasms.txt

14.3.1.26: Allergic Reaction (Immunogenicity) by System Organ Class and Preferred Term - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	Total N	(%)	E	R
Number Of Subjects	362				180				542			
Events	1 (0.3)	1	0		2 (1.1)	2	1		3 (0.6)	3	1	
Eye Disorders												
Eye Swelling	1 (0.3)	1	0		1 (0.6)	1	1		2 (0.4)	2	0	
Skin And Subcutaneous Tissue Disorders												
Urticaria					1 (0.6)	1	1		1 (0.2)	1	0	

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events,
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:40 - t_teae_allergy_neoplasm.sas/t_ae_te_allergy.txt

14.3.1.27: Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Events	49 (13.5)	62	21	22 (12.2)	39	27	71 (13.1)	101	23
Metabolism and nutrition disorders	28 (7.7)	36	12	20 (11.1)	33	23	48 (8.9)	69	16
Hypoglycaemia	22 (6.1)	29	10	17 (9.4)	26	18	39 (7.2)	55	12
Hypoglycaemic unconsciousness	6 (1.7)	6	2	5 (2.8)	5	3	11 (2.0)	11	2
Decreased appetite	1 (0.3)	1	0				1 (0.2)	1	0
Diabetic ketoacidosis				1 (0.6)	1	1	1 (0.2)	1	0
Hypoglycaemic seizure				1 (0.6)	1	1	1 (0.2)	1	0
Infections and infestations	8 (2.2)	8	3	1 (0.6)	1	1	9 (1.7)	9	2
Gastroenteritis	2 (0.6)	2	1				2 (0.4)	2	0
Acute tonsillitis	1 (0.3)	1	0				1 (0.2)	1	0
Ear infection	1 (0.3)	1	0				1 (0.2)	1	0
Gastroenteritis viral				1 (0.6)	1	1	1 (0.2)	1	0
H1N1 influenza	1 (0.3)	1	0				1 (0.2)	1	0
Pharyngitis	1 (0.3)	1	0				1 (0.2)	1	0
Rotavirus infection	1 (0.3)	1	0				1 (0.2)	1	0
Upper respiratory tract infection	1 (0.3)	1	0				1 (0.2)	1	0
Gastrointestinal disorders	6 (1.7)	8	3	2 (1.1)	2	1	8 (1.5)	10	2
Abdominal discomfort	2 (0.6)	2	1				2 (0.4)	2	0
Vomiting	2 (0.6)	2	1				2 (0.4)	2	0
Diarrhoea	1 (0.3)	1	0				1 (0.2)	1	0
Dyspepsia	1 (0.3)	1	0				1 (0.2)	1	0
Food poisoning	1 (0.3)	1	0				1 (0.2)	1	0
Gastritis	1 (0.3)	1	0				1 (0.2)	1	0
Nausea				1 (0.6)	1	1	1 (0.2)	1	0
Pancreatitis chronic				1 (0.6)	1	1	1 (0.2)	1	0

N= Number of subjects

%= Percentage of subjects

E= Number of Events

R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:07 - tsum_events_tpl_t030_v01.sas/t_ae_te_dose_red_soc_pf_sum_sas.txt

Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term -
Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Injury, poisoning and procedural complications	3	(0.8)	3	1	1	(0.6)	1	1	4	(0.7)	4	1
Wrong drug administered	2	(0.6)	2	1					2	(0.4)	2	0
Medication error					1	(0.6)	1	1	1	(0.2)	1	0
Overdose	1	(0.3)	1	0					1	(0.2)	1	0
Nervous system disorders	4	(1.1)	4	1					4	(0.7)	4	1
Headache	3	(0.8)	3	1					3	(0.6)	3	1
Migraine	1	(0.3)	1	0					1	(0.2)	1	0
Skin and subcutaneous tissue disorders	2	(0.6)	2	1					2	(0.4)	2	0
Lipodystrophy												
acquired	1	(0.3)	1	0					1	(0.2)	1	0
Lipohypertrophy	1	(0.3)	1	0					1	(0.2)	1	0
Eye disorders					1	(0.6)	1	1	1	(0.2)	1	0
Vision blurred					1	(0.6)	1	1	1	(0.2)	1	0
General disorders and administration site conditions					1	(0.6)	1	1	1	(0.2)	1	0
Injection site reaction					1	(0.6)	1	1	1	(0.2)	1	0
Reproductive system and breast disorders	1	(0.3)	1	0					1	(0.2)	1	0
Benign prostatic hyperplasia	1	(0.3)	1	0					1	(0.2)	1	0

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:07 - tsum_events_tpl_t030_v01.sas/t_ae_te_dose_red_soc_pf_sum_sas.txt

14.3.1.28: Adjudicated Cardiovascular Events - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180			
EAC Evaluated Events	3	(0.8)	3	1	1	(0.6)	1	1
Non MACE	3	(0.8)	3	1	1	(0.6)	1	1
MACE	0	(0.0)	0	0	0	(0.0)	0	0
Acute coronary syndrome	0	(0.0)	0	0	0	(0.0)	0	0
Unstable Angina pectoris	0	(0.0)	0	0	0	(0.0)	0	0
Myocardial Infarction	0	(0.0)	0	0	0	(0.0)	0	0
STEMI	0	(0.0)	0	0	0	(0.0)	0	0
NSTEMI	0	(0.0)	0	0	0	(0.0)	0	0
Stroke	0	(0.0)	0	0	0	(0.0)	0	0
Cardiovascular Death	0	(0.0)	0	0	0	(0.0)	0	0

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events
R: Event Rate per 100 Exposure Years, EAC:(external) Event Adjudication Committee,
MACE: Major Adverse Cardiovascular Events, NSTEMI: Non-ST-elevation Myocardial Infarction
STEMI: ST-elevation Myocardial Infarction.

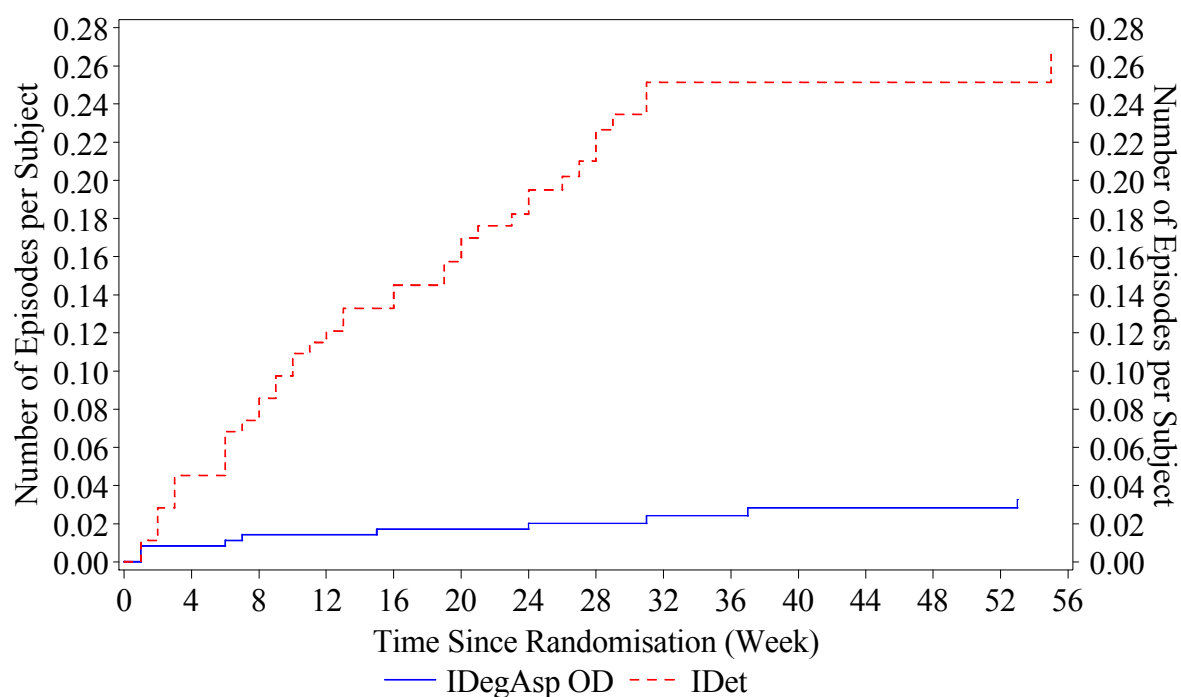
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:50 - tsum_adj_cardio_teae.sas/t_eac_te_sum_sas.txt

14.3.1.29: Injection Site Reaction by System Organ Class and Preferred Term - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	Total N	(%)	E	R
Number Of Subjects	362				180				542			
Events	7	(1.9)	10	3	12	(6.7)	41	28	19	(3.5)	51	12
General Disorders And Administration Site Conditions												
Injection Site Erythema					1	(0.6)	1	1	1	(0.2)	1	0
Injection Site Haematoma					2	(1.1)	2	1	2	(0.4)	2	0
Injection Site Pain	2	(0.6)	2	1	1	(0.6)	1	1	3	(0.6)	3	1
Injection Site Papule					1	(0.6)	1	1	1	(0.2)	1	0
Injection Site Reaction	5	(1.4)	8	3	9	(5.0)	36	25	14	(2.6)	44	10

N: Number of Subjects, %: Percentage of Subjects, E: Number of Events,
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:42 - t_teae_allergy_neoplasm.sas/t_ae_te_injec_sit_react.txt



SAFETY;
Observed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:24:18 - fmean_inj_react.sas/e_inject_site_react_mcf_sas.cgm

14.3.1.30: Injection Site Reactions - Mean Cumulative Function - Safety Analysis Set

14.3.1.31: Medication Errors - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	362				180				542			
Total Events	16	(4.4)	20	7	8	(4.4)	8	5	24	(4.4)	28	6
Serious												
Yes	3	(0.8)	4	1	0	(0.0)	0	0	3	(0.6)	4	1
No	13	(3.6)	16	5	8	(4.4)	8	5	21	(3.9)	24	5
Severity												
Severe	2	(0.6)	3	1	2	(1.1)	2	1	4	(0.7)	5	1
Moderate	6	(1.7)	6	2	3	(1.7)	3	2	9	(1.7)	9	2
Mild	10	(2.8)	11	4	3	(1.7)	3	2	13	(2.4)	14	3
Relationship to IDegAsp/Comparator												
Probable/Possible	6	(1.7)	6	2	3	(1.7)	3	2	9	(1.7)	9	2
Relationship to Insulin Aspart												
Probable/Possible	6	(1.7)	7	2	4	(2.2)	4	3	10	(1.8)	11	2
Outcome												
Recovered	16	(4.4)	20	7	8	(4.4)	8	5	24	(4.4)	28	6
Recovering	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Recovered With Sequelae	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Not Recovered	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Unknown	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Incorrect dose administered	3	(0.8)	3	1	0	(0.0)	0	0	3	(0.6)	3	1
Serious	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relationship to IDegAsp/Comparator												
Probable/Possible	1	(0.3)	1	0	0	(0.0)	0	0	1	(0.2)	1	0
Relationship to Insulin Aspart												
Probable/Possible	2	(0.6)	2	1	0	(0.0)	0	0	2	(0.4)	2	0
Intentional overdose	1	(0.3)	2	1	0	(0.0)	0	0	1	(0.2)	2	0
Serious	1	(0.3)	2	1	0	(0.0)	0	0	1	(0.2)	2	0
Relationship to IDegAsp/Comparator												
Probable/Possible	1	(0.3)	1	0	0	(0.0)	0	0	1	(0.2)	1	0
Relationship to Insulin Aspart												
Probable/Possible	1	(0.3)	2	1	0	(0.0)	0	0	1	(0.2)	2	0
Medication error	2	(0.6)	2	1	2	(1.1)	2	1	4	(0.7)	4	1
Serious	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relationship to IDegAsp/Comparator												
Probable/Possible	1	(0.3)	1	0	1	(0.6)	1	1	2	(0.4)	2	0
Relationship to Insulin Aspart												
Probable/Possible	0	(0.0)	0	0	1	(0.6)	1	1	1	(0.2)	1	0
Overdose	1	(0.3)	1	0	0	(0.0)	0	0	1	(0.2)	1	0
Serious	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relationship to IDegAsp/Comparator												
Probable/Possible	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relationship to Insulin Aspart												
Probable/Possible	1	(0.3)	1	0	0	(0.0)	0	0	1	(0.2)	1	0

N: Number of Subjects, %: Percentage of subjects, E: Number of Events,
R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:38:55 - tsum_teae_med_err.sas/tsum_teae_med_err_sas.txt

Medication Errors - Treatment Emergent - Summary - Safety Analysis Set

	N	IDegAsp (%)	OD E	R	N	IDet (%)	E	R	N	Total (%)	E	R
Wrong drug administered	10	(2.8)	12	4	6	(3.3)	6	4	16	(3.0)	18	4
Serious	2	(0.6)	2	1	0	(0.0)	0	0	2	(0.4)	2	0
Relationship to IDegAsp/Comparator												
Probable/Possible	3	(0.8)	3	1	2	(1.1)	2	1	5	(0.9)	5	1
Relationship to Insulin Aspart												
Probable/Possible	2	(0.6)	2	1	3	(1.7)	3	2	5	(0.9)	5	1

N: Number of Subjects, %: Percentage of subjects, E: Number of Events,
 R: Event Rate per 100 Exposure Years

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:38:55 - tsum_teae_med_err.sas/tsum_teae_med_err_sas.txt

14.3.1.32: Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Confirmed	344 (95.0)	9450	3183	169 (93.9)	5342	3673	513 (94.6)	14792	3344
ADA	355 (98.1)	20460	6892	173 (96.1)	10536	7243	528 (97.4)	30996	7007
Severe	48 (13.3)	79	27	33 (18.3)	65	45	81 (14.9)	144	33
Documented Sympt.	330 (91.2)	14038	4729	162 (90.0)	7611	5232	492 (90.8)	21649	4894
Asymptomatic	283 (78.2)	5879	1980	141 (78.3)	2575	1770	424 (78.2)	8454	1911
Probable Sympt.	84 (23.2)	323	109	48 (26.7)	245	168	132 (24.4)	568	128
Relative	50 (13.8)	141	47	21 (11.7)	40	27	71 (13.1)	181	41
ADA Unclassifiable	119 (32.9)	507	171	57 (31.7)	296	203	176 (32.5)	803	182

N: Number of Subjects

?: Percentage of Subjects with the Event

E: Number of Events

R: Event Rate per 100 Patient Year(s) of Exposure

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:16 - tsum_hypo_class_tpl_t027_v01.sas/t_hypo_te_sum_sas.txt

14.3.1.33: Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Extension Trial Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	254			122			376		
Confirmed	241 (94.9)	7392	2903	117 (95.9)	4449	3628	358 (95.2)	11841	3139
ADA	251 (98.8)	16227	6373	120 (98.4)	8802	7178	371 (98.7)	25029	6635
Severe	34 (13.4)	53	21	24 (19.7)	51	42	58 (15.4)	104	28
Documented Sympt.	233 (91.7)	10860	4265	112 (91.8)	6372	5196	345 (91.8)	17232	4568
Asymptomatic	203 (79.9)	4951	1944	100 (82.0)	2156	1758	303 (80.6)	7107	1884
Probable Sympt.	58 (22.8)	241	95	36 (29.5)	199	162	94 (25.0)	440	117
Relative	38 (15.0)	122	48	14 (11.5)	24	20	52 (13.8)	146	39
ADA Unclassifiable	80 (31.5)	392	154	39 (32.0)	198	161	119 (31.6)	590	156

N: Number of Subjects

%: Percentage of Subjects with the Event

E: Number of Events

R: Event Rate per 100 Patient Year(s) of Exposure

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats

07MAY2011:14:00:24 - tsum_hypo_class_tpl_t027_v01.sas/t_hypo_te_sum_ets.txt

14.3.1.34: Nocturnal Hypoglycaemic Episodes by Classification - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	362			180			542		
Confirmed	221 (61.0)	918	309	135 (75.0)	787	541	356 (65.7)	1705	385
ADA	256 (70.7)	1654	557	147 (81.7)	1171	805	403 (74.4)	2825	639
Severe	13 (3.6)	14	5	14 (7.8)	28	19	27 (5.0)	42	9
Documented Sympt.	224 (61.9)	1275	429	119 (66.1)	904	621	343 (63.3)	2179	493
Asymptomatic	98 (27.1)	303	102	58 (32.2)	176	121	156 (28.8)	479	108
Probable Sympt.	28 (7.7)	56	19	24 (13.3)	58	40	52 (9.6)	114	26
Relative	4 (1.1)	6	2	5 (2.8)	5	3	9 (1.7)	11	2
ADA Unclassified	12 (3.3)	13	4	8 (4.4)	22	15	20 (3.7)	35	8

N: Number of Subjects

%: Percentage of Subjects with the Event

E: Number of Events

R: Event Rate per 100 Patient Year(s) of Exposure

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:33 - tsum_hypo_class_tpl_t027_v01.sas/t_hypo_te_noct_sum_sas.txt

14.3.1.35: Nocturnal Hypoglycaemic Episodes by Classification – Treatment Emergent - Summary - Extension Trial Set

	IDegAsp N (%)	OD E R	IDet N (%)	E R	Total N (%)	E R
Number of Subjects	254		122		376	
Confirmed	156 (61.4)	672 264	99 (81.1)	677 552	255 (67.8)	1349 358
ADA	181 (71.3)	1250 491	106 (86.9)	1018 830	287 (76.3)	2268 601
Severe	9 (3.5)	9 4	11 (9.0)	23 19	20 (5.3)	32 8
Documented Sympt.	155 (61.0)	942 370	87 (71.3)	787 642	242 (64.4)	1729 458
Asymptomatic	78 (30.7)	249 98	46 (37.7)	154 126	124 (33.0)	403 107
Probable Sympt.	21 (8.3)	44 17	19 (15.6)	51 42	40 (10.6)	95 25
Relative	4 (1.6)	6 2	3 (2.5)	3 2	7 (1.9)	9 2
ADA Unclassified	8 (3.1)	8 3	6 (4.9)	19 15	14 (3.7)	27 7

N: Number of Subjects

%: Percentage of Subjects with the Event

E: Number of Events

R: Event Rate per 100 Patient Year(s) of Exposure

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:42 - tsum_hypo_class_tpl_t027_v01.sas/t_hypo_te_noct_sum_ets.txt

14.3.1.36: Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Number of Subjects	362			180			542		
Confirmed	344	(95.0)	9450	169	(93.9)	5342	513	(94.6)	14792
1 - 4 Weeks	277	(76.5)	1307	134	(74.4)	546	411	(75.8)	1853
5 - 8 Weeks	262	(72.4)	1045	125	(69.4)	618	387	(71.4)	1663
9 - 12 Weeks	231	(63.8)	888	129	(71.7)	553	360	(66.4)	1441
13 - 16 Weeks	235	(64.9)	965	120	(66.7)	568	355	(65.5)	1533
17 - 20 Weeks	226	(62.4)	868	112	(62.2)	551	338	(62.4)	1419
21 - 24 Weeks	230	(63.5)	890	111	(61.7)	488	341	(62.9)	1378
25 - 28 Weeks	208	(57.5)	790	111	(61.7)	466	319	(58.9)	1256
29 - 32 Weeks	136	(37.6)	488	68	(37.8)	266	204	(37.6)	754
33 - 36 Weeks	123	(34.0)	379	61	(33.9)	234	184	(33.9)	613
37 - 40 Weeks	127	(35.1)	398	79	(43.9)	239	206	(38.0)	637
41 - 44 Weeks	125	(34.5)	402	66	(36.7)	213	191	(35.2)	615
45 - 48 Weeks	124	(34.3)	377	66	(36.7)	224	190	(35.1)	601
49 - 52 Weeks	119	(32.9)	364	59	(32.8)	217	178	(32.8)	581
> 52 Weeks	118	(32.6)	289	60	(33.3)	159	178	(32.8)	448
ADA	355	(98.1)	20460	173	(96.1)	10536	528	(97.4)	30996
1 - 4 Weeks	316	(87.3)	2586	157	(87.2)	1094	473	(87.3)	3680
5 - 8 Weeks	306	(84.5)	2229	150	(83.3)	1200	456	(84.1)	3429
9 - 12 Weeks	282	(77.9)	1960	149	(82.8)	1066	431	(79.5)	3026
13 - 16 Weeks	283	(78.2)	2051	140	(77.8)	1070	423	(78.0)	3121
17 - 20 Weeks	278	(76.8)	1931	139	(77.2)	987	417	(76.9)	2918
21 - 24 Weeks	265	(73.2)	1941	136	(75.6)	972	401	(74.0)	2913
25 - 28 Weeks	255	(70.4)	1646	133	(73.9)	901	388	(71.6)	2547
29 - 32 Weeks	194	(53.6)	1131	92	(51.1)	547	286	(52.8)	1678
33 - 36 Weeks	181	(50.0)	922	89	(49.4)	476	270	(49.8)	1398
37 - 40 Weeks	176	(48.6)	923	101	(56.1)	499	277	(51.1)	1422
41 - 44 Weeks	180	(49.7)	888	90	(50.0)	458	270	(49.8)	1346
45 - 48 Weeks	165	(45.6)	827	92	(51.1)	456	257	(47.4)	1283
49 - 52 Weeks	167	(46.1)	825	81	(45.0)	476	248	(45.8)	1301
> 52 Weeks	157	(43.4)	600	79	(43.9)	334	236	(43.5)	934

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:49 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_sas.txt

Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Severe	48	(13.3)	79	33	(18.3)	65	81	(14.9)	144
1 - 4 Weeks	9	(2.5)	13	6	(3.3)	7	15	(2.8)	20
5 - 8 Weeks	11	(3.0)	14	5	(2.8)	5	16	(3.0)	19
9 - 12 Weeks	4	(1.1)	4	7	(3.9)	8	11	(2.0)	12
13 - 16 Weeks	8	(2.2)	10	5	(2.8)	5	13	(2.4)	15
17 - 20 Weeks	4	(1.1)	5	6	(3.3)	6	10	(1.8)	11
21 - 24 Weeks	2	(0.6)	2	3	(1.7)	3	5	(0.9)	5
25 - 28 Weeks	6	(1.7)	8	3	(1.7)	3	9	(1.7)	11
29 - 32 Weeks	2	(0.6)	3	3	(1.7)	3	5	(0.9)	6
33 - 36 Weeks	3	(0.8)	4	3	(1.7)	5	6	(1.1)	9
37 - 40 Weeks	3	(0.8)	3	7	(3.9)	7	10	(1.8)	10
41 - 44 Weeks	5	(1.4)	5	3	(1.7)	3	8	(1.5)	8
45 - 48 Weeks	4	(1.1)	5	3	(1.7)	6	7	(1.3)	11
49 - 52 Weeks	2	(0.6)	2	3	(1.7)	3	5	(0.9)	5
> 52 Weeks	1	(0.3)	1	1	(0.6)	1	2	(0.4)	2
Doc. Symptomatic	330	(91.2)	14038	162	(90.0)	7611	492	(90.8)	21649
1 - 4 Weeks	273	(75.4)	1824	128	(71.1)	754	401	(74.0)	2578
5 - 8 Weeks	258	(71.3)	1566	130	(72.2)	881	388	(71.6)	2447
9 - 12 Weeks	236	(65.2)	1316	125	(69.4)	786	361	(66.6)	2102
13 - 16 Weeks	237	(65.5)	1372	109	(60.6)	763	346	(63.8)	2135
17 - 20 Weeks	234	(64.6)	1285	114	(63.3)	720	348	(64.2)	2005
21 - 24 Weeks	221	(61.0)	1345	114	(63.3)	694	335	(61.8)	2039
25 - 28 Weeks	204	(56.4)	1111	110	(61.1)	625	314	(57.9)	1736
29 - 32 Weeks	144	(39.8)	722	75	(41.7)	397	219	(40.4)	1119
33 - 36 Weeks	142	(39.2)	622	71	(39.4)	351	213	(39.3)	973
37 - 40 Weeks	141	(39.0)	617	77	(42.8)	351	218	(40.2)	968
41 - 44 Weeks	135	(37.3)	612	71	(39.4)	318	206	(38.0)	930
45 - 48 Weeks	133	(36.7)	595	70	(38.9)	352	203	(37.5)	947
49 - 52 Weeks	137	(37.8)	611	68	(37.8)	368	205	(37.8)	979
> 52 Weeks	131	(36.2)	440	63	(35.0)	251	194	(35.8)	691

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:49 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_sas.txt

Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Asymptomatic	283	(78.2)	5879	141	(78.3)	2575	424	(78.2)	8454
1 - 4 Weeks	174	(48.1)	651	85	(47.2)	285	259	(47.8)	936
5 - 8 Weeks	164	(45.3)	599	73	(40.6)	281	237	(43.7)	880
9 - 12 Weeks	158	(43.6)	592	70	(38.9)	247	228	(42.1)	839
13 - 16 Weeks	160	(44.2)	632	72	(40.0)	279	232	(42.8)	911
17 - 20 Weeks	144	(39.8)	607	67	(37.2)	250	211	(38.9)	857
21 - 24 Weeks	129	(35.6)	553	66	(36.7)	248	195	(36.0)	801
25 - 28 Weeks	135	(37.3)	490	62	(34.4)	253	197	(36.3)	743
29 - 32 Weeks	103	(28.5)	388	45	(25.0)	130	148	(27.3)	518
33 - 36 Weeks	77	(21.3)	275	40	(22.2)	108	117	(21.6)	383
37 - 40 Weeks	84	(23.2)	286	47	(26.1)	129	131	(24.2)	415
41 - 44 Weeks	79	(21.8)	248	39	(21.7)	125	118	(21.8)	373
45 - 48 Weeks	69	(19.1)	206	29	(16.1)	83	98	(18.1)	289
49 - 52 Weeks	73	(20.2)	201	36	(20.0)	88	109	(20.1)	289
> 52 Weeks	67	(18.5)	151	32	(17.8)	69	99	(18.3)	220
Prob. Symptomatic	84	(23.2)	323	48	(26.7)	245	132	(24.4)	568
1 - 4 Weeks	40	(11.0)	70	15	(8.3)	37	55	(10.1)	107
5 - 8 Weeks	23	(6.4)	34	16	(8.9)	24	39	(7.2)	58
9 - 12 Weeks	21	(5.8)	32	14	(7.8)	23	35	(6.5)	55
13 - 16 Weeks	21	(5.8)	29	11	(6.1)	21	32	(5.9)	50
17 - 20 Weeks	12	(3.3)	18	6	(3.3)	10	18	(3.3)	28
21 - 24 Weeks	12	(3.3)	24	14	(7.8)	23	26	(4.8)	47
25 - 28 Weeks	15	(4.1)	28	10	(5.6)	15	25	(4.6)	43
29 - 32 Weeks	7	(1.9)	11	10	(5.6)	15	17	(3.1)	26
33 - 36 Weeks	11	(3.0)	16	8	(4.4)	12	19	(3.5)	28
37 - 40 Weeks	7	(1.9)	11	4	(2.2)	11	11	(2.0)	22
41 - 44 Weeks	12	(3.3)	17	6	(3.3)	12	18	(3.3)	29
45 - 48 Weeks	10	(2.8)	17	7	(3.9)	15	17	(3.1)	32
49 - 52 Weeks	7	(1.9)	9	8	(4.4)	17	15	(2.8)	26
> 52 Weeks	6	(1.7)	7	5	(2.8)	10	11	(2.0)	17

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:49 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_sas.txt

Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Relative	50	(13.8)	141	21	(11.7)	40	71	(13.1)	181
1 - 4 Weeks	15	(4.1)	28	7	(3.9)	11	22	(4.1)	39
5 - 8 Weeks	10	(2.8)	16	6	(3.3)	9	16	(3.0)	25
9 - 12 Weeks	9	(2.5)	16	2	(1.1)	2	11	(2.0)	18
13 - 16 Weeks	6	(1.7)	8	1	(0.6)	2	7	(1.3)	10
17 - 20 Weeks	11	(3.0)	16	1	(0.6)	1	12	(2.2)	17
21 - 24 Weeks	9	(2.5)	17	2	(1.1)	4	11	(2.0)	21
25 - 28 Weeks	6	(1.7)	9	4	(2.2)	5	10	(1.8)	14
29 - 32 Weeks	7	(1.9)	7	2	(1.1)	2	9	(1.7)	9
33 - 36 Weeks	3	(0.8)	5	0	(0.0)	0	3	(0.6)	5
37 - 40 Weeks	3	(0.8)	6	1	(0.6)	1	4	(0.7)	7
41 - 44 Weeks	4	(1.1)	6	0	(0.0)	0	4	(0.7)	6
45 - 48 Weeks	4	(1.1)	4	0	(0.0)	0	4	(0.7)	4
49 - 52 Weeks	2	(0.6)	2	0	(0.0)	0	2	(0.4)	2
> 52 Weeks	1	(0.3)	1	2	(1.1)	3	3	(0.6)	4
ADA Unclassifiable	119	(32.9)	507	57	(31.7)	296	176	(32.5)	803
1 - 4 Weeks	43	(11.9)	62	5	(2.8)	6	48	(8.9)	68
5 - 8 Weeks	32	(8.8)	66	23	(12.8)	38	55	(10.1)	104
9 - 12 Weeks	34	(9.4)	48	14	(7.8)	36	48	(8.9)	84
13 - 16 Weeks	25	(6.9)	50	16	(8.9)	40	41	(7.6)	90
17 - 20 Weeks	32	(8.8)	75	20	(11.1)	57	52	(9.6)	132
21 - 24 Weeks	29	(8.0)	58	15	(8.3)	49	44	(8.1)	107
25 - 28 Weeks	25	(6.9)	40	12	(6.7)	18	37	(6.8)	58
29 - 32 Weeks	12	(3.3)	23	9	(5.0)	19	21	(3.9)	42
33 - 36 Weeks	8	(2.2)	9	2	(1.1)	4	10	(1.8)	13
37 - 40 Weeks	8	(2.2)	9	4	(2.2)	9	12	(2.2)	18
41 - 44 Weeks	7	(1.9)	9	4	(2.2)	6	11	(2.0)	15
45 - 48 Weeks	6	(1.7)	21	4	(2.2)	6	10	(1.8)	27
49 - 52 Weeks	13	(3.6)	22	3	(1.7)	5	16	(3.0)	27
> 52 Weeks	11	(3.0)	15	2	(1.1)	3	13	(2.4)	18

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:49 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_sas.txt

14.3.1.37: Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Extension Trial Set

	IDegAsp	OD		IDet		Total	
	N	(%)	E	N	(%)	N	(%)
Number of Subjects	254			122		376	
Confirmed	241 (94.9)		7392	117 (95.9)	4449	358 (95.2)	11841
1 - 4 Weeks	189 (74.4)		804	93 (76.2)	403	282 (75.0)	1207
5 - 8 Weeks	176 (69.3)		708	84 (68.9)	449	260 (69.1)	1157
9 - 12 Weeks	167 (65.7)		604	91 (74.6)	416	258 (68.6)	1020
13 - 16 Weeks	170 (66.9)		705	86 (70.5)	431	256 (68.1)	1136
17 - 20 Weeks	164 (64.6)		628	82 (67.2)	429	246 (65.4)	1057
21 - 24 Weeks	175 (68.9)		640	85 (69.7)	388	260 (69.1)	1028
25 - 28 Weeks	157 (61.8)		613	86 (70.5)	382	243 (64.6)	995
29 - 32 Weeks	134 (52.8)		481	67 (54.9)	265	201 (53.5)	746
33 - 36 Weeks	123 (48.4)		379	61 (50.0)	234	184 (48.9)	613
37 - 40 Weeks	127 (50.0)		398	79 (64.8)	239	206 (54.8)	637
41 - 44 Weeks	125 (49.2)		402	66 (54.1)	213	191 (50.8)	615
45 - 48 Weeks	124 (48.8)		377	66 (54.1)	224	190 (50.5)	601
49 - 52 Weeks	119 (46.9)		364	59 (48.4)	217	178 (47.3)	581
> 52 Weeks	118 (46.5)		289	60 (49.2)	159	178 (47.3)	448
ADA	251 (98.8)		16227	120 (98.4)	8802	371 (98.7)	25029
1 - 4 Weeks	217 (85.4)		1679	108 (88.5)	783	325 (86.4)	2462
5 - 8 Weeks	215 (84.6)		1530	103 (84.4)	885	318 (84.6)	2415
9 - 12 Weeks	200 (78.7)		1333	107 (87.7)	790	307 (81.6)	2123
13 - 16 Weeks	209 (82.3)		1485	103 (84.4)	823	312 (83.0)	2308
17 - 20 Weeks	209 (82.3)		1401	102 (83.6)	759	311 (82.7)	2160
21 - 24 Weeks	203 (79.9)		1421	105 (86.1)	767	308 (81.9)	2188
25 - 28 Weeks	196 (77.2)		1270	105 (86.1)	750	301 (80.1)	2020
29 - 32 Weeks	192 (75.6)		1123	91 (74.6)	546	283 (75.3)	1669
33 - 36 Weeks	181 (71.3)		922	89 (73.0)	476	270 (71.8)	1398
37 - 40 Weeks	176 (69.3)		923	101 (82.8)	499	277 (73.7)	1422
41 - 44 Weeks	180 (70.9)		888	90 (73.8)	458	270 (71.8)	1346
45 - 48 Weeks	165 (65.0)		827	92 (75.4)	456	257 (68.4)	1283
49 - 52 Weeks	167 (65.7)		825	81 (66.4)	476	248 (66.0)	1301
> 52 Weeks	157 (61.8)		600	79 (64.8)	334	236 (62.8)	934

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:55 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_ets.txt

Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary -
Extension Trial Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Severe	34	(13.4)	53	24	(19.7)	51	58	(15.4)	104
1 - 4 Weeks	3	(1.2)	3	3	(2.5)	3	6	(1.6)	6
5 - 8 Weeks	6	(2.4)	7	2	(1.6)	2	8	(2.1)	9
9 - 12 Weeks	3	(1.2)	3	6	(4.9)	6	9	(2.4)	9
13 - 16 Weeks	7	(2.8)	9	3	(2.5)	3	10	(2.7)	12
17 - 20 Weeks	2	(0.8)	2	4	(3.3)	4	6	(1.6)	6
21 - 24 Weeks	1	(0.4)	1	2	(1.6)	2	3	(0.8)	3
25 - 28 Weeks	4	(1.6)	5	3	(2.5)	3	7	(1.9)	8
29 - 32 Weeks	2	(0.8)	3	3	(2.5)	3	5	(1.3)	6
33 - 36 Weeks	3	(1.2)	4	3	(2.5)	5	6	(1.6)	9
37 - 40 Weeks	3	(1.2)	3	7	(5.7)	7	10	(2.7)	10
41 - 44 Weeks	5	(2.0)	5	3	(2.5)	3	8	(2.1)	8
45 - 48 Weeks	4	(1.6)	5	3	(2.5)	6	7	(1.9)	11
49 - 52 Weeks	2	(0.8)	2	3	(2.5)	3	5	(1.3)	5
> 52 Weeks	1	(0.4)	1	1	(0.8)	1	2	(0.5)	2
Doc. Symptomatic	233	(91.7)	10860	112	(91.8)	6372	345	(91.8)	17232
1 - 4 Weeks	184	(72.4)	1120	88	(72.1)	542	272	(72.3)	1662
5 - 8 Weeks	177	(69.7)	1037	86	(70.5)	645	263	(69.9)	1682
9 - 12 Weeks	162	(63.8)	846	87	(71.3)	572	249	(66.2)	1418
13 - 16 Weeks	167	(65.7)	941	79	(64.8)	608	246	(65.4)	1549
17 - 20 Weeks	170	(66.9)	902	82	(67.2)	556	252	(67.0)	1458
21 - 24 Weeks	165	(65.0)	960	87	(71.3)	543	252	(67.0)	1503
25 - 28 Weeks	153	(60.2)	836	86	(70.5)	519	239	(63.6)	1355
29 - 32 Weeks	143	(56.3)	721	74	(60.7)	396	217	(57.7)	1117
33 - 36 Weeks	142	(55.9)	622	71	(58.2)	351	213	(56.6)	973
37 - 40 Weeks	141	(55.5)	617	77	(63.1)	351	218	(58.0)	968
41 - 44 Weeks	135	(53.1)	612	71	(58.2)	318	206	(54.8)	930
45 - 48 Weeks	133	(52.4)	595	70	(57.4)	352	203	(54.0)	947
49 - 52 Weeks	137	(53.9)	611	68	(55.7)	368	205	(54.5)	979
> 52 Weeks	131	(51.6)	440	63	(51.6)	251	194	(51.6)	691

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded
PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:55 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_ets.txt

Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Extension Trial Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Asymptomatic	203	(79.9)	4951	100	(82.0)	2156	303	(80.6)	7107
1 - 4 Weeks	124	(48.8)	480	63	(51.6)	211	187	(49.7)	691
5 - 8 Weeks	117	(46.1)	455	54	(44.3)	215	171	(45.5)	670
9 - 12 Weeks	117	(46.1)	454	56	(45.9)	195	173	(46.0)	649
13 - 16 Weeks	126	(49.6)	509	51	(41.8)	195	177	(47.1)	704
17 - 20 Weeks	111	(43.7)	476	52	(42.6)	193	163	(43.4)	669
21 - 24 Weeks	103	(40.6)	430	53	(43.4)	201	156	(41.5)	631
25 - 28 Weeks	106	(41.7)	399	50	(41.0)	214	156	(41.5)	613
29 - 32 Weeks	102	(40.2)	381	45	(36.9)	130	147	(39.1)	511
33 - 36 Weeks	77	(30.3)	275	40	(32.8)	108	117	(31.1)	383
37 - 40 Weeks	84	(33.1)	286	47	(38.5)	129	131	(34.8)	415
41 - 44 Weeks	79	(31.1)	248	39	(32.0)	125	118	(31.4)	373
45 - 48 Weeks	69	(27.2)	206	29	(23.8)	83	98	(26.1)	289
49 - 52 Weeks	73	(28.7)	201	36	(29.5)	88	109	(29.0)	289
> 52 Weeks	67	(26.4)	151	32	(26.2)	69	99	(26.3)	220
Prob. Symptomatic	58	(22.8)	241	36	(29.5)	199	94	(25.0)	440
1 - 4 Weeks	29	(11.4)	50	11	(9.0)	23	40	(10.6)	73
5 - 8 Weeks	16	(6.3)	20	11	(9.0)	19	27	(7.2)	39
9 - 12 Weeks	12	(4.7)	18	9	(7.4)	17	21	(5.6)	35
13 - 16 Weeks	12	(4.7)	18	9	(7.4)	17	21	(5.6)	35
17 - 20 Weeks	6	(2.4)	10	4	(3.3)	5	10	(2.7)	15
21 - 24 Weeks	7	(2.8)	15	12	(9.8)	17	19	(5.1)	32
25 - 28 Weeks	11	(4.3)	22	7	(5.7)	9	18	(4.8)	31
29 - 32 Weeks	7	(2.8)	11	10	(8.2)	15	17	(4.5)	26
33 - 36 Weeks	11	(4.3)	16	8	(6.6)	12	19	(5.1)	28
37 - 40 Weeks	7	(2.8)	11	4	(3.3)	11	11	(2.9)	22
41 - 44 Weeks	12	(4.7)	17	6	(4.9)	12	18	(4.8)	29
45 - 48 Weeks	10	(3.9)	17	7	(5.7)	15	17	(4.5)	32
49 - 52 Weeks	7	(2.8)	9	8	(6.6)	17	15	(4.0)	26
> 52 Weeks	6	(2.4)	7	5	(4.1)	10	11	(2.9)	17

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:55 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_ets.txt

Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary -
Extension Trial Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Relative	38	(15.0)	122	14	(11.5)	24	52	(13.8)	146
1 - 4 Weeks	13	(5.1)	26	3	(2.5)	4	16	(4.3)	30
5 - 8 Weeks	7	(2.8)	11	3	(2.5)	4	10	(2.7)	15
9 - 12 Weeks	6	(2.4)	12	0	(0.0)	0	6	(1.6)	12
13 - 16 Weeks	6	(2.4)	8	0	(0.0)	0	6	(1.6)	8
17 - 20 Weeks	6	(2.4)	11	1	(0.8)	1	7	(1.9)	12
21 - 24 Weeks	7	(2.8)	15	2	(1.6)	4	9	(2.4)	19
25 - 28 Weeks	5	(2.0)	8	4	(3.3)	5	9	(2.4)	13
29 - 32 Weeks	7	(2.8)	7	2	(1.6)	2	9	(2.4)	9
33 - 36 Weeks	3	(1.2)	5	0	(0.0)	0	3	(0.8)	5
37 - 40 Weeks	3	(1.2)	6	1	(0.8)	1	4	(1.1)	7
41 - 44 Weeks	4	(1.6)	6	0	(0.0)	0	4	(1.1)	6
45 - 48 Weeks	4	(1.6)	4	0	(0.0)	0	4	(1.1)	4
49 - 52 Weeks	2	(0.8)	2	0	(0.0)	0	2	(0.5)	2
> 52 Weeks	1	(0.4)	1	2	(1.6)	3	3	(0.8)	4
ADA Unclassifiable	80	(31.5)	392	39	(32.0)	198	119	(31.6)	590
1 - 4 Weeks	30	(11.8)	44	3	(2.5)	3	33	(8.8)	47
5 - 8 Weeks	17	(6.7)	43	14	(11.5)	20	31	(8.2)	63
9 - 12 Weeks	27	(10.6)	39	7	(5.7)	16	34	(9.0)	55
13 - 16 Weeks	18	(7.1)	34	10	(8.2)	12	28	(7.4)	46
17 - 20 Weeks	24	(9.4)	59	15	(12.3)	42	39	(10.4)	101
21 - 24 Weeks	21	(8.3)	40	10	(8.2)	39	31	(8.2)	79
25 - 28 Weeks	15	(5.9)	25	10	(8.2)	14	25	(6.6)	39
29 - 32 Weeks	12	(4.7)	23	9	(7.4)	19	21	(5.6)	42
33 - 36 Weeks	8	(3.1)	9	2	(1.6)	4	10	(2.7)	13
37 - 40 Weeks	8	(3.1)	9	4	(3.3)	9	12	(3.2)	18
41 - 44 Weeks	7	(2.8)	9	4	(3.3)	6	11	(2.9)	15
45 - 48 Weeks	6	(2.4)	21	4	(3.3)	6	10	(2.7)	27
49 - 52 Weeks	13	(5.1)	22	3	(2.5)	5	16	(4.3)	27
> 52 Weeks	11	(4.3)	15	2	(1.6)	3	13	(3.5)	18

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded
PG < 3.1 mmol/L (56mg/dL)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:55 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_week_sum_ets.txt

14.3.1.38: Nocturnal Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N	OD (%)	E	IDet N	(%)	E	Total N	(%)	E
Number of Subjects	362			180			542		
Confirmed	221	(61.0)	918	135	(75.0)	787	356	(65.7)	1705
1 - 4 Weeks	74	(20.4)	125	48	(26.7)	75	122	(22.5)	200
5 - 8 Weeks	66	(18.2)	92	48	(26.7)	68	114	(21.0)	160
9 - 12 Weeks	54	(14.9)	68	45	(25.0)	71	99	(18.3)	139
13 - 16 Weeks	63	(17.4)	101	47	(26.1)	70	110	(20.3)	171
17 - 20 Weeks	58	(16.0)	77	44	(24.4)	76	102	(18.8)	153
21 - 24 Weeks	59	(16.3)	93	32	(17.8)	57	91	(16.8)	150
25 - 28 Weeks	52	(14.4)	78	49	(27.2)	73	101	(18.6)	151
29 - 32 Weeks	32	(8.8)	41	24	(13.3)	44	56	(10.3)	85
33 - 36 Weeks	29	(8.0)	37	21	(11.7)	42	50	(9.2)	79
37 - 40 Weeks	32	(8.8)	40	31	(17.2)	49	63	(11.6)	89
41 - 44 Weeks	30	(8.3)	40	24	(13.3)	35	54	(10.0)	75
45 - 48 Weeks	31	(8.6)	47	26	(14.4)	55	57	(10.5)	102
49 - 52 Weeks	30	(8.3)	41	20	(11.1)	48	50	(9.2)	89
> 52 Weeks	31	(8.6)	38	19	(10.6)	24	50	(9.2)	62
ADA	256	(70.7)	1654	147	(81.7)	1171	403	(74.4)	2825
1 - 4 Weeks	117	(32.3)	229	64	(35.6)	117	181	(33.4)	346
5 - 8 Weeks	92	(25.4)	154	64	(35.6)	112	156	(28.8)	266
9 - 12 Weeks	83	(22.9)	131	59	(32.8)	96	142	(26.2)	227
13 - 16 Weeks	103	(28.5)	195	60	(33.3)	105	163	(30.1)	300
17 - 20 Weeks	82	(22.7)	146	58	(32.2)	102	140	(25.8)	248
21 - 24 Weeks	85	(23.5)	166	46	(25.6)	92	131	(24.2)	258
25 - 28 Weeks	70	(19.3)	125	66	(36.7)	109	136	(25.1)	234
29 - 32 Weeks	48	(13.3)	76	38	(21.1)	63	86	(15.9)	139
33 - 36 Weeks	51	(14.1)	77	30	(16.7)	63	81	(14.9)	140
37 - 40 Weeks	52	(14.4)	81	41	(22.8)	67	93	(17.2)	148
41 - 44 Weeks	48	(13.3)	74	30	(16.7)	57	78	(14.4)	131
45 - 48 Weeks	42	(11.6)	70	33	(18.3)	78	75	(13.8)	148
49 - 52 Weeks	40	(11.0)	66	26	(14.4)	70	66	(12.2)	136
> 52 Weeks	46	(12.7)	64	28	(15.6)	40	74	(13.7)	104

N: Number of Subjects

?: Percentage of Subjects

E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594-3645/freeze_ctr_02/stats

07MAY2011:14:00:58 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_noct_week_sum_sas.txt

Nocturnal Hypoglycaemic Episodes by Classification and Time - Treatment Emergent -
Summary - Safety Analysis Set

	IDegAsp OD N (%)	E	IDet N (%)	E	Total N (%)	E
Severe	13 (3.6)	14	14 (7.8)	28	27 (5.0)	42
1 - 4 Weeks	4 (1.1)	4	0 (0.0)	0	4 (0.7)	4
5 - 8 Weeks	1 (0.3)	1	2 (1.1)	2	3 (0.6)	3
9 - 12 Weeks	0 (0.0)	0	4 (2.2)	4	4 (0.7)	4
13 - 16 Weeks	3 (0.8)	3	2 (1.1)	2	5 (0.9)	5
17 - 20 Weeks	1 (0.3)	1	4 (2.2)	4	5 (0.9)	5
21 - 24 Weeks	1 (0.3)	1	2 (1.1)	2	3 (0.6)	3
25 - 28 Weeks	1 (0.3)	1	1 (0.6)	1	2 (0.4)	2
29 - 32 Weeks	2 (0.6)	2	1 (0.6)	1	3 (0.6)	3
33 - 36 Weeks	0 (0.0)	0	2 (1.1)	4	2 (0.4)	4
37 - 40 Weeks	0 (0.0)	0	3 (1.7)	3	3 (0.6)	3
41 - 44 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
45 - 48 Weeks	0 (0.0)	0	1 (0.6)	3	1 (0.2)	3
49 - 52 Weeks	0 (0.0)	0	1 (0.6)	1	1 (0.2)	1
> 52 Weeks	1 (0.3)	1	1 (0.6)	1	2 (0.4)	2
Doc. Symptomatic	224 (61.9)	1275	119 (66.1)	904	343 (63.3)	2179
1 - 4 Weeks	94 (26.0)	177	51 (28.3)	96	145 (26.8)	273
5 - 8 Weeks	76 (21.0)	131	53 (29.4)	88	129 (23.8)	219
9 - 12 Weeks	67 (18.5)	99	49 (27.2)	79	116 (21.4)	178
13 - 16 Weeks	76 (21.0)	146	47 (26.1)	77	123 (22.7)	223
17 - 20 Weeks	54 (14.9)	104	45 (25.0)	81	99 (18.3)	185
21 - 24 Weeks	70 (19.3)	131	34 (18.9)	67	104 (19.2)	198
25 - 28 Weeks	57 (15.7)	99	51 (28.3)	79	108 (19.9)	178
29 - 32 Weeks	31 (8.6)	50	31 (17.2)	55	62 (11.4)	105
33 - 36 Weeks	39 (10.8)	58	24 (13.3)	46	63 (11.6)	104
37 - 40 Weeks	37 (10.2)	52	28 (15.6)	49	65 (12.0)	101
41 - 44 Weeks	41 (11.3)	61	21 (11.7)	39	62 (11.4)	100
45 - 48 Weeks	36 (9.9)	60	27 (15.0)	65	63 (11.6)	125
49 - 52 Weeks	35 (9.7)	51	23 (12.8)	53	58 (10.7)	104
> 52 Weeks	41 (11.3)	56	22 (12.2)	30	63 (11.6)	86

N: Number of Subjects

%: Percentage of Subjects

E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded
PG < 3.1 mmol/L (56mg/dL)

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:58 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_noct_week_sum_sas.txt

Nocturnal Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp OD			IDet			Total		
	N	(%)	E	N	(%)	E	N	(%)	E
Asymptomatic	98	(27.1)	303	58	(32.2)	176	156	(28.8)	479
1 - 4 Weeks	20	(5.5)	33	12	(6.7)	13	32	(5.9)	46
5 - 8 Weeks	17	(4.7)	19	9	(5.0)	11	26	(4.8)	30
9 - 12 Weeks	21	(5.8)	28	6	(3.3)	8	27	(5.0)	36
13 - 16 Weeks	29	(8.0)	39	14	(7.8)	23	43	(7.9)	62
17 - 20 Weeks	28	(7.7)	35	14	(7.8)	15	42	(7.7)	50
21 - 24 Weeks	20	(5.5)	29	10	(5.6)	18	30	(5.5)	47
25 - 28 Weeks	16	(4.4)	21	17	(9.4)	27	33	(6.1)	48
29 - 32 Weeks	14	(3.9)	21	5	(2.8)	5	19	(3.5)	26
33 - 36 Weeks	13	(3.6)	18	5	(2.8)	5	18	(3.3)	23
37 - 40 Weeks	16	(4.4)	22	11	(6.1)	15	27	(5.0)	37
41 - 44 Weeks	6	(1.7)	9	10	(5.6)	12	16	(3.0)	21
45 - 48 Weeks	7	(1.9)	9	3	(1.7)	5	10	(1.8)	14
49 - 52 Weeks	11	(3.0)	14	5	(2.8)	13	16	(3.0)	27
> 52 Weeks	6	(1.7)	6	5	(2.8)	6	11	(2.0)	12
Prob. Symptomatic	28	(7.7)	56	24	(13.3)	58	52	(9.6)	114
1 - 4 Weeks	12	(3.3)	14	6	(3.3)	7	18	(3.3)	21
5 - 8 Weeks	3	(0.8)	3	5	(2.8)	9	8	(1.5)	12
9 - 12 Weeks	4	(1.1)	4	5	(2.8)	5	9	(1.7)	9
13 - 16 Weeks	6	(1.7)	6	3	(1.7)	3	9	(1.7)	9
17 - 20 Weeks	6	(1.7)	6	2	(1.1)	2	8	(1.5)	8
21 - 24 Weeks	3	(0.8)	4	4	(2.2)	4	7	(1.3)	8
25 - 28 Weeks	3	(0.8)	4	2	(1.1)	2	5	(0.9)	6
29 - 32 Weeks	2	(0.6)	2	2	(1.1)	2	4	(0.7)	4
33 - 36 Weeks	1	(0.3)	1	6	(3.3)	8	7	(1.3)	9
37 - 40 Weeks	3	(0.8)	5	0	(0.0)	0	3	(0.6)	5
41 - 44 Weeks	2	(0.6)	4	4	(2.2)	6	6	(1.1)	10
45 - 48 Weeks	1	(0.3)	1	4	(2.2)	5	5	(0.9)	6
49 - 52 Weeks	1	(0.3)	1	2	(1.1)	3	3	(0.6)	4
> 52 Weeks	1	(0.3)	1	1	(0.6)	2	2	(0.4)	3

N: Number of Subjects

?: Percentage of Subjects

E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:58 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_noct_week_sum_sas.txt

Nocturnal Hypoglycaemic Episodes by Classification and Time - Treatment Emergent - Summary - Safety Analysis Set

	IDegAsp N (%)	OD E	IDet N (%)	E	Total N (%)	E
Relative	4 (1.1)	6	5 (2.8)	5	9 (1.7)	11
1 - 4 Weeks	1 (0.3)	1	1 (0.6)	1	2 (0.4)	2
5 - 8 Weeks	0 (0.0)	0	2 (1.1)	2	2 (0.4)	2
9 - 12 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
13 - 16 Weeks	1 (0.3)	1	0 (0.0)	0	1 (0.2)	1
17 - 20 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
21 - 24 Weeks	1 (0.3)	1	1 (0.6)	1	2 (0.4)	2
25 - 28 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
29 - 32 Weeks	1 (0.3)	1	0 (0.0)	0	1 (0.2)	1
33 - 36 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
37 - 40 Weeks	2 (0.6)	2	0 (0.0)	0	2 (0.4)	2
41 - 44 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
45 - 48 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
49 - 52 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
> 52 Weeks	0 (0.0)	0	1 (0.6)	1	1 (0.2)	1
ADA Unclassifiable	12 (3.3)	13	8 (4.4)	22	20 (3.7)	35
1 - 4 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
5 - 8 Weeks	2 (0.6)	2	1 (0.6)	1	3 (0.6)	3
9 - 12 Weeks	1 (0.3)	1	2 (1.1)	2	3 (0.6)	3
13 - 16 Weeks	1 (0.3)	1	2 (1.1)	2	3 (0.6)	3
17 - 20 Weeks	2 (0.6)	2	3 (1.7)	6	5 (0.9)	8
21 - 24 Weeks	0 (0.0)	0	2 (1.1)	2	2 (0.4)	2
25 - 28 Weeks	2 (0.6)	2	1 (0.6)	2	3 (0.6)	4
29 - 32 Weeks	1 (0.3)	1	2 (1.1)	4	3 (0.6)	5
33 - 36 Weeks	0 (0.0)	0	1 (0.6)	2	1 (0.2)	2
37 - 40 Weeks	0 (0.0)	0	1 (0.6)	1	1 (0.2)	1
41 - 44 Weeks	1 (0.3)	1	0 (0.0)	0	1 (0.2)	1
45 - 48 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
49 - 52 Weeks	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
> 52 Weeks	3 (0.8)	3	0 (0.0)	0	3 (0.6)	3

N: Number of Subjects

%: Percentage of Subjects

E: Number of Events

Confirmed hypoglycaemia: subject unable to treat himself/herself and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:00:58 - tsum_hypo_classtime_tpl_t028_v01.sas/t_hypo_te_noct_week_sum_sas.txt

14.3.1.39: Hypoglycaemic Episodes - Treatment Emergent - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	95% CI
Severe				
LSMeans, Events per 100 PYE				
IDegAsp OD	366	363	18.87	
IDet	182	180	19.20	
Treatment Ratio				
IDegAsp OD / IDet			0.98	[0.54 ; 1.79]
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	366	363	3525.28	
IDet	182	180	3706.84	
Treatment Ratio				
IDegAsp OD / IDet			0.95	[0.79 ; 1.14]

N= Number of subjects contributing to analysis, CI= Confidence Interval, PYE= Patient Years Exposure

The number of events is analysed using a Negative Binomial Regression model using a log link and the logarithm of the exposure time (100 years) as offset. The model includes treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age as covariate.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:01:07 - tstat_find_tpl_t022.sas/t_hypo_te_stat_fas.txt

14.3.1.40: Hypoglycaemic Episodes - Treatment Emergent - Statistical Analysis - Extension Trial Set

	EXT	N	Estimate	95% CI
Severe				
LSMeans, Events per 100 PYE				
IDegAsp OD	254	254	9.61	
IDet	122	122	12.45	
Treatment Ratio				
IDegAsp OD / IDet			0.77	[0.41 ; 1.45]
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	254	254	3248.24	
IDet	122	122	3969.21	
Treatment Ratio				
IDegAsp OD / IDet			0.82	[0.65 ; 1.03]

N= Number of subjects contributing to analysis, CI= Confidence Interval, PYE= Patient Years Exposure

The number of events is analysed using a Negative Binomial Regression model using a log link and the logarithm of the exposure time (100 years) as offset. The model includes treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age as covariate.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:01:16 - tstat_find_tpl_t022.sas/t_hypo_te_stat_ets.txt

14.3.1.41: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent – Statistical Analysis - Full Analysis Set

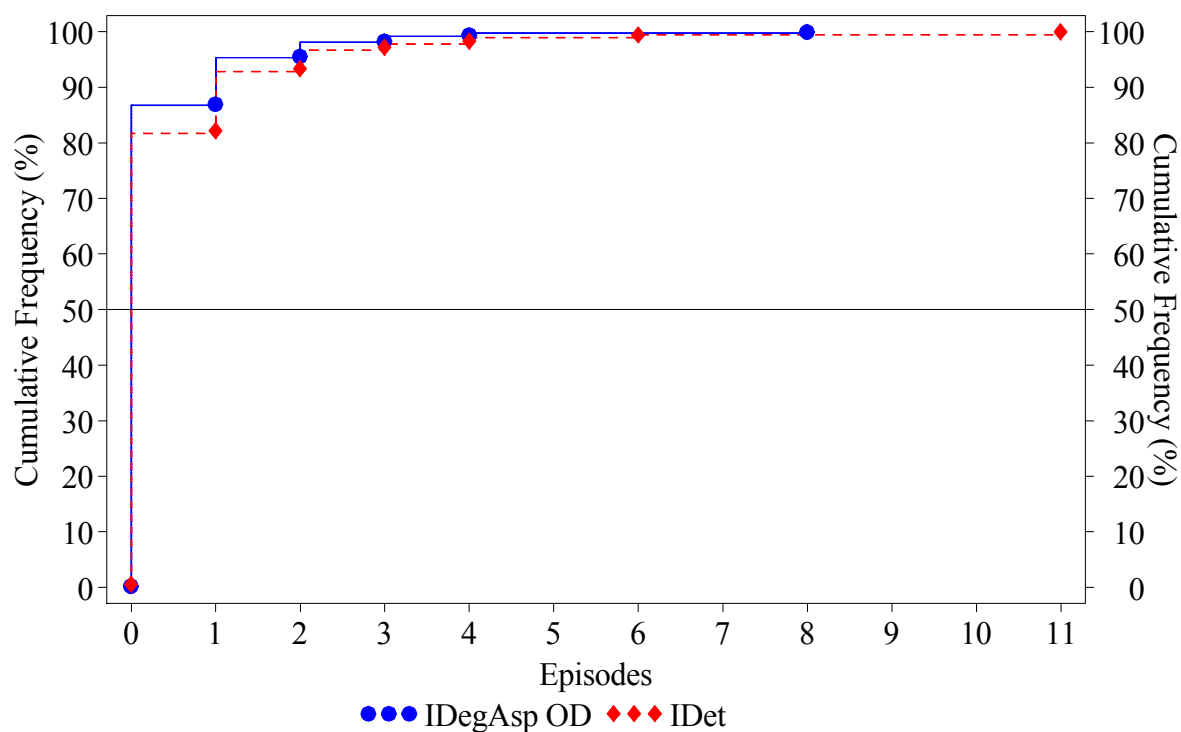
	FAS	N	Estimate	95% CI
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	366	363	261.54	
IDet	182	180	423.39	
Treatment Ratio				
IDegAsp OD / IDet			0.62	[0.48 ; 0.79]

N= Number of subjects contributing to analysis, CI= Confidence Interval, PYE= Patient Years Exposure
The number of events is analysed using a Negative Binomial Regression model using a log link and the logarithm of the exposure time (100 years) as offset. The model includes treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age as covariate.
Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:01:24 - tstat_find_tpl_t022.sas/t_hypo_te_conf_noct_stat_fas.txt

14.3.1.42: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent – Statistical Analysis - Extension Trial Set

	EXT	N	Estimate	95% CI
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	254	254	222.84	
IDet	122	122	485.15	
Treatment Ratio				
IDegAsp OD / IDet			0.46	[0.34 ; 0.62]

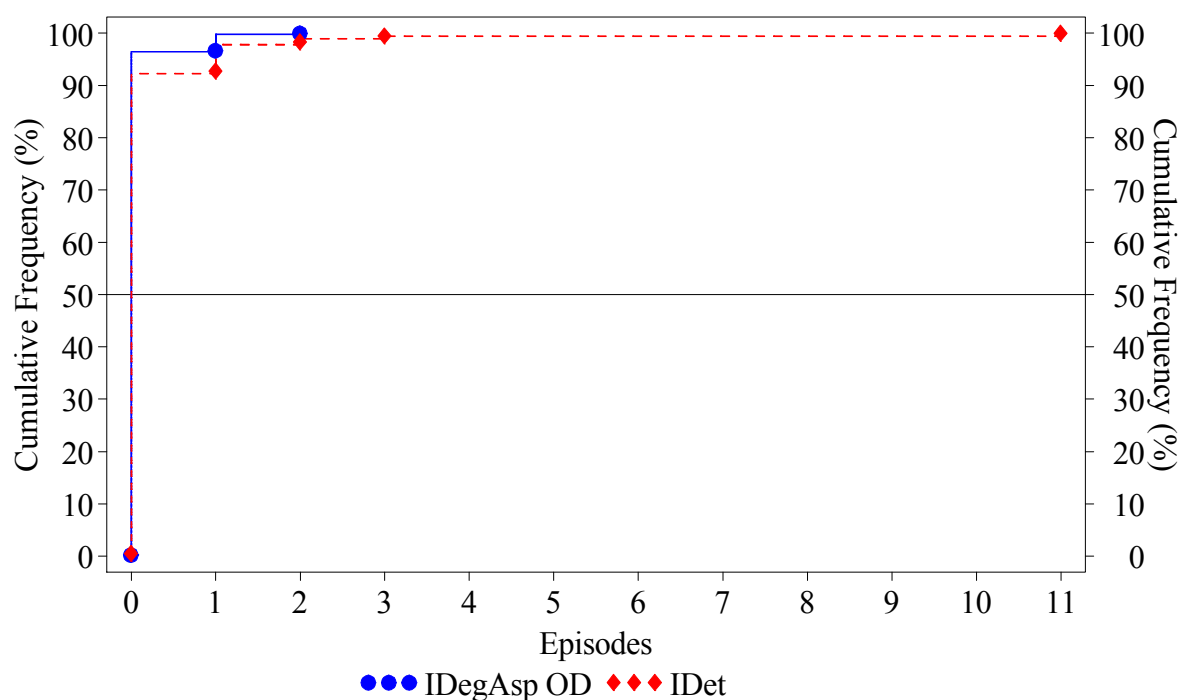
N= Number of subjects contributing to analysis, CI= Confidence Interval, PYE= Patient Years Exposure
The number of events is analysed using a Negative Binomial Regression model using a log link and the logarithm of the exposure time (100 years) as offset. The model includes treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age as covariate.
Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:01:33 - tstat_find_tpl_t022.sas/t_hypo_te_conf_noct_stat_ets.txt



SAFETY; Observed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:01:41 - fedist_numfind_v01.sas/e_hypo_te_sev_cdf_sas.cgm

14.3.1.43: Severe Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set

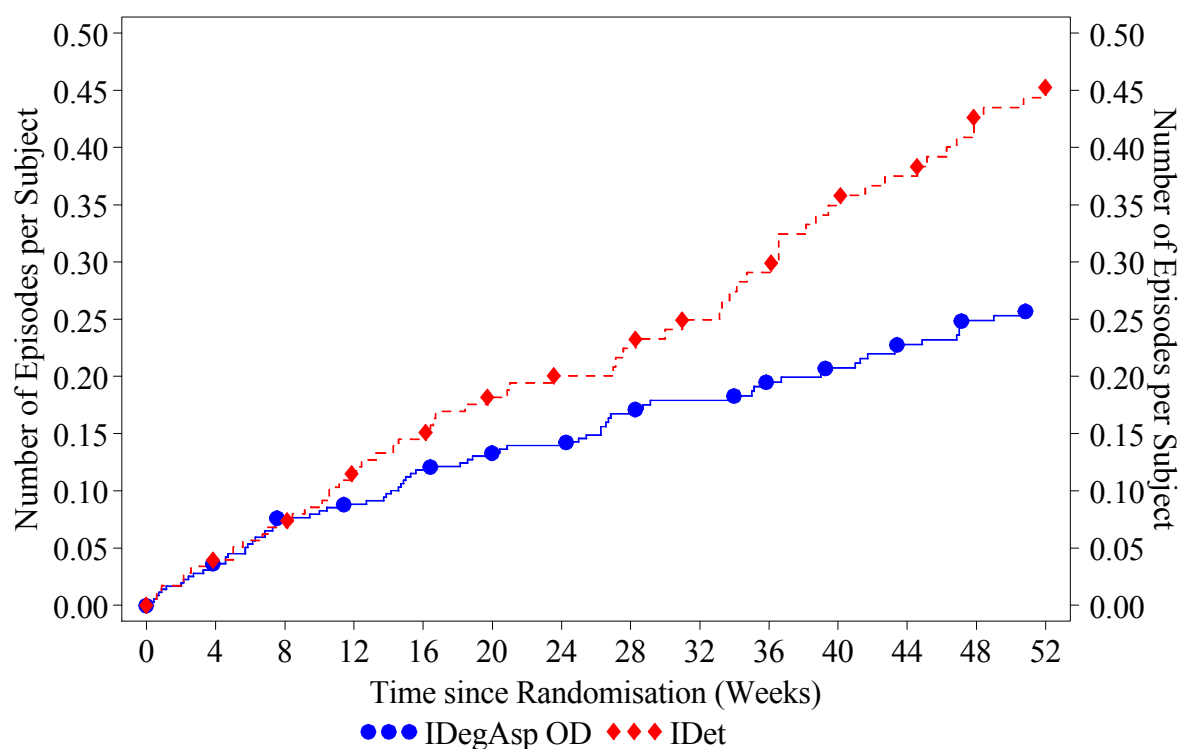


SAFETY: Observed data.

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

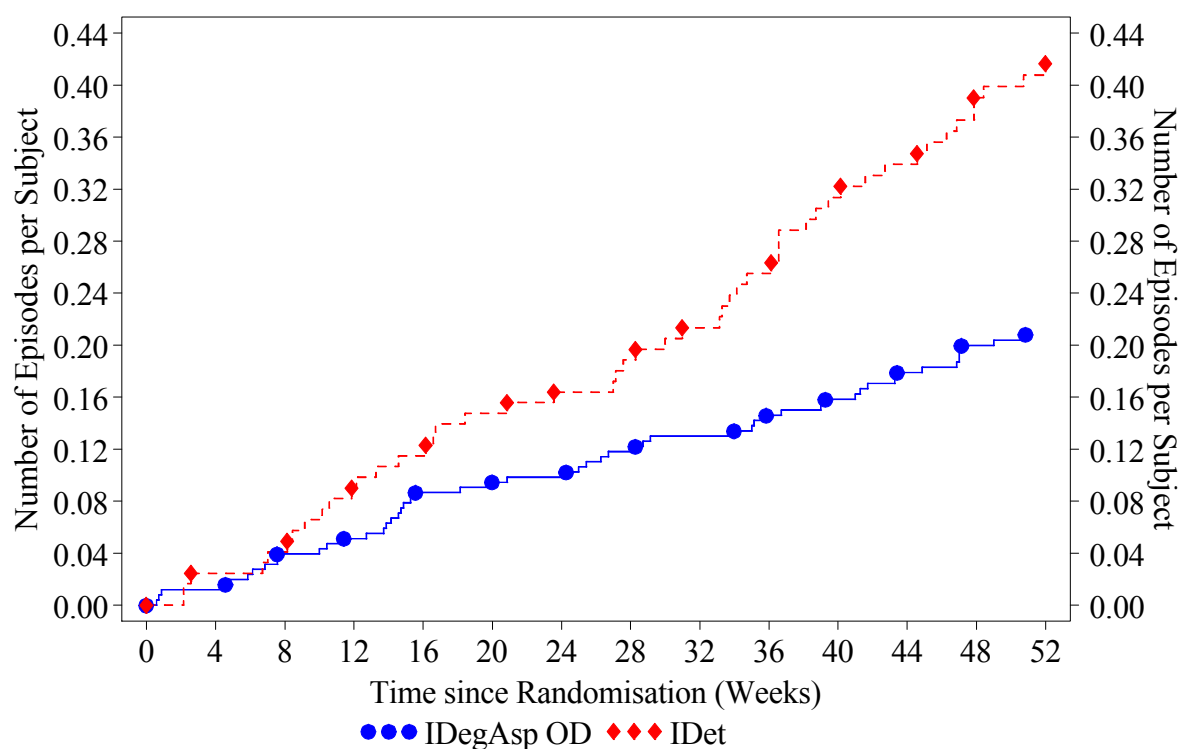
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:01:50 - fedist_numfind_v01.sas/e_hypo_te_sev_noct_cdf_sas.cgm

14.3.1.44: Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set



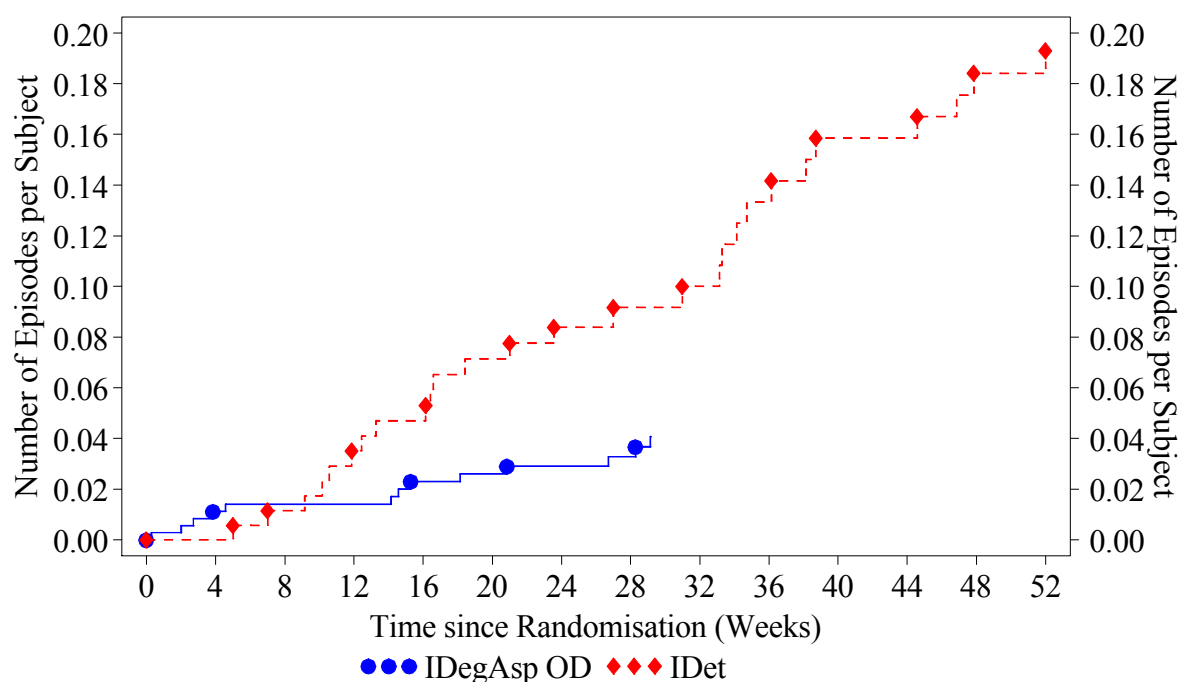
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:01:52 - fmean_cum_v01.sas/e_hypo_te_sev_mcf_sas.cgm

14.3.1.45: Severe Hypoglycaemic Episodes - Treatment Emergent - Mean Cumulative Function - Safety Analysis Set



nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:01:54 - fmean_cum_v01.sas/e_hypo_te_sev_mcf_ets.cgm

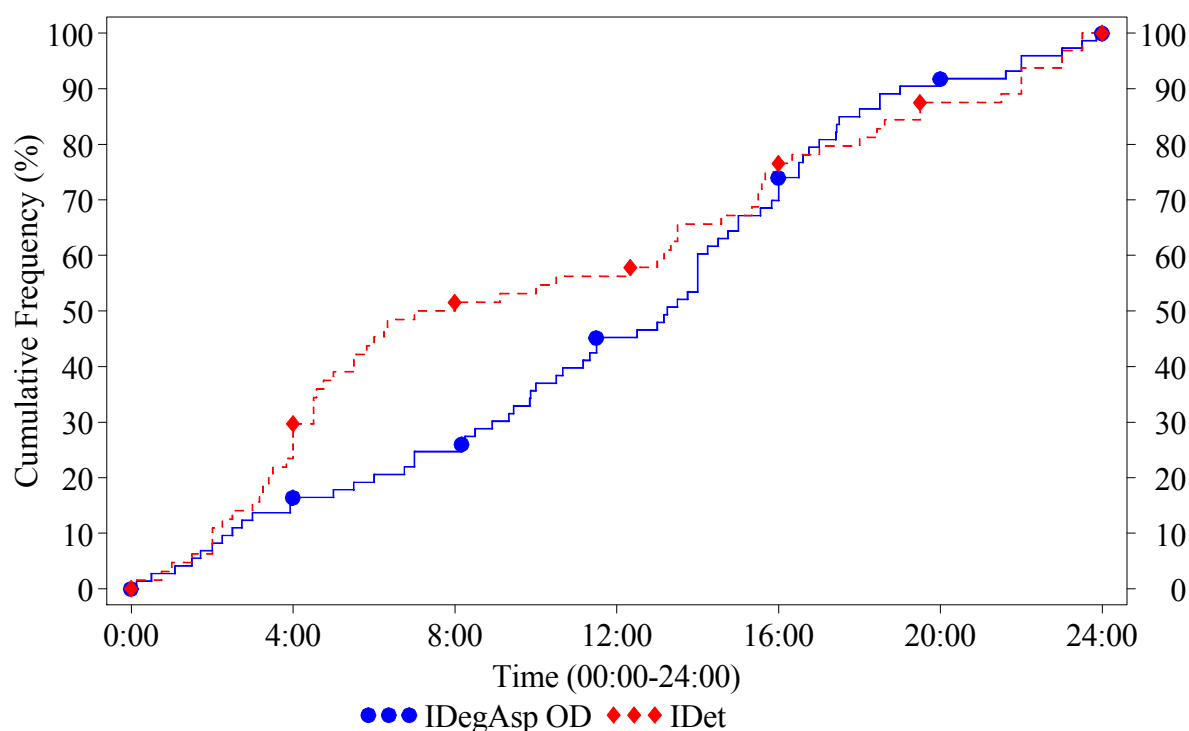
14.3.1.46: Severe Hypoglycaemic Episodes - Treatment Emergent - Mean Cumulative Function - Extension Trial Set



Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).
No events occurred in the IDegAsp OD arm after 28 weeks,
hence the cumulative function is not shown after this time point.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:01:56 - fmean_cum_v01.sas/e_hypo_te_sev_noct_mcf_sas.cgm

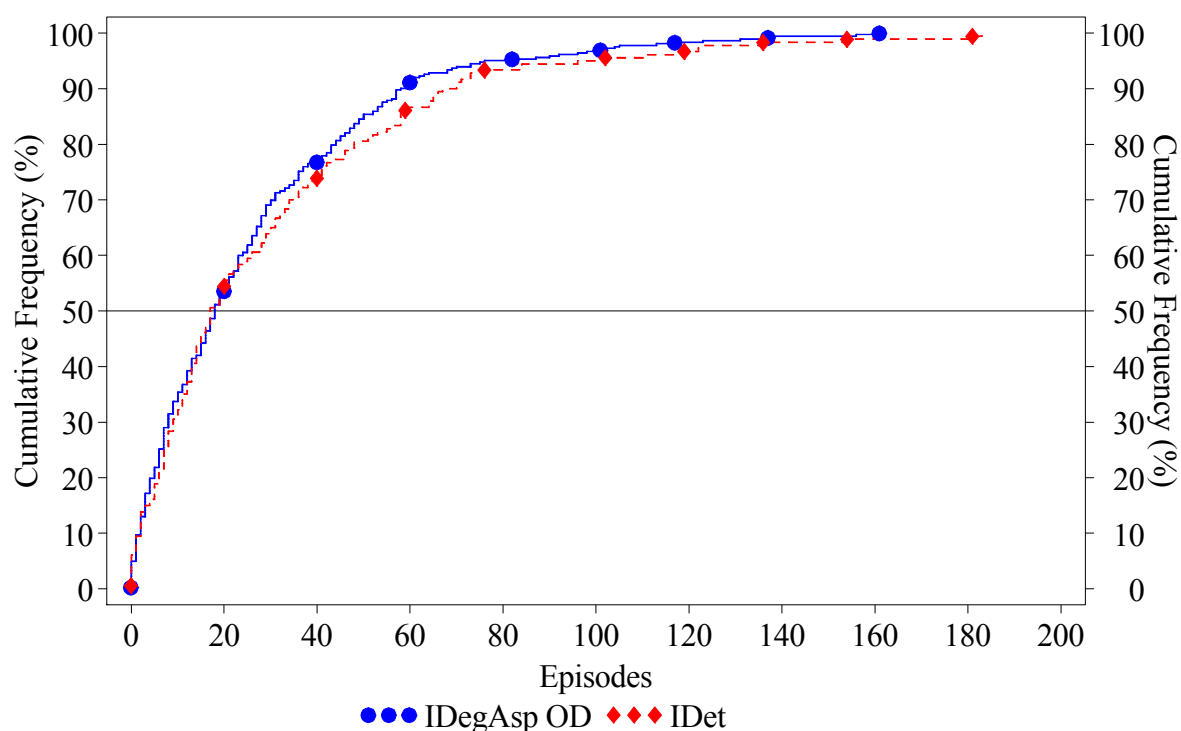
14.3.1.47: Nocturnal Severe Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set



SAFETY

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:01:57 - fcum_time_v01.sas/e_hypo_te_sev_cf_day_sas.cgm

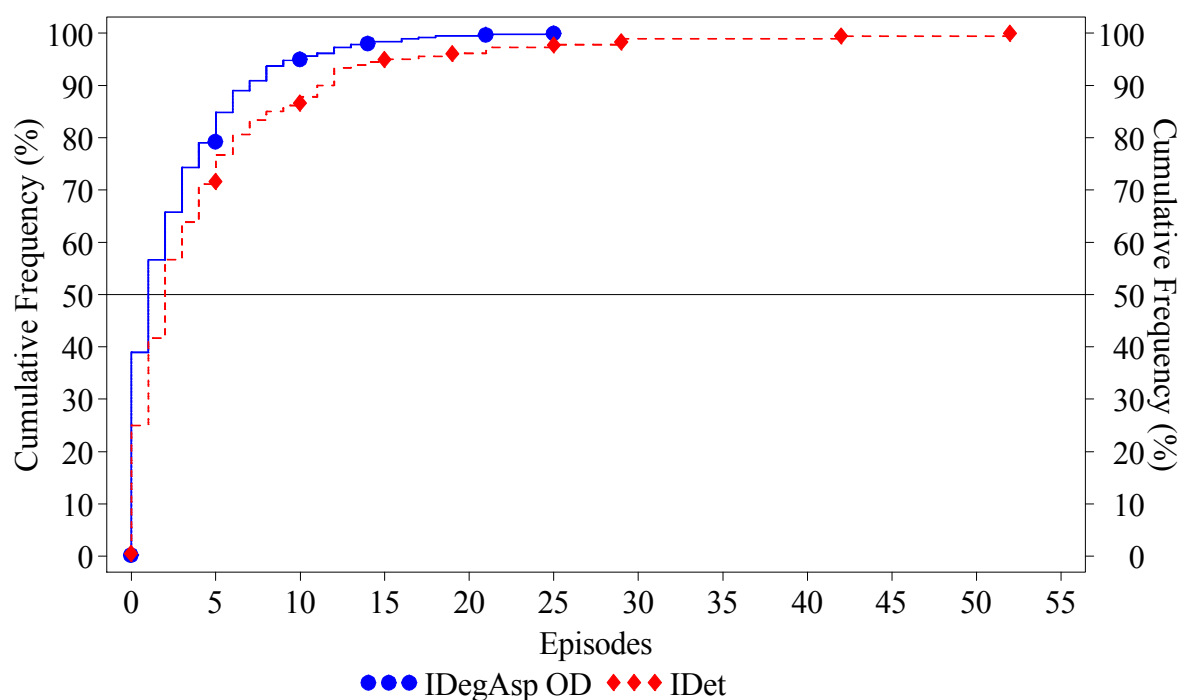
14.3.1.48: Severe Hypoglycaemic Episodes – Treatment Emergent - Cumulative Frequency over Day - Safety Analysis Set



SAFETY; Observed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:02:06 - fedist_numfind_v01.sas/e_hypo_te_conf_cdf_sas.cgm

14.3.1.49: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set

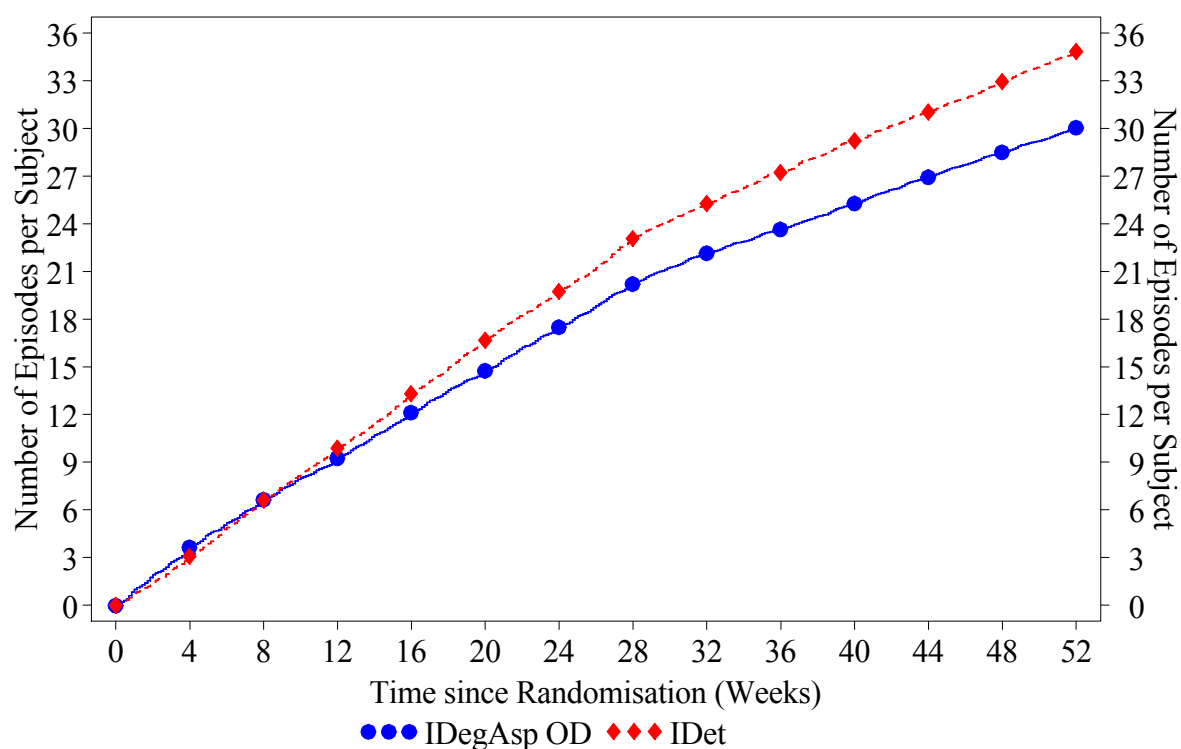


SAFETY: Observed data.

Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

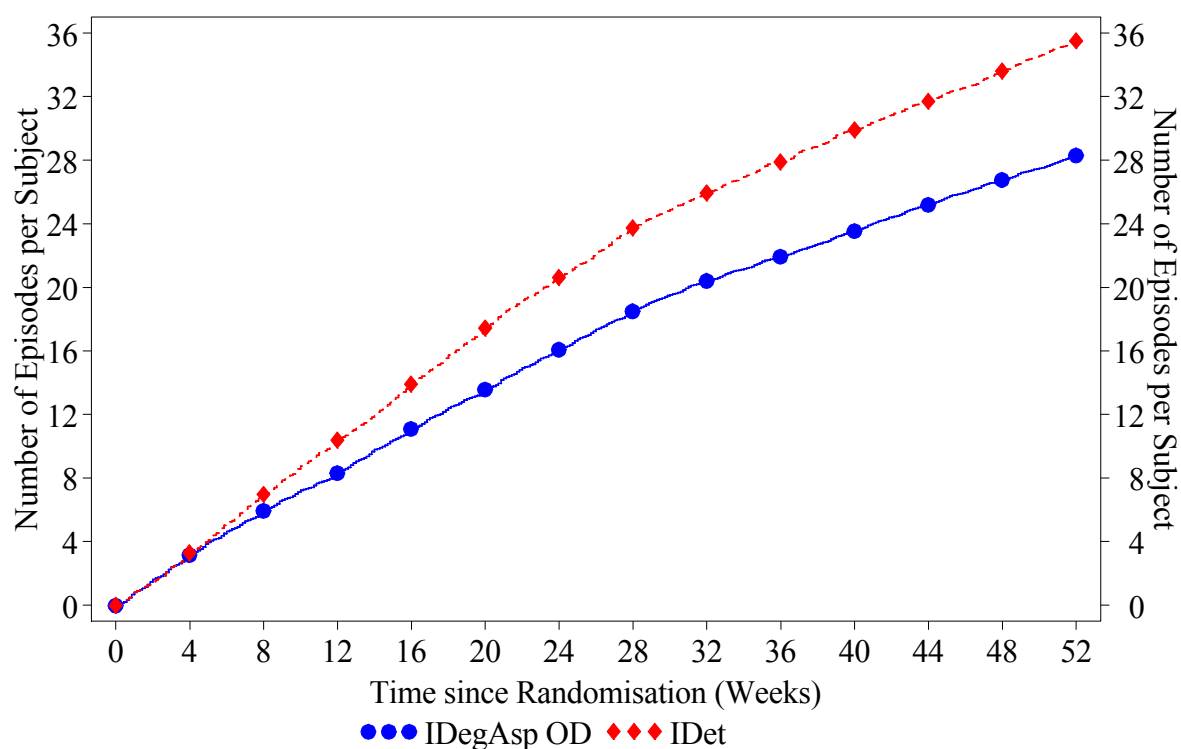
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:02:14 - fedist_numfind_v01.sas/e_hypo_te_conf_noct_cdf_sas.cgm

14.3.1.50: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Empirical Distribution Plot - Safety Analysis Set



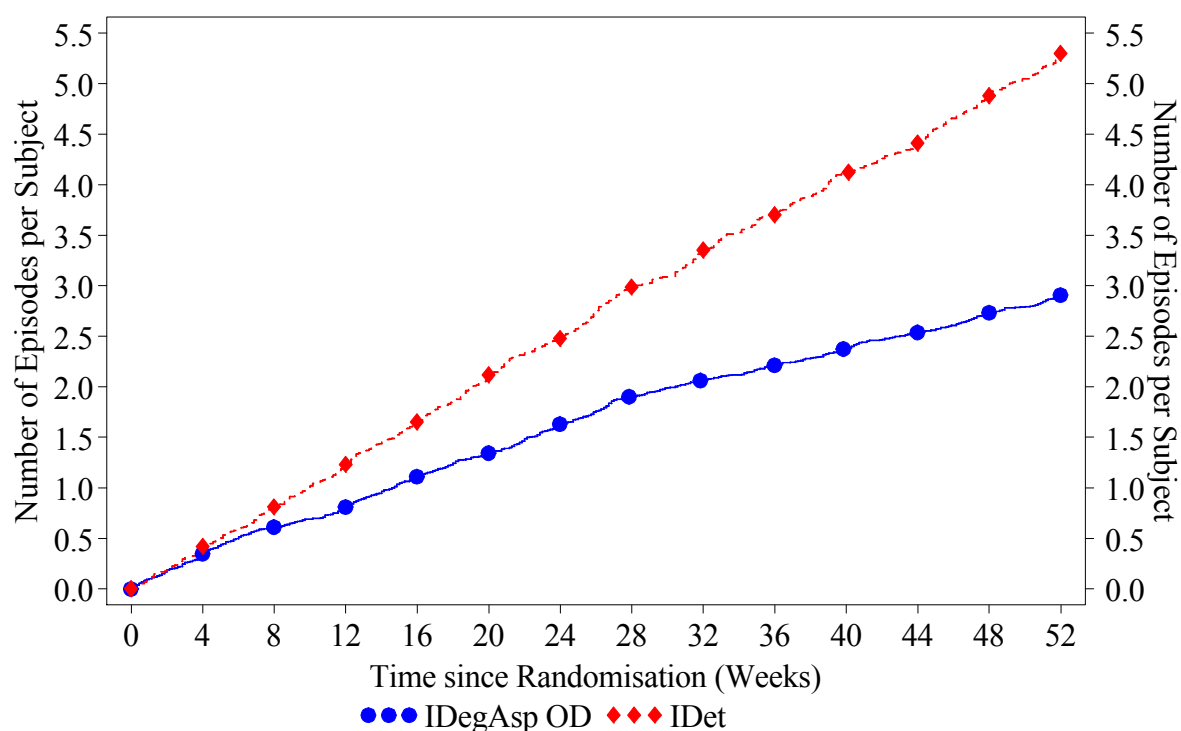
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:02:17 - fmean_cum_v01.sas/e_hypo_te_conf_mcf_sas.cgm

14.3.1.51: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set



nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:02:19 - fmean_cum_v01.sas/e_hypo_te_conf_mcf_ets.cgm

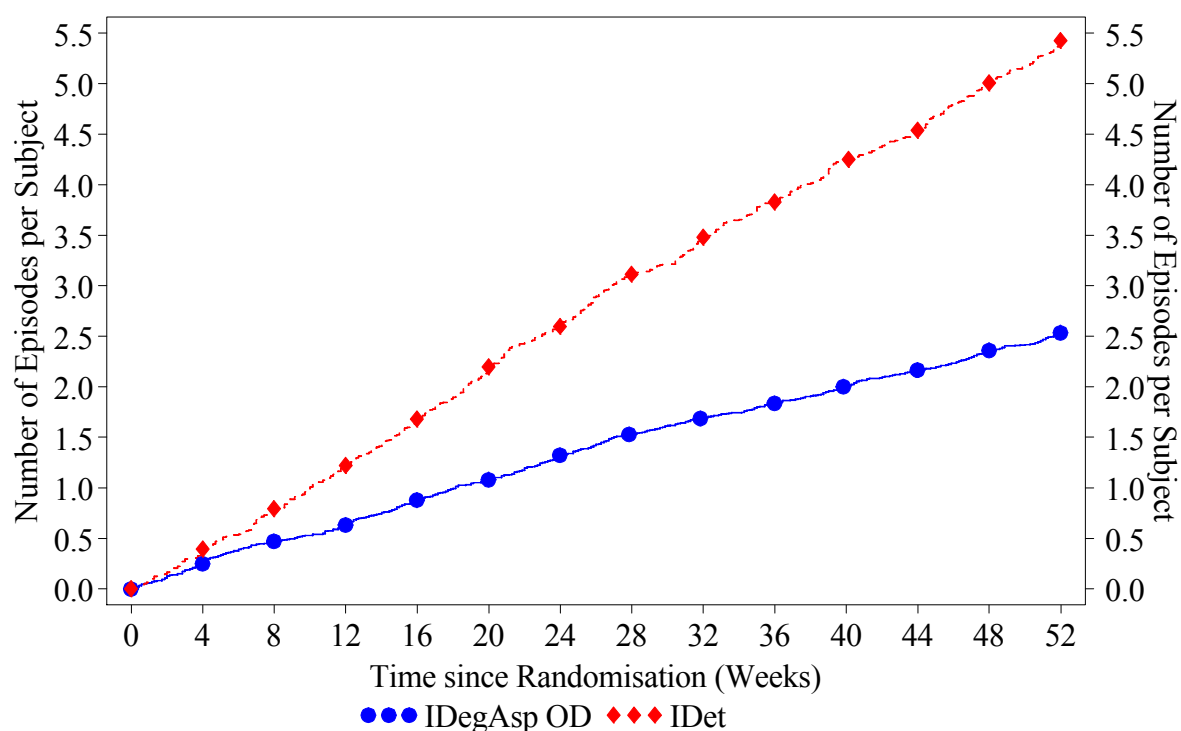
14.3.1.52: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Extension Trial Set



Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:02:22 - fmean_cum_v01.sas/e_hypo_te_conf_noct_mcf_sas.cgm

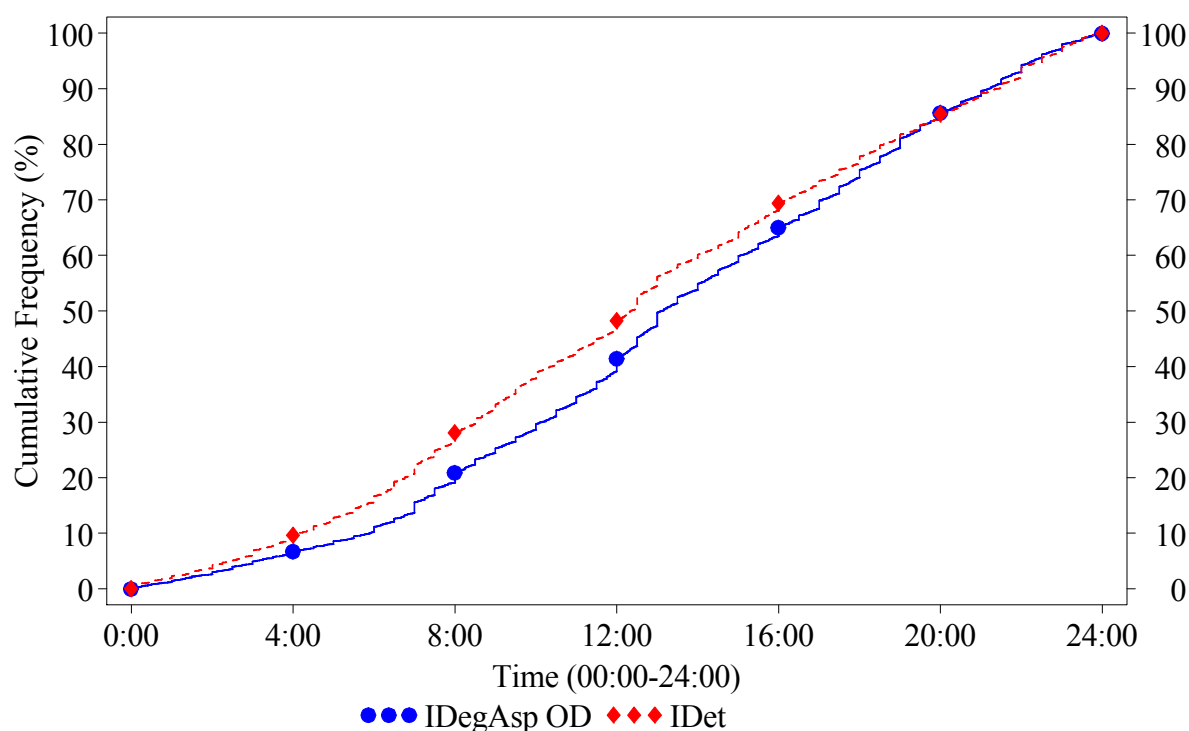
14.3.1.53: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Safety Analysis Set



Nocturnal period: the period between 00:01 and 05:59 a.m. (both included).

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:02:24 - fmean_cum_v01.sas/e_hypo_te_conf_noct_mcf_ets.cgm

14.3.1.54: Nocturnal Confirmed Hypoglycaemic Episodes – Treatment Emergent - Mean Cumulative Function - Extension Trial Set



SAFETY

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:02:26 - fcum_time_v01.sas/e_hypo_te_conf_cf_day_sas.cgm

14.3.1.55: Confirmed Hypoglycaemic Episodes – Treatment Emergent - Cumulative Frequency over Day - Safety Analysis Set

14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

14.3.2.1: Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	AE No.	Diag (Y/N) / Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------	-------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

</										

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	--------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

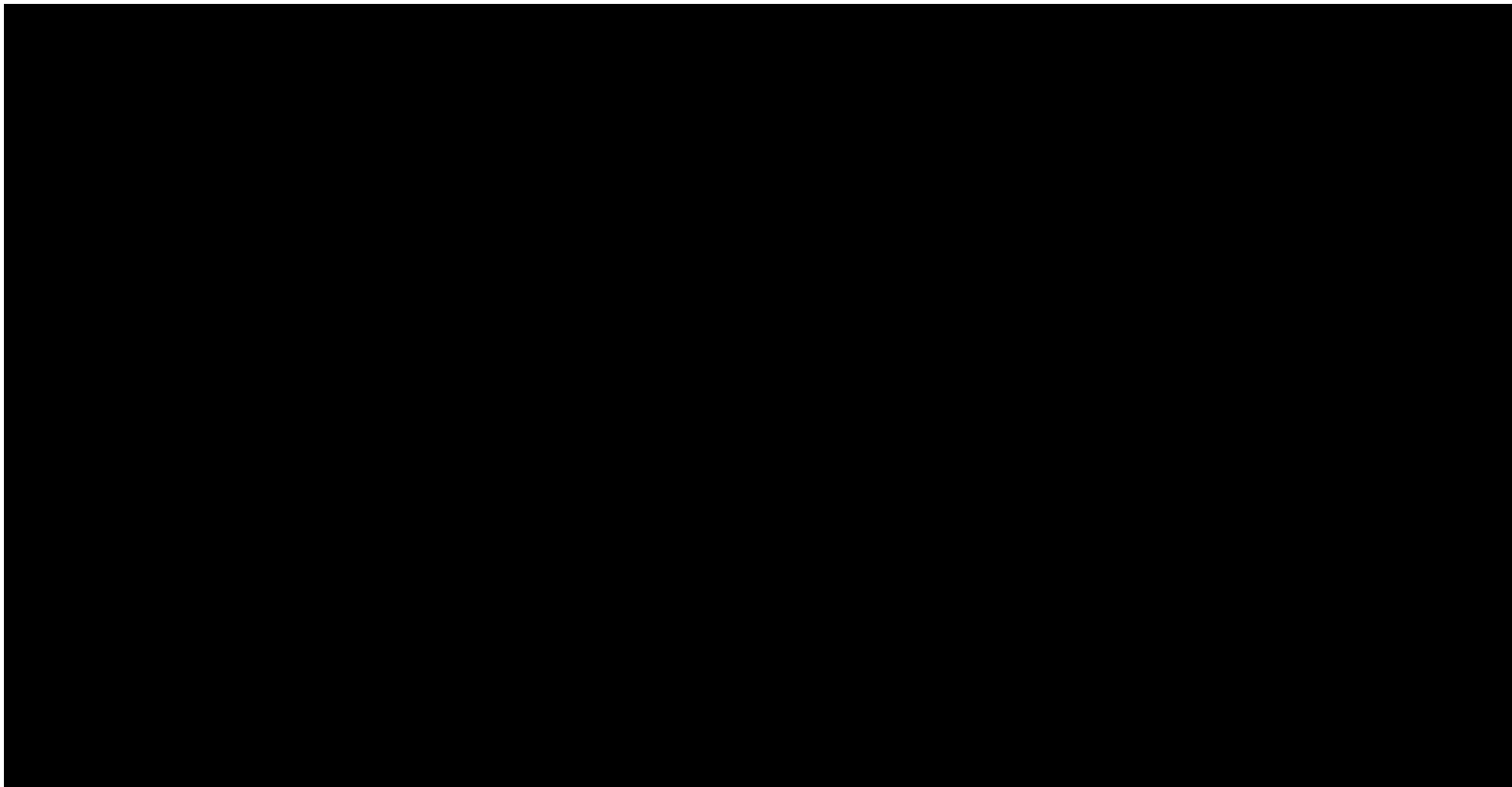
Status:
Page:

Final
Page 663 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

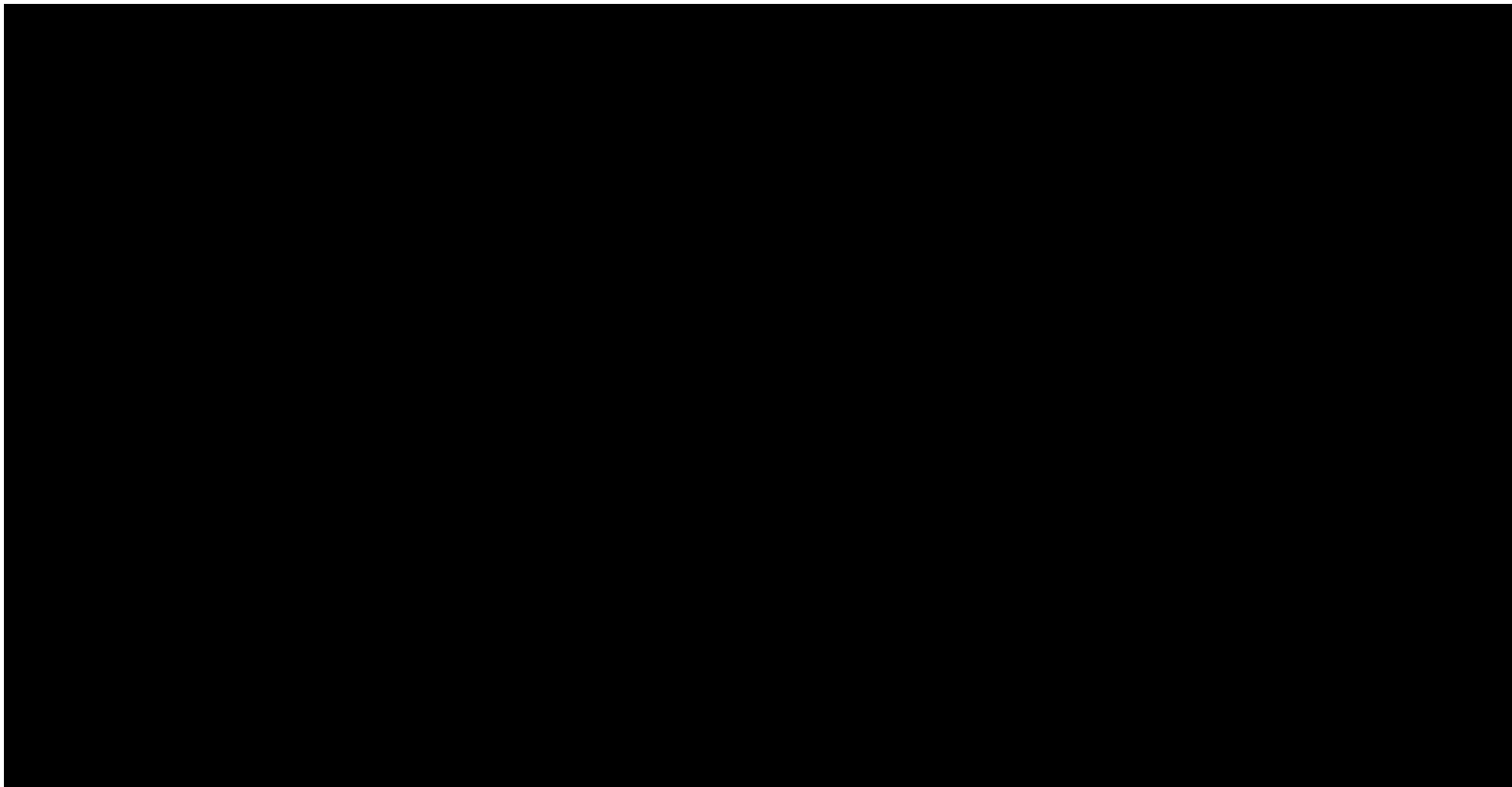
Status:
Page:

Final
Page 666 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

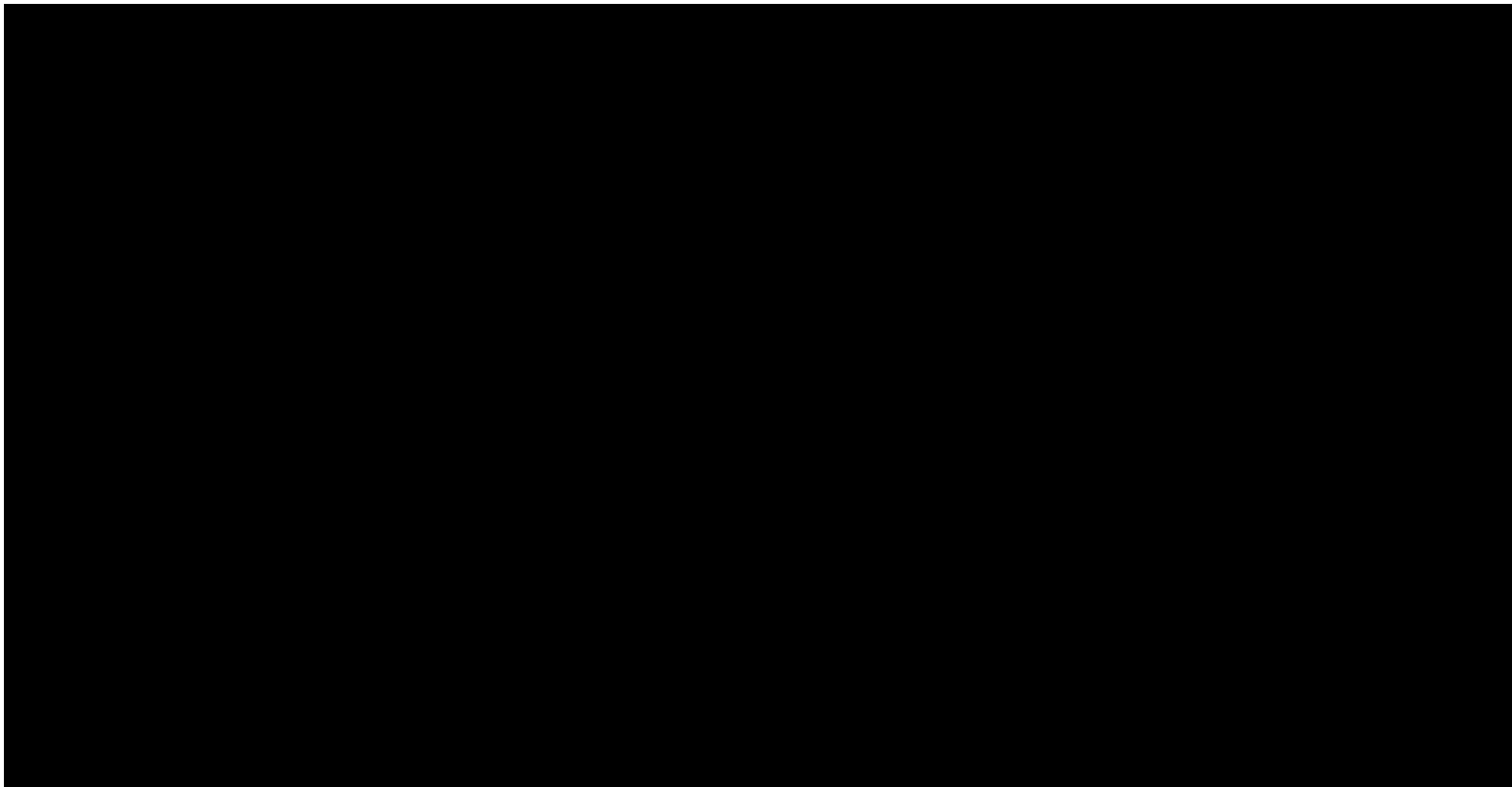
Status:
Page:

Final
Page 668 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

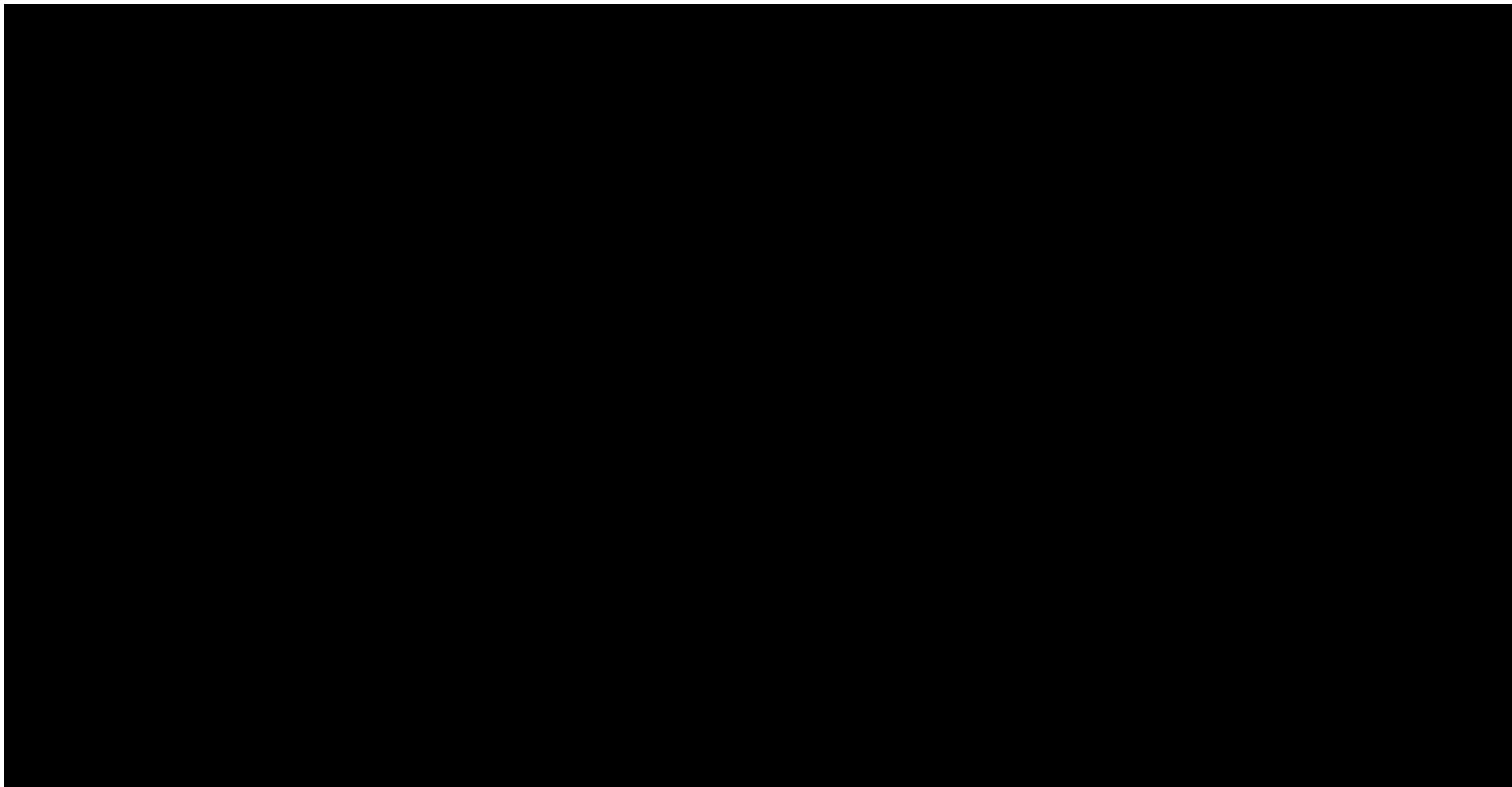
Status:
Page:

Final
Page 670 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 671 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

</										

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

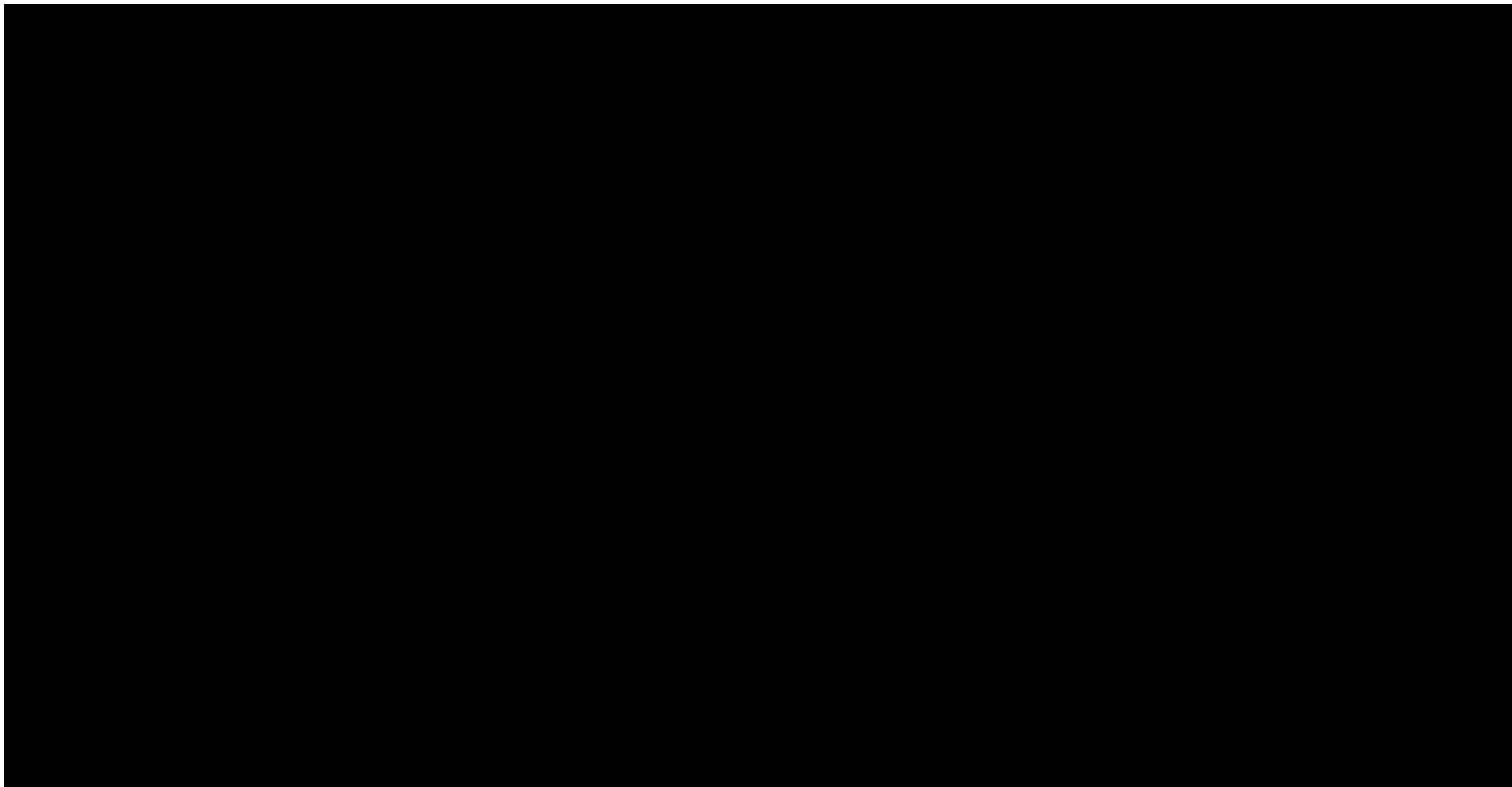
Status:
Page:

Final
Page 673 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 675 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

</										

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

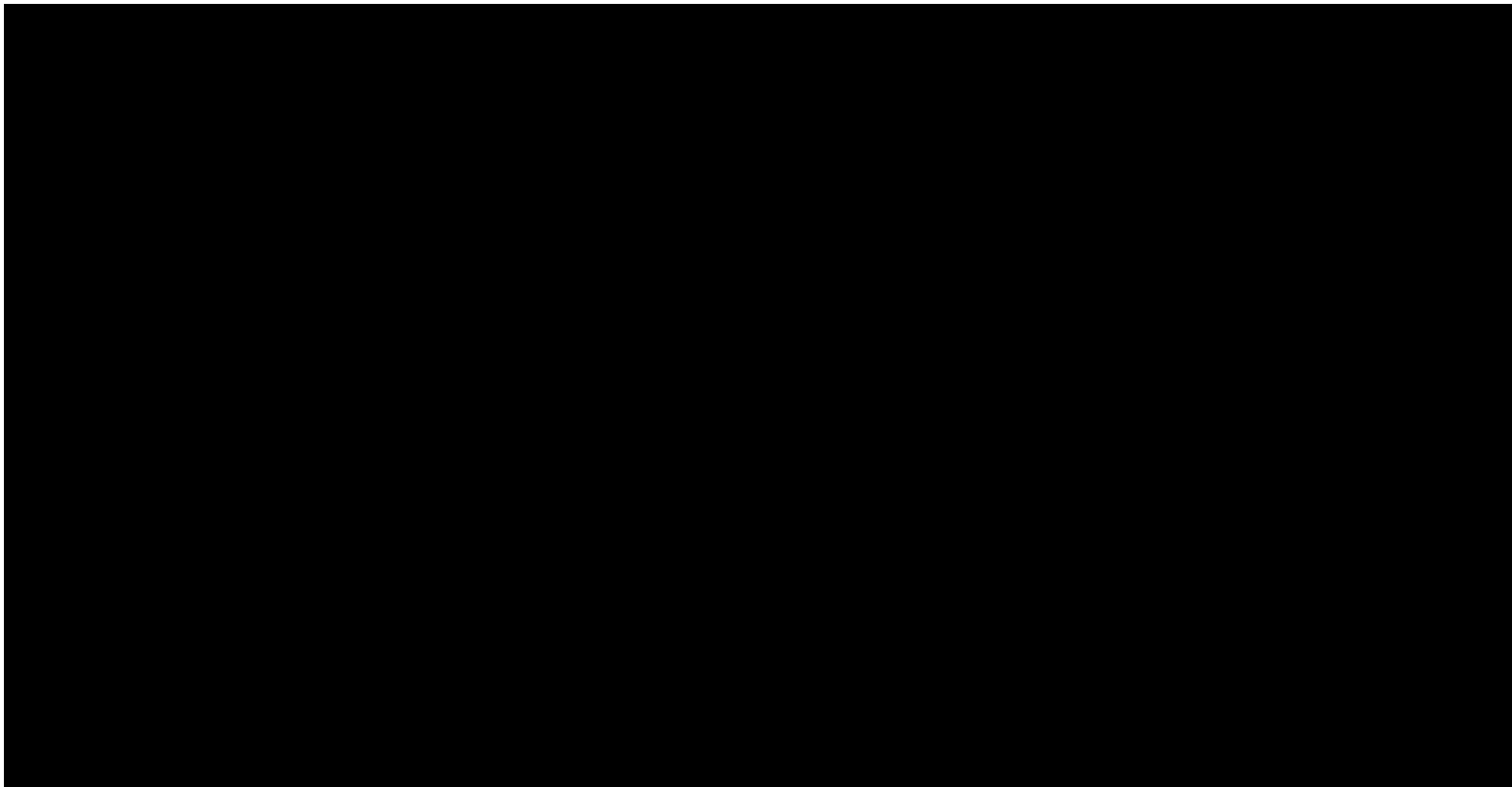
Status:
Page:

Final
Page 676 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 678 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

</										

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

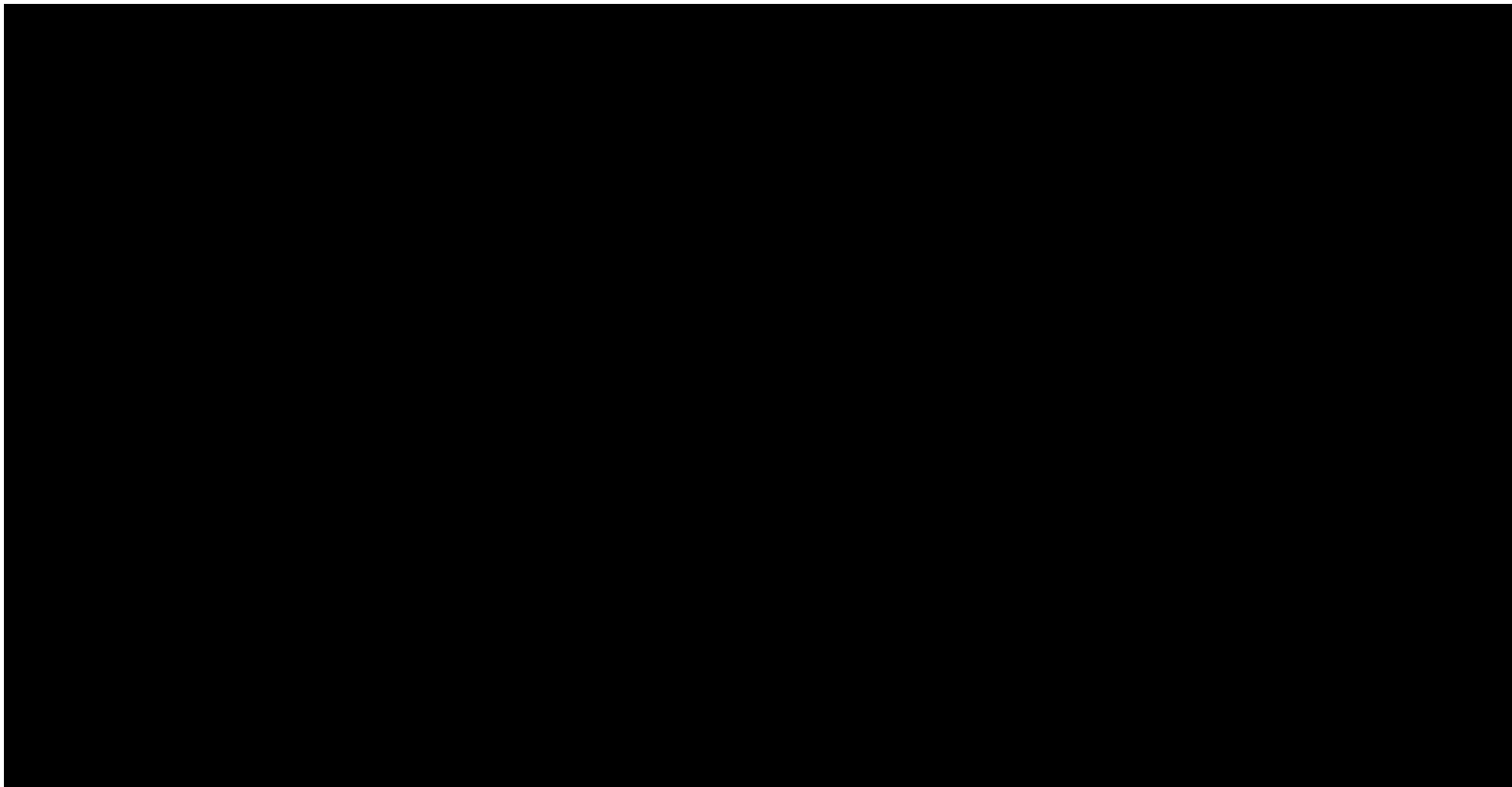
Status:
Page:

Final
Page 679 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

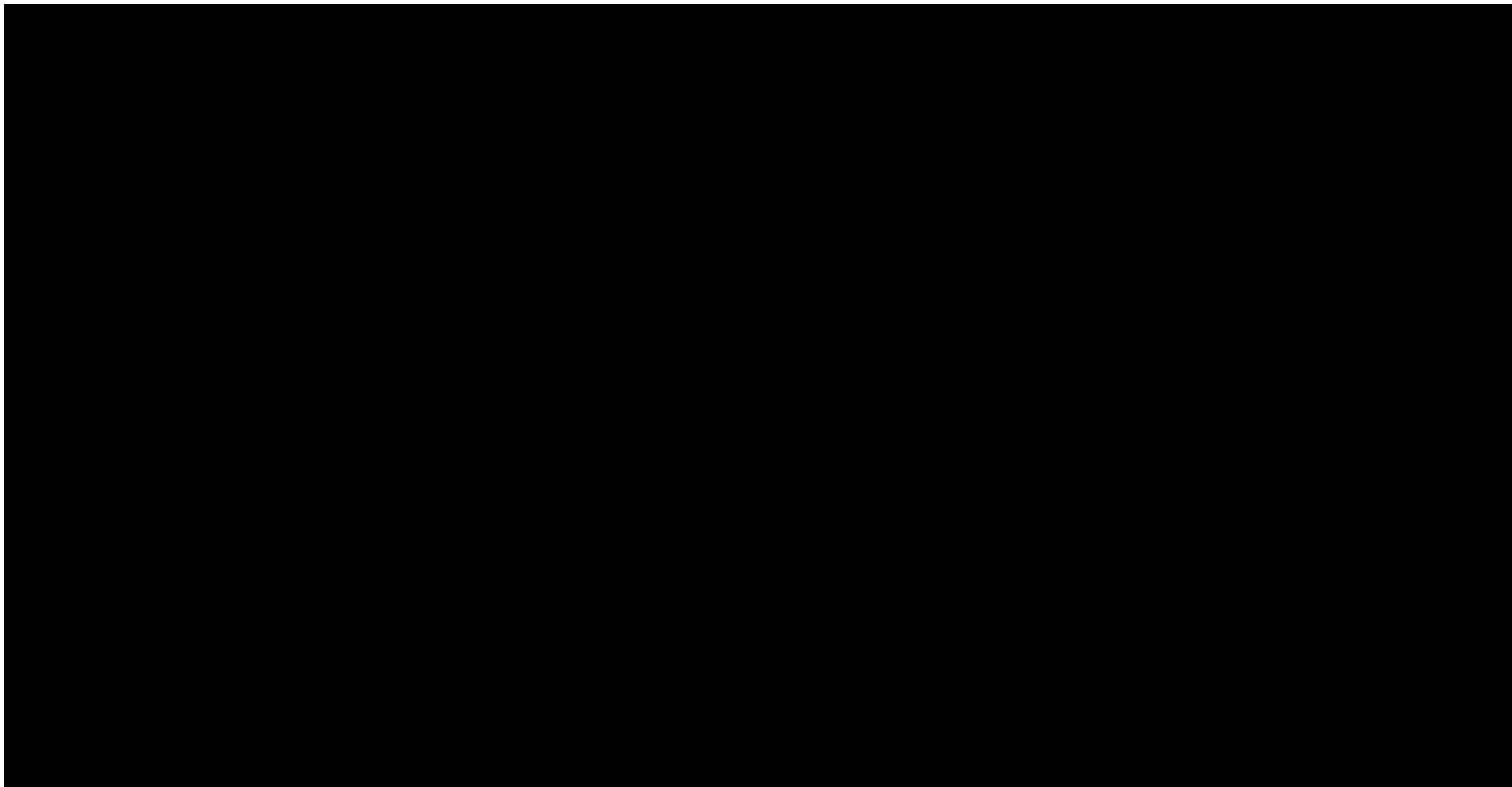
Status:
Page:

Final
Page 681 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

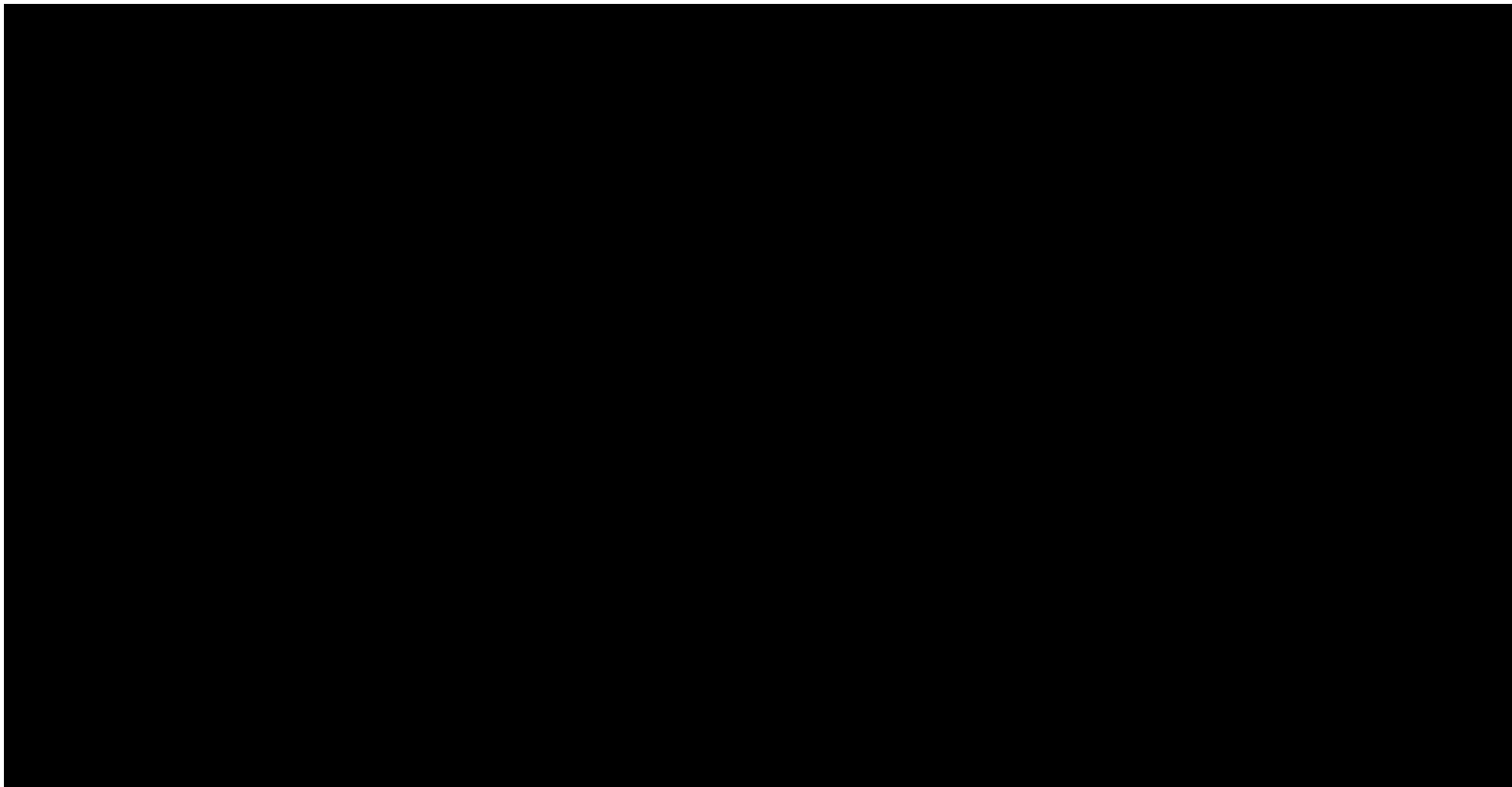
Status:
Page:

Final
Page 682 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	--------------	---------------------

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

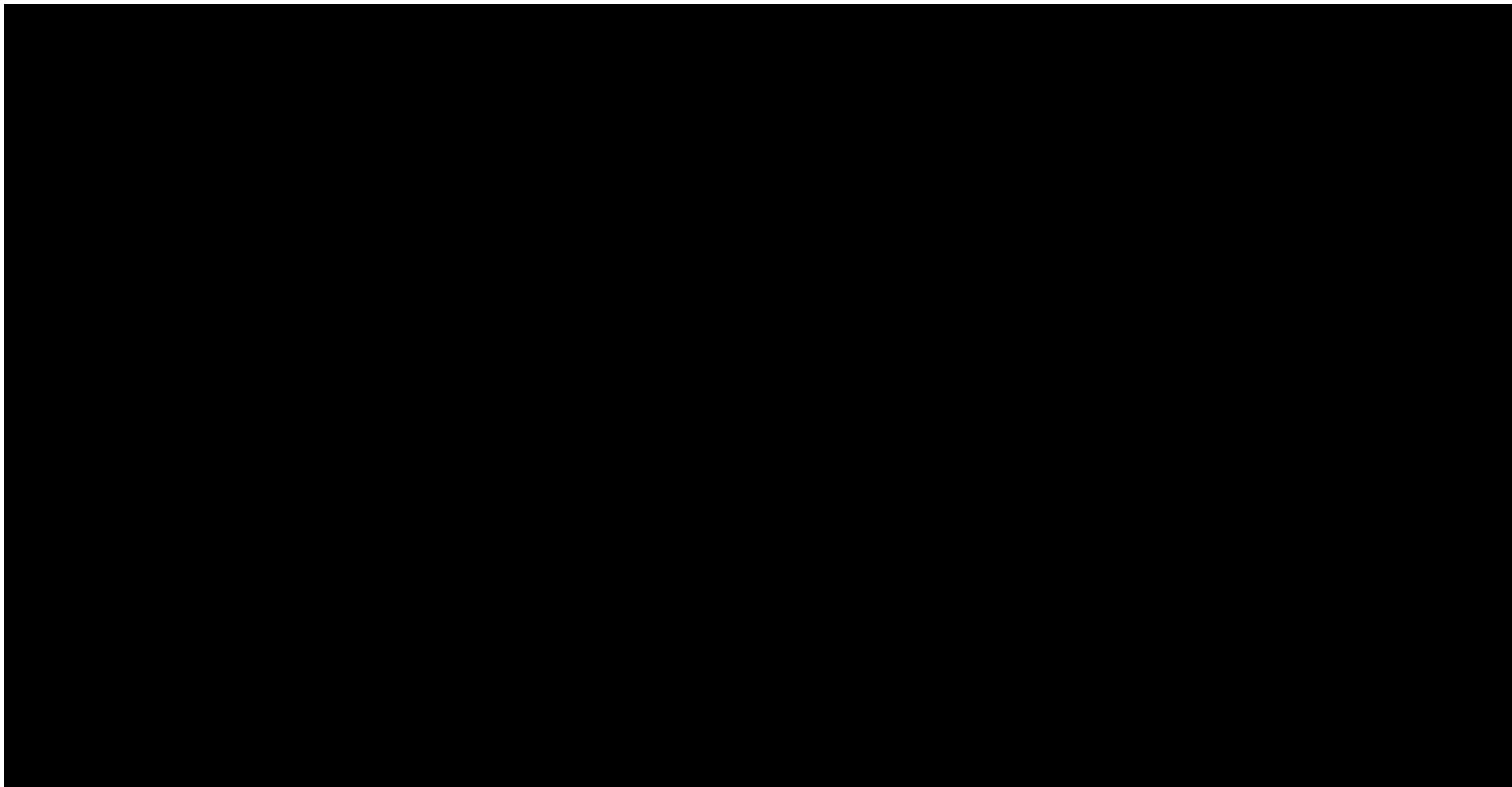
Status:
Page:

Final
Page 686 of 2239

Novo Nordisk

Treatment Emergent Serious Adverse Events - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	----------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------



14.3.2.2: Treatment Emergent Adverse Events with Fatal Outcome - Safety Analysis Set

There is no data for this Listing

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:36:30 - lis_teae.sas/l_teae_fatal_sas.txt

14.3.2.3: Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	--------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	--------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

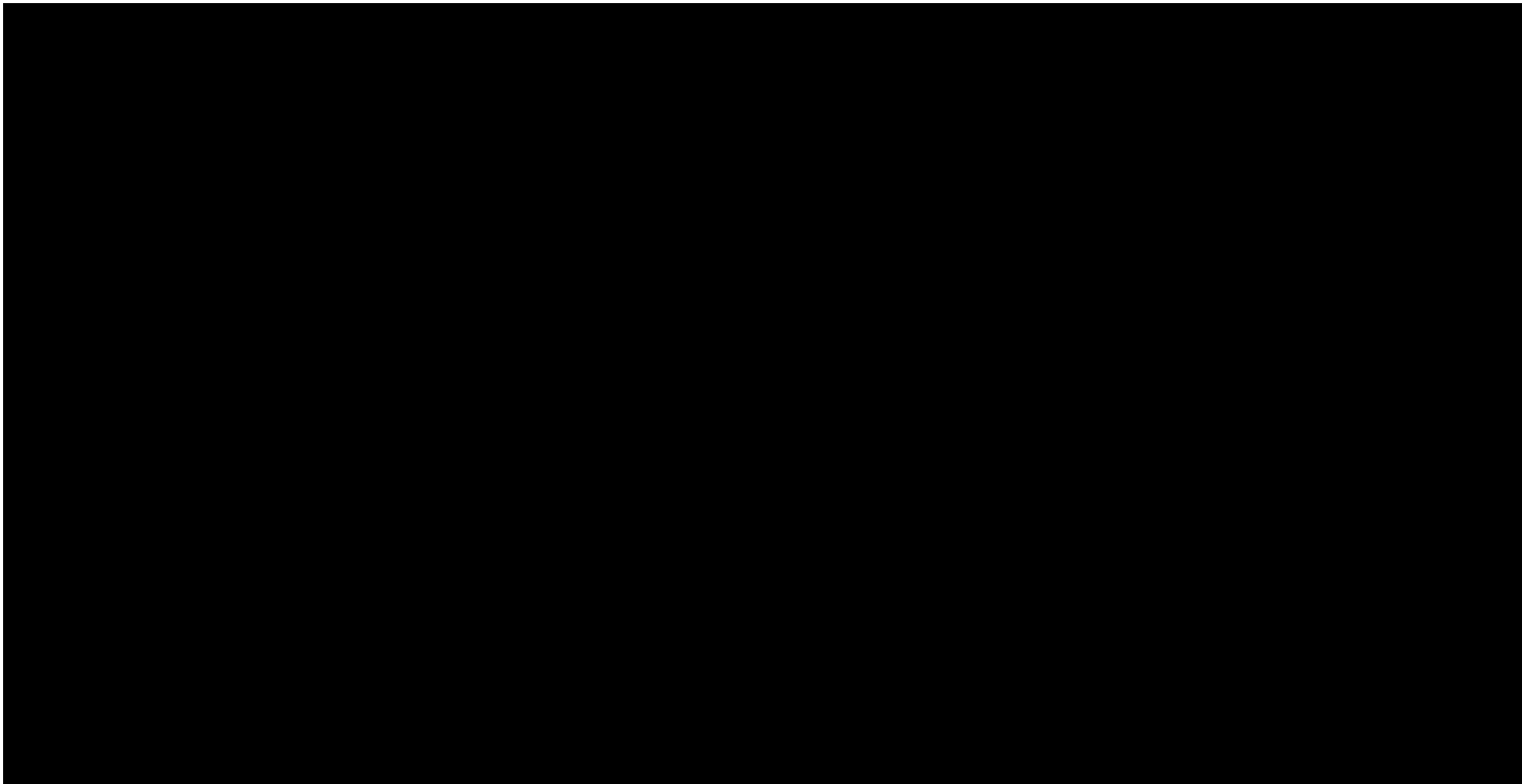
Status:
Page:

Final
Page 693 of 2239

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

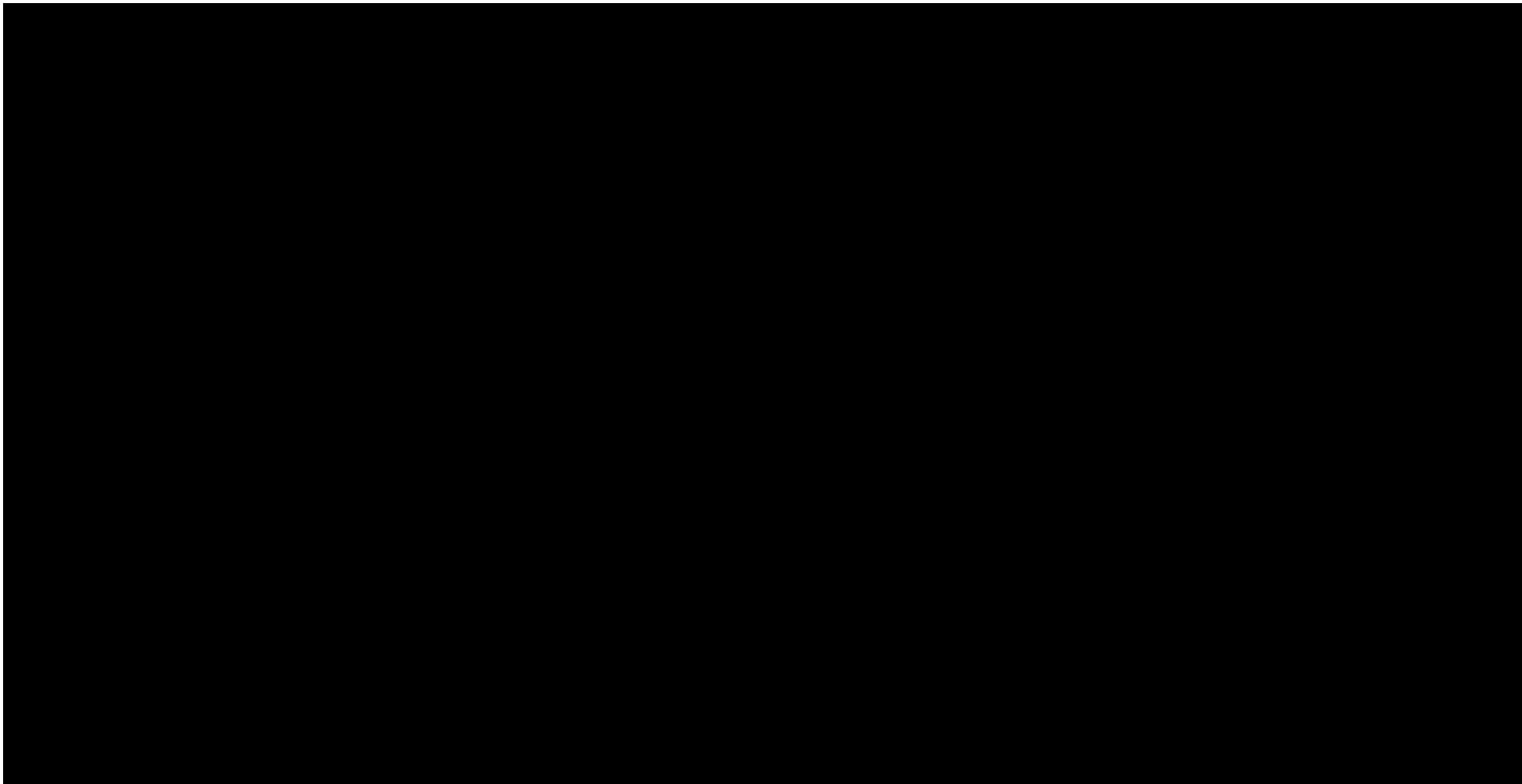
Status:
Page:

Final
Page 696 of 2239

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

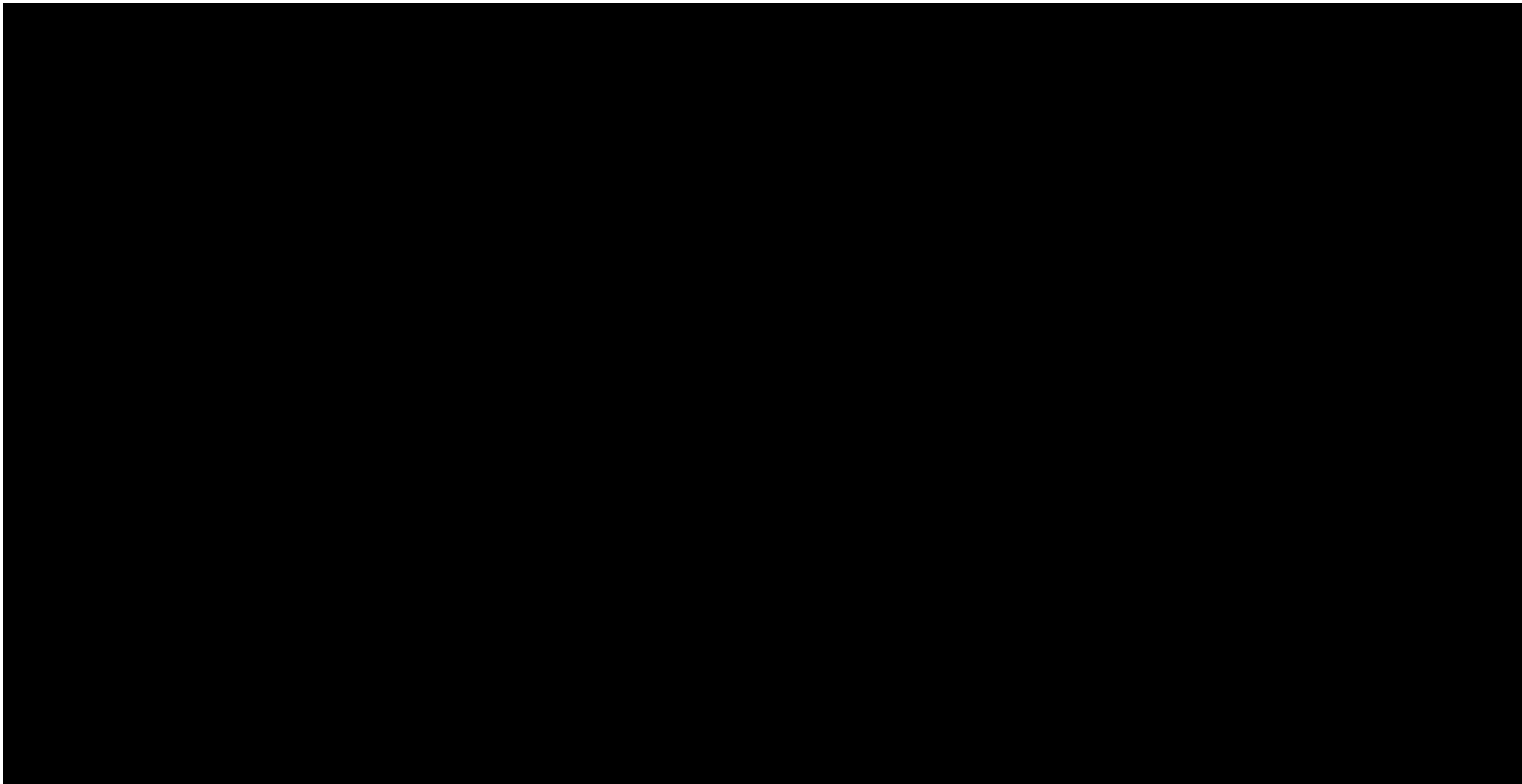
Status:
Page:

Final
Page 697 of 2239

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	--------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 700 of 2239

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

</										

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N) / AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Duration Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	------------------------------	---	------------------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

</									

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

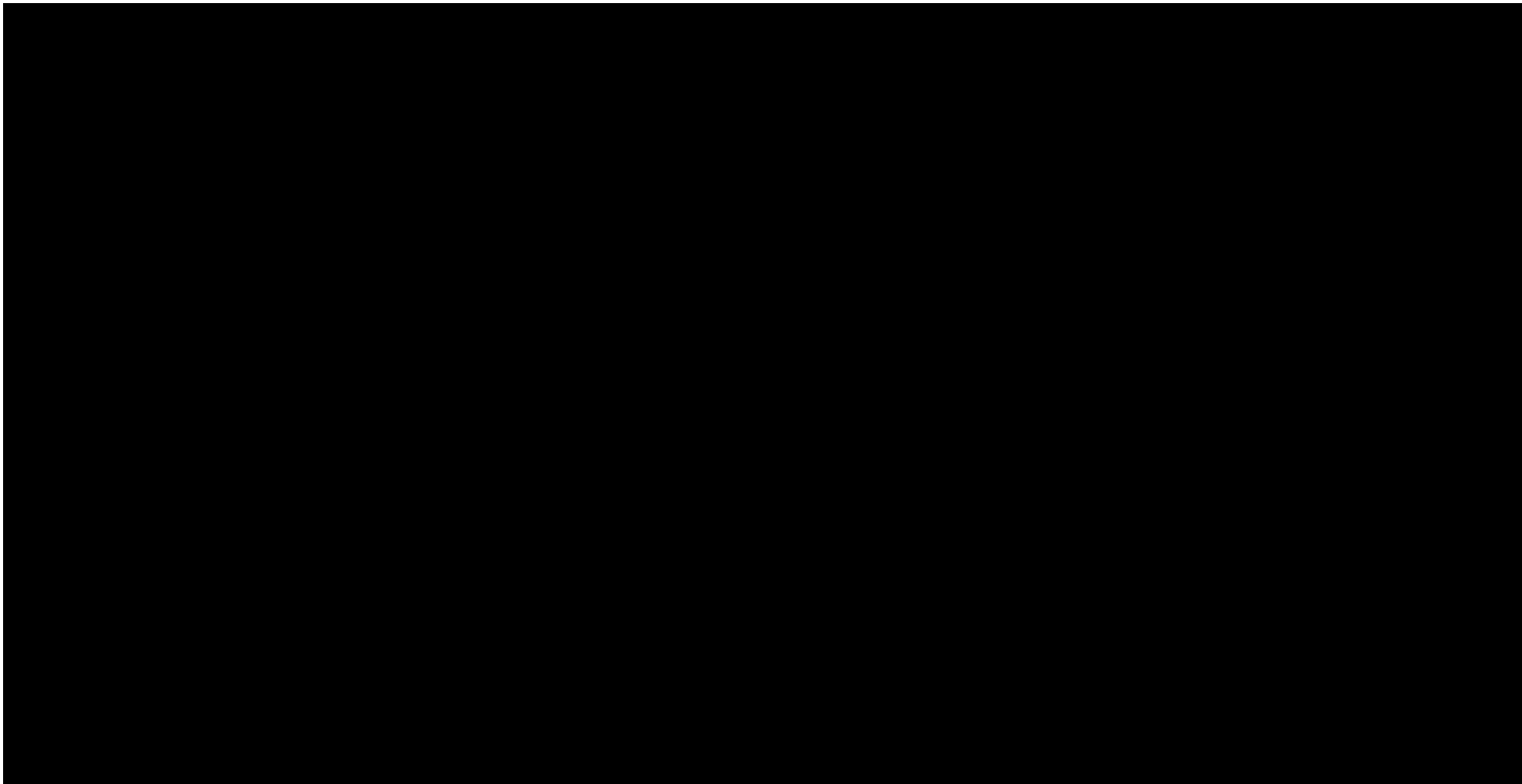
Status:
Page:

Final
Page 703 of 2239

Novo Nordisk

Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------



Treatment Emergent Adverse Events Leading to Dose Reduction of IDegAsp/IDet - Safety Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N) / No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N) / Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	--------------------------------	---	------------------------	----------------------------------	-----------------------------	------------------	---------------	-------------------------	---------------------

14.3.2.4: Adverse Events Leading to Withdrawal - Full Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

Adverse Events Leading to Withdrawal - Full Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	--------------	---------------------

Adverse Events Leading to Withdrawal - Full Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE (Y/N)/ No. Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	Device/ ISR (Y/N)	Relation/ Action
--	-------------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	-------------------------	---------------------

Adverse Events Leading to Withdrawal - Full Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	--------------	---------------------

Adverse Events Leading to Withdrawal - Full Analysis Set

Subject ID/ Treatment/ Age/Sex/BMI	Diag (Y/N)/ AE No.	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/ Severity	Trial Product	Dose/ Unit	ISR (Y/N)	Relation/ Action
--	-----------------------------	---	------------------------	----------------------------------	----------------------------	------------------	---------------	--------------	---------------------

14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

Abbreviation Statement

Please note the definition of the following abbreviation:

SIAC: Soluble Insulin Analogue Combination, NN5401. Synonym previously used for IDegAsp

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 711 of 2239

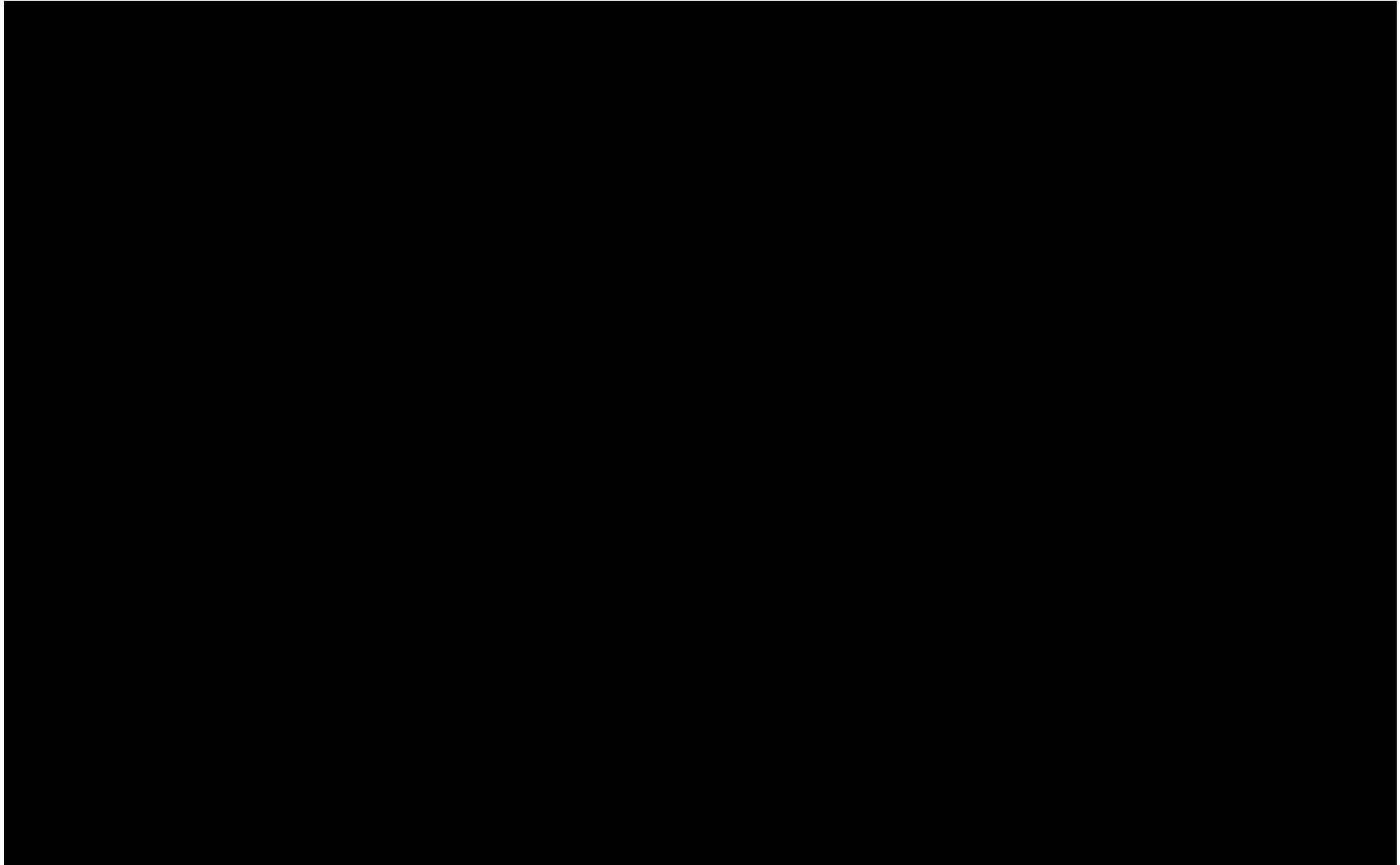
Novo Nordisk

**NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final**

Date: 11-May-2011 00:32:21

Report #:

Period: 01-Jan-1900 Through 05-Jan-2011



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 712 of 2239

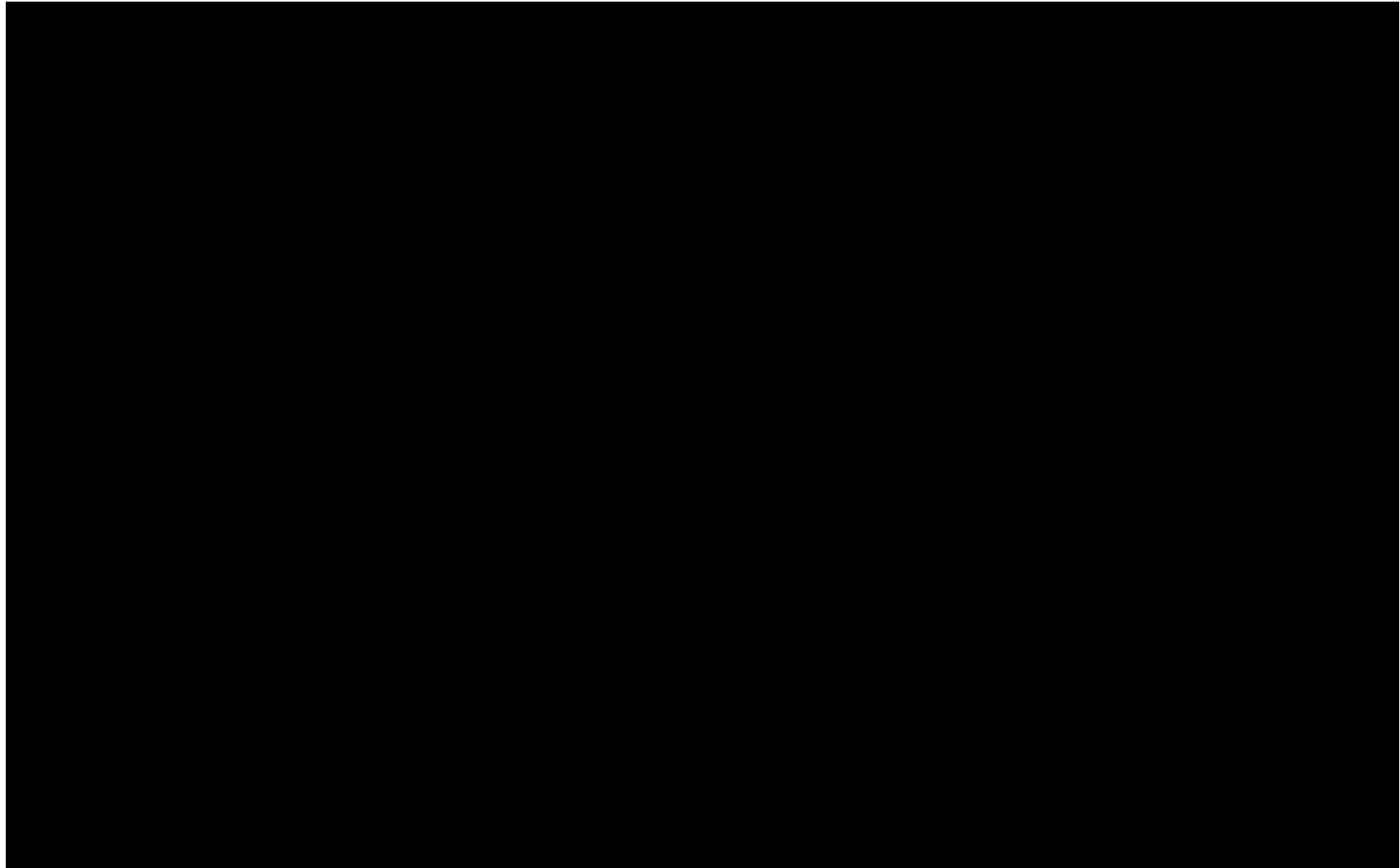
Novo Nordisk

**NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final**

Date: 11-May-2011 00:32:21

Report #:

Period: 01-Jan-1900 Through 05-Jan-2011



Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 715 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 717 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 718 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 719 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 723 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 724 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 729 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 731 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 732 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 733 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 734 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 741 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 742 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 748 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 751 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 754 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 755 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 757 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 759 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 761 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 763 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 765 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 772 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 774 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 778 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 780 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 782 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 785 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 787 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 788 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 790 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 795 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 796 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 798 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 800 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 802 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 803 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 804 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 805 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 806 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 809 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 810 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 815 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 816 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 819 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 820 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 824 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 831 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 832 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 833 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 835 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 843 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 845 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
			Daily Dose [Dose Frequency]	Route				

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 846 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 853 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 857 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 861 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 865 of 2239

Novo Nordisk

NN5401-3594/3645 - Serious / Neoplasm / Allergy / Immunogenicity / Medication Error cases --
Final

Date: 11-May-2011 00:32:21

Report #: Period: 01-Jan-1900 Through 05-Jan-2011

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome

NN5401-3594/NN5401-3645

Study ID: NN5401-3645

IDegAsp Helicobacter gastritis

The event was assessed by Investigator as unlikely related to trial drug and no changes to trial drug regimen were made.

Study ID: NN5401-3594

IDet Skin Papilloma

The event was assessed by Investigator as unlikely related to trial drug and no changes to trial drug regimen were made.

Study ID: NN5401-3645

IDet Thyroid neoplasm

The event was assessed by Investigator as unlikely related to trial drug and changes to trial drug regimen were made.

Study ID: NN5401-3594

IDet Benign neoplasm of thyroid gland

The event was assessed by Investigator as unlikely related to trial drug. No changes to trial drug conduct were made throughout the course of the event.

NN5401-3594/3645 Narratives for non-serious Adverse Events leading to withdrawal

Subject [REDACTED] **(IDet).** [REDACTED]
[REDACTED]
[REDACTED]

Subject [REDACTED] **(IDet).** [REDACTED]
[REDACTED]
[REDACTED]

Subject [REDACTED] **(IDegAsp OD).** [REDACTED]
[REDACTED]
[REDACTED]

Subject [REDACTED] **(IDet).** [REDACTED]
[REDACTED]
[REDACTED]

14.3.4.1: Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Biochemistry Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

14.3.4.2: Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

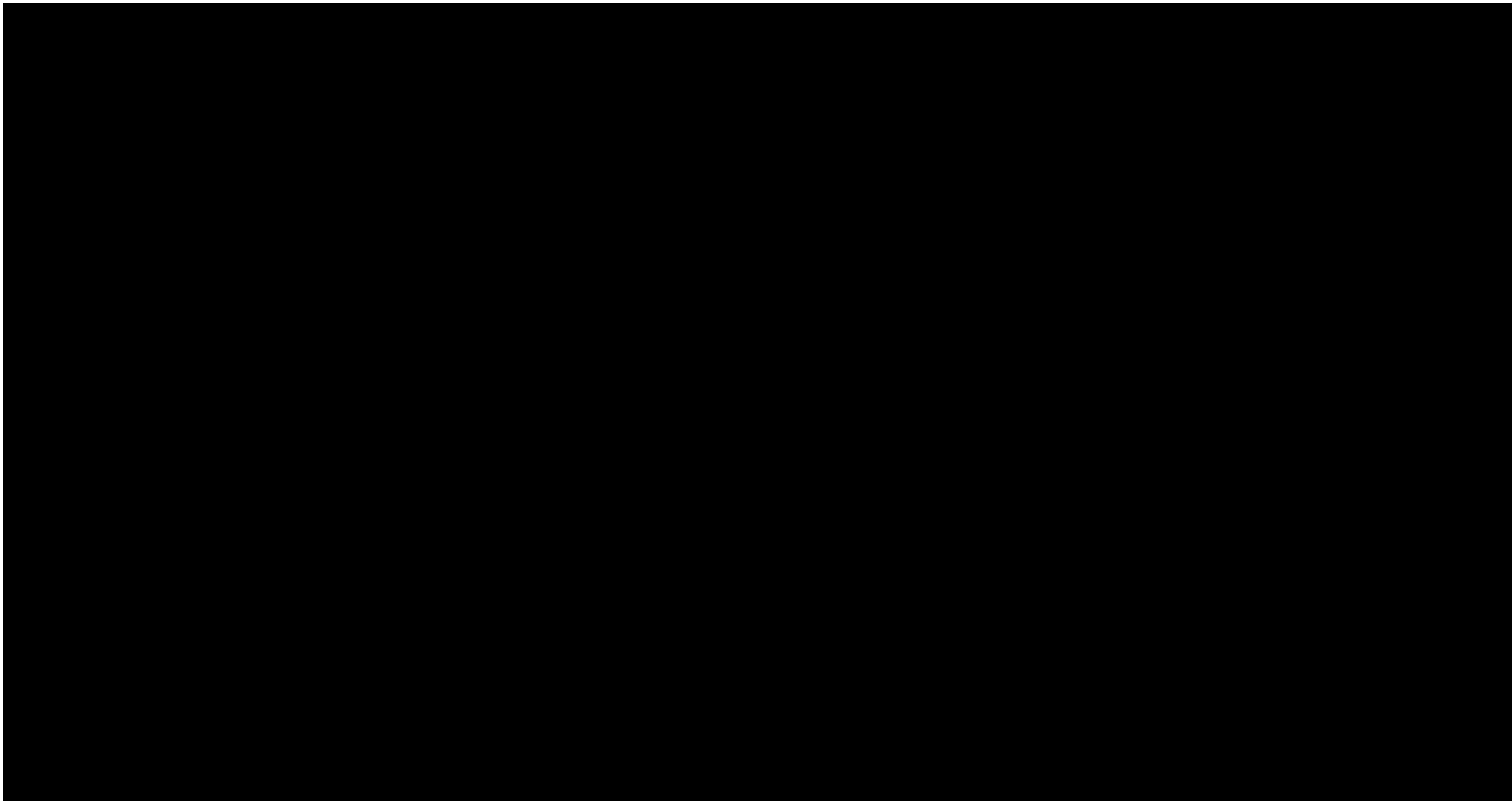
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 891 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

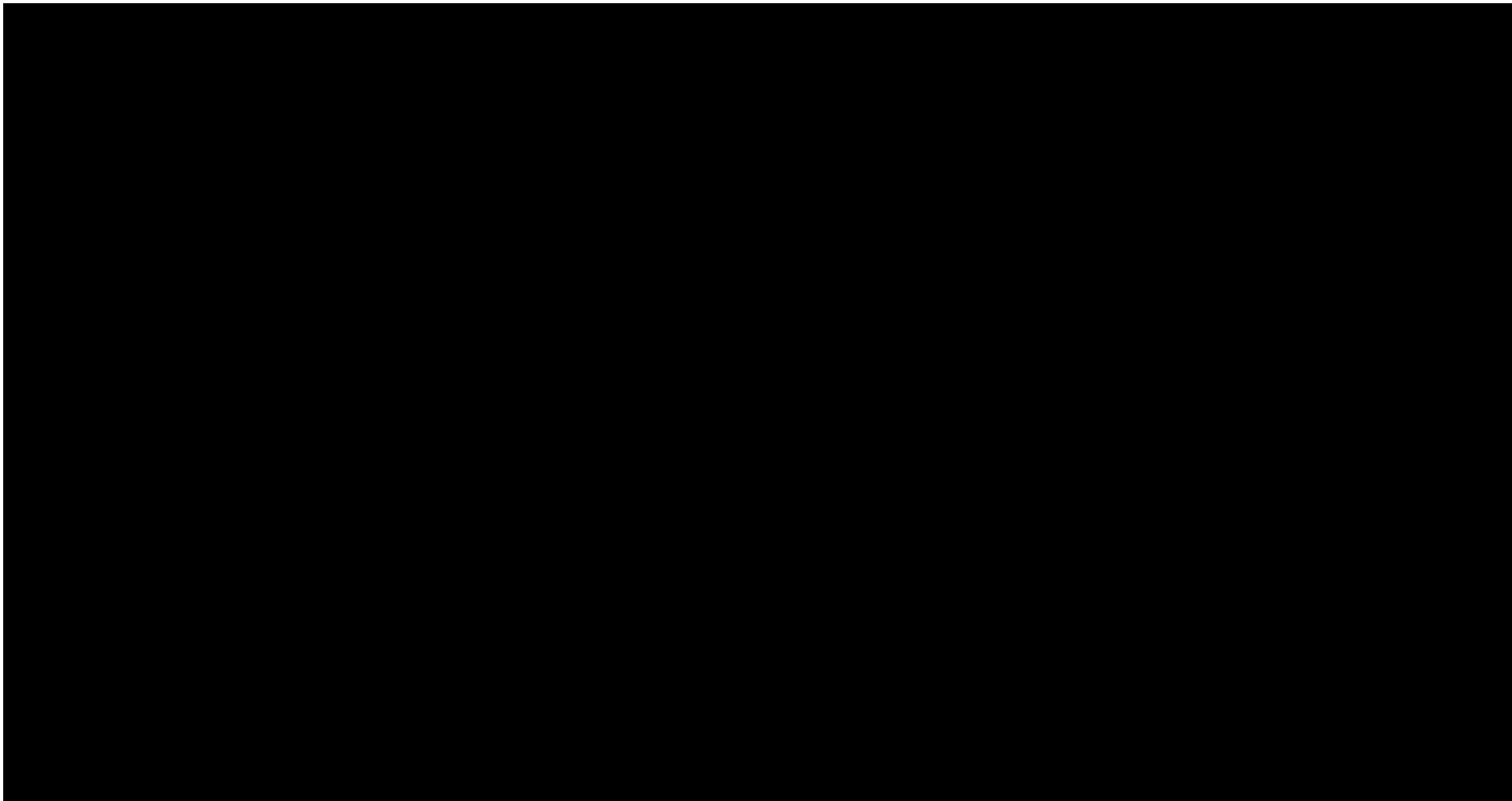
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 892 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

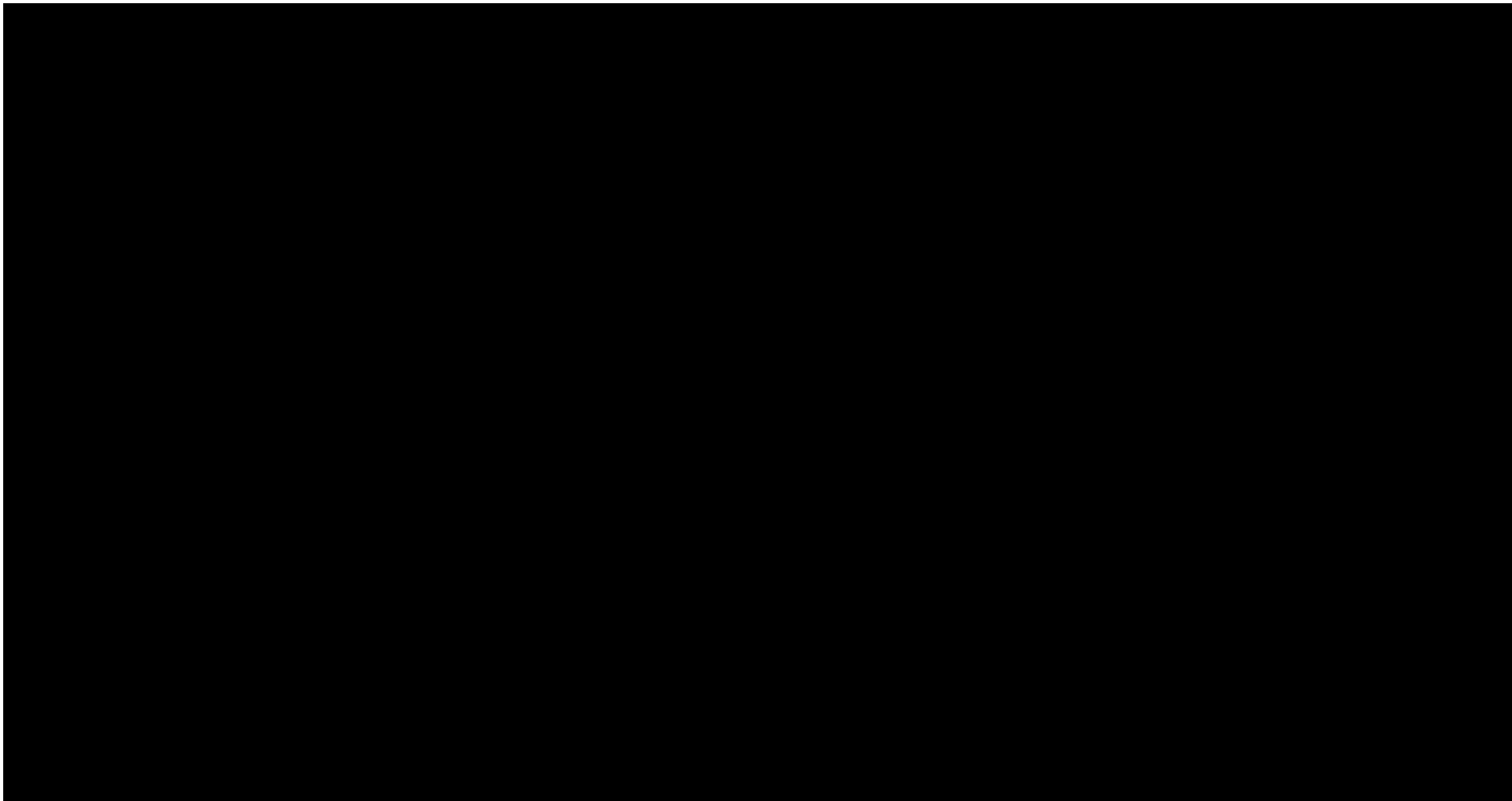
Status:
Page:

Final
Page 893 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

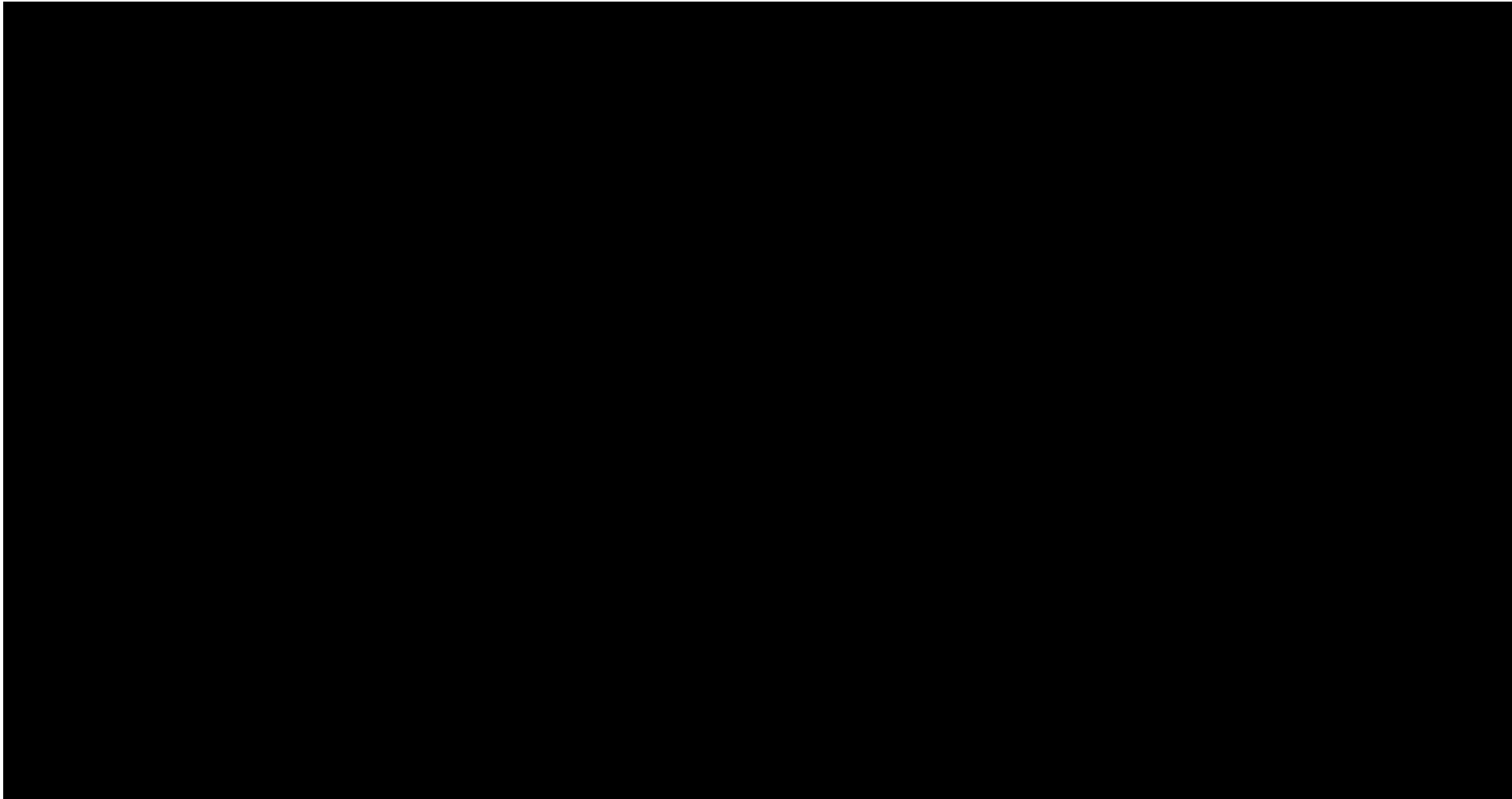
Status:
Page:

Final
Page 894 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

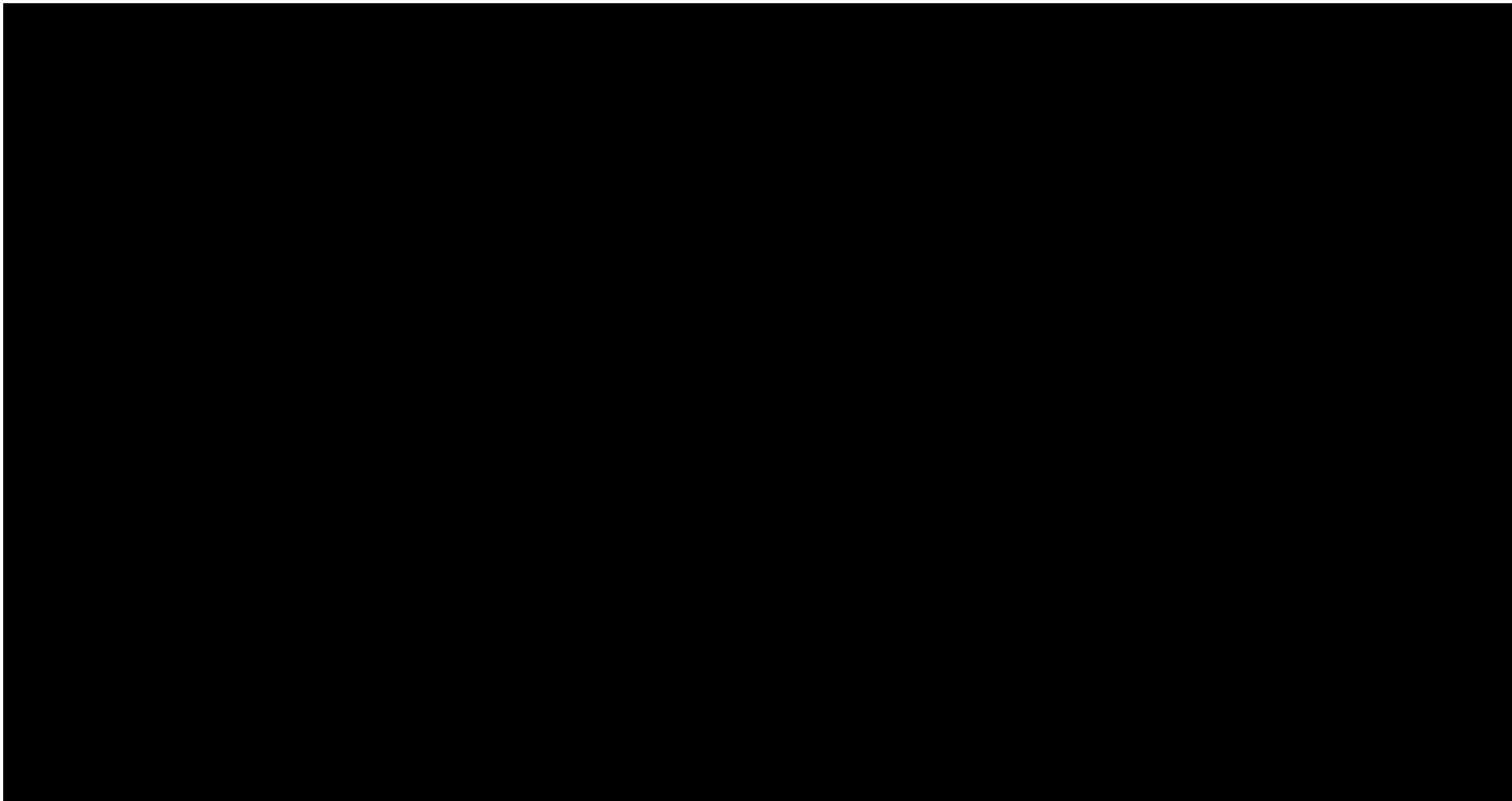
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 895 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

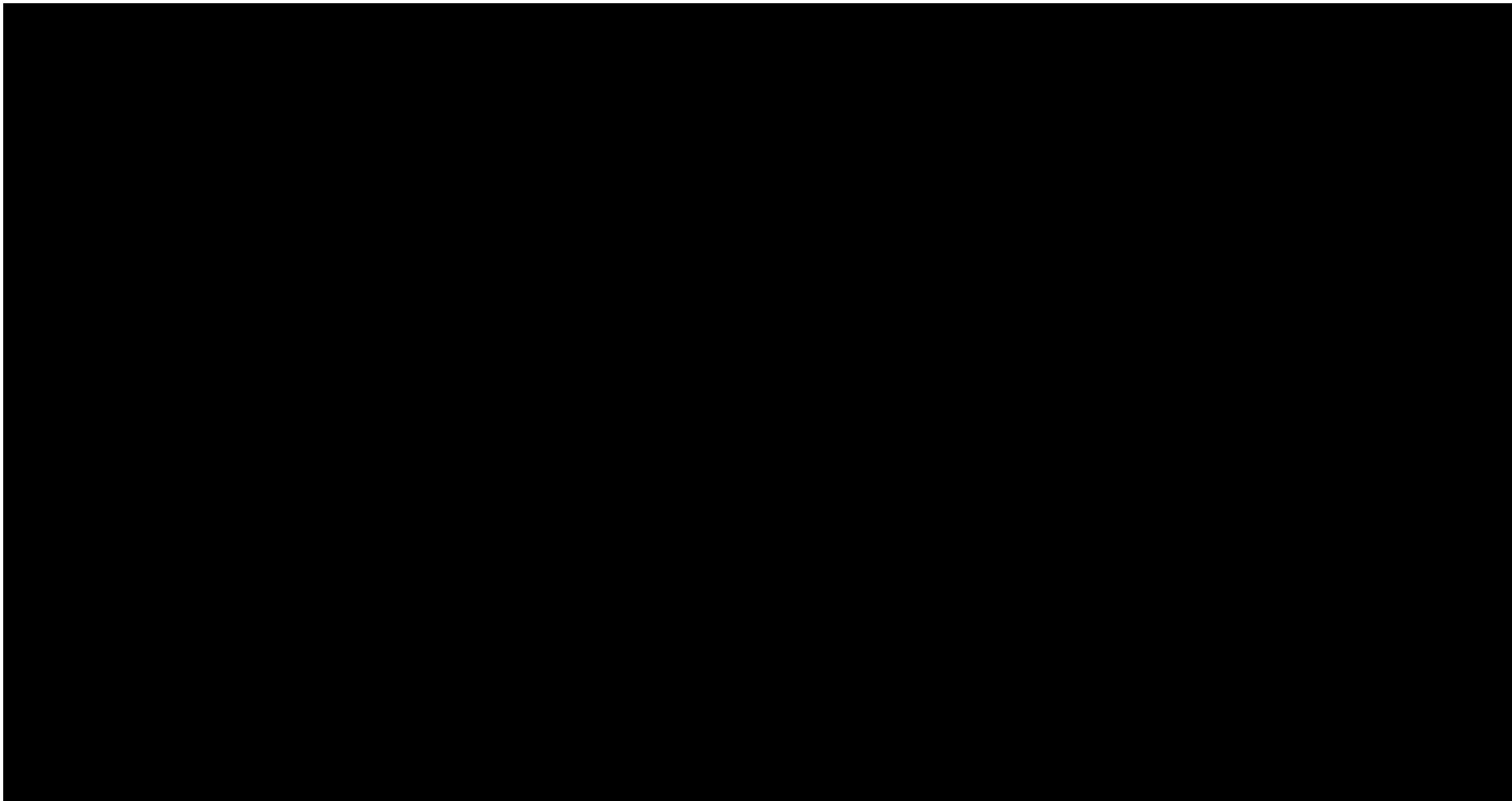
Status:
Page:

Final
Page 896 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

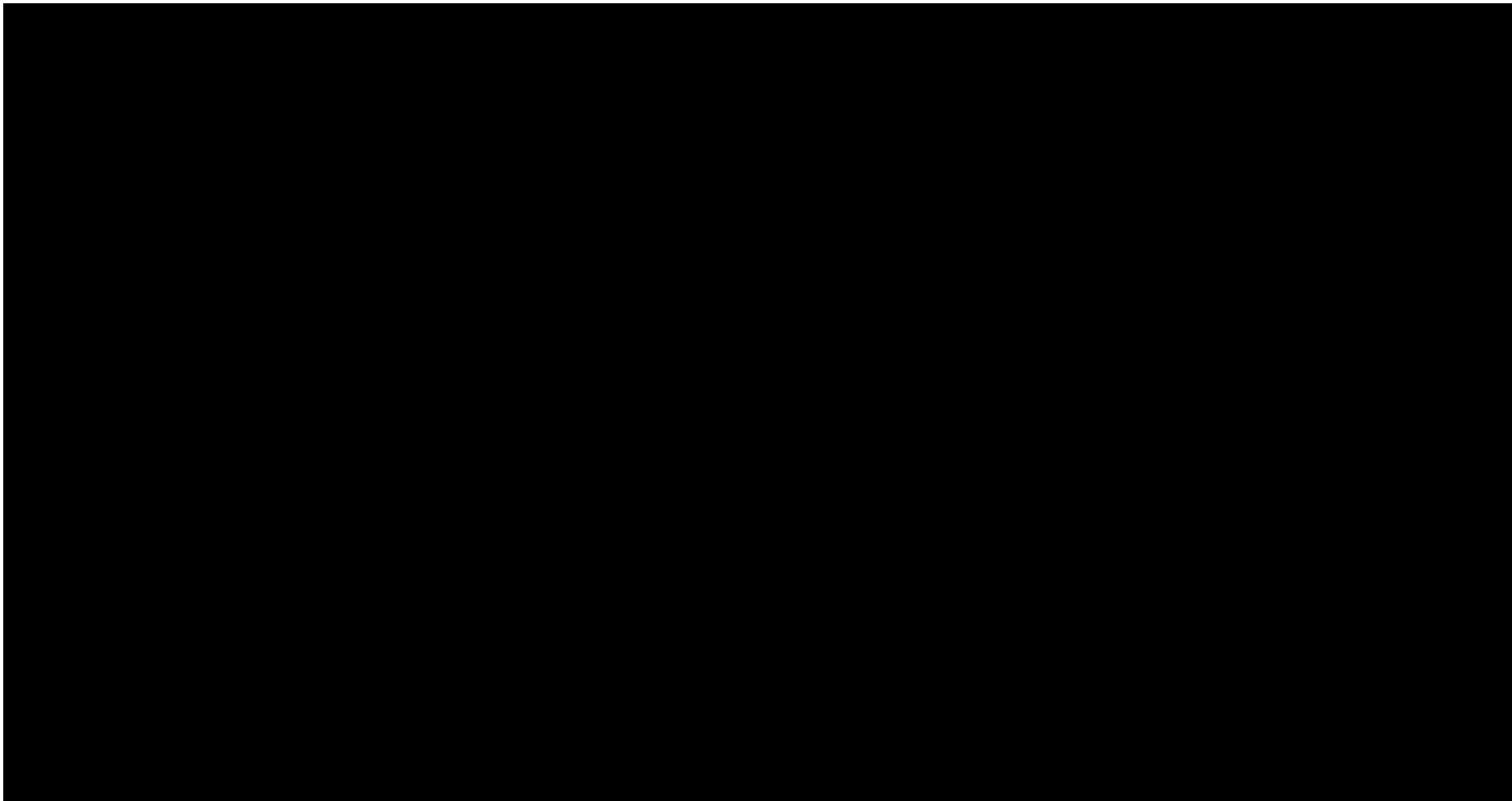
Status:
Page:

Final
Page 897 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

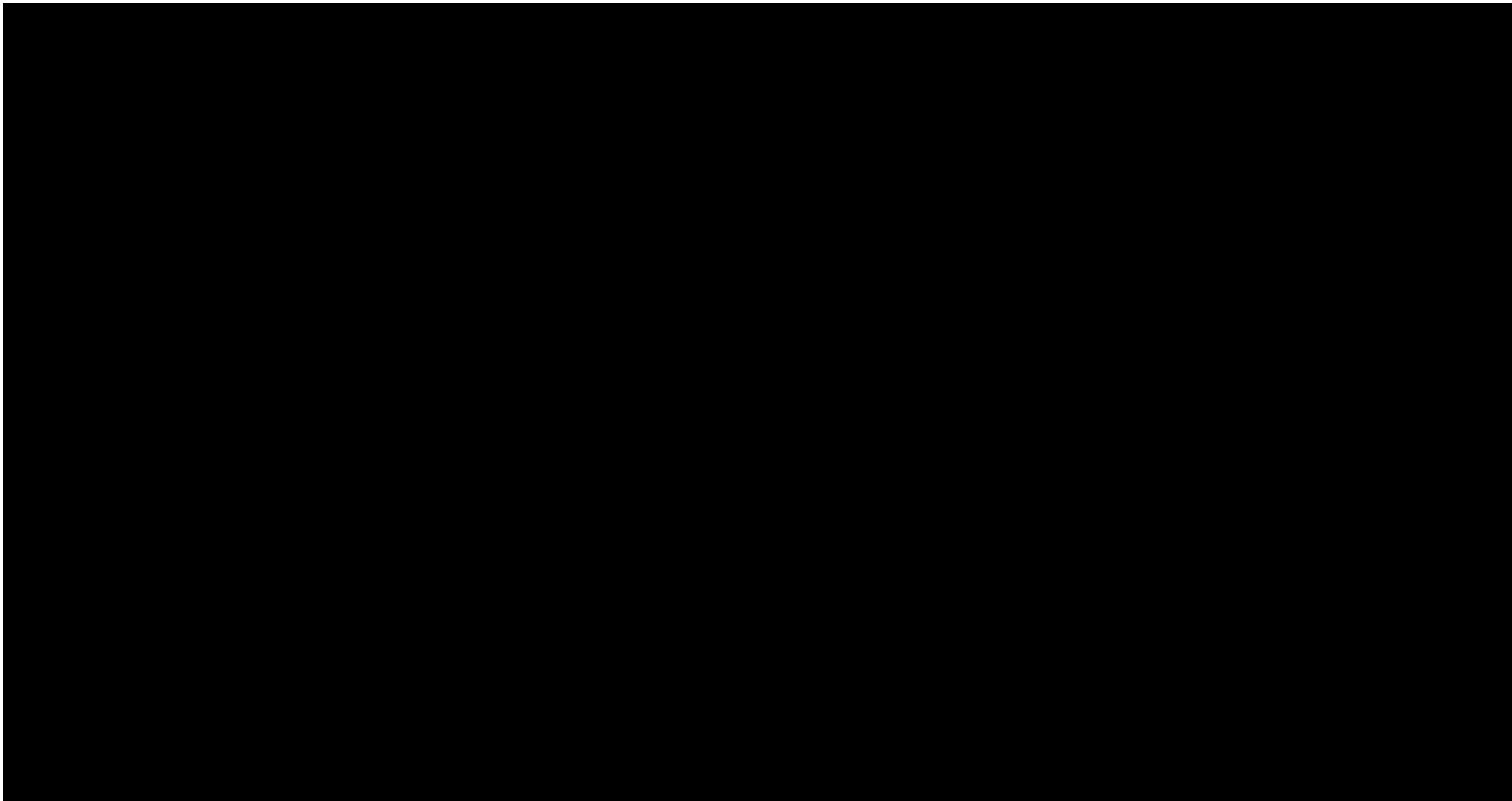
Status:
Page:

Final
Page 898 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

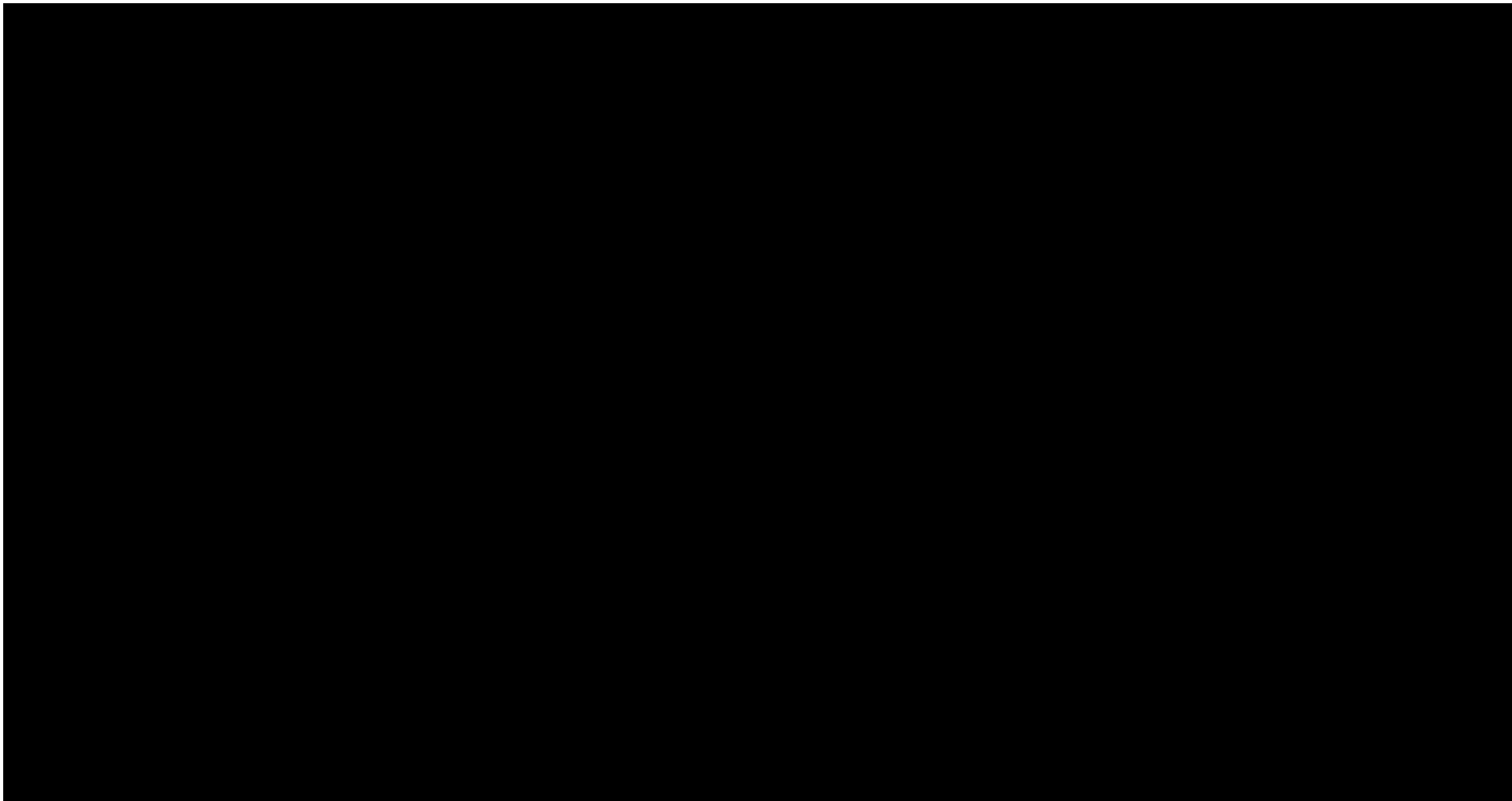
Status:
Page:

Final
Page 899 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

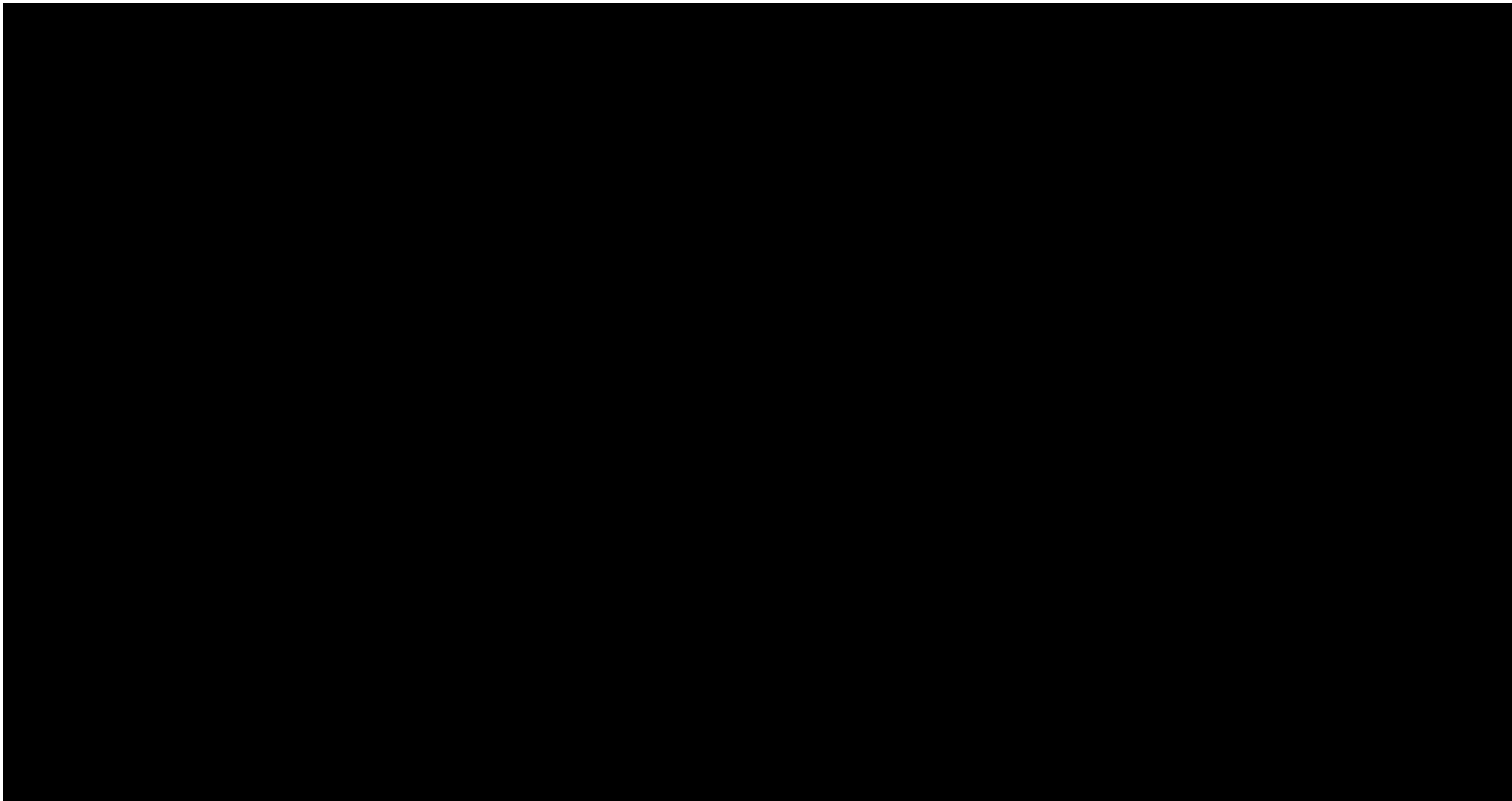
Status:
Page:

Final
Page 900 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

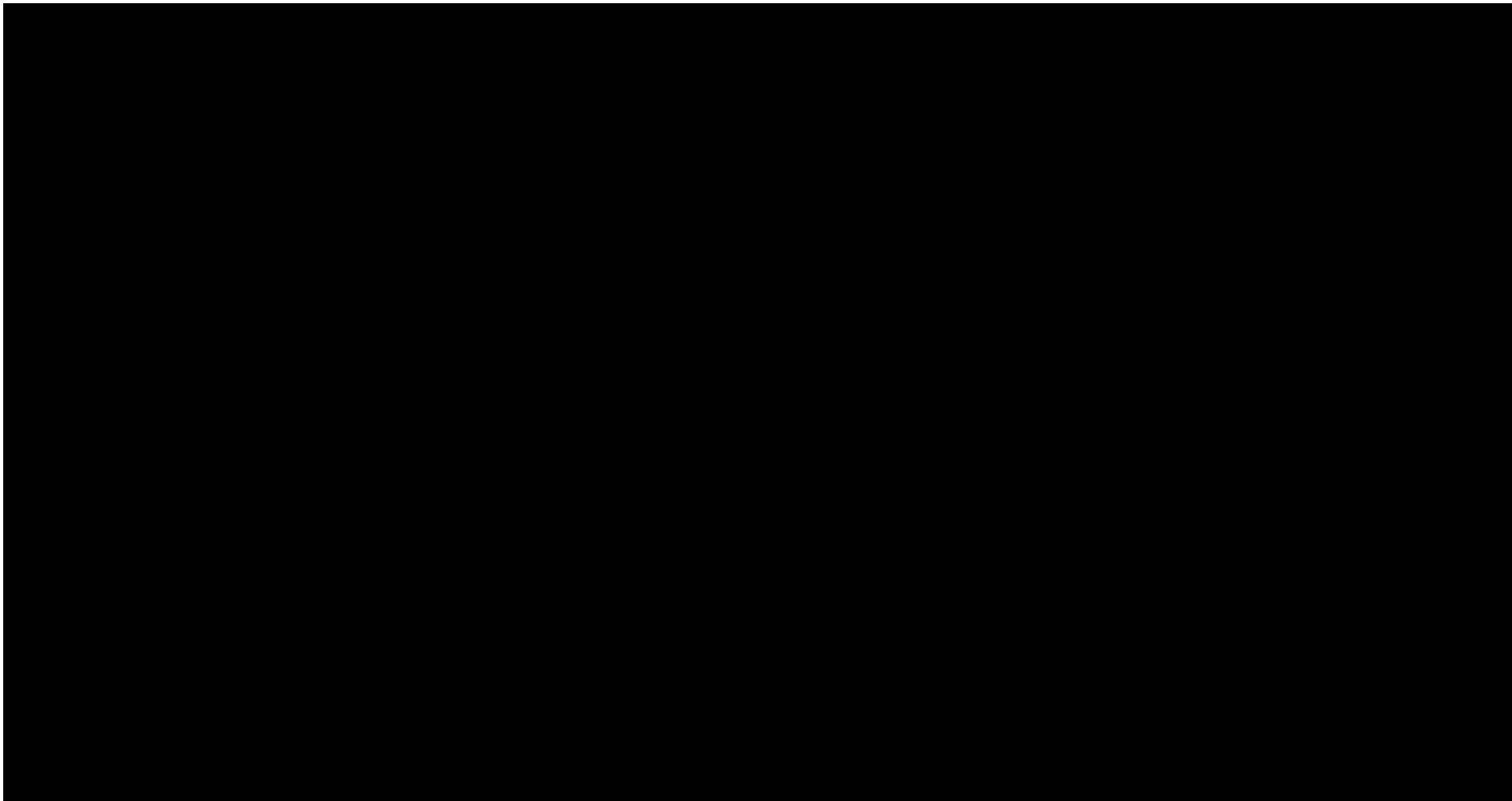
Status:
Page:

Final
Page 901 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

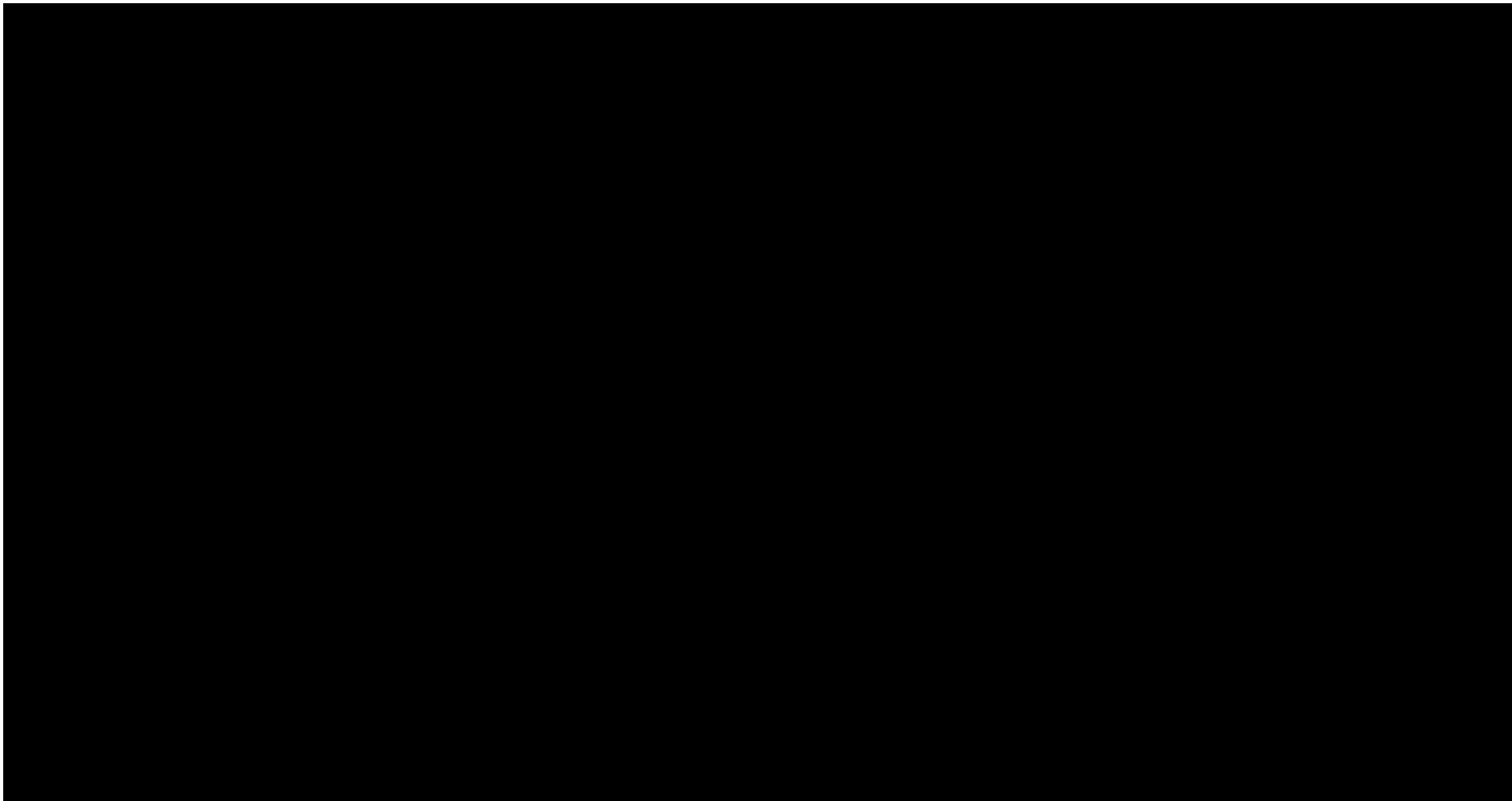
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 902 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

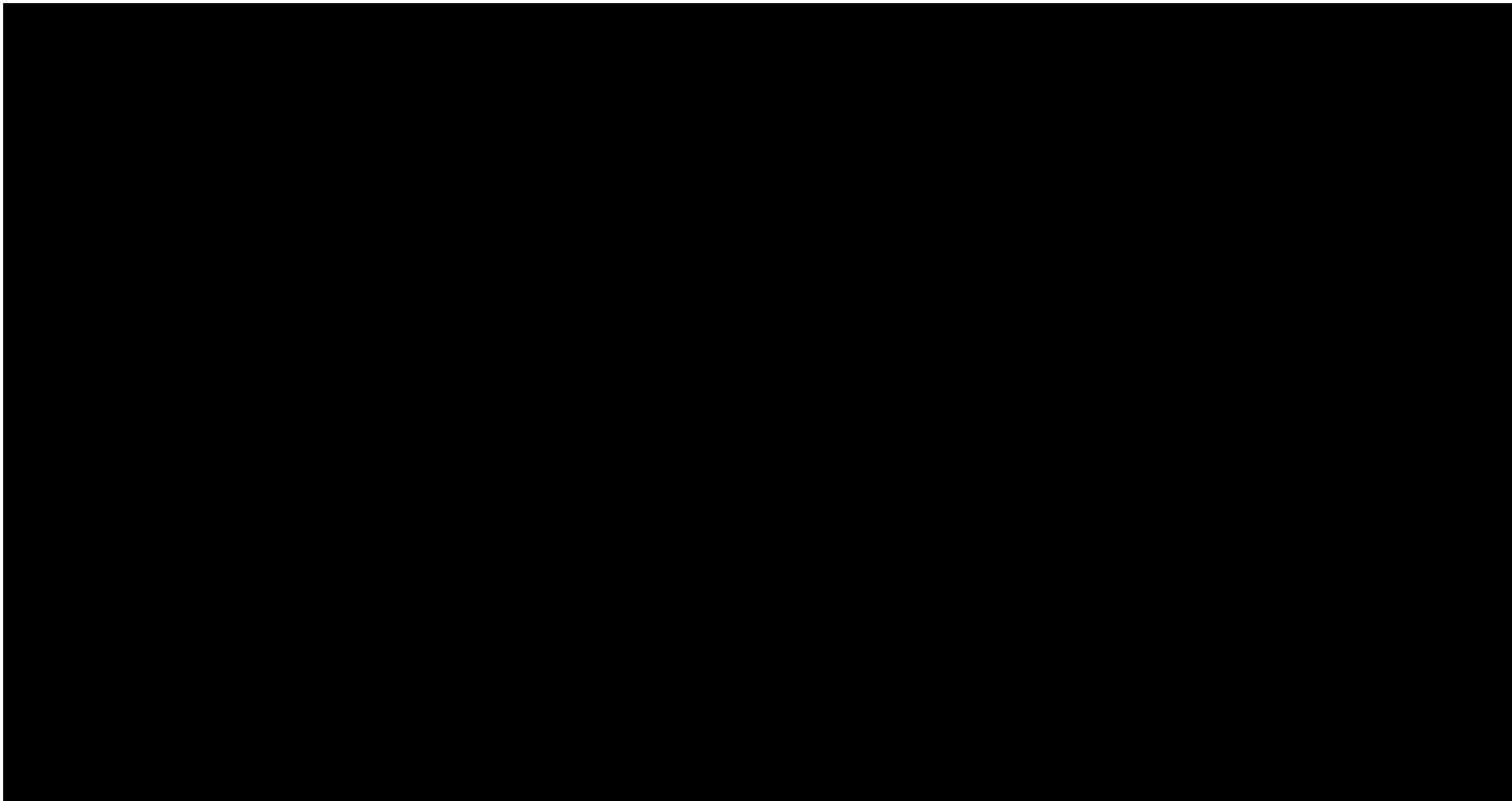
Status:
Page:

Final
Page 903 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

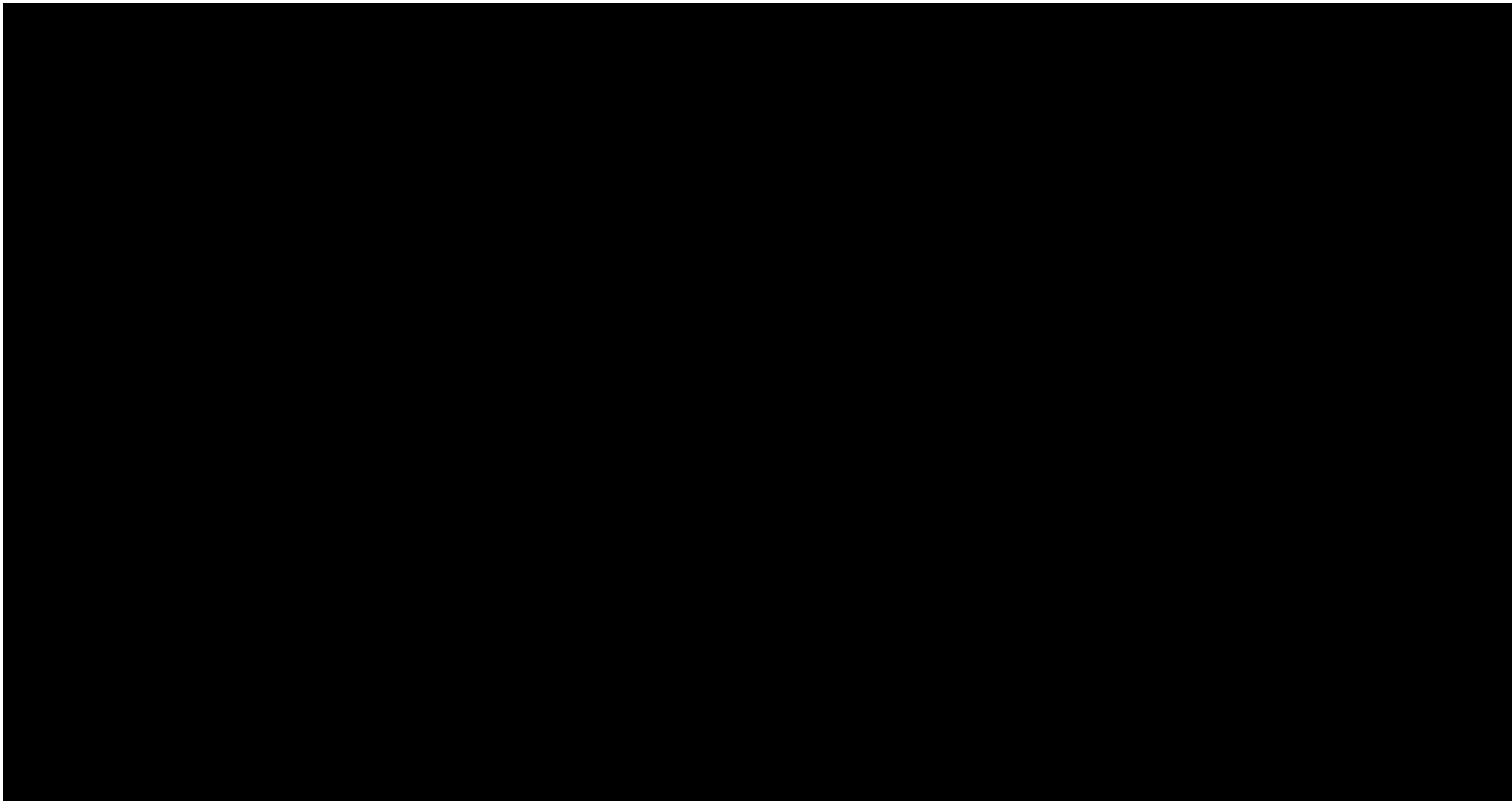
Status:
Page:

Final
Page 904 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

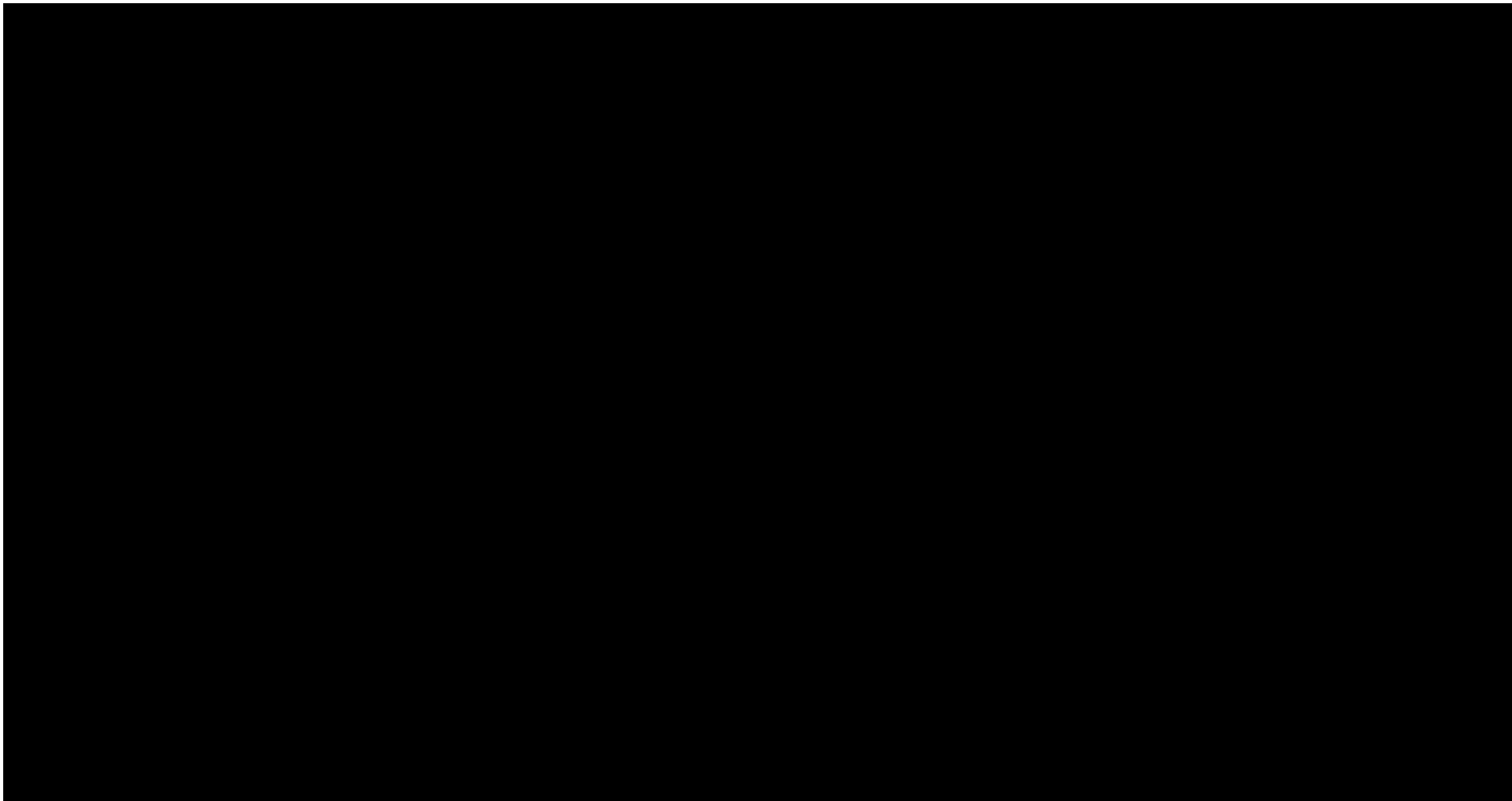
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 905 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

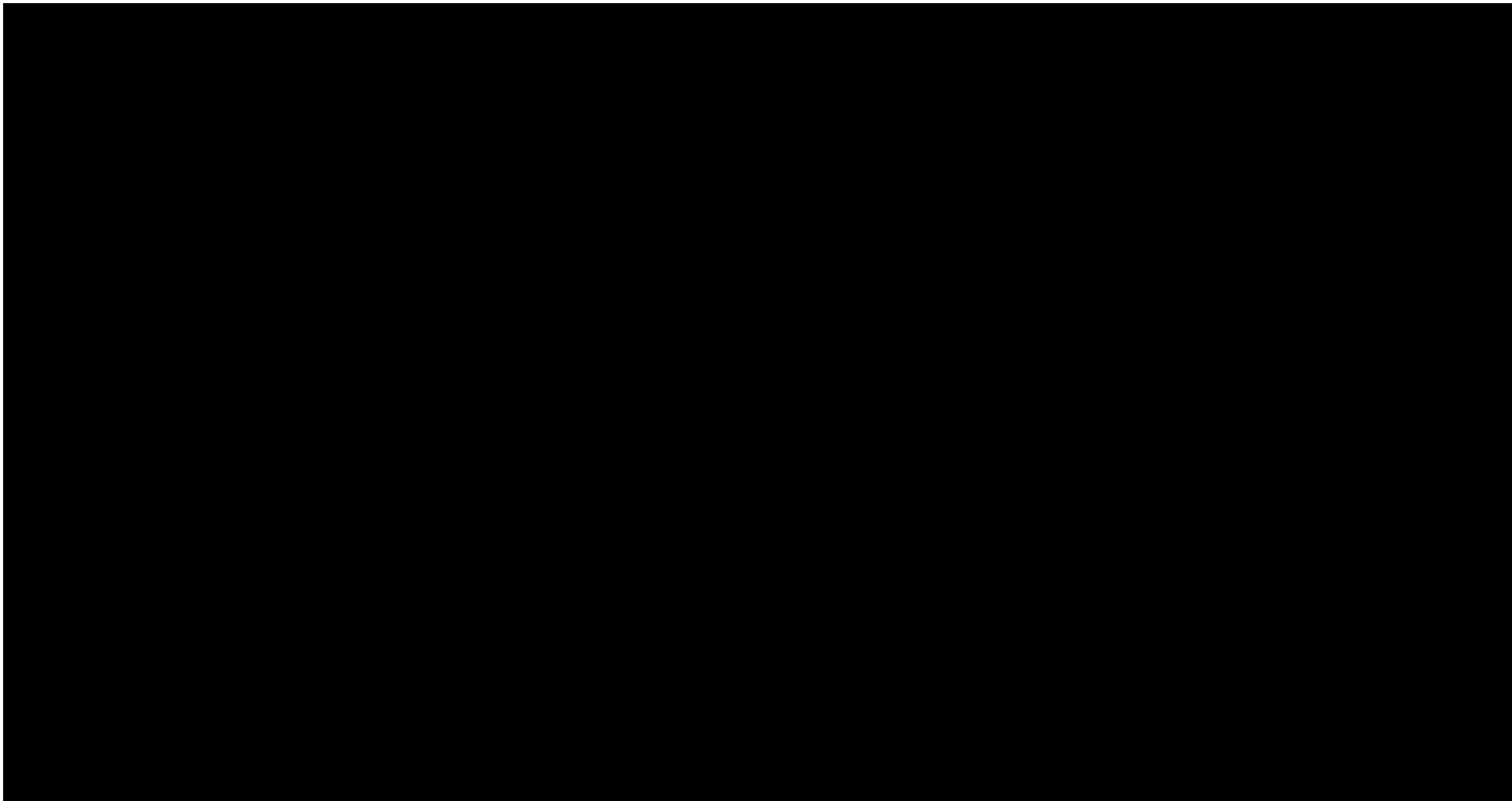
Status:
Page:

Final
Page 906 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

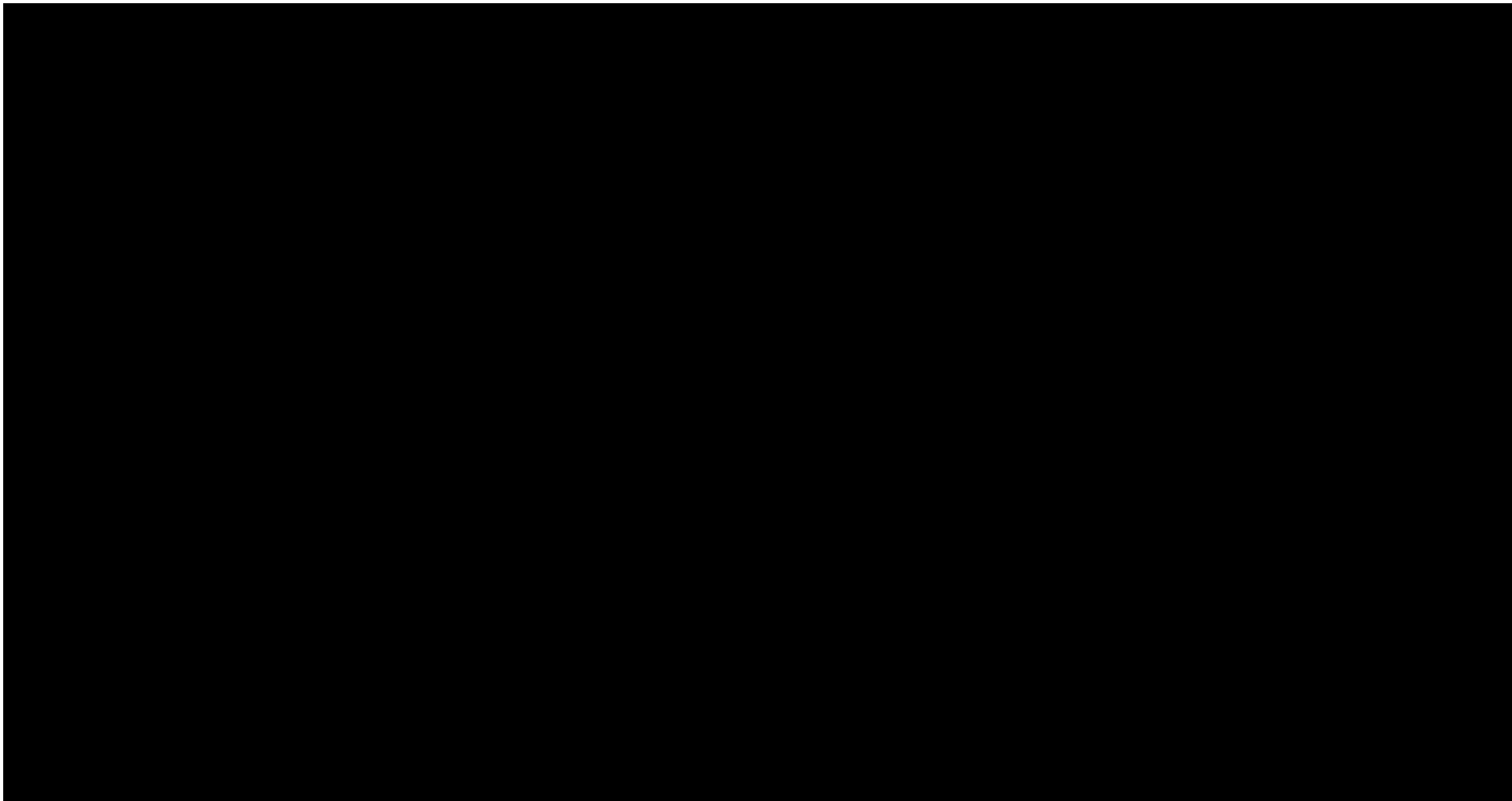
Status:
Page:

Final
Page 907 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

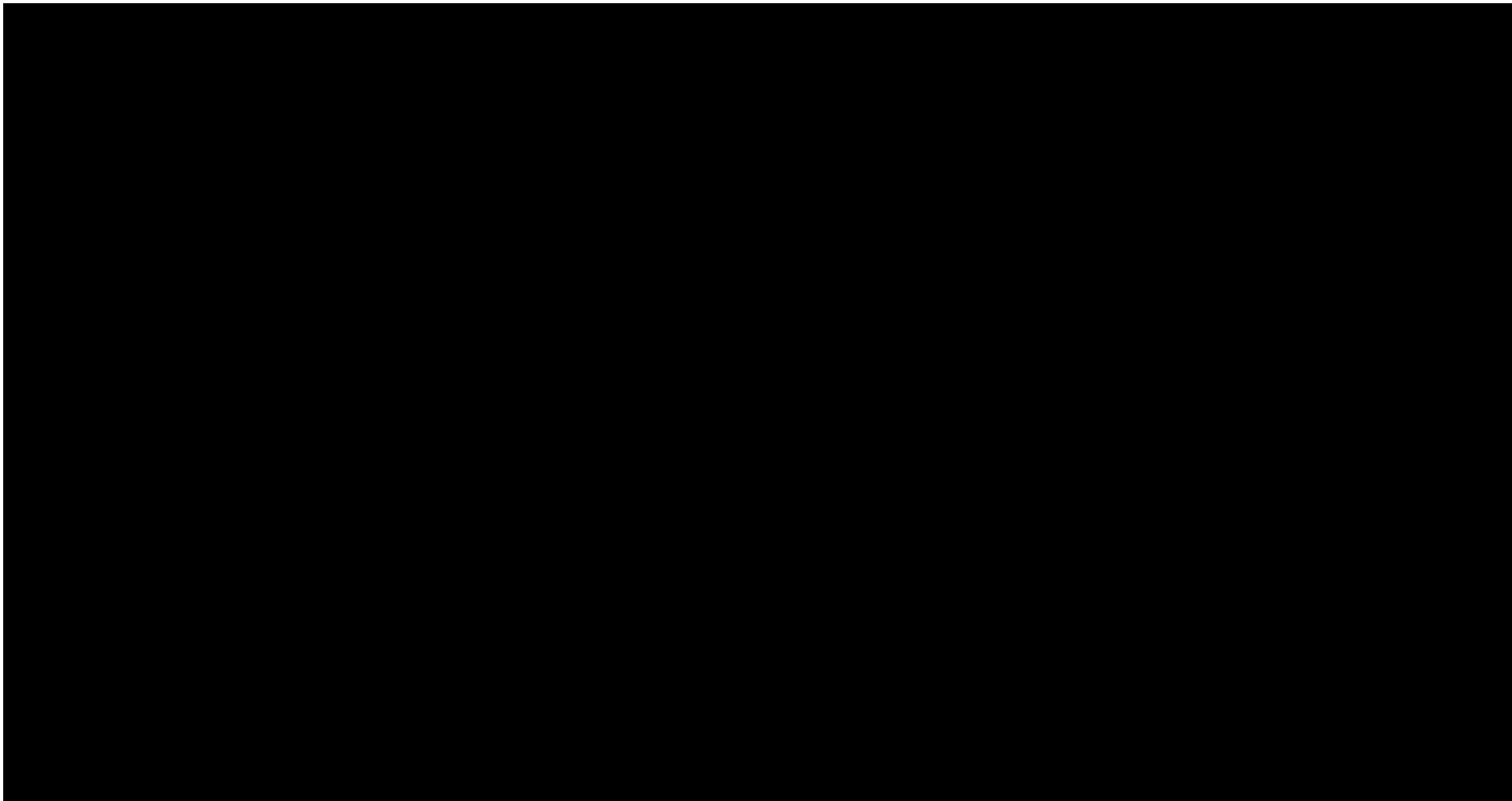
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 908 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

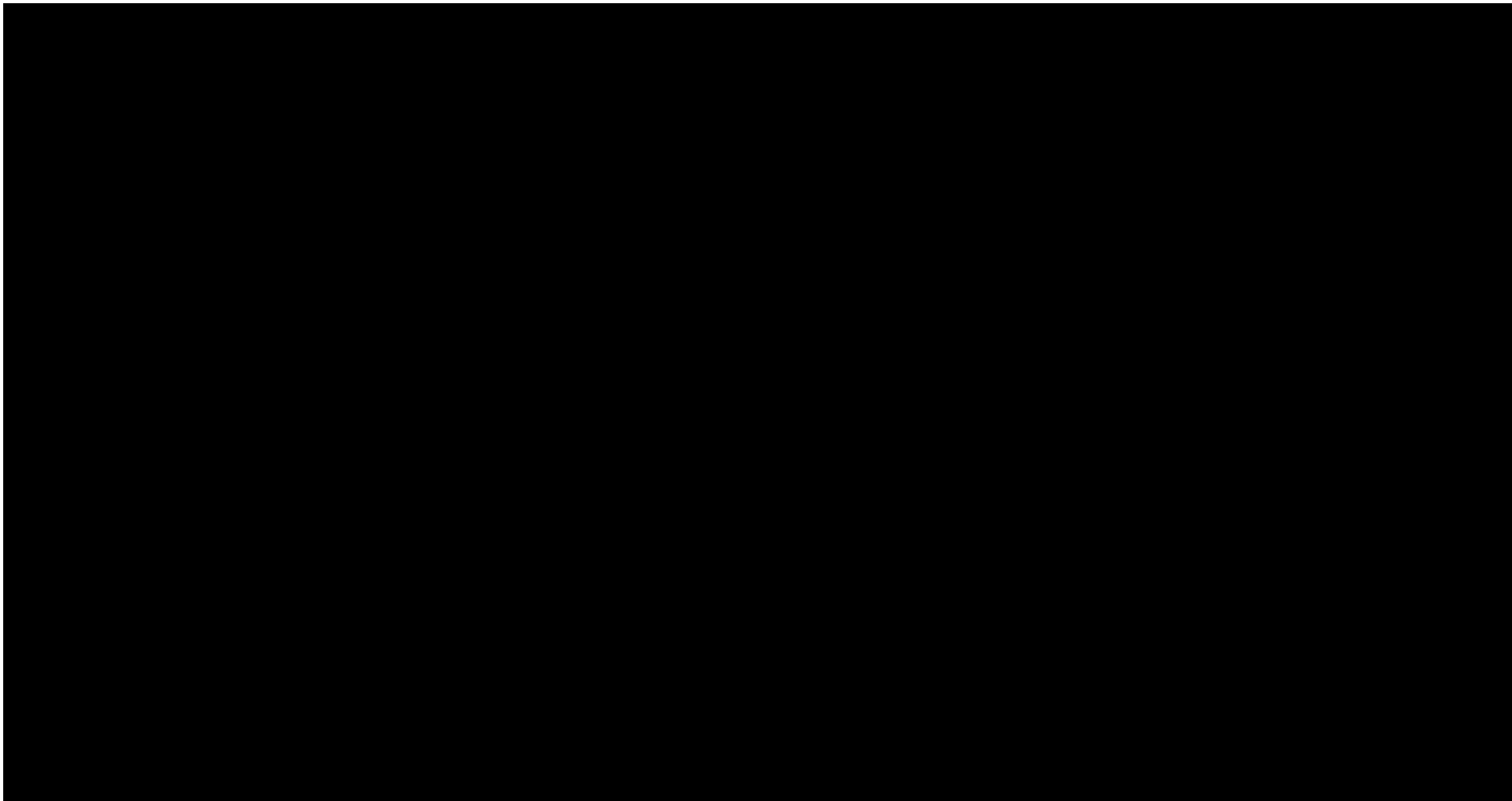
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 909 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

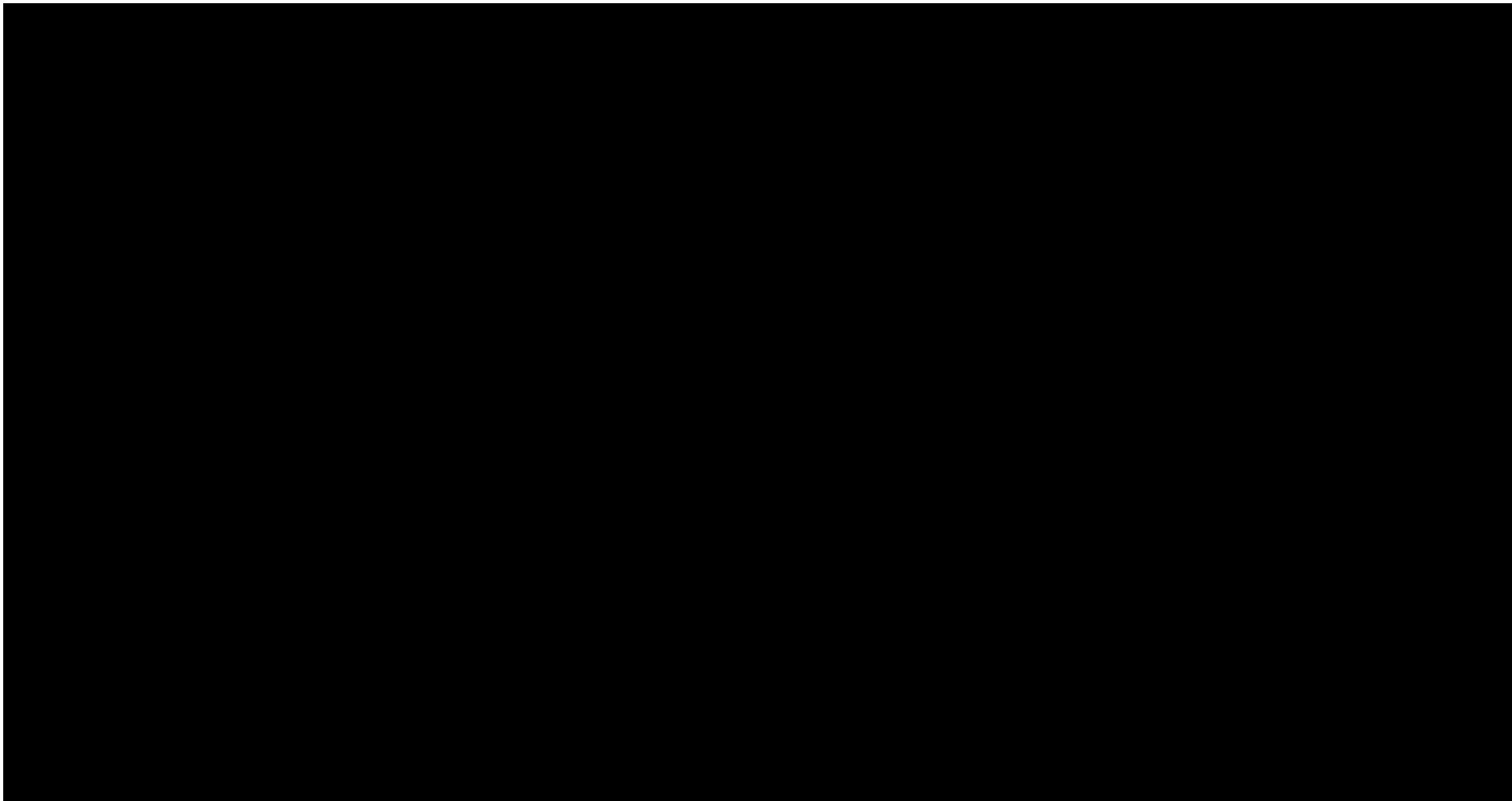
Status:
Page:

Final
Page 910 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 911 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

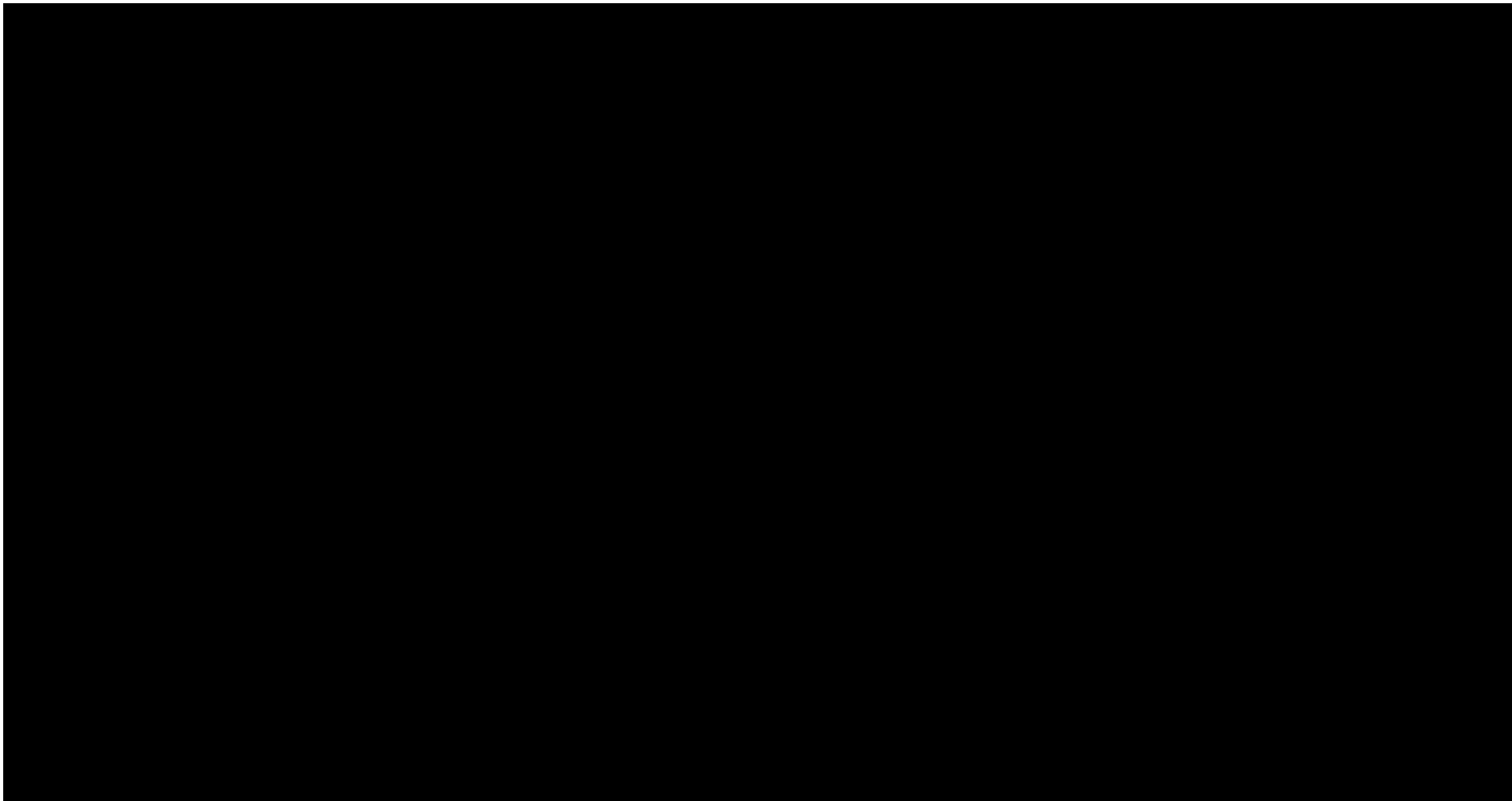
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 912 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

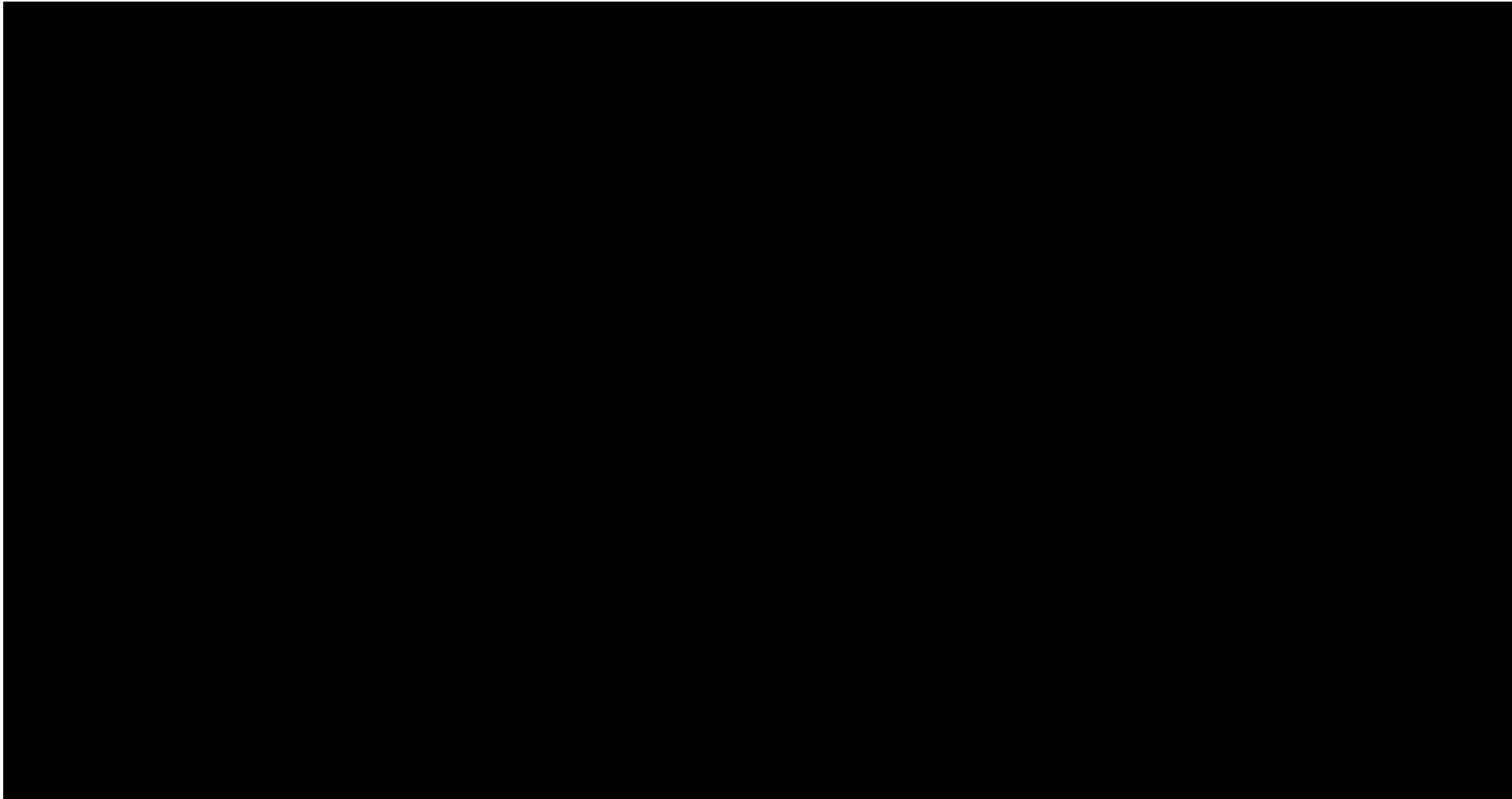
Status:
Page:

Final
Page 913 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

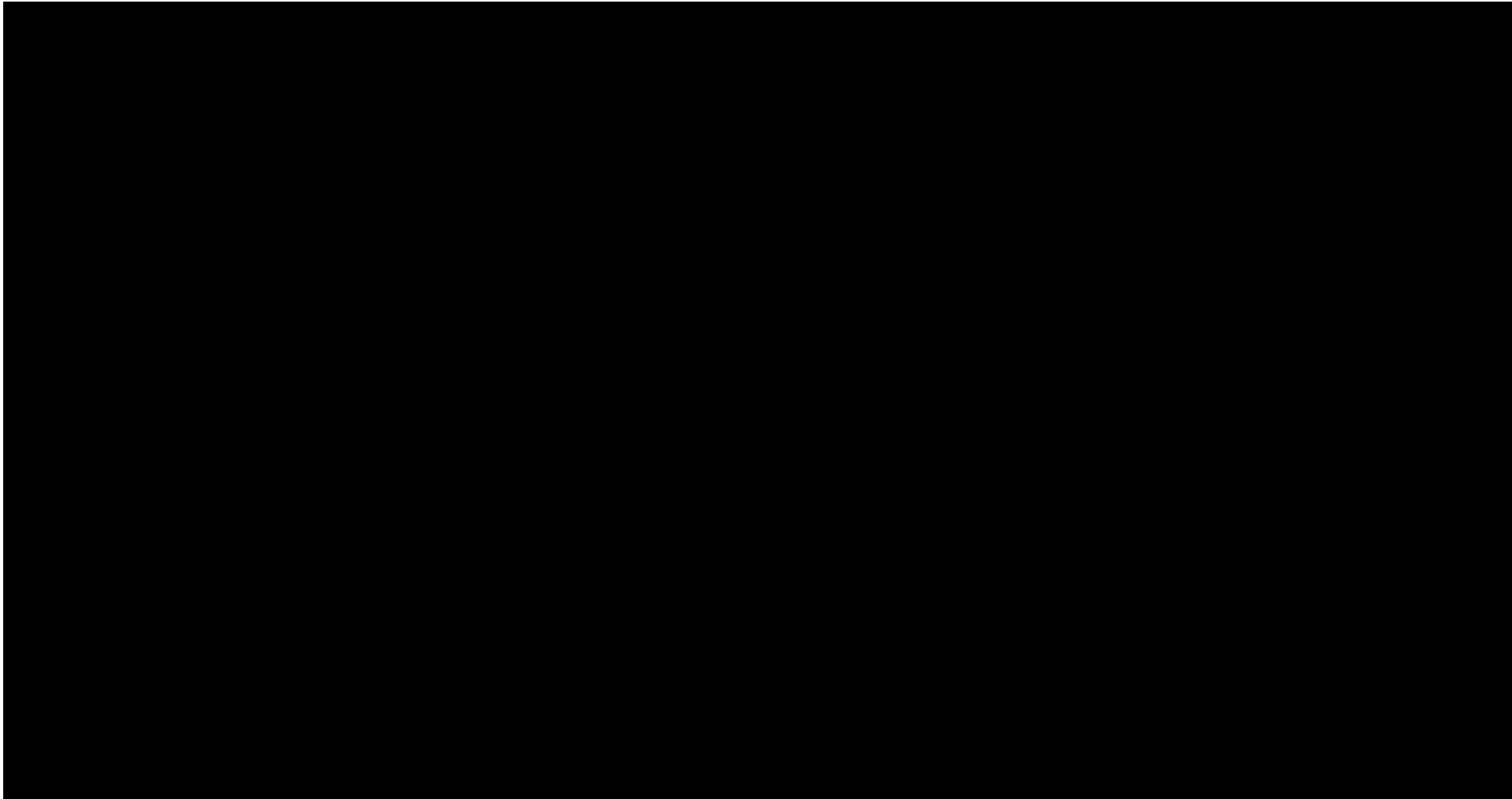
Status:
Page:

Final
Page 914 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

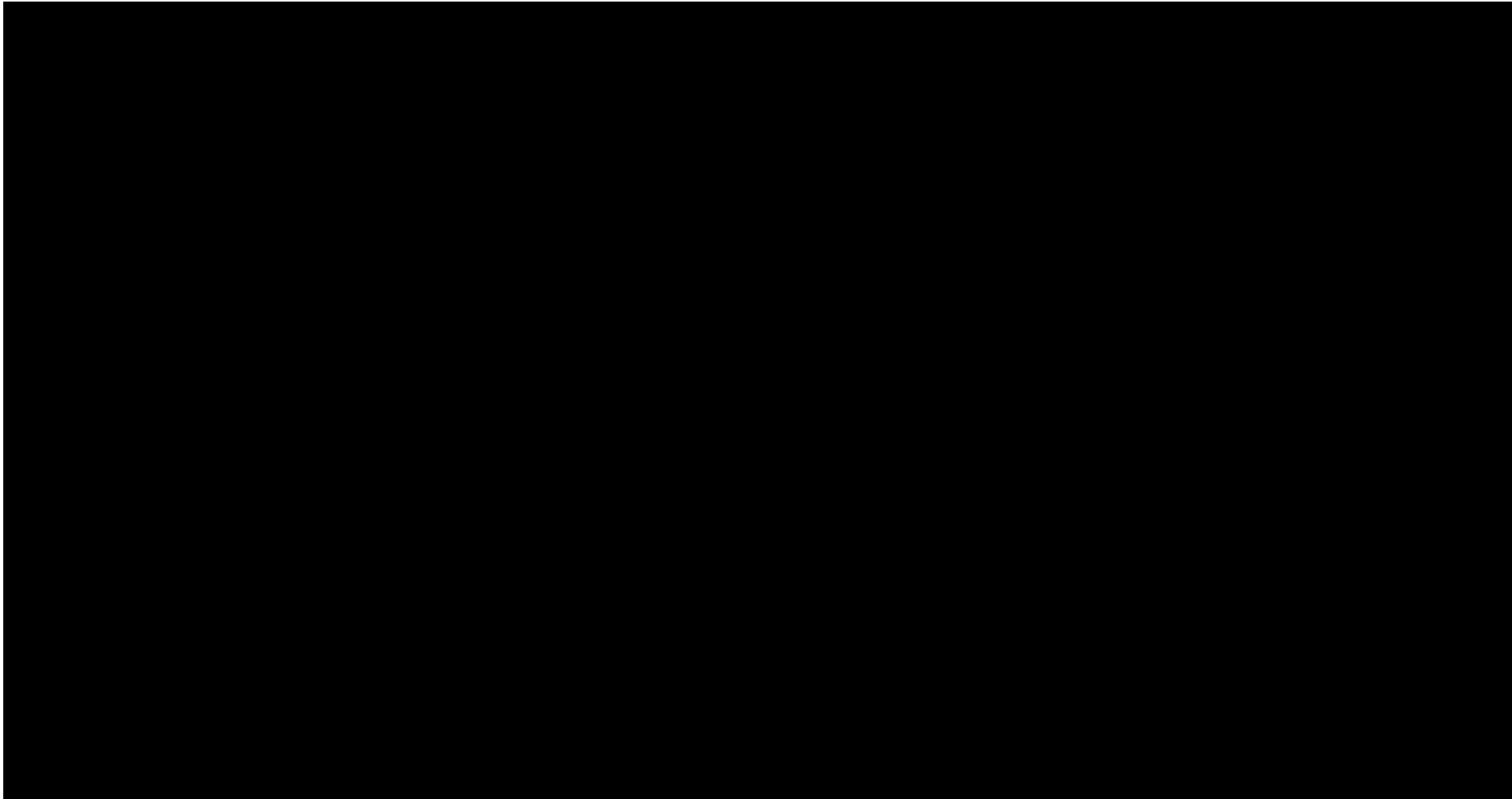
Status:
Page:

Final
Page 915 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

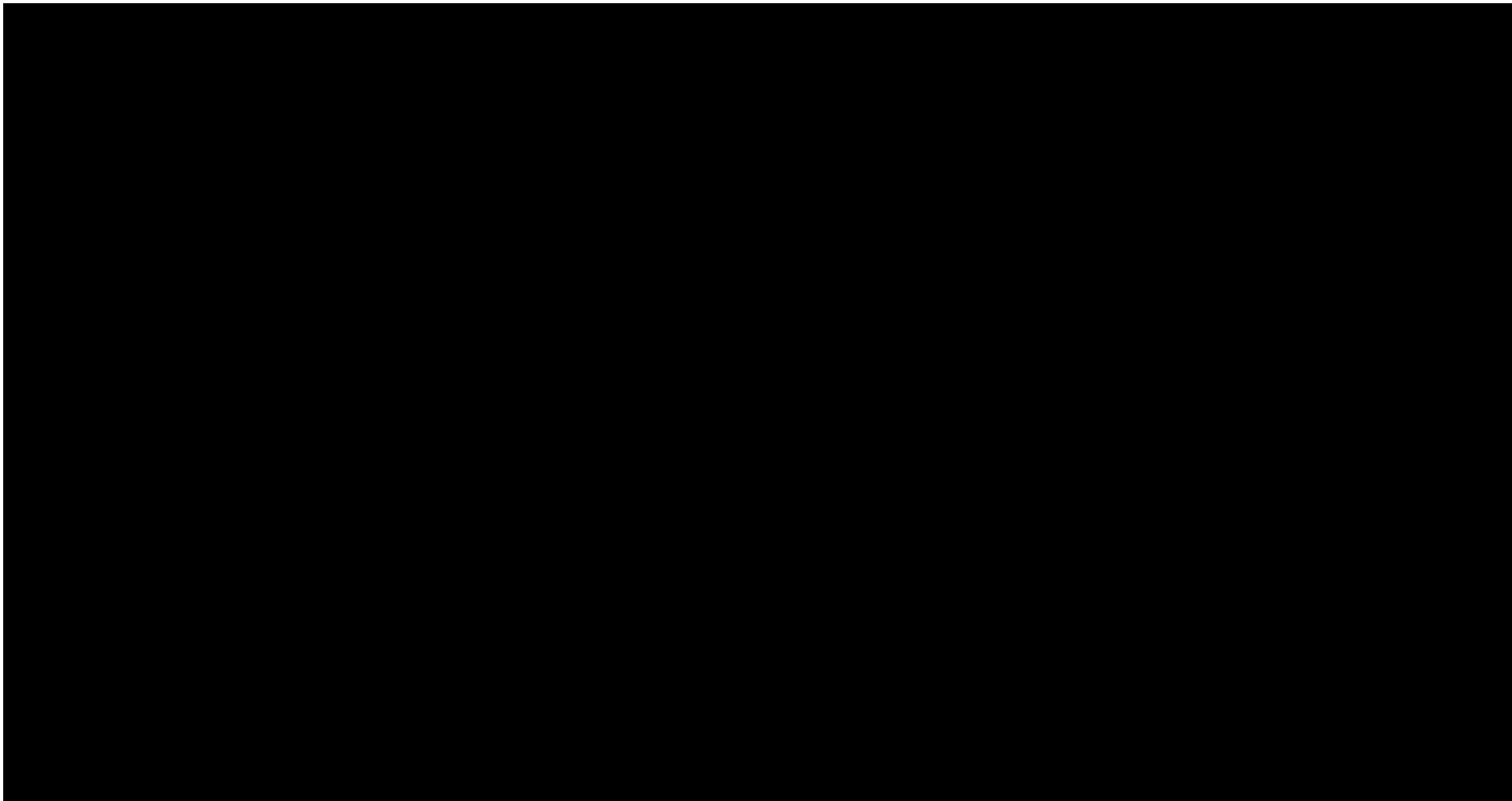
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 916 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date: 03 June 2011
Version: 1.0

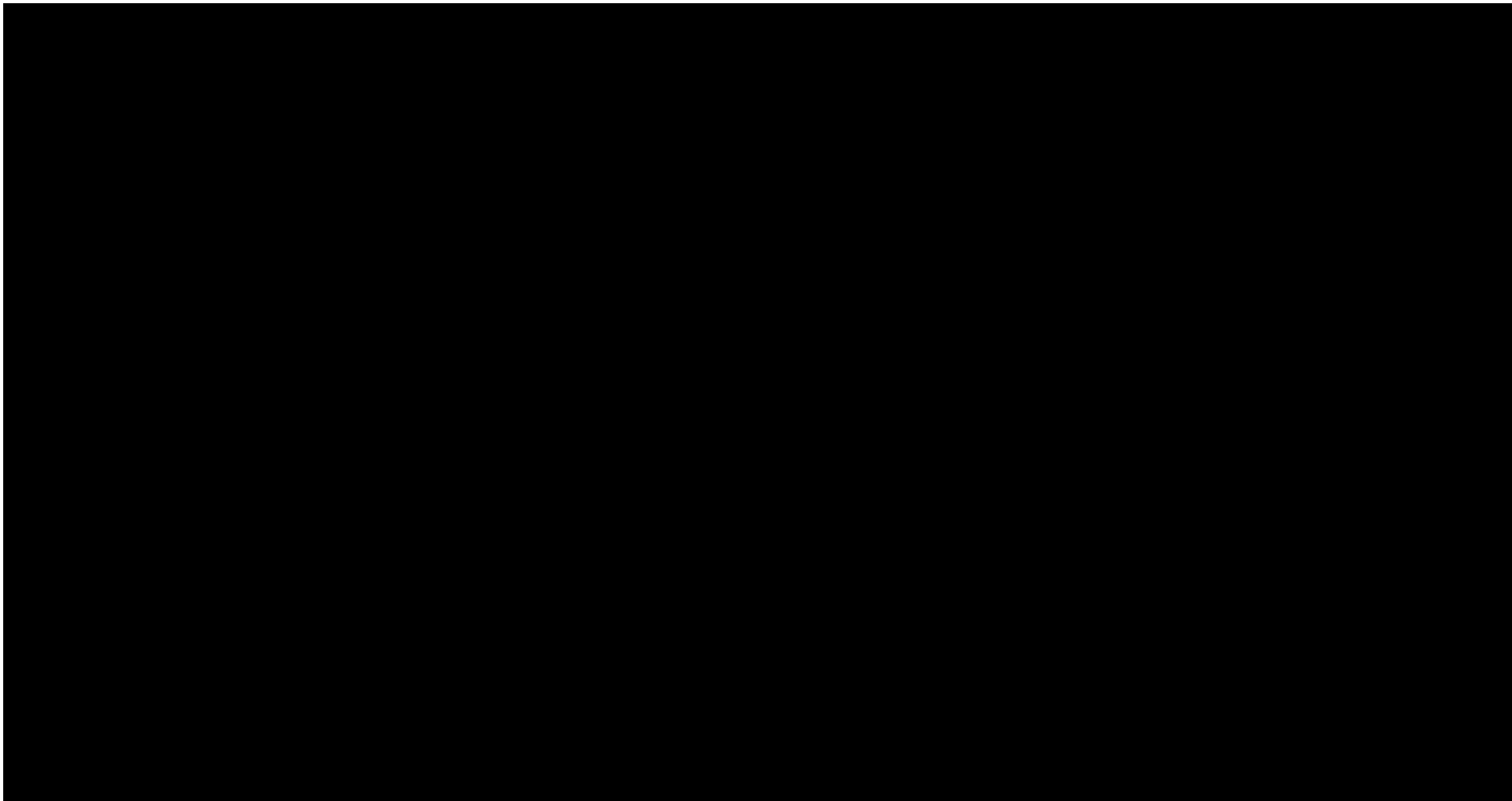
Status:
Page:

Final
Page 917 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

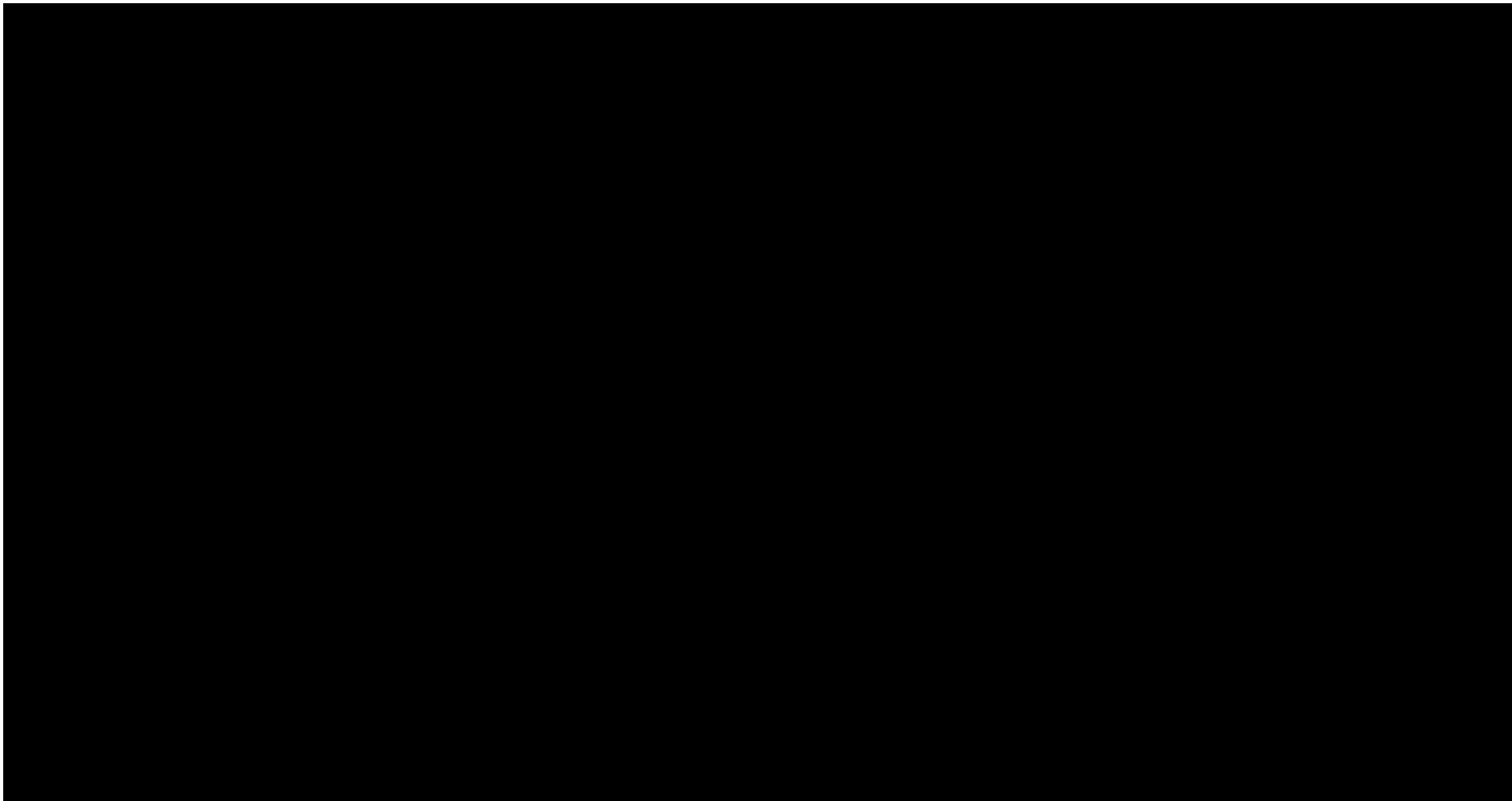
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 918 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

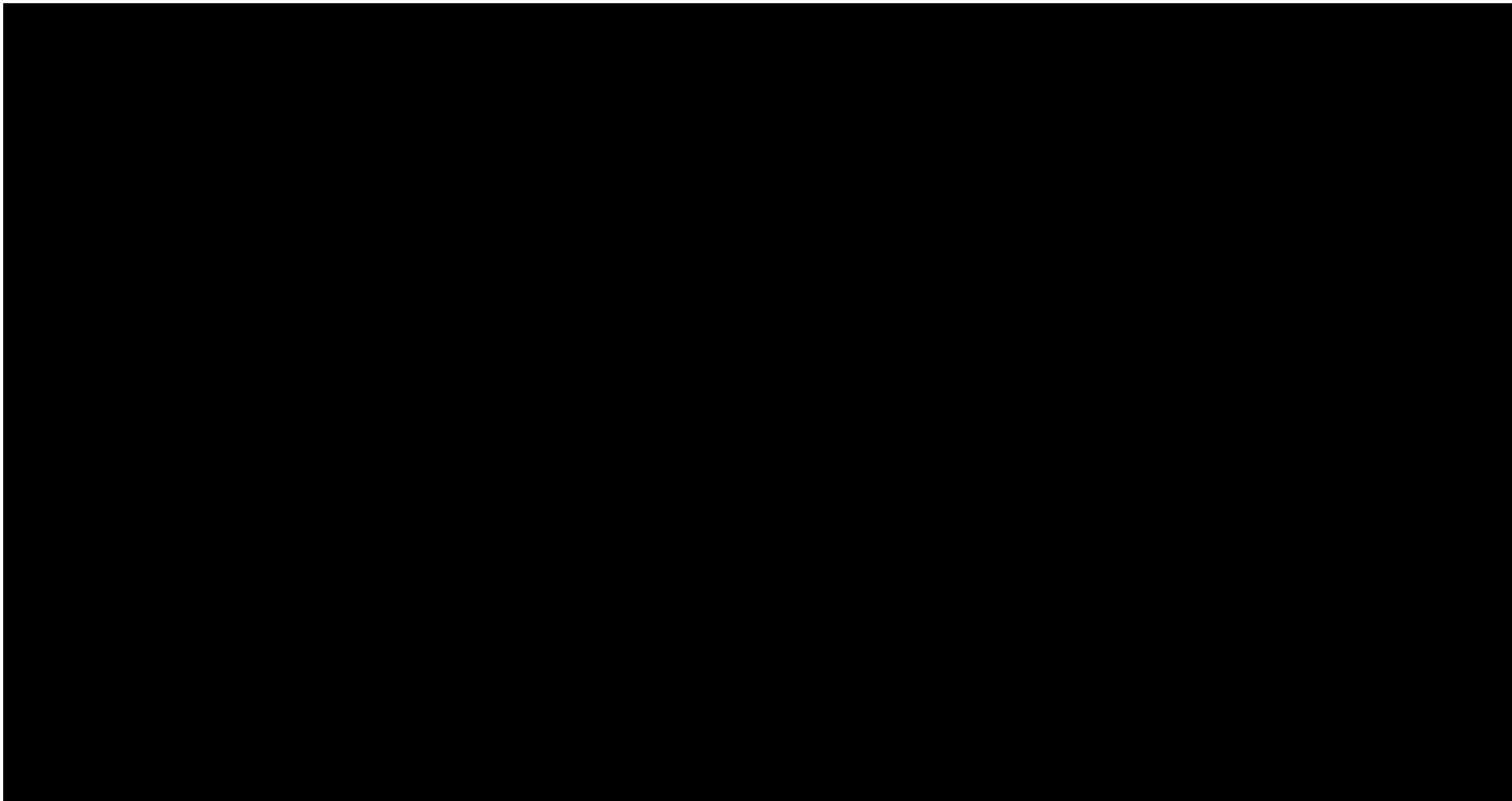
Date: 03 June 2011
Version: 1.0

Status: Final
Page: Page 919 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

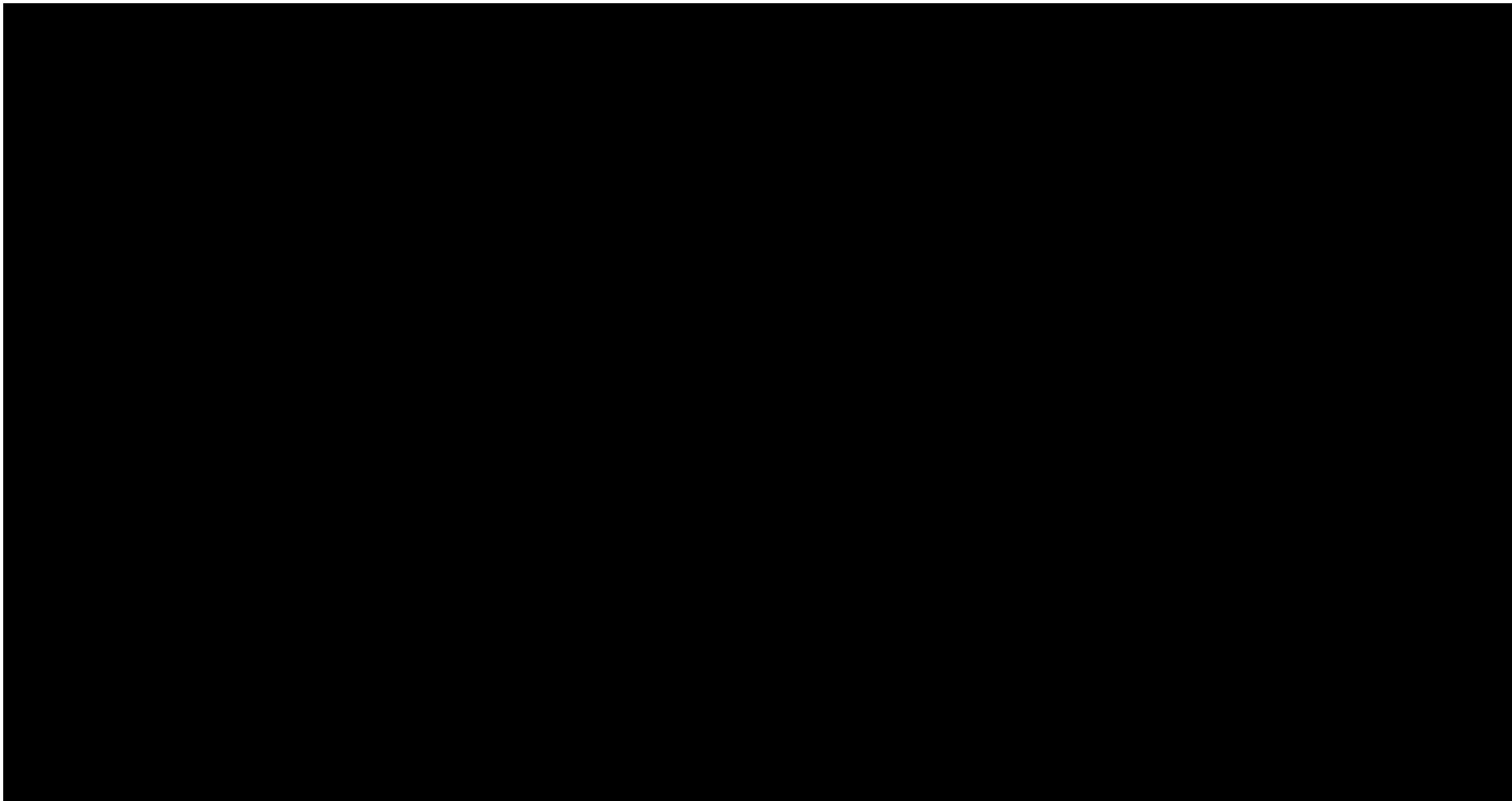
Status:
Page:

Final
Page 920 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

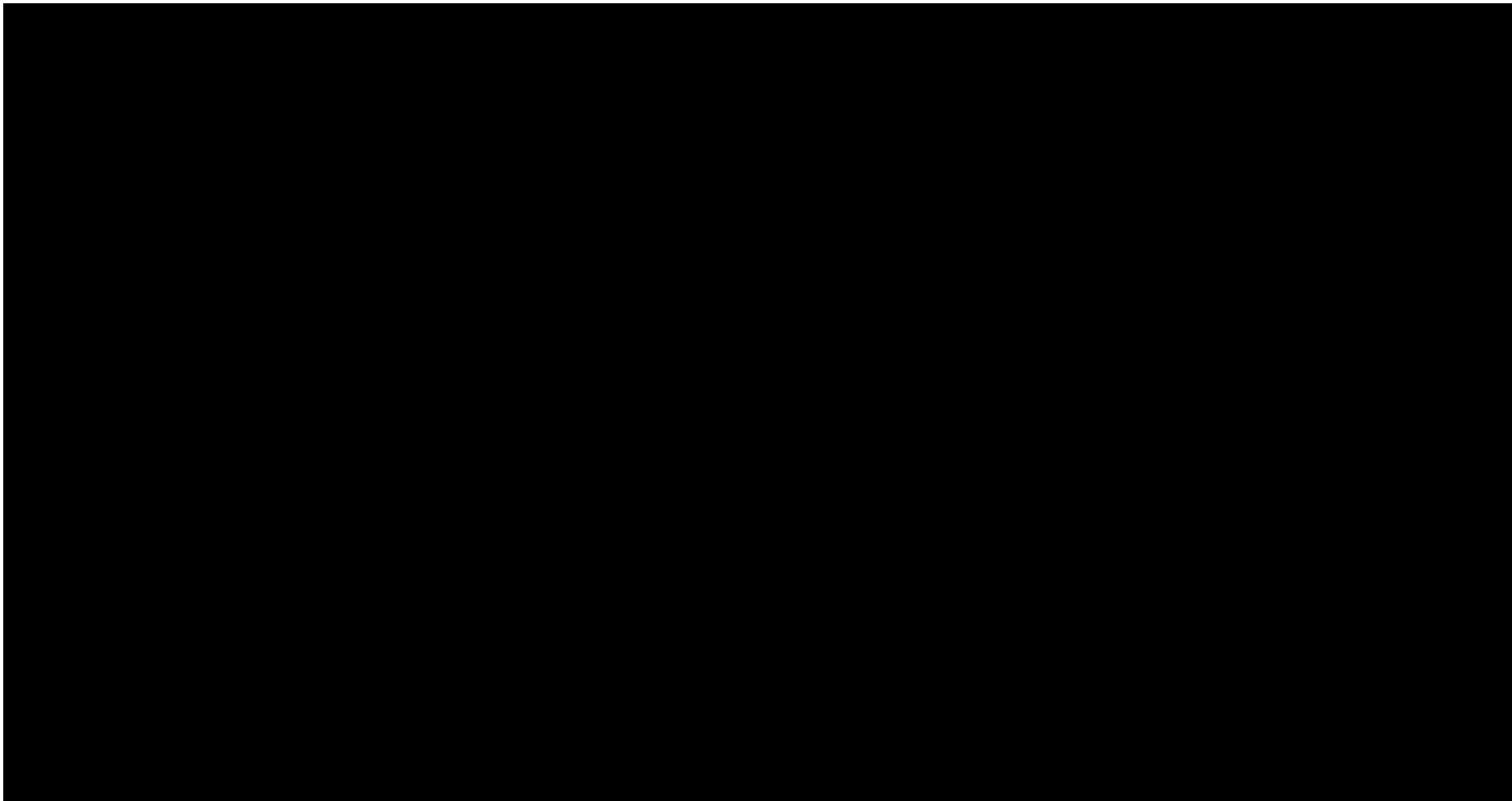
Status:
Page:

Final
Page 921 of 2239

Novo Nordisk

Haematology Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



14.3.4.3: Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

[illegible]

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

[illegible]

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color.

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color.

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

The image is entirely black and contains no visible content.

[illegible]

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------

</									

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

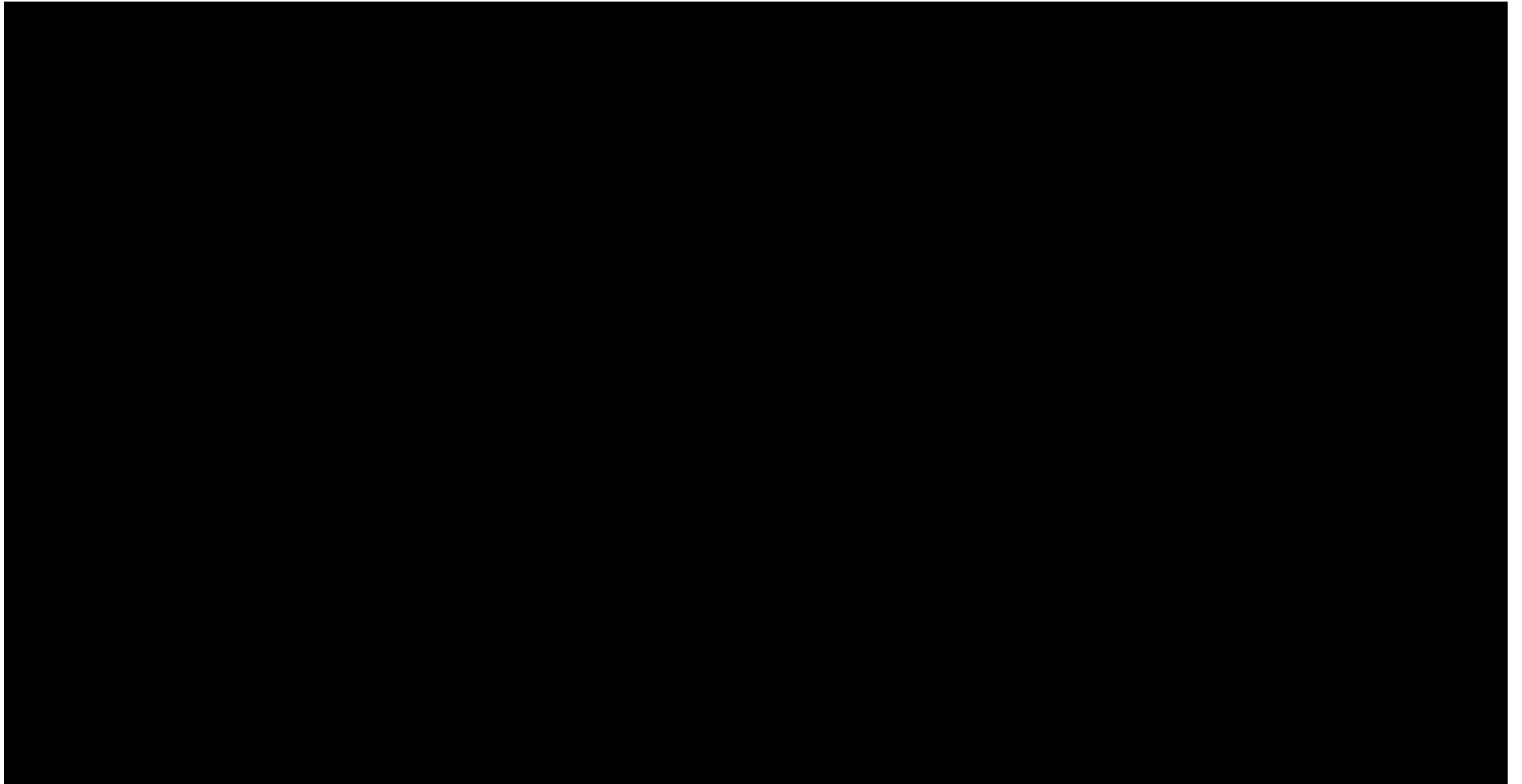
Status:
Page:

Final
Page 968 of 2239

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



[illegible]

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

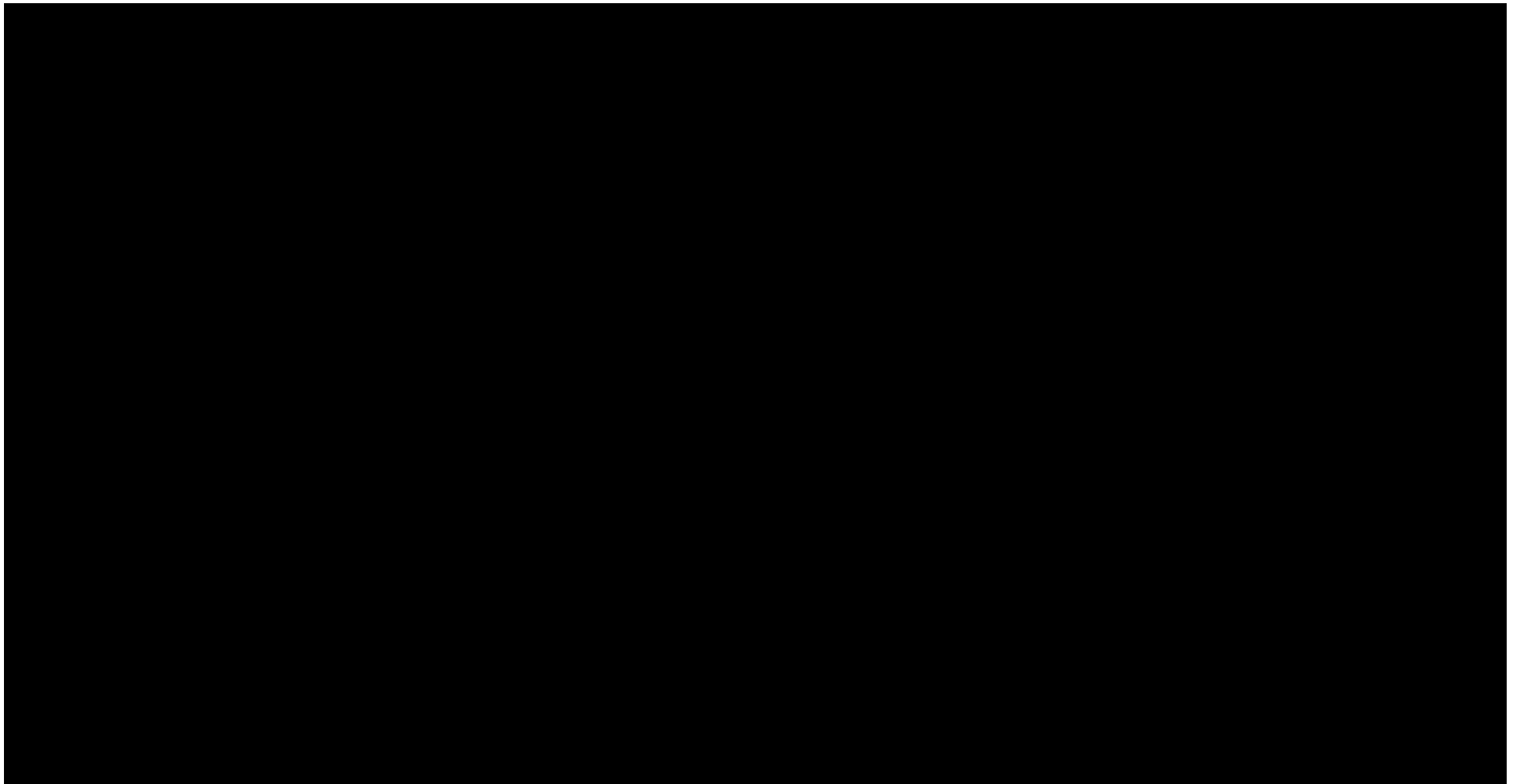
Status:
Page:

Final
Page 970 of 2239

Novo Nordisk

Lipids Laboratory Test Results Outside Reference Range - Safety Analysis Set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
------------	-----------	-------------	-------	-----------	-------	------	------	---------------	---------------



Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

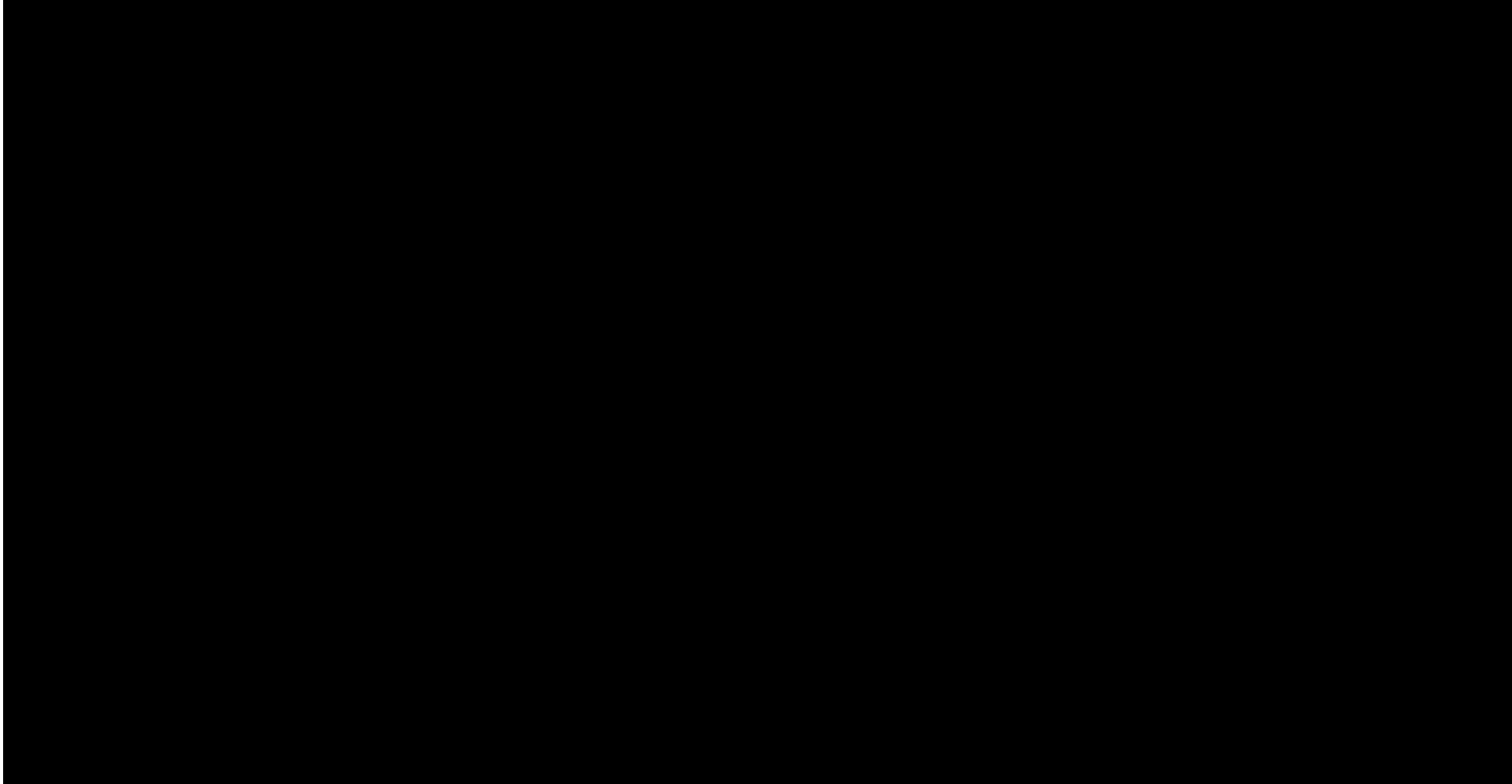
Status:
Page:

Final
Page 972 of 2239

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------

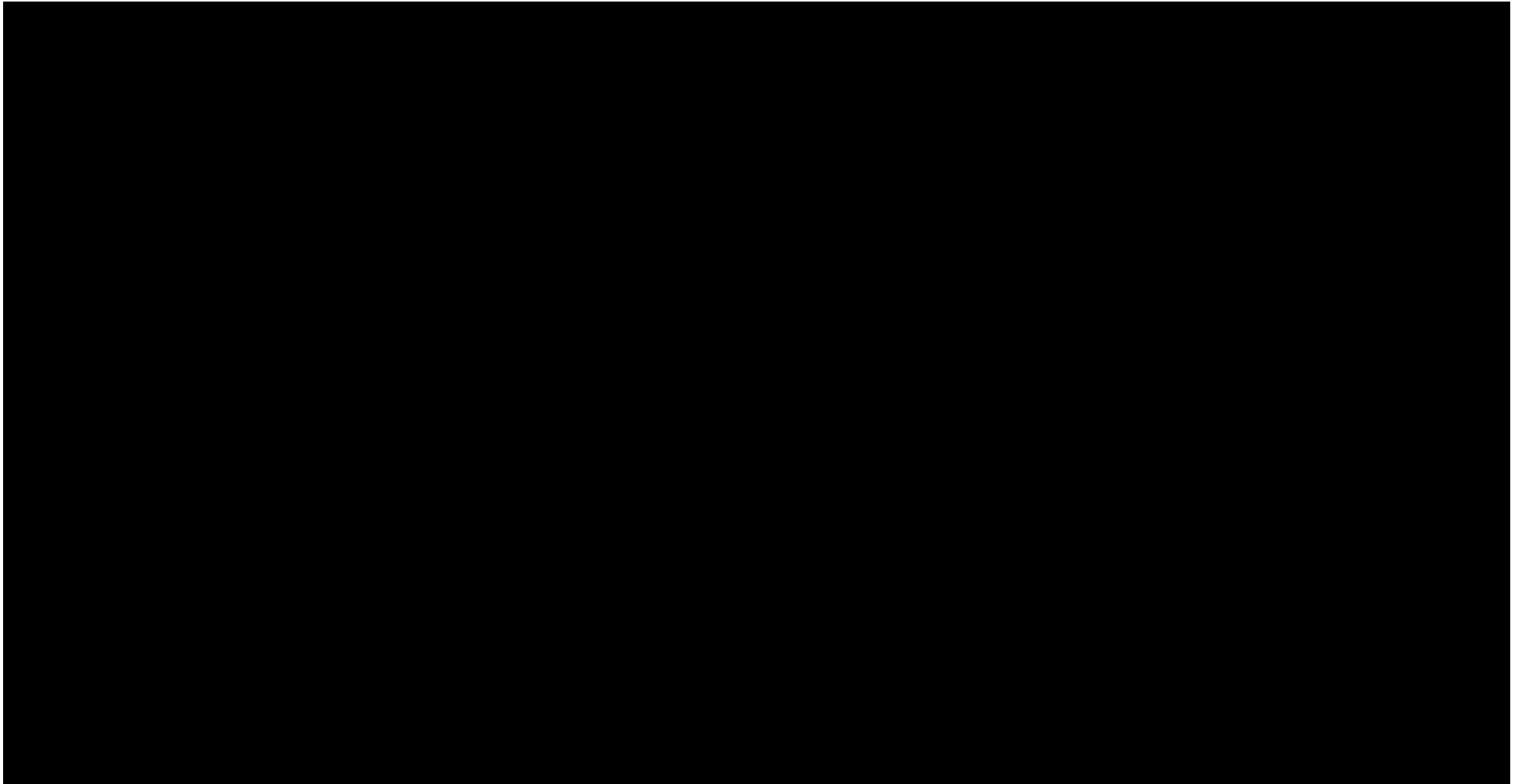


Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

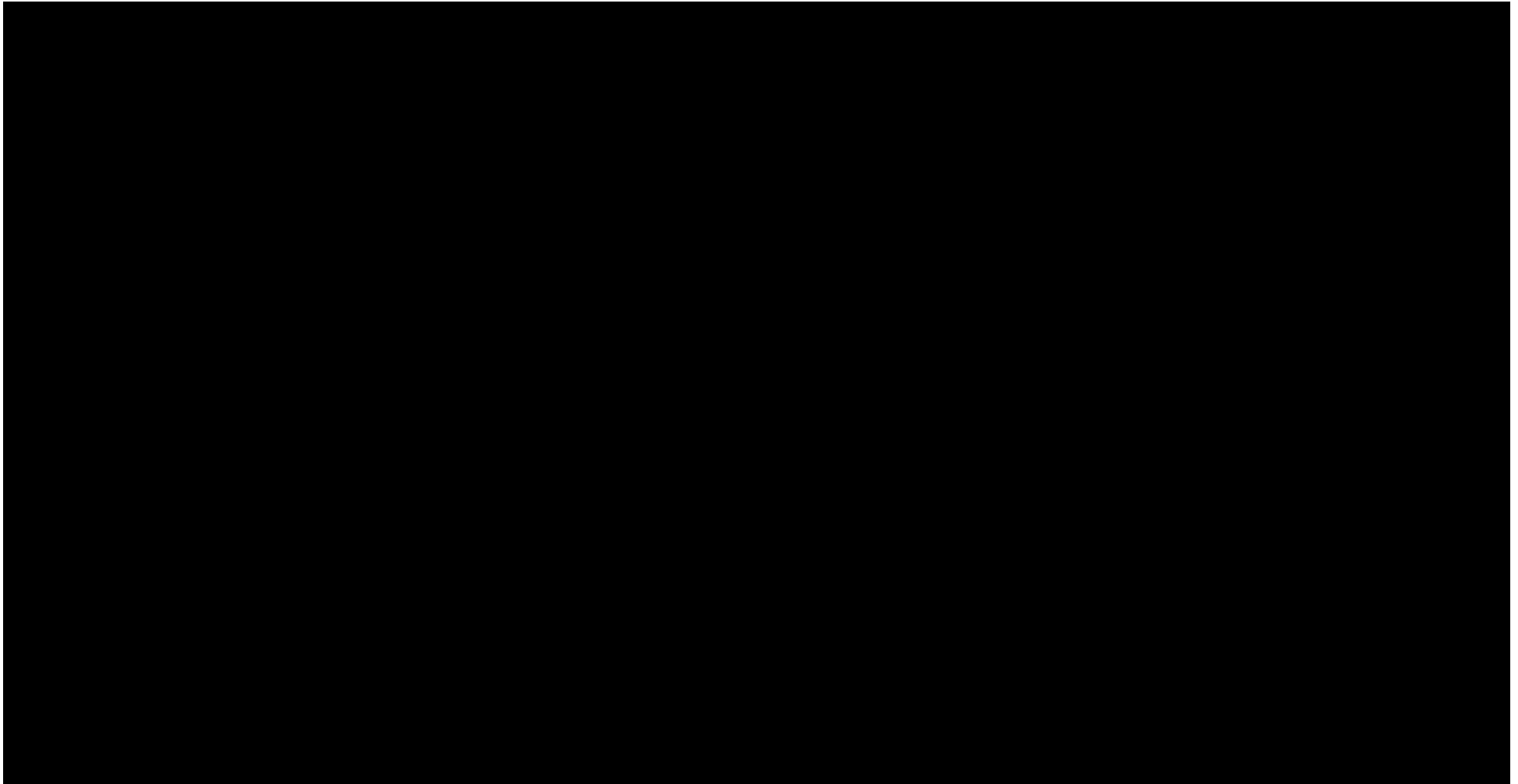
Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------

The image is entirely black and contains no visible content.

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



[illegible]

The image is a uniform, featureless black rectangle. There are no discernible objects, patterns, or textures present.

The image is entirely black and contains no visible content.

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------

The image is entirely black and contains no visible content.

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

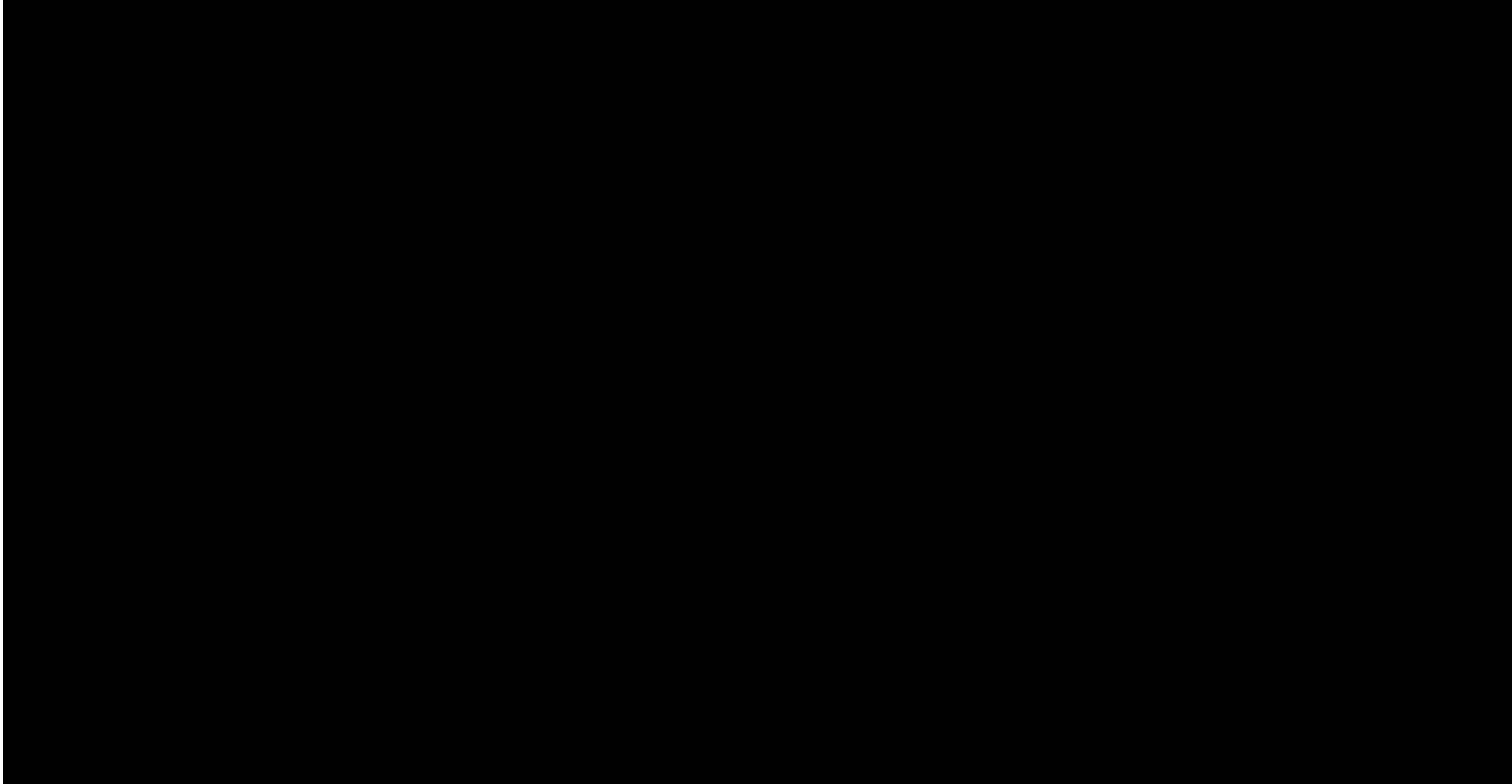
Status:
Page:

Final
Page 985 of 2239

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
---------------	-----------	-----	-----	-----	-------	-----------	-------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

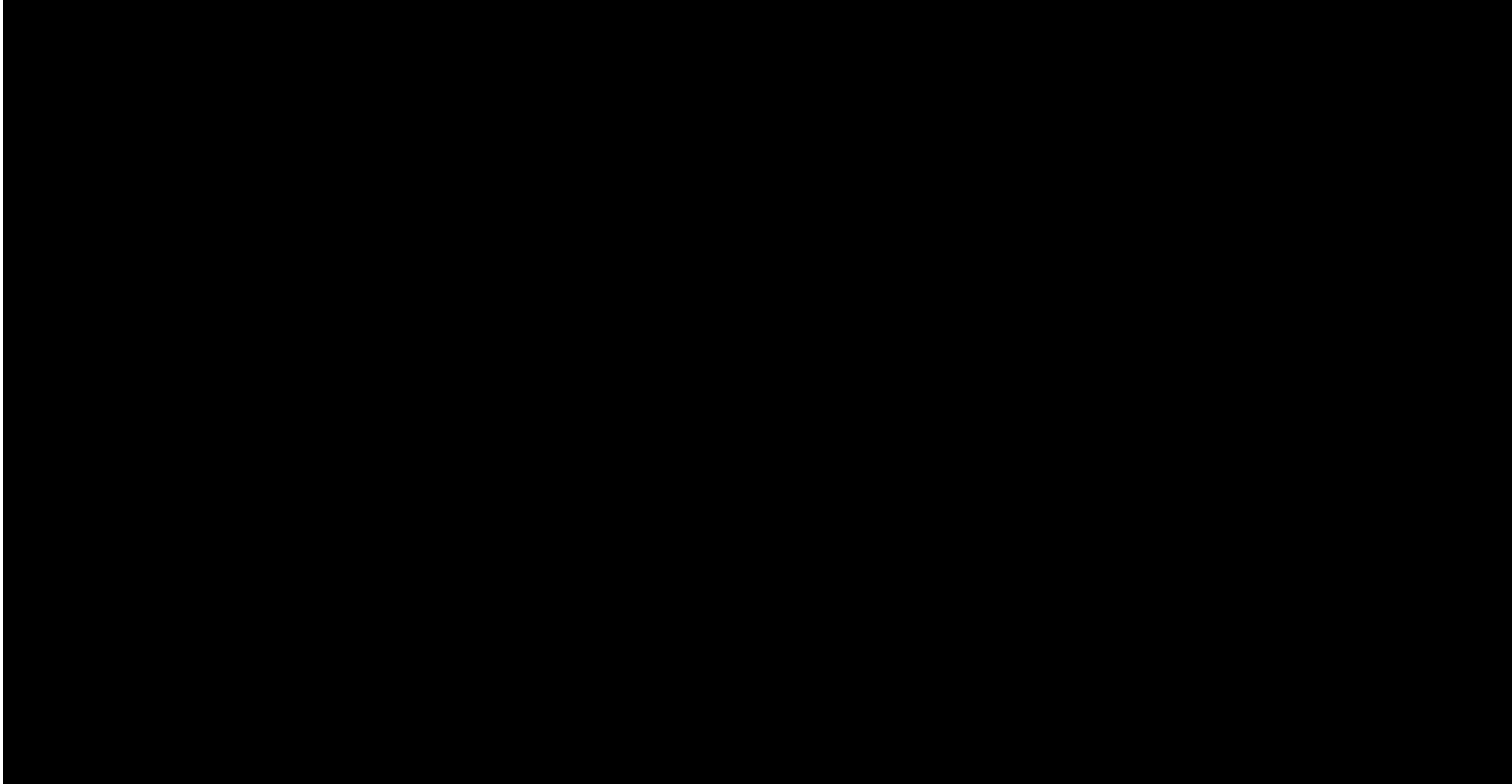
Status:
Page:

Final
Page 986 of 2239

Novo Nordisk

Urinalysis With Positive Test Results - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Visit	Parameter	Value
------------	-----------	-----	-----	-----	-------	-----------	-------



The image is entirely black and contains no visible content.

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

14.3.5 Displays of Laboratory Values

14.3.5.1: Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Albumin serum(g/dL)			
Visit 1			
N	362	180	542
Mean (SD)	4.4 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.7 ; 5.3	3.7 ; 5.1	3.7 ; 5.3
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	4.4 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.5 ; 5.2	3.6 ; 5.0	3.5 ; 5.2
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	4.5 (0.3)	4.7	4.5 (0.2)
Median	4.5	4.7	4.6
Min ; Max	4.2 ; 4.7	4.7 ; 4.7	4.2 ; 4.7
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	4.4 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.6 ; 5.3	3.8 ; 5.2	3.6 ; 5.3
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	4.4 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.5 ; 5.3	3.6 ; 5.2	3.5 ; 5.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:06 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Alanine aminotransferase serum(U/L)			
Visit 1			
N	362	180	542
Mean (SD)	23 (14)	23 (13)	23 (13)
Median	19	19	19
Min ; Max	5 ; 117	6 ; 92	5 ; 117
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	23 (15)	23 (12)	23 (14)
Median	18	20	19
Min ; Max	6 ; 134	6 ; 74	6 ; 134
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	32 (18)	11	27 (18)
Median	30	11	23
Min ; Max	15 ; 51	11 ; 11	11 ; 51
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	23 (13)	24 (13)	23 (13)
Median	20	22	21
Min ; Max	7 ; 85	6 ; 114	6 ; 114
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	23 (14)	24 (20)	24 (16)
Median	19	20	20
Min ; Max	7 ; 108	6 ; 234	6 ; 234

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:06 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Alkaline phosphatase serum(U/L)			
Visit 1			
N	362	180	542
Mean (SD)	78 (26)	78 (26)	78 (26)
Median	75	72	74
Min ; Max	28 ; 296	38 ; 194	28 ; 296
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	77 (26)	79 (25)	78 (25)
Median	73	75	74
Min ; Max	29 ; 231	34 ; 185	29 ; 231
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	101 (51)	65	92 (45)
Median	89	65	77
Min ; Max	57 ; 156	65 ; 65	57 ; 156
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	78 (24)	81 (51)	79 (35)
Median	74	74	74
Min ; Max	36 ; 226	37 ; 573	36 ; 573
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	77 (24)	81 (43)	78 (32)
Median	73	76	74
Min ; Max	29 ; 226	33 ; 573	29 ; 573

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:06 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Creatinine serum(umol/L)			
Visit 1			
N	362	180	542
Mean (SD)	78 (16)	78 (18)	78 (17)
Median	77	76	77
Min ; Max	46 ; 176	25 ; 156	25 ; 176
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	77 (15)	77 (17)	77 (16)
Median	76	75	76
Min ; Max	34 ; 168	43 ; 130	34 ; 168
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	81 (3)	57	75 (12)
Median	82	57	80
Min ; Max	77 ; 83	57 ; 57	57 ; 83
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	77 (16)	76 (15)	77 (16)
Median	77	74	76
Min ; Max	45 ; 175	42 ; 121	42 ; 175
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	77 (16)	77 (19)	77 (17)
Median	76	74	75
Min ; Max	34 ; 175	42 ; 177	34 ; 177

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:06 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Potassium serum (mmol/L)			
Visit 1			
N	362	180	542
Mean (SD)	4.5 (0.4)	4.5 (0.4)	4.5 (0.4)
Median	4.4	4.5	4.4
Min ; Max	3.4 ; 6.0	3.5 ; 5.7	3.4 ; 6.0
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	4.5 (0.5)	4.5 (0.4)	4.5 (0.4)
Median	4.5	4.4	4.4
Min ; Max	2.9 ; 7.0	3.4 ; 6.3	2.9 ; 7.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	5.0 (1.1)	4.7	4.9 (0.9)
Median	4.4	4.7	4.6
Min ; Max	4.3 ; 6.2	4.7 ; 4.7	4.3 ; 6.2
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	4.5 (0.4)	4.5 (0.5)	4.5 (0.5)
Median	4.5	4.5	4.5
Min ; Max	3.5 ; 5.9	3.5 ; 5.9	3.5 ; 5.9
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	4.5 (0.4)	4.5 (0.5)	4.5 (0.4)
Median	4.5	4.4	4.4
Min ; Max	3.5 ; 5.9	3.4 ; 6.3	3.4 ; 6.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:06 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Aspartate aminotransferase serum(U/L)			
Visit 1			
N	362	180	542
Mean (SD)	22 (9)	22 (11)	22 (10)
Median	20	20	20
Min ; Max	10 ; 97	9 ; 113	9 ; 113
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	22 (12)	22 (9)	22 (11)
Median	19	21	19
Min ; Max	11 ; 152	9 ; 60	9 ; 152
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	31 (19)	15	27 (18)
Median	25	15	21
Min ; Max	16 ; 53	15 ; 15	15 ; 53
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	21 (8)	22 (11)	22 (9)
Median	20	20	20
Min ; Max	11 ; 73	9 ; 113	9 ; 113
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	22 (10)	22 (11)	22 (10)
Median	19	20	19
Min ; Max	11 ; 106	9 ; 113	9 ; 113

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:06 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Sodium serum (mmol/L)			
Visit 1			
N	362	180	542
Mean (SD)	140 (3)	140 (3)	140 (3)
Median	140	139	139
Min ; Max	129 ; 151	131 ; 148	129 ; 151
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	141 (3)	141 (3)	141 (3)
Median	141	141	141
Min ; Max	132 ; 156	129 ; 152	129 ; 156
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	140 (2)	141	140 (2)
Median	139	141	140
Min ; Max	138 ; 142	141 ; 141	138 ; 142
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	141 (3)	141 (3)	141 (3)
Median	141	141	141
Min ; Max	130 ; 148	130 ; 147	130 ; 148
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	141 (3)	140 (3)	141 (3)
Median	141	141	141
Min ; Max	130 ; 149	129 ; 147	129 ; 149

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:06 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Total Protein serum(g/dL)			
Visit 1			
N	362	180	542
Mean (SD)	7.1 (0.4)	7.1 (0.4)	7.1 (0.4)
Median	7.1	7.1	7.1
Min ; Max	5.9 ; 8.6	6.1 ; 8.1	5.9 ; 8.6
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	7.0 (0.4)	7.0 (0.4)	7.0 (0.4)
Median	7.0	7.0	7.0
Min ; Max	6.0 ; 9.5	6.0 ; 8.1	6.0 ; 9.5
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	6.9 (0.4)	7.7	7.1 (0.5)
Median	7.1	7.7	7.2
Min ; Max	6.5 ; 7.2	7.7 ; 7.7	6.5 ; 7.7
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	7.2 (0.4)	7.1 (0.4)	7.1 (0.4)
Median	7.2	7.1	7.1
Min ; Max	6.1 ; 8.3	6.1 ; 8.2	6.1 ; 8.3
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	7.1 (0.4)	7.1 (0.4)	7.1 (0.4)
Median	7.1	7.1	7.1
Min ; Max	6.1 ; 8.3	6.1 ; 8.2	6.1 ; 8.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:06 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

Biochemistry by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Total Bilirubin serum(umol/L)			
Visit 1			
N	362	179	541
Mean (SD)	9.0 (5.6)	7.9 (3.7)	8.7 (5.1)
Median	7.0	7.0	7.0
Min ; Max	2.0 ; 39.0	2.0 ; 29.0	2.0 ; 39.0
Visit 28 (Week 26)			
N	319	157	476
Mean (SD)	8.2 (4.0)	7.8 (3.7)	8.1 (3.9)
Median	7.0	7.0	7.0
Min ; Max	2.0 ; 27.0	3.0 ; 32.0	2.0 ; 32.0
Visit 30 (Week 27)			
N	4	1	5
Mean (SD)	11.0 (3.6)	7.0	10.2 (3.6)
Median	11.5	7.0	9.0
Min ; Max	7.0 ; 14.0	7.0 ; 7.0	7.0 ; 14.0
Visit 44 (Week 53)			
N	234	114	348
Mean (SD)	8.6 (3.8)	8.4 (3.8)	8.5 (3.8)
Median	7.0	9.0	7.0
Min ; Max	3.0 ; 24.0	3.0 ; 27.0	3.0 ; 27.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	8.6 (4.6)	7.8 (3.6)	8.3 (4.3)
Median	7.0	7.0	7.0
Min ; Max	2.0 ; 43.0	3.0 ; 27.0	2.0 ; 43.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:06 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_sas.txt

14.3.5.2: Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Number of Subjects	254	122	376
Albumin serum(g/dL)			
Visit 1			
N	254	122	376
Mean (SD)	4.5 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.5	4.4	4.4
Min ; Max	3.8 ; 5.3	3.8 ; 5.1	3.8 ; 5.3
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	4.4 (0.3)	4.4 (0.2)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.8 ; 5.2	3.9 ; 4.9	3.8 ; 5.2
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	4.5 (0.3)	4.7	4.5 (0.2)
Median	4.5	4.7	4.6
Min ; Max	4.2 ; 4.7	4.7 ; 4.7	4.2 ; 4.7
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	4.4 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.6 ; 5.3	3.8 ; 5.2	3.6 ; 5.3
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	4.4 (0.3)	4.4 (0.3)	4.4 (0.3)
Median	4.4	4.4	4.4
Min ; Max	3.6 ; 5.3	3.8 ; 5.2	3.6 ; 5.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:16 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_ets.txt

Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Alanine aminotransferase serum(U/L)			
Visit 1			
N	254	122	376
Mean (SD)	24 (14)	23 (14)	23 (14)
Median	19	20	19
Min ; Max	5 ; 117	6 ; 92	5 ; 117
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	23 (15)	23 (11)	23 (14)
Median	19	21	19
Min ; Max	6 ; 134	6 ; 70	6 ; 134
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	32 (18)	11	27 (18)
Median	30	11	23
Min ; Max	15 ; 51	11 ; 11	11 ; 51
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	23 (13)	24 (13)	23 (13)
Median	20	22	21
Min ; Max	7 ; 85	6 ; 114	6 ; 114
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	23 (13)	24 (13)	23 (13)
Median	20	21	20
Min ; Max	7 ; 93	6 ; 114	6 ; 114

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:16 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_ets.txt

Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Alkaline phosphatase serum(U/L)			
Visit 1			
N	254	122	376
Mean (SD)	79 (26)	78 (26)	79 (26)
Median	77	72	75
Min ; Max	35 ; 296	40 ; 153	35 ; 296
Visit 28 (Week 26)			
N	253	122	375
Mean (SD)	77 (25)	79 (26)	78 (25)
Median	74	74	74
Min ; Max	34 ; 231	34 ; 185	34 ; 231
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	101 (51)	65	92 (45)
Median	89	65	77
Min ; Max	57 ; 156	65 ; 65	57 ; 156
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	78 (24)	81 (51)	79 (35)
Median	74	74	74
Min ; Max	36 ; 226	37 ; 573	36 ; 573
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	78 (24)	82 (50)	79 (34)
Median	75	74	74
Min ; Max	36 ; 226	37 ; 573	36 ; 573

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:16 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_ets.txt

Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Creatinine serum(umol/L)			
Visit 1			
N	254	122	376
Mean (SD)	79 (16)	77 (17)	78 (16)
Median	78	77	78
Min ; Max	46 ; 176	46 ; 126	46 ; 176
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	77 (15)	77 (17)	77 (16)
Median	76	76	76
Min ; Max	46 ; 168	43 ; 130	43 ; 168
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	81 (3)	57	75 (12)
Median	82	57	80
Min ; Max	77 ; 83	57 ; 57	57 ; 83
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	77 (16)	76 (15)	77 (16)
Median	77	74	76
Min ; Max	45 ; 175	42 ; 121	42 ; 175
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	77 (16)	76 (16)	77 (16)
Median	77	74	76
Min ; Max	45 ; 175	42 ; 121	42 ; 175

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:16 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_ets.txt

Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Potassium serum (mmol/L)			
Visit 1			
N	254	122	376
Mean (SD)	4.5 (0.4)	4.5 (0.4)	4.5 (0.4)
Median	4.4	4.4	4.4
Min ; Max	3.5 ; 6.0	3.5 ; 5.7	3.5 ; 6.0
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	4.5 (0.5)	4.5 (0.4)	4.5 (0.5)
Median	4.5	4.4	4.4
Min ; Max	2.9 ; 7.0	3.4 ; 5.6	2.9 ; 7.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	5.0 (1.1)	4.7	4.9 (0.9)
Median	4.4	4.7	4.6
Min ; Max	4.3 ; 6.2	4.7 ; 4.7	4.3 ; 6.2
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	4.5 (0.4)	4.5 (0.5)	4.5 (0.5)
Median	4.5	4.5	4.5
Min ; Max	3.5 ; 5.9	3.5 ; 5.9	3.5 ; 5.9
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	4.5 (0.4)	4.5 (0.5)	4.5 (0.4)
Median	4.5	4.5	4.5
Min ; Max	3.5 ; 5.9	3.5 ; 5.9	3.5 ; 5.9

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:16 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_ets.txt

Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Aspartate aminotransferase serum(U/L)			
Visit 1			
N	254	122	376
Mean (SD)	22 (10)	23 (12)	22 (10)
Median	20	21	20
Min ; Max	11 ; 97	9 ; 113	9 ; 113
Visit 28 (Week 26)			
N	253	122	375
Mean (SD)	22 (12)	22 (8)	22 (11)
Median	19	21	20
Min ; Max	11 ; 152	11 ; 60	11 ; 152
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	31 (19)	15	27 (18)
Median	25	15	21
Min ; Max	16 ; 53	15 ; 15	15 ; 53
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	21 (8)	22 (11)	22 (9)
Median	20	20	20
Min ; Max	11 ; 73	9 ; 113	9 ; 113
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	22 (9)	23 (12)	22 (10)
Median	19	20	20
Min ; Max	11 ; 106	9 ; 113	9 ; 113

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:16 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_ets.txt

Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Sodium serum (mmol/L)			
Visit 1			
N	254	122	376
Mean (SD)	140 (3)	140 (3)	140 (3)
Median	140	140	140
Min ; Max	129 ; 151	131 ; 146	129 ; 151
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	141 (3)	141 (3)	141 (3)
Median	141	140	141
Min ; Max	134 ; 156	129 ; 152	129 ; 156
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	140 (2)	141	140 (2)
Median	139	141	140
Min ; Max	138 ; 142	141 ; 141	138 ; 142
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	141 (3)	141 (3)	141 (3)
Median	141	141	141
Min ; Max	130 ; 148	130 ; 147	130 ; 148
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	141 (3)	140 (3)	141 (3)
Median	141	141	141
Min ; Max	130 ; 148	129 ; 147	129 ; 148

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:16 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_ets.txt

Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Total Protein serum(g/dL)			
Visit 1			
N	254	122	376
Mean (SD)	7.2 (0.5)	7.1 (0.5)	7.1 (0.5)
Median	7.1	7.1	7.1
Min ; Max	5.9 ; 8.6	6.1 ; 8.1	5.9 ; 8.6
Visit 28 (Week 26)			
N	253	122	375
Mean (SD)	7.0 (0.4)	7.0 (0.4)	7.0 (0.4)
Median	6.9	7.0	7.0
Min ; Max	6.0 ; 9.5	6.0 ; 8.1	6.0 ; 9.5
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	6.9 (0.4)	7.7	7.1 (0.5)
Median	7.1	7.7	7.2
Min ; Max	6.5 ; 7.2	7.7 ; 7.7	6.5 ; 7.7
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	7.2 (0.4)	7.1 (0.4)	7.1 (0.4)
Median	7.2	7.1	7.1
Min ; Max	6.1 ; 8.3	6.1 ; 8.2	6.1 ; 8.3
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	7.2 (0.4)	7.1 (0.4)	7.1 (0.4)
Median	7.2	7.1	7.1
Min ; Max	6.1 ; 8.3	6.1 ; 8.2	6.1 ; 8.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:16 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_ets.txt

Biochemistry by Treatment Week - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Total Bilirubin serum(umol/L)			
Visit 1			
N	254	121	375
Mean (SD)	9.2 (5.4)	8.3 (3.9)	8.9 (5.0)
Median	9.0	7.0	7.0
Min ; Max	3.0 ; 38.0	2.0 ; 29.0	2.0 ; 38.0
Visit 28 (Week 26)			
N	253	122	375
Mean (SD)	8.2 (3.9)	8.0 (3.8)	8.2 (3.9)
Median	7.0	7.0	7.0
Min ; Max	3.0 ; 27.0	3.0 ; 32.0	3.0 ; 32.0
Visit 30 (Week 27)			
N	4	1	5
Mean (SD)	11.0 (3.6)	7.0	10.2 (3.6)
Median	11.5	7.0	9.0
Min ; Max	7.0 ; 14.0	7.0 ; 7.0	7.0 ; 14.0
Visit 44 (Week 53)			
N	234	114	348
Mean (SD)	8.6 (3.8)	8.4 (3.8)	8.5 (3.8)
Median	7.0	9.0	7.0
Min ; Max	3.0 ; 24.0	3.0 ; 27.0	3.0 ; 27.0
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	8.5 (3.8)	8.2 (3.8)	8.4 (3.8)
Median	7.0	7.0	7.0
Min ; Max	3.0 ; 24.0	3.0 ; 27.0	3.0 ; 27.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:16 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_abs_descp_ets.txt

14.3.5.3: Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Albumin Serum(g/dL)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	-0.0 (0.2)	-0.0 (0.2)	-0.0 (0.2)
Median	0.0	0.0	0.0
Min ; Max	-0.8 ; 0.7	-0.7 ; 0.7	-0.8 ; 0.7
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-0.3 (0.1)	-0.2	-0.3 (0.1)
Median	-0.3	-0.2	-0.3
Min ; Max	-0.4 ; -0.2	-0.2 ; -0.2	-0.4 ; -0.2
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-0.0 (0.3)	0.0 (0.3)	-0.0 (0.3)
Median	0.0	0.0	0.0
Min ; Max	-0.7 ; 0.8	-0.5 ; 0.8	-0.7 ; 0.8
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	-0.0 (0.3)	-0.0 (0.3)	-0.0 (0.3)
Median	0.0	0.0	0.0
Min ; Max	-0.8 ; 0.8	-0.7 ; 0.8	-0.8 ; 0.8

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:26 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Alanine aminotransferase Serum(U/L)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	-0.2 (14.3)	-0.2 (9.8)	-0.2 (13.0)
Median	0.0	0.0	0.0
Min ; Max	-97.0 ; 96.0	-51.0 ; 35.0	-97.0 ; 96.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	0.3 (14.8)	-3.0	-0.5 (12.2)
Median	4.0	-3.0	0.5
Min ; Max	-16.0 ; 13.0	-3.0 ; -3.0	-16.0 ; 13.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-0.7 (13.8)	0.8 (14.0)	-0.2 (13.8)
Median	0.0	1.5	1.0
Min ; Max	-96.0 ; 52.0	-50.0 ; 102.0	-96.0 ; 102.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	-0.1 (13.4)	1.4 (20.5)	0.4 (16.1)
Median	0.0	1.0	0.0
Min ; Max	-96.0 ; 59.0	-50.0 ; 220.0	-96.0 ; 220.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:26 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Alkaline Phosphatase Serum(U/L)			
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	-1.2 (15.4)	0.1 (16.6)	-0.8 (15.8)
Median	-1.0	1.0	-1.0
Min ; Max	-65.0 ; 70.0	-68.0 ; 49.0	-68.0 ; 70.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-1.7 (36.3)	-5.0	-2.5 (29.7)
Median	-7.0	-5.0	-6.0
Min ; Max	-35.0 ; 37.0	-5.0 ; -5.0	-35.0 ; 37.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-1.1 (14.2)	3.4 (48.2)	0.4 (29.9)
Median	0.0	1.0	0.0
Min ; Max	-70.0 ; 49.0	-62.0 ; 485.0	-70.0 ; 485.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	-0.9 (14.3)	2.5 (39.5)	0.2 (25.6)
Median	0.0	2.0	0.0
Min ; Max	-70.0 ; 70.0	-62.0 ; 485.0	-70.0 ; 485.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:26 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Creatinine Serum(umol/L)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	-1.2 (7.3)	-0.5 (8.7)	-0.9 (7.8)
Median	-1.0	0.0	-1.0
Min ; Max	-27.0 ; 20.0	-37.0 ; 18.0	-37.0 ; 20.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-8.3 (2.5)	4.0	-5.3 (6.5)
Median	-8.0	4.0	-7.0
Min ; Max	-11.0 ; -6.0	4.0 ; 4.0	-11.0 ; 4.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-1.1 (7.8)	-0.9 (8.5)	-1.0 (8.0)
Median	-1.0	-1.0	-1.0
Min ; Max	-27.0 ; 22.0	-36.0 ; 26.0	-36.0 ; 26.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	-1.0 (7.7)	-0.5 (10.0)	-0.8 (8.5)
Median	-1.0	-1.0	-1.0
Min ; Max	-27.0 ; 22.0	-37.0 ; 59.0	-37.0 ; 59.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:26 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Potassium Serum(mmol/L)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	0.0 (0.5)	-0.0 (0.5)	0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-1.6 ; 2.6	-1.7 ; 1.8	-1.7 ; 2.6
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	0.1 (0.2)	-0.3	-0.0 (0.3)
Median	0.2	-0.3	0.0
Min ; Max	-0.2 ; 0.2	-0.3 ; -0.3	-0.3 ; 0.2
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	0.0 (0.5)	-0.0 (0.5)	0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-1.3 ; 1.6	-1.6 ; 1.6	-1.6 ; 1.6
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	0.0 (0.5)	-0.0 (0.5)	0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-1.4 ; 1.6	-1.7 ; 1.8	-1.7 ; 1.8

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:26 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Aspartate aminotransferase Serum(U/L)			
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	0.4 (11.7)	-0.4 (10.6)	0.1 (11.3)
Median	0.0	0.0	0.0
Min ; Max	-71.0 ; 99.0	-98.0 ; 43.0	-98.0 ; 99.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-3.3 (5.8)	0.0	-2.5 (5.0)
Median	0.0	0.0	0.0
Min ; Max	-10.0 ; 0.0	0.0 ; 0.0	-10.0 ; 0.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-0.8 (8.9)	-0.2 (14.3)	-0.6 (10.9)
Median	-1.0	0.0	-1.0
Min ; Max	-61.0 ; 37.0	-98.0 ; 95.0	-98.0 ; 95.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	-0.3 (10.0)	-0.3 (12.2)	-0.3 (10.8)
Median	0.0	0.0	0.0
Min ; Max	-61.0 ; 83.0	-98.0 ; 95.0	-98.0 ; 95.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:26 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Sodium Serum(umol/L)			
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	1.6 (3.4)	1.2 (3.1)	1.5 (3.3)
Median	2.0	1.0	1.0
Min ; Max	-9.0 ; 17.0	-13.0 ; 14.0	-13.0 ; 17.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-0.7 (3.5)	2.0	0.0 (3.2)
Median	-1.0	2.0	0.5
Min ; Max	-4.0 ; 3.0	2.0 ; 2.0	-4.0 ; 3.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	1.2 (3.2)	1.0 (2.9)	1.1 (3.1)
Median	1.0	1.0	1.0
Min ; Max	-8.0 ; 13.0	-8.0 ; 8.0	-8.0 ; 13.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	1.0 (3.3)	0.8 (3.1)	1.0 (3.2)
Median	1.0	1.0	1.0
Min ; Max	-8.0 ; 13.0	-13.0 ; 8.0	-13.0 ; 13.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:26 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Total Protein Serum(g/dL)			
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	-0.1 (0.4)	-0.1 (0.4)	-0.1 (0.4)
Median	-0.1	-0.2	-0.1
Min ; Max	-1.3 ; 1.3	-1.3 ; 0.9	-1.3 ; 1.3
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-0.4 (0.3)	-0.3	-0.4 (0.3)
Median	-0.6	-0.3	-0.5
Min ; Max	-0.6 ; 0.0	-0.3 ; -0.3	-0.6 ; 0.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	0.0 (0.4)	0.0 (0.4)	0.0 (0.4)
Median	0.0	0.0	0.0
Min ; Max	-1.1 ; 1.5	-1.0 ; 1.2	-1.1 ; 1.5
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	-0.0 (0.4)	-0.0 (0.4)	-0.0 (0.4)
Median	0.0	0.0	0.0
Min ; Max	-1.1 ; 1.5	-1.2 ; 1.2	-1.2 ; 1.5

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:26 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Bilirubin Serum (mmol/L)			
Visit 28 (Week 26)			
N	319	156	475
Mean (SD)	-0.8 (3.8)	-0.3 (3.7)	-0.6 (3.7)
Median	0.0	0.0	0.0
Min ; Max	-21.0 ; 9.0	-16.0 ; 12.0	-21.0 ; 12.0
Visit 30 (Week 27)			
N	4	1	5
Mean (SD)	-0.5 (2.1)	-3.0	-1.0 (2.1)
Median	-0.5	-3.0	-1.0
Min ; Max	-3.0 ; 2.0	-3.0 ; -3.0	-3.0 ; 2.0
Visit 44 (Week 53)			
N	234	113	347
Mean (SD)	-0.8 (4.3)	0.1 (3.7)	-0.5 (4.1)
Median	0.0	0.0	0.0
Min ; Max	-26.0 ; 9.0	-10.0 ; 10.0	-26.0 ; 10.0
Visit 44 (Week 53) (LOCF)			
N	362	179	541
Mean (SD)	-0.5 (3.9)	-0.1 (3.6)	-0.3 (3.8)
Median	0.0	0.0	0.0
Min ; Max	-26.0 ; 12.0	-10.0 ; 10.0	-26.0 ; 12.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:26 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_sas.txt

14.3.5.4: Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics - Extension Trial Set

	IDegAsp OD	IDet	Total
Number of Subjects	254	122	376
Ch. Albumin Serum(g/dL)			
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	-0.0 (0.2)	-0.0 (0.2)	-0.0 (0.2)
Median	0.0	0.0	0.0
Min ; Max	-0.7 ; 0.7	-0.7 ; 0.7	-0.7 ; 0.7
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-0.3 (0.1)	-0.2	-0.3 (0.1)
Median	-0.3	-0.2	-0.3
Min ; Max	-0.4 ; -0.2	-0.2 ; -0.2	-0.4 ; -0.2
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-0.0 (0.3)	0.0 (0.3)	-0.0 (0.3)
Median	0.0	0.0	0.0
Min ; Max	-0.7 ; 0.8	-0.5 ; 0.8	-0.7 ; 0.8
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	-0.0 (0.3)	0.0 (0.3)	-0.0 (0.3)
Median	0.0	0.0	0.0
Min ; Max	-0.8 ; 0.8	-0.7 ; 0.8	-0.8 ; 0.8

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:36 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_ets.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics -
 Extension Trial Set

	IDegAsp OD	IDet	Total
Ch. Alanine aminotransferase Serum(U/L)			
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	-0.5 (14.6)	-0.3 (9.9)	-0.4 (13.2)
Median	-1.0	0.0	0.0
Min ; Max	-97.0 ; 96.0	-51.0 ; 20.0	-97.0 ; 96.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	0.3 (14.8)	-3.0	-0.5 (12.2)
Median	4.0	-3.0	0.5
Min ; Max	-16.0 ; 13.0	-3.0 ; -3.0	-16.0 ; 13.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-0.7 (13.8)	0.8 (14.0)	-0.2 (13.8)
Median	0.0	1.5	1.0
Min ; Max	-96.0 ; 52.0	-50.0 ; 102.0	-96.0 ; 102.0
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	-0.3 (13.9)	0.7 (13.9)	-0.0 (13.9)
Median	0.0	1.0	1.0
Min ; Max	-96.0 ; 59.0	-50.0 ; 102.0	-96.0 ; 102.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:36 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_ets.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics -
Extension Trial Set

	IDegAsp OD	IDet	Total
Ch. Alkaline Phosphatase Serum(U/L)			
Visit 28 (Week 26)			
N	253	122	375
Mean (SD)	-1.8 (15.6)	0.3 (16.4)	-1.2 (15.9)
Median	-2.0	0.0	-1.0
Min ; Max	-65.0 ; 63.0	-68.0 ; 49.0	-68.0 ; 63.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-1.7 (36.3)	-5.0	-2.5 (29.7)
Median	-7.0	-5.0	-6.0
Min ; Max	-35.0 ; 37.0	-5.0 ; -5.0	-35.0 ; 37.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-1.1 (14.2)	3.4 (48.2)	0.4 (29.9)
Median	0.0	1.0	0.0
Min ; Max	-70.0 ; 49.0	-62.0 ; 485.0	-70.0 ; 485.0
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	-1.2 (14.3)	3.1 (46.9)	0.2 (29.2)
Median	0.0	1.0	0.0
Min ; Max	-70.0 ; 49.0	-62.0 ; 485.0	-70.0 ; 485.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:36 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_ets.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics -
 Extension Trial Set

	IDegAsp OD	IDet	Total
Ch. Creatinine Serum(umol/L)			
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	-1.3 (7.1)	-0.3 (9.0)	-1.0 (7.8)
Median	-1.0	0.0	0.0
Min ; Max	-23.0 ; 20.0	-37.0 ; 18.0	-37.0 ; 20.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-8.3 (2.5)	4.0	-5.3 (6.5)
Median	-8.0	4.0	-7.0
Min ; Max	-11.0 ; -6.0	4.0 ; 4.0	-11.0 ; 4.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-1.1 (7.8)	-0.9 (8.5)	-1.0 (8.0)
Median	-1.0	-1.0	-1.0
Min ; Max	-27.0 ; 22.0	-36.0 ; 26.0	-36.0 ; 26.0
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	-1.3 (7.9)	-1.0 (9.3)	-1.2 (8.4)
Median	-1.0	-1.0	-1.0
Min ; Max	-27.0 ; 22.0	-37.0 ; 26.0	-37.0 ; 26.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:36 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_ets.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics -
 Extension Trial Set

	IDegAsp OD	IDet	Total
Ch. Potassium Serum (mmol/L)			
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	0.0 (0.5)	-0.0 (0.5)	0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-1.6 ; 2.6	-1.2 ; 1.4	-1.6 ; 2.6
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	0.1 (0.2)	-0.3	-0.0 (0.3)
Median	0.2	-0.3	0.0
Min ; Max	-0.2 ; 0.2	-0.3 ; -0.3	-0.3 ; 0.2
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	0.0 (0.5)	-0.0 (0.5)	0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-1.3 ; 1.6	-1.6 ; 1.6	-1.6 ; 1.6
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	0.0 (0.5)	0.0 (0.5)	0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-1.3 ; 1.6	-1.6 ; 1.6	-1.6 ; 1.6

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:36 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_ets.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics -
 Extension Trial Set

	IDegAsp OD	IDet	Total
Ch. Aspartate aminotransferase Serum(U/L)			
Visit 28 (Week 26)			
N	253	122	375
Mean (SD)	0.3 (11.3)	-0.3 (11.3)	0.1 (11.3)
Median	0.0	0.5	0.0
Min ; Max	-71.0 ; 99.0	-98.0 ; 43.0	-98.0 ; 99.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-3.3 (5.8)	0.0	-2.5 (5.0)
Median	0.0	0.0	0.0
Min ; Max	-10.0 ; 0.0	0.0 ; 0.0	-10.0 ; 0.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	-0.8 (8.9)	-0.2 (14.3)	-0.6 (10.9)
Median	-1.0	0.0	-1.0
Min ; Max	-61.0 ; 37.0	-98.0 ; 95.0	-98.0 ; 95.0
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	-0.6 (9.5)	-0.1 (14.0)	-0.4 (11.1)
Median	-0.5	0.0	0.0
Min ; Max	-61.0 ; 58.0	-98.0 ; 95.0	-98.0 ; 95.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:36 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_ets.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics -
 Extension Trial Set

	IDegAsp OD	IDet	Total
Ch. Sodium Serum(umol/L)			
Visit 28 (Week 26)			
N	254	122	376
Mean (SD)	1.7 (3.4)	1.0 (3.3)	1.5 (3.4)
Median	2.0	1.0	1.0
Min ; Max	-9.0 ; 17.0	-13.0 ; 14.0	-13.0 ; 17.0
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-0.7 (3.5)	2.0	0.0 (3.2)
Median	-1.0	2.0	0.5
Min ; Max	-4.0 ; 3.0	2.0 ; 2.0	-4.0 ; 3.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	1.2 (3.2)	1.0 (2.9)	1.1 (3.1)
Median	1.0	1.0	1.0
Min ; Max	-8.0 ; 13.0	-8.0 ; 8.0	-8.0 ; 13.0
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	1.2 (3.3)	0.8 (3.2)	1.1 (3.3)
Median	1.0	1.0	1.0
Min ; Max	-8.0 ; 13.0	-13.0 ; 8.0	-13.0 ; 13.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:36 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_ets.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics -
 Extension Trial Set

	IDegAsp OD	IDet	Total
Ch. Total Protein Serum(g/dL)			
Visit 28 (Week 26)			
N	253	122	375
Mean (SD)	-0.1 (0.4)	-0.1 (0.4)	-0.1 (0.4)
Median	-0.2	-0.2	-0.2
Min ; Max	-1.3 ; 1.3	-1.3 ; 0.9	-1.3 ; 1.3
Visit 30 (Week 27)			
N	3	1	4
Mean (SD)	-0.4 (0.3)	-0.3	-0.4 (0.3)
Median	-0.6	-0.3	-0.5
Min ; Max	-0.6 ; 0.0	-0.3 ; -0.3	-0.6 ; 0.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	0.0 (0.4)	0.0 (0.4)	0.0 (0.4)
Median	0.0	0.0	0.0
Min ; Max	-1.1 ; 1.5	-1.0 ; 1.2	-1.1 ; 1.5
Visit 44 (Week 53) (LOCF)			
N	254	122	376
Mean (SD)	0.0 (0.4)	0.0 (0.4)	0.0 (0.4)
Median	0.0	0.0	0.0
Min ; Max	-1.1 ; 1.5	-1.0 ; 1.2	-1.1 ; 1.5

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:03:36 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_ets.txt

Biochemistry by Treatment Week - Change from Baseline - Descriptive Statistics -
Extension Trial Set

	IDegAsp OD	IDet	Total
Ch. Bilirubin Serum (mmol/L)			
Visit 28 (Week 26)			
N	253	121	374
Mean (SD)	-0.9 (3.9)	-0.2 (3.8)	-0.7 (3.9)
Median	0.0	0.0	0.0
Min ; Max	-21.0 ; 9.0	-16.0 ; 12.0	-21.0 ; 12.0
Visit 30 (Week 27)			
N	4	1	5
Mean (SD)	-0.5 (2.1)	-3.0	-1.0 (2.1)
Median	-0.5	-3.0	-1.0
Min ; Max	-3.0 ; 2.0	-3.0 ; -3.0	-3.0 ; 2.0
Visit 44 (Week 53)			
N	234	113	347
Mean (SD)	-0.8 (4.3)	0.1 (3.7)	-0.5 (4.1)
Median	0.0	0.0	0.0
Min ; Max	-26.0 ; 9.0	-10.0 ; 10.0	-26.0 ; 10.0
Visit 44 (Week 53) (LOCF)			
N	254	121	375
Mean (SD)	-0.7 (4.2)	-0.1 (3.8)	-0.5 (4.1)
Median	0.0	0.0	0.0
Min ; Max	-26.0 ; 9.0	-10.0 ; 10.0	-26.0 ; 10.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:36 - tdesc_numfind_tpl_t019_v01.sas/t_biochem_chb_descp_ets.txt

14.3.5.5: Biochemistry by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Alanine aminotransferase serum (U/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	2 (0.6)	0	2 (0.4)
Normal	337 (93.1)	167 (92.8)	504 (93.0)
High	23 (6.4)	13 (7.2)	36 (6.6)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	298 (92.8)	148 (94.3)	446 (93.3)
High	23 (7.2)	9 (5.7)	32 (6.7)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	2 (66.7)	1 (100.0)	3 (75.0)
High	1 (33.3)	0	1 (25.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	221 (93.6)	108 (94.7)	329 (94.0)
High	15 (6.4)	6 (5.3)	21 (6.0)
Visit 44 Week 53(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	335 (92.5)	168 (93.3)	503 (92.8)
High	27 (7.5)	12 (6.7)	39 (7.2)
Albumin serum (g/dL)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	360 (99.4)	180 (100.0)	540 (99.6)
High	2 (0.6)	0	2 (0.4)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Normal	320 (99.7)	157 (100.0)	477 (99.8)
High	1 (0.3)	0	1 (0.2)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	3 (100.0)	1 (100.0)	4 (100.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	235 (99.6)	114 (100.0)	349 (99.7)
High	1 (0.4)	0	1 (0.3)
Visit 44 Week 53(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)

N = Number of Subjects

Biochemistry by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Normal	361 (99.7)	180 (100.0)	541 (99.8)
High	1 (0.3)	0	1 (0.2)
Alkaline phosphatase serum (U/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	5 (1.4)	2 (1.1)	7 (1.3)
Normal	329 (90.9)	160 (88.9)	489 (90.2)
High	28 (7.7)	18 (10.0)	46 (8.5)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Low	10 (3.1)	5 (3.2)	15 (3.1)
Normal	284 (88.8)	137 (87.3)	421 (88.3)
High	26 (8.1)	15 (9.6)	41 (8.6)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	2 (66.7)	1 (100.0)	3 (75.0)
High	1 (33.3)	0	1 (25.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Low	4 (1.7)	3 (2.6)	7 (2.0)
Normal	217 (91.9)	102 (89.5)	319 (91.1)
High	15 (6.4)	9 (7.9)	24 (6.9)
Visit 44 Week 53(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	9 (2.5)	4 (2.2)	13 (2.4)
Normal	327 (90.3)	159 (88.3)	486 (89.7)
High	26 (7.2)	17 (9.4)	43 (7.9)
Aspartate aminotransferase serum (U/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	0	2 (1.1)	2 (0.4)
Normal	350 (96.7)	171 (95.0)	521 (96.1)
High	12 (3.3)	7 (3.9)	19 (3.5)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Low	0	1 (0.6)	1 (0.2)
Normal	309 (96.6)	150 (95.5)	459 (96.2)
High	11 (3.4)	6 (3.8)	17 (3.6)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	2 (66.7)	1 (100.0)	3 (75.0)
High	1 (33.3)	0	1 (25.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Low	0	1 (0.9)	1 (0.3)

N = Number of Subjects

Biochemistry by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Normal	229 (97.0)	108 (94.7)	337 (96.3)
High	7 (3.0)	5 (4.4)	12 (3.4)
Visit 44 Week 53 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	0	2 (1.1)	2 (0.4)
Normal	349 (96.4)	171 (95.0)	520 (95.9)
High	13 (3.6)	7 (3.9)	20 (3.7)
Creatinine serum (umol/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	0	1 (0.6)	1 (0.2)
Normal	353 (97.5)	169 (93.9)	522 (96.3)
High	9 (2.5)	10 (5.6)	19 (3.5)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	314 (97.8)	154 (98.1)	468 (97.9)
High	6 (1.9)	3 (1.9)	9 (1.9)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	3 (100.0)	1 (100.0)	4 (100.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	229 (97.0)	111 (97.4)	340 (97.1)
High	7 (3.0)	3 (2.6)	10 (2.9)
Visit 44 Week 53 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	350 (96.7)	173 (96.1)	523 (96.5)
High	11 (3.0)	7 (3.9)	18 (3.3)
Potassium serum (mmol/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	1 (0.6)	2 (0.4)
Normal	355 (98.1)	177 (98.3)	532 (98.2)
High	6 (1.7)	2 (1.1)	8 (1.5)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	1 (0.3)	2 (1.3)	3 (0.6)
Normal	311 (96.9)	153 (97.5)	464 (97.1)
High	9 (2.8)	2 (1.3)	11 (2.3)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	2 (66.7)	1 (100.0)	3 (75.0)
High	1 (33.3)	0	1 (25.0)

N = Number of Subjects

Biochemistry by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	227 (96.2)	111 (97.4)	338 (96.6)
High	9 (3.8)	3 (2.6)	12 (3.4)
Visit 44 Week 53 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	0	1 (0.6)	1 (0.2)
Normal	352 (97.2)	174 (96.7)	526 (97.0)
High	10 (2.8)	5 (2.8)	15 (2.8)
Sodium serum (mmol/L)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	4 (1.1)	1 (0.6)	5 (0.9)
Normal	355 (98.1)	177 (98.3)	532 (98.2)
High	3 (0.8)	2 (1.1)	5 (0.9)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	0	2 (1.3)	2 (0.4)
Normal	312 (97.2)	154 (98.1)	466 (97.5)
High	9 (2.8)	1 (0.6)	10 (2.1)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	3 (100.0)	1 (100.0)	4 (100.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Low	1 (0.4)	1 (0.9)	2 (0.6)
Normal	234 (99.2)	113 (99.1)	347 (99.1)
High	1 (0.4)	0	1 (0.3)
Visit 44 Week 53 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	3 (1.7)	4 (0.7)
Normal	359 (99.2)	177 (98.3)	536 (98.9)
High	2 (0.6)	0	2 (0.4)
Total Bilirubin serum (umol/L)			
Visit 1			
N	362 (100.0)	179 (100.0)	541 (100.0)
Low	1 (0.3)	3 (1.7)	4 (0.7)
Normal	345 (95.3)	175 (97.8)	520 (96.1)
High	16 (4.4)	1 (0.6)	17 (3.1)
Visit 28 (Week 26)			
N	319 (100.0)	157 (100.0)	476 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	314 (98.4)	156 (99.4)	470 (98.7)
High	4 (1.3)	1 (0.6)	5 (1.1)
Visit 30 (Week 27)			

N = Number of Subjects

Biochemistry by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
N	4 (100.0)	1 (100.0)	5 (100.0)
Normal	4 (100.0)	1 (100.0)	5 (100.0)
Visit 44 (Week 53)			
N	234 (100.0)	114 (100.0)	348 (100.0)
Normal	231 (98.7)	113 (99.1)	344 (98.9)
High	3 (1.3)	1 (0.9)	4 (1.1)
Visit 44 Week 53(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	353 (97.5)	179 (99.4)	532 (98.2)
High	8 (2.2)	1 (0.6)	9 (1.7)
Total Protein serum (g/dL)			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	1 (0.3)	0	1 (0.2)
Normal	360 (99.4)	180 (100.0)	540 (99.6)
High	1 (0.3)	0	1 (0.2)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Normal	318 (99.4)	157 (100.0)	475 (99.6)
High	2 (0.6)	0	2 (0.4)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	3 (100.0)	1 (100.0)	4 (100.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	236 (100.0)	114 (100.0)	350 (100.0)
Visit 44 Week 53(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	362 (100.0)	180 (100.0)	542 (100.0)

N = Number of Subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:38:11 - tsum_lab_summary.sas/t_biochem_sum_sas.txt

14.3.5.6: Biochemistry by Treatment Week - Summary - Extension Trial Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	254	122	376
Alanine aminotransferase serum (U/L)			
Visit 1			
N	254 (100.0)	122 (100.0)	376 (100.0)
Low	2 (0.8)	0	2 (0.5)
Normal	235 (92.5)	112 (91.8)	347 (92.3)
High	17 (6.7)	10 (8.2)	27 (7.2)
Visit 28 (Week 26)			
N	254 (100.0)	122 (100.0)	376 (100.0)
Normal	239 (94.1)	116 (95.1)	355 (94.4)
High	15 (5.9)	6 (4.9)	21 (5.6)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	2 (66.7)	1 (100.0)	3 (75.0)
High	1 (33.3)	0	1 (25.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	221 (93.6)	108 (94.7)	329 (94.0)
High	15 (6.4)	6 (5.3)	21 (6.0)
Visit 44 Week 53(LOCF)			
N	254 (100.0)	122 (100.0)	376 (100.0)
Normal	238 (93.7)	115 (94.3)	353 (93.9)
High	16 (6.3)	7 (5.7)	23 (6.1)
Aspartate aminotransferase serum (U/L)			
Visit 1			
N	254 (100.0)	122 (100.0)	376 (100.0)
Low	0	1 (0.8)	1 (0.3)
Normal	244 (96.1)	116 (95.1)	360 (95.7)
High	10 (3.9)	5 (4.1)	15 (4.0)
Visit 28 (Week 26)			
N	253 (100.0)	122 (100.0)	375 (100.0)
Normal	245 (96.8)	117 (95.9)	362 (96.5)
High	8 (3.2)	5 (4.1)	13 (3.5)
Visit 30 (Week 27)			
N	3 (100.0)	1 (100.0)	4 (100.0)
Normal	2 (66.7)	1 (100.0)	3 (75.0)
High	1 (33.3)	0	1 (25.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Low	0	1 (0.9)	1 (0.3)
Normal	229 (97.0)	108 (94.7)	337 (96.3)
High	7 (3.0)	5 (4.4)	12 (3.4)

N = Number of Subjects

Biochemistry by Treatment Week - Summary - Extension Trial Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Visit 44 Week 53 (LOCF)			
N	254 (100.0)	122 (100.0)	376 (100.0)
Low	0	1 (0.8)	1 (0.3)
Normal	246 (96.9)	115 (94.3)	361 (96.0)
High	8 (3.1)	6 (4.9)	14 (3.7)

N = Number of Subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:38:19 - tsum_lab_summary.sas/t_biochem_sum_ets.txt

14.3.5.7: Biochemistry – Shift Table – Baseline to Week 53 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 44 (Week 53)								
Alanine aminotransferase serum (U/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	2 (0.6)	207 (57.2)	12 (3.3)	0 (0.0)	0 (0.0)	102 (56.7)	6 (3.3)	0 (0.0)
High	0 (0.0)	10 (2.8)	5 (1.4)	0 (0.0)	0 (0.0)	3 (1.7)	3 (1.7)	0 (0.0)
Missing	0 (0.0)	120 (33.1)	6 (1.7)	0 (0.0)	0 (0.0)	62 (34.4)	4 (2.2)	0 (0.0)
Albumin serum (g/dL)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	234 (64.6)	1 (0.3)	0 (0.0)	0 (0.0)	114 (63.3)	0 (0.0)	0 (0.0)
High	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	126 (34.8)	0 (0.0)	0 (0.0)	0 (0.0)	66 (36.7)	0 (0.0)	0 (0.0)
Alkaline phosphatase serum (U/L)								
Low	2 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	1 (0.6)	2 (1.1)	0 (0.0)	0 (0.0)
Normal	1 (0.3)	209 (57.7)	7 (1.9)	0 (0.0)	0 (0.0)	96 (53.3)	6 (3.3)	0 (0.0)
High	0 (0.0)	5 (1.4)	10 (2.8)	0 (0.0)	0 (0.0)	3 (1.7)	6 (3.3)	0 (0.0)
Missing	2 (0.6)	113 (31.2)	11 (3.0)	0 (0.0)	1 (0.6)	59 (32.8)	6 (3.3)	0 (0.0)
Aspartate aminotransferase serum (U/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	222 (61.3)	7 (1.9)	0 (0.0)	0 (0.0)	106 (58.9)	2 (1.1)	0 (0.0)
High	0 (0.0)	6 (1.7)	1 (0.3)	0 (0.0)	0 (0.0)	3 (1.7)	2 (1.1)	0 (0.0)
Missing	0 (0.0)	122 (33.7)	4 (1.1)	0 (0.0)	2 (1.1)	61 (33.9)	3 (1.7)	0 (0.0)

N = Number of subjects

Biochemistry - Shift Table - Baseline to Week 53 - Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 44 (Week 53)								
Creatinine serum (umol/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	229 (63.3)	0 (0.0)	0 (0.0)	0 (0.0)	108 (60.0)	3 (1.7)	0 (0.0)
High	0 (0.0)	1 (0.3)	6 (1.7)	0 (0.0)	0 (0.0)	1 (0.6)	2 (1.1)	0 (0.0)
Missing	0 (0.0)	123 (34.0)	3 (0.8)	0 (0.0)	1 (0.6)	60 (33.3)	5 (2.8)	0 (0.0)
Potassium serum (mmol/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	224 (61.9)	3 (0.8)	0 (0.0)	0 (0.0)	110 (61.1)	1 (0.6)	0 (0.0)
High	0 (0.0)	7 (1.9)	2 (0.6)	0 (0.0)	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
Missing	1 (0.3)	124 (34.3)	1 (0.3)	0 (0.0)	1 (0.6)	64 (35.6)	1 (0.6)	0 (0.0)
Sodium serum (mmol/L)								
Low	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	3 (0.8)	228 (63.0)	3 (0.8)	0 (0.0)	0 (0.0)	113 (62.8)	0 (0.0)	0 (0.0)
High	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (0.3)	125 (34.5)	0 (0.0)	0 (0.0)	0 (0.0)	64 (35.6)	2 (1.1)	0 (0.0)
Total Bilirubin serum (umol/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	223 (61.6)	8 (2.2)	0 (0.0)	2 (1.1)	110 (61.1)	0 (0.0)	1 (0.6)
High	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Missing	1 (0.3)	122 (33.7)	5 (1.4)	0 (0.0)	1 (0.6)	65 (36.1)	0 (0.0)	0 (0.0)

N = Number of subjects

Biochemistry - Shift Table - Baseline to Week 53 - Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 44 (Week 53)								
Total Protein serum (g/dL)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	1 (0.3)	234 (64.6)	1 (0.3)	0 (0.0)	0 (0.0)	114 (63.3)	0 (0.0)	0 (0.0)
High	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	126 (34.8)	0 (0.0)	0 (0.0)	0 (0.0)	66 (36.7)	0 (0.0)	0 (0.0)

N = Number of subjects

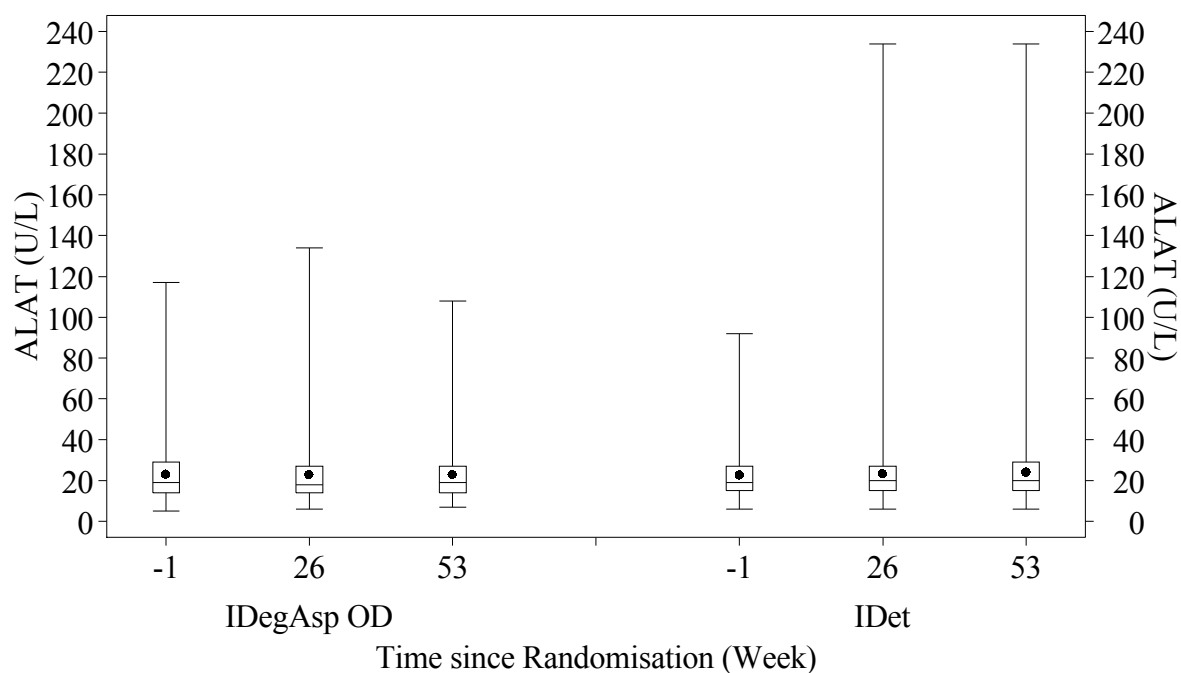
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:36:53 - t_lab_shift.sas/t_biochem_shift_w53_sas.txt

14.3.5.8: Biochemistry – Shift Table – Baseline to Week 53 – Extension Trial Set

Number of Subjects	IDegAsp OD 254				IDet 122			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 44 (Week 53)								
Alanine aminotransferase serum (U/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	2 (0.8)	207 (81.5)	12 (4.7)	0 (0.0)	0 (0.0)	102 (83.6)	6 (4.9)	0 (0.0)
High	0 (0.0)	10 (3.9)	5 (2.0)	0 (0.0)	0 (0.0)	3 (2.5)	3 (2.5)	0 (0.0)
Missing	0 (0.0)	18 (7.1)	0 (0.0)	0 (0.0)	0 (0.0)	7 (5.7)	1 (0.8)	0 (0.0)
Aspartate aminotransferase serum (U/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	222 (87.4)	7 (2.8)	0 (0.0)	0 (0.0)	106 (86.9)	2 (1.6)	0 (0.0)
High	0 (0.0)	6 (2.4)	1 (0.4)	0 (0.0)	0 (0.0)	3 (2.5)	2 (1.6)	0 (0.0)
Missing	0 (0.0)	16 (6.3)	2 (0.8)	0 (0.0)	1 (0.8)	6 (4.9)	1 (0.8)	0 (0.0)

N = Number of subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:03 - t_lab_shift.sas/t_biochem_shift_w53_ets.txt



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

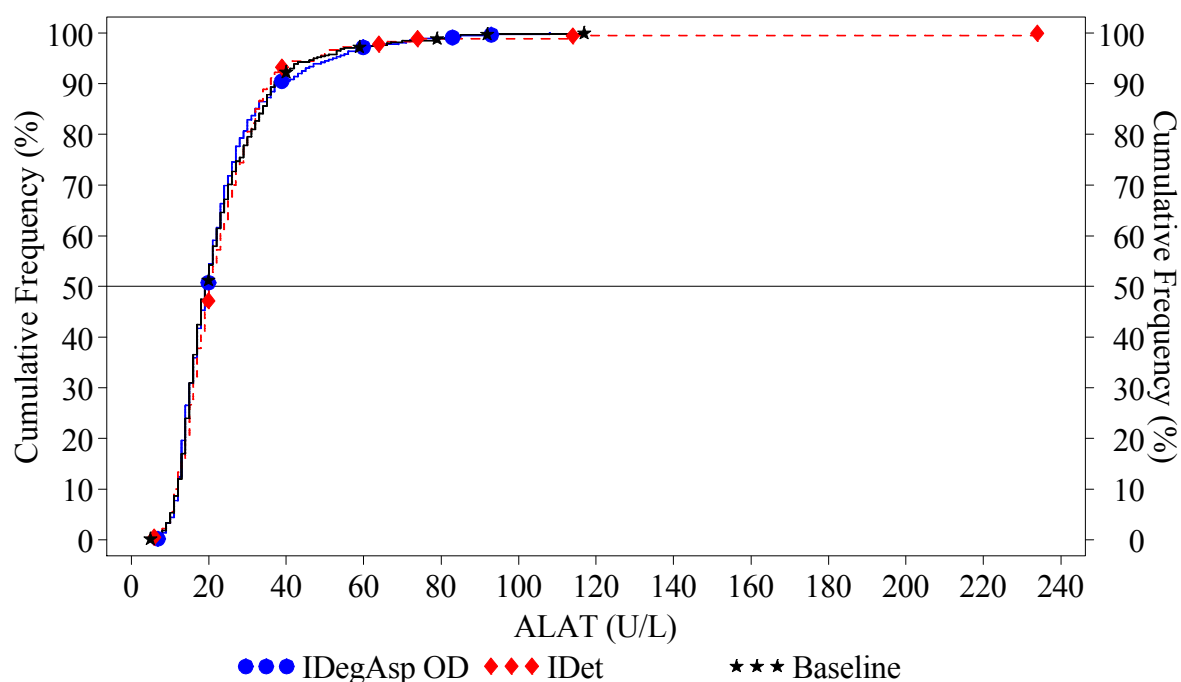
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-91)[6]; Female, Age(18-91)[6]

Upper ref.: Male, Age(18-91)[48]; Female, Age(18-91)[37]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:44 - fbox_numfind_v01.sas/e_ala_amino_s_abs_box_locf_sas.cgm

14.3.5.9: Biochemistry - Alanine Amino Serum - Box Plot - Safety Analysis Set

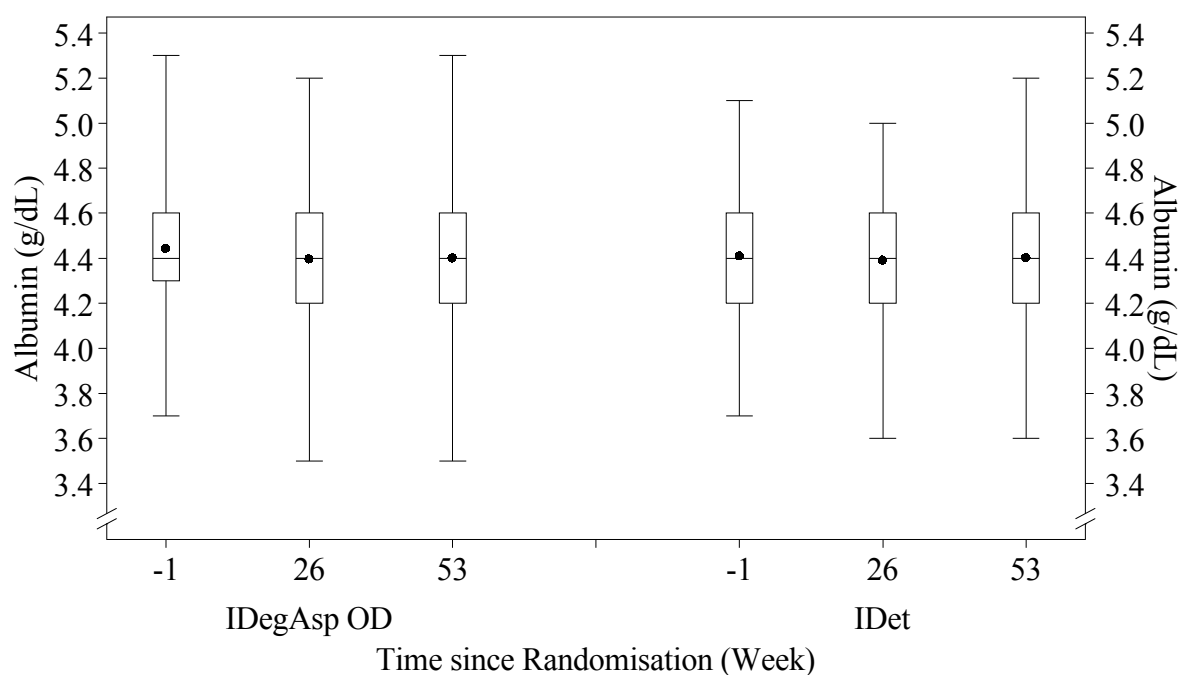


SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-91)[6]; Female, Age(18-91)[6]
Upper ref.: Male, Age(18-91)[48]; Female, Age(18-91)[37]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:03:59 - fedist_numfind_v01.sas/e_ala_amino_s_abs_cdf_locf_sas.cgm

14.3.5.10: Biochemistry - Alanine Amino Serum after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

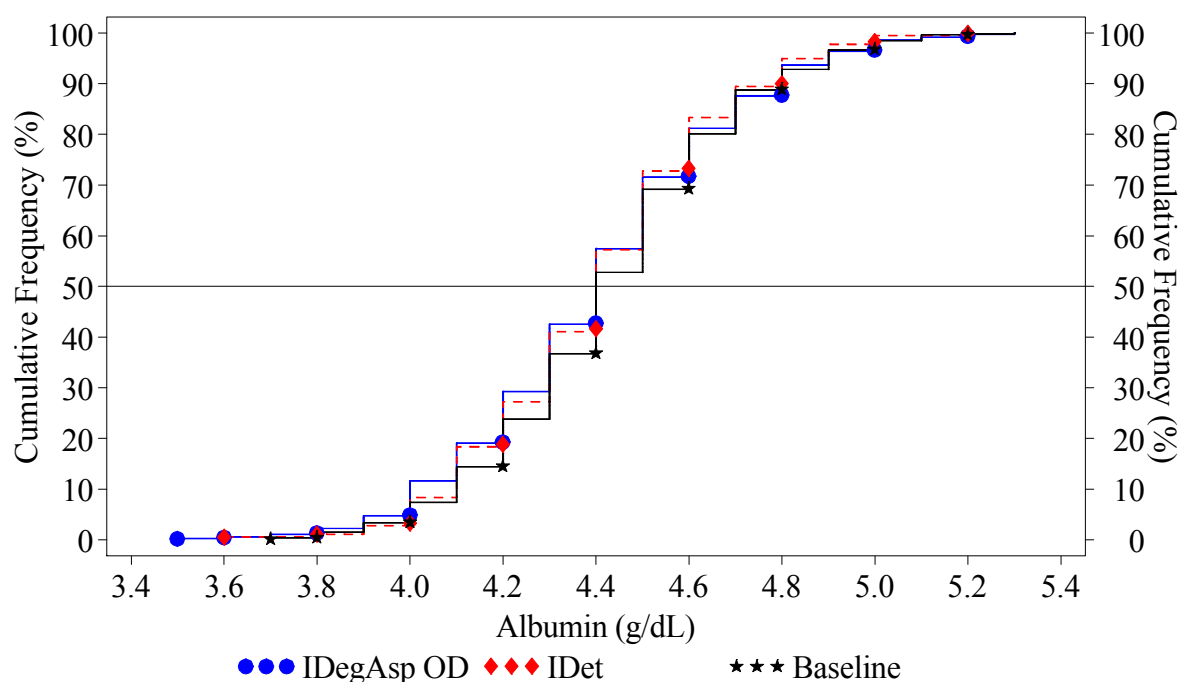
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[3.5], Age(66-91)[3.2]; Female, Age(18-66)[3.5], Age(66-91)[3.2]

Upper ref.: Male, Age(18-66)[5.3], Age(66-91)[4.6]; Female, Age(18-66)[5.3], Age(66-91)[4.6]

07MAY2011:14:04:08 - fbox_numfind_v01.sas/e_albu_s_abs_box_locf_sas.cgm
nn5401/nn5401-3594-3645/freeze_ctr_02/stats

14.3.5.11: Biochemistry - Albumin Serum - Box Plot - Safety Analysis Set



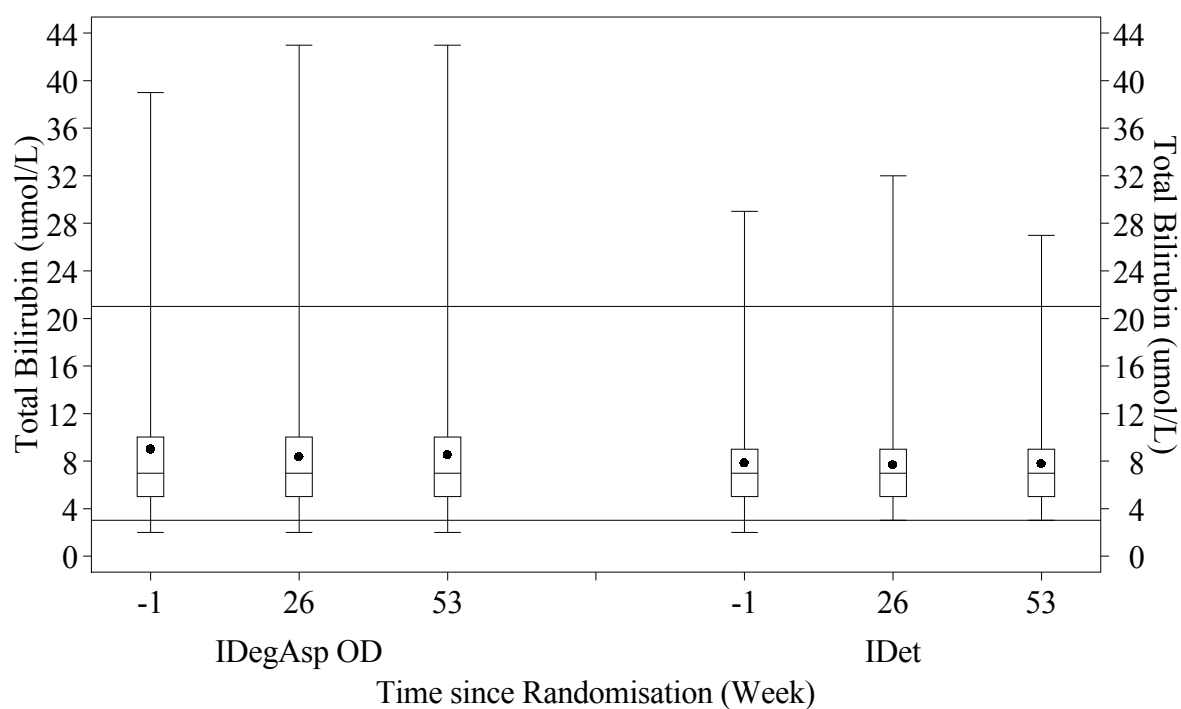
SAFETY; LOCF imputed data

Lower ref.: Male, Age(18-66)[3.5], Age(66-91)[3.2]; Female, Age(18-66)[3.5], Age(66-91)[3.2]

Upper ref.: Male, Age(18-66)[5.3], Age(66-91)[4.6]; Female, Age(18-66)[5.3], Age(66-91)[4.6]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:04:23 - fedist_numfind_v01.sas/e_albu_s_abs_cdf_locf_sas.cgm

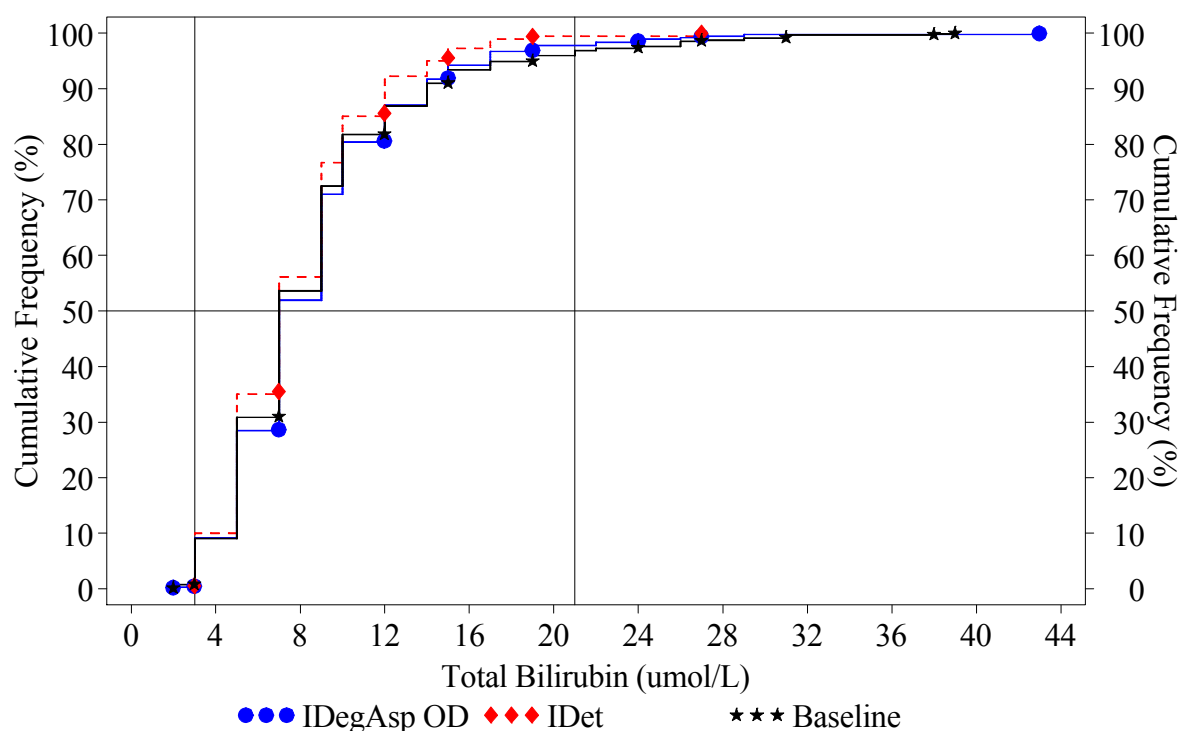
14.3.5.12: Biochemistry - Albumin Serum after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:04:32 - fbox_numfind_v01.sas/e_t_bilirubin_abs_box_locf_sas.cgm

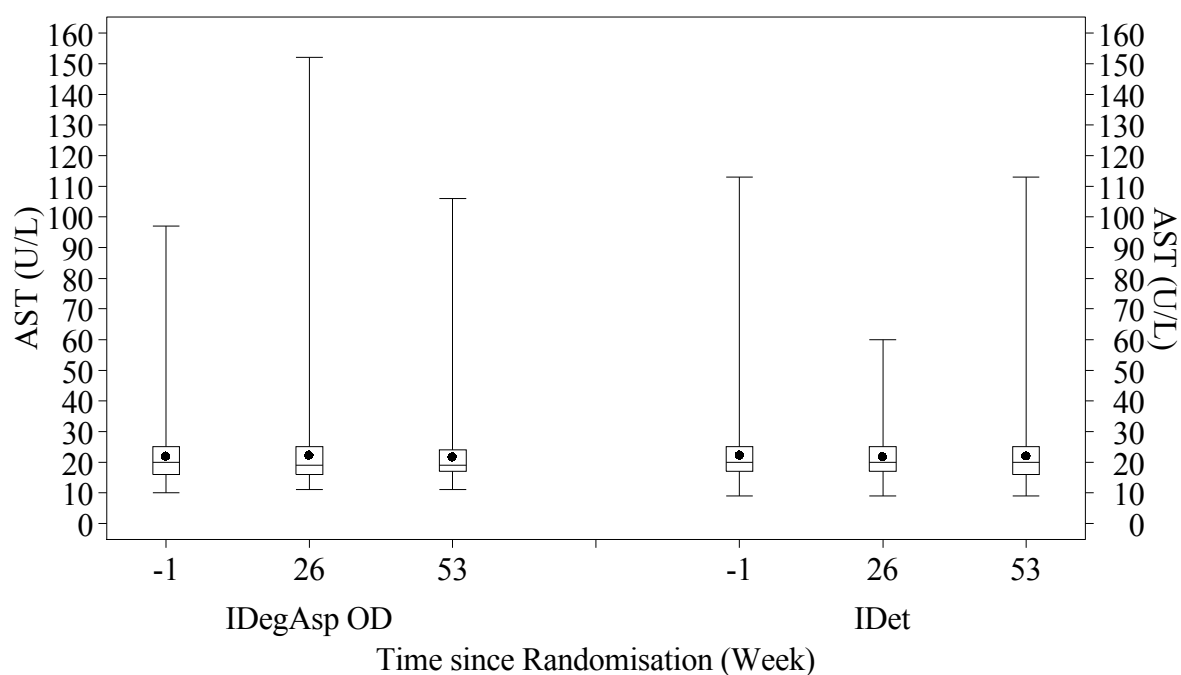
14.3.5.13: Biochemistry - Total Bilirubin - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:04:47 - fedist_numfind_v01.sas/e_t_bilirubin_abs_cdf_locf_sas.cgm

14.3.5.14: Biochemistry - Total Bilirubin after 52 Weeks of Treatment – Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

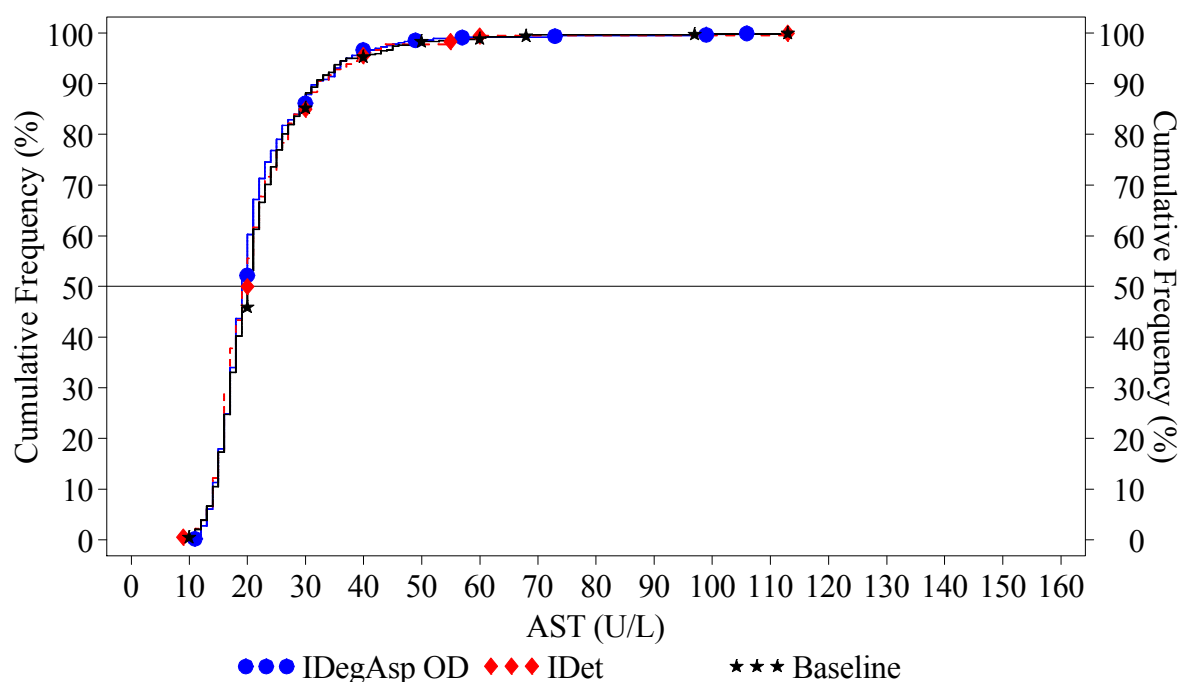
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-91)[10]; Female, Age(18-91)[10]

Upper ref.: Male, Age(18-91)[45]; Female, Age(18-91)[36]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:04:56 - fbox_numfind_v01.sas/e_ast_abs_box_locf_sas.cgm

14.3.5.15: Biochemistry - AST - Box Plot - Safety Analysis Set



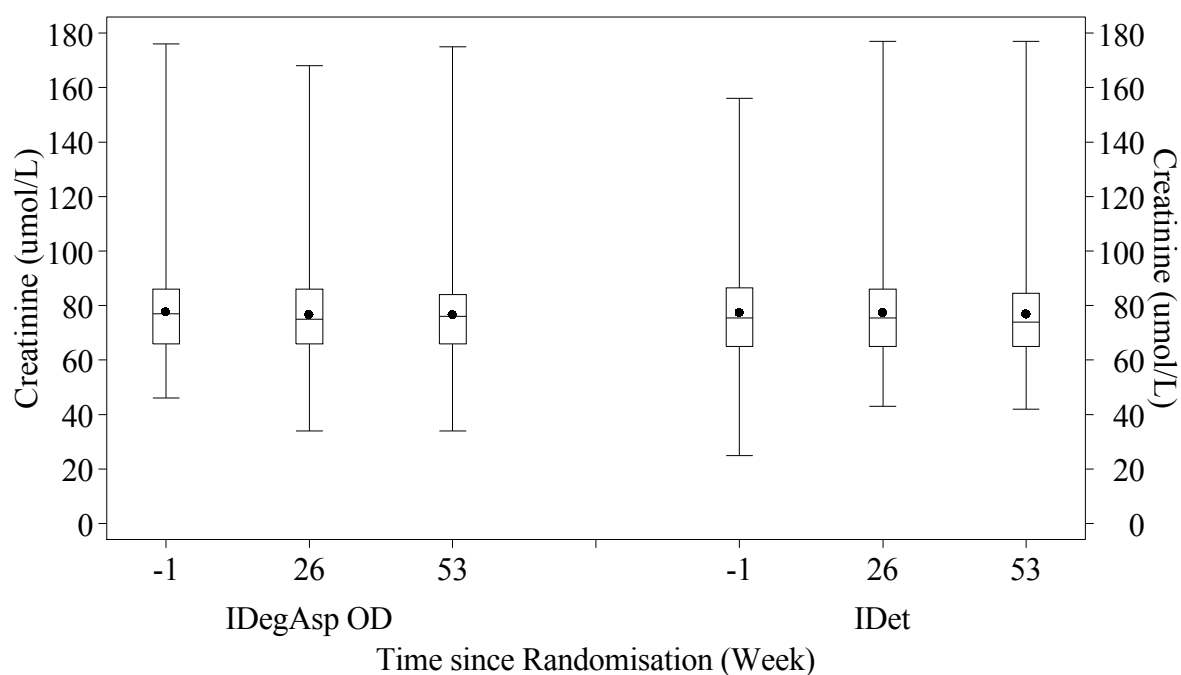
SAFETY; LOCF imputed data

Lower ref.: Male, Age(18-91)[10]; Female, Age(18-91)[10]

Upper ref.: Male, Age(18-91)[45]; Female, Age(18-91)[36]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:05:11 - fedist_numfind_v01.sas/e_ast_abs_cdf_locf_sas.cgm

14.3.5.16: Biochemistry - AST after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

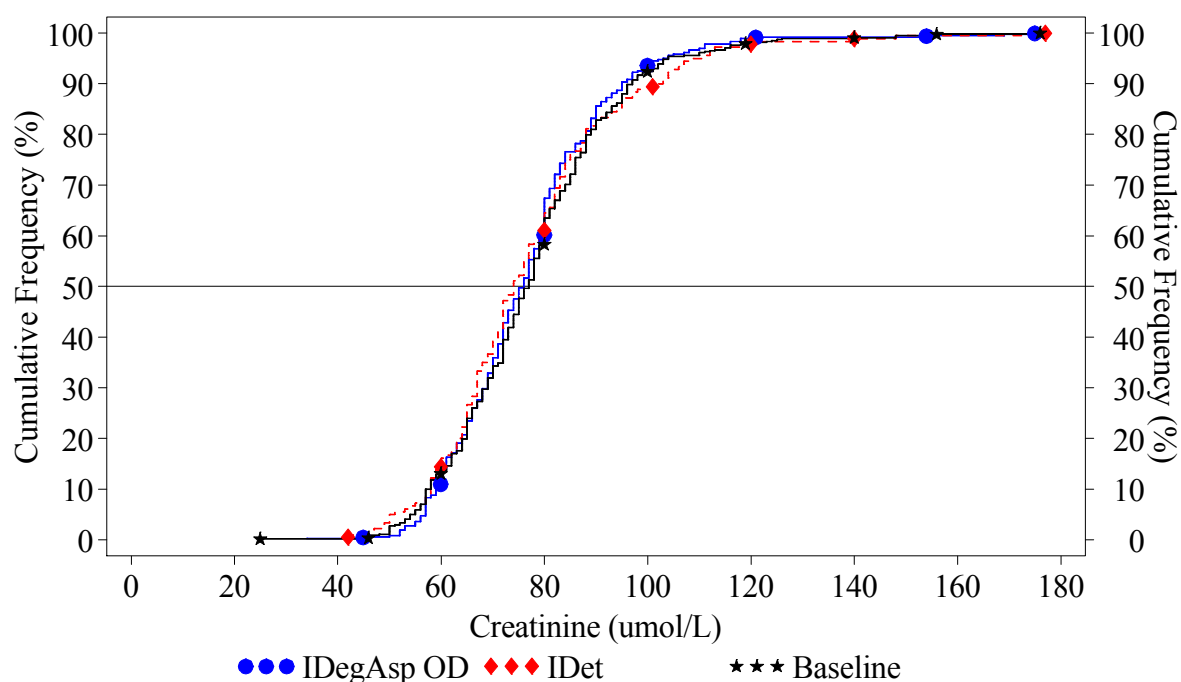
SAFETY: LOCF imputed data

Lower ref.: Male, Age(13-110)[44]; Female, Age(13-110)[35]

Upper ref.: Male, Age(13-110)[115]; Female, Age(13-110)[106]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:05:19 - fbox_numfind_v01.sas/e_crea_abs_box_locf_sas.cgm

14.3.5.17: Biochemistry - Creatinine - Box Plot - Safety Analysis Set



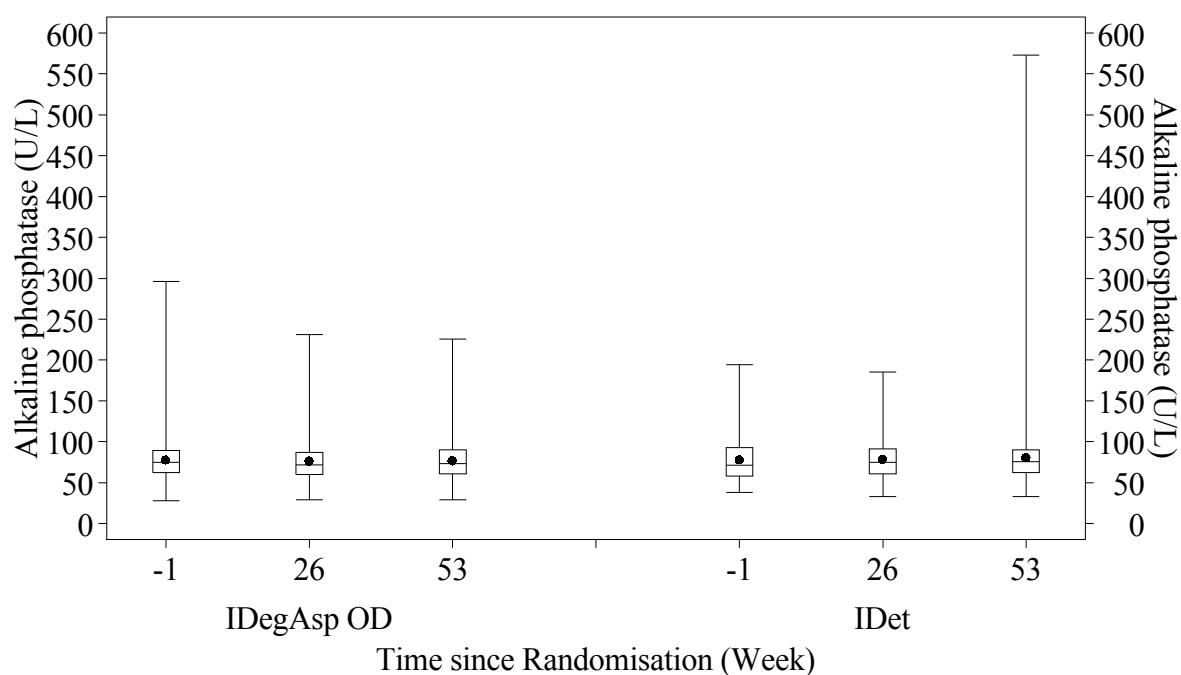
SAFETY: LOCF imputed data

Lower ref.: Male, Age(13-110)[44]; Female, Age(13-110)[35]

Upper ref.: Male, Age(13-110)[115]; Female, Age(13-110)[106]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:05:35 - fedist_numfind_v01.sas/e_crea_abs_cdf_locf_sas.cgm

14.3.5.18: Biochemistry - Creatinine after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

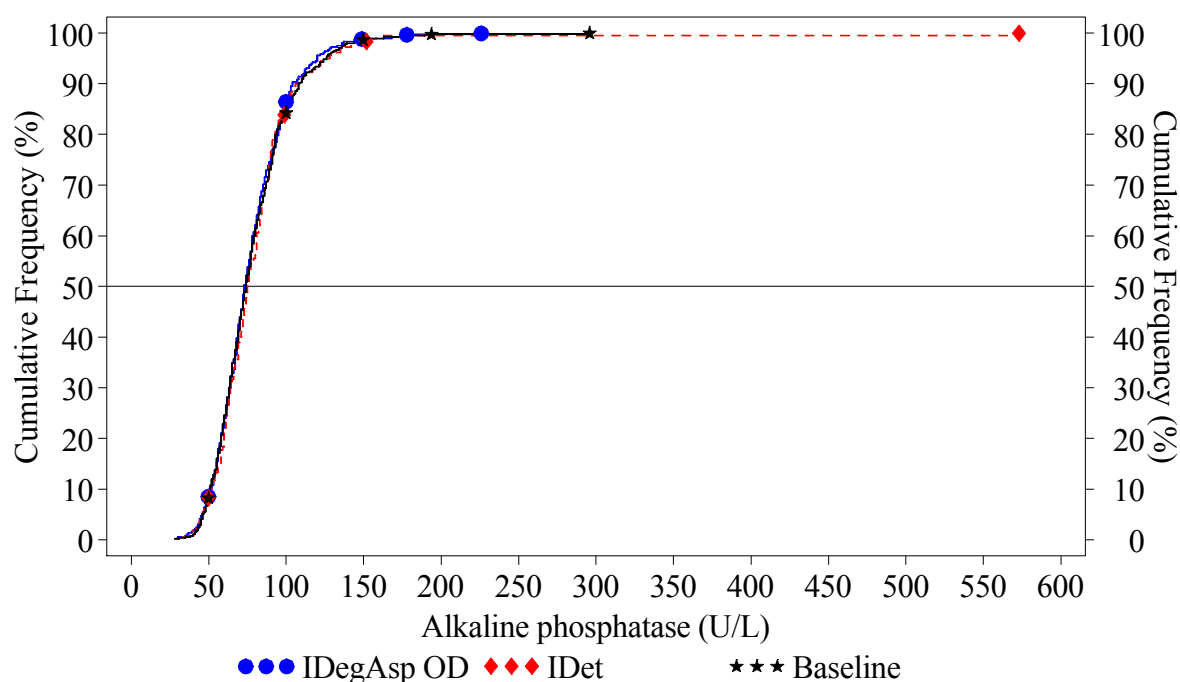
SAFETY: LOCF imputed data

Lower ref.: Male, Age(16-111)[45]; Female, Age(16-111)[40]

Upper ref.: Male, Age(16-111)[145]; Female, Age(16-111)[100]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:05:43 - fbox_numfind_v01.sas/e_alka_phosph_abs_box_locf_sas.cgm

14.3.5.19: Biochemistry - Alkaline phosphatase - Box Plot - Safety Analysis Set

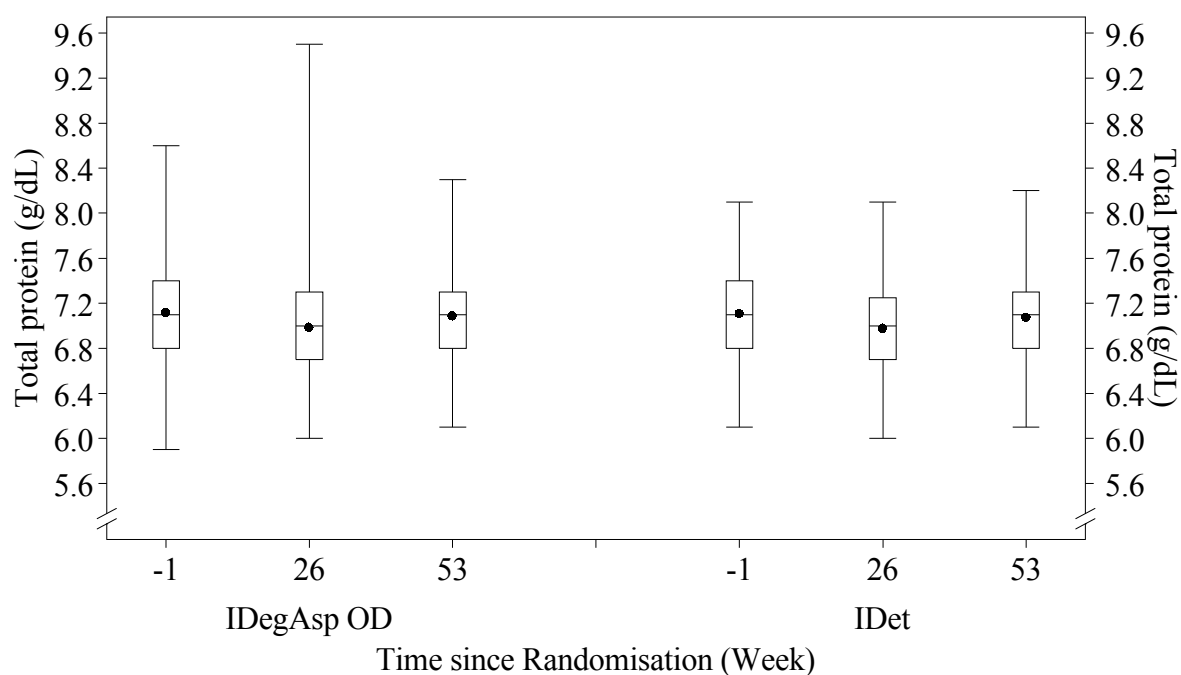


SAFETY: LOCF imputed data

Lower ref.: Male, Age(16-111)[45]; Female, Age(16-111)[40]
Upper ref.: Male, Age(16-111)[145]; Female, Age(16-111)[100]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:05:58 - fedist_numfind_v01.sas/e_alka_phosph_abs_cdf_locf_sas.cgm

14.3.5.20: Biochemistry - Alkaline phosphatase after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

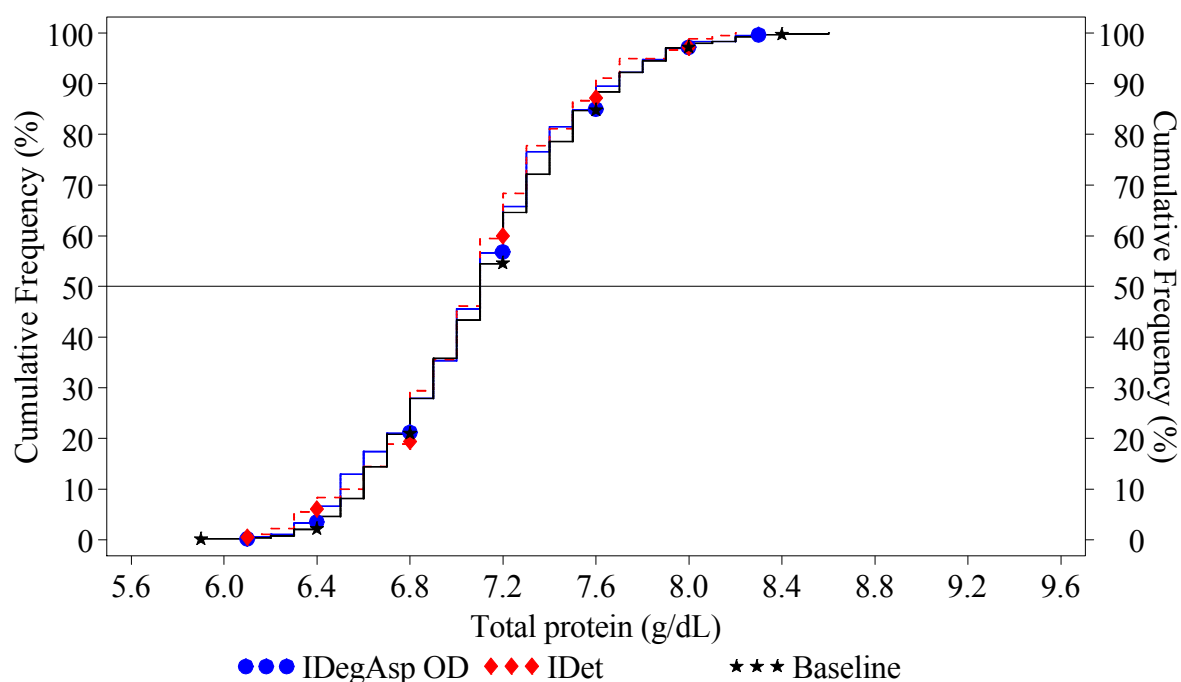
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[6], Age(66-91)[6]; Female, Age(18-66)[6], Age(66-91)[6]

Upper ref.: Male, Age(18-66)[8.4], Age(66-91)[8.3]; Female, Age(18-66)[8.4], Age(66-91)[8.3]

07MAY2011:14:06:07 - fbox_numfind_v01.sas/e_tot_prot_abs_box_locf_sas.cgm
nn5401/nn5401-3594-3645/freeze_ctr_02/stats

14.3.5.21: Biochemistry - Total Protein - Box Plot - Safety Analysis Set



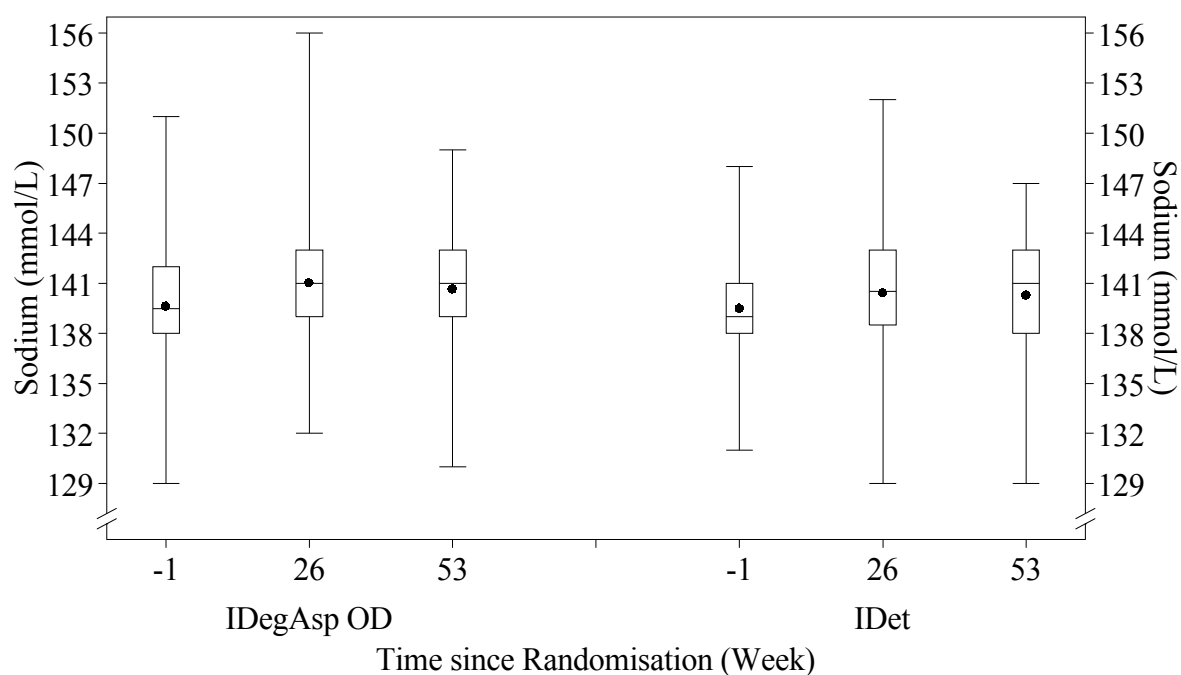
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[6], Age(66-91)[6]; Female, Age(18-66)[6], Age(66-91)[6]

Upper ref.: Male, Age(18-66)[8.4], Age(66-91)[8.3]; Female, Age(18-66)[8.4], Age(66-91)[8.3]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:06:22 - fedist_numfind_v01.sas/e_tot_prot_abs_cdf_locf_sas.cgm

14.3.5.22: Biochemistry - Total Protein after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

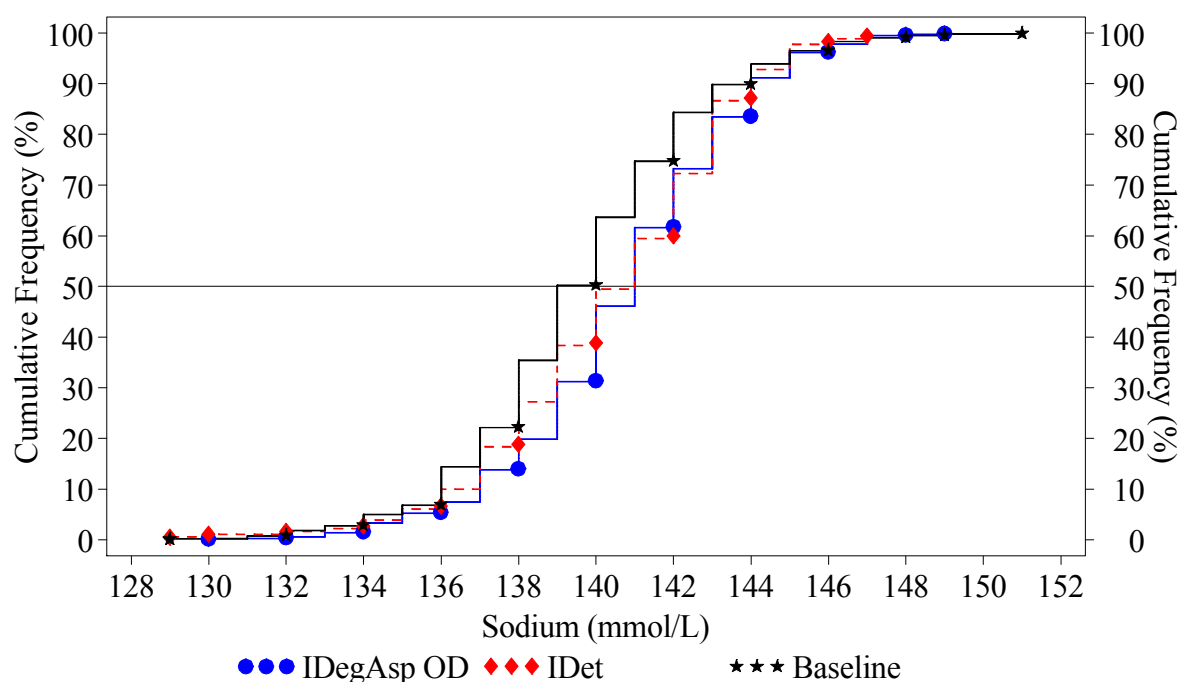
SAFETY: LOCF imputed data

Lower ref.: Male, Age(0-66)[132], Age(66-91)[135]; Female, Age(0-66)[132], Age(66-91)[135]

Upper ref.: Male, Age(0-66)[147], Age(66-91)[148]; Female, Age(0-66)[147], Age(66-91)[148]

07MAY2011:14:06:30 - fbox_numfind_v01.sas/e_sodium_abs_box_locf_sas.cgm

14.3.5.23: Biochemistry - Sodium - Box Plot - Safety Analysis Set

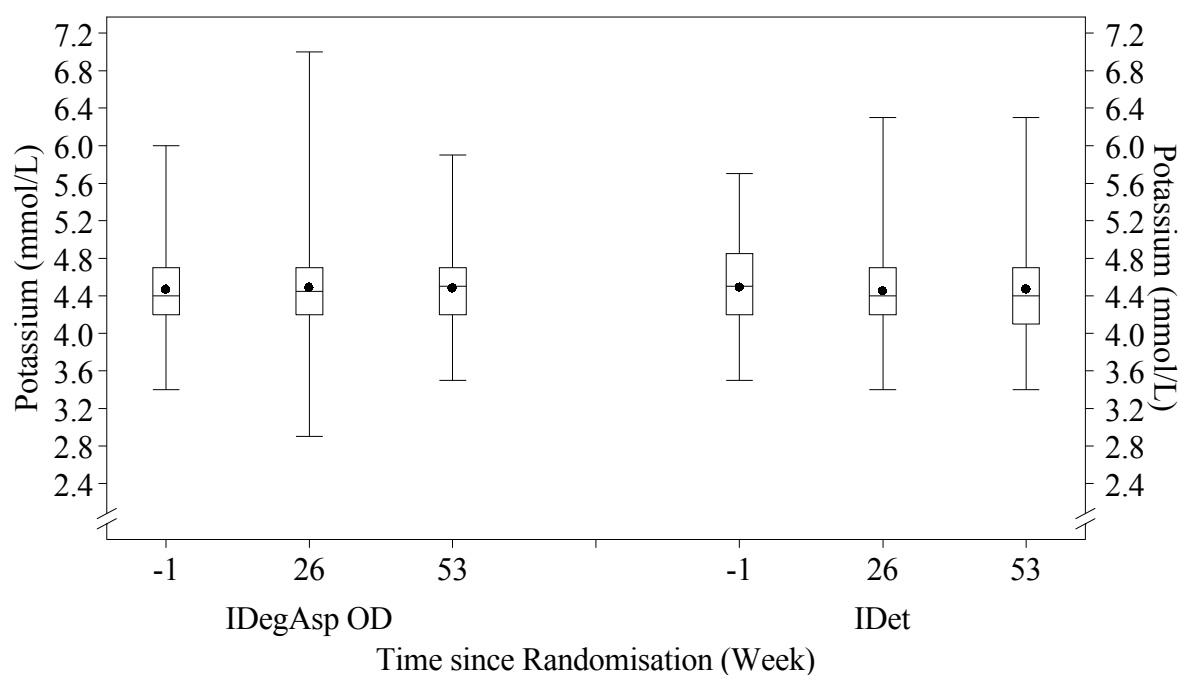


SAFETY: LOCF imputed data

Lower ref.: Male, Age(0-66)[132], Age(66-91)[135]; Female, Age(0-66)[132], Age(66-91)[135]
Upper ref.: Male, Age(0-66)[147], Age(66-91)[148]; Female, Age(0-66)[147], Age(66-91)[148]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:06:46 - fedist_numfind_v01.sas/e_sodium_abs_cdf_locf_sas.cgm

14.3.5.24: Biochemistry - Sodium after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

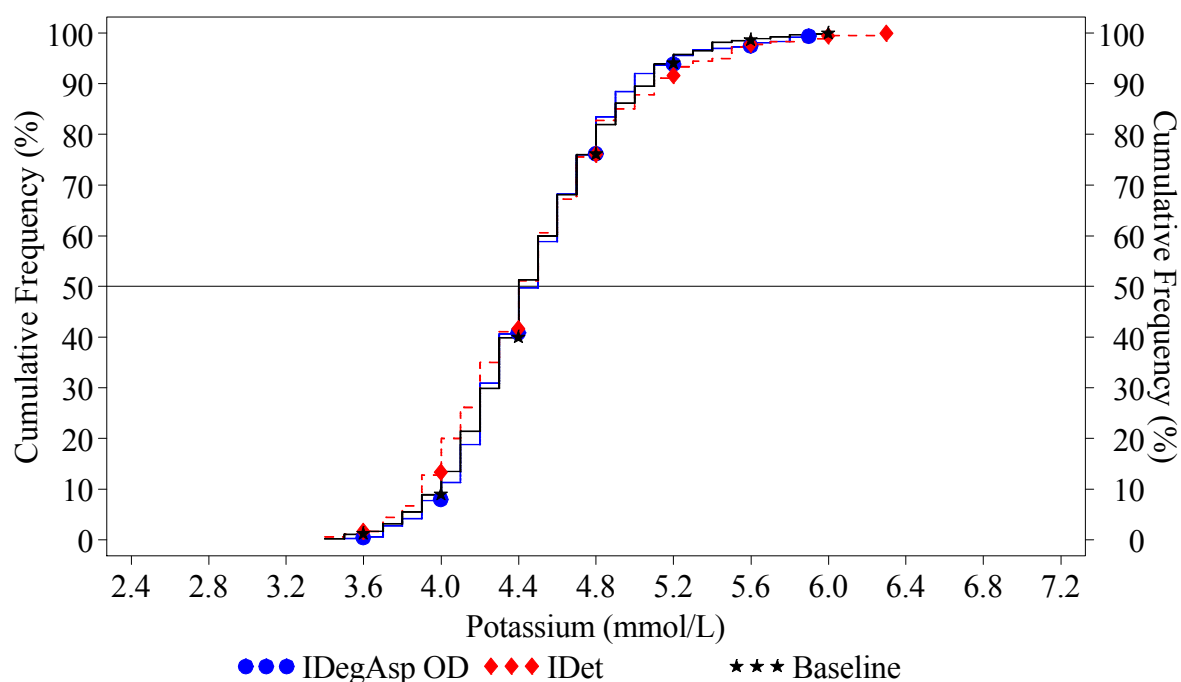
SAFETY: LOCF imputed data

Lower ref.: Male, Age(0-66)[3.5], Age(66-110)[3.6]; Female, Age(0-66)[3.5], Age(66-110)[3.6]

Upper ref.: Male, Age(0-66)[5.5], Age(66-110)[5.5]; Female, Age(0-66)[5.5], Age(66-110)[5.5]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:06:55 - fbox_numfind_v01.sas/e_potas_abs_box_locf_sas.cgm

14.3.5.25: Biochemistry - Potassium - Box Plot - Safety Analysis Set



SAFETY: LOCF imputed data

Lower ref.: Male, Age(0-66)[3.5], Age(66-110)[3.6]; Female, Age(0-66)[3.5], Age(66-110)[3.6]

Upper ref.: Male, Age(0-66)[5.5], Age(66-110)[5.5]; Female, Age(0-66)[5.5], Age(66-110)[5.5]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:10 - fedist_numfind_v01.sas/e_potas_abs_cdf_locf_sas.cgm

14.3.5.26: Biochemistry - Potassium after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.3.5.27: Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Basophils(%)			
Visit 1			
N	359	179	538
Mean (SD)	0.40 (0.24)	0.42 (0.26)	0.41 (0.25)
Median	0.40	0.40	0.40
Min ; Max	0.00 ; 1.80	0.00 ; 1.50	0.00 ; 1.80
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	0.40 (0.23)	0.40 (0.27)	0.40 (0.25)
Median	0.40	0.40	0.40
Min ; Max	0.00 ; 1.90	0.00 ; 1.90	0.00 ; 1.90
Visit 44 (Week 53)			
N	231	113	344
Mean (SD)	0.43 (0.24)	0.44 (0.30)	0.43 (0.26)
Median	0.40	0.40	0.40
Min ; Max	0.00 ; 1.70	0.00 ; 1.80	0.00 ; 1.80
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	0.43 (0.24)	0.44 (0.30)	0.43 (0.26)
Median	0.40	0.40	0.40
Min ; Max	0.00 ; 1.70	0.00 ; 1.80	0.00 ; 1.80

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Eosinophils(%)			
Visit 1			
N	359	179	538
Mean (SD)	2.4 (2.1)	2.6 (2.1)	2.5 (2.1)
Median	1.9	2.1	1.9
Min ; Max	0.1 ; 27.0	0.0 ; 12.3	0.0 ; 27.0
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	2.7 (1.9)	2.9 (2.3)	2.7 (2.0)
Median	2.2	2.3	2.3
Min ; Max	0.1 ; 10.9	0.0 ; 15.3	0.0 ; 15.3
Visit 44 (Week 53)			
N	231	113	344
Mean (SD)	2.7 (1.8)	3.0 (2.4)	2.8 (2.0)
Median	2.2	2.3	2.3
Min ; Max	0.1 ; 11.6	0.0 ; 10.6	0.0 ; 11.6
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	2.7 (1.9)	3.0 (2.4)	2.8 (2.1)
Median	2.2	2.5	2.3
Min ; Max	0.1 ; 11.6	0.0 ; 15.3	0.0 ; 15.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Erythrocytes (10 ¹² /L)			
Visit 1			
N	361	180	541
Mean (SD)	4.6 (0.4)	4.6 (0.5)	4.6 (0.4)
Median	4.6	4.5	4.6
Min ; Max	3.2 ; 6.4	3.1 ; 6.2	3.1 ; 6.4
Visit 28 (Week 26)			
N	317	157	474
Mean (SD)	4.7 (0.4)	4.6 (0.5)	4.6 (0.5)
Median	4.6	4.5	4.6
Min ; Max	3.2 ; 6.2	3.1 ; 6.6	3.1 ; 6.6
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	4.6 (0.4)	4.6 (0.5)	4.6 (0.4)
Median	4.6	4.5	4.6
Min ; Max	3.3 ; 5.8	3.5 ; 6.4	3.3 ; 6.4
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	4.6 (0.4)	4.5 (0.5)	4.6 (0.4)
Median	4.6	4.5	4.6
Min ; Max	3.2 ; 6.2	3.1 ; 6.4	3.1 ; 6.4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Haematocrit(%)			
Visit 1			
N	357	176	533
Mean (SD)	42 (4)	41 (4)	42 (4)
Median	42	42	42
Min ; Max	28 ; 52	29 ; 53	28 ; 53
Visit 28 (Week 26)			
N	299	152	451
Mean (SD)	42 (4)	41 (4)	42 (4)
Median	43	42	42
Min ; Max	30 ; 51	28 ; 52	28 ; 52
Visit 44 (Week 53)			
N	227	110	337
Mean (SD)	42 (4)	42 (4)	42 (4)
Median	43	42	43
Min ; Max	31 ; 54	27 ; 50	27 ; 54
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	42 (4)	41 (4)	42 (4)
Median	43	41	42
Min ; Max	28 ; 54	27 ; 50	27 ; 54

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Haemoglobin (mmol/L)			
Visit 1			
N	361	180	541
Mean (SD)	8.8 (0.8)	8.5 (0.9)	8.7 (0.9)
Median	8.8	8.6	8.7
Min ; Max	5.8 ; 10.6	5.8 ; 10.8	5.8 ; 10.8
Visit 28 (Week 26)			
N	317	157	474
Mean (SD)	8.8 (0.9)	8.6 (0.9)	8.7 (0.9)
Median	8.9	8.7	8.7
Min ; Max	5.9 ; 11.0	5.0 ; 10.7	5.0 ; 11.0
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	8.8 (0.9)	8.6 (0.9)	8.7 (0.9)
Median	8.9	8.7	8.9
Min ; Max	5.8 ; 11.2	5.1 ; 10.5	5.1 ; 11.2
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	8.8 (0.9)	8.5 (0.9)	8.7 (0.9)
Median	8.8	8.6	8.7
Min ; Max	5.8 ; 11.2	5.1 ; 10.5	5.1 ; 11.2

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Lymphocytes blood(%)			
Visit 1			
N	359	179	538
Mean (SD)	29.3 (8.1)	28.3 (8.1)	28.9 (8.1)
Median	29.3	27.7	28.5
Min ; Max	8.1 ; 53.2	12.2 ; 53.0	8.1 ; 53.2
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	30.3 (7.8)	29.4 (8.4)	30.0 (8.0)
Median	30.0	28.7	29.5
Min ; Max	8.9 ; 52.5	12.3 ; 48.1	8.9 ; 52.5
Visit 44 (Week 53)			
N	231	113	344
Mean (SD)	30.2 (7.3)	29.5 (7.9)	29.9 (7.5)
Median	29.4	29.0	29.2
Min ; Max	15.2 ; 52.6	9.7 ; 51.2	9.7 ; 52.6
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	30.4 (7.6)	29.5 (8.2)	30.1 (7.8)
Median	29.4	28.8	29.1
Min ; Max	11.9 ; 57.4	9.7 ; 51.2	9.7 ; 57.4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Monocytes blood(%)			
Visit 1			
N	359	179	538
Mean (SD)	6.0 (2.2)	5.9 (2.1)	6.0 (2.2)
Median	5.9	6.0	5.9
Min ; Max	0.5 ; 13.3	0.2 ; 13.2	0.2 ; 13.3
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	6.2 (2.2)	6.4 (2.3)	6.2 (2.2)
Median	6.0	6.2	6.1
Min ; Max	1.5 ; 14.4	0.5 ; 12.6	0.5 ; 14.4
Visit 44 (Week 53)			
N	231	113	344
Mean (SD)	6.1 (2.1)	6.4 (2.0)	6.2 (2.1)
Median	6.0	6.5	6.1
Min ; Max	0.5 ; 13.0	1.0 ; 12.3	0.5 ; 13.0
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	6.1 (2.2)	6.3 (2.2)	6.2 (2.2)
Median	6.0	6.2	6.0
Min ; Max	0.5 ; 13.0	0.3 ; 12.6	0.3 ; 13.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Neutrophils blood(%)			
Visit 1			
N	359	179	538
Mean (SD)	61.9 (9.4)	62.9 (9.3)	62.2 (9.4)
Median	62.0	64.2	62.3
Min ; Max	36.1 ; 88.2	26.2 ; 84.6	26.2 ; 88.2
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	60.5 (8.8)	60.9 (9.7)	60.6 (9.1)
Median	60.6	61.2	60.7
Min ; Max	31.8 ; 83.4	38.8 ; 82.1	31.8 ; 83.4
Visit 44 (Week 53)			
N	231	113	344
Mean (SD)	60.7 (8.3)	60.7 (9.5)	60.7 (8.7)
Median	61.4	61.1	61.3
Min ; Max	36.4 ; 78.9	32.5 ; 83.0	32.5 ; 83.0
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	60.4 (8.9)	60.8 (9.6)	60.5 (9.2)
Median	61.2	61.2	61.2
Min ; Max	31.8 ; 83.4	32.5 ; 83.0	31.8 ; 83.4

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Thrombocytes (10 ⁹ /L)			
Visit 1			
N	359	180	539
Mean (SD)	247 (58)	252 (59)	249 (59)
Median	242	241	242
Min ; Max	133 ; 532	158 ; 490	133 ; 532
Visit 28 (Week 26)			
N	314	157	471
Mean (SD)	241 (55)	244 (61)	242 (57)
Median	234	231	233
Min ; Max	129 ; 454	128 ; 437	128 ; 454
Visit 44 (Week 53)			
N	233	114	347
Mean (SD)	242 (59)	245 (63)	243 (60)
Median	237	231	233
Min ; Max	116 ; 485	124 ; 479	116 ; 485
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	243 (59)	247 (64)	244 (61)
Median	234	231	233
Min ; Max	116 ; 485	124 ; 479	116 ; 485

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

Haematology by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Leukocytes (10 ⁹ /L)			
Visit 1			
N	361	180	541
Mean (SD)	6.8 (2.0)	6.6 (1.8)	6.8 (1.9)
Median	6.5	6.3	6.4
Min ; Max	3.1 ; 13.9	3.3 ; 12.6	3.1 ; 13.9
Visit 28 (Week 26)			
N	316	157	473
Mean (SD)	6.5 (1.8)	6.3 (1.6)	6.5 (1.7)
Median	6.2	6.1	6.2
Min ; Max	3.5 ; 13.8	3.4 ; 14.4	3.4 ; 14.4
Visit 44 (Week 53)			
N	234	114	348
Mean (SD)	6.6 (1.8)	6.3 (1.8)	6.5 (1.8)
Median	6.3	6.0	6.2
Min ; Max	3.7 ; 12.2	3.5 ; 12.6	3.5 ; 12.6
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	6.7 (1.8)	6.4 (1.6)	6.6 (1.8)
Median	6.3	6.1	6.3
Min ; Max	3.5 ; 12.8	3.5 ; 12.6	3.5 ; 12.8

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:20 - tdesc_numfind_tpl_t019_v01.sas/t_haem_abs_descp_sas.txt

14.3.5.28: Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Basophils Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	-0.0 (0.3)	-0.0 (0.3)	-0.0 (0.3)
Median	0.0	0.0	0.0
Min ; Max	-1.5 ; 1.1	-1.2 ; 1.4	-1.5 ; 1.4
Visit 44 (Week 53)			
N	230	112	342
Mean (SD)	0.0 (0.3)	0.0 (0.3)	0.0 (0.3)
Median	0.0	0.0	0.0
Min ; Max	-1.6 ; 1.2	-1.0 ; 1.6	-1.6 ; 1.6
Visit 44 (Week 53) (LOCF)			
N	359	179	538
Mean (SD)	0.0 (0.3)	0.0 (0.4)	0.0 (0.3)
Median	0.0	0.0	0.0
Min ; Max	-1.6 ; 1.2	-1.0 ; 1.6	-1.6 ; 1.6

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Eosinophils Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	0.3 (2.1)	0.3 (1.8)	0.3 (2.0)
Median	0.3	0.2	0.2
Min ; Max	-17.4 ; 9.2	-6.4 ; 6.7	-17.4 ; 9.2
Visit 44 (Week 53)			
N	230	112	342
Mean (SD)	0.2 (2.0)	0.4 (2.0)	0.3 (2.0)
Median	0.4	0.1	0.3
Min ; Max	-16.5 ; 5.8	-4.1 ; 7.4	-16.5 ; 7.4
Visit 44 (Week 53) (LOCF)			
N	359	179	538
Mean (SD)	0.3 (1.8)	0.5 (1.8)	0.3 (1.8)
Median	0.3	0.2	0.2
Min ; Max	-16.5 ; 6.3	-4.1 ; 7.4	-16.5 ; 7.4

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Erythrocytes Blood($10^{12}/L$)			
Visit 28 (Week 26)			
N	316	157	473
Mean (SD)	0.0 (0.2)	-0.0 (0.2)	-0.0 (0.2)
Median	0.0	0.0	0.0
Min ; Max	-0.8 ; 0.9	-0.7 ; 0.7	-0.8 ; 0.9
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	-0.0 (0.2)	-0.0 (0.2)	-0.0 (0.2)
Median	0.0	0.0	0.0
Min ; Max	-0.9 ; 0.7	-0.9 ; 0.6	-0.9 ; 0.7
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	-0.0 (0.2)	-0.0 (0.3)	-0.0 (0.2)
Median	0.0	0.0	0.0
Min ; Max	-0.9 ; 0.7	-0.9 ; 0.9	-0.9 ; 0.9

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Haematocrit Blood(%)			
Visit 28 (Week 26)			
N	294	149	443
Mean (SD)	0.2 (2.2)	-0.1 (2.2)	0.1 (2.2)
Median	0.3	0.0	0.2
Min ; Max	-6.8 ; 8.5	-6.1 ; 6.7	-6.8 ; 8.5
Visit 44 (Week 53)			
N	224	107	331
Mean (SD)	-0.0 (2.4)	0.2 (2.3)	0.1 (2.4)
Median	-0.1	0.5	0.1
Min ; Max	-8.4 ; 6.3	-8.0 ; 5.8	-8.4 ; 6.3
Visit 44 (Week 53) (LOCF)			
N	357	176	533
Mean (SD)	0.1 (2.3)	0.1 (2.3)	0.1 (2.3)
Median	0.1	0.0	0.0
Min ; Max	-8.4 ; 7.7	-8.0 ; 7.9	-8.4 ; 7.9

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Haemoglobin Blood (mmol/L)			
Visit 28 (Week 26)			
N	316	157	473
Mean (SD)	0.0 (0.5)	-0.0 (0.4)	0.0 (0.5)
Median	0.1	0.0	0.1
Min ; Max	-1.6 ; 2.0	-1.1 ; 1.2	-1.6 ; 2.0
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	-0.0 (0.5)	0.0 (0.5)	-0.0 (0.5)
Median	-0.1	0.1	0.0
Min ; Max	-1.7 ; 1.4	-1.4 ; 1.2	-1.7 ; 1.4
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	-0.0 (0.5)	-0.0 (0.5)	-0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-1.7 ; 1.4	-1.4 ; 1.4	-1.7 ; 1.4

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Lymphocytes Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	1.1 (8.0)	1.0 (8.0)	1.1 (8.0)
Median	0.8	1.5	1.1
Min ; Max	-28.0 ; 40.7	-20.5 ; 28.3	-28.0 ; 40.7
Visit 44 (Week 53)			
N	230	112	342
Mean (SD)	1.4 (8.1)	1.5 (8.2)	1.5 (8.1)
Median	1.3	2.0	1.6
Min ; Max	-23.5 ; 26.4	-25.7 ; 23.1	-25.7 ; 26.4
Visit 44 (Week 53) (LOCF)			
N	359	179	538
Mean (SD)	1.1 (7.8)	1.2 (7.9)	1.1 (7.8)
Median	0.8	1.8	1.0
Min ; Max	-23.5 ; 27.2	-25.7 ; 23.1	-25.7 ; 27.2

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Monocytes Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	0.2 (2.1)	0.4 (2.3)	0.3 (2.1)
Median	0.1	0.4	0.2
Min ; Max	-7.7 ; 9.0	-7.8 ; 9.8	-7.8 ; 9.8
Visit 44 (Week 53)			
N	230	112	342
Mean (SD)	0.2 (2.0)	0.3 (2.0)	0.2 (2.0)
Median	0.1	0.4	0.2
Min ; Max	-6.5 ; 8.7	-7.8 ; 5.4	-7.8 ; 8.7
Visit 44 (Week 53) (LOCF)			
N	359	179	538
Mean (SD)	0.1 (2.0)	0.4 (2.2)	0.2 (2.0)
Median	0.0	0.3	0.1
Min ; Max	-7.7 ; 8.7	-7.8 ; 9.8	-7.8 ; 9.8

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Neutrophils Blood(%)			
Visit 28 (Week 26)			
N	312	156	468
Mean (SD)	-1.6 (9.3)	-1.7 (9.6)	-1.6 (9.4)
Median	-0.8	-1.9	-1.3
Min ; Max	-47.6 ; 31.3	-32.4 ; 22.1	-47.6 ; 31.3
Visit 44 (Week 53)			
N	230	112	342
Mean (SD)	-1.9 (9.3)	-2.3 (9.5)	-2.0 (9.4)
Median	-1.3	-2.6	-1.7
Min ; Max	-33.3 ; 24.2	-23.6 ; 24.8	-33.3 ; 24.8
Visit 44 (Week 53) (LOCF)			
N	359	179	538
Mean (SD)	-1.5 (9.1)	-2.1 (9.2)	-1.7 (9.2)
Median	-0.9	-1.8	-1.2
Min ; Max	-33.3 ; 24.2	-23.6 ; 24.8	-33.3 ; 24.8

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Thrombocytes Blood($10^9/L$)			
Visit 28 (Week 26)			
N	312	157	469
Mean (SD)	-7.6 (35.7)	-9.9 (34.8)	-8.4 (35.4)
Median	-7.0	-14.0	-8.0
Min ; Max	-224 ; 92.0	-91.0 ; 170.0	-224 ; 170.0
Visit 44 (Week 53)			
N	233	114	347
Mean (SD)	-4.0 (34.8)	-4.9 (43.3)	-4.3 (37.7)
Median	-5.0	-5.0	-5.0
Min ; Max	-203 ; 134.0	-161 ; 151.0	-203 ; 151.0
Visit 44 (Week 53) (LOCF)			
N	359	180	539
Mean (SD)	-4.0 (34.8)	-5.1 (40.1)	-4.4 (36.6)
Median	-2.0	-6.0	-4.0
Min ; Max	-203 ; 134.0	-161 ; 151.0	-203 ; 151.0

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

Haematology by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Leukocytes Blood(10 ⁹ /L)			
Visit 28 (Week 26)			
N	315	157	472
Mean (SD)	-0.3 (1.7)	-0.3 (1.6)	-0.3 (1.7)
Median	-0.3	-0.1	-0.2
Min ; Max	-7.6 ; 5.3	-6.2 ; 5.2	-7.6 ; 5.3
Visit 44 (Week 53)			
N	234	114	348
Mean (SD)	-0.2 (1.8)	-0.2 (1.6)	-0.2 (1.7)
Median	0.0	-0.2	-0.0
Min ; Max	-7.6 ; 6.3	-6.3 ; 7.1	-7.6 ; 7.1
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	-0.2 (1.7)	-0.2 (1.5)	-0.2 (1.7)
Median	0.0	-0.1	0.0
Min ; Max	-7.6 ; 6.3	-6.3 ; 7.1	-7.6 ; 7.1

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:30 - tdesc_numfind_tpl_t019_v01.sas/t_haem_chb_descp_sas.txt

14.3.5.29: Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Basophils (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Normal	359 (100.0)	179 (100.0)	538 (100.0)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Normal	314 (100.0)	157 (100.0)	471 (100.0)
Visit 30 (Week 27)			
N	4 (100.0)	4 (100.0)	8 (100.0)
Normal	4 (100.0)	4 (100.0)	8 (100.0)
Visit 44 (Week 53)			
N	231 (100.0)	113 (100.0)	344 (100.0)
Normal	231 (100.0)	113 (100.0)	344 (100.0)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Normal	361 (100.0)	180 (100.0)	541 (100.0)
Eosinophils (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Normal	341 (95.0)	170 (95.0)	511 (95.0)
High	18 (5.0)	9 (5.0)	27 (5.0)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Normal	296 (94.3)	144 (91.7)	440 (93.4)
High	18 (5.7)	13 (8.3)	31 (6.6)
Visit 30 (Week 27)			
N	4 (100.0)	4 (100.0)	8 (100.0)
Normal	4 (100.0)	4 (100.0)	8 (100.0)
Visit 44 (Week 53)			
N	231 (100.0)	113 (100.0)	344 (100.0)
Normal	221 (95.7)	102 (90.3)	323 (93.9)
High	10 (4.3)	11 (9.7)	21 (6.1)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Normal	342 (94.7)	164 (91.1)	506 (93.5)
High	19 (5.3)	16 (8.9)	35 (6.5)
Erythrocytes (10 ¹² /L)			
Visit 1			

N = Number of Subjects

Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	11 (3.0)	6 (3.3)	17 (3.1)
Normal	349 (96.7)	171 (95.0)	520 (96.1)
High	1 (0.3)	3 (1.7)	4 (0.7)
Visit 28 (Week 26)			
N	317 (100.0)	157 (100.0)	474 (100.0)
Low	7 (2.2)	5 (3.2)	12 (2.5)
Normal	309 (97.5)	150 (95.5)	459 (96.8)
High	1 (0.3)	2 (1.3)	3 (0.6)
Visit 30 (Week 27)			
N	4 (100.0)	4 (100.0)	8 (100.0)
Normal	4 (100.0)	3 (75.0)	7 (87.5)
High	0	1 (25.0)	1 (12.5)
Visit 44 (Week 53)			
N	235 (100.0)	114 (100.0)	349 (100.0)
Low	8 (3.4)	3 (2.6)	11 (3.2)
Normal	227 (96.6)	109 (95.6)	336 (96.3)
High	0	2 (1.8)	2 (0.6)
Visit 44 Week 53(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	9 (2.5)	7 (3.9)	16 (3.0)
Normal	352 (97.2)	171 (95.0)	523 (96.5)
High	1 (0.3)	2 (1.1)	3 (0.6)
Haematocrit (%)			
Visit 1			
N	357 (100.0)	176 (100.0)	533 (100.0)
Low	23 (6.4)	20 (11.4)	43 (8.1)
Normal	332 (93.0)	155 (88.1)	487 (91.4)
High	2 (0.6)	1 (0.6)	3 (0.6)
Visit 28 (Week 26)			
N	299 (100.0)	152 (100.0)	451 (100.0)
Low	17 (5.7)	9 (5.9)	26 (5.8)
Normal	282 (94.3)	143 (94.1)	425 (94.2)
Visit 30 (Week 27)			
N	12 (100.0)	7 (100.0)	19 (100.0)
Low	0	1 (14.3)	1 (5.3)
Normal	12 (100.0)	6 (85.7)	18 (94.7)
Visit 44 (Week 53)			
N	227 (100.0)	110 (100.0)	337 (100.0)
Low	16 (7.0)	8 (7.3)	24 (7.1)
Normal	210 (92.5)	101 (91.8)	311 (92.3)
High	1 (0.4)	1 (0.9)	2 (0.6)
Visit 44 Week 53(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	22 (6.1)	15 (8.3)	37 (6.8)
Normal	339 (93.6)	164 (91.1)	503 (92.8)

N = Number of Subjects

Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
High	1 (0.3)	1 (0.6)	2 (0.4)
Haemoglobin (mmol/L)			
Visit 1			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	14 (3.9)	14 (7.8)	28 (5.2)
Normal	346 (95.8)	166 (92.2)	512 (94.6)
High	1 (0.3)	0	1 (0.2)
Visit 28 (Week 26)			
N	317 (100.0)	157 (100.0)	474 (100.0)
Low	16 (5.0)	14 (8.9)	30 (6.3)
Normal	300 (94.6)	143 (91.1)	443 (93.5)
High	1 (0.3)	0	1 (0.2)
Visit 30 (Week 27)			
N	4 (100.0)	4 (100.0)	8 (100.0)
Normal	4 (100.0)	4 (100.0)	8 (100.0)
Visit 44 (Week 53)			
N	235 (100.0)	114 (100.0)	349 (100.0)
Low	15 (6.4)	6 (5.3)	21 (6.0)
Normal	218 (92.8)	108 (94.7)	326 (93.4)
High	2 (0.9)	0	2 (0.6)
Visit 44 Week 53(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	19 (5.2)	15 (8.3)	34 (6.3)
Normal	340 (93.9)	165 (91.7)	505 (93.2)
High	3 (0.8)	0	3 (0.6)
Leukocytes (10 ⁹ /L)			
Visit 1			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	12 (3.3)	8 (4.4)	20 (3.7)
Normal	343 (95.0)	171 (95.0)	514 (95.0)
High	6 (1.7)	1 (0.6)	7 (1.3)
Visit 28 (Week 26)			
N	316 (100.0)	157 (100.0)	473 (100.0)
Low	12 (3.8)	9 (5.7)	21 (4.4)
Normal	302 (95.6)	147 (93.6)	449 (94.9)
High	2 (0.6)	1 (0.6)	3 (0.6)
Visit 30 (Week 27)			
N	4 (100.0)	4 (100.0)	8 (100.0)
Normal	4 (100.0)	4 (100.0)	8 (100.0)
Visit 44 (Week 53)			
N	234 (100.0)	114 (100.0)	348 (100.0)
Low	13 (5.6)	7 (6.1)	20 (5.7)
Normal	221 (94.4)	105 (92.1)	326 (93.7)
High	0	2 (1.8)	2 (0.6)

N = Number of Subjects

Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Visit 44 Week 53 (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Low	16 (4.4)	8 (4.4)	24 (4.4)
Normal	344 (95.0)	170 (94.4)	514 (94.8)
High	2 (0.6)	2 (1.1)	4 (0.7)
Lymphocytes blood (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Low	16 (4.5)	6 (3.4)	22 (4.1)
Normal	335 (93.3)	168 (93.9)	503 (93.5)
High	8 (2.2)	5 (2.8)	13 (2.4)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Low	7 (2.2)	7 (4.5)	14 (3.0)
Normal	301 (95.9)	147 (93.6)	448 (95.1)
High	6 (1.9)	3 (1.9)	9 (1.9)
Visit 30 (Week 27)			
N	4 (100.0)	4 (100.0)	8 (100.0)
Low	0	1 (25.0)	1 (12.5)
Normal	4 (100.0)	3 (75.0)	7 (87.5)
Visit 44 (Week 53)			
N	231 (100.0)	113 (100.0)	344 (100.0)
Low	1 (0.4)	4 (3.5)	5 (1.5)
Normal	223 (96.5)	106 (93.8)	329 (95.6)
High	7 (3.0)	3 (2.7)	10 (2.9)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	4 (1.1)	7 (3.9)	11 (2.0)
Normal	347 (96.1)	169 (93.9)	516 (95.4)
High	10 (2.8)	4 (2.2)	14 (2.6)
Monocytes blood (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Low	30 (8.4)	15 (8.4)	45 (8.4)
Normal	326 (90.8)	163 (91.1)	489 (90.9)
High	3 (0.8)	1 (0.6)	4 (0.7)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Low	20 (6.4)	8 (5.1)	28 (5.9)
Normal	291 (92.7)	148 (94.3)	439 (93.2)
High	3 (1.0)	1 (0.6)	4 (0.8)
Visit 30 (Week 27)			
N	4 (100.0)	4 (100.0)	8 (100.0)
Normal	4 (100.0)	4 (100.0)	8 (100.0)
Visit 44 (Week 53)			

N = Number of Subjects

Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
N	231 (100.0)	113 (100.0)	344 (100.0)
Low	15 (6.5)	5 (4.4)	20 (5.8)
Normal	215 (93.1)	108 (95.6)	323 (93.9)
High	1 (0.4)	0	1 (0.3)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	29 (8.0)	9 (5.0)	38 (7.0)
Normal	330 (91.4)	170 (94.4)	500 (92.4)
High	2 (0.6)	1 (0.6)	3 (0.6)
Neutrophils blood (%)			
Visit 1			
N	359 (100.0)	179 (100.0)	538 (100.0)
Low	5 (1.4)	3 (1.7)	8 (1.5)
Normal	334 (93.0)	167 (93.3)	501 (93.1)
High	20 (5.6)	9 (5.0)	29 (5.4)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Low	7 (2.2)	4 (2.5)	11 (2.3)
Normal	299 (95.2)	146 (93.0)	445 (94.5)
High	8 (2.5)	7 (4.5)	15 (3.2)
Visit 30 (Week 27)			
N	4 (100.0)	4 (100.0)	8 (100.0)
Normal	4 (100.0)	4 (100.0)	8 (100.0)
Visit 44 (Week 53)			
N	231 (100.0)	113 (100.0)	344 (100.0)
Low	6 (2.6)	3 (2.7)	9 (2.6)
Normal	222 (96.1)	104 (92.0)	326 (94.8)
High	3 (1.3)	6 (5.3)	9 (2.6)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	10 (2.8)	6 (3.3)	16 (3.0)
Normal	344 (95.3)	165 (91.7)	509 (94.1)
High	7 (1.9)	9 (5.0)	16 (3.0)
Thrombocytes (10 ⁹ /L)			
Visit 1			
N	359 (100.0)	180 (100.0)	539 (100.0)
Low	4 (1.1)	0	4 (0.7)
Normal	352 (98.1)	179 (99.4)	531 (98.5)
High	3 (0.8)	1 (0.6)	4 (0.7)
Visit 28 (Week 26)			
N	314 (100.0)	157 (100.0)	471 (100.0)
Low	3 (1.0)	1 (0.6)	4 (0.8)
Normal	310 (98.7)	156 (99.4)	466 (98.9)
High	1 (0.3)	0	1 (0.2)
Visit 30 (Week 27)			

N = Number of Subjects

Haematology by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
N	3 (100.0)	4 (100.0)	7 (100.0)
Normal	3 (100.0)	4 (100.0)	7 (100.0)
Visit 44 (Week 53)			
N	233 (100.0)	114 (100.0)	347 (100.0)
Low	2 (0.9)	1 (0.9)	3 (0.9)
Normal	230 (98.7)	110 (96.5)	340 (98.0)
High	1 (0.4)	3 (2.6)	4 (1.2)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	3 (0.8)	1 (0.6)	4 (0.7)
Normal	357 (98.9)	176 (97.8)	533 (98.5)
High	1 (0.3)	3 (1.7)	4 (0.7)

N = Number of Subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:38:28 - tsum_lab_summary.sas/t_haem_sum_sas.txt

14.3.5.30: Haematology – Shift Table – Baseline to Week 53 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 44 (Week 53)								
Basophils (%)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	230 (63.5)	0 (0.0)	1 (0.3)	0 (0.0)	112 (62.2)	0 (0.0)	1 (0.6)
High	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	129 (35.6)	0 (0.0)	2 (0.6)	0 (0.0)	67 (37.2)	0 (0.0)	0 (0.0)
Eosinophils (%)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	212 (58.6)	8 (2.2)	1 (0.3)	0 (0.0)	99 (55.0)	2 (1.1)	1 (0.6)
High	0 (0.0)	5 (1.4)	5 (1.4)	0 (0.0)	0 (0.0)	7 (3.9)	4 (2.2)	0 (0.0)
Missing	0 (0.0)	124 (34.3)	5 (1.4)	2 (0.6)	0 (0.0)	64 (35.6)	3 (1.7)	0 (0.0)
Erythrocytes (10 ¹² /L)								
Low	6 (1.7)	2 (0.6)	0 (0.0)	0 (0.0)	2 (1.1)	1 (0.6)	0 (0.0)	0 (0.0)
Normal	1 (0.3)	226 (62.4)	0 (0.0)	0 (0.0)	2 (1.1)	106 (58.9)	1 (0.6)	0 (0.0)
High	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)
Missing	4 (1.1)	121 (33.4)	1 (0.3)	1 (0.3)	2 (1.1)	64 (35.6)	0 (0.0)	0 (0.0)
Haematocrit (%)								
Low	9 (2.5)	6 (1.7)	0 (0.0)	1 (0.3)	5 (2.8)	3 (1.7)	0 (0.0)	0 (0.0)
Normal	8 (2.2)	200 (55.2)	0 (0.0)	2 (0.6)	6 (3.3)	91 (50.6)	1 (0.6)	3 (1.7)
High	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Missing	6 (1.7)	125 (34.5)	2 (0.6)	2 (0.6)	9 (5.0)	60 (33.3)	0 (0.0)	1 (0.6)

N = Number of subjects

Haematology - Shift Table - Baseline to Week 53 - Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 44 (Week 53)								
Haemoglobin (mmol/L)								
Low	6 (1.7)	9 (2.5)	0 (0.0)	0 (0.0)	5 (2.8)	1 (0.6)	0 (0.0)	0 (0.0)
Normal	2 (0.6)	216 (59.7)	0 (0.0)	0 (0.0)	3 (1.7)	105 (58.3)	0 (0.0)	0 (0.0)
High	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	6 (1.7)	119 (32.9)	1 (0.3)	1 (0.3)	6 (3.3)	60 (33.3)	0 (0.0)	0 (0.0)
Leukocytes (10 ⁹ /L)								
Low	2 (0.6)	11 (3.0)	0 (0.0)	0 (0.0)	3 (1.7)	4 (2.2)	0 (0.0)	0 (0.0)
Normal	5 (1.4)	215 (59.4)	1 (0.3)	0 (0.0)	4 (2.2)	100 (55.6)	1 (0.6)	0 (0.0)
High	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)
Missing	5 (1.4)	117 (32.3)	5 (1.4)	1 (0.3)	1 (0.6)	65 (36.1)	0 (0.0)	0 (0.0)
Lymphocytes blood (%)								
Low	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.6)	3 (1.7)	0 (0.0)	0 (0.0)
Normal	13 (3.6)	206 (56.9)	3 (0.8)	1 (0.3)	3 (1.7)	101 (56.1)	1 (0.6)	1 (0.6)
High	0 (0.0)	7 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	1 (0.6)	0 (0.0)
Missing	3 (0.8)	121 (33.4)	5 (1.4)	2 (0.6)	2 (1.1)	62 (34.4)	3 (1.7)	0 (0.0)
Monocytes blood (%)								
Low	5 (1.4)	10 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.8)	0 (0.0)	0 (0.0)
Normal	18 (5.0)	195 (53.9)	1 (0.3)	1 (0.3)	6 (3.3)	100 (55.6)	1 (0.6)	1 (0.6)
High	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	7 (1.9)	121 (33.4)	1 (0.3)	2 (0.6)	9 (5.0)	58 (32.2)	0 (0.0)	0 (0.0)

N = Number of subjects

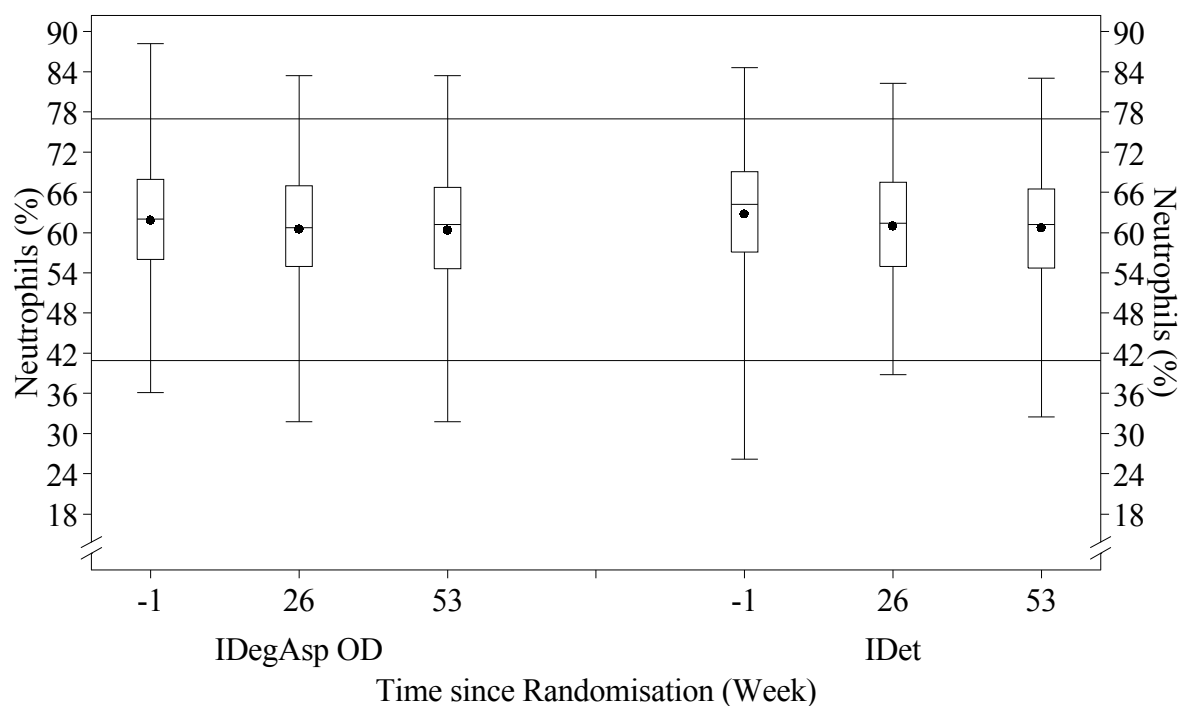
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:14 - t_lab_shift.sas/t_haem_shift_w53_sas.txt

Haematology - Shift Table - Baseline to Week 53 - Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 44 (Week 53)								
Neutrophils blood (%)								
Low	0 (0.0)	6 (1.7)	0 (0.0)	0 (0.0)	1 (0.6)	2 (1.1)	0 (0.0)	0 (0.0)
Normal	3 (0.8)	202 (55.8)	16 (4.4)	1 (0.3)	0 (0.0)	98 (54.4)	5 (2.8)	1 (0.6)
High	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	6 (3.3)	0 (0.0)	0 (0.0)
Missing	2 (0.6)	123 (34.0)	4 (1.1)	2 (0.6)	2 (1.1)	61 (33.9)	4 (2.2)	0 (0.0)
Thrombocytes (10 ⁹ /L)								
Low	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Normal	2 (0.6)	226 (62.4)	2 (0.6)	0 (0.0)	0 (0.0)	110 (61.1)	0 (0.0)	0 (0.0)
High	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
Missing	1 (0.3)	124 (34.3)	1 (0.3)	3 (0.8)	0 (0.0)	65 (36.1)	1 (0.6)	0 (0.0)

N = Number of subjects

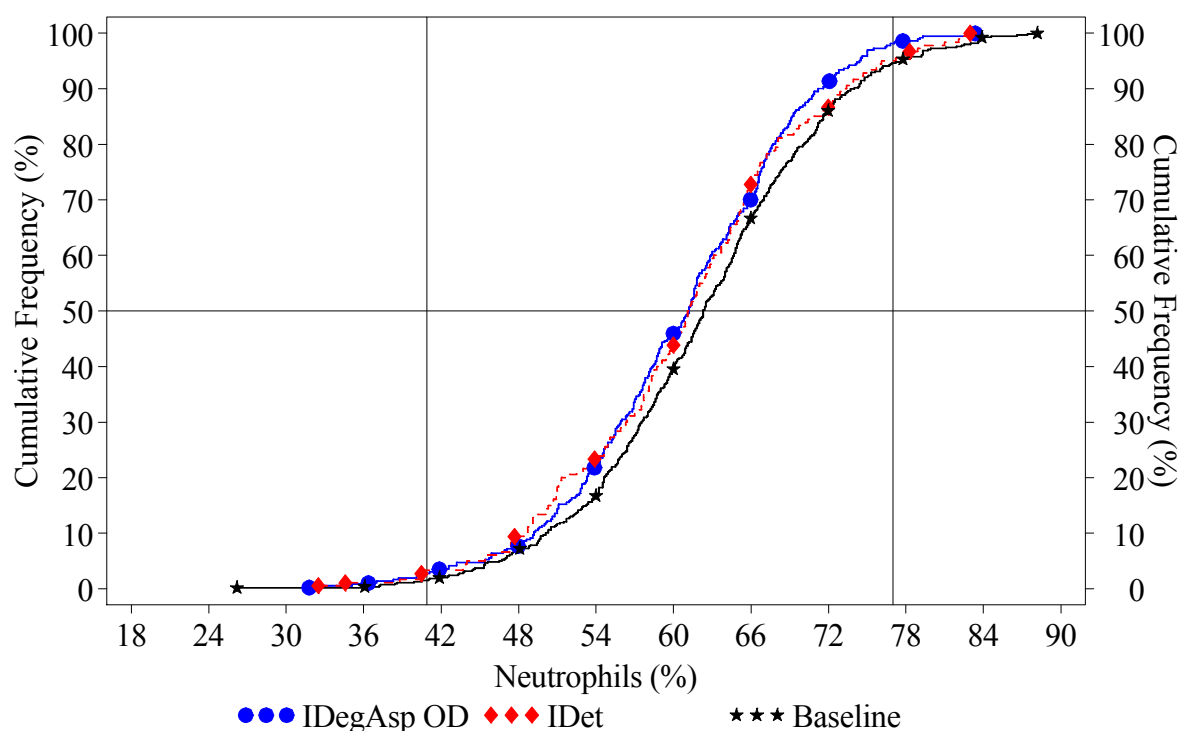
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:14 - t_lab_shift.sas/t_haem_shift_w53_sas.txt



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:38 - fbox_numfind_v01.sas/e_neutrophils_abs_box_locf_sas.cgm

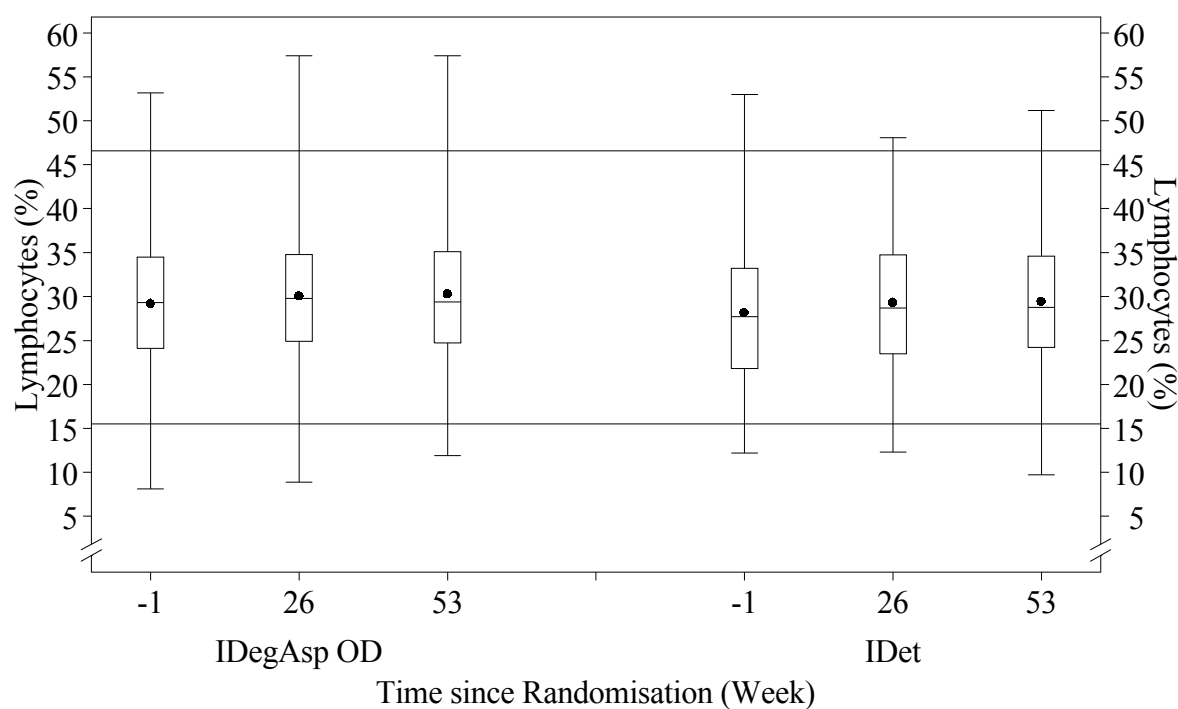
14.3.5.31: Haematology - Neutrophils - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:07:53 - fedist_numfind_v01.sas/e_neutrophils_abs_cdf_locf_sas.cgm

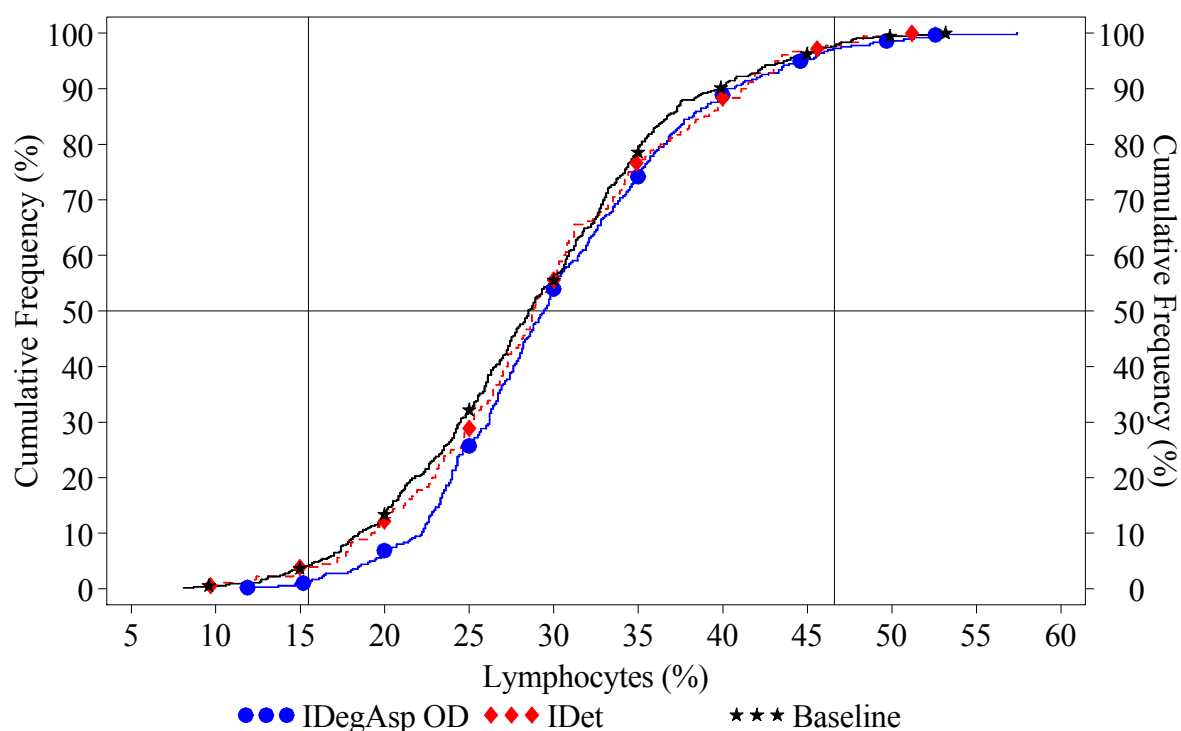
14.3.5.32: Haematology - Neutrophils after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:08:02 - fbox_numfind_v01.sas/e_lymphocytes_abs_box_locf_sas.cgm

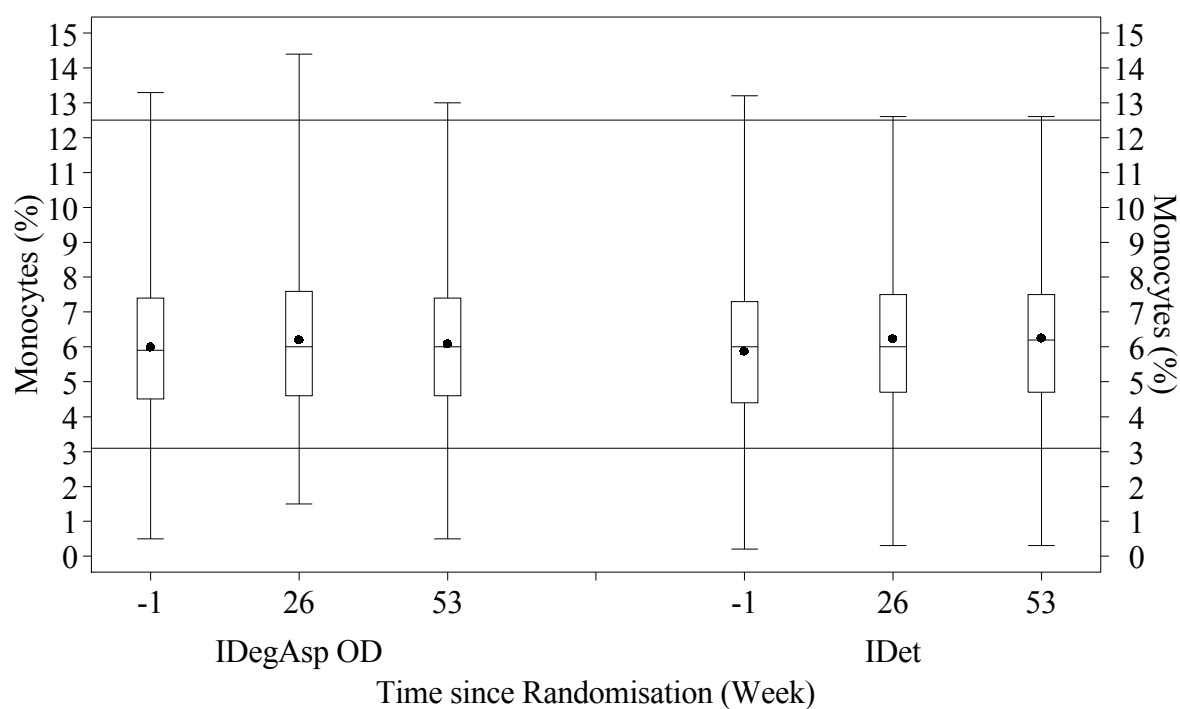
14.3.5.33: Haematology - Lymphocytes - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:08:17 - fedist_numfind_v01.sas/e_lymphocytes_abs_cdf_locf_sas.cgm

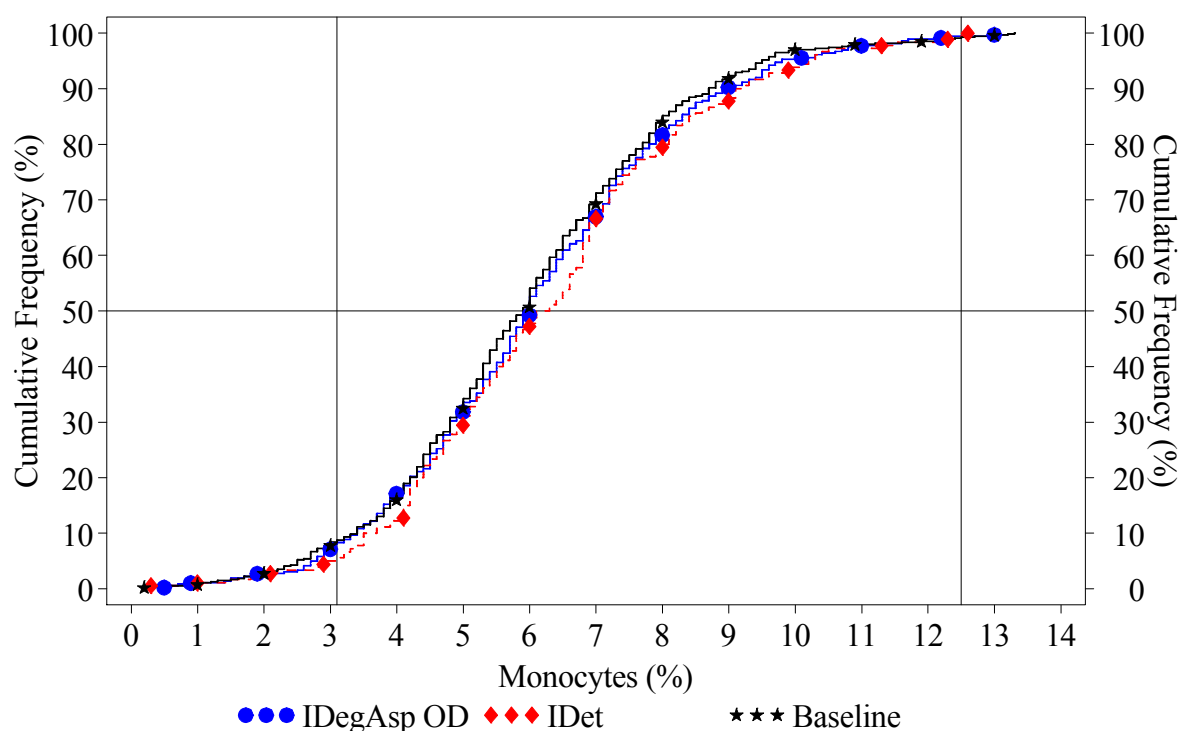
14.3.5.34: Haematology - Lymphocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:08:26 - fbox_numfind_v01.sas/e_monocytes_abs_box_locf_sas.cgm

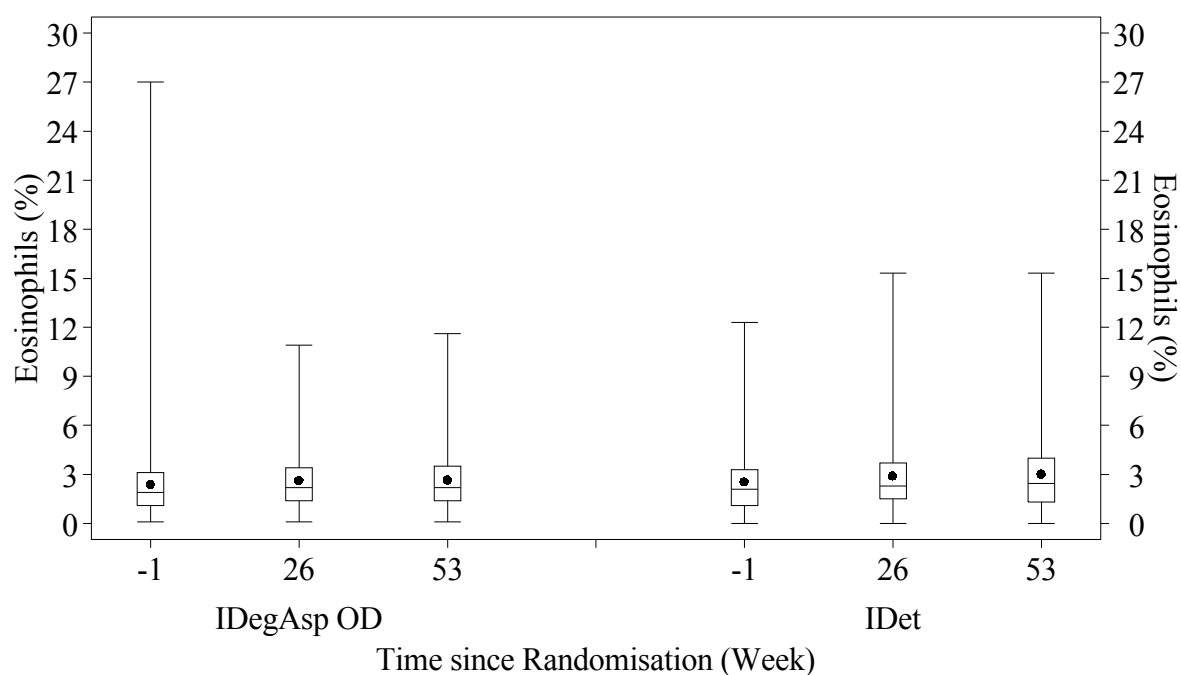
14.3.5.35: Haematology - Monocytes - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:08:41 - fedist_numfind_v01.sas/e_monocytes_abs_cdf_locf_sas.cgm

14.3.5.36: Haematology - Monocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

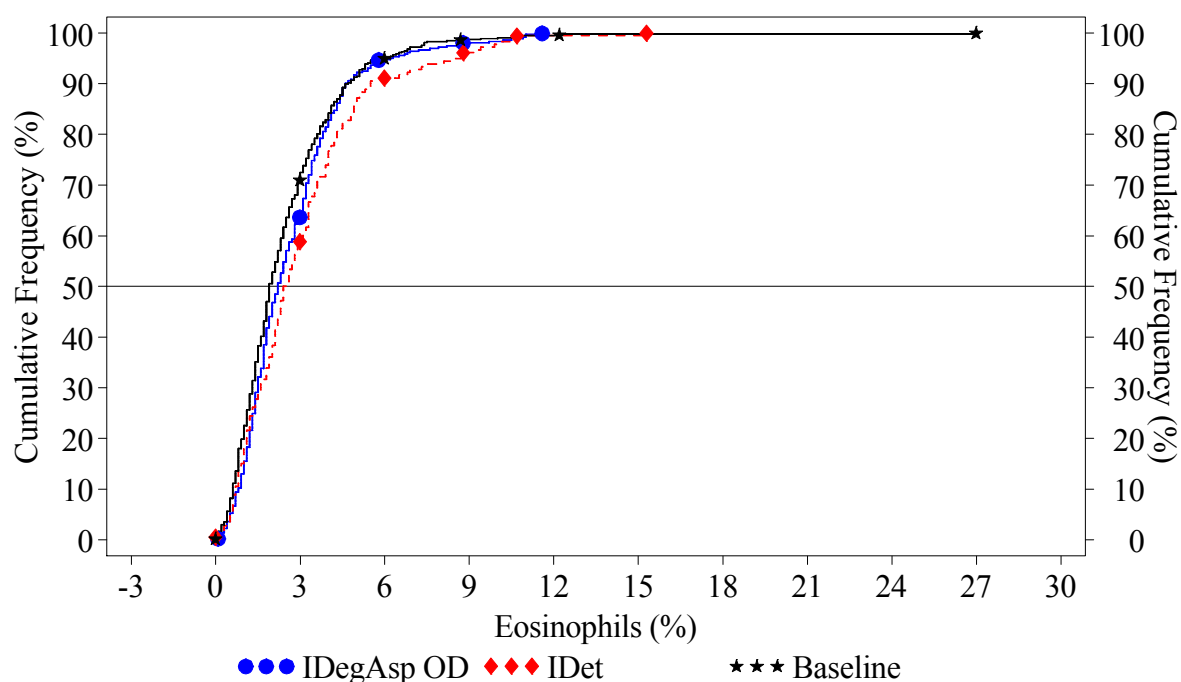
SAFETY: LOCF imputed data

Lower ref.: Male, Age(1-19)[0], Age(19-111)[0]; Female, Age(1-19)[0], Age(19-111)[0]

Upper ref.: Male, Age(1-19)[4.8], Age(19-111)[6]; Female, Age(1-19)[4.8], Age(19-111)[6]

07MAY2011:14:08:49 - fbox_numfind_v01.sas/e_eosinophils_abs_box_locf_sas.cgm
nn5401/nn5401-3594-3645/freeze_ctr_02/stats

14.3.5.37: Haematology - Eosinophils - Box Plot - Safety Analysis Set

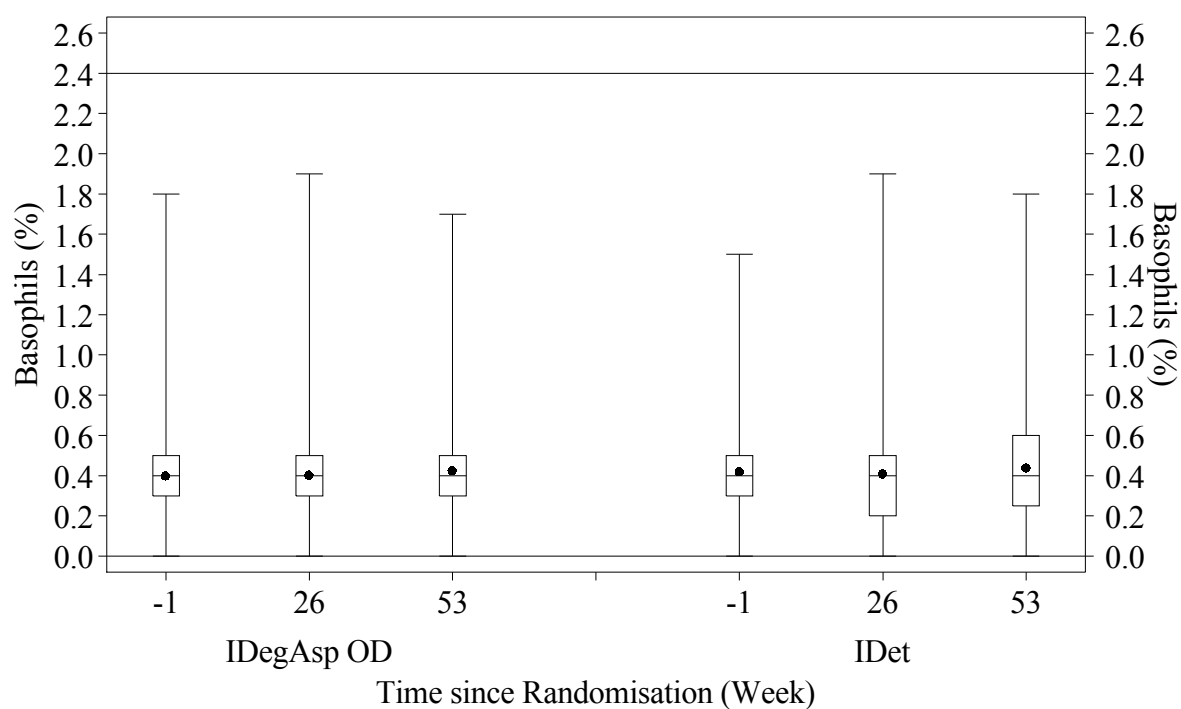


SAFETY; LOCF imputed data

Lower ref.: Male, Age(1-19)[0], Age(19-111)[0]; Female, Age(1-19)[0], Age(19-111)[0]
Upper ref.: Male, Age(1-19)[4.8], Age(19-111)[6]; Female, Age(1-19)[4.8], Age(19-111)[6]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:09:05 - fedist_numfind_v01.sas/e_eosinophils_abs_cdf_locf_sas.cgm

14.3.5.38: Haematology - Eosinophils after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

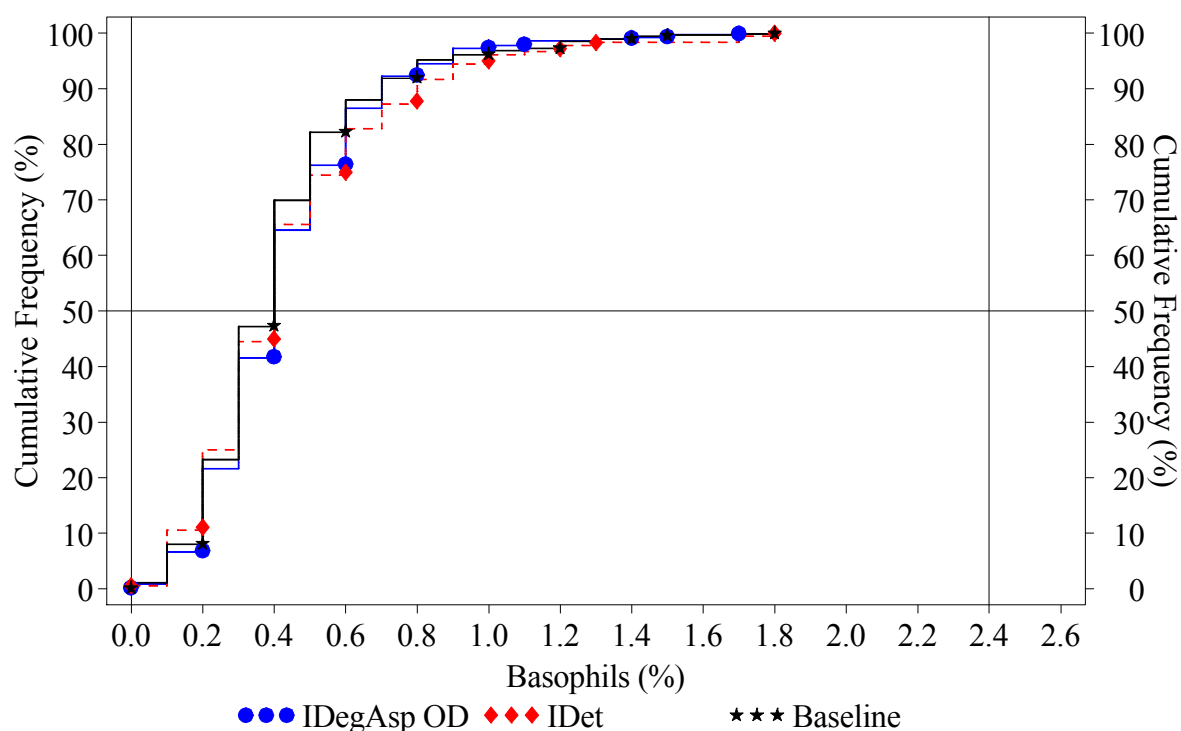


Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:09:13 - fbox_numfind_v01.sas/e_basophils_abs_box_locf_sas.cgm

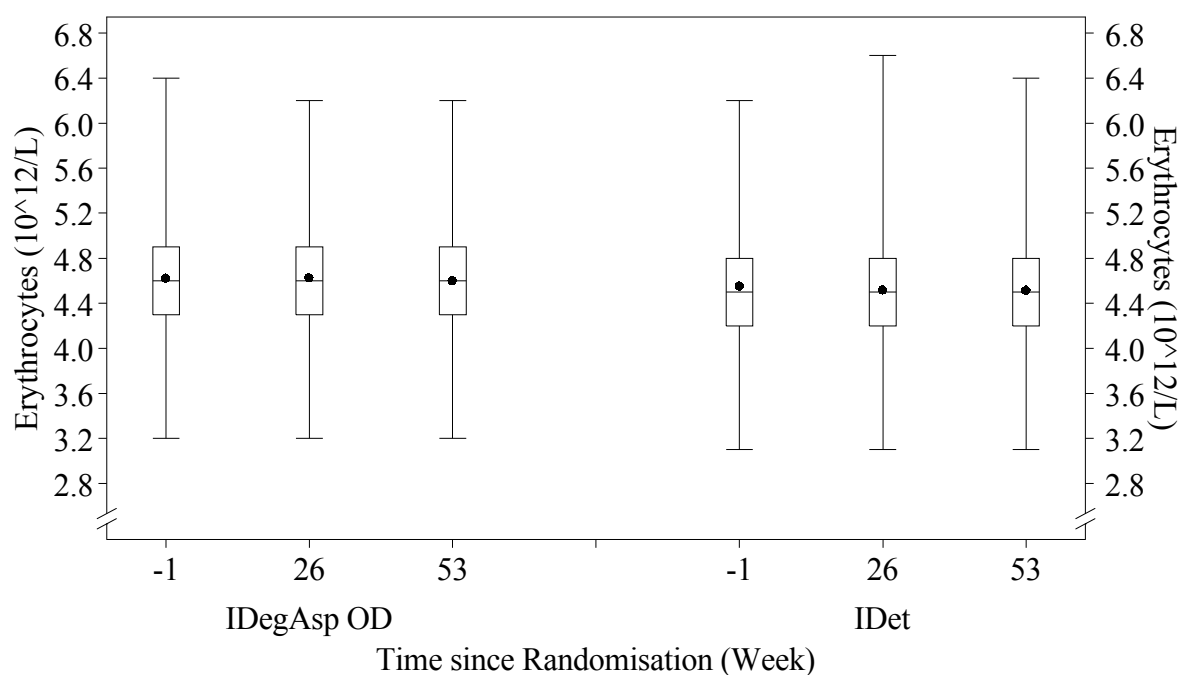
14.3.5.39: Haematology - Basophils - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:09:28 - fedist_numfind_v01.sas/e_basophils_abs_cdf_locf_sas.cgm

14.3.5.40: Haematology - Basophils after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

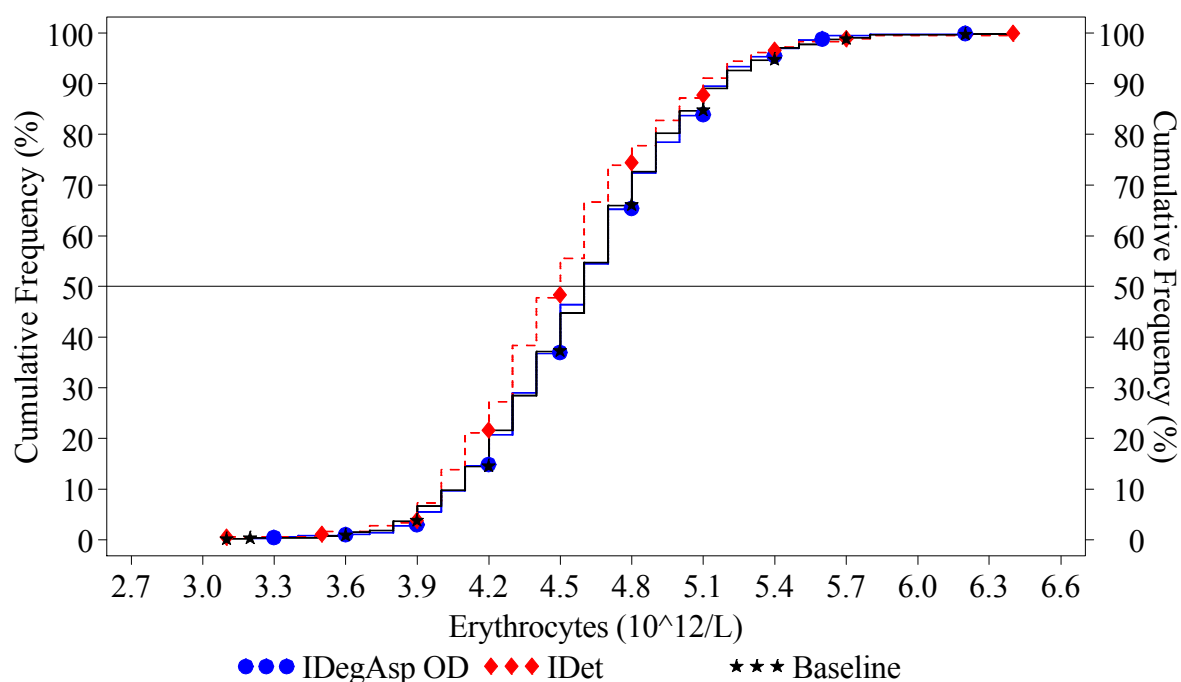
SAFETY: LOCF imputed data

Lower ref.: Male, Age(12-66)[4.1], Age(66-111)[4.1]; Female, Age(12-66)[3.8], Age(66-111)[3.8]

Upper ref.: Male, Age(12-66)[5.9], Age(66-111)[5.8]; Female, Age(12-66)[5.5], Age(66-91)[5.4]

07MAY2011:14:09:36 - fbox_numfind_v01.sas/e_erythrocyt_abs_box_locf_sas.cgm

14.3.5.41: Haematology - Erythrocytes - Box Plot - Safety Analysis Set

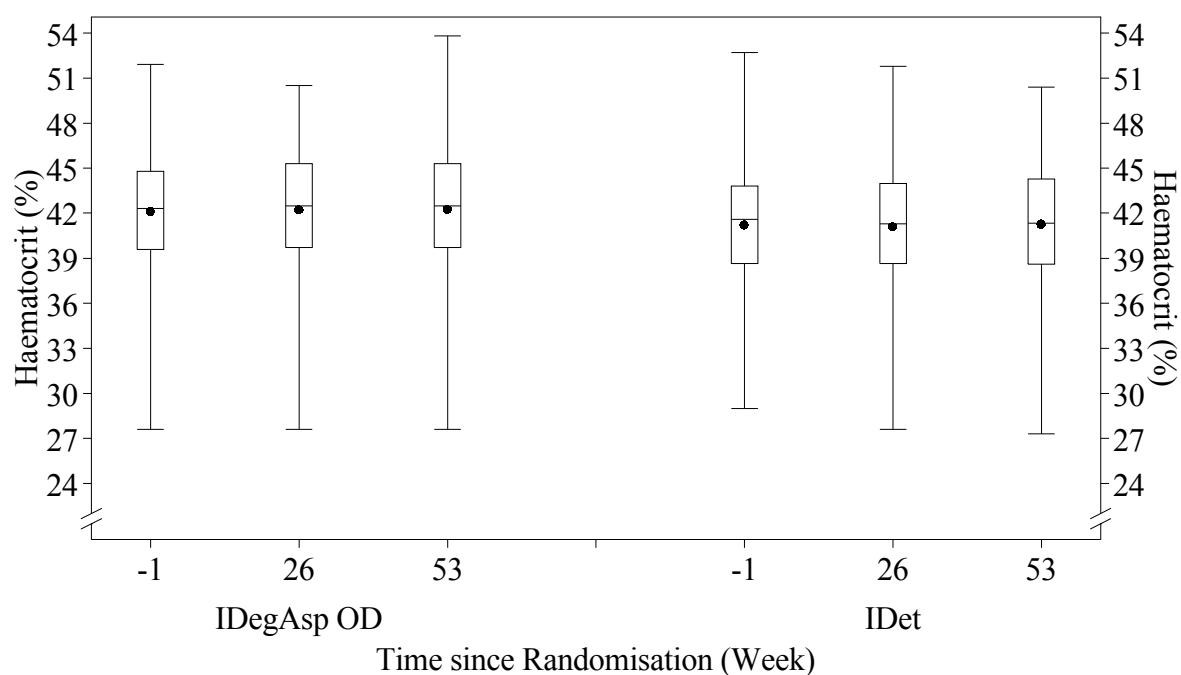


SAFETY: LOCF imputed data

Lower ref.: Male, Age(12-66)[4.1], Age(66-111)[4]; Female, Age(12-66)[3.8], Age(66-111)[3.8]
Upper ref.: Male, Age(12-66)[5.9], Age(66-111)[5.8]; Female, Age(12-66)[5.5], Age(66-111)[5.4]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:09:52 - fedist_numfind_v01.sas/e_erythrocyt_abs_cdf_locf_sas.cgm

14.3.5.42: Haematology - Erythrocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

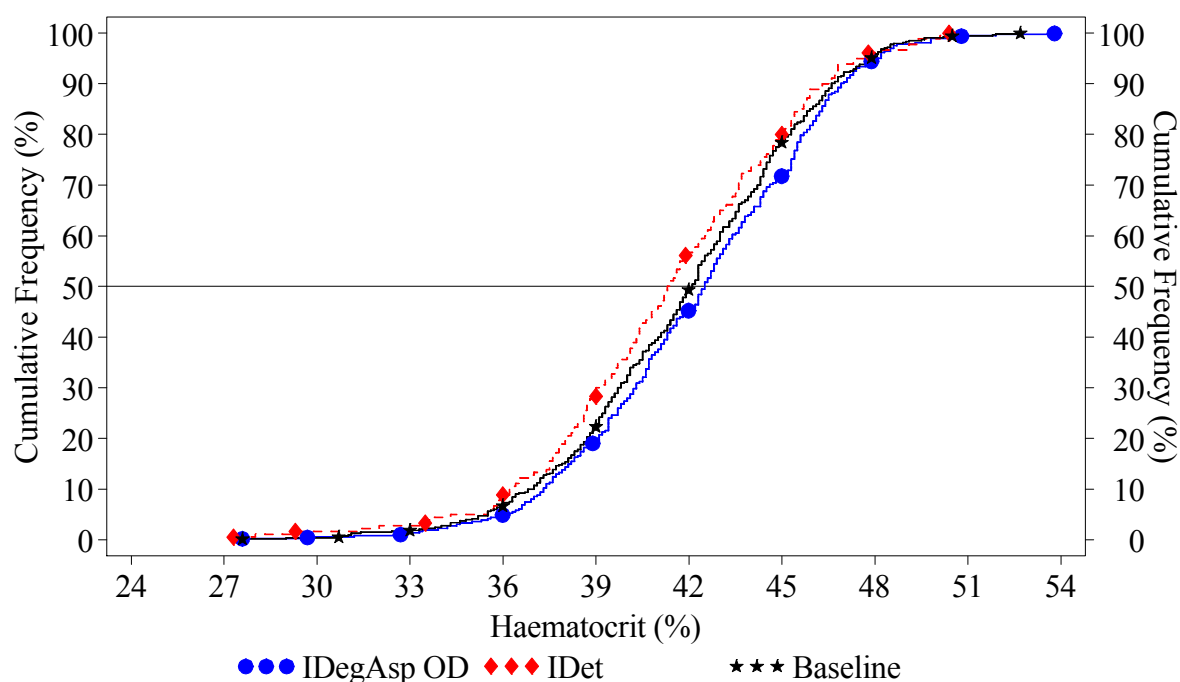
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[40], Age(66-111)[37]; Female, Age(12-66)[35], Age(66-111)[33]

Upper ref.: Male, Age(18-66)[52], Age(66-111)[50]; Female, Age(12-66)[47], Age(66-111)[46]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:10:00 - fbox_numfind_v01.sas/e_haematocr_abs_box_locf_sas.cgm

14.3.5.43: Haematology - Haematocrit - Box Plot - Safety Analysis Set



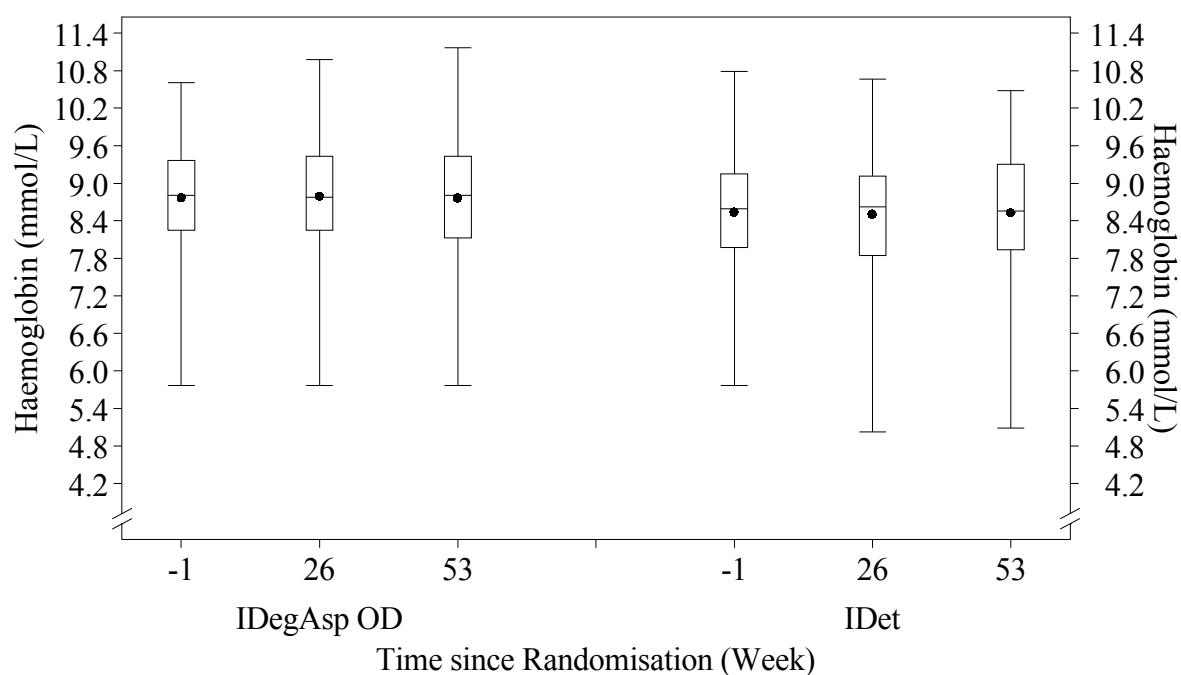
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[40], Age(66-111)[37]; Female, Age(12-66)[35], Age(66-111)[33]

Upper ref.: Male, Age(18-66)[52], Age(66-111)[50]; Female, Age(12-66)[47], Age(66-111)[46]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:10:15 - fedist_numfind_v01.sas/e_haematocr_abs_cdf_locf_sas.cgm

14.3.5.44: Haematology - Haematocrit after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)

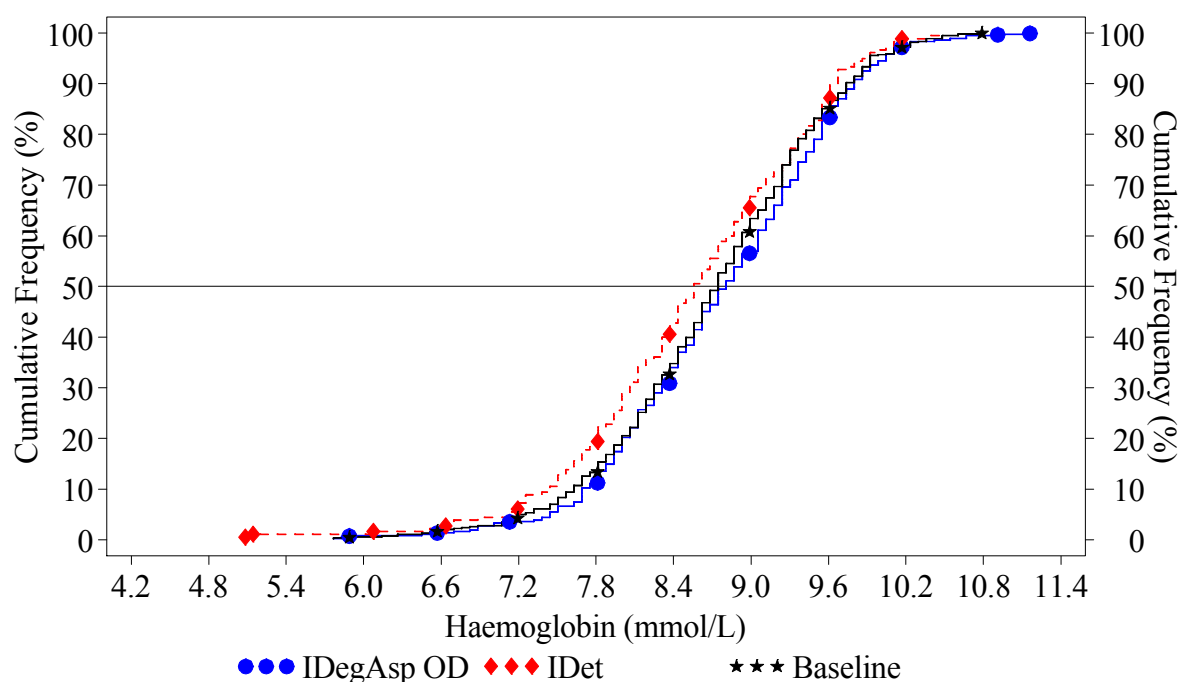
SAFETY: LOCF imputed data

Lower ref.: Male, Age(18-66)[8.1], Age(66-111)[7.8]; Female, Age(12-66)[7.2], Age(66-111)[6.8]

Upper ref.: Male, Age(18-66)[10.9], Age(66-111)[11]; Female, Age(12-66)[10], Age(66-111)[10]

07MAY2011:14:10:24 - fbox_numfind_v01.sas/e_haemoglob_abs_box_locf_sas.cgm

14.3.5.45: Haematology - Haemoglobin - Box Plot - Safety Analysis Set



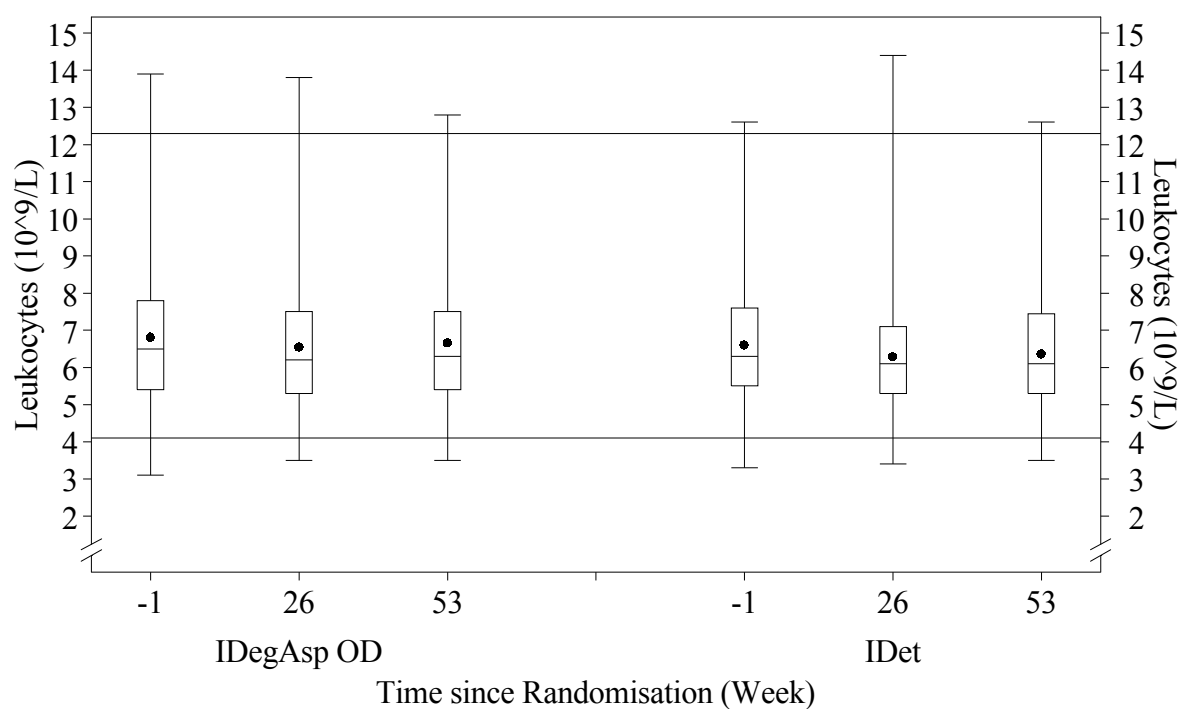
SAFETY; LOCF imputed data

Lower ref.: Male, Age(18-66)[8.1], Age(66-111)[7.8]; Female, Age(12-66)[7.2], Age(66-111)[6.8]

Upper ref.: Male, Age(18-66)[10.9], Age(66-111)[11]; Female, Age(12-66)[10], Age(66-111)[10]

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:10:39 - fedist_numfind_v01.sas/e_haemoglob_abs_cdf_locf_sas.cgm

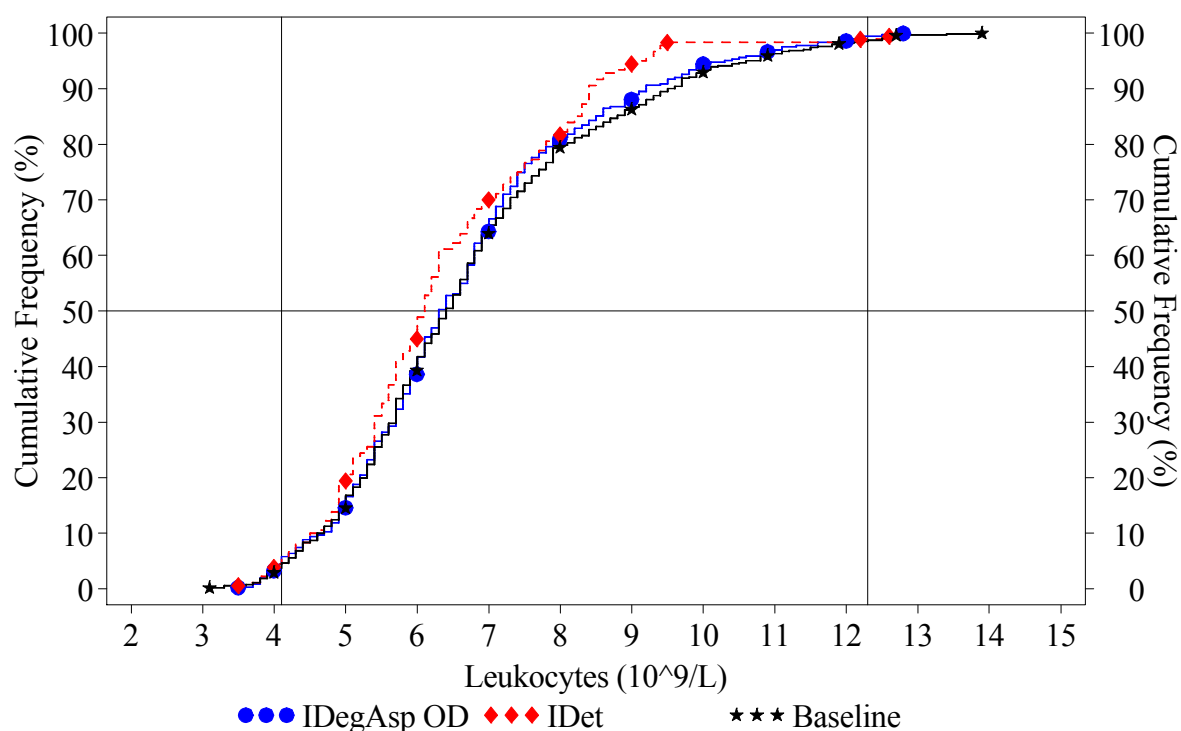
14.3.5.46: Haematology - Haemoglobin after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:10:48 - fbox_numfind_v01.sas/e_leukocyt_abs_box_locf_sas.cgm

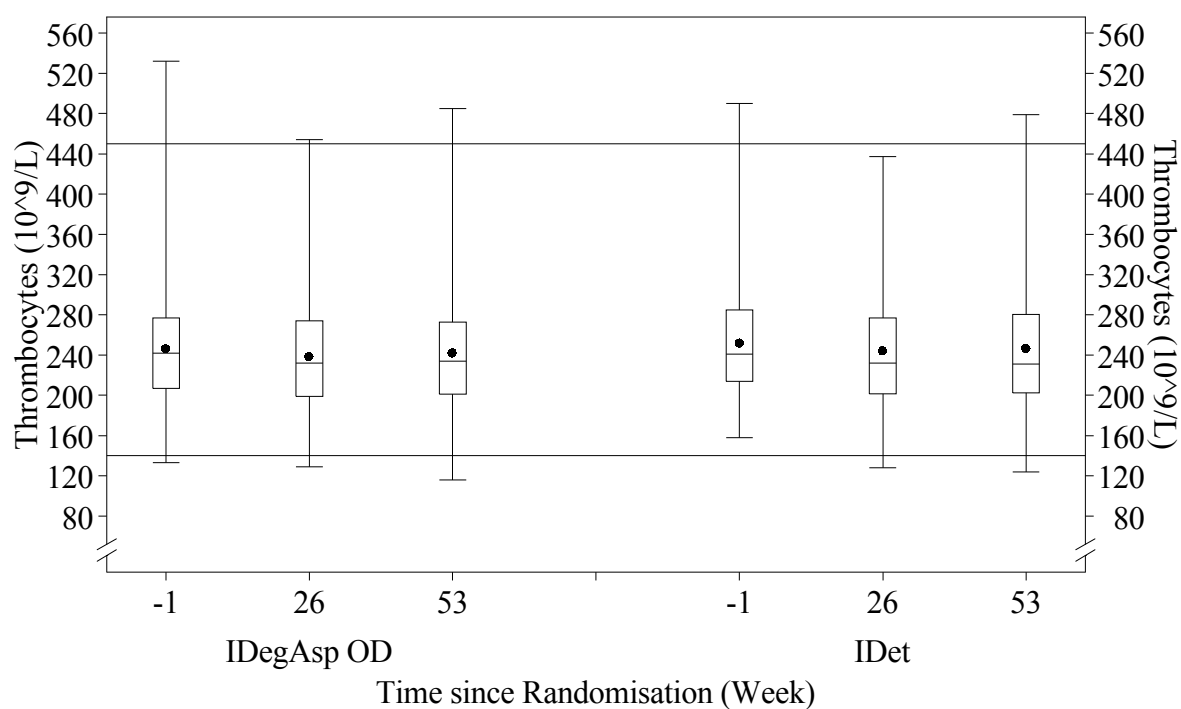
14.3.5.47: Haematology - Leukocytes - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:03 - fedist_numfind_v01.sas/e_leukocyt_abs_cdf_locf_sas.cgm

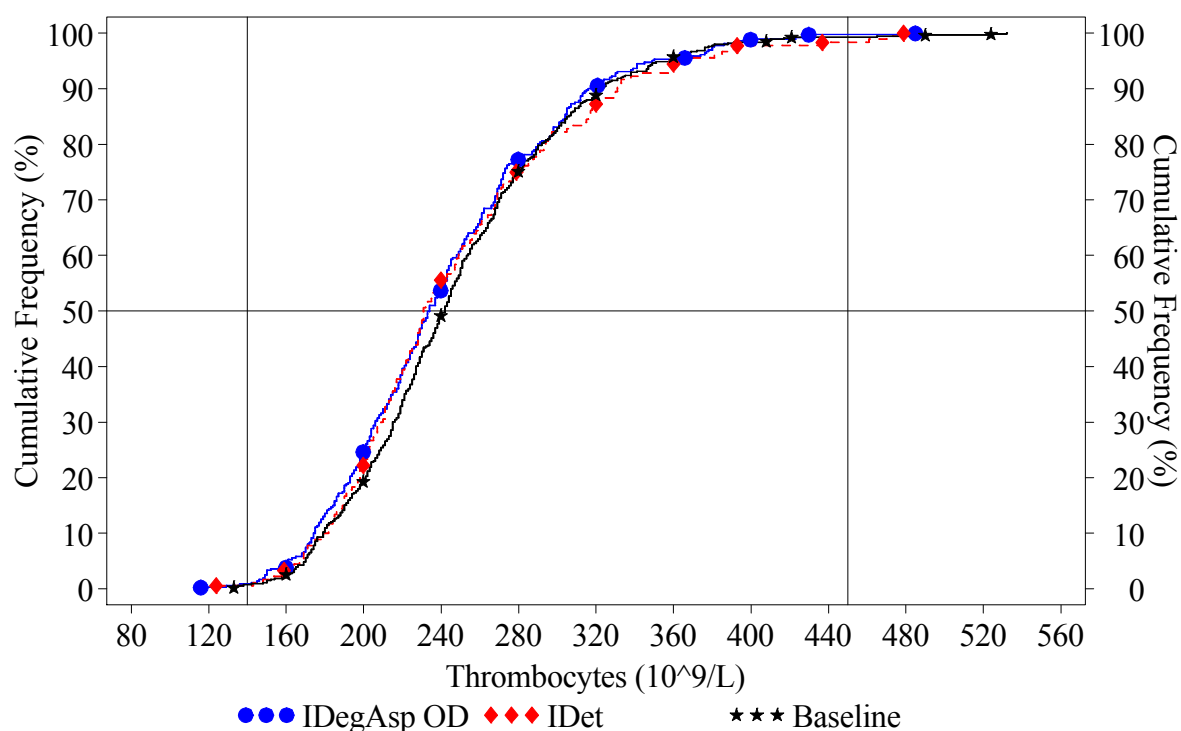
14.3.5.48: Haematology - Leukocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:12 - fbox_numfind_v01.sas/e_thrombocyt_abs_box_locf_sas.cgm

14.3.5.49: Haematology - Thrombocytes - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:27 - fedist_numfind_v01.sas/e_thrombocyt_abs_cdf_locf_sas.cgm

14.3.5.50: Haematology - Thrombocytes after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.3.5.51: Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
HDL Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	1.56 (0.41)	1.61 (0.46)	1.57 (0.43)
Median	1.53	1.55	1.53
Min ; Max	0.65 ; 3.13	0.65 ; 3.39	0.65 ; 3.39
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	1.52 (0.40)	1.59 (0.45)	1.54 (0.42)
Median	1.48	1.53	1.50
Min ; Max	0.65 ; 3.26	0.80 ; 3.34	0.65 ; 3.34
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	1.52 (0.40)	1.59 (0.46)	1.54 (0.42)
Median	1.45	1.48	1.48
Min ; Max	0.75 ; 2.85	0.78 ; 3.11	0.75 ; 3.11
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	1.55 (0.41)	1.60 (0.46)	1.57 (0.43)
Median	1.48	1.53	1.48
Min ; Max	0.65 ; 3.26	0.78 ; 3.11	0.65 ; 3.26

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:36 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_abs_descp_sas.txt

Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
LDL Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	2.69 (0.84)	2.59 (0.74)	2.65 (0.81)
Median	2.62	2.51	2.56
Min ; Max	0.73 ; 6.27	1.01 ; 5.10	0.73 ; 6.27
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	2.74 (0.88)	2.67 (0.76)	2.71 (0.85)
Median	2.63	2.59	2.59
Min ; Max	0.73 ; 6.16	0.88 ; 5.23	0.73 ; 6.16
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	2.76 (0.83)	2.71 (0.77)	2.74 (0.81)
Median	2.64	2.64	2.64
Min ; Max	0.78 ; 5.72	1.22 ; 4.92	0.78 ; 5.72
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	2.72 (0.83)	2.69 (0.78)	2.71 (0.81)
Median	2.59	2.64	2.62
Min ; Max	0.78 ; 6.16	0.88 ; 5.23	0.78 ; 6.16

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:36 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_abs_descp_sas.txt

Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Total Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	4.77 (1.00)	4.68 (0.87)	4.74 (0.96)
Median	4.69	4.51	4.66
Min ; Max	2.25 ; 9.09	3.11 ; 8.16	2.25 ; 9.09
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	4.78 (1.08)	4.75 (0.84)	4.77 (1.00)
Median	4.63	4.64	4.64
Min ; Max	2.12 ; 9.01	2.67 ; 7.02	2.12 ; 9.01
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	4.81 (0.99)	4.82 (0.94)	4.81 (0.98)
Median	4.69	4.70	4.69
Min ; Max	2.51 ; 8.13	2.72 ; 8.00	2.51 ; 8.13
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	4.79 (1.00)	4.82 (0.94)	4.80 (0.98)
Median	4.66	4.69	4.69
Min ; Max	2.51 ; 9.01	2.67 ; 8.00	2.51 ; 9.01

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:36 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_abs_descp_sas.txt

Lipids by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Triglycerides serum (mmol/L)			
Visit 2 (Week 0)			
N	360	179	539
Mean (SD)	1.15 (0.88)	1.08 (1.32)	1.13 (1.04)
Median	0.95	0.87	0.92
Min ; Max	0.36 ; 10.29	0.42 ; 17.62	0.36 ; 17.62
Visit 28 (Week 26)			
N	321	157	478
Mean (SD)	1.19 (1.23)	1.06 (0.57)	1.15 (1.06)
Median	0.90	0.93	0.90
Min ; Max	0.33 ; 13.62	0.45 ; 5.24	0.33 ; 13.62
Visit 44 (Week 53)			
N	235	114	349
Mean (SD)	1.16 (0.96)	1.14 (0.61)	1.16 (0.86)
Median	0.88	0.97	0.93
Min ; Max	0.34 ; 11.99	0.42 ; 3.28	0.34 ; 11.99
Visit 44 (Week 53) (LOCF)			
N	361	180	541
Mean (SD)	1.15 (0.86)	1.15 (0.67)	1.15 (0.80)
Median	0.92	0.95	0.93
Min ; Max	0.33 ; 11.99	0.42 ; 5.24	0.33 ; 11.99

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:36 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_abs_descp_sas.txt

14.3.5.52: Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. HDL Cholesterol Serum (mmol/L)			
Visit 28 (Week 26)			
N	320	156	476
Mean (SD)	-0.0 (0.3)	0.0 (0.3)	-0.0 (0.3)
Median	-0.0	0.0	-0.0
Min ; Max	-0.8 ; 1.4	-0.7 ; 0.7	-0.8 ; 1.4
Visit 44 (Week 53)			
N	235	113	348
Mean (SD)	-0.0 (0.3)	0.0 (0.3)	-0.0 (0.3)
Median	-0.0	0.0	-0.0
Min ; Max	-0.6 ; 1.2	-0.6 ; 1.0	-0.6 ; 1.2
Visit 44 (Week 53) (LOCF)			
N	360	179	539
Mean (SD)	-0.0 (0.3)	-0.0 (0.3)	-0.0 (0.3)
Median	-0.0	0.0	0.0
Min ; Max	-0.6 ; 1.4	-0.7 ; 1.1	-0.7 ; 1.4

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:45 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_chb_descp_sas.txt

Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. LDL Cholesterol Serum (mmol/L)			
Visit 28 (Week 26)			
N	319	156	475
Mean (SD)	0.0 (0.6)	0.1 (0.6)	0.0 (0.6)
Median	0.0	0.0	0.0
Min ; Max	-2.9 ; 3.8	-2.1 ; 2.5	-2.9 ; 3.8
Visit 44 (Week 53)			
N	235	113	348
Mean (SD)	0.0 (0.7)	0.2 (0.7)	0.1 (0.7)
Median	0.0	0.1	0.0
Min ; Max	-2.4 ; 3.3	-1.3 ; 2.5	-2.4 ; 3.3
Visit 44 (Week 53) (LOCF)			
N	360	179	539
Mean (SD)	0.0 (0.7)	0.1 (0.7)	0.1 (0.7)
Median	0.0	0.1	0.0
Min ; Max	-2.4 ; 3.3	-2.4 ; 2.8	-2.4 ; 3.3

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:45 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_chb_descp_sas.txt

Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Triglycerides Serum (mmol/L)			
Visit 28 (Week 26)			
N	320	156	476
Mean (SD)	0.0 (1.0)	0.1 (0.4)	0.0 (0.9)
Median	0.0	0.0	0.0
Min ; Max	-9.0 ; 10.0	-1.5 ; 2.0	-9.0 ; 10.0
Visit 44 (Week 53)			
N	235	113	348
Mean (SD)	0.0 (0.8)	0.2 (0.5)	0.1 (0.7)
Median	0.0	0.1	0.0
Min ; Max	-3.9 ; 8.3	-1.1 ; 2.3	-3.9 ; 8.3
Visit 44 (Week 53) (LOCF)			
N	360	179	539
Mean (SD)	-0.0 (0.9)	0.1 (1.2)	0.0 (1.0)
Median	0.0	0.1	0.0
Min ; Max	-9.0 ; 8.3	-13.9 ; 2.3	-13.9 ; 8.3

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:45 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_chb_descp_sas.txt

Lipids by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Total Cholesterol Serum (mmol/L)			
Visit 28 (Week 26)			
N	319	156	475
Mean (SD)	0.0 (0.8)	0.1 (0.7)	0.0 (0.8)
Median	-0.0	0.1	0.0
Min ; Max	-3.8 ; 4.2	-2.2 ; 2.8	-3.8 ; 4.2
Visit 44 (Week 53)			
N	235	113	348
Mean (SD)	0.0 (0.8)	0.2 (0.8)	0.1 (0.8)
Median	0.0	0.1	0.0
Min ; Max	-2.8 ; 4.0	-1.5 ; 3.5	-2.8 ; 4.0
Visit 44 (Week 53) (LOCF)			
N	360	179	539
Mean (SD)	0.0 (0.8)	0.1 (0.8)	0.1 (0.8)
Median	0.0	0.1	0.0
Min ; Max	-2.8 ; 4.0	-2.6 ; 3.5	-2.8 ; 4.0

N = Number of Subjects, SD = Standard Deviation
Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:45 - tdesc_numfind_tpl_t019_v01.sas/t_lipid_chb_descp_sas.txt

14.3.5.53: Lipids after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Total Cholesterol (mmol/L)					
LSMeans					
IDegAsp OD	366	364	4.86	0.06	
IDet	182	180	4.97	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	366	364	0.13	0.06	
IDet	182	180	0.24	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.10		[-0.24 ; 0.03]
HDL Cholesterol (mmol/L)					
LSMeans					
IDegAsp OD	366	364	1.54	0.02	
IDet	182	180	1.55	0.03	
Change from Baseline					
LSMeans					
IDegAsp OD	366	364	-0.04	0.02	
IDet	182	180	-0.03	0.03	
Treatment Contrast					
IDegAsp OD - IDet			-0.01		[-0.06 ; 0.04]
LDL Cholesterol (mmol/L)					
LSMeans					
IDegAsp OD	366	364	2.78	0.05	
IDet	182	180	2.84	0.06	
Change from Baseline					
LSMeans					
IDegAsp OD	366	364	0.14	0.05	
IDet	182	180	0.19	0.06	
Treatment Contrast					
IDegAsp OD - IDet			-0.06		[-0.17 ; 0.05]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:54 - tstat_find_tpl_t022.sas/t_lipid_stat_locf_fas.txt

Lipids after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

	FAS	N	Estimate	SE	95% CI
Triglycerides (mmol/L)					
LSMeans					
IDegAsp OD	366	364	1.24	0.06	
IDet	182	180	1.27	0.07	
Change from Baseline					
LSMeans					
IDegAsp OD	366	364	0.11	0.06	
IDet	182	180	0.15	0.07	
Treatment Contrast					
IDegAsp OD - IDet			-0.04		[-0.16 ; 0.09]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean
The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
Missing data is imputed using last observation carried forward.
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:11:54 - tstat_find_tpl_t022.sas/t_lipid_stat_locf_fas.txt

14.3.5.54: Lipids after 52 Weeks of Treatment - Statistical Analysis - Extension Trial Set

	EXT	N	Estimate	SE	95% CI
Total Cholesterol (mmol/L)					
LSMeans					
IDegAsp OD	254	253	5.00	0.08	
IDet	122	121	5.14	0.10	
Change from Baseline					
LSMeans					
IDegAsp OD	254	253	0.27	0.08	
IDet	122	121	0.41	0.10	
Treatment Contrast					
IDegAsp OD - IDet			-0.14		[-0.31 ; 0.03]
HDL Cholesterol (mmol/L)					
LSMeans					
IDegAsp OD	254	253	1.52	0.03	
IDet	122	121	1.53	0.03	
Change from Baseline					
LSMeans					
IDegAsp OD	254	253	-0.03	0.03	
IDet	122	121	-0.01	0.03	
Treatment Contrast					
IDegAsp OD - IDet			-0.02		[-0.07 ; 0.04]
LDL Cholesterol (mmol/L)					
LSMeans					
IDegAsp OD	254	253	2.91	0.07	
IDet	122	121	2.99	0.08	
Change from Baseline					
LSMeans					
IDegAsp OD	254	253	0.23	0.07	
IDet	122	121	0.31	0.08	
Treatment Contrast					
IDegAsp OD - IDet			-0.08		[-0.22 ; 0.06]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:12:03 - tstat_find_tpl_t022.sas/t_lipid_stat_locf_ets.txt

Lipids after 52 Weeks of Treatment - Statistical Analysis - Extension Trial Set

	EXT	N	Estimate	SE	95% CI
Triglycerides (mmol/L)					
LSMeans					
IDegAsp OD	254	253	1.25	0.07	
IDet	122	121	1.34	0.09	
Change from Baseline					
LSMeans					
IDegAsp OD	254	253	0.15	0.07	
IDet	122	121	0.25	0.09	
Treatment Contrast					
IDegAsp OD - IDet			-0.10		[-0.25 ; 0.05]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean
The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.
Missing data is imputed using last observation carried forward.
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:12:03 - tstat_find_tpl_t022.sas/t_lipid_stat_locf_ets.txt

14.3.5.55: Lipids by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
HDL Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360 (100.0)	179 (100.0)	539 (100.0)
Low	30 (8.3)	17 (9.5)	47 (8.7)
Normal	293 (81.4)	144 (80.4)	437 (81.1)
High	37 (10.3)	18 (10.1)	55 (10.2)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	26 (8.1)	8 (5.1)	34 (7.1)
Normal	265 (82.6)	130 (82.8)	395 (82.6)
High	30 (9.3)	19 (12.1)	49 (10.3)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Low	1 (50.0)	0	1 (33.3)
Normal	1 (50.0)	1 (100.0)	2 (66.7)
Visit 44 (Week 53)			
N	235 (100.0)	114 (100.0)	349 (100.0)
Low	18 (7.7)	6 (5.3)	24 (6.9)
Normal	195 (83.0)	91 (79.8)	286 (81.9)
High	22 (9.4)	17 (14.9)	39 (11.2)
Visit 44 Week 53(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	28 (7.8)	10 (5.6)	38 (7.0)
Normal	296 (82.0)	144 (80.0)	440 (81.3)
High	37 (10.2)	26 (14.4)	63 (11.6)
LDL Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360 (100.0)	179 (100.0)	539 (100.0)
Normal	296 (82.2)	154 (86.0)	450 (83.5)
High	64 (17.8)	25 (14.0)	89 (16.5)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Normal	254 (79.4)	132 (84.1)	386 (80.9)
High	66 (20.6)	25 (15.9)	91 (19.1)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Visit 44 (Week 53)			
N	235 (100.0)	114 (100.0)	349 (100.0)
Normal	183 (77.9)	94 (82.5)	277 (79.4)
High	52 (22.1)	20 (17.5)	72 (20.6)

N = Number of Subjects

Lipids by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Normal	291 (80.6)	149 (82.8)	440 (81.3)
High	70 (19.4)	31 (17.2)	101 (18.7)
Total Cholesterol serum (mmol/L)			
Visit 2 (Week 0)			
N	360 (100.0)	179 (100.0)	539 (100.0)
Low	25 (6.9)	7 (3.9)	32 (5.9)
Normal	223 (61.9)	127 (70.9)	350 (64.9)
High	112 (31.1)	45 (25.1)	157 (29.1)
Visit 28 (Week 26)			
N	320 (100.0)	157 (100.0)	477 (100.0)
Low	22 (6.9)	6 (3.8)	28 (5.9)
Normal	202 (63.1)	109 (69.4)	311 (65.2)
High	96 (30.0)	42 (26.8)	138 (28.9)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Visit 44 (Week 53)			
N	235 (100.0)	114 (100.0)	349 (100.0)
Low	9 (3.8)	4 (3.5)	13 (3.7)
Normal	153 (65.1)	77 (67.5)	230 (65.9)
High	73 (31.1)	33 (28.9)	106 (30.4)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	18 (5.0)	6 (3.3)	24 (4.4)
Normal	235 (65.1)	123 (68.3)	358 (66.2)
High	108 (29.9)	51 (28.3)	159 (29.4)
Triglycerides serum (mmol/L)			
Visit 2 (Week 0)			
N	360 (100.0)	179 (100.0)	539 (100.0)
Low	20 (5.6)	7 (3.9)	27 (5.0)
Normal	327 (90.8)	170 (95.0)	497 (92.2)
High	13 (3.6)	2 (1.1)	15 (2.8)
Visit 28 (Week 26)			
N	321 (100.0)	157 (100.0)	478 (100.0)
Low	16 (5.0)	3 (1.9)	19 (4.0)
Normal	296 (92.2)	152 (96.8)	448 (93.7)
High	9 (2.8)	2 (1.3)	11 (2.3)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Visit 44 (Week 53)			
N	235 (100.0)	114 (100.0)	349 (100.0)
Low	21 (8.9)	6 (5.3)	27 (7.7)

N = Number of Subjects

Lipids by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Normal	206 (87.7)	105 (92.1)	311 (89.1)
High	8 (3.4)	3 (2.6)	11 (3.2)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Low	25 (6.9)	8 (4.4)	33 (6.1)
Normal	326 (90.3)	167 (92.8)	493 (91.1)
High	10 (2.8)	5 (2.8)	15 (2.8)

N = Number of Subjects

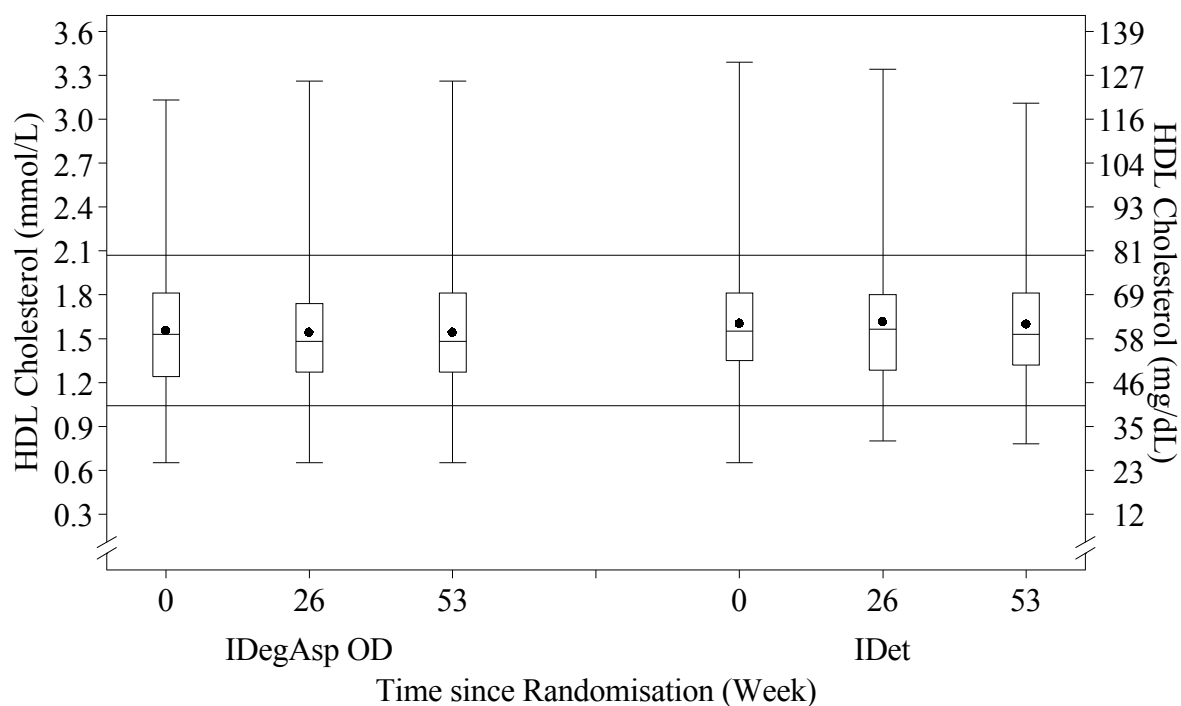
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:38:36 - tsum_lab_summary.sas/t_lipid_sum_sas.txt

14.3.5.56: Lipids – Shift Table – Baseline to Week 53 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 44 (Week 53)								
HDL Cholesterol serum (mmol/L)								
Low	8 (2.2)	10 (2.8)	0 (0.0)	0 (0.0)	3 (1.7)	3 (1.7)	0 (0.0)	0 (0.0)
Normal	8 (2.2)	177 (48.9)	10 (2.8)	0 (0.0)	9 (5.0)	81 (45.0)	1 (0.6)	0 (0.0)
High	0 (0.0)	9 (2.5)	13 (3.6)	0 (0.0)	0 (0.0)	6 (3.3)	10 (5.6)	1 (0.6)
Missing	14 (3.9)	97 (26.8)	14 (3.9)	2 (0.6)	5 (2.8)	54 (30.0)	7 (3.9)	0 (0.0)
LDL Cholesterol serum (mmol/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	171 (47.2)	12 (3.3)	0 (0.0)	0 (0.0)	87 (48.3)	6 (3.3)	1 (0.6)
High	0 (0.0)	22 (6.1)	30 (8.3)	0 (0.0)	0 (0.0)	14 (7.8)	6 (3.3)	0 (0.0)
Missing	0 (0.0)	103 (28.5)	22 (6.1)	2 (0.6)	0 (0.0)	53 (29.4)	13 (7.2)	0 (0.0)
Total Cholesterol serum (mmol/L)								
Low	4 (1.1)	5 (1.4)	0 (0.0)	0 (0.0)	1 (0.6)	3 (1.7)	0 (0.0)	0 (0.0)
Normal	11 (3.0)	116 (32.0)	26 (7.2)	0 (0.0)	4 (2.2)	61 (33.9)	11 (6.1)	1 (0.6)
High	0 (0.0)	27 (7.5)	46 (12.7)	0 (0.0)	1 (0.6)	17 (9.4)	15 (8.3)	0 (0.0)
Missing	10 (2.8)	75 (20.7)	40 (11.0)	2 (0.6)	1 (0.6)	46 (25.6)	19 (10.6)	0 (0.0)
Triglycerides serum (mmol/L)								
Low	8 (2.2)	13 (3.6)	0 (0.0)	0 (0.0)	2 (1.1)	4 (2.2)	0 (0.0)	0 (0.0)
Normal	7 (1.9)	194 (53.6)	5 (1.4)	0 (0.0)	4 (2.2)	100 (55.6)	0 (0.0)	1 (0.6)
High	0 (0.0)	4 (1.1)	4 (1.1)	0 (0.0)	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
Missing	5 (1.4)	116 (32.0)	4 (1.1)	2 (0.6)	1 (0.6)	63 (35.0)	2 (1.1)	0 (0.0)

N = Number of subjects

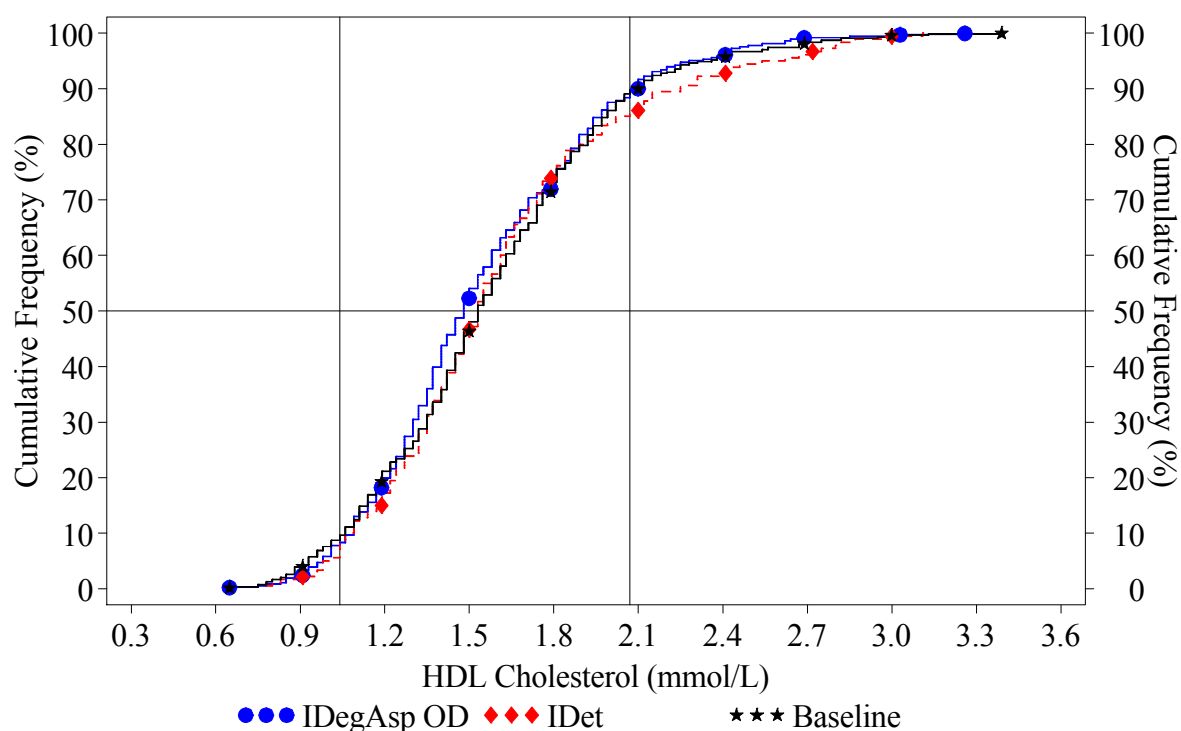
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:25 - t_lab_shift.sas/t_lipid_shift_w53_sas.txt



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:12:12 - fbox_numfind_v01.sas/e_hdl_abs_box_locf_sas.cgm

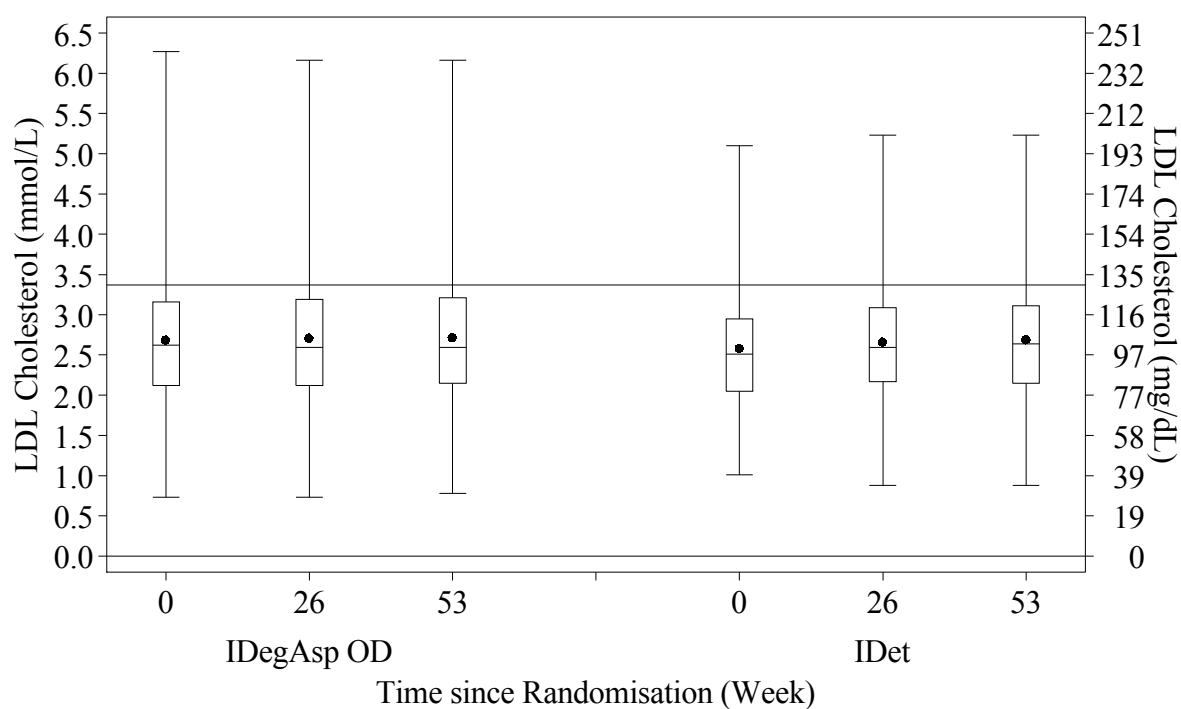
14.3.5.57: Lipid - HDL Cholesterol - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:12:27 - fedist_numfind_v01.sas/e_hdl_abs_cdf_locf_sas.cgm

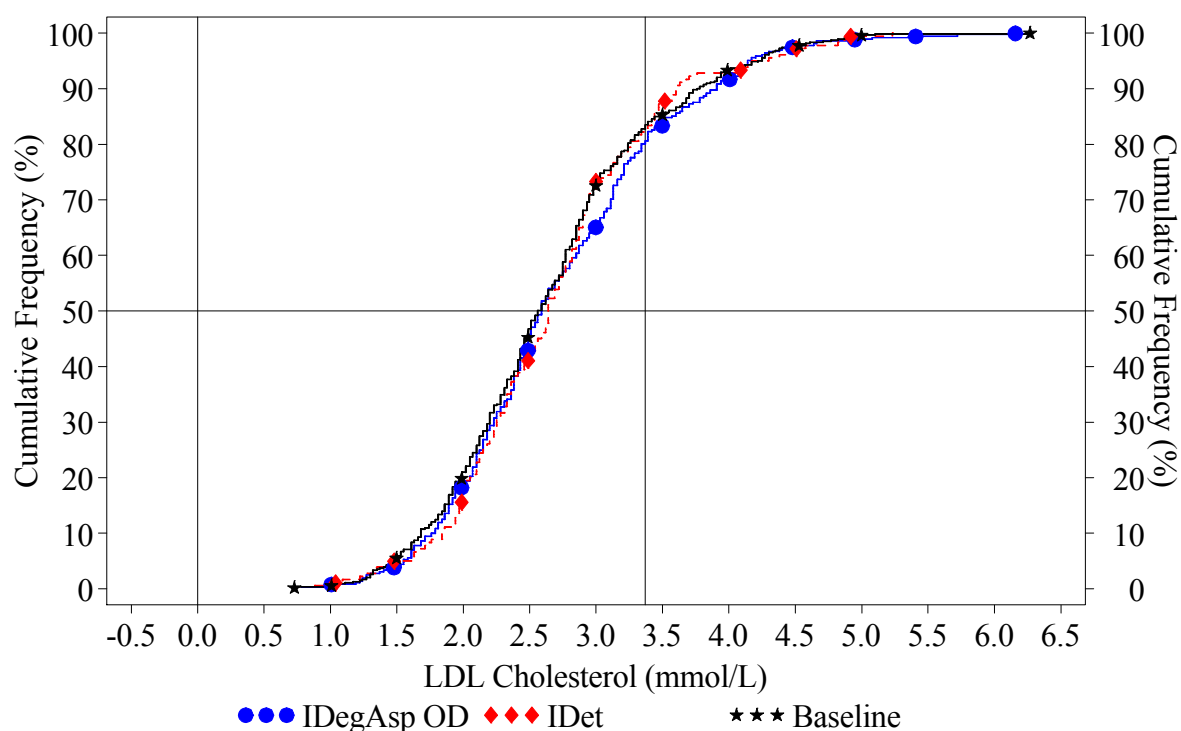
14.3.5.58: Lipid - HDL Cholesterol after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:12:36 - fbox_numfind_v01.sas/e_ldl_abs_box_locf_sas.cgm

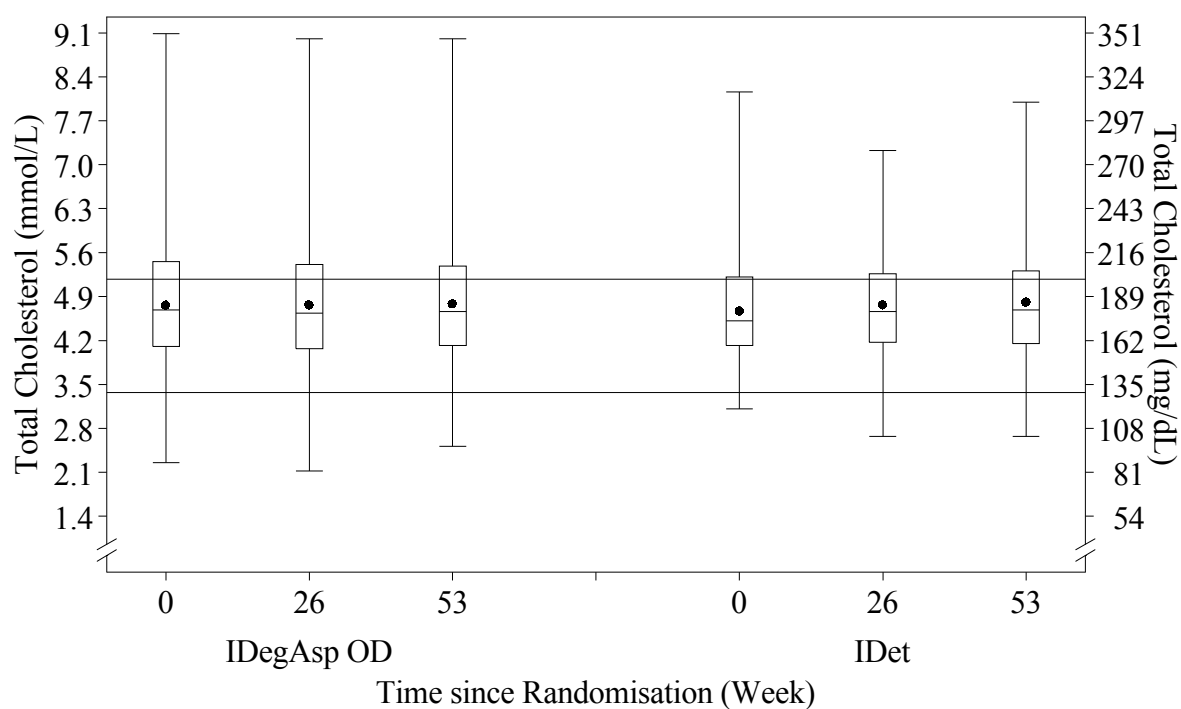
14.3.5.59: Lipid - LDL Cholesterol - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:12:51 - fedist_numfind_v01.sas/e_ldl_abs_cdf_locf_sas.cgm

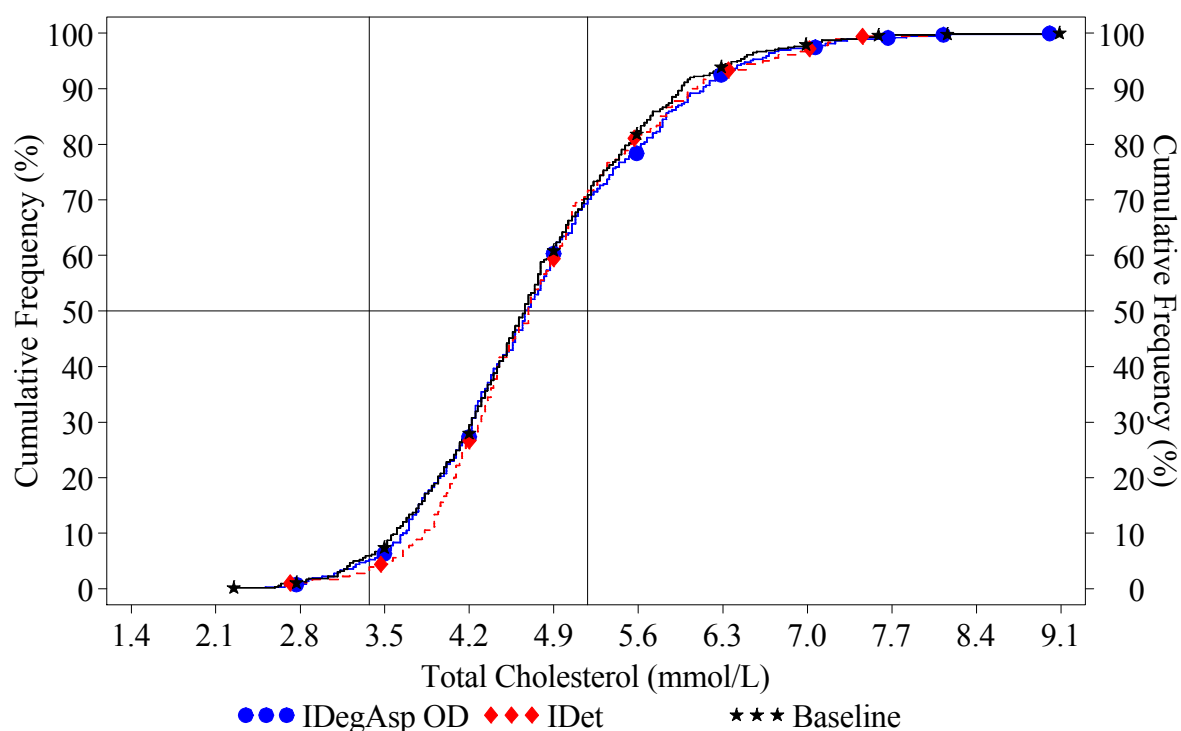
14.3.5.60: Lipid - LDL Cholesterol after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:12:59 - fbox_numfind_v01.sas/e_t_chol_abs_box_locf_sas.cgm

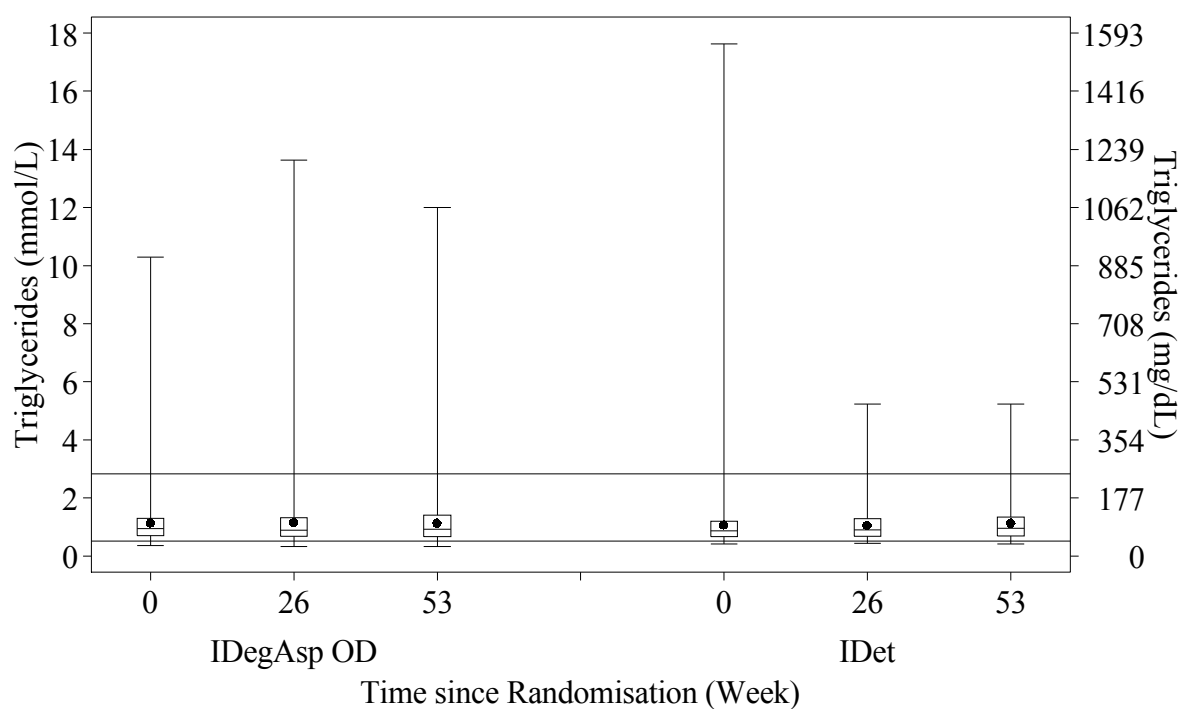
14.3.5.61: Lipid - Tot. Chol. Serum - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:13:14 - fedist_numfind_v01.sas/e_t_chol_abs_cdf_locf_sas.cgm

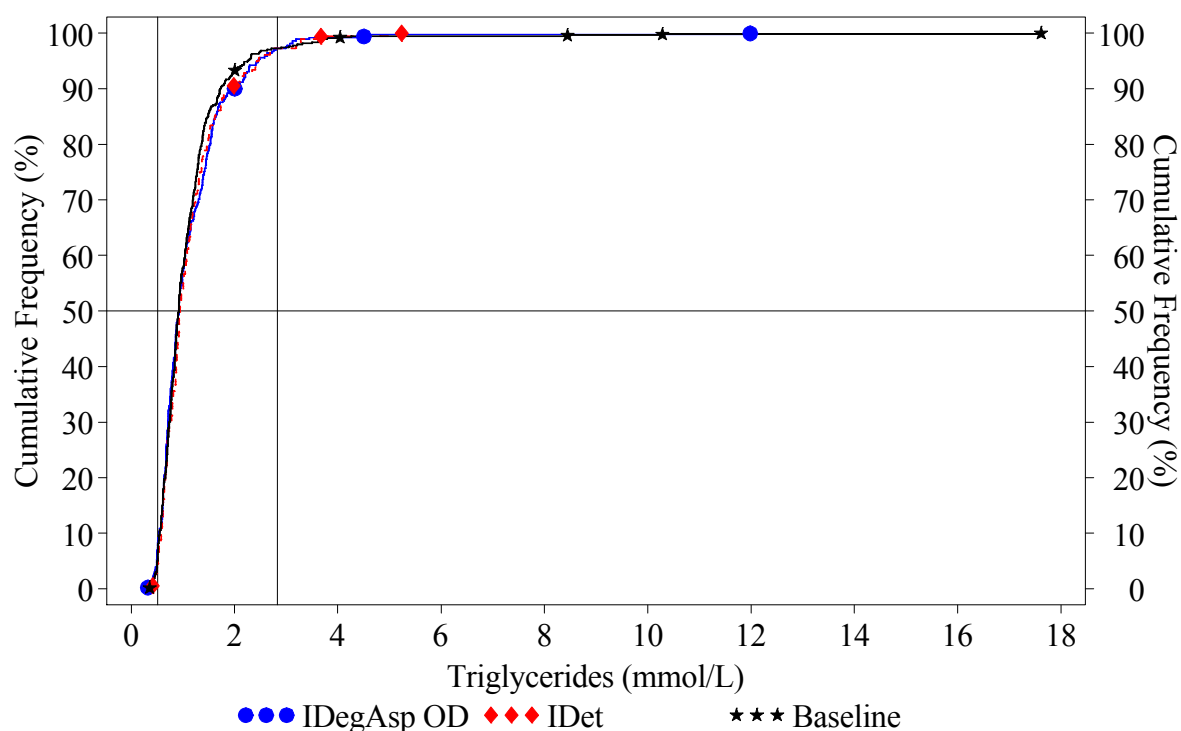
14.3.5.62: Lipid - Tot. Chol. Serum after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
 SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:13:23 - fbox_numfind_v01.sas/e_triglyc_abs_box_locf_sas.cgm

14.3.5.63: Lipid - Triglycerides Serum - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:13:38 - fedist_numfind_v01.sas/e_triglyc_abs_cdf_locf_sas.cgm

14.3.5.64: Lipid - Triglycerides Serum after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set

14.3.5.65: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Albumin/Creatinine Ratio (mg/mmol)			
Visit 2 (Week 0)			
N	358	178	536
Mean (SD)	3.8 (15.1)	4.2 (18.2)	3.9 (16.2)
Median	0.6	0.6	0.6
Min ; Max	0.1 ; 217.6	0.1 ; 200.9	0.1 ; 217.6
Visit 28 (Week 26)			
N	317	154	471
Mean (SD)	4.2 (16.1)	4.8 (21.5)	4.4 (18.0)
Median	0.6	0.6	0.6
Min ; Max	0.1 ; 181.3	0.1 ; 237.5	0.1 ; 237.5
Visit 44 (Week 53)			
N	231	114	345
Mean (SD)	3.0 (10.5)	4.6 (14.7)	3.5 (12.1)
Median	0.7	0.6	0.6
Min ; Max	0.1 ; 132.7	0.1 ; 97.7	0.1 ; 132.7
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	4.4 (18.3)	5.0 (18.1)	4.6 (18.2)
Median	0.7	0.6	0.7
Min ; Max	0.1 ; 217.6	0.1 ; 174.1	0.1 ; 217.6

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:13:47 - tdesc_numfind_tpl_t019_v01.sas/t_urinary_ratio_abs_descp_sas.txt

14.3.5.66: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Albumin / Creatinine Ratio (mg/mmol)			
Visit 28 (Week 26)			
N	313	152	465
Mean (SD)	1.0 (11.0)	1.2 (8.3)	1.1 (10.2)
Median	0.0	0.0	0.0
Min ; Max	-59.0 ; 103.3	-22.1 ; 75.3	-59.0 ; 103.3
Visit 44 (Week 53)			
N	229	113	342
Mean (SD)	0.5 (6.8)	0.6 (17.4)	0.5 (11.4)
Median	0.0	0.0	0.0
Min ; Max	-58.9 ; 62.0	-146.7 ; 82.4	-146.7 ; 82.4
Visit 44 (Week 53) (LOCF)			
N	358	178	536
Mean (SD)	0.6 (9.0)	0.9 (15.2)	0.7 (11.4)
Median	0.0	0.0	0.0
Min ; Max	-58.9 ; 101.2	-146.7 ; 82.4	-146.7 ; 101.2

N = Number of Subjects, SD = Standard Deviation
 Ch = Change from Baseline

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:13:55 - tdesc_numfind_tpl_t019_v01.sas/t_urinary_ratio_chb_descp_sas.txt

14.3.5.67: Urinary Albumin-to-Creatinine Ratio by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Albumin/Creatinine Ratio (mg/mmol)			
Visit 2 (Week 0)			
N	358 (100.0)	178 (100.0)	536 (100.0)
Normal	312 (87.2)	156 (87.6)	468 (87.3)
High	46 (12.8)	22 (12.4)	68 (12.7)
Visit 28 (Week 26)			
N	317 (100.0)	154 (100.0)	471 (100.0)
Normal	275 (86.8)	133 (86.4)	408 (86.6)
High	42 (13.2)	21 (13.6)	63 (13.4)
Visit 30 (Week 27)			
N	5 (100.0)	1 (100.0)	6 (100.0)
Normal	4 (80.0)	1 (100.0)	5 (83.3)
High	1 (20.0)	0	1 (16.7)
Visit 44 (Week 53)			
N	231 (100.0)	114 (100.0)	345 (100.0)
Normal	202 (87.4)	99 (86.8)	301 (87.2)
High	29 (12.6)	15 (13.2)	44 (12.8)
Visit 44 Week 53(LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	314 (86.7)	156 (86.7)	470 (86.7)
High	48 (13.3)	24 (13.3)	72 (13.3)

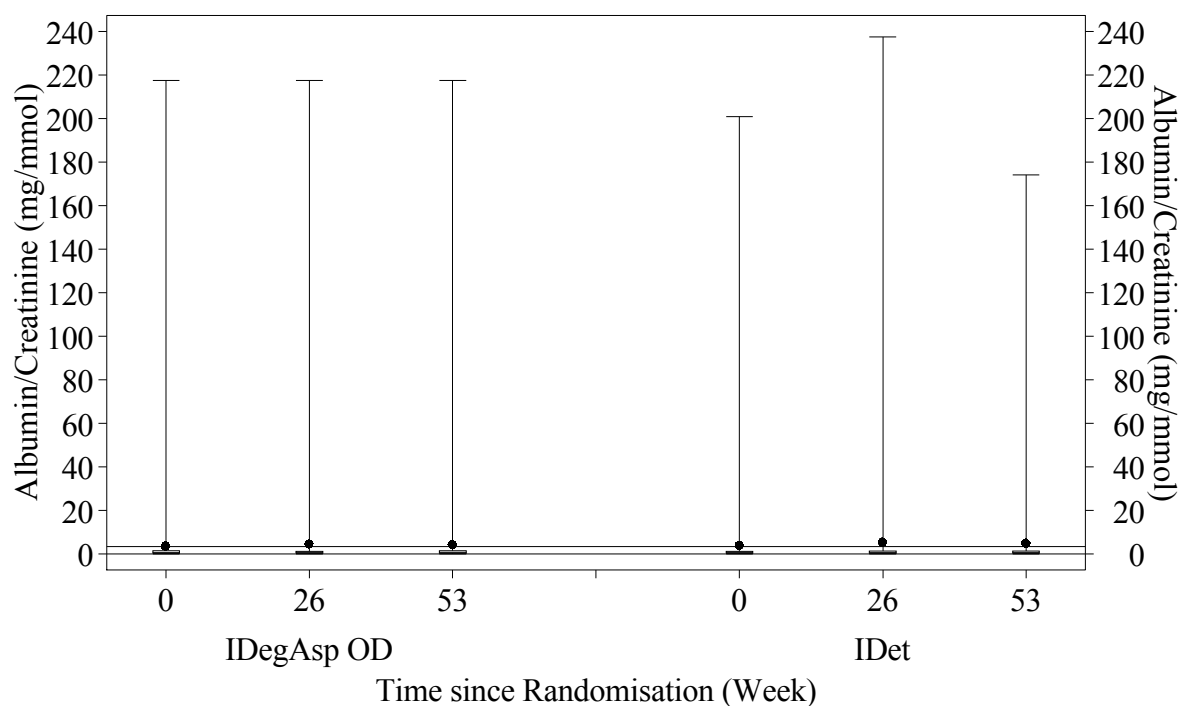
N = Number of Subjects

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:38:44 - tsum_lab_summary.sas/t_urinary_ratio_sum_sas.txt

14.3.5.68: Urinary Albumin-to-Creatinine Ratio – Shift Table – Baseline to Week 53 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline				Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 44 (Week 53)								
Albumin/Creatinine Ratio (mg/mmol)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	192 (53.0)	9 (2.5)	1 (0.3)	0 (0.0)	97 (53.9)	1 (0.6)	1 (0.6)
High	0 (0.0)	10 (2.8)	18 (5.0)	1 (0.3)	0 (0.0)	3 (1.7)	12 (6.7)	0 (0.0)
Missing	0 (0.0)	110 (30.4)	19 (5.2)	2 (0.6)	0 (0.0)	56 (31.1)	9 (5.0)	1 (0.6)

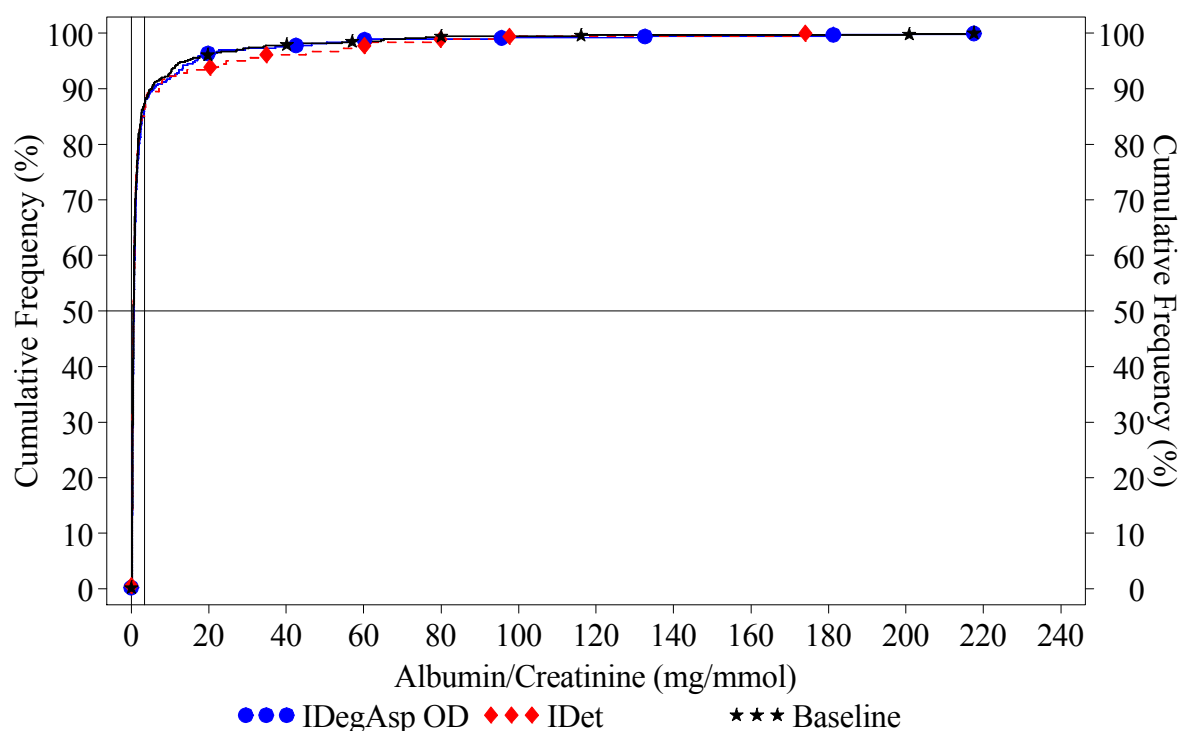
N = Number of subjects



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:04 - fbox_numfind_v01.sas/e_urinary_ratio_abs_box_locf_sas.cgm

14.3.5.69: Urinary Albumin-to-Creatinine Ratio - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:19 - fedist_numfind_v01.sas/e_urinary_ratio_abs_cdf_locf_sas.cgm

14.3.5.70: Urinary Albumin-to-Creatinine Ratio after 52 Weeks of Treatment – Empirical Distribution Plot - Safety Analysis Set

14.3.5.71: Urine by Sticks - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
ERCS Urine			
Visit 1			
N	360 (100.0)	178 (100.0)	538 (100.0)
Negative	324 (90.0)	167 (93.8)	491 (91.3)
Positive	36 (10.0)	11 (6.2)	47 (8.7)
Visit 28 (Week 26)			
N	313 (100.0)	153 (100.0)	466 (100.0)
Negative	297 (94.9)	137 (89.5)	434 (93.1)
Positive	16 (5.1)	16 (10.5)	32 (6.9)
Visit 30 (Week 27)			
N	6 (100.0)	3 (100.0)	9 (100.0)
Negative	6 (100.0)	3 (100.0)	9 (100.0)
Visit 44 (Week 53)			
N	234 (100.0)	114 (100.0)	348 (100.0)
Negative	220 (94.0)	108 (94.7)	328 (94.3)
Positive	9 (3.8)	4 (3.5)	13 (3.7)
Trace	5 (2.1)	2 (1.8)	7 (2.0)
Visit 44 Week 53(LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Negative	334 (92.5)	169 (93.9)	503 (93.0)
Positive	21 (5.8)	9 (5.0)	30 (5.5)
Trace	6 (1.7)	2 (1.1)	8 (1.5)
Ketones			
Visit 1			
N	360 (100.0)	178 (100.0)	538 (100.0)
Negative	298 (82.8)	161 (90.4)	459 (85.3)
Positive	62 (17.2)	17 (9.6)	79 (14.7)
Visit 28 (Week 26)			
N	313 (100.0)	153 (100.0)	466 (100.0)
Negative	290 (92.7)	133 (86.9)	423 (90.8)
Positive	23 (7.3)	20 (13.1)	43 (9.2)
Visit 30 (Week 27)			
N	6 (100.0)	3 (100.0)	9 (100.0)
Negative	6 (100.0)	2 (66.7)	8 (88.9)
Trace	0	1 (33.3)	1 (11.1)
Visit 44 (Week 53)			
N	234 (100.0)	114 (100.0)	348 (100.0)
Negative	218 (93.2)	101 (88.6)	319 (91.7)
Positive	6 (2.6)	5 (4.4)	11 (3.2)
Trace	10 (4.3)	8 (7.0)	18 (5.2)

N = Number of Subjects

Positive: Includes also 1+, 2+, 3+ from the Extension part

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:38:48 - tsum_lab_summary.sas/t_urine_sticks_sum_sas.txt

Urine by Sticks - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Negative	335 (92.8)	153 (85.0)	488 (90.2)
Positive	15 (4.2)	18 (10.0)	33 (6.1)
Trace	11 (3.0)	9 (5.0)	20 (3.7)
Protein-sticks			
Visit 1			
N	360 (100.0)	178 (100.0)	538 (100.0)
Negative	261 (72.5)	137 (77.0)	398 (74.0)
Positive	99 (27.5)	41 (23.0)	140 (26.0)
Visit 28 (Week 26)			
N	313 (100.0)	153 (100.0)	466 (100.0)
Negative	184 (58.8)	107 (69.9)	291 (62.4)
Positive	129 (41.2)	46 (30.1)	175 (37.6)
Visit 30 (Week 27)			
N	6 (100.0)	3 (100.0)	9 (100.0)
Negative	5 (83.3)	3 (100.0)	8 (88.9)
Positive	1 (16.7)	0	1 (11.1)
Visit 44 (Week 53)			
N	234 (100.0)	114 (100.0)	348 (100.0)
Negative	168 (71.8)	81 (71.1)	249 (71.6)
Positive	23 (9.8)	12 (10.5)	35 (10.1)
Trace	43 (18.4)	21 (18.4)	64 (18.4)
Visit 44 Week 53 (LOCF)			
N	361 (100.0)	180 (100.0)	541 (100.0)
Negative	242 (67.0)	123 (68.3)	365 (67.5)
Positive	75 (20.8)	36 (20.0)	111 (20.5)
Trace	44 (12.2)	21 (11.7)	65 (12.0)

N = Number of Subjects

Positive: Includes also 1+, 2+, 3+ from the Extension part

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:38:48 - tsum_lab_summary.sas/t_urine_sticks_sum_sas.txt

14.3.5.72: Urine by Sticks – Shift Table – Baseline to Week 53 – Safety Analysis Set

Number of Subjects	IDegAsp OD 362				IDet 180			
	Baseline			Unknown N (%)	Baseline			Unknown N (%)
	Positive N (%)	Negative N (%)	Trace N (%)		Positive N (%)	Negative N (%)	Trace N (%)	
Visit 44 (Week 53)								
ERCS Urine								
Positive	2 (0.6)	7 (1.9)	0 (0.0)	0 (0.0)	2 (1.1)	2 (1.1)	0 (0.0)	0 (0.0)
Negative	16 (4.4)	203 (56.1)	0 (0.0)	1 (0.3)	4 (2.2)	102 (56.7)	0 (0.0)	2 (1.1)
Trace	1 (0.3)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)
Unknown	17 (4.7)	110 (30.4)	0 (0.0)	1 (0.3)	5 (2.8)	61 (33.9)	0 (0.0)	0 (0.0)
Ketones Urine Stick								
Positive	3 (0.8)	3 (0.8)	0 (0.0)	0 (0.0)	1 (0.6)	4 (2.2)	0 (0.0)	0 (0.0)
Negative	39 (10.8)	178 (49.2)	0 (0.0)	1 (0.3)	9 (5.0)	91 (50.6)	0 (0.0)	1 (0.6)
Trace	2 (0.6)	8 (2.2)	0 (0.0)	0 (0.0)	1 (0.6)	6 (3.3)	0 (0.0)	1 (0.6)
Unknown	18 (5.0)	109 (30.1)	0 (0.0)	1 (0.3)	6 (3.3)	60 (33.3)	0 (0.0)	0 (0.0)
Urine Protein-sticks								
Positive	17 (4.7)	6 (1.7)	0 (0.0)	0 (0.0)	8 (4.4)	2 (1.1)	0 (0.0)	2 (1.1)
Negative	31 (8.6)	136 (37.6)	0 (0.0)	1 (0.3)	10 (5.6)	71 (39.4)	0 (0.0)	0 (0.0)
Trace	15 (4.1)	28 (7.7)	0 (0.0)	0 (0.0)	5 (2.8)	16 (8.9)	0 (0.0)	0 (0.0)
Unknown	36 (9.9)	91 (25.1)	0 (0.0)	1 (0.3)	18 (10.0)	48 (26.7)	0 (0.0)	0 (0.0)

N = Number of subjects, ERCS Urine = Erythrocytes urine
Positive: Includes also 1+, 2+, 3+ from the Extension part

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:37:39 - t_lab_shift.sas/t_urine_sticks_shift_w53_sas.txt

14.3.6 Displays of Vital Signs, Physical Findings and Other Observations Related to Safety

14.3.6.1: Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Cardiovascular System			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	344 (95.0)	166 (92.2)	510 (94.1)
Abnormal, Not Clinically Significant	16 (4.4)	12 (6.7)	28 (5.2)
Abnormal, Clinically Significant	2 (0.6)	2 (1.1)	4 (0.7)
Visit 28 (Week 26)			
N	319 (100.0)	153 (100.0)	472 (100.0)
Normal	300 (94.0)	143 (93.5)	443 (93.9)
Abnormal, Not Clinically Significant	18 (5.6)	7 (4.6)	25 (5.3)
Abnormal, Clinically Significant	1 (0.3)	3 (2.0)	4 (0.8)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Abnormal, Not Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	227 (96.2)	110 (96.5)	337 (96.3)
Abnormal, Not Clinically Significant	9 (3.8)	3 (2.6)	12 (3.4)
Abnormal, Clinically Significant	0 (0.0)	1 (0.9)	1 (0.3)
Visit 44 (Week 53) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	346 (95.6)	168 (93.3)	514 (94.8)
Abnormal, Not Clinically Significant	15 (4.1)	9 (5.0)	24 (4.4)
Abnormal, Clinically Significant	1 (0.3)	3 (1.7)	4 (0.7)

N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:24 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Central and Peripheral Nervous System			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	275 (76.0)	133 (73.9)	408 (75.3)
Abnormal, Not Clinically Significant	74 (20.4)	43 (23.9)	117 (21.6)
Abnormal, Clinically Significant	13 (3.6)	4 (2.2)	17 (3.1)
Visit 28 (Week 26)			
N	319 (100.0)	153 (100.0)	472 (100.0)
Normal	256 (80.3)	119 (77.8)	375 (79.4)
Abnormal, Not Clinically Significant	57 (17.9)	32 (20.9)	89 (18.9)
Abnormal, Clinically Significant	6 (1.9)	2 (1.3)	8 (1.7)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Abnormal, Not Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	186 (78.8)	89 (78.1)	275 (78.6)
Abnormal, Not Clinically Significant	46 (19.5)	25 (21.9)	71 (20.3)
Abnormal, Clinically Significant	4 (1.7)	0 (0.0)	4 (1.1)
Visit 44 (Week 53) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	292 (80.7)	138 (76.7)	430 (79.3)
Abnormal, Not Clinically Significant	64 (17.7)	42 (23.3)	106 (19.6)
Abnormal, Clinically Significant	6 (1.7)	0 (0.0)	6 (1.1)

N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:24 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Gastrointestinal System incl. Mouth			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	355 (98.1)	173 (96.1)	528 (97.4)
Abnormal, Not Clinically Significant	6 (1.7)	7 (3.9)	13 (2.4)
Abnormal, Clinically Significant	1 (0.3)	0 (0.0)	1 (0.2)
Visit 28 (Week 26)			
N	319 (100.0)	153 (100.0)	472 (100.0)
Normal	315 (98.7)	152 (99.3)	467 (98.9)
Abnormal, Not Clinically Significant	3 (0.9)	1 (0.7)	4 (0.8)
Abnormal, Clinically Significant	1 (0.3)	0 (0.0)	1 (0.2)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Abnormal, Not Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	233 (98.7)	113 (99.1)	346 (98.9)
Abnormal, Not Clinically Significant	3 (1.3)	0 (0.0)	3 (0.9)
Abnormal, Clinically Significant	0 (0.0)	1 (0.9)	1 (0.3)
Visit 44 (Week 53) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	356 (98.3)	177 (98.3)	533 (98.3)
Abnormal, Not Clinically Significant	5 (1.4)	2 (1.1)	7 (1.3)
Abnormal, Clinically Significant	1 (0.3)	1 (0.6)	2 (0.4)

N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:24 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Head, Ears, Eyes, Nose, Throat, Neck			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	312 (86.2)	164 (91.1)	476 (87.8)
Abnormal, Not Clinically Significant	45 (12.4)	15 (8.3)	60 (11.1)
Abnormal, Clinically Significant	5 (1.4)	1 (0.6)	6 (1.1)
Visit 28 (Week 26)			
N	319 (100.0)	153 (100.0)	472 (100.0)
Normal	284 (89.0)	142 (92.8)	426 (90.3)
Abnormal, Not Clinically Significant	32 (10.0)	11 (7.2)	43 (9.1)
Abnormal, Clinically Significant	3 (0.9)	0 (0.0)	3 (0.6)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Abnormal, Not Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	214 (90.7)	108 (94.7)	322 (92.0)
Abnormal, Not Clinically Significant	18 (7.6)	6 (5.3)	24 (6.9)
Abnormal, Clinically Significant	4 (1.7)	0 (0.0)	4 (1.1)
Visit 44 (Week 53) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	331 (91.4)	166 (92.2)	497 (91.7)
Abnormal, Not Clinically Significant	27 (7.5)	14 (7.8)	41 (7.6)
Abnormal, Clinically Significant	4 (1.1)	0 (0.0)	4 (0.7)

N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:24 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Musculoskeletal System			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	345 (95.3)	169 (93.9)	514 (94.8)
Abnormal, Not Clinically Significant	15 (4.1)	10 (5.6)	25 (4.6)
Abnormal, Clinically Significant	2 (0.6)	1 (0.6)	3 (0.6)
Visit 28 (Week 26)			
N	319 (100.0)	153 (100.0)	472 (100.0)
Normal	309 (96.9)	145 (94.8)	454 (96.2)
Abnormal, Not Clinically Significant	9 (2.8)	7 (4.6)	16 (3.4)
Abnormal, Clinically Significant	1 (0.3)	1 (0.7)	2 (0.4)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Abnormal, Not Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	227 (96.2)	110 (96.5)	337 (96.3)
Abnormal, Not Clinically Significant	9 (3.8)	4 (3.5)	13 (3.7)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 44 (Week 53) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	349 (96.4)	170 (94.4)	519 (95.8)
Abnormal, Not Clinically Significant	13 (3.6)	10 (5.6)	23 (4.2)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:24 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Respiratory System			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	359 (99.2)	177 (98.3)	536 (98.9)
Abnormal, Not Clinically Significant	3 (0.8)	3 (1.7)	6 (1.1)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 28 (Week 26)			
N	319 (100.0)	153 (100.0)	472 (100.0)
Normal	316 (99.1)	150 (98.0)	466 (98.7)
Abnormal, Not Clinically Significant	3 (0.9)	3 (2.0)	6 (1.3)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Abnormal, Not Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	234 (99.2)	113 (99.1)	347 (99.1)
Abnormal, Not Clinically Significant	2 (0.8)	1 (0.9)	3 (0.9)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 44 (Week 53) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	360 (99.4)	178 (98.9)	538 (99.3)
Abnormal, Not Clinically Significant	2 (0.6)	2 (1.1)	4 (0.7)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)

N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:24 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

Physical Examination by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Skin			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	329 (90.9)	163 (90.6)	492 (90.8)
Abnormal, Not Clinically Significant	29 (8.0)	16 (8.9)	45 (8.3)
Abnormal, Clinically Significant	4 (1.1)	1 (0.6)	5 (0.9)
Visit 28 (Week 26)			
N	319 (100.0)	153 (100.0)	472 (100.0)
Normal	291 (91.2)	133 (86.9)	424 (89.8)
Abnormal, Not Clinically Significant	25 (7.8)	20 (13.1)	45 (9.5)
Abnormal, Clinically Significant	3 (0.9)	0 (0.0)	3 (0.6)
Visit 30 (Week 27)			
N	2 (100.0)	1 (100.0)	3 (100.0)
Normal	2 (100.0)	1 (100.0)	3 (100.0)
Abnormal, Not Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 44 (Week 53)			
N	236 (100.0)	114 (100.0)	350 (100.0)
Normal	213 (90.3)	100 (87.7)	313 (89.4)
Abnormal, Not Clinically Significant	21 (8.9)	13 (11.4)	34 (9.7)
Abnormal, Clinically Significant	2 (0.8)	1 (0.9)	3 (0.9)
Visit 44 (Week 53) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	329 (90.9)	157 (87.2)	486 (89.7)
Abnormal, Not Clinically Significant	31 (8.6)	22 (12.2)	53 (9.8)
Abnormal, Clinically Significant	2 (0.6)	1 (0.6)	3 (0.6)

N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:24 - tsum_catgofind_tpl_t025_v01.sas/t_phys_exam_sum_sas.txt

14.3.6.2: Physical Examination - Shift Table - Baseline to Week 52 - Safety Analysis Set

IDegAsp OD				IDet			
Number of Subjects				362			
				180			
				Visit 44 (Week 53)			
Visit 1	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS	
	N	N	N	N	N	N	
Cardiovascular System							
Normal	224	3	0	107	1	0	
Abnormal, NCS	3	6	0	2	2	0	
Abnormal, CS	0	0	0	1	0	1	
Central and Peripheral Nervous System							
Normal	171	4	0	83	4	0	
Abnormal, NCS	14	39	1	5	19	0	
Abnormal, CS	1	3	3	1	2	0	
Gastrointestinal System incl. Mouth							
Normal	231	2	0	112	0	1	
Abnormal, NCS	2	1	0	1	0	0	
Abnormal, CS	0	0	0	0	0	0	
Head, Ears, Eyes, Nose, Throat, Neck							
Normal	199	3	3	103	2	0	
Abnormal, NCS	14	14	1	5	4	0	
Abnormal, CS	1	1	0	0	0	0	
Musculoskeletal System							
Normal	223	2	0	109	0	0	
Abnormal, NCS	4	6	0	1	3	0	
Abnormal, CS	0	1	0	0	1	0	

N = Number of Subjects, NCS = Not Clinically Significant, CS = Clinically Significant.
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:29 - tshift_catgofind_tpl_t026_v01.sas/t_phys_exam_shift_w52_sas.txt

Physical Examination - Shift Table - Baseline to Week 52 - Safety Analysis Set

IDegAsp OD				IDet		
Number of Subjects				362		
				180		
				Visit 44 (Week 53)		
Visit 1	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
	N	N	N	N	N	N
Respiratory System						
Normal	233	1	0	111	1	0
Abnormal, NCS	1	1	0	2	0	0
Abnormal, CS	0	0	0	0	0	0
Skin						
Normal	202	10	1	96	6	1
Abnormal, NCS	9	10	0	3	7	0
Abnormal, CS	2	1	1	1	0	0

14.3.6.3: Vital Signs by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Mean Diastolic BP (mmHg)			
Visit 1			
N	357	177	534
Mean (SD)	75.8 (8.8)	74.8 (8.2)	75.5 (8.6)
Median	77.0	74.0	75.0
Min ; Max	40.0 ; 103.0	50.0 ; 97.0	40.0 ; 103.0
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	75.0 (8.9)	74.5 (9.4)	74.9 (9.1)
Median	75.0	75.0	75.0
Min ; Max	40.0 ; 96.0	51.0 ; 99.0	40.0 ; 99.0
Visit 30 (Week 27)			
N	250	121	371
Mean (SD)	74.7 (7.8)	73.5 (8.5)	74.3 (8.0)
Median	75.0	74.0	74.0
Min ; Max	54.0 ; 96.0	54.0 ; 102.0	54.0 ; 102.0
Visit 44 (Week 53)			
N	237	114	351
Mean (SD)	75.4 (8.6)	74.7 (8.6)	75.2 (8.6)
Median	75.0	74.5	75.0
Min ; Max	50.0 ; 98.0	51.0 ; 95.0	50.0 ; 98.0
Visit 44 (Week 53) (LOCF)			
N	362	179	541
Mean (SD)	75.1 (8.6)	75.1 (8.9)	75.1 (8.7)
Median	75.0	75.0	75.0
Min ; Max	50.0 ; 98.0	51.0 ; 95.0	50.0 ; 98.0

Vital Signs by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Mean Systolic BP (mmHg)			
Visit 1			
N	357	177	534
Mean (SD)	123.9 (13.9)	123.5 (13.6)	123.8 (13.8)
Median	123.0	122.0	122.5
Min ; Max	91.0 ; 178.0	89.0 ; 166.0	89.0 ; 178.0
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	123.6 (13.5)	123.4 (15.1)	123.5 (14.0)
Median	123.0	122.0	123.0
Min ; Max	83.0 ; 180.0	87.0 ; 180.0	83.0 ; 180.0
Visit 30 (Week 27)			
N	250	121	371
Mean (SD)	122.4 (12.3)	120.7 (13.0)	121.8 (12.6)
Median	122.0	120.0	121.0
Min ; Max	75.0 ; 166.0	90.0 ; 166.0	75.0 ; 166.0
Visit 44 (Week 53)			
N	237	114	351
Mean (SD)	123.4 (13.3)	122.6 (13.5)	123.1 (13.4)
Median	121.0	120.0	121.0
Min ; Max	80.0 ; 182.0	90.0 ; 154.0	80.0 ; 182.0
Visit 44 (Week 53) (LOCF)			
N	362	179	541
Mean (SD)	123.2 (13.6)	124.1 (14.4)	123.5 (13.9)
Median	122.0	122.0	122.0
Min ; Max	80.0 ; 182.0	90.0 ; 180.0	80.0 ; 182.0

Vital Signs by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Pulse (beats/min)			
Visit 1			
N	362	180	542
Mean (SD)	74.6 (10.4)	74.3 (10.4)	74.5 (10.4)
Median	74.0	74.0	74.0
Min ; Max	47.0 ; 112.0	50.0 ; 102.0	47.0 ; 112.0
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	74.8 (10.3)	75.5 (10.8)	75.1 (10.5)
Median	74.0	74.0	74.0
Min ; Max	45.0 ; 110.0	52.0 ; 108.0	45.0 ; 110.0
Visit 30 (Week 27)			
N	250	121	371
Mean (SD)	75.3 (10.4)	73.4 (9.0)	74.7 (10.0)
Median	75.0	73.0	74.0
Min ; Max	47.0 ; 117.0	46.0 ; 100.0	46.0 ; 117.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	75.1 (9.4)	73.9 (10.1)	74.7 (9.6)
Median	75.0	74.5	75.0
Min ; Max	50.0 ; 100.0	50.0 ; 98.0	50.0 ; 100.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	75.2 (9.8)	75.1 (10.8)	75.1 (10.1)
Median	75.0	76.0	75.0
Min ; Max	50.0 ; 109.0	50.0 ; 108.0	50.0 ; 109.0

14.3.6.4: Vital Signs by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

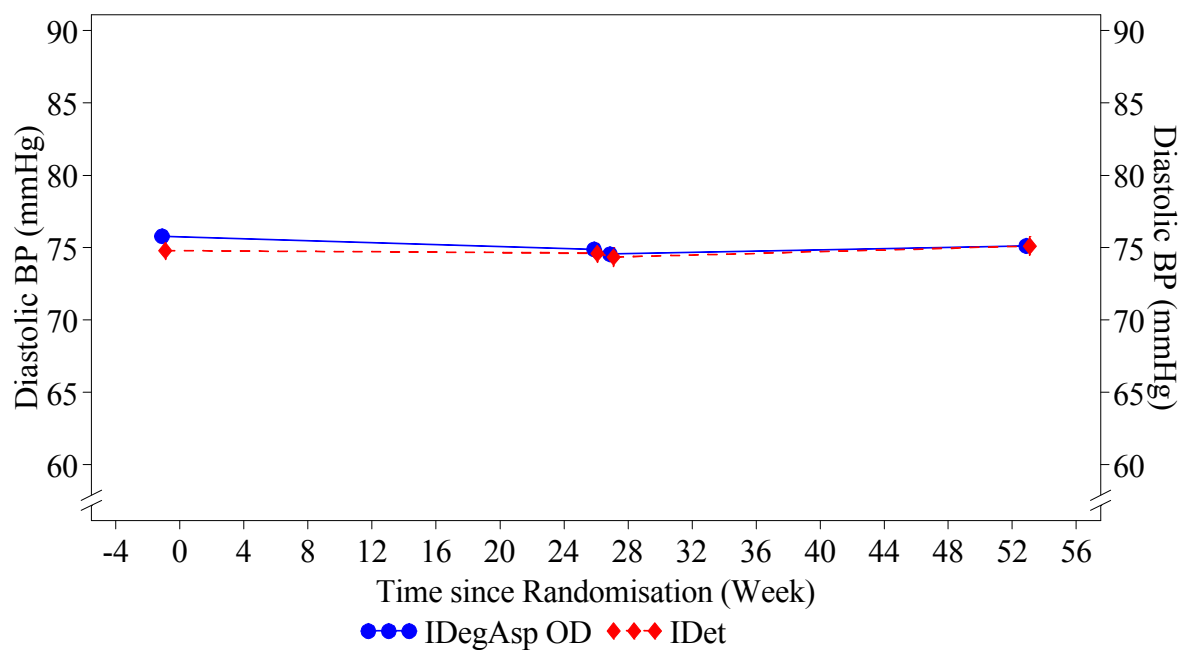
	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Diastolic Blood Pressure (mmHg)			
Visit 28 (Week 26)			
N	315	156	471
Mean (SD)	-0.9 (9.0)	-0.2 (9.4)	-0.7 (9.2)
Median	-1.0	-1.0	-1.0
Min ; Max	-38.0 ; 35.0	-27.0 ; 37.0	-38.0 ; 37.0
Visit 30 (Week 27)			
N	249	121	370
Mean (SD)	-1.8 (8.3)	-0.7 (9.4)	-1.4 (8.7)
Median	-2.0	-1.0	-1.0
Min ; Max	-21.0 ; 34.0	-22.0 ; 41.0	-22.0 ; 41.0
Visit 44 (Week 53)			
N	233	113	346
Mean (SD)	-0.9 (8.5)	0.1 (9.2)	-0.6 (8.8)
Median	-2.0	0.0	-1.0
Min ; Max	-22.0 ; 26.0	-23.0 ; 28.0	-23.0 ; 28.0
Visit 44 (Week 53) (LOCF)			
N	357	177	534
Mean (SD)	-0.6 (8.7)	0.3 (8.8)	-0.3 (8.8)
Median	-1.0	0.0	-1.0
Min ; Max	-23.0 ; 26.0	-25.0 ; 28.0	-25.0 ; 28.0

Vital Signs by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Systolic Blood Pressure (mmHg)			
Visit 28 (Week 26)			
N	315	156	471
Mean (SD)	-0.3 (12.7)	-0.0 (14.0)	-0.2 (13.1)
Median	-1.0	-1.0	-1.0
Min ; Max	-44.0 ; 67.0	-54.0 ; 36.0	-54.0 ; 67.0
Visit 30 (Week 27)			
N	249	121	370
Mean (SD)	-2.3 (12.1)	-1.4 (13.3)	-2.0 (12.5)
Median	-3.0	-2.0	-2.0
Min ; Max	-50.0 ; 34.0	-38.0 ; 41.0	-50.0 ; 41.0
Visit 44 (Week 53)			
N	233	113	346
Mean (SD)	-1.7 (12.6)	0.0 (13.9)	-1.1 (13.0)
Median	-2.0	-1.0	-2.0
Min ; Max	-60.0 ; 39.0	-29.0 ; 47.0	-60.0 ; 47.0
Visit 44 (Week 53) (LOCF)			
N	357	177	534
Mean (SD)	-0.8 (11.9)	0.4 (14.1)	-0.4 (12.7)
Median	-1.0	0.0	0.0
Min ; Max	-60.0 ; 39.0	-54.0 ; 47.0	-60.0 ; 47.0

Vital Signs by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

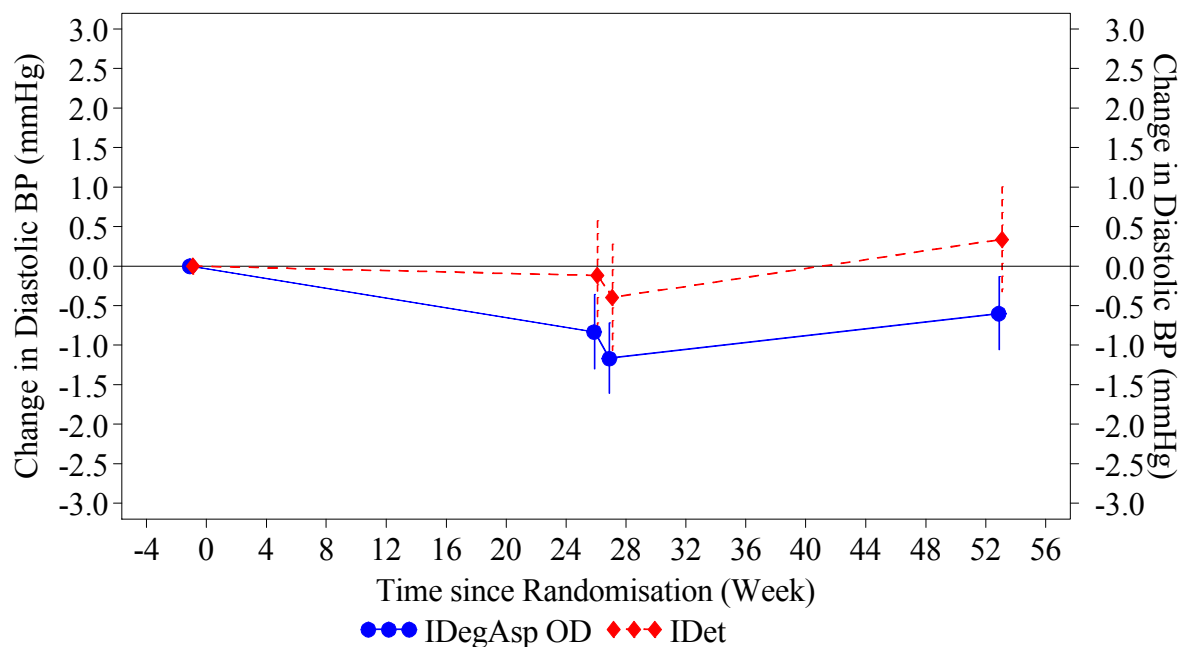
	IDegAsp OD	IDet	Total
Ch. Pulse (beats/min)			
Visit 28 (Week 26)			
N	320	157	477
Mean (SD)	0.2 (10.6)	1.1 (9.4)	0.5 (10.2)
Median	0.0	0.0	0.0
Min ; Max	-38.0 ; 45.0	-30.0 ; 34.0	-38.0 ; 45.0
Visit 30 (Week 27)			
N	250	121	371
Mean (SD)	0.1 (10.4)	-0.3 (9.3)	-0.0 (10.0)
Median	0.0	0.0	0.0
Min ; Max	-44.0 ; 39.0	-24.0 ; 20.0	-44.0 ; 39.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	0.1 (8.7)	0.4 (9.0)	0.2 (8.8)
Median	0.0	0.0	0.0
Min ; Max	-22.0 ; 27.0	-28.0 ; 24.0	-28.0 ; 27.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	0.6 (10.2)	0.7 (9.2)	0.6 (9.8)
Median	0.5	0.0	0.0
Min ; Max	-44.0 ; 45.0	-30.0 ; 31.0	-44.0 ; 45.0



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:14:57 - fmean_numfind_v03.sas/e_vital_diasto_abs_mean_locf_sas.cgm

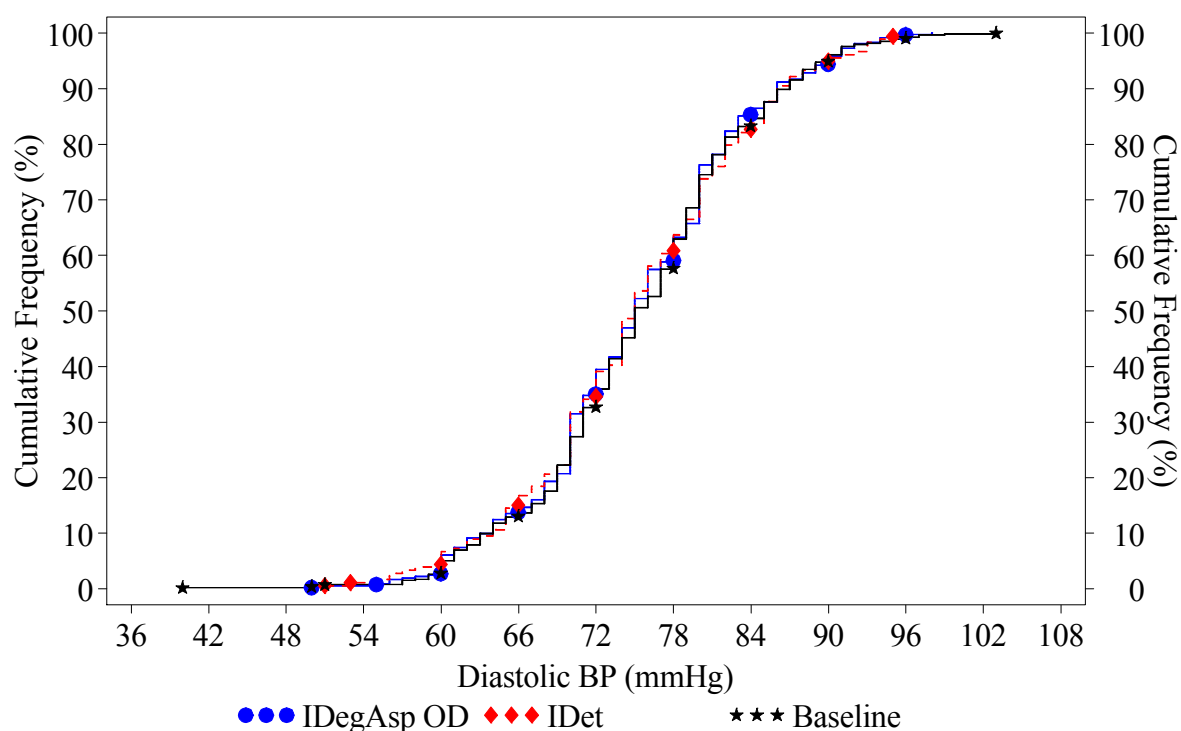
14.3.6.5: Diastolic Blood Pressure - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +/-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:15:06 - fmean_numfind_v03.sas/e_vital_diasto_chb_mean_locf_sas.cgm

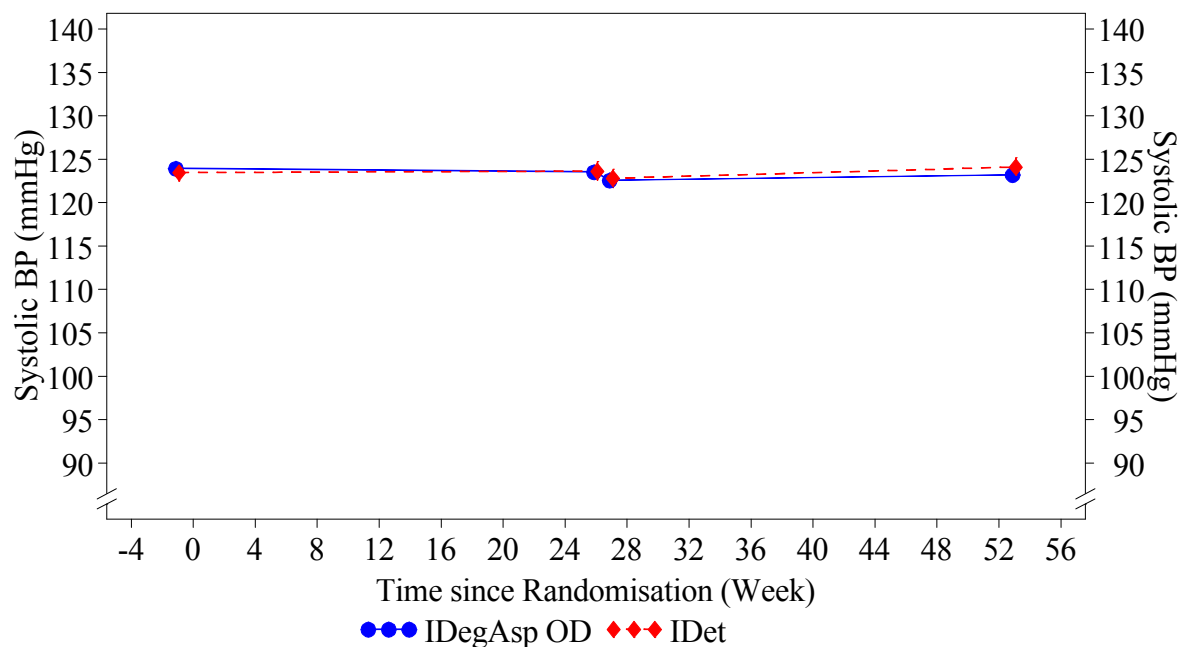
14.3.6.6: Diastolic Blood Pressure - Change from Baseline - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:15:21 - fedist_numfind_v01.sas/e_vital_diasto_abs_cdf_locf_sas.cgm

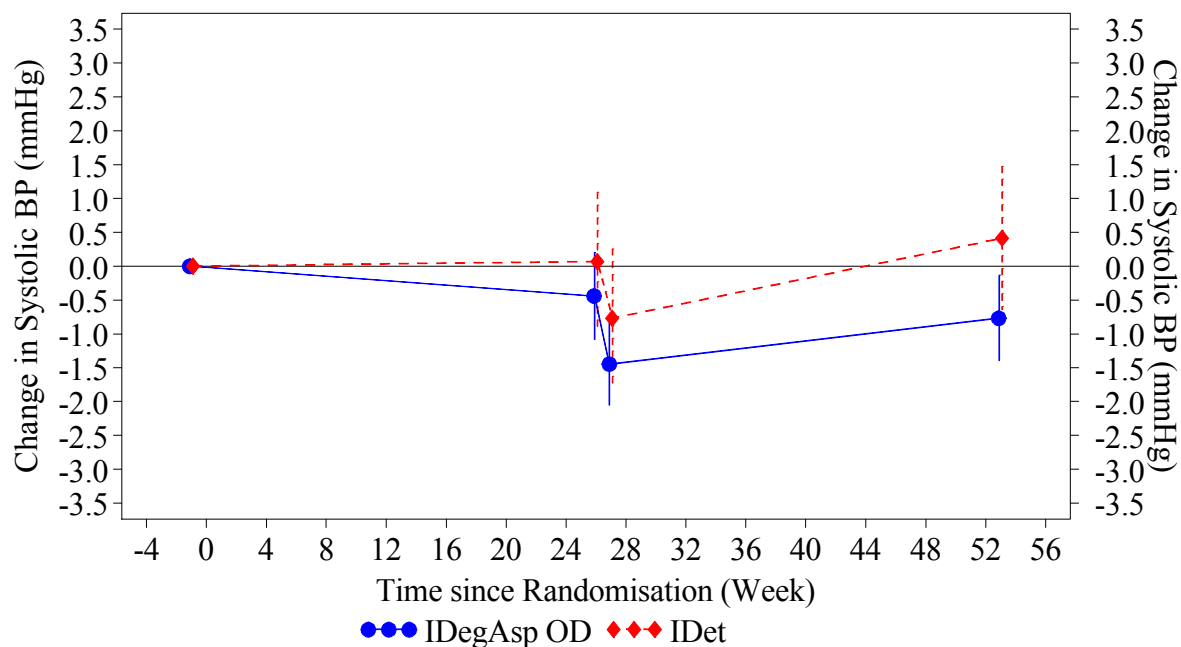
14.3.6.7: Diastolic Blood Pressure after 52 Weeks of Treatment - Empirical Distribution Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +/-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:15:30 - fmean_numfind_v03.sas/e_vital_systo_abs_mean_locf_sas.cgm

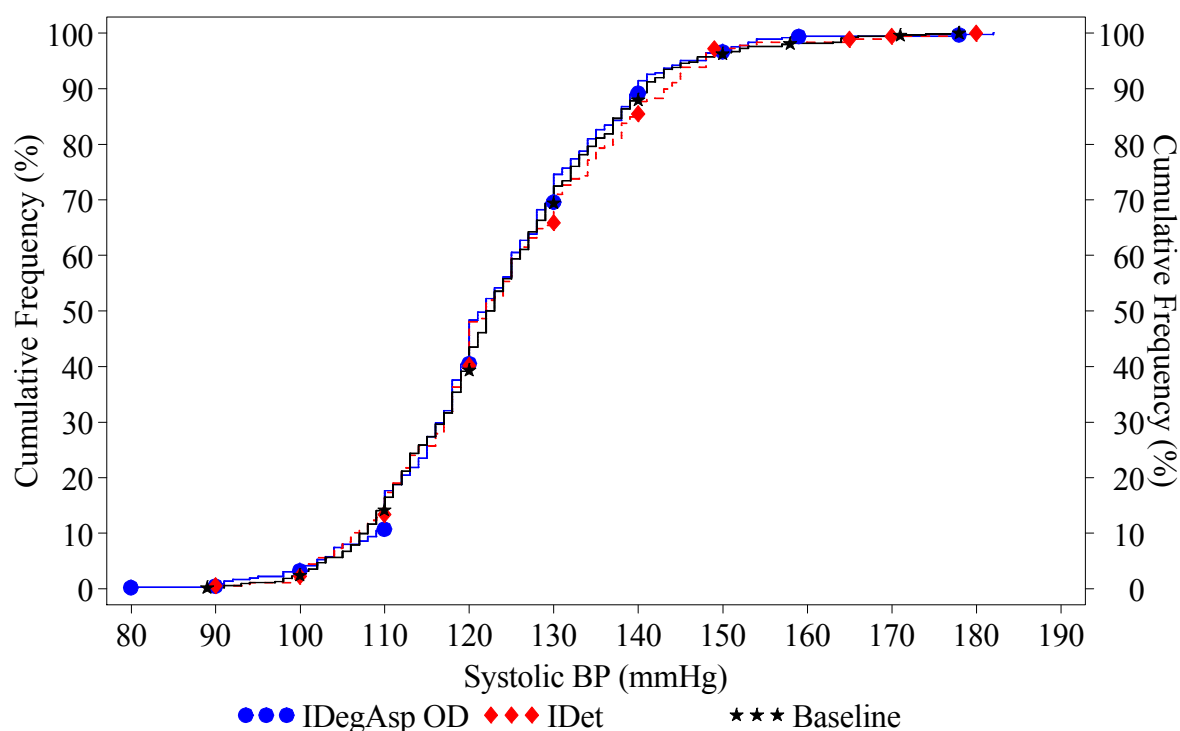
14.3.6.8: Systolic Blood Pressure - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:15:38 - fmean_numfind_v03.sas/e_vital_systo_chb_mean_locf_sas.cgm

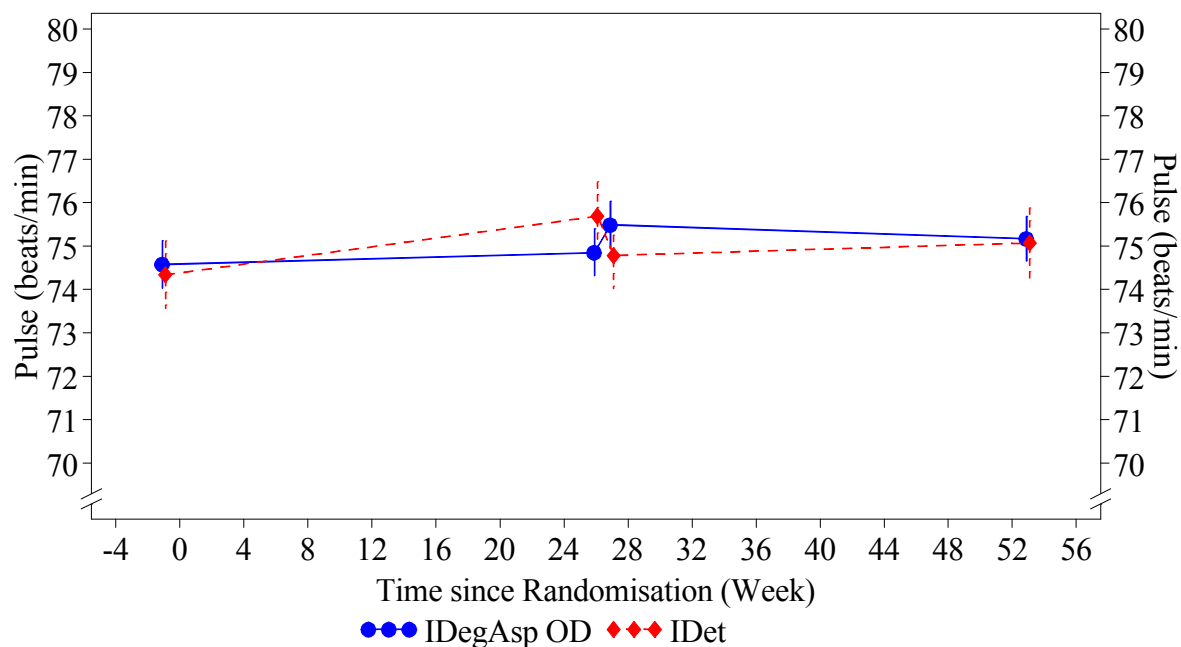
14.3.6.9: Systolic Blood Pressure - Change from Baseline - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:15:54 - fedist_numfind_v01.sas/e_vital_systo_abs_cdf_locf_sas.cgm

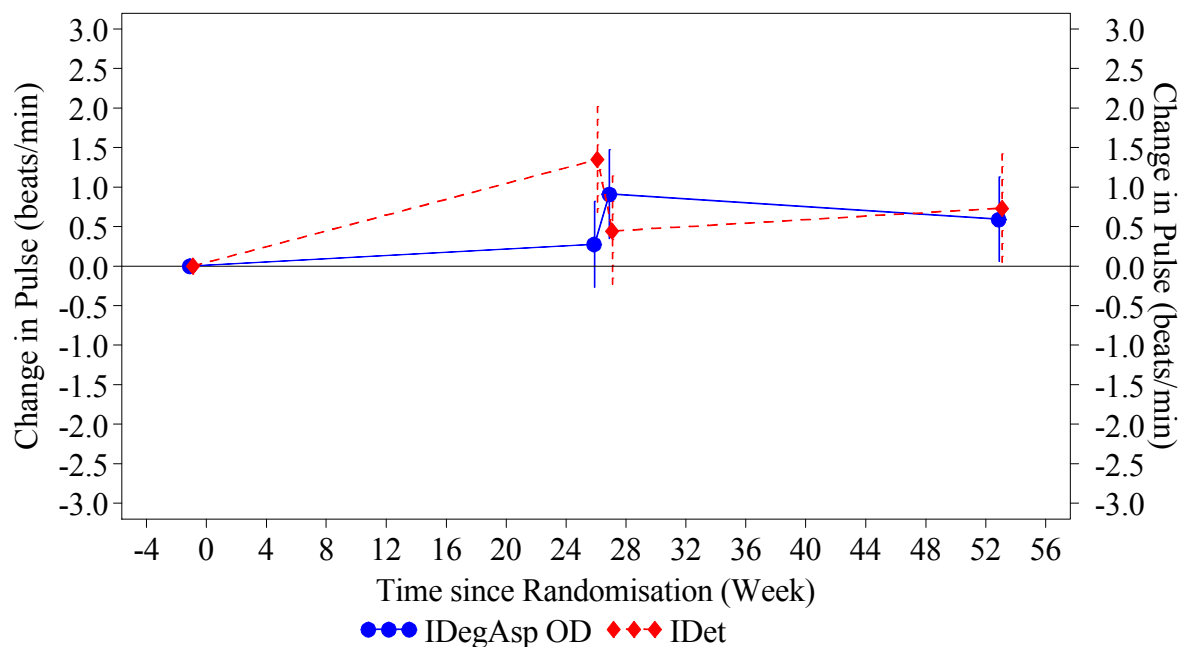
14.3.6.10: Systolic Blood Pressure after 52 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: $\pm$ Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:03 - fmean_numfind_v03.sas/e_vital_pulse_abs_mean_locf_sas.cgm

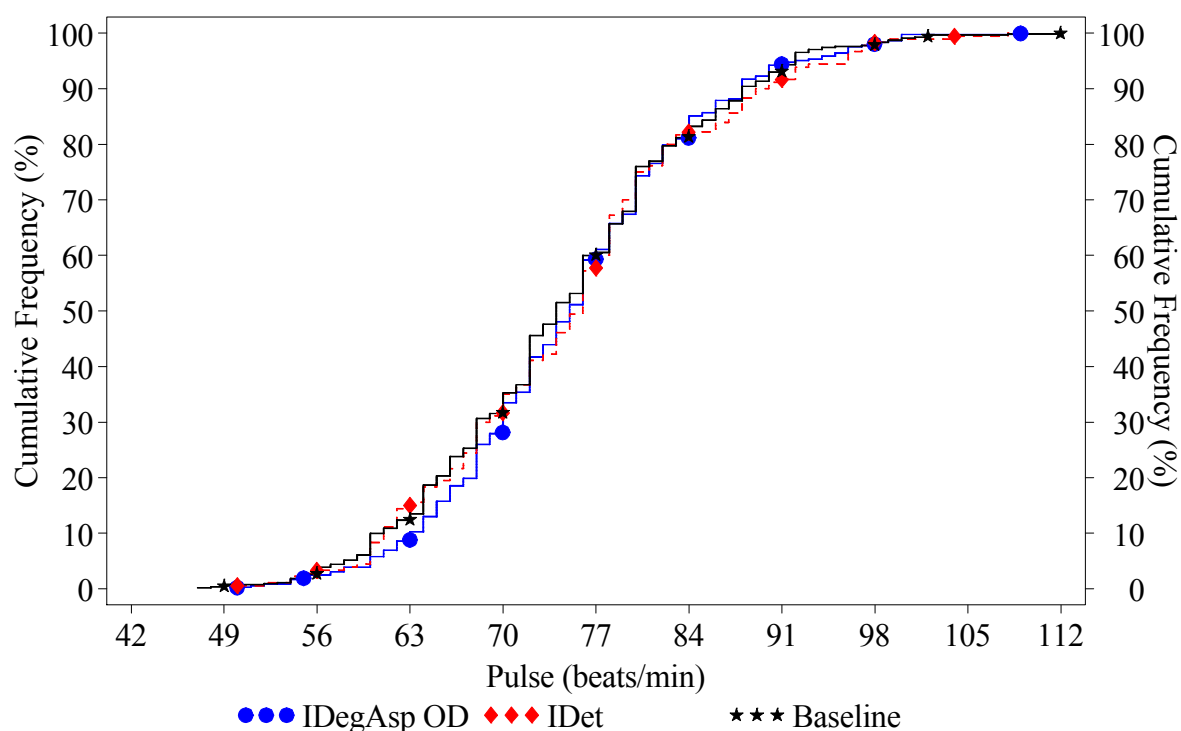
14.3.6.11: Pulse - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:11 - fmean_numfind_v03.sas/e_vital_pulse_chb_mean_locf_sas.cgm

14.3.6.12: Pulse - Change from Baseline - Mean Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:26 - fedist_numfind_v01.sas/e_vital_pulse_abs_cdf_locf_sas.cgm

14.3.6.13: Pulse after 52 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set

14.3.6.14: ECG by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)
Number of Subjects	362	180
ECG		
Visit 1		
N	362 (100.0)	180 (100.0)
Normal	292 (80.7)	150 (83.3)
Abnormal, Not Clinically Significant	68 (18.8)	29 (16.1)
Abnormal, Clinically Significant	2 (0.6)	1 (0.6)
Visit 28 (Week 26)		
N	317 (100.0)	156 (100.0)
Normal	250 (78.9)	134 (85.9)
Abnormal, Not Clinically Significant	65 (20.5)	21 (13.5)
Abnormal, Clinically Significant	2 (0.6)	1 (0.6)
Visit 30 (Week 27)		
N	2 (100.0)	1 (100.0)
Normal	2 (100.0)	1 (100.0)
Abnormal, Not Clinically Significant	0 (0.0)	0 (0.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)
Visit 44 (Week 53)		
N	238 (100.0)	114 (100.0)
Normal	201 (84.5)	95 (83.3)
Abnormal, Not Clinically Significant	37 (15.5)	19 (16.7)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)
Visit 44 (Week 53) (LOCF)		
N	362 (100.0)	180 (100.0)
Normal	294 (81.2)	152 (84.4)
Abnormal, Not Clinically Significant	67 (18.5)	27 (15.0)
Abnormal, Clinically Significant	1 (0.3)	1 (0.6)

ECG = Electrocardiogram, N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:30 - tsum_catgofind_tpl_t025_v01.sas/t_ecg_sum_sas.txt

14.3.6.15: ECG - Shift Table - Baseline to Week 52 - Safety Analysis Set

IDegAsp OD				IDet		
Number of Subjects				362		
				180		
				Visit 44 (Week 53)		
Visit 1	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
	N	N	N	N	N	N
ECG						
Normal	177	16	0	85	8	0
Abnormal, NCS	24	21	0	9	11	0
Abnormal, CS	0	0	0	1	0	0

14.3.6.16: Funduscopy / Fundusphotography by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	362	180	542
Left eye exam			
Visit 1			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	219 (60.5)	103 (57.2)	322 (59.4)
Abnormal, Not Clinically Significant	122 (33.7)	74 (41.1)	196 (36.2)
Abnormal, Clinically Significant	21 (5.8)	3 (1.7)	24 (4.4)
Visit 28 (Week 26)			
N	318 (100.0)	153 (100.0)	471 (100.0)
Normal	197 (61.9)	90 (58.8)	287 (60.9)
Abnormal, Not Clinically Significant	106 (33.3)	61 (39.9)	167 (35.5)
Abnormal, Clinically Significant	15 (4.7)	2 (1.3)	17 (3.6)
Visit 30 (Week 27)			
N	5 (100.0)	2 (100.0)	7 (100.0)
Normal	1 (20.0)	2 (100.0)	3 (42.9)
Abnormal, Not Clinically Significant	2 (40.0)	0 (0.0)	2 (28.6)
Abnormal, Clinically Significant	2 (40.0)	0 (0.0)	2 (28.6)
Visit 44 (Week 53)			
N	234 (100.0)	111 (100.0)	345 (100.0)
Normal	138 (59.0)	63 (56.8)	201 (58.3)
Abnormal, Not Clinically Significant	84 (35.9)	43 (38.7)	127 (36.8)
Abnormal, Clinically Significant	12 (5.1)	5 (4.5)	17 (4.9)
Visit 44 (Week 53) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	229 (63.3)	104 (57.8)	333 (61.4)
Abnormal, Not Clinically Significant	113 (31.2)	70 (38.9)	183 (33.8)
Abnormal, Clinically Significant	20 (5.5)	6 (3.3)	26 (4.8)

N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:39 - tsum_catgofind_tpl_t025_v01.sas/t_fundusum_sas.txt

Funduscopy / Fundusphotography by Treatment Week - Summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Right eye exam			
Visit 1			
N	361 (100.0)	180 (100.0)	541 (100.0)
Normal	225 (62.3)	101 (56.1)	326 (60.3)
Abnormal, Not Clinically Significant	119 (33.0)	75 (41.7)	194 (35.9)
Abnormal, Clinically Significant	17 (4.7)	4 (2.2)	21 (3.9)
Visit 28 (Week 26)			
N	319 (100.0)	152 (100.0)	471 (100.0)
Normal	198 (62.1)	89 (58.6)	287 (60.9)
Abnormal, Not Clinically Significant	106 (33.2)	61 (40.1)	167 (35.5)
Abnormal, Clinically Significant	15 (4.7)	2 (1.3)	17 (3.6)
Visit 30 (Week 27)			
N	5 (100.0)	2 (100.0)	7 (100.0)
Normal	1 (20.0)	2 (100.0)	3 (42.9)
Abnormal, Not Clinically Significant	2 (40.0)	0 (0.0)	2 (28.6)
Abnormal, Clinically Significant	2 (40.0)	0 (0.0)	2 (28.6)
Visit 44 (Week 53)			
N	234 (100.0)	111 (100.0)	345 (100.0)
Normal	134 (57.3)	62 (55.9)	196 (56.8)
Abnormal, Not Clinically Significant	87 (37.2)	46 (41.4)	133 (38.6)
Abnormal, Clinically Significant	13 (5.6)	3 (2.7)	16 (4.6)
Visit 44 (Week 53) (LOCF)			
N	362 (100.0)	180 (100.0)	542 (100.0)
Normal	229 (63.3)	101 (56.1)	330 (60.9)
Abnormal, Not Clinically Significant	111 (30.7)	75 (41.7)	186 (34.3)
Abnormal, Clinically Significant	22 (6.1)	4 (2.2)	26 (4.8)

N = Number of Subjects

Observations at visit 30 were only recorded by investigators in case of changes since visit 28

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:39 - tsum_catgofind_tpl_t025_v01.sas/t_fundu_sum_sas.txt

14.3.6.17: Funduscopy / Fundusphotography - Shift Table - Baseline to Week 52 - Safety Analysis Set

IDegAsp OD				IDet		
Number of Subjects	362			180		
	Visit 44 (Week 53)					
Visit 1	Normal N	Abnormal, NCS N	Abnormal, CS N	Normal N	Abnormal, NCS N	Abnormal, CS N
Left eye exam						
Normal	122	8	3	60	4	2
Abnormal, NCS	15	73	3	3	38	2
Abnormal, CS	1	3	6	0	1	1
Right eye exam						
Normal	118	14	4	60	4	2
Abnormal, NCS	15	71	3	2	40	0
Abnormal, CS	0	2	6	0	2	1

14.3.6.18: Body Weight and BMI by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Body Weight (kg)			
Visit 1			
N	362	180	542
Mean (SD)	76.5 (14.4)	76.1 (13.9)	76.4 (14.2)
Median	75.0	75.5	75.2
Min ; Max	44.8 ; 122.9	41.7 ; 135.0	41.7 ; 135.0
Visit 2 (Week 0)			
N	362	180	542
Mean (SD)	76.6 (14.5)	76.2 (14.0)	76.5 (14.3)
Median	75.0	76.0	75.3
Min ; Max	44.0 ; 123.4	42.9 ; 137.4	42.9 ; 137.4
Visit 14 (Week 12)			
N	335	167	502
Mean (SD)	78.3 (14.9)	77.3 (14.6)	78.0 (14.8)
Median	77.0	77.7	77.1
Min ; Max	42.8 ; 125.2	41.7 ; 141.1	41.7 ; 141.1
Visit 18 (Week 16)			
N	331	161	492
Mean (SD)	79.0 (15.1)	77.8 (14.7)	78.6 (15.0)
Median	77.4	78.0	77.5
Min ; Max	43.0 ; 127.9	42.8 ; 142.9	42.8 ; 142.9
Visit 28 (Week 26)			
N	318	156	474
Mean (SD)	79.4 (15.7)	78.2 (14.9)	79.0 (15.4)
Median	77.1	78.5	77.6
Min ; Max	44.2 ; 132.0	45.5 ; 147.4	44.2 ; 147.4
Visit 30 (Week 27)			
N	252	119	371
Mean (SD)	79.6 (15.8)	79.6 (15.5)	79.6 (15.7)
Median	77.8	78.9	78.3
Min ; Max	44.3 ; 132.0	45.9 ; 145.6	44.3 ; 145.6
Visit 37 (Week 39)			
N	244	117	361
Mean (SD)	79.8 (15.8)	79.9 (15.4)	79.8 (15.6)
Median	78.5	80.0	78.9
Min ; Max	42.4 ; 135.8	43.1 ; 142.3	42.4 ; 142.3
Visit 44 (Week 53)			
N	237	114	351
Mean (SD)	80.5 (15.9)	79.3 (15.4)	80.1 (15.7)
Median	79.0	79.7	79.0
Min ; Max	43.2 ; 140.3	44.8 ; 136.9	43.2 ; 140.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:52 - tdesc_numfind_tpl_t019_v01.sas/t_bw_bmi_abs_descp_sas.txt

Body Weight and BMI by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Body Weight (kg)			
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	79.4 (15.6)	77.4 (14.3)	78.7 (15.2)
Median	77.5	77.2	77.3
Min ; Max	43.2 ; 140.3	44.8 ; 136.9	43.2 ; 140.3

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:52 - tdesc_numfind_tpl_t019_v01.sas/t_bw_bmi_abs_descp_sas.txt

Body Weight and BMI by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
BMI (kg/m ²)			
Visit 1			
N	362	180	542
Mean (SD)	26.2 (3.9)	26.6 (3.8)	26.3 (3.9)
Median	25.7	26.2	25.9
Min ; Max	16.2 ; 35.0	18.6 ; 35.0	16.2 ; 35.0
Visit 2 (Week 0)			
N	362	180	542
Mean (SD)	26.2 (4.0)	26.7 (3.9)	26.4 (3.9)
Median	25.9	26.4	26.0
Min ; Max	16.2 ; 35.6	18.7 ; 36.2	16.2 ; 36.2
Visit 14 (Week 12)			
N	335	167	502
Mean (SD)	26.8 (4.1)	27.0 (4.0)	26.9 (4.1)
Median	26.2	26.6	26.4
Min ; Max	16.9 ; 40.3	18.7 ; 36.1	16.9 ; 40.3
Visit 18 (Week 16)			
N	331	161	492
Mean (SD)	26.9 (4.2)	27.1 (4.1)	27.0 (4.2)
Median	26.4	27.0	26.5
Min ; Max	17.0 ; 40.0	19.0 ; 36.4	17.0 ; 40.0
Visit 28 (Week 26)			
N	318	156	474
Mean (SD)	27.1 (4.3)	27.2 (4.0)	27.1 (4.2)
Median	26.6	26.8	26.7
Min ; Max	17.5 ; 42.0	18.4 ; 38.2	17.5 ; 42.0
Visit 30 (Week 27)			
N	252	119	371
Mean (SD)	27.1 (4.3)	27.4 (3.9)	27.2 (4.2)
Median	26.6	26.9	26.8
Min ; Max	17.5 ; 39.5	18.4 ; 38.5	17.5 ; 39.5
Visit 37 (Week 39)			
N	244	117	361
Mean (SD)	27.2 (4.3)	27.5 (4.0)	27.3 (4.2)
Median	26.7	27.3	26.9
Min ; Max	16.8 ; 40.6	18.4 ; 37.7	16.8 ; 40.6
Visit 44 (Week 53)			
N	237	114	351
Mean (SD)	27.4 (4.4)	27.4 (4.1)	27.4 (4.3)
Median	26.9	27.1	27.0
Min ; Max	17.1 ; 41.9	18.8 ; 38.1	17.1 ; 41.9

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:52 - tdesc_numfind_tpl_t019_v01.sas/t_bw_bmi_abs_descp_sas.txt

Body Weight and BMI by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
BMI (kg/m^2)			
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	27.2 (4.4)	27.1 (4.1)	27.2 (4.3)
Median	26.7	27.0	26.8
Min ; Max	16.2 ; 42.0	18.7 ; 38.1	16.2 ; 42.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:16:52 - tdesc_numfind_tpl_t019_v01.sas/t_bw_bmi_abs_descp_sas.txt

14.3.6.19: Body Weight and BMI by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Ch. Body Weight(kg)			
Visit 14 (Week 12)			
N	335	167	502
Mean (SD)	1.5 (3.0)	0.9 (2.3)	1.3 (2.8)
Median	1.3	0.5	1.0
Min ; Max	-14.8 ; 17.2	-5.0 ; 8.2	-14.8 ; 17.2
Visit 18 (Week 16)			
N	331	161	492
Mean (SD)	2.0 (3.3)	1.2 (2.8)	1.7 (3.1)
Median	1.9	0.9	1.5
Min ; Max	-13.7 ; 18.0	-7.3 ; 9.5	-13.7 ; 18.0
Visit 28 (Week 26)			
N	318	156	474
Mean (SD)	2.4 (4.0)	1.4 (3.5)	2.1 (3.9)
Median	2.0	1.1	1.8
Min ; Max	-13.7 ; 20.4	-13.4 ; 11.9	-13.7 ; 20.4
Visit 30 (Week 27)			
N	252	119	371
Mean (SD)	2.3 (3.7)	1.6 (3.8)	2.1 (3.8)
Median	2.2	1.3	2.0
Min ; Max	-13.7 ; 16.3	-12.7 ; 11.7	-13.7 ; 16.3
Visit 37 (Week 39)			
N	244	117	361
Mean (SD)	2.5 (4.0)	1.3 (4.4)	2.1 (4.2)
Median	2.1	0.9	1.8
Min ; Max	-12.0 ; 20.1	-16.0 ; 13.3	-16.0 ; 20.1
Visit 44 (Week 53)			
N	237	114	351
Mean (SD)	3.1 (4.3)	1.3 (4.6)	2.5 (4.4)
Median	2.9	1.0	2.3
Min ; Max	-12.0 ; 24.6	-15.4 ; 13.5	-15.4 ; 24.6
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	2.8 (4.2)	1.2 (4.1)	2.3 (4.3)
Median	2.4	0.9	2.0
Min ; Max	-12.0 ; 24.6	-15.4 ; 13.5	-15.4 ; 24.6

N = Number of Subjects, SD = Standard Deviation, Ch = Change from Baseline
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:17:01 - tdesc_numfind_tpl_t019_v01.sas/t_bw_bmi_chb_descp_sas.txt

Body Weight and BMI by Treatment Week - Change from Baseline - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Ch. Derived Body Mass Index(kg/m ²)			
Visit 14 (Week 12)			
N	335	167	502
Mean (SD)	0.5 (1.0)	0.3 (0.8)	0.5 (1.0)
Median	0.5	0.2	0.4
Min ; Max	-4.7 ; 6.1	-1.5 ; 3.1	-4.7 ; 6.1
Visit 18 (Week 16)			
N	331	161	492
Mean (SD)	0.7 (1.1)	0.4 (1.0)	0.6 (1.1)
Median	0.7	0.3	0.5
Min ; Max	-5.0 ; 6.4	-2.6 ; 3.6	-5.0 ; 6.4
Visit 28 (Week 26)			
N	318	156	474
Mean (SD)	0.8 (1.4)	0.5 (1.2)	0.7 (1.3)
Median	0.7	0.4	0.6
Min ; Max	-5.0 ; 7.3	-5.3 ; 4.5	-5.3 ; 7.3
Visit 30 (Week 27)			
N	252	119	371
Mean (SD)	0.8 (1.3)	0.6 (1.3)	0.7 (1.3)
Median	0.8	0.5	0.7
Min ; Max	-5.0 ; 5.7	-5.0 ; 4.5	-5.0 ; 5.7
Visit 37 (Week 39)			
N	244	117	361
Mean (SD)	0.8 (1.4)	0.5 (1.5)	0.7 (1.4)
Median	0.7	0.3	0.6
Min ; Max	-4.7 ; 6.5	-6.3 ; 4.6	-6.3 ; 6.5
Visit 44 (Week 53)			
N	237	114	351
Mean (SD)	1.1 (1.4)	0.5 (1.6)	0.9 (1.5)
Median	1.0	0.4	0.8
Min ; Max	-4.7 ; 7.4	-6.1 ; 5.1	-6.1 ; 7.4
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	1.0 (1.4)	0.4 (1.5)	0.8 (1.5)
Median	0.8	0.3	0.7
Min ; Max	-4.7 ; 7.4	-6.1 ; 5.1	-6.1 ; 7.4

14.3.6.20: Body Weight (kg) after 52 Weeks of Treatment - Statistical Analysis - Full Analysis Set

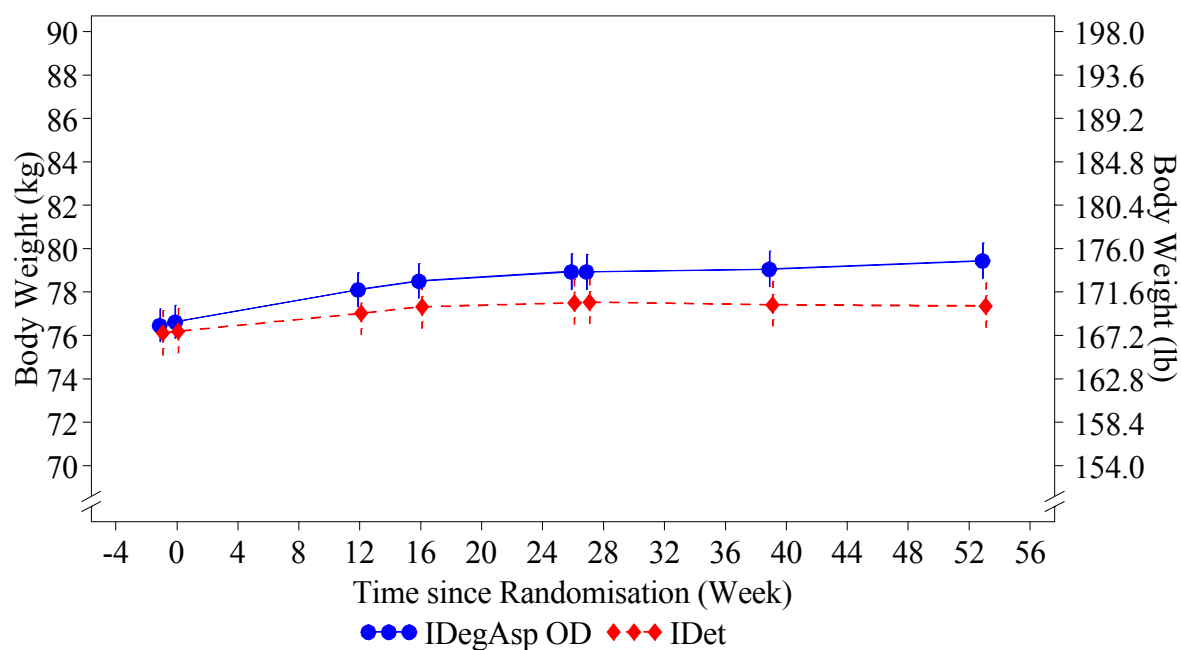
	FAS	N	Estimate	SE	95% CI
Body Weight (kg)					
LSMeans					
IDegAsp OD	366	366	79.79	0.36	
IDet	182	182	78.16	0.42	
Change from Baseline					
LSMeans					
IDegAsp OD	366	366	3.32	0.36	
IDet	182	182	1.69	0.42	
Treatment Contrast					
IDegAsp OD - IDet			1.64		[0.89 ; 2.38]

N= Number of subjects contributing to analysis, CI= Confidence Interval, SE= Standard Error of the Mean

The response and change from baseline in the response after 52 weeks of treatment is analysed using an ANOVA method with treatment, sex, region and antidiabetic treatment at screening as fixed effects, and age and baseline response as covariates.

Missing data is imputed using last observation carried forward.

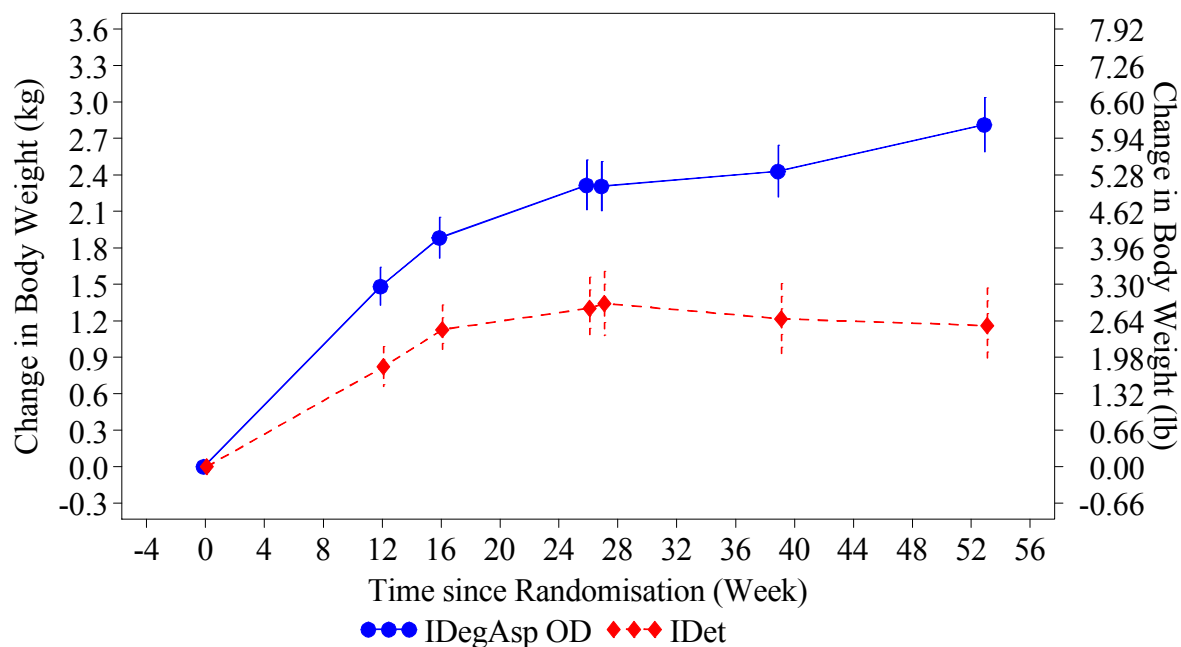
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:17:10 - tstat_find_tpl_t022.sas/t_bw_stat_locf_fas.txt



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:17:19 - fmean_numfind_v03.sas/e_bw_abs_mean_locf_fas.cgm

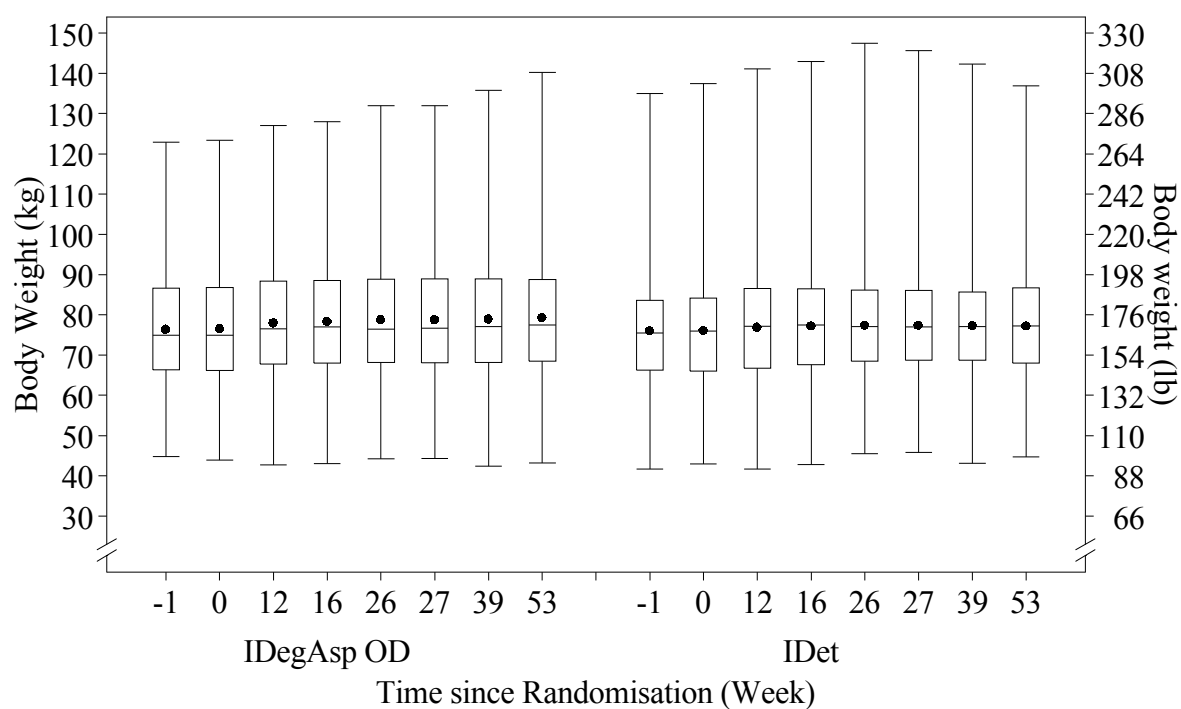
14.3.6.21: Body Weight - Mean Plot - Safety Analysis Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:17:28 - fmean_numfind_v03.sas/e_bw_chb_mean_locf_fas.cgm

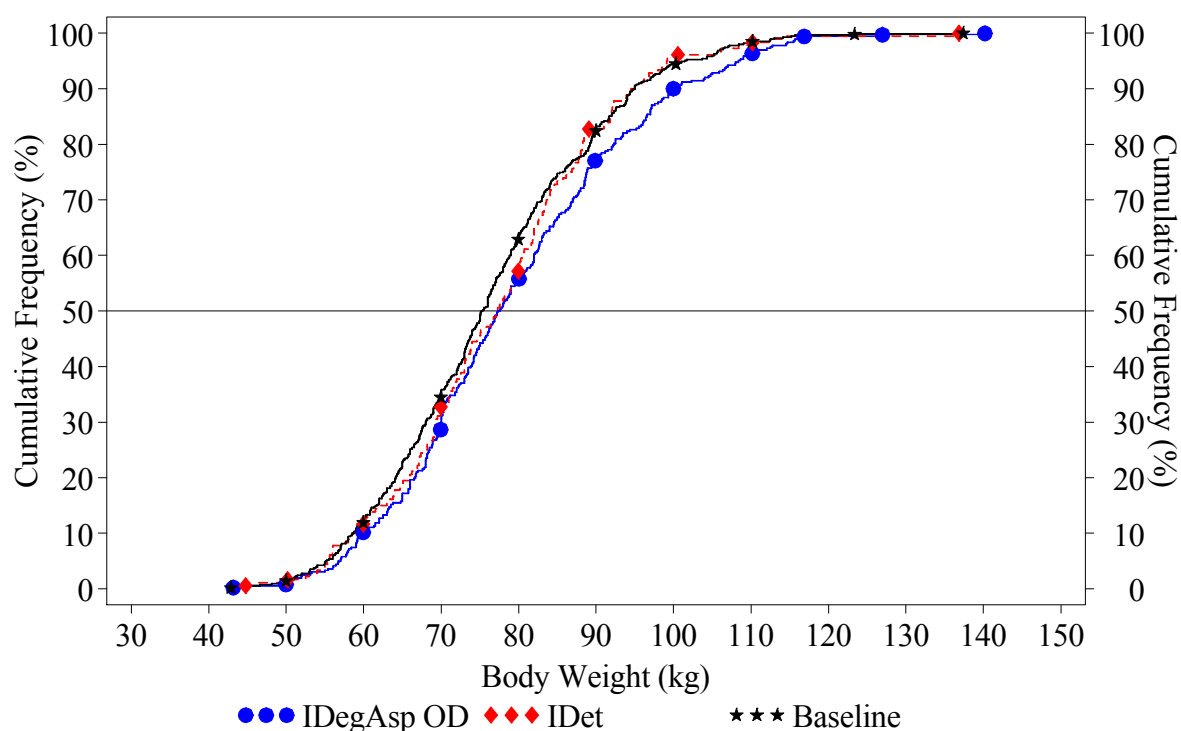
14.3.6.22: Body Weight – Change from Baseline - Mean Plot - Safety Analysis Set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:17:37 - fbox_numfind_v01.sas/e_bw_abs_box_locf_fas.cgm

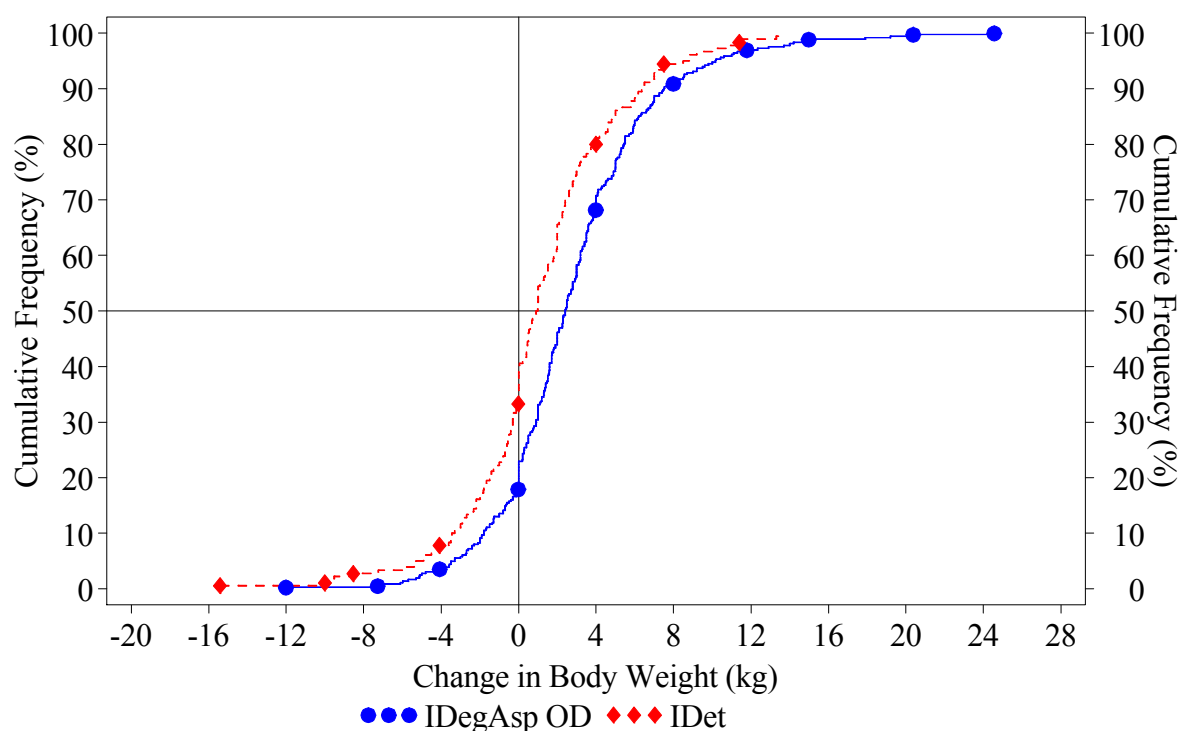
14.3.6.23: Body Weight by Treatment week - Box Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:17:52 - fedist_numfind_v01.sas/e_bw_abs_cdf_locf_fas.cgm

14.3.6.24: Body weight after 52 Weeks of Treatment Empirical Distribution Plot - Safety Analysis Set



SAFETY; LOCF imputed data

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:18:01 - fedist_numfind_v01.sas/e_bw_chb_cdf_locf_fas.cgm

14.3.6.25: Body weight after 52 Weeks of Treatment - Change from Baseline Empirical Distribution Plot - Safety Analysis Set

14.3.6.26: Insulin Degludec Specific Antibodies (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp	OD
Number of Subjects	362	
Insulin Degludec Specific Antibodies(% B/T)		
Visit 2 (Week 0)		
N	362	
Mean (SD)	0.1 (0.5)	
Median	0.0	
Min ; Max	-6.0 ; 4.0	
Visit 14 (Week 12)		
N	332	
Mean (SD)	0.0 (0.4)	
Median	0.0	
Min ; Max	-5.0 ; 2.0	
Visit 28 (Week 26)		
N	316	
Mean (SD)	0.0 (0.2)	
Median	0.0	
Min ; Max	-1.0 ; 2.0	
Visit 29 (Week 27)		
N	308	
Mean (SD)	0.1 (0.4)	
Median	0.0	
Min ; Max	-1.0 ; 3.0	
Visit 37 (Week 39)		
N	245	
Mean (SD)	0.1 (0.5)	
Median	0.0	
Min ; Max	-7.0 ; 2.0	
Visit 44 (Week 53)		
N	235	
Mean (SD)	0.0 (0.3)	
Median	0.0	
Min ; Max	-3.0 ; 2.0	
Visit 44 (Week 53) (LOCF)		
N	362	
Mean (SD)	0.0 (0.3)	
Median	0.0	
Min ; Max	-3.0 ; 2.0	
Visit 45 (Week 54)		
N	236	
Mean (SD)	0.1 (0.4)	
Median	0.0	
Min ; Max	-2.0 ; 3.0	

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
 07MAY2011:14:18:09 - tdesc_numfind_tpl_t019_v01.sas/t_ideg_ab_specific_abs_descp_sas.txt

14.3.6.27: Insulin Aspart Specific Antibodies (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Insulin Aspart Specific Antibodies(% B/T)			
Visit 2 (Week 0)			
N	362	180	542
Mean (SD)	1.0 (2.9)	0.9 (3.0)	1.0 (2.9)
Median	0.0	0.0	0.0
Min ; Max	-1.0 ; 34.0	-1.0 ; 30.0	-1.0 ; 34.0
Visit 14 (Week 12)			
N	333	165	498
Mean (SD)	1.1 (2.6)	1.4 (4.2)	1.2 (3.2)
Median	0.0	0.0	0.0
Min ; Max	-1.0 ; 20.0	-1.0 ; 31.0	-1.0 ; 31.0
Visit 28 (Week 26)			
N	319	155	474
Mean (SD)	1.1 (2.4)	1.7 (5.5)	1.3 (3.7)
Median	0.0	1.0	0.0
Min ; Max	-1.0 ; 19.0	0.0 ; 44.0	-1.0 ; 44.0
Visit 29 (Week 27)			
N	309	148	457
Mean (SD)	1.3 (2.6)	1.4 (3.8)	1.3 (3.0)
Median	0.0	1.0	1.0
Min ; Max	0.0 ; 19.0	0.0 ; 41.0	0.0 ; 41.0
Visit 37 (Week 39)			
N	245	118	363
Mean (SD)	1.0 (2.2)	1.4 (3.7)	1.1 (2.8)
Median	0.0	0.0	0.0
Min ; Max	-1.0 ; 14.0	0.0 ; 31.0	-1.0 ; 31.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	1.1 (2.1)	1.1 (1.9)	1.1 (2.0)
Median	0.0	1.0	0.0
Min ; Max	0.0 ; 13.0	0.0 ; 16.0	0.0 ; 16.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	1.2 (3.0)	1.3 (3.7)	1.3 (3.2)
Median	0.0	0.0	0.0
Min ; Max	0.0 ; 35.0	0.0 ; 31.0	0.0 ; 35.0
Visit 45 (Week 54)			
N	236	111	347
Mean (SD)	1.0 (2.1)	1.1 (1.9)	1.0 (2.0)
Median	0.0	0.0	0.0
Min ; Max	0.0 ; 17.0	-1.0 ; 15.0	-1.0 ; 17.0

N = Number of Subjects, SD = Standard Deviation

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:18:18 - tdesc_numfind_tpl_t019_v01.sas/t_iasp_ab_specific_abs_descp_sas.txt

14.3.6.28: Cross-reacting Antibodies to Human Insulin (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Human insulin reactive antibodies serum(% B/T)			
Visit 2 (Week 0)			
N	362	180	542
Mean (SD)	11.0 (13.9)	11.7 (15.6)	11.3 (14.4)
Median	5.0	5.0	5.0
Min ; Max	0.0 ; 76.0	0.0 ; 68.0	0.0 ; 76.0
Visit 14 (Week 12)			
N	332	165	497
Mean (SD)	12.0 (15.2)	14.2 (16.6)	12.7 (15.7)
Median	6.0	8.0	7.0
Min ; Max	0.0 ; 82.0	0.0 ; 81.0	0.0 ; 82.0
Visit 28 (Week 26)			
N	319	155	474
Mean (SD)	10.7 (14.0)	15.4 (14.6)	12.2 (14.3)
Median	5.0	10.0	7.0
Min ; Max	0.0 ; 76.0	0.0 ; 75.0	0.0 ; 76.0
Visit 29 (Week 27)			
N	310	147	457
Mean (SD)	15.5 (17.3)	26.0 (19.4)	18.9 (18.6)
Median	8.0	23.0	12.0
Min ; Max	0.0 ; 78.0	0.0 ; 77.0	0.0 ; 78.0
Visit 37 (Week 39)			
N	245	118	363
Mean (SD)	8.3 (11.4)	16.6 (14.0)	11.0 (12.9)
Median	4.0	13.0	6.0
Min ; Max	0.0 ; 71.0	0.0 ; 67.0	0.0 ; 71.0
Visit 44 (Week 53)			
N	236	114	350
Mean (SD)	7.2 (10.6)	16.6 (13.3)	10.3 (12.3)
Median	3.0	12.0	5.5
Min ; Max	0.0 ; 70.0	0.0 ; 59.0	0.0 ; 70.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	10.0 (14.2)	18.6 (17.3)	12.9 (15.8)
Median	4.0	11.5	7.0
Min ; Max	0.0 ; 78.0	0.0 ; 71.0	0.0 ; 78.0
Visit 45 (Week 54)			
N	236	111	347
Mean (SD)	12.0 (15.0)	28.7 (18.7)	17.3 (18.0)
Median	6.0	25.0	10.0
Min ; Max	0.0 ; 68.0	1.0 ; 69.0	0.0 ; 69.0

N = Number of Subjects, SD = Standard Deviation

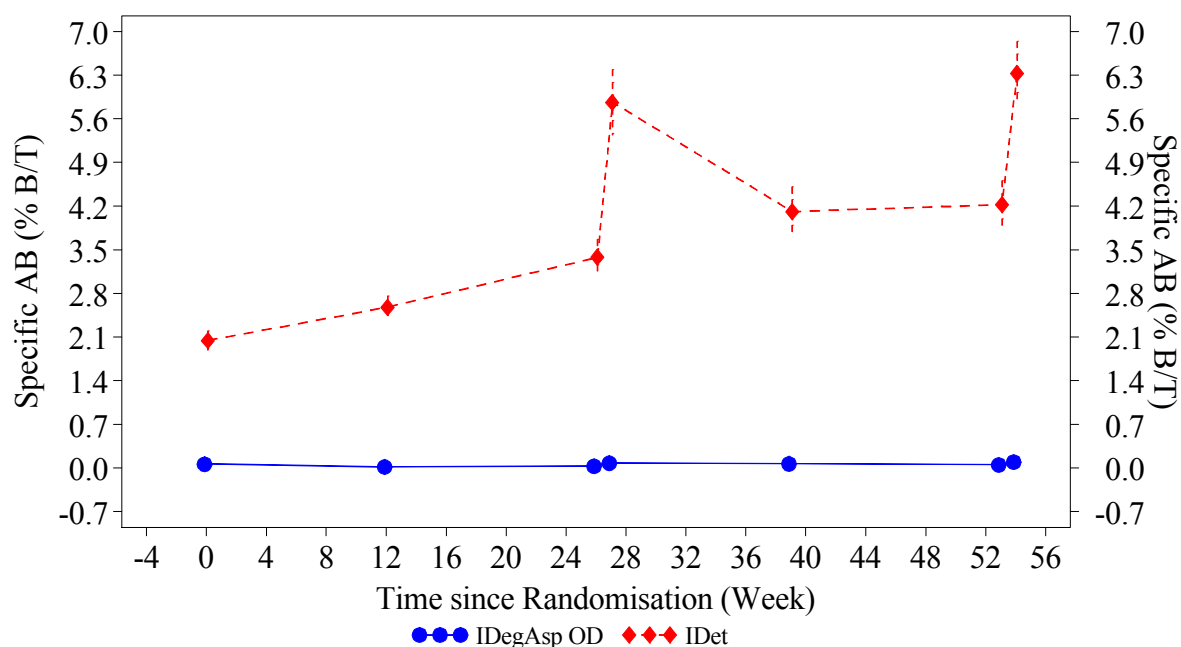
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:18:26 - tdesc_numfind_tpl_t019_v01.sas/t_ab_cros_abs_descp_sas.txt

14.3.6.29: Total Antibodies (% B/T) by Treatment Week - Descriptive Statistics - Safety Analysis Set

	IDegAsp OD	IDet	Total
Number of Subjects	362	180	542
Total Insulin Antibodies(% B/T)			
Visit 2 (Week 0)			
N	361	179	540
Mean (SD)	12.2 (14.2)	14.7 (16.9)	13.0 (15.2)
Median	7.0	8.0	7.0
Min ; Max	-1.0 ; 77.0	0.0 ; 88.0	-1.0 ; 88.0
Visit 14 (Week 12)			
N	331	165	496
Mean (SD)	13.2 (15.9)	18.1 (18.8)	14.8 (17.1)
Median	7.0	12.0	9.0
Min ; Max	0.0 ; 84.0	0.0 ; 93.0	0.0 ; 93.0
Visit 28 (Week 26)			
N	317	154	471
Mean (SD)	11.8 (14.7)	20.6 (18.6)	14.7 (16.6)
Median	6.0	15.0	9.0
Min ; Max	0.0 ; 79.0	0.0 ; 101.0	0.0 ; 101.0
Visit 29 (Week 27)			
N	306	147	453
Mean (SD)	16.7 (18.1)	33.9 (25.8)	22.3 (22.3)
Median	10.0	27.0	15.0
Min ; Max	0.0 ; 88.0	0.0 ; 133.0	0.0 ; 133.0
Visit 37 (Week 39)			
N	243	118	361
Mean (SD)	9.4 (11.9)	21.7 (17.1)	13.4 (15.0)
Median	5.0	17.0	8.0
Min ; Max	0.0 ; 71.0	1.0 ; 84.0	0.0 ; 84.0
Visit 44 (Week 53)			
N	234	113	347
Mean (SD)	8.3 (11.2)	21.6 (15.9)	12.7 (14.3)
Median	4.0	18.0	7.0
Min ; Max	0.0 ; 72.0	1.0 ; 79.0	0.0 ; 79.0
Visit 44 (Week 53) (LOCF)			
N	362	180	542
Mean (SD)	11.2 (14.8)	24.1 (21.2)	15.5 (18.2)
Median	5.0	17.0	8.5
Min ; Max	0.0 ; 88.0	0.0 ; 101.0	0.0 ; 101.0
Visit 45 (Week 54)			
N	235	111	346
Mean (SD)	13.2 (15.6)	37.1 (23.6)	20.9 (21.6)
Median	6.0	31.0	12.0
Min ; Max	0.0 ; 71.0	4.0 ; 96.0	0.0 ; 96.0

N = Number of Subjects, SD = Standard Deviation

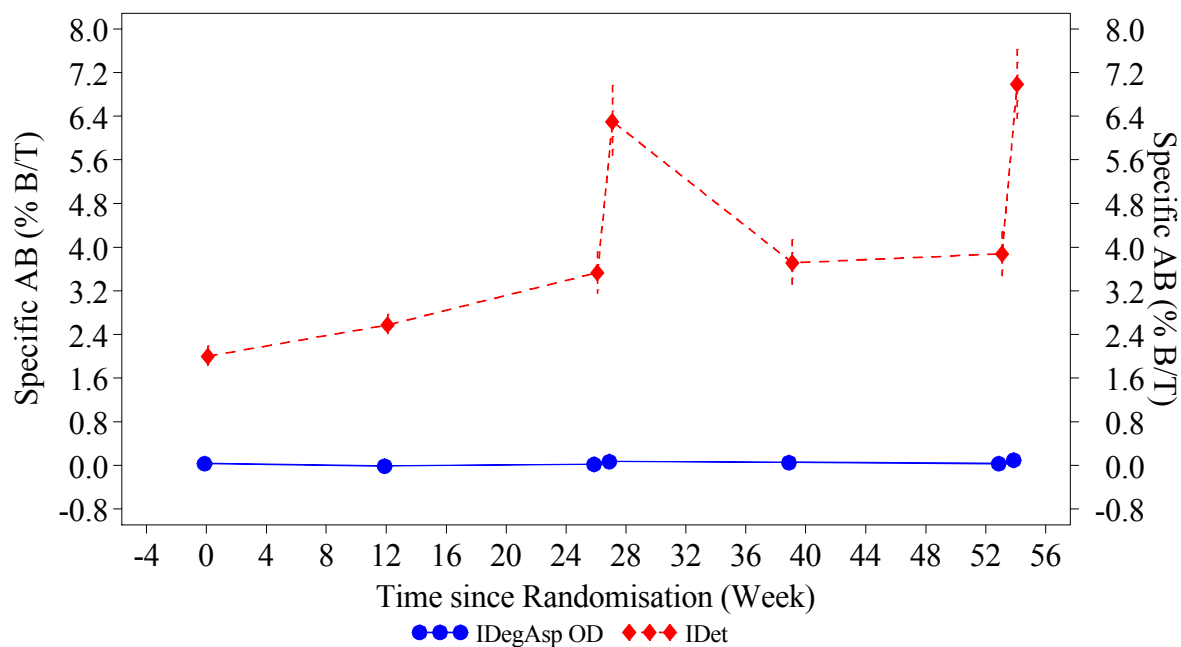
nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:18:35 - tdesc_numfind_tpl_t019_v01.sas/t_ab_tot_abs_descp_sas.txt



SAFETY; LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:18:51 - fmean_numfind_v03.sas/e_ab_spe_imp_abs_mean_locf_sas.cgm

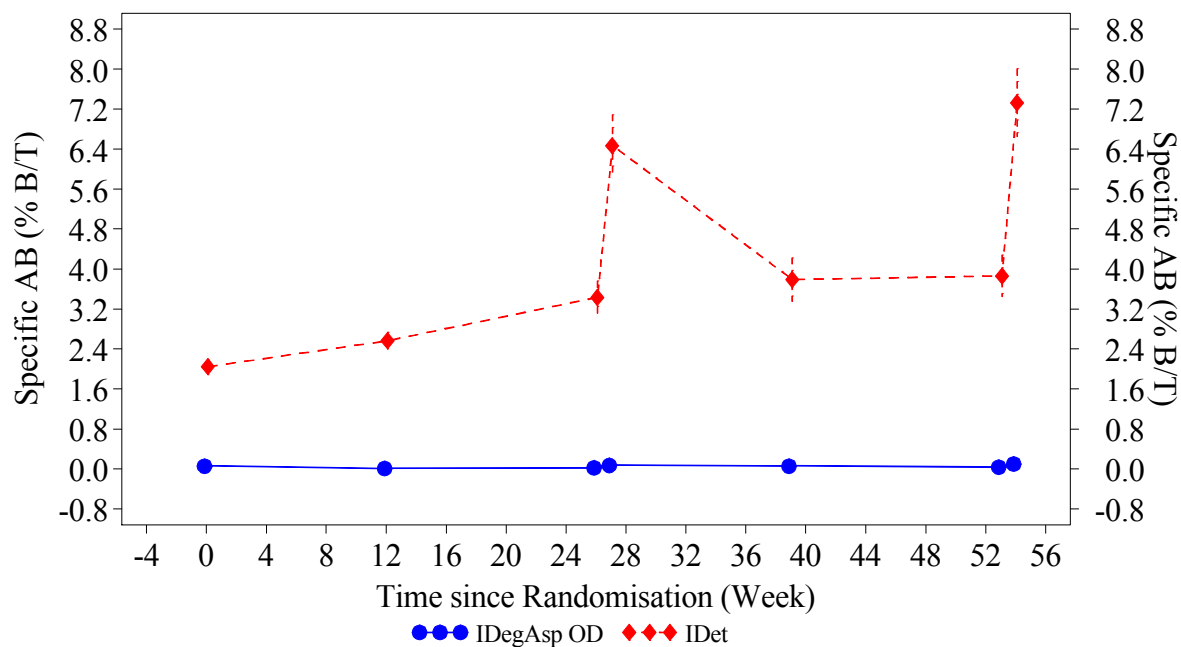
14.3.6.30: IDegAsp / Comparator Specific Antibodies (% B/T) - Mean Plot - Safety Analysis Set



EXT: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:19:06 - fmean_numfind_v03.sas/e_ab_spe_imp_abs_mean_locf_ets.cgm

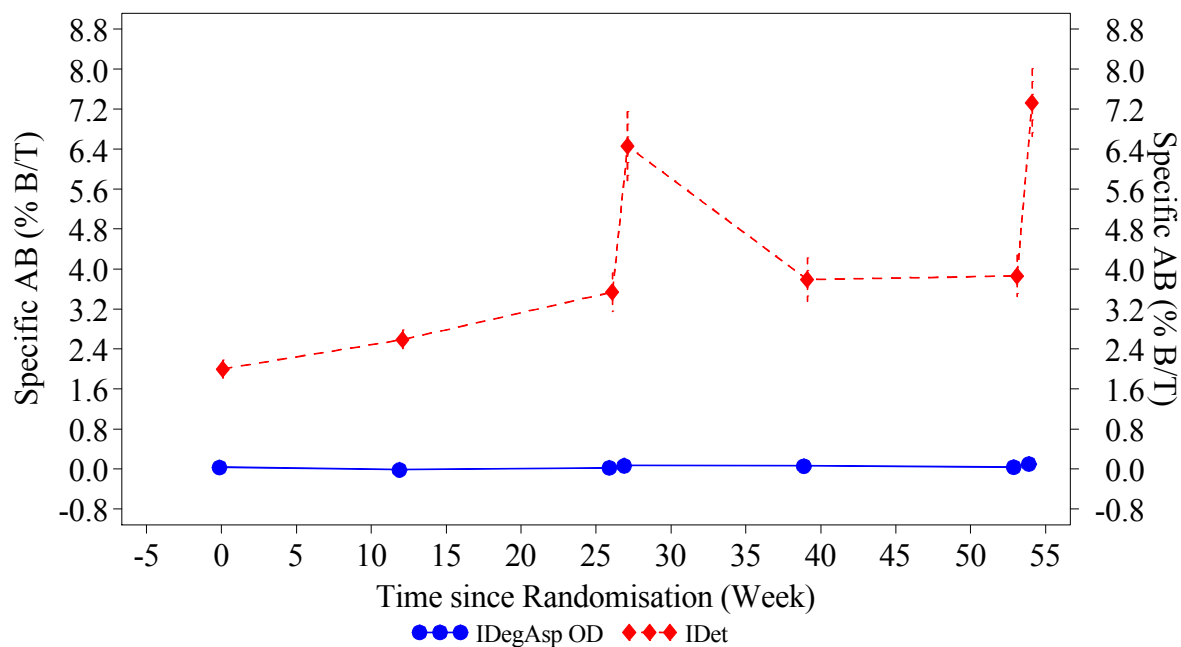
14.3.6.31: IDegAsp / Comparator Specific Antibodies (% B/T) - Mean Plot - Extension Trial Set



SAFETY: Observed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:19:21 - fmean_numfind_v03.sas/e_ab_spe_imp_abs_mean_obs_sas.cgm

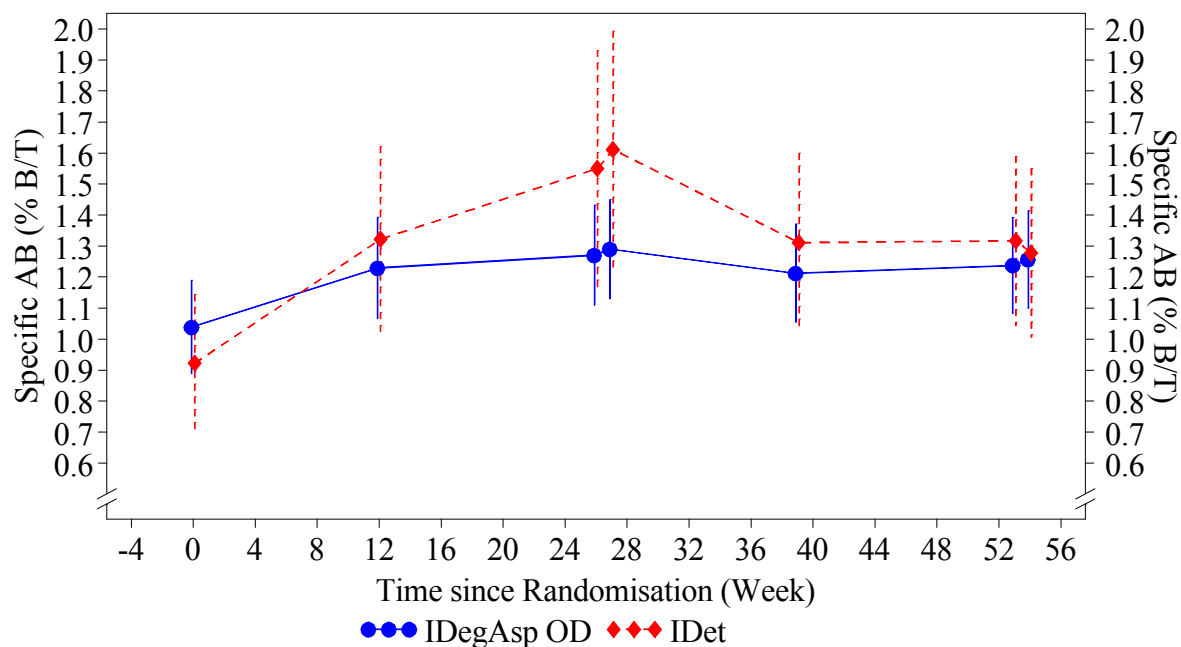
14.3.6.32: IDegAsp / Comparator Specific Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set



EXT: Observed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:19:37 - fmean_numfind_v03.sas/e_ab_spe_imp_abs_mean_obs_ets.cgm

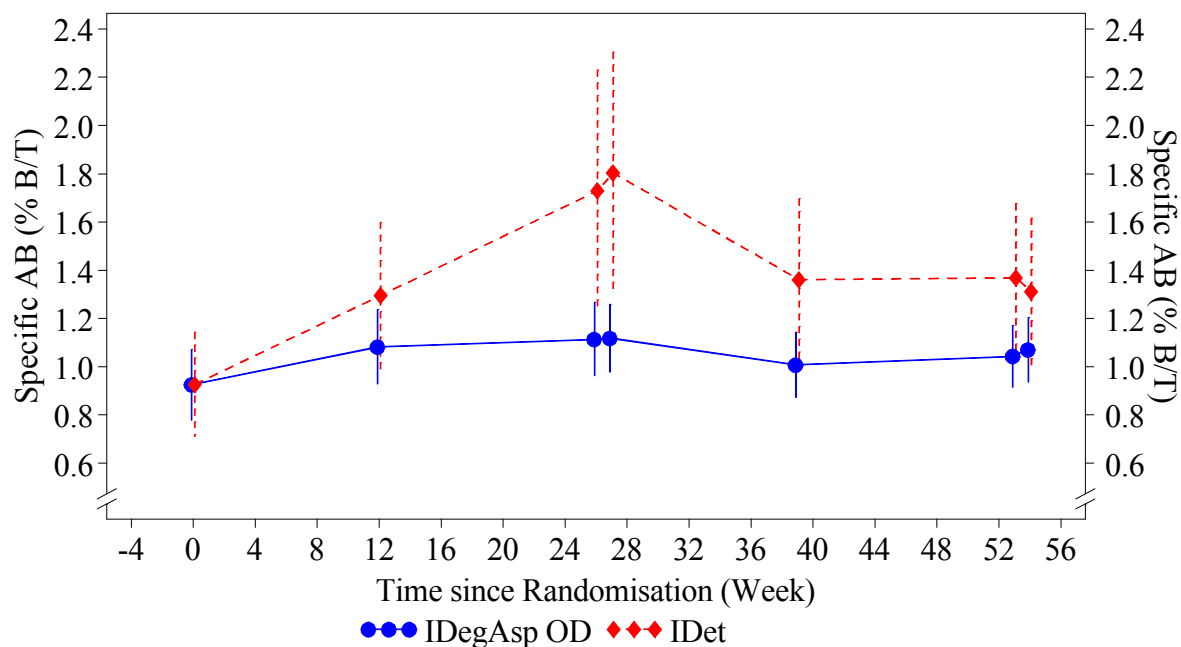
14.3.6.33: IDegAsp / Comparator Specific Antibodies (% B/T) - Mean Plot - Observed Values - Extension Trial Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:19:45 - fmean_numfind_v03.sas/e_ab_spe_iasp_abs_mean_locf_sas.cgm

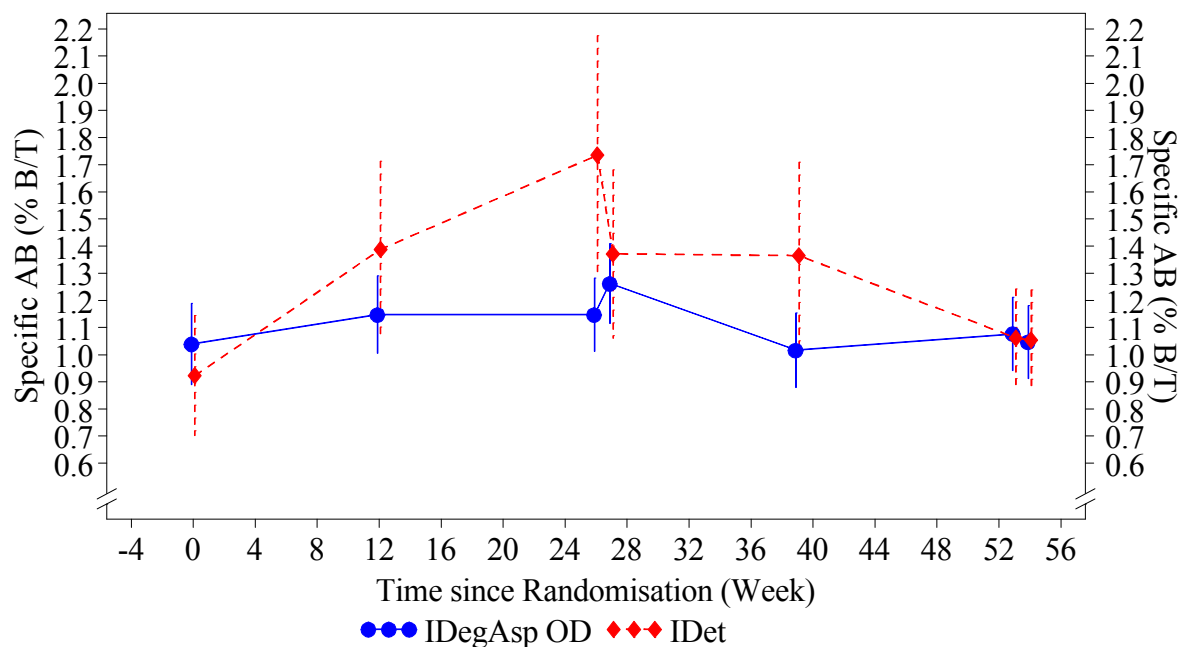
14.3.6.34: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Safety Analysis Set



EXT: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:19:54 - fmean_numfind_v03.sas/e_ab_spe_iasp_abs_mean_locf_ets.cgm

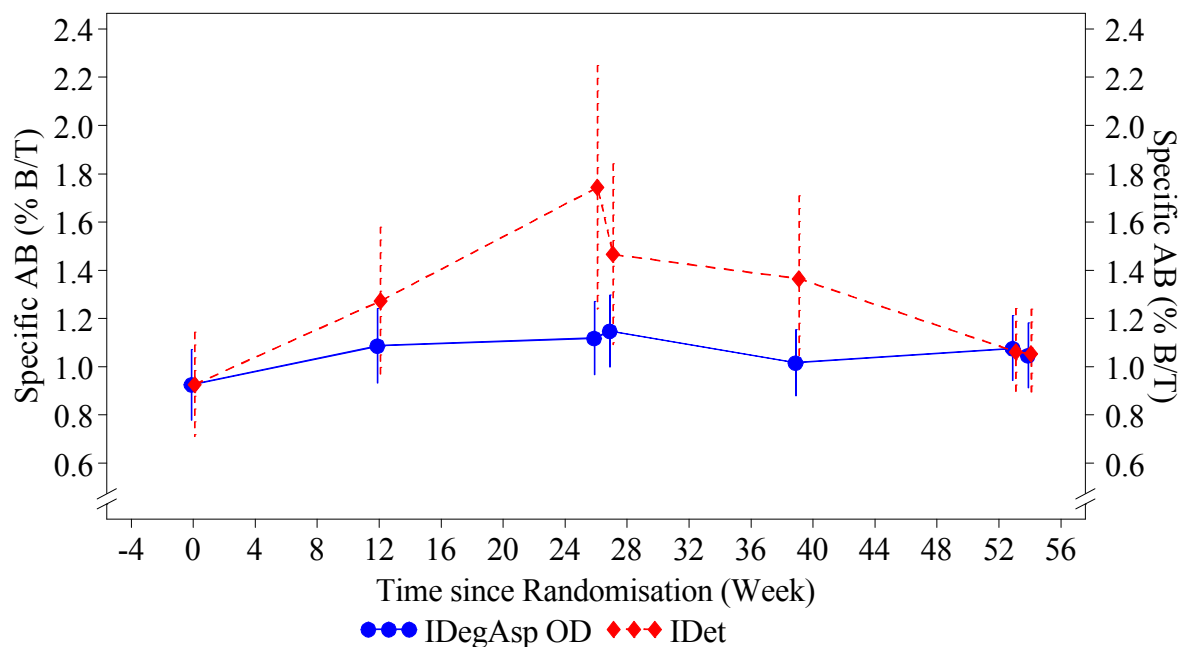
14.3.6.35: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Extension Trial Set



SAFETY: Observed data
Error bars: +/-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:20:03 - fmean_numfind_v03.sas/e_ab_spe_iasp_abs_mean_obs_sas.cgm

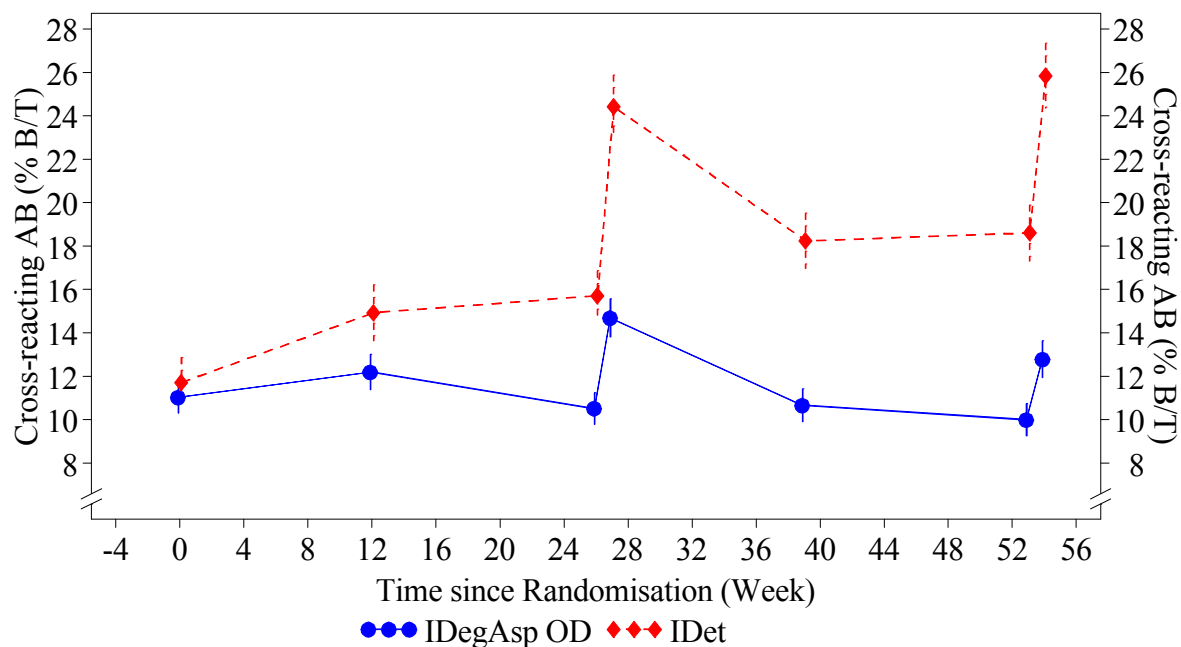
14.3.6.36: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set



EXT: Observed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:20:12 - fmean_numfind_v03.sas/e_ab_spe_iasp_abs_mean_obs_ets.cgm

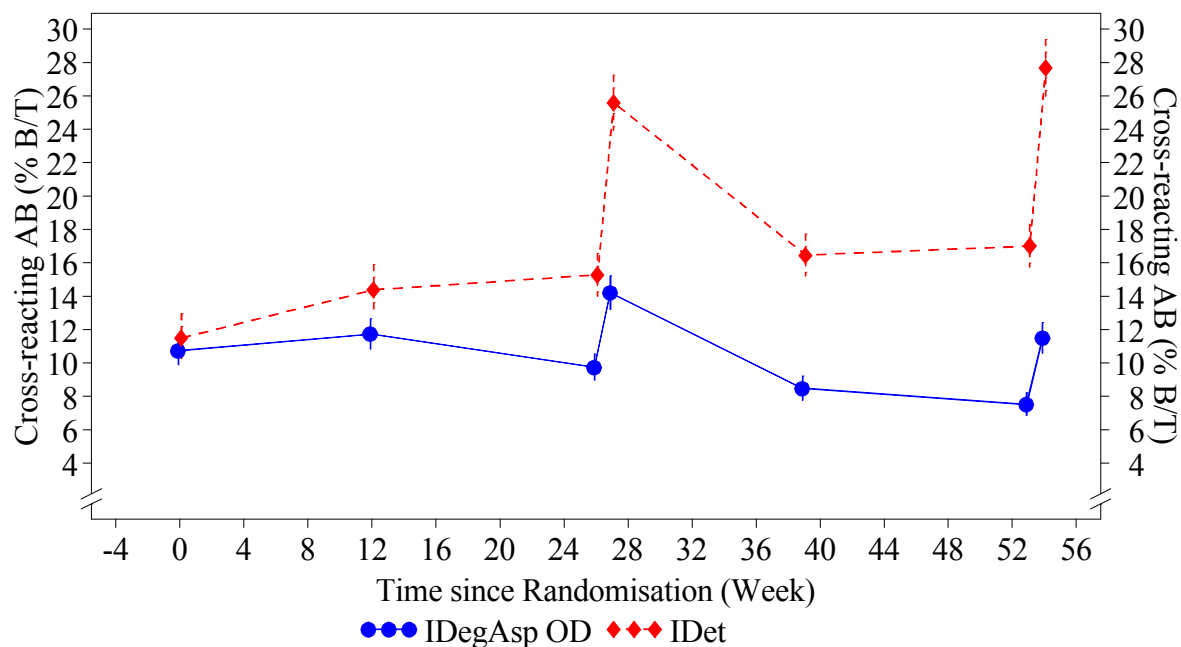
14.3.6.37: Insulin Aspart Specific Antibodies (% B/T) - Mean Plot - Observed Values - Extension Trial Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:20:20 - fmean_numfind_v03.sas/e_ab_cros_abs_mean_locf_sas.cgm

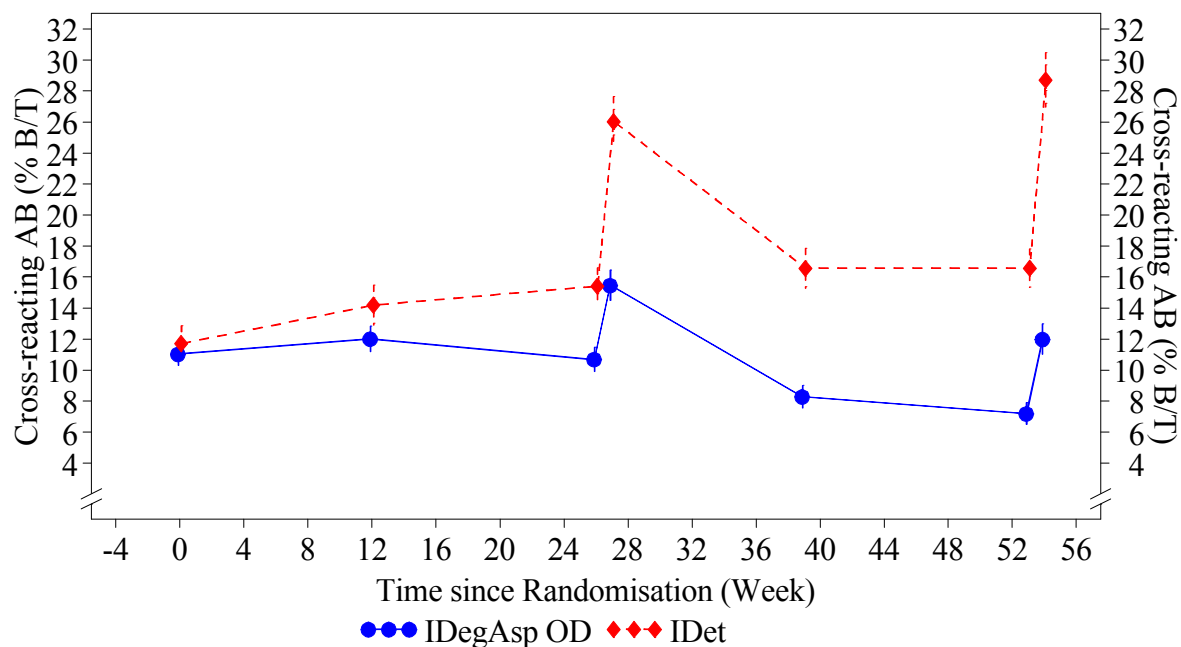
14.3.6.38: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Safety Analysis Set



EXT: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:20:29 - fmean_numfind_v03.sas/e_ab_cros_abs_mean_locf_ets.cgm

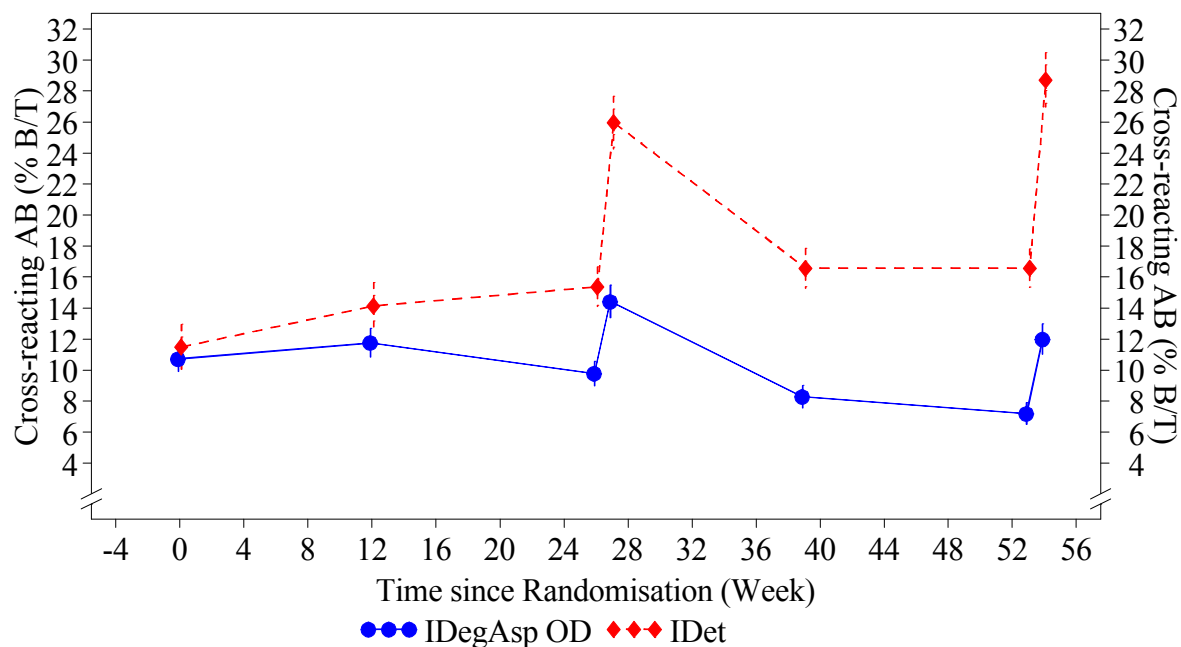
14.3.6.39: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Extension Trial Set



SAFETY: Observed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:20:38 - fmean_numfind_v03.sas/e_ab_cros_abs_mean_obs_sas.cgm

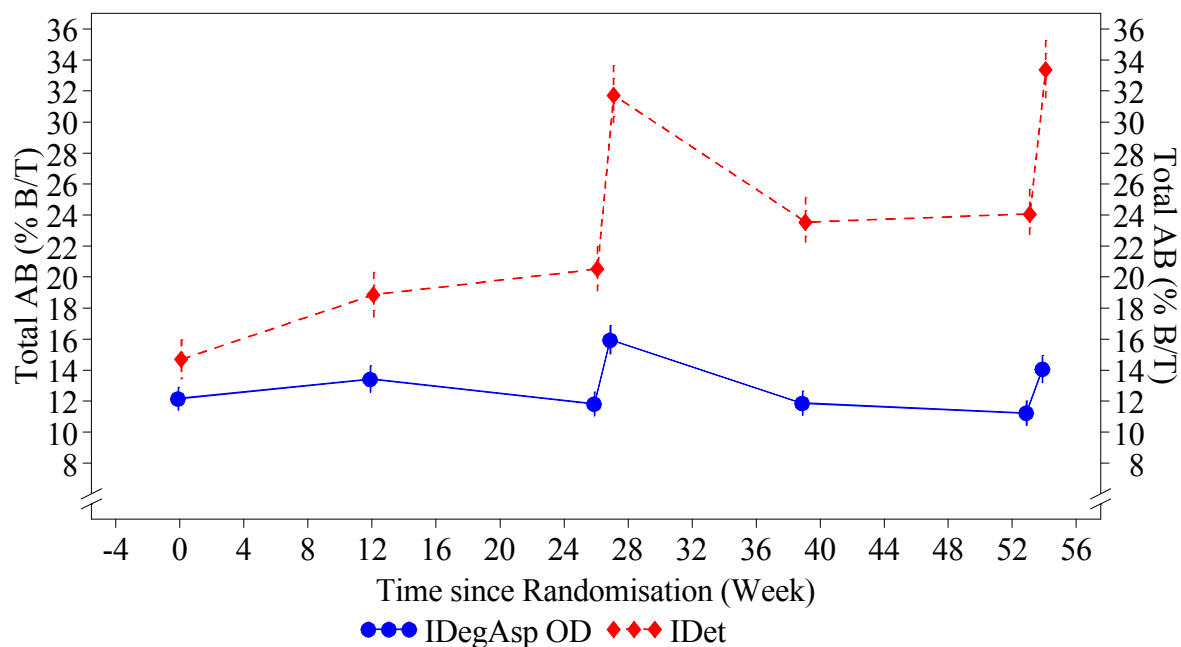
14.3.6.40: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Observed Values - Safety Analysis Set



EXT: Observed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:20:47 - fmean_numfind_v03.sas/e_ab_cros_abs_mean_obs_ets.cgm

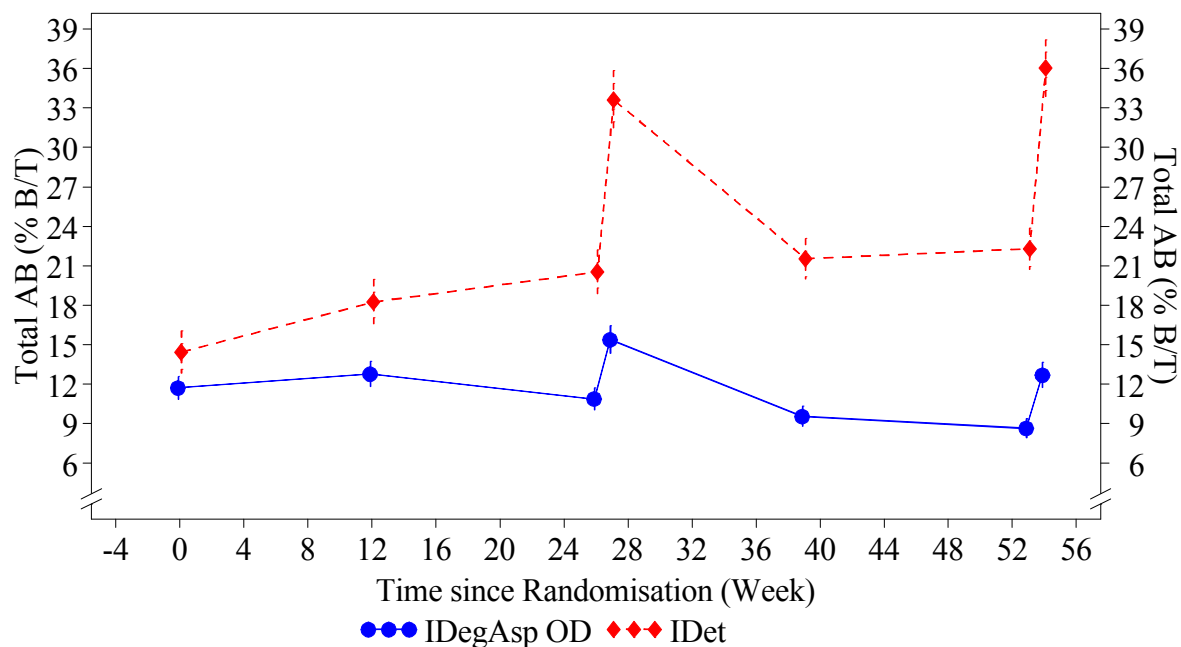
14.3.6.41: Cross-reacting Antibodies to Human Insulin (% B/T) - Mean Plot - Observed Values - Extension Trial Set



SAFETY: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:20:56 - fmean_numfind_v03.sas/e_ab_tot_abs_mean_locf_sas.cgm

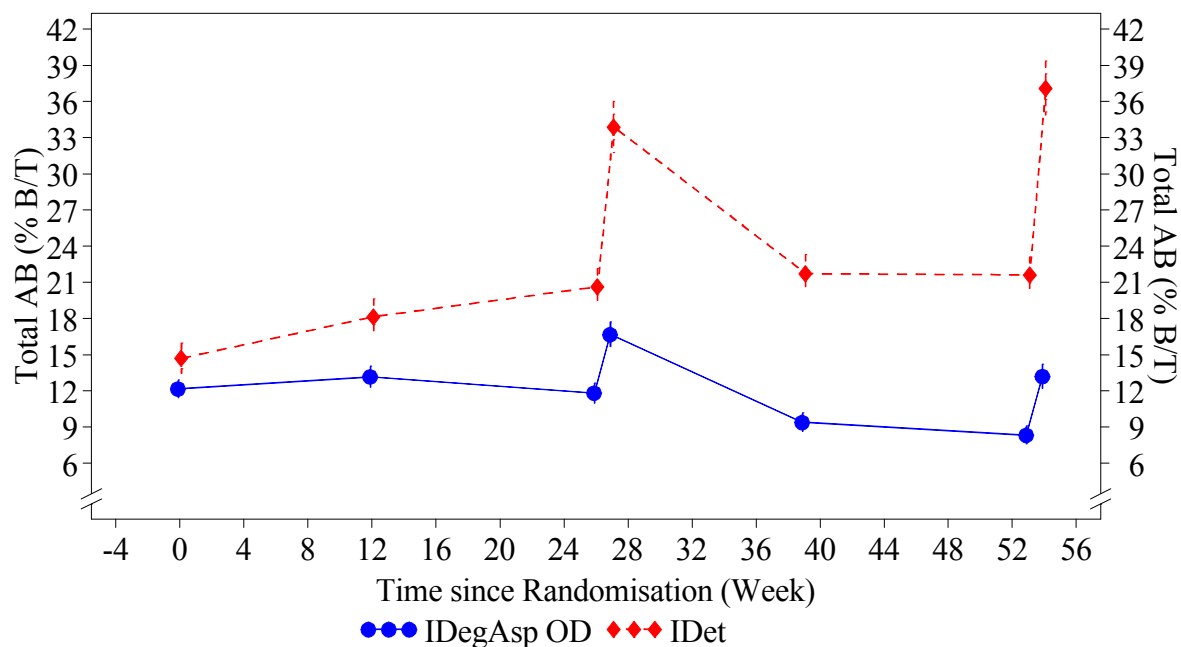
14.3.6.42: Total Antibodies (% B/T) - Mean Plot - Safety Analysis Set



EXT: LOCF imputed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:21:04 - fmean_numfind_v03.sas/e_ab_tot_abs_mean_locf_ets.cgm

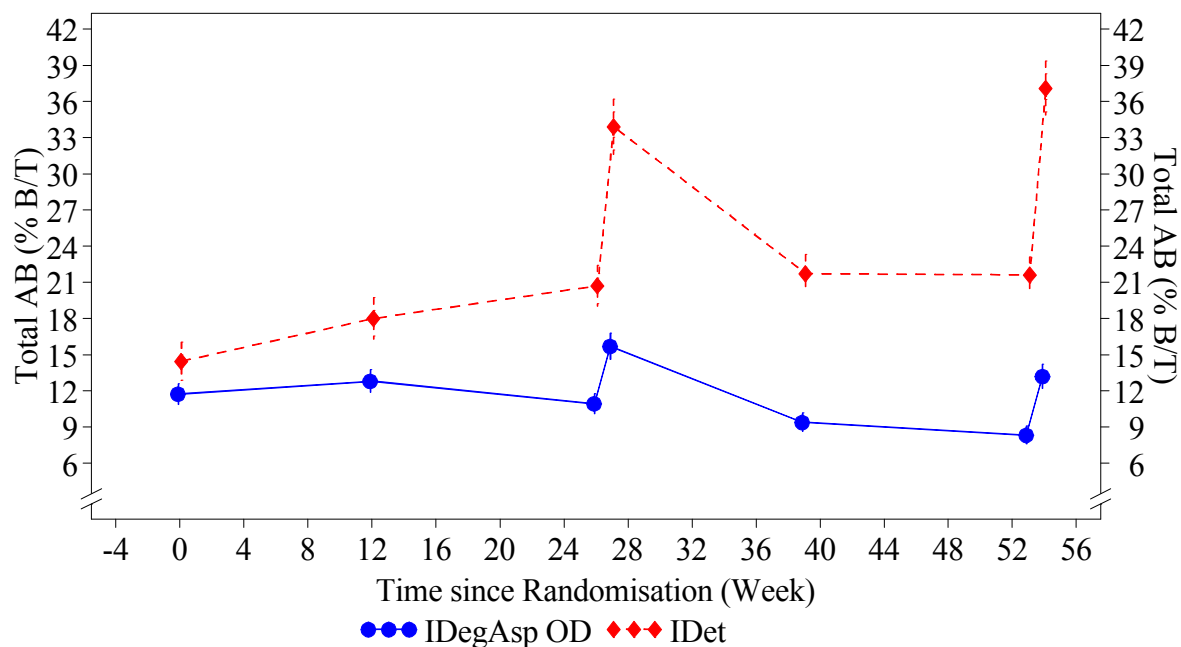
14.3.6.43: Total Antibodies (% B/T) - Mean Plot - Extension Trial Set



SAFETY: Observed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:21:13 - fmean_numfind_v03.sas/e_ab_tot_abs_mean_obs_sas.cgm

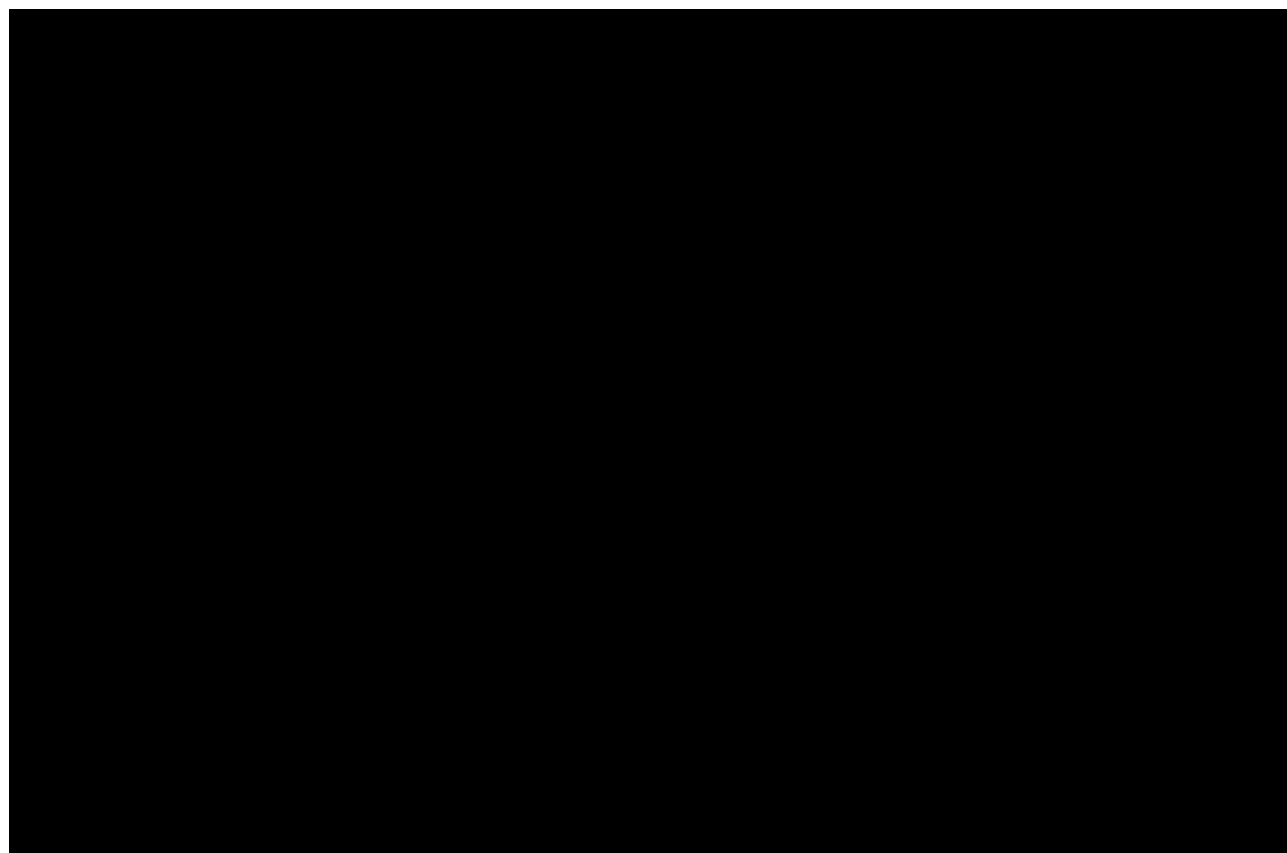
14.3.6.44: Total Antibodies (% B/T) - Mean Plot - Observed Values - Safety Analysis Set



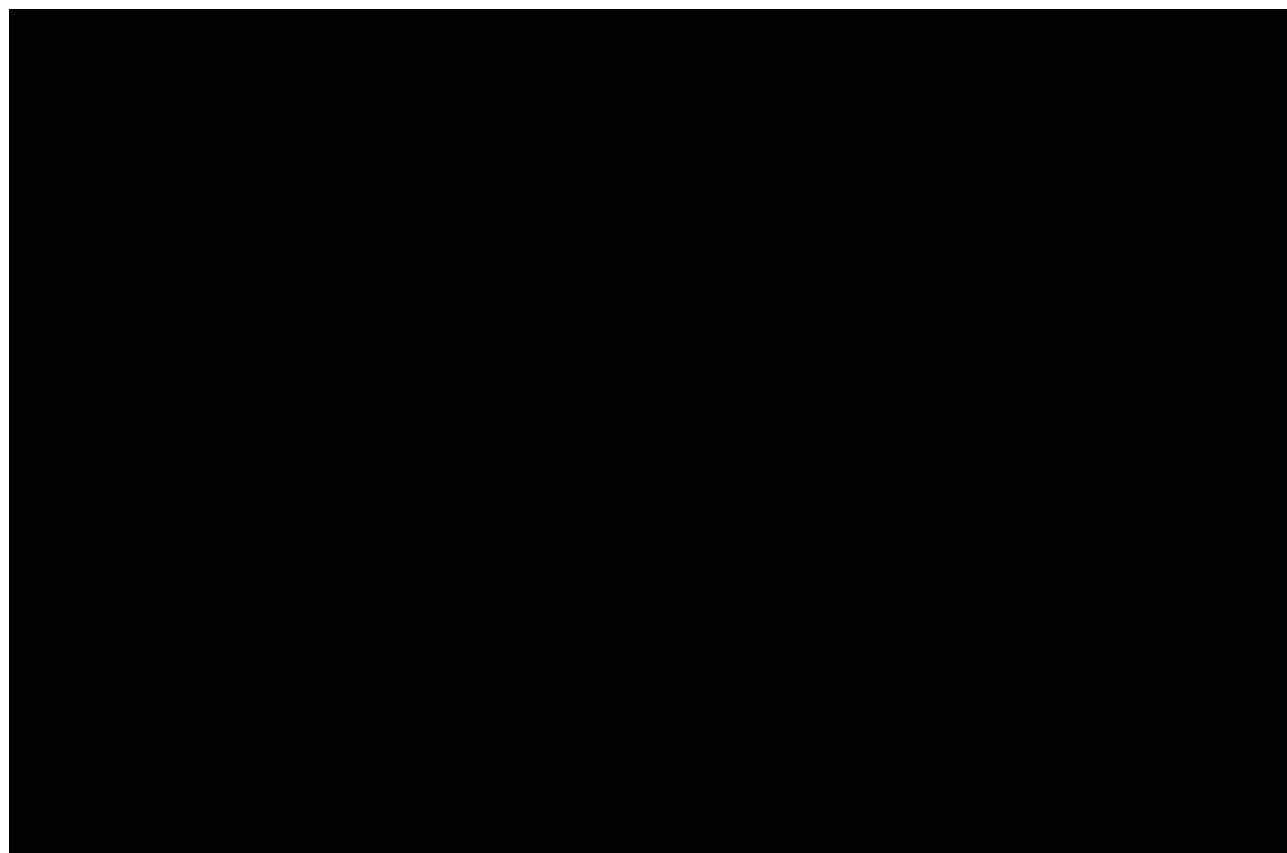
EXT: Observed data
Error bars: +-Standard Error(Mean)

nn5401/nn5401-3594-3645/freeze_ctr_02/stats
07MAY2011:14:21:22 - fmean_numfind_v03.sas/e_ab_tot_abs_mean_obs_ets.cgm

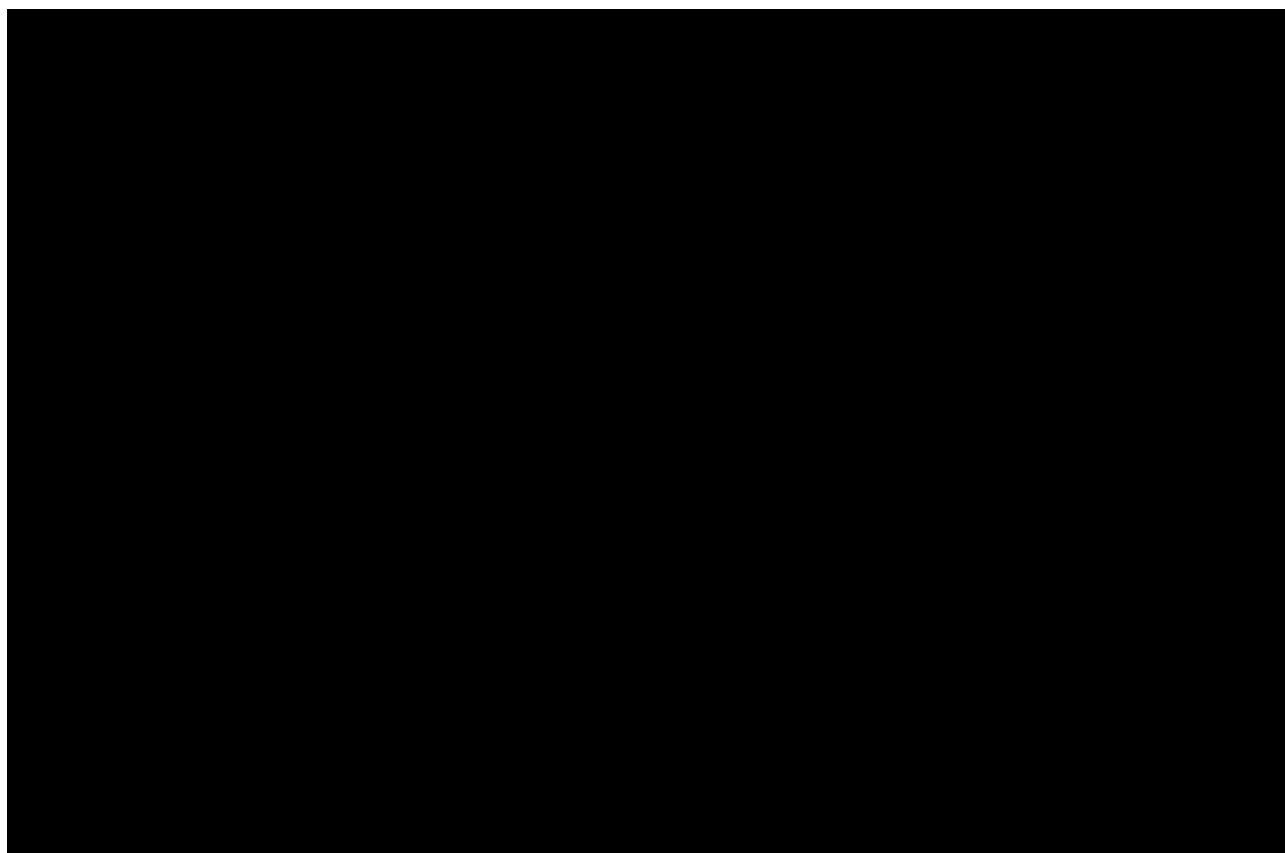
14.3.6.45: Total Antibodies (% B/T) - Mean Plot - Observed Values - Extension Trial Set



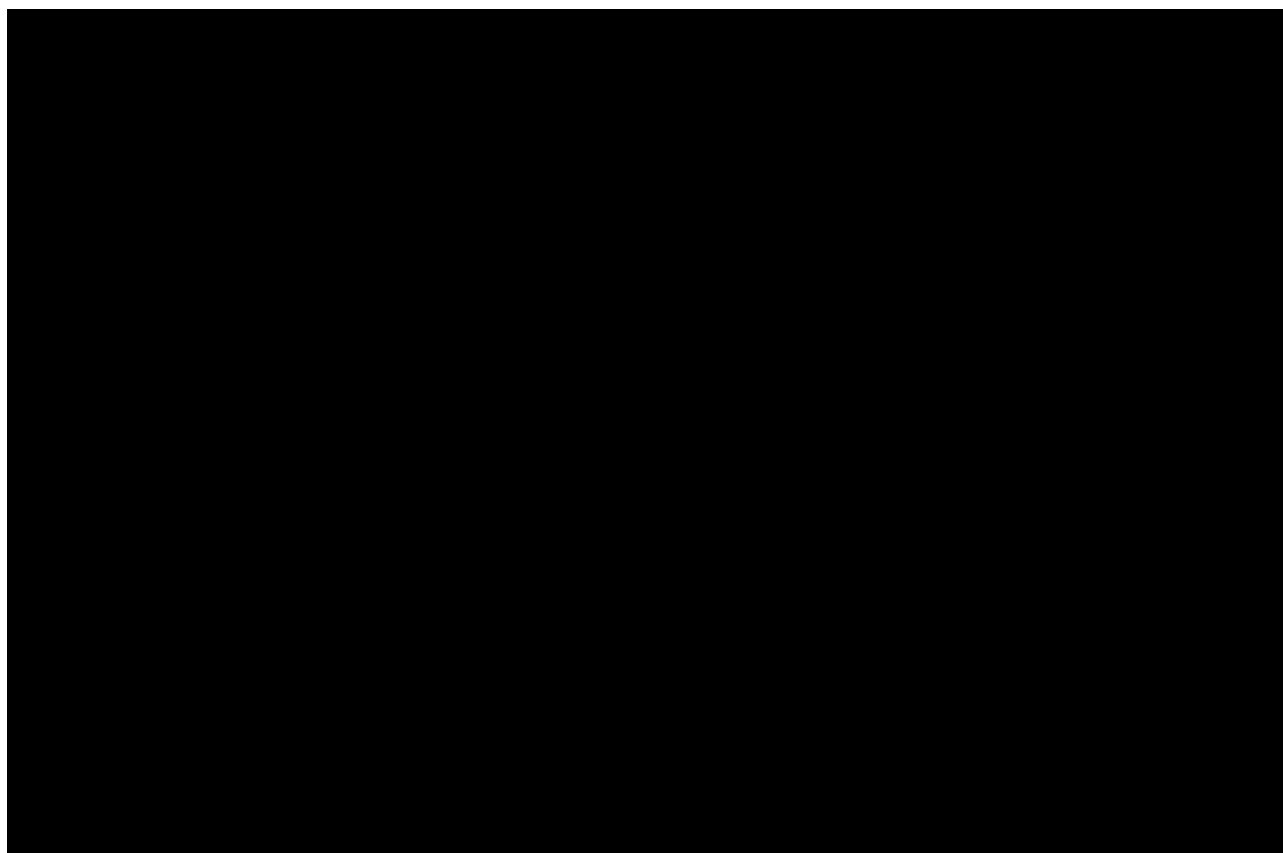
14.3.6.46: Degludec specific Antibodies (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set



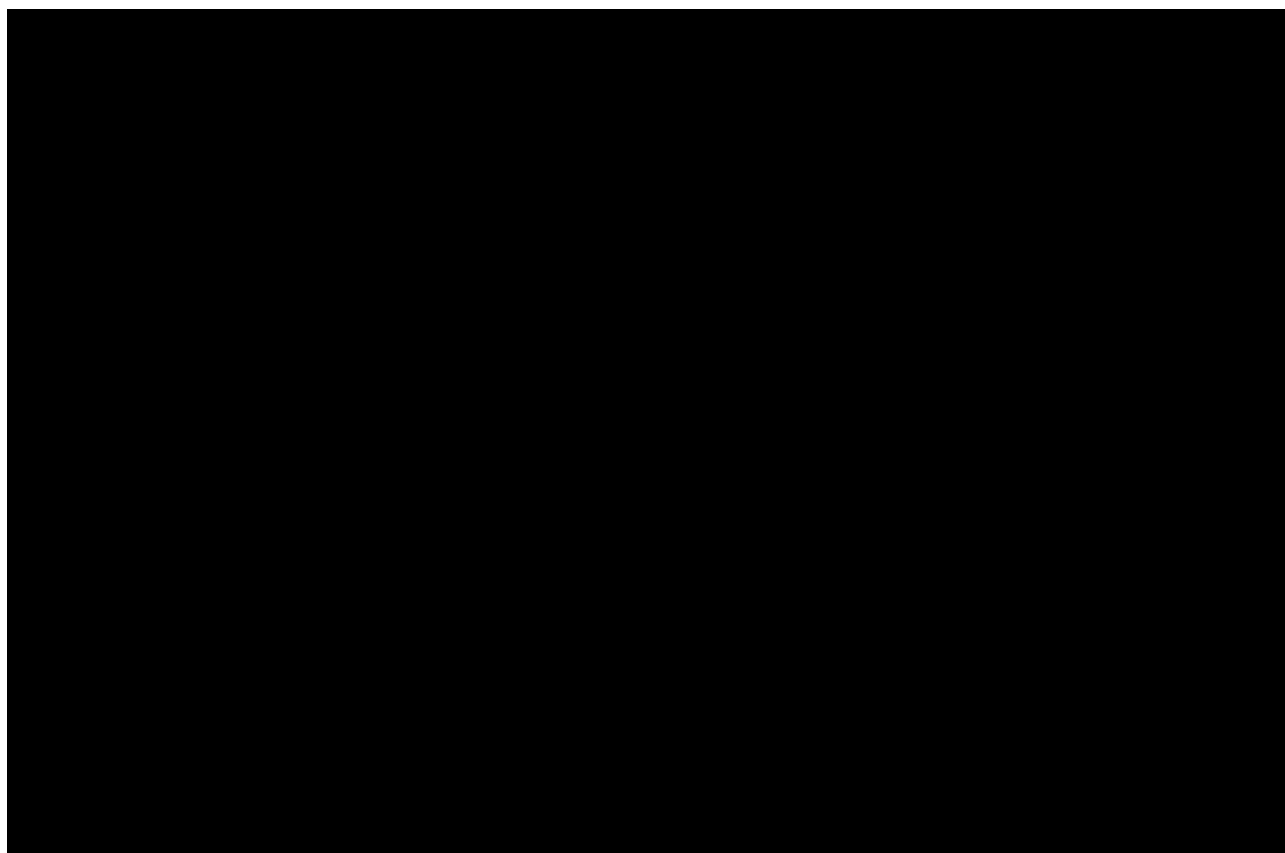
14.3.6.47: Degludec specific Antibodies (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot – Extension Trial Set



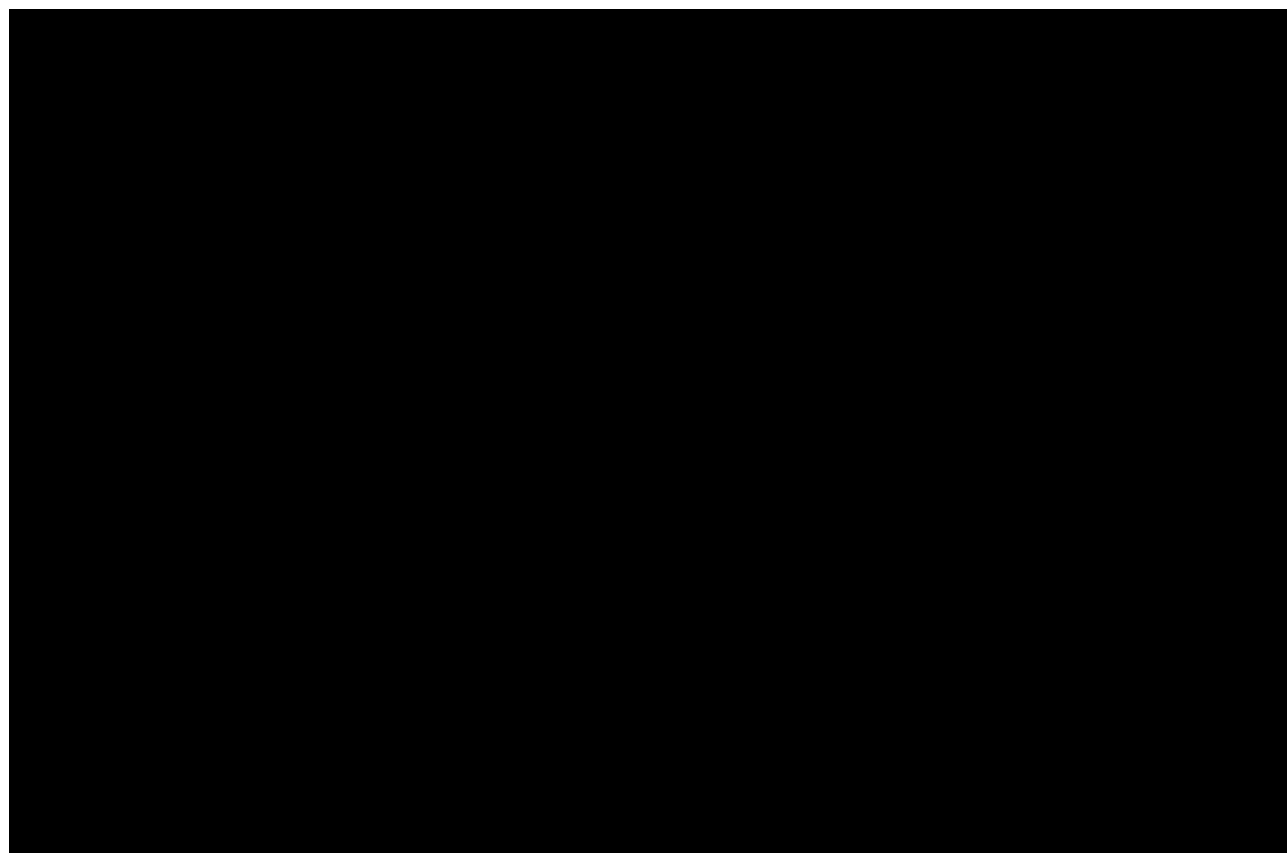
14.3.6.48: Degludec specific Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set



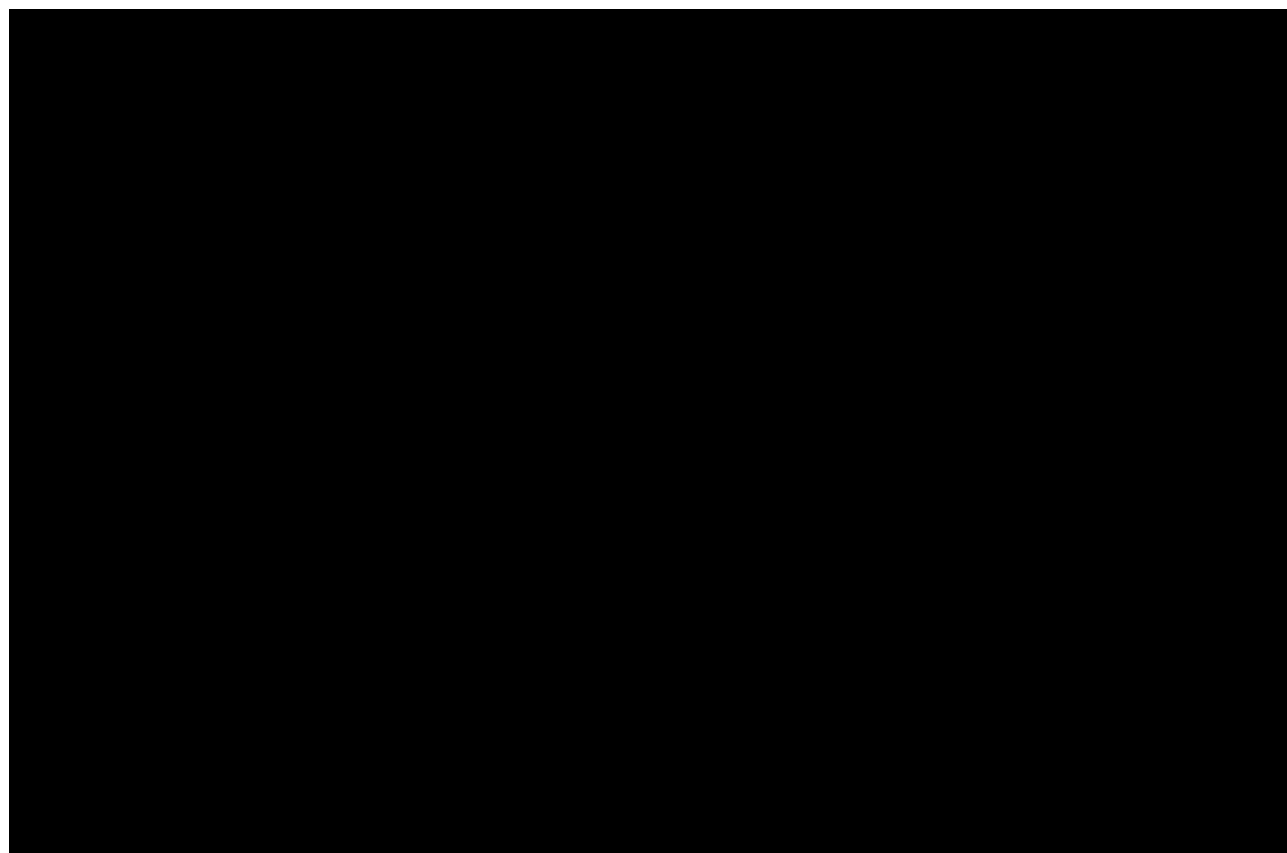
14.3.6.49: Degludec specific Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set



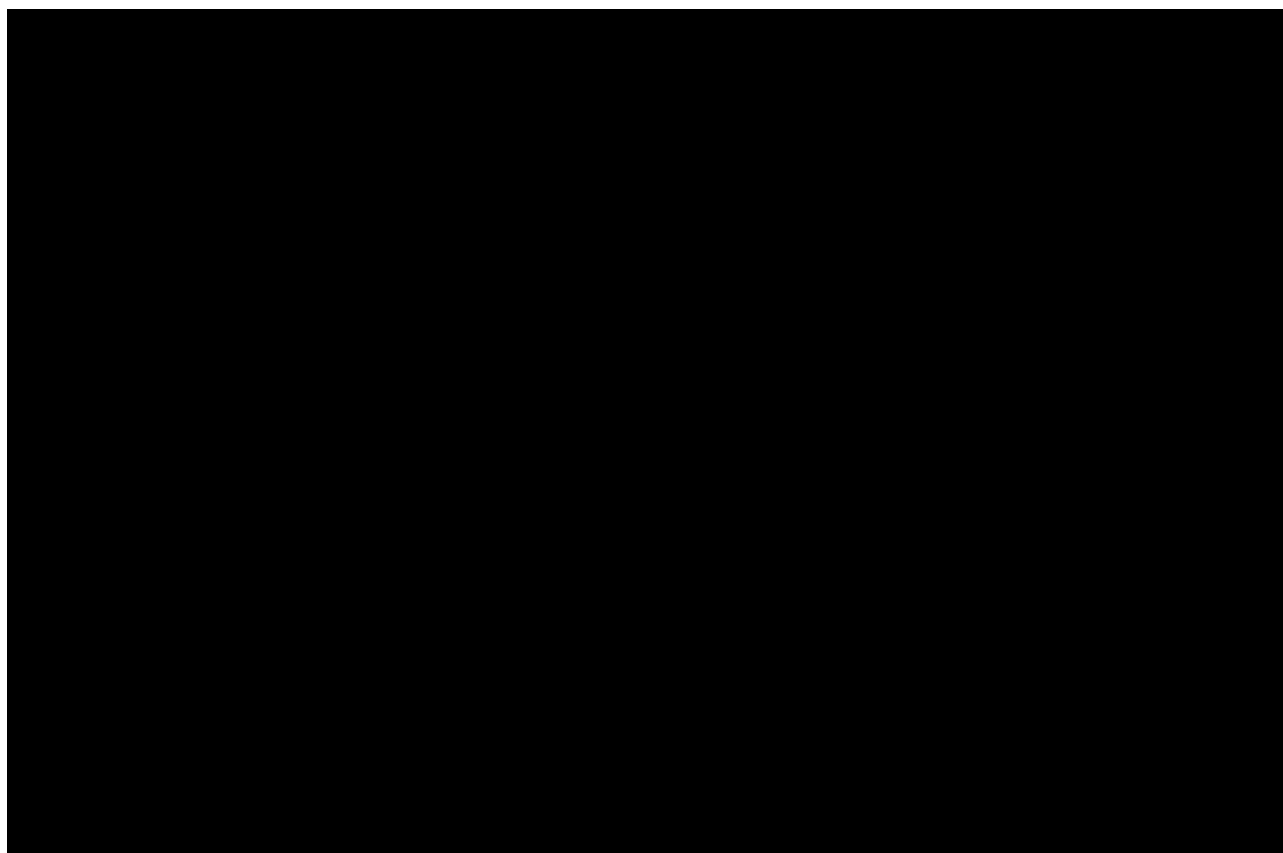
14.3.6.50: Cross-reacting Antibodies to Human Insulin (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set



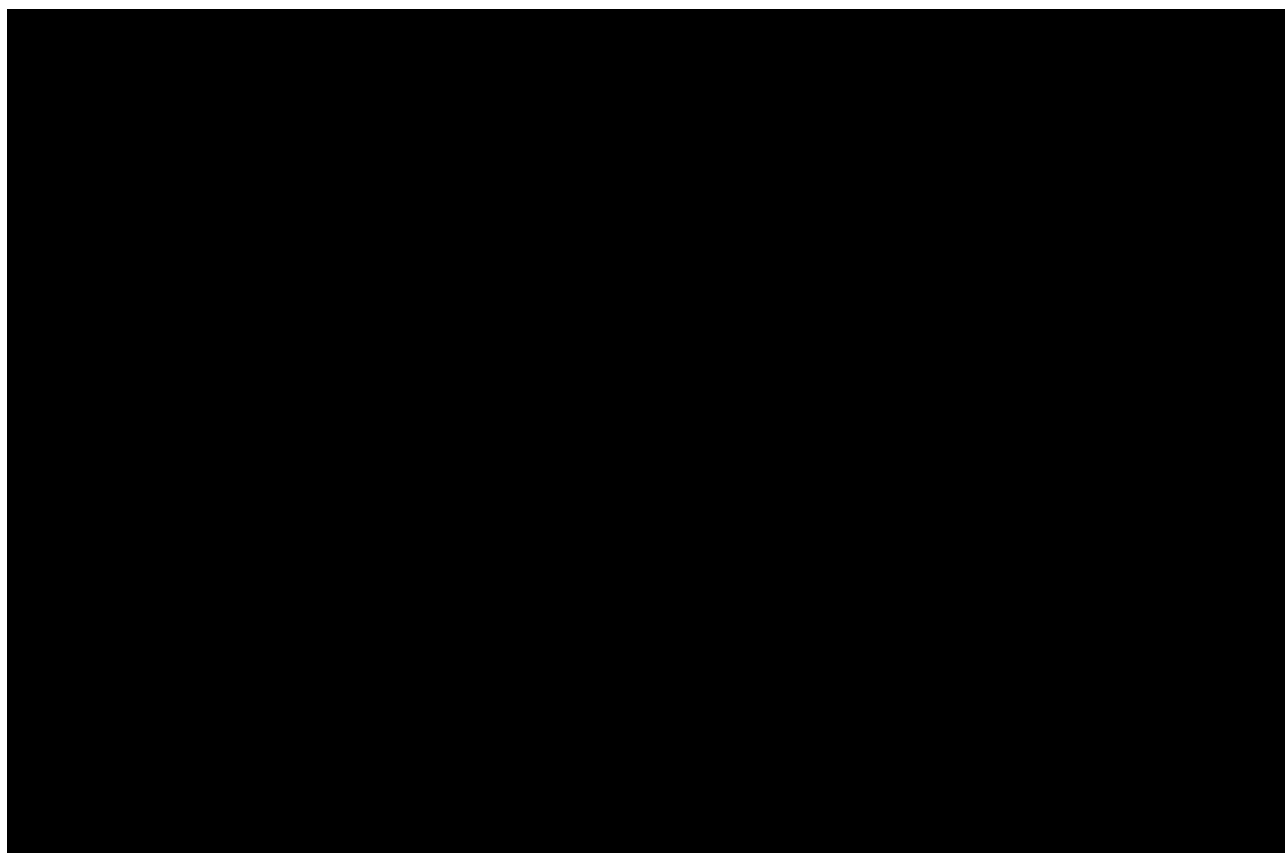
14.3.6.51: Cross-reacting Antibodies to Human Insulin (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set



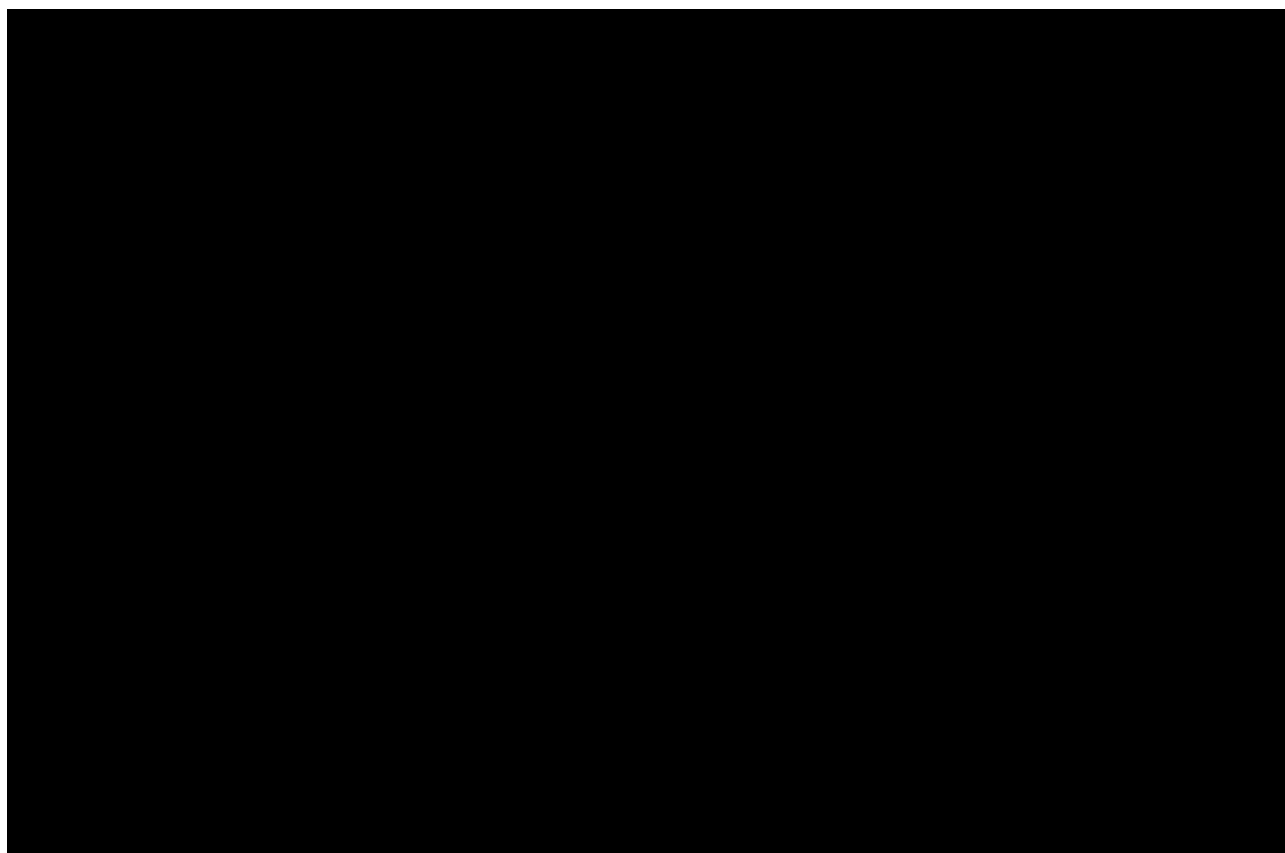
14.3.6.52: Cross-reacting Antibodies to Human Insulin (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set



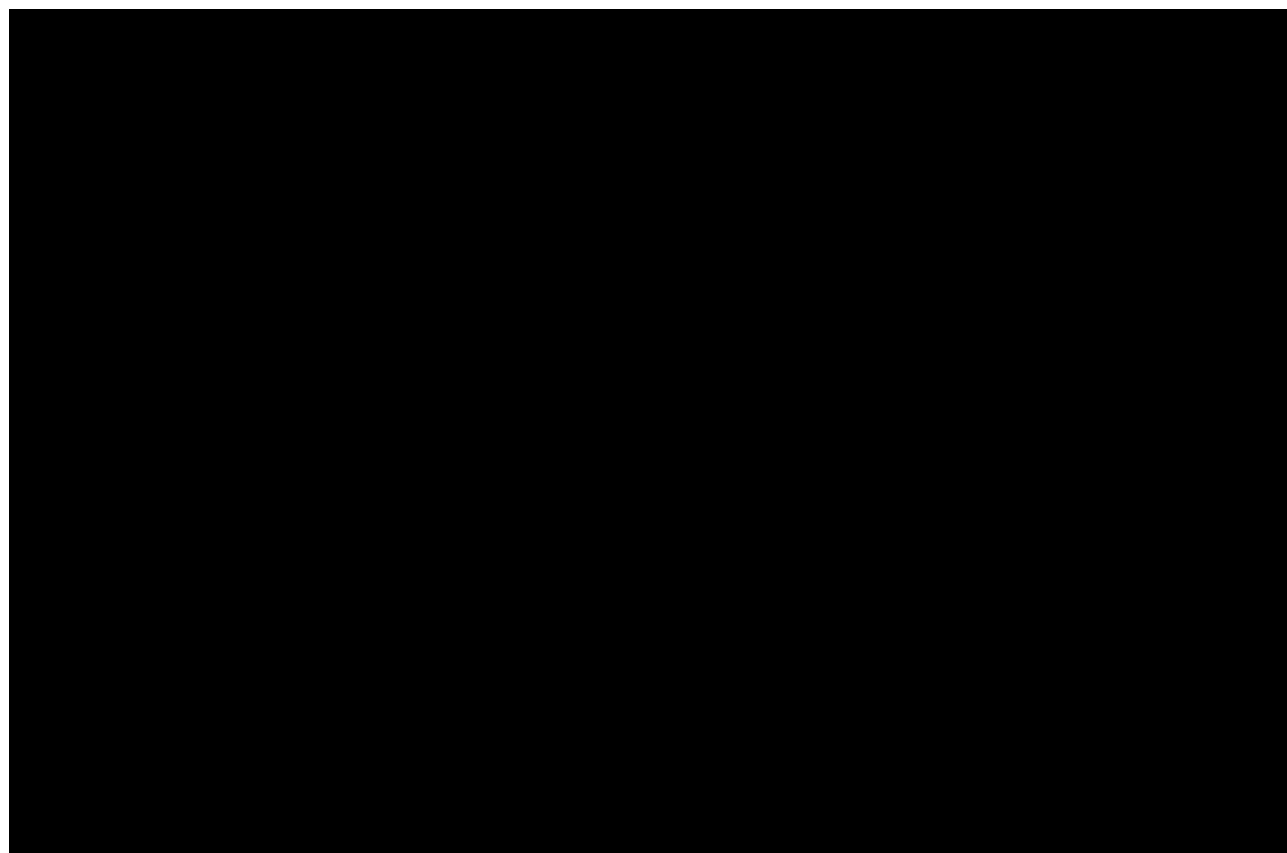
14.3.6.53: Cross-reacting Antibodies to Human Insulin (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set



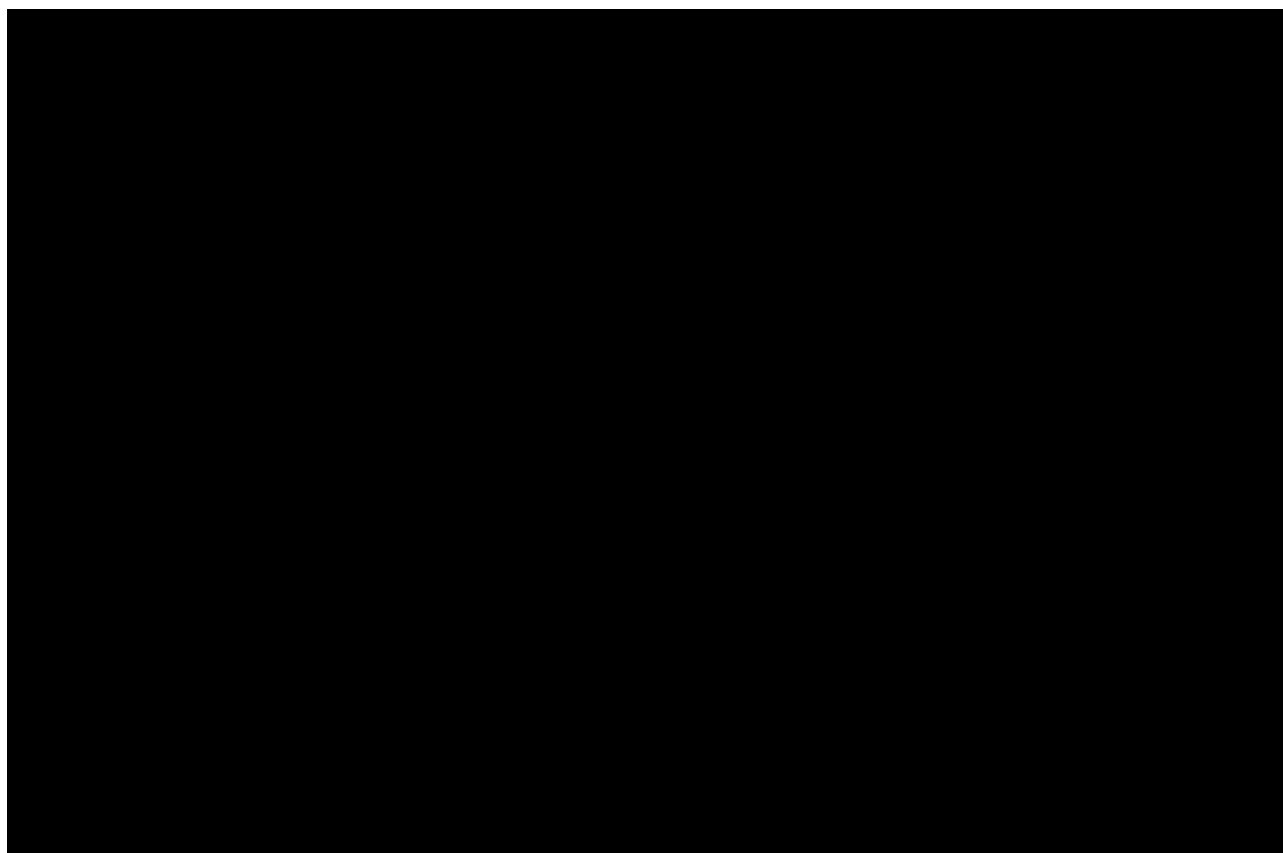
14.3.6.54: Total Antibodies (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set



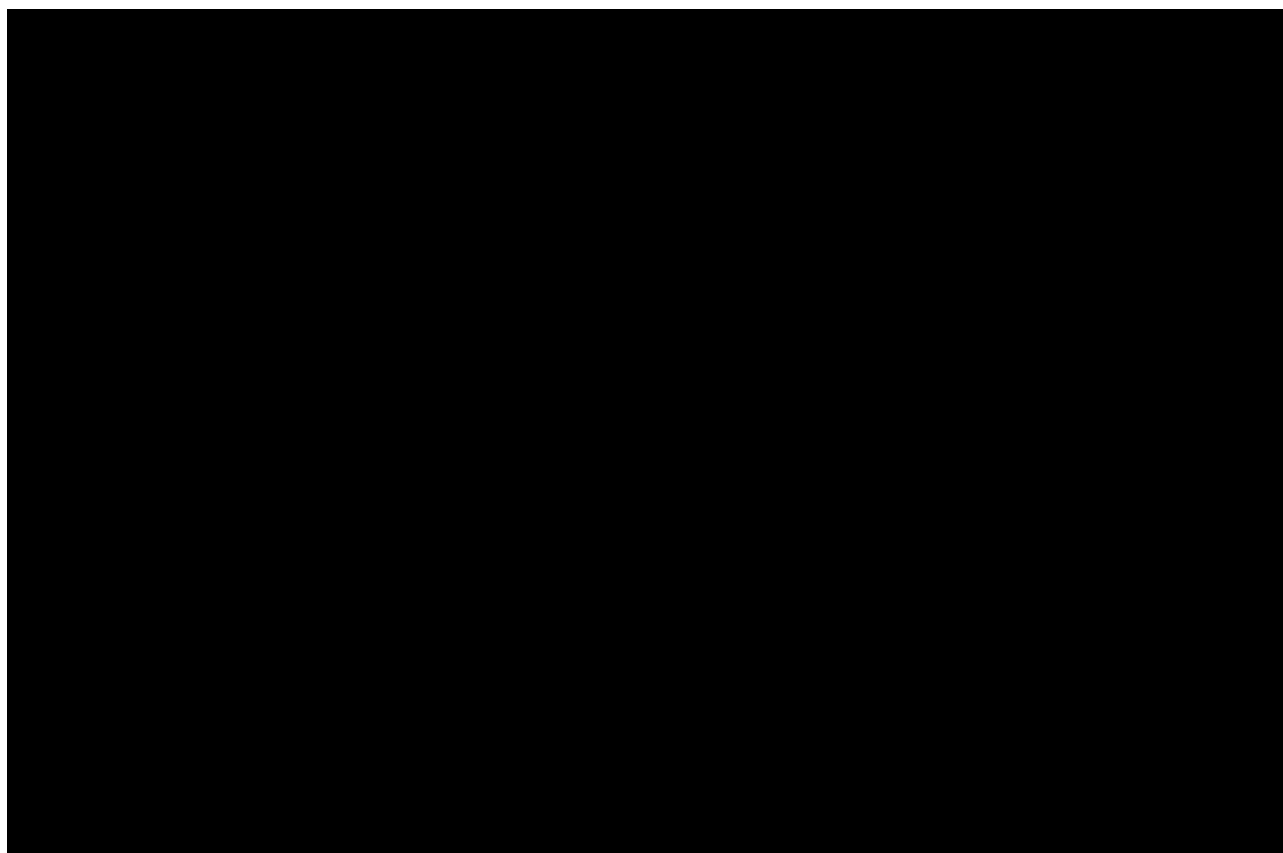
14.3.6.55: Total Antibodies (% B/T) against HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set



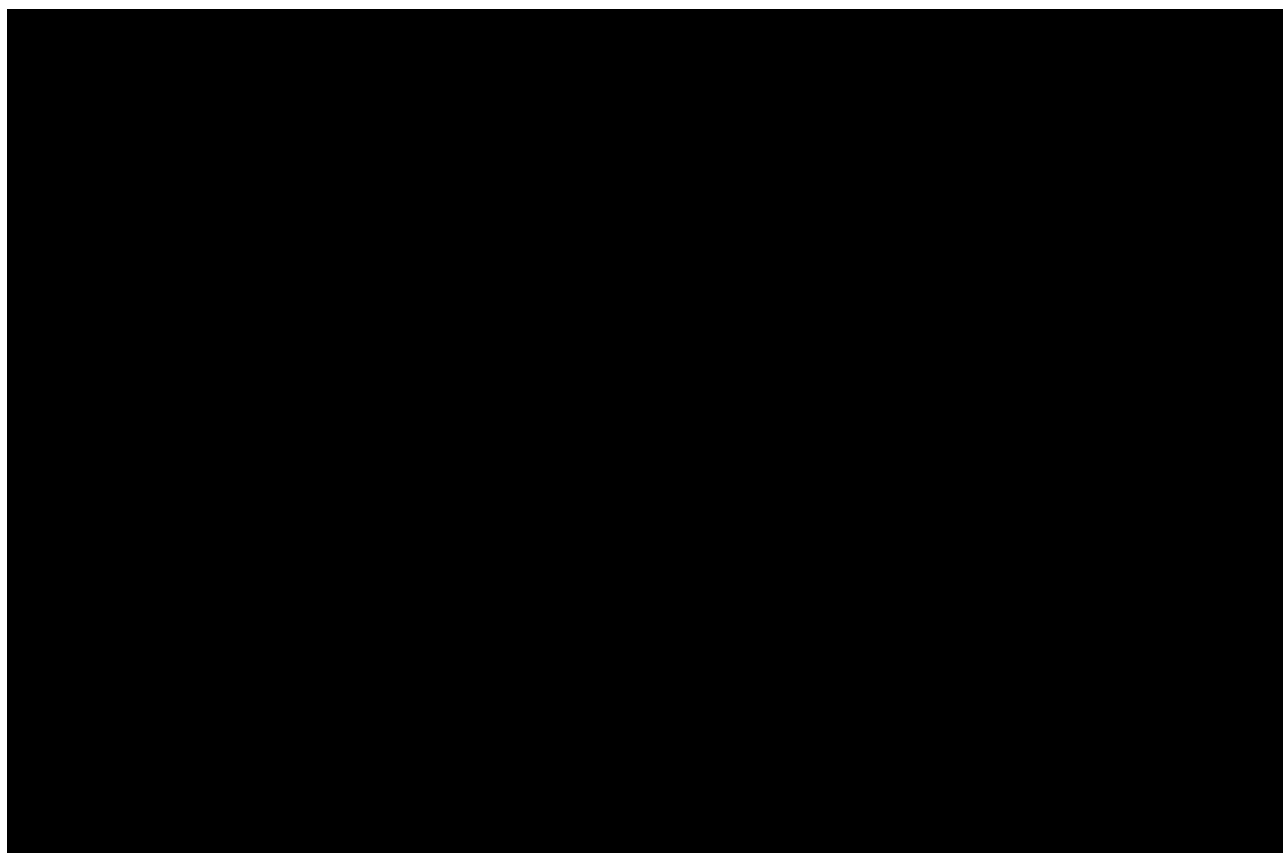
14.3.6.56: Total Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set



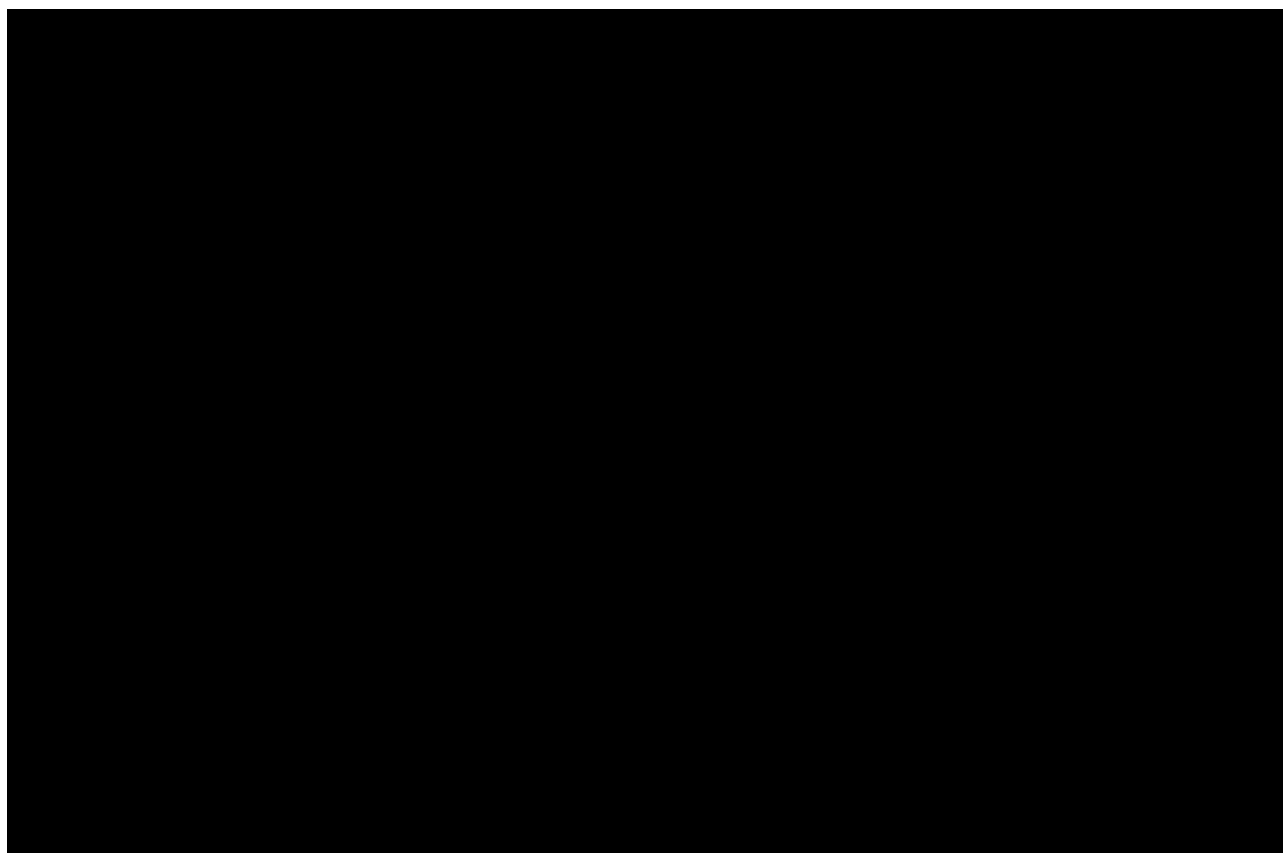
14.3.6.57: Total Antibodies (% B/T) against Change from Baseline in HbA1c (%) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set



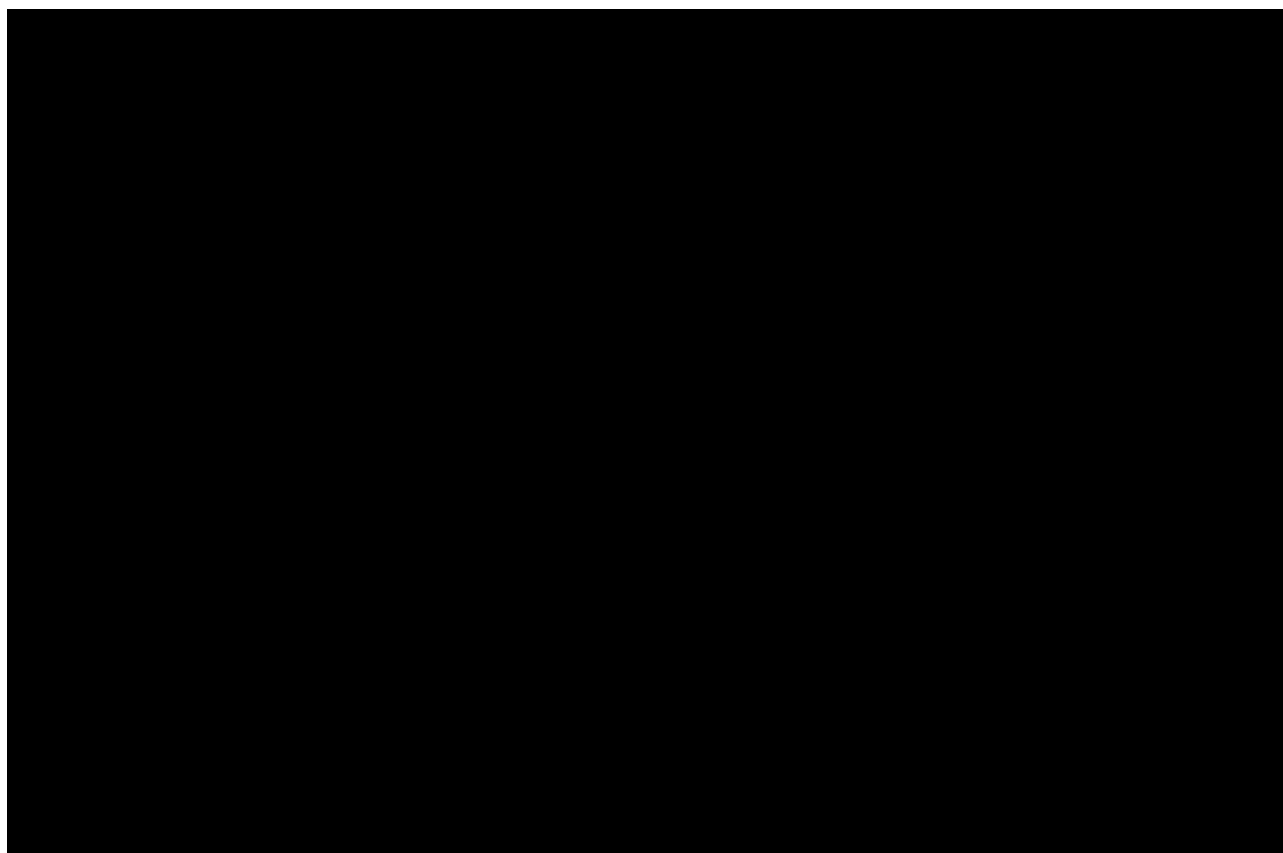
14.3.6.58: Degludec specific Antibodies (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set



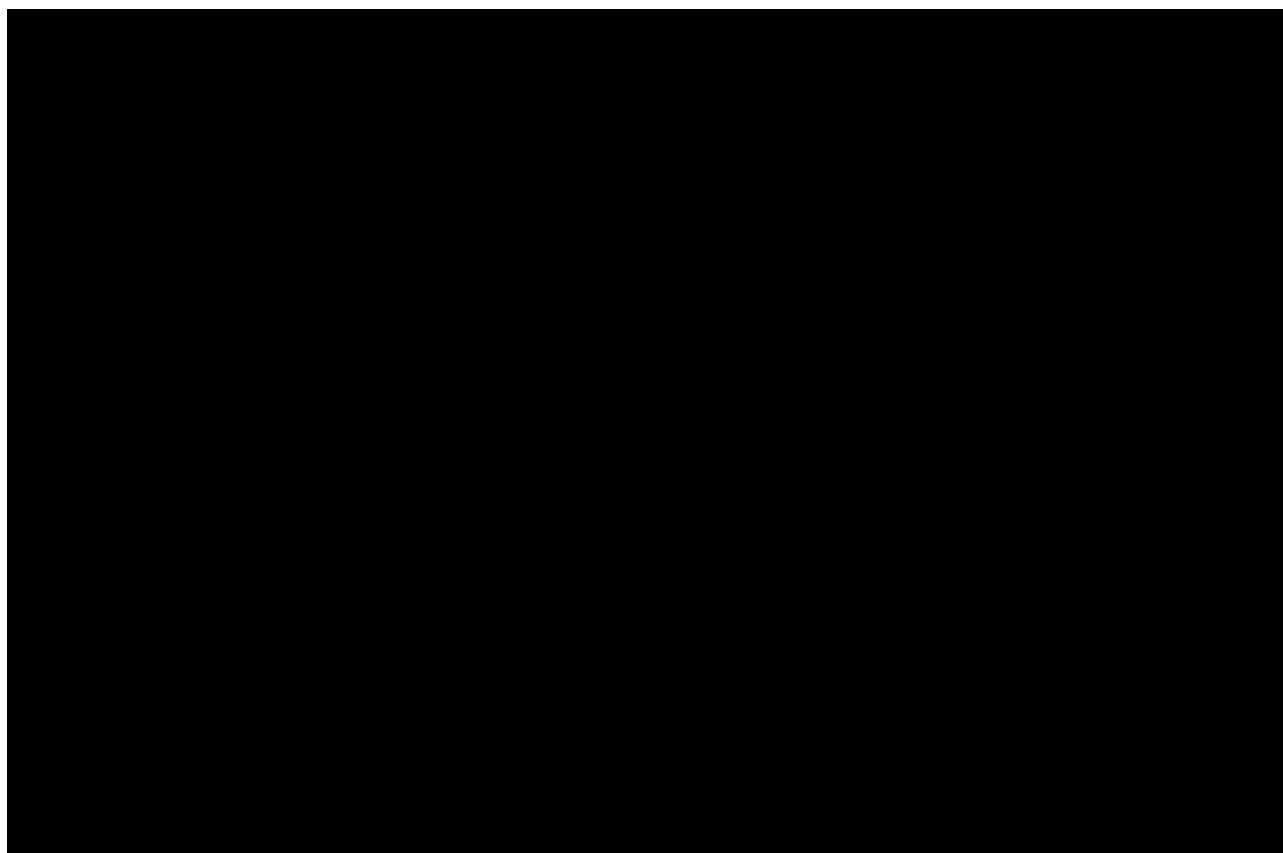
14.3.6.59: Degludec specific Antibodies (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set



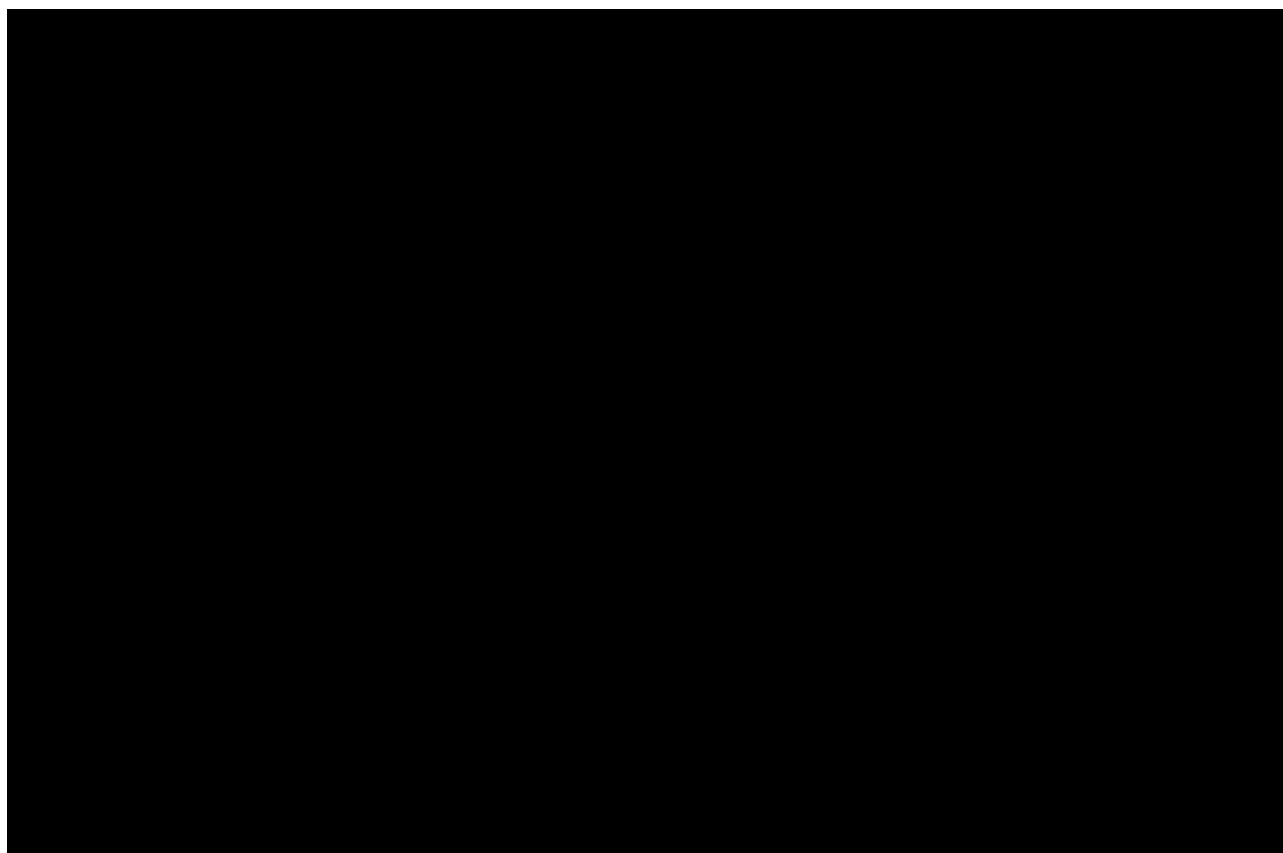
14.3.6.60: Cross-reacting Antibodies to Human Insulin (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set



14.3.6.61: Cross-reacting Antibodies to Human Insulin (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Extension trial Set



14.3.6.62: Total Antibodies (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Safety Analysis Set



14.3.6.63: Total Antibodies (% B/T) against Total Daily Insulin Dose (U/kg) after 52 Weeks of Treatment - Scatter Plot - Extension Trial Set

14.3.7.1: Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	55	M	25.2	1	120	80	72
2	1	62	F	28.5	1	115	75	68
3	1	58	M	22.1	1	110	70	70
4	1	65	F	30.1	1	125	85	75
5	1	52	M	20.5	1	105	65	65
6	1	60	F	27.8	1	118	78	70
7	1	57	M	23.5	1	112	72	68
8	1	63	F	29.2	1	122	82	72
9	1	54	M	21.8	1	108	68	65
10	1	61	F	28.9	1	119	79	70
11	2	55	M	25.2	2	118	78	70
12	2	62	F	28.5	2	115	75	68
13	2	58	M	22.1	2	110	70	70
14	2	65	F	30.1	2	125	85	75
15	2	52	M	20.5	2	105	65	65
16	2	60	F	27.8	2	118	78	70
17	2	57	M	23.5	2	112	72	68
18	2	63	F	29.2	2	122	82	72
19	2	54	M	21.8	2	108	68	65
20	2	61	F	28.9	2	119	79	70

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	55	M	25.2	1	120	80	72
2	1	58	F	28.5	1	115	75	68
3	1	62	M	30.1	1	130	85	75
4	1	65	F	32.4	1	140	90	78
5	1	68	M	35.0	1	150	95	80
6	1	70	F	36.8	1	155	98	82
7	1	72	M	38.2	1	160	100	84
8	1	75	F	40.5	1	165	102	86
9	1	78	M	42.1	1	170	105	88
10	1	80	F	43.5	1	175	108	90
11	2	55	M	25.2	2	118	78	70
12	2	58	F	28.5	2	112	72	66
13	2	62	M	30.1	2	125	82	72
14	2	65	F	32.4	2	135	88	76
15	2	68	M	35.0	2	145	92	78
16	2	70	F	36.8	2	150	95	80
17	2	72	M	38.2	2	155	98	82
18	2	75	F	40.5	2	160	100	84
19	2	78	M	42.1	2	165	102	86
20	2	80	F	43.5	2	170	105	88

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	55	M	25.2	1	120	80	72
2	1	62	F	28.5	1	115	75	68
3	1	58	M	22.1	1	110	70	70
4	1	65	F	30.1	1	125	85	75
5	1	52	M	20.5	1	105	65	65
6	1	60	F	27.8	1	118	78	70
7	1	57	M	23.5	1	112	72	68
8	1	63	F	29.2	1	122	82	72
9	1	54	M	21.8	1	108	68	65
10	1	61	F	28.9	1	119	79	70
11	2	55	M	25.2	2	118	78	70
12	2	62	F	28.5	2	115	75	68
13	2	58	M	22.1	2	110	70	70
14	2	65	F	30.1	2	125	85	75
15	2	52	M	20.5	2	105	65	65
16	2	60	F	27.8	2	118	78	70
17	2	57	M	23.5	2	112	72	68
18	2	63	F	29.2	2	122	82	72
19	2	54	M	21.8	2	108	68	65
20	2	61	F	28.9	2	119	79	70

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	55	M	25.2	1	120	80	72
2	1	62	F	28.5	1	115	75	68
3	1	58	M	22.1	1	110	70	70
4	1	65	F	30.1	1	125	85	75
5	1	52	M	20.5	1	105	65	65
6	1	60	F	27.8	1	118	78	70
7	1	57	M	23.5	1	112	72	68
8	1	63	F	29.2	1	122	82	72
9	1	54	M	21.8	1	108	68	65
10	1	61	F	28.9	1	119	79	70
11	2	55	M	25.2	2	118	78	70
12	2	62	F	28.5	2	115	75	68
13	2	58	M	22.1	2	110	70	70
14	2	65	F	30.1	2	125	85	75
15	2	52	M	20.5	2	105	65	65
16	2	60	F	27.8	2	118	78	70
17	2	57	M	23.5	2	112	72	68
18	2	63	F	29.2	2	122	82	72
19	2	54	M	21.8	2	108	68	65
20	2	61	F	28.9	2	119	79	70

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	55	M	25.2	1	120	80	72
2	1	62	F	28.5	1	115	75	68
3	1	58	M	22.1	1	110	70	70
4	1	65	F	30.1	1	125	85	75
5	1	52	M	20.5	1	105	65	65
6	1	60	F	27.8	1	118	78	70
7	1	57	M	23.5	1	112	72	68
8	1	63	F	29.2	1	122	82	72
9	1	54	M	21.8	1	108	68	65
10	1	61	F	28.9	1	119	79	70
11	2	55	M	25.2	2	118	78	70
12	2	62	F	28.5	2	115	75	68
13	2	58	M	22.1	2	110	70	70
14	2	65	F	30.1	2	125	85	75
15	2	52	M	20.5	2	105	65	65
16	2	60	F	27.8	2	118	78	70
17	2	57	M	23.5	2	112	72	68
18	2	63	F	29.2	2	122	82	72
19	2	54	M	21.8	2	108	68	65
20	2	61	F	28.9	2	119	79	70

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	55	M	25.2	1	120	80	72
2	1	62	F	28.5	1	115	75	68
3	1	58	M	22.1	1	110	70	70
4	1	65	F	30.1	1	125	85	75
5	1	52	M	20.5	1	105	65	65
6	1	60	F	27.8	1	118	78	70
7	1	57	M	23.5	1	112	72	68
8	1	63	F	29.2	1	122	82	72
9	1	54	M	21.8	1	108	68	65
10	1	61	F	28.9	1	119	79	70
11	2	55	M	25.2	2	118	78	70
12	2	62	F	28.5	2	115	75	68
13	2	58	M	22.1	2	110	70	70
14	2	65	F	30.1	2	125	85	75
15	2	52	M	20.5	2	105	65	65
16	2	60	F	27.8	2	118	78	70
17	2	57	M	23.5	2	112	72	68
18	2	63	F	29.2	2	122	82	72
19	2	54	M	21.8	2	108	68	65
20	2	61	F	28.9	2	119	79	70

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
1	1	55	M	25.2	1	120	80	72
2	1	62	F	28.5	1	115	75	68
3	1	58	M	22.1	1	110	70	70
4	1	65	F	30.1	1	125	85	75
5	1	52	M	20.5	1	105	65	65
6	1	60	F	27.8	1	118	78	70
7	1	57	M	23.5	1	112	72	68
8	1	63	F	29.2	1	122	82	72
9	1	54	M	21.8	1	108	68	65
10	1	61	F	28.9	1	119	79	70
11	2	55	M	25.2	2	118	78	70
12	2	62	F	28.5	2	115	75	68
13	2	58	M	22.1	2	110	70	70
14	2	65	F	30.1	2	125	85	75
15	2	52	M	20.5	2	105	65	65
16	2	60	F	27.8	2	118	78	70
17	2	57	M	23.5	2	112	72	68
18	2	63	F	29.2	2	122	82	72
19	2	54	M	21.8	2	108	68	65
20	2	61	F	28.9	2	119	79	70

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

Vital Signs - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)
------------	-----------	-----------	-----------	--------------	-------	--------------------------------	---------------------------------	-------------------

14.3.7.2: ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

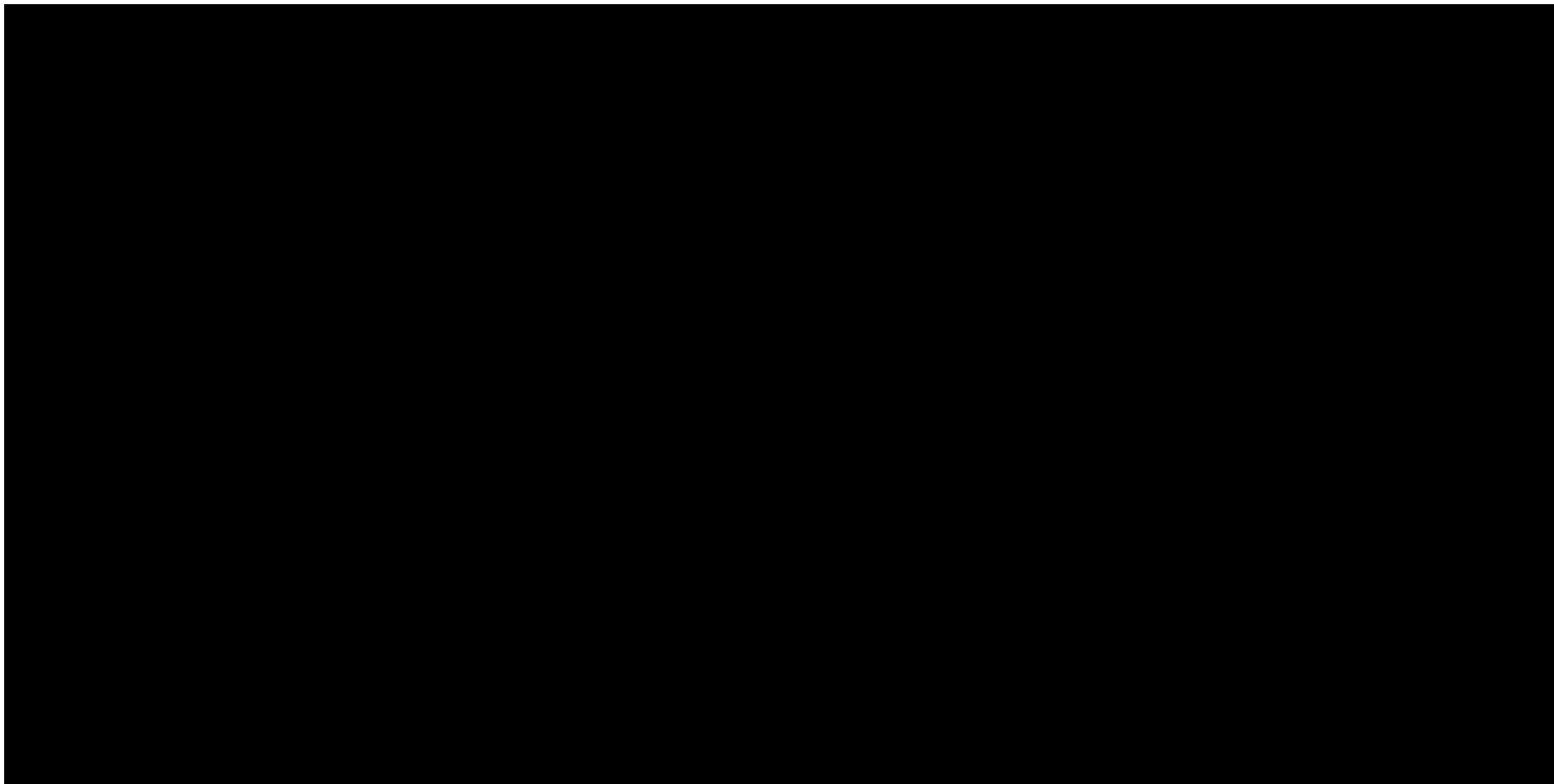
Status:
Page:

Final
Page 1294 of 2239

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

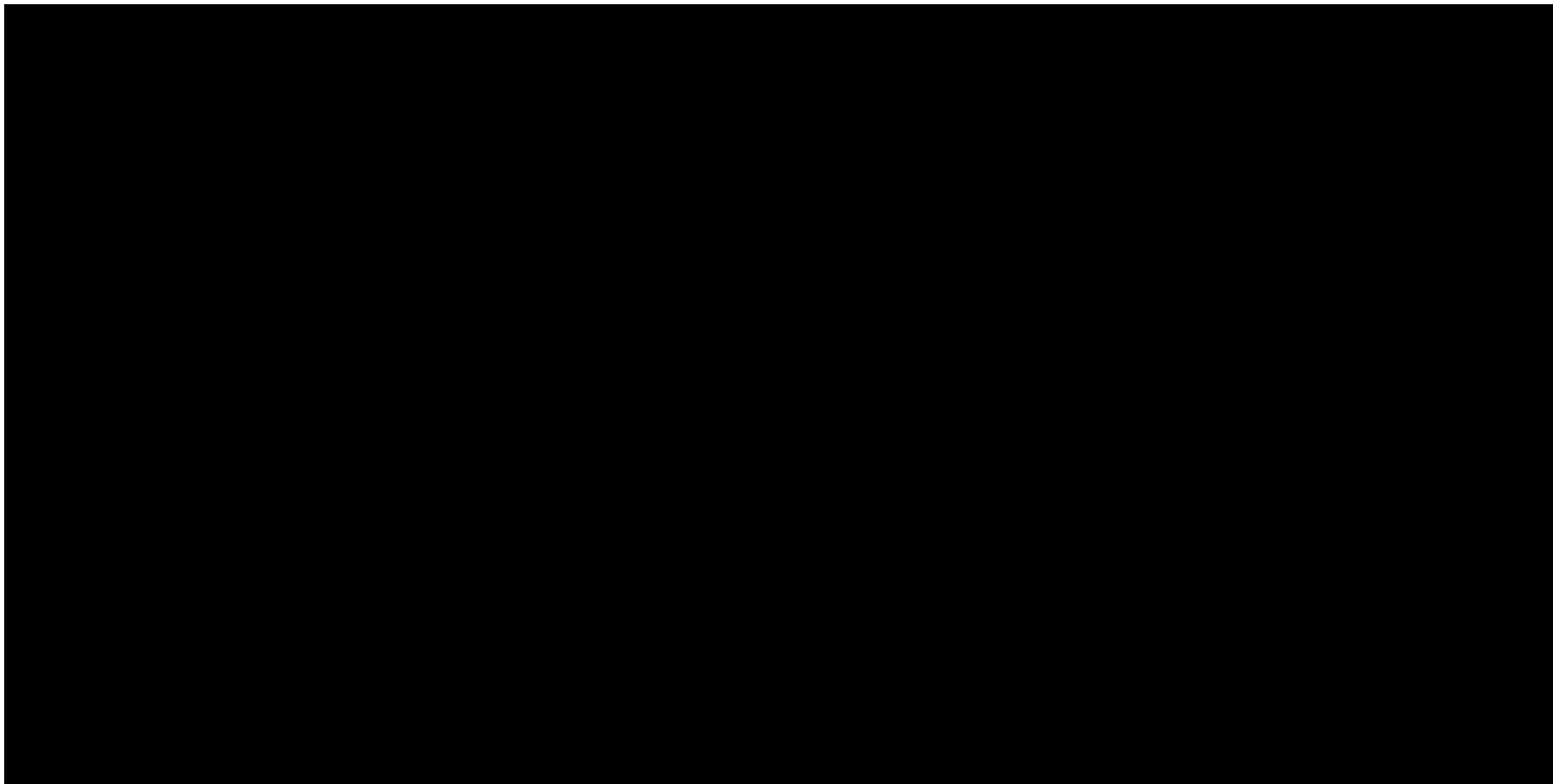
Status:
Page:

Final
Page 1295 of 2239

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

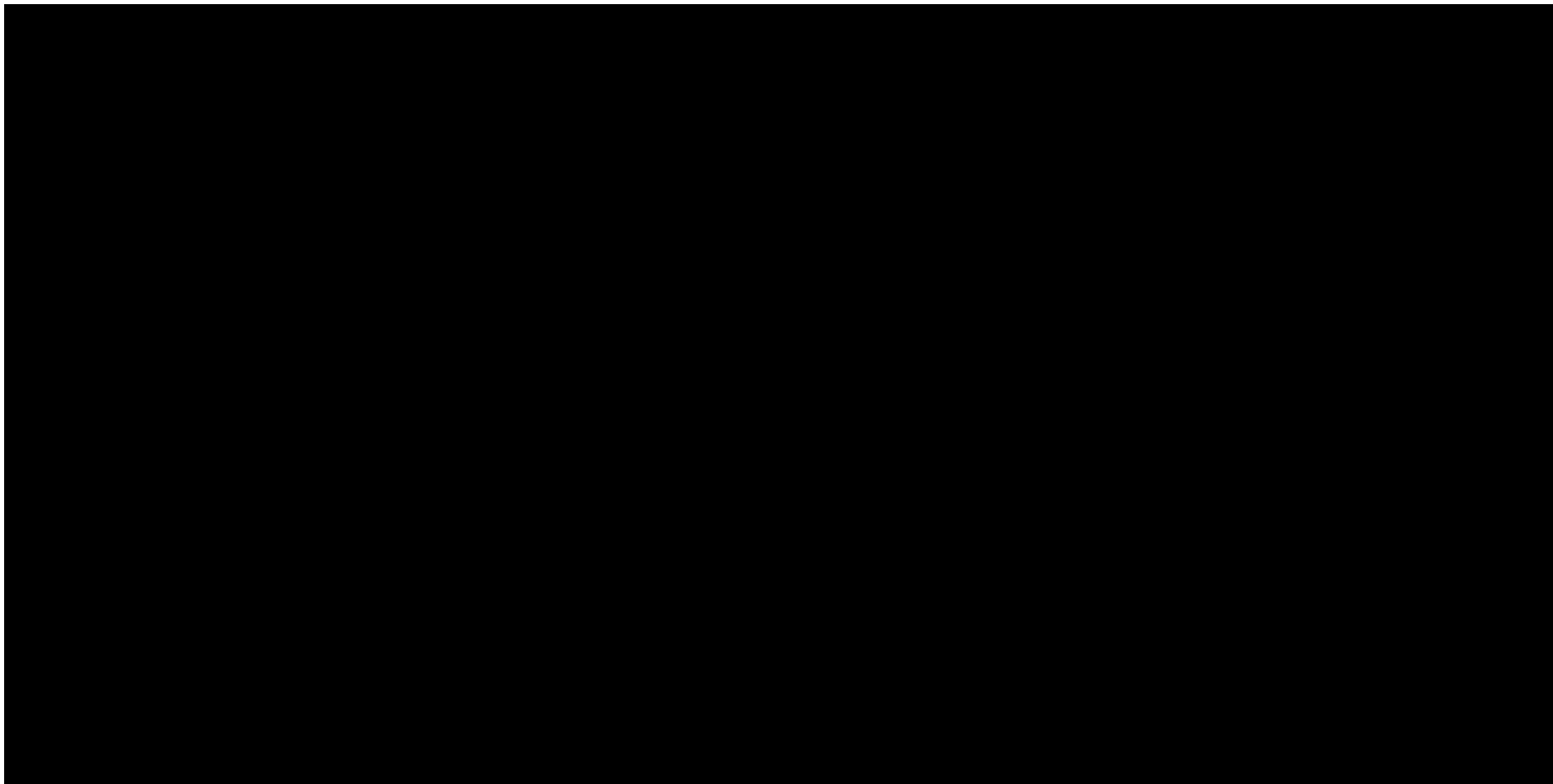
Status:
Page:

Final
Page 1297 of 2239

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

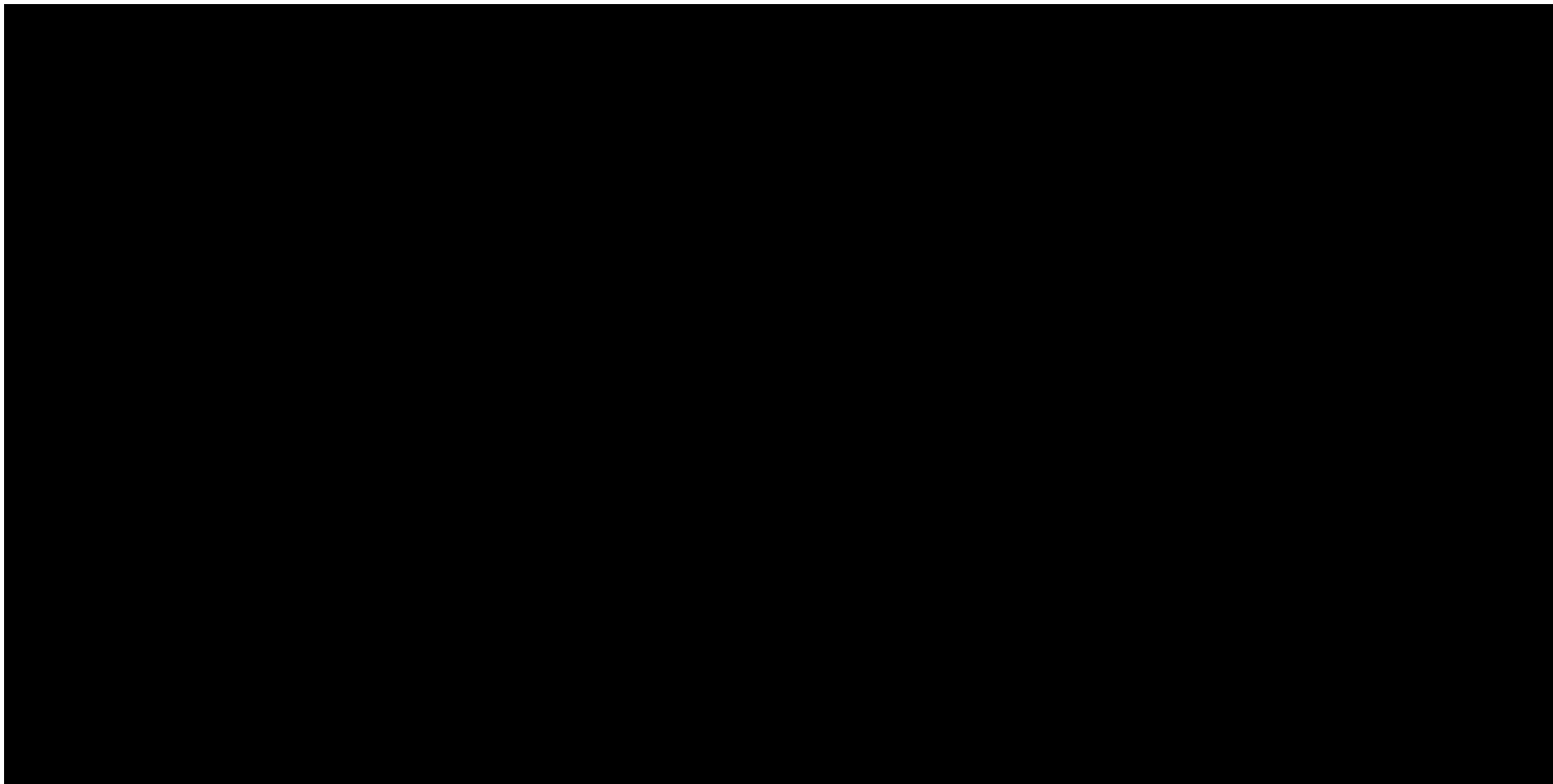
Status:
Page:

Final
Page 1300 of 2239

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

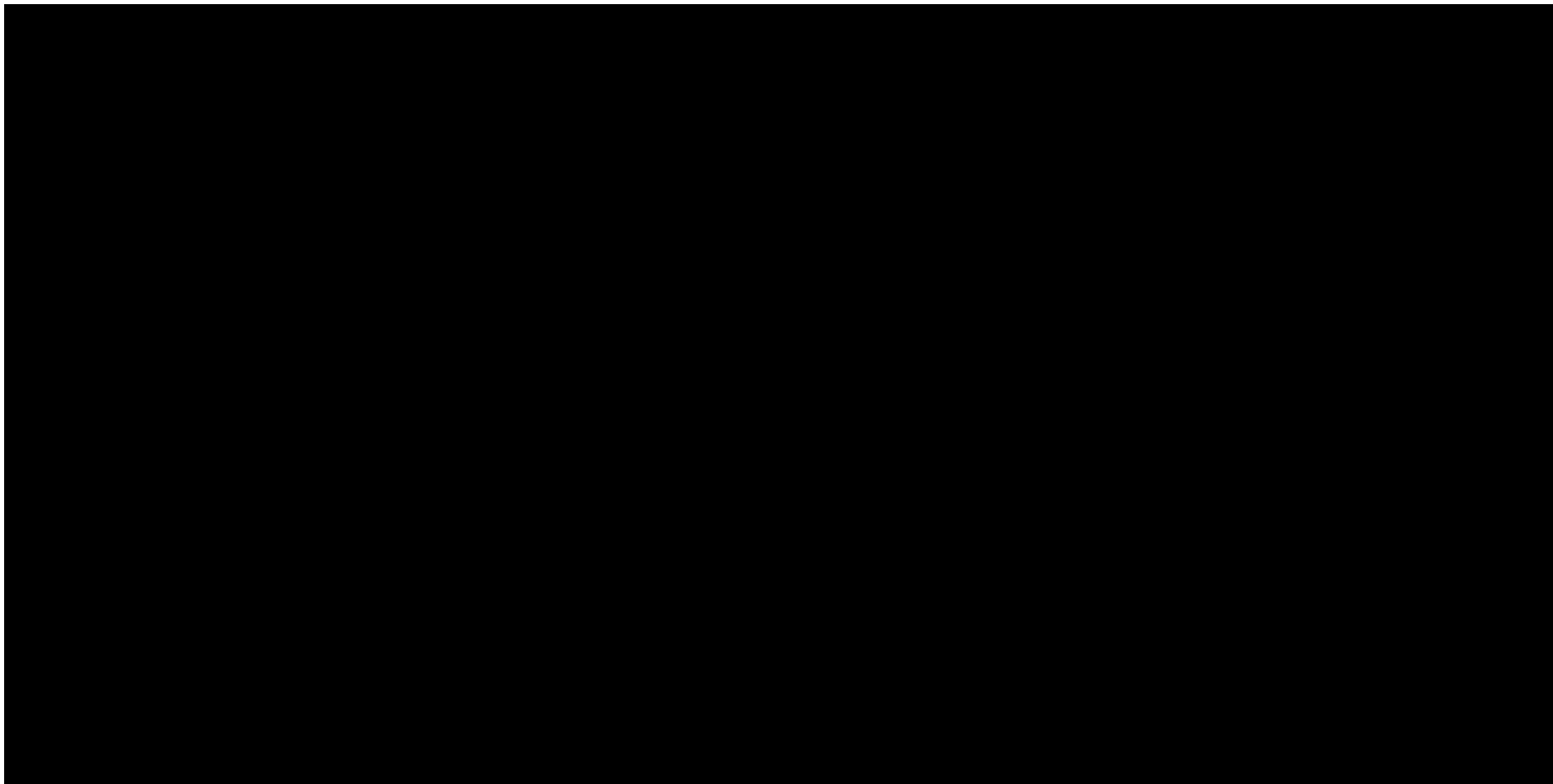
Status:
Page:

Final
Page 1313 of 2239

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

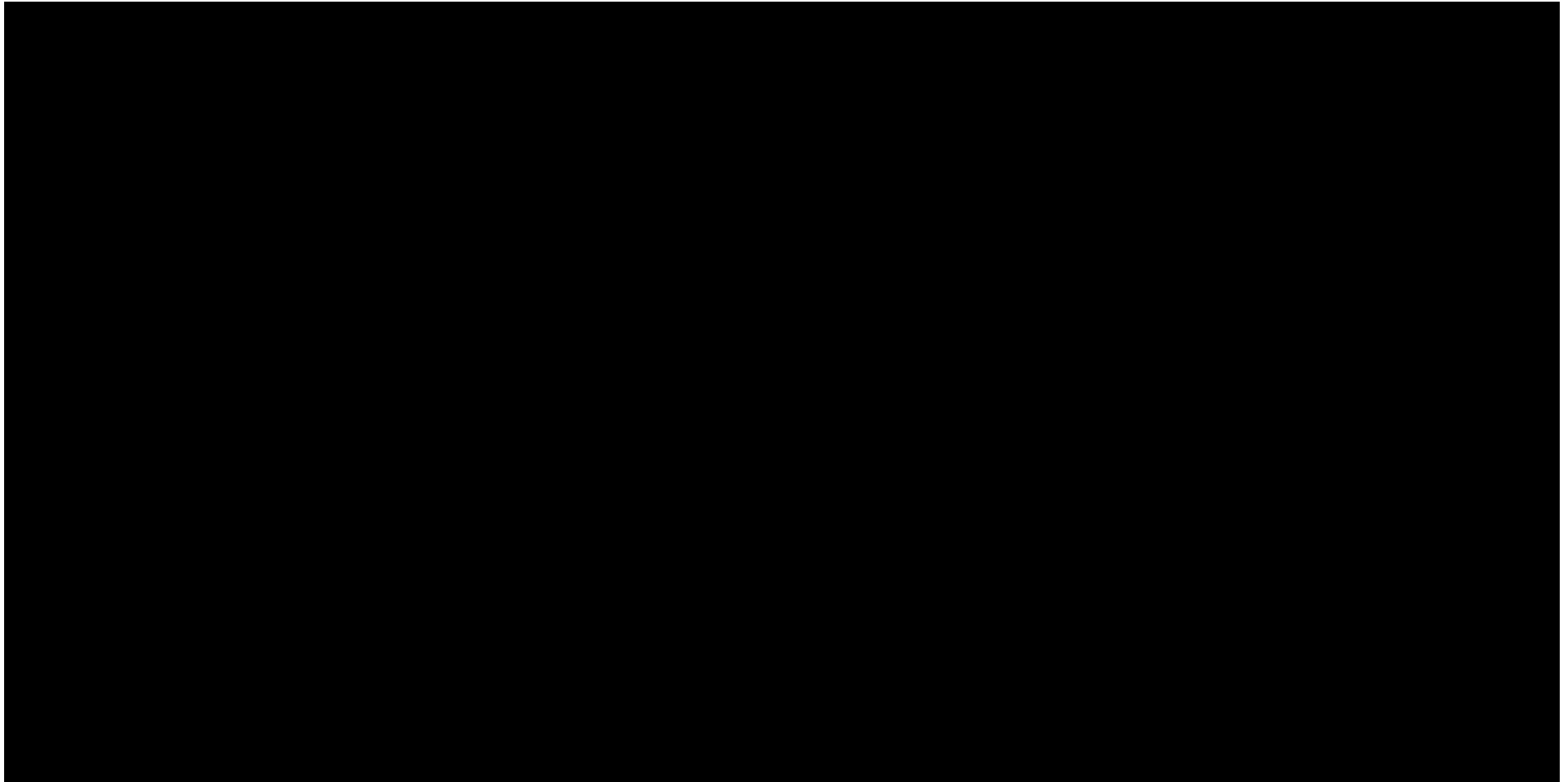
Status:
Page:

Final
Page 1316 of 2239

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

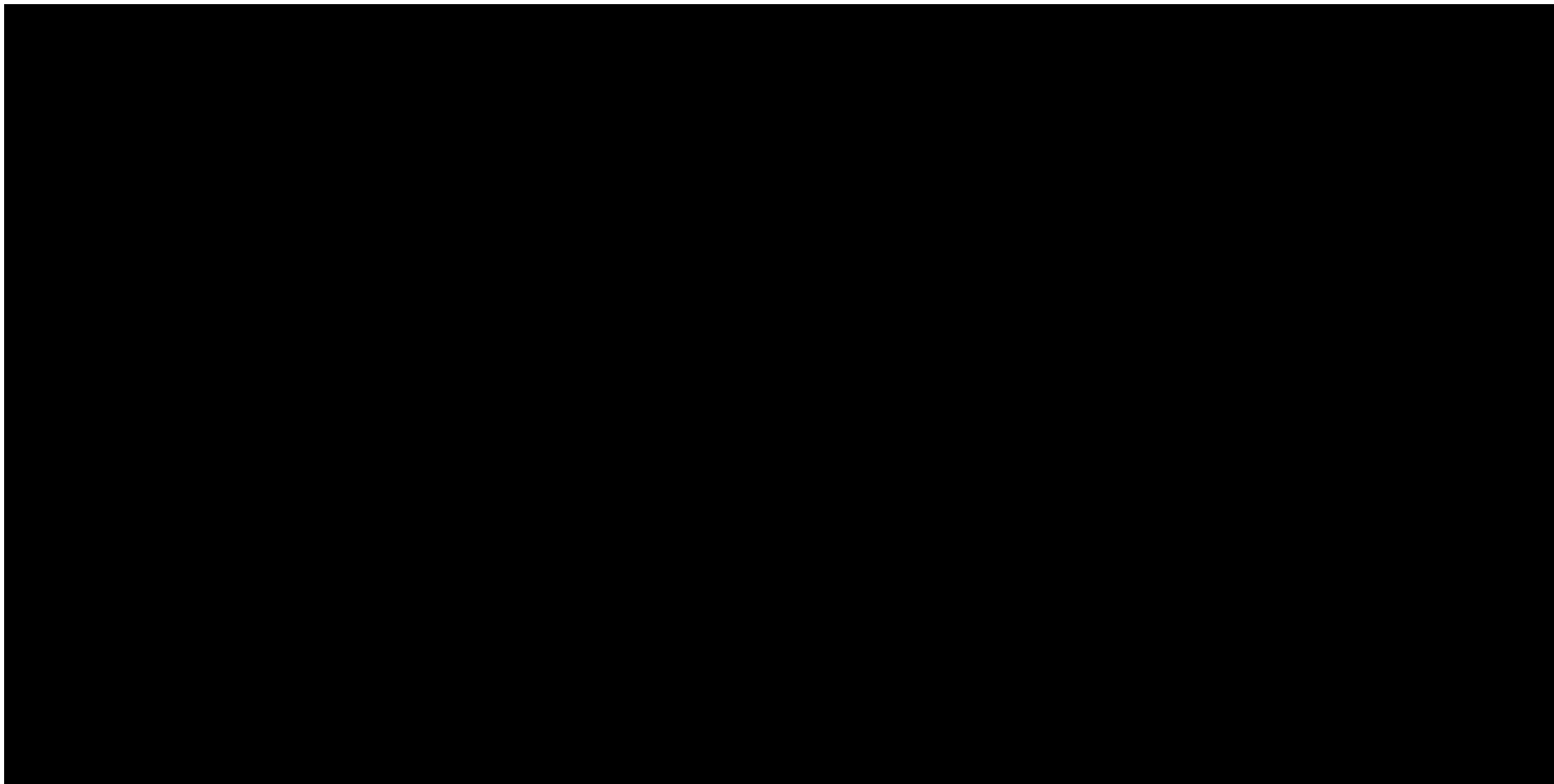
Status:
Page:

Final
Page 1330 of 2239

Novo Nordisk

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Result	Comment
---------------	-----------	--------------	--------------	-----------------------------	-------	------	--------	---------



ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

ECG Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	------	--------	---------

14.3.7.3: Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

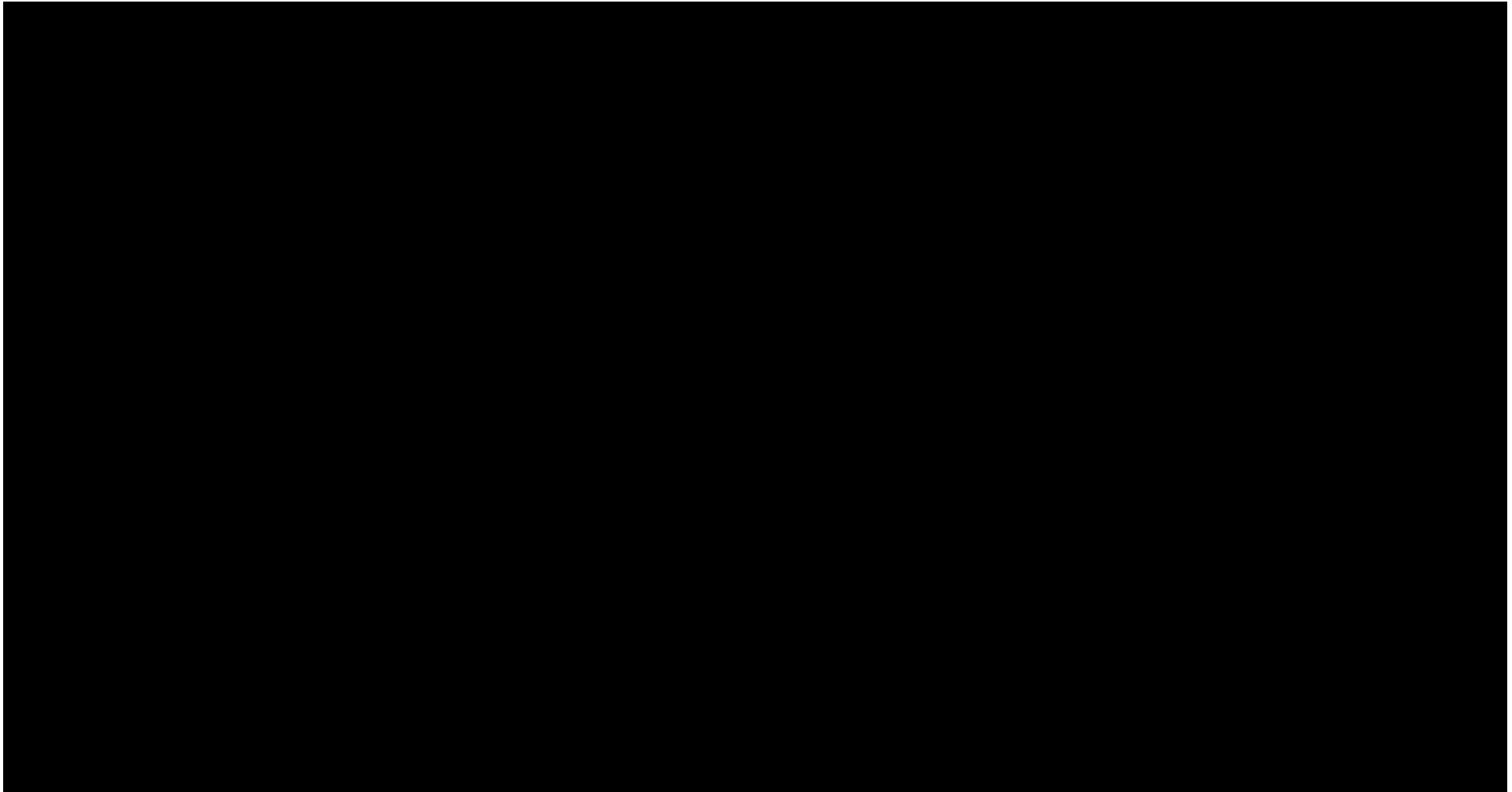
Status:
Page:

Final
Page 1347 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

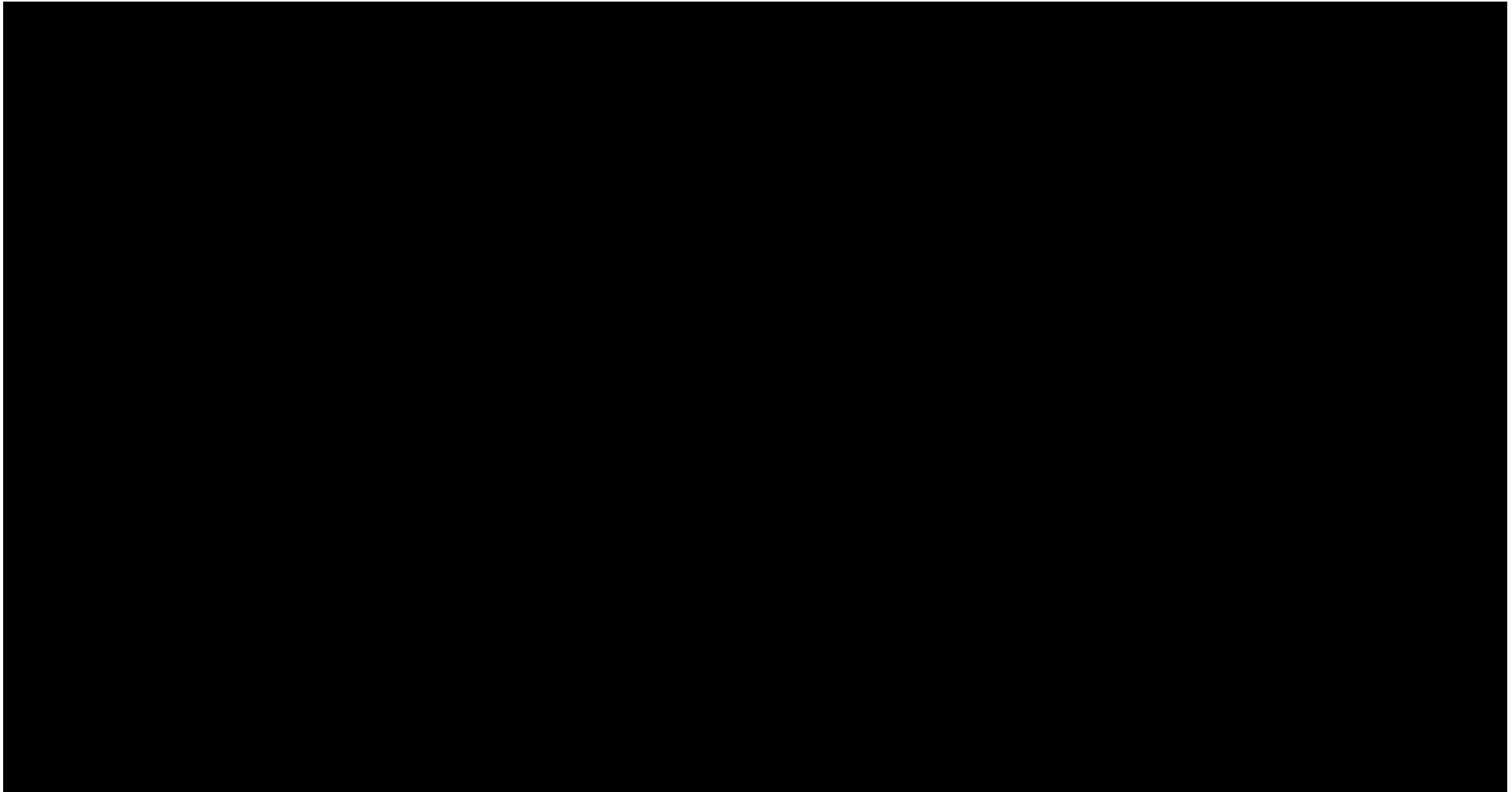
Status:
Page:

Final
Page 1350 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

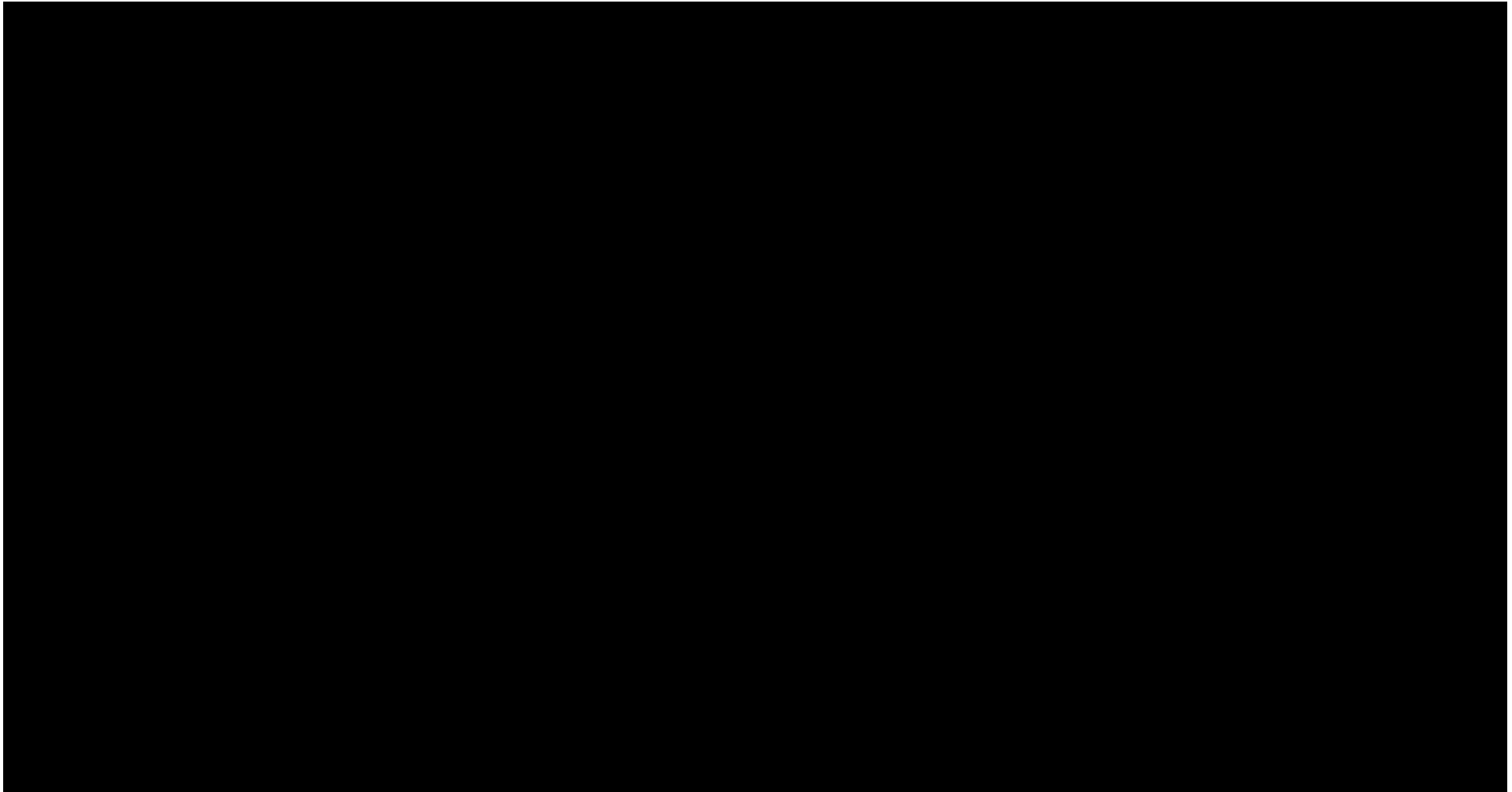
Status:
Page:

Final
Page 1353 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

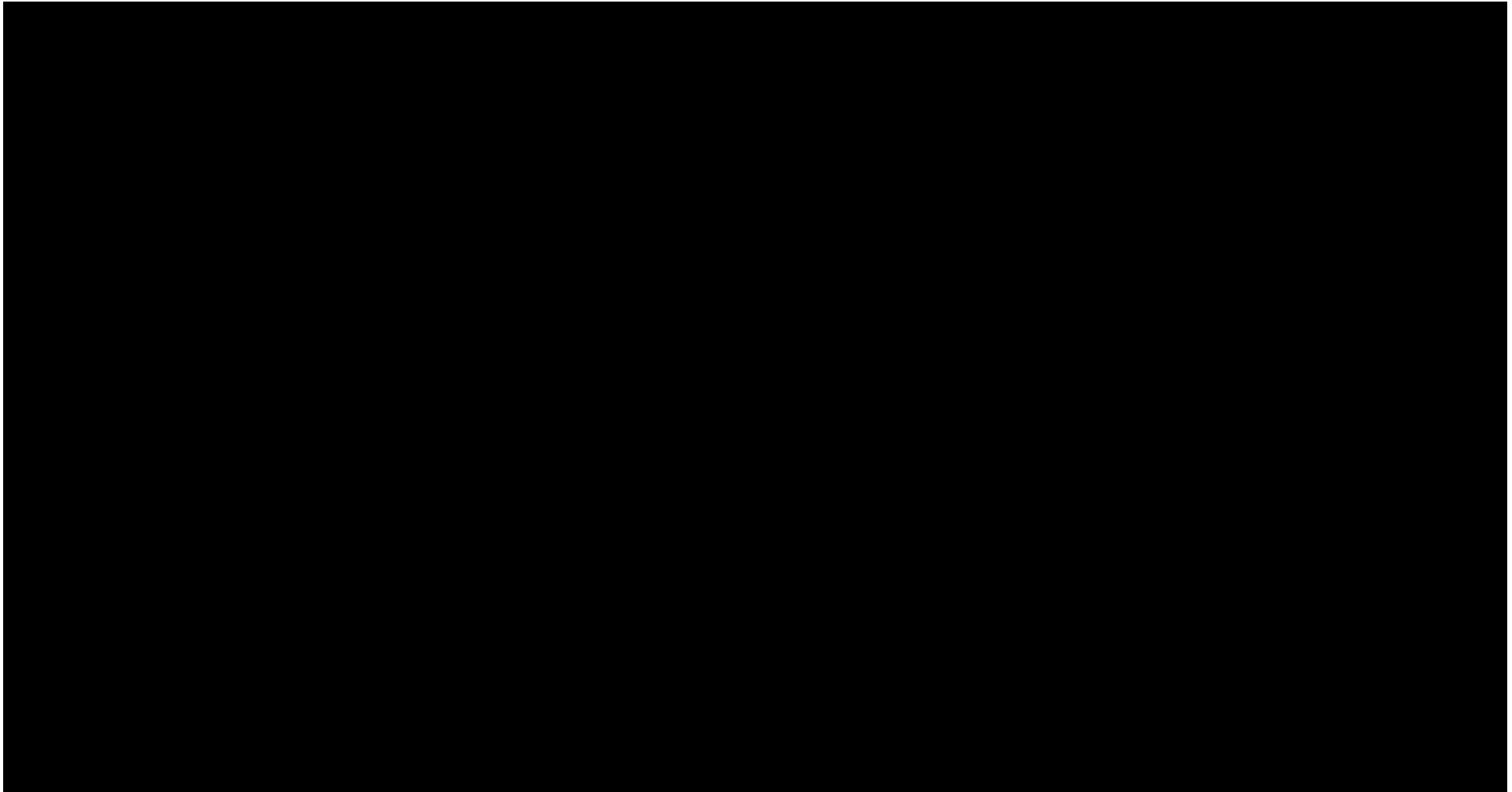
Status:
Page:

Final
Page 1355 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

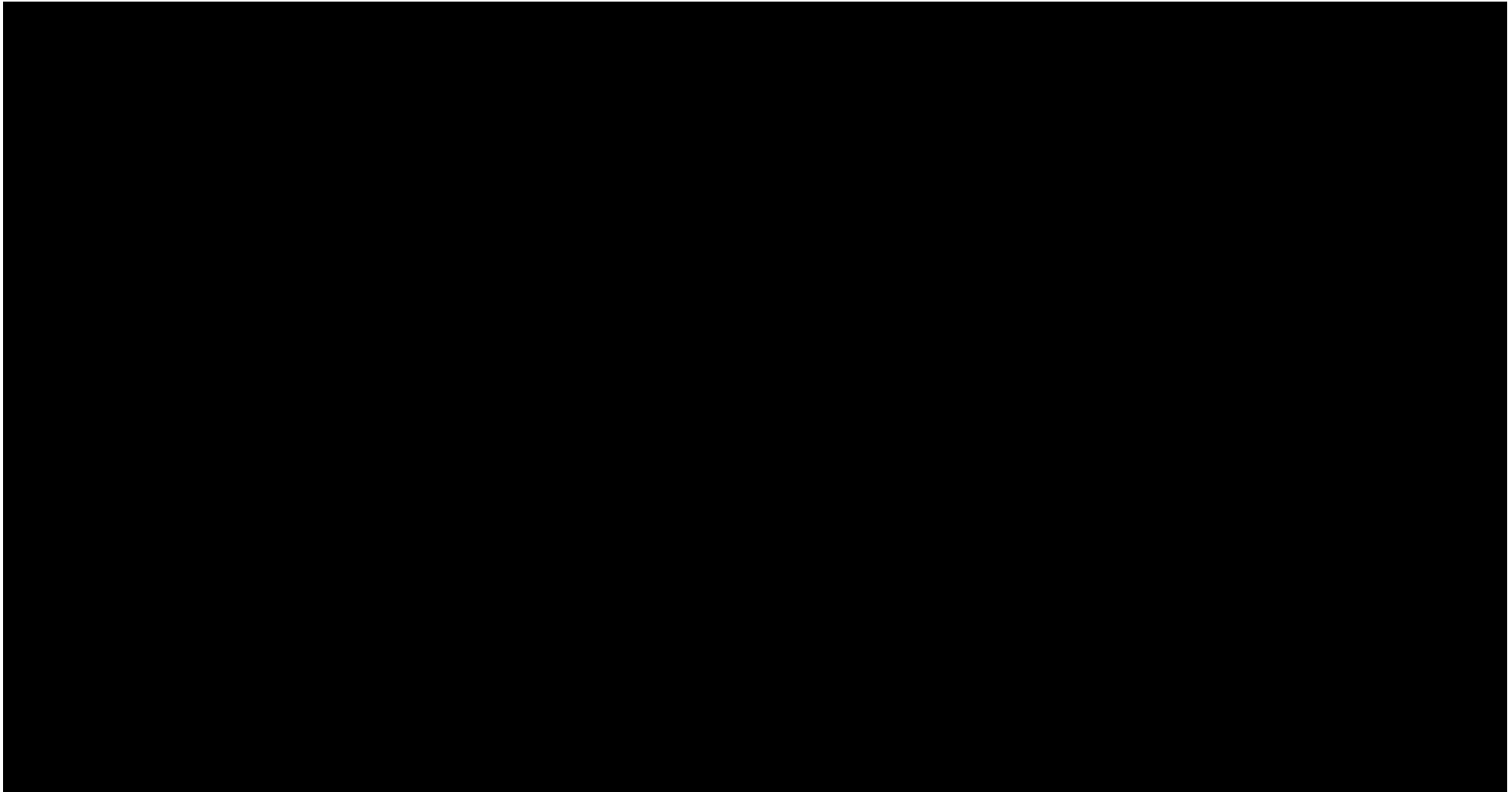
Status:
Page:

Final
Page 1356 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

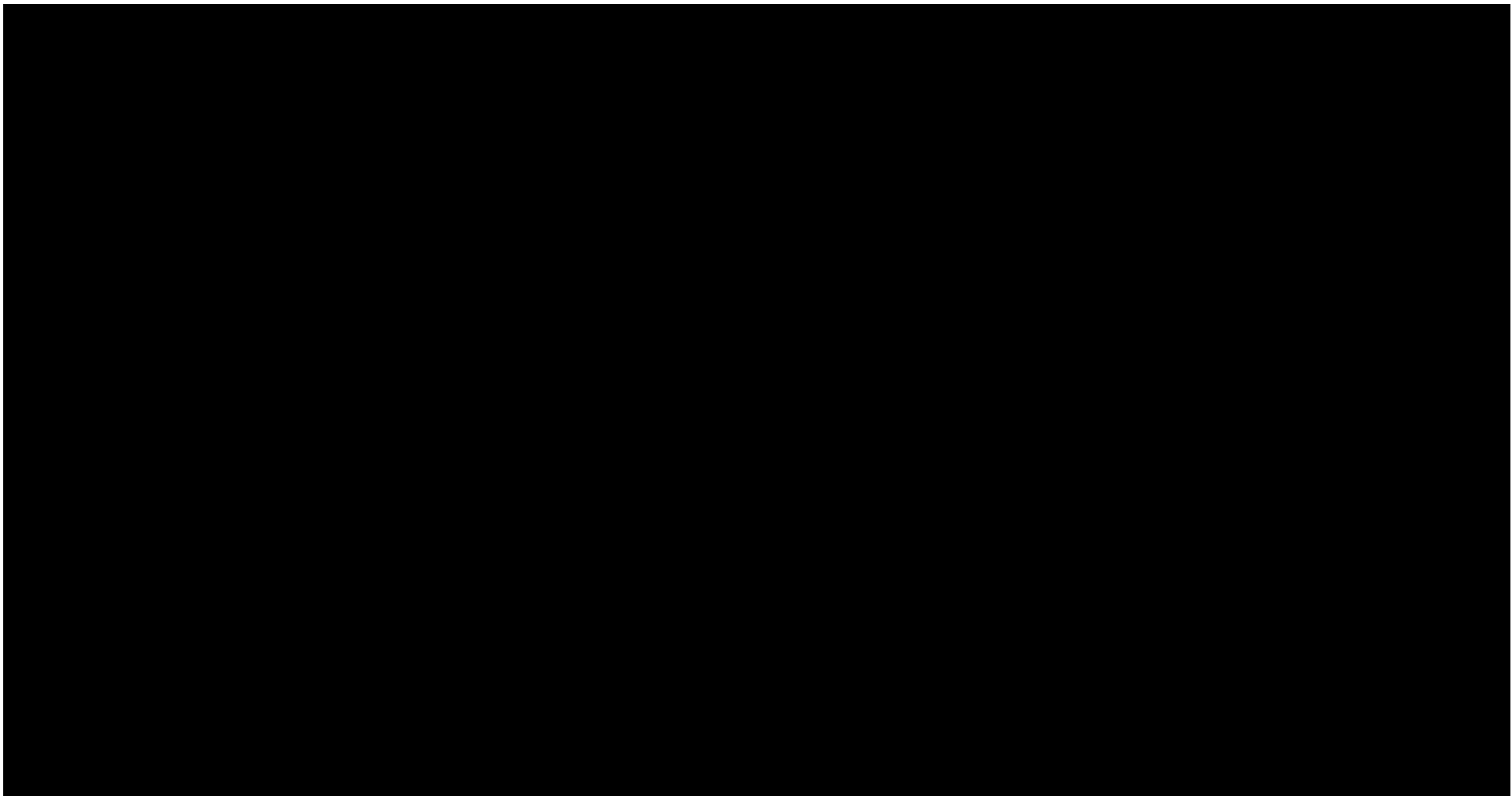
Status:
Page:

Final
Page 1358 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

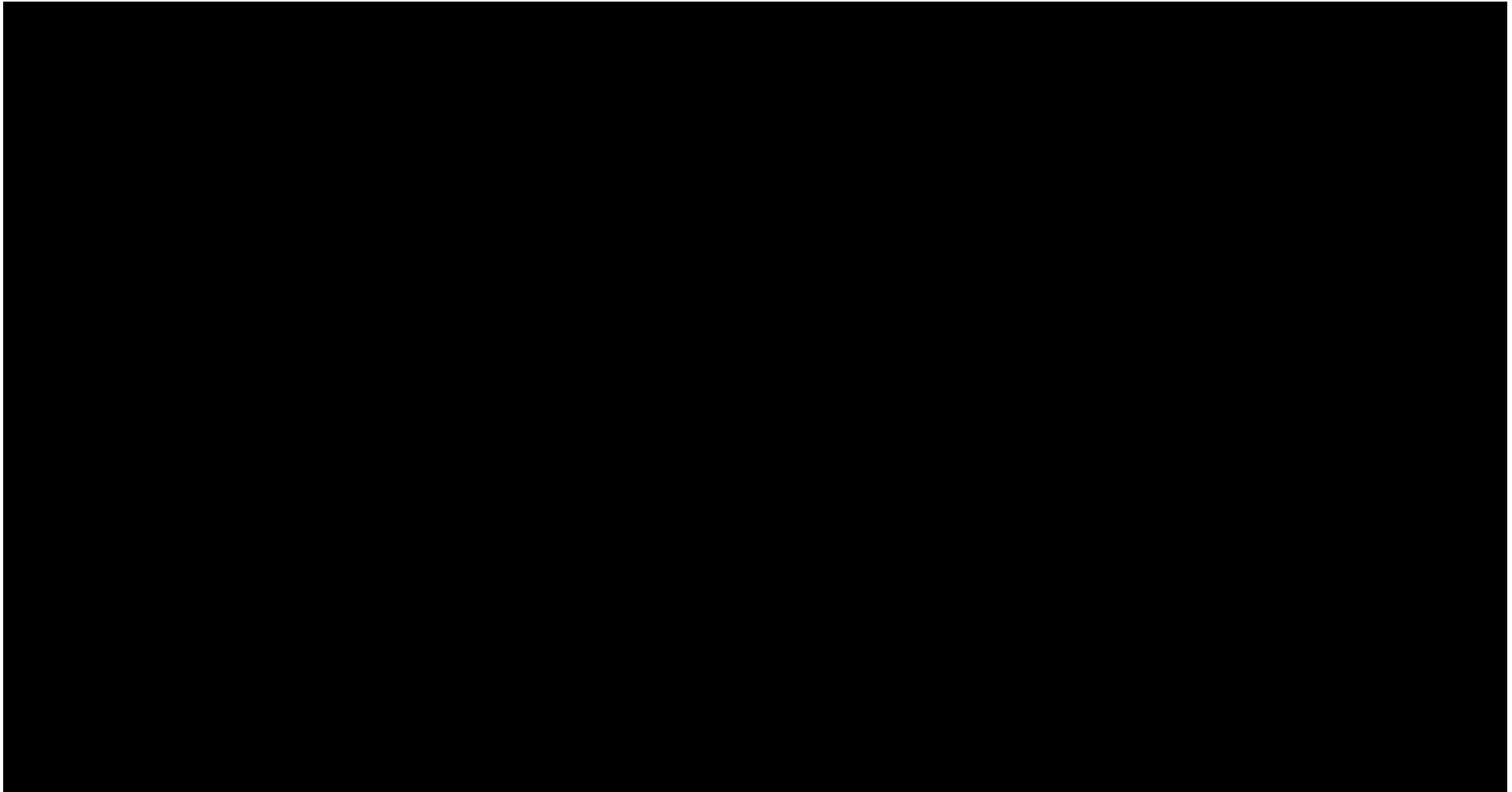
Status:
Page:

Final
Page 1359 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

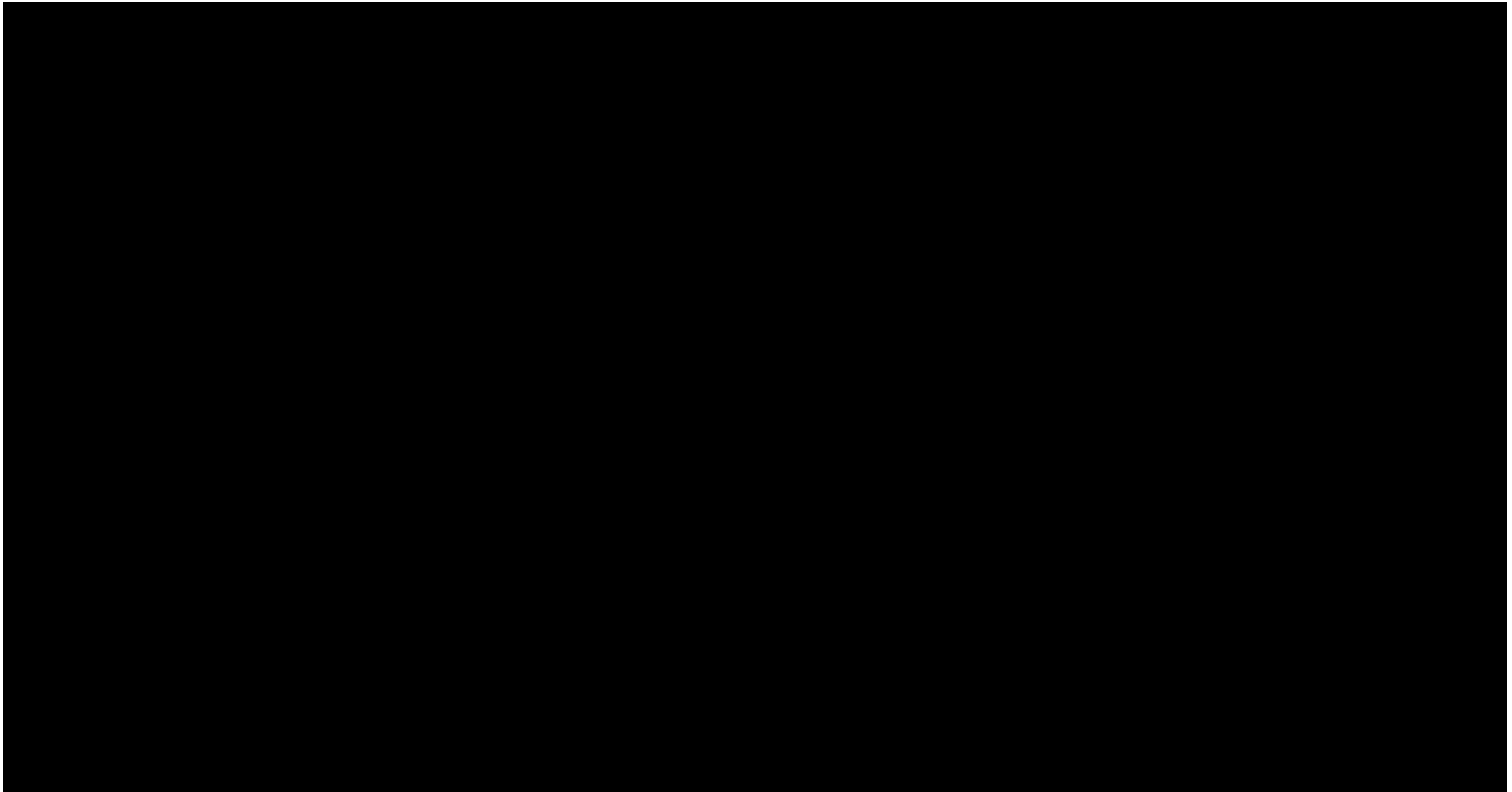
Status:
Page:

Final
Page 1360 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

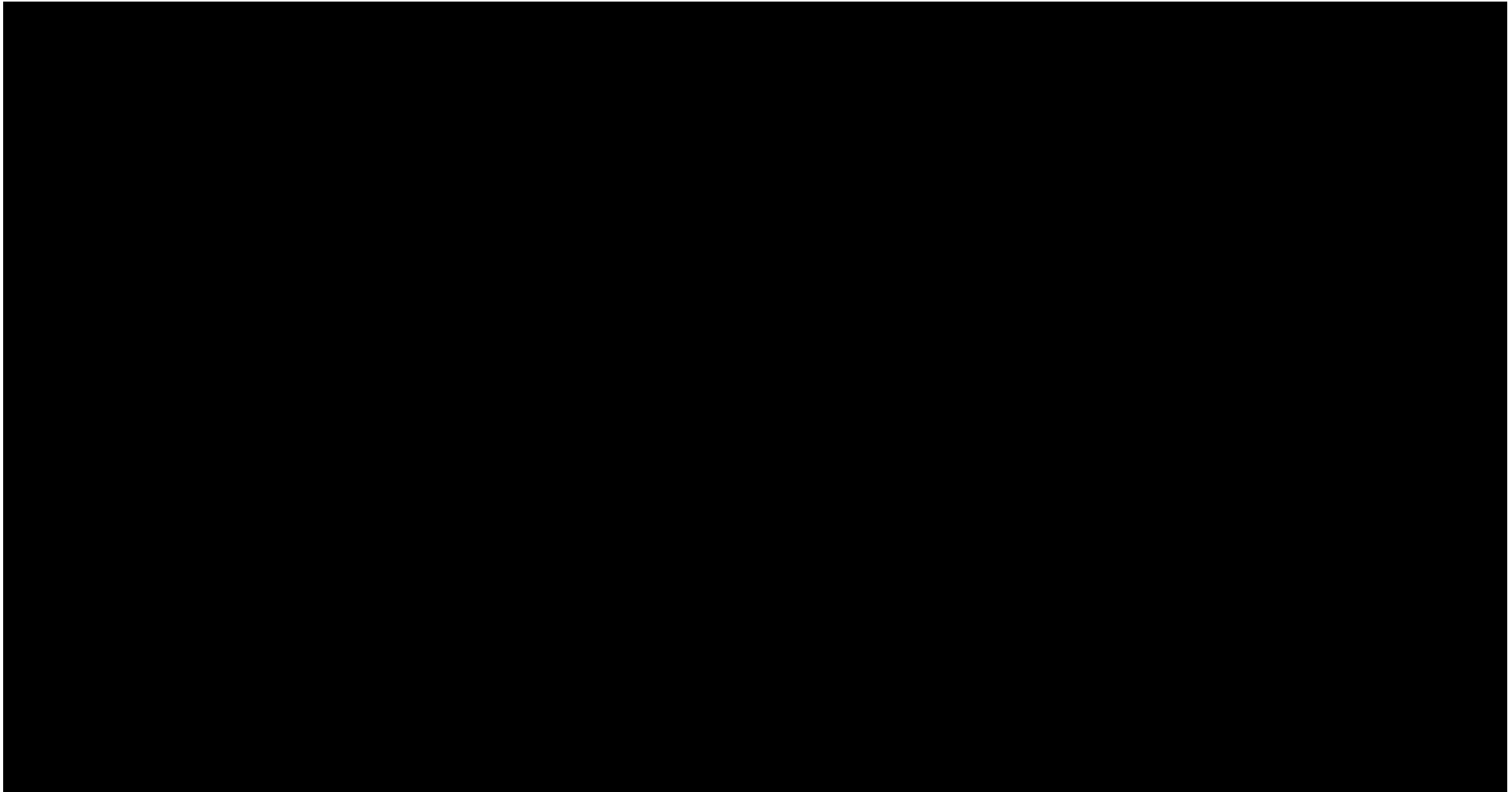
Status:
Page:

Final
Page 1362 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

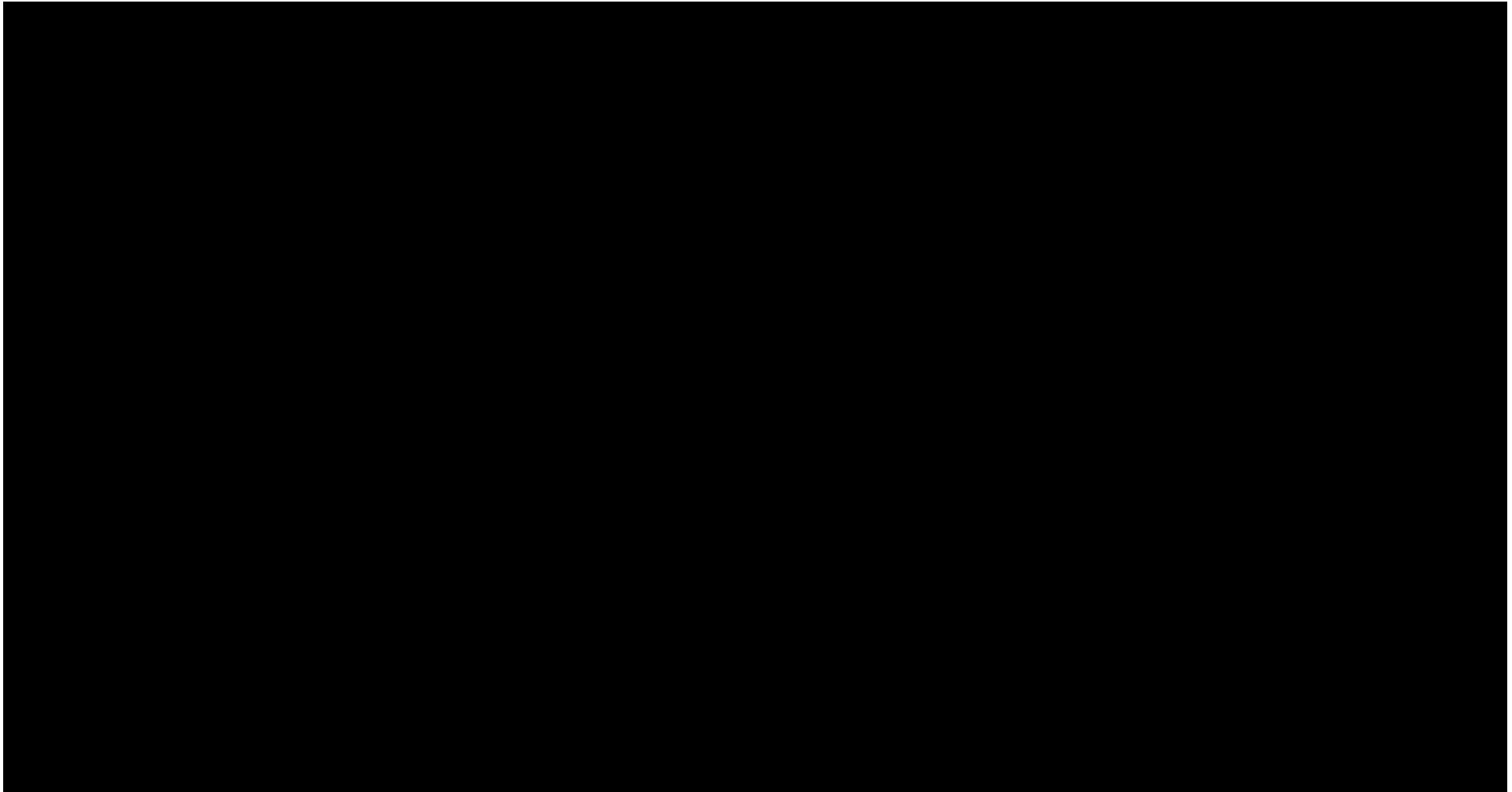
Status:
Page:

Final
Page 1363 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

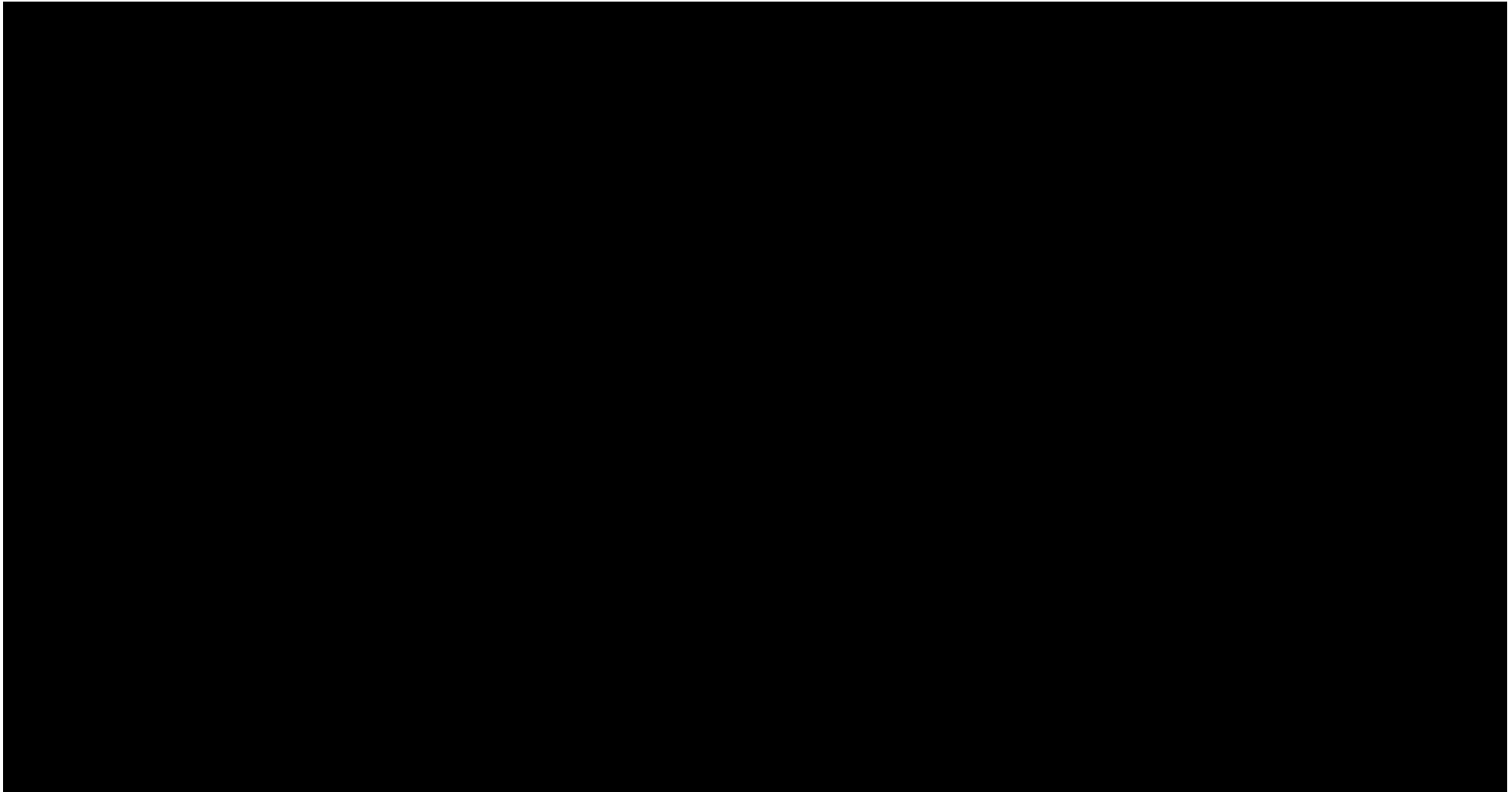
Status:
Page:

Final
Page 1364 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

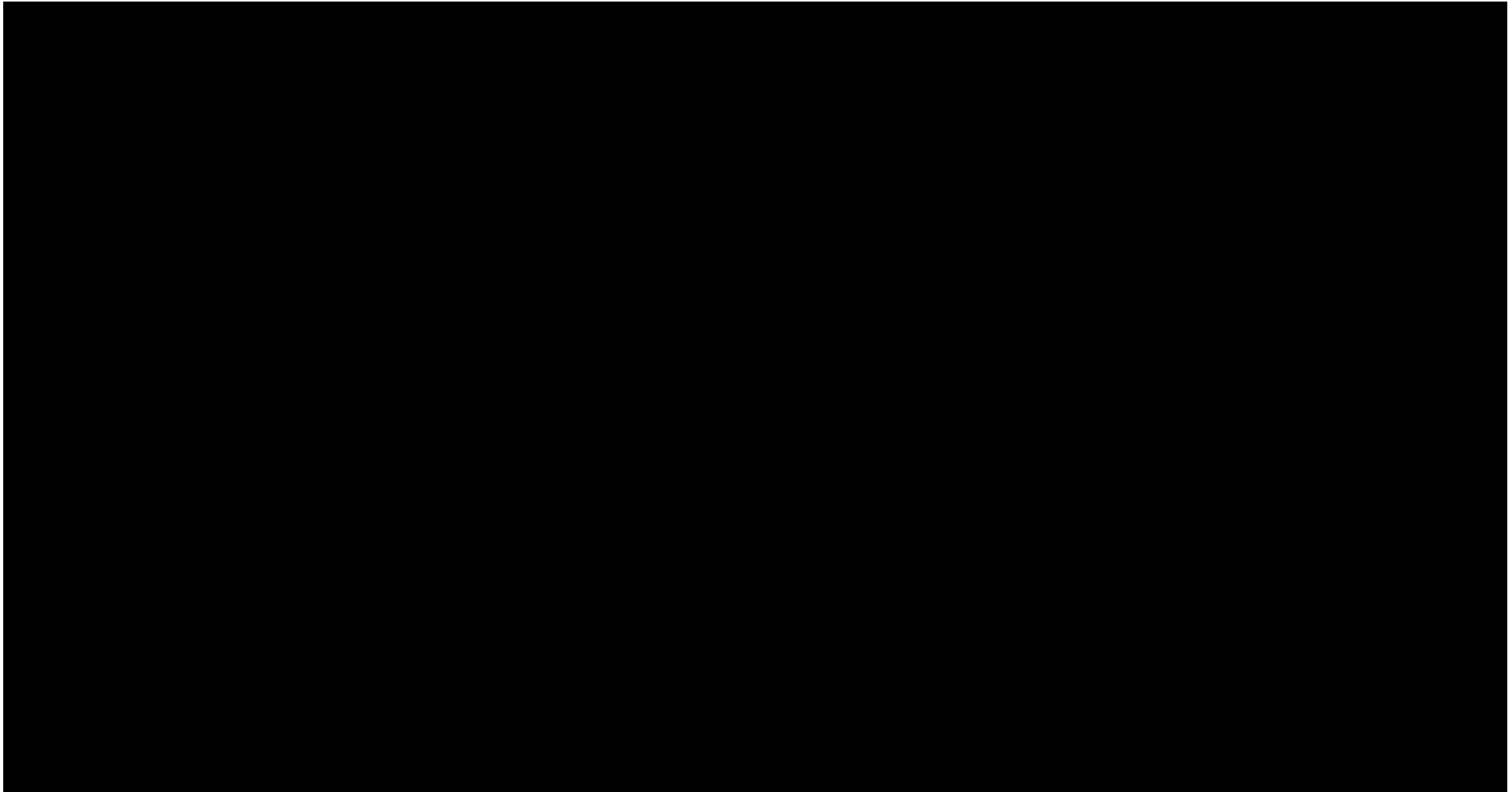
Status:
Page:

Final
Page 1365 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

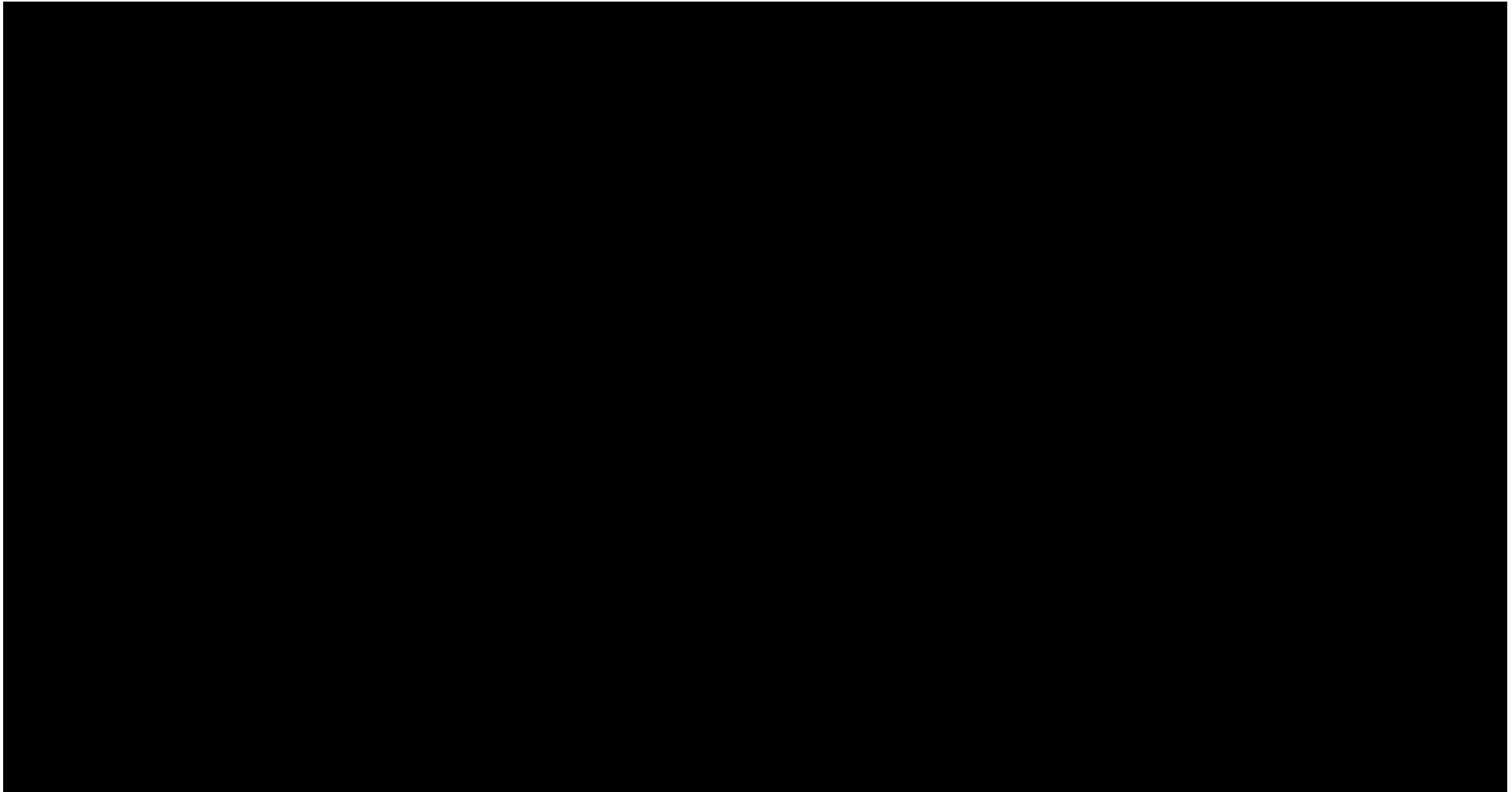
Status:
Page:

Final
Page 1366 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

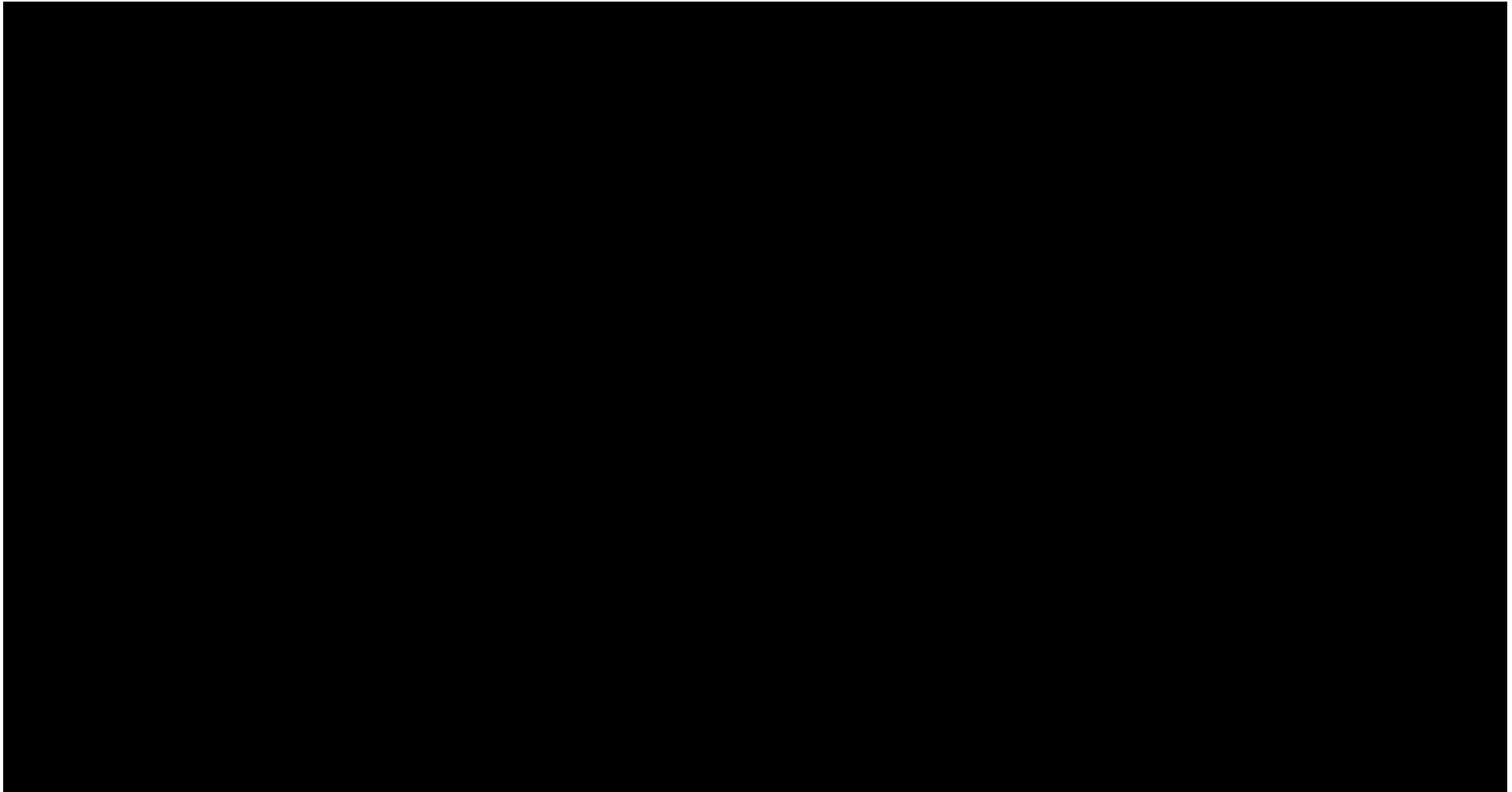
Status:
Page:

Final
Page 1367 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

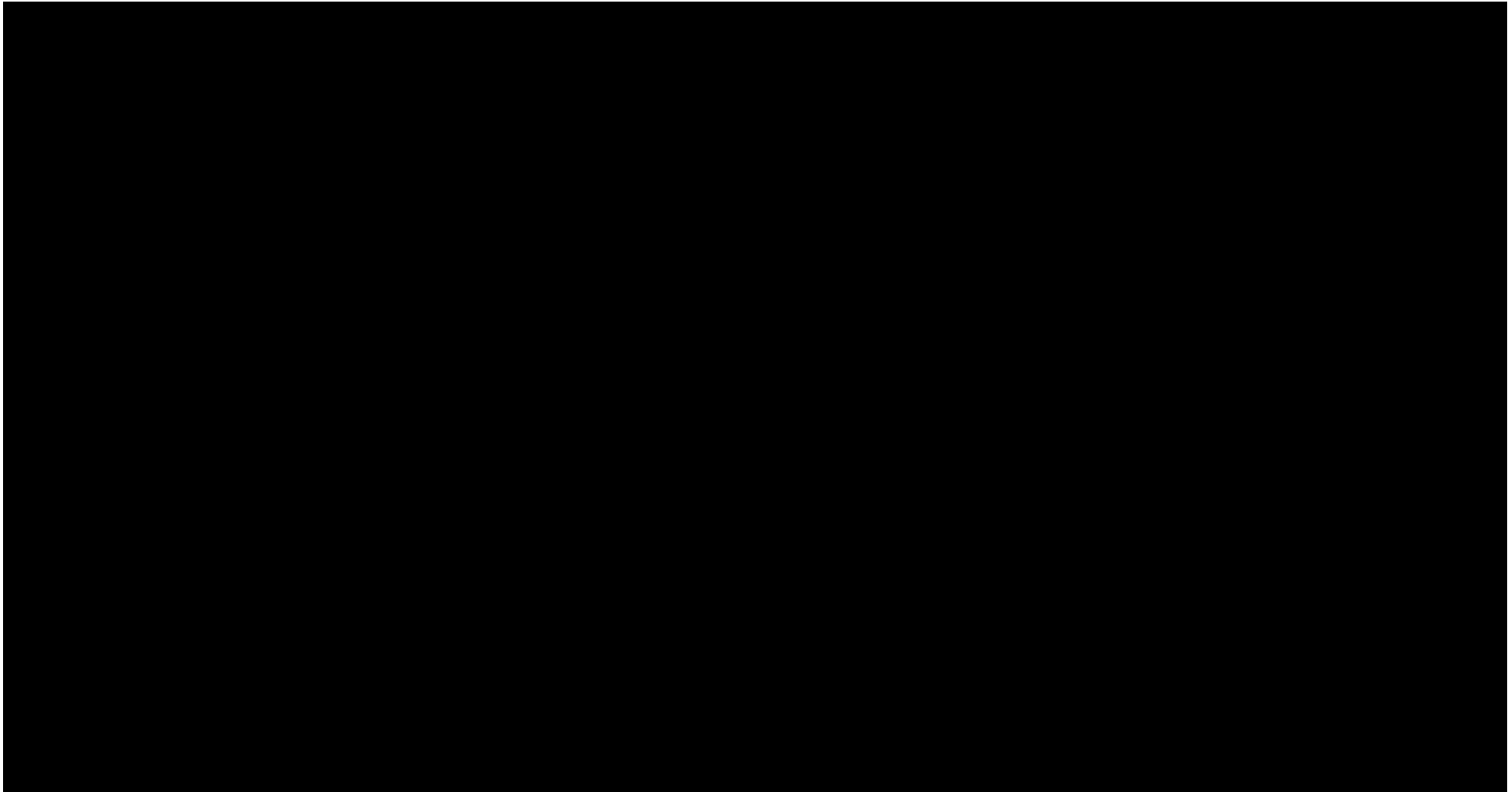
Status:
Page:

Final
Page 1368 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

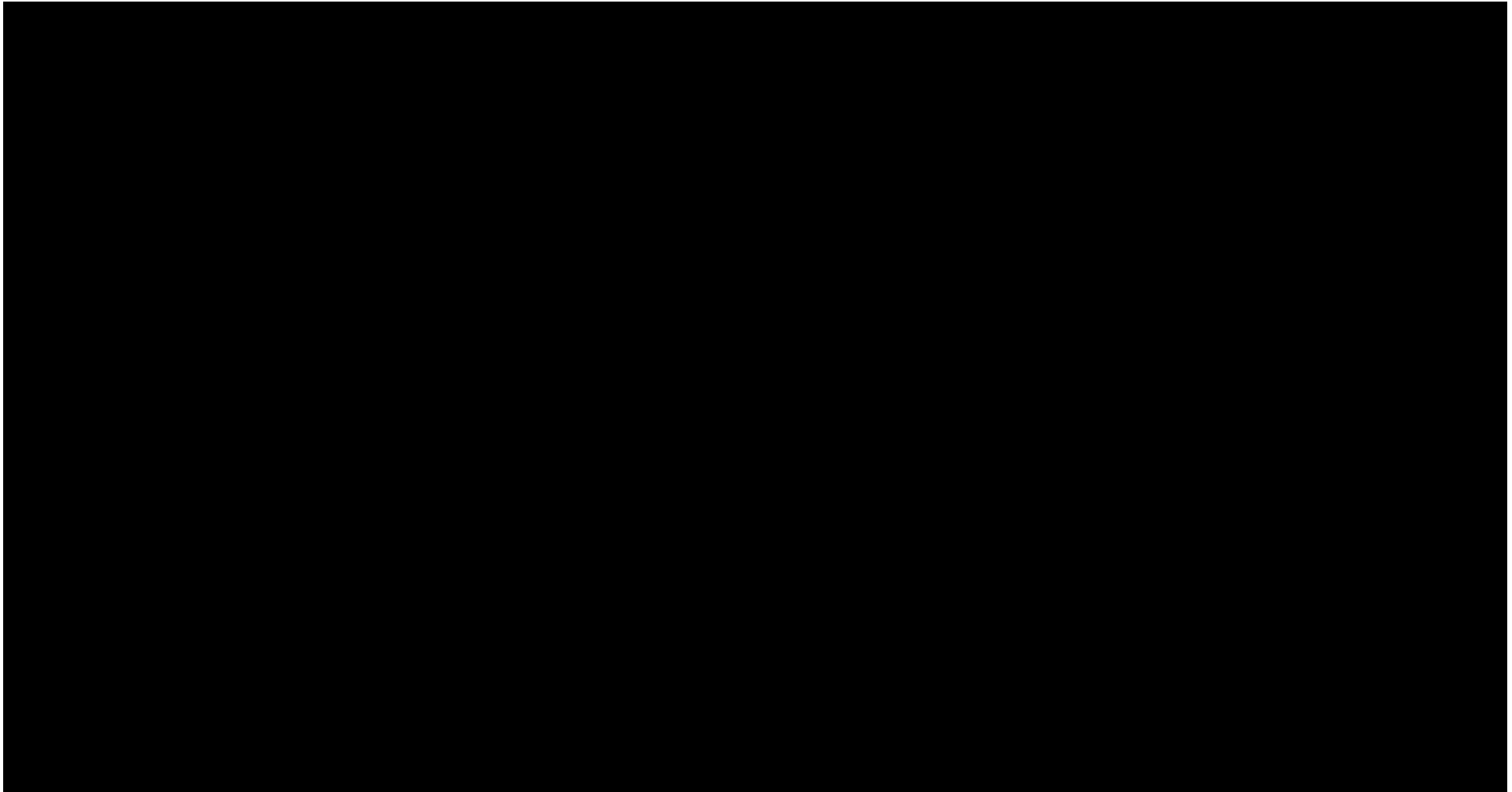
Status:
Page:

Final
Page 1369 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

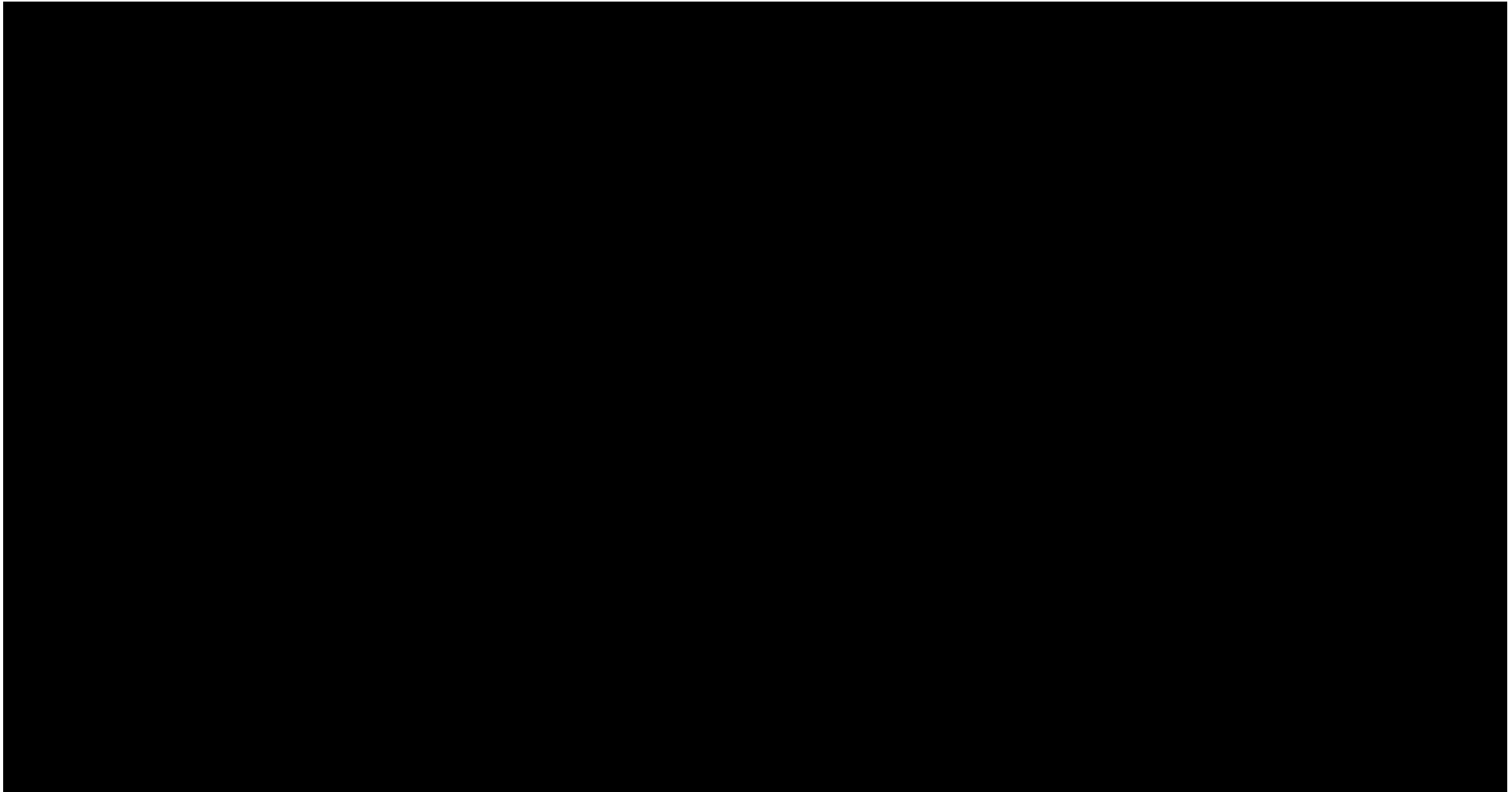
Status:
Page:

Final
Page 1370 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

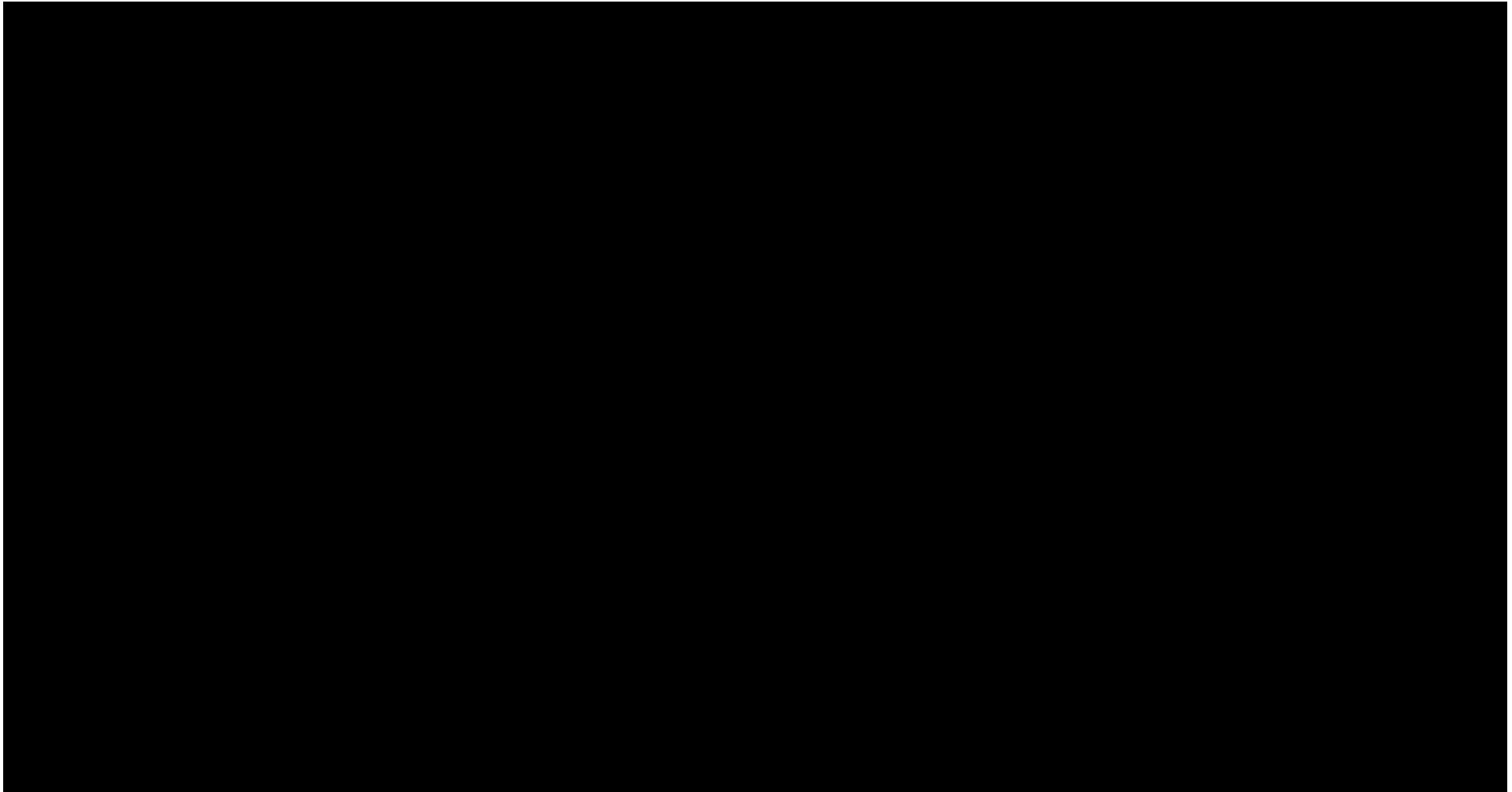
Status:
Page:

Final
Page 1371 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

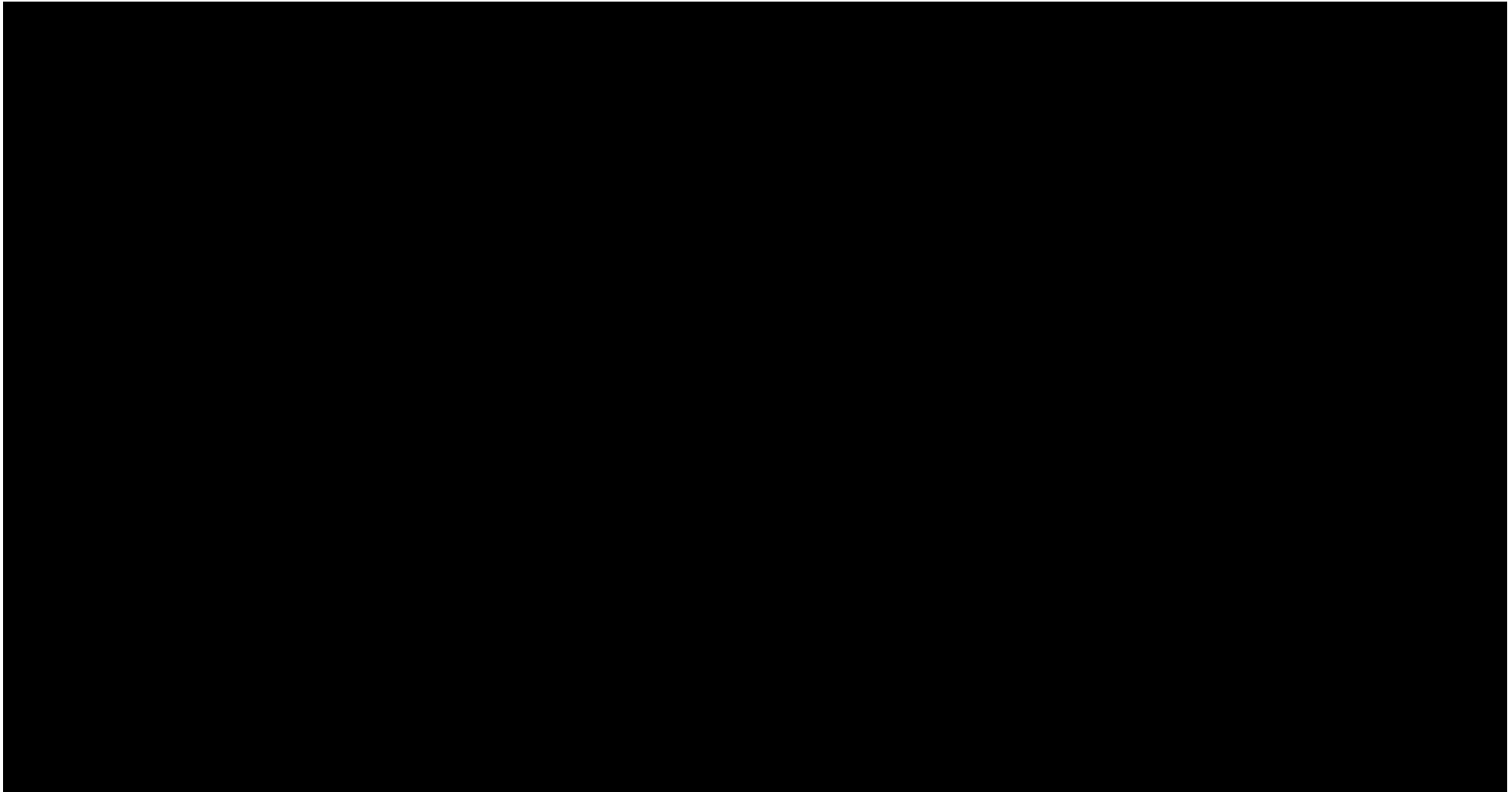
Status:
Page:

Final
Page 1372 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

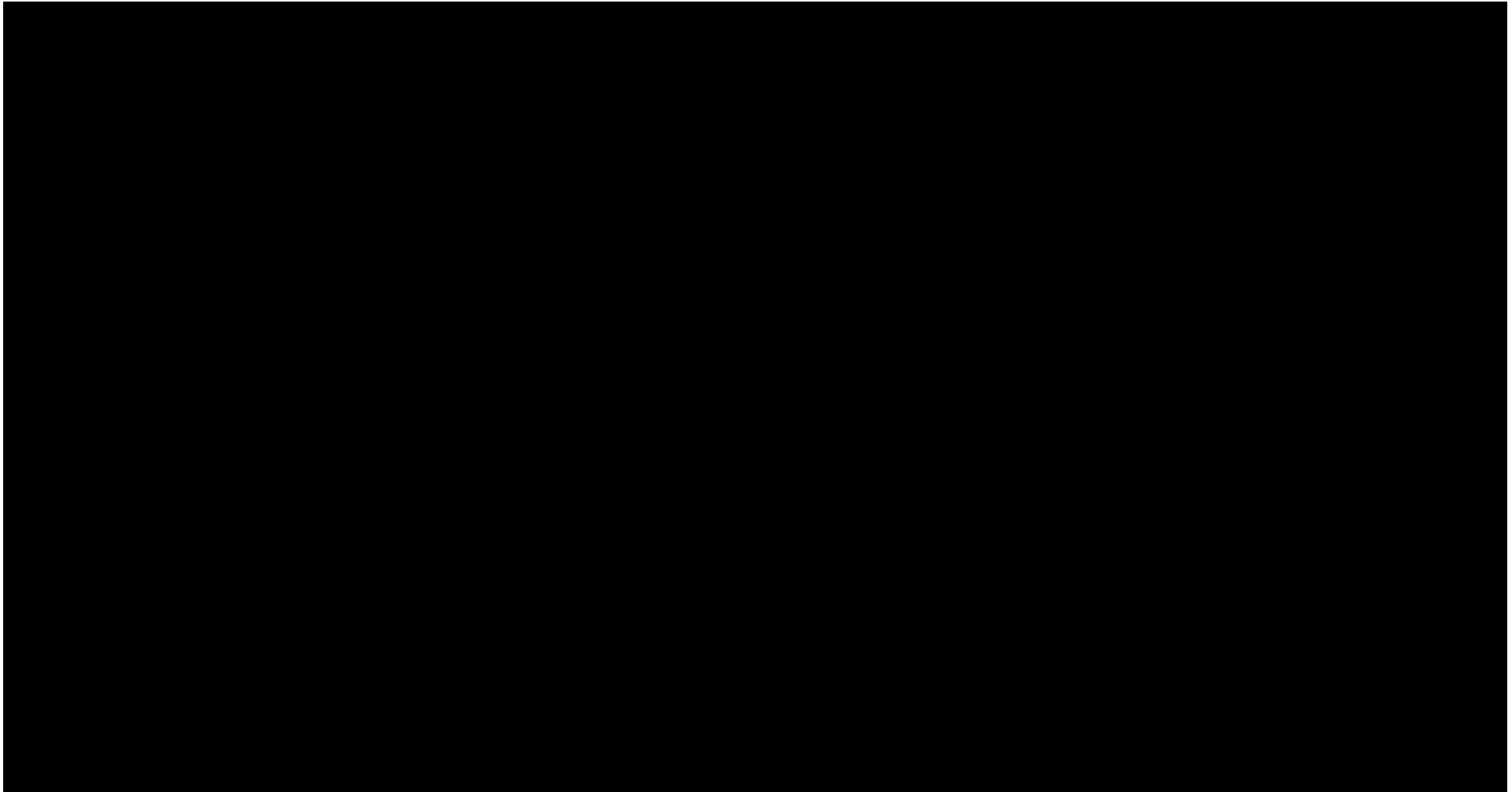
Status:
Page:

Final
Page 1373 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

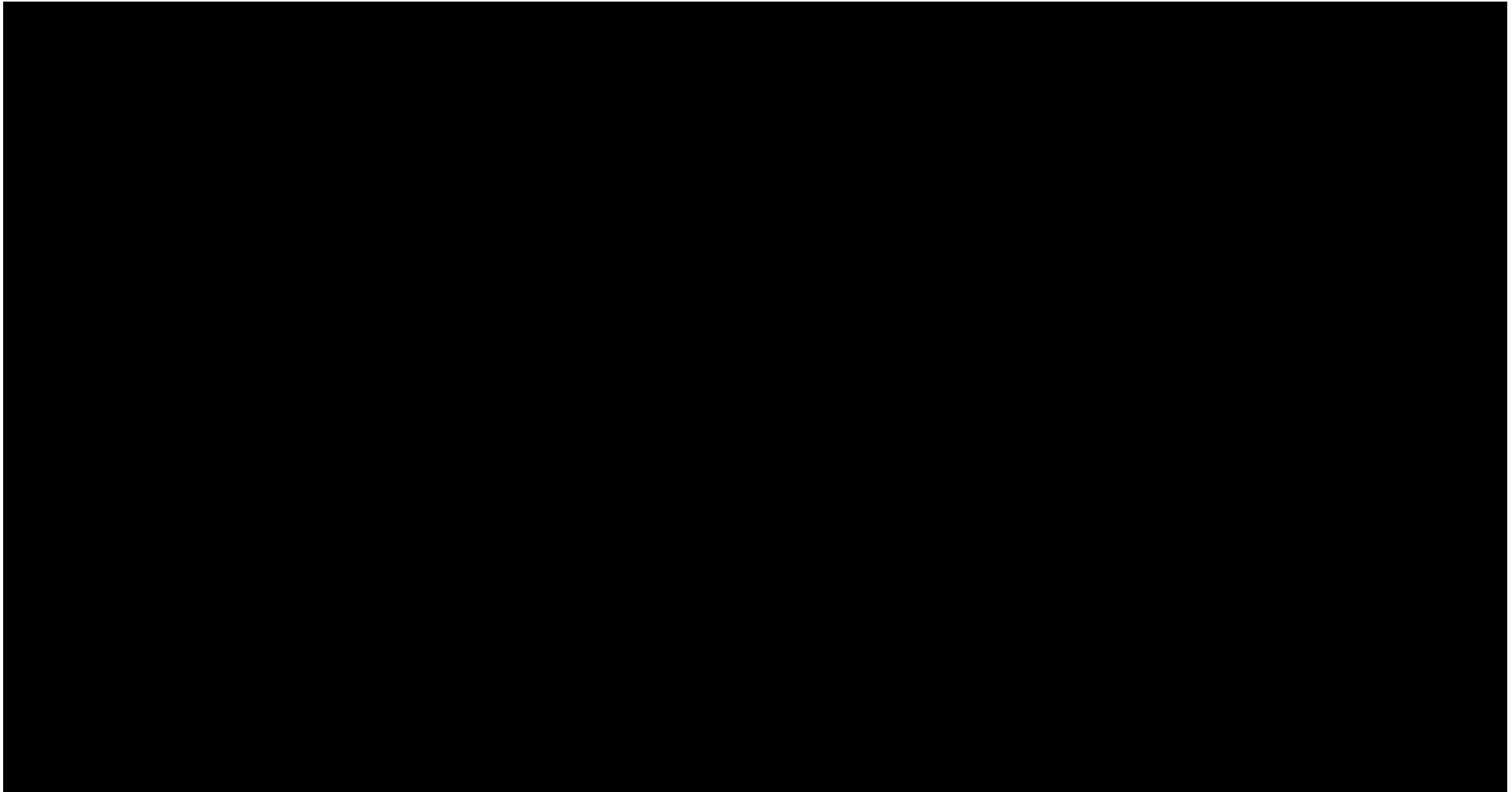
Status:
Page:

Final
Page 1374 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

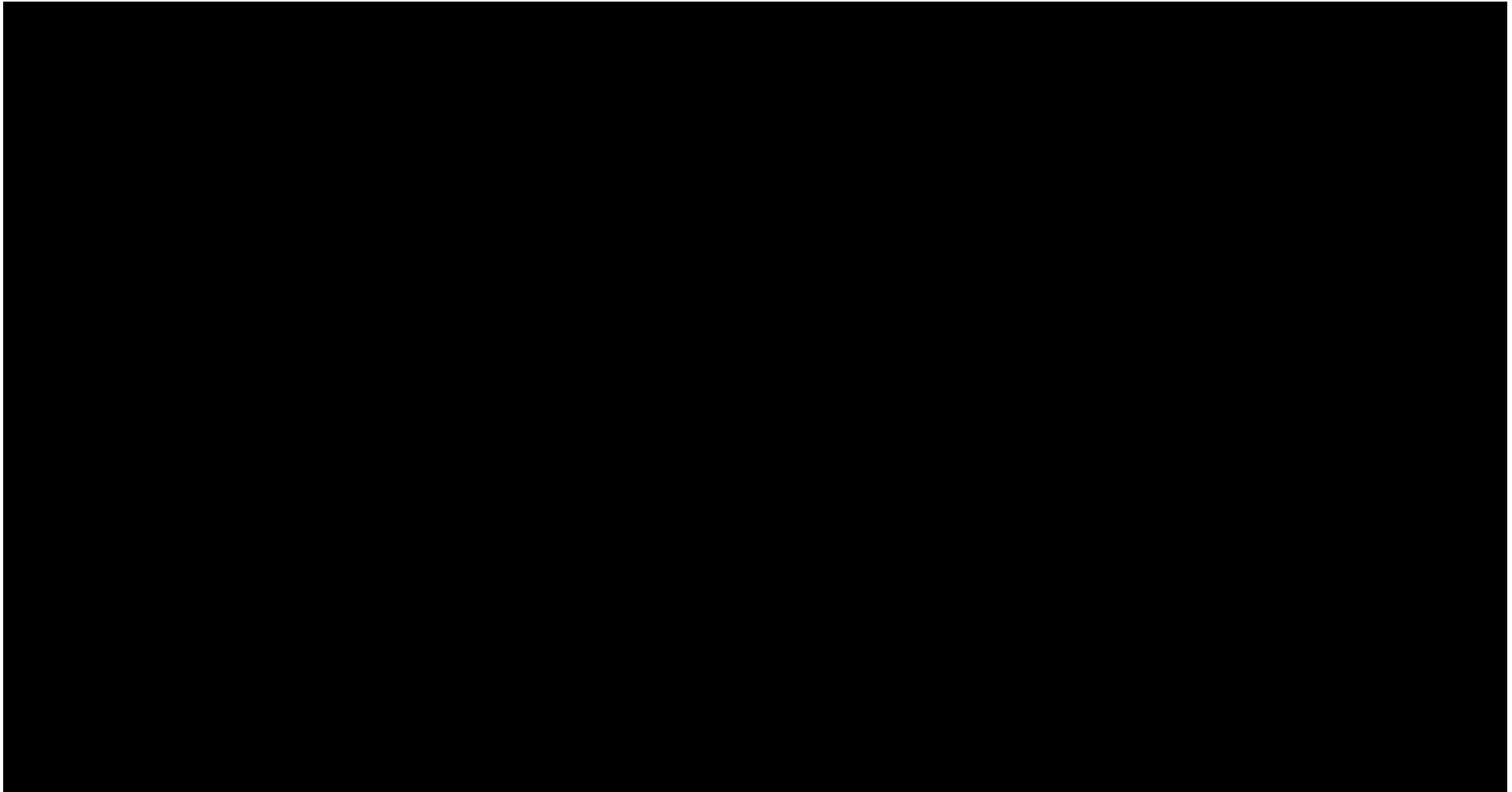
Status:
Page:

Final
Page 1375 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

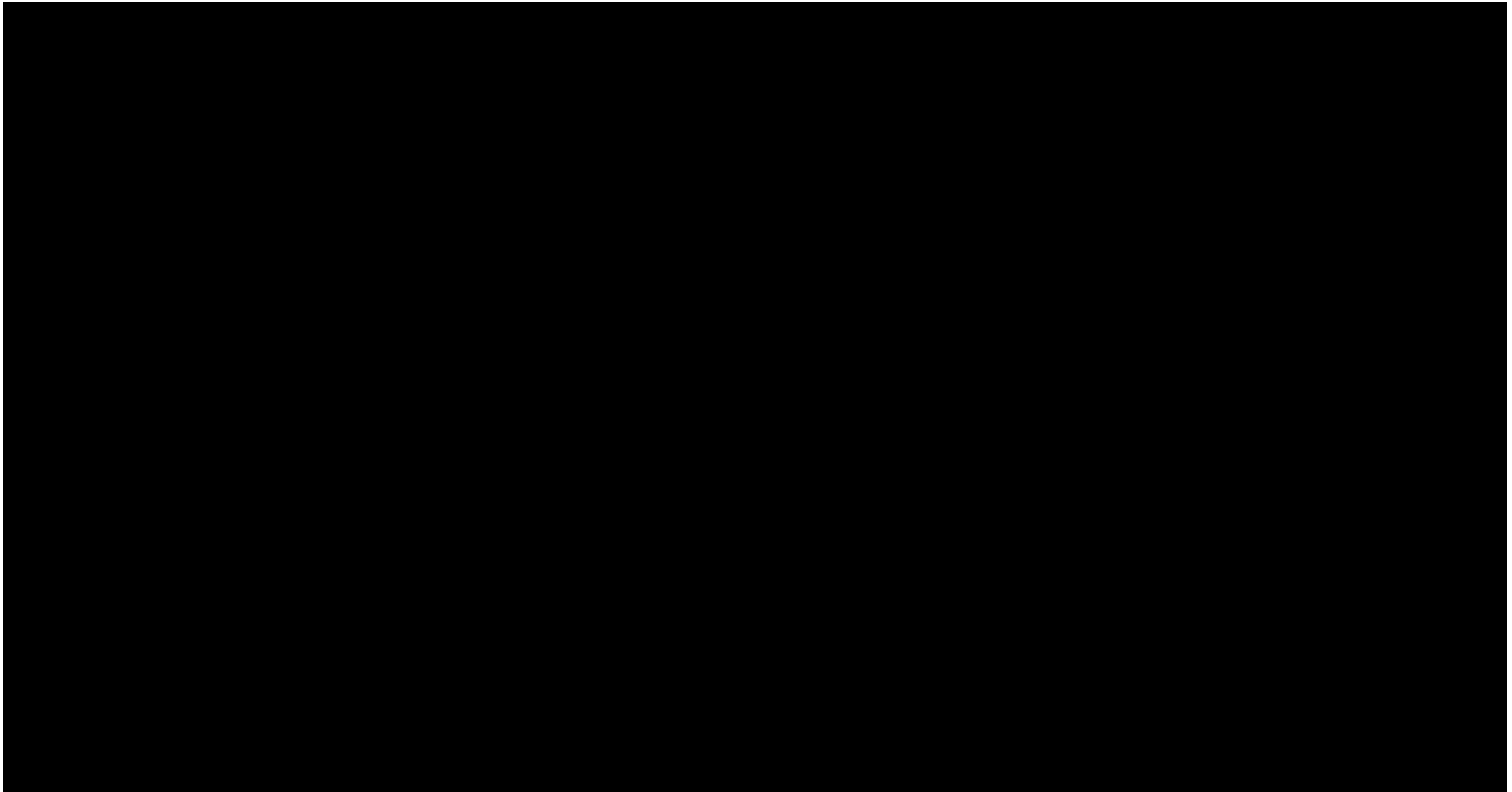
Status:
Page:

Final
Page 1376 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

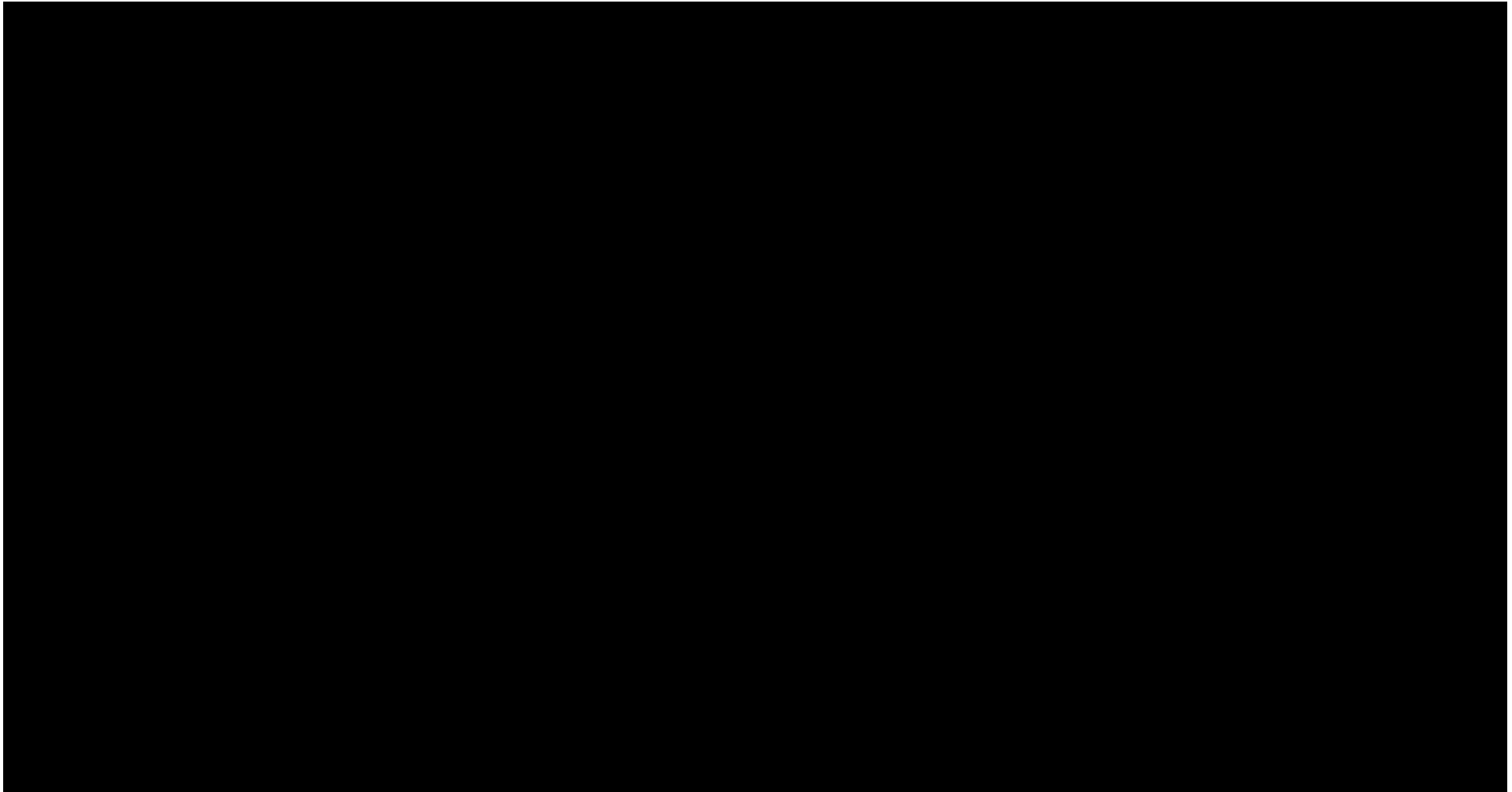
Status:
Page:

Final
Page 1377 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

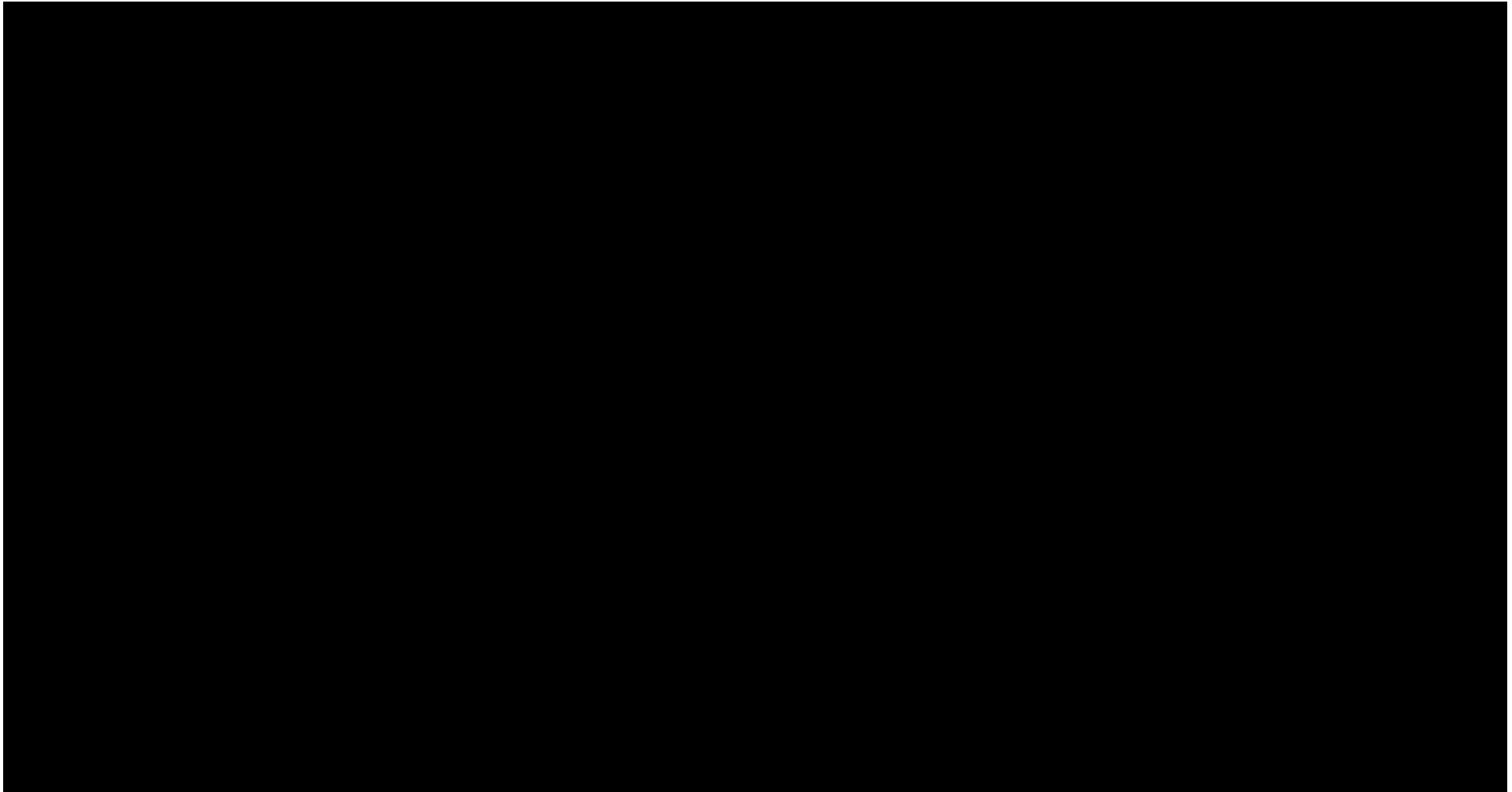
Status:
Page:

Final
Page 1379 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

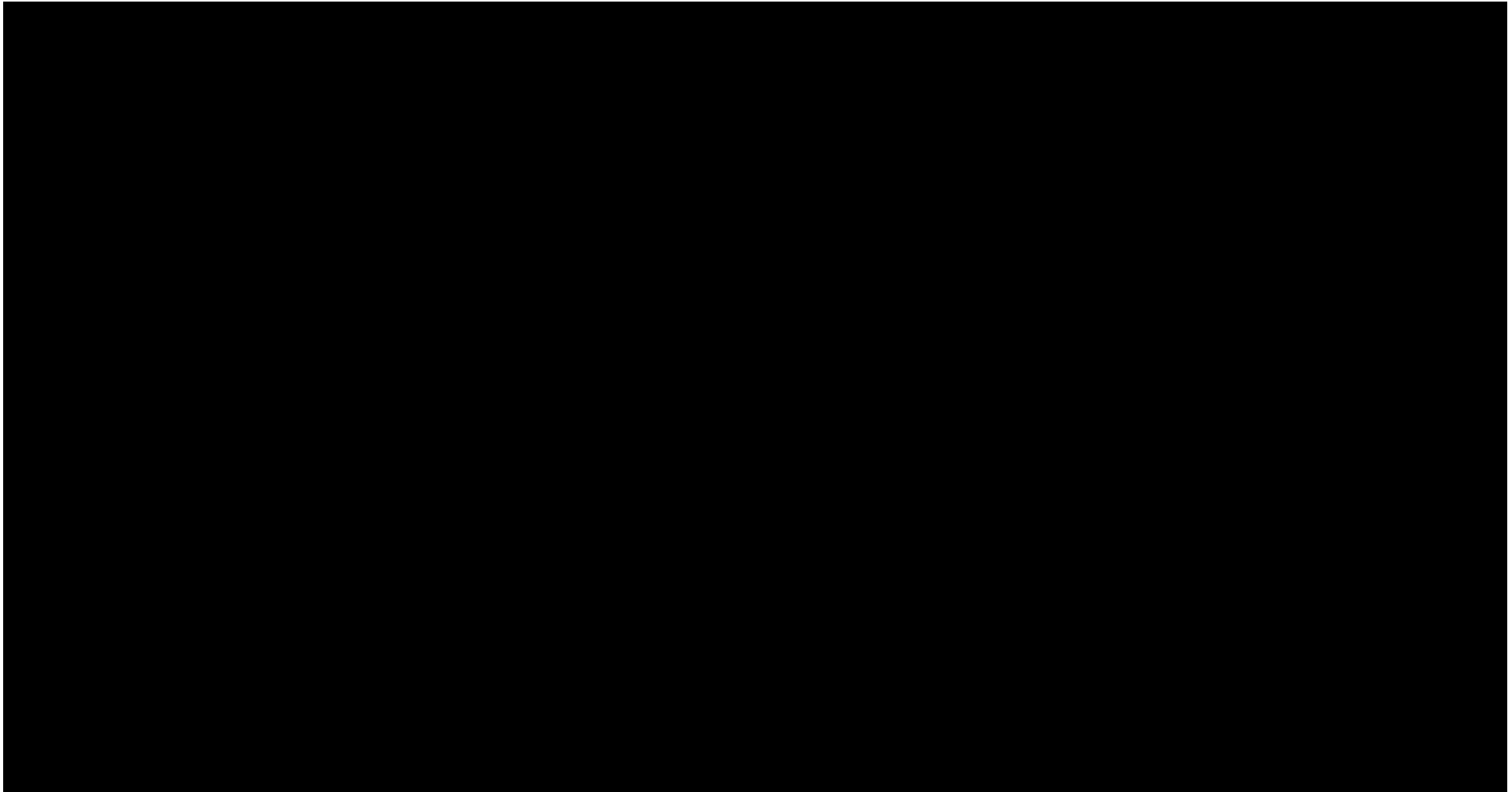
Status:
Page:

Final
Page 1380 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

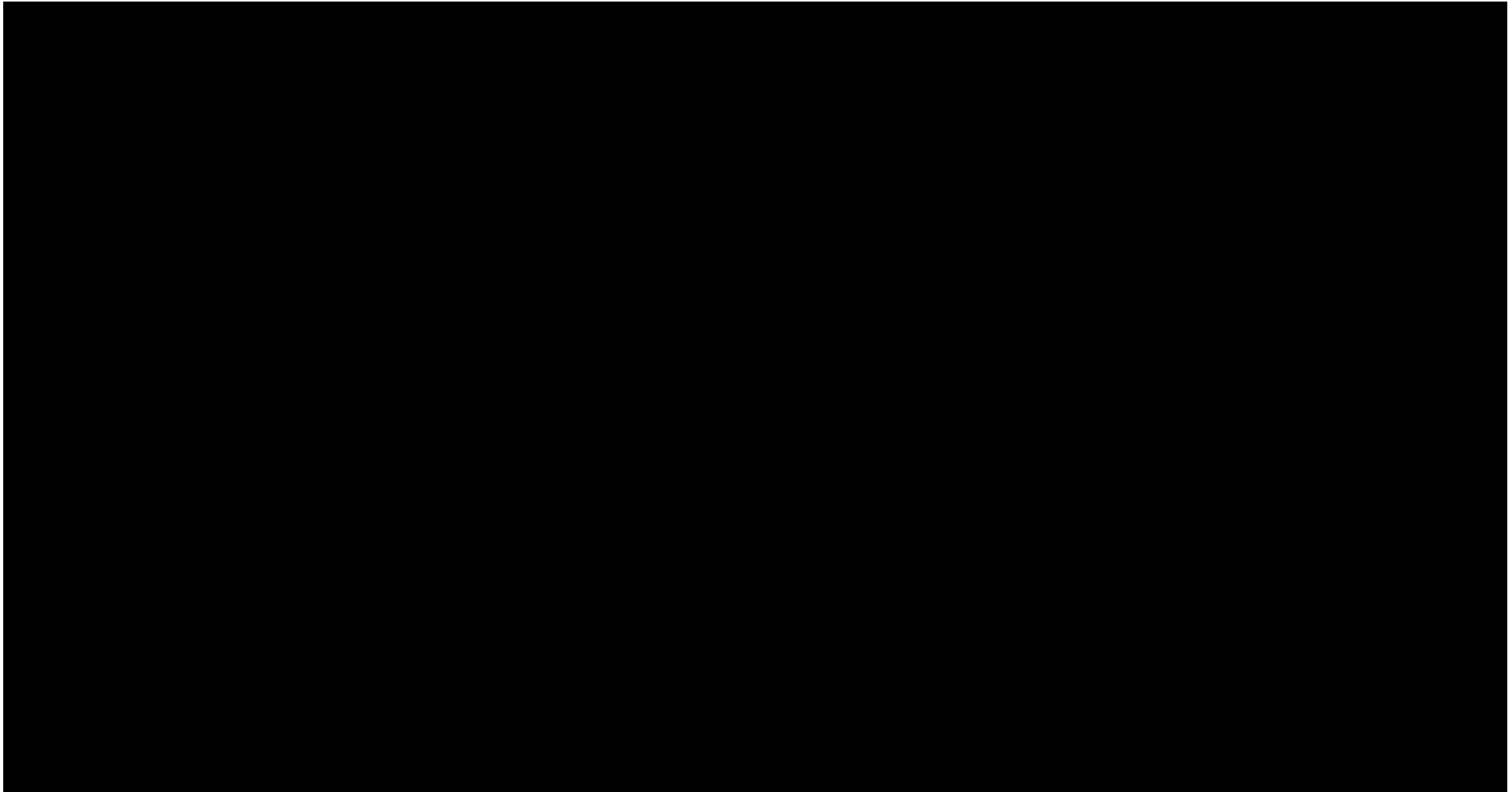
Status:
Page:

Final
Page 1381 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

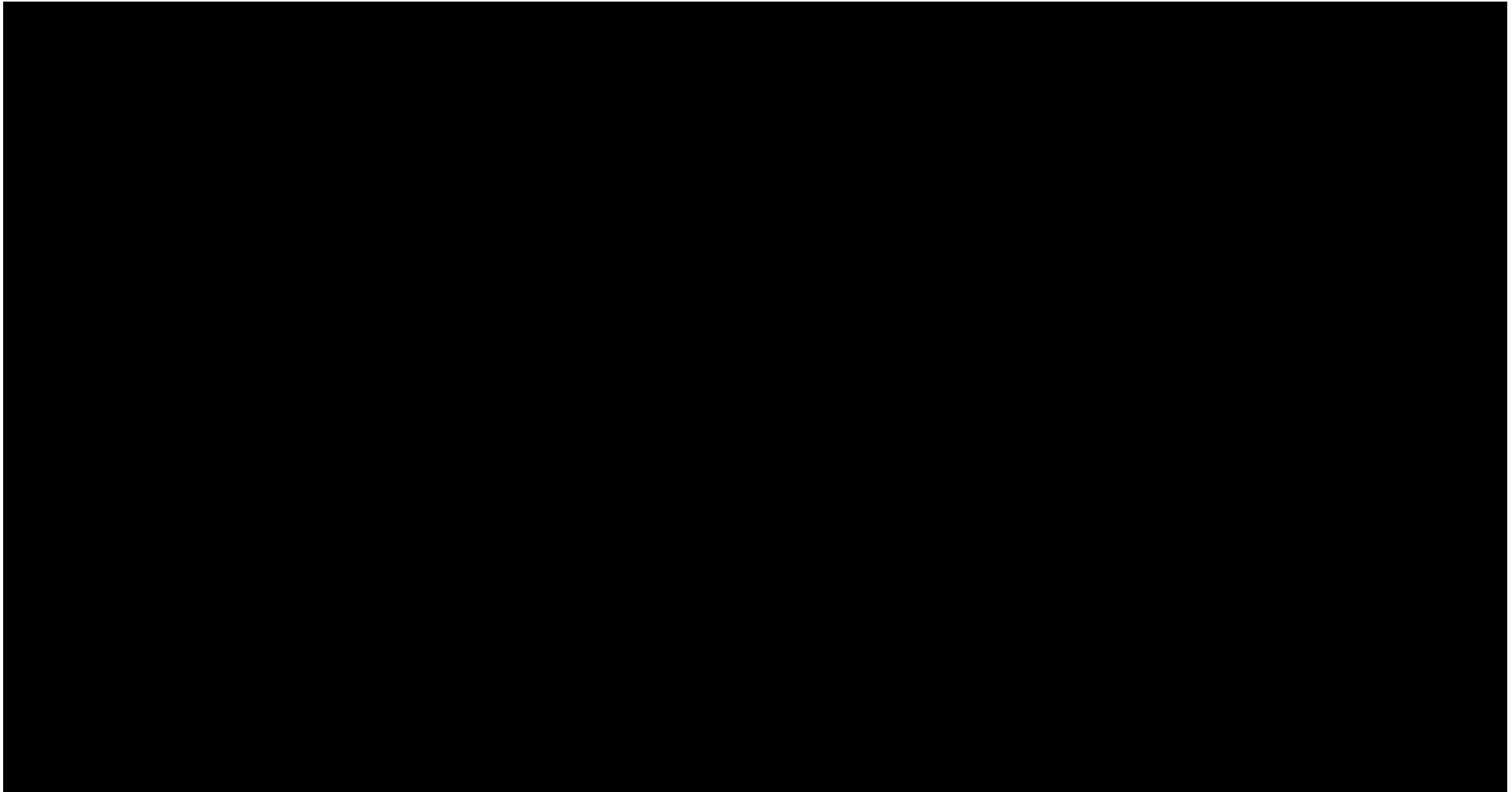
Status:
Page:

Final
Page 1382 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

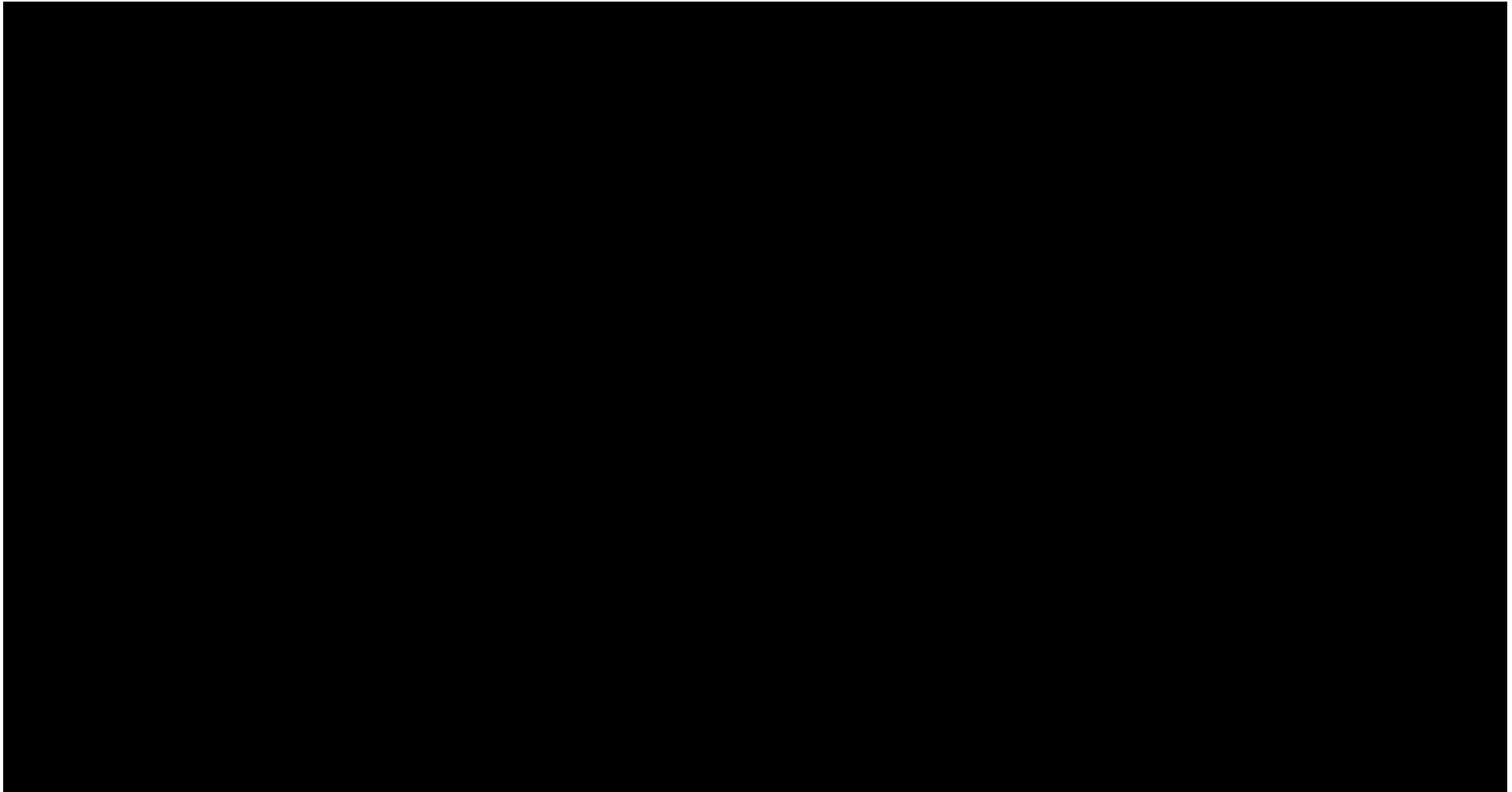
Status:
Page:

Final
Page 1383 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

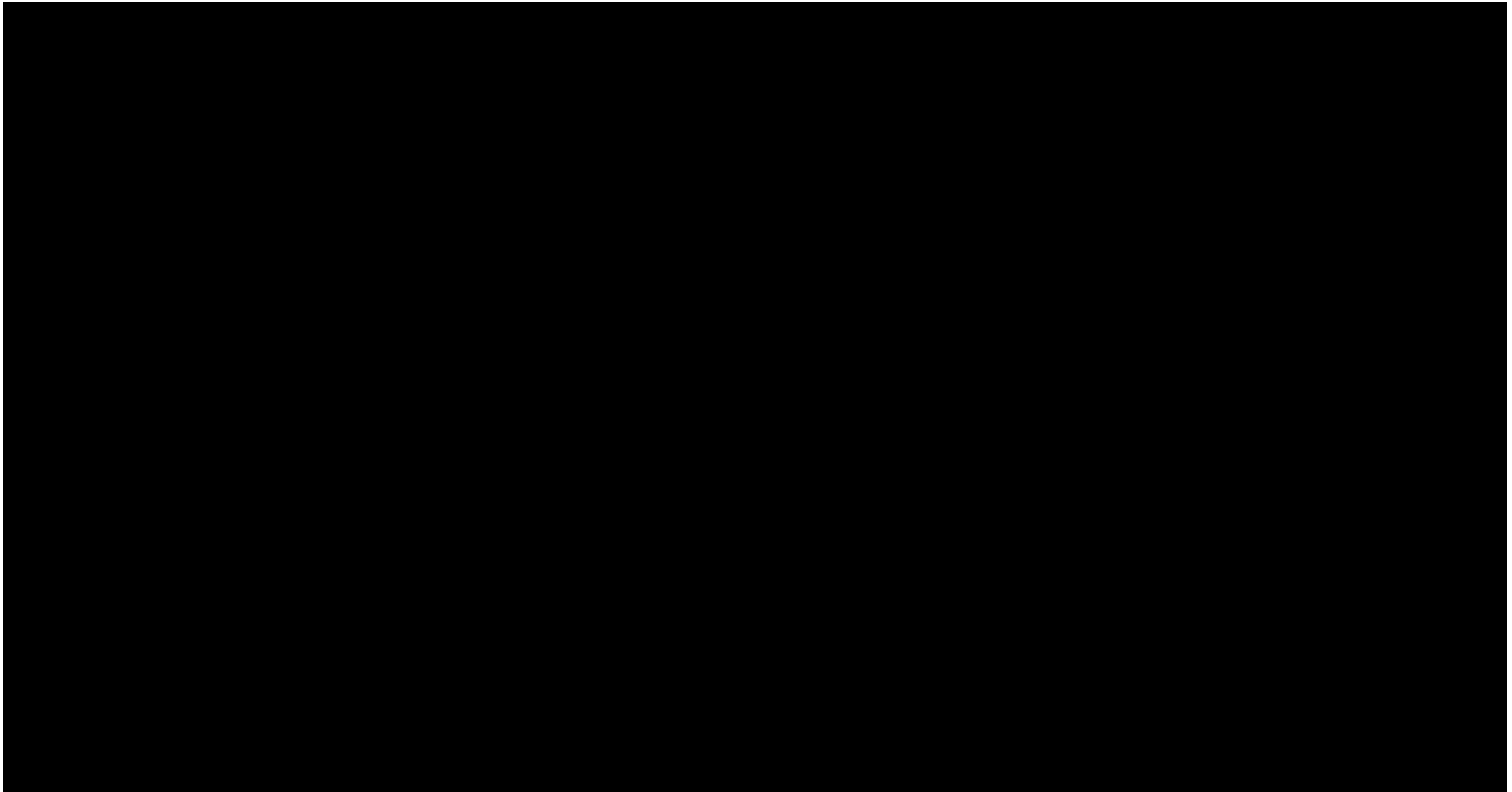
Status:
Page:

Final
Page 1384 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

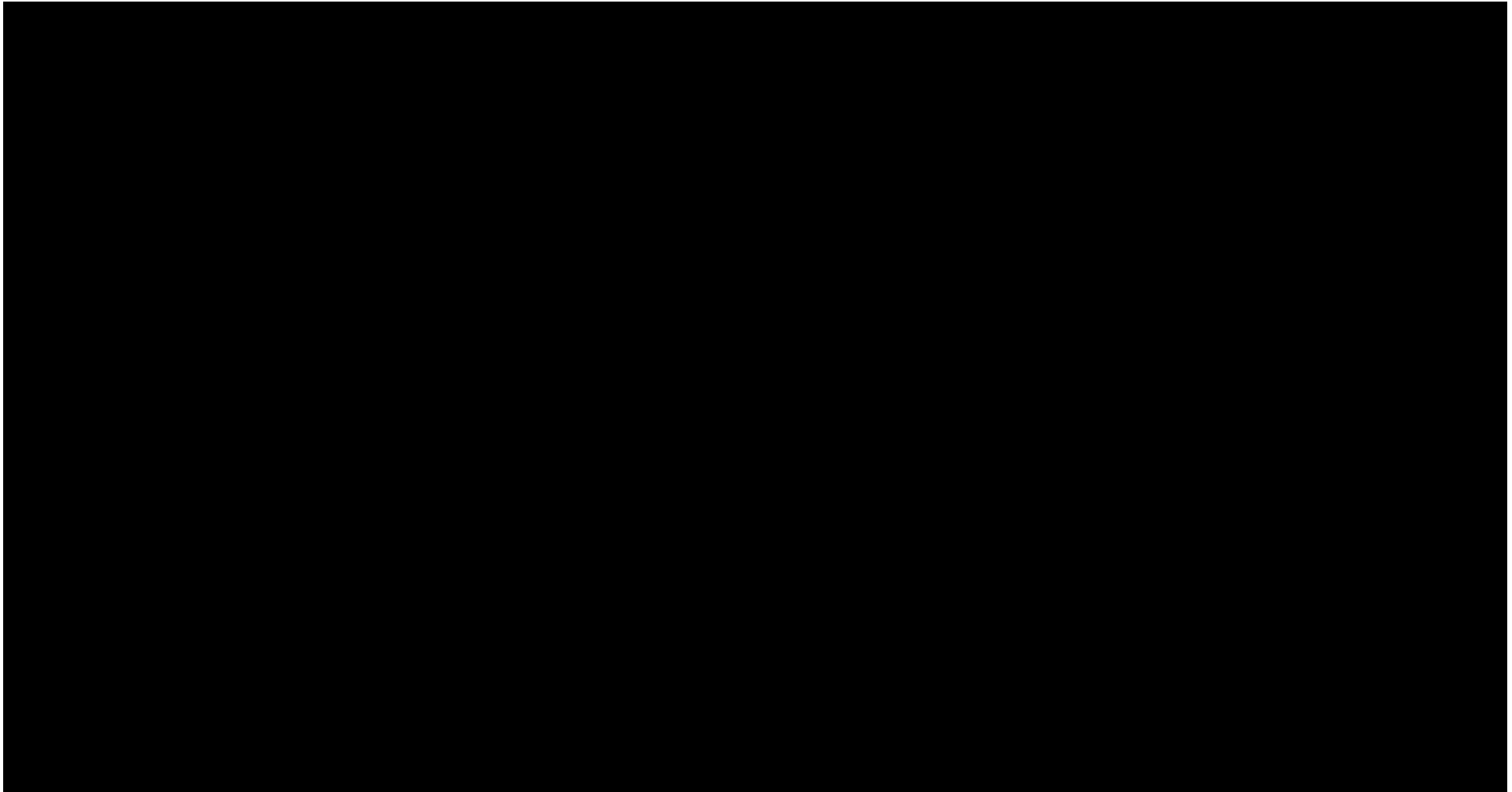
Status:
Page:

Final
Page 1385 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

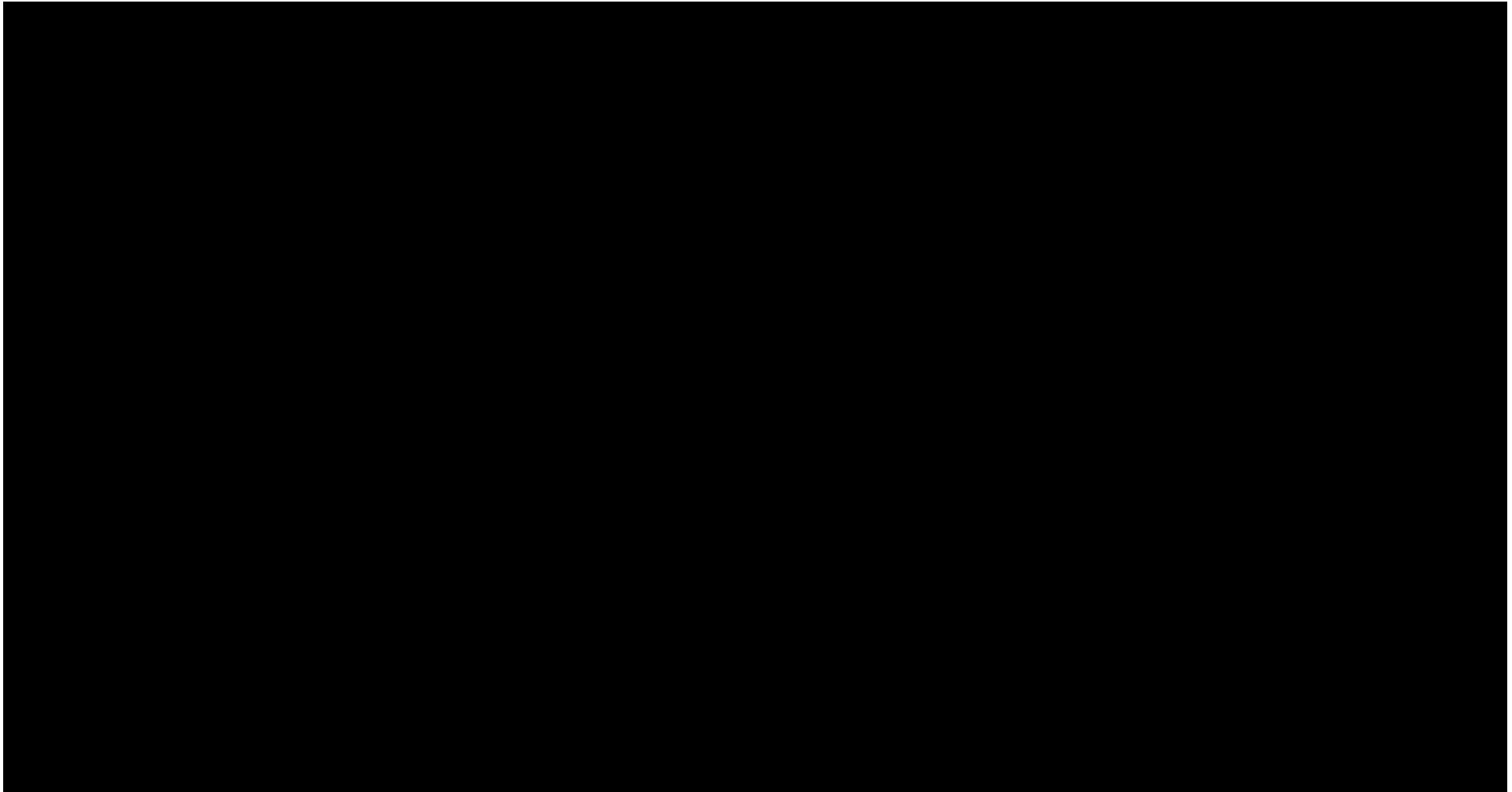
Status:
Page:

Final
Page 1387 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

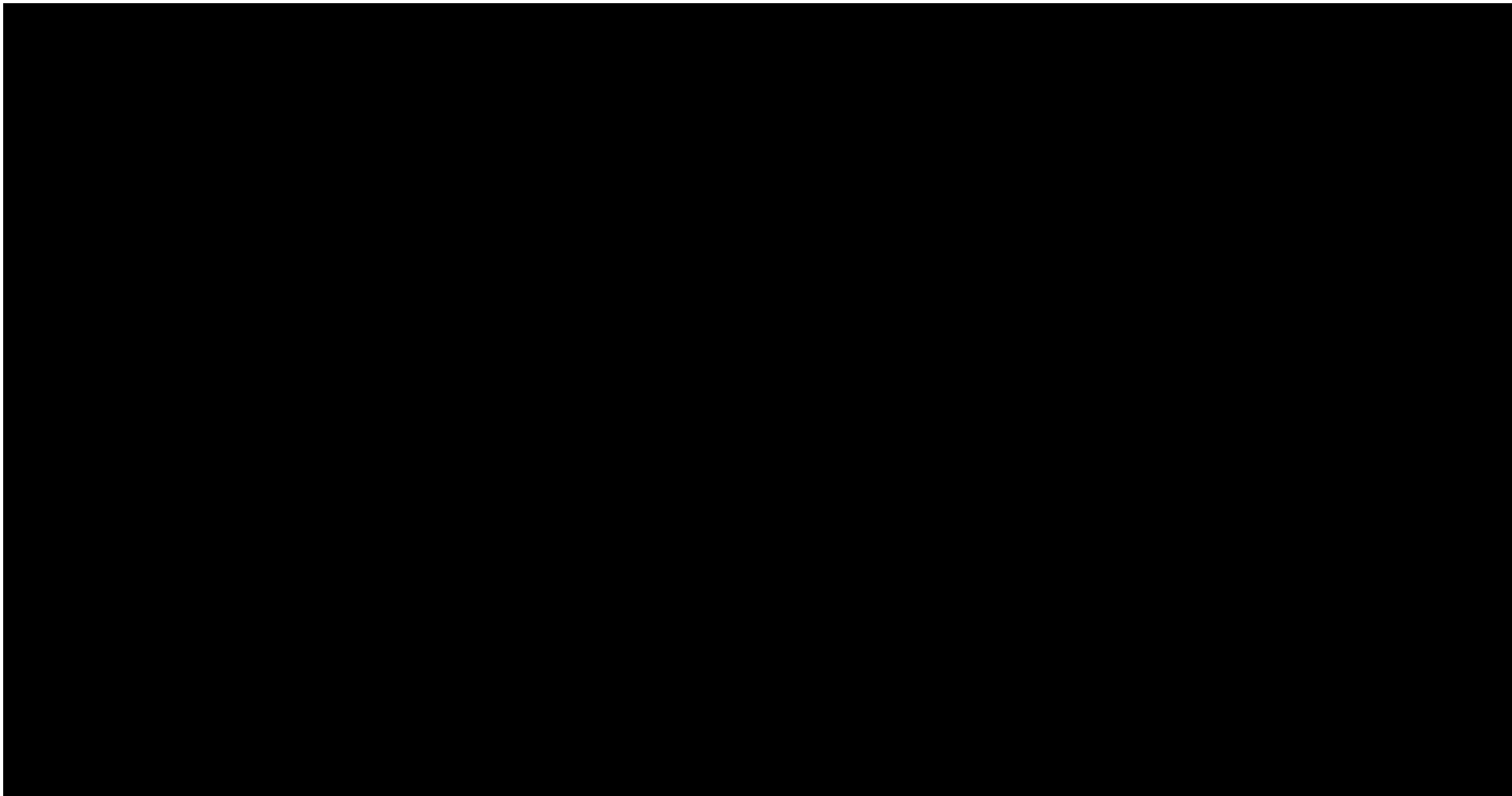
Status:
Page:

Final
Page 1388 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

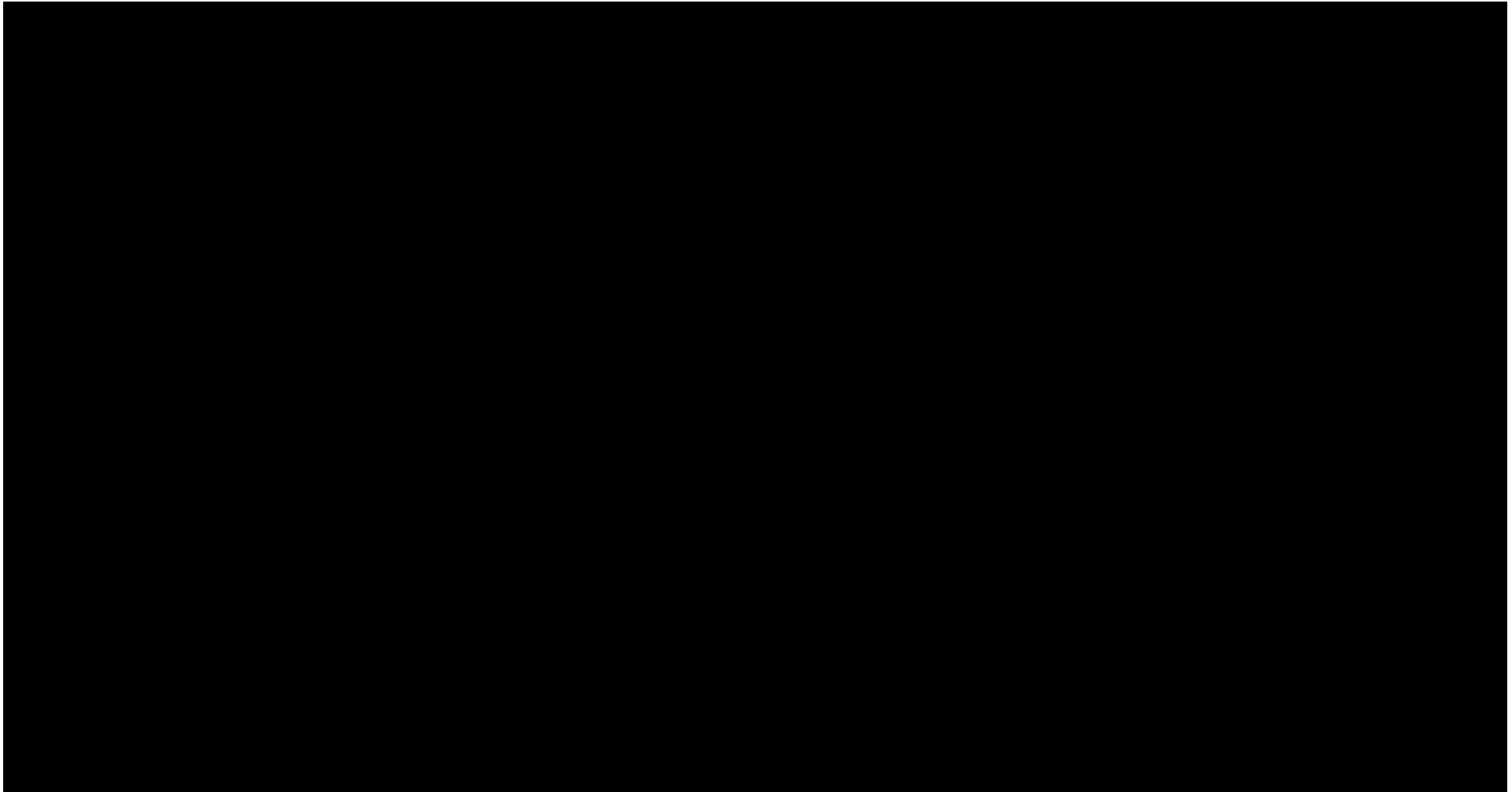
Status:
Page:

Final
Page 1389 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

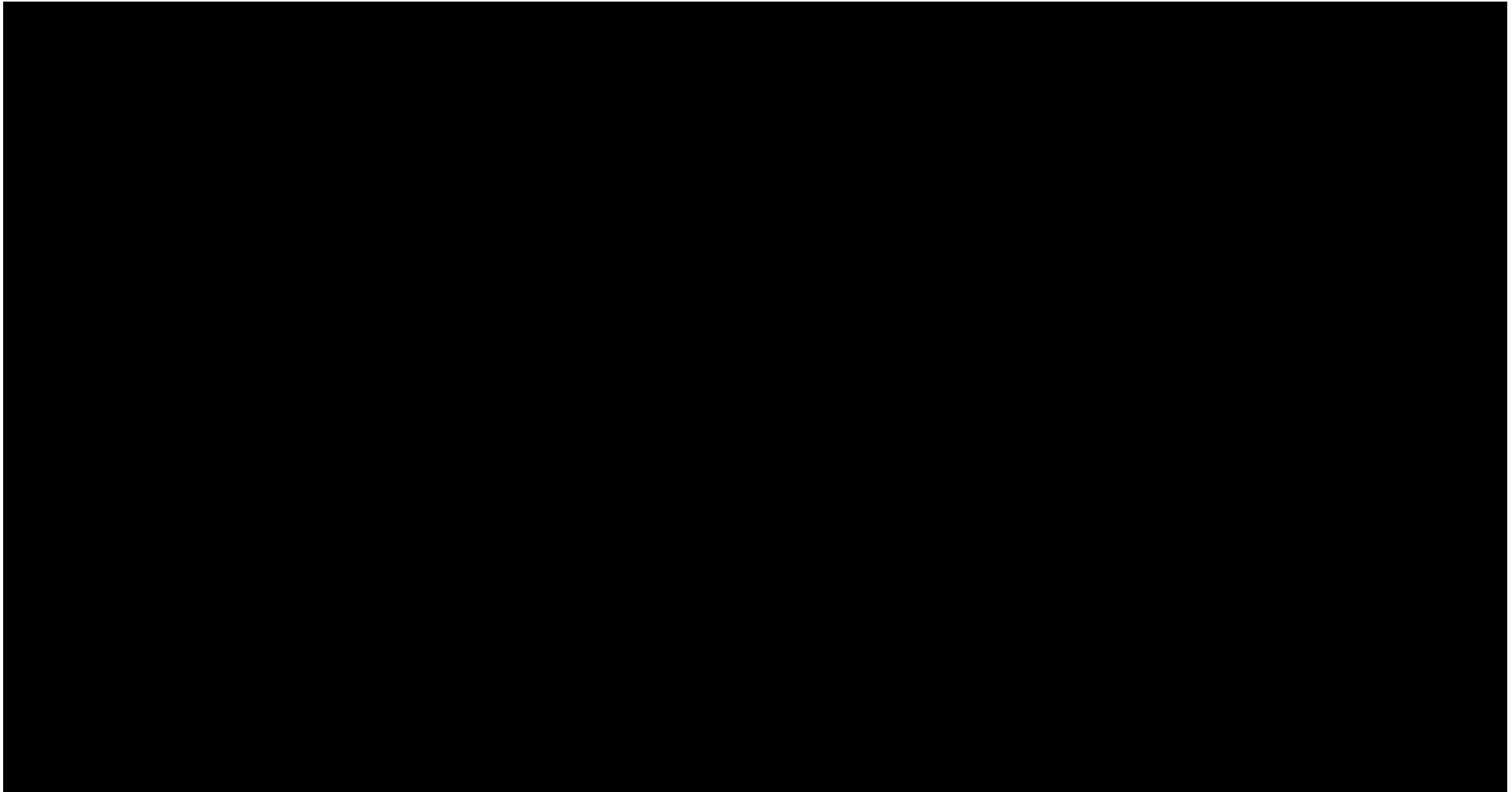
Status:
Page:

Final
Page 1390 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

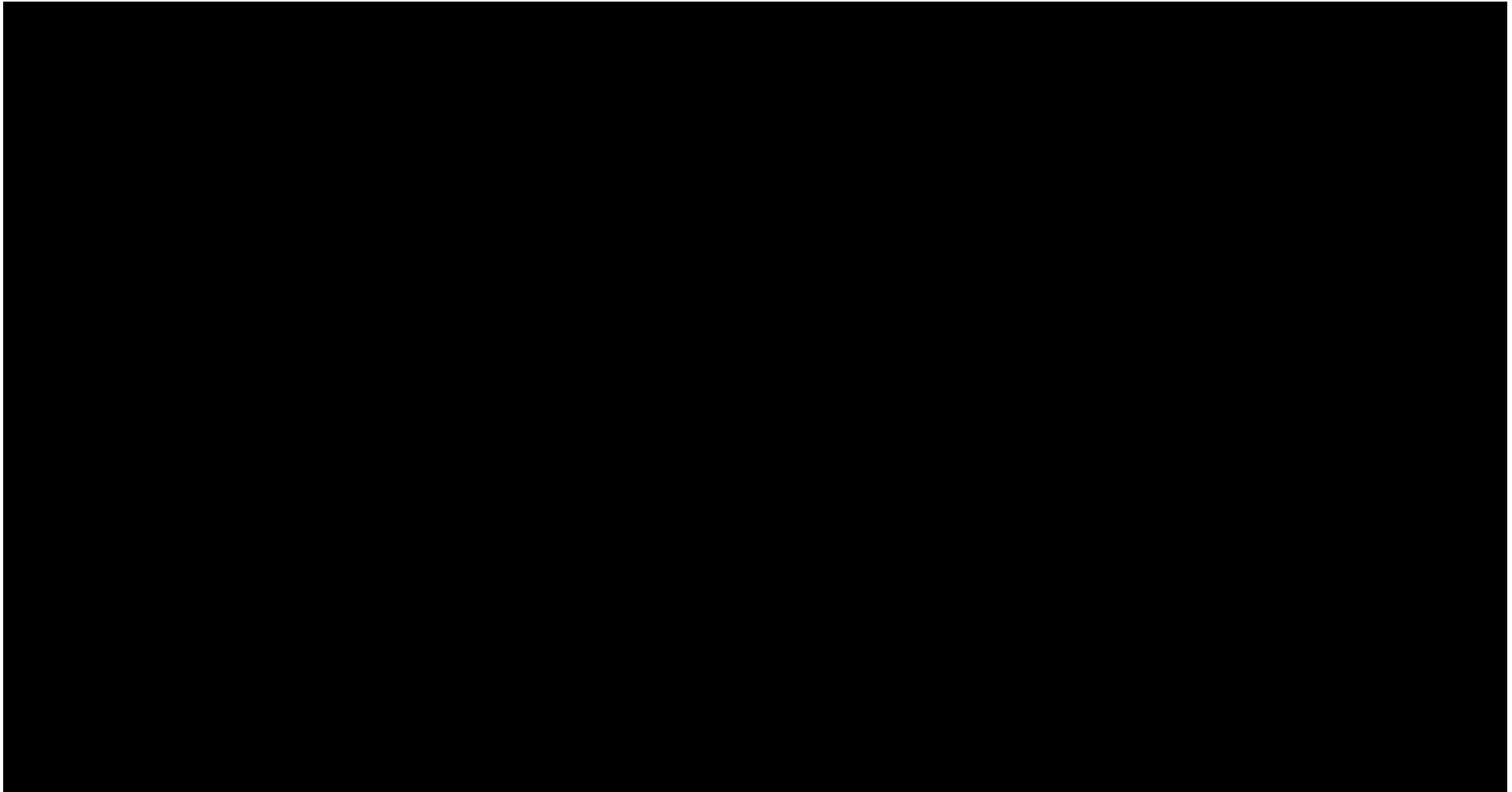
Status:
Page:

Final
Page 1391 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

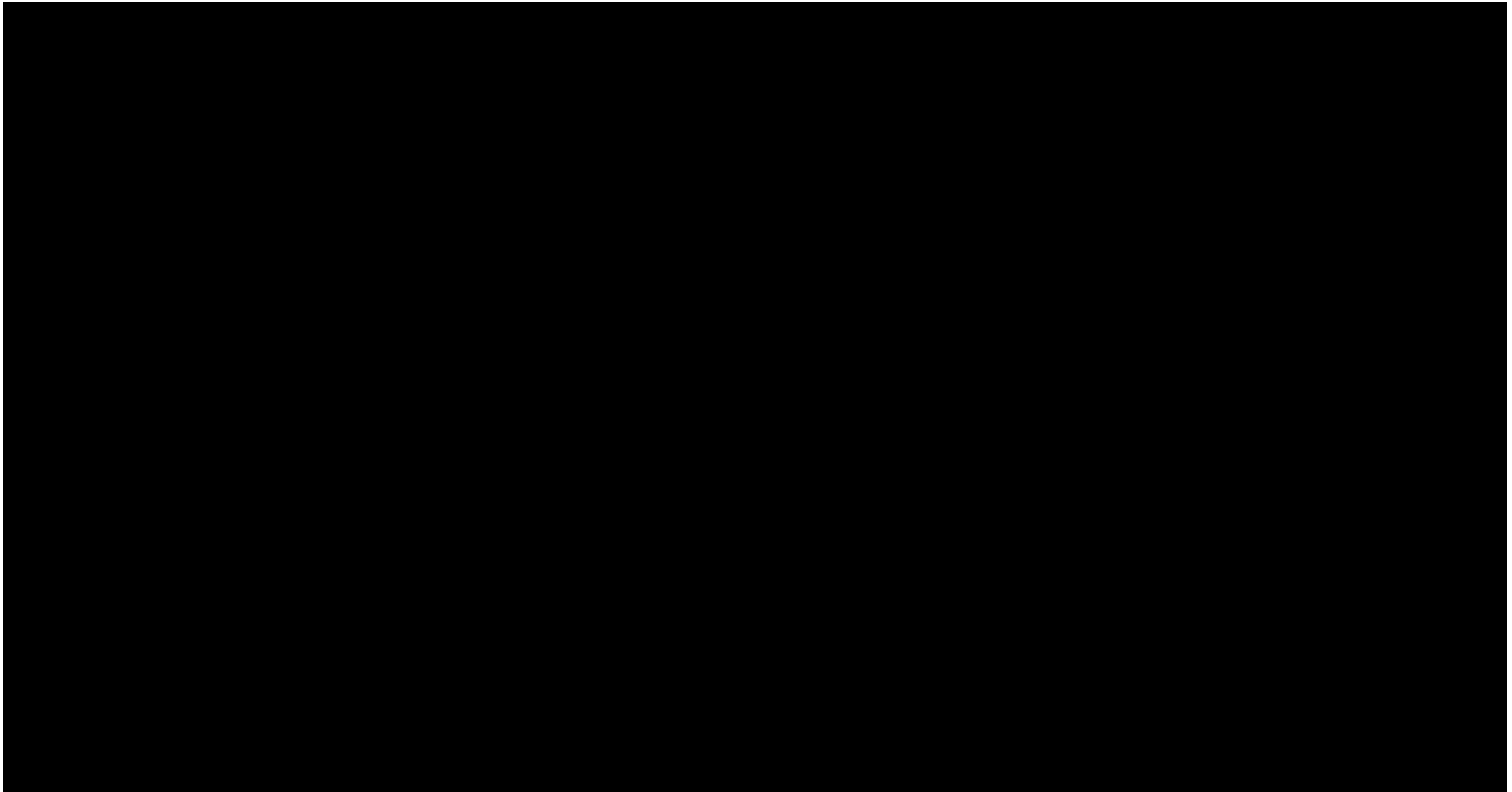
Status:
Page:

Final
Page 1392 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

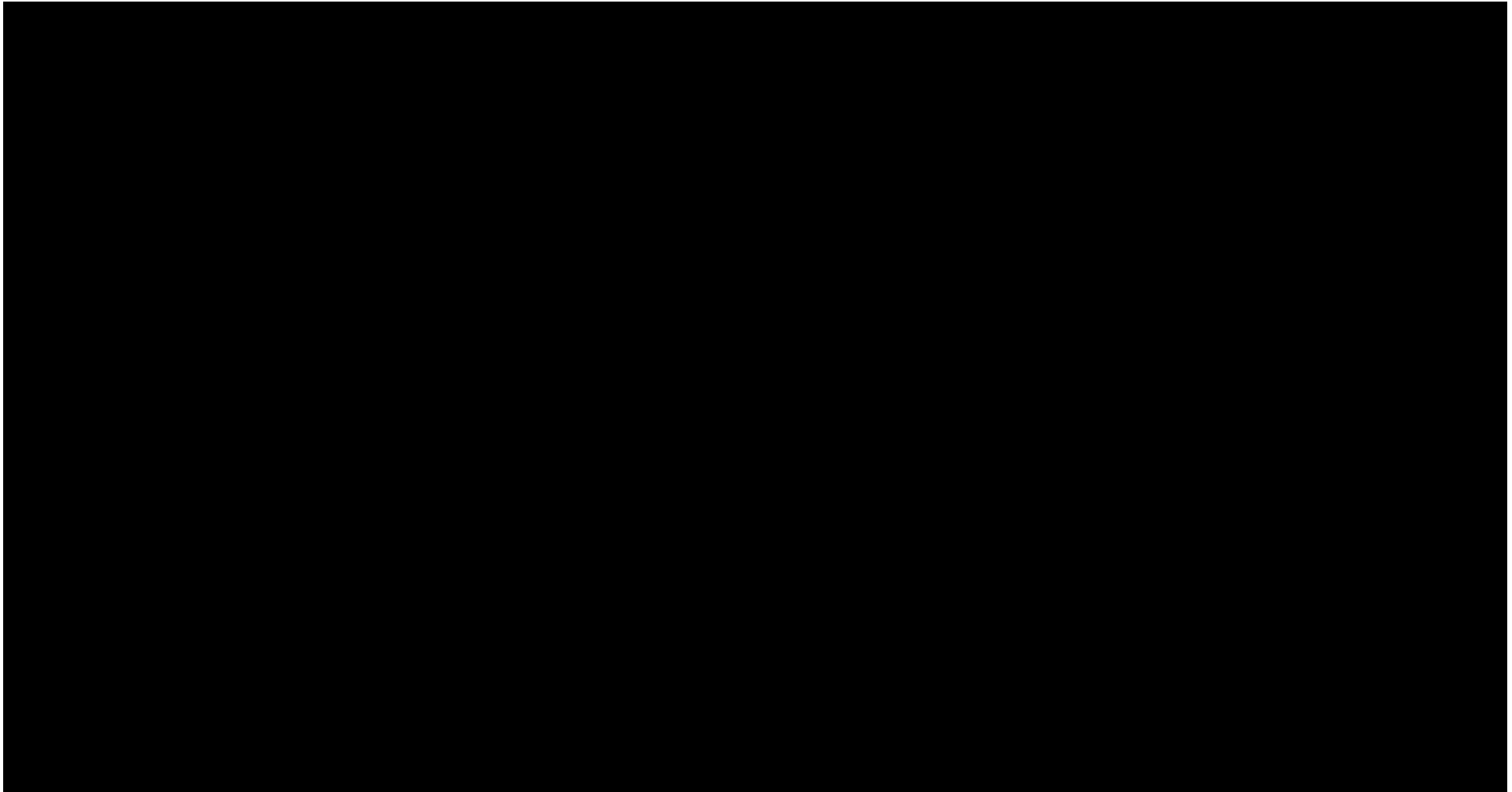
Status:
Page:

Final
Page 1393 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

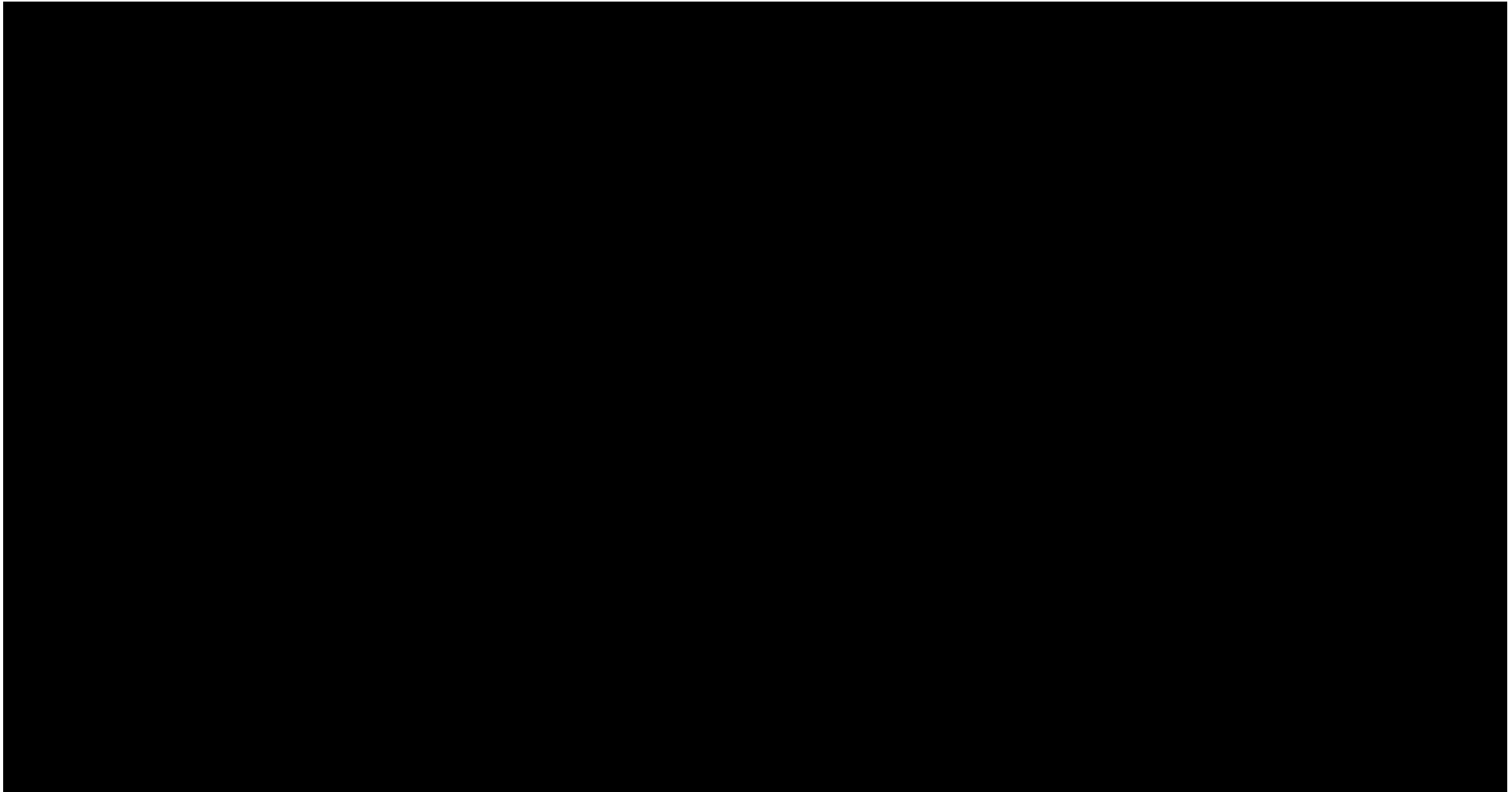
Status:
Page:

Final
Page 1394 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

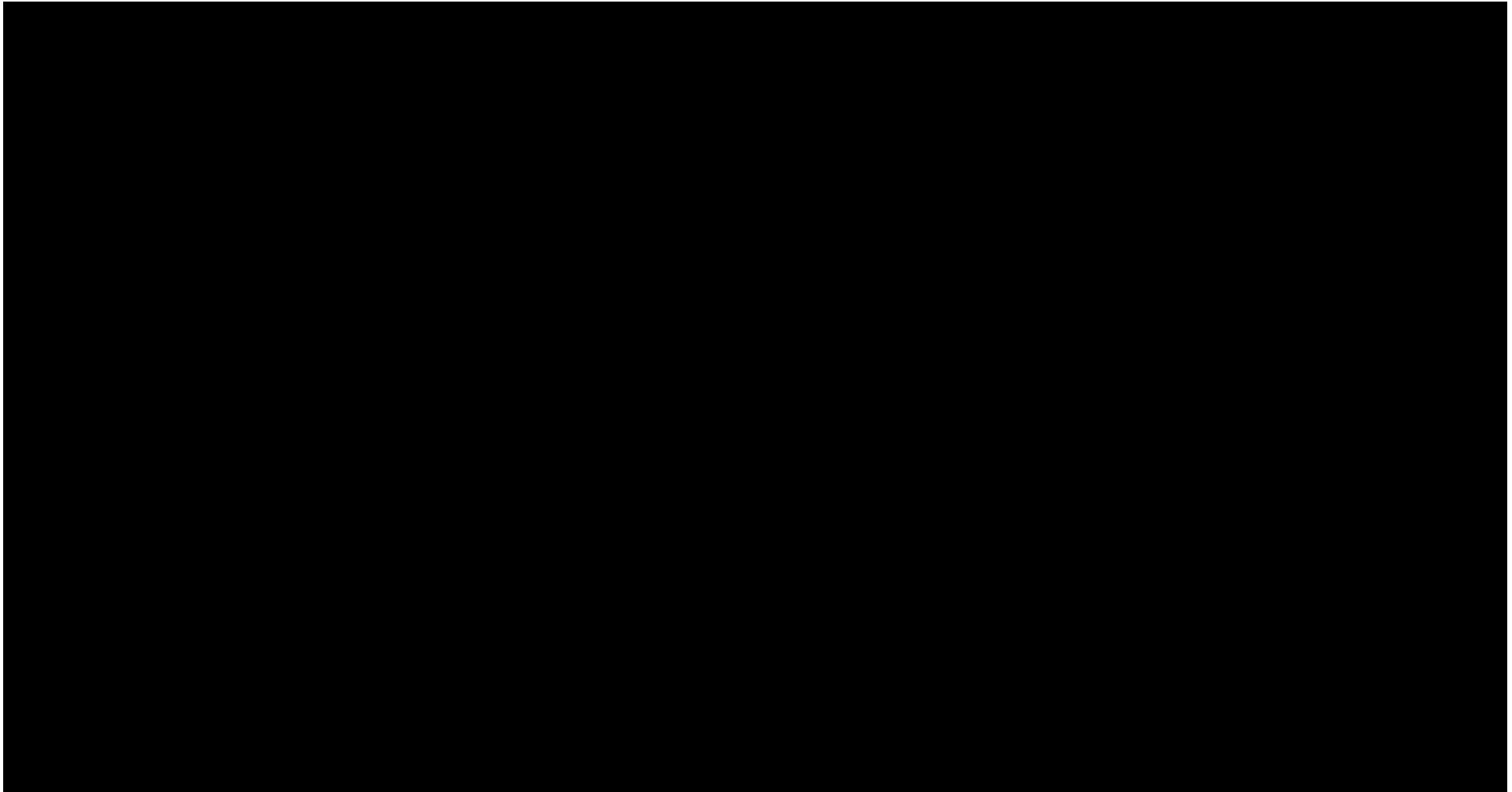
Status:
Page:

Final
Page 1395 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

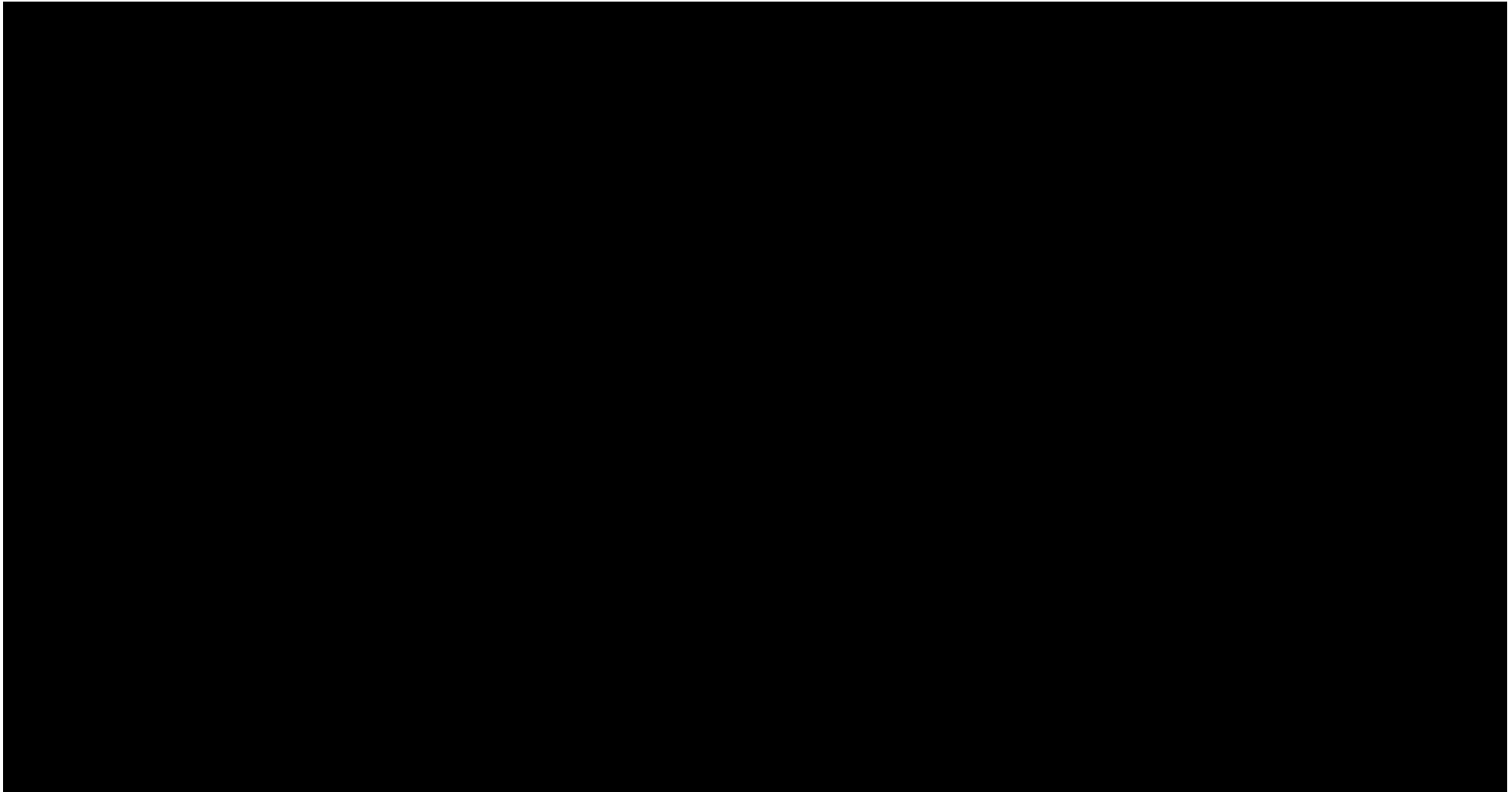
Status:
Page:

Final
Page 1396 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

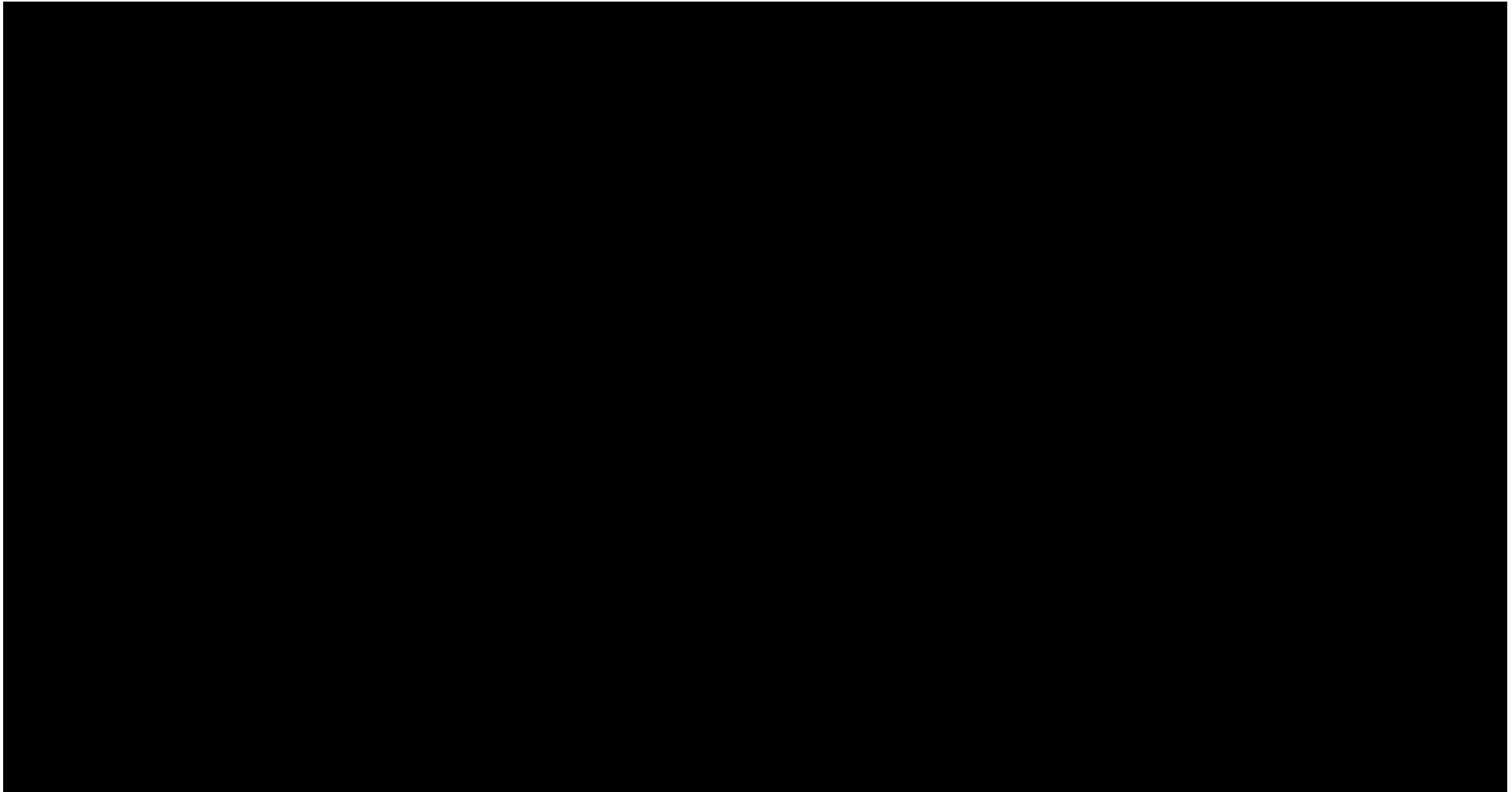
Status:
Page:

Final
Page 1398 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

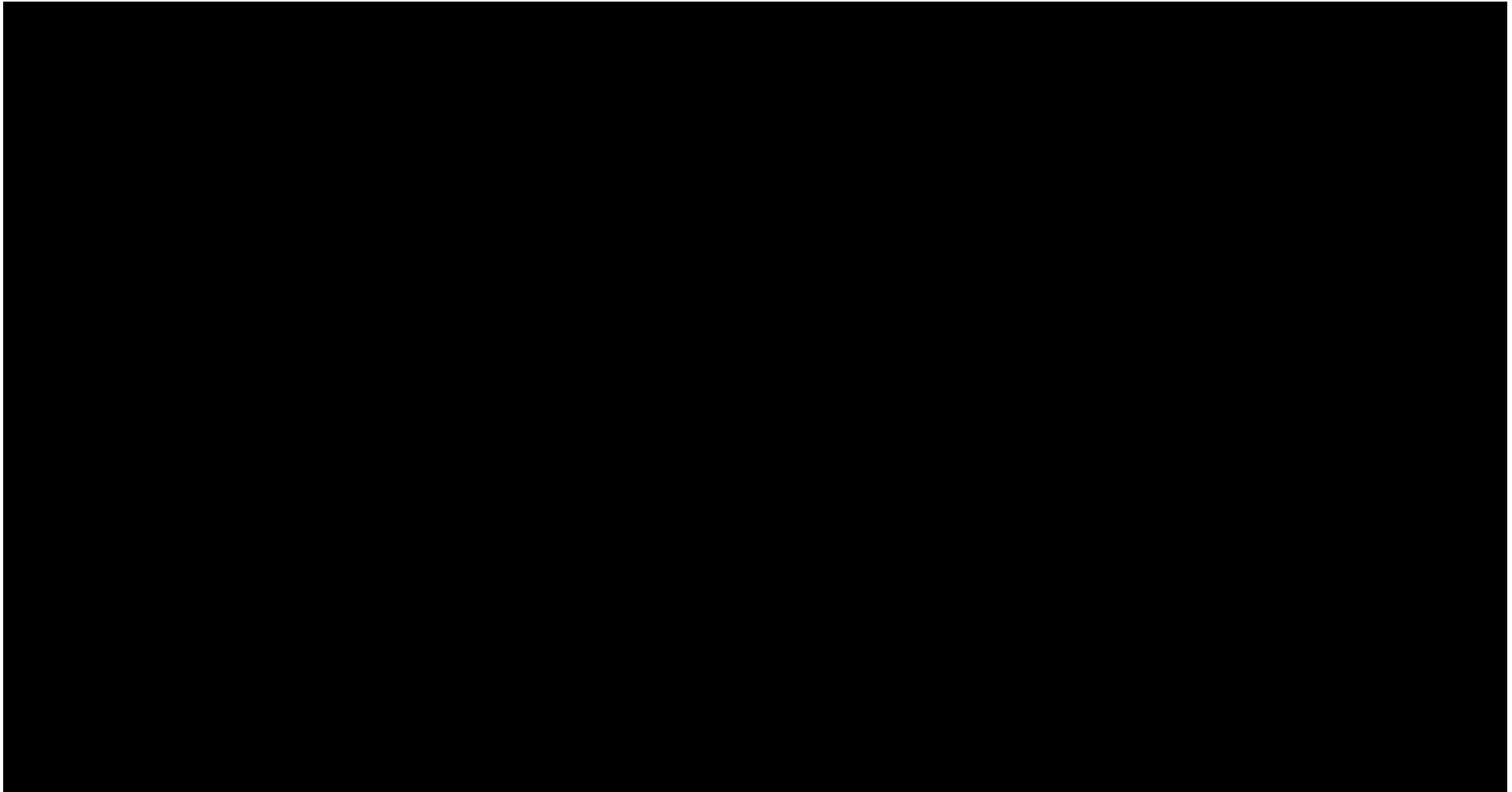
Status:
Page:

Final
Page 1399 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

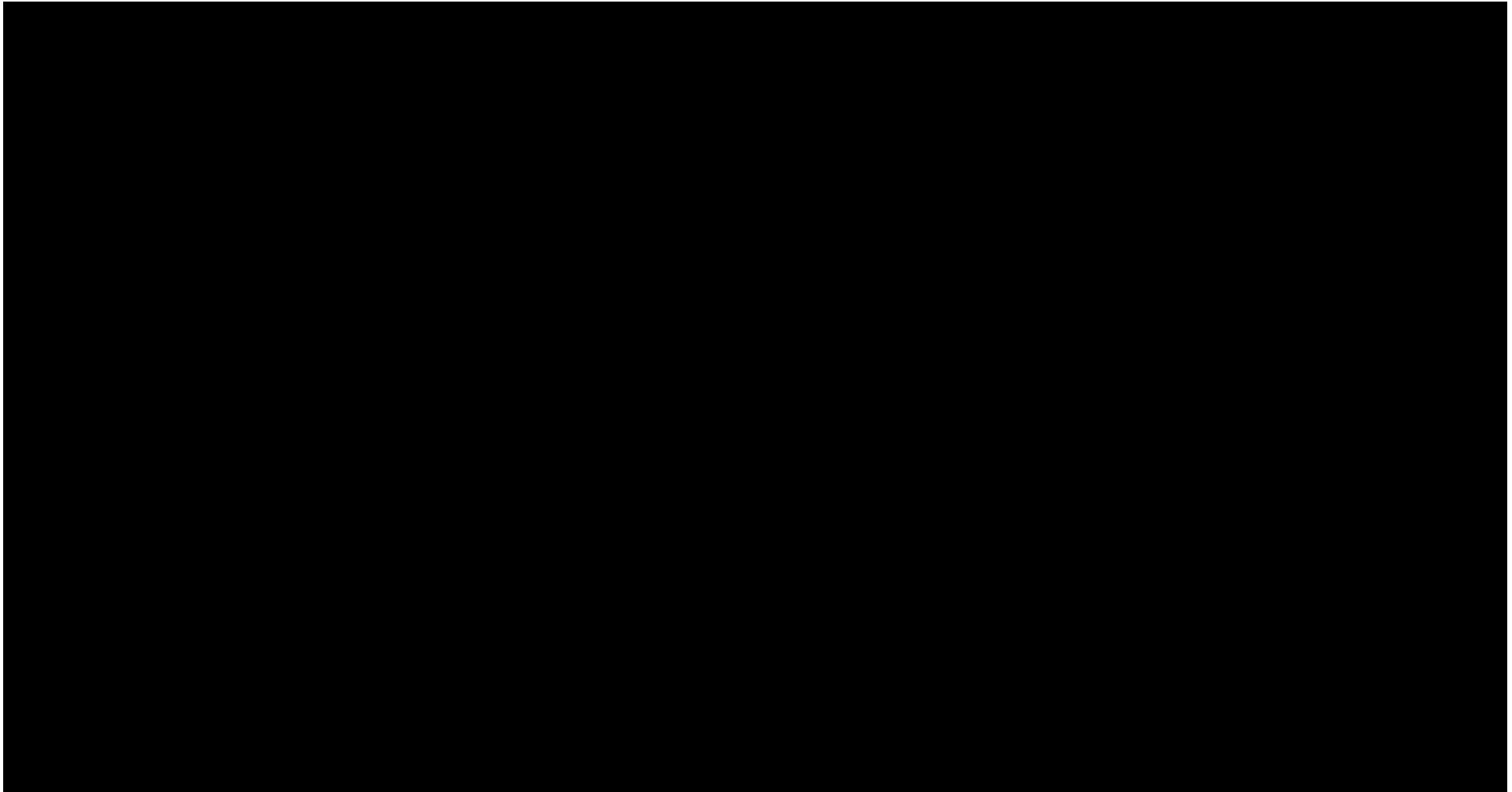
Status:
Page:

Final
Page 1403 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

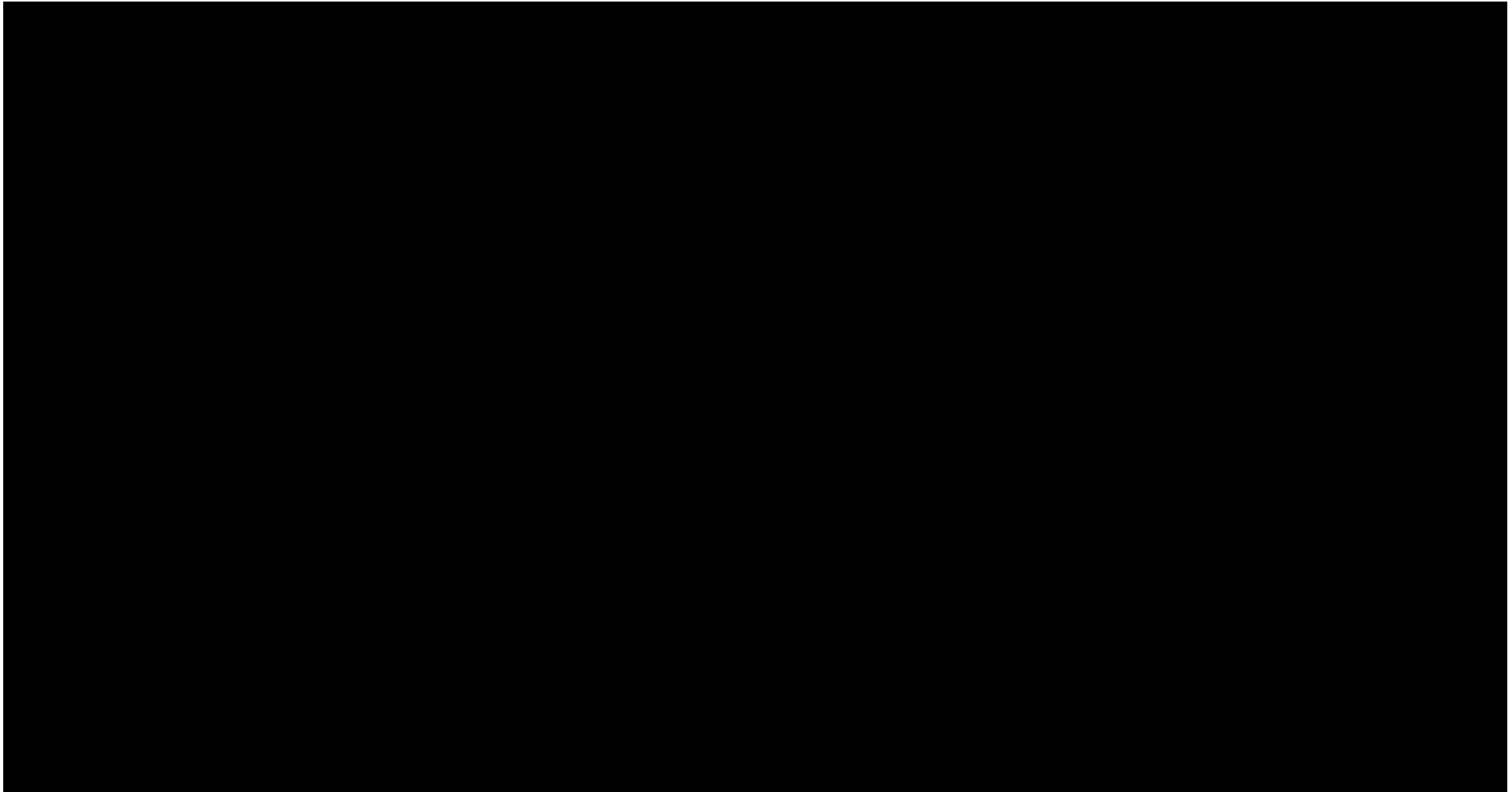
Status:
Page:

Final
Page 1405 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

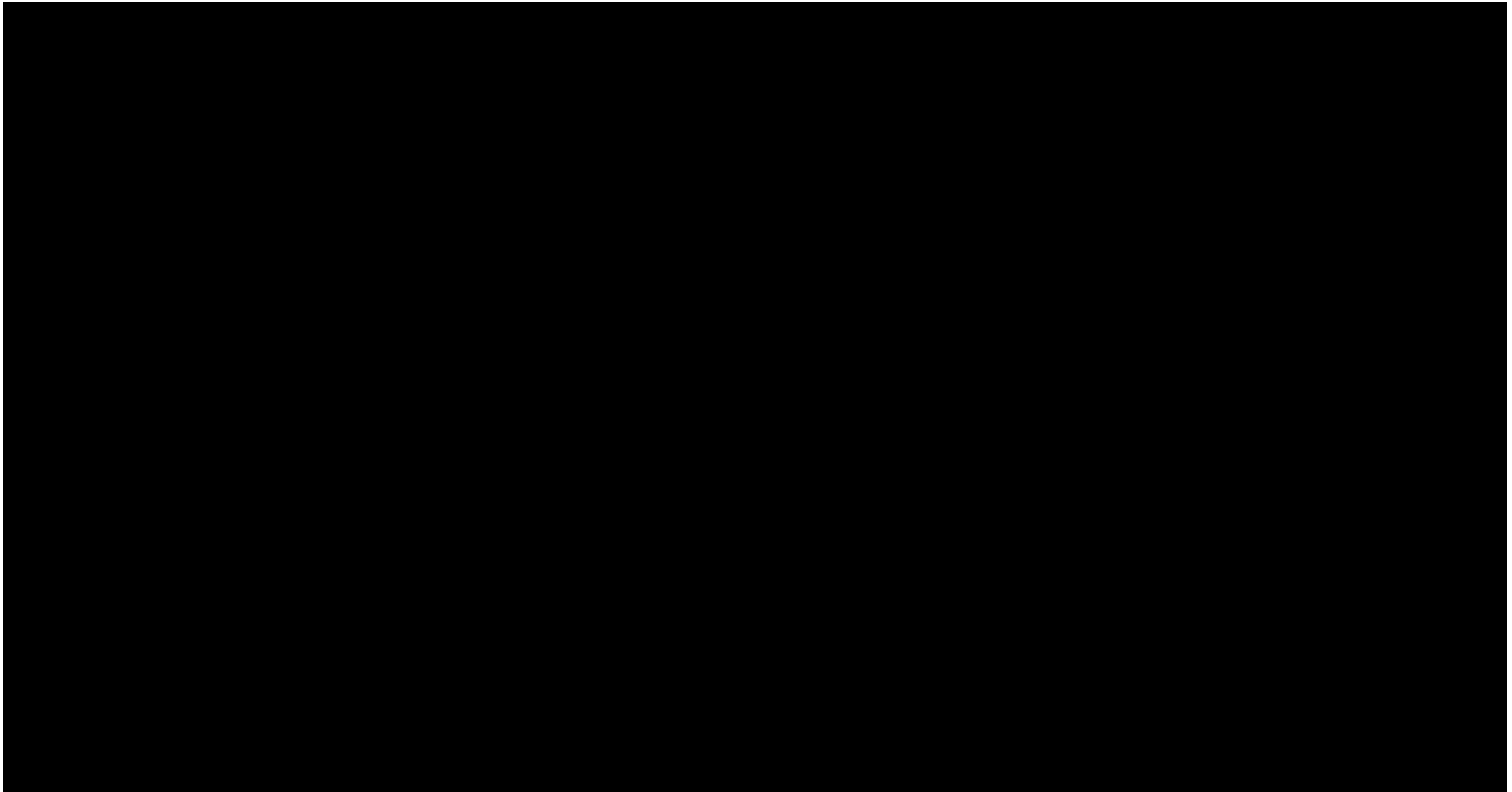
Status:
Page:

Final
Page 1408 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

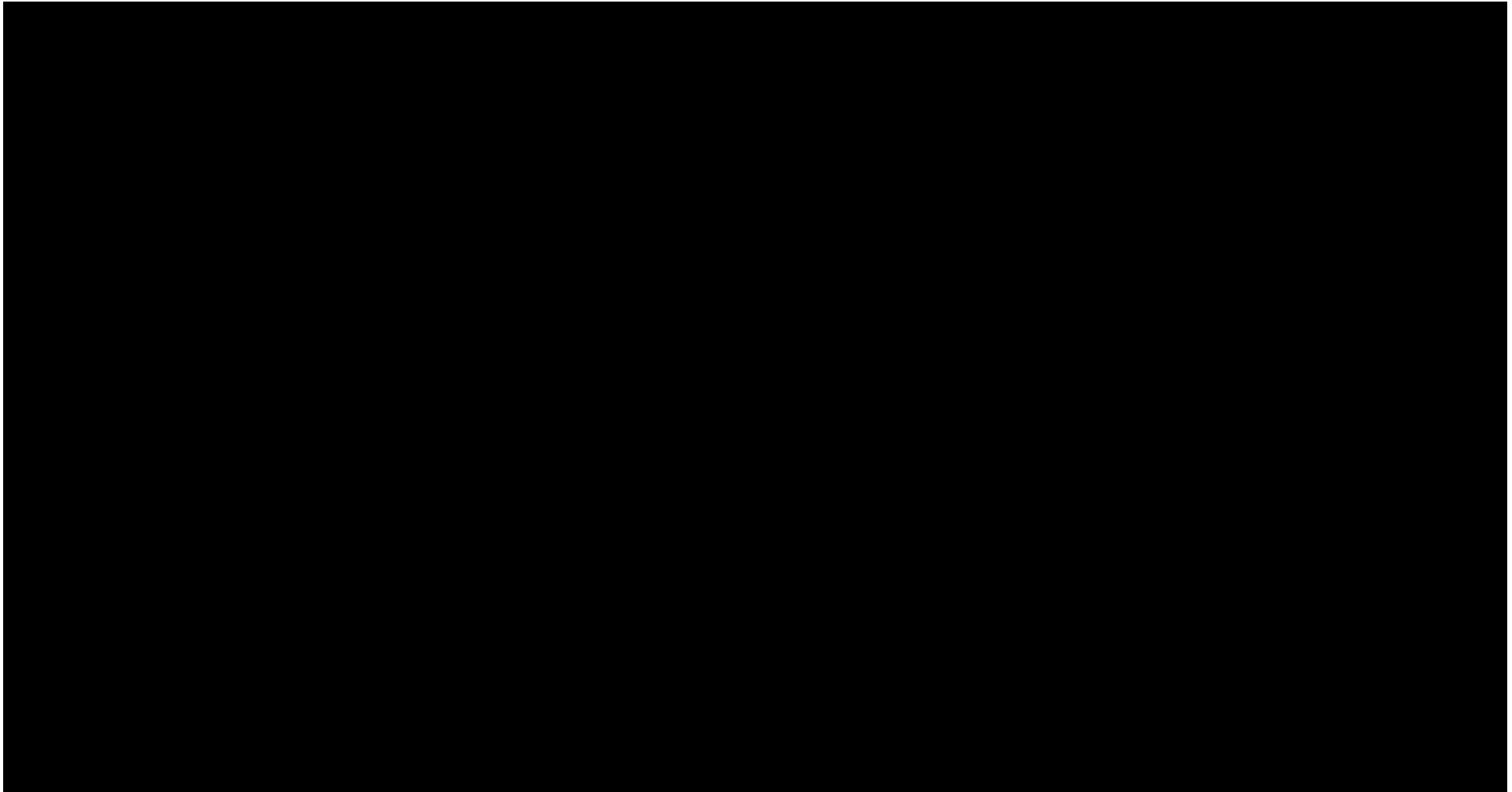
Status:
Page:

Final
Page 1411 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

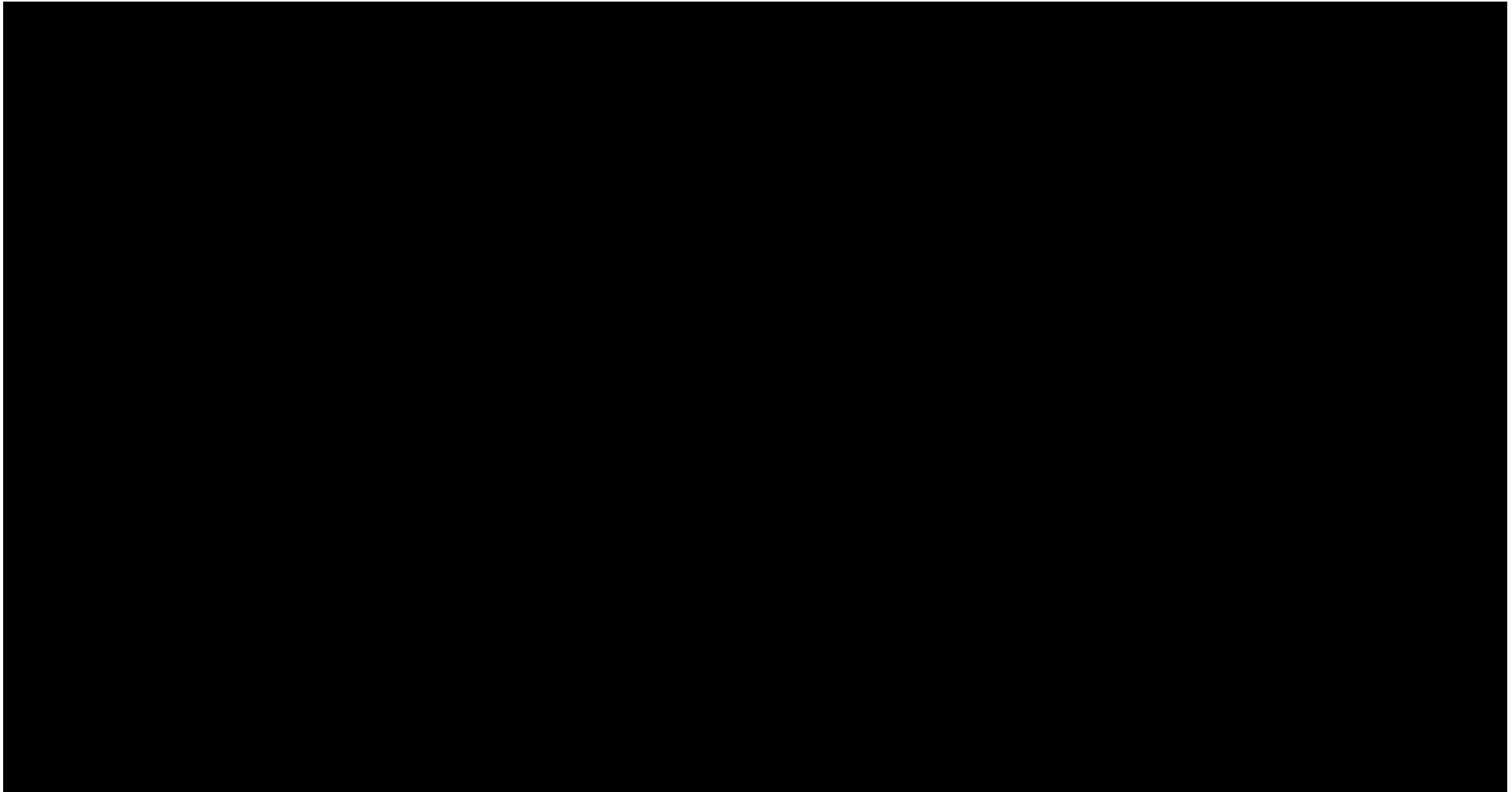
Status:
Page:

Final
Page 1414 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

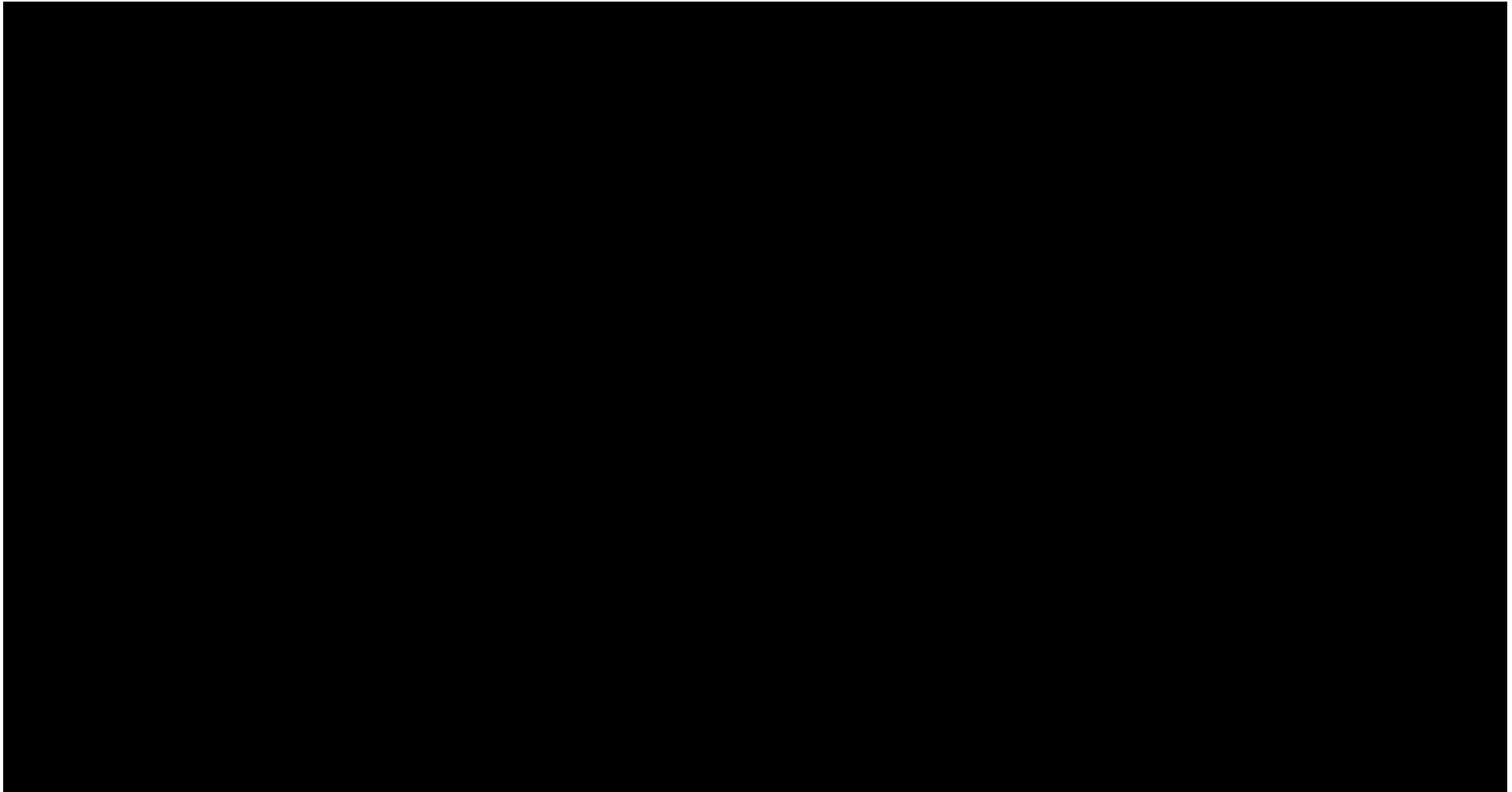
Status:
Page:

Final
Page 1415 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

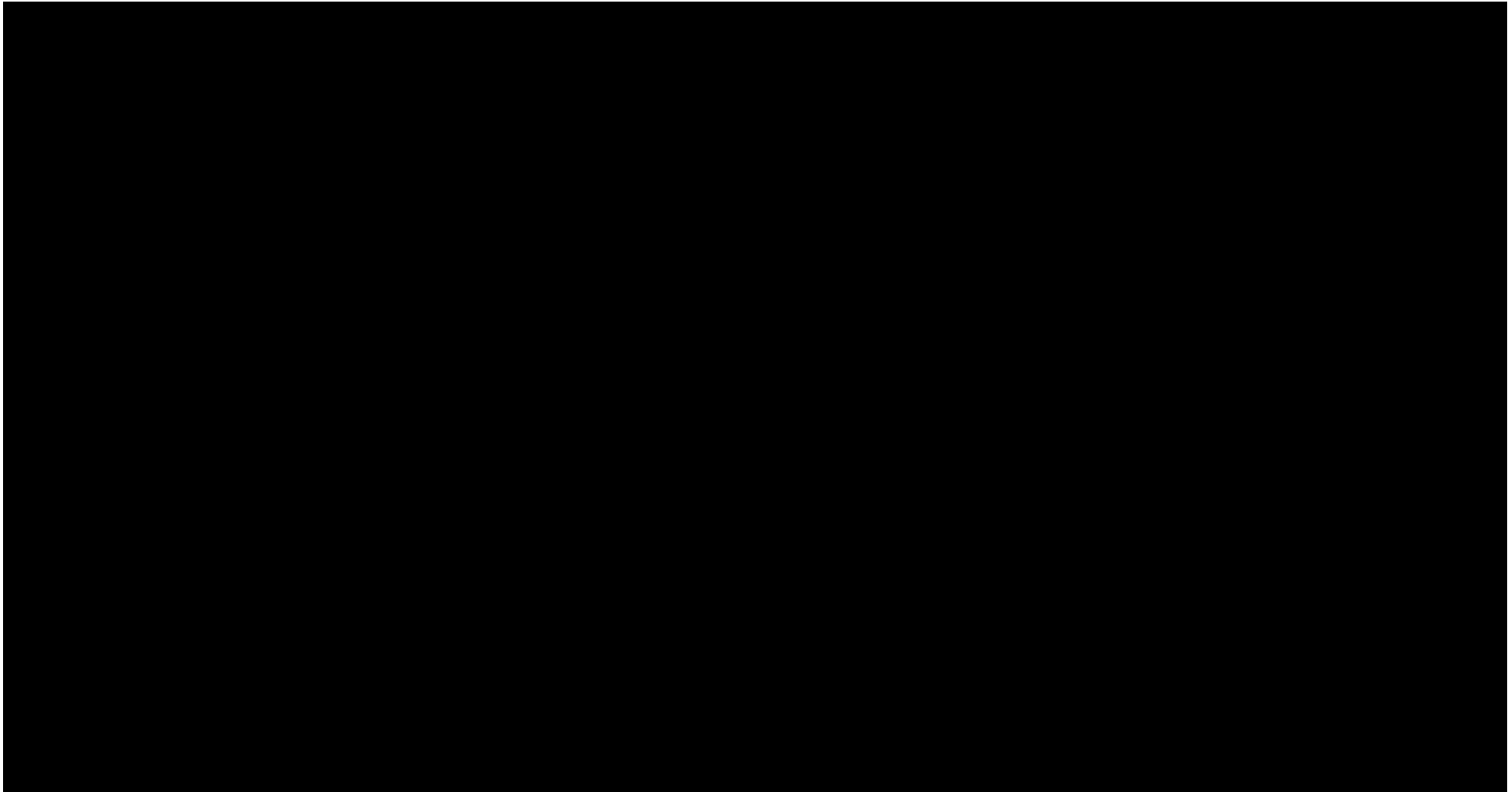
Status:
Page:

Final
Page 1416 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

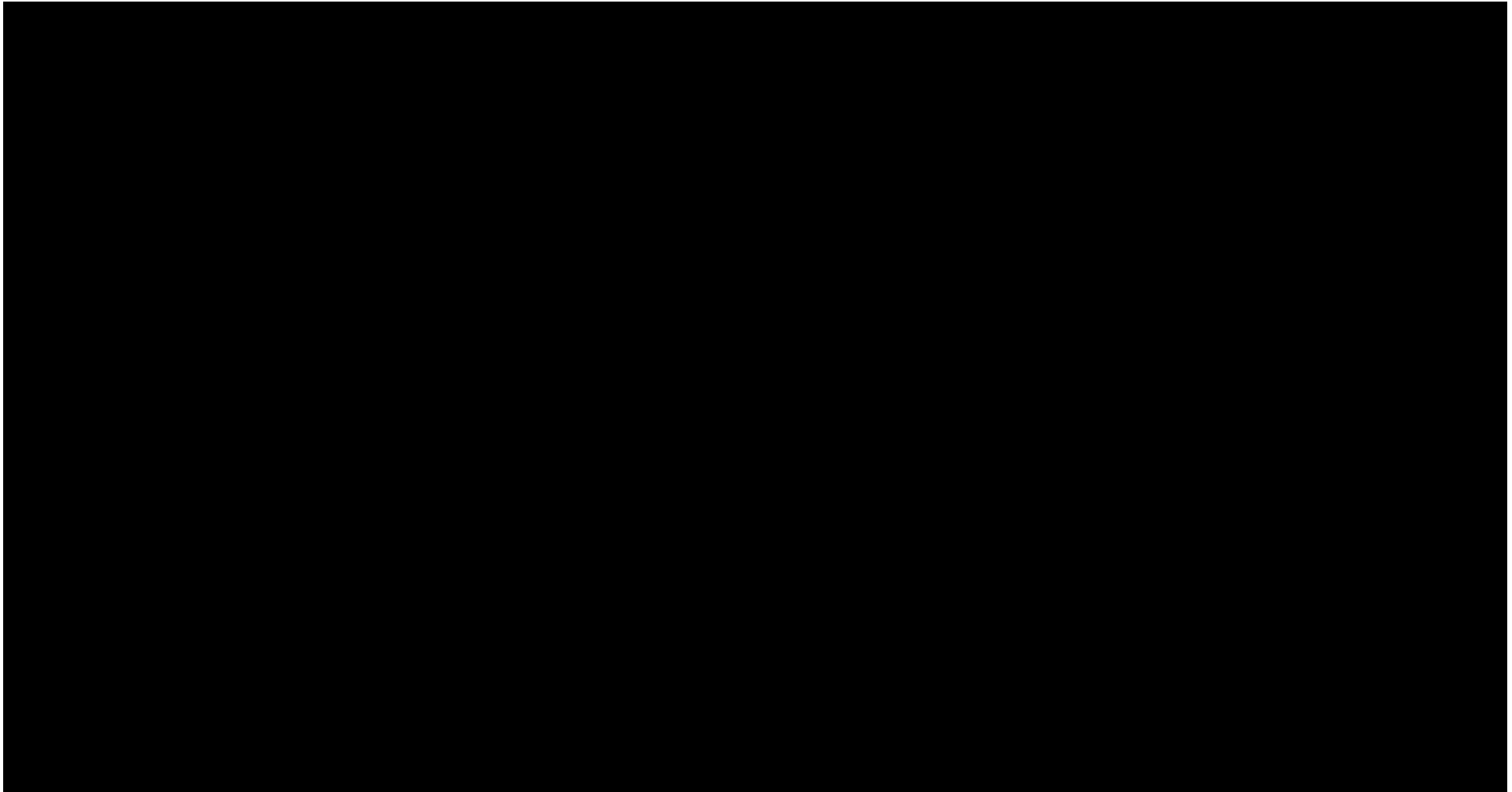
Status:
Page:

Final
Page 1417 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

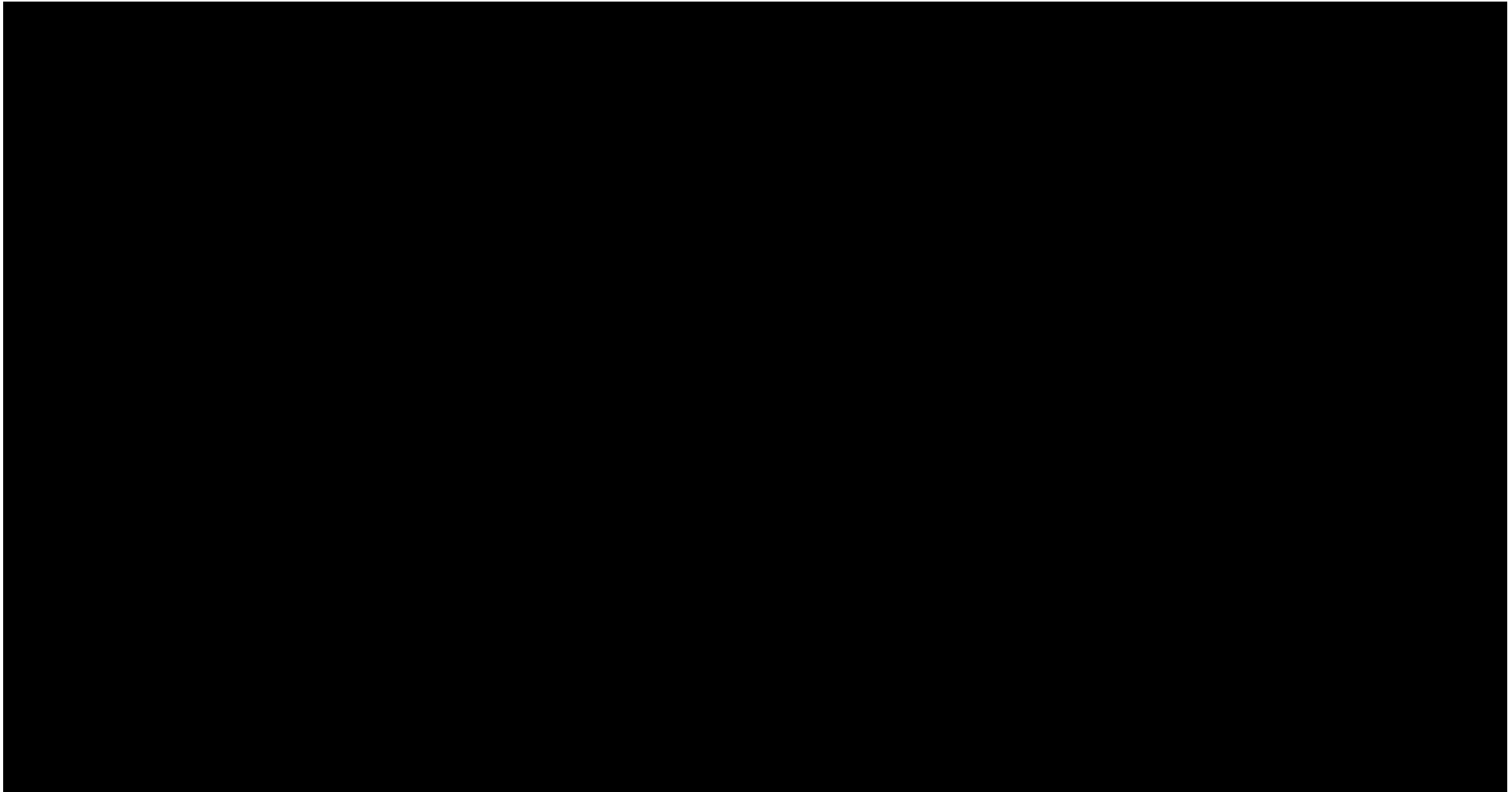
Status:
Page:

Final
Page 1418 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

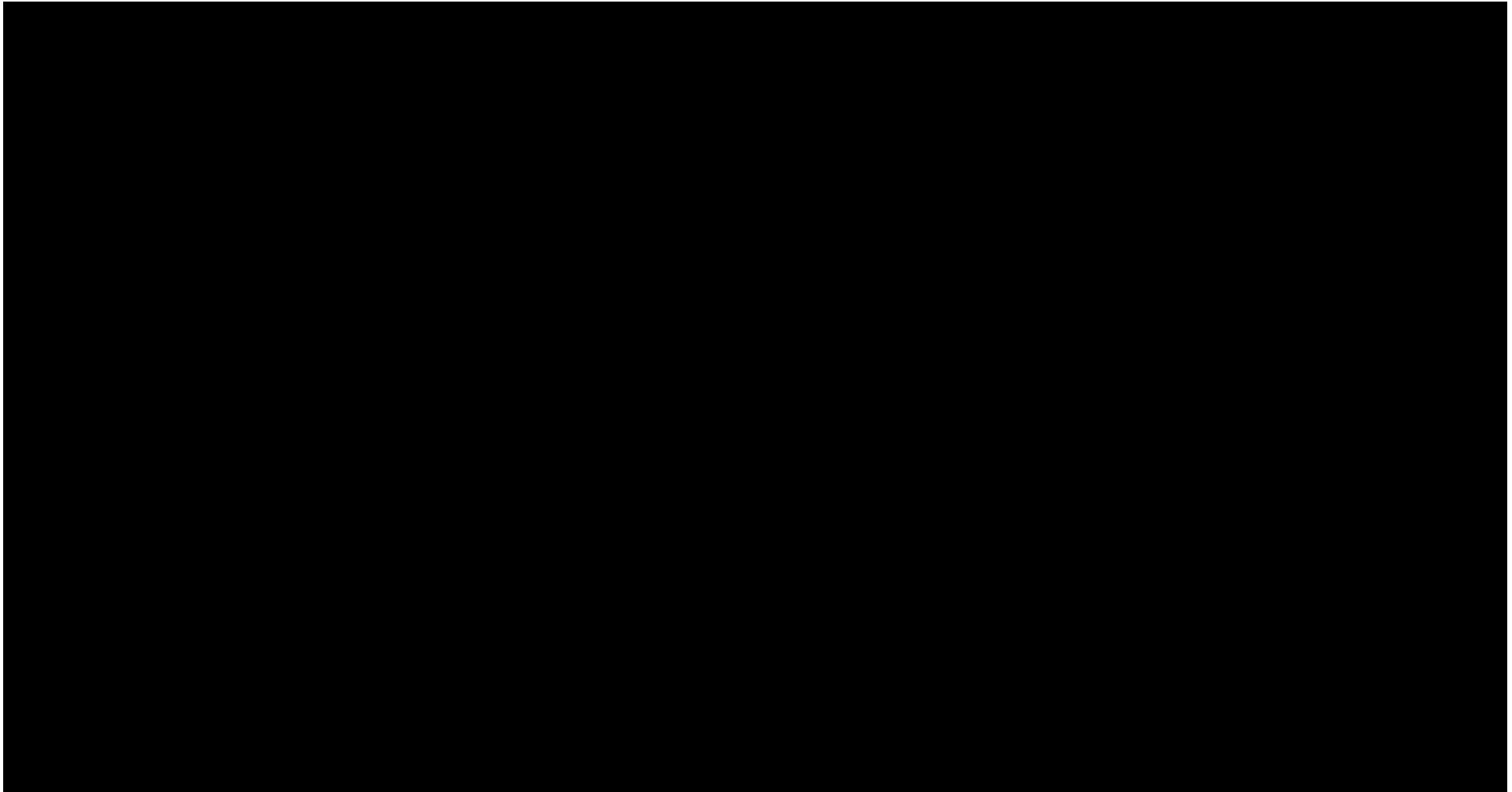
Status:
Page:

Final
Page 1419 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

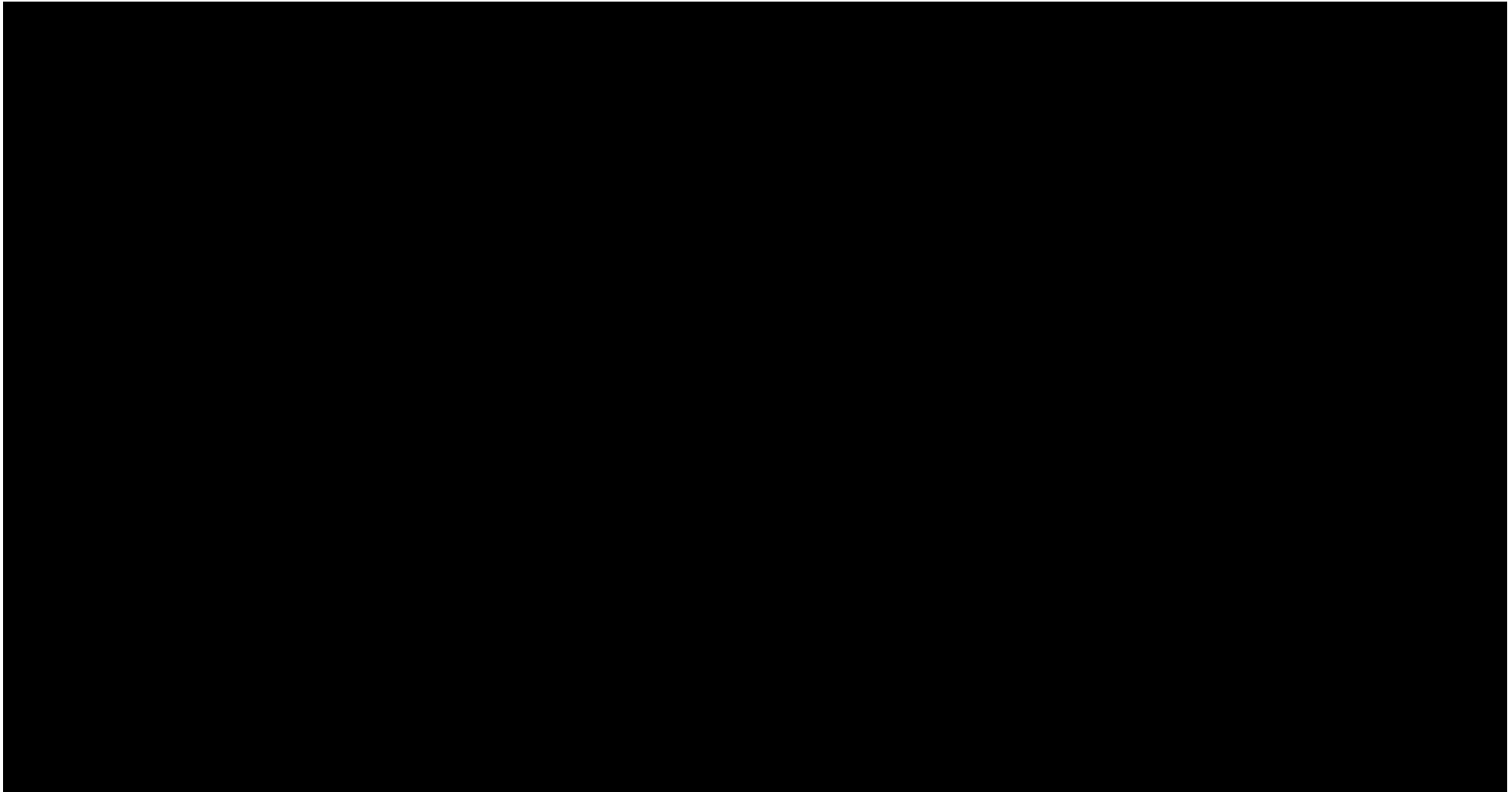
Status:
Page:

Final
Page 1420 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

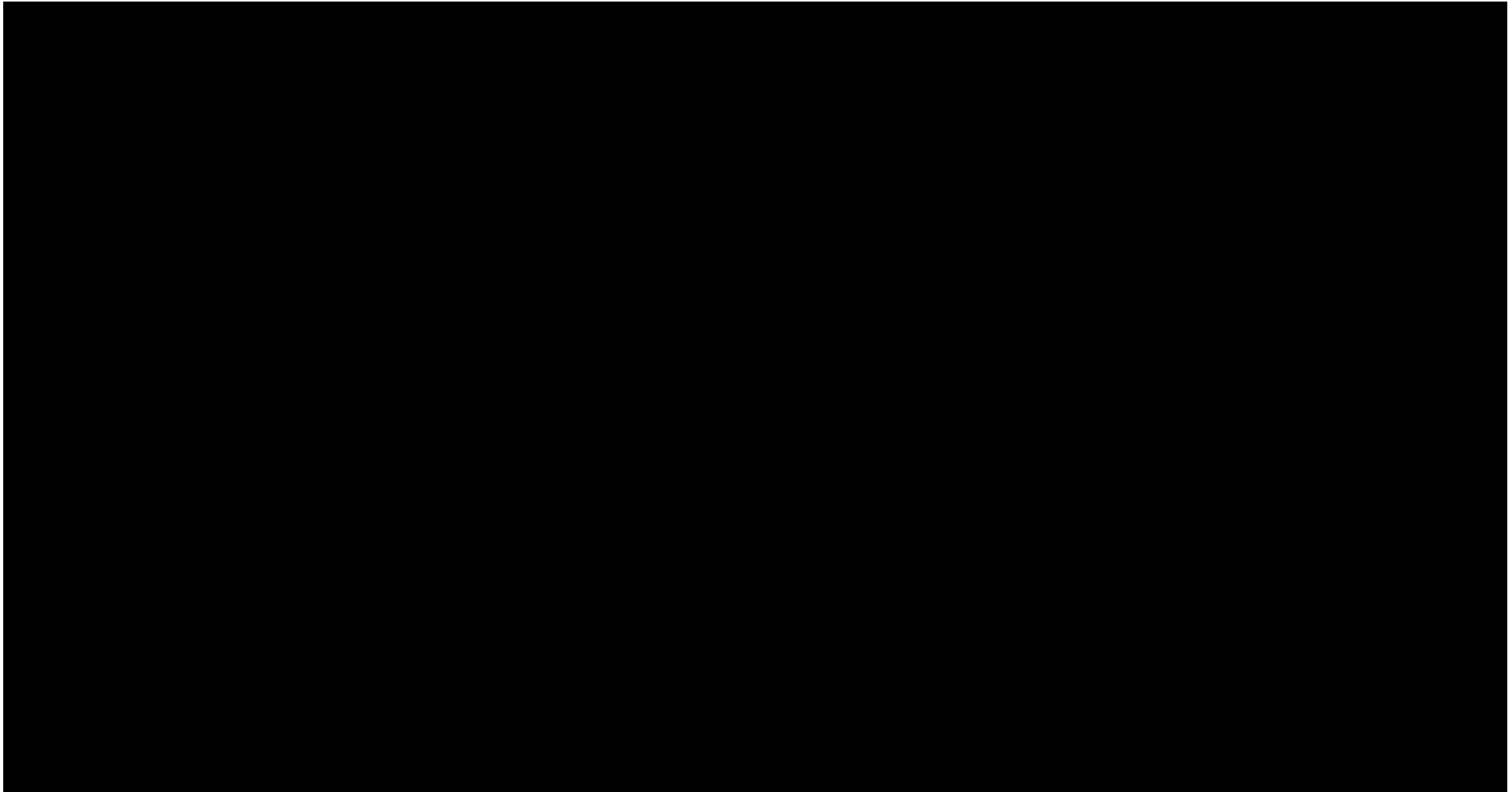
Status:
Page:

Final
Page 1421 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

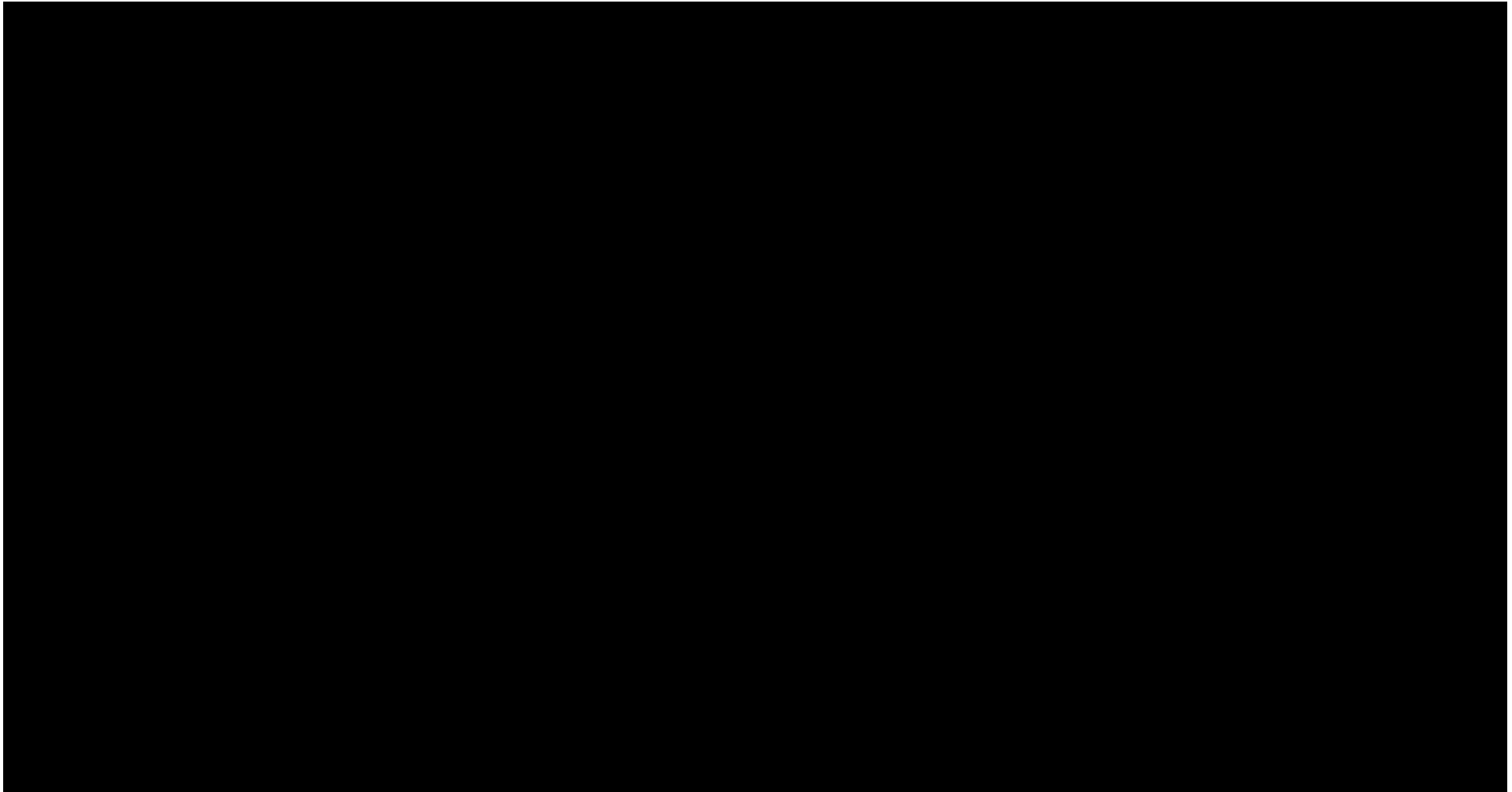
Status:
Page:

Final
Page 1425 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

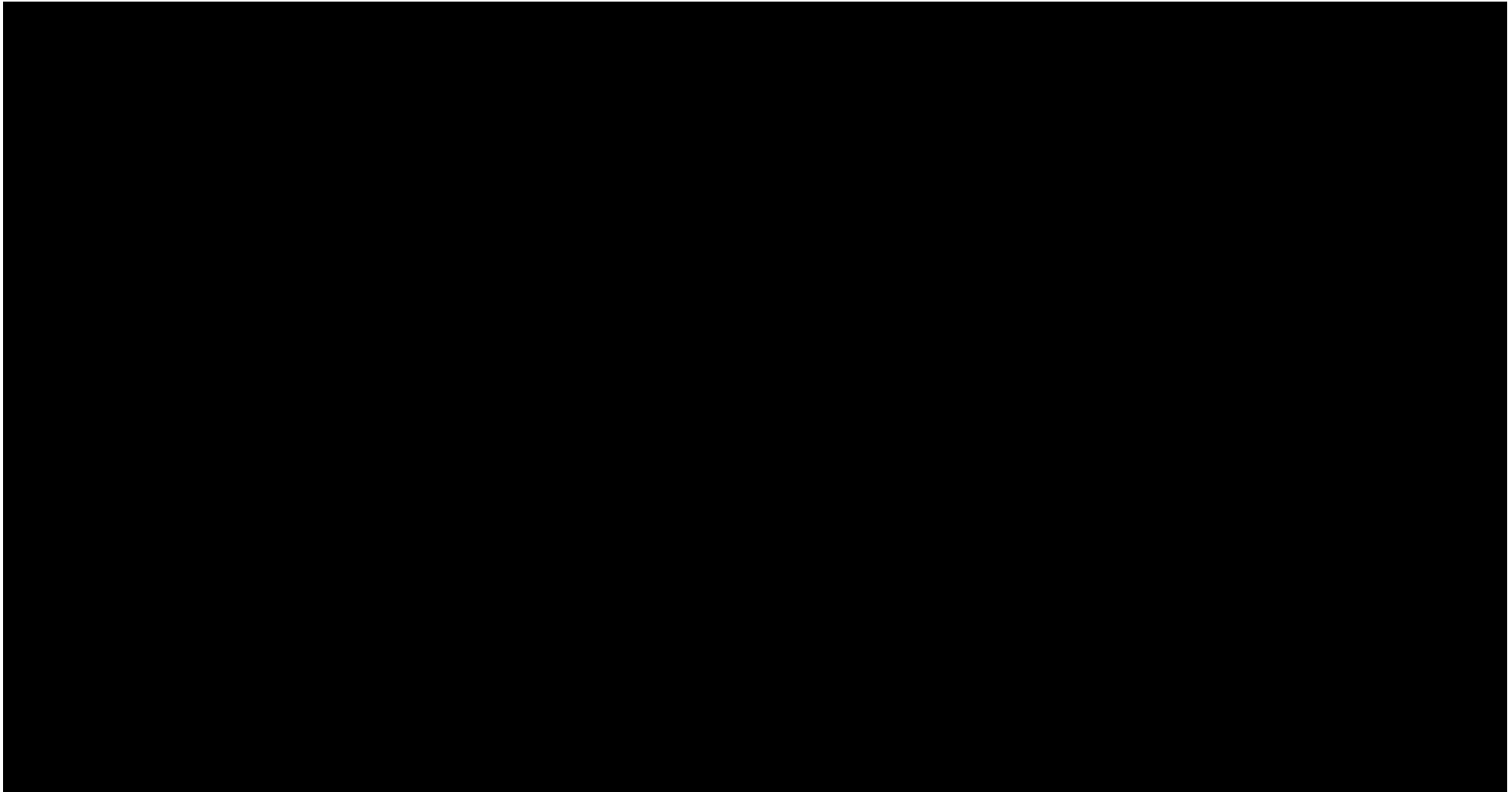
Status:
Page:

Final
Page 1428 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
---------------	-----------	--------------	--------------	-----------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

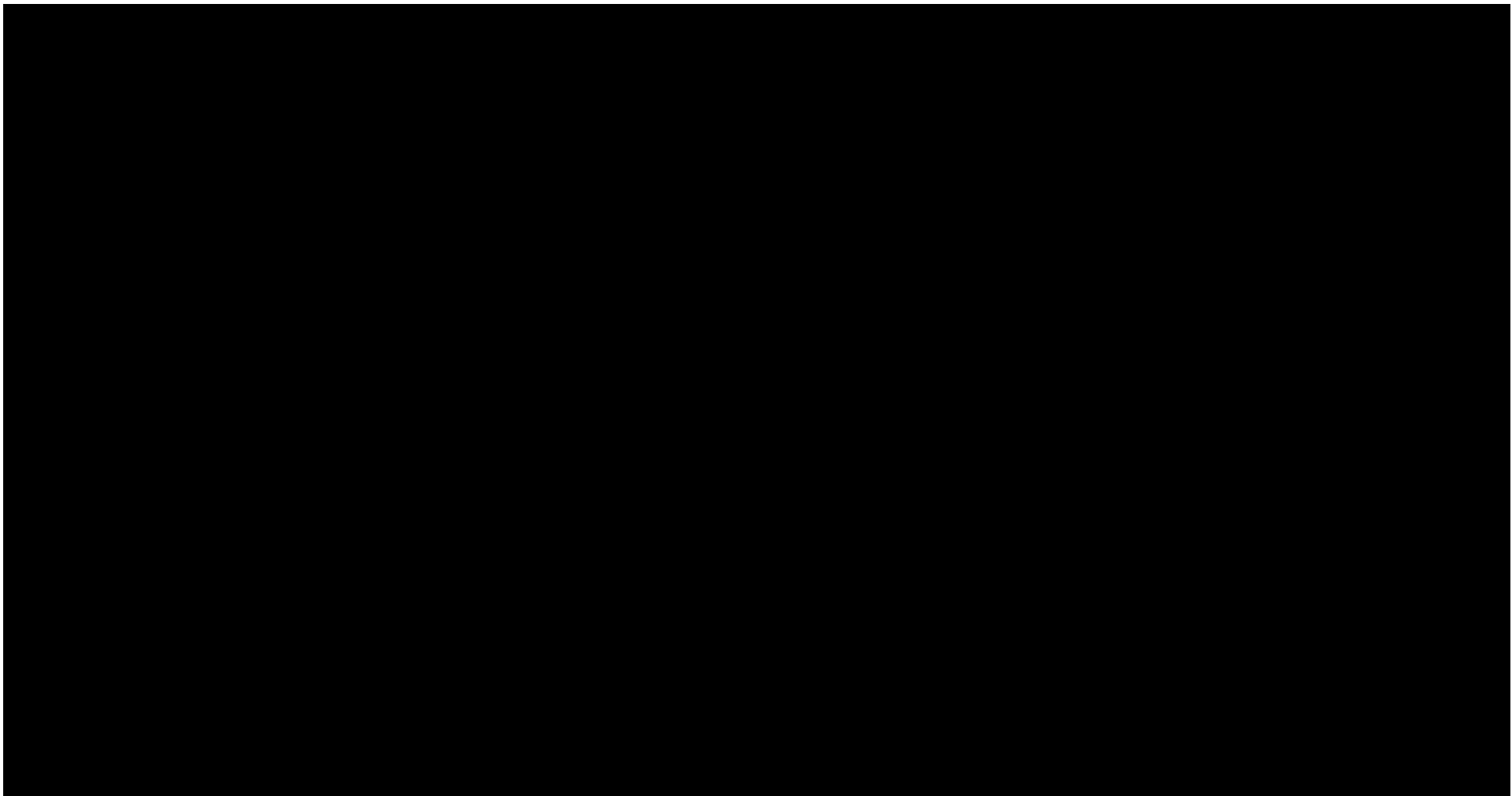
Status:
Page:

Final
Page 1429 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

[illegible]

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

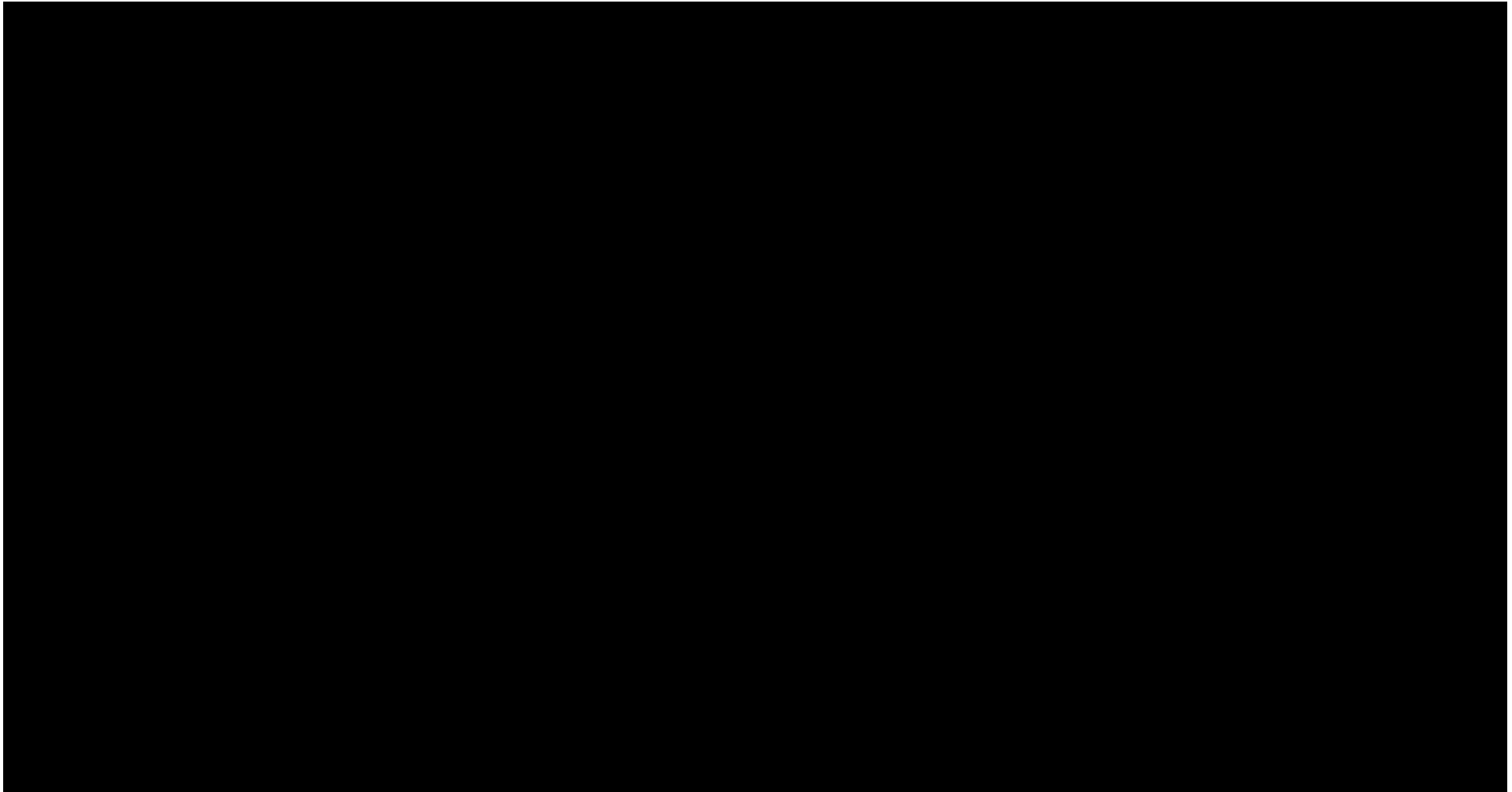
Status:
Page:

Final
Page 1433 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

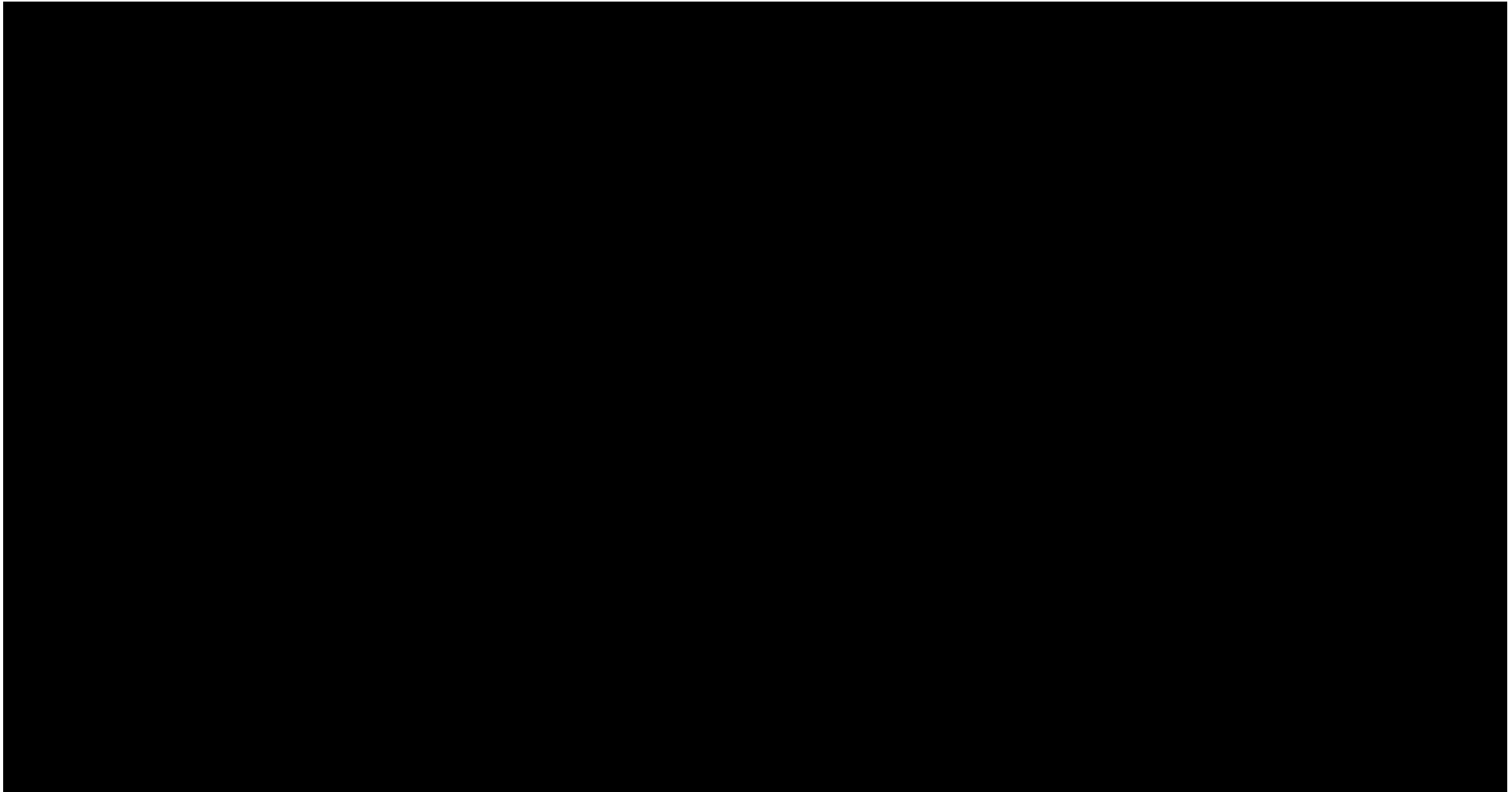
Status:
Page:

Final
Page 1434 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

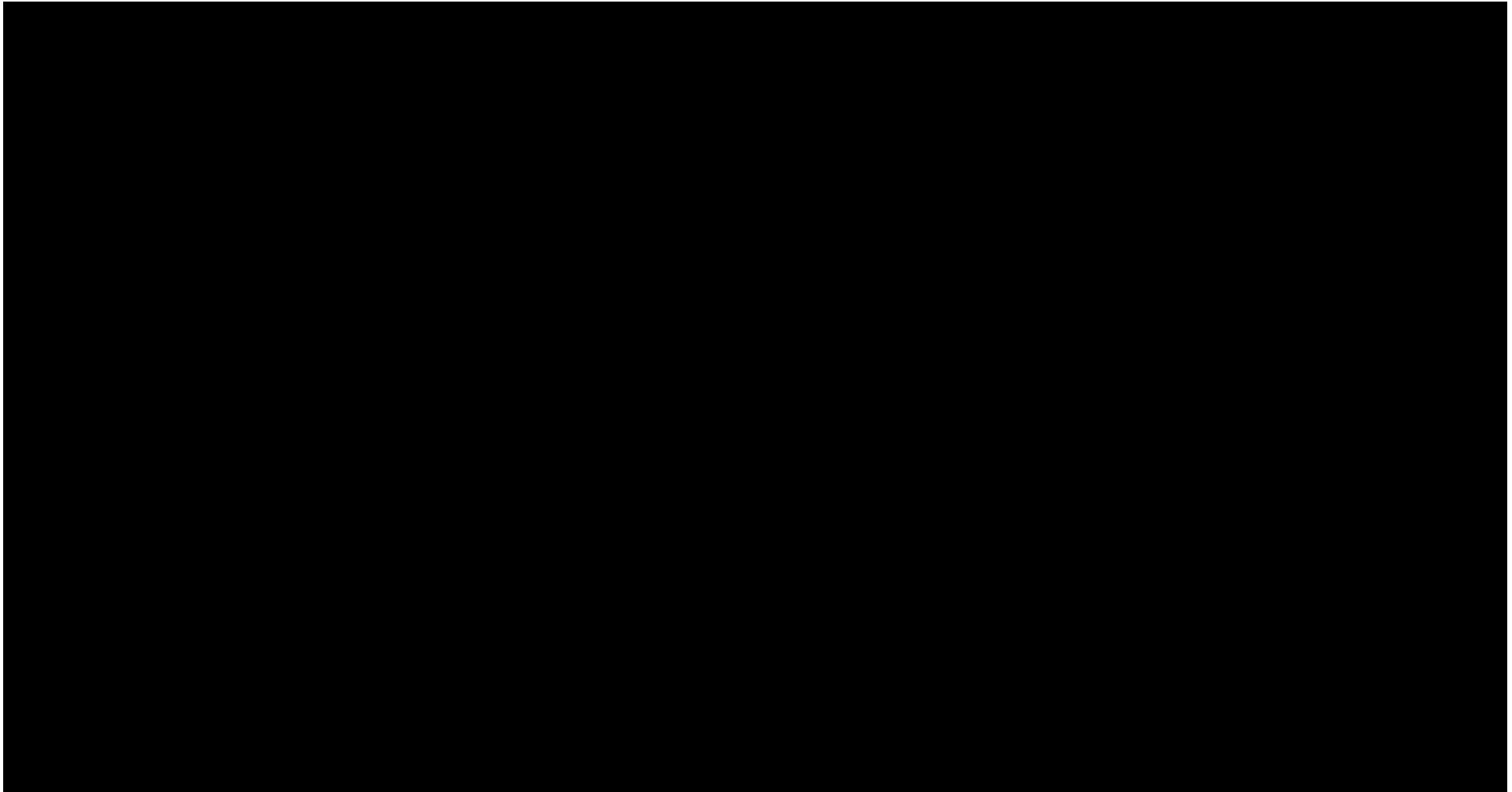
Status:
Page:

Final
Page 1435 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

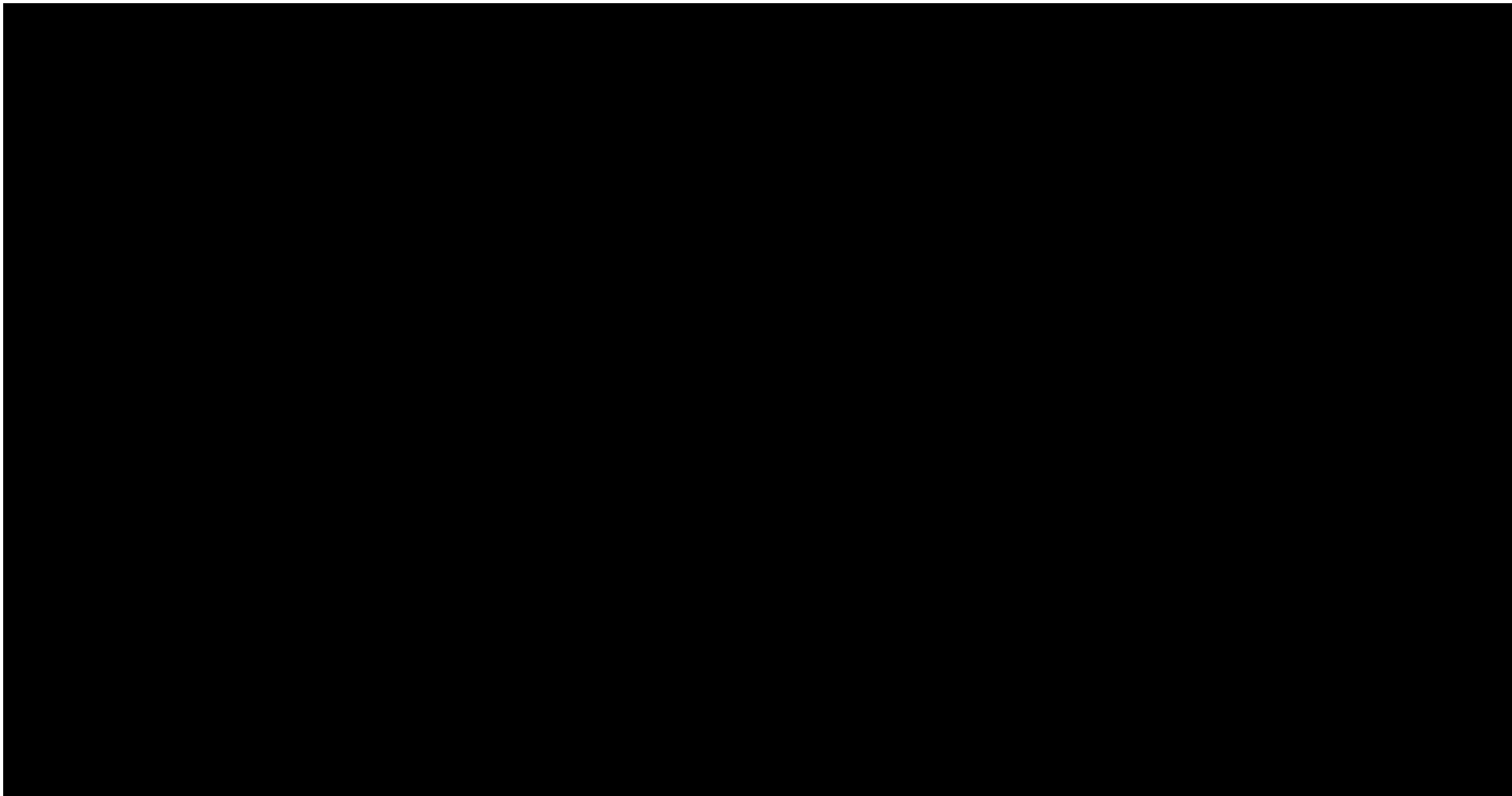
Status:
Page:

Final
Page 1436 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

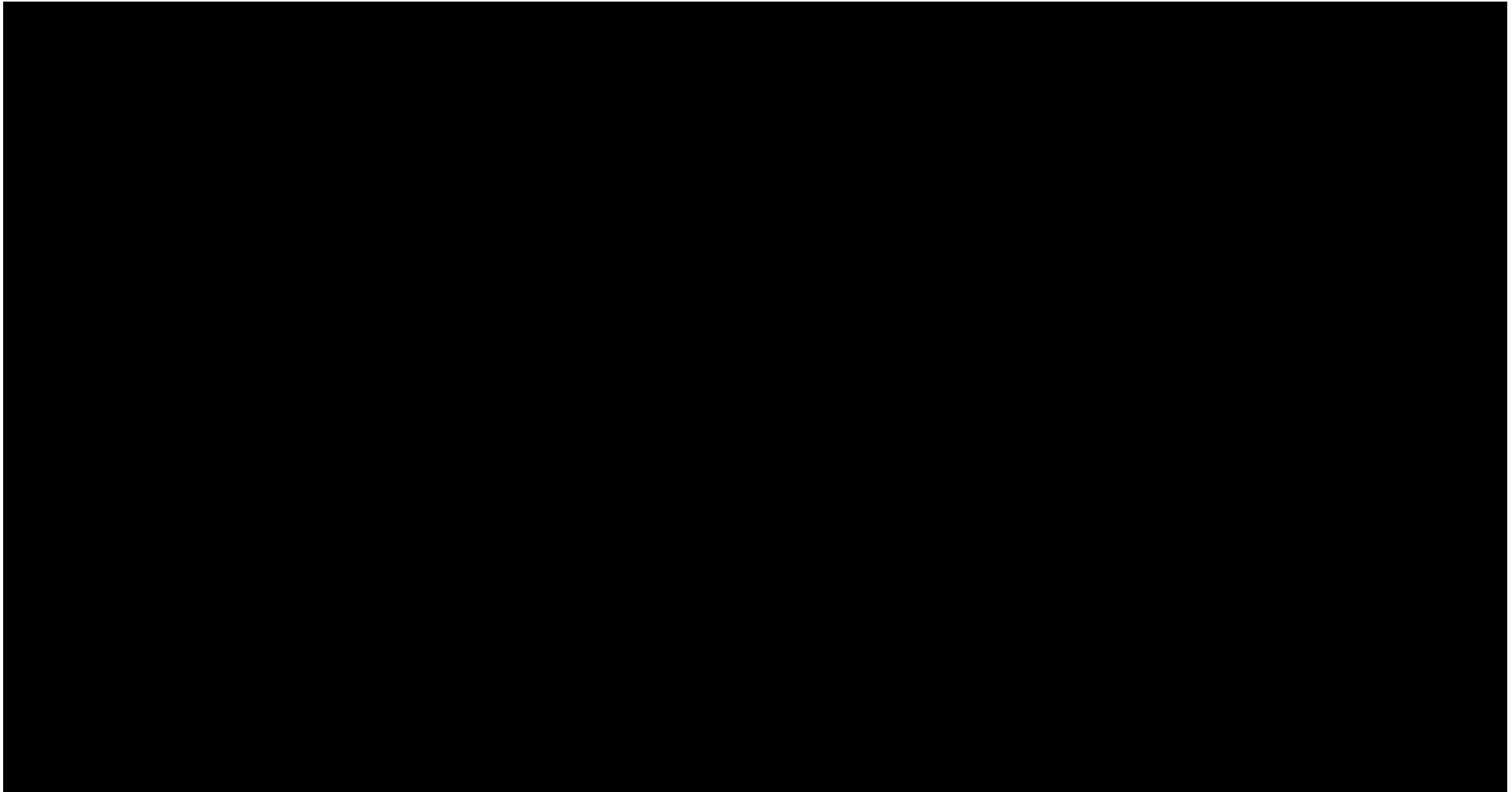
Status:
Page:

Final
Page 1438 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

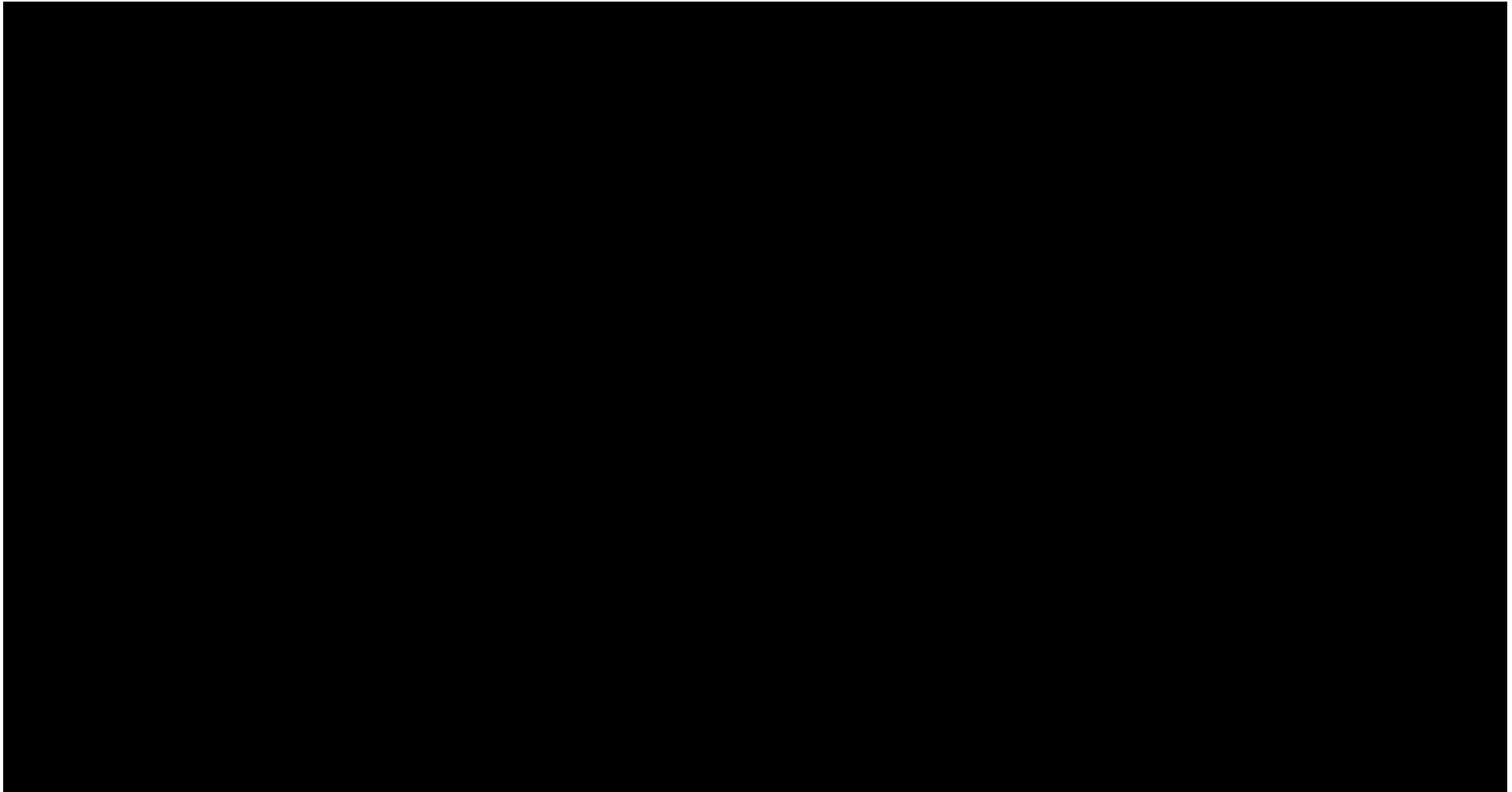
Status:
Page:

Final
Page 1439 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

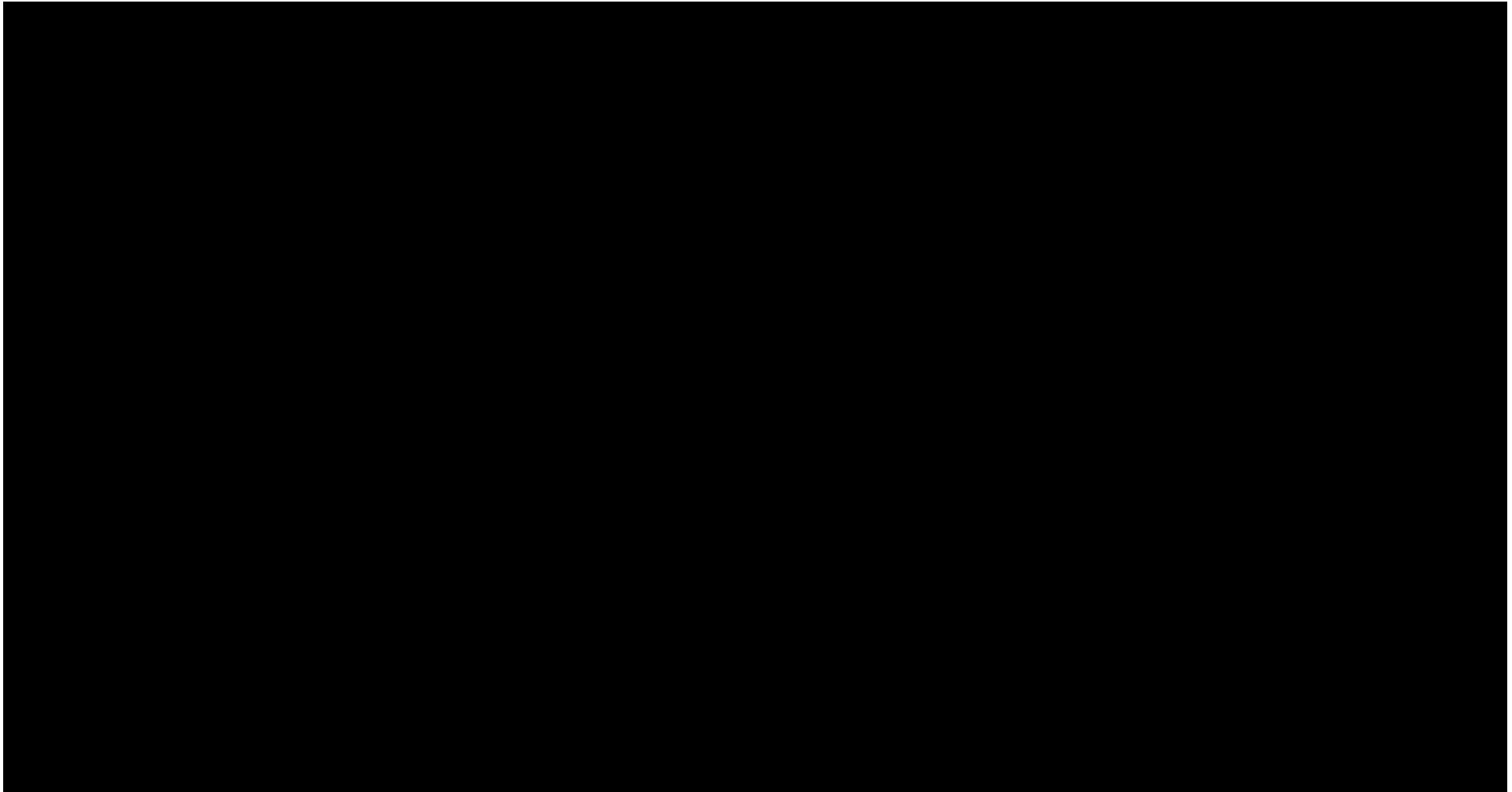
Status:
Page:

Final
Page 1443 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

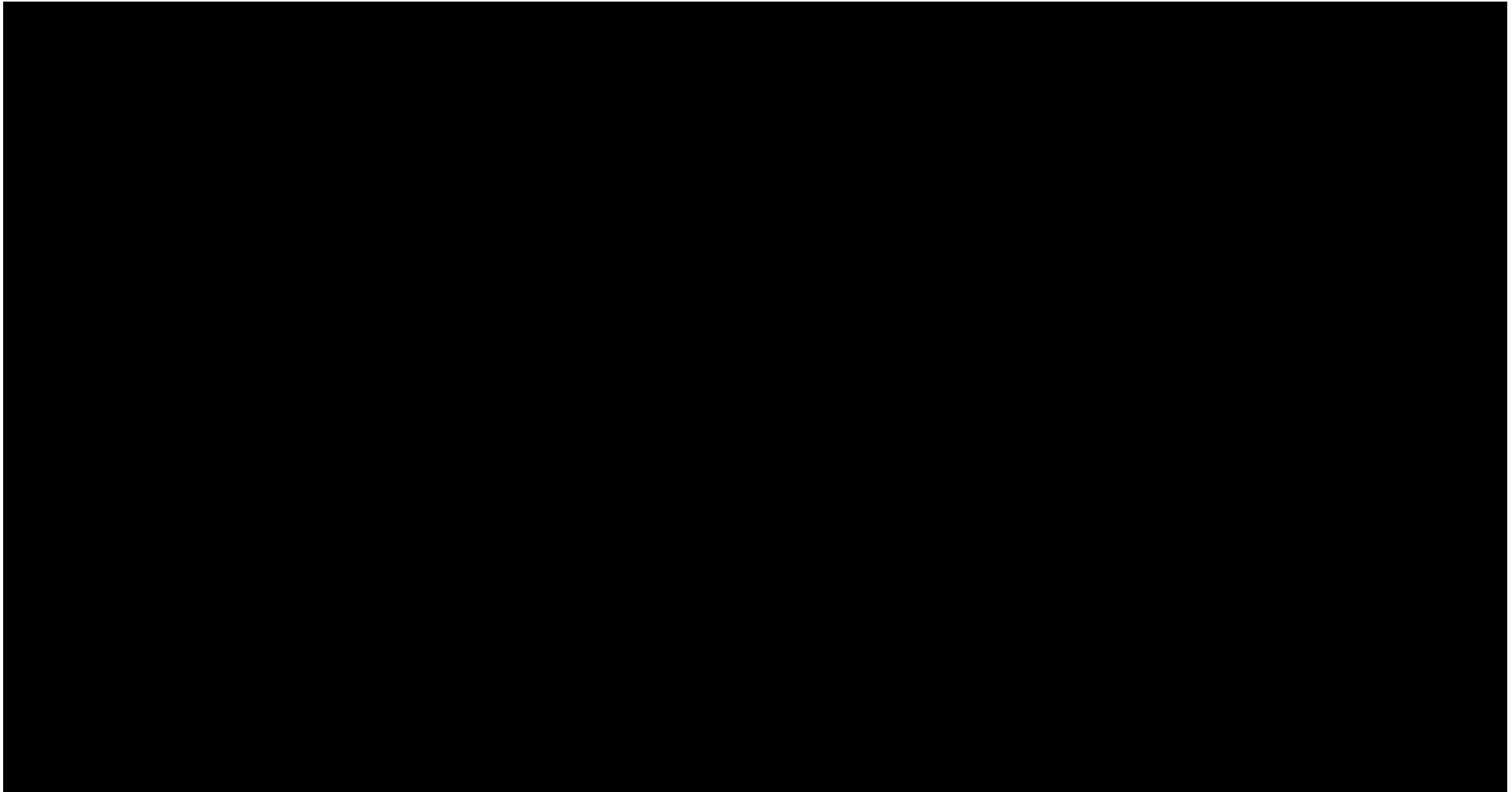
Status:
Page:

Final
Page 1446 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
---------------	-----------	--------------	--------------	-----------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

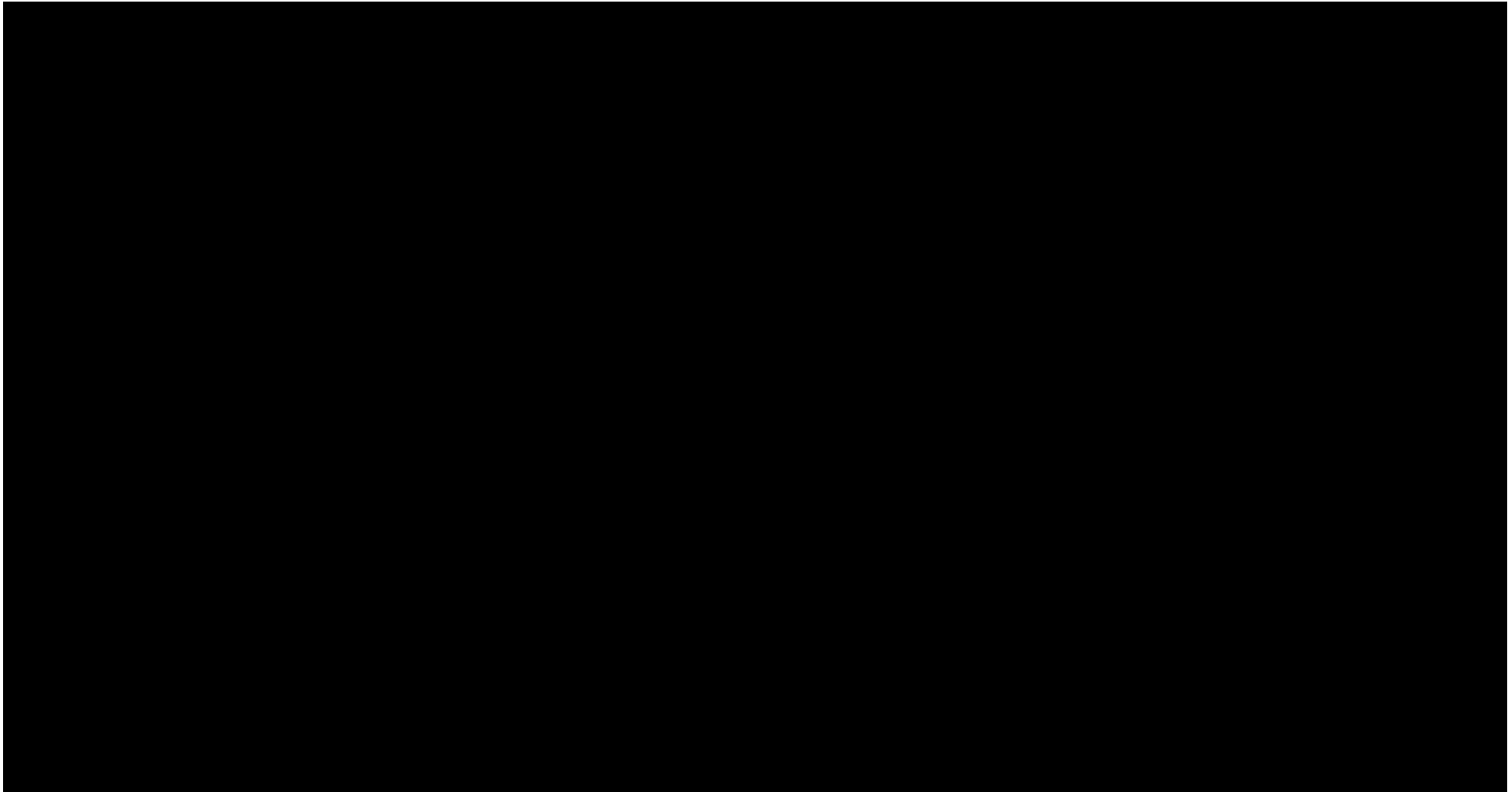
Status:
Page:

Final
Page 1448 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

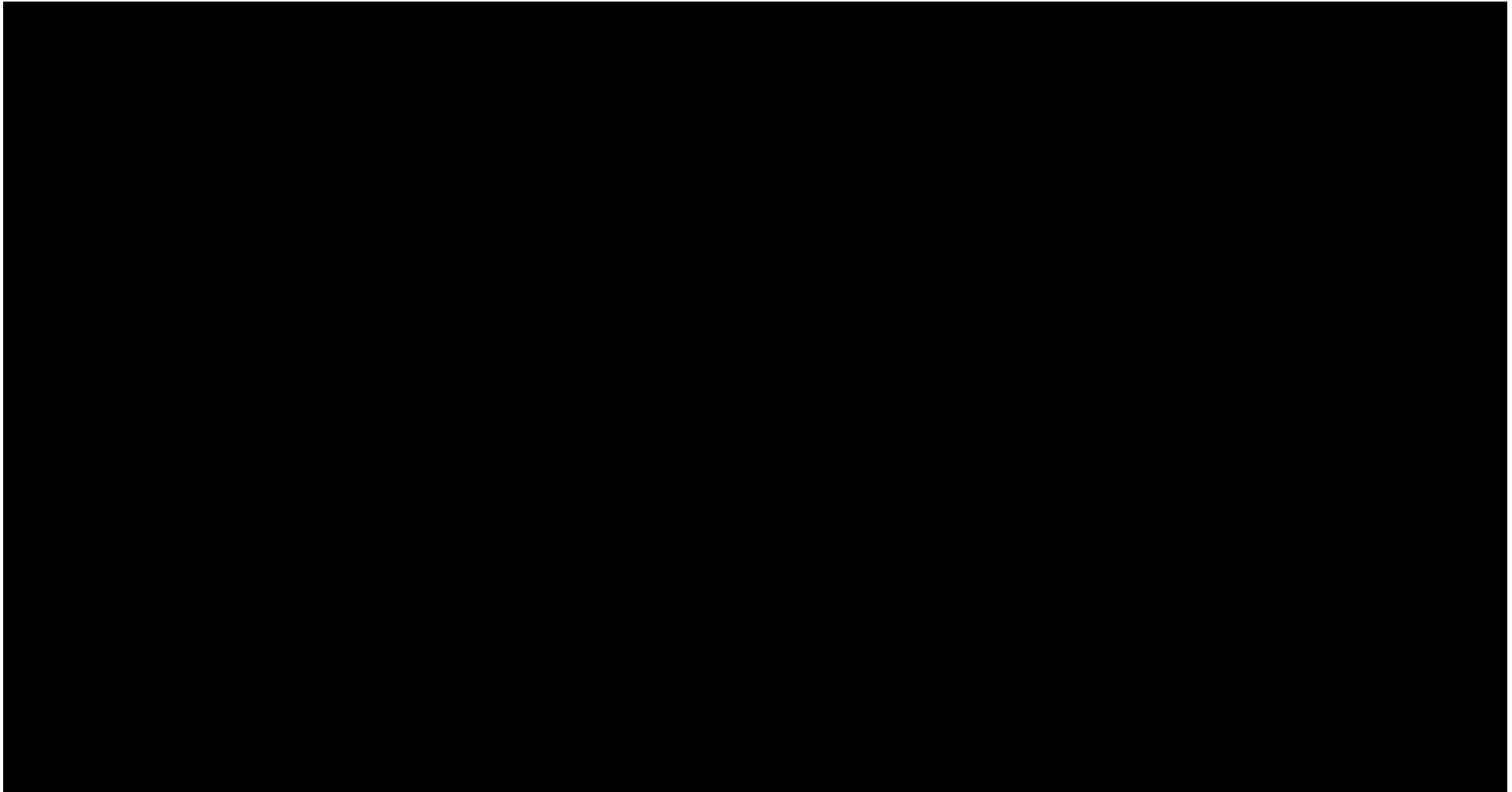
Status:
Page:

Final
Page 1449 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

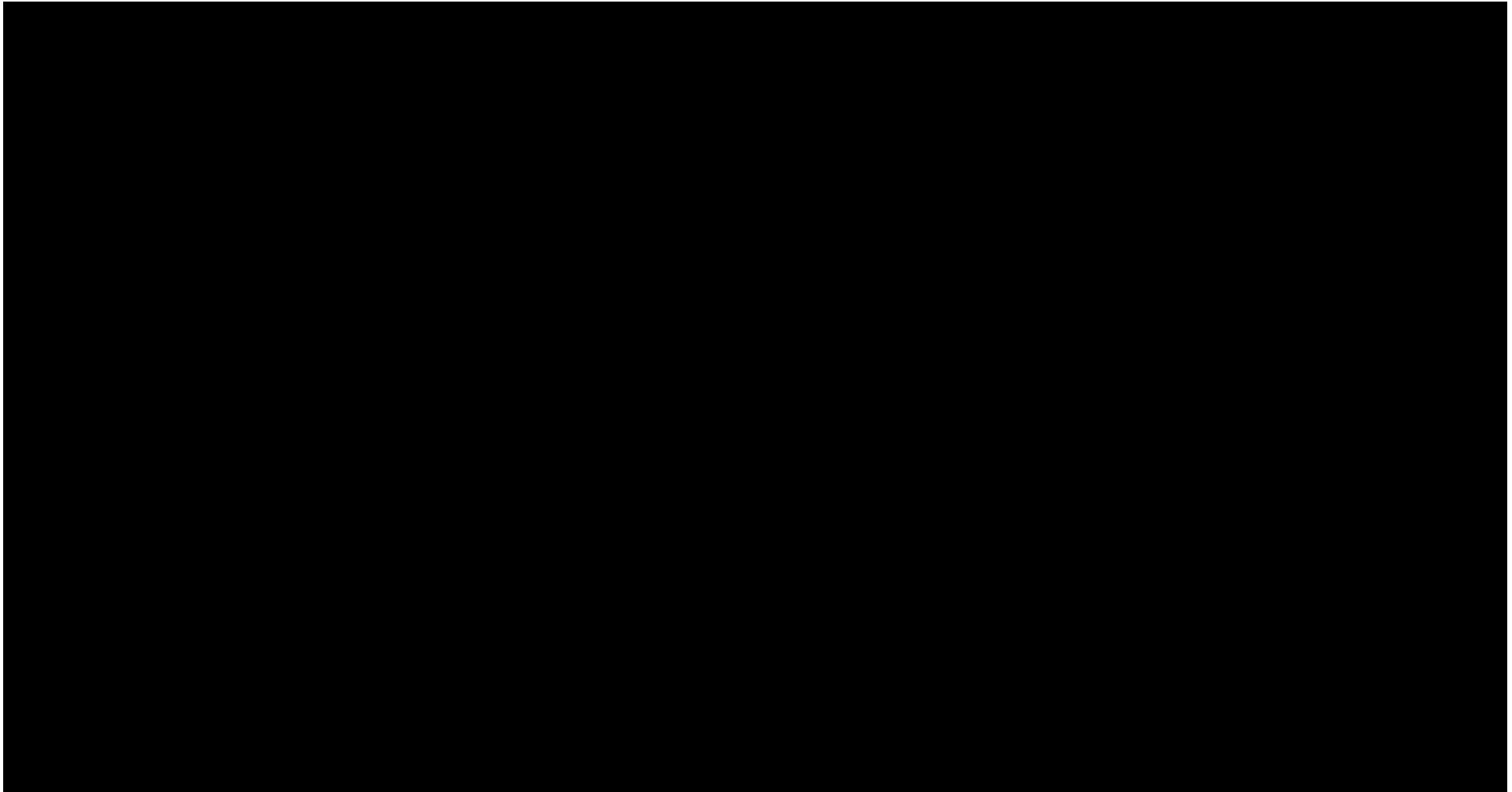
Status:
Page:

Final
Page 1451 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

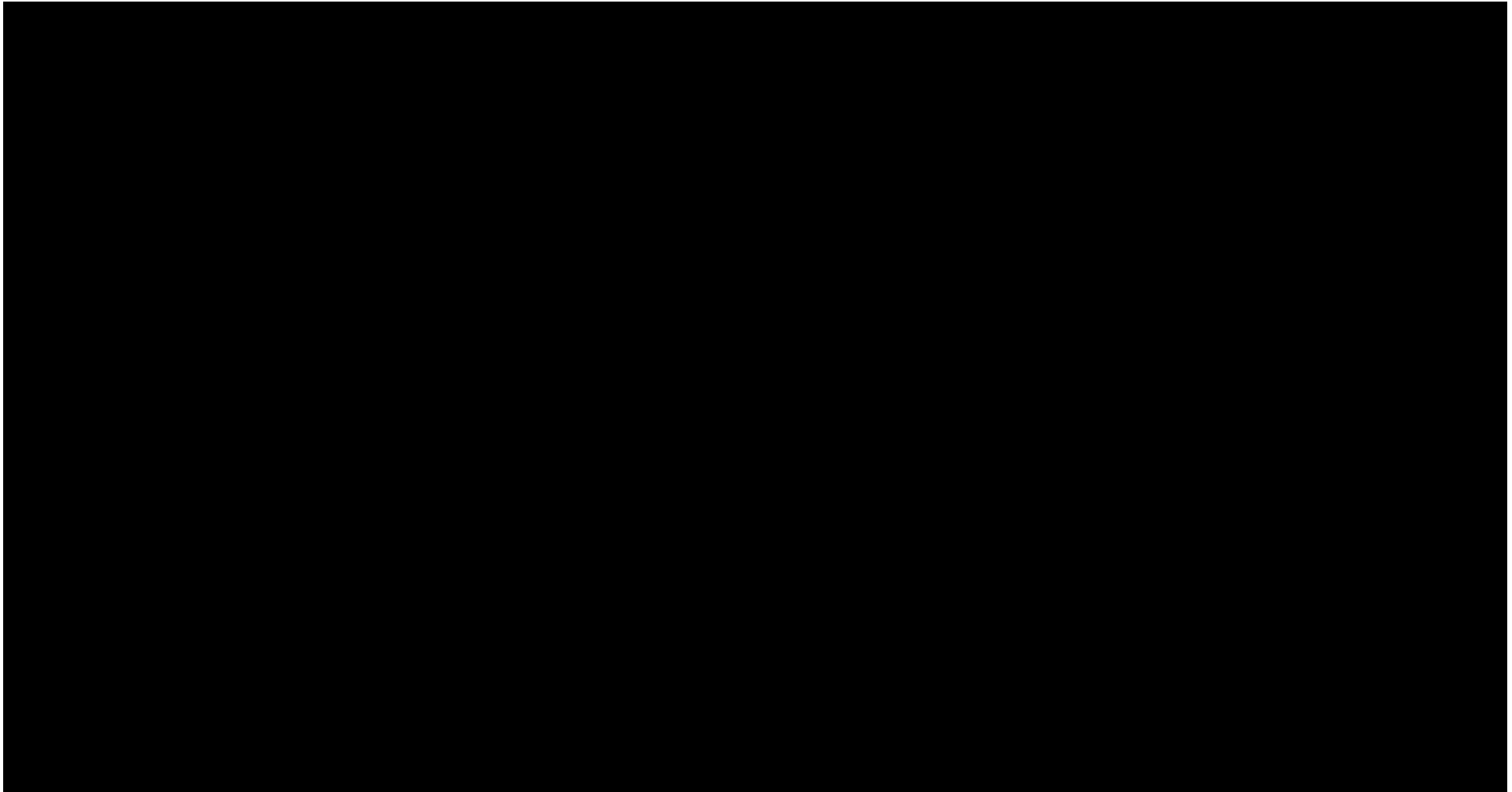
Status:
Page:

Final
Page 1457 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------

</									

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

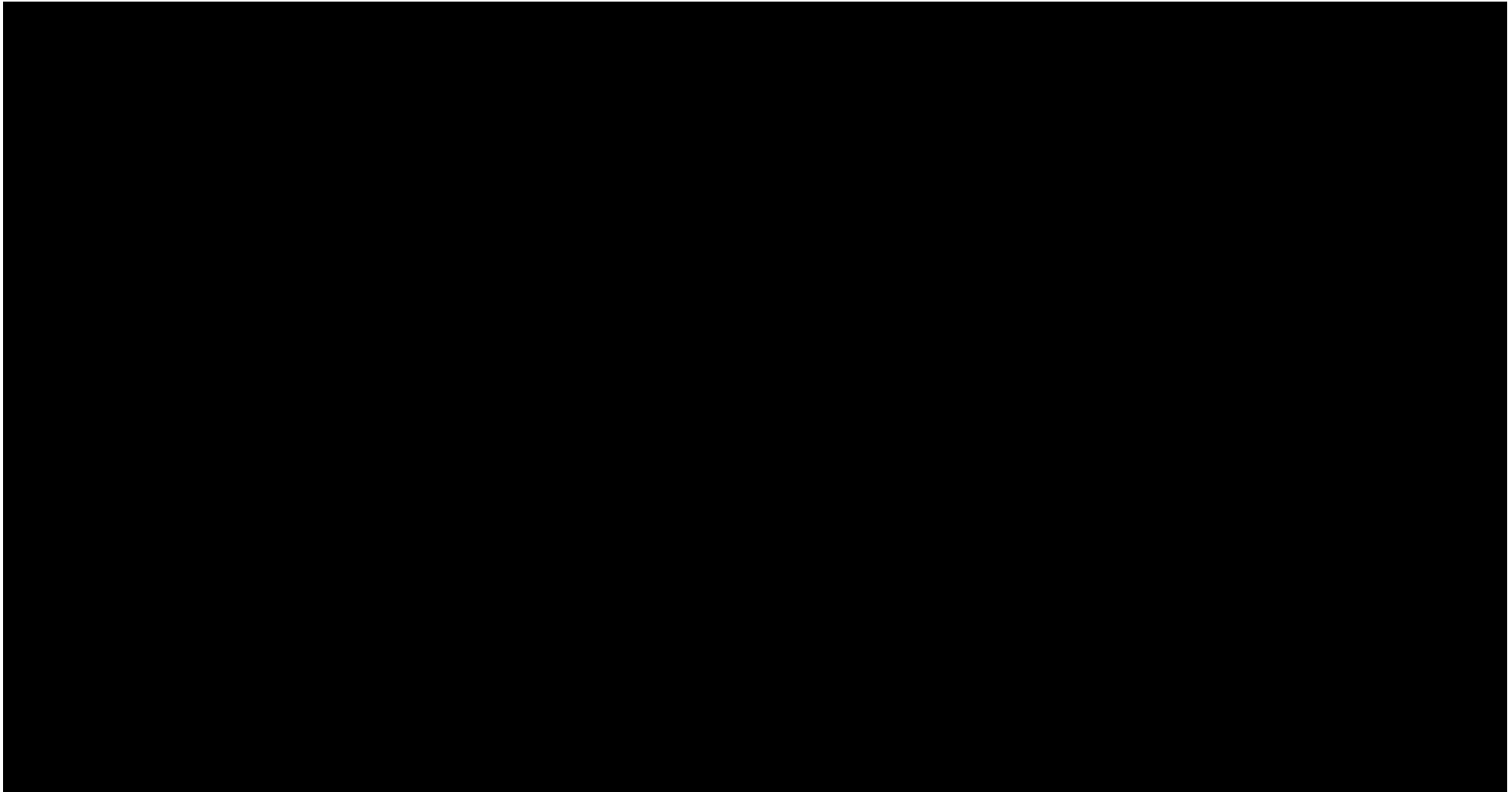
Status:
Page:

Final
Page 1460 of 2239

Novo Nordisk

Fundoscopy / Fundusphotography Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Date	Eye	Interpretation	Comment
------------	-----------	-----------	-----------	--------------	-------	------	-----	----------------	---------



14.3.7.4: Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

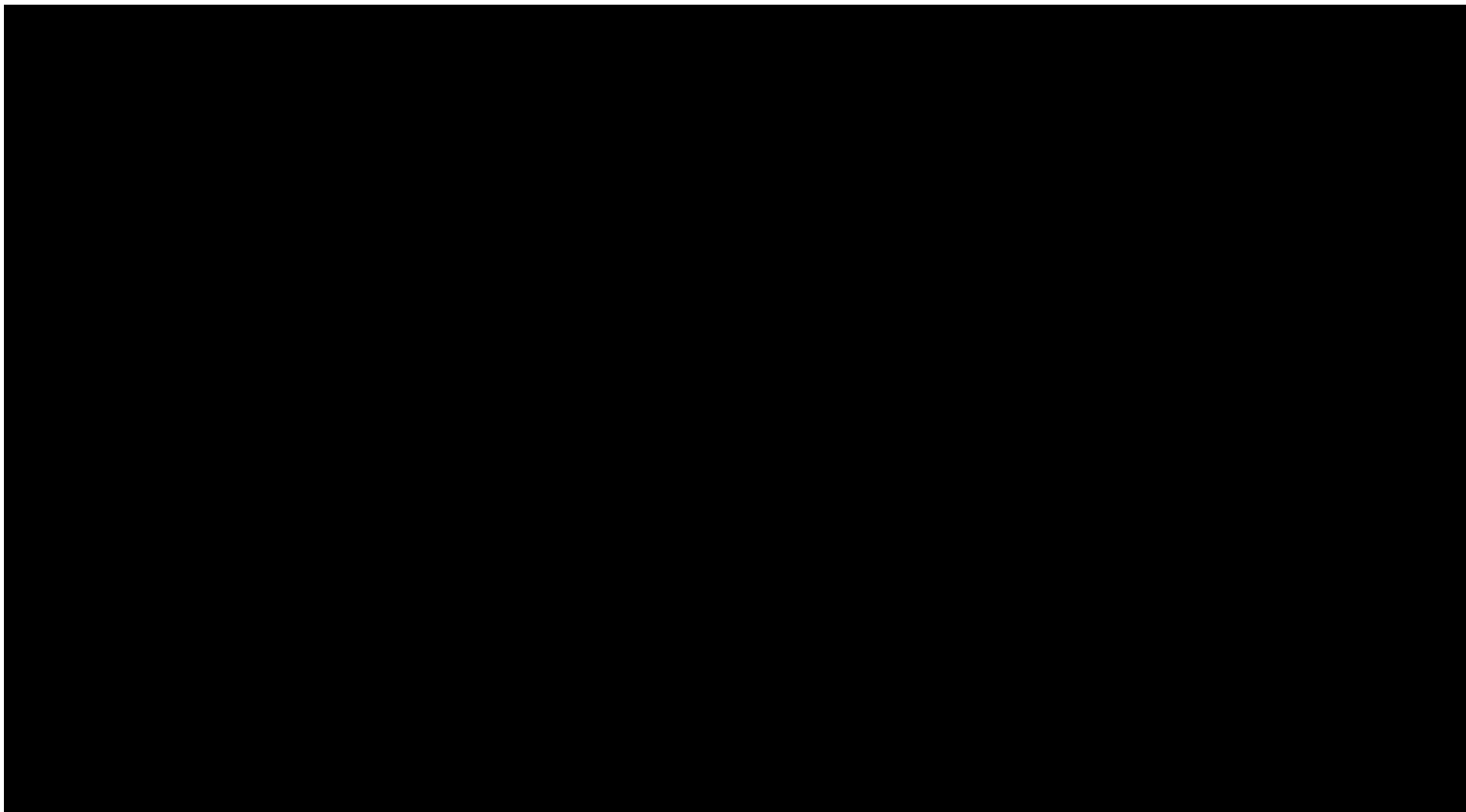
Status:
Page:

Final
Page 1462 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

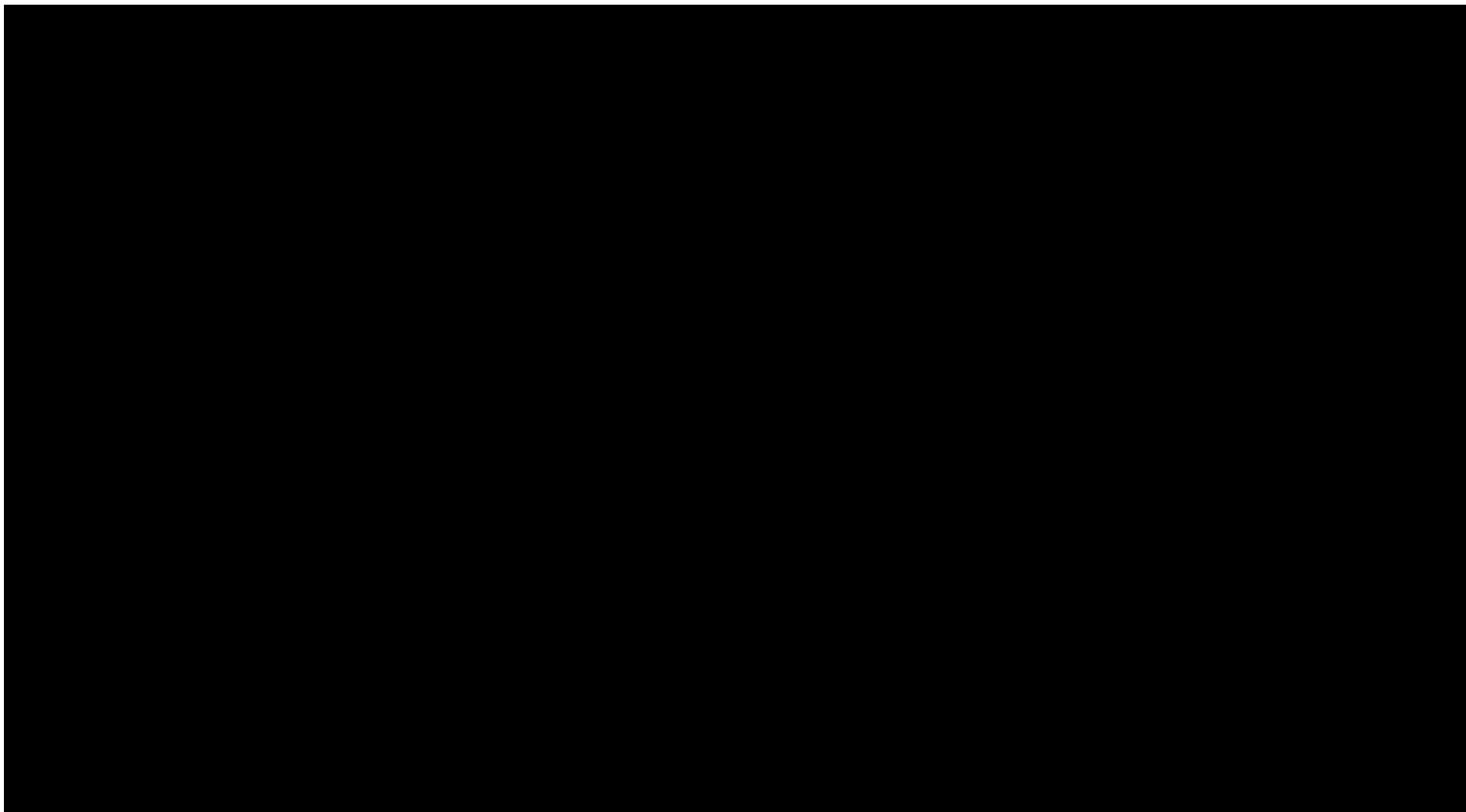
Status:
Page:

Final
Page 1463 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1464 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1465 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

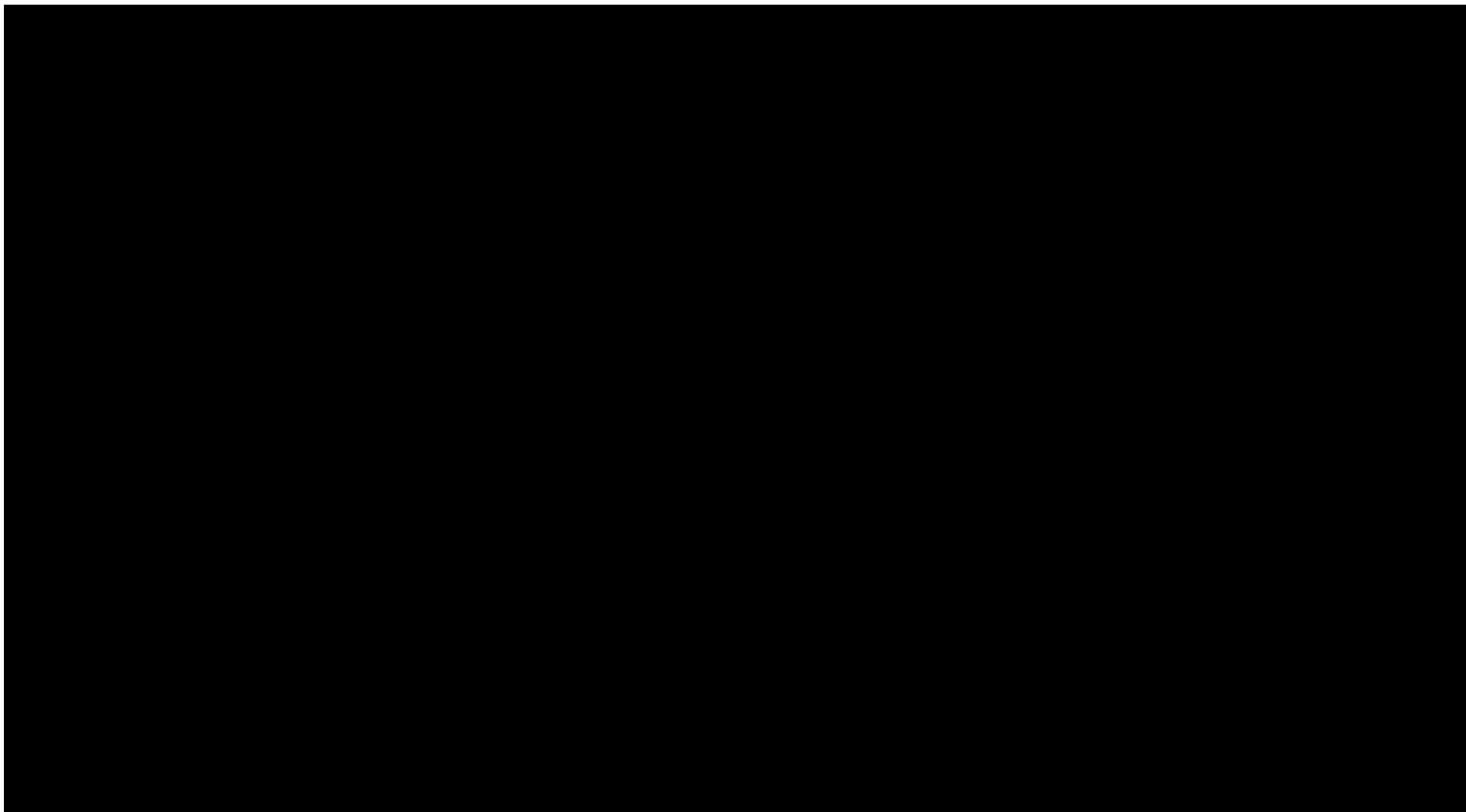
Status:
Page:

Final
Page 1466 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

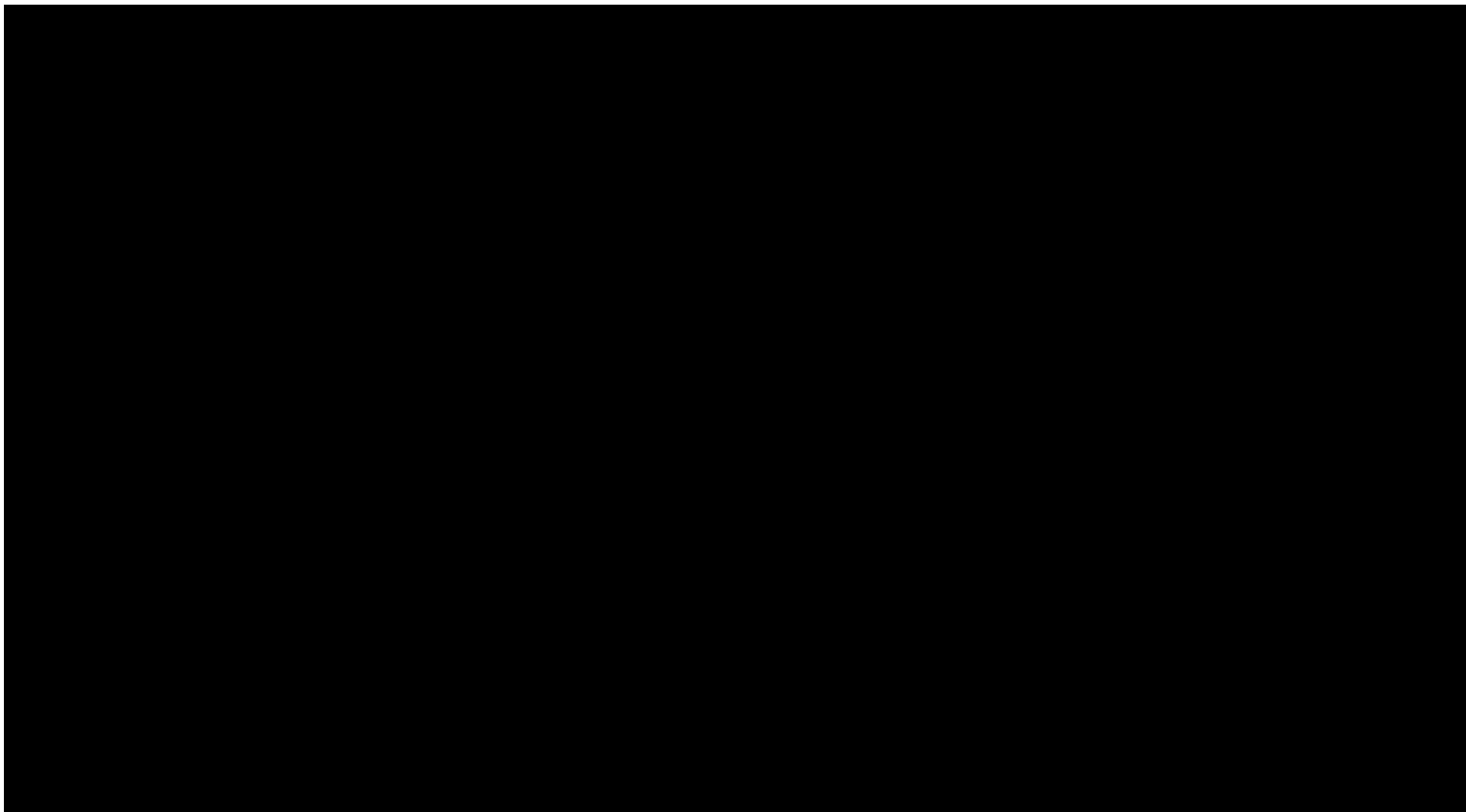
Status:
Page:

Final
Page 1467 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

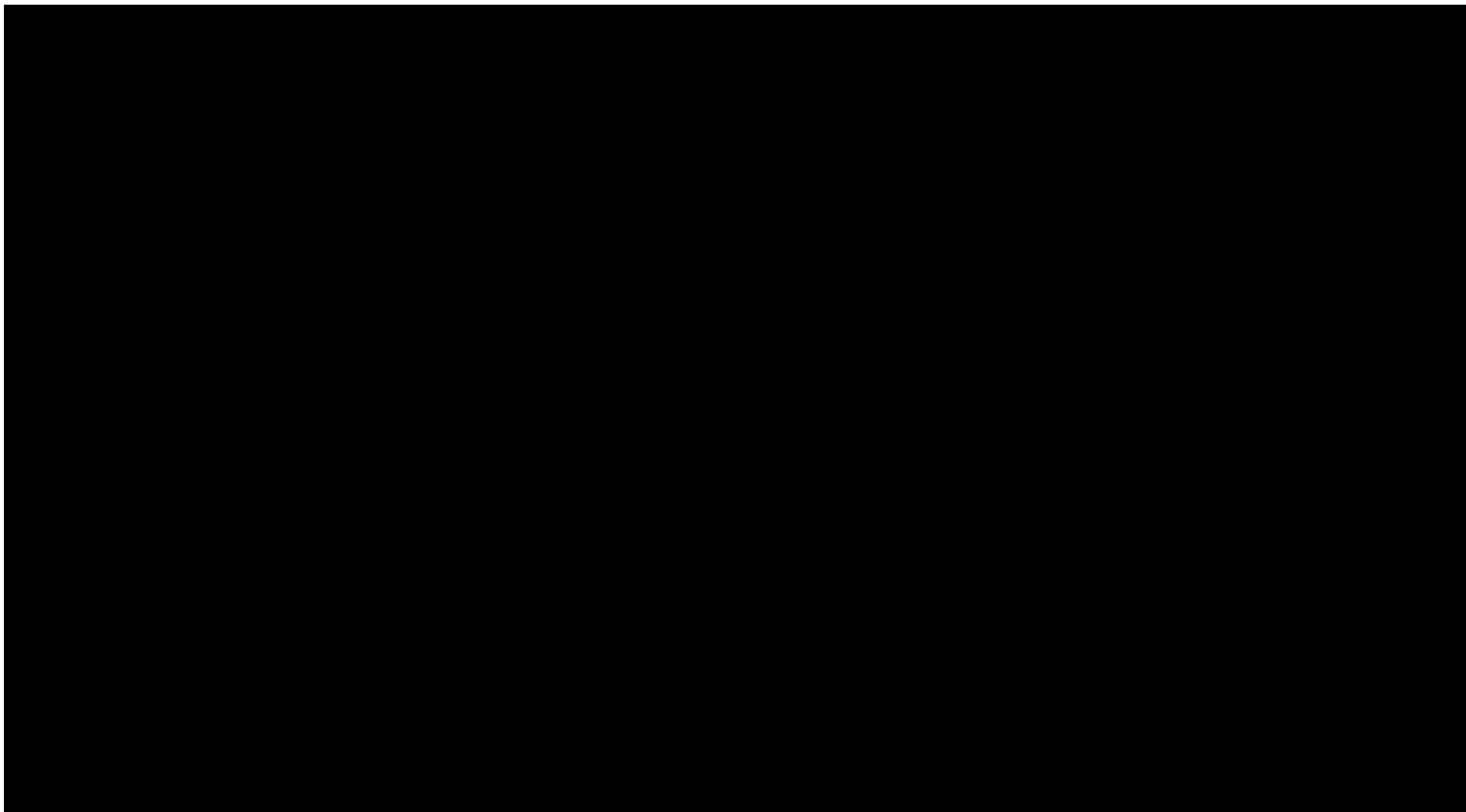
Status:
Page:

Final
Page 1468 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1469 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

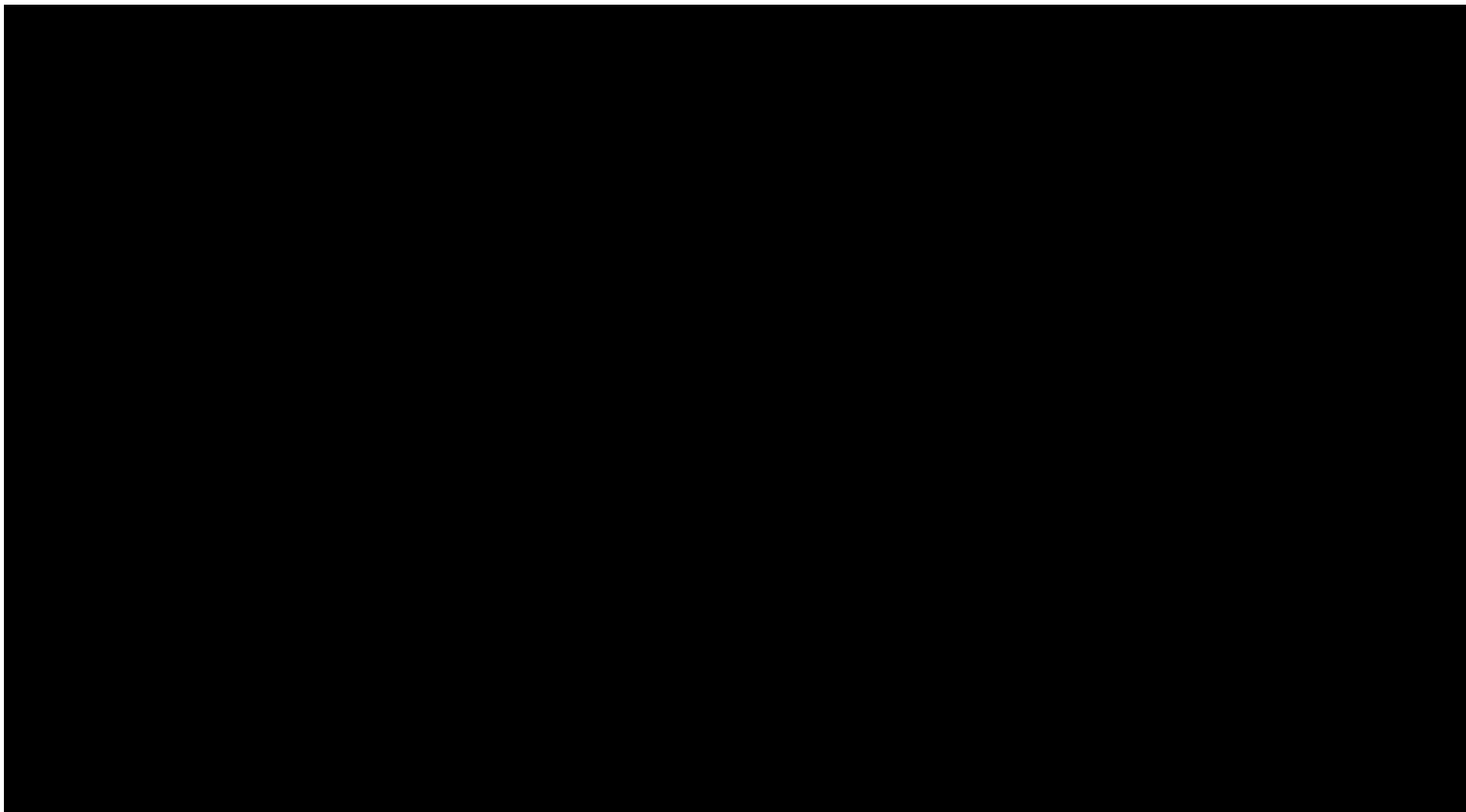
Status:
Page:

Final
Page 1470 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1471 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1472 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

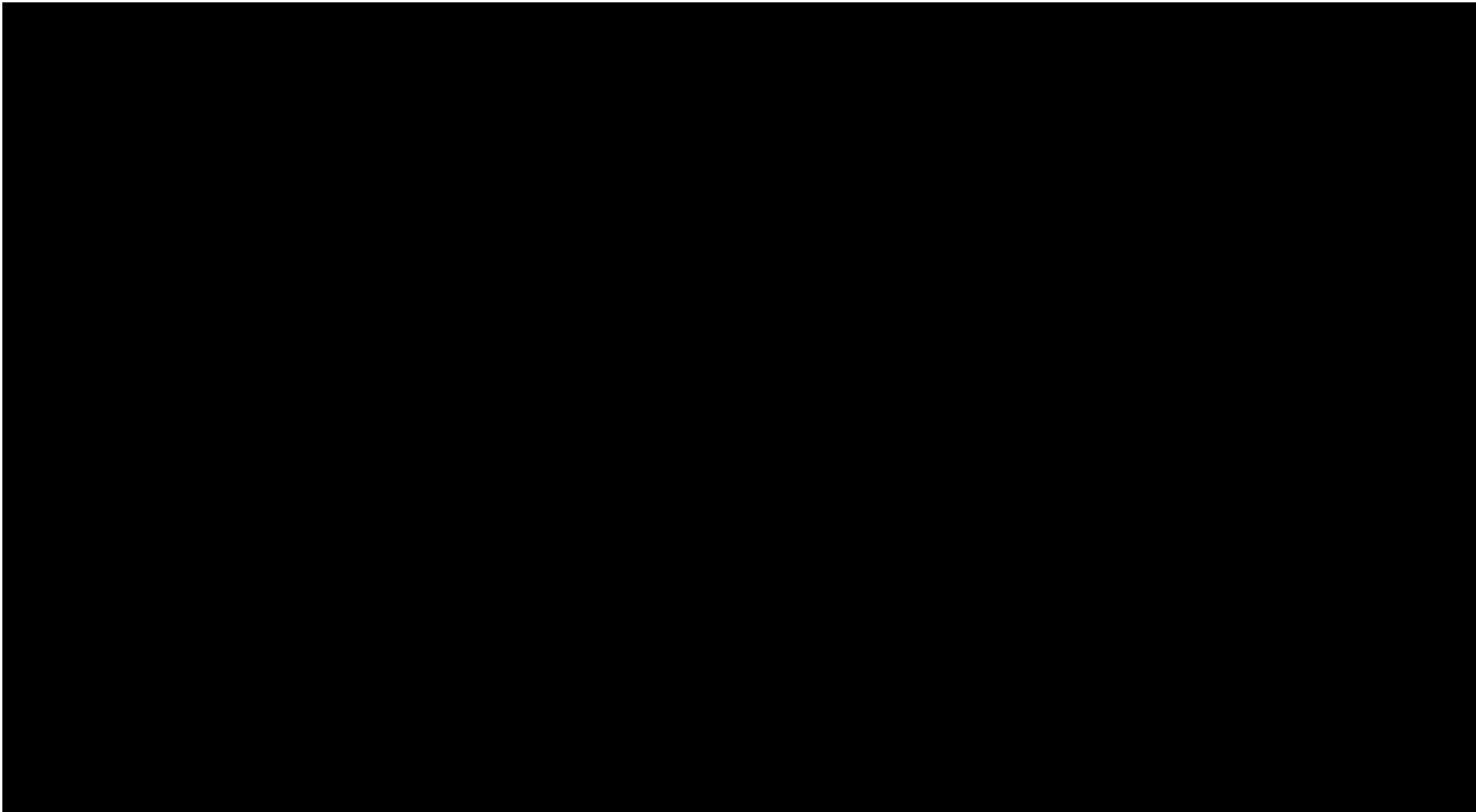
Status:
Page:

Final
Page 1473 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



[illegible]

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

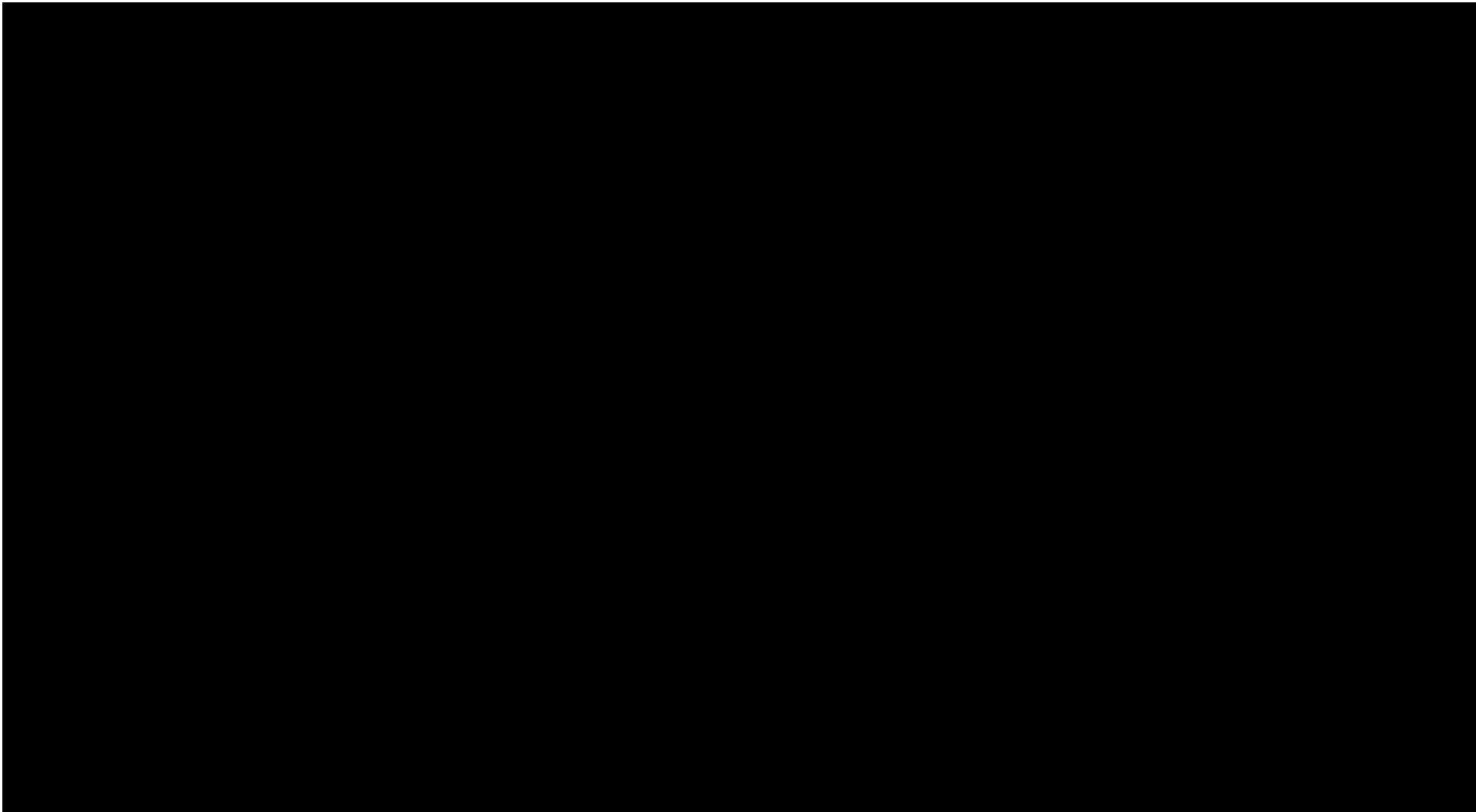
Status:
Page:

Final
Page 1475 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1476 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1478 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1479 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

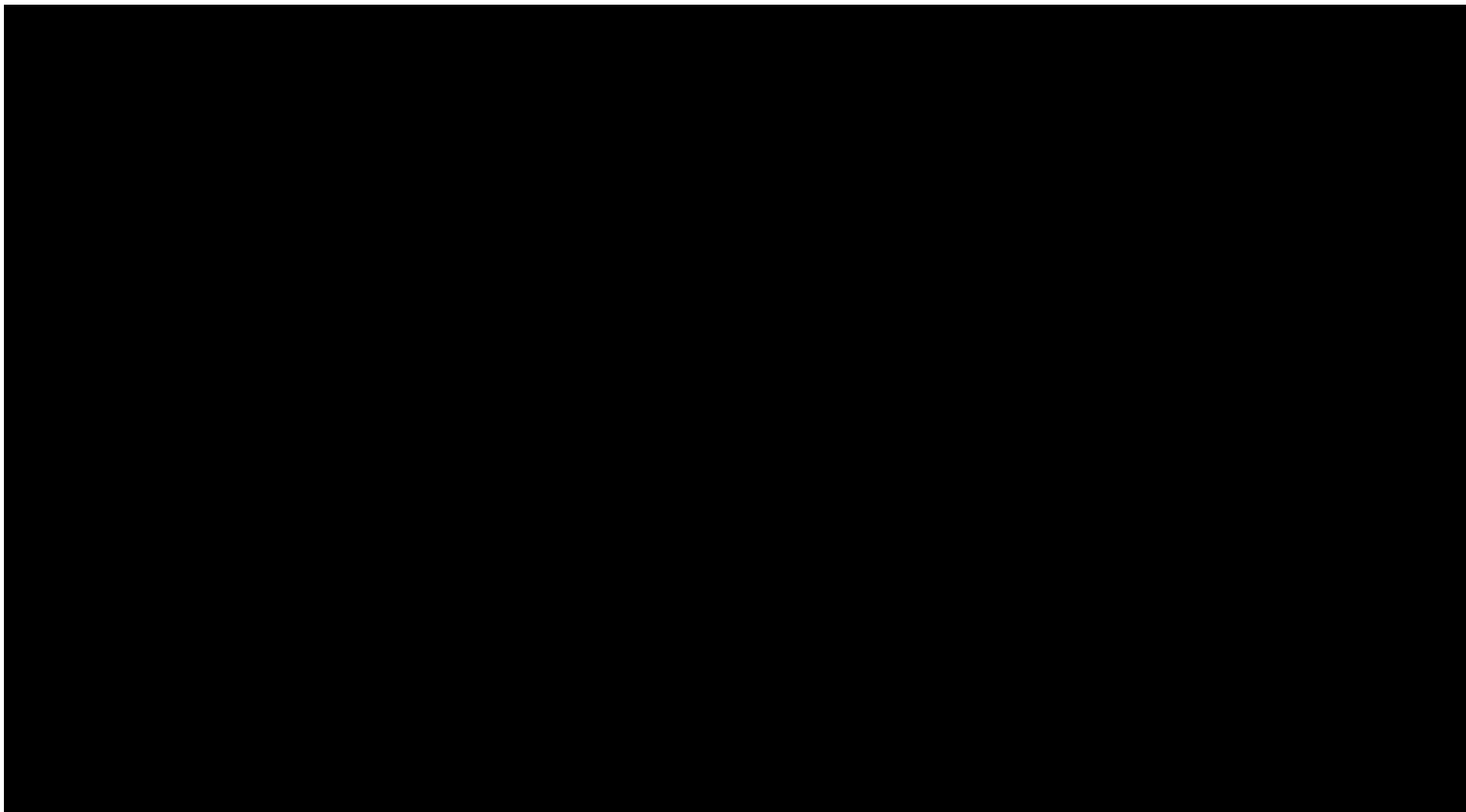
Status:
Page:

Final
Page 1480 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

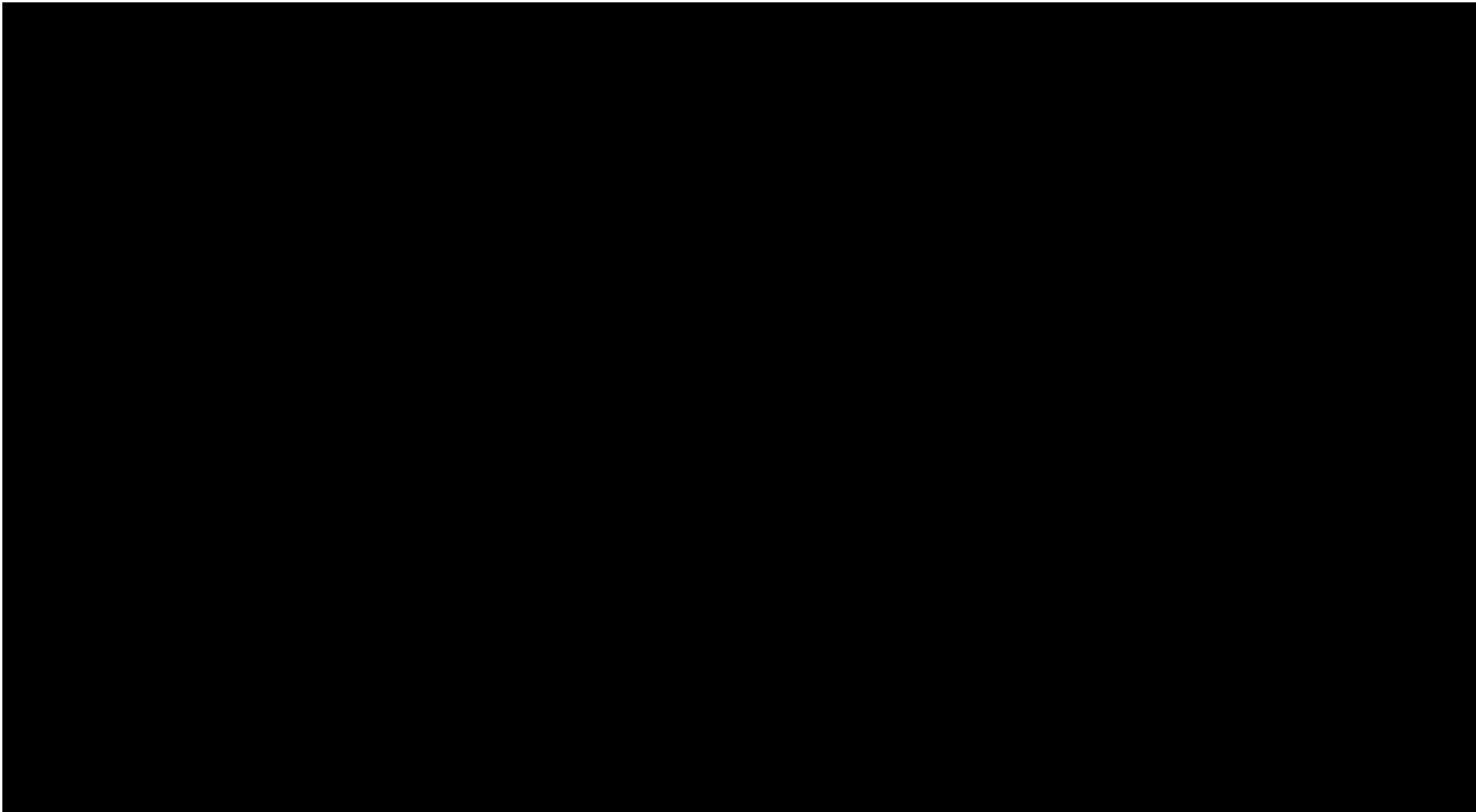
Status:
Page:

Final
Page 1481 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1482 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1483 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1484 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

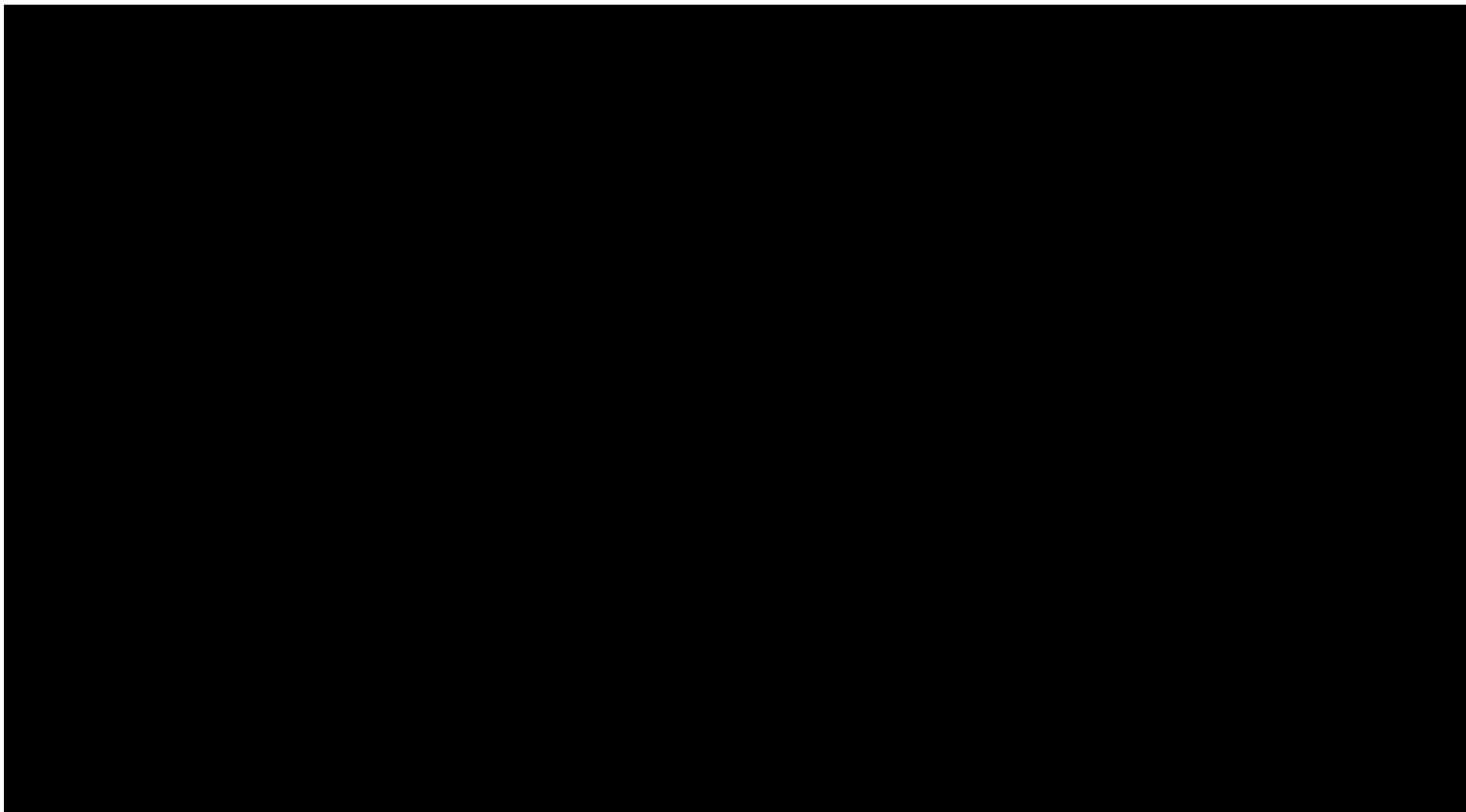
Status:
Page:

Final
Page 1485 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

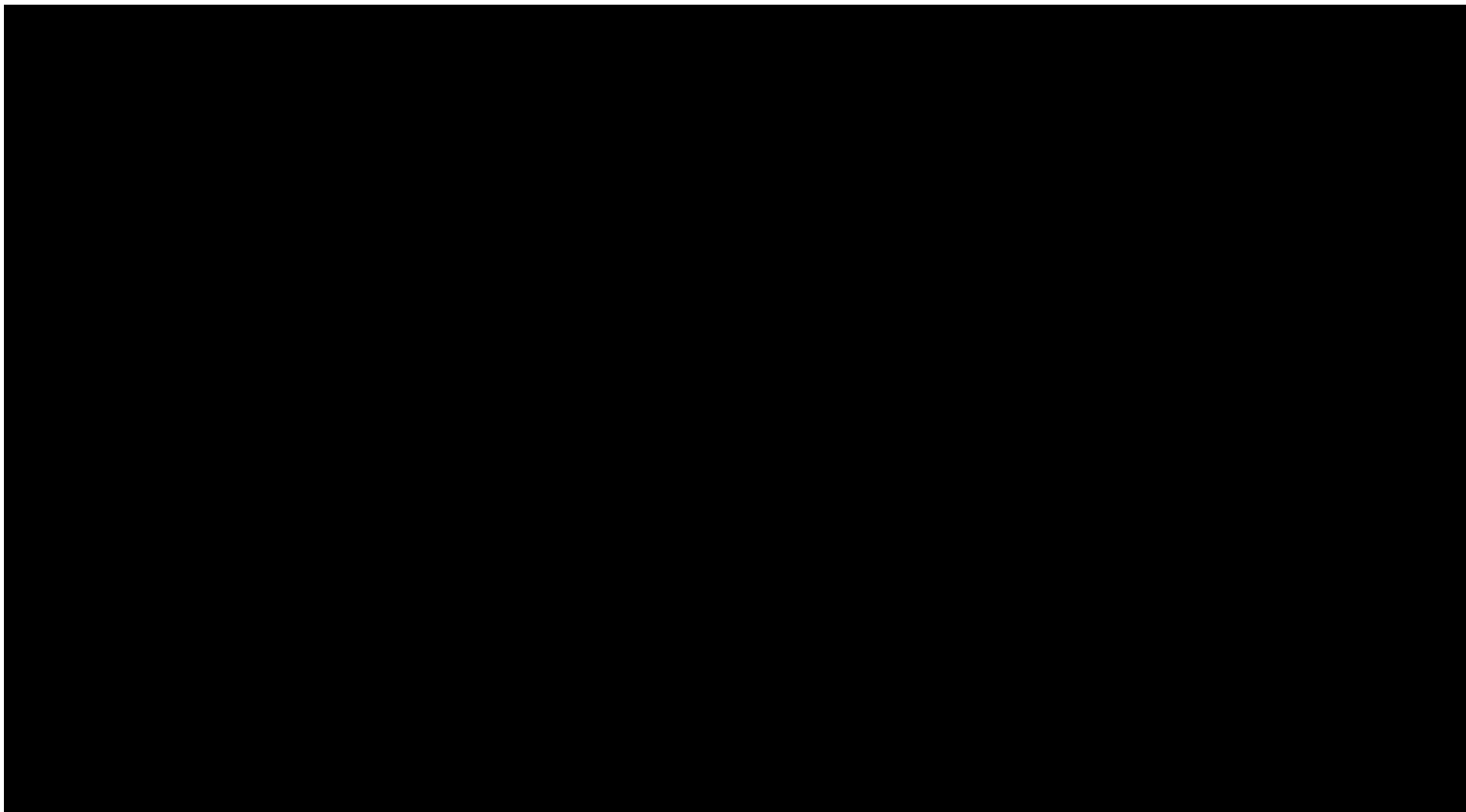
Status:
Page:

Final
Page 1486 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1487 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1488 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

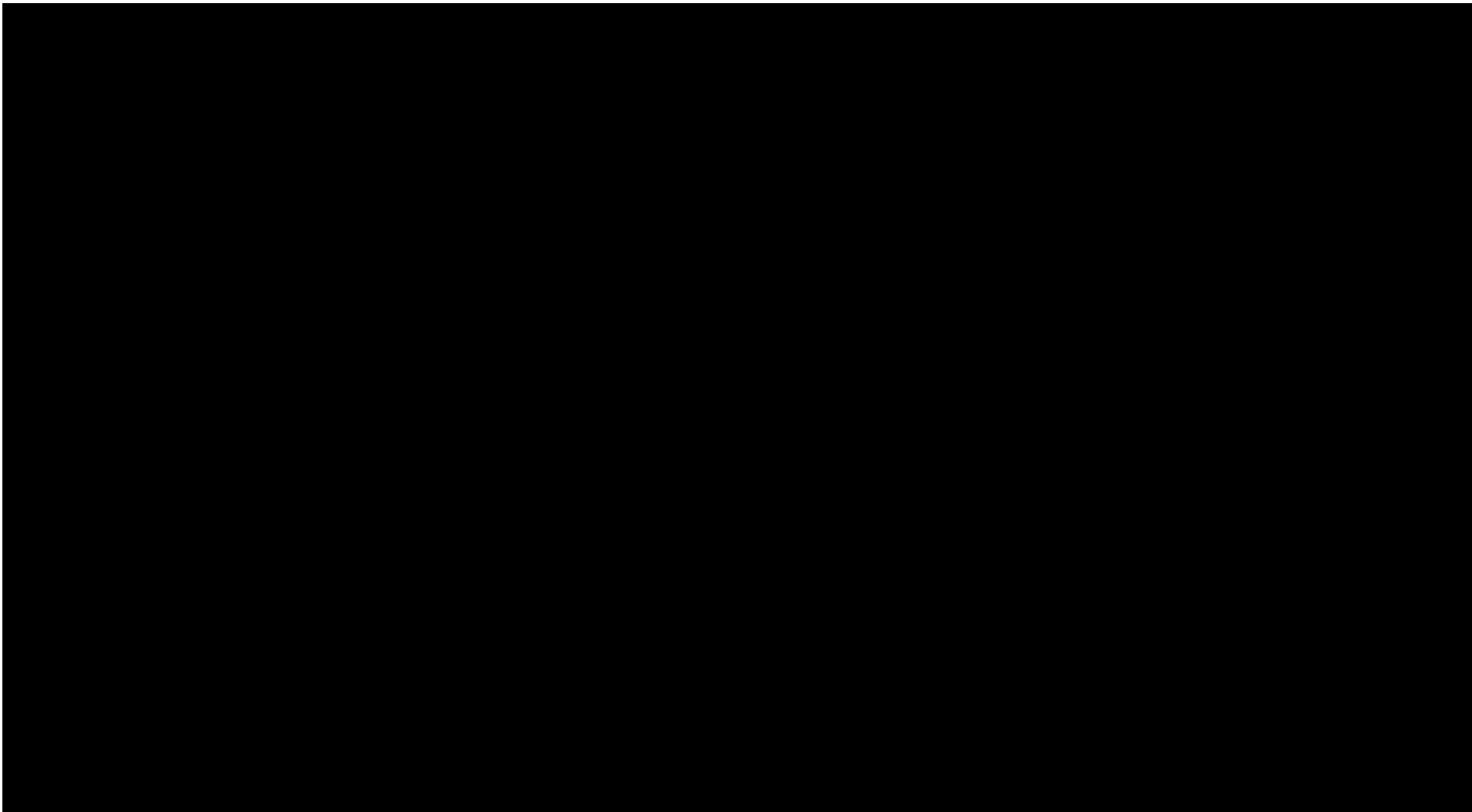
Status:
Page:

Final
Page 1489 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1490 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1491 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1493 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

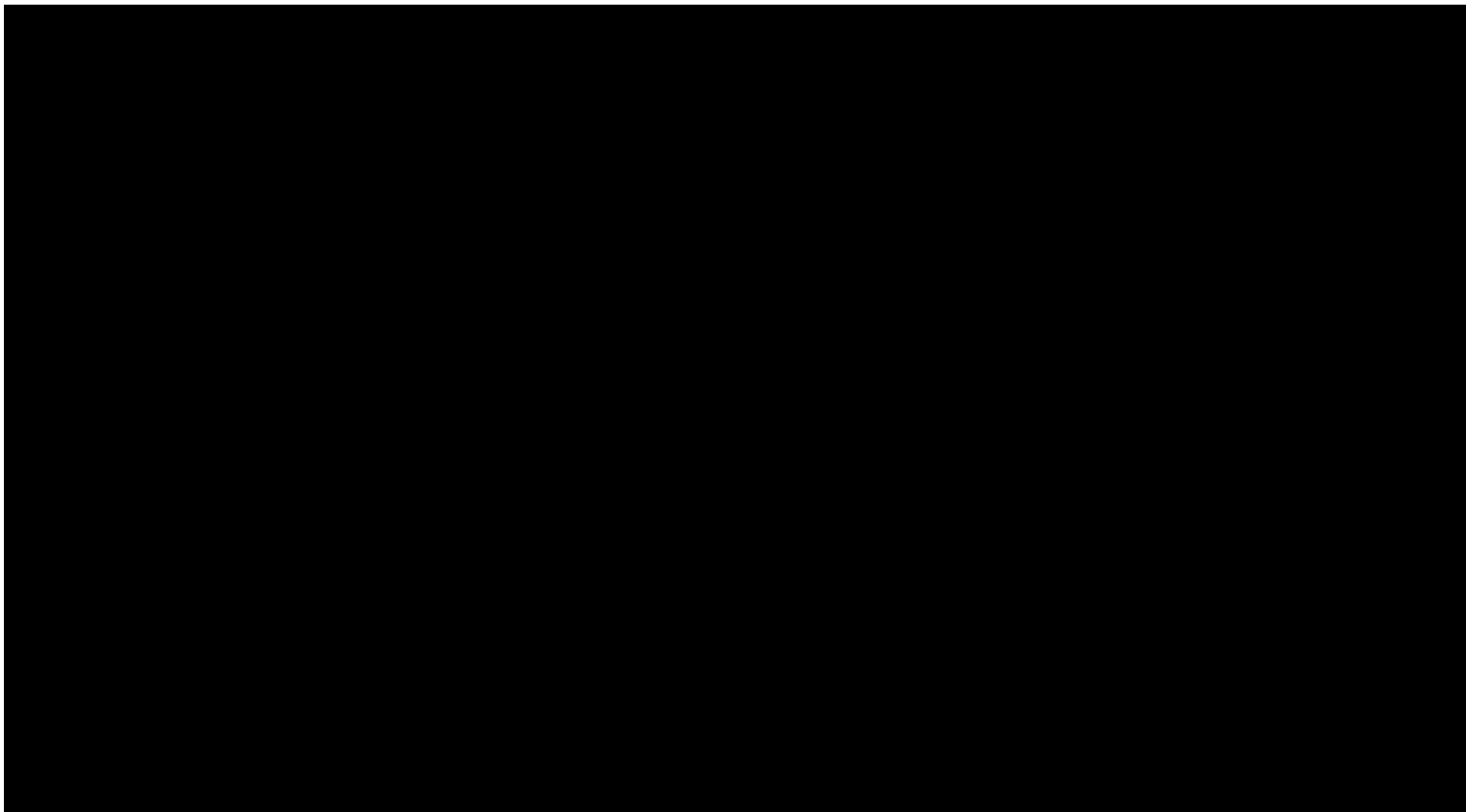
Status:
Page:

Final
Page 1495 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1496 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

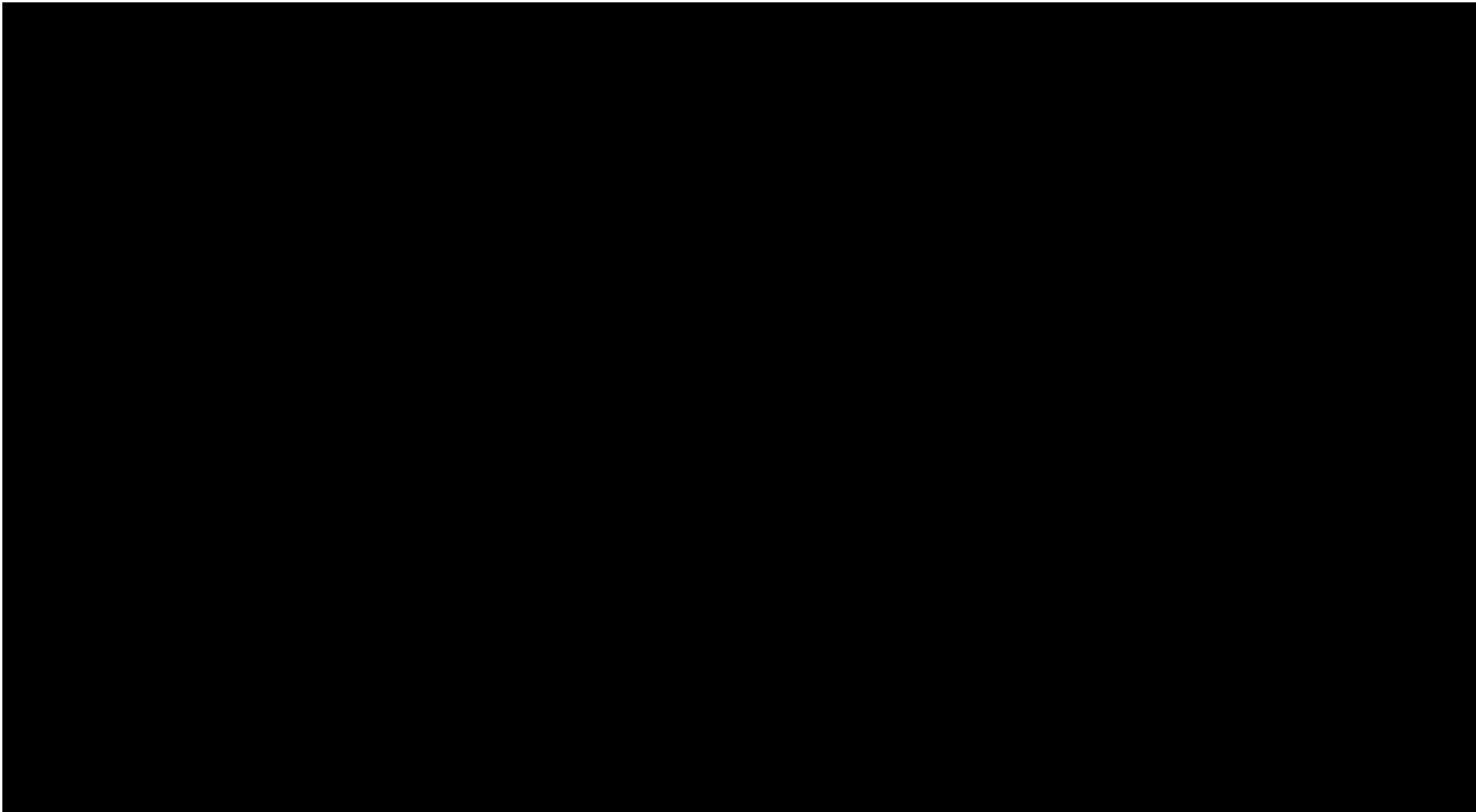
Status:
Page:

Final
Page 1497 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1498 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

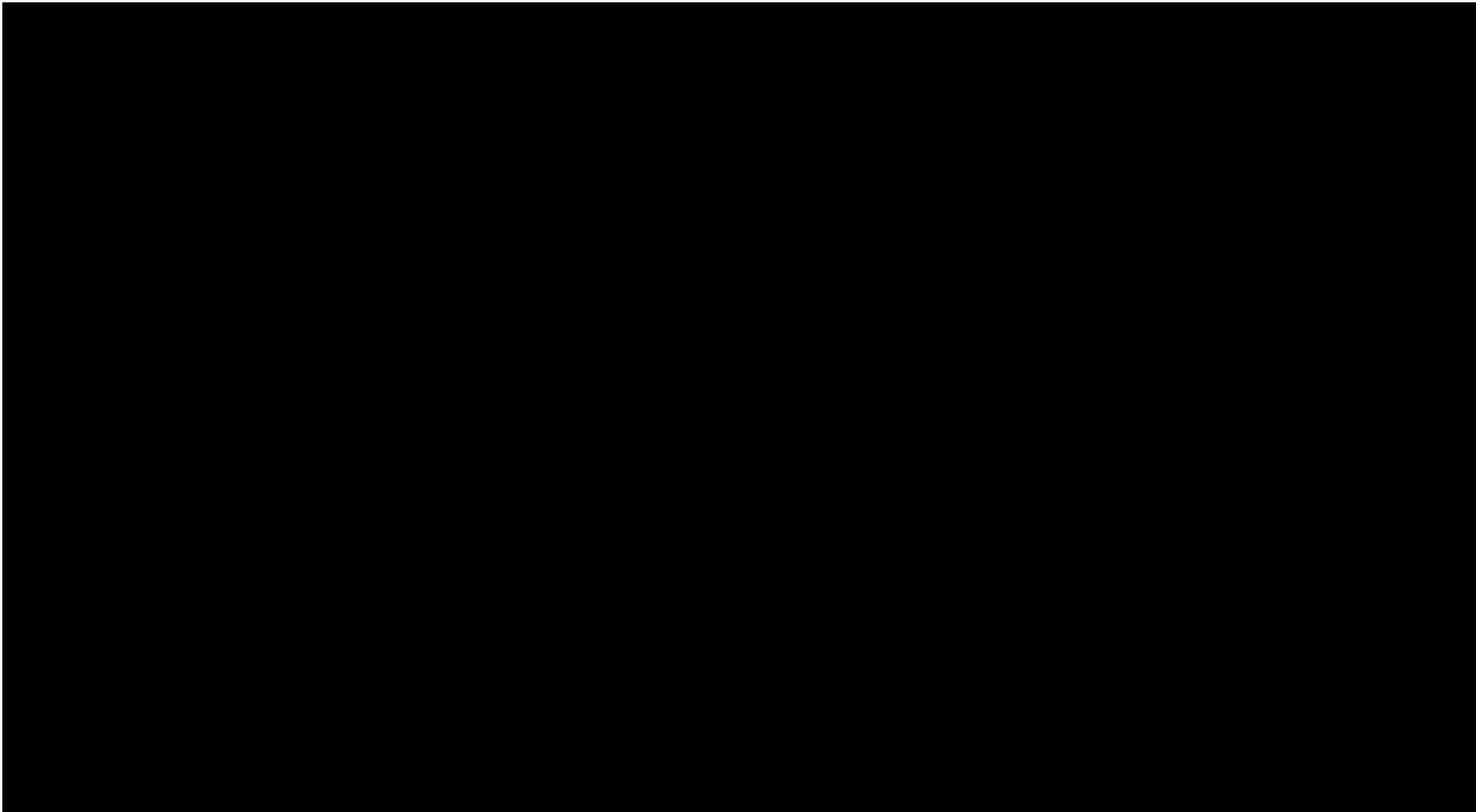
Status:
Page:

Final
Page 1500 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

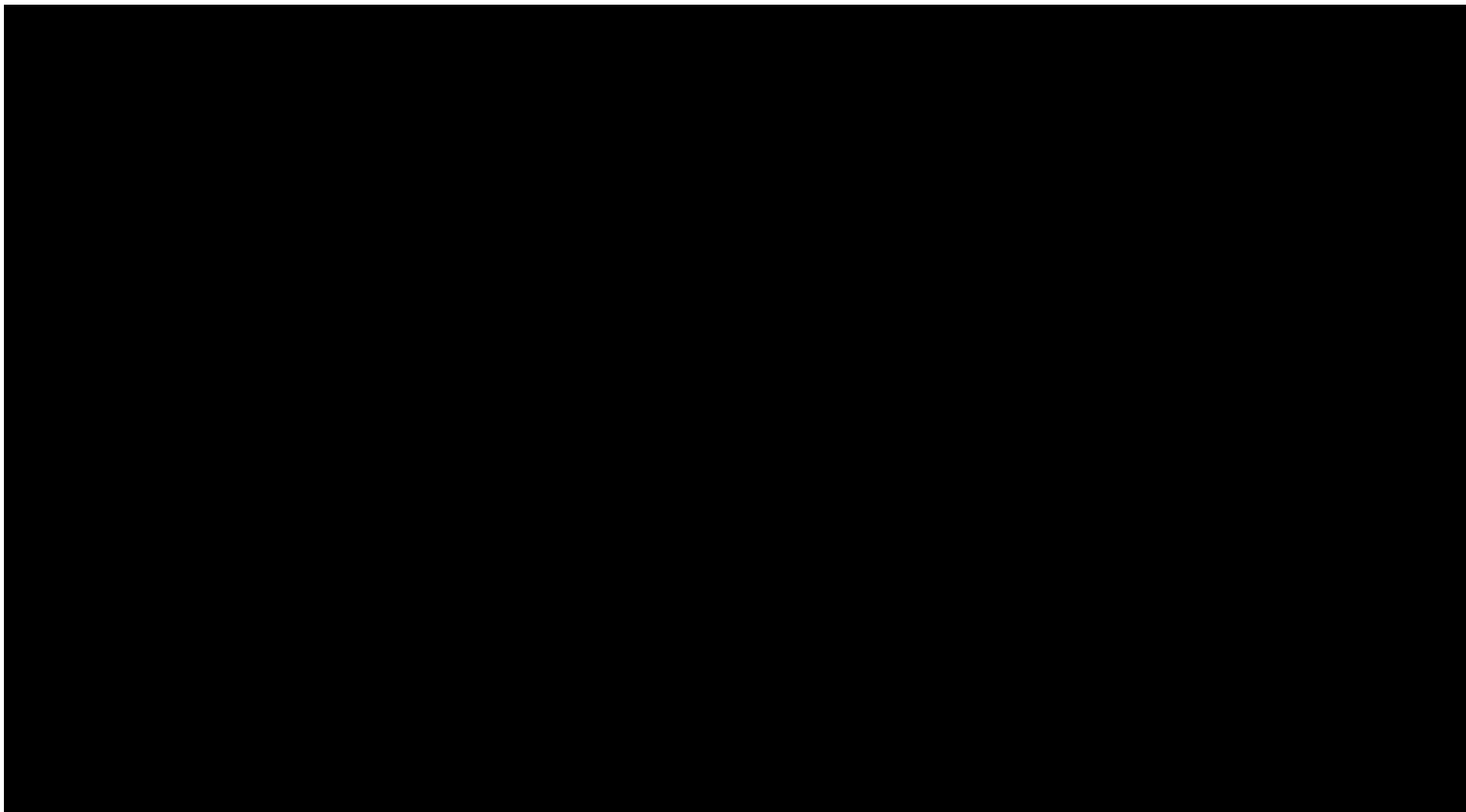
Status:
Page:

Final
Page 1502 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1503 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

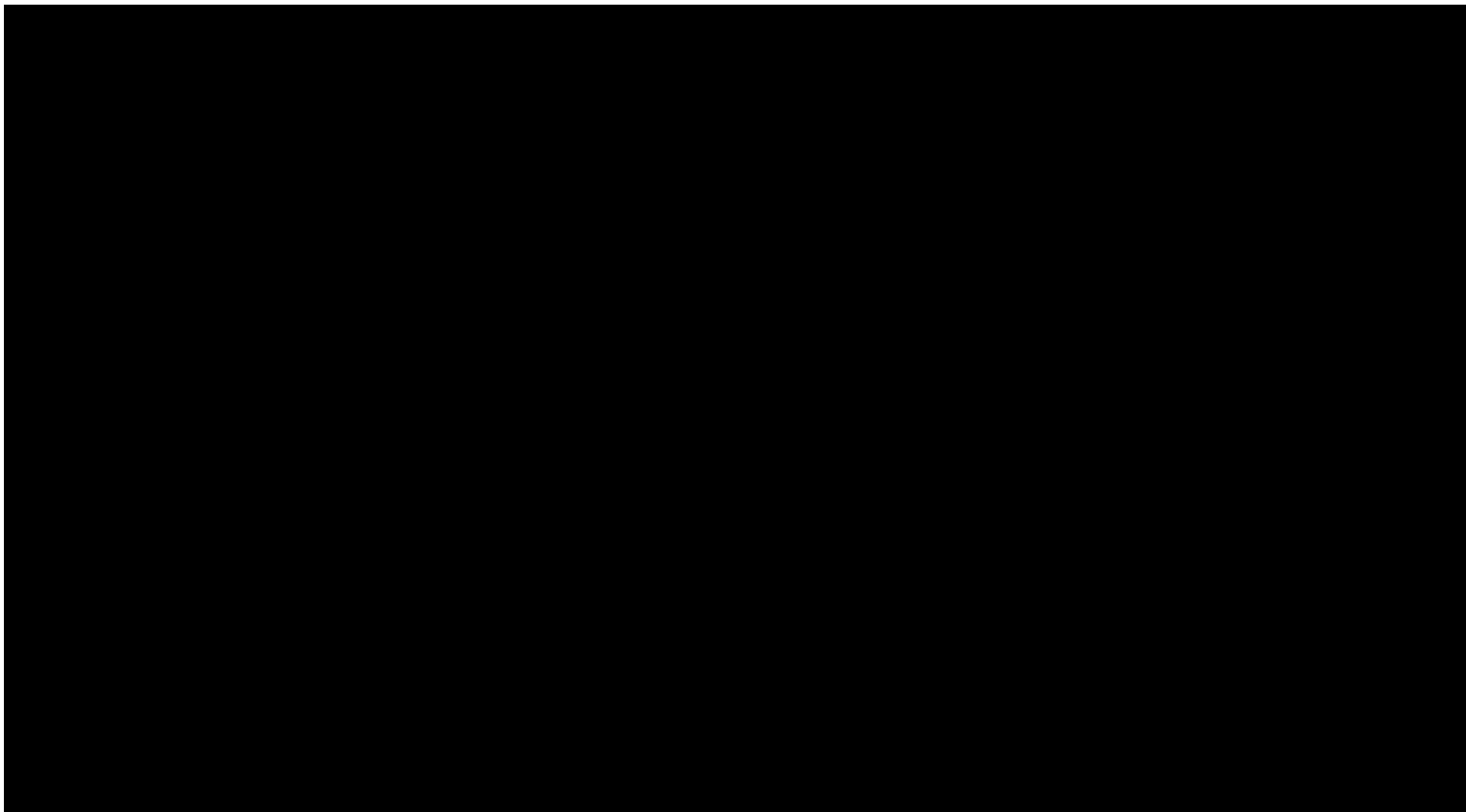
Status:
Page:

Final
Page 1507 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1508 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

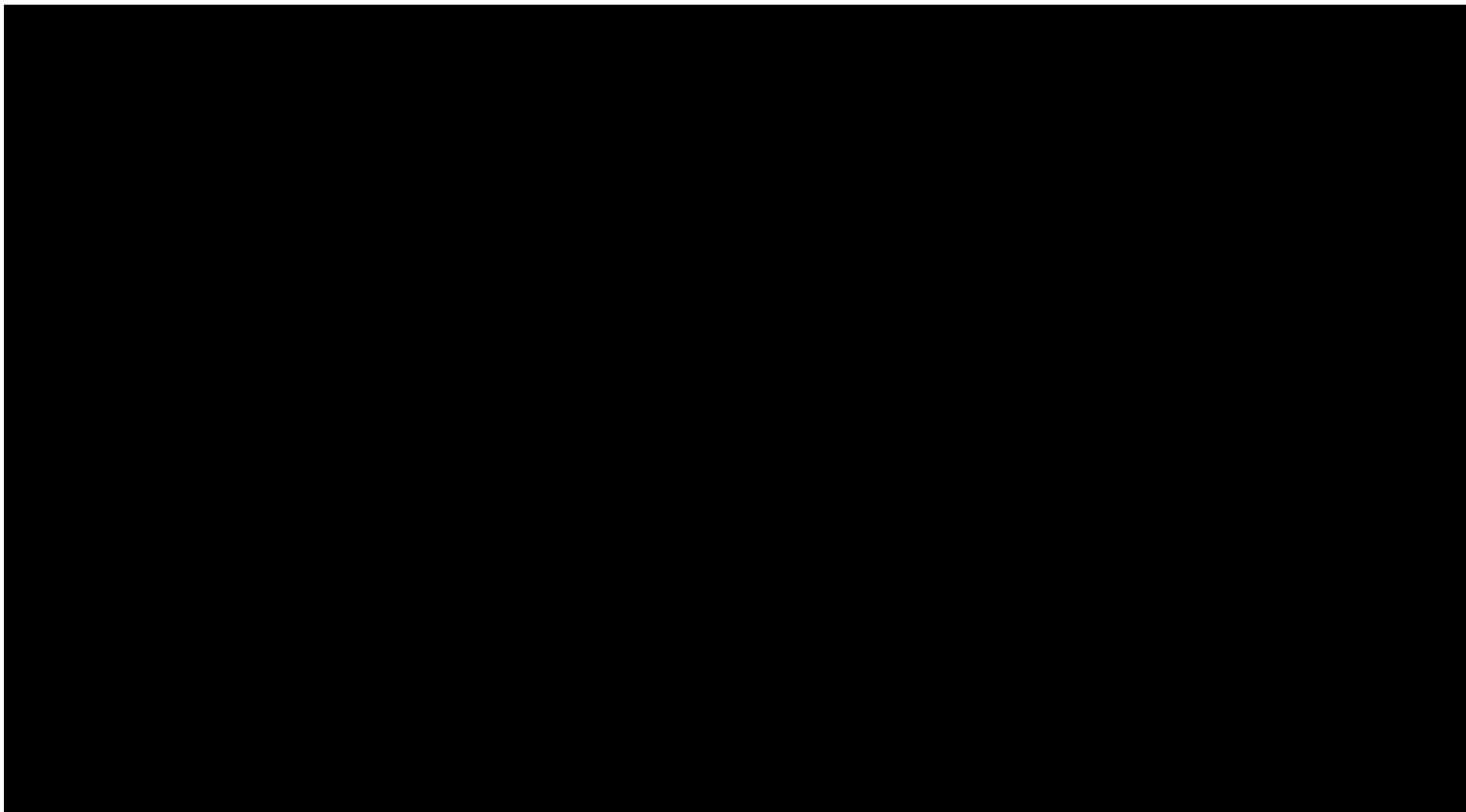
Status:
Page:

Final
Page 1509 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



The image consists of a single, uniform black rectangle. There are no discernible features, text, or patterns other than the solid black color.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1511 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

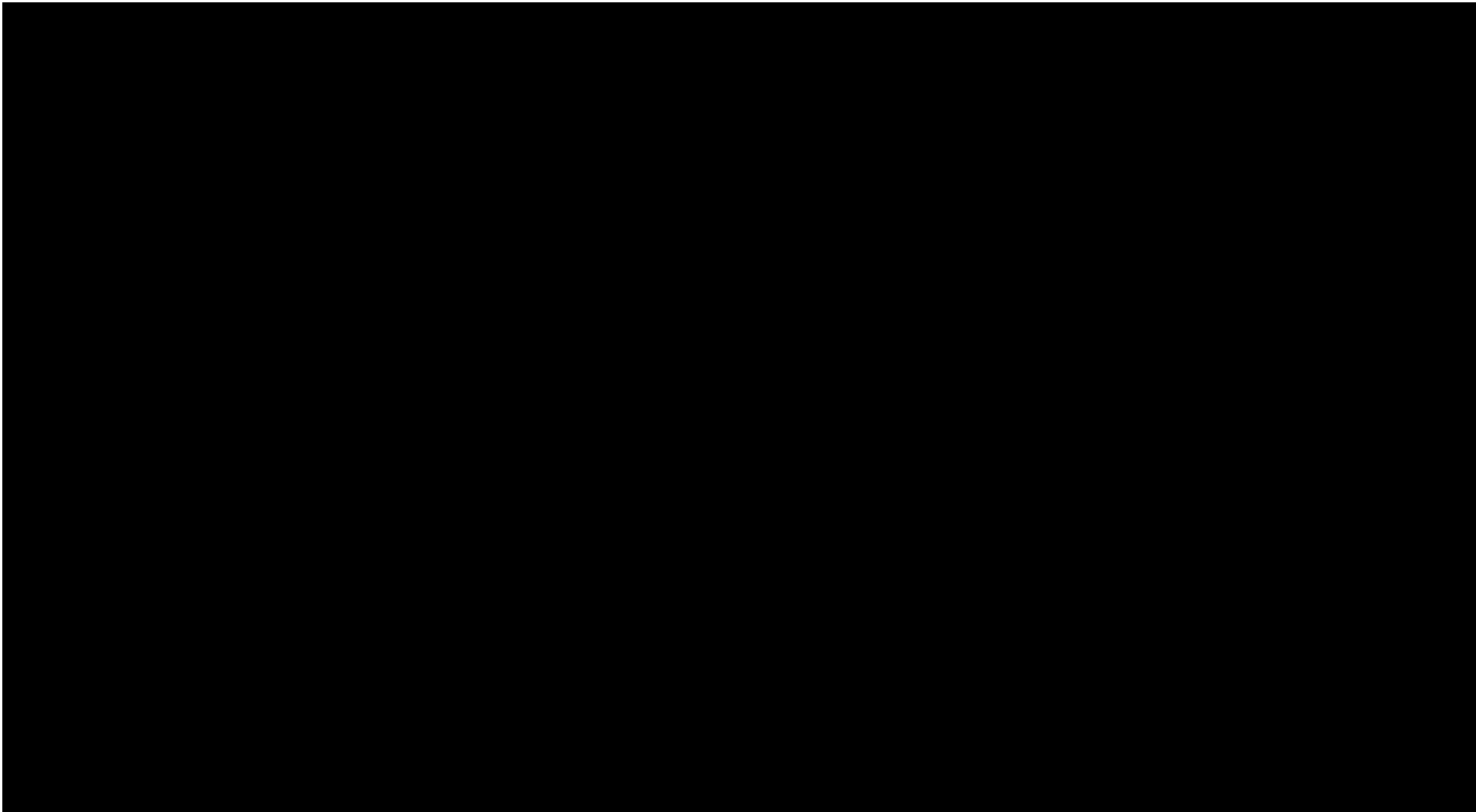
Status:
Page:

Final
Page 1512 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

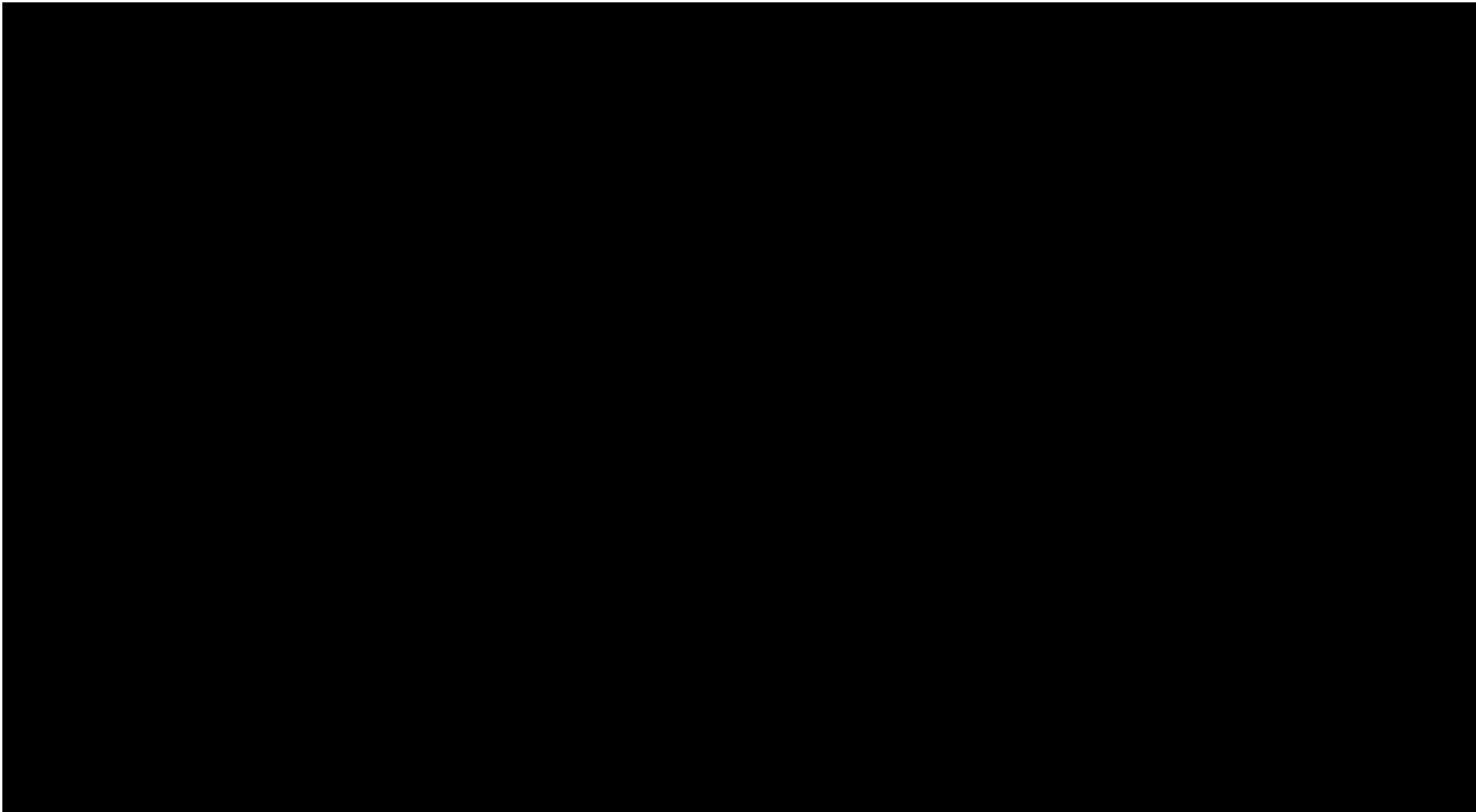
Status:
Page:

Final
Page 1513 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

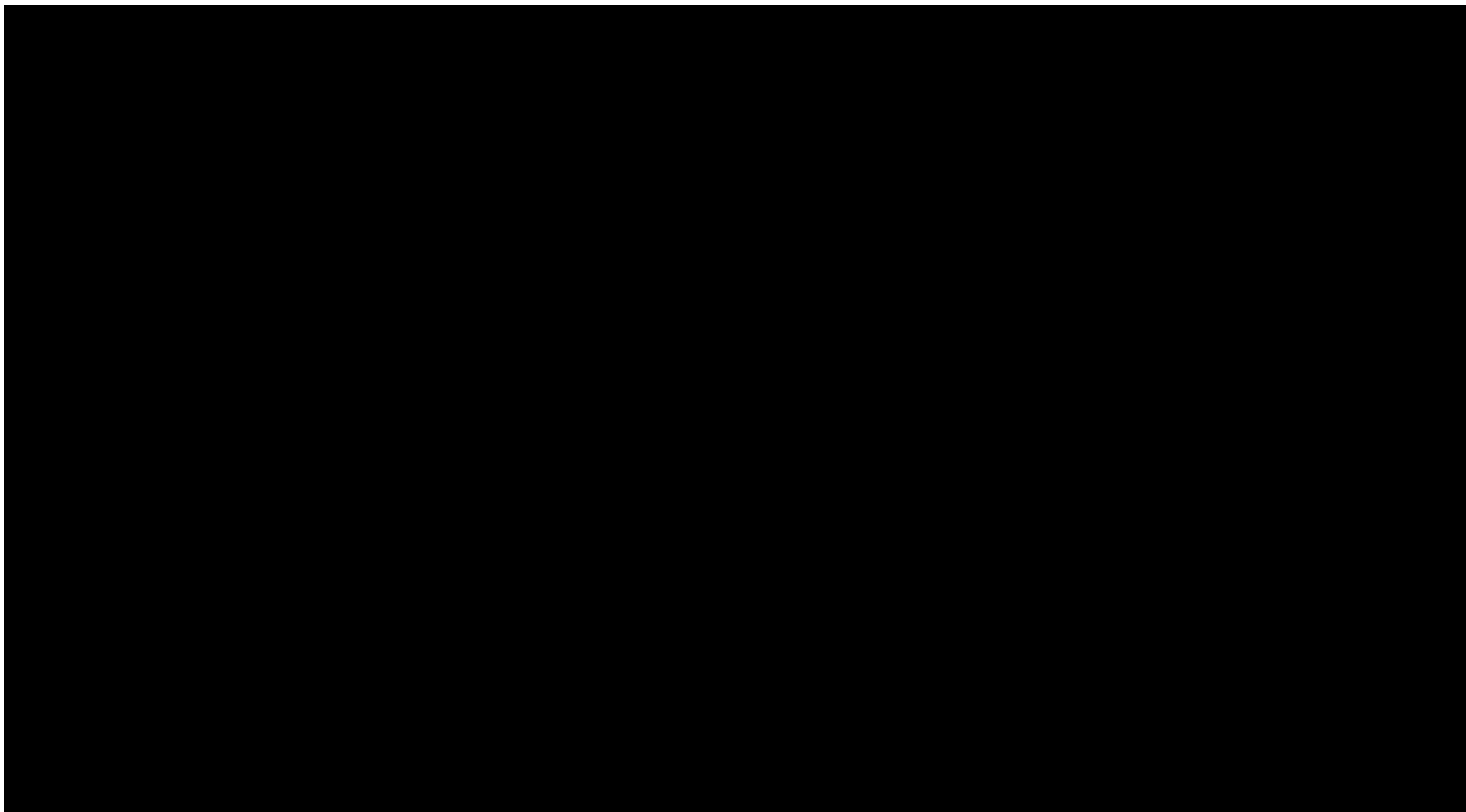
Status:
Page:

Final
Page 1514 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1515 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1516 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1517 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

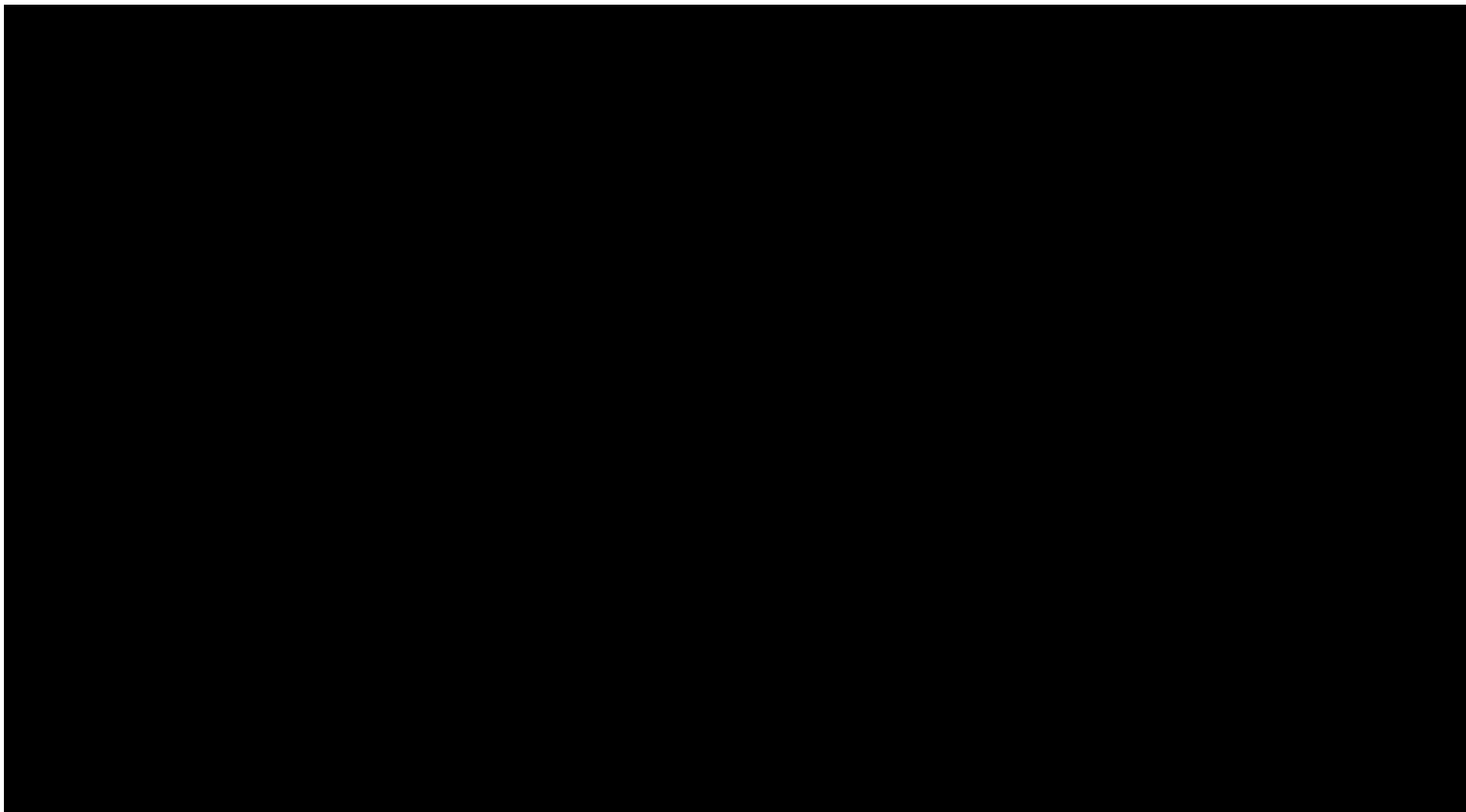
Status:
Page:

Final
Page 1518 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1519 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1520 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

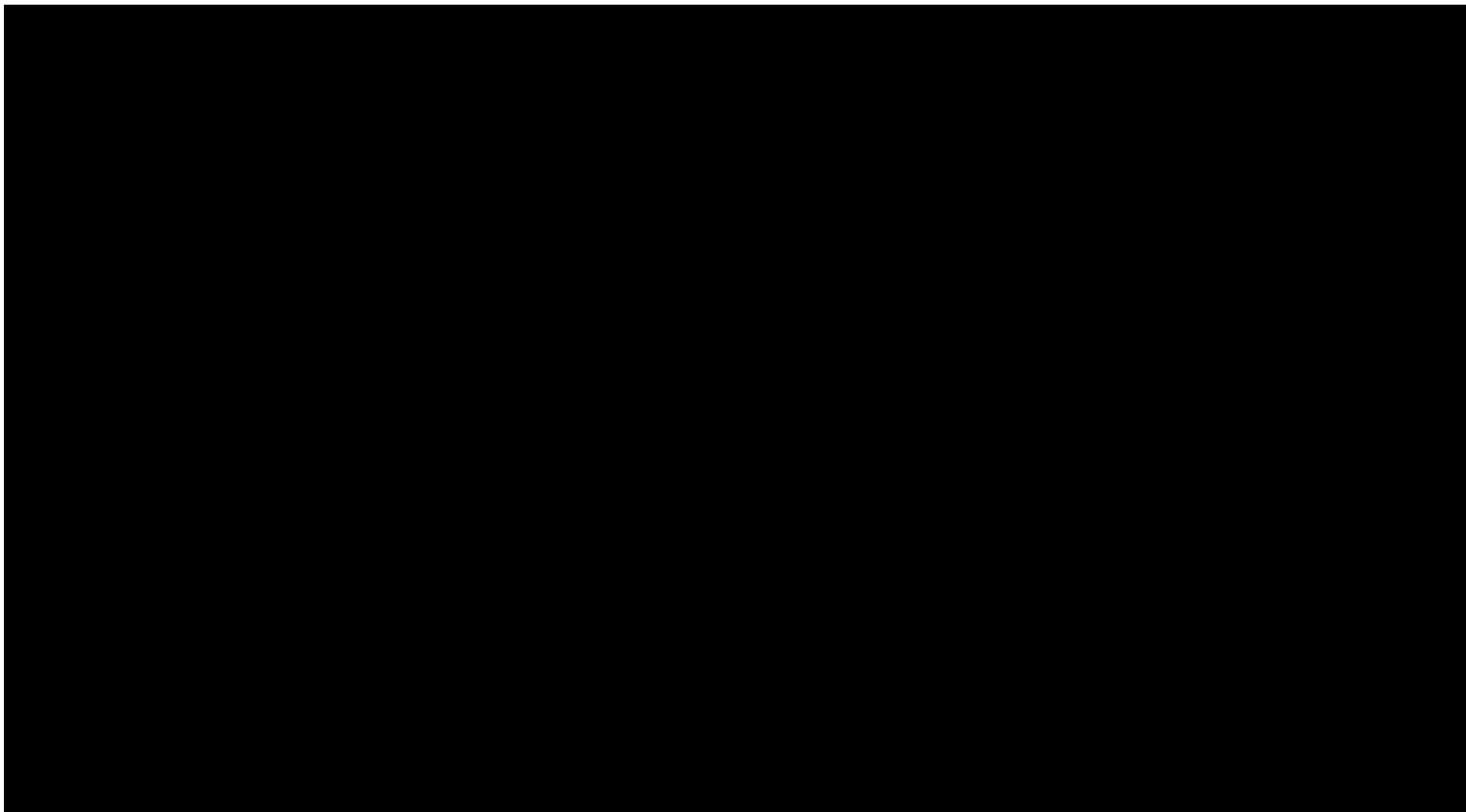
Status:
Page:

Final
Page 1521 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1522 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1524 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1525 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1526 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

The image consists of a single, uniform black rectangle. There are no discernible features, patterns, or variations in color or texture throughout the entire frame.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

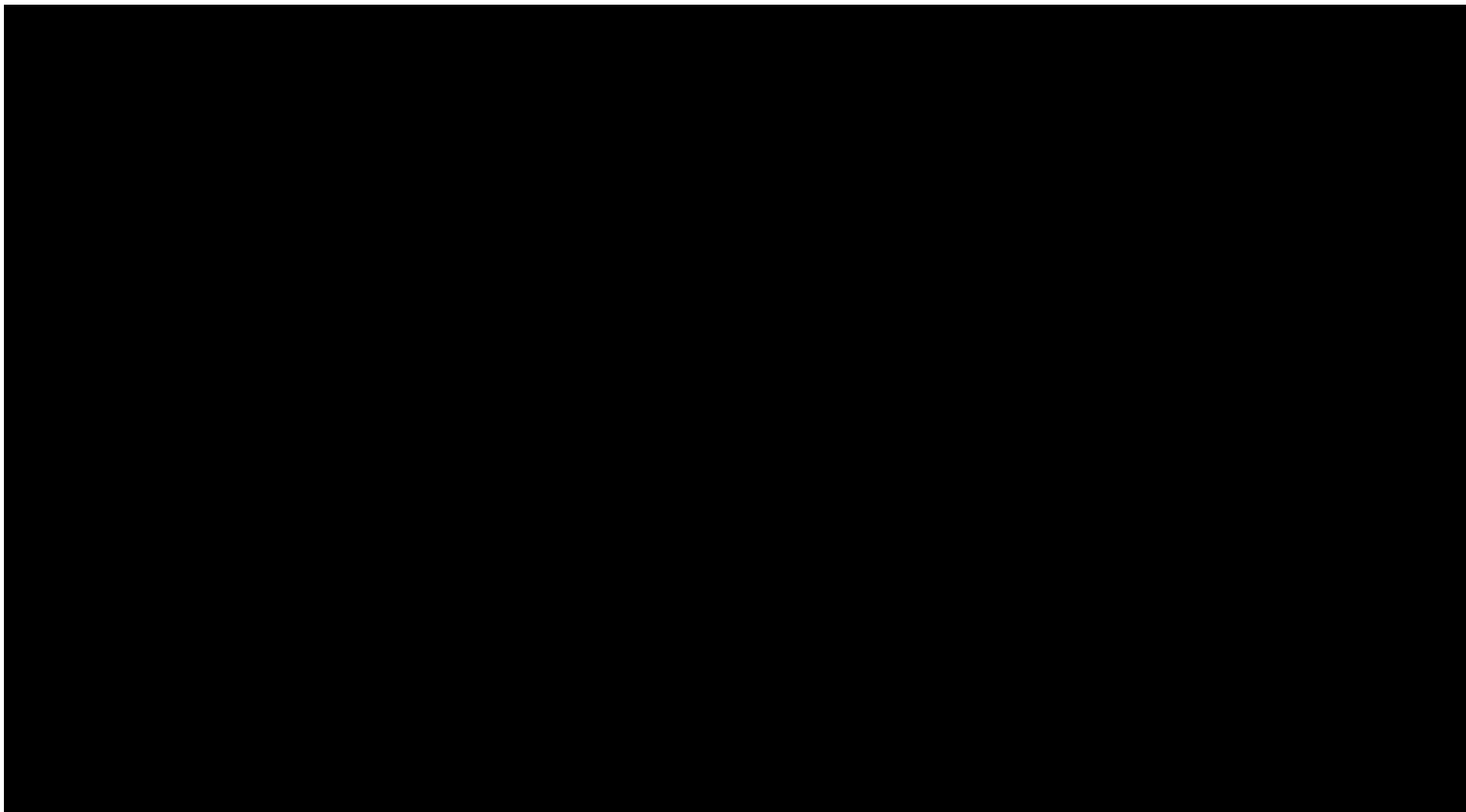
Status:
Page:

Final
Page 1528 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1529 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1530 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1531 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1533 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

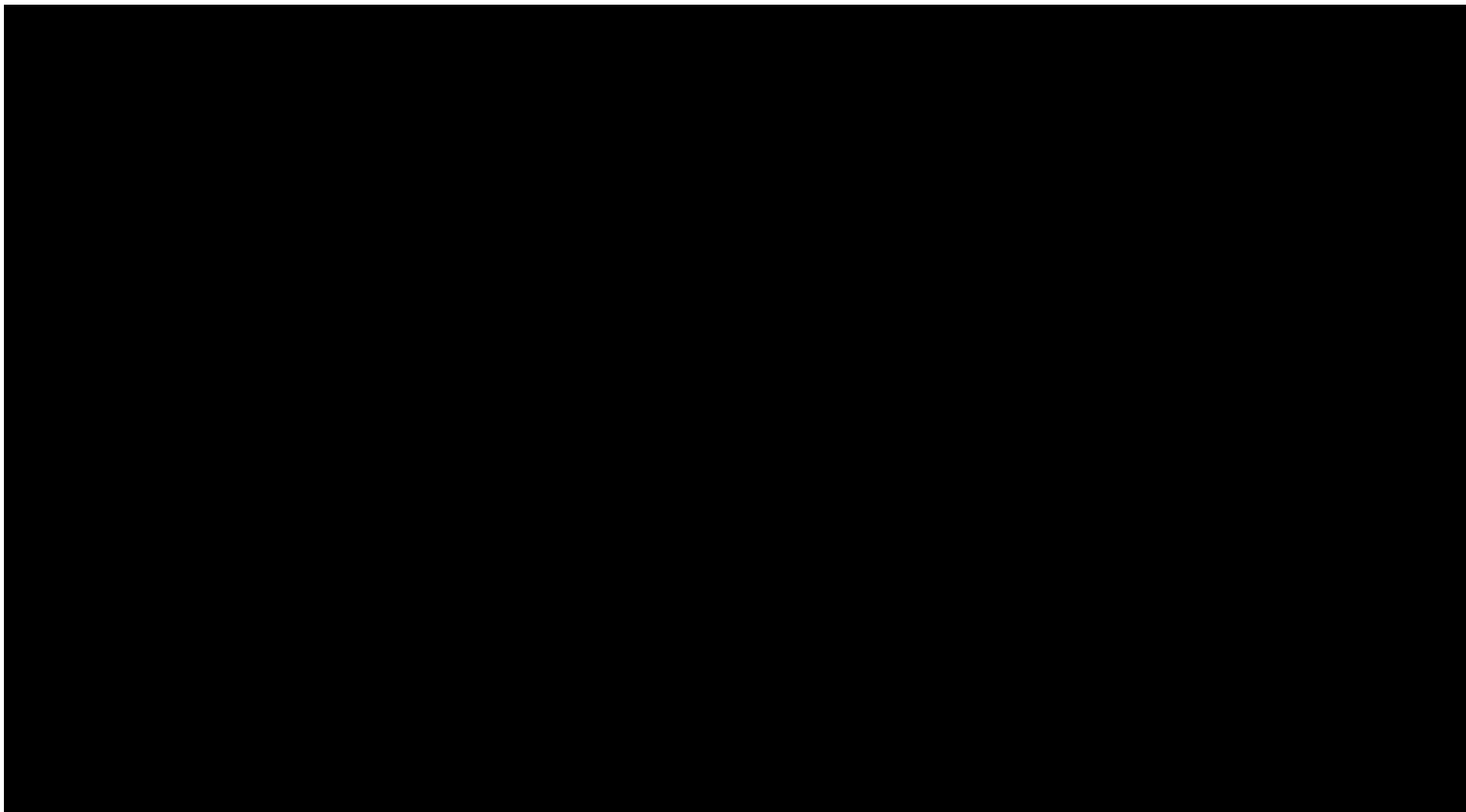
Status:
Page:

Final
Page 1534 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

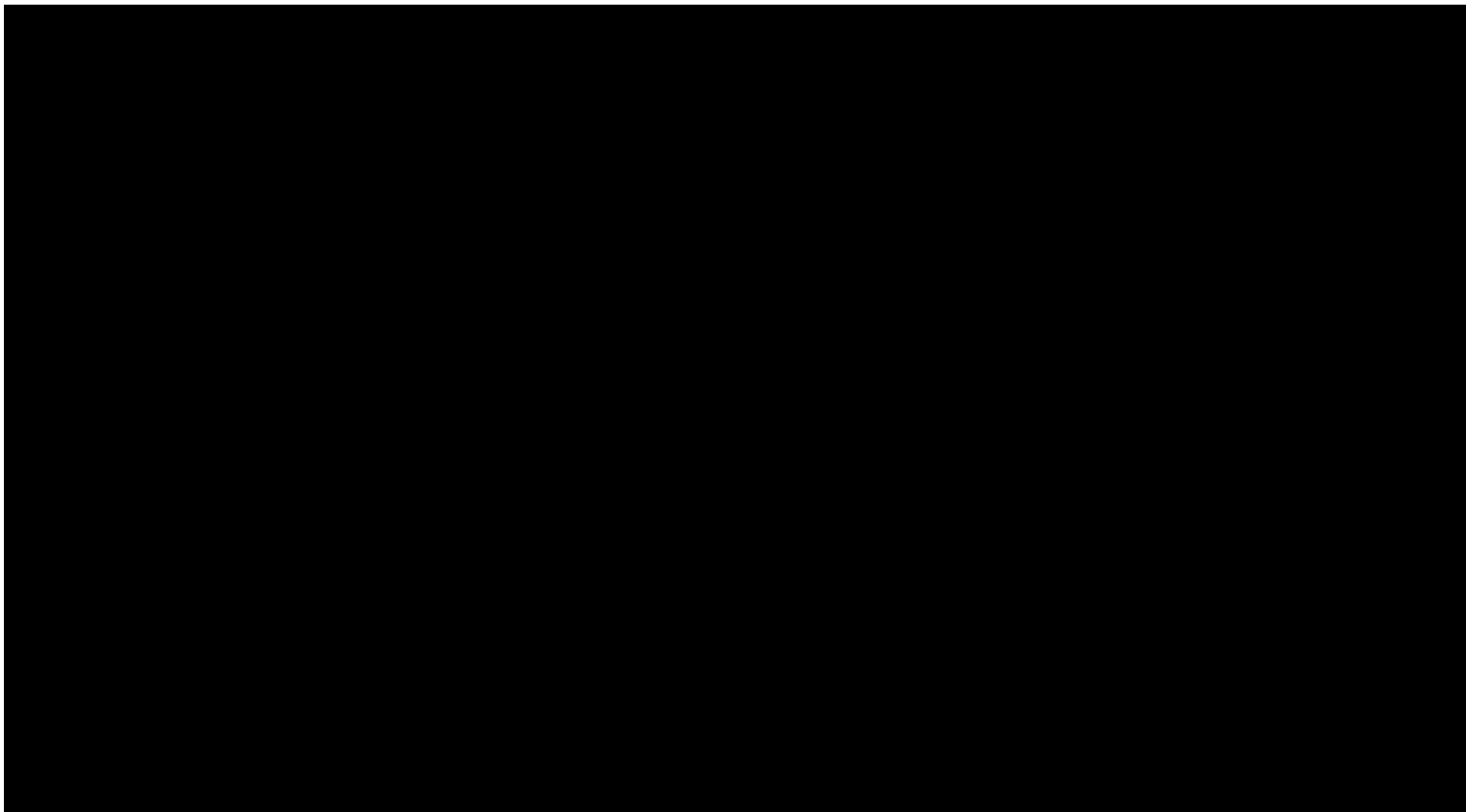
Status:
Page:

Final
Page 1535 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1536 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1537 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1538 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1539 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1540 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

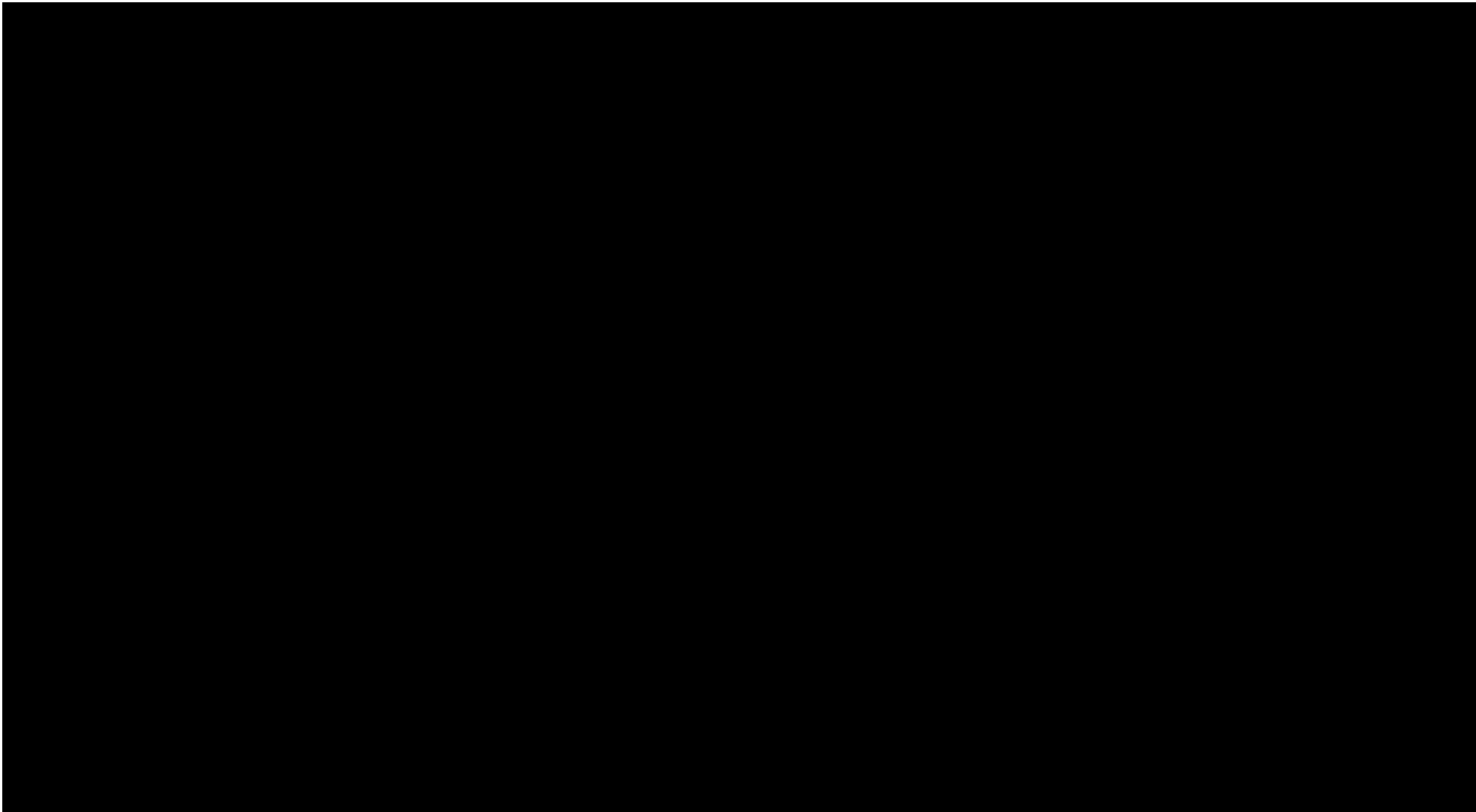
Status:
Page:

Final
Page 1541 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



The image consists of a single, uniform black rectangle. There are no discernible features, patterns, or variations in color or texture throughout the entire frame.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

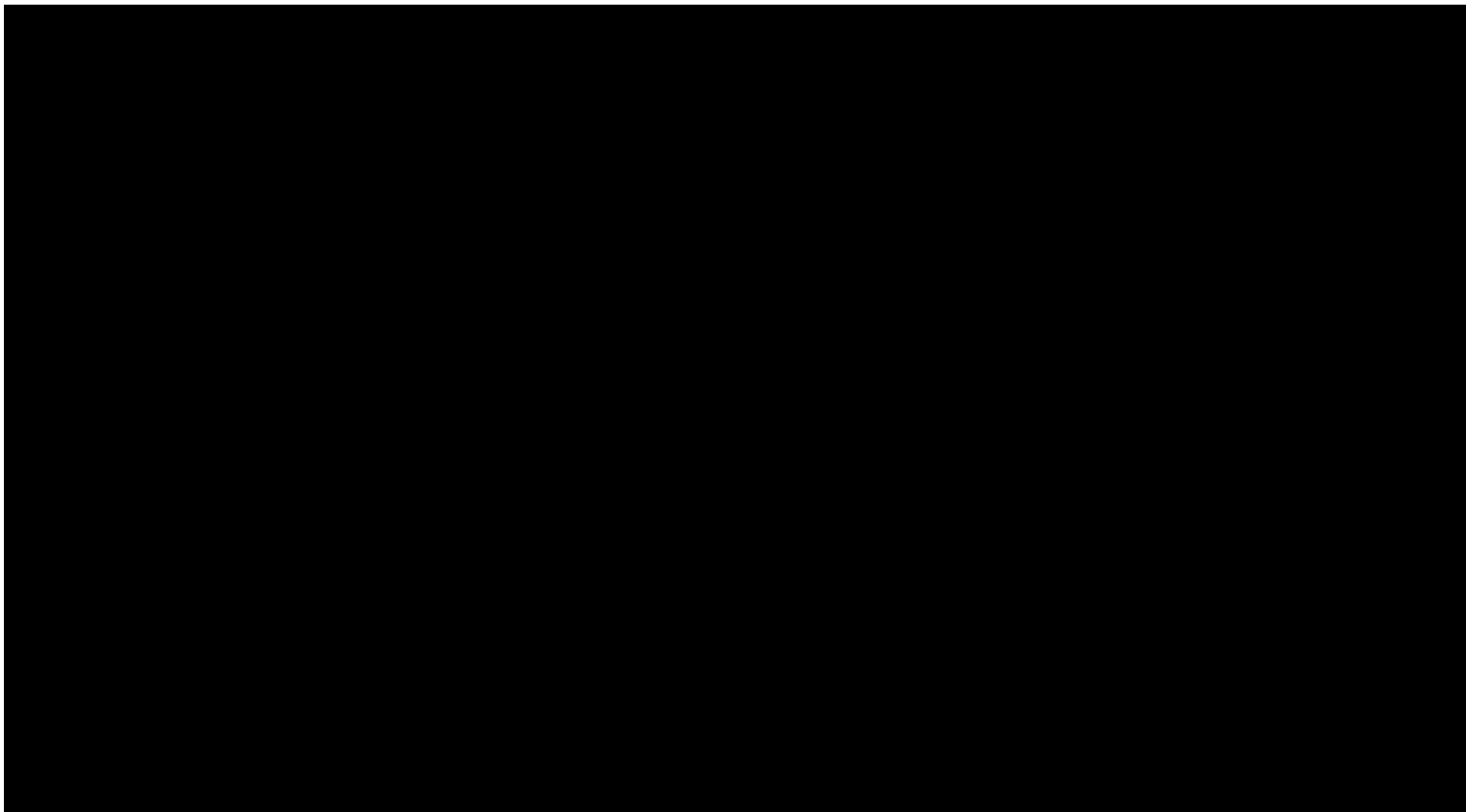
Status:
Page:

Final
Page 1543 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



The image consists of a single, uniform black rectangle. There are no discernible features, text, or patterns other than the solid color.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

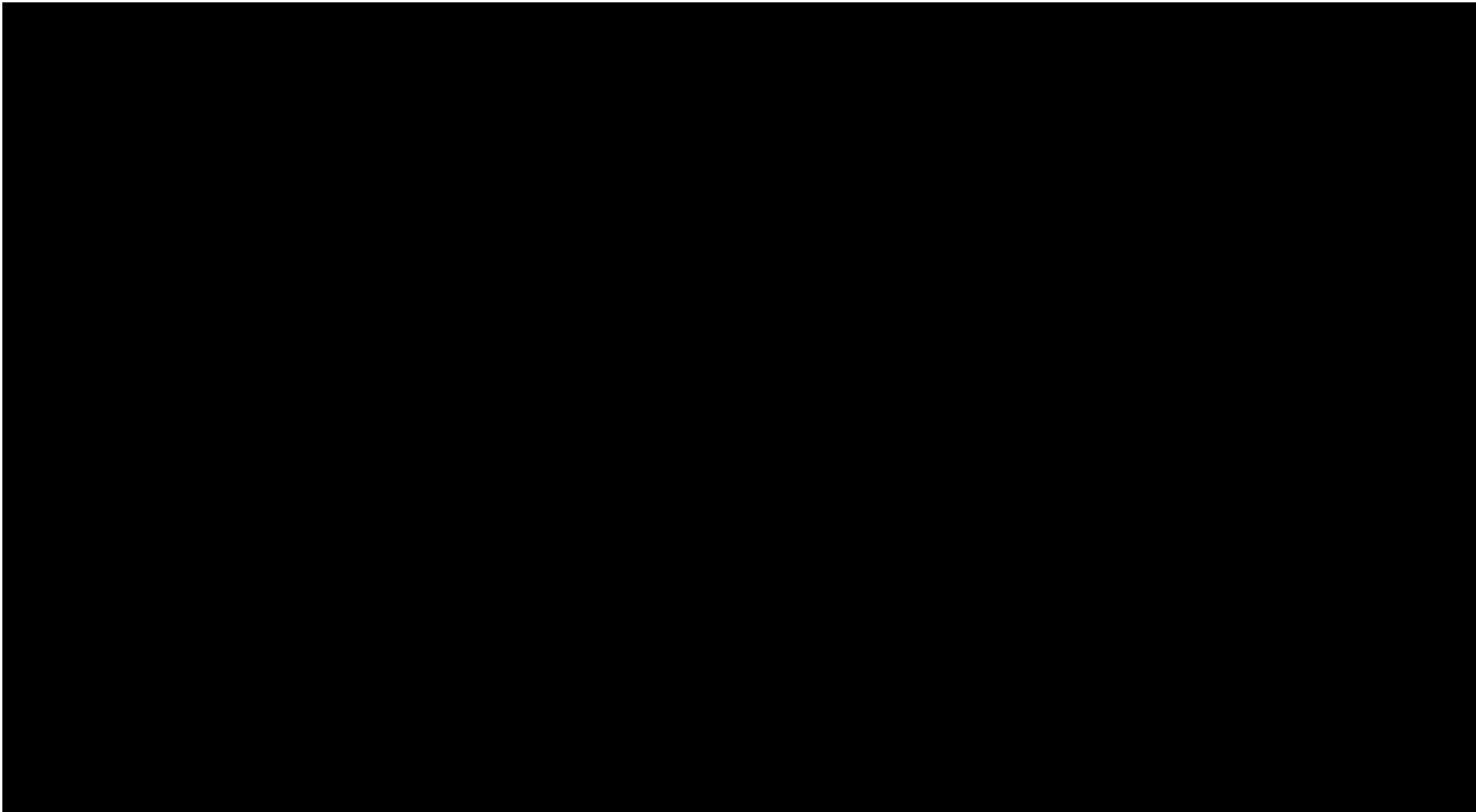
Status:
Page:

Final
Page 1545 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

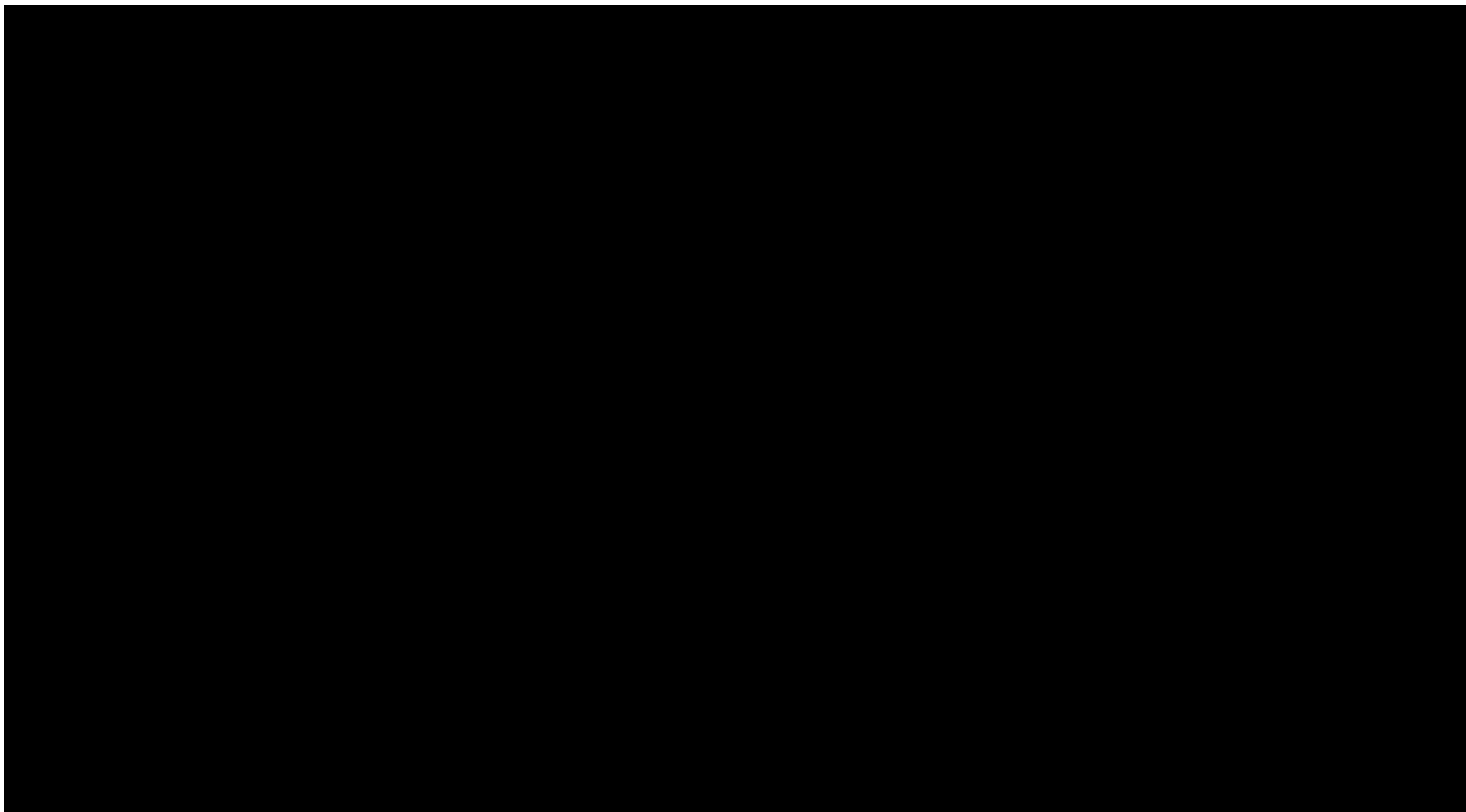
Status:
Page:

Final
Page 1546 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

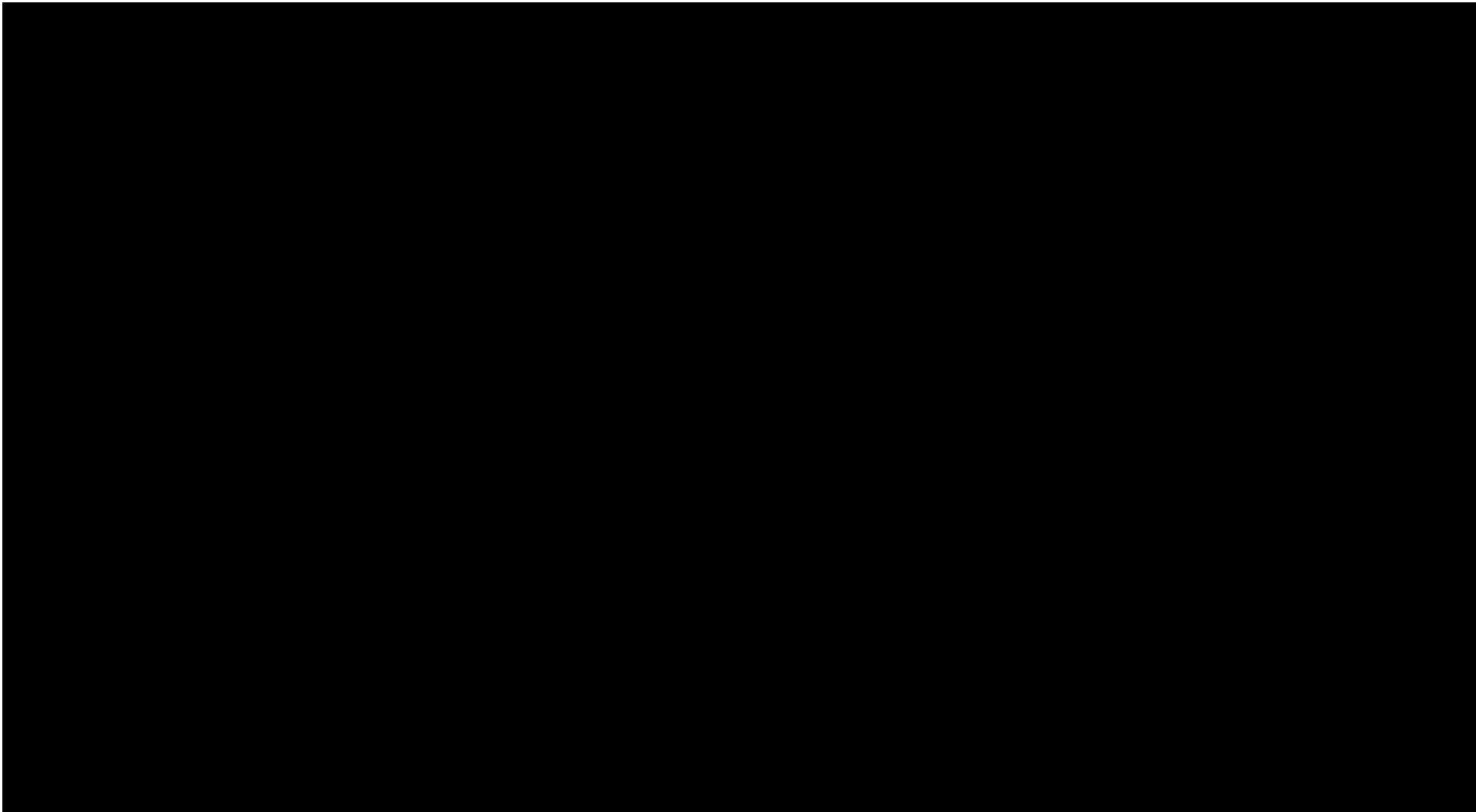
Status:
Page:

Final
Page 1547 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

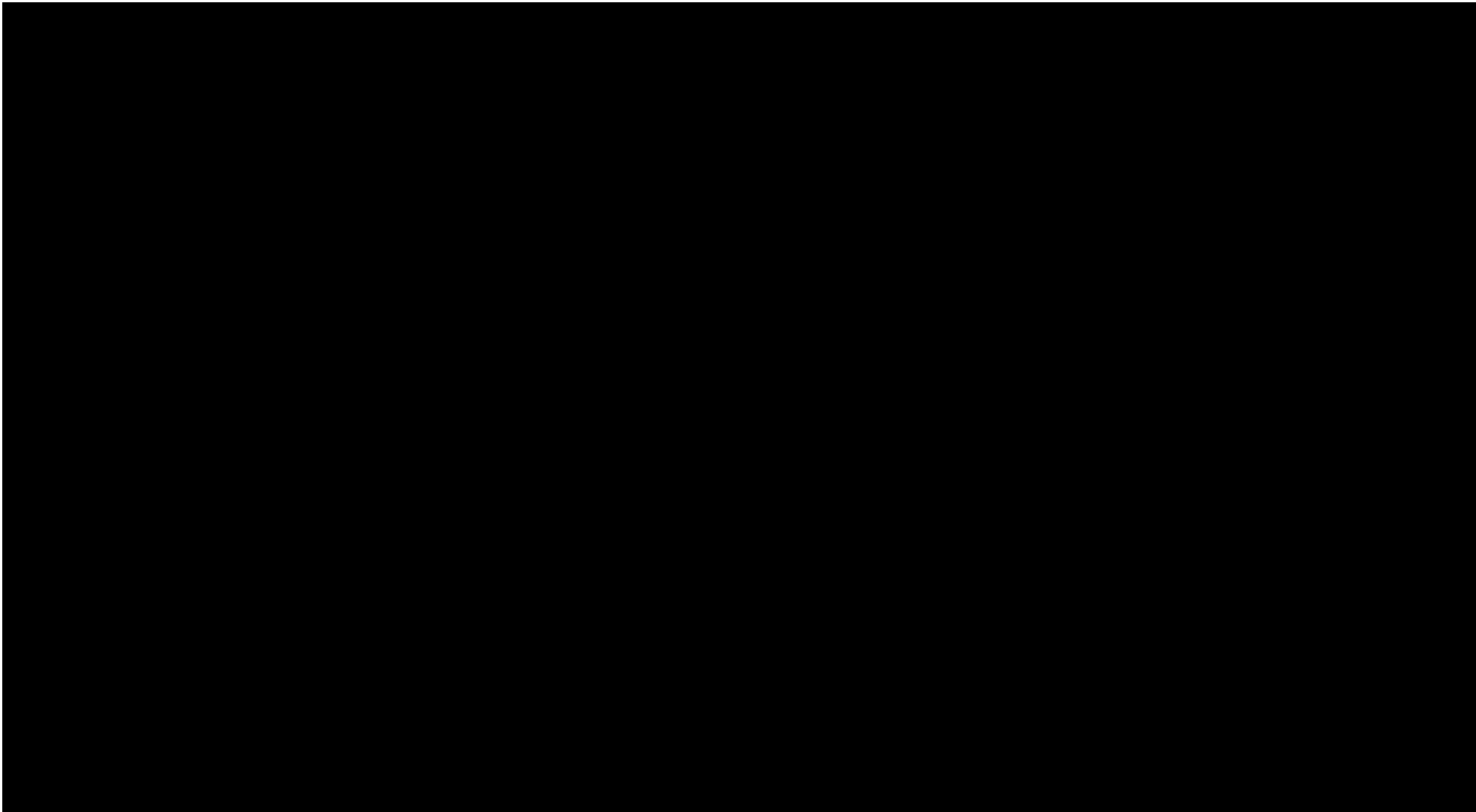
Status:
Page:

Final
Page 1549 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1550 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

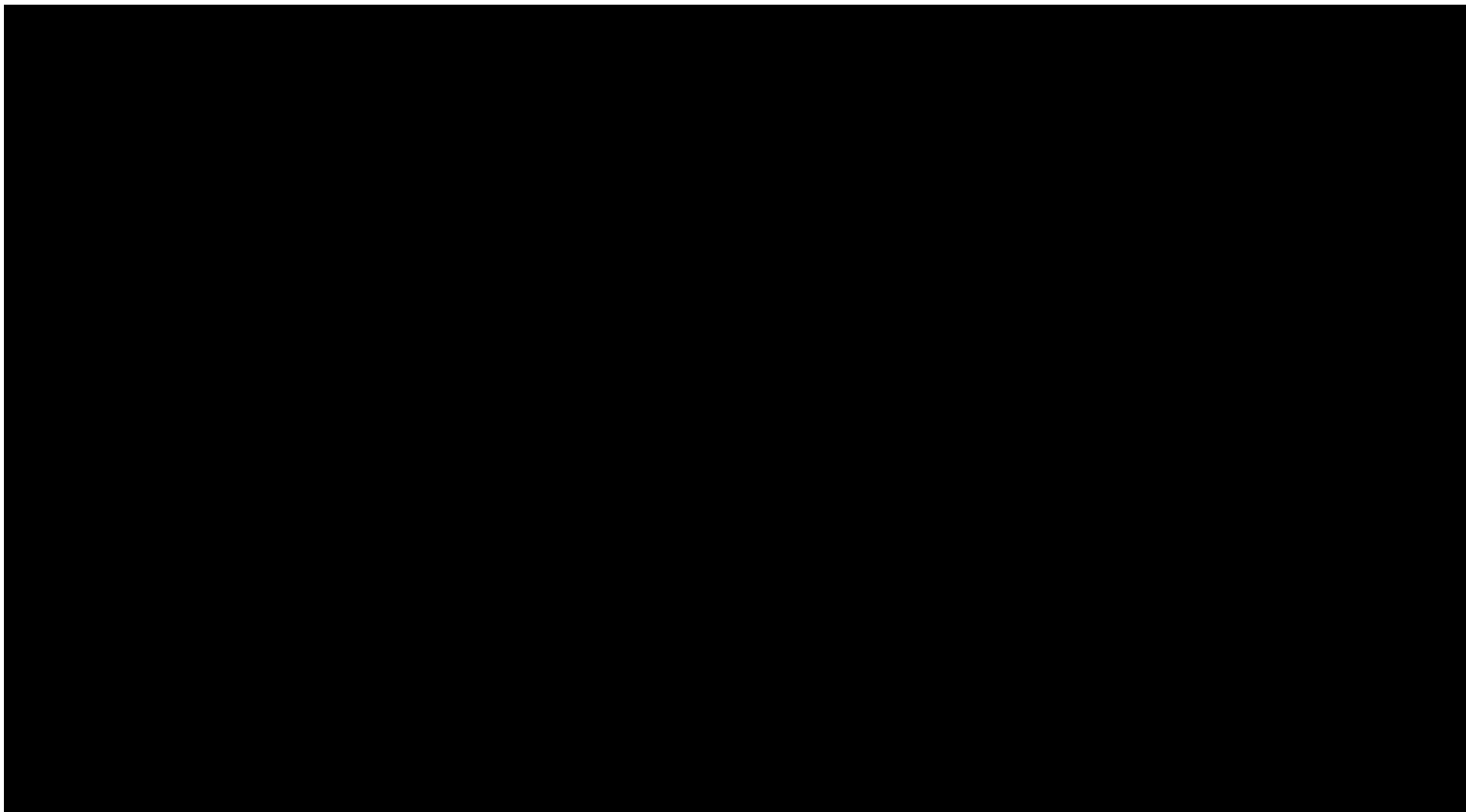
Status:
Page:

Final
Page 1553 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1554 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1555 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1556 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1557 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

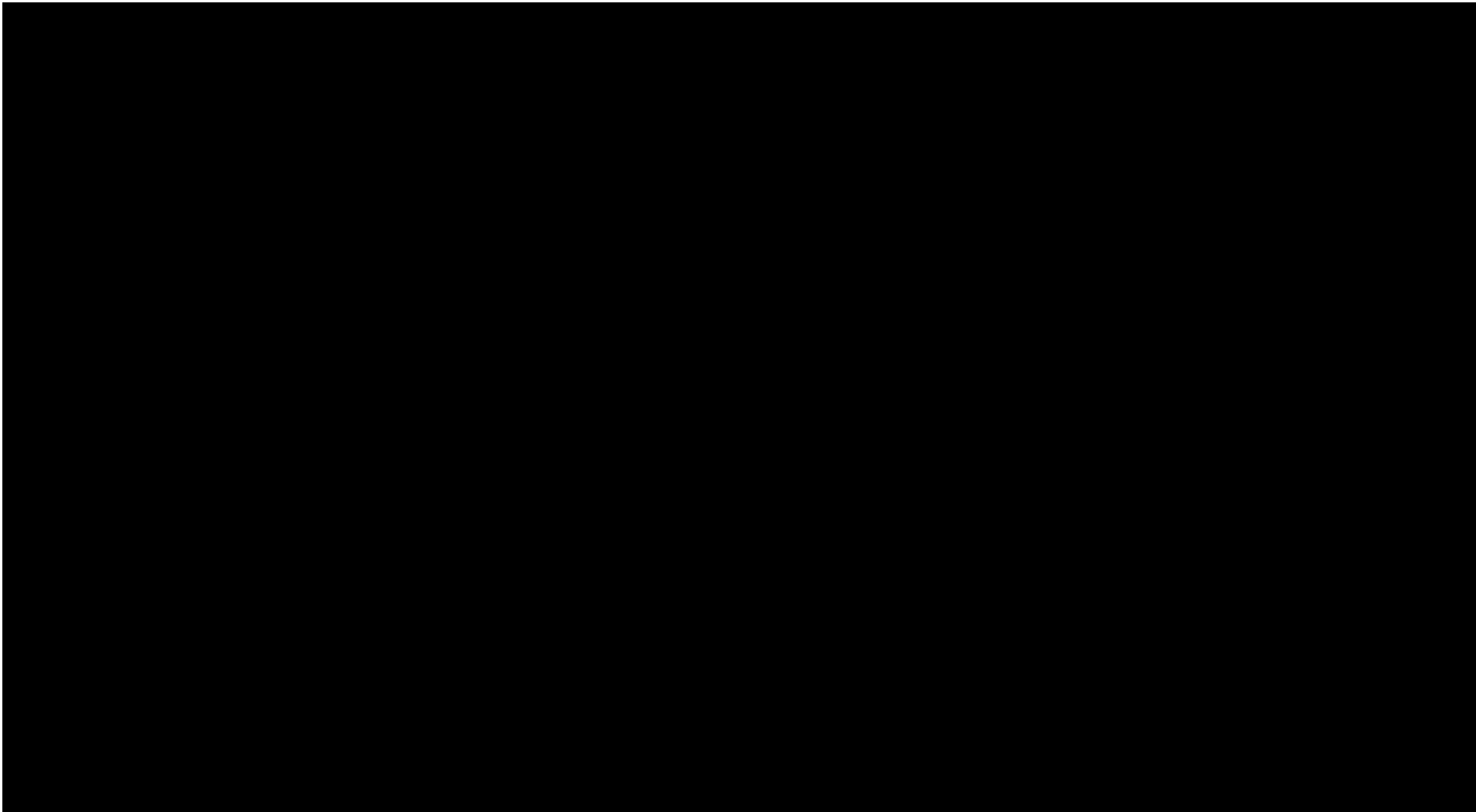
Status:
Page:

Final
Page 1558 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1559 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1560 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

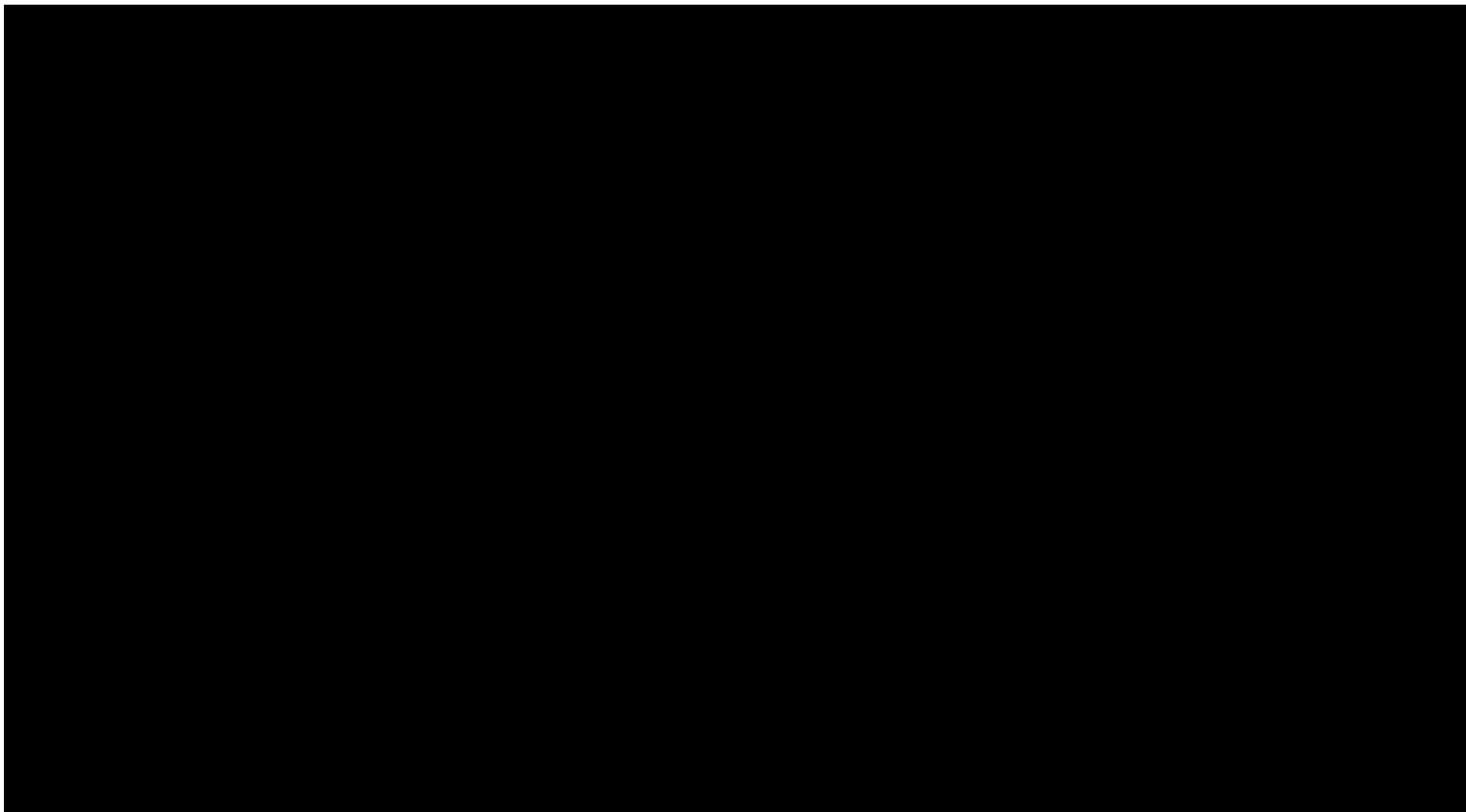
Status:
Page:

Final
Page 1561 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1562 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

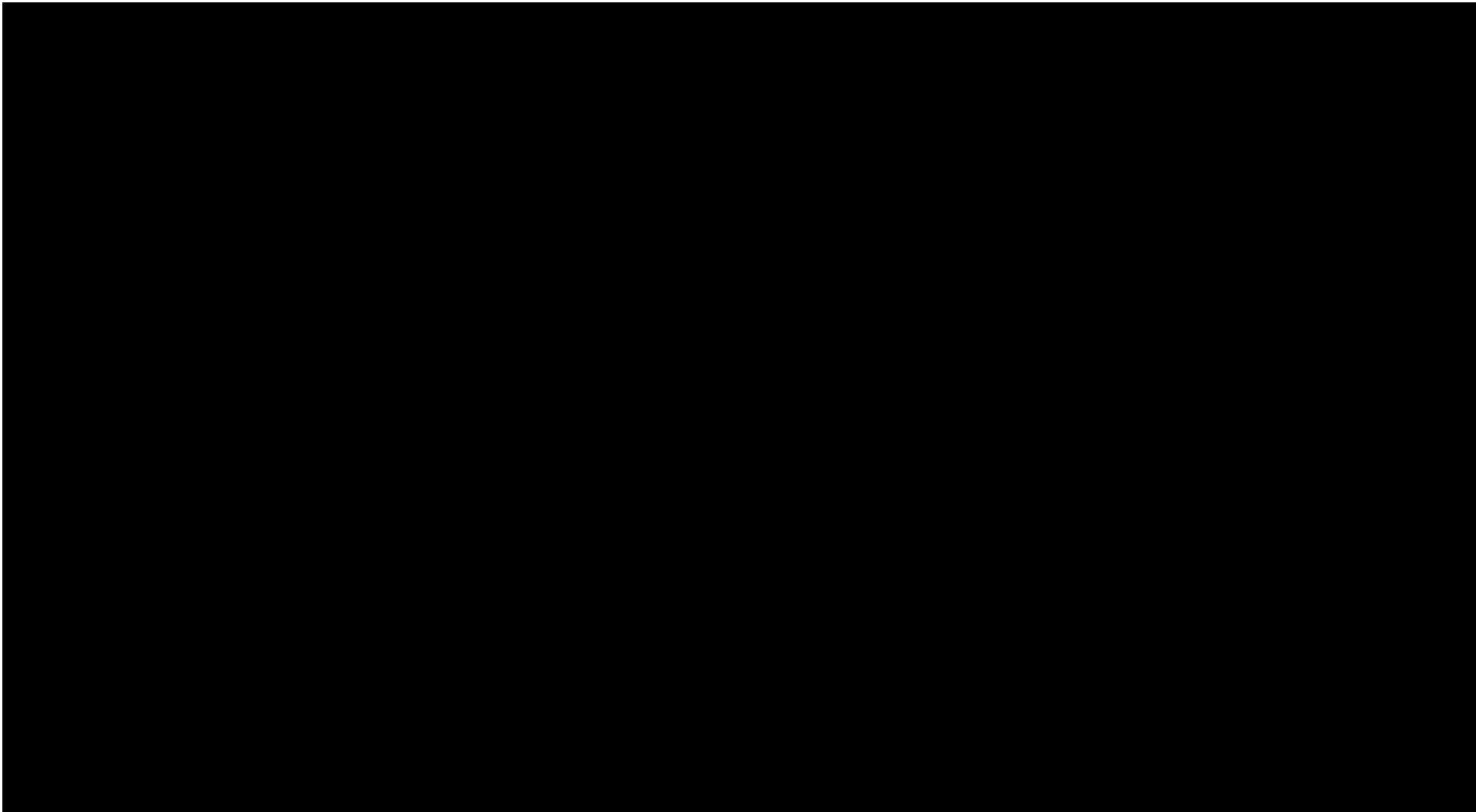
Status:
Page:

Final
Page 1563 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1564 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

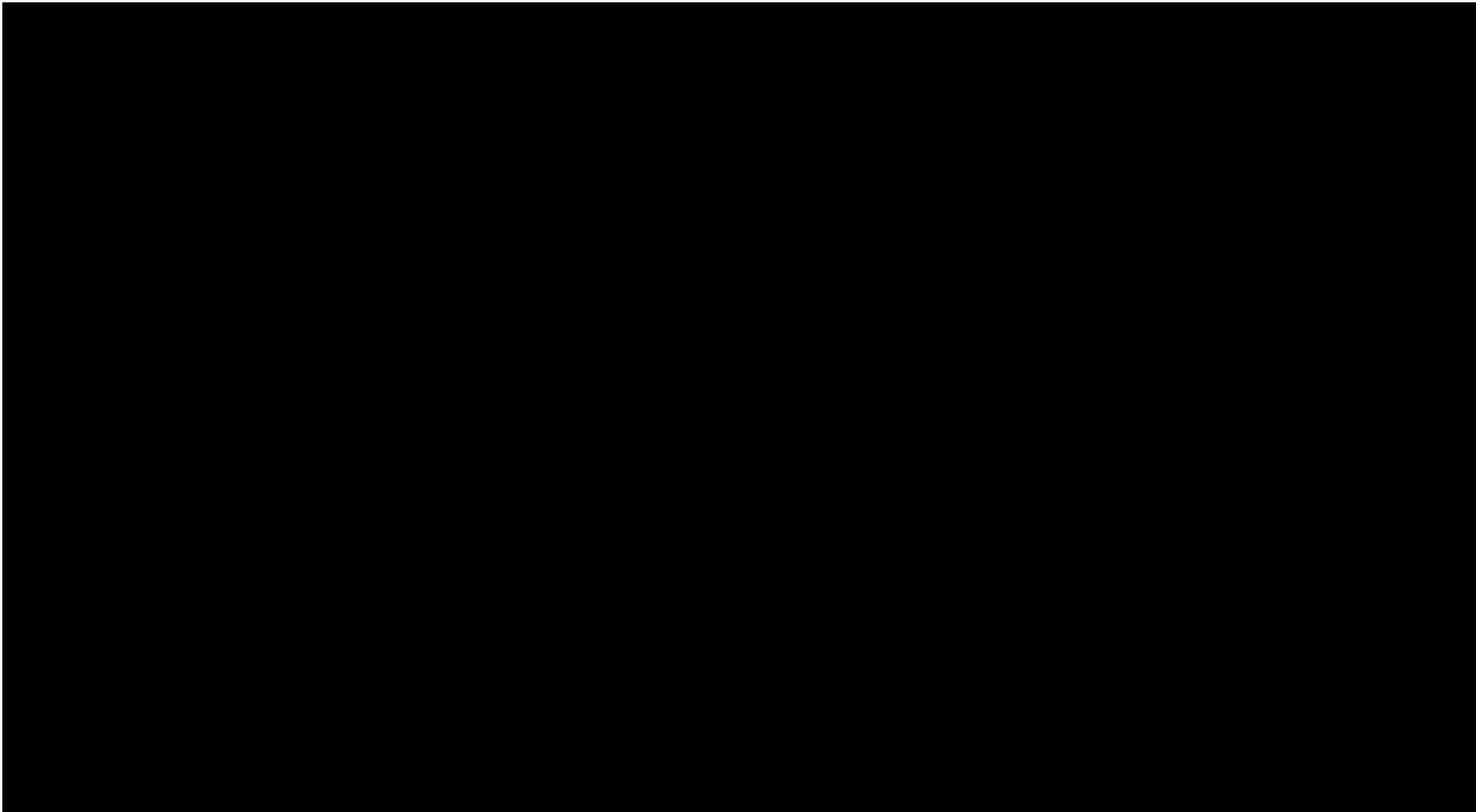


Figure 1 displays a 3x3 grid of scatter plots showing the relationship between the number of children in the household (X-axis) and the number of children in the family (Y-axis) for the USA, Canada, and the UK across the years 1990, 2000, and 2010. Each plot includes a linear regression line and its corresponding R-squared value.

Country	Year	R-squared
USA	1990	0.85
USA	2000	0.85
USA	2010	0.85
Canada	1990	0.85
Canada	2000	0.85
Canada	2010	0.85
UK	1990	0.85
UK	2000	0.85
UK	2010	0.85

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

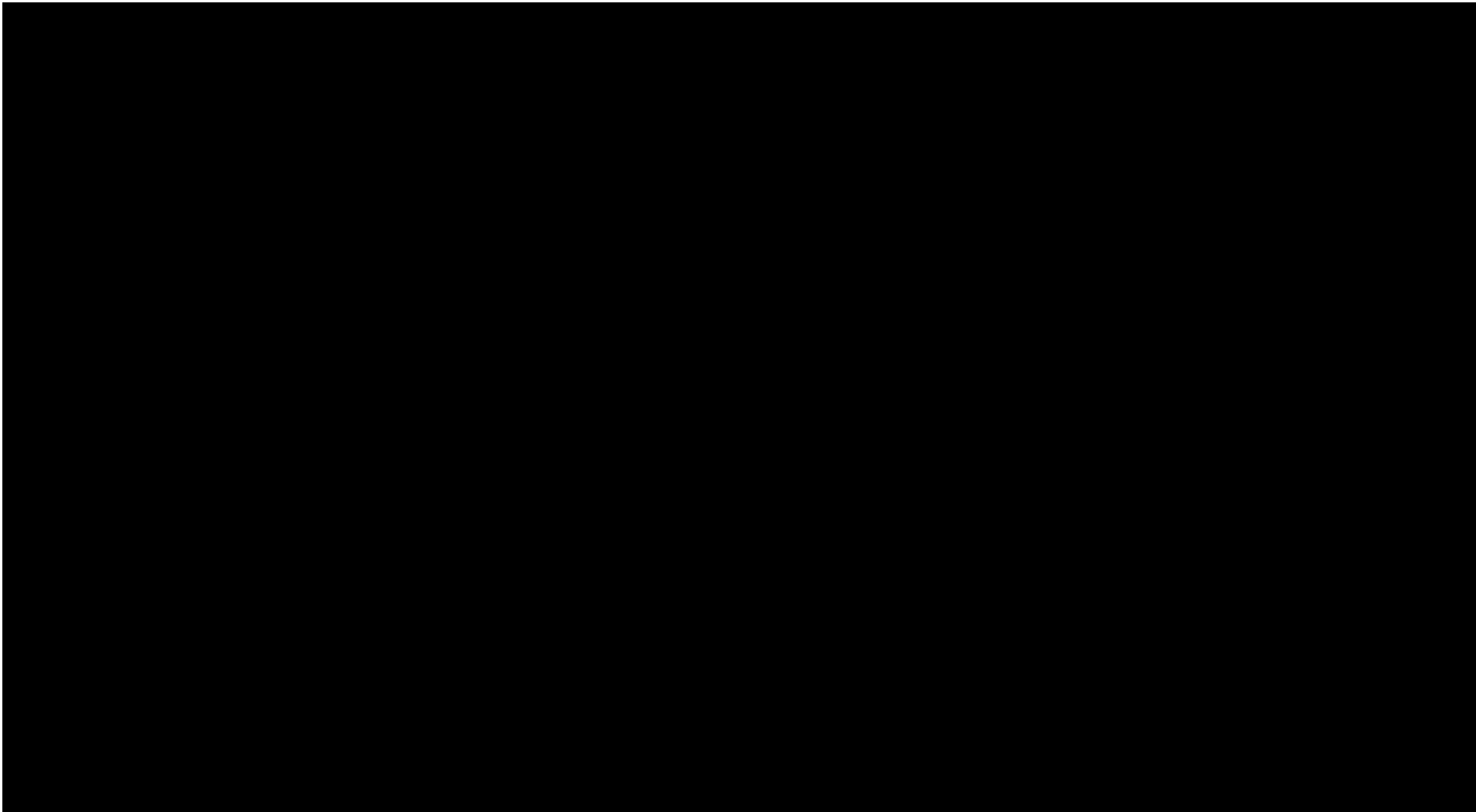
Status:
Page:

Final
Page 1566 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1567 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

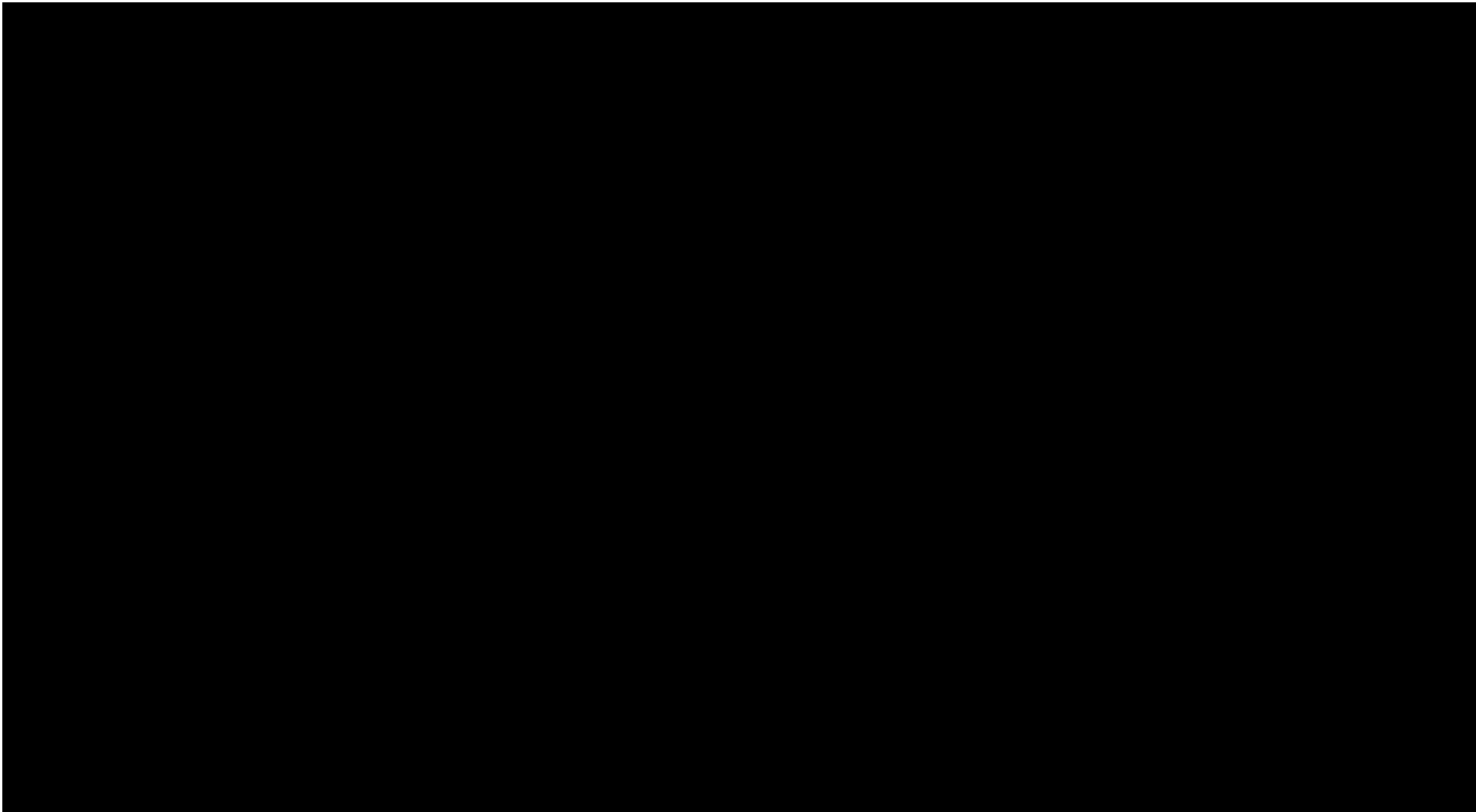
Status:
Page:

Final
Page 1568 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

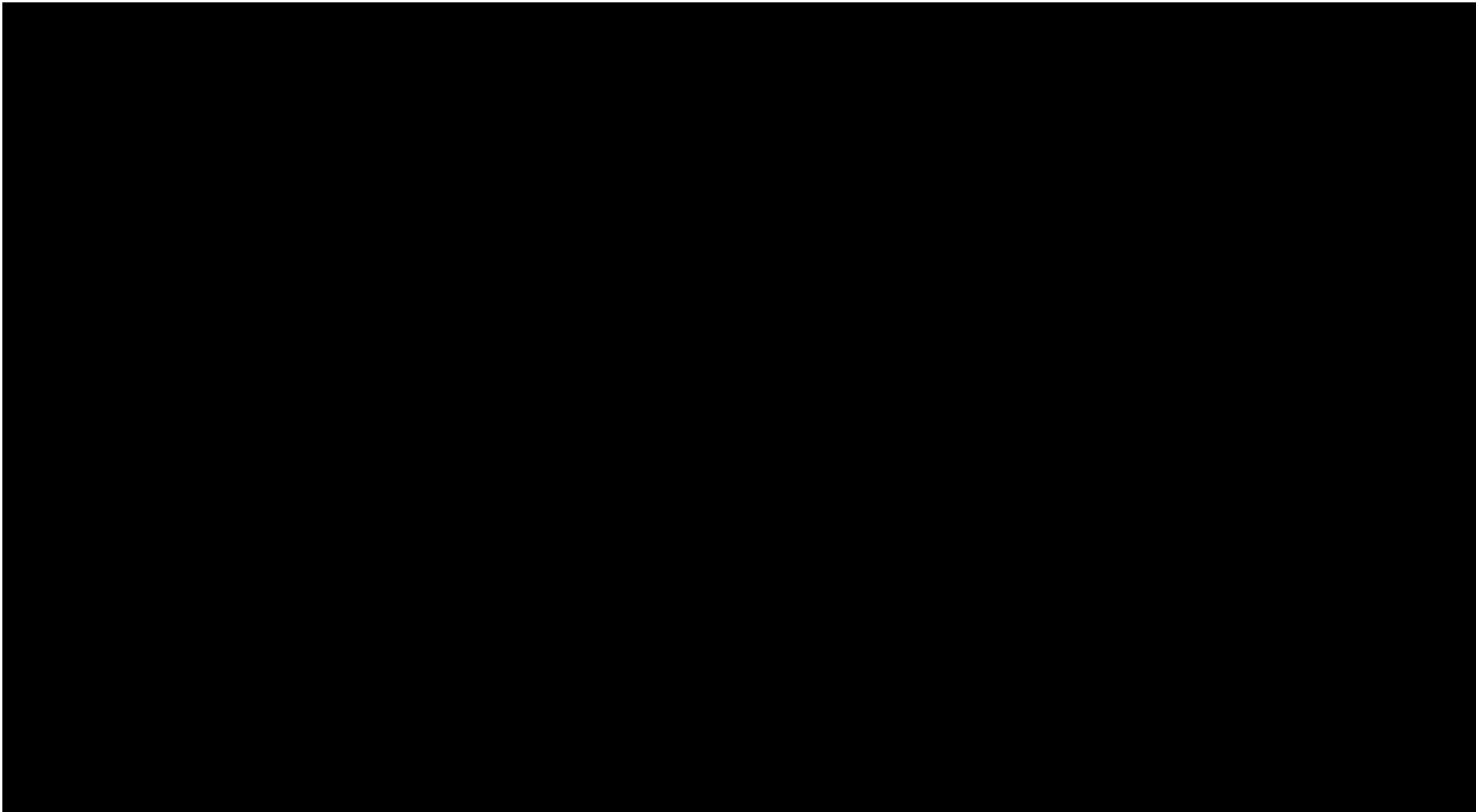
Status:
Page:

Final
Page 1570 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1571 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1572 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

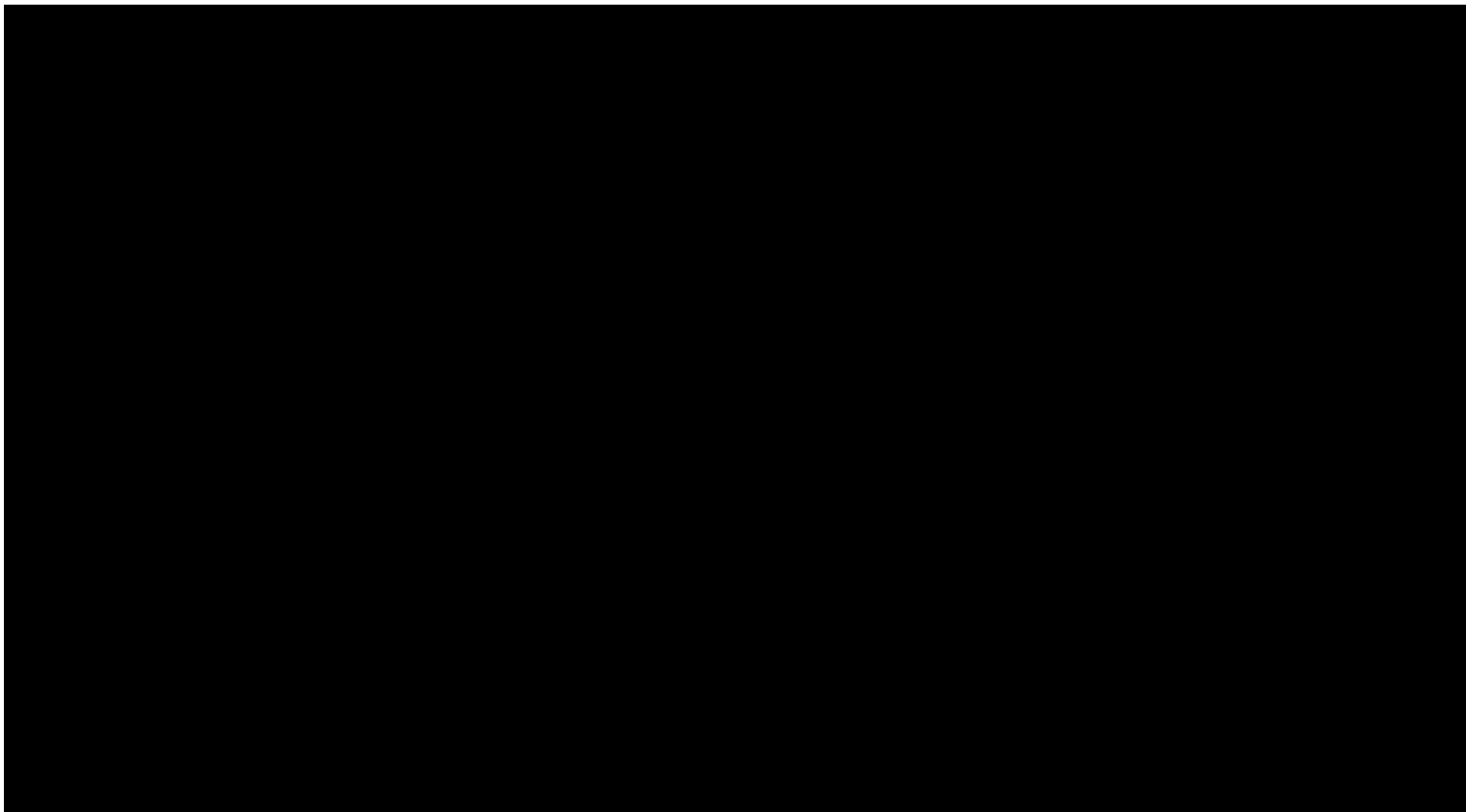
Status:
Page:

Final
Page 1575 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1577 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

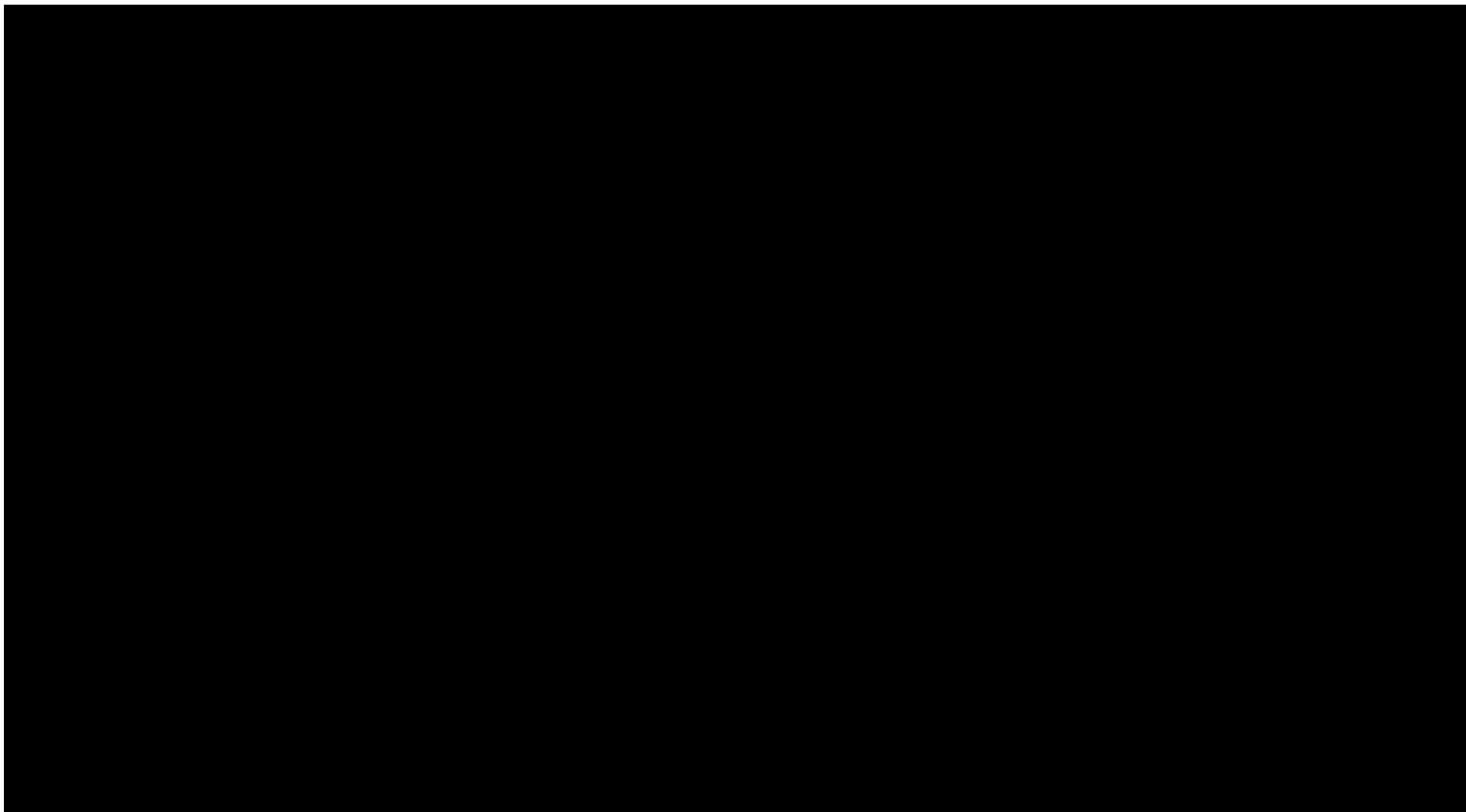
Status:
Page:

Final
Page 1578 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

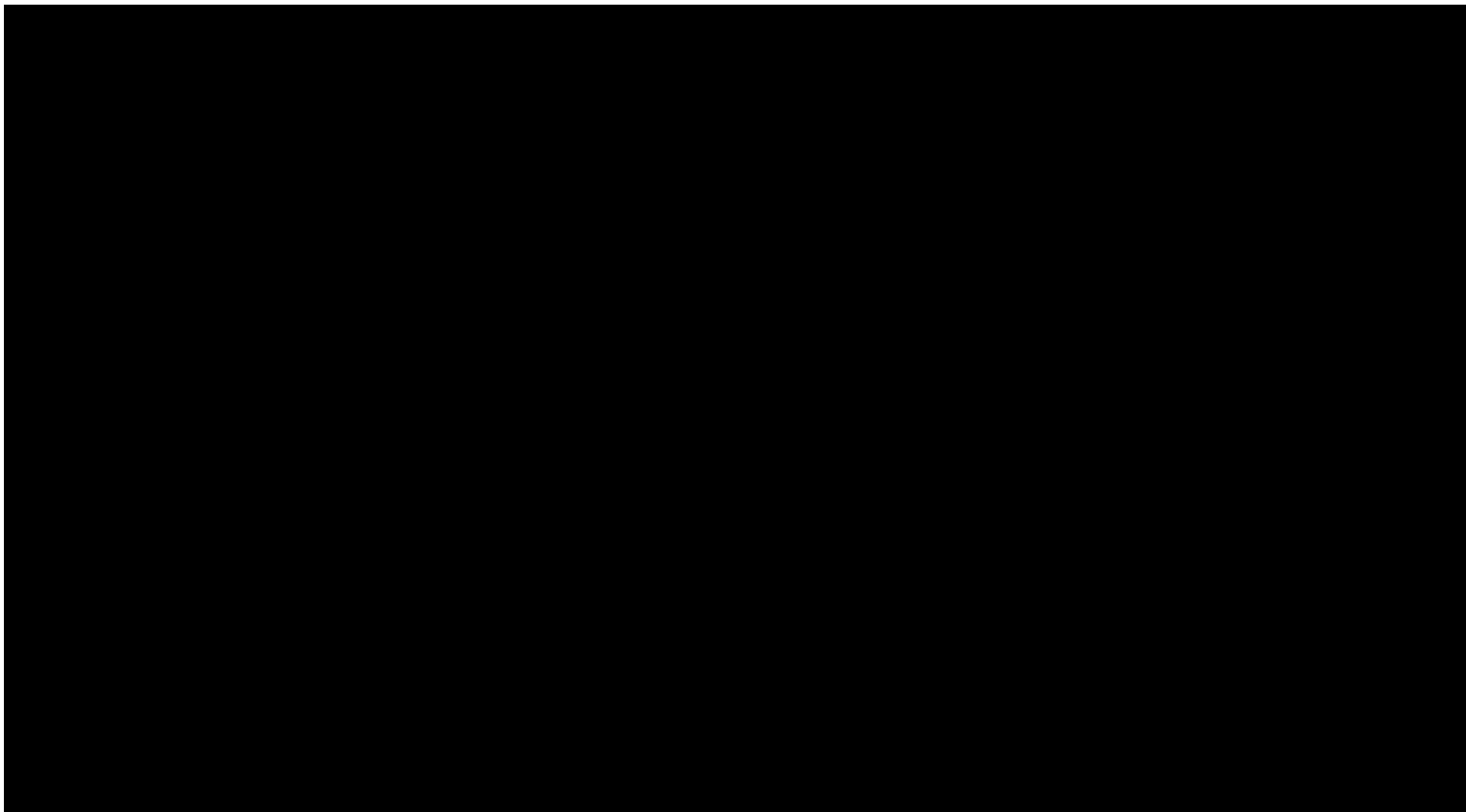
Status:
Page:

Final
Page 1579 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

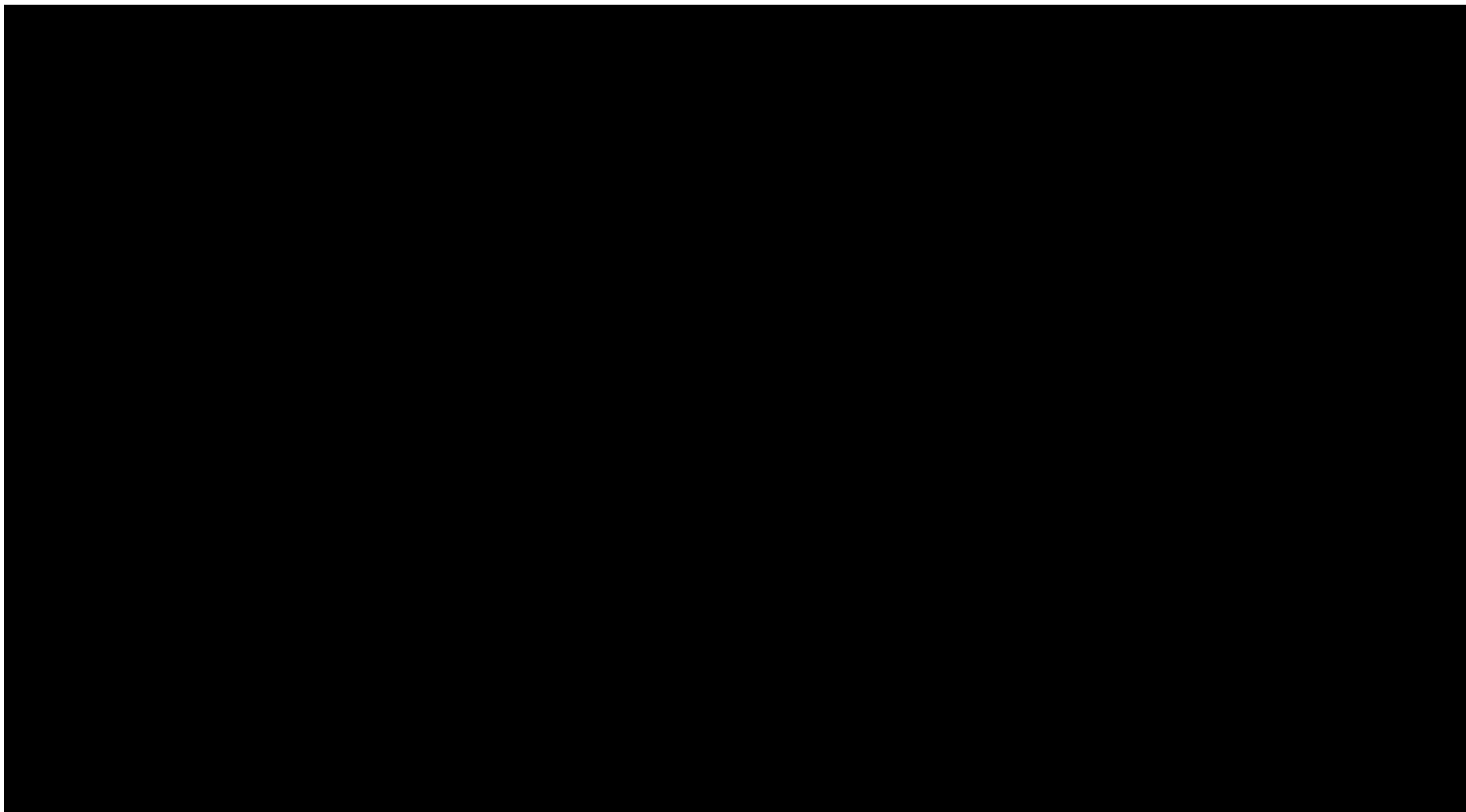
Status:
Page:

Final
Page 1580 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

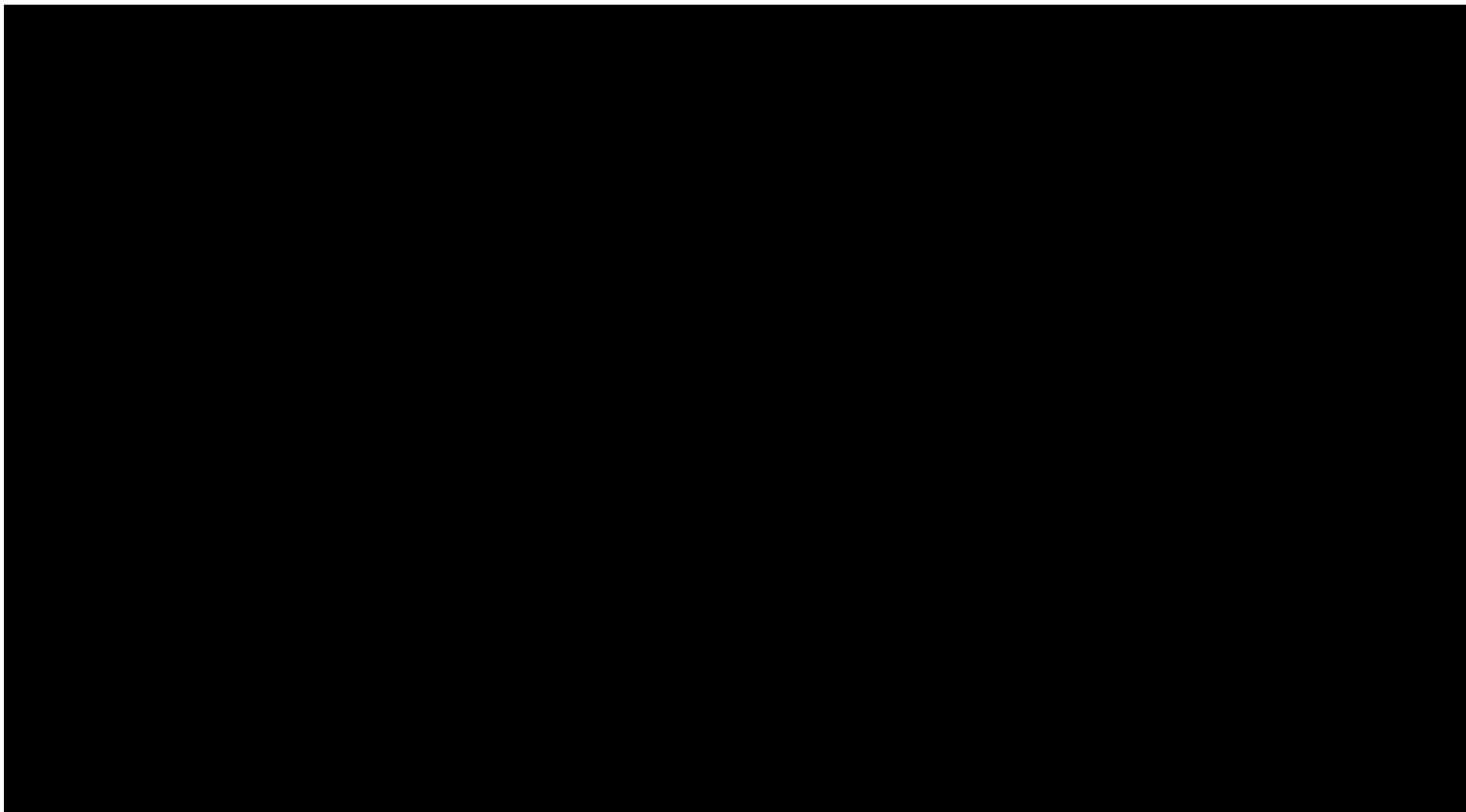
Status:
Page:

Final
Page 1581 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1582 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

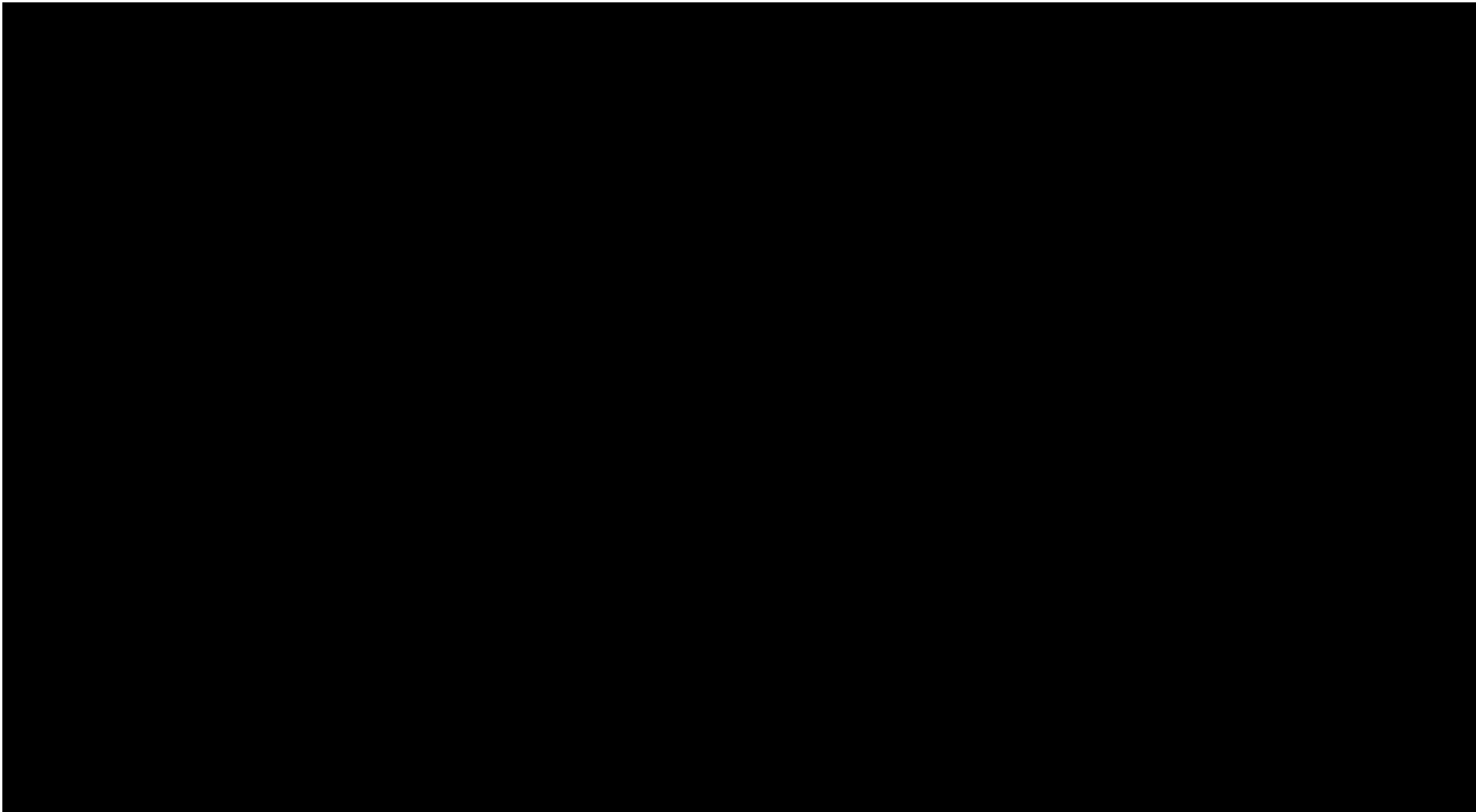
Status:
Page:

Final
Page 1583 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid color.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1585 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

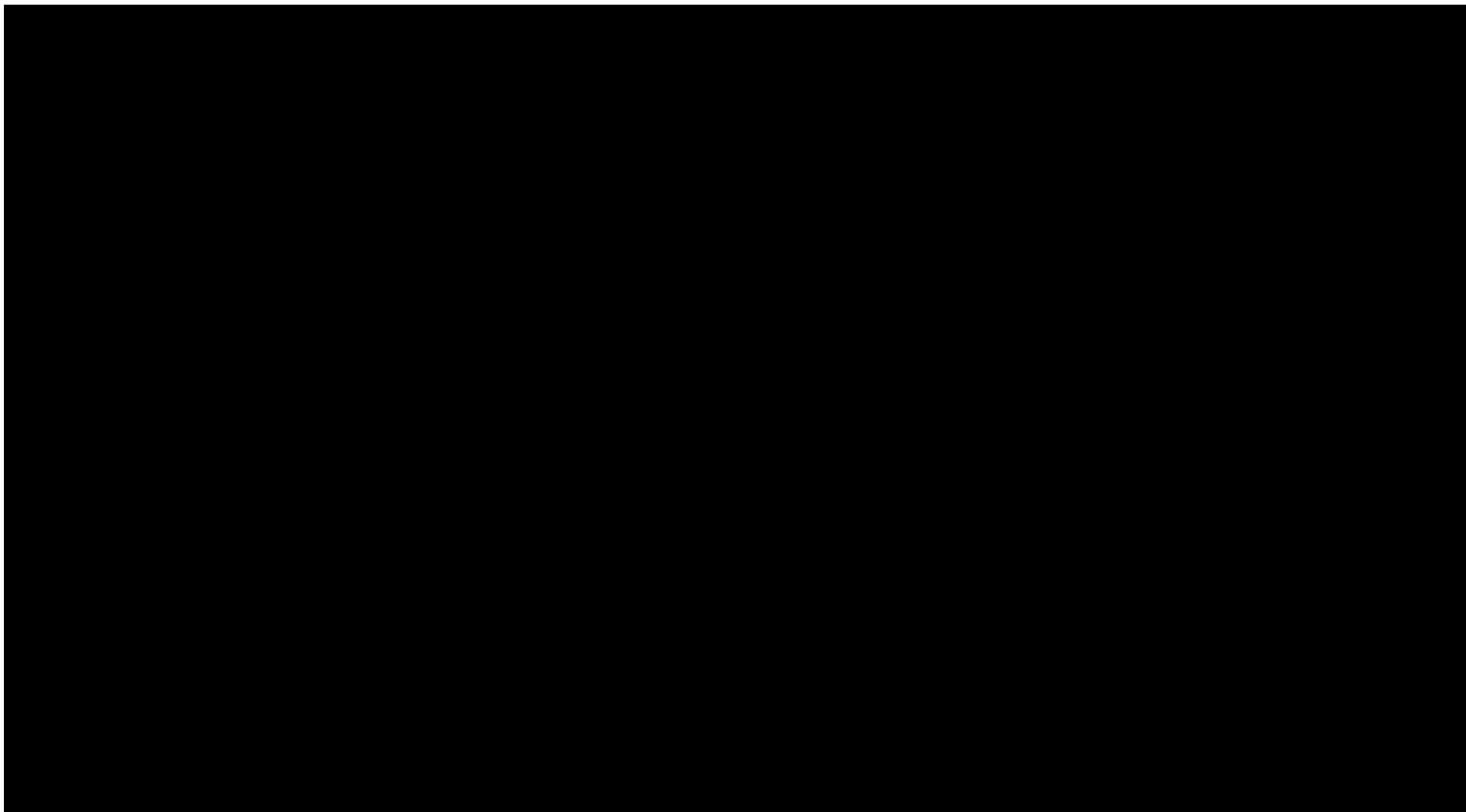
Status:
Page:

Final
Page 1586 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

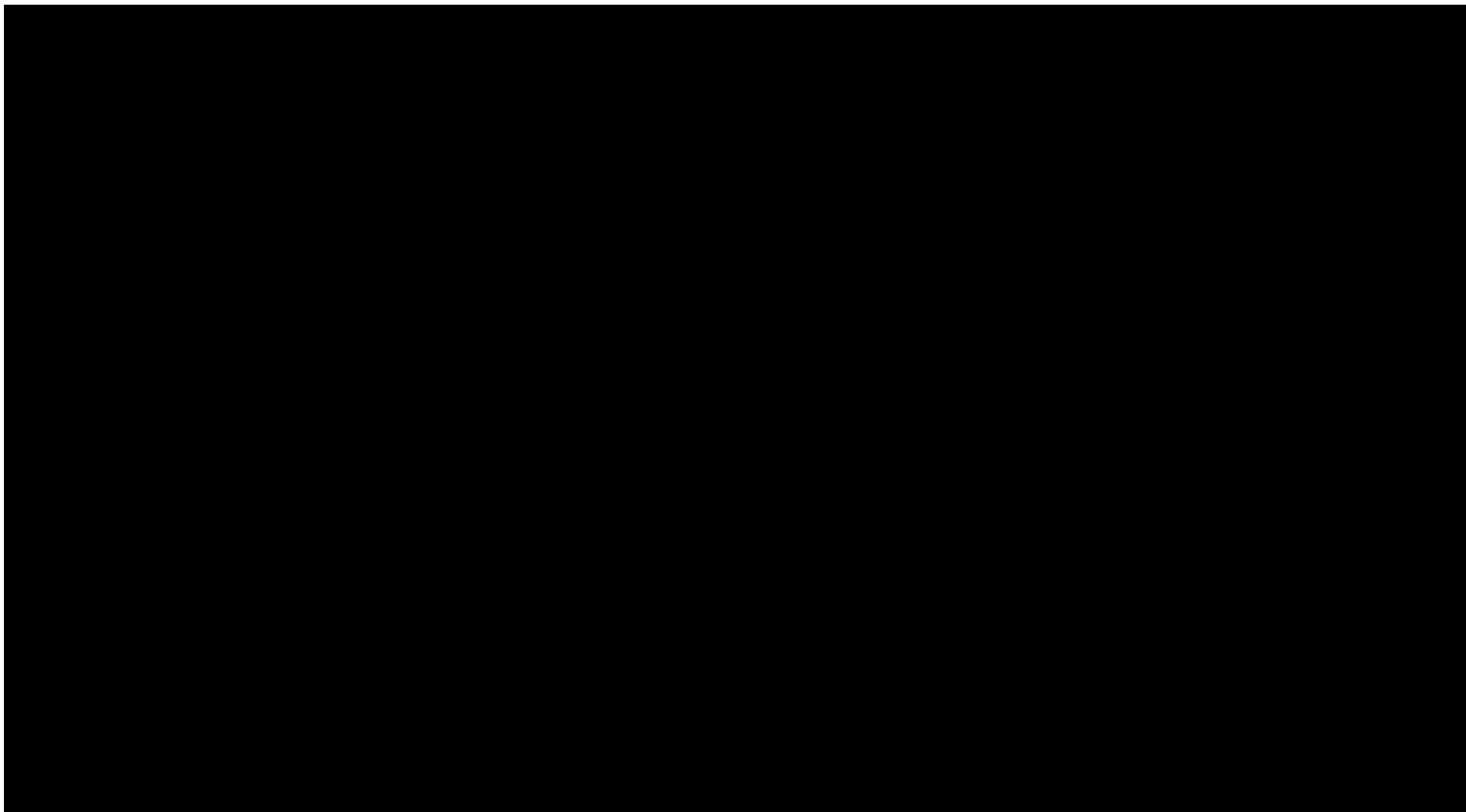
Status:
Page:

Final
Page 1587 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1589 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1590 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

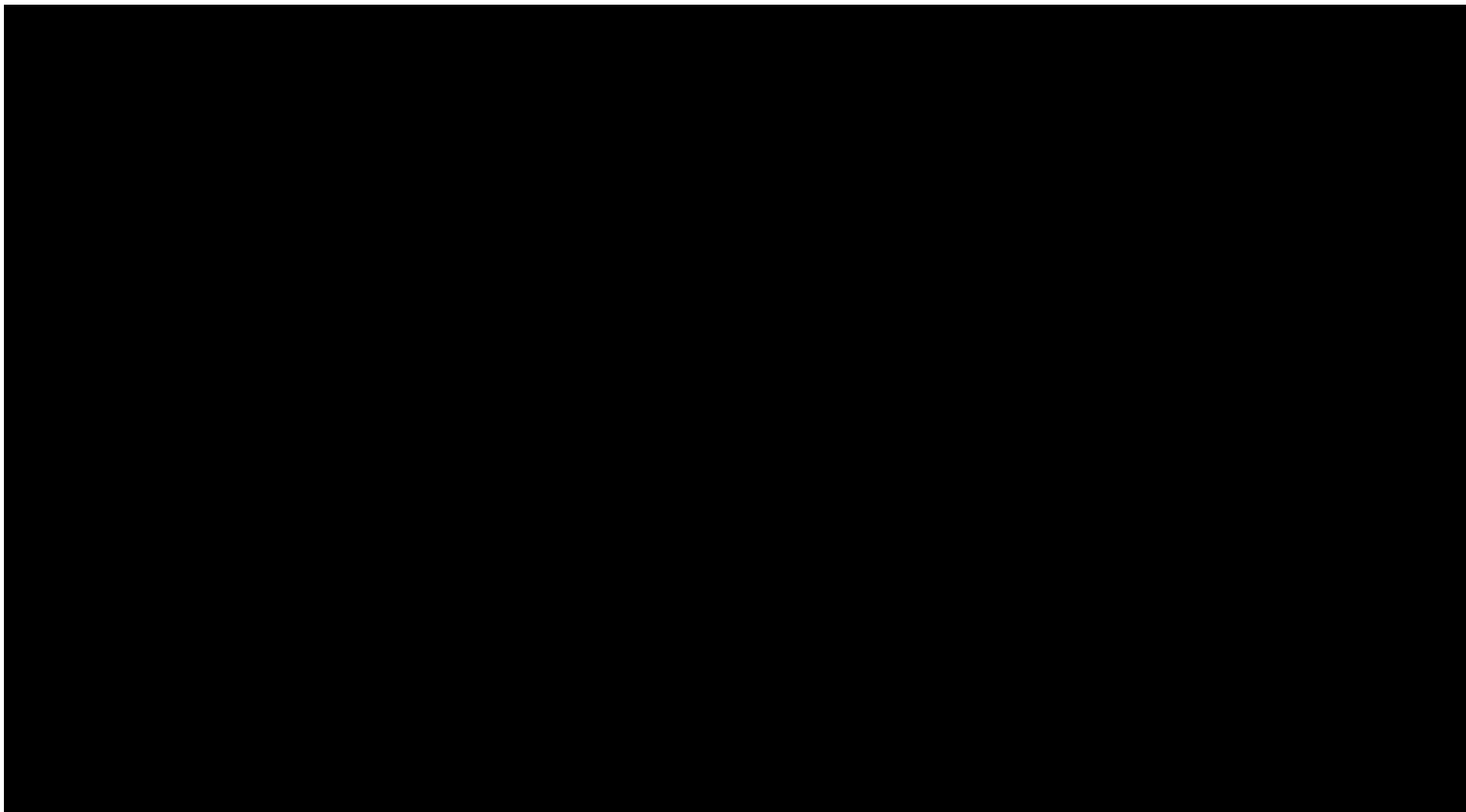
Status:
Page:

Final
Page 1592 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

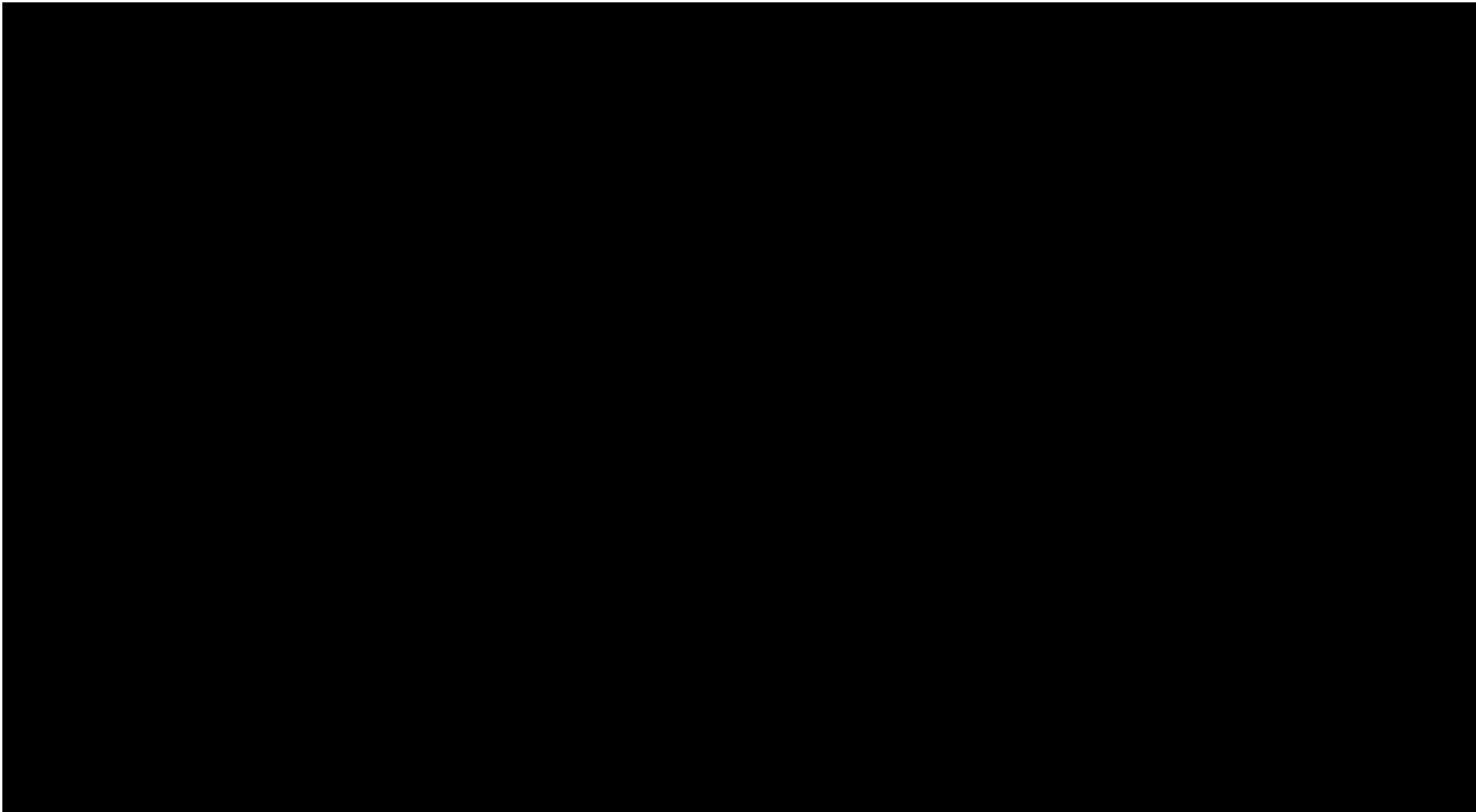
Status:
Page:

Final
Page 1593 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1595 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

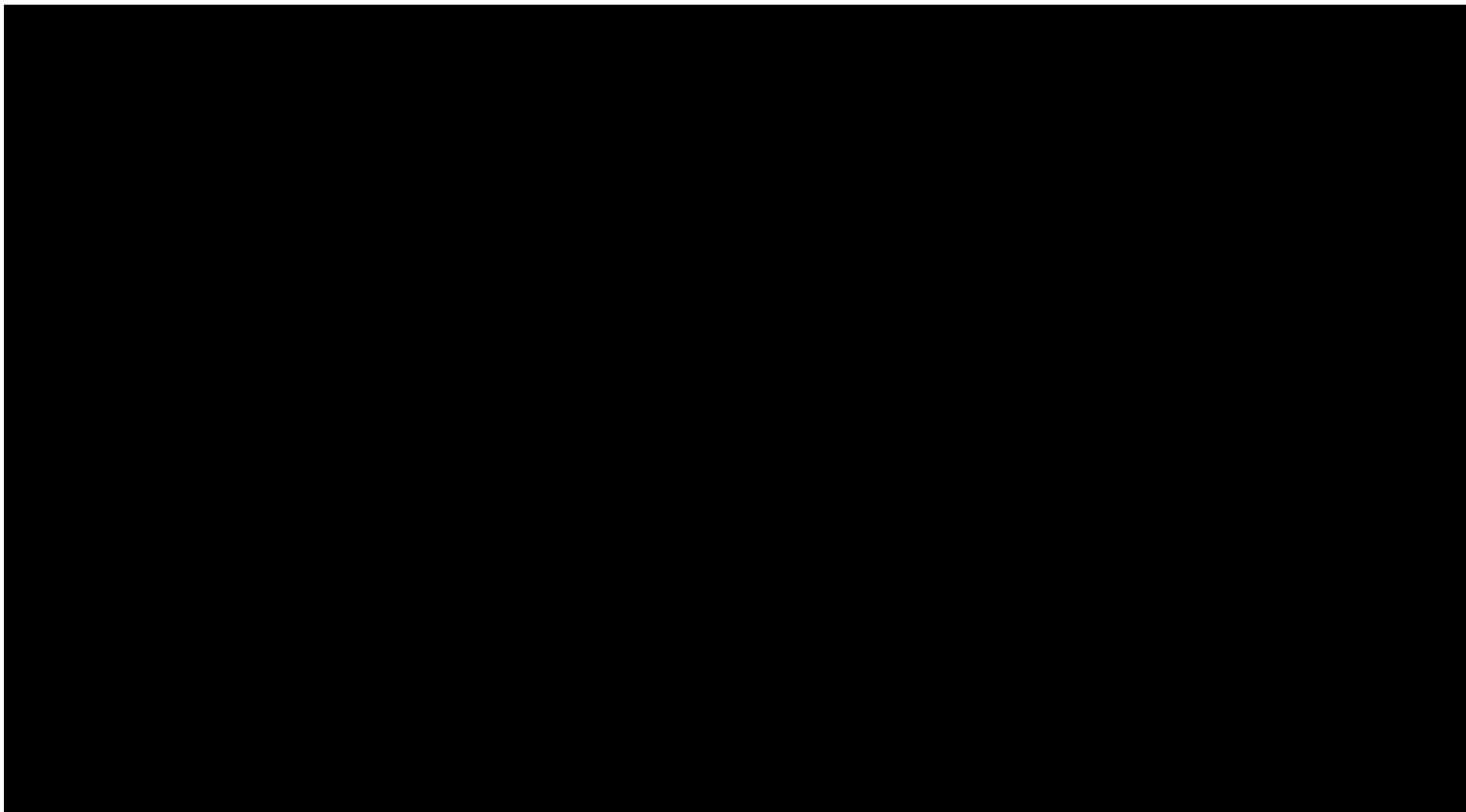
Status:
Page:

Final
Page 1597 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

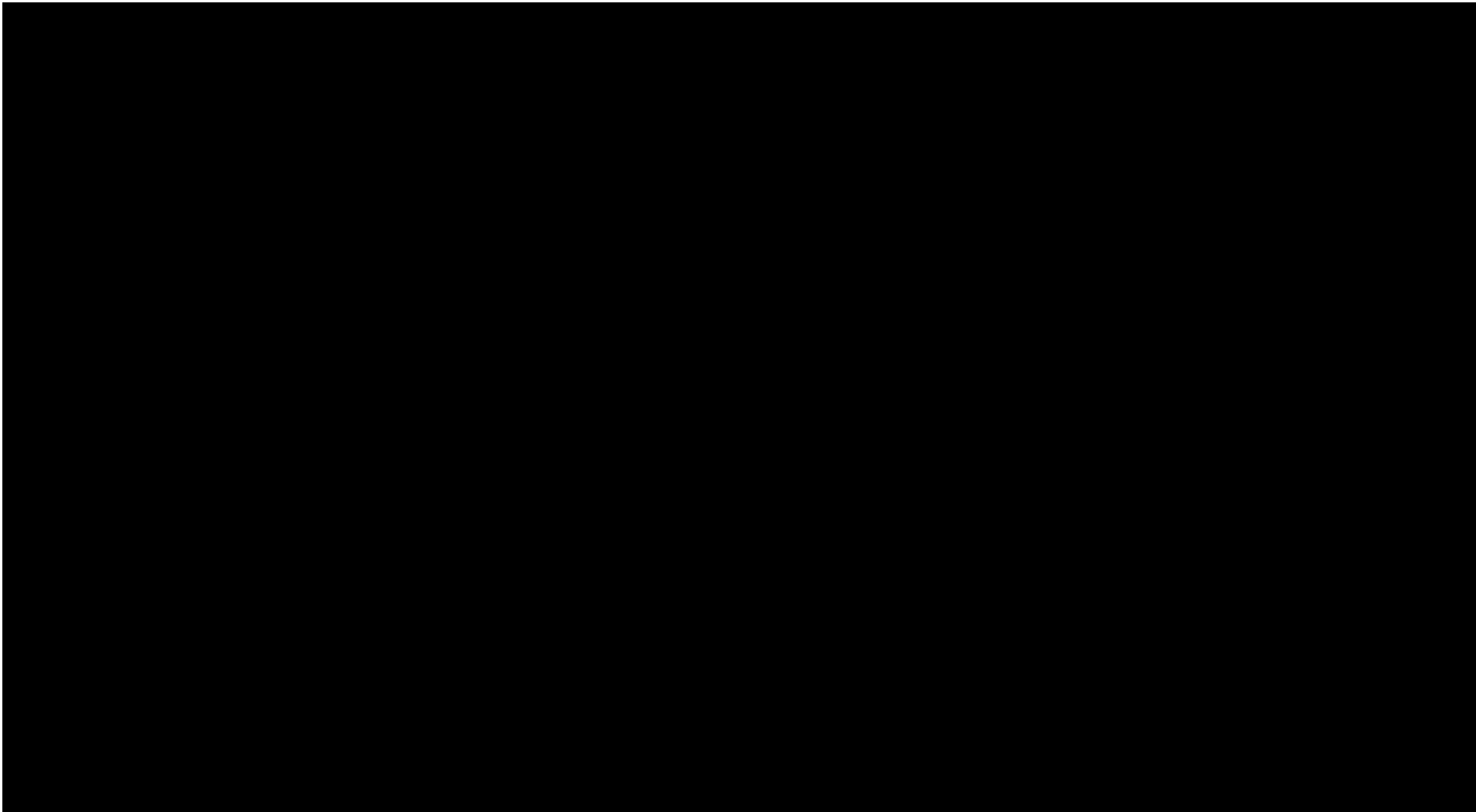
Status:
Page:

Final
Page 1598 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



[illegible]

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

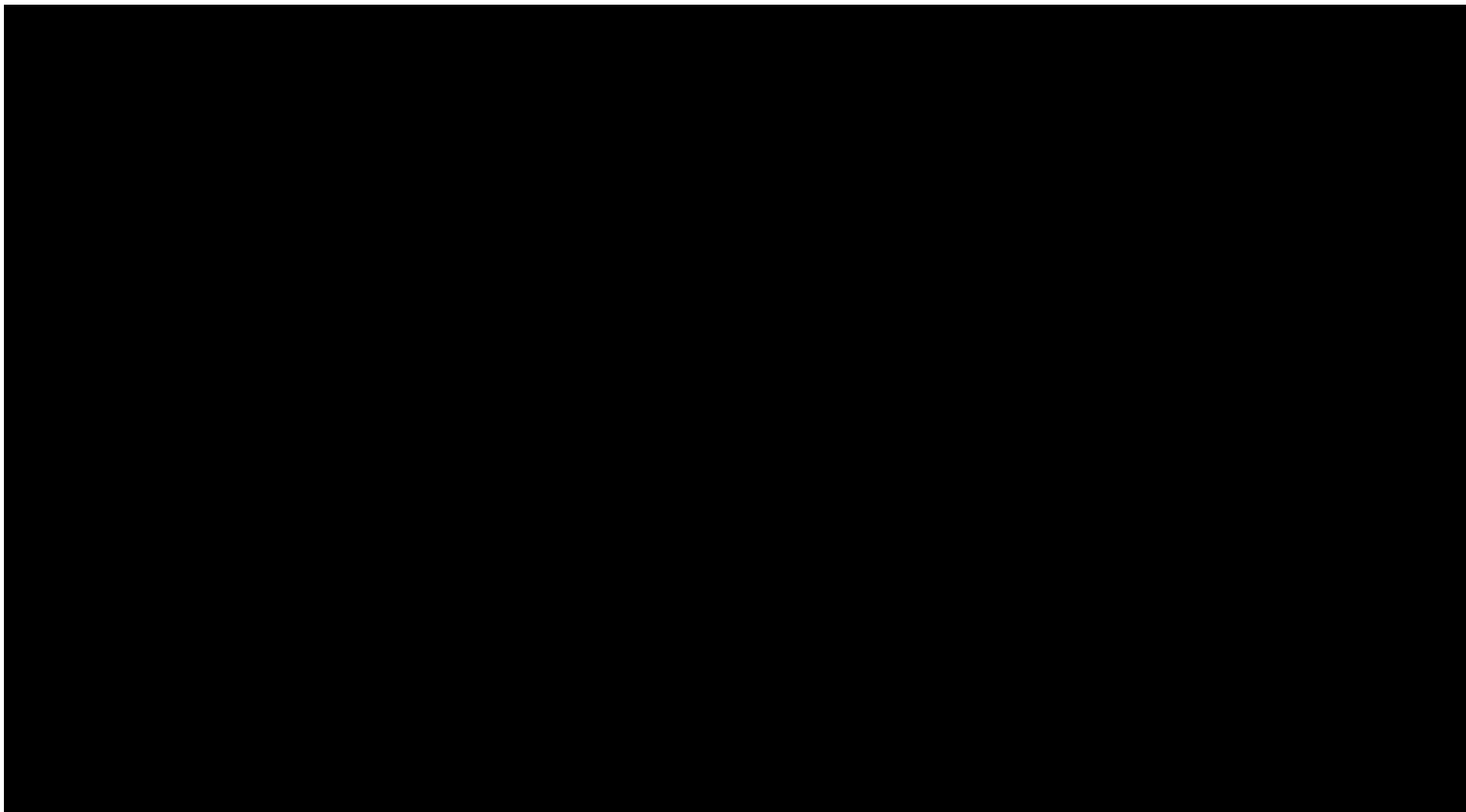
Status:
Page:

Final
Page 1600 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

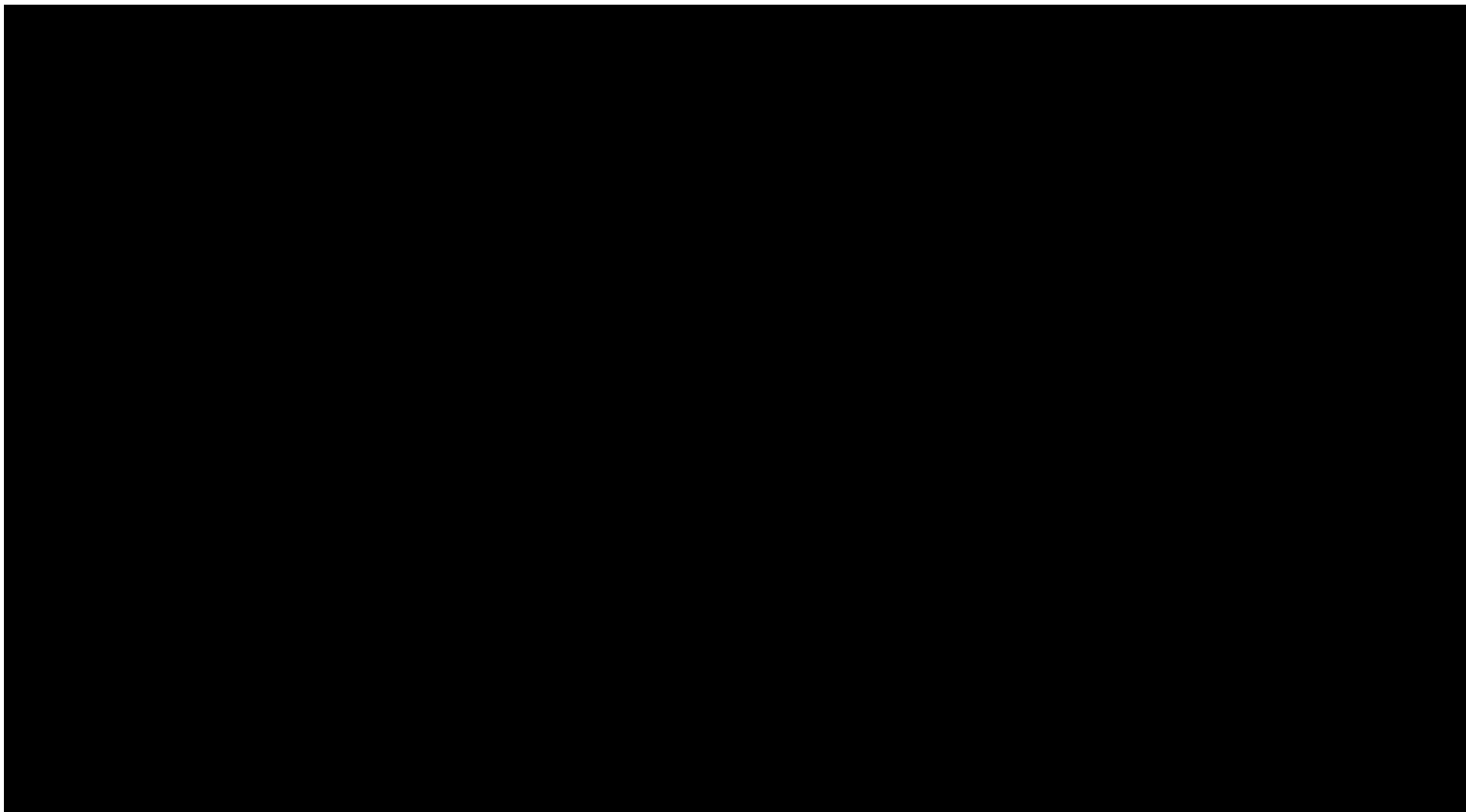
Status:
Page:

Final
Page 1601 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1602 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

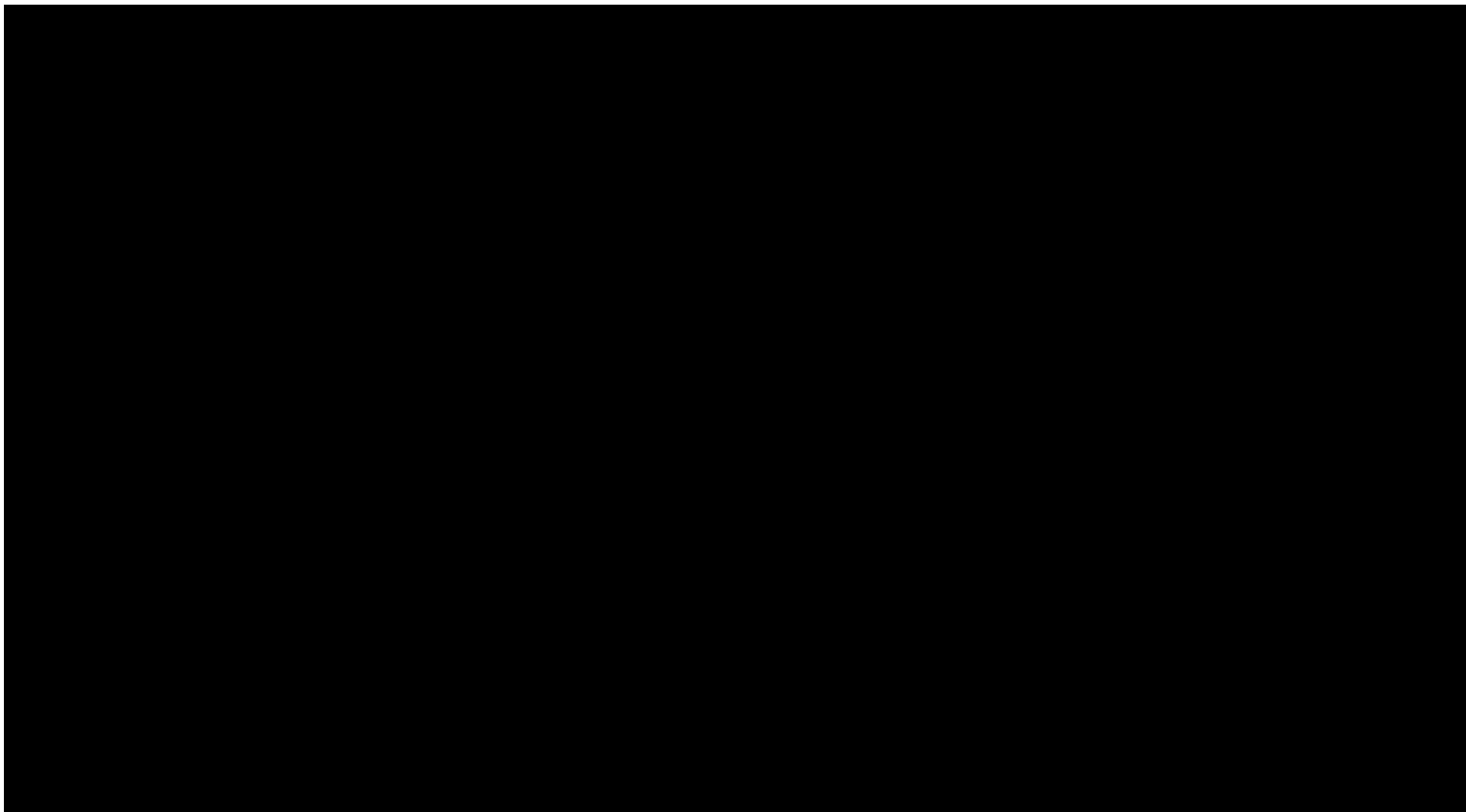
Status:
Page:

Final
Page 1603 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1604 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1605 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1606 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

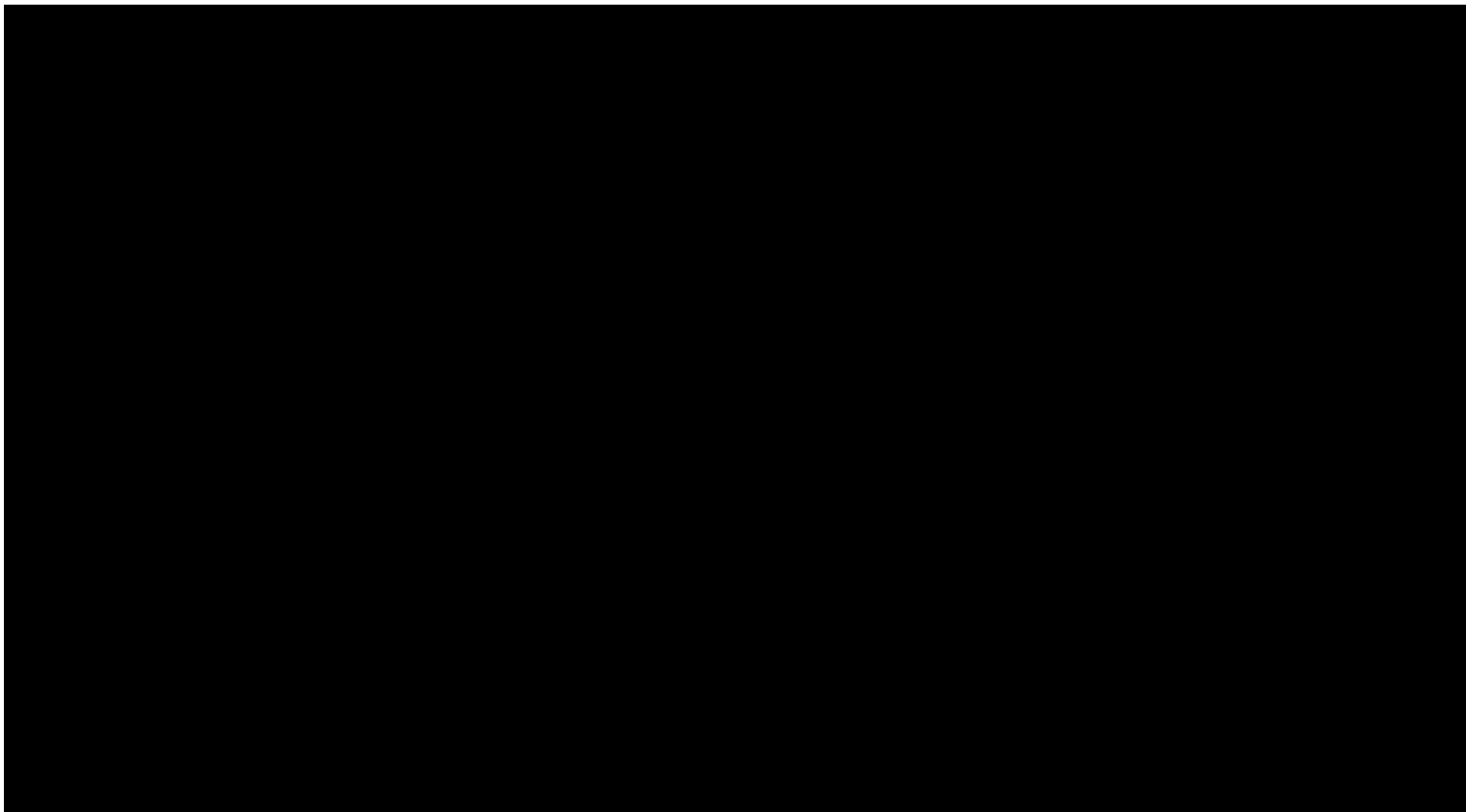
Status:
Page:

Final
Page 1607 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

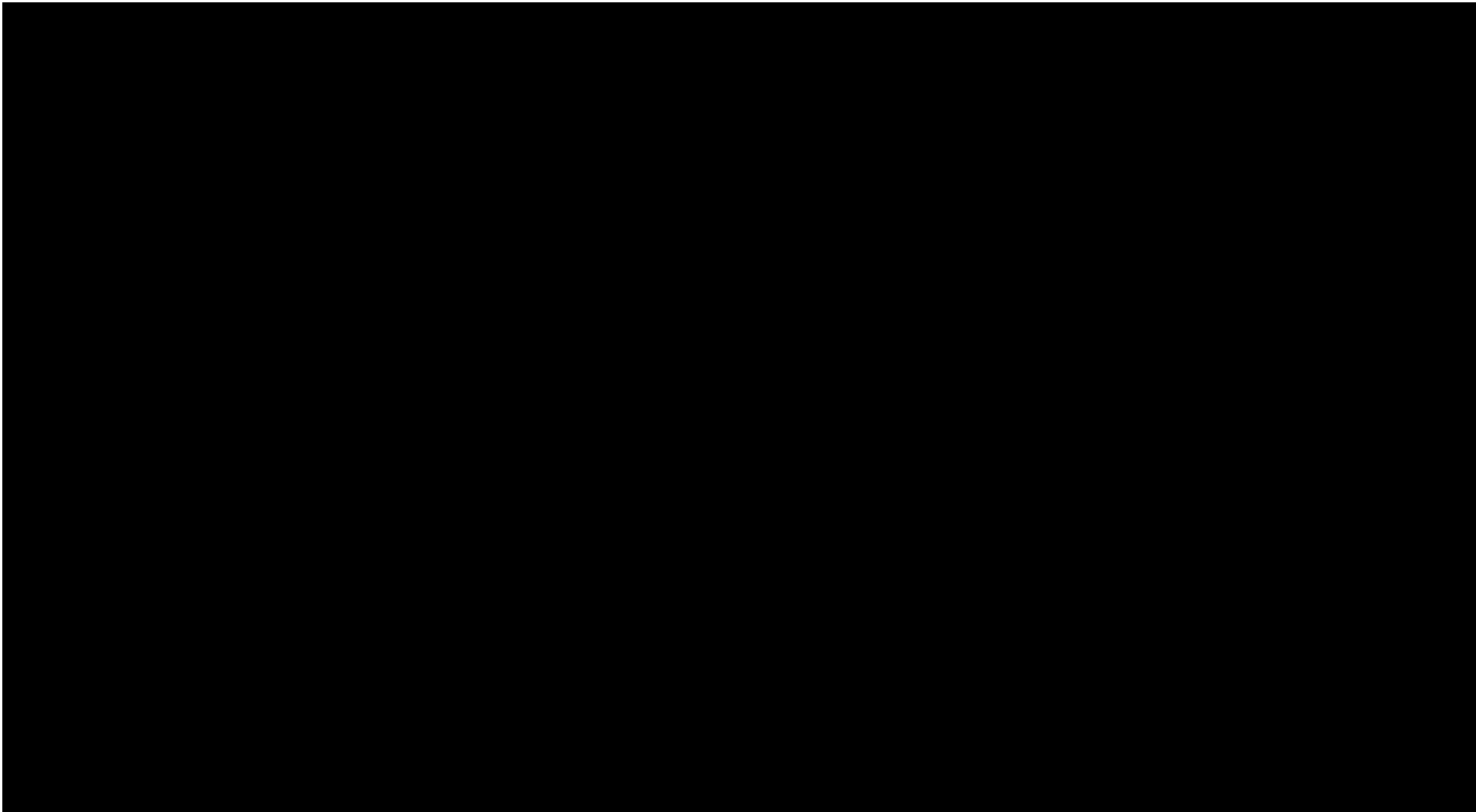
Status:
Page:

Final
Page 1608 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1609 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1610 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1611 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children and the number of children in the household. The rows represent different levels of the 'Number of children' variable (1, 2, 3) and the columns represent different levels of the 'Number of children in the household' variable (1, 2, 3). Each plot shows a positive correlation between the two variables.

The plots are arranged as follows:

- Row 1: Number of children = 1. Column 1: Number of children in the household = 1. Column 2: Number of children in the household = 2. Column 3: Number of children in the household = 3.
- Row 2: Number of children = 2. Column 1: Number of children in the household = 1. Column 2: Number of children in the household = 2. Column 3: Number of children in the household = 3.
- Row 3: Number of children = 3. Column 1: Number of children in the household = 1. Column 2: Number of children in the household = 2. Column 3: Number of children in the household = 3.

Each plot shows a positive correlation between the number of children and the number of children in the household. The plots are arranged in a 3x3 grid, with the rows representing the number of children and the columns representing the number of children in the household.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1613 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1614 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

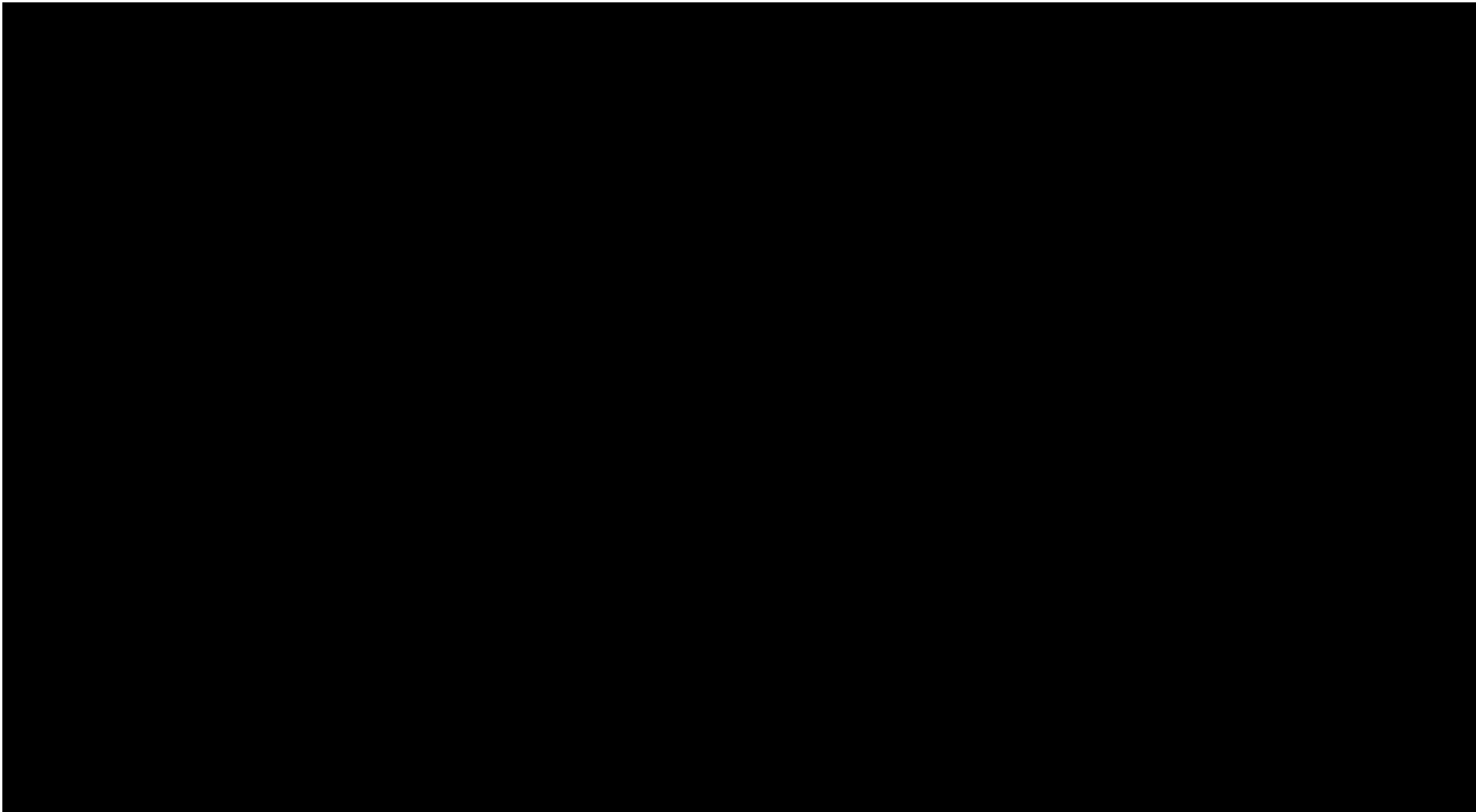
Status:
Page:

Final
Page 1615 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

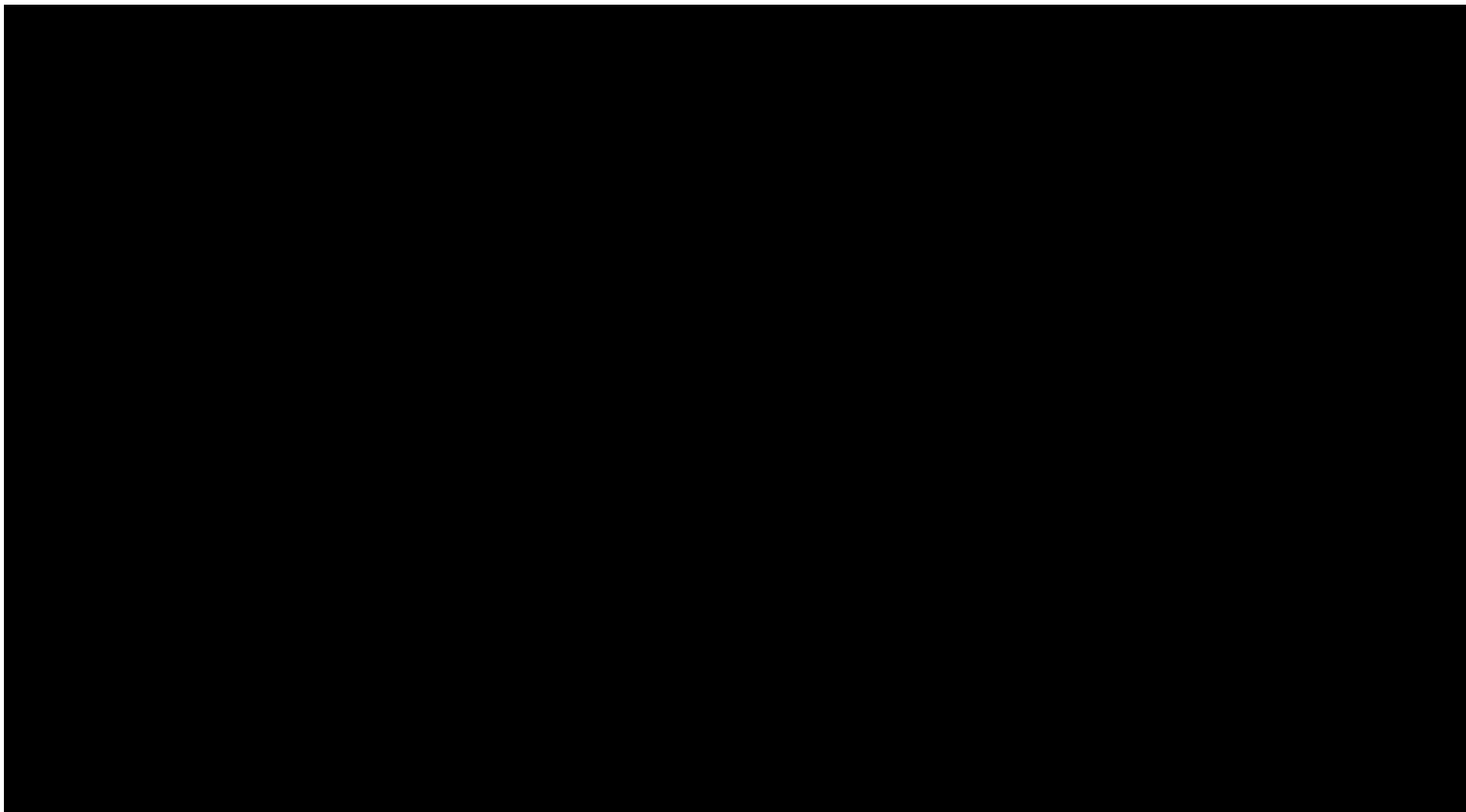
Status:
Page:

Final
Page 1616 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1617 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1618 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

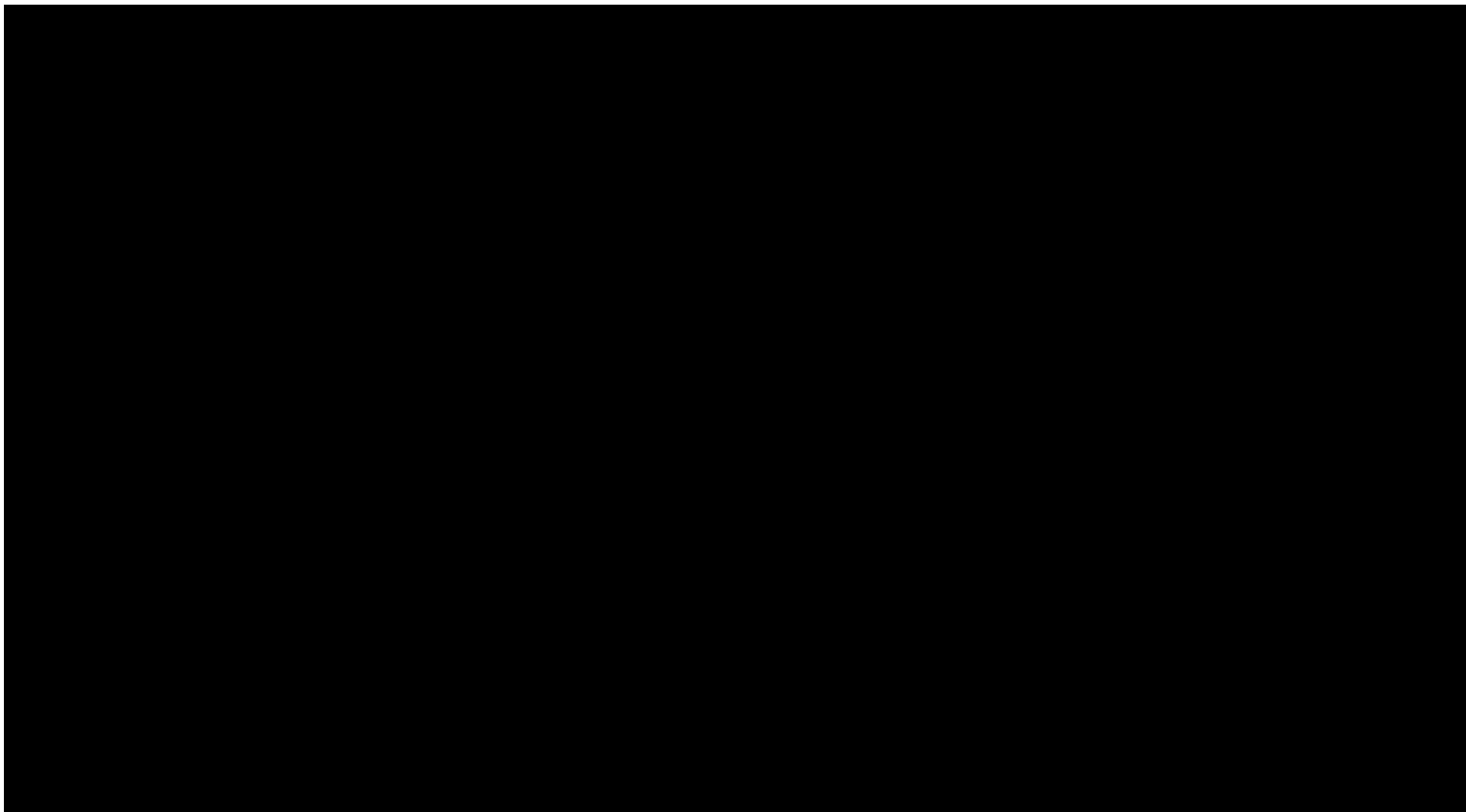
Status:
Page:

Final
Page 1619 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

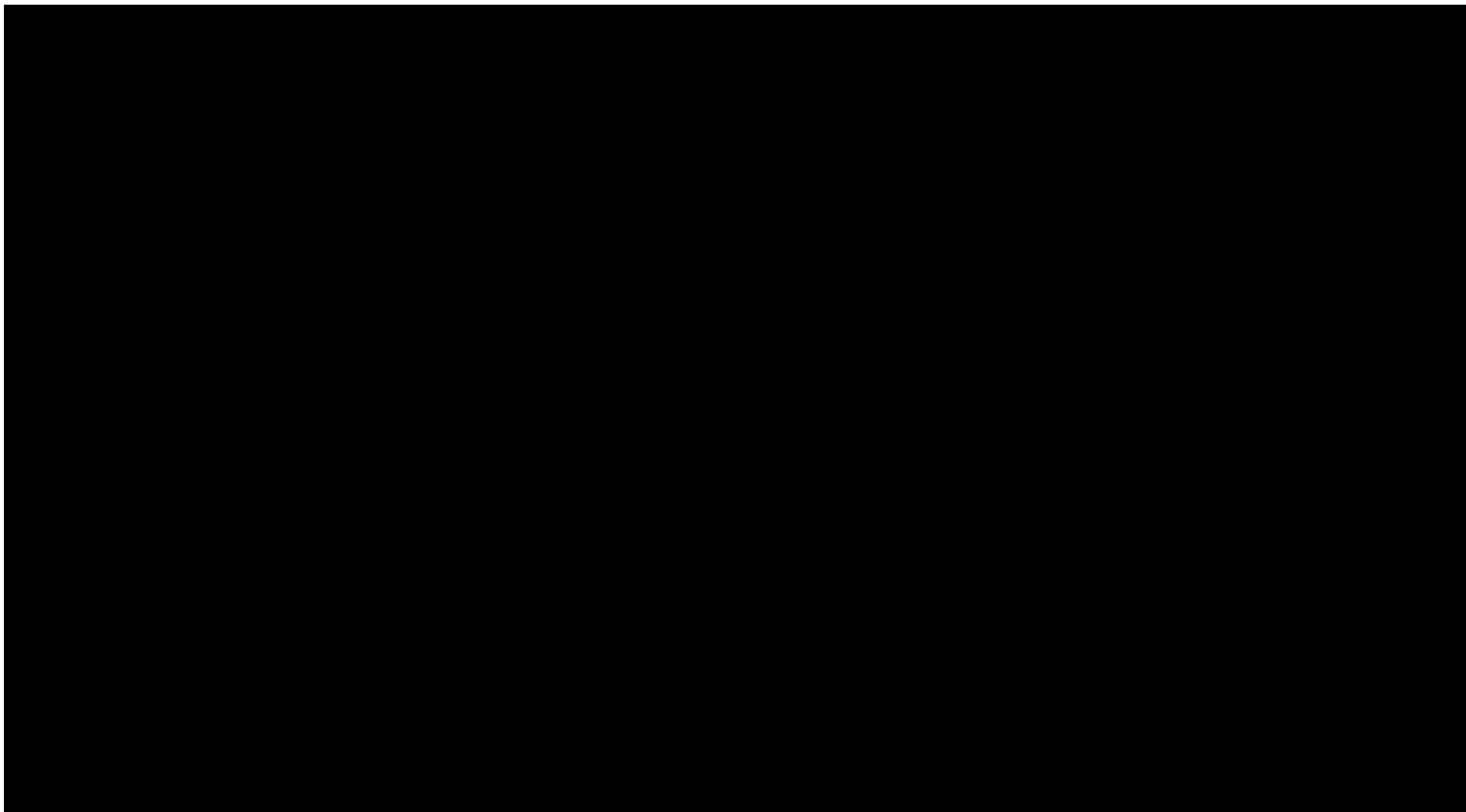
Status:
Page:

Final
Page 1620 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

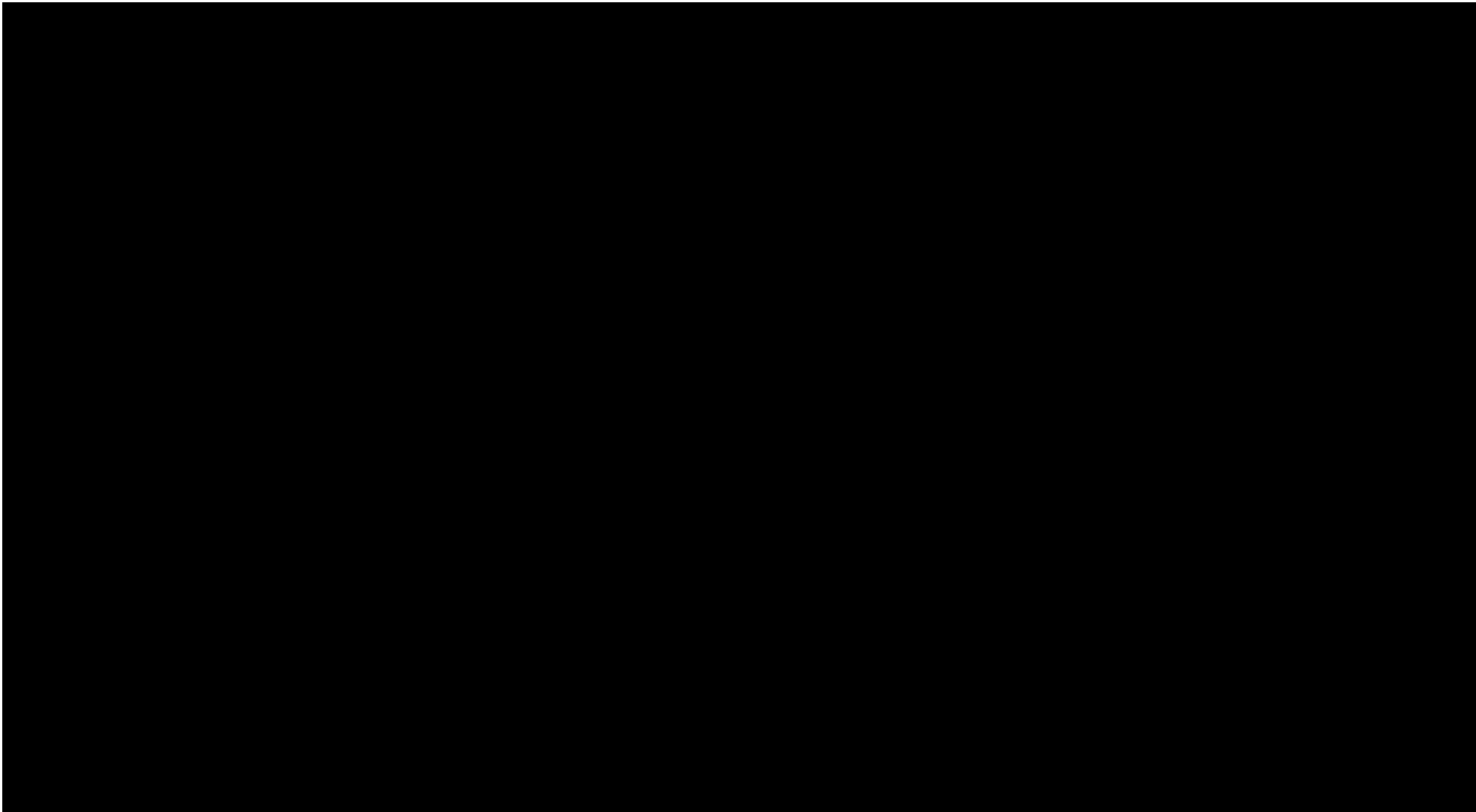
Status:
Page:

Final
Page 1621 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1622 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1623 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

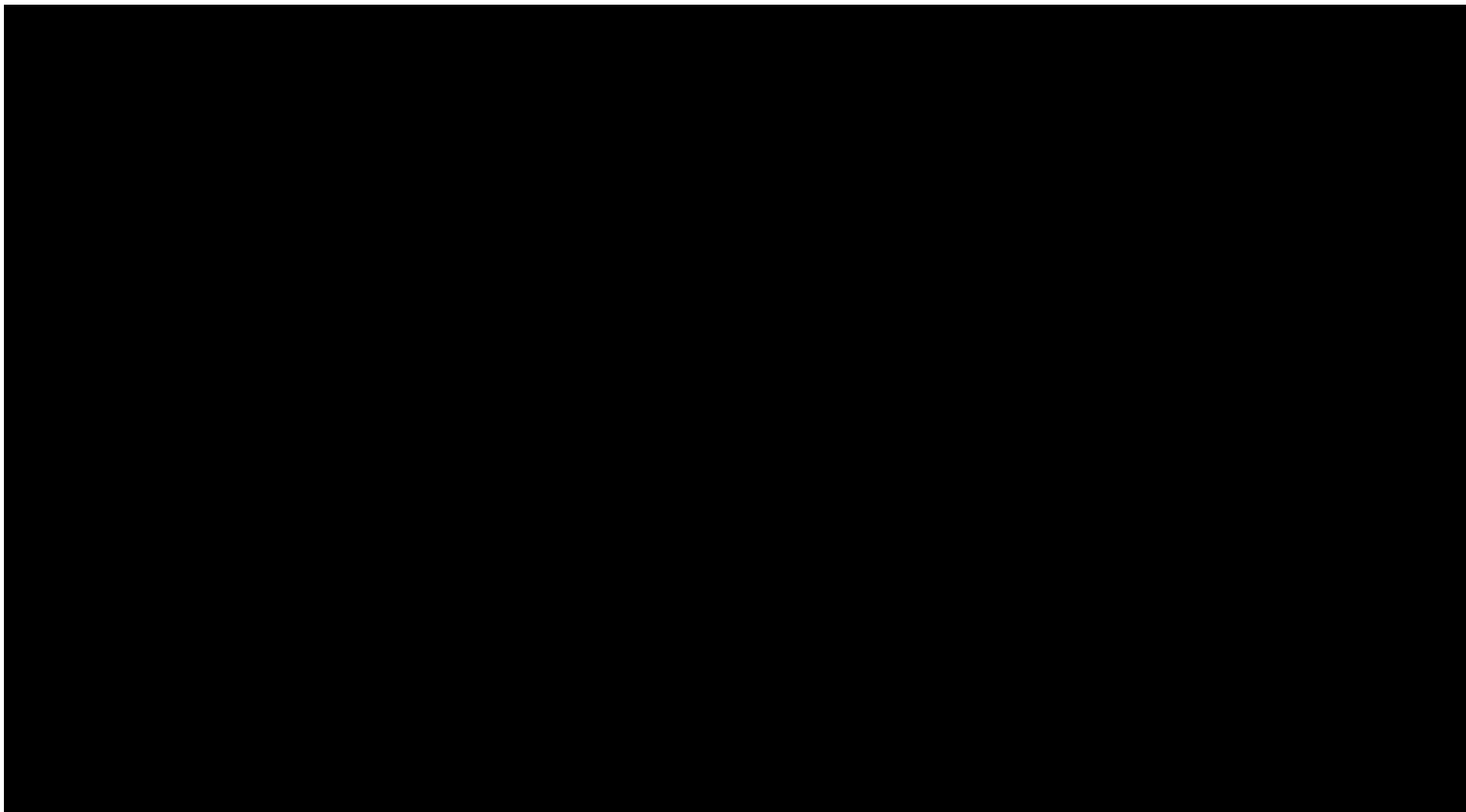
Status:
Page:

Final
Page 1624 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1625 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

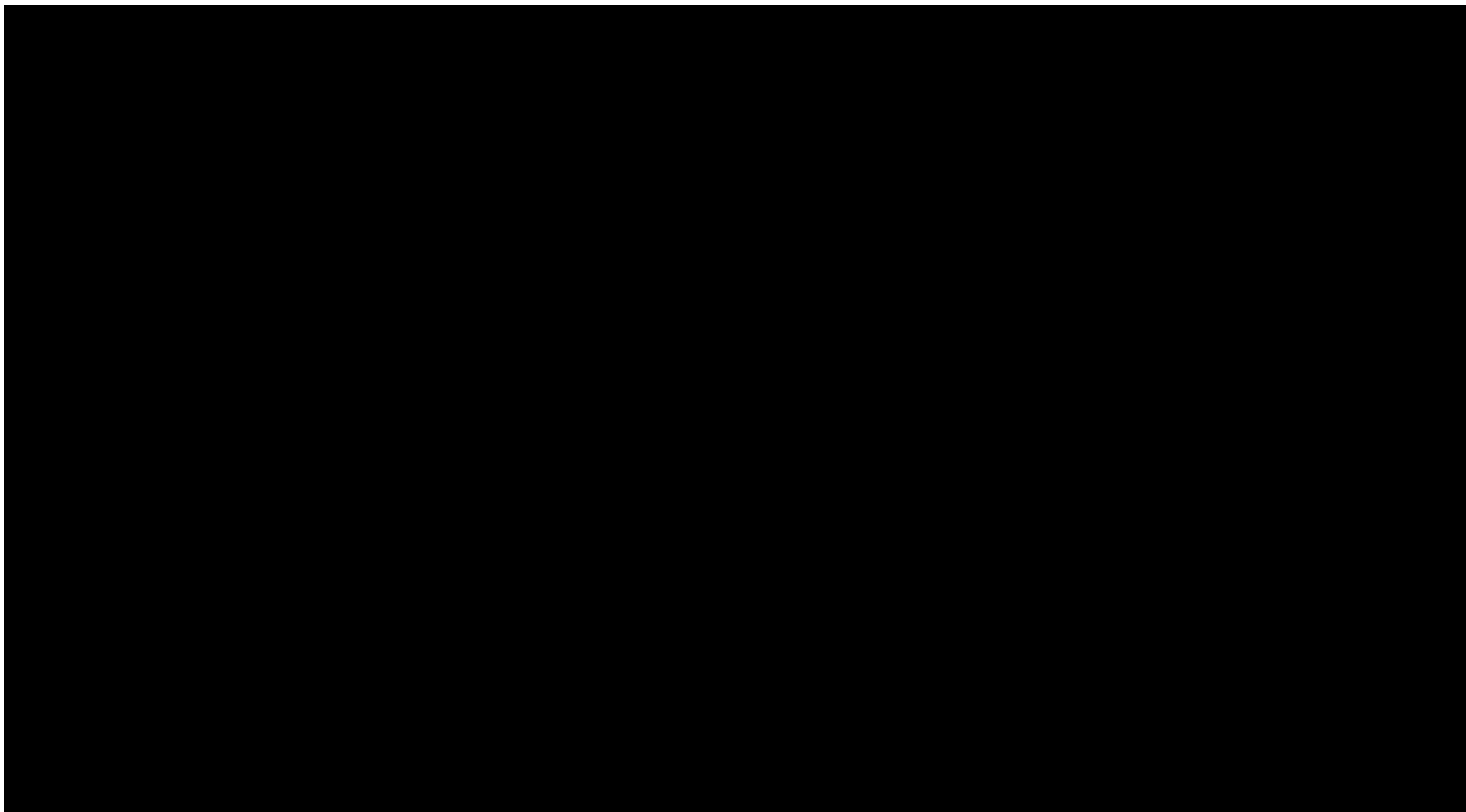
Status:
Page:

Final
Page 1626 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1627 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1628 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

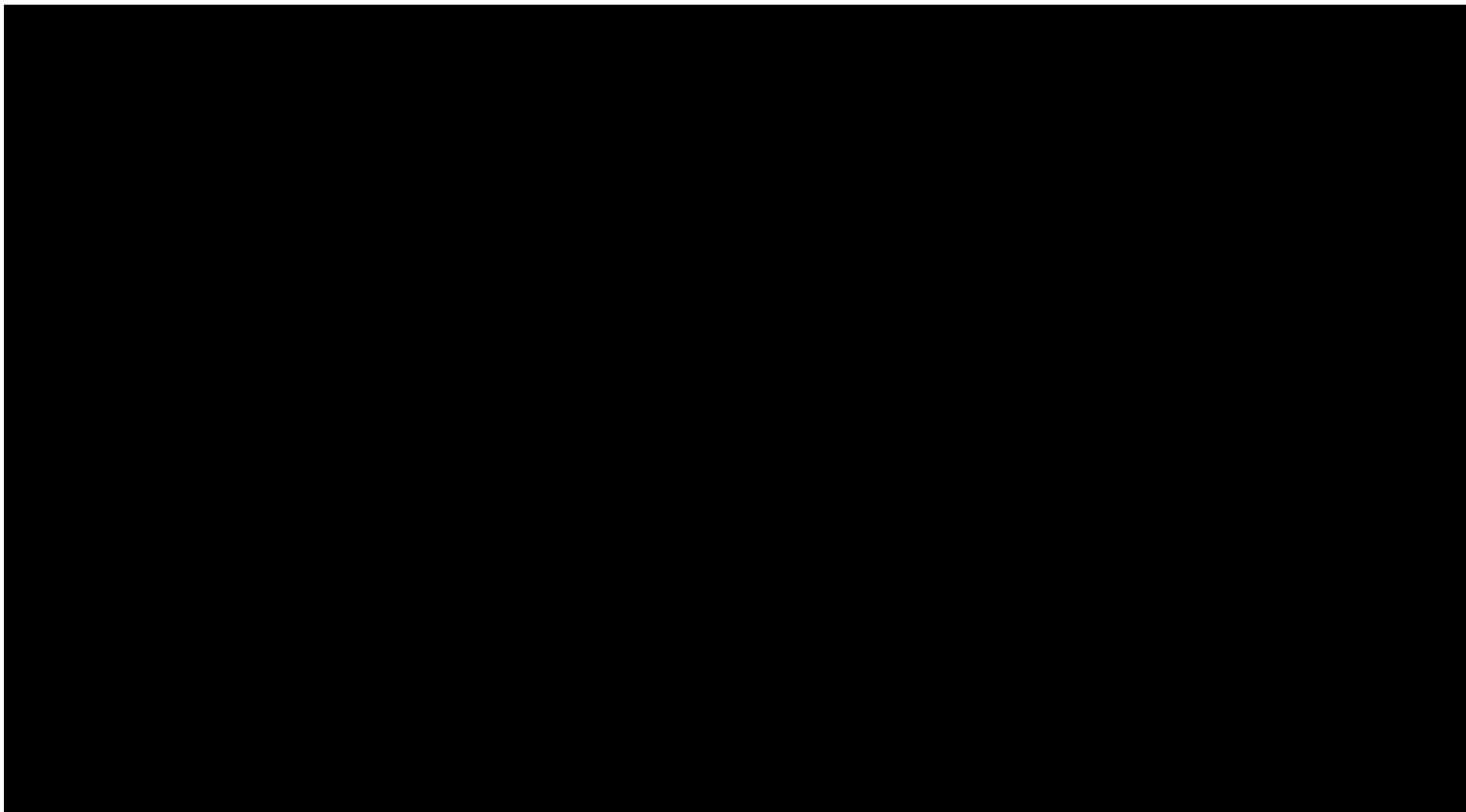
Status:
Page:

Final
Page 1629 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1630 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1632 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1633 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1636 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

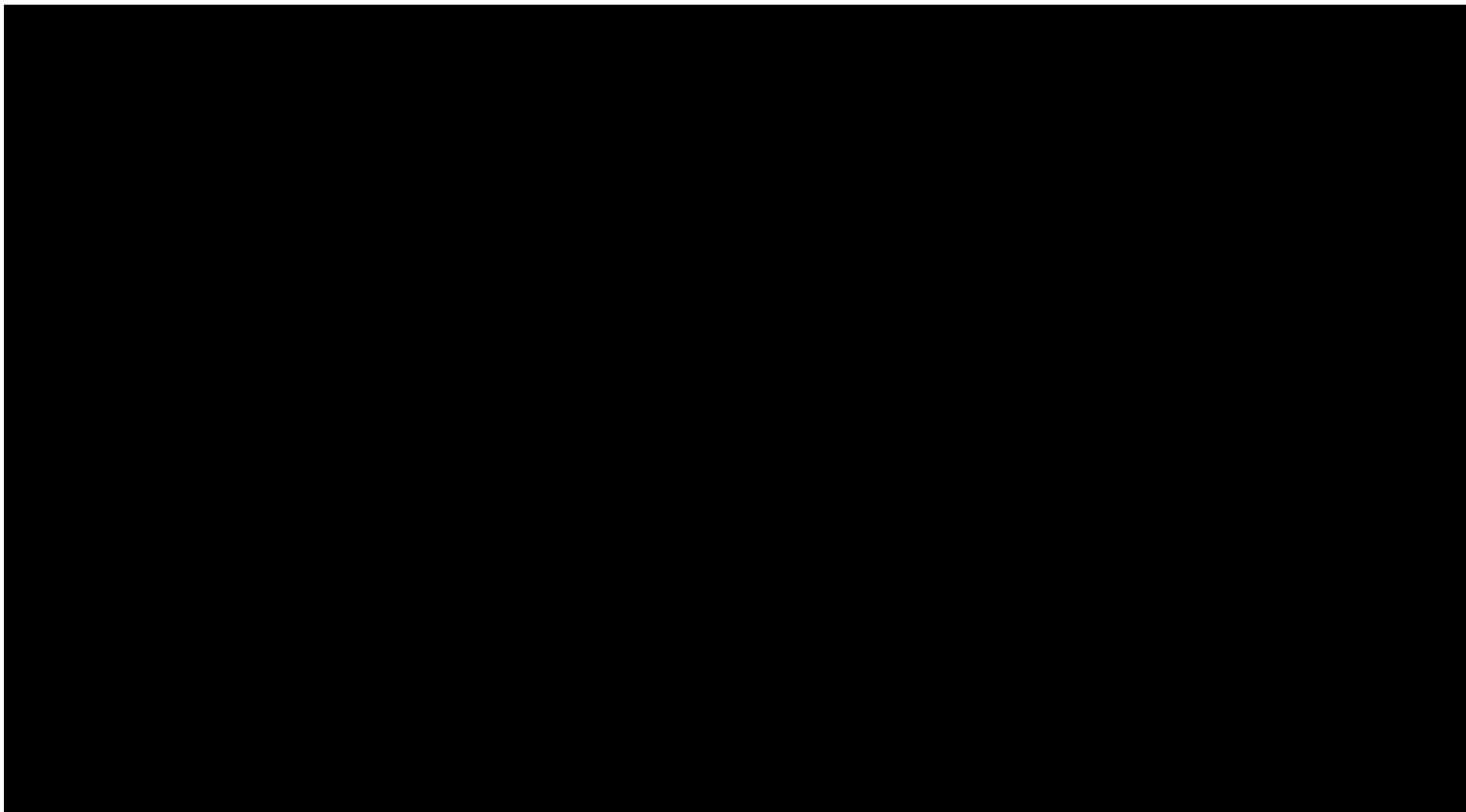
Status:
Page:

Final
Page 1637 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

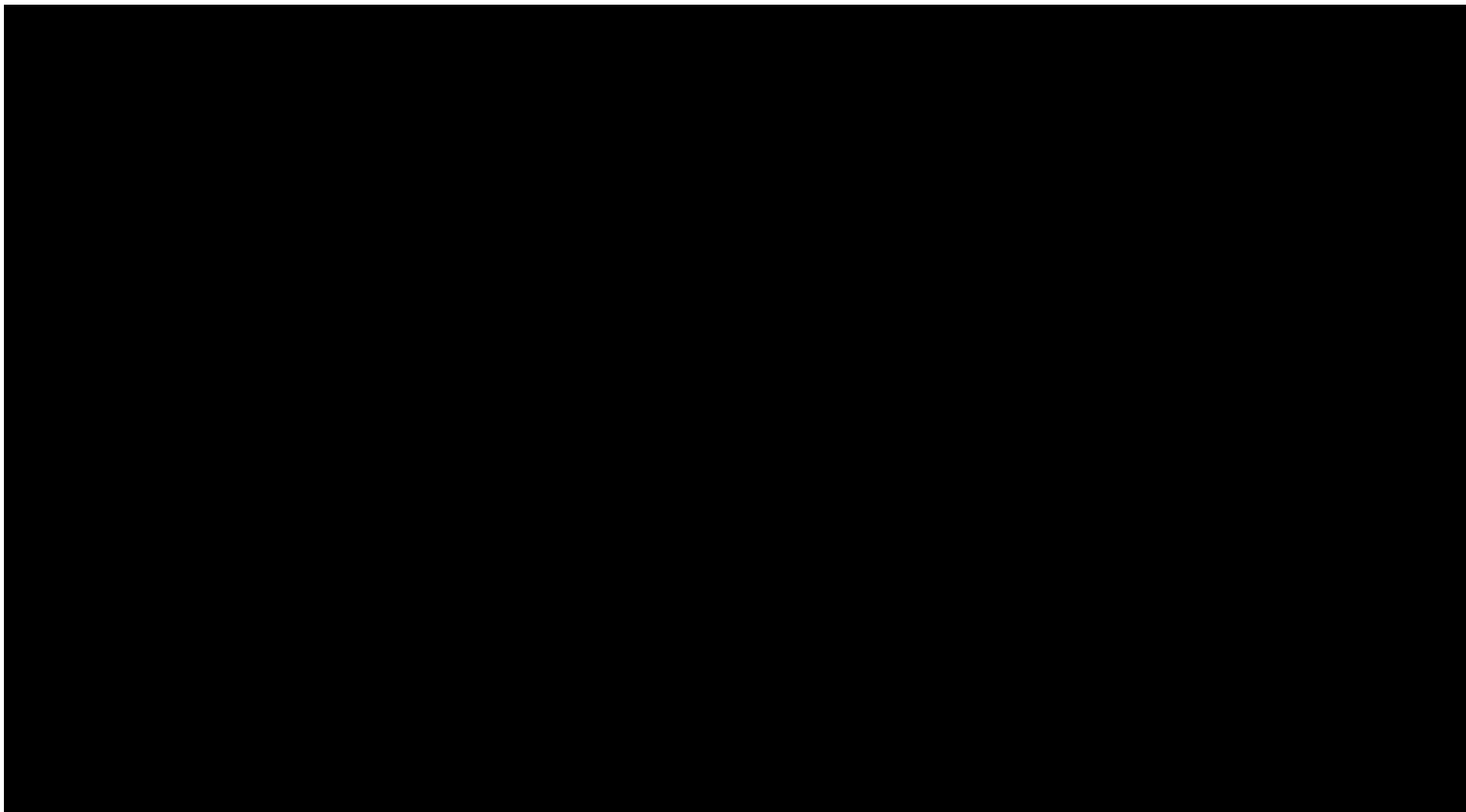
Status:
Page:

Final
Page 1638 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

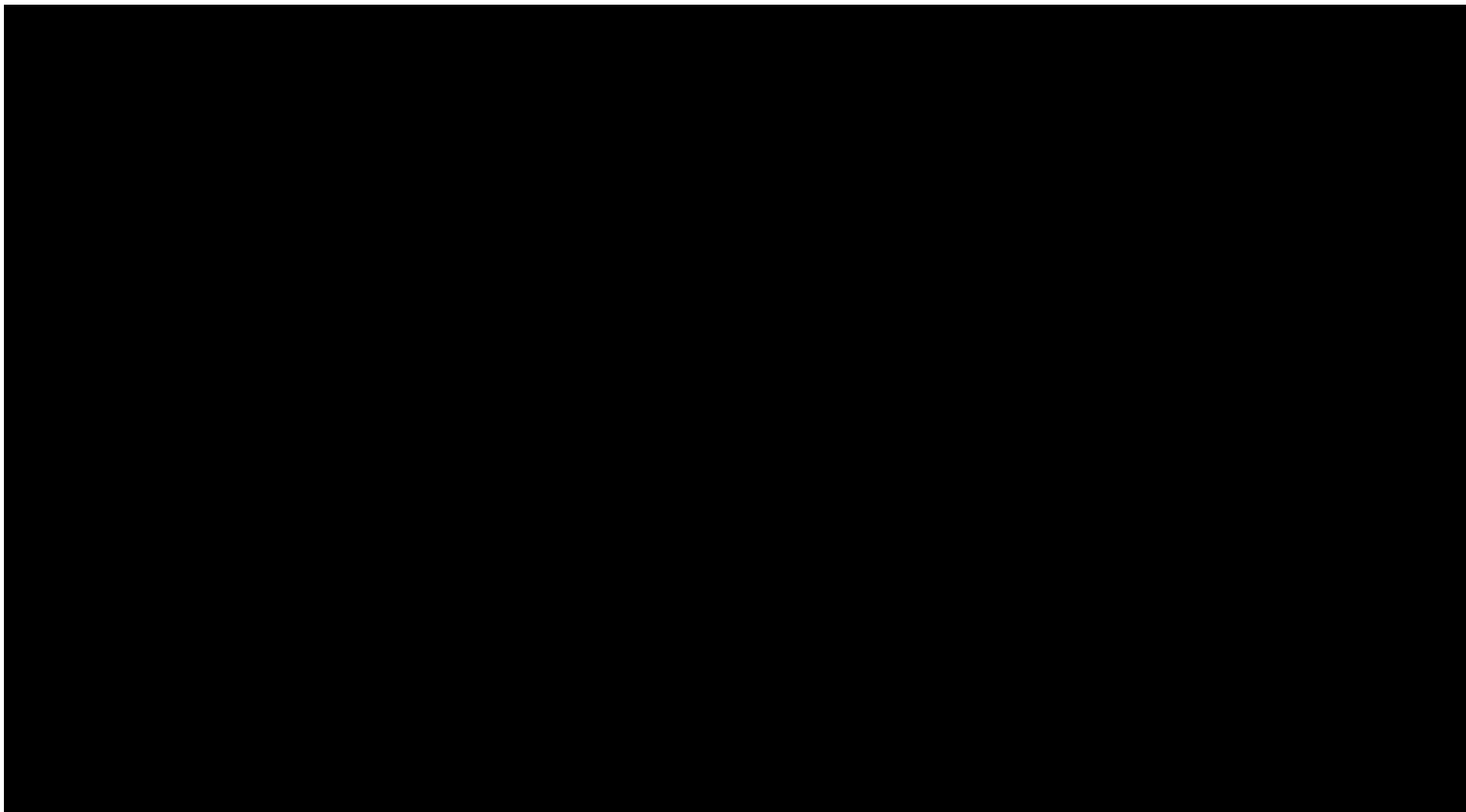
Status:
Page:

Final
Page 1640 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

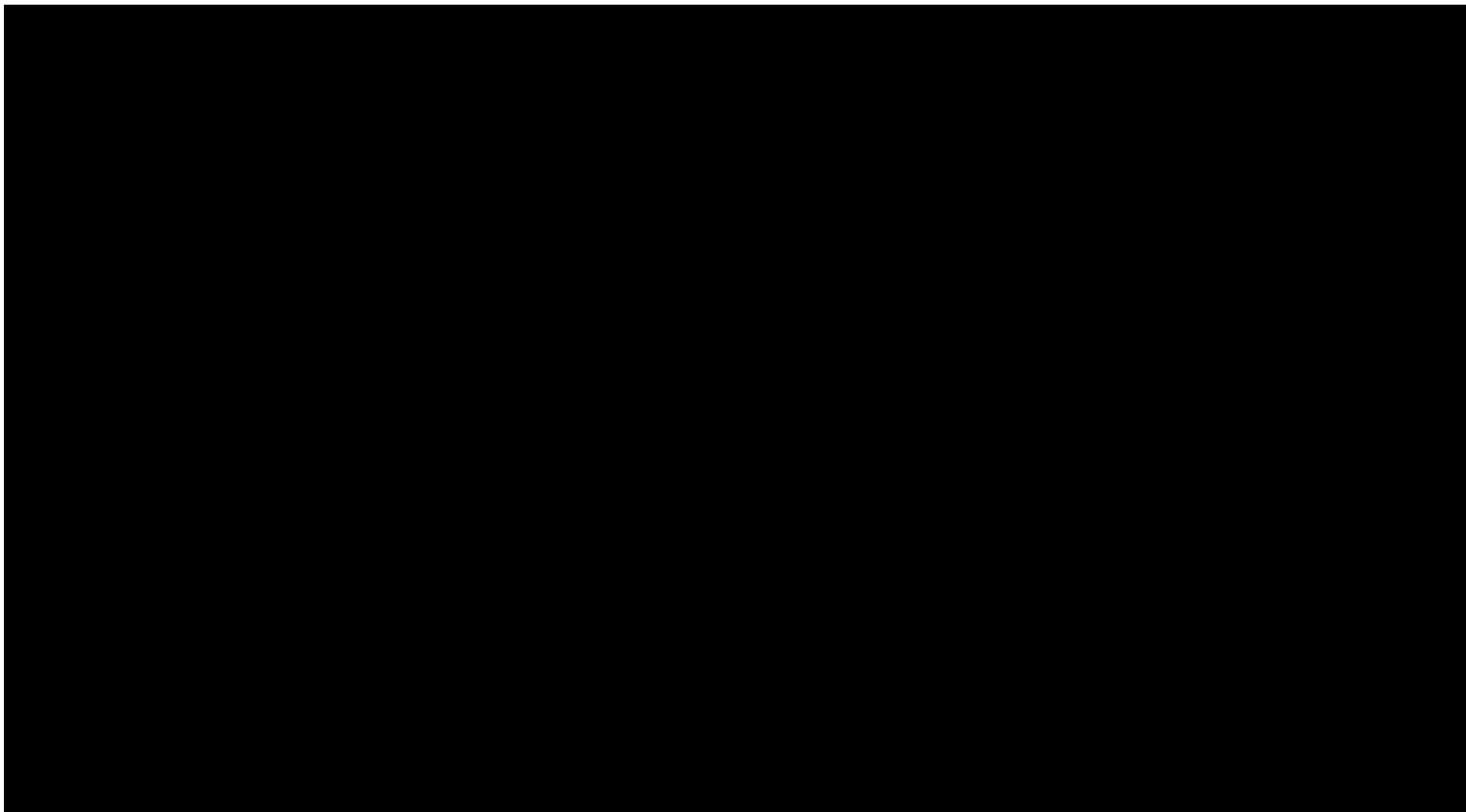
Status:
Page:

Final
Page 1641 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1642 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1643 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

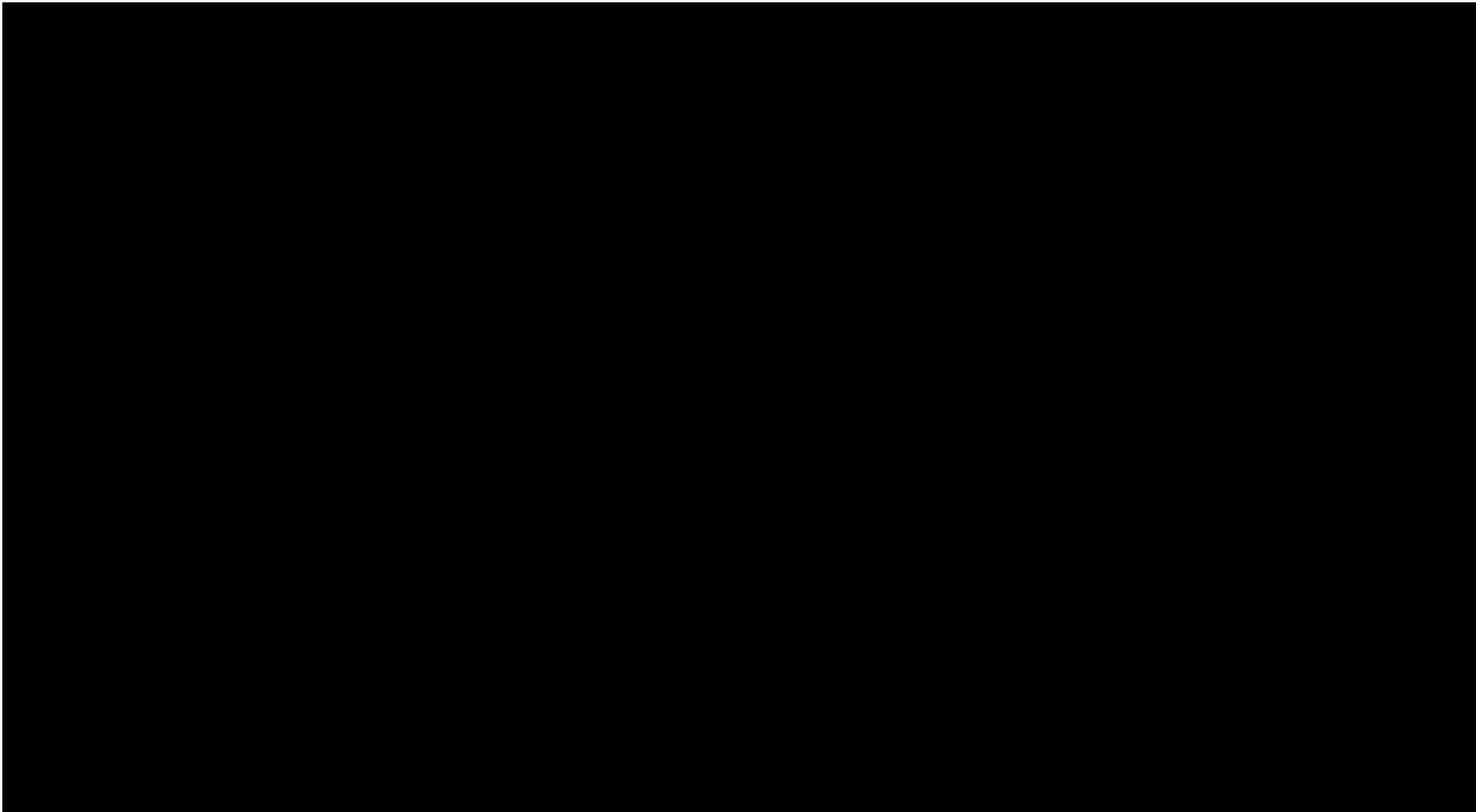
Status:
Page:

Final
Page 1644 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

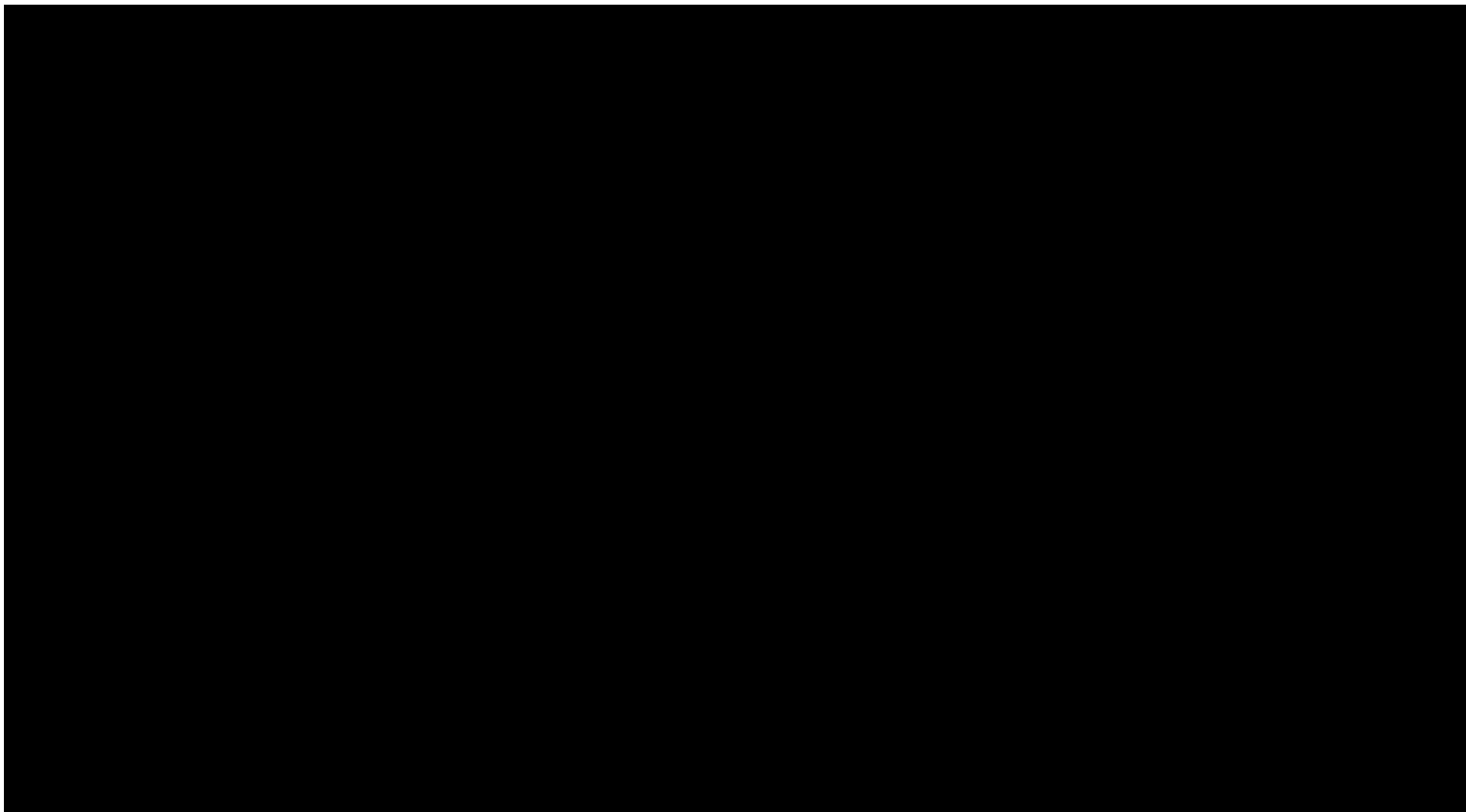
Status:
Page:

Final
Page 1645 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

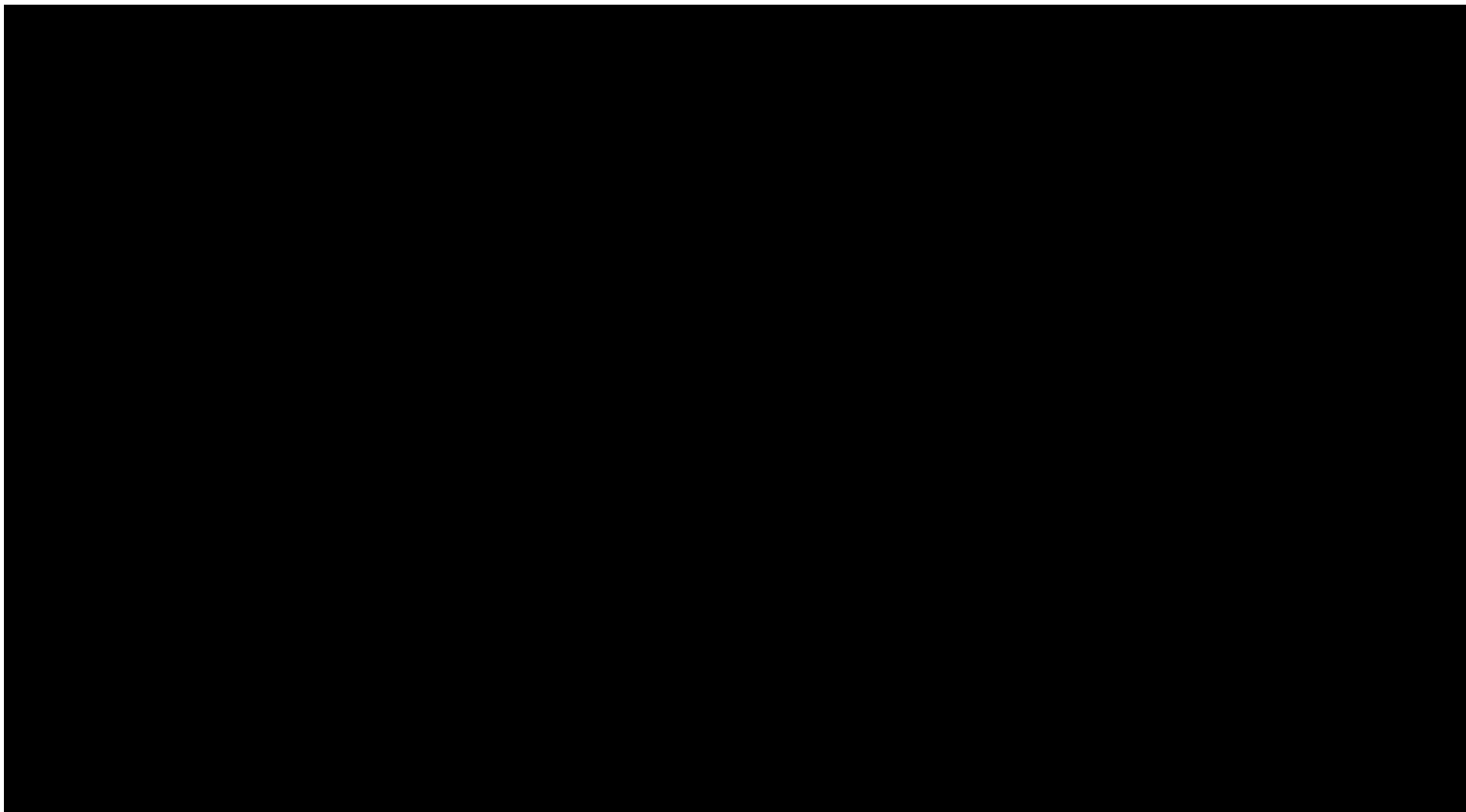
Status:
Page:

Final
Page 1646 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

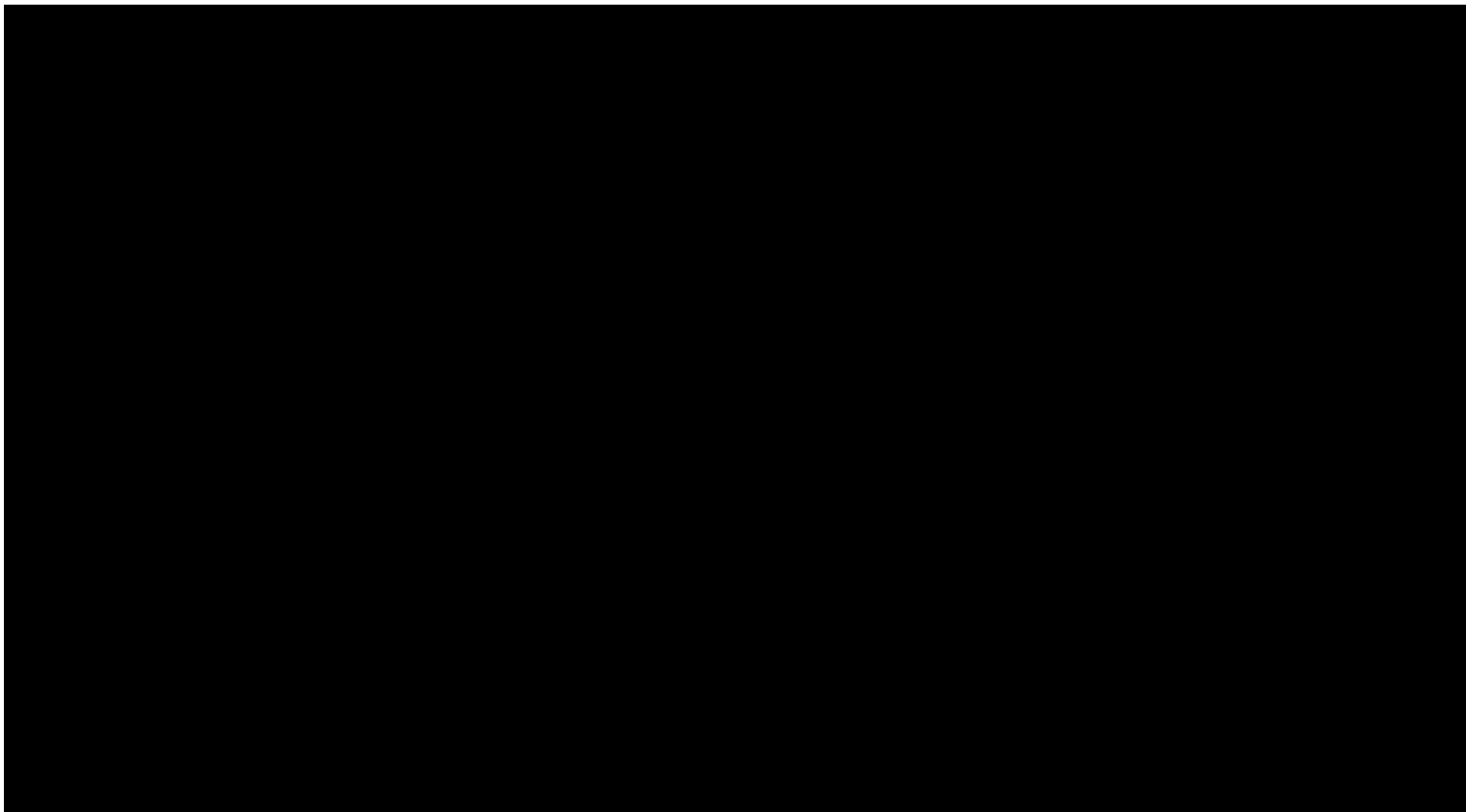
Status:
Page:

Final
Page 1647 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

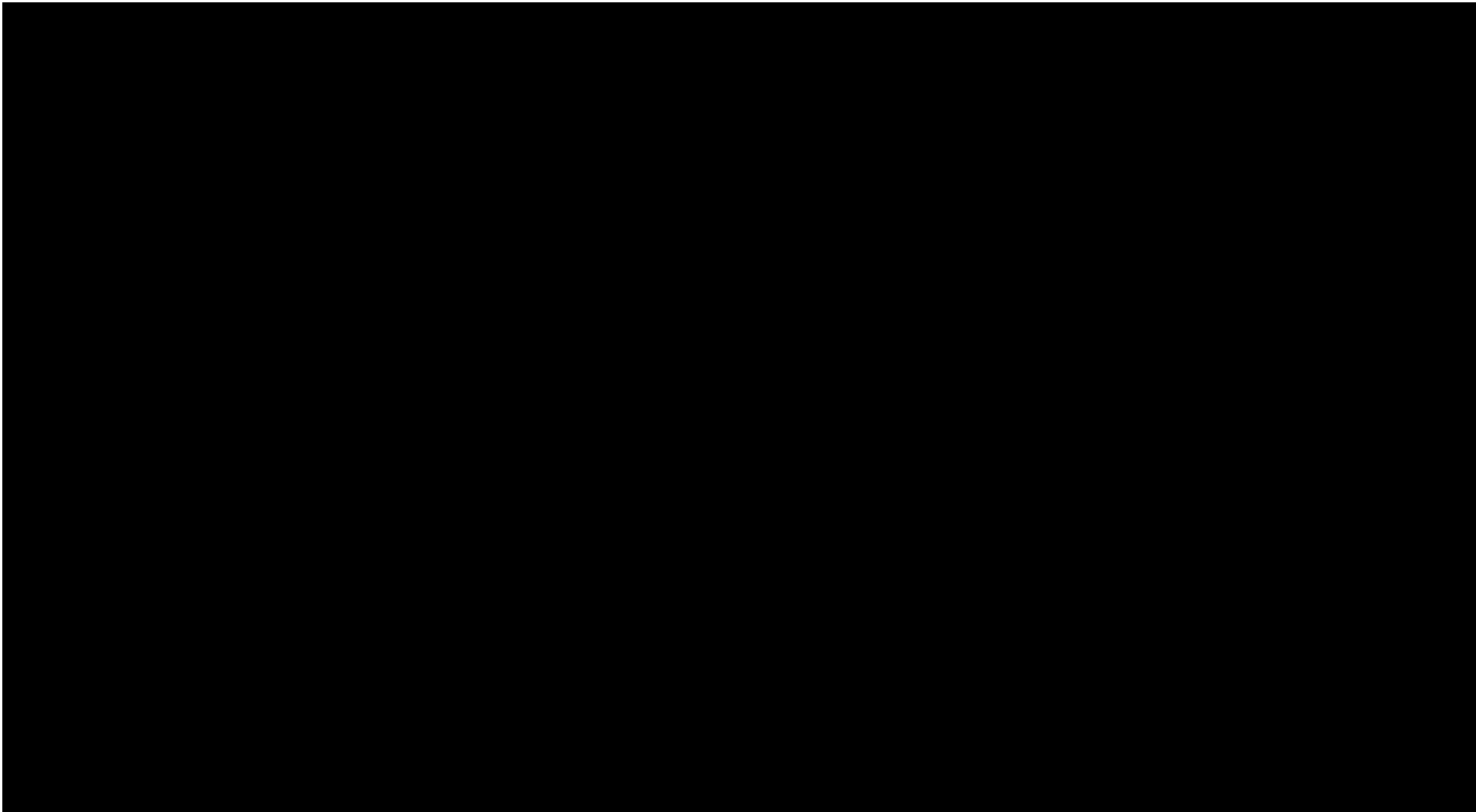
Status:
Page:

Final
Page 1648 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1649 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1650 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1651 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

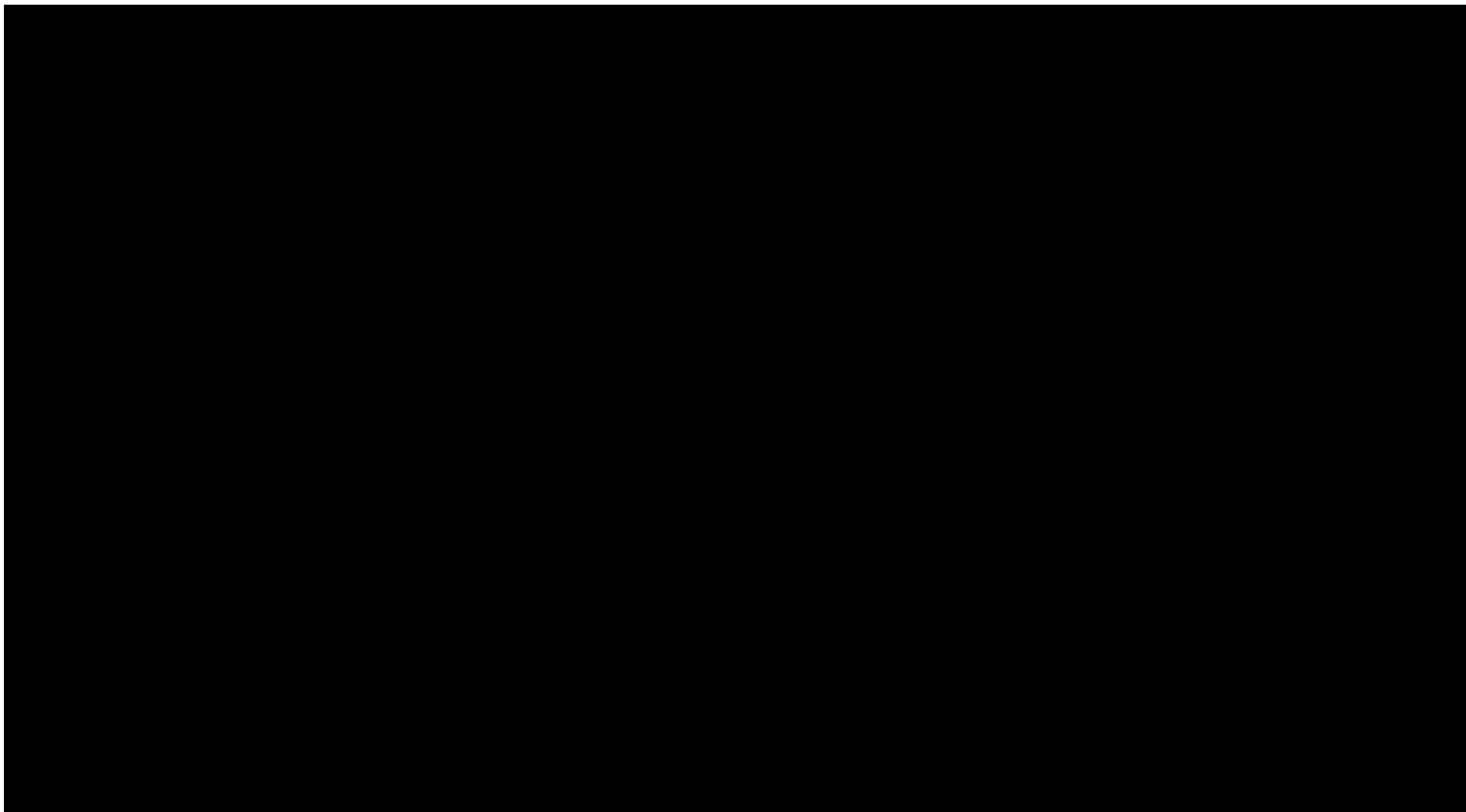
Status:
Page:

Final
Page 1652 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

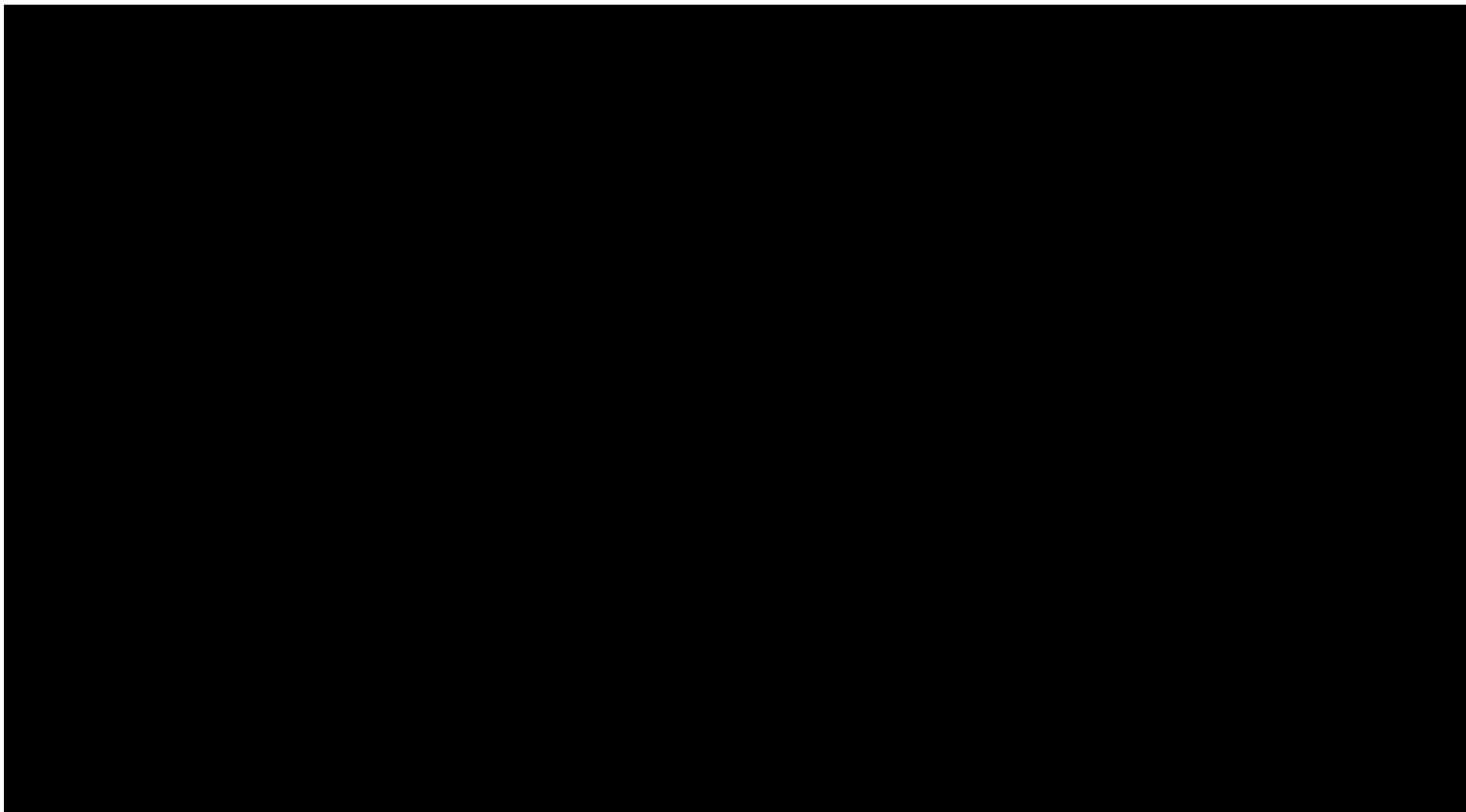
Status:
Page:

Final
Page 1653 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

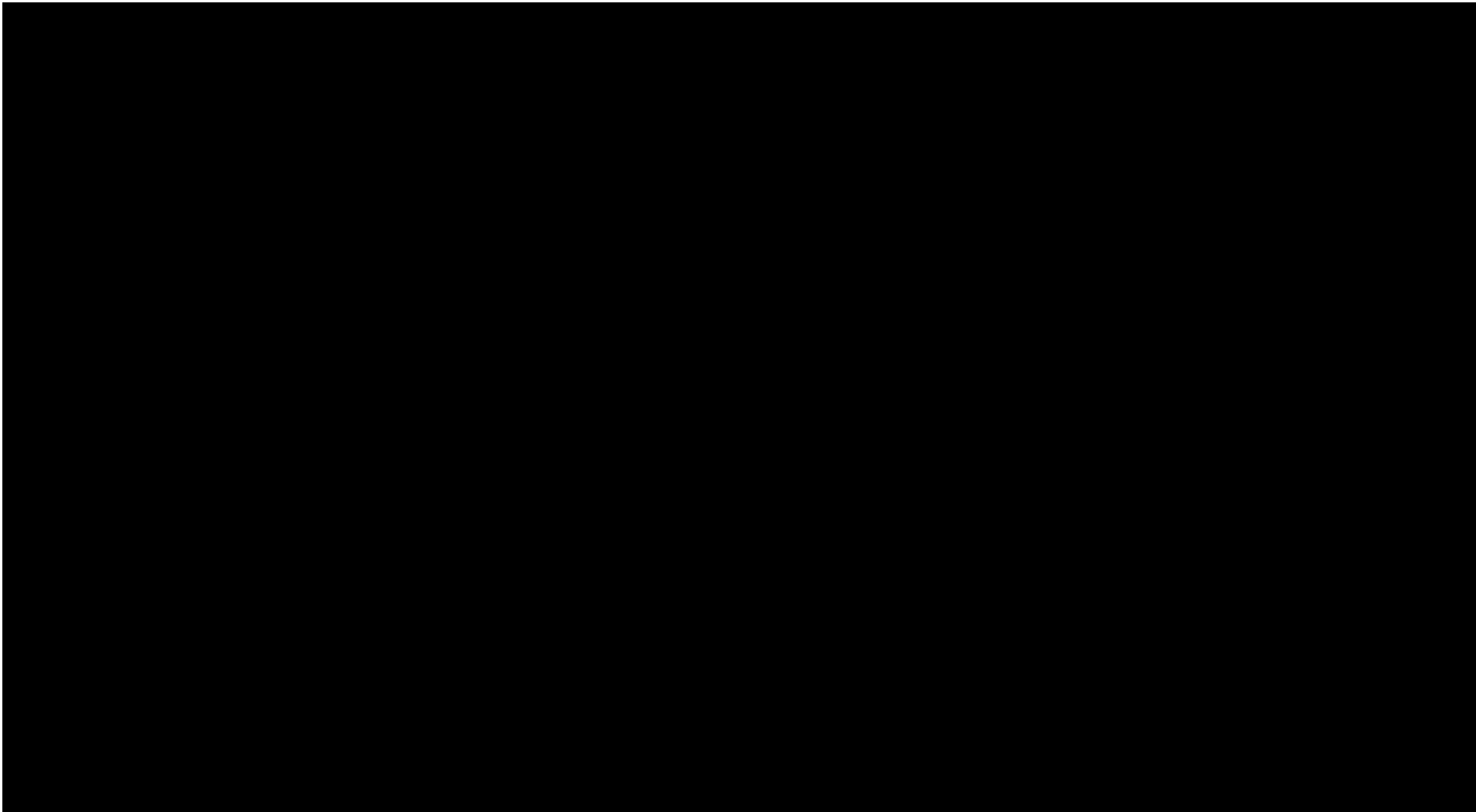
Status:
Page:

Final
Page 1654 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

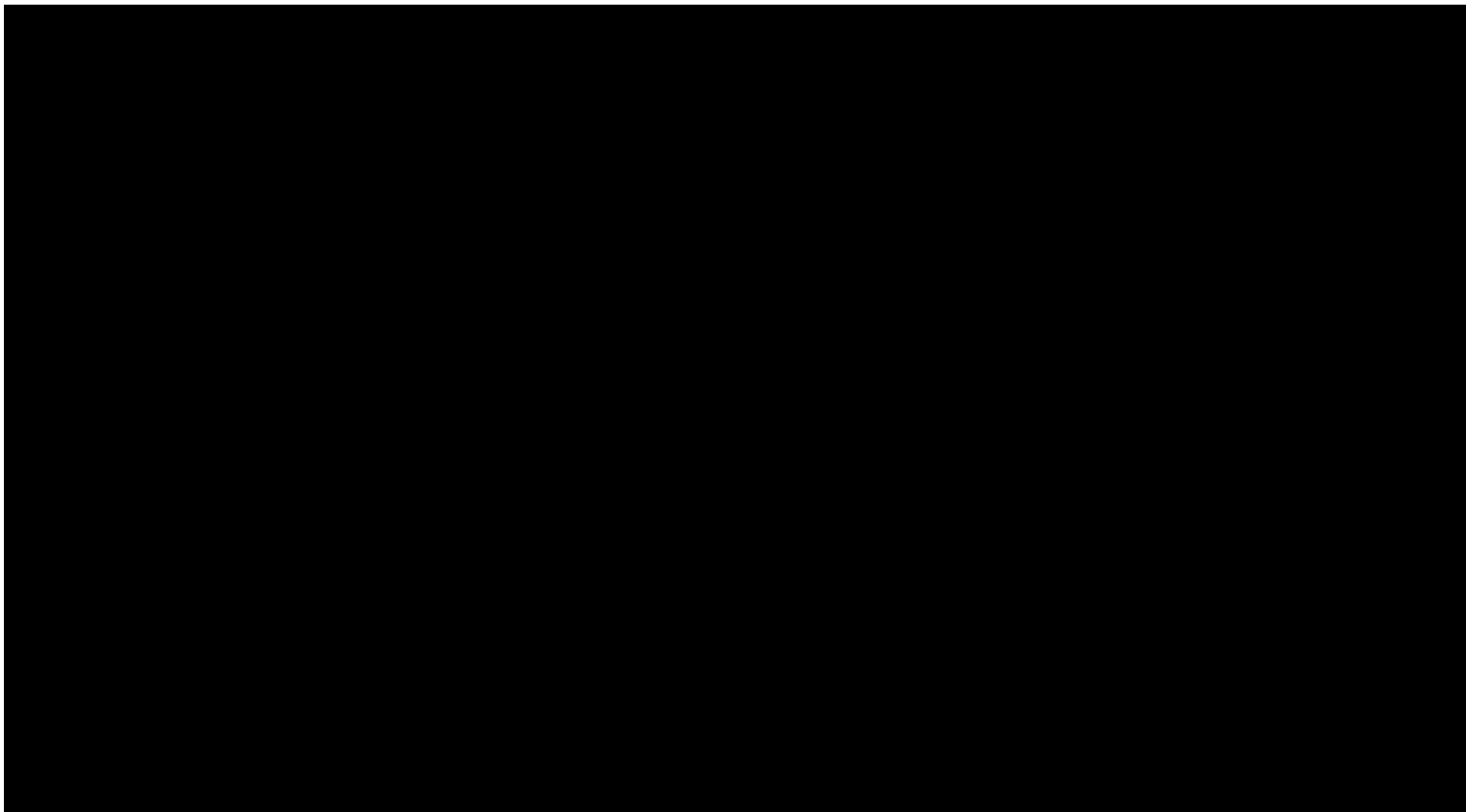
Status:
Page:

Final
Page 1655 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1657 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1658 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1659 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1660 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1661 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

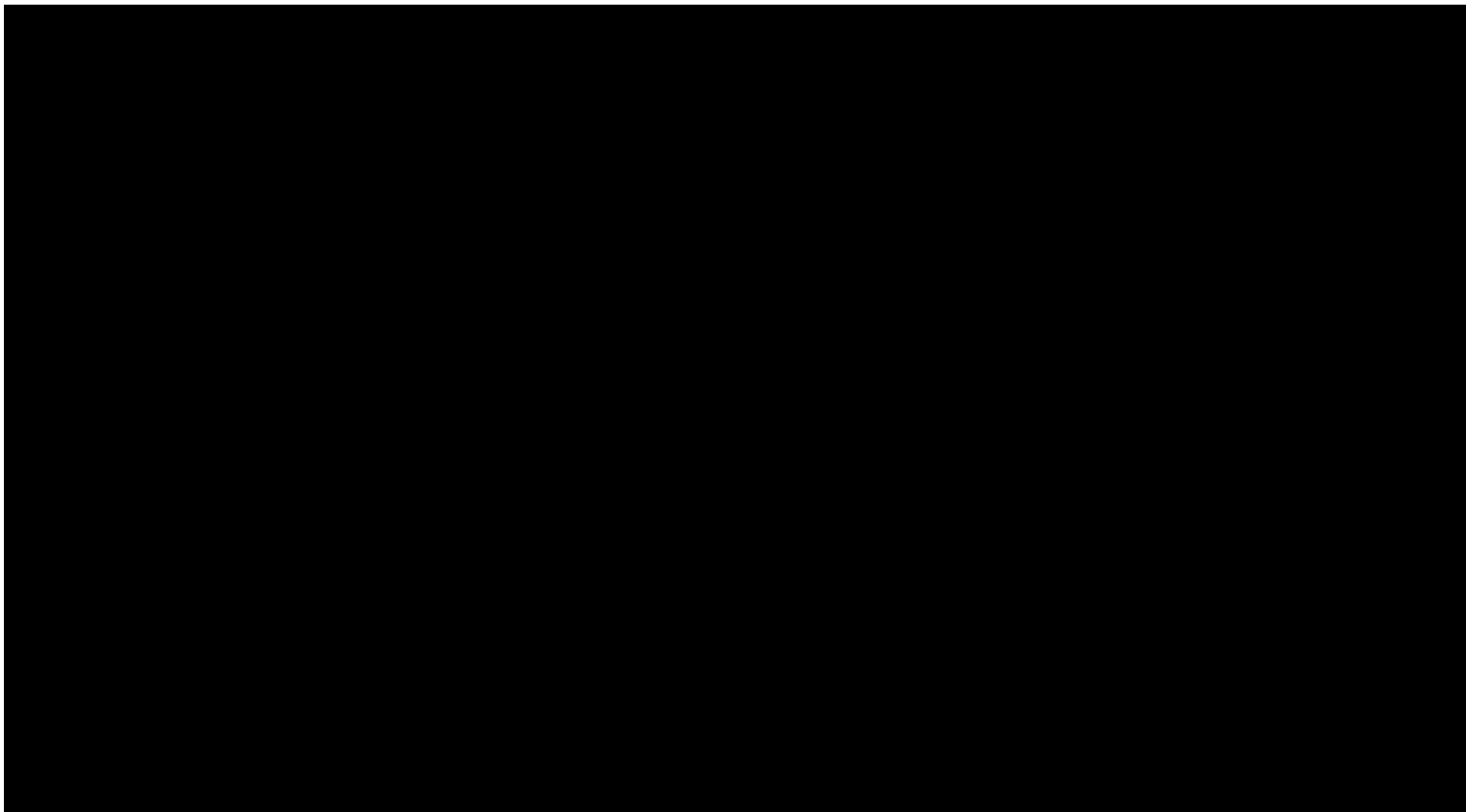
Status:
Page:

Final
Page 1663 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1664 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

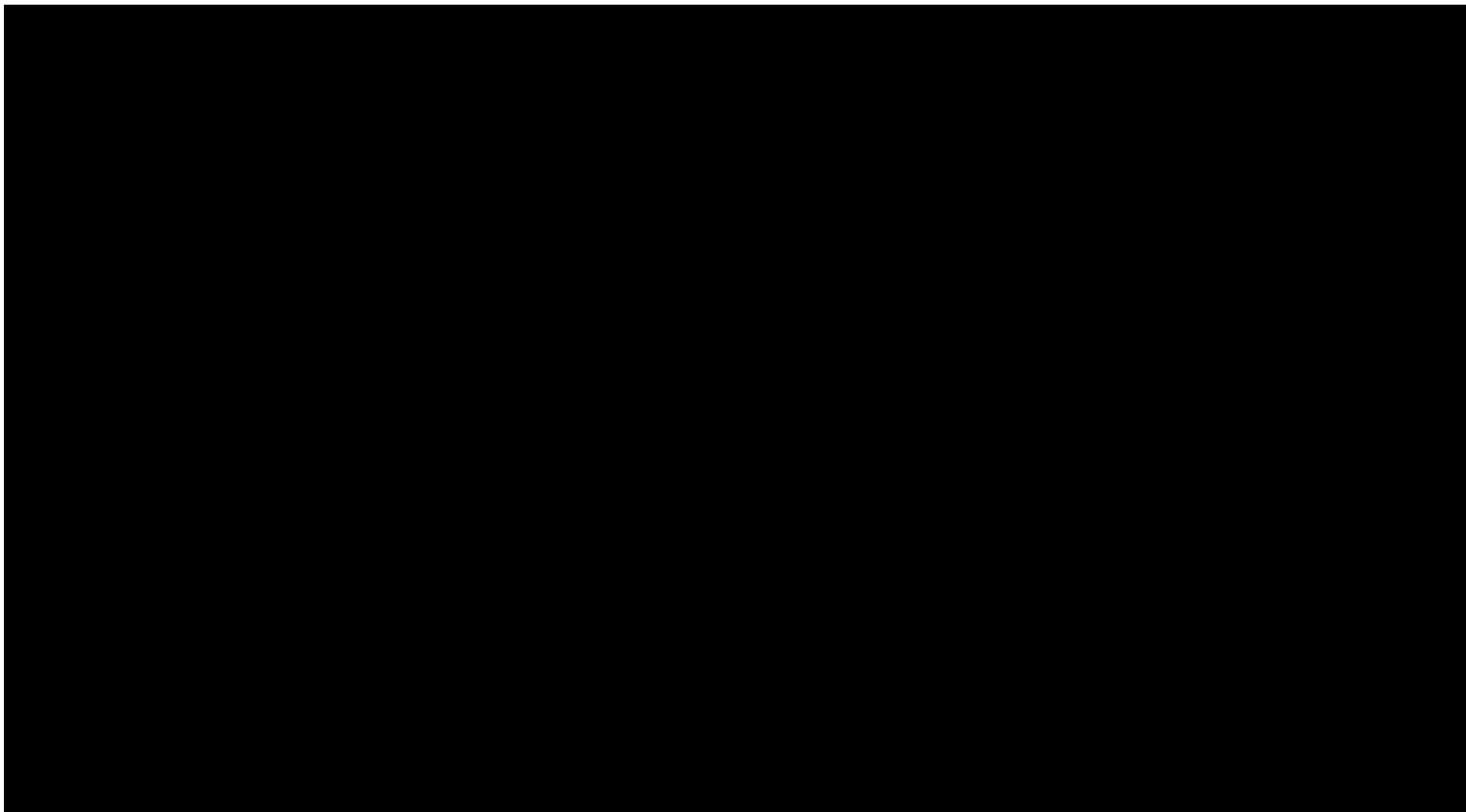
Status:
Page:

Final
Page 1665 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1666 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

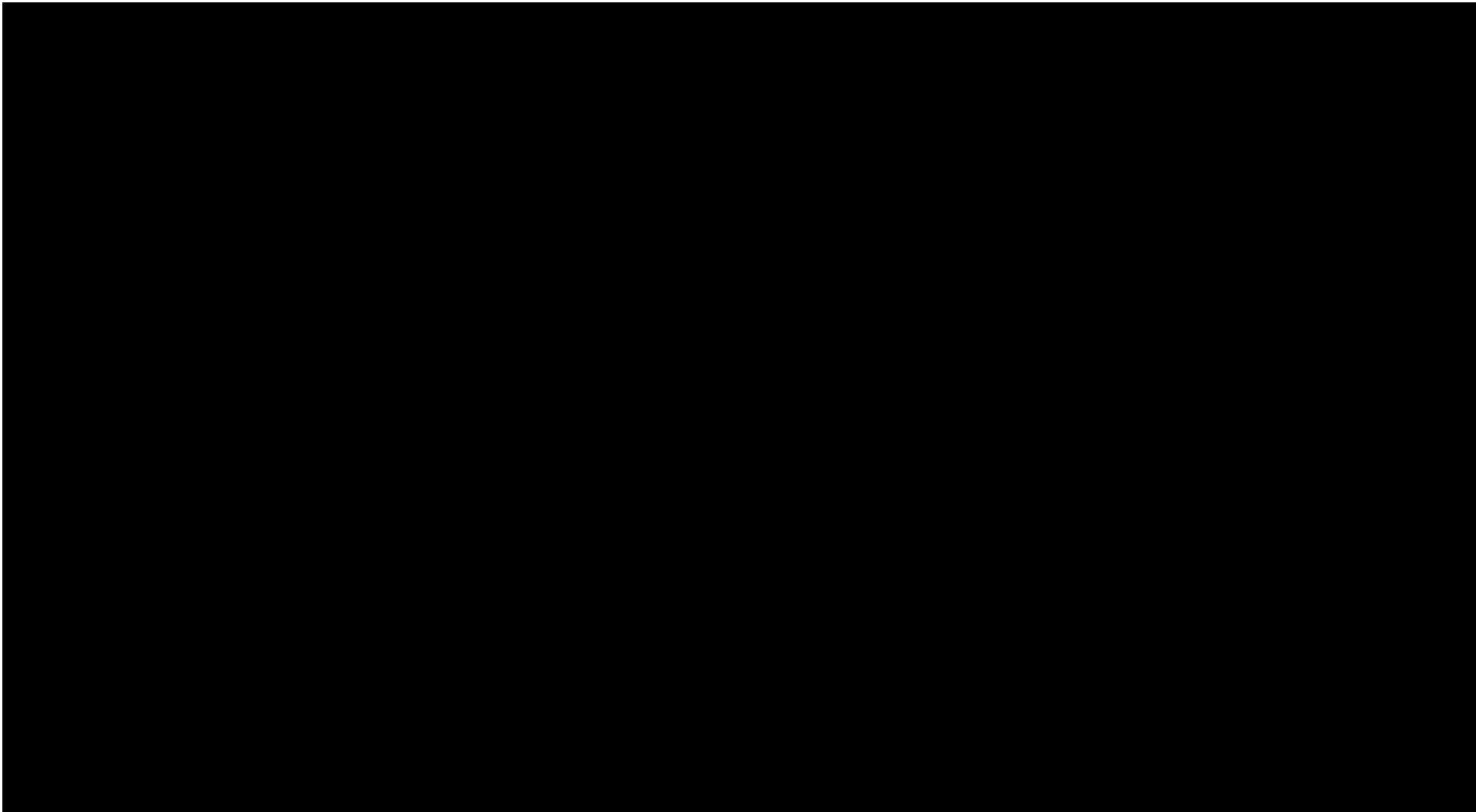
Status:
Page:

Final
Page 1667 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

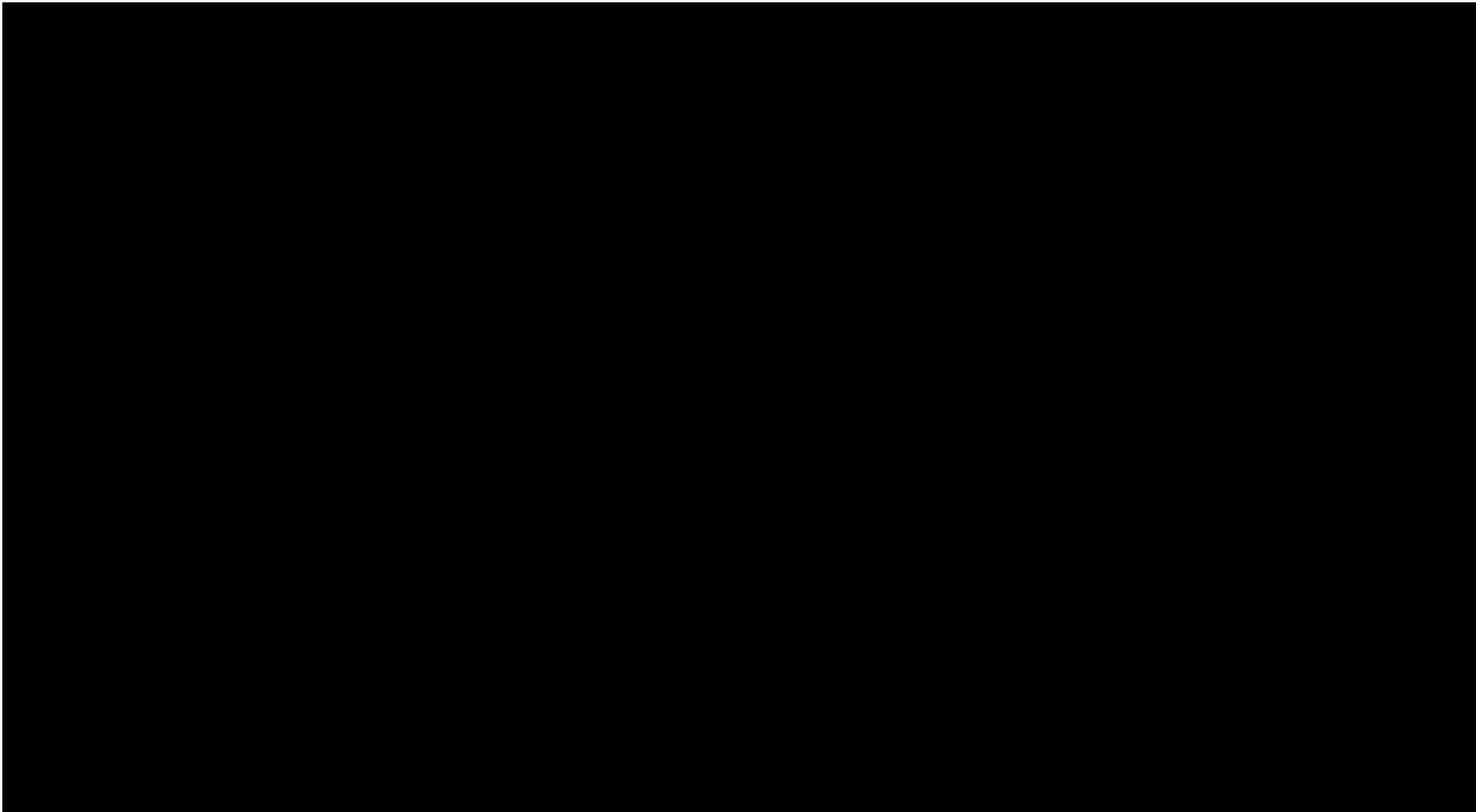
Status:
Page:

Final
Page 1668 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

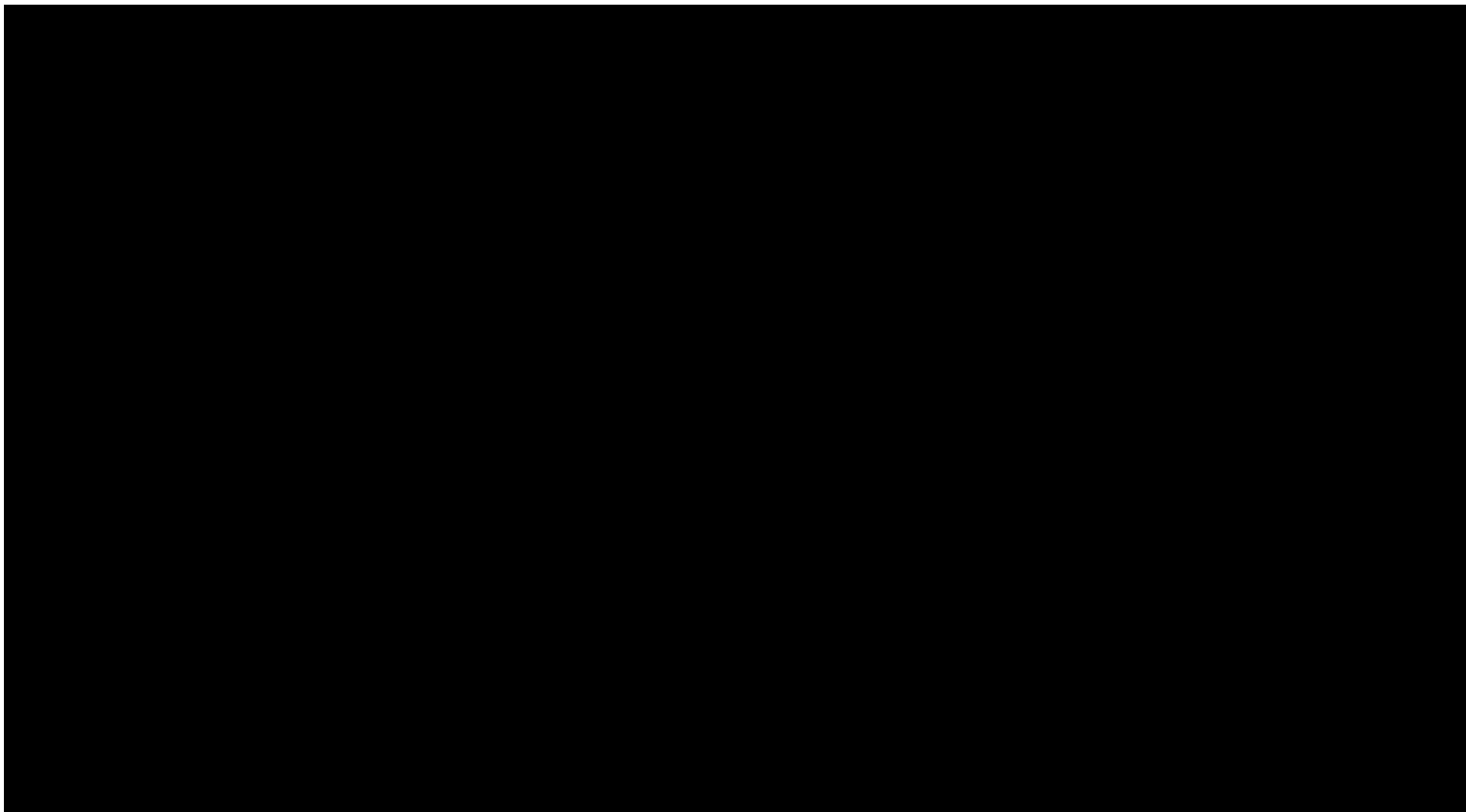
Status:
Page:

Final
Page 1669 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1670 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1671 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1672 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children and the number of children in the household. The rows represent different levels of the 'Number of children' variable (1, 2, 3) and the columns represent different levels of the 'Number of children in the household' variable (1, 2, 3). Each plot shows a positive correlation between the two variables.

The plots are arranged as follows:

- Row 1: Number of children = 1. Column 1: Number of children in the household = 1. Column 2: Number of children in the household = 2. Column 3: Number of children in the household = 3.
- Row 2: Number of children = 2. Column 1: Number of children in the household = 1. Column 2: Number of children in the household = 2. Column 3: Number of children in the household = 3.
- Row 3: Number of children = 3. Column 1: Number of children in the household = 1. Column 2: Number of children in the household = 2. Column 3: Number of children in the household = 3.

Each plot shows a positive correlation between the number of children and the number of children in the household. The plots are arranged in a 3x3 grid, with the rows representing the number of children and the columns representing the number of children in the household.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

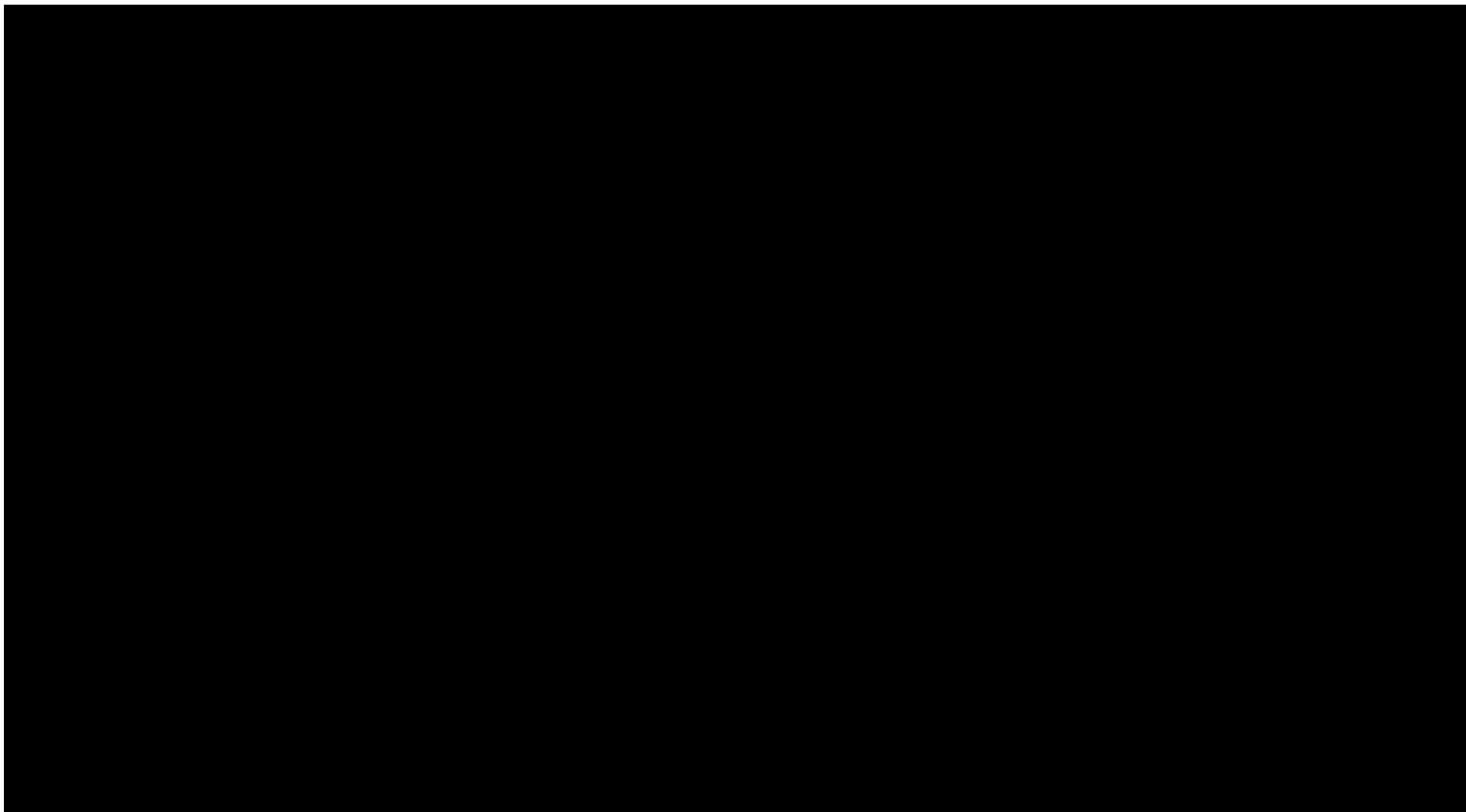
Status:
Page:

Final
Page 1674 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

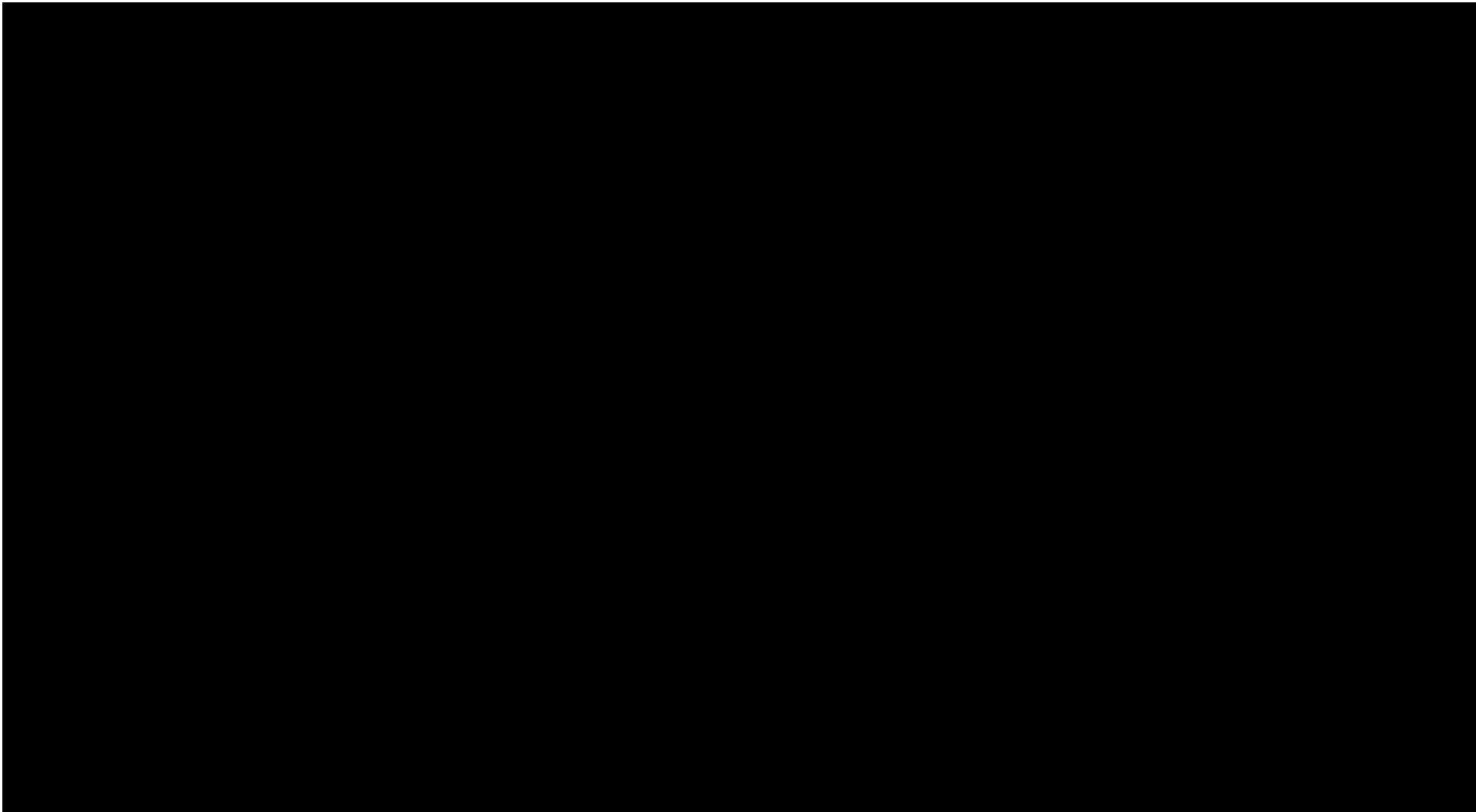
Status:
Page:

Final
Page 1675 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1676 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1677 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

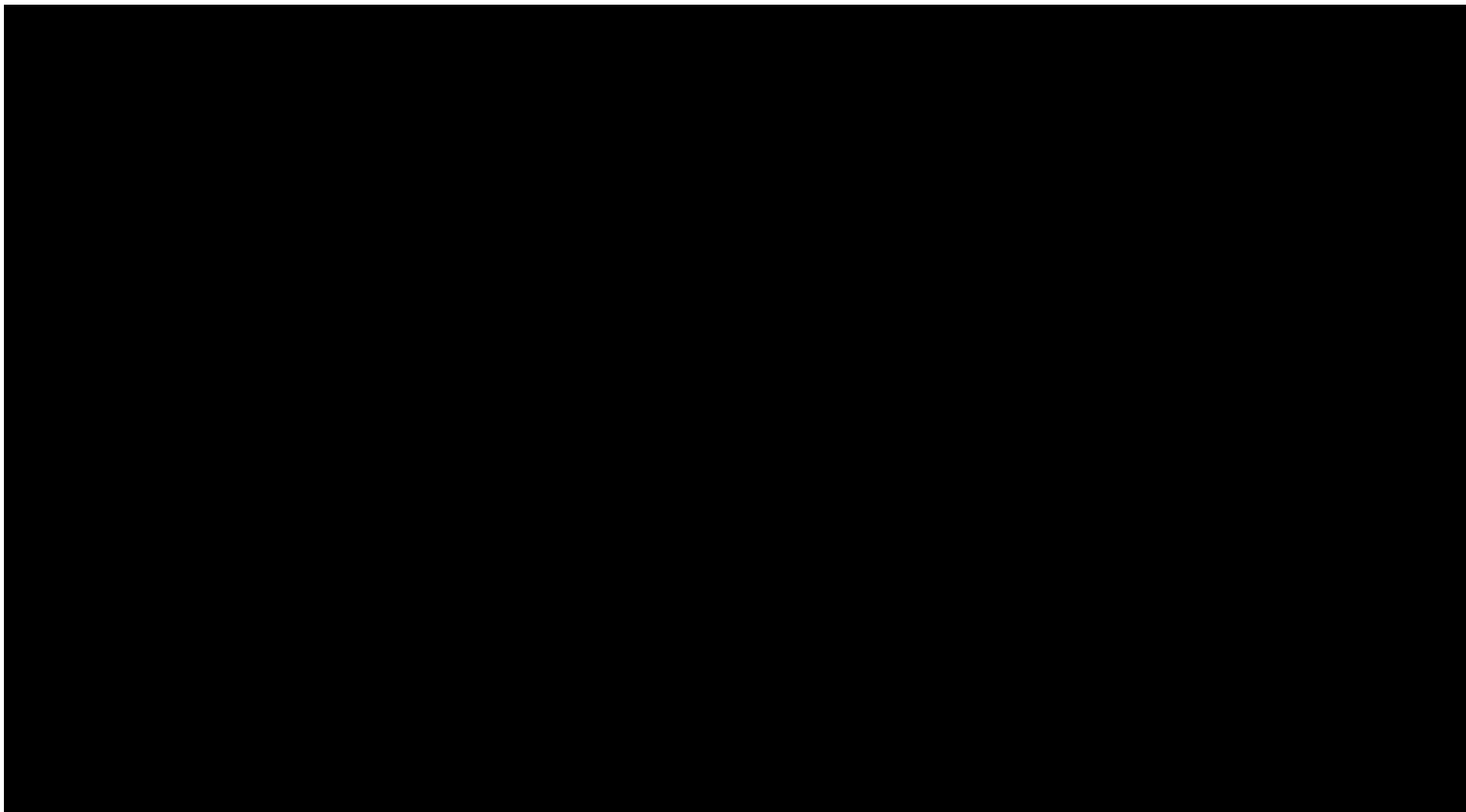
Status:
Page:

Final
Page 1678 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1680 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

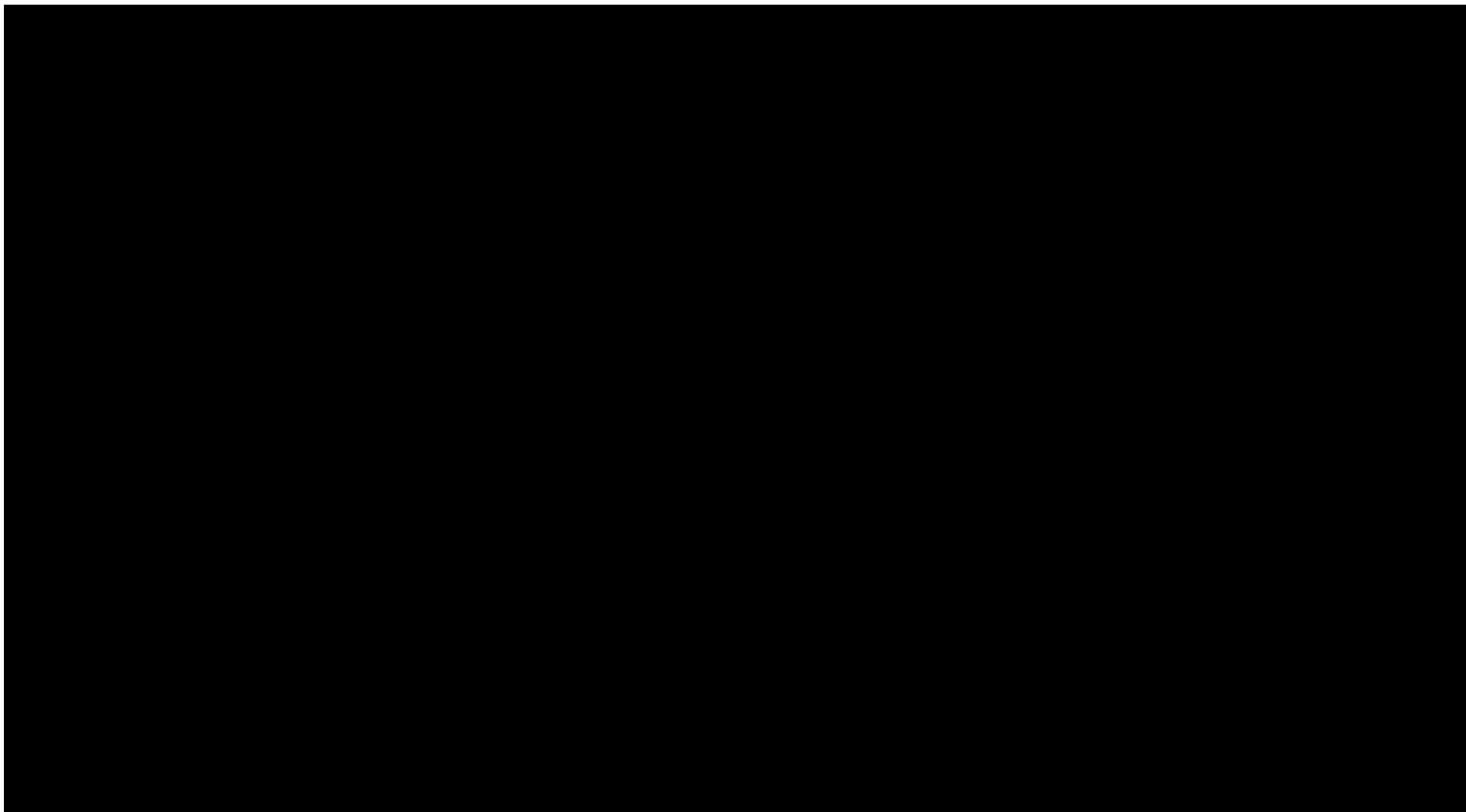
Status:
Page:

Final
Page 1682 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1683 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

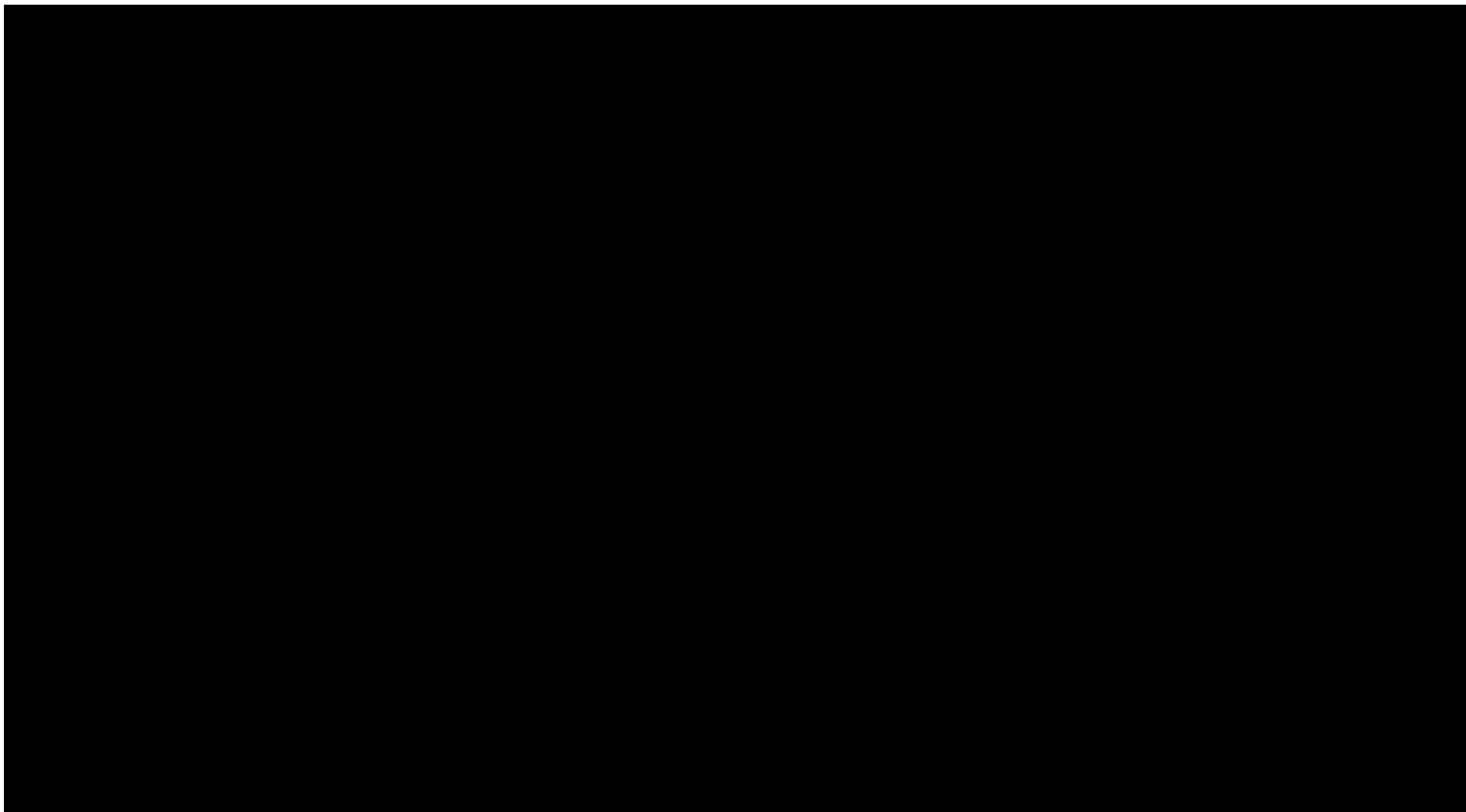
Status:
Page:

Final
Page 1684 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1685 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

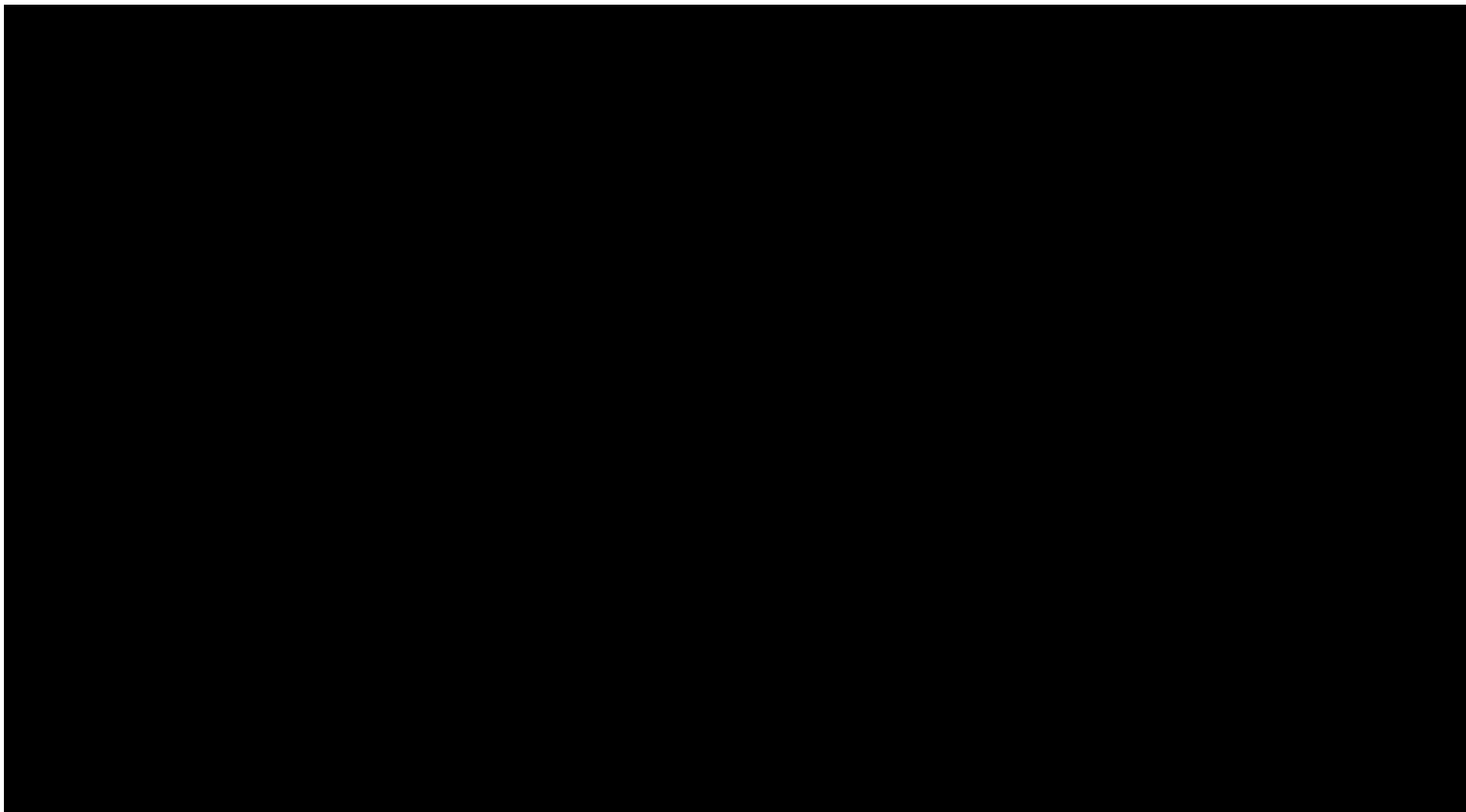
Status:
Page:

Final
Page 1686 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

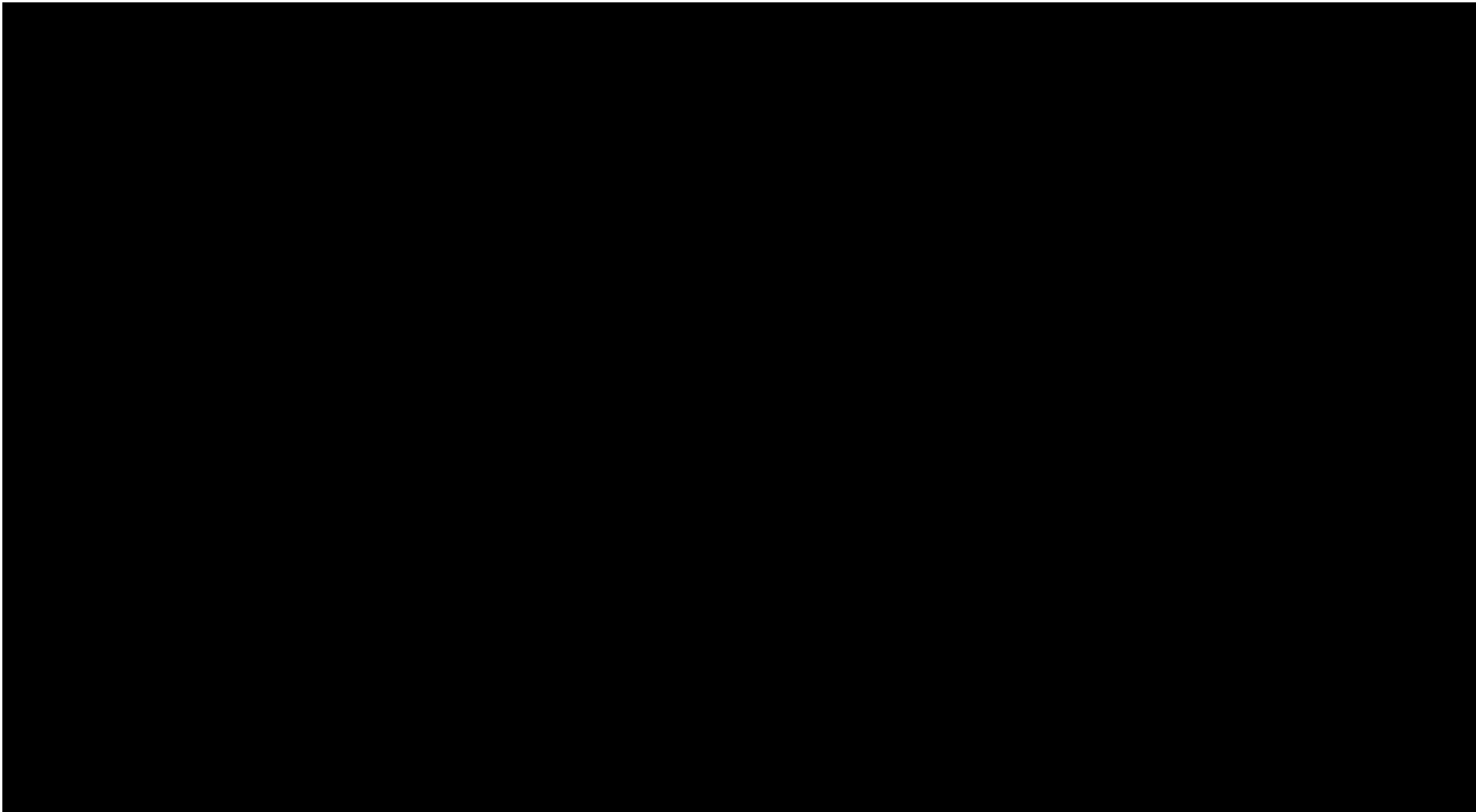
Status:
Page:

Final
Page 1687 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1688 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

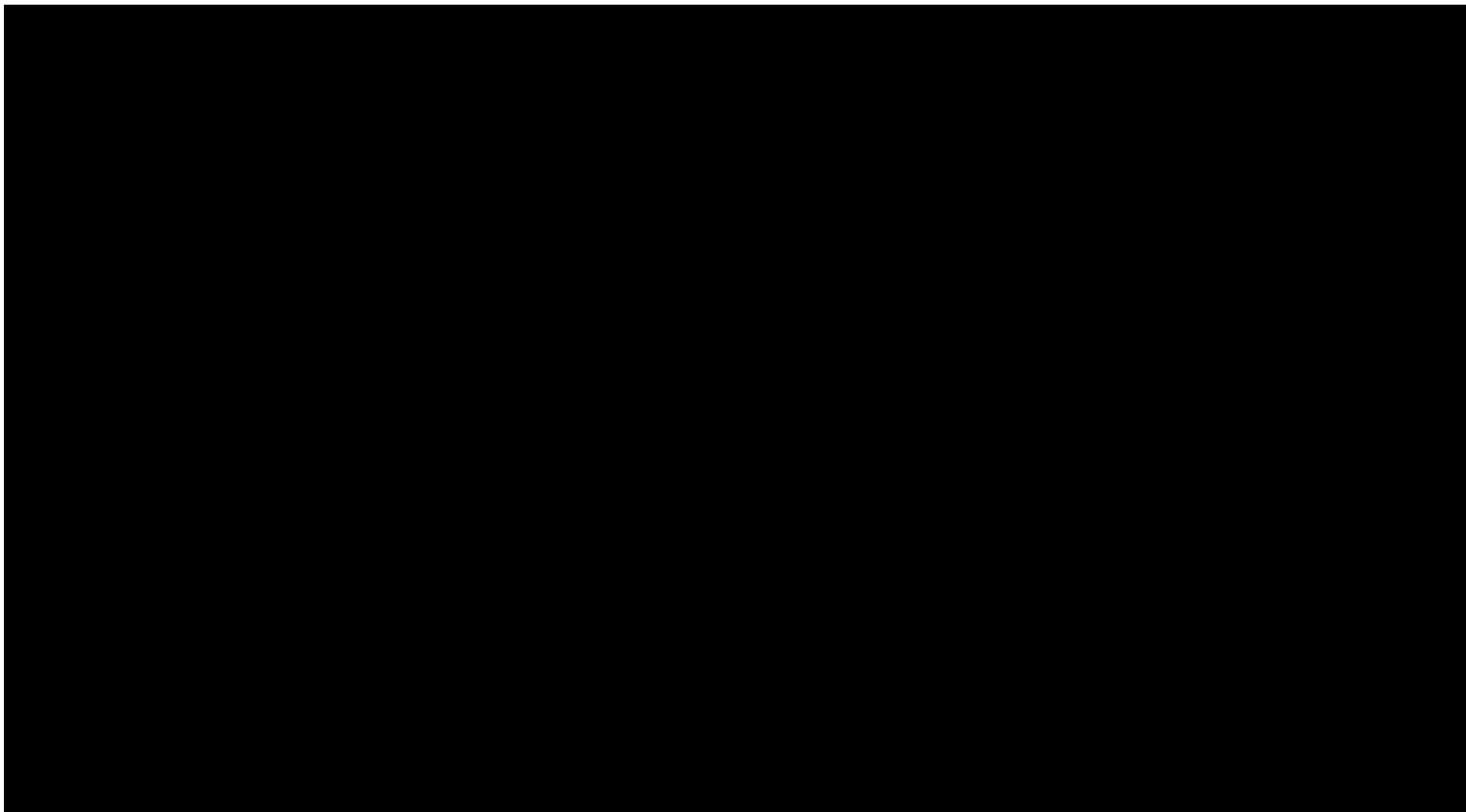
Status:
Page:

Final
Page 1689 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

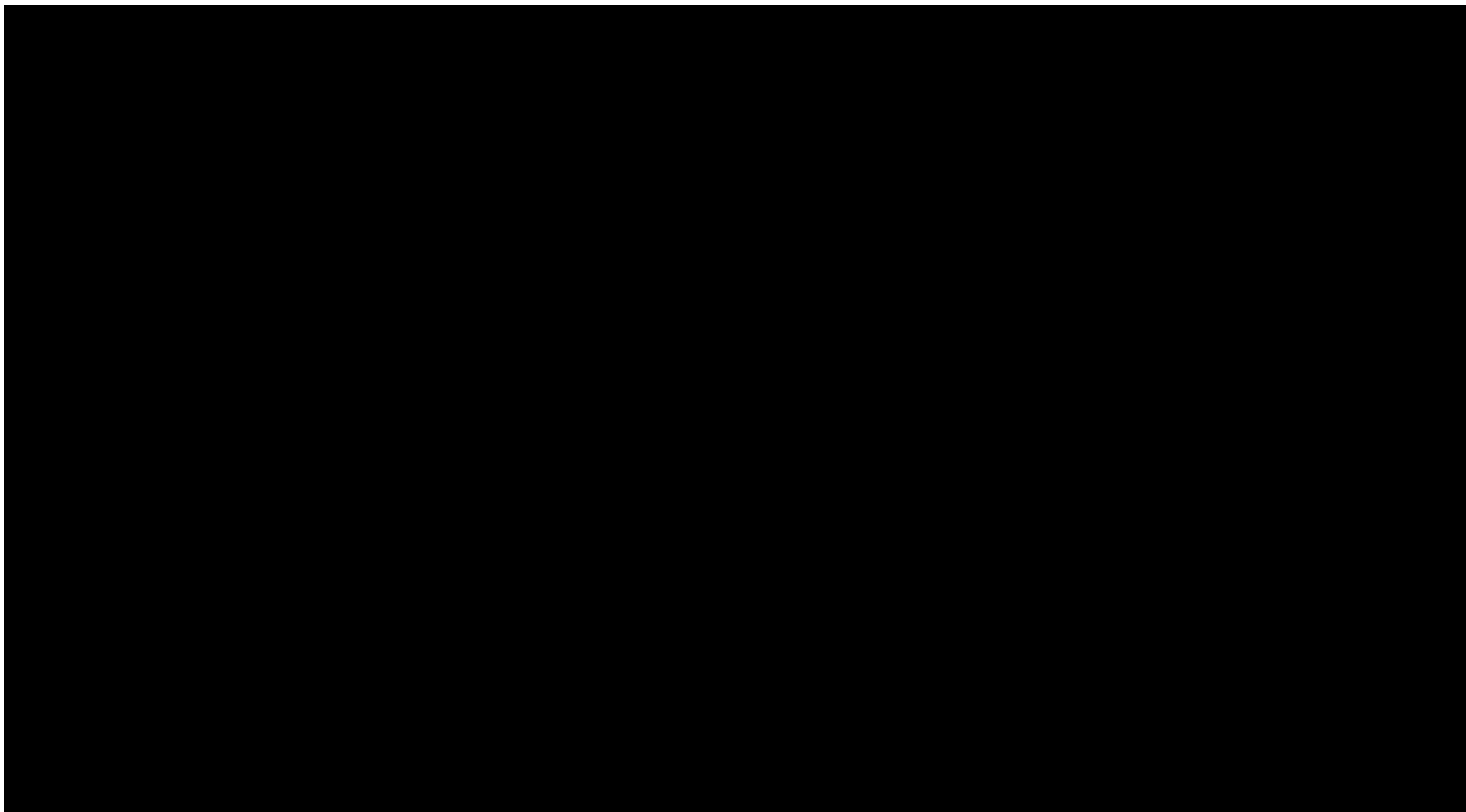
Status:
Page:

Final
Page 1690 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1691 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1692 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

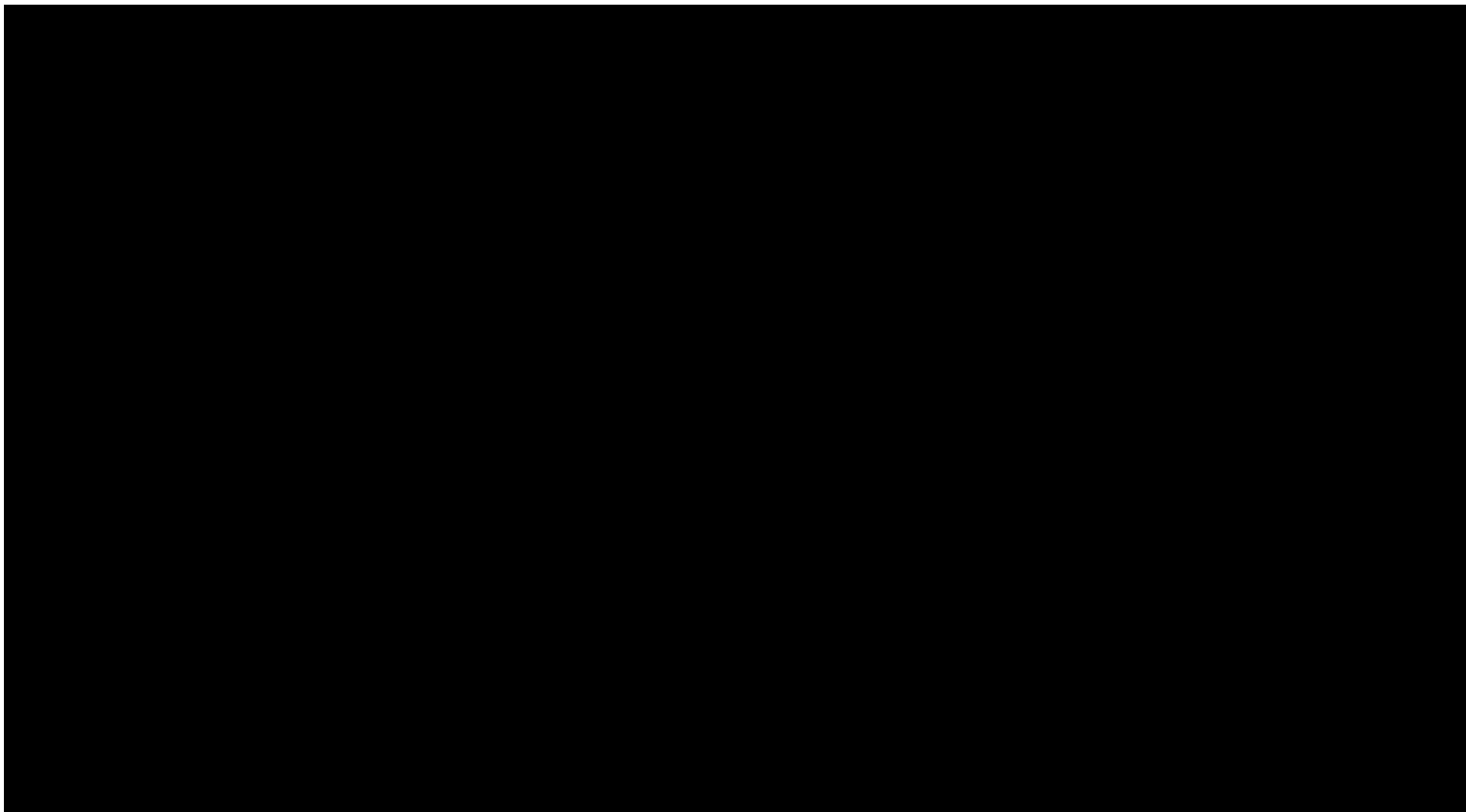
Status:
Page:

Final
Page 1693 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

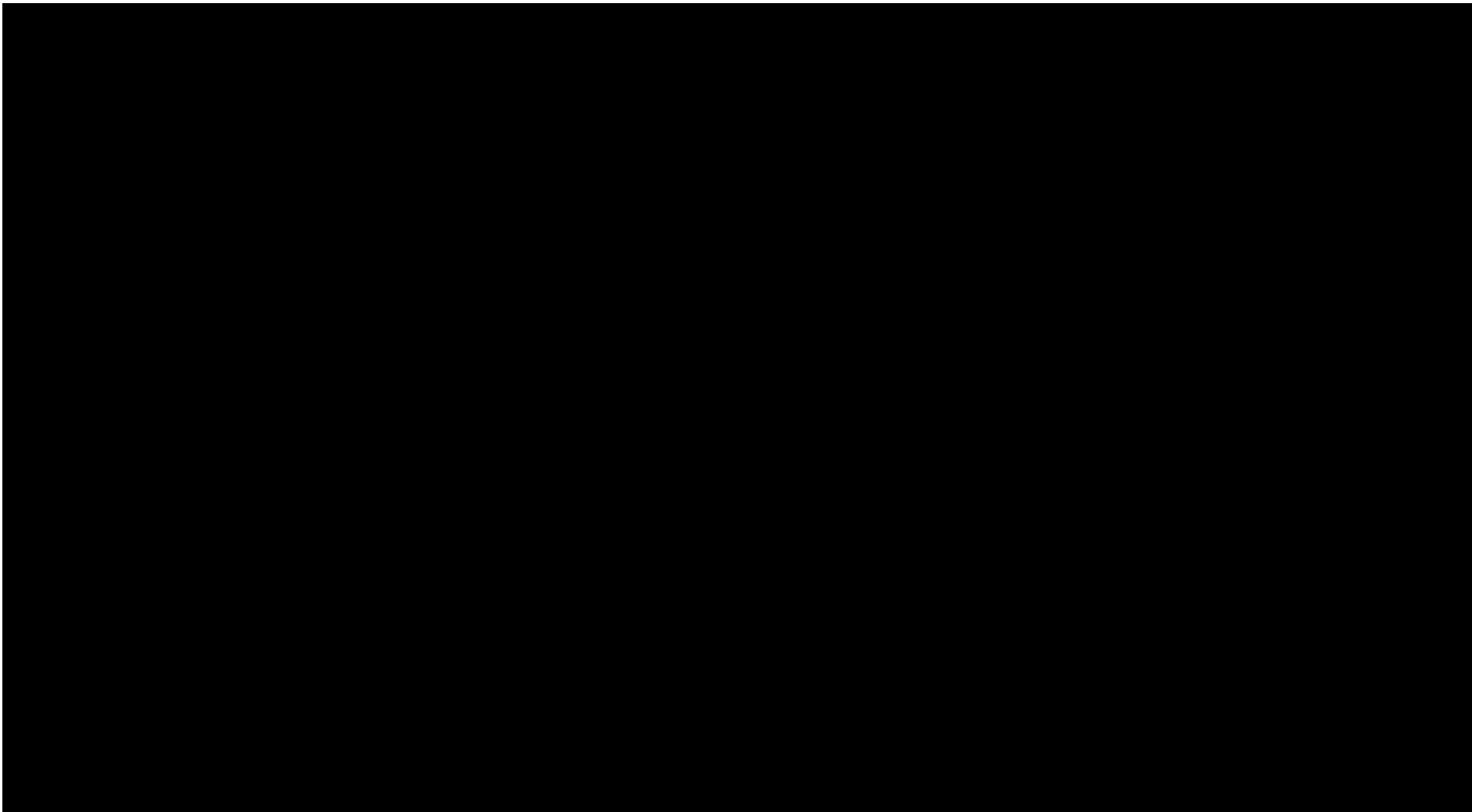
Status:
Page:

Final
Page 1694 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

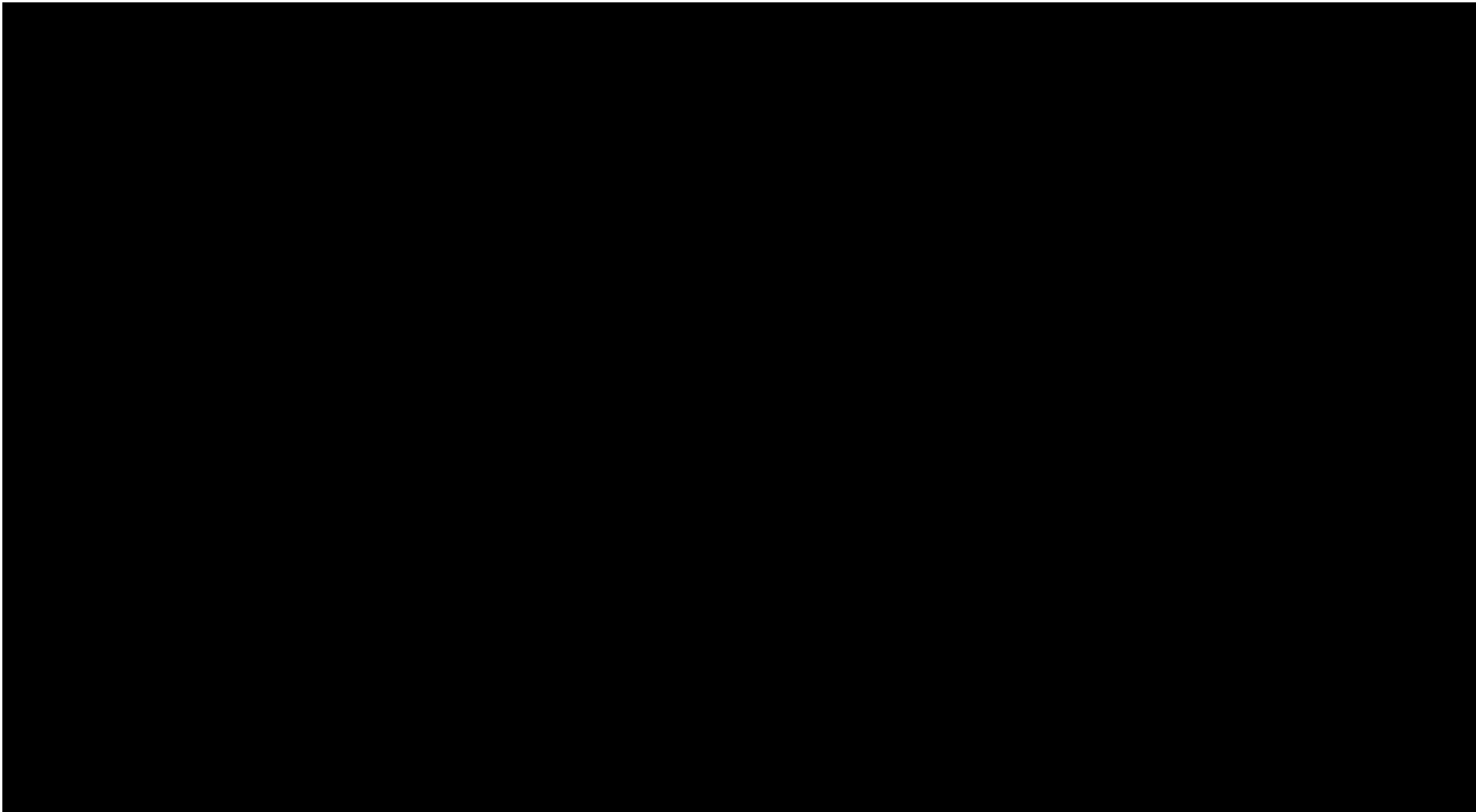
Status:
Page:

Final
Page 1695 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

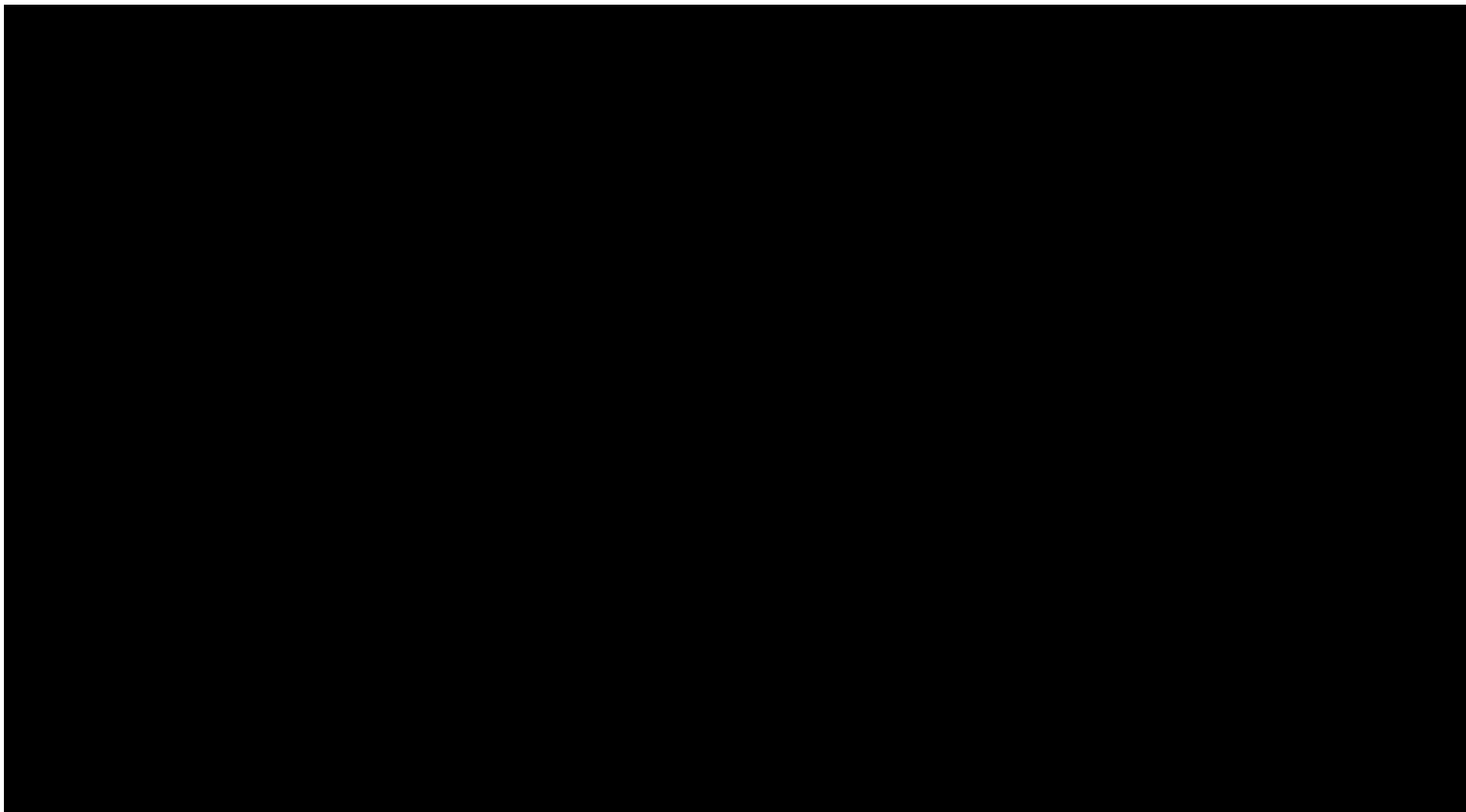
Status:
Page:

Final
Page 1696 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

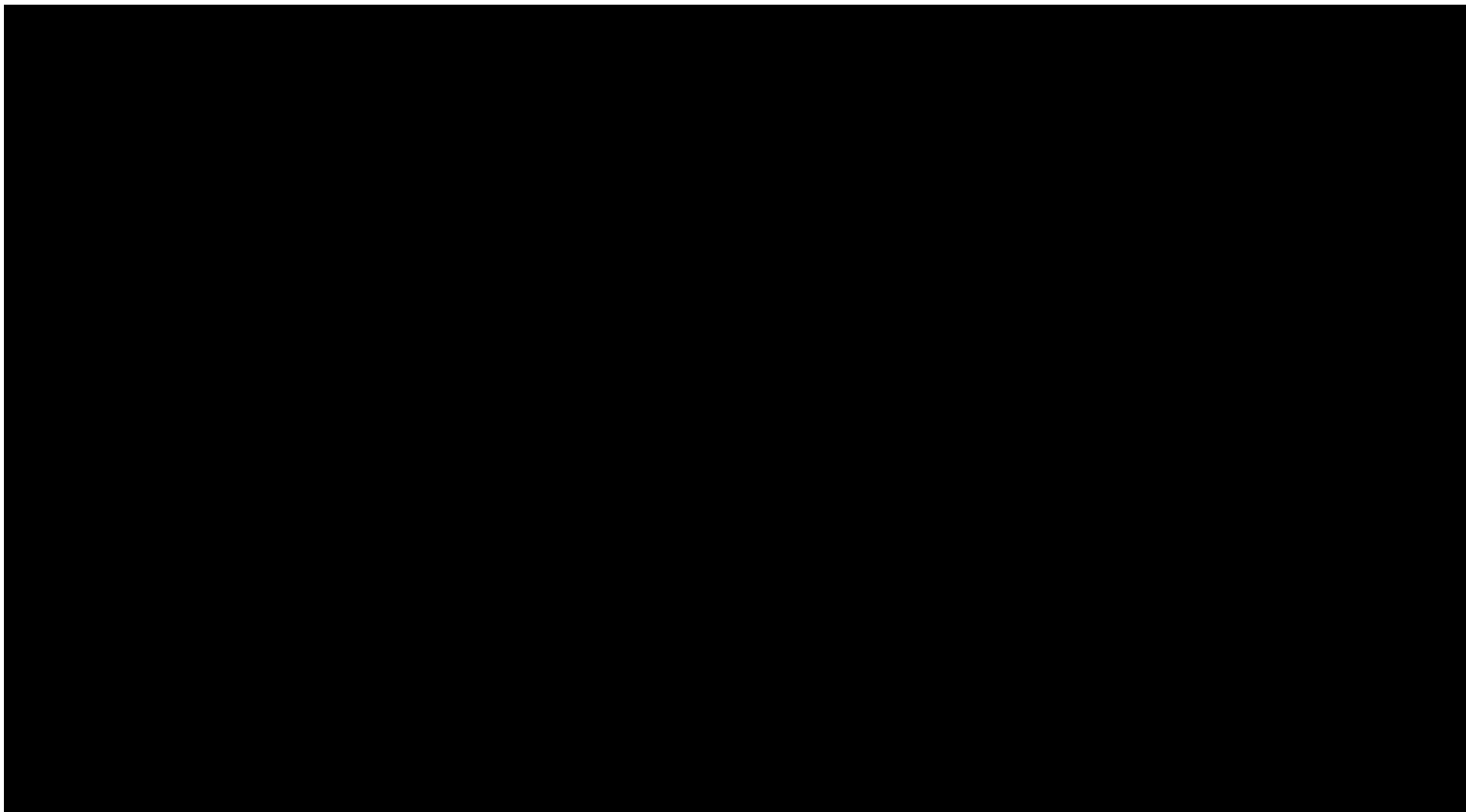
Status:
Page:

Final
Page 1697 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1698 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1699 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

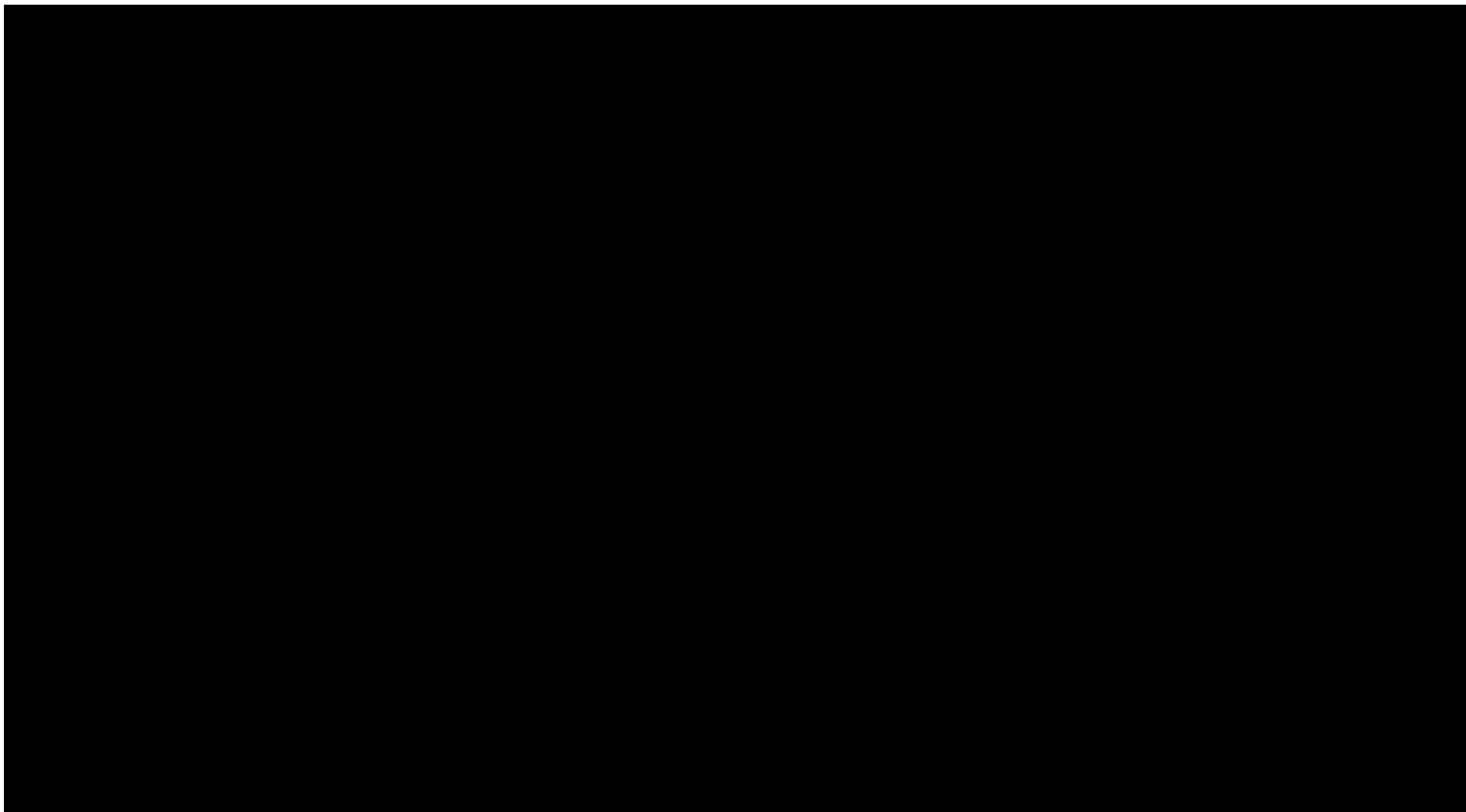
Status:
Page:

Final
Page 1700 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

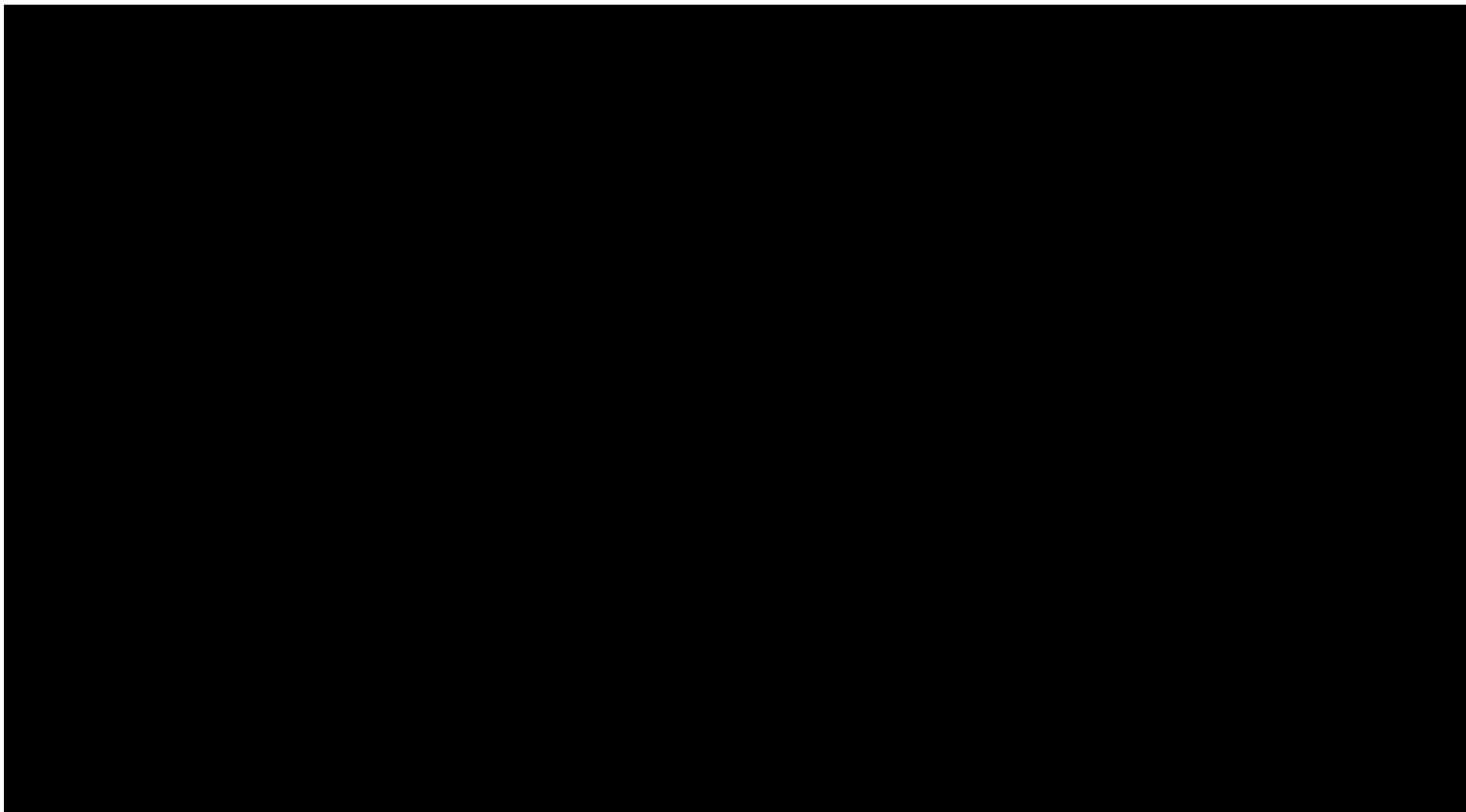
Status:
Page:

Final
Page 1701 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1702 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

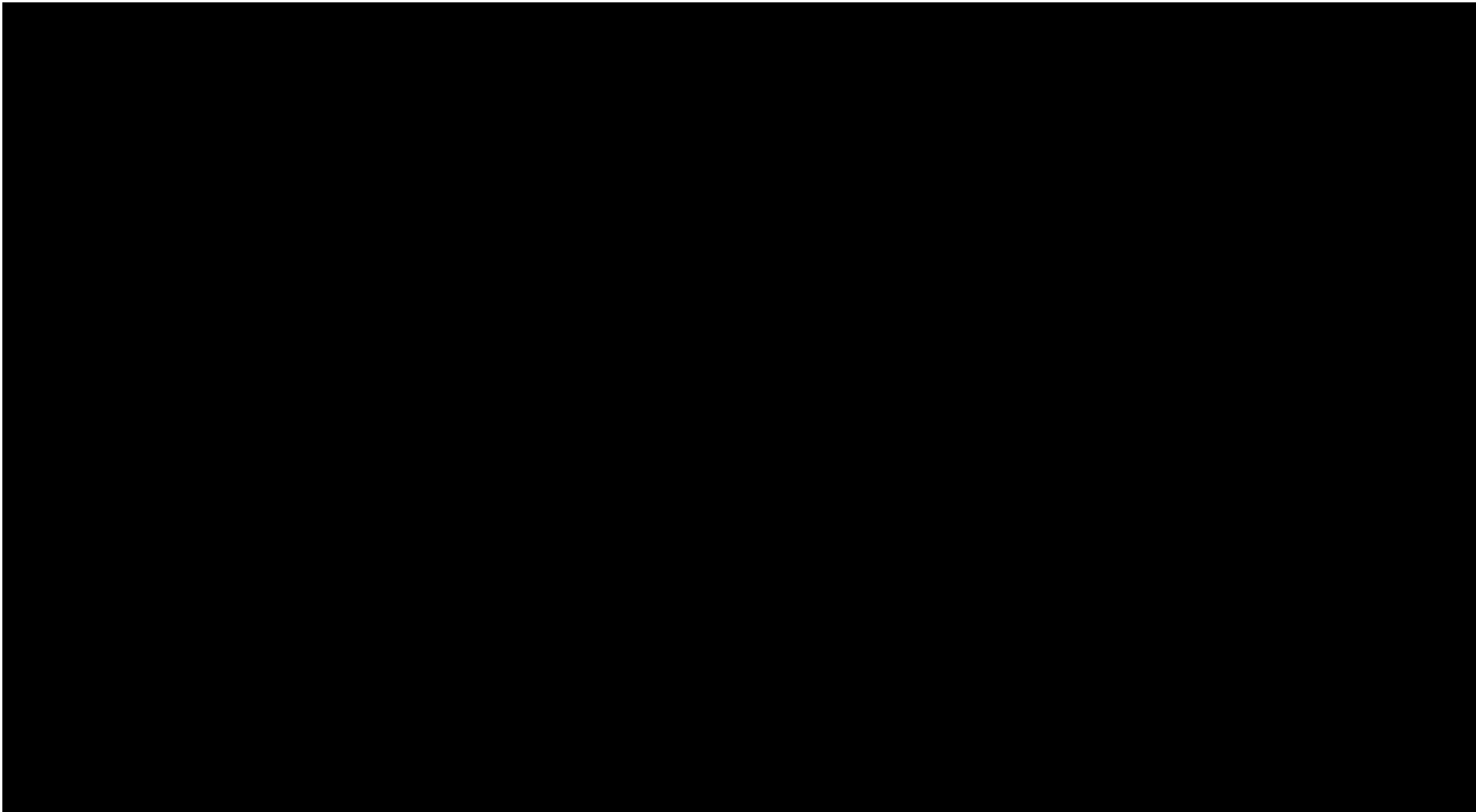
Status:
Page:

Final
Page 1703 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1704 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1705 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1707 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1709 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1711 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

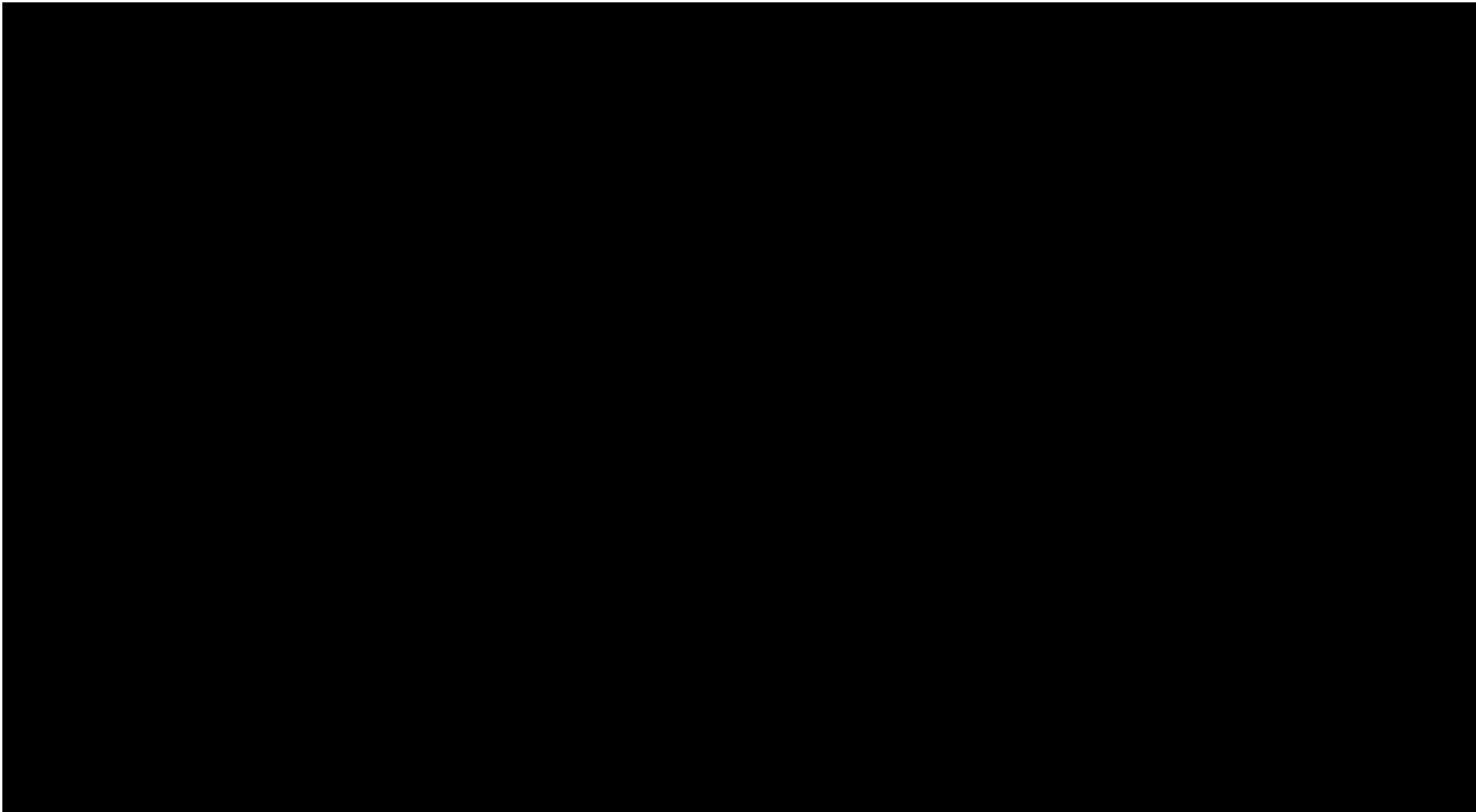
Status:
Page:

Final
Page 1713 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

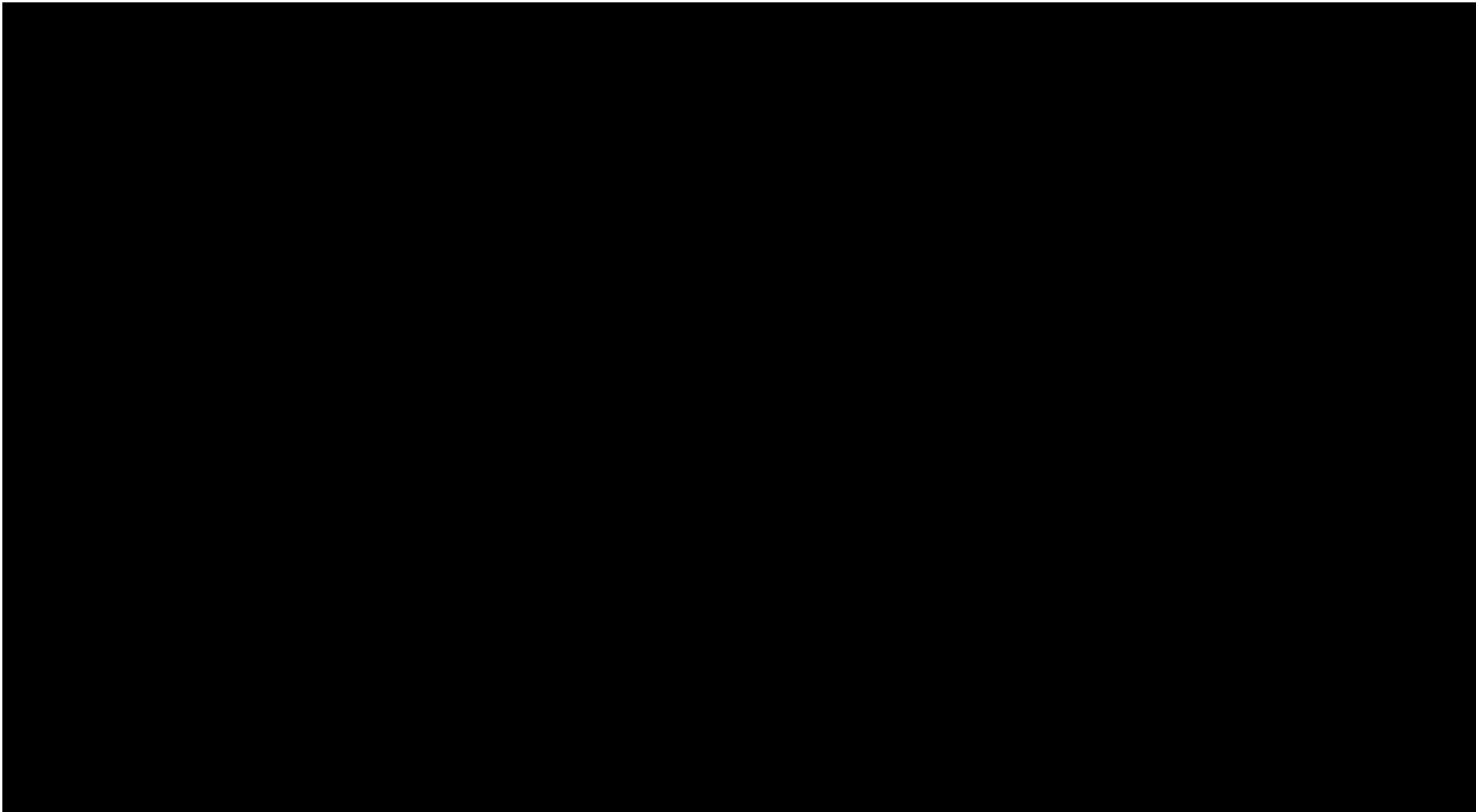
Status:
Page:

Final
Page 1714 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1715 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

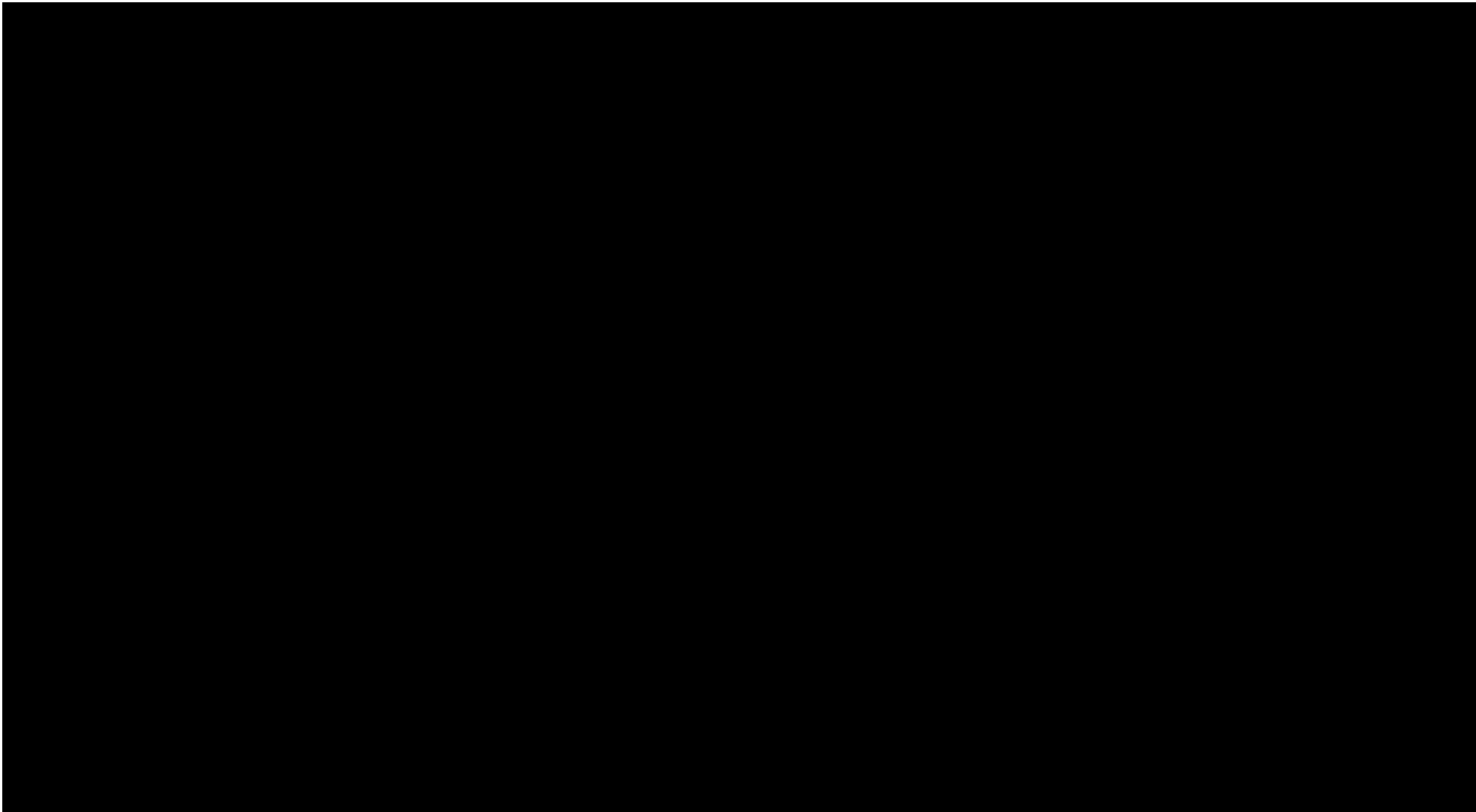
Status:
Page:

Final
Page 1717 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

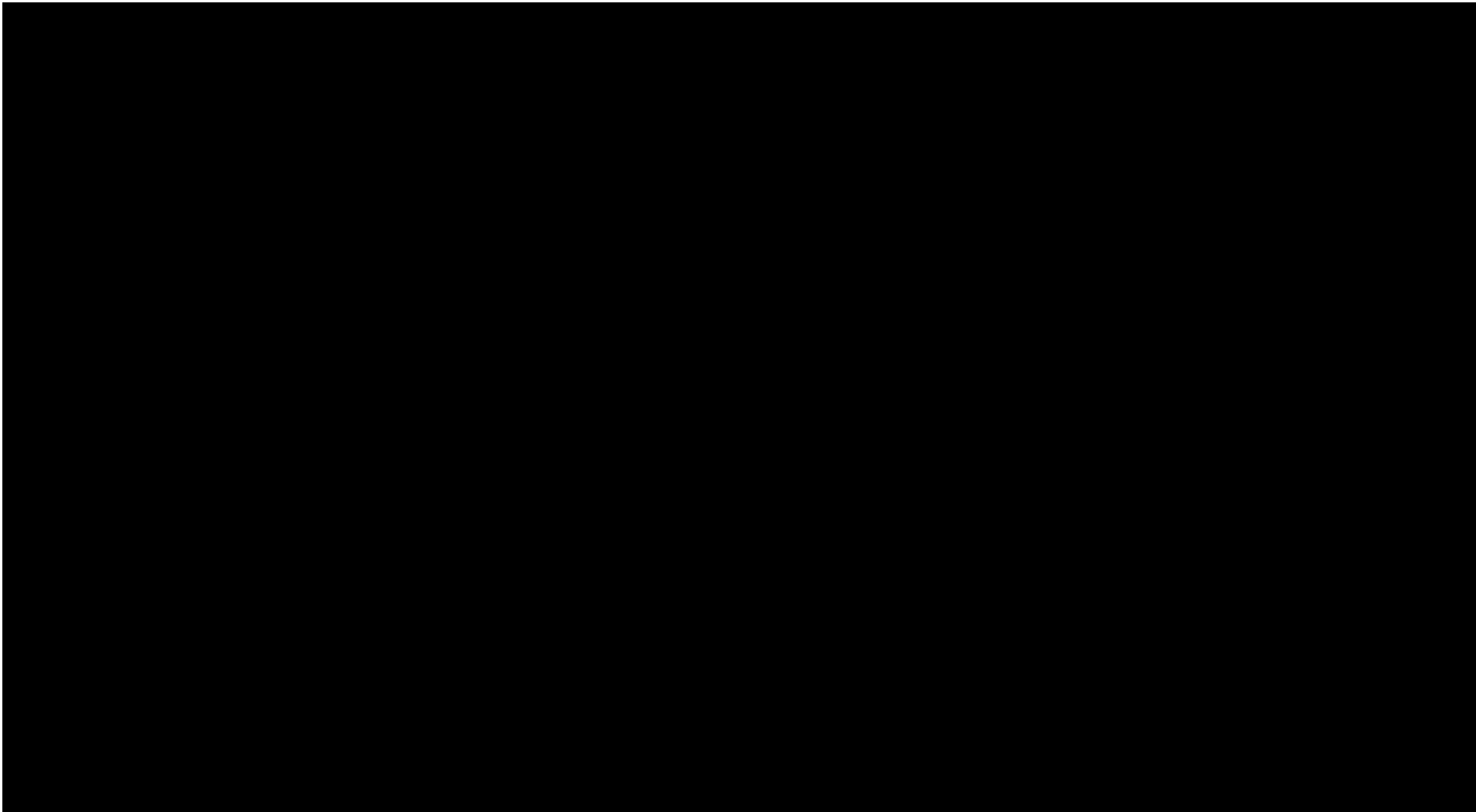
Status:
Page:

Final
Page 1718 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

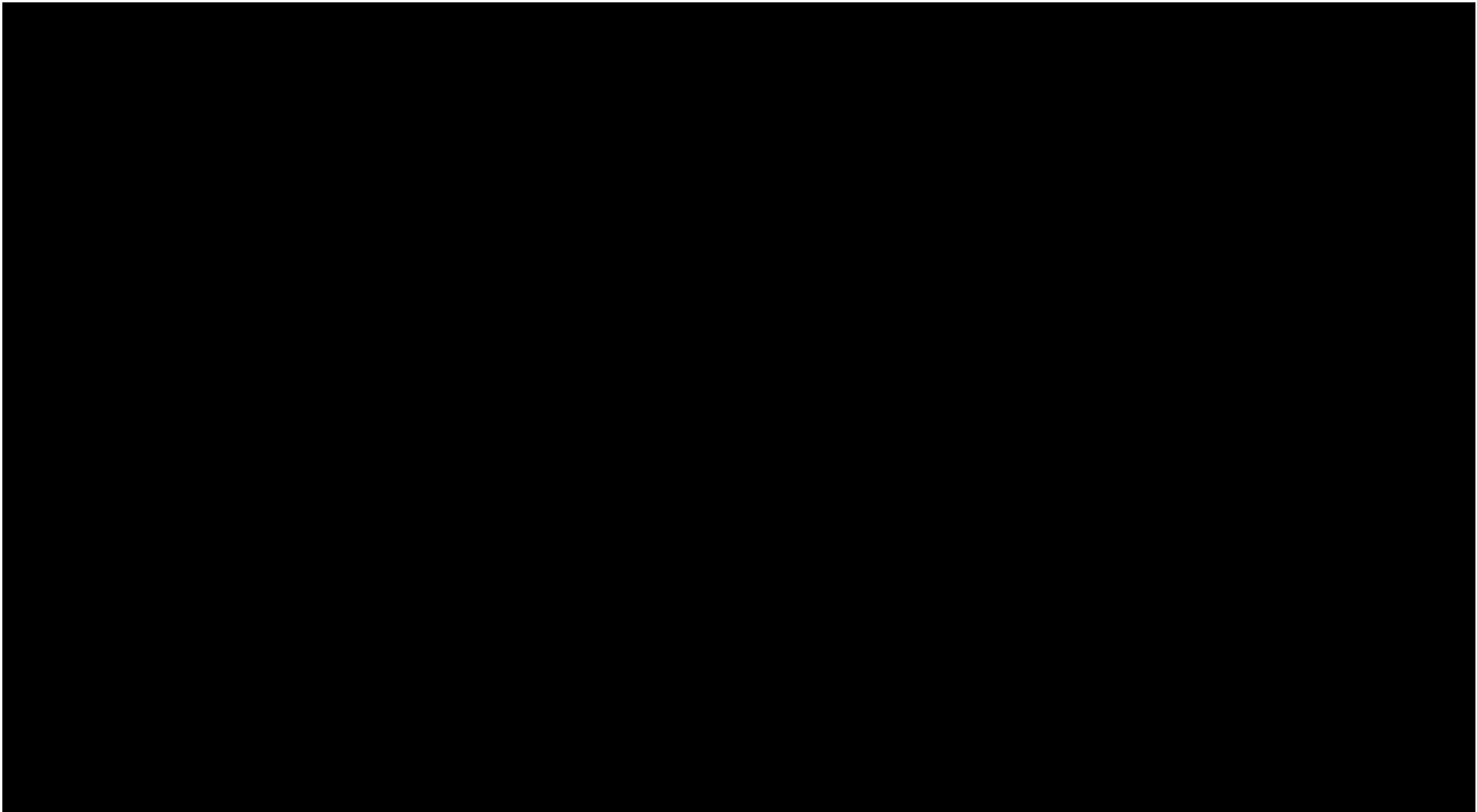
Status:
Page:

Final
Page 1719 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

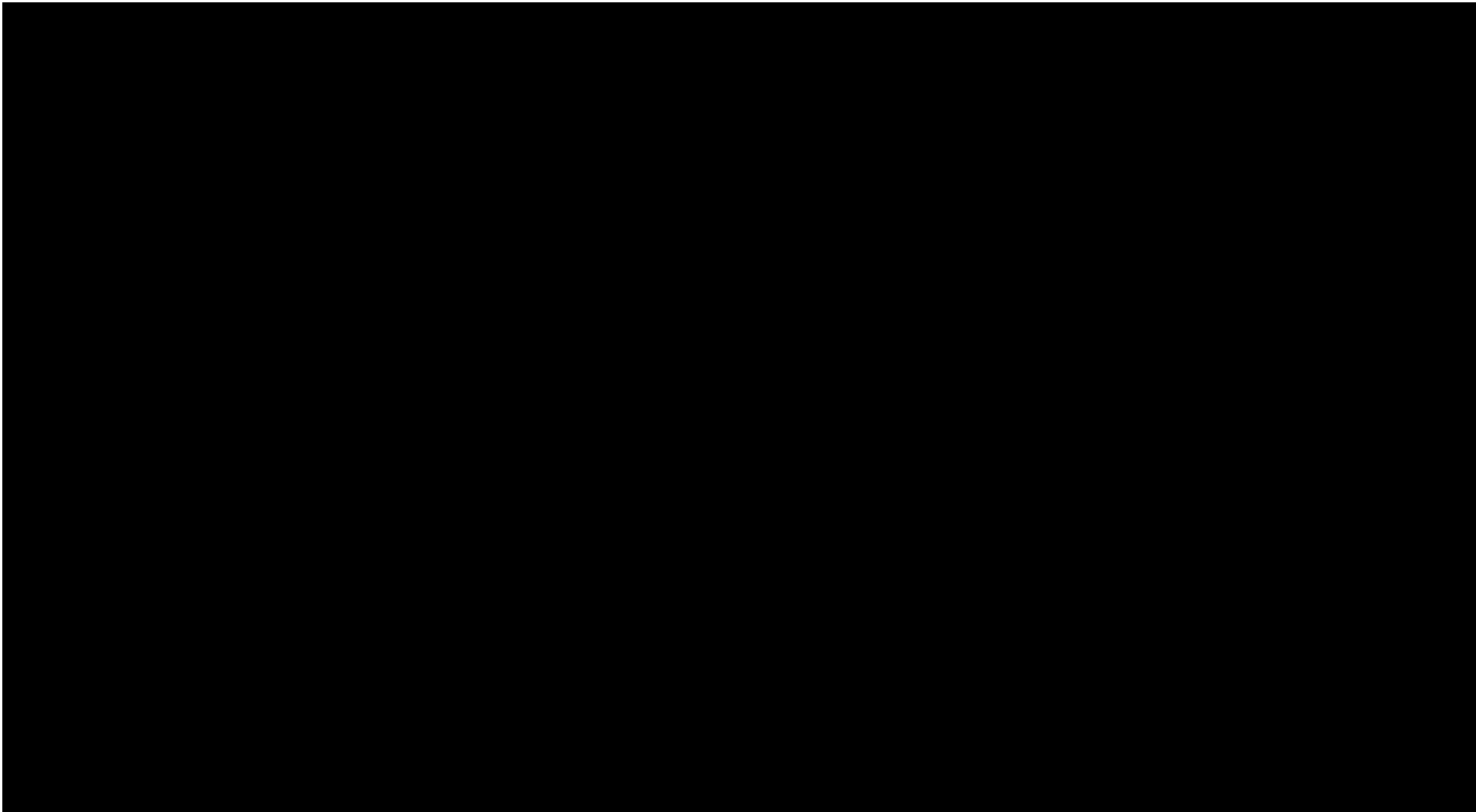
Status:
Page:

Final
Page 1720 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

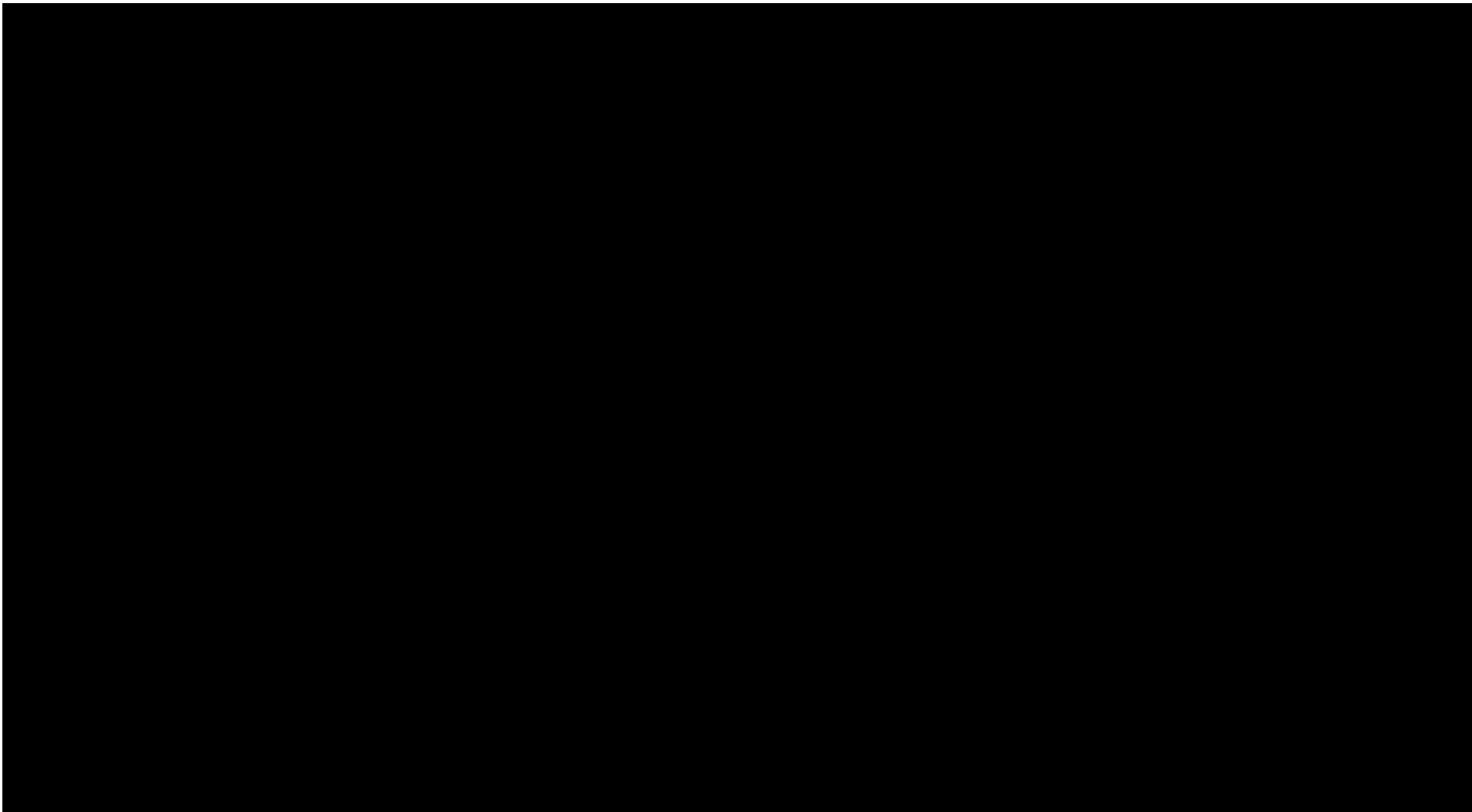
Status:
Page:

Final
Page 1721 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

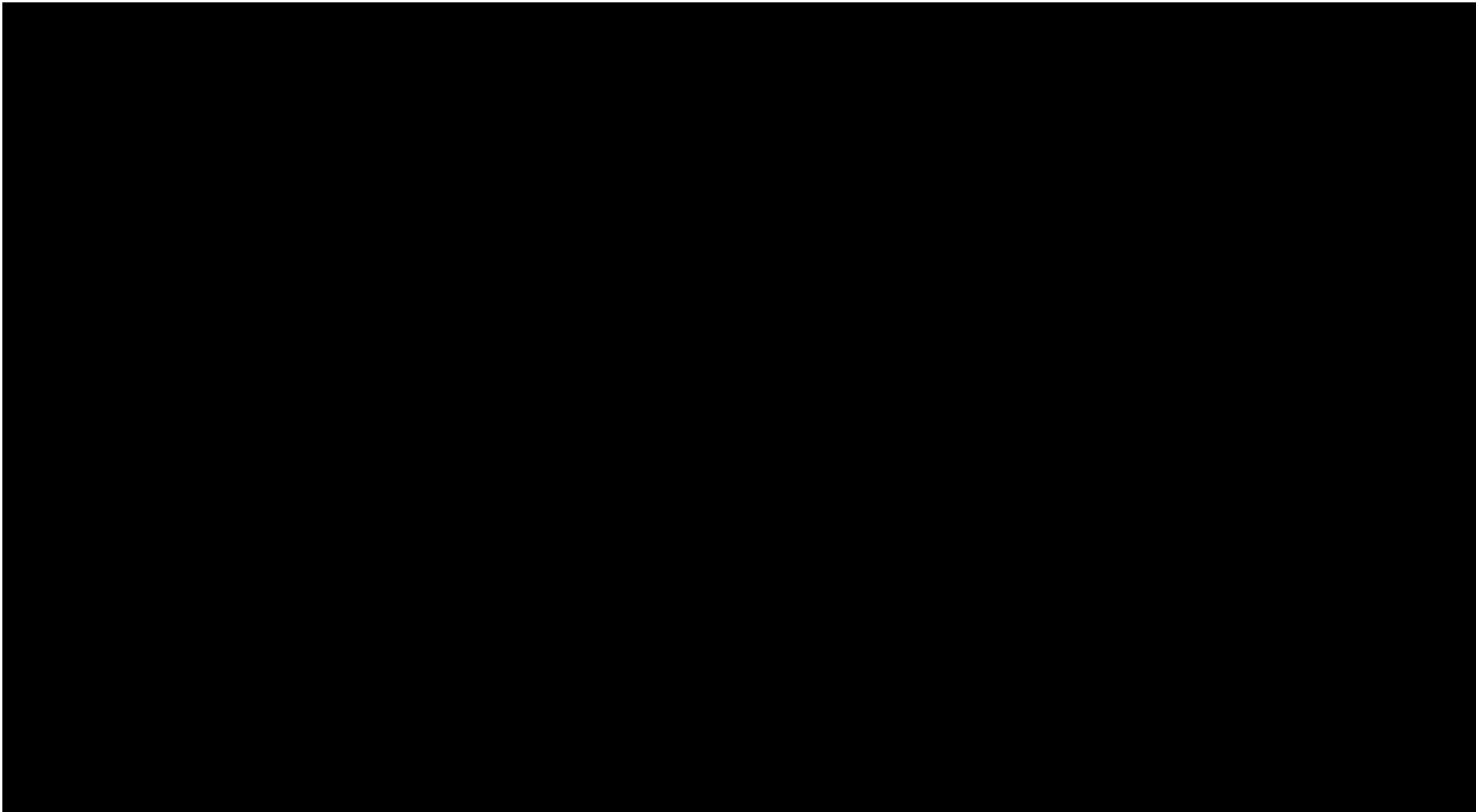
Status:
Page:

Final
Page 1722 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

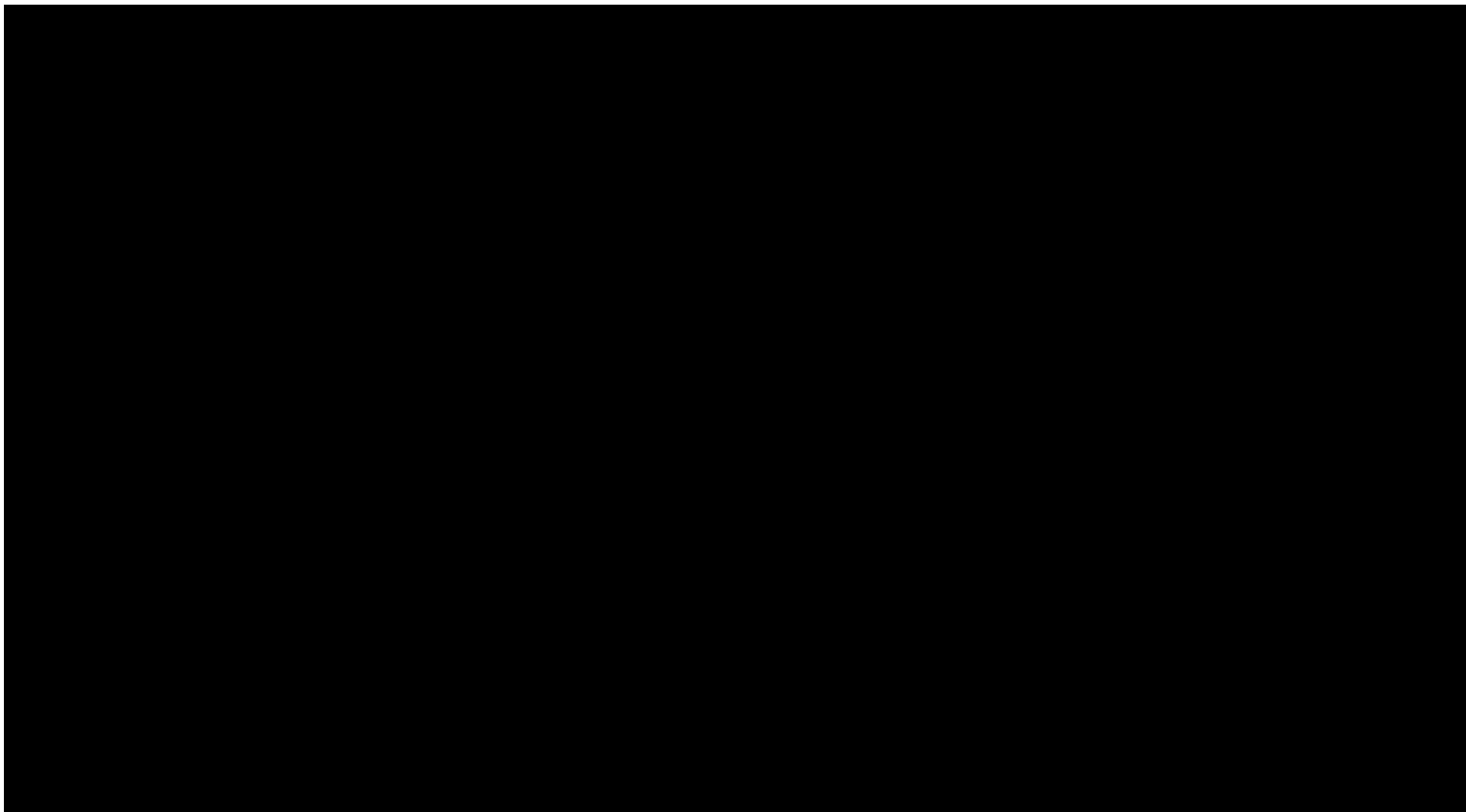
Status:
Page:

Final
Page 1723 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

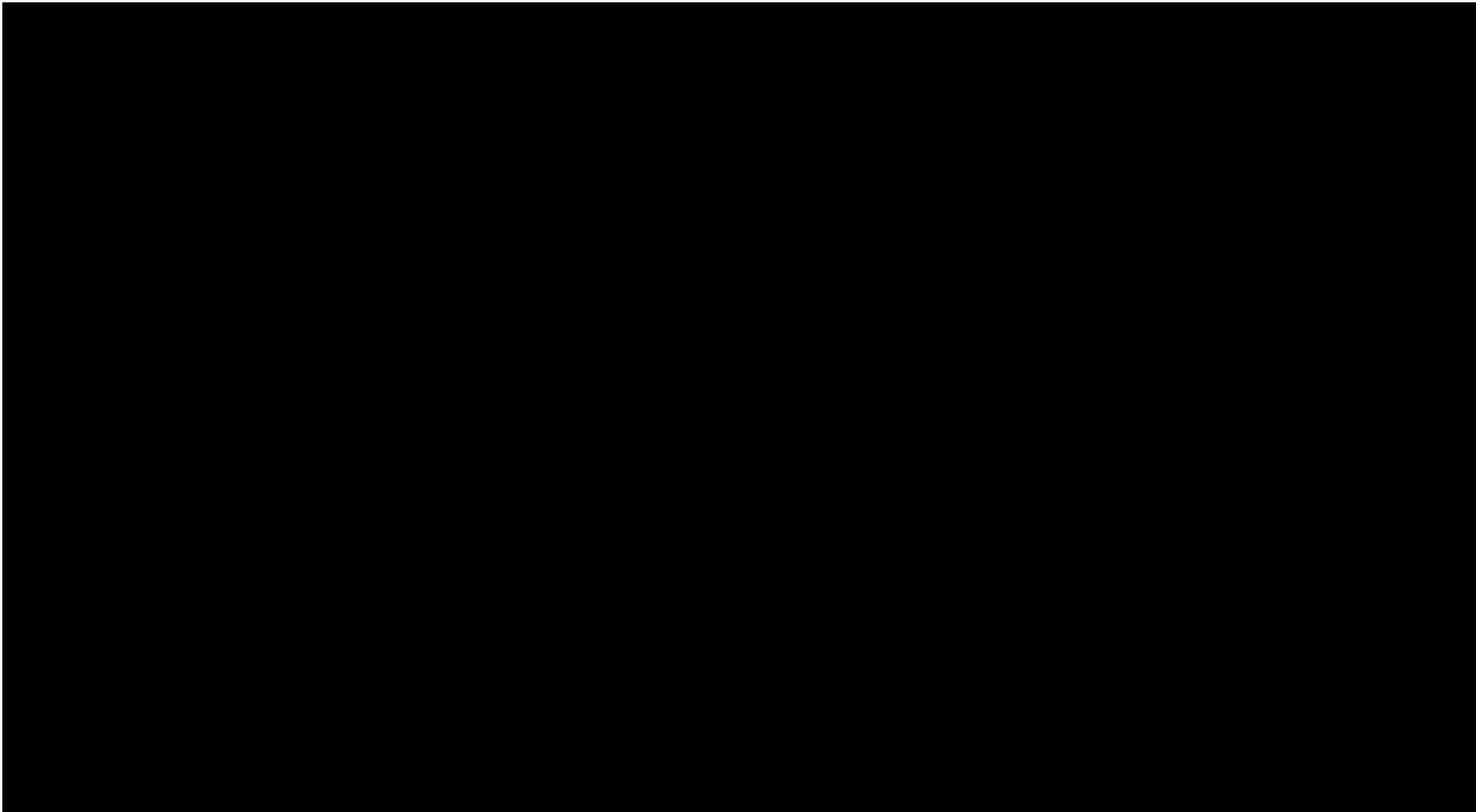
Status:
Page:

Final
Page 1724 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



The image consists of a single, uniform black rectangle. There are no discernible features, patterns, or variations in color or texture throughout the entire frame.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

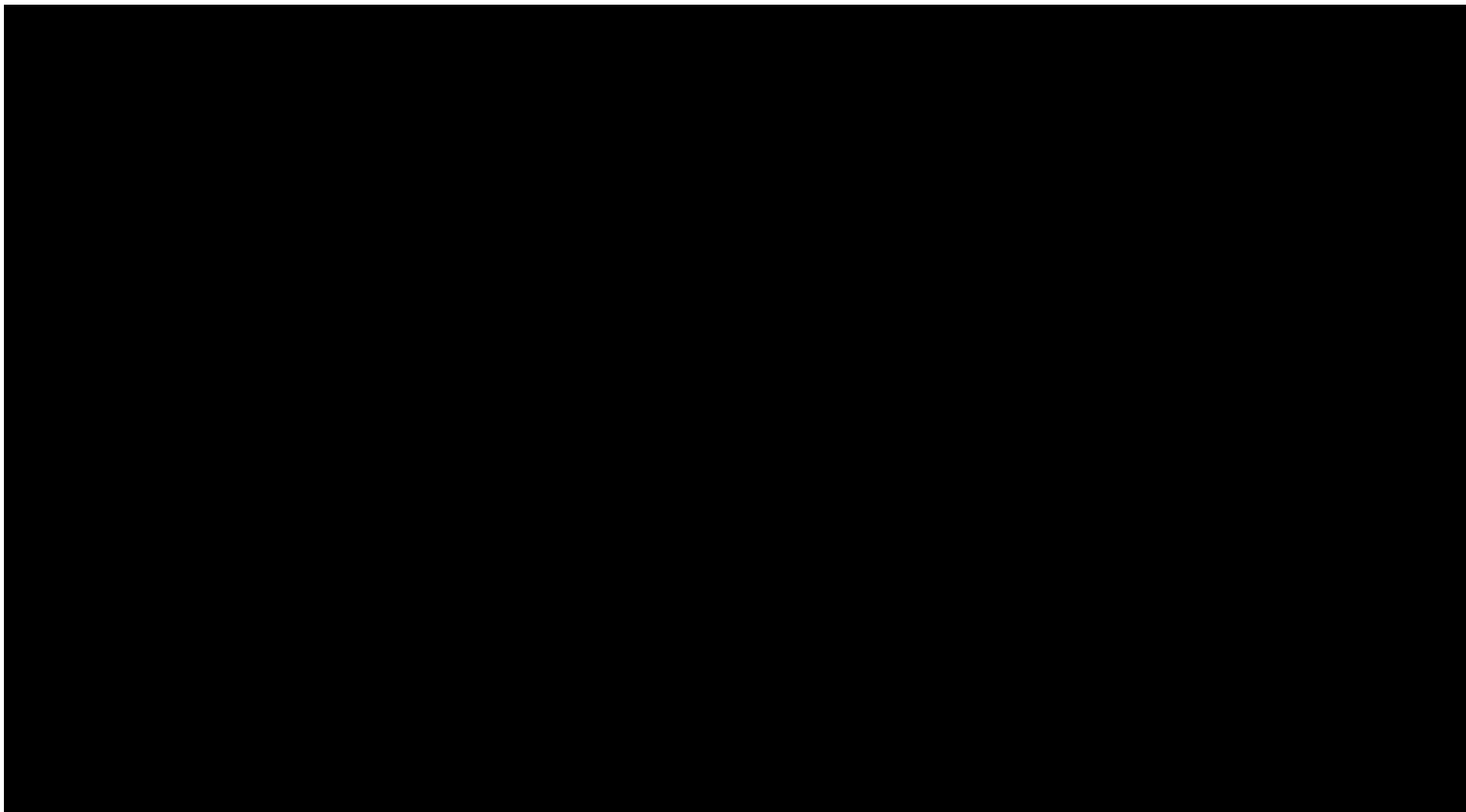
Status:
Page:

Final
Page 1726 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

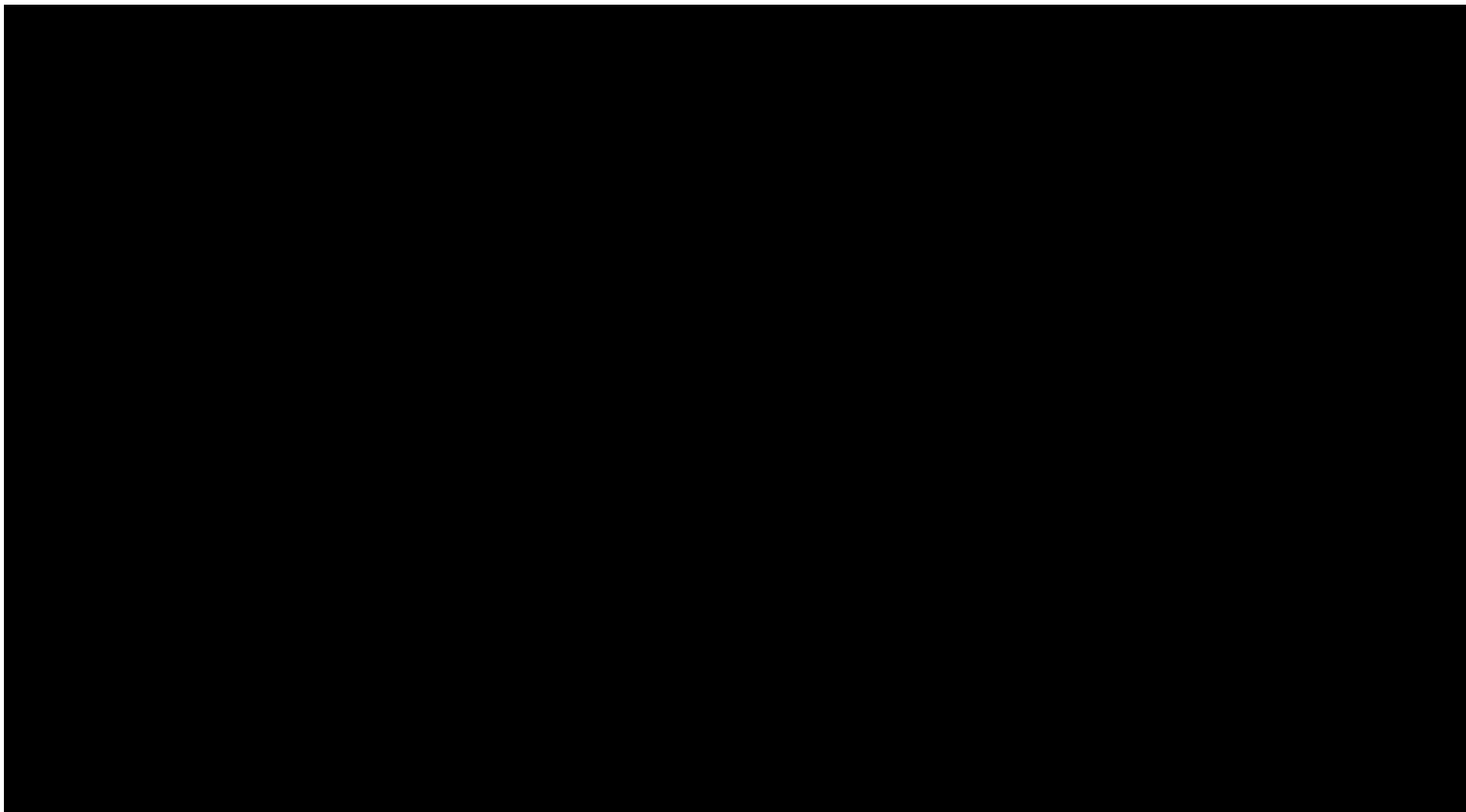
Status:
Page:

Final
Page 1728 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

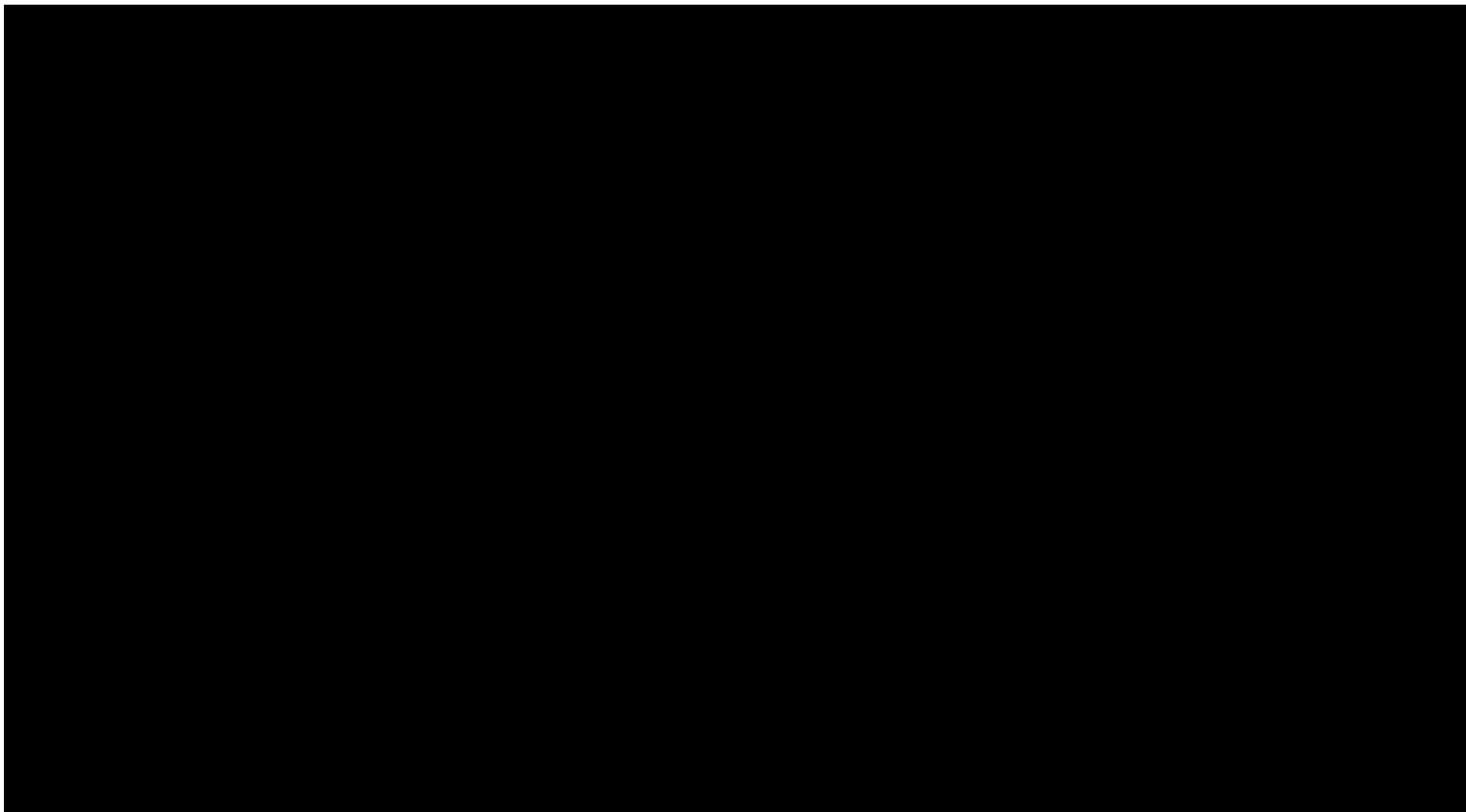
Status:
Page:

Final
Page 1729 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1730 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1731 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1734 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1735 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

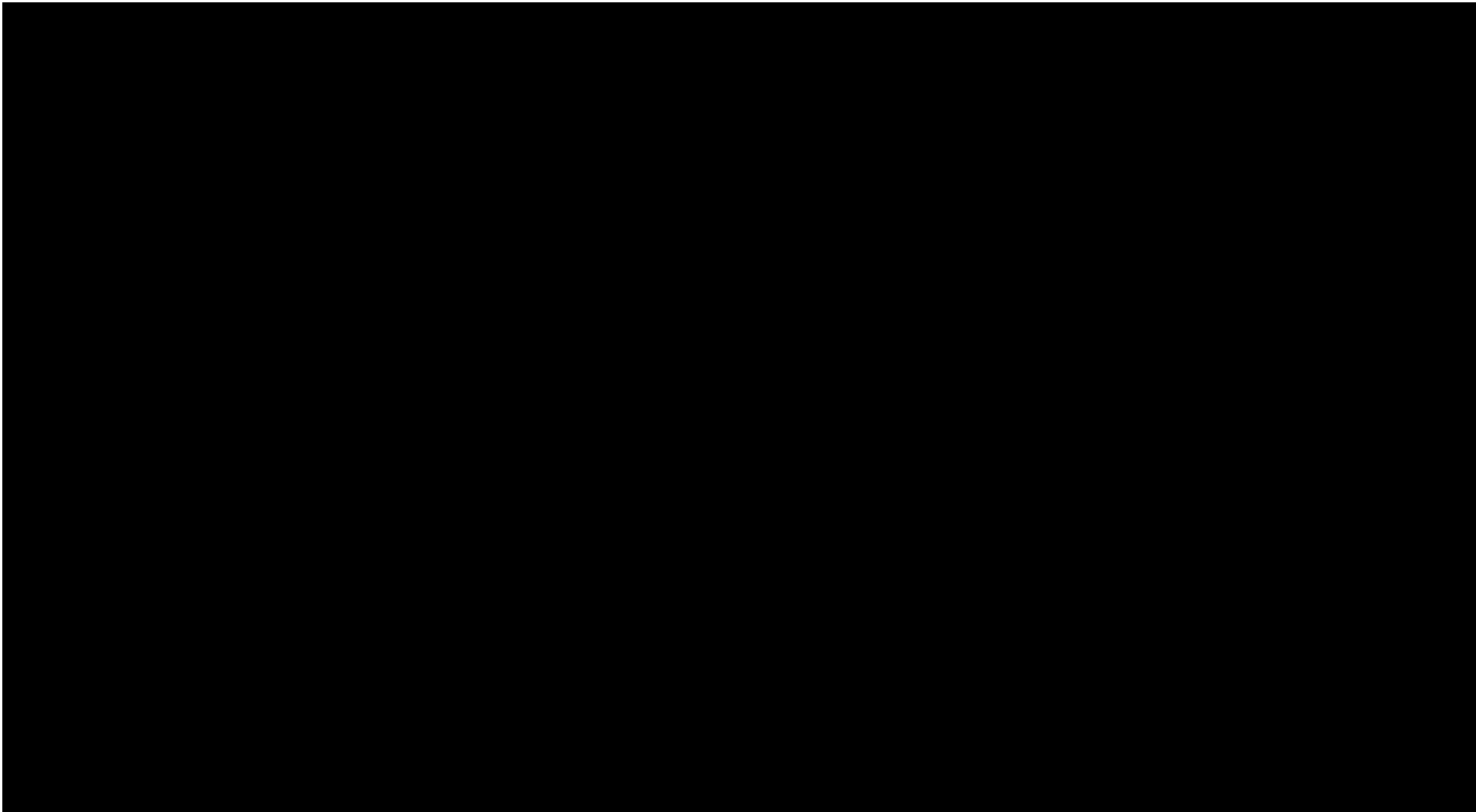
Status:
Page:

Final
Page 1736 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

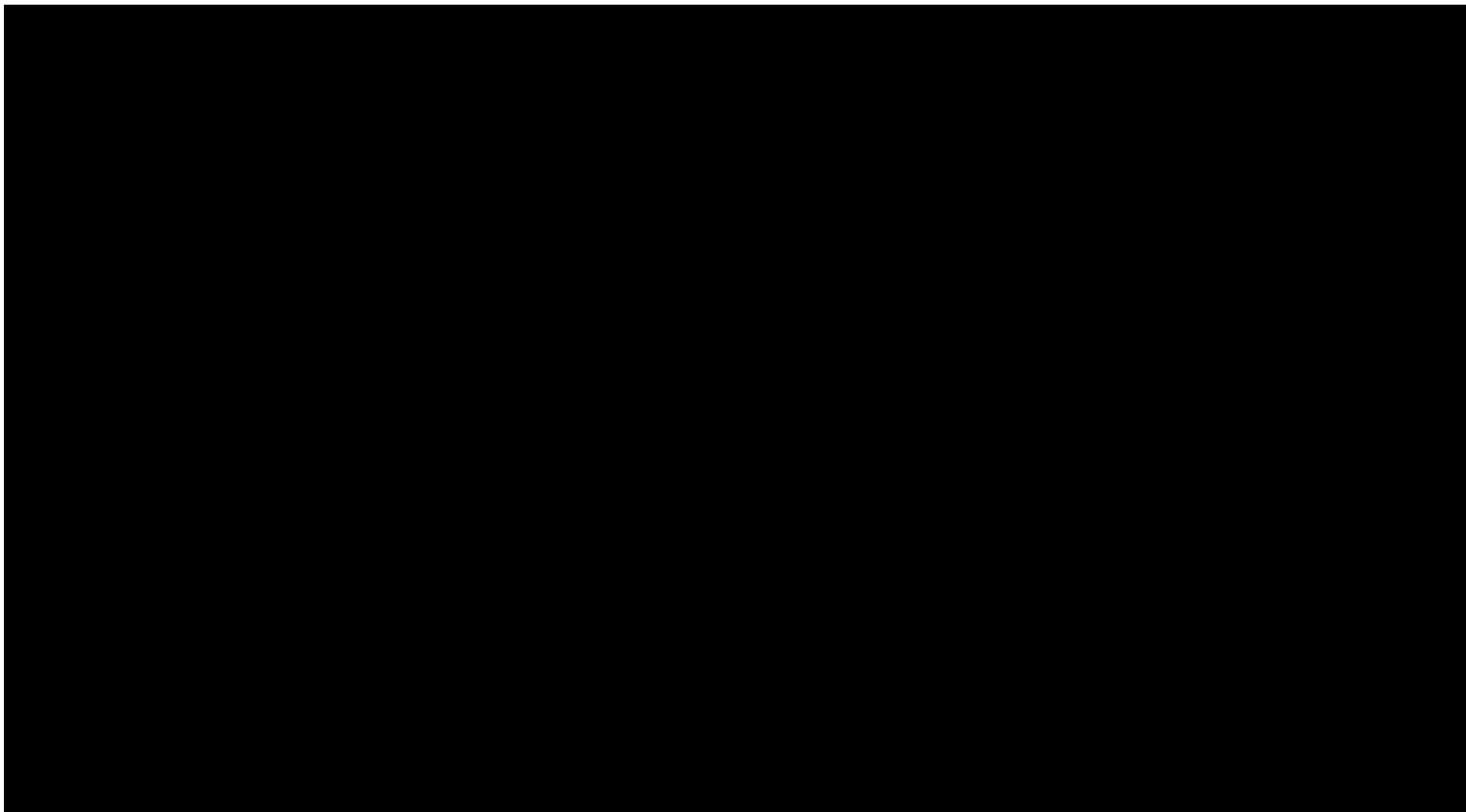
Status:
Page:

Final
Page 1737 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

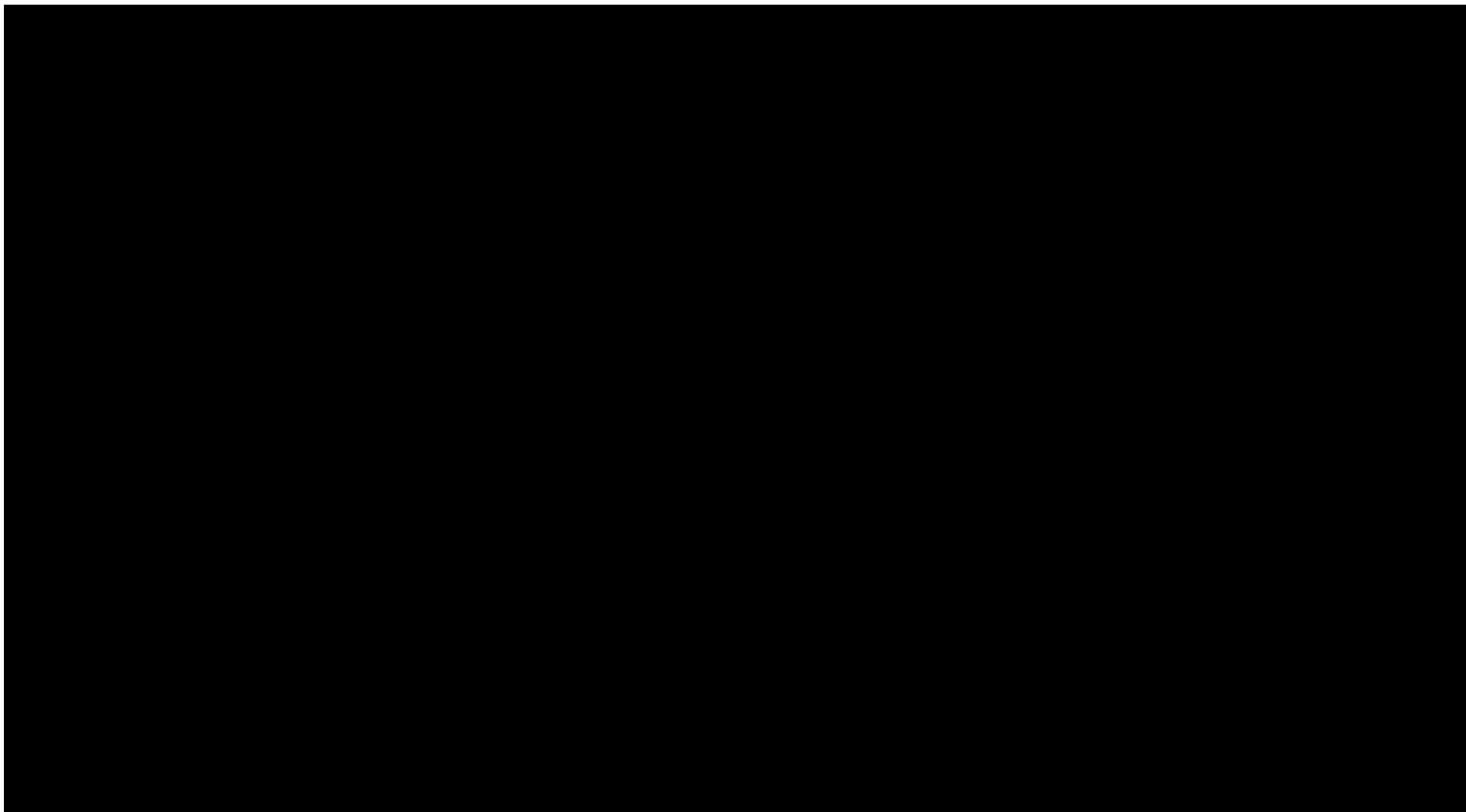
Status:
Page:

Final
Page 1738 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



The image consists of a single, uniform black rectangle. There are no discernible features, text, or patterns other than the solid color.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1740 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

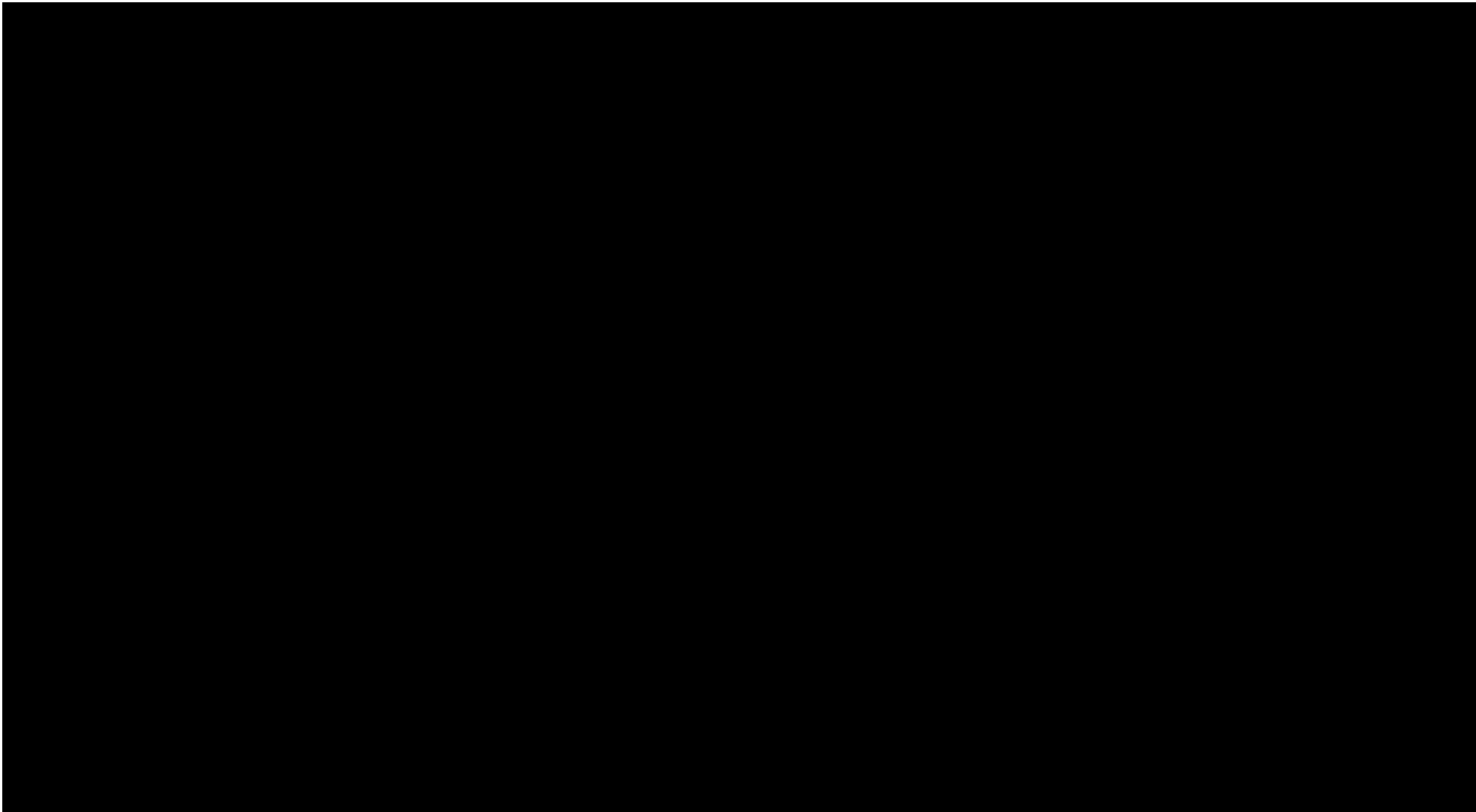
Status:
Page:

Final
Page 1741 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

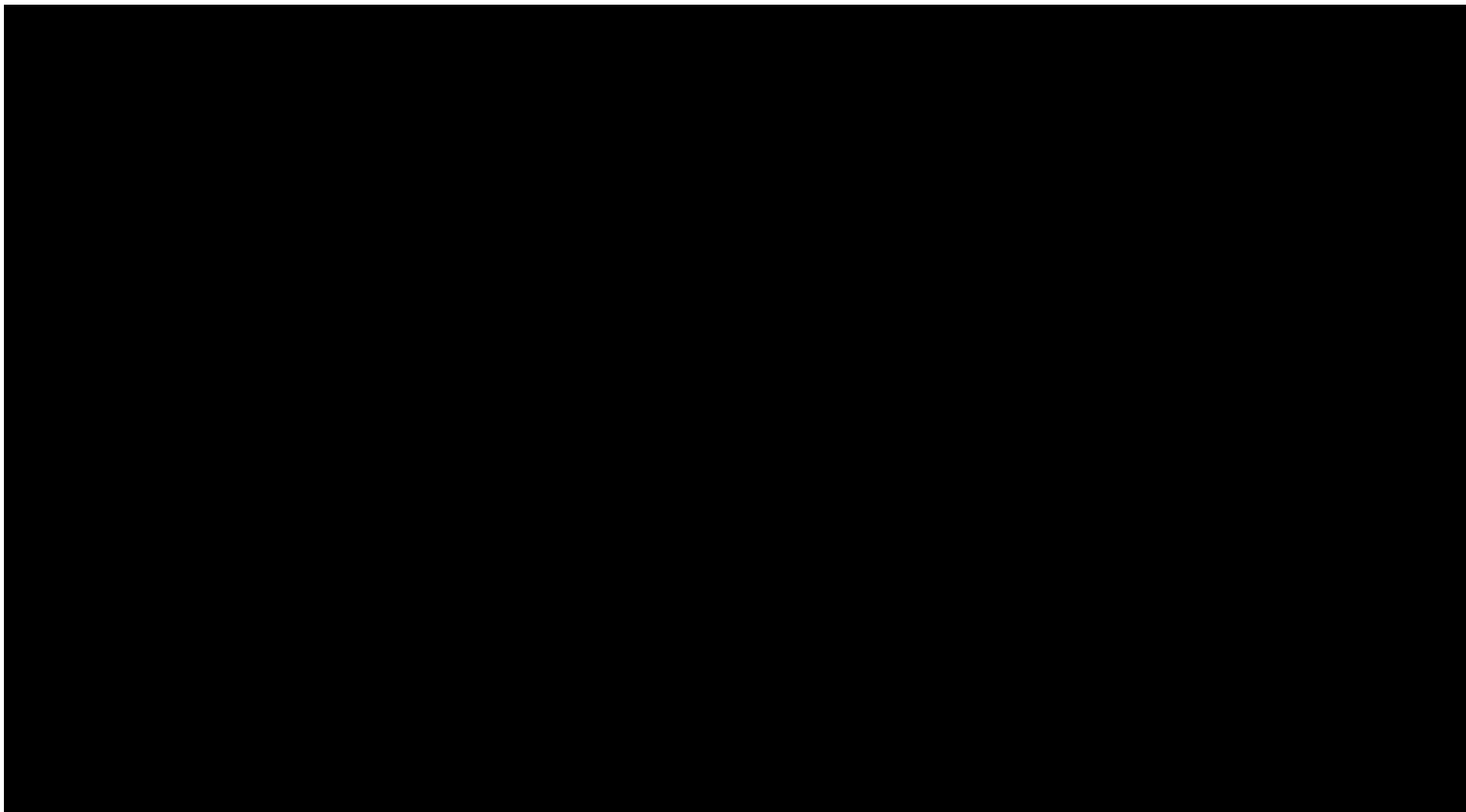
Status:
Page:

Final
Page 1742 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1743 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

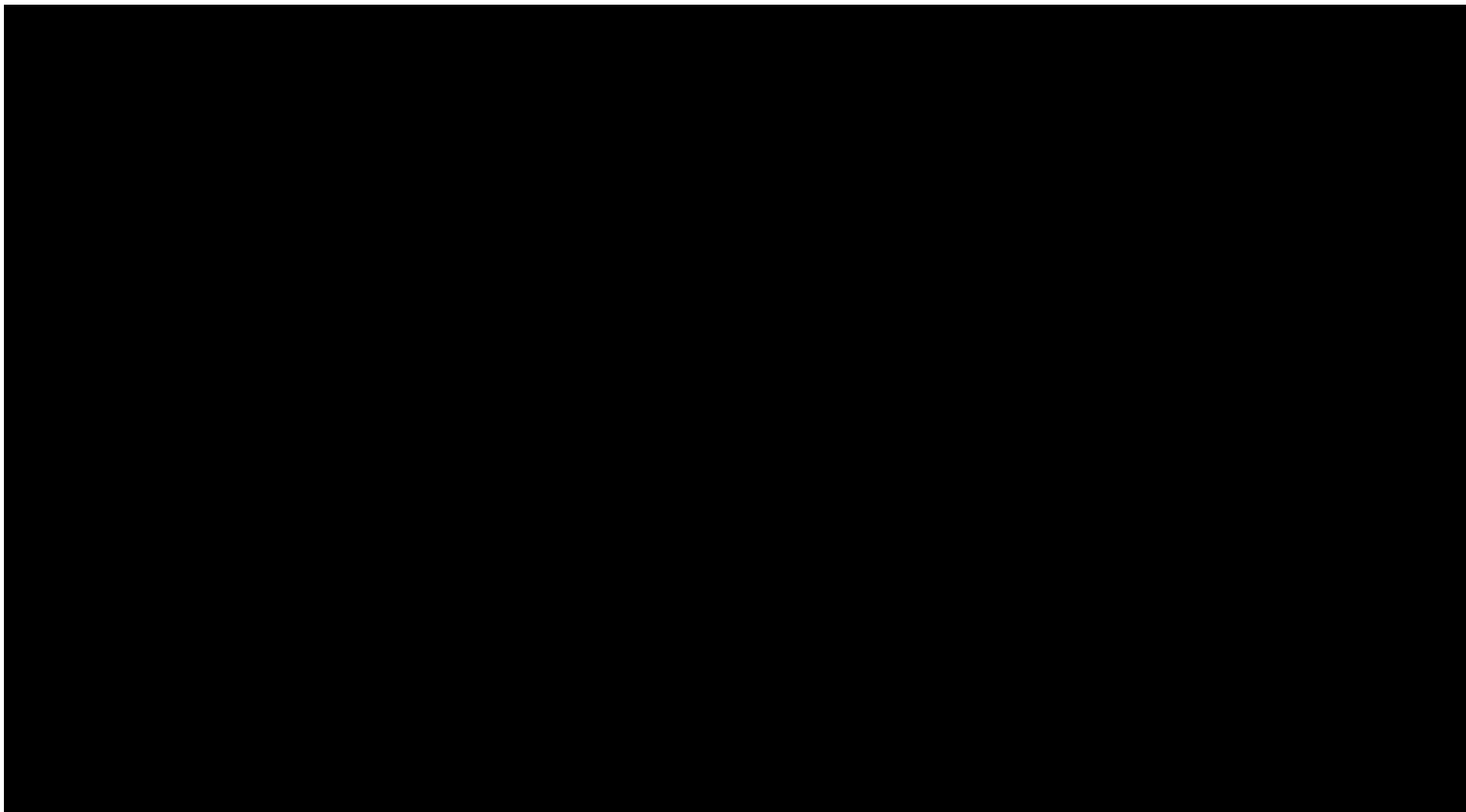
Status:
Page:

Final
Page 1744 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1746 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1747 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1748 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

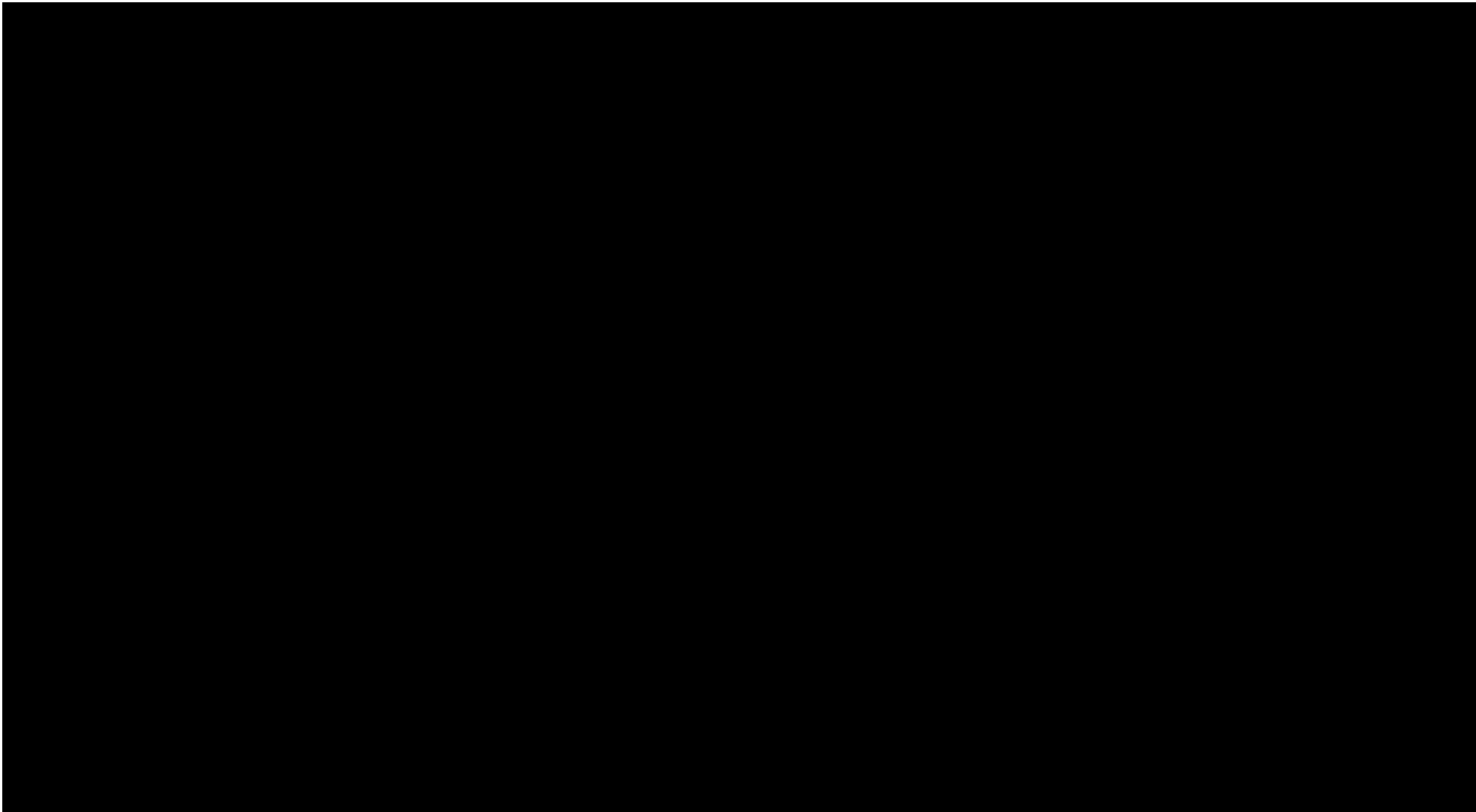
Status:
Page:

Final
Page 1749 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1751 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1752 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1753 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

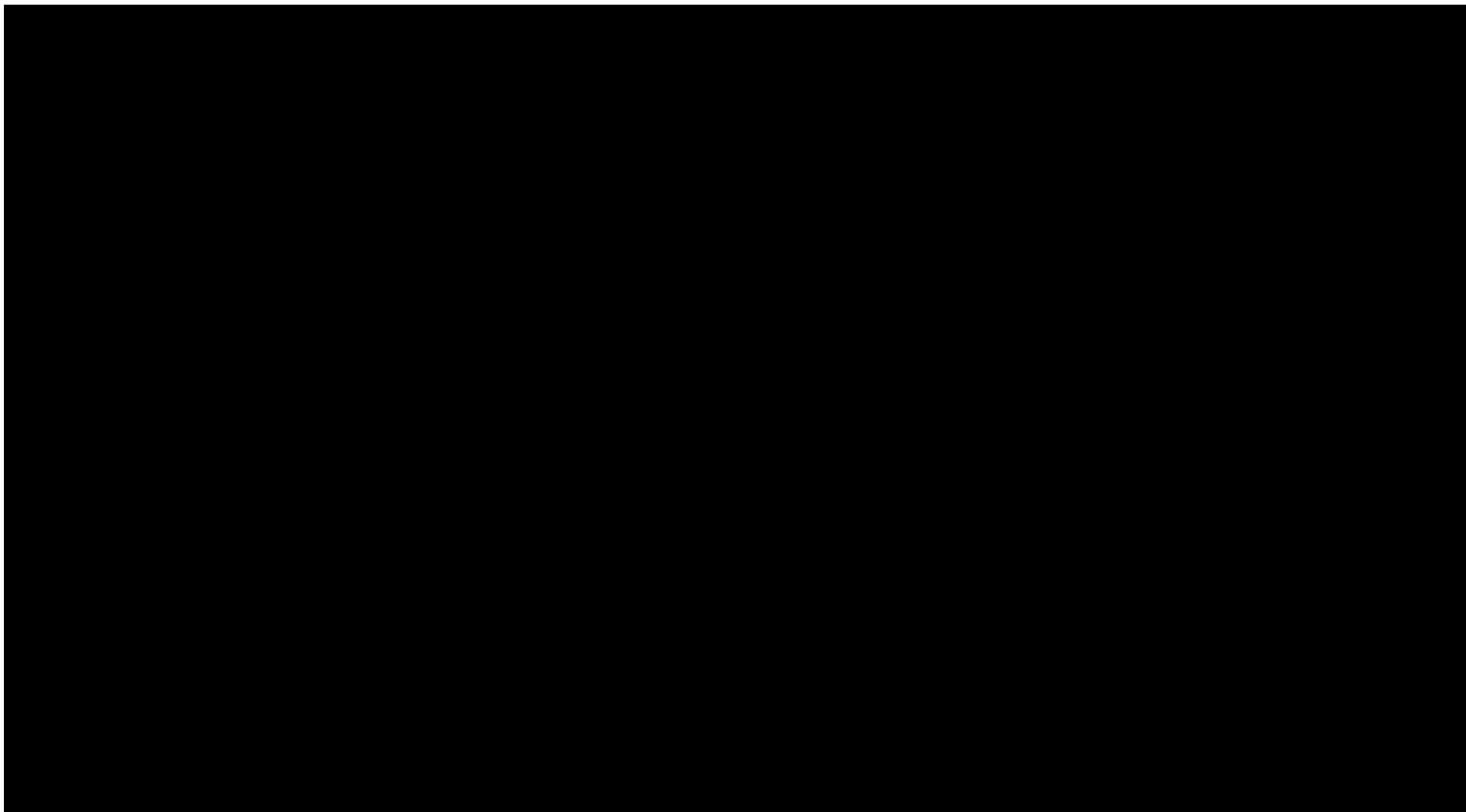
Status:
Page:

Final
Page 1754 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1755 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

The image consists of a single, uniform black rectangle. There are no discernible features, text, or patterns other than the solid black color.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

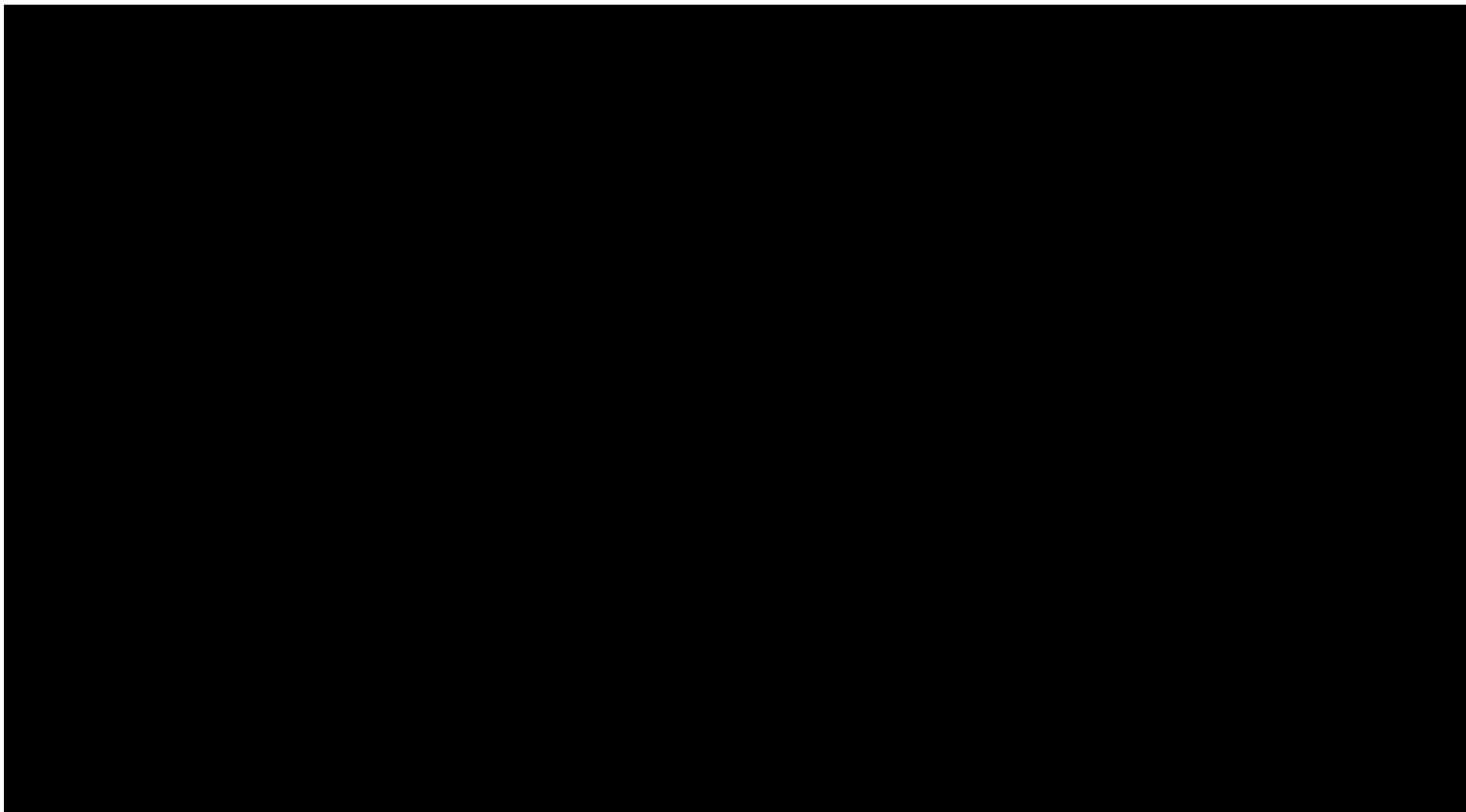
Status:
Page:

Final
Page 1757 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1758 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

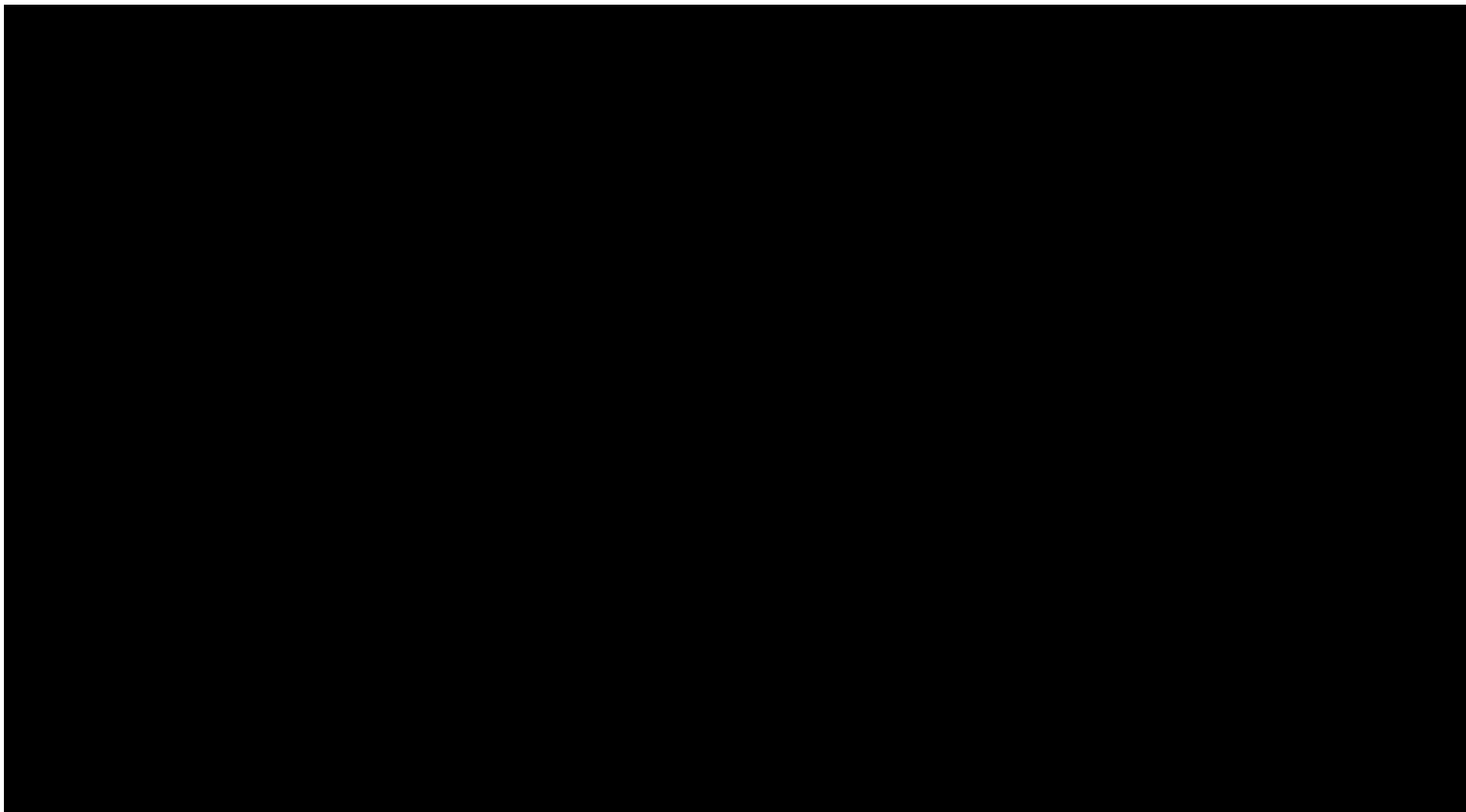
Status:
Page:

Final
Page 1760 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

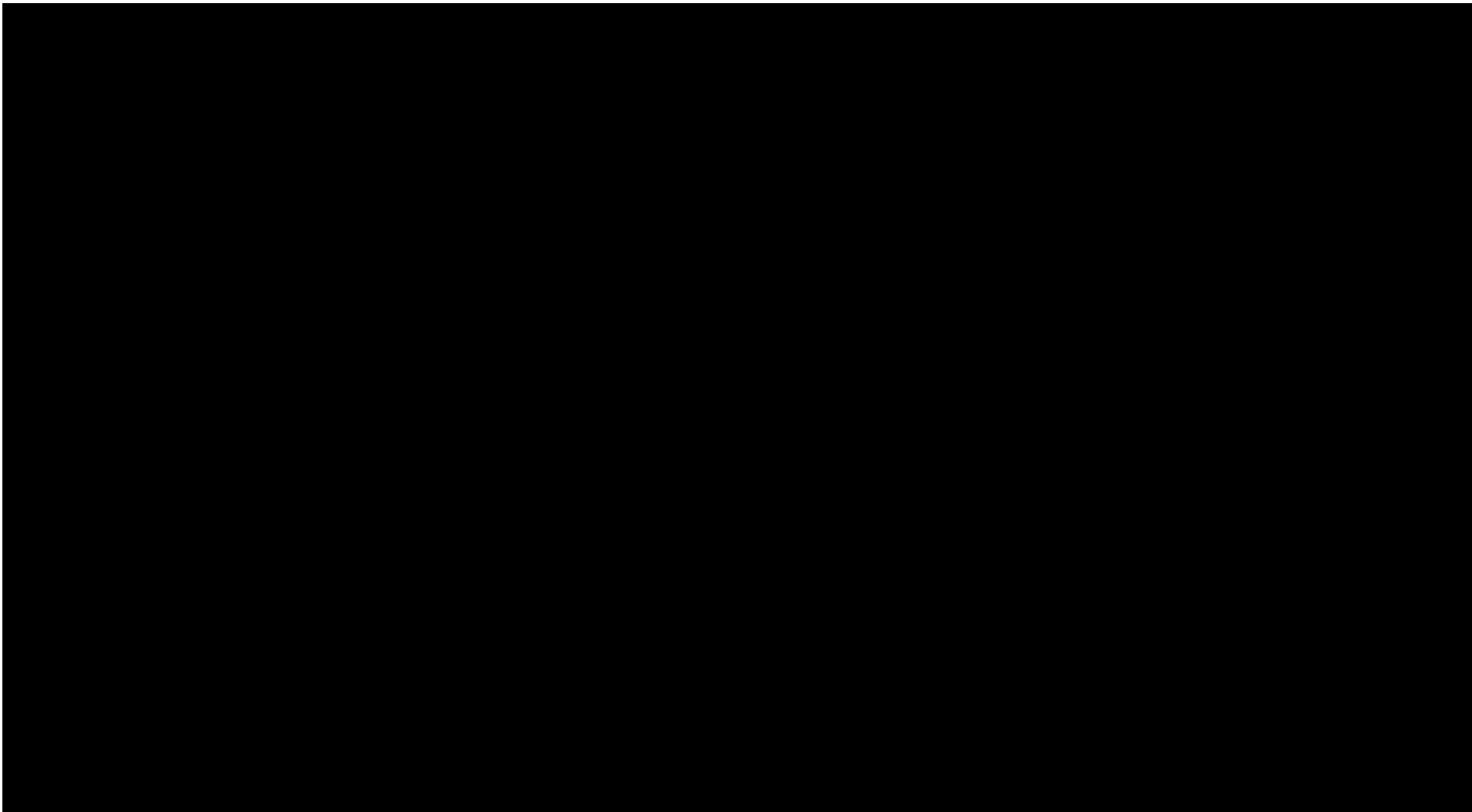
Status:
Page:

Final
Page 1761 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1762 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

The image consists of a single, uniform black rectangle. There are no discernible features, text, or patterns other than the solid black color.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1764 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

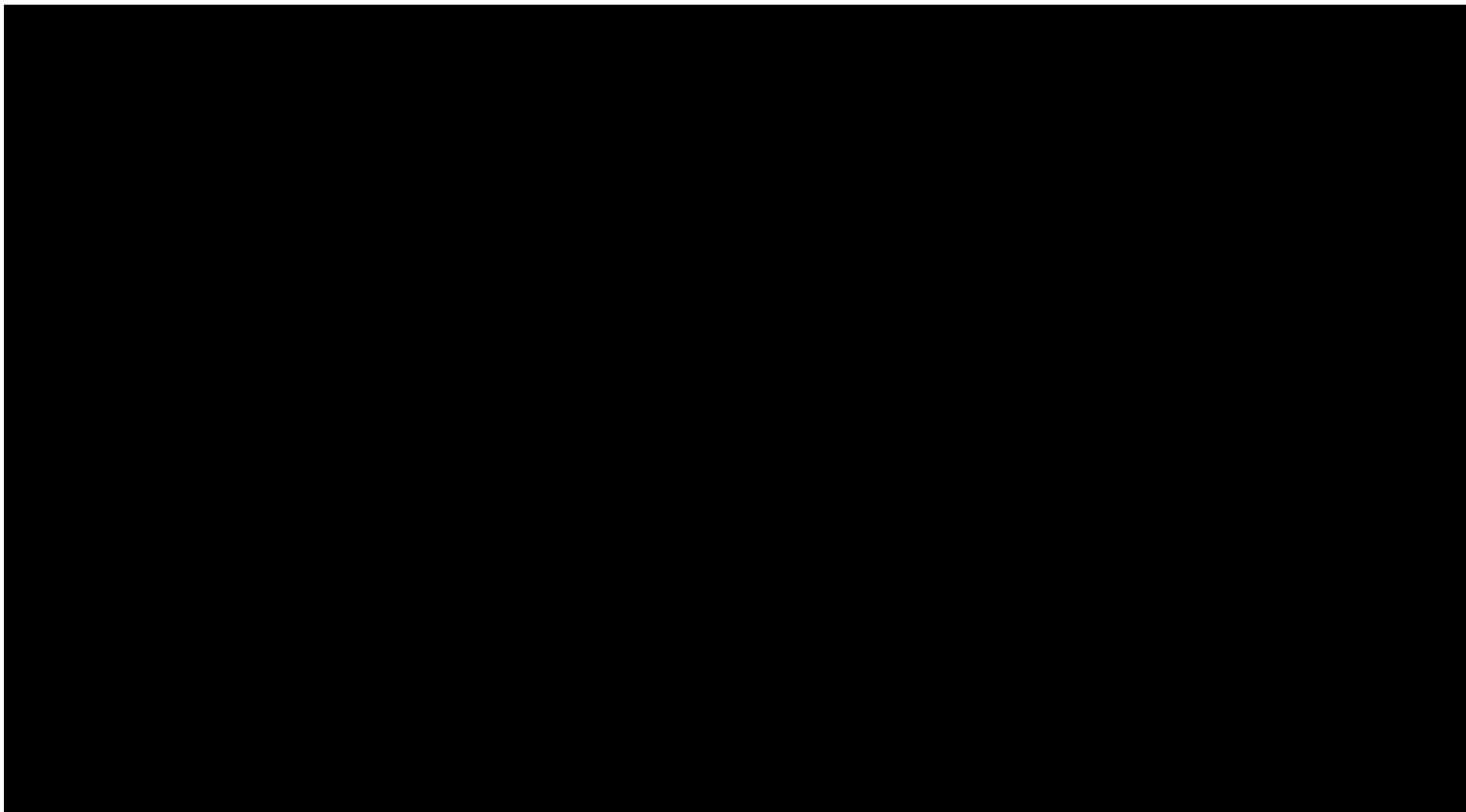
Status:
Page:

Final
Page 1765 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

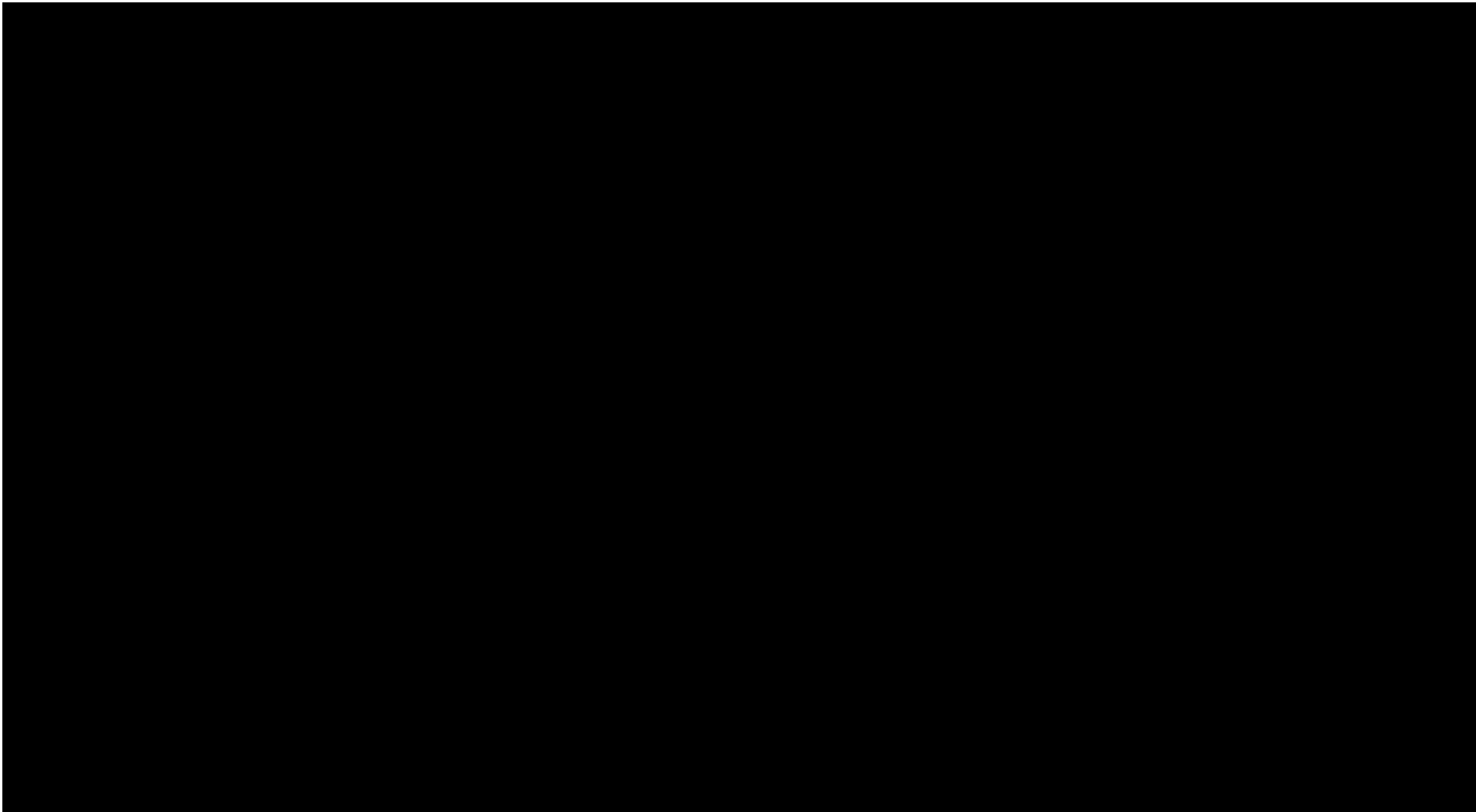
Status:
Page:

Final
Page 1766 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

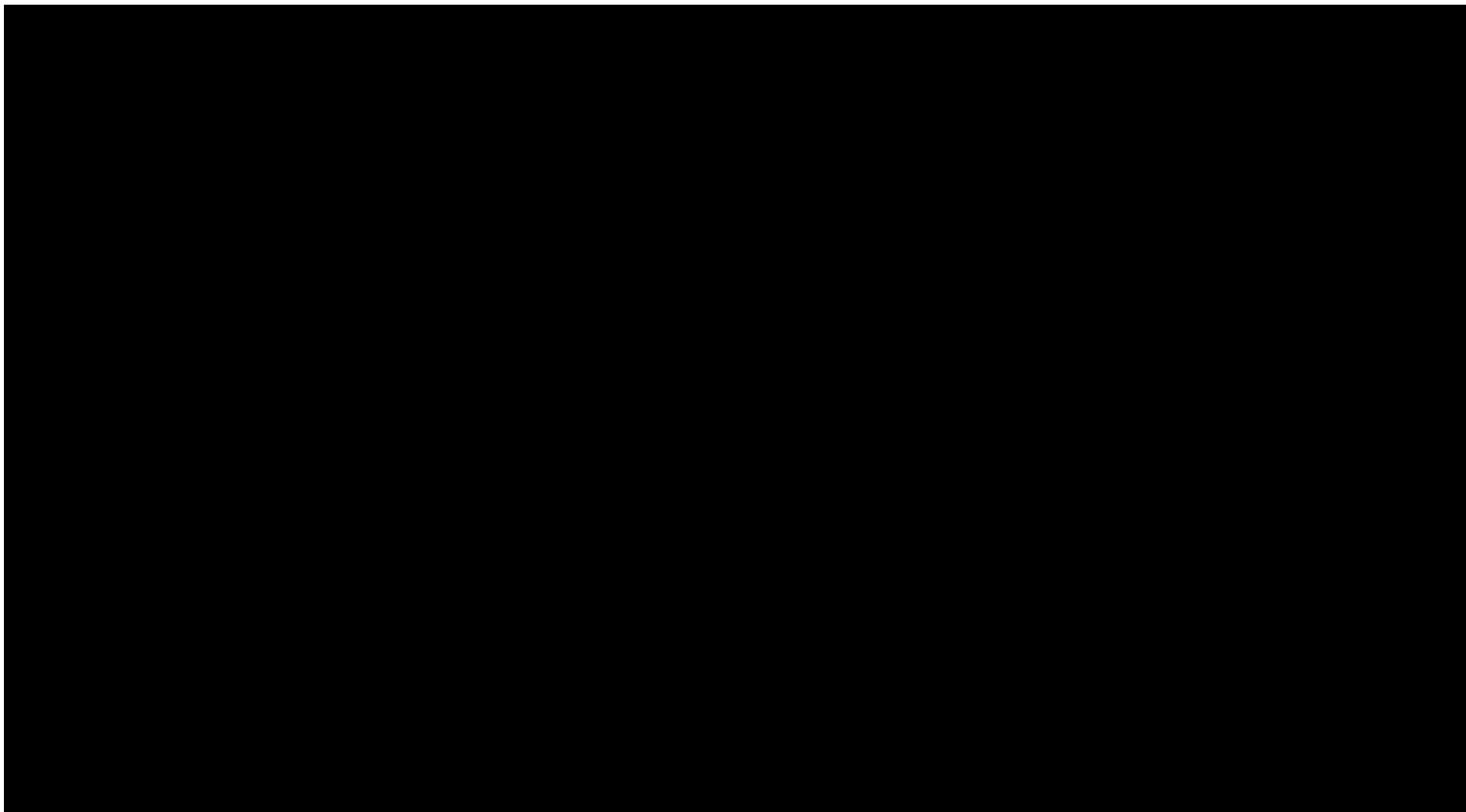
Status:
Page:

Final
Page 1767 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

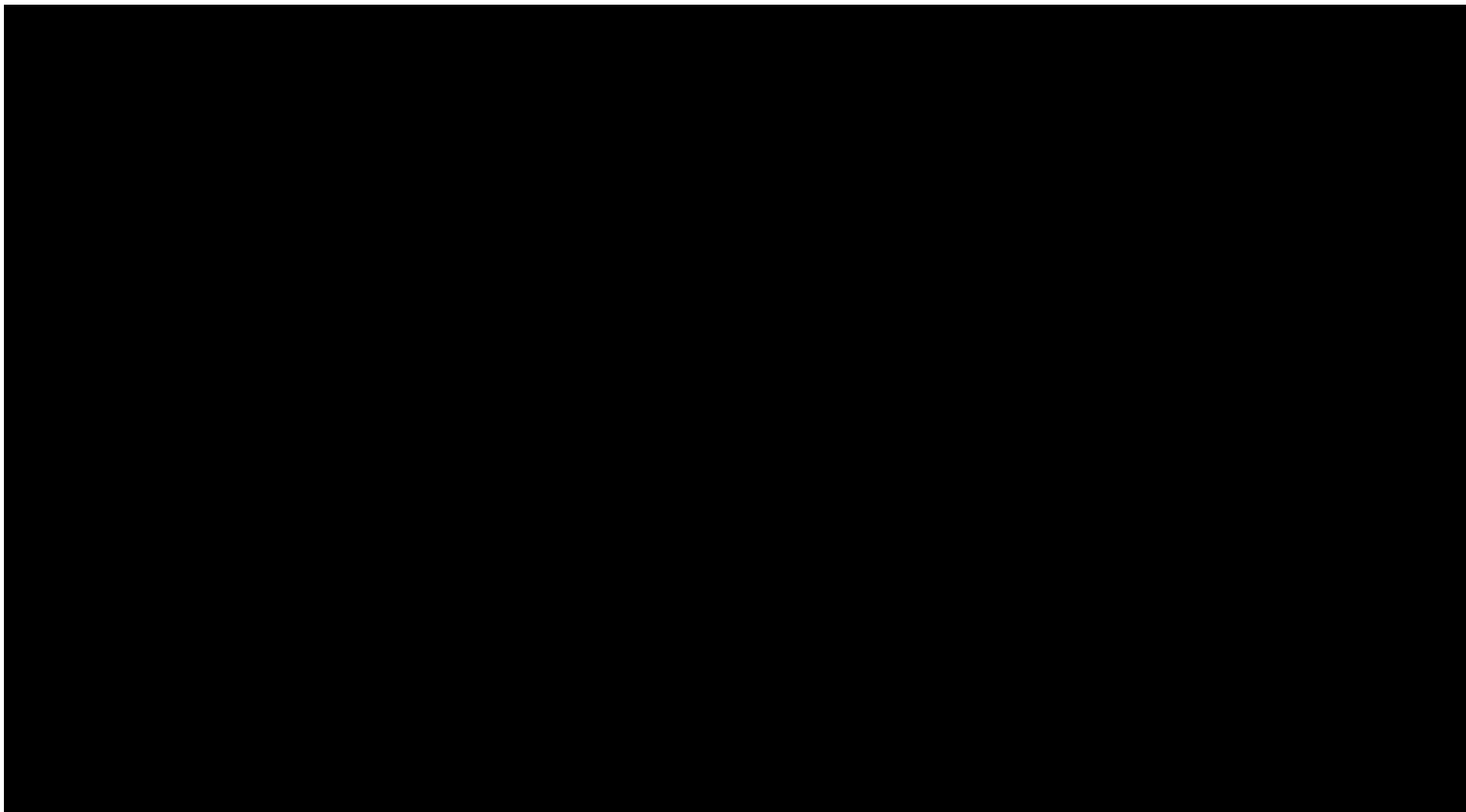
Status:
Page:

Final
Page 1768 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

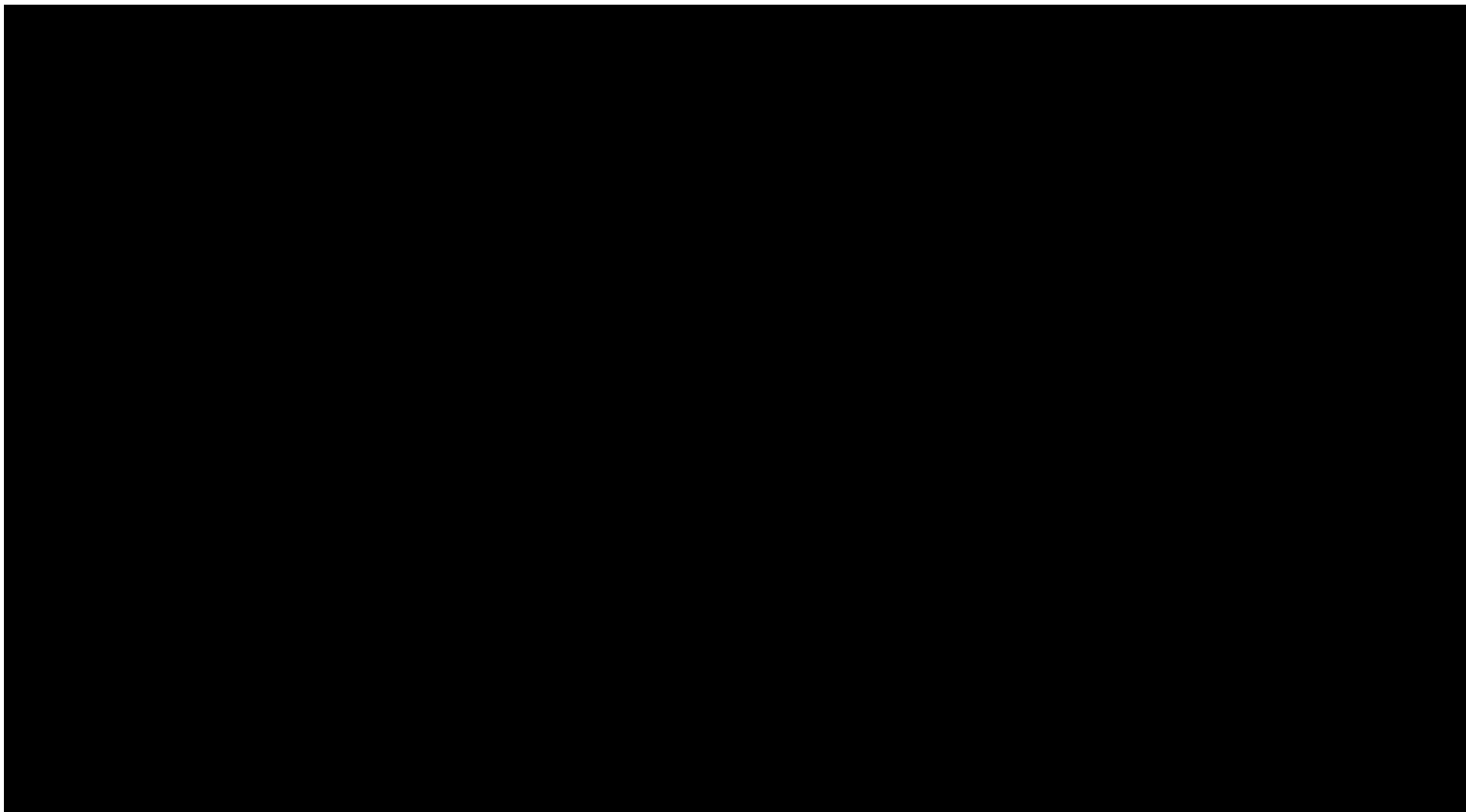
Status:
Page:

Final
Page 1769 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1771 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

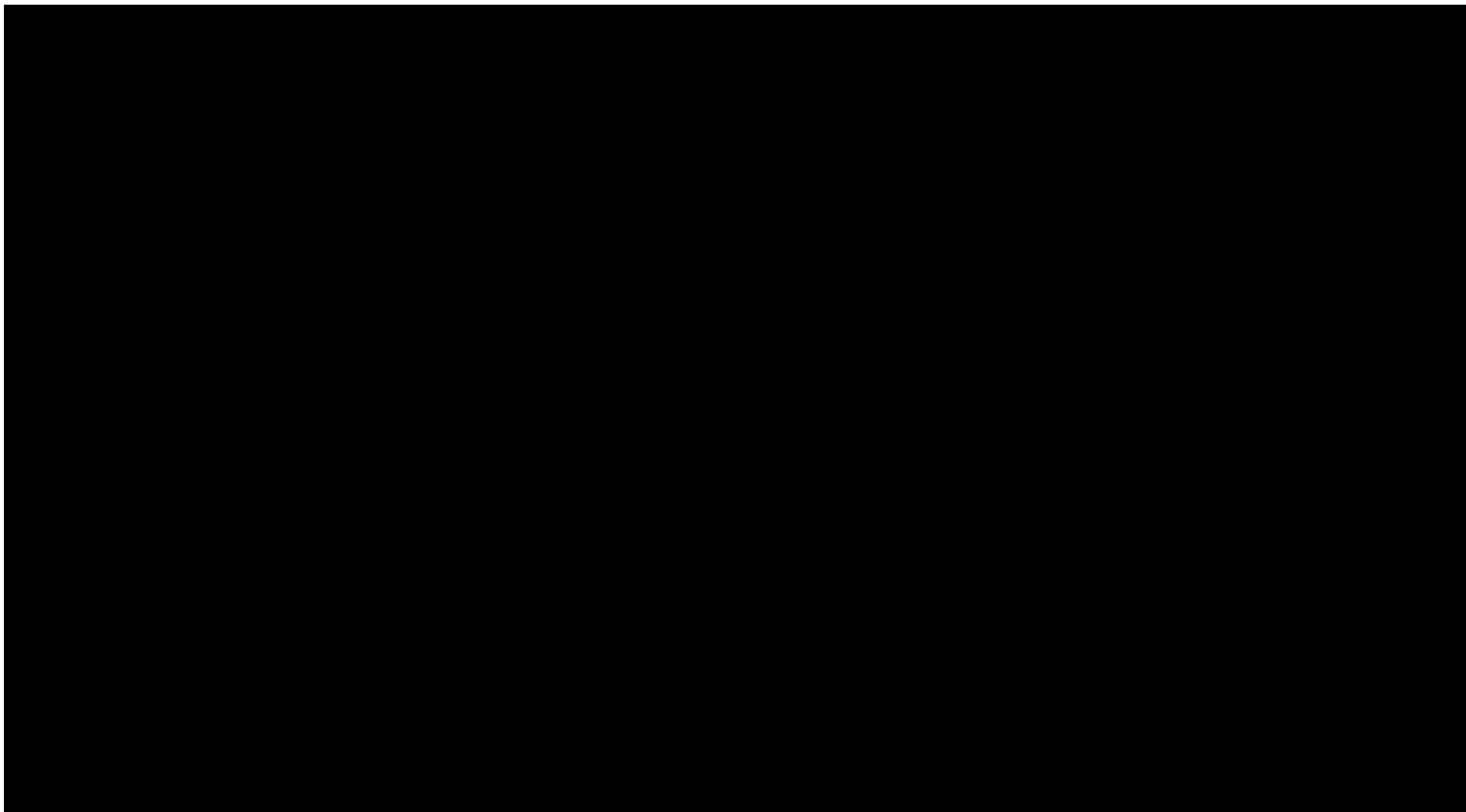
Status:
Page:

Final
Page 1772 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1773 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1774 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

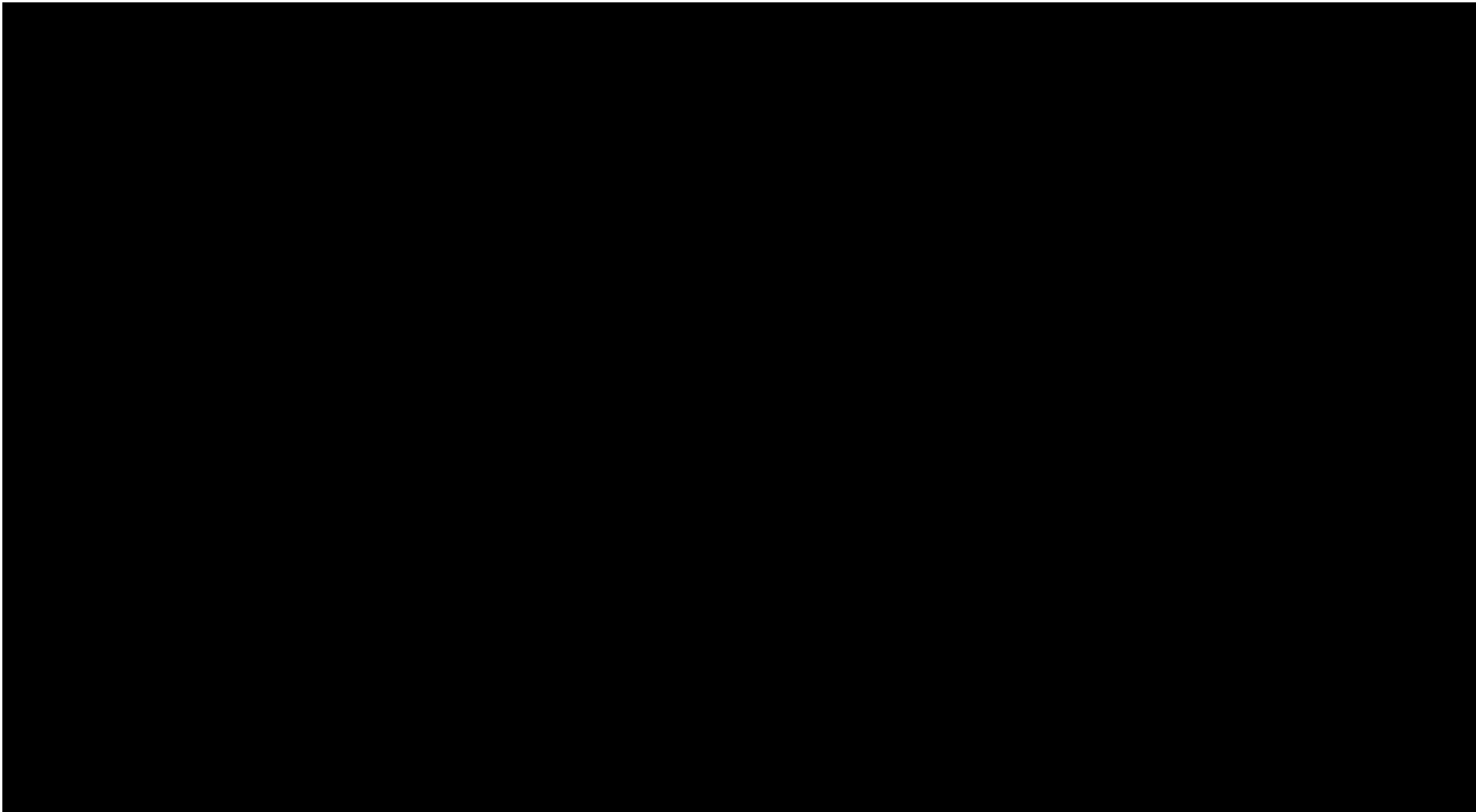
Status:
Page:

Final
Page 1775 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1777 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

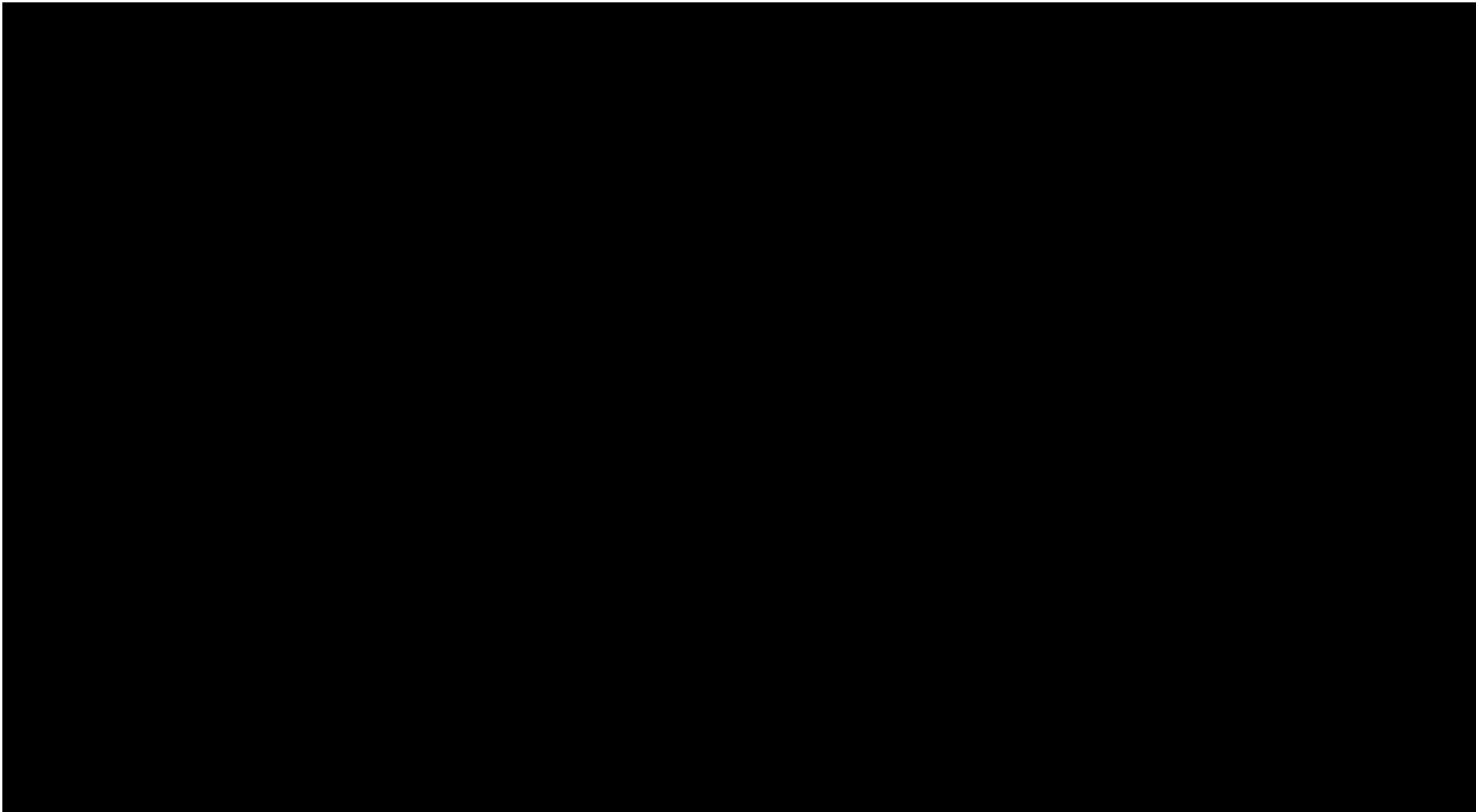
Status:
Page:

Final
Page 1778 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1780 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1781 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1782 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1783 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1784 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1785 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

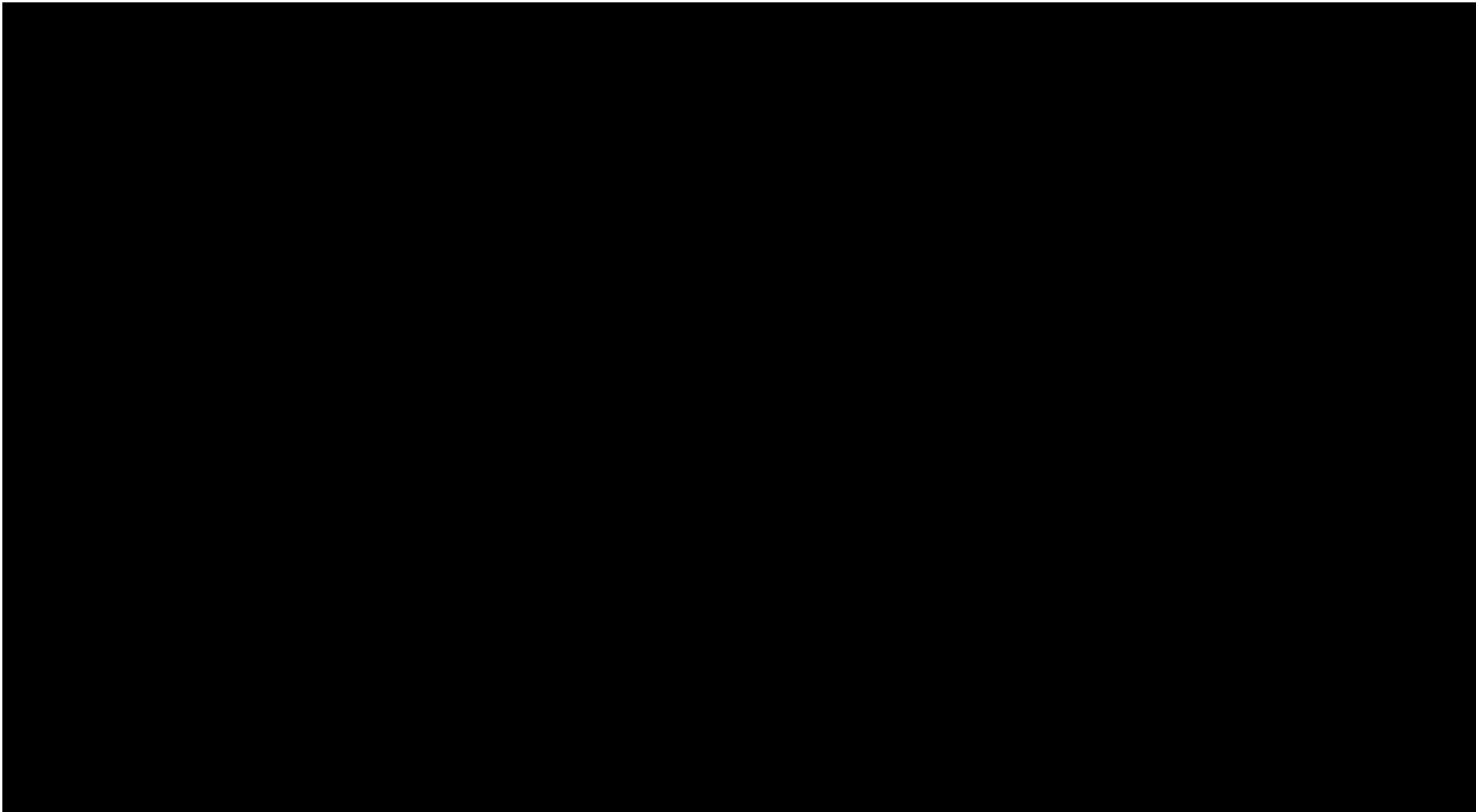
Status:
Page:

Final
Page 1786 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1787 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1788 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

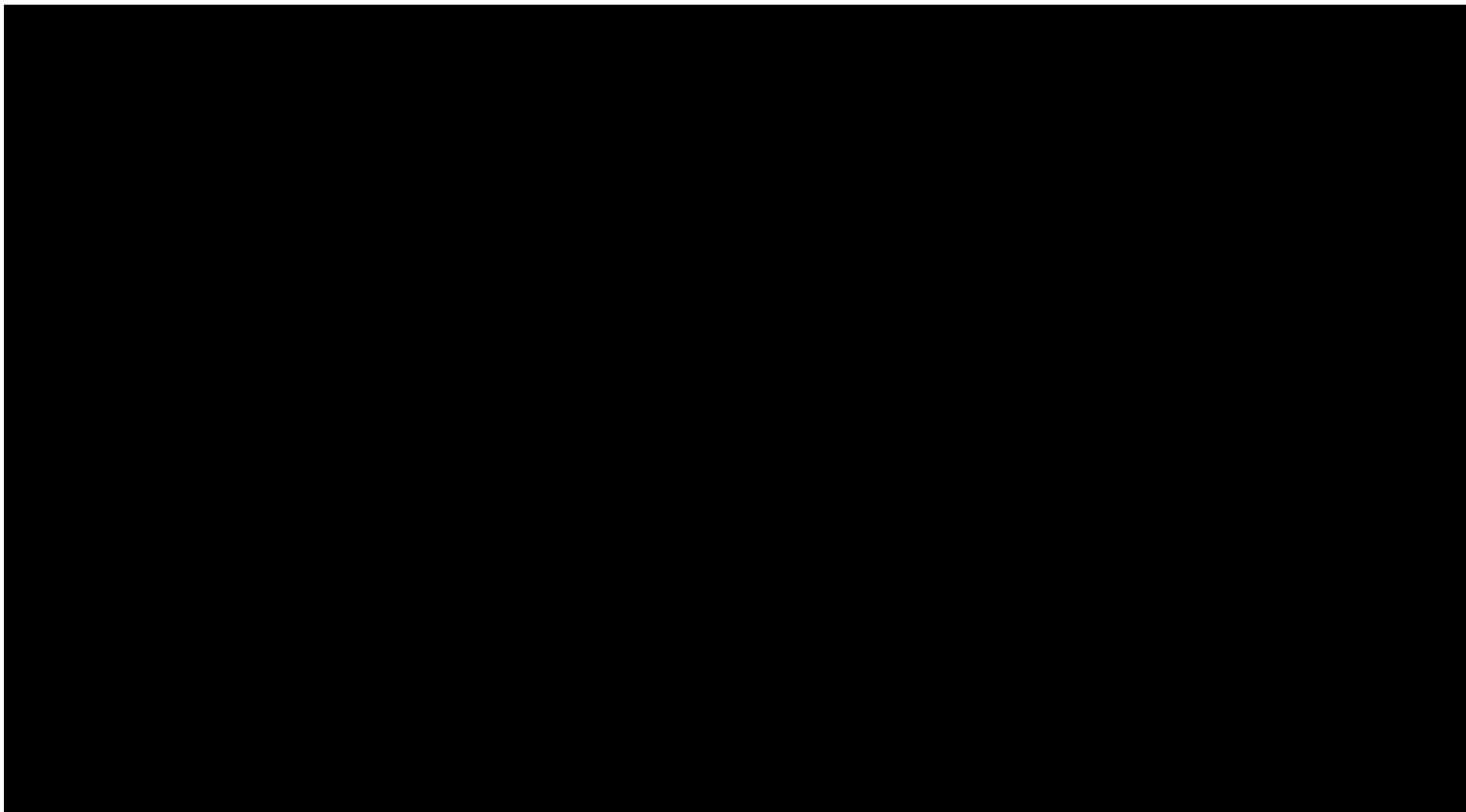
Status:
Page:

Final
Page 1789 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

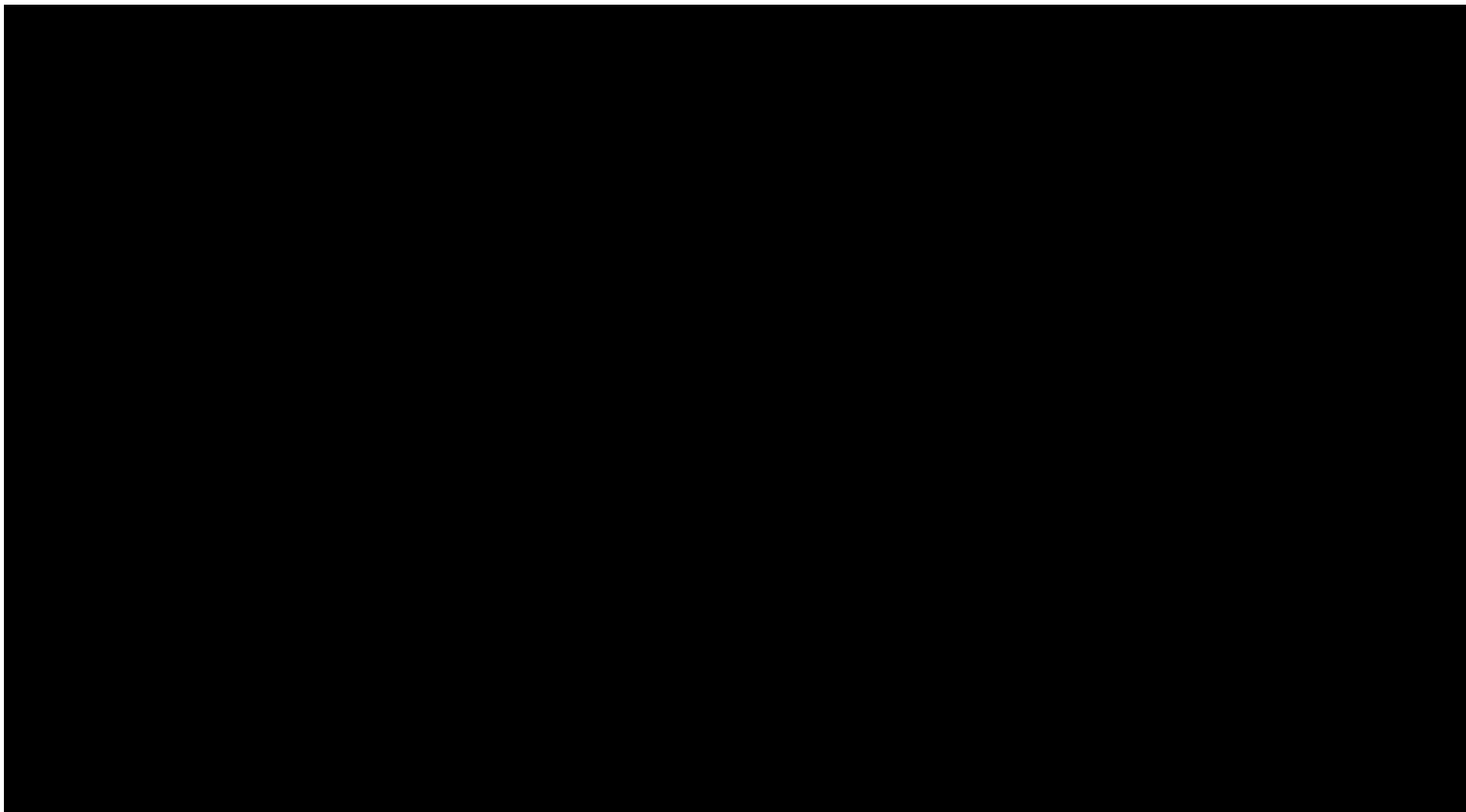
Status:
Page:

Final
Page 1790 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1791 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

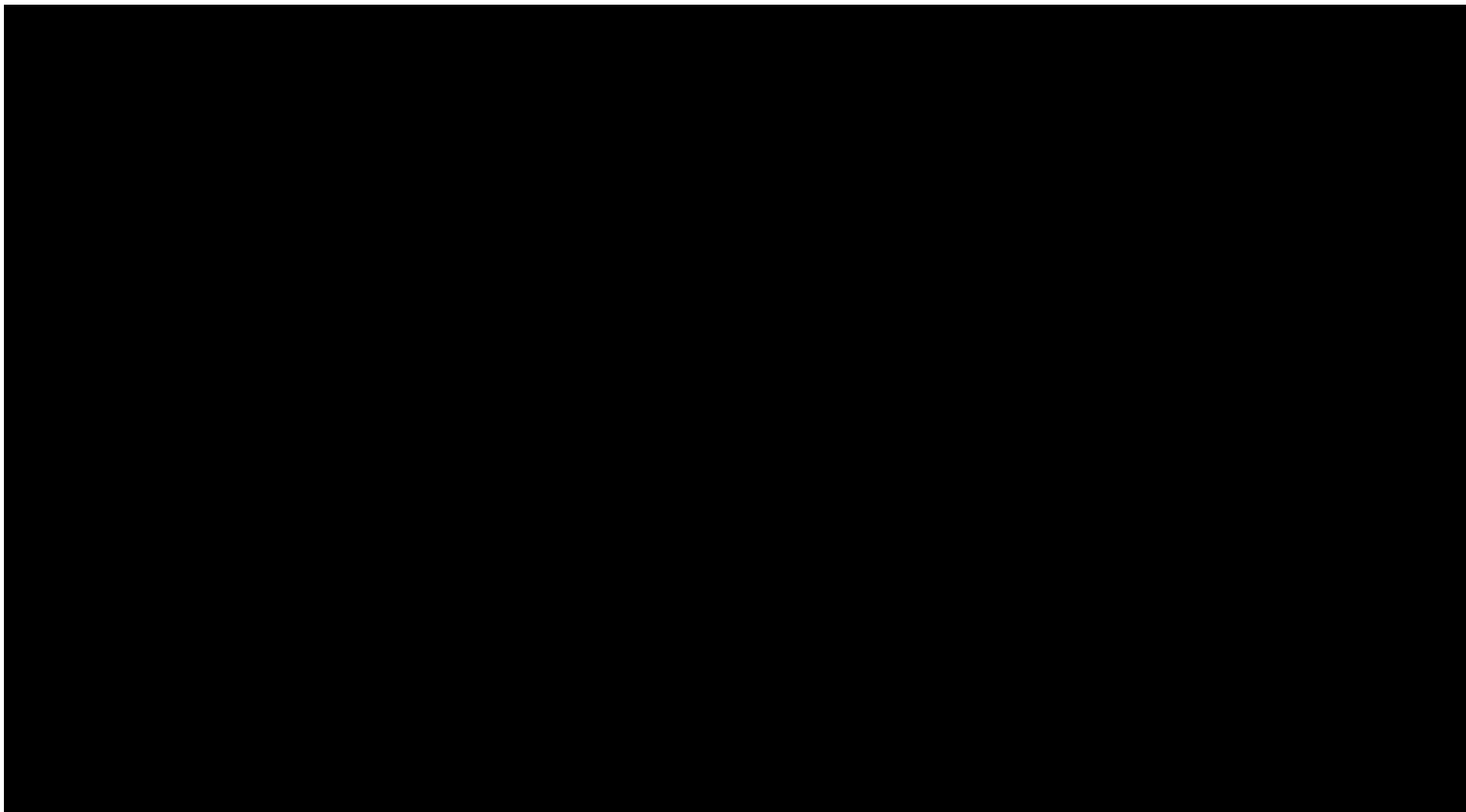
Status:
Page:

Final
Page 1792 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1793 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1795 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

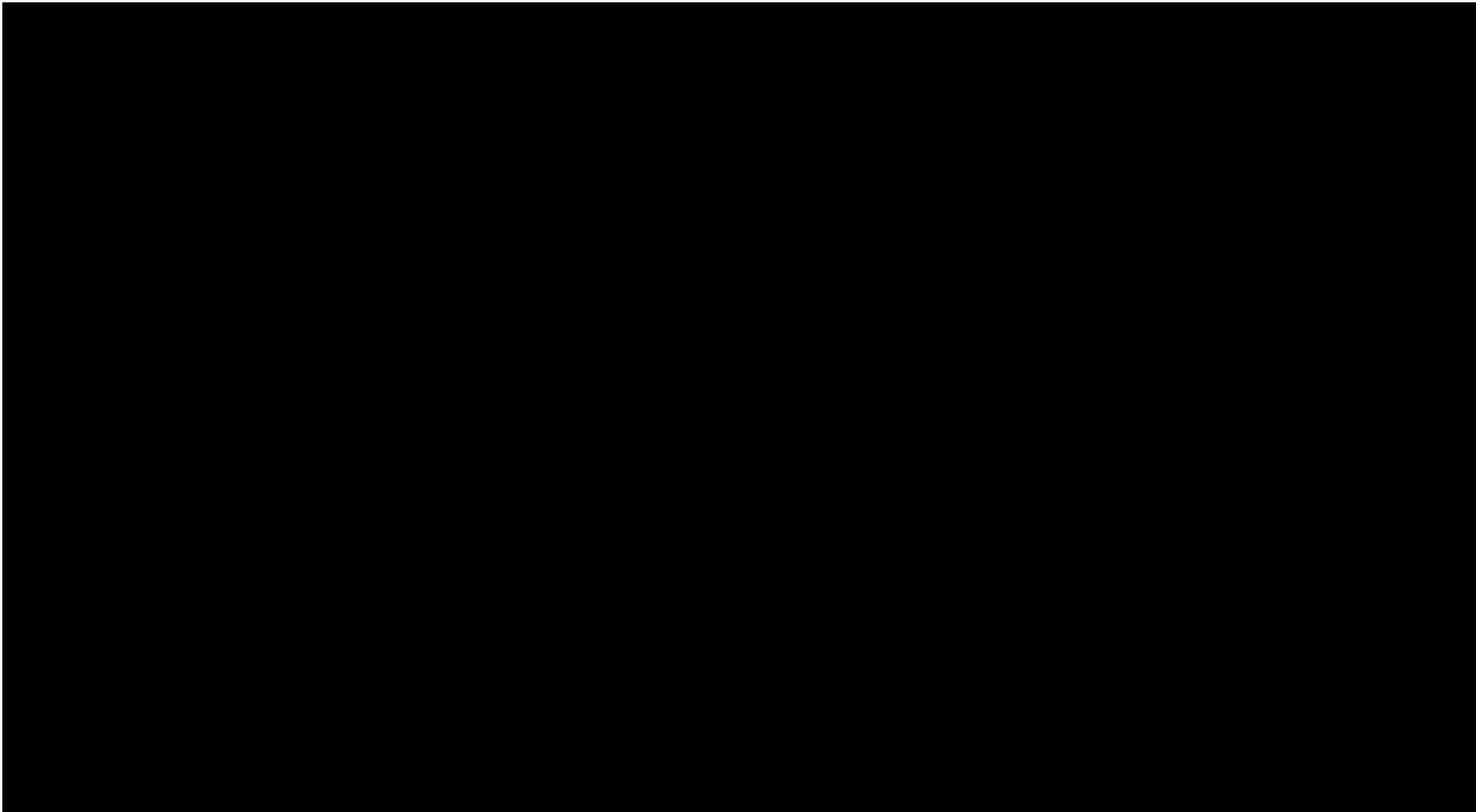
Status:
Page:

Final
Page 1796 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

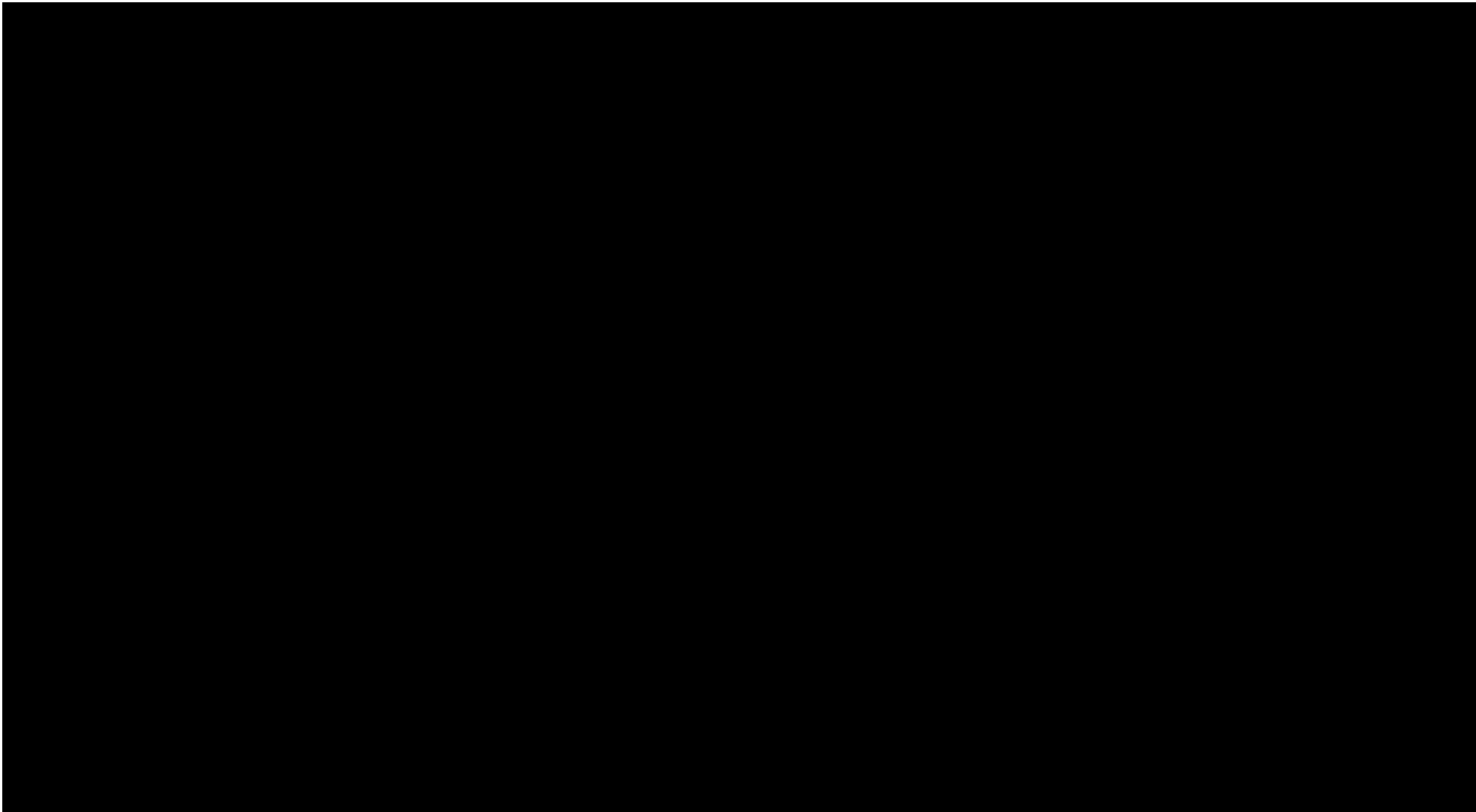
Status:
Page:

Final
Page 1797 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1798 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

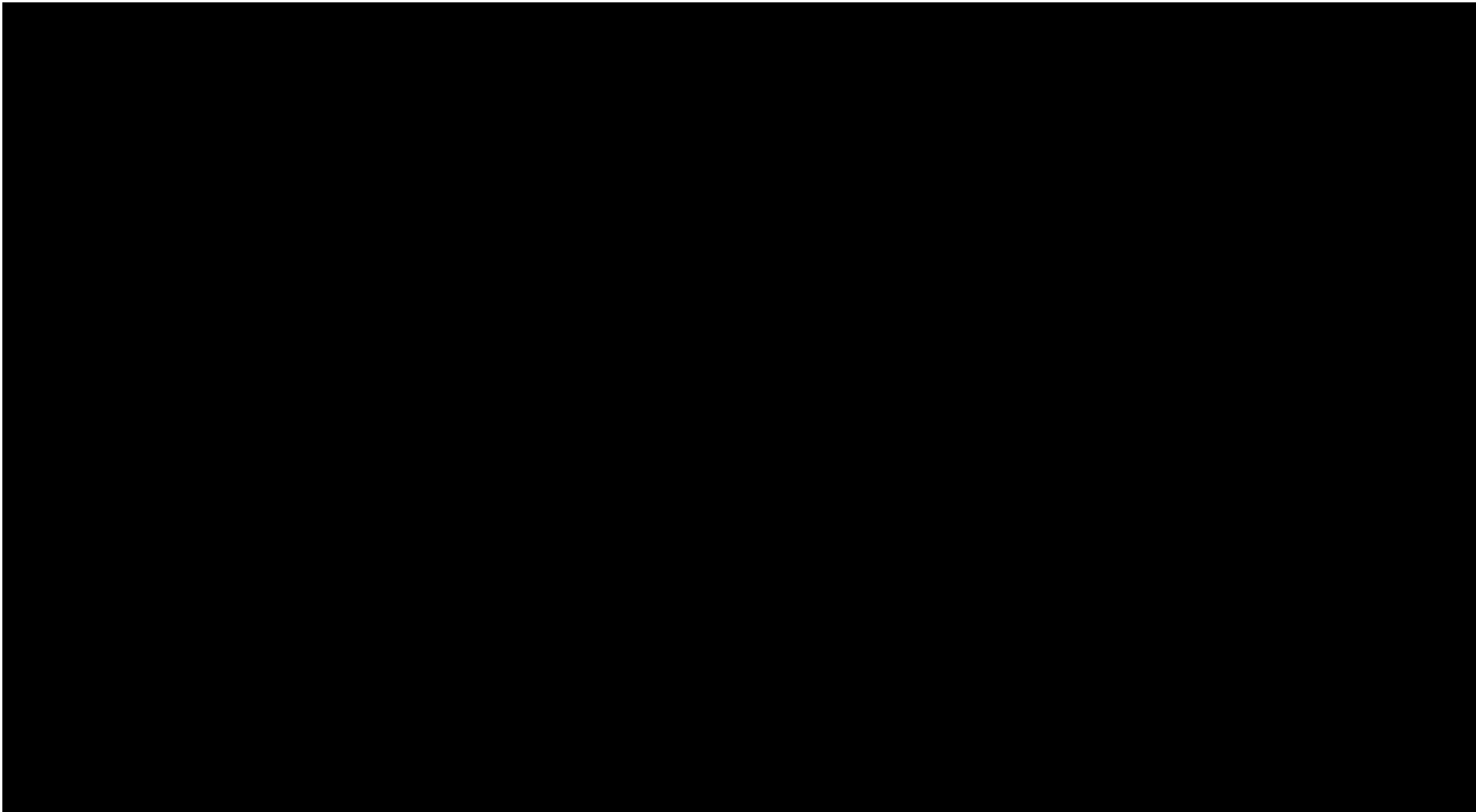
Status:
Page:

Final
Page 1799 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1801 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1802 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

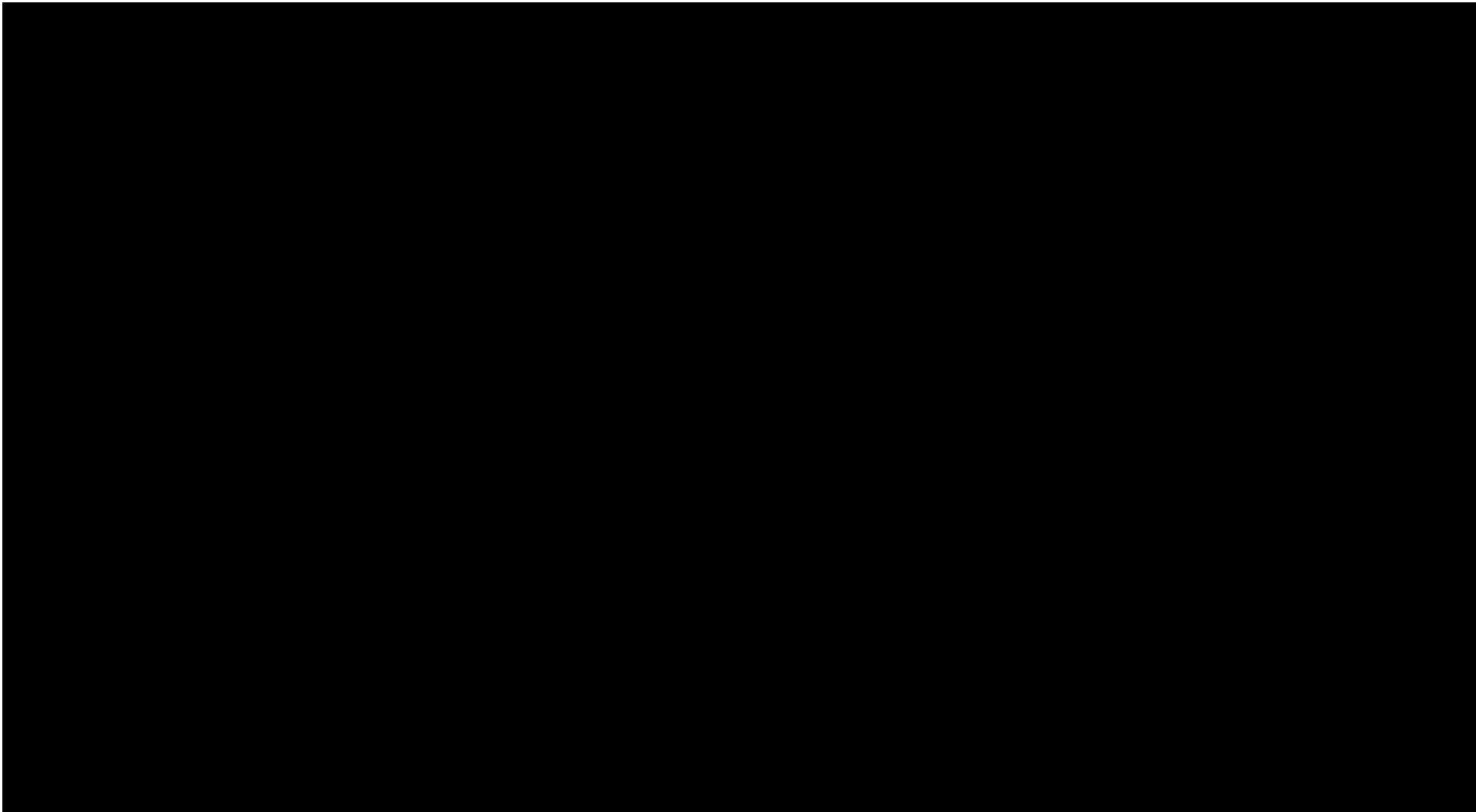
Status:
Page:

Final
Page 1803 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1804 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

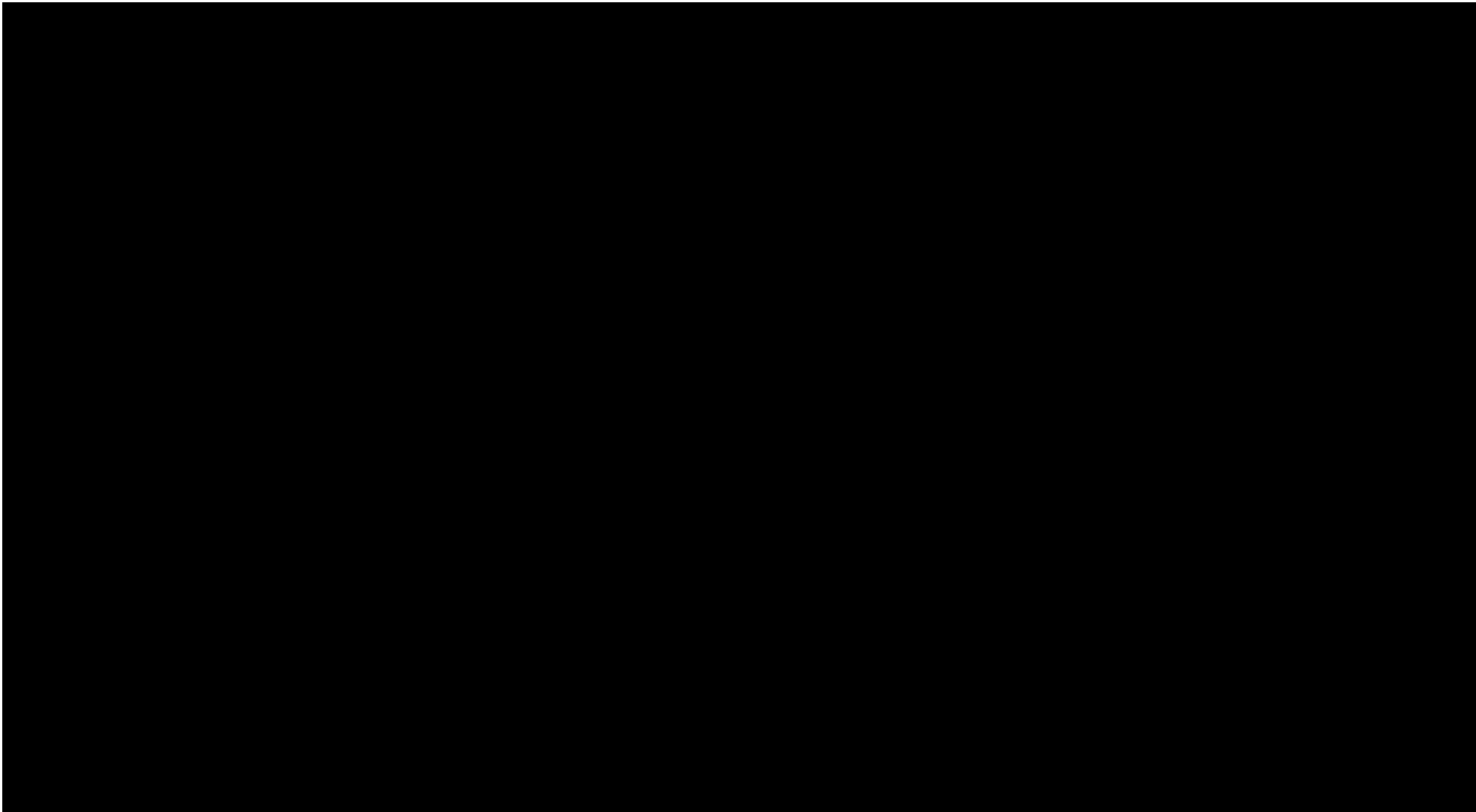
Status:
Page:

Final
Page 1805 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

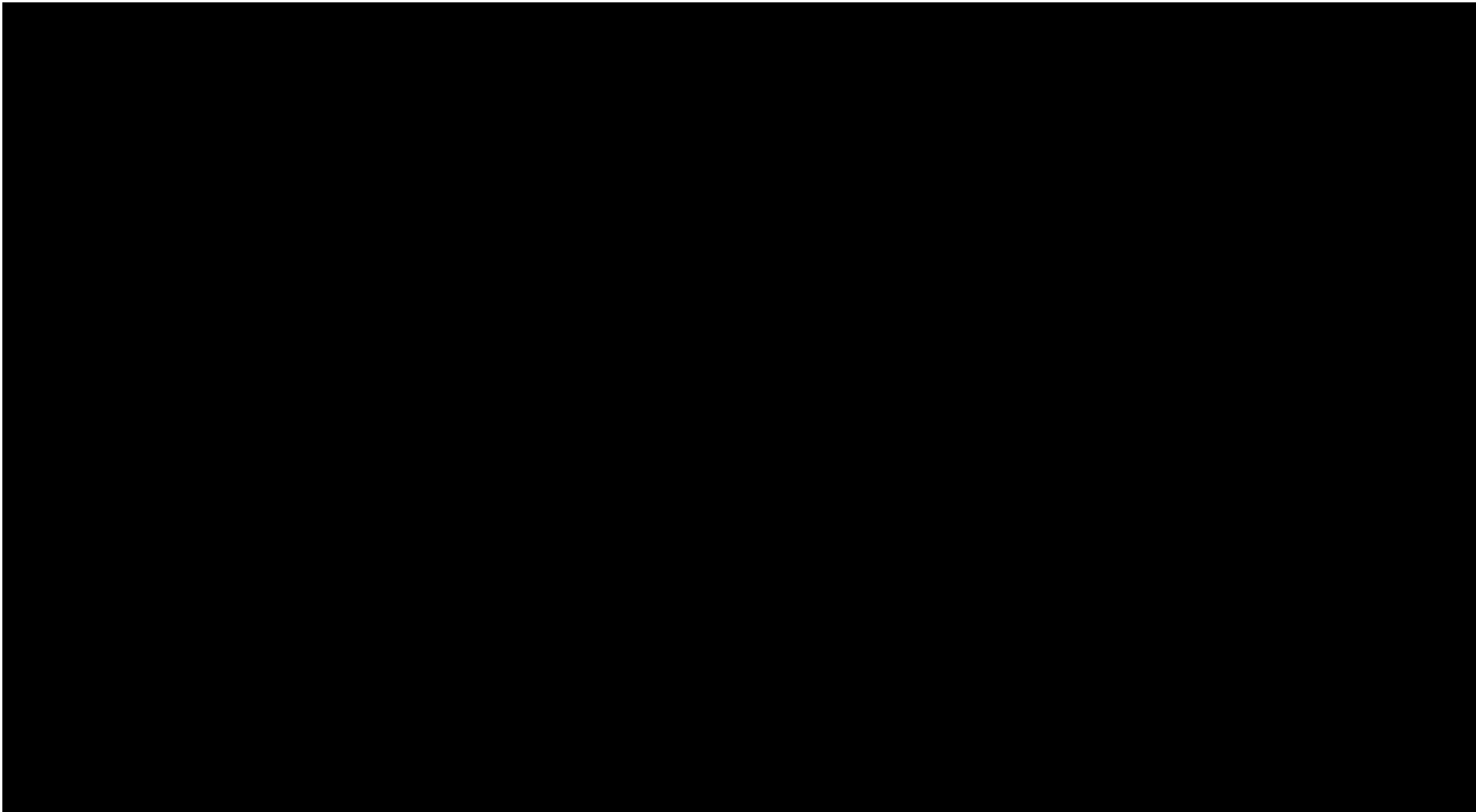
Status:
Page:

Final
Page 1807 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1808 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1809 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

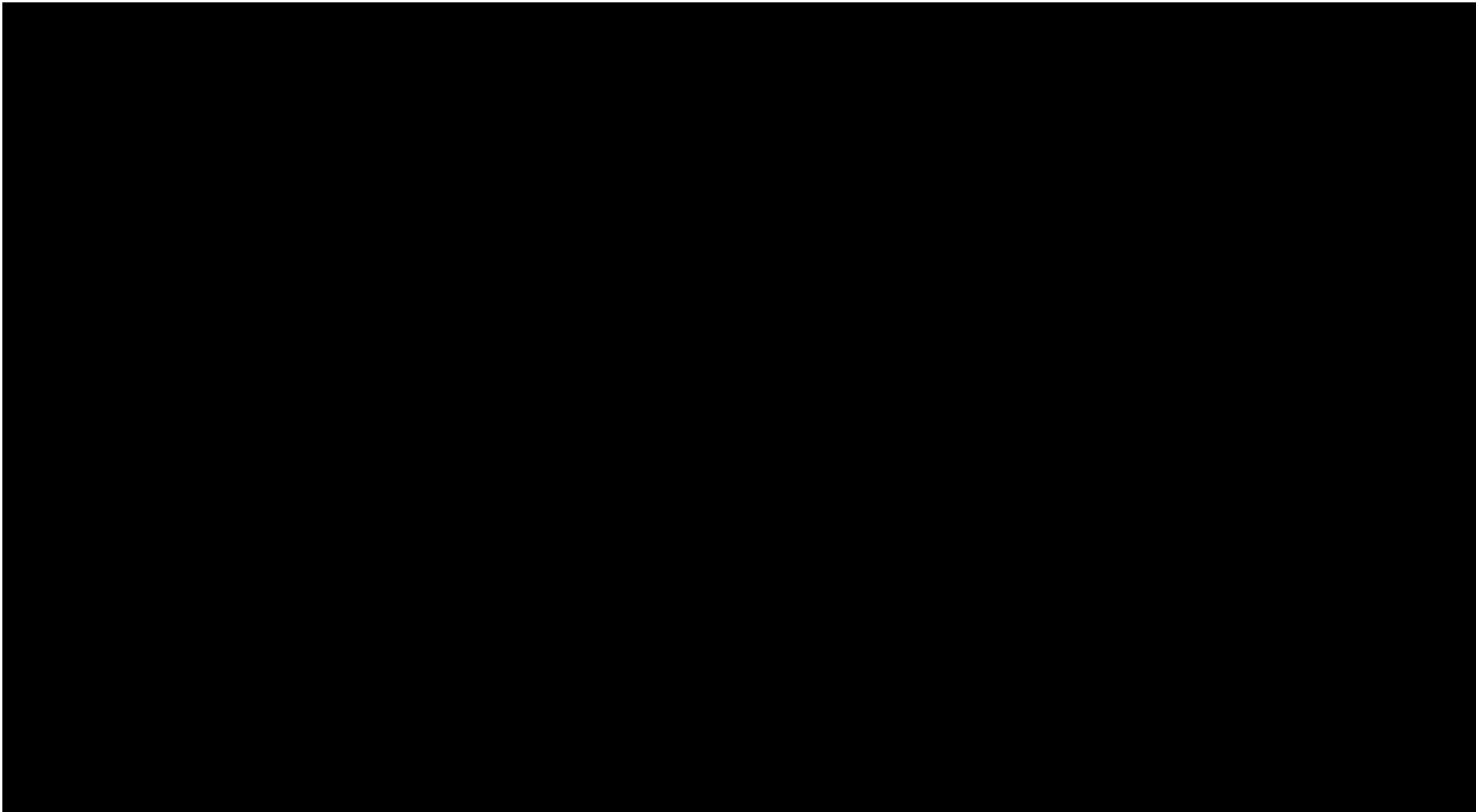
Status:
Page:

Final
Page 1810 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1811 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1812 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1813 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1814 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

The image consists of a single, uniform black rectangle. There are no discernible features, text, or patterns other than the solid color.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

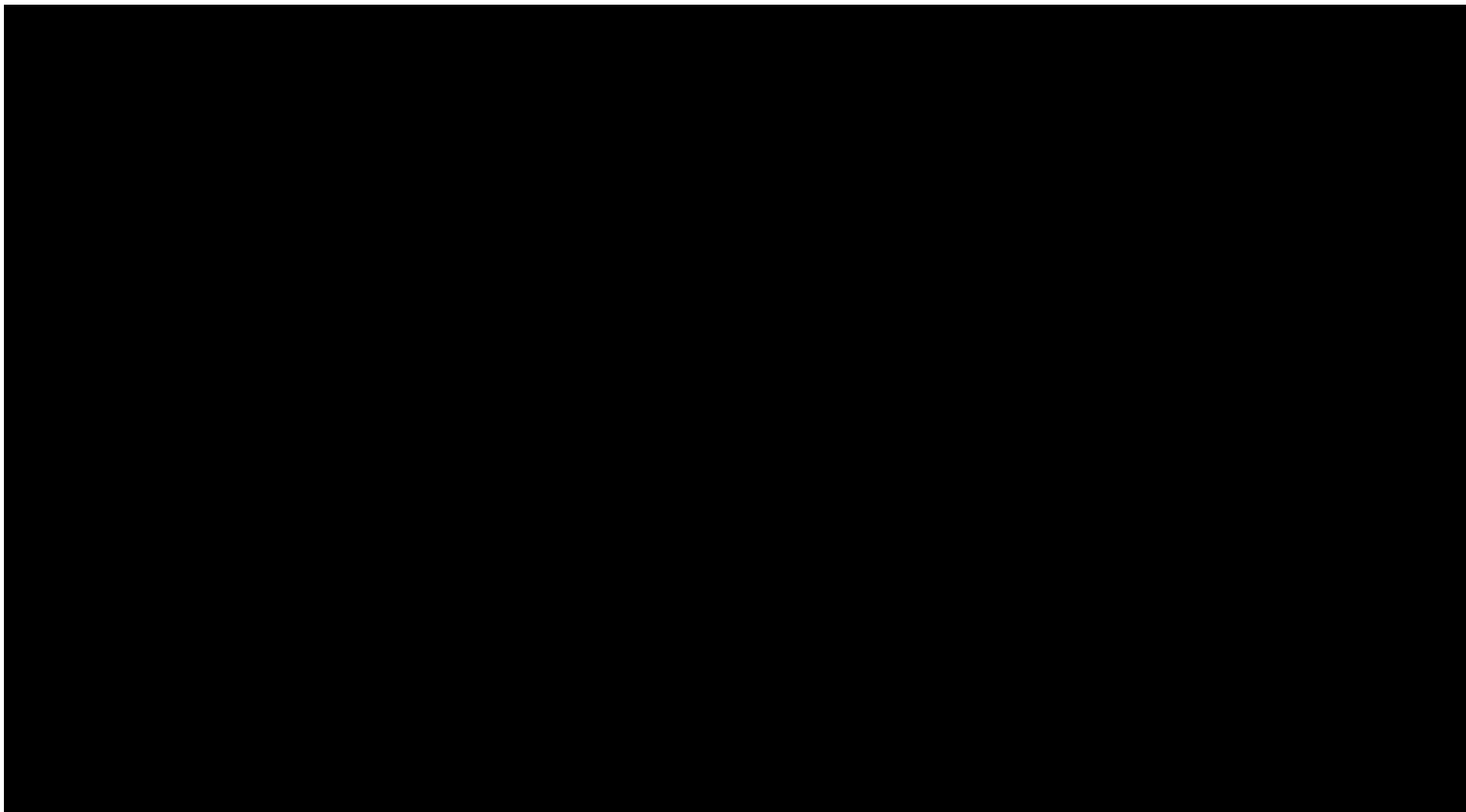
Status:
Page:

Final
Page 1816 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

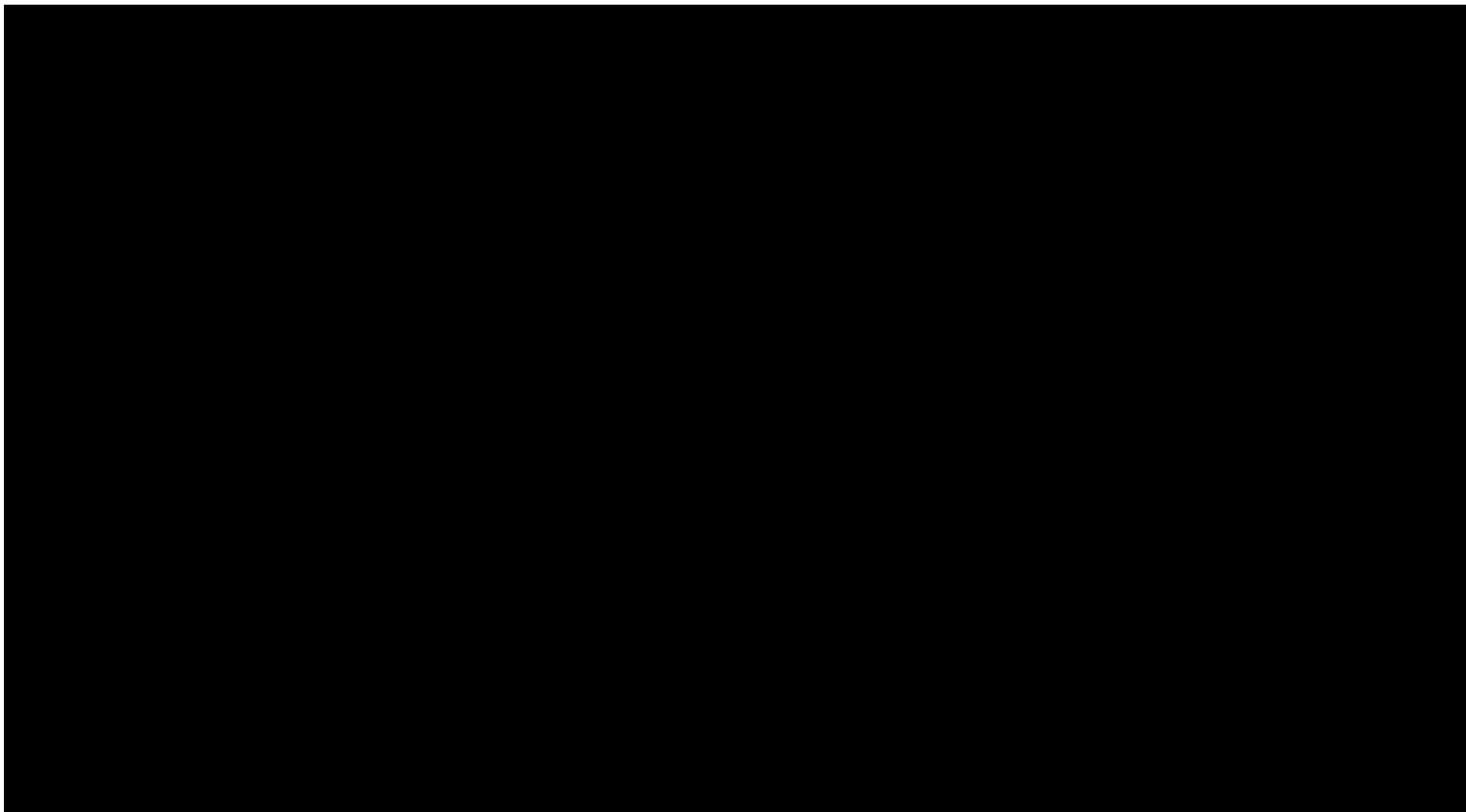
Status:
Page:

Final
Page 1817 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

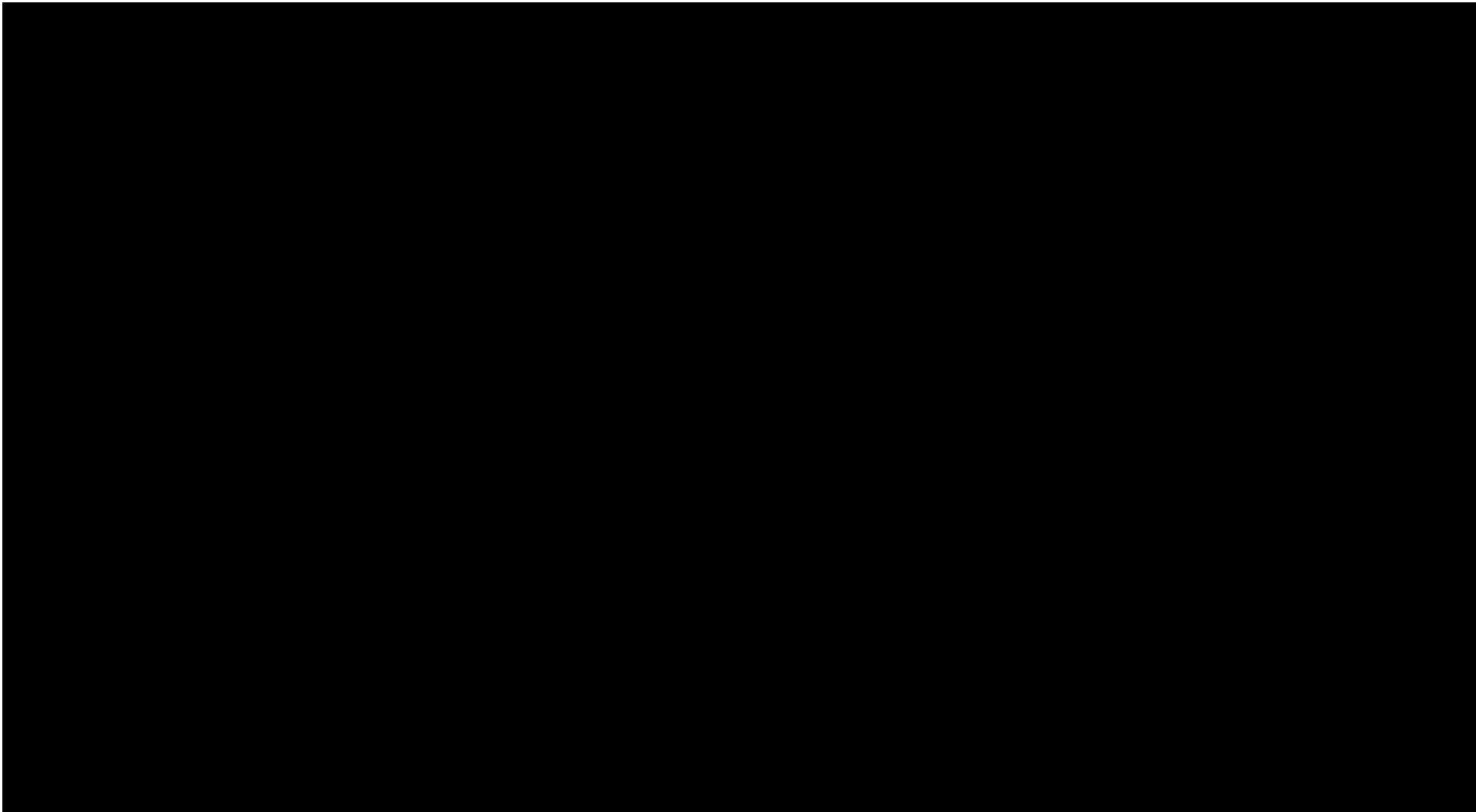
Status:
Page:

Final
Page 1819 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1822 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

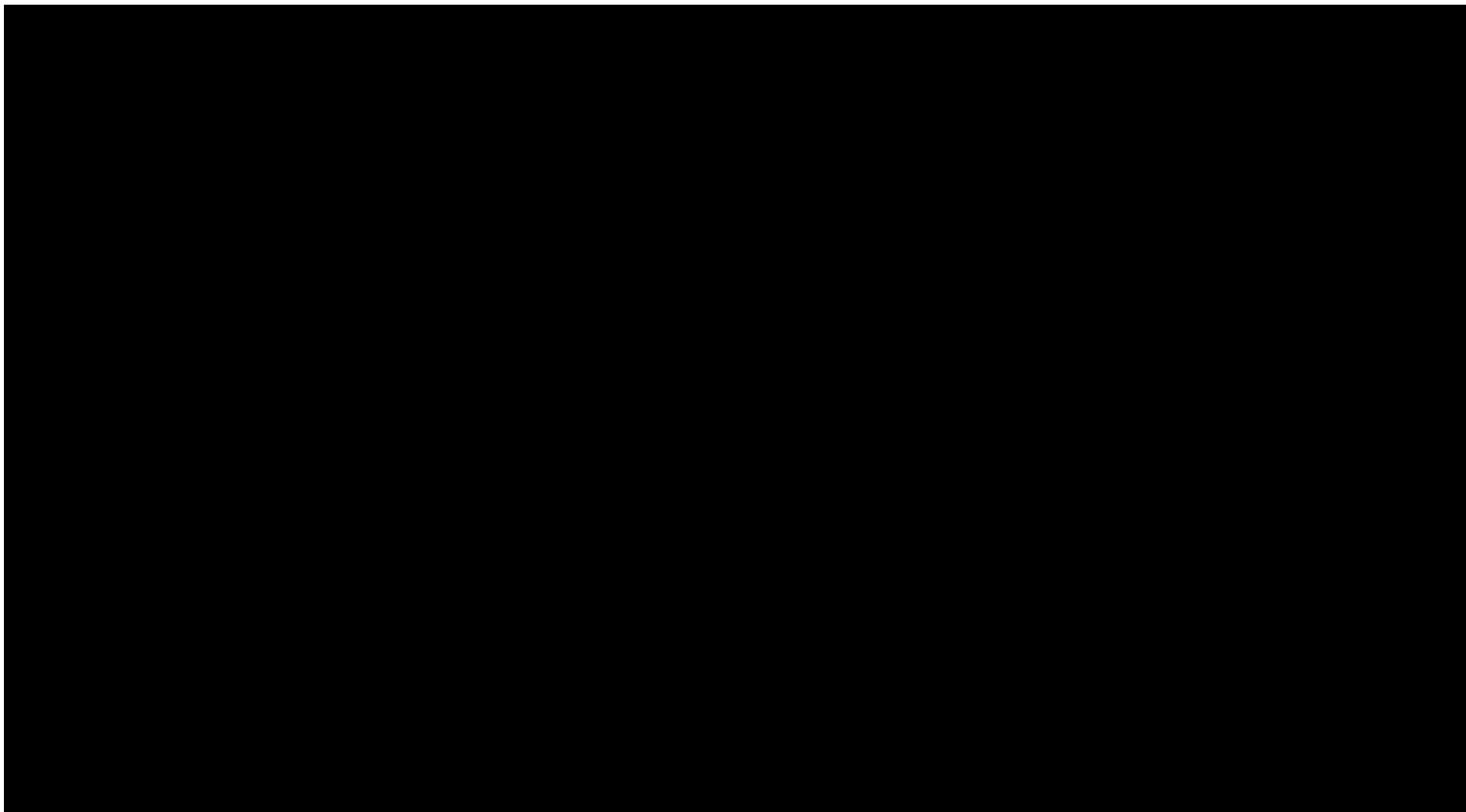
Status:
Page:

Final
Page 1823 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
---------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

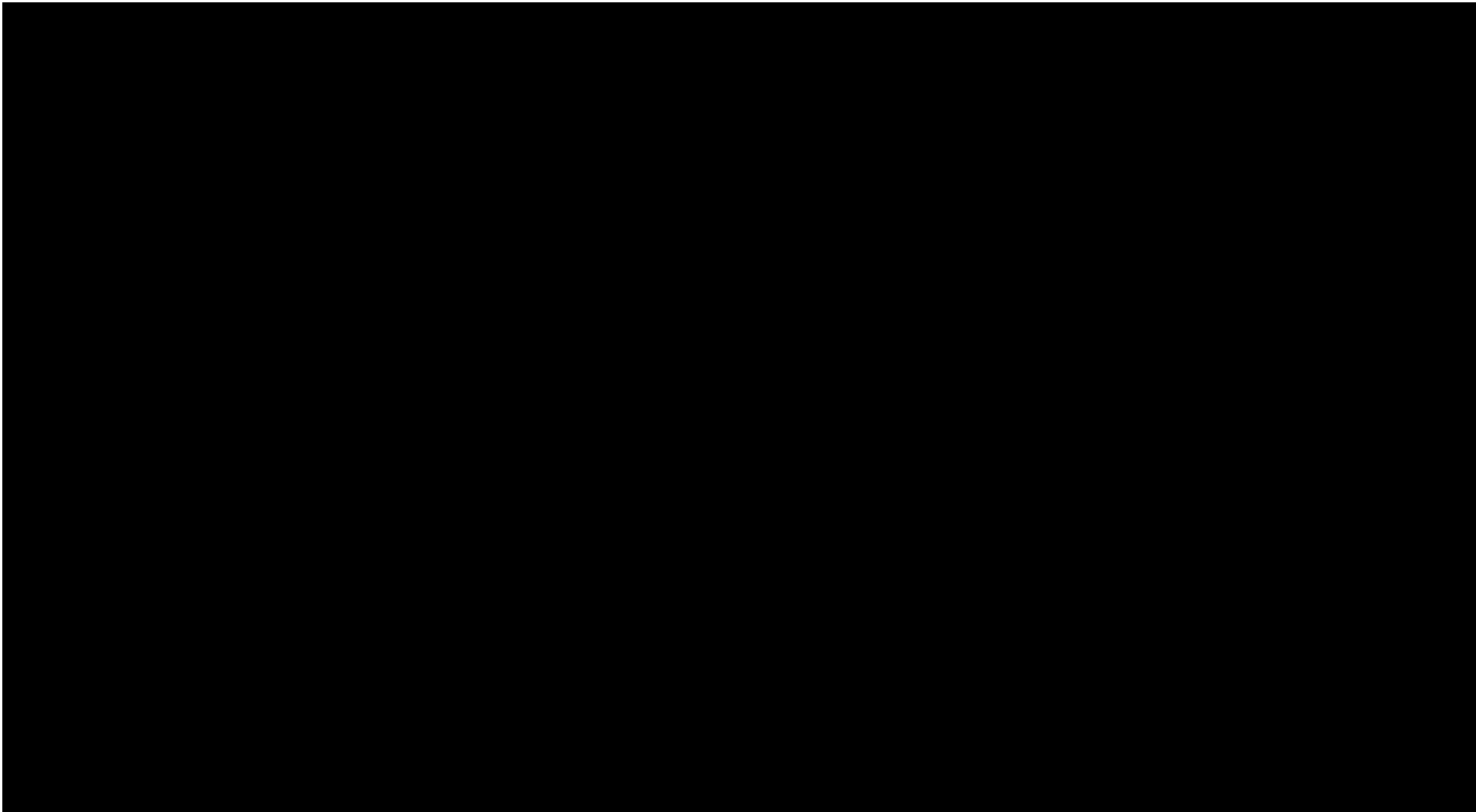
Status:
Page:

Final
Page 1824 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------



NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1825 of 2239

Novo Nordisk

Antibodies - Safety Analysis Set

Subject ID	Treatment	Age	Sex	BMI	Parameter	Visit	Value	Unit
------------	-----------	-----	-----	-----	-----------	-------	-------	------

14.3.7.5: Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Figure 1**

10. **Figure 2**

11. **Figure 3**

12. **Figure 4**

13. **Figure 5**

14. **Figure 6**

15. **Figure 7**

16. **Figure 8**

17. **Figure 9**

18. **Figure 10**

19. **Figure 11**

20. **Figure 12**

21. **Figure 13**

22. **Figure 14**

23. **Figure 15**

24. **Figure 16**

25. **Figure 17**

26. **Figure 18**

27. **Figure 19**

28. **Figure 20**

29. **Figure 21**

30. **Figure 22**

31. **Figure 23**

32. **Figure 24**

33. **Figure 25**

34. **Figure 26**

35. **Figure 27**

36. **Figure 28**

37. **Figure 29**

38. **Figure 30**

39. **Figure 31**

40. **Figure 32**

41. **Figure 33**

42. **Figure 34**

43. **Figure 35**

44. **Figure 36**

45. **Figure 37**

46. **Figure 38**

47. **Figure 39**

48. **Figure 40**

49. **Figure 41**

50. **Figure 42**

51. **Figure 43**

52. **Figure 44**

53. **Figure 45**

54. **Figure 46**

55. **Figure 47**

56. **Figure 48**

57. **Figure 49**

58. **Figure 50**

59. **Figure 51**

60. **Figure 52**

61. **Figure 53**

62. **Figure 54**

63. **Figure 55**

64. **Figure 56**

65. **Figure 57**

66. **Figure 58**

67. **Figure 59**

68. **Figure 60**

69. **Figure 61**

70. **Figure 62**

71. **Figure 63**

72. **Figure 64**

73. **Figure 65**

74. **Figure 66**

75. **Figure 67**

76. **Figure 68**

77. **Figure 69**

78. **Figure 70**

79. **Figure 71**

80. **Figure 72**

81. **Figure 73**

82. **Figure 74**

83. **Figure 75**

84. **Figure 76**

85. **Figure 77**

86. **Figure 78**

87. **Figure 79**

88. **Figure 80**

89. **Figure 81**

90. **Figure 82**

91. **Figure 83**

92. **Figure 84**

93. **Figure 85**

94. **Figure 86**

95. **Figure 87**

96. **Figure 88**

97. **Figure 89**

98. **Figure 90**

99. **Figure 91**

100. **Figure 92**

101. **Figure 93**

102. **Figure 94**

103. **Figure 95**

104. **Figure 96**

105. **Figure 97**

106. **Figure 98**

107. **Figure 99**

108. **Figure 100**

109. **Figure 101**

110. **Figure 102**

111. **Figure 103**

112. **Figure 104**

113. **Figure 105**

114. **Figure 106**

115. **Figure 107**

116. **Figure 108**

117. **Figure 109**

118. **Figure 110**

119. **Figure 111**

120. **Figure 112**

121. **Figure 113**

122. **Figure 114**

123. **Figure 115**

124. **Figure 116**

125. **Figure 117**

126. **Figure 118**

127. **Figure 119**

128. **Figure 120**

129. **Figure 121**

130. **Figure 122**

131. **Figure 123**

132. **Figure 124**

133. **Figure 125**

134. **Figure 126**

135. **Figure 127**

136. **Figure 128**

137. **Figure 129**

138. **Figure 130**

139. **Figure 131**

140. **Figure 132**

141. **Figure 133**

142. **Figure 134**

143. **Figure 135**

144. **Figure 136**

145. **Figure 137**

146. **Figure 138**

147. **Figure 139**

148. **Figure 140**

149. **Figure 141**

150. **Figure 142**

151. **Figure 143**

152. **Figure 144**

153. **Figure 145**

154. **Figure 146**

155. **Figure 147**

156. **Figure 148**

157. **Figure 149**

158. **Figure 150**

159. **Figure 151**

160. **Figure 152**

161. **Figure 153**

162. **Figure 154**

163. **Figure 155**

164. **Figure 156**

165. **Figure 157**

166. **Figure 158**

167. **Figure 159**

168. **Figure 160**

169. **Figure 161**

170. **Figure 162**

171. **Figure 163**

172. **Figure 164**

173. **Figure 165**

174. **Figure 166**

175. **Figure 167**

176. **Figure 168**

177. **Figure 169**

178. **Figure 170**

179. **Figure 171**

180. **Figure 172**

181. **Figure 173**

182. **Figure 174**

183. **Figure 175**

184. **Figure 176**

185. **Figure 177**

186. **Figure 178**

187. **Figure 179**

188. **Figure 180**

189. **Figure 181**

190. **Figure 182**

191. **Figure 183**

192. **Figure 184**

193. **Figure 185**

194. **Figure 186**

195. **Figure 187**

196. **Figure 188**

197. **Figure 189**

198. **Figure 190**

199. **Figure 191**

200. **Figure 192**

201. **Figure 193**

202. **Figure 194**

203. **Figure 195**

204. **Figure 196**

205. **Figure 197**

206. **Figure 198**

207. **Figure 199**

208. **Figure 200**

209. **Figure 201**

210. **Figure 202**

211. **Figure 203**

212. **Figure 204**

213. **Figure 205**

214. **Figure 206**

215. **Figure 207**

216. **Figure 208**

217. **Figure 209**

218. **Figure 210**

219. **Figure 211**

220. **Figure 212**

221. **Figure 213**

222. **Figure 214**

223. **Figure 215**

224. **Figure 216**

225. **Figure 217**

226. **Figure 218**

227. **Figure 219**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

[illegible]

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1837 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Novo Nordisk

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Subject Headings**

16. **MeSH Terms**

17. **Indexing**

18. **Classification**

19. **Numbering**

20. **Ordering**

21. **Grouping**

22. **Labeling**

23. **Marking**

24. **Notation**

25. **Symbolism**

26. **Diagramming**

27. **Flowcharting**

28. **Mapping**

29. **Charting**

30. **Graphing**

31. **Tablemaking**

32. **Formmaking**

33. **Diagrammaking**

34. **Flowchartmaking**

35. **Mappingmaking**

36. **Chartmaking**

37. **Graphmaking**

38. **Tablemaking**

39. **Formmaking**

40. **Diagrammaking**

41. **Flowchartmaking**

42. **Mappingmaking**

43. **Chartmaking**

44. **Graphmaking**

45. **Tablemaking**

46. **Formmaking**

47. **Diagrammaking**

48. **Flowchartmaking**

49. **Mappingmaking**

50. **Chartmaking**

51. **Graphmaking**

52. **Tablemaking**

53. **Formmaking**

54. **Diagrammaking**

55. **Flowchartmaking**

56. **Mappingmaking**

57. **Chartmaking**

58. **Graphmaking**

59. **Tablemaking**

60. **Formmaking**

61. **Diagrammaking**

62. **Flowchartmaking**

63. **Mappingmaking**

64. **Chartmaking**

65. **Graphmaking**

66. **Tablemaking**

67. **Formmaking**

68. **Diagrammaking**

69. **Flowchartmaking**

70. **Mappingmaking**

71. **Chartmaking**

72. **Graphmaking**

73. **Tablemaking**

74. **Formmaking**

75. **Diagrammaking**

76. **Flowchartmaking**

77. **Mappingmaking**

78. **Chartmaking**

79. **Graphmaking**

80. **Tablemaking**

81. **Formmaking**

82. **Diagrammaking**

83. **Flowchartmaking**

84. **Mappingmaking**

85. **Chartmaking**

86. **Graphmaking**

87. **Tablemaking**

88. **Formmaking**

89. **Diagrammaking**

90. **Flowchartmaking**

91. **Mappingmaking**

92. **Chartmaking**

93. **Graphmaking**

94. **Tablemaking**

95. **Formmaking**

96. **Diagrammaking**

97. **Flowchartmaking**

98. **Mappingmaking**

99. **Chartmaking**

100. **Graphmaking**

101. **Tablemaking**

102. **Formmaking**

103. **Diagrammaking**

104. **Flowchartmaking**

105. **Mappingmaking**

106. **Chartmaking**

107. **Graphmaking**

108. **Tablemaking**

109. **Formmaking**

110. **Diagrammaking**

111. **Flowchartmaking**

112. **Mappingmaking**

113. **Chartmaking**

114. **Graphmaking**

115. **Tablemaking**

116. **Formmaking**

117. **Diagrammaking**

118. **Flowchartmaking**

119. **Mappingmaking**

120. **Chartmaking**

121. **Graphmaking**

122. **Tablemaking**

123. **Formmaking**

124. **Diagrammaking**

125. **Flowchartmaking**

126. **Mappingmaking**

127. **Chartmaking**

128. **Graphmaking**

129. **Tablemaking**

130. **Formmaking**

131. **Diagrammaking**

132. **Flowchartmaking**

133. **Mappingmaking**

134. **Chartmaking**

135. **Graphmaking**

136. **Tablemaking**

137. **Formmaking**

138. **Diagrammaking**

139. **Flowchartmaking**

140. **Mappingmaking**

141. **Chartmaking**

142. **Graphmaking**

143. **Tablemaking**

144. **Formmaking**

145. **Diagrammaking**

146. **Flowchartmaking**

147. **Mappingmaking**

148. **Chartmaking**

149. **Graphmaking**

150. **Tablemaking**

151. **Formmaking**

152. **Diagrammaking**

153. **Flowchartmaking**

154. **Mappingmaking**

155. **Chartmaking**

156. **Graphmaking**

157. **Tablemaking**

158. **Formmaking**

159. **Diagrammaking**

160. **Flowchartmaking**

161. **Mappingmaking**

162. **Chartmaking**

163. **Graphmaking**

164. **Tablemaking**

165. **Formmaking**

166. **Diagrammaking**

167. **Flowchartmaking**

168. **Mappingmaking**

169. **Chartmaking**

170. **Graphmaking**

171. **Tablemaking**

172. **Formmaking**

173. **Diagrammaking**

174. **Flowchartmaking**

175. **Mappingmaking**

176. **Chartmaking**

177. **Graphmaking**

178. **Tablemaking**

179. **Formmaking**

180. **Diagrammaking**

181. **Flowchartmaking**

182. **Mappingmaking**

183. **Chartmaking**

184. **Graphmaking**

185. **Tablemaking**

186. **Formmaking**

187. **Diagrammaking**

188. **Flowchartmaking**

189. **Mappingmaking**

190. **Chartmaking**

191. **Graphmaking**

192. **Tablemaking**

193. **Formmaking**

194. **Diagrammaking**

195. **Flowchartmaking**

196. **Mappingmaking**

197. **Chartmaking**

198. **Graphmaking**

199. **Tablemaking**

200. **Formmaking**

201. **Diagrammaking**

202. **Flowchartmaking**

203. **Mappingmaking**

204. **Chartmaking**

205. **Graphmaking**

206. **Tablemaking**

207. **Formmaking**

208. **Diagrammaking**

209. **Flowchartmaking**

210. **Mappingmaking**

211. **Chartmaking**

212. **Graphmaking**

213. **Tablemaking**

214. **Formmaking**

215. **Diagrammaking**

216. **Flowchartmaking**

217. **Mappingmaking**

218. **Chartmaking**

219. **Graphmaking**

220. **Tablemaking**

221. **Formmaking**

222. **Diagrammaking**

223. **Flowchartmaking**

224. **Mappingmaking**

225. **Chartmaking**

226. **Graphmaking**

227. **Tablemaking**

228. **Formmaking**

229. **Diagrammaking**

230. **Flowchartmaking**

231. **Mappingmaking**

232. **Chartmaking**

233. **Graphmaking**

234. **Tablemaking**

235. **Formmaking**

236. **Diagrammaking**

237. **Flowchartmaking**

238. **Mappingmaking**

239. **Chartmaking**

240. **Graphmaking**

241. **Tablemaking**

242. **Formmaking**

243. **Diagrammaking**

244. **Flowchartmaking**

245. **Mappingmaking**

246. **Chartmaking**

247. **Graphmaking**

248. **Tablemaking**

249. **Formmaking**

250. **Diagrammaking**

251. **Flowchartmaking**

252. **Mappingmaking**

253. **Chartmaking**

254. **Graphmaking**

255. **Tablemaking**

256. **Formmaking**

257. **Diagrammaking**

258. **Flowchartmaking**

259. **Mappingmaking**

260.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image is entirely black and contains no visible content.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1853 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1856 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid black color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Figure 1 displays a 3x3 grid of scatter plots showing the relationship between the number of children (X-axis) and the number of adults (Y-axis) in a household. The rows represent different countries (USA, Canada, UK) and the columns represent different years (1990, 2000, 2010). Each plot shows a positive correlation between the number of children and the number of adults, with the slope of the relationship increasing over time and varying by country.

The plots are arranged as follows:

- Row 1: USA (1990, 2000, 2010)
- Row 2: Canada (1990, 2000, 2010)
- Row 3: UK (1990, 2000, 2010)

Each plot includes a fitted curve (solid line) and a confidence interval (dashed lines). The X-axis is labeled 'Number of children' and the Y-axis is labeled 'Number of adults'. The plots show that the relationship between the number of children and the number of adults is positive and increasing over time, with the slope of the relationship increasing over time and varying by country.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children in the household (X-axis) and the number of children in the neighborhood (Y-axis). The rows represent different levels of the 'Number of children in the household' variable (1, 2, 3), and the columns represent different levels of the 'Number of children in the neighborhood' variable (1, 2, 3). Each plot shows a positive correlation between the two variables, with the density of points increasing as the number of children in both the household and the neighborhood increases.

Number of children in the household	Number of children in the neighborhood		
1	1	2	3
2	1	2	3
3	1	2	3

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Figure 1 displays a 3x3 grid of scatter plots showing the relationship between the number of children (X-axis) and the number of adults (Y-axis) in a household. The rows represent different countries (USA, Canada, UK) and the columns represent different years (1990, 2000, 2010). Each plot shows a positive correlation between the number of children and the number of adults, with the slope of the relationship increasing over time and varying by country.

The plots are arranged as follows:

- Row 1: USA (1990, 2000, 2010)
- Row 2: Canada (1990, 2000, 2010)
- Row 3: UK (1990, 2000, 2010)

Each plot includes a fitted curve (solid line) and a confidence interval (dashed lines). The X-axis is labeled 'Number of children' and the Y-axis is labeled 'Number of adults'. The plots show that the relationship between the number of children and the number of adults is positive and increasing over time, with the slope of the relationship increasing over time and varying by country.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1865 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Figure 1**

12. **Figure 2**

13. **Figure 3**

14. **Figure 4**

15. **Figure 5**

16. **Figure 6**

17. **Figure 7**

18. **Figure 8**

19. **Figure 9**

20. **Figure 10**

21. **Figure 11**

22. **Figure 12**

23. **Figure 13**

24. **Figure 14**

25. **Figure 15**

26. **Figure 16**

27. **Figure 17**

28. **Figure 18**

29. **Figure 19**

30. **Figure 20**

31. **Figure 21**

32. **Figure 22**

33. **Figure 23**

34. **Figure 24**

35. **Figure 25**

36. **Figure 26**

37. **Figure 27**

38. **Figure 28**

39. **Figure 29**

40. **Figure 30**

41. **Figure 31**

42. **Figure 32**

43. **Figure 33**

44. **Figure 34**

45. **Figure 35**

46. **Figure 36**

47. **Figure 37**

48. **Figure 38**

49. **Figure 39**

50. **Figure 40**

51. **Figure 41**

52. **Figure 42**

53. **Figure 43**

54. **Figure 44**

55. **Figure 45**

56. **Figure 46**

57. **Figure 47**

58. **Figure 48**

59. **Figure 49**

60. **Figure 50**

61. **Figure 51**

62. **Figure 52**

63. **Figure 53**

64. **Figure 54**

65. **Figure 55**

66. **Figure 56**

67. **Figure 57**

68. **Figure 58**

69. **Figure 59**

70. **Figure 60**

71. **Figure 61**

72. **Figure 62**

73. **Figure 63**

74. **Figure 64**

75. **Figure 65**

76. **Figure 66**

77. **Figure 67**

78. **Figure 68**

79. **Figure 69**

80. **Figure 70**

81. **Figure 71**

82. **Figure 72**

83. **Figure 73**

84. **Figure 74**

85. **Figure 75**

86. **Figure 76**

87. **Figure 77**

88. **Figure 78**

89. **Figure 79**

90. **Figure 80**

91. **Figure 81**

92. **Figure 82**

93. **Figure 83**

94. **Figure 84**

95. **Figure 85**

96. **Figure 86**

97. **Figure 87**

98. **Figure 88**

99. **Figure 89**

100. **Figure 90**

101. **Figure 91**

102. **Figure 92**

103. **Figure 93**

104. **Figure 94**

105. **Figure 95**

106. **Figure 96**

107. **Figure 97**

108. **Figure 98**

109. **Figure 99**

110. **Figure 100**

111. **Figure 101**

112. **Figure 102**

113. **Figure 103**

114. **Figure 104**

115. **Figure 105**

116. **Figure 106**

117. **Figure 107**

118. **Figure 108**

119. **Figure 109**

120. **Figure 110**

121. **Figure 111**

122. **Figure 112**

123. **Figure 113**

124. **Figure 114**

125. **Figure 115**

126. **Figure 116**

127. **Figure 117**

128. **Figure 118**

129. **Figure 119**

130. **Figure 120**

131. **Figure 121**

132. **Figure 122**

133. **Figure 123**

134. **Figure 124**

135. **Figure 125**

136. **Figure 126**

137. **Figure 127**

138. **Figure 128**

139. **Figure 129**

140. **Figure 130**

141. **Figure 131**

142. **Figure 132**

143. **Figure 133**

144. **Figure 134**

145. **Figure 135**

146. **Figure 136**

147. **Figure 137**

148. **Figure 138**

149. **Figure 139**

150. **Figure 140**

151. **Figure 141**

152. **Figure 142**

153. **Figure 143**

154. **Figure 144**

155. **Figure 145**

156. **Figure 146**

157. **Figure 147**

158. **Figure 148**

159. **Figure 149**

160. **Figure 150**

161. **Figure 151**

162. **Figure 152**

163. **Figure 153**

164. **Figure 154**

165. **Figure 155**

166. **Figure 156**

167. **Figure 157**

168. **Figure 158**

169. **Figure 159**

170. **Figure 160**

171. **Figure 161**

172. **Figure 162**

173. **Figure 163**

174. **Figure 164**

175. **Figure 165**

176. **Figure 166**

177. **Figure 167**

178. **Figure 168**

179. **Figure 169**

180. **Figure 170**

181. **Figure 171**

182. **Figure 172**

183. **Figure 173**

184. **Figure 174**

185. **Figure 175**

186. **Figure 176**

187. **Figure 177**

188. **Figure 178**

189. **Figure 179**

190. **Figure 180**

191. **Figure 181**

192. **Figure 182**

193. **Figure 183**

194. **Figure 184**

195. **Figure 185**

196. **Figure 186**

197. **Figure 187**

198. **Figure 188**

199. **Figure 189**

200. **Figure 190**

201. **Figure 191**

202. **Figure 192**

203. **Figure 193**

204. **Figure 194**

205. **Figure 195**

206. **Figure 196**

207. **Figure 197**

208. **Figure 198**

209. **Figure 199**

210. **Figure 200**

211. **Figure 201**

212. **Figure 202**

213. **Figure 203**

214. **Figure 204**

215. **Figure 205**

216. **Figure 206**

217. **Figure 207**

218. **Figure 208**

219. **Figure 209**

220. **Figure 210**

221. **Figure 211**

222. **Figure 212**

223. **Figure 213**

224. **Figure 214**

225. **Figure 215**

226. **Figure 216**

227. **Figure 217**

228.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Figure 1**

10. **Figure 2**

11. **Figure 3**

12. **Figure 4**

13. **Figure 5**

14. **Figure 6**

15. **Figure 7**

16. **Figure 8**

17. **Figure 9**

18. **Figure 10**

19. **Figure 11**

20. **Figure 12**

21. **Figure 13**

22. **Figure 14**

23. **Figure 15**

24. **Figure 16**

25. **Figure 17**

26. **Figure 18**

27. **Figure 19**

28. **Figure 20**

29. **Figure 21**

30. **Figure 22**

31. **Figure 23**

32. **Figure 24**

33. **Figure 25**

34. **Figure 26**

35. **Figure 27**

36. **Figure 28**

37. **Figure 29**

38. **Figure 30**

39. **Figure 31**

40. **Figure 32**

41. **Figure 33**

42. **Figure 34**

43. **Figure 35**

44. **Figure 36**

45. **Figure 37**

46. **Figure 38**

47. **Figure 39**

48. **Figure 40**

49. **Figure 41**

50. **Figure 42**

51. **Figure 43**

52. **Figure 44**

53. **Figure 45**

54. **Figure 46**

55. **Figure 47**

56. **Figure 48**

57. **Figure 49**

58. **Figure 50**

59. **Figure 51**

60. **Figure 52**

61. **Figure 53**

62. **Figure 54**

63. **Figure 55**

64. **Figure 56**

65. **Figure 57**

66. **Figure 58**

67. **Figure 59**

68. **Figure 60**

69. **Figure 61**

70. **Figure 62**

71. **Figure 63**

72. **Figure 64**

73. **Figure 65**

74. **Figure 66**

75. **Figure 67**

76. **Figure 68**

77. **Figure 69**

78. **Figure 70**

79. **Figure 71**

80. **Figure 72**

81. **Figure 73**

82. **Figure 74**

83. **Figure 75**

84. **Figure 76**

85. **Figure 77**

86. **Figure 78**

87. **Figure 79**

88. **Figure 80**

89. **Figure 81**

90. **Figure 82**

91. **Figure 83**

92. **Figure 84**

93. **Figure 85**

94. **Figure 86**

95. **Figure 87**

96. **Figure 88**

97. **Figure 89**

98. **Figure 90**

99. **Figure 91**

100. **Figure 92**

101. **Figure 93**

102. **Figure 94**

103. **Figure 95**

104. **Figure 96**

105. **Figure 97**

106. **Figure 98**

107. **Figure 99**

108. **Figure 100**

109. **Figure 101**

110. **Figure 102**

111. **Figure 103**

112. **Figure 104**

113. **Figure 105**

114. **Figure 106**

115. **Figure 107**

116. **Figure 108**

117. **Figure 109**

118. **Figure 110**

119. **Figure 111**

120. **Figure 112**

121. **Figure 113**

122. **Figure 114**

123. **Figure 115**

124. **Figure 116**

125. **Figure 117**

126. **Figure 118**

127. **Figure 119**

128. **Figure 120**

129. **Figure 121**

130. **Figure 122**

131. **Figure 123**

132. **Figure 124**

133. **Figure 125**

134. **Figure 126**

135. **Figure 127**

136. **Figure 128**

137. **Figure 129**

138. **Figure 130**

139. **Figure 131**

140. **Figure 132**

141. **Figure 133**

142. **Figure 134**

143. **Figure 135**

144. **Figure 136**

145. **Figure 137**

146. **Figure 138**

147. **Figure 139**

148. **Figure 140**

149. **Figure 141**

150. **Figure 142**

151. **Figure 143**

152. **Figure 144**

153. **Figure 145**

154. **Figure 146**

155. **Figure 147**

156. **Figure 148**

157. **Figure 149**

158. **Figure 150**

159. **Figure 151**

160. **Figure 152**

161. **Figure 153**

162. **Figure 154**

163. **Figure 155**

164. **Figure 156**

165. **Figure 157**

166. **Figure 158**

167. **Figure 159**

168. **Figure 160**

169. **Figure 161**

170. **Figure 162**

171. **Figure 163**

172. **Figure 164**

173. **Figure 165**

174. **Figure 166**

175. **Figure 167**

176. **Figure 168**

177. **Figure 169**

178. **Figure 170**

179. **Figure 171**

180. **Figure 172**

181. **Figure 173**

182. **Figure 174**

183. **Figure 175**

184. **Figure 176**

185. **Figure 177**

186. **Figure 178**

187. **Figure 179**

188. **Figure 180**

189. **Figure 181**

190. **Figure 182**

191. **Figure 183**

192. **Figure 184**

193. **Figure 185**

194. **Figure 186**

195. **Figure 187**

196. **Figure 188**

197. **Figure 189**

198. **Figure 190**

199. **Figure 191**

200. **Figure 192**

201. **Figure 193**

202. **Figure 194**

203. **Figure 195**

204. **Figure 196**

205. **Figure 197**

206. **Figure 198**

207. **Figure 199**

208. **Figure 200**

209. **Figure 201**

210. **Figure 202**

211. **Figure 203**

212. **Figure 204**

213. **Figure 205**

214. **Figure 206**

215. **Figure 207**

216. **Figure 208**

217. **Figure 209**

218. **Figure 210**

219. **Figure 211**

220. **Figure 212**

221. **Figure 213**

222. **Figure 214**

223. **Figure 215**

224. **Figure 216**

225. **Figure 217**

226. **Figure 218**

227. **Figure 219**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1890 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Figure 1 is a 3D bar chart illustrating the percentage of respondents by age group and gender who believe that the use of force is justified in certain circumstances. The chart is divided into three sections: 'Justified', 'Not Justified', and 'Don't Know'. The Y-axis represents the percentage of respondents (0% to 100%). The X-axis represents the age group (18-24, 25-34, 35-44, 45-54, 55-64, 65+). The Z-axis represents the gender (Male, Female).

Age Group	Gender	Justified (%)	Not Justified (%)	Don't Know (%)
18-24	Male	75	20	5
18-24	Female	65	30	5
25-34	Male	60	35	5
25-34	Female	55	40	5
35-44	Male	50	45	5
35-44	Female	45	50	5
45-54	Male	40	55	5
45-54	Female	35	60	5
55-64	Male	30	65	5
55-64	Female	25	70	5
65+	Male	20	75	5
65+	Female	15	80	5

Novo Nordisk

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1900 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1903 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children (Y-axis) and the number of adults (X-axis) in a household. The rows represent different levels of the 'Number of children' variable (1, 2, 3), and the columns represent different levels of the 'Number of adults' variable (1, 2, 3). Each plot shows a positive correlation between the two variables, with the density of points increasing as the number of children increases. The plots are arranged in a 3x3 grid, with the top row showing the lowest density of points and the bottom row showing the highest density. The x-axis for all plots is 'Number of adults' and the y-axis is 'Number of children'.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1908 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Novo Nordisk

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1916 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Novo Nordisk

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid black color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1924 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Subject Headings**

16. **MeSH Terms**

17. **Indexing**

18. **Classification**

19. **Numbering**

20. **Ordering**

21. **Grouping**

22. **Labeling**

23. **Marking**

24. **Notation**

25. **Abbreviations**

26. **Acronyms**

27. **Initials**

28. **Figures**

29. **Tables**

30. **Equations**

31. **Formulas**

32. **Diagrams**

33. **Flowcharts**

34. **Maps**

35. **Charts**

36. **Graphs**

37. **Plots**

38. **Images**

39. **Photographs**

40. **Figures**

41. **Tables**

42. **Equations**

43. **Formulas**

44. **Diagrams**

45. **Flowcharts**

46. **Maps**

47. **Charts**

48. **Graphs**

49. **Plots**

50. **Images**

51. **Photographs**

52. **Figures**

53. **Tables**

54. **Equations**

55. **Formulas**

56. **Diagrams**

57. **Flowcharts**

58. **Maps**

59. **Charts**

60. **Graphs**

61. **Plots**

62. **Images**

63. **Photographs**

64. **Figures**

65. **Tables**

66. **Equations**

67. **Formulas**

68. **Diagrams**

69. **Flowcharts**

70. **Maps**

71. **Charts**

72. **Graphs**

73. **Plots**

74. **Images**

75. **Photographs**

76. **Figures**

77. **Tables**

78. **Equations**

79. **Formulas**

80. **Diagrams**

81. **Flowcharts**

82. **Maps**

83. **Charts**

84. **Graphs**

85. **Plots**

86. **Images**

87. **Photographs**

88. **Figures**

89. **Tables**

90. **Equations**

91. **Formulas**

92. **Diagrams**

93. **Flowcharts**

94. **Maps**

95. **Charts**

96. **Graphs**

97. **Plots**

98. **Images**

99. **Photographs**

100. **Figures**

101. **Tables**

102. **Equations**

103. **Formulas**

104. **Diagrams**

105. **Flowcharts**

106. **Maps**

107. **Charts**

108. **Graphs**

109. **Plots**

110. **Images**

111. **Photographs**

112. **Figures**

113. **Tables**

114. **Equations**

115. **Formulas**

116. **Diagrams**

117. **Flowcharts**

118. **Maps**

119. **Charts**

120. **Graphs**

121. **Plots**

122. **Images**

123. **Photographs**

124. **Figures**

125. **Tables**

126. **Equations**

127. **Formulas**

128. **Diagrams**

129. **Flowcharts**

130. **Maps**

131. **Charts**

132. **Graphs**

133. **Plots**

134. **Images**

135. **Photographs**

136. **Figures**

137. **Tables**

138. **Equations**

139. **Formulas**

140. **Diagrams**

141. **Flowcharts**

142. **Maps**

143. **Charts**

144. **Graphs**

145. **Plots**

146. **Images**

147. **Photographs**

148. **Figures**

149. **Tables**

150. **Equations**

151. **Formulas**

152. **Diagrams**

153. **Flowcharts**

154. **Maps**

155. **Charts**

156. **Graphs**

157. **Plots**

158. **Images**

159. **Photographs**

160. **Figures**

161. **Tables**

162. **Equations**

163. **Formulas**

164. **Diagrams**

165. **Flowcharts**

166. **Maps**

167. **Charts**

168. **Graphs**

169. **Plots**

170. **Images**

171. **Photographs**

172. **Figures**

173. **Tables**

174. **Equations**

175. **Formulas**

176. **Diagrams**

177. **Flowcharts**

178. **Maps**

179. **Charts**

180. **Graphs**

181. **Plots**

182. **Images**

183. **Photographs**

184. **Figures**

185. **Tables**

186. **Equations**

187. **Formulas**

188. **Diagrams**

189. **Flowcharts**

190. **Maps**

191. **Charts**

192. **Graphs**

193. **Plots**

194. **Images**

195. **Photographs**

196. **Figures**

197. **Tables**

198. **Equations**

199. **Formulas**

200. **Diagrams**

201. **Flowcharts**

202. **Maps**

203. **Charts**

204. **Graphs**

205. **Plots**

206. **Images**

207. **Photographs**

208. **Figures**

209. **Tables**

210. **Equations**

211. **Formulas**

212. **Diagrams**

213. **Flowcharts**

214. **Maps**

215. **Charts**

216. **Graphs**

217. **Plots**

218. **Images**

219. **Photographs**

220. **Figures**

221. **Tables**

222. **Equations**

223. **Formulas**

224. **Diagrams**

225. **Flowcharts**

226. **Maps**

227. **Charts**

228. **Graphs**

229. **Plots**

230. **Images**

231. **Photographs**

232. **Figures**

233. **Tables**

234. **Equations**

235. **Formulas**

236. **Diagrams**

237. **Flowcharts**

238. **Maps**

239. **Charts**

240. **Graphs**

241. **Plots**

242. **Images**

243. **Photographs**

244. **Figures**

245. **Tables**

246. **Equations**

247. **Formulas**

248. **Diagrams**

249. **Flowcharts**

250. **Maps**

251. **Charts**

252. **Graphs**

253. **Plots**

254. **Images**

255. **Photographs**

256. **Figures**

257. **Tables**

258. **Equations**

259. **Formulas**

260. **Diagrams**

261. **Flowcharts**

262. **Maps**

263. **Charts**

264. **Graphs**

265. **Plots**

266. **Images**

267.

Novo Nordisk

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1937 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children in the household (X-axis) and the number of children in the neighborhood (Y-axis). The rows represent different levels of the 'Number of children in the household' variable (1, 2, 3), and the columns represent different levels of the 'Number of children in the neighborhood' variable (1, 2, 3). Each plot shows a positive correlation between the two variables, with the density of points increasing as the number of children in both the household and the neighborhood increases.

Number of children in the household	Number of children in the neighborhood		
1	1	2	3
2	1	2	3
3	1	2	3

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color.

Figure 1 is a 3D bar chart illustrating the percentage of respondents by age group and gender who believe that the use of force is justified in certain circumstances. The chart is divided into three sections: 'Total', 'Male', and 'Female'. The Y-axis represents the percentage from 0 to 100. The X-axis represents age groups: 18-24, 25-34, 35-44, 45-54, 55-64, 65-74, and 75+. The legend indicates that blue bars represent 'Justified' and red bars represent 'Not Justified'.

Age Group	Gender	Justified (%)	Not Justified (%)
18-24	Total	65	35
18-24	Male	68	32
18-24	Female	62	38
25-34	Total	60	40
25-34	Male	63	37
25-34	Female	57	43
35-44	Total	55	45
35-44	Male	58	42
35-44	Female	52	48
45-54	Total	50	50
45-54	Male	53	47
45-54	Female	47	53
55-64	Total	45	55
55-64	Male	48	52
55-64	Female	42	58
65-74	Total	40	60
65-74	Male	43	57
65-74	Female	37	63
75+	Total	35	65
75+	Male	38	62
75+	Female	32	68

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Subject Headings**

16. **MeSH**

17. **Indexing**

18. **Classification**

19. **Numbering**

20. **Ordering**

21. **Grouping**

22. **Labeling**

23. **Marking**

24. **Notation**

25. **Symbolism**

26. **Diagramming**

27. **Flowcharting**

28. **Mapping**

29. **Charting**

30. **Graphing**

31. **Tablemaking**

32. **Formmaking**

33. **Diagrammaking**

34. **Flowchartmaking**

35. **Mappingmaking**

36. **Chartmaking**

37. **Graphmaking**

38. **Tablemaking**

39. **Formmaking**

40. **Diagrammaking**

41. **Flowchartmaking**

42. **Mappingmaking**

43. **Chartmaking**

44. **Graphmaking**

45. **Tablemaking**

46. **Formmaking**

47. **Diagrammaking**

48. **Flowchartmaking**

49. **Mappingmaking**

50. **Chartmaking**

51. **Graphmaking**

52. **Tablemaking**

53. **Formmaking**

54. **Diagrammaking**

55. **Flowchartmaking**

56. **Mappingmaking**

57. **Chartmaking**

58. **Graphmaking**

59. **Tablemaking**

60. **Formmaking**

61. **Diagrammaking**

62. **Flowchartmaking**

63. **Mappingmaking**

64. **Chartmaking**

65. **Graphmaking**

66. **Tablemaking**

67. **Formmaking**

68. **Diagrammaking**

69. **Flowchartmaking**

70. **Mappingmaking**

71. **Chartmaking**

72. **Graphmaking**

73. **Tablemaking**

74. **Formmaking**

75. **Diagrammaking**

76. **Flowchartmaking**

77. **Mappingmaking**

78. **Chartmaking**

79. **Graphmaking**

80. **Tablemaking**

81. **Formmaking**

82. **Diagrammaking**

83. **Flowchartmaking**

84. **Mappingmaking**

85. **Chartmaking**

86. **Graphmaking**

87. **Tablemaking**

88. **Formmaking**

89. **Diagrammaking**

90. **Flowchartmaking**

91. **Mappingmaking**

92. **Chartmaking**

93. **Graphmaking**

94. **Tablemaking**

95. **Formmaking**

96. **Diagrammaking**

97. **Flowchartmaking**

98. **Mappingmaking**

99. **Chartmaking**

100. **Graphmaking**

101. **Tablemaking**

102. **Formmaking**

103. **Diagrammaking**

104. **Flowchartmaking**

105. **Mappingmaking**

106. **Chartmaking**

107. **Graphmaking**

108. **Tablemaking**

109. **Formmaking**

110. **Diagrammaking**

111. **Flowchartmaking**

112. **Mappingmaking**

113. **Chartmaking**

114. **Graphmaking**

115. **Tablemaking**

116. **Formmaking**

117. **Diagrammaking**

118. **Flowchartmaking**

119. **Mappingmaking**

120. **Chartmaking**

121. **Graphmaking**

122. **Tablemaking**

123. **Formmaking**

124. **Diagrammaking**

125. **Flowchartmaking**

126. **Mappingmaking**

127. **Chartmaking**

128. **Graphmaking**

129. **Tablemaking**

130. **Formmaking**

131. **Diagrammaking**

132. **Flowchartmaking**

133. **Mappingmaking**

134. **Chartmaking**

135. **Graphmaking**

136. **Tablemaking**

137. **Formmaking**

138. **Diagrammaking**

139. **Flowchartmaking**

140. **Mappingmaking**

141. **Chartmaking**

142. **Graphmaking**

143. **Tablemaking**

144. **Formmaking**

145. **Diagrammaking**

146. **Flowchartmaking**

147. **Mappingmaking**

148. **Chartmaking**

149. **Graphmaking**

150. **Tablemaking**

151. **Formmaking**

152. **Diagrammaking**

153. **Flowchartmaking**

154. **Mappingmaking**

155. **Chartmaking**

156. **Graphmaking**

157. **Tablemaking**

158. **Formmaking**

159. **Diagrammaking**

160. **Flowchartmaking**

161. **Mappingmaking**

162. **Chartmaking**

163. **Graphmaking**

164. **Tablemaking**

165. **Formmaking**

166. **Diagrammaking**

167. **Flowchartmaking**

168. **Mappingmaking**

169. **Chartmaking**

170. **Graphmaking**

171. **Tablemaking**

172. **Formmaking**

173. **Diagrammaking**

174. **Flowchartmaking**

175. **Mappingmaking**

176. **Chartmaking**

177. **Graphmaking**

178. **Tablemaking**

179. **Formmaking**

180. **Diagrammaking**

181. **Flowchartmaking**

182. **Mappingmaking**

183. **Chartmaking**

184. **Graphmaking**

185. **Tablemaking**

186. **Formmaking**

187. **Diagrammaking**

188. **Flowchartmaking**

189. **Mappingmaking**

190. **Chartmaking**

191. **Graphmaking**

192. **Tablemaking**

193. **Formmaking**

194. **Diagrammaking**

195. **Flowchartmaking**

196. **Mappingmaking**

197. **Chartmaking**

198. **Graphmaking**

199. **Tablemaking**

200. **Formmaking**

201. **Diagrammaking**

202. **Flowchartmaking**

203. **Mappingmaking**

204. **Chartmaking**

205. **Graphmaking**

206. **Tablemaking**

207. **Formmaking**

208. **Diagrammaking**

209. **Flowchartmaking**

210. **Mappingmaking**

211. **Chartmaking**

212. **Graphmaking**

213. **Tablemaking**

214. **Formmaking**

215. **Diagrammaking**

216. **Flowchartmaking**

217. **Mappingmaking**

218. **Chartmaking**

219. **Graphmaking**

220. **Tablemaking**

221. **Formmaking**

222. **Diagrammaking**

223. **Flowchartmaking**

224. **Mappingmaking**

225. **Chartmaking**

226. **Graphmaking**

227. **Tablemaking**

228. **Formmaking**

229. **Diagrammaking**

230. **Flowchartmaking**

231. **Mappingmaking**

232. **Chartmaking**

233. **Graphmaking**

234. **Tablemaking**

235. **Formmaking**

236. **Diagrammaking**

237. **Flowchartmaking**

238. **Mappingmaking**

239. **Chartmaking**

240. **Graphmaking**

241. **Tablemaking**

242. **Formmaking**

243. **Diagrammaking**

244. **Flowchartmaking**

245. **Mappingmaking**

246. **Chartmaking**

247. **Graphmaking**

248. **Tablemaking**

249. **Formmaking**

250. **Diagrammaking**

251. **Flowchartmaking**

252. **Mappingmaking**

253. **Chartmaking**

254. **Graphmaking**

255. **Tablemaking**

256. **Formmaking**

257. **Diagrammaking**

258. **Flowchartmaking**

259. **Mappingmaking**

260. **Chart**

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Novo Nordisk

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children and the number of children in the household. The rows represent different levels of the 'Number of children' variable (1, 2, 3) and the columns represent different levels of the 'Number of children in the household' variable (1, 2, 3). Each plot shows a positive correlation between the two variables.

The plots are arranged as follows:

- Row 1: Number of children = 1
- Row 2: Number of children = 2
- Row 3: Number of children = 3
- Column 1: Number of children in the household = 1
- Column 2: Number of children in the household = 2
- Column 3: Number of children in the household = 3

Each plot shows a positive correlation between the number of children and the number of children in the household. The plots are arranged in a 3x3 grid, with the rows representing the number of children and the columns representing the number of children in the household.

Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children and the number of children in the household. The rows represent different levels of the 'Number of children' variable (1, 2, 3) and the columns represent different levels of the 'Number of children in the household' variable (1, 2, 3). Each plot shows a positive correlation between the two variables.

The plots are arranged as follows:

- Row 1: Number of children = 1
- Row 2: Number of children = 2
- Row 3: Number of children = 3
- Column 1: Number of children in the household = 1
- Column 2: Number of children in the household = 2
- Column 3: Number of children in the household = 3

Each plot shows a positive correlation between the number of children and the number of children in the household. The plots are arranged in a 3x3 grid, with the rows representing the number of children and the columns representing the number of children in the household.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 1966 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1974 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children and the number of children in the household. The rows represent different levels of the 'Number of children' variable (1, 2, 3) and the columns represent different levels of the 'Number of children in the household' variable (1, 2, 3). Each plot shows a positive correlation between the two variables.

The plots are arranged as follows:

- Row 1: Number of children = 1. Columns: Number of children in the household = 1, 2, 3.
- Row 2: Number of children = 2. Columns: Number of children in the household = 1, 2, 3.
- Row 3: Number of children = 3. Columns: Number of children in the household = 1, 2, 3.

Each plot shows a positive correlation between the number of children and the number of children in the household. The plots are arranged in a 3x3 grid, with the number of children on the x-axis and the number of children in the household on the y-axis.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Figure 1**

12. **Figure 2**

13. **Figure 3**

14. **Figure 4**

15. **Figure 5**

16. **Figure 6**

17. **Figure 7**

18. **Figure 8**

19. **Figure 9**

20. **Figure 10**

21. **Figure 11**

22. **Figure 12**

23. **Figure 13**

24. **Figure 14**

25. **Figure 15**

26. **Figure 16**

27. **Figure 17**

28. **Figure 18**

29. **Figure 19**

30. **Figure 20**

31. **Figure 21**

32. **Figure 22**

33. **Figure 23**

34. **Figure 24**

35. **Figure 25**

36. **Figure 26**

37. **Figure 27**

38. **Figure 28**

39. **Figure 29**

40. **Figure 30**

41. **Figure 31**

42. **Figure 32**

43. **Figure 33**

44. **Figure 34**

45. **Figure 35**

46. **Figure 36**

47. **Figure 37**

48. **Figure 38**

49. **Figure 39**

50. **Figure 40**

51. **Figure 41**

52. **Figure 42**

53. **Figure 43**

54. **Figure 44**

55. **Figure 45**

56. **Figure 46**

57. **Figure 47**

58. **Figure 48**

59. **Figure 49**

60. **Figure 50**

61. **Figure 51**

62. **Figure 52**

63. **Figure 53**

64. **Figure 54**

65. **Figure 55**

66. **Figure 56**

67. **Figure 57**

68. **Figure 58**

69. **Figure 59**

70. **Figure 60**

71. **Figure 61**

72. **Figure 62**

73. **Figure 63**

74. **Figure 64**

75. **Figure 65**

76. **Figure 66**

77. **Figure 67**

78. **Figure 68**

79. **Figure 69**

80. **Figure 70**

81. **Figure 71**

82. **Figure 72**

83. **Figure 73**

84. **Figure 74**

85. **Figure 75**

86. **Figure 76**

87. **Figure 77**

88. **Figure 78**

89. **Figure 79**

90. **Figure 80**

91. **Figure 81**

92. **Figure 82**

93. **Figure 83**

94. **Figure 84**

95. **Figure 85**

96. **Figure 86**

97. **Figure 87**

98. **Figure 88**

99. **Figure 89**

100. **Figure 90**

101. **Figure 91**

102. **Figure 92**

103. **Figure 93**

104. **Figure 94**

105. **Figure 95**

106. **Figure 96**

107. **Figure 97**

108. **Figure 98**

109. **Figure 99**

110. **Figure 100**

111. **Figure 101**

112. **Figure 102**

113. **Figure 103**

114. **Figure 104**

115. **Figure 105**

116. **Figure 106**

117. **Figure 107**

118. **Figure 108**

119. **Figure 109**

120. **Figure 110**

121. **Figure 111**

122. **Figure 112**

123. **Figure 113**

124. **Figure 114**

125. **Figure 115**

126. **Figure 116**

127. **Figure 117**

128. **Figure 118**

129. **Figure 119**

130. **Figure 120**

131. **Figure 121**

132. **Figure 122**

133. **Figure 123**

134. **Figure 124**

135. **Figure 125**

136. **Figure 126**

137. **Figure 127**

138. **Figure 128**

139. **Figure 129**

140. **Figure 130**

141. **Figure 131**

142. **Figure 132**

143. **Figure 133**

144. **Figure 134**

145. **Figure 135**

146. **Figure 136**

147. **Figure 137**

148. **Figure 138**

149. **Figure 139**

150. **Figure 140**

151. **Figure 141**

152. **Figure 142**

153. **Figure 143**

154. **Figure 144**

155. **Figure 145**

156. **Figure 146**

157. **Figure 147**

158. **Figure 148**

159. **Figure 149**

160. **Figure 150**

161. **Figure 151**

162. **Figure 152**

163. **Figure 153**

164. **Figure 154**

165. **Figure 155**

166. **Figure 156**

167. **Figure 157**

168. **Figure 158**

169. **Figure 159**

170. **Figure 160**

171. **Figure 161**

172. **Figure 162**

173. **Figure 163**

174. **Figure 164**

175. **Figure 165**

176. **Figure 166**

177. **Figure 167**

178. **Figure 168**

179. **Figure 169**

180. **Figure 170**

181. **Figure 171**

182. **Figure 172**

183. **Figure 173**

184. **Figure 174**

185. **Figure 175**

186. **Figure 176**

187. **Figure 177**

188. **Figure 178**

189. **Figure 179**

190. **Figure 180**

191. **Figure 181**

192. **Figure 182**

193. **Figure 183**

194. **Figure 184**

195. **Figure 185**

196. **Figure 186**

197. **Figure 187**

198. **Figure 188**

199. **Figure 189**

200. **Figure 190**

201. **Figure 191**

202. **Figure 192**

203. **Figure 193**

204. **Figure 194**

205. **Figure 195**

206. **Figure 196**

207. **Figure 197**

208. **Figure 198**

209. **Figure 199**

210. **Figure 200**

211. **Figure 201**

212. **Figure 202**

213. **Figure 203**

214. **Figure 204**

215. **Figure 205**

216. **Figure 206**

217. **Figure 207**

218. **Figure 208**

219. **Figure 209**

220. **Figure 210**

221. **Figure 211**

222. **Figure 212**

223. **Figure 213**

224. **Figure 214**

225. **Figure 215**

226. **Figure 216**

227. **Figure 217**

228.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1993 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1994 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 1998 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

[illegible]

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 2005 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image consists of a single, uniform black rectangle filling the entire frame. There are no discernible features, text, or patterns other than the solid color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid black color.

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Figure 1**

10. **Figure 2**

11. **Figure 3**

12. **Figure 4**

13. **Figure 5**

14. **Figure 6**

15. **Figure 7**

16. **Figure 8**

17. **Figure 9**

18. **Figure 10**

19. **Figure 11**

20. **Figure 12**

21. **Figure 13**

22. **Figure 14**

23. **Figure 15**

24. **Figure 16**

25. **Figure 17**

26. **Figure 18**

27. **Figure 19**

28. **Figure 20**

29. **Figure 21**

30. **Figure 22**

31. **Figure 23**

32. **Figure 24**

33. **Figure 25**

34. **Figure 26**

35. **Figure 27**

36. **Figure 28**

37. **Figure 29**

38. **Figure 30**

39. **Figure 31**

40. **Figure 32**

41. **Figure 33**

42. **Figure 34**

43. **Figure 35**

44. **Figure 36**

45. **Figure 37**

46. **Figure 38**

47. **Figure 39**

48. **Figure 40**

49. **Figure 41**

50. **Figure 42**

51. **Figure 43**

52. **Figure 44**

53. **Figure 45**

54. **Figure 46**

55. **Figure 47**

56. **Figure 48**

57. **Figure 49**

58. **Figure 50**

59. **Figure 51**

60. **Figure 52**

61. **Figure 53**

62. **Figure 54**

63. **Figure 55**

64. **Figure 56**

65. **Figure 57**

66. **Figure 58**

67. **Figure 59**

68. **Figure 60**

69. **Figure 61**

70. **Figure 62**

71. **Figure 63**

72. **Figure 64**

73. **Figure 65**

74. **Figure 66**

75. **Figure 67**

76. **Figure 68**

77. **Figure 69**

78. **Figure 70**

79. **Figure 71**

80. **Figure 72**

81. **Figure 73**

82. **Figure 74**

83. **Figure 75**

84. **Figure 76**

85. **Figure 77**

86. **Figure 78**

87. **Figure 79**

88. **Figure 80**

89. **Figure 81**

90. **Figure 82**

91. **Figure 83**

92. **Figure 84**

93. **Figure 85**

94. **Figure 86**

95. **Figure 87**

96. **Figure 88**

97. **Figure 89**

98. **Figure 90**

99. **Figure 91**

100. **Figure 92**

101. **Figure 93**

102. **Figure 94**

103. **Figure 95**

104. **Figure 96**

105. **Figure 97**

106. **Figure 98**

107. **Figure 99**

108. **Figure 100**

109. **Figure 101**

110. **Figure 102**

111. **Figure 103**

112. **Figure 104**

113. **Figure 105**

114. **Figure 106**

115. **Figure 107**

116. **Figure 108**

117. **Figure 109**

118. **Figure 110**

119. **Figure 111**

120. **Figure 112**

121. **Figure 113**

122. **Figure 114**

123. **Figure 115**

124. **Figure 116**

125. **Figure 117**

126. **Figure 118**

127. **Figure 119**

128. **Figure 120**

129. **Figure 121**

130. **Figure 122**

131. **Figure 123**

132. **Figure 124**

133. **Figure 125**

134. **Figure 126**

135. **Figure 127**

136. **Figure 128**

137. **Figure 129**

138. **Figure 130**

139. **Figure 131**

140. **Figure 132**

141. **Figure 133**

142. **Figure 134**

143. **Figure 135**

144. **Figure 136**

145. **Figure 137**

146. **Figure 138**

147. **Figure 139**

148. **Figure 140**

149. **Figure 141**

150. **Figure 142**

151. **Figure 143**

152. **Figure 144**

153. **Figure 145**

154. **Figure 146**

155. **Figure 147**

156. **Figure 148**

157. **Figure 149**

158. **Figure 150**

159. **Figure 151**

160. **Figure 152**

161. **Figure 153**

162. **Figure 154**

163. **Figure 155**

164. **Figure 156**

165. **Figure 157**

166. **Figure 158**

167. **Figure 159**

168. **Figure 160**

169. **Figure 161**

170. **Figure 162**

171. **Figure 163**

172. **Figure 164**

173. **Figure 165**

174. **Figure 166**

175. **Figure 167**

176. **Figure 168**

177. **Figure 169**

178. **Figure 170**

179. **Figure 171**

180. **Figure 172**

181. **Figure 173**

182. **Figure 174**

183. **Figure 175**

184. **Figure 176**

185. **Figure 177**

186. **Figure 178**

187. **Figure 179**

188. **Figure 180**

189. **Figure 181**

190. **Figure 182**

191. **Figure 183**

192. **Figure 184**

193. **Figure 185**

194. **Figure 186**

195. **Figure 187**

196. **Figure 188**

197. **Figure 189**

198. **Figure 190**

199. **Figure 191**

200. **Figure 192**

201. **Figure 193**

202. **Figure 194**

203. **Figure 195**

204. **Figure 196**

205. **Figure 197**

206. **Figure 198**

207. **Figure 199**

208. **Figure 200**

209. **Figure 201**

210. **Figure 202**

211. **Figure 203**

212. **Figure 204**

213. **Figure 205**

214. **Figure 206**

215. **Figure 207**

216. **Figure 208**

217. **Figure 209**

218. **Figure 210**

219. **Figure 211**

220. **Figure 212**

221. **Figure 213**

222. **Figure 214**

223. **Figure 215**

224. **Figure 216**

225. **Figure 217**

226. **Figure 218**

227. **Figure 219**

2

The image is entirely black and contains no visible content.

Figure 1 displays a 3x3 grid of scatter plots showing the relationship between the number of children in the household (X-axis) and the number of children in the family (Y-axis). The rows represent different countries (USA, Canada, UK) and the columns represent different years (1990, 2000, 2010). Each plot shows a positive correlation, with the number of children in the family generally increasing as the number of children in the household increases. The USA shows the highest number of children in the family, followed by Canada, and then the UK. The UK shows the lowest number of children in the family, but the relationship is still positive. The plots are labeled with the country and year in the top right corner.

Country	Year	Approximate Range of Children in Household (X)	Approximate Range of Children in Family (Y)
USA	1990	1-4	1-6
USA	2000	1-4	1-6
USA	2010	1-4	1-6
Canada	1990	1-4	1-5
Canada	2000	1-4	1-5
Canada	2010	1-4	1-5
UK	1990	1-4	1-4
UK	2000	1-4	1-4
UK	2010	1-4	1-4

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 2015 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

[illegible]

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Figure 1 displays a 3x3 grid of scatter plots showing the relationship between the number of children in the household (X-axis) and the number of children in the family (Y-axis). The rows represent different family types: Single parent, Two parent, and Three parent. The columns represent different household types: Single parent, Two parent, and Three parent. Each plot shows a positive correlation between the number of children in the household and the number of children in the family, with the correlation being strongest in the 'Single parent' row and 'Single parent' column.

Family Type	Household Type	Correlation
Single parent	Single parent	Strong positive
Single parent	Two parent	Weak positive
Single parent	Three parent	Weak positive
Two parent	Single parent	Weak positive
Two parent	Two parent	Weak positive
Two parent	Three parent	Weak positive
Three parent	Single parent	Weak positive
Three parent	Two parent	Weak positive
Three parent	Three parent	Weak positive

The image is entirely black and contains no visible content.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 2024 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Figure 1 is a 3D bar chart illustrating the percentage of respondents by age group and gender who use various types of mobile devices. The chart is divided into two main sections: 'Smartphone' and 'Tablet'. Each section has bars for 'Male' and 'Female' across four age groups: 18-24, 25-34, 35-44, and 45-54. The y-axis represents the percentage from 0 to 100. The legend indicates that blue bars represent Smartphone and orange bars represent Tablet.

Device Type	Gender	Age Group	Percentage (%)
Smartphone	Male	18-24	95
		25-34	90
		35-44	85
		45-54	80
	Female	18-24	90
		25-34	85
		35-44	80
		45-54	75
Tablet	Male	18-24	10
		25-34	15
		35-44	20
		45-54	25
	Female	18-24	15
		25-34	20
		35-44	25
		45-54	30

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 2035 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Figure 1 displays a 3x3 grid of scatter plots showing the relationship between the number of children in the household (X-axis) and the number of children in the family (Y-axis). The rows represent different countries (USA, Canada, UK) and the columns represent different years (1990, 2000, 2010). Each plot shows a positive correlation, with the number of children in the household generally increasing as the number of children in the family increases. The plots are labeled with the country and year in the top right corner.

Country	Year	Approximate Range of Children in Household (X)	Approximate Range of Children in Family (Y)
USA	1990	0-10	0-10
USA	2000	0-10	0-10
USA	2010	0-10	0-10
Canada	1990	0-10	0-10
Canada	2000	0-10	0-10
Canada	2010	0-10	0-10
UK	1990	0-10	0-10
UK	2000	0-10	0-10
UK	2010	0-10	0-10

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 2045 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Novo Nordisk

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Figure 1**

12. **Figure 2**

13. **Figure 3**

14. **Figure 4**

15. **Figure 5**

16. **Figure 6**

17. **Figure 7**

18. **Figure 8**

19. **Figure 9**

20. **Figure 10**

21. **Figure 11**

22. **Figure 12**

23. **Figure 13**

24. **Figure 14**

25. **Figure 15**

26. **Figure 16**

27. **Figure 17**

28. **Figure 18**

29. **Figure 19**

30. **Figure 20**

31. **Figure 21**

32. **Figure 22**

33. **Figure 23**

34. **Figure 24**

35. **Figure 25**

36. **Figure 26**

37. **Figure 27**

38. **Figure 28**

39. **Figure 29**

40. **Figure 30**

41. **Figure 31**

42. **Figure 32**

43. **Figure 33**

44. **Figure 34**

45. **Figure 35**

46. **Figure 36**

47. **Figure 37**

48. **Figure 38**

49. **Figure 39**

50. **Figure 40**

51. **Figure 41**

52. **Figure 42**

53. **Figure 43**

54. **Figure 44**

55. **Figure 45**

56. **Figure 46**

57. **Figure 47**

58. **Figure 48**

59. **Figure 49**

60. **Figure 50**

61. **Figure 51**

62. **Figure 52**

63. **Figure 53**

64. **Figure 54**

65. **Figure 55**

66. **Figure 56**

67. **Figure 57**

68. **Figure 58**

69. **Figure 59**

70. **Figure 60**

71. **Figure 61**

72. **Figure 62**

73. **Figure 63**

74. **Figure 64**

75. **Figure 65**

76. **Figure 66**

77. **Figure 67**

78. **Figure 68**

79. **Figure 69**

80. **Figure 70**

81. **Figure 71**

82. **Figure 72**

83. **Figure 73**

84. **Figure 74**

85. **Figure 75**

86. **Figure 76**

87. **Figure 77**

88. **Figure 78**

89. **Figure 79**

90. **Figure 80**

91. **Figure 81**

92. **Figure 82**

93. **Figure 83**

94. **Figure 84**

95. **Figure 85**

96. **Figure 86**

97. **Figure 87**

98. **Figure 88**

99. **Figure 89**

100. **Figure 90**

101. **Figure 91**

102. **Figure 92**

103. **Figure 93**

104. **Figure 94**

105. **Figure 95**

106. **Figure 96**

107. **Figure 97**

108. **Figure 98**

109. **Figure 99**

110. **Figure 100**

111. **Figure 101**

112. **Figure 102**

113. **Figure 103**

114. **Figure 104**

115. **Figure 105**

116. **Figure 106**

117. **Figure 107**

118. **Figure 108**

119. **Figure 109**

120. **Figure 110**

121. **Figure 111**

122. **Figure 112**

123. **Figure 113**

124. **Figure 114**

125. **Figure 115**

126. **Figure 116**

127. **Figure 117**

128. **Figure 118**

129. **Figure 119**

130. **Figure 120**

131. **Figure 121**

132. **Figure 122**

133. **Figure 123**

134. **Figure 124**

135. **Figure 125**

136. **Figure 126**

137. **Figure 127**

138. **Figure 128**

139. **Figure 129**

140. **Figure 130**

141. **Figure 131**

142. **Figure 132**

143. **Figure 133**

144. **Figure 134**

145. **Figure 135**

146. **Figure 136**

147. **Figure 137**

148. **Figure 138**

149. **Figure 139**

150. **Figure 140**

151. **Figure 141**

152. **Figure 142**

153. **Figure 143**

154. **Figure 144**

155. **Figure 145**

156. **Figure 146**

157. **Figure 147**

158. **Figure 148**

159. **Figure 149**

160. **Figure 150**

161. **Figure 151**

162. **Figure 152**

163. **Figure 153**

164. **Figure 154**

165. **Figure 155**

166. **Figure 156**

167. **Figure 157**

168. **Figure 158**

169. **Figure 159**

170. **Figure 160**

171. **Figure 161**

172. **Figure 162**

173. **Figure 163**

174. **Figure 164**

175. **Figure 165**

176. **Figure 166**

177. **Figure 167**

178. **Figure 168**

179. **Figure 169**

180. **Figure 170**

181. **Figure 171**

182. **Figure 172**

183. **Figure 173**

184. **Figure 174**

185. **Figure 175**

186. **Figure 176**

187. **Figure 177**

188. **Figure 178**

189. **Figure 179**

190. **Figure 180**

191. **Figure 181**

192. **Figure 182**

193. **Figure 183**

194. **Figure 184**

195. **Figure 185**

196. **Figure 186**

197. **Figure 187**

198. **Figure 188**

199. **Figure 189**

200. **Figure 190**

201. **Figure 191**

202. **Figure 192**

203. **Figure 193**

204. **Figure 194**

205. **Figure 195**

206. **Figure 196**

207. **Figure 197**

208. **Figure 198**

209. **Figure 199**

210. **Figure 200**

211. **Figure 201**

212. **Figure 202**

213. **Figure 203**

214. **Figure 204**

215. **Figure 205**

216. **Figure 206**

217. **Figure 207**

218. **Figure 208**

219. **Figure 209**

220. **Figure 210**

221. **Figure 211**

222. **Figure 212**

223. **Figure 213**

224. **Figure 214**

225. **Figure 215**

226. **Figure 216**

227. **Figure 217**

228.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Novo Nordisk

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m ²)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Figure 1 displays a 3x3 grid of scatter plots showing the relationship between the number of children in the household (X-axis) and the number of children in the family (Y-axis). The rows represent different family types: Single parent, Two parent, and Three parent. The columns represent different household types: Single parent, Two parent, and Three parent. Each plot shows a positive correlation between the number of children in the household and the number of children in the family, with the correlation being stronger for single parent households and weaker for two parent households.

Family Type	Household Type	Correlation
Single parent	Single parent	Strong
Single parent	Two parent	Weak
Single parent	Three parent	Weak
Two parent	Single parent	Weak
Two parent	Two parent	Weak
Two parent	Three parent	Weak
Three parent	Single parent	Weak
Three parent	Two parent	Weak
Three parent	Three parent	Weak

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid black color.

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Figure 1**

10. **Figure 2**

11. **Figure 3**

12. **Figure 4**

13. **Figure 5**

14. **Figure 6**

15. **Figure 7**

16. **Figure 8**

17. **Figure 9**

18. **Figure 10**

19. **Figure 11**

20. **Figure 12**

21. **Figure 13**

22. **Figure 14**

23. **Figure 15**

24. **Figure 16**

25. **Figure 17**

26. **Figure 18**

27. **Figure 19**

28. **Figure 20**

29. **Figure 21**

30. **Figure 22**

31. **Figure 23**

32. **Figure 24**

33. **Figure 25**

34. **Figure 26**

35. **Figure 27**

36. **Figure 28**

37. **Figure 29**

38. **Figure 30**

39. **Figure 31**

40. **Figure 32**

41. **Figure 33**

42. **Figure 34**

43. **Figure 35**

44. **Figure 36**

45. **Figure 37**

46. **Figure 38**

47. **Figure 39**

48. **Figure 40**

49. **Figure 41**

50. **Figure 42**

51. **Figure 43**

52. **Figure 44**

53. **Figure 45**

54. **Figure 46**

55. **Figure 47**

56. **Figure 48**

57. **Figure 49**

58. **Figure 50**

59. **Figure 51**

60. **Figure 52**

61. **Figure 53**

62. **Figure 54**

63. **Figure 55**

64. **Figure 56**

65. **Figure 57**

66. **Figure 58**

67. **Figure 59**

68. **Figure 60**

69. **Figure 61**

70. **Figure 62**

71. **Figure 63**

72. **Figure 64**

73. **Figure 65**

74. **Figure 66**

75. **Figure 67**

76. **Figure 68**

77. **Figure 69**

78. **Figure 70**

79. **Figure 71**

80. **Figure 72**

81. **Figure 73**

82. **Figure 74**

83. **Figure 75**

84. **Figure 76**

85. **Figure 77**

86. **Figure 78**

87. **Figure 79**

88. **Figure 80**

89. **Figure 81**

90. **Figure 82**

91. **Figure 83**

92. **Figure 84**

93. **Figure 85**

94. **Figure 86**

95. **Figure 87**

96. **Figure 88**

97. **Figure 89**

98. **Figure 90**

99. **Figure 91**

100. **Figure 92**

101. **Figure 93**

102. **Figure 94**

103. **Figure 95**

104. **Figure 96**

105. **Figure 97**

106. **Figure 98**

107. **Figure 99**

108. **Figure 100**

109. **Figure 101**

110. **Figure 102**

111. **Figure 103**

112. **Figure 104**

113. **Figure 105**

114. **Figure 106**

115. **Figure 107**

116. **Figure 108**

117. **Figure 109**

118. **Figure 110**

119. **Figure 111**

120. **Figure 112**

121. **Figure 113**

122. **Figure 114**

123. **Figure 115**

124. **Figure 116**

125. **Figure 117**

126. **Figure 118**

127. **Figure 119**

128. **Figure 120**

129. **Figure 121**

130. **Figure 122**

131. **Figure 123**

132. **Figure 124**

133. **Figure 125**

134. **Figure 126**

135. **Figure 127**

136. **Figure 128**

137. **Figure 129**

138. **Figure 130**

139. **Figure 131**

140. **Figure 132**

141. **Figure 133**

142. **Figure 134**

143. **Figure 135**

144. **Figure 136**

145. **Figure 137**

146. **Figure 138**

147. **Figure 139**

148. **Figure 140**

149. **Figure 141**

150. **Figure 142**

151. **Figure 143**

152. **Figure 144**

153. **Figure 145**

154. **Figure 146**

155. **Figure 147**

156. **Figure 148**

157. **Figure 149**

158. **Figure 150**

159. **Figure 151**

160. **Figure 152**

161. **Figure 153**

162. **Figure 154**

163. **Figure 155**

164. **Figure 156**

165. **Figure 157**

166. **Figure 158**

167. **Figure 159**

168. **Figure 160**

169. **Figure 161**

170. **Figure 162**

171. **Figure 163**

172. **Figure 164**

173. **Figure 165**

174. **Figure 166**

175. **Figure 167**

176. **Figure 168**

177. **Figure 169**

178. **Figure 170**

179. **Figure 171**

180. **Figure 172**

181. **Figure 173**

182. **Figure 174**

183. **Figure 175**

184. **Figure 176**

185. **Figure 177**

186. **Figure 178**

187. **Figure 179**

188. **Figure 180**

189. **Figure 181**

190. **Figure 182**

191. **Figure 183**

192. **Figure 184**

193. **Figure 185**

194. **Figure 186**

195. **Figure 187**

196. **Figure 188**

197. **Figure 189**

198. **Figure 190**

199. **Figure 191**

200. **Figure 192**

201. **Figure 193**

202. **Figure 194**

203. **Figure 195**

204. **Figure 196**

205. **Figure 197**

206. **Figure 198**

207. **Figure 199**

208. **Figure 200**

209. **Figure 201**

210. **Figure 202**

211. **Figure 203**

212. **Figure 204**

213. **Figure 205**

214. **Figure 206**

215. **Figure 207**

216. **Figure 208**

217. **Figure 209**

218. **Figure 210**

219. **Figure 211**

220. **Figure 212**

221. **Figure 213**

222. **Figure 214**

223. **Figure 215**

224. **Figure 216**

225. **Figure 217**

226. **Figure 218**

227. **Figure 219**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 2071 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 2088 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Page 2092 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Figure 1 displays a 3x3 grid of scatter plots showing the relationship between the number of children (X-axis) and the number of adults (Y-axis) in a household. The rows represent different countries (USA, Canada, UK) and the columns represent different years (1990, 2000, 2010). Each plot shows a positive correlation between the number of children and the number of adults, with the slope of the relationship increasing over time and varying by country.

The plots are arranged in a 3x3 grid. The rows represent different countries (USA, Canada, UK) and the columns represent different years (1990, 2000, 2010). Each plot shows a positive correlation between the number of children and the number of adults, with the slope of the relationship increasing over time and varying by country.

The X-axis represents the number of children (0 to 10) and the Y-axis represents the number of adults (0 to 10). The plots show that the relationship between the number of children and the number of adults is positive, indicating that households with more children also tend to have more adults. The slope of the relationship is steeper in 2010 compared to 1990 and 2000, suggesting a stronger positive correlation in 2010.

The plots also show that the relationship between the number of children and the number of adults is stronger in the USA and Canada compared to the UK, particularly in 2010. This suggests that the relationship between the number of children and the number of adults is more pronounced in these countries.

[illegible]

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Figure 1 displays a 3x3 grid of scatter plots illustrating the relationship between the number of children in the household (X-axis) and the number of children in the neighborhood (Y-axis). The rows represent different levels of the 'Number of children in the household' variable (1, 2, 3), and the columns represent different levels of the 'Number of children in the neighborhood' variable (1, 2, 3). Each plot shows a positive correlation between the two variables, with the density of points increasing as the number of children in both the household and the neighborhood increases.

Number of children in the household	Number of children in the neighborhood		
1	1	2	3
2	1	2	3
3	1	2	3

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Novo Nordisk

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report

Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 2114 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Figure 1**

12. **Figure 2**

13. **Figure 3**

14. **Figure 4**

15. **Figure 5**

16. **Figure 6**

17. **Figure 7**

18. **Figure 8**

19. **Figure 9**

20. **Figure 10**

21. **Figure 11**

22. **Figure 12**

23. **Figure 13**

24. **Figure 14**

25. **Figure 15**

26. **Figure 16**

27. **Figure 17**

28. **Figure 18**

29. **Figure 19**

30. **Figure 20**

31. **Figure 21**

32. **Figure 22**

33. **Figure 23**

34. **Figure 24**

35. **Figure 25**

36. **Figure 26**

37. **Figure 27**

38. **Figure 28**

39. **Figure 29**

40. **Figure 30**

41. **Figure 31**

42. **Figure 32**

43. **Figure 33**

44. **Figure 34**

45. **Figure 35**

46. **Figure 36**

47. **Figure 37**

48. **Figure 38**

49. **Figure 39**

50. **Figure 40**

51. **Figure 41**

52. **Figure 42**

53. **Figure 43**

54. **Figure 44**

55. **Figure 45**

56. **Figure 46**

57. **Figure 47**

58. **Figure 48**

59. **Figure 49**

60. **Figure 50**

61. **Figure 51**

62. **Figure 52**

63. **Figure 53**

64. **Figure 54**

65. **Figure 55**

66. **Figure 56**

67. **Figure 57**

68. **Figure 58**

69. **Figure 59**

70. **Figure 60**

71. **Figure 61**

72. **Figure 62**

73. **Figure 63**

74. **Figure 64**

75. **Figure 65**

76. **Figure 66**

77. **Figure 67**

78. **Figure 68**

79. **Figure 69**

80. **Figure 70**

81. **Figure 71**

82. **Figure 72**

83. **Figure 73**

84. **Figure 74**

85. **Figure 75**

86. **Figure 76**

87. **Figure 77**

88. **Figure 78**

89. **Figure 79**

90. **Figure 80**

91. **Figure 81**

92. **Figure 82**

93. **Figure 83**

94. **Figure 84**

95. **Figure 85**

96. **Figure 86**

97. **Figure 87**

98. **Figure 88**

99. **Figure 89**

100. **Figure 90**

101. **Figure 91**

102. **Figure 92**

103. **Figure 93**

104. **Figure 94**

105. **Figure 95**

106. **Figure 96**

107. **Figure 97**

108. **Figure 98**

109. **Figure 99**

110. **Figure 100**

111. **Figure 101**

112. **Figure 102**

113. **Figure 103**

114. **Figure 104**

115. **Figure 105**

116. **Figure 106**

117. **Figure 107**

118. **Figure 108**

119. **Figure 109**

120. **Figure 110**

121. **Figure 111**

122. **Figure 112**

123. **Figure 113**

124. **Figure 114**

125. **Figure 115**

126. **Figure 116**

127. **Figure 117**

128. **Figure 118**

129. **Figure 119**

130. **Figure 120**

131. **Figure 121**

132. **Figure 122**

133. **Figure 123**

134. **Figure 124**

135. **Figure 125**

136. **Figure 126**

137. **Figure 127**

138. **Figure 128**

139. **Figure 129**

140. **Figure 130**

141. **Figure 131**

142. **Figure 132**

143. **Figure 133**

144. **Figure 134**

145. **Figure 135**

146. **Figure 136**

147. **Figure 137**

148. **Figure 138**

149. **Figure 139**

150. **Figure 140**

151. **Figure 141**

152. **Figure 142**

153. **Figure 143**

154. **Figure 144**

155. **Figure 145**

156. **Figure 146**

157. **Figure 147**

158. **Figure 148**

159. **Figure 149**

160. **Figure 150**

161. **Figure 151**

162. **Figure 152**

163. **Figure 153**

164. **Figure 154**

165. **Figure 155**

166. **Figure 156**

167. **Figure 157**

168. **Figure 158**

169. **Figure 159**

170. **Figure 160**

171. **Figure 161**

172. **Figure 162**

173. **Figure 163**

174. **Figure 164**

175. **Figure 165**

176. **Figure 166**

177. **Figure 167**

178. **Figure 168**

179. **Figure 169**

180. **Figure 170**

181. **Figure 171**

182. **Figure 172**

183. **Figure 173**

184. **Figure 174**

185. **Figure 175**

186. **Figure 176**

187. **Figure 177**

188. **Figure 178**

189. **Figure 179**

190. **Figure 180**

191. **Figure 181**

192. **Figure 182**

193. **Figure 183**

194. **Figure 184**

195. **Figure 185**

196. **Figure 186**

197. **Figure 187**

198. **Figure 188**

199. **Figure 189**

200. **Figure 190**

201. **Figure 191**

202. **Figure 192**

203. **Figure 193**

204. **Figure 194**

205. **Figure 195**

206. **Figure 196**

207. **Figure 197**

208. **Figure 198**

209. **Figure 199**

210. **Figure 200**

211. **Figure 201**

212. **Figure 202**

213. **Figure 203**

214. **Figure 204**

215. **Figure 205**

216. **Figure 206**

217. **Figure 207**

218. **Figure 208**

219. **Figure 209**

220. **Figure 210**

221. **Figure 211**

222. **Figure 212**

223. **Figure 213**

224. **Figure 214**

225. **Figure 215**

226. **Figure 216**

227. **Figure 217**

228.

NN5401 IDegAsp
Trial ID: NN5401-3645

Clinical Trial Report
Report Body

Date:
Version:

03 June 2011
1.0

Status:
Page:

Final
Page 2122 of 2239

Novo Nordisk

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color.

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, patterns, or variations in color or texture.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

The image consists of a single, uniform black rectangle that fills the entire frame. There are no discernible features, text, or patterns other than the solid black color.

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

1. **Introduction**

2. **Background**

3. **Methodology**

4. **Results**

5. **Discussion**

6. **Conclusion**

7. **References**

8. **Appendix**

9. **Index**

10. **Table of Contents**

11. **Abstract**

12. **Summary**

13. **Key Words**

14. **Keywords**

15. **Keywords**

16. **Keywords**

17. **Keywords**

18. **Keywords**

19. **Keywords**

20. **Keywords**

21. **Keywords**

22. **Keywords**

23. **Keywords**

24. **Keywords**

25. **Keywords**

26. **Keywords**

27. **Keywords**

28. **Keywords**

29. **Keywords**

30. **Keywords**

31. **Keywords**

32. **Keywords**

33. **Keywords**

34. **Keywords**

35. **Keywords**

36. **Keywords**

37. **Keywords**

38. **Keywords**

39. **Keywords**

40. **Keywords**

41. **Keywords**

42. **Keywords**

43. **Keywords**

44. **Keywords**

45. **Keywords**

46. **Keywords**

47. **Keywords**

48. **Keywords**

49. **Keywords**

50. **Keywords**

51. **Keywords**

52. **Keywords**

53. **Keywords**

54. **Keywords**

55. **Keywords**

56. **Keywords**

57. **Keywords**

58. **Keywords**

59. **Keywords**

60. **Keywords**

61. **Keywords**

62. **Keywords**

63. **Keywords**

64. **Keywords**

65. **Keywords**

66. **Keywords**

67. **Keywords**

68. **Keywords**

69. **Keywords**

70. **Keywords**

71. **Keywords**

72. **Keywords**

73. **Keywords**

74. **Keywords**

75. **Keywords**

76. **Keywords**

77. **Keywords**

78. **Keywords**

79. **Keywords**

80. **Keywords**

81. **Keywords**

82. **Keywords**

83. **Keywords**

84. **Keywords**

85. **Keywords**

86. **Keywords**

87. **Keywords**

88. **Keywords**

89. **Keywords**

90. **Keywords**

91. **Keywords**

92. **Keywords**

93. **Keywords**

94. **Keywords**

95. **Keywords**

96. **Keywords**

97. **Keywords**

98. **Keywords**

99. **Keywords**

100. **Keywords**

101. **Keywords**

102. **Keywords**

103. **Keywords**

104. **Keywords**

105. **Keywords**

106. **Keywords**

107. **Keywords**

108. **Keywords**

109. **Keywords**

110. **Keywords**

111. **Keywords**

112. **Keywords**

113. **Keywords**

114. **Keywords**

115. **Keywords**

116. **Keywords**

117. **Keywords**

118. **Keywords**

119. **Keywords**

120. **Keywords**

121. **Keywords**

122. **Keywords**

123. **Keywords**

124. **Keywords**

125. **Keywords**

126. **Keywords**

127. **Keywords**

128. **Keywords**

129. **Keywords**

130. **Keywords**

131. **Keywords**

132. **Keywords**

133. **Keywords**

134. **Keywords**

135. **Keywords**

136. **Keywords**

137. **Keywords**

138. **Keywords**

139. **Keywords**

140. **Keywords**

141. **Keywords**

142. **Keywords**

143. **Keywords**

144. **Keywords**

145. **Keywords**

146. **Keywords**

147. **Keywords**

148. **Keywords**

149. **Keywords**

150. **Keywords**

151. **Keywords**

152. **Keywords**

153. **Keywords**

154. **Keywords**

155. **Keywords**

156. **Keywords**

157. **Keywords**

158. **Keywords**

159. **Keywords**

160. **Keywords**

161. **Keywords**

162. **Keywords**

163. **Keywords**

164. **Keywords**

165. **Keywords**

166. **Keywords**

167. **Keywords**

168. **Keywords**

169. **Keywords**

170. **Keywords**

171. **Keywords**

172. **Keywords**

173. **Keywords**

174. **Keywords**

175. **Keywords**

176. **Keywords**

177. **Keywords**

178. **Keywords**

179. **Keywords**

180. **Keywords**

181. **Keywords**

182. **Keywords**

183. **Keywords**

184. **Keywords**

185. **Keywords**

186. **Keywords**

187. **Keywords**

188. **Keywords**

189. **Keywords**

190. **Keywords**

191. **Keywords**

192. **Keywords**

193. **Keywords**

194. **Keywords**

195. **Keywords**

196. **Keywords**

197. **Keywords**

198. **Keywords**

199. **Keywords**

200. **Keywords**

201. **Keywords**

202. **Keywords**

203. **Keywords**

204. **Keywords**

205. **Keywords**

206. **Keywords**

207. **Keywords**

208. **Keywords**

209. **Keywords**

210. **Keywords**

211. **Keywords**

212. **Keywords**

213. **Keywords**

214. **Keywords**

215. **Keywords**

216. **Keywords**

217. **Keywords**

218. **Keywords**

219. **Keywords**

220. **Keywords**

221. **Keywords**

222. **Keywords**

223. **Keywords**

224. **Keywords**

225. **Keywords**

226. **Keywords**

227. **Keywords**

228. **Keywords**

229. **Keywords**

230. **Keywords**

231. **Keywords**

232. **Keywords**

233. **Keywords**

234. **Keywords**

235. **Keywords**

236. **Keywords**

237. **Keywords**

238. **Keywords**

239. **Keywords**

240. **Keywords**

241. **Keywords**

242. **Keywords**

243. **Keywords**

244. **Keywords**

245. **Keywords**

246. **Keywords**

247. **Keywords**

248. **Keywords**

249. **Keywords**

250. **Keywords**

251. **Keywords**

252. **Keywords**

253. **Keywords**

254. **Keywords**

255. **Keywords**

256. **Keywords**

257. **Keywords**

258. **Keywords**

259. **Keywords**

260. **Keywords**

261. **Keywords**

262. **Keywords**

263. **Keywords**

264. **Keywords**

265. **Keywords**

266. **Keywords**

267. **Keywords**

268. **Keywords**

269. **Keywords**

270. **Keywords**

271. **Keywords**

272. **Keywords**

273. **Keywords**

274. **Keywords**

275. **Keywords**

276. **Keywords**

277. **Keywords**

278. **Keywords**

2

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
</								

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

Physical Examination Findings - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
------------	-----------	-----------	-----------	--------------	-------	-------------	--------	---------

The image is entirely black and contains no visible content.

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

Body Measurements - Safety Analysis Set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)
------------	-----------	-----------	-----------	-------	------------	------------------	--------------

15 Reference List

- 1 World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects - Last amended by the 59th WMA General Assembly, Seoul 2008.
<http://www.wma.net/e/policy/b3.htm>. 2008.
- 2 ICH Harmonised Tripartite Guideline Guideline for Good Clinical Practice.
<http://www.ich.org/LOB/media/MEDIA482.pdf>. 5-1-1996.
- 3 ICH Harmonised Tripartite Guideline Guideline for Good Clinical Practice.
<http://www.ich.org/LOB/media/MEDIA482.pdf>. 5-1-1996.
- 4 Effect of intensive therapy on the microvascular complications of type 1 diabetes mellitus. JAMA 2002; 287(19):2563-2569.
- 5 The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. New Engl J Med 1993; 329(14):977-986.
- 6 Nathan DM, Buse JB, Davidson MB, Ferrannini E, Holman RR, Sherwin R et al. Management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: update regarding thiazolidinediones: a consensus statement from the American Diabetes Association and the European Association for the Study of Diabetes. Diabetes Care 2008; 31(1):173-175.
- 7 Lantus - Summary of Product Characteristics.
<http://www.emea.europa.eu/humandocs/Humans/EPAR/lantus/lantus.htm>. 11-28-2008.
- 8 Lantus - U.S. Label information.
<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&searchTerm=021081&SearchType=BasicSearch>. 4-25-2007.
- 9 Levemir - Summary of Product Characteristics.
<http://www.emea.europa.eu/humandocs/Humans/EPAR/levemir/levemir.htm>. 5-25-2008.
- 10 Levemir - U.S. Label Information.
<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&searchTerm=021536&SearchType=BasicSearch>. 10-19-2005.
- 11 Novo Nordisk A/S. Investigator's Brochure, SIAC (4th Edition). SIAC. 3-23-2009.
- 12 Heise T, Hermanski L, Nosek L, Feldmann A, Rasmussen S, Stryhn TK et al. Insulin degludec: less pharmacodynamic variability than insulin glargine under steady state conditions. Diabetologia 53 (Suppl1), S387. 2010.
- 13 Kurtzhals P, Havelund S, Jonassen I, Kiehr B, Larsen UD, Ribel U et al. Albumin binding of insulins acylated with fatty acids: characterization of the ligand-protein interaction and correlation between binding affinity and timing of the insulin effect in vivo. Biochem J 1995; 312(Pt 3):725-731.

- 14 Philis-Tsimikas A, Charpentier G, Clauson P, Ravn GM, Roberts VL, Thorsteinsson B. Comparison of once-daily insulin detemir with NPH insulin added to a regimen of oral antidiabetic drugs in poorly controlled type 2 diabetes. Clin Ther 2006; 28(10):1569-1581.
- 15 Heise T, Nosek L, Ronn BB, Endahl L, Heinemann L, Kapitza C et al. Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in people with type 1 diabetes. Diabetes 2004; 53(6):1614-1620.
- 16 Bartley PC, Bogoev M, Larsen J, Philotheou A. Long-term efficacy and safety of insulin detemir compared to Neutral Protamine Hagedorn insulin in patients with Type 1 diabetes using a treat-to-target basal-bolus regimen with insulin aspart at meals: a 2-year, randomized, controlled trial. Diabet Med 2008; 25(4):442-449.
- 17 Levemir - Summary of Product Characteristics.
<http://www.emea.europa.eu/humandocs/Humans/EPAR/levemir/levemir.htm>. 5-25-2008.
- 18 Levemir - U.S. Label Information.
<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&searchTerm=021536&SearchType=BasicSearch>. 10-19-2005.
- 19 Home PD, Lindholm A, Riis A. Insulin aspart vs. human insulin in the management of long-term blood glucose control in Type 1 diabetes mellitus: a randomized controlled trial. Diabet Med 2000; 17(11):762-770.
- 20 Lindholm A, McEwen J, Riis AP. Improved postprandial glycemic control with insulin aspart. A randomized double-blind cross-over trial in type 1 diabetes. Diabetes Care 1999; 22(5):801-805.
- 21 Raskin P, Guthrie RA, Leiter L, Riis A, Jovanovic L. Use of insulin aspart, a fast-acting insulin analog, as the mealtime insulin in the management of patients with type 1 diabetes. Diabetes Care 2000; 23(5):583-588.
- 22 Bretzel RG, Arnolds S, Medding J, Linn T. A direct efficacy and safety comparison of insulin aspart, human soluble insulin, and human premix insulin (70/30) in patients with type 2 diabetes. Diabetes Care 2004; 27(5):1023-1027.
- 23 Gallagher A, Home PD. The effect of improved post-prandial blood glucose control on post-prandial metabolism and markers of vascular risk in people with Type 2 diabetes. Diabetes Res Clin Pract 2005; 67(3):196-203.
- 24 Perriello G, Pampanelli S, Porcellati F, Avogaro A, Bosi E, Petrella G et al. Insulin aspart improves meal time glycaemic control in patients with Type 2 diabetes: a randomized, stratified, double-blind and cross-over trial. Diabet Med 2005; 22(5):606-611.
- 25 NovoRapid - Summary of Product Characteristics.
<http://www.emea.europa.eu/humandocs/Humans/EPAR/novorapid/novorapid.htm>. 4-23-2008.

- 26 NovoLog - U.S. Label information.
<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&searchTerm=020986&SearchType=BasicSearch>. 11-28-2008.
- 27 Boston MLB&C. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. NYHA - New York Heart Association 1994;(9th Ed.):253-256.
- 28 ADA - American Diabetes Association. Defining and reporting hypoglycemia in diabetes: a report from the American Diabetes Association Workgroup on Hypoglycemia. Diabetes Care 2005; 28(5):1245-1249.
- 29 ICH Harmonised Tripartite Guideline Guideline for Good Clinical Practice.
<http://www.ich.org/LOB/media/MEDIA482.pdf>. 5-1-1996.
- 30 Food and Drug Administration, Code of Federal Regulations, Guidance for Industry, Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention. Draft Guidance. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071624.pdf>. 2008.
- 31 CPMP/EWP/482/99 - Points to consider on switching between superiority and non-inferiority. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003658.pdf. 2-27-2000.
- 32 ICH Harmonised Tripartite Guideline. Statistical principles for clinical trials E9. International Conference on Harmonisation E9 Expert Working Group.
<http://www.ich.org/LOB/media/MEDIA485.pdf>. 2-5-1998.
- 33 Bartley PC, Bogoev M, Larsen J, Philotheou A. Long-term efficacy and safety of insulin detemir compared to Neutral Protamine Hagedorn insulin in patients with Type 1 diabetes using a treat-to-target basal-bolus regimen with insulin aspart at meals: a 2-year, randomized, controlled trial. Diabet Med 2008; 25(4):442-449.
- 34 Heller S, Koenen C, Bode B. Comparison of insulin detemir and insulin glargine in a basal-bolus regimen, with insulin aspart as the mealtime insulin, in patients with type 1 diabetes: a 52-week, multinational, randomized, open-label, parallel-group, treat-to-target noninferiority trial. Clin Ther 2009; 31(10):2086-2097.
- 35 Bartley PC, Bogoev M, Larsen J, Philotheou A. Long-term efficacy and safety of insulin detemir compared to Neutral Protamine Hagedorn insulin in patients with Type 1 diabetes using a treat-to-target basal-bolus regimen with insulin aspart at meals: a 2-year, randomized, controlled trial. Diabet Med 2008; 25(4):442-449.