Clinical Trial Report

Trial ID: NN5401-3816

A trial investigating the efficacy and safety of insulin degludec/insulin aspart once daily plus insulin aspart for the remaining meals versus insulin detemir once or twice daily plus meal time insulin aspart in children and adolescents with type 1 diabetes mellitus

Trial phase: 3b

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1 Title page

Title of trial	A trial investigating the efficacy and safety of insulin degludec/insulin aspart once daily plus insulin aspart for the remaining meals versus insulin detemir once or twice daily plus meal time insulin aspart in children and adolescents with type 1 diabetes mellitus.
Trial ID	NN5401-3816
Development phase	Phase 3b
UTN	U1111-1133-0958
ClinicalTrials.gov Identifier	NCT01835431
IND number (US only)	073198
EudraCT number	2012-003566-41
Japanese trial registration number	Not applicable
Trial product	Insulin degludec/insulin aspart (IDegAsp)
Indication	Diabetes mellitus
Investigators	There were 63 principal Investigators in the trial. The following was appointed as the signatory Investigator for the trial: [redacted]
Trial sites	The trial was conducted at 63 sites in 14 countries as follows: Belgium: 3 sites; Brazil: 1 sites; Canada: 3 sites; Czech Republic 3 sites; Croatia: 2 sites; Israel: 6 sites; Macedonia: 2 sites; Poland: 3 sites; Russian Federation: 5 sites; Serbia: 4 sites; Slovenia: 1 sites; South Africa: 2 sites; Spain: 5 sites; and Unites States: 23 sites.
Trial initiated	17 October 2013.
Trial completed	07 November 2014
Sponsor	Novo Nordisk A/S Vandtaarnsvej 114, Soeborg, 2860 Denmark
Responsible medical officer	[redacted] Novo Nordisk A/S
Responsible trial managers	[redacted] Novo Nordisk A/S [redacted] Novo Nordisk A/S

Responsible statistician	[redacted] Novo Nordisk Service Centre India Private Ltd.
Responsible medical writers	[redacted] Novo Nordisk A/S. [redacted] Novo Nordisk A/S.
Data cut-off date	26 November 2014
Report date(s)	27 March 2015

The trial was conducted in accordance with the Declaration of Helsinki[1] and ICH Good Clinical Practice[2] and 21 CFR 312.120.

2 Synopsis

Please refer to separate document.

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4 List of abbreviations and definition of terms

ADA	American Diabetes Association
AE	adverse event
ALAT	alanine aminotransferase
ANOVA	analysis of variance
AP	alkaline phosphatase
ASAT	aspartate aminotransferase
BG	blood glucose
BID	*bis in die* (twice daily)
BMI	body mass index
CFR	US Code of Federal Regulations
CLAE	clinical laboratory adverse events
CRF	case report form
CRO	contract research organisation
CV%	coefficient of variation
DBL	database lock
DM	diabetes mellitus
DMC	data monitoring committee
DUN	dispensing unit number
eCRF	electronic case report form
EDC	electronic data capture
EMA	European Medicines Agency
EU	European Union
FAS	full analysis set
FDA	US Food and Drug Administration
FPFV	first patient first visit
FPG	fasting plasma glucose
GCP	Good Clinical Practice
HbA_{1C}	glycosylated haemoglobin
HCG	human chorionic gonadotropin
HDL	high density lipoprotein
IAsp	insulin aspart
IB	Investigator's Brochure
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDeg	insulin degludec
IDegAsp	insulin degludec/insulin aspart
IDet	insulin detemir (Levemir®)
IEC	independent ethics committee
IRB	institutional review board

ISO	International Organisation for Standardisation
ISPAD	International Society for Pediatric and Adolescent Diabetes
IV/WRS	interactive voice/web response system
ITT	intent-to-treat
LDL	low density lipoprotein
LKF	Laboratorium für Klinische Forschung GmbH
LOCF	last observation carried forward
MAR	missing at random
MedDRA	Medical Dictionary for Regulatory Activities
MESI	medical event of special interest
MMRM	mixed model for repeated measurements
NPH	neutral protamine Hagedorn
OAD	oral antidiabetic drug
OD	once daily
PDCO	Paediatric Committee, European Medicines Agency
PG	plasma glucose
PIP	paediatric investigational plan
PP	per-protocol
PRC	protocol review committee
PT	preferred term
SAE	serious adverse event
SAP	statistical analysis plan
SAS	safety analysis set
SD	standard deviation
SIF	safety information form
SmPC	summary of product characteristics
SMPG	self-measured plasma glucose
SOC	system organ class
SUSAR	suspected unexpected serious adverse reaction
TEAE	treatment emergent adverse event
T1DM	type 1 diabetes mellitus
T2DM	type 2 diabetes mellitus
TTT	treat to target
UTN	universal trial number

5 Ethics

5.1 Independent Ethics Committees or Institutional Review Boards

Prior to trial initiation, the protocol, the protocol amendment(s), the consent form, the child assent form and the subject information sheet and other information provided to the subject and parent(s)/subject's legal representative were reviewed and approved according to local regulations by appropriate health authorities, and by an independent ethics committees (IECs)/Institutional Review Boards (IRBs). The IEC is a review panel responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation, which was adequately constituted to provide assurance of that protection (see Appendix 16.1.3).

A list of the IECs and/or IRBs that reviewed and approved the protocol, amendments, and subject information and consent forms is provided in Appendix 16.1.3, including the dates of approval.

During the trial, the Investigator or sponsor (as applicable) was to promptly report the following to the IRB/IEC, in accordance with local requirements:

- Updates to IB
- Unexpected SAEs where a causal relationship cannot be ruled out (SUSARs)
- Amendments to the protocol
- Amendments according to local requirements
- Deviations to the protocol implemented to eliminate immediate hazards to the subjects
- New information that may affect adversely the safety of the subjects or the conduct of the trial (including new risk/benefit analysis in case it will have an impact on the planned follow-up of the subjects)
- Annually written summaries of the trial status
- Other documents as required by the local IRB/IEC.

Protocol amendments were not implemented before IRB/IEC approval/favourable opinion.

5.2 Ethical conduct of the trial

The trial was conducted in accordance with Declaration of Helsinki[1] and ICH Good Clinical Practice[2].

The 21 Code of Federal Regulations (CFR), parts 312, 50, and 56 were followed.

The trial was conducted in accordance with FDA 21 CFR 312.120.

5.3 Subject information and consent

Subject in this trial comprised the child and the parent(s) or legal representative.

Prior to any trial related activity, the Investigator gave the subject and parent(s) or the subject's legal representative oral and written information about the trial in a form that the subject and parent(s)/subject's legal representative could read and understand. This included the use of impartial witness where required.

The requirement for obtaining a subject's legal representative consent was that the subject and/or parent(s) were unable to provide informed consent, and the process had been approved by the relevant IRB/IEC.

A voluntary, signed and personally dated informed consent form was to be obtained from the subject and parent(s)/subject's legal representative prior to any trial-related activity.

If there was a local requirement for a Child Assent form, this was also to be signed and dated by the child, as age appropriate, and the parent(s)/legal representative.

All subjects and parent(s)/legal representatives were to be provided with a copy of their own signed and dated Informed Consent form and, if applicable, Child Assent form.

The responsibility for seeking informed consent was to remain with the Investigator or an adequately medically qualified person delegated by the Investigator. The written informed consent was to be signed and personally dated by the person obtaining the informed consent.

In case of appearance of information relevant for the subject's willingness to continue participating in the trial, the Investigator was to inform the subject and parent(s)/subject's legal representative in a timely manner and obtain a revised written informed consent.

The subjects and parent(s)/subject's legal representative were to be informed that they could withdraw from the trial at any time for any reason. Consent was obtained in writing prior to any trial related activities and the Investigators retained the consent forms.

The consent forms were available to Novo Nordisk 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.

There were notable variations to the master subject information/informed consent (SI/IC) forms in 5 countries (Poland, Spain, Brazil, Israel and United States). These forms are presented in Appendix 16.1.3.

6 Investigators and trial administrative structure

Trial sites

The trial was conducted at 63 sites in 14 countries. All sites that screened subjects also randomised subjects. The distribution was as follows:

- Belgium: 3 sites
- Brazil: 1 site
- Canada: 3 sites
- Croatia: 2 sites
- Czech Republic: 3 sites
- Israel: 6 sites
- Macedonia: 2 sites
- Poland: 3 sites
- Russian Federation: 5 sites
- Serbia: 4 sites
- Slovenia: 1 site
- South Africa: 2 site
- Spain: 5 sites
- United States: 23 sites

In addition to the trial sites listed above, the following numbers of trial sites were approved by the IRB/IEC and/or local health authority, but did not screen any subjects or randomise/assign any subjects to treatment:

- Brazil: 1 site
- Canada: 1 site
- United States: 2 sites

For each investigational site, the adequacy of the research facility to execute the protocol requirements was confirmed by the monitor prior to site initiation and any trial activities.

According to the protocol subjects from India were planned to participate in the trial. However, a complete approval was not received from the Indian health authorities in due time and therefore no subjects were recruited.

A complete overview of all sites, including the principal Investigator(s) and sub-Investigator(s), is provided in the List of Investigators in Appendix 16.1.4. Curricula vitae for Investigators and specialised medical personnel are provided in Appendix 16.1.4 for all sites that screened subjects.

The following Investigator was designated signatory investigator for the trial, and was responsible for reviewing and approving this clinical trial report.

[redacted]

The signature is provided in Appendix 16.1.5.

Sponsor

Novo Nordisk A/S was responsible for:

- Preparing the protocol
- Preparation of electronic case report forms (eCRF) and relevant paper CRF forms
- Providing a trial specific interactive voice/web response system (IV/WRS)
- Supply of trial products and stated equipment
- Monitoring the trial
- Data management
- Titration surveillance
- Safety surveillance
- Performing the statistical analyses
- Preparing the clinical trial report
- Monitoring customer complaints (Customer complaint center)
- Preparing subject diaries

Central/Special laboratory facilities and contract organisations

Name	Address	Responsibility
Central laboratory		
[redacted]		All laboratory analyses except FPG analysis
Special laboratories		
[redacted]		FPG blood sampling
EDC		
[redacted]		eCRF vendor
IV/WRS		
[redacted]		IV/WRS supplier

eCRF: electronic case report form; EDC: electronic data capture system; IV/WRS: interactive voice/web response system; FPG: fasting plasma glucose.

Special committees

Novo Nordisk A/S safety committee

Novo Nordisk constituted an internal safety committee to perform ongoing safety surveillance. This included monitoring of blinded laboratory data despite it being an open label trial. The committee could recommend unblinding of any data for further analysis. If so, an independent ad hoc group were to be established to maintain the blinding of the study group. The purpose of an ad hoc safety group was to review unblinded data and based on analyses recommend further action to the safety committee.

Data monitoring committee

An independent external data monitoring committee (DMC) was established with specialists in paediatrics and endocrinology to review and evaluate accumulated unblinded data, independent of Novo Nordisk, in order to protect the safety of the subjects and to evaluate the

evolving risk-benefit if required. Based on this, recommendations to continue, modify, or terminate the trial could be provided. The DMC only had direct contact with a Novo Nordisk safety adviser and no direct interaction with trial management.

Novo Nordisk Insulin Titration Group

Titration of trial product was monitored by the internal Novo Nordisk Insulin Titration Group.

7 Introduction

7.1 Background

7.1.1 Therapeutic area

Diabetes mellitus (DM) is characterised by chronic hyperglycaemia and encompasses various metabolic disorders. It is generally classified according to aetiological factors, where type 1 and type 2 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 (T1DM) 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[3] have demonstrated the importance of maintaining tight glycaemic control to reduce the risk of long-term complications associated with T1DM. An $HbA_{1c} < 7\%$, without significant hypoglycaemia, is a well-accepted glycaemic target for non-pregnant adults[4]. According to the International Society for Pediatric and Adolescent Diabetes (ISPAD), glycaemic targets for children should be individualized in order to achieve glucose values as close to normal range as possible while minimizing the risk of hypoglycaemia. As a general guideline, ISPAD recommends a target HbA_{1c} of < 7.5% in all paediatric age groups[5].

A reduced risk of hypoglycaemia is particularly relevant for the paediatric population where episodes are often asymptomatic, difficult to detect and thus a challenge to correct[6]. The pathophysiology of T1DM appears to be comparable between adults and paediatric subjects.

7.1.2 IDegAsp

Insulin degludec/insulin aspart (IDegAsp: trade name Ryzodeg®) is a co-formulation of the long-acting insulin degludec (IDeg), and rapid-acting insulin aspart (IAsp)[NovoLog®/NovoRapid®]. The IDegAsp co-formulation used in therapeutic confirmatory trials consists of 70% IDeg and 30% IAsp. In the co-formulation of IAsp and IDeg, the benefits of the long-acting IDeg and the rapid-acting IAsp are combined in one injection, with each component acting independently.

7.1.3 IDegAsp in adults

In adults with T1DM treated with IDegAsp once daily (OD) plus mealtime IAsp for the remaining meals in comparison with basal-bolus treatment with insulin detemir (IDet) plus mealtime IAsp, IDegAsp OD in combination with IAsp effectively improved long-term glycaemic control after 26 weeks (trial NN5401-3594) and 52 weeks of treatment (trial NN5401-3645) as measured by reduction in HbA_{1c}. Non-inferiority of IDegAsp vs. comparator was confirmed. A statistically significantly lower rate of nocturnal confirmed hypoglycaemia was achieved with IDegAsp OD + IAsp relative to IDet + IAsp at similar levels of fasting plasma glucose (FPG). There was no statistically significant difference in the rates of overall confirmed or severe hypoglycaemia. Based on an assessment of clinical safety data from all completed clinical trials, IDegAsp appears to be

safe and well tolerated. Overall, the adverse event (AE) profile was similar with IDegAsp and comparator and no clustering or unexpected patterns in the reported AEs or serious adverse events (SAEs) were seen.

7.1.4 IDegAsp in paediatric population

A clinical pharmacology trial (NN5401-1982) investigated the pharmacokinetic and pharmacodynamic properties of IDegAsp (0.5 U/kg) after a single dose in children (6–11 years) and adolescents (12-17 years) in comparison to adults (18-65 years) with T1DM. With IDegAsp, the between-subject variability in IAsp and IDeg exposure was higher in children than in adults. However, insulin exposure has previously been shown to depend on age[7-9], and the results underline the importance of individual dose adjustment for IDegAsp, as with all other insulin products. Total exposure to the IAsp component in IDegAsp in the first 12 hours ($AUC_{IAsp,0\text{-}12h,SD}$) and maximum concentration ($C_{max,IAsp,SD}$) were higher in children than in adults, and were similar for adolescents and adults. Total exposure of the IDeg component in IDegAsp ($AUC_{IDeg,0\text{-}\infty,SD}$) tended to be higher for children than adults, and was similar for adolescents and adults. Total glucose-lowering effect of IDegAsp after a standard meal ($AUC_{PG\text{-}baseline,0\text{-}6h,meal,SD}$) was similar in children, adolescents and adults. IDegAsp was well tolerated and no unexpected safety issues were identified in this trial.

The basal insulin component of IDegAsp, IDeg, as marketed under the trade name Tresiba® in EU, has recently been approved for use in adolescents and children from 1 year old. Thus, IDeg is approved in EU for treatment of DM in adults, adolescents and children from 1 year old. IDeg has been investigated in the paediatric population from the age of 1 year old in trial NN1250-3561. In that trial, no unexpected safety issues were identified with IDeg with respect to AEs and standard safety parameters.

NN5401-3816 is the first therapeutic confirmatory trial with IDegAsp in the paediatric population.

7.1.5 Insulin detemir (Levemir®)

IDet (trade name: Levemir®) was used as comparator in this trial and is a long-acting insulin analogue approved for the treatment of DM. It is indicated and widely used for the treatment of DM in children down to 2 years of age. Novo Nordisk has conducted a paediatric trial (NN1250-3561) including subjects down to 1 year of age using IDet as comparator to IDeg. No unexpected safety issues were identified in the trial population.

7.1.6 Insulin aspart (NovoRapid®/ Novolog®)

This is a rapid-acting insulin analogue indicated for the treatment of DM in adults as well as children and adolescents aged 2 to 17 years. It can be used in children in preference to soluble human insulin when a rapid onset of action might be beneficial, e.g. in the timing of the injections in relation to meals. Novo Nordisk has conducted a paediatric trial (NN1250-3561) including

subjects down to 1 year of age using IAsp as mealtime insulin. No unexpected safety issues were identified in the trial population.

7.2 Rationale for trial

This trial was conducted in agreement with the European Medicines Agency (EMA) Paediatric Committee (PDCO) as a binding element of the Paediatric Investigation Plan (PIP) for IDegAsp to investigate the efficacy and safety of IDegAsp OD in children and adolescents with T1DM. Fulfilment of the binding elements in the PIP agreed upon with EMA (PDCO) is part of the EU requirement for marketing authorization of IDegAsp.

Although several marketed insulin products can be used by paediatric patients with T1DM, there is still a need for refinement of these products to more closely resemble the physiological action profile of endogenous insulin and to minimize unwanted side effects. The pathophysiology of T1DM appears to be comparable between adults and paediatric patients, and consequently the benefits of IDegAsp treatment for adults are believed to be reflected in the treatment of children and adolescents with the product.

8 Trial objectives

As stated in the protocol and amendments (included in Appendix 16.1.1), the objectives of the trial were:

Primary objective

To confirm the efficacy of IDegAsp administered once daily plus meal-time IAsp for the remaining meals in controlling glycaemia with respect to change from baseline in HbA_{1c} after 16 weeks of treatment. This is done by comparing the difference in change from baseline in HbA_{1c} between IDegAsp + meal-time IAsp for the remaining meals and IDet + meal-time IAsp to a non-inferiority limit of 0.4%, and if non-inferiority is confirmed, to a superiority limit of 0%.

Secondary objective

To compare the efficacy and safety between the two treatment groups.

9 Investigational plan

9.1 Description of trial design

Trial design

Trial 3816 was a 16-week multi-national, multi-centre, open-label, two-arm, parallel group, randomised, treat-to-target (T-T-T), efficacy and safety trial comparing treatment with IDegAsp OD, with a main meal + IAsp for the remaining meals vs. IDet + meal-time IAsp in children and adolescents with T1DM between 1 and less than 18 years of age.

Following screening, the subjects were randomised 1:1 to the treatment groups and stratified by the age groups: 1 year to < 6 years; 6 years to <12 years; and 12 years <18 years. The stratification was employed to ensure an approximately equal distribution of subjects between the treatment groups within each age group.

During the trial treatment period, all subjects were titrated according to the Insulin Titration Guideline Protocol Appendix A (Appendix 16.1.1). The total trial duration for the individual subjects was approximately 18 weeks. The trial included a screening visit (Visit 1), followed by a 16-week randomised treatment period and a follow-up visit (Visit 19) 7−12 days after the actual date of the last treatment visit (Visit 18).

The key efficacy parameters were HbA_{1c}, FPG and self-measured plasma glucose (SMPG) profiles. The key safety parameters were incidence of hypoglycaemia, incidence of hyperglycaemia, adverse events, safety laboratory parameters, body weight/BMI, vital signs and insulin dose.

The trial design is shown schematically in Figure 9–1.

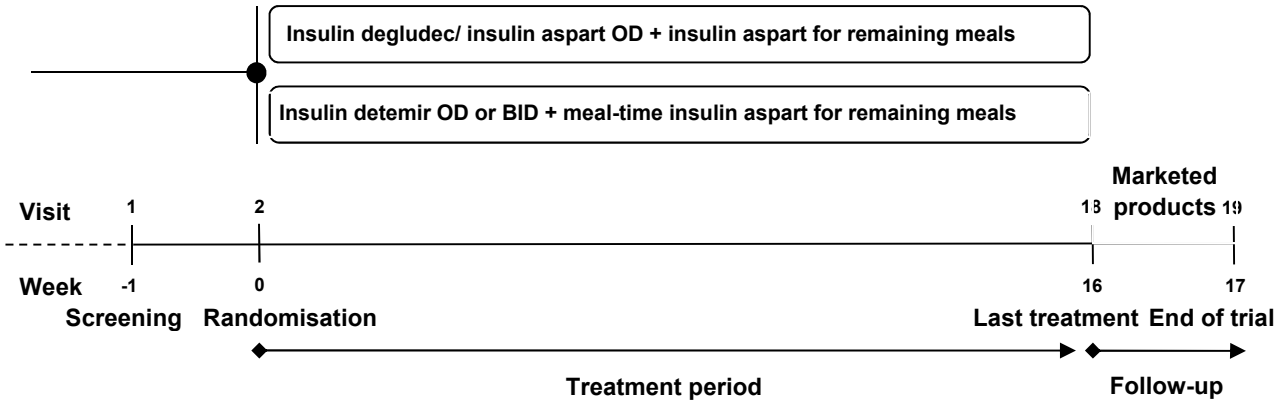


Figure 9–1 Trial design

Please see Section 9.5.1.1 for a detailed flow chart summarising the frequency and timing of visits and the assessments performed at each visit.

Trial population

A total of 346 subjects were planned for enrolment. Subjects were aged 1 to < 18 years at randomisation and diagnosed with type 1 diabetes. For details on the planned trial population, see Section 9.3. In accordance with the approved PIP, at least 60 randomised subjects had to be younger than 6 years at inclusion. Additionally at least 30% and not more than 70% were to be girls.

Subject selection was based on the inclusion and exclusion criteria listed in Sections 9.3.1 and 9.3.2, respectively. Subjects who met all of the inclusion criteria and none of the exclusion criteria were eligible to participate in the trial.

Interim analyses

No interim analyses were performed during the trial.

9.2 Discussion of trial design

Rationale for the trial design

A randomised, open-label trial was chosen since the two treatment regimens require different number of daily injections. The two-arm parallel design was chosen instead of a cross-over design in order to keep the treatment period as short as possible and to avoid carry-over effect. The primary endpoint HbA_{1c} is a laboratory parameter and consequently the probability of assessment bias was limited. The multi-national approach was conducted to strive for results applicable for subjects with different demographic characteristics.

The trial design was agreed upon with EMA (PDCO) as a binding element of the PIP for IDegAsp.

The trial was designed in accordance with requirements for adequate and well-controlled trials[10].

Rationale for the trial population

T1DM is among the most common chronic diseases in childhood and adolescence. Children and adolescents with T1DM are dependent on insulin for survival. Data from the Diabetes Control and Complication Trial[3] shows that intensive treatment is beneficial in terms of reducing the risk for long term complications. ISPAD recommends that all children with diabetes should achieve the lowest HbA_{1c} that can be sustained without disabling or severe hypoglycaemia[11]. This trial offers an opportunity to assess whether the efficacy and safety profile of IDegAsp OD can be demonstrated in the paediatric population with T1DM.

A rise in the incidence of T1DM has been noted in many countries, and in some reports there has been a disproportionately greater increase in children under 5 years, acquiring T1DM[12]. Thus, inclusion of the very young age groups in this trial is required by EMA (PDCO). Infants below the age of 1 year were not eligible for this trial since most cases of diabetes diagnosed below the age of 1 year, are cases of neonatal diabetes which is a different type of diabetes requiring management beyond the capacity of this trial.

See Section 9.3 for further details regarding selection criteria for the trial population.

Rationale for the treatment

The T-T-T approach with frequent contacts throughout the trial was chosen to ensure optimal insulin dosing based on SMPG values and improvement in glycaemic control.

IDegAsp OD and BID is efficacious in terms of lowering HbA_{1c} in the majority of clinical trials both in subjects with T1DM and T2DM. A similar or lower rate of confirmed hypoglycaemic episodes was seen with IDegAsp than with comparator in trials where comparator treatment included prandial insulin. IDegAsp is well tolerated with an AE profile similar to that of other marketed insulin products and no unexpected findings or unacceptable risks have been identified.

Based on the glycaemic response in the previous IDegAsp trials, 16 weeks of treatment were considered sufficient for assessing the efficacy and safety of IDegAsp OD in the paediatric population with T1DM.

IAsp is a marketed product, commonly used as meal-time insulin therapy and therefore selected as mealtime insulin in both treatment groups for this trial.

Comparator

IDet was chosen as the comparator. It is widely used and is indicated in the EU and the US for use in children down to 2 years of age.

Detailed information is available in the current edition of the IB for IDegAsp, any updates hereof, and in the current product information for IDet and for IAsp. Novo Nordisk has conducted a paediatric trial (NN1250-3561) with IDet + IAsp as comparator, including subjects down to 1 year of age. No unexpected safety issues were identified in the trial population.

See Section 9.3.4 for further details regarding the treatments.

9.3 Selection of trial population

9.3.1 Inclusion criteria

1. Informed consent obtained before any trial related activities. Trial related activities are any procedures that are carried out as part of the trial, including activities to determine suitability for the trial.
2. Subjects diagnosed with T1DM
3. Age: 1 to <18 years of age at randomisation
4. Ongoing daily treatment with insulin (any regimen including Continuous Subcutaneous Insulin Infusion) for at least 3 months prior to visit 1
5. Total daily dose of insulin: ≤ 2 U/kg
6. HbA_{1c} ≤ 11.0%
7. Ability and willingness to adhere to the protocol including performance of 4-point and 8-point plasma glucose profiles according to the protocol (child and parent(s) should be evaluated as one)

9.3.2 Exclusion criteria

1. Known or suspected hypersensitivity to trial products or related products
2. Use of oral antidiabetic agents
3. Previous participation in this trial. Participation is defined as screened
4. Receipt of any trial product within 1 month prior to visit 1

5. Female of child-bearing potential who is pregnant, breast-feeding, intends to become pregnant or is not using adequate contraceptive methods. (Adequate contraceptive measures as required by local law or practice*)*
6. Known hypoglycaemic unawareness or recurrent severe hypoglycaemic events as judged by the Investigator
7. More than 1 episode of diabetic ketoacidosis requiring hospitalisation within the last 3 months prior to visit 1
8. Any chronic disorder or significant concomitant disease, which in the Investigator's opinion might jeopardise the subject's safety or compliance with the protocol
9. Mental incapacity, unwillingness or language barriers, precluding adequate understanding or cooperation (child and parent(s) should be evaluated as a unit)
10. Suffering from a life threatening disease (e.g. malignant cancer)

9.3.3 Withdrawal criteria

A subject was to be withdrawn if the following applied:

1. The parent(s) or legal representative(s) of the subject withdraw informed consent at will at any time
2. Investigator decision to withdraw subject from the trial due to a safety concern or if judged non-compliant with trial procedures
3. Randomised in error (not fulfilling the inclusion and/or fulfilling exclusion criteria)
4. Pregnancy or intention of becoming pregnant
5. Participation in other intervention trials during the trial
6. Development of any life threatening disease (e.g. cancer)
7. Initiation or significant change of any systemic treatment which in the Investigator's opinion could interfere with glucose metabolism (inhaled corticosteroids are allowed)

A withdrawn subject was to be called in for the end of treatment visit (visit 18) and if possible for the follow-up visit (visit 19) 7−12 days after last treatment.

Subjects who were withdrawn after randomisation were not to be replaced. See Section 9.7.5 for details on the power calculation.

9.3.4 Screening failures

If the subject was ineligible to participate in the trial the subject was considered a screening failure. Consequently, a screen failure session was to be performed using the IV/WRS, and the following eCRF as minimum completed: Screening failure form (with reason for not continuing in the trial), visit 1 Informed Consent/Demography and visit 1 Inclusion/Exclusion criteria and AE form (if applicable).

SAEs from screening failures were to be transcribed by the Investigator into the eCRF.

9.4 Treatments

9.4.1 Treatments administered

At visit 2 subjects discontinued their current diabetes treatment and were to be randomised into one of two treatment groups as outlined in Figure 9–1.

IDegAsp was to be administered subcutaneously in the thigh, upper arm (deltoid area) or abdomen OD in connection with a main meal. The dosing time could be moved to a different main meal at any time during the trial.

IDet was to be administered subcutaneously according to local labelling. Subjects randomised into the IDet treatment group continued with their pre-trial dosing scheme (OD or BID) and were allowed to switch from OD to BID dosing. IDet is not currently approved for children below the age of 2 years and therefore in this trial IDet was used under careful medical supervision for this age group. This was in line with current practice for this age group. However, Novo Nordisk has conducted a paediatric trial (NN1250-3561) including subjects down to 1 year of age. No unexpected safety issues were identified in the trial population.

IAsp was to be administered subcutaneously according to local labelling as mealtime insulin. IAsp is not currently approved for children below the age of 2 years and therefore in this trial IAsp was used under careful medical supervision for this age group. IAsp was also used meal-time insulin in trial NN1250-3561 described above.

At the last treatment visit (visit 18), after 16 weeks of trial product exposure, subjects were to be instructed to switch to suitable marketed products as recommended by the Investigator.

Detailed guidance on switching from pre-trial basal and bolus insulin to the randomised treatment can be found in the Insulin Titration Guideline in the protocol (Appendix 16.1.1). Titration of insulin was performed regularly in accordance with the T-T-T titration guidelines for insulin products. These guidelines are based on experience from previous studies with IDegAsp in adults with T1DM, and from studies with IDet in the paediatric population with T1DM. The titration was monitored by the Novo Nordisk Insulin Titration Group.

9.4.2 Identity of investigational products

Trial products

The following was defined as trial products for subcutaneous injection for use in this trial:

- insulin degludec/insulin aspart (IDegAsp) 100 U/mL, 3 mL Penfill® cartridge
- insulin aspart (IAsp) 100 U/mL, 3 mL Penfill® cartridge (NovoRapid®/ NovoLog®, Novo Nordisk)
- insulin detemir (IDet) 100 U/mL, 3 mL Penfill® cartridge (Levemir®, Novo Nordisk)

Devices which permit 0.5 Unit dosing increments were to be available to administer all trial products.

For the US:

- IDegAsp and IDet were to be administered with Novopen Junior® (green pen)
- IAsp was to be administered with Novopen Junior® (yellow pen)

For the remaining countries:

- IDegAsp and IDet were administered with Novopen Echo® (green pen)
- IAsp was administered with Novopen Echo® (orange pen)

Novo Nordisk A/S Denmark provided the trial products.

Storage and handling of trial products were to be in accordance with local labelling (if applicable) or as defined below. Trial products both in-use and not in-use were not to be exposed to excessive heat or direct sunlight.

Prior to use, IDegAsp was to be stored in a refrigerator (2°C to 8°C), protected from light and not frozen. Once in use, it was not to be refrigerated or stored above 30°C and used within 4 weeks.

Prior to use, IDet was to be stored in a refrigerator (2°C to 8°C), protected from light and not frozen. Once in use, it was not to be refrigerated or stored above 30°C, and used within 6 weeks. The cap on the pen was to be kept on when not in use to protect from light.

Prior to use, IAsp was to be stored in a refrigerator (2°C to 8°C), protected from light and not frozen. Once in use, it was not to be refrigerated, frozen or stored above 30°C and used within 4 weeks. The cap on the pen was to be kept on when not in use to protect from light.

Batch numbers and expiry

The batch numbers are presented in Table 9–1. No trial products were used after expiry date.

Table 9–1 Trial products

Trial Product	Concentration	Batch Number	Expiry Date
insulin degludec/insulin aspart	100U/mL 3 mL penfill	CW58090	07-Nov-2015
insulin detemir	100U/mL 3 mL penfill	BW55450	24-Mar-2015
insulin aspart	100U/mL 3 mL penfill	CW58127	15-Nov-2015

Cross-reference: Appendix 16.1.6

An additional batch of insulin aspart with batch number BW54935 was registered in this trial, but was not dispensed to any subjects.

Packaging and labelling

Trial products were packaged and labelled by Novo Nordisk Denmark and provided in non-subject specific boxes. Labelling was in accordance with the relevant guidelines[13], local law and trial requirements. Each Investigator site was to be supplied with sufficient trial product for the trial on an ongoing basis controlled by the IV/WRS.

Dispensing/Administration

The trial products were to be dispensed to each subject as required according to treatment group. The IV/WRS was used to allocate trial products to the subject at each dispensing or randomisation visit. If additional trial product was needed, the IV/WRS was contacted in order to have correct medication allocated.

Instructions for use for the trial products were to be given to each subject at each dispensing visit (see Table 9–4).

Auxiliary supplies

The following were supplied by Novo Nordisk:

- Novopen Echo® (orange and green) and Novopen Junior® (green and yellow)
- Directions for use
- Needles for pens (Novofine®)
- Blood glucose meters, lancets, plasma-calibrated test strips, ketone strips and control solutions

9.4.3 Method of assigning subjects to treatment groups

At the randomisation visit (visit 2) eligible subjects (complying with all exclusion/inclusion criteria) were randomised to either IDegAsp or IDet, both in combination with meal-time IAsp. The randomisation was carried out in a 1:1 manner using IV/WRS. Subjects were assigned to the lowest available number allocated to the trial site. The subject number was a 6-digit number (XXXYYY), where XXX referred to the site number and YYY to the subject number at that site. Randomisation was stratified according to three age groups: 1 to less than 6 years; 6 to less than 12 years; and 12 to less than 18 years. Stratification was employed to ensure an approximately equal distribution of subjects between the treatment groups within each age group.

The randomisation scheme for the trial is provided in Appendix 16.1.7.

9.4.4 Doses in the trial

Both treatment groups used IAsp as their mealtime insulin. The starting dose of IDegAsp/IDet and IAsp for each subject was calculated according to the insulin titration guideline in the protocol (Appendix 16.1.1, Appendix A).

At randomisation the Investigator was to reduce the daily total insulin dose with 20 percent as per titration algorithm (Appendix 16.1.1, Appendix A) and aim to adjust the basal-bolus ratio to be between 50:50 and 30:70.

9.4.5 Selection and timing of doses

IDegAsp were to be administered OD with one of the main meals.

IDet could be administered OD or BID according to local labelling. Subjects initially treated with IDet OD may eventually need a second dose. Subjects on a BID regimen were to dose at breakfast and in the evening either at main evening meal or at bedtime. The second dose was to be considered if mean pre-breakfast plasma glucose (PG) reached target (5.0−8.0 mmol/L [90−145 mg/dL]) and mean pre-main evening meal PG > 8.0 mmol/L (145 mg/dL). The starting dose was to be 2−4 units. Titration of the second dose was to be in accordance with Table 9–2.

IAsp was to be given with the main meals, 2−4 times daily in subjects randomised to IDet and 1−3 times daily for subjects randomised to IDegAsp.

Titration of insulin was to be performed regularly in accordance with the titration algorithm in the Protocol (Appendix 16.1.1, Appendix A). The titration was monitored by a Novo Nordisk Internal Titration Group.

Titration of IDegAsp and IDet

Basal insulin titration was done according to the lowest pre-breakfast SMPG value measured on the three days prior to the visit/phone contact for IDegAsp and IDet OD. For IDet BID the morning

dose adjustment was to be based on the lowest pre-main evening meal SMPG value measured on the three days prior to the visit/phone contact, and the evening dose was to be based on the respective pre-breakfast SMPG values. During the trial, the IDegAsp dose could be switched from one meal to another for safety or efficacy reasons at the Investigator's discretion. For details, please see Table 9–2.

Table 9–2 Adjustment of IDegAsp and IDet

Current dose		**< 5U**	**5-15U**	**> 15U**
Pre-breakfast or pre-main evening meal plasma glucose		Adjustment (U)		
mmol/L	mg/dL			
< 5.0	< 90	-½	-1	-2
5.0-8.0	90-145	0	0	0
8.1-10.0	146-180	+½	+1	+2
10.1-15.0	181-270	+1	+2	+4
> 15.0	> 270	+1½	+3	+6

Bolus insulin

At randomisation (visit 2), the subjects were to switch to IAsp from previous bolus insulin doses according to the Protocol Appendix A (Appendix 16.1.1). The total dose could be divided into 2 to 4 daily doses.

IAsp titration was done once weekly based on the lowest of three SMPG values measured prior to the next meal and bedtime on the three days prior to the visit/phone contact:

- Pre-breakfast IAsp was to be adjusted according to lowest SMPG measured pre-lunch
- Pre-lunch IAsp was to be adjusted according to lowest SMPG measured before main evening meal
- Before main evening meal IAsp was to be adjusted according to lowest SMPG measured at bedtime

See Table 9–3 for further details.

Table 9–3 Adjustment of IAsp

Current bolus dose		≤ 5U	> 5U
Lowest pre-meal or bedtime plasma glucose		Adjustment (U)	
mmol/L	mg/dL		
< 5.0	< 90	-1	-2
5.0-8.0	90-145	0	0
8.1-10.0	146-180	+½	+1
10.1-15.0	181-270	+1	+2
> 15.0	> 270	+1½	+3

A third (in subjects receiving IDegAsp) or a fourth (in subjects receiving IDet) IAsp dose was allowed. No dose adjustment recommendation was provided. The dose was to be entered in the diary as "extra IAsp" dose.

Carbohydrate counting and correction factor for IAsp dose adjustment

Instead of the above titration guidance, IAsp could be titrated in accordance with principles of flexible dosing whereby the meal carbohydrate content and pre-prandial PG value are used to determine the bolus insulin dose. When using this method, bolus insulin dose adjustment is conducted multiple times daily in accordance with the insulin/carbohydrate ratio and the PG correction factor. This method was applicable to subjects and care takers who had demonstrated prior hands-on experience with utilizing this method of determining bolus insulin doses. It was the responsibility of the Investigator at visit 2 to ensure that the subject was adequately educated and comfortable with this method. If more training was needed, this was carried out according to local practice. More details of adjustment of IAsp doses using carbohydrate counting and correction factor are presented in protocol titration guideline in the Protocol Appendix A (Appendix 16.1.1).

9.4.6 Blinding

The treatment was open−labelled. Treatment was allocated using centralised IV/WRS.

The internal Novo Nordisk safety committee and the external data monitoring committee (DMC) reviewed safety data on an ongoing basis. The internal safety committee was blinded and the DMC was unblinded. External classification of severe hypoglycaemia was performed blinded.

9.4.7 Prior and concomitant therapy

Subjects had to be on insulin treatment (any regimen) for at least 3 months prior to visit 1. Prior use of oral antidiabetic drugs (OADs) was not permitted. During the trial, it was prohibited to initiate or significantly change any systemic treatment which in the Investigator's opinion could interfere with glucose metabolism, although inhaled corticosteroids were allowed, see Section 9.3.

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. At all visits, subjects were to return all used, partly used and unused trial products. The Investigator was to assess the unused amount of trial products against the prescribed amount and, in case of discrepancies, question the subject. 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. Substantial failure to comply with the insulin regimen could lead to withdrawal.

9.5 Efficacy and safety variables

9.5.1 Efficacy and safety measurements assessed and trial flow chart

9.5.1.1 Trial flow chart

Table 9–4 Trial flow chart – clinic visits

Trial NN5401-3816 – Type 1	**Screen**	**Rand**	**16 weeks**						**Follow up**
Visit Number (V)	**V1**	**V2**	**V3**	**V4**	**V6**	**V10**	**V14**	**V18**	**V19[3]**
☎ Phone Contact number (P) (For details see separate flow chart)					P5	P7 P8 P9	P11 P12 P13	P15 P16 P17	
Time of visit (weeks)[1]	**-1[2]**	**0**	**1**	**2**	**4**	**8**	**12**	**16**	**17**
Visit window (days)	-7/+3		±3	±3	±3	±3	±3	±3	+5
SUBJECT RELATED INFO/ASSESSMENTS									
Informed consent	X								
Child assent form	X								
In/Exclusion criteria	X	X							
Randomisation		X							
Withdrawal criteria			X	X	X	X	X	X	
Demography	X								
Diagnosis of diabetes	X								
Concomitant ill/medical history	X								
Concomitant medication	X	X	X	X	X	X	X	X	
Antidiabetic treatment	X								
EFFICACY									
HbA_{1c}	X	X				X	X	X	
Fasting plasma glucose (home blood sample kit)		X					X	X	
4-point profile			X	X	X	X	X	X	
8-point profile		X					X	X	
SAFETY									
Adverse events and technical complaints	X	X	X	X	X	X	X	X	X
Hypoglycaemic episodes		X	X	X	X	X	X	X	X
Hyperglycaemic episodes		X	X	X	X	X	X	X	X
Physical examination	X							X	
Vital signs	X							X	
Haematology	X						X	X	

Trial NN5401-3816 – Type 1	**Screen**	**Rand**	**16 weeks**						**Follow up**
Visit Number (V)	**V1**	**V2**	**V3**	**V4**	**V6**	**V10**	**V14**	**V18**	**V19[3]**
☎ Phone Contact number (P) (For details see separate flow chart)					P5	P7 P8 P9	P11 P12 P13	P15 P16 P17	
Time of visit (weeks)[1]	**-1[2]**	**0**	**1**	**2**	**4**	**8**	**12**	**16**	**17**
Visit window (days)	-7/+3		±3	±3	±3	±3	±3	±3	+5
Biochemistry	X						X	X	
Lipids	X						X	X	
Body weight	X	X					X	X	
Height		X					X	X	
OTHER ASSESSMENTS									
Pregnancy test[4]	X							X	
TRIAL MATERIAL									
IV/WRS session	X	X			X	X	X	X	
Dispensing visit		X			X	X	X		
Drug accountability (IV/WRS)					X	X	X	X	
REMINDERS									
Hand-out Subject Participation Card	X								
Provide instruction for use for pens		X			X	X	X		
Handling/training in product/device usage and storage		X							
Instruction/hand-out of glucose meter	X								
Hand-out of home blood sample kit	X					X	X		
Hand-out/instruction/collection of diary	X	X	X	X	X	X	X	X	X
Prescribed dose of trial insulin at visit		X	X	X	X	X	X		
First actual date and dose of trial insulin			X						
Dose of trial insulin on 3 days prior to the visit			X	X	X	X	X	X	
Last actual dose and date of trial insulin								X	
End of trial									X

1. Time of visit was always calculated in relation to the actual date of the randomisation visit (Visit 2)
2. Visit 1 could take place no earlier than 14 days and no later than 4 days prior to randomisation
3. Follow-up visit (Visit 19) should take place 7-12 days after the last treatment visit (Visit 18)
4. Only fertile females (having had menarche) were to have serum β-HCG test done. In addition, a pregnancy urine test was performed any time during the trial, if a menstrual period was missed, menarche occurred or if pregnancy was suspected.

Table 9–5 Flow chart – phone contacts

Trial NN5401-3816 - type 1										
Phone contact number (P)[1]	**P5**	**P7**	**P8**	**P9**	**P11**	**P12**	**P13**	**P15**	**P16**	**P17**
Time of Phone contact (weeks)	**3**	**5**	**6**	**7**	**9**	**10**	**11**	**13**	**14**	**15**
Visit window (days)	±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
Concomitant medication	X	X	X	X	X	X	X	X	X	X
EFFICACY										
4-point profile[2]	X	X	X	X	X	X	X	X	X	X
SAFETY										
Adverse events	X	X	X	X	X	X	X	X	X	X
Hypoglycaemic episodes	X	X	X	X	X	X	X	X	X	X
Hyperglycaemic episodes	X	X	X	X	X	X	X	X	X	X
REMINDERS										
Prescribed dose of trial insulin at phone contact	X	X	X	X	X	X	X	X	X	X
Dose of trial insulin on 3 days prior to the contact	X	X	X	X	X	X	X	X	X	X

1. A phone contact could be converted to a visit if preferred
2. 4-point SMPG profile should be started in the morning 3 days before the visit

See Section 9.8 for details of any change of the trial conduct.

Before screening took place, the subject and parent(s)/legal representative were to be provided with written information about the trial and the procedures involved. The subject and parent(s)/legal representative were to be fully informed orally and in writing about their responsibilities and rights while participating in the trial, as well as about possible advantages and disadvantages when being treated with trial medication (IDegAsp 100 U/mL or IDet 100 U/mL). All information was to be presented to the subject in age-appropriate language. The Informed Consent Form was to be signed and dated by at least one of the parent(s)/ a legal representative or according to country specific regulations. If required according to local requirements, a Child Assent Form was to be dated and signed by the child, as age-appropriate, and the parent(s) or legal representative.

Screening (Visit 1)

Subjects were to attend a screening visit (visit 1) to assess eligibility.

Visit 1 was to take place no earlier than 14 days and no later than 4 days prior to randomisation.

Inclusion/exclusion criteria were reviewed and the following were performed and /or recorded in the source documents and the eCRF (electronic case report form) in addition to what is already described in the flow chart and in the assessment sections:

- Date of Informed Consent
- Demography (date of birth, gender, ethnicity, race)
- Date of diagnosis of T1DM
- Medical history/concomitant illness
- Antidiabetic medication and other concomitant medication
- Physical examination
- Vital signs
- Body weight

At visit 1, enrolled subjects were supplied with diary and glucose meter and received instructions on usage for SMPG and ketone measurements.

The subjects were reminded to complete the diary with any AEs, hypo- and hyperglycaemic episodes and/or changes in concomitant medication, perform 8-point profile (prior to visit 2) and measure FPG by use of the home blood sampling kit in the morning on the day of visit 2.

For females of child bearing potential a serum pregnancy test was to be obtained.

If the subject was ineligible to participate in the trial the subject was considered a screening failure. Re-screening was not allowed in this trial.

Randomisation visit (visit 2) to Follow-up visit (visit 19)

For randomisation visit (visit 2) to follow-up visit (visit 19) please see trial flow charts (Table 9–4 and Table 9–5).

Recommended switch from pre-trial insulin to trial insulin is described in Section 9.4.4.

At visit 3, information on first actual date and dose of trial insulin (IDegAsp, IDet, and IAsp) was recorded.

9.5.1.2 Efficacy assessments

The following efficacy assessments were defined:

- Change from baseline in HbA_{1c} (%) after 16 weeks of treatment (primary endpoint)
- Change from baseline in fasting plasma glucose
- SMPG measurements (4-point profiles) obtained throughout the trial for dose adjustments:
  - Mean PG before meals and before bedtime
  - Within-subject variability as measured by the coefficient of variation (CV%)

- SMPG measurements (8-point profiles):
  - 8-point profiles
  - Mean of the 8-point profiles
  - Fluctuation in the 8-point profiles
  - Prandial PG increment from 8-point profiles

The laboratory analyses were performed by a central laboratory unless otherwise specified. Descriptions of assay methods, reference ranges, laboratory supplies and procedures for obtaining samples, handling and storage of samples were described in a trial-specific laboratory manual provided by the central laboratory (Appendix 16.1.10).

Subjects from 1 to 6 years (both inclusive) were to have the following approximate volumes of blood drawn during the trial:

Visit 1: 2.3 mL, visit 2: 1.2 mL, visit 10: 1.2 mL, visit 14: 2.3 mL, visit 18: 2.3 mL. The total volume of blood was approximately 9.3 mL in the main trial period.

Subjects > 6 years were to have the following approximate volumes of blood drawn during the trial:

Visit 1: 6.5 mL, visit 2: 2.0 mL, visit 10: 2.0 mL, visit 14: 6.5 mL, visit 18: 6.5 mL. The total volume of blood was approximately 23.5 mL in the main trial period.

For safety laboratory samples see Section 9.5.1.4.

HbA_{1c}

Blood samples were drawn at visits 1, 2, 10, 14 and 18 and analysed at the central laboratories (Quintiles) to determine levels of HbA_{1c}.

Fasting plasma glucose

Capillary blood samples for fasting plasma glucose (FPG) were taken either at home or at the clinic in the morning on the day of visits 2, 14 and 18 by use of a home blood sampling kit. The subject was provided with the home sampling kit and instructions at visit 1. The samples were to be taken while the subject was fasting and before administration of basal or bolus insulin on that day. If these conditions could not be met, collection of the FPG sample was to be rescheduled within the permitted visit window.

The Special laboratory [redacted] analysed the samples.

Self-measured plasma glucose (SMPG)

At visit 1 subjects were supplied with a glucose meter and instructions on use of the device and regular calibration according to the manufacturer's instructions. Subjects could be re-trained if necessary. The glucose meters were calibrated to plasma values. Therefore, all glucose measurements performed with drawn capillary blood were automatically calibrated to plasma equivalent glucose values. Subjects were instructed in how to record the results of the SMPG values in the diaries provided and were only to record the values based on glucose meter measurements. All SMPG data obtained at a phone contact was to be entered into the eCRF.

It should be noted that the BG meter used in this study could not display PG values lower than 1.1 mmol/L (20 mg/dL) or higher than 27.5 mmol/L (500 mg/dL), but these measurements were displayed as "Low" and "High" respectively on the BG meter. These measurements were reported as "missing values" and treated as missing in descriptive statistics and statistical analyses of SMPG. Any "Low" or "High" measurements were still to be used for assessment of hypoglycaemia or hyperglycaemia respectively.

4-point self-measured plasma glucose

Subjects were asked to perform SMPG measurements before breakfast, lunch, main evening meal and bedtime. Measurements were to be performed on three consecutive days just before each scheduled visit or telephone contact using the glucose meter provided. The 4-point profiles were used for titration of insulin doses (see Section 9.4.5).

8-point self-measured plasma glucose

The SMPG levels were to be measured and recorded in the diary at the time points listed in Table 9–6 always starting with the measurement just before breakfast on the second day before the visit. Subjects were asked to perform an 8-point SMPG profile before visits 2, 14 and 18.

The 8-point profile was to be started with a morning fasting sample two days prior to a visit. When an 8-point profile was performed the time points replaced the corresponding 4-point profile time points, hence subjects did not have to measure blood glucose twice for a given time point.

Table 9–6 8-point profile (O) with the additional 4-point profile (X)

	3 days prior to visit	2 days prior to visit	1 day prior to visit
Before breakfast	X	X O	O X
90 min. after the start of breakfast		O	
Before lunch	X	X O	X
90 min. after the start of lunch		O	
Before main evening meal	X	X O	X
90 min. after the start of main evening meal		O	
Before bedtime	X	X O	X

9.5.1.3 Other baseline assessments

Pregnancy test

A fertile girl was defined as a girl who had had menarche. Fertile girls were to have a serum pregnancy test (beta-human chorionic gonadotropin (β-HCG)), performed in connection with the screening visit (visit 1) and visit 18. If a girl became fertile during the trial, the Investigator was to perform a β-HCG serum test or a urine pregnancy test. Urine pregnancy tests were to be performed locally during the trial if a menstrual period was missed or if pregnancy was suspected.

9.5.1.4 Safety assessments

Adverse events

An adverse event (AE) is any untoward medical occurrence in a subject administered a product, and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a product, whether or not considered related to the product.

AEs include:

- A clinically significant worsening of a concomitant illness.
- A clinical laboratory adverse event: A clinical laboratory abnormality which is clinically significant, i.e. an abnormality that suggests a disease and/or organ toxicity and is of a severity that requires active management. Active management includes active treatment or further investigations, for example change of medicine dose or more frequent follow-up due to the abnormality.

- Hypo- and hyperglycaemic episodes which do not meet the definition of MESI or SAE are AEs, but must be reported on hypo-/hyperglycaemic forms instead of AE forms in the eCRF
- Any episode of self-measured blood ketones >1.5 mmol/L. This must be reported on the AE form in the eCRF

The following should not be reported as AEs:

- Pre-existing conditions, including those found as a result of screening procedures (pre-existing conditions should be reported as medical history or concomitant illness).
- Pre-planned procedures unless the condition for which the procedure was planned has worsened from the first trial related activity after the subject has signed the informed consent.

An AE is either a serious AE (SAE) or a non-serious AE.

A SAE is an experience that at any dose results in any of the following:

- Death
- A life-threatening[a] experience
- In-patient hospitalisation[b] or prolongation of existing hospitalisation
- A persistent or significant disability or incapacity[c]
- A congenital anomaly or birth defect
- Important medical events that may not result in death, be life-threatening[a] or require hospitalisation[b] may be considered an SAE, when based on 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[d]
- Suspicion of transmission of infectious agents must always be considered an SAE

a) 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.

b) The term “hospitalisation” is used when a subject:

Is admitted to a hospital or in-patient, irrespective of the duration of physical stay, or

Stays at the hospital for treatment or observation for more than 24 hours

Medical judgement must always be exercised, and when in doubt, the hospital contact should be regarded as a hospitalisation. Hospitalisations for administrative, trial related and social purposes do not constitute AEs and should therefore not be reported as AEs or SAEs. Hospital admissions for surgical procedures, planned before trial inclusion, are not considered AEs.

c) A substantial disruption of a subject’s ability to conduct normal life functions (e.g. following the event or clinical investigation the subject has significant, persistent or permanent change, impairment, damage or disruption in his/her body function or structure, physical activity and/or quality of life).

d) For example intensive treatment in an emergency room or at home of allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalisation or development of drug dependency or drug abuse.

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

Medical event of special interest

A medical event of special interest (MESI) is an event which, in the evaluation of safety, has a special focus. The following are defined as MESIs in this trial:

1. Medication errors concerning trial products:
   - Administration of wrong drug
   - Wrong route of administration, such as intramuscular instead of subcutaneous
   - Administration of a high dose with the intention to cause harm (e.g. suicide attempt)
   - Administration of an accidental overdose, which is a dose that may lead to significant health consequences as judged by the Investigator, irrespective of whether any SAE criterion is fulfilled.

2. Severe Hypoglycaemia:
   - Any episode of hypoglycaemia which fulfils the ISPAD definition for a severe hypoglycaemia, i.e. the child has altered mental status and cannot assist in their own care, is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose).

3. Neoplasms:
   - All types of neoplasm events, i.e. benign, malignant and unspecified (including cysts and polyps) should always be reported to the department responsible for global safety on an AE form and safety information form (SIF) irrespective of seriousness. Medical history and important follow-up data includes information about malignancy versus non-malignancy, preferable histologically verified.

Severity assessment definitions:

- 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.

The following terms and definitions are used when assessing the relationship between each AE and the relevant trial product(s):

- Probable - Good reason 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 aetiology other than the trial product

The following terms and definitions are used in assessing the final outcome of an AE:

- Recovered/resolved - The subject has fully recovered, or by medical or surgical treatment the condition has returned to the level observed at the first trial-related activity after the subject signed the informed consent.
- Recovering/resolving - This term is only applicable if the subject has completed the trial or has died from another AE. The condition is improving and the subject is expected to recover from the event.
- Recovered/resolved with sequelae - The subject has recovered from the condition, but with lasting effect due to a disease, injury, treatment or procedure. If a sequela meets an SAE criterion, the AE must be reported as an SAE.
- Not recovered/not resolved - The condition of the subject has not improved and the symptoms are unchanged, or the outcome is not known at the time of reporting.
- Fatal - This term is only applicable if the subject died from a condition related to the reported AE. Outcomes of other reported AEs in a subject before he/she died should be assessed as “recovered”, “recovering”, “recovered with sequelae” or “not recovered”. An AE with fatal outcome must be reported as an SAE.
- Unknown - This term is only applicable if the subject is lost to follow-up.

A technical complaint is any communication that alleges defects on trial supplies. The technical complaint may be associated with an AE, but does not concern the AE itself.

Examples of technical complaints:

- The physical or chemical appearance of trial products (e.g. discoloration, particles or contamination)
- The packaging material (e.g. leakage, cracks, rubber membrane issues or errors in labelling text)
- Problems related to devices (e.g. to the injection mechanism, dose setting mechanism, glucose measurement, push button or interface between the pen and the needle)

Reporting of adverse events

All AEs either observed by the Investigator or reported spontaneously by the subjects were to be recorded by the Investigator and evaluated. This included events from the first trial-related activity after the subject had signed the informed consent until the end of the post-treatment follow-up period.

During each contact with the trial site (visit and telephone contacts) the subject was asked about AEs and technical complaints, as follows: “Have you experienced any problems since the last contact?”

Novo Nordisk assessment of expectedness was performed according to the following reference documents: Current edition of the IB for IDegAsp and summary of product characteristics (SmPCs) for IAsp and IDet.

The Investigator was to report the diagnosis, if available. If no diagnosis was available, the Investigator was to record each sign and symptom on individual AE forms. For each SAE also a safety information form was completed in addition to the standard AE form.

MESIs, regardless of seriousness, were to be reported using the AE form, the safety information form and, for medication errors and hypoglycaemic episodes, also the MESI forms medication error form and hypoglycaemic episodes form, respectively.

It was the responsibility of the Investigator to ensure that the worst case severity and seriousness of an event was kept throughout the trial. The Investigator was required to report to Novo Nordisk on the AE form within 24 hours of obtaining knowledge of the SAE or MESI, and to send the safety information paper form within 5 calendar days of obtaining knowledge of the SAE or MESI.

Novo Nordisk were to notify the Investigator of trial product-related suspected unexpected serious adverse reactions (SUSARs) in accordance with local requirements and ICH GCP[2]. In addition, the Investigator was to be informed of any trial-related SAEs warranting changes to any trial procedure.

Follow up on adverse events

All SAEs were to be followed up until the outcome of the event was “recovered”, “recovered with sequelae” or “fatal”, and until all queries had been resolved. Cases of chronic conditions, cancer or AEs ongoing at time of death (where death was due to another AE) could be closed with the outcome “recovering” or “not recovered”, when the subject had completed the follow up period.

The follow-up information was only to include corrections, new or additional information and should be reported within 24 hours of obtaining knowledge of the information. This was also the case for previously non-serious AEs which subsequently became SAEs.

Follow-up information on MESIs (not fulfilling the SAE criterion) were to only include corrections, new or additional information and should be reported within 14 days of obtaining knowledge of the information. This was also the case for previously non-serious AEs which subsequently fulfil the MESI criterion.

Non-serious AEs (not fulfilling the MESI criterion) were to be followed until the outcome of the event was “recovering”, “recovered” or “recovered with sequelae” or until the end of the follow-up period stated in the protocol, whichever came first, and until all queries related to these AEs had been resolved. The Investigator was to record follow-up information on non-serious AEs (not fulfilling the MESI criterion) by updating the AE form in the eCRF.

If for any reason the eCRF was unavailable for updating of follow-up information on forms or access to edit the eCRF was revoked, the Investigator were to record any SAE follow-up information on the provided paper CRFs and send the information by fax, telephone, e-mail or courier to Novo Nordisk.

Queries or follow-up requests from Novo Nordisk should be responded to within 14 days.

Pregnancies

Female subjects were instructed to notify the Investigator immediately if they became pregnant during the trial. The Investigator was to report all information on pregnancies including AEs in the subject, the foetus, and new-born infant on the trial related pregnancy forms.

Hypoglycaemia

The definitions of hypoglycaemic episodes from the International Society for Pediatric and Adolescent Diabetes (ISPAD)[14] and the American Diabetes Association (ADA)[15] guidelines were used.

The subject was to measure PG levels whenever a hypoglycaemic episode was suspected.

PG values ≤3.9 mmol/L (70 mg/dL) or >3.9 mmol/L (70 mg/dL) when they occurred in conjunction with hypoglycaemic symptoms, were to be recorded in a diary by the subjects and transcribed into the eCRF hypoglycaemic episode form throughout the trial.

The record was to include:

- Date and time of hypoglycaemic episode
- The PG level before treating the episode
- Any symptoms related to the episode
- Whether the subject is having altered mental status and cannot assist in their care, is semiconscious, unconscious or in coma with or without convulsions, and may require parenteral therapy (glucagon or i.v. glucose)
- Time of last IDegAsp/IDet dose prior to episode
- Time of last IAsp dose prior to episode
- Whether the episode was related to increased physical activity

A hypoglycaemic episode was defined as treatment-emergent if the onset was on or after the first day of exposure to randomised treatment and no later than 7 days after the last day on randomised treatment. Hypoglycaemic episodes were defined as nocturnal if the time of onset was between 23:00-07:00 (11 p.m. to 7 a.m.) inclusive.

If the hypoglycaemic episode fulfilled the criterion for an SAE and/or a MESI then an AE form and a SIF also were to be completed.

Hypoglycaemic episodes were summarised based on a Novo Nordisk definition and the ADA and ISPAD classification:

Novo Nordisk definition of hypoglycaemia

In normal physiology, symptoms of hypoglycaemia occur below a PG level of 3.1 mmol/L (56 mg/dL)[16]. Therefore, Novo Nordisk has included hypoglycaemia with PG levels below this cut-off point in the definition of confirmed hypoglycaemia.

Confirmed hypoglycaemic episodes were defined as episodes that were either:

- Severe (i.e. the child is having altered mental status and cannot assist in their care, is semiconscious or unconscious or in coma with or without convulsions and may require parenteral therapy (glucagon or i.v. glucose), or
- An episode biochemically confirmed by PG value of <3.1 mmol/L (56 mg/dL), with or without symptoms consistent with hypoglycaemia.

Definition of hypoglycaemia according to ADA/ISPAD

- **Severe hypoglycaemia:** The child is having altered mental status and cannot assist in their care, is semiconscious or unconscious or in coma with or without convulsions and may require parenteral therapy (glucagon or i.v. glucose).

- **Asymptomatic hypoglycaemia:** The child is not symptomatic with hypoglycaemia, but has a measured PG concentration ≤ 3.9 mmol/L (70 mg/dL).

- **Documented symptomatic hypoglycaemia:** The child or parent is aware of, responds to, and treats the hypoglycaemia orally after documenting a measured PG concentration ≤ 3.9 mmol/L (70 mg/dL).

- **Relative hypoglycaemia:** An episode during which the child 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).

- **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).

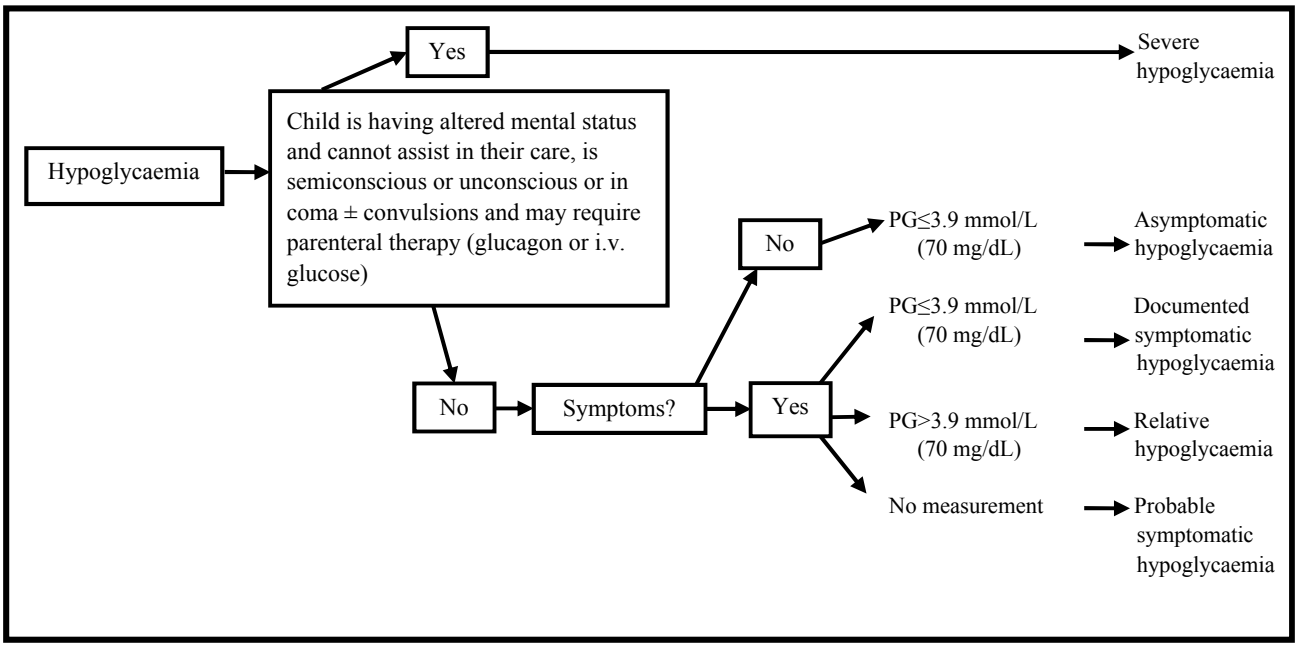


Figure 9–2 Classification of hypoglycaemia according to ADA/ISPAD

External classification of severe hypoglycaemia

The episodes of severe hypoglycaemia according to ADA and ISPAD were reviewed by an external expert in a blinded manner in order to have a centralised assessment of severe hypoglycaemia classification, in accordance with ISPAD. The classification was based on case narratives and paraclinical findings.

The classification of hypoglycaemia according to ADA/ISPAD is illustrated in Figure 9–2.

Hyperglycaemic episodes and ketosis

PG was always to be measured when a hyperglycaemic episode was suspected. If PG values were > 14.0 mmol/L (250 mg/dL), and subject looked/felt ill, blood ketones were to be measured (using the blood glucose meter) and the episode recorded on the diary.

The recordings in the subject diary were to be transcribed into the eCRF throughout the trial. The recordings were to include:

- Whether the subject looks and/or feels ill
- Date and time of hyperglycaemic episode
- The PG level before treating the episode (if available)
- Blood ketone level
- Time of last IDegAsp/IDet dose prior to episode

- Time of last IAsp dose prior to episode
- Whether the subject had an infection at the time of the episode
- Whether the subject missed or reduced a dose of IDegAsp/IDet and/or IAsp prior to episode

Any episode of self-measured blood ketones > 1.5 mmol/L was always be reported as an AE in the eCRF.

Clinical evaluations

Clinical evaluations were performed at visit 1 and visit 18.

Vital signs

Diastolic and systolic blood pressure along with pulse was assessed while subject was in supine or sitting position. Measurements were to be performed after 5 minutes of rest.

Physical examination

Physical examination included: Head, ears, eyes, nose, throat and neck, respiratory system, cardiovascular system, gastrointestinal system including mouth, musculoskeletal system, central and peripheral nervous system and skin.

Clinical laboratory tests

Blood samples for haematology, biochemistry and lipids were drawn at visit 1, visit 14 and visit 18.

The following parameters were measured:

- Haematology (erythrocytes, haematocrit, haemoglobin, leucocytes, thrombocytes)
- Biochemistry (alanine amino transferase [ALAT], aspartate aminotransferase [ASAT], alkaline phosphatase, albumin, bilirubin (total), creatinine, potassium, sodium)
- Lipids (cholesterol, HDL cholesterol, LDL cholesterol)

All clinical laboratory tests were analysed by the central laboratories. For laboratory manuals and reference ranges see Appendix 16.1.10.

Insulin dose

Prescribed and actual insulin dose per day were to be recorded together with time of administration.

The recommended insulin doses were calculated in the eCRF based on recommendations of the Insulin Titration Guideline; see Protocol Appendix A (Appendix 16.1.1).

Height, body weight and BMI

Body weight was measured at visit 1, visit 2, visit 14 and visit 18. Height was measured at visit 2, visit 14 and visit 18.

Height without shoes was measured in meters (m) or inches (inch). Body weight was measured in kilograms (kg) or pounds (lb) wearing only light clothing and no shoes. BMI was calculated using the eCRF for visit 2, visit 14 and visit 18.

Technical complaints and technical complaints samples

All technical complaints which occurred from the time of first usage of trial supplies until the time of the last usage of trial supplies were to be collected and reported to Novo Nordisk. The Investigator assessed whether the technical complaint was related to any AE(s), SAE(s) and/or MESI(s). A technical complaint form in the eCRF was filled in.

Technical complaints were to be reported on a separate technical complaint form and completed for each Novo Nordisk trial product and for auxiliary supplies listed on the technical complaint form. The Investigator was to complete and forward the technical complaint form by fax, e-mail or courier to Novo Nordisk, within the same timelines as for reporting AEs, SAEs and MESIs as follows:

- Technical complaint assessed as related to an SAE and/or MESI within 24 hours of the trial site obtaining knowledge of the complaint
- All other technical complaints within 5 calendar days

9.5.2 Appropriateness of assessments

All assessments were standard for this type of trial (paediatric) and were performed using standard methods. Details on the assessments performed can be found in Appendix 16.1.10.

9.6 Data quality assurance

The trial was conducted in accordance with ICH Good Clinical Practice[2].

The Investigators were required to have been trained in GCP (see Appendix 16.1.4). Training of the Investigators in the protocol was carried out through training sessions and Investigator meetings, in order to ensure compliance and standardise performance across the trial.

All Principal Investigators provided written commitment to comply with GCP and conduct the trial according to the protocol, prior to participation in the trial.

The trial was monitored by the sponsor by means of on-site visits, telephone calls, and regular inspection of the electronic case report forms (eCRFs) with sufficient frequency to verify the following: subject enrolment; compliance with the protocol; the completeness and accuracy of data

entered in the eCRFs/EDC system by verification against original source documents; compliance in the use of trial product accountability; and recording of adverse events.

In total, 4 internal audits were performed at 9 trial sites and Novo Nordisk departments as follows:

- Trial audit of international trial management in Denmark (HQ)
- Trial audit of local trial management and sites [redacted]
- Trial audit of local trial management and sites [redacted]
- Trial audit of local trial management and sites [redacted]

In addition, 1 inspection was performed at site [redacted]

The audits were conducted in order to investigate compliance with the protocol, current GCP, Novo Nordisk policies and clinical trial standard operating procedures, local guidelines/requirements and local standard operating procedures.

Audit certificates are available in Appendix 16.1.8.

The results presented reflect the data available in the clinical database as of 26 November 2014.

9.7 Statistical methods planned and determination of sample size

9.7.1 Determination of sample size

The primary objective of this trial was to confirm the efficacy of IDegAsp administered OD plus meal time IAsp for the remaining meals in controlling glycaemia with respect to change from baseline in HbA_{1c} after 16 weeks of treatment. This was done by comparing the difference in change from baseline in HbA_{1c} between IDegAsp + 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%.

Sample size was determined based on the non-inferiority evaluation.

The non-inferiority margin of 0.4% (absolute) was chosen in accordance with the Food and Drug Administration (FDA) guidance[17] and in agreement with EMA/PDCO as an integrated part of the PIP for IDegAsp.

Let D be the mean treatment difference for change in HbA_{1c} (IDegAsp minus IDet). The null hypothesis was tested against the alternative hypothesis of non-inferiority as given by

$$H_0: D > 0.4\% \quad \text{against} \quad H_A: D \leq 0.4\%$$

Operationally the null hypothesis was rejected and non-inferiority considered confirmed if the upper bound of the two sided 95% confidence interval for the mean HbA_{1c} treatment difference 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 under the assumption of a one-sided test of size 2.5% and a zero mean treatment difference (i.e. D=0%). Based on experience from previous phase 3 trials in children and adolescents with T1DM treated with insulin a conservative estimate for the SD of 1.25% for HbA_{1c} was used in the sample size calculation.

The SD of 1.25% used in the sample size calculation was based on results from two previous paediatric trials with IDet (Trials NN304-1379 and NN304-1689). In NN304-1379 the SD was 0.88 % for HbA_{1c} (%) after 18 weeks of treatment in children with age ranging from 6 to less than 18 years. In NN304-1689, the SD was 1.09% for HbA_{1c} (%) after 26 weeks in children with age ranging from 2 to 16 years. In both trials the drop-out rate was below 9% and of similar magnitude in the two treatment groups.

The sample size calculation was done using SAS 9.3 and the specifications assumed for the sample size calculation are presented in Table 9–7.

Table 9–7 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%	1.25%	0.0%	1:1	80%

SD: Standard deviation

Table 9–8 Sensitivity of sample size (integers) to variations in standard deviation and power

#subjects in total	SD=1.15	SD=1.20	SD=1.25	SD=1.30
Power = 75%	232	252	274	296
Power = 80%	262	286	310	334
Power = 85%	300	326	354	382
Power = 90%	350	382	414	446

SD: Standard deviation

As can be seen from Table 9–8, the minimum sample size required to meet the primary objective with at least 80% power was 310 subjects with an assumed SD of 1.25%.

As this was a non-inferiority trial, sample size was determined such that the anticipated power was at least 80% in the evaluation of the PP analysis set. In previous phase 3 trials, in insulin treated children and adolescents with T1DM, less than 9% of the randomised subjects were excluded from the PP analysis set. In this trial, an estimate of 10% was used and sample size was ceiled in the FAS to have integer sample size for each group that adheres exactly to the group allocation weights (1:1). Hence the total number of randomised subjects was to be at least 346 subjects in order to have at least 80% power in the evaluation of the PP analysis set Table 9–9.

Table 9–9 Anticipated number of subjects in FAS and PP analysis sets

	IDegAsp	IDet	Total
Number of subjects in the FAS	173	173	346
Number of subjects in the PP analysis set	155	155	310

FAS: full analysis set; PP: per protocol.

9.7.2 Definition of analysis sets

The following analysis sets were defined in the protocol and/or statistical analysis plan, prior to unblinding/release of the treatment randomisation, and in accordance with ICH E9[18]:

- Full analysis set (FAS) – includes 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 followed the intention-to-treat (ITT) principle and subjects contributed to the evaluation "as randomised".

- Per protocol (PP) analysis set – The PP analysis set consisted of all subjects in the FAS who fulfilled the following criteria:
  - Have not violated any inclusion criteria
  - Have not fulfilled any exclusion criteria
  - Have a non-missing HbA_{1c} at screening or randomisation
  - Have at least one non-missing HbA_{1c} after 12 weeks of exposure
  - Have at least 12 weeks of exposure

- Safety analysis set – included all subjects receiving at least one dose of the trial product or its comparator. Subjects in the safety set contributed to the evaluation "as treated".

Randomised subjects who were lost to follow up and where no exposure information of the trial product or its comparator was available after randomisation were 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. 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 blinded data review procedures described were carried out as planned.

The decision to exclude any subject or observation from the statistical analysis was the joint responsibility of the clinical study group. The subjects or observations to be excluded and the reason for their exclusion were to be documented and signed by the relevant parties, prior to breaking the randomisation code and database release. The documentation was to be stored together with the remaining trial documentation.

Please note that the definition of subjects included in the FAS population in the protocol has been updated: The updated definition of FAS is aligned with similar trials and is addressed in Protocol Amendment no. 2 (see Section 9.8.2).

9.7.3 General considerations

Section 9.7 presents the planned statistical analyses, as described in the trial protocol, including amendments (Appendix 16.1.1) and/or the Statistical Analysis Plan (Appendix 16.1.9). In case of modifications to a planned analysis, the modified method is described together with the original plan, and the rationale given. Furthermore, all changes from the planned analyses are summarised in Section 9.8.2.

Novo Nordisk analysed and reported data from all sites together. Analyses of all endpoints were based on the full analysis set (FAS). The primary efficacy analysis was repeated on the per protocol (PP) analysis set in accordance with the Committee for Proprietary Medicinal Products Points to Consider[19].

Secondary efficacy endpoints were summarised using the FAS. Safety endpoints were summarised using the Safety Analysis Set (SAS).

Only endpoints derived after 16 weeks of treatment were analysed statistically. The mixed model for repeated measurements (MMRM) data was used to account for missing data in the statistical analysis. The mixed model produces unbiased estimates when the missing data pattern can be explained by the observed data. Since all subjects withdrawing from the trial were asked to attend an end-to-trial visit where HbA_{1c} was assessed, hence withdrawals from the trial due to deterioration of the glycaemic control were accompanied by an HbA_{1c} value that can help explain the dropout and missing data, which further support the use of the MMRM to evaluate the primary endpoint. Applying the MMRM method is in accordance with current comments from FDA[20]. As an alternative method to handle missing data, a sensitivity analysis was performed where the change from baseline in HbA_{1c} after 16 weeks of treatment was analysed with the missing values imputed

using the Last Observation Carried Forward (LOCF) method. Further analysis of the missing data structure was to be investigated if deemed relevant.

All endpoints were summarised descriptively at each visit by treatment and in total using observed data. After 16 weeks of treatment, descriptive statistics were presented based on observed data. Endpoints that are analysed untransformed and endpoints that are 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. Furthermore relevant endpoints (as a minimum demographics, HbA_{1c}, FPG, SMPG, hypoglycaemia, hyperglycaemia and body weight) were also presented descriptively by the 3 age groups.

Only observed data was used as the basis for plotting data if not otherwise specified.

Presentation of results from a statistical analysis includes 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. P-values were only presented for the primary endpoint. The other endpoints were considered supportive and explorative in nature and, hence, no p-values were presented.

For endpoints measured over time mean values were plotted to explore the trajectory over time. Data collected before randomisation was only summarised descriptively.

9.7.4 Endpoints in relation to objectives and hypotheses

9.7.4.1 Primary endpoint

The primary objective of this trial was to confirm the efficacy of IDegAsp administered once daily plus meal-time IAsp for the remaining meals in controlling glycaemia with respect to change from baseline in HbA_{1c} after 16 weeks of treatment. This objective was supported by the primary endpoint:

- Change from baseline in HbA_{1c} (%) after 16 weeks of treatment.

9.7.4.2 Secondary endpoints

The secondary objective of this trial was to compare the efficacy and safety between the two treatment groups. This objective was supported by the secondary endpoints:

Efficacy endpoints

- Change from baseline in FPG after 16 weeks of treatment

- SMPG measurements (4-point profiles) obtained throughout the trial for dose adjustments
  - Mean PG before meals and before bedtime after 16 weeks of treatment
  - Within subject variability as measured by the CV% after 16 weeks of treatment

- SMPG measurements (8-point profiles)
  - 8-point profiles after 16 weeks of treatment
  - Mean of the 8-point profiles after 16 weeks of treatment
  - Fluctuation in the 8-point profiles after 16 weeks of treatment
  - Prandial PG increment from 8-point profiles after 16 weeks of treatment

Safety endpoints

Safety was addressed in terms of the following assessments from which endpoints was calculated, analysed and presented as described in this section:

- Incidence of treatment -emergent AEs during 16 weeks of treatment and 1 week of follow up

- Hypoglycaemia:
  - Number of treatment-emergent confirmed hypoglycaemic episodes (PG<3.1 mmol/L (56 mg/dL) or severe hypoglycaemia)
  - Number of treatment-emergent nocturnal confirmed hypoglycaemic episodes (PG<3.1 mmol/L (56 mg/dL) or severe hypoglycaemia)
  - Number of treatment-emergent hypoglycaemic episodes, in accordance with ISPAD/ADA definitions
  - Number of treatment-emergent nocturnal hypoglycaemic episodes, in accordance with ISPAD/ADA definitions

- Hyperglycaemia
  - Number of hyperglycaemic episodes (PG > 14.0 mmol/L (250 mg/dL) where subject looks/feels ill after 16 weeks of treatment
  - Number of hyperglycaemic episodes (PG > 14.0 mmol/L (250 mg/dL) where subject looks/feels ill with ketosis (blood ketones > 1.5 mmol/L) after 16 weeks of treatment

- Change from baseline during 16 weeks of treatment in:
  - Vital signs

- Change from baseline in central laboratory assessments after 16 weeks of treatment

- Haematology (haemoglobin, haematocrit, erythrocytes, thrombocytes and leucocytes)
- Biochemistry (creatinine, ALAT, ASAT, alkaline phosphatase, sodium, potassium, albumin and total bilirubin)
- Lipid profile (cholesterol, HDL and LDL)

- Insulin doses (units/day and units/kg/day both for total, basal and bolus) after 16 weeks of treatment

- Change from baseline in body weight and BMI after 16 weeks of treatment

9.7.5 Statistical methods

9.7.5.1 Primary endpoint

The primary endpoint was change from baseline in HbA_{1c} (%) after 16 weeks of treatment.

All observed HbA_{1c} measurements available post-randomisation at scheduled measurement times was analysed with a mixed model for repeated measurements (MMRM) with an unstructured covariance matrix. The model included treatment, sex, region, age-group and visit as factors and baseline HbA_{1c} as covariate. Interactions between visit and all factors and covariates were also included in the model. Region was a factor with three levels:

- EU (including Russian Federation and Israel)
- North America
- Other.

Age group was a factor with the following three levels:

- 1 to < 6 years of age
- 6 to < 12 years of age
- 12 to < 18 years of age

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

Degrees of freedom was calculated using the Satterthwaite method (DDFM=SAT) in the MMRM model.

Non-inferiority was considered confirmed if the upper bound of the two-sided 95% confidence interval 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 was the mean treatment difference after 16 weeks of treatment (IDegAsp minus IDet).

If non-inferiority was confirmed, the superiority of the IDegAsp over IDet was investigated. Superiority was considered confirmed if the upper bound of the two-sided 95% confidence interval, which was calculated using the FAS, was below 0%. The PP analysis was considered supportive here.

Please note that changes have been made to the planned statistical analysis in the protocol effective at FPFV. Changes from LOCF to MMRM method as addressed in protocol amendment no.1 and an error in the definition of subjects included in the FAS population in the protocol text has been updated as addressed in protocol amendment no. 2. Please see Section 9.8.2.

Sensitivity analysis

The primary efficacy analysis was repeated on the PP analysis set and the set of all completed subjects (included all randomised subjects who have completed the trial).

The following sensitivity analyses were performed using the FAS only.

Change from baseline in HbA_{1c} after 16 weeks of treatment was analysed using an analysis of variance (ANOVA) method with treatment, sex, region and age group as fixed factors and baseline HbA_{1c} as covariate and where the missing values were imputed using the LOCF method.

The results were compared to the results of the MMRM method. Any marked difference concerning treatment differences between the missing at random (MAR) and LOCF approach were to be commented upon in the clinical trial report.

All observed HbA_{1c} measurements available post-randomisation at scheduled measurement times was also analysed with a MMRM with an unstructured covariance matrix where the only factors were treatment, visit and baseline HbA_{1c} as a covariate. The two interactions between visit and treatment and visit and baseline HbA_{1c} was also included in the model.

9.7.5.2 Secondary endpoints

Fasting Plasma Glucose

FPG was analysed on blood samples from fasting subjects which were analysed centrally.

All observed FPG measurements available post randomisation at scheduled measurement times was analysed with a MMRM with an unstructured covariance matrix. The model included treatment, sex, region, age-group and visit as factors and baseline FPG as covariate. Interactions between visit and all factors and covariates were also included in the model.

4-point SMPG profiles used for titration

The endpoints from SMPG measurements obtained throughout the trial for titration was

- Mean PG before meals and before bedtime after 16 weeks of treatment
- Within-subject variability as measured by CV% after 16 weeks of treatment

All observed mean of before meals and all observed before bedtime PG values available post randomisation at scheduled measurement times was analysed separately with a MMRM with an unstructured covariance matrix. The model included treatment, sex, region, age-group and visit as factors and baseline response value as covariate. Interactions between visit and all factors and covariates were also included in the model.

The logarithmically transformed SMPG values available before breakfast after 16 weeks were analysed as repeated measures in a linear mixed model with treatment, sex, region and age group as fixed factors 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 can be calculated from the corresponding residual variance σ^2 as

$$CV\% = 100\sqrt{\left(\exp\left(\sigma^2\right)-1\right)}.$$

The confidence interval for the CV ratio between treatments was calculated using the delta method.

8-point Profile (SMPG)

The endpoints from the 8-point profiles included:

- 8-point profiles after 16 weeks of treatment
- Mean of the 8-point profiles after 16 weeks of treatment
- Fluctuation in the 8-point profiles after 16 weeks of treatment
- Prandial PG increment from 8-point profiles after 16 weeks of treatment

The mean of the 8-point profile was defined as the area under the profile divided by the measurement time and is calculated using the trapezoidal method. The fluctuation in the 8-point profile was defined as

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

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

Prandial plasma glucose increment

Prandial PG increment for each meal was derived from the 8-point profile as the difference between PG values available after meal (90 minutes) and before meal. Mean prandial PG increment over all meals was derived as the mean of all available meal increments.

All observed mean and fluctuation in the 8-point profile and prandial PG increments available post randomisation at scheduled measurements times was analysed with a MMRM with an unstructured covariance matrix. The model included treatment, sex, region, age-group and visit as factors and baseline values of the response as covariate. Interactions between visit and all factors and covariates were also included in the model. Fluctuation in the 8-point profile was logarithmically transferred before analysed.

All observed 8-point profile (SMPG) measurements available post-randomisation at scheduled measurement times was analysed with a MMRM with an unstructured covariance matrix. The model included treatment, sex, region, age-group, time-point within 8-point profile and visit as factors and corresponding baseline SMPG profile as covariate. Interactions between visit and all factors and covariates were also included in the model, and in addition interaction between treatment and visit and time-point was also included. This analysis was added *post-hoc* (see Section 9.8.2.2).

Nocturnal increment of 8-point Profile (SMPG)

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

Nocturnal increment by treatment week for the 8-point SMPG profile was summarised descriptively.

Please note that additional outputs were added to the planned output included in the protocol, as described in the SAP: The nocturnal increment of 8-point profile (SMPG) was added to the planned derived output (see Section 9.8.2).

Adverse Events

AEs were coded using the most recent version (17.0) of Medical Dictionary for Regulatory Activities (MedDRA) coding. All AEs were presented based on system organ class (SOC) and preferred terms.

A treatment-emergent AE (TEAE) was defined as an event with onset date on or after the first day of exposure to randomised treatment and no later than 7 days after the last day on randomised treatment. In the following TEAEs are referred to as AEs unless otherwise stated.

AEs were summarised descriptively, whereas non-treatment-emergent AEs were presented in listings. AE data was displayed in terms of the number of subjects with at least one event (N), the percentage of subjects with at least one event (%), the number of events (E) and the event rate per 100 patient years of exposure (PYE) (R). Furthermore, AE data were summarised by seriousness, severity, relation to insulin treatment, relation to device, withdrawal due to AEs and outcome.

Furthermore summary tables based on SOC and preferred term were made for

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

The AE tables summarise AEs based on the diagnosis, if available, and only includes symptoms if these are not linked to a diagnosis, whereas the listings include all symptoms and diagnoses, whether linked or not. All AEs reported by the Investigator (both symptoms and diagnoses) are listed in Appendix 16.2.7. If both symptoms and diagnoses were reported, only diagnoses are presented in the summary tables.

Injection site reaction

Injection site reactions were summarised descriptively. The summary table was based on SOC and preferred terms.

Allergic reaction

Allergic reactions were summarised descriptively. The summary table was based on system organ class (SOC) and preferred terms.

Adverse events leading to temporary withdrawal of trial product

Adverse events leading to temporary withdrawal of trial products were summarised descriptively. The summary tables are based on SOC and preferred terms.

Please note that additional safety outputs were added to the planned output included in the protocol, as described in the statistical analysis plan (SAP): Injection site reactions, allergic reactions and adverse events leading to temporary withdrawal of trial product (see Section 9.8.2).

Hypoglycaemic episodes

The information collected regarding hypoglycaemic episodes throughout the trial included PG before treating the episode and whether the subject had altered mental status.

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

Hypoglycaemic episodes were defined as nocturnal if the time of onset was between 23:00-07:00 (11 p.m. to 7 a.m.) inclusive.

Data on treatment-emergent hypoglycaemic episodes was presented in terms of the number of subjects with at least one event (N), the percentage of subjects with at least one event (%), the number of events (E) and the event rate per 100 years (R). Separate summaries were made by severity considering all episodes and nocturnal episodes separately.

The number of treatment-emergent hypoglycaemic episodes was analysed separately using a negative binomial regression model with a log-link function and the logarithm of the time period for which a hypoglycaemic episode was considered treatment-emergent as offset. The model included treatment, sex, region and age group as fixed factors. To the extent where data allowed, separate analyses were performed for severe episodes and confirmed episodes considering all episodes and nocturnal episodes.

Hyperglycaemic Episodes and hyperglycaemic episodes with Ketosis

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

Data on treatment emergent hyperglycaemic episodes and treatment-emergent hyperglycaemic episodes with ketosis was presented separately in terms of the number of subjects with at least one event (N), the percentage of subjects with at least one event (%), the number of events (E) and the event rate per 100 years (R).

The number of treatment-emergent hyperglycaemic episodes and the number of treatment-emergent hyperglycaemic episodes with ketosis was analysed separately using a negative binomial regression model with a log-link function and the logarithm of the time period for which an episode was considered treatment emergent as offset. The model included treatment, sex, region and age group as fixed factors.

Nocturnal hyperglycaemia

Data on treatment-emergent nocturnal hyperglycaemic episodes, and treatment-emergent nocturnal hyperglycaemic episodes with ketosis was presented separately in terms of the number of subjects with at least one event (N), the percentage of subjects with at least one event (%), the number of events (E) and the event rate per 100 years (R).

Please note that additional safety outputs were added to the planned output included in the protocol, as described in the SAP: The treatment-emergent nocturnal confirmed hyperglycaemic episodes and treatment-emergent nocturnal hyperglycaemic episodes with ketosis have been added to the included safety outputs (see Section 9.8.2).

The nocturnal period was defined as the period between 23:00 p.m. and 07:00 a.m. (both included).

Vital Signs

Vital signs included diastolic blood pressure, systolic blood pressure and pulse. The measurements and their change from baseline was summarised descriptively.

Laboratory Assessments

The following laboratory assessments were performed as described in Section 9.5.1.4.

Individual laboratory values were flagged as being below or above existing relevant reference ranges. Change from baseline was summarised descriptively.

Insulin Dose

Prescribed and actual insulin dose per day was recorded together with time of administration. The insulin dose was summarised descriptively according to regimen as dose in units/day and units/kg/day.

Body Weight

Body weight change from baseline was summarised descriptively.

SD score for body weight

SD scores for body weight have been defined as a supportive endpoint. Body weight was expressed as SD score. The rationale for including SD score for body weight is that body weight and change hereof varies depending on age and growth phase within the trial population. In addition, growth differs across populations participating in the study, hence the use of country specific growth curves.

The SD scores were derived from the age and sex of the subjects and the body weight together with growth curves defined for the reference population of each country[5,6,7,8]. Thus, a child with a weight equal to the mean value for its age and sex has an SD score of 0, while a child with a weight 2 SDs above the mean value for its age and sex has an SD score of +2.

For the countries where reference values were not available (Brazil, Canada, Croatia, Israel, Macedonia, Poland, Russian Federation, Serbia, Slovenia and South Africa) US CDC data were used.

SD score for body weight and its change from baseline were summarised descriptively.

All SD score (based on observed weight) measurements available post-randomisation at scheduled measurement times were analysed with a MMRM with an unstructured covariance matrix. The model included treatment, sex, region, age-group and visit as factors and baseline SD score as covariate. Interactions between visit and all factors and covariates were also included in the model.

Please note that changes have been made to the planned endpoints included in the protocol: The SD score for body weight have been added to the included safety endpoints (see Section 9.8.2).

BMI

BMI and its change from baseline was summarised descriptively.

9.7.5.3 Interim analysis and data monitoring

Not applicable.

9.7.6 Other assessments

No other assessments were conducted.

9.8 Changes in the conduct of the trial or planned analyses

9.8.1 Protocol amendments

There were 2 global amendments to the protocol, with a version 1.0 and 2.0 for amendment no.1:

- Amendment no.1, version 1.0, a global amendment from 25 Feb 2014. The protocol was updated upon request from FDA; the MMRM method (applied on non-imputed data) was used instead of the ANOVA method (applied to imputed data by use of LOCF) for analysis of continuous endpoints. Furthermore, the blood volume needed for blood sampling in the age group below 6 years was updated to a smaller volume due to a miscalculation. Furthermore, the text in the master subject information related to the use of Lantus® was updated. Lastly, a few minor typing errors were corrected. This amendment was not submitted in any countries due to discovery of an error that demanded a new internal protocol review committee (PRC) submission (see version 2.0 below).
- Amendment no.1, version 2.0, a global amendment from 01 Apr 2014. In addition to what is described for amendment no. 1, version 1.0, a few typing errors in Section 17 (Statistical considerations) were discovered and corrected. Amendment no. 1, version 2.0 was submitted in all countries.
- Amendment no.2, a global amendment from 30 May 2014. Error corrected in Section 17.2 regarding definition of the Full Analysis Set (FAS).

Protocol amendments were approved according to local requirements prior to implementation (see Section 5.1). Please refer to the protocol amendments in Appendix 16.1.1 for further details.

9.8.2 Changes to the planned statistical analyses

9.8.2.1 Changes to the statistical analysis planned in the protocol

The below changes have all been documented in the SAP and thus before database lock (DBL).

The following were not specified in the protocol effective at FPFV, however, changes to the planned statistical analysis were generated:

- The MMRM method (applied on non-imputed data) was used instead of the ANOVA method (applied to imputed data by use of LOCF) for analysis of continuous endpoints. Predicted values from the MMRM method replaced the LOCF method to account for missing data. Applying the MMRM method is in accordance with current comments from FDA[20]. This change has been addressed in Protocol Amendment no.1
- An error in the definition of subjects included in the FAS population in the protocol text has been updated; “treated” has been corrected to “randomised” in the description of how subjects contributed to the evaluation. The updated definition of FAS is aligned with similar trials and in accordance with guidelines and a request from FDA. This is addressed in Protocol Amendment no. 2

- SD score for body weight: The rationale for including SD score for body weight is that body weight and change hereof varies depending on age and growth phase within the trial population. In addition, growth differs across populations participating in the study, hence the use of country specific growth curves.

Furthermore, the following additional summary outputs were generated according to the SAP (see Appendix 16.1.9):

- Body weight
- Injection site reaction
- Nocturnal hyperglycaemia
- Nocturnal increment in PG
- Adverse events leading to temporary withdrawal of trial product
- Allergic reaction

9.8.2.2 Additional/exploratory analysis

The below analysis was added post-hoc to be consistent with analysis of previous trials.

All observed 8-point profile (SMPG) measurements available post-randomisation at scheduled measurement times was analysed with a MMRM with an unstructured covariance matrix. The model included treatment, sex, region, age-group, time-point within 8-point profile and visit as factors and corresponding baseline SMPG profile as covariate. Interactions between visit and all factors and covariates were also included in the model, and in addition interaction between treatment and visit and time-point was also included.

10 Trial subjects

10.1 Subject disposition

Table 10–1 Subject disposition – summary

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Screened			387
Screening Failures			25
Withdrawn before Randomisation			0
Randomised	182 (100.0)	180 (100.0)	362 (100.0)
Exposed	181 (99.5)	179 (99.4)	360 (99.4)
Withdrawn at/after Randomisation	8 (4.4)	12 (6.7)	20 (5.5)
Adverse Event	1 (0.5)	0 (0.0)	1 (0.3)
Non-Compliance With Protocol	1 (0.5)	0 (0.0)	1 (0.3)
Withdrawal Criteria	6 (3.3)	10 (5.6)	16 (4.4)
Other	0 (0.0)	2 (1.1)	2 (0.6)
Completed	174 (95.6)	168 (93.3)	342 (94.5)
full analysis set	182 (100.0)	180 (100.0)	362 (100.0)
PP analysis set	174 (95.6)	171 (95.0)	345 (95.3)
safety analysis set	181 (99.5)	179 (99.4)	360 (99.4)

N: Number of subjects
%: Proportion of randomised subjects
PP: Per protocol

Cross-reference: EOT Table 14.1.1

The subject disposition was well matched in the 2 treatment groups Table 10–1.

A total of 387 subjects were screened, of which 25 were screening failures, see Table 10–1. Of the subjects who were screening failures, 17 subjects did not meet inclusion criterion 6 (HbA_{1c} ≤11%), 1 subject met exclusion criterion 2 (use of oral antidiabetic agents), 1 subject met exclusion criterion 9 (mental incapacity, unwillingness or language barriers, precluding adequate understanding or cooperation) and 6 subjects withdrew consent, see Appendix 16.2.1, Listing 16.2.1.1.

A total of 362 subjects were randomised to IDegAsp or IDet treatment in a 1:1 ratio. Of the 362 subjects, 1 subject in the IDegAsp group was withdrawn before being exposed due to withdrawal criterion 1 (withdrew consent) and 1 subject in the IDet group was withdrawn before being exposed due to withdrawal criterion 3 (randomised in error). The latter was because the subject was randomised before receiving the results of Visit 1 and therefore withdrawn before being exposed to trial product; see Appendix 16.2.4, Listing 16.2.4.1 and Appendix 16.2.1, Listing 16.2.1.2.

A total of 342 subjects (94.5%) completed the trial with a similar proportion of subjects completing in both treatment groups, see Table 10–1. Of the 20 subjects who withdrew during the trial, 1 subject in the IDegAsp group withdrew due to an adverse event (see Section 12.5.1). The most common reason for withdrawal was fulfilment of withdrawal criterion 1 (withdrew consent). 1 subject in the IDegAsp treatment group withdrew due to non-compliance with the protocol and 2 subjects in the IDet treatment group withdrew due to other reasons. Withdrawals and the reason for withdrawal are listed in Appendix 16.2.1, Listing 16.2.1.2.

There was a similar pattern in time to discontinuation in the IDegAsp group and IDet group; see EOT Figure 14.1.6. From week 12-16 there was 1 withdrawal in the IDegAsp group due to withdrawal criterion 7 (Initiation or significant change of any systemic treatment which in the Investigator's opinion could interfere with glucose metabolism) and there were 6 withdrawals in the IDet group. Of the 6 subjects withdrawn in the IDet group, 4 withdrew due to withdrawal criterion 1 (withdrew consent), 1 withdrew due to withdrawal criterion 2 (Investigator's decision to withdraw subject) and 1 subject withdrew due to other reasons ('[redacted]') (EOT Table 14.1.9).

The procedures for determination of subjects excluded from analysis sets were carried out as planned.

The subject disposition was well matched in the treatment groups for each of the 3 age groups as expected due to the stratification. See Table 10–2, Table 10–3 and Table 10–4 for a summary of randomised subjects of 1-5 years, 6-11 years and 12-17 years respectively.

Table 10–2 Subject disposition - summary - children (1-5 years)

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Randomised	41 (100.0)	41 (100.0)	82 (100.0)
Exposed	40 (97.6)	41 (100.0)	81 (98.8)
Withdrawn at/after Randomisation	3 (7.3)	5 (12.2)	8 (9.8)
Withdrawal Criteria	3 (7.3)	5 (12.2)	8 (9.8)
Completed	38 (92.7)	36 (87.8)	74 (90.2)
full analysis set	41 (100.0)	41 (100.0)	82 (100.0)
PP analysis set	38 (92.7)	39 (95.1)	77 (93.9)
safety analysis set	40 (97.6)	41 (100.0)	81 (98.8)

N: Number of subjects
%: Proportion of randomised subjects
PP: Per protocol
This table is based on randomised subjects

Cross-reference: Modified from EOT Table 14.1.2

Table 10–3 Subject disposition - summary - children (6-11 years)

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Randomised	61 (100.0)	61 (100.0)	122 (100.0)
Exposed	61 (100.0)	61 (100.0)	122 (100.0)
Withdrawn at/after Randomisation	1 (1.6)	2 (3.3)	3 (2.5)
Adverse Event	1 (1.6)	0 (0.0)	1 (0.8)
Withdrawal Criteria	0 (0.0)	1 (1.6)	1 (0.8)
Other	0 (0.0)	1 (1.6)	1 (0.8)
Completed	60 (98.4)	59 (96.7)	119 (97.5)
full analysis set	61 (100.0)	61 (100.0)	122 (100.0)
PP analysis set	59 (96.7)	58 (95.1)	117 (95.9)
safety analysis set	61 (100.0)	61 (100.0)	122 (100.0)

N: Number of subjects
%: Proportion of randomised subjects
PP: Per protocol
This table is based on randomised subjects

Cross-reference: Modified from EOT Table 14.1.3

Table 10–4 Subject disposition - summary - adolescents (12-17 years)

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Randomised	80 (100.0)	78 (100.0)	158 (100.0)
Exposed	80 (100.0)	77 (98.7)	157 (99.4)
Withdrawn at/after Randomisation	4 (5.0)	5 (6.4)	9 (5.7)
Non-Compliance With Protocol	1 (1.3)	0 (0.0)	1 (0.6)
Withdrawal Criteria	3 (3.8)	4 (5.1)	7 (4.4)
Other	0 (0.0)	1 (1.3)	1 (0.6)
Completed	76 (95.0)	73 (93.6)	149 (94.3)
full analysis set	80 (100.0)	78 (100.0)	158 (100.0)
PP analysis set	77 (96.3)	74 (94.9)	151 (95.6)
safety analysis set	80 (100.0)	77 (98.7)	157 (99.4)

N: Number of subjects
%: Proportion of randomised subjects
PP: Per protocol
This table is based on randomised subjects

Cross-reference: Modified from EOT Table 14.1.4

Subject disposition by country, week and trial site is presented in EOT Tables 14.1.5 and EOT Tables 14.1.7–8.

10.2 Demographic and other baseline characteristics

10.2.1 Demographics

The trial population consisted of children and adolescents with T1DM aged from 1 to less than 18 years. Females comprised 51.7% of the trial population (Table 10–5). Approximately 32% of the subjects were from the U.S, 13% were from the Russian Federation and 9% were from Israel. The majority of subjects (93.1%) were 'White'. The majority of subjects (92.3%) were not Hispanic or Latino (Table 10–5). Subjects are listed by gender, race and ethnicity in Appendix 16.2.4, Listing 16.2.4.2.

Subject demographics including age are presented in Appendix 16.2.4, Listing 16.2.4.3.

The treatment groups were similar with regard to age group, sex, ethnicity and race (Table 10–5). In terms of country of residence, more subjects were randomised to IDegAsp than to IDet in the US (64 versus 50 subjects), Canada (8 versus 3 subjects) and the Czech Republic (12 versus 7 subjects). In contrast, more subjects were randomised to IDet than to IDegAsp in Serbia (20 versus 7 subjects)

and Macedonia (13 versus 7 subjects). These differences in nationality were not expected to affect the overall results of the study.

Within each age group, the demographics were well matched between the treatment groups, see EOT Tables 14.1.11−13 and EOT Tables 14.1.15−17.

Table 10–5 Demographics and baseline characteristics - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	182	180	362
Age Group			
N	182 (100.0)	180 (100.0)	362 (100.0)
Children (1-5 yrs)	41 (22.5)	41 (22.8)	82 (22.7)
Children (6-11 years)	61 (33.5)	61 (33.9)	122 (33.7)
Adolescents (12-17 years)	80 (44.0)	78 (43.3)	158 (43.6)
Sex			
N	182 (100.0)	180 (100.0)	362 (100.0)
Female	93 (51.1)	94 (52.2)	187 (51.7)
Male	89 (48.9)	86 (47.8)	175 (48.3)
Country of Residence			
N	182 (100.0)	180 (100.0)	362 (100.0)
Belgium	8 (4.4)	5 (2.8)	13 (3.6)
Brazil	4 (2.2)	3 (1.7)	7 (1.9)
Canada	8 (4.4)	3 (1.7)	11 (3.0)
Croatia	5 (2.7)	7 (3.9)	12 (3.3)
Czech Republic	12 (6.6)	7 (3.9)	19 (5.2)
Israel	16 (8.8)	18 (10.0)	34 (9.4)
Poland	13 (7.1)	15 (8.3)	28 (7.7)
Republic of Macedonia	7 (3.8)	13 (7.2)	20 (5.5)
Russian Federation	21 (11.5)	25 (13.9)	46 (12.7)
Serbia	7 (3.8)	20 (11.1)	27 (7.5)
Slovenia	2 (1.1)	2 (1.1)	4 (1.1)
South Africa	7 (3.8)	5 (2.8)	12 (3.3)
Spain	8 (4.4)	7 (3.9)	15 (4.1)
United States	64 (35.2)	50 (27.8)	114 (31.5)
Ethnicity			
N	182 (100.0)	180 (100.0)	362 (100.0)
Hispanic or Latino	15 (8.2)	13 (7.2)	28 (7.7)
Not Hispanic or Latino	167 (91.8)	167 (92.8)	334 (92.3)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Race			
N	182 (100.0)	180 (100.0)	362 (100.0)
White	169 (92.9)	168 (93.3)	337 (93.1)
Black or African American	8 (4.4)	4 (2.2)	12 (3.3)
Asian Indian	0 (0.0)	1 (0.6)	1 (0.3)
Asian non-Indian	0 (0.0)	0 (0.0)	0 (0.0)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Other	5 (2.7)	7 (3.9)	12 (3.3)

N: Number of subjects
%: Percentages are based on N

Cross-reference: Modified from EOT Table 14.1.10

10.2.2 Baseline and diabetes characteristics

The baseline diabetes characteristics were comparable between the treatment groups apart from slight differences in mean FPG and mean duration of diabetes (Table 10–6). For the overall study population, the mean (SD) FPG at baseline was slightly higher in the IDegAsp group than in the IDet group: 8.6 (4.4) mmol/L versus 8.1 (4.2) mmol/L, respectively. The mean (SD) duration of diabetes was slightly higher in the IDegAsp group than in the IDet group: 4.4 (3.7) years versus 3.8 (3.2) years, respectively.

At baseline, the overall study population had a mean (SD) age of 10.6 (4.5) years (ranging from 1.9 to 17.9 years), a mean (SD) BMI of 19.4 (4.1) kg/m^2 (ranging from 11.0 to 35.1 kg/m^2) and a mean (SD) HbA_{1c} of 8.1 (1.2)% (ranging from 5.1% to 11.1%) (Table 10–6).

The subjects were randomised based on measurements performed on visit 1, and baseline values were recorded approximately 1 week later, at Visit 2.

Baseline and diabetes characteristics are presented by subject in Appendix 16.2.4, Listing 16.2.4.3.

In children 1-5 years and 6-11 years, the baseline and diabetic characteristics were comparable in the 2 treatment groups (EOT Tables 14.1.15−16).

In adolescents 12-17 years, mean (SD) FPG was 8.6 (4.5) mmol/L. Mean FPG was slightly higher in the IDegAsp group: 9.0 (4.7) mmol/L compared to IDet: 8.1 (4.2) mmol/L (EOT Table 14.1.17). Otherwise the treatment groups were comparable.

Table 10–6 Baseline and diabetes characteristics - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
Age (years)			
N	182	180	362
Mean (SD)	10.5 (4.3)	10.8 (4.6)	10.6 (4.5)
Median	11.0	11.4	11.2
Min ; Max	2.2 ; 17.8	1.9 ; 17.9	1.9 ; 17.9
Height (m)			
N	180	179	359
Mean (SD)	1.41 (0.24)	1.42 (0.27)	1.42 (0.25)
Median	1.44	1.48	1.46
Min ; Max	0.90 ; 1.87	0.83 ; 1.91	0.83 ; 1.91
Body Weight (kg)			
N	182	180	362
Mean (SD)	41.1 (20.7)	42.9 (21.2)	42.0 (20.9)
Median	39.4	39.9	39.7
Min ; Max	12.1 ; 117.1	9.4 ; 104.4	9.4 ; 117.1
Duration of Diabetes (years)			
N	182	180	362
Mean (SD)	4.4 (3.7)	3.8 (3.2)	4.1 (3.5)
Median	3.1	2.8	3.0
Min ; Max	0.3 ; 14.6	0.3 ; 13.9	0.3 ; 14.6
BMI (kg/m^2)			
N	180	179	359
Mean (SD)	19.2 (4.2)	19.6 (4.0)	19.4 (4.1)
Median	18.4	18.6	18.5
Min ; Max	11.0 ; 35.1	12.8 ; 31.9	11.0 ; 35.1
HbA1c (%)			
N	182	180	362
Mean (SD)	8.1 (1.2)	8.1 (1.2)	8.1 (1.2)
Median	8.0	8.0	8.0
Min ; Max	5.1 ; 11.1	5.4 ; 10.9	5.1 ; 11.1
FPG (mmol/L)			
N	172	166	338
Mean (SD)	8.6 (4.4)	8.1 (4.2)	8.4 (4.3)
Median	7.7	7.2	7.4
Min ; Max	0.5 ; 20.7	1.9 ; 25.1	0.5 ; 25.1

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

Cross-reference: Modified from EOT Table 14.1.14

Diabetic complications

Diabetic complications were overall similar in the treatment groups. In total, 14 (3.9%) subjects had diabetic complications at screening: 9 (2.5%) subjects had diabetic neuropathy, 4 (1.1%) subjects

had microalbuminuria and 1 (0.3%) subject was diagnosed with cataract diabetic (EOT Table 14.1.20 and Appendix 16.2.4, Listing 16.2.4.6). There were 5 events of diabetic complications in 5 subjects within the IDegAsp group and 9 events of diabetic complications in 9 subjects within the IDet group.

Anti-diabetic regimen at screening

Anti-diabetic regimens at screening were overall similar in the treatment groups. At screening the majority of subjects (333 subjects [92.0%]) were using basal + bolus insulin therapy, 5 (1.4%) using basal + bolus + premix while 24 (6.6%) were using 'other' regimens, i.e. basal, bolus, premix alone or premix in combination with bolus; 'other' could also include an insulin pump regimen (EOT Table 14.1.18).

The type of insulin used at screening is presented in Table 10–7. IDet was the most widely used basal insulin at screening followed by insulin glargine (IGlar). IAsp was the most commonly used bolus insulin, see Table 10–7. Approximately half the subjects had used IDet: 75 (41.2%) in the IDegAsp group and 95 (52.8%) in the IDet group. IGlar was used by 77 (42.3%) and 70 (38.9%) respectively. The most commonly used bolus insulin was IAsp (60.8% overall).

Anti-diabetic treatment at screening per subject is listed in Appendix 16.2.4, Listing 16.2.4.5.

Table 10–7 Insulin type at screening - summary - full analysis set

	IDegAsp OD		IDet		Total	
	N	(%)	N	(%)	N	(%)
Number of Subjects	182		180		362	
Basal insulin	171	(94.0)	171	(95.0)	342	(94.5)
IDet	72	(39.6)	92	(51.1)	164	(45.3)
IDet + Insulin NPH	3	(1.6)	3	(1.7)	6	(1.7)
IGlar	77	(42.3)	70	(38.9)	147	(40.6)
Insulin NPH	19	(10.4)	6	(3.3)	25	(6.9)
Bolus insulin	176	(96.7)	177	(98.3)	353	(97.5)
HI	21	(11.5)	19	(10.6)	40	(11.0)
HI + IAsp	3	(1.6)	5	(2.8)	8	(2.2)
HI + ILis	1	(0.5)	1	(0.6)	2	(0.6)
IAsp	104	(57.1)	108	(60.0)	212	(58.6)
IGlu	6	(3.3)	8	(4.4)	14	(3.9)
ILis	41	(22.5)	36	(20.0)	77	(21.3)
Premix insulin	7	(3.8)	7	(3.9)	14	(3.9)
BHI			2	(1.1)	2	(0.6)
BIAsp	6	(3.3)	3	(1.7)	9	(2.5)
Lispro mix	1	(0.5)	2	(1.1)	3	(0.8)

N: Number of subjects, %: Proportion of subjects
IGlar: Insulin glargine, ILis: Insulin lispro
IAsp: Insulin aspart, NPH: Neutral protamine hagedorn
BHI: Biphasic human insulin, BIAsp: Biphasic insulin aspart
IDet: Insulin detemir, HI: Human insulin, IGlu: Insulin glulistin

Cross-reference: EOT Table 14.1.19

10.2.3 Concomitant illness and medication

The treatment groups were well matched for concomitant illness at screening (EOT Table 14.1.21). The most frequently reported preferred terms were premenarche (111 subjects; 30.7%), asthma (19 subjects; 5.2%), hypothyroidism (17 subjects; 4.7%), seasonal allergy (16 subjects; 4.4%) and coeliac disease (15 subjects; 4.1%). Concomitant illnesses and medical history are listed by subject in Appendix 16.2.4, Listing 16.2.4.6.

Overall, the panel of concomitant medications at screening was similar in the treatment groups. Levothyroxine sodium was reported for 17 (4.7%) subjects. After insulins and levothyroxine sodium, all other concomitant medications were reported by less than 2.5% of subjects. Concomitant medication at screening and prior to screening is summarised in EOT Table 14.1.22.

During the trial, subjects in both treatment groups used a variety of concomitant medications. The most frequent concomitant medications used in the treatment groups during the trial were ibuprofen

and paracetamol, and antibiotics (amoxicillin and azithromycin); see EOT Table 14.1.23. Other concomitant medications were each reported overall by less than 2.5% of subjects.

In the IDegAsp group 2 subjects (Subject ID: [redacted] [redacted] and [redacted] [redacted]) administered insulin glargine during the trial. One (1) subject (Subject ID: [redacted]) administered insulin detemir ([redacted]) during the trial.

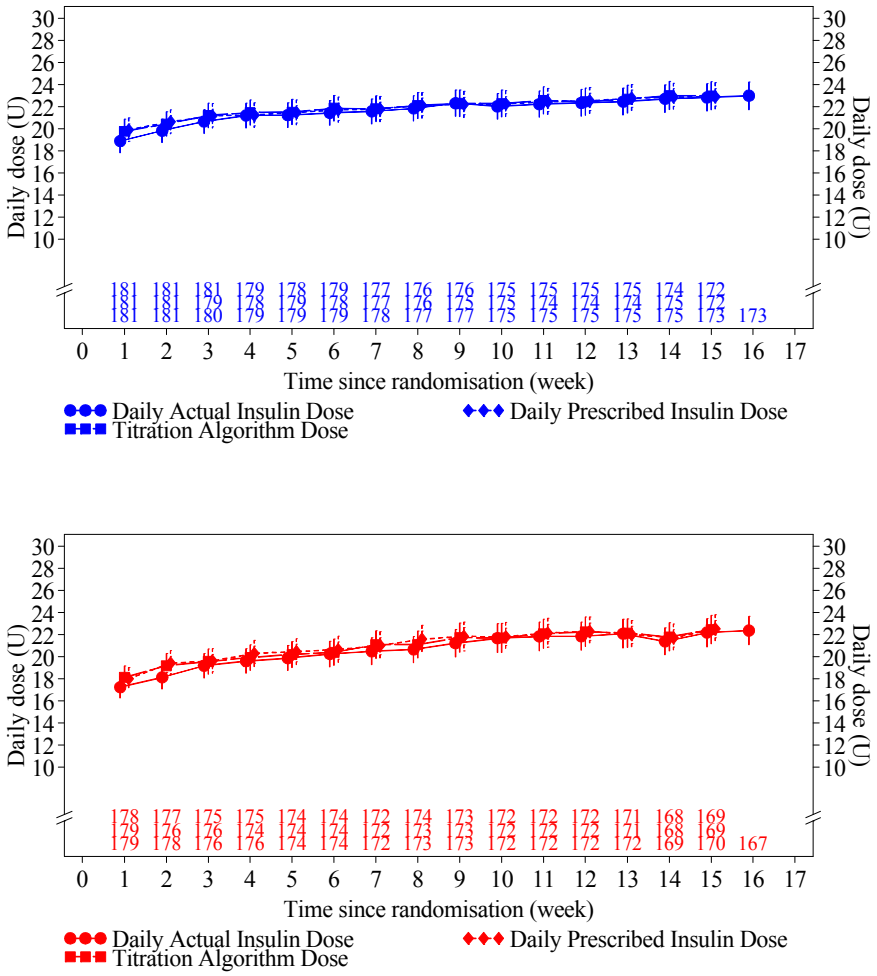
Prior and concomitant medications for individual subjects are provided in Appendix 16.2.4, Listing 16.2.4.5.

10.3 Measurements of treatment compliance

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. Titration was to be performed according to the Insulin Titration Guideline in the protocol.

Drug accountability was performed at weeks 4, 8, 12 and 16 (visits 6, 10, 14 and 18). For the vast majority of subjects, and there was a high level of compliance with the prescribed dose. Prescribed, actual and titration algorithm dose are presented graphically in Figure 10–1.

Prescribed minus actual dose was similar between treatment groups (EOT Table 14.2.170); the mean was between -0.0 and +0.1 units (inclusive) throughout the trial in the IDegAsp group and between -0.1 and +0.3 units (inclusive) in the IDet group. Prescribed minus titration algorithm dose was similar between treatment groups, showing that in most cases the algorithm was followed throughout the trial in both treatment groups (EOT Table 14.2.171).



SAS; Observed data. Error bars + - standard error (mean). Numbers of subjects contributing to the data points are provided in the bottom section of each plot (presented from top to bottom as: children 1-5 years, children 6-11 years, adolescents 12-17 years.)

Cross-reference: EOT Figures 14.2.172 and 14.2.173

Figure 10–1 Daily IDegAsp (upper plot) and daily IDet (lower plot) insulin dose in units by treatment week - prescribed, actual and titration algorithm dose – mean plot - safety analysis set

Compliance to the insulin titration algorithm and compliance to the prescribed dose is listed by subject in Appendix 16.2.5, Listing 16.2.5.2.

10.4 Protocol deviations

10.4.1 Summary of important protocol deviations

Protocol deviations (PDs) were reviewed and classified as important or not important by the study group prior to database lock (26 November 2014). Important deviations were those that were

considered as possibly affecting 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 good clinical practice (GCP). A listing of all important protocol deviations reported in relation to this trial is included in Appendix 16.2.2.

This report includes the protocol deviations that were reported at the time of database lock. However, 3 site level PDs were identified after DBL concerning: a missed monitoring visit, a temperature deviation and a deviation related to an investigator who had not entered titration data within 24 hours as per protocol. None of these post-DBL PDs was judged to have any impact on trial conduct. See Appendix 16.2.2, Listing 16.2.2.6 for further details.

A total of 511 important PDs were reported for this trial: 1 reported at trial level, 0 at country level, 34 at site level and 476 at subject level. The majority of the PDs were related to assessments during the trial out of which a significant number of PDs were related to missing ketones measurements when experiencing hyperglycaemia. None of the PDs were judged to have major impact on the conduct of the trial, the safety of the subjects or the results of the analyses.

10.4.2 Important protocol deviations at trial level

There was 1 trial level PD (Appendix 16.2.2, Listing 16.2.2.1). This was related to registration of start doses in electronic data capture (EDC). Upon request from a few clinical sites, it was realised that in the EDC system, it was not possible to register ½ units in relation to data entry of the initial starting dose, thus in such cases whole units (rounded up or down) were to be entered instead. In total, 24 subjects were affected, for 9 subjects the dose was rounded up and for 15 subjects doses were rounded down. Information on the subjects affected, actual starting dose and dose entered into EDC can be found in the impact report for this PD in Appendix 16.2.2. It was evaluated, that the effect of the issue on safety and trial conduct and analysis of results was not substantial.

10.4.3 Important protocol deviations at country level

No PDs were reported at country level.

10.4.4 Important protocol deviations at trial site and subject level

A total of 34 important PDs were reported at site level and 476 PDs (241 PDs in the IDegAsp group, 227 PDs in the IDet group and 8 PDs in subjects not randomised) were reported at subject level. It should be noted that site level PDs usually cover more than one subject. In some instances the same type of PDs was reported at the trial site and at the subject level, hence these two levels are described together.

PDs were recorded at the trial site according to a set of pre-specified categories, described in the trial specific "Protocol Deviation Categorisation Document", and the site monitors/Investigators classified each PD to a category. The number of PDs in each of the topic categories are summarised in Table 10–8 for trial site PDs and Table 10–9 for subject level PDs. Some PDs occurred for

subjects who later became screening failures (listed as not randomised) and hence did not receive any trial drug.

No trial site or subject level PDs led to exclusion of subjects from any analysis.

There was no apparent pattern or clustering of subject levels PDs according to treatment group.

Several PDs in both treatment groups regarding measuring of blood ketones during hyperglycaemia were reported. Ketone bodies were not measured for approximately 26% of hyperglycaemic episodes in the IDegAsp group and for 33% in the IDet treatment group (see Section 12.7). For considerations regarding the statistical analysis of episodes of hyperglycaemia with ketosis see Section 12.7.

Table 10–8 Summary of important protocol deviations at site level

Protocol deviation category	Number of PDs
Informed consent	**1**
Trial product handling	**9**
Pharmacist not part of log of staff	1
Trial product temperature deviation	1
Wrong device used	1
Trial product temperature not recorded	2
Documentation non-compliance	2
DFU not dispensed	1
Temperature deviation	1[a]
Assessment deviations	**3**
BP not done	1
BP measured with uncalibrated equipment	1
FPG missing	1
Other	**21**
Corrections made to diary by site staff	3
Monitoring visit out of window/interval defined	14
Use of equipment without calibration certificate	1
Late reporting of PSUR to ethics committee	1
Log of staff not reflecting staff performing trial procedures	2
Total	**34**

[a]This protocol deviation has been miscategorised as related to "Other" in Appendix 16.2.2.

Table 10–9 Summary of important protocol deviations at subject level

Protocol deviation category	IDegAsp	IDet	Total
Informed consent	**16**	**13**	**35**[a]
Inclusion/exclusion/rand. criteria	**5**	**9**	**14**
Withdrawal criteria	**1**	**0**	**1**
Trial product handling	**16**	**13**	**29**
DFU not dispensed	5	2	8
Wrong trial product administered/received	1	1	2
Wrong DUN dispensed/DUN not dispensed	1	1	2
Product stored outside temperature range	6	5	11
Trial product used after subject discontinuation	0	1	1
Wrong device used	1	2	3
Timely reporting of complaints	2	1	3
Treatment compliance	**16**	**9**	**25**
Subject exposed to trial product more than 16 weeks	5	4	9
Non-trial insulin administered	1		1
Insufficient DUNs dispensed	0	1	1
Commercial insulin used	5	2	7
Wrong pen used	2		2
Subject visit out of window	1	1	2
Use trial products that should have been returned	1		1
Incorrect reporting of BG values by subject	0	1	1
Wrong dose administered due miscalculation by site	1		1
Assessment deviations	**147**	**158**	**306**[b]
Ketone measurements not done in association with hyperglycaemia	57	57	114
Lab/safety tests not done/deleted/taken out of window	47	51	98
FPG not fasting, not done/deleted,/done by mistake	30	36	66
Source data missing/not documented correctly or in a timely manner	11	5	16
Visits missed	1	3	4
Diary not correctly completed	0	2	2
Subject not invited to perform visit 18 and 19 upon withdrawal	0	1	1
Lab (HbA1c not measured)	0	1	1[c]
Ketones	1	2	3[c]

Protocol deviation category	IDegAsp	IDet	Total
Other	**40**	**25**	**66[d]**
Corrections made to diary by site staff	10	4	14
AE/MESI/Technical complaint late reporting	9	3	12
Missing data/source data discrepancy	2	1	3
Log of staff form not reflecting staff performing trial procedures	2	5	7
Incorrect diary used	1	0	1
Incomplete diary returned	1	2	3
Incorrect subject documentation by Investigator	4	4	8
Trial product not delivered to site	2	0	2
Subject excluded before lab results were received	0	2	2
Screening visit window compromised by Investigator	0	1	1
Randomisation visit out of window	5	2	7
Missing phone contact (no titration data obtained)	1	0	1
Subject refused to come in for visit 19	2	0	2
Deleted PD	0	1	1
Late notification of technical complaint	1	0	1[e]
Total	***241***	***227***	***476[a,b,d]***

[a]6 subjects not randomised; [b]1 subject not randomised; [c]These protocol deviations has been miscategorised as related to "Other" in Appendix 16.2.2,[d]1 subject not randomised, [e]This protocol deviation has been miscategorised as related to "Assessment deviation" in Appendix 16.2.2.

10.5 Data sets analysed

Before data were locked for statistical analysis, a blinded review of the data was performed to identify protocol violations that could affect the results. Subjects were excluded from the PP analysis if they violated the inclusion/exclusion criteria, had less than 12 weeks of exposure, or if they did not have valid assessments of HbA_{1c} at baseline (screening or randomisation) and at least one non-missing HbA_{1c} value after 12 weeks of exposure; see Sections 9.7.2, 10.1 and 10.4.4. 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.

All analyses and summary of efficacy endpoints were based on the FAS. The analysis of the primary endpoint was repeated on the PP analysis set and is considered as supportive evidence. Safety endpoints were summarised using the SAS.

The number of subjects included in each analysis set is shown in Table 10–1. For a definition of the analysis sets, see Section 9.7.2.

In total, 345 subjects (95.3% of the randomised subjects) were included in the PP analysis set. The 17 randomised subjects excluded from the PP population did not have a valid HbA_{1c} measurement after 12 weeks.

No data points were excluded from the efficacy analysis (Appendix 16.2.3, Listing 16.2.3.2).

Twelve (12) subjects in the FAS (5 in the IDegAsp group and 7 in the IDet group) did not contribute information to the HbA_{1c} analysis at 16 weeks of treatment (Appendix 16.2.3, Listing 16.2.3.3). Among these, 11 subjects were excluded from PP population. One subject ([redacted]) was excluded from primary statistical analysis for HbA_{1c} due to missing assessments of HbA_{1c} at scheduled visits.

The safety analysis set contained fewer subjects than the FAS because 2 subjects (1 in each treatment group) were withdrawn before being exposed, see Section 10.1.

For details regarding the composition of the analysis sets per age group, see Table 10–2, Table 10–3 and Table 10–4.

11 Efficacy evaluation

In the following sections, for each endpoint the results based on the overall trial population (FAS) are presented. This is followed by the results of the 3 age groups (1-5 years, 6-11 years and 12-17 years) where relevant. Note that the age groups are sub-populations containing relatively low numbers, and this trial was not powered to show differences by age group. Statistical analyses are presented only for the entire population, and the age groups are summarised by descriptive statistics. Therefore, any trend presented by age group should be interpreted with caution.

Baseline values were obtained at visit 2 (week 0). The last scheduled data points were obtained at visit 18 (week 16) and are reported as the observed values for the trial. Regarding the statistical analysis, estimated treatment differences/ratios will be presented when comparing treatment groups. It should be noted that these estimated means and mean changes are based on statistical models, and therefore they may vary numerically from the observed means presented in graphs and summary tables, which are based on observed data. In general, observed values were used as the basis for plotting data, unless otherwise specified.

11.1 Primary endpoint – Change from baseline in HbA_{1c} after 16 weeks of treatment

The primary objective of this trial was to confirm the efficacy of IDegAsp administered OD + meal-time IAsp for the remaining meals in controlling glycaemia with respect to change from baseline in HbA_{1c} after 16 weeks of treatment.

IDegAsp OD + IAsp maintained glycaemic control as measured by change in HbA_{1c} and non-inferiority to IDet + IAsp in terms of changing HbA_{1c} was confirmed, as the upper limit of the 95% CI for the mean treatment difference was ≤ 0.4%; see Table 11–1. Superiority was not confirmed as the upper limit of the 95% CI for the mean difference was above 0 (see EOT Tables 14.2.174 and 14.2.184).

Table 11–1 HbA1c after 16 weeks of treatment - primary statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	182	177	7.79	0.07	
IDet	180	173	7.83	0.07	
Change from baseline					
LSMeans					
IDegAsp OD	182	177	-0.27	0.07	
IDet	180	173	-0.23	0.07	
Treatment Contrast					
IDegAsp OD - IDet			-0.04		[-0.23; 0.15]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval, SE: Standard error of the mean
All observed HbA1c measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline HbA1c as covariate.
Interactions between visit and all factors and covariates are also included in the model.

Cross-reference: Modified from EOT Table 14.2.183

The trend for the development of HbA_{1c} over time was similar in the IDegAsp and IDet group, with a minor reduction from baseline to week 16 (see Figure 11–1). HbA_{1c} at baseline (week 0) was similar in the IDegAsp and IDet group with an observed mean (SD) of 8.1% (1.2) in the IDegAsp group and 8.1% (1.2) in the IDet group. At week 16 the observed mean (SD) HbA_{1c} was 7.9% (1.2) in the IDegAsp group and 7.8% (1.3) in the IDet group (Table 11–2). The observed change from baseline to week 16 was −0.3%-point in both the IDegAsp and IDet group, calculated based on subjects with available HbA_{1c} measurements at both baseline and week 16 (EOT Table 14.2.179).

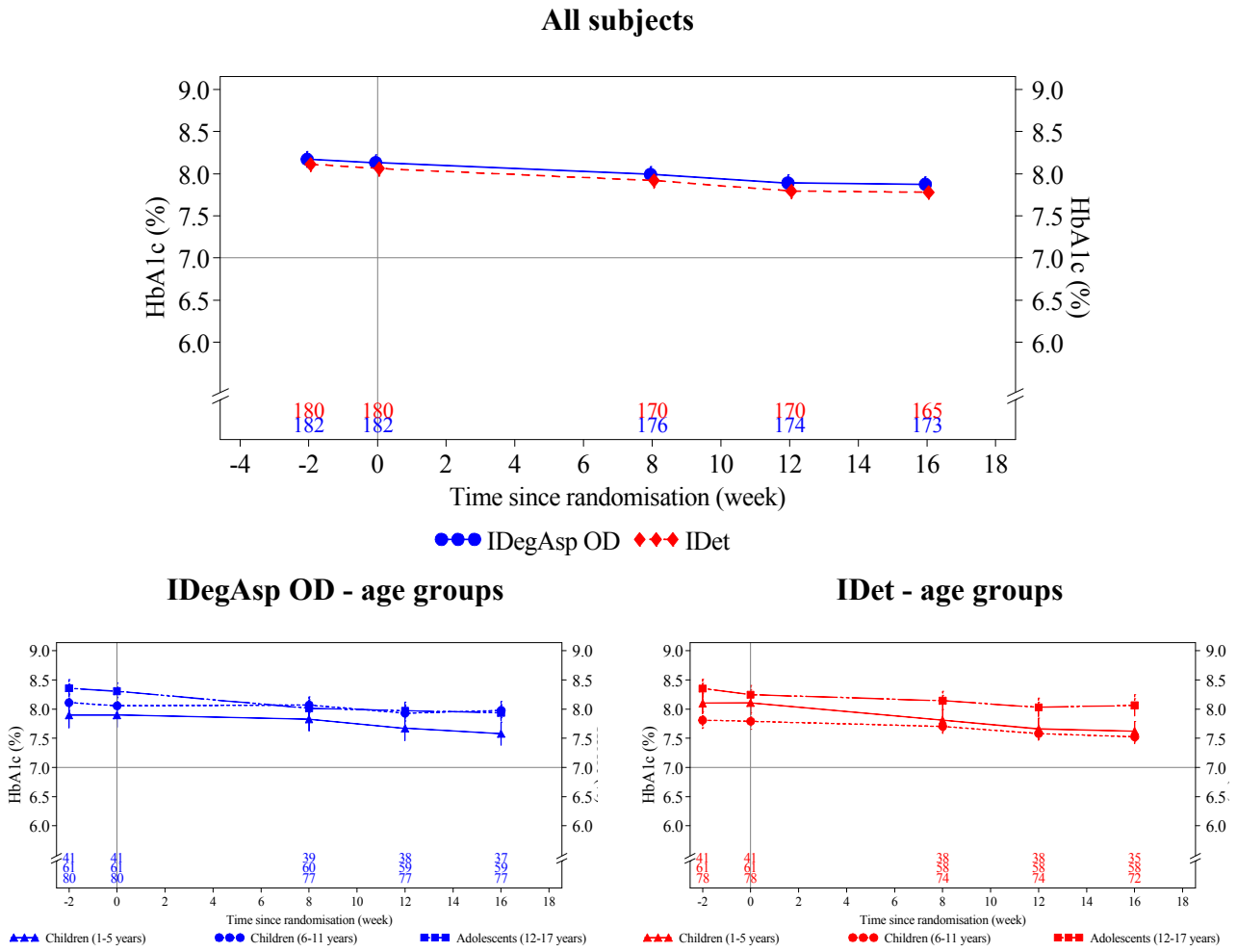
Table 11–2 HbA1c by treatment week – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
HbA1c(%)			
Visit 1			
N	182	180	362
Mean (SD)	8.2 (1.3)	8.1 (1.3)	8.1 (1.3)
Median	8.1	7.9	8.0
Min ; Max	5.1 ; 10.8	5.1 ; 10.9	5.1 ; 10.9
Visit 2 (Week 0)			
N	182	180	362
Mean (SD)	8.1 (1.2)	8.1 (1.2)	8.1 (1.2)
Median	8.0	8.0	8.0
Min ; Max	5.1 ; 11.1	5.4 ; 10.9	5.1 ; 11.1
Visit 10 (Week 8)			
N	176	170	346
Mean (SD)	8.0 (1.2)	7.9 (1.2)	8.0 (1.2)
Median	7.9	7.9	7.9
Min ; Max	5.0 ; 12.1	4.9 ; 11.3	4.9 ; 12.1
Visit 14 (Week 12)			
N	174	170	344
Mean (SD)	7.9 (1.2)	7.8 (1.2)	7.8 (1.2)
Median	7.8	7.7	7.7
Min ; Max	4.5 ; 12.8	5.2 ; 11.1	4.5 ; 12.8
Visit 18 (Week 16)			
N	173	165	338
Mean (SD)	7.9 (1.2)	7.8 (1.3)	7.8 (1.2)
Median	7.8	7.6	7.7
Min ; Max	5.0 ; 14.0	5.3 ; 12.4	5.0 ; 14.0
End of trial visit			
N	182	180	362
Mean (SD)	7.9 (1.3)	7.8 (1.3)	7.9 (1.3)
Median	7.8	7.6	7.7
Min ; Max	4.5 ; 14.0	5.3 ; 12.4	4.5 ; 14.0

N: Number of subjects, SD: Standard deviation

Cross-reference: EOT Table 14.2.175

Plots of HbA_{1c} (FAS) are presented in EOT Figures 14.2.201−204, 14.2.208. HbA_{1c} measurements per subject are presented in Appendix 16.2.6; Listing 16.2.6.2. Change from baseline is presented as LSMean plots in EOT Figure 14.2.197-200.



FAS; Observed data; Error bars + - standard error (mean). Numbers of subjects contributing to the data points are provided in the bottom section of each plot. In the lower panel, the age groups are presented from top to bottom: children 1-5 years, children 6-11 years, adolescents 12-17 years.

Cross-reference: EOT Figures 14.2.189 and 14.2.212−213

Figure 11–1 HbA1c (%) by treatment week - mean plots (upper panel: all subjects; lower panel: age groups)

Mean plots of HbA_{1c} by treatment are presented in mmol/mol in EOT Figure 14.2.193 and by age group within treatment groups in mmol/mol in EOT Figure 14.2.214−215.

Age groups

IDegAsp

Within the IDegAsp treatment group, the trend for HbA_{1c} was similar in all age groups, with a minor reduction from baseline to week 16, see Figure 11–1 and EOT Tables 14.2.176−178 and EOT Tables 14.2.180−182.

IDet

Within the IDet treatment group, the trend for HbA_{1c} was similar in all age groups, with a minor reduction from baseline to week 16, see Figure 11–1 and EOT Tables 14.2.176−178 and EOT Tables 14.2.180−182.

The mean HbA_{1c} profiles with IDegAsp and IDet for the age groups are presented in EOT Figures 14.2.190−192, 14.2.194−196. The respective empirical distribution plots for the age groups are shown in EOT Figures 14.2.205−207, 14.2.209−211.

Sensitivity analyses

Sensitivity analyses were performed by repeating the primary analysis on the PP analysis set, and the set of all completed subjects, Furthermore, sensitivity analysis were performed on the FAS using a simple MMRM model and an ANOVA model using LOCF. All sensitivity analysis showed an estimated mean treatment difference in line with the main analysis and supported the conclusion of non-inferiority, as the upper limit of the 95% CI ≤ 0.4% and the estimated mean treatment differences were close to that for the primary analysis (–0.04%-points); see Table 11–3.

Table 11–3 HbA_{1c} at week 16 – Statistical sensitivity analysis

Analysis (IDegAsp OD – IDet)	Estimated mean treatment difference [CI 95%]
Primary analysis	−0.04 [−0.23; 0.15]
Per protocol (PP)	−0.04 [−0.23; 0.15]
Completers	−0.03 [−0.22; 0.16]
Simple Model	0.00 [−0.19; 0.19]
Last observation carried forward (LOCF)	−0.04 [−0.22; 0.15]

Cross-reference: EOT Tables 14.2.184−188

11.2 Secondary endpoints

11.2.1 Fasting plasma glucose

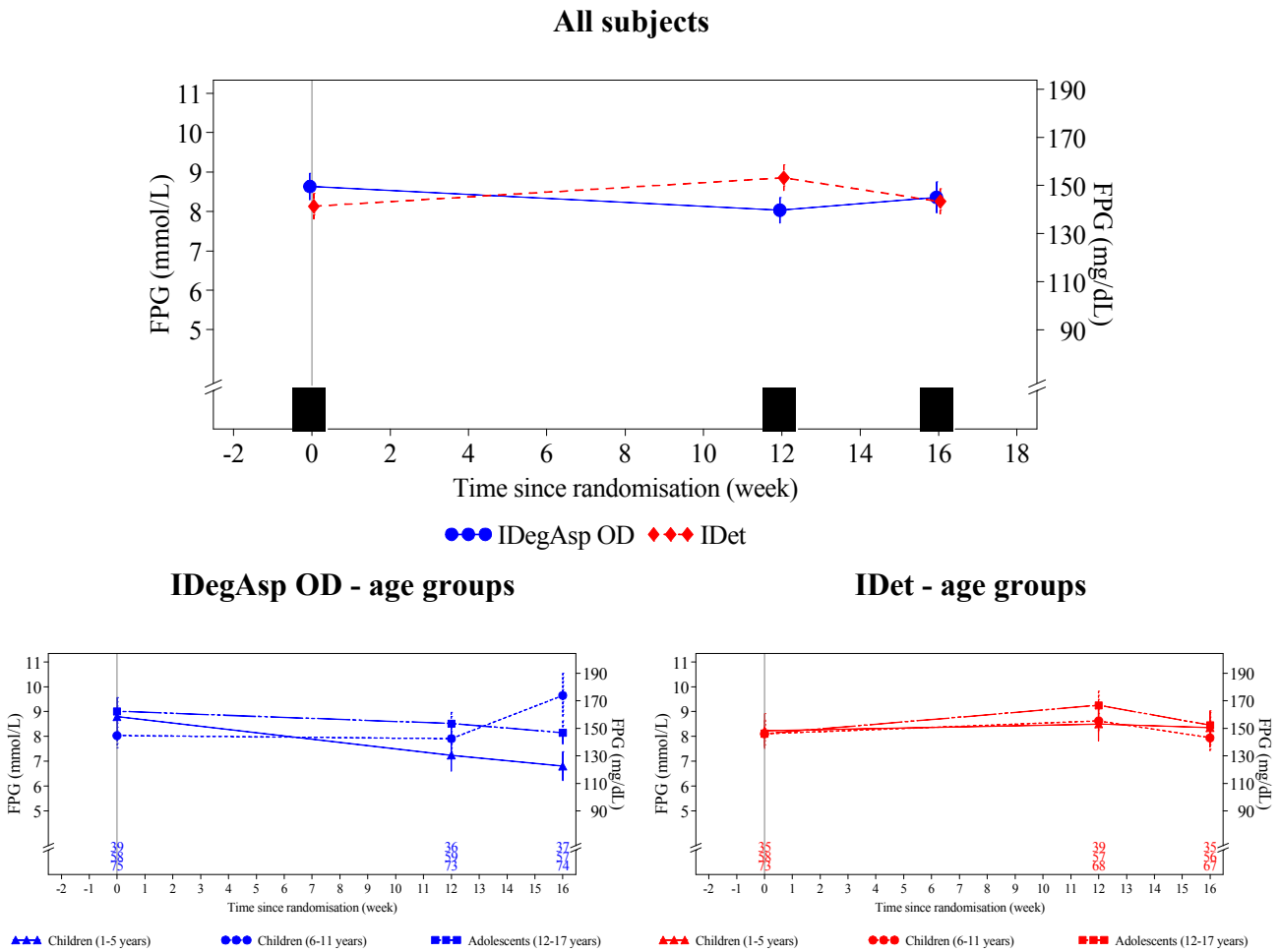
All subjects

In the IDegAsp group, mean FPG was 8.6 mmol/L at baseline and 8.4 mmol/L at week 16. The observed mean change from baseline at week 16 was −0.3 mmol/L, calculated based on subjects

with available FPG measurements at both baseline and week 16. In the IDet group; mean FPG was 8.1 mmol/L at baseline and 8.3 mmol/L at week 16. The observed mean change from baseline at week 16 was −0.1 mmol/L, calculated based on subjects with available FPG measurements at both baseline and week 16 (see EOT Tables 14.2.216 and 14.2.220. In the IDet group, the observed values at baseline (N=166) and week 16 (N=158) indicate an increase in mean FPG from baseline to week 16, however the observed mean change from baseline was calculated based on subjects with available FPG measurements at both baseline and week 16 (N=148) which resulted in a small decrease in the observed mean change in FPG.

The estimated mean treatment difference (IDegAsp OD − IDet) was 0.31 mmol/L $[-0.70; 1.33]_{95\%CI}$ mmol/L for the change from baseline in FPG after 16 weeks of treatment, hence not statistically significant, see EOT Tables 14.2.224.

Change from baseline in FPG is presented as LSMean plot in EOT Figure 14.2.229. FPG measurements per subject are presented in Appendix 16.2.6; Listing 16.2.6.2.



FAS; Observed data. Error bars + - standard error (mean). Numbers of subjects contributing to the data points are provided in the bottom section of each plot. In the lower panel, the age groups are presented from top to bottom: children 1-5 years, children 6-11 years, adolescents 12-17 years.

Cross-reference: EOT Figures 14.2.225 and 239–240

Figure 11–2 Fasting plasma glucose by treatment week – mean plots (upper panel: all subjects; lower panel: age groups)

Empirical distribution plots for FPG are shown in EOT Figures 14.2.231 and 14.2.235 and a box plot is shown in EOT Figure 14.2.230.

Age groups

IDegAsp

Within the IDegAsp treatment group mean FPG followed the overall trend (as seen for all subjects) from baseline to week 16 in children 1-5 years and adolescents 12-17 years, and tended to increase in children 6-11 years (see Figure 11–2 and EOT Tables 14.2.217–219 and 14.2.221–223), which

was caused by a few outliers with elevated FPG levels at week 16 (see Appendix 16.2.6, Listing 16.2.6.2).

IDet

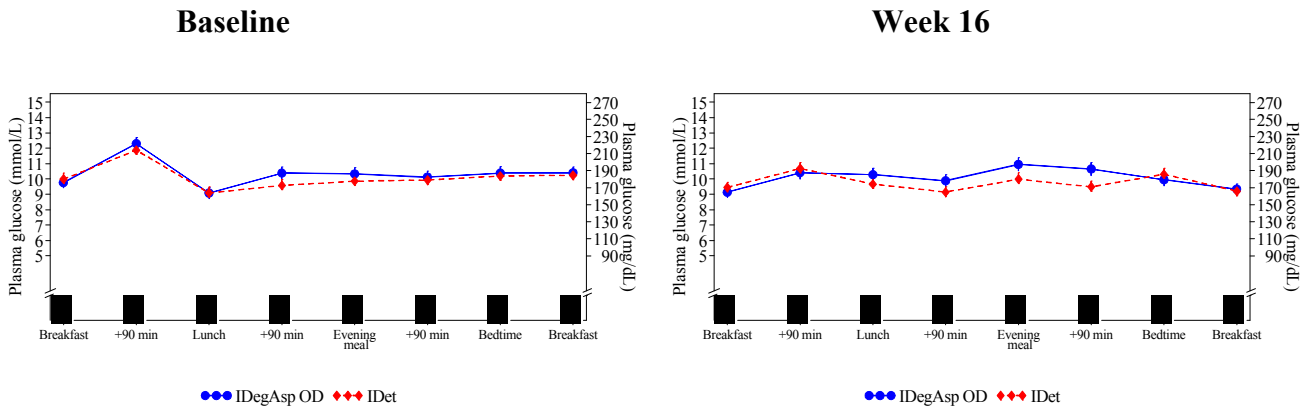
Within the IDet treatment group mean FPG followed the overall trend (as seen for all subjects) from baseline to week 16 in all age groups (see Figure 11–2 and EOT Tables 14.2.217−219 and 14.2.221-223).

The mean FPG profiles with IDegAsp and IDet for the age groups are presented in EOT Figures 14.2.226−228. The respective empirical distribution plots are shown in EOT Figures 14.2.232−234, 14.2.236−238.

11.2.2 8-point self-measured plasma glucose profiles

All subjects

Similar trends in both treatment groups were noted for the SMPG values from baseline to week 16, see EOT Table 14.2.241 and EOT Figures 14.2.246, 14.2.250. The 8-point SMPG profiles at baseline and after 16 weeks are presented as mean plots in Figure 11–3. There were no statistically significant differences between treatments groups at any time points, see EOT Table 14.2.245.



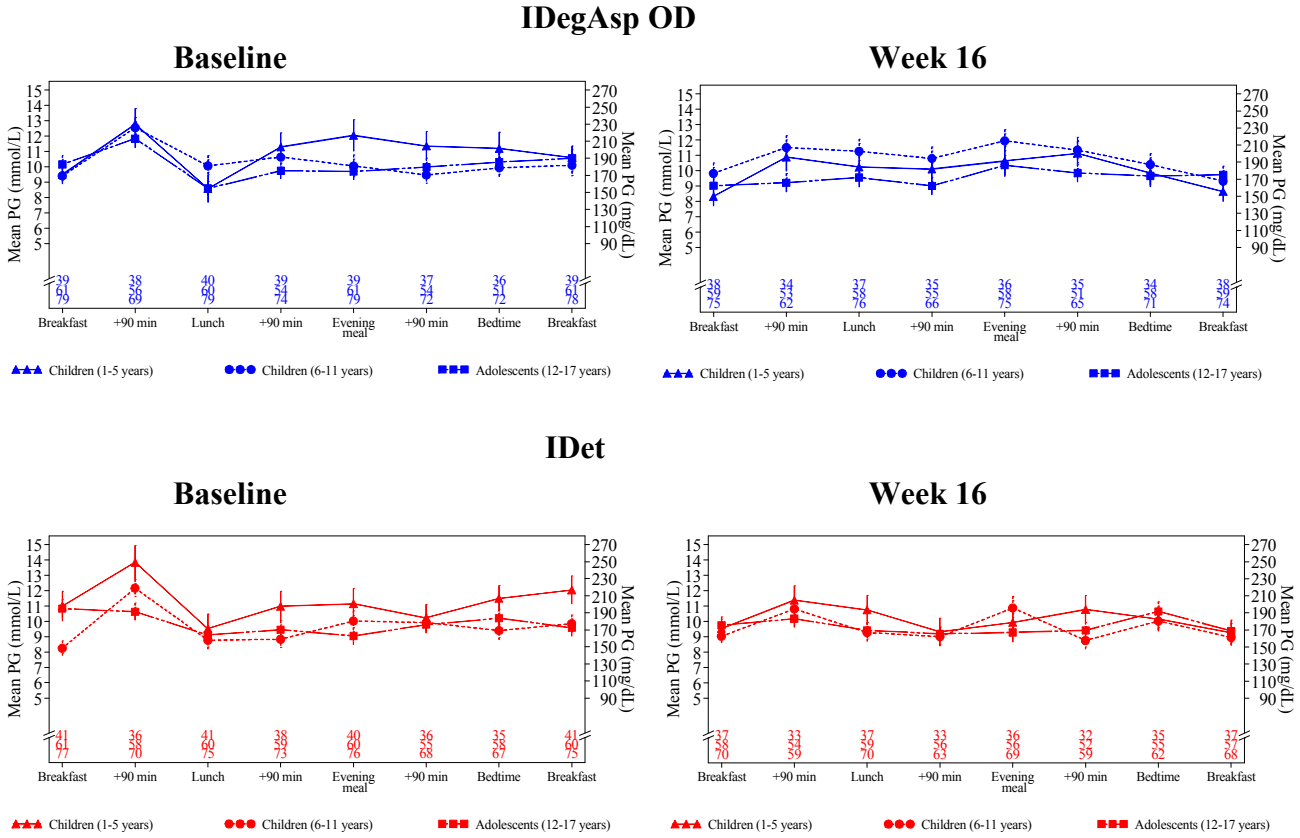
FAS; Observed data. Error bars + - standard error (mean). Numbers of subjects contributing to the data points are provided in the bottom section of each plot.

Cross-reference: EOT Figures 14.2.254 and 14.2.266

Figure 11–3 8-point self-measured plasma glucose profile at baseline (left) and at 16 weeks (right) - mean plot - full analysis set

The 8-point SMPG profiles at week 12 are presented as mean plots in EOT Figures 14.2.260. 8-point SMPG measurements for individual subjects are presented in Appendix 16.2.6, Listing 16.2.6.1.

Age groups



FAS; Observed data. Error bars + - standard error (mean). Numbers of subjects contributing to the data points are provided in the bottom section of each plot.

Cross-reference: EOT Figures 14.2.258−259 and 14.2.270−271

Figure 11–4 8-point self measured plasma glucose profile at baseline (left) and week 16 (right) - mean plot – IDegAsp (Upper panel) and IDet (Lower panel) - by age group - full analysis set

The 8-point SMPG profiles at week 12 by age are presented as mean plots in EOT Figure 14.2.264 for the IDegAsp group and EOT Figure 14.2.265 for the IDet group.

IDegAsp

Within the IDegAsp treatment group trends were similar for the shape of the 8-point SMPG profiles across age groups at week 16 (see Figure 11–4).

8-point SMPG profiles by treatment week for the IDegAsp group are presented in EOT Tables 14.2.242−244 and EOT Figures 14.2.247−249 for the respective age groups.

IDet

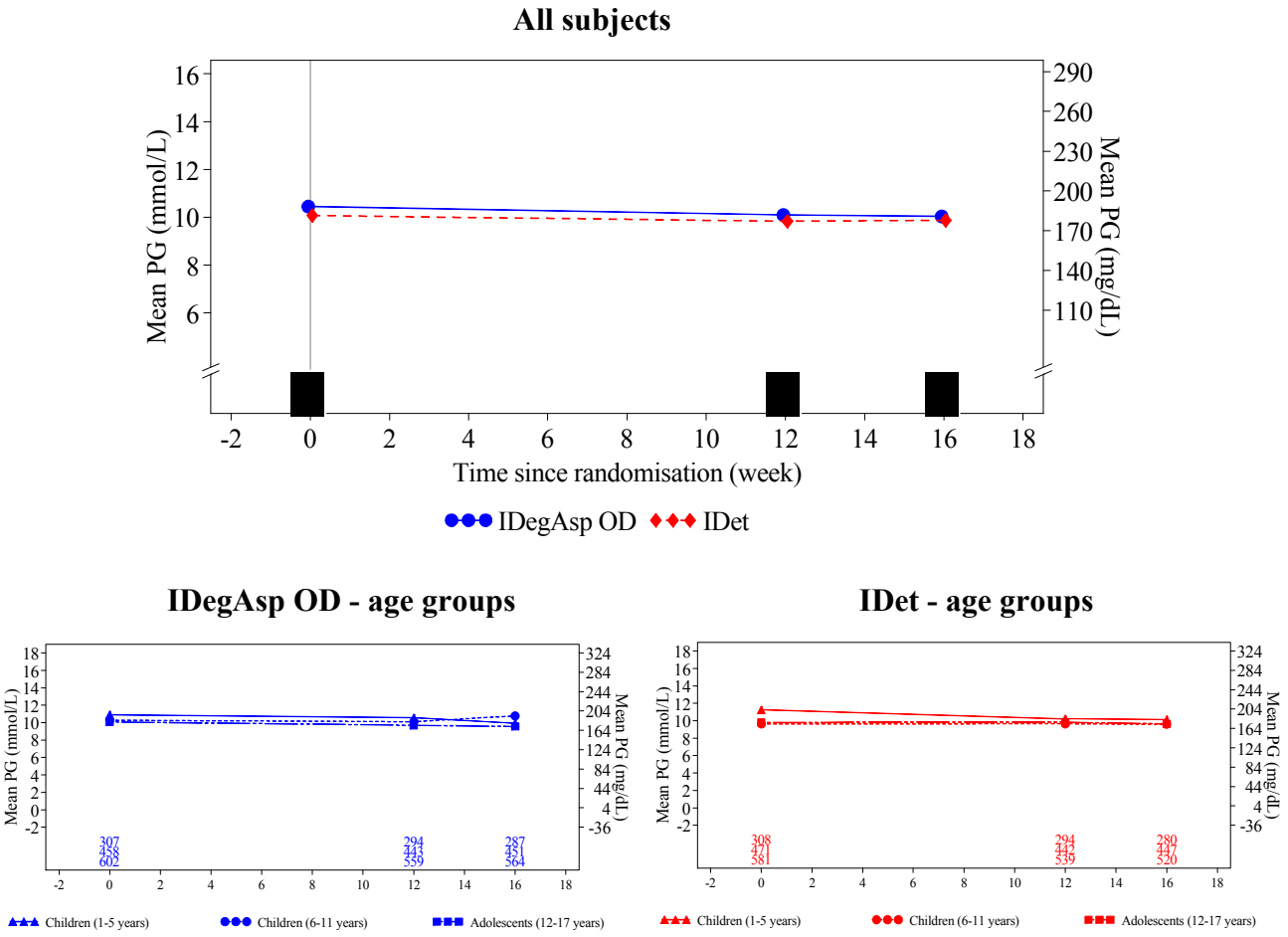
Within the IDet treatment group trends were similar for the shape of the 8-point SMPG profiles across age groups at week 16 (see Figure 11–4).

8-point SMPG profiles by treatment week for the IDet group are presented in EOT Tables 14.2.242–244 and EOT Figures 14.2.251–253 for the respective age groups.

SMPG profiles with IDegAsp and IDet for the age groups at baseline are presented in EOT Figures 14.2.255–257; for week 12 see EOT Figures 14.2.261–263; for week 16 see EOT Figures 14.2.267–269.

11.2.2.1 Mean 8-point SMPG

After 16 weeks the change from baseline of the mean of the 8-point SMPG profiles was similar between the two treatment groups, see Figure 11–5. The observed mean change from baseline at week 16 was −0.3 mmol/L in the IDegAsp group and −0.2 mmol/L in the IDet group, calculated based on subjects with available SMPG measurements at both baseline and week 16 (see EOT Tables 14.2.272, 14.2.276. The estimated mean treatment difference (IDegAsp OD – IDet) was −0.06 mmol/L $[-0.62; 0.51]_{95\%CI}$, see EOT Table 14.2.280. Empirical distribution plots of the mean and change from baseline for the mean are presented in EOT Figures 14.2.286–287. LSMean plot is presented in EOT Figure 14.2.285.



FAS; Observed data. Error bars + - standard error (mean). Numbers of subjects contributing to the data points are provided in the bottom section of each plot. In the lower panel, the age groups are presented from top to bottom: children 1-5 years, children 6-11 years, adolescents 12-17 years.

Cross-reference: EOT Figures 14.2.281 and 14.2.288–289

Figure 11–5 Mean of 8-point self measured plasma glucose profile by treatment week – mean plots (upper panel: all subjects; lower panel: age groups)

Age groups

IDegAsp

Within the IDegAsp treatment group the mean of the 8-point SMPG profiles followed the overall trend (as seen for all subjects) from baseline to week 16 in all age groups, see EOT Tables 14.2.273–275 and 14.2.277–279.

IDet

Within the IDet treatment group the mean of the 8-point SMPG profiles followed the overall trend (as seen for all subjects) from baseline to week 16 in all age groups;
see EOT Tables 14.2.273–275 and 14.2.277–279.

Plots for the mean of 8-point SMPG profiles for the treatment groups by age are presented for the respective age groups in EOT Figures 14.2.282–284.

11.2.2.2 Fluctuation in plasma glucose

All subjects

The observed geometric mean fluctuation in PG in the IDegAsp group was 2.1 mmol/L at baseline and remained unchanged at week 16; in the IDet group it was 2.2 mmol/L at baseline and 2.0 mmol/L at week 16, see EOT Table 14.2.290 and EOT Figure 14.2.295. The estimated mean treatment ratio was not statistically significant, as the ratio IDegAsp OD/IDet was 1.09 $[0.98; 1.22]_{95\%CI}$, see EOT Table 14.2.294.

The ratio to baseline for the mean fluctuation in PG is presented as LSMean plot in EOT Figure 14.2.299. Empirical distribution plots for fluctuation in PG are presented in EOT Figures 14.2.300–301.

Age groups

IDegAsp

Within the IDegAsp treatment group the fluctuation in PG followed the overall trend (as seen for all subjects) from baseline to week 16 in all age groups, see EOT Tables 14.2.291–293 and EOT Figure 14.2.302.

IDet

Within the IDet treatment group the fluctuation in PG followed the overall trend (as seen for all subjects) from baseline to week 16 in all age groups, see EOT Tables 14.2.291–293 and EOT Figure 14.2.303.

Plots of the fluctuation in plasma glucose by treatment week for both the IDegAsp and IDet group are presented for the respective age groups in EOT Figures 14.2.296–298.

11.2.2.3 Prandial plasma glucose increment

All subjects

Overall, mean prandial PG increment decreased from baseline to week 16 in both treatment groups for the mean of all meals (EOT Tables 14.2.304, 14.2.308 and EOT Figures 14.2.340, 14.2.344–346), breakfast (EOT Tables 14.2.304, 14.2.308 and EOT Figures 14.2.313,

14.2.317–319) and lunch (EOT Tables 14.2.304, 14.2.308 and EOT Figures 14.2.322, 14.2.326–328). Mean prandial PG increment for main evening meal was similar at baseline and week 16 in the IDegAsp group and decreased slightly from baseline to week 16 in the IDet group (EOT Tables 14.2.304, 14.2.308 and EOT Figures 14.2.331, 14.2.335–337).

After 16 weeks there were no statistically significant differences in prandial PG increment between the treatment groups for mean of all meals, breakfast, lunch and main evening meal (EOT Table 14.2.312).

Age groups

IDegAsp

Within the IDegAsp treatment group prandial increments followed the overall trend (as seen for all subjects) from baseline to week 16 in all age groups; see EOT Tables 14.2.305–307, 14.2.309–311.

IDet

Within the IDet treatment group prandial increments followed the overall trend (as seen for all subjects) from baseline to week 16 in all age groups; see EOT Tables 14.2.305–307, 14.2.309–311.

Mean plots for prandial PG increment at breakfast are shown for the three age groups in EOT Figures 14.2.314–316 respectively and by treatment across age groups in EOT Figures 14.2.320–321. Mean plots for prandial PG increment at lunch are shown for the three age groups in EOT Figures 14.2.323–325 respectively and by treatment across age groups in EOT Figures 14.2.329–330. Mean plots for prandial PG increment at the main evening meal are shown for the three age groups in EOT Figures 14.2.332–334 respectively and by treatment across age groups in EOT Figures 14.2.338–339. Mean plots for prandial PG increment for all meals are shown for the three age groups in EOT Figures 14.2.341–343 respectively and by treatment across age groups in EOT Figures 14.2.347–348.

Nocturnal increment

No statistical analysis was performed for nocturnal increment in PG; descriptive statistics and mean plots are provided for all subjects and by age group.

The trends for the nocturnal increment were the same for both treatment groups (see EOT Tables 14.2.349, 14.2.353 and EOT Figure 14.2.357) and no marked differences were observed for any of the age groups after 16 weeks of treatment (see EOT Tables 14.2.350–352, 14.2.354–356 and EOT Figures 14.2.358–360).

11.2.3 4-point SMPG for dose adjustment

All subjects

There were no statistically significant treatment differences in pre-breakfast, pre-lunch, pre-main evening meal or pre-bedtime SMPG measurements after 16 weeks (EOT Table 14.2.365).
In both treatment groups mean pre-breakfast, pre-lunch, pre-main evening meal and pre-bedtime SMPG increased from week 0 to 1, and gradually decreased from week 1 to 16 (EOT Tables 14.2.241, 14.2.361 and EOT Figures 14.2.366, 14.2.374, 14.2.382 and 14.2.390). This most likely reflects the proposed decrease of 20% of total insulin at randomisation dose as recommended in the titration algorithm (see Section 9.4.4).

Please note that the baseline values (week 0) were obtained from the 8-point SMPG profile.

Plots for the 4-point SMPG measurements are presented in EOT Figures 14.2.366–14.2.397.

Age groups

IDegAsp

Within the IDegAsp treatment group the SMPG measurements followed the overall trend (as seen for all subjects) from baseline to week 16 (EOT Tables 14.2.242–244, 14.2.362–364).

IDet

Within the IDet treatment group the SMPG measurements followed the overall trend (as seen for all subjects) from baseline to week 16 (EOT Tables 14.2.242–244, 14.2.362–364).

11.2.3.1 Within-subject variability as measured by coefficient of variation (%) after 16 weeks

The within-subject variation in pre-breakfast SMPG was similar for the treatment groups. The estimated mean treatment ratio (IDegAsp OD/IDet) was = 1.02 $[0.91; 1.14]_{95\%CI}$; see EOT Table 14.2.398.

11.3 Efficacy conclusions

Primary endpoint

- **HbA_{1c}**: IDegAsp OD + IAsp effectively maintained glycaemic control and was non-inferior to IDet + IAsp in terms of change from baseline in HbA_{1c}, with an estimated mean treatment difference (IDegAsp OD − IDet) of −0.04%-points $[-0.23; 0.15]_{95\%\ CI}$. Superiority was not confirmed. After 16 weeks of treatment, the observed mean (SD) HbA_{1c} was 7.9% (1.2) with IDegAsp OD + IAsp and 7.8% (1.3) with IDet + IAsp.

Supportive secondary efficacy endpoints

- **FPG**: After 16 weeks of treatment, FPG was 8.4 mmol/L with IDegAsp OD + IAsp and 8.3 mmol/L with IDet + IAsp. The observed mean change from baseline at week 16 was −0.3 mmol/L with IDegAsp OD + IAsp and −0.1 mmol/L with IDet + IAsp. The estimated mean treatment difference (IDegAsp OD – IDet) was not statistically significant, 0.31 mmol/L $[-0.70; 1.33]_{95\%CI}$ mmol/L.

- **8-point SMPG**: There were no statistically significant treatment differences in the mean of the 8 point profile, in prandial PG increments (mean of all meals, breakfast, lunch and main evening meal) or in the SMPG fluctuation at 16 weeks.

- **4-point SMPG**: There were no statistically significant treatment differences in pre-breakfast, pre-lunch, pre-main evening meal or pre-bedtime SMPG at 16 weeks. Within-subject variability in pre-breakfast SMPG after 16 weeks was similar for the two treatment groups; estimated mean treatment ratio IDegAsp OD/IDet = 1.02 $[0.91; 1.14]_{95\%CI}$.

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: 181 subjects in the IDegAsp treatment group and 179 subjects in the IDet treatment group.

The mean exposure was similar between treatment groups (Table 12–1 and EOT Figure 14.2.7). Approximately 97% of subjects had at least 13 weeks of treatment (EOT Table 14.2.2).

Table 12–1 Exposure – descriptive statistics – safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Total Exposure, yrs	54.77	53.92	108.7
Exposure (yrs)			
N	181	179	360
Mean (SD)	0.30 (0.03)	0.30 (0.04)	0.30 (0.04)
Median	0.31	0.31	0.31
Min ; Max	0.06 ; 0.35	0.02 ; 0.34	0.02 ; 0.35

N: Number of subjects, SD: Standard deviation, yrs: Years

Cross-reference: EOT Table 14.2.1

Exposure by gender was similar in both treatment groups (EOT Table 14.2.3) reflecting the equal gender distribution of the trial population (see Table 10–5). There were no apparent treatment differences with respect to exposure by treatment week, race or ethnicity (EOT Tables 14.2.2, 14.2.4–5 respectively).

Exposure - age groups

In all three age groups, exposure to IDegAsp and IDet was similar. This was due to stratification for age groups among treatments groups (to ensure equal distribution of different ages between treatment groups) (EOT Table 14 .2.6).

12.2 Dosing

For treatment compliance, including prescribed, actual and titration algorithm doses see Section 10.3.

12.2.1 Insulin regimen and dosing

A treat-to-target approach and a frequent visit schedule was applied during the treatment period to ensure optimal titration of basal and bolus insulin throughout the trial and thereby improve glycaemic control (see Section 9.3.4 for details). According to the trial protocol, each subject's total daily insulin dose was to be reduced by 20% at randomisation. Guidance on initiation and adjustment of IDegAsp, IDet and IAsp are described in Sections 9.4.4 and 9.4.5. It should be noted that the ultimate decision regarding dosing of basal and bolus insulin was at the discretion of the investigator. The starting dose of basal and bolus insulin for each subject was based to be upon the Insulin Titration Guideline in the protocol (Appendix 16.1.1, Appendix A). For insulin treatment at randomisation, see Section 10.2.2.

Mean daily dose of both insulin types was to be recorded on three consecutive days before the visit at start and end of treatment. Insulin dose is presented in EOT Tables and Figures for:

- Total daily insulin dose
- Daily basal insulin dose (IDeg component of IDegAsp or IDet)
- Daily bolus insulin dose (all IAsp including the IAsp component of IDegAsp)
- Daily IAsp dose (administered as bolus IAsp, not including the IAsp component of IDegAsp)
- Daily IDegAsp/IDet dose

In the following sections dose is presented in units/kg as subjects differ with respect to body weight across age groups. Insulin dose is also presented in units in the following EOT Tables and Figures:

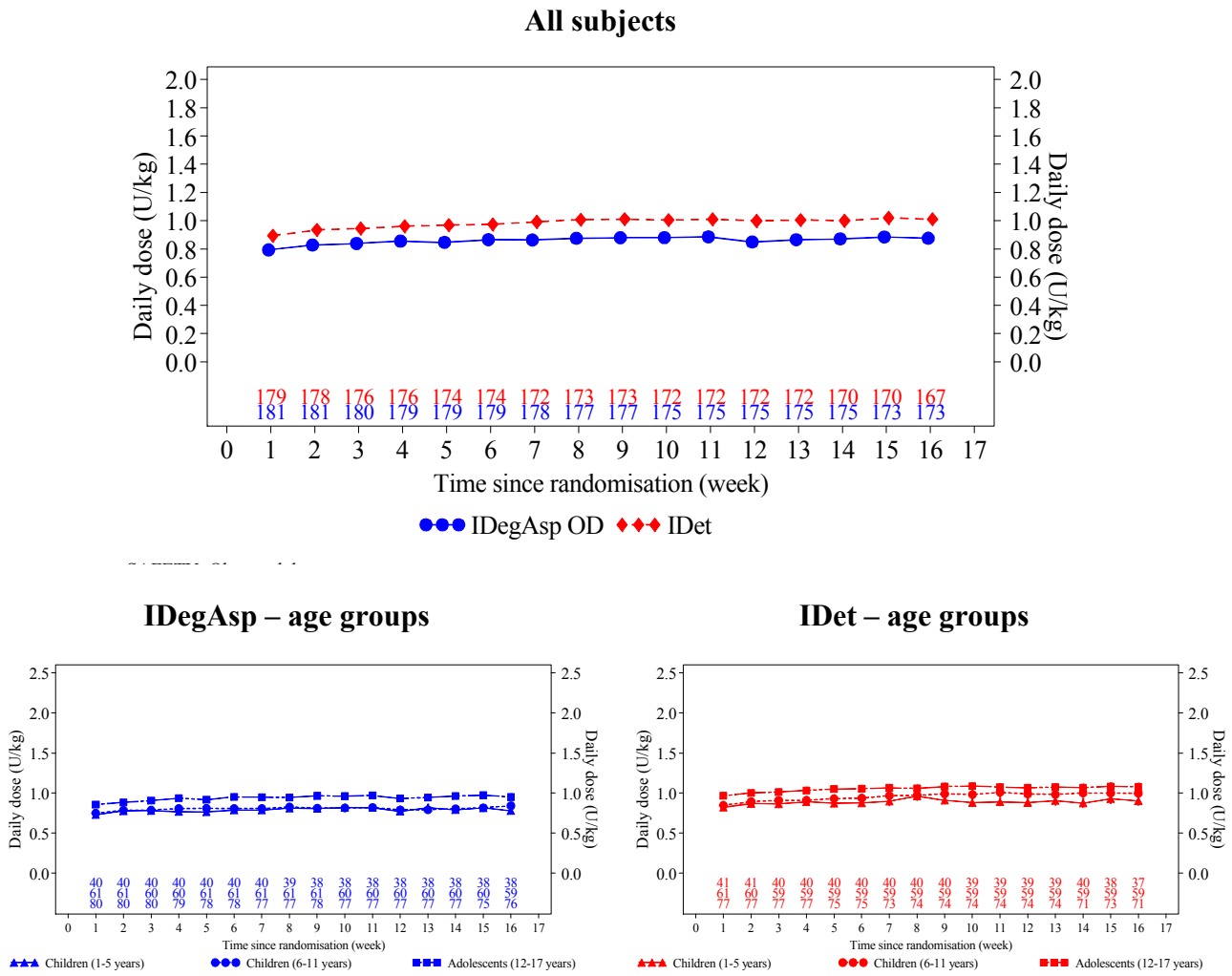
- Total daily insulin dose: EOT Tables 14.2.102–105 and EOT Figures 14.2.118–121, 14.2.138–141, 14.2.154–155
- Daily basal insulin dose: EOT Tables 14.2.46–49 and EOT Figures 14.2.62–65, 14.2.82–85, 14.2.96–97
- Daily bolus insulin dose: EOT Tables 14.2.106–109 and EOT Figures 14.2.122–125, 14.2.142–145, 14.2.158–159
- Daily IAsp dose: EOT Tables 14.2.42–45 and EOT Figures 14.2.58–61, 14.2.78–81, 14.2.94–95
- Daily IDegAsp/IDet dose: EOT Tables 14.2.8–12 and EOT Figures 14.2.17–21, 14.2.28–33, 14.2.38–39

12.2.2 Total daily insulin dose

At randomisation the total daily insulin dose was to be reduced by 20% (Section 9.4.4).

The mean total daily insulin dose was slightly lower in the IDegAsp group compared to the IDet group at week 1 (0.79 vs. 0.89 units/kg, respectively; see Table 12–2). The mean total daily insulin dose in both treatment groups increased slightly during the trial and remained slightly lower in the

IDegAsp group than in the IDet group throughout the 16-week treatment period. At week 16, the mean total daily insulin doses were 0.88 vs. 1.01 units/kg in the IDegAsp and IDet groups, respectively; see Figure 12–1 and Table 12–2.



Safety: Error bars: ± standard error (mean).

Numbers of subjects contributing to the data points are provided in the bottom section of each plot. In the lower panel, the age groups are presented from top to bottom: children 1-5 years, children 6-11 years, adolescents 12-17 years.

Cross-reference: EOT Figures 14.2.126 and 14.2.156–157

Figure 12–1 Total daily insulin dose (actual) in units/kg by treatment week – mean plot (upper panel: all subjects; lower panel: age groups) – safety analysis set

Table 12–2 Total insulin dose (actual) in units/kg by treatment week – descriptive statistics – safety analysis set

				-Descriptive Statistics-				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	0.79	0.28	0.76	0.05	1.69
		IDet	179	179	0.89	0.33	0.85	0.20	1.88
		Total	360	360	0.84	0.31	0.81	0.05	1.88
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	0.83	0.28	0.81	0.05	1.60
		IDet	179	178	0.93	0.33	0.94	0.18	2.13
		Total	360	359	0.88	0.31	0.86	0.05	2.13
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	0.87	0.30	0.85	0.07	1.88
		IDet	179	173	1.01	0.37	0.99	0.21	2.95
		Total	360	350	0.94	0.34	0.91	0.07	2.95
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	0.85	0.28	0.86	0.08	1.78
		IDet	179	172	1.00	0.37	0.95	0.21	3.19
		Total	360	347	0.92	0.34	0.90	0.08	3.19
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	0.88	0.29	0.87	0.13	1.70
		IDet	179	167	1.01	0.40	0.94	0.22	3.41
		Total	360	340	0.94	0.36	0.90	0.13	3.41
End of trial visit	Daily	IDegAsp OD	181	181	0.87	0.29	0.87	0.13	1.70
		IDet	179	179	1.02	0.40	0.95	0.22	3.41
		Total	360	360	0.94	0.36	0.90	0.13	3.41

N: Number of subjects, SD: Standard deviation

Cross-reference: Modified from EOT Table 14.2.110

Actual mean daily total insulin doses in units/kg are presented for the safety analysis set in EOT Table 14.2.110 and EOT Figure 14.2.126. An empirical distribution plot is shown in EOT Figure 14.2.146. Box plots of total daily insulin dose per treatment group are shown in EOT Figures 14.2.134 and 14.2.136.

Total insulin dose – age groups

Actual mean daily total insulin doses in units/kg are presented for each of the three age groups in EOT Tables 14.2.111–113 and EOT Figures 14.2.127–129. Empirical distribution plots for each age group are shown in EOT Figures 14.2.147–149.

IDegAsp

In the IDegAsp treatment group, mean total daily insulin dose per body weight was highest in adolescents throughout the trial; mean dose in children 1-5 years and 6-11 years was similar throughout the trial. The mean total daily dose increased slightly from week 1 to week 16 in all three age groups (Figure 12–1). In children 1-5 years, the mean total daily dose increased from

0.73 units/kg at week 1 to 0.78 units/kg at week 16. In children 6-11 years, the mean daily dose increased from 0.75 to 0.84 units/kg and in adolescents 12-17 years the dose increased from 0.86 to 0.95 units/kg; see EOT Tables 14.2.111–113.

IDet

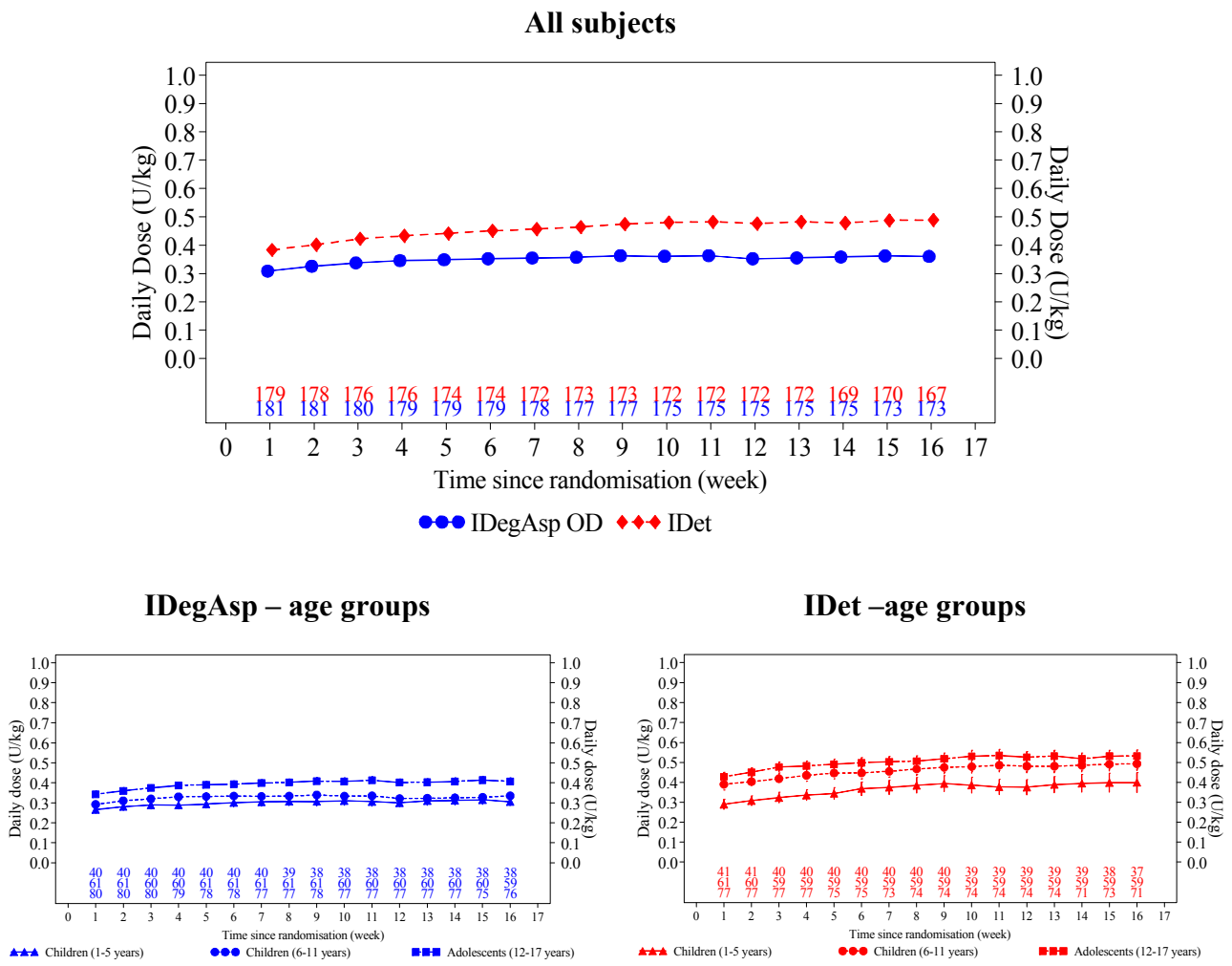
In the IDet treatment group, mean total daily insulin dose per body weight was lowest in children 1-5 years and highest in adolescents 12-17 years throughout the trial. The mean total daily dose increased from week 1 to week 16 in all three age groups (Figure 12–1). In children 1-5 years the mean total daily dose increased from 0.82 units/kg at week 1 to 0.90 units/kg at week 16. In children 6-11 years, the mean daily dose increased from 0.85 to 1.00 units/kg and in adolescents 12-17 years the dose increased from 0.97 to 1.08 units/kg; see EOT Tables 14.2.111–113.

12.2.3 Daily basal insulin dose

At randomisation, subjects were transferred from pre-trial basal insulin to IDegAsp or IDet aiming for a basal:bolus ratio of between 50:50 and 30:70 with no specific recommendations for basal dose reduction. Daily basal insulin dose relates to the daily dose of IDet or IDeg (70% of the IDegAsp OD dose).

At start of treatment (week 1=visit 3) the mean daily basal insulin dose was lower in the IDegAsp group than in the IDet group (0.31 units/kg IDeg vs. 0.38 units/kg IDet, Table 12–3). Initially, in the IDegAsp group there was a small increase in dose from 1-4 weeks, after which the mean IDeg dose remained fairly constant (Figure 12–2). Thus, the mean daily dose of IDeg was 0.31 units/kg at week 1 and 0.36 units/kg at week 16. In the IDet group, there was also a slight increase over time which was most apparent at week 1 to 3, after which the mean IDet dose remained fairly constant (Figure 12–2). The mean daily dose of IDet was 0.38 units/kg at week 1 and 0.49 units/kg at week 16.

After 16 weeks, 97 (54.2%) subjects in the IDet group were using IDet BID (EOT Table 14.2.399).



Safety: Error bars: ± standard error (mean).

Numbers of subjects contributing to the data points are provided in the bottom section of each plot. In the lower panel, the age groups are presented from top to bottom: children 1-5 years, children 6-11 years, adolescents 12-17 years.

Cross-reference: EOT Figures 14.2.70 and 14.2.100–101

Figure 12–2 Daily basal insulin dose (actual) in units/kg by treatment week – mean plot (upper panel: all subjects; lower panel: age groups) – safety analysis set

Table 12–3 Basal insulin dose in units/kg by treatment week – descriptive statistics – safety analysis set

				Descriptive Statistics					
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	0.31	0.13	0.30	0.03	0.74
		IDet	179	179	0.38	0.21	0.34	0.05	1.17
		Total	360	360	0.35	0.18	0.32	0.03	1.17
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	0.33	0.14	0.30	0.03	0.81
		IDet	179	178	0.40	0.21	0.36	0.05	1.13
		Total	360	359	0.36	0.18	0.33	0.03	1.13
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	0.36	0.15	0.36	0.03	0.71
		IDet	179	173	0.46	0.25	0.42	0.05	1.36
		Total	360	350	0.41	0.21	0.39	0.03	1.36
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	0.35	0.14	0.34	0.04	0.76
		IDet	179	172	0.48	0.26	0.43	0.05	1.70
		Total	360	347	0.41	0.22	0.38	0.04	1.70
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	0.36	0.15	0.35	0.05	0.83
		IDet	179	167	0.49	0.27	0.45	0.05	1.77
		Total	360	340	0.42	0.22	0.38	0.05	1.77
End of trial visit	Daily	IDegAsp OD	181	181	0.36	0.15	0.36	0.05	0.83
		IDet	179	179	0.50	0.27	0.46	0.05	1.77
		Total	360	360	0.43	0.23	0.39	0.05	1.77

N: Number of subjects, SD: Standard deviation

Cross-reference: Modified from EOT Table 14.2.54

Actual mean daily basal insulin doses in units/kg for all subjects are presented in EOT Tables 14.2.54 and EOT Figures 14.2.70. Box plots of IDegAsp and IDet are presented in EOT Figures 14.2.75 and 14.2.77. An empirical distribution plot is shown in EOT Figure 14.2.90.

Daily basal dose – age groups

Actual mean daily basal insulin doses in units/kg are presented for each age group in EOT Tables 14.2.55–57 and EOT Figures 14.2.71–73. Empirical distribution plots are shown in EOT Figures 14.2.91–93.

IDegAsp

In the IDegAsp treatment group, mean daily IDeg dose per body weight was lowest in children 1-5 years and highest in adolescents 12-17 years throughout the trial. The mean daily IDeg dose increased from week 1 to week 16 in all three age groups (Figure 12–2). In children 1-5 years, the mean daily dose of IDeg increased from 0.27 units/kg at week 1 to 0.31 units/kg at week 16.

In children 6-11 years, the mean daily dose increased from 0.29 to 0.33 units/kg and in adolescents 12-17 years the dose increased from 0.34 to 0.41 units/kg; see EOT Tables 14.2.55–57.

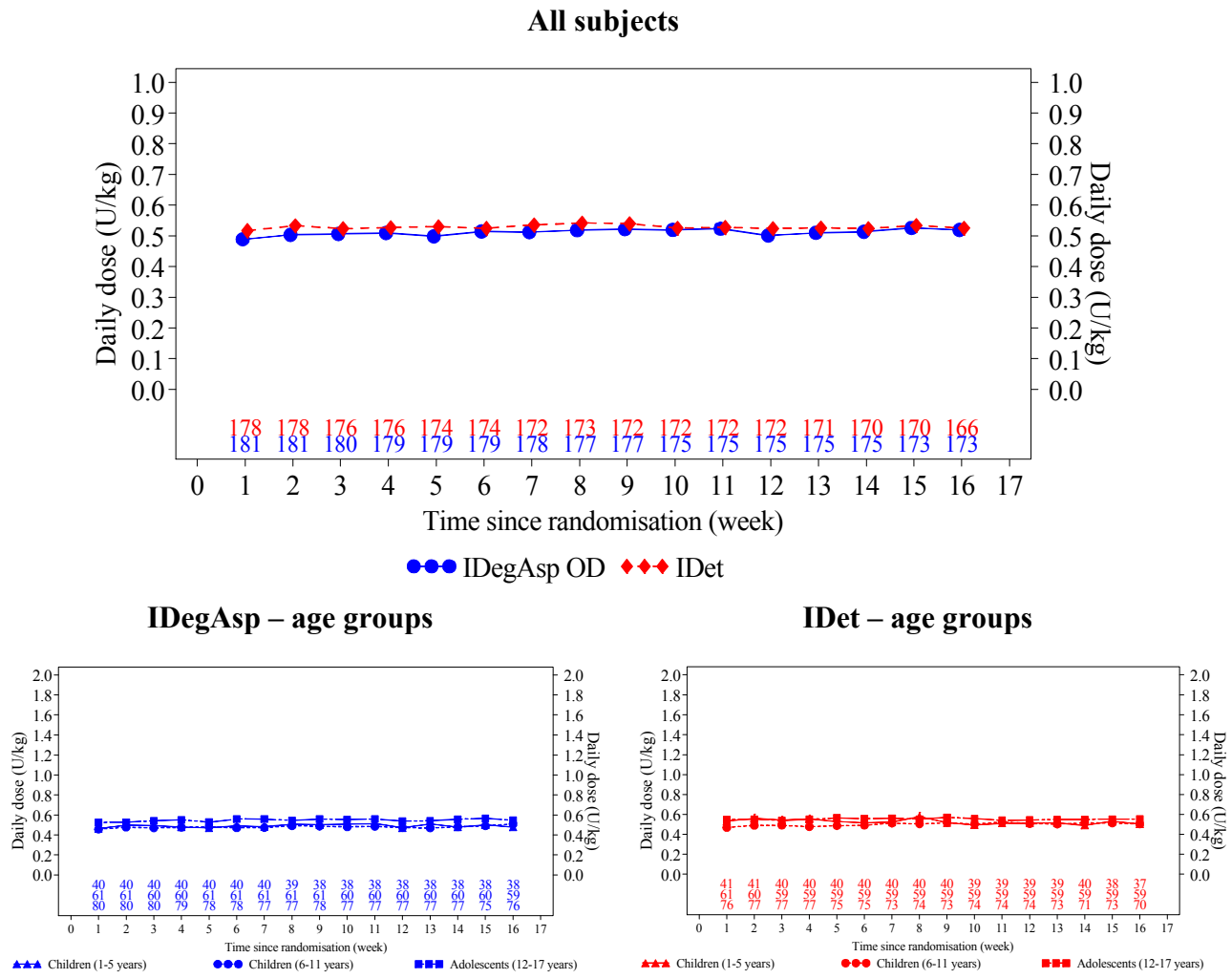
IDet

In the IDet treatment group, mean daily IDet dose per body weight was lowest in children 1-5 years and highest in adolescents 12-17 years throughout the trial. The mean daily dose of IDet increased from week 1 to week 16 in all three age groups (Figure 12–2). In children 1-5 years the mean daily dose increased from 0.29 units/kg at week 1 to 0.40 units/kg at week 16. In children 6-11 years, the mean daily dose increased from 0.39 to 0.49 units/kg and in adolescents 12-17 years the dose increased from 0.43 and 0.53 units/kg; see EOT Tables 14.2.55–57. After 16 weeks, 56.1%, 59.0% and 49.4% of subjects aged 1-5 years, 6-11 years and 12-17 years were using IDet BID, respectively (EOT Table 14.2.399).

12.2.4 Daily bolus insulin dose

In this section, “bolus insulin dose” refers to the total IAsp administered, including the IAsp component of IDegAsp, i.e. the sum of injected IAsp plus the IAsp (30%) from the IDegAsp OD dose.

The mean daily bolus insulin dose was similar in the two treatment groups throughout the trial and the doses remained fairly constant during the trial in both treatment groups (Figure 12–3). At start of treatment (week 1 = visit 3), the mean daily bolus insulin dose was 0.49 and 0.52 units/kg in the IDegAsp and IDet groups, respectively; at week 16, the mean daily bolus insulin dose was 0.52 units/kg in both treatment groups (Table 12–4).



Safety: Error bars: ± standard error (mean).

Numbers of subjects contributing to the data points are provided in the bottom section of each plot. In the lower panel, the age groups are presented from top to bottom: children 1-5 years, children 6-11 years, adolescents 12-17 years.

Cross-reference: EOT Figures 14.2.130 and 14.2.160–161

Figure 12–3 Daily bolus insulin dose (actual) in units/kg by treatment week – mean plot (upper panel: all subjects; lower panel: age groups) – safety analysis set

Table 12–4 Bolus insulin dose (actual) in units/kg by treatment week – descriptive statistics – safety analysis set

				-Descriptive Statistics-					
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	0.49	0.21	0.47	0.03	1.26
		IDet	179	178	0.52	0.22	0.50	0.06	1.35
		Total	360	359	0.50	0.21	0.49	0.03	1.35
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	0.50	0.20	0.49	0.03	1.21
		IDet	179	178	0.53	0.23	0.52	0.04	1.58
		Total	360	359	0.52	0.22	0.50	0.03	1.58
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	0.52	0.20	0.50	0.03	1.28
		IDet	179	173	0.54	0.24	0.53	0.04	1.59
		Total	360	350	0.53	0.22	0.50	0.03	1.59
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	0.50	0.19	0.48	0.05	1.12
		IDet	179	172	0.52	0.22	0.51	0.04	1.49
		Total	360	347	0.51	0.20	0.49	0.04	1.49
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	0.52	0.19	0.51	0.06	1.05
		IDet	179	166	0.52	0.23	0.51	0.06	1.79
		Total	360	339	0.52	0.21	0.51	0.06	1.79
End of trial visit	Daily	IDegAsp OD	181	181	0.52	0.19	0.51	0.06	1.05
		IDet	179	179	0.52	0.22	0.51	0.06	1.79
		Total	360	360	0.52	0.21	0.51	0.06	1.79

N: Number of subjects, SD: Standard deviation

Cross-reference: Modified from EOT Table 14.2.114

Actual mean daily bolus insulin doses in units/kg are presented in EOT Table 14.2.114 and EOT Figures 14.2.130. An empirical distribution plot is shown in EOT Figure 14.2.150. Box plots of daily bolus insulin dose in the two treatment groups are presented in EOT Figures 14.2.135 and 14.2.137.

Daily bolus dose – age groups

Actual mean daily bolus insulin doses in units/kg are presented for each of the three age groups in EOT Table 14.2.115–117 and EOT Figures 14.2.131–133. Empirical distribution plots for each age group are shown in EOT Figures 14.2.151−153.

IDegAsp

In the IDegAsp treatment group, the mean daily bolus insulin dose per body weight was fairly constant in all three age groups during the trial and was similar between age groups (Figure 12–3).

In children 1-5 years, the mean daily bolus dose was 0.46 units/kg at week 1 and 0.48 units/kg at week 16. In children 6-11 years, the mean daily bolus dose was 0.46 units/kg at week 1 and 0.51 units/kg at week 16, and in adolescents 12-17 years, the mean daily bolus dose was 0.53 units/kg at week 1 and 0.55 units/kg at week 16 (EOT Table 14.2.115–117).

IDet

Also in the IDet treatment group, the mean daily bolus insulin dose per body weight was fairly constant in all three age groups during the trial and was similar between age groups (Figure 12–3). In children 1-5 years, the mean daily bolus dose was 0.53 units/kg at week 1and 0.51 units/kg at week 16. In children 6-11 years, the mean daily bolus dose was 0.47 units/kg at week 1 and 0.50 units/kg at week 16, and in adolescents 12-17 years, the mean daily bolus dose was 0.55 units/kg at week 1 and 0.55 units/kg at week 16 (EOT Table 14.2.115–117).

12.2.5 Daily IAsp dose

The daily IAsp dose (excluding IAsp component of IDegAsp) is presented in EOT Tables 14.2.50–53 and EOT Figures 14.2.66–69. Box plots of daily IAsp insulin dose in the two treatment groups are presented in EOT Figures 14.2.74 and 14.2.76. Mean plots by age group are presented in EOT Figures 14.2.98–99. Empirical distribution plots are shown in EOT Figures 14.2.86–89. Mean IAsp doses are listed by subject in Appendix 16.2.5, Listing 16.2.5.3.

Throughout the treatment period, the mean daily IAsp dose (units/kg) was lower in the IDegAsp group than in the IDet group, reflecting the exclusion of the IAsp component of IDegAsp from the dose calculation. The mean daily IAsp dose remained fairly stable throughout the treatment period.

12.2.6 Daily IDegAsp/IDet dose

The daily insulin doses administered as IDegAsp and IDet are presented in EOT Tables 14.2.13–16 and EOT Figures 14.2.17–25. Box plots of daily IDegAsp and IDet insulin doses are presented in EOT Figures 14.2.26–27 (actual) and 14.2.28–29 (prescribed). Mean plots by age group are presented in EOT Figures 14.2.38–41. Empirical distribution plots are shown in EOT Figures 14.2.30–37. Mean IDegAsp/IDet doses are listed by subject in Appendix 16.2.5, Listing 16.2.5.1.

Throughout the treatment period, the mean daily IDegAsp dose (units/kg) was higher than the daily IDet dose, reflecting the inclusion of the IAsp component of IDegAsp in the dose calculation. The mean daily dose of both IDegAsp and IDet increased from week 1 to week 16.

12.2.7 Insulin dose ratio between treatment groups

The dose ratio was calculated as the ratio between mean doses in the two treatment groups at the last scheduled treatment visit (week 16). Missing data have been imputed using predicted values from a MMRM model.

For total daily insulin dose (units/kg), the mean ratio between the two treatment groups (IDegAsp OD/IDet) was 0.86, i.e. total daily insulin dose was 14% lower in the IDegAsp group than the IDet group at the last scheduled treatment visit (EOT Table 14.2.162). Total daily basal insulin dose (units/kg) was 28% lower in the IDegAsp group than in the IDet group (mean ratio IDegAsp OD/IDet of 0.72) based on descriptive statistics.

Total daily bolus insulin dose (units/kg) was almost identical in the two treatment groups, with a mean ratio IDegAsp OD/IDet of 0.99.

Insulin dose ratio between treatment groups – age groups

The insulin dose ratio was similar in each of the age groups to that observed for all subjects (EOT Tables 14.2.163–165). For total daily insulin dose (units/kg), the mean ratio between the two treatment groups (IDegAsp OD/IDet) was 0.85, 0.84 and 0.88 for the age groups 1-5 years, 6-11 years and 12-17 years, respectively.

12.2.8 Insulin dose ratio between basal and bolus insulin

In the IDegAsp group, there was little change in the ratio between basal (IDeg component of IDegAsp) and bolus insulin (IAsp, including the IAsp component of IDegAsp); the ratio was 39% basal to 61% bolus at week 1 and 41% basal to 59% bolus at week 16. In the IDet group, the ratio was 43% basal to 57% bolus at week 1. The percentage of basal insulin increased between week 1 and week 16, with a ratio of 49% basal to 51% bolus at week 16 (EOT Table 14.2.166).

Insulin dose ratio between basal and bolus insulin - age groups

Within each treatment group, the insulin dose ratio between basal and bolus insulin in each of the age groups was similar to that observed for all subjects (EOT Tables 14.2.167–169).

12.3 Adverse events

All AEs described and discussed below are treatment-emergent, unless otherwise specified. A Treatment-Emergent Adverse Event (TEAE) was defined as an event with onset date on or after the first day of exposure to randomised treatment and no later than 7 days after the last day on randomised treatment. Non-treatment-emergent AEs with onset before treatment with trial products and with onset after the defined treatment emergent period are listed by subject in Appendix 16.2.7, Listing 16.2.7.2.

Information about hypoglycaemic episodes was collected and reported separately on the hypoglycaemic episodes form and not on the AE form (except for severe hypoglycaemia which was defined as a MESI, see Section 9.5.1.4 for further details). Hypoglycaemic episodes are therefore analysed and described separately from AEs.

12.3.1 Brief summary of adverse events

The percentage of subjects reporting AEs and the overall rate of AEs per 100 patient years of exposure (PYE) were similar in the IDegAsp and the IDet treatment groups (915 vs. 853 events per 100 PYE, respectively); see Table 12–5. The majority of the AEs in both treatment groups were non-serious, mild in severity and considered unlikely related to trial product. The rates of AEs considered possibly or probably related to trial product (IDegAsp or IDet), as judged by the investigator, were 47 vs. 37 events per 100 PYE, respectively, and approximately 75% of all subjects in either treatment group had an outcome of recovered at end of trial.

No unexpected differences between the 3 age groups with respect to type of AEs were observed in the treatment groups. A slightly higher rate of AEs in the IDegAsp treatment group for children 1-5 years was observed (EOT Table 14.3.1.2).

No subjects died during the trial. The observed rates of SAEs were numerically higher with IDegAsp than with IDet (Table 12–5). This difference was mostly driven by a larger number of hypoglycaemic episodes in the IDegAsp treatment group (EOT Table 14.3.1.14). The number of SAEs considered possibly or probably related to trial product (IDegAsp or IDet) was 5 events in 5 subjects in the IDegAsp treatment group and 1 event in 1 subject in the IDet treatment group (EOT Table 14.3.1.21).

One (1) subject in the IDegAsp group was withdrawn from the trial during the 16-week treatment period due to an event of ‘hypoglycaemic seizure’ (see section 12.5.1).

Table 12–5 Adverse events – treatment emergent – summary – safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	181				179				360			
Events	141	(77.9)	501	915	134	(74.9)	460	853	275	(76.4)	961	884
Serious												
Yes	11	(6.1)	14	26	7	(3.9)	7	13	18	(5.0)	21	19
No	137	(75.7)	487	889	133	(74.3)	453	840	270	(75.0)	940	865
Severity												
Severe	12	(6.6)	14	26	5	(2.8)	5	9	17	(4.7)	19	17
Moderate	52	(28.7)	96	175	30	(16.8)	58	108	82	(22.8)	154	142
Mild	126	(69.6)	391	714	129	(72.1)	397	736	255	(70.8)	788	725
Relationship to Investigational Product												
Probably	13	(7.2)	16	29	11	(6.1)	13	24	24	(6.7)	29	27
Possibly	10	(5.5)	10	18	6	(3.4)	7	13	16	(4.4)	17	16
Unlikely	136	(75.1)	472	862	129	(72.1)	438	812	265	(73.6)	910	837
Missing	2	(1.1)	3	5	2	(1.1)	2	4	4	(1.1)	5	5
Related to Bolus Insulin												
Probably	9	(5.0)	11	20	7	(3.9)	10	19	16	(4.4)	21	19
Possibly	9	(5.0)	9	16	7	(3.9)	7	13	16	(4.4)	16	15
Unlikely	137	(75.7)	478	873	132	(73.7)	441	818	269	(74.7)	919	846
Missing	2	(1.1)	3	5	2	(1.1)	2	4	4	(1.1)	5	5
Related to Device												
Yes	0	(0.0)	0	0	1	(0.6)	1	2	1	(0.3)	1	1
No	141	(77.9)	498	909	134	(74.9)	457	847	275	(76.4)	955	879
Missing	2	(1.1)	3	5	2	(1.1)	2	4	4	(1.1)	5	5
Outcome												
Recovered/Resolved	137	(75.7)	470	858	133	(74.3)	441	818	270	(75.0)	911	838
Recovering/ Resolving	6	(3.3)	6	11	6	(3.4)	7	13	12	(3.3)	13	12
Recovered/ Resolved with Sequelae	1	(0.6)	1	2	0	(0.0)	0	0	1	(0.3)	1	1
Not Recovered/Not Resolved	20	(11.0)	24	44	10	(5.6)	12	22	30	(8.3)	36	33

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events
R: Event Rate per 100 Patient Years of Exposure
Relationship is based on investigator(s)'s assessment.

Cross-reference: EOT Table 14.3.1.1

12.3.2 Analysis of adverse events

12.3.2.1 Adverse events by system organ class/preferred term

AEs by system organ class (SOC) and preferred term are summarised in EOT Table 14.3.1.10. The most frequent AEs occurring in ≥5% and ≥1% of the subjects are summarised in Table 12–6 and EOT Table 14.3.1.7.

Apart from hypoglycaemic episodes reported on the hypoglycaemic episode form (Section 12.6), the most frequently reported AEs (≥5%) in both treatment groups were 'headache', 'nasopharyngitis', 'abdominal pain upper', 'pyrexia' and 'vomiting' (Table 12–6).

Table 12–6 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	181			179			360		
Events	100 (55.2)	242	442	97 (54.2)	243	451	197 (54.7)	485	446
Infections and infestations									
Nasopharyngitis	36 (19.9)	43	79	32 (17.9)	42	78	68 (18.9)	85	78
Upper respiratory tract infection	11 (6.1)	12	22	17 (9.5)	18	33	28 (7.8)	30	28
Influenza	9 (5.0)	10	18	10 (5.6)	12	22	19 (5.3)	22	20
Pharyngitis	3 (1.7)	3	5	10 (5.6)	13	24	13 (3.6)	16	15
Gastrointestinal disorders									
Vomiting	22 (12.2)	25	46	12 (6.7)	13	24	34 (9.4)	38	35
Abdominal pain upper	14 (7.7)	22	40	17 (9.5)	26	48	31 (8.6)	48	44
Abdominal pain	10 (5.5)	13	24	7 (3.9)	13	24	17 (4.7)	26	24
Nervous system disorders									
Headache	23 (12.7)	47	86	32 (17.9)	64	119	55 (15.3)	111	102
Respiratory, thoracic and mediastinal disorders									
Cough	13 (7.2)	16	29	9 (5.0)	9	17	22 (6.1)	25	23
Oropharyngeal pain	9 (5.0)	13	24	13 (7.3)	14	26	22 (6.1)	27	25
General disorders and administration site conditions									
Pyrexia	17 (9.4)	26	47	10 (5.6)	15	28	27 (7.5)	41	38
Metabolism and nutrition disorders									
Hypoglycaemia	11 (6.1)	12	22	3 (1.7)	4	7	14 (3.9)	16	15

N: Number of subjects, %: Percentage of subjects, E: Number of events,
R: Event rate per 100 exposure years

Cross-reference: EOT Table 14.3.1.6

For some system organ classes (SOCs) and preferred terms, the percentages of subjects that reported events were numerically different between treatment groups. Numerical differences in rates were observed with respect to 'hypoglycaemia' (see below for details). Furthermore, 'vomiting', 'cough' and 'pyrexia' were reported more frequently with IDegAsp than with IDet and 'upper respiratory tract infection', 'pharyngitis' and 'headache' were reported more frequently with

IDet than with IDegAsp (Table 12–6). These events are frequently reported for this population and differences in rates are considered a chance finding.

A listing of all treatment emergent AEs by subject is included in Appendix 16.2.7, Listing 16.2.7.1.

Hypoglycaemia related adverse events

A hypoglycaemic episode was to be reported as an AE if it fulfilled the definition of an SAE or a MESI (severe hypoglycaemia as per ISPAD definition); see Section 9.5.1.4 for definitions. Therefore, the reported hypoglycaemia related AEs described in this section are a subset of the total number of hypoglycaemic episodes reported in the trial. Hypoglycaemia related AEs were reported by the following preferred terms in the IDegAsp vs. the IDet treatment groups: 'Hypoglycaemia' (22 vs. 7 events per 100 PYE) and 'hypoglycaemic seizure' (5 vs. 0 events per 100 PYE); see Table 12–7.

Table 12–7 Hypoglycaemia reported as AEs – treatment emergent – summary – safety analysis

	IDegAsp OD			IDet		
	N (%)	E	R	N (%)	E	R
Number of Subjects	181			179		
Hypoglycaemia	11 (6.1)	12	22	3 (1.7)	4	7
Hypoglycaemic seizure	2 (1.1)	3	5			

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

Cross-reference: Modified from EOT Table 14.3.1.10

Adverse events by age groups

The pattern of AEs changed with age: Children 1-5 years had more infections than older children, and similarly 'vomiting' and 'pyrexia' were more commonly reported in children 1-5 years. Older children reported more headache and abdominal pain and puberty related disorders, as expected.

IDegAsp

In the IDegAsp treatment group, the overall rate of AEs was higher in children 1-5 years than in the two older age groups (1192 events per 100 PYE compared to 792 and 872 events per 100 PYE in children 6-11 years and adolescents 12-17 years, respectively) (EOT Tables 14.3.1.2–4). This difference seemed to be related to events within the *infections and infestations* SOC. 'Hypoglycaemia' was recorded at rates of 50, 16 and 12 events per 100 PYE across the 3 age groups (see 12.6 and EOT Tables 14.3.1.11–13).

IDet

The overall rate of AEs was lower in children 1-5 years than in the two older age groups (702 events per 100 PYE compared to 905 and 891 events per 100 PYE in children 6-11 years and adolescents 12-17 years, respectively) (EOT Tables 14.3.1.2–4). 'Hypoglycaemia' was recorded at rates of 16, 0 and 9 events per 100 PYE across the 3 age groups (12.6 and EOT Tables 14.3.1.11–13).

12.3.2.2 Adverse events by relation to trial product(s)

AEs considered possibly or probably related to trial product (IDegAsp or IDet) and to IAsp are summarised by SOC and preferred term in EOT Table 14.3.1.18 and EOT Table 14.3.1.19, respectively.

The overall rates of AEs considered possibly or probably related to trial product (IDegAsp or IDet), as judged by the investigator, were 47 vs. 37 events per 100 PYE, respectively (26 events in 22 subjects with IDegAsp and 20 events in 16 subjects with IDet) (EOT Table 14.3.1.18). The most notable differences between IDegAsp and IDet were hypoglycaemia related AEs considered possibly or probably related to trial product, where more events were reported in the IDegAsp treatment group (see below), followed by events in the *gastrointestinal disorders* SOC, where more events were reported as related to trial product in the IDet treatment group (see below). The overall rates of AEs considered possibly or probably related to IAsp as judged by the investigator, were 37 vs. 32 events per 100 PYE in the IDegAsp vs IDet treatment group, respectively (20 events in 14 subjects with IDegAsp and 17 events in 12 subjects with IDet) (EOT Table 14.3.1.19).

Hypoglycaemia related AEs considered possibly/probably related to trial product (IDegAsp or IDet) across PTs are summarised in Table 12–8 and listed in Appendix 16.2.7, Listing 16.2.7.1. More hypoglycaemia related AEs were reported as possibly or probably related to IDegAsp (12 events in 11 subjects) compared to IDet (3 events in 2 subjects) (Table 12–8 and Appendix 16.2.7, Listing 16.2.7.1). Of the 12 events related to IDegAsp, 6 events in 6 subjects were also related to IAsp. Additionally, in the IDegAsp treatment group 1 event was related to IAsp only. All the 3 events related to IDet were were also related to IAsp. Additionally, in the IDet treatment group 1 event was related to IAsp only (EOT Table 14.3.1.19 and Appendix 16.2.7, Listing 16.2.7.1).

Table 12–8 Hypoglycaemia-related AEs possibly or probably related to investigational medicinal product by system organ class and preferred term - treatment emergent - summary - safety analysis set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Number of Subjects	174				175			
Hypoglycaemia	9	(5.0)	9	16	2	(1.1)	3	6
Hypoglycaemic seizure	2	(1.1)	3	5				

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

Cross-reference: Modified from EOT Table 14.3.1.18

For *gastrointestinal disorders*, more events related to trial product (IDegAsp or IDet) were reported in the IDet treatment group compared to the IDegAsp treatment group (5 events in 4 subjects with IDet and 0 events with IDegAsp) (EOT Table 14.3.1.18 and Appendix 16.2.7, Listing 16.2.7.1). All events were single occurrences under different preferred terms except for 2 events of 'vomiting' in 2 subjects. The same trend was seen for events related to IAsp (5 events in 4 subjects with IDet and 1 event in 1 subject with IDegAsp) (EOT Table 14.3.1.19 and Appendix 16.2.7, Listing 16.2.7.1).

AEs considered related to the device are described in Section 12.3.2.4.

12.3.2.3 Adverse events by severity

AEs by severity are summarised by SOC and preferred term in EOT Tables 14.3.1.24 (severe AEs), 14.3.1.25 (severe AEs considered possibly or probably related to IDegAsp or IDet), 14.3.1.28 (severe AEs considered possibly or probably related to IAsp), (14.3.1.31 (moderate AEs), 14.3.1.32 (mild AEs) and 14.3.1.29 (severe AEs related to device).

The majority of the AEs were mild or moderate in severity. The rates of mild AEs was similar with IDegAsp and IDet (391 events in 126 subjects with IDegAsp and 397 events in 129 subjects with IDet leading to rates of 714 vs. 736 events per 100 PYE, respectively) whereas the rates of moderate AEs (96 events in 52 subjects with IDegAsp and 58 events in 30 subjects with IDet leading to rates of 175 vs. 108 events per 100 PYE) were higher with IDegAsp (Table 12–5). No apparent pattern in the reported events was observed for either mild or moderate events (EOT Tables 14.3.1.31–32).

A total of 6.6% vs. 2.8% of subjects reported severe AEs with IDegAsp and IDet, respectively. The observed rate of severe AEs was numerically higher with IDegAsp compared with IDet (14 events in 12 subjects with IDegAsp and 5 events in 5 subjects with IDet leading to rates of 26 vs. 9 events

per 100 PYE, respectively) (EOT Tables 14.3.1.24). The difference between treatment groups was driven by hypoglycaemia related AEs (9 events in 9 subjects in the IDegAsp group and 2 events in 2 subjects in the IDet group).

All of the hypoglycaemia related events considered severe in the IDegAsp treatment group were possibly or probably related to IDegAsp compared to 1 event in the IDet treatment group that was related to IDet (Table 12–9 and EOT Tables 14.3.1.25). Of the 9 events related to IDegAsp, 6 events in 6 subjects were also related to IAsp. The 1 event related to IDet,was also related to IAsp. Additionally, in the IDet treatment group 1 hypoglycaemia related AE was related to IAsp only (EOT Table 14.3.1.28 and Appendix 16.2.7, Listing 16.2.7.1).

All subjects with severe AEs were recovered or were recovering at end of trial (Appendix 16.2.7, Listing 16.2.7.1). No severe AEs were related to the device (EOT Table 14.3.1.29).

Table 12–9 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	181				179				360			
Events	12	(6.6)	14	26	5	(2.8)	5	9	17	(4.7)	19	17
Metabolism and nutrition disorders	8	(4.4)	8	15	2	(1.1)	2	4	10	(2.8)	10	9
Hypoglycaemia	7	(3.9)	7	13	2	(1.1)	2	4	9	(2.5)	9	8
Diabetic ketoacidosis	1	(0.6)	1	2					1	(0.3)	1	1
Nervous system disorders	2	(1.1)	2	4	2	(1.1)	2	4	4	(1.1)	4	4
Headache					2	(1.1)	2	4	2	(0.6)	2	2
Hypoglycaemic seizure	2	(1.1)	2	4					2	(0.6)	2	2
Injury, poisoning and procedural complications	1	(0.6)	2	4	1	(0.6)	1	2	2	(0.6)	3	3
Fall					1	(0.6)	1	2	1	(0.3)	1	1
Fibula fracture	1	(0.6)	1	2					1	(0.3)	1	1
Tibia fracture	1	(0.6)	1	2					1	(0.3)	1	1
Ear and labyrinth disorders	1	(0.6)	1	2					1	(0.3)	1	1
Deafness neurosensory	1	(0.6)	1	2					1	(0.3)	1	1
Musculoskeletal and connective tissue disorders	1	(0.6)	1	2					1	(0.3)	1	1
Compartment syndrome	1	(0.6)	1	2					1	(0.3)	1	1

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

Cross-reference: EOT Table 14.3.1.24

12.3.2.4 Adverse events by relation to technical complaints

In the IDet treatment group, 1 subject reported a non-serious AE related to the device; 'device breakage' with NovoPen® Junior (US). The AE was [redacted] in severity, probably related to IDet and the subject recovered completely. No other AEs were reported in relation to the device breakage. (EOT Table 14.3.1.20, Appendix 16.2.4, Listing 16.2.4.2 and Appendix 16.2.7, Listing 16.2.7.1 and 16.2.7.7).

12.4 Deaths and other serious adverse events

12.4.1 Deaths

No deaths were reported in this trial (EOT Listing 14.3.2.2).

12.4.2 Serious adverse events

A total of 21 SAEs were reported; 14 events in 11 subjects in the IDegAsp treatment group and 7 events in 7 subjects in the IDet treatment group. The rate of SAEs per 100 PYE was 26 and 13 in the IDegAsp and IDet treatment group, respectively Table 12–10.

Most of the events in both treatment groups were unlikely related to trial product (IDegAsp or IDet) or IAsp. The number of SAEs considered possibly or probably related to trial product (IDegAsp or IDet) was 5 events in 5 subjects in the IDegAsp treatment group and 1 event in 1 subject in the IDet treatment group. All subjects recovered except 1 subject who was recovering from a tibial plateau fracture due to trampoline fall (Table 12–10 and Appendix 16.2.7, Listing 16.2.7.1). When evaluating rates between treatment groups the low number of subjects with few events should be taken into consideration.

Table 12–10 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	181				179				360			
Events	11	(6.1)	14	26	7	(3.9)	7	13	18	(5.0)	21	19
Severity												
Severe	7	(3.9)	9	16	2	(1.1)	2	4	9	(2.5)	11	10
Moderate	3	(1.7)	3	5	3	(1.7)	3	6	6	(1.7)	6	6
Mild	2	(1.1)	2	4	2	(1.1)	2	4	4	(1.1)	4	4
Relationship to Investigational Product												
Probably	4	(2.2)	4	7	0	(0.0)	0	0	4	(1.1)	4	4
Possibly	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Unlikely	6	(3.3)	9	16	6	(3.4)	6	11	12	(3.3)	15	14
Related to Bolus Insulin												
Probably	2	(1.1)	2	4	0	(0.0)	0	0	2	(0.6)	2	2
Possibly	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Unlikely	8	(4.4)	11	20	5	(2.8)	5	9	13	(3.6)	16	15
Related to Device												
No	11	(6.1)	14	26	7	(3.9)	7	13	18	(5.0)	21	19
Outcome												
Recovered/ Resolved	11	(6.1)	14	26	6	(3.4)	6	11	17	(4.7)	20	18
Recovering/ Resolving	0	(0.0)	0	0	1	(0.6)	1	2	1	(0.3)	1	1

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events
R: Event Rate per 100 Patient Years of Exposure
Relationship is based on investigator(s)'s assessment.

Cross-reference: EOT Table 14.3.1.5

SAEs are summarised by SOC and preferred term in Table 12–11, listed by subject in EOT Listing 14.3.2.1 and Appendix 16.2.7, Listing 16.2.7.1. No SAEs were reported by ≥5% of subjects (EOT Table 14.3.1.8). SAEs by preferred term reported in ≥1% of subjects were related to 'hypoglycaemia' and are shown in EOT Table 14.3.1.9. For IDegAsp, the most frequently reported SAE were hypoglycaemia related AEs; 5 events of 'hypoglycaemia' in 5 subjects and 1 event in 1 subject of 'hypoglycaemic seizure' vs 1 event of 'hypoglycaemia' in the IDet treatment group (Table 12–12). All other SAEs were single occurrences in both treatment groups (Table 12–11).

Table 12–11 Serious 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	181				179				360			
Events	11	(6.1)	14	26	7	(3.9)	7	13	18	(5.0)	21	19
Metabolism and nutrition disorders	6	(3.3)	6	11	3	(1.7)	3	6	9	(2.5)	9	8
Hypoglycaemia	5	(2.8)	5	9	1	(0.6)	1	2	6	(1.7)	6	6
Diabetic ketoacidosis	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Hyperglycaemia					1	(0.6)	1	2	1	(0.3)	1	1
Infections and infestations	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Viral infection	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Laryngitis					1	(0.6)	1	2	1	(0.3)	1	1
Gastrointestinal disorders	2	(1.1)	2	4					2	(0.6)	2	2
Constipation	1	(0.6)	1	2					1	(0.3)	1	1
Gastritis	1	(0.6)	1	2					1	(0.3)	1	1
Injury, poisoning and procedural complications	1	(0.6)	2	4	1	(0.6)	1	2	2	(0.6)	3	3
Fall					1	(0.6)	1	2	1	(0.3)	1	1
Fibula fracture	1	(0.6)	1	2					1	(0.3)	1	1
Tibia fracture	1	(0.6)	1	2					1	(0.3)	1	1
Nervous system disorders	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Hypoglycaemic seizure	1	(0.6)	1	2					1	(0.3)	1	1
Loss of consciousness					1	(0.6)	1	2	1	(0.3)	1	1
Congenital, familial and genetic disorders	1	(0.6)	1	2					1	(0.3)	1	1
Developmental glaucoma	1	(0.6)	1	2					1	(0.3)	1	1
Musculoskeletal and connective tissue disorders	1	(0.6)	1	2					1	(0.3)	1	1
Compartment syndrome	1	(0.6)	1	2					1	(0.3)	1	1

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

Cross-reference: EOT Table 14.3.1.14

Table 12–12 Hypoglycaemia SAEs - treatment emergent - summary - safety analysis set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Number of Subjects	181				179			
Serious AEs as evaluated by investigator								
Hypoglycaemia	5	(2.8)	5	9	1	(0.6)	1	2
Hypoglycaemia seizure	1	(0.6)	1	2				
Additional Serious AEs as evaluated by sponsor								
Hypoglycaemia	1	(0.6)	1					

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

Cross-reference: Modified from EOT Table 14.3.1.14 and Section 14.3.3 (narrative)

One SUSAR (suspected unexpected serious adverse reaction), 'loss of consciousness', was reported by 1 subject ([redacted]) in the IDet treatment group [redacted] after treatment initiation. The subject [redacted] without treatment. It is unknown whether the event was related to hypoglycaemia. Please refer to Section 14.3.3 for further details.

Regarding non-treatment emergent SAEs, one subject ([redacted]) reported one SAE ('hypoglycaemia') [redacted] whereas no SAEs were reported after the last day on trial products; see Appendix 16.2.7, Listing 16.2.7.2 for further details.

Only a subset (9 events in the IDegAsp treatment group and 2 events in the IDet treatment group) of the SAEs were severe in severity. Five (5) out of 9 severe SAEs in the IDegAsp treatment group and 1 out 2 severe SAEs in the IDet treatment group were hypoglycaemia related AEs (EOT Table 14.3.1.30).

One AE (Subject [redacted]) of 'severe hypoglycaemia' was reported as a [redacted] by the investigator but [redacted] serious by Novo Nordisk, who considered this event 'medically significant'. As the clinical database reflects the investigator reported data, this event is included as a [redacted] in the clinical database (tables and listings), but is included as an SAE in the narratives in Section 14.3.3. This event has not been included in the calculation of the event rate per 100 PYE (Table 12–12).

For further information related to this event, see the brief narrative included below as well as the full narrative in Section 14.3.3.

- *Subject* [redacted] The investigator considered the event ('severe hypoglycaemia') probably related to IDegAsp and IAsp, whereas Novo Nordisk considered the event possibly related to IDegAsp and unlikely related to IAsp, due to the timing of the event.

Serious adverse events across age groups

IDegAsp

The number of subjects with SAEs by age group was very low and therefore no evaluation of trends among age groups could be made (EOT Tables 14.3.1.15–17).

IDet

As with IDegAsp, the number of subjects with SAEs by age group was very low and therefore no evaluation of trends among age groups could be made (EOT Tables 14.3.1.15–17).

Serious adverse events by relationship

Five (5) subjects reported 5 SAEs that were considered possibly or probably related to IDegAsp and 1 subject reported 1 SAE that was considered possibly or probably related to IDet, leading to a higher reporting rate with IDegAsp compared to IDet (9 vs. 2 events per 100 PYE) (Table 12–13). All but 1 event ('loss of consciousness' in the IDet treatment group) were hypoglycaemia related. The number of SAEs considered probably or possibly related to IAsp was low and similar between the treatment groups (3 events in 3 subjects with IDegAsp and 2 events in 2 subjects with IDet) (EOT Table 14.3.1.22). Three (3) SAEs in 3 subjects were related to both IDegAsp and IAsp and 1 SAE was related to both IDet and IAsp ('loss of consciousness') (Appendix 16.2.7, Listing 16.2.7.1). No SAEs were related to the device (EOT Table 14.3.1.23).

Table 12–13 Serious adverse events possibly or probably related to investigational medicinal product 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	181				179				360			
Events	5	(2.8)	5	9	1	(0.6)	1	2	6	(1.7)	6	6
Metabolism and nutrition disorders	4	(2.2)	4	7					4	(1.1)	4	4
Hypoglycaemia	4	(2.2)	4	7					4	(1.1)	4	4
Nervous system disorders	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Hypoglycaemic seizure	1	(0.6)	1	2					1	(0.3)	1	1
Loss of consciousness					1	(0.6)	1	2	1	(0.3)	1	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

Cross-reference: EOT Table 14.3.1.21

In the IDegAsp treatment group, 5 subjects reported 5 SAEs considered possibly or probably related to IDegAsp:

- *Subject* [redacted]: [redacted] treated with IDegAsp experienced 'hypoglycaemia' [redacted] The investigator assessed the event as probably related to IDegAsp and IAsp. The doses of IDegAsp and IAsp remained unchanged.

- *Subject* [redacted] treated with IDegAsp experienced 'hypoglycaemia' [redacted]

[redacted] The investigator assessed the event as probably related to IDegAsp and possibly related to IAsp. The doses of IDegAsp and IAsp were reduced after the event.

- *Subject* [redacted] treated with IDegAsp experienced 'hypoglycaemic seizure' [redacted] he investigator assessed the event as probably related to IDegAsp and IAsp. The dose of IDegAsp remained unchanged and the dose of IAsp was reduced.

- *Subject* [redacted] treated with IDegAsp experienced 'hypoglycaemia' [redacted] The investigator assessed the event as probably related to IDegAsp and unlikely related to IAsp. The doses of IDegAsp and IAsp remained unchanged.

- *Subject* [redacted] treated with IDegAsp experienced 'hypoglycaemia' [redacted] he investigator assessed the event as possibly related to IDegAsp and unlikely related to IAsp, however based on the pharmacological effect of the products a causal relationship to any of the insulins cannot be ruled out. The dose of IDegAsp was reduced and the dose of IAsp remained unchanged.

In the IDet treatment group, 1 [redacted] reported 1 SAE ('loss of consciousness') considered possibly related to IAsp:

- *Subject* [redacted] with IDet for T1DM experienced 'loss of consciousness' [redacted]

[redacted] he investigator assessed the event as possibly related to both IDet and IAsp, however, the doses of IDet and IAsp remained unchanged.

For further details, please refer to the complete narratives in Section 14.3.3.

12.5 Other significant adverse events

12.5.1 Adverse events leading to withdrawal

One (1) subject in the IDegAsp treatment group was withdrawn from the trial due to an AE ('hypoglycaemic seizure') (EOT Listing 14.3.2.5).

- *Subject* [redacted] treated with IDegAsp [redacted] The investigator assessed the event as probably related to IDegAsp and unlikely related to IAsp (last dose unknown). Trial product was discontinued initiated by the patient and [redacted] was withdrawn from the trial. For further details on this event, please see narrative in Section 14.3.3.

In addition, 1 subject ([redacted]) in the IDet treatment group was withdrawn to due to 'other' reasons described as "[redacted]" (Appendix 16.2.1, Listing 16.2.1.2).

12.5.2 Adverse events leading to dose reduction

The number of AEs leading to dose reduction of IDegAsp, IDet and/or IAsp was numerically higher with IDegAsp compared with IDet (21 events in 15 subjects in the IDegAsp treatment group and 9 events in 8 subjects in the IDet treatment group, leading to rates of 38 vs. 17 events per 100 PYE, respectively) (EOT Table 14.3.1.36).

Dose reduction due to AEs was most frequently related to events of infection or because of gastrointestinal disorders and events of 'hypoglycaemia'. In both treatment groups most of the events related to dose reduction were reported in the SOC *Infections and infestations* (6 events in 5 subjects with IDegAsp and 6 events in 6 subjects with IDet, respectively). Insulin adjustments are normally required in connection with infections. The infections themselves may result in a need for higher insulin doses but the associated symptoms, such as vomiting, decreased appetite and diarrhoea, may cause a need for reducing the dose. Five (5) hypoglycaemia related AEs led to dose reductions in the IDegAsp treatment group compared to 0 events in the IDet treatment group.

Among the AEs leading to dose reduction, 5 subjects reported 5 AEs that were considered possibly or probably related to IDegAsp (3 cases of 'hypoglycaemia', 1 'wrong drug administered' and 1 'overdose') and 1 subject reported 1 AE that was considered probably related to IDet ('accidental overdose'). The AEs considered probably or possibly related to IAsp were 2 events in 2 subjects in the IDegAsp treatment group and no events in the IDet group (EOT Table 14.3.1.33). In the IDegAsp treatment group 1 event that led to an IDegAsp dose reduction ('hypoglycaemia') was related to both IDegAsp and IAsp (EOT Listing 14.3.2.3).

Adverse events leading to dose reduction of IDegAsp or IDet are presented by subject in EOT Listing 14.3.2.3. Eleven (11) subjects had at least one AE that led to a dose reduction of IDegAsp (15 events in total) and 5 subjects had an AE that led to a dose reduction of IDet (5 events in total). Twelve (12) subjects in the IDegAsp group had at least 1 AE that led to an IAsp dose reduction (16 events in total) and 7 subjects in the IDet group had at least one AE that led to an IAsp dose reduction (EOT Table 14.3.1.33).

Five (5) of the events leading to dose reduction were serious in the IDegAsp treatment group, while none was serious in the IDet treatment group (EOT Table 14.3.1.33). All subjects recovered from the events that led to dose reduction (EOT Table 14.3.1.33 and EOT Listing 14.3.2.3).

12.5.3 Adverse events leading to temporary withdrawal of trial product

In total, 3 subjects (0.8%) had 3 AEs leading to temporary withdrawal of trial product; 2 subjects (1.1%) in the IDegAsp treatment group and 1 subject (0.6%) in the IDet treatment group (EOT Table 14.3.1.26). The events were 'gastroenteritis', 'wrong drug administered' and 'fall', respectively (EOT Table 14.3.1.27).

All three events were considered unlikely related to trial product. Both subjects in the IDegAsp treatment group [redacted] from the events. The 1 subject in the IDet treatment group [redacted] at end of the trial ('Fall', [redacted]). All AEs leading to temporary withdrawal of trial product are listed in EOT Listing 14.3.2.4.

12.5.4 Adverse events of special interest

Medication errors concerning trial products

The terms used to identify medication errors are listed in Appendix 16.2.7, Listing 16.2.7.3.

Medication errors are summarised in EOT Table 14.3.1.41. Eight (8) events of medication error occurred in 7 subjects in the IDegAsp treatment group (1 'overdose' and 7 'wrong drug administered') and 6 events in 6 subjects in the IDet treatment group (2 'accidental overdose', 1 'drug dispensing error' and 3 'wrong drug administered'). All of the 'wrong drug administered' events were due to mix-up of insulins by the subjects' carer. In the IDegAsp treatment group, 5 out of the 7 'wrong drug administered' events were due to mix-up between the two trial products, and 2 events (both in subject [redacted]) were due to mix-up between the trial product and the pre-trial insulin. In the IDet treatment group, out of the 3 'wrong drug administered' events, 1 was due to mix-up between the two trial insulins, and 2 were due to mix-up with the pre-trial insulin product.

None of the events were reported as SAEs. Most of the events were mild in severity and all subjects recovered from the events. For further details, please see narratives in Section 14.3.3.

Severe hypoglycaemia

For severe hypoglycaemia please refer to Section 12.6.2.

Neoplasms

The terms used to identify neoplasms are listed in Appendix 16.2.7, Listing 16.2.7.3.

No neoplasms were reported with IDegAsp, while 1 event of 'skin papilloma' was reported with IDet. This event was non-serious, [redacted] in severity, considered unlikely related to trial product and the subject [redacted] (EOT Table 14.3.1.34 and Appendix 16.2.7, Listing 16.2.7.1).

Allergic reactions

The terms used to identify allergic reactions are listed in Appendix 16.2.7, Listing 16.2.7.3.

A total of 9 events of allergic reactions occurred in 6 subjects in the IDegAsp treatment group and 5 events in 4 subjects in the IDet treatment group leading to rates of 16 vs. 9 events per 100 PYE, respectively (EOT Table 14.3.1.35). This difference was mostly driven by 5 events of 'hypersensitivity' in 2 subjects in the IDegAsp treatment group vs. no events in the IDet treatment group. All of the events were unlikely related to trial product and the dose of trial product did not change because of the events (Appendix 16.2.7, Listing 16.2.7.1).

Injection site reactions

The terms used to identify injection site reactions are listed in Appendix 16.2.7, Listing 16.2.7.3.

One (1) event of 'injection site hypertrophy' was reported in 1 subject with IDegAsp and 3 events of injection site reactions (2 events of 'injection site hypertrophy' and 1 event of 'injection site swelling') in 3 subjects were reported with IDet (EOT Table 14.3.1.37). One (1) event was considered possibly or probably related to IDegAsp or IDet in each treatment group respectively (EOT Table 14.3.1.93 and Appendix 16.2.7, Listing 16.2.7.8). Additionally, 1 injection site reaction in each treatment group was considered possibly or probably related to IAsp (EOT Table 14.3.1.94 and Appendix 16.2.7, Listing 16.2.7.8).

None of the injection site reactions were serious. One (1) event of 'injection site hypertrophy' in the IDet treatment group was of moderate severity and 3 events were mild in severity (EOT Tables 14.3.1.14, 14.3.1.31–32 and Appendix 16.2.7, Listing 16.2.7.8). None of the subjects withdrew due to injection site reactions. Two events of 'injection site swelling' had an outcome of not recovered (Appendix 16.2.7, Listing 16.2.7.8).

Across age groups, 1 event of 'injection site hypertrophy' in the IDet treatment group was reported in children 1-5 years, no events were reported in children 6-11 years, and the remaining 3 events were reported in adolescents 12-17 years (EOT Tables 14.3.1.38–40).

Suspected transmission of an infectious agent via a trial product

There were no AEs related to suspected transmission of infectious agents in this trial (EOT Table 14.3.1.10).

12.5.5 Clinical laboratory adverse events

Few abnormal laboratory measurements were reported as AEs. Apart from events related to hypoglycaemia and hyperglycaemia (including 'blood ketone body increased') AEs related to abnormal laboratory measurements were few and without any clustering to specific preferred terms.

The majority of AEs related to 'blood ketone bodies increased' were reported based on the subjects' self-measured values in relation to hyperglycaemia.

For further details on laboratory assessments, please see Section 12.8.

12.5.6 Adverse events related to other safety observations

AEs related to other safety observations e.g. clinically significant changes in vital signs, body weight or physical examinations are included in Section 12.3.2 as part of the AE tabulations.

12.6 Hypoglycaemic episodes

This section summarise s hypoglycaemic episodes. Hypoglycaemic episodes were categorised and analysed according to the definitions in Section 9.5.1.4.

12.6.1 Confirmed hypoglycaemic episodes

Almost all subjects experienced confirmed hypoglycaemic episodes during the 16-week treatment period with IDegAsp (N=168 [92.8%]) or IDet (N=164 [91.6%]) and the observed rate of confirmed hypoglycaemic episodes per 100 PYE was 4623 with IDegAsp and 4955 with IDet (Table 12–14).There was no statistically significant difference between treatment arms in the rate of confirmed hypoglycaemia (estimated mean treatment ratio of IDegAsp OD/IDet was 0.95 [0.76; 1.17]$_{95\%CI}$), see (Table 12–15).

Overall, there was a tendency to a higher rate for children 6-11 years (Figure 12–4). This may be due to challenges in controlling glycaemia during school hours. The majority of the confirmed hypoglycaemic episodes occurred during daytime (diurnal) for both treatment groups overall and across all age groups (EOT Figures 14.3.1.70–73 and 14.3.1.95–96). Approximately 50% of the subjects in both treatment groups reported 10 or fewer confirmed hypoglycaemic episodes (EOT Figure 14.3.1.60).

Confirmed hypoglycaemia over time is shown in Figure 12–4 and Appendix 16.2., Listing 16.2.7.5.

Table 12–14 Hypoglycaemic episodes by classification – treatment emergent – summary - safety analysis set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Number of Subjects	181				179			
Confirmed	168	(92.8)	2532	4623	164	(91.6)	2672	4955
ISPAD	178	(98.3)	5833	10651	170	(95.0)	5922	10982
Severe	11	(6.1)	14	26	3	(1.7)	4	7
Documented Sympt.	167	(92.3)	3005	5487	160	(89.4)	3648	6765
Asymptomatic	158	(87.3)	2763	5045	145	(81.0)	2226	4128
Probable Sympt.	2	(1.1)	2	4	4	(2.2)	5	9
Relative	16	(8.8)	49	89	11	(6.1)	39	72
ISPAD Unclassifiable	28	(15.5)	120	219	31	(17.3)	168	312

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in his care,is semiconscious or unconscious,or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

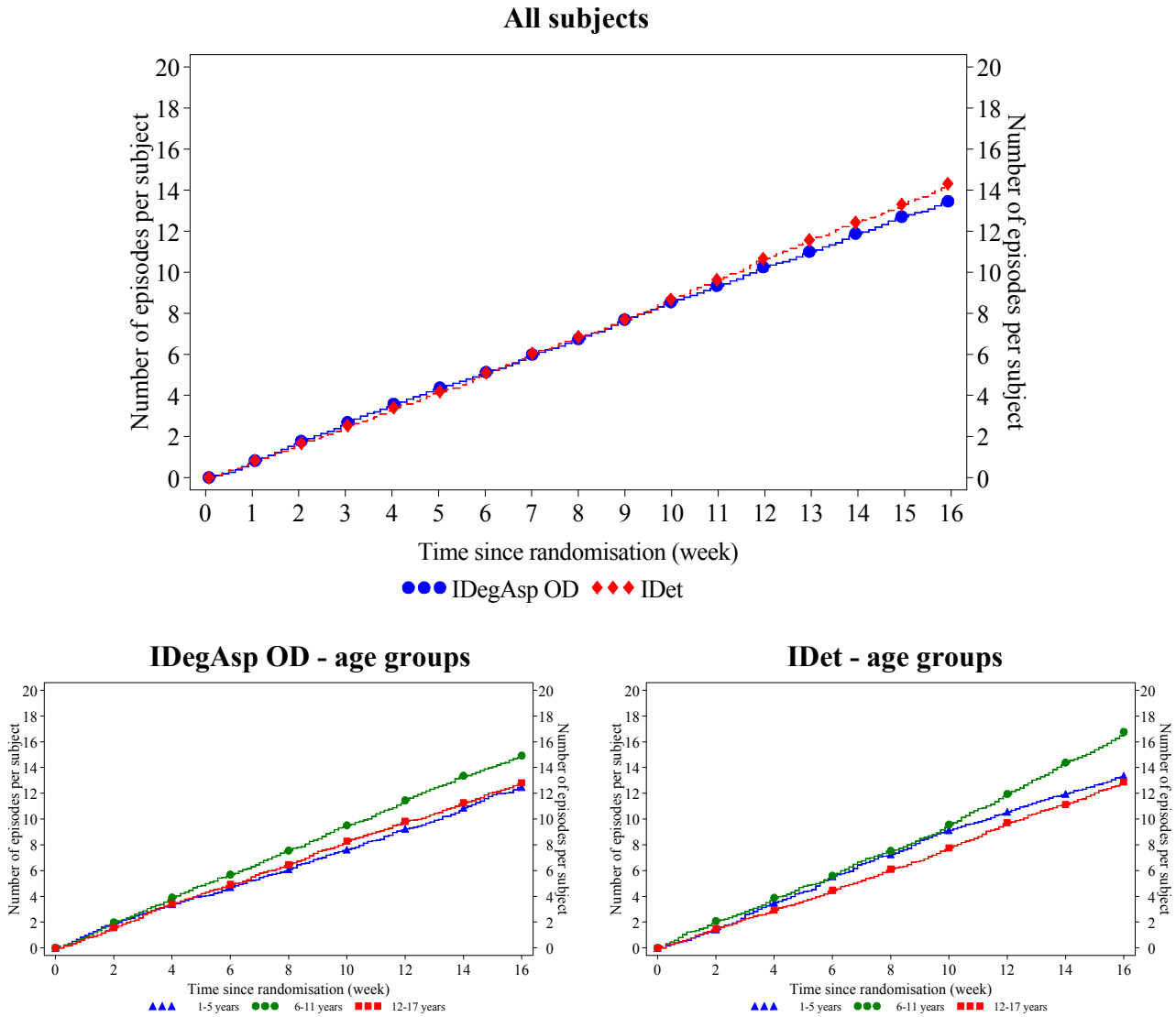
Cross-reference: Modified from EOT Table 14.3.1.42

Table 12–15 Hypoglycaemic episodes - treatment emergent - statistical analysis - full analysis set

	FAS	N	Estimate	95% CI
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	4311.98	
IDet	180	179	4561.22	
Treatment Ratio				
IDegAsp OD / IDet			0.95	[0.76 ; 1.17]

FAS: Full analaysis set, 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 function and the logarithm of the exposure time (100 years) as offset. The model includes treatment, sex, region and age group as fixed effects.

Cross-reference: Modified from EOT Table 14.3.1.52



Safety analysis set

Cross-reference: EOT Figures 14.3.1.62 and 14.3.1.87–88

Figure 12–4 Confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function (upper panel: all subjects; lower panel: age groups) – safety analysis set

Confirmed hypoglycaemic episodes across age groups

IDegAsp

Confirmed hypoglycaemic episodes are summarised by age group in Table 12–16 and illustrated in Figure 12–4. In general, the same trend was observed for all age groups compared to the overall

population in the IDegAsp group, regarding confirmed hypoglycaemic episodes over time, with a slightly higher rate for children 6-11 years (EOT Figures 14.3.1 63–65).

IDet

Confirmed hypoglycaemic episodes are summarised by age group in Table 12–16 and illustrated in Figure 12–4. Compared to the overall population in the IDet treatment group, all age groups followed the same trend over time regarding confirmed hypoglycaemic episodes, with a slightly higher rate for children 6-11 years and a slightly lower rate for adolescents 12-17 years (EOT Figures 14.3.1 63–65).

Table 12–16 Hypoglycaemic episodes by classification and age group – treatment emergent – summary – safety analysis set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Children 1-5 Years								
Number of Subjects	40				41			
Confirmed	39	(97.5)	520	4335	37	(90.2)	559	4564
ISPAD	40	(100.0)	1272	10605	39	(95.1)	1238	10107
Severe	4	(10.0)	5	42	2	(4.9)	2	16
Documented Sympt.	36	(90.0)	337	2810	34	(82.9)	446	3641
Asymptomatic	38	(95.0)	928	7737	38	(92.7)	786	6417
Probable Sympt.	0	(0.0)	0	0	1	(2.4)	1	8
Relative	2	(5.0)	2	17	2	(4.9)	3	24
ISPAD Unclassifiable	5	(12.5)	15	125	7	(17.1)	88	718
Children 6-11 Years								
Number of Subjects	61				61			
Confirmed	56	(91.8)	960	5140	58	(95.1)	1065	5809
ISPAD	59	(96.7)	2221	11891	58	(95.1)	2493	13599
Severe	3	(4.9)	4	21	0	(0.0)	0	0
Documented Sympt.	55	(90.2)	1282	6864	57	(93.4)	1522	8302
Asymptomatic	57	(93.4)	932	4990	50	(82.0)	946	5160
Probable Sympt.	0	(0.0)	0	0	0	(0.0)	0	0
Relative	3	(4.9)	3	16	2	(3.3)	25	136
ISPAD Unclassifiable	9	(14.8)	30	161	11	(18.0)	26	142
Adolescents 12-17 Years								
Number of Subjects	80				77			
Confirmed	73	(91.3)	1052	4366	69	(89.6)	1048	4490
ISPAD	79	(98.8)	2340	9712	73	(94.8)	2191	9386
Severe	4	(5.0)	5	21	1	(1.3)	2	9
Documented Sympt.	76	(95.0)	1386	5753	69	(89.6)	1680	7197
Asymptomatic	63	(78.8)	903	3748	57	(74.0)	494	2116
Probable Sympt.	2	(2.5)	2	8	3	(3.9)	4	17
Relative	11	(13.8)	44	183	7	(9.1)	11	47
ISPAD Unclassifiable	14	(17.5)	75	311	13	(16.9)	54	231

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in his care,is semiconscious or unconscious,or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL).

Cross-reference: Modified from EOT Tables 14.3.1.43–45

12.6.2 Severe hypoglycaemic episodes

The majority of subjects had no severe hypoglycaemic episodes neither in the IDegAsp treatment group [170 (93.9%)] nor in the IDet treatment group [176 (98.3%)]. In the IDegAsp treatment group, 11 subjects (6.1%) reported 14 severe hypoglycaemic episodes (Table 12–14), leading to a rate of 26 episodes per 100 PYE (Table 12–18). In the IDet treatment group, 3 subjects (1.7%) reported 4 severe hypoglycaemic episodes leading to a rate of 7 episodes per 100 PYE (Table 12–14 and Table 12–18). There was no statistically significant difference between treatment groups (Table 12–17).

When evaluating severe hypoglycaemic episodes it is important to note that these were mostly single occurrences in individual subjects. Three (3) subjects in the IDegAsp treatment group reported 2 severe hypoglycaemic episodes each (1 of these subjects reported the events within 19 minutes and it was evaluated to be the same episode by the external classifier; see below) and 1 subject in the IDet treatment group reported 2 severe episodes (Figure 12–5) and Appendix 16.2.7, Listing 16.2.7.6). Two (2) of the episodes in the IDegAsp group and 1 in the IDet group appeared to be related to exercise (Appendix 16.2.7, Listing 16.2.7.6 and Section 14.3.3).

As evident from the slope in Figure 12–6 (all subjects) and EOT Table 14.3.1.50, the observed rate of severe hypoglycaemic episodes was higher with IDegAsp than with IDet throughout the trial (EOT Table 14.3.1.50 and Figures 14.3.1.56–58). The majority of the severe hypoglycaemic episodes occurred during daytime (diurnal) in both treatment groups (EOT Figure 14.3.1.59). For a distribution plot of severe hypoglycaemic episodes, see EOT Figure 14.3.1.54.

Table 12–17 Severe hypoglycaemic episodes - treatment emergent - statistical analysis - full analysis set

	FAS	N	Estimate	95% CI
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	15.71	
IDet	180	179	4.91	
Treatment Ratio				
IDegAsp OD / IDet			3.20	[0.88 ; 11.66]

FAS: Full analysis set, 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 function and the logarithm of the exposure time (100 years) as offset. The model includes treatment,sex,region and age group as fixed effects.

Cross-reference: Modified from EOT Table 14.3.1.52

The ISPAD definition of severe hypoglycaemia is very broad and determining whether an episode fulfils the definition can be challenging, especially in the youngest age group. Therefore, all reported episodes of severe hypoglycaemia were reviewed by an independent, external paediatric endocrinologist in a blinded manner, who determined whether the episodes fulfilled criteria for severe hypoglycaemia or not. Of the episodes sent for classification, 7 events (in 6 subjects) in IDegAsp treatment group were classified as severe based on the most subjective criterion 'altered mental status and cannot assist in his care'; no events in the IDet treatment group met this criteria. Additionally, 6 events (in 5 subjects) in the IDegAsp treatment group and 4 events (in 3 subjects) in the IDet treatment group involved the child being semiconscious or unconscious, or in a coma ± convulsions; see Table 12–18. One event was rejected as severe hypoglycaemia as the event was evaluated to be identical to another event occurring 19 minutes before, thus the subjects was still in the process of recovering from the first event. Therefore, as a result of the evaluation 13 and not 14 severe hypoglycaemic episodes occurred in the IDegAsp treatment group; see Table 12–18. A list of externally classified severe hypoglycaemic episodes for individual subjects are included in Appendix 16.2.7, Listing 16.2.7.6.

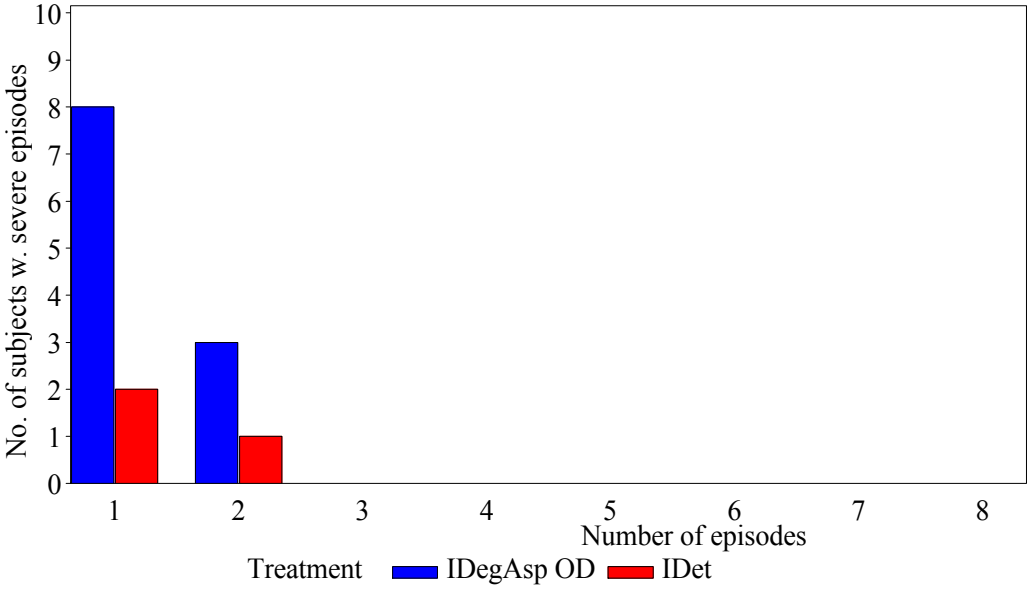
For hypoglycaemia related AEs please see Sections 12.3.2.1 and 12.3.2.2 for details.

Table 12–18 External classified severe hypoglycaemic episodes – treatment emergent - summary - safety analysis set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Number of Subjects	181				179			
All reported severe hypoglycaemia	11	(6.1)	14	26	3	(1.7)	4	7
Externally classified episodes	11	(6.1)	14	26	3	(1.7)	4	7
Severe hypoglycaemia	11	(6.1)	13	24	3	(1.7)	4	7
Altered mental status and cannot assist in his care	6	(3.3)	7	13				
Semiconscious or unconscious	3	(1.7)	3	5	2	(1.1)	3	6
Coma ± convulsions	2	(1.1)	3	5	1	(0.6)	1	2
Not severe hypoglycaemia	1	(0.6)	1	2				

N: Number of subjects, %: Percentage of subjects with the event, E: Number of events
R: Event rate per 100 patient year(s) of exposure

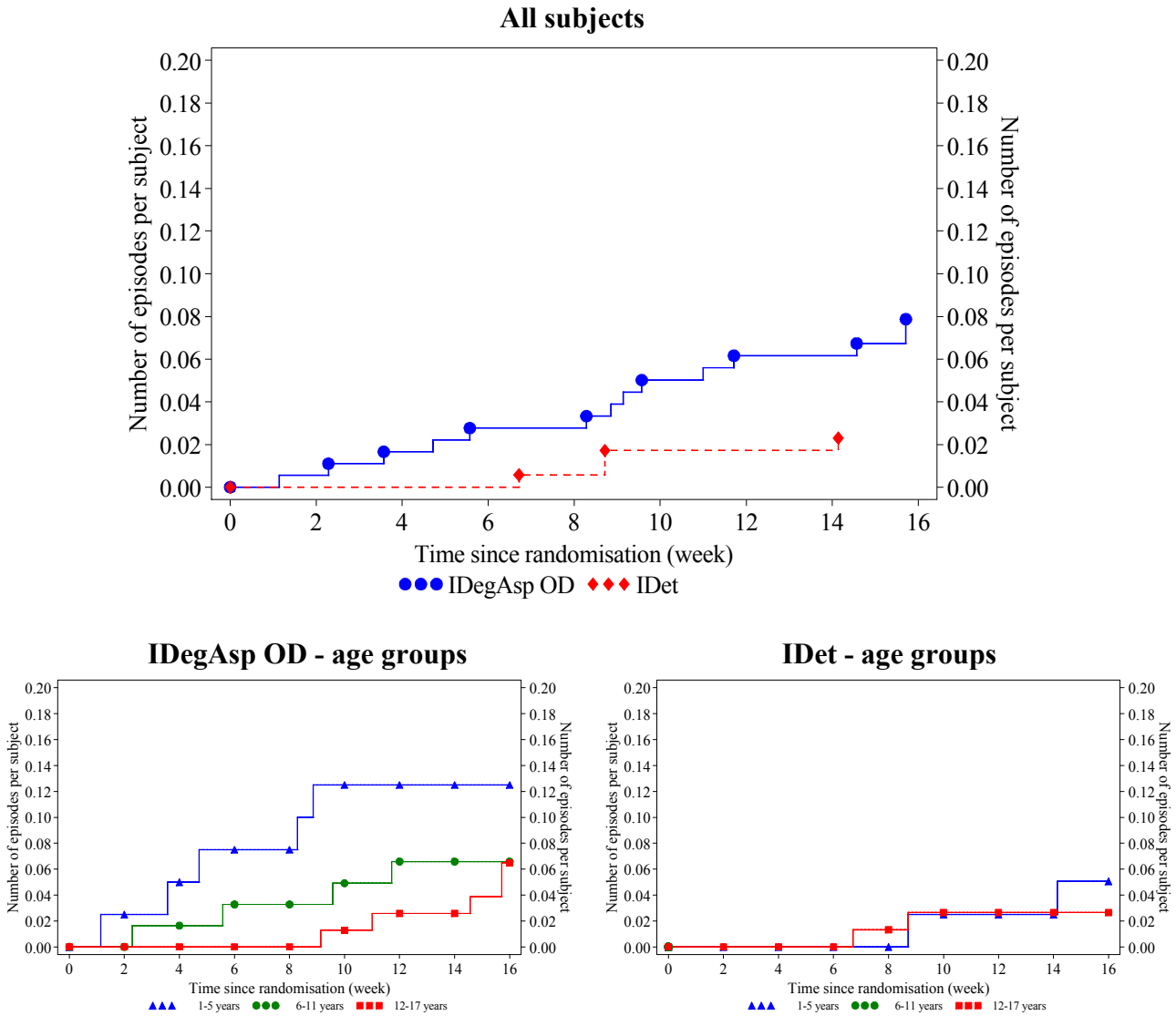
Cross-reference: EOT Table 14.3.1.74



The x-axis denotes observed subject counts of severe hypoglycaemic episodes.
The height of a bar (measured on the y-axis) gives the number of patients experiencing a given number of severe hypoglycaemic episodes.
Safety analysis set

Cross-reference: EOT Figure 14.3.1.86

Figure 12–5 Distribution of severe hypoglycaemic episodes - subject counts against number of episodes - safety analysis set



Safety analysis set

Cross-reference: EOT Figures 14.3.1.55 and 14.3.1.89–90

Figure 12–6 Severe hypoglycaemic episodes - treatment emergent - mean cumulative function (upper panel: all subjects; lower panel: age groups) – safety analysis set

Severe hypoglycaemic episodes across age groups

IDegAsp

The number of severe hypoglycaemic episodes was similar between age groups; 5 episodes in 4 subjects were reported in children 1-5 years and in adolescents 12-17 years while 4 episodes in 3 subjects were reported in children 6-11 years (Figure 12–6 and Table 12–19). The rate for children

1-5 years was higher compared to other age groups, although it should be noted that the rates are based on few episodes.

IDet

Two (2) episodes in 2 subjects were reported in children 1-5 years and 2 episodes in 1 subject were reported in adolescents 12-17 years. No episodes were reported in children 6-11 years (Figure 12–6 and Table 12–19).

Table 12–19 Severe hypoglycaemic episodes across age groups – treatment emergent – summary – safety analysis set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Children 1-5 Years								
Number of Subjects	40				41			
ISPAD	40	(100.0)	1272	10605	39	(95.1)	1238	10107
Severe	4	(10.0)	5	42	2	(4.9)	2	16
Externally classified	4	(10.0)	5	42	2	(4.9)	2	16
Children 6-11 Years								
Number of Subjects	61				61			
ISPAD	59	(96.7)	2221	11891	58	(95.1)	2493	13599
Severe	3	(4.9)	4	21	0	(0.0)	0	0
Externally classified	3	(4.9)	4	21	0	(0.0)	0	0
Adolescents 12-17 Years								
Number of Subjects	80				77			
ISPAD	79	(98.8)	2340	9712	73	(94.8)	2191	9386
Severe	4	(5.0)	5	21	1	(1.3)	2	9
Externally classified	4	(5.0)	4	21	1	(1.3)	2	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
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious,
or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Cross-reference: Modified from EOT Tables 14.3.1.43–45 and 14.3.1.85

12.6.3 Nocturnal confirmed hypoglycaemic episodes

The percentages of subjects experiencing nocturnal confirmed hypoglycaemic episodes were similar with IDegAsp (N= 101 [55.8%]) and IDet (N= 106 [59.2%]) as was the observed rates per 100 PYE (577 with IDegAsp and 540 with IDet) (Table 12–20 and EOT Table 14.3.1.51). No statistically

significant difference was observed between the treatment arms (IDegAsp OD/IDet: 1.09 [0.81; 1.48]$_{95\%CI}$); see Table 12–21. Approximately 90% of the subjects in both treatment groups reported 4 or fewer nocturnal confirmed hypoglycaemic episodes during the trial (EOT Figure 14.3.1.61).

Table 12–20 Nocturnal hypoglycaemic episodes by classification - treatment emergent - summary - safety analysis set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Number of Subjects	181				179			
Confirmed	101	(55.8)	316	577	106	(59.2)	291	540
ISPAD	134	(74.0)	732	1337	134	(74.9)	680	1261
Severe	1	(0.6)	2	4	2	(1.1)	2	4
Documented Sympt.	91	(50.3)	337	615	90	(50.3)	348	645
Asymptomatic	89	(49.2)	384	701	86	(48.0)	325	603
Probable Sympt.	0	(0.0)	0	0	0	(0.0)	0	0
Relative	5	(2.8)	9	16	5	(2.8)	5	9
ISPAD Unclassifiable	4	(2.2)	5	9	3	(1.7)	17	32

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in his care,is semiconscious or unconscious,or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL). Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).

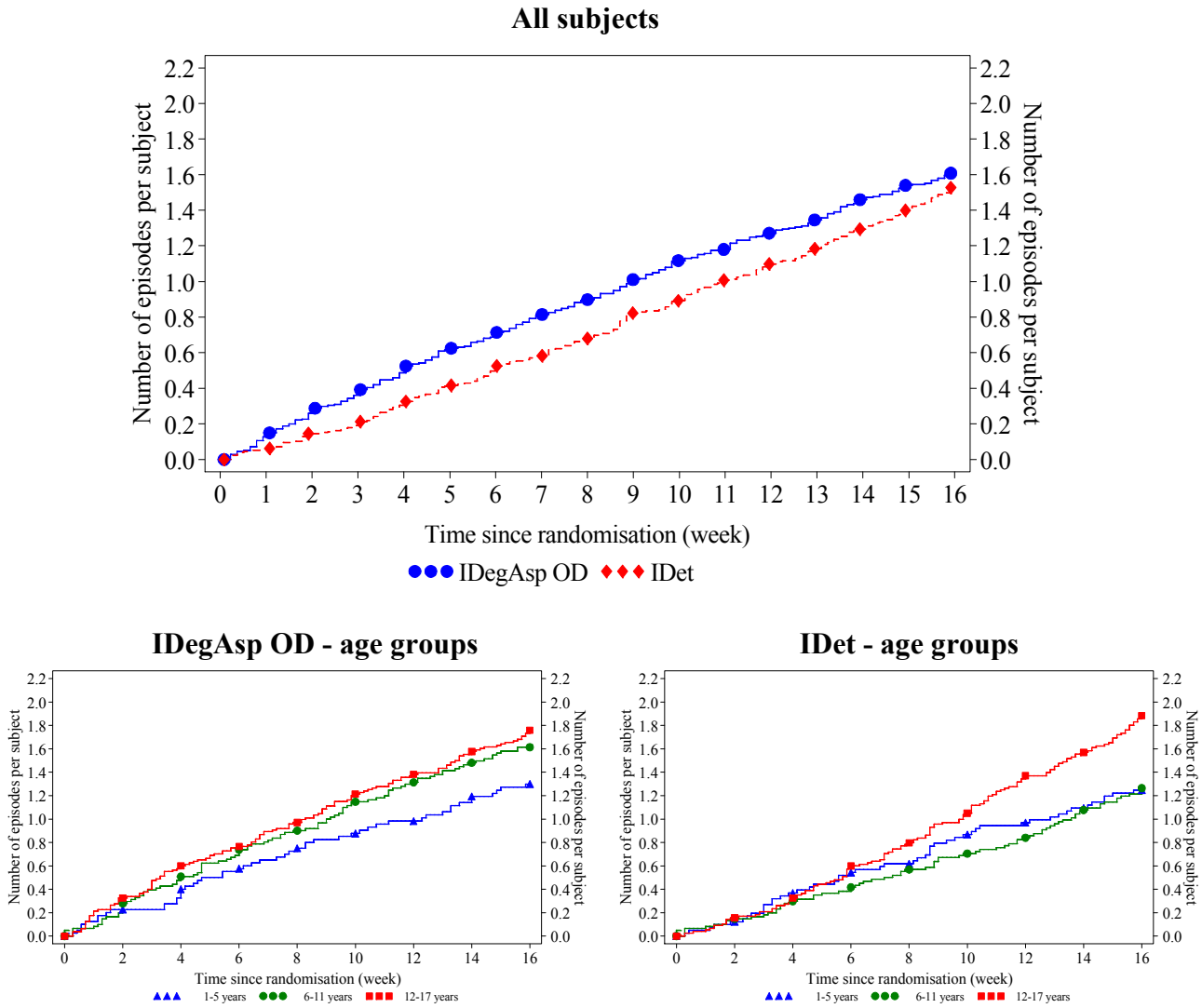
Cross-reference: Modified from Table 14.3.1.46

Table 12–21 Nocturnal confirmed hypoglycaemic episodes - treatment emergent - statistical analysis - full analysis set

	FAS	N	Estimate	95% CI
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	537.91	
IDet	180	179	492.11	
Treatment Ratio				
IDegAsp OD / IDet			1.09	[0.81 ; 1.48]

FAS: Full analysis set, 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 function and the logarithm of the exposure time (100 years) as offset. The model includes treatment,sex,region and age group as fixed effects.
Nocturnal period: the period between 23:00 and 07:00(both included)

Cross-reference: EOT Table 14.3.1.53



Safety analysis set

Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included)

Cross-reference: EOT Figures 14.3.1.66 and 14.3.1.91–92

Figure 12–7 Nocturnal confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function (upper panel: all subjects; lower panel: age groups) – safety analysis set

Nocturnal confirmed hypoglycaemic episodes across age groups

The rate of nocturnal confirmed hypoglycaemic episodes tended to increase with increasing age. Thus, the rate was higher in adolescents 12-17 years as compared to the overall trial population and lower in children 1 to 5 years. The higher rate in adolescents may be attributed to adolescent lifestyle.

IDegAsp

Nocturnal confirmed hypoglycaemic episodes are summarised by age group in Table 12–22. The trend observed for the overall population in the IDegAsp treatment group was followed by all age groups with children 1-5 years having slightly lower rates (Figure 12–7 and EOT Figures 14.3.1.67–69).

IDet

The trend observed for the overall population in the IDet treatment group was followed by all age groups with adolescents 12-17 years having slightly higher rates (Figure 12–7 and EOT Figures 14.3.1.67–69).

Table 12–22 Nocturnal hypoglycaemic episodes by classification and age group – treatment emergent – summary – safety summary set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Children 1-5 Years								
Number of Subjects	40				41			
Confirmed	18	(45.0)	55	459	21	(51.2)	52	425
ISPAD	28	(70.0)	132	1101	25	(61.0)	125	1020
Severe	0	(0.0)	0	0	1	(2.4)	1	8
Documented Sympt.	13	(32.5)	35	292	12	(29.3)	31	253
Asymptomatic	23	(57.5)	96	800	22	(53.7)	91	743
Probable Sympt.	0	(0.0)	0	0	0	(0.0)	0	0
Relative	1	(2.5)	1	8	2	(4.9)	2	16
ISPAD Unclassifiable	1	(2.5)	1	8	2	(4.9)	12	98
Children 6-11 Years								
Number of Subjects	61				61			
Confirmed	38	(62.3)	108	578	34	(55.7)	85	464
ISPAD	48	(78.7)	258	1381	48	(78.7)	238	1298
Severe	1	(1.6)	2	11	0	(0.0)	0	0
Documented Sympt.	32	(52.5)	97	519	28	(45.9)	84	458
Asymptomatic	36	(59.0)	159	851	35	(57.4)	154	840
Probable Sympt.	0	(0.0)	0	0	0	(0.0)	0	0
Relative	0	(0.0)	0	0	0	(0.0)	0	0
ISPAD Unclassifiable	1	(1.6)	1	5	0	(0.0)	0	0
Adolescents 12-17 Years								
Number of Subjects	80				77			
Confirmed	45	(56.3)	153	635	51	(66.2)	154	660
ISPAD	58	(72.5)	342	1419	61	(79.2)	317	1358
Severe	0	(0.0)	0	0	1	(1.3)	1	4
Documented Sympt.	46	(57.5)	205	851	50	(64.9)	233	998
Asymptomatic	30	(37.5)	129	535	29	(37.7)	80	343
Probable Sympt.	0	(0.0)	0	0	0	(0.0)	0	0
Relative	4	(5.0)	8	33	3	(3.9)	3	13
ISPAD Unclassifiable	2	(2.5)	3	12	1	(1.3)	5	21

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in his care, is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL). Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).

Cross-reference: Modified from EOT Tables 14.3.1.47–49

12.6.4 Nocturnal severe hypoglycaemic episodes

The number of nocturnal severe hypoglycaemic episodes was low in both treatment groups, which precluded meaningful statistical analysis comparison between treatments (Table 12–20).

Two (2) nocturnal severe hypoglycaemic episodes in 1 subject was reported in the IDegAsp treatment group (children 6-11 years) and 2 episodes in 2 subjects was reported in the IDet treatment group (1 subject in children 1-5 years and 1 subject in adolescents 12-17 years); see Table 12–20 and Table 12–22.

12.6.5 Hypoglycaemic episodes according to ISPAD

The rate of hypoglycaemic episodes according to the ISPAD 2009 classification (see Section 9.5.1.4) was similar with IDegAsp and IDet (10651 and 10982 episodes per 100 PYE, respectively) (Table 12–14). The majority of the ISPAD classified episodes were documented symptomatic or asymptomatic episodes with a plasma glucose ≤ 3.9 mmol/L. The rate of nocturnal hypoglycaemic episodes according to the ISPAD 2009 classification was also similar with IDegAsp and IDet (1337 and 1261 episodes per 100 PYE, respectively) (Table 12–20). ISPAD 2009 classified hypoglycaemic episodes over time and by age group are tabulated in EOT Tables 14.3.1.50 and EOT Tables 14.3.1.43–45, respectively. ISPAD 2009 classified nocturnal hypoglycaemic episodes over time and by age group are tabulated in EOT Tables 14.3.1.51 and EOT Tables 14.3.1.47–49, respectively.

12.7 Hyperglycaemic episodes and ketosis

According to the protocol, subjects were to report a hyperglycaemic episode whenever a glucose measurement was 14.0 mmol/L (250 mg/dL) or above, and the subject looked/felt ill. Subjects having a hyperglycaemic episode as described were to also measure ketone bodies. The ketone measurement involved an additional finger prick. Ketosis was considered present if blood ketones were higher than 1.5 mmol/L.

The percentages of subjects experiencing hyperglycaemic episodes were similar between IDegAsp (N= 72 [39.8%]) and IDet (N= 73 [40.8%]) treatment groups. The observed rate of hyperglycaemic episodes per 100 PYE was 1094 with IDegAsp and 833 with IDet (Table 12–23).

The percentages of subjects experiencing hyperglycaemic episodes with ketosis (blood ketones > 1.5 mmol/L) were numerically lower with IDegAsp (N= 4 [2.2%]) compared to IDet (N= 8 [4.5%]) (Table 12–23). The rate per 100 PYE was 11 with IDegAsp and 22 with IDet. There were no statistically significant differences between treatment groups in the rates of hyperglycaemic episodes or hyperglycaemic episodes with ketosis (Table 12–24).

In order to assess the hyperglycaemic episodes with ketosis in the trial, it has to be considered that many subjects did not measure ketone bodies as per protocol (see Section 10.4) Ketone bodies were measured for approximately 74% of hyperglycaemic episodes in the IDegAsp treatment group and

for 67% in the IDet treatment group (EOT Table 14.3.1.77). This imbalance in ketone body measurement among groups would be expected to result in more ketosis episodes identified in the IDegAsp treatment group. However, less episodes of ketosis were reported in the IDegAsp treatment group than in the IDet treatment group (6 episodes in 4 subjects with IDegAsp versus 12 episodes in 8 subjects with IDet), implying that the difference in episodes of ketosis in favour of IDegAsp might have been underestimated.

Regarding subjects experiencing nocturnal hyperglycaemic episodes, the percentages of subjects were similar between IDegAsp (N= 26 [14.4%]) compared to the IDet (N= 30 [16.8%]) treatment group. The respective rates per 100 PYE were 184 with IDegAsp and 98 with IDet (Table 12–23). Regarding nocturnal hyperglycaemic episodes with ketosis (blood ketones > 1.5 mmol/L), 1 episode in 1 subject was reported with IDegAsp vs 2 episodes in 2 subjects with IDet (Table 12–23). No statistical analysis was performed for nocturnal hyperglycaemic episodes nor for nocturnal hyperglycaemic episodes with ketosis.

Table 12–23 Hyperglycaemic episodes and episodes of ketosis – treatment emergent – summary - safety analysis set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
All hyperglycaemic episodes								
Number of Subjects	181				179			
Hyperglycaemic episodes	72	(39.8)	599	1094	73	(40.8)	449	833
Hyperglycaemia with ketones measured	57	(31.5)	441	805	60	(33.5)	301	558
Hyperglycaemia with ketones (> 1.5 mmol/L)	4	(2.2)	6	11	8	(4.5)	12	22
Nocturnal hyperglycaemic episodes								
Number of Subjects	181				179			
Hyperglycaemic episodes	26	(14.4)	101	184	30	(16.8)	53	98
Hyperglycaemia with ketones measured	21	(11.6)	79	144	17	(9.5)	29	54
Hyperglycaemia with ketones (> 1.5 mmol/L)	1	(0.6)	1	2	2	(1.1)	2	4

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L where subject looks/feels ill
Ketosis:(blood ketones > 1.5 mmol/L)
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included)

Cross-reference: Modified from EOT Tables 14.3.1.75, 14.3.1.77, 14.3.1.79 and 14.3.1.81

Table 12–24 Hyperglycaemic episodes – treatment emergent – statistical analysis – full analysis set

	FAS	N	Estimate	95% CI
All hyperglycaemic episodes				
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	823.79	
IDet	180	179	763.54	
Treatment Ratio				
IDegAsp OD / IDet			1.08	[0.64 ; 1.81]
Ketosis (blood ketones > 1.5 mmol/L)				
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	2.41	
IDet	180	179	5.48	
Treatment Ratio				
IDegAsp OD / IDet			0.44	[0.11 ; 1.74]

FAS: Full analysis set, 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 function and the logarithm of the exposure time (100 years) as offset. The model includes treatment,sex,region and age group as fixed effects.
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L where subject looks/feels ill.
Ketosis: (blood ketones > 1.5 mmol/L)

Cross-reference: Modified from EOT Tables 14.3.1.83–84

Treatment emergent hyperglycaemic episodes and episodes of ketosis for individual subjects are listed in Appendix 16.2.7, listing 16.2.7.4.

Hyperglycaemic episodes across age groups

IDegAsp

Children 6-11 years had higher rate per 100 PYE (1751) of hyperglycaemic episodes compared to children 1-5 years (817) and adolescents 12-17 years (722). The number of hyperglycaemic episodes with ketosis was 3 in children 1-5 years, 1 in children 6-11 years and 2 in adolescents 12-17 years (Table 12–25).

The percentage of subjects with nocturnal hyperglycaemic episodes was similar between age groups (EOT Table 14.3.1.80). The number of nocturnal hyperglycaemic episodes with ketosis was very low for all age groups (EOT Table 14.3.1.82).

IDet

Children 1-5 years had a higher rate per 100 PYE (955) of hyperglycaemic episodes compared to children 6-11 years (758) and adolescents 12-17 years (827). The number of hypoglycaemic episodes with ketosis was 4 in children 1-5 years, 3 in children 6-11 years and 5 in adolescents 12-17 years (Table 12–25).

The percentage of subjects with nocturnal hyperglycaemic episodes was similar between children 1-5 years and children 6-11 years and slightly higher for the adolescents 12-17 years (EOT Table 14.3.1.80). The number of nocturnal hyperglycaemic episodes with ketosis was very low for all age groups (EOT Table 14.3.1.82).

Table 12–25 Hyperglycaemic episodes and episodes of ketosis by age group – treatment emergent – summary - safety analysis set

	IDegAsp OD				IDet			
	N	(%)	E	R	N	(%)	E	R
Children 1-5 years	40				41			
Hyperglycaemic episodes	19	(47.5)	98	817	14	(34.1)	117	955
Episodes of ketosis	2	(5.0)	3	25	2	(4.9)	4	33
Children 6-11 years	61				61			
Hyperglycaemic episodes	25	(41.0)	327	1751	25	(41.0)	139	758
Episodes of ketosis	1	(1.6)	1	5	3	(4.9)	3	16
Adolescents 12-17 years	80				77			
Hyperglycaemic episodes	28	(35.0)	174	722	34	(44.2)	193	827
Episodes of ketosis	1	(1.3)	2	8	3	(3.9)	5	21

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L where subject looks/feels ill
Ketosis:(blood ketones > 1.5 mmol/L)

Cross-reference: Modified from EOT Tables 14.3.1.76 and 14.3.1.78

12.8 Clinical laboratory evaluation

12.8.1 Laboratory values over time

Mean biochemistry, haematology and lipids laboratory values remained stable during the trial, and there were no apparent differences between the two treatment groups in mean values or in mean change from baseline for these values (EOT Tables 14.3.5.1–4, 14.3.5.13–16, 14.3.5.22–25 and

EOT Figures 14.3.5.5–12, 14.3.5.17–21, 14.3.5.26–28). The reference ranges for all laboratory parameters are shown in Appendix 16.2.8, Listing 16.2.8.1. All individual laboratory measurements are listed by subject in Appendix 16.2.8, Listings 16.2.8.2–5.

12.8.2 Individual subject changes

The majority of subjects had only minor changes in biochemistry (EOT Tables 14.3.5.1–4 and Figures 14.3.5.5–12), haematology and lipid values levels throughout the trial. The majority of subjects' values remained within the reference ranges at baseline and at the end of trial (EOT Listing 14.3.4.1–3). Shifts in laboratory values from normal at baseline to high or low values occurred with a similar pattern in both treatment groups. In general, there was no difference between the treatment groups for any of the parameters and no clinically relevant concerns were raised. For biochemistry please see EOT Tables 14.3.5.1–4 and Figures 14.3.5.5–12; for haematology see EOT Tables 14.3.5.13–16 and Figures 14.3.5.17–21; for lipids see EOT Tables 14.3.5.22–25 and Figures 14.3.5.26–28.

12.8.3 Individual clinically significant abnormalities

Clinically significant changes in biochemistry, haematology and lipids parameters were reported as AEs (e.g. 'blood ketone body increased','hypercreatinaemia', 'hyperkalaemia' and 'acetonaemia') and are therefore included as part of the AE evaluation (Section 12.5.5).

12.9 Vital signs, physical findings and other observations related to safety

12.9.1 Vital signs

At Week 16, the mean blood pressure (systolic/diastolic) and pulse were similar between the IDegAsp treatment group (106/66 mmHg and 83 beats/min) compared to the IDet treatment group (108/66 mmHg and 82 beats/min); virtually unchanged from the mean baseline levels (visit 1) (EOT Tables 14.3.6.2–6).

Blood pressure and pulse are listed by subject in EOT Listing 14.3.7.1.

12.9.2 Physical examination

The majority of subjects had normal physical examination recordings at baseline and at Week 16 in both treatment groups (EOT Tables 14.3.6.1). Physical examination findings are listed by subject in EOT Listing 14.3.7.2.

12.9.3 Weight

Body weight was measured at screening, randomisation, week 12 and week 16 during the trial. Individual measurements of height, weight and BMI are listed in EOT Listing 14.3.7.3. Body weight and BMI are summarised in EOT Tables 14.3.6.7–14 and plots of body weight are presented in EOT Figures 14.3.6.15–22.

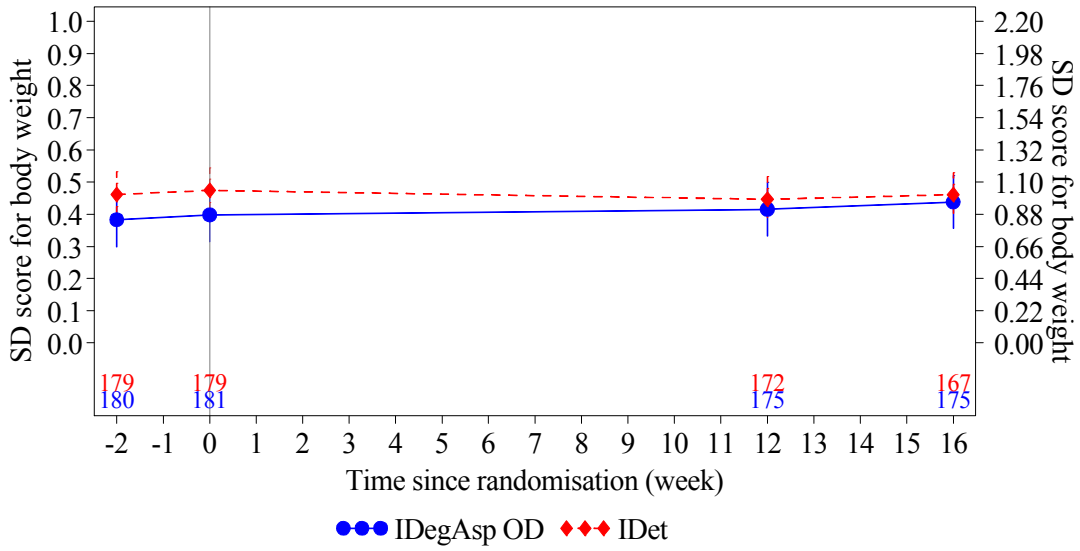
As the trial population was heterogeneous with respect to age and country of origin, it was decided to include the SD score for body weight as an endpoint in order to be able to compare body weight across age groups and sex. To estimate the growth of children, standardised weight was calculated for each year of age and for each sex. Thus, a child with a weight equal to the mean value for its age and sex has an SD score of 0, while a child with a weight 2 SDs above the mean value for its age and sex has an SD score of +2. Standardised weight scores are often referred to as 'Z-scores' where standardisation is done by first subtracting the mean value and then dividing by the standard deviation. However, not all standardised scores are calculated as Z-scores. In Trial 3816, SD scores are calculated based on published data on weight distributions for the individual countries represented in the trial and these are in some cases calculated using other methods. Please see the statistical analysis plan in Appendix 16.1.9 for additional details.

Subjects in the IDegAsp treatment group had similar weight SD score at baseline to subjects in the IDet treatment group (means of 0.40 vs. 0.47). After 16 weeks, the mean weight SD score was 0.44 with IDegAsp and 0.46 with IDet (EOT Table 14.3.6.23). During the treatment period, there was an increase in weight SD score of +0.06 in the IDegAsp treatment group and a decrease of -0.02 in the IDet treatment group, see Table 12–26, Figure 12–8, EOT Table 14.3.6.27 and EOT Figure 14.3.6.32. Change from baseline in weight SD score is presented as LSMean plot in EOT Figure 14.3.6.36.

Table 12–26 Mean body weight and mean standard deviation (SD) score of weight, safety analysis set

	IDegAsp OD		IDet	
	Body weight(kg)	Weight SD score	Body weight(kg)	Weight SD score
Total group				
Baseline (Visit 2)	41.3	0.40	42.9	0.47
At 16 weeks	42.6	0.44	44.0	0.46
Change from baseline	1.4	0.06	0.7	-0.02
Children 1-5 Years				
Baseline (Visit 2)	18.9	0.41	17.7	0.16
At 16 weeks	20.0	0.43	18.1	0.17
Change from baseline	1.0	0.07	0.6	0.03
Children 6-11 Years				
Baseline (Visit 2)	32.6	0.15	35.2	0.53
At 16 weeks	33.8	0.20	36.0	0.48
Change from baseline	1.5	0.07	1.0	-0.04
Adolescents 12-17 Years				
Baseline (Visit 2)	59.1	0.58	62.4	0.60
At 16 weeks	60.7	0.63	62.9	0.59
Change from baseline	1.6	0.05	0.6	0.02

Cross-reference: Modified from EOT Tables 14.3.6.7–14 and 14.3.6.23–30



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

Cross-reference: EOT Figure 14.3.6.32

Figure 12–8 Standard deviation (SD) score for body weight – mean plot - safety analysis set

Statistical analysis of change from baseline in weight SD score showed a statistically significant treatment difference (IDegAsp OD-IDet) 0.07 $[0.02; 0.12]_{95\% \text{ CI}}$ in favour of IDet (i.e., no increase in weight SD score) during the 16-week treatment period (EOT Table 14.3.6.31). The clinical significance of this difference is considered to be limited.

Body weight SD scores across age groups

IDegAsp

The mean SD score increased from baseline to end of trial across all three groups (Table 12–26).

IDet

Treatment with IDet resulted in a small decrease in SD score in children 6-11 years while an almost unchanged SD score was observed in children 1-5 years and adolescents 12-17 years (Table 12–26).

Further output for body weight and SD scores according to age groups are shown in EOT Figures 14.3.6.16–18, 14.3.6.20–22 and 14.3.6.33–35.

12.9.4 Pregnancy

There were no pregnancies reported during this trial. Pregnancy tests are listed in Appendix 16.8.2, Listing 16.2.8.6.

12.9.5 Technical complaints

One (1) subject in the IDet treatment group reported 1 technical complaint related to 1 AE ('device breakage'), see Appendix 16, Listing 16.2.7.7 and Section 12.3.2.4 for details.

12.10 Safety conclusions

After 16 weeks of treatment with IDegAsp OD + IAsp or IDet + IAsp, the following can be concluded:

Secondary endpoints

- **Adverse events:** The rate for AEs was 915 events per 100 PYE in the IDegAsp treatment group and 853 events per 100 PYE in the IDet treatment group. The majority of AEs were of mild or moderate severity in both treatment groups. Apart from hypoglycaemic episodes reported on the hypoglycaemic episode form, the most frequently reported AEs (>5%) in both treatment groups were 'headache','nasopharyngitis', 'abdominal pain upper', 'pyrexia' and 'vomiting'. The rate of AEs considered possibly or probably related to trial drug by the investigator was numerically higher with IDegAsp compared to IDet (47 vs. 37 events per 100 PYE, respectively). The most frequently reported AE assessed as possibly or probably related to trial drug was hypoglycaemia related AEs, where more events were reported in the IDegAsp treatment group (12 events in 11 subjects) compared to the IDet treatment group (3 events in 2 subjects), followed by events in the *gastrointestinal disorders* SOC, where more events were reported as related to trial product in the IDet treatment group (5 events in 4 subjects with IDet and 0 events with IDegAsp).

- **Deaths, serious adverse events and other significant adverse events:** No deaths were reported in this trial. More subjects reported SAEs with IDegAsp than with IDet (6.1% vs. 3.9%) and the number of reported SAEs was low both with IDegAsp and IDet (14 events vs. 7 events, respectively). The rates of SAEs were generally low, however, numerically higher with IDegAsp compared to IDet (26 vs. 13 events per 100 PYE, respectively). For IDegAsp, the most frequently reported SAE included 5 events of 'hypoglycaemia' that were reported by 5 subjects compared with 1 event in 1 subject in the IDet treatment group. One (1) subject withdrew from the trial due to an AE in the IDegAsp treatment group ('hypoglycaemic seizure'). Additionally, 1 subject withdrew due to "[redacted]" in the IDet treatment group, reported under 'other' reasons for withdrawal.

- **Medication errors:** One (1) event of 'overdose' and 7 events of 'wrong drug administered' were reported in the IDegAsp treatment group. Two (2) episodes of 'accidental overdose', 1 event of 'drug dispensing error' and 3 events of 'wrong drug administered' were reported in the IDet treatment group. All of the 'wrong drug administered' events were due to mix-up of insulins by the subjects' carer.

- **Confirmed hypoglycaemia:** The observed rates of confirmed hypoglycaemic episodes were 4623 and 4955 episodes per 100 PYE for IDegAsp and IDet, respectively, and there was no statistically significant difference between treatment arms (IDegAsp OD/IDet: 0.95 [0.76; 1.17]$_{95\%CI}$).

- **Severe hypoglycaemia:** In the IDegAsp treatment group, 11 subjects (6.1%) reported 14 severe hypoglycaemic episodes and in the IDet treatment group 3 subjects (1.7%) reported 4 severe hypoglycaemic episodes. The observed rate of severe hypoglycaemic episodes was numerically higher with IDegAsp than with IDet (26 vs. 7 episodes per 100 PYE, respectively. There was no statistically significant difference between treatment groups (IDegAsp OD/IDet: 3.20 [0.88; 11.66]$_{95\%CI}$).

- **Nocturnal hypoglycaemic episodes:** The observed rates of nocturnal confirmed hypoglycaemic episodes were 577 and 540 episodes per 100 PYE for IDegAsp and IDet, respectively, and there was no statistically significant difference between treatment groups (IDegAsp OD/IDet: 1.09 [0.81; 1.48]$_{95\%CI}$). There were 2 nocturnal severe hypoglycaemic episodes in each treatment group.

- **Hyperglycaemic episodes:** There was no statistically significant difference between IDegAsp and IDet with respect to the rate of hyperglycaemic episodes (1.08 [0.64; 1.81]$_{95\%CI}$). The observed rate of hyperglycaemia episodes with ketosis was numerically lower with IDegAsp than with IDet (11 vs. 22 episodes per 100 PYE, respectively. There was no statistically significant difference between treatment groups (IDegAsp OD/IDet: 0.44 [0.11; 1.74]$_{95\%CI}$).

- **Vital signs, 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, physical examination and laboratory values.

- **Body weight:** During the treatment period, there was an increase in weight SD score of +0.06 in the IDegAsp treatment group and a decrease of -0.02 in the IDet treatment group. Statistical analysis of change from baseline in weight SD score showed a statistically significant treatment difference in favour of IDet during the 16-week treatment period (IDegAsp OD-IDet: 0.07 [0.02; 0.12]$_{95\%\ CI}$).

- **Insulin dose:** The mean daily total (basal plus bolus) insulin dose after 16 weeks was 14% lower in the IDegAsp treatment group (0.88 units/kg) than in the IDet treatment group (1.01 units/kg). The mean daily basal insulin dose after 16 weeks was 28% lower in the IDegAsp treatment group (0.36 units/kg) than in the IDet treatment group (0.49 units/kg). Daily bolus insulin dose was similar in the two treatment groups at week 16 (0.52 units/kg in both treatment groups).

13 Discussion and overall conclusions

13.1 Discussion

This multinational trial investigated the efficacy and safety of IDegAsp OD in combination with IAsp as bolus insulin, and was conducted in 14 countries and included 362 children and adolescents with T1DM spanning in age from 1 year to less than 18 years. The trial was conducted in agreement with the European Medicines Agency (EMA) Paediatric Committee (PDCO) as a binding element of the PIP to investigate the efficacy and safety of IDegAsp OD in children and adolescents with T1DM.

The trial was a 16-week multi-national, multi-centre, open-label, two-arm, parallel group, randomised, treat-to-target, efficacy and safety trial comparing treatment with IDegAsp OD with a main meal + IAsp for the remaining meals vs. IDet once or twice daily + meal-time IAsp. Randomisation was stratified according to age group (1 to less than 6 years, 6 to less than 12 years and 12 to less than 18 years of age). The trial was powered to include at least 310 subjects, and the primary statistical analysis was based on the FAS. The stratification by age group in this trial was to ensure an equal representation of age groups between the treatment groups. The trial was not statistically powered to allow for statistical comparisons between the age groups. This should be noted when assessing the summarised trial results per age group.

The primary objective was to compare the glycaemic control between the treatment groups, as measured by change from baseline in HbA_{1c} after 16 weeks of treatment. The secondary objectives were to compare IDegAsp OD + IAsp with IDet + IAsp with respect to other parameters of glycaemic control and safety endpoints including hypoglycaemia and hyperglycaemia with ketosis.

Glycaemic control

Analysis of the primary endpoint, change in HbA_{1c} after 16 weeks of treatment confirmed that IDegAsp OD + IAsp was non-inferior to IDet + IAsp. Both treatment regimens effectively maintained glycaemic control over 16 weeks. IDegAsp OD + IAsp maintained glycaemic control as measured by change in HbA_{1c} and non-inferiority to IDet + IAsp in terms of changing HbA_{1c} was confirmed, as the upper limit of the 95% CI for the mean treatment difference was ≤0.4%. The trend regarding change of HbA_{1c} from baseline was similar among all age groups in both arms.

FPG decreased slightly in both the IDegAsp and IDet group after 16 weeks with no statistical differences between treatment groups. There were no statistically significant treatment differences at 16 weeks in the mean of the 8 point profiles, fluctuation in plasma glucose or prandial increments. Furthermore, there were no statistically significant differences in within subject variability (CV%). This reflects the similar performance in glycaemic control in the treatment groups.

Insulin doses and titration

According to the trial protocol, each subject's total daily insulin dose was to be reduced by 20% at randomisation. An initial transient increase in the pre-breakfast, pre-lunch, pre-dinner and pre-bedtime SMPG concentrations was noted in both treatment groups, probably reflecting the dose reduction at baseline.

During the trial the insulin dose was to be titrated individually according to the titration algorithm. Overall, the total insulin dose increased slightly in both treatment groups. There was a lower total daily insulin dose requirement in the IDegAsp group compared to the IDet group, primarily consisting of a lower basal daily dose requirement. The lower basal insulin requirement in the IDegAsp treatment group may be related to the fact that 97 (54.2%) subjects were using IDet BID at the end of the trial, as it is well-known that BID dosing generally leads to higher basal doses[22,23]. Daily bolus insulin dose was similar between the two treatments.

Hypoglycaemia

Fear of hypoglycaemia remains a major limiting factor in attempts to achieve near normal blood glucose levels[11]. For children and adolescents, avoiding hypoglycaemia is challenged by variable eating habits and erratic activity, plus a limited ability of small children to detect hypoglycaemia[24]. Furthermore, the easiness and acceptance of the insulin regimen has to be balanced against the risk of hypoglycaemia occurrence for the individual patient.

In this trial, hypoglycaemic episodes were evaluated based both on the ISPAD classification and the Novo Nordisk definition of confirmed hypoglycaemic episodes. There was no statistically significant difference between treatment arms regarding confirmed hypoglycaemic episodes and the rates of ISPAD classified hypoglycaemic episodes were similar between treatment groups.

Regarding severe hypoglycaemic episodes, there was no statistically significant difference between treatment groups. However a tendency towards higher numbers of reported events in the IDegAsp group was noted across age groups.

While severity of hypoglycaemia in adults has often been based on the subject's ability to treat him/herself, the ISPAD 2009 definition of severe hypoglycaemic episodes used in this trial contains a somewhat broader and subjective component: "The child is having altered mental status and cannot assist in their care", as mentioned above. Given the challenge of assessing whether a hypoglycaemic episode meets criteria for being severe, particularly in very young children, all reported episodes of severe hypoglycaemia were reviewed and classified by an external, independent, blinded paediatric endocrinologist. No major differences were noted between the numbers of severe hypoglycaemia reported by the Investigator and the ones confirmed by the external review of those episodes. In the IDegAsp treatment group, most of the severe hypoglycaemia episodes were classified as severe due to "child having altered mental status and cannot assist in their care", which entails a subjective element of judgement. It should be noted that this is an open-label trial which might influence the reporting rate of severe hypoglycaemia based on subjective judgement, especially for those that continued previous treatment regiments which is the case for approximately half of the subjects in the IDet treatment group. Regarding severe hypoglycaemic episodes based on more objective criteria ('semiconscious or unconscious and coma +/- convulsions'), rates were similar between treatment groups.

This tendency towards numerically higher rates of severe hypoglycaemia needs to be taken into consideration when a fixed combination insulin regimen is to be prescribed to a young patient. Patients and parents' preferences for a fixed combination insulin resulting in an insulin regimen with less injections per day, have to be balanced with the hypoglycaemic tendency for the specific patient.

Hyperglycaemia

There were no statistically significant differences between treatment groups in the rates of hyperglycaemic episodes or hyperglycaemic episodes with ketosis, however, it should be noted that ketone measurements were only available for 74% of episodes in the IDegAsp group and 67% of episodes in the IDet group. This imbalance in ketone body measurement among groups would be expected to result in more ketosis episodes identified in the IDegAsp treatment group. However, less episodes of ketosis were reported as AEs in the IDegAsp group than in the IDet group, implying that the difference in episodes of ketosis in favour of IDegAsp might have been underestimated. A reduced risk of hyperglycaemia with ketosis with IDegAsp treatment reinforces the clinical benefit of IDegAsp in maintaining good glycaemic control via the ultra-long duration of action of the IDeg component of IDegAsp.

Safety and tolerability

In general, IDegAsp was well tolerated and the majority of events were typical of a paediatric population with T1DM. The vast majority of events were mild or moderate in severity and were judged as unlikely to be related to trial products. The rate of AEs per 100 PYE was similar between the two treatment groups. Hypoglycaemic episodes and hypoglycaemic seizures were reported as AEs (i.e., events that met the criteria for an SAE or a MESI) by 13 (7.2%) subjects in the IDegAsp group and 3 (1.7%) subjects in the IDet group. Of these, 6 (3.3%) subjects in the IDegAsp group and 1 (0.6%) subject in the IDet group had hypoglycaemia related AEs that were serious; 4 of them (3 in the IDegAsp group and 1 in the IDet group) were considered to be possibly or probably related to IAsp.

As with any insulin therapy, injection site reactions may occur. Injection site reactions were reported by 1 subject in the IDegAsp group and 3 subjects in the IDet group; all were mild or moderate in severity and all were non-serious.

Body weight was assessed by an analysis of weight SD score, which showed a statistically significant difference (IDegAsp-IDet: 0.07 $[0.02; 0.12]_{95\% CI}$) with a lower weight gain in the IDet group. This is in accordance with previous studies where adult and paediatric subjects with T1DM and adults with T2DM typically gain less weight with IDet than with other basal insulins[25-27].

No clinically relevant differences were observed with respect to measurements of haematology, biochemistry, lipids or vital signs between the treatment groups.

13.2 Overall conclusions

- IDegAsp OD + IAsp effectively maintained glycaemic control and was non-inferior to IDet + IAsp in terms of change from baseline in HbA_{1c}. No differences were shown in FPG or SMPG parameters between the treatment groups
- On average, subjects in the IDegAsp treatment group had lower daily basal insulin and total daily insulin doses than in the IDet treatment group. Daily bolus insulin dose was similar between the two treatments
- The rate of confirmed hypoglycaemic episodes was not statistically significantly different between the IDegAsp and IDet treatment groups
- A numerically higher rate of severe hypoglycaemic episodes (ISPAD 2009 definition) was observed in the IDegAsp treatment group compared to IDet treatment group
- The rate of hyperglycaemic episodes was not statistically significantly different between the IDegAsp and IDet treatment groups. A numerically lower rate of hyperglycaemic episodes with ketosis was observed in the IDegAsp treatment group compared to the IDet treatment group
- The overall AE profile was similar between treatment groups and no new safety issues were identified

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			387
Screening Failures			25
Withdrawn before Randomisation			0
Randomised	182 (100.0)	180 (100.0)	362 (100.0)
Exposed	181 (99.5)	179 (99.4)	360 (99.4)
Withdrawn at/after Randomisation	8 (4.4)	12 (6.7)	20 (5.5)
Adverse Event	1 (0.5)	0 (0.0)	1 (0.3)
Non-Compliance With Protocol	1 (0.5)	0 (0.0)	1 (0.3)
Withdrawal Criteria	6 (3.3)	10 (5.6)	16 (4.4)
Other	0 (0.0)	2 (1.1)	2 (0.6)
Completed	174 (95.6)	168 (93.3)	342 (94.5)
full analysis set	182 (100.0)	180 (100.0)	362 (100.0)
PP analysis set	174 (95.6)	171 (95.0)	345 (95.3)
safety analysis set	181 (99.5)	179 (99.4)	360 (99.4)

N: Number of subjects
%: Proportion of randomised subjects
PP: Per protocol

14.1.2 Subject disposition - summary - children (1-5 years)

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Screened			82
Screening Failures			0
Withdrawn before Randomisation			0
Randomised	41 (100.0)	41 (100.0)	82 (100.0)
Exposed	40 (97.6)	41 (100.0)	81 (98.8)
Withdrawn at/after Randomisation	3 (7.3)	5 (12.2)	8 (9.8)
Withdrawal Criteria	3 (7.3)	5 (12.2)	8 (9.8)
Completed	38 (92.7)	36 (87.8)	74 (90.2)
full analysis set	41 (100.0)	41 (100.0)	82 (100.0)
PP analysis set	38 (92.7)	39 (95.1)	77 (93.9)
safety analysis set	40 (97.6)	41 (100.0)	81 (98.8)

N: Number of subjects
%: Proportion of randomised subjects
PP: Per protocol
This table is based on randomized subjects

14.1.3 Subject disposition - summary - children (6-11 years)

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Screened			122
Screening Failures			0
Withdrawn before Randomisation			0
Randomised	61 (100.0)	61 (100.0)	122 (100.0)
Exposed	61 (100.0)	61 (100.0)	122 (100.0)
Withdrawn at/after Randomisation	1 (1.6)	2 (3.3)	3 (2.5)
Adverse Event	1 (1.6)	0 (0.0)	1 (0.8)
Withdrawal Criteria	0 (0.0)	1 (1.6)	1 (0.8)
Other	0 (0.0)	1 (1.6)	1 (0.8)
Completed	60 (98.4)	59 (96.7)	119 (97.5)
full analysis set	61 (100.0)	61 (100.0)	122 (100.0)
PP analysis set	59 (96.7)	58 (95.1)	117 (95.9)
safety analysis set	61 (100.0)	61 (100.0)	122 (100.0)

N: Number of subjects
%: Proportion of randomised subjects
PP: Per protocol
This table is based on randomized subjects

14.1.4 Subject disposition - summary - adolescents (12-17 years)

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Screened			158
Screening Failures			0
Withdrawn before Randomisation			0
Randomised	80 (100.0)	78 (100.0)	158 (100.0)
Exposed	80 (100.0)	77 (98.7)	157 (99.4)
Withdrawn at/after Randomisation	4 (5.0)	5 (6.4)	9 (5.7)
Non-Compliance With Protocol	1 (1.3)	0 (0.0)	1 (0.6)
Withdrawal Criteria	3 (3.8)	4 (5.1)	7 (4.4)
Other	0 (0.0)	1 (1.3)	1 (0.6)
Completed	76 (95.0)	73 (93.6)	149 (94.3)
full analysis set	80 (100.0)	78 (100.0)	158 (100.0)
PP analysis set	77 (96.3)	74 (94.9)	151 (95.6)
safety analysis set	80 (100.0)	77 (98.7)	157 (99.4)

N: Number of subjects
%: Proportion of randomised subjects
PP: Per protocol
This table is based on randomized subjects

14.1.5 Subject disposition by country - summary - all subjects

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Belgium			
Screened			13
Randomised	8 (100.0)	5 (100.0)	13 (100.0)
Exposed	8 (100.0)	5 (100.0)	13 (100.0)
Completed	8 (100.0)	5 (100.0)	13 (100.0)
Full Analysis Set	8 (100.0)	5 (100.0)	13 (100.0)
PP Analysis Set	8 (100.0)	5 (100.0)	13 (100.0)
Safety Analysis Set	8 (100.0)	5 (100.0)	13 (100.0)
Brazil			
Screened			7
Randomised	4 (100.0)	3 (100.0)	7 (100.0)
Exposed	4 (100.0)	3 (100.0)	7 (100.0)
Completed	4 (100.0)	1 (33.3)	5 (71.4)
Full Analysis Set	4 (100.0)	3 (100.0)	7 (100.0)
PP Analysis Set	4 (100.0)	2 (66.7)	6 (85.7)
Safety Analysis Set	4 (100.0)	3 (100.0)	7 (100.0)
Canada			
Screened			11
Randomised	8 (100.0)	3 (100.0)	11 (100.0)
Exposed	8 (100.0)	3 (100.0)	11 (100.0)
Completed	8 (100.0)	3 (100.0)	11 (100.0)
Full Analysis Set	8 (100.0)	3 (100.0)	11 (100.0)
PP Analysis Set	8 (100.0)	3 (100.0)	11 (100.0)
Safety Analysis Set	8 (100.0)	3 (100.0)	11 (100.0)
Croatia			
Screened			12
Randomised	5 (100.0)	7 (100.0)	12 (100.0)
Exposed	5 (100.0)	7 (100.0)	12 (100.0)
Completed	5 (100.0)	7 (100.0)	12 (100.0)
Full Analysis Set	5 (100.0)	7 (100.0)	12 (100.0)
PP Analysis Set	5 (100.0)	7 (100.0)	12 (100.0)
Safety Analysis Set	5 (100.0)	7 (100.0)	12 (100.0)
Czech Republic			
Screened			20
Randomised	12 (100.0)	7 (100.0)	19 (100.0)
Exposed	12 (100.0)	7 (100.0)	19 (100.0)
Completed	12 (100.0)	7 (100.0)	19 (100.0)
Full Analysis Set	12 (100.0)	7 (100.0)	19 (100.0)
PP Analysis Set	12 (100.0)	7 (100.0)	19 (100.0)
Safety Analysis Set	12 (100.0)	7 (100.0)	19 (100.0)
Israel			
Screened			41
Randomised	16 (100.0)	18 (100.0)	34 (100.0)
Exposed	16 (100.0)	18 (100.0)	34 (100.0)
Completed	16 (100.0)	16 (88.9)	32 (94.1)
Full Analysis Set	16 (100.0)	18 (100.0)	34 (100.0)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

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Subject disposition by country - summary - all subjects

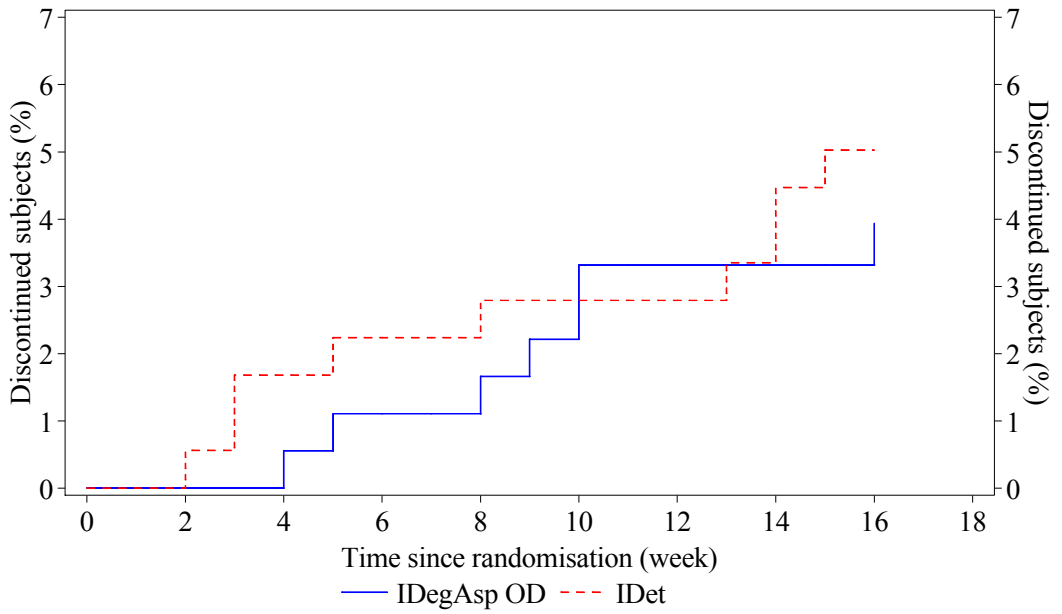
	IDegAsp OD N (%)	IDet N (%)	Total N (%)
PP Analysis Set	16 (100.0)	15 (83.3)	31 (91.2)
Safety Analysis Set	16 (100.0)	18 (100.0)	34 (100.0)
Poland			
Screened			32
Randomised	13 (100.0)	15 (100.0)	28 (100.0)
Exposed	13 (100.0)	15 (100.0)	28 (100.0)
Completed	12 (92.3)	15 (100.0)	27 (96.4)
Full Analysis Set	13 (100.0)	15 (100.0)	28 (100.0)
PP Analysis Set	12 (92.3)	15 (100.0)	27 (96.4)
Safety Analysis Set	13 (100.0)	15 (100.0)	28 (100.0)
Republic of Macedonia			
Screened			20
Randomised	7 (100.0)	13 (100.0)	20 (100.0)
Exposed	7 (100.0)	13 (100.0)	20 (100.0)
Completed	7 (100.0)	13 (100.0)	20 (100.0)
Full Analysis Set	7 (100.0)	13 (100.0)	20 (100.0)
PP Analysis Set	7 (100.0)	13 (100.0)	20 (100.0)
Safety Analysis Set	7 (100.0)	13 (100.0)	20 (100.0)
Russian Federation			
Screened			47
Randomised	21 (100.0)	25 (100.0)	46 (100.0)
Exposed	21 (100.0)	25 (100.0)	46 (100.0)
Completed	21 (100.0)	24 (96.0)	45 (97.8)
Full Analysis Set	21 (100.0)	25 (100.0)	46 (100.0)
PP Analysis Set	20 (95.2)	24 (96.0)	44 (95.7)
Safety Analysis Set	21 (100.0)	25 (100.0)	46 (100.0)
Serbia			
Screened			29
Randomised	7 (100.0)	20 (100.0)	27 (100.0)
Exposed	7 (100.0)	19 (95.0)	26 (96.3)
Completed	6 (85.7)	19 (95.0)	25 (92.6)
Full Analysis Set	7 (100.0)	20 (100.0)	27 (100.0)
PP Analysis Set	6 (85.7)	19 (95.0)	25 (92.6)
Safety Analysis Set	7 (100.0)	19 (95.0)	26 (96.3)
Slovenia			
Screened			4
Randomised	2 (100.0)	2 (100.0)	4 (100.0)
Exposed	2 (100.0)	2 (100.0)	4 (100.0)
Completed	2 (100.0)	2 (100.0)	4 (100.0)
Full Analysis Set	2 (100.0)	2 (100.0)	4 (100.0)
PP Analysis Set	2 (100.0)	2 (100.0)	4 (100.0)
Safety Analysis Set	2 (100.0)	2 (100.0)	4 (100.0)
South Africa			
Screened			15
Randomised	7 (100.0)	5 (100.0)	12 (100.0)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by country - summary - all subjects

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Exposed	7 (100.0)	5 (100.0)	12 (100.0)
Completed	7 (100.0)	5 (100.0)	12 (100.0)
Full Analysis Set	7 (100.0)	5 (100.0)	12 (100.0)
PP Analysis Set	7 (100.0)	4 (80.0)	11 (91.7)
Safety Analysis Set	7 (100.0)	5 (100.0)	12 (100.0)
Spain			
Screened			16
Randomised	8 (100.0)	7 (100.0)	15 (100.0)
Exposed	8 (100.0)	7 (100.0)	15 (100.0)
Completed	8 (100.0)	6 (85.7)	14 (93.3)
Full Analysis Set	8 (100.0)	7 (100.0)	15 (100.0)
PP Analysis Set	8 (100.0)	6 (85.7)	14 (93.3)
Safety Analysis Set	8 (100.0)	7 (100.0)	15 (100.0)
United States			
Screened			120
Randomised	64 (100.0)	50 (100.0)	114 (100.0)
Exposed	63 (98.4)	50 (100.0)	113 (99.1)
Completed	58 (90.6)	45 (90.0)	103 (90.4)
Full Analysis Set	64 (100.0)	50 (100.0)	114 (100.0)
PP Analysis Set	59 (92.2)	49 (98.0)	108 (94.7)
Safety Analysis Set	63 (98.4)	50 (100.0)	113 (99.1)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects



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14.1.6 Time to discontinuation (weeks) - full analysis set

14.1.7 Subject disposition by week - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	182	180	362
Attending			
Visit 1	182 (100.0)	180 (100.0)	362 (100.0)
Visit 2 (Week 0)	182 (100.0)	180 (100.0)	362 (100.0)
Visit 3 (Week 1)	181 (99.5)	179 (99.4)	360 (99.4)
Visit 4 (Week 2)	181 (99.5)	177 (98.3)	358 (98.9)
Visit 5 (Week 3)	181 (99.5)	176 (97.8)	357 (98.6)
Visit 6 (Week 4)	179 (98.4)	176 (97.8)	355 (98.1)
Visit 7 (Week 5)	179 (98.4)	174 (96.7)	353 (97.5)
Visit 8 (Week 6)	179 (98.4)	174 (96.7)	353 (97.5)
Visit 9 (Week 7)	178 (97.8)	173 (96.1)	351 (97.0)
Visit 10 (Week 8)	176 (96.7)	174 (96.7)	350 (96.7)
Visit 11 (Week 9)	176 (96.7)	173 (96.1)	349 (96.4)
Visit 12 (Week 10)	175 (96.2)	172 (95.6)	347 (95.9)
Visit 13 (Week 11)	175 (96.2)	172 (95.6)	347 (95.9)
Visit 14 (Week 12)	175 (96.2)	172 (95.6)	347 (95.9)
Visit 15 (Week 13)	175 (96.2)	172 (95.6)	347 (95.9)
Visit 16 (Week 14)	175 (96.2)	169 (93.9)	344 (95.0)
Visit 17 (Week 15)	173 (95.1)	171 (95.0)	344 (95.0)
Visit 18 (Week 16)	180 (98.9)	178 (98.9)	358 (98.9)
Visit 19 (Week 17)	175 (96.2)	171 (95.0)	346 (95.6)

N: Number of Subjects
%: Percentages are based on N

14.1.8 Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Screened			7
	Randomised	4 (100.0)	3 (100.0)	7 (100.0)
	Exposed	4 (100.0)	3 (100.0)	7 (100.0)
	Completed	4 (100.0)	1 (33.3)	5 (71.4)
	Full Analysis Set	4 (100.0)	3 (100.0)	7 (100.0)
	PP Analysis Set	4 (100.0)	2 (66.7)	6 (85.7)
	Safety Analysis Set	4 (100.0)	3 (100.0)	7 (100.0)
	Screened			6
	Randomised	6 (100.0)		6 (100.0)
	Exposed	6 (100.0)		6 (100.0)
	Completed	6 (100.0)		6 (100.0)
	Full Analysis Set	6 (100.0)		6 (100.0)
	PP Analysis Set	6 (100.0)		6 (100.0)
	Safety Analysis Set	6 (100.0)		6 (100.0)
	Screened			3
	Randomised	2 (100.0)	1 (100.0)	3 (100.0)
	Exposed	2 (100.0)	1 (100.0)	3 (100.0)
	Completed	2 (100.0)	1 (100.0)	3 (100.0)
	Full Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	PP Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Safety Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Screened			4
	Randomised		4 (100.0)	4 (100.0)
	Exposed		4 (100.0)	4 (100.0)
	Completed		4 (100.0)	4 (100.0)
	Full Analysis Set		4 (100.0)	4 (100.0)
	PP Analysis Set		4 (100.0)	4 (100.0)
	Safety Analysis Set		4 (100.0)	4 (100.0)
	Screened			3
	Randomised	3 (100.0)		3 (100.0)
	Exposed	3 (100.0)		3 (100.0)
	Completed	3 (100.0)		3 (100.0)
	Full Analysis Set	3 (100.0)		3 (100.0)
	PP Analysis Set	3 (100.0)		3 (100.0)
	Safety Analysis Set	3 (100.0)		3 (100.0)
	Screened			5
	Randomised	3 (100.0)	2 (100.0)	5 (100.0)
	Exposed	3 (100.0)	2 (100.0)	5 (100.0)
	Completed	3 (100.0)	2 (100.0)	5 (100.0)
	Full Analysis Set	3 (100.0)	2 (100.0)	5 (100.0)
	PP Analysis Set	3 (100.0)	2 (100.0)	5 (100.0)
	Safety Analysis Set	3 (100.0)	2 (100.0)	5 (100.0)
	Screened			3
	Randomised	2 (100.0)	1 (100.0)	3 (100.0)
	Exposed	2 (100.0)	1 (100.0)	3 (100.0)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Completed	2 (100.0)	1 (100.0)	3 (100.0)
	Full Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	PP Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Safety Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Screened			6
	Randomised	3 (100.0)	3 (100.0)	6 (100.0)
	Exposed	3 (100.0)	3 (100.0)	6 (100.0)
	Completed	3 (100.0)	3 (100.0)	6 (100.0)
	Full Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	PP Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	Safety Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	Screened			6
	Randomised	2 (100.0)	4 (100.0)	6 (100.0)
	Exposed	2 (100.0)	4 (100.0)	6 (100.0)
	Completed	2 (100.0)	4 (100.0)	6 (100.0)
	Full Analysis Set	2 (100.0)	4 (100.0)	6 (100.0)
	PP Analysis Set	2 (100.0)	4 (100.0)	6 (100.0)
	Safety Analysis Set	2 (100.0)	4 (100.0)	6 (100.0)
	Screened			6
	Randomised	3 (100.0)	3 (100.0)	6 (100.0)
	Exposed	3 (100.0)	3 (100.0)	6 (100.0)
	Completed	3 (100.0)	3 (100.0)	6 (100.0)
	Full Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	PP Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	Safety Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	Screened			6
	Randomised	4 (100.0)	2 (100.0)	6 (100.0)
	Exposed	4 (100.0)	2 (100.0)	6 (100.0)
	Completed	4 (100.0)	2 (100.0)	6 (100.0)
	Full Analysis Set	4 (100.0)	2 (100.0)	6 (100.0)
	PP Analysis Set	4 (100.0)	2 (100.0)	6 (100.0)
	Safety Analysis Set	4 (100.0)	2 (100.0)	6 (100.0)
	Screened			8
	Randomised	5 (100.0)	2 (100.0)	7 (100.0)
	Exposed	5 (100.0)	2 (100.0)	7 (100.0)
	Completed	5 (100.0)	2 (100.0)	7 (100.0)
	Full Analysis Set	5 (100.0)	2 (100.0)	7 (100.0)
	PP Analysis Set	5 (100.0)	2 (100.0)	7 (100.0)
	Safety Analysis Set	5 (100.0)	2 (100.0)	7 (100.0)
	Screened			16
	Randomised	5 (100.0)	8 (100.0)	13 (100.0)
	Exposed	5 (100.0)	8 (100.0)	13 (100.0)
	Completed	5 (100.0)	8 (100.0)	13 (100.0)
	Full Analysis Set	5 (100.0)	8 (100.0)	13 (100.0)
	PP Analysis Set	5 (100.0)	8 (100.0)	13 (100.0)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Safety Analysis Set	5 (100.0)	8 (100.0)	13 (100.0)
	Screened			2
	Randomised		1 (100.0)	1 (100.0)
	Exposed		1 (100.0)	1 (100.0)
	Completed			
	Full Analysis Set		1 (100.0)	1 (100.0)
	PP Analysis Set			
	Safety Analysis Set		1 (100.0)	1 (100.0)
	Screened			8
	Randomised	4 (100.0)	3 (100.0)	7 (100.0)
	Exposed	4 (100.0)	3 (100.0)	7 (100.0)
	Completed	4 (100.0)	3 (100.0)	7 (100.0)
	Full Analysis Set	4 (100.0)	3 (100.0)	7 (100.0)
	PP Analysis Set	4 (100.0)	3 (100.0)	7 (100.0)
	Safety Analysis Set	4 (100.0)	3 (100.0)	7 (100.0)
	Screened			2
	Randomised		2 (100.0)	2 (100.0)
	Exposed		2 (100.0)	2 (100.0)
	Completed		1 (50.0)	1 (50.0)
	Full Analysis Set		2 (100.0)	2 (100.0)
	PP Analysis Set		1 (50.0)	1 (50.0)
	Safety Analysis Set		2 (100.0)	2 (100.0)
	Screened			6
	Randomised	3 (100.0)	3 (100.0)	6 (100.0)
	Exposed	3 (100.0)	3 (100.0)	6 (100.0)
	Completed	3 (100.0)	3 (100.0)	6 (100.0)
	Full Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	PP Analysis Set	3 (100.0)	2 (66.7)	5 (83.3)
	Safety Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	Screened			7
	Randomised	4 (100.0)	1 (100.0)	5 (100.0)
	Exposed	4 (100.0)	1 (100.0)	5 (100.0)
	Completed	4 (100.0)	1 (100.0)	5 (100.0)
	Full Analysis Set	4 (100.0)	1 (100.0)	5 (100.0)
	PP Analysis Set	4 (100.0)	1 (100.0)	5 (100.0)
	Safety Analysis Set	4 (100.0)	1 (100.0)	5 (100.0)
	Screened			13
	Randomised	5 (100.0)	8 (100.0)	13 (100.0)
	Exposed	5 (100.0)	8 (100.0)	13 (100.0)
	Completed	5 (100.0)	8 (100.0)	13 (100.0)
	Full Analysis Set	5 (100.0)	8 (100.0)	13 (100.0)
	PP Analysis Set	5 (100.0)	8 (100.0)	13 (100.0)
	Safety Analysis Set	5 (100.0)	8 (100.0)	13 (100.0)
	Screened			7

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Randomised	2 (100.0)	5 (100.0)	7 (100.0)
	Exposed	2 (100.0)	5 (100.0)	7 (100.0)
	Completed	2 (100.0)	5 (100.0)	7 (100.0)
	Full Analysis Set	2 (100.0)	5 (100.0)	7 (100.0)
	PP Analysis Set	2 (100.0)	5 (100.0)	7 (100.0)
	Safety Analysis Set	2 (100.0)	5 (100.0)	7 (100.0)
	Screened			8
	Randomised	4 (100.0)	4 (100.0)	8 (100.0)
	Exposed	4 (100.0)	4 (100.0)	8 (100.0)
	Completed	3 (75.0)	4 (100.0)	7 (87.5)
	Full Analysis Set	4 (100.0)	4 (100.0)	8 (100.0)
	PP Analysis Set	3 (75.0)	4 (100.0)	7 (87.5)
	Safety Analysis Set	4 (100.0)	4 (100.0)	8 (100.0)
	Screened			12
	Randomised	5 (100.0)	6 (100.0)	11 (100.0)
	Exposed	5 (100.0)	6 (100.0)	11 (100.0)
	Completed	5 (100.0)	6 (100.0)	11 (100.0)
	Full Analysis Set	5 (100.0)	6 (100.0)	11 (100.0)
	PP Analysis Set	5 (100.0)	6 (100.0)	11 (100.0)
	Safety Analysis Set	5 (100.0)	6 (100.0)	11 (100.0)
	Screened			12
	Randomised	4 (100.0)	5 (100.0)	9 (100.0)
	Exposed	4 (100.0)	5 (100.0)	9 (100.0)
	Completed	4 (100.0)	5 (100.0)	9 (100.0)
	Full Analysis Set	4 (100.0)	5 (100.0)	9 (100.0)
	PP Analysis Set	4 (100.0)	5 (100.0)	9 (100.0)
	Safety Analysis Set	4 (100.0)	5 (100.0)	9 (100.0)
	Screened			8
	Randomised	3 (100.0)	5 (100.0)	8 (100.0)
	Exposed	3 (100.0)	5 (100.0)	8 (100.0)
	Completed	3 (100.0)	5 (100.0)	8 (100.0)
	Full Analysis Set	3 (100.0)	5 (100.0)	8 (100.0)
	PP Analysis Set	3 (100.0)	5 (100.0)	8 (100.0)
	Safety Analysis Set	3 (100.0)	5 (100.0)	8 (100.0)
	Screened			5
	Randomised	2 (100.0)	3 (100.0)	5 (100.0)
	Exposed	2 (100.0)	3 (100.0)	5 (100.0)
	Completed	2 (100.0)	3 (100.0)	5 (100.0)
	Full Analysis Set	2 (100.0)	3 (100.0)	5 (100.0)
	PP Analysis Set	2 (100.0)	3 (100.0)	5 (100.0)
	Safety Analysis Set	2 (100.0)	3 (100.0)	5 (100.0)
	Screened			10
	Randomised	4 (100.0)	5 (100.0)	9 (100.0)
	Exposed	4 (100.0)	5 (100.0)	9 (100.0)
	Completed	4 (100.0)	4 (80.0)	8 (88.9)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Full Analysis Set	4 (100.0)	5 (100.0)	9 (100.0)
	PP Analysis Set	4 (100.0)	4 (80.0)	8 (88.9)
	Safety Analysis Set	4 (100.0)	5 (100.0)	9 (100.0)
	Screened			14
	Randomised	6 (100.0)	8 (100.0)	14 (100.0)
	Exposed	6 (100.0)	8 (100.0)	14 (100.0)
	Completed	6 (100.0)	8 (100.0)	14 (100.0)
	Full Analysis Set	6 (100.0)	8 (100.0)	14 (100.0)
	PP Analysis Set	6 (100.0)	8 (100.0)	14 (100.0)
	Safety Analysis Set	6 (100.0)	8 (100.0)	14 (100.0)
	Screened			10
	Randomised	6 (100.0)	4 (100.0)	10 (100.0)
	Exposed	6 (100.0)	4 (100.0)	10 (100.0)
	Completed	6 (100.0)	4 (100.0)	10 (100.0)
	Full Analysis Set	6 (100.0)	4 (100.0)	10 (100.0)
	PP Analysis Set	5 (83.3)	4 (100.0)	9 (90.0)
	Safety Analysis Set	6 (100.0)	4 (100.0)	10 (100.0)
	Screened			7
	Randomised	1 (100.0)	6 (100.0)	7 (100.0)
	Exposed	1 (100.0)	6 (100.0)	7 (100.0)
	Completed	1 (100.0)	6 (100.0)	7 (100.0)
	Full Analysis Set	1 (100.0)	6 (100.0)	7 (100.0)
	PP Analysis Set	1 (100.0)	6 (100.0)	7 (100.0)
	Safety Analysis Set	1 (100.0)	6 (100.0)	7 (100.0)
	Screened			10
	Randomised	3 (100.0)	6 (100.0)	9 (100.0)
	Exposed	3 (100.0)	5 (83.3)	8 (88.9)
	Completed	3 (100.0)	5 (83.3)	8 (88.9)
	Full Analysis Set	3 (100.0)	6 (100.0)	9 (100.0)
	PP Analysis Set	3 (100.0)	5 (83.3)	8 (88.9)
	Safety Analysis Set	3 (100.0)	5 (83.3)	8 (88.9)
	Screened			4
	Randomised	1 (100.0)	3 (100.0)	4 (100.0)
	Exposed	1 (100.0)	3 (100.0)	4 (100.0)
	Completed		3 (100.0)	3 (75.0)
	Full Analysis Set	1 (100.0)	3 (100.0)	4 (100.0)
	PP Analysis Set		3 (100.0)	3 (75.0)
	Safety Analysis Set	1 (100.0)	3 (100.0)	4 (100.0)
	Screened			8
	Randomised	2 (100.0)	5 (100.0)	7 (100.0)
	Exposed	2 (100.0)	5 (100.0)	7 (100.0)
	Completed	2 (100.0)	5 (100.0)	7 (100.0)
	Full Analysis Set	2 (100.0)	5 (100.0)	7 (100.0)
	PP Analysis Set	2 (100.0)	5 (100.0)	7 (100.0)
	Safety Analysis Set	2 (100.0)	5 (100.0)	7 (100.0)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Screened			4
	Randomised	2 (100.0)	2 (100.0)	4 (100.0)
	Exposed	2 (100.0)	2 (100.0)	4 (100.0)
	Completed	2 (100.0)	2 (100.0)	4 (100.0)
	Full Analysis Set	2 (100.0)	2 (100.0)	4 (100.0)
	PP Analysis Set	2 (100.0)	2 (100.0)	4 (100.0)
	Safety Analysis Set	2 (100.0)	2 (100.0)	4 (100.0)
	Screened			6
	Randomised	4 (100.0)	2 (100.0)	6 (100.0)
	Exposed	4 (100.0)	2 (100.0)	6 (100.0)
	Completed	4 (100.0)	2 (100.0)	6 (100.0)
	Full Analysis Set	4 (100.0)	2 (100.0)	6 (100.0)
	PP Analysis Set	4 (100.0)	2 (100.0)	6 (100.0)
	Safety Analysis Set	4 (100.0)	2 (100.0)	6 (100.0)
	Screened			9
	Randomised	3 (100.0)	3 (100.0)	6 (100.0)
	Exposed	3 (100.0)	3 (100.0)	6 (100.0)
	Completed	3 (100.0)	3 (100.0)	6 (100.0)
	Full Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	PP Analysis Set	3 (100.0)	2 (66.7)	5 (83.3)
	Safety Analysis Set	3 (100.0)	3 (100.0)	6 (100.0)
	Screened			3
	Randomised	2 (100.0)	1 (100.0)	3 (100.0)
	Exposed	2 (100.0)	1 (100.0)	3 (100.0)
	Completed	2 (100.0)	1 (100.0)	3 (100.0)
	Full Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	PP Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Safety Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Screened			3
	Randomised		2 (100.0)	2 (100.0)
	Exposed		2 (100.0)	2 (100.0)
	Completed		1 (50.0)	1 (50.0)
	Full Analysis Set		2 (100.0)	2 (100.0)
	PP Analysis Set		1 (50.0)	1 (50.0)
	Safety Analysis Set		2 (100.0)	2 (100.0)
	Screened			5
	Randomised	3 (100.0)	2 (100.0)	5 (100.0)
	Exposed	3 (100.0)	2 (100.0)	5 (100.0)
	Completed	3 (100.0)	2 (100.0)	5 (100.0)
	Full Analysis Set	3 (100.0)	2 (100.0)	5 (100.0)
	PP Analysis Set	3 (100.0)	2 (100.0)	5 (100.0)
	Safety Analysis Set	3 (100.0)	2 (100.0)	5 (100.0)
	Screened			3
	Randomised	2 (100.0)	1 (100.0)	3 (100.0)
	Exposed	2 (100.0)	1 (100.0)	3 (100.0)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Completed	2 (100.0)	1 (100.0)	3 (100.0)
	Full Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	PP Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Safety Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Screened			2
	Randomised	1 (100.0)	1 (100.0)	2 (100.0)
	Exposed	1 (100.0)	1 (100.0)	2 (100.0)
	Completed	1 (100.0)	1 (100.0)	2 (100.0)
	Full Analysis Set	1 (100.0)	1 (100.0)	2 (100.0)
	PP Analysis Set	1 (100.0)	1 (100.0)	2 (100.0)
	Safety Analysis Set	1 (100.0)	1 (100.0)	2 (100.0)
	Screened			2
	Randomised	1 (100.0)	1 (100.0)	2 (100.0)
	Exposed	1 (100.0)	1 (100.0)	2 (100.0)
	Completed	1 (100.0)	1 (100.0)	2 (100.0)
	Full Analysis Set	1 (100.0)	1 (100.0)	2 (100.0)
	PP Analysis Set	1 (100.0)	1 (100.0)	2 (100.0)
	Safety Analysis Set	1 (100.0)	1 (100.0)	2 (100.0)
	Screened			8
	Randomised	1 (100.0)	7 (100.0)	8 (100.0)
	Exposed	1 (100.0)	7 (100.0)	8 (100.0)
	Completed	1 (100.0)	6 (85.7)	7 (87.5)
	Full Analysis Set	1 (100.0)	7 (100.0)	8 (100.0)
	PP Analysis Set	1 (100.0)	6 (85.7)	7 (87.5)
	Safety Analysis Set	1 (100.0)	7 (100.0)	8 (100.0)
	Screened			11
	Randomised	6 (100.0)	4 (100.0)	10 (100.0)
	Exposed	6 (100.0)	4 (100.0)	10 (100.0)
	Completed	5 (83.3)	4 (100.0)	9 (90.0)
	Full Analysis Set	6 (100.0)	4 (100.0)	10 (100.0)
	PP Analysis Set	5 (83.3)	4 (100.0)	9 (90.0)
	Safety Analysis Set	6 (100.0)	4 (100.0)	10 (100.0)
	Screened			13
	Randomised	5 (100.0)	7 (100.0)	12 (100.0)
	Exposed	5 (100.0)	7 (100.0)	12 (100.0)
	Completed	4 (80.0)	6 (85.7)	10 (83.3)
	Full Analysis Set	5 (100.0)	7 (100.0)	12 (100.0)
	PP Analysis Set	4 (80.0)	7 (100.0)	11 (91.7)
	Safety Analysis Set	5 (100.0)	7 (100.0)	12 (100.0)
	Screened			4
	Randomised	2 (100.0)	2 (100.0)	4 (100.0)
	Exposed	2 (100.0)	2 (100.0)	4 (100.0)
	Completed	2 (100.0)	1 (50.0)	3 (75.0)
	Full Analysis Set	2 (100.0)	2 (100.0)	4 (100.0)
	PP Analysis Set	2 (100.0)	2 (100.0)	4 (100.0)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Safety Analysis Set	2 (100.0)	2 (100.0)	4 (100.0)
	Screened			4
	Randomised	2 (100.0)	1 (100.0)	3 (100.0)
	Exposed	2 (100.0)	1 (100.0)	3 (100.0)
	Completed	2 (100.0)	1 (100.0)	3 (100.0)
	Full Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	PP Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Safety Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Screened			3
	Randomised	2 (100.0)	1 (100.0)	3 (100.0)
	Exposed	2 (100.0)	1 (100.0)	3 (100.0)
	Completed	1 (50.0)	1 (100.0)	2 (66.7)
	Full Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	PP Analysis Set	1 (50.0)	1 (100.0)	2 (66.7)
	Safety Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Screened			8
	Randomised	3 (100.0)	5 (100.0)	8 (100.0)
	Exposed	3 (100.0)	5 (100.0)	8 (100.0)
	Completed	3 (100.0)	5 (100.0)	8 (100.0)
	Full Analysis Set	3 (100.0)	5 (100.0)	8 (100.0)
	PP Analysis Set	3 (100.0)	5 (100.0)	8 (100.0)
	Safety Analysis Set	3 (100.0)	5 (100.0)	8 (100.0)
	Screened			4
	Randomised	3 (100.0)	1 (100.0)	4 (100.0)
	Exposed	3 (100.0)	1 (100.0)	4 (100.0)
	Completed	3 (100.0)	1 (100.0)	4 (100.0)
	Full Analysis Set	3 (100.0)	1 (100.0)	4 (100.0)
	PP Analysis Set	3 (100.0)	1 (100.0)	4 (100.0)
	Safety Analysis Set	3 (100.0)	1 (100.0)	4 (100.0)
	Screened			3
	Randomised	2 (100.0)	1 (100.0)	3 (100.0)
	Exposed	2 (100.0)	1 (100.0)	3 (100.0)
	Completed	2 (100.0)	1 (100.0)	3 (100.0)
	Full Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	PP Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Safety Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Screened			9
	Randomised	5 (100.0)	4 (100.0)	9 (100.0)
	Exposed	5 (100.0)	4 (100.0)	9 (100.0)
	Completed	4 (80.0)	4 (100.0)	8 (88.9)
	Full Analysis Set	5 (100.0)	4 (100.0)	9 (100.0)
	PP Analysis Set	5 (100.0)	4 (100.0)	9 (100.0)
	Safety Analysis Set	5 (100.0)	4 (100.0)	9 (100.0)
	Screened			2

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Randomised	2 (100.0)		2 (100.0)
	Exposed	2 (100.0)		2 (100.0)
	Completed	2 (100.0)		2 (100.0)
	Full Analysis Set	2 (100.0)		2 (100.0)
	PP Analysis Set	2 (100.0)		2 (100.0)
	Safety Analysis Set	2 (100.0)		2 (100.0)
	Screened			4
	Randomised	3 (100.0)		3 (100.0)
	Exposed	3 (100.0)		3 (100.0)
	Completed	3 (100.0)		3 (100.0)
	Full Analysis Set	3 (100.0)		3 (100.0)
	PP Analysis Set	3 (100.0)		3 (100.0)
	Safety Analysis Set	3 (100.0)		3 (100.0)
	Screened			3
	Randomised	1 (100.0)	2 (100.0)	3 (100.0)
	Exposed	1 (100.0)	2 (100.0)	3 (100.0)
	Completed	1 (100.0)	2 (100.0)	3 (100.0)
	Full Analysis Set	1 (100.0)	2 (100.0)	3 (100.0)
	PP Analysis Set	1 (100.0)	2 (100.0)	3 (100.0)
	Safety Analysis Set	1 (100.0)	2 (100.0)	3 (100.0)
	Screened			7
	Randomised	3 (100.0)	4 (100.0)	7 (100.0)
	Exposed	3 (100.0)	4 (100.0)	7 (100.0)
	Completed	3 (100.0)	4 (100.0)	7 (100.0)
	Full Analysis Set	3 (100.0)	4 (100.0)	7 (100.0)
	PP Analysis Set	3 (100.0)	4 (100.0)	7 (100.0)
	Safety Analysis Set	3 (100.0)	4 (100.0)	7 (100.0)
	Screened			4
	Randomised	4 (100.0)		4 (100.0)
	Exposed	4 (100.0)		4 (100.0)
	Completed	4 (100.0)		4 (100.0)
	Full Analysis Set	4 (100.0)		4 (100.0)
	PP Analysis Set	4 (100.0)		4 (100.0)
	Safety Analysis Set	4 (100.0)		4 (100.0)
	Screened			5
	Randomised	3 (100.0)	1 (100.0)	4 (100.0)
	Exposed	3 (100.0)	1 (100.0)	4 (100.0)
	Completed	3 (100.0)	1 (100.0)	4 (100.0)
	Full Analysis Set	3 (100.0)	1 (100.0)	4 (100.0)
	PP Analysis Set	3 (100.0)	1 (100.0)	4 (100.0)
	Safety Analysis Set	3 (100.0)	1 (100.0)	4 (100.0)
	Screened			3
	Randomised	1 (100.0)	2 (100.0)	3 (100.0)
	Exposed	1 (100.0)	2 (100.0)	3 (100.0)
	Completed	1 (100.0)	2 (100.0)	3 (100.0)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

Subject disposition by trial site number - summary - all subjects

Trial Site Number		IDegAsp OD N (%)	IDet N (%)	Total N (%)
[redacted]	Full Analysis Set	1 (100.0)	2 (100.0)	3 (100.0)
	PP Analysis Set	1 (100.0)	2 (100.0)	3 (100.0)
	Safety Analysis Set	1 (100.0)	2 (100.0)	3 (100.0)
	Screened			3
	Randomised	2 (100.0)		2 (100.0)
	Exposed	2 (100.0)		2 (100.0)
	Completed	2 (100.0)		2 (100.0)
	Full Analysis Set	2 (100.0)		2 (100.0)
	PP Analysis Set	2 (100.0)		2 (100.0)
	Safety Analysis Set	2 (100.0)		2 (100.0)
	Screened			4
	Randomised	4 (100.0)		4 (100.0)
	Exposed	3 (75.0)		3 (75.0)
	Completed	3 (75.0)		3 (75.0)
	Full Analysis Set	4 (100.0)		4 (100.0)
	PP Analysis Set	3 (75.0)		3 (75.0)
	Safety Analysis Set	3 (75.0)		3 (75.0)
	Screened			2
	Randomised	1 (100.0)	1 (100.0)	2 (100.0)
	Exposed	1 (100.0)	1 (100.0)	2 (100.0)
	Completed		1 (100.0)	1 (50.0)
	Full Analysis Set	1 (100.0)	1 (100.0)	2 (100.0)
	PP Analysis Set		1 (100.0)	1 (50.0)
	Safety Analysis Set	1 (100.0)	1 (100.0)	2 (100.0)
	Screened			11
	Randomised	6 (100.0)	5 (100.0)	11 (100.0)
	Exposed	6 (100.0)	5 (100.0)	11 (100.0)
	Completed	6 (100.0)	4 (80.0)	10 (90.9)
	Full Analysis Set	6 (100.0)	5 (100.0)	11 (100.0)
	PP Analysis Set	6 (100.0)	5 (100.0)	11 (100.0)
	Safety Analysis Set	6 (100.0)	5 (100.0)	11 (100.0)
	Screened			3
	Randomised	2 (100.0)	1 (100.0)	3 (100.0)
	Exposed	2 (100.0)	1 (100.0)	3 (100.0)
	Completed	2 (100.0)		2 (66.7)
	Full Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	PP Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)
	Safety Analysis Set	2 (100.0)	1 (100.0)	3 (100.0)

N: Number of subjects
PP: Per protocol
%: Proportion of randomised subjects

14.1.9 Reasons for discontinuation from week 12 and onwards - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	182	180	362
Withdrawn Main Trial (12 - 16 weeks)	1 (0.5)	6 (3.3)	7 (1.9)
Adverse Event	0	0	0
Ineffective Therapy	0	0	0
Non-Compliance With Protocol	0	0	0
Withdrawal Criteria	1 (0.5)	5 (2.8)	6 (1.7)
Withdrawal Criteria 1	0	4 (2.2)	4 (1.1)
Withdrawal Criteria 2	0	1 (0.6)	1 (0.3)
Withdrawal Criteria 3	0	0	0
Withdrawal Criteria 4	0	0	0
Withdrawal Criteria 5	0	0	0
Withdrawal Criteria 6	0	0	0
Withdrawal Criteria 7	1 (0.5)	0	1 (0.3)
Other	0 (0.0)	1 (0.6)	1 (0.3)

N: Number of subjects
%: Percentages are based on N

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14.1.10 Demographics and baseline characteristics - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	182	180	362
Age Group			
N	182 (100.0)	180 (100.0)	362 (100.0)
Adolescents (12-17 years)	80 (44.0)	78 (43.3)	158 (43.6)
Children (1-5 yrs)	41 (22.5)	41 (22.8)	82 (22.7)
Children (6-11 years)	61 (33.5)	61 (33.9)	122 (33.7)
Sex			
N	182 (100.0)	180 (100.0)	362 (100.0)
Female	93 (51.1)	94 (52.2)	187 (51.7)
Male	89 (48.9)	86 (47.8)	175 (48.3)
Country of Residence			
N	182 (100.0)	180 (100.0)	362 (100.0)
Belgium	8 (4.4)	5 (2.8)	13 (3.6)
Brazil	4 (2.2)	3 (1.7)	7 (1.9)
Canada	8 (4.4)	3 (1.7)	11 (3.0)
Croatia	5 (2.7)	7 (3.9)	12 (3.3)
Czech Republic	12 (6.6)	7 (3.9)	19 (5.2)
Israel	16 (8.8)	18 (10.0)	34 (9.4)
Poland	13 (7.1)	15 (8.3)	28 (7.7)
Republic of Macedonia	7 (3.8)	13 (7.2)	20 (5.5)
Russian Federation	21 (11.5)	25 (13.9)	46 (12.7)
Serbia	7 (3.8)	20 (11.1)	27 (7.5)
Slovenia	2 (1.1)	2 (1.1)	4 (1.1)
South Africa	7 (3.8)	5 (2.8)	12 (3.3)
Spain	8 (4.4)	7 (3.9)	15 (4.1)
United States	64 (35.2)	50 (27.8)	114 (31.5)
Ethnicity			
N	182 (100.0)	180 (100.0)	362 (100.0)
Hispanic or Latino	15 (8.2)	13 (7.2)	28 (7.7)
Not Hispanic or Latino	167 (91.8)	167 (92.8)	334 (92.3)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Race			
N	182 (100.0)	180 (100.0)	362 (100.0)
White	169 (92.9)	168 (93.3)	337 (93.1)
Black or African American	8 (4.4)	4 (2.2)	12 (3.3)
Asian Indian	0 (0.0)	1 (0.6)	1 (0.3)
Asian non-Indian	0 (0.0)	0 (0.0)	0 (0.0)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Other	5 (2.7)	7 (3.9)	12 (3.3)

N: Number of subjects
%: Percentages are based on N

14.1.11 Demographics and baseline characteristics - summary - children (1-5 years) - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	41	41	82
Sex			
N	41 (100.0)	41 (100.0)	82 (100.0)
Female	20 (48.8)	24 (58.5)	44 (53.7)
Male	21 (51.2)	17 (41.5)	38 (46.3)
Country of Residence			
N	41 (100.0)	41 (100.0)	82 (100.0)
Belgium	1 (2.4)	1 (2.4)	2 (2.4)
Brazil	4 (9.8)	3 (7.3)	7 (8.5)
Canada	1 (2.4)	0 (0.0)	1 (1.2)
Croatia	1 (2.4)	2 (4.9)	3 (3.7)
Czech Republic	1 (2.4)	0 (0.0)	1 (1.2)
Israel	3 (7.3)	3 (7.3)	6 (7.3)
Poland	5 (12.2)	4 (9.8)	9 (11.0)
Republic of Macedonia	1 (2.4)	5 (12.2)	6 (7.3)
Russian Federation	7 (17.1)	7 (17.1)	14 (17.1)
Serbia	2 (4.9)	2 (4.9)	4 (4.9)
South Africa	2 (4.9)	1 (2.4)	3 (3.7)
Spain	0 (0.0)	1 (2.4)	1 (1.2)
United States	13 (31.7)	12 (29.3)	25 (30.5)
Ethnicity			
N	41 (100.0)	41 (100.0)	82 (100.0)
Hispanic or Latino	5 (12.2)	4 (9.8)	9 (11.0)
Not Hispanic or Latino	36 (87.8)	37 (90.2)	73 (89.0)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Race			
N	41 (100.0)	41 (100.0)	82 (100.0)
White	38 (92.7)	37 (90.2)	75 (91.5)
Black or African American	1 (2.4)	2 (4.9)	3 (3.7)
Asian Indian	0 (0.0)	0 (0.0)	0 (0.0)
Asian non-Indian	0 (0.0)	0 (0.0)	0 (0.0)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Other	2 (4.9)	2 (4.9)	4 (4.9)

N: Number of subjects
%: Percentages are based on N
Oth.: Other

14.1.12 Demographics and baseline characteristics - summary - children (6-11 years) - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	61	61	122
Sex			
N	61 (100.0)	61 (100.0)	122 (100.0)
Female	32 (52.5)	27 (44.3)	59 (48.4)
Male	29 (47.5)	34 (55.7)	63 (51.6)
Country of Residence			
N	61 (100.0)	61 (100.0)	122 (100.0)
Belgium	1 (1.6)	1 (1.6)	2 (1.6)
Canada	6 (9.8)	0 (0.0)	6 (4.9)
Croatia	1 (1.6)	2 (3.3)	3 (2.5)
Czech Republic	5 (8.2)	3 (4.9)	8 (6.6)
Israel	7 (11.5)	5 (8.2)	12 (9.8)
Poland	3 (4.9)	7 (11.5)	10 (8.2)
Republic of Macedonia	3 (4.9)	3 (4.9)	6 (4.9)
Russian Federation	10 (16.4)	13 (21.3)	23 (18.9)
Serbia	4 (6.6)	8 (13.1)	12 (9.8)
Slovenia	0 (0.0)	1 (1.6)	1 (0.8)
South Africa	3 (4.9)	4 (6.6)	7 (5.7)
Spain	3 (4.9)	3 (4.9)	6 (4.9)
United States	15 (24.6)	11 (18.0)	26 (21.3)
Ethnicity			
N	61 (100.0)	61 (100.0)	122 (100.0)
Hispanic or Latino	4 (6.6)	3 (4.9)	7 (5.7)
Not Hispanic or Latino	57 (93.4)	58 (95.1)	115 (94.3)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Race			
N	61 (100.0)	61 (100.0)	122 (100.0)
White	59 (96.7)	58 (95.1)	117 (95.9)
Black or African American	2 (3.3)	1 (1.6)	3 (2.5)
Asian Indian	0 (0.0)	0 (0.0)	0 (0.0)
Asian non-Indian	0 (0.0)	0 (0.0)	0 (0.0)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	2 (3.3)	2 (1.6)

N: Number of subjects
%: Percentages are based on N
Oth.: Other

14.1.13 Demographics and baseline characteristics - summary - adolescents (12-17 years) - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	80	78	158
Sex			
N	80 (100.0)	78 (100.0)	158 (100.0)
Female	41 (51.3)	43 (55.1)	84 (53.2)
Male	39 (48.8)	35 (44.9)	74 (46.8)
Country of Residence			
N	80 (100.0)	78 (100.0)	158 (100.0)
Belgium	6 (7.5)	3 (3.8)	9 (5.7)
Canada	1 (1.3)	3 (3.8)	4 (2.5)
Croatia	3 (3.8)	3 (3.8)	6 (3.8)
Czech Republic	6 (7.5)	4 (5.1)	10 (6.3)
Israel	6 (7.5)	10 (12.8)	16 (10.1)
Poland	5 (6.3)	4 (5.1)	9 (5.7)
Republic of Macedonia	3 (3.8)	5 (6.4)	8 (5.1)
Russian Federation	4 (5.0)	5 (6.4)	9 (5.7)
Serbia	1 (1.3)	10 (12.8)	11 (7.0)
Slovenia	2 (2.5)	1 (1.3)	3 (1.9)
South Africa	2 (2.5)	0 (0.0)	2 (1.3)
Spain	5 (6.3)	3 (3.8)	8 (5.1)
United States	36 (45.0)	27 (34.6)	63 (39.9)
Ethnicity			
N	80 (100.0)	78 (100.0)	158 (100.0)
Hispanic or Latino	6 (7.5)	6 (7.7)	12 (7.6)
Not Hispanic or Latino	74 (92.5)	72 (92.3)	146 (92.4)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Race			
N	80 (100.0)	78 (100.0)	158 (100.0)
White	72 (90.0)	73 (93.6)	145 (91.8)
Black or African American	5 (6.3)	1 (1.3)	6 (3.8)
Asian Indian	0 (0.0)	1 (1.3)	1 (0.6)
Asian non-Indian	0 (0.0)	0 (0.0)	0 (0.0)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Oth. Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Not Applicable	0 (0.0)	0 (0.0)	0 (0.0)
Other	3 (3.8)	3 (3.8)	6 (3.8)

N: Number of subjects
%: Percentages are based on N
Oth.: Other

14.1.14 Baseline and diabetes characteristics - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
Age (years)			
N	182	180	362
Mean (SD)	10.5 (4.3)	10.8 (4.6)	10.6 (4.5)
Median	11.0	11.4	11.2
Min ; Max	2.2 ; 17.8	1.9 ; 17.9	1.9 ; 17.9
Height (m)			
N	180	179	359
Mean (SD)	1.41 (0.24)	1.42 (0.27)	1.42 (0.25)
Median	1.44	1.48	1.46
Min ; Max	0.90 ; 1.87	0.83 ; 1.91	0.83 ; 1.91
Body Weight (kg)			
N	182	180	362
Mean (SD)	41.1 (20.7)	42.9 (21.2)	42.0 (20.9)
Median	39.4	39.9	39.7
Min ; Max	12.1 ; 117.1	9.4 ; 104.4	9.4 ; 117.1
Body Weight (lb)			
N	182	180	362
Mean (SD)	90.7 (45.6)	94.6 (46.8)	92.7 (46.1)
Median	86.8	88.0	87.4
Min ; Max	26.7 ; 258.2	20.7 ; 230.2	20.7 ; 258.2
Duration of Diabetes (years)			
N	182	180	362
Mean (SD)	4.4 (3.7)	3.8 (3.2)	4.1 (3.5)
Median	3.1	2.8	3.0
Min ; Max	0.3 ; 14.6	0.3 ; 13.9	0.3 ; 14.6
BMI (kg/m^2)			
N	180	179	359
Mean (SD)	19.2 (4.2)	19.6 (4.0)	19.4 (4.1)
Median	18.4	18.6	18.5
Min ; Max	11.0 ; 35.1	12.8 ; 31.9	11.0 ; 35.1
HbA1c (%)			
N	182	180	362
Mean (SD)	8.1 (1.2)	8.1 (1.2)	8.1 (1.2)
Median	8.0	8.0	8.0
Min ; Max	5.1 ; 11.1	5.4 ; 10.9	5.1 ; 11.1
HbA1c (mmol/mol)			
N	182	180	362
Mean (SD)	65.4 (13.6)	64.6 (13.6)	65.0 (13.6)
Median	63.9	63.4	63.9
Min ; Max	32.2 ; 97.8	35.5 ; 95.6	32.2 ; 97.8

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

Baseline and diabetes characteristics - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
FPG (mmol/L)			
N	172	166	338
Mean (SD)	8.6 (4.4)	8.1 (4.2)	8.4 (4.3)
Median	7.7	7.2	7.4
Min ; Max	0.5 ; 20.7	1.9 ; 25.1	0.5 ; 25.1
FPG (mg/dL)			
N	172	166	338
Mean (SD)	155.6 (80.2)	146.5 (74.9)	151.1 (77.6)
Median	139.0	130.1	133.0
Min ; Max	9.0 ; 373.0	35.0 ; 452.1	9.0 ; 452.1

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

14.1.15 Baseline and diabetes characteristics - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
Age (years)			
N	41	41	82
Mean (SD)	4.6 (1.1)	4.3 (1.1)	4.4 (1.1)
Median	4.6	4.3	4.3
Min ; Max	2.2 ; 6.0	1.9 ; 6.0	1.9 ; 6.0
Height (m)			
N	40	41	81
Mean (SD)	1.07 (0.08)	1.04 (0.10)	1.05 (0.09)
Median	1.08	1.05	1.06
Min ; Max	0.90 ; 1.21	0.83 ; 1.18	0.83 ; 1.21
Body Weight (kg)			
N	41	41	82
Mean (SD)	18.8 (3.9)	17.7 (3.6)	18.3 (3.8)
Median	18.8	18.1	18.3
Min ; Max	12.1 ; 35.1	9.4 ; 28.1	9.4 ; 35.1
Body Weight (lb)			
N	41	41	82
Mean (SD)	41.5 (8.7)	39.0 (8.0)	40.3 (8.4)
Median	41.4	39.9	40.3
Min ; Max	26.7 ; 77.4	20.7 ; 61.9	20.7 ; 77.4
BMI (kg/m^2)			
N	40	41	81
Mean (SD)	16.4 (2.2)	16.2 (1.6)	16.3 (1.9)
Median	16.2	16.1	16.1
Min ; Max	11.0 ; 25.2	12.8 ; 20.6	11.0 ; 25.2
Duration of Diabetes (years)			
N	41	41	82
Mean (SD)	1.8 (1.2)	1.5 (0.8)	1.6 (1.0)
Median	1.5	1.3	1.4
Min ; Max	0.3 ; 4.5	0.3 ; 3.1	0.3 ; 4.5
HbA1c (%)			
N	41	41	82
Mean (SD)	7.9 (1.4)	8.1 (1.1)	8.0 (1.2)
Median	7.8	7.9	7.9
Min ; Max	5.2 ; 11.1	6.0 ; 10.3	5.2 ; 11.1
HbA1c (mmol/mol)			
N	41	41	82
Mean (SD)	62.8 (15.0)	65.1 (11.9)	64.0 (13.5)
Median	61.8	62.8	62.3
Min ; Max	33.3 ; 97.8	42.1 ; 89.1	33.3 ; 97.8

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

Baseline and diabetes characteristics - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
FPG (mmol/L)			
N	39	35	74
Mean (SD)	8.8 (4.8)	8.2 (4.2)	8.5 (4.5)
Median	7.6	7.3	7.5
Min ; Max	2.8 ; 19.5	2.6 ; 18.7	2.6 ; 19.5
FPG (mg/dL)			
N	39	35	74
Mean (SD)	158.5 (86.4)	148.1 (75.1)	153.6 (80.9)
Median	136.9	132.1	135.0
Min ; Max	50.1 ; 351.0	45.9 ; 336.9	45.9 ; 351.0

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

14.1.16 Baseline and diabetes characteristics - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Age (years)			
N	61	61	122
Mean (SD)	9.2 (1.7)	9.4 (1.9)	9.3 (1.8)
Median	9.0	9.4	9.3
Min ; Max	6.0 ; 11.7	6.0 ; 12.0	6.0 ; 12.0
Height (m)			
N	61	61	122
Mean (SD)	1.35 (0.12)	1.38 (0.13)	1.37 (0.12)
Median	1.35	1.39	1.36
Min ; Max	1.09 ; 1.63	1.10 ; 1.68	1.09 ; 1.68
Body Weight (kg)			
N	61	61	122
Mean (SD)	32.6 (11.4)	35.2 (10.0)	33.9 (10.7)
Median	30.4	33.9	32.0
Min ; Max	20.4 ; 78.6	21.0 ; 66.2	20.4 ; 78.6
Body Weight (lb)			
N	61	61	122
Mean (SD)	71.9 (25.1)	77.5 (22.0)	74.7 (23.7)
Median	67.0	74.7	70.5
Min ; Max	45.0 ; 173.3	46.3 ; 145.9	45.0 ; 173.3
BMI (kg/m^2)			
N	61	61	122
Mean (SD)	17.4 (3.3)	18.1 (2.8)	17.8 (3.1)
Median	16.3	17.4	17.1
Min ; Max	13.6 ; 29.6	14.0 ; 25.9	13.6 ; 29.6
Duration of Diabetes (years)			
N	61	61	122
Mean (SD)	3.4 (2.5)	3.2 (2.4)	3.3 (2.4)
Median	2.9	2.4	2.8
Min ; Max	0.4 ; 8.7	0.3 ; 9.6	0.3 ; 9.6
HbA1c (%)			
N	61	61	122
Mean (SD)	8.1 (1.1)	7.8 (1.1)	7.9 (1.1)
Median	8.0	7.9	7.9
Min ; Max	5.1 ; 10.1	5.4 ; 10.8	5.1 ; 10.8
HbA1c (mmol/mol)			
N	61	61	122
Mean (SD)	64.6 (12.3)	61.6 (12.3)	63.1 (12.3)
Median	63.9	62.8	62.8
Min ; Max	32.2 ; 86.9	35.5 ; 94.5	32.2 ; 94.5

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

Baseline and diabetes characteristics - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
FPG (mmol/L)			
N	58	58	116
Mean (SD)	8.0 (3.9)	8.1 (4.2)	8.1 (4.0)
Median	7.4	7.3	7.3
Min ; Max	1.6 ; 18.0	1.9 ; 25.1	1.6 ; 25.1
FPG (mg/dL)			
N	58	58	116
Mean (SD)	144.7 (70.0)	146.0 (75.3)	145.4 (72.4)
Median	133.0	131.0	132.0
Min ; Max	29.0 ; 324.0	35.0 ; 452.1	29.0 ; 452.1

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

14.1.17 Baseline and diabetes characteristics - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
Age (years)			
N	80	78	158
Mean (SD)	14.5 (1.6)	15.2 (1.7)	14.9 (1.7)
Median	14.4	15.6	14.8
Min ; Max	12.0 ; 17.8	12.2 ; 17.9	12.0 ; 17.9
Height (m)			
N	79	77	156
Mean (SD)	1.63 (0.10)	1.66 (0.11)	1.64 (0.11)
Median	1.62	1.66	1.64
Min ; Max	1.38 ; 1.87	1.42 ; 1.91	1.38 ; 1.91
Body Weight (kg)			
N	80	78	158
Mean (SD)	59.1 (15.2)	62.3 (14.0)	60.7 (14.7)
Median	55.7	61.7	59.3
Min ; Max	35.0 ; 117.1	32.6 ; 104.4	32.6 ; 117.1
Body Weight (lb)			
N	80	78	158
Mean (SD)	130.3 (33.6)	137.3 (30.8)	133.7 (32.3)
Median	122.8	135.9	130.6
Min ; Max	77.2 ; 258.2	71.9 ; 230.2	71.9 ; 258.2
BMI (kg/m^2)			
N	79	77	156
Mean (SD)	22.0 (3.9)	22.5 (3.8)	22.2 (3.8)
Median	21.4	22.0	21.7
Min ; Max	15.5 ; 35.1	13.8 ; 31.9	13.8 ; 35.1
Duration of Diabetes (years)			
N	80	78	158
Mean (SD)	6.4 (4.2)	5.6 (3.5)	6.0 (3.9)
Median	5.6	4.5	5.0
Min ; Max	0.3 ; 14.6	0.4 ; 13.9	0.3 ; 14.6
HbA1c (%)			
N	80	78	158
Mean (SD)	8.3 (1.3)	8.2 (1.4)	8.3 (1.3)
Median	8.4	8.3	8.3
Min ; Max	5.4 ; 10.6	5.5 ; 10.9	5.4 ; 10.9
HbA1c (mmol/mol)			
N	80	78	158
Mean (SD)	67.3 (13.7)	66.6 (15.0)	67.0 (14.3)
Median	67.8	66.7	67.2
Min ; Max	35.5 ; 92.4	36.6 ; 95.6	35.5 ; 95.6

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

Baseline and diabetes characteristics - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
FPG (mmol/L)			
N	75	73	148
Mean (SD)	9.0 (4.7)	8.1 (4.2)	8.6 (4.5)
Median	8.9	6.9	7.8
Min ; Max	0.5 ; 20.7	2.4 ; 21.5	0.5 ; 21.5
FPG (mg/dL)			
N	75	73	148
Mean (SD)	162.4 (84.3)	146.1 (75.5)	154.4 (80.2)
Median	160.0	124.0	140.0
Min ; Max	9.0 ; 373.0	44.0 ; 387.0	9.0 ; 387.0

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

14.1.18 Anti-diabetic treatment regimen at screening - full analysis set

	IDegAsp OD		IDet		Total	
	N	(%)	N	(%)	N	(%)
Number of Subjects	182		180		362	
Basal-Bolus Therapy	169	(92.9)	169	(93.9)	338	(93.4)
Basal + Bolus	168	(92.3)	165	(91.7)	333	(92.0)
Basal + Bolus + Premix	1	(0.5)	4	(2.2)	5	(1.4)
Other	13	(7.1)	11	(6.1)	24	(6.6)
Basal insulin	2	(1.1)	2	(1.1)	4	(1.1)
Bolus insulin	5	(2.7)	6	(3.3)	11	(3.0)
Premix insulin	4	(2.2)	1	(0.6)	5	(1.4)
Premix + Bolus	2	(1.1)	2	(1.1)	4	(1.1)

N: Number of subjects, %: Proportion of subjects

14.1.19 Insulin type at screening - summary - full analysis set

	IDegAsp OD		IDet		Total	
	N	(%)	N	(%)	N	(%)
Number of Subjects	182		180		362	
Basal insulin	171	(94.0)	171	(95.0)	342	(94.5)
IDet	72	(39.6)	92	(51.1)	164	(45.3)
IDet + Insulin NPH	3	(1.6)	3	(1.7)	6	(1.7)
IGlar	77	(42.3)	70	(38.9)	147	(40.6)
Insulin NPH	19	(10.4)	6	(3.3)	25	(6.9)
Bolus insulin	176	(96.7)	177	(98.3)	353	(97.5)
HI	21	(11.5)	19	(10.6)	40	(11.0)
HI + IAsp	3	(1.6)	5	(2.8)	8	(2.2)
HI + ILis	1	(0.5)	1	(0.6)	2	(0.6)
IAsp	104	(57.1)	108	(60.0)	212	(58.6)
IGlu	6	(3.3)	8	(4.4)	14	(3.9)
ILis	41	(22.5)	36	(20.0)	77	(21.3)
Premix insulin	7	(3.8)	7	(3.9)	14	(3.9)
BHI			2	(1.1)	2	(0.6)
BIAsp	6	(3.3)	3	(1.7)	9	(2.5)
Lispro mix	1	(0.5)	2	(1.1)	3	(0.8)

N: Number of subjects, %: Proportion of subjects
IGlar: Insulin glargine, ILis: Insulin lispro
IAsp: Insulin aspart, NPH: Neutral protamine hagedorn
BHI: Biphasic human insulin, BIAsp: Biphasic insulin aspart
IDet: Insulin detemir, HI: Human insulin, IGlu: Insulin glulistin

14.1.20 Diabetes complications at screening - summary - full analysis set

	IDegAsp OD N	(%)	E	IDet N	(%)	E	Total N	(%)	E
Number of Subjects	182			180			362		
All Complications	5	(2.7)	5	9	(5.0)	9	14	(3.9)	14
Neurological complications	4	(2.2)	4	5	(2.8)	5	9	(2.5)	9
Diabetic neuropathy	4	(2.2)	4	5	(2.8)	5	9	(2.5)	9
Renal complications	1	(0.5)	1	3	(1.7)	3	4	(1.1)	4
Microalbuminuria	1	(0.5)	1	3	(1.7)	3	4	(1.1)	4
Ophthalmic complications				1	(0.6)	1	1	(0.3)	1
Cataract diabetic				1	(0.6)	1	1	(0.3)	1

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

14.1.21 Concomitant illness at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	182	180	362
Social circumstances	60 (33.0)	57 (31.7)	117 (32.3)
Premenarche	57 (31.3)	54 (30.0)	111 (30.7)
Menarche	3 (1.6)	2 (1.1)	5 (1.4)
Corrective lens user		1 (0.6)	1 (0.3)
Skin and subcutaneous tissue disorders	17 (9.3)	20 (11.1)	37 (10.2)
Acne	3 (1.6)	8 (4.4)	11 (3.0)
Lipohypertrophy	7 (3.8)	3 (1.7)	10 (2.8)
Lipodystrophy acquired	3 (1.6)	5 (2.8)	8 (2.2)
Dermatitis atopic	2 (1.1)	1 (0.6)	3 (0.8)
Dermatitis	1 (0.5)		1 (0.3)
Dermatitis contact	1 (0.5)		1 (0.3)
Dry skin		1 (0.6)	1 (0.3)
Granuloma annulare	1 (0.5)		1 (0.3)
Nail pigmentation		1 (0.6)	1 (0.3)
Parapsoriasis		1 (0.6)	1 (0.3)
Psoriasis	1 (0.5)		1 (0.3)
Endocrine disorders	18 (9.9)	16 (8.9)	34 (9.4)
Hypothyroidism	11 (6.0)	6 (3.3)	17 (4.7)
Autoimmune thyroiditis	5 (2.7)	9 (5.0)	14 (3.9)
Goitre	3 (1.6)	2 (1.1)	5 (1.4)
Hypoparathyroidism	1 (0.5)		1 (0.3)
Precocious puberty		1 (0.6)	1 (0.3)
Primary hypothyroidism	1 (0.5)		1 (0.3)
Gastrointestinal disorders	13 (7.1)	17 (9.4)	30 (8.3)
Coeliac disease	8 (4.4)	7 (3.9)	15 (4.1)
Abdominal pain upper	2 (1.1)	1 (0.6)	3 (0.8)
Gastroduodenitis		3 (1.7)	3 (0.8)
Gastrooesophageal reflux disease	1 (0.5)	2 (1.1)	3 (0.8)
Constipation		2 (1.1)	2 (0.6)
Dental caries		2 (1.1)	2 (0.6)
Breath odour	1 (0.5)		1 (0.3)
Duodenitis	1 (0.5)		1 (0.3)
Nausea	1 (0.5)		1 (0.3)
Tooth impacted	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects

Concomitant illness at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Respiratory, thoracic and mediastinal disorders	14 (7.7)	16 (8.9)	30 (8.3)
Asthma	9 (4.9)	10 (5.6)	19 (5.2)
Rhinitis allergic		5 (2.8)	5 (1.4)
Cough	2 (1.1)		2 (0.6)
Asthma exercise induced	1 (0.5)		1 (0.3)
Bronchospasm		1 (0.6)	1 (0.3)
Epistaxis		1 (0.6)	1 (0.3)
Respiratory disorder		1 (0.6)	1 (0.3)
Rhinitis perennial		1 (0.6)	1 (0.3)
Rhinorrhoea	1 (0.5)		1 (0.3)
Wheezing	1 (0.5)		1 (0.3)
Immune system disorders	17 (9.3)	12 (6.7)	29 (8.0)
Seasonal allergy	9 (4.9)	7 (3.9)	16 (4.4)
Drug hypersensitivity	3 (1.6)	1 (0.6)	4 (1.1)
Food allergy	3 (1.6)	1 (0.6)	4 (1.1)
Multiple allergies	1 (0.5)	1 (0.6)	2 (0.6)
Allergy to animal		1 (0.6)	1 (0.3)
Allergy to arthropod bite	1 (0.5)		1 (0.3)
Allergy to plants	1 (0.5)		1 (0.3)
Hypersensitivity		1 (0.6)	1 (0.3)
Selective IgA immunodeficiency	1 (0.5)		1 (0.3)
Metabolism and nutrition disorders	9 (4.9)	19 (10.6)	28 (7.7)
Vitamin D deficiency	3 (1.6)	9 (5.0)	12 (3.3)
Hypercholesterolaemia	1 (0.5)	5 (2.8)	6 (1.7)
Obesity	2 (1.1)	3 (1.7)	5 (1.4)
Hypomagnesaemia	2 (1.1)	1 (0.6)	3 (0.8)
Dyslipidaemia		2 (1.1)	2 (0.6)
Failure to thrive	1 (0.5)		1 (0.3)
Hyperlipidaemia		1 (0.6)	1 (0.3)
Weight gain poor		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects

Concomitant illness at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Infections and infestations	12 (6.6)	14 (7.8)	26 (7.2)
Giardiasis	2 (1.1)	2 (1.1)	4 (1.1)
Rhinitis	3 (1.6)	1 (0.6)	4 (1.1)
Sinusitis	2 (1.1)	2 (1.1)	4 (1.1)
Chronic tonsillitis		3 (1.7)	3 (0.8)
Otitis media	1 (0.5)	1 (0.6)	2 (0.6)
Pharyngitis	1 (0.5)	1 (0.6)	2 (0.6)
Acute sinusitis	1 (0.5)		1 (0.3)
Adenoiditis		1 (0.6)	1 (0.3)
Candida infection		1 (0.6)	1 (0.3)
Chronic sinusitis		1 (0.6)	1 (0.3)
Fungal infection	1 (0.5)		1 (0.3)
Gastroenteritis		1 (0.6)	1 (0.3)
Tonsillitis	1 (0.5)		1 (0.3)
Upper respiratory tract infection	1 (0.5)		1 (0.3)
Viral upper respiratory tract infection		1 (0.6)	1 (0.3)
Vulvovaginal mycotic infection		1 (0.6)	1 (0.3)
Nervous system disorders	16 (8.8)	10 (5.6)	26 (7.2)
Headache	8 (4.4)	2 (1.1)	10 (2.8)
Diabetic neuropathy	4 (2.2)	5 (2.8)	9 (2.5)
Autonomic nervous system imbalance	2 (1.1)	2 (1.1)	4 (1.1)
Migraine	1 (0.5)	1 (0.6)	2 (0.6)
Speech disorder	2 (1.1)		2 (0.6)
Cerebral disorder	1 (0.5)		1 (0.3)
Convulsion	1 (0.5)		1 (0.3)
Disturbance in attention	1 (0.5)		1 (0.3)
Dizziness		1 (0.6)	1 (0.3)
Hypoglycaemic seizure		1 (0.6)	1 (0.3)
Hypotonia	1 (0.5)		1 (0.3)
Movement disorder	1 (0.5)		1 (0.3)
Nystagmus		1 (0.6)	1 (0.3)
Partial seizures		1 (0.6)	1 (0.3)
Psychomotor hyperactivity	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects

Concomitant illness at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Psychiatric disorders	12 (6.6)	12 (6.7)	24 (6.6)
Attention deficit/hyperactivity disorder	9 (4.9)	6 (3.3)	15 (4.1)
Depression	1 (0.5)	4 (2.2)	5 (1.4)
Anxiety		2 (1.1)	2 (0.6)
Insomnia	1 (0.5)	1 (0.6)	2 (0.6)
Tic	1 (0.5)	1 (0.6)	2 (0.6)
Abnormal behaviour	1 (0.5)		1 (0.3)
Adjustment disorder		1 (0.6)	1 (0.3)
Affect lability		1 (0.6)	1 (0.3)
Autism spectrum disorder	1 (0.5)		1 (0.3)
Emotional disorder	1 (0.5)		1 (0.3)
Generalised anxiety disorder	1 (0.5)		1 (0.3)
Panic attack	1 (0.5)		1 (0.3)
Psychomotor retardation	1 (0.5)		1 (0.3)
Eye disorders	11 (6.0)	10 (5.6)	21 (5.8)
Hypermetropia	3 (1.6)	5 (2.8)	8 (2.2)
Myopia	4 (2.2)	3 (1.7)	7 (1.9)
Retinopathy	4 (2.2)		4 (1.1)
Strabismus	1 (0.5)	1 (0.6)	2 (0.6)
Anisometropia		1 (0.6)	1 (0.3)
Astigmatism		1 (0.6)	1 (0.3)
Cataract diabetic		1 (0.6)	1 (0.3)
Retinal vascular disorder	1 (0.5)		1 (0.3)
Musculoskeletal and connective tissue disorders	12 (6.6)	8 (4.4)	20 (5.5)
Posture abnormal	4 (2.2)	4 (2.2)	8 (2.2)
Foot deformity	4 (2.2)	2 (1.1)	6 (1.7)
Scoliosis	4 (2.2)	1 (0.6)	5 (1.4)
Growth retardation	2 (1.1)	1 (0.6)	3 (0.8)
Ankylosing spondylitis		1 (0.6)	1 (0.3)
Arthropathy	1 (0.5)		1 (0.3)
Joint range of motion decreased		1 (0.6)	1 (0.3)
Limb deformity	1 (0.5)		1 (0.3)
Myalgia	1 (0.5)		1 (0.3)
Patellofemoral pain syndrome	1 (0.5)		1 (0.3)
Pelvic deformity	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects

Concomitant illness at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Renal and urinary disorders	6 (3.3)	9 (5.0)	15 (4.1)
Enuresis	2 (1.1)	2 (1.1)	4 (1.1)
Microalbuminuria	1 (0.5)	3 (1.7)	4 (1.1)
Hyperoxaluria	1 (0.5)	1 (0.6)	2 (0.6)
Dysuria		1 (0.6)	1 (0.3)
Hydronephrosis		1 (0.6)	1 (0.3)
Ketonuria		1 (0.6)	1 (0.3)
Nephroptosis	1 (0.5)		1 (0.3)
Neurogenic bladder	1 (0.5)		1 (0.3)
Renal disorder	1 (0.5)		1 (0.3)
Investigations	6 (3.3)	6 (3.3)	12 (3.3)
Blood cholesterol increased	1 (0.5)	1 (0.6)	2 (0.6)
Cardiac murmur functional		2 (1.1)	2 (0.6)
Anti-transglutaminase antibody	1 (0.5)		1 (0.3)
Blood alkaline phosphatase increased		1 (0.6)	1 (0.3)
Blood thyroid stimulating hormone increased		1 (0.6)	1 (0.3)
Body height below normal	1 (0.5)		1 (0.3)
Cardiac murmur	1 (0.5)		1 (0.3)
Hepatic enzyme increased	1 (0.5)		1 (0.3)
Menstruation normal	1 (0.5)		1 (0.3)
Weight increased		1 (0.6)	1 (0.3)
Blood and lymphatic system disorders	3 (1.6)	4 (2.2)	7 (1.9)
Anaemia	1 (0.5)	2 (1.1)	3 (0.8)
Lymphadenopathy	1 (0.5)	1 (0.6)	2 (0.6)
Hypercoagulation		1 (0.6)	1 (0.3)
Lymphoid tissue hyperplasia	1 (0.5)		1 (0.3)
Congenital, familial and genetic disorders	6 (3.3)	1 (0.6)	7 (1.9)
Phimosis	2 (1.1)		2 (0.6)
Cerebral palsy		1 (0.6)	1 (0.3)
Coarctation of the aorta	1 (0.5)		1 (0.3)
Exomphalos	1 (0.5)		1 (0.3)
Foetal alcohol syndrome	1 (0.5)		1 (0.3)
Haemangioma of retina	1 (0.5)		1 (0.3)
Hepatobiliary disorders	1 (0.5)	4 (2.2)	5 (1.4)
Hepatic steatosis	1 (0.5)	2 (1.1)	3 (0.8)
Biliary tract disorder		1 (0.6)	1 (0.3)
Gallbladder disorder		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects

Concomitant illness at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Injury, poisoning and procedural complications	4 (2.2)	1 (0.6)	5 (1.4)
Head injury	1 (0.5)		1 (0.3)
Scar	1 (0.5)		1 (0.3)
Spinal compression fracture	1 (0.5)		1 (0.3)
Traumatic haematoma	1 (0.5)		1 (0.3)
Wrist fracture		1 (0.6)	1 (0.3)
Vascular disorders	2 (1.1)	3 (1.7)	5 (1.4)
Hypertension	1 (0.5)	2 (1.1)	3 (0.8)
Hypertensive angiopathy		1 (0.6)	1 (0.3)
Vasospasm	1 (0.5)		1 (0.3)
General disorders and administration site conditions		4 (2.2)	4 (1.1)
Fatigue		2 (1.1)	2 (0.6)
Dysplasia		1 (0.6)	1 (0.3)
Gait disturbance		1 (0.6)	1 (0.3)
Malaise		1 (0.6)	1 (0.3)
Cardiac disorders	2 (1.1)	1 (0.6)	3 (0.8)
Cardiac ventricular disorder	2 (1.1)	1 (0.6)	3 (0.8)
Reproductive system and breast disorders	2 (1.1)	1 (0.6)	3 (0.8)
Breast enlargement	1 (0.5)		1 (0.3)
Polycystic ovaries		1 (0.6)	1 (0.3)
Testicular retraction	1 (0.5)		1 (0.3)
Ear and labyrinth disorders	2 (1.1)		2 (0.6)
Ear pain	1 (0.5)		1 (0.3)
Eustachian tube dysfunction	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects

14.1.22 Concomitant medication at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	182	180	362
INSULIN ASPART	107 (58.8)	113 (62.8)	220 (60.8)
INSULIN DETEMIR	75 (41.2)	95 (52.8)	170 (47.0)
INSULIN GLARGINE	77 (42.3)	70 (38.9)	147 (40.6)
INSULIN LISPRO	42 (23.1)	37 (20.6)	79 (21.8)
INSULIN HUMAN	25 (13.7)	27 (15.0)	52 (14.4)
INSULIN HUMAN INJECTION, ISOPHANE	16 (8.8)	7 (3.9)	23 (6.4)
LEVOTHYROXINE SODIUM	9 (4.9)	8 (4.4)	17 (4.7)
INSULIN GLULISINE	6 (3.3)	8 (4.4)	14 (3.9)
NOVOMIX	6 (3.3)	3 (1.7)	9 (2.5)
ONDANSETRON	4 (2.2)	4 (2.2)	8 (2.2)
VITAMINS NOS	5 (2.7)	3 (1.7)	8 (2.2)
SALBUTAMOL	2 (1.1)	4 (2.2)	6 (1.7)
CETIRIZINE HYDROCHLORIDE		5 (2.8)	5 (1.4)
ISOPHANE INSULIN	5 (2.7)		5 (1.4)
METHYLPHENIDATE HYDROCHLORIDE	2 (1.1)	3 (1.7)	5 (1.4)
MONTELUKAST SODIUM	3 (1.6)	2 (1.1)	5 (1.4)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
VITAMIN D NOS	3 (1.6)	2 (1.1)	5 (1.4)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.5)	3 (1.7)	4 (1.1)
IBUPROFEN	1 (0.5)	3 (1.7)	4 (1.1)
LEVOTHYROXINE	4 (2.2)		4 (1.1)
POTASSIUM IODIDE	2 (1.1)	2 (1.1)	4 (1.1)
ASCORBIC ACID	3 (1.6)		3 (0.8)
FEXOFENADINE HYDROCHLORIDE		3 (1.7)	3 (0.8)
FLUTICASONE PROPIONATE	1 (0.5)	2 (1.1)	3 (0.8)
HUMALOG MIX	1 (0.5)	2 (1.1)	3 (0.8)
LORATADINE	3 (1.6)		3 (0.8)
SERTRALINE HYDROCHLORIDE	2 (1.1)	1 (0.6)	3 (0.8)
AIDA / [redacted]		2 (1.1)	2 (0.6)
AMBROXOL HYDROCHLORIDE	1 (0.5)	1 (0.6)	2 (0.6)
ATORVASTATIN CALCIUM	1 (0.5)	1 (0.6)	2 (0.6)
BUDESONIDE	1 (0.5)	1 (0.6)	2 (0.6)
CALCIUM	1 (0.5)	1 (0.6)	2 (0.6)
COLECALCIFEROL		2 (1.1)	2 (0.6)

N= Number of subjects
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Generic names of the drugs are presented.

Concomitant medication at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
EUGYNON / [redacted]	1 (0.5)	1 (0.6)	2 (0.6)
FLUOXETINE	1 (0.5)	1 (0.6)	2 (0.6)
GLUCAGON	1 (0.5)	1 (0.6)	2 (0.6)
GUANFACINE HYDROCHLORIDE	1 (0.5)	1 (0.6)	2 (0.6)
HUMAN MIXTARD		2 (1.1)	2 (0.6)
LISDEXAMFETAMINE MESILATE	1 (0.5)	1 (0.6)	2 (0.6)
MACROGOL		2 (1.1)	2 (0.6)
MELATONIN	1 (0.5)	1 (0.6)	2 (0.6)
RAMIPRIL		2 (1.1)	2 (0.6)
SIMVASTATIN		2 (1.1)	2 (0.6)
ACETYLCYSTEINE		1 (0.6)	1 (0.3)
ALPRAZOLAM	1 (0.5)		1 (0.3)
AMFETAMINE	1 (0.5)		1 (0.3)
AMINOPHYLLINE		1 (0.6)	1 (0.3)
AMOXICILLIN		1 (0.6)	1 (0.3)
ASCORBIC ACID W/BETACAROTENE/BIOTIN/ [redacted]	1 (0.5)		1 (0.3)
ATOMOXETINE HYDROCHLORIDE	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
AZITHROMYCIN		1 (0.6)	1 (0.3)
BECLOMETASONE DIPROPIONATE		1 (0.6)	1 (0.3)
BENZOYL PEROXIDE		1 (0.6)	1 (0.3)
BENZYDAMINE HYDROCHLORIDE		1 (0.6)	1 (0.3)
CALCIUM W/MAGNESIUM	1 (0.5)		1 (0.3)
CEFDINIR	1 (0.5)		1 (0.3)
CILEST	1 (0.5)		1 (0.3)
CLARITHROMYCIN	1 (0.5)		1 (0.3)
CLOTRIMAZOLE	1 (0.5)		1 (0.3)
CYANOCOBALAMIN	1 (0.5)		1 (0.3)
DEXTROMETHORPHAN HYDROBROMIDE	1 (0.5)		1 (0.3)
DIANE		1 (0.6)	1 (0.3)
DULERA		1 (0.6)	1 (0.3)
ENALAPRIL MALEATE		1 (0.6)	1 (0.3)
EPINEPHRINE	1 (0.5)		1 (0.3)
ESCITALOPRAM OXALATE		1 (0.6)	1 (0.3)
ETODOLAC	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
EXPECTORANTS		1 (0.6)	1 (0.3)
FEMODENE		1 (0.6)	1 (0.3)
FISH OIL	1 (0.5)		1 (0.3)
FLUOXETINE HYDROCHLORIDE		1 (0.6)	1 (0.3)
FOLIC ACID		1 (0.6)	1 (0.3)
HERBAL NOS W/MINERALS NOS		1 (0.6)	1 (0.3)
INSULIN ISOPHANE PORCINE	1 (0.5)		1 (0.3)
INTERFERON GAMMA		1 (0.6)	1 (0.3)
ISOTRETINOIN		1 (0.6)	1 (0.3)
ISOTREXIN		1 (0.6)	1 (0.3)
JUICE PLUS	1 (0.5)		1 (0.3)
LACTOBACILLUS ACIDOPHILUS		1 (0.6)	1 (0.3)
LEVOCETIRIZINE DIHYDROCHLORIDE	1 (0.5)		1 (0.3)
LEVOSALBUTAMOL HYDROCHLORIDE		1 (0.6)	1 (0.3)
LEVOSALBUTAMOL TARTRATE	1 (0.5)		1 (0.3)
LORATADINE W/PSEUDOEPHEDRINE	1 (0.5)		1 (0.3)
MAGNESIUM		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
MAGNESIUM GLYCEROPHOSPHATE		1 (0.6)	1 (0.3)
MAGNESIUM LACTATE	1 (0.5)		1 (0.3)
MAGNOSOLV	1 (0.5)		1 (0.3)
MEDROXYPROGESTERONE ACETATE	1 (0.5)		1 (0.3)
METHOTREXATE SODIUM		1 (0.6)	1 (0.3)
METHYLPREDNISOLONE ACEPONATE	1 (0.5)		1 (0.3)
MINOCYCLINE		1 (0.6)	1 (0.3)
MINOCYCLINE HYDROCHLORIDE		1 (0.6)	1 (0.3)
MULTIVITAMINS	1 (0.5)		1 (0.3)
MULTIVITAMINS, PLAIN	1 (0.5)		1 (0.3)
NIMESULIDE	1 (0.5)		1 (0.3)
NYSTATIN		1 (0.6)	1 (0.3)
OBETROL / [redacted]	1 (0.5)		1 (0.3)
OMEPRAZOLE	1 (0.5)		1 (0.3)
OXYMETAZOLINE HYDROCHLORIDE		1 (0.6)	1 (0.3)
PANCREATIN		1 (0.6)	1 (0.3)
PARACETAMOL	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication at screening - summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
PROCATEROL HYDROCHLORIDE		1 (0.6)	1 (0.3)
RANITIDINE		1 (0.6)	1 (0.3)
SALBUTAMOL SULFATE	1 (0.5)		1 (0.3)
SERETIDE		1 (0.6)	1 (0.3)
SODIUM CHLORIDE		1 (0.6)	1 (0.3)
SYNALAR NASAL		1 (0.6)	1 (0.3)
THIOCTIC ACID		1 (0.6)	1 (0.3)
TRIAMCINOLONE ACETONIDE	1 (0.5)		1 (0.3)
VITAMINS / [redacted]		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

14.1.23 Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	182	180	362
IBUPROFEN	41 (22.5)	42 (23.3)	83 (22.9)
PARACETAMOL	37 (20.3)	40 (22.2)	77 (21.3)
AMOXICILLIN	13 (7.1)	15 (8.3)	28 (7.7)
AZITHROMYCIN	9 (4.9)	8 (4.4)	17 (4.7)
ACETYLCYSTEINE	4 (2.2)	4 (2.2)	8 (2.2)
MEDINITE	5 (2.7)	3 (1.7)	8 (2.2)
CEFALEXIN	2 (1.1)	5 (2.8)	7 (1.9)
DIPHENHYDRAMINE HYDROCHLORIDE	4 (2.2)	3 (1.7)	7 (1.9)
LORATADINE	2 (1.1)	5 (2.8)	7 (1.9)
AMBROXOL HYDROCHLORIDE	2 (1.1)	4 (2.2)	6 (1.7)
AMOXICILLIN TRIHYDRATE	4 (2.2)	2 (1.1)	6 (1.7)
BENZYDAMINE HYDROCHLORIDE	3 (1.6)	3 (1.7)	6 (1.7)
DIMENHYDRINATE	3 (1.6)	3 (1.7)	6 (1.7)
GUAIFENESIN	4 (2.2)	2 (1.1)	6 (1.7)
OXYMETAZOLINE HYDROCHLORIDE	2 (1.1)	4 (2.2)	6 (1.7)
SACCHAROMYCES BOULARDII	2 (1.1)	4 (2.2)	6 (1.7)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DEXTROMETHORPHAN HYDROBROMIDE	2 (1.1)	3 (1.7)	5 (1.4)
FEXOFENADINE HYDROCHLORIDE	2 (1.1)	3 (1.7)	5 (1.4)
METAMIZOLE SODIUM	2 (1.1)	3 (1.7)	5 (1.4)
NAPROXEN SODIUM	2 (1.1)	3 (1.7)	5 (1.4)
SALBUTAMOL	4 (2.2)	1 (0.6)	5 (1.4)
SODIUM CHLORIDE	3 (1.6)	2 (1.1)	5 (1.4)
ALUPENT EXPECTORANT	2 (1.1)	2 (1.1)	4 (1.1)
AMOXI-CLAVULANICO	1 (0.5)	3 (1.7)	4 (1.1)
BISMUTH SUBSALICYLATE	3 (1.6)	1 (0.6)	4 (1.1)
CEFIXIME	3 (1.6)	1 (0.6)	4 (1.1)
CLARITHROMYCIN	1 (0.5)	3 (1.7)	4 (1.1)
FLUTICASONE PROPIONATE	1 (0.5)	3 (1.7)	4 (1.1)
INFLUENZA VACCINE	3 (1.6)	1 (0.6)	4 (1.1)
INSULIN ASPART	2 (1.1)	2 (1.1)	4 (1.1)
MONTELUKAST SODIUM	1 (0.5)	3 (1.7)	4 (1.1)
UNSPECIFIED HERBAL	1 (0.5)	3 (1.7)	4 (1.1)
VICKS FORMULA 44M / [redacted]	3 (1.6)	1 (0.6)	4 (1.1)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
AMBROXOL	3 (1.6)		3 (0.8)
BACTRIM	2 (1.1)	1 (0.6)	3 (0.8)
BIFIDOBACTERIUM LACTIS	1 (0.5)	2 (1.1)	3 (0.8)
BROMFED	2 (1.1)	1 (0.6)	3 (0.8)
CARBOCISTEINE		3 (1.7)	3 (0.8)
CETIRIZINE HYDROCHLORIDE	3 (1.6)		3 (0.8)
DICLOFENAC SODIUM	1 (0.5)	2 (1.1)	3 (0.8)
DIMETANE DECONGESTANT	2 (1.1)	1 (0.6)	3 (0.8)
DIMETICONE	2 (1.1)	1 (0.6)	3 (0.8)
DOMPERIDONE	1 (0.5)	2 (1.1)	3 (0.8)
FUSAFUNGINE	2 (1.1)	1 (0.6)	3 (0.8)
HEDERA HELIX LEAF	2 (1.1)	1 (0.6)	3 (0.8)
KETOROLAC TROMETHAMINE	1 (0.5)	2 (1.1)	3 (0.8)
LACTOBACILLUS ACIDOPHILUS		3 (1.7)	3 (0.8)
LOPERAMIDE HYDROCHLORIDE	2 (1.1)	1 (0.6)	3 (0.8)
MACROGOL	3 (1.6)		3 (0.8)
METOCLOPRAMIDE HYDROCHLORIDE	2 (1.1)	1 (0.6)	3 (0.8)

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Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
MINERAL SUPPLEMENTS	1 (0.5)	2 (1.1)	3 (0.8)
MONTELUKAST	2 (1.1)	1 (0.6)	3 (0.8)
OMEPRAZOLE	1 (0.5)	2 (1.1)	3 (0.8)
OXYMETAZOLINE	2 (1.1)	1 (0.6)	3 (0.8)
PREDNISOLONE	3 (1.6)		3 (0.8)
PREDNISONE	2 (1.1)	1 (0.6)	3 (0.8)
SIMETICONE	1 (0.5)	2 (1.1)	3 (0.8)
ACETYLSALICYLIC ACID		2 (1.1)	2 (0.6)
ACICLOVIR		2 (1.1)	2 (0.6)
AFRIN MOISTURIZING SALINE	1 (0.5)	1 (0.6)	2 (0.6)
AMOXICILINA + CLAVULANICO	1 (0.5)	1 (0.6)	2 (0.6)
ARBIDOL	1 (0.5)	1 (0.6)	2 (0.6)
BENZONATATE	1 (0.5)	1 (0.6)	2 (0.6)
BRILLIANT GREEN CI 42040	2 (1.1)		2 (0.6)
BROMHEXINE		2 (1.1)	2 (0.6)
BROMHEXINE HYDROCHLORIDE	1 (0.5)	1 (0.6)	2 (0.6)
BUDESONIDE	1 (0.5)	1 (0.6)	2 (0.6)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CEFDINIR	1 (0.5)	1 (0.6)	2 (0.6)
CEFTRIAXONE SODIUM	1 (0.5)	1 (0.6)	2 (0.6)
CHLOROPYRAMINE	2 (1.1)		2 (0.6)
CHLORPHENAMINE MALEATE	2 (1.1)		2 (0.6)
CIPROFLOXACIN HYDROCHLORIDE	1 (0.5)	1 (0.6)	2 (0.6)
CLEMASTINE FUMARATE	1 (0.5)	1 (0.6)	2 (0.6)
DESLORATADINE		2 (1.1)	2 (0.6)
DIAZEPAM	2 (1.1)		2 (0.6)
DICLOFENAC		2 (1.1)	2 (0.6)
DROTAVERINE HYDROCHLORIDE	1 (0.5)	1 (0.6)	2 (0.6)
ELECTROLYTES NOS W/GLUCOSE	2 (1.1)		2 (0.6)
FENSPIRIDE HYDROCHLORIDE	1 (0.5)	1 (0.6)	2 (0.6)
FLUTICASONE FUROATE		2 (1.1)	2 (0.6)
GENERAL NUTRIENTS	1 (0.5)	1 (0.6)	2 (0.6)
GLUCAGON	2 (1.1)		2 (0.6)
HEDERA HELIX	1 (0.5)	1 (0.6)	2 (0.6)
HEDERA HELIX EXTRACT	2 (1.1)		2 (0.6)

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Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HEXETIDINE	2 (1.1)		2 (0.6)
HOMEOPATHIC PREPARATION	1 (0.5)	1 (0.6)	2 (0.6)
HYDROMORPHONE HYDROCHLORIDE	1 (0.5)	1 (0.6)	2 (0.6)
HYOSCINE BUTYLBROMIDE		2 (1.1)	2 (0.6)
INSULIN GLARGINE	2 (1.1)		2 (0.6)
INTERFERON GAMMA	2 (1.1)		2 (0.6)
KAGOCEL	1 (0.5)	1 (0.6)	2 (0.6)
KETOPROFEN	2 (1.1)		2 (0.6)
METHYLPHENIDATE HYDROCHLORIDE	1 (0.5)	1 (0.6)	2 (0.6)
METOCLOPRAMIDE		2 (1.1)	2 (0.6)
MIDOL / [redacted]	1 (0.5)	1 (0.6)	2 (0.6)
MORPHINE	1 (0.5)	1 (0.6)	2 (0.6)
NAPROXEN	1 (0.5)	1 (0.6)	2 (0.6)
NASAL DECONGESTANTS FOR SYSTEMIC USE		2 (1.1)	2 (0.6)
NASAL PREPARATIONS		2 (1.1)	2 (0.6)
NUSSIDEX	1 (0.5)	1 (0.6)	2 (0.6)
ONDANSETRON	1 (0.5)	1 (0.6)	2 (0.6)

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Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
OTHER NASAL PREPARATIONS	1 (0.5)	1 (0.6)	2 (0.6)
OXYCOCET	1 (0.5)	1 (0.6)	2 (0.6)
PENICILLIN NOS	1 (0.5)	1 (0.6)	2 (0.6)
PHOLCODINE	1 (0.5)	1 (0.6)	2 (0.6)
SEA WATER	1 (0.5)	1 (0.6)	2 (0.6)
SINUPRET / [redacted]	1 (0.5)	1 (0.6)	2 (0.6)
STELAMIN	1 (0.5)	1 (0.6)	2 (0.6)
STREPSILS / [redacted]	2 (1.1)		2 (0.6)
TETANUS VACCINE	1 (0.5)	1 (0.6)	2 (0.6)
TRAMAZOLINE HYDROCHLORIDE	2 (1.1)		2 (0.6)
VITAMINS NOS	1 (0.5)	1 (0.6)	2 (0.6)
XYLOMETAZOLINE HYDROCHLORIDE		2 (1.1)	2 (0.6)
ACICLOVIR SODIUM	1 (0.5)		1 (0.3)
ACIDOPHILUS BIFIDUS		1 (0.6)	1 (0.3)
ACONITUM NAPELLUS		1 (0.6)	1 (0.3)
ACTIDUE		1 (0.6)	1 (0.3)
ADEMETIONINE		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ADVIL PM / [redacted]	1 (0.5)		1 (0.3)
AKRITOIN		1 (0.6)	1 (0.3)
ALKA-SELTZER PLUS COLD & FLU MEDICINE	1 (0.5)		1 (0.3)
AMBROXOL ACEFYLLINATE		1 (0.6)	1 (0.3)
AMOXICILLIN W/CLAVULANATE POTASSIUM		1 (0.6)	1 (0.3)
ANTIBIOTICS	1 (0.5)		1 (0.3)
ANTIDIARRHEAL MICROORGANISMS	1 (0.5)		1 (0.3)
ASCORBIC ACID W/HERBAL NOS/ LEVOGLUTAMIDE/LYSI	1 (0.5)		1 (0.3)
ASCORUTIN		1 (0.6)	1 (0.3)
AZOXIMER BROMID	1 (0.5)		1 (0.3)
AZULENE W/EUCALYPTUS GLOBULUS TINCTURE/ HERBAL	1 (0.5)		1 (0.3)
BACILLUS CLAUSII		1 (0.6)	1 (0.3)
BECLOMETASONE DIPROPIONATE		1 (0.6)	1 (0.3)
BENZACLIN TOPICAL	1 (0.5)		1 (0.3)
BENZOCAINE	1 (0.5)		1 (0.3)
BROMPHENIRAMINE		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
BRONCHOSEDAL		1 (0.6)	1 (0.3)
BUTAMIRATE		1 (0.6)	1 (0.3)
BUTAMIRATE CITRATE	1 (0.5)		1 (0.3)
CALCIUM		1 (0.6)	1 (0.3)
CALCIUM CARBONATE		1 (0.6)	1 (0.3)
CEFADROXIL		1 (0.6)	1 (0.3)
CEFALEXIN MONOHYDRATE		1 (0.6)	1 (0.3)
CEFAZOLIN	1 (0.5)		1 (0.3)
CEFAZOLIN SODIUM	1 (0.5)		1 (0.3)
CEFOTAXIME	1 (0.5)		1 (0.3)
CEFPODOXIME PROXETIL	1 (0.5)		1 (0.3)
CEFPROZIL		1 (0.6)	1 (0.3)
CEFUROXIME AXETIL		1 (0.6)	1 (0.3)
CEPHALOSPORIN C		1 (0.6)	1 (0.3)
CETIRIZINE		1 (0.6)	1 (0.3)
CETRARIA ISLANDICA		1 (0.6)	1 (0.3)
CHERATUSSIN		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
CHLORAMPHENICOL		1 (0.6)	1 (0.3)
CHLORHEXIDINE		1 (0.6)	1 (0.3)
CHLORHEXIDINE W/LIDOCAINE		1 (0.6)	1 (0.3)
CHLOROPYRAMINE HYDROCHLORIDE		1 (0.6)	1 (0.3)
CHOLINE SALICYLATE		1 (0.6)	1 (0.3)
CLEBOPRIDE MALATE		1 (0.6)	1 (0.3)
CLENBUTEROL		1 (0.6)	1 (0.3)
CO-ADVIL	1 (0.5)		1 (0.3)
CODEINE		1 (0.6)	1 (0.3)
COLDEX / [redacted]	1 (0.5)		1 (0.3)
COLECALCIFEROL		1 (0.6)	1 (0.3)
COLLUDOL	1 (0.5)		1 (0.3)
COMBIVENT	1 (0.5)		1 (0.3)
CONTAC / [redacted]		1 (0.6)	1 (0.3)
COPHENE / [redacted]		1 (0.6)	1 (0.3)
CORYX / [redacted]	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
COUGH AND COLD PREPARATIONS		1 (0.6)	1 (0.3)
COUGH SYRUP	1 (0.5)		1 (0.3)
COULDINA / [redacted]		1 (0.6)	1 (0.3)
CROMOGLICATE SODIUM	1 (0.5)		1 (0.3)
DAPSONE		1 (0.6)	1 (0.3)
DEMAZIN / [redacted]		1 (0.6)	1 (0.3)
DERMATOLOGICALS		1 (0.6)	1 (0.3)
DESFLURANE	1 (0.5)		1 (0.3)
DESMOPRESSIN	1 (0.5)		1 (0.3)
DEXA-RHINOSPRAY / [redacted]	1 (0.5)		1 (0.3)
DEXAMETHASONE	1 (0.5)		1 (0.3)
DEXAMETHASONE W/NEOMYCIN		1 (0.6)	1 (0.3)
DEXTROMETHORPHAN		1 (0.6)	1 (0.3)
DEXTROSE AND SODIUM CHLORIDE INJECTION	1 (0.5)		1 (0.3)
DIMETINDENE W/PHENYLEPHRINE	1 (0.5)		1 (0.3)
DIPHENHYDRAMINE	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
DOCOSAHEXAENOIC ACID		1 (0.6)	1 (0.3)
DOCUSATE SODIUM		1 (0.6)	1 (0.3)
DOLO MOBILAT / [redacted]	1 (0.5)		1 (0.3)
DROPROPIZINE	1 (0.5)		1 (0.3)
DUOVENT		1 (0.6)	1 (0.3)
EBASTINE		1 (0.6)	1 (0.3)
EMERGEN C		1 (0.6)	1 (0.3)
EPIDUO		1 (0.6)	1 (0.3)
ERYTHROMYCIN		1 (0.6)	1 (0.3)
ESCIN	1 (0.5)		1 (0.3)
ESCITALOPRAM	1 (0.5)		1 (0.3)
EUGYNON / [redacted]	1 (0.5)		1 (0.3)
EXCEDRIN P.M. / [redacted]	1 (0.5)		1 (0.3)
EXPECTORANTS		1 (0.6)	1 (0.3)
FEMODENE	1 (0.5)		1 (0.3)
FENOTEROL W/IPRATROPIUM		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
FENSPIRIDE		1 (0.6)	1 (0.3)
FENTANYL	1 (0.5)		1 (0.3)
FLEBOBAG RING LACT	1 (0.5)		1 (0.3)
FLUDRONEF		1 (0.6)	1 (0.3)
FRAMYCETIN SULFATE		1 (0.6)	1 (0.3)
FRUBIENZYM	1 (0.5)		1 (0.3)
GABAPENTIN		1 (0.6)	1 (0.3)
GLUCOSE	1 (0.5)		1 (0.3)
HEXAMIDINE	1 (0.5)		1 (0.3)
HEXAMIDINE ISETIONATE		1 (0.6)	1 (0.3)
HOT COLDREX	1 (0.5)		1 (0.3)
HUMAN MIXTARD		1 (0.6)	1 (0.3)
HUMAN PAPILLOMA VACCINE	1 (0.5)		1 (0.3)
IBUPROFEN LYSINATE		1 (0.6)	1 (0.3)
IBUPROFEN W/PARACETAMOL		1 (0.6)	1 (0.3)
INFLUENZA VACCINES	1 (0.5)		1 (0.3)
INSULIN DETEMIR	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
INTERFERONS	1 (0.5)		1 (0.3)
IODINE		1 (0.6)	1 (0.3)
ISOTRETINOIN	1 (0.5)		1 (0.3)
KETAMINE	1 (0.5)		1 (0.3)
LACTOBACILLUS REUTERI	1 (0.5)		1 (0.3)
LACTOBACILLUS RHAMNOSUS		1 (0.6)	1 (0.3)
LACTULOSE		1 (0.6)	1 (0.3)
LANSOPRAZOLE	1 (0.5)		1 (0.3)
LEMOCIN		1 (0.6)	1 (0.3)
LEVOCETIRIZINE		1 (0.6)	1 (0.3)
LEVOTHYROXINE SODIUM	1 (0.5)		1 (0.3)
LIDOCAINE	1 (0.5)		1 (0.3)
LISDEXAMFETAMINE MESILATE	1 (0.5)		1 (0.3)
LYSINE	1 (0.5)		1 (0.3)
LYSO-B	1 (0.5)		1 (0.3)
MEBENDAZOLE		1 (0.6)	1 (0.3)
MELATONIN	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
METAMIZOLE	1 (0.5)		1 (0.3)
METHYLPHENIDATE		1 (0.6)	1 (0.3)
METHYLPREDNISOLONE	1 (0.5)		1 (0.3)
MICONAZOLE	1 (0.5)		1 (0.3)
MIDAZOLAM HYDROCHLORIDE	1 (0.5)		1 (0.3)
MIDECAMYCIN ACETATE		1 (0.6)	1 (0.3)
MIDOL / [redacted]	1 (0.5)		1 (0.3)
MIRTAZAPINE		1 (0.6)	1 (0.3)
MOXIFLOXACIN HYDROCHLORIDE	1 (0.5)		1 (0.3)
MUCALTIN / [redacted]	1 (0.5)		1 (0.3)
MULTIVITAMINS, OTHER COMBINATIONS		1 (0.6)	1 (0.3)
MULTIVITAMINS, PLAIN		1 (0.6)	1 (0.3)
MUPIROCIN		1 (0.6)	1 (0.3)
MYLANTA-II / [redacted]	1 (0.5)		1 (0.3)
NARINE / [redacted]	1 (0.5)		1 (0.3)
NEO ANGIN / [redacted]		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
NEOSTIGMINE	1 (0.5)		1 (0.3)
NIMESULIDE	1 (0.5)		1 (0.3)
NO-FLU F		1 (0.6)	1 (0.3)
NUROFEN COLD AND FLU	1 (0.5)		1 (0.3)
OFLOXACIN	1 (0.5)		1 (0.3)
OLEA EUROPAEA LEAF EXTRACT	1 (0.5)		1 (0.3)
ONDANSETRON HYDROCHLORIDE	1 (0.5)		1 (0.3)
ORASOL		1 (0.6)	1 (0.3)
OROFAR / [redacted]	1 (0.5)		1 (0.3)
OTHER ANTIDIARRHEALS	1 (0.5)		1 (0.3)
OTHER COUGH SUPPRESSANTS	1 (0.5)		1 (0.3)
OTHER I.V. SOLUTION ADDITIVES	1 (0.5)		1 (0.3)
OTHER RESPIRATORY SYSTEM PRODUCTS		1 (0.6)	1 (0.3)
OTIX / [redacted]		1 (0.6)	1 (0.3)
OXYCODONE HYDROCHLORIDE		1 (0.6)	1 (0.3)
PANADEINE CO	1 (0.5)		1 (0.3)
PAPILLOMAVIRUS VACCINES	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
PARADRYL EXPECT		1 (0.6)	1 (0.3)
PARAFFIN, LIQUID	1 (0.5)		1 (0.3)
PECTIN		1 (0.6)	1 (0.3)
PELARGONIUM SIDOIDES		1 (0.6)	1 (0.3)
PERMETHRIN		1 (0.6)	1 (0.3)
PHENOXYMETHYLPENICILLIN POTASSIUM		1 (0.6)	1 (0.3)
PHENYLEPHRINE		1 (0.6)	1 (0.3)
PHENYLEPHRINE HYDROCHLORIDE	1 (0.5)		1 (0.3)
PROBIOTICS / [redacted]		1 (0.6)	1 (0.3)
PROBUCOL		1 (0.6)	1 (0.3)
PROCAINE HYDROCHLORIDE		1 (0.6)	1 (0.3)
PROCET / [redacted]	1 (0.5)		1 (0.3)
PROPOFOL	1 (0.5)		1 (0.3)
PROVAX		1 (0.6)	1 (0.3)
PSEUDOEPHEDRINE	1 (0.5)		1 (0.3)
PYRANTEL EMBONATE		1 (0.6)	1 (0.3)
RACECADOTRIL		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
RANITIDINE		1 (0.6)	1 (0.3)
RAPOLYTE		1 (0.6)	1 (0.3)
REHIDRAT		1 (0.6)	1 (0.3)
ROCURONIUM	1 (0.5)		1 (0.3)
ROXITHROMYCIN	1 (0.5)		1 (0.3)
SALICYLIC ACID		1 (0.6)	1 (0.3)
SAMBUCUS NIGRA		1 (0.6)	1 (0.3)
SEDINAL	1 (0.5)		1 (0.3)
SERETIDE		1 (0.6)	1 (0.3)
SERTRALINE HYDROCHLORIDE		1 (0.6)	1 (0.3)
SEVOFLURANE	1 (0.5)		1 (0.3)
SILICON DIOXIDE	1 (0.5)		1 (0.3)
SINGLET / [redacted]	1 (0.5)		1 (0.3)
SOFRASOLONE O.R.L.	1 (0.5)		1 (0.3)
SPEKTRAMOX	1 (0.5)		1 (0.3)
SUPRAGESIC / [redacted]		1 (0.6)	1 (0.3)
TETRYZOLINE HYDROCHLORIDE		1 (0.6)	1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
THIOCTIC ACID		1 (0.6)	1 (0.3)
THOMAPYRIN N	1 (0.5)		1 (0.3)
TOBRAMYCIN		1 (0.6)	1 (0.3)
TOLPERISONE HYDROCHLORIDE		1 (0.6)	1 (0.3)
TRIOGESIC		1 (0.6)	1 (0.3)
TROPICAMIDE	1 (0.5)		1 (0.3)
TROSPIUM CHLORIDE		1 (0.6)	1 (0.3)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		1 (0.6)	1 (0.3)
VICKS FORMULA 44 SORE THROAT	1 (0.5)		1 (0.3)
VICKS NYQUIL COLD AND FLU MULTI-SYMPTOM	1 (0.5)		1 (0.3)
VILAZODONE HYDROCHLORIDE		1 (0.6)	1 (0.3)
VITAMIN D NOS		1 (0.6)	1 (0.3)
VITAMINS / [redacted]	1 (0.5)		1 (0.3)
VITAMINS, OTHER COMBINATIONS	1 (0.5)		1 (0.3)
XYLOMETAZOLINE	1 (0.5)		1 (0.3)
YEAST DRIED		1 (0.6)	1 (0.3)
ZINC GLUCONATE	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

Concomitant medication started after screening – summary - full analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
ZINPLEX JUNIOR	1 (0.5)		1 (0.3)
ZONISAMIDE	1 (0.5)		1 (0.3)

N= Number of subjects
%= Percentage of subjects
Generic names of the drugs are presented.

14.2 Efficacy data

14.2.1 Exposure - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Total Exposure, yrs	54.77	53.92	108.7
Exposure (yrs)			
N	181	179	360
Mean (SD)	0.30 (0.03)	0.30 (0.04)	0.30 (0.04)
Median	0.31	0.31	0.31
Min ; Max	0.06 ; 0.35	0.02 ; 0.34	0.02 ; 0.35

N: Number of subjects, SD: Standard deviation, yrs: Years

14.2.2 Exposure by treatment week - summary - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Exposed , N (%)			
N	181 (100.0)	179 (100.0)	360 (100.0)
1 - 4 Weeks	1 (0.6)	3 (1.7)	4 (1.1)
5 - 8 Weeks	2 (1.1)	2 (1.1)	4 (1.1)
9 - 12 Weeks	3 (1.7)	0 (0.0)	3 (0.8)
13 - 16 Weeks	102 (56.4)	95 (53.1)	197 (54.7)
17 - 20 Weeks	73 (40.3)	79 (44.1)	152 (42.2)

N: Number of subjects
%: Percentage of subjects

14.2.3 Exposure by sex and treatment week - summary - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Exposure, yrs (%)			
Total	54.8 (100.0)	53.9 (100.0)	108.7 (100.0)
Female	27.8 (50.8)	28.3 (52.5)	56.1 (51.6)
Male	27.0 (49.2)	25.6 (47.5)	52.6 (48.4)
Exposed Female, N (%)			
N	93 (100.0)	94 (100.0)	187 (100.0)
1 - 4 Weeks	1 (1.1)	1 (1.1)	2 (1.1)
5 - 8 Weeks	1 (1.1)	2 (2.1)	3 (1.6)
9 - 12 Weeks	3 (3.2)	0 (0.0)	3 (1.6)
13 - 16 Weeks	53 (57.0)	50 (53.2)	103 (55.1)
17 - 20 Weeks	35 (37.6)	41 (43.6)	76 (40.6)
Exposed Male, N (%)			
N	88 (100.0)	85 (100.0)	173 (100.0)
1 - 4 Weeks	0 (0.0)	2 (2.4)	2 (1.2)
5 - 8 Weeks	1 (1.1)	0 (0.0)	1 (0.6)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	49 (55.7)	45 (52.9)	94 (54.3)
17 - 20 Weeks	38 (43.2)	38 (44.7)	76 (43.9)

N: Number of subjects
%: Percentage of subjects
yrs: Years

14.2.4 Exposure by race and treatment week - summary - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Exposure, yrs (%)			
Total	54.8 (100.0)	53.9 (100.0)	108.7 (100.0)
White	51.0 (93.1)	50.3 (93.2)	101.3 (93.2)
Black	2.2 (4.1)	1.2 (2.3)	3.5 (3.2)
Asian Indian	0.0 (0.0)	0.3 (0.6)	0.3 (0.3)
Asian non-Indian	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
American Indian	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Pacific Islander	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Other	1.5 (2.8)	2.1 (3.9)	3.6 (3.4)
NA	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Exposed White, N (%)			
N	168 (100.0)	167 (100.0)	335 (100.0)
1 - 4 Weeks	1 (0.6)	3 (1.8)	4 (1.2)
5 - 8 Weeks	1 (0.6)	2 (1.2)	3 (0.9)
9 - 12 Weeks	3 (1.8)	0 (0.0)	3 (0.9)
13 - 16 Weeks	95 (56.5)	88 (52.7)	183 (54.6)
17 - 20 Weeks	68 (40.5)	74 (44.3)	142 (42.4)
Exposed Black, N (%)			
N	8 (100.0)	4 (100.0)	12 (100.0)
1 - 4 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
5 - 8 Weeks	1 (12.5)	0 (0.0)	1 (8.3)
9 - 12 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
13 - 16 Weeks	3 (37.5)	3 (75.0)	6 (50.0)
17 - 20 Weeks	4 (50.0)	1 (25.0)	5 (41.7)
Exposed Asian Indian, N (%)			
N	0 (0.0)	1 (100.0)	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)	1 (100.0)	1 (100.0)
Exposed Asian non-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)

N: Number of subjects
%: Percentage of subjects, NA: Not applicable
yrs: Years, Black: Black or african american
American Indian: American indian or alaska Native
Pacific Islander: Native hawaiian or other pacific islander

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)
Exposed Pacific Islander, 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)
Exposed Other, N (%)			
N	5 (100.0)	7 (100.0)	12 (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	4 (80.0)	4 (57.1)	8 (66.7)
17 - 20 Weeks	1 (20.0)	3 (42.9)	4 (33.3)
Exposed NA, 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)

N: Number of subjects
%: Percentage of subjects, NA: Not applicable
yrs: Years, Black: Black or african american
American Indian: American indian or alaska Native
Pacific Islander: Native hawaiian or other pacific islander

14.2.5 Exposure by ethnicity and treatment week - summary - safety analysis set

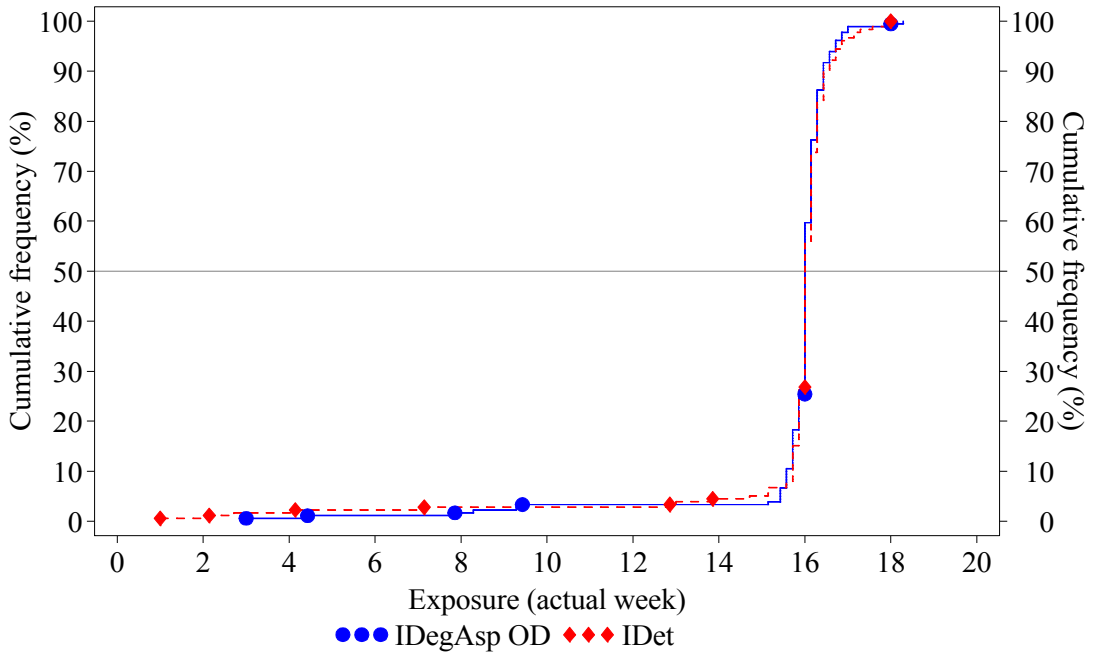
	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Exposure, yrs (%)			
Total	54.8 (100.0)	53.9 (100.0)	108.7 (100.0)
Hispanic	4.5 (8.2)	4.0 (7.4)	8.5 (7.8)
Not Hispanic	50.3 (91.8)	49.9 (92.6)	100.2 (92.2)
NA	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Exposed Hispanic, N (%)			
N	15 (100.0)	13 (100.0)	28 (100.0)
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	1 (6.7)	0 (0.0)	1 (3.6)
13 - 16 Weeks	9 (60.0)	6 (46.2)	15 (53.6)
17 - 20 Weeks	5 (33.3)	7 (53.8)	12 (42.9)
Exposed Not Hispanic, N (%)			
N	166 (100.0)	166 (100.0)	332 (100.0)
1 - 4 Weeks	1 (0.6)	3 (1.8)	4 (1.2)
5 - 8 Weeks	2 (1.2)	2 (1.2)	4 (1.2)
9 - 12 Weeks	2 (1.2)	0 (0.0)	2 (0.6)
13 - 16 Weeks	93 (56.0)	89 (53.6)	182 (54.8)
17 - 20 Weeks	68 (41.0)	72 (43.4)	140 (42.2)
Exposed NA, 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)

N: Number of subjects
%: Percentage of subjects
NA: Not applicable, yrs: Years
Hispanic: Hispanic or latino

14.2.6 Exposure by age group and treatment week - summary - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Exposure, yrs (%)			
Total	54.8 (100.0)	53.9 (100.0)	108.7 (100.0)
Children (1-5 yrs)	12.0 (21.9)	12.2 (22.7)	24.2 (22.3)
Children (6-11 years)	18.7 (34.1)	18.3 (34.0)	37.0 (34.1)
Adolescents (12-17 years)	24.1 (44.0)	23.3 (43.3)	47.4 (43.6)
Exposed Children (1-5 yrs), N (%)			
N	40 (100.0)	41 (100.0)	81 (100.0)
1 - 4 Weeks	0 (0.0)	1 (2.4)	1 (1.2)
5 - 8 Weeks	1 (2.5)	0 (0.0)	1 (1.2)
9 - 12 Weeks	1 (2.5)	0 (0.0)	1 (1.2)
13 - 16 Weeks	21 (52.5)	26 (63.4)	47 (58.0)
17 - 20 Weeks	17 (42.5)	14 (34.1)	31 (38.3)
Exposed Children (6-11 years), N (%)			
N	61 (100.0)	61 (100.0)	122 (100.0)
1 - 4 Weeks	0 (0.0)	2 (3.3)	2 (1.6)
5 - 8 Weeks	0 (0.0)	0 (0.0)	0 (0.0)
9 - 12 Weeks	1 (1.6)	0 (0.0)	1 (0.8)
13 - 16 Weeks	36 (59.0)	28 (45.9)	64 (52.5)
17 - 20 Weeks	24 (39.3)	31 (50.8)	55 (45.1)
Exposed Adolescents (12-17 years), N (%)			
N	80 (100.0)	77 (100.0)	157 (100.0)
1 - 4 Weeks	1 (1.3)	0 (0.0)	1 (0.6)
5 - 8 Weeks	1 (1.3)	2 (2.6)	3 (1.9)
9 - 12 Weeks	1 (1.3)	0 (0.0)	1 (0.6)
13 - 16 Weeks	45 (56.3)	41 (53.2)	86 (54.8)
17 - 20 Weeks	32 (40.0)	34 (44.2)	66 (42.0)

N: Number of subjects
%: Percentage of subjects, yrs: Years



SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:34:55 - 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

				Descriptive Statistics					
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	19	14	15	1	100
		IDet	179	179	17	13	14	1	65
		Total	360	360	18	14	15	1	100
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	20	14	15	1	90
		IDet	179	178	18	14	14	1	74
		Total	360	359	19	14	15	1	90
Visit 5 (Week 3)	Daily	IDegAsp OD	181	180	21	15	16	1	82
		IDet	179	176	19	15	15	1	79
		Total	360	356	20	15	16	1	82
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	21	15	18	1	80
		IDet	179	176	20	15	15	1	82
		Total	360	355	20	15	17	1	82
Visit 7 (Week 5)	Daily	IDegAsp OD	181	179	21	15	18	2	80
		IDet	179	174	20	15	15	1	84
		Total	360	353	21	15	17	1	84
Visit 8 (Week 6)	Daily	IDegAsp OD	181	179	21	15	18	2	80
		IDet	179	174	20	15	15	1	88
		Total	360	353	21	15	17	1	88
Visit 9 (Week 7)	Daily	IDegAsp OD	181	178	22	15	18	2	80
		IDet	179	172	20	16	17	1	96
		Total	360	350	21	15	17	1	96
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	22	15	18	2	80
		IDet	179	173	21	16	17	1	98
		Total	360	350	21	15	18	1	98
Visit 11 (Week 9)	Daily	IDegAsp OD	181	177	22	16	19	2	80
		IDet	179	173	21	16	17	1	98
		Total	360	350	22	16	18	1	98
Visit 12 (Week 10)	Daily	IDegAsp OD	181	175	22	15	19	2	80
		IDet	179	172	22	17	17	1	103
		Total	360	347	22	16	18	1	103
Visit 13 (Week 11)	Daily	IDegAsp OD	181	175	22	16	19	2	80
		IDet	179	172	22	17	17	1	100
		Total	360	347	22	16	18	1	100
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	22	16	19	2	82
		IDet	179	172	22	17	17	1	83
		Total	360	347	22	16	18	1	83

N: Number of subjects, SD: Standard deviation

IDegAsp/Comparator insulin dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	175	22	16	18	2	86
		IDet	179	172	22	17	17	1	86
		Total	360	347	22	17	17	1	86
Visit 16 (Week 14)	Daily	IDegAsp OD	181	175	23	16	19	2	86
		IDet	179	169	21	16	16	1	75
		Total	360	344	22	16	18	1	86
Visit 17 (Week 15)	Daily	IDegAsp OD	181	173	23	17	19	2	86
		IDet	179	170	22	17	17	1	76
		Total	360	343	23	17	18	1	86
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	23	17	19	2	86
		IDet	179	167	22	17	17	1	76
		Total	360	340	23	17	18	1	86
End of trial visit	Daily	IDegAsp OD	181	181	23	17	19	2	86
		IDet	179	179	23	18	17	1	86
		Total	360	360	23	17	19	1	86

N: Number of subjects, SD: Standard deviation

14.2.9 IDegAsp/Comparator insulin dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	7	4	6	1	17
		IDet	41	41	5	3	5	1	15
		Total	81	81	6	3	5	1	17
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	8	4	7	1	17
		IDet	41	41	5	3	6	1	13
		Total	81	81	7	3	6	1	17
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	8	4	7	1	19
		IDet	41	40	6	3	6	1	13
		Total	81	80	7	4	6	1	19
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	8	4	7	1	19
		IDet	41	40	6	3	6	1	13
		Total	81	80	7	4	6	1	19
Visit 7 (Week 5)	Daily	IDegAsp OD	40	40	8	4	8	2	19
		IDet	41	40	6	3	6	1	13
		Total	81	80	7	4	6	1	19
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	8	4	7	2	19
		IDet	41	40	6	4	6	1	15
		Total	81	80	7	4	7	1	19
Visit 9 (Week 7)	Daily	IDegAsp OD	40	40	8	4	7	2	21
		IDet	41	40	7	4	6	1	17
		Total	81	80	7	4	7	1	21
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	8	5	8	2	21
		IDet	41	40	7	4	6	1	19
		Total	81	79	8	4	7	1	21
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	8	5	8	2	19
		IDet	41	40	7	4	6	1	19
		Total	81	78	8	5	7	1	19
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	9	4	8	2	19
		IDet	41	39	7	5	7	1	21
		Total	81	77	8	5	7	1	21
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	8	5	8	2	19
		IDet	41	39	7	4	6	1	21
		Total	81	77	8	5	7	1	21
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	9	5	8	2	25
		IDet	41	39	7	5	6	1	23
		Total	81	77	8	5	7	1	25

N: Number of subjects, SD: Standard deviation

IDegAsp/Comparator insulin dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	9	5	8	2	25
		IDet	41	39	7	5	6	1	25
		Total	81	77	8	5	7	1	25
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	9	5	8	2	25
		IDet	41	39	7	5	7	1	29
		Total	81	77	8	5	7	1	29
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	9	5	8	2	25
		IDet	41	38	7	5	6	1	30
		Total	81	76	8	5	7	1	30
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	9	5	8	2	23
		IDet	41	37	7	6	7	1	32
		Total	81	75	8	5	7	1	32
End of trial visit	Daily	IDegAsp OD	40	40	9	5	8	2	23
		IDet	41	41	8	6	7	1	32
		Total	81	81	8	5	7	1	32

N: Number of subjects, SD: Standard deviation

14.2.10 IDegAsp/Comparator insulin dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	61	61	14	8	13	4	45
		IDet	61	61	14	9	11	1	40
		Total	122	122	14	9	12	1	45
Visit 4 (Week 2)	Daily	IDegAsp OD	61	61	14	9	13	4	45
		IDet	61	60	14	9	12	1	45
		Total	122	121	14	9	12	1	45
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	15	9	13	4	45
		IDet	61	59	15	9	13	1	48
		Total	122	119	15	9	13	1	48
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	16	9	13	4	45
		IDet	61	59	16	10	14	1	49
		Total	122	119	16	9	13	1	49
Visit 7 (Week 5)	Daily	IDegAsp OD	61	61	16	9	13	4	43
		IDet	61	59	16	10	14	1	52
		Total	122	120	16	10	13	1	52
Visit 8 (Week 6)	Daily	IDegAsp OD	61	61	16	9	13	4	46
		IDet	61	59	16	10	13	1	54
		Total	122	120	16	10	13	1	54
Visit 9 (Week 7)	Daily	IDegAsp OD	61	61	16	9	13	4	50
		IDet	61	59	16	11	13	1	54
		Total	122	120	16	10	13	1	54
Visit 10 (Week 8)	Daily	IDegAsp OD	61	61	16	10	13	4	50
		IDet	61	59	17	11	14	1	53
		Total	122	120	16	10	13	1	53
Visit 11 (Week 9)	Daily	IDegAsp OD	61	61	16	10	13	4	48
		IDet	61	59	17	11	14	1	52
		Total	122	120	17	10	14	1	52
Visit 12 (Week 10)	Daily	IDegAsp OD	61	60	16	9	13	4	44
		IDet	61	59	17	11	15	1	54
		Total	122	119	16	10	14	1	54
Visit 13 (Week 11)	Daily	IDegAsp OD	61	60	16	9	13	4	46
		IDet	61	59	18	11	15	1	58
		Total	122	119	17	10	14	1	58
Visit 14 (Week 12)	Daily	IDegAsp OD	61	60	16	9	13	5	46
		IDet	61	59	18	11	15	1	60
		Total	122	119	17	10	14	1	60

N: Number of subjects, SD: Standard deviation

IDegAsp/Comparator insulin dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	61	60	16	9	14	5	46
		IDet	61	59	18	11	15	1	60
		Total	122	119	17	10	14	1	60
Visit 16 (Week 14)	Daily	IDegAsp OD	61	60	16	9	14	4	46
		IDet	61	59	18	11	15	1	60
		Total	122	119	17	10	14	1	60
Visit 17 (Week 15)	Daily	IDegAsp OD	61	60	16	9	14	5	46
		IDet	61	59	18	11	15	1	60
		Total	122	119	17	10	14	1	60
Visit 18 (Week 16)	Daily	IDegAsp OD	61	59	16	9	14	5	50
		IDet	61	59	18	12	15	2	60
		Total	122	118	17	11	15	2	60
End of trial visit	Daily	IDegAsp OD	61	61	17	10	14	5	50
		IDet	61	61	19	12	16	2	60
		Total	122	122	18	11	15	2	60

N: Number of subjects, SD: Standard deviation

14.2.11 IDegAsp/Comparator insulin dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	80	29	15	26	3	100
		IDet	77	77	26	13	22	5	65
		Total	157	157	28	14	25	3	100
Visit 4 (Week 2)	Daily	IDegAsp OD	80	80	30	14	28	4	90
		IDet	77	77	28	14	24	5	74
		Total	157	157	29	14	27	4	90
Visit 5 (Week 3)	Daily	IDegAsp OD	80	80	31	14	30	3	82
		IDet	77	77	29	15	27	5	79
		Total	157	157	30	14	28	3	82
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	32	14	31	3	80
		IDet	77	77	30	15	27	6	82
		Total	157	156	31	15	29	3	82
Visit 7 (Week 5)	Daily	IDegAsp OD	80	78	32	14	32	4	80
		IDet	77	75	30	15	28	6	84
		Total	157	153	31	15	29	4	84
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	33	14	32	4	80
		IDet	77	75	31	15	28	7	88
		Total	157	153	32	15	30	4	88
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	33	14	31	3	80
		IDet	77	73	31	16	28	7	96
		Total	157	150	32	15	30	3	96
Visit 10 (Week 8)	Daily	IDegAsp OD	80	77	33	14	32	4	80
		IDet	77	74	31	16	28	7	98
		Total	157	151	32	15	30	4	98
Visit 11 (Week 9)	Daily	IDegAsp OD	80	78	34	15	33	4	80
		IDet	77	74	32	17	28	8	98
		Total	157	152	33	16	31	4	98
Visit 12 (Week 10)	Daily	IDegAsp OD	80	77	34	15	31	4	80
		IDet	77	74	33	18	28	8	103
		Total	157	151	33	16	30	4	103
Visit 13 (Week 11)	Daily	IDegAsp OD	80	77	34	15	31	5	80
		IDet	77	74	33	18	28	8	100
		Total	157	151	34	16	30	5	100
Visit 14 (Week 12)	Daily	IDegAsp OD	80	77	34	15	32	5	82
		IDet	77	74	33	17	28	8	83
		Total	157	151	34	16	30	5	83

N: Number of subjects, SD: Standard deviation

IDegAsp/Comparator insulin dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	34	16	31	5	86
		IDet	77	74	33	17	29	9	86
		Total	157	151	34	16	30	5	86
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	35	16	32	5	86
		IDet	77	71	32	16	29	9	75
		Total	157	148	33	16	30	5	86
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	35	16	33	6	86
		IDet	77	73	33	17	30	9	76
		Total	157	148	34	16	32	6	86
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	35	16	33	6	86
		IDet	77	71	33	17	30	9	76
		Total	157	147	34	17	32	6	86
End of trial visit	Daily	IDegAsp OD	80	80	36	17	34	6	86
		IDet	77	77	35	18	31	9	86
		Total	157	157	35	17	33	6	86

N: Number of subjects, SD: Standard deviation

14.2.12 IDegAsp/Comparator insulin dose (prescribed) in units by treatment week - descriptive statistics - safety analysis set

			-Descriptive Statistics-						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	20	14	15	1	90
		IDet	179	178	18	14	14	1	74
		Total	360	359	19	14	15	1	90
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	21	15	16	1	85
		IDet	179	177	19	15	16	1	79
		Total	360	358	20	15	16	1	85
Visit 5 (Week 3)	Daily	IDegAsp OD	181	181	21	15	18	1	80
		IDet	179	175	20	15	15	1	82
		Total	360	356	20	15	17	1	82
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	21	15	18	1	80
		IDet	179	175	20	16	16	1	84
		Total	360	354	21	15	17	1	84
Visit 7 (Week 5)	Daily	IDegAsp OD	181	178	21	15	18	1	80
		IDet	179	174	20	16	15	1	88
		Total	360	352	21	15	17	1	88
Visit 8 (Week 6)	Daily	IDegAsp OD	181	179	22	15	18	2	80
		IDet	179	174	21	16	16	1	96
		Total	360	353	21	16	17	1	96
Visit 9 (Week 7)	Daily	IDegAsp OD	181	177	22	15	18	2	80
		IDet	179	172	21	16	17	1	98
		Total	360	349	21	16	17	1	98
Visit 10 (Week 8)	Daily	IDegAsp OD	181	176	22	15	19	2	80
		IDet	179	174	22	16	17	1	96
		Total	360	350	22	16	18	1	96
Visit 11 (Week 9)	Daily	IDegAsp OD	181	176	22	16	19	2	80
		IDet	179	173	22	17	17	1	106
		Total	360	349	22	16	18	1	106
Visit 12 (Week 10)	Daily	IDegAsp OD	181	175	22	16	19	2	80
		IDet	179	172	22	17	17	1	100
		Total	360	347	22	16	18	1	100
Visit 13 (Week 11)	Daily	IDegAsp OD	181	175	22	16	18	2	82
		IDet	179	172	22	17	17	1	94
		Total	360	347	22	17	18	1	94
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	23	16	19	2	86
		IDet	179	172	22	17	17	1	86
		Total	360	347	22	17	18	1	86

N: Number of subjects, SD: Standard deviation

IDegAsp/Comparator insulin dose (prescribed) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	175	23	16	19	2	86
		IDet	179	171	22	17	17	1	76
		Total	360	346	22	17	18	1	86
Visit 16 (Week 14)	Daily	IDegAsp OD	181	174	23	17	19	2	86
		IDet	179	168	22	16	16	1	76
		Total	360	342	22	16	18	1	86
Visit 17 (Week 15)	Daily	IDegAsp OD	181	172	23	17	19	2	86
		IDet	179	169	23	17	17	1	76
		Total	360	341	23	17	18	1	86
End of trial visit	Daily	IDegAsp OD	181	181	24	17	19	2	86
		IDet	179	178	23	18	18	1	86
		Total	360	359	23	17	19	1	86

N: Number of subjects, SD: Standard deviation

14.2.13 IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	0.44	0.19	0.43	0.04	1.06
		IDet	179	179	0.38	0.21	0.34	0.05	1.17
		Total	360	360	0.41	0.20	0.38	0.04	1.17
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	0.46	0.19	0.43	0.04	1.16
		IDet	179	178	0.40	0.21	0.36	0.05	1.13
		Total	360	359	0.43	0.20	0.39	0.04	1.16
Visit 5 (Week 3)	Daily	IDegAsp OD	181	180	0.48	0.20	0.47	0.04	1.10
		IDet	179	176	0.42	0.22	0.38	0.05	1.13
		Total	360	356	0.45	0.21	0.42	0.04	1.13
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	0.49	0.20	0.49	0.04	1.08
		IDet	179	176	0.43	0.22	0.39	0.05	1.19
		Total	360	355	0.46	0.21	0.43	0.04	1.19
Visit 7 (Week 5)	Daily	IDegAsp OD	181	179	0.50	0.20	0.50	0.05	1.02
		IDet	179	174	0.44	0.22	0.39	0.05	1.25
		Total	360	353	0.47	0.22	0.43	0.05	1.25
Visit 8 (Week 6)	Daily	IDegAsp OD	181	179	0.50	0.20	0.51	0.05	1.02
		IDet	179	174	0.45	0.23	0.40	0.05	1.23
		Total	360	353	0.48	0.22	0.44	0.05	1.23
Visit 9 (Week 7)	Daily	IDegAsp OD	181	178	0.51	0.21	0.51	0.04	1.02
		IDet	179	172	0.46	0.24	0.40	0.05	1.34
		Total	360	350	0.48	0.22	0.44	0.04	1.34
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	0.51	0.21	0.51	0.05	1.02
		IDet	179	173	0.46	0.25	0.42	0.05	1.36
		Total	360	350	0.49	0.23	0.45	0.05	1.36
Visit 11 (Week 9)	Daily	IDegAsp OD	181	177	0.52	0.21	0.51	0.05	1.02
		IDet	179	173	0.47	0.25	0.43	0.05	1.47
		Total	360	350	0.50	0.23	0.46	0.05	1.47
Visit 12 (Week 10)	Daily	IDegAsp OD	181	175	0.51	0.21	0.50	0.05	1.04
		IDet	179	172	0.48	0.26	0.43	0.05	1.53
		Total	360	347	0.50	0.24	0.46	0.05	1.53
Visit 13 (Week 11)	Daily	IDegAsp OD	181	175	0.52	0.22	0.50	0.06	1.04
		IDet	179	172	0.48	0.26	0.43	0.05	1.65
		Total	360	347	0.50	0.24	0.46	0.05	1.65
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	0.50	0.21	0.48	0.06	1.08
		IDet	179	172	0.48	0.26	0.43	0.05	1.70
		Total	360	347	0.49	0.23	0.45	0.05	1.70

N: Number of subjects, SD: Standard deviation

IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	175	0.51	0.21	0.50	0.06	1.08
		IDet	179	172	0.48	0.26	0.44	0.05	1.70
		Total	360	347	0.49	0.24	0.46	0.05	1.70
Visit 16 (Week 14)	Daily	IDegAsp OD	181	175	0.51	0.21	0.50	0.07	1.11
		IDet	179	169	0.48	0.26	0.44	0.05	1.70
		Total	360	344	0.50	0.24	0.47	0.05	1.70
Visit 17 (Week 15)	Daily	IDegAsp OD	181	173	0.52	0.21	0.50	0.07	1.17
		IDet	179	170	0.49	0.27	0.44	0.05	1.70
		Total	360	343	0.50	0.24	0.48	0.05	1.70
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	0.51	0.21	0.51	0.07	1.19
		IDet	179	167	0.49	0.27	0.45	0.05	1.77
		Total	360	340	0.50	0.24	0.47	0.05	1.77
End of trial visit	Daily	IDegAsp OD	181	181	0.52	0.22	0.51	0.07	1.19
		IDet	179	179	0.50	0.27	0.46	0.05	1.77
		Total	360	360	0.51	0.25	0.48	0.05	1.77

N: Number of subjects, SD: Standard deviation

14.2.14 IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics					
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	0.38	0.17	0.35	0.04	0.91
		IDet	41	41	0.29	0.16	0.26	0.05	0.86
		Total	81	81	0.33	0.17	0.31	0.04	0.91
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	0.40	0.17	0.38	0.04	0.83
		IDet	41	41	0.31	0.16	0.29	0.06	0.72
		Total	81	81	0.35	0.17	0.33	0.04	0.83
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	0.41	0.18	0.38	0.04	0.83
		IDet	41	40	0.32	0.17	0.31	0.05	0.83
		Total	81	80	0.37	0.18	0.34	0.04	0.83
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	0.41	0.18	0.38	0.04	0.83
		IDet	41	40	0.34	0.17	0.34	0.05	0.79
		Total	81	80	0.37	0.18	0.36	0.04	0.83
Visit 7 (Week 5)	Daily	IDegAsp OD	40	40	0.42	0.18	0.38	0.07	0.82
		IDet	41	40	0.34	0.18	0.34	0.05	0.79
		Total	81	80	0.38	0.18	0.37	0.05	0.82
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	0.43	0.19	0.40	0.07	0.83
		IDet	41	40	0.37	0.21	0.35	0.05	0.90
		Total	81	80	0.40	0.20	0.37	0.05	0.90
Visit 9 (Week 7)	Daily	IDegAsp OD	40	40	0.43	0.19	0.41	0.07	0.83
		IDet	41	40	0.37	0.23	0.36	0.05	1.02
		Total	81	80	0.40	0.21	0.37	0.05	1.02
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	0.44	0.19	0.42	0.07	0.83
		IDet	41	40	0.38	0.25	0.36	0.08	1.14
		Total	81	79	0.41	0.22	0.38	0.07	1.14
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	0.44	0.19	0.42	0.07	0.83
		IDet	41	40	0.39	0.26	0.34	0.06	1.14
		Total	81	78	0.42	0.23	0.39	0.06	1.14
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	0.44	0.20	0.42	0.07	0.83
		IDet	41	39	0.39	0.25	0.35	0.08	1.26
		Total	81	77	0.41	0.22	0.40	0.07	1.26
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	0.44	0.20	0.42	0.07	0.85
		IDet	41	39	0.38	0.24	0.32	0.08	1.26
		Total	81	77	0.41	0.22	0.37	0.07	1.26
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	0.43	0.19	0.41	0.07	0.79
		IDet	41	39	0.38	0.24	0.35	0.08	1.27
		Total	81	77	0.40	0.22	0.37	0.07	1.27

N: Number of subjects, SD: Standard deviation

IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	0.44	0.20	0.42	0.07	0.86
		IDet	41	39	0.39	0.25	0.34	0.08	1.38
		Total	81	77	0.41	0.23	0.38	0.07	1.38
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	0.45	0.20	0.43	0.07	0.86
		IDet	41	39	0.39	0.28	0.34	0.08	1.60
		Total	81	77	0.42	0.24	0.41	0.07	1.60
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	0.45	0.20	0.42	0.07	0.86
		IDet	41	38	0.40	0.29	0.37	0.08	1.66
		Total	81	76	0.42	0.25	0.40	0.07	1.66
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	0.44	0.18	0.43	0.07	0.81
		IDet	41	37	0.40	0.30	0.37	0.08	1.77
		Total	81	75	0.42	0.25	0.39	0.07	1.77
End of trial visit	Daily	IDegAsp OD	40	40	0.44	0.18	0.43	0.07	0.81
		IDet	41	41	0.42	0.31	0.38	0.08	1.77
		Total	81	81	0.43	0.25	0.40	0.07	1.77

N: Number of subjects, SD: Standard deviation

14.2.15 IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	61	61	0.42	0.17	0.43	0.11	0.78
		IDet	61	61	0.39	0.23	0.34	0.05	1.17
		Total	122	122	0.40	0.20	0.38	0.05	1.17
Visit 4 (Week 2)	Daily	IDegAsp OD	61	61	0.44	0.18	0.43	0.14	0.86
		IDet	61	60	0.40	0.22	0.36	0.05	1.13
		Total	122	121	0.42	0.20	0.39	0.05	1.13
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	0.46	0.18	0.44	0.14	0.86
		IDet	61	59	0.42	0.22	0.37	0.05	1.13
		Total	122	119	0.44	0.20	0.40	0.05	1.13
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	0.47	0.18	0.45	0.14	0.80
		IDet	61	59	0.43	0.23	0.39	0.05	1.19
		Total	122	119	0.45	0.21	0.40	0.05	1.19
Visit 7 (Week 5)	Daily	IDegAsp OD	61	61	0.47	0.19	0.42	0.14	0.87
		IDet	61	59	0.45	0.24	0.39	0.05	1.25
		Total	122	120	0.46	0.21	0.42	0.05	1.25
Visit 8 (Week 6)	Daily	IDegAsp OD	61	61	0.48	0.19	0.45	0.14	0.90
		IDet	61	59	0.45	0.23	0.39	0.05	1.19
		Total	122	120	0.46	0.21	0.42	0.05	1.19
Visit 9 (Week 7)	Daily	IDegAsp OD	61	61	0.47	0.19	0.45	0.14	0.97
		IDet	61	59	0.45	0.24	0.39	0.05	1.30
		Total	122	120	0.46	0.22	0.42	0.05	1.30
Visit 10 (Week 8)	Daily	IDegAsp OD	61	61	0.48	0.19	0.46	0.14	0.97
		IDet	61	59	0.47	0.25	0.40	0.05	1.36
		Total	122	120	0.47	0.22	0.44	0.05	1.36
Visit 11 (Week 9)	Daily	IDegAsp OD	61	61	0.48	0.19	0.45	0.14	0.93
		IDet	61	59	0.47	0.25	0.43	0.05	1.47
		Total	122	120	0.48	0.22	0.44	0.05	1.47
Visit 12 (Week 10)	Daily	IDegAsp OD	61	60	0.48	0.18	0.46	0.15	0.84
		IDet	61	59	0.48	0.25	0.43	0.05	1.53
		Total	122	119	0.48	0.22	0.44	0.05	1.53
Visit 13 (Week 11)	Daily	IDegAsp OD	61	60	0.48	0.18	0.45	0.16	0.95
		IDet	61	59	0.49	0.26	0.44	0.05	1.65
		Total	122	119	0.48	0.22	0.44	0.05	1.65
Visit 14 (Week 12)	Daily	IDegAsp OD	61	60	0.46	0.17	0.44	0.16	0.89
		IDet	61	59	0.48	0.27	0.43	0.05	1.70
		Total	122	119	0.47	0.22	0.43	0.05	1.70

N: Number of subjects, SD: Standard deviation

IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	61	60	0.46	0.17	0.45	0.16	0.96
		IDet	61	59	0.48	0.27	0.43	0.05	1.70
		Total	122	119	0.47	0.22	0.44	0.05	1.70
Visit 16 (Week 14)	Daily	IDegAsp OD	61	60	0.46	0.17	0.46	0.14	0.96
		IDet	61	59	0.49	0.27	0.43	0.05	1.70
		Total	122	119	0.47	0.22	0.44	0.05	1.70
Visit 17 (Week 15)	Daily	IDegAsp OD	61	60	0.47	0.17	0.47	0.16	0.96
		IDet	61	59	0.49	0.27	0.44	0.05	1.70
		Total	122	119	0.48	0.22	0.46	0.05	1.70
Visit 18 (Week 16)	Daily	IDegAsp OD	61	59	0.48	0.18	0.46	0.16	1.00
		IDet	61	59	0.49	0.26	0.44	0.05	1.62
		Total	122	118	0.49	0.22	0.45	0.05	1.62
End of trial visit	Daily	IDegAsp OD	61	61	0.48	0.19	0.46	0.16	1.00
		IDet	61	61	0.50	0.26	0.45	0.05	1.62
		Total	122	122	0.49	0.23	0.45	0.05	1.62

N: Number of subjects, SD: Standard deviation

14.2.16 IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week– descriptive statistics – adolescents (12-17 years) - safety analysis set

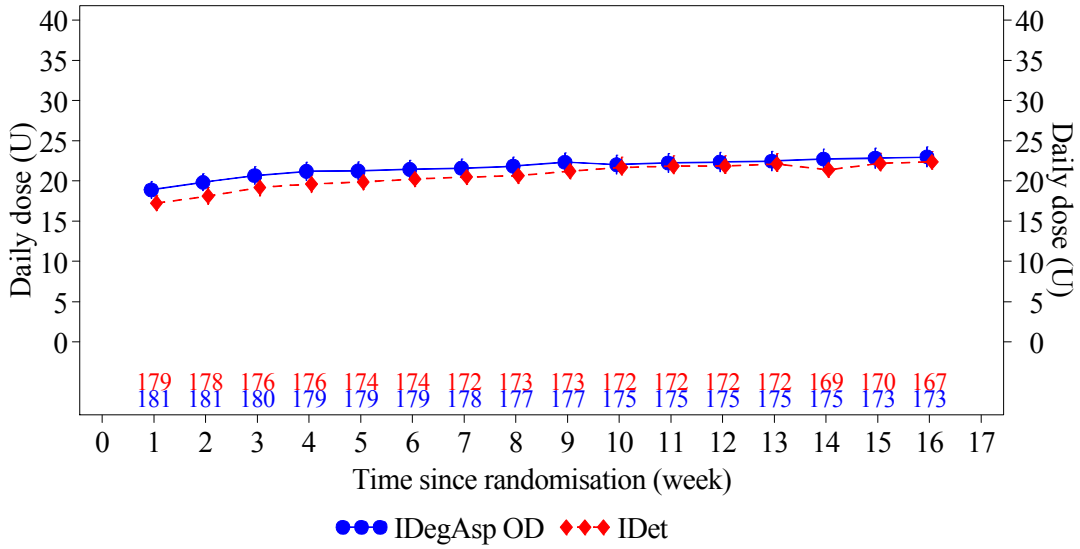
				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	80	0.49	0.20	0.48	0.04	1.06
		IDet	77	77	0.43	0.19	0.39	0.09	0.91
		Total	157	157	0.46	0.20	0.42	0.04	1.06
Visit 4 (Week 2)	Daily	IDegAsp OD	80	80	0.51	0.20	0.52	0.05	1.16
		IDet	77	77	0.45	0.20	0.41	0.09	1.03
		Total	157	157	0.48	0.21	0.46	0.05	1.16
Visit 5 (Week 3)	Daily	IDegAsp OD	80	80	0.53	0.21	0.56	0.04	1.10
		IDet	77	77	0.48	0.22	0.44	0.10	1.10
		Total	157	157	0.51	0.21	0.49	0.04	1.10
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	0.55	0.21	0.58	0.04	1.08
		IDet	77	77	0.48	0.22	0.43	0.11	1.14
		Total	157	156	0.52	0.22	0.49	0.04	1.14
Visit 7 (Week 5)	Daily	IDegAsp OD	80	78	0.56	0.21	0.60	0.05	1.02
		IDet	77	75	0.49	0.22	0.43	0.12	1.17
		Total	157	153	0.52	0.22	0.51	0.05	1.17
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	0.56	0.21	0.60	0.05	1.02
		IDet	77	75	0.50	0.23	0.44	0.13	1.23
		Total	157	153	0.53	0.22	0.51	0.05	1.23
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	0.57	0.21	0.60	0.04	1.02
		IDet	77	73	0.50	0.23	0.44	0.13	1.34
		Total	157	150	0.54	0.22	0.53	0.04	1.34
Visit 10 (Week 8)	Daily	IDegAsp OD	80	77	0.57	0.22	0.59	0.05	1.02
		IDet	77	74	0.51	0.24	0.45	0.13	1.36
		Total	157	151	0.54	0.23	0.53	0.05	1.36
Visit 11 (Week 9)	Daily	IDegAsp OD	80	78	0.58	0.22	0.60	0.05	1.02
		IDet	77	74	0.52	0.25	0.46	0.12	1.36
		Total	157	152	0.55	0.24	0.53	0.05	1.36
Visit 12 (Week 10)	Daily	IDegAsp OD	80	77	0.58	0.22	0.59	0.05	1.04
		IDet	77	74	0.53	0.25	0.47	0.12	1.44
		Total	157	151	0.56	0.24	0.54	0.05	1.44
Visit 13 (Week 11)	Daily	IDegAsp OD	80	77	0.59	0.23	0.60	0.06	1.04
		IDet	77	74	0.53	0.26	0.47	0.12	1.39
		Total	157	151	0.56	0.24	0.55	0.06	1.39
Visit 14 (Week 12)	Daily	IDegAsp OD	80	77	0.57	0.22	0.59	0.06	1.08
		IDet	77	74	0.53	0.24	0.48	0.14	1.07
		Total	157	151	0.55	0.23	0.54	0.06	1.08

N: Number of subjects, SD: Standard deviation

IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week- descriptive statistics - adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	0.58	0.22	0.58	0.06	1.08
		IDet	77	74	0.53	0.25	0.47	0.15	1.11
		Total	157	151	0.55	0.23	0.54	0.06	1.11
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	0.58	0.23	0.58	0.07	1.11
		IDet	77	71	0.52	0.24	0.48	0.15	1.18
		Total	157	148	0.55	0.24	0.55	0.07	1.18
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	0.59	0.23	0.58	0.10	1.17
		IDet	77	73	0.53	0.25	0.48	0.15	1.18
		Total	157	148	0.56	0.24	0.56	0.10	1.18
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	0.58	0.23	0.57	0.10	1.19
		IDet	77	71	0.53	0.25	0.48	0.14	1.22
		Total	157	147	0.56	0.24	0.54	0.10	1.22
End of trial visit	Daily	IDegAsp OD	80	80	0.59	0.23	0.59	0.10	1.19
		IDet	77	77	0.55	0.26	0.53	0.14	1.22
		Total	157	157	0.57	0.24	0.55	0.10	1.22

N: Number of subjects, SD: Standard deviation



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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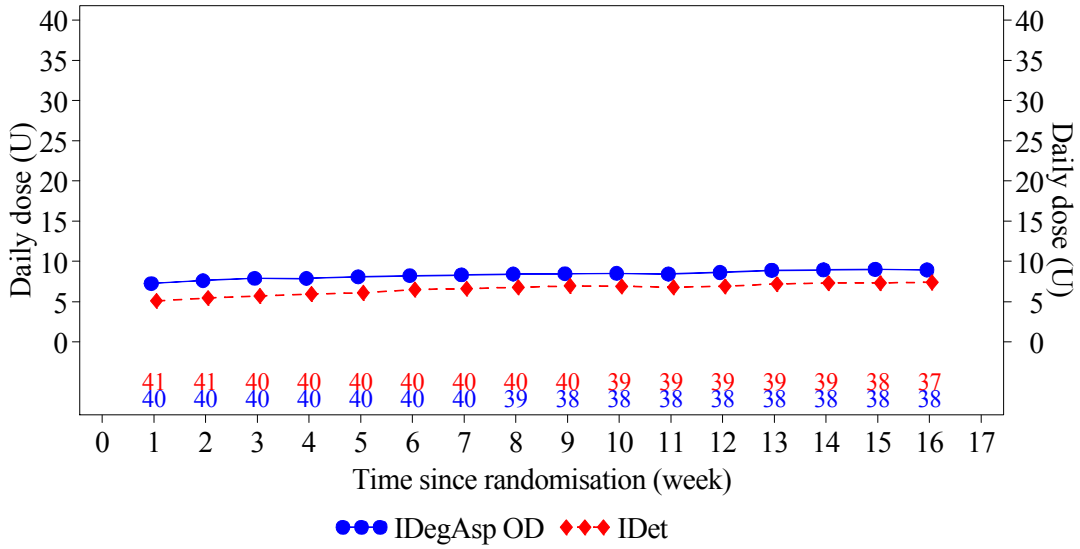
14.2.17 Daily IDegAsp/Comparator insulin dose (actual) in units by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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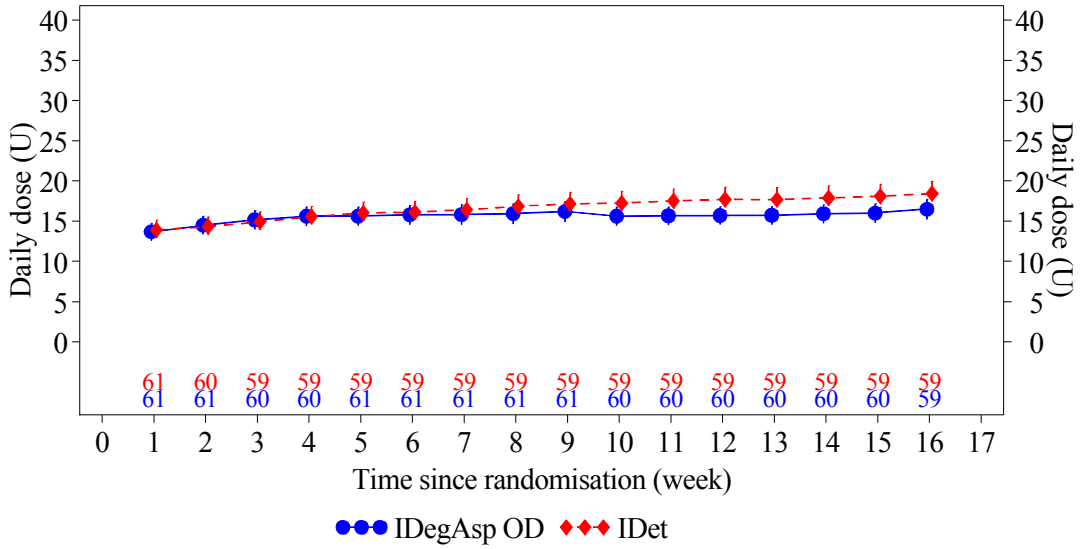
14.2.18 Daily IDegAsp/Comparator insulin dose (actual) in units by treatment week - mean plot – children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

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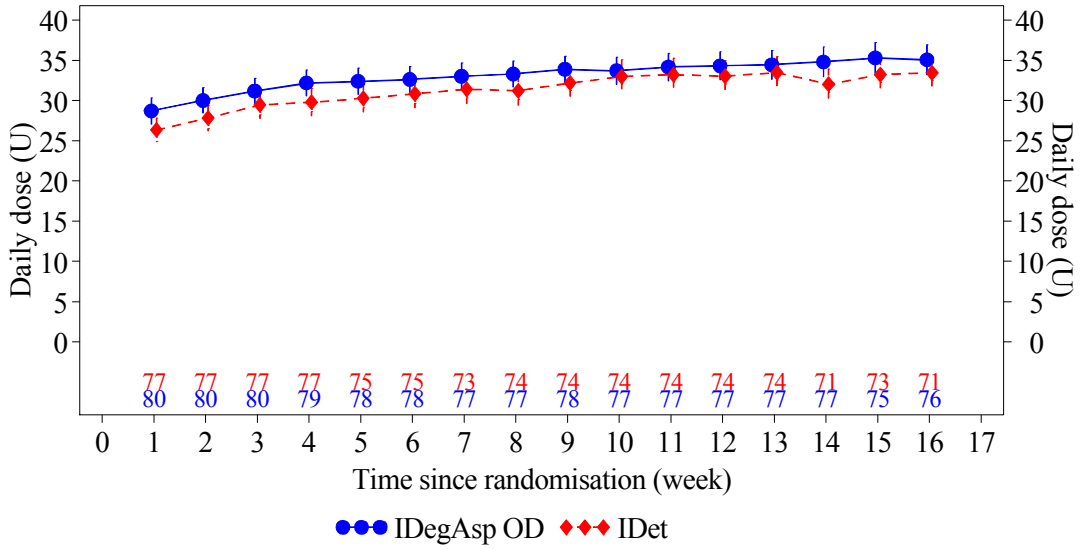
14.2.19 Daily IDegAsp/Comparator insulin dose (actual) in units by treatment week - mean plot – children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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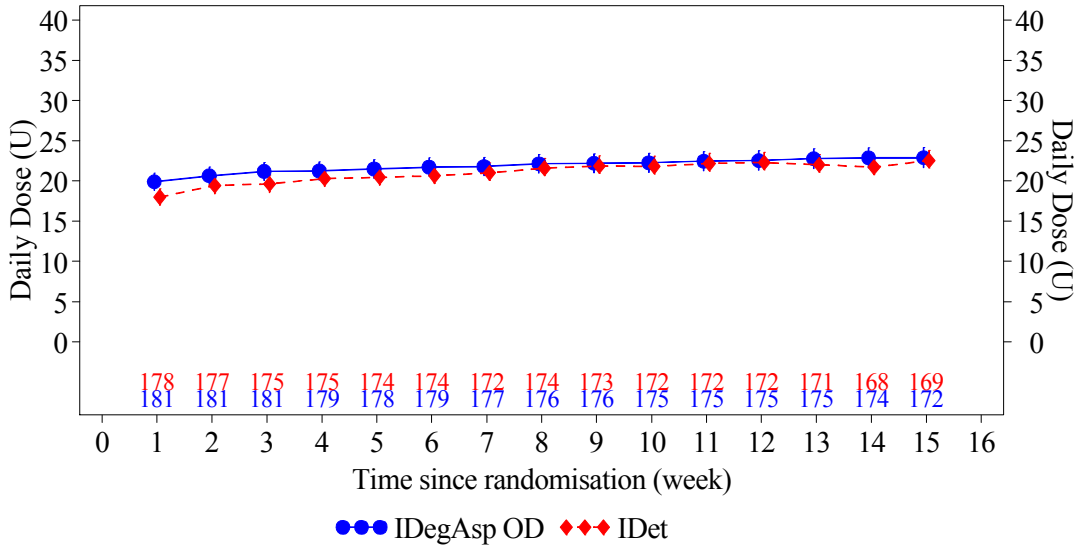
14.2.20 Daily IDegAsp/Comparator insulin dose (actual) in units by treatment week - mean plot – adolescents (12-17 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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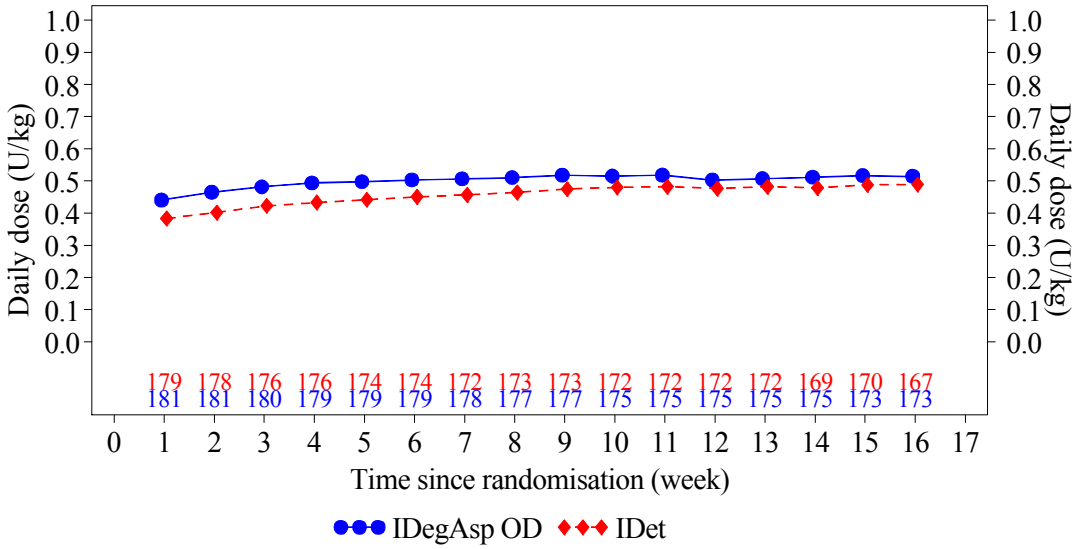
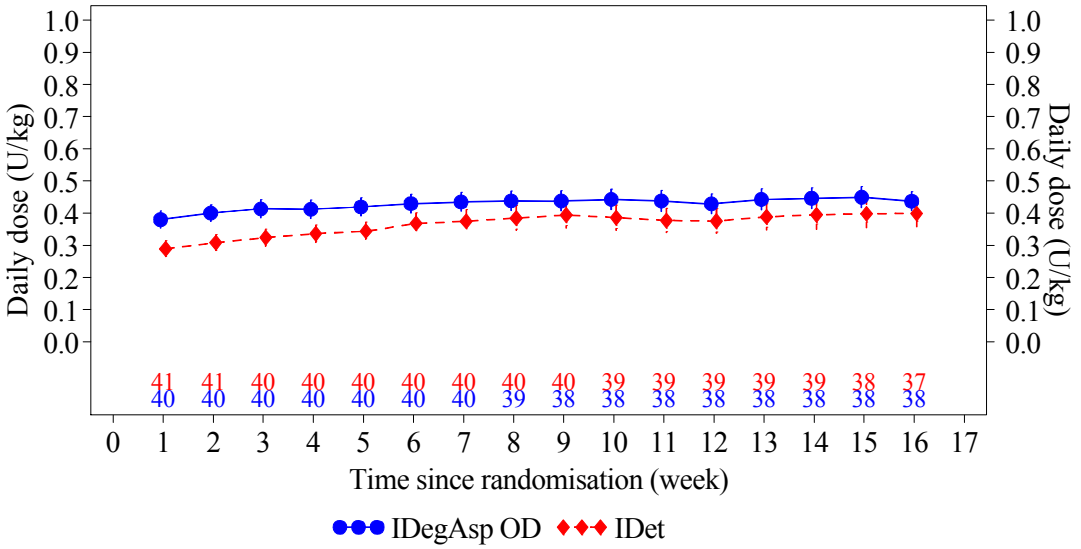
14.2.21 Daily IDegAsp/Comparator insulin dose (prescribed) in units by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:39:06 - fmean_numfind_deg_cust.sas/e_ins_d_ac_ukg_mean_ob_sas.cgm

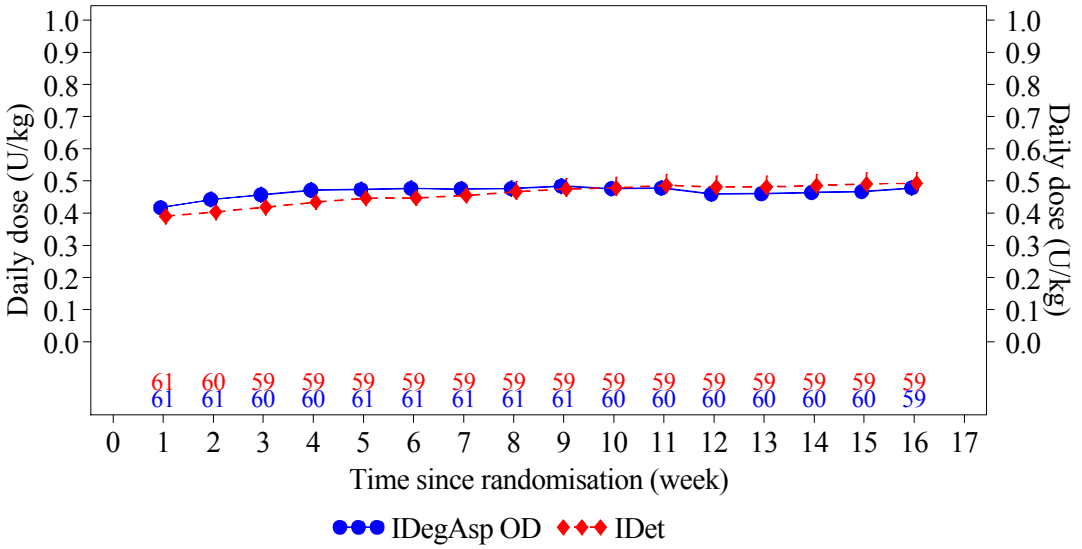
14.2.22 Daily IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:39:06 - fmean_numfind_deg_cust.sas/e_ins_d_ac_ukg_mean_ob_age1_sas.cgm

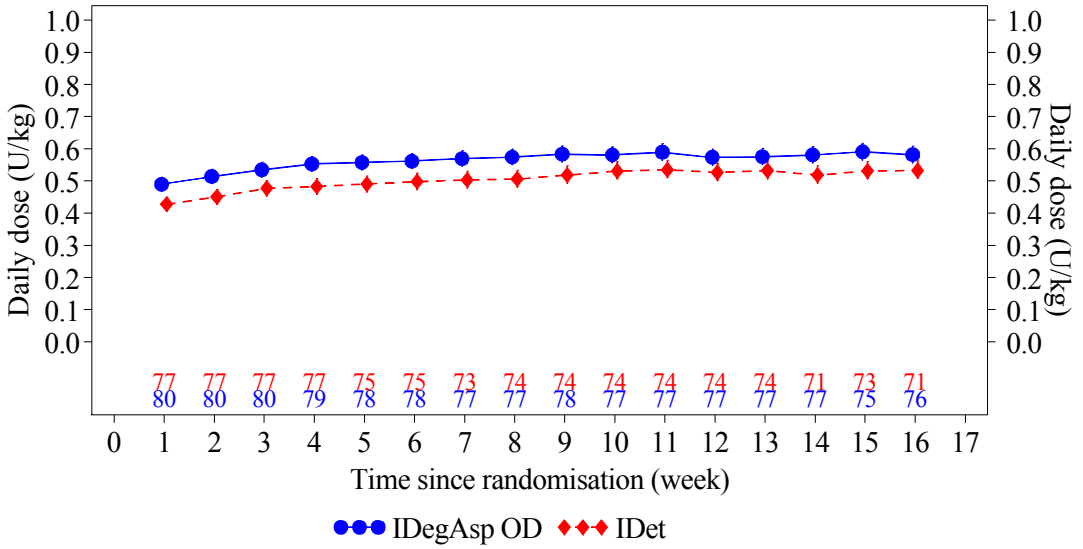
14.2.23 Daily IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week - mean plot – children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:39:15 - fmean_numfind_deg_cust.sas/e_ins_d_ac_ukg_mean_ob_age2_sas.cgm

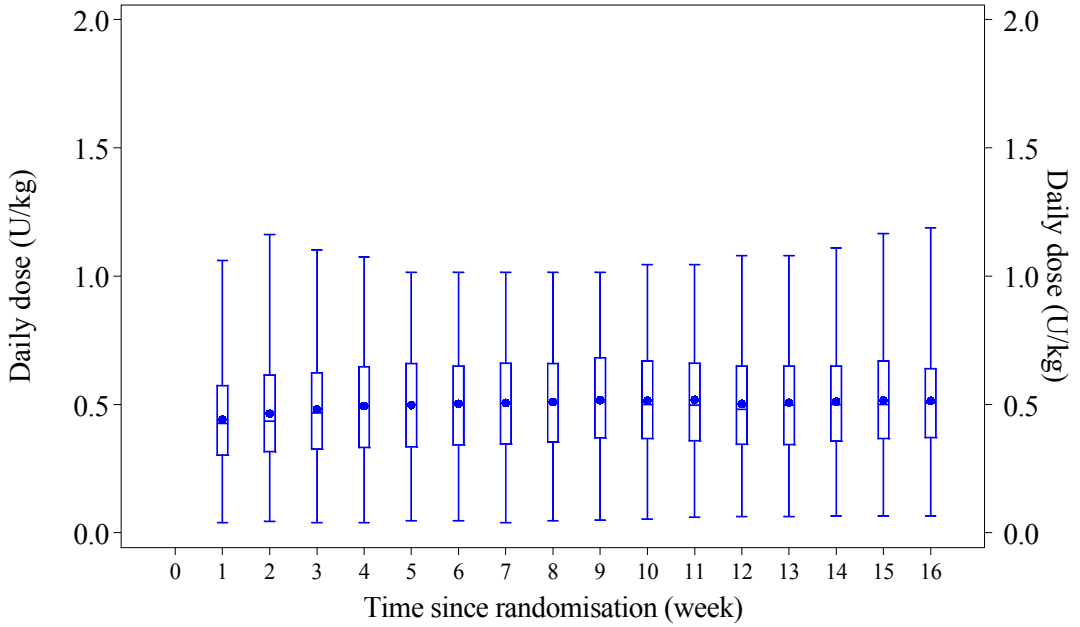
14.2.24 Daily IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week - mean plot – children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:39:14 - fmean_numfind_deg_cust.sas/e_ins_d_ac_ukg_mean_ob_age3_sas.cgm

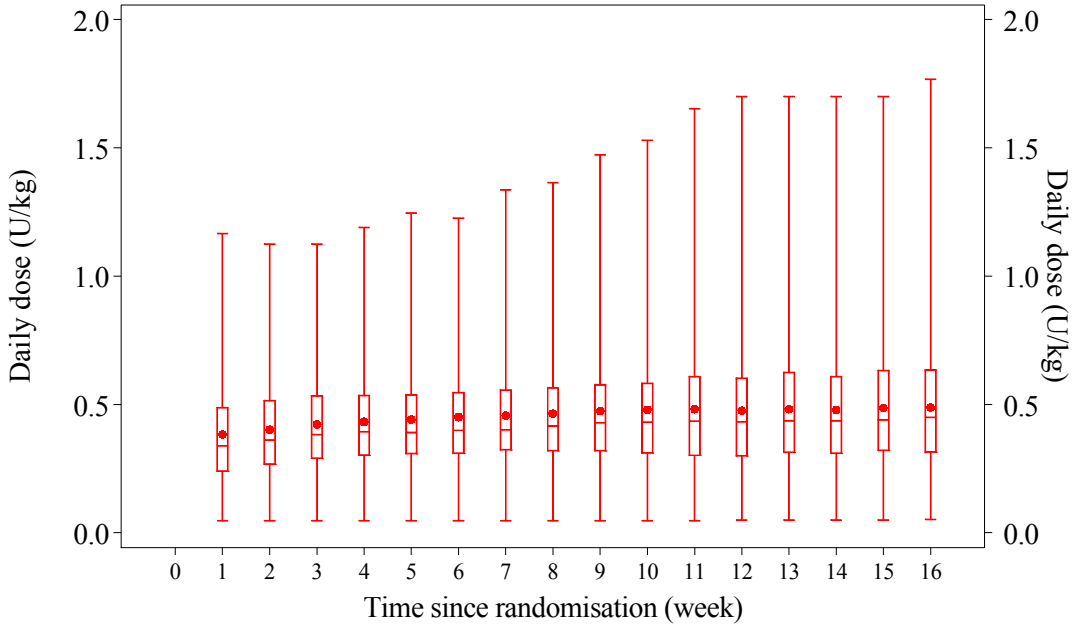
14.2.25 Daily IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week - mean plot – adolescents (12-17 years) - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:16 - fbox_numfind_v02.sas/e_ins_d_iv1_act_ukg_box_obs_sas.cgm

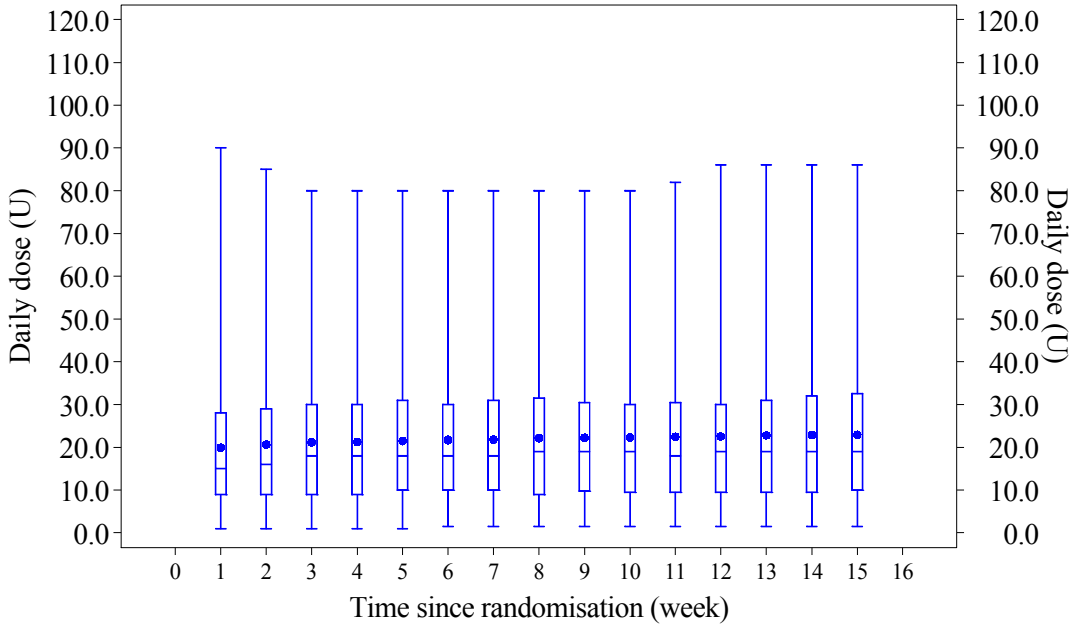
14.2.26 Daily IDegAsp OD dose (actual) in units/kg by treatment week – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:16 - fbox_numfind_v02.sas/e_ins_d_com_act_ukg_box_obs_sas.cgm

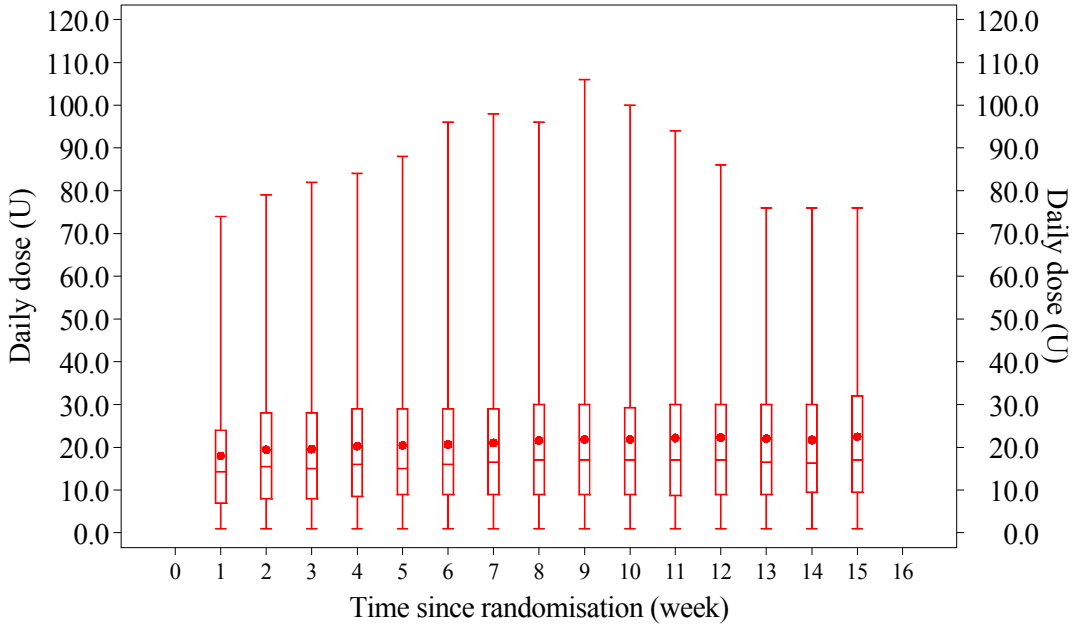
14.2.27 Daily IDet dose (actual) in units/kg by treatment week – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:16 - fbox_numfind_v02.sas/e_ins_d_iv1_prscb_u_box_obs_sas.cgm

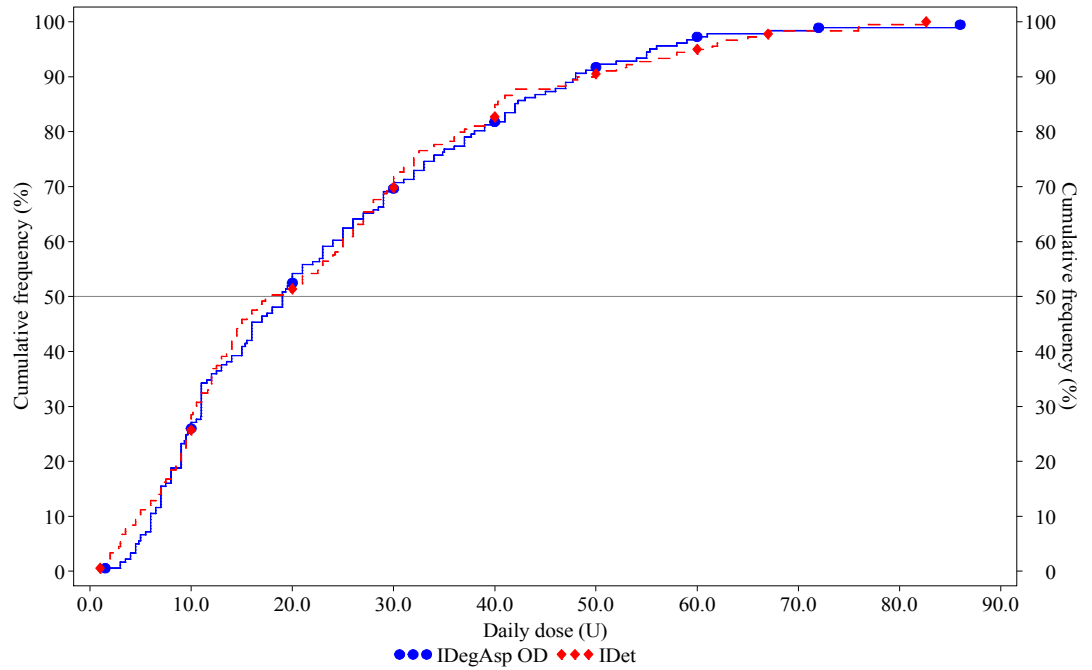
14.2.28 Daily IDegAsp OD dose (prescribed) in units by treatment week – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:16 - fbox_numfind_v02.sas/e_ins_d_com_prscb_u_box_obs_sas.cgm

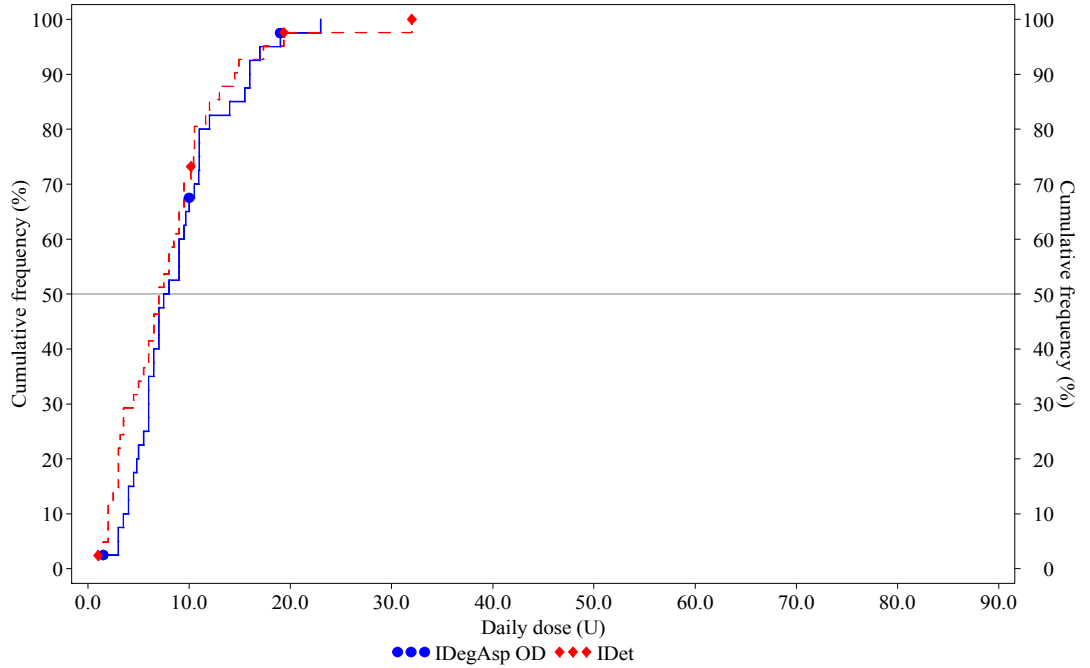
14.2.29 Daily IDet dose (prescribed) in units by treatment week – box plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:17 - fedist_numfind_v01.sas/e_ins_d_d_act_u_cdf_pred_sas.cgm

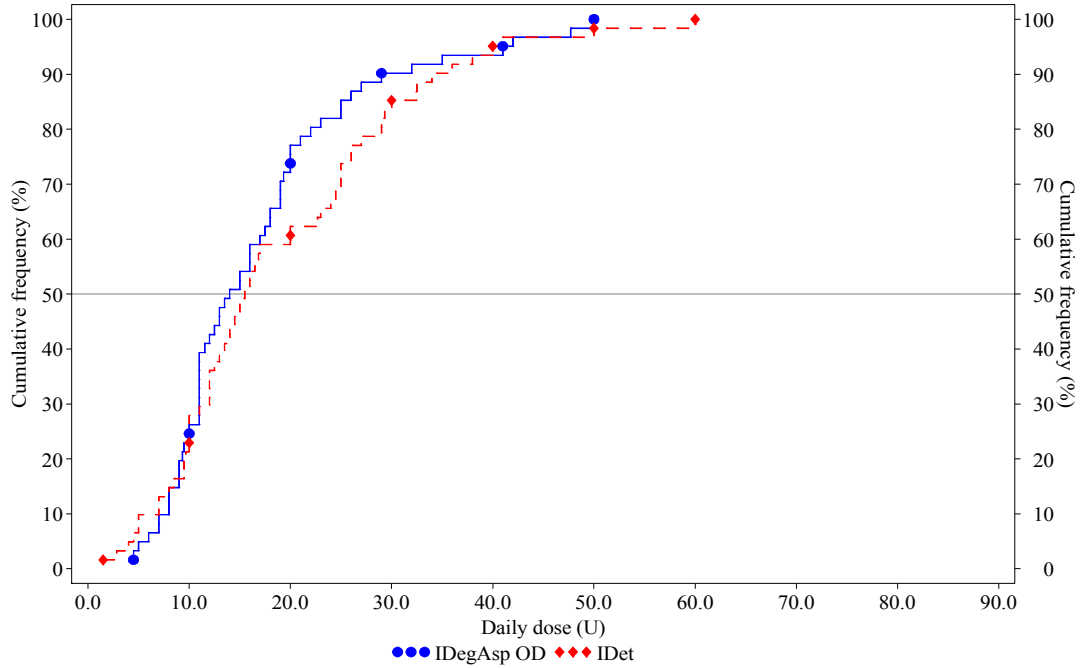
14.2.30 Daily IDegAsp/Comparator insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:17 - fedist_numfind_v01.sas/e_ins_d_d_act_u_cdf_pred_age1_sas.cgm

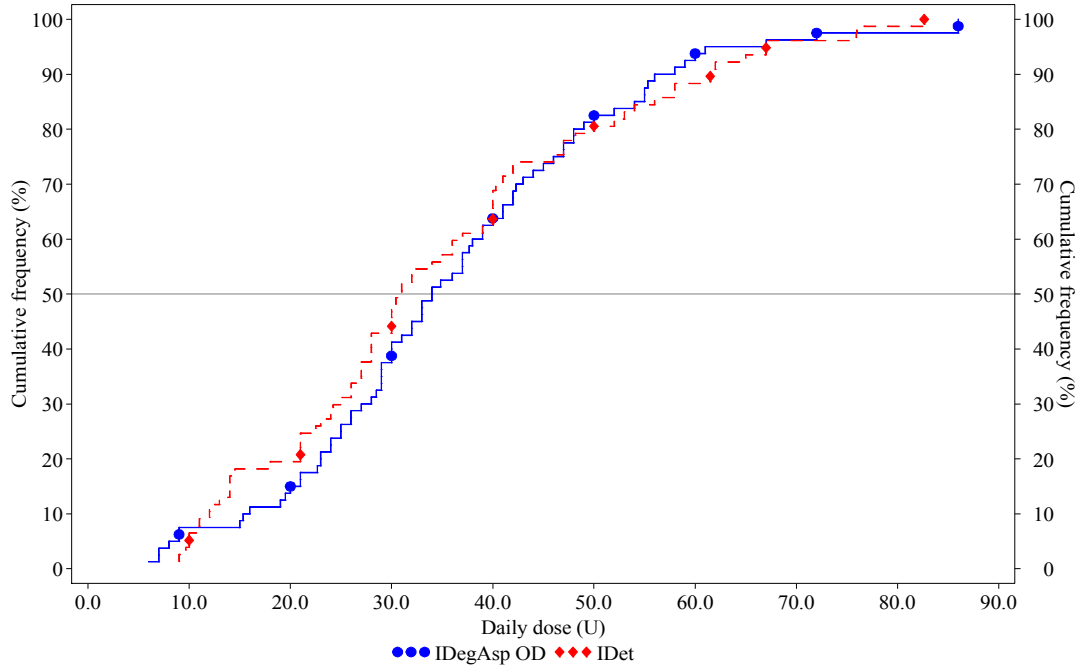
14.2.31 Daily IDegAsp/Comparator insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:22 - fedist_numfind_v01.sas/e_ins_d_d_act_u_cdf_pred_age2_sas.cgm

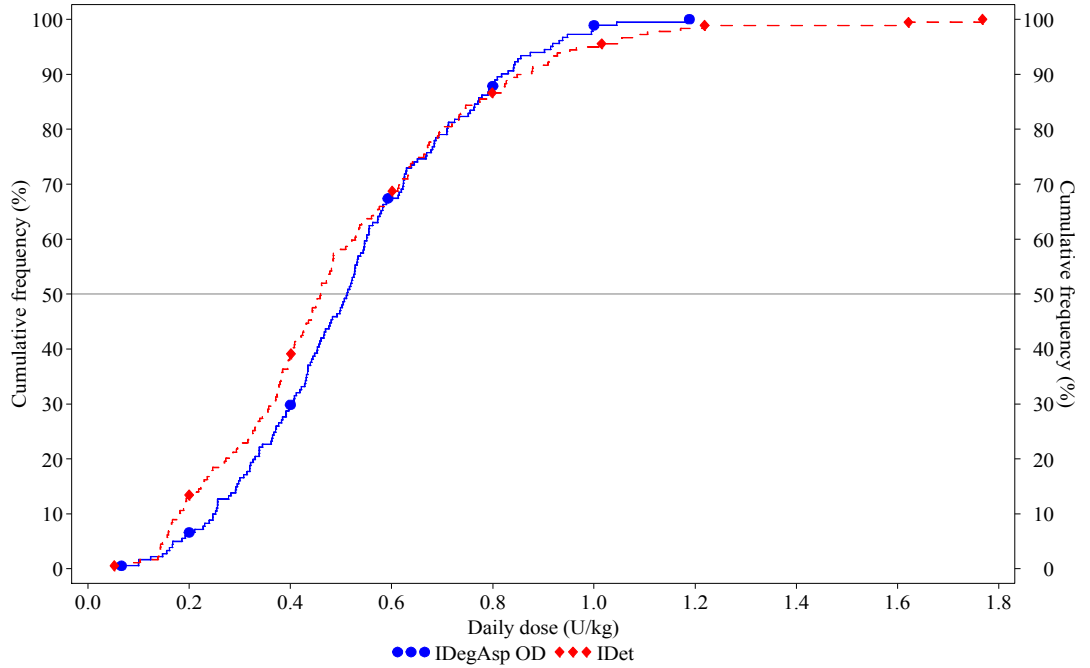
14.2.32 Daily IDegAsp/Comparator insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:24 - fedist_numfind_v01.sas/e_ins_d_d_act_u_cdf_pred_age3_sas.cgm

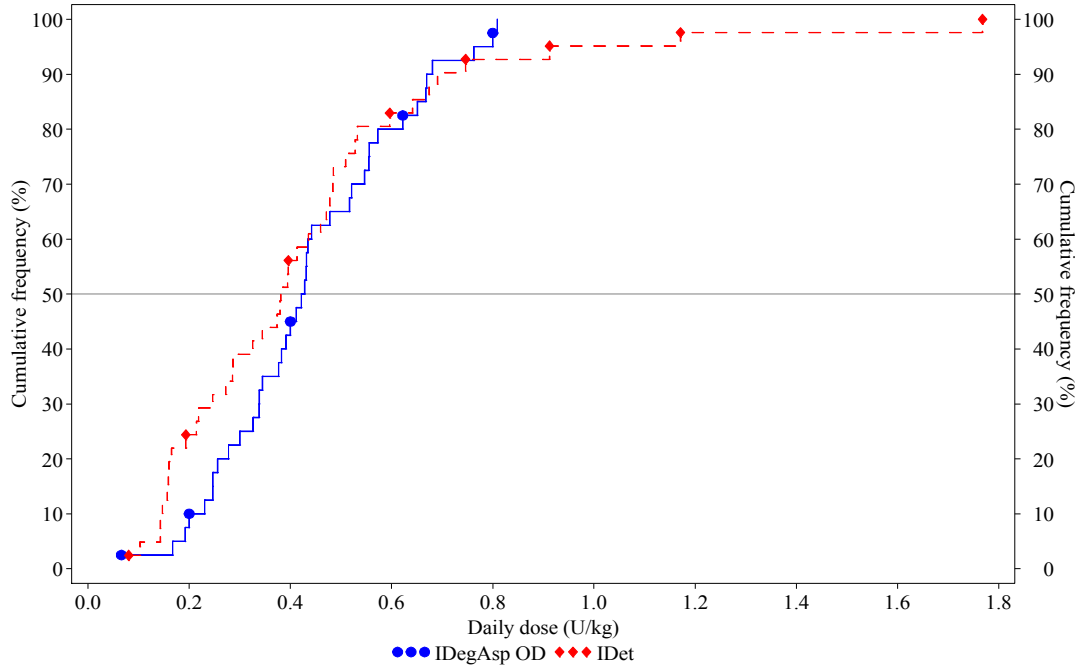
14.2.33 Daily IDegAsp/Comparator insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - adolsecents (12-17 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:25 - fedist_numfind_v01.sas/e_ins_d_act_ukg_cdf_pred_sas.cgm

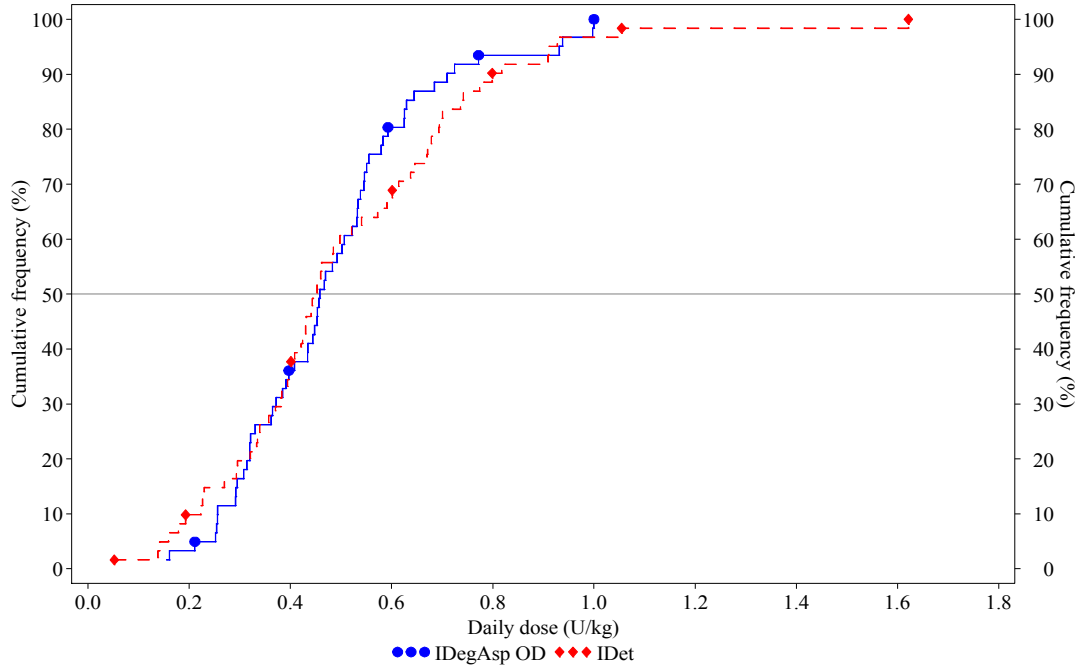
14.2.34 Daily IDegAsp/Comparator insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:26 - fedist_numfind_v01.sas/e_ins_d_act_ukg_cdf_pred_age1_sas.cgm

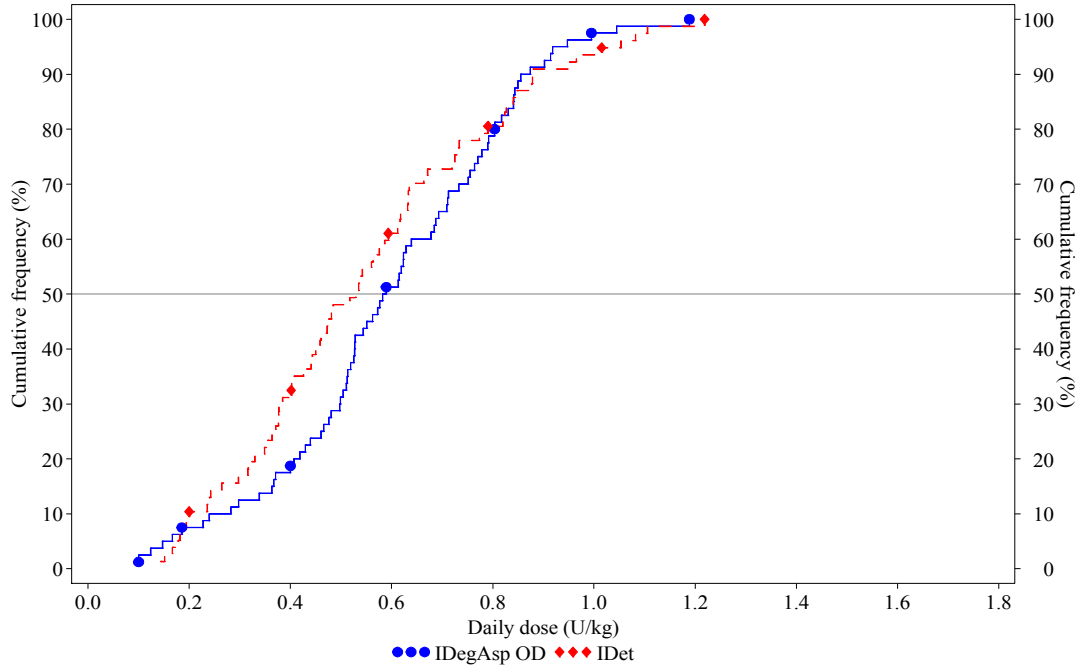
14.2.35 Daily IDegAsp/Comparator insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:25 - fedist_numfind_v01.sas/e_ins_d_act_ukg_cdf_pred_age2_sas.cgm

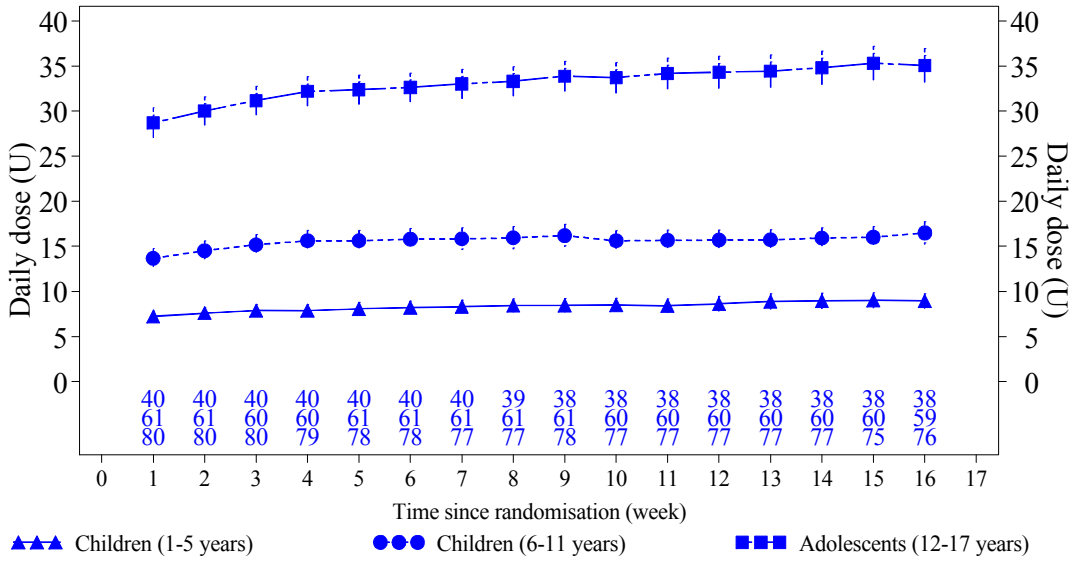
14.2.36 Daily IDegAsp/Comparator insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:39:26 - fedist_numfind_v01.sas/e_ins_d_act_ukg_cdf_pred_age3_sas.cgm

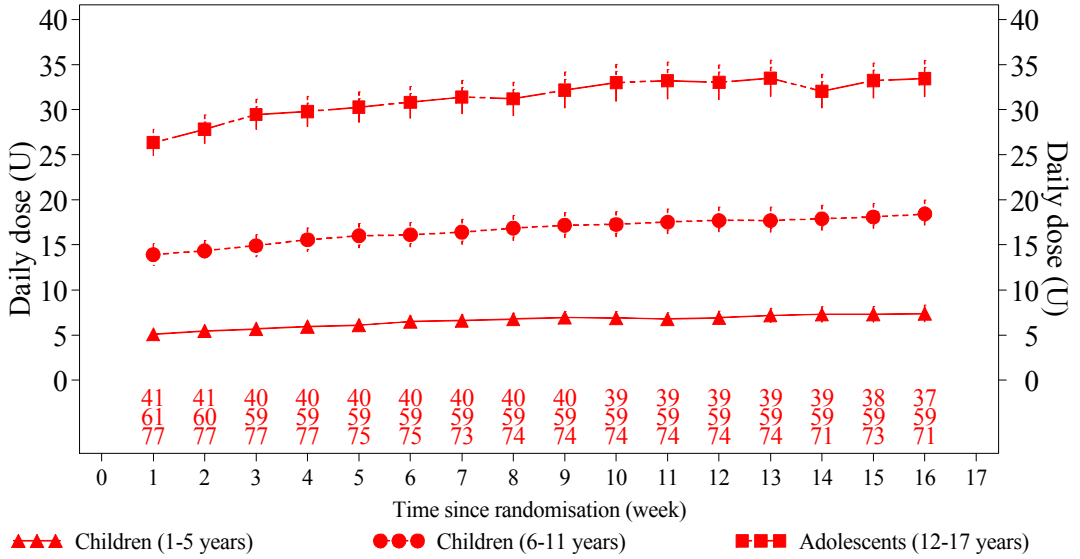
14.2.37 Daily IDegAsp/Comparator insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - adolescents(12-17 years) - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:27:40 - dose_fplot_treatment_age.sas/e_ins_dos_d_u_ideg_sas.cgm

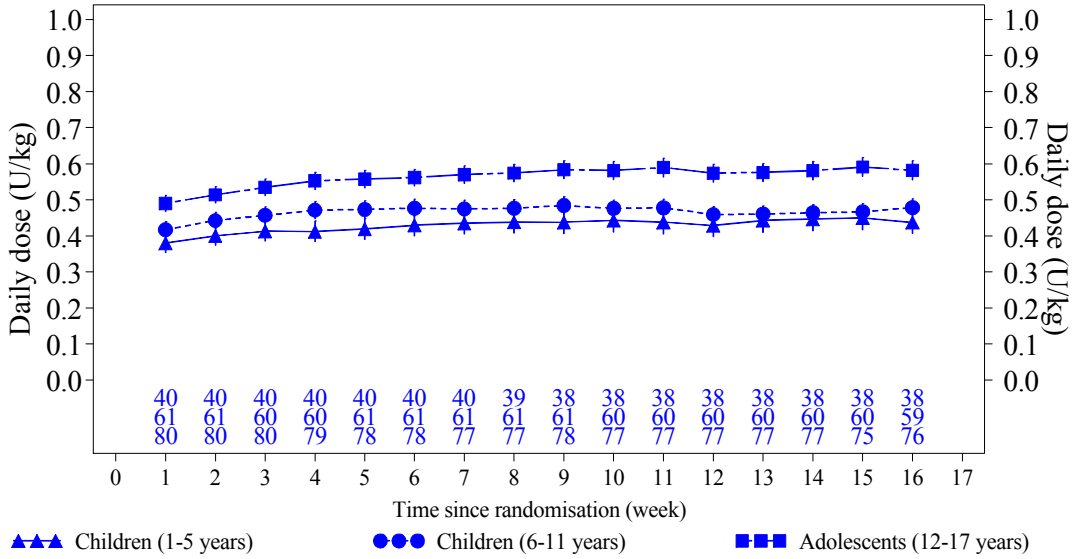
14.2.38 Daily IDegAsp/Comparator insulin dose (actual) in units by treatment week - mean plot – IDegAsp OD – by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:27:45 - dose_fplot_treatment_age.sas/e_ins_dos_d_u_idet_sas.cgm

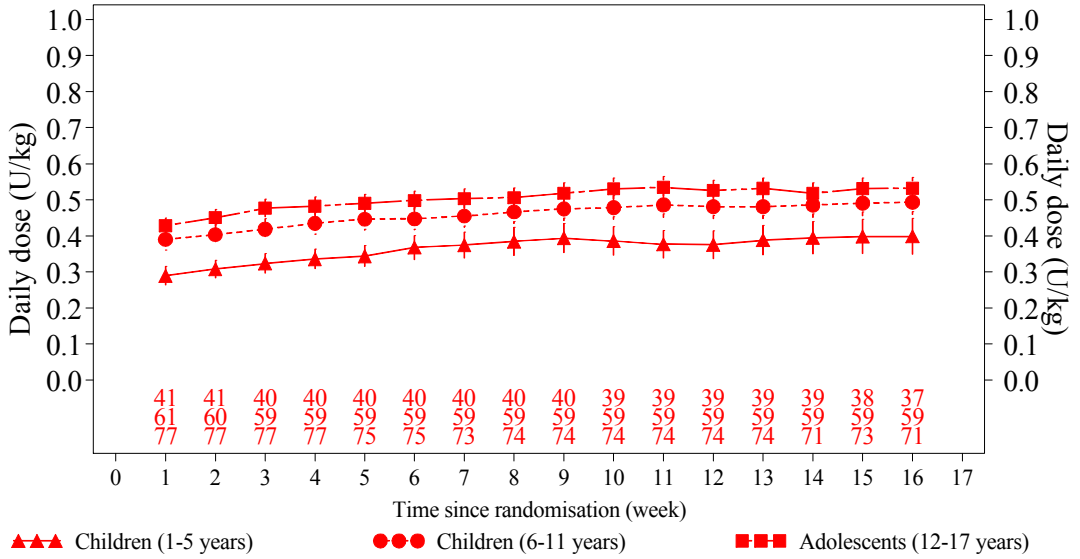
14.2.39 Daily IDegAsp/Comparator insulin dose (actual) in units by treatment week - mean plot – IDet – by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:27:49 - dose_fplot_treatment_age.sas/e_ins_dos_d_ukg_ideg_sas.cgm

14.2.40 Daily IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week - mean plot – IDegAsp OD – by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:27:53 - dose_fplot_treatment_age.sas/e_ins_dos_d_ukg_idet_sas.cgm

14.2.41 Daily IDegAsp/Comparator insulin dose (actual) in units/kg by treatment week - mean plot – IDet – by age group - safety analysis set

14.2.42 IAsp dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	178	15	11	12	1	64
		IDet	179	178	23	17	18	1	110
		Total	360	356	19	15	14	1	110
	Breakfast	IDegAsp OD	181	126	6	4	4	1	20
		IDet	179	176	7	5	6	1	39
		Total	360	302	6	5	5	1	39
	Lunch	IDegAsp OD	181	163	6	4	5	1	28
		IDet	179	174	7	5	6	1	30
		Total	360	337	6	5	5	1	30
	Main Evening Meal	IDegAsp OD	181	112	5	4	4	1	23
		IDet	179	176	7	5	5	1	27
		Total	360	288	6	5	5	1	27
	Other	IDegAsp OD	181	105	5	6	4	1	34
		IDet	179	108	5	5	4	1	26
		Total	360	213	5	6	4	1	34
Visit 4 (Week 2)	Daily	IDegAsp OD	181	179	15	11	12	1	70
		IDet	179	178	23	16	19	1	91
		Total	360	357	19	14	15	1	91
	Breakfast	IDegAsp OD	181	129	6	4	5	1	20
		IDet	179	178	7	5	5	1	25
		Total	360	307	6	5	5	1	25
	Lunch	IDegAsp OD	181	164	6	4	5	1	26
		IDet	179	175	7	5	6	1	27
		Total	360	339	6	5	5	1	27
	Main Evening Meal	IDegAsp OD	181	124	5	4	4	1	21
		IDet	179	174	7	5	6	1	30
		Total	360	298	6	5	5	1	30
	Other	IDegAsp OD	181	112	5	5	3	1	40
		IDet	179	105	6	5	5	1	30
		Total	360	217	5	5	4	1	40
Visit 5 (Week 3)	Daily	IDegAsp OD	181	179	15	11	12	2	53
		IDet	179	176	23	16	20	2	94
		Total	360	355	19	14	15	2	94
	Breakfast	IDegAsp OD	181	126	6	4	5	1	21
		IDet	179	173	7	5	6	1	26
		Total	360	299	7	5	5	1	26

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 5 (Week 3)	Lunch	IDegAsp OD	181	167	6	4	5	1	24
		IDet	179	172	7	5	6	1	24
		Total	360	339	6	5	5	1	24
	Main Evening Meal	IDegAsp OD	181	120	5	4	4	1	21
		IDet	179	173	7	5	6	1	29
		Total	360	293	6	5	5	1	29
	Other	IDegAsp OD	181	108	5	5	4	1	31
		IDet	179	106	5	4	4	1	23
		Total	360	214	5	4	4	1	31
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	15	10	12	1	57
		IDet	179	176	23	17	19	3	96
		Total	360	355	19	15	15	1	96
	Breakfast	IDegAsp OD	181	125	6	5	5	1	21
		IDet	179	175	7	5	5	1	28
		Total	360	300	7	5	5	1	28
	Lunch	IDegAsp OD	181	160	6	4	5	1	26
		IDet	179	172	7	5	6	1	26
		Total	360	332	7	5	5	1	26
	Main Evening Meal	IDegAsp OD	181	122	5	4	4	1	20
		IDet	179	174	7	5	6	1	26
		Total	360	296	6	5	5	1	26
	Other	IDegAsp OD	181	100	5	5	3	1	37
		IDet	179	101	5	4	4	1	31
		Total	360	201	5	5	4	1	37
Visit 7 (Week 5)	Daily	IDegAsp OD	181	176	14	10	12	1	60
		IDet	179	174	23	17	19	1	99
		Total	360	350	19	15	15	1	99
	Breakfast	IDegAsp OD	181	126	6	4	5	1	20
		IDet	179	171	7	5	5	1	30
		Total	360	297	7	5	5	1	30
	Lunch	IDegAsp OD	181	162	6	4	5	1	21
		IDet	179	170	7	5	6	1	26
		Total	360	332	7	5	5	1	26
	Main Evening Meal	IDegAsp OD	181	116	5	4	4	1	20
		IDet	179	171	7	5	6	1	26
		Total	360	287	6	5	5	1	26

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 7 (Week 5)	Other	IDegAsp OD	181	103	5	4	3	1	26
		IDet	179	105	5	5	4	1	30
		Total	360	208	5	5	4	1	30
Visit 8 (Week 6)	Daily	IDegAsp OD	181	177	15	11	12	1	63
		IDet	179	174	23	16	19	2	88
		Total	360	351	19	15	14	1	88
	Breakfast	IDegAsp OD	181	127	6	5	5	1	21
		IDet	179	171	7	5	6	1	30
		Total	360	298	7	5	5	1	30
	Lunch	IDegAsp OD	181	163	6	5	5	1	25
		IDet	179	170	7	5	6	1	26
		Total	360	333	7	5	5	1	26
	Main Evening Meal	IDegAsp OD	181	115	5	4	4	1	22
		IDet	179	171	7	5	6	1	26
		Total	360	286	6	5	5	1	26
	Other	IDegAsp OD	181	104	5	5	3	1	28
		IDet	179	105	5	5	4	1	23
		Total	360	209	5	5	4	1	28
Visit 9 (Week 7)	Daily	IDegAsp OD	181	176	15	11	12	1	68
		IDet	179	172	23	17	20	1	88
		Total	360	348	19	15	15	1	88
	Breakfast	IDegAsp OD	181	127	6	4	5	1	20
		IDet	179	171	8	6	6	1	30
		Total	360	298	7	5	5	1	30
	Lunch	IDegAsp OD	181	161	6	4	5	1	26
		IDet	179	169	7	5	6	1	26
		Total	360	330	7	5	5	1	26
	Main Evening Meal	IDegAsp OD	181	115	5	4	4	1	22
		IDet	179	170	7	6	6	1	29
		Total	360	285	6	5	5	1	29
	Other	IDegAsp OD	181	108	5	5	3	1	36
		IDet	179	101	5	4	4	1	21
		Total	360	209	5	5	3	1	36
Visit 10 (Week 8)	Daily	IDegAsp OD	181	175	15	11	13	2	70
		IDet	179	173	23	16	19	1	82
		Total	360	348	19	14	15	1	82

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 10 (Week 8)	Breakfast	IDegAsp OD	181	128	6	4	5	1	22
		IDet	179	171	7	5	5	1	28
		Total	360	299	7	5	5	1	28
	Lunch	IDegAsp OD	181	159	6	4	5	1	27
		IDet	179	168	7	5	6	1	26
		Total	360	327	7	5	6	1	27
	Main Evening Meal	IDegAsp OD	181	114	5	4	4	1	20
		IDet	179	170	7	5	6	1	26
		Total	360	284	6	5	5	1	26
	Other	IDegAsp OD	181	100	5	5	3	1	34
		IDet	179	104	5	4	4	1	20
		Total	360	204	5	5	3	1	34
Visit 11 (Week 9)	Daily	IDegAsp OD	181	175	15	11	11	1	67
		IDet	179	172	24	17	19	3	95
		Total	360	347	19	15	15	1	95
	Breakfast	IDegAsp OD	181	128	6	5	5	1	33
		IDet	179	170	7	5	5	1	28
		Total	360	298	7	5	5	1	33
	Lunch	IDegAsp OD	181	160	6	4	5	1	27
		IDet	179	169	7	5	6	1	25
		Total	360	329	7	5	6	1	27
	Main Evening Meal	IDegAsp OD	181	112	5	4	4	1	22
		IDet	179	170	7	5	6	1	24
		Total	360	282	6	5	5	1	24
	Other	IDegAsp OD	181	109	5	5	3	1	26
		IDet	179	103	5	5	4	1	24
		Total	360	212	5	5	3	1	26
Visit 12 (Week 10)	Daily	IDegAsp OD	181	173	15	11	12	1	64
		IDet	179	172	23	16	19	2	81
		Total	360	345	19	14	14	1	81
	Breakfast	IDegAsp OD	181	127	6	4	5	1	24
		IDet	179	170	7	5	5	1	27
		Total	360	297	7	5	5	1	27
	Lunch	IDegAsp OD	181	159	6	4	5	1	26
		IDet	179	169	7	6	6	1	26
		Total	360	328	7	5	5	1	26

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week - descriptive statistics - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 12 (Week 10)	Main Evening Meal	IDegAsp OD	181	115	5	5	4	1	41
		IDet	179	169	7	5	6	1	27
		Total	360	284	6	5	5	1	41
	Other	IDegAsp OD	181	103	4	4	3	1	22
		IDet	179	103	5	5	4	1	24
		Total	360	206	5	4	3	1	24
Visit 13 (Week 11)	Daily	IDegAsp OD	181	173	15	11	12	1	80
		IDet	179	172	23	16	19	2	91
		Total	360	345	19	14	15	1	91
	Breakfast	IDegAsp OD	181	127	6	4	5	1	20
		IDet	179	168	7	5	5	1	29
		Total	360	295	7	5	5	1	29
	Lunch	IDegAsp OD	181	158	6	5	5	1	23
		IDet	179	168	7	5	6	1	29
		Total	360	326	7	5	6	1	29
	Main Evening Meal	IDegAsp OD	181	109	5	4	4	1	19
		IDet	179	168	7	5	6	1	30
		Total	360	277	6	5	5	1	30
	Other	IDegAsp OD	181	105	4	5	3	1	38
		IDet	179	101	5	4	3	1	23
		Total	360	206	5	4	3	1	38
Visit 14 (Week 12)	Daily	IDegAsp OD	181	173	15	12	12	1	78
		IDet	179	172	23	16	20	1	97
		Total	360	345	19	15	15	1	97
	Breakfast	IDegAsp OD	181	128	6	4	5	1	22
		IDet	179	171	7	5	6	1	30
		Total	360	299	7	5	5	1	30
	Lunch	IDegAsp OD	181	157	6	5	5	1	26
		IDet	179	167	7	5	6	1	27
		Total	360	324	7	5	5	1	27
	Main Evening Meal	IDegAsp OD	181	109	5	5	4	1	31
		IDet	179	168	7	5	6	1	31
		Total	360	277	7	5	5	1	31
	Other	IDegAsp OD	181	107	4	5	3	1	36
		IDet	179	101	6	5	4	1	29
		Total	360	208	5	5	4	1	36

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week - descriptive statistics - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	174	15	11	13	1	69
		IDet	179	171	23	16	20	1	85
		Total	360	345	19	14	16	1	85
	Breakfast	IDegAsp OD	181	128	6	4	4	1	20
		IDet	179	171	7	5	6	1	29
		Total	360	299	7	5	5	1	29
	Lunch	IDegAsp OD	181	158	6	4	5	1	23
		IDet	179	167	7	5	6	1	31
		Total	360	325	7	5	6	1	31
	Main Evening Meal	IDegAsp OD	181	115	5	5	4	1	25
		IDet	179	167	7	6	6	1	32
		Total	360	282	6	5	5	1	32
	Other	IDegAsp OD	181	104	5	4	3	1	27
		IDet	179	94	5	4	4	1	25
		Total	360	198	5	4	4	1	27
Visit 16 (Week 14)	Daily	IDegAsp OD	181	174	15	11	12	1	69
		IDet	179	170	23	16	20	1	86
		Total	360	344	19	14	15	1	86
	Breakfast	IDegAsp OD	181	127	6	4	5	1	21
		IDet	179	168	7	5	6	1	30
		Total	360	295	7	5	5	1	30
	Lunch	IDegAsp OD	181	156	6	4	5	1	29
		IDet	179	166	7	5	6	1	25
		Total	360	322	7	5	5	1	29
	Main Evening Meal	IDegAsp OD	181	115	5	4	5	1	18
		IDet	179	165	7	5	6	1	33
		Total	360	280	6	5	5	1	33
	Other	IDegAsp OD	181	104	5	4	3	1	27
		IDet	179	94	5	4	4	1	23
		Total	360	198	5	4	4	1	27
Visit 17 (Week 15)	Daily	IDegAsp OD	181	172	16	11	12	1	67
		IDet	179	170	24	17	19	2	88
		Total	360	342	20	15	16	1	88
	Breakfast	IDegAsp OD	181	128	6	4	5	1	23
		IDet	179	169	7	6	6	1	30
		Total	360	297	7	5	5	1	30

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 17 (Week 15)	Lunch	IDegAsp OD	181	154	6	4	5	1	21
		IDet	179	167	7	6	6	1	31
		Total	360	321	7	5	6	1	31
	Main Evening Meal	IDegAsp OD	181	114	6	5	4	1	39
		IDet	179	165	7	5	6	1	34
		Total	360	279	7	5	5	1	39
	Other	IDegAsp OD	181	104	5	5	3	1	25
		IDet	179	98	5	4	4	1	23
		Total	360	202	5	4	4	1	25
Visit 18 (Week 16)	Daily	IDegAsp OD	181	172	15	11	12	1	76
		IDet	179	166	23	17	20	2	90
		Total	360	338	19	15	16	1	90
	Breakfast	IDegAsp OD	181	128	6	4	5	1	19
		IDet	179	165	7	6	5	1	29
		Total	360	293	7	5	5	1	29
	Lunch	IDegAsp OD	181	155	6	4	5	1	24
		IDet	179	162	7	5	6	1	31
		Total	360	317	7	5	5	1	31
	Main Evening Meal	IDegAsp OD	181	112	5	5	4	1	27
		IDet	179	161	7	6	6	1	35
		Total	360	273	7	5	5	1	35
	Other	IDegAsp OD	181	110	5	5	3	1	34
		IDet	179	100	4	3	3	1	17
		Total	360	210	5	4	3	1	34
End of trial visit	Daily	IDegAsp OD	181	181	15	11	12	1	76
		IDet	179	179	23	16	20	2	90
		Total	360	360	19	14	16	1	90
	Breakfast	IDegAsp OD	181	154	6	4	5	1	19
		IDet	179	179	7	6	5	1	29
		Total	360	333	7	5	5	1	29
	Lunch	IDegAsp OD	181	175	6	4	5	1	24
		IDet	179	177	7	5	6	1	31
		Total	360	352	7	5	5	1	31

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
End of trial visit	Main Evening Meal	IDegAsp OD	181	154	5	5	4	1	39
		IDet	179	178	7	6	6	1	35
		Total	360	332	6	6	5	1	39
	Other	IDegAsp OD	181	159	4	4	3	1	34
		IDet	179	153	4	3	3	1	20
		Total	360	312	4	4	3	1	34

N: Number of subjects, SD: Standard deviation

14.2.43 IAsp dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	7	3	6	1	19
		IDet	41	41	9	4	9	5	23
		Total	81	81	8	4	7	1	23
	Breakfast	IDegAsp OD	40	25	3	1	2	1	5
		IDet	41	41	3	2	3	1	8
		Total	81	66	3	2	2	1	8
	Lunch	IDegAsp OD	40	35	3	1	2	1	6
		IDet	41	40	3	1	2	1	8
		Total	81	75	3	1	2	1	8
	Main Evening Meal	IDegAsp OD	40	27	2	1	2	1	6
		IDet	41	40	3	1	2	1	7
		Total	81	67	3	1	2	1	7
	Other	IDegAsp OD	40	24	2	2	2	1	11
		IDet	41	25	3	2	2	1	8
		Total	81	49	3	2	2	1	11
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	7	4	6	2	21
		IDet	41	41	10	5	9	3	26
		Total	81	81	8	5	7	2	26
	Breakfast	IDegAsp OD	40	24	3	1	3	1	5
		IDet	41	41	3	2	2	1	10
		Total	81	65	3	2	2	1	10
	Lunch	IDegAsp OD	40	35	3	1	3	1	6
		IDet	41	41	3	1	2	1	7
		Total	81	76	3	1	3	1	7
	Main Evening Meal	IDegAsp OD	40	32	3	2	3	1	9
		IDet	41	39	3	1	3	1	7
		Total	81	71	3	1	3	1	9
	Other	IDegAsp OD	40	29	2	2	2	1	8
		IDet	41	26	3	3	3	1	14
		Total	81	55	3	2	2	1	14
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	7	4	6	2	20
		IDet	41	40	10	5	9	2	23
		Total	81	80	8	5	7	2	23
	Breakfast	IDegAsp OD	40	25	2	1	2	1	5
		IDet	41	40	3	2	3	1	10
		Total	81	65	3	2	3	1	10

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 5 (Week 3)	Lunch	IDegAsp OD	40	38	3	2	2	1	12
		IDet	41	40	2	1	2	1	8
		Total	81	78	3	2	2	1	12
	Main Evening Meal	IDegAsp OD	40	32	3	1	2	1	6
		IDet	41	39	3	1	2	1	6
		Total	81	71	3	1	2	1	6
	Other	IDegAsp OD	40	25	3	2	3	1	7
		IDet	41	23	3	2	3	1	9
		Total	81	48	3	2	3	1	9
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	7	3	7	2	15
		IDet	41	40	10	5	9	4	27
		Total	81	80	8	4	8	2	27
	Breakfast	IDegAsp OD	40	27	2	2	2	1	6
		IDet	41	40	3	2	3	1	8
		Total	81	67	3	2	3	1	8
	Lunch	IDegAsp OD	40	33	3	2	3	1	10
		IDet	41	40	3	1	3	1	8
		Total	81	73	3	2	3	1	10
	Main Evening Meal	IDegAsp OD	40	30	3	1	2	1	6
		IDet	41	40	3	1	3	1	7
		Total	81	70	3	1	2	1	7
	Other	IDegAsp OD	40	26	2	1	2	1	5
		IDet	41	25	3	2	3	1	12
		Total	81	51	3	2	2	1	12
Visit 7 (Week 5)	Daily	IDegAsp OD	40	39	7	4	6	1	17
		IDet	41	40	9	4	8	3	18
		Total	81	79	8	4	7	1	18
	Breakfast	IDegAsp OD	40	27	2	1	3	1	6
		IDet	41	40	3	1	3	1	6
		Total	81	67	3	1	3	1	6
	Lunch	IDegAsp OD	40	33	3	2	2	1	9
		IDet	41	40	3	1	2	1	7
		Total	81	73	3	1	2	1	9

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 7 (Week 5)	Main Evening Meal	IDegAsp OD	40	31	2	1	2	1	8
		IDet	41	40	2	1	2	1	5
		Total	81	71	2	1	2	1	8
	Other	IDegAsp OD	40	28	2	1	1	1	5
		IDet	41	26	3	1	3	1	6
		Total	81	54	2	2	2	1	6
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	7	3	7	1	13
		IDet	41	40	9	4	9	2	19
		Total	81	80	8	3	7	1	19
	Breakfast	IDegAsp OD	40	28	3	1	2	1	7
		IDet	41	39	3	1	2	1	6
		Total	81	67	3	1	2	1	7
	Lunch	IDegAsp OD	40	34	3	2	2	1	10
		IDet	41	40	3	1	2	1	6
		Total	81	74	3	1	2	1	10
	Main Evening Meal	IDegAsp OD	40	32	3	1	3	1	6
		IDet	41	39	3	1	2	1	6
		Total	81	71	3	1	3	1	6
	Other	IDegAsp OD	40	24	2	1	2	1	6
		IDet	41	27	3	2	2	1	10
		Total	81	51	2	2	2	1	10
Visit 9 (Week 7)	Daily	IDegAsp OD	40	39	7	3	7	2	20
		IDet	41	40	9	4	8	3	21
		Total	81	79	8	4	7	2	21
	Breakfast	IDegAsp OD	40	28	3	1	3	1	5
		IDet	41	40	3	1	3	1	6
		Total	81	68	3	1	3	1	6
	Lunch	IDegAsp OD	40	35	3	2	2	1	10
		IDet	41	40	3	1	2	1	6
		Total	81	75	3	1	2	1	10
	Main Evening Meal	IDegAsp OD	40	32	2	1	2	1	5
		IDet	41	39	3	1	3	1	6
		Total	81	71	2	1	3	1	6

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) – safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 9 (Week 7)	Other	IDegAsp OD	40	24	2	1	2	1	6
		IDet	41	27	3	2	3	1	7
		Total	81	51	3	2	2	1	7
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	7	4	7	2	21
		IDet	41	40	10	5	9	2	29
		Total	81	79	9	5	7	2	29
	Breakfast	IDegAsp OD	40	27	3	1	3	1	6
		IDet	41	40	3	1	3	1	7
		Total	81	67	3	1	3	1	7
	Lunch	IDegAsp OD	40	32	3	2	3	1	11
		IDet	41	40	3	1	3	1	6
		Total	81	72	3	2	3	1	11
	Main Evening Meal	IDegAsp OD	40	31	2	1	2	1	8
		IDet	41	39	3	1	3	1	7
		Total	81	70	3	1	2	1	8
	Other	IDegAsp OD	40	23	2	1	2	1	6
		IDet	41	25	4	3	2	1	16
		Total	81	48	3	3	2	1	16
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	7	4	7	2	21
		IDet	41	40	9	4	9	3	17
		Total	81	78	8	4	8	2	21
	Breakfast	IDegAsp OD	40	27	3	1	3	1	5
		IDet	41	40	3	1	3	1	7
		Total	81	67	3	1	3	1	7
	Lunch	IDegAsp OD	40	32	3	2	3	1	13
		IDet	41	40	3	1	3	1	5
		Total	81	72	3	2	3	1	13
	Main Evening Meal	IDegAsp OD	40	30	2	1	2	1	6
		IDet	41	40	2	1	2	1	5
		Total	81	70	2	1	2	1	6
	Other	IDegAsp OD	40	23	2	2	2	1	7
		IDet	41	23	3	2	2	1	9
		Total	81	46	2	2	2	1	9
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	7	4	7	1	17
		IDet	41	39	9	4	7	4	17
		Total	81	77	8	4	7	1	17

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 12 (Week 10)	Breakfast	IDegAsp OD	40	28	3	1	3	1	5
		IDet	41	39	3	1	3	1	5
		Total	81	67	3	1	3	1	5
	Lunch	IDegAsp OD	40	34	3	2	2	1	11
		IDet	41	39	3	1	2	1	5
		Total	81	73	3	2	2	1	11
	Main Evening Meal	IDegAsp OD	40	32	3	1	3	1	6
		IDet	41	39	2	1	2	1	5
		Total	81	71	2	1	2	1	6
	Other	IDegAsp OD	40	21	2	2	2	1	9
		IDet	41	24	3	2	2	1	7
		Total	81	45	2	2	2	1	9
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	7	4	7	1	23
		IDet	41	39	9	4	9	3	17
		Total	81	77	8	4	8	1	23
	Breakfast	IDegAsp OD	40	27	3	1	3	1	6
		IDet	41	39	3	1	3	1	5
		Total	81	66	3	1	3	1	6
	Lunch	IDegAsp OD	40	33	3	2	3	1	14
		IDet	41	39	2	1	2	1	5
		Total	81	72	3	2	2	1	14
	Main Evening Meal	IDegAsp OD	40	31	2	1	3	1	6
		IDet	41	38	2	1	2	1	6
		Total	81	69	2	1	2	1	6
	Other	IDegAsp OD	40	22	2	1	2	1	7
		IDet	41	25	3	1	2	1	7
		Total	81	47	2	1	2	1	7
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	7	4	7	1	21
		IDet	41	39	9	4	10	3	18
		Total	81	77	8	4	7	1	21
	Breakfast	IDegAsp OD	40	27	3	1	3	1	5
		IDet	41	39	3	1	3	1	6
		Total	81	66	3	1	3	1	6
	Lunch	IDegAsp OD	40	32	3	2	2	1	12
		IDet	41	39	3	1	2	1	5
		Total	81	71	3	2	2	1	12

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
				Descriptive Statistics					
Visit 14 (Week 12)	Main Evening Meal	IDegAsp OD	40	28	2	1	2	1	5
		IDet	41	38	3	1	2	1	6
		Total	81	66	2	1	2	1	6
	Other	IDegAsp OD	40	26	2	1	2	1	7
		IDet	41	25	3	2	3	1	8
		Total	81	51	2	2	2	1	8
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	8	5	7	1	31
		IDet	41	39	9	4	9	4	21
		Total	81	77	8	5	8	1	31
	Breakfast	IDegAsp OD	40	28	3	1	3	1	7
		IDet	41	39	3	1	3	1	8
		Total	81	67	3	1	3	1	8
	Lunch	IDegAsp OD	40	32	3	2	3	1	12
		IDet	41	39	3	1	3	1	5
		Total	81	71	3	2	3	1	12
	Main Evening Meal	IDegAsp OD	40	32	3	4	2	1	25
		IDet	41	38	3	1	2	1	8
		Total	81	70	3	3	2	1	25
	Other	IDegAsp OD	40	24	2	2	2	1	7
		IDet	41	23	3	2	2	1	7
		Total	81	47	2	2	2	1	7
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	7	3	7	1	18
		IDet	41	40	9	4	9	3	16
		Total	81	78	8	4	8	1	18
	Breakfast	IDegAsp OD	40	26	3	1	3	1	5
		IDet	41	39	3	1	2	1	7
		Total	81	65	3	1	3	1	7
	Lunch	IDegAsp OD	40	32	3	2	2	1	10
		IDet	41	40	2	1	2	1	6
		Total	81	72	3	1	2	1	10
	Main Evening Meal	IDegAsp OD	40	31	2	1	2	1	6
		IDet	41	39	3	1	2	1	6
		Total	81	70	2	1	2	1	6

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 16 (Week 14)	Other	IDegAsp OD	40	23	2	1	2	1	6
		IDet	41	22	3	1	3	1	6
		Total	81	45	2	1	2	1	6
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	7	4	7	1	21
		IDet	41	38	9	4	10	4	19
		Total	81	76	8	4	8	1	21
	Breakfast	IDegAsp OD	40	27	3	1	3	1	5
		IDet	41	38	3	1	3	1	8
		Total	81	65	3	1	3	1	8
	Lunch	IDegAsp OD	40	32	3	2	3	1	13
		IDet	41	38	2	1	2	1	4
		Total	81	70	3	2	2	1	13
	Main Evening Meal	IDegAsp OD	40	31	2	1	2	1	6
		IDet	41	37	3	1	3	1	6
		Total	81	68	3	1	2	1	6
	Other	IDegAsp OD	40	23	2	1	2	1	6
		IDet	41	22	3	2	3	1	6
		Total	81	45	2	2	2	1	6
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	7	4	7	1	19
		IDet	41	37	9	4	9	3	21
		Total	81	75	8	4	8	1	21
	Breakfast	IDegAsp OD	40	27	3	1	3	1	5
		IDet	41	37	3	1	3	1	6
		Total	81	64	3	1	3	1	6
	Lunch	IDegAsp OD	40	33	3	2	2	1	10
		IDet	41	37	3	1	2	1	5
		Total	81	70	3	1	2	1	10
	Main Evening Meal	IDegAsp OD	40	30	2	1	2	1	5
		IDet	41	36	3	1	2	1	6
		Total	81	66	3	1	2	1	6
	Other	IDegAsp OD	40	22	2	2	2	1	6
		IDet	41	23	3	2	3	1	9
		Total	81	45	2	2	2	1	9

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
End of trial visit	Daily	IDegAsp OD	40	40	7	3	7	1	19
		IDet	41	41	9	4	9	3	21
		Total	81	81	8	4	8	1	21
	Breakfast	IDegAsp OD	40	34	3	1	3	1	6
		IDet	41	41	3	1	3	1	6
		Total	81	75	3	1	3	1	6
	Lunch	IDegAsp OD	40	39	3	2	2	1	12
		IDet	41	41	3	1	3	1	5
		Total	81	80	3	2	2	1	12
	Main Evening Meal	IDegAsp OD	40	37	3	4	3	1	25
		IDet	41	41	3	1	2	1	6
		Total	81	78	3	3	2	1	25
	Other	IDegAsp OD	40	38	2	1	1	1	6
		IDet	41	35	3	2	3	1	9
		Total	81	73	2	2	2	1	9

N: Number of subjects, SD: Standard deviation

14.2.44 IAsp dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	61	59	11	5	10	2	26
		IDet	61	61	17	9	16	1	44
		Total	122	120	14	8	12	1	44
	Breakfast	IDegAsp OD	61	41	4	2	4	1	11
		IDet	61	61	5	3	5	1	15
		Total	122	102	5	3	4	1	15
	Lunch	IDegAsp OD	61	54	4	2	4	1	10
		IDet	61	59	5	3	5	1	15
		Total	122	113	5	3	4	1	15
	Main Evening Meal	IDegAsp OD	61	38	4	2	3	1	10
		IDet	61	60	5	3	5	1	16
		Total	122	98	5	3	4	1	16
	Other	IDegAsp OD	61	33	4	3	3	1	10
		IDet	61	38	3	2	3	1	8
		Total	122	71	3	2	3	1	10
Visit 4 (Week 2)	Daily	IDegAsp OD	61	60	11	7	9	3	39
		IDet	61	60	18	10	16	1	44
		Total	122	120	14	9	13	1	44
	Breakfast	IDegAsp OD	61	43	5	3	4	2	20
		IDet	61	60	5	3	5	1	15
		Total	122	103	5	3	5	1	20
	Lunch	IDegAsp OD	61	54	4	2	4	1	12
		IDet	61	57	5	3	5	1	17
		Total	122	111	5	3	5	1	17
	Main Evening Meal	IDegAsp OD	61	42	4	2	4	1	11
		IDet	61	59	5	3	5	1	16
		Total	122	101	5	3	4	1	16
	Other	IDegAsp OD	61	32	4	3	3	1	13
		IDet	61	37	4	4	4	1	18
		Total	122	69	4	3	3	1	18
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	11	6	10	3	35
		IDet	61	59	18	10	16	2	46
		Total	122	119	14	9	12	2	46
	Breakfast	IDegAsp OD	61	42	5	2	5	1	11
		IDet	61	59	5	3	5	1	15
		Total	122	101	5	3	5	1	15

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 5 (Week 3)	Lunch	IDegAsp OD	61	53	4	2	4	1	12
		IDet	61	56	5	3	5	1	17
		Total	122	109	5	3	4	1	17
	Main Evening Meal	IDegAsp OD	61	40	4	3	4	1	14
		IDet	61	58	5	3	4	1	20
		Total	122	98	5	3	4	1	20
	Other	IDegAsp OD	61	36	3	3	3	1	10
		IDet	61	37	4	3	3	1	16
		Total	122	73	4	3	3	1	16
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	11	6	10	1	31
		IDet	61	59	17	9	16	3	41
		Total	122	119	14	8	12	1	41
	Breakfast	IDegAsp OD	61	40	5	2	5	1	12
		IDet	61	59	5	3	5	1	13
		Total	122	99	5	3	5	1	13
	Lunch	IDegAsp OD	61	53	4	2	4	1	11
		IDet	61	56	5	3	5	1	17
		Total	122	109	5	3	4	1	17
	Main Evening Meal	IDegAsp OD	61	42	4	3	4	1	20
		IDet	61	58	5	3	5	1	16
		Total	122	100	5	3	4	1	20
	Other	IDegAsp OD	61	30	3	2	3	1	8
		IDet	61	34	4	2	4	1	9
		Total	122	64	4	2	3	1	9
Visit 7 (Week 5)	Daily	IDegAsp OD	61	60	11	5	10	3	21
		IDet	61	59	18	10	16	1	43
		Total	122	119	14	8	12	1	43
	Breakfast	IDegAsp OD	61	43	5	3	5	1	12
		IDet	61	58	6	3	5	1	15
		Total	122	101	5	3	5	1	15
	Lunch	IDegAsp OD	61	54	4	2	4	1	12
		IDet	61	57	5	3	5	1	17
		Total	122	111	5	3	4	1	17

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 7 (Week 5)	Main Evening Meal	IDegAsp OD	61	38	4	2	3	1	9
		IDet	61	58	5	3	5	1	14
		Total	122	96	5	3	4	1	14
	Other	IDegAsp OD	61	32	3	2	3	1	7
		IDet	61	37	4	3	3	1	13
		Total	122	69	4	2	3	1	13
Visit 8 (Week 6)	Daily	IDegAsp OD	61	59	11	5	11	3	24
		IDet	61	59	17	10	16	2	44
		Total	122	118	14	8	13	2	44
	Breakfast	IDegAsp OD	61	42	4	2	4	1	10
		IDet	61	58	5	3	5	1	15
		Total	122	100	5	3	5	1	15
	Lunch	IDegAsp OD	61	53	5	2	4	1	12
		IDet	61	56	5	3	5	1	15
		Total	122	109	5	3	5	1	15
	Main Evening Meal	IDegAsp OD	61	38	4	2	3	1	8
		IDet	61	58	6	3	5	1	18
		Total	122	96	5	3	4	1	18
	Other	IDegAsp OD	61	33	3	2	3	1	8
		IDet	61	33	4	3	3	1	16
		Total	122	66	4	3	3	1	16
Visit 9 (Week 7)	Daily	IDegAsp OD	61	60	11	5	10	1	28
		IDet	61	59	18	11	17	1	63
		Total	122	119	14	9	13	1	63
	Breakfast	IDegAsp OD	61	43	4	2	4	1	10
		IDet	61	58	6	4	5	1	26
		Total	122	101	5	4	5	1	26
	Lunch	IDegAsp OD	61	53	4	2	4	1	14
		IDet	61	57	5	3	5	1	16
		Total	122	110	5	3	4	1	16
	Main Evening Meal	IDegAsp OD	61	39	4	2	4	1	10
		IDet	61	58	6	3	5	2	19
		Total	122	97	5	3	4	1	19

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 9 (Week 7)	Other	IDegAsp OD	61	34	3	2	3	1	11
		IDet	61	35	4	3	3	1	14
		Total	122	69	3	3	3	1	14
Visit 10 (Week 8)	Daily	IDegAsp OD	61	60	11	5	10	2	24
		IDet	61	59	18	11	16	1	56
		Total	122	119	15	9	13	1	56
	Breakfast	IDegAsp OD	61	45	4	2	5	1	11
		IDet	61	58	6	4	5	1	26
		Total	122	103	5	3	5	1	26
	Lunch	IDegAsp OD	61	53	4	2	4	1	10
		IDet	61	56	6	3	5	1	16
		Total	122	109	5	3	5	1	16
	Main Evening Meal	IDegAsp OD	61	39	4	2	4	1	9
		IDet	61	58	5	3	5	1	17
		Total	122	97	5	3	4	1	17
	Other	IDegAsp OD	61	35	3	3	3	1	15
		IDet	61	39	3	3	3	1	15
		Total	122	74	3	3	3	1	15
Visit 11 (Week 9)	Daily	IDegAsp OD	61	60	11	5	10	3	31
		IDet	61	59	18	12	16	4	83
		Total	122	119	15	10	13	3	83
	Breakfast	IDegAsp OD	61	45	5	3	5	1	18
		IDet	61	58	6	4	5	1	25
		Total	122	103	5	4	5	1	25
	Lunch	IDegAsp OD	61	54	4	2	4	1	9
		IDet	61	57	6	3	5	1	20
		Total	122	111	5	3	5	1	20
	Main Evening Meal	IDegAsp OD	61	39	4	3	4	1	13
		IDet	61	58	6	4	5	1	22
		Total	122	97	5	3	4	1	22
	Other	IDegAsp OD	61	40	3	3	2	1	14
		IDet	61	38	4	3	3	1	17
		Total	122	78	3	3	3	1	17
Visit 12 (Week 10)	Daily	IDegAsp OD	61	59	11	5	10	3	25
		IDet	61	59	18	10	15	2	61
		Total	122	118	14	9	12	2	61

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 12 (Week 10)	Breakfast	IDegAsp OD	61	44	4	2	4	1	11
		IDet	61	58	6	4	5	1	21
		Total	122	102	5	3	4	1	21
	Lunch	IDegAsp OD	61	53	4	2	5	2	11
		IDet	61	57	6	3	5	1	18
		Total	122	110	5	3	5	1	18
	Main Evening Meal	IDegAsp OD	61	38	4	2	3	1	10
		IDet	61	58	6	3	5	1	19
		Total	122	96	5	3	4	1	19
	Other	IDegAsp OD	61	36	3	2	2	1	9
		IDet	61	35	4	2	3	1	10
		Total	122	71	3	2	3	1	10
Visit 13 (Week 11)	Daily	IDegAsp OD	61	59	11	5	11	3	28
		IDet	61	59	19	12	16	2	71
		Total	122	118	15	10	12	2	71
	Breakfast	IDegAsp OD	61	45	5	2	4	2	10
		IDet	61	59	6	4	5	1	21
		Total	122	104	5	3	5	1	21
	Lunch	IDegAsp OD	61	52	4	2	4	1	14
		IDet	61	56	6	4	5	1	22
		Total	122	108	5	3	5	1	22
	Main Evening Meal	IDegAsp OD	61	37	4	2	4	1	9
		IDet	61	58	6	4	5	1	27
		Total	122	95	5	3	4	1	27
	Other	IDegAsp OD	61	38	3	2	2	1	11
		IDet	61	39	3	2	3	1	10
		Total	122	77	3	2	2	1	11
Visit 14 (Week 12)	Daily	IDegAsp OD	61	59	11	4	11	3	23
		IDet	61	59	18	10	18	1	53
		Total	122	118	15	9	13	1	53
	Breakfast	IDegAsp OD	61	45	5	2	5	2	12
		IDet	61	59	6	4	5	1	18
		Total	122	104	5	3	5	1	18
	Lunch	IDegAsp OD	61	52	4	2	4	1	9
		IDet	61	56	6	3	5	1	15
		Total	122	108	5	3	5	1	15

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
				Descriptive Statistics					
Visit 14 (Week 12)	Main Evening Meal	IDegAsp OD	61	38	4	2	4	1	9
		IDet	61	58	6	4	5	1	21
		Total	122	96	5	3	4	1	21
	Other	IDegAsp OD	61	36	3	2	2	1	10
		IDet	61	36	4	3	4	1	13
		Total	122	72	3	3	3	1	13
Visit 15 (Week 13)	Daily	IDegAsp OD	61	59	11	4	10	3	25
		IDet	61	59	18	10	17	1	64
		Total	122	118	15	9	13	1	64
	Breakfast	IDegAsp OD	61	45	4	2	4	1	10
		IDet	61	59	6	4	5	1	22
		Total	122	104	5	3	5	1	22
	Lunch	IDegAsp OD	61	53	4	2	4	1	10
		IDet	61	56	6	3	6	1	20
		Total	122	109	5	3	5	1	20
	Main Evening Meal	IDegAsp OD	61	39	4	2	3	1	8
		IDet	61	58	6	3	5	1	21
		Total	122	97	5	3	4	1	21
	Other	IDegAsp OD	61	33	3	3	3	1	12
		IDet	61	35	4	2	4	1	9
		Total	122	68	3	3	3	1	12
Visit 16 (Week 14)	Daily	IDegAsp OD	61	59	11	6	11	3	37
		IDet	61	59	19	11	18	1	70
		Total	122	118	15	10	13	1	70
	Breakfast	IDegAsp OD	61	45	5	2	4	1	11
		IDet	61	59	6	4	5	1	24
		Total	122	104	5	3	5	1	24
	Lunch	IDegAsp OD	61	52	4	3	4	1	17
		IDet	61	56	6	4	5	1	24
		Total	122	108	5	3	5	1	24
	Main Evening Meal	IDegAsp OD	61	39	4	2	4	1	11
		IDet	61	57	6	3	5	1	21
		Total	122	96	5	3	5	1	21

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 16 (Week 14)	Other	IDegAsp OD	61	33	3	3	3	1	11
		IDet	61	37	4	2	3	1	12
		Total	122	70	4	2	3	1	12
Visit 17 (Week 15)	Daily	IDegAsp OD	61	59	11	5	10	3	24
		IDet	61	59	19	11	18	2	66
		Total	122	118	15	9	13	2	66
	Breakfast	IDegAsp OD	61	48	5	2	4	1	10
		IDet	61	59	6	4	5	1	23
		Total	122	107	5	3	5	1	23
	Lunch	IDegAsp OD	61	51	4	2	4	1	9
		IDet	61	57	6	4	5	1	25
		Total	122	108	5	3	5	1	25
	Main Evening Meal	IDegAsp OD	61	38	4	2	4	1	9
		IDet	61	57	6	3	5	1	16
		Total	122	95	5	3	5	1	16
	Other	IDegAsp OD	61	32	4	3	2	1	15
		IDet	61	36	4	2	3	1	9
		Total	122	68	4	3	3	1	15
Visit 18 (Week 16)	Daily	IDegAsp OD	61	58	12	5	11	3	30
		IDet	61	59	18	11	17	2	66
		Total	122	117	15	9	14	2	66
	Breakfast	IDegAsp OD	61	47	5	2	4	1	10
		IDet	61	58	6	4	5	1	29
		Total	122	105	5	4	5	1	29
	Lunch	IDegAsp OD	61	50	5	2	5	1	11
		IDet	61	56	6	3	5	1	16
		Total	122	106	5	3	5	1	16
	Main Evening Meal	IDegAsp OD	61	38	4	2	4	1	9
		IDet	61	57	6	4	5	1	22
		Total	122	95	5	3	5	1	22
	Other	IDegAsp OD	61	39	3	3	3	1	14
		IDet	61	38	3	2	3	1	8
		Total	122	77	3	3	3	1	14

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
End of trial visit	Daily	IDegAsp OD	61	61	12	5	11	1	30
		IDet	61	61	18	10	17	2	66
		Total	122	122	15	9	14	1	66
	Breakfast	IDegAsp OD	61	51	5	2	4	1	10
		IDet	61	61	6	4	5	1	29
		Total	122	112	5	3	5	1	29
	Lunch	IDegAsp OD	61	58	5	2	5	1	11
		IDet	61	59	5	3	5	1	16
		Total	122	117	5	3	5	1	16
	Main Evening Meal	IDegAsp OD	61	52	4	2	4	1	11
		IDet	61	60	6	4	5	1	22
		Total	122	112	5	3	4	1	22
	Other	IDegAsp OD	61	52	3	3	2	1	14
		IDet	61	55	3	2	3	1	9
		Total	122	107	3	3	3	1	14

N: Number of subjects, SD: Standard deviation

14.2.45 IAsp dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	79	22	13	21	1	64
		IDet	77	76	34	18	32	4	110
		Total	157	155	28	17	26	1	110
	Breakfast	IDegAsp OD	80	60	8	5	7	1	20
		IDet	77	74	10	6	9	2	39
		Total	157	134	9	5	9	1	39
	Lunch	IDegAsp OD	80	74	8	4	7	2	28
		IDet	77	75	11	5	9	1	30
		Total	157	149	9	5	8	1	30
	Main Evening Meal	IDegAsp OD	80	47	8	5	6	1	23
		IDet	77	76	10	6	9	1	27
		Total	157	123	9	5	8	1	27
	Other	IDegAsp OD	80	48	8	8	6	1	34
		IDet	77	45	8	6	7	1	26
		Total	157	93	8	7	6	1	34
Visit 4 (Week 2)	Daily	IDegAsp OD	80	79	22	11	20	1	70
		IDet	77	77	35	17	34	4	91
		Total	157	156	28	16	26	1	91
	Breakfast	IDegAsp OD	80	62	8	4	8	1	20
		IDet	77	77	10	5	9	1	25
		Total	157	139	9	5	8	1	25
	Lunch	IDegAsp OD	80	75	8	4	7	2	26
		IDet	77	77	10	5	10	1	27
		Total	157	152	9	5	9	1	27
	Main Evening Meal	IDegAsp OD	80	50	8	5	7	2	21
		IDet	77	76	11	6	10	1	30
		Total	157	126	10	5	9	1	30
	Other	IDegAsp OD	80	51	7	7	5	1	40
		IDet	77	42	9	6	8	2	30
		Total	157	93	8	7	6	1	40
Visit 5 (Week 3)	Daily	IDegAsp OD	80	79	22	11	20	3	53
		IDet	77	77	34	17	32	4	94
		Total	157	156	28	15	25	3	94
	Breakfast	IDegAsp OD	80	59	9	5	8	1	21
		IDet	77	74	10	5	10	1	26
		Total	157	133	10	5	9	1	26

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 5 (Week 3)	Lunch	IDegAsp OD	80	76	9	4	8	2	24
		IDet	77	76	11	5	10	2	24
		Total	157	152	10	5	9	2	24
	Main Evening Meal	IDegAsp OD	80	48	8	5	7	2	21
		IDet	77	76	11	6	10	1	29
		Total	157	124	10	6	9	1	29
	Other	IDegAsp OD	80	47	7	6	6	1	31
		IDet	77	46	7	5	6	1	23
		Total	157	93	7	5	6	1	31
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	22	11	20	1	57
		IDet	77	77	35	18	32	4	96
		Total	157	156	28	16	26	1	96
	Breakfast	IDegAsp OD	80	58	9	5	8	1	21
		IDet	77	76	11	6	10	2	28
		Total	157	134	10	5	9	1	28
	Lunch	IDegAsp OD	80	74	9	4	8	1	26
		IDet	77	76	11	5	10	3	26
		Total	157	150	10	5	9	1	26
	Main Evening Meal	IDegAsp OD	80	50	8	4	7	2	20
		IDet	77	76	11	5	10	1	26
		Total	157	126	9	5	9	1	26
	Other	IDegAsp OD	80	44	8	7	6	1	37
		IDet	77	42	7	6	5	1	31
		Total	157	86	8	6	6	1	37
Visit 7 (Week 5)	Daily	IDegAsp OD	80	77	21	12	19	2	60
		IDet	77	75	36	18	33	4	99
		Total	157	152	28	17	26	2	99
	Breakfast	IDegAsp OD	80	56	9	5	8	1	20
		IDet	77	73	11	6	10	2	30
		Total	157	129	10	5	9	1	30
	Lunch	IDegAsp OD	80	75	8	4	8	2	21
		IDet	77	73	11	5	11	2	26
		Total	157	148	10	5	9	2	26

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 7 (Week 5)	Main Evening Meal	IDegAsp OD	80	47	7	5	6	1	20
		IDet	77	73	11	6	10	1	26
		Total	157	120	10	6	9	1	26
	Other	IDegAsp OD	80	43	7	6	6	2	26
		IDet	77	42	9	6	7	1	30
		Total	157	85	8	6	6	1	30
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	22	12	20	3	63
		IDet	77	75	35	17	32	4	88
		Total	157	153	29	16	26	3	88
	Breakfast	IDegAsp OD	80	57	9	5	9	1	21
		IDet	77	74	11	6	10	1	30
		Total	157	131	10	6	9	1	30
	Lunch	IDegAsp OD	80	76	9	5	9	2	25
		IDet	77	74	11	5	11	2	26
		Total	157	150	10	5	10	2	26
	Main Evening Meal	IDegAsp OD	80	45	8	5	7	2	22
		IDet	77	74	11	5	10	2	26
		Total	157	119	10	5	9	2	26
	Other	IDegAsp OD	80	47	7	6	5	1	28
		IDet	77	45	8	5	6	1	23
		Total	157	92	7	6	6	1	28
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	22	13	21	2	68
		IDet	77	73	36	17	34	3	88
		Total	157	150	29	16	26	2	88
	Breakfast	IDegAsp OD	80	56	9	5	8	1	20
		IDet	77	73	11	6	11	1	30
		Total	157	129	10	5	10	1	30
	Lunch	IDegAsp OD	80	73	9	4	8	1	26
		IDet	77	72	11	5	10	1	26
		Total	157	145	10	5	9	1	26
	Main Evening Meal	IDegAsp OD	80	44	8	6	7	1	22
		IDet	77	73	11	6	10	1	29
		Total	157	117	10	6	9	1	29

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 9 (Week 7)	Other	IDegAsp OD	80	50	7	7	5	1	36
		IDet	77	39	7	5	5	1	21
		Total	157	89	7	6	5	1	36
Visit 10 (Week 8)	Daily	IDegAsp OD	80	76	22	13	20	2	70
		IDet	77	74	34	16	32	4	82
		Total	157	150	28	16	25	2	82
	Breakfast	IDegAsp OD	80	56	8	5	8	1	22
		IDet	77	73	10	5	10	2	28
		Total	157	129	10	5	9	1	28
	Lunch	IDegAsp OD	80	74	9	5	8	1	27
		IDet	77	72	11	5	10	1	26
		Total	157	146	10	5	9	1	27
	Main Evening Meal	IDegAsp OD	80	44	8	5	7	1	20
		IDet	77	73	11	5	10	1	26
		Total	157	117	10	5	9	1	26
	Other	IDegAsp OD	80	42	7	7	5	2	34
		IDet	77	40	7	5	6	2	20
		Total	157	82	7	6	5	2	34
Visit 11 (Week 9)	Daily	IDegAsp OD	80	77	22	12	21	1	67
		IDet	77	73	36	17	34	4	95
		Total	157	150	29	16	27	1	95
	Breakfast	IDegAsp OD	80	56	9	6	8	1	33
		IDet	77	72	10	6	10	1	28
		Total	157	128	10	6	9	1	33
	Lunch	IDegAsp OD	80	74	9	4	8	2	27
		IDet	77	72	11	5	10	2	25
		Total	157	146	10	5	9	2	27
	Main Evening Meal	IDegAsp OD	80	43	9	5	8	2	22
		IDet	77	72	11	5	10	1	24
		Total	157	115	10	5	9	1	24
	Other	IDegAsp OD	80	46	7	5	6	2	26
		IDet	77	42	8	6	6	1	24
		Total	157	88	8	6	6	1	26
Visit 12 (Week 10)	Daily	IDegAsp OD	80	76	22	12	22	3	64
		IDet	77	74	35	16	33	4	81
		Total	157	150	29	15	26	3	81

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 12 (Week 10)	Breakfast	IDegAsp OD	80	55	9	5	8	1	24
		IDet	77	73	11	5	10	1	27
		Total	157	128	10	5	10	1	27
	Lunch	IDegAsp OD	80	72	9	5	9	1	26
		IDet	77	73	11	6	10	2	26
		Total	157	145	10	5	9	1	26
	Main Evening Meal	IDegAsp OD	80	45	9	7	8	1	41
		IDet	77	72	11	5	10	2	27
		Total	157	117	10	6	9	1	41
	Other	IDegAsp OD	80	46	7	5	5	1	22
		IDet	77	44	8	6	5	1	24
		Total	157	90	7	5	5	1	24
Visit 13 (Week 11)	Daily	IDegAsp OD	80	76	22	13	20	2	80
		IDet	77	74	34	15	33	4	91
		Total	157	150	28	15	26	2	91
	Breakfast	IDegAsp OD	80	55	9	5	8	1	20
		IDet	77	70	10	5	10	1	29
		Total	157	125	10	5	9	1	29
	Lunch	IDegAsp OD	80	73	9	5	8	1	23
		IDet	77	73	11	5	9	2	29
		Total	157	146	10	5	9	1	29
	Main Evening Meal	IDegAsp OD	80	41	8	5	7	2	19
		IDet	77	72	11	5	10	2	30
		Total	157	113	10	5	9	2	30
	Other	IDegAsp OD	80	45	7	6	5	2	38
		IDet	77	37	7	5	6	2	23
		Total	157	82	7	6	6	2	38
Visit 14 (Week 12)	Daily	IDegAsp OD	80	76	22	14	20	2	78
		IDet	77	74	34	16	32	4	97
		Total	157	150	28	16	25	2	97
	Breakfast	IDegAsp OD	80	56	8	5	8	2	22
		IDet	77	73	11	6	10	1	30
		Total	157	129	10	5	9	1	30
	Lunch	IDegAsp OD	80	73	9	5	8	2	26
		IDet	77	72	11	5	10	1	27
		Total	157	145	10	5	9	1	27

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 14 (Week 12)	Main Evening Meal	IDegAsp OD	80	43	9	6	7	1	31
		IDet	77	72	11	5	10	2	31
		Total	157	115	10	6	9	1	31
	Other	IDegAsp OD	80	45	7	6	4	2	36
		IDet	77	40	9	6	7	1	29
		Total	157	85	8	6	6	1	36
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	22	12	20	2	69
		IDet	77	73	35	17	34	3	85
		Total	157	150	28	16	25	2	85
	Breakfast	IDegAsp OD	80	55	9	5	9	1	20
		IDet	77	73	11	6	10	1	29
		Total	157	128	10	6	9	1	29
	Lunch	IDegAsp OD	80	73	9	4	9	2	23
		IDet	77	72	11	6	10	2	31
		Total	157	145	10	5	9	2	31
	Main Evening Meal	IDegAsp OD	80	44	8	5	7	3	24
		IDet	77	71	11	6	10	2	32
		Total	157	115	10	6	9	2	32
	Other	IDegAsp OD	80	47	7	5	5	2	27
		IDet	77	36	8	5	6	2	25
		Total	157	83	7	5	5	2	27
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	23	12	21	3	69
		IDet	77	71	34	15	32	3	86
		Total	157	148	28	15	27	3	86
	Breakfast	IDegAsp OD	80	56	9	5	9	1	21
		IDet	77	70	10	5	10	1	30
		Total	157	126	10	5	9	1	30
	Lunch	IDegAsp OD	80	72	9	5	9	2	29
		IDet	77	70	11	5	10	1	25
		Total	157	142	10	5	9	1	29
	Main Evening Meal	IDegAsp OD	80	45	9	5	7	2	18
		IDet	77	69	11	6	10	3	33
		Total	157	114	10	5	10	2	33

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 16 (Week 14)	Other	IDegAsp OD	80	48	7	5	5	1	27
		IDet	77	35	8	5	6	2	23
		Total	157	83	7	5	6	1	27
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	23	12	21	2	67
		IDet	77	73	35	17	32	3	88
		Total	157	148	29	16	26	2	88
	Breakfast	IDegAsp OD	80	53	9	5	9	2	23
		IDet	77	72	11	6	10	1	30
		Total	157	125	10	6	10	1	30
	Lunch	IDegAsp OD	80	71	9	4	9	2	21
		IDet	77	72	11	6	10	1	31
		Total	157	143	10	5	9	1	31
	Main Evening Meal	IDegAsp OD	80	45	9	7	8	1	39
		IDet	77	71	11	6	10	2	34
		Total	157	116	10	6	10	1	39
	Other	IDegAsp OD	80	49	7	5	6	2	25
		IDet	77	40	8	5	6	1	23
		Total	157	89	7	5	6	1	25
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	22	12	22	2	76
		IDet	77	70	35	17	34	3	90
		Total	157	146	28	16	26	2	90
	Breakfast	IDegAsp OD	80	54	9	4	9	1	19
		IDet	77	70	11	6	10	1	29
		Total	157	124	10	5	10	1	29
	Lunch	IDegAsp OD	80	72	9	4	9	2	24
		IDet	77	69	11	6	10	2	31
		Total	157	141	10	5	9	2	31
	Main Evening Meal	IDegAsp OD	80	44	9	6	7	2	27
		IDet	77	68	11	6	10	2	35
		Total	157	112	10	6	10	2	35
	Other	IDegAsp OD	80	49	7	6	5	1	34
		IDet	77	39	6	4	5	1	17
		Total	157	88	7	5	5	1	34

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
End of trial visit	Daily	IDegAsp OD	80	80	22	12	21	2	76
		IDet	77	77	35	17	34	3	90
		Total	157	157	28	16	26	2	90
	Breakfast	IDegAsp OD	80	69	8	4	8	1	19
		IDet	77	77	10	6	10	1	29
		Total	157	146	9	5	9	1	29
	Lunch	IDegAsp OD	80	78	9	4	9	2	24
		IDet	77	77	11	6	10	1	31
		Total	157	155	10	5	9	1	31
	Main Evening Meal	IDegAsp OD	80	65	8	6	7	1	39
		IDet	77	77	11	6	10	1	35
		Total	157	142	10	6	9	1	39
	Other	IDegAsp OD	80	69	7	6	5	1	34
		IDet	77	63	6	4	5	1	20
		Total	157	132	6	5	5	1	34

N: Number of subjects, SD: Standard deviation

14.2.46 Basal insulin dose (actual) in units by treatment week - descriptive statistics - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	13	10	11	1	70
		IDet	179	179	17	13	14	1	65
		Total	360	360	15	12	12	1	70
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	14	10	11	1	63
		IDet	179	178	18	14	14	1	74
		Total	360	359	16	12	12	1	74
Visit 5 (Week 3)	Daily	IDegAsp OD	181	180	14	10	11	1	57
		IDet	179	176	19	15	15	1	79
		Total	360	356	17	13	13	1	79
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	15	10	13	1	56
		IDet	179	176	20	15	15	1	82
		Total	360	355	17	13	14	1	82
Visit 7 (Week 5)	Daily	IDegAsp OD	181	179	15	10	13	1	56
		IDet	179	174	20	15	15	1	84
		Total	360	353	17	13	14	1	84
Visit 8 (Week 6)	Daily	IDegAsp OD	181	179	15	10	13	1	56
		IDet	179	174	20	15	15	1	88
		Total	360	353	18	13	14	1	88
Visit 9 (Week 7)	Daily	IDegAsp OD	181	178	15	11	13	1	56
		IDet	179	172	20	16	17	1	96
		Total	360	350	18	14	14	1	96
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	15	11	13	1	56
		IDet	179	173	21	16	17	1	98
		Total	360	350	18	14	14	1	98
Visit 11 (Week 9)	Daily	IDegAsp OD	181	177	16	11	13	1	56
		IDet	179	173	21	16	17	1	98
		Total	360	350	18	14	15	1	98
Visit 12 (Week 10)	Daily	IDegAsp OD	181	175	15	11	13	1	56
		IDet	179	172	22	17	17	1	103
		Total	360	347	19	15	15	1	103
Visit 13 (Week 11)	Daily	IDegAsp OD	181	175	16	11	13	1	56
		IDet	179	172	22	17	17	1	100
		Total	360	347	19	15	15	1	100
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	16	11	13	1	57
		IDet	179	172	22	17	17	1	83
		Total	360	347	19	15	15	1	83

N: Number of subjects, SD: Standard deviation

Basal insulin dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	175	16	11	13	1	60
		IDet	179	172	22	17	17	1	86
		Total	360	347	19	15	14	1	86
Visit 16 (Week 14)	Daily	IDegAsp OD	181	175	16	11	13	1	60
		IDet	179	169	21	16	16	1	75
		Total	360	344	19	14	14	1	75
Visit 17 (Week 15)	Daily	IDegAsp OD	181	173	16	12	13	1	60
		IDet	179	170	22	17	17	1	76
		Total	360	343	19	15	15	1	76
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	16	12	13	1	60
		IDet	179	167	22	17	17	1	76
		Total	360	340	19	15	15	1	76
End of trial visit	Daily	IDegAsp OD	181	181	16	12	13	1	60
		IDet	179	179	23	18	17	1	86
		Total	360	360	20	15	15	1	86

N: Number of subjects, SD: Standard deviation

14.2.47 Basal insulin dose (actual) in units by treatment week - descriptive statistics - children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	5	3	4	1	12
		IDet	41	41	5	3	5	1	15
		Total	81	81	5	3	5	1	15
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	5	3	5	1	12
		IDet	41	41	5	3	6	1	13
		Total	81	81	5	3	5	1	13
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	6	3	5	1	13
		IDet	41	40	6	3	6	1	13
		Total	81	80	6	3	6	1	13
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	6	3	5	1	13
		IDet	41	40	6	3	6	1	13
		Total	81	80	6	3	6	1	13
Visit 7 (Week 5)	Daily	IDegAsp OD	40	40	6	3	5	1	13
		IDet	41	40	6	3	6	1	13
		Total	81	80	6	3	6	1	13
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	6	3	5	1	13
		IDet	41	40	6	4	6	1	15
		Total	81	80	6	3	6	1	15
Visit 9 (Week 7)	Daily	IDegAsp OD	40	40	6	3	5	1	15
		IDet	41	40	7	4	6	1	17
		Total	81	80	6	4	6	1	17
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	6	3	6	1	15
		IDet	41	40	7	4	6	1	19
		Total	81	79	6	4	6	1	19
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	6	3	5	1	13
		IDet	41	40	7	4	6	1	19
		Total	81	78	6	4	6	1	19
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	6	3	6	1	13
		IDet	41	39	7	5	7	1	21
		Total	81	77	6	4	6	1	21
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	6	3	5	1	13
		IDet	41	39	7	4	6	1	21
		Total	81	77	6	4	6	1	21
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	6	4	5	1	18
		IDet	41	39	7	5	6	1	23
		Total	81	77	6	4	6	1	23

N: Number of subjects, SD: Standard deviation

Basal insulin dose (actual) in units by treatment week - descriptive statistics - children (1-5 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
				-Descriptive Statistics-					
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	6	4	5	1	18
		IDet	41	39	7	5	6	1	25
		Total	81	77	7	4	6	1	25
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	6	4	6	1	18
		IDet	41	39	7	5	7	1	29
		Total	81	77	7	5	6	1	29
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	6	4	5	1	18
		IDet	41	38	7	5	6	1	30
		Total	81	76	7	5	6	1	30
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	6	3	5	1	16
		IDet	41	37	7	6	7	1	32
		Total	81	75	7	5	6	1	32
End of trial visit	Daily	IDegAsp OD	40	40	6	3	5	1	16
		IDet	41	41	8	6	7	1	32
		Total	81	81	7	5	6	1	32

N: Number of subjects, SD: Standard deviation

14.2.48 Basal insulin dose (actual) in units by treatment week - descriptive statistics - children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	61	61	10	6	9	3	32
		IDet	61	61	14	9	11	1	40
		Total	122	122	12	8	10	1	40
Visit 4 (Week 2)	Daily	IDegAsp OD	61	61	10	6	9	3	32
		IDet	61	60	14	9	12	1	45
		Total	122	121	12	8	10	1	45
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	11	6	9	3	32
		IDet	61	59	15	9	13	1	48
		Total	122	119	13	8	11	1	48
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	11	6	9	3	32
		IDet	61	59	16	10	14	1	49
		Total	122	119	13	9	11	1	49
Visit 7 (Week 5)	Daily	IDegAsp OD	61	61	11	6	9	3	30
		IDet	61	59	16	10	14	1	52
		Total	122	120	13	9	12	1	52
Visit 8 (Week 6)	Daily	IDegAsp OD	61	61	11	6	9	3	32
		IDet	61	59	16	10	13	1	54
		Total	122	120	14	9	11	1	54
Visit 9 (Week 7)	Daily	IDegAsp OD	61	61	11	7	9	3	35
		IDet	61	59	16	11	13	1	54
		Total	122	120	14	9	12	1	54
Visit 10 (Week 8)	Daily	IDegAsp OD	61	61	11	7	9	3	35
		IDet	61	59	17	11	14	1	53
		Total	122	120	14	9	12	1	53
Visit 11 (Week 9)	Daily	IDegAsp OD	61	61	11	7	9	3	34
		IDet	61	59	17	11	14	1	52
		Total	122	120	14	9	13	1	52
Visit 12 (Week 10)	Daily	IDegAsp OD	61	60	11	6	9	3	31
		IDet	61	59	17	11	15	1	54
		Total	122	119	14	9	12	1	54
Visit 13 (Week 11)	Daily	IDegAsp OD	61	60	11	6	9	3	32
		IDet	61	59	18	11	15	1	58
		Total	122	119	14	10	12	1	58
Visit 14 (Week 12)	Daily	IDegAsp OD	61	60	11	6	9	3	32
		IDet	61	59	18	11	15	1	60
		Total	122	119	14	10	12	1	60

N: Number of subjects, SD: Standard deviation

Basal insulin dose (actual) in units by treatment week - descriptive statistics - children (6-11 years) - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	61	60	11	6	10	3	32
		IDet	61	59	18	11	15	1	60
		Total	122	119	14	10	12	1	60
Visit 16 (Week 14)	Daily	IDegAsp OD	61	60	11	6	10	3	32
		IDet	61	59	18	11	15	1	60
		Total	122	119	14	10	12	1	60
Visit 17 (Week 15)	Daily	IDegAsp OD	61	60	11	6	10	3	32
		IDet	61	59	18	11	15	1	60
		Total	122	119	15	10	12	1	60
Visit 18 (Week 16)	Daily	IDegAsp OD	61	59	12	7	10	3	35
		IDet	61	59	18	12	15	2	60
		Total	122	118	15	10	12	2	60
End of trial visit	Daily	IDegAsp OD	61	61	12	7	10	3	35
		IDet	61	61	19	12	16	2	60
		Total	122	122	15	10	13	2	60

N: Number of subjects, SD: Standard deviation

14.2.49 Basal insulin dose (actual) in units by treatment week - descriptive statistics - adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	80	20	10	18	2	70
		IDet	77	77	26	13	22	5	65
		Total	157	157	23	12	20	2	70
Visit 4 (Week 2)	Daily	IDegAsp OD	80	80	21	10	20	2	63
		IDet	77	77	28	14	24	5	74
		Total	157	157	24	12	22	2	74
Visit 5 (Week 3)	Daily	IDegAsp OD	80	80	22	10	21	2	57
		IDet	77	77	29	15	27	5	79
		Total	157	157	26	13	24	2	79
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	23	10	22	2	56
		IDet	77	77	30	15	27	6	82
		Total	157	156	26	13	25	2	82
Visit 7 (Week 5)	Daily	IDegAsp OD	80	78	23	10	22	2	56
		IDet	77	75	30	15	28	6	84
		Total	157	153	26	13	25	2	84
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	23	10	22	2	56
		IDet	77	75	31	15	28	7	88
		Total	157	153	27	13	25	2	88
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	23	10	22	2	56
		IDet	77	73	31	16	28	7	96
		Total	157	150	27	14	25	2	96
Visit 10 (Week 8)	Daily	IDegAsp OD	80	77	23	10	22	2	56
		IDet	77	74	31	16	28	7	98
		Total	157	151	27	14	25	2	98
Visit 11 (Week 9)	Daily	IDegAsp OD	80	78	24	10	23	3	56
		IDet	77	74	32	17	28	8	98
		Total	157	152	28	15	26	3	98
Visit 12 (Week 10)	Daily	IDegAsp OD	80	77	24	10	22	3	56
		IDet	77	74	33	18	28	8	103
		Total	157	151	28	15	26	3	103
Visit 13 (Week 11)	Daily	IDegAsp OD	80	77	24	11	22	3	56
		IDet	77	74	33	18	28	8	100
		Total	157	151	28	15	26	3	100
Visit 14 (Week 12)	Daily	IDegAsp OD	80	77	24	11	22	3	57
		IDet	77	74	33	17	28	8	83
		Total	157	151	28	15	26	3	83

N: Number of subjects, SD: Standard deviation

Basal insulin dose (actual) in units by treatment week - descriptive statistics - adolescents (12-17 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
			-Descriptive Statistics-						
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	24	11	22	3	60
		IDet	77	74	33	17	29	9	86
		Total	157	151	29	15	27	3	86
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	24	11	22	4	60
		IDet	77	71	32	16	29	9	75
		Total	157	148	28	14	26	4	75
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	25	11	23	4	60
		IDet	77	73	33	17	30	9	76
		Total	157	148	29	15	27	4	76
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	25	11	23	4	60
		IDet	77	71	33	17	30	9	76
		Total	157	147	29	15	27	4	76
End of trial visit	Daily	IDegAsp OD	80	80	25	12	24	4	60
		IDet	77	77	35	18	31	9	86
		Total	157	157	30	16	27	4	86

N: Number of subjects, SD: Standard deviation

14.2.50 IAsp dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	178	0.36	0.18	0.34	0.01	1.07
		IDet	179	178	0.52	0.22	0.50	0.06	1.35
		Total	360	356	0.44	0.22	0.42	0.01	1.35
	Breakfast	IDegAsp OD	181	126	0.14	0.07	0.13	0.01	0.42
		IDet	179	176	0.16	0.08	0.15	0.04	0.44
		Total	360	302	0.15	0.07	0.14	0.01	0.44
	Lunch	IDegAsp OD	181	163	0.14	0.06	0.13	0.02	0.31
		IDet	179	174	0.15	0.07	0.14	0.02	0.41
		Total	360	337	0.15	0.07	0.14	0.02	0.41
	Main Evening Meal	IDegAsp OD	181	112	0.13	0.07	0.11	0.01	0.42
		IDet	179	176	0.15	0.07	0.15	0.02	0.40
		Total	360	288	0.14	0.07	0.14	0.01	0.42
	Other	IDegAsp OD	181	105	0.13	0.11	0.10	0.01	0.61
		IDet	179	108	0.12	0.09	0.10	0.01	0.45
		Total	360	213	0.13	0.10	0.10	0.01	0.61
Visit 4 (Week 2)	Daily	IDegAsp OD	181	179	0.37	0.18	0.33	0.01	1.05
		IDet	179	178	0.53	0.23	0.52	0.04	1.58
		Total	360	357	0.45	0.22	0.42	0.01	1.58
	Breakfast	IDegAsp OD	181	129	0.14	0.07	0.12	0.01	0.42
		IDet	179	178	0.15	0.07	0.15	0.03	0.48
		Total	360	307	0.15	0.07	0.14	0.01	0.48
	Lunch	IDegAsp OD	181	164	0.14	0.06	0.14	0.03	0.36
		IDet	179	175	0.16	0.07	0.15	0.02	0.42
		Total	360	339	0.15	0.06	0.14	0.02	0.42
	Main Evening Meal	IDegAsp OD	181	124	0.14	0.07	0.13	0.02	0.44
		IDet	179	174	0.16	0.07	0.15	0.02	0.43
		Total	360	298	0.15	0.07	0.14	0.02	0.44
	Other	IDegAsp OD	181	112	0.12	0.10	0.08	0.02	0.55
		IDet	179	105	0.14	0.12	0.12	0.02	0.82
		Total	360	217	0.13	0.11	0.10	0.02	0.82
Visit 5 (Week 3)	Daily	IDegAsp OD	181	179	0.36	0.17	0.35	0.04	1.06
		IDet	179	176	0.52	0.23	0.51	0.08	1.30
		Total	360	355	0.44	0.21	0.42	0.04	1.30
	Breakfast	IDegAsp OD	181	126	0.14	0.08	0.13	0.01	0.44
		IDet	179	173	0.16	0.08	0.15	0.02	0.48
		Total	360	299	0.16	0.08	0.15	0.01	0.48

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics					
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 5 (Week 3)	Lunch	IDegAsp OD	181	167	0.14	0.07	0.13	0.03	0.57
		IDet	179	172	0.16	0.07	0.15	0.02	0.40
		Total	360	339	0.15	0.07	0.14	0.02	0.57
	Main Evening Meal	IDegAsp OD	181	120	0.13	0.07	0.12	0.02	0.44
		IDet	179	173	0.16	0.07	0.15	0.02	0.57
		Total	360	293	0.15	0.07	0.14	0.02	0.57
	Other	IDegAsp OD	181	108	0.13	0.09	0.10	0.02	0.52
		IDet	179	106	0.12	0.08	0.10	0.01	0.55
		Total	360	214	0.12	0.09	0.10	0.01	0.55
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	0.36	0.17	0.34	0.02	1.07
		IDet	179	176	0.53	0.22	0.53	0.07	1.28
		Total	360	355	0.44	0.21	0.42	0.02	1.28
	Breakfast	IDegAsp OD	181	125	0.15	0.08	0.14	0.02	0.43
		IDet	179	175	0.16	0.08	0.15	0.02	0.38
		Total	360	300	0.16	0.08	0.15	0.02	0.43
	Lunch	IDegAsp OD	181	160	0.14	0.06	0.14	0.02	0.32
		IDet	179	172	0.16	0.07	0.15	0.02	0.37
		Total	360	332	0.15	0.07	0.14	0.02	0.37
	Main Evening Meal	IDegAsp OD	181	122	0.13	0.07	0.13	0.03	0.42
		IDet	179	174	0.16	0.07	0.15	0.02	0.41
		Total	360	296	0.15	0.07	0.14	0.02	0.42
	Other	IDegAsp OD	181	100	0.12	0.09	0.10	0.02	0.48
		IDet	179	101	0.12	0.09	0.11	0.02	0.65
		Total	360	201	0.12	0.09	0.11	0.02	0.65
Visit 7 (Week 5)	Daily	IDegAsp OD	181	176	0.36	0.17	0.32	0.02	1.04
		IDet	179	174	0.53	0.22	0.51	0.05	1.29
		Total	360	350	0.44	0.22	0.42	0.02	1.29
	Breakfast	IDegAsp OD	181	126	0.15	0.08	0.13	0.01	0.42
		IDet	179	171	0.16	0.07	0.16	0.03	0.43
		Total	360	297	0.16	0.08	0.15	0.01	0.43
	Lunch	IDegAsp OD	181	162	0.14	0.06	0.13	0.03	0.33
		IDet	179	170	0.16	0.07	0.15	0.03	0.36
		Total	360	332	0.15	0.07	0.14	0.03	0.36
	Main Evening Meal	IDegAsp OD	181	116	0.13	0.07	0.11	0.01	0.42
		IDet	179	171	0.16	0.07	0.15	0.03	0.41
		Total	360	287	0.15	0.07	0.14	0.01	0.42

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 7 (Week 5)	Other	IDegAsp OD	181	103	0.11	0.08	0.09	0.01	0.49
		IDet	179	105	0.13	0.08	0.11	0.01	0.36
		Total	360	208	0.12	0.08	0.10	0.01	0.49
Visit 8 (Week 6)	Daily	IDegAsp OD	181	177	0.37	0.17	0.36	0.03	1.17
		IDet	179	174	0.52	0.21	0.52	0.07	1.25
		Total	360	351	0.45	0.21	0.43	0.03	1.25
	Breakfast	IDegAsp OD	181	127	0.15	0.08	0.14	0.01	0.44
		IDet	179	171	0.16	0.08	0.15	0.02	0.42
		Total	360	298	0.16	0.08	0.15	0.01	0.44
	Lunch	IDegAsp OD	181	163	0.15	0.07	0.14	0.03	0.41
		IDet	179	170	0.16	0.07	0.15	0.04	0.42
		Total	360	333	0.15	0.07	0.14	0.03	0.42
	Main Evening Meal	IDegAsp OD	181	115	0.13	0.07	0.12	0.02	0.44
		IDet	179	171	0.16	0.07	0.15	0.03	0.51
		Total	360	286	0.15	0.07	0.14	0.02	0.51
	Other	IDegAsp OD	181	104	0.12	0.09	0.09	0.01	0.62
		IDet	179	105	0.12	0.09	0.10	0.02	0.46
		Total	360	209	0.12	0.09	0.10	0.01	0.62
Visit 9 (Week 7)	Daily	IDegAsp OD	181	176	0.36	0.17	0.33	0.03	1.02
		IDet	179	172	0.54	0.23	0.53	0.06	1.77
		Total	360	348	0.45	0.22	0.43	0.03	1.77
	Breakfast	IDegAsp OD	181	127	0.15	0.08	0.13	0.02	0.41
		IDet	179	171	0.17	0.09	0.16	0.03	0.75
		Total	360	298	0.16	0.09	0.15	0.02	0.75
	Lunch	IDegAsp OD	181	161	0.14	0.06	0.13	0.03	0.40
		IDet	179	169	0.16	0.07	0.15	0.03	0.45
		Total	360	330	0.15	0.07	0.14	0.03	0.45
	Main Evening Meal	IDegAsp OD	181	115	0.13	0.07	0.12	0.01	0.44
		IDet	179	170	0.16	0.07	0.15	0.01	0.53
		Total	360	285	0.15	0.07	0.14	0.01	0.53
	Other	IDegAsp OD	181	108	0.11	0.08	0.08	0.01	0.45
		IDet	179	101	0.12	0.08	0.11	0.01	0.38
		Total	360	209	0.12	0.08	0.09	0.01	0.45
Visit 10 (Week 8)	Daily	IDegAsp OD	181	175	0.37	0.18	0.34	0.02	1.03
		IDet	179	173	0.54	0.24	0.53	0.04	1.59
		Total	360	348	0.46	0.23	0.43	0.02	1.59

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 10 (Week 8)	Breakfast	IDegAsp OD	181	128	0.15	0.08	0.14	0.02	0.40
		IDet	179	171	0.17	0.08	0.16	0.02	0.73
		Total	360	299	0.16	0.08	0.15	0.02	0.73
	Lunch	IDegAsp OD	181	159	0.15	0.07	0.14	0.03	0.42
		IDet	179	168	0.16	0.07	0.15	0.03	0.45
		Total	360	327	0.16	0.07	0.15	0.03	0.45
	Main Evening Meal	IDegAsp OD	181	114	0.13	0.08	0.11	0.01	0.40
		IDet	179	170	0.16	0.07	0.16	0.01	0.48
		Total	360	284	0.15	0.08	0.14	0.01	0.48
	Other	IDegAsp OD	181	100	0.12	0.10	0.09	0.02	0.64
		IDet	179	104	0.13	0.11	0.11	0.02	0.85
		Total	360	204	0.12	0.10	0.09	0.02	0.85
Visit 11 (Week 9)	Daily	IDegAsp OD	181	175	0.37	0.18	0.33	0.02	1.04
		IDet	179	172	0.54	0.24	0.54	0.08	2.35
		Total	360	347	0.45	0.23	0.43	0.02	2.35
	Breakfast	IDegAsp OD	181	128	0.16	0.09	0.14	0.01	0.51
		IDet	179	170	0.16	0.08	0.15	0.03	0.71
		Total	360	298	0.16	0.08	0.15	0.01	0.71
	Lunch	IDegAsp OD	181	160	0.14	0.06	0.15	0.02	0.41
		IDet	179	169	0.16	0.08	0.15	0.04	0.56
		Total	360	329	0.15	0.07	0.15	0.02	0.56
	Main Evening Meal	IDegAsp OD	181	112	0.14	0.07	0.12	0.02	0.39
		IDet	179	170	0.16	0.08	0.15	0.01	0.61
		Total	360	282	0.15	0.08	0.14	0.01	0.61
	Other	IDegAsp OD	181	109	0.11	0.08	0.09	0.01	0.49
		IDet	179	103	0.12	0.09	0.10	0.02	0.48
		Total	360	212	0.12	0.09	0.10	0.01	0.49
Visit 12 (Week 10)	Daily	IDegAsp OD	181	173	0.37	0.17	0.36	0.05	1.01
		IDet	179	172	0.53	0.22	0.51	0.07	1.73
		Total	360	345	0.45	0.21	0.42	0.05	1.73
	Breakfast	IDegAsp OD	181	127	0.14	0.08	0.13	0.01	0.43
		IDet	179	170	0.16	0.08	0.16	0.03	0.59
		Total	360	297	0.16	0.08	0.14	0.01	0.59
	Lunch	IDegAsp OD	181	159	0.15	0.07	0.14	0.03	0.40
		IDet	179	169	0.16	0.08	0.15	0.04	0.51
		Total	360	328	0.16	0.07	0.14	0.03	0.51

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics					
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 12 (Week 10)	Main Evening Meal	IDegAsp OD	181	115	0.14	0.10	0.12	0.01	0.88
		IDet	179	169	0.16	0.07	0.15	0.02	0.54
		Total	360	284	0.15	0.08	0.14	0.01	0.88
	Other	IDegAsp OD	181	103	0.11	0.08	0.08	0.01	0.48
		IDet	179	103	0.12	0.08	0.10	0.01	0.45
		Total	360	206	0.12	0.08	0.09	0.01	0.48
Visit 13 (Week 11)	Daily	IDegAsp OD	181	173	0.37	0.17	0.35	0.03	1.08
		IDet	179	172	0.53	0.23	0.52	0.07	2.02
		Total	360	345	0.45	0.22	0.42	0.03	2.02
	Breakfast	IDegAsp OD	181	127	0.15	0.07	0.14	0.01	0.41
		IDet	179	168	0.16	0.08	0.16	0.03	0.59
		Total	360	295	0.16	0.08	0.15	0.01	0.59
	Lunch	IDegAsp OD	181	158	0.15	0.07	0.14	0.03	0.41
		IDet	179	168	0.16	0.08	0.15	0.04	0.59
		Total	360	326	0.15	0.07	0.15	0.03	0.59
	Main Evening Meal	IDegAsp OD	181	109	0.14	0.07	0.13	0.03	0.41
		IDet	179	168	0.16	0.08	0.15	0.02	0.76
		Total	360	277	0.15	0.08	0.14	0.02	0.76
	Other	IDegAsp OD	181	105	0.11	0.08	0.09	0.01	0.51
		IDet	179	101	0.11	0.08	0.09	0.02	0.43
		Total	360	206	0.11	0.08	0.09	0.01	0.51
Visit 14 (Week 12)	Daily	IDegAsp OD	181	173	0.35	0.16	0.34	0.03	0.98
		IDet	179	172	0.52	0.22	0.51	0.04	1.49
		Total	360	345	0.44	0.21	0.41	0.03	1.49
	Breakfast	IDegAsp OD	181	128	0.15	0.07	0.14	0.02	0.37
		IDet	179	171	0.16	0.08	0.15	0.03	0.51
		Total	360	299	0.15	0.07	0.14	0.02	0.51
	Lunch	IDegAsp OD	181	157	0.14	0.07	0.14	0.02	0.37
		IDet	179	167	0.16	0.07	0.15	0.03	0.38
		Total	360	324	0.15	0.07	0.15	0.02	0.38
	Main Evening Meal	IDegAsp OD	181	109	0.13	0.08	0.12	0.01	0.44
		IDet	179	168	0.16	0.08	0.15	0.02	0.59
		Total	360	277	0.15	0.08	0.14	0.01	0.59
	Other	IDegAsp OD	181	107	0.10	0.08	0.08	0.01	0.47
		IDet	179	101	0.13	0.08	0.11	0.01	0.44
		Total	360	208	0.12	0.08	0.10	0.01	0.47

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	174	0.36	0.17	0.35	0.03	0.95
		IDet	179	171	0.53	0.23	0.50	0.04	1.80
		Total	360	345	0.44	0.22	0.41	0.03	1.80
	Breakfast	IDegAsp OD	181	128	0.14	0.08	0.13	0.01	0.40
		IDet	179	171	0.16	0.08	0.15	0.02	0.62
		Total	360	299	0.15	0.08	0.14	0.01	0.62
	Lunch	IDegAsp OD	181	158	0.14	0.06	0.14	0.02	0.38
		IDet	179	167	0.16	0.08	0.15	0.03	0.57
		Total	360	325	0.15	0.07	0.15	0.02	0.57
	Main Evening Meal	IDegAsp OD	181	115	0.13	0.08	0.12	0.02	0.65
		IDet	179	167	0.16	0.08	0.15	0.02	0.59
		Total	360	282	0.15	0.08	0.14	0.02	0.65
	Other	IDegAsp OD	181	104	0.11	0.08	0.08	0.02	0.38
		IDet	179	94	0.12	0.07	0.10	0.02	0.39
		Total	360	198	0.11	0.07	0.09	0.02	0.39
Visit 16 (Week 14)	Daily	IDegAsp OD	181	174	0.36	0.16	0.35	0.04	0.93
		IDet	179	170	0.52	0.23	0.50	0.04	1.97
		Total	360	344	0.44	0.22	0.41	0.04	1.97
	Breakfast	IDegAsp OD	181	127	0.14	0.07	0.14	0.01	0.39
		IDet	179	168	0.16	0.08	0.15	0.02	0.68
		Total	360	295	0.15	0.08	0.14	0.01	0.68
	Lunch	IDegAsp OD	181	156	0.14	0.06	0.14	0.03	0.42
		IDet	179	166	0.16	0.08	0.14	0.03	0.68
		Total	360	322	0.15	0.07	0.14	0.03	0.68
	Main Evening Meal	IDegAsp OD	181	115	0.13	0.07	0.12	0.02	0.36
		IDet	179	165	0.16	0.08	0.15	0.03	0.60
		Total	360	280	0.15	0.08	0.14	0.02	0.60
	Other	IDegAsp OD	181	104	0.11	0.08	0.08	0.02	0.46
		IDet	179	94	0.12	0.07	0.11	0.02	0.34
		Total	360	198	0.11	0.07	0.10	0.02	0.46
Visit 17 (Week 15)	Daily	IDegAsp OD	181	172	0.37	0.17	0.37	0.03	1.02
		IDet	179	170	0.53	0.23	0.52	0.06	1.88
		Total	360	342	0.45	0.22	0.43	0.03	1.88
	Breakfast	IDegAsp OD	181	128	0.15	0.08	0.13	0.02	0.42
		IDet	179	169	0.17	0.08	0.15	0.02	0.66
		Total	360	297	0.16	0.08	0.15	0.02	0.66

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 17 (Week 15)	Lunch	IDegAsp OD	181	154	0.14	0.06	0.14	0.03	0.34
		IDet	179	167	0.16	0.08	0.15	0.03	0.70
		Total	360	321	0.15	0.07	0.14	0.03	0.70
	Main Evening Meal	IDegAsp OD	181	114	0.14	0.09	0.13	0.01	0.80
		IDet	179	165	0.16	0.07	0.15	0.04	0.46
		Total	360	279	0.15	0.08	0.14	0.01	0.80
	Other	IDegAsp OD	181	104	0.12	0.09	0.09	0.02	0.64
		IDet	179	98	0.12	0.07	0.11	0.02	0.34
		Total	360	202	0.12	0.08	0.10	0.02	0.64
Visit 18 (Week 16)	Daily	IDegAsp OD	181	172	0.37	0.17	0.35	0.03	0.92
		IDet	179	166	0.52	0.23	0.51	0.06	1.79
		Total	360	338	0.44	0.21	0.43	0.03	1.79
	Breakfast	IDegAsp OD	181	128	0.15	0.07	0.14	0.01	0.38
		IDet	179	165	0.16	0.09	0.15	0.02	0.77
		Total	360	293	0.16	0.08	0.15	0.01	0.77
	Lunch	IDegAsp OD	181	155	0.14	0.06	0.14	0.02	0.35
		IDet	179	162	0.16	0.07	0.15	0.03	0.43
		Total	360	317	0.15	0.07	0.14	0.02	0.43
	Main Evening Meal	IDegAsp OD	181	112	0.13	0.07	0.13	0.02	0.37
		IDet	179	161	0.16	0.08	0.15	0.02	0.58
		Total	360	273	0.15	0.07	0.14	0.02	0.58
	Other	IDegAsp OD	181	110	0.11	0.08	0.09	0.02	0.49
		IDet	179	100	0.10	0.08	0.09	0.01	0.44
		Total	360	210	0.11	0.08	0.09	0.01	0.49
End of trial visit	Daily	IDegAsp OD	181	181	0.36	0.17	0.35	0.02	0.92
		IDet	179	179	0.52	0.22	0.51	0.06	1.79
		Total	360	360	0.44	0.21	0.42	0.02	1.79
	Breakfast	IDegAsp OD	181	154	0.14	0.07	0.14	0.01	0.38
		IDet	179	179	0.16	0.08	0.15	0.02	0.77
		Total	360	333	0.15	0.08	0.14	0.01	0.77
	Lunch	IDegAsp OD	181	175	0.14	0.07	0.14	0.02	0.57
		IDet	179	177	0.16	0.07	0.14	0.02	0.43
		Total	360	352	0.15	0.07	0.14	0.02	0.57

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics					
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
End of trial visit	Main Evening Meal	IDegAsp OD	181	154	0.13	0.10	0.12	0.02	0.80
		IDet	179	178	0.16	0.08	0.15	0.01	0.58
		Total	360	332	0.15	0.09	0.14	0.01	0.80
	Other	IDegAsp OD	181	159	0.10	0.08	0.08	0.01	0.49
		IDet	179	153	0.10	0.07	0.09	0.01	0.44
		Total	360	312	0.10	0.08	0.08	0.01	0.49

N: Number of subjects, SD: Standard deviation

14.2.51 IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics					
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	0.35	0.18	0.34	0.07	1.07
		IDet	41	41	0.53	0.22	0.53	0.16	1.11
		Total	81	81	0.44	0.22	0.41	0.07	1.11
	Breakfast	IDegAsp OD	40	25	0.13	0.06	0.12	0.03	0.23
		IDet	41	41	0.17	0.08	0.16	0.04	0.38
		Total	81	66	0.15	0.08	0.15	0.03	0.38
	Lunch	IDegAsp OD	40	35	0.14	0.07	0.13	0.02	0.28
		IDet	41	40	0.15	0.07	0.14	0.03	0.36
		Total	81	75	0.14	0.07	0.13	0.02	0.36
	Main Evening Meal	IDegAsp OD	40	27	0.13	0.06	0.12	0.04	0.26
		IDet	41	40	0.15	0.06	0.15	0.07	0.33
		Total	81	67	0.14	0.06	0.14	0.04	0.33
	Other	IDegAsp OD	40	24	0.13	0.12	0.10	0.02	0.61
		IDet	41	25	0.16	0.11	0.11	0.04	0.45
		Total	81	49	0.15	0.12	0.11	0.02	0.61
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	0.38	0.18	0.35	0.13	1.02
		IDet	41	41	0.56	0.28	0.56	0.14	1.58
		Total	81	81	0.47	0.25	0.41	0.13	1.58
	Breakfast	IDegAsp OD	40	24	0.13	0.06	0.12	0.04	0.24
		IDet	41	41	0.16	0.09	0.16	0.03	0.48
		Total	81	65	0.15	0.08	0.15	0.03	0.48
	Lunch	IDegAsp OD	40	35	0.15	0.05	0.14	0.04	0.24
		IDet	41	41	0.15	0.07	0.14	0.05	0.30
		Total	81	76	0.15	0.06	0.14	0.04	0.30
	Main Evening Meal	IDegAsp OD	40	32	0.16	0.08	0.14	0.04	0.41
		IDet	41	39	0.16	0.07	0.16	0.04	0.33
		Total	81	71	0.16	0.07	0.15	0.04	0.41
	Other	IDegAsp OD	40	29	0.11	0.08	0.08	0.03	0.37
		IDet	41	26	0.18	0.16	0.15	0.03	0.82
		Total	81	55	0.14	0.13	0.12	0.03	0.82
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	0.37	0.16	0.37	0.10	0.79
		IDet	41	40	0.54	0.26	0.51	0.08	1.29
		Total	81	80	0.46	0.23	0.40	0.08	1.29
	Breakfast	IDegAsp OD	40	25	0.12	0.06	0.11	0.03	0.27
		IDet	41	40	0.18	0.09	0.16	0.03	0.48
		Total	81	65	0.16	0.09	0.15	0.03	0.48

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 5 (Week 3)	Lunch	IDegAsp OD	40	38	0.15	0.09	0.13	0.03	0.57
		IDet	41	40	0.14	0.07	0.13	0.02	0.39
		Total	81	78	0.15	0.08	0.13	0.02	0.57
	Main Evening Meal	IDegAsp OD	40	32	0.14	0.06	0.14	0.05	0.28
		IDet	41	39	0.15	0.06	0.14	0.06	0.27
		Total	81	71	0.14	0.06	0.14	0.05	0.28
	Other	IDegAsp OD	40	25	0.15	0.08	0.13	0.02	0.29
		IDet	41	23	0.16	0.12	0.13	0.03	0.55
		Total	81	48	0.15	0.10	0.13	0.02	0.55
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	0.35	0.15	0.37	0.11	0.73
		IDet	41	40	0.56	0.23	0.55	0.19	1.28
		Total	81	80	0.46	0.22	0.41	0.11	1.28
	Breakfast	IDegAsp OD	40	27	0.13	0.08	0.12	0.03	0.32
		IDet	41	40	0.17	0.08	0.16	0.03	0.38
		Total	81	67	0.15	0.08	0.14	0.03	0.38
	Lunch	IDegAsp OD	40	33	0.15	0.06	0.14	0.03	0.29
		IDet	41	40	0.15	0.07	0.14	0.02	0.36
		Total	81	73	0.15	0.07	0.14	0.02	0.36
	Main Evening Meal	IDegAsp OD	40	30	0.14	0.06	0.14	0.03	0.26
		IDet	41	40	0.16	0.07	0.14	0.05	0.31
		Total	81	70	0.15	0.06	0.14	0.03	0.31
	Other	IDegAsp OD	40	26	0.11	0.07	0.09	0.02	0.30
		IDet	41	25	0.17	0.12	0.16	0.04	0.65
		Total	81	51	0.14	0.10	0.13	0.02	0.65
Visit 7 (Week 5)	Daily	IDegAsp OD	40	39	0.35	0.16	0.33	0.07	0.83
		IDet	41	40	0.53	0.21	0.51	0.19	0.98
		Total	81	79	0.44	0.21	0.42	0.07	0.98
	Breakfast	IDegAsp OD	40	27	0.13	0.06	0.13	0.03	0.32
		IDet	41	40	0.16	0.07	0.15	0.03	0.33
		Total	81	67	0.15	0.07	0.14	0.03	0.33
	Lunch	IDegAsp OD	40	33	0.14	0.07	0.14	0.03	0.28
		IDet	41	40	0.16	0.07	0.14	0.07	0.34
		Total	81	73	0.15	0.07	0.14	0.03	0.34

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 7 (Week 5)	Main Evening Meal	IDegAsp OD	40	31	0.13	0.06	0.13	0.04	0.34
		IDet	41	40	0.14	0.06	0.13	0.05	0.28
		Total	81	71	0.14	0.06	0.13	0.04	0.34
	Other	IDegAsp OD	40	28	0.10	0.07	0.08	0.02	0.27
		IDet	41	26	0.17	0.08	0.17	0.04	0.36
		Total	81	54	0.13	0.08	0.11	0.02	0.36
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	0.36	0.13	0.37	0.08	0.65
		IDet	41	40	0.52	0.20	0.51	0.08	0.95
		Total	81	80	0.44	0.18	0.41	0.08	0.95
	Breakfast	IDegAsp OD	40	28	0.14	0.06	0.15	0.02	0.27
		IDet	41	39	0.15	0.07	0.14	0.03	0.33
		Total	81	67	0.15	0.07	0.14	0.02	0.33
	Lunch	IDegAsp OD	40	34	0.13	0.07	0.13	0.03	0.28
		IDet	41	40	0.15	0.07	0.13	0.05	0.33
		Total	81	74	0.14	0.07	0.13	0.03	0.33
	Main Evening Meal	IDegAsp OD	40	32	0.14	0.06	0.15	0.03	0.27
		IDet	41	39	0.15	0.06	0.13	0.05	0.34
		Total	81	71	0.15	0.06	0.14	0.03	0.34
	Other	IDegAsp OD	40	24	0.11	0.06	0.10	0.02	0.29
		IDet	41	27	0.16	0.10	0.14	0.02	0.46
		Total	81	51	0.13	0.09	0.12	0.02	0.46
Visit 9 (Week 7)	Daily	IDegAsp OD	40	39	0.36	0.15	0.35	0.10	0.73
		IDet	41	40	0.52	0.21	0.52	0.12	1.23
		Total	81	79	0.44	0.20	0.41	0.10	1.23
	Breakfast	IDegAsp OD	40	28	0.14	0.07	0.14	0.02	0.27
		IDet	41	40	0.16	0.07	0.16	0.03	0.33
		Total	81	68	0.15	0.07	0.15	0.02	0.33
	Lunch	IDegAsp OD	40	35	0.13	0.06	0.12	0.03	0.29
		IDet	41	40	0.15	0.06	0.14	0.05	0.36
		Total	81	75	0.14	0.06	0.13	0.03	0.36
	Main Evening Meal	IDegAsp OD	40	32	0.13	0.06	0.14	0.03	0.24
		IDet	41	39	0.15	0.06	0.14	0.05	0.29
		Total	81	71	0.14	0.06	0.14	0.03	0.29

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 9 (Week 7)	Other	IDegAsp OD	40	24	0.10	0.07	0.09	0.03	0.28
		IDet	41	27	0.16	0.08	0.14	0.04	0.33
		Total	81	51	0.14	0.08	0.13	0.03	0.33
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	0.38	0.16	0.37	0.09	0.72
		IDet	41	40	0.58	0.27	0.56	0.09	1.58
		Total	81	79	0.48	0.24	0.44	0.09	1.58
	Breakfast	IDegAsp OD	40	27	0.15	0.07	0.17	0.02	0.31
		IDet	41	40	0.17	0.07	0.16	0.03	0.38
		Total	81	67	0.16	0.07	0.16	0.02	0.38
	Lunch	IDegAsp OD	40	32	0.15	0.06	0.17	0.03	0.31
		IDet	41	40	0.16	0.06	0.15	0.05	0.31
		Total	81	72	0.16	0.06	0.15	0.03	0.31
	Main Evening Meal	IDegAsp OD	40	31	0.13	0.07	0.13	0.02	0.35
		IDet	41	39	0.16	0.07	0.14	0.08	0.33
		Total	81	70	0.15	0.07	0.13	0.02	0.35
	Other	IDegAsp OD	40	23	0.11	0.07	0.09	0.02	0.29
		IDet	41	25	0.19	0.18	0.15	0.03	0.85
		Total	81	48	0.15	0.14	0.11	0.02	0.85
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	0.37	0.16	0.38	0.10	0.73
		IDet	41	40	0.52	0.18	0.52	0.12	0.92
		Total	81	78	0.45	0.19	0.45	0.10	0.92
	Breakfast	IDegAsp OD	40	27	0.15	0.07	0.15	0.02	0.27
		IDet	41	40	0.16	0.07	0.15	0.03	0.42
		Total	81	67	0.15	0.07	0.15	0.02	0.42
	Lunch	IDegAsp OD	40	32	0.14	0.07	0.14	0.02	0.36
		IDet	41	40	0.15	0.05	0.15	0.05	0.27
		Total	81	72	0.14	0.06	0.15	0.02	0.36
	Main Evening Meal	IDegAsp OD	40	30	0.13	0.06	0.13	0.04	0.30
		IDet	41	40	0.14	0.06	0.13	0.04	0.29
		Total	81	70	0.14	0.06	0.13	0.04	0.30
	Other	IDegAsp OD	40	23	0.11	0.08	0.09	0.03	0.36
		IDet	41	23	0.15	0.10	0.12	0.02	0.48
		Total	81	46	0.13	0.10	0.09	0.02	0.48
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	0.38	0.18	0.36	0.08	0.85
		IDet	41	39	0.49	0.20	0.50	0.17	0.90
		Total	81	77	0.44	0.20	0.39	0.08	0.90

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 12 (Week 10)	Breakfast	IDegAsp OD	40	28	0.14	0.07	0.13	0.02	0.25
		IDet	41	39	0.15	0.07	0.14	0.03	0.38
		Total	81	67	0.15	0.07	0.14	0.02	0.38
	Lunch	IDegAsp OD	40	34	0.14	0.06	0.13	0.03	0.32
		IDet	41	39	0.15	0.06	0.13	0.07	0.27
		Total	81	73	0.14	0.06	0.13	0.03	0.32
	Main Evening Meal	IDegAsp OD	40	32	0.14	0.07	0.15	0.03	0.28
		IDet	41	39	0.14	0.06	0.12	0.04	0.29
		Total	81	71	0.14	0.06	0.13	0.03	0.29
	Other	IDegAsp OD	40	21	0.12	0.10	0.09	0.03	0.47
		IDet	41	24	0.14	0.08	0.12	0.03	0.41
		Total	81	45	0.13	0.09	0.11	0.03	0.47
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	0.38	0.16	0.39	0.08	0.82
		IDet	41	39	0.51	0.19	0.51	0.13	0.94
		Total	81	77	0.45	0.19	0.44	0.08	0.94
	Breakfast	IDegAsp OD	40	27	0.15	0.06	0.16	0.02	0.24
		IDet	41	39	0.16	0.07	0.16	0.03	0.38
		Total	81	66	0.15	0.07	0.16	0.02	0.38
	Lunch	IDegAsp OD	40	33	0.14	0.07	0.16	0.04	0.41
		IDet	41	39	0.14	0.06	0.11	0.05	0.26
		Total	81	72	0.14	0.06	0.13	0.04	0.41
	Main Evening Meal	IDegAsp OD	40	31	0.13	0.07	0.14	0.04	0.27
		IDet	41	38	0.14	0.06	0.13	0.03	0.31
		Total	81	69	0.14	0.06	0.13	0.03	0.31
	Other	IDegAsp OD	40	22	0.11	0.07	0.10	0.03	0.37
		IDet	41	25	0.15	0.09	0.13	0.05	0.43
		Total	81	47	0.13	0.09	0.11	0.03	0.43
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	0.34	0.14	0.35	0.05	0.57
		IDet	41	39	0.51	0.20	0.49	0.16	0.99
		Total	81	77	0.43	0.19	0.41	0.05	0.99
	Breakfast	IDegAsp OD	40	27	0.14	0.06	0.14	0.02	0.26
		IDet	41	39	0.15	0.07	0.14	0.05	0.35
		Total	81	66	0.15	0.07	0.14	0.02	0.35
	Lunch	IDegAsp OD	40	32	0.13	0.06	0.14	0.02	0.31
		IDet	41	39	0.14	0.05	0.14	0.06	0.26
		Total	81	71	0.14	0.06	0.14	0.02	0.31

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 14 (Week 12)	Main Evening Meal	IDegAsp OD	40	28	0.13	0.06	0.12	0.02	0.22
		IDet	41	38	0.14	0.06	0.14	0.03	0.31
		Total	81	66	0.13	0.06	0.13	0.02	0.31
	Other	IDegAsp OD	40	26	0.10	0.06	0.09	0.02	0.30
		IDet	41	25	0.16	0.10	0.13	0.04	0.44
		Total	81	51	0.13	0.09	0.12	0.02	0.44
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	0.38	0.18	0.39	0.04	0.81
		IDet	41	39	0.52	0.22	0.48	0.18	1.04
		Total	81	77	0.45	0.21	0.42	0.04	1.04
	Breakfast	IDegAsp OD	40	28	0.13	0.06	0.13	0.03	0.25
		IDet	41	39	0.16	0.07	0.15	0.05	0.35
		Total	81	67	0.15	0.07	0.14	0.03	0.35
	Lunch	IDegAsp OD	40	32	0.14	0.07	0.14	0.02	0.31
		IDet	41	39	0.15	0.06	0.15	0.06	0.26
		Total	81	71	0.14	0.06	0.14	0.02	0.31
	Main Evening Meal	IDegAsp OD	40	32	0.14	0.11	0.13	0.02	0.65
		IDet	41	38	0.15	0.07	0.14	0.03	0.40
		Total	81	70	0.14	0.09	0.13	0.02	0.65
	Other	IDegAsp OD	40	24	0.11	0.08	0.08	0.03	0.31
		IDet	41	23	0.15	0.09	0.13	0.03	0.39
		Total	81	47	0.13	0.09	0.10	0.03	0.39
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	0.34	0.15	0.36	0.04	0.66
		IDet	41	40	0.49	0.19	0.49	0.15	0.86
		Total	81	78	0.42	0.18	0.42	0.04	0.86
	Breakfast	IDegAsp OD	40	26	0.13	0.06	0.13	0.03	0.25
		IDet	41	39	0.15	0.07	0.14	0.05	0.35
		Total	81	65	0.14	0.07	0.13	0.03	0.35
	Lunch	IDegAsp OD	40	32	0.14	0.06	0.13	0.03	0.26
		IDet	41	40	0.14	0.06	0.14	0.05	0.30
		Total	81	72	0.14	0.06	0.13	0.03	0.30
	Main Evening Meal	IDegAsp OD	40	31	0.12	0.06	0.12	0.02	0.24
		IDet	41	39	0.14	0.07	0.14	0.03	0.31
		Total	81	70	0.13	0.06	0.13	0.02	0.31

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 16 (Week 14)	Other	IDegAsp OD	40	23	0.10	0.06	0.08	0.03	0.25
		IDet	41	22	0.15	0.08	0.15	0.05	0.34
		Total	81	45	0.13	0.08	0.11	0.03	0.34
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	0.37	0.15	0.38	0.03	0.63
		IDet	41	38	0.53	0.21	0.53	0.19	1.01
		Total	81	76	0.45	0.20	0.44	0.03	1.01
	Breakfast	IDegAsp OD	40	27	0.14	0.06	0.13	0.04	0.25
		IDet	41	38	0.17	0.08	0.15	0.05	0.38
		Total	81	65	0.15	0.07	0.15	0.04	0.38
	Lunch	IDegAsp OD	40	32	0.15	0.07	0.14	0.04	0.34
		IDet	41	38	0.14	0.05	0.14	0.06	0.24
		Total	81	70	0.14	0.06	0.14	0.04	0.34
	Main Evening Meal	IDegAsp OD	40	31	0.12	0.06	0.12	0.02	0.25
		IDet	41	37	0.15	0.06	0.15	0.05	0.31
		Total	81	68	0.14	0.06	0.14	0.02	0.31
	Other	IDegAsp OD	40	23	0.11	0.07	0.10	0.02	0.32
		IDet	41	22	0.16	0.08	0.13	0.05	0.34
		Total	81	45	0.13	0.08	0.12	0.02	0.34
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	0.35	0.15	0.33	0.04	0.65
		IDet	41	37	0.51	0.21	0.49	0.19	1.01
		Total	81	75	0.43	0.20	0.40	0.04	1.01
	Breakfast	IDegAsp OD	40	27	0.14	0.07	0.14	0.04	0.28
		IDet	41	37	0.15	0.07	0.14	0.05	0.33
		Total	81	64	0.15	0.07	0.14	0.04	0.33
	Lunch	IDegAsp OD	40	33	0.13	0.06	0.12	0.03	0.27
		IDet	41	37	0.14	0.06	0.14	0.05	0.28
		Total	81	70	0.14	0.06	0.13	0.03	0.28
	Main Evening Meal	IDegAsp OD	40	30	0.12	0.05	0.12	0.03	0.21
		IDet	41	36	0.15	0.07	0.14	0.02	0.29
		Total	81	66	0.13	0.06	0.13	0.02	0.29
	Other	IDegAsp OD	40	22	0.10	0.08	0.09	0.02	0.29
		IDet	41	23	0.15	0.11	0.13	0.03	0.44
		Total	81	45	0.13	0.10	0.11	0.02	0.44

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
End of trial visit	Daily	IDegAsp OD	40	40	0.35	0.15	0.33	0.04	0.65
		IDet	41	41	0.50	0.21	0.49	0.15	1.01
		Total	81	81	0.42	0.19	0.40	0.04	1.01
	Breakfast	IDegAsp OD	40	34	0.14	0.07	0.13	0.03	0.31
		IDet	41	41	0.15	0.06	0.14	0.05	0.33
		Total	81	75	0.14	0.07	0.14	0.03	0.33
	Lunch	IDegAsp OD	40	39	0.14	0.09	0.12	0.03	0.57
		IDet	41	41	0.14	0.06	0.14	0.05	0.28
		Total	81	80	0.14	0.08	0.13	0.03	0.57
	Main Evening Meal	IDegAsp OD	40	37	0.13	0.10	0.12	0.03	0.65
		IDet	41	41	0.14	0.07	0.14	0.02	0.29
		Total	81	78	0.14	0.08	0.13	0.02	0.65
	Other	IDegAsp OD	40	38	0.10	0.07	0.08	0.02	0.29
		IDet	41	35	0.15	0.10	0.14	0.03	0.44
		Total	81	73	0.12	0.09	0.10	0.02	0.44

N: Number of subjects, SD: Standard deviation

14.2.52 IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	61	59	0.34	0.16	0.33	0.07	0.90
		IDet	61	61	0.47	0.19	0.45	0.06	0.89
		Total	122	120	0.41	0.19	0.40	0.06	0.90
	Breakfast	IDegAsp OD	61	41	0.13	0.05	0.13	0.04	0.24
		IDet	61	61	0.15	0.07	0.14	0.04	0.42
		Total	122	102	0.14	0.07	0.13	0.04	0.42
	Lunch	IDegAsp OD	61	54	0.14	0.06	0.13	0.04	0.28
		IDet	61	59	0.14	0.07	0.13	0.02	0.37
		Total	122	113	0.14	0.06	0.13	0.02	0.37
	Main Evening Meal	IDegAsp OD	61	38	0.12	0.05	0.11	0.04	0.23
		IDet	61	60	0.14	0.06	0.14	0.05	0.28
		Total	122	98	0.14	0.06	0.13	0.04	0.28
	Other	IDegAsp OD	61	33	0.12	0.09	0.11	0.01	0.40
		IDet	61	38	0.09	0.06	0.07	0.02	0.27
		Total	122	71	0.10	0.08	0.08	0.01	0.40
Visit 4 (Week 2)	Daily	IDegAsp OD	61	60	0.35	0.17	0.34	0.10	0.79
		IDet	61	60	0.49	0.20	0.47	0.04	1.11
		Total	122	120	0.42	0.20	0.41	0.04	1.11
	Breakfast	IDegAsp OD	61	43	0.14	0.07	0.12	0.04	0.40
		IDet	61	60	0.14	0.07	0.14	0.03	0.42
		Total	122	103	0.14	0.07	0.14	0.03	0.42
	Lunch	IDegAsp OD	61	54	0.14	0.05	0.13	0.05	0.28
		IDet	61	57	0.15	0.06	0.14	0.05	0.31
		Total	122	111	0.14	0.06	0.14	0.05	0.31
	Main Evening Meal	IDegAsp OD	61	42	0.13	0.06	0.13	0.02	0.27
		IDet	61	59	0.15	0.06	0.13	0.04	0.39
		Total	122	101	0.14	0.06	0.13	0.02	0.39
	Other	IDegAsp OD	61	32	0.12	0.11	0.08	0.03	0.55
		IDet	61	37	0.12	0.08	0.11	0.02	0.35
		Total	122	69	0.12	0.09	0.10	0.02	0.55
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	0.33	0.15	0.31	0.09	0.71
		IDet	61	59	0.49	0.21	0.47	0.08	1.30
		Total	122	119	0.41	0.20	0.40	0.08	1.30
	Breakfast	IDegAsp OD	61	42	0.15	0.07	0.14	0.03	0.31
		IDet	61	59	0.15	0.07	0.14	0.03	0.41
		Total	122	101	0.15	0.07	0.14	0.03	0.41

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 5 (Week 3)	Lunch	IDegAsp OD	61	53	0.12	0.05	0.12	0.04	0.23
		IDet	61	56	0.15	0.06	0.14	0.05	0.30
		Total	122	109	0.13	0.05	0.13	0.04	0.30
	Main Evening Meal	IDegAsp OD	61	40	0.13	0.06	0.13	0.02	0.28
		IDet	61	58	0.15	0.08	0.14	0.05	0.57
		Total	122	98	0.14	0.07	0.13	0.02	0.57
	Other	IDegAsp OD	61	36	0.11	0.08	0.08	0.02	0.45
		IDet	61	37	0.11	0.07	0.09	0.02	0.35
		Total	122	73	0.11	0.08	0.08	0.02	0.45
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	0.33	0.15	0.31	0.02	0.65
		IDet	61	59	0.48	0.20	0.45	0.12	1.15
		Total	122	119	0.40	0.19	0.39	0.02	1.15
	Breakfast	IDegAsp OD	61	40	0.15	0.07	0.14	0.04	0.33
		IDet	61	59	0.15	0.07	0.14	0.02	0.38
		Total	122	99	0.15	0.07	0.14	0.02	0.38
	Lunch	IDegAsp OD	61	53	0.13	0.05	0.12	0.02	0.24
		IDet	61	56	0.15	0.06	0.14	0.05	0.30
		Total	122	109	0.14	0.06	0.13	0.02	0.30
	Main Evening Meal	IDegAsp OD	61	42	0.13	0.07	0.13	0.03	0.38
		IDet	61	58	0.14	0.07	0.14	0.05	0.41
		Total	122	100	0.14	0.07	0.13	0.03	0.41
	Other	IDegAsp OD	61	30	0.11	0.07	0.09	0.03	0.33
		IDet	61	34	0.11	0.06	0.11	0.02	0.26
		Total	122	64	0.11	0.06	0.10	0.02	0.33
Visit 7 (Week 5)	Daily	IDegAsp OD	61	60	0.34	0.14	0.32	0.10	0.65
		IDet	61	59	0.49	0.20	0.46	0.05	0.97
		Total	122	119	0.41	0.19	0.39	0.05	0.97
	Breakfast	IDegAsp OD	61	43	0.15	0.07	0.14	0.03	0.38
		IDet	61	58	0.16	0.07	0.14	0.05	0.43
		Total	122	101	0.15	0.07	0.14	0.03	0.43
	Lunch	IDegAsp OD	61	54	0.14	0.06	0.13	0.04	0.28
		IDet	61	57	0.15	0.07	0.14	0.05	0.34
		Total	122	111	0.14	0.06	0.13	0.04	0.34

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 7 (Week 5)	Main Evening Meal	IDegAsp OD	61	38	0.13	0.06	0.10	0.03	0.28
		IDet	61	58	0.15	0.06	0.15	0.04	0.39
		Total	122	96	0.14	0.06	0.14	0.03	0.39
	Other	IDegAsp OD	61	32	0.11	0.07	0.10	0.01	0.30
		IDet	61	37	0.10	0.08	0.09	0.01	0.34
		Total	122	69	0.11	0.08	0.09	0.01	0.34
Visit 8 (Week 6)	Daily	IDegAsp OD	61	59	0.34	0.13	0.34	0.08	0.66
		IDet	61	59	0.49	0.22	0.45	0.09	1.25
		Total	122	118	0.42	0.19	0.40	0.08	1.25
	Breakfast	IDegAsp OD	61	42	0.14	0.07	0.13	0.02	0.37
		IDet	61	58	0.15	0.08	0.14	0.05	0.42
		Total	122	100	0.15	0.07	0.14	0.02	0.42
	Lunch	IDegAsp OD	61	53	0.14	0.05	0.14	0.04	0.27
		IDet	61	56	0.15	0.07	0.15	0.04	0.42
		Total	122	109	0.15	0.06	0.14	0.04	0.42
	Main Evening Meal	IDegAsp OD	61	38	0.11	0.05	0.10	0.04	0.24
		IDet	61	58	0.15	0.07	0.14	0.06	0.51
		Total	122	96	0.14	0.07	0.13	0.04	0.51
	Other	IDegAsp OD	61	33	0.11	0.07	0.09	0.01	0.32
		IDet	61	33	0.10	0.08	0.08	0.02	0.35
		Total	122	66	0.11	0.08	0.09	0.01	0.35
Visit 9 (Week 7)	Daily	IDegAsp OD	61	60	0.34	0.15	0.32	0.06	0.75
		IDet	61	59	0.51	0.27	0.47	0.06	1.77
		Total	122	119	0.42	0.23	0.38	0.06	1.77
	Breakfast	IDegAsp OD	61	43	0.14	0.07	0.14	0.03	0.38
		IDet	61	58	0.17	0.12	0.14	0.06	0.75
		Total	122	101	0.16	0.10	0.14	0.03	0.75
	Lunch	IDegAsp OD	61	53	0.14	0.05	0.13	0.04	0.29
		IDet	61	57	0.15	0.08	0.13	0.04	0.45
		Total	122	110	0.14	0.07	0.13	0.04	0.45
	Main Evening Meal	IDegAsp OD	61	39	0.12	0.05	0.12	0.04	0.24
		IDet	61	58	0.16	0.08	0.15	0.05	0.53
		Total	122	97	0.14	0.07	0.14	0.04	0.53

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
					-Descriptive Statistics-				
Visit 9 (Week 7)	Other	IDegAsp OD	61	34	0.11	0.08	0.08	0.01	0.45
		IDet	61	35	0.10	0.08	0.08	0.02	0.38
		Total	122	69	0.10	0.08	0.08	0.01	0.45
Visit 10 (Week 8)	Daily	IDegAsp OD	61	60	0.35	0.16	0.33	0.10	1.02
		IDet	61	59	0.50	0.24	0.47	0.04	1.59
		Total	122	119	0.43	0.22	0.42	0.04	1.59
	Breakfast	IDegAsp OD	61	45	0.14	0.07	0.14	0.03	0.34
		IDet	61	58	0.17	0.10	0.14	0.04	0.73
		Total	122	103	0.16	0.09	0.14	0.03	0.73
	Lunch	IDegAsp OD	61	53	0.14	0.05	0.13	0.03	0.26
		IDet	61	56	0.16	0.08	0.14	0.04	0.45
		Total	122	109	0.15	0.07	0.13	0.03	0.45
	Main Evening Meal	IDegAsp OD	61	39	0.12	0.06	0.11	0.04	0.28
		IDet	61	58	0.15	0.07	0.14	0.04	0.48
		Total	122	97	0.14	0.07	0.13	0.04	0.48
	Other	IDegAsp OD	61	35	0.11	0.11	0.09	0.02	0.64
		IDet	61	39	0.10	0.06	0.08	0.02	0.33
		Total	122	74	0.10	0.09	0.08	0.02	0.64
Visit 11 (Week 9)	Daily	IDegAsp OD	61	60	0.35	0.14	0.33	0.11	0.68
		IDet	61	59	0.52	0.31	0.46	0.15	2.35
		Total	122	119	0.43	0.25	0.40	0.11	2.35
	Breakfast	IDegAsp OD	61	45	0.15	0.07	0.14	0.03	0.35
		IDet	61	58	0.16	0.10	0.15	0.04	0.71
		Total	122	103	0.16	0.09	0.14	0.03	0.71
	Lunch	IDegAsp OD	61	54	0.14	0.05	0.14	0.04	0.24
		IDet	61	57	0.16	0.09	0.14	0.04	0.56
		Total	122	111	0.15	0.07	0.14	0.04	0.56
	Main Evening Meal	IDegAsp OD	61	39	0.13	0.06	0.12	0.02	0.26
		IDet	61	58	0.16	0.09	0.14	0.02	0.61
		Total	122	97	0.14	0.08	0.14	0.02	0.61
	Other	IDegAsp OD	61	40	0.10	0.08	0.08	0.01	0.37
		IDet	61	38	0.10	0.09	0.10	0.02	0.47
		Total	122	78	0.10	0.08	0.09	0.01	0.47
Visit 12 (Week 10)	Daily	IDegAsp OD	61	59	0.34	0.13	0.34	0.10	0.63
		IDet	61	59	0.50	0.26	0.45	0.08	1.73
		Total	122	118	0.42	0.22	0.38	0.08	1.73

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 12 (Week 10)	Breakfast	IDegAsp OD	61	44	0.13	0.06	0.13	0.03	0.31
		IDet	61	58	0.16	0.09	0.14	0.04	0.59
		Total	122	102	0.15	0.08	0.14	0.03	0.59
	Lunch	IDegAsp OD	61	53	0.14	0.06	0.13	0.05	0.28
		IDet	61	57	0.16	0.09	0.13	0.04	0.51
		Total	122	110	0.15	0.07	0.13	0.04	0.51
	Main Evening Meal	IDegAsp OD	61	38	0.12	0.05	0.12	0.04	0.23
		IDet	61	58	0.15	0.08	0.14	0.02	0.54
		Total	122	96	0.14	0.07	0.13	0.02	0.54
	Other	IDegAsp OD	61	36	0.10	0.06	0.08	0.01	0.24
		IDet	61	35	0.11	0.07	0.10	0.03	0.30
		Total	122	71	0.10	0.06	0.09	0.01	0.30
Visit 13 (Week 11)	Daily	IDegAsp OD	61	59	0.35	0.12	0.34	0.10	0.66
		IDet	61	59	0.52	0.29	0.47	0.08	2.02
		Total	122	118	0.44	0.24	0.38	0.08	2.02
	Breakfast	IDegAsp OD	61	45	0.14	0.06	0.13	0.05	0.31
		IDet	61	59	0.17	0.09	0.15	0.04	0.59
		Total	122	104	0.16	0.08	0.14	0.04	0.59
	Lunch	IDegAsp OD	61	52	0.14	0.06	0.13	0.03	0.29
		IDet	61	56	0.16	0.10	0.14	0.04	0.59
		Total	122	108	0.15	0.08	0.14	0.03	0.59
	Main Evening Meal	IDegAsp OD	61	37	0.13	0.07	0.13	0.03	0.39
		IDet	61	58	0.16	0.10	0.14	0.02	0.76
		Total	122	95	0.15	0.09	0.14	0.02	0.76
	Other	IDegAsp OD	61	38	0.10	0.08	0.08	0.01	0.41
		IDet	61	39	0.10	0.07	0.08	0.02	0.35
		Total	122	77	0.10	0.07	0.08	0.01	0.41
Visit 14 (Week 12)	Daily	IDegAsp OD	61	59	0.34	0.13	0.32	0.09	0.79
		IDet	61	59	0.51	0.24	0.48	0.04	1.49
		Total	122	118	0.42	0.21	0.39	0.04	1.49
	Breakfast	IDegAsp OD	61	45	0.15	0.06	0.14	0.03	0.31
		IDet	61	59	0.16	0.08	0.14	0.04	0.51
		Total	122	104	0.15	0.07	0.14	0.03	0.51
	Lunch	IDegAsp OD	61	52	0.14	0.05	0.13	0.04	0.24
		IDet	61	56	0.16	0.07	0.14	0.03	0.38
		Total	122	108	0.15	0.06	0.14	0.03	0.38

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 14 (Week 12)	Main Evening Meal	IDegAsp OD	61	38	0.12	0.06	0.12	0.04	0.27
		IDet	61	58	0.16	0.09	0.14	0.02	0.59
		Total	122	96	0.14	0.08	0.14	0.02	0.59
	Other	IDegAsp OD	61	36	0.10	0.08	0.07	0.01	0.41
		IDet	61	36	0.11	0.07	0.11	0.01	0.30
		Total	122	72	0.10	0.08	0.09	0.01	0.41
Visit 15 (Week 13)	Daily	IDegAsp OD	61	59	0.34	0.13	0.34	0.09	0.79
		IDet	61	59	0.50	0.25	0.47	0.04	1.80
		Total	122	118	0.42	0.22	0.38	0.04	1.80
	Breakfast	IDegAsp OD	61	45	0.14	0.07	0.13	0.03	0.36
		IDet	61	59	0.16	0.09	0.14	0.04	0.62
		Total	122	104	0.15	0.08	0.14	0.03	0.62
	Lunch	IDegAsp OD	61	53	0.13	0.06	0.13	0.04	0.38
		IDet	61	56	0.16	0.09	0.14	0.03	0.57
		Total	122	109	0.15	0.07	0.14	0.03	0.57
	Main Evening Meal	IDegAsp OD	61	39	0.11	0.05	0.12	0.02	0.20
		IDet	61	58	0.15	0.09	0.13	0.02	0.59
		Total	122	97	0.14	0.08	0.13	0.02	0.59
	Other	IDegAsp OD	61	33	0.10	0.08	0.08	0.02	0.38
		IDet	61	35	0.10	0.06	0.09	0.02	0.22
		Total	122	68	0.10	0.07	0.09	0.02	0.38
Visit 16 (Week 14)	Daily	IDegAsp OD	61	59	0.35	0.15	0.33	0.10	0.76
		IDet	61	59	0.52	0.28	0.48	0.04	1.97
		Total	122	118	0.43	0.24	0.38	0.04	1.97
	Breakfast	IDegAsp OD	61	45	0.14	0.06	0.14	0.02	0.32
		IDet	61	59	0.16	0.10	0.16	0.04	0.68
		Total	122	104	0.15	0.08	0.14	0.02	0.68
	Lunch	IDegAsp OD	61	52	0.13	0.06	0.13	0.04	0.31
		IDet	61	56	0.16	0.10	0.14	0.03	0.68
		Total	122	108	0.15	0.08	0.14	0.03	0.68
	Main Evening Meal	IDegAsp OD	61	39	0.13	0.06	0.12	0.03	0.28
		IDet	61	57	0.16	0.09	0.14	0.06	0.60
		Total	122	96	0.15	0.08	0.14	0.03	0.60

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 16 (Week 14)	Other	IDegAsp OD	61	33	0.11	0.09	0.08	0.02	0.46
		IDet	61	37	0.10	0.06	0.10	0.02	0.27
		Total	122	70	0.10	0.07	0.08	0.02	0.46
Visit 17 (Week 15)	Daily	IDegAsp OD	61	59	0.36	0.15	0.34	0.09	0.99
		IDet	61	59	0.51	0.26	0.49	0.09	1.88
		Total	122	118	0.44	0.22	0.41	0.09	1.88
	Breakfast	IDegAsp OD	61	48	0.15	0.07	0.13	0.03	0.34
		IDet	61	59	0.16	0.09	0.14	0.04	0.66
		Total	122	107	0.15	0.08	0.14	0.03	0.66
	Lunch	IDegAsp OD	61	51	0.13	0.05	0.12	0.04	0.24
		IDet	61	57	0.16	0.10	0.14	0.03	0.70
		Total	122	108	0.15	0.08	0.14	0.03	0.70
	Main Evening Meal	IDegAsp OD	61	38	0.12	0.05	0.13	0.03	0.24
		IDet	61	57	0.15	0.06	0.14	0.05	0.45
		Total	122	95	0.14	0.06	0.14	0.03	0.45
	Other	IDegAsp OD	61	32	0.12	0.11	0.08	0.02	0.64
		IDet	61	36	0.11	0.07	0.09	0.02	0.30
		Total	122	68	0.11	0.09	0.09	0.02	0.64
Visit 18 (Week 16)	Daily	IDegAsp OD	61	58	0.37	0.15	0.36	0.09	0.85
		IDet	61	59	0.50	0.24	0.49	0.07	1.79
		Total	122	117	0.44	0.21	0.41	0.07	1.79
	Breakfast	IDegAsp OD	61	47	0.15	0.06	0.14	0.02	0.36
		IDet	61	58	0.16	0.10	0.14	0.04	0.77
		Total	122	105	0.15	0.09	0.14	0.02	0.77
	Lunch	IDegAsp OD	61	50	0.14	0.05	0.14	0.04	0.26
		IDet	61	56	0.15	0.08	0.14	0.03	0.43
		Total	122	106	0.15	0.07	0.14	0.03	0.43
	Main Evening Meal	IDegAsp OD	61	38	0.13	0.05	0.14	0.02	0.24
		IDet	61	57	0.16	0.08	0.14	0.04	0.58
		Total	122	95	0.15	0.07	0.14	0.02	0.58
	Other	IDegAsp OD	61	39	0.11	0.09	0.08	0.02	0.49
		IDet	61	38	0.09	0.06	0.08	0.02	0.24
		Total	122	77	0.10	0.08	0.08	0.02	0.49

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
End of trial visit	Daily	IDegAsp OD	61	61	0.36	0.15	0.35	0.02	0.85
		IDet	61	61	0.50	0.24	0.49	0.07	1.79
		Total	122	122	0.43	0.21	0.41	0.02	1.79
	Breakfast	IDegAsp OD	61	51	0.14	0.06	0.14	0.02	0.36
		IDet	61	61	0.16	0.10	0.14	0.03	0.77
		Total	122	112	0.15	0.09	0.14	0.02	0.77
	Lunch	IDegAsp OD	61	58	0.14	0.06	0.13	0.02	0.38
		IDet	61	59	0.15	0.08	0.13	0.03	0.43
		Total	122	117	0.14	0.07	0.13	0.02	0.43
	Main Evening Meal	IDegAsp OD	61	52	0.13	0.06	0.13	0.02	0.24
		IDet	61	60	0.16	0.08	0.14	0.02	0.58
		Total	122	112	0.14	0.07	0.14	0.02	0.58
	Other	IDegAsp OD	61	52	0.10	0.08	0.08	0.01	0.49
		IDet	61	55	0.09	0.07	0.08	0.02	0.29
		Total	122	107	0.10	0.08	0.08	0.01	0.49

N: Number of subjects, SD: Standard deviation

14.2.53 IAsp dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	79	0.38	0.20	0.37	0.01	0.98
		IDet	77	76	0.55	0.23	0.51	0.11	1.35
		Total	157	155	0.46	0.23	0.44	0.01	1.35
	Breakfast	IDegAsp OD	80	60	0.15	0.08	0.13	0.01	0.42
		IDet	77	74	0.16	0.07	0.16	0.04	0.44
		Total	157	134	0.15	0.08	0.15	0.01	0.44
	Lunch	IDegAsp OD	80	74	0.14	0.06	0.13	0.03	0.31
		IDet	77	75	0.17	0.08	0.17	0.02	0.41
		Total	157	149	0.15	0.07	0.14	0.02	0.41
	Main Evening Meal	IDegAsp OD	80	47	0.14	0.09	0.11	0.01	0.42
		IDet	77	76	0.16	0.08	0.15	0.02	0.40
		Total	157	123	0.15	0.08	0.14	0.01	0.42
	Other	IDegAsp OD	80	48	0.14	0.12	0.09	0.02	0.53
		IDet	77	45	0.13	0.10	0.11	0.01	0.45
		Total	157	93	0.13	0.11	0.10	0.01	0.53
Visit 4 (Week 2)	Daily	IDegAsp OD	80	79	0.38	0.19	0.31	0.01	1.05
		IDet	77	77	0.55	0.23	0.55	0.11	1.22
		Total	157	156	0.46	0.23	0.46	0.01	1.22
	Breakfast	IDegAsp OD	80	62	0.14	0.08	0.12	0.01	0.42
		IDet	77	77	0.16	0.07	0.16	0.03	0.37
		Total	157	139	0.15	0.07	0.14	0.01	0.42
	Lunch	IDegAsp OD	80	75	0.14	0.07	0.13	0.03	0.36
		IDet	77	77	0.17	0.07	0.17	0.02	0.42
		Total	157	152	0.16	0.07	0.15	0.02	0.42
	Main Evening Meal	IDegAsp OD	80	50	0.13	0.08	0.11	0.02	0.44
		IDet	77	76	0.17	0.07	0.16	0.02	0.43
		Total	157	126	0.15	0.08	0.15	0.02	0.44
	Other	IDegAsp OD	80	51	0.13	0.10	0.08	0.02	0.52
		IDet	77	42	0.15	0.11	0.12	0.03	0.60
		Total	157	93	0.14	0.11	0.10	0.02	0.60
Visit 5 (Week 3)	Daily	IDegAsp OD	80	79	0.39	0.19	0.35	0.04	1.06
		IDet	77	77	0.54	0.22	0.53	0.08	1.18
		Total	157	156	0.46	0.22	0.43	0.04	1.18
	Breakfast	IDegAsp OD	80	59	0.15	0.09	0.12	0.01	0.44
		IDet	77	74	0.17	0.07	0.17	0.02	0.38
		Total	157	133	0.16	0.08	0.15	0.01	0.44

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 5 (Week 3)	Lunch	IDegAsp OD	80	76	0.15	0.07	0.15	0.03	0.30
		IDet	77	76	0.17	0.07	0.17	0.02	0.40
		Total	157	152	0.16	0.07	0.16	0.02	0.40
	Main Evening Meal	IDegAsp OD	80	48	0.13	0.08	0.11	0.02	0.44
		IDet	77	76	0.17	0.08	0.17	0.02	0.54
		Total	157	124	0.15	0.08	0.15	0.02	0.54
	Other	IDegAsp OD	80	47	0.13	0.10	0.11	0.02	0.52
		IDet	77	46	0.11	0.07	0.10	0.01	0.31
		Total	157	93	0.12	0.09	0.10	0.01	0.52
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	0.38	0.20	0.35	0.02	1.07
		IDet	77	77	0.55	0.22	0.55	0.07	1.09
		Total	157	156	0.47	0.22	0.43	0.02	1.09
	Breakfast	IDegAsp OD	80	58	0.16	0.09	0.15	0.02	0.43
		IDet	77	76	0.17	0.08	0.16	0.04	0.35
		Total	157	134	0.17	0.08	0.16	0.02	0.43
	Lunch	IDegAsp OD	80	74	0.15	0.07	0.14	0.02	0.32
		IDet	77	76	0.17	0.07	0.17	0.05	0.37
		Total	157	150	0.16	0.07	0.15	0.02	0.37
	Main Evening Meal	IDegAsp OD	80	50	0.13	0.08	0.12	0.03	0.42
		IDet	77	76	0.17	0.07	0.17	0.02	0.35
		Total	157	126	0.16	0.08	0.15	0.02	0.42
	Other	IDegAsp OD	80	44	0.13	0.10	0.11	0.02	0.48
		IDet	77	42	0.11	0.07	0.09	0.03	0.35
		Total	157	86	0.12	0.09	0.10	0.02	0.48
Visit 7 (Week 5)	Daily	IDegAsp OD	80	77	0.37	0.20	0.32	0.02	1.04
		IDet	77	75	0.56	0.23	0.55	0.07	1.29
		Total	157	152	0.46	0.24	0.44	0.02	1.29
	Breakfast	IDegAsp OD	80	56	0.15	0.09	0.13	0.01	0.42
		IDet	77	73	0.17	0.08	0.17	0.03	0.37
		Total	157	129	0.16	0.08	0.16	0.01	0.42
	Lunch	IDegAsp OD	80	75	0.15	0.07	0.13	0.03	0.33
		IDet	77	73	0.18	0.08	0.17	0.03	0.36
		Total	157	148	0.16	0.07	0.15	0.03	0.36

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 7 (Week 5)	Main Evening Meal	IDegAsp OD	80	47	0.12	0.08	0.10	0.01	0.42
		IDet	77	73	0.18	0.08	0.18	0.03	0.41
		Total	157	120	0.16	0.08	0.15	0.01	0.42
	Other	IDegAsp OD	80	43	0.12	0.09	0.10	0.03	0.49
		IDet	77	42	0.13	0.08	0.11	0.02	0.35
		Total	157	85	0.13	0.08	0.10	0.02	0.49
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	0.39	0.21	0.35	0.03	1.17
		IDet	77	75	0.56	0.22	0.57	0.07	1.01
		Total	157	153	0.47	0.23	0.46	0.03	1.17
	Breakfast	IDegAsp OD	80	57	0.16	0.10	0.15	0.01	0.44
		IDet	77	74	0.17	0.08	0.17	0.02	0.34
		Total	157	131	0.17	0.09	0.16	0.01	0.44
	Lunch	IDegAsp OD	80	76	0.16	0.08	0.14	0.03	0.41
		IDet	77	74	0.18	0.07	0.17	0.04	0.35
		Total	157	150	0.17	0.08	0.16	0.03	0.41
	Main Evening Meal	IDegAsp OD	80	45	0.13	0.08	0.11	0.02	0.44
		IDet	77	74	0.17	0.07	0.17	0.03	0.34
		Total	157	119	0.16	0.07	0.15	0.02	0.44
	Other	IDegAsp OD	80	47	0.13	0.11	0.09	0.01	0.62
		IDet	77	45	0.12	0.08	0.09	0.02	0.41
		Total	157	92	0.12	0.10	0.09	0.01	0.62
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	0.39	0.20	0.35	0.03	1.02
		IDet	77	73	0.56	0.21	0.56	0.08	1.02
		Total	157	150	0.47	0.22	0.46	0.03	1.02
	Breakfast	IDegAsp OD	80	56	0.16	0.09	0.13	0.02	0.41
		IDet	77	73	0.18	0.08	0.17	0.03	0.37
		Total	157	129	0.17	0.08	0.16	0.02	0.41
	Lunch	IDegAsp OD	80	73	0.15	0.07	0.14	0.03	0.40
		IDet	77	72	0.18	0.07	0.17	0.03	0.31
		Total	157	145	0.17	0.07	0.16	0.03	0.40
	Main Evening Meal	IDegAsp OD	80	44	0.13	0.09	0.10	0.01	0.44
		IDet	77	73	0.17	0.07	0.17	0.01	0.35
		Total	157	117	0.16	0.08	0.15	0.01	0.44

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 9 (Week 7)	Other	IDegAsp OD	80	50	0.12	0.09	0.08	0.02	0.41
		IDet	77	39	0.11	0.07	0.09	0.01	0.26
		Total	157	89	0.11	0.08	0.09	0.01	0.41
Visit 10 (Week 8)	Daily	IDegAsp OD	80	76	0.38	0.20	0.34	0.02	1.03
		IDet	77	74	0.55	0.21	0.56	0.07	1.13
		Total	157	150	0.46	0.23	0.45	0.02	1.13
	Breakfast	IDegAsp OD	80	56	0.15	0.09	0.13	0.02	0.40
		IDet	77	73	0.17	0.08	0.18	0.02	0.36
		Total	157	129	0.16	0.08	0.16	0.02	0.40
	Lunch	IDegAsp OD	80	74	0.16	0.08	0.15	0.03	0.42
		IDet	77	72	0.17	0.07	0.17	0.03	0.31
		Total	157	146	0.16	0.08	0.16	0.03	0.42
	Main Evening Meal	IDegAsp OD	80	44	0.14	0.09	0.10	0.01	0.40
		IDet	77	73	0.18	0.08	0.18	0.01	0.41
		Total	157	117	0.16	0.09	0.15	0.01	0.41
	Other	IDegAsp OD	80	42	0.13	0.10	0.09	0.03	0.52
		IDet	77	40	0.11	0.06	0.11	0.02	0.28
		Total	157	82	0.12	0.08	0.10	0.02	0.52
Visit 11 (Week 9)	Daily	IDegAsp OD	80	77	0.39	0.21	0.34	0.02	1.04
		IDet	77	73	0.57	0.22	0.56	0.08	1.11
		Total	157	150	0.48	0.23	0.47	0.02	1.11
	Breakfast	IDegAsp OD	80	56	0.17	0.10	0.14	0.01	0.51
		IDet	77	72	0.17	0.08	0.17	0.03	0.33
		Total	157	128	0.17	0.09	0.16	0.01	0.51
	Lunch	IDegAsp OD	80	74	0.15	0.07	0.15	0.04	0.41
		IDet	77	72	0.18	0.07	0.16	0.05	0.39
		Total	157	146	0.16	0.07	0.16	0.04	0.41
	Main Evening Meal	IDegAsp OD	80	43	0.15	0.09	0.13	0.03	0.39
		IDet	77	72	0.17	0.07	0.17	0.01	0.45
		Total	157	115	0.16	0.08	0.15	0.01	0.45
	Other	IDegAsp OD	80	46	0.12	0.09	0.09	0.03	0.49
		IDet	77	42	0.12	0.08	0.11	0.02	0.33
		Total	157	88	0.12	0.09	0.10	0.02	0.49
Visit 12 (Week 10)	Daily	IDegAsp OD	80	76	0.39	0.20	0.37	0.05	1.01
		IDet	77	74	0.56	0.20	0.56	0.07	1.03
		Total	157	150	0.47	0.22	0.47	0.05	1.03

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 12 (Week 10)	Breakfast	IDegAsp OD	80	55	0.15	0.09	0.14	0.01	0.43
		IDet	77	73	0.17	0.07	0.18	0.03	0.30
		Total	157	128	0.16	0.08	0.16	0.01	0.43
	Lunch	IDegAsp OD	80	72	0.16	0.08	0.14	0.03	0.40
		IDet	77	73	0.18	0.08	0.18	0.04	0.34
		Total	157	145	0.17	0.08	0.16	0.03	0.40
	Main Evening Meal	IDegAsp OD	80	45	0.15	0.14	0.12	0.01	0.88
		IDet	77	72	0.18	0.07	0.17	0.05	0.35
		Total	157	117	0.17	0.10	0.15	0.01	0.88
	Other	IDegAsp OD	80	46	0.12	0.09	0.09	0.01	0.48
		IDet	77	44	0.12	0.09	0.09	0.01	0.45
		Total	157	90	0.12	0.09	0.09	0.01	0.48
Visit 13 (Week 11)	Daily	IDegAsp OD	80	76	0.39	0.20	0.35	0.03	1.08
		IDet	77	74	0.54	0.20	0.55	0.07	1.03
		Total	157	150	0.46	0.22	0.44	0.03	1.08
	Breakfast	IDegAsp OD	80	55	0.15	0.09	0.15	0.01	0.41
		IDet	77	70	0.17	0.07	0.17	0.03	0.34
		Total	157	125	0.16	0.08	0.15	0.01	0.41
	Lunch	IDegAsp OD	80	73	0.16	0.07	0.14	0.03	0.32
		IDet	77	73	0.17	0.07	0.17	0.04	0.35
		Total	157	146	0.16	0.07	0.15	0.03	0.35
	Main Evening Meal	IDegAsp OD	80	41	0.14	0.08	0.12	0.03	0.41
		IDet	77	72	0.18	0.07	0.17	0.06	0.35
		Total	157	113	0.16	0.08	0.16	0.03	0.41
	Other	IDegAsp OD	80	45	0.12	0.09	0.09	0.02	0.51
		IDet	77	37	0.11	0.07	0.09	0.02	0.26
		Total	157	82	0.11	0.08	0.09	0.02	0.51
Visit 14 (Week 12)	Daily	IDegAsp OD	80	76	0.37	0.19	0.36	0.03	0.98
		IDet	77	74	0.54	0.21	0.54	0.07	1.05
		Total	157	150	0.46	0.22	0.43	0.03	1.05
	Breakfast	IDegAsp OD	80	56	0.15	0.08	0.14	0.03	0.37
		IDet	77	73	0.17	0.08	0.17	0.03	0.33
		Total	157	129	0.16	0.08	0.15	0.03	0.37
	Lunch	IDegAsp OD	80	73	0.15	0.08	0.14	0.04	0.37
		IDet	77	72	0.17	0.07	0.17	0.03	0.32
		Total	157	145	0.16	0.07	0.16	0.03	0.37

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 14 (Week 12)	Main Evening Meal	IDegAsp OD	80	43	0.14	0.10	0.12	0.01	0.44
		IDet	77	72	0.17	0.07	0.17	0.05	0.36
		Total	157	115	0.16	0.08	0.15	0.01	0.44
	Other	IDegAsp OD	80	45	0.10	0.08	0.09	0.03	0.47
		IDet	77	40	0.13	0.08	0.12	0.01	0.31
		Total	157	85	0.12	0.08	0.10	0.01	0.47
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	0.37	0.18	0.35	0.03	0.95
		IDet	77	73	0.55	0.22	0.53	0.06	1.10
		Total	157	150	0.46	0.22	0.42	0.03	1.10
	Breakfast	IDegAsp OD	80	55	0.16	0.09	0.16	0.01	0.40
		IDet	77	73	0.17	0.08	0.17	0.02	0.35
		Total	157	128	0.16	0.08	0.16	0.01	0.40
	Lunch	IDegAsp OD	80	73	0.15	0.06	0.15	0.03	0.33
		IDet	77	72	0.17	0.08	0.17	0.04	0.35
		Total	157	145	0.16	0.07	0.15	0.03	0.35
	Main Evening Meal	IDegAsp OD	80	44	0.13	0.08	0.13	0.03	0.35
		IDet	77	71	0.18	0.09	0.16	0.03	0.47
		Total	157	115	0.16	0.08	0.15	0.03	0.47
	Other	IDegAsp OD	80	47	0.11	0.08	0.07	0.03	0.38
		IDet	77	36	0.11	0.06	0.10	0.03	0.27
		Total	157	83	0.11	0.07	0.09	0.03	0.38
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	0.38	0.18	0.36	0.05	0.93
		IDet	77	71	0.55	0.21	0.54	0.06	1.06
		Total	157	148	0.46	0.21	0.44	0.05	1.06
	Breakfast	IDegAsp OD	80	56	0.15	0.08	0.14	0.01	0.39
		IDet	77	70	0.17	0.08	0.16	0.02	0.37
		Total	157	126	0.16	0.08	0.15	0.01	0.39
	Lunch	IDegAsp OD	80	72	0.16	0.07	0.15	0.03	0.42
		IDet	77	70	0.17	0.08	0.17	0.03	0.34
		Total	157	142	0.16	0.07	0.15	0.03	0.42
	Main Evening Meal	IDegAsp OD	80	45	0.14	0.07	0.12	0.03	0.36
		IDet	77	69	0.18	0.08	0.17	0.04	0.45
		Total	157	114	0.16	0.08	0.15	0.03	0.45

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 16 (Week 14)	Other	IDegAsp OD	80	48	0.11	0.07	0.08	0.02	0.42
		IDet	77	35	0.12	0.07	0.11	0.02	0.27
		Total	157	83	0.11	0.07	0.09	0.02	0.42
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	0.39	0.19	0.38	0.03	1.02
		IDet	77	73	0.55	0.22	0.54	0.06	1.06
		Total	157	148	0.47	0.22	0.44	0.03	1.06
	Breakfast	IDegAsp OD	80	53	0.16	0.09	0.13	0.02	0.42
		IDet	77	72	0.17	0.08	0.16	0.02	0.34
		Total	157	125	0.16	0.09	0.15	0.02	0.42
	Lunch	IDegAsp OD	80	71	0.15	0.06	0.15	0.03	0.29
		IDet	77	72	0.18	0.08	0.16	0.03	0.42
		Total	157	143	0.16	0.07	0.16	0.03	0.42
	Main Evening Meal	IDegAsp OD	80	45	0.16	0.13	0.13	0.01	0.80
		IDet	77	71	0.17	0.08	0.16	0.04	0.46
		Total	157	116	0.17	0.10	0.15	0.01	0.80
	Other	IDegAsp OD	80	49	0.12	0.08	0.10	0.03	0.37
		IDet	77	40	0.11	0.06	0.11	0.02	0.25
		Total	157	89	0.12	0.07	0.11	0.02	0.37
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	0.37	0.19	0.36	0.03	0.92
		IDet	77	70	0.55	0.22	0.56	0.06	1.19
		Total	157	146	0.46	0.22	0.44	0.03	1.19
	Breakfast	IDegAsp OD	80	54	0.16	0.08	0.14	0.01	0.38
		IDet	77	70	0.17	0.08	0.16	0.02	0.33
		Total	157	124	0.16	0.08	0.16	0.01	0.38
	Lunch	IDegAsp OD	80	72	0.15	0.07	0.15	0.02	0.35
		IDet	77	69	0.18	0.08	0.16	0.04	0.41
		Total	157	141	0.16	0.07	0.16	0.02	0.41
	Main Evening Meal	IDegAsp OD	80	44	0.14	0.09	0.12	0.02	0.37
		IDet	77	68	0.18	0.08	0.17	0.04	0.46
		Total	157	112	0.16	0.08	0.15	0.02	0.46
	Other	IDegAsp OD	80	49	0.12	0.08	0.09	0.02	0.40
		IDet	77	39	0.09	0.05	0.09	0.01	0.22
		Total	157	88	0.10	0.07	0.09	0.01	0.40

N: Number of subjects, SD: Standard deviation

IAsp dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
End of trial visit	Daily	IDegAsp OD	80	80	0.37	0.18	0.35	0.03	0.92
		IDet	77	77	0.54	0.22	0.54	0.06	1.19
		Total	157	157	0.45	0.22	0.44	0.03	1.19
	Breakfast	IDegAsp OD	80	69	0.14	0.08	0.13	0.01	0.38
		IDet	77	77	0.16	0.08	0.16	0.02	0.33
		Total	157	146	0.15	0.08	0.15	0.01	0.38
	Lunch	IDegAsp OD	80	78	0.15	0.07	0.15	0.02	0.35
		IDet	77	77	0.17	0.08	0.16	0.02	0.41
		Total	157	155	0.16	0.07	0.15	0.02	0.41
	Main Evening Meal	IDegAsp OD	80	65	0.14	0.12	0.11	0.02	0.80
		IDet	77	77	0.17	0.08	0.17	0.01	0.46
		Total	157	142	0.16	0.10	0.14	0.01	0.80
	Other	IDegAsp OD	80	69	0.11	0.08	0.08	0.01	0.40
		IDet	77	63	0.09	0.06	0.08	0.01	0.23
		Total	157	132	0.10	0.07	0.08	0.01	0.40

N: Number of subjects, SD: Standard deviation

14.2.54 Basal insulin dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	0.31	0.13	0.30	0.03	0.74
		IDet	179	179	0.38	0.21	0.34	0.05	1.17
		Total	360	360	0.35	0.18	0.32	0.03	1.17
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	0.33	0.14	0.30	0.03	0.81
		IDet	179	178	0.40	0.21	0.36	0.05	1.13
		Total	360	359	0.36	0.18	0.33	0.03	1.13
Visit 5 (Week 3)	Daily	IDegAsp OD	181	180	0.34	0.14	0.33	0.03	0.77
		IDet	179	176	0.42	0.22	0.38	0.05	1.13
		Total	360	356	0.38	0.19	0.36	0.03	1.13
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	0.35	0.14	0.34	0.03	0.75
		IDet	179	176	0.43	0.22	0.39	0.05	1.19
		Total	360	355	0.39	0.19	0.37	0.03	1.19
Visit 7 (Week 5)	Daily	IDegAsp OD	181	179	0.35	0.14	0.35	0.03	0.71
		IDet	179	174	0.44	0.22	0.39	0.05	1.25
		Total	360	353	0.39	0.19	0.37	0.03	1.25
Visit 8 (Week 6)	Daily	IDegAsp OD	181	179	0.35	0.14	0.36	0.03	0.71
		IDet	179	174	0.45	0.23	0.40	0.05	1.23
		Total	360	353	0.40	0.20	0.38	0.03	1.23
Visit 9 (Week 7)	Daily	IDegAsp OD	181	178	0.35	0.14	0.35	0.03	0.71
		IDet	179	172	0.46	0.24	0.40	0.05	1.34
		Total	360	350	0.40	0.20	0.38	0.03	1.34
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	0.36	0.15	0.36	0.03	0.71
		IDet	179	173	0.46	0.25	0.42	0.05	1.36
		Total	360	350	0.41	0.21	0.39	0.03	1.36
Visit 11 (Week 9)	Daily	IDegAsp OD	181	177	0.36	0.15	0.36	0.03	0.71
		IDet	179	173	0.47	0.25	0.43	0.05	1.47
		Total	360	350	0.42	0.21	0.39	0.03	1.47
Visit 12 (Week 10)	Daily	IDegAsp OD	181	175	0.36	0.15	0.35	0.04	0.73
		IDet	179	172	0.48	0.26	0.43	0.05	1.53
		Total	360	347	0.42	0.22	0.40	0.04	1.53
Visit 13 (Week 11)	Daily	IDegAsp OD	181	175	0.36	0.15	0.35	0.04	0.73
		IDet	179	172	0.48	0.26	0.43	0.05	1.65
		Total	360	347	0.42	0.22	0.39	0.04	1.65
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	0.35	0.14	0.34	0.04	0.76
		IDet	179	172	0.48	0.26	0.43	0.05	1.70
		Total	360	347	0.41	0.22	0.38	0.04	1.70

N: Number of subjects, SD: Standard deviation

Basal insulin dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
			-Descriptive Statistics-						
Visit 15 (Week 13)	Daily	IDegAsp OD	181	175	0.36	0.15	0.35	0.04	0.76
		IDet	179	172	0.48	0.26	0.44	0.05	1.70
		Total	360	347	0.42	0.22	0.39	0.04	1.70
Visit 16 (Week 14)	Daily	IDegAsp OD	181	175	0.36	0.15	0.35	0.05	0.78
		IDet	179	169	0.48	0.26	0.44	0.05	1.70
		Total	360	344	0.42	0.22	0.39	0.05	1.70
Visit 17 (Week 15)	Daily	IDegAsp OD	181	173	0.36	0.15	0.35	0.05	0.82
		IDet	179	170	0.49	0.27	0.44	0.05	1.70
		Total	360	343	0.42	0.22	0.39	0.05	1.70
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	0.36	0.15	0.35	0.05	0.83
		IDet	179	167	0.49	0.27	0.45	0.05	1.77
		Total	360	340	0.42	0.22	0.38	0.05	1.77
End of trial visit	Daily	IDegAsp OD	181	181	0.36	0.15	0.36	0.05	0.83
		IDet	179	179	0.50	0.27	0.46	0.05	1.77
		Total	360	360	0.43	0.23	0.39	0.05	1.77

N: Number of subjects, SD: Standard deviation

14.2.55 Basal insulin dose (actual) in units/kg by treatment week - descriptive statistics - children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	0.27	0.12	0.24	0.03	0.64
		IDet	41	41	0.29	0.16	0.26	0.05	0.86
		Total	81	81	0.28	0.14	0.25	0.03	0.86
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	0.28	0.12	0.27	0.03	0.58
		IDet	41	41	0.31	0.16	0.29	0.06	0.72
		Total	81	81	0.29	0.14	0.28	0.03	0.72
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	0.29	0.12	0.26	0.03	0.58
		IDet	41	40	0.32	0.17	0.31	0.05	0.83
		Total	81	80	0.31	0.15	0.29	0.03	0.83
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	0.29	0.13	0.26	0.03	0.58
		IDet	41	40	0.34	0.17	0.34	0.05	0.79
		Total	81	80	0.31	0.15	0.31	0.03	0.79
Visit 7 (Week 5)	Daily	IDegAsp OD	40	40	0.29	0.13	0.27	0.05	0.57
		IDet	41	40	0.34	0.18	0.34	0.05	0.79
		Total	81	80	0.32	0.16	0.33	0.05	0.79
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	0.30	0.13	0.28	0.05	0.58
		IDet	41	40	0.37	0.21	0.35	0.05	0.90
		Total	81	80	0.33	0.18	0.32	0.05	0.90
Visit 9 (Week 7)	Daily	IDegAsp OD	40	40	0.30	0.13	0.28	0.05	0.58
		IDet	41	40	0.37	0.23	0.36	0.05	1.02
		Total	81	80	0.34	0.19	0.32	0.05	1.02
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	0.31	0.13	0.29	0.05	0.58
		IDet	41	40	0.38	0.25	0.36	0.08	1.14
		Total	81	79	0.35	0.20	0.31	0.05	1.14
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	0.31	0.14	0.30	0.05	0.58
		IDet	41	40	0.39	0.26	0.34	0.06	1.14
		Total	81	78	0.35	0.21	0.32	0.05	1.14
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	0.31	0.14	0.29	0.05	0.58
		IDet	41	39	0.39	0.25	0.35	0.08	1.26
		Total	81	77	0.35	0.20	0.31	0.05	1.26
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	0.31	0.14	0.29	0.05	0.59
		IDet	41	39	0.38	0.24	0.32	0.08	1.26
		Total	81	77	0.34	0.20	0.30	0.05	1.26
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	0.30	0.13	0.29	0.05	0.55
		IDet	41	39	0.38	0.24	0.35	0.08	1.27
		Total	81	77	0.34	0.20	0.30	0.05	1.27

N: Number of subjects, SD: Standard deviation

Basal insulin dose (actual) in units/kg by treatment week - descriptive statistics - children (1-5 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
				-Descriptive Statistics-					
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	0.31	0.14	0.30	0.05	0.60
		IDet	41	39	0.39	0.25	0.34	0.08	1.38
		Total	81	77	0.35	0.21	0.32	0.05	1.38
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	0.31	0.14	0.30	0.05	0.60
		IDet	41	39	0.39	0.28	0.34	0.08	1.60
		Total	81	77	0.35	0.22	0.33	0.05	1.60
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	0.31	0.14	0.30	0.05	0.60
		IDet	41	38	0.40	0.29	0.37	0.08	1.66
		Total	81	76	0.36	0.23	0.31	0.05	1.66
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	0.31	0.13	0.30	0.05	0.57
		IDet	41	37	0.40	0.30	0.37	0.08	1.77
		Total	81	75	0.35	0.23	0.30	0.05	1.77
End of trial visit	Daily	IDegAsp OD	40	40	0.31	0.13	0.30	0.05	0.57
		IDet	41	41	0.42	0.31	0.38	0.08	1.77
		Total	81	81	0.37	0.25	0.30	0.05	1.77

N: Number of subjects, SD: Standard deviation

14.2.56 Basal insulin dose (actual) in units/kg by treatment week - descriptive statistics - children (6-11 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
					Descriptive Statistics				
Visit 3 (Week 1)	Daily	IDegAsp OD	61	61	0.29	0.12	0.30	0.07	0.54
		IDet	61	61	0.39	0.23	0.34	0.05	1.17
		Total	122	122	0.34	0.19	0.31	0.05	1.17
Visit 4 (Week 2)	Daily	IDegAsp OD	61	61	0.31	0.13	0.30	0.09	0.60
		IDet	61	60	0.40	0.22	0.36	0.05	1.13
		Total	122	121	0.36	0.19	0.33	0.05	1.13
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	0.32	0.13	0.31	0.09	0.60
		IDet	61	59	0.42	0.22	0.37	0.05	1.13
		Total	122	119	0.37	0.19	0.35	0.05	1.13
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	0.33	0.13	0.32	0.09	0.56
		IDet	61	59	0.43	0.23	0.39	0.05	1.19
		Total	122	119	0.38	0.19	0.36	0.05	1.19
Visit 7 (Week 5)	Daily	IDegAsp OD	61	61	0.33	0.13	0.29	0.09	0.61
		IDet	61	59	0.45	0.24	0.39	0.05	1.25
		Total	122	120	0.39	0.20	0.37	0.05	1.25
Visit 8 (Week 6)	Daily	IDegAsp OD	61	61	0.33	0.13	0.31	0.09	0.63
		IDet	61	59	0.45	0.23	0.39	0.05	1.19
		Total	122	120	0.39	0.20	0.37	0.05	1.19
Visit 9 (Week 7)	Daily	IDegAsp OD	61	61	0.33	0.13	0.32	0.10	0.68
		IDet	61	59	0.45	0.24	0.39	0.05	1.30
		Total	122	120	0.39	0.20	0.37	0.05	1.30
Visit 10 (Week 8)	Daily	IDegAsp OD	61	61	0.33	0.13	0.32	0.10	0.68
		IDet	61	59	0.47	0.25	0.40	0.05	1.36
		Total	122	120	0.40	0.21	0.37	0.05	1.36
Visit 11 (Week 9)	Daily	IDegAsp OD	61	61	0.34	0.13	0.32	0.09	0.65
		IDet	61	59	0.47	0.25	0.43	0.05	1.47
		Total	122	120	0.41	0.21	0.38	0.05	1.47
Visit 12 (Week 10)	Daily	IDegAsp OD	61	60	0.33	0.12	0.32	0.10	0.59
		IDet	61	59	0.48	0.25	0.43	0.05	1.53
		Total	122	119	0.41	0.21	0.39	0.05	1.53
Visit 13 (Week 11)	Daily	IDegAsp OD	61	60	0.33	0.13	0.32	0.11	0.67
		IDet	61	59	0.49	0.26	0.44	0.05	1.65
		Total	122	119	0.41	0.22	0.39	0.05	1.65
Visit 14 (Week 12)	Daily	IDegAsp OD	61	60	0.32	0.12	0.31	0.11	0.63
		IDet	61	59	0.48	0.27	0.43	0.05	1.70
		Total	122	119	0.40	0.22	0.37	0.05	1.70

N: Number of subjects, SD: Standard deviation

Basal insulin dose (actual) in units/kg by treatment week - descriptive statistics - children (6-11 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
				-Descriptive Statistics-					
Visit 15 (Week 13)	Daily	IDegAsp OD	61	60	0.32	0.12	0.32	0.11	0.68
		IDet	61	59	0.48	0.27	0.43	0.05	1.70
		Total	122	119	0.40	0.22	0.37	0.05	1.70
Visit 16 (Week 14)	Daily	IDegAsp OD	61	60	0.32	0.12	0.32	0.10	0.68
		IDet	61	59	0.49	0.27	0.43	0.05	1.70
		Total	122	119	0.40	0.22	0.37	0.05	1.70
Visit 17 (Week 15)	Daily	IDegAsp OD	61	60	0.33	0.12	0.33	0.11	0.68
		IDet	61	59	0.49	0.27	0.44	0.05	1.70
		Total	122	119	0.41	0.22	0.37	0.05	1.70
Visit 18 (Week 16)	Daily	IDegAsp OD	61	59	0.33	0.13	0.32	0.11	0.70
		IDet	61	59	0.49	0.26	0.44	0.05	1.62
		Total	122	118	0.41	0.22	0.38	0.05	1.62
End of trial visit	Daily	IDegAsp OD	61	61	0.34	0.13	0.32	0.11	0.70
		IDet	61	61	0.50	0.26	0.45	0.05	1.62
		Total	122	122	0.42	0.22	0.38	0.05	1.62

N: Number of subjects, SD: Standard deviation

14.2.57 Basal insulin dose (actual) in units/kg by treatment week - descriptive statistics - children (12-17 years) - safety analysis set

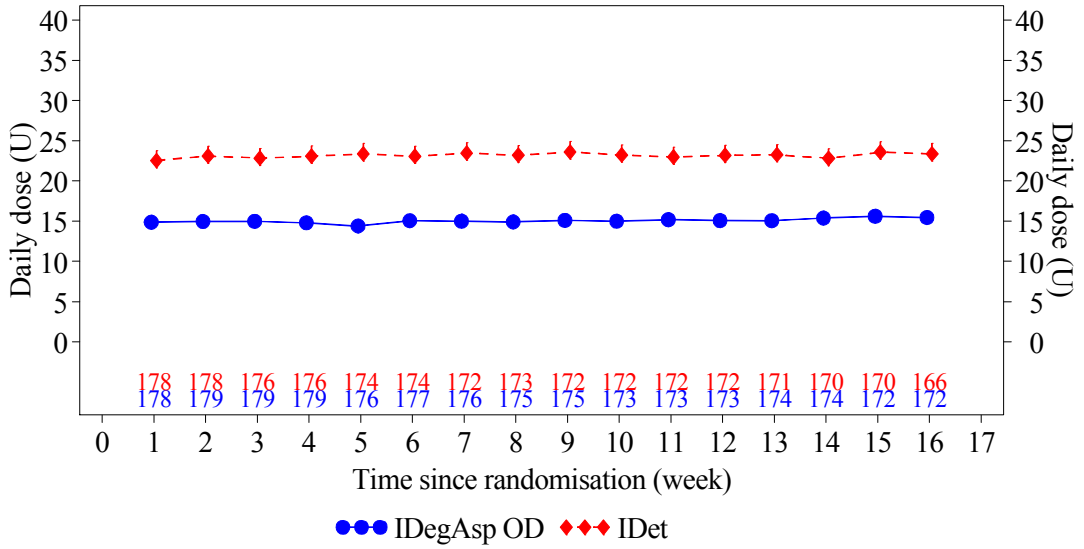
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	80	0.34	0.14	0.34	0.03	0.74
		IDet	77	77	0.43	0.19	0.39	0.09	0.91
		Total	157	157	0.38	0.17	0.36	0.03	0.91
Visit 4 (Week 2)	Daily	IDegAsp OD	80	80	0.36	0.14	0.36	0.03	0.81
		IDet	77	77	0.45	0.20	0.41	0.09	1.03
		Total	157	157	0.40	0.18	0.39	0.03	1.03
Visit 5 (Week 3)	Daily	IDegAsp OD	80	80	0.37	0.14	0.39	0.03	0.77
		IDet	77	77	0.48	0.22	0.44	0.10	1.10
		Total	157	157	0.42	0.19	0.41	0.03	1.10
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	0.39	0.15	0.41	0.03	0.75
		IDet	77	77	0.48	0.22	0.43	0.11	1.14
		Total	157	156	0.43	0.19	0.42	0.03	1.14
Visit 7 (Week 5)	Daily	IDegAsp OD	80	78	0.39	0.15	0.42	0.03	0.71
		IDet	77	75	0.49	0.22	0.43	0.12	1.17
		Total	157	153	0.44	0.19	0.42	0.03	1.17
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	0.39	0.15	0.42	0.03	0.71
		IDet	77	75	0.50	0.23	0.44	0.13	1.23
		Total	157	153	0.44	0.20	0.43	0.03	1.23
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	0.40	0.15	0.42	0.03	0.71
		IDet	77	73	0.50	0.23	0.44	0.13	1.34
		Total	157	150	0.45	0.20	0.42	0.03	1.34
Visit 10 (Week 8)	Daily	IDegAsp OD	80	77	0.40	0.15	0.42	0.03	0.71
		IDet	77	74	0.51	0.24	0.45	0.13	1.36
		Total	157	151	0.45	0.20	0.44	0.03	1.36
Visit 11 (Week 9)	Daily	IDegAsp OD	80	78	0.41	0.16	0.42	0.03	0.71
		IDet	77	74	0.52	0.25	0.46	0.12	1.36
		Total	157	152	0.46	0.21	0.44	0.03	1.36
Visit 12 (Week 10)	Daily	IDegAsp OD	80	77	0.41	0.16	0.42	0.04	0.73
		IDet	77	74	0.53	0.25	0.47	0.12	1.44
		Total	157	151	0.47	0.22	0.44	0.04	1.44
Visit 13 (Week 11)	Daily	IDegAsp OD	80	77	0.41	0.16	0.42	0.04	0.73
		IDet	77	74	0.53	0.26	0.47	0.12	1.39
		Total	157	151	0.47	0.22	0.45	0.04	1.39
Visit 14 (Week 12)	Daily	IDegAsp OD	80	77	0.40	0.15	0.41	0.04	0.76
		IDet	77	74	0.53	0.24	0.48	0.14	1.07
		Total	157	151	0.46	0.21	0.44	0.04	1.07

N: Number of subjects, SD: Standard deviation

Basal insulin dose (actual) in units/kg by treatment week - descriptive statistics - children (12-17 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
			-Descriptive Statistics-						
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	0.40	0.16	0.41	0.04	0.76
		IDet	77	74	0.53	0.25	0.47	0.15	1.11
		Total	157	151	0.47	0.21	0.44	0.04	1.11
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	0.41	0.16	0.41	0.05	0.78
		IDet	77	71	0.52	0.24	0.48	0.15	1.18
		Total	157	148	0.46	0.21	0.44	0.05	1.18
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	0.41	0.16	0.41	0.07	0.82
		IDet	77	73	0.53	0.25	0.48	0.15	1.18
		Total	157	148	0.47	0.21	0.44	0.07	1.18
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	0.41	0.16	0.40	0.07	0.83
		IDet	77	71	0.53	0.25	0.48	0.14	1.22
		Total	157	147	0.47	0.22	0.44	0.07	1.22
End of trial visit	Daily	IDegAsp OD	80	80	0.41	0.16	0.41	0.07	0.83
		IDet	77	77	0.55	0.26	0.53	0.14	1.22
		Total	157	157	0.48	0.22	0.45	0.07	1.22

N: Number of subjects, SD: Standard deviation



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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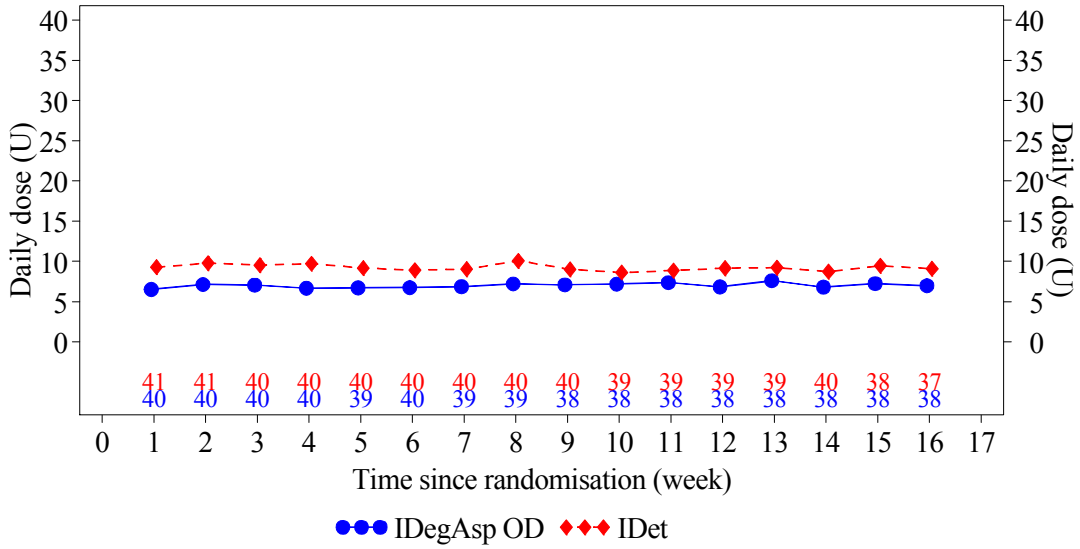
14.2.58 Daily IAsp dose (actual) in units by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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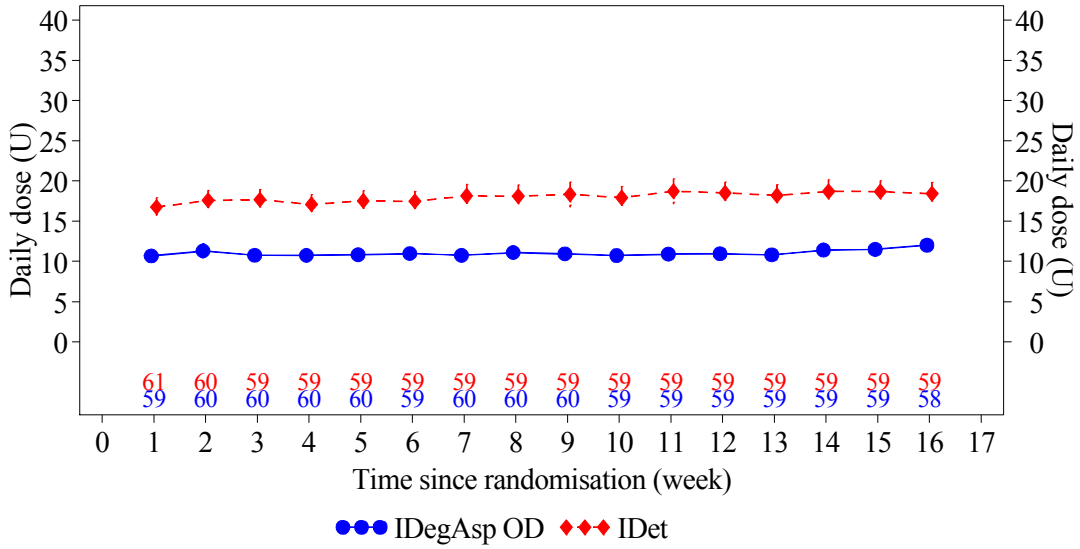
14.2.59 Daily IAsp dose (actual) in units by treatment week - mean plot – children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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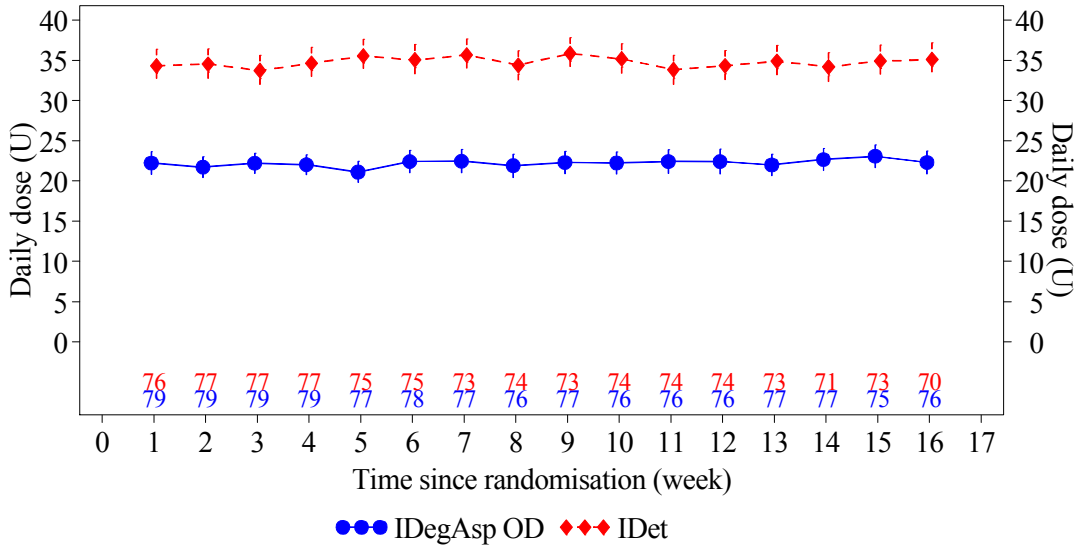
14.2.60 Daily IAsp dose (actual) in units by treatment week - mean plot – children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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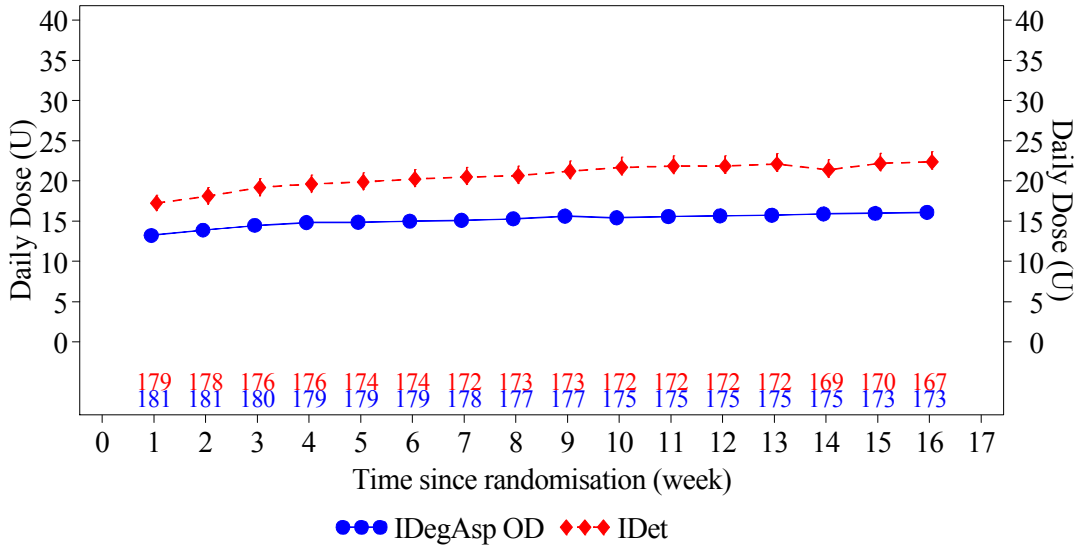
14.2.61 Daily IAsp dose (actual) in units by treatment week - mean plot – adolescents (12-17 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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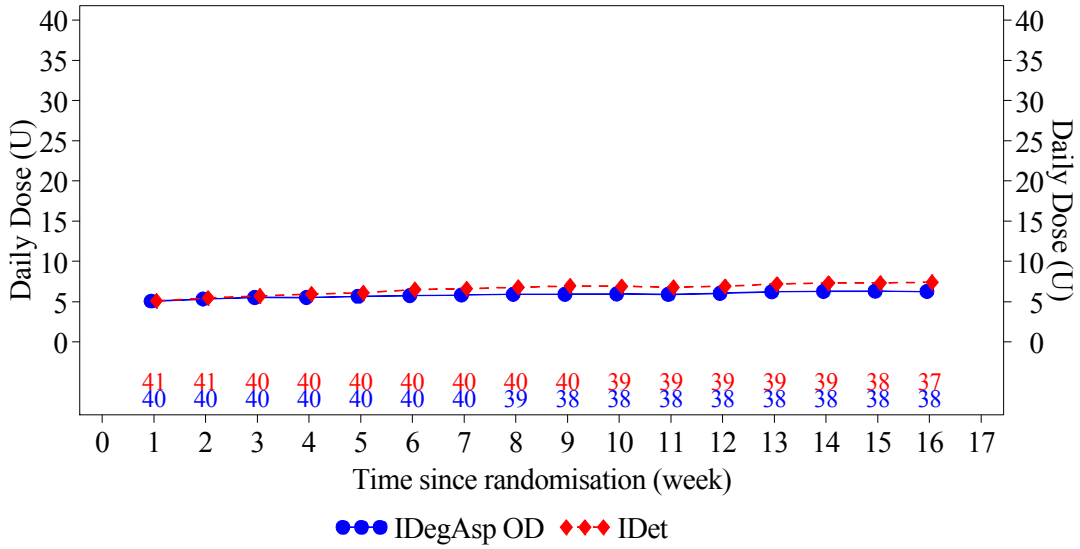
14.2.62 Daily basal insulin dose (actual) in units by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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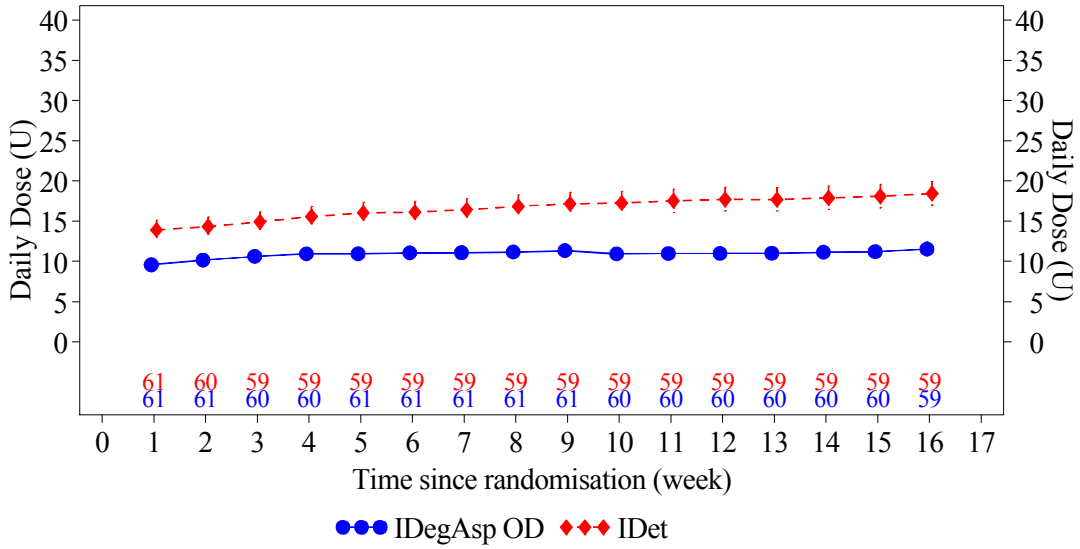
14.2.63 Daily basal insulin dose (actual) in units by treatment week - mean plot - children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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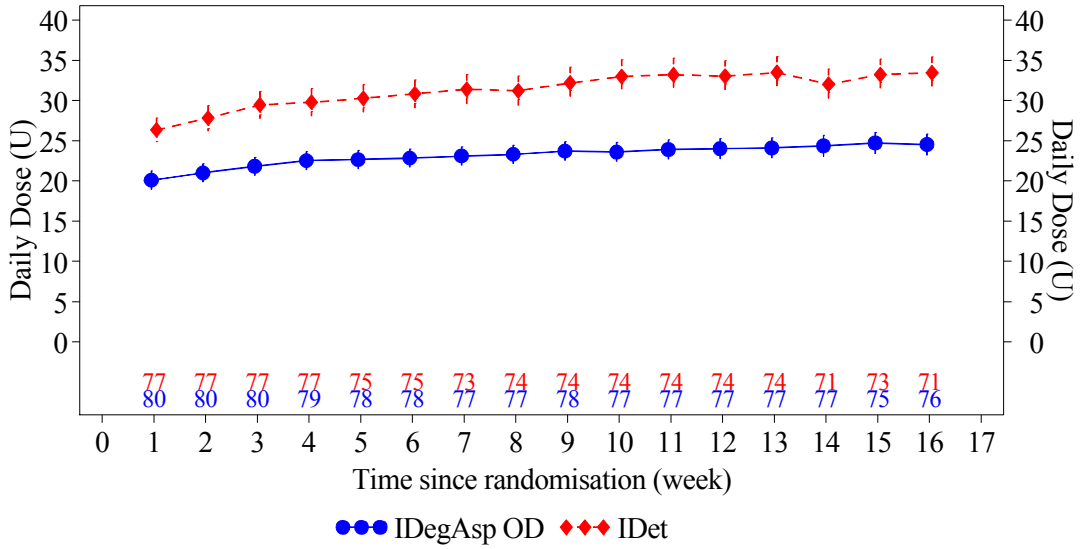
14.2.64 Daily basal insulin dose (actual) in units by treatment week - mean plot - children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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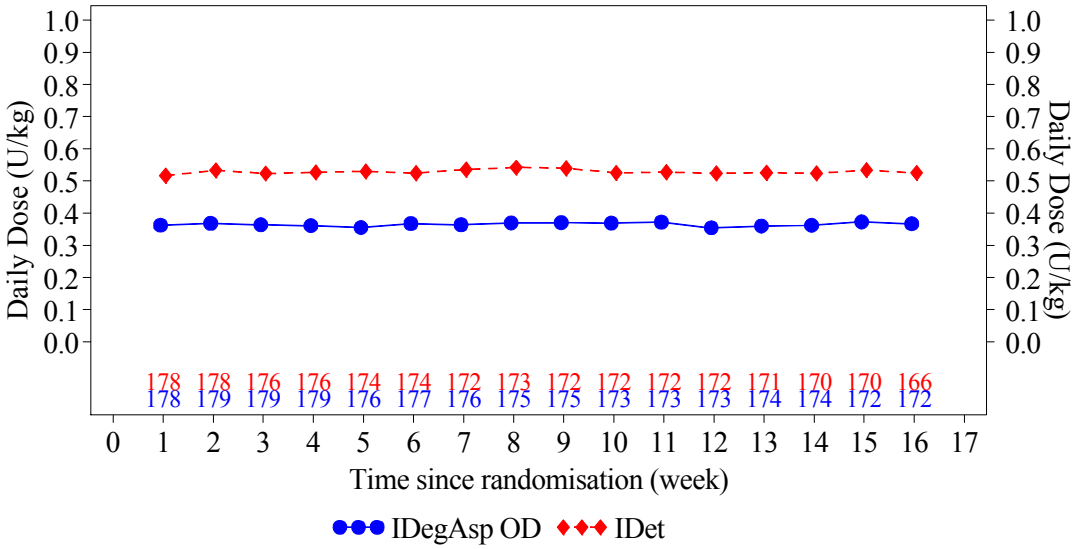
14.2.65 Daily basal insulin dose (actual) in units by treatment week - mean plot - adolescents (12-17 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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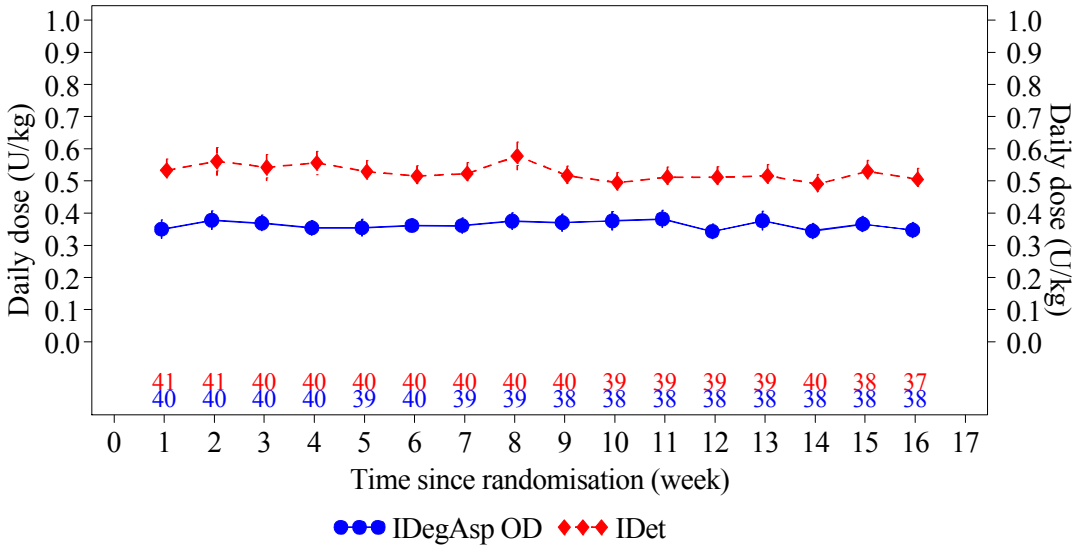
14.2.66 Daily IAsp dose (actual) in units/kg by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
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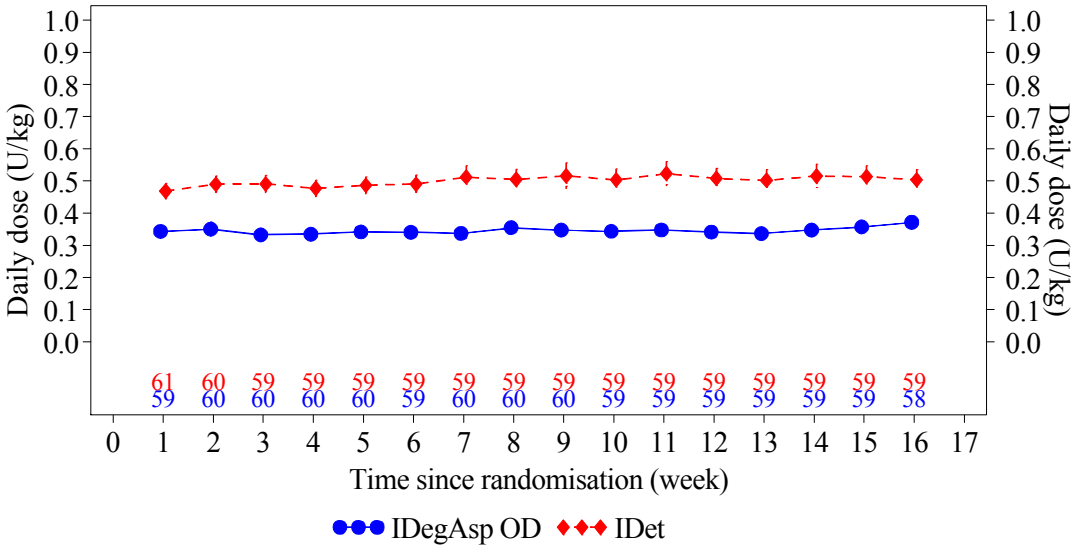
14.2.67 Daily IAsp dose (actual) in units/kg by treatment week - mean plot – children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

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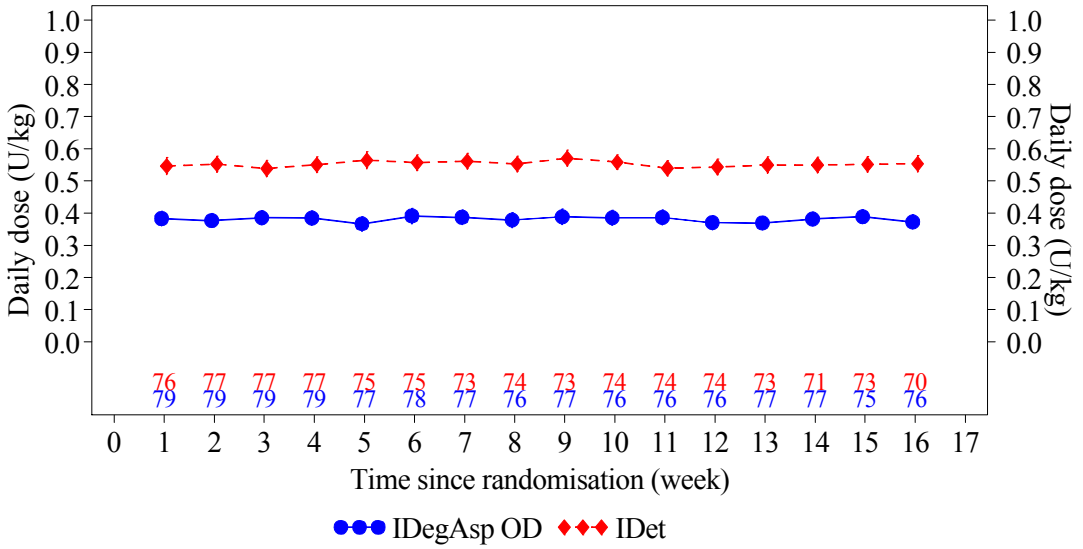
14.2.68 Daily IAsp dose (actual) in units/kg by treatment week - mean plot – children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

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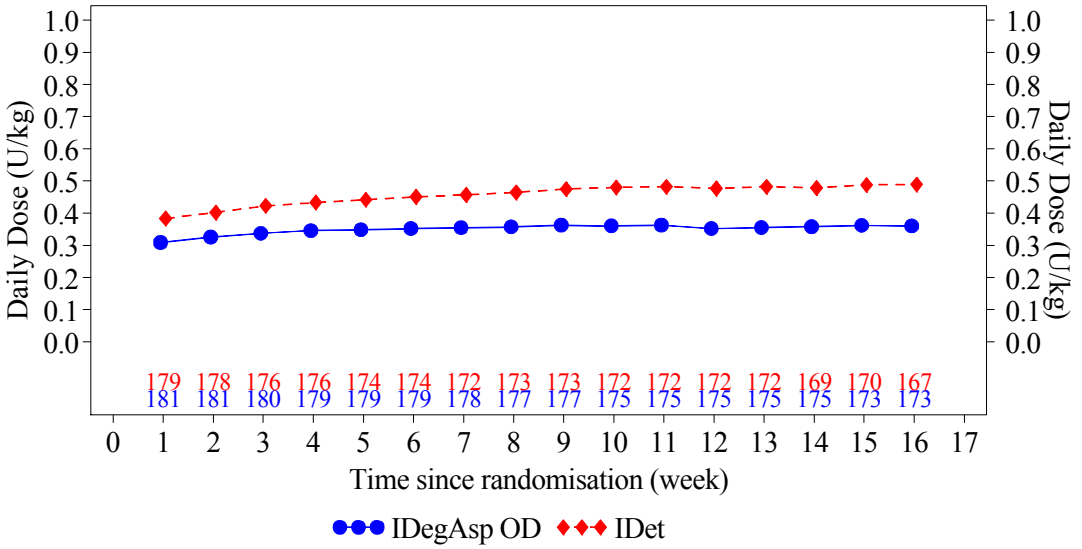
14.2.69 Daily IAsp dose (actual) in units/kg by treatment week - mean plot – adolescents (12-17 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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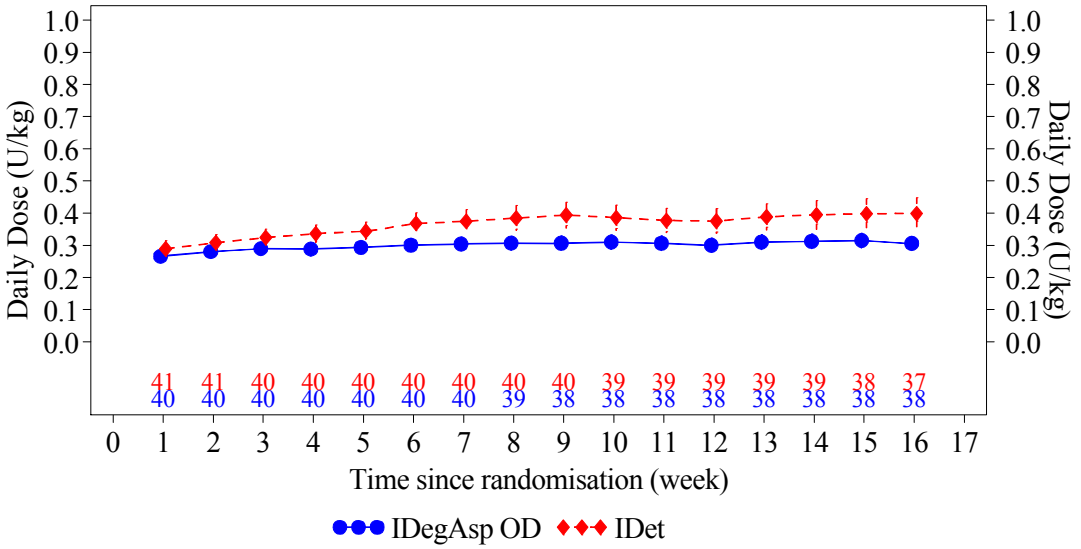
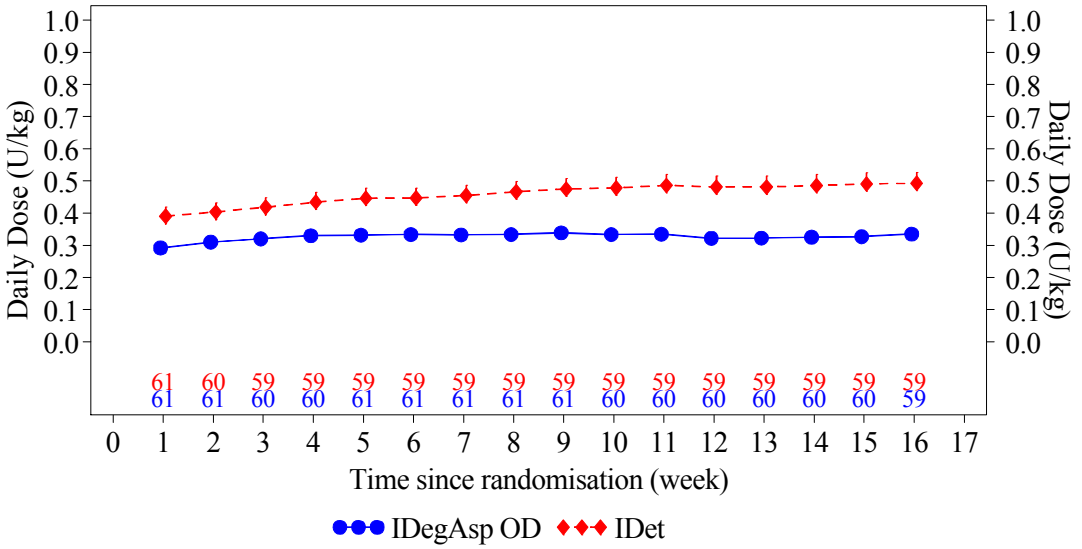
14.2.70 Daily basal insulin dose (actual) in units/kg by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:39:59 - fmean_numfind_deg_cust.sas/e_ba_dos_ac_ukg_mean_ob_age1_sas.cgm

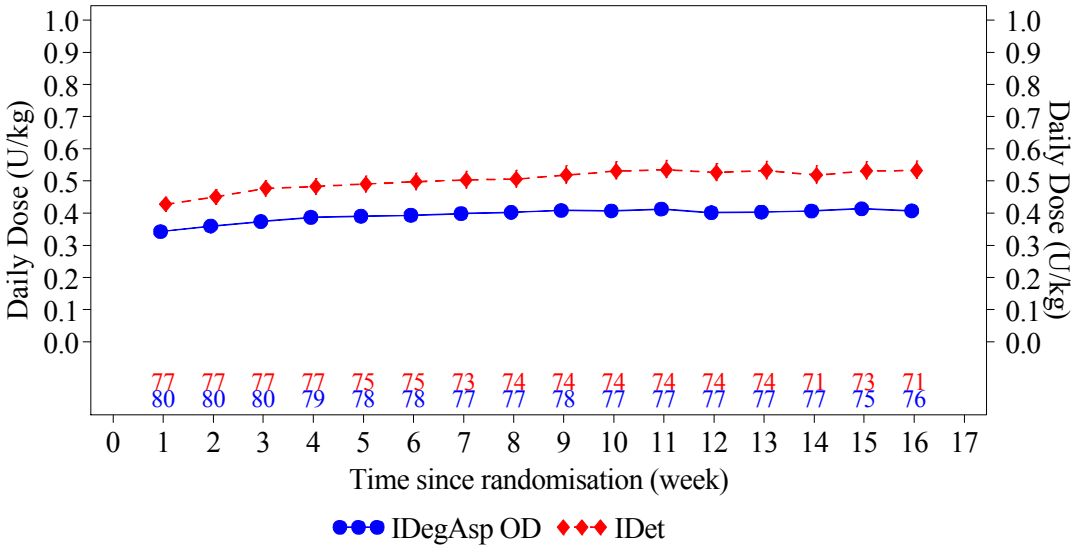
14.2.71 Daily basal insulin dose (actual) in units/kg by treatment week - mean plot - children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:00 - fmean_numfind_deg_cust.sas/e_ba_dos_ac_ukg_mean_ob_age2_sas.cgm

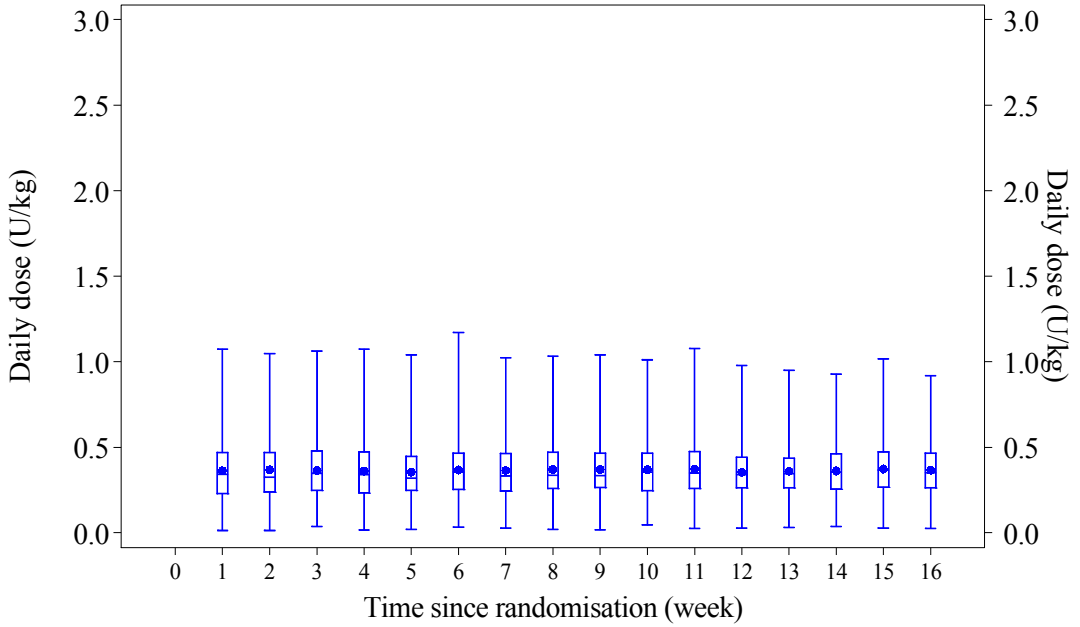
14.2.72 Daily basal insulin dose (actual) in units/kg by treatment week - mean plot - children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:01 - fmean_numfind_deg_cust.sas/e_ba_dos_ac_ukg_mean_ob_age3_sas.cgm

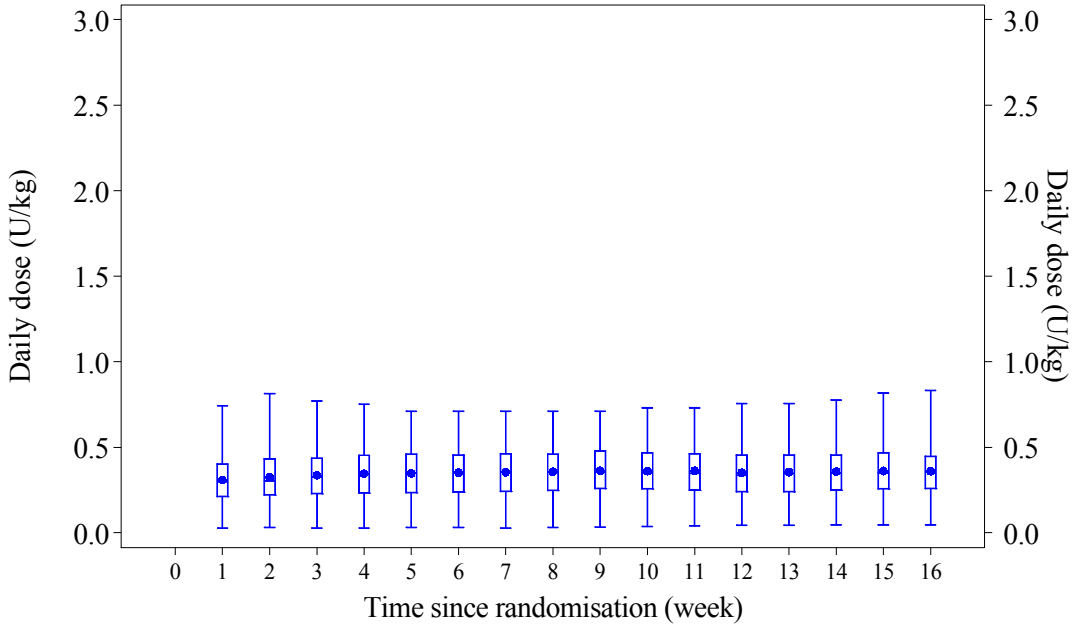
14.2.73 Daily basal insulin dose (actual) in units/kg by treatment week - mean plot - adolescents (12-17 years) - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:01 - fbox_numfind_v02.sas/e_b_d_inv1_act_ukg_box_obs_sas.cgm

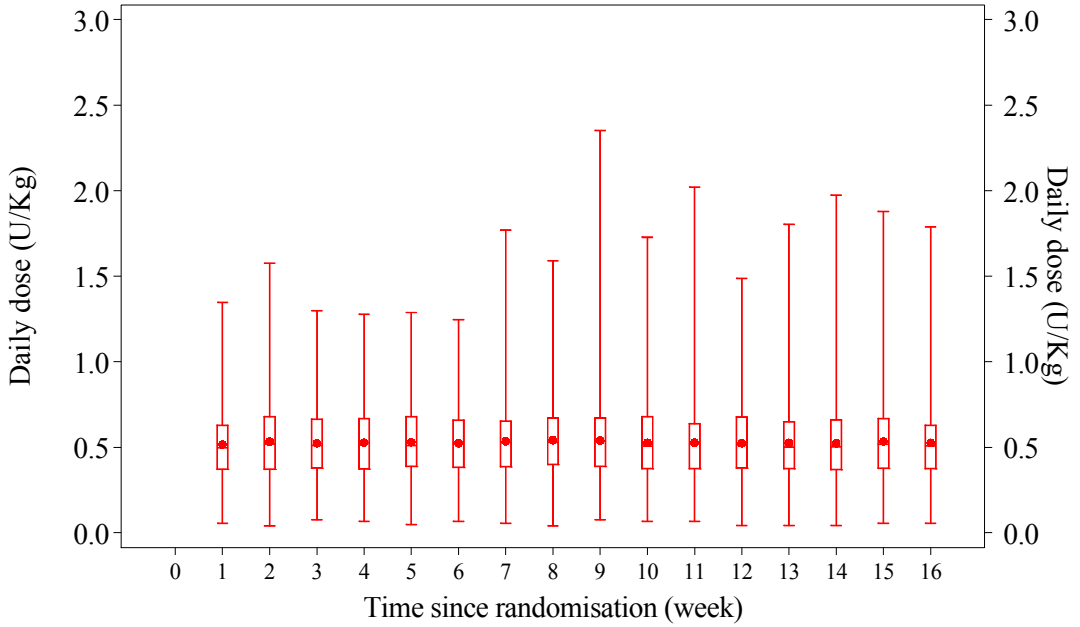
14.2.74 Daily IAsp dose (actual) in units/kg by treatment week – IDegAsp OD - box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:01 - fbox_numfind_v02.sas/e_basal_d_inv1_act_ukg_box_obs_sas.cgm

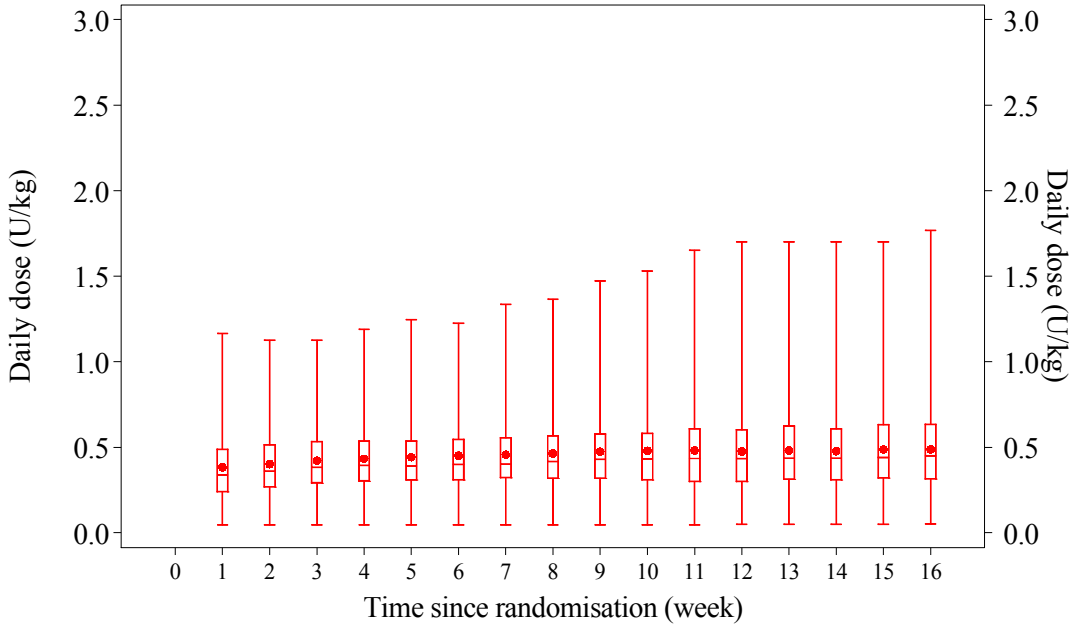
14.2.75 Daily basal insulin dose (actual) in units/kg by treatment week - IDegAsp OD - box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:01 - fbox_numfind_v02.sas/e_b_d_com_act_ukg_box_obs_sas.cgm

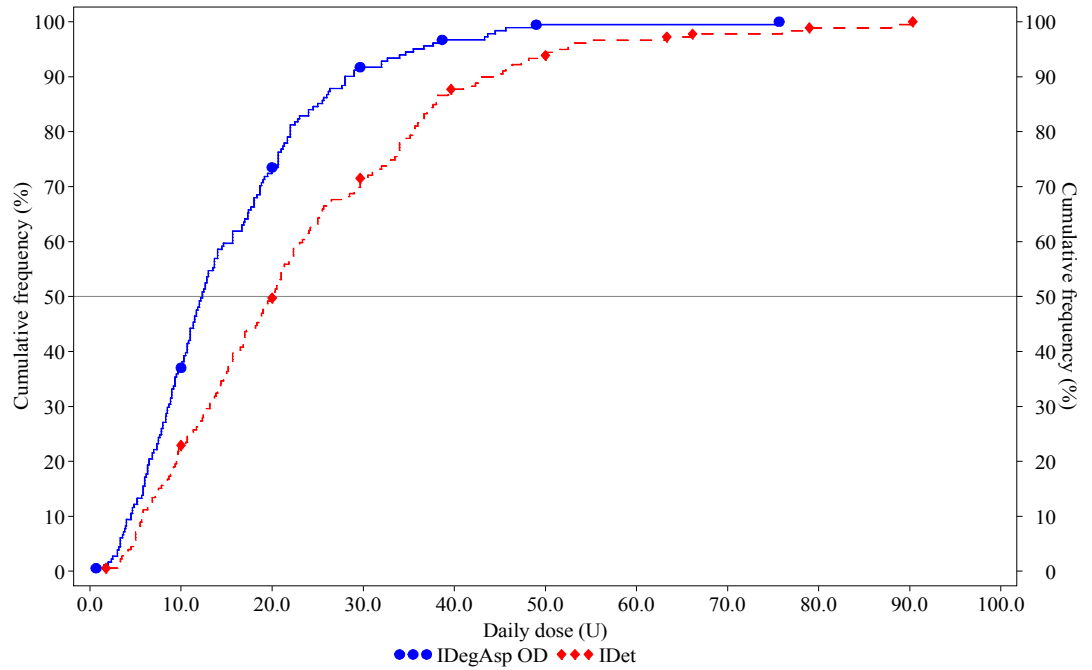
14.2.76 Daily IAsp dose (actual) in units/kg by treatment week - IDet - box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:05 - fbox_numfind_v02.sas/e_basal_d_com_act_ukg_box_obs_sas.cgm

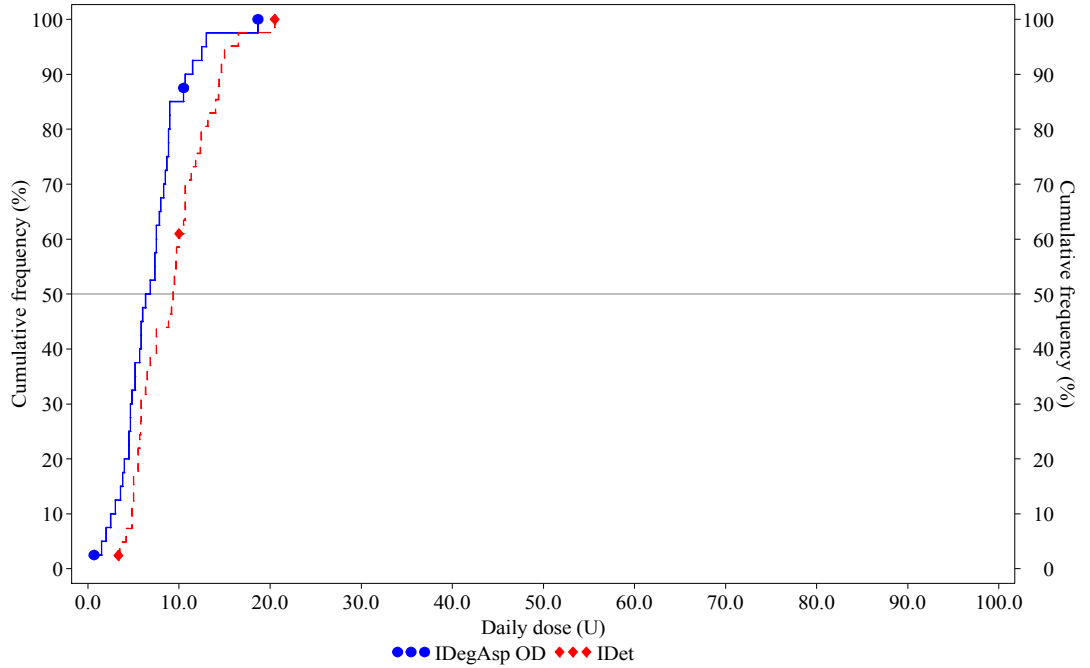
14.2.77 Daily basal insulin dose (actual) in units/kg by treatment week - IDet - box plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:08 - fedist_numfind_v01.sas/e_b_d_d_act_u_cdf_pred_sas.cgm

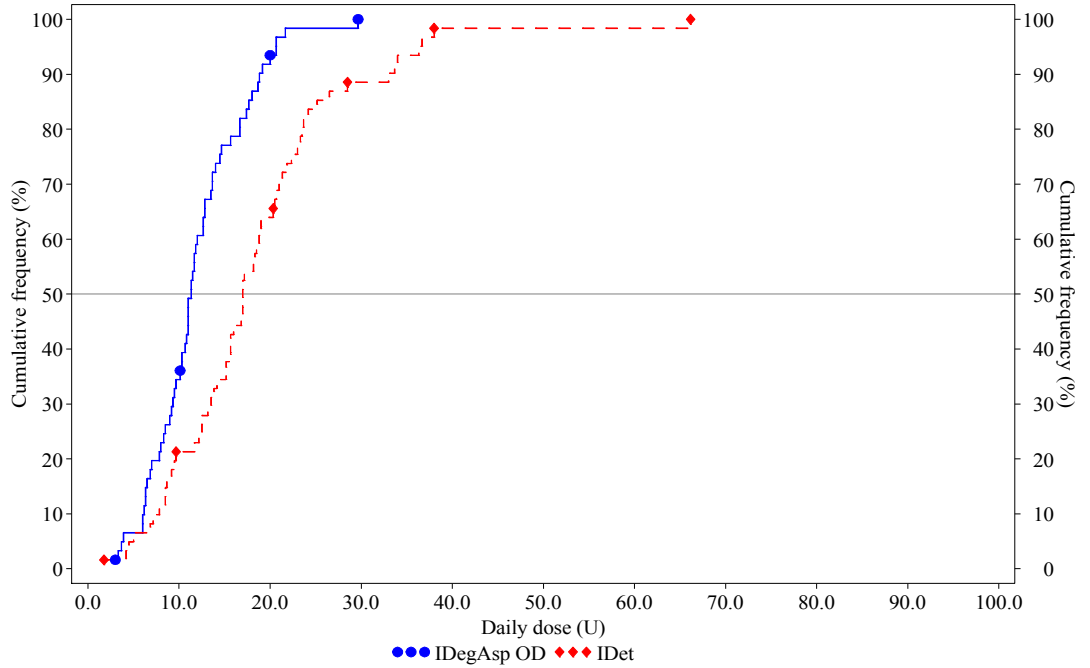
14.2.78 Daily IAsp dose (actual) in units after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:08 - fedist_numfind_v01.sas/e_b_d_d_act_u_cdf_pred_age1_sas.cgm

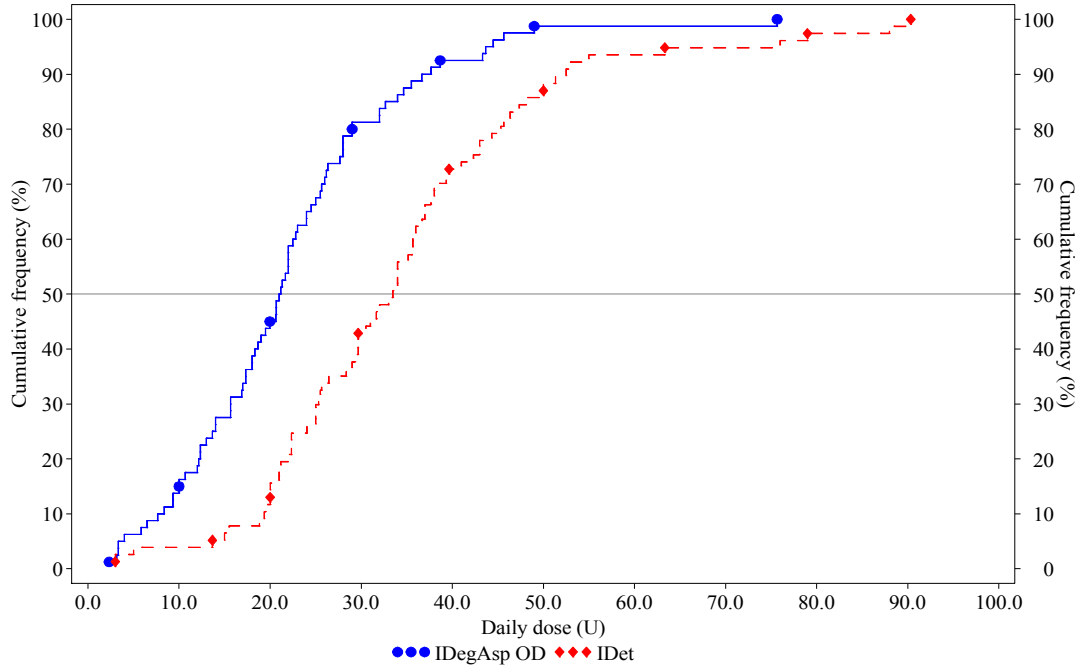
14.2.79 Daily IAsp dose (actual) in units after 16 weeks of treatment - empirical distribution plot - children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:07 - fedist_numfind_v01.sas/e_b_d_d_act_u_cdf_pred_age2_sas.cgm

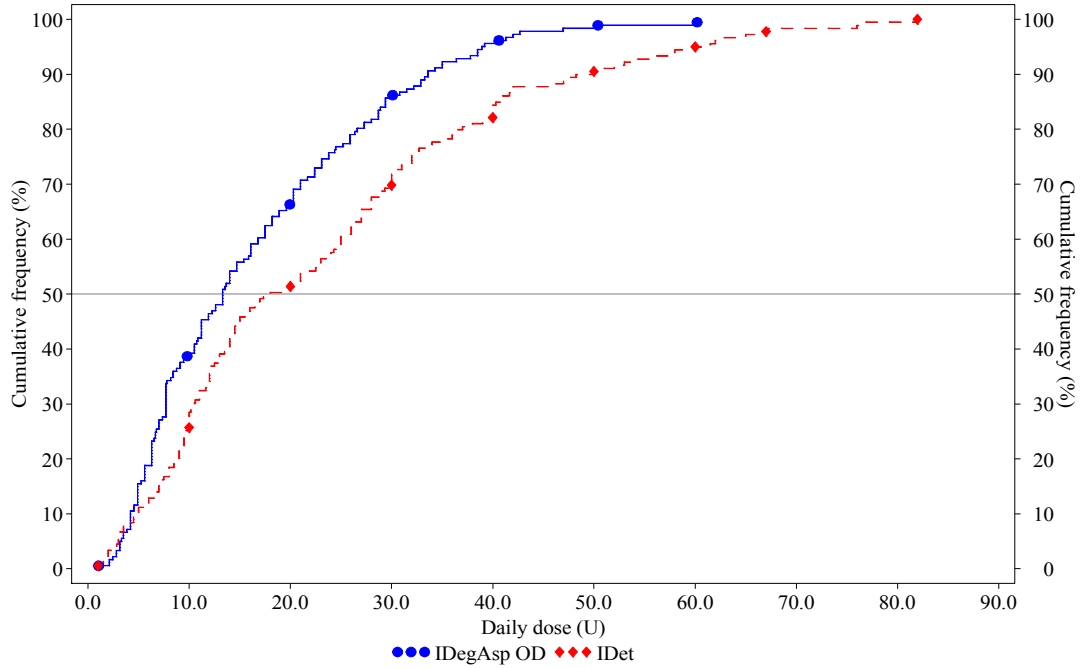
14.2.80 Daily IAsp dose (actual) in units after 16 weeks of treatment - empirical distribution plot - children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:09 - fedist_numfind_v01.sas/e_b_d_d_act_u_cdf_pred_age3_sas.cgm

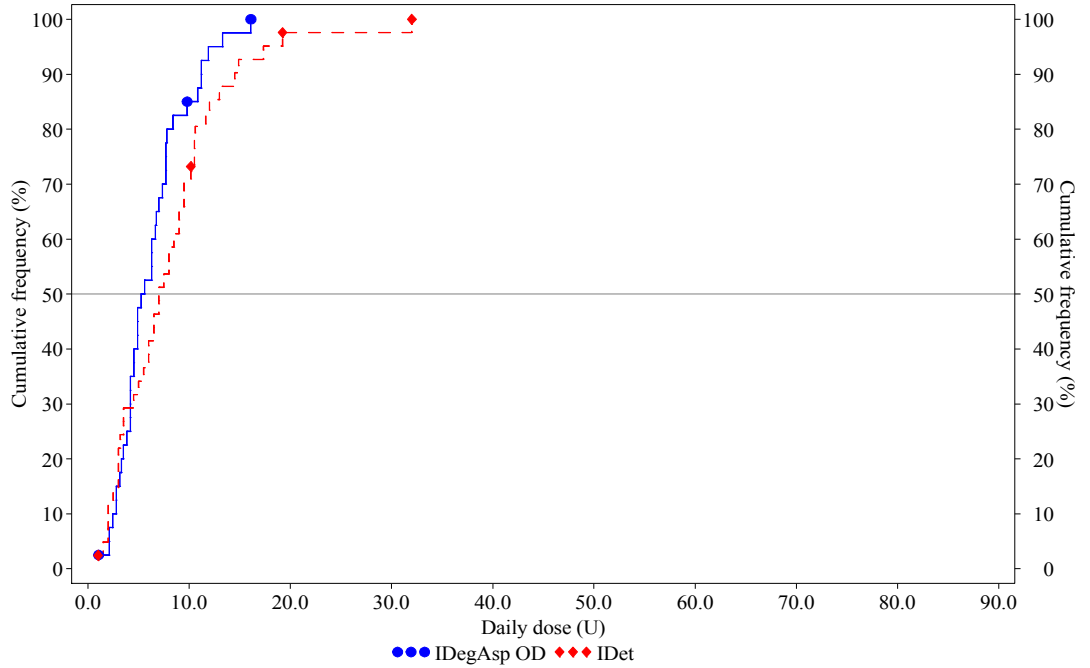
14.2.81 Daily IAsp dose (actual) in units after 16 weeks of treatment - empirical distribution plot - adolescents (12-17 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:09 - fedist_numfind_v01.sas/e_bs_d_d_act_u_cdf_pred_sas.cgm

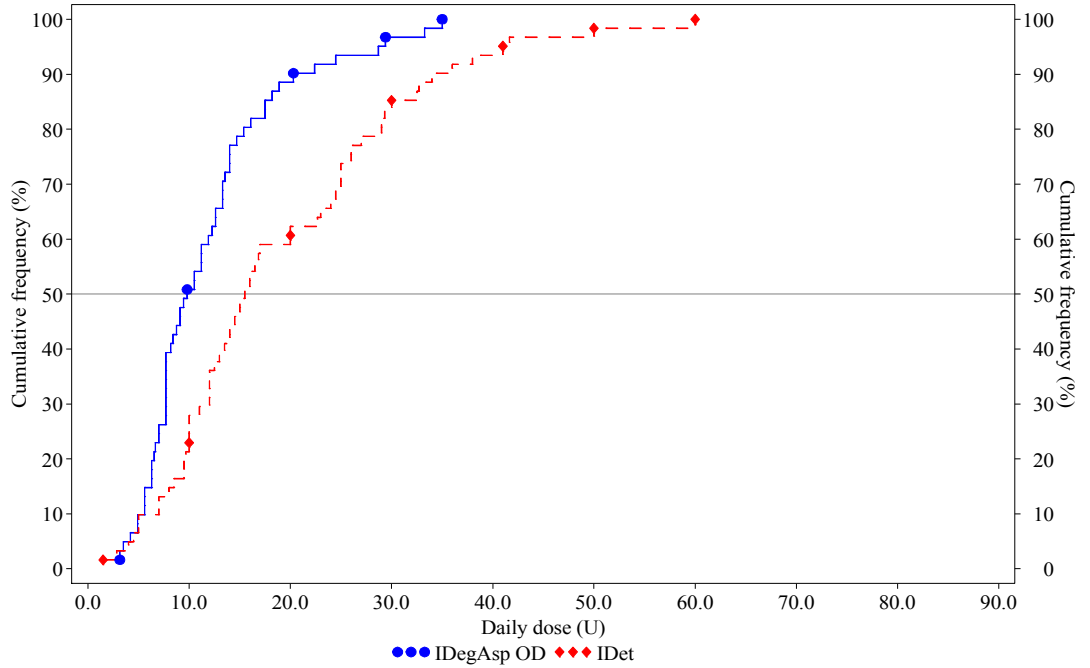
14.2.82 Daily basal insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:09 - fedist_numfind_v01.sas/e_bs_d_d_act_u_cdf_pred_age1_sas.cgm

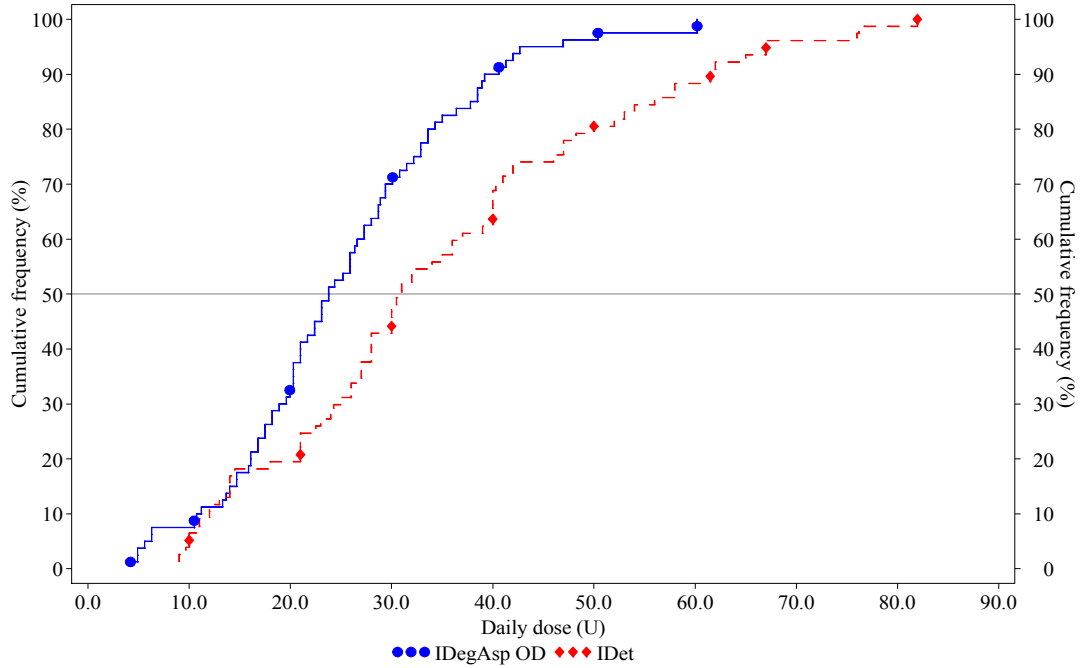
14.2.83 Daily basal insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:09 - fedist_numfind_v01.sas/e_bs_d_d_act_u_cdf_pred_age2_sas.cgm

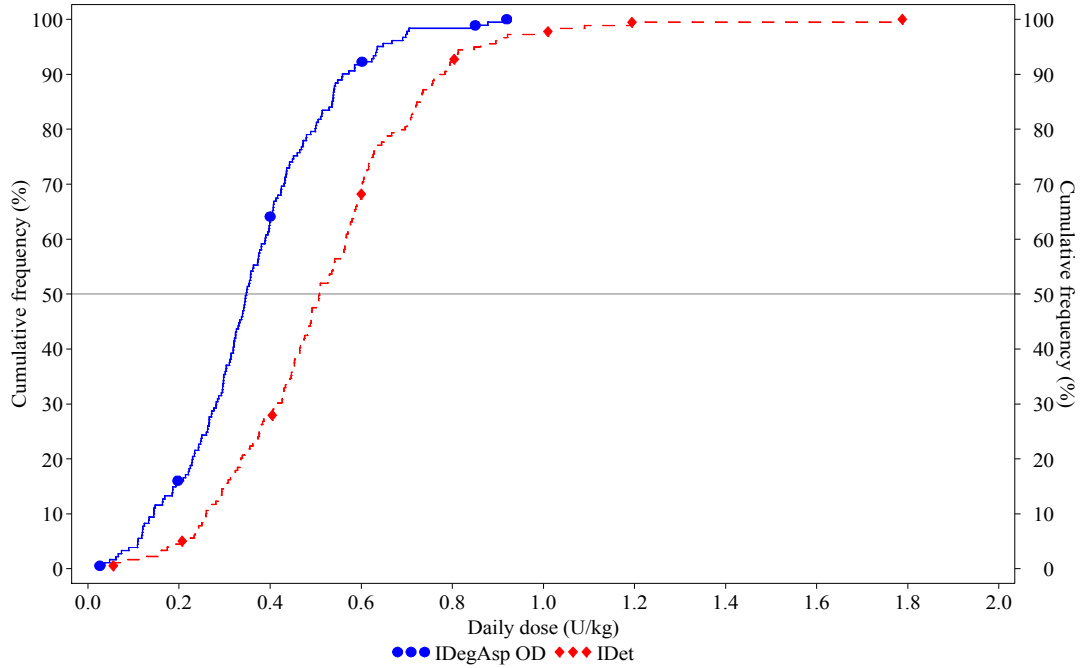
14.2.84 Daily basal insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:11 - fedist_numfind_v01.sas/e_bs_d_d_act_u_cdf_pred_age3_sas.cgm

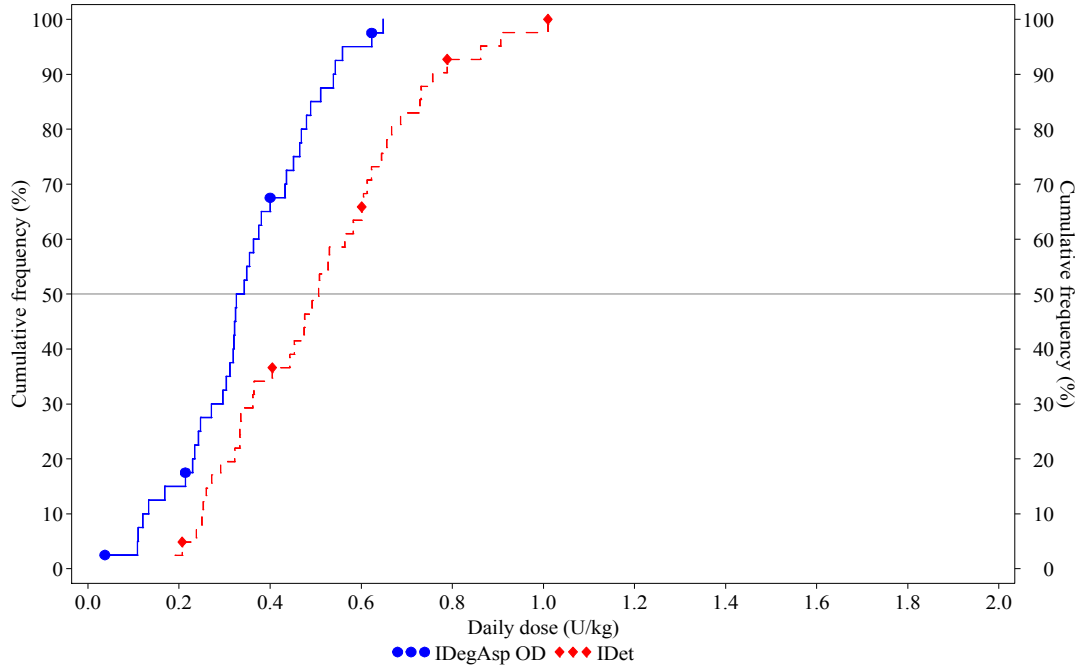
14.2.85 Daily basal insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - adolescents (12-17 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:15 - fedist_numfind_v01.sas/e_b_d_d_act_ukg_cdf_pred_sas.cgm

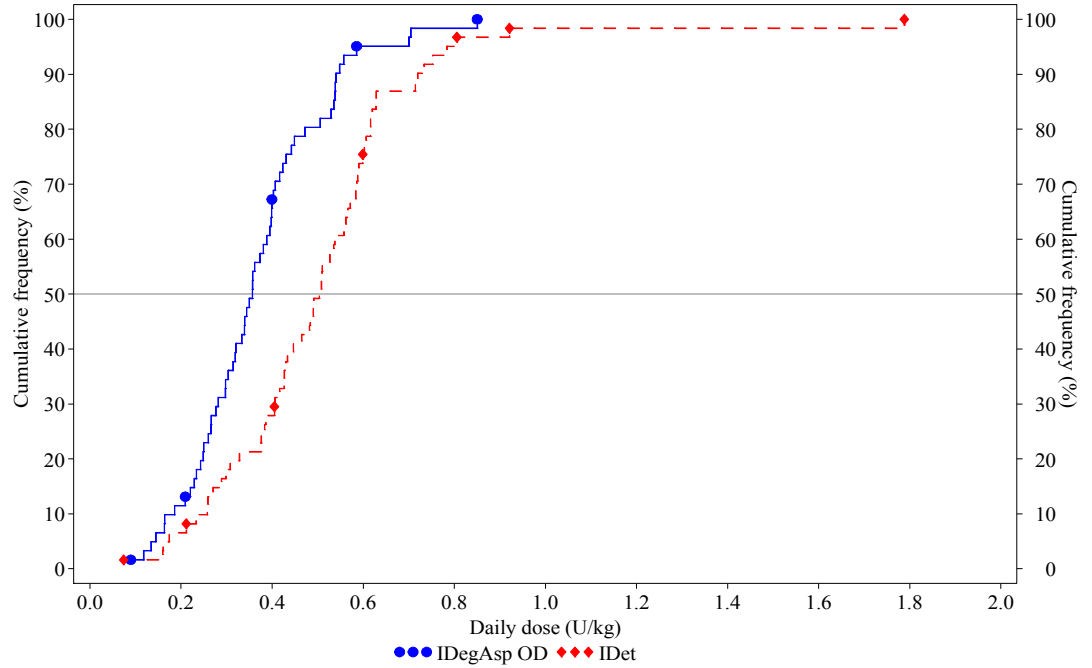
14.2.86 Daily IAsp dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:16 - fedist_numfind_v01.sas/e_b_d_d_act_ukg_cdf_pred_age1_sas.cgm

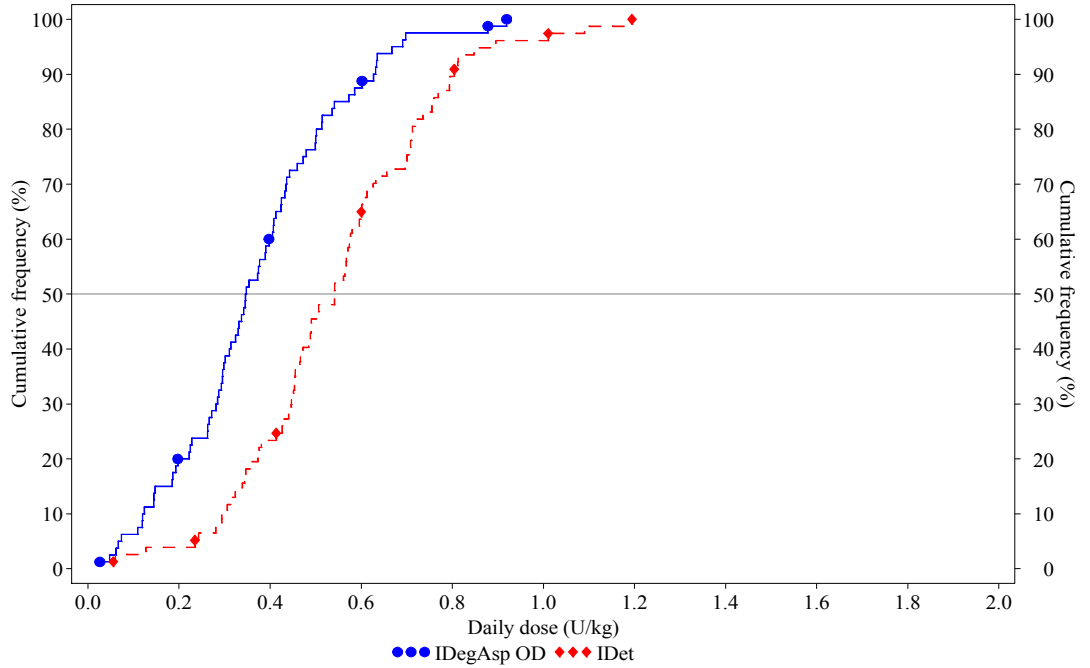
14.2.87 Daily IAsp dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:16 - fedist_numfind_v01.sas/e_b_d_d_act_ukg_cdf_pred_age2_sas.cgm

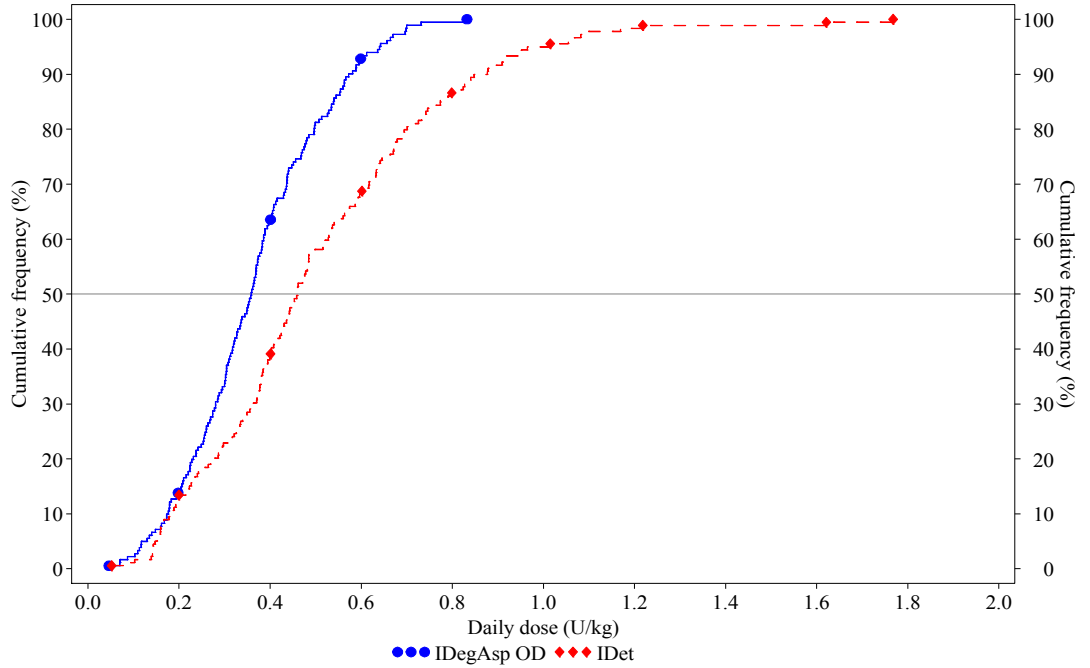
14.2.88 Daily IAsp dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:16 - fedist_numfind_v01.sas/e_b_d_d_act_ukg_cdf_pred_age3_sas.cgm

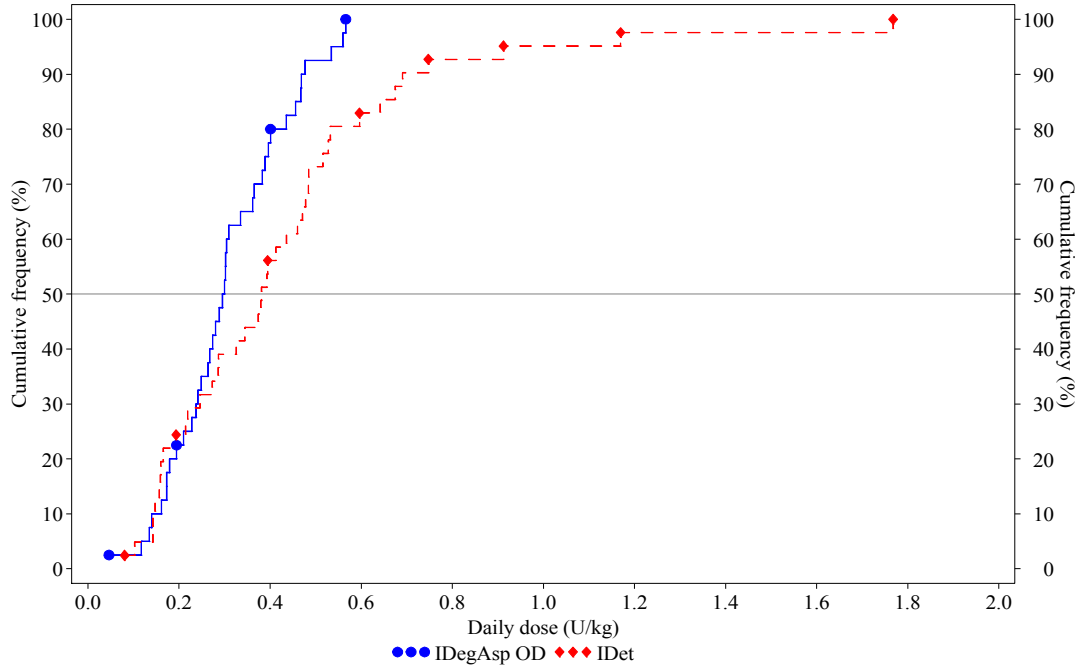
14.2.89 Daily IAsp dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - adolescents (12-17 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:16 - fedist_numfind_v01.sas/e_bs_d_d_act_ukg_cdf_prd_sas.cgm

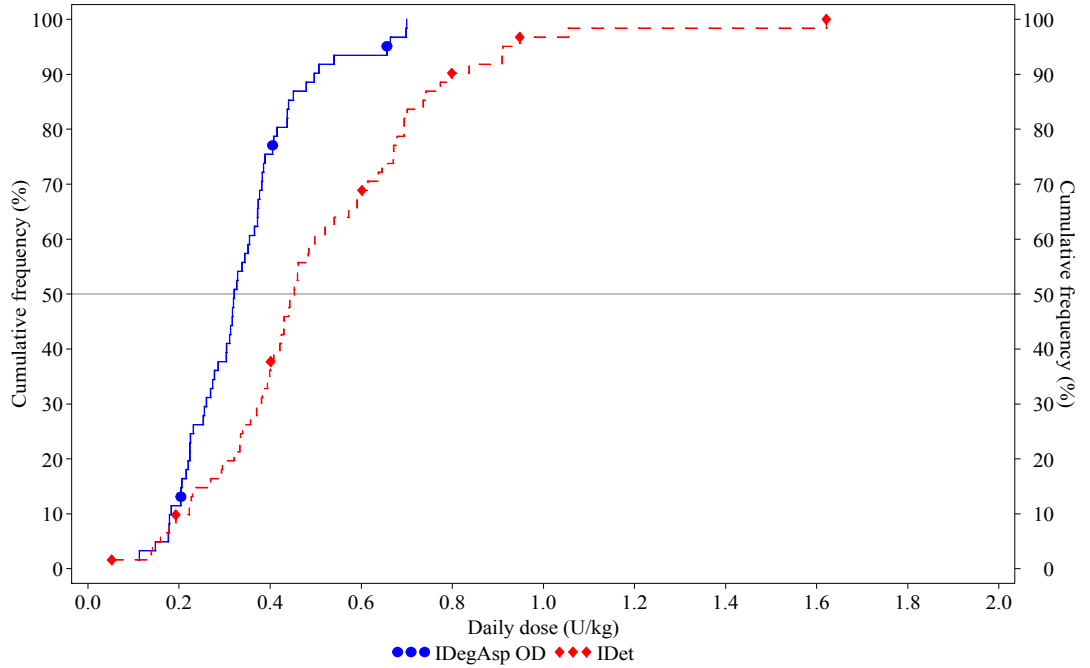
14.2.90 Daily basal insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:17 - fedist_numfind_v01.sas/e_bs_d_d_act_ukg_cdf_prd_age1_sas.cgm

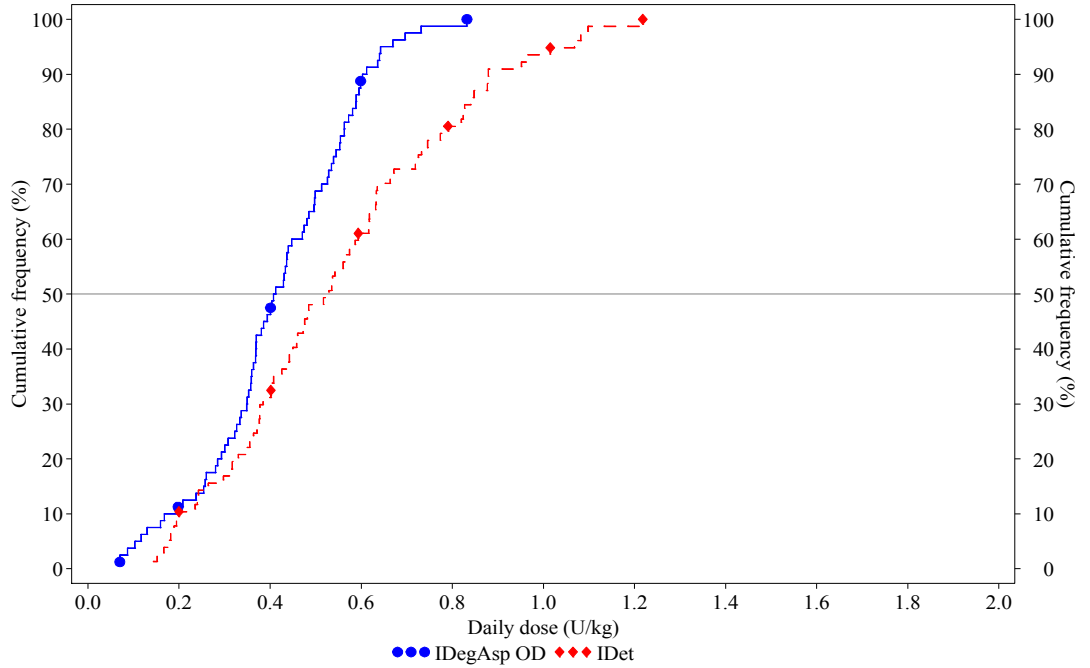
14.2.91 Daily basal insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:17 - fedist_numfind_v01.sas/e_bs_d_d_act_ukg_cdf_prd_age2_sas.cgm

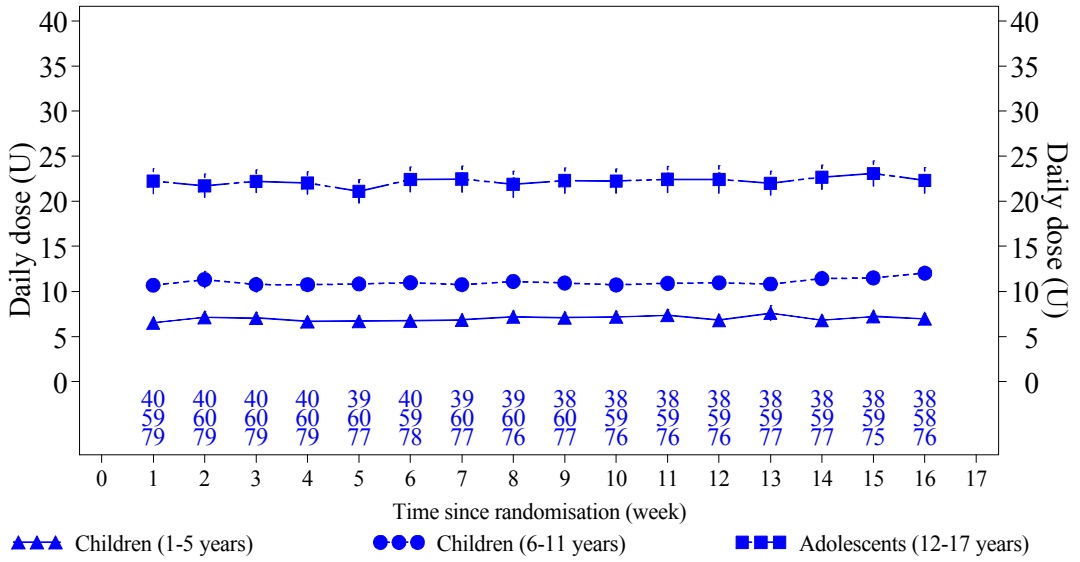
14.2.92 Daily basal insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:40:18 - fedist_numfind_v01.sas/e_bs_d_d_act_ukg_cdf_prd_age3_sas.cgm

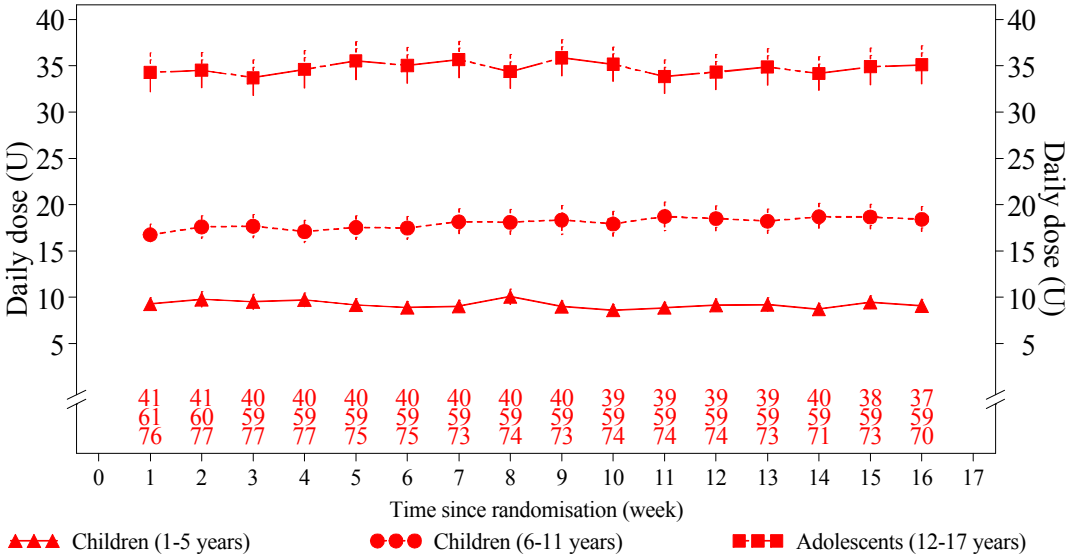
14.2.93 Daily basal insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - adolescents (12-17 years) - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:27:58 - dose_fplot_treatment_age.sas/e_bol_dos_d_u_ideg_sas.cgm

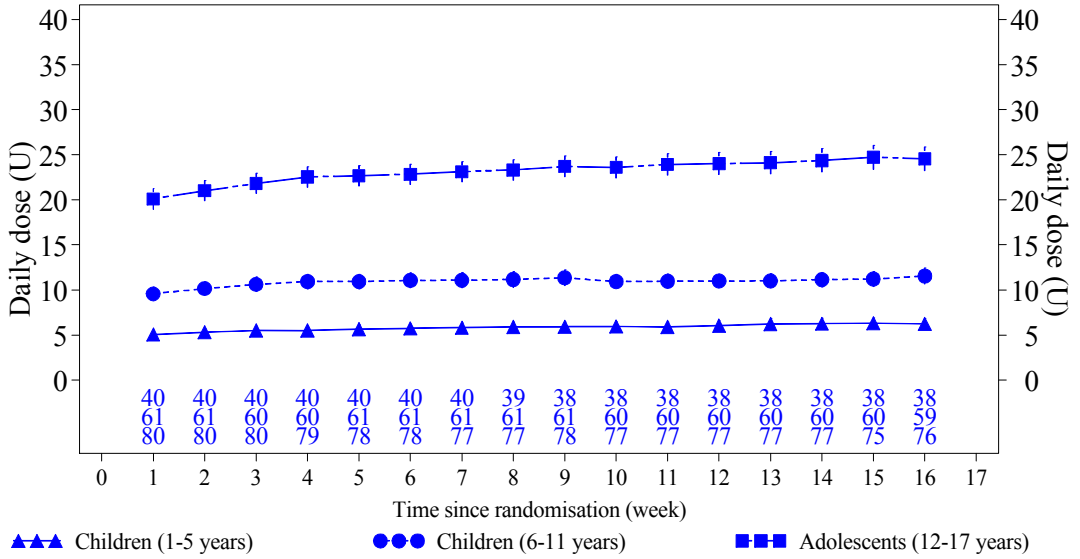
14.2.94 Daily IAsp dose (actual) in units by treatment week - mean plot – IDegAsp OD - by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:03 - dose_fplot_treatment_age.sas/e_bol_dos_d_u_idet_sas.cgm

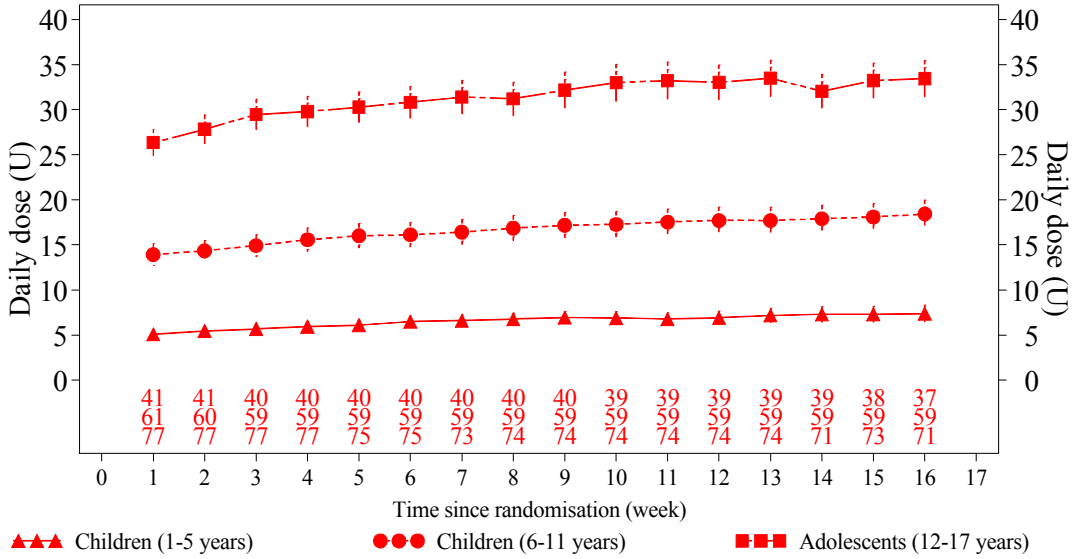
14.2.95 Daily IAsp dose (actual) in units by treatment week - mean plot – IDet - by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:36 - dose_fplot_treatment_age.sas/e_basal_dos_d_u_ideg_sas.cgm

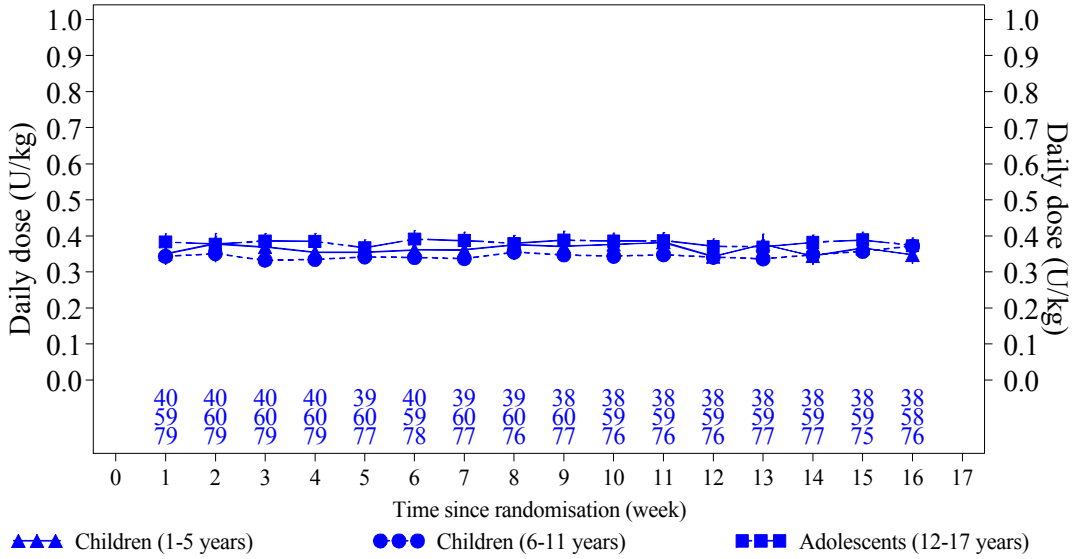
14.2.96 Daily basal insulin dose (actual) in units by treatment week - mean plot – IDegAsp OD – by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:41 - dose_fplot_treatment_age.sas/e_basal_dos_d_u_idet_sas.cgm

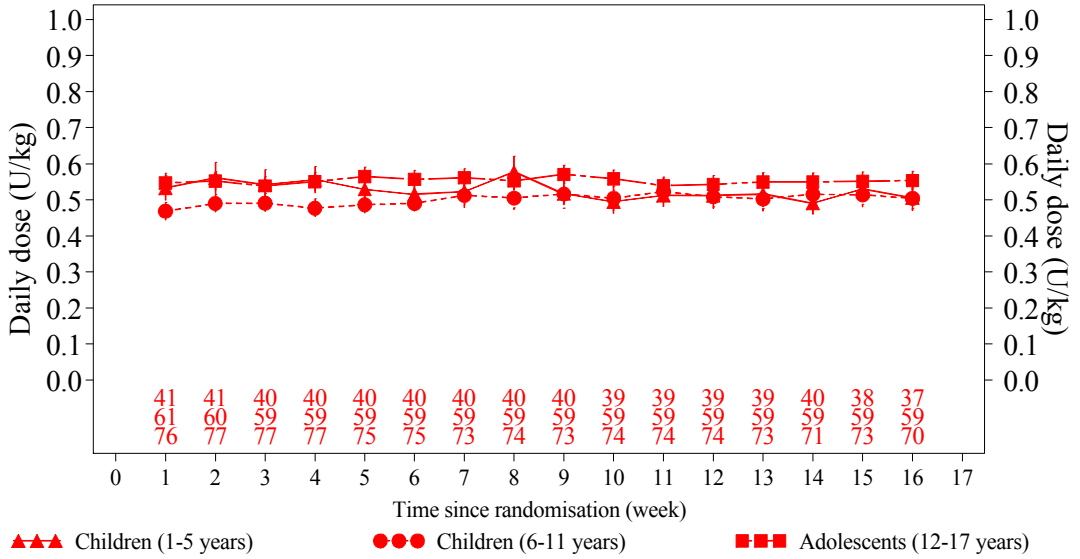
14.2.97 Daily basal insulin dose (actual) in units by treatment week - mean plot – IDet – by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:08 - dose_fplot_treatment_age.sas/e_bol_dos_d_ukg_ideg_sas.cgm

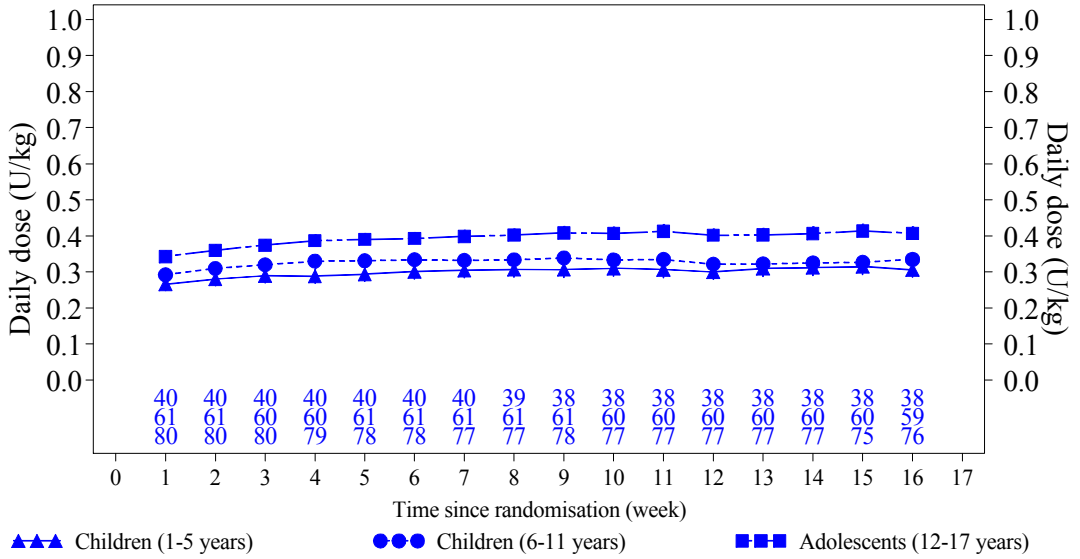
14.2.98 Daily IAsp dose (actual) in units/kg by treatment week - mean plot – IDegAsp OD - by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:13 - dose_fplot_treatment_age.sas/e_bol_dos_d_ukg_idet_sas.cgm

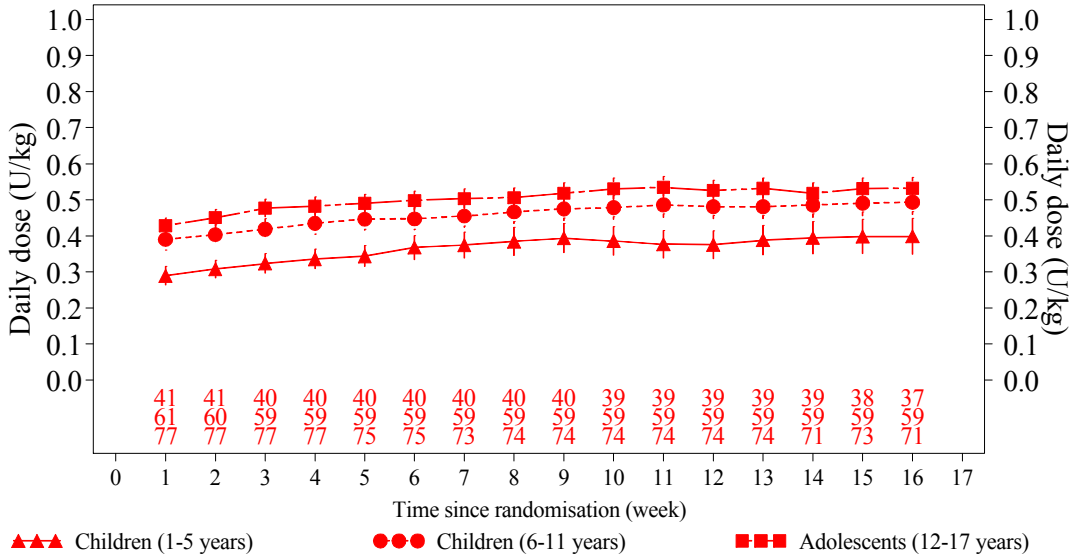
14.2.99 Daily IAsp dose (actual) in units/kg by treatment week - mean plot – IDet - by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:45 - dose_fplot_treatment_age.sas/e_basal_dos_d_ukg_ideg_sas.cgm

14.2.100 Daily basal insulin dose (actual) in units/kg by treatment week - mean plot – IDegAsp OD - by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:50 - dose_fplot_treatment_age.sas/e_basal_dos_d_ukg_idet_sas.cgm

14.2.101 Daily basal insulin dose (actual) in units/kg by treatment week - mean plot – IDet - by age group - safety analysis set

14.2.102 Total insulin dose (actual) in units by treatment week - descriptive statistics - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	33	23	28	4	140
		IDet	179	179	40	27	34	4	166
		Total	360	360	36	25	30	4	166
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	34	22	28	4	137
		IDet	179	178	41	27	36	4	139
		Total	360	359	38	25	33	4	139
Visit 5 (Week 3)	Daily	IDegAsp OD	181	180	35	23	29	4	135
		IDet	179	176	42	28	37	4	148
		Total	360	356	39	26	33	4	148
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	36	23	31	4	132
		IDet	179	176	43	29	37	4	162
		Total	360	355	39	26	33	4	162
Visit 7 (Week 5)	Daily	IDegAsp OD	181	179	35	23	30	4	138
		IDet	179	174	43	30	37	5	161
		Total	360	353	39	27	33	4	161
Visit 8 (Week 6)	Daily	IDegAsp OD	181	179	36	24	31	4	135
		IDet	179	174	43	29	38	5	156
		Total	360	353	40	27	34	4	156
Visit 9 (Week 7)	Daily	IDegAsp OD	181	178	36	24	31	4	148
		IDet	179	172	44	30	38	6	156
		Total	360	350	40	28	34	4	156
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	37	24	31	4	150
		IDet	179	173	44	29	39	5	141
		Total	360	350	40	27	34	4	150
Visit 11 (Week 9)	Daily	IDegAsp OD	181	177	37	24	30	4	144
		IDet	179	173	45	31	37	5	159
		Total	360	350	41	28	34	4	159
Visit 12 (Week 10)	Daily	IDegAsp OD	181	175	37	24	31	4	144
		IDet	179	172	45	30	38	5	145
		Total	360	347	41	28	35	4	145
Visit 13 (Week 11)	Daily	IDegAsp OD	181	175	37	25	32	4	160
		IDet	179	172	45	30	38	5	141
		Total	360	347	41	28	34	4	160
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	37	25	32	4	160
		IDet	179	172	45	30	40	5	165
		Total	360	347	41	28	35	4	165

N: Number of subjects, SD: Standard deviation

Total insulin dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	175	37	25	31	5	155
		IDet	179	172	45	31	39	5	152
		Total	360	347	41	28	34	5	155
Visit 16 (Week 14)	Daily	IDegAsp OD	181	175	38	25	32	5	155
		IDet	179	170	44	29	39	5	142
		Total	360	345	41	27	34	5	155
Visit 17 (Week 15)	Daily	IDegAsp OD	181	173	38	25	33	4	153
		IDet	179	170	46	31	39	6	155
		Total	360	343	42	28	35	4	155
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	38	25	32	5	162
		IDet	179	167	46	31	38	7	146
		Total	360	340	42	28	35	5	162
End of trial visit	Daily	IDegAsp OD	181	181	38	25	32	5	162
		IDet	179	179	46	31	39	7	146
		Total	360	360	42	29	36	5	162

N: Number of subjects, SD: Standard deviation

14.2.103 Total insulin dose (actual) in units by treatment week - descriptive statistics – children (1-5 years) - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	14	6	12	4	30
		IDet	41	41	14	5	14	7	28
		Total	81	81	14	5	14	4	30
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	15	6	14	5	27
		IDet	41	41	15	6	15	6	34
		Total	81	81	15	6	14	5	34
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	15	6	14	4	35
		IDet	41	40	15	7	16	5	32
		Total	81	80	15	6	15	4	35
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	15	6	14	4	32
		IDet	41	40	16	6	16	5	34
		Total	81	80	15	6	14	4	34
Visit 7 (Week 5)	Daily	IDegAsp OD	40	40	15	6	13	4	34
		IDet	41	40	15	6	14	6	28
		Total	81	80	15	6	14	4	34
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	15	5	14	4	27
		IDet	41	40	15	6	15	6	31
		Total	81	80	15	6	14	4	31
Visit 9 (Week 7)	Daily	IDegAsp OD	40	40	15	6	13	4	41
		IDet	41	40	16	7	15	7	38
		Total	81	80	15	6	14	4	41
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	16	7	14	4	42
		IDet	41	40	17	7	16	7	31
		Total	81	79	16	7	15	4	42
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	16	7	14	4	40
		IDet	41	40	16	6	16	6	29
		Total	81	78	16	6	15	4	40
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	16	6	14	4	34
		IDet	41	39	15	6	15	7	33
		Total	81	77	16	6	14	4	34
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	16	7	14	4	42
		IDet	41	39	16	6	15	7	33
		Total	81	77	16	7	14	4	42
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	15	7	13	4	46
		IDet	41	39	16	6	17	6	31
		Total	81	77	16	7	14	4	46

N: Number of subjects, SD: Standard deviation

Total insulin dose (actual) in units by treatment week - descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	16	9	14	5	56
		IDet	41	39	16	8	14	6	37
		Total	81	77	16	8	14	5	56
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	16	7	14	5	43
		IDet	41	40	16	7	15	5	41
		Total	81	78	16	7	15	5	43
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	16	7	14	4	46
		IDet	41	38	17	8	16	6	44
		Total	81	76	16	7	14	4	46
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	16	7	14	5	42
		IDet	41	37	16	7	15	7	41
		Total	81	75	16	7	14	5	42
End of trial visit	Daily	IDegAsp OD	40	40	16	7	14	5	42
		IDet	41	41	16	7	15	7	41
		Total	81	81	16	7	14	5	42

N: Number of subjects, SD: Standard deviation

14.2.104 Total insulin dose (actual) in units by treatment week - descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	61	61	24	12	21	9	66
		IDet	61	61	30	16	27	4	84
		Total	122	122	27	14	25	4	84
Visit 4 (Week 2)	Daily	IDegAsp OD	61	61	26	14	23	7	72
		IDet	61	60	32	17	28	4	83
		Total	122	121	29	15	26	4	83
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	26	13	23	6	64
		IDet	61	59	33	17	30	4	85
		Total	122	119	29	16	27	4	85
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	26	13	24	8	71
		IDet	61	59	33	17	30	4	83
		Total	122	119	29	16	27	4	83
Visit 7 (Week 5)	Daily	IDegAsp OD	61	61	26	12	23	8	63
		IDet	61	59	33	18	30	5	95
		Total	122	120	30	16	27	5	95
Visit 8 (Week 6)	Daily	IDegAsp OD	61	61	26	13	23	9	70
		IDet	61	59	34	18	31	5	93
		Total	122	120	30	16	28	5	93
Visit 9 (Week 7)	Daily	IDegAsp OD	61	61	26	13	22	10	64
		IDet	61	59	35	19	32	6	109
		Total	122	120	30	17	28	6	109
Visit 10 (Week 8)	Daily	IDegAsp OD	61	61	27	13	25	9	72
		IDet	61	59	35	20	31	5	104
		Total	122	120	31	17	28	5	104
Visit 11 (Week 9)	Daily	IDegAsp OD	61	61	26	13	24	8	63
		IDet	61	59	35	21	32	5	135
		Total	122	120	31	18	28	5	135
Visit 12 (Week 10)	Daily	IDegAsp OD	61	60	26	12	23	9	65
		IDet	61	59	35	19	33	5	115
		Total	122	119	31	17	28	5	115
Visit 13 (Week 11)	Daily	IDegAsp OD	61	60	26	12	23	10	64
		IDet	61	59	36	21	33	5	130
		Total	122	119	31	18	28	5	130
Visit 14 (Week 12)	Daily	IDegAsp OD	61	60	26	12	23	9	69
		IDet	61	59	36	20	33	5	113
		Total	122	119	31	17	27	5	113

N: Number of subjects, SD: Standard deviation

Total insulin dose (actual) in units by treatment week - descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	61	60	26	12	24	9	68
		IDet	61	59	36	20	34	5	124
		Total	122	119	31	17	28	5	124
Visit 16 (Week 14)	Daily	IDegAsp OD	61	60	27	13	23	8	68
		IDet	61	59	37	21	33	5	130
		Total	122	119	32	18	28	5	130
Visit 17 (Week 15)	Daily	IDegAsp OD	61	60	27	13	24	9	69
		IDet	61	59	37	21	33	6	126
		Total	122	119	32	18	28	6	126
Visit 18 (Week 16)	Daily	IDegAsp OD	61	59	28	13	25	9	72
		IDet	61	59	37	21	33	7	126
		Total	122	118	33	18	29	7	126
End of trial visit	Daily	IDegAsp OD	61	61	29	14	25	9	72
		IDet	61	61	37	21	33	7	126
		Total	122	122	33	18	29	7	126

N: Number of subjects, SD: Standard deviation

14.2.105 Total insulin dose (actual) in units by treatment week - descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	80	50	23	47	4	140
		IDet	77	77	60	25	57	11	166
		Total	157	157	55	24	52	4	166
Visit 4 (Week 2)	Daily	IDegAsp OD	80	80	51	20	49	4	137
		IDet	77	77	62	24	60	10	139
		Total	157	157	57	23	53	4	139
Visit 5 (Week 3)	Daily	IDegAsp OD	80	80	52	22	52	4	135
		IDet	77	77	63	25	59	10	148
		Total	157	157	58	24	55	4	148
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	54	21	52	4	132
		IDet	77	77	64	27	61	9	162
		Total	157	156	59	25	57	4	162
Visit 7 (Week 5)	Daily	IDegAsp OD	80	78	53	22	51	5	138
		IDet	77	75	66	28	61	10	161
		Total	157	153	59	26	53	5	161
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	55	23	52	4	135
		IDet	77	75	66	27	63	10	156
		Total	157	153	60	25	55	4	156
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	55	23	53	5	148
		IDet	77	73	67	28	64	11	156
		Total	157	150	61	26	56	5	156
Visit 10 (Week 8)	Daily	IDegAsp OD	80	77	55	23	52	5	150
		IDet	77	74	66	26	61	11	141
		Total	157	151	60	25	57	5	150
Visit 11 (Week 9)	Daily	IDegAsp OD	80	78	56	23	52	5	144
		IDet	77	74	68	29	62	12	159
		Total	157	152	61	27	56	5	159
Visit 12 (Week 10)	Daily	IDegAsp OD	80	77	56	23	54	8	144
		IDet	77	74	68	28	62	12	145
		Total	157	151	62	26	57	8	145
Visit 13 (Week 11)	Daily	IDegAsp OD	80	77	56	24	54	7	160
		IDet	77	74	67	27	62	12	141
		Total	157	151	62	26	57	7	160
Visit 14 (Week 12)	Daily	IDegAsp OD	80	77	56	25	53	6	160
		IDet	77	74	67	27	63	12	165
		Total	157	151	61	27	56	6	165

N: Number of subjects, SD: Standard deviation

Total insulin dose (actual) in units by treatment week - descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	56	24	54	7	155
		IDet	77	74	68	29	64	12	152
		Total	157	151	62	27	58	7	155
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	57	24	55	9	155
		IDet	77	71	66	26	64	12	142
		Total	157	148	62	25	58	9	155
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	58	24	55	9	153
		IDet	77	73	68	29	66	12	155
		Total	157	148	63	27	59	9	155
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	57	25	54	10	162
		IDet	77	71	68	29	65	12	146
		Total	157	147	62	28	58	10	162
End of trial visit	Daily	IDegAsp OD	80	80	57	25	54	10	162
		IDet	77	77	69	30	65	12	146
		Total	157	157	63	28	58	10	162

N: Number of subjects, SD: Standard deviation

14.2.106 Total bolus insulin dose (actual) in units by treatment week - descriptive statistics - safety analysis set

			Descriptive Statistics						
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	20	14	17	2	84
		IDet	179	178	23	17	18	1	110
		Total	360	359	21	16	18	1	110
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	21	14	18	2	90
		IDet	179	178	23	16	19	1	91
		Total	360	359	22	15	19	1	91
Visit 5 (Week 3)	Daily	IDegAsp OD	181	180	21	14	17	3	77
		IDet	179	176	23	16	20	2	94
		Total	360	356	22	15	18	2	94
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	21	14	17	2	80
		IDet	179	176	23	17	19	3	96
		Total	360	355	22	15	18	2	96
Visit 7 (Week 5)	Daily	IDegAsp OD	181	179	21	14	18	3	82
		IDet	179	174	23	17	19	1	99
		Total	360	353	22	16	18	1	99
Visit 8 (Week 6)	Daily	IDegAsp OD	181	179	21	15	18	3	79
		IDet	179	174	23	16	19	2	88
		Total	360	353	22	16	18	2	88
Visit 9 (Week 7)	Daily	IDegAsp OD	181	178	21	15	18	3	92
		IDet	179	172	23	17	20	1	88
		Total	360	350	22	16	18	1	92
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	21	15	18	3	94
		IDet	179	173	23	16	19	1	82
		Total	360	350	22	15	18	1	94
Visit 11 (Week 9)	Daily	IDegAsp OD	181	177	22	15	18	2	88
		IDet	179	172	24	17	19	3	95
		Total	360	349	23	16	18	2	95
Visit 12 (Week 10)	Daily	IDegAsp OD	181	175	21	14	18	3	88
		IDet	179	172	23	16	19	2	81
		Total	360	347	22	15	18	2	88
Visit 13 (Week 11)	Daily	IDegAsp OD	181	175	22	15	18	3	104
		IDet	179	172	23	16	19	2	91
		Total	360	347	22	15	18	2	104
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	22	15	18	3	103
		IDet	179	172	23	16	20	1	97
		Total	360	347	22	16	18	1	103

N: Number of subjects, SD: Standard deviation

Total bolus insulin dose (actual) in units by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	175	22	15	18	4	94
		IDet	179	171	23	16	20	1	85
		Total	360	346	22	16	18	1	94
Visit 16 (Week 14)	Daily	IDegAsp OD	181	175	22	15	18	3	95
		IDet	179	170	23	16	20	1	86
		Total	360	345	22	15	19	1	95
Visit 17 (Week 15)	Daily	IDegAsp OD	181	173	22	15	18	3	93
		IDet	179	170	24	17	19	2	88
		Total	360	343	23	16	19	2	93
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	22	15	18	4	101
		IDet	179	166	23	17	20	2	90
		Total	360	339	23	16	19	2	101
End of trial visit	Daily	IDegAsp OD	181	181	22	15	19	4	101
		IDet	179	179	23	16	20	2	90
		Total	360	360	23	16	19	2	101

N: Number of subjects, SD: Standard deviation

14.2.107 Total bolus insulin dose (actual) in units by treatment week - descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	9	4	8	3	23
		IDet	41	41	9	4	9	5	23
		Total	81	81	9	4	8	3	23
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	9	4	8	4	22
		IDet	41	41	10	5	9	3	26
		Total	81	81	10	5	9	3	26
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	9	4	8	3	25
		IDet	41	40	10	5	9	2	23
		Total	81	80	9	5	9	2	25
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	9	4	8	3	20
		IDet	41	40	10	5	9	4	27
		Total	81	80	9	4	9	3	27
Visit 7 (Week 5)	Daily	IDegAsp OD	40	40	9	4	8	3	21
		IDet	41	40	9	4	8	3	18
		Total	81	80	9	4	8	3	21
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	9	3	9	3	18
		IDet	41	40	9	4	9	2	19
		Total	81	80	9	3	9	2	19
Visit 9 (Week 7)	Daily	IDegAsp OD	40	40	9	4	8	3	26
		IDet	41	40	9	4	8	3	21
		Total	81	80	9	4	8	3	26
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	10	5	9	3	27
		IDet	41	40	10	5	9	2	29
		Total	81	79	10	5	9	2	29
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	10	4	9	3	26
		IDet	41	40	9	4	9	3	17
		Total	81	78	9	4	9	3	26
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	10	4	9	3	22
		IDet	41	39	9	4	7	4	17
		Total	81	77	9	4	9	3	22
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	10	5	9	3	29
		IDet	41	39	9	4	9	3	17
		Total	81	77	9	4	9	3	29
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	9	4	9	3	28
		IDet	41	39	9	4	10	3	18
		Total	81	77	9	4	9	3	28

N: Number of subjects, SD: Standard deviation

Total bolus insulin dose (actual) in units by treatment week - descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	10	6	10	4	39
		IDet	41	39	9	4	9	4	21
		Total	81	77	10	5	9	4	39
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	9	4	9	3	26
		IDet	41	40	9	4	9	3	16
		Total	81	78	9	4	9	3	26
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	10	4	9	3	29
		IDet	41	38	9	4	10	4	19
		Total	81	76	10	4	9	3	29
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	10	4	9	4	26
		IDet	41	37	9	4	9	3	21
		Total	81	75	9	4	9	3	26
End of trial visit	Daily	IDegAsp OD	40	40	10	4	9	4	26
		IDet	41	41	9	4	9	3	21
		Total	81	81	9	4	9	3	26

N: Number of subjects, SD: Standard deviation

14.2.108 Total bolus insulin dose (actual) in units by treatment week - descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	61	61	14	7	13	4	38
		IDet	61	61	17	9	16	1	44
		Total	122	122	16	8	14	1	44
Visit 4 (Week 2)	Daily	IDegAsp OD	61	61	15	9	14	4	45
		IDet	61	60	18	10	16	1	44
		Total	122	121	17	9	15	1	45
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	15	8	14	4	43
		IDet	61	59	18	10	16	2	46
		Total	122	119	16	9	15	2	46
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	15	8	14	5	43
		IDet	61	59	17	9	16	3	41
		Total	122	119	16	8	15	3	43
Visit 7 (Week 5)	Daily	IDegAsp OD	61	61	15	7	14	5	33
		IDet	61	59	18	10	16	1	43
		Total	122	120	16	8	15	1	43
Visit 8 (Week 6)	Daily	IDegAsp OD	61	61	15	7	15	4	38
		IDet	61	59	17	10	16	2	44
		Total	122	120	16	9	15	2	44
Visit 9 (Week 7)	Daily	IDegAsp OD	61	61	15	7	14	4	36
		IDet	61	59	18	11	17	1	63
		Total	122	120	17	9	15	1	63
Visit 10 (Week 8)	Daily	IDegAsp OD	61	61	16	7	14	5	37
		IDet	61	59	18	11	16	1	56
		Total	122	120	17	9	16	1	56
Visit 11 (Week 9)	Daily	IDegAsp OD	61	61	16	7	15	5	39
		IDet	61	59	18	12	16	4	83
		Total	122	120	17	10	16	4	83
Visit 12 (Week 10)	Daily	IDegAsp OD	61	60	15	7	14	6	34
		IDet	61	59	18	10	15	2	61
		Total	122	119	17	9	15	2	61
Visit 13 (Week 11)	Daily	IDegAsp OD	61	60	15	7	15	6	37
		IDet	61	59	19	12	16	2	71
		Total	122	119	17	10	15	2	71
Visit 14 (Week 12)	Daily	IDegAsp OD	61	60	15	6	15	6	37
		IDet	61	59	18	10	18	1	53
		Total	122	119	17	9	16	1	53

N: Number of subjects, SD: Standard deviation

Total bolus insulin dose (actual) in units by treatment week - descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	61	60	15	6	15	5	35
		IDet	61	59	18	10	17	1	64
		Total	122	119	17	9	16	1	64
Visit 16 (Week 14)	Daily	IDegAsp OD	61	60	16	8	15	5	46
		IDet	61	59	19	11	18	1	70
		Total	122	119	17	10	16	1	70
Visit 17 (Week 15)	Daily	IDegAsp OD	61	60	16	7	15	5	37
		IDet	61	59	19	11	18	2	66
		Total	122	119	17	9	16	2	66
Visit 18 (Week 16)	Daily	IDegAsp OD	61	59	17	7	16	5	42
		IDet	61	59	18	11	17	2	66
		Total	122	118	18	9	16	2	66
End of trial visit	Daily	IDegAsp OD	61	61	17	7	16	5	42
		IDet	61	61	18	10	17	2	66
		Total	122	122	18	9	16	2	66

N: Number of subjects, SD: Standard deviation

14.2.109 Total bolus insulin dose (actual) in units by treatment week - descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	80	31	15	27	2	84
		IDet	77	76	34	18	32	4	110
		Total	157	156	32	17	30	2	110
Visit 4 (Week 2)	Daily	IDegAsp OD	80	80	30	14	28	2	90
		IDet	77	77	35	17	34	4	91
		Total	157	157	32	15	30	2	91
Visit 5 (Week 3)	Daily	IDegAsp OD	80	80	31	14	30	4	77
		IDet	77	77	34	17	32	4	94
		Total	157	157	32	15	31	4	94
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	32	13	31	2	80
		IDet	77	77	35	18	32	4	96
		Total	157	156	33	16	31	2	96
Visit 7 (Week 5)	Daily	IDegAsp OD	80	78	31	14	29	3	82
		IDet	77	75	36	18	33	4	99
		Total	157	153	33	16	31	3	99
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	32	15	30	4	79
		IDet	77	75	35	17	32	4	88
		Total	157	153	34	16	31	4	88
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	32	15	31	3	92
		IDet	77	73	36	17	34	3	88
		Total	157	150	34	16	32	3	92
Visit 10 (Week 8)	Daily	IDegAsp OD	80	77	32	15	29	3	94
		IDet	77	74	34	16	32	4	82
		Total	157	151	33	16	31	3	94
Visit 11 (Week 9)	Daily	IDegAsp OD	80	78	32	15	30	2	88
		IDet	77	73	36	17	34	4	95
		Total	157	151	34	16	32	2	95
Visit 12 (Week 10)	Daily	IDegAsp OD	80	77	32	15	32	5	88
		IDet	77	74	35	16	33	4	81
		Total	157	151	34	15	33	4	88
Visit 13 (Week 11)	Daily	IDegAsp OD	80	77	32	16	30	3	104
		IDet	77	74	34	15	33	4	91
		Total	157	151	33	16	31	3	104
Visit 14 (Week 12)	Daily	IDegAsp OD	80	77	32	17	29	3	103
		IDet	77	74	34	16	32	4	97
		Total	157	151	33	16	30	3	103

N: Number of subjects, SD: Standard deviation

Total bolus insulin dose (actual) in units by treatment week - descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	32	15	31	4	94
		IDet	77	73	35	17	34	3	85
		Total	157	150	34	16	31	3	94
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	33	15	31	6	95
		IDet	77	71	34	15	32	3	86
		Total	157	148	34	15	31	3	95
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	34	15	32	4	93
		IDet	77	73	35	17	32	3	88
		Total	157	148	34	16	32	3	93
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	33	15	31	5	101
		IDet	77	70	35	17	34	3	90
		Total	157	146	34	16	32	3	101
End of trial visit	Daily	IDegAsp OD	80	80	33	15	31	5	101
		IDet	77	77	35	17	34	3	90
		Total	157	157	34	16	32	3	101

N: Number of subjects, SD: Standard deviation

14.2.110 Total insulin dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	0.79	0.28	0.76	0.05	1.69
		IDet	179	179	0.89	0.33	0.85	0.20	1.88
		Total	360	360	0.84	0.31	0.81	0.05	1.88
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	0.83	0.28	0.81	0.05	1.60
		IDet	179	178	0.93	0.33	0.94	0.18	2.13
		Total	360	359	0.88	0.31	0.86	0.05	2.13
Visit 5 (Week 3)	Daily	IDegAsp OD	181	180	0.84	0.29	0.84	0.05	1.62
		IDet	179	176	0.94	0.34	0.94	0.17	2.37
		Total	360	356	0.89	0.32	0.89	0.05	2.37
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	0.85	0.29	0.85	0.05	1.71
		IDet	179	176	0.96	0.35	0.94	0.17	2.34
		Total	360	355	0.91	0.33	0.90	0.05	2.34
Visit 7 (Week 5)	Daily	IDegAsp OD	181	179	0.85	0.29	0.84	0.07	1.70
		IDet	179	174	0.97	0.36	0.94	0.18	2.21
		Total	360	353	0.91	0.33	0.90	0.07	2.21
Visit 8 (Week 6)	Daily	IDegAsp OD	181	179	0.87	0.30	0.83	0.06	1.81
		IDet	179	174	0.97	0.36	0.96	0.19	2.44
		Total	360	353	0.92	0.33	0.91	0.06	2.44
Visit 9 (Week 7)	Daily	IDegAsp OD	181	178	0.86	0.30	0.84	0.07	1.84
		IDet	179	172	0.99	0.38	0.96	0.21	3.07
		Total	360	350	0.93	0.35	0.91	0.07	3.07
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	0.87	0.30	0.85	0.07	1.88
		IDet	179	173	1.01	0.37	0.99	0.21	2.95
		Total	360	350	0.94	0.34	0.91	0.07	2.95
Visit 11 (Week 9)	Daily	IDegAsp OD	181	177	0.88	0.31	0.86	0.07	1.96
		IDet	179	173	1.01	0.41	0.98	0.21	3.82
		Total	360	350	0.94	0.37	0.91	0.07	3.82
Visit 12 (Week 10)	Daily	IDegAsp OD	181	175	0.88	0.30	0.89	0.10	1.70
		IDet	179	172	1.00	0.38	0.96	0.21	3.26
		Total	360	347	0.94	0.35	0.93	0.10	3.26
Visit 13 (Week 11)	Daily	IDegAsp OD	181	175	0.89	0.30	0.90	0.09	1.74
		IDet	179	172	1.01	0.40	0.98	0.22	3.67
		Total	360	347	0.95	0.36	0.94	0.09	3.67
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	0.85	0.28	0.86	0.08	1.78
		IDet	179	172	1.00	0.37	0.95	0.21	3.19
		Total	360	347	0.92	0.34	0.90	0.08	3.19

N: Number of subjects, SD: Standard deviation

Total insulin dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	175	0.86	0.29	0.86	0.10	1.83
		IDet	179	172	1.00	0.40	0.95	0.21	3.50
		Total	360	347	0.93	0.36	0.90	0.10	3.50
Visit 16 (Week 14)	Daily	IDegAsp OD	181	175	0.87	0.29	0.87	0.13	1.81
		IDet	179	170	1.00	0.41	0.94	0.21	3.67
		Total	360	345	0.93	0.36	0.90	0.13	3.67
Visit 17 (Week 15)	Daily	IDegAsp OD	181	173	0.88	0.29	0.89	0.13	1.70
		IDet	179	170	1.02	0.41	0.94	0.21	3.58
		Total	360	343	0.95	0.36	0.91	0.13	3.58
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	0.88	0.29	0.87	0.13	1.70
		IDet	179	167	1.01	0.40	0.94	0.22	3.41
		Total	360	340	0.94	0.36	0.90	0.13	3.41
End of trial visit	Daily	IDegAsp OD	181	181	0.87	0.29	0.87	0.13	1.70
		IDet	179	179	1.02	0.40	0.95	0.22	3.41
		Total	360	360	0.94	0.36	0.90	0.13	3.41

N: Number of subjects, SD: Standard deviation

14.2.111 Total insulin dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	0.73	0.25	0.71	0.16	1.69
		IDet	41	41	0.82	0.28	0.80	0.34	1.62
		Total	81	81	0.78	0.27	0.73	0.16	1.69
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	0.78	0.25	0.72	0.22	1.31
		IDet	41	41	0.87	0.32	0.86	0.37	2.06
		Total	81	81	0.82	0.29	0.79	0.22	2.06
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	0.78	0.24	0.75	0.19	1.27
		IDet	41	40	0.87	0.33	0.85	0.33	1.89
		Total	81	80	0.82	0.29	0.76	0.19	1.89
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	0.77	0.24	0.75	0.16	1.27
		IDet	41	40	0.89	0.30	0.89	0.43	1.71
		Total	81	80	0.83	0.28	0.79	0.16	1.71
Visit 7 (Week 5)	Daily	IDegAsp OD	40	40	0.76	0.25	0.76	0.18	1.35
		IDet	41	40	0.87	0.30	0.89	0.41	1.62
		Total	81	80	0.82	0.28	0.79	0.18	1.62
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	0.79	0.21	0.79	0.19	1.20
		IDet	41	40	0.88	0.31	0.83	0.40	1.85
		Total	81	80	0.83	0.27	0.80	0.19	1.85
Visit 9 (Week 7)	Daily	IDegAsp OD	40	40	0.79	0.22	0.76	0.16	1.20
		IDet	41	40	0.90	0.35	0.85	0.38	2.25
		Total	81	80	0.84	0.30	0.80	0.16	2.25
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	0.81	0.24	0.81	0.17	1.28
		IDet	41	40	0.96	0.35	0.89	0.47	1.88
		Total	81	79	0.89	0.31	0.84	0.17	1.88
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	0.81	0.25	0.80	0.16	1.26
		IDet	41	40	0.91	0.30	0.87	0.50	1.72
		Total	81	78	0.86	0.28	0.84	0.16	1.72
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	0.82	0.25	0.76	0.18	1.25
		IDet	41	39	0.88	0.31	0.89	0.43	2.00
		Total	81	77	0.85	0.28	0.83	0.18	2.00
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	0.82	0.25	0.80	0.19	1.24
		IDet	41	39	0.89	0.30	0.80	0.48	1.97
		Total	81	77	0.85	0.28	0.80	0.19	1.97
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	0.77	0.22	0.76	0.18	1.19
		IDet	41	39	0.88	0.29	0.86	0.44	1.72
		Total	81	77	0.83	0.26	0.80	0.18	1.72

N: Number of subjects, SD: Standard deviation

Total insulin dose (actual) in units/kg by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	0.82	0.25	0.81	0.21	1.46
		IDet	41	39	0.90	0.36	0.83	0.43	2.03
		Total	81	77	0.86	0.31	0.82	0.21	2.03
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	0.79	0.22	0.81	0.20	1.16
		IDet	41	40	0.88	0.35	0.81	0.36	2.28
		Total	81	78	0.83	0.29	0.81	0.20	2.28
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	0.82	0.22	0.79	0.19	1.24
		IDet	41	38	0.93	0.37	0.83	0.44	2.45
		Total	81	76	0.87	0.31	0.81	0.19	2.45
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	0.78	0.19	0.80	0.23	1.13
		IDet	41	37	0.90	0.35	0.84	0.46	2.27
		Total	81	75	0.84	0.29	0.81	0.23	2.27
End of trial visit	Daily	IDegAsp OD	40	40	0.78	0.19	0.80	0.23	1.13
		IDet	41	41	0.90	0.35	0.84	0.37	2.27
		Total	81	81	0.84	0.29	0.81	0.23	2.27

N: Number of subjects, SD: Standard deviation

14.2.112 Total insulin dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	61	61	0.75	0.26	0.74	0.28	1.39
		IDet	61	61	0.85	0.33	0.82	0.20	1.74
		Total	122	122	0.80	0.30	0.76	0.20	1.74
Visit 4 (Week 2)	Daily	IDegAsp OD	61	61	0.79	0.28	0.81	0.24	1.40
		IDet	61	60	0.89	0.33	0.84	0.18	2.13
		Total	122	121	0.84	0.31	0.82	0.18	2.13
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	0.79	0.26	0.82	0.22	1.27
		IDet	61	59	0.91	0.35	0.91	0.17	2.37
		Total	122	119	0.85	0.31	0.85	0.17	2.37
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	0.81	0.27	0.83	0.24	1.38
		IDet	61	59	0.91	0.36	0.93	0.17	2.34
		Total	122	119	0.86	0.32	0.86	0.17	2.34
Visit 7 (Week 5)	Daily	IDegAsp OD	61	61	0.81	0.25	0.81	0.27	1.26
		IDet	61	59	0.93	0.36	0.93	0.21	2.21
		Total	122	120	0.87	0.31	0.88	0.21	2.21
Visit 8 (Week 6)	Daily	IDegAsp OD	61	61	0.81	0.26	0.79	0.27	1.36
		IDet	61	59	0.94	0.37	0.95	0.25	2.44
		Total	122	120	0.87	0.33	0.88	0.25	2.44
Visit 9 (Week 7)	Daily	IDegAsp OD	61	61	0.81	0.27	0.77	0.26	1.35
		IDet	61	59	0.97	0.43	0.93	0.26	3.07
		Total	122	120	0.89	0.36	0.83	0.26	3.07
Visit 10 (Week 8)	Daily	IDegAsp OD	61	61	0.83	0.26	0.83	0.26	1.49
		IDet	61	59	0.97	0.41	0.94	0.24	2.95
		Total	122	120	0.90	0.35	0.87	0.24	2.95
Visit 11 (Week 9)	Daily	IDegAsp OD	61	61	0.81	0.25	0.81	0.21	1.31
		IDet	61	59	0.99	0.49	0.95	0.21	3.82
		Total	122	120	0.90	0.39	0.89	0.21	3.82
Visit 12 (Week 10)	Daily	IDegAsp OD	61	60	0.81	0.25	0.83	0.31	1.43
		IDet	61	59	0.98	0.44	0.96	0.21	3.26
		Total	122	119	0.90	0.36	0.88	0.21	3.26
Visit 13 (Week 11)	Daily	IDegAsp OD	61	60	0.82	0.25	0.80	0.33	1.38
		IDet	61	59	1.01	0.48	0.97	0.23	3.67
		Total	122	119	0.91	0.39	0.88	0.23	3.67
Visit 14 (Week 12)	Daily	IDegAsp OD	61	60	0.79	0.23	0.80	0.30	1.32
		IDet	61	59	0.99	0.43	0.95	0.23	3.19
		Total	122	119	0.89	0.36	0.87	0.23	3.19

N: Number of subjects, SD: Standard deviation

Total insulin dose (actual) in units/kg by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	61	60	0.79	0.24	0.80	0.29	1.42
		IDet	61	59	0.98	0.44	0.97	0.21	3.50
		Total	122	119	0.89	0.37	0.87	0.21	3.50
Visit 16 (Week 14)	Daily	IDegAsp OD	61	60	0.80	0.25	0.80	0.27	1.51
		IDet	61	59	1.00	0.47	0.97	0.22	3.67
		Total	122	119	0.90	0.39	0.87	0.22	3.67
Visit 17 (Week 15)	Daily	IDegAsp OD	61	60	0.82	0.25	0.79	0.29	1.51
		IDet	61	59	1.00	0.46	0.94	0.22	3.58
		Total	122	119	0.91	0.38	0.88	0.22	3.58
Visit 18 (Week 16)	Daily	IDegAsp OD	61	59	0.84	0.26	0.86	0.28	1.70
		IDet	61	59	1.00	0.44	0.94	0.23	3.41
		Total	122	118	0.92	0.37	0.90	0.23	3.41
End of trial visit	Daily	IDegAsp OD	61	61	0.84	0.26	0.86	0.28	1.70
		IDet	61	61	1.01	0.43	0.95	0.23	3.41
		Total	122	122	0.92	0.37	0.90	0.23	3.41

N: Number of subjects, SD: Standard deviation

14.2.113 Total insulin dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	80	0.86	0.30	0.88	0.05	1.54
		IDet	77	77	0.97	0.34	0.92	0.21	1.88
		Total	157	157	0.91	0.32	0.90	0.05	1.88
Visit 4 (Week 2)	Daily	IDegAsp OD	80	80	0.88	0.29	0.90	0.05	1.60
		IDet	77	77	1.00	0.32	0.96	0.19	1.67
		Total	157	157	0.94	0.31	0.94	0.05	1.67
Visit 5 (Week 3)	Daily	IDegAsp OD	80	80	0.91	0.31	0.93	0.05	1.62
		IDet	77	77	1.01	0.34	1.01	0.18	1.72
		Total	157	157	0.96	0.33	0.95	0.05	1.72
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	0.94	0.32	0.98	0.05	1.71
		IDet	77	77	1.03	0.35	1.02	0.17	1.83
		Total	157	156	0.98	0.34	1.01	0.05	1.83
Visit 7 (Week 5)	Daily	IDegAsp OD	80	78	0.92	0.32	0.93	0.07	1.70
		IDet	77	75	1.05	0.37	1.01	0.18	2.17
		Total	157	153	0.98	0.35	0.96	0.07	2.17
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	0.95	0.34	0.97	0.06	1.81
		IDet	77	75	1.05	0.36	1.04	0.19	1.96
		Total	157	153	1.00	0.35	0.99	0.06	1.96
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	0.95	0.33	0.99	0.07	1.84
		IDet	77	73	1.06	0.35	1.04	0.21	1.95
		Total	157	150	1.01	0.35	1.03	0.07	1.95
Visit 10 (Week 8)	Daily	IDegAsp OD	80	77	0.95	0.34	0.97	0.07	1.88
		IDet	77	74	1.06	0.35	1.04	0.21	1.92
		Total	157	151	1.00	0.35	1.00	0.07	1.92
Visit 11 (Week 9)	Daily	IDegAsp OD	80	78	0.97	0.35	0.98	0.07	1.96
		IDet	77	74	1.08	0.38	1.05	0.23	2.11
		Total	157	152	1.02	0.37	1.02	0.07	2.11
Visit 12 (Week 10)	Daily	IDegAsp OD	80	77	0.96	0.34	1.00	0.10	1.70
		IDet	77	74	1.09	0.35	1.07	0.22	2.01
		Total	157	151	1.02	0.35	1.03	0.10	2.01
Visit 13 (Week 11)	Daily	IDegAsp OD	80	77	0.97	0.35	0.98	0.09	1.74
		IDet	77	74	1.07	0.35	1.06	0.22	1.89
		Total	157	151	1.02	0.35	1.03	0.09	1.89
Visit 14 (Week 12)	Daily	IDegAsp OD	80	77	0.93	0.32	0.95	0.08	1.78
		IDet	77	74	1.07	0.35	1.11	0.21	1.99
		Total	157	151	1.00	0.34	0.98	0.08	1.99

N: Number of subjects, SD: Standard deviation

Total insulin dose (actual) in units/kg by treatment week – descriptive statistics – adolescents (12-17 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
			-Descriptive Statistics-						
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	0.94	0.32	0.94	0.10	1.83
		IDet	77	74	1.07	0.38	1.10	0.21	2.20
		Total	157	151	1.01	0.36	0.97	0.10	2.20
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	0.96	0.33	0.99	0.13	1.81
		IDet	77	71	1.07	0.36	1.11	0.21	1.92
		Total	157	148	1.01	0.35	1.00	0.13	1.92
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	0.97	0.33	0.98	0.13	1.70
		IDet	77	73	1.08	0.38	1.12	0.21	2.17
		Total	157	148	1.03	0.36	1.00	0.13	2.17
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	0.95	0.34	0.98	0.13	1.68
		IDet	77	71	1.08	0.39	1.15	0.22	1.93
		Total	157	147	1.01	0.37	1.01	0.13	1.93
End of trial visit	Daily	IDegAsp OD	80	80	0.95	0.34	0.97	0.13	1.68
		IDet	77	77	1.09	0.38	1.15	0.22	1.93
		Total	157	157	1.02	0.37	1.01	0.13	1.93

N: Number of subjects, SD: Standard deviation

14.2.114 Total bolus insulin dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	181	181	0.49	0.21	0.47	0.03	1.26
		IDet	179	178	0.52	0.22	0.50	0.06	1.35
		Total	360	359	0.50	0.21	0.49	0.03	1.35
Visit 4 (Week 2)	Daily	IDegAsp OD	181	181	0.50	0.20	0.49	0.03	1.21
		IDet	179	178	0.53	0.23	0.52	0.04	1.58
		Total	360	359	0.52	0.22	0.50	0.03	1.58
Visit 5 (Week 3)	Daily	IDegAsp OD	181	180	0.51	0.19	0.50	0.05	1.23
		IDet	179	176	0.52	0.23	0.51	0.08	1.30
		Total	360	356	0.51	0.21	0.51	0.05	1.30
Visit 6 (Week 4)	Daily	IDegAsp OD	181	179	0.51	0.19	0.51	0.03	1.27
		IDet	179	176	0.53	0.22	0.53	0.07	1.28
		Total	360	355	0.52	0.21	0.52	0.03	1.28
Visit 7 (Week 5)	Daily	IDegAsp OD	181	179	0.50	0.20	0.49	0.03	1.23
		IDet	179	174	0.53	0.22	0.51	0.05	1.29
		Total	360	353	0.51	0.21	0.50	0.03	1.29
Visit 8 (Week 6)	Daily	IDegAsp OD	181	179	0.51	0.20	0.49	0.05	1.37
		IDet	179	174	0.52	0.21	0.52	0.07	1.25
		Total	360	353	0.52	0.21	0.51	0.05	1.37
Visit 9 (Week 7)	Daily	IDegAsp OD	181	178	0.51	0.20	0.49	0.04	1.25
		IDet	179	172	0.54	0.23	0.53	0.06	1.77
		Total	360	350	0.52	0.22	0.51	0.04	1.77
Visit 10 (Week 8)	Daily	IDegAsp OD	181	177	0.52	0.20	0.50	0.03	1.28
		IDet	179	173	0.54	0.24	0.53	0.04	1.59
		Total	360	350	0.53	0.22	0.50	0.03	1.59
Visit 11 (Week 9)	Daily	IDegAsp OD	181	177	0.52	0.20	0.51	0.03	1.32
		IDet	179	172	0.54	0.24	0.54	0.08	2.35
		Total	360	349	0.53	0.23	0.52	0.03	2.35
Visit 12 (Week 10)	Daily	IDegAsp OD	181	175	0.52	0.20	0.50	0.07	1.21
		IDet	179	172	0.53	0.22	0.51	0.07	1.73
		Total	360	347	0.52	0.21	0.50	0.07	1.73
Visit 13 (Week 11)	Daily	IDegAsp OD	181	175	0.52	0.20	0.50	0.04	1.28
		IDet	179	172	0.53	0.23	0.52	0.07	2.02
		Total	360	347	0.53	0.21	0.51	0.04	2.02
Visit 14 (Week 12)	Daily	IDegAsp OD	181	175	0.50	0.19	0.48	0.05	1.12
		IDet	179	172	0.52	0.22	0.51	0.04	1.49
		Total	360	347	0.51	0.20	0.49	0.04	1.49

N: Number of subjects, SD: Standard deviation

Total bolus insulin dose (actual) in units/kg by treatment week - descriptive statistics - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	181	175	0.51	0.19	0.49	0.05	1.14
		IDet	179	171	0.53	0.23	0.50	0.04	1.80
		Total	360	346	0.52	0.21	0.50	0.04	1.80
Visit 16 (Week 14)	Daily	IDegAsp OD	181	175	0.51	0.19	0.51	0.08	1.08
		IDet	179	170	0.52	0.23	0.50	0.04	1.97
		Total	360	345	0.52	0.21	0.50	0.04	1.97
Visit 17 (Week 15)	Daily	IDegAsp OD	181	173	0.53	0.19	0.51	0.06	1.11
		IDet	179	170	0.53	0.23	0.52	0.06	1.88
		Total	360	343	0.53	0.21	0.51	0.06	1.88
Visit 18 (Week 16)	Daily	IDegAsp OD	181	173	0.52	0.19	0.51	0.06	1.05
		IDet	179	166	0.52	0.23	0.51	0.06	1.79
		Total	360	339	0.52	0.21	0.51	0.06	1.79
End of trial visit	Daily	IDegAsp OD	181	181	0.52	0.19	0.51	0.06	1.05
		IDet	179	179	0.52	0.22	0.51	0.06	1.79
		Total	360	360	0.52	0.21	0.51	0.06	1.79

N: Number of subjects, SD: Standard deviation

14.2.115 Total bolus insulin dose (actual) in units/kg by treatment week - descriptive statistics-children (1-5 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	40	40	0.46	0.19	0.47	0.12	1.26
		IDet	41	41	0.53	0.22	0.53	0.16	1.11
		Total	81	81	0.50	0.21	0.49	0.12	1.26
Visit 4 (Week 2)	Daily	IDegAsp OD	40	40	0.50	0.19	0.45	0.19	1.10
		IDet	41	41	0.56	0.28	0.56	0.14	1.58
		Total	81	81	0.53	0.24	0.49	0.14	1.58
Visit 5 (Week 3)	Daily	IDegAsp OD	40	40	0.49	0.17	0.48	0.15	0.91
		IDet	41	40	0.54	0.26	0.51	0.08	1.29
		Total	81	80	0.52	0.22	0.49	0.08	1.29
Visit 6 (Week 4)	Daily	IDegAsp OD	40	40	0.48	0.16	0.48	0.12	0.86
		IDet	41	40	0.56	0.23	0.55	0.19	1.28
		Total	81	80	0.52	0.20	0.52	0.12	1.28
Visit 7 (Week 5)	Daily	IDegAsp OD	40	40	0.47	0.18	0.46	0.13	0.97
		IDet	41	40	0.53	0.21	0.51	0.19	0.98
		Total	81	80	0.50	0.20	0.48	0.13	0.98
Visit 8 (Week 6)	Daily	IDegAsp OD	40	40	0.49	0.13	0.51	0.15	0.77
		IDet	41	40	0.52	0.20	0.51	0.08	0.95
		Total	81	80	0.50	0.17	0.51	0.08	0.95
Visit 9 (Week 7)	Daily	IDegAsp OD	40	40	0.48	0.16	0.46	0.12	0.85
		IDet	41	40	0.52	0.21	0.52	0.12	1.23
		Total	81	80	0.50	0.19	0.49	0.12	1.23
Visit 10 (Week 8)	Daily	IDegAsp OD	40	39	0.51	0.16	0.48	0.12	0.87
		IDet	41	40	0.58	0.27	0.56	0.09	1.58
		Total	81	79	0.54	0.23	0.50	0.09	1.58
Visit 11 (Week 9)	Daily	IDegAsp OD	40	38	0.50	0.17	0.52	0.12	0.88
		IDet	41	40	0.52	0.18	0.52	0.12	0.92
		Total	81	78	0.51	0.18	0.52	0.12	0.92
Visit 12 (Week 10)	Daily	IDegAsp OD	40	38	0.51	0.18	0.48	0.13	0.97
		IDet	41	39	0.49	0.20	0.50	0.17	0.90
		Total	81	77	0.50	0.19	0.49	0.13	0.97
Visit 13 (Week 11)	Daily	IDegAsp OD	40	38	0.51	0.17	0.51	0.15	0.94
		IDet	41	39	0.51	0.19	0.51	0.13	0.94
		Total	81	77	0.51	0.18	0.51	0.13	0.94
Visit 14 (Week 12)	Daily	IDegAsp OD	40	38	0.47	0.15	0.46	0.14	0.73
		IDet	41	39	0.51	0.20	0.49	0.16	0.99
		Total	81	77	0.49	0.18	0.48	0.14	0.99

N: Number of subjects, SD: Standard deviation

Total bolus insulin dose (actual) in units/kg by treatment week - descriptive statistics- children (1-5 years) - safety analysis set

				Descriptive Statistics					
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	40	38	0.51	0.18	0.49	0.16	1.01
		IDet	41	39	0.52	0.22	0.48	0.18	1.04
		Total	81	77	0.51	0.20	0.49	0.16	1.04
Visit 16 (Week 14)	Daily	IDegAsp OD	40	38	0.48	0.15	0.51	0.15	0.74
		IDet	41	40	0.49	0.19	0.49	0.15	0.86
		Total	81	78	0.48	0.17	0.50	0.15	0.86
Visit 17 (Week 15)	Daily	IDegAsp OD	40	38	0.50	0.14	0.50	0.14	0.75
		IDet	41	38	0.53	0.21	0.53	0.19	1.01
		Total	81	76	0.52	0.18	0.51	0.14	1.01
Visit 18 (Week 16)	Daily	IDegAsp OD	40	38	0.48	0.14	0.47	0.19	0.75
		IDet	41	37	0.51	0.21	0.49	0.19	1.01
		Total	81	75	0.49	0.18	0.48	0.19	1.01
End of trial visit	Daily	IDegAsp OD	40	40	0.48	0.14	0.47	0.19	0.75
		IDet	41	41	0.50	0.21	0.49	0.15	1.01
		Total	81	81	0.49	0.18	0.48	0.15	1.01

N: Number of subjects, SD: Standard deviation

14.2.116 Total bolus insulin dose (actual) in units/kg by treatment week - descriptive statistics-children (6-11 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	61	61	0.46	0.18	0.46	0.12	1.05
		IDet	61	61	0.47	0.19	0.45	0.06	0.89
		Total	122	122	0.46	0.19	0.46	0.06	1.05
Visit 4 (Week 2)	Daily	IDegAsp OD	61	61	0.48	0.19	0.47	0.13	0.92
		IDet	61	60	0.49	0.20	0.47	0.04	1.11
		Total	122	121	0.48	0.20	0.47	0.04	1.11
Visit 5 (Week 3)	Daily	IDegAsp OD	61	60	0.47	0.17	0.46	0.14	0.87
		IDet	61	59	0.49	0.21	0.47	0.08	1.30
		Total	122	119	0.48	0.19	0.47	0.08	1.30
Visit 6 (Week 4)	Daily	IDegAsp OD	61	60	0.48	0.17	0.45	0.13	0.84
		IDet	61	59	0.48	0.20	0.45	0.12	1.15
		Total	122	119	0.48	0.19	0.45	0.12	1.15
Visit 7 (Week 5)	Daily	IDegAsp OD	61	61	0.48	0.16	0.46	0.17	0.82
		IDet	61	59	0.49	0.20	0.46	0.05	0.97
		Total	122	120	0.48	0.18	0.46	0.05	0.97
Visit 8 (Week 6)	Daily	IDegAsp OD	61	61	0.47	0.17	0.47	0.16	0.83
		IDet	61	59	0.49	0.22	0.45	0.09	1.25
		Total	122	120	0.48	0.19	0.45	0.09	1.25
Visit 9 (Week 7)	Daily	IDegAsp OD	61	61	0.47	0.17	0.45	0.15	0.89
		IDet	61	59	0.51	0.27	0.47	0.06	1.77
		Total	122	120	0.49	0.23	0.46	0.06	1.77
Visit 10 (Week 8)	Daily	IDegAsp OD	61	61	0.49	0.18	0.48	0.15	1.16
		IDet	61	59	0.50	0.24	0.47	0.04	1.59
		Total	122	120	0.50	0.21	0.47	0.04	1.59
Visit 11 (Week 9)	Daily	IDegAsp OD	61	61	0.49	0.16	0.48	0.15	0.83
		IDet	61	59	0.52	0.31	0.46	0.15	2.35
		Total	122	120	0.50	0.24	0.47	0.15	2.35
Visit 12 (Week 10)	Daily	IDegAsp OD	61	60	0.48	0.16	0.46	0.17	0.87
		IDet	61	59	0.50	0.26	0.45	0.08	1.73
		Total	122	119	0.49	0.21	0.46	0.08	1.73
Visit 13 (Week 11)	Daily	IDegAsp OD	61	60	0.49	0.15	0.48	0.17	0.83
		IDet	61	59	0.52	0.29	0.47	0.08	2.02
		Total	122	119	0.50	0.23	0.47	0.08	2.02
Visit 14 (Week 12)	Daily	IDegAsp OD	61	60	0.47	0.16	0.46	0.16	0.91
		IDet	61	59	0.51	0.24	0.48	0.04	1.49
		Total	122	119	0.49	0.20	0.47	0.04	1.49

N: Number of subjects, SD: Standard deviation

Total bolus insulin dose (actual) in units/kg by treatment week - descriptive statistics- children (6-11 years) - safety analysis set

				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 15 (Week 13)	Daily	IDegAsp OD	61	60	0.47	0.16	0.46	0.16	0.90
		IDet	61	59	0.50	0.25	0.47	0.04	1.80
		Total	122	119	0.49	0.21	0.47	0.04	1.80
Visit 16 (Week 14)	Daily	IDegAsp OD	61	60	0.48	0.17	0.46	0.16	0.93
		IDet	61	59	0.52	0.28	0.48	0.04	1.97
		Total	122	119	0.50	0.23	0.47	0.04	1.97
Visit 17 (Week 15)	Daily	IDegAsp OD	61	60	0.49	0.17	0.47	0.16	1.11
		IDet	61	59	0.51	0.26	0.49	0.09	1.88
		Total	122	119	0.50	0.22	0.48	0.09	1.88
Visit 18 (Week 16)	Daily	IDegAsp OD	61	59	0.51	0.17	0.51	0.16	1.00
		IDet	61	59	0.50	0.24	0.49	0.07	1.79
		Total	122	118	0.51	0.21	0.50	0.07	1.79
End of trial visit	Daily	IDegAsp OD	61	61	0.51	0.17	0.51	0.16	1.00
		IDet	61	61	0.50	0.24	0.49	0.07	1.79
		Total	122	122	0.50	0.21	0.50	0.07	1.79

N: Number of subjects, SD: Standard deviation

14.2.117 Total bolus insulin dose (actual) in units/kg by treatment week - descriptive statistics-adolescents (12-17 years) - safety analysis set

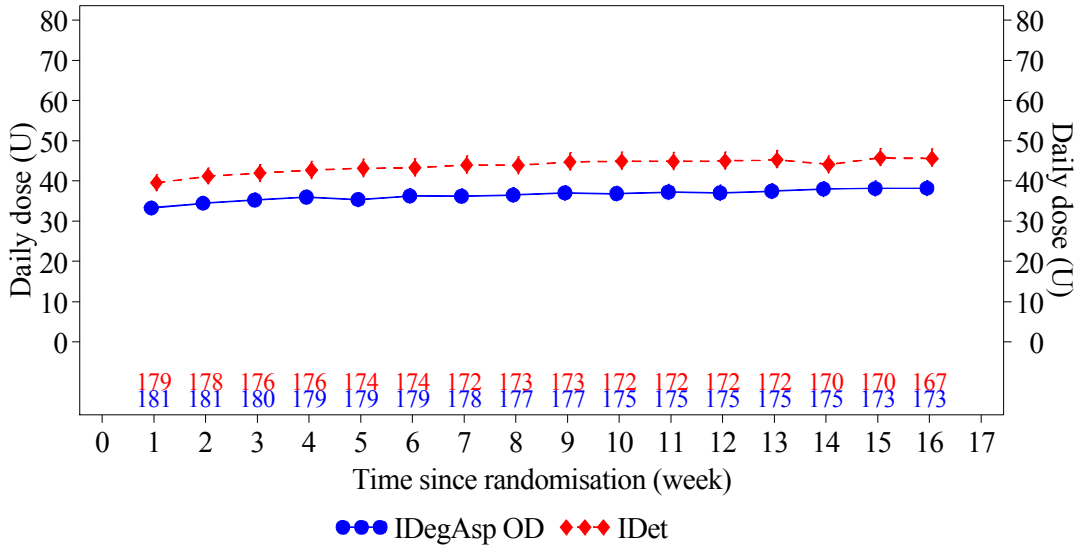
				Descriptive Statistics				
Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
Visit 3 (Week 1)	Daily	IDegAsp OD	80	80	0.53	0.22	0.52	0.03	1.15
		IDet	77	76	0.55	0.23	0.51	0.11	1.35
		Total	157	156	0.54	0.23	0.51	0.03	1.35
Visit 4 (Week 2)	Daily	IDegAsp OD	80	80	0.53	0.21	0.50	0.03	1.21
		IDet	77	77	0.55	0.23	0.55	0.11	1.22
		Total	157	157	0.54	0.22	0.53	0.03	1.22
Visit 5 (Week 3)	Daily	IDegAsp OD	80	80	0.54	0.22	0.54	0.05	1.23
		IDet	77	77	0.54	0.22	0.53	0.08	1.18
		Total	157	157	0.54	0.22	0.53	0.05	1.23
Visit 6 (Week 4)	Daily	IDegAsp OD	80	79	0.55	0.22	0.54	0.03	1.27
		IDet	77	77	0.55	0.22	0.55	0.07	1.09
		Total	157	156	0.55	0.22	0.54	0.03	1.27
Visit 7 (Week 5)	Daily	IDegAsp OD	80	78	0.53	0.22	0.51	0.03	1.23
		IDet	77	75	0.56	0.23	0.55	0.07	1.29
		Total	157	153	0.55	0.23	0.53	0.03	1.29
Visit 8 (Week 6)	Daily	IDegAsp OD	80	78	0.56	0.24	0.54	0.05	1.37
		IDet	77	75	0.56	0.22	0.57	0.07	1.01
		Total	157	153	0.56	0.23	0.55	0.05	1.37
Visit 9 (Week 7)	Daily	IDegAsp OD	80	77	0.56	0.23	0.54	0.04	1.25
		IDet	77	73	0.56	0.21	0.56	0.08	1.02
		Total	157	150	0.56	0.22	0.55	0.04	1.25
Visit 10 (Week 8)	Daily	IDegAsp OD	80	77	0.55	0.23	0.50	0.03	1.28
		IDet	77	74	0.55	0.21	0.56	0.07	1.13
		Total	157	151	0.55	0.22	0.54	0.03	1.28
Visit 11 (Week 9)	Daily	IDegAsp OD	80	78	0.56	0.24	0.53	0.03	1.32
		IDet	77	73	0.57	0.22	0.56	0.08	1.11
		Total	157	151	0.56	0.23	0.55	0.03	1.32
Visit 12 (Week 10)	Daily	IDegAsp OD	80	77	0.55	0.23	0.55	0.07	1.21
		IDet	77	74	0.56	0.20	0.56	0.07	1.03
		Total	157	151	0.56	0.22	0.55	0.07	1.21
Visit 13 (Week 11)	Daily	IDegAsp OD	80	77	0.56	0.23	0.52	0.04	1.28
		IDet	77	74	0.54	0.20	0.55	0.07	1.03
		Total	157	151	0.55	0.22	0.54	0.04	1.28
Visit 14 (Week 12)	Daily	IDegAsp OD	80	77	0.54	0.22	0.53	0.05	1.12
		IDet	77	74	0.54	0.21	0.54	0.07	1.05
		Total	157	151	0.54	0.21	0.53	0.05	1.12

N: Number of subjects, SD: Standard deviation

Total bolus insulin dose (actual) in units/kg by treatment week - descriptive statistics- adolescents (12-17 years) - safety analysis set

Visit	Endpoint	Treatment	SAFETY	N	Mean	SD	Median	Minimum	Maximum
			-Descriptive Statistics-						
Visit 15 (Week 13)	Daily	IDegAsp OD	80	77	0.54	0.21	0.53	0.05	1.14
		IDet	77	73	0.55	0.22	0.53	0.06	1.10
		Total	157	150	0.55	0.21	0.53	0.05	1.14
Visit 16 (Week 14)	Daily	IDegAsp OD	80	77	0.56	0.21	0.55	0.08	1.08
		IDet	77	71	0.55	0.21	0.54	0.06	1.06
		Total	157	148	0.55	0.21	0.55	0.06	1.08
Visit 17 (Week 15)	Daily	IDegAsp OD	80	75	0.57	0.21	0.55	0.06	1.05
		IDet	77	73	0.55	0.22	0.54	0.06	1.06
		Total	157	148	0.56	0.21	0.55	0.06	1.06
Visit 18 (Week 16)	Daily	IDegAsp OD	80	76	0.55	0.22	0.54	0.06	1.05
		IDet	77	70	0.55	0.22	0.56	0.06	1.19
		Total	157	146	0.55	0.22	0.54	0.06	1.19
End of trial visit	Daily	IDegAsp OD	80	80	0.55	0.21	0.54	0.06	1.05
		IDet	77	77	0.54	0.22	0.54	0.06	1.19
		Total	157	157	0.54	0.21	0.54	0.06	1.19

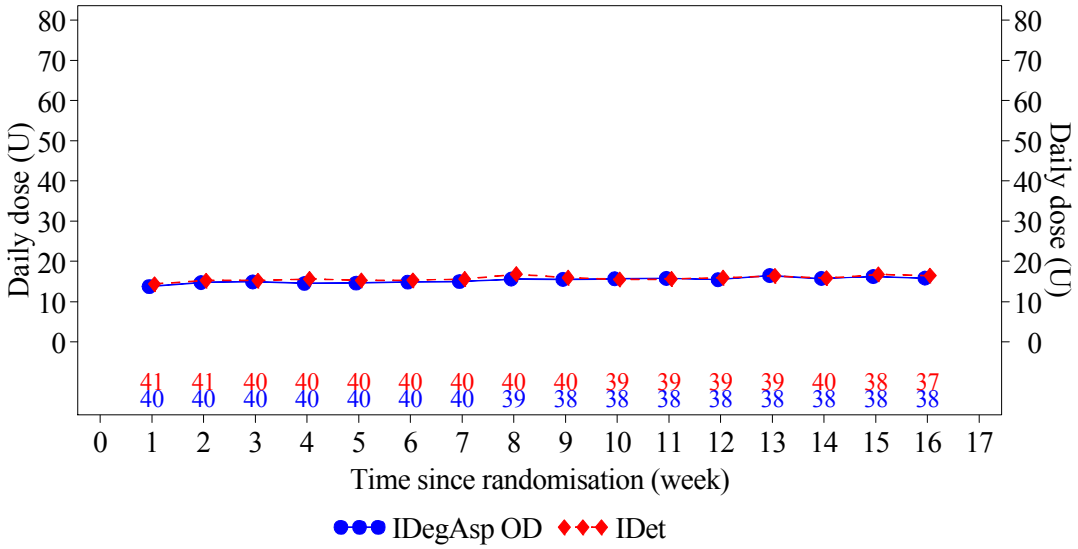
N: Number of subjects, SD: Standard deviation



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:48 - fmean_numfind_deg_cust.sas/e_tot_dos_d_ac_u_mean_ob_sas.cgm

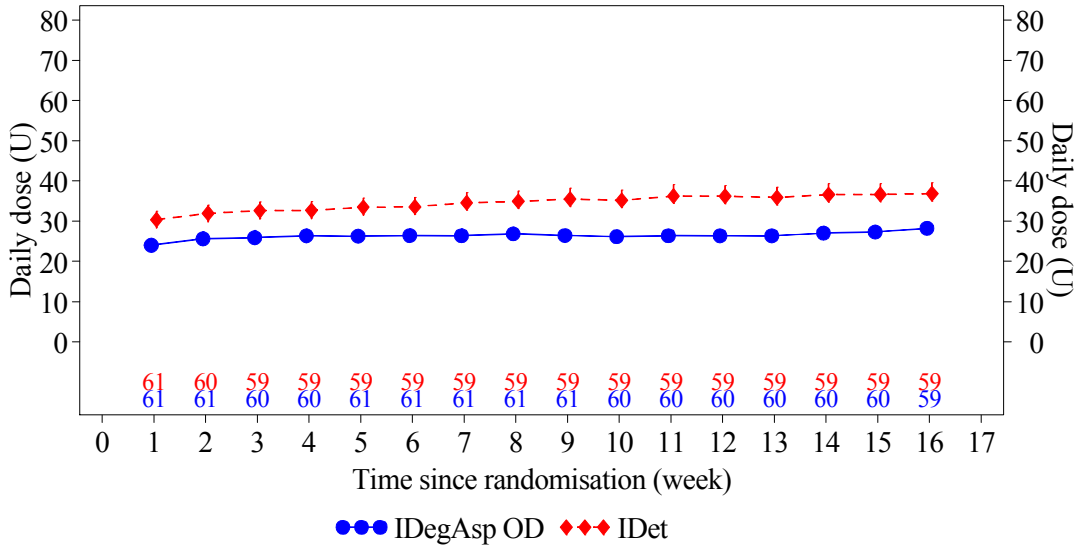
14.2.118 Total daily insulin dose (actual) in units by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:49 - fmean_numfind_deg_cust.sas/e_tot_dos_d_ac_u_mean_ob_age1_sas.cgm

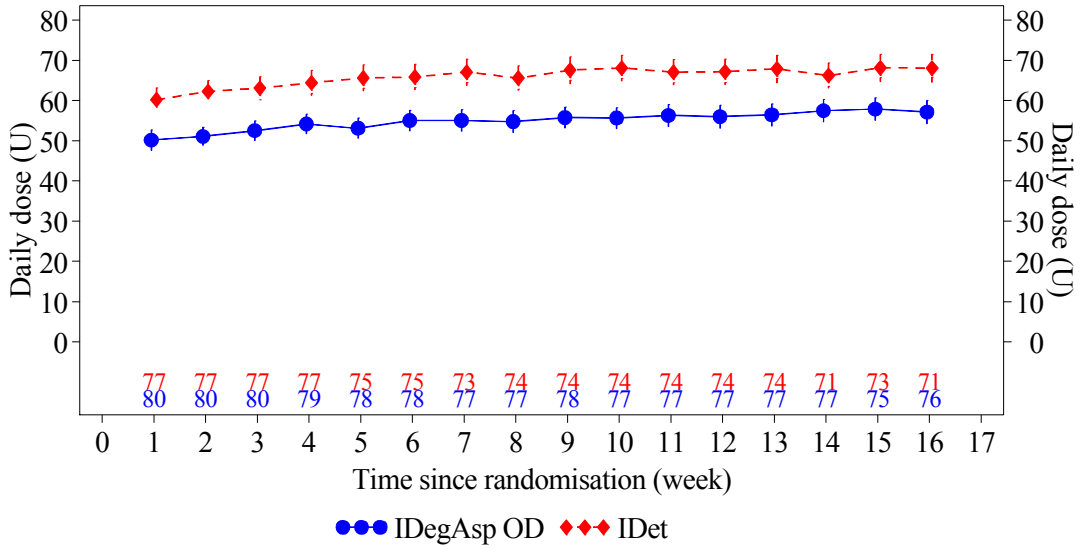
14.2.119 Total daily insulin dose (actual) in units by treatment week - mean plot – children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:50 - fmean_numfind_deg_cust.sas/e_tot_dos_d_ac_u_mean_ob_age2_sas.cgm

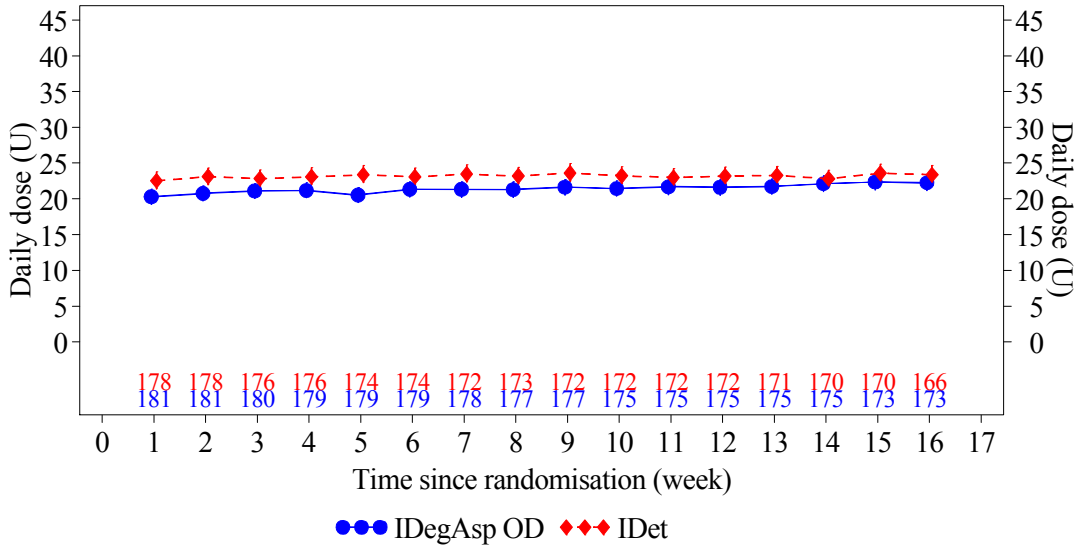
14.2.120 Total daily insulin dose (actual) in units by treatment week - mean plot – children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:50 - fmean_numfind_deg_cust.sas/e_tot_dos_d_ac_u_mean_ob_age3_sas.cgm

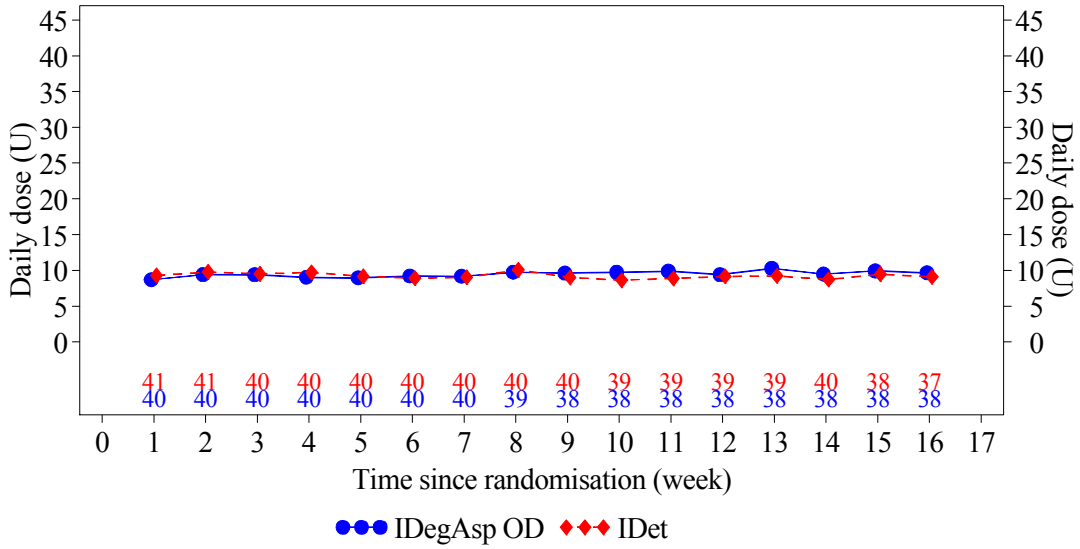
14.2.121 Total daily insulin dose (actual) in units by treatment week - mean plot – adolescents (12-17 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:51 - fmean_numfind_deg_cust.sas/e_tot_b_dos_d_ac_u_mean_ob_sas.cgm

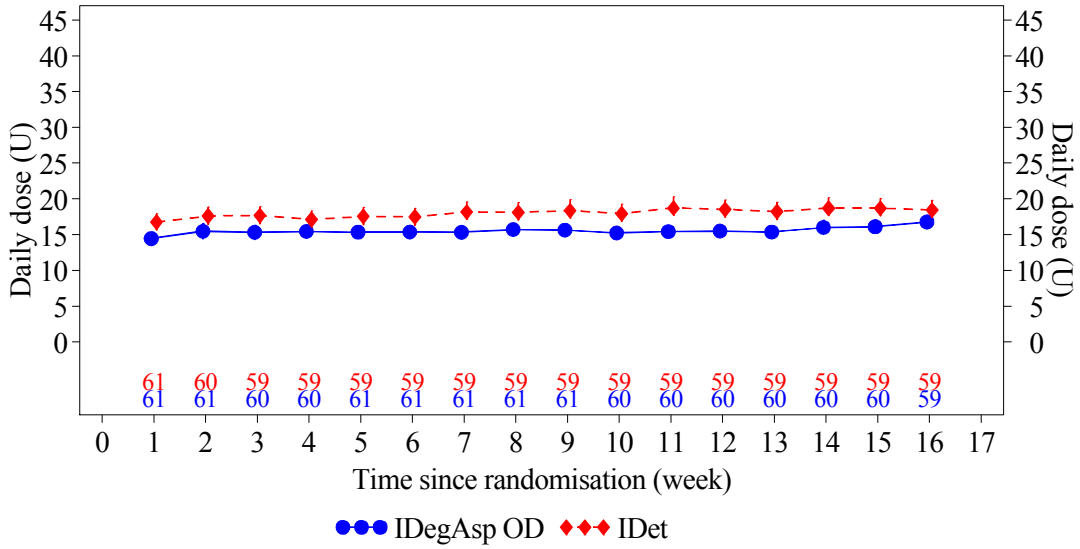
14.2.122 Total bolus daily insulin dose (actual) in units by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:51 - fmean_numfind_deg_cust.sas/e_tot_b_dos_d_ac_u_mean_ob_a1_sas.cgm

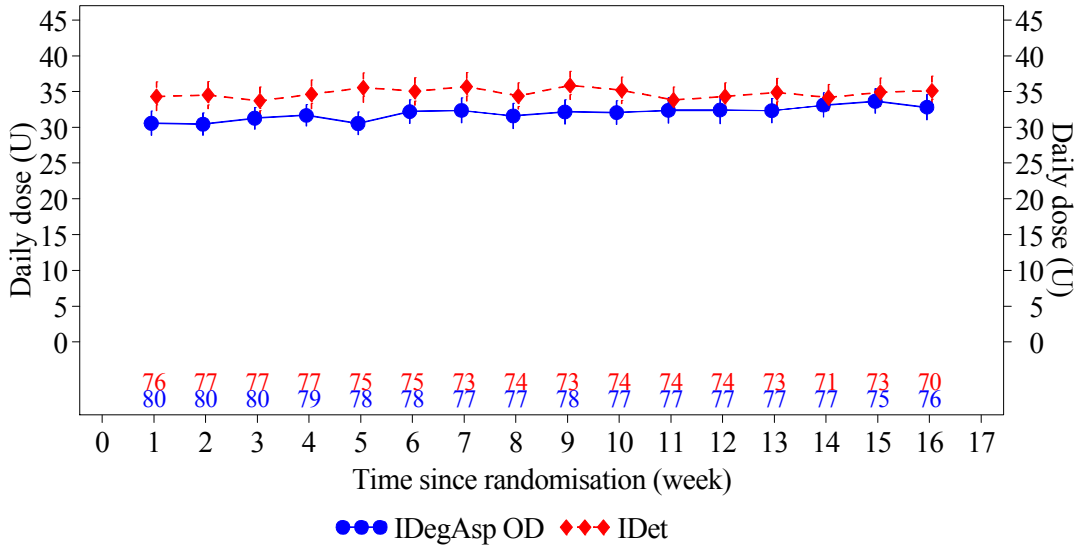
14.2.123 Total bolus daily insulin dose (actual) in units by treatment week - mean plot - children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:51 - fmean_numfind_deg_cust.sas/e_tot_b_dos_d_ac_u_mean_ob_a2_sas.cgm

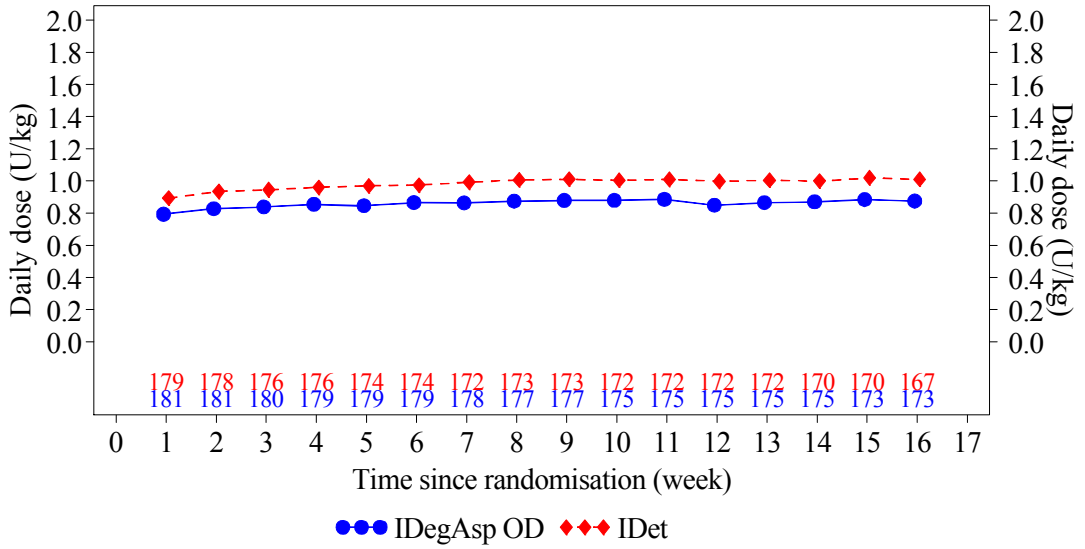
14.2.124 Total bolus daily insulin dose (actual) in units by treatment week - mean plot - children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:51 - fmean_numfind_deg_cust.sas/e_tot_b_dos_d_ac_u_mean_ob_a3_sas.cgm

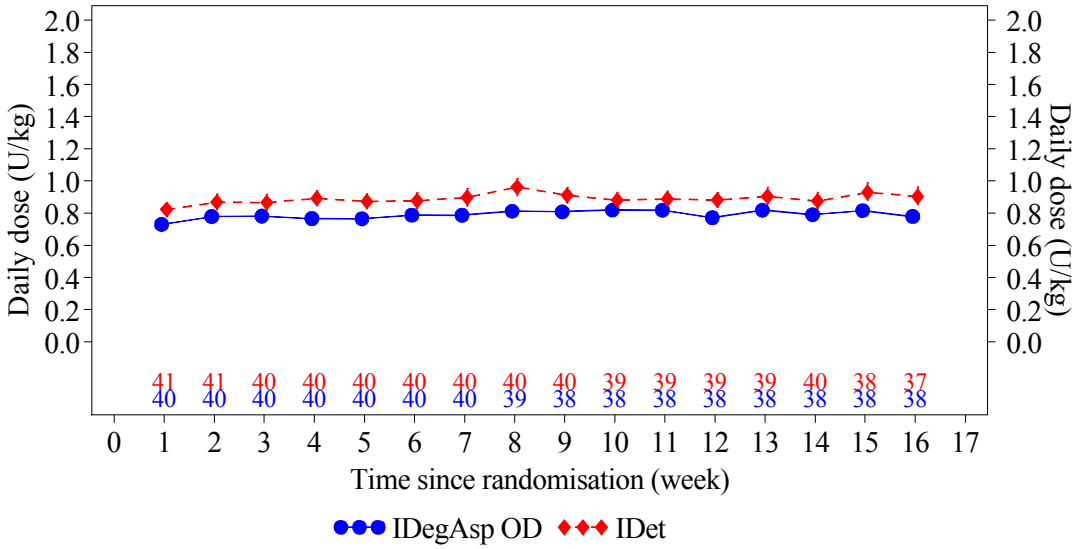
14.2.125 Total bolus daily insulin dose (actual) in units by treatment week - mean plot - adolescents (12-17 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:40:58 - fmean_numfind_deg_cust.sas/e_t_dos_d_at_ukg_mean_ob_sas.cgm

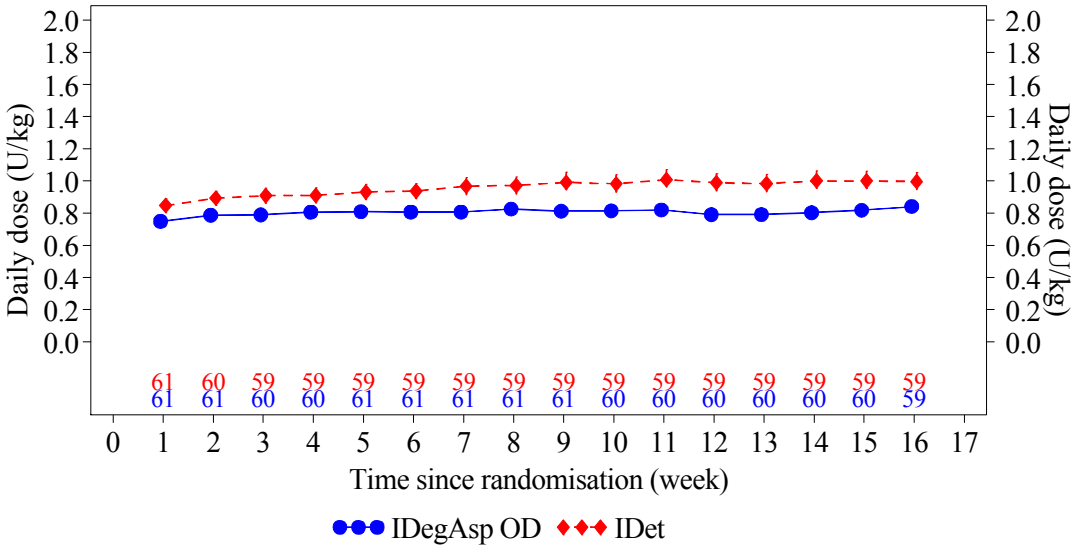
14.2.126 Total daily insulin dose (actual) in units/kg by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:00 - fmean_numfind_deg_cust.sas/e_t_dos_d_ac_ukg_mean_ob_age1_sas.cgm

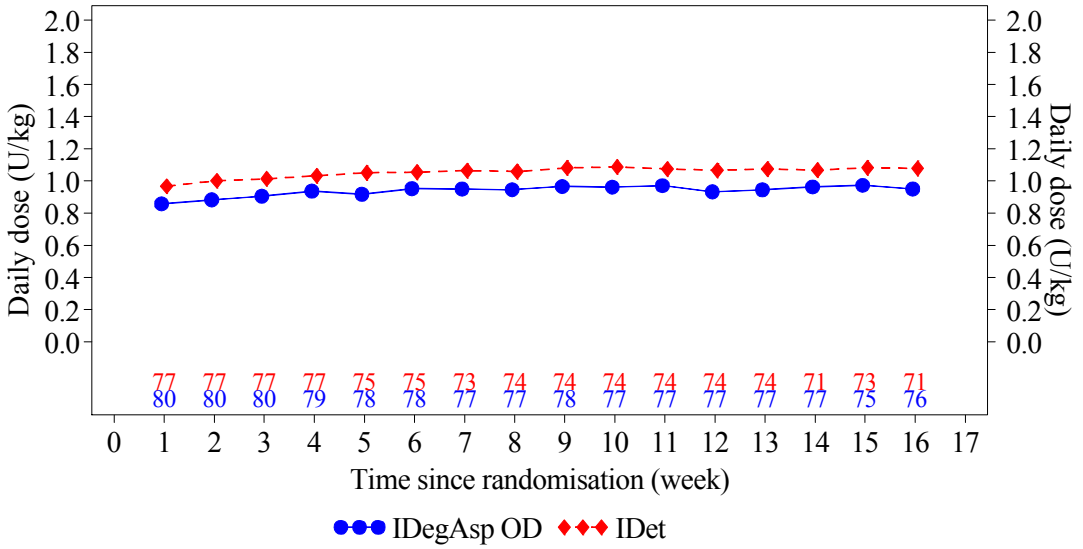
14.2.127 Total daily insulin dose (actual) in units/kg by treatment week - mean plot – children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:01 - fmean_numfind_deg_cust.sas/e_t_dos_d_ac_ukg_mean_ob_age2_sas.cgm

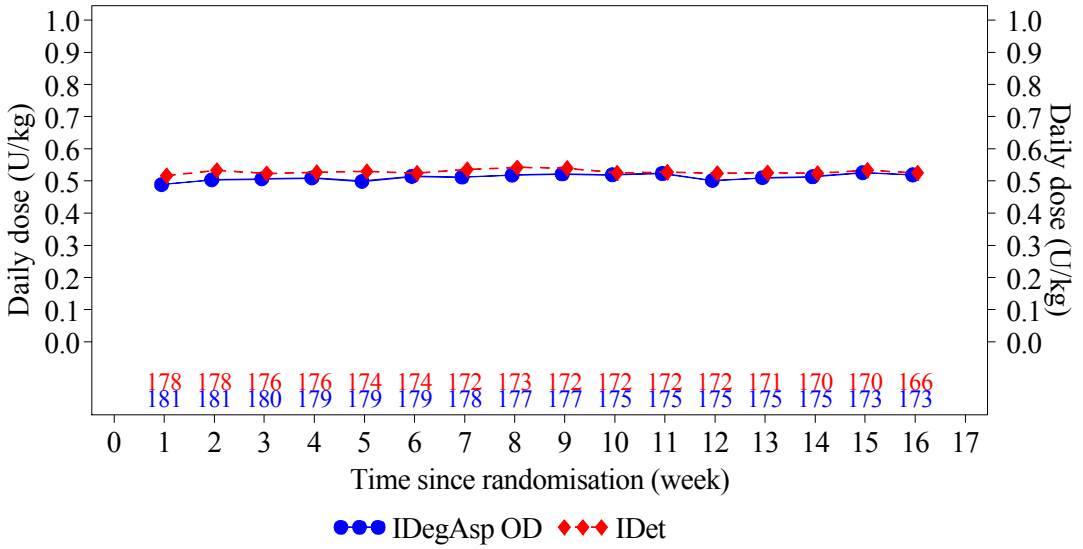
14.2.128 Total daily insulin dose (actual) in units/kg by treatment week - mean plot – children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:01 - fmean_numfind_deg_cust.sas/e_t_dos_d_ac_ukg_mean_ob_age3_sas.cgm

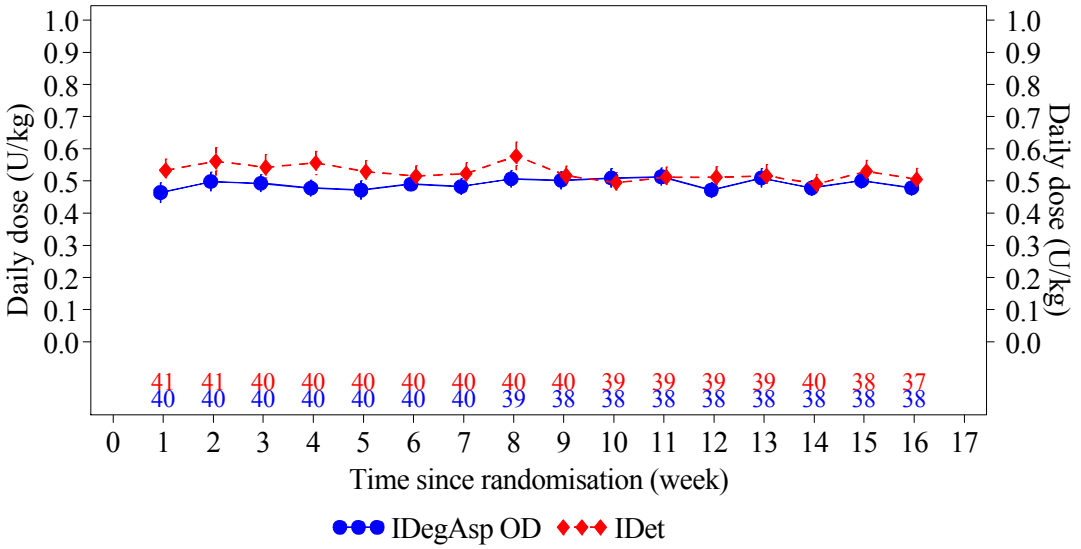
14.2.129 Total daily insulin dose (actual) in units/kg by treatment week - mean plot – adolescents (12-17 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:01 - fmean_numfind_deg_cust.sas/e_tot_b_dos_d_ac_ukg_mean_ob_sas.cgm

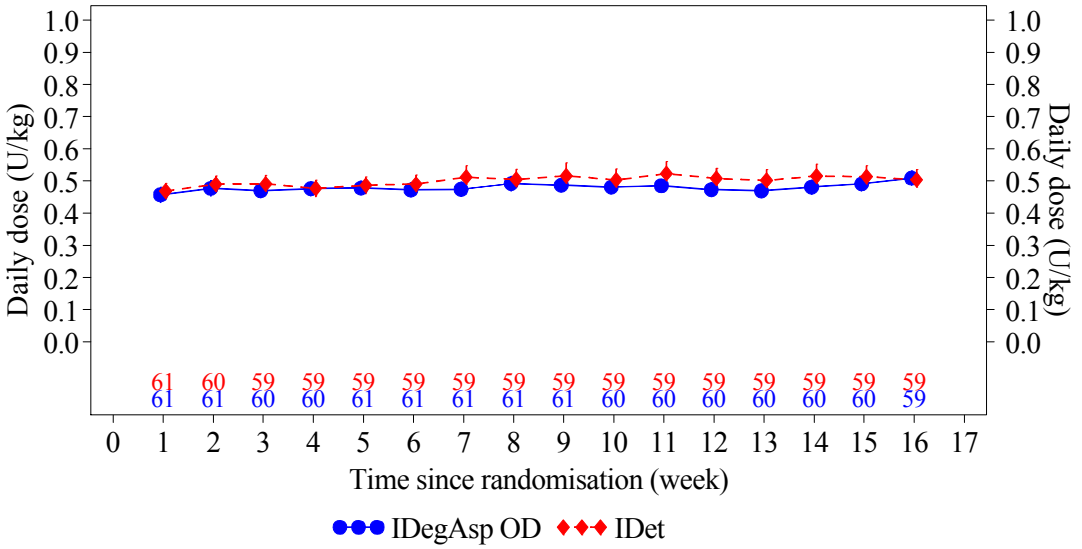
14.2.130 Total bolus daily insulin dose (actual) in units/kg by treatment week - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:01 - fmean_numfind_deg_cust.sas/e_tot_b_d_d_ac_ukg_mean_ob_a1_sas.cgm

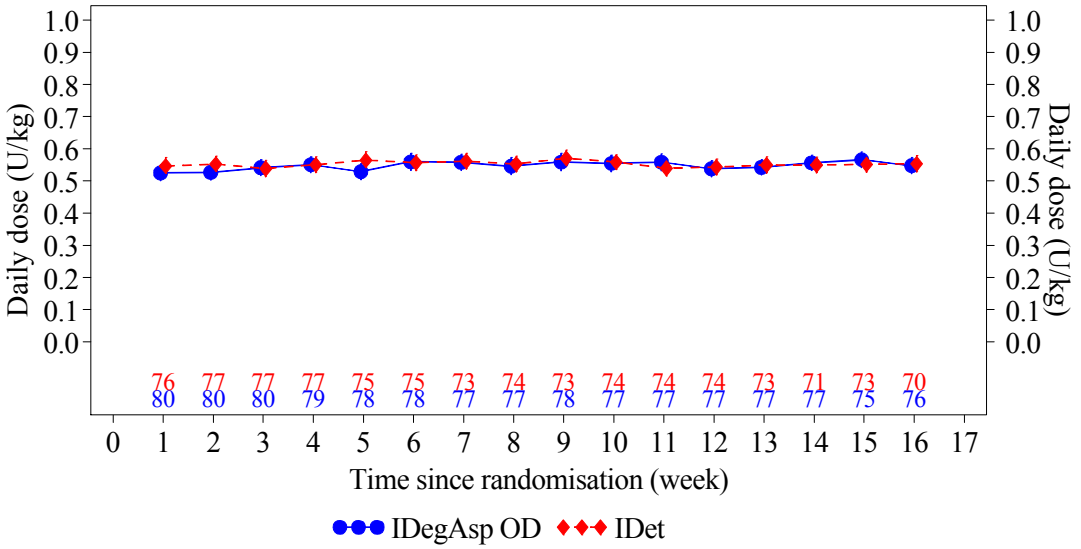
14.2.131 Total bolus daily insulin dose (actual) in units/kg by treatment week - mean plot- children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:02 - fmean_numfind_deg_cust.sas/e_tot_b_d_d_ac_ukg_mean_ob_a2_sas.cgm

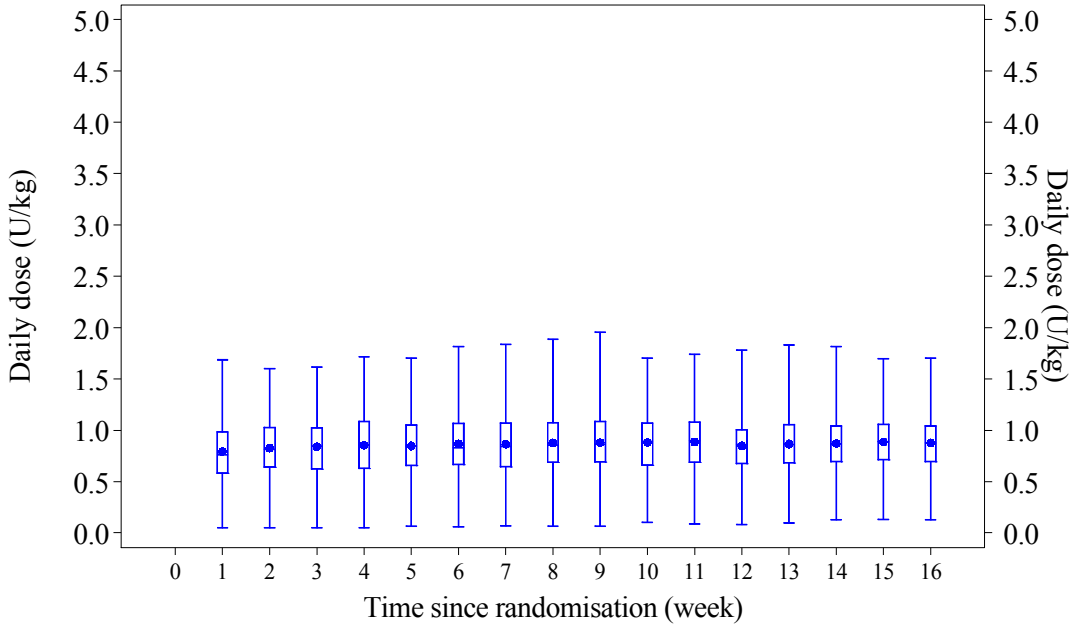
14.2.132 Total bolus daily insulin dose (actual) in units/kg by treatment week - mean plot- children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:01 - fmean_numfind_deg_cust.sas/e_tot_b_d_d_ac_ukg_mean_ob_a3_sas.cgm

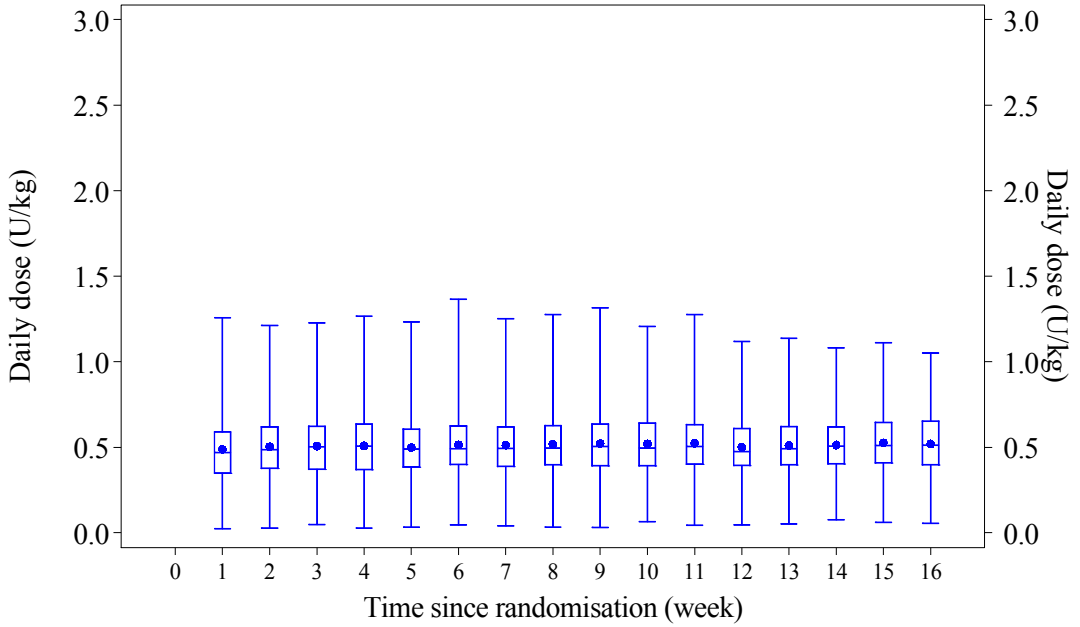
14.2.133 Total bolus daily insulin dose (actual) in units/kg by treatment week - mean plot- adolescents (12-17 years) - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:07 - fbox_numfind_v02.sas/e_tot_d_iv1_act_ukg_box_obs_sas.cgm

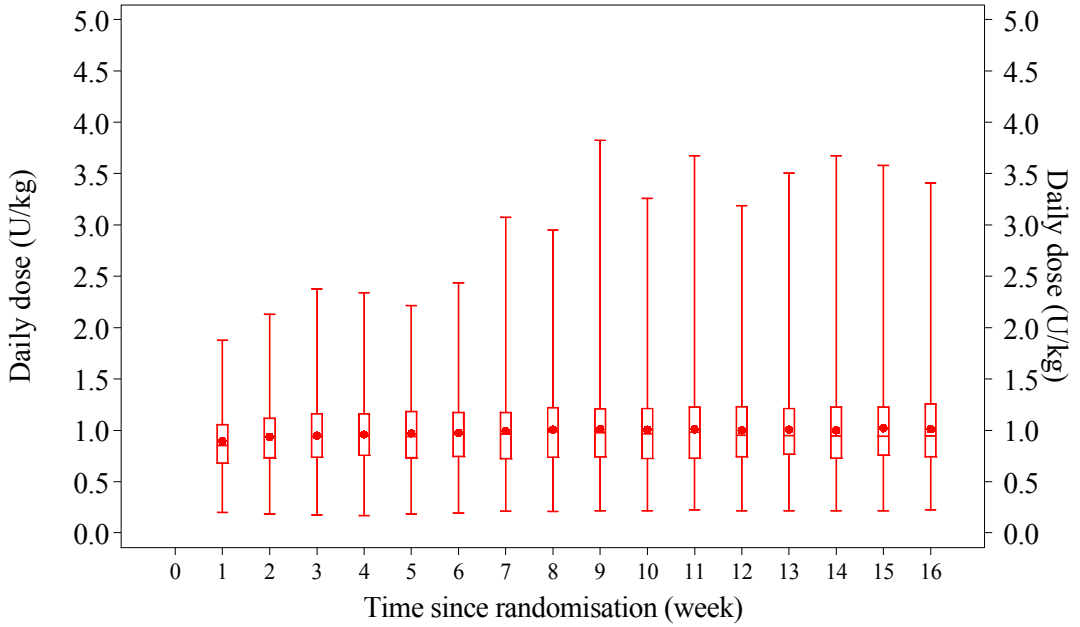
14.2.134 Total daily insulin dose (actual) in units/kg by treatment week – IDegAsp OD - box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:08 - fbox_numfind_v02.sas/e_tbolus_d_inv1_act_ukg_box_obs_sas.cgm

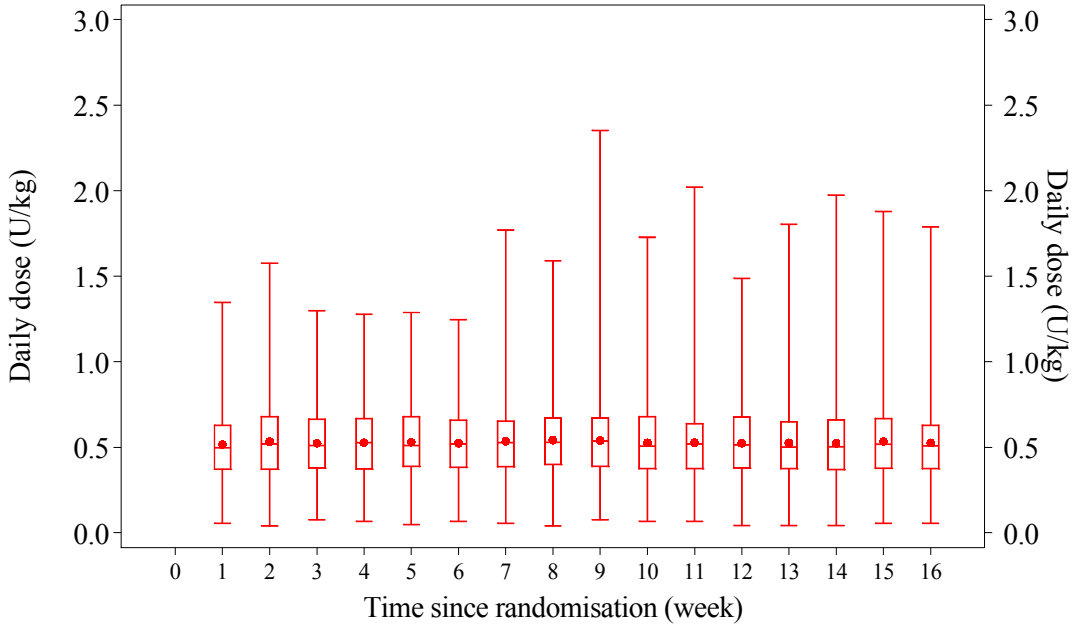
14.2.135 Total bolus daily insulin dose (actual) in units/kg by treatment week – box plot - IDegAsp OD - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:11 - fbox_numfind_v02.sas/e_tot_d_cm_act_ukg_box_obs_sas.cgm

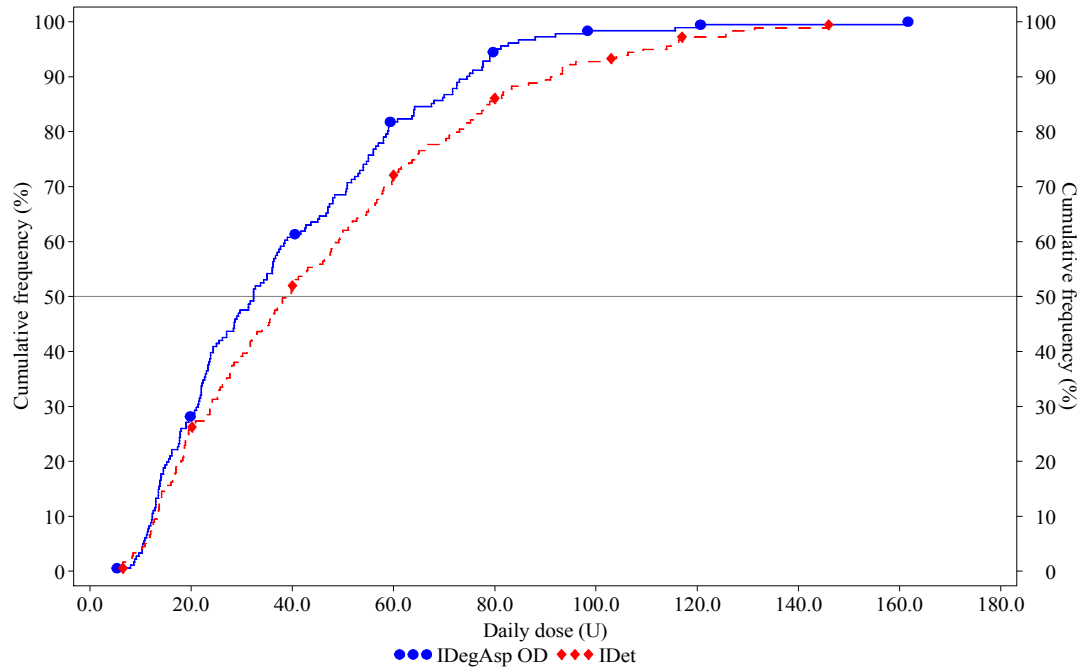
14.2.136 Total daily insulin dose (actual) in units/kg by treatment week – IDet - box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:11 - fbox_numfind_v02.sas/e_tbolus_d_com_act_ukg_box_obs_sas.cgm

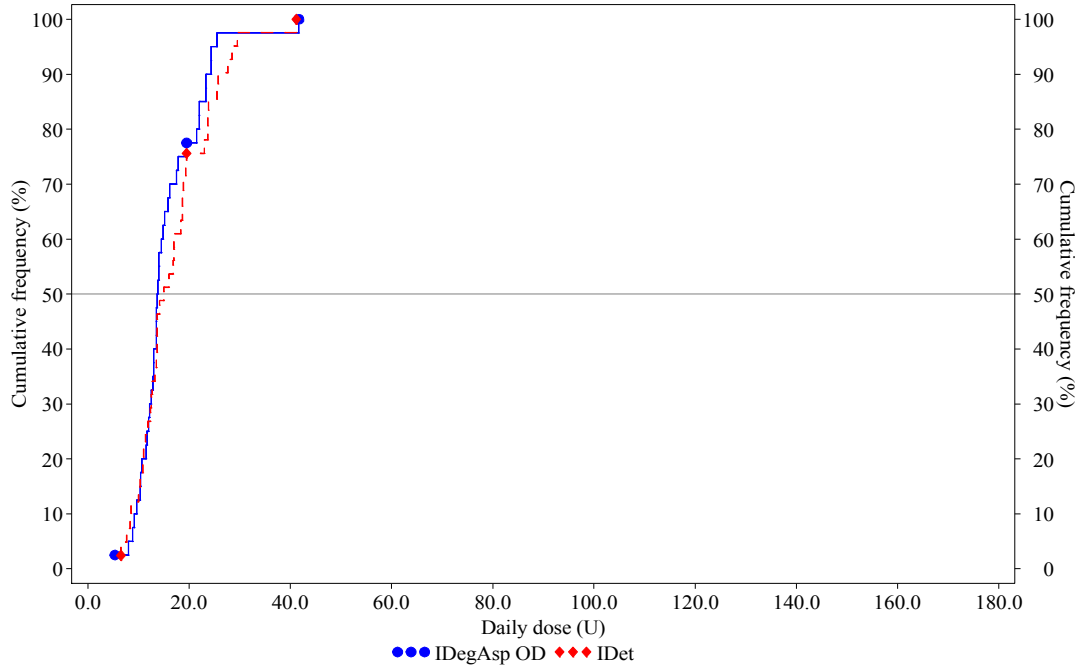
14.2.137 Total bolus daily insulin dose (actual) in units/kg by treatment week – box plot - IDet - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:12 - fedist_numfind_v01.sas/e_tot_d_act_u_cdf_pred_sas.cgm

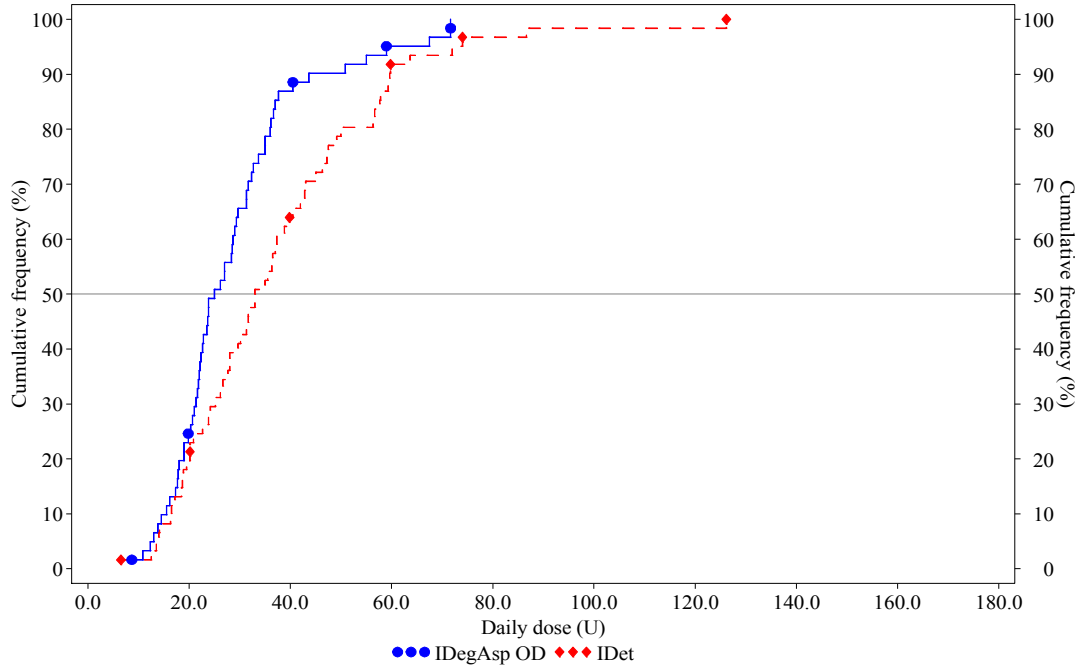
14.2.138 Total daily insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:12 - fedist_numfind_v01.sas/e_tot_d_act_u_cdf_pred_age1_sas.cgm

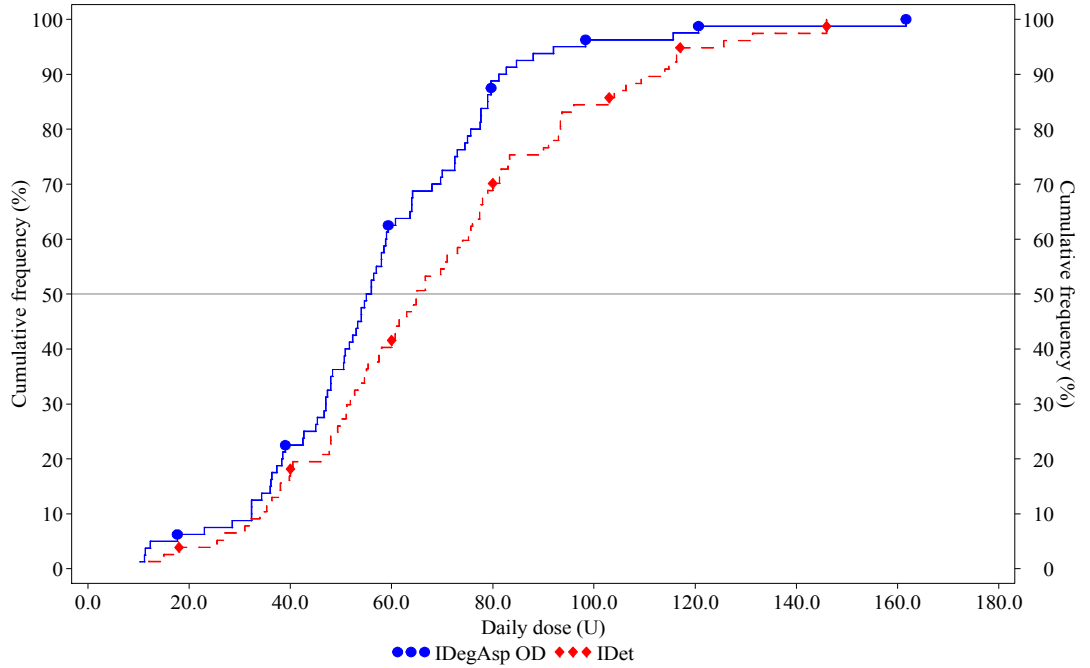
14.2.139 Total daily insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:12 - fedist_numfind_v01.sas/e_tot_d_act_u_cdf_pred_age2_sas.cgm

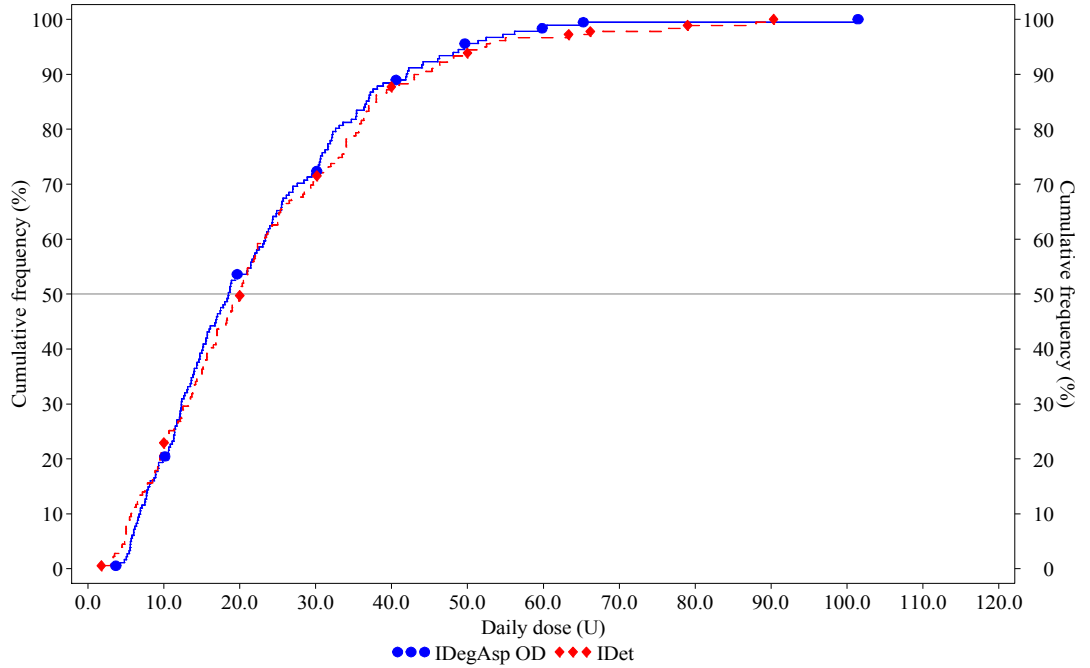
14.2.140 Total daily insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:11 - fedist_numfind_v01.sas/e_tot_d_act_u_cdf_pred_age3_sas.cgm

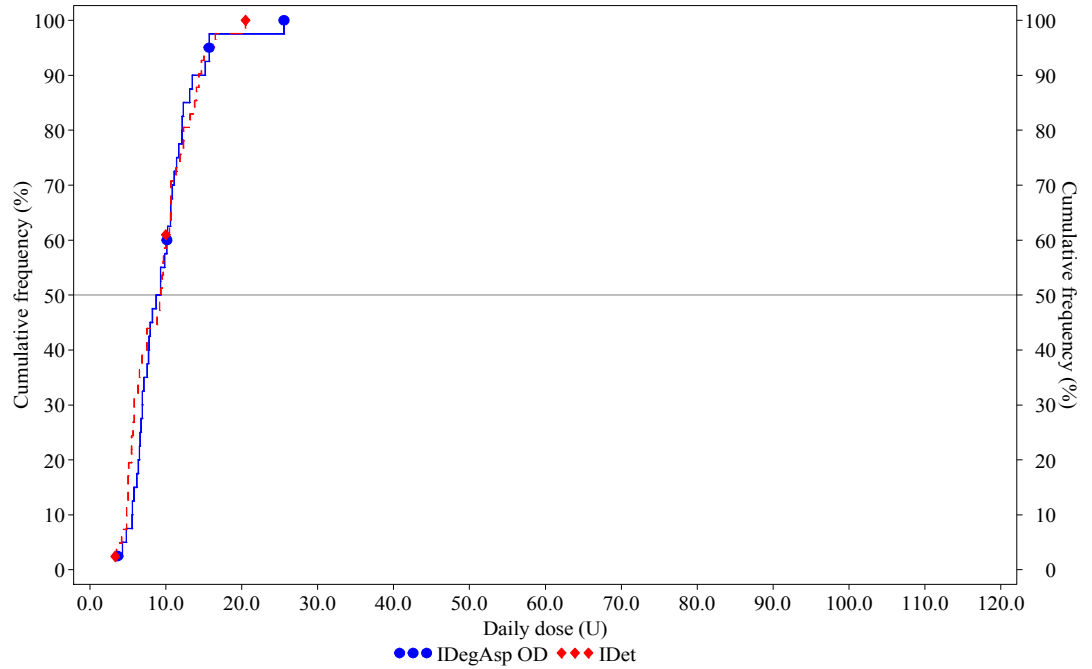
14.2.141 Total daily insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - adolescents (12-17 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:15 - fedist_numfind_v01.sas/e_tot_d_d_act_u_cdf_pred_sas.cgm

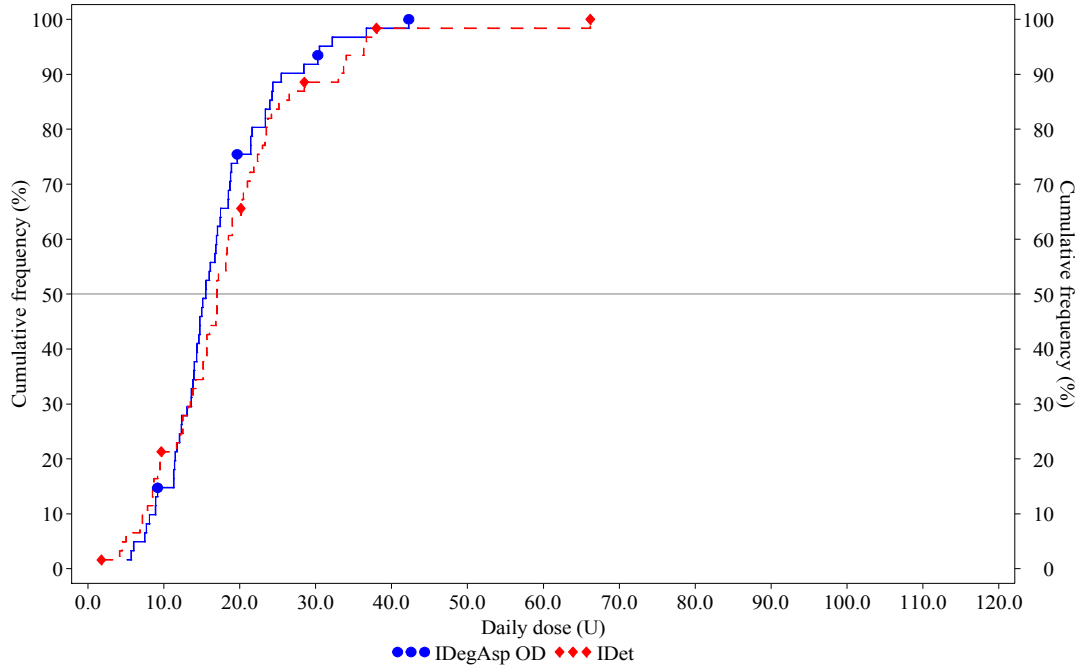
14.2.142 Total bolus daily insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:16 - fedist_numfind_v01.sas/e_tot_d_d_act_u_cdf_pred_a1_sas.cgm

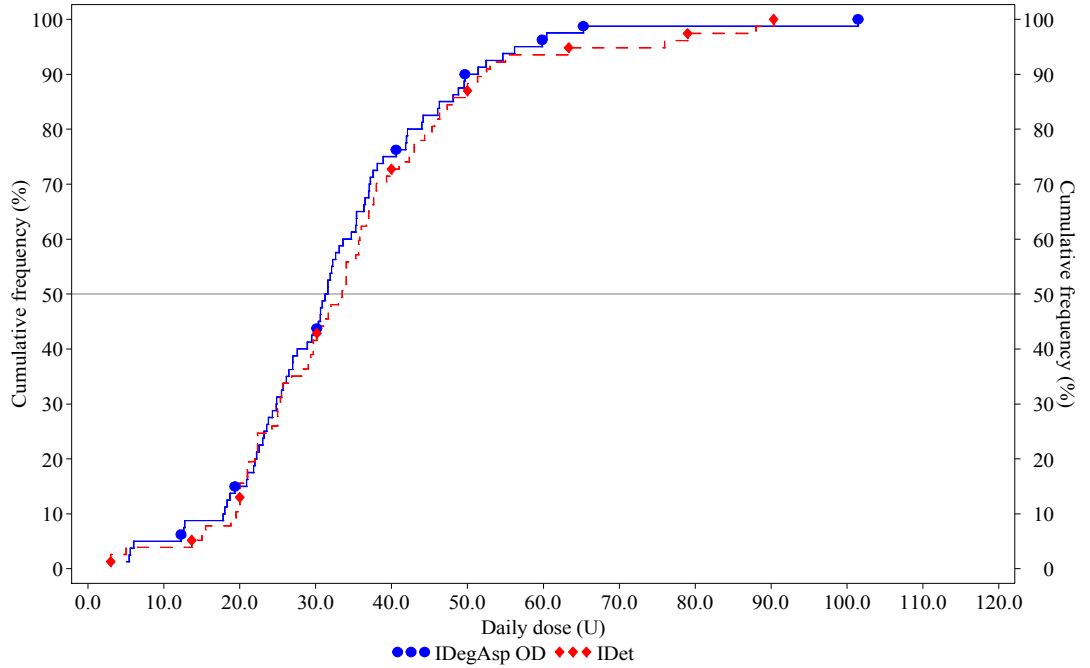
14.2.143 Total bolus daily insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot- children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:21 - fedist_numfind_v01.sas/e_tot_d_d_act_u_cdf_pred_a2_sas.cgm

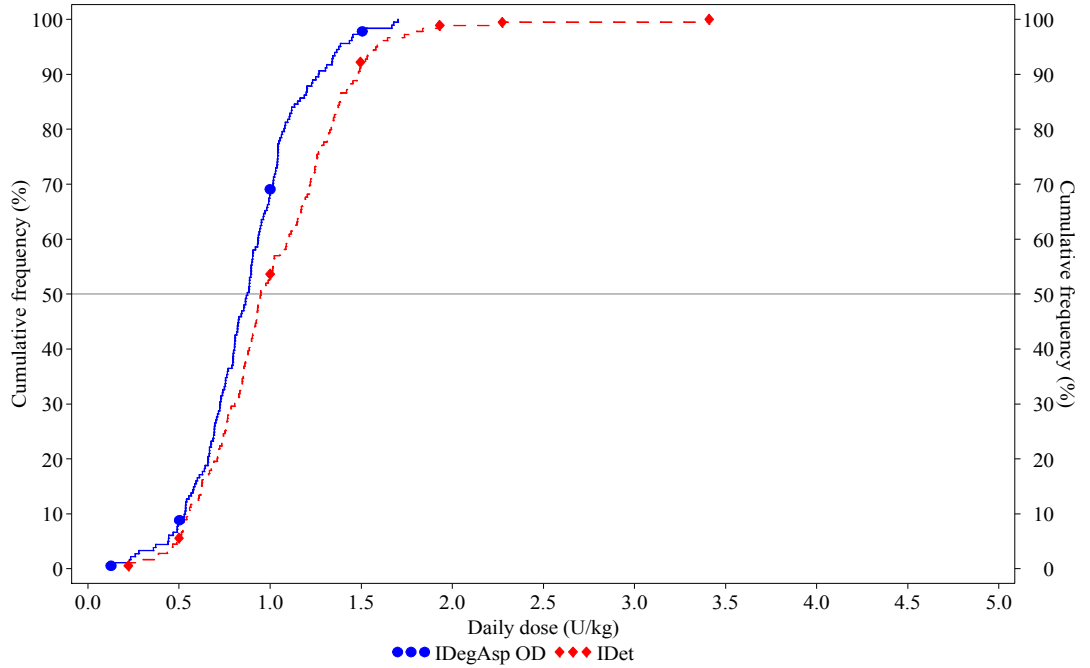
14.2.144 Total bolus daily insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot- children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:22 - fedist_numfind_v01.sas/e_tot_d_d_act_u_cdf_pred_a3_sas.cgm

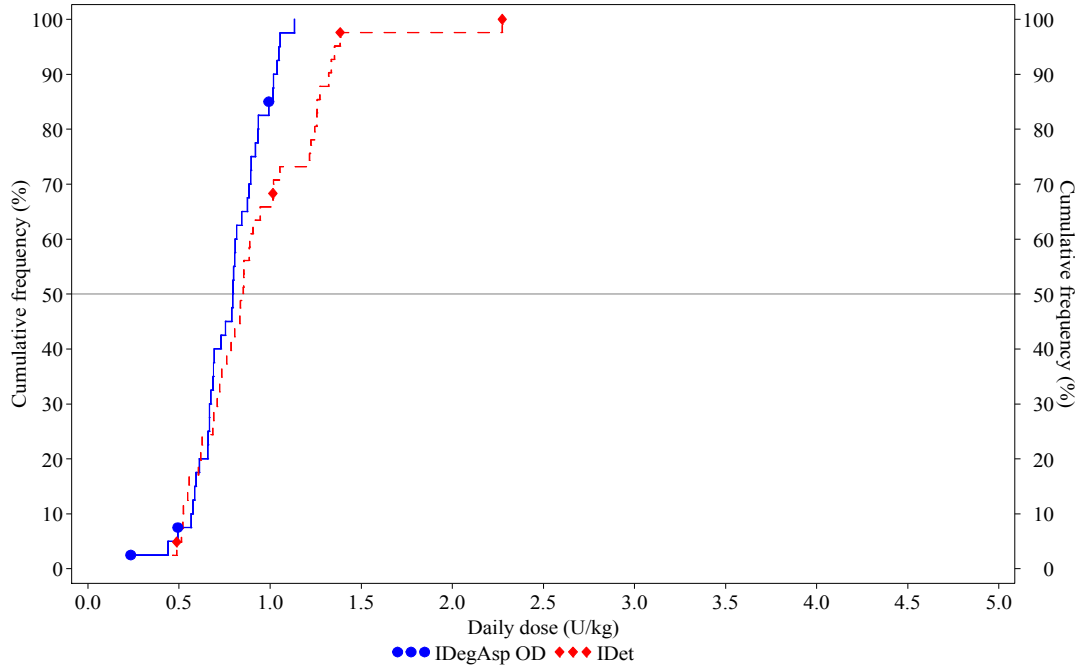
14.2.145 Total bolus daily insulin dose (actual) in units after 16 weeks of treatment - empirical distribution plot- adolescents (12-17 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:22 - fedist_numfind_v01.sas/e_tot_d_act_ukg_cdf_pred_sas.cgm

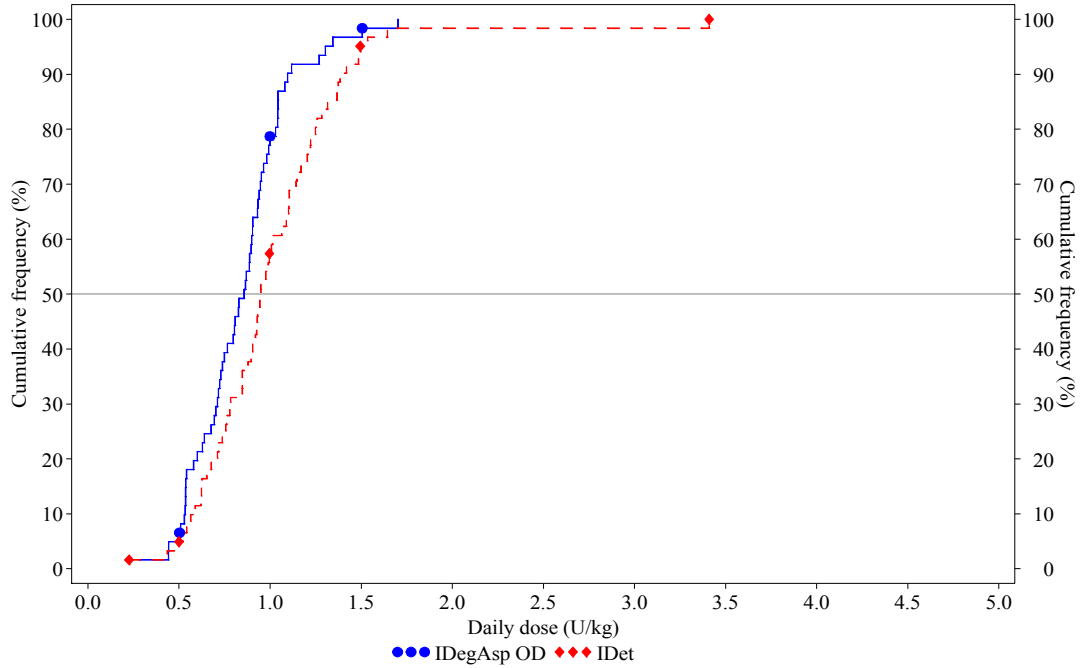
14.2.146 Total daily insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:21 - fedist_numfind_v01.sas/e_tot_d_act_ukg_cdf_pred_age1_sas.cgm

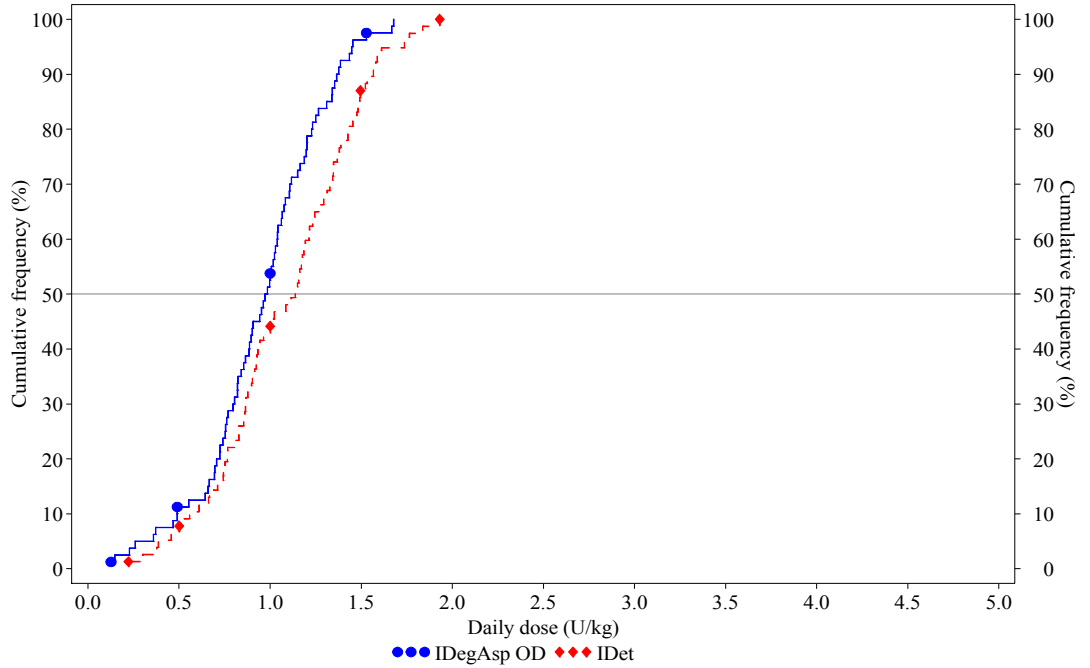
14.2.147 Total daily insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:22 - fedist_numfind_v01.sas/e_tot_d_act_ukg_cdf_pred_age2_sas.cgm

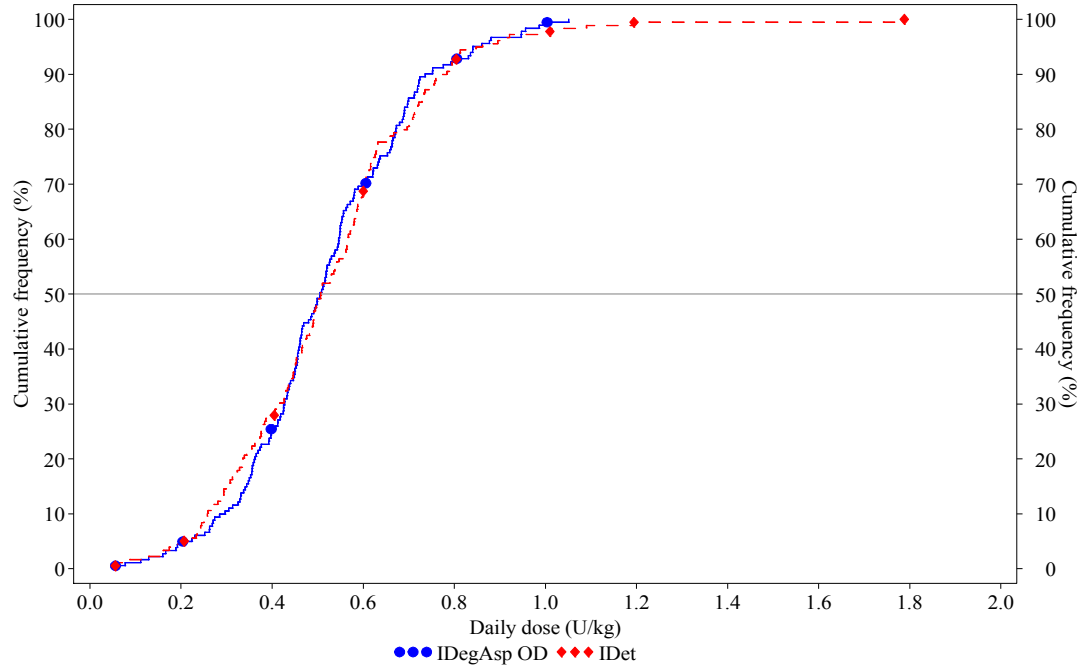
14.2.148 Total daily insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:22 - fedist_numfind_v01.sas/e_tot_d_act_ukg_cdf_pred_age3_sas.cgm

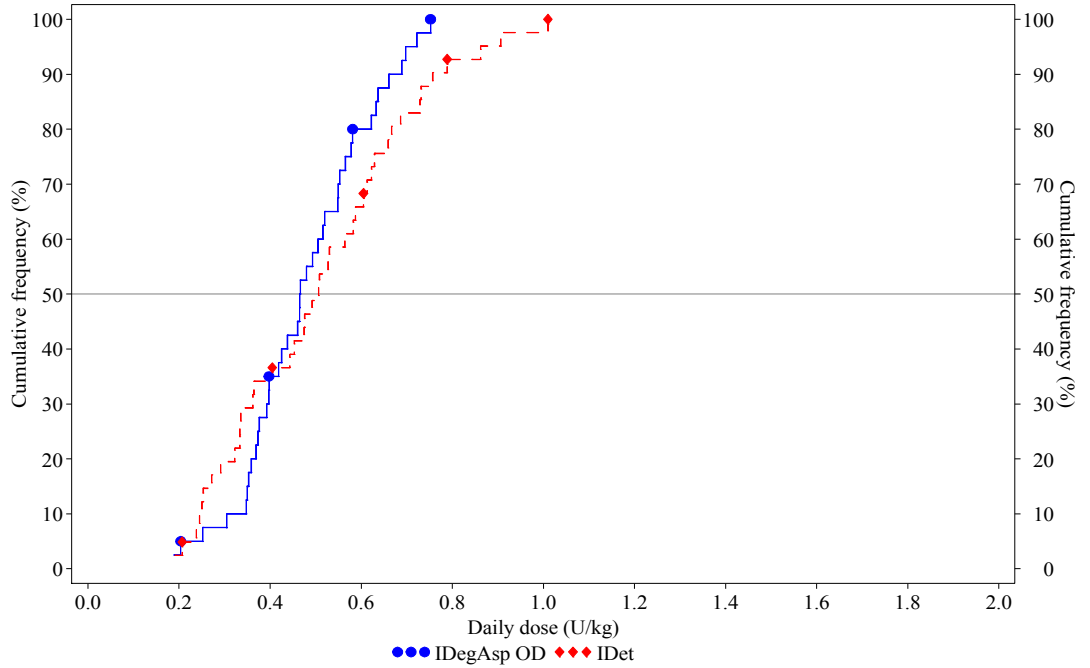
14.2.149 Total daily insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - adolescents (12-17 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:24 - fedist_numfind_v01.sas/e_tot_d_d_act_ukg_cdf_pred_sas.cgm

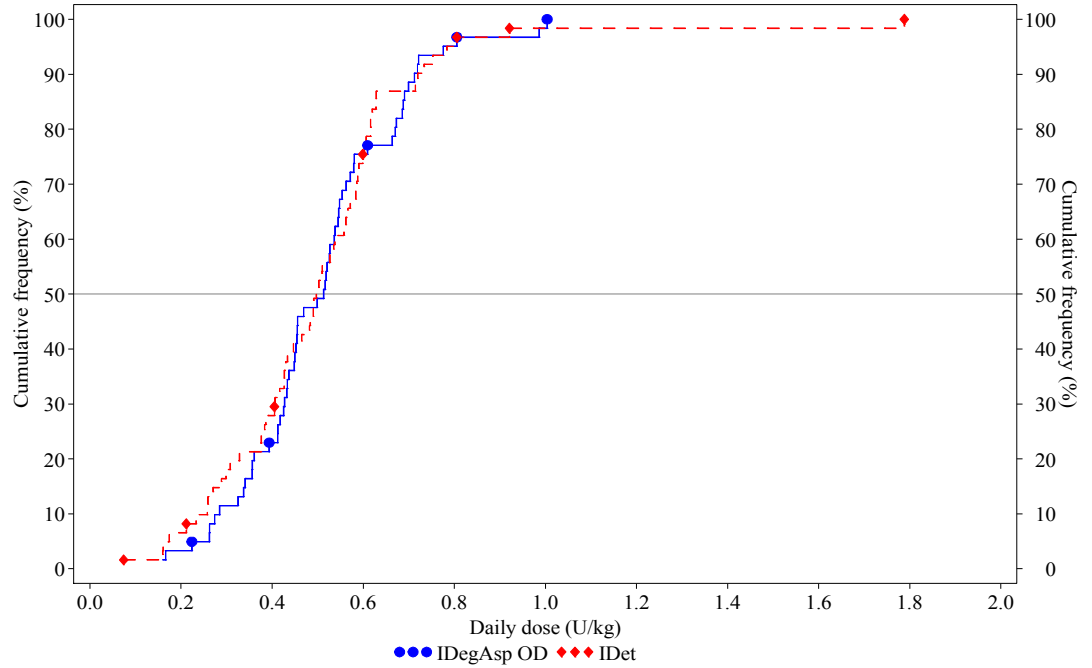
14.2.150 Total bolus daily insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:25 - fedist_numfind_v01.sas/e_tot_d_d_act_ukg_cdf_pred_a1_sas.cgm

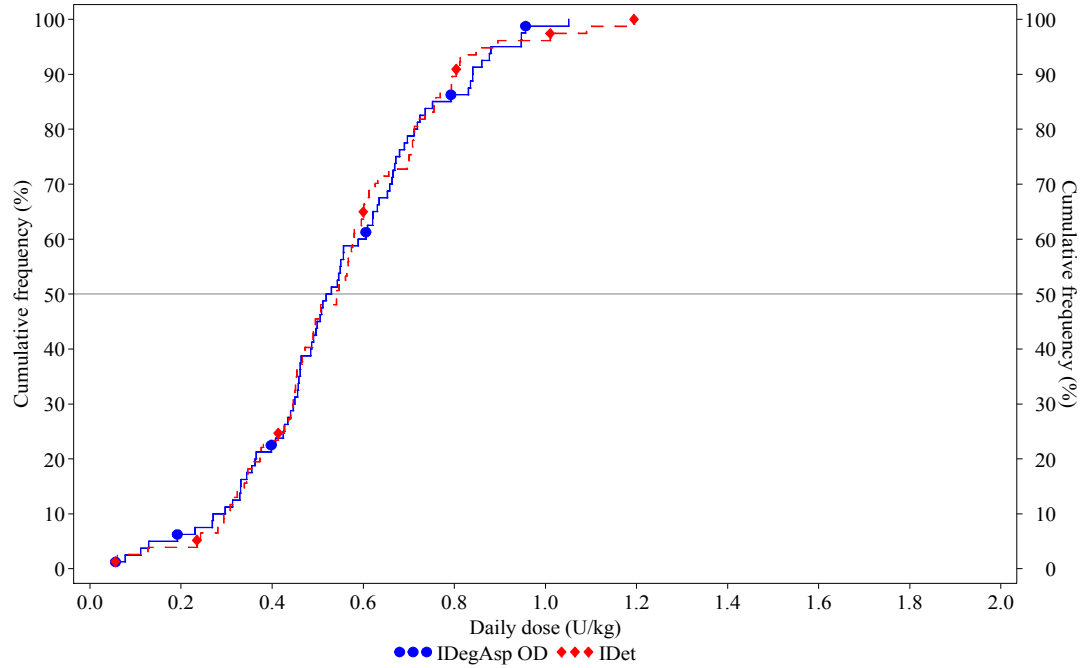
14.2.151 Total bolus daily insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot- children (1-5 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:30 - fedist_numfind_v01.sas/e_tot_d_d_act_ukg_cdf_pred_a2_sas.cgm

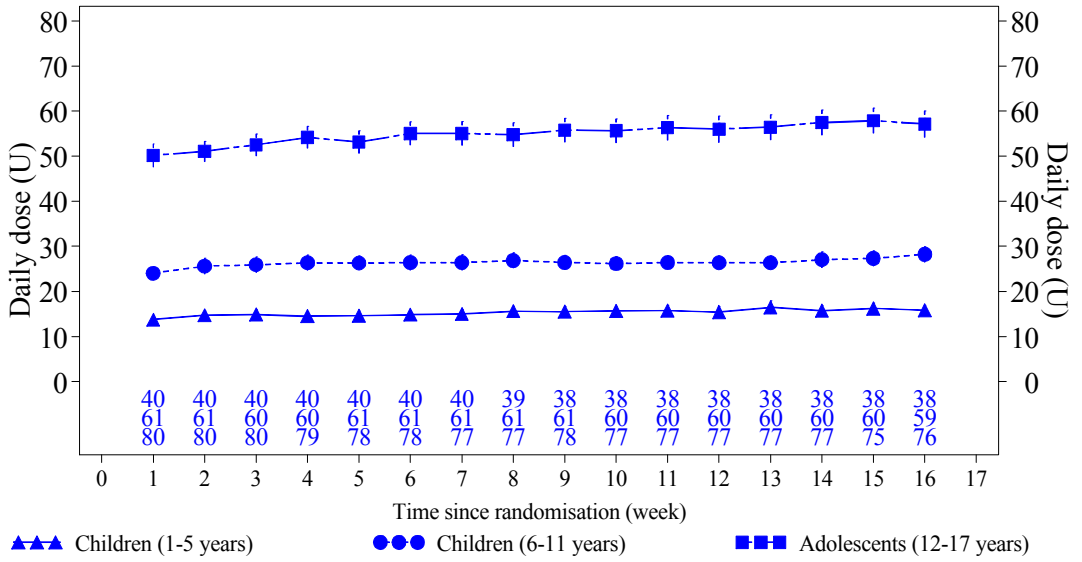
14.2.152 Total bolus daily insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot- children (6-11 years) - safety analysis set



SAFETY; Observed data
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:41:32 - fedist_numfind_v01.sas/e_tot_d_d_act_ukg_cdf_pred_a3_sas.cgm

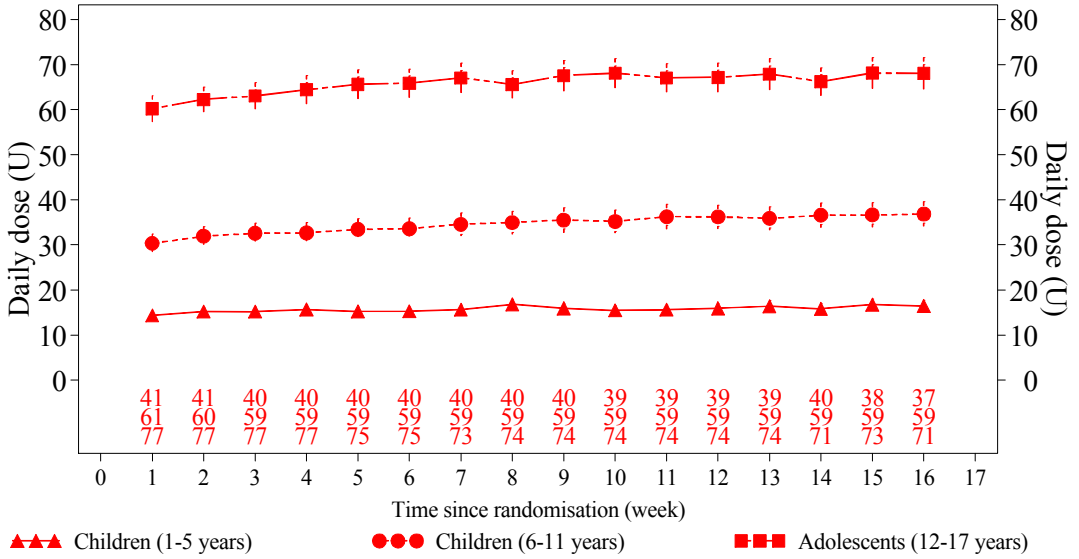
14.2.153 Total bolus daily insulin dose (actual) in units/kg after 16 weeks of treatment - empirical distribution plot- adolescents (12-17 years) - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:17 - dose_fplot_treatment_age.sas/e_tot_dos_d_u_ideg_sas.cgm

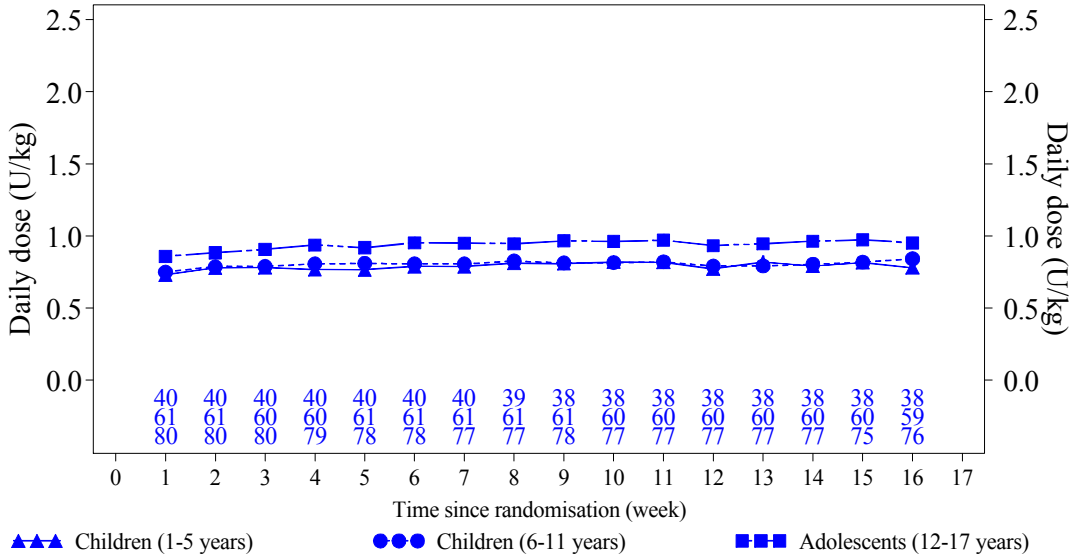
14.2.154 Total daily insulin dose (actual) in units by treatment week - mean plot – IDegAsp OD - by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:22 - dose_fplot_treatment_age.sas/e_tot_dos_d_u_idet_sas.cgm

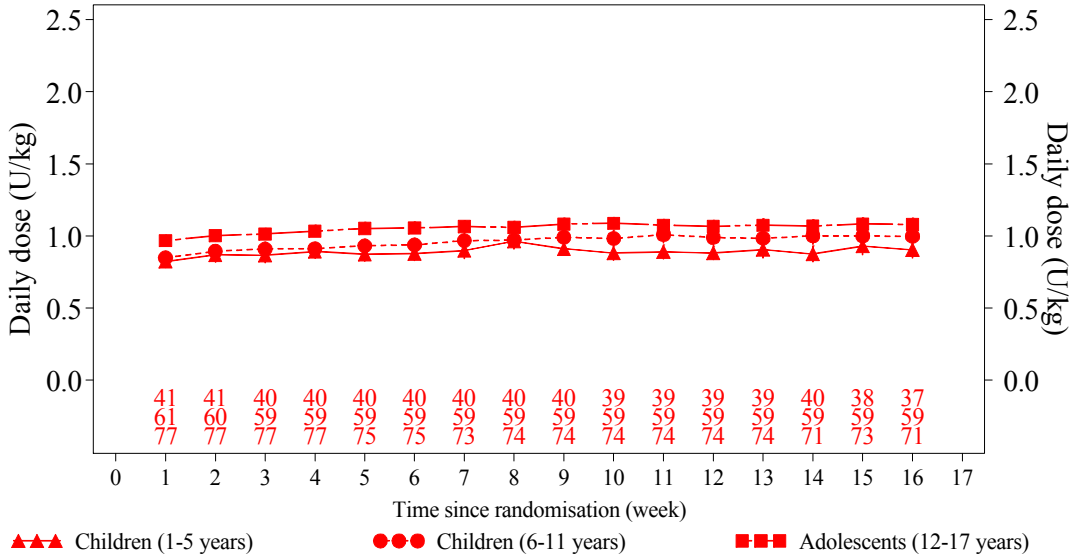
14.2.155 Total daily insulin dose (actual) in units by treatment week - mean plot – IDet - by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:27 - dose_fplot_treatment_age.sas/e_tot_dos_d_ukg_ideg_sas.cgm

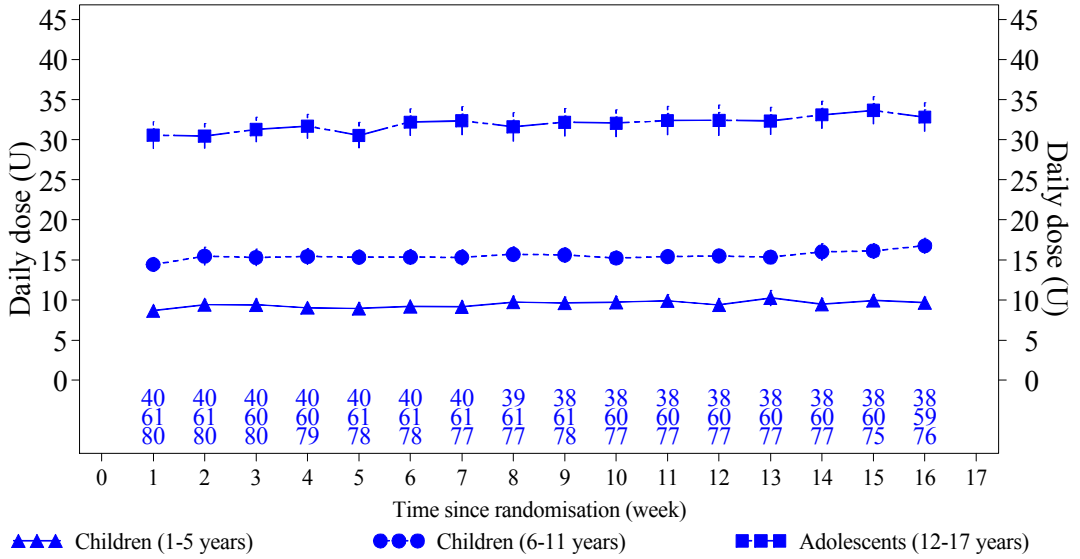
14.2.156 Total daily insulin dose (actual) in units/kg by treatment week - mean plot – IDegAsp OD - by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:09:28:31 - dose_fplot_treatment_age.sas/e_tot_dos_d_ukg_idet_sas.cgm

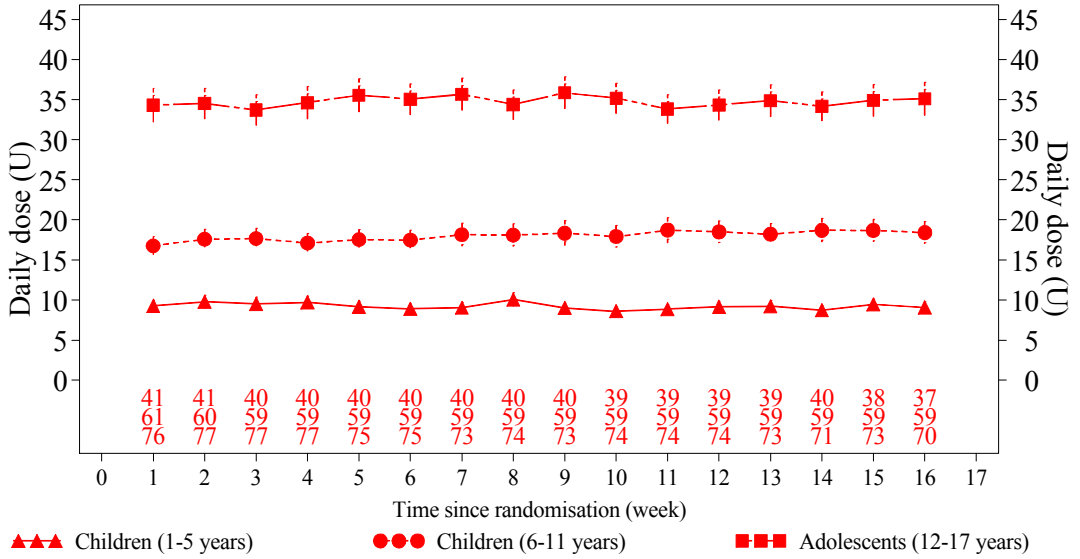
14.2.157 Total daily insulin dose (actual) in units/kg by treatment week - mean plot – IDet - by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:54 - dose_fplot_treatment_age.sas/e_tot_b_dos_d_u_ideg_sas.cgm

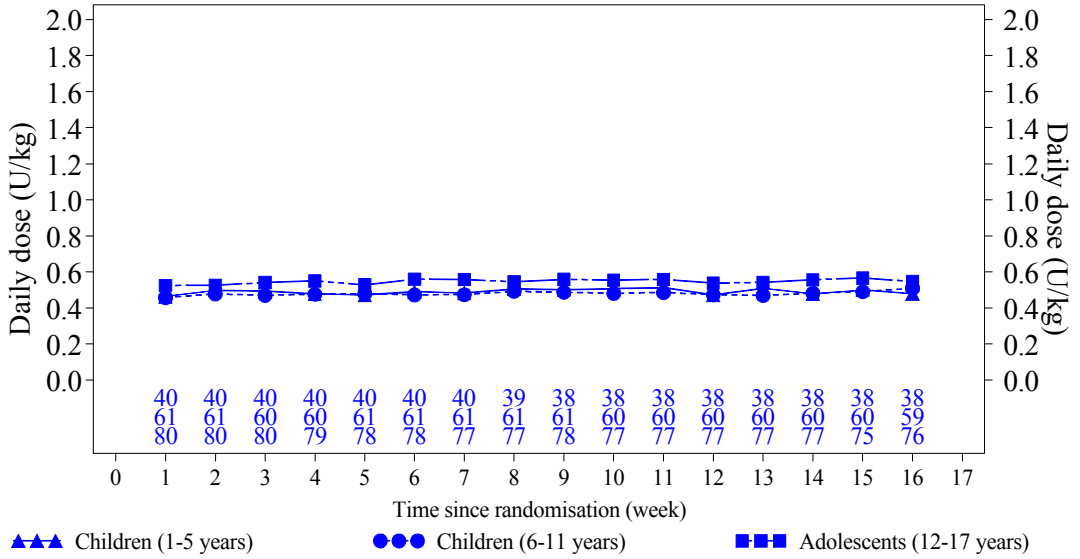
14.2.158 Total bolus daily insulin dose (actual) in units by treatment week - mean plot – IDegAsp OD – by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:58 - dose_fplot_treatment_age.sas/e_tot_b_dos_d_u_idet_sas.cgm

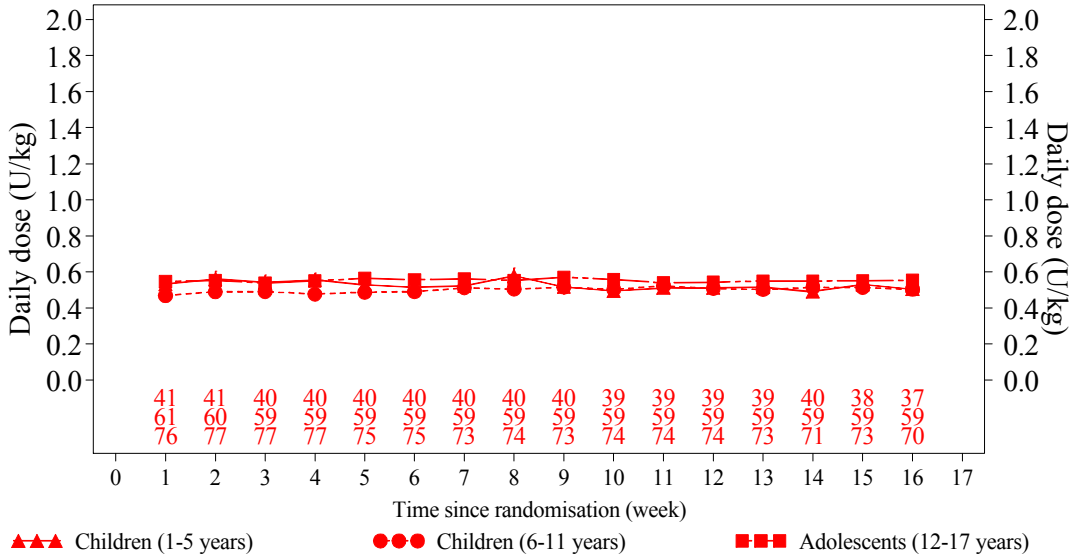
14.2.159 Total bolus daily insulin dose (actual) in units by treatment week - mean plot – IDet – by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:03 - dose_fplot_treatment_age.sas/e_tot_b_dos_d_ukg_ideg_sas.cgm

14.2.160 Total bolus daily insulin dose (actual) in units/kg by treatment week - mean plot – IDegAsp OD – by age group - safety analysis set



SAFETY; Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area; Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:08 - dose_fplot_treatment_age.sas/e_tot_b_dos_d_ukg_idet_sas.cgm

14.2.161 Total bolus daily insulin dose (actual) in units/kg by treatment week - mean plot – IDet – by age group - safety analysis set

14.2.162 Insulin dose ratio (actual) after 16 weeks of treatment - summary – safety analysis set

Treatment Ratio	Mean Ratio (U)	Mean Ratio (U/kg)
Basal insulin dose IDegAsp OD / IDet	0.71	0.72
Total bolus insulin dose IDegAsp OD / IDet	0.95	0.99
Total daily insulin dose IDegAsp OD / IDet	0.83	0.86

Mean ratio is calculated as the ratio between mean doses at last scheduled treatment visit, where missing data have been imputed using predicted values from a MMRM model.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:19 - tsum_dose_ratio.sas/t_ins_dose_ratio_pred_sas.txt

14.2.163 Insulin dose ratio (actual) after 16 weeks of treatment - summary – children (1-5 years) - safety analysis set

Treatment Ratio	Mean Ratio# (U)	Mean Ratio# (U/kg)
Basal insulin dose IDegAsp OD / IDet	0.78	0.72
Total bolus insulin dose IDegAsp OD / IDet	1.04	0.94
Total daily insulin dose IDegAsp OD / IDet	0.94	0.85

Mean ratio is calculated as the ratio between mean doses at last scheduled treatment visit, where missing data have been imputed using predicted values from a MMRM model.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:13 - tsum_dose_ratio_age1.sas/t_ins_dose_ratio_pred_age1_sas.txt

14.2.164 Insulin dose ratio (actual) after 16 weeks of treatment - summary – children (6-11 years) - safety analysis set

Treatment Ratio	Mean Ratio# (U)	Mean Ratio# (U/kg)
Basal insulin dose IDegAsp OD / IDet	0.62	0.67
Total bolus insulin dose IDegAsp OD / IDet	0.92	1.01
Total daily insulin dose IDegAsp OD / IDet	0.77	0.84

Mean ratio is calculated as the ratio between mean doses at last scheduled treatment visit, where missing data have been imputed using predicted values from a MMRM model.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:16 - tsum_dose_ratio_age2.sas/t_ins_dose_ratio_pred_age2_sas.txt

14.2.165 Insulin dose ratio (actual) after 16 weeks of treatment - summary - adolescents (12-17 years) - safety analysis set

Treatment Ratio	Mean Ratio# (U)	Mean Ratio# (U/kg)
Basal insulin dose IDegAsp OD / IDet	0.73	0.76
Total bolus insulin dose IDegAsp OD / IDet	0.95	1.00
Total daily insulin dose IDegAsp OD / IDet	0.84	0.88

Mean ratio is calculated as the ratio between mean doses at last scheduled treatment visit, where missing data have been imputed using predicted values from a MMRM model.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:18 - tsum_dose_ratio_age3.sas/t_ins_dose_ratio_pred_age3_sas.txt

14.2.166 Basal - bolus split of total daily insulin dose (u/kg) - summary - safety analysis set

	IDegAsp OD Basal / Bolus	IDet Basal / Bolus
Visit 3 (Week 1)	39 / 61	43 / 57
Visit 18 (Week 16)	41 / 59	49 / 51

Basal: Percentage basal insulin, Bolus: Percentage bolus insulin
Basal-bolus split is derived from mean doses.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:01 - tsum_bas_bol_dose.sas/t_basal_bolus_mmrm_sas.txt

14.2.167 Basal - bolus split of total daily insulin dose (u/kg) - summary - children (1-5 years) - safety analysis set

	IDegAsp OD Basal / Bolus	IDet Basal / Bolus
Visit 3 (Week 1)	36 / 64	35 / 65
Visit 18 (Week 16)	39 / 61	46 / 54

Basal: Percentage basal insulin, Bolus: Percentage bolus insulin
Basal-bolus split is derived from mean doses.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:03 - tsum_bas_bol_dose_age1.sas/t_basal_bolus_mmrm_age1_sas.txt

14.2.168 Basal - bolus split of total daily insulin dose (u/kg) - summary - children (6-11 years) - safety analysis set

	IDegAsp OD Basal / Bolus	IDet Basal / Bolus
Visit 3 (Week 1)	39 / 61	45 / 55
Visit 18 (Week 16)	40 / 60	50 / 50

Basal: Percentage basal insulin, Bolus: Percentage bolus insulin
Basal-bolus split is derived from mean doses.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:05 - tsum_bas_bol_dose_age2.sas/t_basal_bolus_mmrm_age2_sas.txt

14.2.169 Basal - bolus split of total daily insulin dose (u/kg) - summary - adolescents (12-17 years) - safety analysis set

	IDegAsp OD Basal / Bolus	IDet Basal / Bolus
Visit 3 (Week 1)	39 / 61	44 / 56
Visit 18 (Week 16)	43 / 57	50 / 50

Basal: Percentage basal insulin, Bolus: Percentage bolus insulin
Basal-bolus split is derived from mean doses.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:07 - tsum_bas_bol_dose_age3.sas/t_basal_bolus_mmrm_age3_sas.txt

14.2.170 Prescribed minus actual daily insulin dose in units by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Prescrib Compliance(U)			
Visit 3 (Week 1)			
N	181	178	359
Mean (SD)	0.1 (1.7)	-0.1 (1.2)	-0.0 (1.5)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 21.0	-7.7 ; 7.0	-7.7 ; 21.0
Visit 4 (Week 2)			
N	180	176	356
Mean (SD)	0.0 (0.8)	0.2 (2.3)	0.1 (1.7)
Median	0.0	0.0	0.0
Min ; Max	-4.0 ; 6.0	-5.0 ; 20.0	-5.0 ; 20.0
Visit 5 (Week 3)			
N	179	175	354
Mean (SD)	-0.0 (0.5)	0.3 (2.4)	0.1 (1.7)
Median	0.0	0.0	0.0
Min ; Max	-5.0 ; 2.0	-4.0 ; 20.0	-5.0 ; 20.0
Visit 6 (Week 4)			
N	179	174	353
Mean (SD)	-0.0 (0.6)	0.1 (2.0)	0.1 (1.5)
Median	0.0	0.0	0.0
Min ; Max	-3.0 ; 3.0	-5.3 ; 24.0	-5.3 ; 24.0

N: Number of subjects, SD: Standard deviation

Prescribed minus actual daily insulin dose in units by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Prescrib Compliance(U)			
Visit 7 (Week 5)			
N	178	174	352
Mean (SD)	0.1 (1.0)	0.2 (2.0)	0.1 (1.6)
Median	0.0	0.0	0.0
Min ; Max	-3.3 ; 11.0	-4.0 ; 24.0	-4.0 ; 24.0
Visit 8 (Week 6)			
N	179	174	353
Mean (SD)	-0.0 (0.6)	0.1 (1.9)	0.0 (1.4)
Median	0.0	0.0	0.0
Min ; Max	-4.0 ; 4.8	-3.0 ; 24.0	-4.0 ; 24.0
Visit 9 (Week 7)			
N	177	171	348
Mean (SD)	-0.0 (0.5)	0.1 (1.9)	0.0 (1.4)
Median	0.0	0.0	0.0
Min ; Max	-3.0 ; 2.0	-2.0 ; 24.0	-3.0 ; 24.0
Visit 10 (Week 8)			
N	176	173	349
Mean (SD)	-0.0 (0.4)	0.3 (2.7)	0.1 (1.9)
Median	0.0	0.0	0.0
Min ; Max	-2.0 ; 2.7	-8.0 ; 24.0	-8.0 ; 24.0
Visit 11 (Week 9)			
N	175	172	347
Mean (SD)	0.0 (0.7)	0.2 (1.9)	0.1 (1.4)
Median	0.0	0.0	0.0
Min ; Max	-5.0 ; 3.0	-1.3 ; 24.0	-5.0 ; 24.0

N: Number of subjects, SD: Standard deviation

Prescribed minus actual daily insulin dose in units by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Prescrib Compliance(U)			
Visit 12 (Week 10)			
N	175	172	347
Mean (SD)	0.0 (0.5)	-0.0 (0.6)	-0.0 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-2.7 ; 2.0	-3.7 ; 4.0	-3.7 ; 4.0
Visit 13 (Week 11)			
N	175	172	347
Mean (SD)	0.1 (0.4)	0.3 (2.4)	0.2 (1.7)
Median	0.0	0.0	0.0
Min ; Max	-0.7 ; 2.0	-4.0 ; 26.3	-4.0 ; 26.3
Visit 14 (Week 12)			
N	175	172	347
Mean (SD)	0.1 (0.6)	0.2 (1.3)	0.1 (1.0)
Median	0.0	0.0	0.0
Min ; Max	-1.5 ; 6.0	-3.0 ; 14.0	-3.0 ; 14.0
Visit 15 (Week 13)			
N	175	171	346
Mean (SD)	0.1 (0.7)	0.1 (0.9)	0.1 (0.8)
Median	0.0	0.0	0.0
Min ; Max	-3.0 ; 6.0	-2.3 ; 8.0	-3.0 ; 8.0
Visit 16 (Week 14)			
N	174	168	342
Mean (SD)	0.0 (0.6)	0.1 (0.6)	0.0 (0.6)
Median	0.0	0.0	0.0
Min ; Max	-2.5 ; 4.0	-2.0 ; 4.0	-2.5 ; 4.0

N: Number of subjects, SD: Standard deviation

Prescribed minus actual daily insulin dose in units by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Prescrib Compliance(U)			
Visit 17 (Week 15)			
N	171	167	338
Mean (SD)	0.1 (0.5)	0.0 (0.6)	0.1 (0.5)
Median	0.0	0.0	0.0
Min ; Max	-2.0 ; 2.2	-2.0 ; 4.0	-2.0 ; 4.0
End of trial visit			
N	181	178	359
Mean (SD)	0.1 (0.5)	0.0 (0.7)	0.0 (0.6)
Median	0.0	0.0	0.0
Min ; Max	-2.0 ; 2.2	-5.7 ; 4.0	-5.7 ; 4.0

N: Number of subjects, SD: Standard deviation

14.2.171 Prescribed minus titration algorithm daily insulin dose in units by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Titration Compliance(U)			
Visit 3 (Week 1)			
N	181	178	359
Mean (SD)	0.1 (1.8)	-0.0 (2.7)	0.1 (2.3)
Median	0.0	0.0	0.0
Min ; Max	-8.0 ; 9.0	-7.0 ; 25.0	-8.0 ; 25.0
Visit 4 (Week 2)			
N	181	176	357
Mean (SD)	0.2 (1.2)	0.2 (2.8)	0.2 (2.1)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 5.0	-6.0 ; 22.5	-6.0 ; 22.5
Visit 5 (Week 3)			
N	179	175	354
Mean (SD)	-0.1 (1.5)	0.3 (2.9)	0.1 (2.3)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 7.0	-7.0 ; 20.0	-7.0 ; 20.0
Visit 6 (Week 4)			
N	178	174	352
Mean (SD)	-0.2 (1.6)	0.4 (3.9)	0.1 (3.0)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 5.0	-8.0 ; 38.0	-8.0 ; 38.0

N: Number of subjects, SD: Standard deviation

Prescribed minus titration algorithm daily insulin dose in units by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Titration Compliance(U)			
Visit 7 (Week 5)			
N	178	174	352
Mean (SD)	-0.0 (1.3)	0.3 (2.7)	0.1 (2.2)
Median	0.0	0.0	0.0
Min ; Max	-4.0 ; 7.0	-17.0 ; 24.0	-17.0 ; 24.0
Visit 8 (Week 6)			
N	178	174	352
Mean (SD)	-0.0 (1.2)	0.3 (2.6)	0.1 (2.0)
Median	0.0	0.0	0.0
Min ; Max	-4.0 ; 3.0	-8.0 ; 24.0	-8.0 ; 24.0
Visit 9 (Week 7)			
N	177	172	349
Mean (SD)	-0.0 (1.3)	-0.1 (2.4)	-0.0 (1.9)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 3.0	-6.0 ; 24.0	-6.0 ; 24.0
Visit 10 (Week 8)			
N	176	173	349
Mean (SD)	0.0 (1.3)	0.2 (2.8)	0.1 (2.2)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 3.0	-8.0 ; 24.0	-8.0 ; 24.0

N: Number of subjects, SD: Standard deviation

Prescribed minus titration algorithm daily insulin dose in units by treatment week - descriptive statistics - safety analysis set

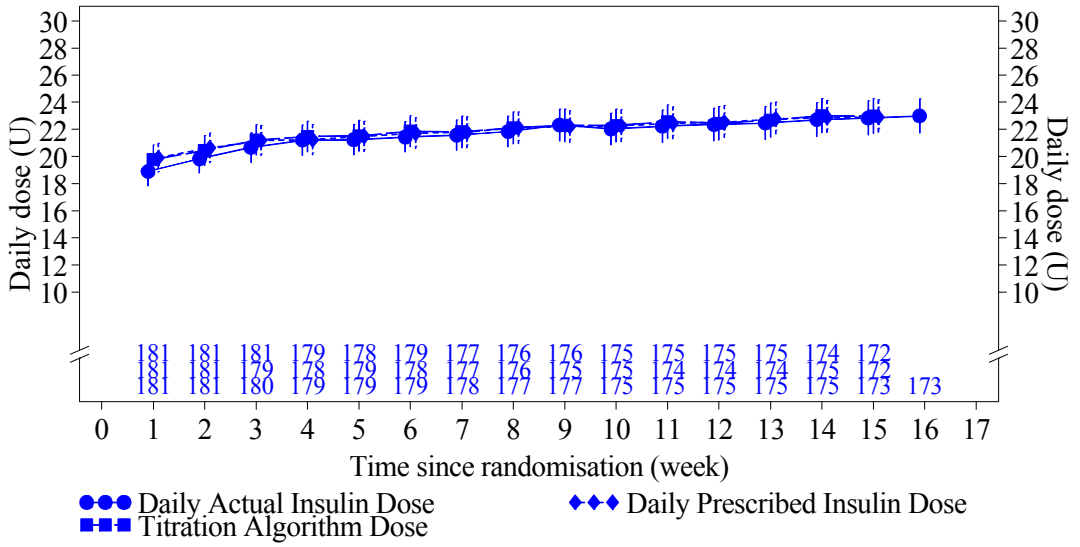
	IDegAsp OD	IDet	Total
Titration Compliance(U)			
Visit 11 (Week 9)			
N	175	173	348
Mean (SD)	-0.3 (1.4)	0.1 (2.4)	-0.1 (2.0)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 2.0	-10.0 ; 24.0	-10.0 ; 24.0
Visit 12 (Week 10)			
N	175	172	347
Mean (SD)	-0.0 (1.3)	0.1 (1.9)	0.0 (1.6)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 6.0	-8.0 ; 16.0	-8.0 ; 16.0
Visit 13 (Week 11)			
N	174	172	346
Mean (SD)	-0.0 (1.4)	0.1 (2.6)	0.0 (2.1)
Median	0.0	0.0	0.0
Min ; Max	-5.0 ; 5.0	-8.0 ; 25.0	-8.0 ; 25.0
Visit 14 (Week 12)			
N	174	172	346
Mean (SD)	-0.1 (1.6)	0.0 (1.8)	-0.0 (1.7)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 4.0	-6.0 ; 14.0	-6.0 ; 14.0

N: Number of subjects, SD: Standard deviation

Prescribed minus titration algorithm daily insulin dose in units by treatment week - descriptive statistics - safety analysis set

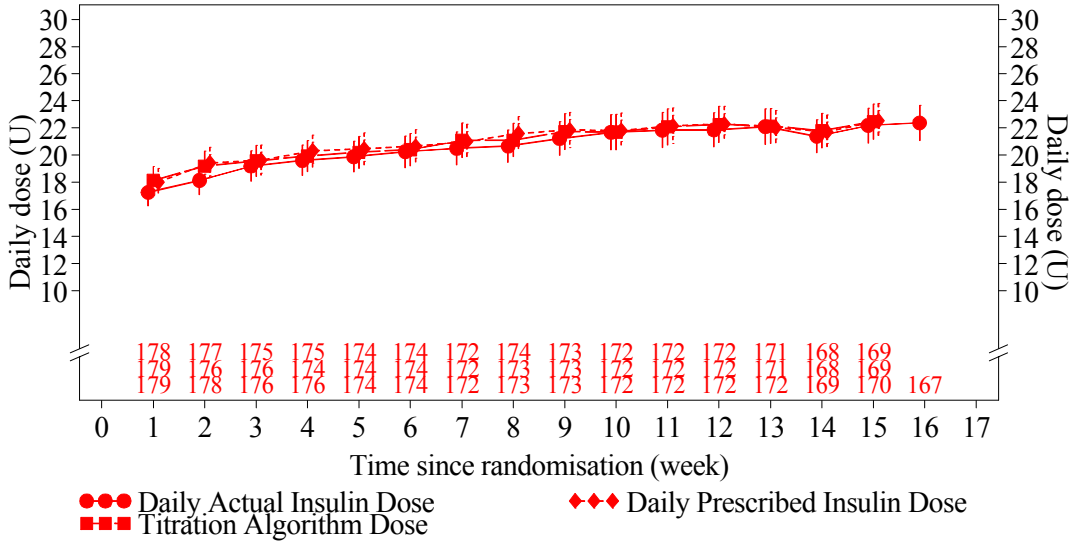
	IDegAsp OD	IDet	Total
Titration Compliance(U)			
Visit 15 (Week 13)			
N	174	171	345
Mean (SD)	0.1 (1.2)	-0.1 (1.4)	-0.0 (1.3)
Median	0.0	0.0	0.0
Min ; Max	-5.0 ; 4.0	-6.0 ; 4.0	-6.0 ; 4.0
Visit 16 (Week 14)			
N	174	168	342
Mean (SD)	-0.1 (1.2)	-0.1 (1.8)	-0.1 (1.5)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 2.0	-8.0 ; 10.0	-8.0 ; 10.0
Visit 17 (Week 15)			
N	172	169	341
Mean (SD)	-0.1 (1.5)	0.1 (2.2)	-0.0 (1.9)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 4.0	-5.0 ; 23.0	-6.0 ; 23.0
End of trial visit			
N	181	178	359
Mean (SD)	-0.1 (1.5)	0.3 (3.6)	0.1 (2.8)
Median	0.0	0.0	0.0
Min ; Max	-6.0 ; 4.0	-5.0 ; 38.0	-6.0 ; 38.0

N: Number of subjects, SD: Standard deviation



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD INSULIN_DOSE_DAILY_ACT_U 2. IDegAsp OD INSULIN_DOSE_DAILY_ALGORITHM_U 3. IDegAsp OD INSULIN_DOSE_DAILY_PRESCRIB_U
nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:43 - fmean_numfind_deg_cust.sas/e_ins_comp_ivl_u_mean_ob_sas.cgm

14.2.172 Daily treatment (IDegAsp OD) insulin dose in units by treatment week - prescribed, actual and titration algorithm dose - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDet INSULIN_DOSE_DAILY_ACT_U 2. IDet INSULIN_DOSE_DAILY_ALGORITHM_U
3. IDet INSULIN_DOSE_DAILY_PRESCRIB_U

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:43 - fmean_numfind_deg_cust.sas/e_ins_comp_cm_u_mean_ob_sas.cgm

14.2.173 Daily treatment (IDet) insulin dose in units by treatment week - prescribed, actual and titration algorithm dose - mean plot - safety analysis set

14.2.174 Confirmatory statistical analyses - full analysis set

Endpoint	Estimate [95% CI]	p-value	Conclusion
PRIMARY			
Change in HbA1c(%) after 16 Weeks of Treatment			
Treatment Contrast			
IDegAsp OD - IDet	-0.04 [-0.23; 0.15]	<0.001	Non-inferiority

p-value is from the 1-sided test for non-inferiority evaluated at the 2.5% level.
CI: Confidence interval

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:26 - tstat_conf.sas/t_conclusion_fas.txt

14.2.175 HbA1c by treatment week – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
HbA1c(%)			
Visit 1			
N	182	180	362
Mean (SD)	8.2 (1.3)	8.1 (1.3)	8.1 (1.3)
Median	8.1	7.9	8.0
Min ; Max	5.1 ; 10.8	5.1 ; 10.9	5.1 ; 10.9
Visit 2 (Week 0)			
N	182	180	362
Mean (SD)	8.1 (1.2)	8.1 (1.2)	8.1 (1.2)
Median	8.0	8.0	8.0
Min ; Max	5.1 ; 11.1	5.4 ; 10.9	5.1 ; 11.1
Visit 10 (Week 8)			
N	176	170	346
Mean (SD)	8.0 (1.2)	7.9 (1.2)	8.0 (1.2)
Median	7.9	7.9	7.9
Min ; Max	5.0 ; 12.1	4.9 ; 11.3	4.9 ; 12.1
Visit 14 (Week 12)			
N	174	170	344
Mean (SD)	7.9 (1.2)	7.8 (1.2)	7.8 (1.2)
Median	7.8	7.7	7.7
Min ; Max	4.5 ; 12.8	5.2 ; 11.1	4.5 ; 12.8
Visit 18 (Week 16)			
N	173	165	338
Mean (SD)	7.9 (1.2)	7.8 (1.3)	7.8 (1.2)
Median	7.8	7.6	7.7
Min ; Max	5.0 ; 14.0	5.3 ; 12.4	5.0 ; 14.0
End of trial visit			
N	182	180	362
Mean (SD)	7.9 (1.3)	7.8 (1.3)	7.9 (1.3)
Median	7.8	7.6	7.7
Min ; Max	4.5 ; 14.0	5.3 ; 12.4	4.5 ; 14.0

N: Number of subjects, SD: Standard deviation

HbA1c by treatment week – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
HbA1c(mmol/mol)			
Visit 1			
N	182	180	362
Mean (SD)	65.8 (14.0)	65.2 (13.7)	65.5 (13.8)
Median	65.0	62.8	63.9
Min ; Max	32.2 ; 94.5	32.2 ; 95.6	32.2 ; 95.6
Visit 2 (Week 0)			
N	182	180	362
Mean (SD)	65.4 (13.6)	64.6 (13.6)	65.0 (13.6)
Median	63.9	63.4	63.9
Min ; Max	32.2 ; 97.8	35.5 ; 95.6	32.2 ; 97.8
Visit 10 (Week 8)			
N	176	170	346
Mean (SD)	63.8 (13.5)	63.0 (13.1)	63.5 (13.3)
Median	62.8	62.8	62.8
Min ; Max	31.2 ; 108.8	30.1 ; 100.0	30.1 ; 108.8
Visit 14 (Week 12)			
N	174	170	344
Mean (SD)	62.8 (13.5)	61.7 (12.8)	62.2 (13.2)
Median	61.8	60.7	60.7
Min ; Max	25.7 ; 116.4	33.3 ; 97.8	25.7 ; 116.4
Visit 18 (Week 16)			
N	173	165	338
Mean (SD)	62.6 (13.2)	61.5 (13.7)	62.1 (13.5)
Median	61.8	59.6	60.7
Min ; Max	31.2 ; 129.5	34.4 ; 112.0	31.2 ; 129.5
End of trial visit			
N	182	180	362
Mean (SD)	62.8 (13.8)	62.1 (14.1)	62.4 (13.9)
Median	61.8	59.6	60.7
Min ; Max	25.7 ; 129.5	34.4 ; 112.0	25.7 ; 129.5

N: Number of subjects, SD: Standard deviation

14.2.176 HbA1c by treatment week – descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
HbA1c(%)			
Visit 1			
N	41	41	82
Mean (SD)	7.9 (1.4)	8.1 (1.1)	8.0 (1.2)
Median	7.8	7.9	7.9
Min ; Max	5.1 ; 10.7	5.8 ; 10.5	5.1 ; 10.7
Visit 2 (Week 0)			
N	41	41	82
Mean (SD)	7.9 (1.4)	8.1 (1.1)	8.0 (1.2)
Median	7.8	7.9	7.9
Min ; Max	5.2 ; 11.1	6.0 ; 10.3	5.2 ; 11.1
Visit 10 (Week 8)			
N	39	38	77
Mean (SD)	7.8 (1.3)	7.8 (1.1)	7.8 (1.2)
Median	7.8	7.9	7.8
Min ; Max	5.0 ; 10.5	5.4 ; 11.1	5.0 ; 11.1
Visit 14 (Week 12)			
N	38	38	76
Mean (SD)	7.7 (1.3)	7.7 (1.1)	7.7 (1.2)
Median	7.6	7.7	7.7
Min ; Max	4.5 ; 10.3	5.2 ; 10.4	4.5 ; 10.4
Visit 18 (Week 16)			
N	37	35	72
Mean (SD)	7.6 (1.2)	7.6 (1.0)	7.6 (1.1)
Median	7.6	7.6	7.6
Min ; Max	5.0 ; 10.3	5.8 ; 9.6	5.0 ; 10.3
End of trial visit			
N	41	41	82
Mean (SD)	7.6 (1.4)	7.7 (1.0)	7.7 (1.2)
Median	7.6	7.6	7.6
Min ; Max	4.5 ; 10.6	5.8 ; 10.3	4.5 ; 10.6

N: Number of subjects, SD: Standard deviation

HbA1c by treatment week – descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
HbA1c(mmol/mol)			
Visit 1			
N	41	41	82
Mean (SD)	62.8 (15.3)	65.1 (11.8)	63.9 (13.6)
Median	61.8	62.8	62.3
Min ; Max	32.2 ; 93.5	39.9 ; 91.3	32.2 ; 93.5
Visit 2 (Week 0)			
N	41	41	82
Mean (SD)	62.8 (15.0)	65.1 (11.9)	64.0 (13.5)
Median	61.8	62.8	62.3
Min ; Max	33.3 ; 97.8	42.1 ; 89.1	33.3 ; 97.8
Visit 10 (Week 8)			
N	39	38	77
Mean (SD)	62.1 (14.0)	61.9 (12.3)	62.0 (13.1)
Median	61.8	62.3	61.8
Min ; Max	31.2 ; 91.3	35.5 ; 97.8	31.2 ; 97.8
Visit 14 (Week 12)			
N	38	38	76
Mean (SD)	60.3 (14.2)	60.2 (12.4)	60.3 (13.2)
Median	59.6	60.7	60.1
Min ; Max	25.7 ; 89.1	33.3 ; 90.2	25.7 ; 90.2
Visit 18 (Week 16)			
N	37	35	72
Mean (SD)	59.3 (13.1)	59.8 (10.6)	59.6 (11.9)
Median	59.6	59.6	59.6
Min ; Max	31.2 ; 89.1	39.9 ; 81.4	31.2 ; 89.1
End of trial visit			
N	41	41	82
Mean (SD)	59.7 (15.2)	60.6 (10.8)	60.1 (13.1)
Median	59.6	59.6	59.6
Min ; Max	25.7 ; 92.4	39.9 ; 89.1	25.7 ; 92.4

N: Number of subjects, SD: Standard deviation

14.2.177 HbA1c by treatment week – descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
HbA1c(%)			
Visit 1			
N	61	61	122
Mean (SD)	8.1 (1.1)	7.8 (1.1)	8.0 (1.1)
Median	8.1	7.9	8.0
Min ; Max	5.1 ; 10.7	5.1 ; 10.5	5.1 ; 10.7
Visit 2 (Week 0)			
N	61	61	122
Mean (SD)	8.1 (1.1)	7.8 (1.1)	7.9 (1.1)
Median	8.0	7.9	7.9
Min ; Max	5.1 ; 10.1	5.4 ; 10.8	5.1 ; 10.8
Visit 10 (Week 8)			
N	60	58	118
Mean (SD)	8.1 (1.1)	7.7 (0.9)	7.9 (1.0)
Median	8.1	7.8	7.9
Min ; Max	5.0 ; 11.9	5.4 ; 9.8	5.0 ; 11.9
Visit 14 (Week 12)			
N	59	58	117
Mean (SD)	7.9 (1.1)	7.6 (0.9)	7.8 (1.0)
Median	8.0	7.6	7.7
Min ; Max	5.2 ; 12.8	5.4 ; 9.9	5.2 ; 12.8
Visit 18 (Week 16)			
N	59	58	117
Mean (SD)	8.0 (1.2)	7.5 (0.9)	7.8 (1.1)
Median	8.0	7.5	7.7
Min ; Max	5.3 ; 14.0	5.3 ; 9.4	5.3 ; 14.0
End of trial visit			
N	61	61	122
Mean (SD)	8.0 (1.2)	7.5 (0.9)	7.7 (1.1)
Median	8.0	7.5	7.7
Min ; Max	5.3 ; 14.0	5.3 ; 9.4	5.3 ; 14.0

N: Number of subjects, SD: Standard deviation

HbA1c by treatment week – descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
HbA1c(mmol/mol)			
Visit 1			
N	61	61	122
Mean (SD)	65.1 (12.5)	61.9 (12.5)	63.5 (12.5)
Median	65.0	62.8	63.9
Min ; Max	32.2 ; 93.5	32.2 ; 91.3	32.2 ; 93.5
Visit 2 (Week 0)			
N	61	61	122
Mean (SD)	64.6 (12.3)	61.6 (12.3)	63.1 (12.3)
Median	63.9	62.8	62.8
Min ; Max	32.2 ; 86.9	35.5 ; 94.5	32.2 ; 94.5
Visit 10 (Week 8)			
N	60	58	118
Mean (SD)	64.7 (12.0)	60.7 (10.2)	62.7 (11.3)
Median	64.5	61.2	62.8
Min ; Max	31.2 ; 106.6	35.5 ; 83.6	31.2 ; 106.6
Visit 14 (Week 12)			
N	59	58	117
Mean (SD)	63.2 (12.2)	59.3 (9.5)	61.3 (11.1)
Median	63.9	59.6	60.7
Min ; Max	33.3 ; 116.4	35.5 ; 84.7	33.3 ; 116.4
Visit 18 (Week 16)			
N	59	58	117
Mean (SD)	63.7 (13.0)	58.7 (9.8)	61.2 (11.7)
Median	63.9	57.9	60.7
Min ; Max	34.4 ; 129.5	34.4 ; 79.2	34.4 ; 129.5
End of trial visit			
N	61	61	122
Mean (SD)	63.5 (13.4)	58.7 (9.6)	61.1 (11.9)
Median	63.9	58.5	60.7
Min ; Max	34.4 ; 129.5	34.4 ; 79.2	34.4 ; 129.5

N: Number of subjects, SD: Standard deviation

14.2.178 HbA1c by treatment week – descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
HbA1c(%)			
Visit 1			
N	80	78	158
Mean (SD)	8.4 (1.3)	8.4 (1.4)	8.4 (1.3)
Median	8.3	8.5	8.4
Min ; Max	5.2 ; 10.8	5.5 ; 10.9	5.2 ; 10.9
Visit 2 (Week 0)			
N	80	78	158
Mean (SD)	8.3 (1.3)	8.2 (1.4)	8.3 (1.3)
Median	8.4	8.3	8.3
Min ; Max	5.4 ; 10.6	5.5 ; 10.9	5.4 ; 10.9
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	8.0 (1.3)	8.1 (1.4)	8.1 (1.3)
Median	7.7	8.0	7.9
Min ; Max	5.5 ; 12.1	4.9 ; 11.3	4.9 ; 12.1
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	8.0 (1.3)	8.0 (1.4)	8.0 (1.3)
Median	7.7	8.0	7.8
Min ; Max	5.9 ; 11.5	5.8 ; 11.1	5.8 ; 11.5
Visit 18 (Week 16)			
N	77	72	149
Mean (SD)	7.9 (1.2)	8.1 (1.6)	8.0 (1.4)
Median	7.7	7.8	7.7
Min ; Max	5.9 ; 11.1	5.8 ; 12.4	5.8 ; 12.4
End of trial visit			
N	80	78	158
Mean (SD)	8.0 (1.2)	8.2 (1.6)	8.1 (1.4)
Median	7.8	7.9	7.8
Min ; Max	5.9 ; 11.1	5.8 ; 12.4	5.8 ; 12.4

N: Number of subjects, SD: Standard deviation

HbA1c by treatment week – descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
HbA1c(mmol/mol)			
Visit 1			
N	80	78	158
Mean (SD)	67.8 (14.2)	67.8 (15.0)	67.8 (14.6)
Median	67.2	68.9	68.3
Min ; Max	33.3 ; 94.5	36.6 ; 95.6	33.3 ; 95.6
Visit 2 (Week 0)			
N	80	78	158
Mean (SD)	67.3 (13.7)	66.6 (15.0)	67.0 (14.3)
Median	67.8	66.7	67.2
Min ; Max	35.5 ; 92.4	36.6 ; 95.6	35.5 ; 95.6
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	64.1 (14.3)	65.5 (15.1)	64.8 (14.7)
Median	60.7	63.9	62.8
Min ; Max	36.6 ; 108.8	30.1 ; 100.0	30.1 ; 108.8
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	63.6 (14.2)	64.3 (14.9)	63.9 (14.5)
Median	60.7	63.4	61.8
Min ; Max	41.0 ; 102.2	39.9 ; 97.8	39.9 ; 102.2
Visit 18 (Week 16)			
N	77	72	149
Mean (SD)	63.3 (13.4)	64.6 (16.9)	63.9 (15.2)
Median	60.7	61.2	60.7
Min ; Max	41.0 ; 97.8	39.9 ; 112.0	39.9 ; 112.0
End of trial visit			
N	80	78	158
Mean (SD)	63.8 (13.4)	65.7 (17.5)	64.7 (15.5)
Median	61.2	62.3	61.8
Min ; Max	41.0 ; 97.8	39.9 ; 112.0	39.9 ; 112.0

N: Number of subjects, SD: Standard deviation

14.2.179 HbA1c by treatment week - change from baseline - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
Ch HbA1c(%)			
Visit 10 (Week 8)			
N	176	170	346
Mean (SD)	-0.1 (0.9)	-0.1 (0.8)	-0.1 (0.8)
Median	-0.1	-0.1	-0.1
Min ; Max	-2.7 ; 2.7	-2.6 ; 4.2	-2.7 ; 4.2
Visit 14 (Week 12)			
N	174	170	344
Mean (SD)	-0.2 (1.0)	-0.2 (0.8)	-0.2 (0.9)
Median	-0.2	-0.2	-0.2
Min ; Max	-3.4 ; 3.1	-2.6 ; 3.8	-3.4 ; 3.8
Visit 18 (Week 16)			
N	173	165	338
Mean (SD)	-0.3 (1.0)	-0.3 (0.9)	-0.3 (1.0)
Median	-0.3	-0.3	-0.3
Min ; Max	-3.2 ; 3.9	-2.5 ; 3.5	-3.2 ; 3.9
End of trial visit			
N	182	180	362
Mean (SD)	-0.2 (1.0)	-0.2 (0.9)	-0.2 (1.0)
Median	-0.3	-0.2	-0.2
Min ; Max	-3.2 ; 3.9	-2.5 ; 3.5	-3.2 ; 3.9

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

HbA1c by treatment week - change from baseline - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Ch HbA1c(mmol/mol)			
Visit 10 (Week 8)			
N	176	170	346
Mean (SD)	-1.1 (9.4)	-1.2 (8.3)	-1.1 (8.9)
Median	-1.1	-1.1	-1.1
Min ; Max	-29.5 ; 29.5	-28.4 ; 45.9	-29.5 ; 45.9
Visit 14 (Week 12)			
N	174	170	344
Mean (SD)	-2.2 (10.4)	-2.4 (9.1)	-2.3 (9.8)
Median	-2.2	-2.2	-2.2
Min ; Max	-37.2 ; 33.9	-28.4 ; 41.5	-37.2 ; 41.5
Visit 18 (Week 16)			
N	173	165	338
Mean (SD)	-2.8 (11.2)	-2.8 (10.2)	-2.8 (10.7)
Median	-3.3	-3.3	-3.3
Min ; Max	-35.0 ; 42.6	-27.3 ; 38.3	-35.0 ; 42.6
End of trial visit			
N	182	180	362
Mean (SD)	-2.6 (11.3)	-2.5 (10.0)	-2.5 (10.6)
Median	-3.3	-2.2	-2.2
Min ; Max	-35.0 ; 42.6	-27.3 ; 38.3	-35.0 ; 42.6

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

14.2.180 HbA1c by treatment week - change from baseline - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
Ch HbA1c(%)			
Visit 10 (Week 8)			
N	39	38	77
Mean (SD)	-0.0 (0.9)	-0.3 (0.8)	-0.1 (0.8)
Median	-0.2	-0.2	-0.2
Min ; Max	-2.4 ; 2.7	-2.6 ; 2.0	-2.6 ; 2.7
Visit 14 (Week 12)			
N	38	38	76
Mean (SD)	-0.2 (0.9)	-0.4 (0.8)	-0.3 (0.8)
Median	-0.2	-0.2	-0.2
Min ; Max	-2.4 ; 2.3	-2.6 ; 1.5	-2.6 ; 2.3
Visit 18 (Week 16)			
N	37	35	72
Mean (SD)	-0.4 (1.0)	-0.5 (0.8)	-0.4 (0.9)
Median	-0.4	-0.4	-0.4
Min ; Max	-3.0 ; 1.7	-2.0 ; 2.2	-3.0 ; 2.2
End of trial visit			
N	41	41	82
Mean (SD)	-0.3 (1.1)	-0.4 (0.8)	-0.4 (1.0)
Median	-0.2	-0.3	-0.3
Min ; Max	-3.0 ; 3.1	-2.0 ; 2.2	-3.0 ; 3.1

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

HbA1c by treatment week - change from baseline - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Ch HbA1c(mmol/mol)			
Visit 10 (Week 8)			
N	39	38	77
Mean (SD)	-0.3 (9.7)	-3.0 (8.6)	-1.6 (9.2)
Median	-2.2	-2.2	-2.2
Min ; Max	-26.2 ; 29.5	-28.4 ; 21.9	-28.4 ; 29.5
Visit 14 (Week 12)			
N	38	38	76
Mean (SD)	-2.6 (9.4)	-3.9 (9.1)	-3.2 (9.2)
Median	-2.2	-2.2	-2.2
Min ; Max	-26.2 ; 25.1	-28.4 ; 16.4	-28.4 ; 25.1
Visit 18 (Week 16)			
N	37	35	72
Mean (SD)	-4.3 (11.0)	-5.0 (9.2)	-4.7 (10.1)
Median	-4.4	-4.4	-4.4
Min ; Max	-32.8 ; 18.6	-21.9 ; 24.0	-32.8 ; 24.0
End of trial visit			
N	41	41	82
Mean (SD)	-3.2 (12.1)	-4.6 (8.8)	-3.9 (10.6)
Median	-2.2	-3.3	-2.7
Min ; Max	-32.8 ; 33.9	-21.9 ; 24.0	-32.8 ; 33.9

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

14.2.181 HbA1c by treatment week - change from baseline - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Ch HbA1c(%)			
Visit 10 (Week 8)			
N	60	58	118
Mean (SD)	0.0 (0.9)	-0.1 (0.7)	-0.0 (0.8)
Median	0.1	-0.2	0.0
Min ; Max	-2.7 ; 2.0	-1.5 ; 1.9	-2.7 ; 2.0
Visit 14 (Week 12)			
N	59	58	117
Mean (SD)	-0.1 (1.0)	-0.2 (0.9)	-0.2 (1.0)
Median	-0.2	-0.3	-0.2
Min ; Max	-3.4 ; 3.1	-2.0 ; 3.8	-3.4 ; 3.8
Visit 18 (Week 16)			
N	59	58	117
Mean (SD)	-0.1 (1.0)	-0.3 (0.9)	-0.2 (1.0)
Median	-0.2	-0.3	-0.3
Min ; Max	-3.2 ; 3.9	-2.3 ; 2.8	-3.2 ; 3.9
End of trial visit			
N	61	61	122
Mean (SD)	-0.1 (1.0)	-0.3 (0.9)	-0.2 (1.0)
Median	-0.2	-0.3	-0.3
Min ; Max	-3.2 ; 3.9	-2.3 ; 2.8	-3.2 ; 3.9

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

HbA1c by treatment week - change from baseline - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Ch HbA1c(mmol/mol)			
Visit 10 (Week 8)			
N	60	58	118
Mean (SD)	0.4 (9.6)	-1.1 (8.0)	-0.3 (8.8)
Median	1.1	-1.6	0.0
Min ; Max	-29.5 ; 21.9	-16.4 ; 20.8	-29.5 ; 21.9
Visit 14 (Week 12)			
N	59	58	117
Mean (SD)	-0.7 (11.0)	-2.6 (10.2)	-1.7 (10.6)
Median	-2.2	-3.3	-2.2
Min ; Max	-37.2 ; 33.9	-21.9 ; 41.5	-37.2 ; 41.5
Visit 18 (Week 16)			
N	59	58	117
Mean (SD)	-1.1 (11.4)	-3.2 (9.9)	-2.1 (10.7)
Median	-2.2	-3.3	-3.3
Min ; Max	-35.0 ; 42.6	-25.1 ; 30.6	-35.0 ; 42.6
End of trial visit			
N	61	61	122
Mean (SD)	-1.1 (11.2)	-3.0 (9.7)	-2.0 (10.5)
Median	-2.2	-3.3	-2.7
Min ; Max	-35.0 ; 42.6	-25.1 ; 30.6	-35.0 ; 42.6

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

14.2.182 HbA1c by treatment week - change from baseline - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
Ch HbA1c(%)			
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	-0.2 (0.8)	-0.0 (0.8)	-0.1 (0.8)
Median	-0.2	0.0	-0.1
Min ; Max	-2.5 ; 2.1	-1.7 ; 4.2	-2.5 ; 4.2
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	-0.3 (0.9)	-0.1 (0.8)	-0.2 (0.9)
Median	-0.4	-0.1	-0.2
Min ; Max	-2.5 ; 2.2	-2.5 ; 1.9	-2.5 ; 2.2
Visit 18 (Week 16)			
N	77	72	149
Mean (SD)	-0.3 (1.0)	-0.1 (1.0)	-0.2 (1.0)
Median	-0.3	-0.2	-0.3
Min ; Max	-2.7 ; 2.4	-2.5 ; 3.5	-2.7 ; 3.5
End of trial visit			
N	80	78	158
Mean (SD)	-0.3 (1.0)	-0.1 (1.0)	-0.2 (1.0)
Median	-0.3	-0.1	-0.2
Min ; Max	-2.7 ; 2.4	-2.5 ; 3.5	-2.7 ; 3.5

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

HbA1c by treatment week - change from baseline - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Ch HbA1c(mmol/mol)			
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	-2.6 (8.9)	-0.3 (8.4)	-1.5 (8.7)
Median	-2.2	0.0	-1.1
Min ; Max	-27.3 ; 23.0	-18.6 ; 45.9	-27.3 ; 45.9
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	-3.1 (10.4)	-1.6 (8.2)	-2.3 (9.4)
Median	-4.4	-1.1	-2.2
Min ; Max	-27.3 ; 24.0	-27.3 ; 20.8	-27.3 ; 24.0
Visit 18 (Week 16)			
N	77	72	149
Mean (SD)	-3.5 (11.0)	-1.3 (10.8)	-2.4 (10.9)
Median	-3.3	-2.2	-3.3
Min ; Max	-29.5 ; 26.2	-27.3 ; 38.3	-29.5 ; 38.3
End of trial visit			
N	80	78	158
Mean (SD)	-3.5 (10.9)	-1.0 (10.6)	-2.3 (10.8)
Median	-3.3	-1.1	-2.2
Min ; Max	-29.5 ; 26.2	-27.3 ; 38.3	-29.5 ; 38.3

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

14.2.183 HbA1c after 16 weeks of treatment - primary statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	182	177	7.79	0.07	
IDet	180	173	7.83	0.07	
Change from baseline					
LSMeans					
IDegAsp OD	182	177	-0.27	0.07	
IDet	180	173	-0.23	0.07	
Treatment Contrast					
IDegAsp OD - IDet			-0.04		[-0.23; 0.15]
HbA1c (mmol/mol)					
LSMeans					
IDegAsp OD	182	177	61.68	0.73	
IDet	180	173	62.13	0.74	
Change from baseline					
LSMeans					
IDegAsp OD	182	177	-2.98	0.73	
IDet	180	173	-2.53	0.74	
Treatment Contrast					
IDegAsp OD - IDet			-0.45		[-2.51; 1.60]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval, SE: Standard error of the mean
All observed HbA1c measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline HbA1c as covariate.
Interactions between visit and all factors and covariates are also included in the model.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:40 - ID14208900_tstat_3816.sas/t_hba1c_conf_stat_mmrm_fas.txt

14.2.184 HbA1c after 16 weeks of treatment - parameter estimates on observed scale - full analysis set

	Estimate	DF	95% CI
HbA1c (%)			
Treatment			
IDegAspOD	-0.04	342	[-0.23; 0.15]
IDet	0.00		
Sex			
Female	0.08	341	[-0.10; 0.27]
Male	0.00		
Region			
Europe	-0.30	359	[-0.74; 0.14]
NorthAmerica	0.14	357	[-0.32; 0.59]
Other	0.00		
Age group			
Adolescents(12-17)years	0.26	343	[0.01; 0.51]
Children(1-5)years	0.00		
Children(6-11)years	0.25	344	[-0.01; 0.50]
Regression			
Baseline response	0.67	344	[0.59; 0.75]
HbA1c (mmol/mol)			
Treatment			
IDegAspOD	-0.45	342	[-2.51; 1.60]
IDet	0.00		
Sex			
Female	0.93	341	[-1.14; 2.99]
Male	0.00		
Region			
Europe	-3.27	359	[-8.08; 1.55]
NorthAmerica	1.49	357	[-3.46; 6.45]
Other	0.00		
Age group			
Adolescents(12-17)years	2.79	343	[0.06; 5.53]
Children(1-5)years	0.00		
Children(6-11)years	2.71	344	[-0.10; 5.52]
Regression			
Baseline response	0.67	344	[0.59; 0.75]

DF: Degrees of freedom, CI: Confidence interval
All observed HbA1c measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline HbA1c as covariate. Interactions between visit and all factors and covariates are also included in the model.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:42 - ID14209000_param_estimates_3816.sas/t_hba1c_conf_stat_parm_mmrm_fas.

14.2.185 HbA1c after 16 weeks of treatment - statistical sensitivity analysis - PP analysis set

	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	174	174	7.80	0.07	
IDet	171	170	7.84	0.07	
Change from baseline					
LSMeans					
IDegAsp OD	174	174	-0.27	0.07	
IDet	171	170	-0.24	0.07	
Treatment Contrast					
IDegAsp OD - IDet			-0.04		[-0.23; 0.15]
HbA1c (mmol/mol)					
LSMeans					
IDegAsp OD	174	174	61.78	0.74	
IDet	171	170	62.17	0.75	
Change from baseline					
LSMeans					
IDegAsp OD	174	174	-2.99	0.74	
IDet	171	170	-2.60	0.75	
Treatment Contrast					
IDegAsp OD - IDet			-0.39		[-2.46; 1.68]

PP: Per protocol set, N: Number of subjects contributing to analysis, CI: Confidence interval, SE: Standard error of the mean
All observed HbA1c measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex region, age-group and visit as factors and baseline HbA1c as covariate. Interactions between visit and all factors and covariates are also included in the model.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:42 - ID14209100_tstat_3816.sas/t_hba1c_sens_stat_mmrm_pp.txt

14.2.186 HbA1c after 16 weeks of treatment - statistical sensitivity analysis - completers

	Completers	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	174	174	7.79	0.07	
IDet	168	168	7.82	0.07	
Change from baseline					
LSMeans					
IDegAsp OD	174	174	-0.27	0.07	
IDet	168	168	-0.24	0.07	
Treatment Contrast					
IDegAsp OD - IDet			-0.03		[-0.22; 0.16]
HbA1c (mmol/mol)					
LSMeans					
IDegAsp OD	174	174	61.62	0.74	
IDet	168	168	61.98	0.75	
Change from baseline					
LSMeans					
IDegAsp OD	174	174	-2.94	0.74	
IDet	168	168	-2.58	0.75	
Treatment Contrast					
IDegAsp OD - IDet			-0.37		[-2.45; 1.72]

N: Number of subjects contributing to analysis, CI: Confidence interval, SE: Standard error of the mean
All observed HbA1c measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline HbA1c as covariate. Interactions between visit and all factors and covariates are also included in the model.

14.2.187 HbA1c after 16 weeks of treatment - statistical sensitivity analysis - simple model - full analysis set

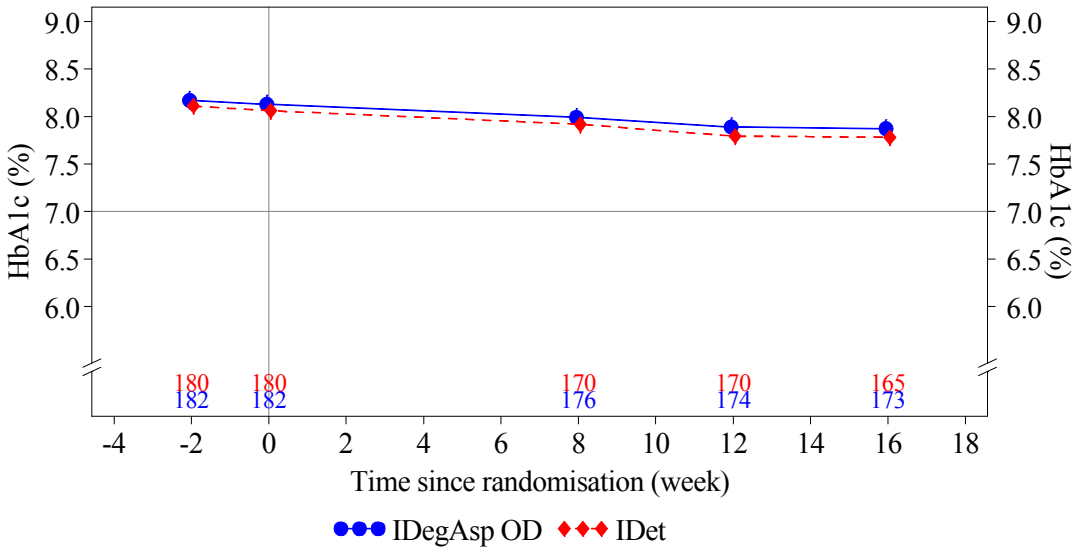
	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	182	177	7.81	0.07	
IDet	180	173	7.81	0.07	
Change from baseline					
LSMeans					
IDegAsp OD	182	177	-0.25	0.07	
IDet	180	173	-0.26	0.07	
Treatment Contrast					
IDegAsp OD - IDet			0.00		[-0.19; 0.19]
HbA1c (mmol/mol)					
LSMeans					
IDegAsp OD	182	177	61.90	0.74	
IDet	180	173	61.87	0.76	
Change from baseline					
LSMeans					
IDegAsp OD	182	177	-2.76	0.74	
IDet	180	173	-2.79	0.76	
Treatment Contrast					
IDegAsp OD - IDet			0.02		[-2.06; 2.11]

N: Number of subjects contributing to analysis, CI: Confidence interval, SE: Standard error of the mean
All observed HbA1c measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment and visit as factors and baseline HbA1c as covariate. Interactions between visit and treatment and visit and baseline HbA1c are also included in the model.

14.2.188 HbA1c after 16 weeks of treatment - statistical sensitivity analysis – ANOVA model - full analysis set

	FAS	N	Estimate	SE	95% CI
HbA1c (%)					
LSMeans					
IDegAsp OD	182	182	7.84	0.07	
IDet	180	180	7.88	0.07	
Change from Baseline					
LSMeans					
IDegAsp OD	182	182	-0.25	0.07	
IDet	180	180	-0.21	0.07	
Treatment Contrast					
IDegAsp OD - IDet			-0.04		[-0.22 ; 0.15]
HbA1c (mmol/mol)					
LSMeans					
IDegAsp OD	182	182	62.23	0.72	
IDet	180	180	62.65	0.73	
Change from Baseline					
LSMeans					
IDegAsp OD	182	182	-2.76	0.72	
IDet	180	180	-2.33	0.73	
Treatment Contrast					
IDegAsp OD - IDet			-0.43		[-2.46 ; 1.60]

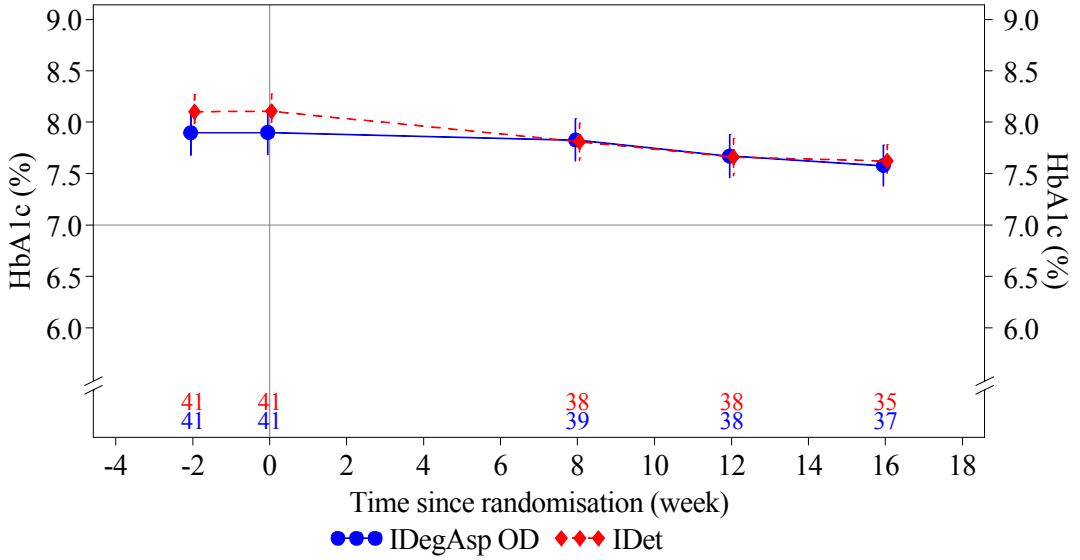
FAS: Full analysis set, N: Number of subjects contributing to analysis
CI: Confidence interval, SE: Standard error of the mean
The response and change from baseline in the response after 16 weeks of treatment
is analysed using an ANOVA method with treatment, sex, region and age group as fixed effects
and HbA1c baseline response as covariates.
Missing data is imputed using last observation carried forward.



FAS: Observed data
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:51 - fmean_numfind_deg_cust.sas/e_hba1c_ab_mean_ob_fas.cgm

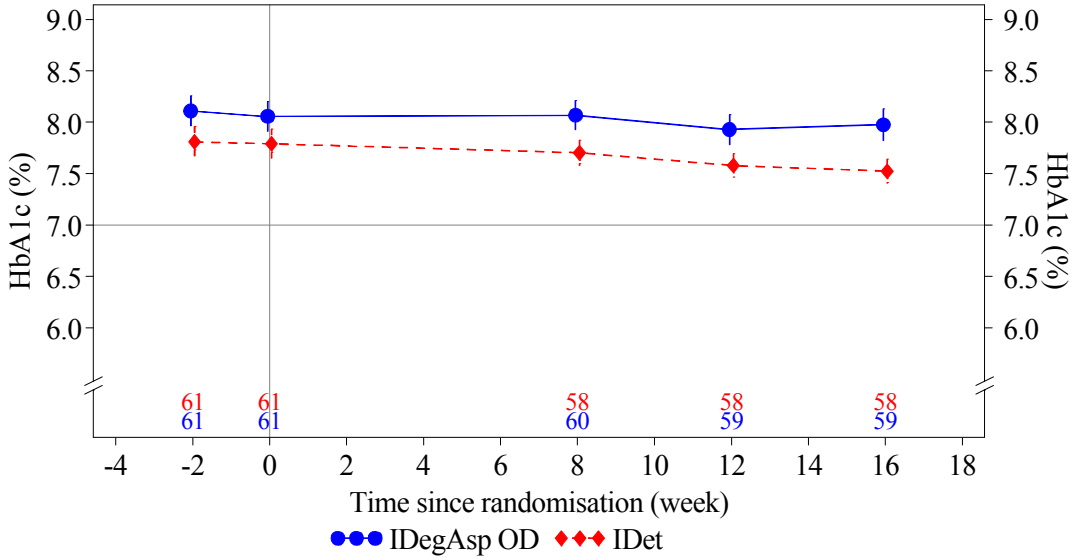
14.2.189 HbA1c (%) by treatment week - mean plot - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:51 - fmean_numfind_deg_cust.sas/e_hba1c_ab_mean_ob_age1_fas.cgm

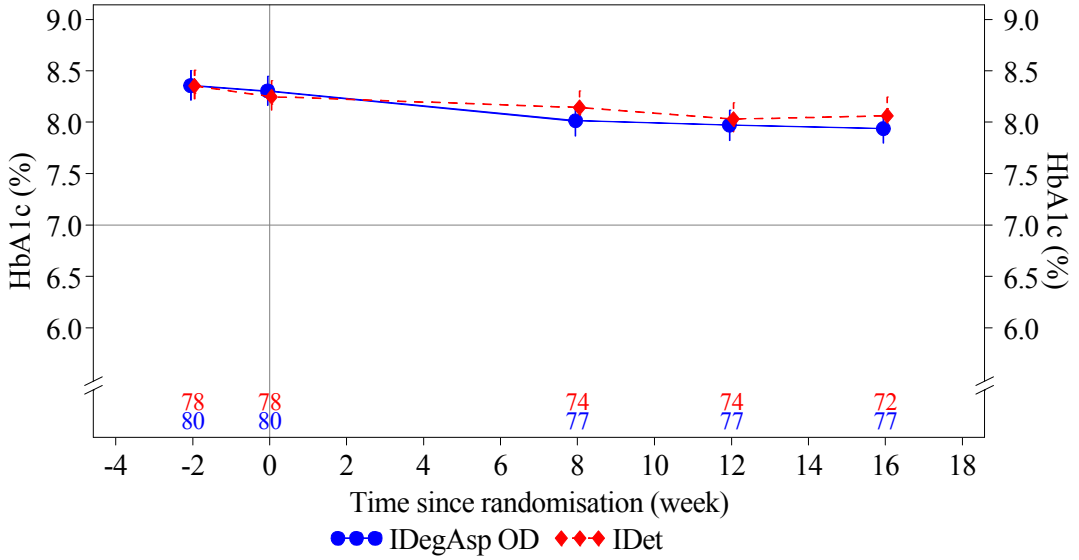
14.2.190 HbA1c (%) by treatment week – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:52 - fmean_numfind_deg_cust.sas/e_hba1c_ab_mean_ob_age2_fas.cgm

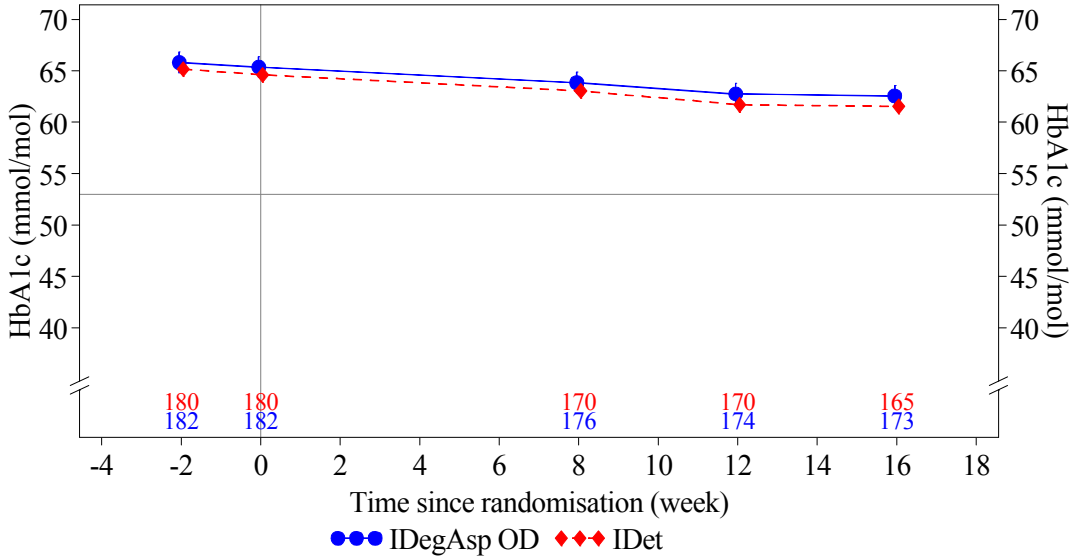
14.2.191 HbA1c (%) by treatment week – mean plot – children (6-11 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:53 - fmean_numfind_deg_cust.sas/e_hba1c_ab_mean_ob_age3_fas.cgm

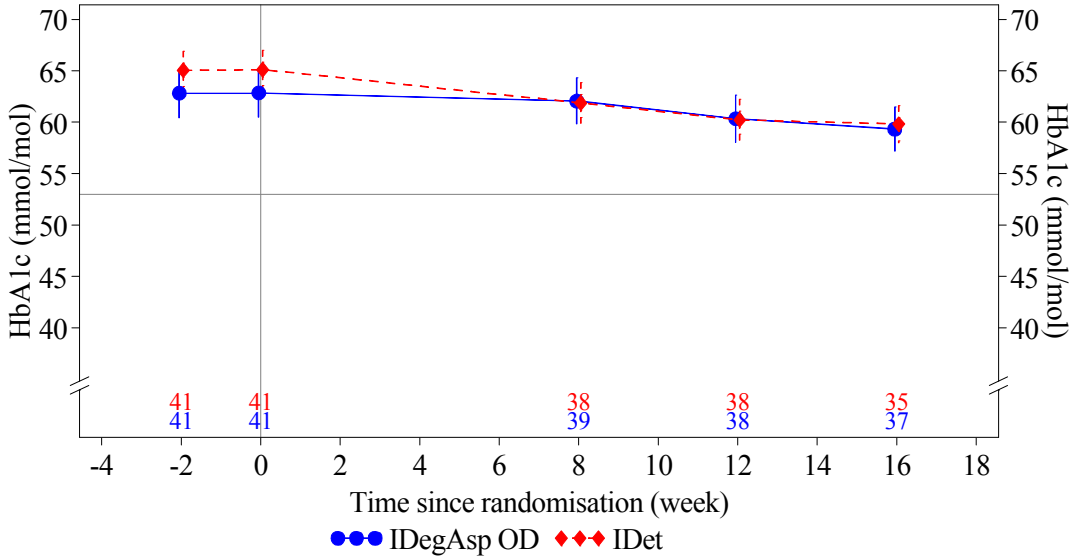
14.2.192 HbA1c (%) by treatment week – mean plot – adolescents (12-17 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:53 - fmean_numfind_deg_cust.sas/e_hba1c_ab_mean_ob_mm_fas.cgm

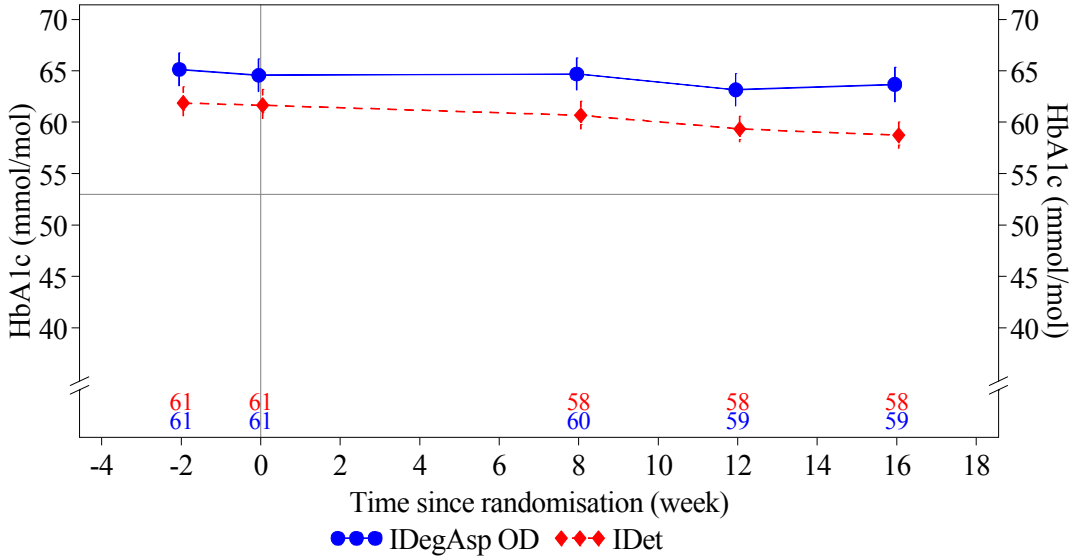
14.2.193 HbA1c (mmol/mol) by treatment week - mean plot - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:59 - fmean_numfind_deg_cust.sas/e_hba1c_ab_mean_ob_mm_age1_fas.cgm

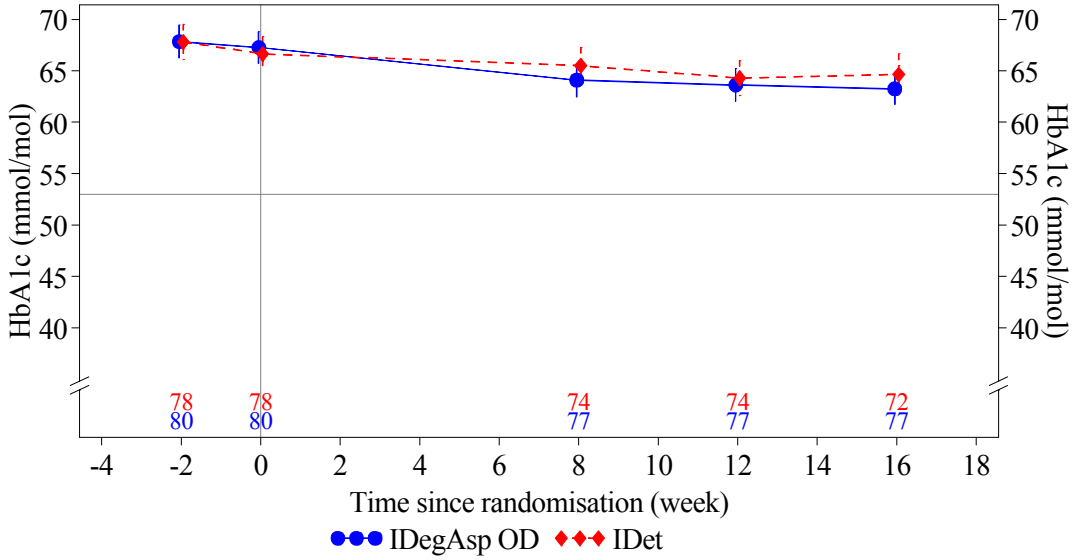
14.2.194 HbA1c (mmol/mol) by treatment week – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:59 - fmean_numfind_deg_cust.sas/e_hba1c_ab_mean_ob_mm_age2_fas.cgm

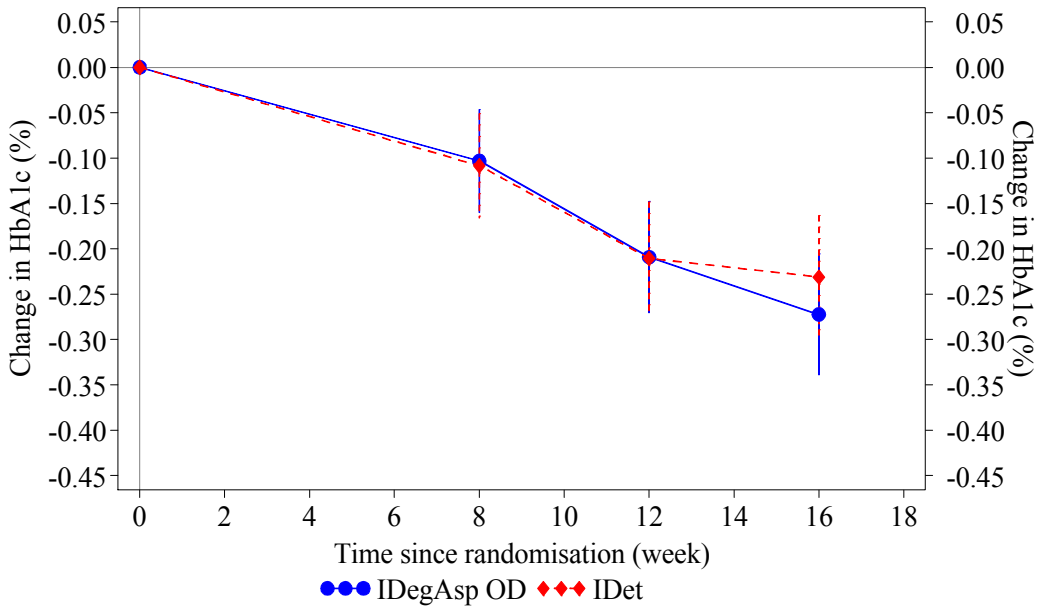
14.2.195 HbA1c (mmol/mol) by treatment week – mean plot – children (6-11 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:59 - fmean_numfind_deg_cust.sas/e_hba1c_ab_mean_ob_mm_age3_fas.cgm

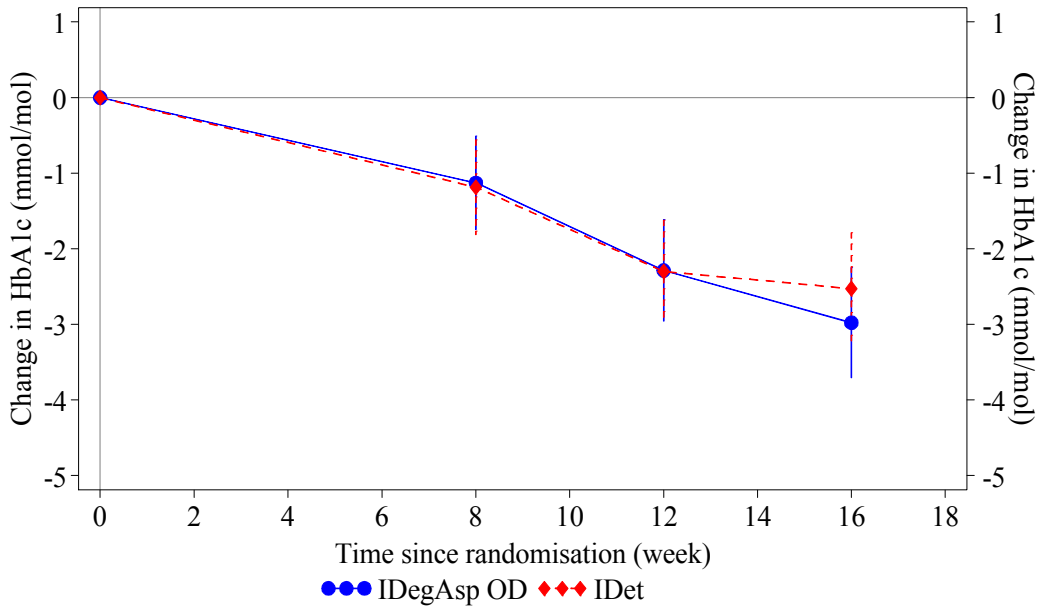
14.2.196 HbA1c (mmol/mol) by treatment week – mean plot – adolescents (12-17 years) - full analysis set



FAS: MMRM data
FAS: Full analysis set, Eror bars: +- Standard error of estimates from MMRM model
MMRM: Mixed model for repeated measurements

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:54 - flsmean_mmrm_3816/e_hba1c_chb_lsmean_fas.cgm

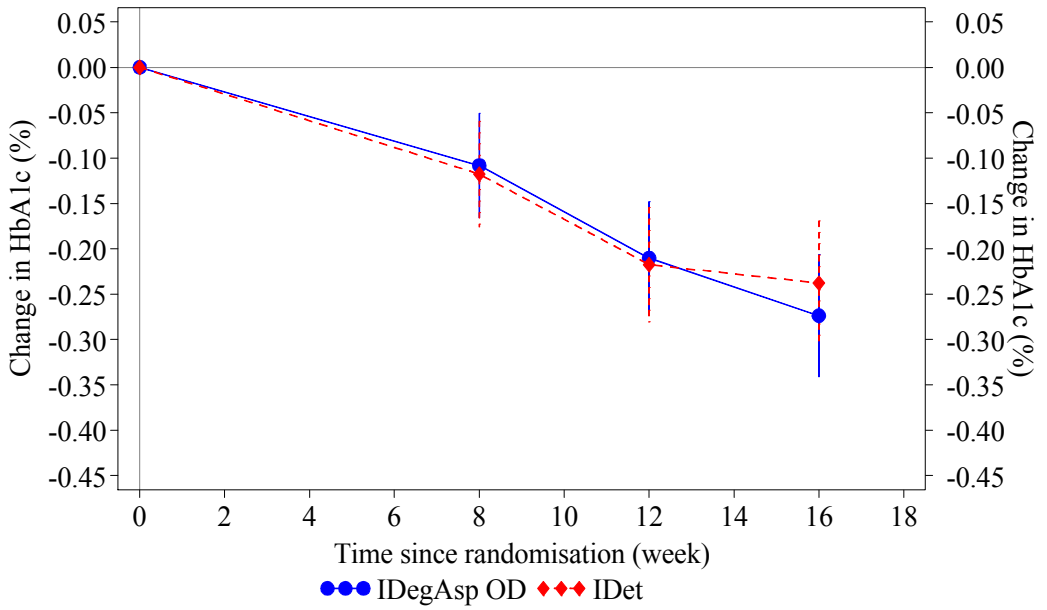
14.2.197 HbA1c (%) by treatment week – change from baseline - lsmean plot – full analysis set



FAS: MMRM data
FAS: Full analysis set, Eror bars: +- Standard error of estimates from MMRM model
MMRM: Mixed model for repeated measurements

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:55 - flsmean_mmrm_3816/e_hba1c_chb_lsmean_conv_fas.cgm

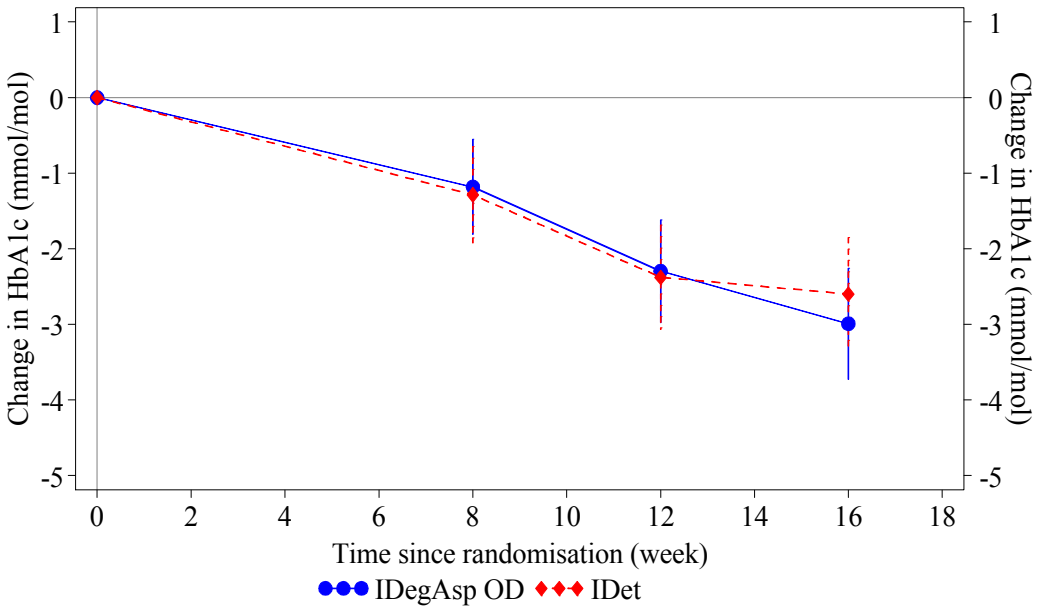
14.2.198 HbA1c (mmol/mol) by treatment week – change from baseline - lsmean plot – full analysis set



PP: MMRM data
PP: Per protocol set, Eror bars: +- Standard error of estimates from MMRM model
MMRM: Mixed model for repeated measurements

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:56 - flsmean_mmrm_3816/e_hba1c_chb_lsmean_pp.cgm

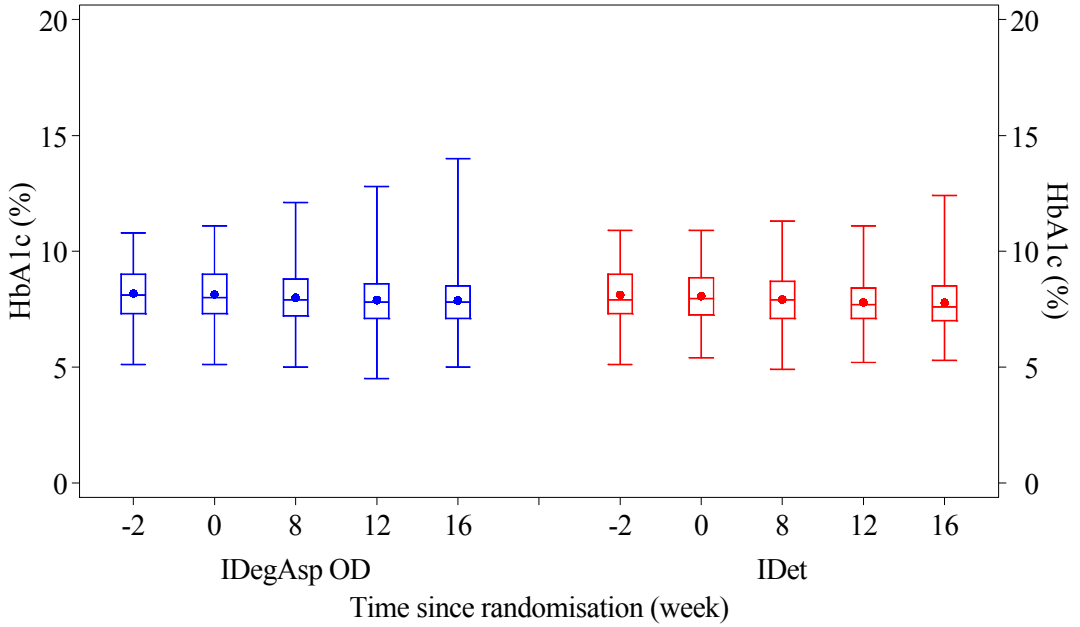
14.2.199 HbA1c (%) by treatment week – change from baseline - lsmean plot – pp analysis set



PP: MMRM data
PP: Per protocol set, Eror bars: +- Standard error of estimates from MMRM model
MMRM: Mixed model for repeated measurements

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:41:56 - flsmean_mmrm_3816/e_hba1c_chb_lsmean_conv_pp.cgm

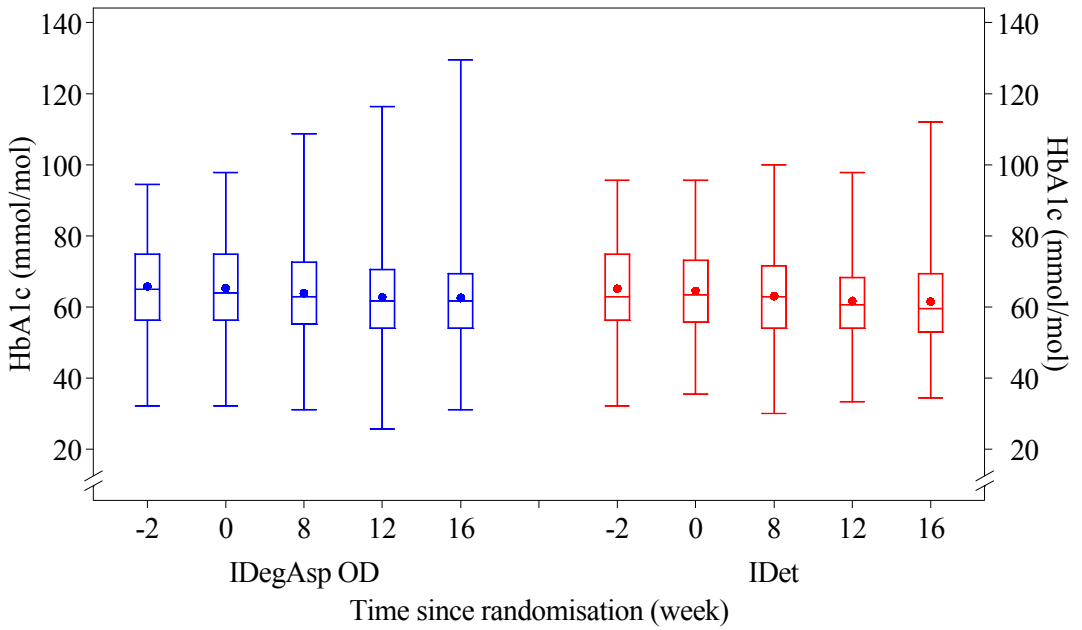
14.2.200 HbA1c (mmol/mol) by treatment week – change from baseline - lsmean plot – pp analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:04 - fbox_numfind_v02.sas/e_hba1c_abs_box_obs_fas.cgm

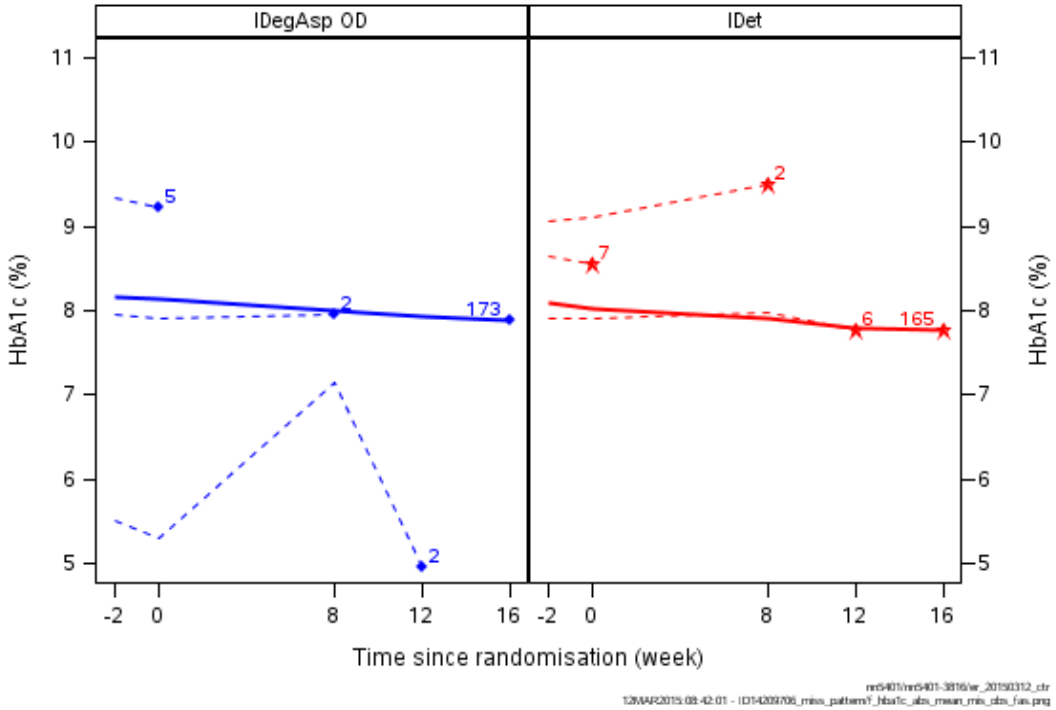
14.2.201 HbA1c (%) by treatment week – box plot - full analysis set



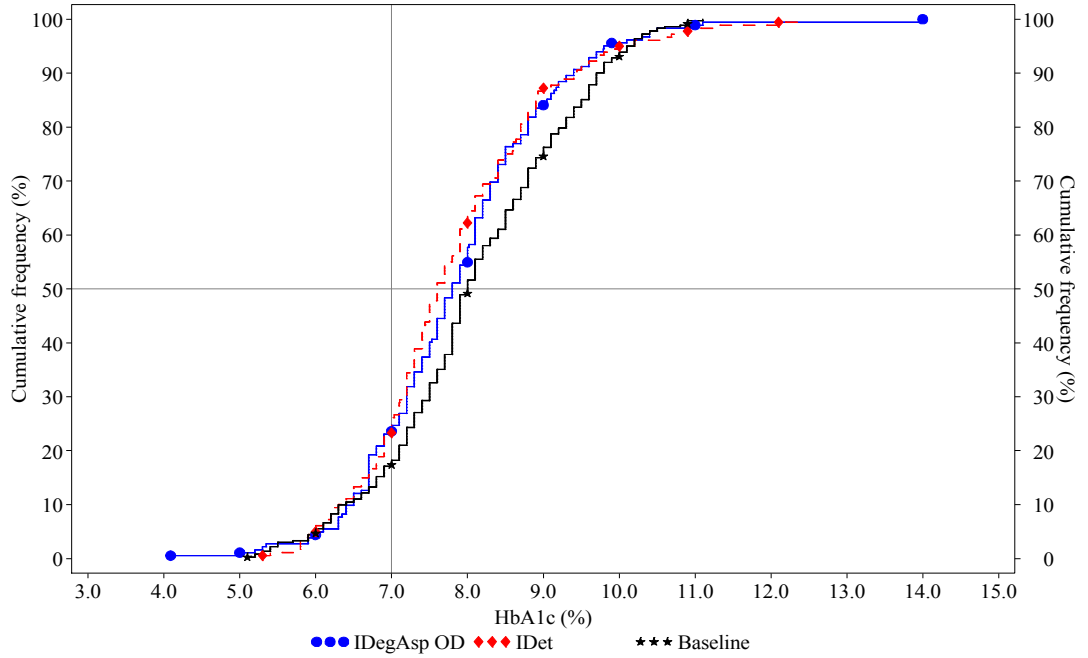
Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:03 - fbox_numfind_v02.sas/e_hba1c_abs_box_obs_conv_fas.cgm

14.2.202 HbA1c (mmol/mol) by treatment week – box plot - full analysis set



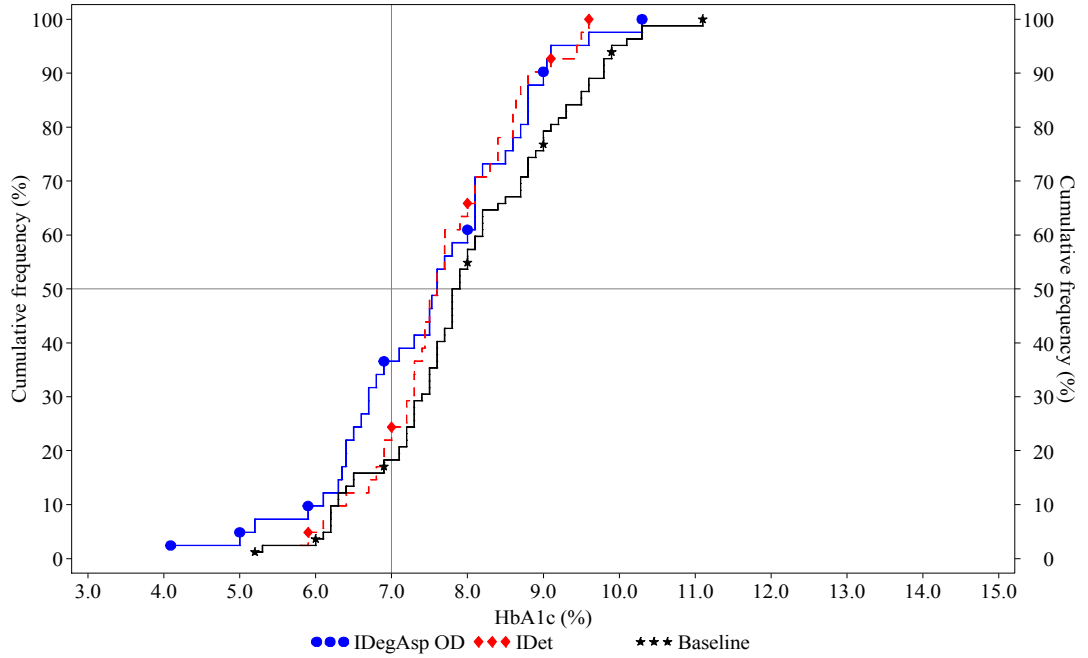
14.2.203 HbA1c (%) by treatment week and missing data pattern - mean plot - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:10 - fedist_numfind_v01.sas/e_hba1c_abs_cdf_pred_fas.cgm

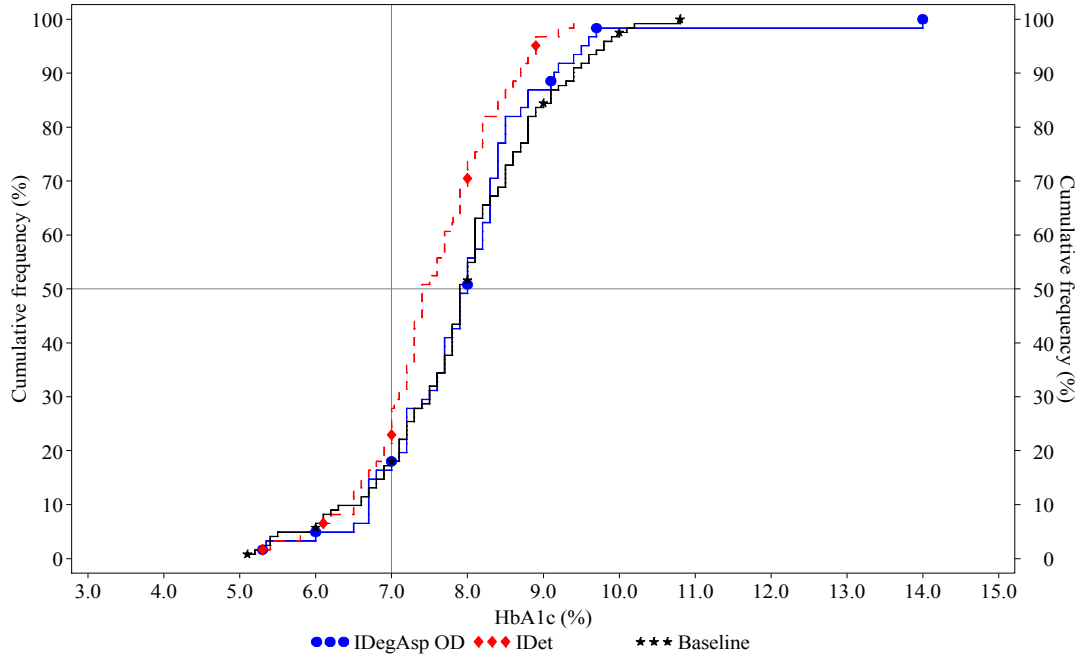
14.2.204 HbA1c (%) after 16 weeks of treatment – empirical distribution plot - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:09 - fedist_numfind_v01.sas/e_hba1c_abs_cdf_pred_age1_fas.cgm

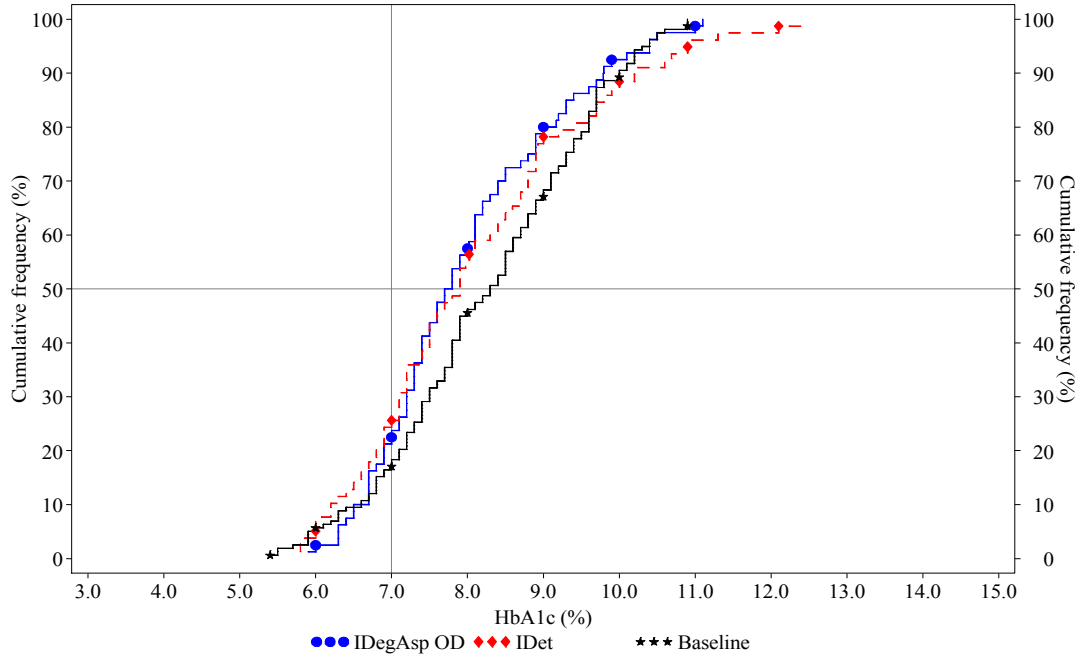
14.2.205 HbA1c (%) after 16 weeks of treatment – empirical distribution plot – children (1-5 years) - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:13 - fedist_numfind_v01.sas/e_hba1c_abs_cdf_pred_age2_fas.cgm

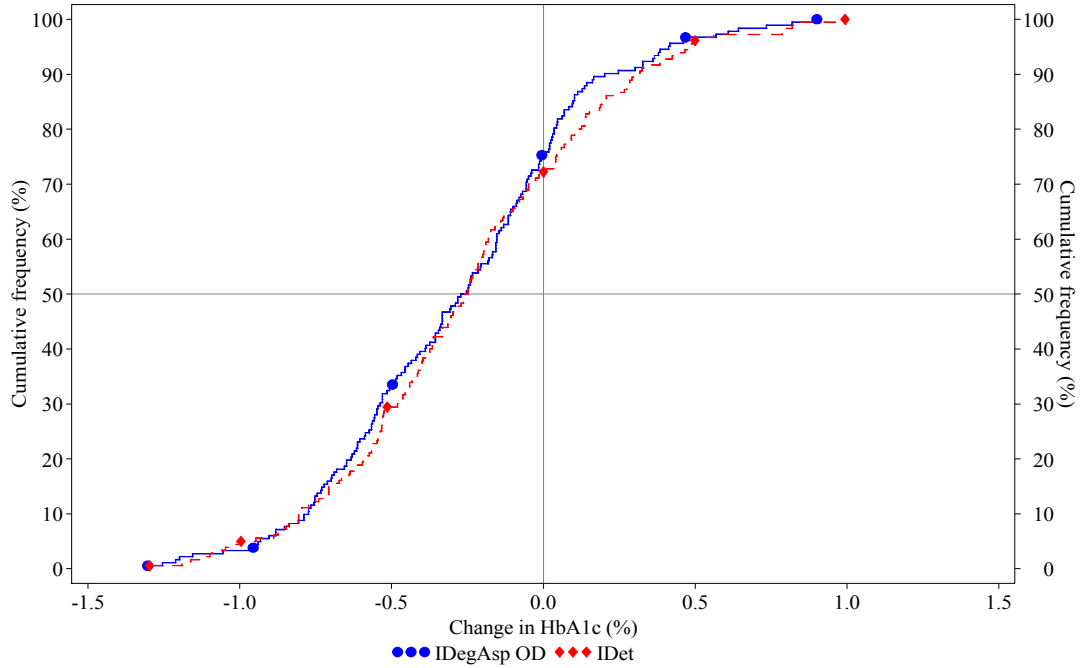
14.2.206 HbA1c (%) after 16 weeks of treatment – empirical distribution plot – children (6-11 years) - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:13 - fedist_numfind_v01.sas/e_hba1c_abs_cdf_pred_age3_fas.cgm

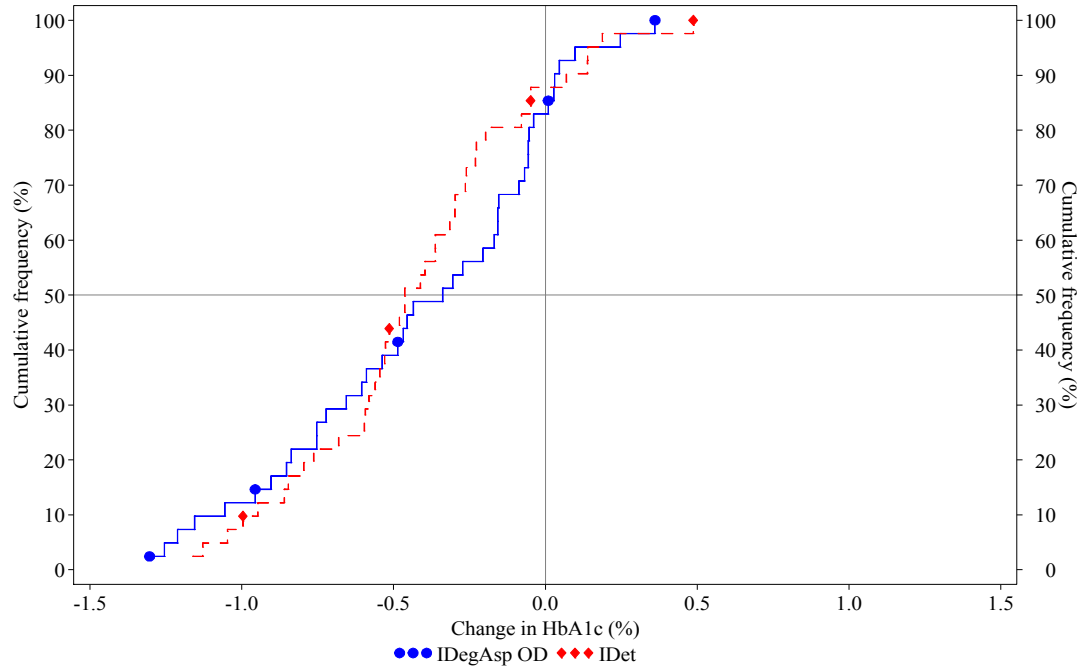
14.2.207 HbA1c (%) after 16 weeks of treatment – empirical distribution plot – adolescents (12-17 years) - full analysis set



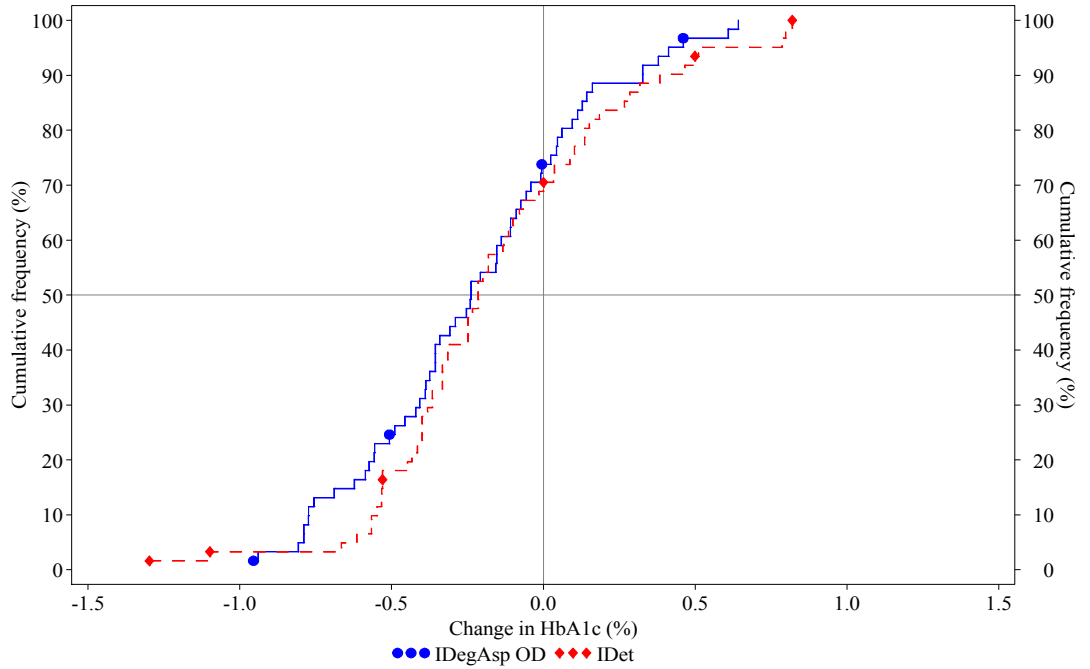
FAS; Observed data
Predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:11 - fedist_numfind_v01.sas/e_hba1c_chb_cdf_pred_fas.cgm

14.2.208 HbA1c (%) after 16 weeks of treatment – change from baseline - empirical distribution plot - full analysis set



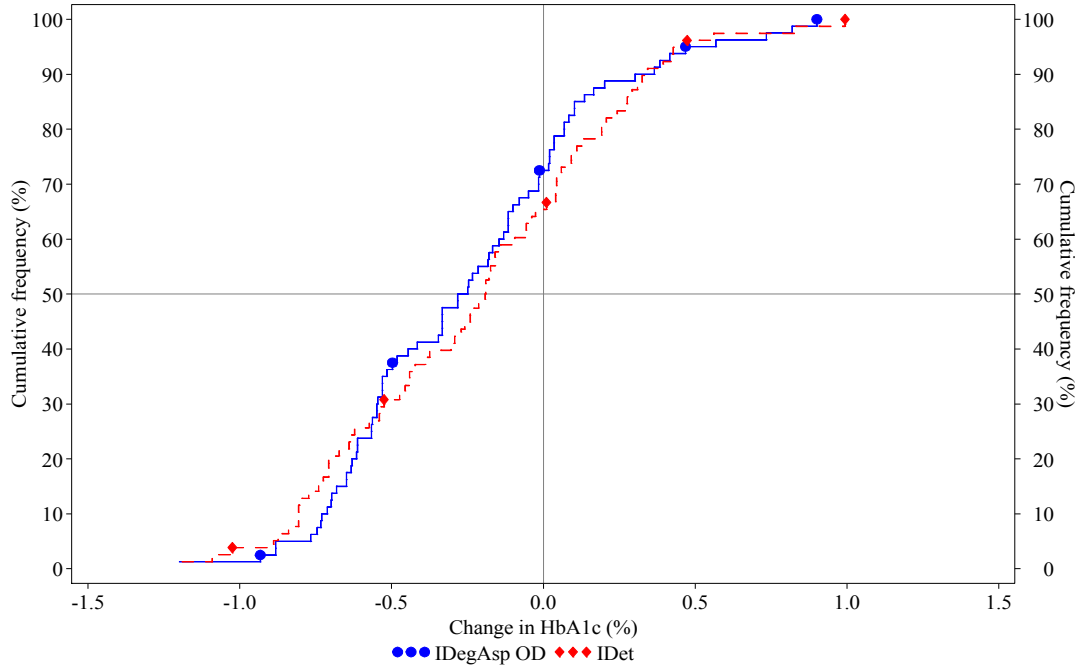
14.2.209 HbA1c (%) after 16 weeks of treatment – change from baseline - empirical distribution plot – children (1-5 years) - full analysis set



FAS; Observed data
Predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:14 - fedist_numfind_v01.sas/e_hba1c_chb_cdf_pred_age2_fas.cgm

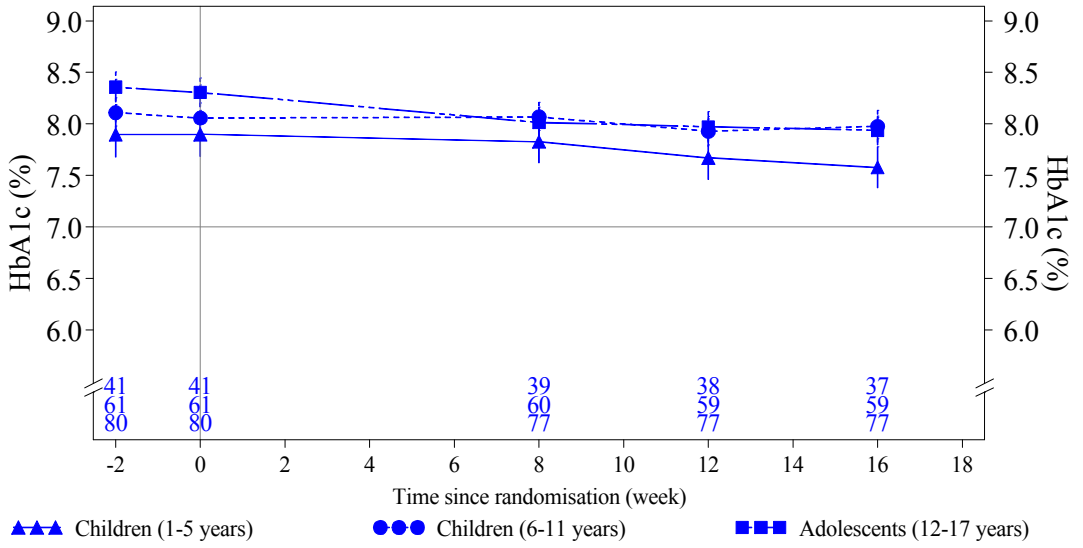
14.2.210 HbA1c (%) after 16 weeks of treatment – change from baseline - empirical distribution plot – children (6-11 years) - full analysis set



FAS; Observed data
Predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:17 - fedist_numfind_v01.sas/e_hba1c_chb_cdf_pred_age3_fas.cgm

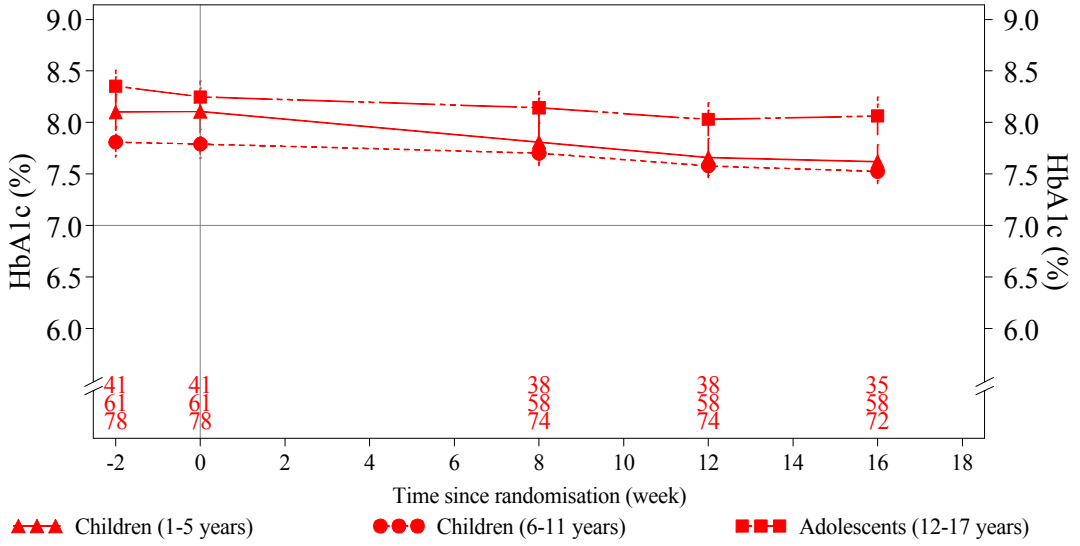
14.2.211 HbA1c (%) after 16 weeks of treatment – change from baseline - empirical distribution plot – adolescents (12-17 years) - full analysis set



FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:14 - hba1c_fplot_treatment_age.sas/e_hba1c_mean_ideg_fas.cgm

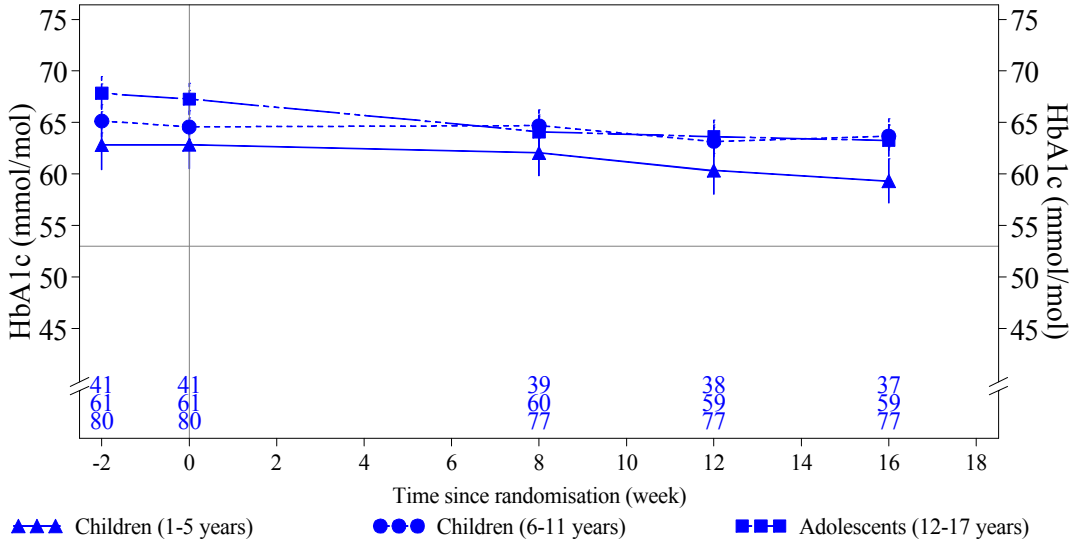
14.2.212 HbA1c (%) by treatment week – mean plot - IDegAsp OD - by age group - full analysis set



FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:19 - hba1c_fplot_treatment_age/e_hba1c_mean_idet_fas.cgm

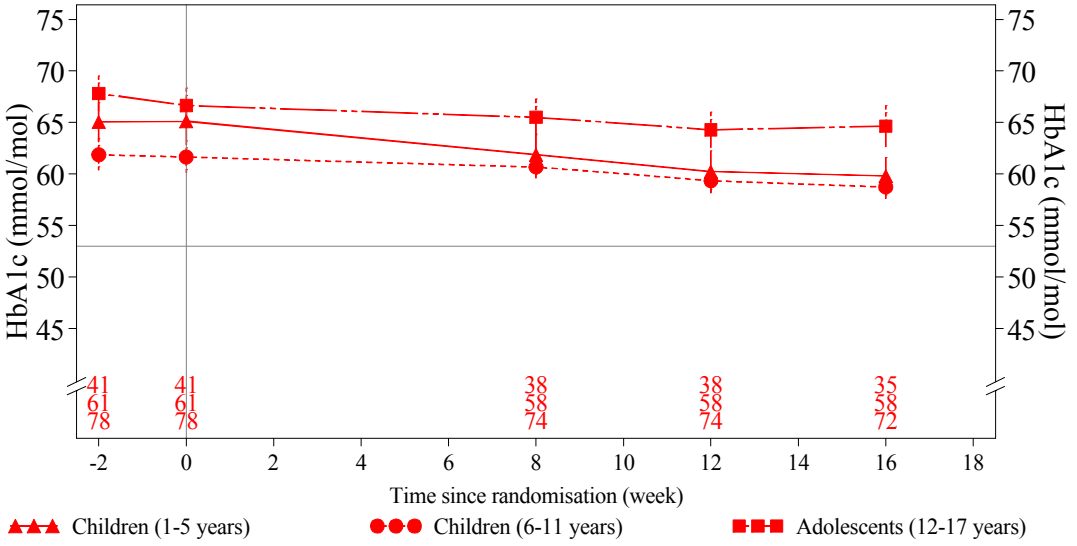
14.2.213 HbA1c (%) by treatment week – mean plot - IDet - by age group - full analysis set



FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:24 - hba1c_fplot_treatment_age.sas/e_hba1c_mean_mm_ideg_fas.cgm

14.2.214 HbA1c (mmol/mol) by treatment week – mean plot - IDegAsp OD - by age group - full analysis set



FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:28 - hba1c_fplot_treatment_age/e_hba1c_mean_mm_idet_fas.cgm

14.2.215 HbA1c (mmol/mol) by treatment week – mean plot - IDet - by age group - full analysis set

14.2.216 Fasting plasma glucose by treatment week - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
FPG(mmol/L)			
Visit 2 (Week 0)			
N	172	166	338
Mean (SD)	8.6 (4.4)	8.1 (4.2)	8.4 (4.3)
Median	7.7	7.2	7.4
Min ; Max	0.5 ; 20.7	1.9 ; 25.1	0.5 ; 25.1
Visit 14 (Week 12)			
N	168	164	332
Mean (SD)	8.0 (4.2)	8.9 (4.2)	8.4 (4.2)
Median	7.2	8.4	7.7
Min ; Max	1.1 ; 23.3	0.6 ; 22.2	0.6 ; 23.3
Visit 18 (Week 16)			
N	168	158	326
Mean (SD)	8.4 (5.1)	8.3 (4.0)	8.3 (4.6)
Median	7.4	7.6	7.4
Min ; Max	1.8 ; 40.5	1.5 ; 20.2	1.5 ; 40.5
End of trial visit			
N	179	178	357
Mean (SD)	8.5 (5.2)	8.4 (4.2)	8.5 (4.7)
Median	7.5	7.6	7.6
Min ; Max	1.2 ; 40.5	1.5 ; 20.2	1.2 ; 40.5

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

Fasting plasma glucose by treatment week - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
FPG(mg/dL)			
Visit 2 (Week 0)			
N	172	166	338
Mean (SD)	155.6 (80.2)	146.5 (74.9)	151.1 (77.6)
Median	139.0	130.1	133.0
Min ; Max	9.0 ; 373.0	35.0 ; 452.1	9.0 ; 452.1
Visit 14 (Week 12)			
N	168	164	332
Mean (SD)	144.7 (75.6)	159.5 (75.8)	152.0 (75.9)
Median	130.1	152.1	138.5
Min ; Max	20.0 ; 420.0	11.0 ; 400.0	11.0 ; 420.0
Visit 18 (Week 16)			
N	168	158	326
Mean (SD)	150.6 (92.3)	148.7 (72.5)	149.7 (83.2)
Median	133.5	136.9	134.1
Min ; Max	32.1 ; 730.1	27.0 ; 364.0	27.0 ; 730.1
End of trial visit			
N	179	178	357
Mean (SD)	153.9 (93.8)	151.7 (75.1)	152.8 (84.9)
Median	135.0	137.5	136.0
Min ; Max	22.0 ; 730.1	27.0 ; 364.0	22.0 ; 730.1

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

14.2.217 Fasting plasma glucose by treatment week - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
FPG(mmol/L)			
Visit 2 (Week 0)			
N	39	35	74
Mean (SD)	8.8 (4.8)	8.2 (4.2)	8.5 (4.5)
Median	7.6	7.3	7.5
Min ; Max	2.8 ; 19.5	2.6 ; 18.7	2.6 ; 19.5
Visit 14 (Week 12)			
N	36	39	75
Mean (SD)	7.2 (3.8)	8.5 (4.3)	7.9 (4.1)
Median	6.7	8.4	7.2
Min ; Max	1.1 ; 16.2	0.6 ; 17.3	0.6 ; 17.3
Visit 18 (Week 16)			
N	37	35	72
Mean (SD)	6.8 (3.6)	8.4 (4.0)	7.6 (3.9)
Median	6.4	8.3	7.1
Min ; Max	2.2 ; 17.7	1.5 ; 18.8	1.5 ; 18.8
End of trial visit			
N	40	41	81
Mean (SD)	7.1 (3.6)	8.8 (4.5)	8.0 (4.2)
Median	6.7	8.5	7.4
Min ; Max	2.2 ; 17.7	1.5 ; 19.7	1.5 ; 19.7

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

Fasting plasma glucose by treatment week - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
FPG(mg/dL)			
Visit 2 (Week 0)			
N	39	35	74
Mean (SD)	158.5 (86.4)	148.1 (75.1)	153.6 (80.9)
Median	136.9	132.1	135.0
Min ; Max	50.1 ; 351.0	45.9 ; 336.9	45.9 ; 351.0
Visit 14 (Week 12)			
N	36	39	75
Mean (SD)	130.5 (68.6)	153.1 (76.8)	142.2 (73.4)
Median	121.0	152.1	130.1
Min ; Max	20.0 ; 292.1	11.0 ; 311.0	11.0 ; 311.0
Visit 18 (Week 16)			
N	37	35	72
Mean (SD)	122.5 (64.3)	150.5 (72.6)	136.1 (69.4)
Median	116.0	150.1	127.0
Min ; Max	38.9 ; 318.0	27.0 ; 338.0	27.0 ; 338.0
End of trial visit			
N	40	41	81
Mean (SD)	128.0 (65.6)	159.0 (81.9)	143.7 (75.5)
Median	120.0	153.0	134.1
Min ; Max	38.9 ; 318.0	27.0 ; 354.1	27.0 ; 354.1

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

14.2.218 Fasting plasma glucose by treatment week - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
FPG(mmol/L)			
Visit 2 (Week 0)			
N	58	58	116
Mean (SD)	8.0 (3.9)	8.1 (4.2)	8.1 (4.0)
Median	7.4	7.3	7.3
Min ; Max	1.6 ; 18.0	1.9 ; 25.1	1.6 ; 25.1
Visit 14 (Week 12)			
N	59	57	116
Mean (SD)	7.9 (4.8)	8.6 (3.6)	8.3 (4.2)
Median	6.4	7.9	7.2
Min ; Max	1.4 ; 23.3	1.4 ; 18.3	1.4 ; 23.3
Visit 18 (Week 16)			
N	57	56	113
Mean (SD)	9.6 (6.7)	7.9 (4.0)	8.8 (5.6)
Median	7.7	6.9	7.3
Min ; Max	2.2 ; 40.5	1.6 ; 17.7	1.6 ; 40.5
End of trial visit			
N	60	61	121
Mean (SD)	9.9 (6.8)	7.8 (3.9)	8.8 (5.6)
Median	7.7	6.8	7.3
Min ; Max	2.2 ; 40.5	1.6 ; 17.7	1.6 ; 40.5

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

Fasting plasma glucose by treatment week - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
FPG(mg/dL)			
Visit 2 (Week 0)			
N	58	58	116
Mean (SD)	144.7 (70.0)	146.0 (75.3)	145.4 (72.4)
Median	133.0	131.0	132.0
Min ; Max	29.0 ; 324.0	35.0 ; 452.1	29.0 ; 452.1
Visit 14 (Week 12)			
N	59	57	116
Mean (SD)	142.5 (85.8)	155.3 (64.2)	148.8 (75.9)
Median	116.0	143.1	129.0
Min ; Max	25.9 ; 420.0	25.0 ; 330.1	25.0 ; 420.0
Visit 18 (Week 16)			
N	57	56	113
Mean (SD)	173.8 (121.6)	143.2 (71.8)	158.7 (100.8)
Median	138.0	125.0	131.0
Min ; Max	38.9 ; 730.1	29.0 ; 318.0	29.0 ; 730.1
End of trial visit			
N	60	61	121
Mean (SD)	178.6 (122.0)	140.2 (70.8)	159.3 (101.0)
Median	138.9	122.0	131.0
Min ; Max	38.9 ; 730.1	29.0 ; 318.0	29.0 ; 730.1

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

14.2.219 Fasting plasma glucose by treatment week - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
FPG(mmol/L)			
Visit 2 (Week 0)			
N	75	73	148
Mean (SD)	9.0 (4.7)	8.1 (4.2)	8.6 (4.5)
Median	8.9	6.9	7.8
Min ; Max	0.5 ; 20.7	2.4 ; 21.5	0.5 ; 21.5
Visit 14 (Week 12)			
N	73	68	141
Mean (SD)	8.5 (3.9)	9.3 (4.7)	8.9 (4.3)
Median	7.6	8.8	8.4
Min ; Max	2.2 ; 19.8	1.4 ; 22.2	1.4 ; 22.2
Visit 18 (Week 16)			
N	74	67	141
Mean (SD)	8.1 (4.0)	8.4 (4.1)	8.3 (4.1)
Median	7.7	7.8	7.8
Min ; Max	1.8 ; 21.0	1.7 ; 20.2	1.7 ; 21.0
End of trial visit			
N	79	76	155
Mean (SD)	8.2 (4.2)	8.7 (4.1)	8.5 (4.2)
Median	7.6	7.9	7.8
Min ; Max	1.2 ; 21.0	1.7 ; 20.2	1.2 ; 21.0

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:20 - tdesc_numfind_tpl_t019_v01_3816.sas/t_fpg_abs_descp_age3_fas.txt

Fasting plasma glucose by treatment week - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
FPG(mg/dL)			
Visit 2 (Week 0)			
N	75	73	148
Mean (SD)	162.4 (84.3)	146.1 (75.5)	154.4 (80.2)
Median	160.0	124.0	140.0
Min ; Max	9.0 ; 373.0	44.0 ; 387.0	9.0 ; 387.0
Visit 14 (Week 12)			
N	73	68	141
Mean (SD)	153.5 (69.7)	166.7 (84.2)	159.9 (77.1)
Median	136.0	159.0	152.1
Min ; Max	38.9 ; 356.9	25.0 ; 400.0	25.0 ; 400.0
Visit 18 (Week 16)			
N	74	67	141
Mean (SD)	146.8 (72.6)	152.2 (73.9)	149.4 (73.0)
Median	138.0	140.0	140.0
Min ; Max	32.1 ; 378.0	31.0 ; 364.0	31.0 ; 378.0
End of trial visit			
N	79	76	155
Mean (SD)	148.2 (76.2)	157.0 (74.6)	152.5 (75.3)
Median	136.0	142.5	140.0
Min ; Max	22.0 ; 378.0	31.0 ; 364.0	22.0 ; 378.0

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose

14.2.220 Fasting plasma glucose by treatment week - change from baseline - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
Ch FPG(mmol/L)			
Visit 14 (Week 12)			
N	162	153	315
Mean (SD)	-0.6 (5.7)	0.9 (5.4)	0.1 (5.6)
Median	-0.28	0.61	0.50
Min ; Max	-16.6 ; 15.7	-14.7 ; 18.1	-16.6 ; 18.1
Visit 18 (Week 16)			
N	162	148	310
Mean (SD)	-0.3 (6.4)	-0.1 (4.8)	-0.2 (5.7)
Median	-0.59	0.06	-0.20
Min ; Max	-15.2 ; 31.1	-17.2 ; 12.7	-17.2 ; 31.1
End of trial visit			
N	172	166	338
Mean (SD)	-0.1 (6.4)	-0.0 (4.6)	-0.1 (5.6)
Median	-0.47	0.00	-0.06
Min ; Max	-15.2 ; 31.1	-17.2 ; 12.7	-17.2 ; 31.1

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose, Ch: Change

Fasting plasma glucose by treatment week - change from baseline - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Ch FPG(mg/dL)			
Visit 14 (Week 12)			
N	162	153	315
Mean (SD)	-11.5 (103.6)	15.7 (96.8)	1.7 (101.1)
Median	-5.0	11.0	9.0
Min ; Max	-299 ; 282.9	-264 ; 325.9	-299 ; 325.9
Visit 18 (Week 16)			
N	162	148	310
Mean (SD)	-5.8 (114.7)	-2.4 (86.4)	-4.2 (102.0)
Median	-10.5	1.1	-3.5
Min ; Max	-273 ; 561.1	-310 ; 229.0	-310 ; 561.1
End of trial visit			
N	172	166	338
Mean (SD)	-2.1 (115.2)	-0.7 (83.4)	-1.4 (100.7)
Median	-8.5	0.0	-1.0
Min ; Max	-273 ; 561.1	-310 ; 229.0	-310 ; 561.1

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose, Ch: Change

14.2.221 Fasting plasma glucose by treatment week - change from baseline - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
Ch FPG(mmol/L)			
Visit 14 (Week 12)			
N	35	34	69
Mean (SD)	-1.3 (5.9)	0.7 (5.1)	-0.3 (5.6)
Median	0.50	0.56	0.50
Min ; Max	-16.6 ; 8.5	-9.0 ; 10.7	-16.6 ; 10.7
Visit 18 (Week 16)			
N	36	31	67
Mean (SD)	-1.8 (6.5)	-0.4 (4.5)	-1.2 (5.7)
Median	-1.00	-0.17	-0.50
Min ; Max	-15.2 ; 14.2	-10.4 ; 8.5	-15.2 ; 14.2
End of trial visit			
N	39	35	74
Mean (SD)	-1.6 (6.5)	-0.3 (4.3)	-1.0 (5.6)
Median	-1.00	-0.16	-0.50
Min ; Max	-15.2 ; 14.2	-10.4 ; 8.5	-15.2 ; 14.2

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose, Ch: Change

Fasting plasma glucose by treatment week - change from baseline - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Ch FPG(mg/dL)			
Visit 14 (Week 12)			
N	35	34	69
Mean (SD)	-22.9 (105.9)	12.9 (92.2)	-5.2 (100.3)
Median	9.0	10.0	9.0
Min ; Max	-299 ; 153.2	-162 ; 192.1	-299 ; 192.1
Visit 18 (Week 16)			
N	36	31	67
Mean (SD)	-33.1 (117.1)	-7.0 (80.8)	-21.0 (102.0)
Median	-18.0	-3.1	-9.0
Min ; Max	-273 ; 255.0	-188 ; 153.0	-273 ; 255.0
End of trial visit			
N	39	35	74
Mean (SD)	-29.4 (117.1)	-5.8 (77.4)	-18.3 (100.3)
Median	-18.0	-2.9	-9.0
Min ; Max	-273 ; 255.0	-188 ; 153.0	-273 ; 255.0

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose, Ch: Change

14.2.222 Fasting plasma glucose by treatment week - change from baseline - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Ch FPG(mmol/L)			
Visit 14 (Week 12)			
N	57	54	111
Mean (SD)	-0.1 (5.6)	0.6 (4.9)	0.2 (5.3)
Median	0.11	0.78	0.44
Min ; Max	-11.4 ; 15.7	-14.7 ; 10.2	-14.7 ; 15.7
Visit 18 (Week 16)			
N	55	53	108
Mean (SD)	1.6 (6.6)	-0.6 (4.9)	0.5 (5.9)
Median	0.28	-0.16	0.03
Min ; Max	-11.9 ; 31.1	-17.2 ; 12.7	-17.2 ; 31.1
End of trial visit			
N	58	58	116
Mean (SD)	1.9 (6.8)	-0.5 (4.7)	0.7 (5.9)
Median	0.31	-0.08	0.06
Min ; Max	-11.9 ; 31.1	-17.2 ; 12.7	-17.2 ; 31.1

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose, Ch: Change

Fasting plasma glucose by treatment week - change from baseline - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Ch FPG(mg/dL)			
Visit 14 (Week 12)			
N	57	54	111
Mean (SD)	-2.0 (100.3)	10.0 (89.0)	3.9 (94.8)
Median	2.0	14.0	7.9
Min ; Max	-205 ; 282.9	-264 ; 184.1	-264 ; 282.9
Visit 18 (Week 16)			
N	55	53	108
Mean (SD)	29.3 (119.7)	-11.4 (88.6)	9.3 (107.1)
Median	5.0	-2.9	0.5
Min ; Max	-215 ; 561.1	-310 ; 229.0	-310 ; 561.1
End of trial visit			
N	58	58	116
Mean (SD)	34.5 (121.6)	-9.1 (85.5)	12.7 (107.0)
Median	5.5	-1.4	1.0
Min ; Max	-215 ; 561.1	-310 ; 229.0	-310 ; 561.1

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose, Ch: Change

14.2.223 Fasting plasma glucose by treatment week - change from baseline - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
Ch FPG(mmol/L)			
Visit 14 (Week 12)			
N	70	65	135
Mean (SD)	-0.8 (5.9)	1.2 (5.9)	0.2 (5.9)
Median	-0.39	0.66	0.50
Min ; Max	-15.1 ; 14.5	-11.0 ; 18.1	-15.1 ; 18.1
Visit 18 (Week 16)			
N	71	64	135
Mean (SD)	-1.1 (5.8)	0.4 (4.9)	-0.4 (5.4)
Median	-1.44	0.70	-0.44
Min ; Max	-12.7 ; 14.0	-8.2 ; 10.4	-12.7 ; 14.0
End of trial visit			
N	75	73	148
Mean (SD)	-0.9 (5.7)	0.5 (4.7)	-0.2 (5.3)
Median	-0.72	0.50	0.00
Min ; Max	-12.7 ; 14.0	-8.2 ; 10.4	-12.7 ; 14.0

N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose, Ch: Change

Fasting plasma glucose by treatment week - change from baseline - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Ch FPG(mg/dL)			
Visit 14 (Week 12)			
N	70	65	135
Mean (SD)	-13.6 (105.8)	22.0 (106.0)	3.5 (107.0)
Median	-6.9	11.9	9.0
Min ; Max	-272 ; 261.1	-198 ; 325.9	-272 ; 325.9
Visit 18 (Week 16)			
N	71	64	135
Mean (SD)	-19.2 (103.9)	7.2 (87.5)	-6.7 (97.0)
Median	-25.9	12.5	-7.9
Min ; Max	-228 ; 252.1	-148 ; 187.0	-228 ; 252.1
End of trial visit			
N	75	73	148
Mean (SD)	-16.2 (102.9)	8.4 (84.7)	-4.1 (94.8)
Median	-13.0	9.0	0.0
Min ; Max	-228 ; 252.1	-148 ; 187.0	-228 ; 252.1

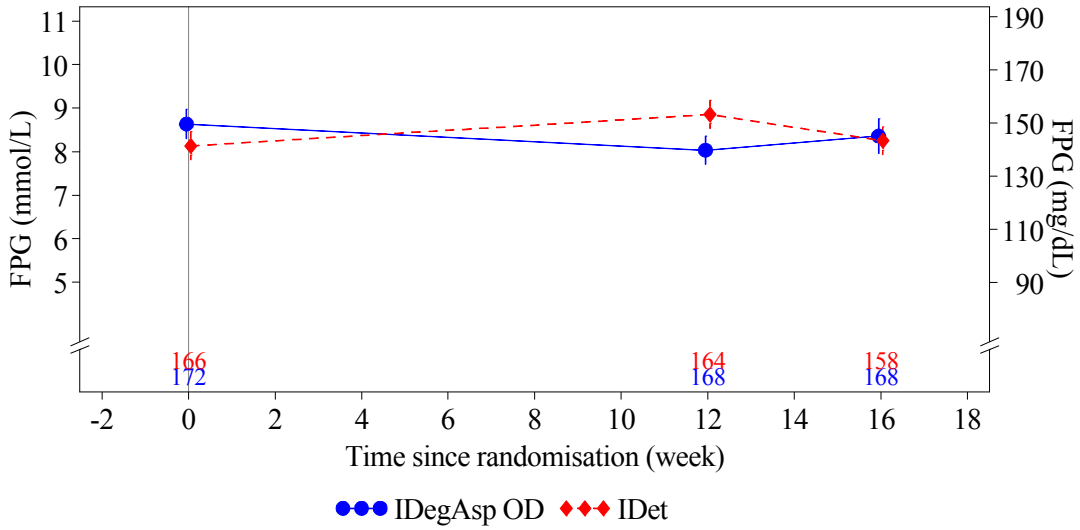
N: Number of subjects, SD: Standard deviation
FPG: Fasting plasma glucose, Ch: Change

14.2.224 Fasting plasma glucose after 16 weeks of treatment - statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
FPG (mmol/L)					
LSMeans					
IDegAsp OD	182	166	8.37	0.36	
IDet	180	157	8.06	0.37	
Change from baseline					
LSMeans					
IDegAsp OD	182	166	-0.04	0.36	
IDet	180	157	-0.36	0.37	
Treatment Contrast					
IDegAsp OD - IDet			0.31		[-0.70; 1.33]
FPG (mg/dL)					
LSMeans					
IDegAsp OD	182	166	150.82	6.41	
IDet	180	157	145.18	6.71	
Change from baseline					
LSMeans					
IDegAsp OD	182	166	-0.77	6.41	
IDet	180	157	-6.41	6.71	
Treatment Contrast					
IDegAsp OD - IDet			5.64		[-12.69; 23.97]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval, SE: Standard error of the mean
All observed FPG measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline FPG as covariate.
Interactions between visit and all factors and covariates are also included in the model.

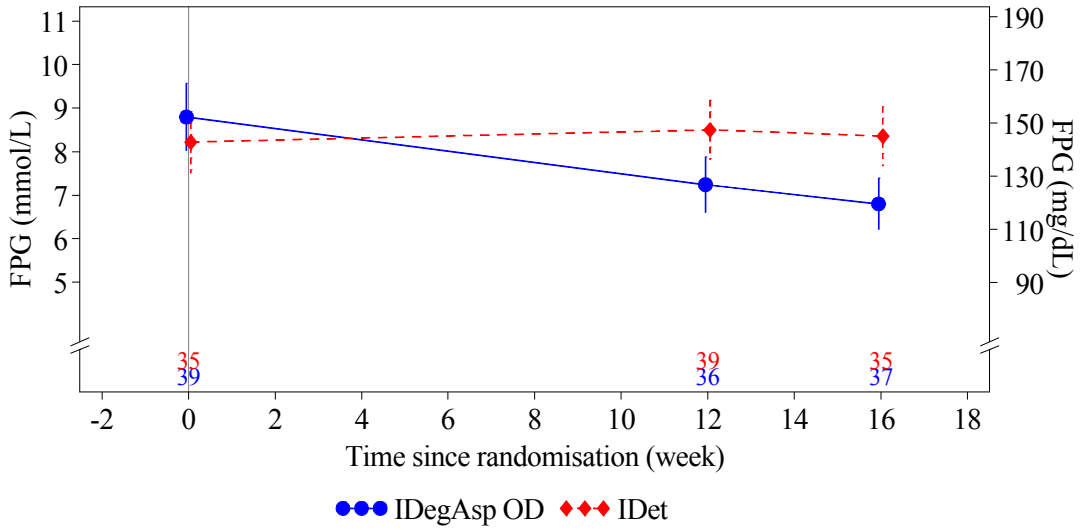
nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:19 - ID14211300_tstat_3816.sas/t_fpg_stat_mmrm_fas.txt



FAS: Observed data
FPG: Fasting plasma glucose
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:25 - fmean_numfind_deg_cust.sas/e_fpg_ab_mean_ob_fas.cgm

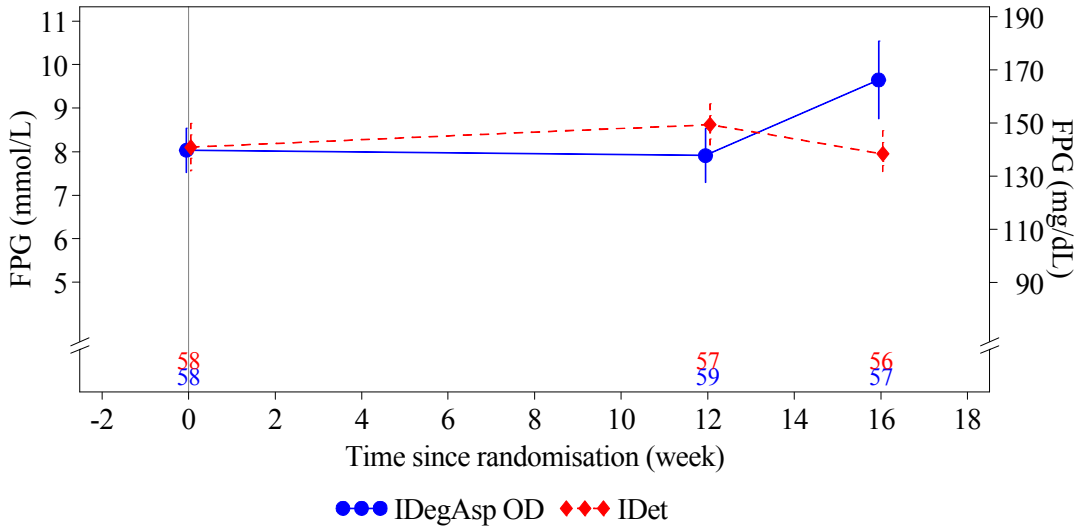
14.2.225 Fasting plasma glucose by treatment week - mean plot - full analysis set



FAS: Observed data
FPG: Fasting plasma glucose
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:26 - fmean_numfind_deg_cust.sas/e_fpg_ab_mean_ob_age1_fas.cgm

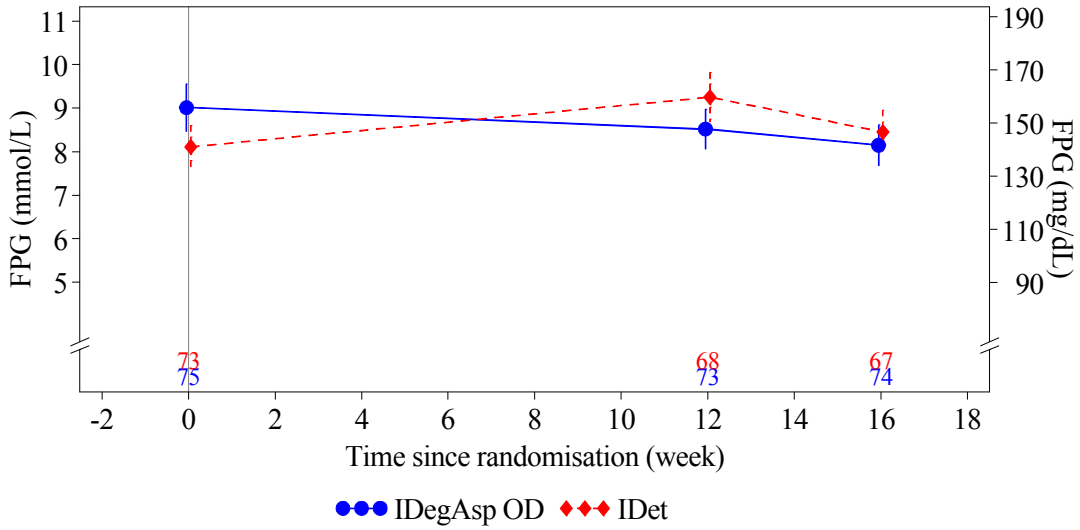
14.2.226 Fasting plasma glucose by treatment week - mean plot – children (1-5 years) - full analysis set



FAS: Observed data
FPG: Fasting plasma glucose
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:27 - fmean_numfind_deg_cust.sas/e_fpg_ab_mean_ob_age2_fas.cgm

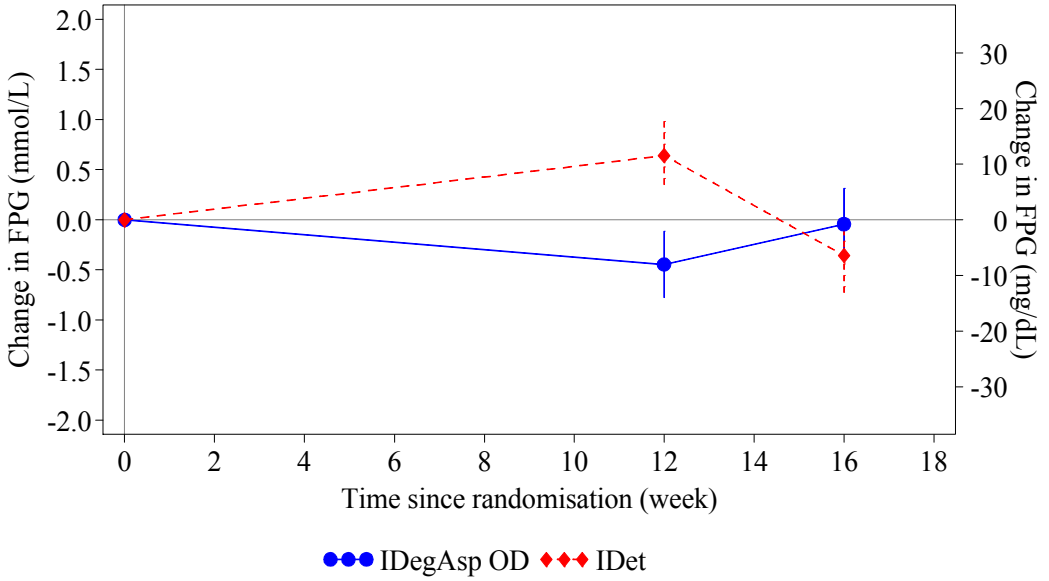
14.2.227 Fasting plasma glucose by treatment week - mean plot – children (6-11 years) - full analysis set



FAS: Observed data
FPG: Fasting plasma glucose
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:28 - fmean_numfind_deg_cust.sas/e_fpg_ab_mean_ob_age3_fas.cgm

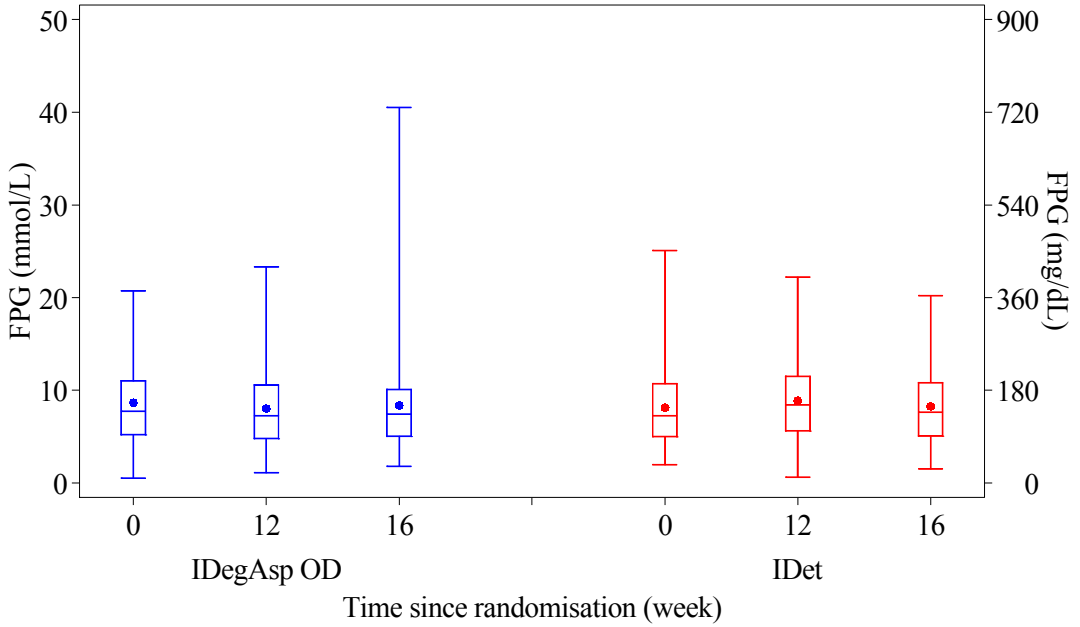
14.2.228 Fasting plasma glucose by treatment week - mean plot – adolescents (12-17 years) - full analysis set



FAS: MMRM data
FAS: Full analysis set, Eror bars: +- Standard error of estimates from MMRM model
MMRM: Mixed model for repeated measurements

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:23 - flsmean_mmrm_3816/e_fpg_chb_lsmean_fas.cgm

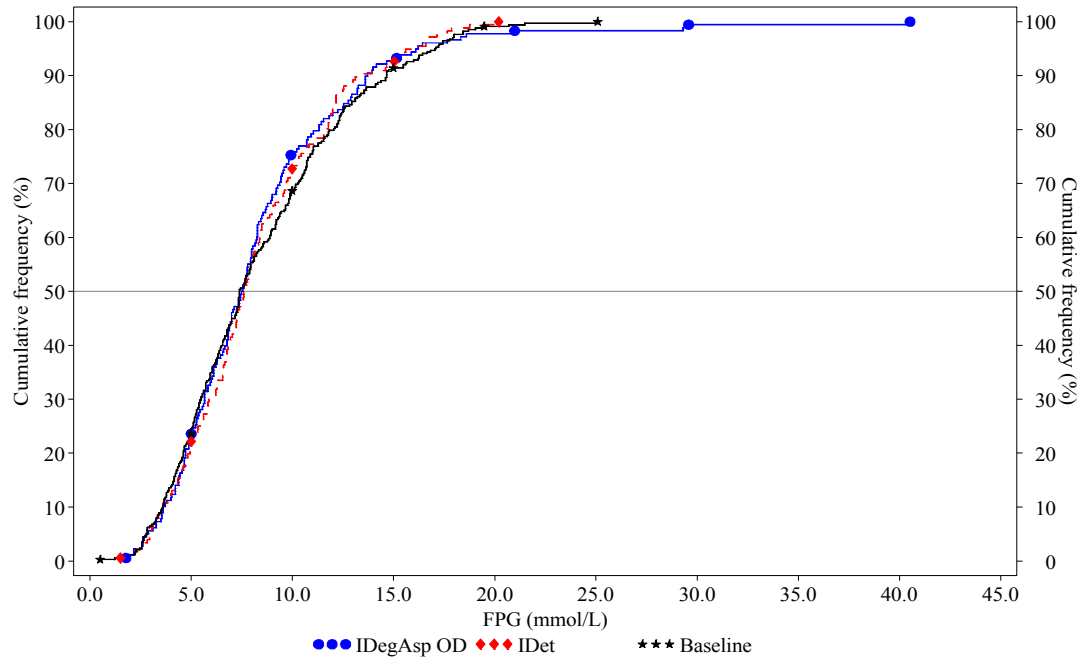
14.2.229 Fasting plasma glucose by treatment week – change from baseline - lsmean plot – full analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FPG: Fasting plasma glucose, FAS: Full analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:29 - fbox_numfind_v02.sas/e_fpg_abs_box_obs_fas.cgm

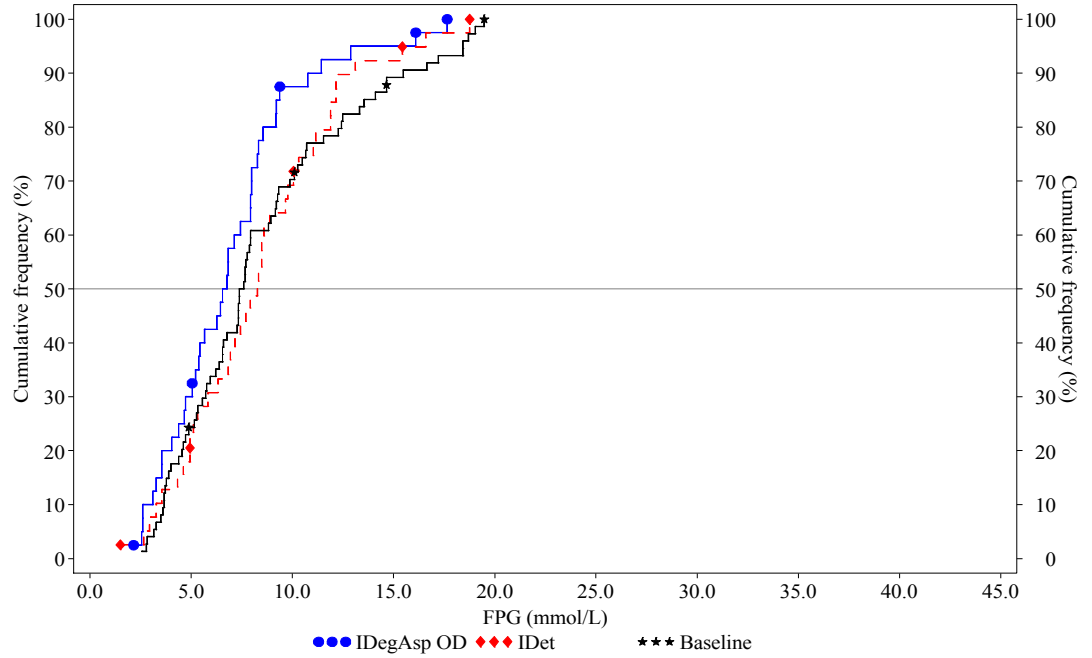
14.2.230 Fasting plasma glucose by treatment week - box plot - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:35 - fedist_numfind_v01.sas/e_fpg_abs_mean_cdf_pred_fas.cgm

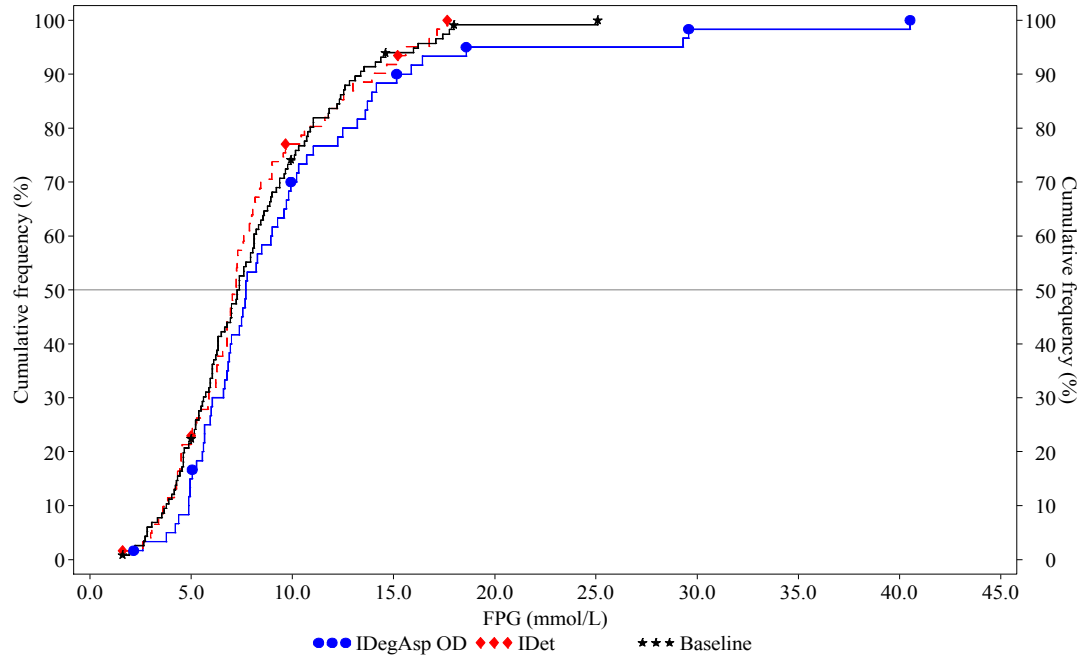
14.2.231 Fasting plasma glucose after 16 weeks of treatment – empirical distribution plot - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:37 - fedist_numfind_v01.sas/e_fpg_abs_mean_cdf_pred_age1_fas.cgm

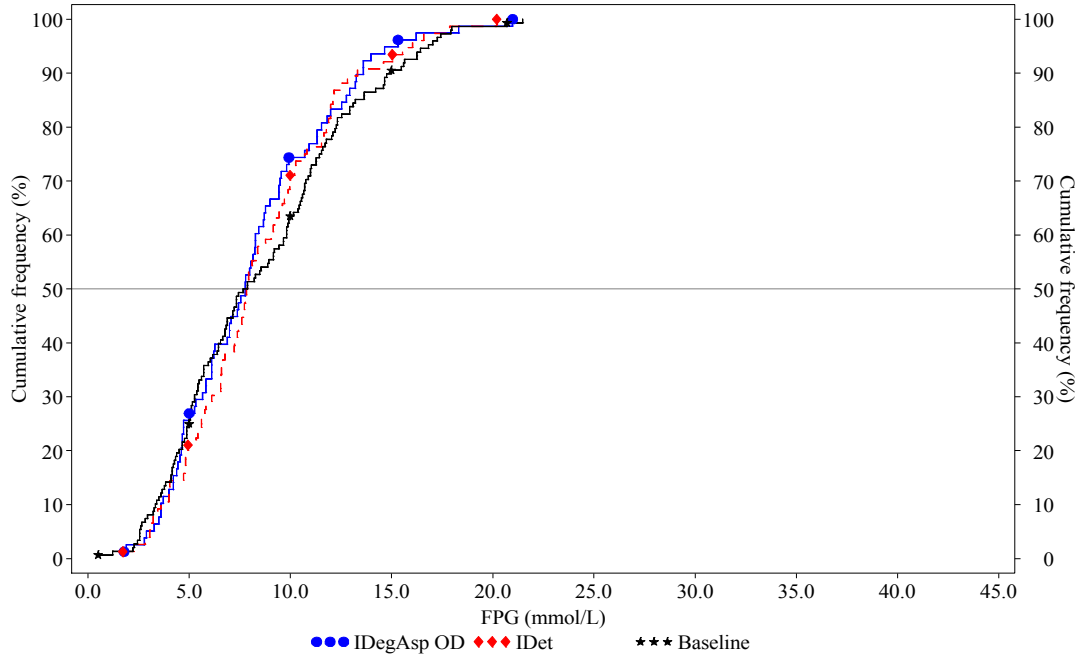
14.2.232 Fasting plasma glucose after 16 weeks of treatment – empirical distribution plot – children (1-5 years) - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:39 - fedist_numfind_v01.sas/e_fpg_abs_mean_cdf_pred_age2_fas.cgm

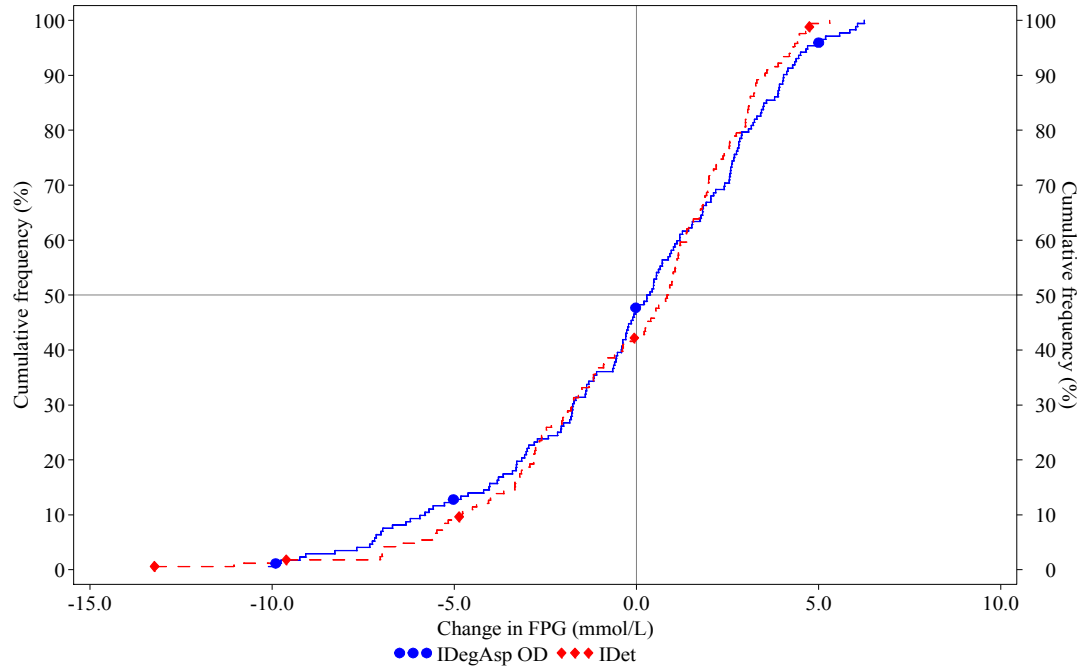
14.2.233 Fasting plasma glucose after 16 weeks of treatment – empirical distribution plot – children (6-11 years) - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For patients without a measurement at week 16, the predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:39 - fedist_numfind_v01.sas/e_fpg_abs_mean_cdf_pred_age3_fas.cgm

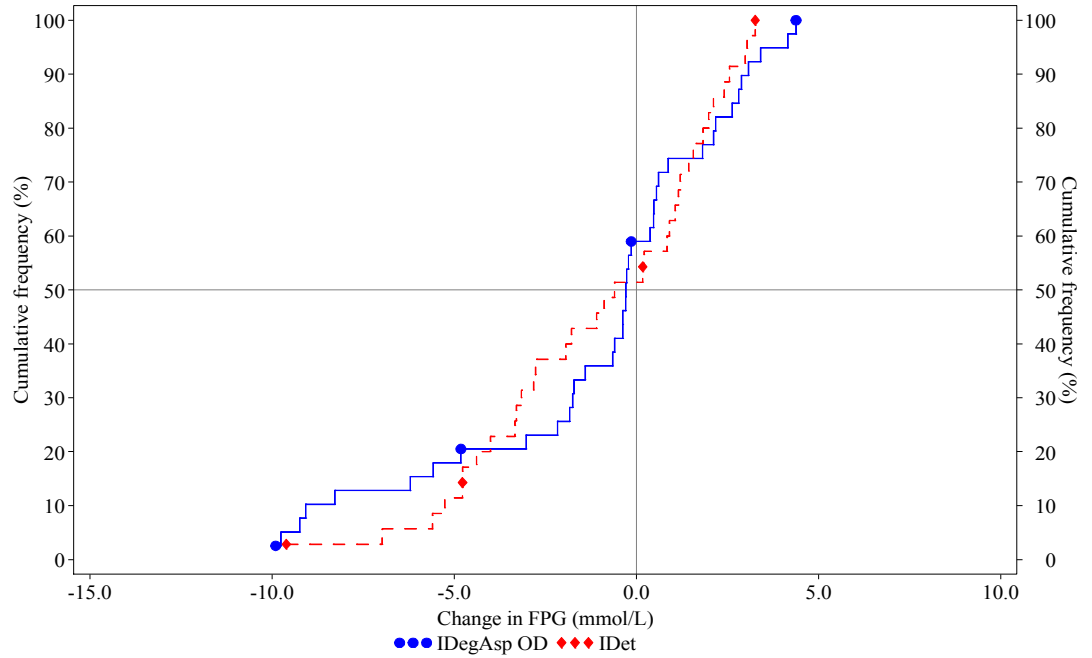
14.2.234 Fasting plasma glucose after 16 weeks of treatment – empirical distribution plot – adolescents (12-17 years) - full analysis set



FAS; Observed data
Predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:36 - fedist_numfind_v01.sas/e_fpg_chb_cdf_pred_fas.cgm

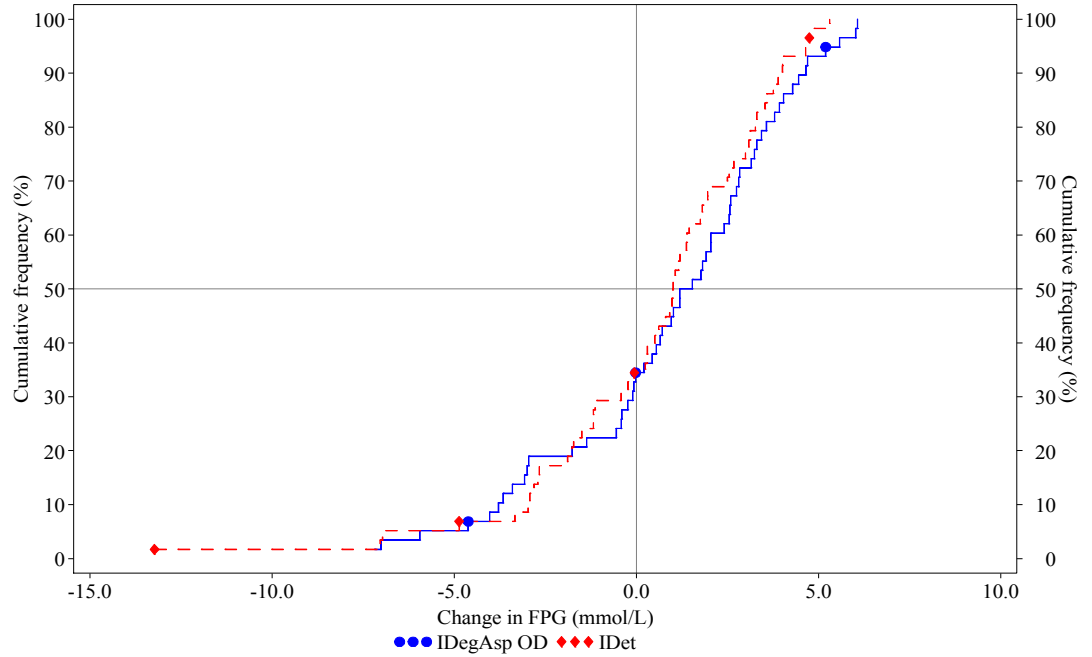
14.2.235 Fasting plasma glucose after 16 weeks of treatment – change from baseline - empirical distribution plot - full analysis set



FAS: Observed data
FAS: Full analysis set
Predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:37 - fedist_numfind_v01.sas/e_fpg_chb_cdf_pred_age1_fas.cgm

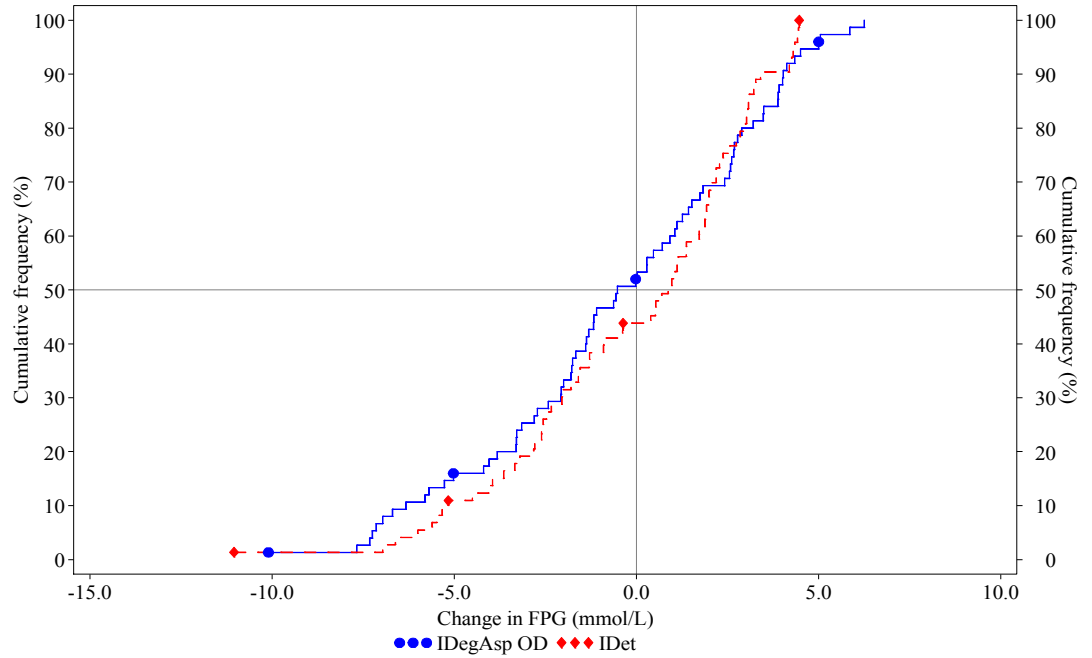
14.2.236 Fasting plasma glucose after 16 weeks of treatment – change from baseline - empirical distribution plot – children (1-5 years) - full analysis set



FAS: Observed data
FAS: Full analysis set
Predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:38 - fedist_numfind_v01.sas/e_fpg_chb_cdf_pred_age2_fas.cgm

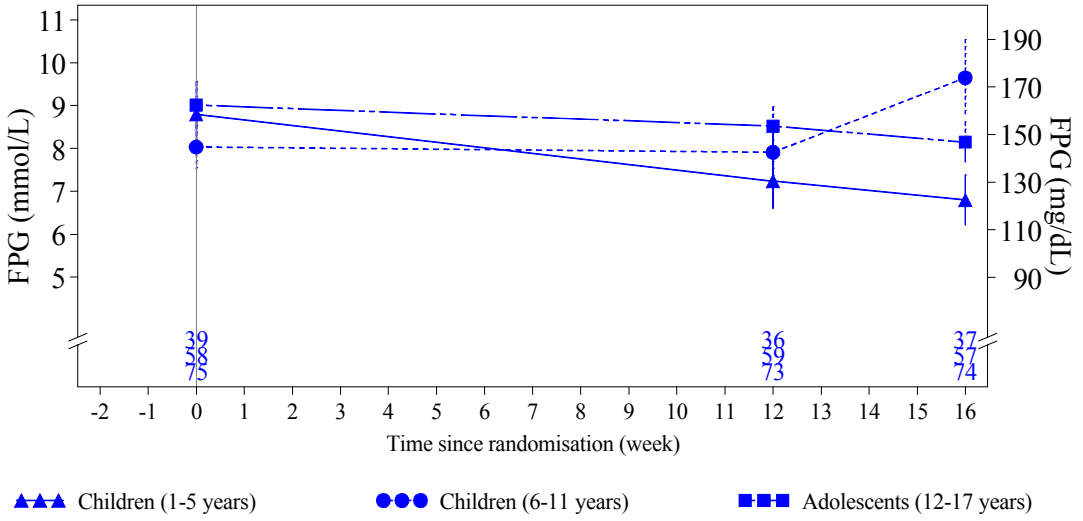
14.2.237 Fasting plasma glucose after 16 weeks of treatment – change from baseline - empirical distribution plot – children (6-11 years) - full analysis set



FAS: Observed data
FAS: Full analysis set
Predicted values from a MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:42:39 - fedist_numfind_v01.sas/e_fpg_chb_cdf_pred_age3_fas.cgm

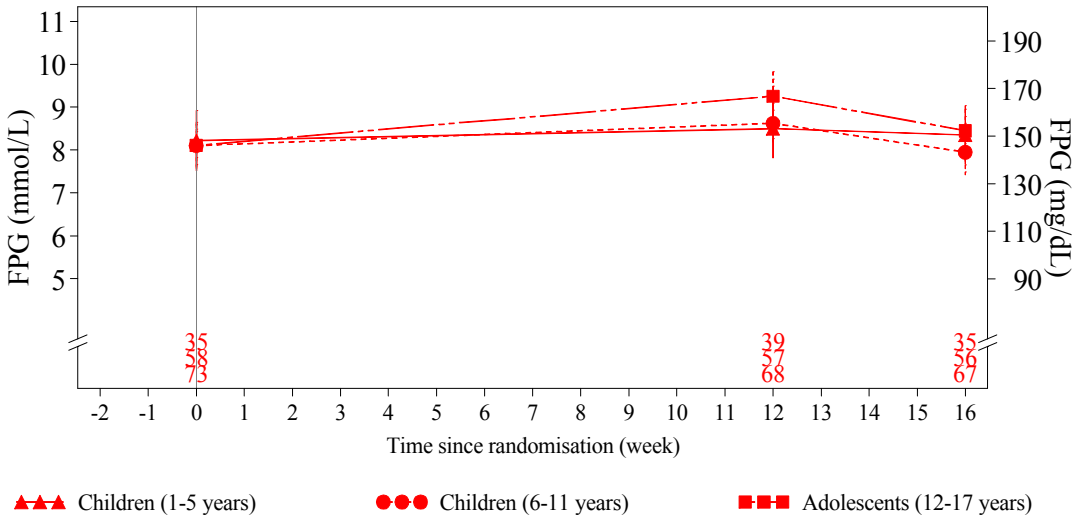
14.2.238 Fasting plasma glucose after 16 weeks of treatment – change from baseline - empirical distribution plot – adolescents (12-17 years) - full analysis set



FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:11 - fpg_fplot_treatment_age.sas/e_fpg_mean_ideg_fas.cgm

14.2.239 Fasting plasma glucose by treatment week – mean plot - IDegAsp OD - by age group - full analysis set



FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:15 - fpg_fplot_treatment_age.sas/e_fpg_mean_idet_fas.cgm

14.2.240 Fasting plasma glucose by treatment week – mean plot - IDet - by age group - full analysis set

14.2.241 8-point self measured plasma glucose profile by treatment week - descriptive statistics - full analysis set

	IDegAsp OD			IDet		
	N	Mean	SD	N	Mean	SD
Number Of Subjects	182			180		
SMPG(mmol/L)						
Visit 2 (Week 0)						
Before breakfast	179	9.8	4.5	179	10.0	5.2
90 minutes after start of breakfast	163	12.3	5.2	164	11.9	5.1
Before lunch	179	9.1	4.9	176	9.1	5.3
90 minutes after start of lunch	167	10.4	5.0	170	9.6	5.0
Before main evening meal	179	10.3	5.5	176	9.9	5.3
90 min after main evening meal	163	10.1	4.9	159	9.9	4.4
Before bedtime	159	10.4	5.3	160	10.2	4.9
Before breakfast the following day	178	10.4	5.0	176	10.2	4.9
Visit 14 (Week 12)						
Before breakfast	173	9.6	4.3	172	9.5	4.4
90 minutes after start of breakfast	145	10.9	5.0	147	10.8	4.8
Before lunch	170	9.7	5.5	171	8.8	4.1
90 minutes after start of lunch	147	10.3	5.4	147	9.1	4.5
Before main evening meal	175	10.3	5.3	168	10.9	5.5
90 min after main evening meal	147	9.9	5.0	146	10.7	5.2
Before bedtime	166	10.5	4.8	156	9.7	4.4
Before breakfast the following day	173	9.3	3.9	168	9.5	4.1
Visit 18 (Week 16)						
Before breakfast	172	9.1	4.5	165	9.4	4.2
90 minutes after start of breakfast	149	10.4	5.2	146	10.7	4.7
Before lunch	171	10.3	5.6	166	9.7	4.8
90 minutes after start of lunch	156	9.9	5.1	152	9.2	4.3
Before main evening meal	169	11.0	5.6	161	10.0	5.3
90 min after main evening meal	151	10.6	5.2	143	9.5	4.6
Before bedtime	163	10.0	5.1	152	10.3	4.8
Before breakfast the following day	171	9.3	4.4	162	9.2	4.1
End of trial visit						
Before breakfast	179	9.2	4.5	178	9.5	4.3
90 minutes after start of breakfast	154	10.5	5.2	152	10.7	4.7
Before lunch	177	10.3	5.6	178	10.0	5.2
90 minutes after start of lunch	161	10.0	5.1	159	9.1	4.3
Before main evening meal	176	11.0	5.6	173	10.2	5.4
90 min after main evening meal	156	10.8	5.3	150	9.6	4.8
Before bedtime	168	10.1	5.2	165	10.4	5.0
Before breakfast the following day	179	9.4	4.4	175	9.4	4.3

N: Number of subjects, SD: Standard deviation,
SMPG: Self measured plasma glucose

8-point self measured plasma glucose profile by treatment week - descriptive statistics - full analysis set

	IDegAsp OD			IDet		
	N	Mean	SD	N	Mean	SD
SMPG(mg/dL)						
Visit 2 (Week 0)						
Before breakfast	179	175.9	81.4	179	179.9	93.7
90 minutes after start of breakfast	163	221.6	93.7	164	214.0	92.5
Before lunch	179	163.7	87.6	176	163.7	95.0
90 minutes after start of lunch	167	187.2	89.8	170	172.6	90.6
Before main evening meal	179	186.1	98.2	176	177.6	95.0
90 min after main evening meal	163	182.4	87.4	159	178.9	79.7
Before bedtime	159	187.2	95.4	160	183.7	87.8
Before breakfast the following day	178	187.5	90.7	176	184.5	89.0
Visit 14 (Week 12)						
Before breakfast	173	172.2	76.8	172	170.3	79.0
90 minutes after start of breakfast	145	195.5	90.8	147	195.0	85.8
Before lunch	170	175.5	99.8	171	158.0	73.4
90 minutes after start of lunch	147	185.4	96.6	147	164.3	81.2
Before main evening meal	175	185.0	95.4	168	197.2	98.3
90 min after main evening meal	147	178.7	89.7	146	192.7	92.9
Before bedtime	166	189.1	86.8	156	174.8	79.0
Before breakfast the following day	173	167.1	71.0	168	171.4	73.3
Visit 18 (Week 16)						
Before breakfast	172	164.7	81.7	165	170.2	75.1
90 minutes after start of breakfast	149	187.5	93.4	146	192.5	85.0
Before lunch	171	185.3	100.4	166	174.1	87.3
90 minutes after start of lunch	156	178.0	91.7	152	164.9	77.3
Before main evening meal	169	197.4	101.1	161	179.9	96.2
90 min after main evening meal	151	191.9	93.6	143	170.9	83.1
Before bedtime	163	179.4	92.1	152	185.8	86.2
Before breakfast the following day	171	168.4	78.9	162	165.9	74.7
End of trial visit						
Before breakfast	179	165.4	81.5	178	171.1	77.2
90 minutes after start of breakfast	154	188.7	93.2	152	193.6	85.0
Before lunch	177	186.2	101.7	178	180.0	93.3
90 minutes after start of lunch	161	179.7	91.8	159	164.2	77.4
Before main evening meal	176	198.7	100.6	173	183.3	97.9
90 min after main evening meal	156	194.0	95.6	150	173.9	85.6
Before bedtime	168	181.2	93.6	165	186.9	90.4
Before breakfast the following day	179	169.6	79.7	175	169.3	77.1

N: Number of subjects, SD: Standard deviation,
SMPG: Self measured plasma glucose

14.2.242 8-point self measured plasma glucose profile by treatment week - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD			IDet		
	N	Mean	SD	N	Mean	SD
Number Of Subjects	41			41		
SMPG(mmol/L)						
Visit 2 (Week 0)						
Before breakfast	39	9.5	3.8	41	11.0	6.1
90 minutes after start of breakfast	38	12.8	6.3	36	13.9	6.5
Before lunch	40	8.6	5.7	41	9.5	6.1
90 minutes after start of lunch	39	11.3	5.7	38	11.0	5.9
Before main evening meal	39	12.0	6.4	40	11.1	6.3
90 min after main evening meal	37	11.3	5.7	36	10.2	5.3
Before bedtime	36	11.2	6.3	35	11.5	4.9
Before breakfast the following day	39	10.6	4.8	41	12.0	5.8
Visit 14 (Week 12)						
Before breakfast	38	10.5	4.4	39	9.2	4.2
90 minutes after start of breakfast	36	12.8	5.7	36	12.6	5.5
Before lunch	38	9.8	6.1	38	8.1	3.9
90 minutes after start of lunch	36	9.7	5.3	34	9.4	4.3
Before main evening meal	38	10.3	5.8	39	11.5	5.7
90 min after main evening meal	35	10.6	5.0	34	11.2	5.6
Before bedtime	35	11.1	5.0	36	10.5	5.0
Before breakfast the following day	38	9.8	4.6	38	9.4	4.9
Visit 18 (Week 16)						
Before breakfast	38	8.3	3.8	37	9.5	3.7
90 minutes after start of breakfast	34	10.9	5.2	33	11.4	5.4
Before lunch	37	10.2	5.3	37	10.7	5.7
90 minutes after start of lunch	35	10.1	5.0	33	9.3	5.1
Before main evening meal	36	10.6	6.0	36	9.9	5.4
90 min after main evening meal	35	11.1	5.0	32	10.8	5.2
Before bedtime	34	9.8	5.1	35	10.2	4.6
Before breakfast the following day	38	8.6	4.0	37	9.3	5.0
End of trial visit						
Before breakfast	39	8.3	3.7	41	9.4	3.6
90 minutes after start of breakfast	35	11.2	5.4	34	11.6	5.4
Before lunch	39	10.6	5.6	41	11.6	6.3
90 minutes after start of lunch	36	10.2	5.0	35	9.0	5.0
Before main evening meal	38	10.7	5.8	40	10.5	5.9
90 min after main evening meal	36	11.5	5.3	34	10.8	5.1
Before bedtime	36	10.1	5.1	39	10.1	4.5
Before breakfast the following day	40	8.7	3.9	41	9.2	5.1

N: Number of subjects, SD: Standard deviation,
SMPG: Self measured plasma glucose

8-point self measured plasma glucose profile by treatment week - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD			IDet		
	N	Mean	SD	N	Mean	SD
SMPG(mg/dL)						
Visit 2 (Week 0)						
Before breakfast	39	171.3	68.8	41	198.1	110.5
90 minutes after start of breakfast	38	230.3	113.4	36	249.6	117.8
Before lunch	40	154.7	102.5	41	171.6	109.7
90 minutes after start of lunch	39	203.4	102.9	38	197.8	107.0
Before main evening meal	39	216.9	115.7	40	200.8	112.7
90 min after main evening meal	37	204.5	103.4	36	184.2	95.2
Before bedtime	36	201.7	114.3	35	207.1	87.9
Before breakfast the following day	39	190.8	86.1	41	217.0	104.7
Visit 14 (Week 12)						
Before breakfast	38	189.0	79.4	39	166.0	75.6
90 minutes after start of breakfast	36	229.9	102.1	36	227.7	99.4
Before lunch	38	176.6	110.2	38	145.8	70.9
90 minutes after start of lunch	36	175.6	95.0	34	168.9	78.4
Before main evening meal	38	184.9	104.1	39	207.5	103.0
90 min after main evening meal	35	190.8	89.5	34	201.6	101.7
Before bedtime	35	200.0	90.1	36	188.7	90.1
Before breakfast the following day	38	177.3	83.2	38	170.2	88.7
Visit 18 (Week 16)						
Before breakfast	38	149.9	67.9	37	171.9	67.2
90 minutes after start of breakfast	34	196.0	93.0	33	205.1	97.2
Before lunch	37	184.5	95.5	37	193.7	103.1
90 minutes after start of lunch	35	182.0	89.9	33	168.0	91.0
Before main evening meal	36	191.6	107.8	36	179.0	97.5
90 min after main evening meal	35	200.5	89.5	32	194.2	93.4
Before bedtime	34	177.4	91.7	35	183.0	82.8
Before breakfast the following day	38	155.7	71.3	37	167.0	89.9
End of trial visit						
Before breakfast	39	149.3	67.1	41	169.1	65.7
90 minutes after start of breakfast	35	201.2	96.8	34	208.6	97.9
Before lunch	39	190.9	100.2	41	209.5	114.4
90 minutes after start of lunch	36	183.9	89.4	35	163.0	90.8
Before main evening meal	38	193.6	105.2	40	189.7	107.0
90 min after main evening meal	36	206.3	94.9	34	193.7	92.5
Before bedtime	36	181.6	92.7	39	182.8	81.2
Before breakfast the following day	40	156.2	70.3	41	166.5	91.4

N: Number of subjects, SD: Standard deviation,
SMPG: Self measured plasma glucose

14.2.243 8-point self measured plasma glucose profile by treatment week - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD			IDet		
	N	Mean	SD	N	Mean	SD
Number Of Subjects	61			61		
SMPG(mmol/L)						
Visit 2 (Week 0)						
Before breakfast	61	9.4	4.2	61	8.3	3.7
90 minutes after start of breakfast	56	12.5	4.9	58	12.2	4.3
Before lunch	60	10.1	5.2	60	8.8	5.0
90 minutes after start of lunch	54	10.6	5.1	59	8.8	4.3
Before main evening meal	61	10.1	5.6	60	10.0	5.1
90 min after main evening meal	54	9.5	4.1	55	9.9	3.9
Before bedtime	51	9.9	4.9	58	9.4	4.8
Before breakfast the following day	61	10.1	5.5	60	9.8	4.5
Visit 14 (Week 12)						
Before breakfast	60	9.3	4.3	59	8.7	3.9
90 minutes after start of breakfast	50	11.0	5.4	51	10.0	4.8
Before lunch	58	10.5	6.4	59	9.0	4.0
90 minutes after start of lunch	50	10.2	6.4	53	9.4	4.5
Before main evening meal	60	9.6	4.6	57	11.4	5.7
90 min after main evening meal	50	10.2	5.7	52	10.0	5.0
Before bedtime	56	11.1	5.4	53	9.3	4.2
Before breakfast the following day	59	9.2	4.0	58	9.6	3.8
Visit 18 (Week 16)						
Before breakfast	59	9.8	5.1	58	9.0	4.0
90 minutes after start of breakfast	53	11.5	5.6	54	10.8	4.9
Before lunch	58	11.3	6.0	59	9.3	5.0
90 minutes after start of lunch	55	10.8	5.6	56	9.0	4.6
Before main evening meal	58	11.9	5.5	56	10.9	5.6
90 min after main evening meal	51	11.3	5.9	52	8.8	4.8
Before bedtime	58	10.4	5.5	55	10.0	4.8
Before breakfast the following day	59	9.3	4.1	57	9.0	3.6
End of trial visit						
Before breakfast	61	9.9	5.0	60	8.9	4.1
90 minutes after start of breakfast	55	11.5	5.5	55	10.9	5.0
Before lunch	60	11.1	5.9	60	9.3	5.0
90 minutes after start of lunch	57	10.8	5.5	57	9.1	4.5
Before main evening meal	60	12.0	5.4	58	10.9	5.5
90 min after main evening meal	53	11.5	5.9	53	8.8	4.8
Before bedtime	60	10.6	5.7	57	9.9	4.8
Before breakfast the following day	61	9.3	4.1	59	9.0	3.6

N: Number of subjects, SD: Standard deviation,
SMPG: Self measured plasma glucose

8-point self measured plasma glucose profile by treatment week - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD			IDet		
	N	Mean	SD	N	Mean	SD
SMPG(mg/dL)						
Visit 2 (Week 0)						
Before breakfast	61	169.5	75.3	61	148.7	66.9
90 minutes after start of breakfast	56	226.1	88.4	58	219.0	77.4
Before lunch	60	181.3	93.8	60	157.9	90.7
90 minutes after start of lunch	54	191.7	91.5	59	159.2	76.6
Before main evening meal	61	181.2	100.0	60	180.5	91.2
90 min after main evening meal	54	170.6	73.4	55	178.7	70.0
Before bedtime	51	178.9	87.4	58	169.3	86.0
Before breakfast the following day	61	182.1	98.4	60	177.3	81.0
Visit 14 (Week 12)						
Before breakfast	60	167.1	77.6	59	156.3	70.8
90 minutes after start of breakfast	50	197.6	97.9	51	180.5	86.5
Before lunch	58	188.4	115.5	59	162.8	72.3
90 minutes after start of lunch	50	184.6	115.2	53	168.9	80.6
Before main evening meal	60	173.7	82.0	57	204.6	102.5
90 min after main evening meal	50	184.0	102.5	52	180.6	90.7
Before bedtime	56	200.1	97.9	53	167.6	76.4
Before breakfast the following day	59	165.3	72.4	58	172.2	67.6
Visit 18 (Week 16)						
Before breakfast	59	177.0	91.7	58	162.7	72.8
90 minutes after start of breakfast	53	207.3	101.1	54	194.8	88.5
Before lunch	58	202.8	107.4	59	167.1	90.8
90 minutes after start of lunch	55	194.5	101.0	56	162.2	82.1
Before main evening meal	58	215.2	98.8	56	195.9	101.0
90 min after main evening meal	51	204.3	106.5	52	157.9	86.9
Before bedtime	58	187.2	99.3	55	180.6	86.3
Before breakfast the following day	59	167.9	74.0	57	161.3	65.0
End of trial visit						
Before breakfast	61	177.5	90.3	60	159.9	73.1
90 minutes after start of breakfast	55	206.7	99.4	55	197.2	89.6
Before lunch	60	199.8	107.0	60	167.6	90.1
90 minutes after start of lunch	57	195.0	99.2	57	163.1	81.6
Before main evening meal	60	215.4	97.3	58	195.6	100.0
90 min after main evening meal	53	207.8	106.9	53	159.1	86.5
Before bedtime	60	191.3	101.9	57	177.8	86.4
Before breakfast the following day	61	166.7	73.4	59	162.5	64.4

N: Number of subjects, SD: Standard deviation,
SMPG: Self measured plasma glucose

14.2.244 8-point self measured plasma glucose profile by treatment week - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD			IDet		
	N	Mean	SD	N	Mean	SD
Number Of Subjects	80			78		
SMPG(mmol/L)						
Visit 2 (Week 0)						
Before breakfast	79	10.2	5.1	77	10.8	5.4
90 minutes after start of breakfast	69	11.8	4.8	70	10.6	4.7
Before lunch	79	8.6	4.0	75	9.1	5.0
90 minutes after start of lunch	74	9.7	4.5	73	9.5	5.0
Before main evening meal	79	9.7	4.7	76	9.0	4.8
90 min after main evening meal	72	10.0	4.8	68	9.8	4.4
Before bedtime	72	10.3	5.1	67	10.2	4.9
Before breakfast the following day	78	10.6	4.9	75	9.6	4.6
Visit 14 (Week 12)						
Before breakfast	75	9.3	4.1	74	10.2	4.7
90 minutes after start of breakfast	59	9.6	3.9	60	10.4	4.0
Before lunch	74	9.1	4.4	74	8.9	4.2
90 minutes after start of lunch	61	10.7	4.5	60	8.7	4.7
Before main evening meal	77	10.8	5.6	72	10.3	5.1
90 min after main evening meal	62	9.3	4.3	60	11.0	5.0
Before bedtime	75	9.8	4.2	67	9.6	4.1
Before breakfast the following day	76	9.1	3.5	72	9.5	3.9
Visit 18 (Week 16)						
Before breakfast	75	9.0	4.4	70	9.7	4.5
90 minutes after start of breakfast	62	9.2	4.6	59	10.2	4.1
Before lunch	76	9.6	5.4	70	9.4	4.1
90 minutes after start of lunch	66	9.0	4.6	63	9.2	3.6
Before main evening meal	75	10.3	5.5	69	9.3	5.1
90 min after main evening meal	65	9.8	4.7	59	9.4	4.0
Before bedtime	71	9.7	4.8	62	10.7	4.9
Before breakfast the following day	74	9.7	4.8	68	9.4	4.1
End of trial visit						
Before breakfast	79	9.1	4.5	77	10.0	4.7
90 minutes after start of breakfast	64	9.2	4.5	63	10.1	4.0
Before lunch	78	9.6	5.4	77	9.7	4.5
90 minutes after start of lunch	68	9.1	4.7	67	9.2	3.7
Before main evening meal	78	10.5	5.6	75	9.5	5.0
90 min after main evening meal	67	9.8	4.7	63	9.7	4.4
Before bedtime	72	9.6	4.8	69	10.9	5.5
Before breakfast the following day	78	9.9	4.9	75	9.8	4.3

N: Number of subjects, SD: Standard deviation,
SMPG: Self measured plasma glucose

8-point self measured plasma glucose profile by treatment week - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD			IDet		
	N	Mean	SD	N	Mean	SD
SMPG(mg/dL)						
Visit 2 (Week 0)						
Before breakfast	79	183.1	91.4	77	195.0	97.0
90 minutes after start of breakfast	69	213.2	86.5	70	191.4	83.9
Before lunch	79	154.9	72.4	75	164.1	90.6
90 minutes after start of lunch	74	175.4	80.3	73	170.4	90.3
Before main evening meal	79	174.8	84.8	76	163.0	86.0
90 min after main evening meal	72	180.0	87.3	68	176.3	79.1
Before bedtime	72	185.8	91.0	67	183.8	88.0
Before breakfast the following day	78	190.1	87.7	75	172.5	82.5
Visit 14 (Week 12)						
Before breakfast	75	167.8	74.5	74	183.7	85.4
90 minutes after start of breakfast	59	172.7	69.5	60	187.7	71.6
Before lunch	74	164.8	79.1	74	160.4	75.9
90 minutes after start of lunch	61	191.9	80.8	60	157.6	84.2
Before main evening meal	77	193.9	100.8	72	185.8	92.4
90 min after main evening meal	62	167.6	78.1	60	198.2	89.9
Before bedtime	75	175.8	74.9	67	173.1	74.7
Before breakfast the following day	76	163.5	63.4	72	171.4	69.7
Visit 18 (Week 16)						
Before breakfast	75	162.6	79.4	70	175.6	81.2
90 minutes after start of breakfast	62	166.0	83.2	59	183.3	74.2
Before lunch	76	172.2	96.4	70	169.7	74.0
90 minutes after start of lunch	66	162.2	82.8	63	165.6	65.5
Before main evening meal	75	186.5	98.9	69	167.2	91.0
90 min after main evening meal	65	177.4	83.9	59	169.7	71.8
Before bedtime	71	173.9	86.9	62	191.9	88.8
Before breakfast the following day	74	175.3	86.2	68	169.0	74.1
End of trial visit						
Before breakfast	79	163.9	80.2	77	180.9	85.2
90 minutes after start of breakfast	64	166.5	81.9	63	182.2	72.5
Before lunch	78	173.3	98.0	77	174.0	80.5
90 minutes after start of lunch	68	164.6	85.4	67	165.7	66.7
Before main evening meal	78	188.3	100.5	75	170.4	90.7
90 min after main evening meal	67	176.5	84.3	63	175.6	79.9
Before bedtime	72	172.6	87.0	69	196.8	98.5
Before breakfast the following day	78	178.7	88.4	75	176.3	78.2

N: Number of subjects, SD: Standard deviation,
SMPG: Self measured plasma glucose

14.2.245 8-point self measured plasma glucose profile after 16 weeks of treatment - statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
SMPG (mmol/L)					
Before breakfast					
LSMeans					
IDegAsp OD	182	174	9.10	0.33	
IDet	180	172	9.53	0.34	
Treatment Contrast					
IDegAsp OD - IDet			-0.42		[-1.36; 0.52]
90 minutes after start of breakfast					
LSMeans					
IDegAsp OD	182	147	10.48	0.41	
IDet	180	153	11.03	0.41	
Treatment Contrast					
IDegAsp OD - IDet			-0.55		[-1.68; 0.58]
Before lunch					
LSMeans					
IDegAsp OD	182	172	10.19	0.39	
IDet	180	170	9.83	0.39	
Treatment Contrast					
IDegAsp OD - IDet			0.37		[-0.72; 1.45]
90 minutes after start of lunch					
LSMeans					
IDegAsp OD	182	155	9.66	0.36	
IDet	180	159	9.35	0.37	
Treatment Contrast					
IDegAsp OD - IDet			0.31		[-0.70; 1.32]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval,
SE: Standard error of the mean
SMPG: Self measured plasma glucose
All observed 8-point profile (SMPG) measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix.
The model includes treatment, sex, region, age-group, time-point within 8-point profile and visit as factors and corresponding baseline SMPG profile as covariate.
Interactions between visit and all factors and covariates are also included in the model, and in addition interaction between treatment and visit and time-point also included.

8-point self measured plasma glucose profile after 16 weeks of treatment - statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
Before main evening meal					
LSMeans					
IDegAsp OD	182	174	10.82	0.41	
IDet	180	168	10.17	0.42	
Treatment Contrast					
IDegAsp OD - IDet			0.66		[-0.51; 1.82]
90 min after main evening meal					
LSMeans					
IDegAsp OD	182	148	10.76	0.39	
IDet	180	150	9.75	0.40	
Treatment Contrast					
IDegAsp OD - IDet			1.01		[-0.09; 2.12]
Before bedtime					
LSMeans					
IDegAsp OD	182	153	9.65	0.40	
IDet	180	149	10.45	0.41	
Treatment Contrast					
IDegAsp OD - IDet			-0.80		[-1.94; 0.34]
Before breakfast the following day					
LSMeans					
IDegAsp OD	182	172	9.04	0.32	
IDet	180	168	9.24	0.33	
Treatment Contrast					
IDegAsp OD - IDet			-0.20		[-1.10; 0.70]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval,
SE: Standard error of the mean
SMPG: Self measured plasma glucose
All observed 8-point profile (SMPG) measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix.
The model includes treatment, sex, region, age-group, time-point within 8-point profile and visit as factors and corresponding baseline SMPG profile as covariate.
Interactions between visit and all factors and covariates are also included in the model, and in addition interaction between treatment and visit and time-point also included.

8-point self measured plasma glucose profile after 16 weeks of treatment - statistical analysis - full analysis set

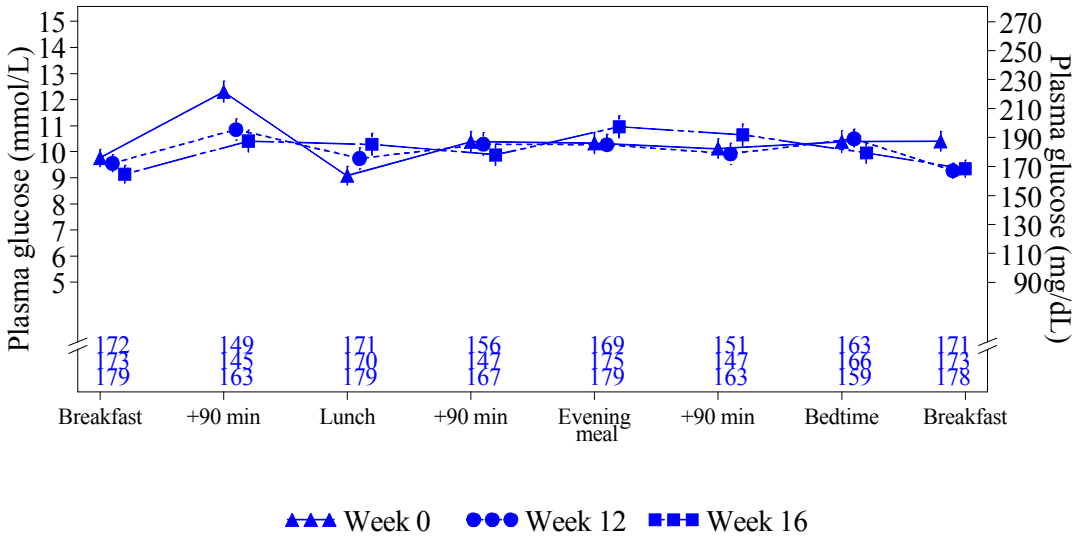
	FAS	N	Estimate	SE	95% CI
SMPG (mg/dL)					
Before breakfast					
LSMeans					
IDegAsp OD	182	174	164.04	6.02	
IDet	180	172	171.64	6.12	
Treatment Contrast					
IDegAsp OD - IDet			-7.60		[-24.51; 9.31]
90 minutes after start of breakfast					
LSMeans					
IDegAsp OD	182	147	188.77	7.34	
IDet	180	153	198.68	7.38	
Treatment Contrast					
IDegAsp OD - IDet			-9.91		[-30.32; 10.51]
Before lunch					
LSMeans					
IDegAsp OD	182	172	183.69	6.96	
IDet	180	170	177.10	7.07	
Treatment Contrast					
IDegAsp OD - IDet			6.60		[-12.91; 26.10]
90 minutes after start of lunch					
LSMeans					
IDegAsp OD	182	155	174.05	6.51	
IDet	180	159	168.48	6.59	
Treatment Contrast					
IDegAsp OD - IDet			5.57		[-12.67; 23.82]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval,
SE: Standard error of the mean
SMPG: Self measured plasma glucose
All observed 8-point profile (SMPG) measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix.
The model includes treatment, sex, region, age-group, time-point within 8-point profile and visit as factors and corresponding baseline SMPG profile as covariate.
Interactions between visit and all factors and covariates are also included in the model, and in addition interaction between treatment and visit and time-point also included.

8-point self measured plasma glucose profile after 16 weeks of treatment - statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
Before main evening meal					
LSMeans					
IDegAsp OD	182	174	195.04	7.42	
IDet	180	168	183.22	7.62	
Treatment Contrast					
IDegAsp OD - IDet			11.83		[-9.12; 32.78]
90 min after main evening meal					
LSMeans					
IDegAsp OD	182	148	193.91	7.07	
IDet	180	150	175.63	7.22	
Treatment Contrast					
IDegAsp OD - IDet			18.27		[-1.65; 38.19]
Before bedtime					
LSMeans					
IDegAsp OD	182	153	173.82	7.30	
IDet	180	149	188.22	7.41	
Treatment Contrast					
IDegAsp OD - IDet			-14.40		[-34.88; 6.07]
Before breakfast the following day					
LSMeans					
IDegAsp OD	182	172	162.87	5.75	
IDet	180	168	166.41	5.89	
Treatment Contrast					
IDegAsp OD - IDet			-3.54		[-19.77; 12.68]

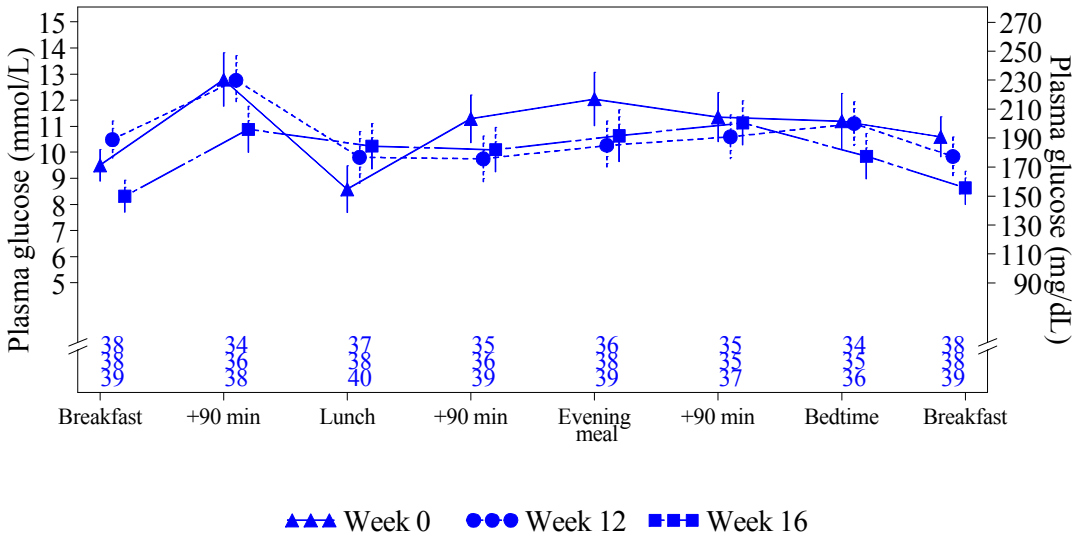
FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval,
SE: Standard error of the mean
SMPG: Self measured plasma glucose
All observed 8-point profile (SMPG) measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix.
The model includes treatment, sex, region, age-group, time-point within 8-point profile and visit as factors and corresponding baseline SMPG profile as covariate.
Interactions between visit and all factors and covariates are also included in the model, and in addition interaction between treatment and visit and time-point also included.



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. Week 0 2. Week 12 3. Week 16

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:13 - fplot_8PP_treatment.sas/e_8pp_al_w_iv1_ab_mean_ob_fas.cgm

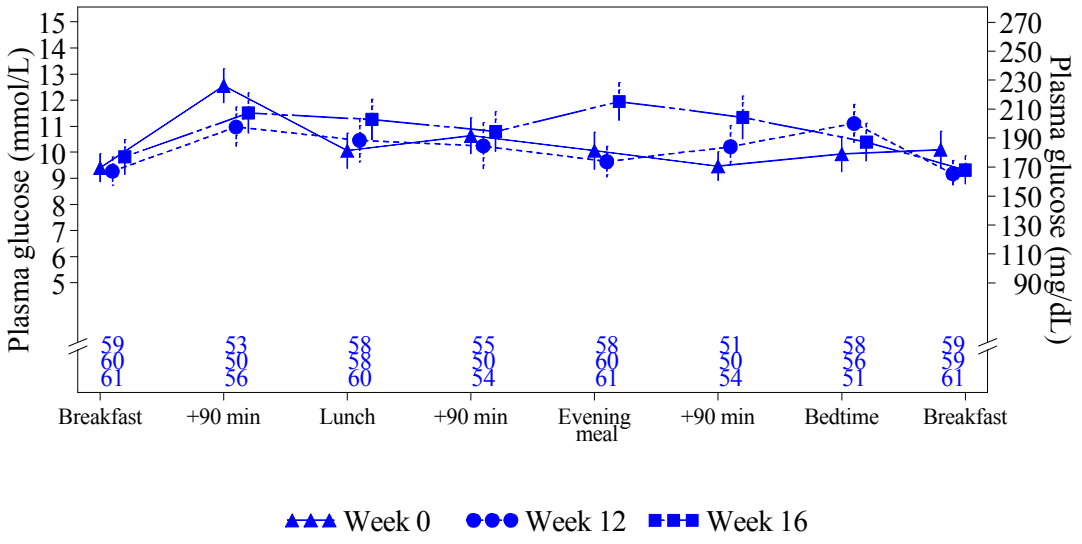
14.2.246 8-point self measured plasma glucose profile by treatment weeks - mean plot - IDegAsp OD - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. Week 0 2. Week 12 3. Week 16

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:18 - fplot_8PP_treatment.sas/e_8pp_al_w_iv1_ab_mean_ob_a1_fas.cgm

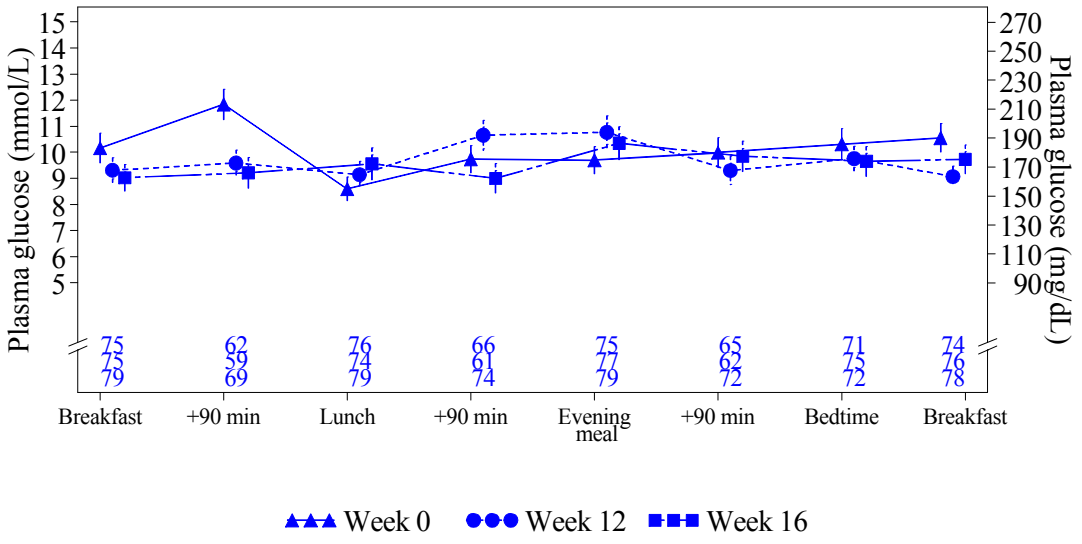
14.2.247 8-point self measured plasma glucose profile by treatment weeks - mean plot - IDegAsp OD - children (1-5 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. Week 0 2. Week 12 3. Week 16

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:22 - fplot_8PP_treatment.sas/e_8pp_al_w_iv1_ab_mean_ob_a2_fas.cgm

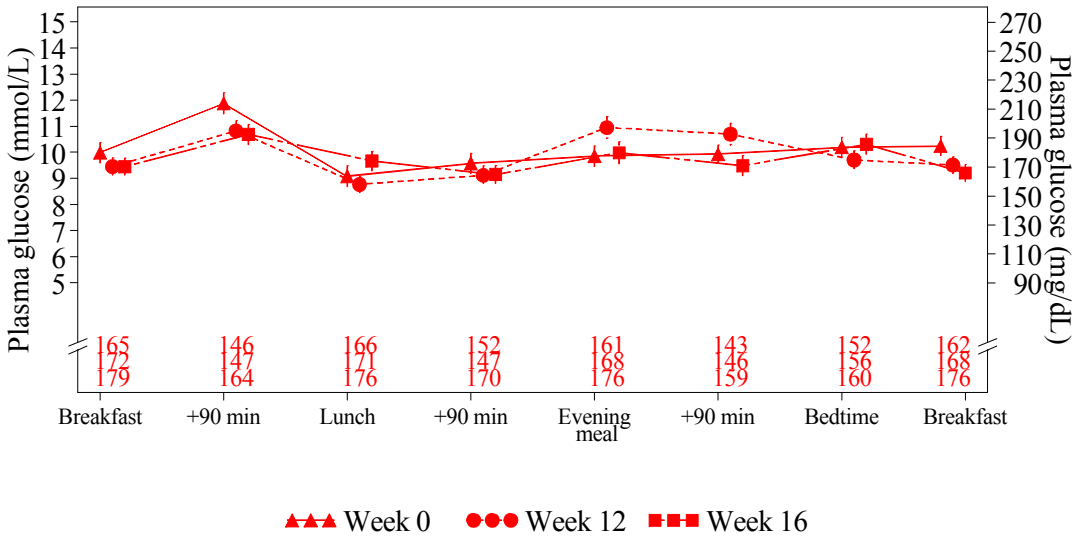
14.2.248 8-point self measured plasma glucose profile by treatment weeks - mean plot - IDegAsp OD - children (6-11 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. Week 0 2. Week 12 3. Week 16

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:27 - fplot_8PP_treatment.sas/e_8pp_al_w_iv1_ab_mean_ob_a3_fas.cgm

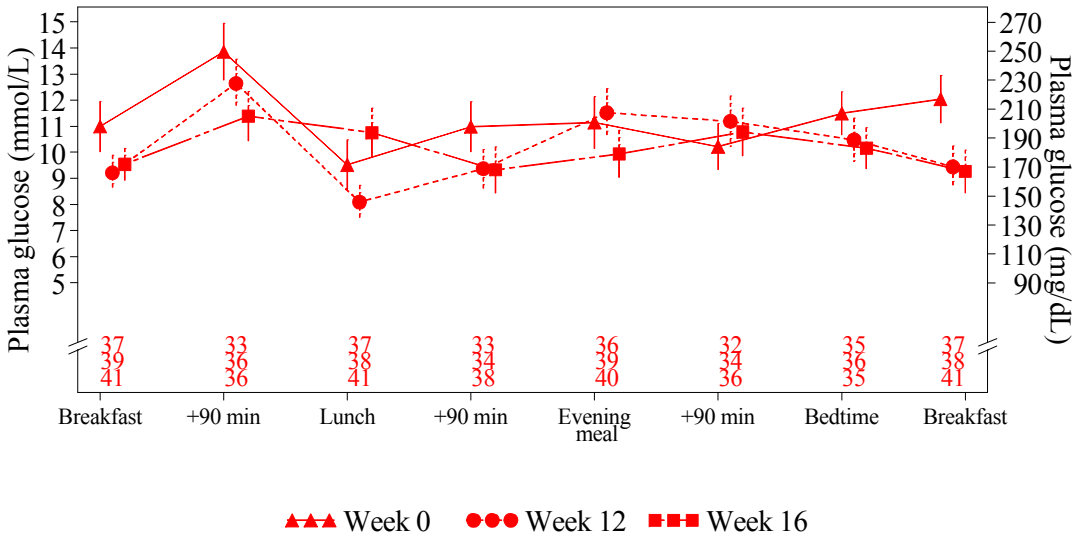
14.2.249 8-point self measured plasma glucose profile by treatment weeks - mean plot - IDegAsp OD - adolescents (12-17 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. Week 0 2. Week 12 3. Week 16

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:32 - fplot_8PP_treatment.sas/e_8pp_al_w_cm_ab_mean_ob_fas.cgm

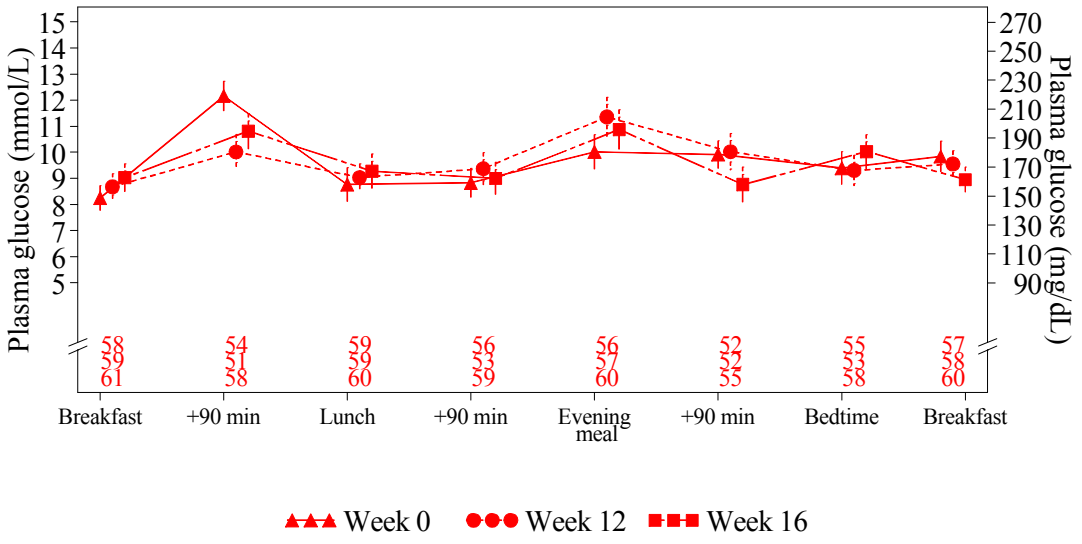
14.2.250 8-point self measured plasma glucose profile by treatment weeks - mean plot - IDet - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. Week 0 2. Week 12 3. Week 16

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:36 - fplot_8PP_treatment.sas/e_8pp_al_w_cm_ab_mean_ob_a1_fas.cgm

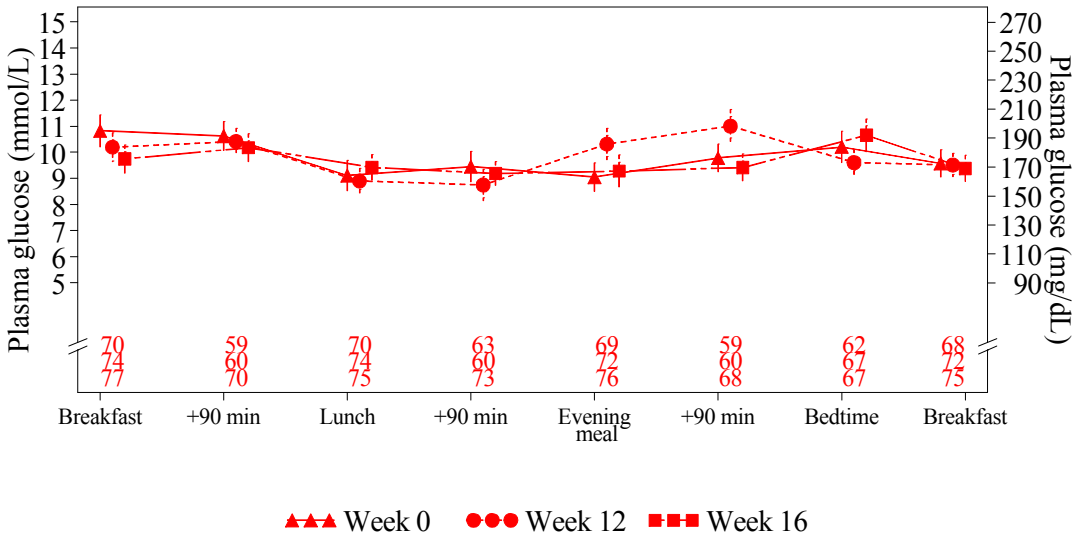
14.2.251 8-point self measured plasma glucose profile by treatment weeks - mean plot - IDet - children (1-5 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. Week 0 2. Week 12 3. Week 16

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:41 - fplot_8PP_treatment.sas/e_8pp_al_w_cm_ab_mean_ob_a2_fas.cgm

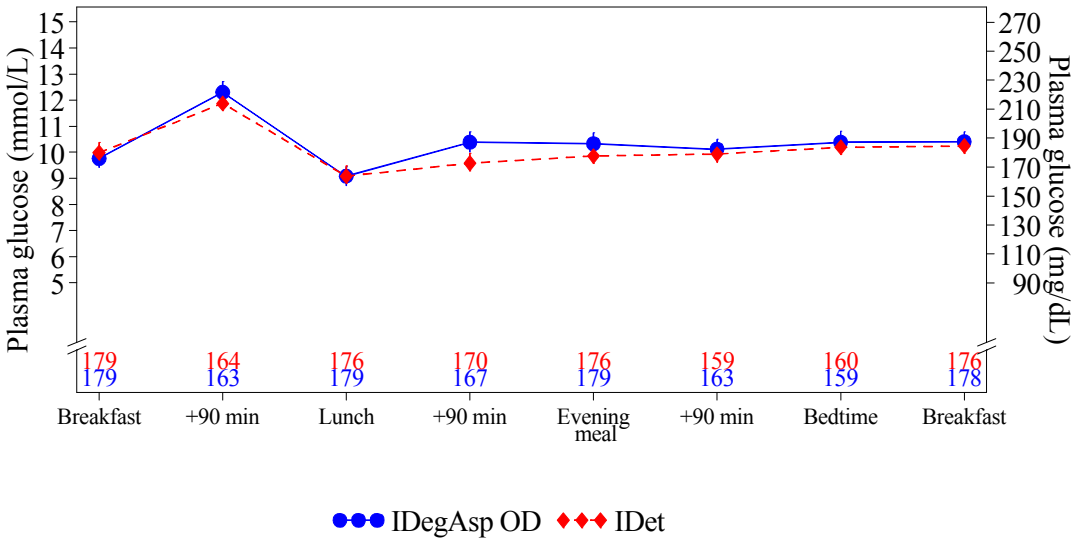
14.2.252 8-point self measured plasma glucose profile by treatment weeks - mean plot - IDet - children (6-11 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. Week 0 2. Week 12 3. Week 16

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:47 - fplot_8PP_treatment.sas/e_8pp_al_w_cm_ab_mean_ob_a3_fas.cgm

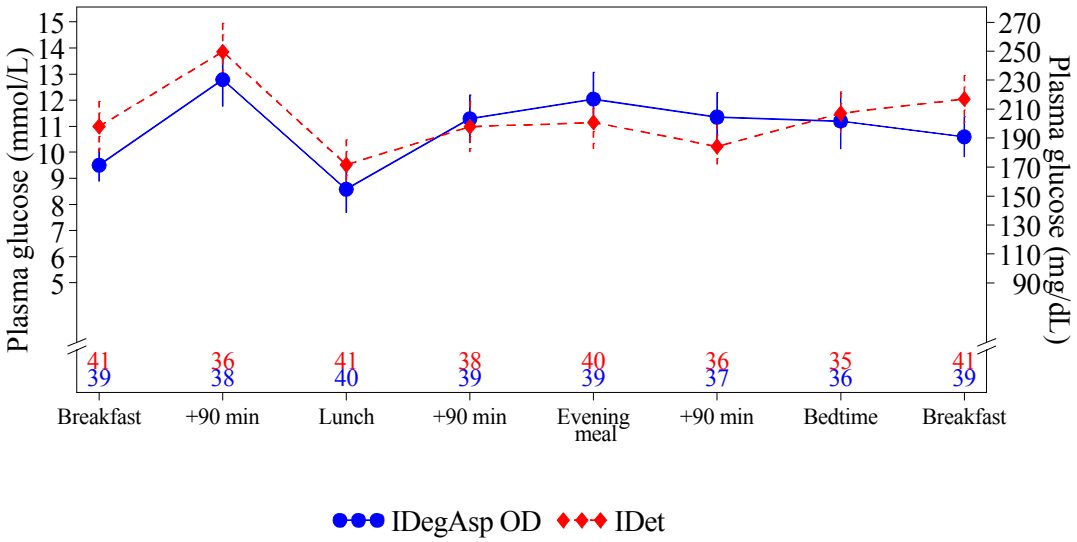
14.2.253 8-point self measured plasma glucose profile by treatment weeks - mean plot - IDet - adolescents (12-17 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:15 - fplot_8PP_treatment.sas/e_8pp_week0_ab_mean_ob_fas.cgm

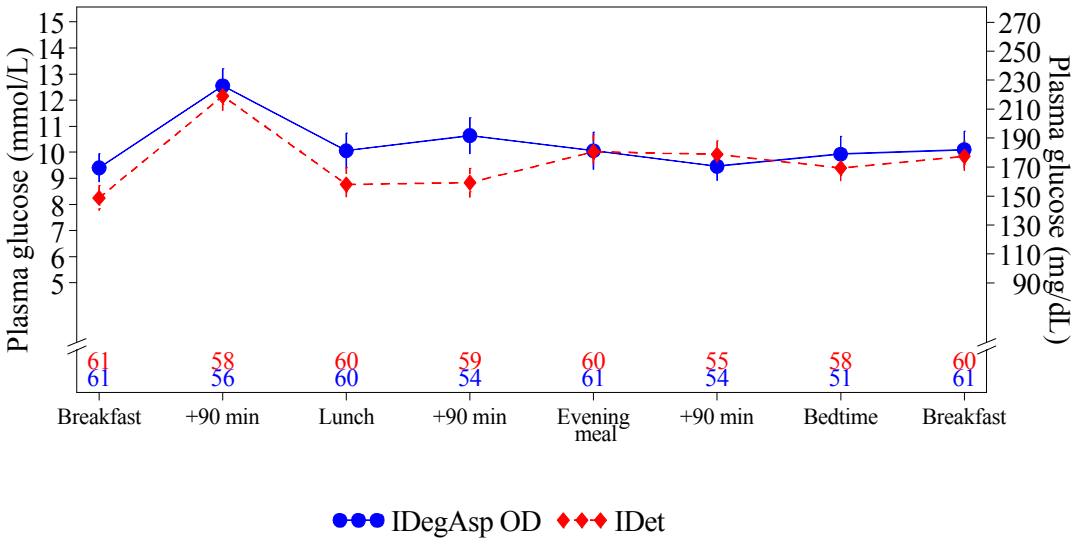
14.2.254 8-point self measured plasma glucose profile at baseline - mean plot - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:20 - fplot_8PP_treatment.sas/e_8pp_week0_ab_mean_ob_a1_fas.cgm

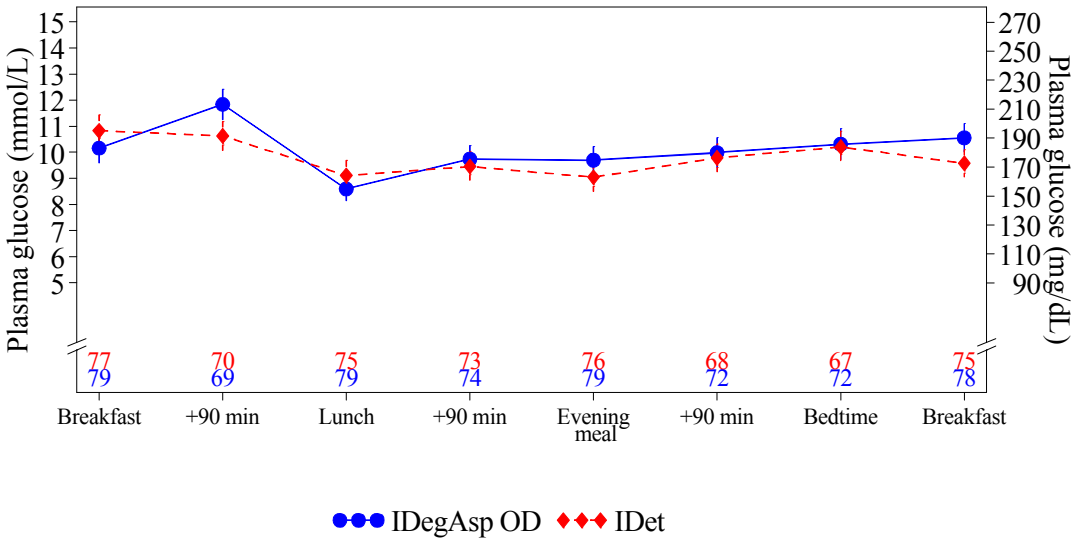
14.2.255 8-point self measured plasma glucose profile at baseline - mean plot – children (1-5 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:24 - fplot_8PP_treatment.sas/e_8pp_week0_ab_mean_ob_a2_fas.cgm

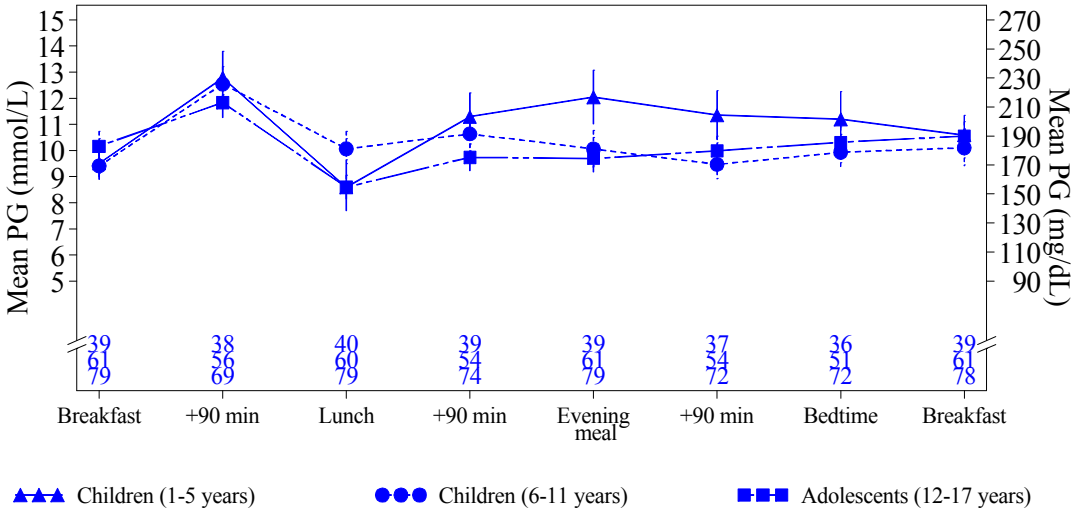
14.2.256 8-point self measured plasma glucose profile at baseline - mean plot – children (6-11 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:29 - fplot_8PP_treatment.sas/e_8pp_week0_ab_mean_ob_a3_fas.cgm

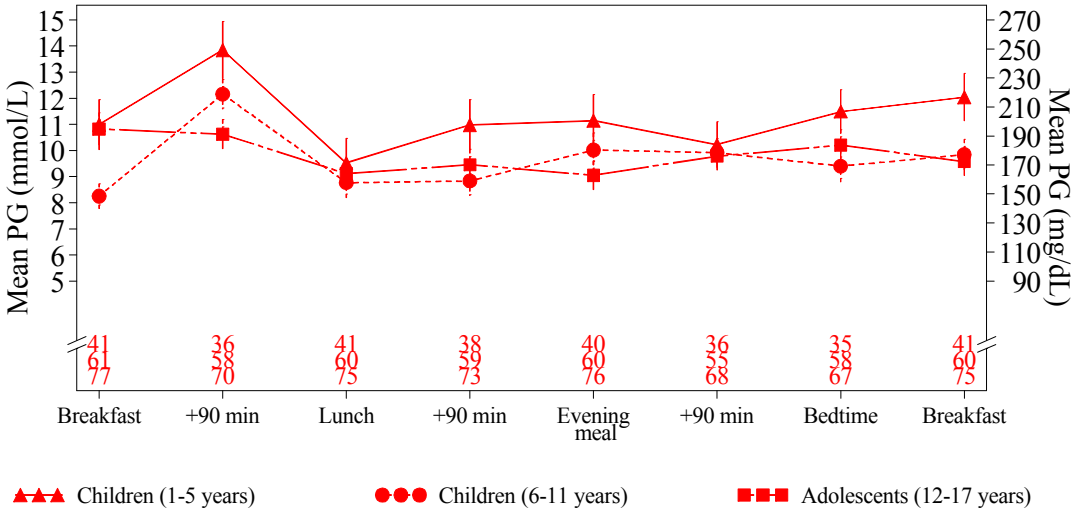
14.2.257 8-point self measured plasma glucose profile at baseline - mean plot - adolescents (12-17 years) - full analysis set



SMPG: Self-measured plasma glucose, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:27 - mean_8pp_smpg_bas_fplot_treatment_age.sas/e_mean_8pp_smpg_bas_ideg_fas.cgm

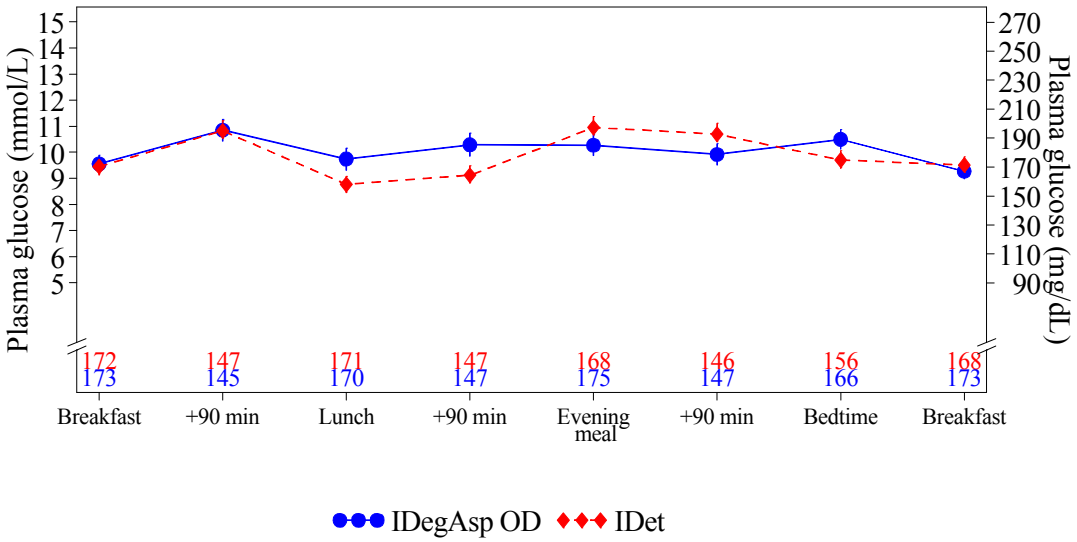
14.2.258 8-point self measured plasma glucose profile at baseline - mean plot – IDegAsp OD - by age group- full analysis set



SMPG: Self-measured plasma glucose, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:32 - mean_8pp_smpg_bas_fplot_treatment_age.sas/e_mean_8pp_smpg_bas_idet_fas.cgm

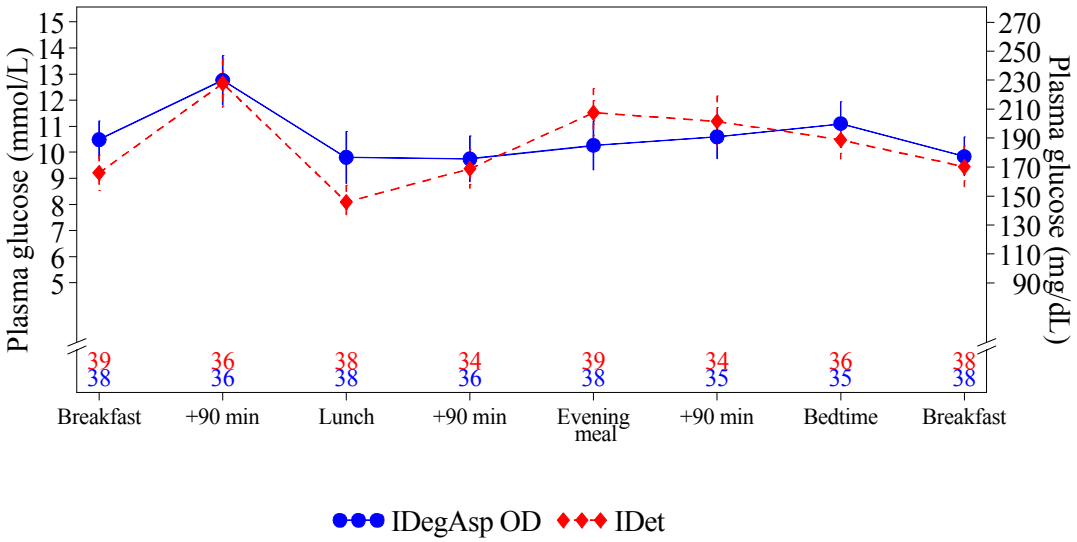
14.2.259 8-point self measured plasma glucose profile at baseline - mean plot – IDet - by age group - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:33 - fplot_8PP_treatment.sas/e_8pp_week12_ab_mean_ob_fas.cgm

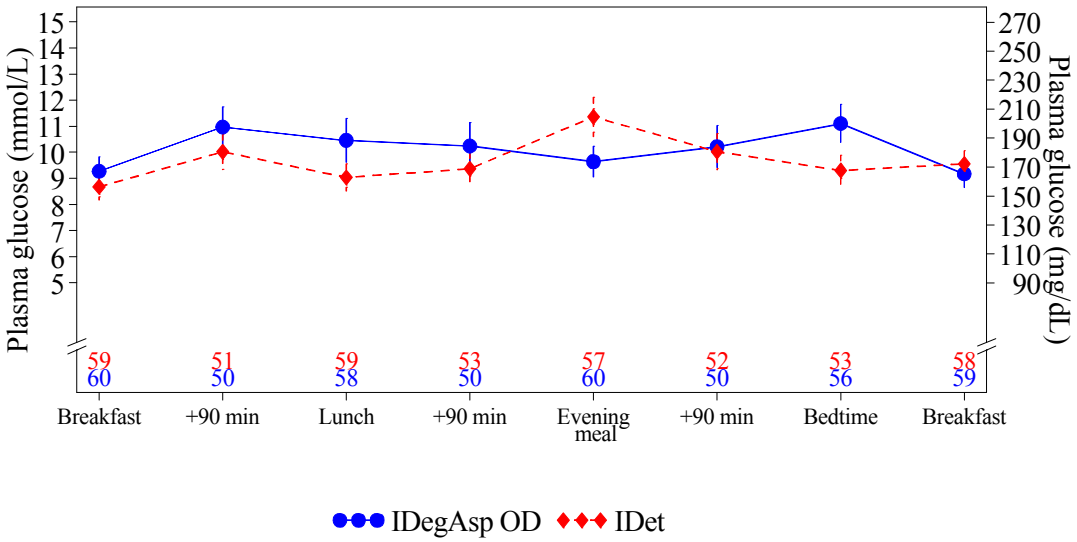
14.2.260 8-point self measured plasma glucose profile at week 12 - mean plot - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:38 - fplot_8PP_treatment.sas/e_8pp_week12_ab_mean_ob_a1_fas.cgm

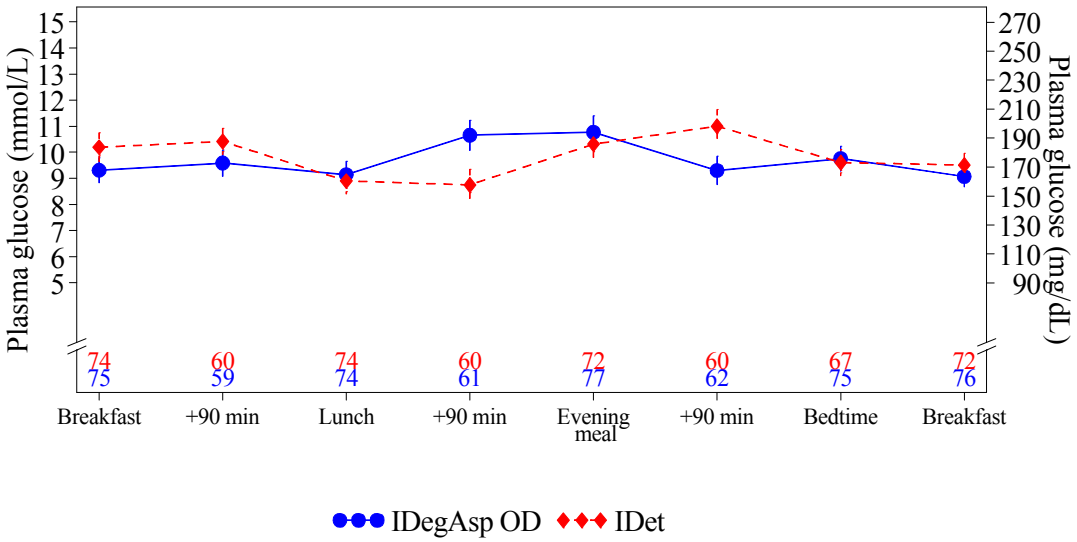
14.2.261 8-point self measured plasma glucose profile at week 12 - mean plot – children (1-5 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:42 - fplot_8PP_treatment.sas/e_8pp_week12_ab_mean_ob_a2_fas.cgm

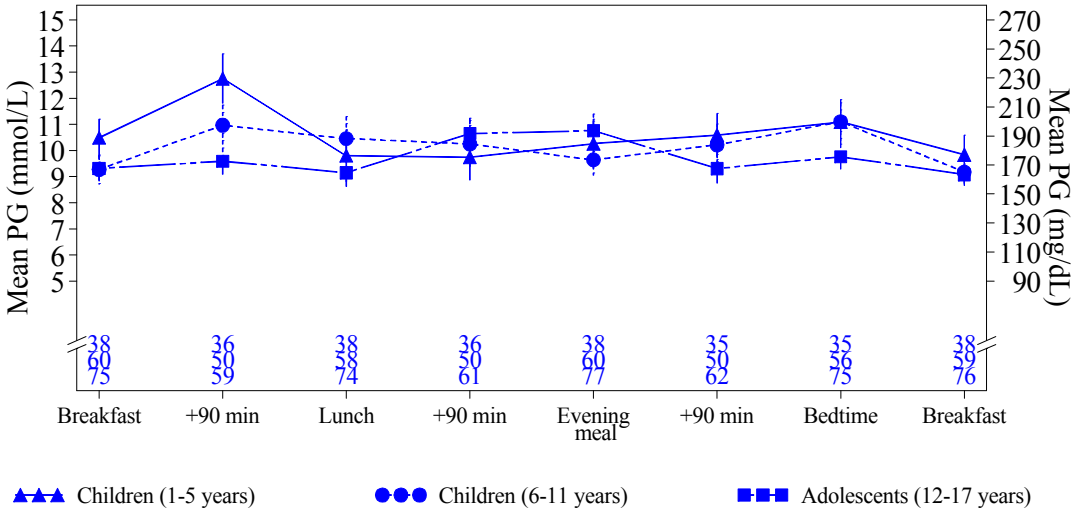
14.2.262 8-point self measured plasma glucose profile at week 12 - mean plot – children (6-11 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:47 - fplot_8PP_treatment.sas/e_8pp_week12_ab_mean_ob_a3_fas.cgm

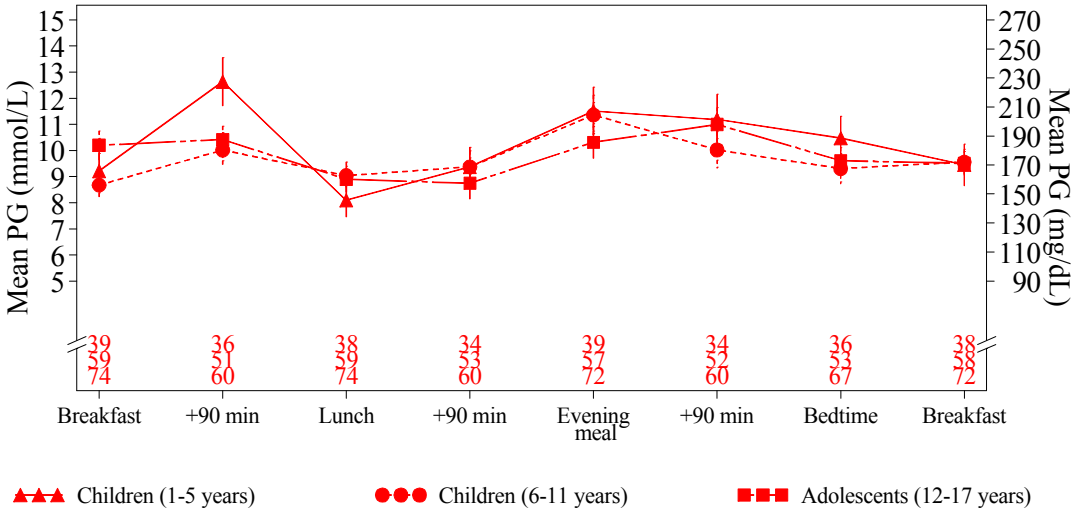
14.2.263 8-point self measured plasma glucose profile at week 12 - mean plot - adolescents (12-17 years) - full analysis set



SMPG: Self-measured plasma glucose, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:30 - mean_8pp_smpg_w12_fplot_treatment_age.sas/e_mean_8pp_smpg_w12_ideg_fas.cgm

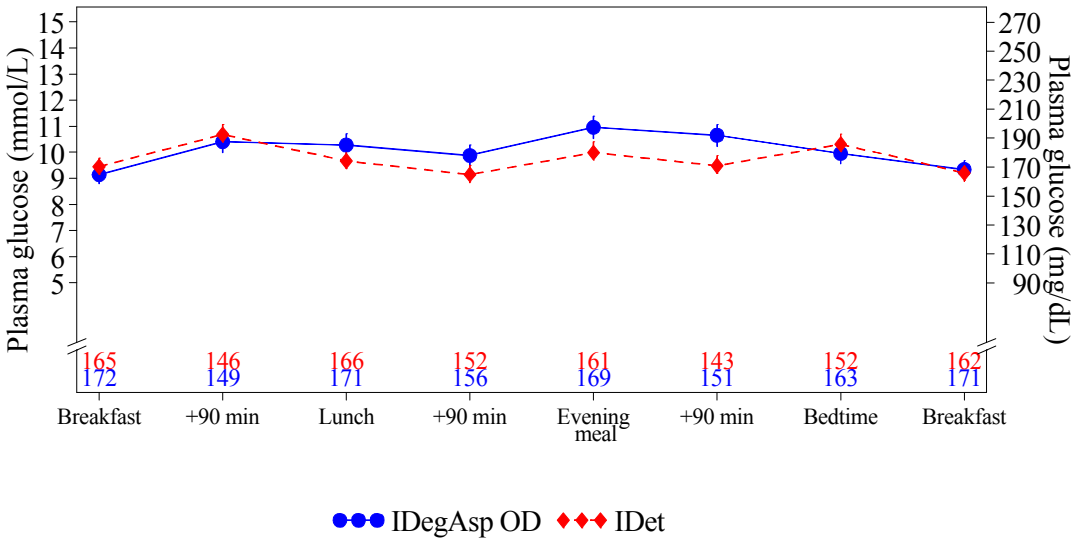
14.2.264 8-point self measured plasma glucose profile at week 12 - mean plot – IDegAsp OD - by age group - full analysis set



SMPG: Self-measured plasma glucose, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:35 - mean_8pp_smpg_w12_fplot_treatment_age.sas/e_mean_8pp_smpg_w12_idet_fas.cgm

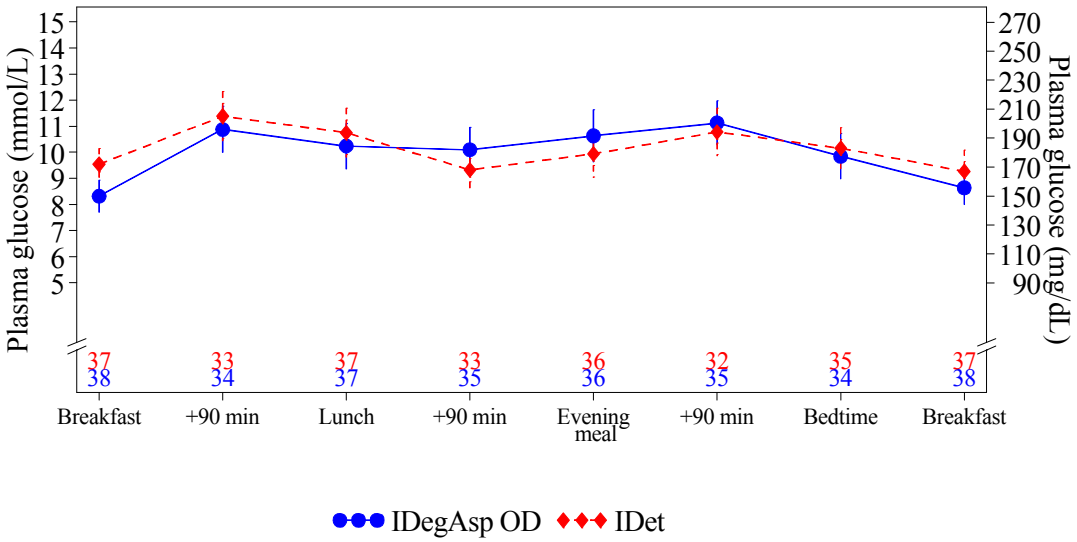
14.2.265 8-point self measured plasma glucose profile at week 12 - mean plot – IDet - by age group - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:53 - fplot_8PP_treatment.sas/e_8pp_week16_ab_mean_ob_fas.cgm

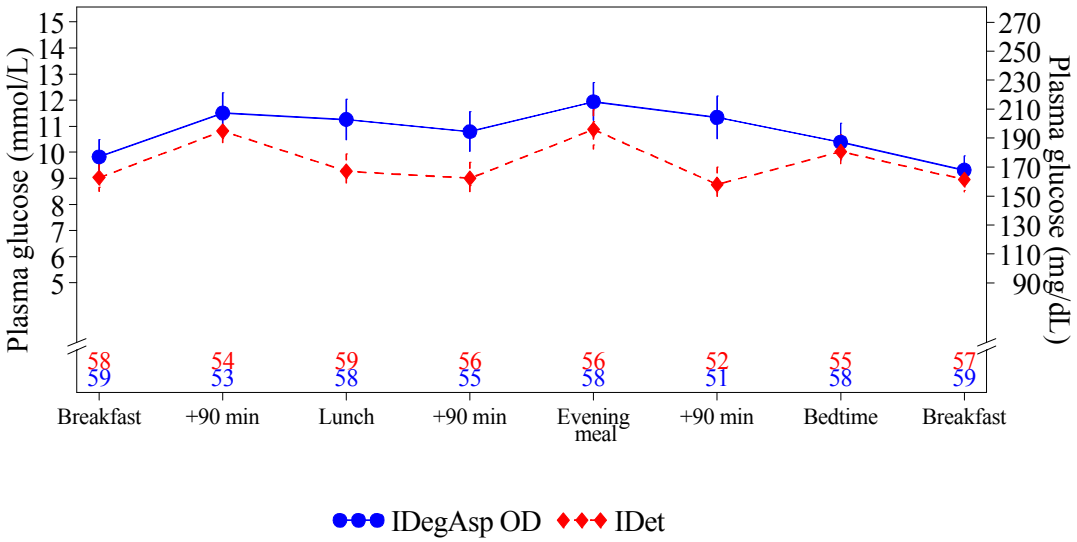
14.2.266 8-point self measured plasma glucose profile at week 16 - mean plot - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:58 - fplot_8PP_treatment.sas/e_8pp_week16_ab_mean_ob_a1_fas.cgm

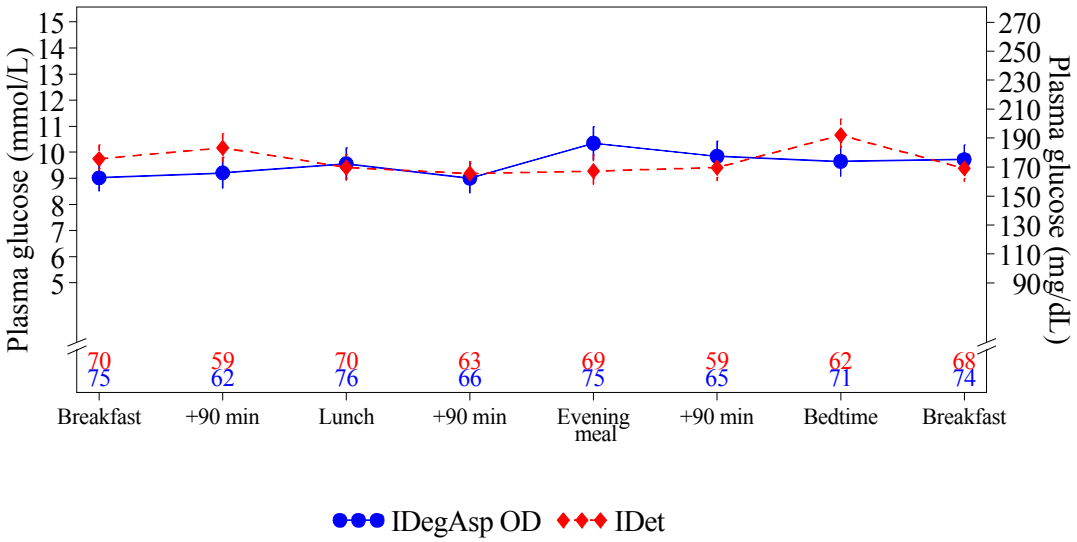
14.2.267 8-point self measured plasma glucose profile at week 16 - mean plot – children (1-5 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:03 - fplot_8PP_treatment.sas/e_8pp_week16_ab_mean_ob_a2_fas.cgm

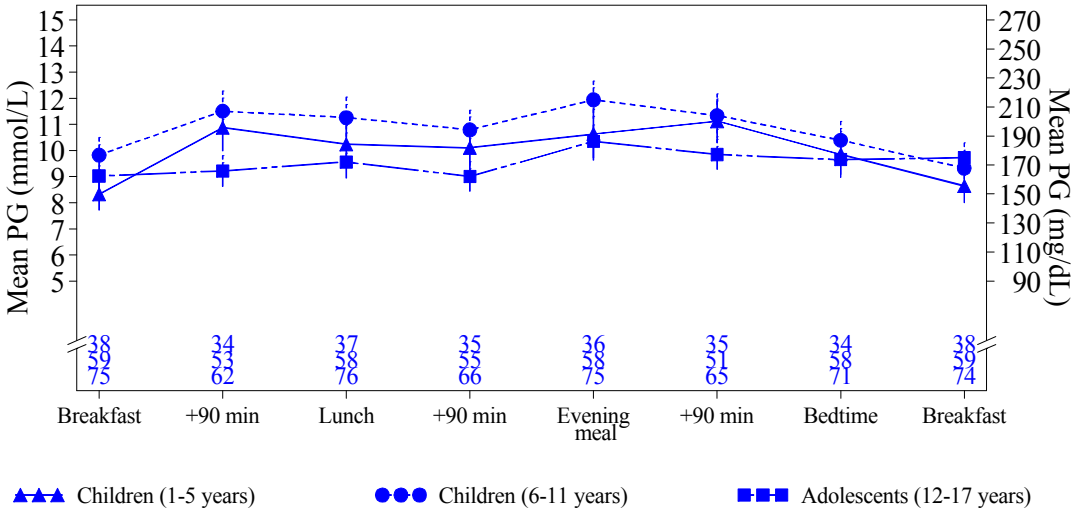
14.2.268 8-point self measured plasma glucose profile at week 16 - mean plot – children (6-11 years) - full analysis set



FAS: Observed data
FAS: Full analysis set, Error bars: +-Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points. From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:08 - fplot_8PP_treatment.sas/e_8pp_week16_ab_mean_ob_a3_fas.cgm

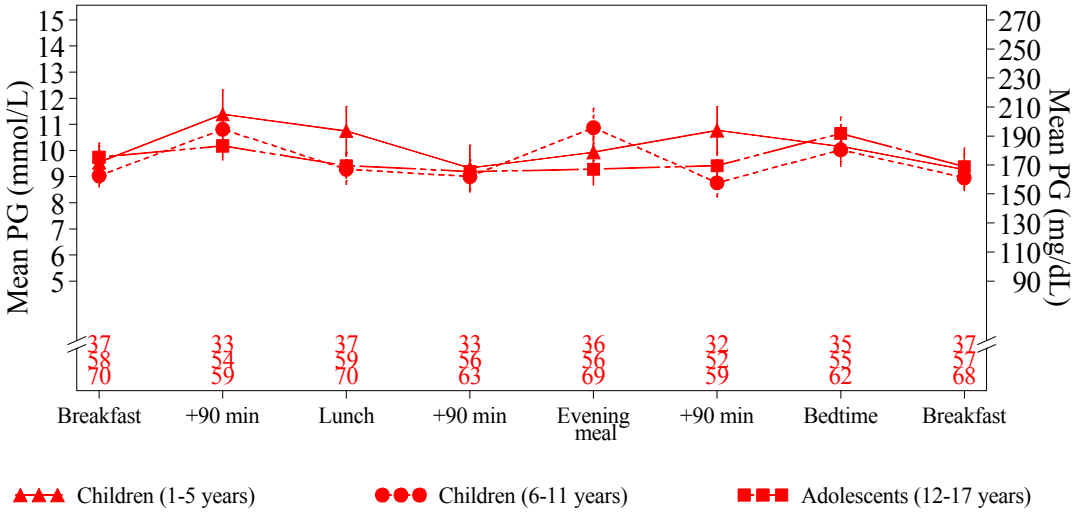
14.2.269 8-point self measured plasma glucose profile at week 16 - mean plot - adolescents (12-17 years) - full analysis set



SMPG: Self-measured plasma glucose, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:32 - mean_8pp_smpg_w16_fplot_treatment_age.sas/e_mean_8pp_smpg_w16_ideg_fas.cgm

14.2.270 8-point self measured plasma glucose profile at week 16 - mean plot – IDegAsp OD - by age group - full analysis set



SMPG: Self-measured plasma glucose, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:37 - mean_8pp_smpg_w16_fplot_treatment_age.sas/e_mean_8pp_smpg_w16_idet_fas.cgm

14.2.271 8-point self measured plasma glucose profile at week 16 - mean plot – IDet - by age group - full analysis set

14.2.272 Mean of 8-point self measured plasma glucose profile by treatment week – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
Mean 8-PP (SMPG)(mmol/L)			
Visit 2 (Week 0)			
N	178	176	354
Mean (SD)	10.4 (3.1)	10.1 (2.8)	10.3 (3.0)
Median	9.8	9.8	9.8
Min ; Max	5.2 ; 22.7	4.3 ; 18.9	4.3 ; 22.7
Visit 14 (Week 12)			
N	173	168	341
Mean (SD)	10.1 (2.8)	9.8 (2.5)	10.0 (2.7)
Median	9.8	9.5	9.6
Min ; Max	3.1 ; 19.6	4.4 ; 17.8	3.1 ; 19.6
Visit 18 (Week 16)			
N	168	165	333
Mean (SD)	10.0 (2.8)	9.9 (2.7)	10.0 (2.8)
Median	9.5	9.5	9.5
Min ; Max	5.3 ; 19.3	4.6 ; 19.0	4.6 ; 19.3
End of trial visit			
N	180	178	358
Mean (SD)	10.1 (2.9)	10.0 (2.8)	10.1 (2.8)
Median	9.6	9.6	9.6
Min ; Max	5.2 ; 19.3	4.6 ; 19.0	4.6 ; 19.3

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

Mean of 8-point self measured plasma glucose profile by treatment week - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Mean 8-PP (SMPG)(mg/dL)			
Visit 2 (Week 0)			
N	178	176	354
Mean (SD)	188.2 (55.6)	181.4 (50.9)	184.8 (53.3)
Median	177.5	177.3	177.5
Min ; Max	93.8 ; 408.6	77.0 ; 339.8	77.0 ; 408.6
Visit 14 (Week 12)			
N	173	168	341
Mean (SD)	181.9 (51.2)	177.1 (44.9)	179.5 (48.2)
Median	177.0	171.1	173.7
Min ; Max	56.4 ; 352.5	78.4 ; 321.4	56.4 ; 352.5
Visit 18 (Week 16)			
N	168	165	333
Mean (SD)	180.8 (50.4)	177.8 (48.8)	179.3 (49.6)
Median	171.0	171.6	171.0
Min ; Max	95.4 ; 347.7	82.6 ; 342.9	82.6 ; 347.7
End of trial visit			
N	180	178	358
Mean (SD)	182.5 (51.7)	180.2 (49.8)	181.3 (50.7)
Median	172.9	172.8	172.8
Min ; Max	93.8 ; 347.7	82.6 ; 342.9	82.6 ; 347.7

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

14.2.273 Mean of 8-point self measured plasma glucose profile by treatment week – descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
Mean 8-PP (SMPG)(mmol/L)			
Visit 2 (Week 0)			
N	40	41	81
Mean (SD)	11.2 (3.5)	11.3 (3.1)	11.2 (3.3)
Median	10.9	11.3	11.2
Min ; Max	6.5 ; 22.7	5.8 ; 18.9	5.8 ; 22.7
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	10.6 (3.3)	10.2 (2.5)	10.4 (2.9)
Median	9.7	10.3	9.9
Min ; Max	6.2 ; 19.2	6.1 ; 14.8	6.1 ; 19.2
Visit 18 (Week 16)			
N	37	37	74
Mean (SD)	10.0 (2.4)	10.2 (2.9)	10.1 (2.7)
Median	9.3	9.6	9.4
Min ; Max	5.7 ; 16.3	5.0 ; 19.0	5.0 ; 19.0
End of trial visit			
N	40	41	81
Mean (SD)	10.2 (2.5)	10.3 (2.9)	10.3 (2.7)
Median	9.4	9.7	9.6
Min ; Max	5.7 ; 16.3	5.0 ; 19.0	5.0 ; 19.0

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

Mean of 8-point self measured plasma glucose profile by treatment week – descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Mean 8-PP (SMPG)(mg/dL)			
Visit 2 (Week 0)			
N	40	41	81
Mean (SD)	202.2 (63.1)	202.9 (56.5)	202.6 (59.5)
Median	197.1	204.3	202.2
Min ; Max	117.3 ; 408.6	105.4 ; 339.8	105.4 ; 408.6
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	190.8 (58.7)	183.6 (45.7)	187.2 (52.3)
Median	173.9	186.5	178.6
Min ; Max	110.9 ; 346.2	110.0 ; 266.4	110.0 ; 346.2
Visit 18 (Week 16)			
N	37	37	74
Mean (SD)	180.0 (43.4)	183.7 (52.6)	181.9 (47.9)
Median	166.9	173.1	168.7
Min ; Max	103.1 ; 292.9	90.8 ; 342.9	90.8 ; 342.9
End of trial visit			
N	40	41	81
Mean (SD)	184.3 (45.2)	186.4 (53.0)	185.4 (49.0)
Median	168.7	174.5	172.7
Min ; Max	103.1 ; 292.9	90.8 ; 342.9	90.8 ; 342.9

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

14.2.274 Mean of 8-point self measured plasma glucose profile by treatment week – descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Mean 8-PP (SMPG)(mmol/L)			
Visit 2 (Week 0)			
N	59	60	119
Mean (SD)	10.3 (2.8)	9.7 (2.4)	10.0 (2.6)
Median	9.9	9.3	9.7
Min ; Max	5.7 ; 18.9	5.5 ; 16.7	5.5 ; 18.9
Visit 14 (Week 12)			
N	59	58	117
Mean (SD)	10.2 (2.9)	9.7 (2.2)	9.9 (2.6)
Median	10.3	9.2	9.8
Min ; Max	3.1 ; 19.6	5.9 ; 15.5	3.1 ; 19.6
Visit 18 (Week 16)			
N	57	59	116
Mean (SD)	10.6 (2.8)	9.8 (2.4)	10.2 (2.6)
Median	10.2	9.6	9.9
Min ; Max	6.3 ; 19.2	6.3 ; 16.9	6.3 ; 19.2
End of trial visit			
N	61	60	121
Mean (SD)	10.7 (2.8)	9.8 (2.4)	10.2 (2.6)
Median	10.2	9.6	9.9
Min ; Max	6.3 ; 19.2	6.3 ; 16.9	6.3 ; 19.2

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

Mean of 8-point self measured plasma glucose profile by treatment week – descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Mean 8-PP (SMPG)(mg/dL)			
Visit 2 (Week 0)			
N	59	60	119
Mean (SD)	185.4 (51.2)	175.6 (43.9)	180.5 (47.7)
Median	177.6	167.0	175.4
Min ; Max	102.8 ; 340.6	99.3 ; 301.4	99.3 ; 340.6
Visit 14 (Week 12)			
N	59	58	117
Mean (SD)	184.4 (52.6)	173.9 (39.0)	179.2 (46.5)
Median	184.9	166.7	176.6
Min ; Max	56.4 ; 352.5	105.7 ; 280.1	56.4 ; 352.5
Visit 18 (Week 16)			
N	57	59	116
Mean (SD)	190.8 (50.4)	176.0 (43.1)	183.3 (47.2)
Median	184.0	172.6	178.0
Min ; Max	113.1 ; 345.5	114.1 ; 304.5	113.1 ; 345.5
End of trial visit			
N	61	60	121
Mean (SD)	192.6 (49.7)	176.6 (43.0)	184.7 (47.0)
Median	184.2	173.0	179.3
Min ; Max	113.1 ; 345.5	114.1 ; 304.5	113.1 ; 345.5

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

14.2.275 Mean of 8-point self measured plasma glucose profile by treatment week – descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
Mean 8-PP (SMPG)(mmol/L)			
Visit 2 (Week 0)			
N	79	75	154
Mean (SD)	10.2 (3.0)	9.7 (2.8)	9.9 (2.9)
Median	9.8	9.4	9.7
Min ; Max	5.2 ; 19.5	4.3 ; 17.0	4.3 ; 19.5
Visit 14 (Week 12)			
N	76	71	147
Mean (SD)	9.7 (2.5)	9.8 (2.7)	9.8 (2.6)
Median	9.7	9.5	9.6
Min ; Max	5.1 ; 15.1	4.4 ; 17.8	4.4 ; 17.8
Visit 18 (Week 16)			
N	74	69	143
Mean (SD)	9.6 (2.9)	9.8 (2.9)	9.7 (2.9)
Median	9.2	9.0	9.2
Min ; Max	5.3 ; 19.3	4.6 ; 17.6	4.6 ; 19.3
End of trial visit			
N	79	77	156
Mean (SD)	9.6 (3.1)	10.0 (3.0)	9.8 (3.0)
Median	9.2	9.3	9.2
Min ; Max	5.2 ; 19.3	4.6 ; 17.8	4.6 ; 19.3

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

Mean of 8-point self measured plasma glucose profile by treatment week – descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Mean 8-PP (SMPG)(mg/dL)			
Visit 2 (Week 0)			
N	79	75	154
Mean (SD)	183.2 (54.3)	174.2 (50.2)	178.8 (52.4)
Median	176.1	170.2	175.4
Min ; Max	93.8 ; 351.1	77.0 ; 306.3	77.0 ; 351.1
Visit 14 (Week 12)			
N	76	71	147
Mean (SD)	175.4 (45.6)	176.1 (48.9)	175.7 (47.1)
Median	174.8	171.7	172.4
Min ; Max	92.4 ; 272.9	78.4 ; 321.4	78.4 ; 321.4
Visit 18 (Week 16)			
N	74	69	143
Mean (SD)	173.5 (53.0)	176.2 (51.7)	174.8 (52.2)
Median	166.4	162.4	165.3
Min ; Max	95.4 ; 347.7	82.6 ; 317.6	82.6 ; 347.7
End of trial visit			
N	79	77	156
Mean (SD)	173.8 (55.1)	179.6 (53.2)	176.7 (54.1)
Median	166.4	168.3	166.4
Min ; Max	93.8 ; 347.7	82.6 ; 321.4	82.6 ; 347.7

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

14.2.276 Mean of 8-point self measured plasma glucose profile by treatment week – change from baseline - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
Change in Mean PG(mmol/L)			
Visit 14 (Week 12)			
N	171	166	337
Mean (SD)	-0.4 (3.5)	-0.3 (2.8)	-0.3 (3.1)
Median	-0.2	-0.2	-0.2
Min ; Max	-10.1 ; 7.9	-9.3 ; 8.3	-10.1 ; 8.3
Visit 18 (Week 16)			
N	167	163	330
Mean (SD)	-0.3 (3.6)	-0.2 (3.3)	-0.3 (3.4)
Median	-0.2	-0.0	-0.1
Min ; Max	-11.2 ; 9.4	-10.1 ; 8.8	-11.2 ; 9.4
End of trial visit			
N	178	176	354
Mean (SD)	-0.3 (3.6)	-0.1 (3.3)	-0.2 (3.4)
Median	-0.1	0.0	0.0
Min ; Max	-11.2 ; 9.4	-10.1 ; 8.8	-11.2 ; 9.4

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.

Mean of 8-point self measured plasma glucose profile by treatment week - change from baseline - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Change in Mean PG(mg/dL)			
Visit 14 (Week 12)			
N	171	166	337
Mean (SD)	-6.7 (62.4)	-5.1 (50.0)	-5.9 (56.6)
Median	-2.7	-4.1	-3.2
Min ; Max	-181.9 ; 143.0	-168.3 ; 150.0	-181.9 ; 150.0
Visit 18 (Week 16)			
N	167	163	330
Mean (SD)	-6.2 (64.1)	-3.8 (59.0)	-5.0 (61.6)
Median	-3.9	-0.2	-2.0
Min ; Max	-202.1 ; 169.9	-182.1 ; 158.0	-202.1 ; 169.9
End of trial visit			
N	178	176	354
Mean (SD)	-6.2 (64.0)	-1.9 (58.7)	-4.1 (61.4)
Median	-1.8	0.0	0.0
Min ; Max	-202.1 ; 169.9	-182.1 ; 158.0	-202.1 ; 169.9

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.

14.2.277 Mean of 8-point self measured plasma glucose profile by treatment week – change from baseline - descriptive statistics - children(1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
Change in Mean PG(mmol/L)			
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	-0.6 (4.2)	-1.2 (3.3)	-0.9 (3.8)
Median	-0.5	-0.8	-0.8
Min ; Max	-10.1 ; 7.9	-9.3 ; 8.3	-10.1 ; 8.3
Visit 18 (Week 16)			
N	37	37	74
Mean (SD)	-0.9 (3.4)	-1.2 (3.5)	-1.0 (3.4)
Median	-0.7	-0.3	-0.4
Min ; Max	-7.8 ; 5.8	-10.1 ; 4.1	-10.1 ; 5.8
End of trial visit			
N	40	41	81
Mean (SD)	-1.0 (3.6)	-0.9 (3.6)	-1.0 (3.6)
Median	-0.5	0.0	-0.3
Min ; Max	-9.2 ; 5.8	-10.1 ; 5.9	-10.1 ; 5.9

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.

Mean of 8-point self measured plasma glucose profile by treatment week - change from baseline - descriptive statistics - children(1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Change in Mean PG(mg/dL)			
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	-10.8 (75.9)	-21.1 (60.2)	-16.0 (68.2)
Median	-8.4	-15.1	-14.6
Min ; Max	-181.9 ; 143.0	-168.3 ; 150.0	-181.9 ; 150.0
Visit 18 (Week 16)			
N	37	37	74
Mean (SD)	-16.0 (61.1)	-21.2 (63.1)	-18.6 (61.7)
Median	-13.0	-4.6	-8.0
Min ; Max	-140.7 ; 104.6	-182.1 ; 74.7	-182.1 ; 104.6
End of trial visit			
N	40	41	81
Mean (SD)	-17.9 (64.2)	-16.5 (64.8)	-17.2 (64.1)
Median	-9.9	0.8	-5.3
Min ; Max	-166.4 ; 104.6	-182.1 ; 107.1	-182.1 ; 107.1

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.

14.2.278 Mean of 8-point self measured plasma glucose profile by treatment week – change from baseline - descriptive statistics - children(6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Change in Mean PG(mmol/L)			
Visit 14 (Week 12)			
N	57	58	115
Mean (SD)	-0.1 (3.4)	-0.1 (2.2)	-0.1 (2.8)
Median	0.2	-0.1	0.0
Min ; Max	-8.7 ; 6.7	-5.6 ; 4.4	-8.7 ; 6.7
Visit 18 (Week 16)			
N	56	59	115
Mean (SD)	0.3 (3.6)	0.1 (3.0)	0.2 (3.3)
Median	0.7	-0.2	0.1
Min ; Max	-11.2 ; 9.4	-6.1 ; 6.9	-11.2 ; 9.4
End of trial visit			
N	59	60	119
Mean (SD)	0.3 (3.5)	0.1 (3.0)	0.2 (3.2)
Median	0.7	-0.1	0.1
Min ; Max	-11.2 ; 9.4	-6.1 ; 6.9	-11.2 ; 9.4

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.

Mean of 8-point self measured plasma glucose profile by treatment week - change from baseline - descriptive statistics - children(6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Change in Mean PG(mg/dL)			
Visit 14 (Week 12)			
N	57	58	115
Mean (SD)	-2.6 (61.5)	-1.4 (39.4)	-2.0 (51.3)
Median	2.9	-2.1	0.5
Min ; Max	-157.3 ; 120.9	-101.0 ; 78.7	-157.3 ; 120.9
Visit 18 (Week 16)			
N	56	59	115
Mean (SD)	5.4 (64.8)	1.0 (53.6)	3.2 (59.1)
Median	12.9	-3.7	1.2
Min ; Max	-202.1 ; 169.9	-110.8 ; 125.0	-202.1 ; 169.9
End of trial visit			
N	59	60	119
Mean (SD)	5.9 (63.3)	1.0 (53.2)	3.5 (58.2)
Median	12.5	-2.0	1.1
Min ; Max	-202.1 ; 169.9	-110.8 ; 125.0	-202.1 ; 169.9

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.

14.2.279 Mean of 8-point self measured plasma glucose profile by treatment week – change from baseline - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
Change in Mean PG(mmol/L)			
Visit 14 (Week 12)			
N	76	69	145
Mean (SD)	-0.4 (3.1)	0.0 (2.8)	-0.2 (3.0)
Median	-0.2	0.5	-0.0
Min ; Max	-10.0 ; 5.7	-7.6 ; 5.7	-10.0 ; 5.7
Visit 18 (Week 16)			
N	74	67	141
Mean (SD)	-0.6 (3.6)	0.1 (3.3)	-0.2 (3.5)
Median	-0.2	0.2	-0.1
Min ; Max	-10.2 ; 8.8	-7.9 ; 8.8	-10.2 ; 8.8
End of trial visit			
N	79	75	154
Mean (SD)	-0.5 (3.5)	0.2 (3.3)	-0.2 (3.4)
Median	-0.2	0.1	0.0
Min ; Max	-10.2 ; 8.8	-7.9 ; 8.8	-10.2 ; 8.8

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.

Mean of 8-point self measured plasma glucose profile by treatment week - change from baseline - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Change in Mean PG(mg/dL)			
Visit 14 (Week 12)			
N	76	69	145
Mean (SD)	-7.7 (56.1)	0.8 (50.6)	-3.6 (53.5)
Median	-3.8	9.8	-0.1
Min ; Max	-180.2 ; 103.2	-136.5 ; 102.1	-180.2 ; 103.2
Visit 18 (Week 16)			
N	74	67	141
Mean (SD)	-10.0 (64.6)	1.7 (60.2)	-4.5 (62.6)
Median	-4.1	3.0	-1.8
Min ; Max	-183.3 ; 158.7	-142.3 ; 158.0	-183.3 ; 158.7
End of trial visit			
N	79	75	154
Mean (SD)	-9.3 (63.9)	3.6 (58.9)	-3.0 (61.6)
Median	-3.9	2.0	0.0
Min ; Max	-183.3 ; 158.7	-142.3 ; 158.0	-183.3 ; 158.7

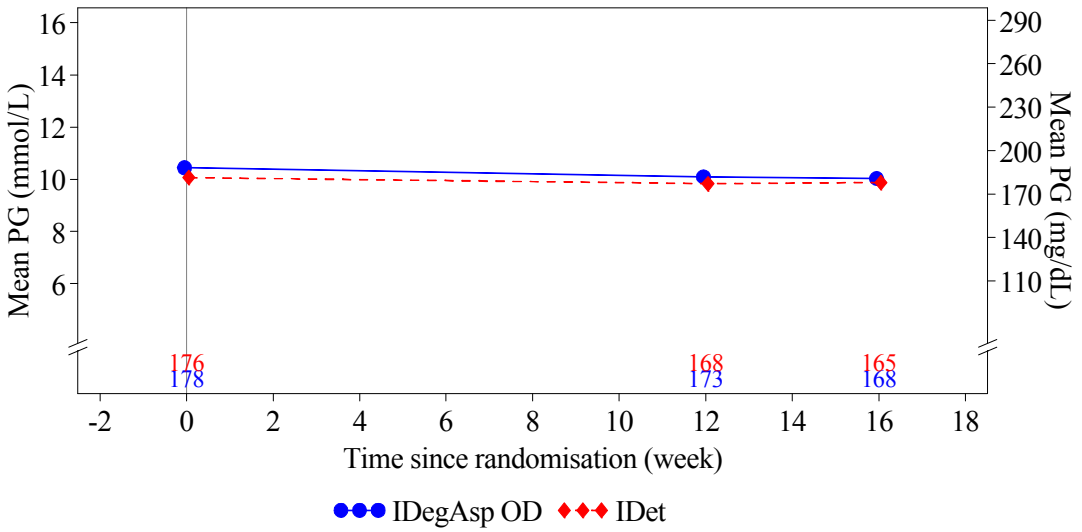
N: Number of subjects, SD: Standard deviation
The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

14.2.280 Mean of 8-point self measured plasma glucose profile after 16 weeks of treatment – statistical analysis – full analysis set

	FAS	N	Estimate	SE	95% CI
Mean 8-PP (SMPG)(mmol/L)					
LSMeans					
IDegAsp OD	182	172	9.94	0.20	
IDet	180	168	9.99	0.20	
Treatment Contrast					
IDegAsp OD - IDet			-0.06		[-0.62; 0.51]
Mean 8-PP (SMPG)(mg/dL)					
LSMeans					
IDegAsp OD	182	172	179.03	3.60	
IDet	180	168	180.03	3.67	
Treatment Contrast					
IDegAsp OD - IDet			-1.00		[-11.15; 9.16]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval
SE: Standard error of the mean
All observed mean SMPG measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline mean SMPG as covariate. Interactions between visit and all factors and covariates are also included in the model. The mean profile value is defined as the area under the profile divided by measurement time and is calculated using the trapezoidal method.

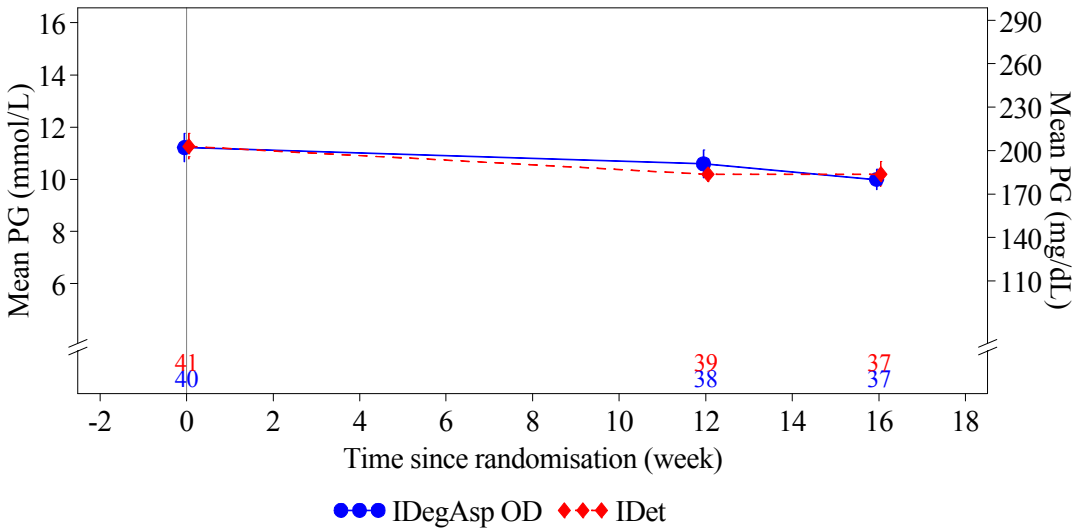
nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:49 - ID14212720_tstat_smpg_mean_3816/t_8pp_mean_stat_mmrm_fas.txt



FAS: Observed data
PG: plasma glucose
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:54 - fmean_numfind_deg_cust.sas/e_8pp_ab_mean_mean_ob_fas.cgm

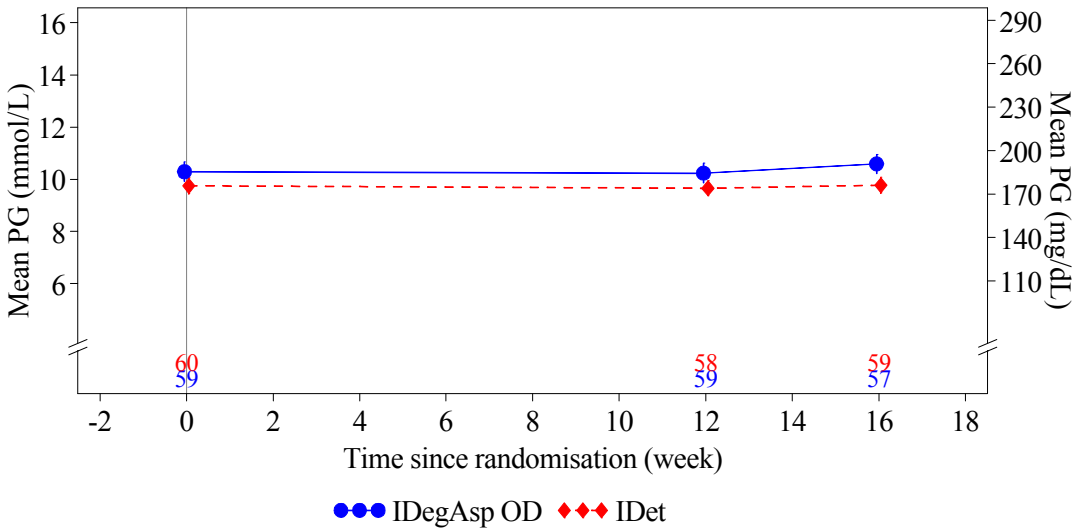
14.2.281 Mean of 8-point self measured plasma glucose profile by treatment week - mean plot - full analysis set



FAS: Observed data
PG: Plasma glucose
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:56 - fmean_numfind_deg_cust.sas/e_8pp_ab_mean_mean_ob_age1_fas.cgm

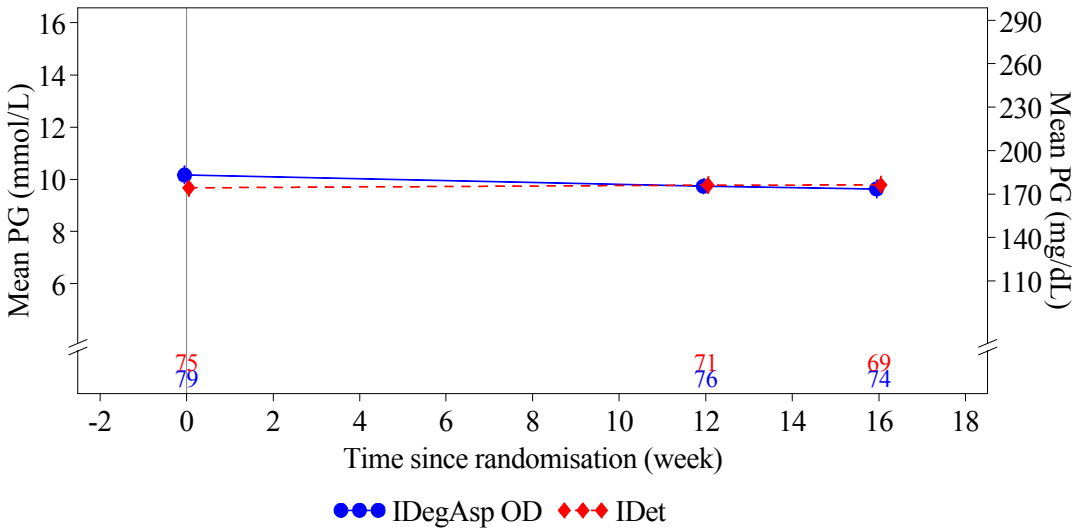
14.2.282 Mean of 8-point self measured plasma glucose profile by treatment week – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
PG: Plasma glucose
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:59 - fmean_numfind_deg_cust.sas/e_8pp_ab_mean_mean_ob_age2_fas.cgm

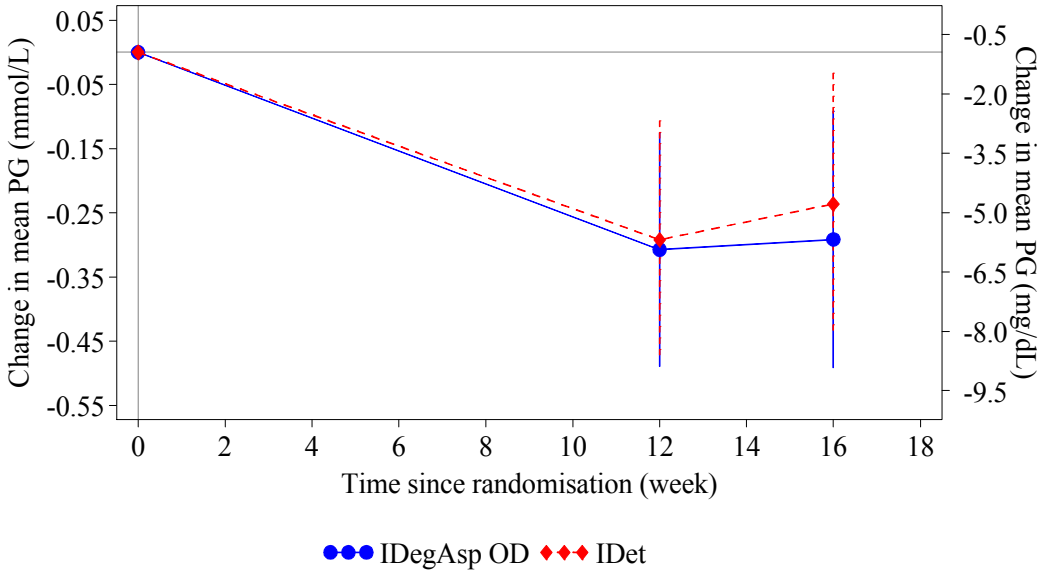
14.2.283 Mean of 8-point self measured plasma glucose profile by treatment week – mean plot – children (6-11 years) - full analysis set



FAS: Observed data
PG: Plasma glucose
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:00 - fmean_numfind_deg_cust.sas/e_8pp_ab_mean_mean_ob_age3_fas.cgm

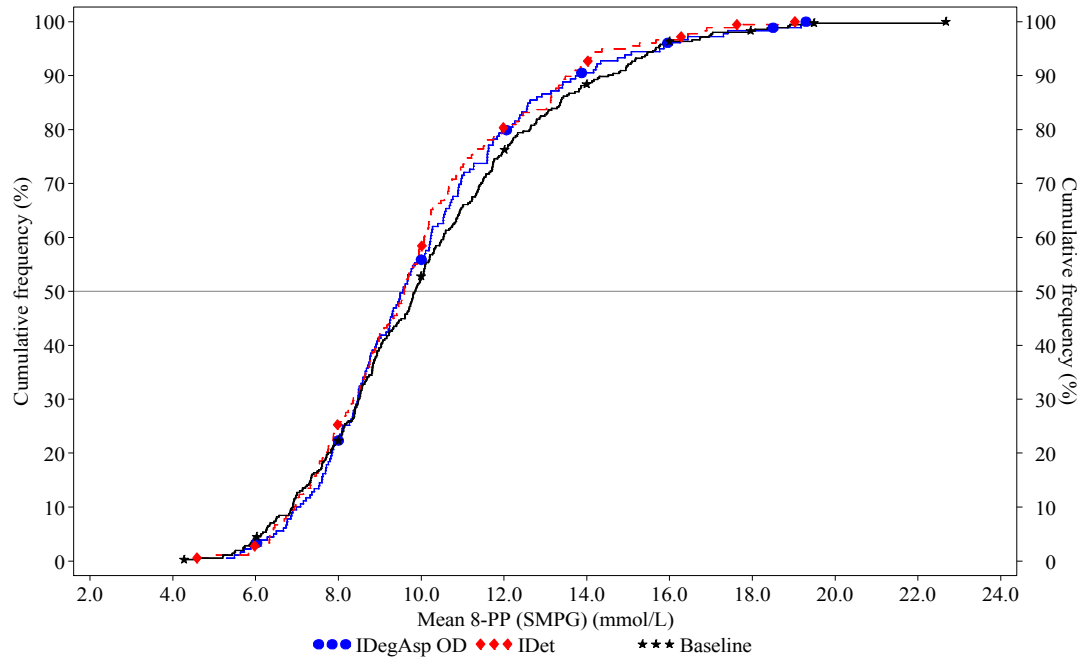
14.2.284 Mean of 8-point self measured plasma glucose profile by treatment week – mean plot – adolescents (12-17 years) - full analysis set



FAS: MMRM data
FAS: Full analysis set, Eror bars: +- Standard error of estimates from MMRM model
MMRM: Mixed model for repeated measurements

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:42:56 - flsmean_mmrm_3816/e_8pp_chb_mean_lsmean_fas.cgm

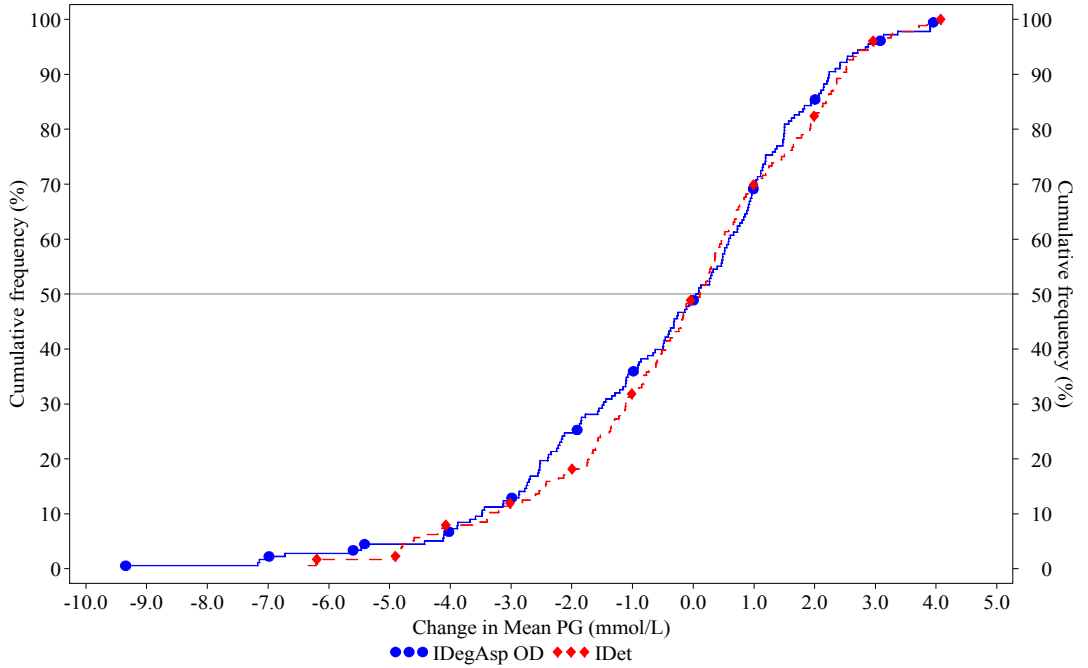
14.2.285 Mean of 8-point self measured plasma glucose profile by treatment week – change from baseline - lsmean plot – full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For subjects without a measurement at week 16, the predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:04 - fedist_numfind_v01.sas/e_8pp_abs_mean_cdf_pred_fas.cgm

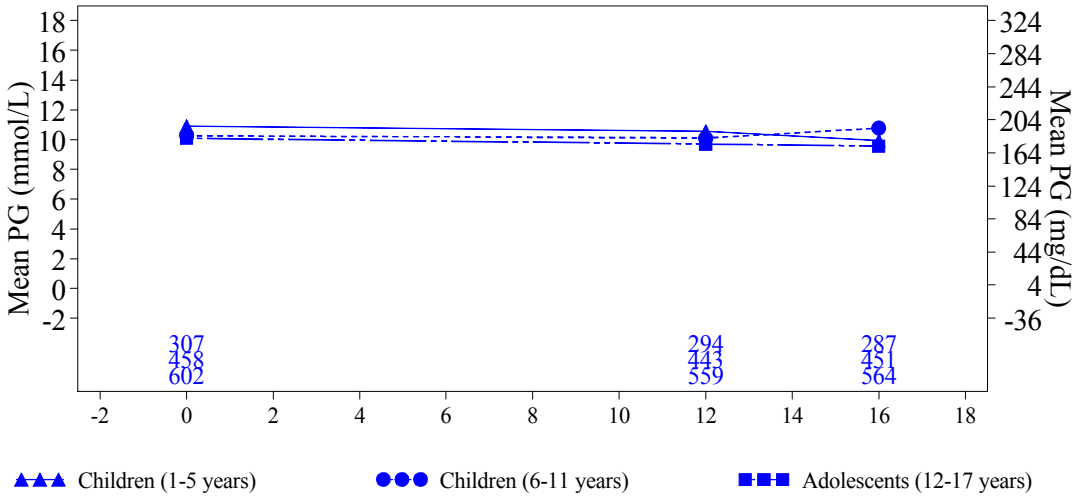
14.2.286 Mean of 8-point self measured plasma glucose profile (mmol/L) after 16 weeks of treatment – empirical distribution plot - full analysis set



FAS; Observed data
For all subjects predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:06 - fedist_numfind_v01.sas/e_8pp_chb_mean_cdf_pred_fas.cgm

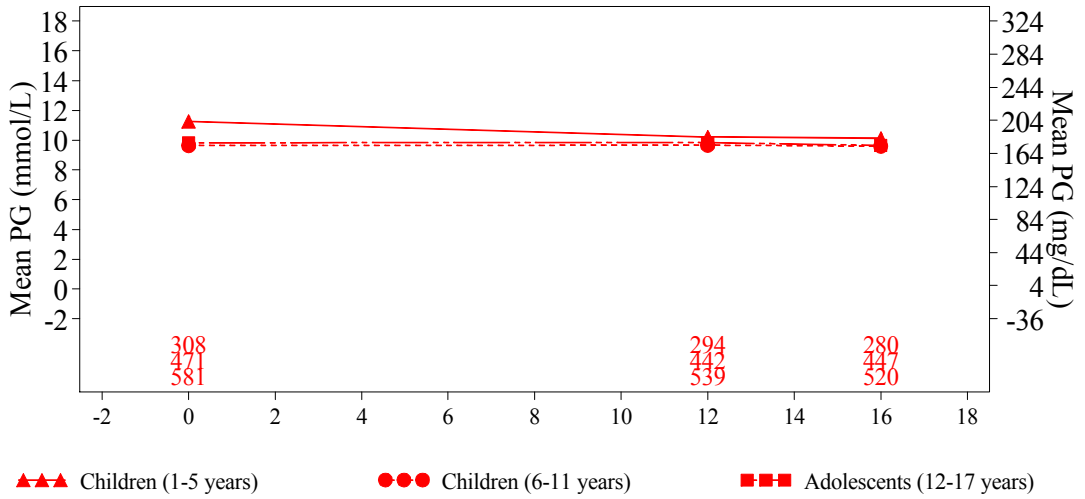
14.2.287 Mean of 8-point self measured plasma glucose profile (mmol/L) after 16 weeks of treatment - change from baseline - empirical distribution plot - full analysis set



SMPG: Self-measured plasma glucose, 8-PP: 8 Point profile
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:30 - mean_8pp_smpg_fplot_treatment_age.sas/e_mean_8pp_smpg_ideg_fas.cgm

14.2.288 Mean of 8-point self measured plasma glucose profile by treatment week – mean plot – IDegAsp OD - by age group - full analysis set



SMPG: Self-measured plasma glucose, 8-PP: 8 Point profile
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:34 - mean_8pp_smpg_fplot_treatment_age.sas/e_mean_8pp_smpg_idet_fas.cgm

14.2.289 Mean of 8-point self measured plasma glucose profile by treatment week – mean plot - IDet - by age group - full analysis set

14.2.290 Fluctuation in 8-point self measured plasma glucose profile by treatment week - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
Fluc. 8-PP (SMPG)(mmol/L)			
Visit 2 (Week 0)			
N	178	176	354
Geometric mean	2.1	2.2	2.2
CV	48.11	47.29	47.70
Median	2.2	2.3	2.3
Min ; Max	0.7 ; 6.3	0.5 ; 7.1	0.5 ; 7.1
Visit 14 (Week 12)			
N	173	168	341
Geometric mean	2.0	2.0	2.0
CV	49.48	44.85	47.41
Median	2.1	2.1	2.1
Min ; Max	0.4 ; 6.5	0.3 ; 5.3	0.3 ; 6.5
Visit 18 (Week 16)			
N	168	165	333
Geometric mean	2.1	2.0	2.1
CV	52.79	50.19	51.78
Median	2.3	2.2	2.3
Min ; Max	0.3 ; 8.1	0.3 ; 5.5	0.3 ; 8.1
End of trial visit			
N	180	178	358
Geometric mean	2.1	2.0	2.1
CV	52.98	53.01	53.03
Median	2.3	2.2	2.3
Min ; Max	0.3 ; 8.1	0.3 ; 7.9	0.3 ; 8.1

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
Fluc.:Fluctuation, Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time.

Fluctuation in 8-point self measured plasma glucose profile by treatment week - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Fluc. 8-PP (SMPG)(mg/dL)			
Visit 2 (Week 0)			
N	178	176	354
Geometric mean	38.0	39.8	38.9
CV	48.11	47.29	47.70
Median	39.8	41.5	40.9
Min ; Max	11.9 ; 113.8	9.9 ; 127.7	9.9 ; 127.7
Visit 14 (Week 12)			
N	173	168	341
Geometric mean	36.8	35.3	36.0
CV	49.48	44.85	47.41
Median	38.4	38.2	38.2
Min ; Max	7.0 ; 116.4	6.3 ; 95.1	6.3 ; 116.4
Visit 18 (Week 16)			
N	168	165	333
Geometric mean	38.7	35.4	37.0
CV	52.79	50.19	51.78
Median	41.2	38.9	40.8
Min ; Max	5.0 ; 146.5	6.1 ; 99.7	5.0 ; 146.5
End of trial visit			
N	180	178	358
Geometric mean	38.7	36.2	37.4
CV	52.98	53.01	53.03
Median	41.3	40.0	41.1
Min ; Max	5.0 ; 146.5	6.1 ; 142.0	5.0 ; 146.5

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
Fluc.:Fluctuation, Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time.

14.2.291 Fluctuation in 8-point self measured plasma glucose profile by treatment week - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
Fluc. 8-PP (SMPG)(mmol/L)			
Visit 2 (Week 0)			
N	40	41	81
Geometric mean	2.4	2.4	2.4
CV	49.68	52.19	50.76
Median	2.8	2.7	2.7
Min ; Max	0.7 ; 5.9	0.6 ; 7.1	0.6 ; 7.1
Visit 14 (Week 12)			
N	38	39	77
Geometric mean	2.3	2.2	2.2
CV	45.46	43.32	44.13
Median	2.1	2.4	2.2
Min ; Max	1.0 ; 5.3	0.4 ; 4.8	0.4 ; 5.3
Visit 18 (Week 16)			
N	37	37	74
Geometric mean	2.2	2.2	2.2
CV	47.56	43.37	45.26
Median	2.5	2.5	2.5
Min ; Max	0.5 ; 5.5	0.4 ; 4.8	0.4 ; 5.5
End of trial visit			
N	40	41	81
Geometric mean	2.3	2.3	2.3
CV	47.90	50.40	48.92
Median	2.5	2.5	2.5
Min ; Max	0.5 ; 5.5	0.4 ; 7.9	0.4 ; 7.9

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
Fluc.:Fluctuation, Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time.

Fluctuation in 8-point self measured plasma glucose profile by treatment week - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Fluc. 8-PP (SMPG)(mg/dL)			
Visit 2 (Week 0)			
N	40	41	81
Geometric mean	42.7	44.0	43.4
CV	49.68	52.19	50.76
Median	50.2	49.0	49.1
Min ; Max	11.9 ; 106.3	10.4 ; 127.7	10.4 ; 127.7
Visit 14 (Week 12)			
N	38	39	77
Geometric mean	40.9	39.0	39.9
CV	45.46	43.32	44.13
Median	37.8	43.6	39.3
Min ; Max	18.2 ; 95.5	7.8 ; 86.2	7.8 ; 95.5
Visit 18 (Week 16)			
N	37	37	74
Geometric mean	40.4	40.0	40.2
CV	47.56	43.37	45.26
Median	45.3	45.3	45.3
Min ; Max	8.8 ; 99.4	6.7 ; 86.7	6.7 ; 99.4
End of trial visit			
N	40	41	81
Geometric mean	40.7	41.9	41.3
CV	47.90	50.40	48.92
Median	45.6	45.3	45.3
Min ; Max	8.8 ; 99.4	6.7 ; 142.0	6.7 ; 142.0

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
Fluc.:Fluctuation, Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time.

14.2.292 Fluctuation in 8-point self measured plasma glucose profile by treatment week - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Fluc. 8-PP (SMPG)(mmol/L)			
Visit 2 (Week 0)			
N	59	60	119
Geometric mean	2.1	2.1	2.1
CV	50.68	42.03	46.47
Median	2.0	2.2	2.2
Min ; Max	0.8 ; 6.3	0.7 ; 4.5	0.7 ; 6.3
Visit 14 (Week 12)			
N	59	58	117
Geometric mean	2.1	2.0	2.1
CV	51.62	42.34	48.00
Median	2.3	2.1	2.2
Min ; Max	0.4 ; 6.5	0.4 ; 4.6	0.4 ; 6.5
Visit 18 (Week 16)			
N	57	59	116
Geometric mean	2.2	2.2	2.2
CV	58.75	41.74	51.17
Median	2.3	2.3	2.3
Min ; Max	0.6 ; 8.1	0.4 ; 4.9	0.4 ; 8.1
End of trial visit			
N	61	60	121
Geometric mean	2.3	2.2	2.2
CV	56.94	41.68	50.52
Median	2.3	2.3	2.3
Min ; Max	0.6 ; 8.1	0.4 ; 4.9	0.4 ; 8.1

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
Fluc.:Fluctuation, Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time.

Fluctuation in 8-point self measured plasma glucose profile by treatment week - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Fluc. 8-PP (SMPG)(mg/dL)			
Visit 2 (Week 0)			
N	59	60	119
Geometric mean	38.1	38.2	38.2
CV	50.68	42.03	46.47
Median	36.7	39.6	39.6
Min ; Max	14.1 ; 113.8	12.4 ; 80.4	12.4 ; 113.8
Visit 14 (Week 12)			
N	59	58	117
Geometric mean	38.6	36.2	37.4
CV	51.62	42.34	48.00
Median	42.1	37.8	39.9
Min ; Max	8.1 ; 116.4	7.4 ; 82.5	7.4 ; 116.4
Visit 18 (Week 16)			
N	57	59	116
Geometric mean	40.3	39.9	40.1
CV	58.75	41.74	51.17
Median	40.8	42.2	41.2
Min ; Max	11.0 ; 146.5	6.4 ; 88.1	6.4 ; 146.5
End of trial visit			
N	61	60	121
Geometric mean	41.2	39.8	40.5
CV	56.94	41.68	50.52
Median	40.9	41.9	41.3
Min ; Max	11.0 ; 146.5	6.4 ; 88.1	6.4 ; 146.5

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
Fluc.:Fluctuation, Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time.

14.2.293 Fluctuation in 8-point self measured plasma glucose profile by treatment week - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
Fluc. 8-PP (SMPG)(mmol/L)			
Visit 2 (Week 0)			
N	79	75	154
Geometric mean	2.0	2.2	2.1
CV	42.04	45.67	44.32
Median	2.1	2.3	2.2
Min ; Max	0.7 ; 5.3	0.5 ; 6.3	0.5 ; 6.3
Visit 14 (Week 12)			
N	76	71	147
Geometric mean	1.9	1.8	1.8
CV	48.35	47.25	47.70
Median	2.0	2.0	2.0
Min ; Max	0.4 ; 5.5	0.3 ; 5.3	0.3 ; 5.5
Visit 18 (Week 16)			
N	74	69	143
Geometric mean	2.0	1.7	1.8
CV	49.77	61.11	55.19
Median	2.3	1.7	1.9
Min ; Max	0.3 ; 6.4	0.3 ; 5.5	0.3 ; 6.4
End of trial visit			
N	79	77	156
Geometric mean	2.0	1.7	1.9
CV	51.53	62.70	56.87
Median	2.3	1.7	2.0
Min ; Max	0.3 ; 6.4	0.3 ; 6.3	0.3 ; 6.4

N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
Fluc.:Fluctuation, Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time.

Fluctuation in 8-point self measured plasma glucose profile by treatment week - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Fluc. 8-PP (SMPG)(mg/dL)			
Visit 2 (Week 0)			
N	79	75	154
Geometric mean	35.8	38.9	37.3
CV	42.04	45.67	44.32
Median	38.0	41.0	39.5
Min ; Max	12.2 ; 95.8	9.9 ; 113.1	9.9 ; 113.1
Visit 14 (Week 12)			
N	76	71	147
Geometric mean	33.6	32.7	33.2
CV	48.35	47.25	47.70
Median	36.5	36.5	36.5
Min ; Max	7.0 ; 99.7	6.3 ; 95.1	6.3 ; 99.7
Visit 18 (Week 16)			
N	74	69	143
Geometric mean	36.6	29.9	33.2
CV	49.77	61.11	55.19
Median	41.3	30.8	33.9
Min ; Max	5.0 ; 115.9	6.1 ; 99.7	5.0 ; 115.9
End of trial visit			
N	79	77	156
Geometric mean	35.9	31.1	33.5
CV	51.53	62.70	56.87
Median	41.1	31.2	35.4
Min ; Max	5.0 ; 115.9	6.1 ; 113.1	5.0 ; 115.9

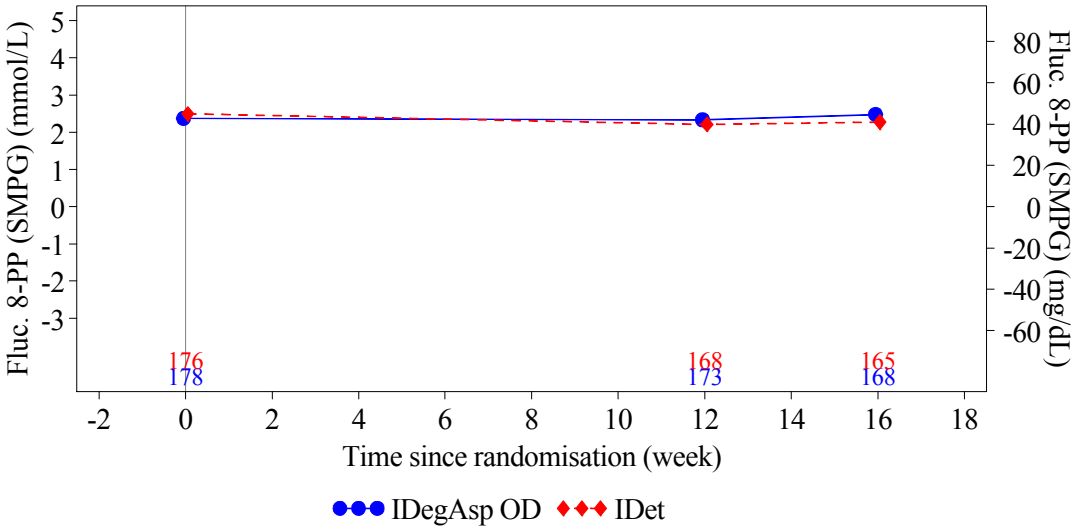
N: Number of subjects, SD: Standard deviation, SMPG: Self measured plasma glucose
Fluc.:Fluctuation, Fluctuation is defined as the integrated absolute distance from mean profile value divided by measurement time.

14.2.294 Fluctuation of 8-point self measured plasma glucose profile after 16 weeks of treatment – statistical analysis – full analysis set

	FAS	N	Estimate	SE	95% CI
Fluctuation 8-PP (SMPG)(mmol/L)					
LSMeans					
IDegAsp OD	182	172	2.15	0.04	
IDet	180	168	1.97	0.04	
Treatment Ratio					
IDegAsp OD / IDet			1.09		[0.98; 1.22]
Fluctuation 8-PP (SMPG)(mg/dL)					
LSMeans					
IDegAsp OD	182	172	38.78	0.04	
IDet	180	168	35.44	0.04	
Treatment Ratio					
IDegAsp OD / IDet			1.09		[0.98; 1.22]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval
SE: Standard error of the mean
All observed SMPG fluctuation measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline SMPG fluctuation as covariate. Interactions between visit and all factors and covariates are also included in the model.

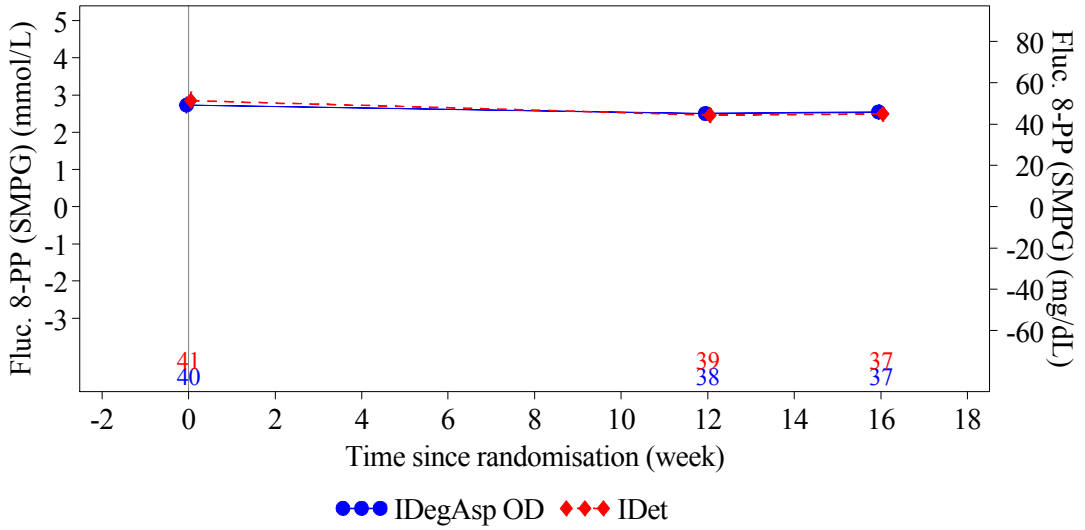
nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:03 - ID14213300_tstat_smpg_fluc_3816/t_8pp_fluc_stat_mmrm_fas.txt



FAS: Observed data
SMPG: Self-measured plasma glucose, Fluc.: Fluctuation, 8-PP: 8 Point profile
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:09 - fmean_numfind_deg_cust.sas/e_8pp_abs_fluc_mean_obs_fas.cgm

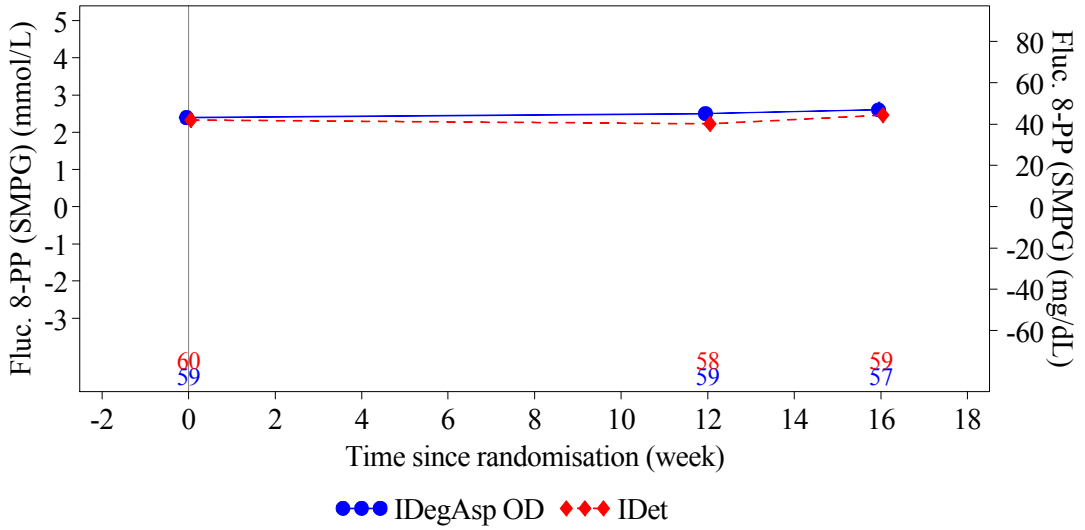
14.2.295 Fluctuation in 8-point self measured plasma glucose profile by treatment week - mean plot - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Fluc.: Fluctuation, 8-PP: 8 Point profile
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:09 - fmean_numfind_deg_cust.sas/e_8pp_abs_fluc_mean_obs_age1_fas.cgm

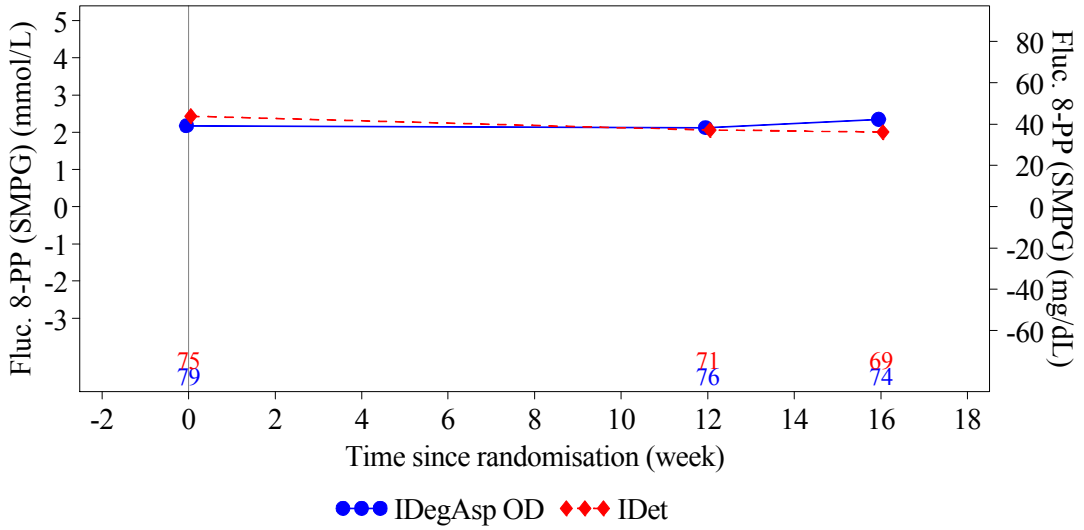
14.2.296 Fluctuation in 8-point self measured plasma glucose profile by treatment week – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Fluc.: Fluctuation, 8-PP: 8 Point profile
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:10 - fmean_numfind_deg_cust.sas/e_8pp_abs_fluc_mean_obs_age2_fas.cgm

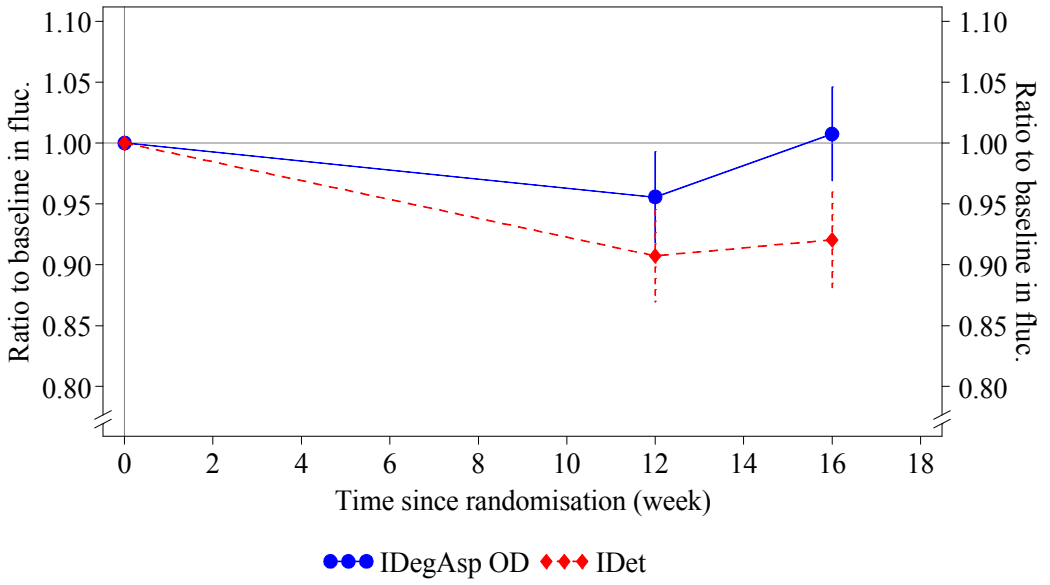
14.2.297 Fluctuation in 8-point self measured plasma glucose profile by treatment week – mean plot – children (6-11 years) - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Fluc.: Fluctuation, 8-PP: 8 Point profile
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:11 - fmean_numfind_deg_cust.sas/e_8pp_abs_fluc_mean_obs_age3_fas.cgm

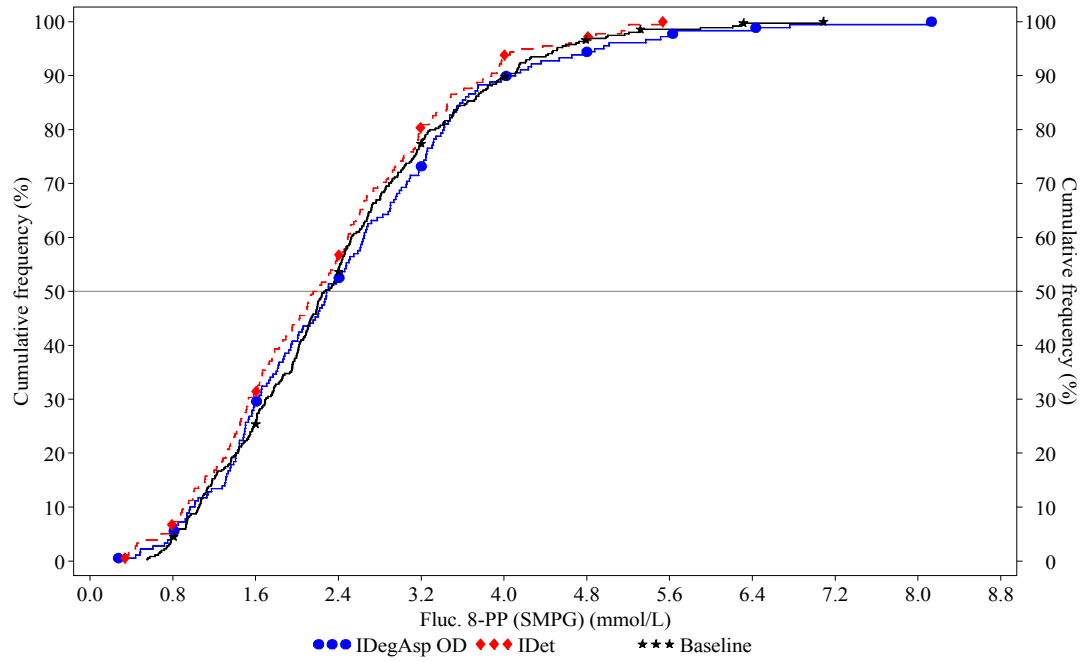
14.2.298 Fluctuation in 8-point self measured plasma glucose profile by treatment week – mean plot – adolescents (12-17 years) - full analysis set



FAS: MMRM data
FAS: Full analysis set, Eror bars: +- Standard error of estimates from MMRM model
MMRM: Mixed model for repeated measurements, Fluct.: Fluctuation

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:07 - flsmean_mmrm_3816/e_8pp_chb_fluc_lsmean_fas.cgm

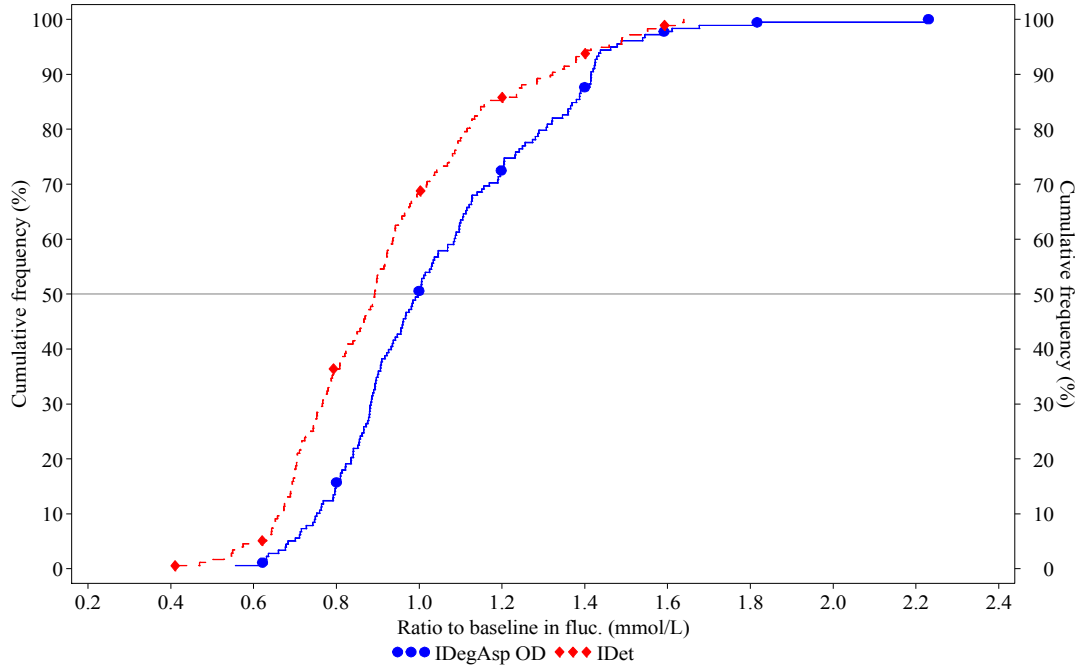
14.2.299 Fluctuation in 8-point self measured plasma glucose profile by treatment week - ratio to baseline - lsmean plot - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For subjects without a measurement at week 16, the predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:17 - fedist_numfind_v01.sas/e_8pp_abs_fluc_cdf_pred_fas.cgm

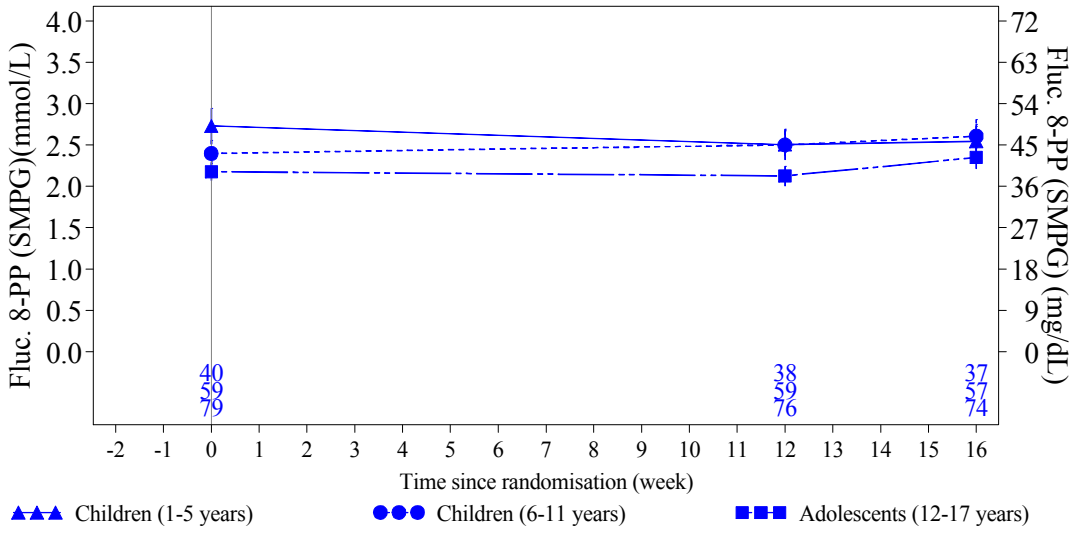
14.2.300 Fluctuation in 8-point self measured plasma glucose (mmol/L) profile after 16 weeks of treatment - empirical distribution plot - full analysis set



FAS; Observed data
For all subjects predicted values from MMRM model were used. Fluct.: Fluctuation

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:17 - fedist_numfind_v01.sas/e_8pp_chb_fluc_cdf_pred_fas.cgm

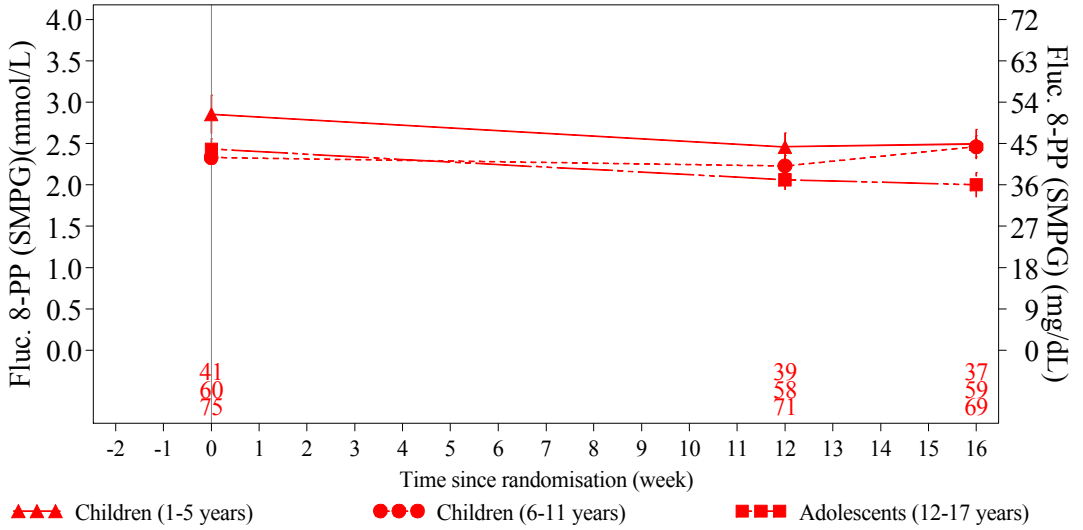
14.2.301 Fluctuation in 8-point self measured plasma glucose profile (mmol/L) after 16 weeks of treatment - ratio to baseline - empirical distribution plot - full analysis set



SMPG: Self-measured plasma glucose, Fluc.: Fluctuation, 8-PP: 8 Point profile
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:23 - mean_8pp_fluc_fplot_treatment_age.sas/e_mean_8pp_fluc_ideg_fas.cgm

14.2.302 Fluctuation in 8-point self measured plasma glucose profile by treatment week – mean plot – IDegAsp OD - by age group - full analysis set



SMPG: Self-measured plasma glucose, Fluc.: Fluctuation, 8-PP: 8 Point profile
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:27 - mean_8pp_fluc_fplot_treatment_age.sas/e_mean_8pp_fluc_idet_fas.cgm

14.2.303 Fluctuation in 8-point self measured plasma glucose profile by treatment week – mean plot – IDet - by age group - full analysis set

14.2.304 Prandial increment by treatment week - 8-point self measured plasma glucose profile-descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
All Meals(mmol/L)			
Visit 2 (Week 0)			
N	164	160	324
Mean (SD)	1.3 (3.3)	0.9 (3.5)	1.1 (3.4)
Median	1.3	1.0	1.1
Min ; Max	-6.9 ; 11.2	-8.9 ; 12.1	-8.9 ; 12.1
Visit 14 (Week 12)			
N	148	145	293
Mean (SD)	0.6 (4.0)	0.7 (3.3)	0.7 (3.7)
Median	0.7	0.8	0.8
Min ; Max	-12.0 ; 11.1	-5.9 ; 10.6	-12.0 ; 11.1
Visit 18 (Week 16)			
N	151	143	294
Mean (SD)	0.5 (3.8)	0.3 (3.1)	0.4 (3.5)
Median	0.3	0.3	0.3
Min ; Max	-15.8 ; 15.3	-8.4 ; 11.8	-15.8 ; 15.3
End of trial visit			
N	178	174	352
Mean (SD)	0.4 (3.9)	0.4 (3.4)	0.4 (3.7)
Median	0.3	0.5	0.4
Min ; Max	-15.8 ; 15.3	-9.8 ; 11.8	-15.8 ; 15.3

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile- descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Breakfast(mmol/L)			
Visit 2 (Week 0)			
N	162	164	326
Mean (SD)	2.5 (5.6)	2.0 (5.9)	2.2 (5.7)
Median	2.4	2.5	2.4
Min ; Max	-13.7 ; 17.0	-21.0 ; 13.7	-21.0 ; 17.0
Visit 14 (Week 12)			
N	144	147	291
Mean (SD)	1.5 (5.4)	1.6 (5.5)	1.5 (5.5)
Median	1.4	1.5	1.5
Min ; Max	-14.7 ; 16.0	-17.4 ; 15.4	-17.4 ; 16.0
Visit 18 (Week 16)			
N	149	145	294
Mean (SD)	1.5 (5.8)	1.4 (5.3)	1.4 (5.5)
Median	1.6	1.6	1.6
Min ; Max	-15.1 ; 18.9	-13.7 ; 17.5	-15.1 ; 18.9
End of trial visit			
N	175	175	350
Mean (SD)	1.4 (5.8)	1.6 (5.6)	1.5 (5.7)
Median	1.5	1.7	1.6
Min ; Max	-15.1 ; 18.9	-13.7 ; 17.5	-15.1 ; 18.9

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile- descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Lunch(mmol/L)			
Visit 2 (Week 0)			
N	167	169	336
Mean (SD)	1.3 (5.9)	0.5 (6.7)	0.9 (6.4)
Median	1.3	0.9	1.0
Min ; Max	-13.8 ; 16.3	-16.1 ; 26.6	-16.1 ; 26.6
Visit 14 (Week 12)			
N	144	146	290
Mean (SD)	0.8 (6.4)	0.7 (5.4)	0.8 (5.9)
Median	1.4	0.2	0.8
Min ; Max	-20.2 ; 19.7	-13.8 ; 17.4	-20.2 ; 19.7
Visit 18 (Week 16)			
N	156	152	308
Mean (SD)	-0.0 (5.8)	-0.3 (5.7)	-0.2 (5.7)
Median	0.6	-0.1	0.3
Min ; Max	-14.8 ; 13.7	-20.5 ; 14.8	-20.5 ; 14.8
End of trial visit			
N	176	177	353
Mean (SD)	-0.1 (5.8)	-0.4 (6.0)	-0.2 (5.9)
Median	0.6	0.0	0.2
Min ; Max	-14.8 ; 13.7	-22.5 ; 14.8	-22.5 ; 14.8

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile- descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Ev. Meal(mmol/L)			
Visit 2 (Week 0)			
N	162	157	319
Mean (SD)	0.0 (5.4)	0.2 (5.6)	0.1 (5.5)
Median	0.5	0.6	0.6
Min ; Max	-22.0 ; 11.4	-11.7 ; 17.0	-22.0 ; 17.0
Visit 14 (Week 12)			
N	147	144	291
Mean (SD)	-0.5 (6.0)	-0.2 (5.4)	-0.3 (5.7)
Median	-0.6	-0.1	-0.3
Min ; Max	-27.2 ; 16.9	-15.6 ; 13.4	-27.2 ; 16.9
Visit 18 (Week 16)			
N	150	140	290
Mean (SD)	-0.1 (6.5)	-0.3 (5.6)	-0.2 (6.1)
Median	0.1	0.2	0.2
Min ; Max	-26.0 ; 22.5	-14.9 ; 16.8	-26.0 ; 22.5
End of trial visit			
N	178	174	352
Mean (SD)	-0.2 (6.9)	-0.0 (6.0)	-0.1 (6.5)
Median	-0.2	0.2	0.0
Min ; Max	-27.2 ; 22.5	-14.9 ; 16.8	-27.2 ; 22.5

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile-descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
All Meals(mg/dL)			
Visit 2 (Week 0)			
N	164	160	324
Mean (SD)	22.9 (60.0)	16.7 (63.2)	19.8 (61.6)
Median	23.3	17.3	20.0
Min ; Max	-125.0 ; 202.4	-160.0 ; 218.3	-160.0 ; 218.3
Visit 14 (Week 12)			
N	148	145	293
Mean (SD)	10.8 (72.9)	13.1 (58.8)	11.9 (66.2)
Median	13.0	14.0	14.0
Min ; Max	-216.8 ; 200.3	-106.0 ; 191.6	-216.8 ; 200.3
Visit 18 (Week 16)			
N	151	143	294
Mean (SD)	9.4 (68.7)	4.6 (56.1)	7.1 (62.8)
Median	5.3	6.0	6.0
Min ; Max	-284.0 ; 276.0	-150.5 ; 212.0	-284.0 ; 276.0
End of trial visit			
N	178	174	352
Mean (SD)	6.7 (70.7)	6.4 (61.4)	6.6 (66.2)
Median	6.0	8.2	6.9
Min ; Max	-284.0 ; 276.0	-177.0 ; 212.0	-284.0 ; 276.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile-descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Breakfast(mg/dL)			
Visit 2 (Week 0)			
N	162	164	326
Mean (SD)	44.5 (100.9)	35.9 (105.9)	40.1 (103.4)
Median	42.6	45.0	43.2
Min ; Max	-247.0 ; 307.0	-378.4 ; 246.8	-378.4 ; 307.0
Visit 14 (Week 12)			
N	144	147	291
Mean (SD)	27.2 (98.2)	28.1 (99.8)	27.7 (98.8)
Median	25.2	27.0	27.0
Min ; Max	-265.0 ; 288.0	-314.0 ; 277.5	-314.0 ; 288.0
Visit 18 (Week 16)			
N	149	145	294
Mean (SD)	27.7 (104.2)	24.5 (95.8)	26.1 (100.0)
Median	29.0	28.8	28.9
Min ; Max	-272.1 ; 341.0	-247.0 ; 315.3	-272.1 ; 341.0
End of trial visit			
N	175	175	350
Mean (SD)	24.4 (104.8)	28.6 (100.5)	26.5 (102.5)
Median	27.0	30.6	29.5
Min ; Max	-272.1 ; 341.0	-247.0 ; 315.3	-272.1 ; 341.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile-descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Lunch(mg/dL)			
Visit 2 (Week 0)			
N	167	169	336
Mean (SD)	23.7 (106.9)	9.3 (121.5)	16.4 (114.6)
Median	23.4	17.0	18.0
Min ; Max	-249.0 ; 293.7	-290.0 ; 479.9	-290.0 ; 479.9
Visit 14 (Week 12)			
N	144	146	290
Mean (SD)	14.9 (115.8)	12.8 (97.7)	13.9 (106.9)
Median	25.2	3.6	14.4
Min ; Max	-364.0 ; 355.0	-248.6 ; 314.0	-364.0 ; 355.0
Visit 18 (Week 16)			
N	156	152	308
Mean (SD)	-0.5 (103.8)	-5.6 (102.4)	-3.0 (103.0)
Median	10.5	-1.0	6.0
Min ; Max	-266.0 ; 246.0	-370.0 ; 266.0	-370.0 ; 266.0
End of trial visit			
N	176	177	353
Mean (SD)	-1.2 (104.1)	-6.6 (107.7)	-3.9 (105.8)
Median	10.0	0.0	3.6
Min ; Max	-266.0 ; 246.0	-405.0 ; 266.0	-405.0 ; 266.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile-descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Ev. Meal(mg/dL)			
Visit 2 (Week 0)			
N	162	157	319
Mean (SD)	0.3 (96.5)	2.8 (101.0)	1.5 (98.6)
Median	9.0	10.8	10.0
Min ; Max	-397.0 ; 205.4	-210.0 ; 306.3	-397.0 ; 306.3
Visit 14 (Week 12)			
N	147	144	291
Mean (SD)	-8.8 (107.9)	-2.9 (97.7)	-5.9 (102.9)
Median	-10.0	-1.0	-5.0
Min ; Max	-490.1 ; 305.0	-281.0 ; 242.0	-490.1 ; 305.0
Visit 18 (Week 16)			
N	150	140	290
Mean (SD)	-2.6 (116.5)	-5.9 (101.6)	-4.2 (109.4)
Median	1.8	3.0	3.0
Min ; Max	-467.9 ; 406.0	-268.0 ; 302.7	-467.9 ; 406.0
End of trial visit			
N	178	174	352
Mean (SD)	-3.9 (123.8)	-0.1 (108.7)	-2.0 (116.5)
Median	-3.3	3.0	0.0
Min ; Max	-490.1 ; 406.0	-268.0 ; 302.7	-490.1 ; 406.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

14.2.305 Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
All Meals(mmol/L)			
Visit 2 (Week 0)			
N	37	37	74
Mean (SD)	1.9 (3.5)	1.3 (4.5)	1.6 (4.0)
Median	1.8	1.1	1.4
Min ; Max	-6.7 ; 11.2	-7.4 ; 12.1	-7.4 ; 12.1
Visit 14 (Week 12)			
N	36	34	70
Mean (SD)	0.7 (5.0)	1.8 (3.3)	1.2 (4.2)
Median	1.2	1.5	1.4
Min ; Max	-10.1 ; 11.1	-5.6 ; 9.7	-10.1 ; 11.1
Visit 18 (Week 16)			
N	35	32	67
Mean (SD)	1.0 (5.5)	0.5 (3.4)	0.7 (4.6)
Median	0.7	0.5	0.6
Min ; Max	-15.8 ; 15.3	-8.4 ; 6.4	-15.8 ; 15.3
End of trial visit			
N	40	40	80
Mean (SD)	0.5 (5.5)	0.7 (4.3)	0.6 (4.9)
Median	0.5	0.5	0.5
Min ; Max	-15.8 ; 15.3	-9.8 ; 9.7	-15.8 ; 15.3

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Breakfast(mmol/L)			
Visit 2 (Week 0)			
N	37	36	73
Mean (SD)	3.0 (5.4)	2.9 (7.6)	2.9 (6.5)
Median	1.7	4.0	2.7
Min ; Max	-7.4 ; 15.4	-21.0 ; 13.7	-21.0 ; 15.4
Visit 14 (Week 12)			
N	36	36	72
Mean (SD)	2.3 (6.5)	3.7 (5.6)	3.0 (6.1)
Median	1.5	5.4	3.2
Min ; Max	-13.5 ; 16.0	-8.5 ; 15.4	-13.5 ; 16.0
Visit 18 (Week 16)			
N	34	33	67
Mean (SD)	2.5 (6.7)	1.9 (6.2)	2.2 (6.4)
Median	2.2	2.6	2.6
Min ; Max	-10.6 ; 18.9	-13.7 ; 15.4	-13.7 ; 18.9
End of trial visit			
N	39	40	79
Mean (SD)	2.7 (6.5)	3.0 (6.5)	2.8 (6.4)
Median	1.8	2.9	2.8
Min ; Max	-10.6 ; 18.9	-13.7 ; 15.4	-13.7 ; 18.9

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Lunch(mmol/L)			
Visit 2 (Week 0)			
N	39	38	77
Mean (SD)	2.6 (6.7)	1.5 (9.1)	2.1 (7.9)
Median	1.8	1.6	1.7
Min ; Max	-13.8 ; 16.3	-14.2 ; 26.6	-14.2 ; 26.6
Visit 14 (Week 12)			
N	36	33	69
Mean (SD)	-0.1 (6.6)	1.7 (5.1)	0.8 (5.9)
Median	1.2	1.7	1.4
Min ; Max	-17.2 ; 10.4	-9.0 ; 13.6	-17.2 ; 13.6
Visit 18 (Week 16)			
N	35	33	68
Mean (SD)	0.2 (6.0)	-1.0 (6.8)	-0.4 (6.4)
Median	0.9	-1.8	0.6
Min ; Max	-14.7 ; 12.3	-20.5 ; 10.4	-20.5 ; 12.3
End of trial visit			
N	40	40	80
Mean (SD)	-0.5 (6.1)	-0.9 (8.0)	-0.7 (7.0)
Median	0.3	-0.8	0.1
Min ; Max	-14.7 ; 12.3	-22.5 ; 13.6	-22.5 ; 13.6

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Ev. Meal(mmol/L)			
Visit 2 (Week 0)			
N	36	35	71
Mean (SD)	-0.6 (7.0)	-0.5 (6.7)	-0.5 (6.8)
Median	-0.1	-0.7	-0.4
Min ; Max	-22.0 ; 11.0	-11.5 ; 15.2	-22.0 ; 15.2
Visit 14 (Week 12)			
N	35	34	69
Mean (SD)	0.7 (6.9)	-0.3 (6.2)	0.2 (6.5)
Median	1.8	0.0	0.9
Min ; Max	-15.5 ; 14.0	-11.6 ; 12.4	-15.5 ; 14.0
Visit 18 (Week 16)			
N	34	31	65
Mean (SD)	0.5 (9.1)	1.0 (5.3)	0.7 (7.5)
Median	0.1	1.6	1.4
Min ; Max	-26.0 ; 22.5	-8.2 ; 12.0	-26.0 ; 22.5
End of trial visit			
N	40	40	80
Mean (SD)	0.3 (9.3)	1.0 (6.4)	0.7 (7.9)
Median	-1.2	1.8	1.3
Min ; Max	-26.0 ; 22.5	-11.5 ; 12.4	-26.0 ; 22.5

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
All Meals(mg/dL)			
Visit 2 (Week 0)			
N	37	37	74
Mean (SD)	34.2 (63.8)	22.6 (80.9)	28.4 (72.6)
Median	32.3	20.0	25.8
Min ; Max	-120.0 ; 202.4	-133.5 ; 218.3	-133.5 ; 218.3
Visit 14 (Week 12)			
N	36	34	70
Mean (SD)	12.9 (89.3)	32.4 (59.3)	22.3 (76.3)
Median	22.0	27.0	25.3
Min ; Max	-182.5 ; 200.3	-100.3 ; 175.5	-182.5 ; 200.3
Visit 18 (Week 16)			
N	35	32	67
Mean (SD)	17.4 (99.3)	9.2 (60.6)	13.5 (82.6)
Median	12.3	8.8	10.2
Min ; Max	-284.0 ; 276.0	-150.5 ; 114.7	-284.0 ; 276.0
End of trial visit			
N	40	40	80
Mean (SD)	8.7 (99.3)	12.5 (77.2)	10.6 (88.4)
Median	9.6	8.8	9.3
Min ; Max	-284.0 ; 276.0	-177.0 ; 175.5	-284.0 ; 276.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Breakfast(mg/dL)			
Visit 2 (Week 0)			
N	37	36	73
Mean (SD)	54.1 (96.8)	51.4 (136.1)	52.7 (117.0)
Median	30.6	72.6	48.6
Min ; Max	-134.0 ; 277.0	-378.4 ; 246.8	-378.4 ; 277.0
Visit 14 (Week 12)			
N	36	36	72
Mean (SD)	40.6 (117.1)	66.2 (101.2)	53.4 (109.4)
Median	26.1	97.9	57.7
Min ; Max	-243.2 ; 288.0	-153.0 ; 277.5	-243.2 ; 288.0
Visit 18 (Week 16)			
N	34	33	67
Mean (SD)	44.4 (120.8)	34.2 (112.5)	39.4 (116.0)
Median	39.4	46.0	46.0
Min ; Max	-191.0 ; 341.0	-247.0 ; 278.0	-247.0 ; 341.0
End of trial visit			
N	39	40	79
Mean (SD)	48.1 (116.3)	53.3 (117.4)	50.7 (116.2)
Median	32.0	52.5	50.0
Min ; Max	-191.0 ; 341.0	-247.0 ; 278.0	-247.0 ; 341.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Lunch(mg/dL)			
Visit 2 (Week 0)			
N	39	38	77
Mean (SD)	47.7 (120.2)	27.6 (164.2)	37.8 (143.0)
Median	33.0	29.4	30.0
Min ; Max	-249.0 ; 293.7	-255.9 ; 479.9	-255.9 ; 479.9
Visit 14 (Week 12)			
N	36	33	69
Mean (SD)	-1.0 (118.2)	30.5 (91.1)	14.1 (106.5)
Median	22.5	30.6	25.2
Min ; Max	-310.0 ; 188.0	-162.0 ; 245.0	-310.0 ; 245.0
Visit 18 (Week 16)			
N	35	33	68
Mean (SD)	3.2 (107.6)	-18.9 (122.9)	-7.5 (114.9)
Median	16.0	-32.4	10.4
Min ; Max	-264.0 ; 221.0	-370.0 ; 187.0	-370.0 ; 221.0
End of trial visit			
N	40	40	80
Mean (SD)	-8.4 (109.2)	-16.3 (143.7)	-12.3 (126.8)
Median	6.0	-15.2	2.0
Min ; Max	-264.0 ; 221.0	-405.0 ; 245.0	-405.0 ; 245.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Ev. Meal(mg/dL)			
Visit 2 (Week 0)			
N	36	35	71
Mean (SD)	-10.1 (126.0)	-8.8 (120.1)	-9.5 (122.2)
Median	-2.5	-12.0	-8.0
Min ; Max	-397.0 ; 198.0	-208.0 ; 274.0	-397.0 ; 274.0
Visit 14 (Week 12)			
N	35	34	69
Mean (SD)	12.5 (123.5)	-5.6 (112.2)	3.6 (117.6)
Median	32.4	0.5	16.0
Min ; Max	-279.0 ; 252.0	-209.0 ; 223.0	-279.0 ; 252.0
Visit 18 (Week 16)			
N	34	31	65
Mean (SD)	9.2 (164.8)	18.0 (95.7)	13.4 (135.3)
Median	1.3	28.8	25.2
Min ; Max	-467.9 ; 406.0	-147.7 ; 216.2	-467.9 ; 406.0
End of trial visit			
N	40	40	80
Mean (SD)	5.7 (167.6)	18.1 (115.7)	11.9 (143.2)
Median	-22.2	32.4	24.1
Min ; Max	-467.9 ; 406.0	-208.0 ; 223.0	-467.9 ; 406.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

14.2.306 Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
All Meals(mmol/L)			
Visit 2 (Week 0)			
N	54	55	109
Mean (SD)	1.1 (3.4)	1.4 (3.2)	1.3 (3.3)
Median	1.2	1.3	1.2
Min ; Max	-5.6 ; 10.6	-6.3 ; 7.9	-6.3 ; 10.6
Visit 14 (Week 12)			
N	50	52	102
Mean (SD)	1.3 (3.8)	0.3 (3.5)	0.8 (3.7)
Median	1.6	0.4	0.7
Min ; Max	-8.3 ; 10.2	-5.8 ; 10.6	-8.3 ; 10.6
Visit 18 (Week 16)			
N	51	52	103
Mean (SD)	0.7 (3.6)	-0.0 (3.7)	0.4 (3.7)
Median	0.5	0.1	0.3
Min ; Max	-11.6 ; 9.7	-8.3 ; 11.8	-11.6 ; 11.8
End of trial visit			
N	60	59	119
Mean (SD)	1.0 (3.6)	0.1 (3.7)	0.6 (3.6)
Median	0.7	0.1	0.4
Min ; Max	-11.6 ; 9.7	-8.3 ; 11.8	-11.6 ; 11.8

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Breakfast(mmol/L)			
Visit 2 (Week 0)			
N	56	58	114
Mean (SD)	3.1 (4.9)	3.8 (4.9)	3.5 (4.9)
Median	3.1	4.2	3.6
Min ; Max	-10.2 ; 12.2	-9.8 ; 13.2	-10.2 ; 13.2
Visit 14 (Week 12)			
N	50	51	101
Mean (SD)	2.0 (5.9)	1.5 (5.0)	1.8 (5.4)
Median	2.0	1.3	1.7
Min ; Max	-9.9 ; 13.6	-12.5 ; 10.5	-12.5 ; 13.6
Visit 18 (Week 16)			
N	53	53	106
Mean (SD)	2.1 (5.3)	1.9 (5.4)	2.0 (5.3)
Median	2.4	1.6	2.2
Min ; Max	-15.1 ; 12.8	-8.4 ; 17.5	-15.1 ; 17.5
End of trial visit			
N	60	60	120
Mean (SD)	1.8 (5.5)	2.3 (5.5)	2.1 (5.5)
Median	2.4	2.2	2.3
Min ; Max	-15.1 ; 12.8	-8.4 ; 17.5	-15.1 ; 17.5

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Lunch(mmol/L)			
Visit 2 (Week 0)			
N	54	59	113
Mean (SD)	0.6 (6.0)	0.1 (6.0)	0.3 (6.0)
Median	1.1	0.9	0.9
Min ; Max	-13.2 ; 15.3	-16.1 ; 13.4	-16.1 ; 15.3
Visit 14 (Week 12)			
N	49	53	102
Mean (SD)	0.7 (7.5)	0.4 (6.2)	0.6 (6.8)
Median	1.0	0.5	0.6
Min ; Max	-20.2 ; 19.7	-13.8 ; 17.4	-20.2 ; 19.7
Visit 18 (Week 16)			
N	55	56	111
Mean (SD)	0.1 (6.3)	-0.2 (6.2)	-0.0 (6.2)
Median	0.3	-0.4	-0.1
Min ; Max	-14.8 ; 13.7	-19.0 ; 14.8	-19.0 ; 14.8
End of trial visit			
N	60	60	120
Mean (SD)	0.3 (6.3)	0.1 (6.1)	0.2 (6.1)
Median	0.6	0.2	0.4
Min ; Max	-14.8 ; 13.7	-19.0 ; 14.8	-19.0 ; 14.8

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Ev. Meal(mmol/L)			
Visit 2 (Week 0)			
N	54	54	108
Mean (SD)	-0.3 (5.2)	-0.1 (4.9)	-0.2 (5.1)
Median	0.5	0.7	0.6
Min ; Max	-13.1 ; 11.4	-11.0 ; 10.2	-13.1 ; 11.4
Visit 14 (Week 12)			
N	50	51	101
Mean (SD)	0.1 (5.4)	-1.1 (4.9)	-0.5 (5.1)
Median	-0.4	-1.1	-0.7
Min ; Max	-12.3 ; 14.9	-15.6 ; 9.8	-15.6 ; 14.9
Visit 18 (Week 16)			
N	51	50	101
Mean (SD)	-0.5 (6.0)	-2.1 (6.6)	-1.3 (6.3)
Median	-0.4	-1.9	-1.5
Min ; Max	-15.8 ; 16.5	-14.9 ; 10.9	-15.8 ; 16.5
End of trial visit			
N	60	59	119
Mean (SD)	0.1 (6.4)	-2.0 (6.5)	-1.0 (6.5)
Median	-0.2	-1.9	-1.0
Min ; Max	-15.8 ; 16.5	-14.9 ; 10.9	-15.8 ; 16.5

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
All Meals(mg/dL)			
Visit 2 (Week 0)			
N	54	55	109
Mean (SD)	20.3 (61.8)	24.9 (57.6)	22.6 (59.5)
Median	21.3	24.0	22.2
Min ; Max	-100.9 ; 190.3	-113.5 ; 142.3	-113.5 ; 190.3
Visit 14 (Week 12)			
N	50	52	102
Mean (SD)	23.6 (68.9)	6.3 (63.4)	14.8 (66.4)
Median	29.4	7.8	12.0
Min ; Max	-150.2 ; 184.3	-104.5 ; 191.6	-150.2 ; 191.6
Visit 18 (Week 16)			
N	51	52	103
Mean (SD)	13.2 (64.7)	-0.0 (67.4)	6.5 (66.1)
Median	8.4	1.9	4.7
Min ; Max	-208.4 ; 174.3	-148.6 ; 212.0	-208.4 ; 212.0
End of trial visit			
N	60	59	119
Mean (SD)	17.4 (64.0)	2.7 (66.7)	10.1 (65.5)
Median	12.9	2.4	7.2
Min ; Max	-208.4 ; 174.3	-148.6 ; 212.0	-208.4 ; 212.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Breakfast(mg/dL)			
Visit 2 (Week 0)			
N	56	58	114
Mean (SD)	55.7 (88.0)	68.5 (88.5)	62.2 (88.1)
Median	56.4	74.8	64.4
Min ; Max	-183.0 ; 219.8	-176.0 ; 238.0	-183.0 ; 238.0
Visit 14 (Week 12)			
N	50	51	101
Mean (SD)	36.3 (105.6)	27.3 (90.1)	31.8 (97.6)
Median	35.5	24.0	30.6
Min ; Max	-178.4 ; 245.0	-226.0 ; 190.0	-226.0 ; 245.0
Visit 18 (Week 16)			
N	53	53	106
Mean (SD)	37.0 (95.2)	33.4 (97.1)	35.2 (95.7)
Median	43.2	29.0	39.7
Min ; Max	-272.1 ; 231.0	-151.4 ; 315.3	-272.1 ; 315.3
End of trial visit			
N	60	60	120
Mean (SD)	32.8 (99.0)	41.6 (99.0)	37.2 (98.7)
Median	43.1	39.7	41.7
Min ; Max	-272.1 ; 231.0	-151.4 ; 315.3	-272.1 ; 315.3

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Lunch(mg/dL)			
Visit 2 (Week 0)			
N	54	59	113
Mean (SD)	11.4 (108.6)	0.9 (107.7)	5.9 (107.8)
Median	19.5	16.0	16.0
Min ; Max	-237.8 ; 275.0	-290.0 ; 241.4	-290.0 ; 275.0
Visit 14 (Week 12)			
N	49	53	102
Mean (SD)	13.2 (135.2)	7.5 (110.9)	10.3 (122.6)
Median	18.0	9.0	10.5
Min ; Max	-364.0 ; 355.0	-248.6 ; 314.0	-364.0 ; 355.0
Visit 18 (Week 16)			
N	55	56	111
Mean (SD)	2.7 (113.1)	-2.9 (111.0)	-0.1 (111.6)
Median	6.0	-6.4	-2.0
Min ; Max	-266.0 ; 246.0	-342.0 ; 266.0	-342.0 ; 266.0
End of trial visit			
N	60	60	120
Mean (SD)	5.0 (112.8)	1.5 (109.2)	3.2 (110.5)
Median	11.1	3.5	6.5
Min ; Max	-266.0 ; 246.0	-342.0 ; 266.0	-342.0 ; 266.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Ev. Meal(mg/dL)			
Visit 2 (Week 0)			
N	54	54	108
Mean (SD)	-6.2 (94.2)	-2.1 (88.6)	-4.1 (91.0)
Median	9.5	11.7	10.8
Min ; Max	-236.0 ; 205.4	-198.0 ; 183.8	-236.0 ; 205.4
Visit 14 (Week 12)			
N	50	51	101
Mean (SD)	2.4 (96.7)	-19.8 (87.9)	-8.8 (92.6)
Median	-7.9	-20.0	-13.0
Min ; Max	-221.6 ; 268.5	-281.0 ; 177.0	-281.0 ; 268.5
Visit 18 (Week 16)			
N	51	50	101
Mean (SD)	-8.3 (108.0)	-37.6 (118.9)	-22.8 (113.9)
Median	-7.2	-34.2	-27.0
Min ; Max	-284.0 ; 297.3	-268.0 ; 196.4	-284.0 ; 297.3
End of trial visit			
N	60	59	119
Mean (SD)	1.5 (115.1)	-36.8 (116.4)	-17.4 (116.8)
Median	-3.3	-34.2	-18.0
Min ; Max	-284.0 ; 297.3	-268.0 ; 196.4	-284.0 ; 297.3

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

14.2.307 Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
All Meals(mmol/L)			
Visit 2 (Week 0)			
N	73	68	141
Mean (SD)	1.1 (3.1)	0.4 (3.1)	0.7 (3.1)
Median	1.2	0.7	0.9
Min ; Max	-6.9 ; 9.0	-8.9 ; 7.8	-8.9 ; 9.0
Visit 14 (Week 12)			
N	62	59	121
Mean (SD)	-0.0 (3.6)	0.4 (2.9)	0.2 (3.3)
Median	0.4	0.5	0.5
Min ; Max	-12.0 ; 6.7	-5.9 ; 7.2	-12.0 ; 7.2
Visit 18 (Week 16)			
N	65	59	124
Mean (SD)	0.1 (2.7)	0.3 (2.3)	0.2 (2.5)
Median	-0.3	0.6	0.2
Min ; Max	-5.9 ; 7.9	-5.7 ; 4.7	-5.9 ; 7.9
End of trial visit			
N	78	75	153
Mean (SD)	-0.1 (3.1)	0.3 (2.6)	0.1 (2.9)
Median	-0.3	0.6	0.2
Min ; Max	-12.0 ; 7.9	-8.9 ; 4.9	-12.0 ; 7.9

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Breakfast(mmol/L)			
Visit 2 (Week 0)			
N	69	70	139
Mean (SD)	1.7 (6.2)	0.0 (5.1)	0.9 (5.7)
Median	1.5	-0.2	1.1
Min ; Max	-13.7 ; 17.0	-12.9 ; 8.9	-13.7 ; 17.0
Visit 14 (Week 12)			
N	58	60	118
Mean (SD)	0.6 (4.2)	0.3 (5.6)	0.5 (5.0)
Median	0.6	-0.1	0.3
Min ; Max	-14.7 ; 7.7	-17.4 ; 11.5	-17.4 ; 11.5
Visit 18 (Week 16)			
N	62	59	121
Mean (SD)	0.6 (5.6)	0.6 (4.7)	0.6 (5.1)
Median	0.7	0.4	0.5
Min ; Max	-11.9 ; 14.4	-12.5 ; 11.9	-12.5 ; 14.4
End of trial visit			
N	76	75	151
Mean (SD)	0.3 (5.6)	0.3 (4.9)	0.3 (5.2)
Median	0.7	0.3	0.4
Min ; Max	-13.7 ; 14.4	-12.9 ; 11.9	-13.7 ; 14.4

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Lunch(mmol/L)			
Visit 2 (Week 0)			
N	74	72	146
Mean (SD)	1.1 (5.4)	0.4 (5.9)	0.7 (5.6)
Median	1.3	0.6	0.8
Min ; Max	-11.7 ; 14.4	-13.3 ; 12.2	-13.3 ; 14.4
Visit 14 (Week 12)			
N	59	60	119
Mean (SD)	1.4 (5.3)	0.4 (4.9)	0.9 (5.1)
Median	1.7	-0.2	0.4
Min ; Max	-15.6 ; 15.3	-10.2 ; 14.0	-15.6 ; 15.3
Visit 18 (Week 16)			
N	66	63	129
Mean (SD)	-0.3 (5.3)	-0.1 (4.5)	-0.2 (4.9)
Median	0.6	0.3	0.4
Min ; Max	-14.5 ; 12.0	-12.0 ; 11.1	-14.5 ; 12.0
End of trial visit			
N	76	77	153
Mean (SD)	-0.1 (5.3)	-0.4 (4.6)	-0.3 (4.9)
Median	0.6	-0.1	0.2
Min ; Max	-14.5 ; 12.0	-13.3 ; 11.1	-14.5 ; 12.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Ev. Meal(mmol/L)			
Visit 2 (Week 0)			
N	72	68	140
Mean (SD)	0.6 (4.5)	0.7 (5.6)	0.6 (5.0)
Median	0.6	1.0	0.8
Min ; Max	-10.2 ; 10.5	-11.7 ; 17.0	-11.7 ; 17.0
Visit 14 (Week 12)			
N	62	59	121
Mean (SD)	-1.7 (5.8)	0.7 (5.3)	-0.5 (5.7)
Median	-1.2	1.0	-0.4
Min ; Max	-27.2 ; 16.9	-13.7 ; 13.4	-27.2 ; 16.9
Visit 18 (Week 16)			
N	65	59	124
Mean (SD)	-0.2 (5.1)	0.5 (4.5)	0.1 (4.8)
Median	0.4	0.5	0.5
Min ; Max	-13.8 ; 9.8	-9.4 ; 16.8	-13.8 ; 16.8
End of trial visit			
N	78	75	153
Mean (SD)	-0.7 (5.7)	1.1 (5.1)	0.2 (5.5)
Median	0.2	0.6	0.4
Min ; Max	-27.2 ; 9.8	-9.4 ; 16.8	-27.2 ; 16.8

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
All Meals(mg/dL)			
Visit 2 (Week 0)			
N	73	68	141
Mean (SD)	19.0 (56.6)	6.8 (55.8)	13.1 (56.4)
Median	21.3	12.7	15.3
Min ; Max	-125.0 ; 163.0	-160.0 ; 140.5	-160.0 ; 163.0
Visit 14 (Week 12)			
N	62	59	121
Mean (SD)	-0.7 (64.5)	7.9 (52.6)	3.5 (58.9)
Median	8.0	9.0	8.3
Min ; Max	-216.8 ; 120.0	-106.0 ; 129.1	-216.8 ; 129.1
Visit 18 (Week 16)			
N	65	59	124
Mean (SD)	2.2 (49.5)	6.1 (41.3)	4.1 (45.7)
Median	-4.8	10.3	4.1
Min ; Max	-107.0 ; 142.7	-102.0 ; 85.0	-107.0 ; 142.7
End of trial visit			
N	78	75	153
Mean (SD)	-2.5 (56.5)	6.2 (46.4)	1.8 (51.8)
Median	-5.5	10.7	4.0
Min ; Max	-216.8 ; 142.7	-160.0 ; 87.7	-216.8 ; 142.7

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Breakfast(mg/dL)			
Visit 2 (Week 0)			
N	69	70	139
Mean (SD)	30.2 (111.9)	0.9 (91.4)	15.4 (102.8)
Median	27.0	-2.8	19.0
Min ; Max	-247.0 ; 307.0	-232.0 ; 160.0	-247.0 ; 307.0
Visit 14 (Week 12)			
N	58	60	118
Mean (SD)	11.1 (75.6)	5.9 (101.6)	8.4 (89.4)
Median	10.0	-0.9	6.2
Min ; Max	-265.0 ; 138.7	-314.0 ; 208.0	-314.0 ; 208.0
Visit 18 (Week 16)			
N	62	59	121
Mean (SD)	10.5 (100.9)	11.1 (83.9)	10.8 (92.6)
Median	12.8	7.2	9.0
Min ; Max	-215.0 ; 259.0	-225.2 ; 215.0	-225.2 ; 259.0
End of trial visit			
N	76	75	151
Mean (SD)	5.6 (101.0)	5.1 (87.5)	5.4 (94.2)
Median	12.8	5.0	8.0
Min ; Max	-247.0 ; 259.0	-232.0 ; 215.0	-247.0 ; 259.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Lunch(mg/dL)			
Visit 2 (Week 0)			
N	74	72	146
Mean (SD)	19.9 (97.4)	6.4 (105.6)	13.2 (101.4)
Median	22.5	10.0	13.7
Min ; Max	-210.0 ; 259.0	-240.0 ; 219.0	-240.0 ; 259.0
Visit 14 (Week 12)			
N	59	60	119
Mean (SD)	26.0 (96.2)	7.7 (88.7)	16.8 (92.6)
Median	30.6	-3.0	8.0
Min ; Max	-281.0 ; 275.0	-184.0 ; 252.0	-281.0 ; 275.0
Visit 18 (Week 16)			
N	66	63	129
Mean (SD)	-5.1 (94.7)	-1.0 (81.7)	-3.1 (88.3)
Median	10.5	5.0	8.0
Min ; Max	-261.0 ; 217.0	-217.0 ; 200.0	-261.0 ; 217.0
End of trial visit			
N	76	77	153
Mean (SD)	-2.3 (95.0)	-7.9 (83.0)	-5.1 (88.9)
Median	10.5	-1.0	3.6
Min ; Max	-261.0 ; 217.0	-240.0 ; 200.0	-261.0 ; 217.0

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - 8-point self measured plasma glucose profile – descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Inc. Ev. Meal(mg/dL)			
Visit 2 (Week 0)			
N	72	68	140
Mean (SD)	10.4 (80.6)	12.7 (100.1)	11.5 (90.3)
Median	9.9	18.5	14.0
Min ; Max	-183.8 ; 189.2	-210.0 ; 306.3	-210.0 ; 306.3
Visit 14 (Week 12)			
N	62	59	121
Mean (SD)	-29.8 (105.1)	13.2 (95.9)	-8.8 (102.6)
Median	-22.5	18.0	-7.2
Min ; Max	-490.1 ; 305.0	-246.0 ; 242.0	-490.1 ; 305.0
Visit 18 (Week 16)			
N	65	59	124
Mean (SD)	-4.4 (91.6)	8.3 (81.8)	1.7 (86.9)
Median	8.0	9.0	8.5
Min ; Max	-248.6 ; 177.0	-170.0 ; 302.7	-248.6 ; 302.7
End of trial visit			
N	78	75	153
Mean (SD)	-13.0 (103.5)	19.2 (91.3)	2.8 (98.7)
Median	3.8	10.8	7.2
Min ; Max	-490.1 ; 177.0	-170.0 ; 302.7	-490.1 ; 302.7

N: Number of subjects, SD: Standard deviation
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

14.2.308 Prandial increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
All Meals, Change(mmol/L)			
Visit 14 (Week 12)			
N	136	135	271
Mean (SD)	-0.6 (4.4)	-0.2 (4.3)	-0.4 (4.3)
Median	-0.8	-0.4	-0.5
Min ; Max	-19.8 ; 11.0	-10.8 ; 11.3	-19.8 ; 11.3
Visit 18 (Week 16)			
N	140	133	273
Mean (SD)	-0.7 (4.5)	-0.7 (4.5)	-0.7 (4.5)
Median	-0.9	-0.7	-0.8
Min ; Max	-14.4 ; 22.0	-15.8 ; 14.2	-15.8 ; 22.0
End of trial visit			
N	164	160	324
Mean (SD)	-0.7 (4.5)	-0.6 (4.7)	-0.7 (4.6)
Median	-0.4	-0.5	-0.4
Min ; Max	-19.8 ; 22.0	-16.6 ; 14.2	-19.8 ; 22.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Breakfast, Change(mmol/L)			
Visit 14 (Week 12)			
N	133	139	272
Mean (SD)	-0.9 (6.9)	-0.3 (7.7)	-0.6 (7.3)
Median	-0.1	-1.1	-0.4
Min ; Max	-21.3 ; 18.2	-19.9 ; 36.4	-21.3 ; 36.4
Visit 18 (Week 16)			
N	139	135	274
Mean (SD)	-1.2 (6.6)	-0.8 (7.2)	-1.0 (6.9)
Median	-0.9	-1.1	-1.0
Min ; Max	-18.2 ; 18.1	-19.4 ; 25.4	-19.4 ; 25.4
End of trial visit			
N	162	164	326
Mean (SD)	-1.2 (6.7)	-0.3 (7.7)	-0.7 (7.2)
Median	-0.2	-0.4	-0.2
Min ; Max	-21.3 ; 18.2	-19.4 ; 36.4	-21.3 ; 36.4

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Lunch, Change(mmol/L)			
Visit 14 (Week 12)			
N	135	141	276
Mean (SD)	-0.7 (7.6)	0.2 (7.5)	-0.3 (7.6)
Median	-0.4	0.3	-0.1
Min ; Max	-27.9 ; 19.7	-18.2 ; 23.6	-27.9 ; 23.6
Visit 18 (Week 16)			
N	148	144	292
Mean (SD)	-1.5 (7.8)	-0.7 (8.6)	-1.1 (8.2)
Median	-1.4	-0.0	-0.8
Min ; Max	-27.5 ; 19.4	-24.6 ; 19.7	-27.5 ; 19.7
End of trial visit			
N	167	169	336
Mean (SD)	-1.6 (7.7)	-0.9 (8.4)	-1.2 (8.1)
Median	-0.9	0.0	-0.5
Min ; Max	-27.9 ; 19.4	-26.9 ; 19.7	-27.9 ; 19.7

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change(mmol/L)			
Visit 14 (Week 12)			
N	133	132	265
Mean (SD)	-0.3 (7.9)	-0.3 (7.8)	-0.3 (7.8)
Median	-0.1	-0.4	-0.1
Min ; Max	-35.5 ; 20.3	-18.4 ; 23.4	-35.5 ; 23.4
Visit 18 (Week 16)			
N	137	128	265
Mean (SD)	-0.0 (7.4)	-0.4 (8.0)	-0.2 (7.7)
Median	-0.3	-0.6	-0.5
Min ; Max	-18.9 ; 40.1	-21.3 ; 21.7	-21.3 ; 40.1
End of trial visit			
N	162	157	319
Mean (SD)	0.0 (7.7)	-0.0 (8.3)	0.0 (8.0)
Median	0.0	-0.3	0.0
Min ; Max	-35.5 ; 40.1	-21.3 ; 23.4	-35.5 ; 40.1

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
All Meals, Change(mg/dL)			
Visit 14 (Week 12)			
N	136	135	271
Mean (SD)	-10.9 (78.7)	-3.2 (76.9)	-7.1 (77.7)
Median	-13.8	-6.7	-9.6
Min ; Max	-356.2 ; 198.5	-194.3 ; 203.1	-356.2 ; 203.1
Visit 18 (Week 16)			
N	140	133	273
Mean (SD)	-13.3 (80.6)	-11.8 (81.5)	-12.5 (80.9)
Median	-16.0	-13.0	-15.0
Min ; Max	-260.1 ; 396.0	-285.3 ; 256.0	-285.3 ; 396.0
End of trial visit			
N	164	160	324
Mean (SD)	-13.5 (81.6)	-10.0 (83.9)	-11.7 (82.6)
Median	-7.8	-8.7	-8.1
Min ; Max	-356.2 ; 396.0	-298.6 ; 256.0	-356.2 ; 396.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Breakfast, Change(mg/dL)			
Visit 14 (Week 12)			
N	133	139	272
Mean (SD)	-16.3 (123.8)	-6.1 (139.6)	-11.1 (132.0)
Median	-1.0	-19.0	-7.1
Min ; Max	-383.0 ; 327.9	-358.0 ; 655.9	-383.0 ; 655.9
Visit 18 (Week 16)			
N	139	135	274
Mean (SD)	-22.4 (119.3)	-14.5 (129.4)	-18.5 (124.2)
Median	-16.0	-19.0	-18.5
Min ; Max	-327.9 ; 326.1	-349.0 ; 456.9	-349.0 ; 456.9
End of trial visit			
N	162	164	326
Mean (SD)	-20.8 (120.7)	-4.8 (138.8)	-12.7 (130.2)
Median	-2.7	-7.6	-4.3
Min ; Max	-383.0 ; 327.9	-349.0 ; 655.9	-383.0 ; 655.9

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Lunch, Change(mg/dL)			
Visit 14 (Week 12)			
N	135	141	276
Mean (SD)	-13.3 (137.6)	3.2 (135.5)	-4.9 (136.5)
Median	-8.0	5.4	-0.9
Min ; Max	-502.7 ; 355.0	-327.9 ; 425.0	-502.7 ; 425.0
Visit 18 (Week 16)			
N	148	144	292
Mean (SD)	-27.4 (140.9)	-12.4 (155.5)	-20.0 (148.2)
Median	-24.5	-0.6	-15.2
Min ; Max	-495.9 ; 350.0	-444.0 ; 355.0	-495.9 ; 355.0
End of trial visit			
N	167	169	336
Mean (SD)	-28.1 (139.2)	-16.3 (151.4)	-22.2 (145.4)
Median	-16.0	0.0	-8.5
Min ; Max	-502.7 ; 350.0	-484.9 ; 355.0	-502.7 ; 355.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change(mg/dL)			
Visit 14 (Week 12)			
N	133	132	265
Mean (SD)	-6.2 (143.1)	-5.5 (139.8)	-5.8 (141.2)
Median	-1.8	-6.6	-1.8
Min ; Max	-639.6 ; 366.0	-332.0 ; 422.0	-639.6 ; 422.0
Visit 18 (Week 16)			
N	137	128	265
Mean (SD)	-0.3 (133.0)	-6.5 (144.4)	-3.3 (138.4)
Median	-5.4	-10.8	-9.0
Min ; Max	-340.0 ; 721.9	-383.8 ; 391.0	-383.8 ; 721.9
End of trial visit			
N	162	157	319
Mean (SD)	0.8 (138.2)	-0.6 (149.5)	0.1 (143.6)
Median	0.0	-5.0	0.0
Min ; Max	-639.6 ; 721.9	-383.8 ; 422.0	-639.6 ; 721.9

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

14.2.309 Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
All Meals, Change(mmol/L)			
Visit 14 (Week 12)			
N	33	31	64
Mean (SD)	-0.5 (4.5)	0.4 (5.1)	-0.0 (4.8)
Median	-1.1	-0.2	-1.0
Min ; Max	-9.3 ; 10.9	-8.5 ; 11.3	-9.3 ; 11.3
Visit 18 (Week 16)			
N	33	31	64
Mean (SD)	-0.6 (6.4)	-1.0 (5.9)	-0.8 (6.1)
Median	-0.5	-0.3	-0.3
Min ; Max	-14.4 ; 22.0	-15.8 ; 9.3	-15.8 ; 22.0
End of trial visit			
N	37	37	74
Mean (SD)	-0.8 (6.1)	-0.6 (6.6)	-0.7 (6.3)
Median	-0.5	0.0	-0.3
Min ; Max	-14.4 ; 22.0	-16.6 ; 11.3	-16.6 ; 22.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Breakfast, Change(mmol/L)			
Visit 14 (Week 12)			
N	35	33	68
Mean (SD)	-0.6 (5.9)	0.9 (10.0)	0.2 (8.1)
Median	0.6	-0.2	0.2
Min ; Max	-16.3 ; 8.4	-17.5 ; 36.4	-17.5 ; 36.4
Visit 18 (Week 16)			
N	33	29	62
Mean (SD)	-0.4 (8.5)	-1.7 (8.5)	-1.0 (8.5)
Median	0.5	-1.1	-0.2
Min ; Max	-18.2 ; 18.1	-19.4 ; 25.4	-19.4 ; 25.4
End of trial visit			
N	37	36	73
Mean (SD)	-0.2 (8.0)	0.6 (10.8)	0.2 (9.4)
Median	0.5	-0.4	0.1
Min ; Max	-18.2 ; 18.1	-19.4 ; 36.4	-19.4 ; 36.4

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Lunch, Change(mmol/L)			
Visit 14 (Week 12)			
N	35	32	67
Mean (SD)	-2.9 (8.9)	0.4 (7.6)	-1.3 (8.4)
Median	-1.6	0.3	-0.2
Min ; Max	-27.9 ; 13.7	-16.7 ; 13.2	-27.9 ; 13.7
Visit 18 (Week 16)			
N	34	31	65
Mean (SD)	-2.6 (7.4)	-1.9 (11.6)	-2.3 (9.5)
Median	-2.5	-1.2	-2.4
Min ; Max	-16.4 ; 15.3	-24.6 ; 19.7	-24.6 ; 19.7
End of trial visit			
N	39	38	77
Mean (SD)	-3.0 (8.1)	-2.3 (11.5)	-2.7 (9.8)
Median	-1.9	-0.4	-1.8
Min ; Max	-27.9 ; 15.3	-26.9 ; 19.7	-27.9 ; 19.7

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change(mmol/L)			
Visit 14 (Week 12)			
N	31	29	60
Mean (SD)	2.0 (8.8)	-0.3 (8.7)	0.9 (8.8)
Median	2.6	-1.1	0.9
Min ; Max	-23.1 ; 20.3	-16.3 ; 23.4	-23.1 ; 23.4
Visit 18 (Week 16)			
N	31	29	60
Mean (SD)	1.6 (10.0)	0.8 (9.9)	1.2 (9.9)
Median	-0.1	-0.3	-0.2
Min ; Max	-12.5 ; 40.1	-14.5 ; 21.7	-14.5 ; 40.1
End of trial visit			
N	36	35	71
Mean (SD)	1.8 (9.6)	1.7 (10.5)	1.8 (10.0)
Median	0.0	0.0	0.0
Min ; Max	-12.5 ; 40.1	-14.5 ; 23.4	-14.5 ; 40.1

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
All Meals, Change(mg/dL)			
Visit 14 (Week 12)			
N	33	31	64
Mean (SD)	-8.6 (81.9)	7.9 (92.3)	-0.6 (86.8)
Median	-20.4	-3.3	-18.0
Min ; Max	-167.3 ; 197.0	-152.6 ; 203.1	-167.3 ; 203.1
Visit 18 (Week 16)			
N	33	31	64
Mean (SD)	-10.8 (114.6)	-17.3 (106.3)	-14.0 (109.8)
Median	-9.0	-5.4	-5.7
Min ; Max	-260.1 ; 396.0	-285.3 ; 167.6	-285.3 ; 396.0
End of trial visit			
N	37	37	74
Mean (SD)	-13.6 (109.2)	-11.2 (119.0)	-12.4 (113.4)
Median	-9.0	0.0	-5.4
Min ; Max	-260.1 ; 396.0	-298.6 ; 203.1	-298.6 ; 396.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Breakfast, Change(mg/dL)			
Visit 14 (Week 12)			
N	35	33	68
Mean (SD)	-10.6 (105.9)	17.0 (181.0)	2.8 (146.7)
Median	11.0	-3.0	4.5
Min ; Max	-293.7 ; 151.0	-316.0 ; 655.9	-316.0 ; 655.9
Visit 18 (Week 16)			
N	33	29	62
Mean (SD)	-6.9 (152.7)	-29.9 (153.5)	-17.6 (152.3)
Median	9.0	-19.8	-3.4
Min ; Max	-327.9 ; 326.1	-349.0 ; 456.9	-349.0 ; 456.9
End of trial visit			
N	37	36	73
Mean (SD)	-2.9 (144.8)	10.9 (194.2)	3.9 (169.9)
Median	9.0	-6.3	2.0
Min ; Max	-327.9 ; 326.1	-349.0 ; 655.9	-349.0 ; 655.9

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Lunch, Change(mg/dL)			
Visit 14 (Week 12)			
N	35	32	67
Mean (SD)	-52.2 (160.8)	6.7 (137.6)	-24.0 (152.0)
Median	-28.8	4.5	-3.0
Min ; Max	-502.7 ; 247.0	-300.9 ; 237.8	-502.7 ; 247.0
Visit 18 (Week 16)			
N	34	31	65
Mean (SD)	-47.6 (133.8)	-33.4 (208.2)	-40.8 (172.0)
Median	-44.9	-21.6	-43.0
Min ; Max	-295.5 ; 276.0	-444.0 ; 355.0	-444.0 ; 355.0
End of trial visit			
N	39	38	77
Mean (SD)	-54.4 (145.6)	-41.0 (206.9)	-47.8 (177.4)
Median	-35.0	-7.2	-32.4
Min ; Max	-502.7 ; 276.0	-484.9 ; 355.0	-502.7 ; 355.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change(mg/dL)			
Visit 14 (Week 12)			
N	31	29	60
Mean (SD)	36.1 (159.4)	-5.5 (156.3)	16.0 (158.0)
Median	46.0	-19.8	15.6
Min ; Max	-417.0 ; 366.0	-293.7 ; 422.0	-417.0 ; 422.0
Visit 18 (Week 16)			
N	31	29	60
Mean (SD)	29.4 (179.5)	15.0 (178.2)	22.4 (177.5)
Median	-1.8	-5.0	-3.4
Min ; Max	-225.2 ; 721.9	-261.3 ; 391.0	-261.3 ; 721.9
End of trial visit			
N	36	35	71
Mean (SD)	32.4 (173.2)	31.2 (188.4)	31.8 (179.6)
Median	0.0	0.0	0.0
Min ; Max	-225.2 ; 721.9	-261.3 ; 422.0	-261.3 ; 721.9

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

14.2.310 Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
All Meals, Change(mmol/L)			
Visit 14 (Week 12)			
N	44	49	93
Mean (SD)	-0.1 (3.7)	-1.2 (3.8)	-0.6 (3.8)
Median	-0.2	-1.4	-0.7
Min ; Max	-7.8 ; 11.0	-10.8 ; 7.1	-10.8 ; 11.0
Visit 18 (Week 16)			
N	46	48	94
Mean (SD)	-0.4 (4.1)	-1.2 (4.2)	-0.8 (4.2)
Median	-0.3	-1.3	-1.1
Min ; Max	-10.1 ; 8.8	-8.9 ; 14.2	-10.1 ; 14.2
End of trial visit			
N	54	55	109
Mean (SD)	-0.1 (4.1)	-1.2 (4.3)	-0.7 (4.2)
Median	0.0	-1.3	-0.5
Min ; Max	-10.1 ; 11.0	-10.8 ; 14.2	-10.8 ; 14.2

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Breakfast, Change(mmol/L)			
Visit 14 (Week 12)			
N	46	49	95
Mean (SD)	-0.9 (6.4)	-1.8 (6.3)	-1.3 (6.3)
Median	-0.5	-2.1	-1.1
Min ; Max	-16.1 ; 14.3	-15.8 ; 18.4	-16.1 ; 18.4
Visit 18 (Week 16)			
N	49	51	100
Mean (SD)	-1.7 (6.2)	-1.7 (6.3)	-1.7 (6.2)
Median	-1.8	-1.8	-1.8
Min ; Max	-16.6 ; 17.9	-12.5 ; 13.1	-16.6 ; 17.9
End of trial visit			
N	56	58	114
Mean (SD)	-1.5 (5.8)	-1.4 (6.4)	-1.4 (6.1)
Median	-1.6	-1.5	-1.6
Min ; Max	-16.6 ; 17.9	-12.5 ; 14.9	-16.6 ; 17.9

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Lunch, Change(mmol/L)			
Visit 14 (Week 12)			
N	43	52	95
Mean (SD)	-0.3 (7.7)	0.5 (7.1)	0.2 (7.4)
Median	-0.3	1.7	0.1
Min ; Max	-22.9 ; 19.7	-18.2 ; 12.7	-22.9 ; 19.7
Visit 18 (Week 16)			
N	49	55	104
Mean (SD)	-0.9 (9.4)	0.1 (8.1)	-0.4 (8.7)
Median	-0.5	0.5	0.1
Min ; Max	-27.5 ; 19.4	-20.9 ; 18.2	-27.5 ; 19.4
End of trial visit			
N	54	59	113
Mean (SD)	-0.9 (9.0)	0.1 (7.9)	-0.4 (8.4)
Median	-0.2	0.5	0.0
Min ; Max	-27.5 ; 19.4	-20.9 ; 18.2	-27.5 ; 19.4

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change(mmol/L)			
Visit 14 (Week 12)			
N	44	48	92
Mean (SD)	0.5 (7.1)	-1.6 (7.0)	-0.6 (7.1)
Median	-0.1	-1.2	-0.6
Min ; Max	-14.1 ; 20.0	-18.4 ; 13.5	-18.4 ; 20.0
Visit 18 (Week 16)			
N	46	45	91
Mean (SD)	0.1 (6.7)	-1.9 (7.5)	-0.9 (7.1)
Median	0.5	-1.7	-0.7
Min ; Max	-18.9 ; 16.5	-20.1 ; 17.1	-20.1 ; 17.1
End of trial visit			
N	54	54	108
Mean (SD)	0.7 (6.8)	-1.9 (7.7)	-0.6 (7.4)
Median	0.0	-0.9	-0.1
Min ; Max	-18.9 ; 20.0	-20.1 ; 17.1	-20.1 ; 20.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
All Meals, Change(mg/dL)			
Visit 14 (Week 12)			
N	44	49	93
Mean (SD)	-0.9 (66.6)	-21.2 (68.5)	-11.6 (68.0)
Median	-3.0	-24.6	-13.2
Min ; Max	-141.1 ; 198.5	-194.3 ; 128.7	-194.3 ; 198.5
Visit 18 (Week 16)			
N	46	48	94
Mean (SD)	-7.4 (73.9)	-21.7 (76.3)	-14.7 (75.1)
Median	-5.4	-23.7	-19.5
Min ; Max	-181.3 ; 158.3	-160.3 ; 256.0	-181.3 ; 256.0
End of trial visit			
N	54	55	109
Mean (SD)	-2.3 (73.7)	-21.0 (76.8)	-11.8 (75.5)
Median	0.0	-22.8	-9.6
Min ; Max	-181.3 ; 198.5	-194.3 ; 256.0	-194.3 ; 256.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Breakfast, Change(mg/dL)			
Visit 14 (Week 12)			
N	46	49	95
Mean (SD)	-16.6 (115.4)	-31.5 (113.2)	-24.3 (113.9)
Median	-8.9	-37.0	-19.8
Min ; Max	-290.1 ; 257.7	-284.0 ; 332.0	-290.1 ; 332.0
Visit 18 (Week 16)			
N	49	51	100
Mean (SD)	-29.8 (111.3)	-31.4 (113.4)	-30.6 (111.8)
Median	-32.4	-32.4	-32.4
Min ; Max	-299.1 ; 322.0	-225.0 ; 236.0	-299.1 ; 322.0
End of trial visit			
N	56	58	114
Mean (SD)	-26.7 (104.4)	-25.0 (115.2)	-25.8 (109.6)
Median	-29.5	-26.1	-28.0
Min ; Max	-299.1 ; 322.0	-225.0 ; 268.0	-299.1 ; 322.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Lunch, Change(mg/dL)			
Visit 14 (Week 12)			
N	43	52	95
Mean (SD)	-5.3 (139.2)	9.7 (127.7)	2.9 (132.5)
Median	-5.4	30.0	2.0
Min ; Max	-413.0 ; 355.0	-327.9 ; 228.0	-413.0 ; 355.0
Visit 18 (Week 16)			
N	49	55	104
Mean (SD)	-16.3 (169.4)	1.4 (146.5)	-6.9 (157.2)
Median	-9.0	9.0	1.2
Min ; Max	-495.9 ; 350.0	-376.0 ; 328.0	-495.9 ; 350.0
End of trial visit			
N	54	59	113
Mean (SD)	-16.8 (161.8)	1.4 (142.0)	-7.3 (151.4)
Median	-4.3	9.0	0.0
Min ; Max	-495.9 ; 350.0	-376.0 ; 328.0	-495.9 ; 350.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change(mg/dL)			
Visit 14 (Week 12)			
N	44	48	92
Mean (SD)	8.4 (128.7)	-28.1 (127.0)	-10.7 (128.4)
Median	-0.9	-20.7	-10.8
Min ; Max	-254.1 ; 361.0	-332.0 ; 244.0	-332.0 ; 361.0
Visit 18 (Week 16)			
N	46	45	91
Mean (SD)	2.2 (119.9)	-33.6 (135.6)	-15.5 (128.5)
Median	8.1	-30.6	-13.0
Min ; Max	-340.0 ; 298.0	-362.2 ; 309.0	-362.2 ; 309.0
End of trial visit			
N	54	54	108
Mean (SD)	12.0 (123.2)	-35.0 (138.8)	-11.5 (132.7)
Median	0.0	-16.5	-0.9
Min ; Max	-340.0 ; 361.0	-362.2 ; 309.0	-362.2 ; 361.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

14.2.311 Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
All Meals, Change(mmol/L)			
Visit 14 (Week 12)			
N	59	55	114
Mean (SD)	-1.1 (4.7)	0.4 (4.0)	-0.4 (4.5)
Median	-0.9	0.6	-0.4
Min ; Max	-19.8 ; 7.4	-7.5 ; 8.7	-19.8 ; 8.7
Visit 18 (Week 16)			
N	61	54	115
Mean (SD)	-1.1 (3.5)	0.0 (3.8)	-0.6 (3.7)
Median	-1.1	-0.7	-1.0
Min ; Max	-9.5 ; 9.2	-8.7 ; 8.2	-9.5 ; 9.2
End of trial visit			
N	73	68	141
Mean (SD)	-1.2 (3.9)	-0.0 (3.6)	-0.6 (3.8)
Median	-0.8	-0.2	-0.5
Min ; Max	-19.8 ; 9.2	-8.7 ; 8.2	-19.8 ; 9.2

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Breakfast, Change(mmol/L)			
Visit 14 (Week 12)			
N	52	57	109
Mean (SD)	-1.1 (7.9)	0.1 (7.3)	-0.5 (7.6)
Median	-0.2	-0.4	-0.2
Min ; Max	-21.3 ; 18.2	-19.9 ; 21.7	-21.3 ; 21.7
Visit 18 (Week 16)			
N	57	55	112
Mean (SD)	-1.4 (5.8)	0.5 (7.1)	-0.4 (6.5)
Median	-0.9	-0.1	-0.8
Min ; Max	-12.9 ; 14.3	-14.5 ; 22.9	-14.5 ; 22.9
End of trial visit			
N	69	70	139
Mean (SD)	-1.4 (6.7)	0.2 (6.8)	-0.6 (6.7)
Median	-0.6	0.0	-0.1
Min ; Max	-21.3 ; 18.2	-14.5 ; 22.9	-21.3 ; 22.9

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Lunch, Change(mmol/L)			
Visit 14 (Week 12)			
N	57	57	114
Mean (SD)	0.3 (6.5)	-0.3 (7.9)	-0.0 (7.2)
Median	-0.3	-0.8	-0.4
Min ; Max	-16.6 ; 16.0	-13.4 ; 23.6	-16.6 ; 23.6
Visit 18 (Week 16)			
N	65	58	123
Mean (SD)	-1.4 (6.7)	-0.8 (7.3)	-1.1 (6.9)
Median	-1.1	-0.4	-1.0
Min ; Max	-16.6 ; 13.9	-16.0 ; 14.5	-16.6 ; 14.5
End of trial visit			
N	74	72	146
Mean (SD)	-1.2 (6.5)	-1.0 (6.8)	-1.1 (6.6)
Median	-0.9	0.0	-0.5
Min ; Max	-16.6 ; 13.9	-16.0 ; 14.5	-16.6 ; 14.5

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change(mmol/L)			
Visit 14 (Week 12)			
N	58	55	113
Mean (SD)	-2.2 (7.7)	0.8 (7.8)	-0.7 (7.9)
Median	-0.6	1.6	-0.1
Min ; Max	-35.5 ; 12.2	-17.4 ; 22.1	-35.5 ; 22.1
Visit 18 (Week 16)			
N	60	54	114
Mean (SD)	-1.0 (6.2)	0.3 (7.2)	-0.4 (6.7)
Median	-0.9	0.0	-0.8
Min ; Max	-15.6 ; 11.0	-21.3 ; 15.7	-21.3 ; 15.7
End of trial visit			
N	72	68	140
Mean (SD)	-1.3 (7.0)	0.6 (7.3)	-0.4 (7.2)
Median	-0.2	0.0	0.0
Min ; Max	-35.5 ; 11.0	-21.3 ; 22.1	-35.5 ; 22.1

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
All Meals, Change(mg/dL)			
Visit 14 (Week 12)			
N	59	55	114
Mean (SD)	-19.7 (85.2)	6.5 (72.8)	-7.1 (80.2)
Median	-16.3	10.0	-6.3
Min ; Max	-356.2 ; 133.3	-134.5 ; 157.4	-356.2 ; 157.4
Visit 18 (Week 16)			
N	61	54	115
Mean (SD)	-19.1 (62.3)	0.3 (68.6)	-10.0 (65.8)
Median	-20.7	-12.7	-17.8
Min ; Max	-170.6 ; 165.6	-157.4 ; 147.3	-170.6 ; 165.6
End of trial visit			
N	73	68	141
Mean (SD)	-21.6 (70.3)	-0.3 (64.4)	-11.4 (68.1)
Median	-15.0	-4.3	-8.7
Min ; Max	-356.2 ; 165.6	-157.4 ; 147.3	-356.2 ; 165.6

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Breakfast, Change(mg/dL)			
Visit 14 (Week 12)			
N	52	57	109
Mean (SD)	-19.9 (142.9)	2.3 (131.8)	-8.3 (137.0)
Median	-2.7	-7.2	-3.6
Min ; Max	-383.0 ; 327.9	-358.0 ; 391.0	-383.0 ; 391.0
Visit 18 (Week 16)			
N	57	55	112
Mean (SD)	-25.0 (104.4)	9.4 (128.2)	-8.1 (117.4)
Median	-16.0	-1.0	-13.5
Min ; Max	-232.0 ; 257.0	-261.0 ; 413.0	-261.0 ; 413.0
End of trial visit			
N	69	70	139
Mean (SD)	-25.5 (119.8)	3.9 (121.9)	-10.7 (121.3)
Median	-11.0	0.0	-1.0
Min ; Max	-383.0 ; 327.9	-261.0 ; 413.0	-383.0 ; 413.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Lunch, Change(mg/dL)			
Visit 14 (Week 12)			
N	57	57	114
Mean (SD)	4.5 (117.3)	-4.8 (142.9)	-0.2 (130.2)
Median	-6.0	-14.4	-7.0
Min ; Max	-300.0 ; 289.0	-241.0 ; 425.0	-300.0 ; 425.0
Visit 18 (Week 16)			
N	65	58	123
Mean (SD)	-25.3 (120.5)	-14.3 (130.7)	-20.1 (125.0)
Median	-19.8	-7.1	-18.0
Min ; Max	-300.0 ; 251.0	-288.0 ; 261.0	-300.0 ; 261.0
End of trial visit			
N	74	72	146
Mean (SD)	-22.5 (116.4)	-17.9 (121.9)	-20.2 (118.7)
Median	-16.5	0.0	-9.4
Min ; Max	-300.0 ; 251.0	-288.0 ; 261.0	-300.0 ; 261.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

Prandial increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Main Ev Meal, Change(mg/dL)			
Visit 14 (Week 12)			
N	58	55	113
Mean (SD)	-39.8 (138.7)	14.3 (140.8)	-13.4 (141.8)
Median	-10.8	28.0	-1.8
Min ; Max	-639.6 ; 219.0	-313.5 ; 398.0	-639.6 ; 398.0
Visit 18 (Week 16)			
N	60	54	114
Mean (SD)	-17.5 (112.4)	4.6 (130.2)	-7.0 (121.1)
Median	-16.0	0.5	-14.4
Min ; Max	-281.1 ; 198.0	-383.8 ; 282.9	-383.8 ; 282.9
End of trial visit			
N	72	68	140
Mean (SD)	-23.3 (126.4)	10.2 (131.1)	-7.0 (129.4)
Median	-2.7	0.0	0.0
Min ; Max	-639.6 ; 198.0	-383.8 ; 398.0	-639.6 ; 398.0

N: Number of subjects, SD: Standard deviation, Change: Change from baseline
All meals: Mean of all increments
SMPG: Self measured plasma glucose, Inc.: Increment
Prandial increment is the difference between SMPG values after meal (90 min.) and before meal.

14.2.312 Prandial increment after 16 weeks of treatment - 8-point self measured plasma glucose profile - statistical analysis - full analysis set

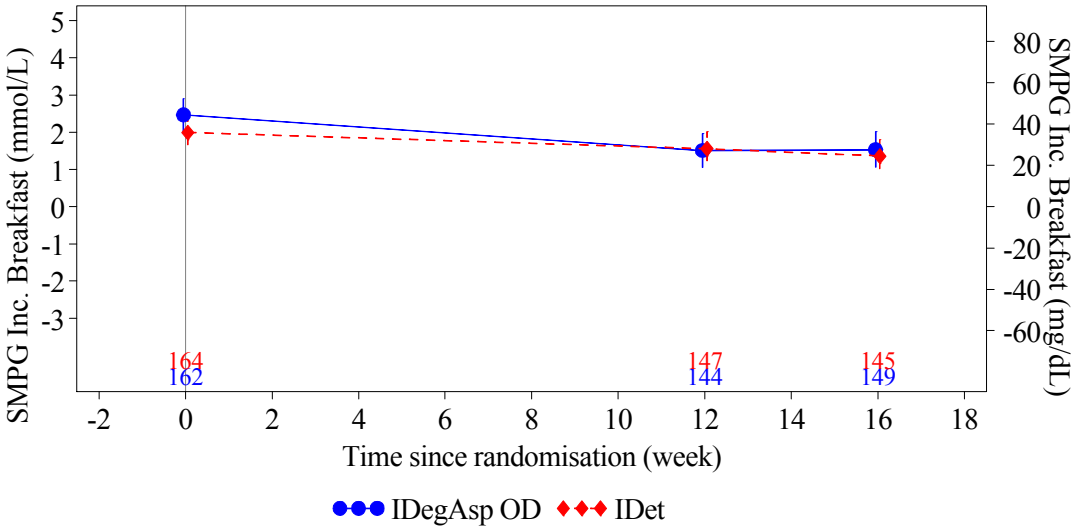
	FAS	N	Estimate	SE	95% CI
All meals (mmol/L)					
LSMeans					
IDegAsp OD	182	149	0.57	0.28	
IDet	180	150	0.42	0.29	
Treatment Contrast					
IDegAsp OD - IDet			0.15		[-0.65; 0.95]
Increment breakfast(mmol/L)					
LSMeans					
IDegAsp OD	182	147	1.33	0.46	
IDet	180	153	1.81	0.47	
Treatment Contrast					
IDegAsp OD - IDet			-0.49		[-1.79; 0.82]
Increment lunch (mmol/L)					
LSMeans					
IDegAsp OD	182	155	-0.21	0.48	
IDet	180	158	-0.38	0.49	
Treatment Contrast					
IDegAsp OD - IDet			0.17		[-1.17; 1.51]
Increment evening meal (mmol/L)					
LSMeans					
IDegAsp OD	182	147	0.03	0.51	
IDet	180	147	-0.16	0.53	
Treatment Contrast					
IDegAsp OD - IDet			0.19		[-1.27; 1.65]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval
SE: Standard error of the mean
All observed prandial measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline increments as covariate. Interactions between visit and all factors and covariates are also included in the model.

Prandial increment after 16 weeks of treatment - 8-point self measured plasma glucose profile - statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
All meals (mg/dL)					
LSMeans					
IDegAsp OD	182	149	10.24	5.07	
IDet	180	150	7.53	5.24	
Treatment Contrast					
IDegAsp OD - IDet			2.70		[-11.73; 17.14]
Increment breakfast (mg/dL)					
LSMeans					
IDegAsp OD	182	147	23.92	8.29	
IDet	180	153	32.66	8.52	
Treatment Contrast					
IDegAsp OD - IDet			-8.74		[-32.21; 14.73]
Increment lunch (mg/dL)					
LSMeans					
IDegAsp OD	182	155	-3.73	8.56	
IDet	180	158	-6.78	8.76	
Treatment Contrast					
IDegAsp OD - IDet			3.05		[-21.15; 27.25]
Increment evening meal (mg/dL)					
LSMeans					
IDegAsp OD	182	147	0.56	9.18	
IDet	180	147	-2.82	9.59	
Treatment Contrast					
IDegAsp OD - IDet			3.38		[-22.88; 29.64]

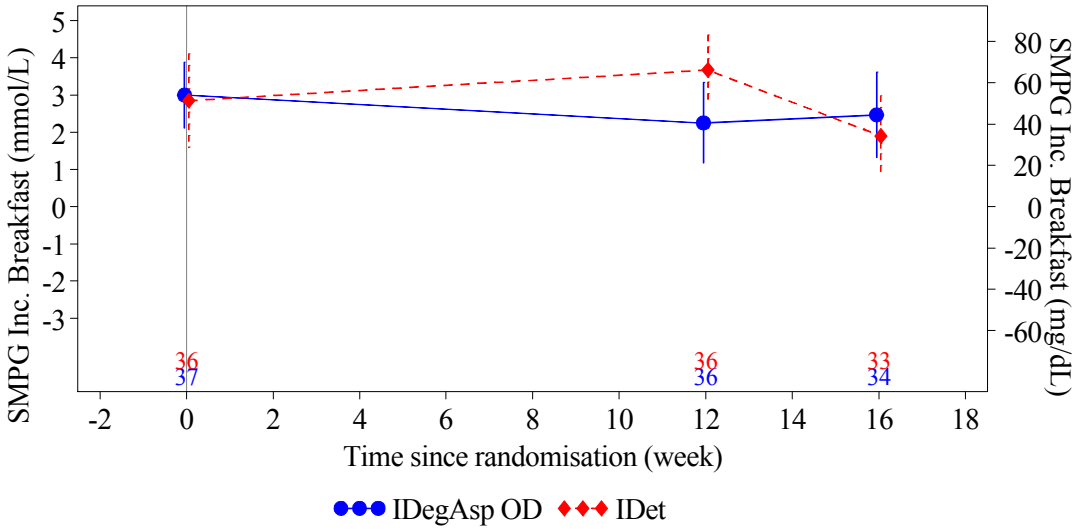
FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval
SE: Standard error of the mean
All observed prandial measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline increments as covariate. Interactions between visit and all factors and covariates are also included in the model.



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:24 - fmean_numfind_deg_cust.sas/e_8pp_ab_bf_inc_mean_ob_fas.cgm

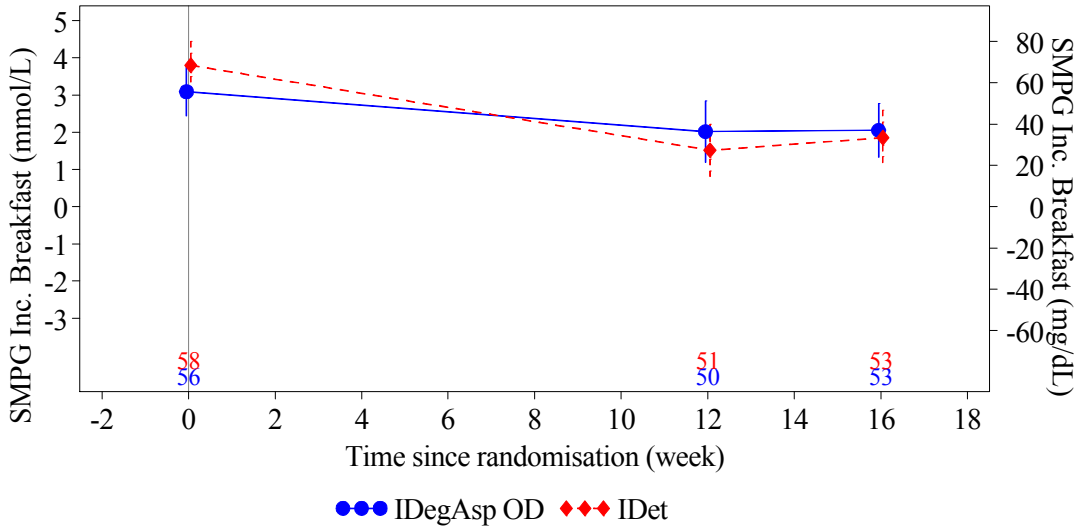
14.2.313 Breakfast increment by treatment week - 8-point self measured plasma glucose profile - mean plot - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:26 - fmean_numfind_deg_cust.sas/e_8pp_ab_bf_inc_mean_ob_age1_fas.cgm

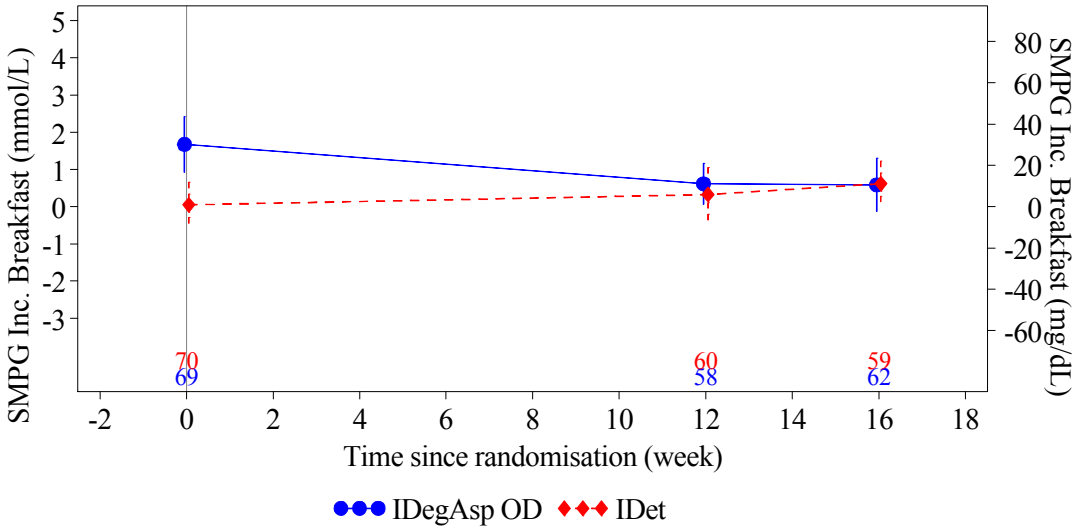
14.2.314 Breakfast increment by treatment week - 8-point self measured plasma glucose profile – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:25 - fmean_numfind_deg_cust.sas/e_8pp_ab_bf_inc_mean_ob_age2_fas.cgm

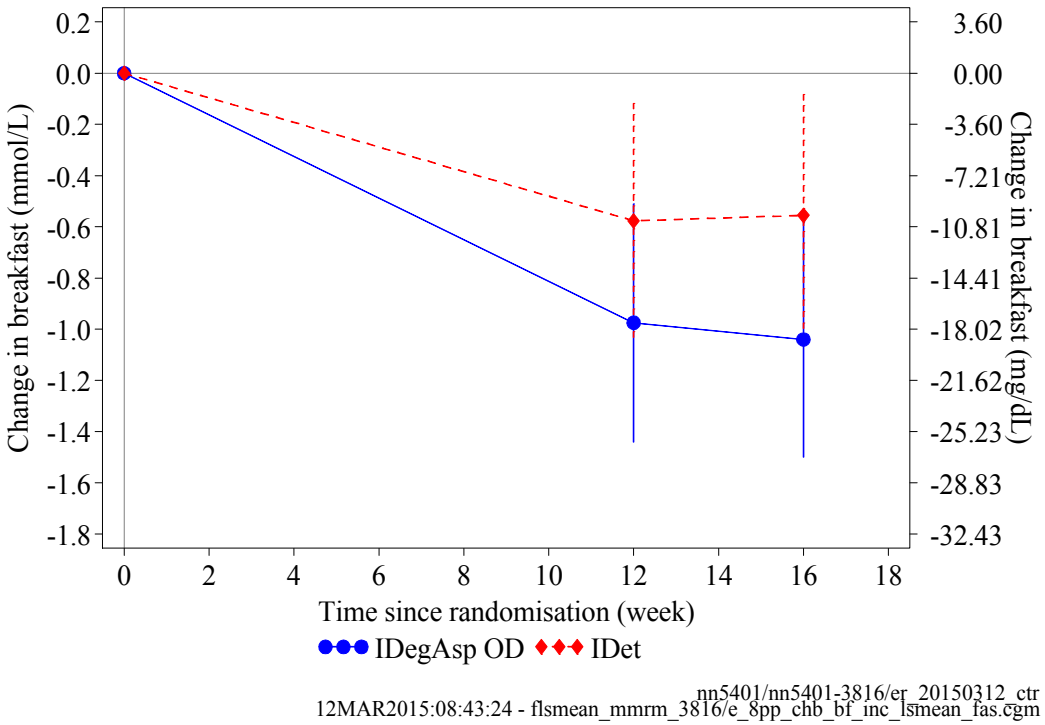
14.2.315 Breakfast increment by treatment week - 8-point self measured plasma glucose profile – mean plot – children (6-11 years) - full analysis set



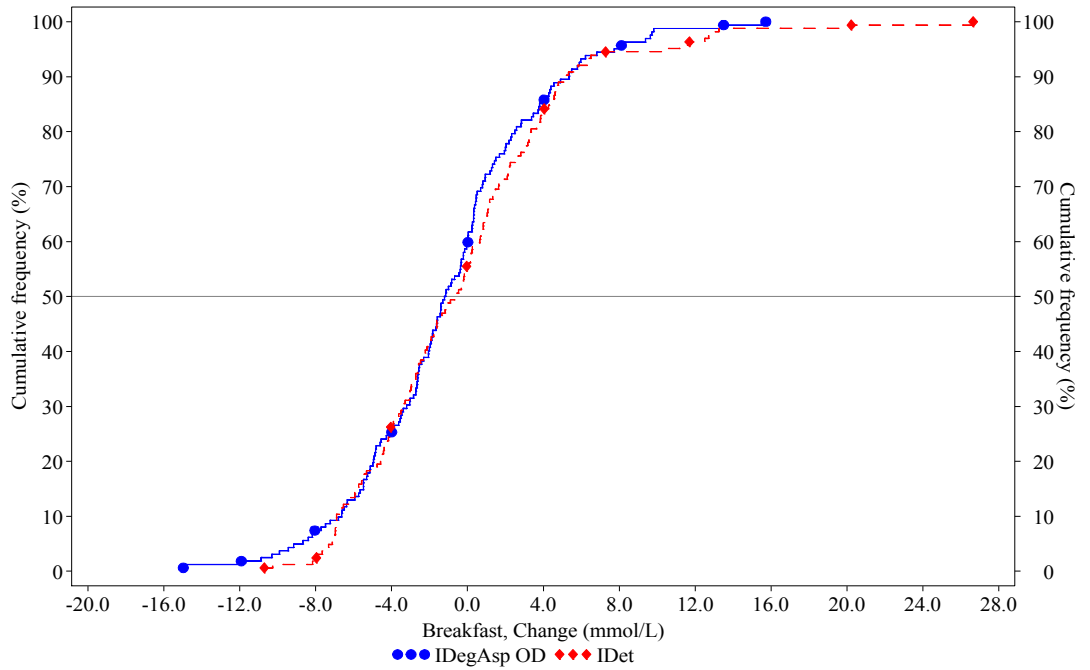
FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:27 - fmean_numfind_deg_cust.sas/e_8pp_ab_bf_inc_mean_ob_age3_fas.cgm

14.2.316 Breakfast increment by treatment week - 8-point self measured plasma glucose profile – mean plot – adolescents (12-17 years) - full analysis set



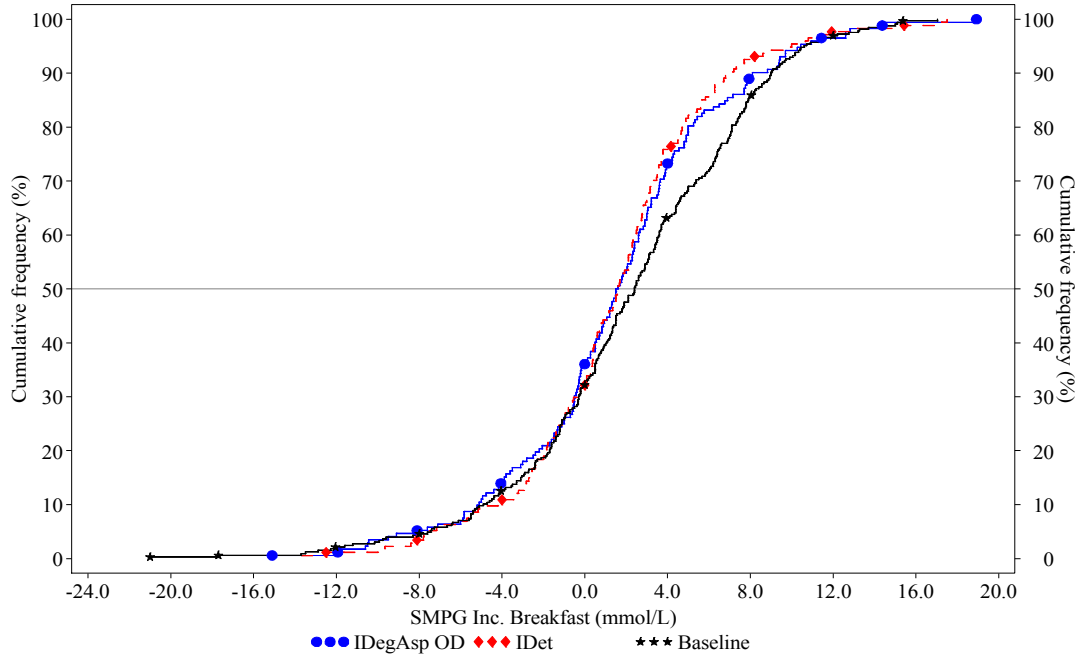
14.2.317 Breakfast increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - lsmean plot - full analysis set



FAS; Observed data
For all subjects predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:33 - fedist_numfind_v01.sas/e_8pp_chb_bf_mc_cdf_pred_fas.cgm

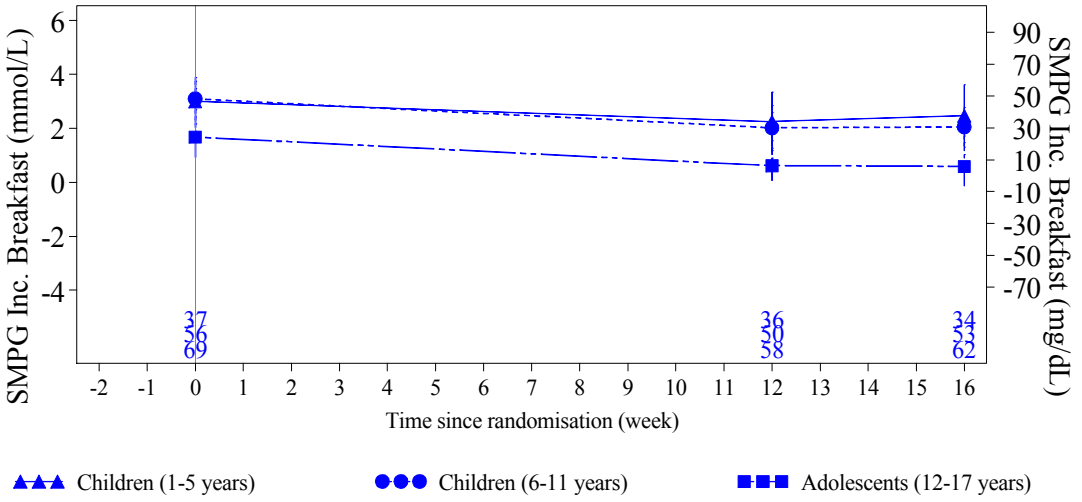
14.2.318 Breakfast increment after 16 weeks of treatment - change from baseline - 8-point self measured plasma glucose profile (mmol/L) - empirical distribution plot - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For subjects without a measurement at week 16, the predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:36 - fedist_numfind_v01.sas/e_8pp_abs_bf_inc_cdf_pred_fas.cgm

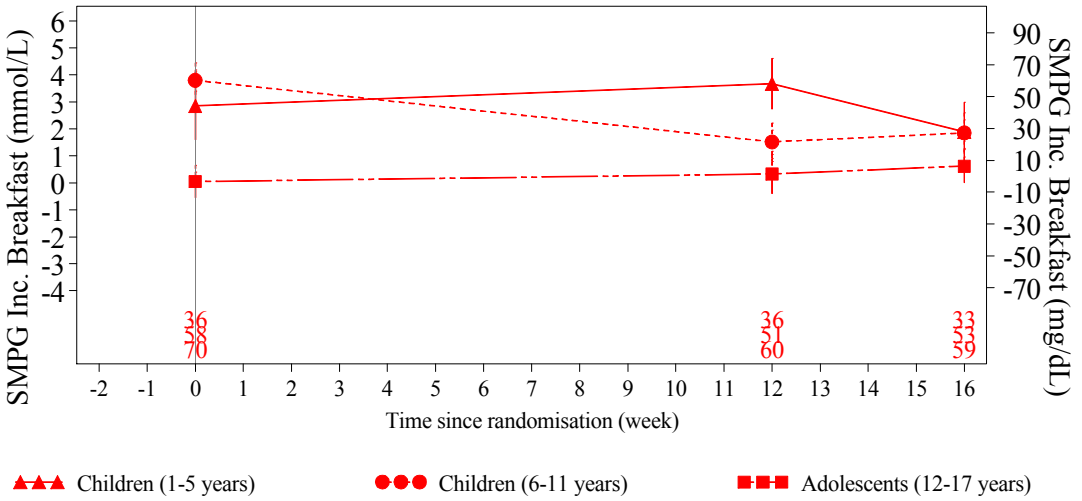
14.2.319 Breakfast increment after 16 weeks of treatment - 8-point self measured plasma glucose profile (mmol/L) - empirical distribution plot - full analysis set



SMPG: Self-measured plasma glucose, Inc.: Increment, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:39 - smpg_mean_inc_fplot_treatment_age.sas/e_smpg_mean_inc_b_ideg_fas.cgm

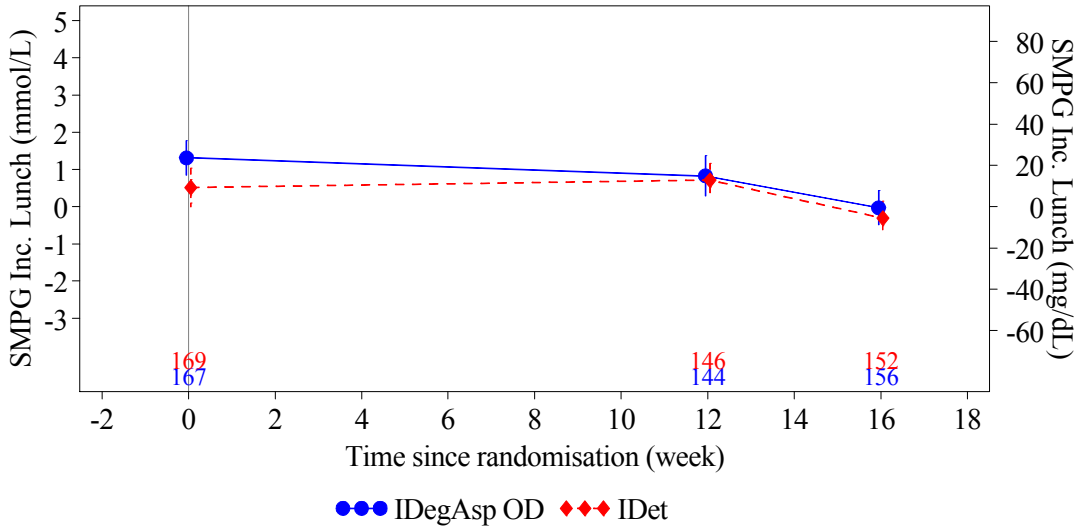
14.2.320 Breakfast increment by treatment week - 8-point self measured plasma glucose profile - mean plot – IDegAsp OD - by age group - full analysis set



SMPG: Self-measured plasma glucose, Inc.: Increment, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:44 - smpg_mean_inc_fplot_treatment_age.sas/e_smpg_mean_inc_b_idet_fas.cgm

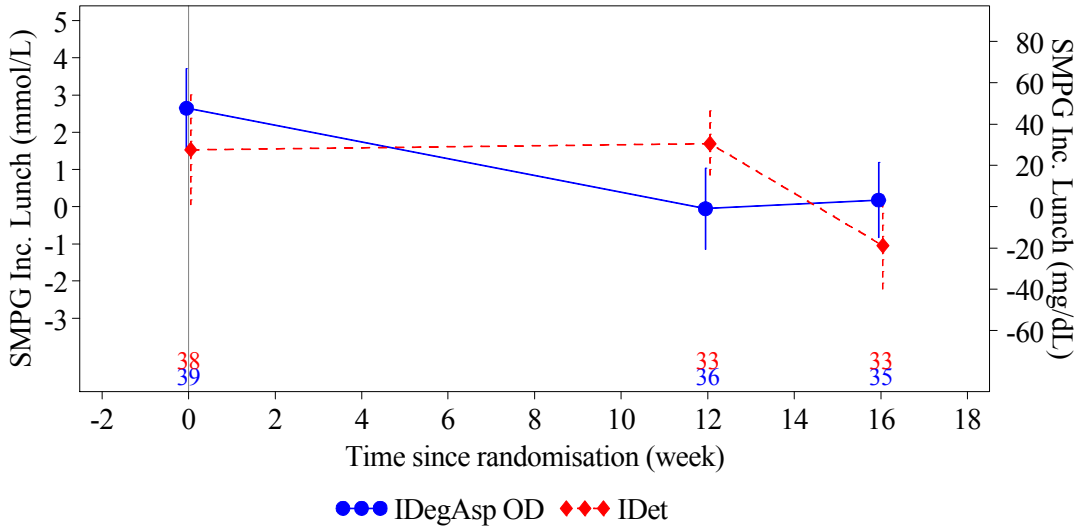
14.2.321 Breakfast increment by treatment week - 8-point self measured plasma glucose profile - mean plot – IDet - by age group - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:33 - fmean_numfind_deg_cust.sas/e_8pp_ab_l_inc_mean_ob_fas.cgm

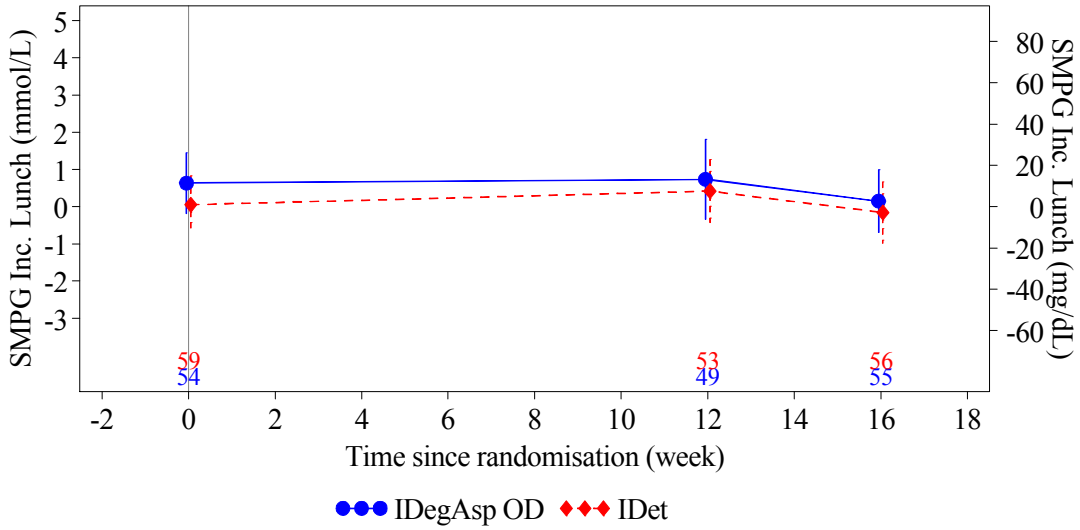
14.2.322 Lunch increment by treatment week - 8-point self measured plasma glucose profile - mean plot - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:32 - fmean_numfind_deg_cust.sas/e_8pp_ab_1_inc_mean_ob_age1_fas.cgm

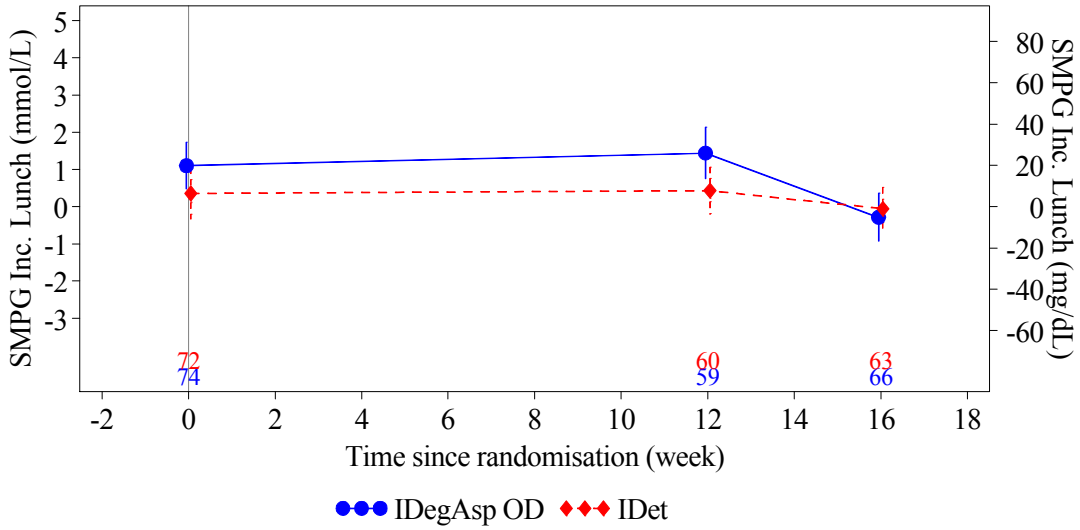
14.2.323 Lunch increment by treatment week - 8-point self measured plasma glucose profile – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:34 - fmean_numfind_deg_cust.sas/e_8pp_ab_1_inc_mean_ob_age2_fas.cgm

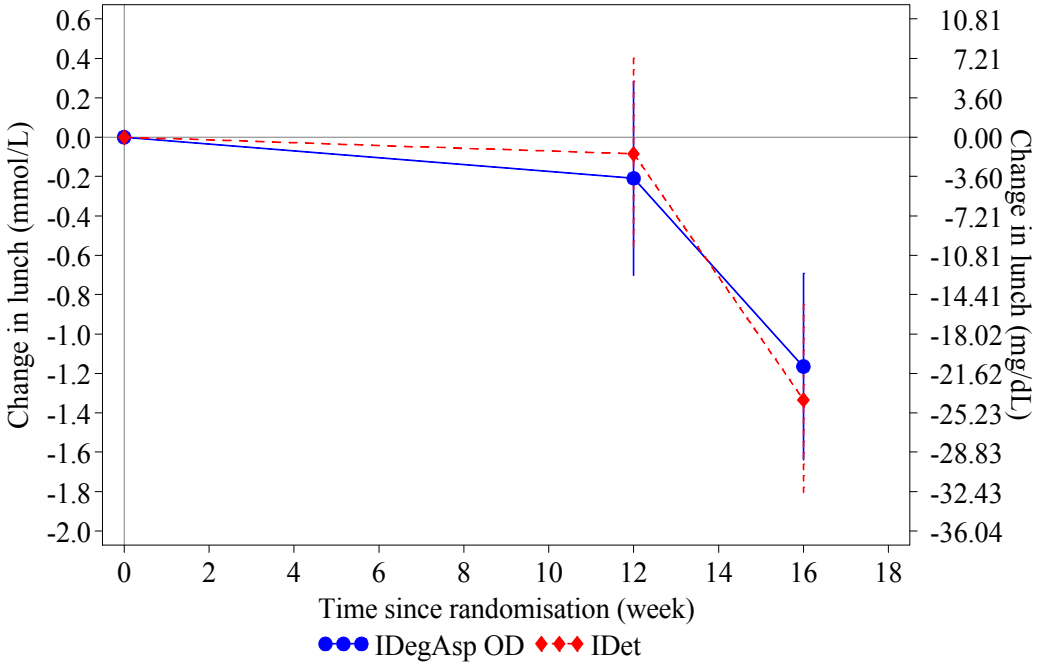
14.2.324 Lunch increment by treatment week - 8-point self measured plasma glucose profile – mean plot – children (6-11 years) - full analysis set



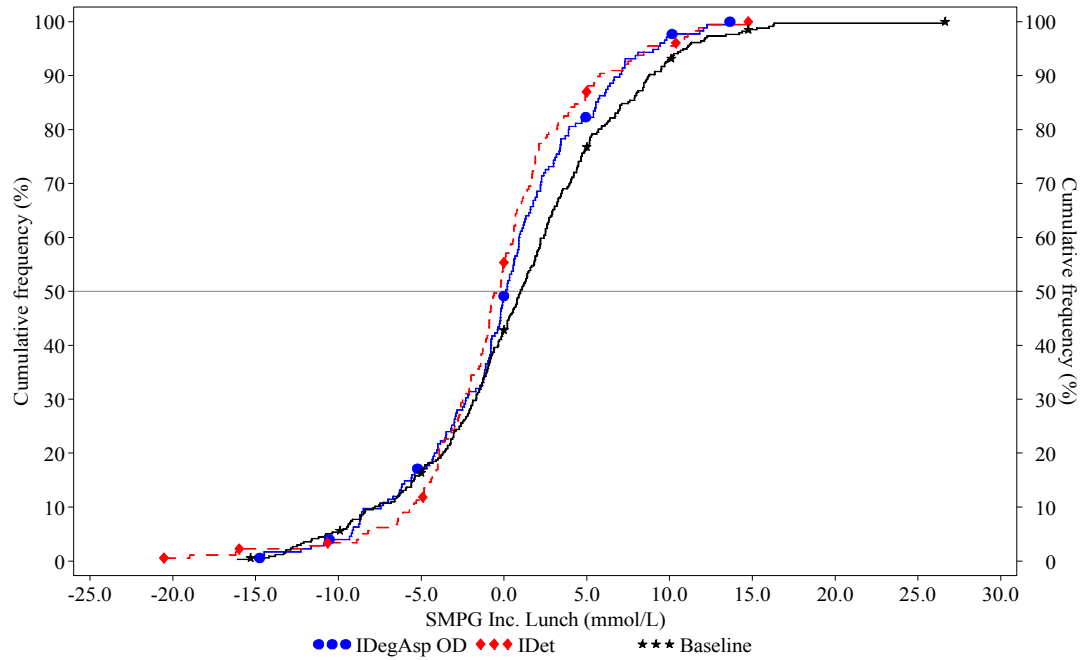
FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:34 - fmean_numfind_deg_cust.sas/e_8pp_ab_1_inc_mean_ob_age3_fas.cgm

14.2.325 Lunch increment by treatment week - 8-point self measured plasma glucose profile – mean plot – adolescents (12-17 years) - full analysis set



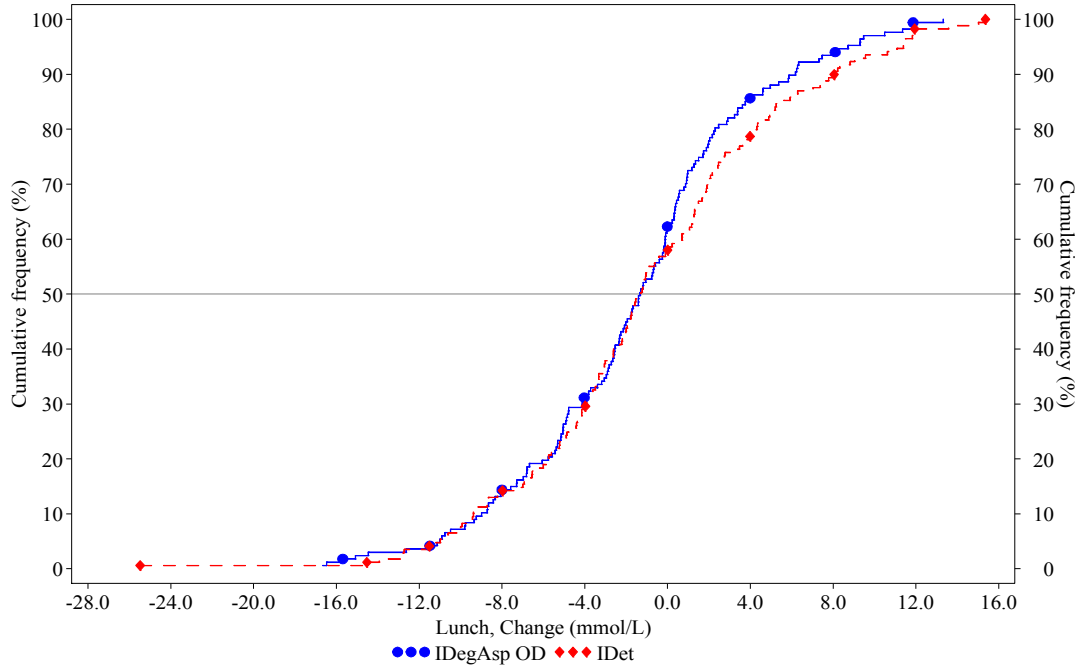
14.2.326 Lunch increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - lsmean plot - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For subjects without a measurement at week 16, the predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:41 - fedist_numfind_v01.sas/e_8pp_abs_1_inc_cdf_pred_fas.cgm

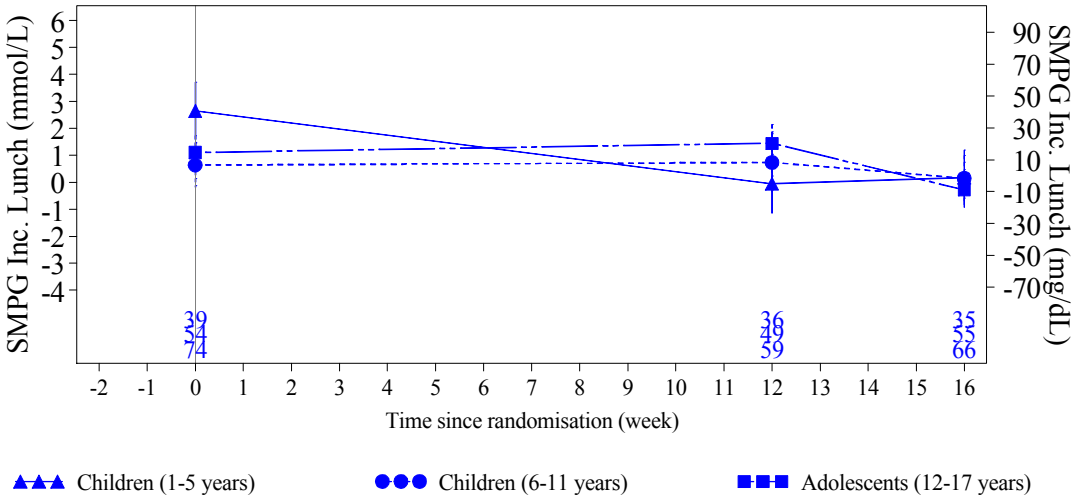
14.2.327 Lunch increment after 16 weeks of treatment - 8-point self measured plasma glucose profile (mmol/L) - empirical distribution plot - full analysis set



FAS; Observed data
For all subjects predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:42 - fedist_numfind_v01.sas/e_8pp_chb_l_inc_cdf_pred_fas.cgm

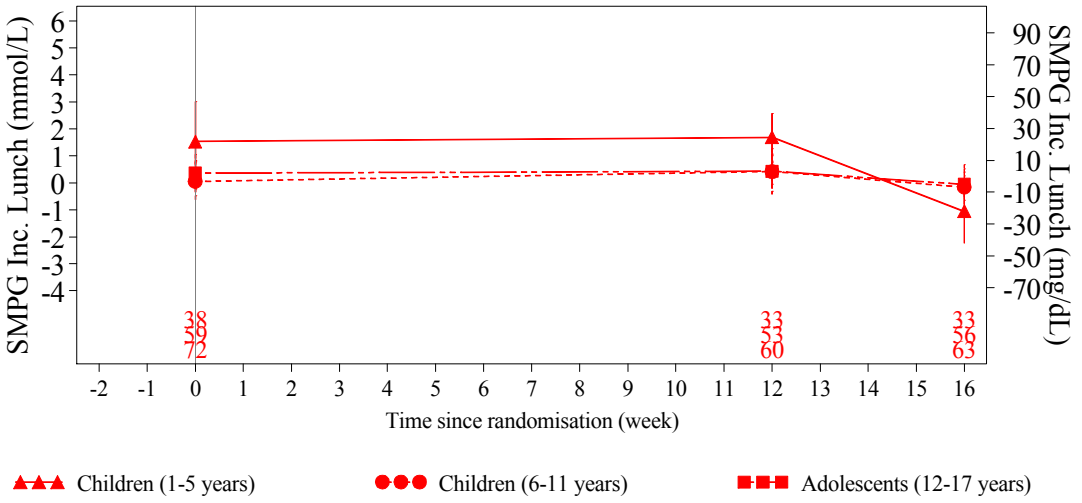
14.2.328 Lunch increment after 16 weeks of treatment - change from baseline - 8-point self measured plasma glucose profile (mmol/L) - empirical distribution plot - full analysis set



SMPG: Self-measured plasma glucose, Inc.: Increment, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:49 - smpg_mean_inc_fplot_treatment_age.sas/e_smpg_mean_inc_t_ideg_fas.cgm

14.2.329 Lunch increment by treatment week - 8-point self measured plasma glucose profile - mean plot – IDegAsp OD -by age group - full analysis set

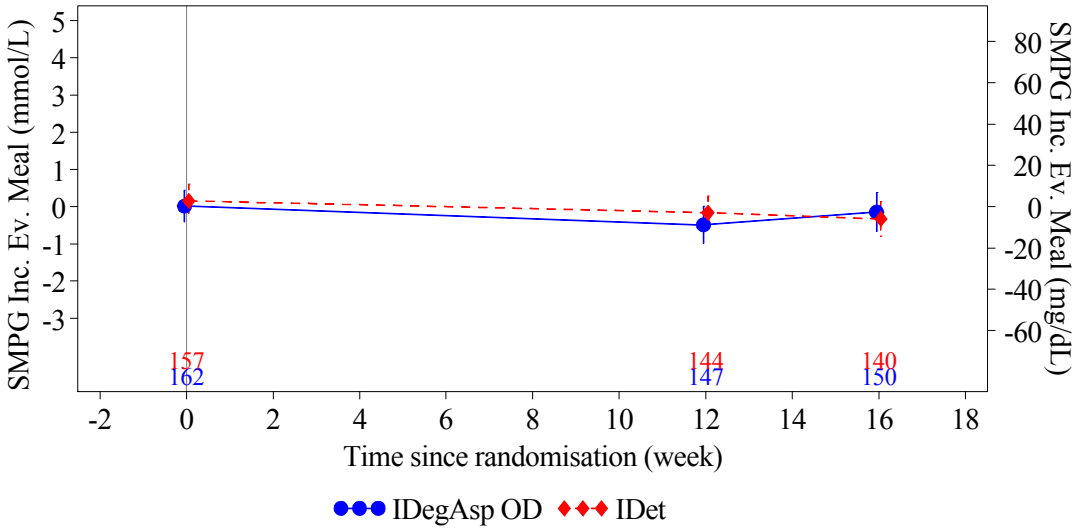


▲▲▲ Children (1-5 years) ●●● Children (6-11 years) ■■■ Adolescents (12-17 years)

SMPG: Self-measured plasma glucose, Inc.: Increment, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:54 - smpg_mean_inc_fplot_treatment_age.sas/e_smpg_mean_inc_1_idet_fas.cgm

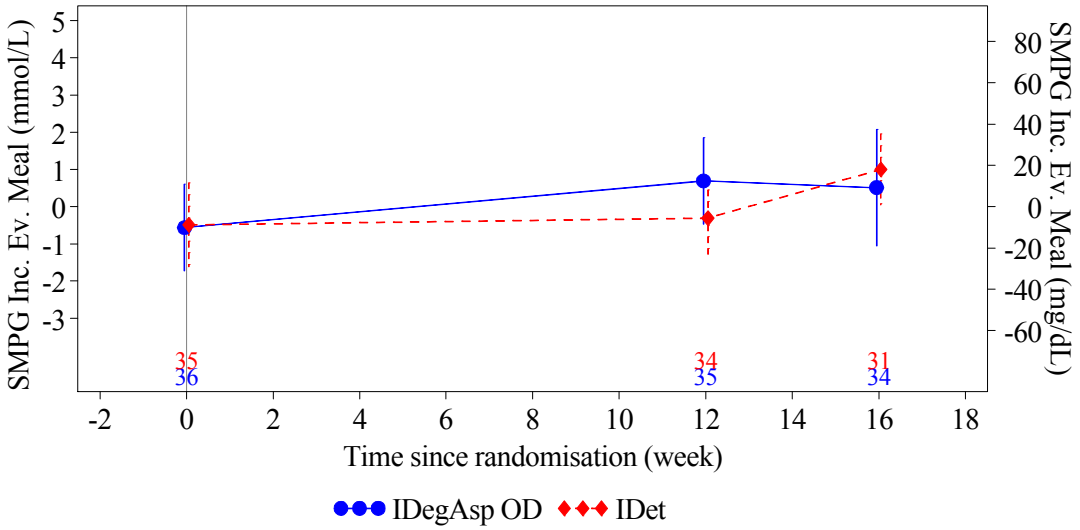
14.2.330 Lunch increment by treatment week - 8-point self measured plasma glucose profile - mean plot – IDet - by age group - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment, Ev.: Evening
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:40 - fmean_numfind_deg_cust.sas/e_8pp_ab_ev_inc_mean_ob_fas.cgm

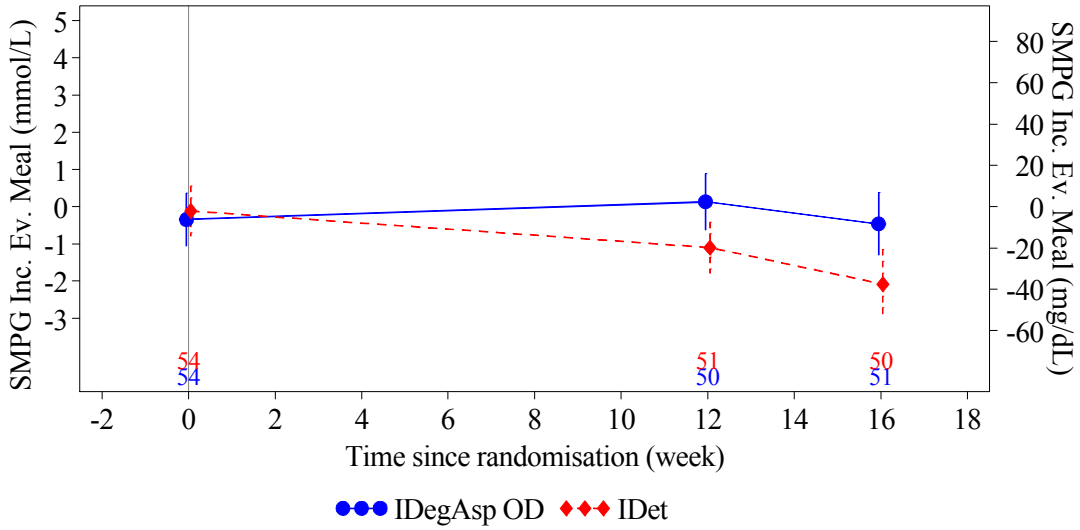
14.2.331 Main evening meal increment by treatment week - 8-point self measured plasma glucose profile - mean plot - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment, Ev.: Evening
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:41 - fmean_numfind_deg_cust.sas/e_8pp_ab_ev_inc_mean_ob_age1_fas.cgm

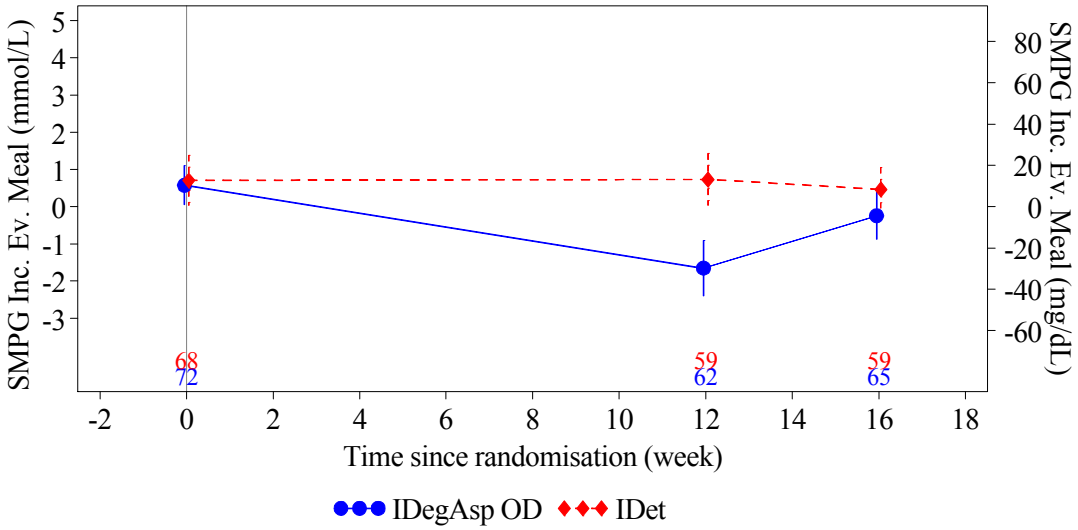
14.2.332 Main evening meal increment by treatment week - 8-point self measured plasma glucose profile – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment, Ev.: Evening
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:41 - fmean_numfind_deg_cust.sas/e_8pp_ab_ev_inc_mean_ob_age2_fas.cgm

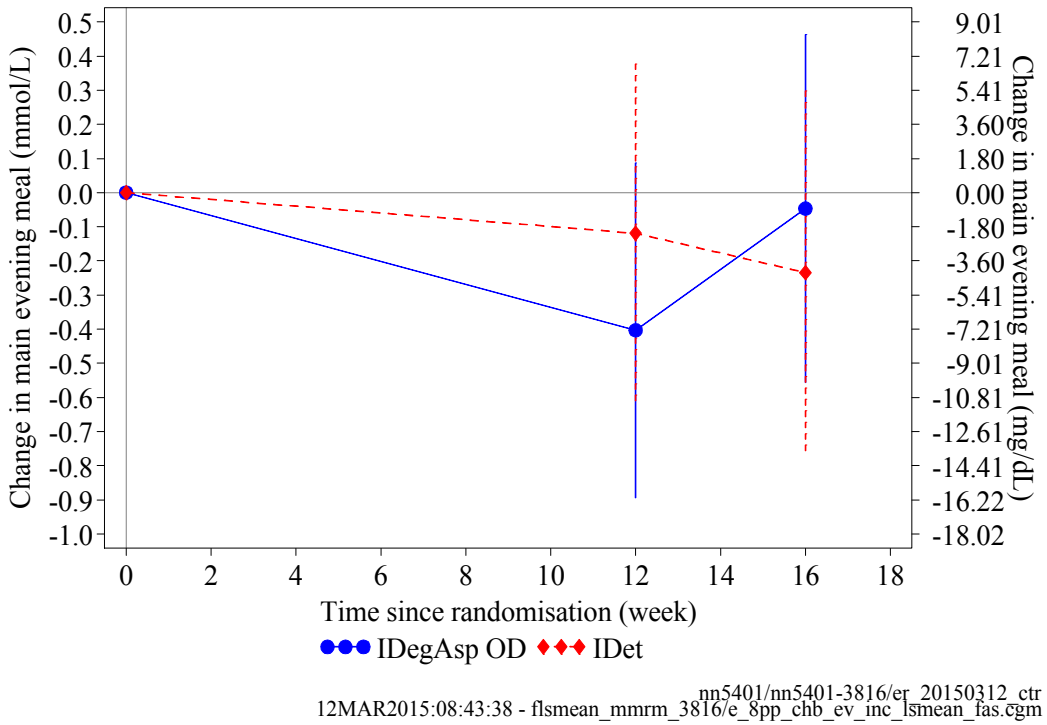
14.2.333 Main evening meal increment by treatment week - 8-point self measured plasma glucose profile – mean plot – children (6-11 years) - full analysis set



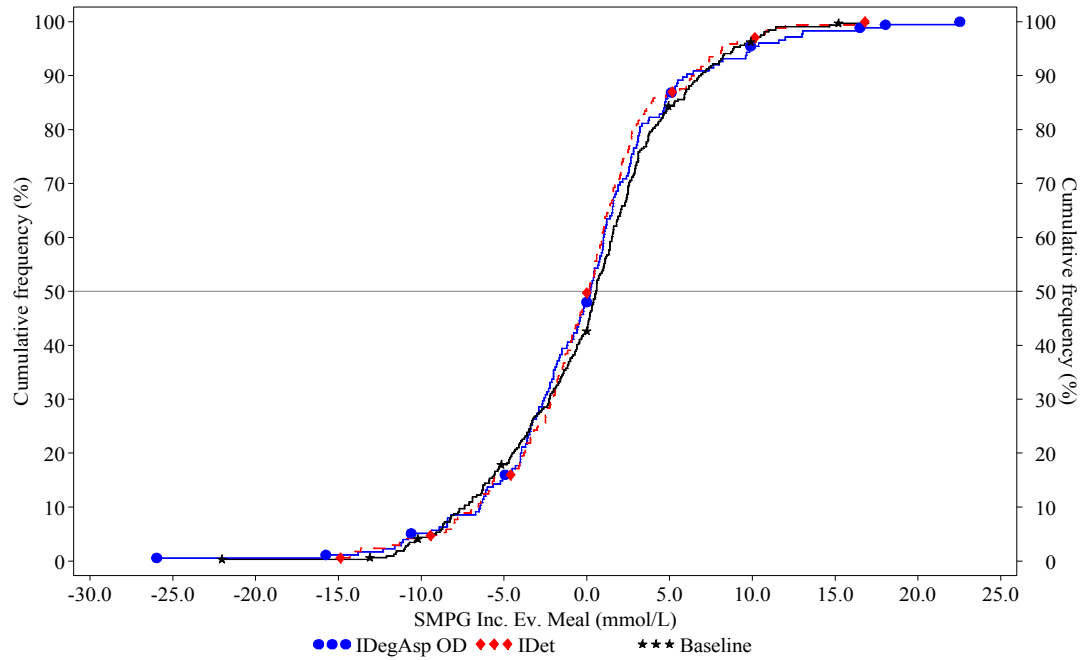
FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment, Ev.: Evening
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:41 - fmean_numfind_deg_cust.sas/e_8pp_ab_ev_inc_mean_ob_age3_fas.cgm

14.2.334 Main evening meal increment by treatment week - 8-point self measured plasma glucose profile – mean plot – adolescents (12-17 years) - full analysis set



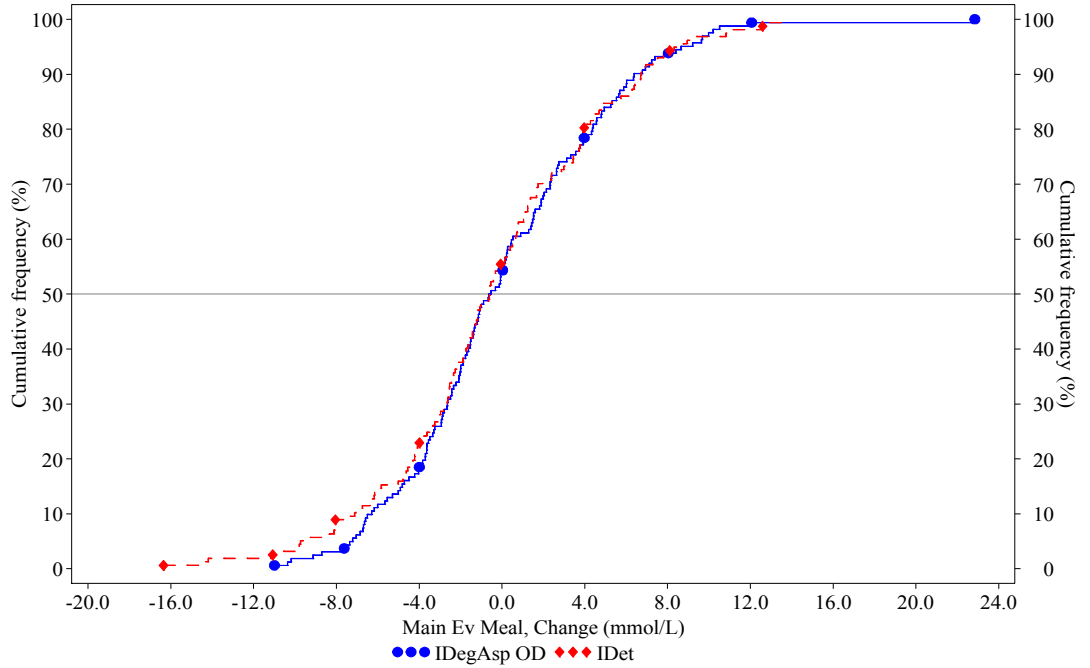
14.2.335 Main evening meal increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - lsmean plot - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For subjects without a measurement at week 16, the predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:48 - fedist_numfind_v01.sas/e_8pp_abs_ev_inc_cdf_pred_fas.cgm

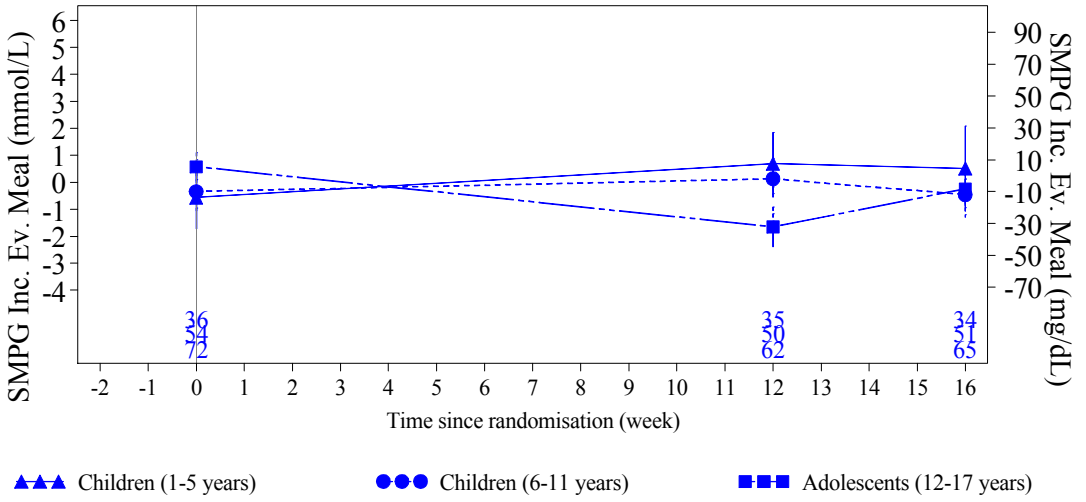
14.2.336 Main evening meal increment after 16 weeks of treatment - 8-point self measured plasma glucose profile (mmol/L) - empirical distribution plot - full analysis set



FAS; Observed data
For all subjects predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:48 - fedist_numfind_v01.sas/e_8pp_chb_ev_inc_cdf_pred_fas.cgm

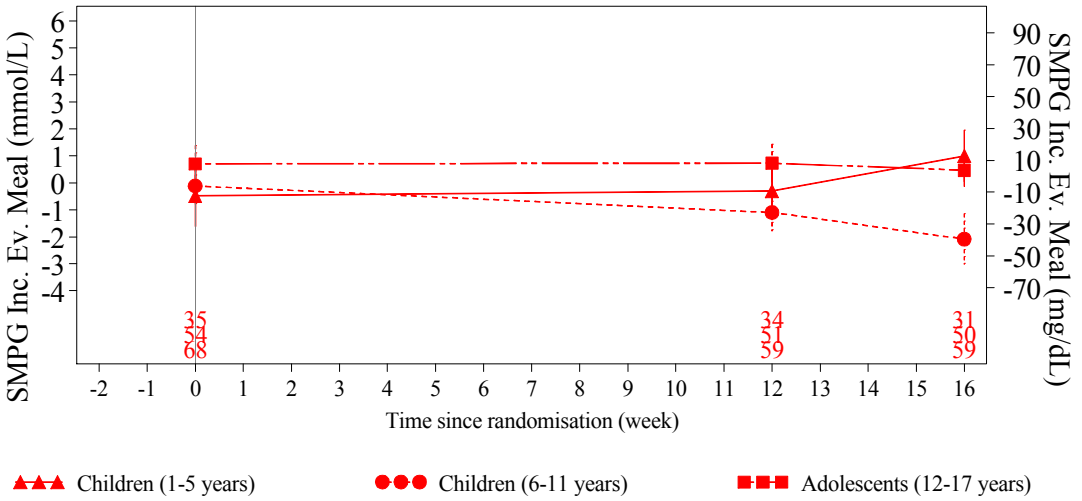
14.2.337 Main evening meal increment after 16 weeks of treatment - change from baseline - 8-point self measured plasma glucose profile (mmol/L) - empirical distribution plot - full analysis set



SMPG: Self-measured plasma glucose, Inc.: Increment, Ev.: Evening
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:58 - smpg_mean_inc_fplot_treatment_age.sas/e_smpg_mean_inc_ev_ideg_fas.cgm

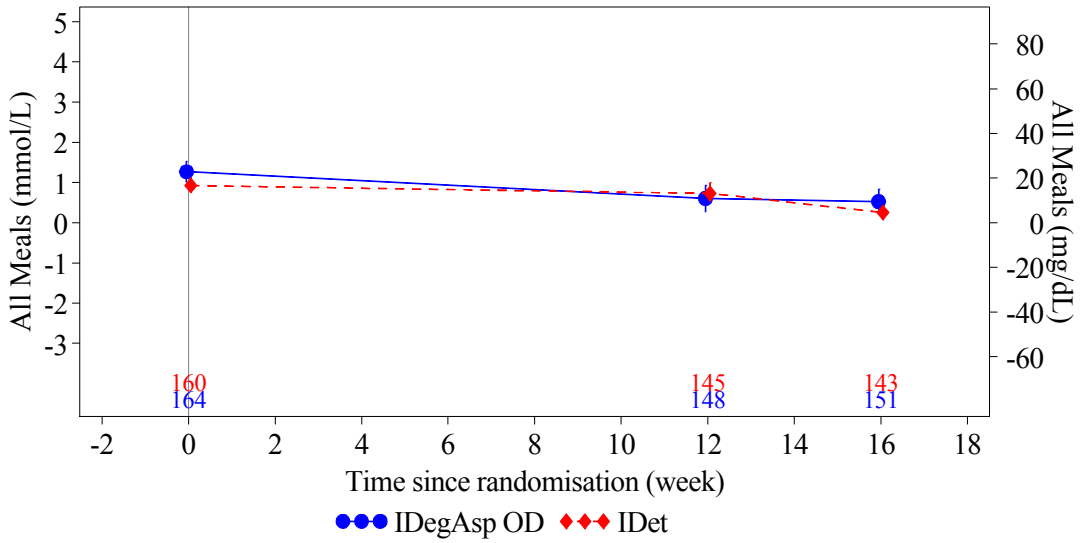
14.2.338 Main evening meal increment by treatment week - 8-point self measured plasma glucose profile - mean plot – IDegAsp OD - by age group - full analysis set



SMPG: Self-measured plasma glucose, Inc.: Increment, Ev.: Evening
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:03 - smpg_mean_inc_fplot_treatment_age.sas/e_smpg_mean_inc_ev_idet_fas.cgm

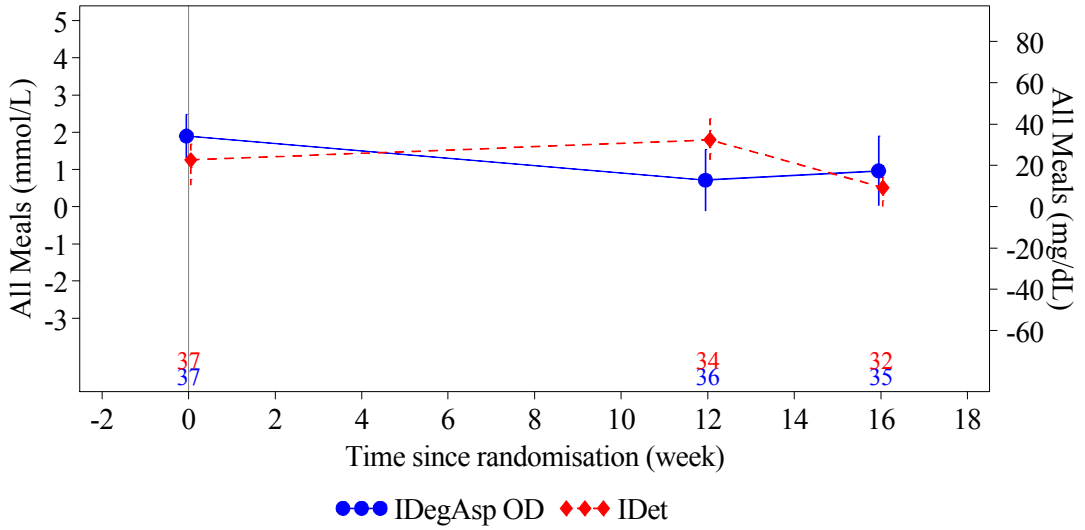
14.2.339 Main evening meal increment by treatment week - 8-point self measured plasma glucose profile - mean plot – IDet - by age group - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:49 - fmean_numfind_deg_cust.sas/e_8pp_ab_pran_ic_mean_ob_fas.cgm

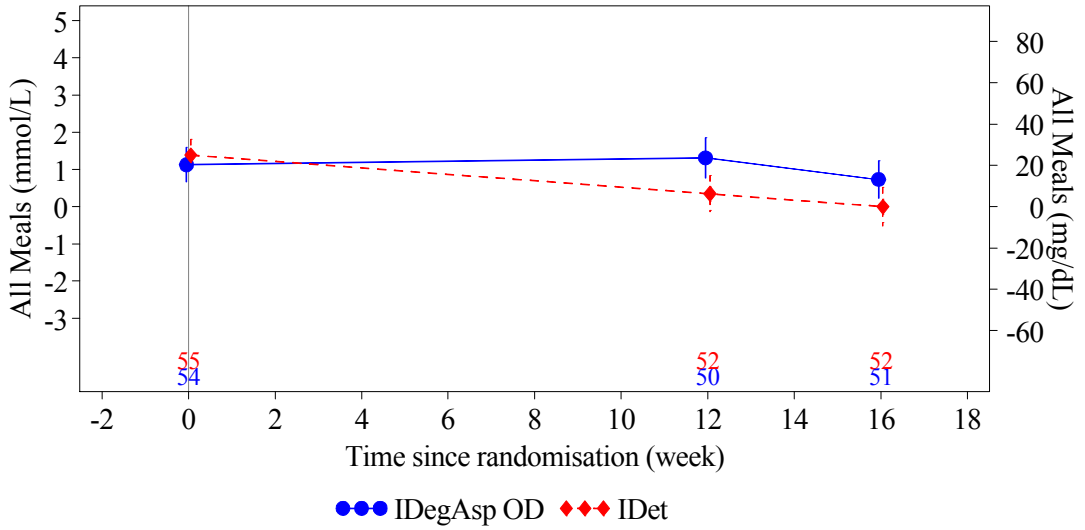
14.2.340 All meals increment by treatment week - 8-point self measured plasma glucose profile - mean plot - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:49 - fmean_numfind_deg_cust.sas/e_8pp_ab_pran_ic_mean_ob_age1_fas.cgm

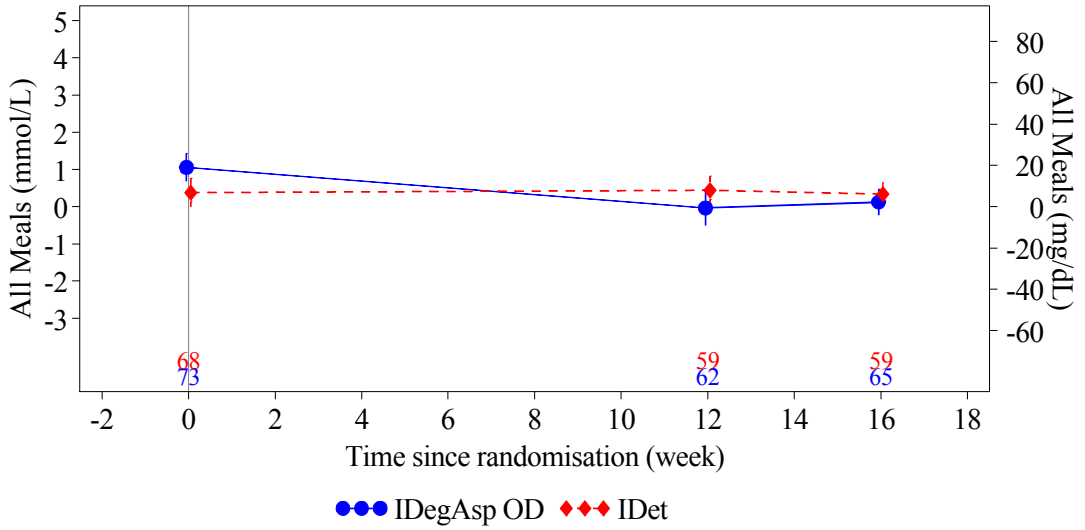
14.2.341 All meals increment by treatment week - 8-point self measured plasma glucose profile – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:49 - fmean_numfind_deg_cust.sas/e_8pp_ab_pran_ic_mean_ob_age2_fas.cgm

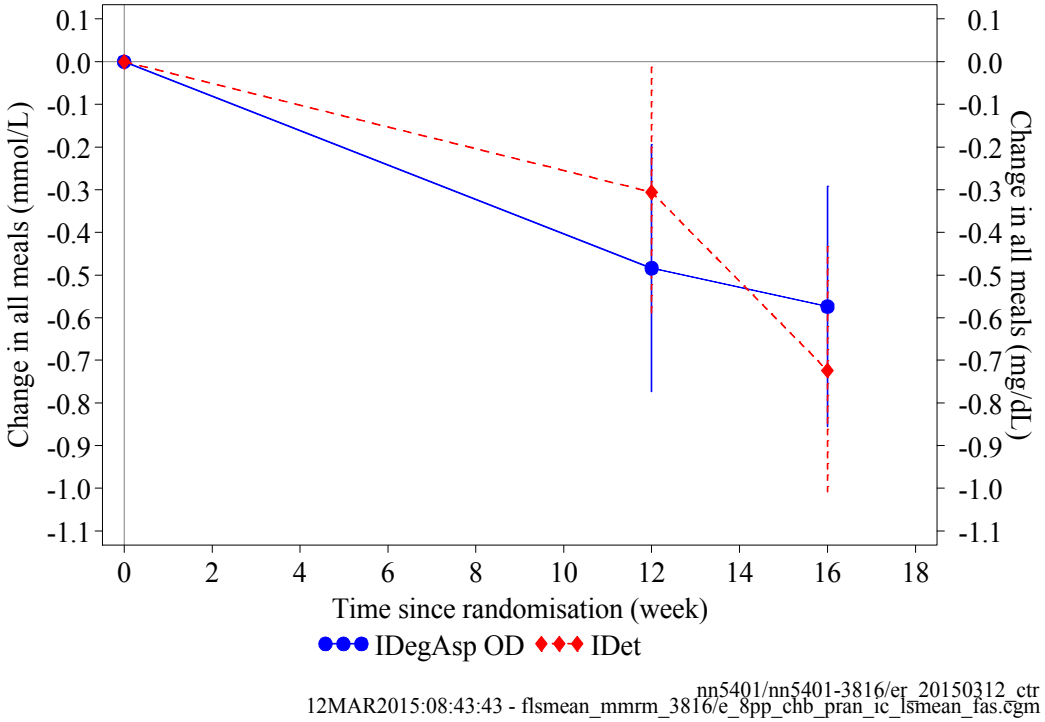
14.2.342 All meals increment by treatment week - 8-point self measured plasma glucose profile – mean plot – children (6-11 years) - full analysis set



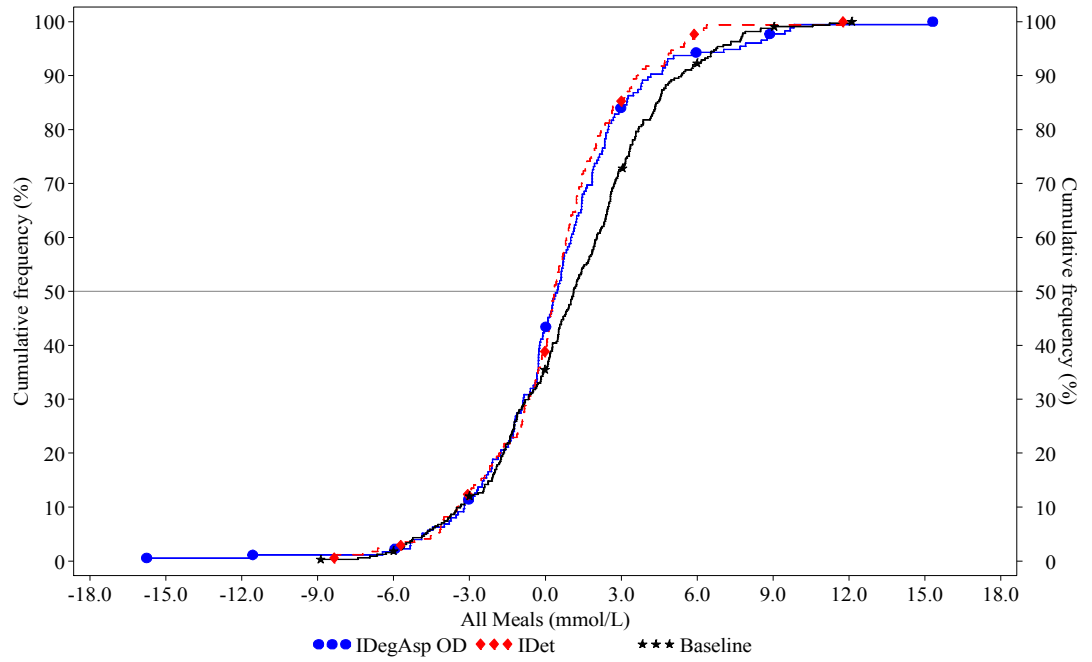
FAS: Observed data
SMPG: Self-measured plasma glucose, Inc.: Increment
Error bars: +- Standard error (mean), FAS: Full analysis set
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:43:49 - fmean_numfind_deg_cust.sas/e_8pp_ab_pran_ic_mean_ob_age3_fas.cgm

14.2.343 All meals increment by treatment week - 8-point self measured plasma glucose profile – mean plot – adolescents (12-17 years) - full analysis set



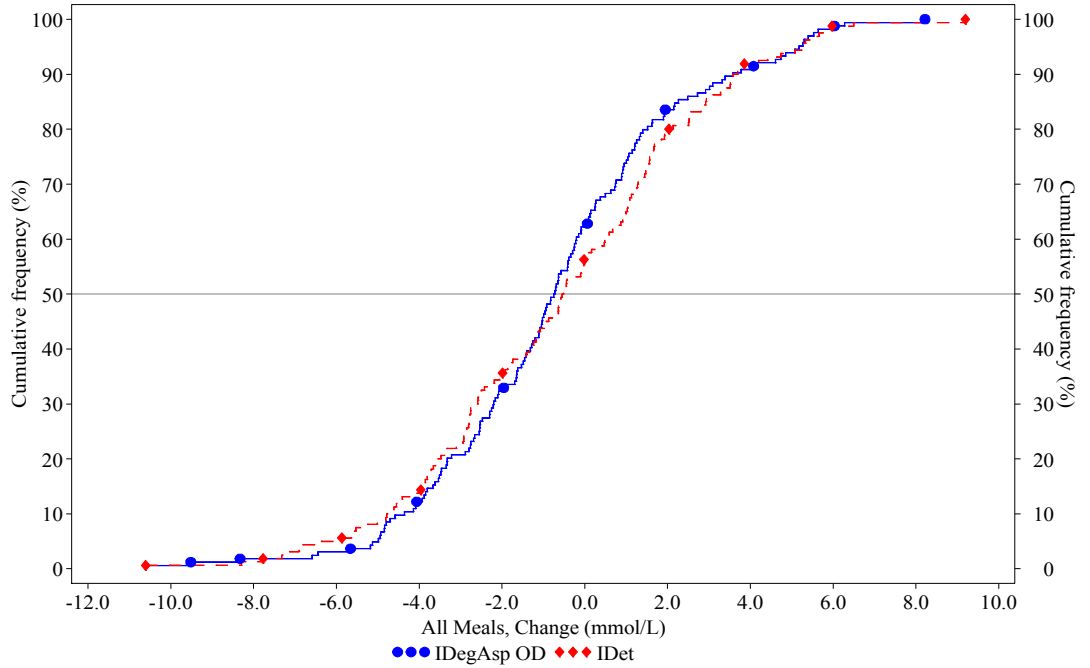
14.2.344 All meals increment by treatment week - change from baseline - 8-point self measured plasma glucose profile - lsmean plot - full analysis set



FAS; Observed data
Baseline is pooled treatment groups.
For subjects without a measurement at week 16, the predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:53 - fedist_numfind_v01.sas/e_8pp_abs_prand_mc_cdf_pred_fas.cgm

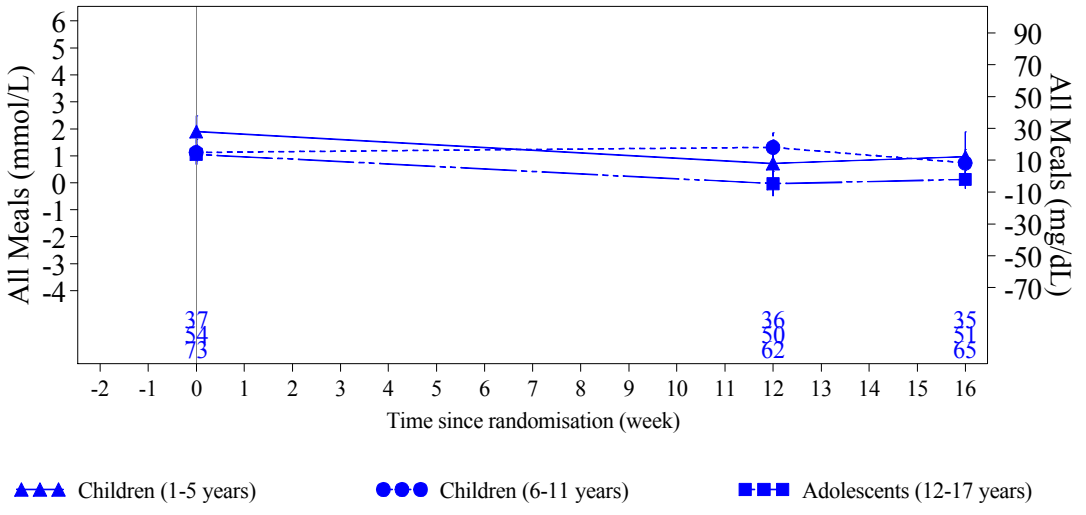
14.2.345 All meals increment after 16 weeks of treatment - 8-point self measured plasma glucose profile (mmol/L) - empirical distribution plot - full analysis set



FAS; Observed data
For all subjects predicted values from MMRM model were used.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:43:53 - fedist_numfind_v01.sas/e_8pp_chb_prand_inc_cdf_pred_fas.cgm

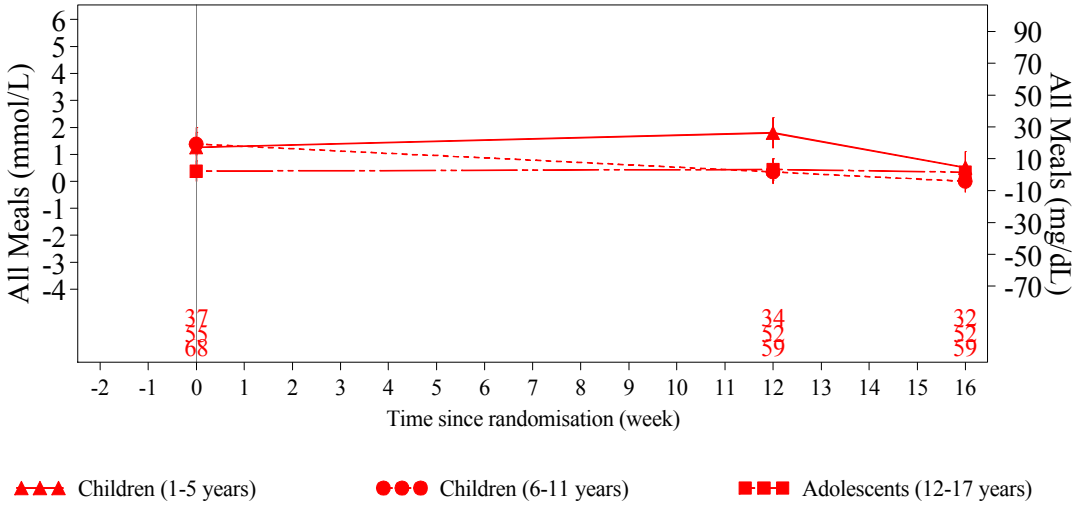
14.2.346 All meals increment after 16 weeks of treatment - change from baseline - 8-point self measured plasma glucose profile (mmol/L) - empirical distribution plot - full analysis set



SMPG: Self-measured plasma glucose, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:08 - smpg_mean_inc_fplot_treatment_age.sas/e_smpg_mean_inc_pran_ideg_fas.cgm

14.2.347 All meals increment by treatment week - 8-point self measured plasma glucose profile - mean plot – IDegAsp OD - by age group - full analysis set



SMPG: Self-measured plasma glucose, FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:12 - smpg_mean_inc_fplot_treatment_age.sas/e_smpg_mean_inc_pran_idet_fas.cgm

14.2.348 All meals increment by treatment week - 8-point self measured plasma glucose profile - mean plot – IDet - by age group - full analysis set

14.2.349 Nocturnal increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
SMPG Increment (Bedtime to Breakfast) (mmol/L)			
Visit 2 (Week 0)			
N	157	157	314
Mean (SD)	0.0 (6.0)	-0.2 (5.8)	-0.1 (5.9)
Median	-0.4	-0.1	-0.2
Min ; Max	-16.6 ; 16.5	-17.9 ; 14.6	-17.9 ; 16.5
Visit 14 (Week 12)			
N	164	151	315
Mean (SD)	-1.3 (5.8)	-0.4 (5.6)	-0.9 (5.7)
Median	-0.8	-0.8	-0.8
Min ; Max	-15.3 ; 18.1	-15.8 ; 17.5	-15.8 ; 18.1
Visit 18 (Week 16)			
N	160	149	309
Mean (SD)	-0.6 (6.5)	-1.2 (5.8)	-0.9 (6.1)
Median	-0.6	-0.6	-0.6
Min ; Max	-30.5 ; 22.1	-18.3 ; 12.7	-30.5 ; 22.1
End of trial visit			
N	180	177	357
Mean (SD)	-0.7 (6.6)	-0.6 (6.4)	-0.7 (6.5)
Median	-0.6	-0.5	-0.6
Min ; Max	-30.5 ; 22.1	-18.3 ; 18.5	-30.5 ; 22.1

N: Number of subjects, SD: Standard deviation

Nocturnal increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
SMPG Increment (Bedtime to Breakfast) (mg/dL)			
Visit 2 (Week 0)			
N	157	157	314
Mean (SD)	0.8 (107.5)	-3.6 (104.4)	-1.4 (105.8)
Median	-7.2	-1.0	-3.6
Min ; Max	-300 ; 298.0	-322 ; 263.0	-322 ; 298.0
Visit 14 (Week 12)			
N	164	151	315
Mean (SD)	-23.8 (104.4)	-6.4 (101.1)	-15.4 (103.1)
Median	-14.0	-15.0	-15.0
Min ; Max	-275 ; 326.0	-285 ; 315.0	-285 ; 326.0
Visit 18 (Week 16)			
N	160	149	309
Mean (SD)	-10.4 (116.6)	-21.6 (104.1)	-15.8 (110.7)
Median	-11.0	-10.8	-11.0
Min ; Max	-550 ; 398.0	-330 ; 228.8	-550 ; 398.0
End of trial visit			
N	180	177	357
Mean (SD)	-12.4 (119.4)	-11.5 (116.0)	-12.0 (117.6)
Median	-11.0	-9.0	-10.8
Min ; Max	-550 ; 398.0	-330 ; 333.3	-550 ; 398.0

N: Number of subjects, SD: Standard deviation

14.2.350 Nocturnal increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
SMPG Increment (Bedtime to Breakfast) (mmol/L)			
Visit 2 (Week 0)			
N	35	35	70
Mean (SD)	-0.6 (6.7)	-0.1 (6.8)	-0.3 (6.7)
Median	-1.2	0.5	0.0
Min ; Max	-16.6 ; 16.5	-17.9 ; 12.7	-17.9 ; 16.5
Visit 14 (Week 12)			
N	35	34	69
Mean (SD)	-1.6 (5.9)	-1.3 (6.3)	-1.4 (6.1)
Median	-0.9	-1.4	-1.1
Min ; Max	-13.6 ; 11.6	-15.8 ; 10.2	-15.8 ; 11.6
Visit 18 (Week 16)			
N	33	35	68
Mean (SD)	-1.1 (5.9)	-1.0 (6.6)	-1.0 (6.2)
Median	-0.2	-0.5	-0.5
Min ; Max	-16.0 ; 12.1	-18.3 ; 12.7	-18.3 ; 12.7
End of trial visit			
N	40	41	81
Mean (SD)	-1.0 (6.0)	-0.6 (6.4)	-0.8 (6.1)
Median	-0.1	-0.5	-0.4
Min ; Max	-16.0 ; 12.1	-18.3 ; 12.7	-18.3 ; 12.7

N: Number of subjects, SD: Standard deviation

Nocturnal increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics – children (1-5 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Increment (Bedtime to Breakfast) (mg/dL)			
Visit 2 (Week 0)			
N	35	35	70
Mean (SD)	-10.1 (120.9)	-1.4 (122.4)	-5.7 (120.8)
Median	-21.0	9.0	0.5
Min ; Max	-300 ; 298.0	-322 ; 228.0	-322 ; 298.0
Visit 14 (Week 12)			
N	35	34	69
Mean (SD)	-28.2 (106.0)	-23.8 (113.6)	-26.0 (109.0)
Median	-16.2	-25.2	-20.0
Min ; Max	-245 ; 209.0	-285 ; 183.8	-285 ; 209.0
Visit 18 (Week 16)			
N	33	35	68
Mean (SD)	-19.3 (105.4)	-17.2 (118.6)	-18.2 (111.5)
Median	-4.0	-9.0	-9.0
Min ; Max	-288 ; 218.0	-330 ; 228.8	-330 ; 228.8
End of trial visit			
N	40	41	81
Mean (SD)	-17.8 (107.3)	-10.6 (114.5)	-14.2 (110.4)
Median	-2.0	-9.0	-7.0
Min ; Max	-288 ; 218.0	-330 ; 228.8	-330 ; 228.8

N: Number of subjects, SD: Standard deviation

14.2.351 Nocturnal increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
SMPG Increment (Bedtime to Breakfast) (mmol/L)			
Visit 2 (Week 0)			
N	51	57	108
Mean (SD)	0.6 (6.2)	0.1 (6.4)	0.3 (6.2)
Median	-0.3	0.3	-0.1
Min ; Max	-14.1 ; 16.1	-15.4 ; 14.6	-15.4 ; 16.1
Visit 14 (Week 12)			
N	55	52	107
Mean (SD)	-1.8 (6.9)	-0.1 (5.5)	-1.0 (6.3)
Median	-1.7	-0.4	-1.3
Min ; Max	-15.3 ; 18.1	-10.8 ; 17.5	-15.3 ; 18.1
Visit 18 (Week 16)			
N	58	53	111
Mean (SD)	-1.0 (6.9)	-1.1 (5.7)	-1.1 (6.3)
Median	-0.8	-0.1	-0.5
Min ; Max	-30.5 ; 20.0	-14.3 ; 9.2	-30.5 ; 20.0
End of trial visit			
N	61	60	121
Mean (SD)	-1.3 (6.9)	-0.4 (6.2)	-0.8 (6.6)
Median	-1.3	0.3	-0.2
Min ; Max	-30.5 ; 20.0	-14.3 ; 17.5	-30.5 ; 20.0

N: Number of subjects, SD: Standard deviation

Nocturnal increment by treatment week - 8-point self measured plasma glucose profile - descriptive statistics – children (6-11 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Increment (Bedtime to Breakfast) (mg/dL)			
Visit 2 (Week 0)			
N	51	57	108
Mean (SD)	10.8 (111.1)	1.6 (114.7)	5.9 (112.6)
Median	-5.0	5.4	-1.5
Min ; Max	-254 ; 291.0	-277 ; 263.0	-277 ; 291.0
Visit 14 (Week 12)			
N	55	52	107
Mean (SD)	-33.2 (125.0)	-1.3 (99.7)	-17.7 (114.0)
Median	-30.0	-6.3	-23.4
Min ; Max	-275 ; 326.0	-194 ; 315.0	-275 ; 326.0
Visit 18 (Week 16)			
N	58	53	111
Mean (SD)	-18.3 (124.1)	-20.4 (103.3)	-19.3 (114.2)
Median	-13.7	-1.8	-9.0
Min ; Max	-550 ; 360.4	-258 ; 166.0	-550 ; 360.4
End of trial visit			
N	61	60	121
Mean (SD)	-23.7 (125.0)	-6.7 (111.8)	-15.3 (118.4)
Median	-23.4	6.0	-3.6
Min ; Max	-550 ; 360.4	-258 ; 315.0	-550 ; 360.4

N: Number of subjects, SD: Standard deviation

14.2.352 Nocturnal increment by treatment week – 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
SMPG Increment (Bedtime to Breakfast) (mmol/L)			
Visit 2 (Week 0)			
N	71	65	136
Mean (SD)	-0.1 (5.5)	-0.5 (4.7)	-0.3 (5.1)
Median	-0.1	-0.3	-0.3
Min ; Max	-16.0 ; 14.2	-13.9 ; 12.4	-16.0 ; 14.2
Visit 14 (Week 12)			
N	74	65	139
Mean (SD)	-0.8 (4.8)	-0.1 (5.3)	-0.5 (5.0)
Median	-0.4	-0.8	-0.6
Min ; Max	-11.6 ; 11.8	-14.5 ; 15.9	-14.5 ; 15.9
Visit 18 (Week 16)			
N	69	61	130
Mean (SD)	0.0 (6.4)	-1.4 (5.4)	-0.6 (6.0)
Median	-0.5	-0.8	-0.7
Min ; Max	-15.7 ; 22.1	-16.2 ; 11.1	-16.2 ; 22.1
End of trial visit			
N	79	76	155
Mean (SD)	-0.1 (6.7)	-0.9 (6.7)	-0.5 (6.7)
Median	-0.5	-0.8	-0.6
Min ; Max	-16.0 ; 22.1	-16.2 ; 18.5	-16.2 ; 22.1

N: Number of subjects, SD: Standard deviation

Nocturnal increment by treatment week – 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
SMPG Increment (Bedtime to Breakfast) (mg/dL)			
Visit 2 (Week 0)			
N	71	65	136
Mean (SD)	-0.9 (98.5)	-9.2 (84.0)	-4.9 (91.6)
Median	-1.0	-5.0	-5.0
Min ; Max	-288 ; 255.0	-251 ; 223.0	-288 ; 255.0
Visit 14 (Week 12)			
N	74	65	139
Mean (SD)	-14.7 (86.1)	-1.5 (95.8)	-8.5 (90.7)
Median	-8.1	-14.4	-10.8
Min ; Max	-209 ; 212.6	-261 ; 286.0	-261 ; 286.0
Visit 18 (Week 16)			
N	69	61	130
Mean (SD)	0.5 (115.8)	-25.1 (97.4)	-11.6 (107.9)
Median	-9.0	-15.0	-11.8
Min ; Max	-283 ; 398.0	-292 ; 200.0	-292 ; 398.0
End of trial visit			
N	79	76	155
Mean (SD)	-0.9 (121.3)	-15.8 (121.2)	-8.2 (121.1)
Median	-9.0	-14.7	-11.0
Min ; Max	-288 ; 398.0	-292 ; 333.3	-292 ; 398.0

N: Number of subjects, SD: Standard deviation

14.2.353 Nocturnal increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
Ch. SMPG Increment (Bedtime to Breakfast(mmol/L)			
Visit 14 (Week 12)			
N	145	135	280
Mean (SD)	-1.6 (7.3)	-0.1 (7.9)	-0.9 (7.6)
Median	-1.4	0.3	-0.7
Min ; Max	-20.8 ; 19.0	-22.2 ; 27.7	-22.2 ; 27.7
Visit 18 (Week 16)			
N	139	134	273
Mean (SD)	-0.6 (8.5)	-0.8 (7.5)	-0.7 (8.0)
Median	0.0	-0.8	-0.3
Min ; Max	-42.4 ; 22.8	-25.2 ; 20.4	-42.4 ; 22.8
End of trial visit			
N	157	157	314
Mean (SD)	-0.5 (8.4)	-0.4 (7.8)	-0.4 (8.1)
Median	0.0	-0.4	-0.0
Min ; Max	-42.4 ; 22.8	-25.2 ; 21.9	-42.4 ; 22.8

N: Number of subjects, SD: Standard deviation, Ch.: Change

Nocturnal increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Ch. SMPG Increment (Bedtime to Breakfast(mg/dL)			
Visit 14 (Week 12)			
N	145	135	280
Mean (SD)	-29.2 (131.3)	-1.0 (142.3)	-15.6 (137.2)
Median	-26.0	5.4	-13.5
Min ; Max	-375 ; 342.3	-400 ; 499.1	-400 ; 499.1
Visit 18 (Week 16)			
N	139	134	273
Mean (SD)	-10.3 (152.9)	-14.1 (136.0)	-12.1 (144.5)
Median	0.0	-13.8	-5.4
Min ; Max	-764 ; 410.0	-454 ; 367.6	-764 ; 410.0
End of trial visit			
N	157	157	314
Mean (SD)	-8.7 (151.5)	-7.1 (139.9)	-7.9 (145.6)
Median	0.0	-7.2	-0.5
Min ; Max	-764 ; 410.0	-454 ; 394.0	-764 ; 410.0

N: Number of subjects, SD: Standard deviation, Ch.: Change

14.2.354 Nocturnal increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1 -5 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
Ch. SMPG Increment (Bedtime to Breakfast(mmol/L)			
Visit 14 (Week 12)			
N	31	29	60
Mean (SD)	-1.6 (9.0)	-1.4 (10.5)	-1.5 (9.7)
Median	-1.4	-0.4	-1.1
Min ; Max	-20.0 ; 19.0	-22.2 ; 21.9	-22.2 ; 21.9
Visit 18 (Week 16)			
N	29	30	59
Mean (SD)	0.2 (6.3)	-0.8 (9.0)	-0.3 (7.7)
Median	1.3	0.3	1.2
Min ; Max	-16.9 ; 16.4	-25.2 ; 14.0	-25.2 ; 16.4
End of trial visit			
N	35	35	70
Mean (SD)	0.2 (7.4)	-0.5 (9.4)	-0.2 (8.4)
Median	1.3	0.0	0.3
Min ; Max	-18.3 ; 19.0	-25.2 ; 21.9	-25.2 ; 21.9

N: Number of subjects, SD: Standard deviation, Ch.: Change

Nocturnal increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (1 -5 years) - full analysis set

	IDegAsp OD	IDet	Total
Ch. SMPG Increment (Bedtime to Breakfast(mg/dL)			
Visit 14 (Week 12)			
N	31	29	60
Mean (SD)	-28.1 (162.7)	-24.5 (189.2)	-26.4 (174.5)
Median	-25.0	-7.2	-18.9
Min ; Max	-360 ; 342.3	-400 ; 394.0	-400 ; 394.0
Visit 18 (Week 16)			
N	29	30	59
Mean (SD)	3.0 (112.8)	-14.7 (161.6)	-6.0 (138.8)
Median	23.0	4.5	21.6
Min ; Max	-305 ; 296.0	-454 ; 252.3	-454 ; 296.0
End of trial visit			
N	35	35	70
Mean (SD)	4.4 (133.9)	-9.9 (169.5)	-2.7 (151.8)
Median	23.0	0.0	4.5
Min ; Max	-329 ; 342.3	-454 ; 394.0	-454 ; 394.0

N: Number of subjects, SD: Standard deviation, Ch.: Change

14.2.355 Nocturnal increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6 -11 years) - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Ch. SMPG Increment (Bedtime to Breakfast(mmol/L)			
Visit 14 (Week 12)			
N	47	50	97
Mean (SD)	-2.8 (7.0)	-0.2 (7.9)	-1.4 (7.5)
Median	-2.4	0.6	-1.2
Min ; Max	-20.8 ; 16.3	-16.5 ; 27.7	-20.8 ; 27.7
Visit 18 (Week 16)			
N	48	51	99
Mean (SD)	-1.5 (9.8)	-1.1 (7.8)	-1.3 (8.8)
Median	-0.2	-0.7	-0.4
Min ; Max	-42.4 ; 19.7	-19.5 ; 20.4	-42.4 ; 20.4
End of trial visit			
N	51	57	108
Mean (SD)	-1.6 (9.6)	-1.0 (7.4)	-1.3 (8.5)
Median	-0.3	0.0	-0.1
Min ; Max	-42.4 ; 19.7	-19.5 ; 20.4	-42.4 ; 20.4

N: Number of subjects, SD: Standard deviation, Ch.: Change

Nocturnal increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – children (6 -11 years) - full analysis set

	IDegAsp OD	IDet	Total
Ch. SMPG Increment (Bedtime to Breakfast(mg/dL)			
Visit 14 (Week 12)			
N	47	50	97
Mean (SD)	-50.4 (126.0)	-3.0 (141.7)	-25.9 (135.7)
Median	-43.2	10.8	-21.6
Min ; Max	-375 ; 293.7	-298 ; 499.1	-375 ; 499.1
Visit 18 (Week 16)			
N	48	51	99
Mean (SD)	-26.4 (176.5)	-19.9 (141.4)	-23.0 (158.6)
Median	-3.7	-12.6	-8.0
Min ; Max	-764 ; 355.0	-351 ; 367.6	-764 ; 367.6
End of trial visit			
N	51	57	108
Mean (SD)	-29.0 (172.1)	-17.2 (133.9)	-22.7 (152.5)
Median	-5.4	0.0	-1.9
Min ; Max	-764 ; 355.0	-351 ; 367.6	-764 ; 367.6

N: Number of subjects, SD: Standard deviation, Ch.: Change

14.2.356 Nocturnal increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

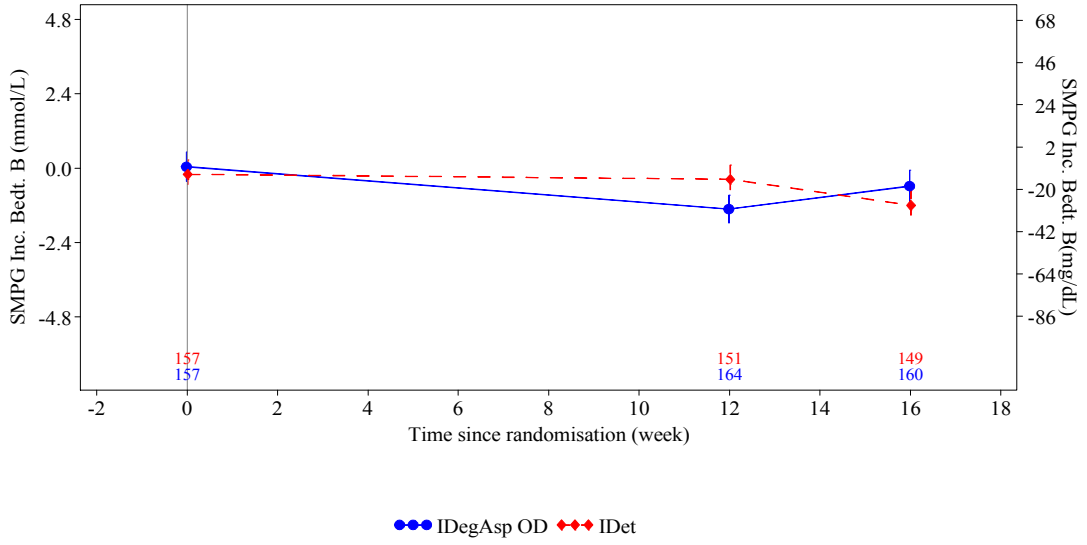
	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
Ch. SMPG Increment (Bedtime to Breakfast(mmol/L)			
Visit 14 (Week 12)			
N	67	56	123
Mean (SD)	-0.8 (6.6)	0.7 (6.3)	-0.1 (6.4)
Median	-0.6	-0.1	-0.5
Min ; Max	-18.4 ; 15.6	-13.5 ; 20.9	-18.4 ; 20.9
Visit 18 (Week 16)			
N	62	53	115
Mean (SD)	-0.2 (8.4)	-0.5 (6.4)	-0.3 (7.5)
Median	-0.3	-1.0	-0.7
Min ; Max	-25.7 ; 22.8	-17.7 ; 16.9	-25.7 ; 22.8
End of trial visit			
N	71	65	136
Mean (SD)	-0.0 (8.0)	0.2 (7.1)	0.1 (7.6)
Median	0.0	-0.8	-0.4
Min ; Max	-25.7 ; 22.8	-17.7 ; 20.9	-25.7 ; 22.8

N: Number of subjects, SD: Standard deviation, Ch.: Change

Nocturnal increment by treatment week – change from baseline - 8-point self measured plasma glucose profile - descriptive statistics – adolescents (12-17 years) - full analysis set

	IDegAsp OD	IDet	Total
Ch. SMPG Increment (Bedtime to Breakfast(mg/dL)			
Visit 14 (Week 12)			
N	67	56	123
Mean (SD)	-14.9 (118.3)	13.0 (112.7)	-2.1 (116.1)
Median	-11.0	-1.3	-9.0
Min ; Max	-331 ; 282.0	-243 ; 377.0	-331 ; 377.0
Visit 18 (Week 16)			
N	62	53	115
Mean (SD)	-4.1 (150.6)	-8.1 (115.9)	-6.0 (135.2)
Median	-5.0	-18.0	-12.0
Min ; Max	-463 ; 410.0	-319 ; 304.5	-463 ; 410.0
End of trial visit			
N	71	65	136
Mean (SD)	-0.5 (144.4)	3.1 (128.8)	1.2 (136.7)
Median	0.0	-15.0	-7.0
Min ; Max	-463 ; 410.0	-319 ; 377.0	-463 ; 410.0

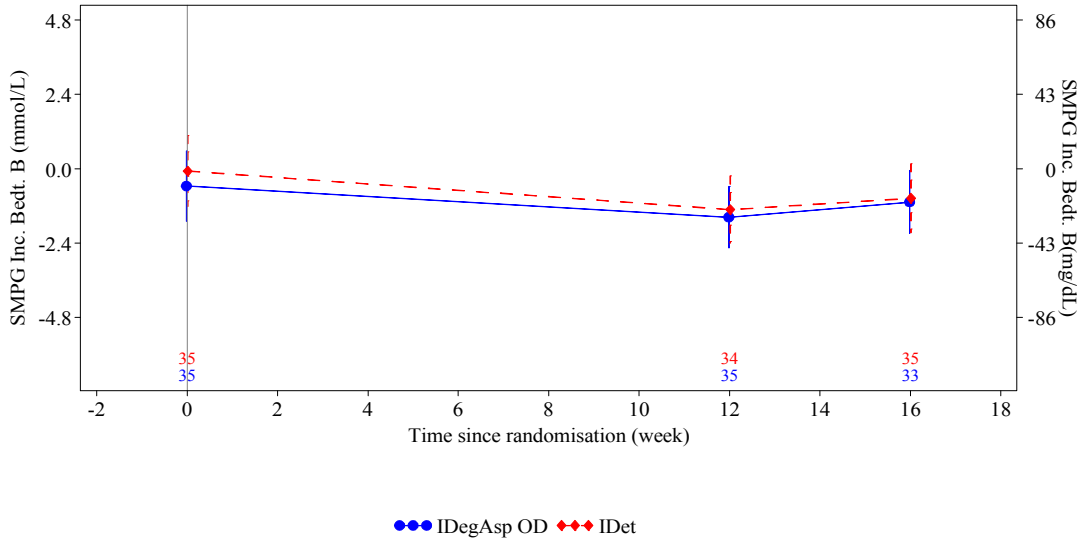
N: Number of subjects, SD: Standard deviation, Ch.: Change



FAS: Observed data
SMPG: Self measured plasma glucose, Inc.: Increment, Bedt.: Bedtime, B: Breakfast
FAS: Full analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:03 - fmean_numfind_deg_cust.sas/e_8pp_abs_bt_bf_ic_mn_pr_fas.cgm

14.2.357 Nocturnal increment (bedtime to breakfast) by treatment week - 8-point self measured plasma glucose profile – mean plot - full analysis set



FAS: Observed data
SMPG: Self measured plasma glucose, Inc.: Increment, Bedt.: Bedtime, B: Breakfast
FAS: Full analysis set, Error bars: +/- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
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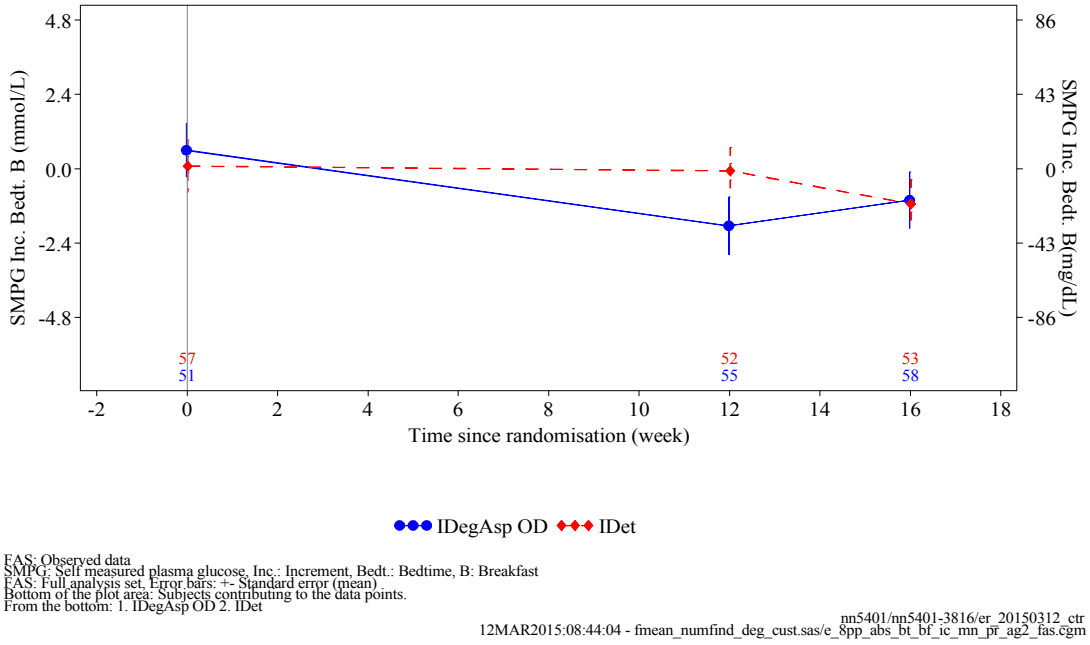
14.2.358 Nocturnal increment (bedtime to breakfast) by treatment week - 8-point self measured plasma glucose profile – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
SMPG: Self measured plasma glucose, Inc.: Increment, Bedt.: Bedtime, B: Breakfast
FAS: Full analysis set, Error bars: +/- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

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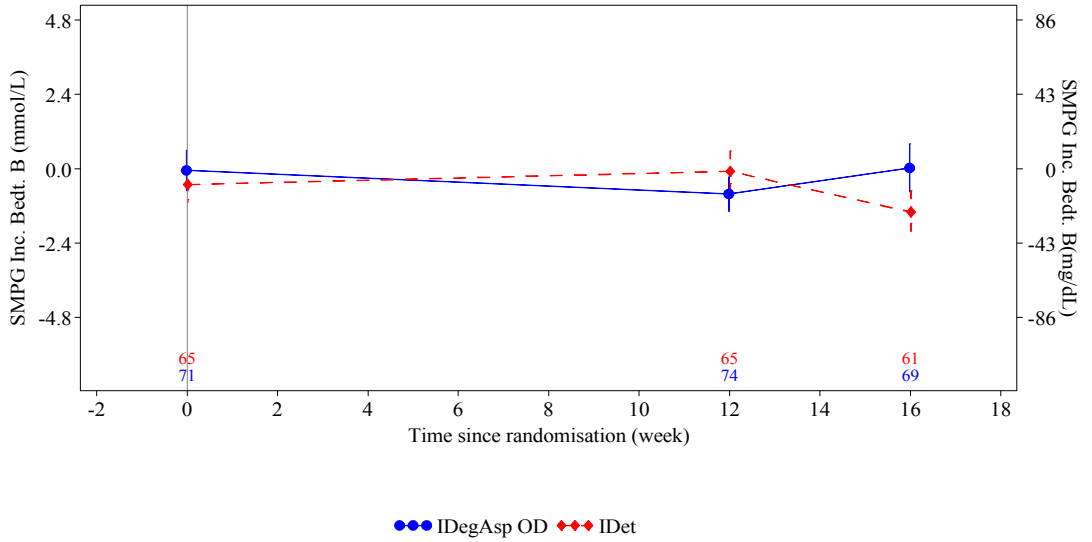
14.2.359 Nocturnal increment (bedtime to breakfast) by treatment week - 8-point self measured plasma glucose profile – mean plot – children (6-11 years) - full analysis set



FAS: Observed data
SMPG: Self measured plasma glucose, Inc.: Increment, Bedt.: Bedtime, B: Breakfast
FAS: Full analysis set, Error bars: +/- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:04 - fmean_numfind_deg_cust.sas/e_8pp_abs_bt_bf_ic_mn_pr_ag3_fas.cgm

14.2.360 Nocturnal increment (bedtime to breakfast) by treatment week - 8-point self measured plasma glucose profile – mean plot – adolescents (12-17 years) - full analysis set

14.2.361 Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	182	180	362
Before Breakfast(mmol/L)			
Visit 3 (Week 1)			
N	180	179	359
Mean (SD)	10.8 (4.1)	10.8 (4.3)	10.8 (4.2)
Median	10.3	10.2	10.3
Min ; Max	3.7 ; 20.1	4.0 ; 25.5	3.7 ; 25.5
Visit 4 (Week 2)			
N	181	178	359
Mean (SD)	10.2 (3.8)	10.8 (4.0)	10.5 (3.9)
Median	9.6	10.3	10.0
Min ; Max	3.2 ; 21.3	3.7 ; 22.3	3.2 ; 22.3
Visit 5 (Week 3)			
N	179	176	355
Mean (SD)	10.3 (4.0)	10.1 (3.8)	10.2 (3.9)
Median	9.8	9.5	9.7
Min ; Max	3.8 ; 23.4	3.5 ; 25.0	3.5 ; 25.0
Visit 6 (Week 4)			
N	178	175	353
Mean (SD)	9.6 (3.4)	10.3 (4.0)	10.0 (3.7)
Median	9.3	9.6	9.5
Min ; Max	2.8 ; 24.5	3.3 ; 22.9	2.8 ; 24.5
Visit 7 (Week 5)			
N	177	174	351
Mean (SD)	9.4 (3.2)	9.7 (3.3)	9.6 (3.3)
Median	8.9	9.1	9.0
Min ; Max	3.6 ; 20.3	3.7 ; 20.9	3.6 ; 20.9
Visit 8 (Week 6)			
N	179	174	353
Mean (SD)	9.4 (3.3)	9.3 (3.1)	9.4 (3.2)
Median	8.7	8.7	8.7
Min ; Max	3.9 ; 19.6	3.1 ; 17.6	3.1 ; 19.6
Visit 9 (Week 7)			
N	178	172	350
Mean (SD)	9.3 (2.8)	9.5 (3.3)	9.4 (3.0)
Median	8.9	9.0	9.0
Min ; Max	3.3 ; 19.5	3.5 ; 22.6	3.3 ; 22.6
Visit 10 (Week 8)			
N	176	173	349
Mean (SD)	9.5 (3.0)	9.8 (3.5)	9.6 (3.3)
Median	8.9	9.2	9.0
Min ; Max	4.4 ; 20.9	2.9 ; 23.5	2.9 ; 23.5

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

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Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mmol/L)			
Visit 11 (Week 9)			
N	176	173	349
Mean (SD)	9.5 (3.2)	9.3 (3.2)	9.4 (3.2)
Median	8.7	8.8	8.7
Min ; Max	4.7 ; 21.5	3.4 ; 23.0	3.4 ; 23.0
Visit 12 (Week 10)			
N	175	172	347
Mean (SD)	9.2 (3.2)	9.2 (3.1)	9.2 (3.1)
Median	8.6	8.5	8.5
Min ; Max	3.3 ; 21.8	3.7 ; 19.7	3.3 ; 21.8
Visit 13 (Week 11)			
N	175	171	346
Mean (SD)	9.3 (3.1)	9.5 (3.3)	9.4 (3.2)
Median	8.7	8.7	8.7
Min ; Max	3.4 ; 19.4	3.4 ; 22.5	3.4 ; 22.5
Visit 14 (Week 12)			
N	174	172	346
Mean (SD)	9.5 (3.1)	9.5 (3.0)	9.5 (3.1)
Median	8.9	8.9	8.9
Min ; Max	4.3 ; 20.3	3.8 ; 18.4	3.8 ; 20.3
Visit 15 (Week 13)			
N	175	171	346
Mean (SD)	9.3 (2.9)	9.4 (3.3)	9.4 (3.1)
Median	8.9	8.5	8.8
Min ; Max	4.5 ; 19.0	2.9 ; 21.8	2.9 ; 21.8
Visit 16 (Week 14)			
N	175	170	345
Mean (SD)	9.4 (2.9)	9.3 (3.2)	9.3 (3.0)
Median	9.0	8.9	9.0
Min ; Max	3.8 ; 20.5	3.1 ; 20.3	3.1 ; 20.5
Visit 17 (Week 15)			
N	173	170	343
Mean (SD)	9.7 (3.1)	9.6 (3.0)	9.7 (3.1)
Median	9.3	9.1	9.3
Min ; Max	4.4 ; 19.8	3.8 ; 19.1	3.8 ; 19.8
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	9.4 (3.1)	9.4 (3.2)	9.4 (3.2)
Median	9.1	8.9	9.0
Min ; Max	4.1 ; 19.4	3.6 ; 26.1	3.6 ; 26.1

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mmol/L)			
End of trial visit			
N	181	179	360
Mean (SD)	9.5 (3.2)	9.5 (3.6)	9.5 (3.4)
Median	9.2	8.9	9.1
Min ; Max	4.1 ; 19.4	1.8 ; 26.1	1.8 ; 26.1

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
Visit 3 (Week 1)			
N	180	179	359
Mean (SD)	11.4 (4.4)	10.6 (4.3)	11.0 (4.4)
Median	11.0	10.2	10.6
Min ; Max	3.1 ; 27.2	2.9 ; 23.6	2.9 ; 27.2
Visit 4 (Week 2)			
N	181	178	359
Mean (SD)	11.4 (4.8)	10.4 (4.3)	10.9 (4.6)
Median	10.7	9.6	9.9
Min ; Max	3.1 ; 27.7	3.7 ; 26.5	3.1 ; 27.7
Visit 5 (Week 3)			
N	179	176	355
Mean (SD)	10.3 (4.2)	10.3 (4.1)	10.3 (4.1)
Median	9.4	9.9	9.7
Min ; Max	3.4 ; 23.4	3.1 ; 28.9	3.1 ; 28.9
Visit 6 (Week 4)			
N	178	175	353
Mean (SD)	10.2 (4.0)	10.2 (4.1)	10.2 (4.0)
Median	9.2	9.2	9.2
Min ; Max	2.9 ; 25.7	3.8 ; 24.0	2.9 ; 25.7
Visit 7 (Week 5)			
N	176	174	350
Mean (SD)	10.6 (3.8)	9.7 (3.5)	10.1 (3.7)
Median	9.7	9.1	9.5
Min ; Max	3.7 ; 23.5	3.7 ; 20.8	3.7 ; 23.5
Visit 8 (Week 6)			
N	179	174	353
Mean (SD)	10.0 (3.5)	9.6 (3.6)	9.8 (3.6)
Median	9.1	8.9	9.0
Min ; Max	2.7 ; 23.3	2.4 ; 24.4	2.4 ; 24.4
Visit 9 (Week 7)			
N	178	172	350
Mean (SD)	9.7 (3.5)	9.2 (3.4)	9.5 (3.5)
Median	9.1	8.5	8.7
Min ; Max	3.7 ; 21.9	2.9 ; 25.4	2.9 ; 25.4
Visit 10 (Week 8)			
N	175	173	348
Mean (SD)	10.4 (4.2)	9.6 (3.3)	10.0 (3.8)
Median	9.7	9.2	9.4
Min ; Max	3.3 ; 25.1	3.3 ; 20.6	3.3 ; 25.1

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
Visit 11 (Week 9)			
N	176	173	349
Mean (SD)	9.7 (3.9)	9.7 (3.6)	9.7 (3.8)
Median	9.2	9.0	9.2
Min ; Max	3.3 ; 26.1	3.9 ; 28.0	3.3 ; 28.0
Visit 12 (Week 10)			
N	175	172	347
Mean (SD)	10.0 (3.8)	9.3 (3.3)	9.7 (3.6)
Median	9.0	8.9	8.9
Min ; Max	3.0 ; 26.2	3.5 ; 23.0	3.0 ; 26.2
Visit 13 (Week 11)			
N	175	171	346
Mean (SD)	9.8 (3.5)	9.2 (3.3)	9.5 (3.5)
Median	9.0	8.6	8.8
Min ; Max	4.2 ; 25.7	2.9 ; 23.1	2.9 ; 25.7
Visit 14 (Week 12)			
N	174	172	346
Mean (SD)	10.0 (4.1)	9.3 (3.2)	9.6 (3.7)
Median	9.0	8.5	8.8
Min ; Max	3.4 ; 23.6	4.2 ; 21.3	3.4 ; 23.6
Visit 15 (Week 13)			
N	174	171	345
Mean (SD)	9.9 (3.7)	9.6 (3.4)	9.8 (3.6)
Median	9.2	9.0	9.1
Min ; Max	3.1 ; 23.3	2.8 ; 21.4	2.8 ; 23.3
Visit 16 (Week 14)			
N	175	170	345
Mean (SD)	9.8 (3.6)	9.3 (3.5)	9.6 (3.5)
Median	9.3	8.5	8.9
Min ; Max	3.0 ; 20.2	3.7 ; 21.4	3.0 ; 21.4
Visit 17 (Week 15)			
N	172	170	342
Mean (SD)	10.0 (3.6)	9.4 (3.1)	9.7 (3.3)
Median	9.5	9.0	9.2
Min ; Max	3.9 ; 19.1	3.8 ; 18.9	3.8 ; 19.1
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	10.0 (4.0)	9.3 (3.5)	9.7 (3.8)
Median	9.4	8.6	8.7
Min ; Max	3.0 ; 27.0	3.6 ; 23.8	3.0 ; 27.0

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
End of trial visit			
N	181	179	360
Mean (SD)	10.1 (4.0)	9.5 (3.7)	9.8 (3.9)
Median	9.4	8.6	8.8
Min ; Max	3.0 ; 27.0	3.6 ; 23.8	3.0 ; 27.0

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/ L)			
Visit 3 (Week 1)			
N	180	179	359
Mean (SD)	11.7 (4.6)	11.5 (4.6)	11.6 (4.6)
Median	10.9	10.7	10.8
Min ; Max	3.4 ; 31.1	3.2 ; 24.3	3.2 ; 31.1
Visit 4 (Week 2)			
N	181	178	359
Mean (SD)	11.1 (4.4)	10.9 (3.9)	11.0 (4.1)
Median	10.5	10.3	10.4
Min ; Max	2.1 ; 27.1	3.7 ; 21.2	2.1 ; 27.1
Visit 5 (Week 3)			
N	180	176	356
Mean (SD)	11.2 (4.3)	10.6 (4.1)	10.9 (4.2)
Median	10.1	9.6	9.9
Min ; Max	1.7 ; 24.5	3.8 ; 26.9	1.7 ; 26.9
Visit 6 (Week 4)			
N	177	175	352
Mean (SD)	10.5 (3.5)	10.9 (4.3)	10.7 (3.9)
Median	10.0	10.1	10.1
Min ; Max	3.7 ; 22.4	2.7 ; 25.8	2.7 ; 25.8
Visit 7 (Week 5)			
N	177	174	351
Mean (SD)	10.7 (4.0)	10.9 (3.8)	10.8 (3.9)
Median	10.0	10.7	10.4
Min ; Max	4.0 ; 23.9	3.4 ; 21.6	3.4 ; 23.9
Visit 8 (Week 6)			
N	179	174	353
Mean (SD)	10.6 (3.7)	10.4 (3.3)	10.5 (3.5)
Median	10.3	10.0	10.2
Min ; Max	3.1 ; 21.0	3.9 ; 21.8	3.1 ; 21.8
Visit 9 (Week 7)			
N	177	172	349
Mean (SD)	10.5 (3.8)	10.4 (3.7)	10.4 (3.7)
Median	10.0	9.8	9.9
Min ; Max	2.5 ; 25.9	2.3 ; 22.6	2.3 ; 25.9
Visit 10 (Week 8)			
N	176	173	349
Mean (SD)	10.6 (3.8)	10.5 (4.0)	10.6 (3.9)
Median	9.8	9.8	9.8
Min ; Max	2.2 ; 23.3	3.7 ; 24.3	2.2 ; 24.3

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
Visit 11 (Week 9)			
N	175	173	348
Mean (SD)	10.9 (4.1)	10.1 (3.7)	10.5 (3.9)
Median	9.9	9.5	9.6
Min ; Max	4.2 ; 28.4	2.9 ; 24.2	2.9 ; 28.4
Visit 12 (Week 10)			
N	175	171	346
Mean (SD)	10.7 (4.1)	9.9 (3.4)	10.3 (3.8)
Median	9.9	9.6	9.7
Min ; Max	2.4 ; 30.3	3.8 ; 24.7	2.4 ; 30.3
Visit 13 (Week 11)			
N	174	171	345
Mean (SD)	10.2 (4.0)	10.4 (3.9)	10.3 (3.9)
Median	9.4	9.6	9.5
Min ; Max	2.9 ; 25.4	2.6 ; 24.5	2.6 ; 25.4
Visit 14 (Week 12)			
N	174	172	346
Mean (SD)	10.4 (3.9)	10.4 (3.7)	10.4 (3.8)
Median	9.7	9.8	9.8
Min ; Max	2.9 ; 22.4	3.9 ; 21.9	2.9 ; 22.4
Visit 15 (Week 13)			
N	175	171	346
Mean (SD)	10.9 (3.9)	10.4 (3.8)	10.6 (3.9)
Median	10.4	9.5	9.9
Min ; Max	2.7 ; 22.5	5.2 ; 24.1	2.7 ; 24.1
Visit 16 (Week 14)			
N	175	170	345
Mean (SD)	10.3 (3.4)	10.4 (3.7)	10.3 (3.5)
Median	9.7	9.6	9.6
Min ; Max	3.2 ; 21.3	3.4 ; 24.5	3.2 ; 24.5
Visit 17 (Week 15)			
N	173	170	343
Mean (SD)	10.7 (3.5)	10.3 (3.6)	10.5 (3.5)
Median	10.2	10.0	10.1
Min ; Max	2.7 ; 22.2	2.4 ; 25.5	2.4 ; 25.5
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	10.7 (3.6)	10.0 (3.7)	10.4 (3.6)
Median	10.2	9.0	9.8
Min ; Max	4.1 ; 22.6	2.3 ; 27.1	2.3 ; 27.1

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
End of trial visit			
N	181	179	360
Mean (SD)	10.8 (3.6)	9.9 (3.7)	10.3 (3.7)
Median	10.2	9.0	9.8
Min ; Max	4.1 ; 22.6	2.3 ; 27.1	2.3 ; 27.1

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
Visit 3 (Week 1)			
N	176	179	355
Mean (SD)	11.4 (4.2)	10.6 (3.8)	11.0 (4.0)
Median	10.7	9.9	10.4
Min ; Max	2.7 ; 27.6	3.6 ; 22.5	2.7 ; 27.6
Visit 4 (Week 2)			
N	178	178	356
Mean (SD)	11.5 (4.2)	10.7 (4.1)	11.1 (4.2)
Median	10.8	9.9	10.3
Min ; Max	2.6 ; 26.3	3.5 ; 27.2	2.6 ; 27.2
Visit 5 (Week 3)			
N	180	175	355
Mean (SD)	10.8 (4.5)	10.3 (3.9)	10.5 (4.2)
Median	9.8	9.5	9.6
Min ; Max	2.1 ; 27.8	4.1 ; 22.0	2.1 ; 27.8
Visit 6 (Week 4)			
N	176	174	350
Mean (SD)	10.6 (3.7)	10.2 (3.6)	10.4 (3.6)
Median	10.0	9.2	9.6
Min ; Max	2.7 ; 25.2	2.8 ; 22.4	2.7 ; 25.2
Visit 7 (Week 5)			
N	177	173	350
Mean (SD)	10.6 (4.2)	10.1 (4.1)	10.4 (4.2)
Median	9.7	9.1	9.6
Min ; Max	3.6 ; 27.2	2.8 ; 25.3	2.8 ; 27.2
Visit 8 (Week 6)			
N	177	173	350
Mean (SD)	10.6 (4.0)	9.8 (3.3)	10.2 (3.7)
Median	9.7	9.5	9.6
Min ; Max	4.3 ; 23.8	3.0 ; 25.7	3.0 ; 25.7
Visit 9 (Week 7)			
N	177	172	349
Mean (SD)	10.9 (3.8)	9.9 (3.6)	10.4 (3.7)
Median	10.0	9.2	9.6
Min ; Max	4.6 ; 24.8	2.8 ; 23.1	2.8 ; 24.8
Visit 10 (Week 8)			
N	172	172	344
Mean (SD)	10.9 (4.1)	10.1 (3.5)	10.5 (3.8)
Median	10.3	9.5	10.1
Min ; Max	4.0 ; 26.9	3.1 ; 21.2	3.1 ; 26.9

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
Visit 11 (Week 9)			
N	172	171	343
Mean (SD)	10.4 (3.7)	10.0 (3.7)	10.2 (3.7)
Median	9.7	9.2	9.4
Min ; Max	3.6 ; 22.0	3.9 ; 19.9	3.6 ; 22.0
Visit 12 (Week 10)			
N	175	172	347
Mean (SD)	10.6 (3.6)	9.9 (3.8)	10.3 (3.7)
Median	9.9	9.5	9.6
Min ; Max	3.2 ; 23.0	3.3 ; 25.8	3.2 ; 25.8
Visit 13 (Week 11)			
N	173	171	344
Mean (SD)	10.2 (3.7)	9.6 (3.6)	9.9 (3.7)
Median	9.9	9.2	9.4
Min ; Max	3.3 ; 20.8	4.1 ; 20.4	3.3 ; 20.8
Visit 14 (Week 12)			
N	174	172	346
Mean (SD)	10.5 (3.9)	10.1 (3.5)	10.3 (3.7)
Median	9.9	9.9	9.9
Min ; Max	3.6 ; 23.7	4.0 ; 22.6	3.6 ; 23.7
Visit 15 (Week 13)			
N	173	171	344
Mean (SD)	10.2 (3.6)	9.9 (3.7)	10.1 (3.6)
Median	9.5	9.3	9.4
Min ; Max	3.1 ; 25.5	2.8 ; 22.2	2.8 ; 25.5
Visit 16 (Week 14)			
N	173	170	343
Mean (SD)	10.6 (3.8)	10.1 (3.4)	10.4 (3.6)
Median	10.0	9.8	9.9
Min ; Max	3.1 ; 22.2	2.9 ; 23.3	2.9 ; 23.3
Visit 17 (Week 15)			
N	171	169	340
Mean (SD)	10.9 (4.2)	9.9 (3.4)	10.4 (3.8)
Median	10.4	9.4	9.8
Min ; Max	3.2 ; 24.2	3.0 ; 19.7	3.0 ; 24.2
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	10.4 (4.2)	9.6 (3.2)	10.0 (3.7)
Median	9.5	9.1	9.3
Min ; Max	2.4 ; 24.3	3.0 ; 21.2	2.4 ; 24.3

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
End of trial visit			
N	181	179	360
Mean (SD)	10.4 (4.3)	9.7 (3.3)	10.1 (3.9)
Median	9.4	9.2	9.3
Min ; Max	2.4 ; 25.3	3.0 ; 21.2	2.4 ; 25.3

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
Visit 3 (Week 1)			
N	180	179	359
Mean (SD)	194.2 (74.2)	194.9 (78.2)	194.6 (76.1)
Median	185.1	184.6	185.0
Min ; Max	67.0 ; 363.0	72.7 ; 460.1	67.0 ; 460.1
Visit 4 (Week 2)			
N	181	178	359
Mean (SD)	184.5 (68.4)	194.8 (71.9)	189.6 (70.3)
Median	172.6	186.5	180.0
Min ; Max	57.1 ; 383.6	66.0 ; 401.0	57.1 ; 401.0
Visit 5 (Week 3)			
N	179	176	355
Mean (SD)	185.0 (72.2)	182.7 (68.3)	183.9 (70.2)
Median	176.6	171.8	174.2
Min ; Max	68.7 ; 421.0	63.1 ; 450.0	63.1 ; 450.0
Visit 6 (Week 4)			
N	178	175	353
Mean (SD)	173.2 (60.7)	185.9 (71.3)	179.5 (66.3)
Median	167.3	173.3	171.2
Min ; Max	49.7 ; 441.0	59.7 ; 413.3	49.7 ; 441.0
Visit 7 (Week 5)			
N	177	174	351
Mean (SD)	170.1 (57.6)	175.0 (60.1)	172.5 (58.9)
Median	160.0	164.5	162.3
Min ; Max	64.0 ; 366.6	67.3 ; 376.6	64.0 ; 376.6
Visit 8 (Week 6)			
N	179	174	353
Mean (SD)	170.2 (59.1)	167.8 (56.0)	169.0 (57.5)
Median	157.4	155.9	156.2
Min ; Max	69.7 ; 352.6	56.7 ; 317.3	56.7 ; 352.6
Visit 9 (Week 7)			
N	178	172	350
Mean (SD)	167.8 (50.8)	172.0 (58.6)	169.9 (54.7)
Median	161.1	162.5	162.0
Min ; Max	60.0 ; 350.8	62.7 ; 408.0	60.0 ; 408.0
Visit 10 (Week 8)			
N	176	173	349
Mean (SD)	170.6 (54.1)	176.0 (63.8)	173.2 (59.1)
Median	161.1	165.6	162.6
Min ; Max	78.7 ; 377.0	51.7 ; 423.0	51.7 ; 423.0

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
Visit 11 (Week 9)			
N	176	173	349
Mean (SD)	171.7 (57.5)	167.1 (56.9)	169.4 (57.2)
Median	157.5	158.0	157.6
Min ; Max	84.3 ; 386.6	61.9 ; 414.5	61.9 ; 414.5
Visit 12 (Week 10)			
N	175	172	347
Mean (SD)	166.0 (57.2)	165.3 (55.9)	165.6 (56.5)
Median	155.0	153.5	153.8
Min ; Max	59.7 ; 392.0	66.7 ; 355.6	59.7 ; 392.0
Visit 13 (Week 11)			
N	175	171	346
Mean (SD)	167.3 (55.3)	171.2 (59.0)	169.2 (57.1)
Median	156.3	156.8	156.5
Min ; Max	60.7 ; 350.0	60.7 ; 405.6	60.7 ; 405.6
Visit 14 (Week 12)			
N	174	172	346
Mean (SD)	171.2 (55.3)	170.6 (54.8)	170.9 (55.0)
Median	160.1	161.1	160.5
Min ; Max	77.5 ; 366.6	68.3 ; 332.0	68.3 ; 366.6
Visit 15 (Week 13)			
N	175	171	346
Mean (SD)	168.4 (52.0)	169.0 (59.1)	168.7 (55.5)
Median	159.8	152.3	157.7
Min ; Max	80.5 ; 342.3	52.9 ; 392.3	52.9 ; 392.3
Visit 16 (Week 14)			
N	175	170	345
Mean (SD)	169.4 (52.2)	167.4 (57.7)	168.4 (54.9)
Median	161.6	161.1	161.3
Min ; Max	68.0 ; 368.8	56.5 ; 366.0	56.5 ; 368.8
Visit 17 (Week 15)			
N	173	170	343
Mean (SD)	175.4 (56.4)	172.8 (54.6)	174.1 (55.4)
Median	167.0	163.9	167.0
Min ; Max	78.7 ; 357.4	68.3 ; 344.7	68.3 ; 357.4
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	168.7 (56.0)	169.3 (58.0)	169.0 (56.9)
Median	164.1	161.0	163.0
Min ; Max	73.3 ; 350.2	64.7 ; 470.9	64.7 ; 470.9

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
End of trial visit			
N	181	179	360
Mean (SD)	170.8 (57.5)	170.8 (64.0)	170.8 (60.8)
Median	165.0	161.0	163.2
Min ; Max	73.3 ; 350.2	32.0 ; 470.9	32.0 ; 470.9

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
Visit 3 (Week 1)			
N	180	179	359
Mean (SD)	205.7 (79.2)	191.3 (77.4)	198.5 (78.6)
Median	198.5	184.3	191.3
Min ; Max	56.3 ; 489.6	52.3 ; 425.0	52.3 ; 489.6
Visit 4 (Week 2)			
N	181	178	359
Mean (SD)	205.2 (86.9)	187.7 (77.3)	196.5 (82.6)
Median	193.6	172.7	179.0
Min ; Max	56.0 ; 499.9	66.3 ; 477.5	56.0 ; 499.9
Visit 5 (Week 3)			
N	179	176	355
Mean (SD)	185.1 (75.7)	185.9 (74.0)	185.5 (74.8)
Median	168.8	177.7	175.0
Min ; Max	61.3 ; 421.0	55.9 ; 520.9	55.9 ; 520.9
Visit 6 (Week 4)			
N	178	175	353
Mean (SD)	183.5 (71.4)	183.2 (74.6)	183.4 (72.9)
Median	165.8	166.4	166.3
Min ; Max	51.7 ; 462.6	69.3 ; 432.3	51.7 ; 462.6
Visit 7 (Week 5)			
N	176	174	350
Mean (SD)	190.3 (69.3)	175.3 (63.2)	182.9 (66.6)
Median	175.6	164.3	170.9
Min ; Max	66.1 ; 423.6	67.3 ; 375.6	66.1 ; 423.6
Visit 8 (Week 6)			
N	179	174	353
Mean (SD)	179.3 (63.7)	173.0 (65.3)	176.2 (64.5)
Median	163.6	160.5	163.0
Min ; Max	49.3 ; 420.0	43.7 ; 440.2	43.7 ; 440.2
Visit 9 (Week 7)			
N	178	172	350
Mean (SD)	175.5 (62.7)	165.9 (61.6)	170.8 (62.2)
Median	163.4	153.3	157.4
Min ; Max	66.1 ; 394.6	52.9 ; 457.9	52.9 ; 457.9
Visit 10 (Week 8)			
N	175	173	348
Mean (SD)	187.0 (76.5)	172.8 (60.2)	180.0 (69.2)
Median	174.6	165.8	170.1
Min ; Max	60.0 ; 452.0	59.3 ; 372.0	59.3 ; 452.0

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
Visit 11 (Week 9)			
N	176	173	349
Mean (SD)	174.3 (69.9)	174.2 (65.5)	174.2 (67.7)
Median	165.9	163.0	165.2
Min ; Max	59.5 ; 469.9	71.0 ; 505.1	59.5 ; 505.1
Visit 12 (Week 10)			
N	175	172	347
Mean (SD)	180.3 (69.3)	167.7 (59.0)	174.0 (64.7)
Median	163.0	161.0	161.0
Min ; Max	54.7 ; 472.1	63.1 ; 415.0	54.7 ; 472.1
Visit 13 (Week 11)			
N	175	171	346
Mean (SD)	177.1 (63.9)	166.2 (60.2)	171.7 (62.2)
Median	162.0	155.6	158.0
Min ; Max	75.3 ; 462.9	52.3 ; 416.8	52.3 ; 462.9
Visit 14 (Week 12)			
N	174	172	346
Mean (SD)	179.9 (73.0)	167.2 (58.2)	173.6 (66.3)
Median	162.6	153.1	158.8
Min ; Max	61.0 ; 425.8	75.1 ; 383.8	61.0 ; 425.8
Visit 15 (Week 13)			
N	174	171	345
Mean (SD)	178.0 (66.6)	173.7 (61.7)	175.9 (64.2)
Median	166.1	162.2	164.6
Min ; Max	56.0 ; 419.6	49.7 ; 385.0	49.7 ; 419.6
Visit 16 (Week 14)			
N	175	170	345
Mean (SD)	177.1 (64.9)	167.6 (62.6)	172.4 (63.9)
Median	167.0	154.0	160.0
Min ; Max	53.7 ; 363.6	66.0 ; 385.6	53.7 ; 385.6
Visit 17 (Week 15)			
N	172	170	342
Mean (SD)	180.6 (64.2)	170.2 (55.1)	175.4 (60.0)
Median	170.3	161.5	165.8
Min ; Max	69.7 ; 345.0	69.1 ; 340.6	69.1 ; 345.0
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	180.6 (72.6)	167.1 (62.3)	174.0 (67.9)
Median	168.6	154.4	156.8
Min ; Max	54.7 ; 486.5	65.5 ; 428.8	54.7 ; 486.5

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
End of trial visit			
N	181	179	360
Mean (SD)	181.9 (72.7)	171.0 (65.9)	176.5 (69.5)
Median	169.0	155.6	159.1
Min ; Max	54.7 ; 486.5	65.5 ; 428.8	54.7 ; 486.5

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
Visit 3 (Week 1)			
N	180	179	359
Mean (SD)	211.6 (83.0)	207.5 (83.5)	209.5 (83.1)
Median	197.0	192.3	194.6
Min ; Max	62.0 ; 560.4	58.3 ; 437.2	58.3 ; 560.4
Visit 4 (Week 2)			
N	181	178	359
Mean (SD)	199.6 (79.4)	196.6 (69.6)	198.1 (74.6)
Median	189.3	185.6	187.4
Min ; Max	38.4 ; 487.4	67.0 ; 381.3	38.4 ; 487.4
Visit 5 (Week 3)			
N	180	176	356
Mean (SD)	202.3 (78.3)	190.2 (74.5)	196.3 (76.6)
Median	181.5	173.3	179.1
Min ; Max	30.0 ; 441.4	69.1 ; 484.6	30.0 ; 484.6
Visit 6 (Week 4)			
N	177	175	352
Mean (SD)	190.0 (62.2)	196.3 (77.1)	193.1 (70.0)
Median	180.8	182.0	181.3
Min ; Max	67.0 ; 403.6	48.0 ; 464.4	48.0 ; 464.4
Visit 7 (Week 5)			
N	177	174	351
Mean (SD)	193.0 (71.8)	197.1 (67.6)	195.0 (69.7)
Median	180.8	192.9	187.4
Min ; Max	71.7 ; 430.0	60.5 ; 389.5	60.5 ; 430.0
Visit 8 (Week 6)			
N	179	174	353
Mean (SD)	191.0 (66.7)	186.7 (59.1)	188.9 (63.0)
Median	186.2	179.5	184.3
Min ; Max	55.3 ; 379.0	69.7 ; 393.3	55.3 ; 393.3
Visit 9 (Week 7)			
N	177	172	349
Mean (SD)	188.9 (67.7)	187.0 (66.9)	188.0 (67.2)
Median	180.3	175.8	178.4
Min ; Max	45.0 ; 466.1	41.0 ; 408.0	41.0 ; 466.1
Visit 10 (Week 8)			
N	176	173	349
Mean (SD)	190.6 (69.3)	190.0 (71.3)	190.3 (70.2)
Median	176.6	177.0	176.6
Min ; Max	40.2 ; 420.0	66.0 ; 438.0	40.2 ; 438.0

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
Visit 11 (Week 9)			
N	175	173	348
Mean (SD)	197.1 (73.6)	182.3 (66.4)	189.8 (70.4)
Median	178.0	170.3	173.3
Min ; Max	75.0 ; 511.1	52.0 ; 436.6	52.0 ; 511.1
Visit 12 (Week 10)			
N	175	171	346
Mean (SD)	192.0 (73.4)	179.2 (60.6)	185.7 (67.6)
Median	179.0	173.0	175.4
Min ; Max	42.7 ; 545.3	68.0 ; 445.0	42.7 ; 545.3
Visit 13 (Week 11)			
N	174	171	345
Mean (SD)	184.4 (71.2)	187.9 (70.1)	186.1 (70.6)
Median	169.4	172.6	171.8
Min ; Max	52.9 ; 456.9	46.2 ; 440.8	46.2 ; 456.9
Visit 14 (Week 12)			
N	174	172	346
Mean (SD)	188.0 (70.1)	187.6 (65.9)	187.8 (68.0)
Median	175.6	176.3	176.0
Min ; Max	51.7 ; 403.3	70.3 ; 395.0	51.7 ; 403.3
Visit 15 (Week 13)			
N	175	171	346
Mean (SD)	196.6 (70.4)	187.1 (68.5)	191.9 (69.5)
Median	187.5	171.0	178.8
Min ; Max	49.0 ; 406.0	93.7 ; 434.2	49.0 ; 434.2
Visit 16 (Week 14)			
N	175	170	345
Mean (SD)	185.8 (60.4)	186.8 (66.4)	186.3 (63.4)
Median	174.8	173.5	173.6
Min ; Max	57.3 ; 384.0	61.3 ; 440.5	57.3 ; 440.5
Visit 17 (Week 15)			
N	173	170	343
Mean (SD)	193.1 (63.0)	185.5 (64.2)	189.3 (63.6)
Median	184.4	180.0	181.6
Min ; Max	49.3 ; 400.0	42.6 ; 458.9	42.6 ; 458.9
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	192.4 (64.3)	180.9 (66.4)	186.8 (65.5)
Median	183.2	162.2	177.0
Min ; Max	73.0 ; 407.6	41.0 ; 487.7	41.0 ; 487.7

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
End of trial visit			
N	181	179	360
Mean (SD)	194.3 (64.5)	178.2 (66.8)	186.3 (66.1)
Median	183.3	161.6	176.5
Min ; Max	73.0 ; 407.6	41.0 ; 487.7	41.0 ; 487.7

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
Visit 3 (Week 1)			
N	176	179	355
Mean (SD)	204.8 (75.2)	191.7 (68.9)	198.2 (72.3)
Median	192.6	179.0	187.4
Min ; Max	47.7 ; 497.3	64.9 ; 405.5	47.7 ; 497.3
Visit 4 (Week 2)			
N	178	178	356
Mean (SD)	206.5 (76.5)	193.1 (73.2)	199.8 (75.1)
Median	193.7	178.4	185.3
Min ; Max	46.0 ; 473.4	62.5 ; 490.9	46.0 ; 490.9
Visit 5 (Week 3)			
N	180	175	355
Mean (SD)	193.7 (80.7)	186.1 (70.1)	190.0 (75.6)
Median	176.3	170.6	173.6
Min ; Max	37.8 ; 500.9	73.3 ; 396.5	37.8 ; 500.9
Visit 6 (Week 4)			
N	176	174	350
Mean (SD)	190.8 (65.9)	183.2 (65.4)	187.0 (65.6)
Median	180.6	165.8	173.6
Min ; Max	48.0 ; 453.5	49.5 ; 403.0	48.0 ; 453.5
Visit 7 (Week 5)			
N	177	173	350
Mean (SD)	191.9 (76.2)	182.0 (73.9)	187.0 (75.1)
Median	174.8	163.4	172.4
Min ; Max	64.0 ; 489.9	50.0 ; 455.9	50.0 ; 489.9
Visit 8 (Week 6)			
N	177	173	350
Mean (SD)	191.7 (72.4)	176.9 (59.3)	184.4 (66.6)
Median	175.3	170.6	173.0
Min ; Max	77.7 ; 429.3	54.3 ; 463.3	54.3 ; 463.3
Visit 9 (Week 7)			
N	177	172	349
Mean (SD)	196.6 (68.3)	178.7 (65.6)	187.8 (67.5)
Median	181.0	165.8	173.6
Min ; Max	83.7 ; 446.5	50.5 ; 416.5	50.5 ; 446.5
Visit 10 (Week 8)			
N	172	172	344
Mean (SD)	197.0 (73.8)	181.9 (63.0)	189.4 (69.0)
Median	184.8	171.7	181.1
Min ; Max	72.3 ; 484.9	56.0 ; 382.5	56.0 ; 484.9

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
Visit 11 (Week 9)			
N	172	171	343
Mean (SD)	187.3 (66.4)	180.5 (66.1)	183.9 (66.2)
Median	174.0	165.8	170.0
Min ; Max	65.0 ; 396.0	69.7 ; 358.0	65.0 ; 396.0
Visit 12 (Week 10)			
N	175	172	347
Mean (SD)	190.7 (64.1)	179.1 (68.3)	185.0 (66.3)
Median	178.0	170.7	173.0
Min ; Max	58.3 ; 415.3	59.5 ; 464.0	58.3 ; 464.0
Visit 13 (Week 11)			
N	173	171	344
Mean (SD)	184.2 (67.3)	173.8 (64.1)	179.0 (65.8)
Median	178.6	165.6	169.2
Min ; Max	58.9 ; 374.6	74.3 ; 368.0	58.9 ; 374.6
Visit 14 (Week 12)			
N	174	172	346
Mean (SD)	189.3 (71.1)	182.8 (63.4)	186.1 (67.4)
Median	177.7	177.6	177.7
Min ; Max	65.5 ; 427.0	72.0 ; 408.0	65.5 ; 427.0
Visit 15 (Week 13)			
N	173	171	344
Mean (SD)	184.7 (64.5)	177.7 (65.9)	181.2 (65.2)
Median	172.0	167.6	170.0
Min ; Max	55.0 ; 459.5	50.5 ; 400.6	50.5 ; 459.5
Visit 16 (Week 14)			
N	173	170	343
Mean (SD)	190.7 (67.7)	182.4 (60.7)	186.6 (64.4)
Median	181.0	176.9	178.3
Min ; Max	56.5 ; 400.3	52.3 ; 420.4	52.3 ; 420.4
Visit 17 (Week 15)			
N	171	169	340
Mean (SD)	196.6 (74.8)	178.9 (61.4)	187.8 (68.9)
Median	188.0	170.0	175.7
Min ; Max	58.3 ; 436.5	53.5 ; 355.0	53.5 ; 436.5
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	187.4 (74.9)	173.0 (57.0)	180.4 (67.0)
Median	171.3	164.0	167.6
Min ; Max	44.0 ; 437.8	53.5 ; 382.6	44.0 ; 437.8

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

Self measured plasma glucose for dose adjustment – descriptive statistics - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
End of trial visit			
N	181	179	360
Mean (SD)	187.5 (78.3)	174.6 (59.7)	181.1 (69.9)
Median	170.0	166.0	168.2
Min ; Max	44.0 ; 455.9	53.5 ; 382.6	44.0 ; 455.9

N: Number of subjects, SD: Standard deviation,
Endpoint is calculated as the mean of the available SMPG values

14.2.362 Self measured plasma glucose for dose adjustment – descriptive statistics – children (1-5 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	41	41	82
Before Breakfast(mmol/L)			
Visit 3 (Week 1)			
N	40	41	81
Mean (SD)	9.7 (3.7)	12.1 (5.3)	10.9 (4.7)
Median	9.8	11.2	10.4
Min ; Max	3.7 ; 17.9	4.0 ; 25.5	3.7 ; 25.5
Visit 4 (Week 2)			
N	40	41	81
Mean (SD)	9.7 (3.7)	11.1 (4.7)	10.4 (4.3)
Median	8.9	9.9	9.8
Min ; Max	3.2 ; 16.7	3.8 ; 22.3	3.2 ; 22.3
Visit 5 (Week 3)			
N	40	40	80
Mean (SD)	9.7 (3.7)	10.7 (4.4)	10.2 (4.1)
Median	9.3	10.1	9.6
Min ; Max	3.9 ; 21.9	4.8 ; 25.0	3.9 ; 25.0
Visit 6 (Week 4)			
N	40	40	80
Mean (SD)	9.3 (3.6)	10.7 (4.7)	10.0 (4.2)
Median	9.2	9.5	9.2
Min ; Max	2.8 ; 18.2	4.7 ; 21.4	2.8 ; 21.4
Visit 7 (Week 5)			
N	39	40	79
Mean (SD)	9.4 (3.4)	10.8 (4.3)	10.1 (3.9)
Median	9.2	9.9	9.5
Min ; Max	3.6 ; 16.9	5.1 ; 20.9	3.6 ; 20.9
Visit 8 (Week 6)			
N	40	40	80
Mean (SD)	9.5 (3.5)	9.5 (3.7)	9.5 (3.6)
Median	8.5	8.7	8.6
Min ; Max	4.8 ; 19.6	3.1 ; 17.6	3.1 ; 19.6
Visit 9 (Week 7)			
N	40	40	80
Mean (SD)	9.0 (2.7)	9.2 (3.5)	9.1 (3.1)
Median	8.7	8.4	8.7
Min ; Max	4.5 ; 19.5	3.5 ; 16.8	3.5 ; 19.5
Visit 10 (Week 8)			
N	38	40	78
Mean (SD)	9.3 (2.7)	10.3 (4.3)	9.8 (3.6)
Median	9.0	8.6	8.7
Min ; Max	4.4 ; 17.1	2.9 ; 21.3	2.9 ; 21.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mmol/L)			
Visit 11 (Week 9)			
N	38	40	78
Mean (SD)	8.8 (2.7)	9.4 (3.2)	9.1 (3.0)
Median	8.3	9.0	8.7
Min ; Max	5.0 ; 16.9	4.1 ; 16.6	4.1 ; 16.9
Visit 12 (Week 10)			
N	38	39	77
Mean (SD)	9.4 (3.0)	9.3 (3.7)	9.3 (3.4)
Median	9.1	8.2	8.7
Min ; Max	5.5 ; 20.1	3.7 ; 19.3	3.7 ; 20.1
Visit 13 (Week 11)			
N	38	39	77
Mean (SD)	9.4 (3.5)	9.9 (3.8)	9.7 (3.6)
Median	8.9	8.4	8.7
Min ; Max	4.6 ; 18.6	4.7 ; 19.1	4.6 ; 19.1
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	9.8 (3.3)	9.5 (3.5)	9.7 (3.4)
Median	9.1	8.6	8.9
Min ; Max	4.3 ; 20.3	3.9 ; 16.8	3.9 ; 20.3
Visit 15 (Week 13)			
N	38	39	77
Mean (SD)	8.8 (2.9)	10.2 (4.5)	9.5 (3.8)
Median	8.1	8.7	8.4
Min ; Max	4.7 ; 18.6	2.9 ; 21.8	2.9 ; 21.8
Visit 16 (Week 14)			
N	38	40	78
Mean (SD)	9.1 (2.4)	8.9 (3.3)	9.0 (2.9)
Median	8.7	8.8	8.8
Min ; Max	4.8 ; 14.9	3.1 ; 17.4	3.1 ; 17.4
Visit 17 (Week 15)			
N	38	38	76
Mean (SD)	8.8 (2.0)	9.9 (3.3)	9.4 (2.8)
Median	8.7	8.7	8.7
Min ; Max	4.7 ; 13.2	4.8 ; 16.6	4.7 ; 16.6
Visit 18 (Week 16)			
N	38	37	75
Mean (SD)	8.8 (2.6)	9.5 (3.4)	9.2 (3.0)
Median	8.6	9.1	9.0
Min ; Max	4.4 ; 14.8	3.6 ; 17.3	3.6 ; 17.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (1-5 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mmol/L)			
End of trial visit			
N	40	41	81
Mean (SD)	9.0 (2.7)	9.5 (3.7)	9.2 (3.2)
Median	9.0	9.1	9.0
Min ; Max	4.4 ; 14.8	1.8 ; 17.3	1.8 ; 17.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
Visit 3 (Week 1)			
N	40	41	81
Mean (SD)	12.6 (4.6)	11.2 (4.4)	11.9 (4.6)
Median	12.2	10.6	11.7
Min ; Max	3.8 ; 26.7	3.7 ; 19.7	3.7 ; 26.7
Visit 4 (Week 2)			
N	40	41	81
Mean (SD)	12.3 (5.1)	11.1 (5.4)	11.7 (5.2)
Median	11.4	10.3	10.9
Min ; Max	3.1 ; 22.9	3.9 ; 24.0	3.1 ; 24.0
Visit 5 (Week 3)			
N	40	40	80
Mean (SD)	10.8 (4.9)	10.4 (4.8)	10.6 (4.8)
Median	10.0	9.1	9.4
Min ; Max	3.4 ; 23.4	3.1 ; 22.5	3.1 ; 23.4
Visit 6 (Week 4)			
N	40	40	80
Mean (SD)	11.7 (4.7)	10.2 (4.6)	11.0 (4.7)
Median	10.1	9.1	9.8
Min ; Max	4.8 ; 25.7	3.8 ; 21.0	3.8 ; 25.7
Visit 7 (Week 5)			
N	39	40	79
Mean (SD)	11.6 (3.8)	10.5 (4.0)	11.1 (3.9)
Median	10.3	10.2	10.3
Min ; Max	5.7 ; 23.5	4.3 ; 20.8	4.3 ; 23.5
Visit 8 (Week 6)			
N	40	40	80
Mean (SD)	11.4 (4.3)	10.1 (4.0)	10.7 (4.2)
Median	10.6	9.3	10.1
Min ; Max	2.7 ; 23.3	3.5 ; 24.4	2.7 ; 24.4
Visit 9 (Week 7)			
N	40	40	80
Mean (SD)	10.5 (3.5)	10.2 (4.2)	10.4 (3.8)
Median	9.5	9.7	9.7
Min ; Max	3.9 ; 20.8	4.2 ; 25.4	3.9 ; 25.4
Visit 10 (Week 8)			
N	38	40	78
Mean (SD)	11.6 (4.3)	11.4 (3.4)	11.5 (3.8)
Median	11.0	11.0	11.0
Min ; Max	5.5 ; 25.1	3.7 ; 20.6	3.7 ; 25.1

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
Visit 11 (Week 9)			
N	38	40	78
Mean (SD)	9.5 (3.0)	10.1 (3.7)	9.8 (3.4)
Median	9.2	9.7	9.4
Min ; Max	4.2 ; 18.1	4.1 ; 23.5	4.1 ; 23.5
Visit 12 (Week 10)			
N	38	39	77
Mean (SD)	10.4 (3.7)	11.2 (4.1)	10.8 (3.9)
Median	9.9	10.3	10.1
Min ; Max	3.8 ; 18.1	4.9 ; 23.0	3.8 ; 23.0
Visit 13 (Week 11)			
N	38	39	77
Mean (SD)	10.2 (3.6)	10.1 (3.7)	10.2 (3.6)
Median	9.3	9.3	9.3
Min ; Max	4.8 ; 21.0	4.7 ; 23.1	4.7 ; 23.1
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	10.0 (4.1)	9.5 (3.6)	9.7 (3.9)
Median	9.0	8.5	8.5
Min ; Max	5.0 ; 23.1	4.8 ; 19.2	4.8 ; 23.1
Visit 15 (Week 13)			
N	38	39	77
Mean (SD)	10.7 (4.3)	11.1 (3.5)	10.9 (3.9)
Median	10.1	10.6	10.5
Min ; Max	4.2 ; 20.4	4.1 ; 21.4	4.1 ; 21.4
Visit 16 (Week 14)			
N	38	40	78
Mean (SD)	9.9 (3.4)	9.7 (3.8)	9.8 (3.6)
Median	9.2	8.9	9.0
Min ; Max	4.2 ; 19.2	4.0 ; 20.2	4.0 ; 20.2
Visit 17 (Week 15)			
N	38	38	76
Mean (SD)	11.2 (3.4)	10.0 (3.3)	10.6 (3.4)
Median	10.5	9.2	9.9
Min ; Max	5.8 ; 19.1	4.4 ; 18.9	4.4 ; 19.1
Visit 18 (Week 16)			
N	38	37	75
Mean (SD)	9.9 (3.7)	9.7 (3.9)	9.8 (3.7)
Median	8.6	8.7	8.6
Min ; Max	5.3 ; 21.9	4.5 ; 20.9	4.5 ; 21.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
End of trial visit			
N	40	41	81
Mean (SD)	10.0 (3.6)	10.4 (4.3)	10.2 (3.9)
Median	8.8	9.1	8.9
Min ; Max	5.3 ; 21.9	4.5 ; 20.9	4.5 ; 21.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
Visit 3 (Week 1)			
N	40	41	81
Mean (SD)	13.3 (4.0)	13.0 (5.0)	13.1 (4.5)
Median	11.8	13.2	12.2
Min ; Max	5.7 ; 22.9	3.2 ; 23.0	3.2 ; 23.0
Visit 4 (Week 2)			
N	40	41	81
Mean (SD)	11.2 (4.0)	12.1 (4.2)	11.7 (4.1)
Median	11.0	11.3	11.2
Min ; Max	3.7 ; 23.6	5.4 ; 21.2	3.7 ; 23.6
Visit 5 (Week 3)			
N	40	40	80
Mean (SD)	11.5 (4.2)	10.5 (3.4)	11.0 (3.8)
Median	10.0	10.1	10.0
Min ; Max	5.8 ; 22.8	3.8 ; 18.7	3.8 ; 22.8
Visit 6 (Week 4)			
N	40	40	80
Mean (SD)	11.8 (2.9)	12.2 (4.3)	12.0 (3.7)
Median	11.5	12.2	11.9
Min ; Max	7.4 ; 18.7	4.7 ; 25.8	4.7 ; 25.8
Visit 7 (Week 5)			
N	39	40	79
Mean (SD)	11.3 (3.9)	12.3 (4.1)	11.8 (4.0)
Median	11.2	11.2	11.2
Min ; Max	4.2 ; 22.6	3.4 ; 20.8	3.4 ; 22.6
Visit 8 (Week 6)			
N	40	40	80
Mean (SD)	11.7 (4.0)	11.4 (3.7)	11.5 (3.9)
Median	11.4	11.0	11.1
Min ; Max	4.3 ; 21.0	5.6 ; 19.9	4.3 ; 21.0
Visit 9 (Week 7)			
N	40	40	80
Mean (SD)	11.0 (4.5)	11.2 (3.9)	11.1 (4.2)
Median	11.0	10.2	10.6
Min ; Max	2.5 ; 25.9	5.1 ; 22.6	2.5 ; 25.9
Visit 10 (Week 8)			
N	38	40	78
Mean (SD)	10.6 (3.3)	11.4 (4.3)	11.0 (3.8)
Median	10.9	10.3	10.5
Min ; Max	4.2 ; 19.6	4.4 ; 24.3	4.2 ; 24.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
Visit 11 (Week 9)			
N	38	40	78
Mean (SD)	11.1 (4.1)	10.7 (4.2)	10.9 (4.1)
Median	9.6	10.0	9.7
Min ; Max	4.5 ; 21.1	3.7 ; 24.2	3.7 ; 24.2
Visit 12 (Week 10)			
N	38	39	77
Mean (SD)	11.8 (4.9)	10.3 (3.8)	11.0 (4.5)
Median	11.1	10.4	10.6
Min ; Max	4.9 ; 26.6	3.8 ; 24.7	3.8 ; 26.6
Visit 13 (Week 11)			
N	38	39	77
Mean (SD)	10.4 (4.2)	11.9 (4.5)	11.2 (4.4)
Median	9.5	11.1	10.6
Min ; Max	4.3 ; 21.3	5.8 ; 24.5	4.3 ; 24.5
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	10.3 (4.4)	10.4 (3.8)	10.3 (4.1)
Median	9.2	9.2	9.2
Min ; Max	4.4 ; 22.4	5.8 ; 19.6	4.4 ; 22.4
Visit 15 (Week 13)			
N	38	39	77
Mean (SD)	12.0 (4.2)	11.8 (3.8)	11.9 (4.0)
Median	10.6	10.5	10.5
Min ; Max	6.1 ; 22.5	7.4 ; 24.1	6.1 ; 24.1
Visit 16 (Week 14)			
N	38	40	78
Mean (SD)	11.3 (4.0)	11.1 (3.9)	11.2 (3.9)
Median	10.6	10.7	10.6
Min ; Max	3.2 ; 21.3	3.4 ; 20.1	3.2 ; 21.3
Visit 17 (Week 15)			
N	38	38	76
Mean (SD)	10.7 (3.4)	12.3 (3.8)	11.5 (3.7)
Median	10.5	11.8	10.9
Min ; Max	2.7 ; 20.7	6.7 ; 25.5	2.7 ; 25.5
Visit 18 (Week 16)			
N	38	37	75
Mean (SD)	10.9 (3.7)	10.9 (4.5)	10.9 (4.1)
Median	10.3	9.9	9.9
Min ; Max	4.1 ; 22.6	5.3 ; 27.1	4.1 ; 27.1

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (1-5 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
End of trial visit			
N	40	41	81
Mean (SD)	10.9 (3.7)	10.5 (4.5)	10.7 (4.1)
Median	10.3	9.8	9.9
Min ; Max	4.1 ; 22.6	3.2 ; 27.1	3.2 ; 27.1

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
Visit 3 (Week 1)			
N	40	41	81
Mean (SD)	11.6 (4.5)	11.3 (3.9)	11.4 (4.2)
Median	10.7	10.7	10.7
Min ; Max	3.9 ; 22.2	3.6 ; 22.5	3.6 ; 22.5
Visit 4 (Week 2)			
N	39	41	80
Mean (SD)	11.8 (4.6)	11.8 (4.3)	11.8 (4.4)
Median	11.2	11.0	11.2
Min ; Max	4.9 ; 26.3	4.6 ; 20.7	4.6 ; 26.3
Visit 5 (Week 3)			
N	40	40	80
Mean (SD)	10.4 (4.2)	10.4 (4.5)	10.4 (4.3)
Median	9.2	9.1	9.1
Min ; Max	3.9 ; 25.3	4.1 ; 21.8	3.9 ; 25.3
Visit 6 (Week 4)			
N	39	40	79
Mean (SD)	11.6 (4.1)	10.7 (4.1)	11.2 (4.1)
Median	11.1	10.3	10.7
Min ; Max	4.7 ; 22.0	2.8 ; 22.4	2.8 ; 22.4
Visit 7 (Week 5)			
N	39	40	79
Mean (SD)	11.4 (4.4)	11.1 (5.1)	11.3 (4.8)
Median	10.6	10.0	10.3
Min ; Max	5.3 ; 21.7	4.4 ; 24.2	4.4 ; 24.2
Visit 8 (Week 6)			
N	40	40	80
Mean (SD)	11.2 (4.3)	10.2 (2.9)	10.7 (3.7)
Median	10.3	10.2	10.3
Min ; Max	5.5 ; 23.8	4.7 ; 16.9	4.7 ; 23.8
Visit 9 (Week 7)			
N	40	40	80
Mean (SD)	11.6 (4.2)	10.5 (4.1)	11.0 (4.2)
Median	11.1	9.9	10.4
Min ; Max	6.5 ; 24.4	3.2 ; 23.1	3.2 ; 24.4
Visit 10 (Week 8)			
N	37	40	77
Mean (SD)	11.7 (4.6)	11.2 (4.2)	11.4 (4.4)
Median	10.4	11.1	10.6
Min ; Max	5.1 ; 24.5	3.5 ; 20.6	3.5 ; 24.5

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
Visit 11 (Week 9)			
N	38	40	78
Mean (SD)	10.3 (3.2)	10.8 (4.4)	10.5 (3.8)
Median	9.7	10.1	10.0
Min ; Max	4.3 ; 19.7	4.4 ; 19.9	4.3 ; 19.9
Visit 12 (Week 10)			
N	38	39	77
Mean (SD)	10.7 (3.5)	11.0 (4.6)	10.9 (4.0)
Median	10.3	11.0	10.4
Min ; Max	3.6 ; 17.9	4.5 ; 25.8	3.6 ; 25.8
Visit 13 (Week 11)			
N	38	39	77
Mean (SD)	10.2 (3.6)	10.6 (3.8)	10.4 (3.6)
Median	9.6	9.8	9.7
Min ; Max	4.6 ; 18.1	5.2 ; 20.4	4.6 ; 20.4
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	12.0 (4.6)	11.1 (3.4)	11.5 (4.1)
Median	11.3	11.2	11.3
Min ; Max	3.6 ; 23.7	5.2 ; 17.7	3.6 ; 23.7
Visit 15 (Week 13)			
N	38	39	77
Mean (SD)	10.7 (3.3)	11.2 (4.6)	11.0 (4.0)
Median	10.1	10.2	10.2
Min ; Max	5.7 ; 17.6	4.6 ; 22.2	4.6 ; 22.2
Visit 16 (Week 14)			
N	38	40	78
Mean (SD)	11.9 (4.1)	10.1 (3.0)	11.0 (3.6)
Median	11.3	9.5	10.4
Min ; Max	5.0 ; 20.5	5.4 ; 18.8	5.0 ; 20.5
Visit 17 (Week 15)			
N	38	38	76
Mean (SD)	10.9 (4.0)	10.5 (3.9)	10.7 (4.0)
Median	10.7	9.7	10.6
Min ; Max	4.8 ; 24.2	3.7 ; 19.7	3.7 ; 24.2
Visit 18 (Week 16)			
N	38	37	75
Mean (SD)	10.8 (3.7)	9.9 (3.1)	10.4 (3.4)
Median	10.5	9.5	10.1
Min ; Max	4.8 ; 19.0	3.0 ; 17.2	3.0 ; 19.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (1-5 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
End of trial visit			
N	40	41	81
Mean (SD)	10.8 (3.8)	10.3 (3.6)	10.5 (3.7)
Median	10.5	9.5	10.2
Min ; Max	4.8 ; 19.0	3.0 ; 20.4	3.0 ; 20.4

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
Visit 3 (Week 1)			
N	40	41	81
Mean (SD)	174.0 (67.2)	218.1 (95.8)	196.3 (85.4)
Median	176.6	201.6	188.0
Min ; Max	67.0 ; 322.0	72.7 ; 460.1	67.0 ; 460.1
Visit 4 (Week 2)			
N	40	41	81
Mean (SD)	174.1 (66.9)	200.3 (84.8)	187.4 (77.1)
Median	159.8	179.0	176.0
Min ; Max	57.1 ; 300.3	68.3 ; 401.0	57.1 ; 401.0
Visit 5 (Week 3)			
N	40	40	80
Mean (SD)	174.2 (67.0)	192.6 (78.6)	183.4 (73.2)
Median	167.6	182.5	172.4
Min ; Max	71.0 ; 394.0	87.3 ; 450.0	71.0 ; 450.0
Visit 6 (Week 4)			
N	40	40	80
Mean (SD)	168.4 (64.2)	193.0 (83.9)	180.7 (75.3)
Median	165.5	171.8	166.4
Min ; Max	49.7 ; 327.9	85.0 ; 385.0	49.7 ; 385.0
Visit 7 (Week 5)			
N	39	40	79
Mean (SD)	168.5 (61.2)	195.2 (78.0)	182.0 (71.1)
Median	166.0	179.1	171.8
Min ; Max	64.0 ; 303.9	91.3 ; 376.6	64.0 ; 376.6
Visit 8 (Week 6)			
N	40	40	80
Mean (SD)	170.8 (63.3)	170.4 (66.8)	170.6 (64.7)
Median	153.1	156.1	155.3
Min ; Max	85.7 ; 352.6	56.7 ; 317.3	56.7 ; 352.6
Visit 9 (Week 7)			
N	40	40	80
Mean (SD)	162.6 (47.9)	165.9 (62.8)	164.2 (55.5)
Median	156.5	152.0	155.9
Min ; Max	81.3 ; 350.8	62.7 ; 303.0	62.7 ; 350.8
Visit 10 (Week 8)			
N	38	40	78
Mean (SD)	166.9 (47.8)	185.0 (78.1)	176.2 (65.3)
Median	161.9	155.1	157.4
Min ; Max	78.7 ; 308.1	51.7 ; 384.3	51.7 ; 384.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
Visit 11 (Week 9)			
N	38	40	78
Mean (SD)	159.0 (49.3)	170.3 (58.0)	164.8 (53.9)
Median	148.7	162.2	157.1
Min ; Max	89.5 ; 305.1	74.0 ; 299.3	74.0 ; 305.1
Visit 12 (Week 10)			
N	38	39	77
Mean (SD)	169.0 (53.8)	167.0 (67.0)	168.0 (60.5)
Median	164.6	148.0	156.6
Min ; Max	98.7 ; 362.8	66.7 ; 348.6	66.7 ; 362.8
Visit 13 (Week 11)			
N	38	39	77
Mean (SD)	170.0 (63.0)	178.7 (68.2)	174.4 (65.4)
Median	160.2	151.4	157.0
Min ; Max	82.7 ; 336.0	85.5 ; 344.7	82.7 ; 344.7
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	176.8 (60.0)	172.0 (63.4)	174.4 (61.4)
Median	163.4	155.6	160.3
Min ; Max	77.5 ; 366.6	70.3 ; 303.3	70.3 ; 366.6
Visit 15 (Week 13)			
N	38	39	77
Mean (SD)	159.4 (52.9)	184.2 (80.6)	172.0 (69.1)
Median	146.8	157.4	151.0
Min ; Max	85.3 ; 334.6	52.9 ; 392.3	52.9 ; 392.3
Visit 16 (Week 14)			
N	38	40	78
Mean (SD)	163.5 (43.4)	161.1 (58.7)	162.3 (51.5)
Median	157.1	157.7	157.7
Min ; Max	86.0 ; 269.3	56.5 ; 313.0	56.5 ; 313.0
Visit 17 (Week 15)			
N	38	38	76
Mean (SD)	158.6 (36.0)	178.4 (59.9)	168.5 (50.1)
Median	155.9	157.5	156.5
Min ; Max	84.3 ; 237.6	86.3 ; 299.3	84.3 ; 299.3
Visit 18 (Week 16)			
N	38	37	75
Mean (SD)	158.9 (46.9)	171.7 (60.5)	165.2 (54.1)
Median	155.5	163.4	162.6
Min ; Max	80.0 ; 266.1	64.7 ; 311.6	64.7 ; 311.6

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (1-5 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
End of trial visit			
N	40	41	81
Mean (SD)	162.5 (48.5)	170.7 (66.2)	166.6 (57.9)
Median	161.5	163.4	162.8
Min ; Max	80.0 ; 266.1	32.0 ; 311.6	32.0 ; 311.6

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
Visit 3 (Week 1)			
N	40	41	81
Mean (SD)	227.4 (83.4)	201.3 (79.7)	214.2 (82.1)
Median	219.3	191.3	211.6
Min ; Max	68.5 ; 481.9	66.1 ; 355.0	66.1 ; 481.9
Visit 4 (Week 2)			
N	40	41	81
Mean (SD)	221.0 (91.3)	199.6 (96.5)	210.1 (94.0)
Median	205.6	186.2	196.6
Min ; Max	56.0 ; 412.0	71.0 ; 432.0	56.0 ; 432.0
Visit 5 (Week 3)			
N	40	40	80
Mean (SD)	194.7 (88.4)	186.6 (85.9)	190.6 (86.7)
Median	179.5	164.1	169.3
Min ; Max	61.3 ; 421.0	55.9 ; 405.5	55.9 ; 421.0
Visit 6 (Week 4)			
N	40	40	80
Mean (SD)	210.9 (84.9)	183.9 (83.3)	197.4 (84.6)
Median	182.0	164.5	177.1
Min ; Max	86.5 ; 462.6	69.3 ; 377.6	69.3 ; 462.6
Visit 7 (Week 5)			
N	39	40	79
Mean (SD)	209.0 (68.3)	189.5 (72.9)	199.2 (70.9)
Median	185.0	183.8	185.0
Min ; Max	102.7 ; 423.6	78.1 ; 375.6	78.1 ; 423.6
Visit 8 (Week 6)			
N	40	40	80
Mean (SD)	204.8 (78.2)	182.4 (72.8)	193.6 (75.9)
Median	190.7	167.1	181.5
Min ; Max	49.3 ; 420.0	62.3 ; 440.2	49.3 ; 440.2
Visit 9 (Week 7)			
N	40	40	80
Mean (SD)	188.9 (62.4)	184.6 (76.0)	186.8 (69.1)
Median	171.1	174.5	174.5
Min ; Max	69.7 ; 375.0	75.7 ; 457.9	69.7 ; 457.9
Visit 10 (Week 8)			
N	38	40	78
Mean (SD)	208.6 (76.6)	204.7 (60.5)	206.6 (68.4)
Median	197.5	198.9	197.5
Min ; Max	99.7 ; 452.0	66.7 ; 372.0	66.7 ; 452.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
Visit 11 (Week 9)			
N	38	40	78
Mean (SD)	170.5 (53.8)	182.0 (67.4)	176.4 (61.1)
Median	165.5	175.5	169.0
Min ; Max	75.7 ; 325.5	74.0 ; 424.3	74.0 ; 424.3
Visit 12 (Week 10)			
N	38	39	77
Mean (SD)	186.7 (67.1)	201.2 (73.1)	194.1 (70.1)
Median	178.7	185.0	181.3
Min ; Max	67.7 ; 325.6	87.7 ; 415.0	67.7 ; 415.0
Visit 13 (Week 11)			
N	38	39	77
Mean (SD)	183.4 (64.1)	182.5 (67.0)	182.9 (65.2)
Median	167.0	167.0	167.0
Min ; Max	85.7 ; 378.0	84.7 ; 416.8	84.7 ; 416.8
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	180.3 (74.4)	170.3 (65.6)	175.3 (69.8)
Median	162.0	153.2	153.3
Min ; Max	90.1 ; 415.5	86.5 ; 345.3	86.5 ; 415.5
Visit 15 (Week 13)			
N	38	39	77
Mean (SD)	192.1 (77.3)	200.9 (64.0)	196.6 (70.5)
Median	181.3	191.6	189.0
Min ; Max	75.3 ; 368.0	74.5 ; 385.0	74.5 ; 385.0
Visit 16 (Week 14)			
N	38	40	78
Mean (SD)	179.3 (62.1)	174.8 (68.5)	177.0 (65.1)
Median	165.9	159.5	162.0
Min ; Max	76.3 ; 346.0	72.1 ; 364.6	72.1 ; 364.6
Visit 17 (Week 15)			
N	38	38	76
Mean (SD)	201.6 (62.2)	179.9 (59.8)	190.8 (61.6)
Median	189.9	165.9	179.1
Min ; Max	104.3 ; 345.0	79.3 ; 340.3	79.3 ; 345.0
Visit 18 (Week 16)			
N	38	37	75
Mean (SD)	178.8 (66.2)	174.3 (69.7)	176.6 (67.5)
Median	155.4	156.2	155.6
Min ; Max	95.0 ; 395.2	81.7 ; 377.3	81.7 ; 395.2

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (1-5 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
End of trial visit			
N	40	41	81
Mean (SD)	180.5 (65.0)	186.9 (77.1)	183.7 (71.0)
Median	157.8	163.4	160.0
Min ; Max	95.0 ; 395.2	81.7 ; 377.3	81.7 ; 395.2

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
Visit 3 (Week 1)			
N	40	41	81
Mean (SD)	240.0 (72.9)	233.6 (90.3)	236.8 (81.7)
Median	212.8	238.6	220.0
Min ; Max	102.0 ; 412.0	58.3 ; 414.4	58.3 ; 414.4
Visit 4 (Week 2)			
N	40	41	81
Mean (SD)	201.5 (72.9)	218.3 (75.4)	210.0 (74.2)
Median	198.5	203.3	202.3
Min ; Max	66.3 ; 425.5	97.3 ; 381.3	66.3 ; 425.5
Visit 5 (Week 3)			
N	40	40	80
Mean (SD)	207.0 (75.8)	189.9 (60.7)	198.5 (68.7)
Median	179.6	182.3	180.5
Min ; Max	105.3 ; 411.3	69.1 ; 336.6	69.1 ; 411.3
Visit 6 (Week 4)			
N	40	40	80
Mean (SD)	213.2 (52.9)	220.1 (78.2)	216.6 (66.4)
Median	207.3	219.3	213.7
Min ; Max	133.3 ; 336.3	84.0 ; 464.4	84.0 ; 464.4
Visit 7 (Week 5)			
N	39	40	79
Mean (SD)	204.1 (70.5)	220.8 (73.6)	212.6 (72.1)
Median	201.6	202.3	201.6
Min ; Max	75.1 ; 406.6	60.5 ; 374.0	60.5 ; 406.6
Visit 8 (Week 6)			
N	40	40	80
Mean (SD)	209.9 (72.5)	205.3 (67.3)	207.6 (69.5)
Median	204.9	197.3	199.8
Min ; Max	77.3 ; 379.0	100.9 ; 358.0	77.3 ; 379.0
Visit 9 (Week 7)			
N	40	40	80
Mean (SD)	197.9 (81.3)	201.0 (69.7)	199.4 (75.2)
Median	197.5	183.6	191.3
Min ; Max	45.0 ; 466.1	92.5 ; 408.0	45.0 ; 466.1
Visit 10 (Week 8)			
N	38	40	78
Mean (SD)	190.9 (60.2)	206.1 (76.9)	198.7 (69.2)
Median	196.0	186.2	189.5
Min ; Max	75.7 ; 353.5	78.7 ; 438.0	75.7 ; 438.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
Visit 11 (Week 9)			
N	38	40	78
Mean (SD)	200.1 (73.4)	193.3 (75.5)	196.6 (74.1)
Median	172.6	179.6	174.9
Min ; Max	81.0 ; 380.0	67.3 ; 436.6	67.3 ; 436.6
Visit 12 (Week 10)			
N	38	39	77
Mean (SD)	212.8 (88.9)	185.3 (69.1)	198.9 (80.2)
Median	200.8	186.8	191.0
Min ; Max	89.0 ; 479.6	68.0 ; 445.0	68.0 ; 479.6
Visit 13 (Week 11)			
N	38	39	77
Mean (SD)	187.6 (75.3)	214.4 (81.1)	201.2 (78.9)
Median	170.7	199.3	191.0
Min ; Max	78.0 ; 383.0	103.9 ; 440.8	78.0 ; 440.8
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	185.4 (79.2)	187.1 (69.2)	186.3 (73.8)
Median	165.5	166.5	166.5
Min ; Max	79.0 ; 403.3	104.0 ; 353.2	79.0 ; 403.3
Visit 15 (Week 13)			
N	38	39	77
Mean (SD)	215.8 (75.3)	212.8 (68.9)	214.3 (71.7)
Median	190.3	189.8	189.8
Min ; Max	110.3 ; 406.0	133.0 ; 434.2	110.3 ; 434.2
Visit 16 (Week 14)			
N	38	40	78
Mean (SD)	202.7 (71.3)	200.8 (69.8)	201.7 (70.1)
Median	191.8	193.4	191.8
Min ; Max	57.3 ; 384.0	61.3 ; 361.6	57.3 ; 384.0
Visit 17 (Week 15)			
N	38	38	76
Mean (SD)	192.7 (61.1)	220.9 (69.3)	206.8 (66.4)
Median	189.8	213.1	196.4
Min ; Max	49.3 ; 373.6	121.5 ; 458.9	49.3 ; 458.9
Visit 18 (Week 16)			
N	38	37	75
Mean (SD)	196.0 (66.7)	196.2 (80.6)	196.1 (73.4)
Median	186.3	178.6	179.0
Min ; Max	73.0 ; 407.6	94.7 ; 487.7	73.0 ; 487.7

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (1-5 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
End of trial visit			
N	40	41	81
Mean (SD)	196.3 (66.1)	190.0 (81.8)	193.1 (74.1)
Median	186.3	177.2	179.0
Min ; Max	73.0 ; 407.6	58.0 ; 487.7	58.0 ; 487.7

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
Visit 3 (Week 1)			
N	40	41	81
Mean (SD)	208.8 (81.1)	203.3 (70.6)	206.0 (75.5)
Median	193.2	192.0	192.8
Min ; Max	70.3 ; 400.6	64.9 ; 405.5	64.9 ; 405.5
Visit 4 (Week 2)			
N	39	41	80
Mean (SD)	211.9 (82.9)	212.8 (77.6)	212.4 (79.7)
Median	201.6	199.0	201.1
Min ; Max	88.3 ; 473.4	82.3 ; 372.3	82.3 ; 473.4
Visit 5 (Week 3)			
N	40	40	80
Mean (SD)	187.4 (75.4)	187.3 (80.6)	187.3 (77.6)
Median	165.6	163.7	163.7
Min ; Max	70.3 ; 456.4	73.3 ; 393.5	70.3 ; 456.4
Visit 6 (Week 4)			
N	39	40	79
Mean (SD)	208.8 (73.8)	193.4 (73.7)	201.0 (73.7)
Median	200.0	184.8	193.0
Min ; Max	84.1 ; 396.6	49.5 ; 403.0	49.5 ; 403.0
Visit 7 (Week 5)			
N	39	40	79
Mean (SD)	205.6 (80.1)	200.9 (91.7)	203.2 (85.7)
Median	191.0	179.8	186.2
Min ; Max	95.0 ; 391.0	78.7 ; 436.0	78.7 ; 436.0
Visit 8 (Week 6)			
N	40	40	80
Mean (SD)	201.8 (77.6)	183.4 (52.4)	192.6 (66.5)
Median	186.2	183.6	185.3
Min ; Max	99.3 ; 429.3	85.3 ; 303.6	85.3 ; 429.3
Visit 9 (Week 7)			
N	40	40	80
Mean (SD)	209.2 (75.0)	188.8 (74.5)	199.0 (75.0)
Median	200.8	177.6	186.8
Min ; Max	117.1 ; 440.0	58.0 ; 416.5	58.0 ; 440.0
Visit 10 (Week 8)			
N	37	40	77
Mean (SD)	211.1 (83.0)	201.4 (76.0)	206.1 (79.1)
Median	188.0	200.0	191.0
Min ; Max	92.0 ; 441.3	63.1 ; 371.3	63.1 ; 441.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (1-5 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
Visit 11 (Week 9)			
N	38	40	78
Mean (SD)	184.8 (58.2)	193.8 (78.7)	189.4 (69.2)
Median	174.5	182.7	180.5
Min ; Max	77.5 ; 354.6	78.7 ; 358.0	77.5 ; 358.0
Visit 12 (Week 10)			
N	38	39	77
Mean (SD)	193.0 (62.6)	198.4 (82.5)	195.7 (72.9)
Median	185.6	197.6	188.0
Min ; Max	64.9 ; 322.5	81.1 ; 464.0	64.9 ; 464.0
Visit 13 (Week 11)			
N	38	39	77
Mean (SD)	184.4 (64.1)	191.0 (67.6)	187.7 (65.5)
Median	173.3	176.6	174.8
Min ; Max	82.3 ; 326.3	93.0 ; 367.0	82.3 ; 367.0
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	215.3 (83.6)	200.5 (61.9)	207.8 (73.3)
Median	203.9	201.2	203.0
Min ; Max	65.5 ; 427.0	93.7 ; 318.3	65.5 ; 427.0
Visit 15 (Week 13)			
N	38	39	77
Mean (SD)	193.0 (59.3)	201.7 (83.0)	197.4 (71.9)
Median	182.6	183.2	183.2
Min ; Max	103.3 ; 316.5	83.7 ; 400.6	83.7 ; 400.6
Visit 16 (Week 14)			
N	38	40	78
Mean (SD)	215.0 (73.8)	182.6 (53.2)	198.4 (65.7)
Median	203.1	171.2	187.0
Min ; Max	89.3 ; 369.4	97.3 ; 338.5	89.3 ; 369.4
Visit 17 (Week 15)			
N	38	38	76
Mean (SD)	195.5 (72.5)	190.0 (71.0)	192.8 (71.4)
Median	192.6	175.1	190.6
Min ; Max	85.9 ; 436.5	67.3 ; 355.0	67.3 ; 436.5
Visit 18 (Week 16)			
N	38	37	75
Mean (SD)	194.8 (67.0)	178.2 (55.1)	186.6 (61.6)
Median	189.5	171.2	182.6
Min ; Max	86.5 ; 341.5	53.5 ; 310.0	53.5 ; 341.5

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (1-5 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
End of trial visit			
N	40	41	81
Mean (SD)	193.8 (68.2)	185.2 (65.7)	189.5 (66.7)
Median	189.5	171.8	184.0
Min ; Max	86.5 ; 341.5	53.5 ; 367.0	53.5 ; 367.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

14.2.363 Self measured plasma glucose for dose adjustment – descriptive statistics – children (6-11 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Before Breakfast(mmol/L)			
Visit 3 (Week 1)			
N	61	61	122
Mean (SD)	10.5 (4.2)	10.3 (3.8)	10.4 (4.0)
Median	9.8	9.3	9.6
Min ; Max	4.0 ; 20.1	4.3 ; 20.4	4.0 ; 20.4
Visit 4 (Week 2)			
N	61	60	121
Mean (SD)	9.9 (3.8)	10.2 (3.6)	10.0 (3.7)
Median	9.1	9.9	9.5
Min ; Max	4.2 ; 21.3	4.5 ; 18.3	4.2 ; 21.3
Visit 5 (Week 3)			
N	60	59	119
Mean (SD)	10.5 (4.6)	9.9 (3.8)	10.2 (4.2)
Median	9.6	9.0	9.3
Min ; Max	3.8 ; 23.4	3.5 ; 20.6	3.5 ; 23.4
Visit 6 (Week 4)			
N	60	59	119
Mean (SD)	9.1 (2.8)	9.6 (3.4)	9.3 (3.1)
Median	9.3	9.6	9.4
Min ; Max	4.3 ; 18.3	3.8 ; 20.6	3.8 ; 20.6
Visit 7 (Week 5)			
N	61	59	120
Mean (SD)	9.2 (3.1)	8.9 (2.4)	9.1 (2.8)
Median	8.3	9.0	8.6
Min ; Max	4.2 ; 20.3	3.7 ; 14.0	3.7 ; 20.3
Visit 8 (Week 6)			
N	61	59	120
Mean (SD)	8.9 (3.0)	9.1 (2.8)	9.0 (2.9)
Median	7.9	8.5	8.2
Min ; Max	4.2 ; 16.0	4.4 ; 17.4	4.2 ; 17.4
Visit 9 (Week 7)			
N	61	59	120
Mean (SD)	8.9 (2.8)	9.6 (3.4)	9.2 (3.1)
Median	8.5	9.1	8.8
Min ; Max	3.3 ; 18.8	4.7 ; 22.6	3.3 ; 22.6
Visit 10 (Week 8)			
N	61	59	120
Mean (SD)	9.6 (3.3)	9.7 (3.7)	9.7 (3.5)
Median	9.2	9.2	9.2
Min ; Max	4.5 ; 20.7	5.0 ; 23.5	4.5 ; 23.5

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mmol/L)			
Visit 11 (Week 9)			
N	61	59	120
Mean (SD)	9.5 (3.4)	9.4 (3.3)	9.4 (3.3)
Median	8.5	8.4	8.4
Min ; Max	4.9 ; 18.9	4.0 ; 23.0	4.0 ; 23.0
Visit 12 (Week 10)			
N	60	59	119
Mean (SD)	8.6 (3.2)	8.8 (3.0)	8.7 (3.1)
Median	7.6	8.4	8.1
Min ; Max	3.3 ; 16.9	4.5 ; 18.7	3.3 ; 18.7
Visit 13 (Week 11)			
N	60	59	119
Mean (SD)	8.6 (2.7)	9.7 (3.2)	9.2 (3.0)
Median	8.4	9.0	8.7
Min ; Max	3.4 ; 16.9	4.5 ; 22.3	3.4 ; 22.3
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	9.5 (3.0)	9.1 (2.8)	9.3 (2.9)
Median	9.1	8.7	8.8
Min ; Max	5.2 ; 18.2	4.6 ; 16.7	4.6 ; 18.2
Visit 15 (Week 13)			
N	60	59	119
Mean (SD)	9.3 (2.8)	8.7 (2.6)	9.0 (2.7)
Median	9.0	8.0	8.5
Min ; Max	4.6 ; 16.8	4.8 ; 16.2	4.6 ; 16.8
Visit 16 (Week 14)			
N	60	59	119
Mean (SD)	9.0 (2.8)	9.3 (3.3)	9.2 (3.0)
Median	8.6	9.0	9.0
Min ; Max	4.5 ; 16.1	4.8 ; 20.3	4.5 ; 20.3
Visit 17 (Week 15)			
N	60	59	119
Mean (SD)	9.7 (3.1)	9.5 (2.8)	9.6 (2.9)
Median	9.5	9.6	9.6
Min ; Max	4.6 ; 19.2	4.8 ; 17.2	4.6 ; 19.2
Visit 18 (Week 16)			
N	59	59	118
Mean (SD)	9.6 (3.1)	9.2 (3.5)	9.4 (3.3)
Median	9.4	8.8	9.2
Min ; Max	4.1 ; 18.5	3.7 ; 26.1	3.7 ; 26.1

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (6-11 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mmol/L)			
End of trial visit			
N	61	61	122
Mean (SD)	9.7 (3.1)	9.2 (3.5)	9.4 (3.3)
Median	9.7	8.8	9.2
Min ; Max	4.1 ; 18.5	3.7 ; 26.1	3.7 ; 26.1

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
Visit 3 (Week 1)			
N	61	61	122
Mean (SD)	11.6 (4.6)	9.6 (4.2)	10.6 (4.5)
Median	10.9	9.8	10.3
Min ; Max	4.3 ; 27.2	2.9 ; 23.6	2.9 ; 27.2
Visit 4 (Week 2)			
N	61	60	121
Mean (SD)	11.9 (5.3)	9.7 (3.6)	10.8 (4.6)
Median	10.8	9.3	9.7
Min ; Max	5.3 ; 27.7	3.7 ; 18.8	3.7 ; 27.7
Visit 5 (Week 3)			
N	60	59	119
Mean (SD)	10.0 (4.1)	10.0 (3.6)	10.0 (3.9)
Median	8.6	10.0	9.8
Min ; Max	4.1 ; 20.2	3.5 ; 28.9	3.5 ; 28.9
Visit 6 (Week 4)			
N	60	59	119
Mean (SD)	9.9 (3.8)	9.8 (4.2)	9.9 (4.0)
Median	9.0	8.7	8.8
Min ; Max	4.8 ; 20.5	4.6 ; 24.0	4.6 ; 24.0
Visit 7 (Week 5)			
N	60	59	119
Mean (SD)	10.7 (4.3)	9.2 (3.3)	10.0 (3.9)
Median	9.6	8.6	8.9
Min ; Max	3.7 ; 20.5	3.9 ; 20.1	3.7 ; 20.5
Visit 8 (Week 6)			
N	61	59	120
Mean (SD)	9.8 (3.2)	9.3 (3.7)	9.6 (3.4)
Median	9.5	8.5	8.8
Min ; Max	4.5 ; 19.0	2.4 ; 21.0	2.4 ; 21.0
Visit 9 (Week 7)			
N	61	59	120
Mean (SD)	10.0 (3.9)	9.0 (3.1)	9.5 (3.6)
Median	9.1	8.7	8.8
Min ; Max	3.7 ; 21.9	2.9 ; 17.5	2.9 ; 21.9
Visit 10 (Week 8)			
N	60	59	119
Mean (SD)	10.2 (4.2)	9.2 (3.6)	9.7 (3.9)
Median	9.3	8.7	9.0
Min ; Max	3.3 ; 22.7	4.3 ; 18.4	3.3 ; 22.7

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
Visit 11 (Week 9)			
N	61	59	120
Mean (SD)	9.7 (4.4)	9.9 (4.3)	9.8 (4.3)
Median	9.4	9.0	9.2
Min ; Max	3.3 ; 24.1	4.7 ; 28.0	3.3 ; 28.0
Visit 12 (Week 10)			
N	60	59	119
Mean (SD)	10.7 (4.3)	8.4 (2.9)	9.6 (3.8)
Median	9.4	8.0	8.6
Min ; Max	5.0 ; 26.2	3.5 ; 16.5	3.5 ; 26.2
Visit 13 (Week 11)			
N	60	59	119
Mean (SD)	10.0 (3.4)	9.4 (3.4)	9.7 (3.4)
Median	9.6	8.8	8.9
Min ; Max	4.7 ; 19.0	4.2 ; 19.8	4.2 ; 19.8
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	10.5 (4.6)	9.4 (3.1)	9.9 (3.9)
Median	9.7	9.0	9.4
Min ; Max	4.3 ; 23.6	4.2 ; 21.3	4.2 ; 23.6
Visit 15 (Week 13)			
N	59	59	118
Mean (SD)	9.7 (3.8)	9.2 (3.5)	9.5 (3.6)
Median	9.1	8.3	8.6
Min ; Max	4.3 ; 23.3	4.6 ; 20.3	4.3 ; 23.3
Visit 16 (Week 14)			
N	60	59	119
Mean (SD)	10.1 (3.7)	8.7 (2.7)	9.4 (3.3)
Median	9.1	8.4	8.6
Min ; Max	4.4 ; 20.2	4.6 ; 16.2	4.4 ; 20.2
Visit 17 (Week 15)			
N	60	59	119
Mean (SD)	10.6 (3.8)	9.4 (3.1)	10.0 (3.5)
Median	10.2	9.2	9.6
Min ; Max	4.6 ; 19.0	4.2 ; 18.9	4.2 ; 19.0
Visit 18 (Week 16)			
N	58	59	117
Mean (SD)	10.8 (4.8)	8.9 (3.6)	9.9 (4.3)
Median	9.9	8.3	8.8
Min ; Max	3.0 ; 27.0	3.9 ; 23.8	3.0 ; 27.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (6-11 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
End of trial visit			
N	61	61	122
Mean (SD)	10.8 (4.7)	9.0 (3.6)	9.9 (4.3)
Median	10.1	8.6	9.0
Min ; Max	3.0 ; 27.0	3.9 ; 23.8	3.0 ; 27.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
Visit 3 (Week 1)			
N	61	61	122
Mean (SD)	11.9 (4.9)	11.4 (4.6)	11.7 (4.8)
Median	10.8	10.8	10.8
Min ; Max	3.4 ; 31.1	5.2 ; 22.3	3.4 ; 31.1
Visit 4 (Week 2)			
N	61	60	121
Mean (SD)	11.2 (4.4)	10.4 (4.0)	10.8 (4.2)
Median	10.4	9.6	10.0
Min ; Max	4.3 ; 23.1	3.7 ; 21.1	3.7 ; 23.1
Visit 5 (Week 3)			
N	60	59	119
Mean (SD)	11.9 (4.6)	10.6 (4.3)	11.3 (4.4)
Median	11.6	9.2	10.3
Min ; Max	4.0 ; 24.5	4.4 ; 21.5	4.0 ; 24.5
Visit 6 (Week 4)			
N	60	59	119
Mean (SD)	10.7 (3.8)	10.5 (4.4)	10.6 (4.1)
Median	10.0	9.9	10.0
Min ; Max	4.4 ; 22.4	2.7 ; 22.7	2.7 ; 22.7
Visit 7 (Week 5)			
N	61	59	120
Mean (SD)	11.0 (4.4)	10.3 (3.5)	10.7 (3.9)
Median	9.7	10.3	9.9
Min ; Max	4.0 ; 23.9	5.2 ; 18.4	4.0 ; 23.9
Visit 8 (Week 6)			
N	61	59	120
Mean (SD)	10.3 (3.6)	10.3 (3.5)	10.3 (3.5)
Median	10.3	9.7	10.0
Min ; Max	3.1 ; 17.5	3.9 ; 21.8	3.1 ; 21.8
Visit 9 (Week 7)			
N	61	59	120
Mean (SD)	10.6 (3.4)	10.6 (3.6)	10.6 (3.5)
Median	10.0	10.7	10.1
Min ; Max	4.7 ; 21.9	3.2 ; 19.0	3.2 ; 21.9
Visit 10 (Week 8)			
N	61	59	120
Mean (SD)	10.9 (4.4)	10.4 (4.0)	10.7 (4.2)
Median	10.5	9.5	9.7
Min ; Max	2.2 ; 23.3	5.1 ; 21.1	2.2 ; 23.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
Visit 11 (Week 9)			
N	61	59	120
Mean (SD)	11.5 (4.5)	10.2 (3.7)	10.9 (4.1)
Median	10.7	9.0	9.8
Min ; Max	4.9 ; 28.4	4.1 ; 20.1	4.1 ; 28.4
Visit 12 (Week 10)			
N	60	59	119
Mean (SD)	11.2 (4.3)	10.0 (3.0)	10.6 (3.8)
Median	10.7	9.5	10.2
Min ; Max	4.2 ; 30.3	5.1 ; 20.1	4.2 ; 30.3
Visit 13 (Week 11)			
N	60	59	119
Mean (SD)	10.8 (4.2)	10.3 (3.8)	10.5 (4.0)
Median	9.7	9.2	9.4
Min ; Max	4.6 ; 25.4	2.6 ; 21.0	2.6 ; 25.4
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	10.1 (3.4)	10.5 (3.5)	10.3 (3.5)
Median	10.2	10.0	10.2
Min ; Max	2.9 ; 19.2	3.9 ; 20.5	2.9 ; 20.5
Visit 15 (Week 13)			
N	60	59	119
Mean (SD)	10.4 (4.1)	10.2 (3.9)	10.3 (4.0)
Median	9.6	9.5	9.5
Min ; Max	2.7 ; 20.4	5.2 ; 22.1	2.7 ; 22.1
Visit 16 (Week 14)			
N	60	59	119
Mean (SD)	10.3 (3.4)	10.5 (3.6)	10.4 (3.5)
Median	9.7	10.3	10.1
Min ; Max	5.0 ; 19.4	4.2 ; 19.4	4.2 ; 19.4
Visit 17 (Week 15)			
N	60	59	119
Mean (SD)	11.3 (3.9)	10.1 (3.4)	10.7 (3.7)
Median	11.0	9.4	9.8
Min ; Max	4.2 ; 21.7	5.1 ; 24.1	4.2 ; 24.1
Visit 18 (Week 16)			
N	59	59	118
Mean (SD)	10.8 (3.2)	10.2 (3.5)	10.5 (3.4)
Median	10.4	9.7	10.1
Min ; Max	4.9 ; 19.1	4.6 ; 23.9	4.6 ; 23.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (6-11 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
End of trial visit			
N	61	61	122
Mean (SD)	10.9 (3.3)	10.1 (3.5)	10.5 (3.4)
Median	10.6	9.7	10.1
Min ; Max	4.9 ; 19.1	3.8 ; 23.9	3.8 ; 23.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
Visit 3 (Week 1)			
N	59	61	120
Mean (SD)	11.3 (4.2)	9.8 (3.7)	10.6 (4.0)
Median	10.7	9.0	9.5
Min ; Max	2.7 ; 27.6	4.2 ; 21.0	2.7 ; 27.6
Visit 4 (Week 2)			
N	61	60	121
Mean (SD)	12.2 (4.4)	10.6 (3.8)	11.4 (4.2)
Median	11.5	9.7	10.7
Min ; Max	4.1 ; 21.8	3.5 ; 19.9	3.5 ; 21.8
Visit 5 (Week 3)			
N	60	58	118
Mean (SD)	11.4 (4.3)	9.9 (3.3)	10.6 (3.9)
Median	10.5	9.5	10.0
Min ; Max	3.7 ; 23.0	4.2 ; 19.8	3.7 ; 23.0
Visit 6 (Week 4)			
N	60	59	119
Mean (SD)	10.6 (4.2)	10.3 (3.9)	10.5 (4.0)
Median	9.5	8.9	9.3
Min ; Max	2.7 ; 25.2	3.8 ; 20.8	2.7 ; 25.2
Visit 7 (Week 5)			
N	61	59	120
Mean (SD)	11.0 (4.4)	9.6 (3.7)	10.3 (4.2)
Median	9.9	9.0	9.6
Min ; Max	3.9 ; 27.2	2.8 ; 21.0	2.8 ; 27.2
Visit 8 (Week 6)			
N	59	59	118
Mean (SD)	10.9 (4.2)	9.8 (3.3)	10.3 (3.8)
Median	10.6	9.2	9.9
Min ; Max	4.4 ; 20.2	3.7 ; 17.1	3.7 ; 20.2
Visit 9 (Week 7)			
N	60	59	119
Mean (SD)	11.5 (3.5)	9.6 (3.5)	10.6 (3.6)
Median	10.5	8.8	9.9
Min ; Max	6.0 ; 23.8	2.8 ; 17.0	2.8 ; 23.8
Visit 10 (Week 8)			
N	59	59	118
Mean (SD)	11.4 (4.1)	10.1 (3.1)	10.8 (3.7)
Median	11.0	9.8	10.2
Min ; Max	4.0 ; 22.9	3.1 ; 19.5	3.1 ; 22.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
Visit 11 (Week 9)			
N	60	59	119
Mean (SD)	10.8 (3.9)	9.5 (3.1)	10.2 (3.6)
Median	10.5	9.0	9.4
Min ; Max	4.1 ; 22.0	3.9 ; 18.0	3.9 ; 22.0
Visit 12 (Week 10)			
N	60	59	119
Mean (SD)	10.7 (4.0)	9.7 (3.4)	10.2 (3.7)
Median	9.5	9.1	9.4
Min ; Max	3.2 ; 23.0	3.3 ; 19.8	3.2 ; 23.0
Visit 13 (Week 11)			
N	59	59	118
Mean (SD)	10.6 (3.9)	9.5 (3.9)	10.1 (3.9)
Median	10.5	8.3	8.8
Min ; Max	3.6 ; 20.8	4.1 ; 20.4	3.6 ; 20.8
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	11.0 (3.9)	9.7 (3.3)	10.4 (3.7)
Median	10.9	9.8	10.1
Min ; Max	5.4 ; 22.1	4.0 ; 18.9	4.0 ; 22.1
Visit 15 (Week 13)			
N	59	59	118
Mean (SD)	11.0 (4.0)	9.2 (3.2)	10.1 (3.7)
Median	10.5	8.5	9.5
Min ; Max	4.3 ; 25.5	4.3 ; 18.8	4.3 ; 25.5
Visit 16 (Week 14)			
N	59	59	118
Mean (SD)	10.3 (3.6)	10.2 (3.7)	10.2 (3.7)
Median	9.9	9.8	9.8
Min ; Max	3.1 ; 21.3	2.9 ; 23.3	2.9 ; 23.3
Visit 17 (Week 15)			
N	60	59	119
Mean (SD)	11.3 (4.4)	10.2 (3.4)	10.8 (4.0)
Median	10.1	9.6	9.8
Min ; Max	3.2 ; 22.7	3.0 ; 17.9	3.0 ; 22.7
Visit 18 (Week 16)			
N	59	59	118
Mean (SD)	10.7 (4.6)	9.3 (3.3)	10.0 (4.0)
Median	9.0	8.8	8.9
Min ; Max	4.0 ; 24.3	3.7 ; 21.2	3.7 ; 24.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
End of trial visit			
N	61	61	122
Mean (SD)	10.8 (4.7)	9.3 (3.2)	10.0 (4.1)
Median	9.0	9.1	9.0
Min ; Max	4.0 ; 24.3	3.7 ; 21.2	3.7 ; 24.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
Visit 3 (Week 1)			
N	61	61	122
Mean (SD)	189.8 (75.4)	186.4 (69.0)	188.1 (72.0)
Median	177.0	167.0	172.1
Min ; Max	72.0 ; 363.0	76.7 ; 367.0	72.0 ; 367.0
Visit 4 (Week 2)			
N	61	60	121
Mean (SD)	178.5 (68.9)	182.9 (65.3)	180.7 (66.9)
Median	164.6	177.7	171.2
Min ; Max	75.7 ; 383.6	81.7 ; 330.3	75.7 ; 383.6
Visit 5 (Week 3)			
N	60	59	119
Mean (SD)	188.5 (82.8)	178.9 (68.8)	183.7 (76.0)
Median	173.6	162.8	168.2
Min ; Max	68.7 ; 421.0	63.1 ; 370.3	63.1 ; 421.0
Visit 6 (Week 4)			
N	60	59	119
Mean (SD)	163.7 (49.9)	173.2 (61.1)	168.4 (55.7)
Median	168.2	173.3	170.0
Min ; Max	76.7 ; 329.0	69.1 ; 370.3	69.1 ; 370.3
Visit 7 (Week 5)			
N	61	59	120
Mean (SD)	165.5 (56.7)	161.3 (44.1)	163.4 (50.7)
Median	148.9	162.3	155.5
Min ; Max	75.3 ; 366.6	67.3 ; 253.0	67.3 ; 366.6
Visit 8 (Week 6)			
N	61	59	120
Mean (SD)	160.2 (54.9)	163.8 (49.9)	162.0 (52.3)
Median	142.9	154.0	146.8
Min ; Max	76.5 ; 287.7	79.9 ; 313.5	76.5 ; 313.5
Visit 9 (Week 7)			
N	61	59	120
Mean (SD)	160.2 (49.6)	173.0 (60.7)	166.5 (55.5)
Median	153.8	164.6	159.2
Min ; Max	60.0 ; 338.6	84.7 ; 408.0	60.0 ; 408.0
Visit 10 (Week 8)			
N	61	59	120
Mean (SD)	173.3 (59.6)	175.4 (66.8)	174.3 (63.0)
Median	165.8	166.4	166.1
Min ; Max	80.5 ; 372.3	90.3 ; 423.0	80.5 ; 423.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
Visit 11 (Week 9)			
N	61	59	120
Mean (SD)	170.7 (61.1)	169.0 (59.7)	169.8 (60.1)
Median	152.6	152.0	152.0
Min ; Max	87.7 ; 341.0	72.7 ; 414.5	72.7 ; 414.5
Visit 12 (Week 10)			
N	60	59	119
Mean (SD)	155.4 (58.1)	158.5 (54.4)	156.9 (56.1)
Median	136.3	152.0	145.9
Min ; Max	59.7 ; 303.9	80.5 ; 336.6	59.7 ; 336.6
Visit 13 (Week 11)			
N	60	59	119
Mean (SD)	155.5 (49.4)	175.5 (57.2)	165.4 (54.1)
Median	152.0	161.6	157.4
Min ; Max	60.7 ; 305.1	81.1 ; 402.6	60.7 ; 402.6
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	171.5 (54.2)	164.9 (49.7)	168.2 (51.9)
Median	164.1	156.0	158.6
Min ; Max	93.7 ; 328.0	83.7 ; 301.0	83.7 ; 328.0
Visit 15 (Week 13)			
N	60	59	119
Mean (SD)	167.7 (50.4)	156.2 (47.0)	162.0 (48.9)
Median	161.3	144.7	152.6
Min ; Max	82.0 ; 302.7	85.9 ; 292.6	82.0 ; 302.7
Visit 16 (Week 14)			
N	60	59	119
Mean (SD)	162.4 (50.6)	168.0 (58.6)	165.2 (54.6)
Median	154.4	162.8	161.3
Min ; Max	80.7 ; 290.0	85.9 ; 366.0	80.7 ; 366.0
Visit 17 (Week 15)			
N	60	59	119
Mean (SD)	174.0 (56.2)	170.7 (50.0)	172.4 (53.0)
Median	172.0	173.0	172.3
Min ; Max	82.9 ; 345.6	86.0 ; 310.3	82.9 ; 345.6
Visit 18 (Week 16)			
N	59	59	118
Mean (SD)	173.2 (55.7)	165.8 (62.9)	169.5 (59.2)
Median	169.6	158.0	165.2
Min ; Max	73.3 ; 332.7	67.0 ; 470.9	67.0 ; 470.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (6-11 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
End of trial visit			
N	61	61	122
Mean (SD)	174.4 (55.1)	165.0 (62.4)	169.7 (58.8)
Median	174.0	158.0	166.1
Min ; Max	73.3 ; 332.7	67.0 ; 470.9	67.0 ; 470.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
Visit 3 (Week 1)			
N	61	61	122
Mean (SD)	209.1 (83.5)	172.9 (76.0)	191.0 (81.6)
Median	196.6	176.6	185.5
Min ; Max	76.9 ; 489.6	52.3 ; 425.0	52.3 ; 489.6
Visit 4 (Week 2)			
N	61	60	121
Mean (SD)	213.8 (95.2)	175.6 (64.2)	194.9 (83.2)
Median	194.0	166.8	175.0
Min ; Max	94.9 ; 499.9	66.3 ; 339.6	66.3 ; 499.9
Visit 5 (Week 3)			
N	60	59	119
Mean (SD)	179.8 (74.1)	179.3 (65.4)	179.6 (69.6)
Median	155.3	179.6	177.2
Min ; Max	73.3 ; 364.6	62.5 ; 520.9	62.5 ; 520.9
Visit 6 (Week 4)			
N	60	59	119
Mean (SD)	179.1 (68.0)	176.5 (75.0)	177.8 (71.3)
Median	162.6	156.6	158.0
Min ; Max	85.7 ; 368.6	82.3 ; 432.3	82.3 ; 432.3
Visit 7 (Week 5)			
N	60	59	119
Mean (SD)	192.6 (77.5)	165.8 (59.4)	179.3 (70.1)
Median	173.4	155.6	161.0
Min ; Max	66.1 ; 368.6	69.7 ; 362.6	66.1 ; 368.6
Visit 8 (Week 6)			
N	61	59	120
Mean (SD)	176.9 (58.0)	167.6 (66.3)	172.3 (62.2)
Median	171.2	153.8	158.6
Min ; Max	81.1 ; 342.0	43.7 ; 378.4	43.7 ; 378.4
Visit 9 (Week 7)			
N	61	59	120
Mean (SD)	179.3 (69.8)	161.6 (56.5)	170.6 (64.0)
Median	164.6	156.8	158.6
Min ; Max	66.1 ; 394.6	52.9 ; 314.5	52.9 ; 394.6
Visit 10 (Week 8)			
N	60	59	119
Mean (SD)	184.5 (75.8)	165.6 (64.4)	175.1 (70.7)
Median	167.3	156.8	162.0
Min ; Max	60.0 ; 409.0	77.0 ; 330.9	60.0 ; 409.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
Visit 11 (Week 9)			
N	61	59	120
Mean (SD)	175.6 (78.8)	179.0 (77.9)	177.3 (78.1)
Median	168.8	162.2	165.6
Min ; Max	59.5 ; 433.6	84.7 ; 505.1	59.5 ; 505.1
Visit 12 (Week 10)			
N	60	59	119
Mean (SD)	192.3 (77.6)	151.7 (52.1)	172.1 (69.0)
Median	169.6	144.7	154.3
Min ; Max	89.5 ; 472.1	63.1 ; 297.3	63.1 ; 472.1
Visit 13 (Week 11)			
N	60	59	119
Mean (SD)	180.2 (60.6)	168.6 (62.1)	174.4 (61.4)
Median	173.5	159.2	159.8
Min ; Max	84.0 ; 342.6	75.3 ; 357.3	75.3 ; 357.3
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	188.3 (82.0)	168.6 (55.8)	178.5 (70.6)
Median	175.5	163.0	169.4
Min ; Max	78.1 ; 425.8	75.1 ; 383.8	75.1 ; 425.8
Visit 15 (Week 13)			
N	59	59	118
Mean (SD)	174.1 (69.1)	166.5 (62.6)	170.3 (65.7)
Median	164.6	148.9	155.5
Min ; Max	77.0 ; 419.6	82.7 ; 366.6	77.0 ; 419.6
Visit 16 (Week 14)			
N	60	59	119
Mean (SD)	181.2 (66.9)	157.3 (49.4)	169.4 (59.8)
Median	164.2	151.0	155.0
Min ; Max	79.3 ; 363.6	82.7 ; 291.6	79.3 ; 363.6
Visit 17 (Week 15)			
N	60	59	119
Mean (SD)	190.5 (68.6)	168.5 (55.8)	179.6 (63.3)
Median	184.6	166.4	172.3
Min ; Max	83.0 ; 342.3	75.1 ; 340.6	75.1 ; 342.3
Visit 18 (Week 16)			
N	58	59	117
Mean (SD)	194.7 (86.4)	161.1 (65.2)	177.7 (77.9)
Median	178.2	149.3	158.6
Min ; Max	54.7 ; 486.5	69.7 ; 428.8	54.7 ; 486.5

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (6-11 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
End of trial visit			
N	61	61	122
Mean (SD)	194.6 (85.3)	162.5 (64.9)	178.6 (77.2)
Median	181.4	154.4	161.4
Min ; Max	54.7 ; 486.5	69.7 ; 428.8	54.7 ; 486.5

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
Visit 3 (Week 1)			
N	61	61	122
Mean (SD)	214.7 (88.9)	205.7 (83.0)	210.2 (85.8)
Median	195.3	194.6	195.0
Min ; Max	62.0 ; 560.4	93.1 ; 402.4	62.0 ; 560.4
Visit 4 (Week 2)			
N	61	60	121
Mean (SD)	202.7 (78.6)	187.8 (71.3)	195.3 (75.1)
Median	188.0	172.2	179.6
Min ; Max	76.9 ; 416.8	67.0 ; 379.6	67.0 ; 416.8
Visit 5 (Week 3)			
N	60	59	119
Mean (SD)	214.6 (82.1)	191.7 (77.1)	203.3 (80.1)
Median	208.7	165.2	185.0
Min ; Max	71.5 ; 441.4	78.7 ; 388.0	71.5 ; 441.4
Visit 6 (Week 4)			
N	60	59	119
Mean (SD)	193.0 (68.8)	189.7 (78.4)	191.4 (73.4)
Median	181.0	178.3	179.6
Min ; Max	78.7 ; 403.6	48.0 ; 408.3	48.0 ; 408.3
Visit 7 (Week 5)			
N	61	59	120
Mean (SD)	197.9 (78.6)	186.4 (62.7)	192.3 (71.1)
Median	174.0	186.2	178.8
Min ; Max	71.7 ; 430.0	93.3 ; 332.0	71.7 ; 430.0
Visit 8 (Week 6)			
N	61	59	120
Mean (SD)	185.6 (65.3)	185.8 (62.6)	185.7 (63.7)
Median	186.2	175.4	180.4
Min ; Max	55.3 ; 315.6	69.7 ; 393.3	55.3 ; 393.3
Visit 9 (Week 7)			
N	61	59	120
Mean (SD)	191.6 (60.8)	190.4 (64.6)	191.0 (62.4)
Median	180.3	192.8	182.3
Min ; Max	85.3 ; 395.0	58.3 ; 342.9	58.3 ; 395.0
Visit 10 (Week 8)			
N	61	59	120
Mean (SD)	196.4 (79.5)	188.1 (72.6)	192.3 (76.0)
Median	189.8	171.8	175.1
Min ; Max	40.2 ; 420.0	91.3 ; 379.6	40.2 ; 420.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
Visit 11 (Week 9)			
N	61	59	120
Mean (SD)	207.3 (80.8)	183.3 (66.3)	195.5 (74.7)
Median	192.0	162.2	177.4
Min ; Max	88.9 ; 511.1	73.3 ; 361.3	73.3 ; 511.1
Visit 12 (Week 10)			
N	60	59	119
Mean (SD)	201.8 (78.3)	180.1 (54.1)	191.1 (68.0)
Median	192.9	172.0	184.4
Min ; Max	75.3 ; 545.3	92.3 ; 362.0	75.3 ; 545.3
Visit 13 (Week 11)			
N	60	59	119
Mean (SD)	193.8 (76.2)	186.1 (69.0)	190.0 (72.5)
Median	173.9	166.0	168.6
Min ; Max	82.0 ; 456.9	46.2 ; 379.0	46.2 ; 456.9
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	182.7 (61.1)	190.0 (63.8)	186.3 (62.3)
Median	184.5	179.3	184.4
Min ; Max	51.7 ; 345.3	70.3 ; 369.4	51.7 ; 369.4
Visit 15 (Week 13)			
N	60	59	119
Mean (SD)	187.2 (74.2)	184.4 (69.5)	185.8 (71.6)
Median	173.2	171.0	171.0
Min ; Max	49.0 ; 367.0	94.3 ; 397.5	49.0 ; 397.5
Visit 16 (Week 14)			
N	60	59	119
Mean (SD)	185.5 (61.2)	189.3 (65.0)	187.4 (62.9)
Median	174.8	185.0	182.3
Min ; Max	90.7 ; 349.3	75.7 ; 350.2	75.7 ; 350.2
Visit 17 (Week 15)			
N	60	59	119
Mean (SD)	203.3 (70.8)	182.5 (60.8)	193.0 (66.5)
Median	198.6	170.0	177.2
Min ; Max	75.3 ; 391.6	92.3 ; 434.2	75.3 ; 434.2
Visit 18 (Week 16)			
N	59	59	118
Mean (SD)	194.7 (58.1)	183.9 (63.2)	189.3 (60.7)
Median	187.4	174.6	181.9
Min ; Max	87.7 ; 344.5	82.0 ; 430.6	82.0 ; 430.6

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (6-11 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
End of trial visit			
N	61	61	122
Mean (SD)	197.0 (58.6)	181.8 (63.9)	189.4 (61.5)
Median	191.0	174.2	181.9
Min ; Max	87.7 ; 344.5	68.0 ; 430.6	68.0 ; 430.6

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
Visit 3 (Week 1)			
N	59	61	120
Mean (SD)	203.7 (75.9)	177.0 (65.8)	190.1 (71.9)
Median	192.3	161.6	172.0
Min ; Max	47.7 ; 497.3	75.7 ; 378.3	47.7 ; 497.3
Visit 4 (Week 2)			
N	61	60	121
Mean (SD)	219.6 (79.8)	191.1 (68.5)	205.4 (75.5)
Median	206.6	174.8	192.8
Min ; Max	73.0 ; 393.0	62.5 ; 359.2	62.5 ; 393.0
Visit 5 (Week 3)			
N	60	58	118
Mean (SD)	205.1 (77.6)	177.8 (59.2)	191.7 (70.2)
Median	188.7	171.6	180.5
Min ; Max	66.3 ; 414.0	76.0 ; 356.0	66.3 ; 414.0
Visit 6 (Week 4)			
N	60	59	119
Mean (SD)	191.2 (76.0)	186.0 (69.8)	188.7 (72.7)
Median	171.8	160.4	167.0
Min ; Max	48.0 ; 453.5	68.5 ; 375.4	48.0 ; 453.5
Visit 7 (Week 5)			
N	61	59	120
Mean (SD)	198.6 (80.1)	172.8 (67.2)	185.9 (74.9)
Median	179.0	162.8	172.5
Min ; Max	70.3 ; 489.9	50.0 ; 378.4	50.0 ; 489.9
Visit 8 (Week 6)			
N	59	59	118
Mean (SD)	195.9 (74.8)	175.9 (59.3)	185.9 (67.9)
Median	191.0	165.2	178.7
Min ; Max	79.9 ; 364.0	67.0 ; 307.5	67.0 ; 364.0
Visit 9 (Week 7)			
N	60	59	119
Mean (SD)	207.8 (63.9)	172.4 (62.5)	190.3 (65.4)
Median	188.3	159.2	178.6
Min ; Max	107.5 ; 428.0	50.5 ; 306.5	50.5 ; 428.0
Visit 10 (Week 8)			
N	59	59	118
Mean (SD)	205.0 (74.5)	182.8 (55.3)	193.9 (66.3)
Median	198.8	177.2	184.3
Min ; Max	72.3 ; 413.0	56.0 ; 350.8	56.0 ; 413.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - children (6-11 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
Visit 11 (Week 9)			
N	60	59	119
Mean (SD)	195.5 (70.5)	171.8 (55.3)	183.8 (64.2)
Median	189.6	162.2	170.0
Min ; Max	73.3 ; 396.0	69.7 ; 324.9	69.7 ; 396.0
Visit 12 (Week 10)			
N	60	59	119
Mean (SD)	193.5 (72.3)	174.0 (61.1)	183.9 (67.4)
Median	171.6	164.6	170.0
Min ; Max	58.3 ; 415.3	59.5 ; 356.5	58.3 ; 415.3
Visit 13 (Week 11)			
N	59	59	118
Mean (SD)	191.6 (70.7)	172.0 (69.8)	181.8 (70.6)
Median	190.0	149.5	159.1
Min ; Max	65.5 ; 374.6	74.3 ; 368.0	65.5 ; 374.6
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	198.9 (70.1)	174.9 (60.1)	187.0 (66.2)
Median	195.6	176.3	182.0
Min ; Max	97.3 ; 398.2	72.0 ; 341.3	72.0 ; 398.2
Visit 15 (Week 13)			
N	59	59	118
Mean (SD)	197.7 (72.0)	164.9 (57.8)	181.3 (67.1)
Median	188.6	154.0	170.6
Min ; Max	77.0 ; 459.5	77.5 ; 338.1	77.0 ; 459.5
Visit 16 (Week 14)			
N	59	59	118
Mean (SD)	185.5 (65.7)	183.3 (66.5)	184.4 (65.8)
Median	178.3	176.6	177.2
Min ; Max	56.5 ; 383.0	52.3 ; 420.4	52.3 ; 420.4
Visit 17 (Week 15)			
N	60	59	119
Mean (SD)	204.2 (80.0)	183.2 (61.8)	193.8 (72.1)
Median	182.1	172.4	176.6
Min ; Max	58.3 ; 408.5	53.5 ; 321.9	53.5 ; 408.5
Visit 18 (Week 16)			
N	59	59	118
Mean (SD)	192.2 (83.1)	166.8 (59.1)	179.5 (72.9)
Median	161.6	159.2	161.0
Min ; Max	71.5 ; 437.8	67.3 ; 382.6	67.3 ; 437.8

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – children (6-11 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
End of trial visit			
N	61	61	122
Mean (SD)	194.3 (84.4)	167.8 (58.5)	181.0 (73.6)
Median	161.6	164.0	162.8
Min ; Max	71.5 ; 437.8	67.3 ; 382.6	67.3 ; 437.8

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

14.2.364 Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	78	158
Before Breakfast(mmol/L)			
Visit 3 (Week 1)			
N	79	77	156
Mean (SD)	11.5 (4.1)	10.5 (4.1)	11.0 (4.1)
Median	11.5	10.1	10.4
Min ; Max	3.9 ; 20.0	4.2 ; 24.1	3.9 ; 24.1
Visit 4 (Week 2)			
N	80	77	157
Mean (SD)	10.8 (3.8)	11.2 (3.8)	11.0 (3.8)
Median	10.3	11.1	10.4
Min ; Max	3.4 ; 20.8	3.7 ; 22.0	3.4 ; 22.0
Visit 5 (Week 3)			
N	79	77	156
Mean (SD)	10.4 (3.7)	10.0 (3.5)	10.2 (3.6)
Median	10.4	9.6	10.0
Min ; Max	4.3 ; 21.1	3.7 ; 19.7	3.7 ; 21.1
Visit 6 (Week 4)			
N	78	76	154
Mean (SD)	10.2 (3.6)	10.7 (3.9)	10.4 (3.8)
Median	9.5	9.8	9.6
Min ; Max	4.8 ; 24.5	3.3 ; 22.9	3.3 ; 24.5
Visit 7 (Week 5)			
N	77	75	152
Mean (SD)	9.7 (3.2)	9.7 (3.2)	9.7 (3.2)
Median	9.6	9.1	9.1
Min ; Max	3.7 ; 17.6	5.1 ; 20.2	3.7 ; 20.2
Visit 8 (Week 6)			
N	78	75	153
Mean (SD)	9.9 (3.3)	9.4 (3.0)	9.6 (3.2)
Median	9.6	8.7	9.0
Min ; Max	3.9 ; 18.0	4.0 ; 17.4	3.9 ; 18.0
Visit 9 (Week 7)			
N	77	73	150
Mean (SD)	9.8 (2.9)	9.7 (3.0)	9.7 (3.0)
Median	9.1	9.0	9.1
Min ; Max	4.8 ; 16.8	4.5 ; 18.1	4.5 ; 18.1
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	9.4 (3.0)	9.5 (2.9)	9.5 (2.9)
Median	8.8	9.1	8.9
Min ; Max	4.8 ; 20.9	4.4 ; 18.1	4.4 ; 20.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.
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Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mmol/L)			
Visit 11 (Week 9)			
N	77	74	151
Mean (SD)	9.9 (3.2)	9.1 (3.0)	9.5 (3.1)
Median	9.3	8.4	9.0
Min ; Max	4.7 ; 21.5	3.4 ; 18.0	3.4 ; 21.5
Visit 12 (Week 10)			
N	77	74	151
Mean (SD)	9.6 (3.2)	9.4 (2.8)	9.5 (3.0)
Median	8.9	9.1	9.0
Min ; Max	4.6 ; 21.8	4.8 ; 19.7	4.6 ; 21.8
Visit 13 (Week 11)			
N	77	73	150
Mean (SD)	9.7 (3.0)	9.1 (3.1)	9.4 (3.1)
Median	8.9	8.3	8.7
Min ; Max	5.2 ; 19.4	3.4 ; 22.5	3.4 ; 22.5
Visit 14 (Week 12)			
N	76	74	150
Mean (SD)	9.3 (3.0)	9.7 (3.0)	9.5 (3.0)
Median	8.7	9.3	9.0
Min ; Max	4.4 ; 18.0	3.8 ; 18.4	3.8 ; 18.4
Visit 15 (Week 13)			
N	77	73	150
Mean (SD)	9.6 (2.9)	9.5 (2.9)	9.6 (2.9)
Median	9.0	9.1	9.0
Min ; Max	4.5 ; 19.0	4.9 ; 16.9	4.5 ; 19.0
Visit 16 (Week 14)			
N	77	71	148
Mean (SD)	9.9 (3.1)	9.5 (3.2)	9.7 (3.1)
Median	9.8	8.9	9.3
Min ; Max	3.8 ; 20.5	4.2 ; 17.7	3.8 ; 20.5
Visit 17 (Week 15)			
N	75	73	148
Mean (SD)	10.3 (3.5)	9.5 (3.1)	9.9 (3.3)
Median	9.5	9.0	9.3
Min ; Max	4.4 ; 19.8	3.8 ; 19.1	3.8 ; 19.8
Visit 18 (Week 16)			
N	75	69	144
Mean (SD)	9.4 (3.4)	9.5 (2.9)	9.5 (3.1)
Median	9.0	9.0	9.0
Min ; Max	4.4 ; 19.4	3.8 ; 17.4	3.8 ; 19.4

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mmol/L)			
End of trial visit			
N	80	77	157
Mean (SD)	9.6 (3.5)	9.7 (3.6)	9.6 (3.5)
Median	9.1	9.0	9.0
Min ; Max	4.4 ; 19.4	3.8 ; 22.8	3.8 ; 22.8

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
Visit 3 (Week 1)			
N	79	77	156
Mean (SD)	10.7 (4.0)	11.1 (4.2)	10.9 (4.1)
Median	10.2	10.5	10.5
Min ; Max	3.1 ; 20.9	3.1 ; 23.2	3.1 ; 23.2
Visit 4 (Week 2)			
N	80	77	157
Mean (SD)	10.6 (4.2)	10.6 (4.2)	10.6 (4.2)
Median	9.8	9.6	9.7
Min ; Max	3.7 ; 21.4	4.0 ; 26.5	3.7 ; 26.5
Visit 5 (Week 3)			
N	79	77	156
Mean (SD)	10.2 (3.9)	10.6 (4.1)	10.4 (4.0)
Median	9.5	9.8	9.7
Min ; Max	4.0 ; 23.0	4.7 ; 21.7	4.0 ; 23.0
Visit 6 (Week 4)			
N	78	76	154
Mean (SD)	9.6 (3.5)	10.4 (3.9)	10.0 (3.7)
Median	9.0	9.6	9.3
Min ; Max	2.9 ; 19.9	4.8 ; 21.6	2.9 ; 21.6
Visit 7 (Week 5)			
N	77	75	152
Mean (SD)	9.9 (3.4)	9.7 (3.3)	9.8 (3.3)
Median	8.8	9.4	9.1
Min ; Max	4.4 ; 19.9	3.7 ; 20.6	3.7 ; 20.6
Visit 8 (Week 6)			
N	78	75	153
Mean (SD)	9.3 (3.1)	9.6 (3.4)	9.4 (3.2)
Median	8.8	9.1	9.0
Min ; Max	3.7 ; 19.9	3.4 ; 19.6	3.4 ; 19.9
Visit 9 (Week 7)			
N	77	73	150
Mean (SD)	9.2 (3.1)	8.8 (3.1)	9.0 (3.1)
Median	8.7	8.1	8.3
Min ; Max	4.1 ; 20.4	4.1 ; 20.1	4.1 ; 20.4
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	9.9 (4.2)	9.0 (2.8)	9.4 (3.6)
Median	9.1	8.9	9.0
Min ; Max	3.7 ; 25.0	3.3 ; 15.1	3.3 ; 25.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
Visit 11 (Week 9)			
N	77	74	151
Mean (SD)	9.7 (3.9)	9.2 (2.9)	9.5 (3.4)
Median	9.2	8.8	9.0
Min ; Max	4.2 ; 26.1	3.9 ; 18.0	3.9 ; 26.1
Visit 12 (Week 10)			
N	77	74	151
Mean (SD)	9.3 (3.4)	9.0 (2.7)	9.2 (3.1)
Median	8.4	8.4	8.4
Min ; Max	3.0 ; 20.2	4.4 ; 15.2	3.0 ; 20.2
Visit 13 (Week 11)			
N	77	73	150
Mean (SD)	9.5 (3.7)	8.6 (2.9)	9.1 (3.4)
Median	8.6	8.3	8.4
Min ; Max	4.2 ; 25.7	2.9 ; 17.7	2.9 ; 25.7
Visit 14 (Week 12)			
N	76	74	150
Mean (SD)	9.6 (3.6)	9.1 (3.1)	9.4 (3.4)
Median	8.7	8.3	8.6
Min ; Max	3.4 ; 20.4	4.4 ; 20.4	3.4 ; 20.4
Visit 15 (Week 13)			
N	77	73	150
Mean (SD)	9.7 (3.2)	9.2 (3.1)	9.4 (3.2)
Median	9.2	8.4	8.7
Min ; Max	3.1 ; 20.3	2.8 ; 18.0	2.8 ; 20.3
Visit 16 (Week 14)			
N	77	71	148
Mean (SD)	9.6 (3.6)	9.6 (3.8)	9.6 (3.7)
Median	9.3	8.7	8.9
Min ; Max	3.0 ; 18.8	3.7 ; 21.4	3.0 ; 21.4
Visit 17 (Week 15)			
N	74	73	147
Mean (SD)	9.0 (3.2)	9.2 (2.9)	9.1 (3.0)
Median	8.5	8.7	8.6
Min ; Max	3.9 ; 18.4	3.8 ; 15.8	3.8 ; 18.4
Visit 18 (Week 16)			
N	75	69	144
Mean (SD)	9.5 (3.5)	9.3 (3.1)	9.4 (3.3)
Median	9.2	8.6	8.8
Min ; Max	4.0 ; 21.8	3.6 ; 17.7	3.6 ; 21.8

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mmol/L)			
End of trial visit			
N	80	77	157
Mean (SD)	9.6 (3.6)	9.4 (3.3)	9.5 (3.4)
Median	9.0	8.6	8.8
Min ; Max	4.0 ; 21.8	3.6 ; 21.1	3.6 ; 21.8

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
Visit 3 (Week 1)			
N	79	77	156
Mean (SD)	10.8 (4.4)	10.8 (4.3)	10.8 (4.4)
Median	10.0	10.1	10.0
Min ; Max	5.0 ; 27.5	3.6 ; 24.3	3.6 ; 27.5
Visit 4 (Week 2)			
N	80	77	157
Mean (SD)	10.9 (4.7)	10.7 (3.5)	10.8 (4.1)
Median	10.1	10.2	10.1
Min ; Max	2.1 ; 27.1	4.4 ; 20.0	2.1 ; 27.1
Visit 5 (Week 3)			
N	80	77	157
Mean (SD)	10.6 (4.2)	10.5 (4.4)	10.5 (4.3)
Median	9.5	9.5	9.5
Min ; Max	1.7 ; 22.6	4.5 ; 26.9	1.7 ; 26.9
Visit 6 (Week 4)			
N	77	76	153
Mean (SD)	9.7 (3.2)	10.5 (4.1)	10.1 (3.7)
Median	9.5	9.1	9.4
Min ; Max	3.7 ; 18.9	3.8 ; 23.7	3.7 ; 23.7
Visit 7 (Week 5)			
N	77	75	152
Mean (SD)	10.2 (3.7)	10.7 (3.7)	10.4 (3.7)
Median	9.6	10.3	9.9
Min ; Max	4.6 ; 20.7	4.6 ; 21.6	4.6 ; 21.6
Visit 8 (Week 6)			
N	78	75	153
Mean (SD)	10.3 (3.5)	9.9 (2.7)	10.1 (3.2)
Median	9.9	9.3	9.8
Min ; Max	4.2 ; 20.2	5.1 ; 17.8	4.2 ; 20.2
Visit 9 (Week 7)			
N	76	73	149
Mean (SD)	10.1 (3.6)	9.8 (3.7)	10.0 (3.6)
Median	9.5	8.9	9.3
Min ; Max	4.4 ; 21.5	2.3 ; 20.7	2.3 ; 21.5
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	10.3 (3.6)	10.1 (3.7)	10.2 (3.6)
Median	9.6	9.8	9.6
Min ; Max	4.8 ; 21.6	3.7 ; 20.6	3.7 ; 21.6

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
Visit 11 (Week 9)			
N	76	74	150
Mean (SD)	10.4 (3.7)	9.7 (3.4)	10.1 (3.6)
Median	9.2	9.5	9.4
Min ; Max	4.2 ; 19.8	2.9 ; 19.0	2.9 ; 19.8
Visit 12 (Week 10)			
N	77	73	150
Mean (SD)	9.7 (3.1)	9.7 (3.4)	9.7 (3.2)
Median	8.9	8.8	8.8
Min ; Max	2.4 ; 18.6	4.8 ; 22.7	2.4 ; 22.7
Visit 13 (Week 11)			
N	76	73	149
Mean (SD)	9.7 (3.6)	9.7 (3.4)	9.7 (3.5)
Median	9.4	8.6	9.1
Min ; Max	2.9 ; 19.7	3.5 ; 21.4	2.9 ; 21.4
Visit 14 (Week 12)			
N	76	74	150
Mean (SD)	10.7 (4.0)	10.3 (3.7)	10.5 (3.9)
Median	9.6	9.5	9.6
Min ; Max	4.6 ; 22.0	4.7 ; 21.9	4.6 ; 22.0
Visit 15 (Week 13)			
N	77	73	150
Mean (SD)	10.8 (3.5)	9.7 (3.6)	10.3 (3.6)
Median	10.4	8.8	9.7
Min ; Max	4.0 ; 21.8	5.2 ; 20.7	4.0 ; 21.8
Visit 16 (Week 14)			
N	77	71	148
Mean (SD)	9.9 (2.9)	9.8 (3.6)	9.8 (3.3)
Median	9.5	9.2	9.3
Min ; Max	4.8 ; 18.5	3.5 ; 24.5	3.5 ; 24.5
Visit 17 (Week 15)			
N	75	73	148
Mean (SD)	10.3 (3.1)	9.4 (3.2)	9.8 (3.2)
Median	9.8	9.2	9.6
Min ; Max	4.6 ; 22.2	2.4 ; 20.0	2.4 ; 22.2
Visit 18 (Week 16)			
N	75	69	144
Mean (SD)	10.5 (3.8)	9.4 (3.3)	10.0 (3.6)
Median	9.5	8.5	8.9
Min ; Max	4.2 ; 20.1	2.3 ; 20.2	2.3 ; 20.2

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mmol/L)			
End of trial visit			
N	80	77	157
Mean (SD)	10.6 (3.8)	9.4 (3.3)	10.0 (3.6)
Median	9.5	8.5	9.0
Min ; Max	4.2 ; 20.1	2.3 ; 20.2	2.3 ; 20.2

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
Visit 3 (Week 1)			
N	77	77	154
Mean (SD)	11.3 (4.0)	10.9 (3.8)	11.1 (3.9)
Median	10.7	10.9	10.7
Min ; Max	3.9 ; 22.2	4.0 ; 22.3	3.9 ; 22.3
Visit 4 (Week 2)			
N	78	77	155
Mean (SD)	10.7 (3.8)	10.2 (4.1)	10.5 (3.9)
Median	10.2	9.5	9.9
Min ; Max	2.6 ; 19.8	4.8 ; 27.2	2.6 ; 27.2
Visit 5 (Week 3)			
N	80	77	157
Mean (SD)	10.5 (4.7)	10.6 (4.0)	10.5 (4.4)
Median	9.7	9.6	9.6
Min ; Max	2.1 ; 27.8	4.7 ; 22.0	2.1 ; 27.8
Visit 6 (Week 4)			
N	77	75	152
Mean (SD)	10.1 (2.8)	9.7 (3.1)	9.9 (3.0)
Median	9.8	9.1	9.3
Min ; Max	4.8 ; 16.7	4.7 ; 17.8	4.7 ; 17.8
Visit 7 (Week 5)			
N	77	74	151
Mean (SD)	10.0 (3.9)	9.9 (3.7)	10.0 (3.8)
Median	9.0	9.4	9.1
Min ; Max	3.6 ; 21.7	4.2 ; 25.3	3.6 ; 25.3
Visit 8 (Week 6)			
N	78	74	152
Mean (SD)	10.2 (3.8)	9.7 (3.5)	9.9 (3.6)
Median	9.4	9.4	9.4
Min ; Max	4.3 ; 20.3	3.0 ; 25.7	3.0 ; 25.7
Visit 9 (Week 7)			
N	77	73	150
Mean (SD)	10.1 (3.7)	9.9 (3.5)	10.0 (3.6)
Median	9.3	9.3	9.3
Min ; Max	4.6 ; 24.8	3.4 ; 20.5	3.4 ; 24.8
Visit 10 (Week 8)			
N	76	73	149
Mean (SD)	10.2 (3.7)	9.5 (3.3)	9.8 (3.5)
Median	10.1	8.8	9.3
Min ; Max	4.0 ; 26.9	4.6 ; 21.2	4.0 ; 26.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
Visit 11 (Week 9)			
N	74	72	146
Mean (SD)	10.1 (3.7)	10.0 (3.7)	10.1 (3.7)
Median	9.3	8.8	9.3
Min ; Max	3.6 ; 19.8	4.7 ; 19.3	3.6 ; 19.8
Visit 12 (Week 10)			
N	77	74	151
Mean (SD)	10.4 (3.2)	9.6 (3.6)	10.0 (3.4)
Median	9.5	9.2	9.4
Min ; Max	4.2 ; 18.4	3.9 ; 23.8	3.9 ; 23.8
Visit 13 (Week 11)			
N	76	73	149
Mean (SD)	9.9 (3.7)	9.2 (3.1)	9.6 (3.4)
Median	9.3	9.4	9.4
Min ; Max	3.3 ; 20.6	4.2 ; 18.9	3.3 ; 20.6
Visit 14 (Week 12)			
N	76	74	150
Mean (SD)	9.4 (3.3)	10.0 (3.6)	9.7 (3.5)
Median	9.1	9.5	9.2
Min ; Max	4.6 ; 22.9	4.8 ; 22.6	4.6 ; 22.9
Visit 15 (Week 13)			
N	76	73	149
Mean (SD)	9.5 (3.2)	9.7 (3.3)	9.6 (3.2)
Median	9.1	9.8	9.2
Min ; Max	3.1 ; 23.3	2.8 ; 17.8	2.8 ; 23.3
Visit 16 (Week 14)			
N	76	71	147
Mean (SD)	10.1 (3.6)	10.1 (3.4)	10.1 (3.4)
Median	9.6	10.1	9.8
Min ; Max	4.3 ; 22.2	3.8 ; 19.5	3.8 ; 22.2
Visit 17 (Week 15)			
N	73	72	145
Mean (SD)	10.6 (4.0)	9.4 (3.0)	10.0 (3.6)
Median	10.0	9.3	9.5
Min ; Max	3.9 ; 21.1	4.5 ; 17.5	3.9 ; 21.1
Visit 18 (Week 16)			
N	74	69	143
Mean (SD)	10.0 (4.0)	9.7 (3.1)	9.9 (3.6)
Median	9.2	8.9	9.0
Min ; Max	2.4 ; 20.9	3.5 ; 19.2	2.4 ; 20.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mmol/L)			
End of trial visit			
N	80	77	157
Mean (SD)	9.9 (4.3)	9.7 (3.2)	9.8 (3.8)
Median	9.0	8.9	8.9
Min ; Max	2.4 ; 25.3	3.5 ; 19.2	2.4 ; 25.3

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
Visit 3 (Week 1)			
N	79	77	156
Mean (SD)	207.9 (74.7)	189.3 (73.1)	198.7 (74.3)
Median	206.6	182.0	186.6
Min ; Max	70.3 ; 359.6	75.7 ; 434.0	70.3 ; 434.0
Visit 4 (Week 2)			
N	80	77	157
Mean (SD)	194.3 (68.3)	201.2 (69.1)	197.7 (68.6)
Median	185.6	200.6	187.6
Min ; Max	61.3 ; 375.6	66.0 ; 397.0	61.3 ; 397.0
Visit 5 (Week 3)			
N	79	77	156
Mean (SD)	187.9 (66.2)	180.6 (62.3)	184.3 (64.2)
Median	187.4	173.6	179.9
Min ; Max	77.3 ; 380.2	66.7 ; 355.6	66.7 ; 380.2
Visit 6 (Week 4)			
N	78	76	154
Mean (SD)	183.0 (65.5)	192.1 (71.0)	187.5 (68.2)
Median	171.9	175.7	173.1
Min ; Max	85.9 ; 441.0	59.7 ; 413.3	59.7 ; 441.0
Visit 7 (Week 5)			
N	77	75	152
Mean (SD)	174.5 (57.0)	175.1 (57.9)	174.8 (57.2)
Median	173.3	164.0	164.5
Min ; Max	67.3 ; 318.0	92.5 ; 364.5	67.3 ; 364.5
Visit 8 (Week 6)			
N	78	75	153
Mean (SD)	177.7 (59.6)	169.6 (54.9)	173.8 (57.3)
Median	172.3	156.2	162.0
Min ; Max	69.7 ; 324.6	72.7 ; 313.0	69.7 ; 324.6
Visit 9 (Week 7)			
N	77	73	150
Mean (SD)	176.4 (52.4)	174.7 (54.9)	175.5 (53.5)
Median	164.0	162.6	163.3
Min ; Max	87.1 ; 302.0	80.5 ; 326.6	80.5 ; 326.6
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	170.2 (53.2)	171.5 (52.2)	170.9 (52.5)
Median	159.3	164.6	159.6
Min ; Max	86.7 ; 377.0	79.3 ; 326.7	79.3 ; 377.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
Visit 11 (Week 9)			
N	77	74	151
Mean (SD)	178.8 (57.9)	163.9 (54.6)	171.5 (56.6)
Median	168.2	150.9	161.6
Min ; Max	84.3 ; 386.6	61.9 ; 325.0	61.9 ; 386.6
Visit 12 (Week 10)			
N	77	74	151
Mean (SD)	172.7 (57.7)	169.8 (50.8)	171.3 (54.2)
Median	161.0	163.5	161.6
Min ; Max	83.7 ; 392.0	87.3 ; 355.6	83.7 ; 392.0
Visit 13 (Week 11)			
N	77	73	150
Mean (SD)	175.0 (54.9)	163.8 (55.0)	169.6 (55.0)
Median	160.0	150.2	155.9
Min ; Max	93.3 ; 350.0	60.7 ; 405.6	60.7 ; 405.6
Visit 14 (Week 12)			
N	76	74	150
Mean (SD)	168.2 (54.2)	174.3 (54.2)	171.2 (54.1)
Median	157.6	167.1	161.9
Min ; Max	78.7 ; 324.0	68.3 ; 332.0	68.3 ; 332.0
Visit 15 (Week 13)			
N	77	73	150
Mean (SD)	173.4 (52.8)	171.2 (52.5)	172.3 (52.5)
Median	162.2	163.4	162.2
Min ; Max	80.5 ; 342.3	88.3 ; 305.1	80.5 ; 342.3
Visit 16 (Week 14)			
N	77	71	148
Mean (SD)	177.7 (56.6)	170.4 (57.0)	174.2 (56.7)
Median	177.3	160.6	167.6
Min ; Max	68.0 ; 368.8	75.0 ; 319.5	68.0 ; 368.8
Visit 17 (Week 15)			
N	75	73	148
Mean (SD)	185.1 (63.1)	171.5 (55.8)	178.4 (59.8)
Median	171.0	161.3	167.8
Min ; Max	78.7 ; 357.4	68.3 ; 344.7	68.3 ; 357.4
Visit 18 (Week 16)			
N	75	69	144
Mean (SD)	170.0 (60.5)	171.0 (52.7)	170.5 (56.7)
Median	163.0	161.6	162.3
Min ; Max	78.4 ; 350.2	69.1 ; 314.1	69.1 ; 350.2

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Breakfast(mg/dL)			
End of trial visit			
N	80	77	157
Mean (SD)	172.3 (63.4)	175.4 (64.5)	173.9 (63.8)
Median	163.6	161.6	162.0
Min ; Max	78.4 ; 350.2	69.1 ; 410.0	69.1 ; 410.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
Visit 3 (Week 1)			
N	79	77	156
Mean (SD)	192.1 (71.6)	200.4 (75.7)	196.2 (73.5)
Median	183.8	189.2	188.6
Min ; Max	56.3 ; 376.0	56.0 ; 417.3	56.0 ; 417.3
Visit 4 (Week 2)			
N	80	77	157
Mean (SD)	190.7 (76.2)	190.9 (74.9)	190.8 (75.3)
Median	177.0	173.3	175.6
Min ; Max	67.0 ; 385.6	71.7 ; 477.5	67.0 ; 477.5
Visit 5 (Week 3)			
N	79	77	156
Mean (SD)	184.3 (70.5)	190.6 (74.2)	187.4 (72.2)
Median	171.8	176.6	175.0
Min ; Max	72.7 ; 414.0	85.3 ; 391.6	72.7 ; 414.0
Visit 6 (Week 4)			
N	78	76	154
Mean (SD)	172.8 (63.3)	188.1 (69.9)	180.3 (66.8)
Median	162.5	172.6	167.4
Min ; Max	51.7 ; 358.3	86.7 ; 388.3	51.7 ; 388.3
Visit 7 (Week 5)			
N	77	75	152
Mean (SD)	179.0 (61.2)	175.2 (59.9)	177.2 (60.4)
Median	158.6	169.0	164.3
Min ; Max	79.3 ; 359.3	67.3 ; 371.8	67.3 ; 371.8
Visit 8 (Week 6)			
N	78	75	153
Mean (SD)	168.1 (56.6)	172.3 (60.5)	170.2 (58.4)
Median	158.0	164.6	161.3
Min ; Max	67.3 ; 359.3	61.0 ; 353.6	61.0 ; 359.3
Visit 9 (Week 7)			
N	77	73	150
Mean (SD)	165.5 (55.6)	159.2 (55.2)	162.4 (55.3)
Median	156.0	146.0	150.0
Min ; Max	74.5 ; 367.3	73.3 ; 362.0	73.3 ; 367.3
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	178.4 (76.0)	161.4 (50.6)	170.1 (65.2)
Median	164.0	160.3	161.6
Min ; Max	66.7 ; 451.0	59.3 ; 271.3	59.3 ; 451.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
Visit 11 (Week 9)			
N	77	74	151
Mean (SD)	175.1 (70.2)	166.1 (52.4)	170.7 (62.1)
Median	165.0	158.3	161.6
Min ; Max	75.1 ; 469.9	71.0 ; 323.6	71.0 ; 469.9
Visit 12 (Week 10)			
N	77	74	151
Mean (SD)	167.8 (62.0)	162.8 (49.0)	165.3 (55.9)
Median	151.0	151.2	151.0
Min ; Max	54.7 ; 364.3	79.3 ; 273.6	54.7 ; 364.3
Visit 13 (Week 11)			
N	77	73	150
Mean (SD)	171.6 (66.7)	155.6 (52.9)	163.8 (60.7)
Median	155.6	148.7	151.4
Min ; Max	75.3 ; 462.9	52.3 ; 319.0	52.3 ; 462.9
Visit 14 (Week 12)			
N	76	74	150
Mean (SD)	173.0 (64.6)	164.4 (56.7)	168.8 (60.8)
Median	156.3	150.0	154.6
Min ; Max	61.0 ; 367.0	79.0 ; 367.3	61.0 ; 367.3
Visit 15 (Week 13)			
N	77	73	150
Mean (SD)	174.0 (58.6)	165.1 (56.2)	169.7 (57.4)
Median	166.4	151.6	156.8
Min ; Max	56.0 ; 365.0	49.7 ; 323.7	49.7 ; 365.0
Visit 16 (Week 14)			
N	77	71	148
Mean (SD)	172.8 (65.2)	172.1 (68.5)	172.4 (66.6)
Median	167.6	156.6	161.0
Min ; Max	53.7 ; 339.3	66.0 ; 385.6	53.7 ; 385.6
Visit 17 (Week 15)			
N	74	73	147
Mean (SD)	161.9 (56.8)	166.5 (52.1)	164.2 (54.4)
Median	152.6	156.6	154.3
Min ; Max	69.7 ; 332.0	69.1 ; 284.1	69.1 ; 332.0
Visit 18 (Week 16)			
N	75	69	144
Mean (SD)	170.7 (62.5)	168.3 (55.6)	169.6 (59.1)
Median	165.3	155.6	157.7
Min ; Max	72.1 ; 393.0	65.5 ; 318.9	65.5 ; 393.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Lunch(mg/dL)			
End of trial visit			
N	80	77	157
Mean (SD)	172.8 (65.0)	169.3 (59.3)	171.1 (62.1)
Median	162.5	155.6	159.0
Min ; Max	72.1 ; 393.0	65.5 ; 380.0	65.5 ; 393.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
Visit 3 (Week 1)			
N	79	77	156
Mean (SD)	194.8 (79.7)	194.9 (77.9)	194.9 (78.6)
Median	180.2	181.4	180.2
Min ; Max	91.0 ; 495.9	64.0 ; 437.2	64.0 ; 495.9
Visit 4 (Week 2)			
N	80	77	157
Mean (SD)	196.3 (83.9)	192.0 (63.2)	194.2 (74.3)
Median	182.0	184.4	182.6
Min ; Max	38.4 ; 487.4	78.7 ; 360.5	38.4 ; 487.4
Visit 5 (Week 3)			
N	80	77	157
Mean (SD)	190.7 (75.8)	189.1 (79.7)	189.9 (77.5)
Median	170.8	171.0	171.0
Min ; Max	30.0 ; 408.0	80.5 ; 484.6	30.0 ; 484.6
Visit 6 (Week 4)			
N	77	76	153
Mean (SD)	175.6 (57.8)	188.8 (73.9)	182.2 (66.4)
Median	170.3	164.3	169.0
Min ; Max	67.0 ; 341.1	68.5 ; 427.6	67.0 ; 427.6
Visit 7 (Week 5)			
N	77	75	152
Mean (SD)	183.6 (66.5)	192.8 (66.0)	188.1 (66.2)
Median	172.6	185.6	179.1
Min ; Max	83.7 ; 373.6	83.0 ; 389.5	83.0 ; 389.5
Visit 8 (Week 6)			
N	78	75	153
Mean (SD)	185.4 (63.6)	177.5 (49.3)	181.5 (57.0)
Median	178.6	167.6	176.0
Min ; Max	75.7 ; 364.0	92.0 ; 321.5	75.7 ; 364.0
Visit 9 (Week 7)			
N	76	73	149
Mean (SD)	182.0 (65.3)	176.5 (66.4)	179.3 (65.7)
Median	172.0	161.0	167.0
Min ; Max	79.7 ; 386.6	41.0 ; 372.6	41.0 ; 386.6
Visit 10 (Week 8)			
N	77	74	151
Mean (SD)	185.9 (65.1)	182.9 (66.5)	184.4 (65.6)
Median	172.4	177.1	173.3
Min ; Max	86.7 ; 389.6	66.0 ; 371.2	66.0 ; 389.6

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
Visit 11 (Week 9)			
N	76	74	150
Mean (SD)	187.4 (67.1)	175.6 (61.1)	181.6 (64.3)
Median	165.6	171.3	168.8
Min ; Max	75.0 ; 356.6	52.0 ; 341.6	52.0 ; 356.6
Visit 12 (Week 10)			
N	77	73	150
Mean (SD)	174.0 (55.7)	175.2 (61.3)	174.6 (58.3)
Median	161.0	159.2	159.4
Min ; Max	42.7 ; 335.0	86.3 ; 409.0	42.7 ; 409.0
Visit 13 (Week 11)			
N	76	73	149
Mean (SD)	175.3 (64.6)	175.2 (61.3)	175.2 (62.8)
Median	168.9	154.6	164.6
Min ; Max	52.9 ; 355.0	62.3 ; 386.2	52.9 ; 386.2
Visit 14 (Week 12)			
N	76	74	150
Mean (SD)	193.5 (72.4)	185.9 (66.7)	189.7 (69.5)
Median	173.8	170.8	172.3
Min ; Max	82.3 ; 397.0	84.7 ; 395.0	82.3 ; 397.0
Visit 15 (Week 13)			
N	77	73	150
Mean (SD)	194.3 (63.5)	175.4 (64.7)	185.1 (64.6)
Median	187.5	157.7	175.4
Min ; Max	72.0 ; 392.6	93.7 ; 372.3	72.0 ; 392.6
Visit 16 (Week 14)			
N	77	71	148
Mean (SD)	177.7 (52.5)	176.9 (65.0)	177.3 (58.7)
Median	171.3	165.6	167.6
Min ; Max	86.3 ; 333.3	62.5 ; 440.5	62.5 ; 440.5
Visit 17 (Week 15)			
N	75	73	148
Mean (SD)	185.1 (56.7)	169.5 (57.6)	177.4 (57.5)
Median	176.3	165.3	172.2
Min ; Max	83.3 ; 400.0	42.6 ; 359.6	42.6 ; 400.0
Visit 18 (Week 16)			
N	75	69	144
Mean (SD)	188.6 (68.2)	170.2 (59.5)	179.8 (64.6)
Median	171.3	153.6	159.9
Min ; Max	75.0 ; 362.8	41.0 ; 364.0	41.0 ; 364.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Evening Meal(mg/dL)			
End of trial visit			
N	80	77	157
Mean (SD)	191.3 (68.5)	169.0 (59.6)	180.4 (65.1)
Median	171.8	152.6	161.6
Min ; Max	75.0 ; 362.8	41.0 ; 364.0	41.0 ; 364.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
Visit 3 (Week 1)			
N	77	77	154
Mean (SD)	203.5 (72.5)	197.1 (69.3)	200.3 (70.7)
Median	192.6	196.4	192.7
Min ; Max	70.7 ; 399.6	72.1 ; 401.3	70.7 ; 401.3
Visit 4 (Week 2)			
N	78	77	155
Mean (SD)	193.5 (69.1)	184.1 (73.2)	188.8 (71.1)
Median	183.8	170.6	177.5
Min ; Max	46.0 ; 357.0	87.0 ; 490.9	46.0 ; 490.9
Visit 5 (Week 3)			
N	80	77	157
Mean (SD)	188.4 (85.3)	191.8 (72.2)	190.0 (78.9)
Median	174.5	172.3	172.6
Min ; Max	37.8 ; 500.9	85.3 ; 396.5	37.8 ; 500.9
Visit 6 (Week 4)			
N	77	75	152
Mean (SD)	181.3 (50.3)	175.5 (56.4)	178.4 (53.3)
Median	177.2	164.6	167.9
Min ; Max	87.0 ; 301.0	84.7 ; 321.0	84.7 ; 321.0
Visit 7 (Week 5)			
N	77	74	151
Mean (SD)	179.6 (69.8)	179.0 (67.2)	179.3 (68.3)
Median	161.6	169.2	163.6
Min ; Max	64.0 ; 391.0	76.3 ; 455.9	64.0 ; 455.9
Visit 8 (Week 6)			
N	78	74	152
Mean (SD)	183.4 (67.7)	174.2 (63.2)	178.9 (65.5)
Median	169.5	169.5	169.5
Min ; Max	77.7 ; 366.0	54.3 ; 463.3	54.3 ; 463.3
Visit 9 (Week 7)			
N	77	73	150
Mean (SD)	181.4 (65.9)	178.3 (63.1)	179.9 (64.4)
Median	167.3	167.6	167.5
Min ; Max	83.7 ; 446.5	62.0 ; 370.0	62.0 ; 446.5
Visit 10 (Week 8)			
N	76	73	149
Mean (SD)	183.8 (67.1)	170.4 (59.1)	177.3 (63.4)
Median	181.5	158.6	167.0
Min ; Max	72.3 ; 484.9	83.7 ; 382.5	72.3 ; 484.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment - descriptive statistics - adolescents (12-17 years) - full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
Visit 11 (Week 9)			
N	74	72	146
Mean (SD)	181.9 (67.2)	180.2 (66.3)	181.1 (66.6)
Median	168.0	158.3	167.4
Min ; Max	65.0 ; 356.8	85.0 ; 347.6	65.0 ; 356.8
Visit 12 (Week 10)			
N	77	74	151
Mean (SD)	187.5 (58.4)	173.1 (64.4)	180.4 (61.6)
Median	171.3	166.0	170.0
Min ; Max	75.0 ; 332.3	69.7 ; 429.0	69.7 ; 429.0
Visit 13 (Week 11)			
N	76	73	149
Mean (SD)	178.3 (66.4)	166.0 (56.1)	172.3 (61.7)
Median	167.8	168.6	168.6
Min ; Max	58.9 ; 371.5	75.0 ; 341.3	58.9 ; 371.5
Visit 14 (Week 12)			
N	76	74	150
Mean (SD)	168.7 (59.1)	179.8 (65.7)	174.2 (62.5)
Median	163.1	171.9	165.8
Min ; Max	83.5 ; 412.6	87.1 ; 408.0	83.5 ; 412.6
Visit 15 (Week 13)			
N	76	73	149
Mean (SD)	170.4 (58.4)	175.3 (58.9)	172.8 (58.5)
Median	164.0	177.3	165.3
Min ; Max	55.0 ; 419.0	50.5 ; 320.0	50.5 ; 419.0
Visit 16 (Week 14)			
N	76	71	147
Mean (SD)	182.5 (64.0)	181.7 (60.4)	182.1 (62.1)
Median	173.8	181.3	176.0
Min ; Max	77.5 ; 400.3	69.0 ; 350.5	69.0 ; 400.3
Visit 17 (Week 15)			
N	73	72	145
Mean (SD)	191.0 (71.9)	169.4 (54.7)	180.3 (64.6)
Median	180.3	167.5	170.6
Min ; Max	70.3 ; 380.5	80.5 ; 315.3	70.3 ; 380.5
Visit 18 (Week 16)			
N	74	69	143
Mean (SD)	179.9 (72.0)	175.5 (56.4)	177.8 (64.8)
Median	165.5	161.0	161.5
Min ; Max	44.0 ; 376.0	62.5 ; 346.6	44.0 ; 376.0

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

Self measured plasma glucose for dose adjustment – descriptive statistics – adolescents (12-17 years) – full analysis set - full analysis set

	IDegAsp OD	IDet	Total
Before Bedtime(mg/dL)			
End of trial visit			
N	80	77	157
Mean (SD)	179.2 (78.2)	174.4 (57.3)	176.9 (68.6)
Median	162.5	161.0	161.0
Min ; Max	44.0 ; 455.9	62.5 ; 346.6	44.0 ; 455.9

N: Number of subjects, SD: Standard deviation
Endpoint is calculated as the mean of the available SMPG values.

14.2.365 Self measured plasma glucose for dose adjustment after 16 treatment weeks - statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
Mean SMPG before breakfast (mmol/L)					
LSMeans					
IDegAsp OD	182	179	9.37	0.24	
IDet	180	179	9.49	0.24	
Treatment Contrast					
IDegAsp OD - IDet			-0.12		[-0.79; 0.56]
Mean SMPG before lunch (mmol/L)					
LSMeans					
IDegAsp OD	182	179	9.97	0.27	
IDet	180	176	9.42	0.28	
Treatment Contrast					
IDegAsp OD - IDet			0.54		[-0.22; 1.31]
Mean SMPG before evening main evening meal (mmol/L)					
LSMeans					
IDegAsp OD	182	179	10.60	0.26	
IDet	180	176	10.15	0.27	
Treatment Contrast					
IDegAsp OD - IDet			0.45		[-0.29; 1.19]
Mean SMPG before bedtime (mmol/L)					
LSMeans					
IDegAsp OD	182	159	10.17	0.29	
IDet	180	160	9.89	0.30	
Treatment Contrast					
IDegAsp OD - IDet			0.28		[-0.54; 1.11]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval
SE: Standard error of the mean
All observed mean in the 4-point profile measurements available post randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline values of the response as covariate. Interactions between visit and all factors and covariates are also included in the model.
Endpoint is calculated as the mean of the available SMPG values

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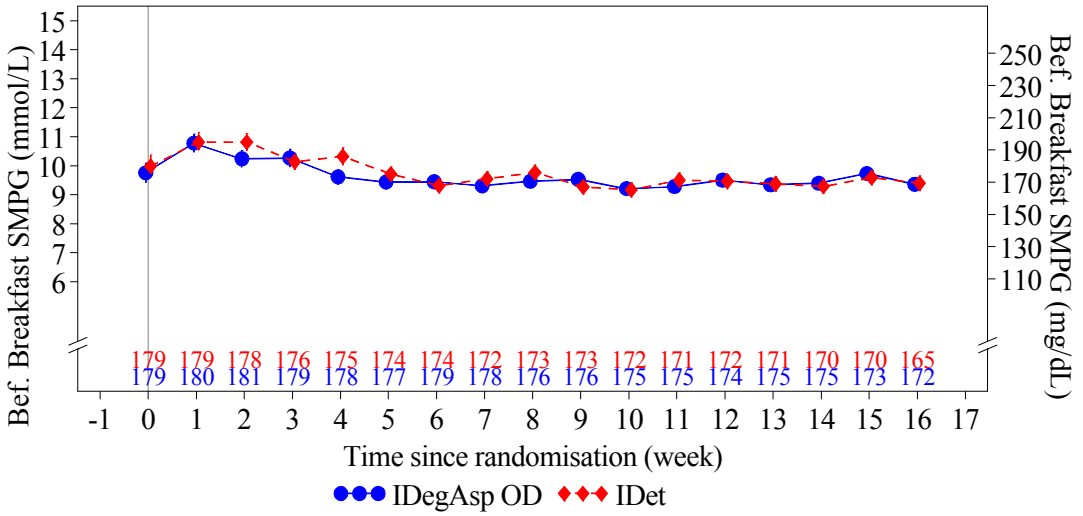
12MAR2015:08:44:03 - ID14217600_tstat_smpg_dose/t_smpg_stat_mmrm_fas.txt

Self measured plasma glucose for dose adjustment after 16 treatment weeks - statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
Mean SMPG before breakfast (mg/dL)					
LSMeans					
IDegAsp OD	182	179	168.78	4.32	
IDet	180	179	170.90	4.40	
Treatment Contrast					
IDegAsp OD - IDet			-2.12		[-14.29; 10.04]
Mean SMPG before lunch (mg/dL)					
LSMeans					
IDegAsp OD	182	179	179.58	4.87	
IDet	180	176	169.79	4.98	
Treatment Contrast					
IDegAsp OD - IDet			9.79		[-3.96; 23.54]
Mean SMPG before evening main evening meal (mg/dL)					
LSMeans					
IDegAsp OD	182	179	191.06	4.69	
IDet	180	176	182.93	4.82	
Treatment Contrast					
IDegAsp OD - IDet			8.13		[-5.15; 21.41]
Mean SMPG before bedtime (mg/dL)					
LSMeans					
IDegAsp OD	182	159	183.31	5.31	
IDet	180	160	178.19	5.35	
Treatment Contrast					
IDegAsp OD - IDet			5.13		[-9.76; 20.02]

FAS: Full analysis set, N: Number of subjects contributing to analysis, CI: Confidence interval
SE: Standard error of the mean
All observed mean in the 4-point profile measurements available post randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline values of the response as covariate. Interactions between visit and all factors and covariates are also included in the model.
Endpoint is calculated as the mean of the available SMPG values



FAS: Observed data
At Week0: values taken from 8-point SMPG profiles, Bef.: Before, SMPG: Self-measured plasma glucose,
FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.

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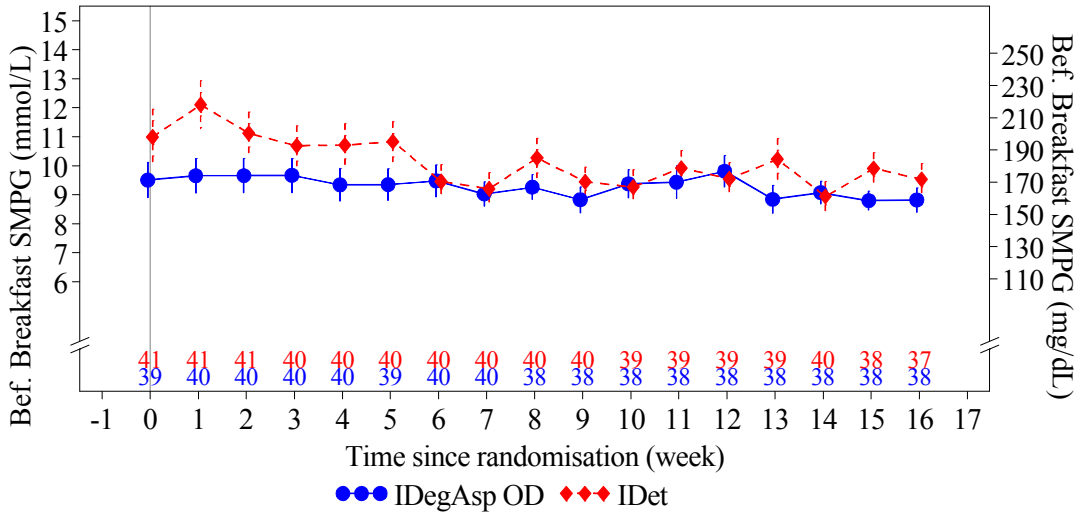
12MAR2015:08:44:14 - fmean_numfind_deg_cust.sas/e_smpg_ab_bf_mean_ob_fas.cgm

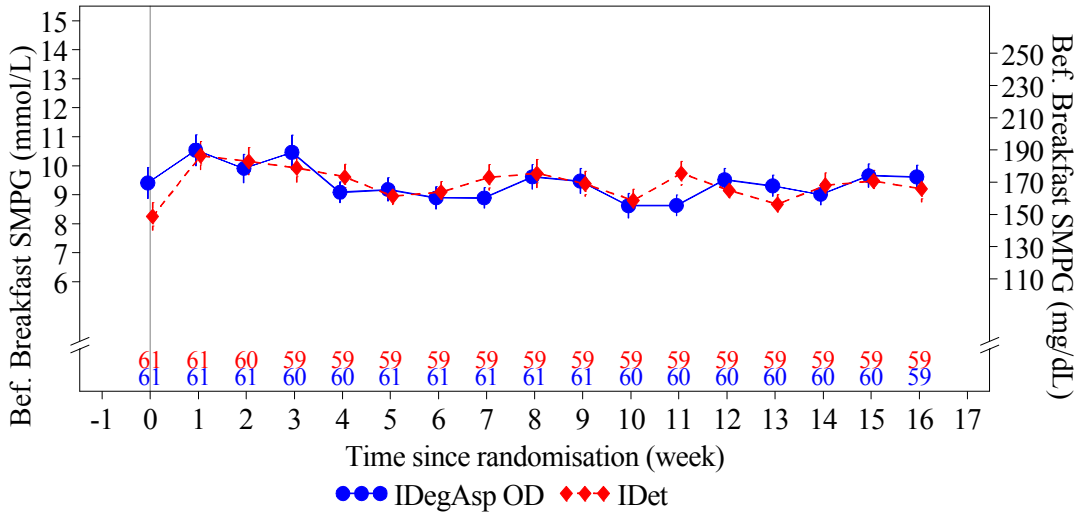
14.2.366 Mean before breakfast self measured plasma glucose for dose adjustment by treatment week - mean plot - full analysis set



FAS: Observed data
At Week0: values taken from 8-point SMPG profiles, Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:13 - fmean_numfind_deg_cust.sas/e_smpg_ab_bf_mean_ob_age1_fas.cgm

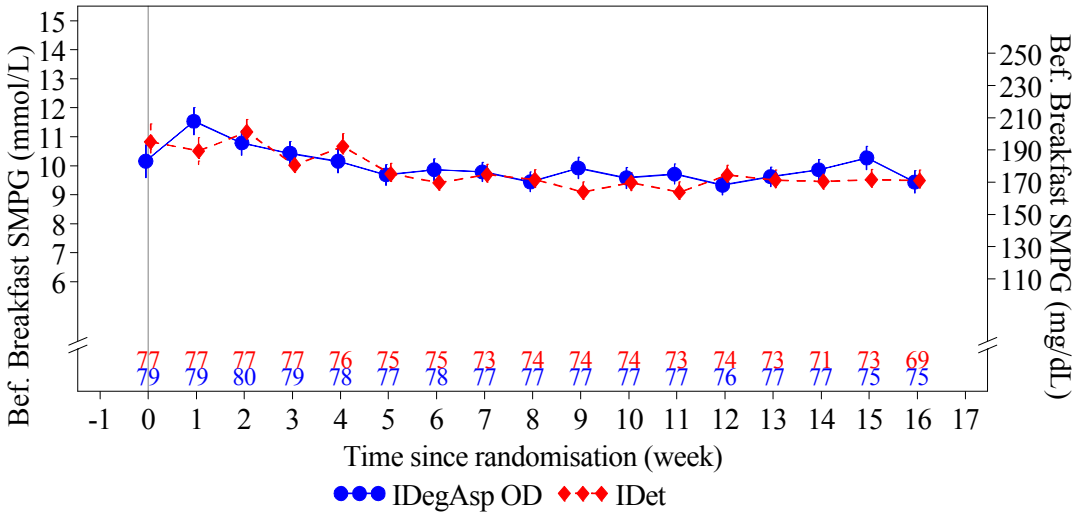
14.2.367 Mean before breakfast self measured plasma glucose for dose adjustment by treatment week – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
At Week0: values taken from 8-point SMPG profiles, Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:13 - fmean_numfind_deg_cust.sas/e_smpg_ab_bf_mean_ob_age2_fas.cgm

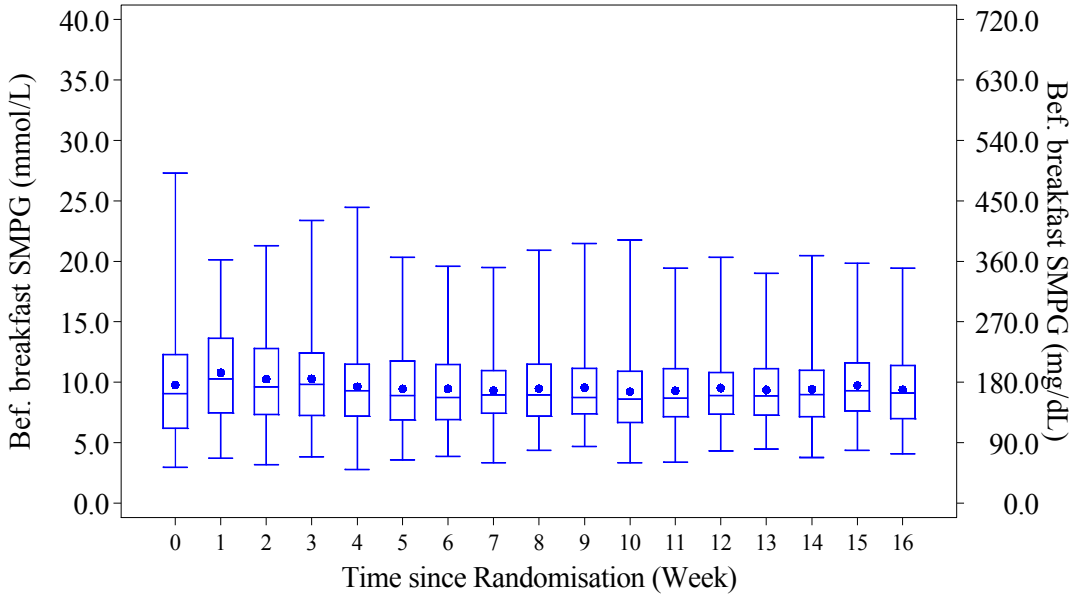
14.2.368 Mean before breakfast self measured plasma glucose for dose adjustment by treatment week – mean plot – children (6-11 years) - full analysis set



FAS: Observed data
At Week0: values taken from 8-point SMPG profiles, Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:14 - fmean_numfind_deg_cust.sas/e_smpg_ab_bf_mean_ob_age3_fas.cgm

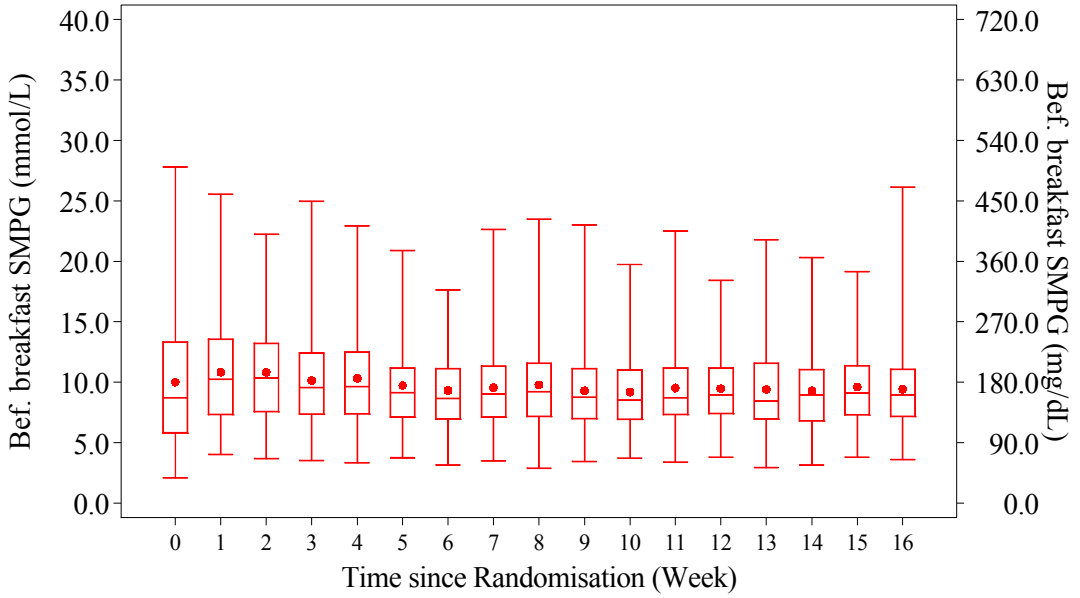
14.2.369 Mean before breakfast self measured plasma glucose for dose adjustment by treatment week – mean plot – adolescents (12-17 years) - full analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set, Endpoint is calculated as the mean of the available SMPG values
Bef.: Before, SMPG: Self measured plasma glucose
At Week0: values taken from 8-point SMPG profiles

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:44:19 - fbox_numfind_v02.sas/e_smpg_inv1_abs_bf_box_obs_fas.cgm

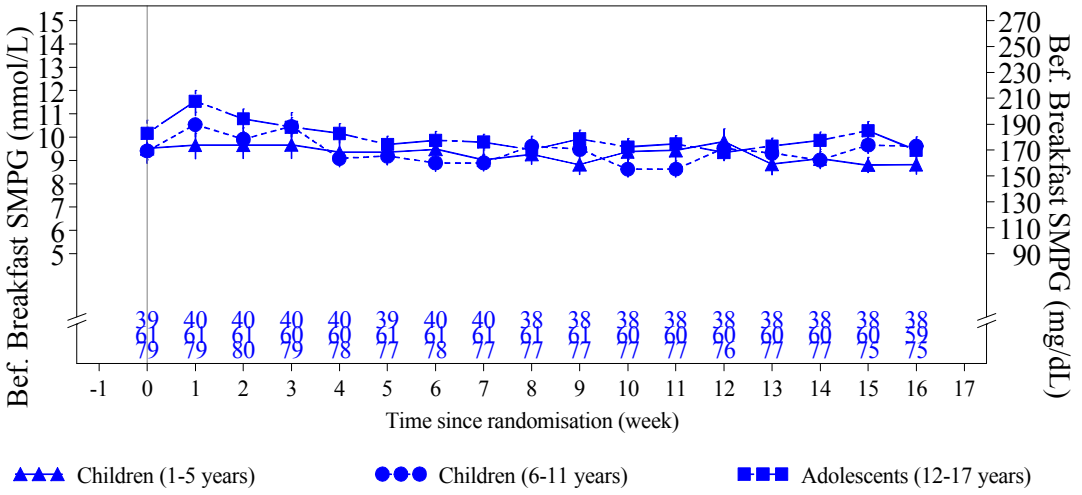
14.2.370 Mean before breakfast self measured plasma glucose for dose adjustment by treatment week – IDegAsp OD - box plot - full analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set, Endpoint is calculated as the mean of the available SMPG values
Bef.: Before, SMPG: Self measured plasma glucose
At Week0: values taken from 8-point SMPG profiles

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:44:20 - fbox_numfind_v02.sas/e_smpg_com_abs_bf_box_obs_fas.cgm

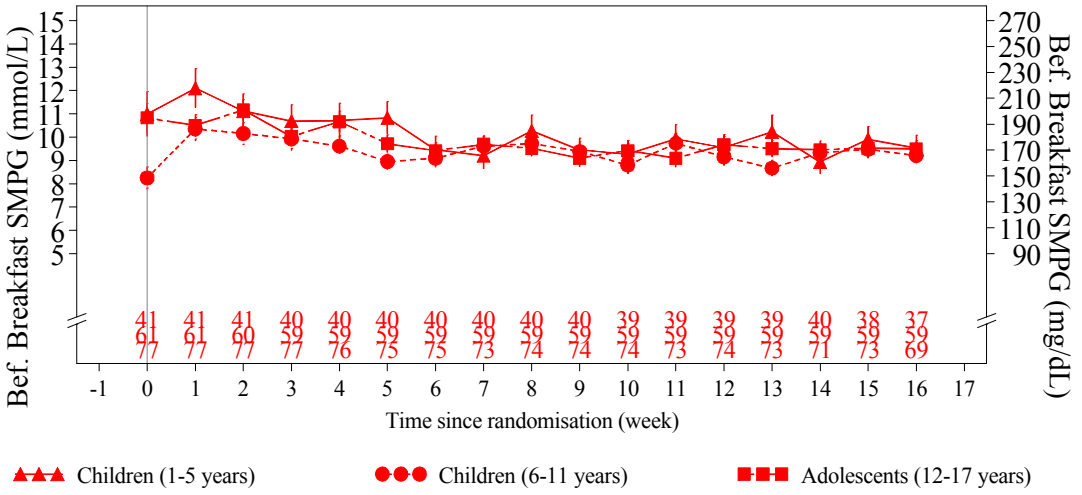
14.2.371 Mean before breakfast self measured plasma glucose for dose adjustment by treatment week – IDet - box plot - full analysis set



Bef.: Before, SMPG: Self-measured plasma glucose
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:38 - smpg_mean_bef_fplot_treatment_age.sas/e_smpg_mean_bef_b_ideg_fas.cgm

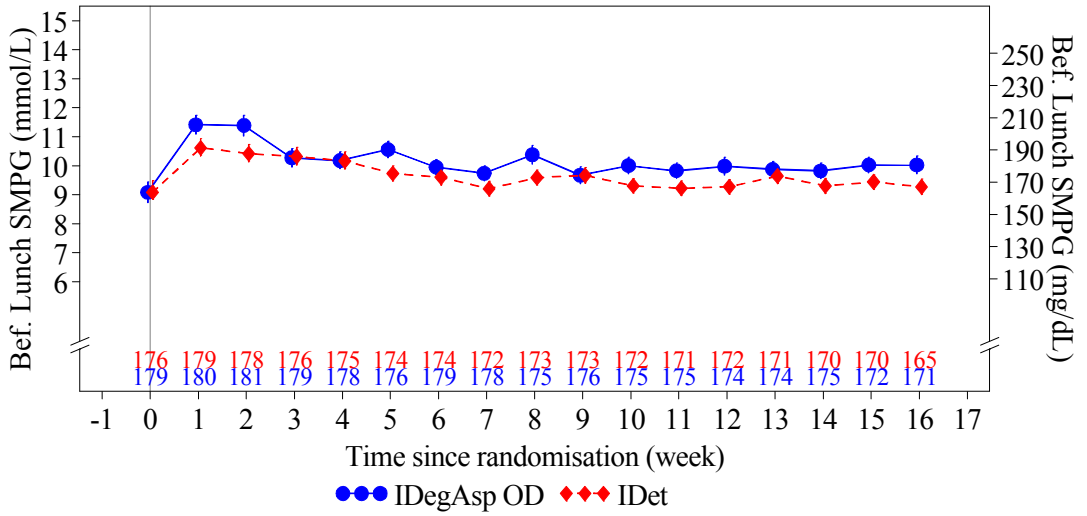
14.2.372 Mean before breakfast self measured plasma glucose for dose adjustment by treatment week – mean plot - IDegAsp OD - by age group - full analysis set



Bef.: Before, SMPG: Self-measured plasma glucose
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:43 - smpg_mean_bef_fplot_treatment_age.sas/e_smpg_mean_bef_b_idet_fas.cgm

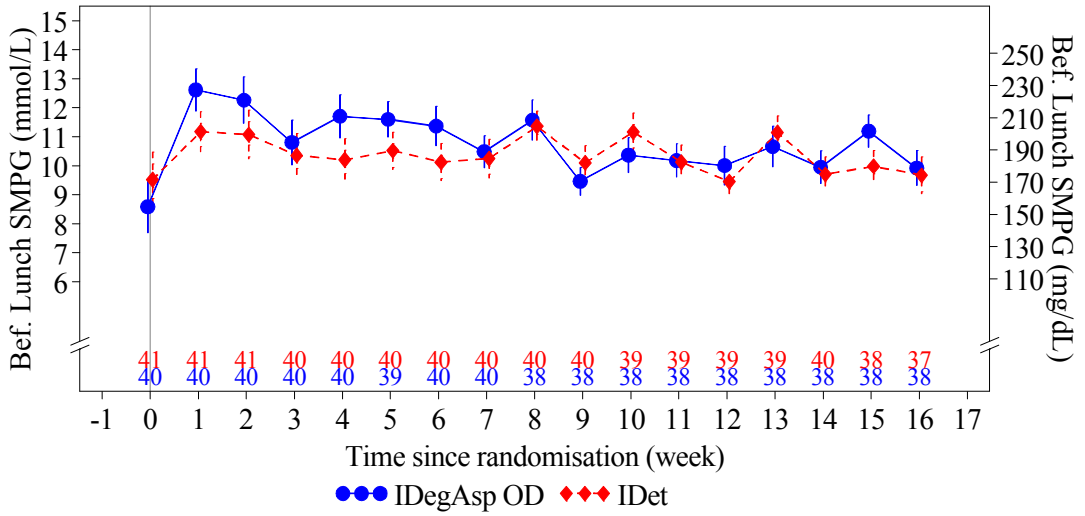
14.2.373 Mean before breakfast self measured plasma glucose for dose adjustment by treatment week – mean plot - IDet - by age group - full analysis set



FAS: Observed data
Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:22 - fmean_numfind_deg_cust.sas/e_smpg_ab_l_mean_ob_fas.cgm

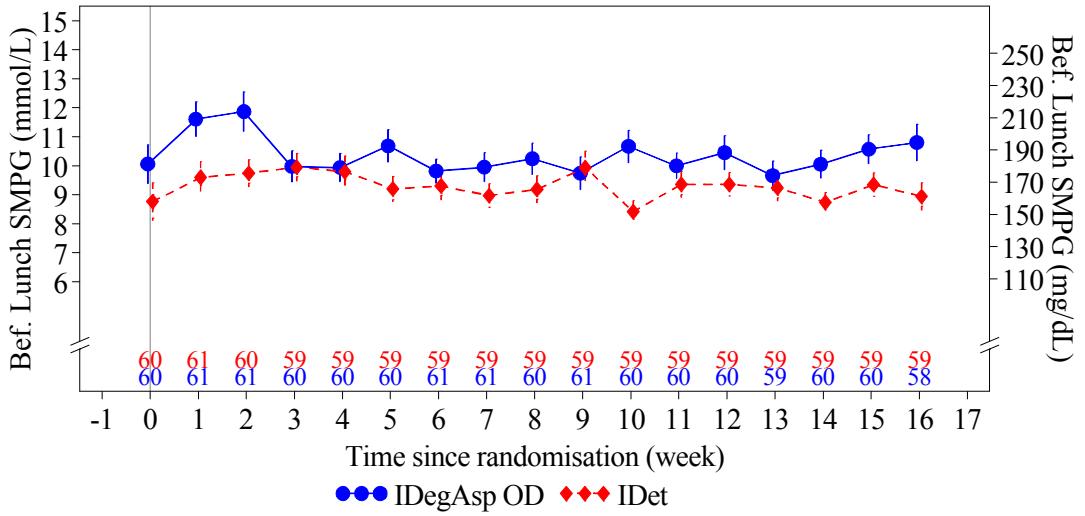
14.2.374 Mean before lunch self measured plasma glucose for dose adjustment by treatment week - mean plot - full analysis set



FAS: Observed data
Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:23 - fmean_numfind_deg_cust.sas/e_smpg_ab_1_mean_ob_age1_fas.cgm

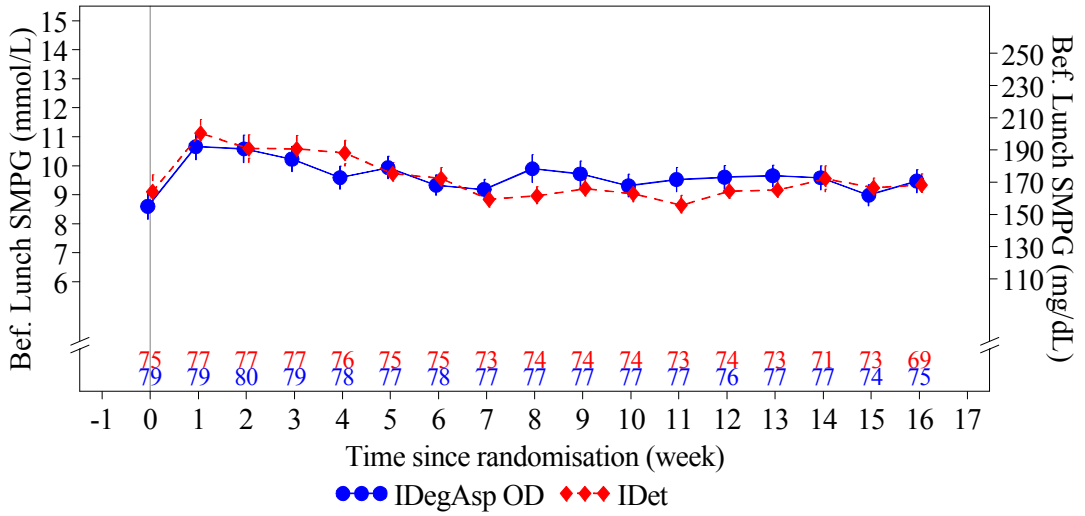
14.2.375 Mean before lunch self measured plasma glucose for dose adjustment by treatment week – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:23 - fmean_numfind_deg_cust.sas/e_smpg_ab_1_mean_ob_age2_fas.cgm

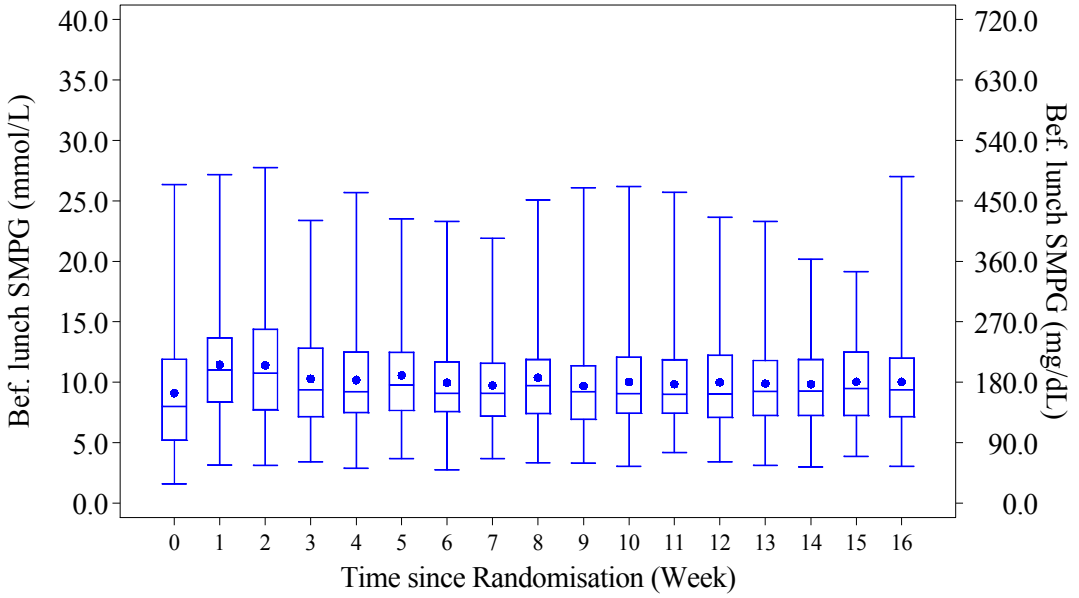
14.2.376 Mean before lunch self measured plasma glucose for dose adjustment by treatment week – mean plot – children (6-11 years) - full analysis set



FAS: Observed data
Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:23 - fmean_numfind_deg_cust.sas/e_smpg_ab_1_mean_ob_age3_fas.cgm

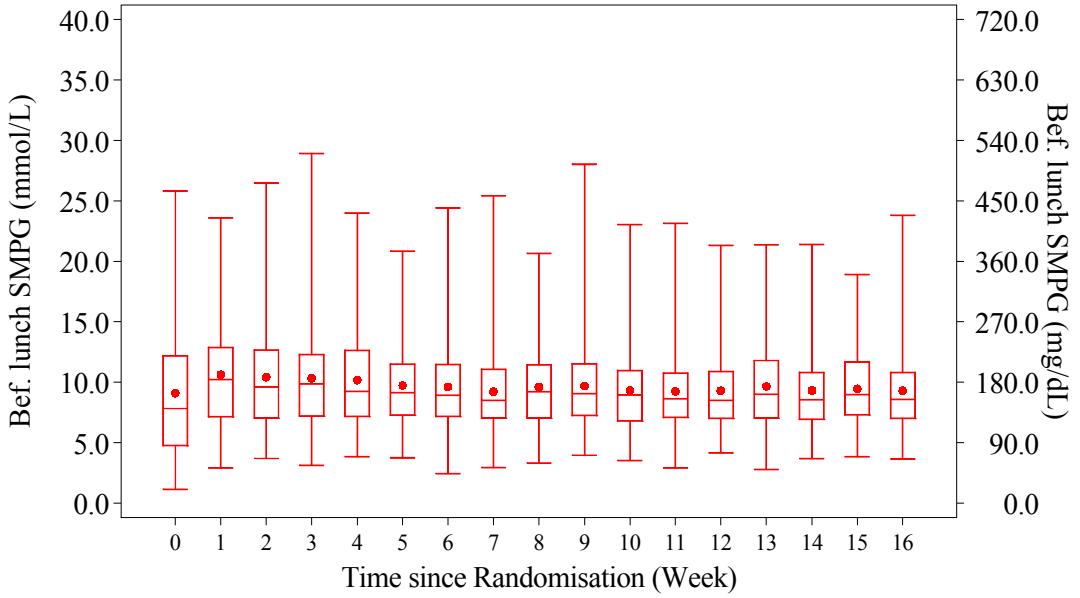
14.2.377 Mean before lunch self measured plasma glucose for dose adjustment by treatment week – mean plot – adolescents (12-17 years) - full analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set, Endpoint is calculated as the mean of the available SMPG values
Bef.: Before, SMPG: Self measured plasma glucose
At Week0: values taken from 8-point SMPG profiles

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:44:25 - fbox_numfind_v02.sas/e_smpg_inv1_abs_1_box_obs_fas.cgm

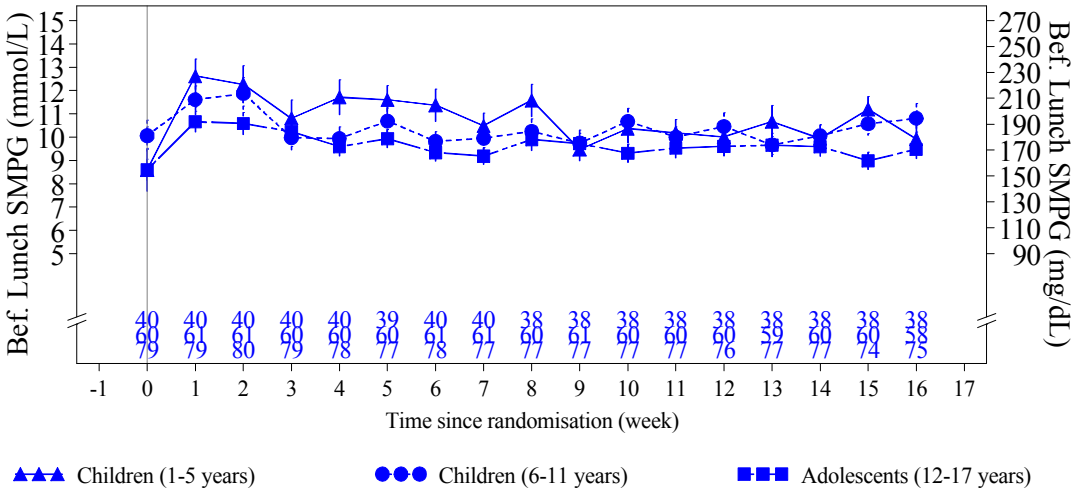
14.2.378 Mean before lunch self measured plasma glucose for dose adjustment by treatment week – IDegAsp OD - box plot - full analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set, Endpoint is calculated as the mean of the available SMPG values
Bef.: Before, SMPG: Self measured plasma glucose
At Week0: values taken from 8-point SMPG profiles

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:44:25 - fbox_numfind_v02.sas/e_smpg_com_abs_1_box_obs_fas.cgm

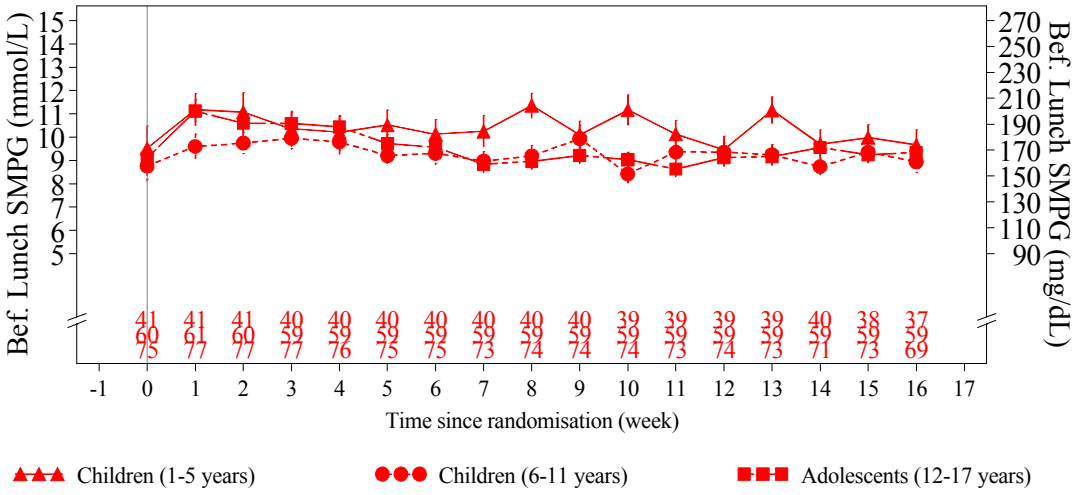
14.2.379 Mean before lunch self measured plasma glucose for dose adjustment by treatment week – IDet OD - box plot - full analysis set



Bef.: Before, SMPG: Self-measured plasma glucose
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:47 - smpg_mean_bef_fplot_treatment_age.sas/e_smpg_mean_bef_f_ideg_fas.cgm

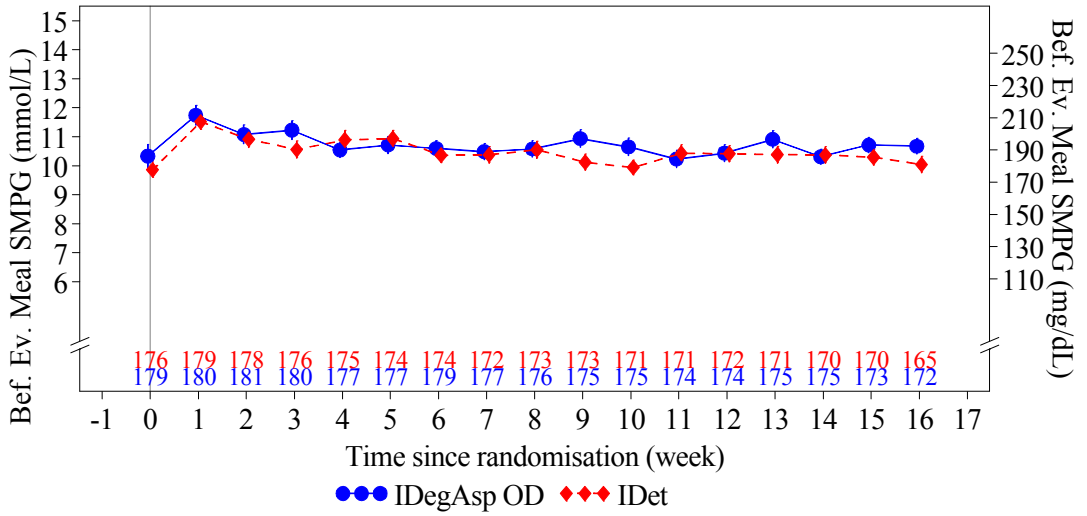
14.2.380 Mean before lunch self measured plasma glucose for dose adjustment by treatment week – mean plot - IDegAsp OD - by age group - full analysis set



Bef.: Before, SMPG: Self-measured plasma glucose
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:52 - smpg_mean_bef_fplot_treatment_age.sas/e_smpg_mean_bef_1_idet_fas.cgm

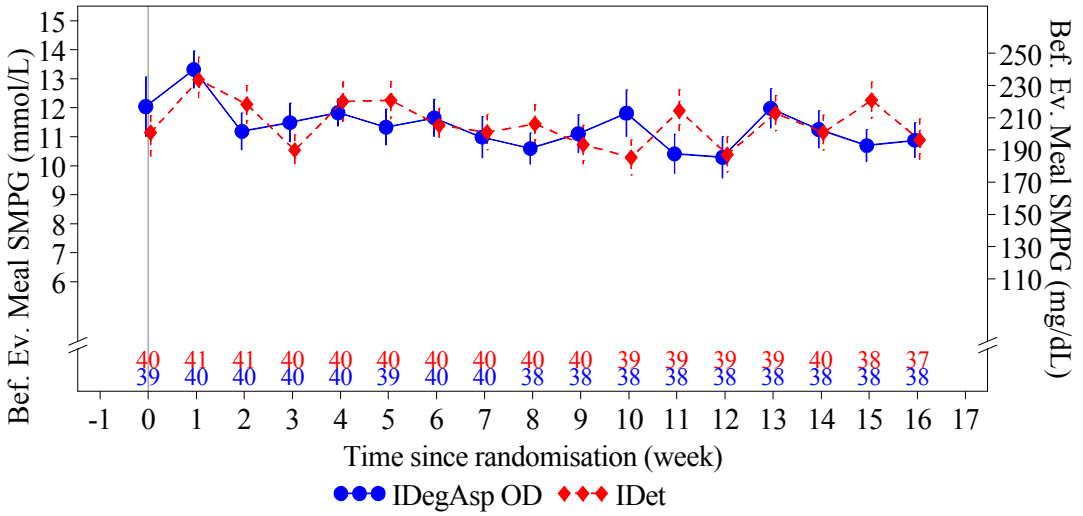
14.2.381 Mean before lunch self measured plasma glucose for dose adjustment by treatment week – mean plot - IDet - by age group - full analysis set



FAS: Observed data
Bef.: Before, EV.: Evening, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:29 - fmean_numfind_deg_cust.sas/e_smpg_ab_ev_mean_ob_fas.cgm

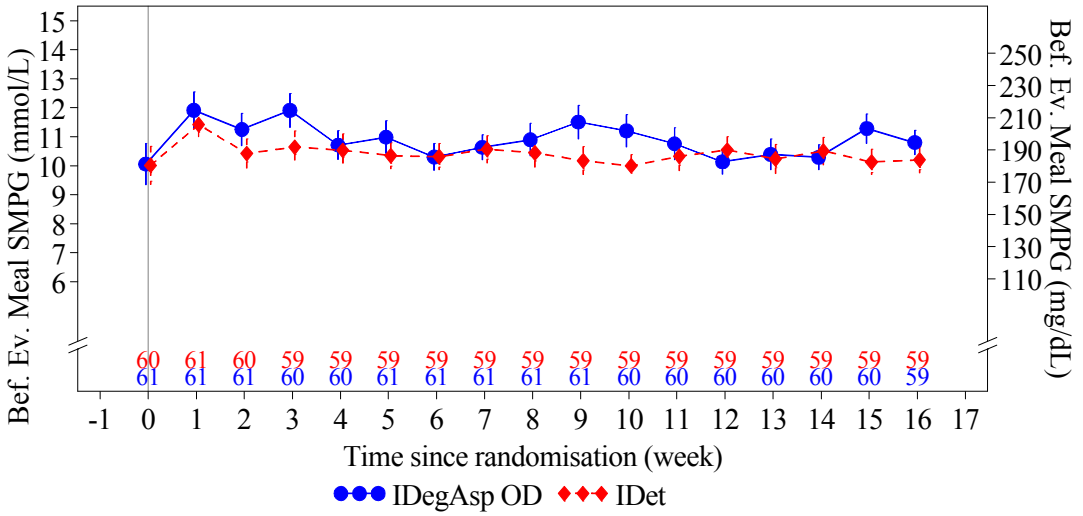
14.2.382 Mean before main evening meal self measured plasma glucose for dose adjustment by treatment week - mean plot - full analysis set



FAS: Observed data
Bef.: Before, EV.: Evening, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:30 - fmean_numfind_deg_cust.sas/e_smpg_ab_ev_mean_ob_age1_fas.cgm

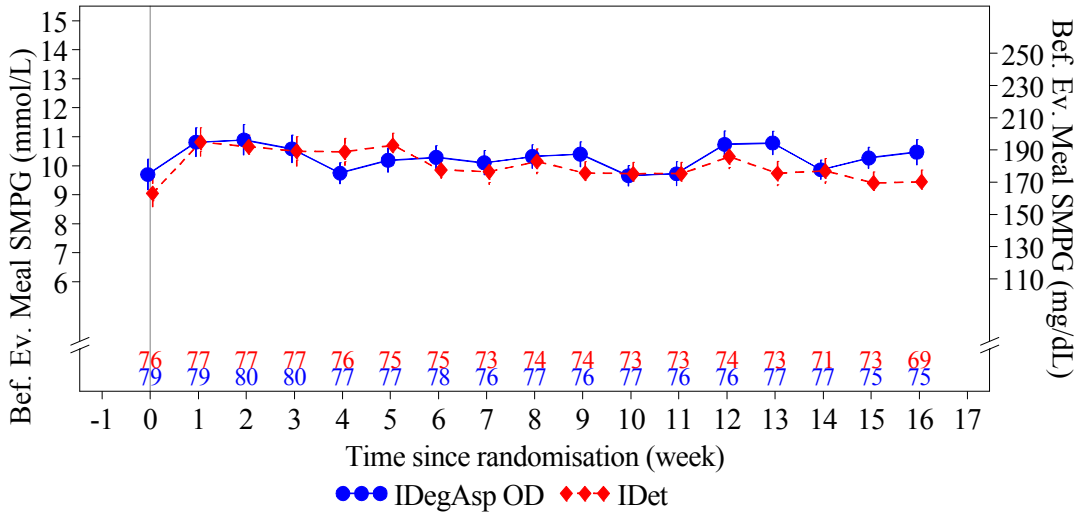
14.2.383 Mean before main evening meal self measured plasma glucose for dose adjustment by treatment week – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
Bef.: Before, EV.: Evening, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:33 - fmean_numfind_deg_cust.sas/e_smpg_ab_ev_mean_ob_age2_fas.cgm

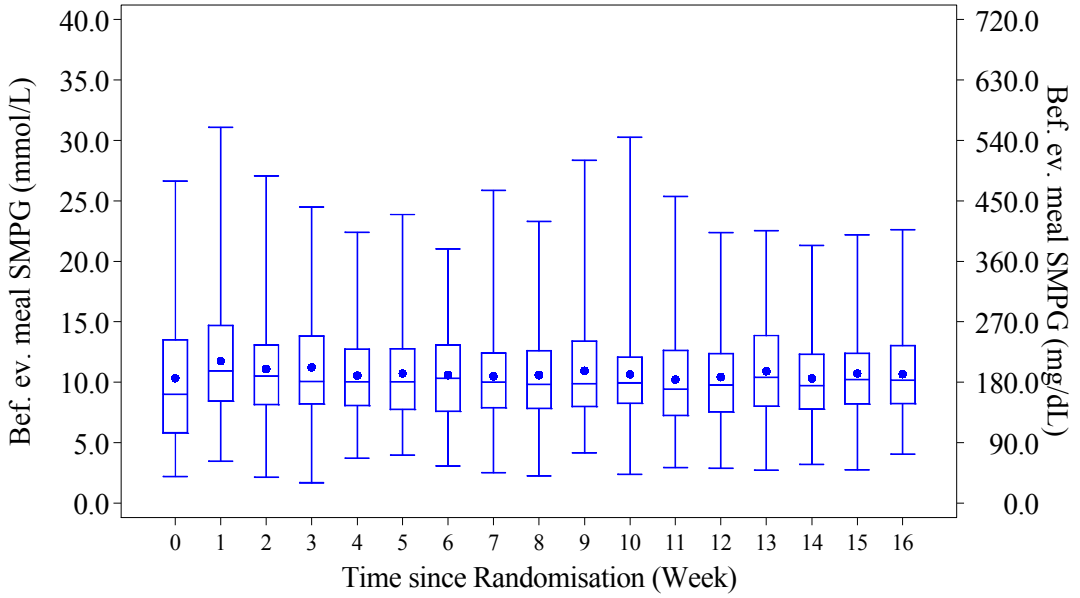
14.2.384 Mean before main evening meal self measured plasma glucose for dose adjustment by treatment week – mean plot – children (6-11 years) - full analysis set



FAS: Observed data
Bef.: Before, EV.: Evening, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:34 - fmean_numfind_deg_cust.sas/e_smpg_ab_ev_mean_ob_age3_fas.cgm

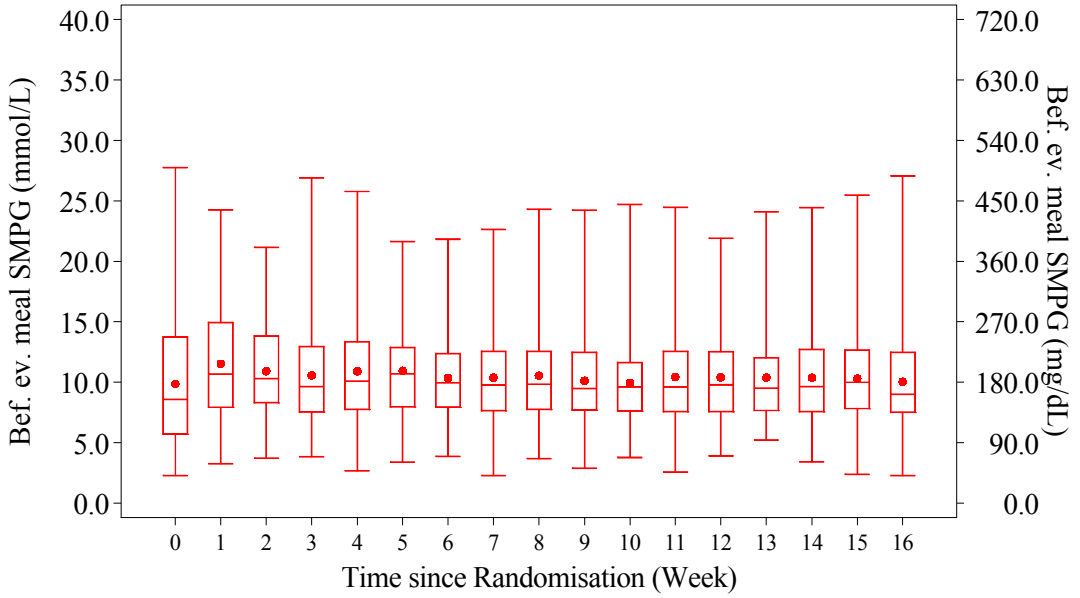
14.2.385 Mean before main evening meal self measured plasma glucose for dose adjustment by treatment week – mean plot – adolescents (12-17 years) - full analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set, Endpoint is calculated as the mean of the available SMPG values
Bef.: Before, ev.: Evening, SMPG: Self measured plasma glucose
At Week0: values taken from 8-point SMPG profiles

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:44:33 - fbox_numfind_v02.sas/e_smpg_inv1_abs_ev_box_obs_fas.cgm

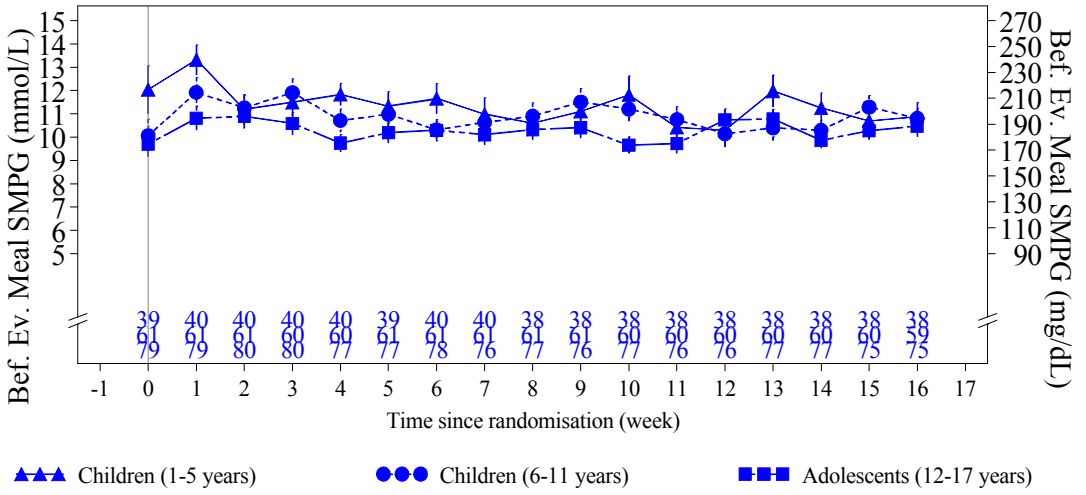
14.2.386 Mean before main evening meal self measured plasma glucose for dose adjustment by treatment week – IDegAsp OD - box plot - full analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set, Endpoint is calculated as the mean of the available SMPG values
Bef.: Before, ev.: Evening, SMPG: Self measured plasma glucose
At Week0: values taken from 8-point SMPG profiles

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:44:33 - fbox_numfind_v02.sas/e_smpg_com_abs_ev_box_obs_fas.cgm

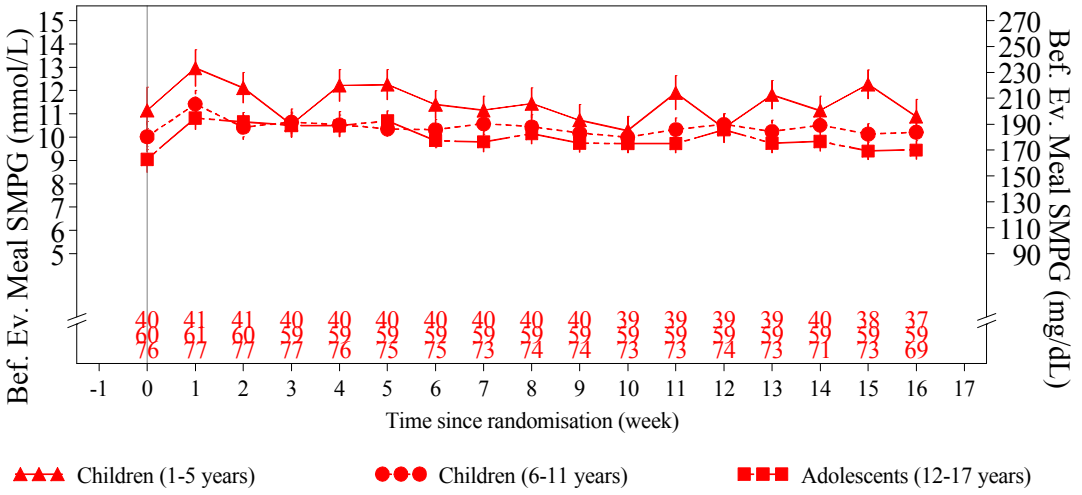
14.2.387 Mean before main evening meal self measured plasma glucose for dose adjustment by treatment week – IDet OD - box plot - full analysis set



Bef.: Before, EV.: Evening, SMPG: Self-measured plasma glucose
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:56 - smpg_mean_bef_fplot_treatment_age.sas/e_smpg_mean_bef_ev_ideg_fas.cgm

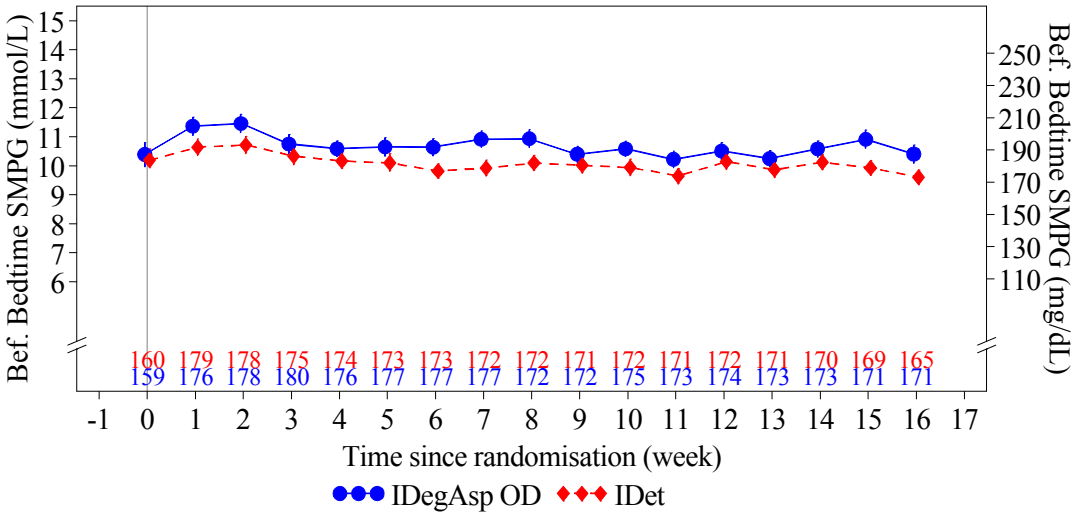
14.2.388 Mean before main evening meal self measured plasma glucose for dose adjustment by treatment week – mean plot - IDegAsp OD - by age group - full analysis set



Bef.: Before, EV.: Evening, SMPG: Self-measured plasma glucose
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:01 - smpg_mean_bef_fplot_treatment_age.sas/e_smpg_mean_bef_ev_idet_fas.cgm

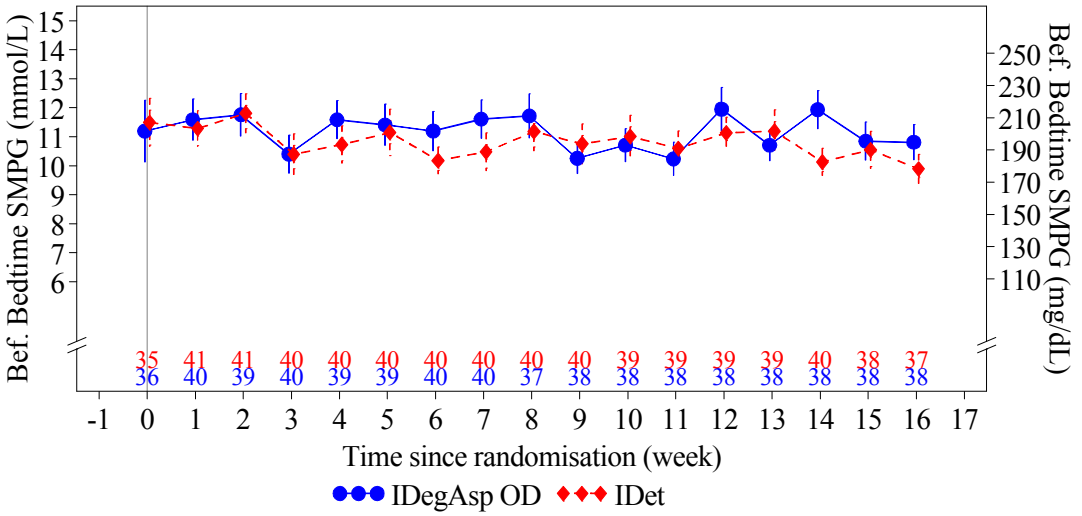
14.2.389 Mean before main evening meal self measured plasma glucose for dose adjustment by treatment week – mean plot - IDet - by age group - full analysis set



FAS: Observed data
Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:36 - fmean_numfind_deg_cust.sas/e_smpg_ab_bt_mean_ob_fas.cgm

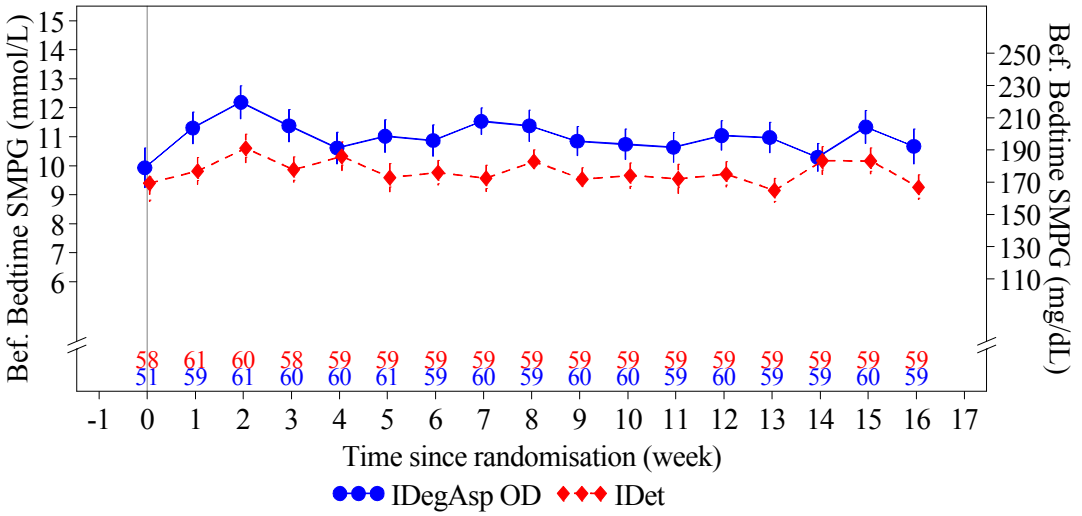
14.2.390 Mean before bedtime self measured plasma glucose for dose adjustment by treatment week - mean plot - full analysis set



FAS: Observed data
Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:36 - fmean_numfind_deg_cust.sas/e_smpg_ab_bt_mean_ob_age1_fas.cgm

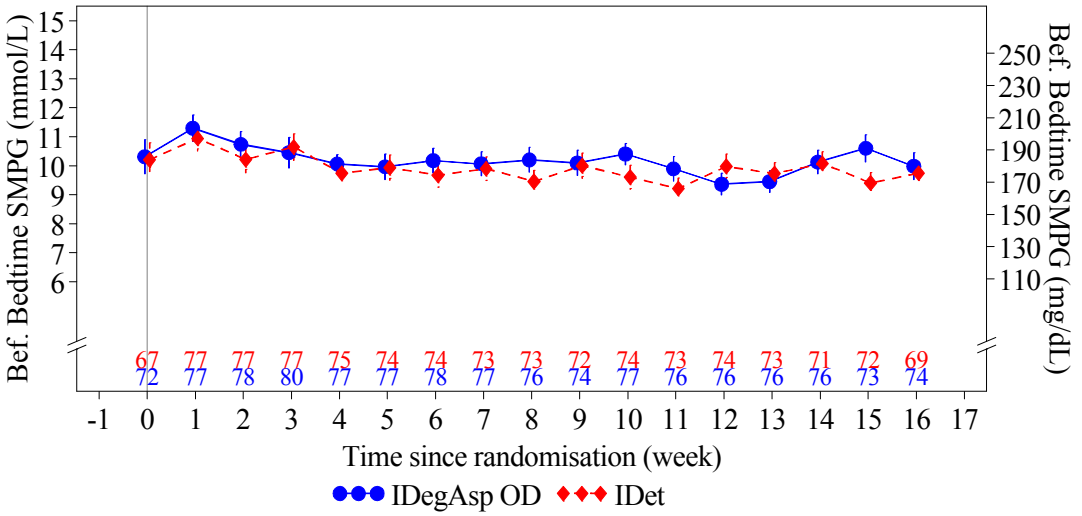
14.2.391 Mean before bedtime self measured plasma glucose for dose adjustment by treatment week – mean plot – children (1-5 years) - full analysis set



FAS: Observed data
Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:40 - fmean_numfind_deg_cust.sas/e_smpg_ab_bt_mean_ob_age2_fas.cgm

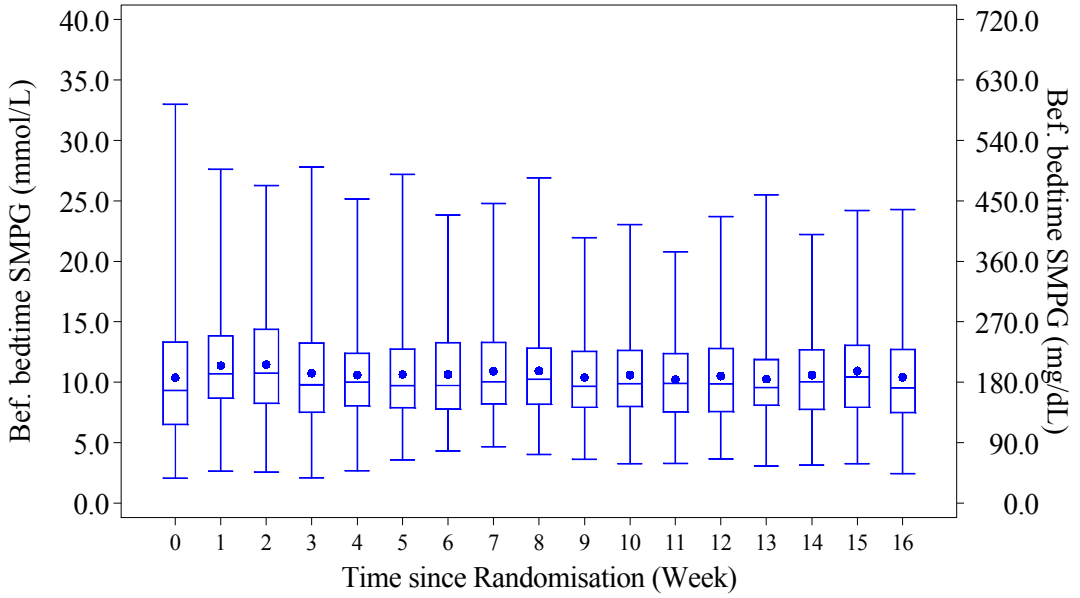
14.2.392 Mean before bedtime self measured plasma glucose for dose adjustment by treatment week – mean plot – children (6-11 years) - full analysis set



FAS: Observed data
Bef.: Before, SMPG: Self-measured plasma glucose, FAS: Full analysis set
Endpoint is calculated as the mean of the available SMPG values
Error bars: +- Standard error (mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:40 - fmean_numfind_deg_cust.sas/e_smpg_ab_bt_mean_ob_age3_fas.cgm

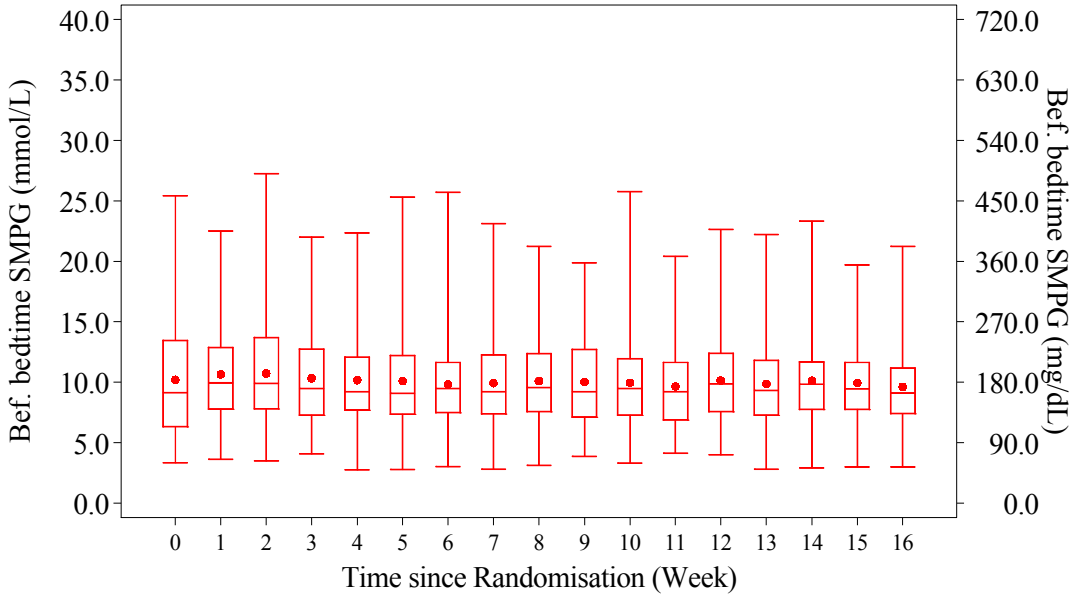
14.2.393 Mean before bedtime self measured plasma glucose for dose adjustment by treatment week – mean plot – adolescents (12-17 years) - full analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set, Endpoint is calculated as the mean of the available SMPG values
Bef.: Before, SMPG: Self measured plasma glucose
At Week0: values taken from 8-point SMPG profiles

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:44:43 - fbox_numfind_v02.sas/e_smpg_inv1_abs_bt_box_obs_fas.cgm

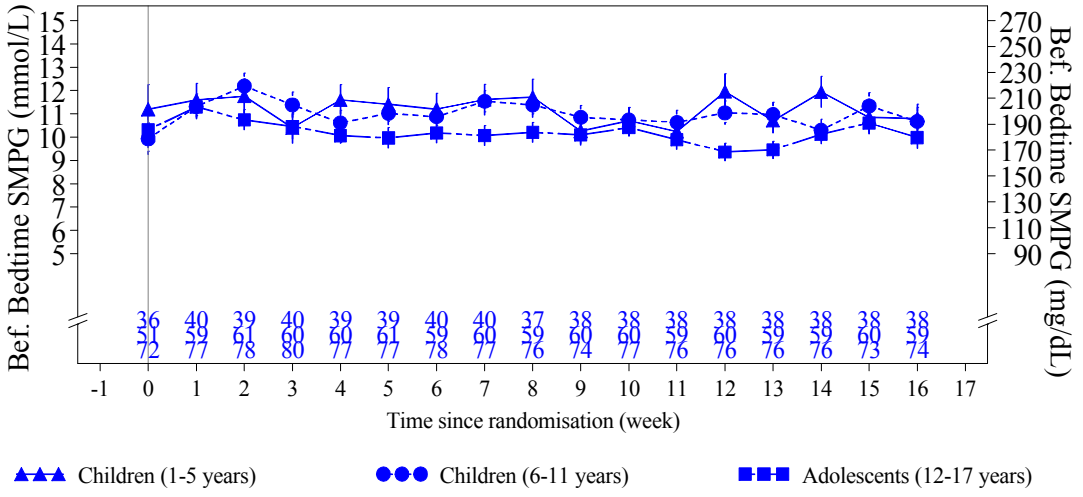
14.2.394 Mean before bedtime self measured plasma glucose for dose adjustment by treatment week – IDegAsp OD - box plot - full analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
FAS: Observed data
FAS: Full analysis set, Endpoint is calculated as the mean of the available SMPG values
Bef.: Before, SMPG: Self measured plasma glucose
At Week0: values taken from 8-point SMPG profiles

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:44:43 - fbox_numfind_v02.sas/e_smpg_com_abs_bt_box_obs_fas.cgm

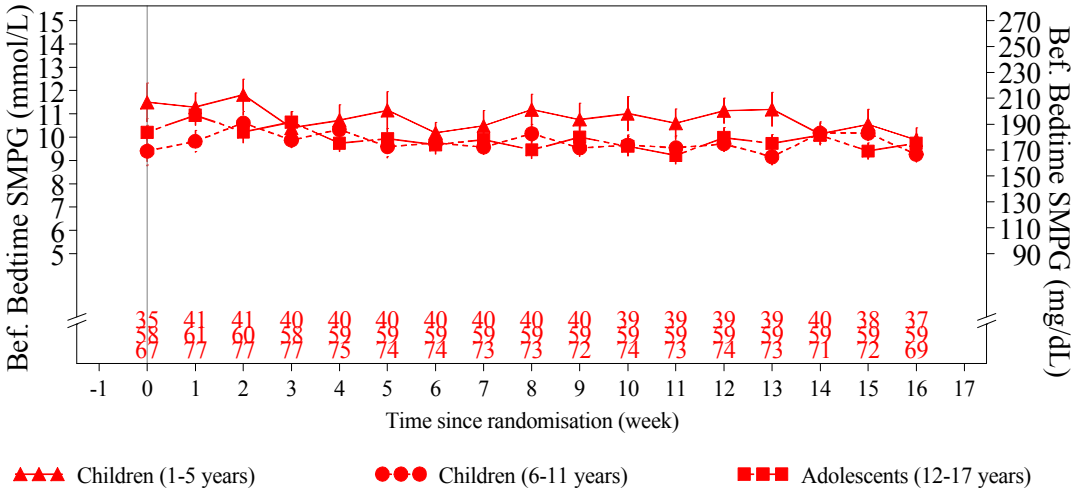
14.2.395 Mean before bedtime self measured plasma glucose for dose adjustment by treatment week – IDet OD - box plot - full analysis set



Bef.: Before, SMPG: Self-measured plasma glucose
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:05 - smpg_mean_bef_fplot_treatment_age.sas/e_smpg_mean_bef_bt_ideg_fas.cgm

14.2.396 Mean before bedtime self measured plasma glucose for dose adjustment by treatment week – mean plot - IDegAsp OD - by age group - full analysis set



Bef.: Before, SMPG: Self-measured plasma glucose
FAS: Observed data ,FAS: Full analysis set
Error bars:+- standard error(mean)
At Week0: values taken from 8-point SMPG profiles
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. Adolescents (12-17 years) 2. Children (6-11 years) 3. Children (1-5 yrs)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:48:09 - smpg_mean_bef_fplot_treatment_age.sas/e_smpg_mean_bef_bt_idet_fas.cgm

14.2.397 Mean before bedtime self measured plasma glucose for dose adjustment by treatment week – mean plot - IDet - by age group - full analysis set

14.2.398 Within-subject variation in self measured plasma glucose for dose adjustment after 16 treatment weeks - statistical analysis - full analysis set

	FAS	N	Estimate	95% CI
Before Breakfast				
Within-Subject CV (%)				
IDegAsp OD	182	180	39.38	
IDet	180	179	38.57	
Treatment Ratio				
IDegAsp OD /IDet			1.02	[0.91; 1.14]

N: Number of subjects contributing to analysis
CI: Confidence Interval
CV: Coefficient of Variation
Log-transformed self measured plasma glucose values after 16 treatment weeks are analysed as repeated measures in a mixed linear model with treatment, sex, region and age group as fixed effects and subject as random effect.
The model assumes independent within and between subject variances with variances depending on treatment. The NLmixed procedure in SAS is applied.

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:41 - t_stat_within_smpg_var.sas/t_smpg_within_var_stat_mmrm_fas.txt

14.2.399 Dosing IDet BID at end of trial - safety analysis set

	IDet BID at end of trial		
Age group	N	n	(%)
All subjects	179	97	(54.2)
Children (1-5 years)	41	23	(56.1)
Children (6-11 years)	61	36	(59.0)
Adolescents (12-17 years)	77	38	(49.4)

N: Number of subjects, n: Number of subjects dosing BID at end of trial
%: Proportion of subjects with IDet BID dosing at end of trial
End of trial: a subject's last trial visit excluding the follow-up visit

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:44:42 - t_idetbid_eot_sas.sas/t_idetbid_eot_sas.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	181				179				360			
Events	141	(77.9)	501	915	134	(74.9)	460	853	275	(76.4)	961	884
Serious												
Yes	11	(6.1)	14	26	7	(3.9)	7	13	18	(5.0)	21	19
No	137	(75.7)	487	889	133	(74.3)	453	840	270	(75.0)	940	865
Severity												
Severe	12	(6.6)	14	26	5	(2.8)	5	9	17	(4.7)	19	17
Moderate	52	(28.7)	96	175	30	(16.8)	58	108	82	(22.8)	154	142
Mild	126	(69.6)	391	714	129	(72.1)	397	736	255	(70.8)	788	725
Relationship to Investigational Product												
Probably	13	(7.2)	16	29	11	(6.1)	13	24	24	(6.7)	29	27
Possibly	10	(5.5)	10	18	6	(3.4)	7	13	16	(4.4)	17	16
Unlikely	136	(75.1)	472	862	129	(72.1)	438	812	265	(73.6)	910	837
Missing	2	(1.1)	3	5	2	(1.1)	2	4	4	(1.1)	5	5
Related to Bolus Insulin												
Probably	9	(5.0)	11	20	7	(3.9)	10	19	16	(4.4)	21	19
Possibly	9	(5.0)	9	16	7	(3.9)	7	13	16	(4.4)	16	15
Unlikely	137	(75.7)	478	873	132	(73.7)	441	818	269	(74.7)	919	846
Missing	2	(1.1)	3	5	2	(1.1)	2	4	4	(1.1)	5	5
Related to Device												
Yes	0	(0.0)	0	0	1	(0.6)	1	2	1	(0.3)	1	1
No	141	(77.9)	498	909	134	(74.9)	457	847	275	(76.4)	955	879
Missing	2	(1.1)	3	5	2	(1.1)	2	4	4	(1.1)	5	5
Outcome												
Recovered/Resolved	137	(75.7)	470	858	133	(74.3)	441	818	270	(75.0)	911	838
Recovering/ Resolving	6	(3.3)	6	11	6	(3.4)	7	13	12	(3.3)	13	12
Recovered/ Resolved with Sequelae	1	(0.6)	1	2	0	(0.0)	0	0	1	(0.3)	1	1
Not Recovered/Not Resolved	20	(11.0)	24	44	10	(5.6)	12	22	30	(8.3)	36	33

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events
R: Event Rate per 100 Patient Years of Exposure
Relationship is based on investigator(s)'s assessment.

14.3.1.2 Adverse events - treatment emergent – summary – children (1-5 years) - safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	40				41				81			
Events	35	(87.5)	143	1192	26	(63.4)	86	702	61	(75.3)	229	945
Serious												
Yes	3	(7.5)	4	33	3	(7.3)	3	24	6	(7.4)	7	29
No	34	(85.0)	139	1159	26	(63.4)	83	678	60	(74.1)	222	916
Severity												
Severe	3	(7.5)	3	25	2	(4.9)	2	16	5	(6.2)	5	21
Moderate	11	(27.5)	22	183	6	(14.6)	11	90	17	(21.0)	33	136
Mild	33	(82.5)	118	984	25	(61.0)	73	596	58	(71.6)	191	788
Relationship to Investigational Product												
Probably	3	(7.5)	3	25	1	(2.4)	1	8	4	(4.9)	4	16
Possibly	4	(10.0)	4	33	1	(2.4)	1	8	5	(6.2)	5	21
Unlikely	34	(85.0)	136	1134	26	(63.4)	84	686	60	(74.1)	220	907
Related to Bolus Insulin												
Probably	3	(7.5)	4	33	1	(2.4)	1	8	4	(4.9)	5	21
Possibly	1	(2.5)	1	8	2	(4.9)	2	16	3	(3.7)	3	12
Unlikely	35	(87.5)	138	1151	26	(63.4)	83	678	61	(75.3)	221	912
Related to Device												
No	35	(87.5)	143	1192	26	(63.4)	86	702	61	(75.3)	229	945
Outcome												
Recovered/Resolved	35	(87.5)	135	1126	26	(63.4)	82	669	61	(75.3)	217	895
Recovering/ Resolving	1	(2.5)	1	8	2	(4.9)	2	16	3	(3.7)	3	12
Not Recovered/Not Resolved	5	(12.5)	7	58	2	(4.9)	2	16	7	(8.6)	9	37

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events
R: Event Rate per 100 Patient Years of Exposure
Relationship is based on investigator(s)'s assessment.

14.3.1.3 Adverse events - treatment emergent – summary – children (6-11 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	61			61			122		
Events	44 (72.1)	148	792	48 (78.7)	166	905	92 (75.4)	314	848
Serious									
Yes	4 (6.6)	4	21	1 (1.6)	1	5	5 (4.1)	5	14
No	42 (68.9)	144	771	48 (78.7)	165	900	90 (73.8)	309	835
Severity									
Severe	3 (4.9)	3	16	2 (3.3)	2	11	5 (4.1)	5	14
Moderate	15 (24.6)	32	171	12 (19.7)	20	109	27 (22.1)	52	141
Mild	40 (65.6)	113	605	47 (77.0)	144	785	87 (71.3)	257	694
Relationship to Investigational Product									
Probably	7 (11.5)	10	54	3 (4.9)	4	22	10 (8.2)	14	38
Possibly	4 (6.6)	4	21	1 (1.6)	1	5	5 (4.1)	5	14
Unlikely	40 (65.6)	134	717	47 (77.0)	161	878	87 (71.3)	295	797
Related to Bolus Insulin									
Probably	4 (6.6)	5	27	1 (1.6)	2	11	5 (4.1)	7	19
Possibly	6 (9.8)	6	32	2 (3.3)	2	11	8 (6.6)	8	22
Unlikely	41 (67.2)	137	733	48 (78.7)	162	884	89 (73.0)	299	808
Related to Device									
Yes	0 (0.0)	0	0	1 (1.6)	1	5	1 (0.8)	1	3
No	44 (72.1)	148	792	48 (78.7)	165	900	92 (75.4)	313	846
Outcome									
Recovered/Resolved	43 (70.5)	137	733	48 (78.7)	161	878	91 (74.6)	298	805
Recovering/ Resolving	4 (6.6)	4	21	1 (1.6)	1	5	5 (4.1)	5	14
Not Recovered/Not Resolved	6 (9.8)	7	37	3 (4.9)	4	22	9 (7.4)	11	30

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events
R: Event Rate per 100 Patient Years of Exposure
Relationship is based on investigator(s)'s assessment.

14.3.1.4 Adverse events - treatment emergent – summary – adolescents (12-17 years) - safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	80				77				157			
Events	62	(77.5)	210	872	60	(77.9)	208	891	122	(77.7)	418	881
Serious												
Yes	4	(5.0)	6	25	3	(3.9)	3	13	7	(4.5)	9	19
No	61	(76.3)	204	847	59	(76.6)	205	878	120	(76.4)	409	862
Severity												
Severe	6	(7.5)	8	33	1	(1.3)	1	4	7	(4.5)	9	19
Moderate	26	(32.5)	42	174	12	(15.6)	27	116	38	(24.2)	69	145
Mild	53	(66.3)	160	664	57	(74.0)	180	771	110	(70.1)	340	717
Relationship to Investigational Product												
Probably	3	(3.8)	3	12	7	(9.1)	8	34	10	(6.4)	11	23
Possibly	2	(2.5)	2	8	4	(5.2)	5	21	6	(3.8)	7	15
Unlikely	62	(77.5)	202	838	56	(72.7)	193	827	118	(75.2)	395	833
Missing	2	(2.5)	3	12	2	(2.6)	2	9	4	(2.5)	5	11
Related to Bolus Insulin												
Probably	2	(2.5)	2	8	5	(6.5)	7	30	7	(4.5)	9	19
Possibly	2	(2.5)	2	8	3	(3.9)	3	13	5	(3.2)	5	11
Unlikely	61	(76.3)	203	843	58	(75.3)	196	840	119	(75.8)	399	841
Missing	2	(2.5)	3	12	2	(2.6)	2	9	4	(2.5)	5	11
Related to Device												
No	62	(77.5)	207	859	60	(77.9)	206	882	122	(77.7)	413	871
Missing	2	(2.5)	3	12	2	(2.6)	2	9	4	(2.5)	5	11
Outcome												
Recovered/Resolved	59	(73.8)	198	822	59	(76.6)	198	848	118	(75.2)	396	835
Recovering/ Resolving	1	(1.3)	1	4	3	(3.9)	4	17	4	(2.5)	5	11
Recovered/ Resolved with Sequelae	1	(1.3)	1	4	0	(0.0)	0	0	1	(0.6)	1	2
Not Recovered/Not Resolved	9	(11.3)	10	42	5	(6.5)	6	26	14	(8.9)	16	34

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events
R: Event Rate per 100 Patient Years of Exposure
Relationship is based on investigator(s)'s assessment.

14.3.1.5 Serious adverse events – treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	181			179			360		
Events	11 (6.1)	14	26	7 (3.9)	7	13	18 (5.0)	21	19
Severity									
Severe	7 (3.9)	9	16	2 (1.1)	2	4	9 (2.5)	11	10
Moderate	3 (1.7)	3	5	3 (1.7)	3	6	6 (1.7)	6	6
Mild	2 (1.1)	2	4	2 (1.1)	2	4	4 (1.1)	4	4
Relationship to Investigational Product									
Probably	4 (2.2)	4	7	0 (0.0)	0	0	4 (1.1)	4	4
Possibly	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Unlikely	6 (3.3)	9	16	6 (3.4)	6	11	12 (3.3)	15	14
Related to Bolus Insulin									
Probably	2 (1.1)	2	4	0 (0.0)	0	0	2 (0.6)	2	2
Possibly	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Unlikely	8 (4.4)	11	20	5 (2.8)	5	9	13 (3.6)	16	15
Related to Device									
No	11 (6.1)	14	26	7 (3.9)	7	13	18 (5.0)	21	19
Outcome									
Recovered/ Resolved	11 (6.1)	14	26	6 (3.4)	6	11	17 (4.7)	20	18
Recovering/ Resolving	0 (0.0)	0	0	1 (0.6)	1	2	1 (0.3)	1	1

N: Number of Subjects
%: Percentage of Subjects
E: Number of Events
R: Event Rate per 100 Patient Years of Exposure
Relationship is based on investigator(s)'s assessment.

14.3.1.6 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	181				179				360			
Events	100	(55.2)	242	442	97	(54.2)	243	451	197	(54.7)	485	446
Infections and infestations												
Nasopharyngitis	36	(19.9)	43	79	32	(17.9)	42	78	68	(18.9)	85	78
Upper respiratory tract infection	11	(6.1)	12	22	17	(9.5)	18	33	28	(7.8)	30	28
Influenza	9	(5.0)	10	18	10	(5.6)	12	22	19	(5.3)	22	20
Pharyngitis	3	(1.7)	3	5	10	(5.6)	13	24	13	(3.6)	16	15
Gastrointestinal disorders												
Vomiting	22	(12.2)	25	46	12	(6.7)	13	24	34	(9.4)	38	35
Abdominal pain upper	14	(7.7)	22	40	17	(9.5)	26	48	31	(8.6)	48	44
Abdominal pain	10	(5.5)	13	24	7	(3.9)	13	24	17	(4.7)	26	24
Nervous system disorders												
Headache	23	(12.7)	47	86	32	(17.9)	64	119	55	(15.3)	111	102
Respiratory, thoracic and mediastinal disorders												
Cough	13	(7.2)	16	29	9	(5.0)	9	17	22	(6.1)	25	23
Oropharyngeal pain	9	(5.0)	13	24	13	(7.3)	14	26	22	(6.1)	27	25
General disorders and administration site conditions												
Pyrexia	17	(9.4)	26	47	10	(5.6)	15	28	27	(7.5)	41	38
Metabolism and nutrition disorders												
Hypoglycaemia	11	(6.1)	12	22	3	(1.7)	4	7	14	(3.9)	16	15

N: Number of subjects, %: Percentage of subjects, E: Number of events,
R: Event rate per 100 exposure years

14.3.1.7 Adverse events by system organ class and preferred term - most frequent [>=1%]- treatment emergent - summary - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	181				179				360			
Events	135	(74.6)	440	803	127	(70.9)	396	734	262	(72.8)	836	769
Infections and infestations												
Nasopharyngitis	36	(19.9)	43	79	32	(17.9)	42	78	68	(18.9)	85	78
Upper respiratory tract infection	11	(6.1)	12	22	17	(9.5)	18	33	28	(7.8)	30	28
Influenza	9	(5.0)	10	18	10	(5.6)	12	22	19	(5.3)	22	20
Gastroenteritis	5	(2.8)	5	9	8	(4.5)	8	15	13	(3.6)	13	12
Pharyngitis	3	(1.7)	3	5	10	(5.6)	13	24	13	(3.6)	16	15
Gastroenteritis viral	7	(3.9)	10	18	5	(2.8)	5	9	12	(3.3)	15	14
Viral infection	4	(2.2)	4	7	7	(3.9)	7	13	11	(3.1)	11	10
Rhinitis	6	(3.3)	8	15	3	(1.7)	3	6	9	(2.5)	11	10
Bronchitis	5	(2.8)	5	9	2	(1.1)	2	4	7	(1.9)	7	6
Sinusitis	3	(1.7)	3	5	4	(2.2)	4	7	7	(1.9)	7	6
Viral upper respiratory tract infection	4	(2.2)	5	9	2	(1.1)	2	4	6	(1.7)	7	6
Otitis media	5	(2.8)	6	11					5	(1.4)	6	6
Pharyngitis streptococcal	4	(2.2)	4	7	1	(0.6)	1	2	5	(1.4)	5	5
Acute tonsillitis	1	(0.6)	1	2	2	(1.1)	3	6	3	(0.8)	4	4
Ear infection	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Respiratory tract infection	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Tonsillitis	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Varicella	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Conjunctivitis					2	(1.1)	2	4	2	(0.6)	2	2
Croup infectious	2	(1.1)	2	4					2	(0.6)	2	2
Pharyngotonsillitis	2	(1.1)	2	4					2	(0.6)	2	2
Gastrointestinal disorders												
Vomiting	22	(12.2)	25	46	12	(6.7)	13	24	34	(9.4)	38	35
Abdominal pain upper	14	(7.7)	22	40	17	(9.5)	26	48	31	(8.6)	48	44
Abdominal pain	10	(5.5)	13	24	7	(3.9)	13	24	17	(4.7)	26	24
Nausea	6	(3.3)	6	11	8	(4.5)	10	19	14	(3.9)	16	15
Diarrhoea	7	(3.9)	8	15	6	(3.4)	6	11	13	(3.6)	14	13
Abdominal discomfort	6	(3.3)	6	11	2	(1.1)	3	6	8	(2.2)	9	8
Gastritis	3	(1.7)	4	7	5	(2.8)	6	11	8	(2.2)	10	9
Toothache	4	(2.2)	8	15	4	(2.2)	6	11	8	(2.2)	14	13
Constipation	4	(2.2)	4	7					4	(1.1)	4	4
Odynophagia	3	(1.7)	4	7					3	(0.8)	4	4
Respiratory, thoracic and mediastinal disorders												
Cough	13	(7.2)	16	29	9	(5.0)	9	17	22	(6.1)	25	23
Oropharyngeal pain	9	(5.0)	13	24	13	(7.3)	14	26	22	(6.1)	27	25
Nasal congestion	3	(1.7)	3	5	5	(2.8)	6	11	8	(2.2)	9	8
Rhinorrhoea	1	(0.6)	1	2	6	(3.4)	10	19	7	(1.9)	11	10
Respiratory disorder	4	(2.2)	5	9	2	(1.1)	2	4	6	(1.7)	7	6
Rhinitis allergic	2	(1.1)	2	4					2	(0.6)	2	2
Nervous system disorders												
Headache	23	(12.7)	47	86	32	(17.9)	64	119	55	(15.3)	111	102
Dizziness	3	(1.7)	3	5					3	(0.8)	3	3

N: Number of subjects, %: Percentage of subjects, E: Number of events,
R: Event rate per 100 exposure years

Adverse events by system organ class and preferred term - most frequent [>=1%]-
treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Migraine	1 (0.6)	6	11	2 (1.1)	4	7	3 (0.8)	10	9
Sinus headache	2 (1.1)	3	5	1 (0.6)	1	2	3 (0.8)	4	4
Hypoglycaemic seizure	2 (1.1)	3	5				2 (0.6)	3	3
General disorders and administration site conditions									
Pyrexia	17 (9.4)	26	47	10 (5.6)	15	28	27 (7.5)	41	38
Fatigue	2 (1.1)	2	4	3 (1.7)	3	6	5 (1.4)	5	5
Local swelling	3 (1.7)	3	5	1 (0.6)	2	4	4 (1.1)	5	5
Hypertrophy	2 (1.1)	3	5	1 (0.6)	1	2	3 (0.8)	4	4
Injection site hypertrophy	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Pain				2 (1.1)	2	4	2 (0.6)	2	2
Metabolism and nutrition disorders									
Hypoglycaemia	11 (6.1)	12	22	3 (1.7)	4	7	14 (3.9)	16	15
Hypercreatininaemia	3 (1.7)	3	5	2 (1.1)	2	4	5 (1.4)	5	5
Hyperkalaemia	3 (1.7)	3	5	2 (1.1)	2	4	5 (1.4)	5	5
Decreased appetite	3 (1.7)	3	5				3 (0.8)	3	3
Hyperglycaemia	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Acetonaemia	2 (1.1)	3	5				2 (0.6)	3	3
Injury, poisoning and procedural complications									
Wrong drug administered	6 (3.3)	7	13	3 (1.7)	3	6	9 (2.5)	10	9
Joint injury	2 (1.1)	2	4	3 (1.7)	3	6	5 (1.4)	5	5
Laceration	1 (0.6)	1	2	3 (1.7)	3	6	4 (1.1)	4	4
Ligament sprain	3 (1.7)	4	7				3 (0.8)	4	4
Limb injury	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Accidental overdose				2 (1.1)	2	4	2 (0.6)	2	2
Fibula fracture	2 (1.1)	2	4				2 (0.6)	2	2
Musculoskeletal and connective tissue disorders									
Arthralgia	4 (2.2)	4	7	3 (1.7)	3	6	7 (1.9)	7	6
Pain in extremity	1 (0.6)	1	2	3 (1.7)	3	6	4 (1.1)	4	4
Myalgia	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Muscle spasms				2 (1.1)	2	4	2 (0.6)	2	2
Investigations									
Blood ketone body increased	2 (1.1)	2	4	7 (3.9)	9	17	9 (2.5)	11	10
Reproductive system and breast disorders									
Dysmenorrhoea	3 (1.7)	5	9	5 (2.8)	5	9	8 (2.2)	10	9
Ear and labyrinth disorders									
Ear pain	2 (1.1)	2	4	2 (1.1)	2	4	4 (1.1)	4	4
Motion sickness	2 (1.1)	4	7				2 (0.6)	4	4
Skin and subcutaneous tissue disorders									
Rash	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3

N: Number of subjects, %: Percentage of subjects, E: Number of events,
R: Event rate per 100 exposure years

Adverse events by system organ class and preferred term - most frequent [>=1%]-
treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lipohypertrophy	2 (1.1)	2	4				2 (0.6)	2	2
Immune system disorders									
Hypersensitivity	2 (1.1)	5	9				2 (0.6)	5	5
Seasonal allergy	2 (1.1)	2	4				2 (0.6)	2	2
Eye disorders									
Vision blurred	2 (1.1)	2	4				2 (0.6)	2	2

N: Number of subjects, %: Percentage of subjects, E: Number of events,
R: Event rate per 100 exposure years

14.3.1.8 Serious adverse events by system organ class and preferred term - most frequent [>=5%]- treatment emergent - summary - safety analysis set

There is no data for this table

14.3.1.9 Serious adverse events by system organ class and preferred term - most frequent [>=1%]- treatment emergent - summary - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	181				179				360			
Events	5	(2.8)	5	9	1	(0.6)	1	2	6	(1.7)	6	6
Metabolism and nutrition disorders												
Hypoglycaemia	5	(2.8)	5	9	1	(0.6)	1	2	6	(1.7)	6	6

N: Number of subjects, %: Percentage of subjects, E: Number of events,
R: Event rate per 100 exposure years

14.3.1.10 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	181				179				360			
Events	141	(77.9)	501	915	134	(74.9)	460	853	275	(76.4)	961	884
Infections and infestations	82	(45.3)	141	257	89	(49.7)	141	261	171	(47.5)	282	259
Nasopharyngitis	36	(19.9)	43	79	32	(17.9)	42	78	68	(18.9)	85	78
Upper respiratory tract infection	11	(6.1)	12	22	17	(9.5)	18	33	28	(7.8)	30	28
Influenza	9	(5.0)	10	18	10	(5.6)	12	22	19	(5.3)	22	20
Gastroenteritis	5	(2.8)	5	9	8	(4.5)	8	15	13	(3.6)	13	12
Pharyngitis	3	(1.7)	3	5	10	(5.6)	13	24	13	(3.6)	16	15
Gastroenteritis viral	7	(3.9)	10	18	5	(2.8)	5	9	12	(3.3)	15	14
Viral infection	4	(2.2)	4	7	7	(3.9)	7	13	11	(3.1)	11	10
Rhinitis	6	(3.3)	8	15	3	(1.7)	3	6	9	(2.5)	11	10
Bronchitis	5	(2.8)	5	9	2	(1.1)	2	4	7	(1.9)	7	6
Sinusitis	3	(1.7)	3	5	4	(2.2)	4	7	7	(1.9)	7	6
Viral upper respiratory tract infection	4	(2.2)	5	9	2	(1.1)	2	4	6	(1.7)	7	6
Otitis media	5	(2.8)	6	11					5	(1.4)	6	6
Pharyngitis streptococcal	4	(2.2)	4	7	1	(0.6)	1	2	5	(1.4)	5	5
Acute tonsillitis	1	(0.6)	1	2	2	(1.1)	3	6	3	(0.8)	4	4
Ear infection	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Respiratory tract infection	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Tonsillitis	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Varicella	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Conjunctivitis					2	(1.1)	2	4	2	(0.6)	2	2
Croup infectious	2	(1.1)	2	4					2	(0.6)	2	2
Febrile infection	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Gastrointestinal infection	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Laryngitis	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Pharyngotonsillitis	2	(1.1)	2	4					2	(0.6)	2	2
Urinary tract infection	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Viral pharyngitis	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Abscess	1	(0.6)	1	2					1	(0.3)	1	1
Conjunctivitis viral					1	(0.6)	1	2	1	(0.3)	1	1
Fungal skin infection					1	(0.6)	1	2	1	(0.3)	1	1
Gingivitis					1	(0.6)	1	2	1	(0.3)	1	1
Herpes zoster	1	(0.6)	1	2					1	(0.3)	1	1
Hordeolum					1	(0.6)	1	2	1	(0.3)	1	1
Lice infestation					1	(0.6)	1	2	1	(0.3)	1	1

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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
Lower respiratory tract infection				1 (0.6)	1	2	1 (0.3)	1	1
Oral candidiasis	1 (0.6)	1	2				1 (0.3)	1	1
Oral herpes	1 (0.6)	1	2				1 (0.3)	1	1
Pneumonia				1 (0.6)	1	2	1 (0.3)	1	1
Pyelonephritis				1 (0.6)	1	2	1 (0.3)	1	1
Tracheitis	1 (0.6)	1	2				1 (0.3)	1	1
Tracheobronchitis				1 (0.6)	1	2	1 (0.3)	1	1
Viral diarrhoea	1 (0.6)	1	2				1 (0.3)	1	1
Gastrointestinal disorders	55 (30.4)	104	190	49 (27.4)	91	169	104 (28.9)	195	179
Vomiting	22 (12.2)	25	46	12 (6.7)	13	24	34 (9.4)	38	35
Abdominal pain upper	14 (7.7)	22	40	17 (9.5)	26	48	31 (8.6)	48	44
Abdominal pain	10 (5.5)	13	24	7 (3.9)	13	24	17 (4.7)	26	24
Nausea	6 (3.3)	6	11	8 (4.5)	10	19	14 (3.9)	16	15
Diarrhoea	7 (3.9)	8	15	6 (3.4)	6	11	13 (3.6)	14	13
Abdominal discomfort	6 (3.3)	6	11	2 (1.1)	3	6	8 (2.2)	9	8
Gastritis	3 (1.7)	4	7	5 (2.8)	6	11	8 (2.2)	10	9
Toothache	4 (2.2)	8	15	4 (2.2)	6	11	8 (2.2)	14	13
Constipation	4 (2.2)	4	7				4 (1.1)	4	4
Odynophagia	3 (1.7)	4	7				3 (0.8)	4	4
Abdominal distension	1 (0.6)	1	2				1 (0.3)	1	1
Aphthous stomatitis				1 (0.6)	1	2	1 (0.3)	1	1
Dental caries				1 (0.6)	1	2	1 (0.3)	1	1
Dyspepsia				1 (0.6)	1	2	1 (0.3)	1	1
Enterocolitis	1 (0.6)	1	2				1 (0.3)	1	1
Eructation				1 (0.6)	1	2	1 (0.3)	1	1
Gastric disorder				1 (0.6)	1	2	1 (0.3)	1	1
Gastric mucosal hypertrophy				1 (0.6)	1	2	1 (0.3)	1	1
Gastrointestinal disorder				1 (0.6)	1	2	1 (0.3)	1	1
Gastrointestinal motility disorder	1 (0.6)	1	2				1 (0.3)	1	1
Mouth haemorrhage	1 (0.6)	1	2				1 (0.3)	1	1
Stomatitis				1 (0.6)	1	2	1 (0.3)	1	1

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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
Nervous system disorders	30 (16.6)	65	119	34 (19.0)	71	132	64 (17.8)	136	125
Headache	23 (12.7)	47	86	32 (17.9)	64	119	55 (15.3)	111	102
Dizziness	3 (1.7)	3	5				3 (0.8)	3	3
Migraine	1 (0.6)	6	11	2 (1.1)	4	7	3 (0.8)	10	9
Sinus headache	2 (1.1)	3	5	1 (0.6)	1	2	3 (0.8)	4	4
Hypoglycaemic seizure	2 (1.1)	3	5				2 (0.6)	3	3
Convulsion	1 (0.6)	1	2				1 (0.3)	1	1
Diabetic neuropathy	1 (0.6)	1	2				1 (0.3)	1	1
Hypoaesthesia				1 (0.6)	1	2	1 (0.3)	1	1
Loss of consciousness				1 (0.6)	1	2	1 (0.3)	1	1
Neuropathy peripheral	1 (0.6)	1	2				1 (0.3)	1	1
Respiratory, thoracic and mediastinal disorders	32 (17.7)	43	79	29 (16.2)	46	85	61 (16.9)	89	82
Cough	13 (7.2)	16	29	9 (5.0)	9	17	22 (6.1)	25	23
Oropharyngeal pain	9 (5.0)	13	24	13 (7.3)	14	26	22 (6.1)	27	25
Nasal congestion	3 (1.7)	3	5	5 (2.8)	6	11	8 (2.2)	9	8
Rhinorrhoea	1 (0.6)	1	2	6 (3.4)	10	19	7 (1.9)	11	10
Respiratory disorder	4 (2.2)	5	9	2 (1.1)	2	4	6 (1.7)	7	6
Asthma	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Rhinitis allergic	2 (1.1)	2	4				2 (0.6)	2	2
Allergic respiratory symptom				1 (0.6)	1	2	1 (0.3)	1	1
Dyspnoea	1 (0.6)	1	2				1 (0.3)	1	1
Epistaxis				1 (0.6)	1	2	1 (0.3)	1	1
Nasal discomfort				1 (0.6)	1	2	1 (0.3)	1	1
Pulmonary congestion				1 (0.6)	1	2	1 (0.3)	1	1
Throat irritation	1 (0.6)	1	2				1 (0.3)	1	1

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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
General disorders and administration site conditions	26 (14.4)	39	71	19 (10.6)	28	52	45 (12.5)	67	62
Pyrexia	17 (9.4)	26	47	10 (5.6)	15	28	27 (7.5)	41	38
Fatigue	2 (1.1)	2	4	3 (1.7)	3	6	5 (1.4)	5	5
Local swelling	3 (1.7)	3	5	1 (0.6)	2	4	4 (1.1)	5	5
Hypertrophy	2 (1.1)	3	5	1 (0.6)	1	2	3 (0.8)	4	4
Injection site hypertrophy	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Pain				2 (1.1)	2	4	2 (0.6)	2	2
Chest pain	1 (0.6)	1	2				1 (0.3)	1	1
Device breakage				1 (0.6)	1	2	1 (0.3)	1	1
Discomfort				1 (0.6)	1	2	1 (0.3)	1	1
Drug intolerance	1 (0.6)	1	2				1 (0.3)	1	1
Injection site swelling				1 (0.6)	1	2	1 (0.3)	1	1
Malaise	1 (0.6)	1	2				1 (0.3)	1	1
Nodule	1 (0.6)	1	2				1 (0.3)	1	1
Injury, poisoning and procedural complications	21 (11.6)	29	53	16 (8.9)	19	35	37 (10.3)	48	44
Wrong drug administered	6 (3.3)	7	13	3 (1.7)	3	6	9 (2.5)	10	9
Joint injury	2 (1.1)	2	4	3 (1.7)	3	6	5 (1.4)	5	5
Laceration	1 (0.6)	1	2	3 (1.7)	3	6	4 (1.1)	4	4
Ligament sprain	3 (1.7)	4	7				3 (0.8)	4	4
Limb injury	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Accidental overdose				2 (1.1)	2	4	2 (0.6)	2	2
Fibula fracture	2 (1.1)	2	4				2 (0.6)	2	2
Concussion	1 (0.6)	1	2				1 (0.3)	1	1
Contusion				1 (0.6)	1	2	1 (0.3)	1	1
Drug dispensing error				1 (0.6)	1	2	1 (0.3)	1	1
Excoriation	1 (0.6)	1	2				1 (0.3)	1	1
Face injury				1 (0.6)	1	2	1 (0.3)	1	1
Fall				1 (0.6)	1	2	1 (0.3)	1	1
Head injury				1 (0.6)	1	2	1 (0.3)	1	1
Heat stroke	1 (0.6)	1	2				1 (0.3)	1	1
Muscle injury	1 (0.6)	1	2				1 (0.3)	1	1
Muscle strain	1 (0.6)	2	4				1 (0.3)	2	2
Overdose	1 (0.6)	1	2				1 (0.3)	1	1
Post procedural inflammation	1 (0.6)	1	2				1 (0.3)	1	1
Sunburn	1 (0.6)	2	4				1 (0.3)	2	2
Thermal burn				1 (0.6)	1	2	1 (0.3)	1	1
Tibia fracture	1 (0.6)	1	2				1 (0.3)	1	1
Wound	1 (0.6)	1	2				1 (0.3)	1	1

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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
Metabolism and nutrition disorders	22 (12.2)	27	49	10 (5.6)	12	22	32 (8.9)	39	36
Hypoglycaemia	11 (6.1)	12	22	3 (1.7)	4	7	14 (3.9)	16	15
Hypercreatininaemia	3 (1.7)	3	5	2 (1.1)	2	4	5 (1.4)	5	5
Hyperkalaemia	3 (1.7)	3	5	2 (1.1)	2	4	5 (1.4)	5	5
Decreased appetite	3 (1.7)	3	5				3 (0.8)	3	3
Hyperglycaemia	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Acetonaemia	2 (1.1)	3	5				2 (0.6)	3	3
Diabetic ketoacidosis	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Hyponatraemia	1 (0.6)	1	2				1 (0.3)	1	1
Ketosis				1 (0.6)	1	2	1 (0.3)	1	1
Musculoskeletal and connective tissue disorders	9 (5.0)	9	16	12 (6.7)	15	28	21 (5.8)	24	22
Arthralgia	4 (2.2)	4	7	3 (1.7)	3	6	7 (1.9)	7	6
Pain in extremity	1 (0.6)	1	2	3 (1.7)	3	6	4 (1.1)	4	4
Myalgia	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Muscle spasms				2 (1.1)	2	4	2 (0.6)	2	2
Musculoskeletal pain	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Back pain	1 (0.6)	1	2				1 (0.3)	1	1
Compartment syndrome	1 (0.6)	1	2				1 (0.3)	1	1
Epiphysiolysis				1 (0.6)	1	2	1 (0.3)	1	1
Growing pains				1 (0.6)	1	2	1 (0.3)	1	1
Neck pain				1 (0.6)	1	2	1 (0.3)	1	1
Spinal pain				1 (0.6)	1	2	1 (0.3)	1	1

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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
Investigations	7	(3.9)	9	16	13	(7.3)	16	30	20	(5.6)	25	23
Blood ketone body increased	2	(1.1)	2	4	7	(3.9)	9	17	9	(2.5)	11	10
Alanine aminotransferase increased	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Blood glucose increased	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Glycosylated haemoglobin increased	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Aspartate aminotransferase increased	1	(0.6)	1	2					1	(0.3)	1	1
Blood alkaline phosphatase increased	1	(0.6)	1	2					1	(0.3)	1	1
Blood bilirubin increased					1	(0.6)	1	2	1	(0.3)	1	1
Blood creatinine increased					1	(0.6)	1	2	1	(0.3)	1	1
Blood glucose fluctuation	1	(0.6)	1	2					1	(0.3)	1	1
Blood immunoglobulin A abnormal					1	(0.6)	1	2	1	(0.3)	1	1
Ultrasound thyroid abnormal	1	(0.6)	1	2					1	(0.3)	1	1
Weight decreased					1	(0.6)	1	2	1	(0.3)	1	1
Skin and subcutaneous tissue disorders	6	(3.3)	6	11	6	(3.4)	6	11	12	(3.3)	12	11
Rash	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Ingrowing nail	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Lipohypertrophy	2	(1.1)	2	4					2	(0.6)	2	2
Blister					1	(0.6)	1	2	1	(0.3)	1	1
Dermatitis					1	(0.6)	1	2	1	(0.3)	1	1
Dermatitis allergic	1	(0.6)	1	2					1	(0.3)	1	1
Keratosis pilaris	1	(0.6)	1	2					1	(0.3)	1	1
Scar pain					1	(0.6)	1	2	1	(0.3)	1	1
Reproductive system and breast disorders	3	(1.7)	5	9	6	(3.4)	6	11	9	(2.5)	11	10
Dysmenorrhoea	3	(1.7)	5	9	5	(2.8)	5	9	8	(2.2)	10	9
Pelvic pain					1	(0.6)	1	2	1	(0.3)	1	1

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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
Ear and labyrinth disorders	5 (2.8)	8	15	2 (1.1)	2	4	7 (1.9)	10	9
Ear pain	2 (1.1)	2	4	2 (1.1)	2	4	4 (1.1)	4	4
Motion sickness	2 (1.1)	4	7				2 (0.6)	4	4
Deafness neurosensory	1 (0.6)	1	2				1 (0.3)	1	1
Vertigo	1 (0.6)	1	2				1 (0.3)	1	1
Immune system disorders	4 (2.2)	7	13	1 (0.6)	1	2	5 (1.4)	8	7
Hypersensitivity	2 (1.1)	5	9				2 (0.6)	5	5
Seasonal allergy	2 (1.1)	2	4				2 (0.6)	2	2
Multiple allergies				1 (0.6)	1	2	1 (0.3)	1	1
Eye disorders	3 (1.7)	3	5	1 (0.6)	1	2	4 (1.1)	4	4
Vision blurred	2 (1.1)	2	4				2 (0.6)	2	2
Eye pain	1 (0.6)	1	2				1 (0.3)	1	1
Eyelid disorder				1 (0.6)	1	2	1 (0.3)	1	1
Psychiatric disorders	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Insomnia	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Anxiety disorder				1 (0.6)	1	2	1 (0.3)	1	1
Renal and urinary disorders	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Urethral pain	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Vascular disorders	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Haematoma	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Blood and lymphatic system disorders	1 (0.6)	1	2				1 (0.3)	1	1
Lymphadenitis	1 (0.6)	1	2				1 (0.3)	1	1
Congenital, familial and genetic disorders	1 (0.6)	1	2				1 (0.3)	1	1
Developmental glaucoma	1 (0.6)	1	2				1 (0.3)	1	1
Endocrine disorders	1 (0.6)	1	2				1 (0.3)	1	1
Hypothyroidism	1 (0.6)	1	2				1 (0.3)	1	1

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%= Percentage of subjects
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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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				1 (0.6)	1	2	1 (0.3)	1	1
Skin papilloma				1 (0.6)	1	2	1 (0.3)	1	1

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

14.3.1.11 Adverse events by system organ class and preferred term - treatment emergent - summary - children (1-5 years) - safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	40				41				81			
Events	35	(87.5)	143	1192	26	(63.4)	86	702	61	(75.3)	229	945
Infections and infestations	24	(60.0)	49	409	20	(48.8)	39	318	44	(54.3)	88	363
Nasopharyngitis	9	(22.5)	12	100	8	(19.5)	12	98	17	(21.0)	24	99
Influenza	3	(7.5)	4	33	5	(12.2)	7	57	8	(9.9)	11	45
Upper respiratory tract infection	4	(10.0)	5	42	4	(9.8)	4	33	8	(9.9)	9	37
Rhinitis	4	(10.0)	5	42	2	(4.9)	2	16	6	(7.4)	7	29
Gastroenteritis	2	(5.0)	2	17	2	(4.9)	2	16	4	(4.9)	4	16
Otitis media	3	(7.5)	4	33					3	(3.7)	4	16
Sinusitis	1	(2.5)	1	8	2	(4.9)	2	16	3	(3.7)	3	12
Bronchitis	2	(5.0)	2	17					2	(2.5)	2	8
Pharyngitis streptococcal	2	(5.0)	2	17					2	(2.5)	2	8
Respiratory tract infection	1	(2.5)	1	8	1	(2.4)	1	8	2	(2.5)	2	8
Tonsillitis	2	(5.0)	2	17					2	(2.5)	2	8
Viral infection	2	(5.0)	2	17					2	(2.5)	2	8
Viral upper respiratory tract infection	1	(2.5)	1	8	1	(2.4)	1	8	2	(2.5)	2	8
Abscess	1	(2.5)	1	8					1	(1.2)	1	4
Acute tonsillitis					1	(2.4)	2	16	1	(1.2)	2	8
Conjunctivitis					1	(2.4)	1	8	1	(1.2)	1	4
Conjunctivitis viral					1	(2.4)	1	8	1	(1.2)	1	4
Croup infectious	1	(2.5)	1	8					1	(1.2)	1	4
Ear infection	1	(2.5)	1	8					1	(1.2)	1	4
Gastroenteritis viral					1	(2.4)	1	8	1	(1.2)	1	4
Laryngitis					1	(2.4)	1	8	1	(1.2)	1	4
Pharyngitis	1	(2.5)	1	8					1	(1.2)	1	4
Tracheitis	1	(2.5)	1	8					1	(1.2)	1	4
Urinary tract infection					1	(2.4)	1	8	1	(1.2)	1	4
Varicella					1	(2.4)	1	8	1	(1.2)	1	4
Viral diarrhoea	1	(2.5)	1	8					1	(1.2)	1	4

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

Adverse events by system organ class and preferred term - treatment emergent - summary - children (1-5 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal disorders	13 (32.5)	26	217	8 (19.5)	12	98	21 (25.9)	38	157
Vomiting	10 (25.0)	12	100	5 (12.2)	6	49	15 (18.5)	18	74
Abdominal pain upper	2 (5.0)	2	17	2 (4.9)	2	16	4 (4.9)	4	16
Diarrhoea	1 (2.5)	1	8	1 (2.4)	1	8	2 (2.5)	2	8
Abdominal discomfort	1 (2.5)	1	8				1 (1.2)	1	4
Abdominal pain				1 (2.4)	1	8	1 (1.2)	1	4
Constipation	1 (2.5)	1	8				1 (1.2)	1	4
Enterocolitis	1 (2.5)	1	8				1 (1.2)	1	4
Eructation				1 (2.4)	1	8	1 (1.2)	1	4
Gastritis	1 (2.5)	1	8				1 (1.2)	1	4
Gastrointestinal disorder				1 (2.4)	1	8	1 (1.2)	1	4
Mouth haemorrhage	1 (2.5)	1	8				1 (1.2)	1	4
Nausea	1 (2.5)	1	8				1 (1.2)	1	4
Toothache	1 (2.5)	5	42				1 (1.2)	5	21
Respiratory, thoracic and mediastinal disorders	12 (30.0)	15	125	5 (12.2)	9	73	17 (21.0)	24	99
Cough	5 (12.5)	5	42				5 (6.2)	5	21
Respiratory disorder	3 (7.5)	4	33	1 (2.4)	1	8	4 (4.9)	5	21
Nasal congestion				2 (4.9)	3	24	2 (2.5)	3	12
Oropharyngeal pain	2 (5.0)	3	25				2 (2.5)	3	12
Rhinorrhoea				2 (4.9)	4	33	2 (2.5)	4	16
Allergic respiratory symptom				1 (2.4)	1	8	1 (1.2)	1	4
Asthma	1 (2.5)	1	8				1 (1.2)	1	4
Dyspnoea	1 (2.5)	1	8				1 (1.2)	1	4
Throat irritation	1 (2.5)	1	8				1 (1.2)	1	4
General disorders and administration site conditions	12 (30.0)	17	142	4 (9.8)	7	57	16 (19.8)	24	99
Pyrexia	11 (27.5)	15	125	3 (7.3)	5	41	14 (17.3)	20	82
Discomfort				1 (2.4)	1	8	1 (1.2)	1	4
Fatigue	1 (2.5)	1	8				1 (1.2)	1	4
Injection site hypertrophy				1 (2.4)	1	8	1 (1.2)	1	4
Nodule	1 (2.5)	1	8				1 (1.2)	1	4

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

Adverse events by system organ class and preferred term - treatment emergent - summary - children (1-5 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Metabolism and nutrition disorders	10 (25.0)	15	125	5 (12.2)	6	49	15 (18.5)	21	87
Hypoglycaemia	5 (12.5)	6	50	2 (4.9)	2	16	7 (8.6)	8	33
Hypercreatininaemia	3 (7.5)	3	25	2 (4.9)	2	16	5 (6.2)	5	21
Hyperkalaemia	2 (5.0)	2	17	1 (2.4)	1	8	3 (3.7)	3	12
Acetonaemia	1 (2.5)	2	17				1 (1.2)	2	8
Decreased appetite	1 (2.5)	1	8				1 (1.2)	1	4
Hyperglycaemia				1 (2.4)	1	8	1 (1.2)	1	4
Hyponatraemia	1 (2.5)	1	8				1 (1.2)	1	4
Nervous system disorders	4 (10.0)	4	33	3 (7.3)	4	33	7 (8.6)	8	33
Headache	3 (7.5)	3	25	2 (4.9)	3	24	5 (6.2)	6	25
Convulsion	1 (2.5)	1	8				1 (1.2)	1	4
Hypoaesthesia				1 (2.4)	1	8	1 (1.2)	1	4
Injury, poisoning and procedural complications	3 (7.5)	3	25	3 (7.3)	3	24	6 (7.4)	6	25
Joint injury	1 (2.5)	1	8	1 (2.4)	1	8	2 (2.5)	2	8
Wrong drug administered	2 (5.0)	2	17				2 (2.5)	2	8
Accidental overdose				1 (2.4)	1	8	1 (1.2)	1	4
Laceration				1 (2.4)	1	8	1 (1.2)	1	4
Investigations	3 (7.5)	4	33	2 (4.9)	3	24	5 (6.2)	7	29
Blood ketone body increased	1 (2.5)	1	8	2 (4.9)	3	24	3 (3.7)	4	16
Alanine aminotransferase increased	1 (2.5)	1	8				1 (1.2)	1	4
Aspartate aminotransferase increased	1 (2.5)	1	8				1 (1.2)	1	4
Blood alkaline phosphatase increased	1 (2.5)	1	8				1 (1.2)	1	4
Musculoskeletal and connective tissue disorders	1 (2.5)	1	8	2 (4.9)	2	16	3 (3.7)	3	12
Back pain	1 (2.5)	1	8				1 (1.2)	1	4
Growing pains				1 (2.4)	1	8	1 (1.2)	1	4
Pain in extremity				1 (2.4)	1	8	1 (1.2)	1	4

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

Adverse events by system organ class and preferred term - treatment emergent - summary - children (1-5 years) - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Skin and subcutaneous tissue disorders	2	(5.0)	2	17	1	(2.4)	1	8	3	(3.7)	3	12
Dermatitis allergic	1	(2.5)	1	8					1	(1.2)	1	4
Ingrowing nail					1	(2.4)	1	8	1	(1.2)	1	4
Rash	1	(2.5)	1	8					1	(1.2)	1	4
Ear and labyrinth disorders	2	(5.0)	4	33					2	(2.5)	4	16
Motion sickness	2	(5.0)	4	33					2	(2.5)	4	16
Endocrine disorders	1	(2.5)	1	8					1	(1.2)	1	4
Hypothyroidism	1	(2.5)	1	8					1	(1.2)	1	4
Immune system disorders	1	(2.5)	1	8					1	(1.2)	1	4
Seasonal allergy	1	(2.5)	1	8					1	(1.2)	1	4
Vascular disorders	1	(2.5)	1	8					1	(1.2)	1	4
Haematoma	1	(2.5)	1	8					1	(1.2)	1	4

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

14.3.1.12 Adverse events by system organ class and preferred term - treatment emergent - summary - children (6-11 years) - safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	61				61				122			
Events	44	(72.1)	148	792	48	(78.7)	166	905	92	(75.4)	314	848
Infections and infestations	26	(42.6)	44	236	33	(54.1)	52	284	59	(48.4)	96	259
Nasopharyngitis	13	(21.3)	14	75	13	(21.3)	18	98	26	(21.3)	32	86
Pharyngitis	1	(1.6)	1	5	6	(9.8)	9	49	7	(5.7)	10	27
Upper respiratory tract infection	3	(4.9)	3	16	4	(6.6)	5	27	7	(5.7)	8	22
Gastroenteritis viral	3	(4.9)	6	32	2	(3.3)	2	11	5	(4.1)	8	22
Gastroenteritis	2	(3.3)	2	11	2	(3.3)	2	11	4	(3.3)	4	11
Influenza	1	(1.6)	1	5	3	(4.9)	3	16	4	(3.3)	4	11
Rhinitis	2	(3.3)	3	16	1	(1.6)	1	5	3	(2.5)	4	11
Febrile infection	1	(1.6)	1	5	1	(1.6)	1	5	2	(1.6)	2	5
Sinusitis	1	(1.6)	1	5	1	(1.6)	1	5	2	(1.6)	2	5
Varicella	1	(1.6)	1	5	1	(1.6)	1	5	2	(1.6)	2	5
Viral infection					2	(3.3)	2	11	2	(1.6)	2	5
Viral pharyngitis	1	(1.6)	1	5	1	(1.6)	1	5	2	(1.6)	2	5
Viral upper respiratory tract infection	2	(3.3)	3	16					2	(1.6)	3	8
Acute tonsillitis					1	(1.6)	1	5	1	(0.8)	1	3
Conjunctivitis					1	(1.6)	1	5	1	(0.8)	1	3
Croup infectious	1	(1.6)	1	5					1	(0.8)	1	3
Ear infection	1	(1.6)	1	5					1	(0.8)	1	3
Gastrointestinal infection					1	(1.6)	1	5	1	(0.8)	1	3
Gingivitis					1	(1.6)	1	5	1	(0.8)	1	3
Laryngitis	1	(1.6)	1	5					1	(0.8)	1	3
Lice infestation					1	(1.6)	1	5	1	(0.8)	1	3
Otitis media	1	(1.6)	1	5					1	(0.8)	1	3
Pharyngotonsillitis	1	(1.6)	1	5					1	(0.8)	1	3
Respiratory tract infection	1	(1.6)	1	5					1	(0.8)	1	3
Tonsillitis					1	(1.6)	1	5	1	(0.8)	1	3
Urinary tract infection	1	(1.6)	1	5					1	(0.8)	1	3

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

Adverse events by system organ class and preferred term - treatment emergent - summary - children (6-11 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal disorders	16 (26.2)	28	150	15 (24.6)	28	153	31 (25.4)	56	151
Vomiting	6 (9.8)	6	32	2 (3.3)	2	11	8 (6.6)	8	22
Abdominal pain upper	3 (4.9)	6	32	4 (6.6)	7	38	7 (5.7)	13	35
Abdominal pain	3 (4.9)	3	16	3 (4.9)	7	38	6 (4.9)	10	27
Diarrhoea	3 (4.9)	3	16	3 (4.9)	3	16	6 (4.9)	6	16
Gastritis	2 (3.3)	3	16	3 (4.9)	3	16	5 (4.1)	6	16
Constipation	2 (3.3)	2	11				2 (1.6)	2	5
Nausea	1 (1.6)	1	5	1 (1.6)	1	5	2 (1.6)	2	5
Abdominal discomfort	1 (1.6)	1	5				1 (0.8)	1	3
Abdominal distension	1 (1.6)	1	5				1 (0.8)	1	3
Aphthous stomatitis				1 (1.6)	1	5	1 (0.8)	1	3
Dental caries				1 (1.6)	1	5	1 (0.8)	1	3
Odynophagia	1 (1.6)	2	11				1 (0.8)	2	5
Stomatitis				1 (1.6)	1	5	1 (0.8)	1	3
Toothache				1 (1.6)	2	11	1 (0.8)	2	5
Nervous system disorders	9 (14.8)	21	112	10 (16.4)	26	142	19 (15.6)	47	127
Headache	5 (8.2)	16	86	10 (16.4)	26	142	15 (12.3)	42	113
Dizziness	2 (3.3)	2	11				2 (1.6)	2	5
Diabetic neuropathy	1 (1.6)	1	5				1 (0.8)	1	3
Hypoglycaemic seizure	1 (1.6)	2	11				1 (0.8)	2	5
Respiratory, thoracic and mediastinal disorders	6 (9.8)	13	70	13 (21.3)	21	115	19 (15.6)	34	92
Cough	3 (4.9)	6	32	5 (8.2)	5	27	8 (6.6)	11	30
Oropharyngeal pain	2 (3.3)	4	21	6 (9.8)	7	38	8 (6.6)	11	30
Nasal congestion	1 (1.6)	1	5	2 (3.3)	2	11	3 (2.5)	3	8
Rhinorrhoea				3 (4.9)	5	27	3 (2.5)	5	14
Epistaxis				1 (1.6)	1	5	1 (0.8)	1	3
Nasal discomfort				1 (1.6)	1	5	1 (0.8)	1	3
Respiratory disorder	1 (1.6)	1	5				1 (0.8)	1	3
Rhinitis allergic	1 (1.6)	1	5				1 (0.8)	1	3

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

Adverse events by system organ class and preferred term - treatment emergent - summary - children (6-11 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
General disorders and administration site conditions	7 (11.5)	13	70	8 (13.1)	10	55	15 (12.3)	23	62
Pyrexia	2 (3.3)	6	32	6 (9.8)	7	38	8 (6.6)	13	35
Local swelling	2 (3.3)	2	11	1 (1.6)	2	11	3 (2.5)	4	11
Hypertrophy	2 (3.3)	3	16				2 (1.6)	3	8
Device breakage				1 (1.6)	1	5	1 (0.8)	1	3
Drug intolerance	1 (1.6)	1	5				1 (0.8)	1	3
Malaise	1 (1.6)	1	5				1 (0.8)	1	3
Injury, poisoning and procedural complications	5 (8.2)	5	27	6 (9.8)	8	44	11 (9.0)	13	35
Joint injury	1 (1.6)	1	5	2 (3.3)	2	11	3 (2.5)	3	8
Limb injury	1 (1.6)	1	5	2 (3.3)	2	11	3 (2.5)	3	8
Wrong drug administered	1 (1.6)	1	5	1 (1.6)	1	5	2 (1.6)	2	5
Face injury				1 (1.6)	1	5	1 (0.8)	1	3
Laceration				1 (1.6)	1	5	1 (0.8)	1	3
Muscle injury	1 (1.6)	1	5				1 (0.8)	1	3
Thermal burn				1 (1.6)	1	5	1 (0.8)	1	3
Wound	1 (1.6)	1	5				1 (0.8)	1	3
Metabolism and nutrition disorders	7 (11.5)	7	37	1 (1.6)	1	5	8 (6.6)	8	22
Hypoglycaemia	3 (4.9)	3	16				3 (2.5)	3	8
Decreased appetite	2 (3.3)	2	11				2 (1.6)	2	5
Acetonaemia	1 (1.6)	1	5				1 (0.8)	1	3
Hyperglycaemia				1 (1.6)	1	5	1 (0.8)	1	3
Hyperkalaemia	1 (1.6)	1	5				1 (0.8)	1	3
Investigations	2 (3.3)	2	11	5 (8.2)	5	27	7 (5.7)	7	19
Blood ketone body increased				3 (4.9)	3	16	3 (2.5)	3	8
Blood glucose fluctuation	1 (1.6)	1	5				1 (0.8)	1	3
Blood immunoglobulin A abnormal				1 (1.6)	1	5	1 (0.8)	1	3
Ultrasound thyroid abnormal	1 (1.6)	1	5				1 (0.8)	1	3
Weight decreased				1 (1.6)	1	5	1 (0.8)	1	3

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

Adverse events by system organ class and preferred term - treatment emergent - summary - children (6-11 years) - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Musculoskeletal and connective tissue disorders	1	(1.6)	1	5	5	(8.2)	6	33	6	(4.9)	7	19
Pain in extremity	1	(1.6)	1	5	2	(3.3)	2	11	3	(2.5)	3	8
Arthralgia					1	(1.6)	1	5	1	(0.8)	1	3
Epiphysiolysis					1	(1.6)	1	5	1	(0.8)	1	3
Muscle spasms					1	(1.6)	1	5	1	(0.8)	1	3
Neck pain					1	(1.6)	1	5	1	(0.8)	1	3
Skin and subcutaneous tissue disorders	3	(4.9)	3	16	2	(3.3)	2	11	5	(4.1)	5	14
Lipohypertrophy	2	(3.3)	2	11					2	(1.6)	2	5
Blister					1	(1.6)	1	5	1	(0.8)	1	3
Keratosis pilaris	1	(1.6)	1	5					1	(0.8)	1	3
Rash					1	(1.6)	1	5	1	(0.8)	1	3
Ear and labyrinth disorders	2	(3.3)	2	11	2	(3.3)	2	11	4	(3.3)	4	11
Ear pain	2	(3.3)	2	11	2	(3.3)	2	11	4	(3.3)	4	11
Eye disorders	2	(3.3)	2	11	1	(1.6)	1	5	3	(2.5)	3	8
Eye pain	1	(1.6)	1	5					1	(0.8)	1	3
Eyelid disorder					1	(1.6)	1	5	1	(0.8)	1	3
Vision blurred	1	(1.6)	1	5					1	(0.8)	1	3
Immune system disorders	2	(3.3)	5	27	1	(1.6)	1	5	3	(2.5)	6	16
Hypersensitivity	2	(3.3)	5	27					2	(1.6)	5	14
Multiple allergies					1	(1.6)	1	5	1	(0.8)	1	3
Renal and urinary disorders	1	(1.6)	1	5	1	(1.6)	1	5	2	(1.6)	2	5
Urethral pain	1	(1.6)	1	5	1	(1.6)	1	5	2	(1.6)	2	5
Blood and lymphatic system disorders	1	(1.6)	1	5					1	(0.8)	1	3
Lymphadenitis	1	(1.6)	1	5					1	(0.8)	1	3
Reproductive system and breast disorders					1	(1.6)	1	5	1	(0.8)	1	3
Pelvic pain					1	(1.6)	1	5	1	(0.8)	1	3
Vascular disorders					1	(1.6)	1	5	1	(0.8)	1	3
Haematoma					1	(1.6)	1	5	1	(0.8)	1	3

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

14.3.1.13 Adverse events by system organ class and preferred term - treatment emergent - summary - adolescents (12-17 years) - safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	80				77				157			
Events	62	(77.5)	210	872	60	(77.9)	208	891	122	(77.7)	418	881
Infections and infestations	32	(40.0)	48	199	36	(46.8)	50	214	68	(43.3)	98	207
Nasopharyngitis	14	(17.5)	17	71	11	(14.3)	12	51	25	(15.9)	29	61
Upper respiratory tract infection	4	(5.0)	4	17	9	(11.7)	9	39	13	(8.3)	13	27
Influenza	5	(6.3)	5	21	2	(2.6)	2	9	7	(4.5)	7	15
Viral infection	2	(2.5)	2	8	5	(6.5)	5	21	7	(4.5)	7	15
Gastroenteritis viral	4	(5.0)	4	17	2	(2.6)	2	9	6	(3.8)	6	13
Bronchitis	3	(3.8)	3	12	2	(2.6)	2	9	5	(3.2)	5	11
Gastroenteritis	1	(1.3)	1	4	4	(5.2)	4	17	5	(3.2)	5	11
Pharyngitis	1	(1.3)	1	4	4	(5.2)	4	17	5	(3.2)	5	11
Pharyngitis streptococcal	2	(2.5)	2	8	1	(1.3)	1	4	3	(1.9)	3	6
Sinusitis	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Viral upper respiratory tract infection	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Acute tonsillitis	1	(1.3)	1	4					1	(0.6)	1	2
Ear infection					1	(1.3)	1	4	1	(0.6)	1	2
Fungal skin infection					1	(1.3)	1	4	1	(0.6)	1	2
Gastrointestinal infection	1	(1.3)	1	4					1	(0.6)	1	2
Herpes zoster	1	(1.3)	1	4					1	(0.6)	1	2
Hordeolum					1	(1.3)	1	4	1	(0.6)	1	2
Lower respiratory tract infection					1	(1.3)	1	4	1	(0.6)	1	2
Oral candidiasis	1	(1.3)	1	4					1	(0.6)	1	2
Oral herpes	1	(1.3)	1	4					1	(0.6)	1	2
Otitis media	1	(1.3)	1	4					1	(0.6)	1	2
Pharyngotonsillitis	1	(1.3)	1	4					1	(0.6)	1	2
Pneumonia					1	(1.3)	1	4	1	(0.6)	1	2
Pyelonephritis					1	(1.3)	1	4	1	(0.6)	1	2
Tracheobronchitis					1	(1.3)	1	4	1	(0.6)	1	2

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

Adverse events by system organ class and preferred term - treatment emergent - summary - adolescents (12-17 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal disorders	26 (32.5)	50	208	26 (33.8)	51	218	52 (33.1)	101	213
Abdominal pain upper	9 (11.3)	14	58	11 (14.3)	17	73	20 (12.7)	31	65
Nausea	4 (5.0)	4	17	7 (9.1)	9	39	11 (7.0)	13	27
Vomiting	6 (7.5)	7	29	5 (6.5)	5	21	11 (7.0)	12	25
Abdominal pain	7 (8.8)	10	42	3 (3.9)	5	21	10 (6.4)	15	32
Abdominal discomfort	4 (5.0)	4	17	2 (2.6)	3	13	6 (3.8)	7	15
Toothache	3 (3.8)	3	12	3 (3.9)	4	17	6 (3.8)	7	15
Diarrhoea	3 (3.8)	4	17	2 (2.6)	2	9	5 (3.2)	6	13
Gastritis				2 (2.6)	3	13	2 (1.3)	3	6
Odynophagia	2 (2.5)	2	8				2 (1.3)	2	4
Constipation	1 (1.3)	1	4				1 (0.6)	1	2
Dyspepsia				1 (1.3)	1	4	1 (0.6)	1	2
Gastric disorder				1 (1.3)	1	4	1 (0.6)	1	2
Gastric mucosal hypertrophy				1 (1.3)	1	4	1 (0.6)	1	2
Gastrointestinal motility disorder	1 (1.3)	1	4				1 (0.6)	1	2
Nervous system disorders	17 (21.3)	40	166	21 (27.3)	41	176	38 (24.2)	81	171
Headache	15 (18.8)	28	116	20 (26.0)	35	150	35 (22.3)	63	133
Migraine	1 (1.3)	6	25	2 (2.6)	4	17	3 (1.9)	10	21
Sinus headache	2 (2.5)	3	12	1 (1.3)	1	4	3 (1.9)	4	8
Dizziness	1 (1.3)	1	4				1 (0.6)	1	2
Hypoglycaemic seizure	1 (1.3)	1	4				1 (0.6)	1	2
Loss of consciousness				1 (1.3)	1	4	1 (0.6)	1	2
Neuropathy peripheral	1 (1.3)	1	4				1 (0.6)	1	2
Respiratory, thoracic and mediastinal disorders	14 (17.5)	15	62	11 (14.3)	16	69	25 (15.9)	31	65
Oropharyngeal pain	5 (6.3)	6	25	7 (9.1)	7	30	12 (7.6)	13	27
Cough	5 (6.3)	5	21	4 (5.2)	4	17	9 (5.7)	9	19
Nasal congestion	2 (2.5)	2	8	1 (1.3)	1	4	3 (1.9)	3	6
Rhinorrhoea	1 (1.3)	1	4	1 (1.3)	1	4	2 (1.3)	2	4
Asthma				1 (1.3)	1	4	1 (0.6)	1	2
Pulmonary congestion				1 (1.3)	1	4	1 (0.6)	1	2
Respiratory disorder				1 (1.3)	1	4	1 (0.6)	1	2
Rhinitis allergic	1 (1.3)	1	4				1 (0.6)	1	2

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

Adverse events by system organ class and preferred term - treatment emergent - summary - adolescents (12-17 years) - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Injury, poisoning and procedural complications	13	(16.3)	21	87	7	(9.1)	8	34	20	(12.7)	29	61
Wrong drug administered	3	(3.8)	4	17	2	(2.6)	2	9	5	(3.2)	6	13
Ligament sprain	3	(3.8)	4	17					3	(1.9)	4	8
Fibula fracture	2	(2.5)	2	8					2	(1.3)	2	4
Laceration	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Accidental overdose					1	(1.3)	1	4	1	(0.6)	1	2
Concussion	1	(1.3)	1	4					1	(0.6)	1	2
Contusion					1	(1.3)	1	4	1	(0.6)	1	2
Drug dispensing error					1	(1.3)	1	4	1	(0.6)	1	2
Excoriation	1	(1.3)	1	4					1	(0.6)	1	2
Fall					1	(1.3)	1	4	1	(0.6)	1	2
Head injury					1	(1.3)	1	4	1	(0.6)	1	2
Heat stroke	1	(1.3)	1	4					1	(0.6)	1	2
Muscle strain	1	(1.3)	2	8					1	(0.6)	2	4
Overdose	1	(1.3)	1	4					1	(0.6)	1	2
Post procedural inflammation	1	(1.3)	1	4					1	(0.6)	1	2
Sunburn	1	(1.3)	2	8					1	(0.6)	2	4
Tibia fracture	1	(1.3)	1	4					1	(0.6)	1	2
General disorders and administration site conditions	7	(8.8)	9	37	7	(9.1)	11	47	14	(8.9)	20	42
Pyrexia	4	(5.0)	5	21	1	(1.3)	3	13	5	(3.2)	8	17
Fatigue	1	(1.3)	1	4	3	(3.9)	3	13	4	(2.5)	4	8
Injection site hypertrophy	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Pain					2	(2.6)	2	9	2	(1.3)	2	4
Chest pain	1	(1.3)	1	4					1	(0.6)	1	2
Hypertrophy					1	(1.3)	1	4	1	(0.6)	1	2
Injection site swelling					1	(1.3)	1	4	1	(0.6)	1	2
Local swelling	1	(1.3)	1	4					1	(0.6)	1	2
Musculoskeletal and connective tissue disorders	7	(8.8)	7	29	5	(6.5)	7	30	12	(7.6)	14	30
Arthralgia	4	(5.0)	4	17	2	(2.6)	2	9	6	(3.8)	6	13
Myalgia	1	(1.3)	1	4	2	(2.6)	2	9	3	(1.9)	3	6
Musculoskeletal pain	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Compartment syndrome	1	(1.3)	1	4					1	(0.6)	1	2
Muscle spasms					1	(1.3)	1	4	1	(0.6)	1	2
Spinal pain					1	(1.3)	1	4	1	(0.6)	1	2

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

Adverse events by system organ class and preferred term - treatment emergent - summary - adolescents (12-17 years) - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders	5	(6.3)	5	21	4	(5.2)	5	21	9	(5.7)	10	21
Hypoglycaemia	3	(3.8)	3	12	1	(1.3)	2	9	4	(2.5)	5	11
Diabetic ketoacidosis	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Hyperglycaemia	1	(1.3)	1	4					1	(0.6)	1	2
Hyperkalaemia					1	(1.3)	1	4	1	(0.6)	1	2
Ketosis					1	(1.3)	1	4	1	(0.6)	1	2
Investigations	2	(2.5)	3	12	6	(7.8)	8	34	8	(5.1)	11	23
Blood ketone body increased	1	(1.3)	1	4	2	(2.6)	3	13	3	(1.9)	4	8
Blood glucose increased	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Glycosylated haemoglobin increased	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Alanine aminotransferase increased					1	(1.3)	1	4	1	(0.6)	1	2
Blood bilirubin increased					1	(1.3)	1	4	1	(0.6)	1	2
Blood creatinine increased					1	(1.3)	1	4	1	(0.6)	1	2
Reproductive system and breast disorders	3	(3.8)	5	21	5	(6.5)	5	21	8	(5.1)	10	21
Dysmenorrhoea	3	(3.8)	5	21	5	(6.5)	5	21	8	(5.1)	10	21
Skin and subcutaneous tissue disorders	1	(1.3)	1	4	3	(3.9)	3	13	4	(2.5)	4	8
Dermatitis					1	(1.3)	1	4	1	(0.6)	1	2
Ingrowing nail	1	(1.3)	1	4					1	(0.6)	1	2
Rash					1	(1.3)	1	4	1	(0.6)	1	2
Scar pain					1	(1.3)	1	4	1	(0.6)	1	2
Psychiatric disorders	1	(1.3)	1	4	2	(2.6)	2	9	3	(1.9)	3	6
Insomnia	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Anxiety disorder					1	(1.3)	1	4	1	(0.6)	1	2
Congenital, familial and genetic disorders	1	(1.3)	1	4					1	(0.6)	1	2
Developmental glaucoma	1	(1.3)	1	4					1	(0.6)	1	2

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

Adverse events by system organ class and preferred term - treatment emergent - summary - adolescents (12-17 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Ear and labyrinth disorders	1 (1.3)	2	8				1 (0.6)	2	4
Deafness neurosensory	1 (1.3)	1	4				1 (0.6)	1	2
Vertigo	1 (1.3)	1	4				1 (0.6)	1	2
Eye disorders	1 (1.3)	1	4				1 (0.6)	1	2
Vision blurred	1 (1.3)	1	4				1 (0.6)	1	2
Immune system disorders	1 (1.3)	1	4				1 (0.6)	1	2
Seasonal allergy	1 (1.3)	1	4				1 (0.6)	1	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				1 (1.3)	1	4	1 (0.6)	1	2
Skin papilloma				1 (1.3)	1	4	1 (0.6)	1	2

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

14.3.1.14 Serious 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	181				179				360			
Events	11	(6.1)	14	26	7	(3.9)	7	13	18	(5.0)	21	19
Metabolism and nutrition disorders	6	(3.3)	6	11	3	(1.7)	3	6	9	(2.5)	9	8
Hypoglycaemia	5	(2.8)	5	9	1	(0.6)	1	2	6	(1.7)	6	6
Diabetic ketoacidosis	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Hyperglycaemia					1	(0.6)	1	2	1	(0.3)	1	1
Infections and infestations	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Viral infection	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Laryngitis					1	(0.6)	1	2	1	(0.3)	1	1
Gastrointestinal disorders	2	(1.1)	2	4					2	(0.6)	2	2
Constipation	1	(0.6)	1	2					1	(0.3)	1	1
Gastritis	1	(0.6)	1	2					1	(0.3)	1	1
Injury, poisoning and procedural complications	1	(0.6)	2	4	1	(0.6)	1	2	2	(0.6)	3	3
Fall					1	(0.6)	1	2	1	(0.3)	1	1
Fibula fracture	1	(0.6)	1	2					1	(0.3)	1	1
Tibia fracture	1	(0.6)	1	2					1	(0.3)	1	1
Nervous system disorders	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Hypoglycaemic seizure	1	(0.6)	1	2					1	(0.3)	1	1
Loss of consciousness					1	(0.6)	1	2	1	(0.3)	1	1
Congenital, familial and genetic disorders	1	(0.6)	1	2					1	(0.3)	1	1
Developmental glaucoma	1	(0.6)	1	2					1	(0.3)	1	1
Musculoskeletal and connective tissue disorders	1	(0.6)	1	2					1	(0.3)	1	1
Compartment syndrome	1	(0.6)	1	2					1	(0.3)	1	1

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

14.3.1.15 Serious adverse events by system organ class and preferred term – treatment emergent - summary - children (1-5 years) - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	40				41				81			
Events	3	(7.5)	4	33	3	(7.3)	3	24	6	(7.4)	7	29
Metabolism and nutrition disorders	3	(7.5)	3	25	2	(4.9)	2	16	5	(6.2)	5	21
Hypoglycaemia	3	(7.5)	3	25	1	(2.4)	1	8	4	(4.9)	4	16
Hyperglycaemia					1	(2.4)	1	8	1	(1.2)	1	4
Infections and infestations	1	(2.5)	1	8	1	(2.4)	1	8	2	(2.5)	2	8
Laryngitis					1	(2.4)	1	8	1	(1.2)	1	4
Viral infection	1	(2.5)	1	8					1	(1.2)	1	4

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

14.3.1.16 Serious adverse events by system organ class and preferred term – treatment emergent - summary - children (6-11 years) - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	61				61				122			
Events	4	(6.6)	4	21	1	(1.6)	1	5	5	(4.1)	5	14
Gastrointestinal disorders	2	(3.3)	2	11					2	(1.6)	2	5
Constipation	1	(1.6)	1	5					1	(0.8)	1	3
Gastritis	1	(1.6)	1	5					1	(0.8)	1	3
Metabolism and nutrition disorders	2	(3.3)	2	11					2	(1.6)	2	5
Hypoglycaemia	2	(3.3)	2	11					2	(1.6)	2	5
Infections and infestations					1	(1.6)	1	5	1	(0.8)	1	3
Viral infection					1	(1.6)	1	5	1	(0.8)	1	3

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

14.3.1.17 Serious adverse events by system organ class and preferred term – treatment emergent - summary - adolescents (12-17 years) - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	80				77				157			
Events	4	(5.0)	6	25	3	(3.9)	3	13	7	(4.5)	9	19
Injury, poisoning and procedural complications	1	(1.3)	2	8	1	(1.3)	1	4	2	(1.3)	3	6
Fall					1	(1.3)	1	4	1	(0.6)	1	2
Fibula fracture	1	(1.3)	1	4					1	(0.6)	1	2
Tibia fracture	1	(1.3)	1	4					1	(0.6)	1	2
Metabolism and nutrition disorders	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Diabetic ketoacidosis	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Nervous system disorders	1	(1.3)	1	4	1	(1.3)	1	4	2	(1.3)	2	4
Hypoglycaemic seizure	1	(1.3)	1	4					1	(0.6)	1	2
Loss of consciousness					1	(1.3)	1	4	1	(0.6)	1	2
Congenital, familial and genetic disorders	1	(1.3)	1	4					1	(0.6)	1	2
Developmental glaucoma	1	(1.3)	1	4					1	(0.6)	1	2
Musculoskeletal and connective tissue disorders	1	(1.3)	1	4					1	(0.6)	1	2
Compartment syndrome	1	(1.3)	1	4					1	(0.6)	1	2

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

14.3.1.18 Adverse events possibly or probably related to investigational medicinal product 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	181				179				360			
Events	22	(12.2)	26	47	16	(8.9)	20	37	38	(10.6)	46	42
Metabolism and nutrition disorders	9	(5.0)	9	16	4	(2.2)	5	9	13	(3.6)	14	13
Hypoglycaemia	9	(5.0)	9	16	2	(1.1)	3	6	11	(3.1)	12	11
Hyperglycaemia					1	(0.6)	1	2	1	(0.3)	1	1
Ketosis					1	(0.6)	1	2	1	(0.3)	1	1
General disorders and administration site conditions	6	(3.3)	7	13	4	(2.2)	5	9	10	(2.8)	12	11
Hypertrophy	2	(1.1)	3	5	1	(0.6)	1	2	3	(0.8)	4	4
Local swelling	2	(1.1)	2	4	1	(0.6)	2	4	3	(0.8)	4	4
Device breakage					1	(0.6)	1	2	1	(0.3)	1	1
Injection site hypertrophy	1	(0.6)	1	2					1	(0.3)	1	1
Injection site swelling					1	(0.6)	1	2	1	(0.3)	1	1
Nodule	1	(0.6)	1	2					1	(0.3)	1	1
Nervous system disorders	4	(2.2)	5	9	1	(0.6)	1	2	5	(1.4)	6	6
Hypoglycaemic seizure	2	(1.1)	3	5					2	(0.6)	3	3
Convulsion	1	(0.6)	1	2					1	(0.3)	1	1
Dizziness	1	(0.6)	1	2					1	(0.3)	1	1
Loss of consciousness					1	(0.6)	1	2	1	(0.3)	1	1
Gastrointestinal disorders					4	(2.2)	5	9	4	(1.1)	5	5
Vomiting					2	(1.1)	2	4	2	(0.6)	2	2
Diarrhoea					1	(0.6)	1	2	1	(0.3)	1	1
Gastric disorder					1	(0.6)	1	2	1	(0.3)	1	1
Gastric mucosal hypertrophy					1	(0.6)	1	2	1	(0.3)	1	1
Injury, poisoning and procedural complications	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Accidental overdose					1	(0.6)	1	2	1	(0.3)	1	1
Overdose	1	(0.6)	1	2					1	(0.3)	1	1
Wrong drug administered	1	(0.6)	1	2					1	(0.3)	1	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

Adverse events possibly or probably related to 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
Investigations				3 (1.7)	3	6	3 (0.8)	3	3
Blood ketone body increased				2 (1.1)	2	4	2 (0.6)	2	2
Glycosylated haemoglobin increased				1 (0.6)	1	2	1 (0.3)	1	1
Skin and subcutaneous tissue disorders	2 (1.1)	2	4				2 (0.6)	2	2
Lipohypertrophy	2 (1.1)	2	4				2 (0.6)	2	2
Eye disorders	1 (0.6)	1	2				1 (0.3)	1	1
Vision blurred	1 (0.6)	1	2				1 (0.3)	1	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)’s assessment.

14.3.1.19 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	181				179				360			
Events	14	(7.7)	20	37	12	(6.7)	17	32	26	(7.2)	37	34
General disorders and administration site conditions	6	(3.3)	7	13	3	(1.7)	4	7	9	(2.5)	11	10
Hypertrophy	2	(1.1)	3	5	1	(0.6)	1	2	3	(0.8)	4	4
Local swelling	2	(1.1)	2	4	1	(0.6)	2	4	3	(0.8)	4	4
Injection site hypertrophy	1	(0.6)	1	2					1	(0.3)	1	1
Injection site swelling					1	(0.6)	1	2	1	(0.3)	1	1
Nodule	1	(0.6)	1	2					1	(0.3)	1	1
Metabolism and nutrition disorders	5	(2.8)	5	9	3	(1.7)	4	7	8	(2.2)	9	8
Hypoglycaemia	5	(2.8)	5	9	3	(1.7)	4	7	8	(2.2)	9	8
Gastrointestinal disorders	1	(0.6)	1	2	4	(2.2)	5	9	5	(1.4)	6	6
Abdominal pain	1	(0.6)	1	2					1	(0.3)	1	1
Diarrhoea					1	(0.6)	1	2	1	(0.3)	1	1
Gastric disorder					1	(0.6)	1	2	1	(0.3)	1	1
Gastric mucosal hypertrophy					1	(0.6)	1	2	1	(0.3)	1	1
Nausea					1	(0.6)	1	2	1	(0.3)	1	1
Vomiting					1	(0.6)	1	2	1	(0.3)	1	1
Nervous system disorders	3	(1.7)	3	5	2	(1.1)	2	4	5	(1.4)	5	5
Hypoglycaemic seizure	2	(1.1)	2	4					2	(0.6)	2	2
Dizziness	1	(0.6)	1	2					1	(0.3)	1	1
Headache					1	(0.6)	1	2	1	(0.3)	1	1
Loss of consciousness					1	(0.6)	1	2	1	(0.3)	1	1
Injury, poisoning and procedural complications	2	(1.1)	2	4					2	(0.6)	2	2
Wrong drug administered	2	(1.1)	2	4					2	(0.6)	2	2
Investigations					2	(1.1)	2	4	2	(0.6)	2	2
Blood ketone body increased					2	(1.1)	2	4	2	(0.6)	2	2

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

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
Eye disorders	1 (0.6)	1	2				1 (0.3)	1	1
Vision blurred	1 (0.6)	1	2				1 (0.3)	1	1
Skin and subcutaneous tissue disorders	1 (0.6)	1	2				1 (0.3)	1	1
Lipohypertrophy	1 (0.6)	1	2				1 (0.3)	1	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

14.3.1.20 Adverse events related to device 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	181				179				360			
Events					1	(0.6)	1	2	1	(0.3)	1	1
General disorders and administration site conditions					1	(0.6)	1	2	1	(0.3)	1	1
Device breakage					1	(0.6)	1	2	1	(0.3)	1	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

14.3.1.21 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 N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	181				179				360			
Events	5	(2.8)	5	9	1	(0.6)	1	2	6	(1.7)	6	6
Metabolism and nutrition disorders	4	(2.2)	4	7					4	(1.1)	4	4
Hypoglycaemia	4	(2.2)	4	7					4	(1.1)	4	4
Nervous system disorders	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Hypoglycaemic seizure	1	(0.6)	1	2					1	(0.3)	1	1
Loss of consciousness					1	(0.6)	1	2	1	(0.3)	1	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

14.3.1.22 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 N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	181				179				360			
Events	3	(1.7)	3	5	2	(1.1)	2	4	5	(1.4)	5	5
Metabolism and nutrition disorders	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Hypoglycaemia	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Nervous system disorders	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Hypoglycaemic seizure	1	(0.6)	1	2					1	(0.3)	1	1
Loss of consciousness					1	(0.6)	1	2	1	(0.3)	1	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

14.3.1.23 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

14.3.1.24 Severe 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	181				179				360			
Events	12	(6.6)	14	26	5	(2.8)	5	9	17	(4.7)	19	17
Metabolism and nutrition disorders	8	(4.4)	8	15	2	(1.1)	2	4	10	(2.8)	10	9
Hypoglycaemia	7	(3.9)	7	13	2	(1.1)	2	4	9	(2.5)	9	8
Diabetic ketoacidosis	1	(0.6)	1	2					1	(0.3)	1	1
Nervous system disorders	2	(1.1)	2	4	2	(1.1)	2	4	4	(1.1)	4	4
Headache					2	(1.1)	2	4	2	(0.6)	2	2
Hypoglycaemic seizure	2	(1.1)	2	4					2	(0.6)	2	2
Injury, poisoning and procedural complications	1	(0.6)	2	4	1	(0.6)	1	2	2	(0.6)	3	3
Fall					1	(0.6)	1	2	1	(0.3)	1	1
Fibula fracture	1	(0.6)	1	2					1	(0.3)	1	1
Tibia fracture	1	(0.6)	1	2					1	(0.3)	1	1
Ear and labyrinth disorders	1	(0.6)	1	2					1	(0.3)	1	1
Deafness neurosensory	1	(0.6)	1	2					1	(0.3)	1	1
Musculoskeletal and connective tissue disorders	1	(0.6)	1	2					1	(0.3)	1	1
Compartment syndrome	1	(0.6)	1	2					1	(0.3)	1	1

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

14.3.1.25 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 OD N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	181				179				360			
Events	9	(5.0)	9	16	1	(0.6)	1	2	10	(2.8)	10	9
Metabolism and nutrition disorders	7	(3.9)	7	13	1	(0.6)	1	2	8	(2.2)	8	7
Hypoglycaemia	7	(3.9)	7	13	1	(0.6)	1	2	8	(2.2)	8	7
Nervous system disorders	2	(1.1)	2	4					2	(0.6)	2	2
Hypoglycaemic seizure	2	(1.1)	2	4					2	(0.6)	2	2

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

14.3.1.26 Adverse events leading to temporary withdrawal of trial product - treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	181			179			360		
Events	2 (1.1)	2	4	1 (0.6)	1	2	3 (0.8)	3	3
Serious									
Yes	0			1 (0.6)	1	2	1 (0.3)	1	1
No	2 (1.1)	2	4	0			2 (0.6)	2	2
Missing	0			0			0		
Severity									
Severe	0			1 (0.6)	1	2	1 (0.3)	1	1
Moderate	2 (1.1)	2	4	0			2 (0.6)	2	2
Mild	0			0			0		
Missing	0			0			0		
Relationship to Investigational Product									
Probable	0			0			0		
Possible	0			0			0		
Unlikely	2 (1.1)	2	4	1 (0.6)	1	2	3 (0.8)	3	3
Missing	0			0			0		
Unknown	0			0			0		
Related to Bolus Insulin									
Probable	0			0			0		
Possible	0			0			0		
Unlikely	1 (0.6)	1	2	0			1 (0.3)	1	1
Missing	0			0			0		
Unknown	0			0			0		
Related to Device									
Yes	0			0			0		
No	2 (1.1)	2	4	1 (0.6)	1	2	3 (0.8)	3	3
Missing	0			0			0		

N: Number of subjects, %: Percentage of subjects, E: Number of events, R: Event rate per 100 exposure years
Relationship to trial product is based on investigator(s)'s assessment.

Adverse events leading to temporary withdrawal of trial product - treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Product withdrawn temporarily									
IDegAsp/Comparator	2 (1.1)	2	4	1 (0.6)	1	2	3 (0.8)	3	3
Insulin Aspart	1 (0.6)	1	2	0			1 (0.3)	1	1
Outcome									
Recovered/Resolved	2 (1.1)	2	4	0			2 (0.6)	2	2
Recovering/Resolving	0			1 (0.6)	1	2	1 (0.3)	1	1
Recovered/Resolved With Sequelae	0			0			0		
Not Recovered/Not Resolved	0			0			0		
Fatal	0			0			0		
Unknown	0			0			0		
Missing	0			0			0		

N: Number of subjects, %: Percentage of subjects, E: Number of events, R: Event rate per 100 exposure years
Relationship to trial product is based on investigator(s)'s assessment.

14.3.1.27 Adverse events leading to temporary withdrawal of trial product 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	181				179				360			
Events	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Injury, poisoning and procedural complications	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Fall					1	(0.6)	1	2	1	(0.3)	1	1
Wrong drug administered	1	(0.6)	1	2					1	(0.3)	1	1
Infections and infestations	1	(0.6)	1	2					1	(0.3)	1	1
Gastroenteritis	1	(0.6)	1	2					1	(0.3)	1	1

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

14.3.1.28 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 N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	181				179				360			
Events	6	(3.3)	6	11	2	(1.1)	2	4	8	(2.2)	8	7
Metabolism and nutrition disorders	4	(2.2)	4	7	2	(1.1)	2	4	6	(1.7)	6	6
Hypoglycaemia	4	(2.2)	4	7	2	(1.1)	2	4	6	(1.7)	6	6
Nervous system disorders	2	(1.1)	2	4					2	(0.6)	2	2
Hypoglycaemic seizure	2	(1.1)	2	4					2	(0.6)	2	2

N= Number of subjects
%= Percentage of subjects
E= Number of Events
R= Event Rate per 100 Exposure Years
Relationship is based on investigator(s)'s assessment.

14.3.1.29 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

14.3.1.30 Serious severe 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	181				179				360			
Events	7	(3.9)	9	16	2	(1.1)	2	4	9	(2.5)	11	10
Metabolism and nutrition disorders	5	(2.8)	5	9	1	(0.6)	1	2	6	(1.7)	6	6
Hypoglycaemia	4	(2.2)	4	7	1	(0.6)	1	2	5	(1.4)	5	5
Diabetic ketoacidosis	1	(0.6)	1	2					1	(0.3)	1	1
Injury, poisoning and procedural complications	1	(0.6)	2	4	1	(0.6)	1	2	2	(0.6)	3	3
Fall					1	(0.6)	1	2	1	(0.3)	1	1
Fibula fracture	1	(0.6)	1	2					1	(0.3)	1	1
Tibia fracture	1	(0.6)	1	2					1	(0.3)	1	1
Musculoskeletal and connective tissue disorders	1	(0.6)	1	2					1	(0.3)	1	1
Compartment syndrome	1	(0.6)	1	2					1	(0.3)	1	1
Nervous system disorders	1	(0.6)	1	2					1	(0.3)	1	1
Hypoglycaemic seizure	1	(0.6)	1	2					1	(0.3)	1	1

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

14.3.1.31 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	181				179				360			
Events	52	(28.7)	96	175	30	(16.8)	58	108	82	(22.8)	154	142
Infections and infestations	29	(16.0)	37	68	19	(10.6)	26	48	48	(13.3)	63	58
Gastroenteritis	2	(1.1)	2	4	3	(1.7)	3	6	5	(1.4)	5	5
Gastroenteritis viral	3	(1.7)	3	5	2	(1.1)	2	4	5	(1.4)	5	5
Influenza	3	(1.7)	3	5	2	(1.1)	3	6	5	(1.4)	6	6
Nasopharyngitis	3	(1.7)	4	7	2	(1.1)	4	7	5	(1.4)	8	7
Viral infection	4	(2.2)	4	7	1	(0.6)	1	2	5	(1.4)	5	5
Pharyngitis streptococcal	3	(1.7)	3	5	1	(0.6)	1	2	4	(1.1)	4	4
Upper respiratory tract infection	2	(1.1)	2	4	2	(1.1)	2	4	4	(1.1)	4	4
Bronchitis	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Pharyngitis					3	(1.7)	4	7	3	(0.8)	4	4
Sinusitis	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Respiratory tract infection	2	(1.1)	2	4					2	(0.6)	2	2
Urinary tract infection	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Acute tonsillitis	1	(0.6)	1	2					1	(0.3)	1	1
Croup infectious	1	(0.6)	1	2					1	(0.3)	1	1
Ear infection	1	(0.6)	1	2					1	(0.3)	1	1
Laryngitis					1	(0.6)	1	2	1	(0.3)	1	1
Oral candidiasis	1	(0.6)	1	2					1	(0.3)	1	1
Oral herpes	1	(0.6)	1	2					1	(0.3)	1	1
Otitis media	1	(0.6)	1	2					1	(0.3)	1	1
Pneumonia					1	(0.6)	1	2	1	(0.3)	1	1
Rhinitis					1	(0.6)	1	2	1	(0.3)	1	1
Tonsillitis	1	(0.6)	1	2					1	(0.3)	1	1
Tracheitis	1	(0.6)	1	2					1	(0.3)	1	1
Viral upper respiratory tract infection	1	(0.6)	1	2					1	(0.3)	1	1

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

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
Gastrointestinal disorders	12 (6.6)	16	29	7 (3.9)	10	19	19 (5.3)	26	24
Vomiting	4 (2.2)	4	7	2 (1.1)	2	4	6 (1.7)	6	6
Abdominal pain	3 (1.7)	3	5	2 (1.1)	2	4	5 (1.4)	5	5
Abdominal pain upper	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Nausea	2 (1.1)	2	4	1 (0.6)	2	4	3 (0.8)	4	4
Constipation	2 (1.1)	2	4				2 (0.6)	2	2
Gastritis	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Toothache	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Abdominal discomfort	1 (0.6)	1	2				1 (0.3)	1	1
Diarrhoea	1 (0.6)	1	2				1 (0.3)	1	1
Injury, poisoning and procedural complications	8 (4.4)	8	15	2 (1.1)	2	4	10 (2.8)	10	9
Wrong drug administered	3 (1.7)	3	5	1 (0.6)	1	2	4 (1.1)	4	4
Fibula fracture	1 (0.6)	1	2				1 (0.3)	1	1
Heat stroke	1 (0.6)	1	2				1 (0.3)	1	1
Laceration	1 (0.6)	1	2				1 (0.3)	1	1
Limb injury				1 (0.6)	1	2	1 (0.3)	1	1
Muscle strain	1 (0.6)	1	2				1 (0.3)	1	1
Post procedural inflammation	1 (0.6)	1	2				1 (0.3)	1	1
General disorders and administration site conditions	6 (3.3)	6	11	3 (1.7)	4	7	9 (2.5)	10	9
Pyrexia	4 (2.2)	4	7	2 (1.1)	3	6	6 (1.7)	7	6
Chest pain	1 (0.6)	1	2				1 (0.3)	1	1
Drug intolerance	1 (0.6)	1	2				1 (0.3)	1	1
Injection site hypertrophy				1 (0.6)	1	2	1 (0.3)	1	1
Metabolism and nutrition disorders	5 (2.8)	6	11	3 (1.7)	4	7	8 (2.2)	10	9
Hypoglycaemia	3 (1.7)	4	7	1 (0.6)	2	4	4 (1.1)	6	6
Acetonaemia	1 (0.6)	1	2				1 (0.3)	1	1
Decreased appetite	1 (0.6)	1	2				1 (0.3)	1	1
Diabetic ketoacidosis				1 (0.6)	1	2	1 (0.3)	1	1
Hyperglycaemia				1 (0.6)	1	2	1 (0.3)	1	1

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

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
Nervous system disorders	4 (2.2)	10	18	3 (1.7)	3	6	7 (1.9)	13	12
Headache	2 (1.1)	8	15	3 (1.7)	3	6	5 (1.4)	11	10
Convulsion	1 (0.6)	1	2				1 (0.3)	1	1
Hypoglycaemic seizure	1 (0.6)	1	2				1 (0.3)	1	1
Respiratory, thoracic and mediastinal disorders	2 (1.1)	2	4	3 (1.7)	4	7	5 (1.4)	6	6
Oropharyngeal pain	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Asthma				1 (0.6)	1	2	1 (0.3)	1	1
Cough				1 (0.6)	1	2	1 (0.3)	1	1
Nasal congestion				1 (0.6)	1	2	1 (0.3)	1	1
Rhinitis allergic	1 (0.6)	1	2				1 (0.3)	1	1
Ear and labyrinth disorders	2 (1.1)	2	4	1 (0.6)	1	2	3 (0.8)	3	3
Ear pain				1 (0.6)	1	2	1 (0.3)	1	1
Motion sickness	1 (0.6)	1	2				1 (0.3)	1	1
Vertigo	1 (0.6)	1	2				1 (0.3)	1	1
Investigations	1 (0.6)	1	2	2 (1.1)	3	6	3 (0.8)	4	4
Blood glucose increased	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Blood ketone body increased				1 (0.6)	2	4	1 (0.3)	2	2
Skin and subcutaneous tissue disorders	2 (1.1)	2	4	1 (0.6)	1	2	3 (0.8)	3	3
Lipohypertrophy	2 (1.1)	2	4				2 (0.6)	2	2
Scar pain				1 (0.6)	1	2	1 (0.3)	1	1
Reproductive system and breast disorders	2 (1.1)	2	4				2 (0.6)	2	2
Dysmenorrhoea	2 (1.1)	2	4				2 (0.6)	2	2
Blood and lymphatic system disorders	1 (0.6)	1	2				1 (0.3)	1	1
Lymphadenitis	1 (0.6)	1	2				1 (0.3)	1	1

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

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
Congenital, familial and genetic disorders	1	(0.6)	1	2					1	(0.3)	1	1
Developmental glaucoma	1	(0.6)	1	2					1	(0.3)	1	1
Eye disorders	1	(0.6)	1	2					1	(0.3)	1	1
Vision blurred	1	(0.6)	1	2					1	(0.3)	1	1
Musculoskeletal and connective tissue disorders	1	(0.6)	1	2					1	(0.3)	1	1
Arthralgia	1	(0.6)	1	2					1	(0.3)	1	1

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

14.3.1.32 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	181				179				360			
Events	126	(69.6)	391	714	129	(72.1)	397	736	255	(70.8)	788	725
Infections and infestations	69	(38.1)	104	190	79	(44.1)	115	213	148	(41.1)	219	201
Nasopharyngitis	33	(18.2)	39	71	30	(16.8)	38	70	63	(17.5)	77	71
Upper respiratory tract infection	9	(5.0)	10	18	15	(8.4)	16	30	24	(6.7)	26	24
Influenza	6	(3.3)	7	13	9	(5.0)	9	17	15	(4.2)	16	15
Pharyngitis	3	(1.7)	3	5	7	(3.9)	9	17	10	(2.8)	12	11
Gastroenteritis	3	(1.7)	3	5	5	(2.8)	5	9	8	(2.2)	8	7
Gastroenteritis viral	5	(2.8)	7	13	3	(1.7)	3	6	8	(2.2)	10	9
Rhinitis	6	(3.3)	8	15	2	(1.1)	2	4	8	(2.2)	10	9
Viral infection					6	(3.4)	6	11	6	(1.7)	6	6
Viral upper respiratory tract infection	3	(1.7)	4	7	2	(1.1)	2	4	5	(1.4)	6	6
Bronchitis	3	(1.7)	3	5	1	(0.6)	1	2	4	(1.1)	4	4
Otitis media	4	(2.2)	5	9					4	(1.1)	5	5
Sinusitis	1	(0.6)	1	2	3	(1.7)	3	6	4	(1.1)	4	4
Varicella	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Acute tonsillitis					2	(1.1)	3	6	2	(0.6)	3	3
Conjunctivitis					2	(1.1)	2	4	2	(0.6)	2	2
Ear infection	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Febrile infection	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Gastrointestinal infection	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Pharyngotonsillitis	2	(1.1)	2	4					2	(0.6)	2	2
Tonsillitis	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Viral pharyngitis	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Abscess	1	(0.6)	1	2					1	(0.3)	1	1
Conjunctivitis viral					1	(0.6)	1	2	1	(0.3)	1	1
Croup infectious	1	(0.6)	1	2					1	(0.3)	1	1
Fungal skin infection					1	(0.6)	1	2	1	(0.3)	1	1
Gingivitis					1	(0.6)	1	2	1	(0.3)	1	1
Herpes zoster	1	(0.6)	1	2					1	(0.3)	1	1
Hordeolum					1	(0.6)	1	2	1	(0.3)	1	1
Laryngitis	1	(0.6)	1	2					1	(0.3)	1	1
Lice infestation					1	(0.6)	1	2	1	(0.3)	1	1
Lower respiratory tract infection					1	(0.6)	1	2	1	(0.3)	1	1
Pharyngitis streptococcal	1	(0.6)	1	2					1	(0.3)	1	1
Pyelonephritis					1	(0.6)	1	2	1	(0.3)	1	1

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

Mild 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
Respiratory tract infection				1 (0.6)	1	2	1 (0.3)	1	1
Tracheobronchitis				1 (0.6)	1	2	1 (0.3)	1	1
Viral diarrhoea	1 (0.6)	1	2				1 (0.3)	1	1
Gastrointestinal disorders	47 (26.0)	88	161	46 (25.7)	81	150	93 (25.8)	169	155
Abdominal pain upper	13 (7.2)	21	38	16 (8.9)	24	45	29 (8.1)	45	41
Vomiting	18 (9.9)	21	38	10 (5.6)	11	20	28 (7.8)	32	29
Abdominal pain	8 (4.4)	10	18	6 (3.4)	11	20	14 (3.9)	21	19
Diarrhoea	6 (3.3)	7	13	6 (3.4)	6	11	12 (3.3)	13	12
Nausea	4 (2.2)	4	7	7 (3.9)	8	15	11 (3.1)	12	11
Abdominal discomfort	5 (2.8)	5	9	2 (1.1)	3	6	7 (1.9)	8	7
Gastritis	3 (1.7)	3	5	4 (2.2)	5	9	7 (1.9)	8	7
Toothache	3 (1.7)	7	13	3 (1.7)	5	9	6 (1.7)	12	11
Odynophagia	3 (1.7)	4	7				3 (0.8)	4	4
Constipation	2 (1.1)	2	4				2 (0.6)	2	2
Abdominal distension	1 (0.6)	1	2				1 (0.3)	1	1
Aphthous stomatitis				1 (0.6)	1	2	1 (0.3)	1	1
Dental caries				1 (0.6)	1	2	1 (0.3)	1	1
Dyspepsia				1 (0.6)	1	2	1 (0.3)	1	1
Enterocolitis	1 (0.6)	1	2				1 (0.3)	1	1
Eructation				1 (0.6)	1	2	1 (0.3)	1	1
Gastric disorder				1 (0.6)	1	2	1 (0.3)	1	1
Gastric mucosal hypertrophy				1 (0.6)	1	2	1 (0.3)	1	1
Gastrointestinal disorder				1 (0.6)	1	2	1 (0.3)	1	1
Gastrointestinal motility disorder	1 (0.6)	1	2				1 (0.3)	1	1
Mouth haemorrhage	1 (0.6)	1	2				1 (0.3)	1	1
Stomatitis				1 (0.6)	1	2	1 (0.3)	1	1
Nervous system disorders	27 (14.9)	53	97	32 (17.9)	66	122	59 (16.4)	119	109
Headache	22 (12.2)	39	71	30 (16.8)	59	109	52 (14.4)	98	90
Dizziness	3 (1.7)	3	5				3 (0.8)	3	3
Migraine	1 (0.6)	6	11	2 (1.1)	4	7	3 (0.8)	10	9
Sinus headache	2 (1.1)	3	5	1 (0.6)	1	2	3 (0.8)	4	4
Diabetic neuropathy	1 (0.6)	1	2				1 (0.3)	1	1
Hypoaesthesia				1 (0.6)	1	2	1 (0.3)	1	1
Loss of consciousness				1 (0.6)	1	2	1 (0.3)	1	1
Neuropathy peripheral	1 (0.6)	1	2				1 (0.3)	1	1

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

Mild 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
Respiratory, thoracic and mediastinal disorders	31	(17.1)	41	75	28	(15.6)	42	78	59	(16.4)	83	76
Cough	13	(7.2)	16	29	8	(4.5)	8	15	21	(5.8)	24	22
Oropharyngeal pain	9	(5.0)	12	22	12	(6.7)	13	24	21	(5.8)	25	23
Nasal congestion	3	(1.7)	3	5	4	(2.2)	5	9	7	(1.9)	8	7
Rhinorrhoea	1	(0.6)	1	2	6	(3.4)	10	19	7	(1.9)	11	10
Respiratory disorder	4	(2.2)	5	9	2	(1.1)	2	4	6	(1.7)	7	6
Allergic respiratory symptom					1	(0.6)	1	2	1	(0.3)	1	1
Asthma	1	(0.6)	1	2					1	(0.3)	1	1
Dyspnoea	1	(0.6)	1	2					1	(0.3)	1	1
Epistaxis					1	(0.6)	1	2	1	(0.3)	1	1
Nasal discomfort					1	(0.6)	1	2	1	(0.3)	1	1
Pulmonary congestion					1	(0.6)	1	2	1	(0.3)	1	1
Rhinitis allergic	1	(0.6)	1	2					1	(0.3)	1	1
Throat irritation	1	(0.6)	1	2					1	(0.3)	1	1
General disorders and administration site conditions	21	(11.6)	33	60	17	(9.5)	24	45	38	(10.6)	57	52
Pyrexia	14	(7.7)	22	40	9	(5.0)	12	22	23	(6.4)	34	31
Fatigue	2	(1.1)	2	4	3	(1.7)	3	6	5	(1.4)	5	5
Local swelling	3	(1.7)	3	5	1	(0.6)	2	4	4	(1.1)	5	5
Hypertrophy	2	(1.1)	3	5	1	(0.6)	1	2	3	(0.8)	4	4
Injection site hypertrophy	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Pain					2	(1.1)	2	4	2	(0.6)	2	2
Device breakage					1	(0.6)	1	2	1	(0.3)	1	1
Discomfort					1	(0.6)	1	2	1	(0.3)	1	1
Injection site swelling					1	(0.6)	1	2	1	(0.3)	1	1
Malaise	1	(0.6)	1	2					1	(0.3)	1	1
Nodule	1	(0.6)	1	2					1	(0.3)	1	1

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

Mild 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
Injury, poisoning and procedural complications	15	(8.3)	19	35	13	(7.3)	16	30	28	(7.8)	35	32
Joint injury	2	(1.1)	2	4	3	(1.7)	3	6	5	(1.4)	5	5
Wrong drug administered	3	(1.7)	4	7	2	(1.1)	2	4	5	(1.4)	6	6
Laceration					3	(1.7)	3	6	3	(0.8)	3	3
Ligament sprain	3	(1.7)	4	7					3	(0.8)	4	4
Accidental overdose					2	(1.1)	2	4	2	(0.6)	2	2
Limb injury	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Concussion	1	(0.6)	1	2					1	(0.3)	1	1
Contusion					1	(0.6)	1	2	1	(0.3)	1	1
Drug dispensing error					1	(0.6)	1	2	1	(0.3)	1	1
Excoriation	1	(0.6)	1	2					1	(0.3)	1	1
Face injury					1	(0.6)	1	2	1	(0.3)	1	1
Head injury					1	(0.6)	1	2	1	(0.3)	1	1
Muscle injury	1	(0.6)	1	2					1	(0.3)	1	1
Muscle strain	1	(0.6)	1	2					1	(0.3)	1	1
Overdose	1	(0.6)	1	2					1	(0.3)	1	1
Sunburn	1	(0.6)	2	4					1	(0.3)	2	2
Thermal burn					1	(0.6)	1	2	1	(0.3)	1	1
Wound	1	(0.6)	1	2					1	(0.3)	1	1
Musculoskeletal and connective tissue disorders	7	(3.9)	7	13	12	(6.7)	15	28	19	(5.3)	22	20
Arthralgia	3	(1.7)	3	5	3	(1.7)	3	6	6	(1.7)	6	6
Pain in extremity	1	(0.6)	1	2	3	(1.7)	3	6	4	(1.1)	4	4
Myalgia	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Muscle spasms					2	(1.1)	2	4	2	(0.6)	2	2
Musculoskeletal pain	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Back pain	1	(0.6)	1	2					1	(0.3)	1	1
Epiphysiolysis					1	(0.6)	1	2	1	(0.3)	1	1
Growing pains					1	(0.6)	1	2	1	(0.3)	1	1
Neck pain					1	(0.6)	1	2	1	(0.3)	1	1
Spinal pain					1	(0.6)	1	2	1	(0.3)	1	1

N= Number of subjects
%= Percentage of subjects
E= Number of Events
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Mild 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
Investigations	7	(3.9)	8	15	11	(6.1)	13	24	18	(5.0)	21	19
Blood ketone body increased	2	(1.1)	2	4	6	(3.4)	7	13	8	(2.2)	9	8
Alanine aminotransferase increased	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Glycosylated haemoglobin increased	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Aspartate aminotransferase increased	1	(0.6)	1	2					1	(0.3)	1	1
Blood alkaline phosphatase increased	1	(0.6)	1	2					1	(0.3)	1	1
Blood bilirubin increased					1	(0.6)	1	2	1	(0.3)	1	1
Blood creatinine increased					1	(0.6)	1	2	1	(0.3)	1	1
Blood glucose fluctuation	1	(0.6)	1	2					1	(0.3)	1	1
Blood immunoglobulin A abnormal					1	(0.6)	1	2	1	(0.3)	1	1
Ultrasound thyroid abnormal	1	(0.6)	1	2					1	(0.3)	1	1
Weight decreased					1	(0.6)	1	2	1	(0.3)	1	1
Metabolism and nutrition disorders	9	(5.0)	13	24	5	(2.8)	6	11	14	(3.9)	19	17
Hypercreatininaemia	3	(1.7)	3	5	2	(1.1)	2	4	5	(1.4)	5	5
Hyperkalaemia	3	(1.7)	3	5	2	(1.1)	2	4	5	(1.4)	5	5
Decreased appetite	2	(1.1)	2	4					2	(0.6)	2	2
Hyperglycaemia	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Acetonaemia	1	(0.6)	2	4					1	(0.3)	2	2
Hypoglycaemia	1	(0.6)	1	2					1	(0.3)	1	1
Hyponatraemia	1	(0.6)	1	2					1	(0.3)	1	1
Ketosis					1	(0.6)	1	2	1	(0.3)	1	1
Skin and subcutaneous tissue disorders	4	(2.2)	4	7	5	(2.8)	5	9	9	(2.5)	9	8
Rash	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Ingrowing nail	1	(0.6)	1	2	1	(0.6)	1	2	2	(0.6)	2	2
Blister					1	(0.6)	1	2	1	(0.3)	1	1
Dermatitis					1	(0.6)	1	2	1	(0.3)	1	1
Dermatitis allergic	1	(0.6)	1	2					1	(0.3)	1	1
Keratosis pilaris	1	(0.6)	1	2					1	(0.3)	1	1

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

Mild 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)	3	5	6 (3.4)	6	11	7 (1.9)	9	8
Dysmenorrhoea	1 (0.6)	3	5	5 (2.8)	5	9	6 (1.7)	8	7
Pelvic pain				1 (0.6)	1	2	1 (0.3)	1	1
Ear and labyrinth disorders	4 (2.2)	5	9	1 (0.6)	1	2	5 (1.4)	6	6
Ear pain	2 (1.1)	2	4	1 (0.6)	1	2	3 (0.8)	3	3
Motion sickness	2 (1.1)	3	5				2 (0.6)	3	3
Immune system disorders	4 (2.2)	7	13	1 (0.6)	1	2	5 (1.4)	8	7
Hypersensitivity	2 (1.1)	5	9				2 (0.6)	5	5
Seasonal allergy	2 (1.1)	2	4				2 (0.6)	2	2
Multiple allergies				1 (0.6)	1	2	1 (0.3)	1	1
Eye disorders	2 (1.1)	2	4	1 (0.6)	1	2	3 (0.8)	3	3
Eye pain	1 (0.6)	1	2				1 (0.3)	1	1
Eyelid disorder				1 (0.6)	1	2	1 (0.3)	1	1
Vision blurred	1 (0.6)	1	2				1 (0.3)	1	1
Psychiatric disorders	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Insomnia	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Anxiety disorder				1 (0.6)	1	2	1 (0.3)	1	1
Renal and urinary disorders	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Urethral pain	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Vascular disorders	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Haematoma	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
Endocrine disorders	1 (0.6)	1	2				1 (0.3)	1	1
Hypothyroidism	1 (0.6)	1	2				1 (0.3)	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				1 (0.6)	1	2	1 (0.3)	1	1
Skin papilloma				1 (0.6)	1	2	1 (0.3)	1	1

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

14.3.1.33 Adverse events leading to dose reduction - treatment emergent - summary - safety analysis set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	181			179			360		
Events	15 (8.3)	21	38	8 (4.5)	9	17	23 (6.4)	30	28
Serious									
Yes	4 (2.2)	5	9	0			4 (1.1)	5	5
No	11 (6.1)	16	29	8 (4.5)	9	17	19 (5.3)	25	23
Severity									
Severe	3 (1.7)	3	5	0			3 (0.8)	3	3
Moderate	7 (3.9)	8	15	2 (1.1)	2	4	9 (2.5)	10	9
Mild	8 (4.4)	10	18	6 (3.4)	7	13	14 (3.9)	17	16
Relationship to Investigational Product									
Probable	3 (1.7)	3	5	1 (0.6)	1	2	4 (1.1)	4	4
Possible	2 (1.1)	2	4	0			2 (0.6)	2	2
Unlikely	6 (3.3)	10	18	4 (2.2)	4	7	10 (2.8)	14	13
Missing	0			0			0		
Relationship to Bolus Insulin									
Probable	1 (0.6)	1	2	0			1 (0.3)	1	1
Possible	1 (0.6)	1	2	0			1 (0.3)	1	1
Unlikely	10 (5.5)	14	26	7 (3.9)	8	15	17 (4.7)	22	20
Missing	5 (2.8)	5	9	1 (0.6)	1	2	6 (1.7)	6	6
Dose Reduction	15 (8.3)	31	57	8 (4.5)	13	24	23 (6.4)	44	40
IDegAsp/Comparator	11 (6.1)	15	27	5 (2.8)	5	9	16 (4.4)	20	18
Insulin Aspart	12 (6.6)	16	29	7 (3.9)	8	15	19 (5.3)	24	22
Outcome									
Recovered/Resolved	15 (8.3)	21	38	8 (4.5)	9	17	23 (6.4)	30	28
Recovering/Resolving	0			0			0		
Recovered/Resolved With Sequelae	0			0			0		
Not Recovered/Not Resolved	0			0			0		
Fatal	0			0			0		
Unknown	0			0			0		

N: Number of subjects, %: Percentage of subjects, E: Number of events
R: Event rate per 100 patient years of exposure
Relationship is based on investigator(s)'s assessment.

14.3.1.34 Neoplasms 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	181				179				360			
Total Events					1	(0.6)	1	2	1	(0.3)	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					1	(0.6)	1	2	1	(0.3)	1	1
Skin papilloma					1	(0.6)	1	2	1	(0.3)	1	1

Note: Only pre-selected preferred terms are included
N: Number of subjects, %: Percentage of subjects, E: Number of events
R: Event rate per 100 exposure years

14.3.1.35 Allergic reaction (immunogenicity) by system organ class and preferred term - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	181				179				360			
Total Events	6	(3.3)	9	16	4	(2.2)	5	9	10	(2.8)	14	13
Skin and subcutaneous tissue disorders	2	(1.1)	2	4	3	(1.7)	3	6	5	(1.4)	5	5
Rash	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Dermatitis					1	(0.6)	1	2	1	(0.3)	1	1
Dermatitis allergic	1	(0.6)	1	2					1	(0.3)	1	1
Immune system disorders	2	(1.1)	5	9	1	(0.6)	1	2	3	(0.8)	6	6
Hypersensitivity	2	(1.1)	5	9					2	(0.6)	5	5
Multiple allergies					1	(0.6)	1	2	1	(0.3)	1	1
Respiratory, thoracic and mediastinal disorders	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Rhinitis allergic	2	(1.1)	2	4					2	(0.6)	2	2
Allergic respiratory symptom					1	(0.6)	1	2	1	(0.3)	1	1

Note: Only pre-selected preferred terms are included
N: Number of subjects, %: Percentage of subjects, E: Number of events
R: Event rate per 100 exposure years

14.3.1.36 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	181				179				360			
Events	15	(8.3)	21	38	8	(4.5)	9	17	23	(6.4)	30	28
Infections and infestations	5	(2.8)	6	11	6	(3.4)	6	11	11	(3.1)	12	11
Gastroenteritis viral	1	(0.6)	1	2	3	(1.7)	3	6	4	(1.1)	4	4
Nasopharyngitis	1	(0.6)	1	2	2	(1.1)	2	4	3	(0.8)	3	3
Gastroenteritis	2	(1.1)	2	4					2	(0.6)	2	2
Influenza					1	(0.6)	1	2	1	(0.3)	1	1
Upper respiratory tract infection	1	(0.6)	1	2					1	(0.3)	1	1
Viral infection	1	(0.6)	1	2					1	(0.3)	1	1
Gastrointestinal disorders	3	(1.7)	5	9	2	(1.1)	2	4	5	(1.4)	7	6
Gastritis	2	(1.1)	3	5					2	(0.6)	3	3
Vomiting					2	(1.1)	2	4	2	(0.6)	2	2
Enterocolitis	1	(0.6)	1	2					1	(0.3)	1	1
Toothache	1	(0.6)	1	2					1	(0.3)	1	1
Metabolism and nutrition disorders	5	(2.8)	5	9					5	(1.4)	5	5
Hypoglycaemia	4	(2.2)	4	7					4	(1.1)	4	4
Decreased appetite	1	(0.6)	1	2					1	(0.3)	1	1
Injury, poisoning and procedural complications	2	(1.1)	2	4	1	(0.6)	1	2	3	(0.8)	3	3
Accidental overdose					1	(0.6)	1	2	1	(0.3)	1	1
Overdose	1	(0.6)	1	2					1	(0.3)	1	1
Wrong drug administered	1	(0.6)	1	2					1	(0.3)	1	1
Nervous system disorders	2	(1.1)	2	4					2	(0.6)	2	2
Headache	1	(0.6)	1	2					1	(0.3)	1	1
Hypoglycaemic seizure	1	(0.6)	1	2					1	(0.3)	1	1

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

Adverse events leading to dose reduction 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
Respiratory, thoracic and mediastinal disorders	1	(0.6)	1	2					1	(0.3)	1	1
Oropharyngeal pain	1	(0.6)	1	2					1	(0.3)	1	1

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

14.3.1.37 Injection site reaction 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	181			179			360		
Total Events	1 (0.6)	1	2	3 (1.7)	3	6	4 (1.1)	4	4
General disorders and administration site conditions	1 (0.6)	1	2	3 (1.7)	3	6	4 (1.1)	4	4
Injection site hypertrophy	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3
Injection site swelling				1 (0.6)	1	2	1 (0.3)	1	1

Note: Only pre-selected preferred terms are included
N: Number of subjects, %: Percentage of subjects, E: Number of events
R: Event rate per 100 exposure years

14.3.1.38 Injection site reactions by system organ class and preferred term – summary – children (1-5 years) - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	40				41				81			
Total Events					1	(2.4)	1	8	1	(1.2)	1	4
General disorders and administration site conditions					1	(2.4)	1	8	1	(1.2)	1	4
Injection site hypertrophy					1	(2.4)	1	8	1	(1.2)	1	4

Note: Only pre-selected preferred terms are included
N: Number of subjects, %: Percentage of subjects, E: Number of events
R: Event rate per 100 exposure years

14.3.1.39 Injection site reactions by system organ class and preferred term – summary – children (6-11 years) - safety analysis set

There is no data for this table

14.3.1.40 Injection site reactions by system organ class and preferred term – summary – adolescents (12-17 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	80			77			157		
Total Events	1 (1.3)	1	4	2 (2.6)	2	9	3 (1.9)	3	6
General disorders and administration site conditions	1 (1.3)	1	4	2 (2.6)	2	9	3 (1.9)	3	6
Injection site hypertrophy	1 (1.3)	1	4	1 (1.3)	1	4	2 (1.3)	2	4
Injection site swelling				1 (1.3)	1	4	1 (0.6)	1	2

Note: Only pre-selected preferred terms are included
N: Number of subjects, %: Percentage of subjects, E: Number of events
R: Event rate per 100 exposure years

14.3.1.41 Medication errors - treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	181			179			360		
Total Events	7 (3.9)	8	15	6 (3.4)	6	11	13 (3.6)	14	13
Serious									
Yes	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
No	7 (3.9)	8	15	6 (3.4)	6	11	13 (3.6)	14	13
Severity									
Severe	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Moderate	3 (1.7)	3	5	1 (0.6)	1	2	4 (1.1)	4	4
Mild	4 (2.2)	5	9	5 (2.8)	5	9	9 (2.5)	10	9
Relationship to IDegAsp/Comparator									
Probable/Possible	2 (1.1)	2	4	1 (0.6)	1	2	3 (0.8)	3	3
Unlikely	5 (2.8)	6	11	5 (2.8)	5	9	10 (2.8)	11	10
Relationship to Insulin Aspart									
Probable/Possible	2 (1.1)	2	4	0 (0.0)	0	0	2 (0.6)	2	2
Unlikely	5 (2.8)	6	11	6 (3.4)	6	11	11 (3.1)	12	11
Outcome									
Recovered/Resolved	7 (3.9)	8	15	6 (3.4)	6	11	13 (3.6)	14	13
Recovering/Resolving	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Recovered/Resolved with Sequelae	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Not Recovered/Not Resolved	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

N: Number of subjects, %: Percentage of subjects, E: Number of events
R: Event rate per 100 exposure years
Relationship is based on investigator(s)’s assessment.

Medication errors - treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Accidental overdose	0 (0.0)	0	0	2 (1.1)	2	4	2 (0.6)	2	2
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	1 (0.6)	1	2	1 (0.3)	1	1
Unlikely	0 (0.0)	0	0	1 (0.6)	1	2	1 (0.3)	1	1
Relationship to Insulin Aspart									
Probable/Possible	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Unlikely	0 (0.0)	0	0	2 (1.1)	2	4	2 (0.6)	2	2
Drug dispensing error	0 (0.0)	0	0	1 (0.6)	1	2	1 (0.3)	1	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
Unlikely	0 (0.0)	0	0	1 (0.6)	1	2	1 (0.3)	1	1
Relationship to Insulin Aspart									
Probable/Possible	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Unlikely	0 (0.0)	0	0	1 (0.6)	1	2	1 (0.3)	1	1
Overdose	1 (0.6)	1	2	0 (0.0)	0	0	1 (0.3)	1	1
Serious	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Relationship to IDegAsp/Comparator									
Probable/Possible	1 (0.6)	1	2	0 (0.0)	0	0	1 (0.3)	1	1
Unlikely	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Relationship to Insulin Aspart									
Probable/Possible	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Unlikely	1 (0.6)	1	2	0 (0.0)	0	0	1 (0.3)	1	1

N: Number of subjects, %: Percentage of subjects, E: Number of events
R: Event rate per 100 exposure years
Relationship is based on investigator(s)'s assessment.

Medication errors - treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Wrong drug administered	6 (3.3)	7	13	3 (1.7)	3	6	9 (2.5)	10	9
Serious	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Relationship to IDegAsp/Comparator									
Probable/Possible	1 (0.6)	1	2	0 (0.0)	0	0	1 (0.3)	1	1
Unlikely	5 (2.8)	6	11	3 (1.7)	3	6	8 (2.2)	9	8
Relationship to Insulin Aspart									
Probable/Possible	2 (1.1)	2	4	0 (0.0)	0	0	2 (0.6)	2	2
Unlikely	4 (2.2)	5	9	3 (1.7)	3	6	7 (1.9)	8	7

N: Number of subjects, %: Percentage of subjects, E: Number of events
R: Event rate per 100 exposure years
Relationship is based on investigator(s)’s assessment.

14.3.1.42 Hypoglycaemic episodes by classification - treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	181			179			360		
Confirmed	168 (92.8)	2532	4623	164 (91.6)	2672	4955	332 (92.2)	5204	4788
ISPAD	178 (98.3)	5833	10651	170 (95.0)	5922	10982	348 (96.7)	11755	10815
Severe	11 (6.1)	14	26	3 (1.7)	4	7	14 (3.9)	18	17
Documented Sympt.	167 (92.3)	3005	5487	160 (89.4)	3648	6765	327 (90.8)	6653	6121
Asymptomatic	158 (87.3)	2763	5045	145 (81.0)	2226	4128	303 (84.2)	4989	4590
Probable Sympt.	2 (1.1)	2	4	4 (2.2)	5	9	6 (1.7)	7	6
Relative	16 (8.8)	49	89	11 (6.1)	39	72	27 (7.5)	88	81
ISPAD Unclassifiable	28 (15.5)	120	219	31 (17.3)	168	312	59 (16.4)	288	265

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

14.3.1.43 Hypoglycaemic episodes by classification - treatment emergent - summary - children (1-5 years) - safety analysis set

	IDegAsp OD N (%)	E	R	IDet N (%)	E	R	Total N (%)	E	R
Number of Subjects	40			41			81		
Confirmed	39 (97.5)	520	4335	37 (90.2)	559	4564	76 (93.8)	1079	4451
ISPAD	40 (100.0)	1272	10605	39 (95.1)	1238	10107	79 (97.5)	2510	10353
Severe	4 (10.0)	5	42	2 (4.9)	2	16	6 (7.4)	7	29
Documented Sympt.	36 (90.0)	337	2810	34 (82.9)	446	3641	70 (86.4)	783	3230
Asymptomatic	38 (95.0)	928	7737	38 (92.7)	786	6417	76 (93.8)	1714	7070
Probable Sympt.	0 (0.0)	0	0	1 (2.4)	1	8	1 (1.2)	1	4
Relative	2 (5.0)	2	17	2 (4.9)	3	24	4 (4.9)	5	21
ISPAD Unclassifiable	5 (12.5)	15	125	7 (17.1)	88	718	12 (14.8)	103	425

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

14.3.1.44 Hypoglycaemic episodes by classification - treatment emergent - summary - children (6-11 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	61			61			122		
Confirmed	56 (91.8)	960	5140	58 (95.1)	1065	5809	114 (93.4)	2025	5471
ISPAD	59 (96.7)	2221	11891	58 (95.1)	2493	13599	117 (95.9)	4714	12737
Severe	3 (4.9)	4	21	0 (0.0)	0	0	3 (2.5)	4	11
Documented Sympt.	55 (90.2)	1282	6864	57 (93.4)	1522	8302	112 (91.8)	2804	7576
Asymptomatic	57 (93.4)	932	4990	50 (82.0)	946	5160	107 (87.7)	1878	5074
Probable Sympt.	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Relative	3 (4.9)	3	16	2 (3.3)	25	136	5 (4.1)	28	76
ISPAD Unclassifiable	9 (14.8)	30	161	11 (18.0)	26	142	20 (16.4)	56	151

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

14.3.1.45 Hypoglycaemic episodes by classification - treatment emergent - summary - adolescents (12-17 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	80			77			157		
Confirmed	73 (91.3)	1052	4366	69 (89.6)	1048	4490	142 (90.4)	2100	4427
ISPAD	79 (98.8)	2340	9712	73 (94.8)	2191	9386	152 (96.8)	4531	9552
Severe	4 (5.0)	5	21	1 (1.3)	2	9	5 (3.2)	7	15
Documented Sympt.	76 (95.0)	1386	5753	69 (89.6)	1680	7197	145 (92.4)	3066	6463
Asymptomatic	63 (78.8)	903	3748	57 (74.0)	494	2116	120 (76.4)	1397	2945
Probable Sympt.	2 (2.5)	2	8	3 (3.9)	4	17	5 (3.2)	6	13
Relative	11 (13.8)	44	183	7 (9.1)	11	47	18 (11.5)	55	116
ISPAD Unclassifiable	14 (17.5)	75	311	13 (16.9)	54	231	27 (17.2)	129	272

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

14.3.1.46 Nocturnal hypoglycaemic episodes by classification - treatment emergent - summary - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	181				179				360			
Confirmed	101	(55.8)	316	577	106	(59.2)	291	540	207	(57.5)	607	558
ISPAD	134	(74.0)	732	1337	134	(74.9)	680	1261	268	(74.4)	1412	1299
Severe	1	(0.6)	2	4	2	(1.1)	2	4	3	(0.8)	4	4
Documented Sympt.	91	(50.3)	337	615	90	(50.3)	348	645	181	(50.3)	685	630
Asymptomatic	89	(49.2)	384	701	86	(48.0)	325	603	175	(48.6)	709	652
Probable Sympt.	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relative	5	(2.8)	9	16	5	(2.8)	5	9	10	(2.8)	14	13
ISPAD Unclassifiable	4	(2.2)	5	9	3	(1.7)	17	32	7	(1.9)	22	20

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL). Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).

14.3.1.47 Nocturnal hypoglycaemic episodes by classification - treatment emergent - summary - children (1-5 years) - safety analysis set

	IDegAsp OD N (%) E R	IDet N (%) E R	Total N (%) E R
Number of Subjects	40	41	81
Confirmed	18 (45.0) 55 459	21 (51.2) 52 425	39 (48.1) 107 441
ISPAD	28 (70.0) 132 1101	25 (61.0) 125 1020	53 (65.4) 257 1060
Severe	0 (0.0) 0 0	1 (2.4) 1 8	1 (1.2) 1 4
Documented Sympt.	13 (32.5) 35 292	12 (29.3) 31 253	25 (30.9) 66 272
Asymptomatic	23 (57.5) 96 800	22 (53.7) 91 743	45 (55.6) 187 771
Probable Sympt.	0 (0.0) 0 0	0 (0.0) 0 0	0 (0.0) 0 0
Relative	1 (2.5) 1 8	2 (4.9) 2 16	3 (3.7) 3 12
ISPAD Unclassifiable	1 (2.5) 1 8	2 (4.9) 12 98	3 (3.7) 13 54

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL). Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).

14.3.1.48 Nocturnal hypoglycaemic episodes by classification - treatment emergent - summary - children (6-11 years) - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	61			61			122		
Confirmed	38 (62.3)	108	578	34 (55.7)	85	464	72 (59.0)	193	521
ISPAD	48 (78.7)	258	1381	48 (78.7)	238	1298	96 (78.7)	496	1340
Severe	1 (1.6)	2	11	0 (0.0)	0	0	1 (0.8)	2	5
Documented Sympt.	32 (52.5)	97	519	28 (45.9)	84	458	60 (49.2)	181	489
Asymptomatic	36 (59.0)	159	851	35 (57.4)	154	840	71 (58.2)	313	846
Probable Sympt.	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Relative	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
ISPAD Unclassifiable	1 (1.6)	1	5	0 (0.0)	0	0	1 (0.8)	1	3

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL). Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).

14.3.1.49 Nocturnal hypoglycaemic episodes by classification - treatment emergent - summary - adolescents (12-17 years) - safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	80				77				157			
Confirmed	45	(56.3)	153	635	51	(66.2)	154	660	96	(61.1)	307	647
ISPAD	58	(72.5)	342	1419	61	(79.2)	317	1358	119	(75.8)	659	1389
Severe	0	(0.0)	0	0	1	(1.3)	1	4	1	(0.6)	1	2
Documented Sympt.	46	(57.5)	205	851	50	(64.9)	233	998	96	(61.1)	438	923
Asymptomatic	30	(37.5)	129	535	29	(37.7)	80	343	59	(37.6)	209	441
Probable Sympt.	0	(0.0)	0	0	0	(0.0)	0	0	0	(0.0)	0	0
Relative	4	(5.0)	8	33	3	(3.9)	3	13	7	(4.5)	11	23
ISPAD Unclassifiable	2	(2.5)	3	12	1	(1.3)	5	21	3	(1.9)	8	17

N: Number of Subjects
%: Percentage of Subjects with the Event
E: Number of Events
R: Event Rate per 100 Patient Year(s) of Exposure
ISPAD: International society for pediatric and adolescent diabetes, Sympt.: Symptomatic
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious, or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL). Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).

14.3.1.50 Hypoglycaemic episodes by classification and time – treatment emergent – summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	181			179			360		
Confirmed	168(92.8)	2532	4623	164(91.6)	2672	4955	332(92.2)	5204	4788
1 - 4 Weeks	134(74.0)	647	1181	141(78.8)	605	1122	275(76.4)	1252	1152
5 - 8 Weeks	130(71.8)	569	1039	127(70.9)	606	1124	257(71.4)	1175	1081
9 - 12 Weeks	137(75.7)	619	1130	132(73.7)	663	1229	269(74.7)	1282	1180
13 - 16 Weeks	124(68.5)	561	1024	128(71.5)	630	1168	252(70.0)	1191	1096
>16 Weeks	64(35.4)	136	248	69(38.5)	168	312	133(36.9)	304	280
ISPAD	178(98.3)	5833	10651	170(95.0)	5922	10982	348(96.7)	11755	10815
1 - 4 Weeks	167(92.3)	1453	2653	163(91.1)	1402	2600	330(91.7)	2855	2627
5 - 8 Weeks	158(87.3)	1337	2441	156(87.2)	1346	2496	314(87.2)	2683	2468
9 - 12 Weeks	163(90.1)	1450	2648	155(86.6)	1468	2722	318(88.3)	2918	2685
13 - 16 Weeks	159(87.8)	1282	2341	153(85.5)	1335	2476	312(86.7)	2617	2408
>16 Weeks	95(52.5)	311	568	95(53.1)	371	688	190(52.8)	682	627
Severe	11(6.1)	14	26	3(1.7)	4	7	14(3.9)	18	17
1 - 4 Weeks	3(1.7)	3	5	0(0.0)	0	0	3(0.8)	3	3
5 - 8 Weeks	2(1.1)	2	4	1(0.6)	1	2	3(0.8)	3	3
9 - 12 Weeks	6(3.3)	6	11	2(1.1)	2	4	8(2.2)	8	7
13 - 16 Weeks	2(1.1)	3	5	1(0.6)	1	2	3(0.8)	4	4
>16 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
Documented Sympt.	167(92.3)	3005	5487	160(89.4)	3648	6765	327(90.8)	6653	6121
1 - 4 Weeks	137(75.7)	763	1393	134(74.9)	868	1610	271(75.3)	1631	1501
5 - 8 Weeks	120(66.3)	690	1260	128(71.5)	794	1472	248(68.9)	1484	1365
9 - 12 Weeks	125(69.1)	735	1342	124(69.3)	919	1704	249(69.2)	1654	1522
13 - 16 Weeks	121(66.9)	663	1211	116(64.8)	811	1504	237(65.8)	1474	1356
>16 Weeks	67(37.0)	154	281	71(39.7)	256	475	138(38.3)	410	377

N: Number of subjects, %: Percentage of subjects with the event, E: Number of events, Sympt.: Symptomatic,
R: Event rate per 100 patient year(s) of exposure, ISPAD: International society for pediatric and adolescent diabetes.
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious,
or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

Hypoglycaemic episodes by classification and time - treatment emergent - summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Asymptomatic	158(87.3)	2763	5045	145(81.0)	2226	4128	303(84.2)	4989	4590
1 - 4 Weeks	117(64.6)	667	1218	114(63.7)	519	962	231(64.2)	1186	1091
5 - 8 Weeks	115(63.5)	637	1163	108(60.3)	538	998	223(61.9)	1175	1081
9 - 12 Weeks	116(64.1)	696	1271	107(59.8)	543	1007	223(61.9)	1239	1140
13 - 16 Weeks	111(61.3)	607	1108	104(58.1)	517	959	215(59.7)	1124	1034
>16 Weeks	57(31.5)	156	285	47(26.3)	109	202	104(28.9)	265	244
Probable Sympt.	2(1.1)	2	4	4(2.2)	5	9	6(1.7)	7	6
1 - 4 Weeks	2(1.1)	2	4	3(1.7)	3	6	5(1.4)	5	5
5 - 8 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
9 - 12 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
13 - 16 Weeks	0(0.0)	0	0	1(0.6)	1	2	1(0.3)	1	1
>16 Weeks	0(0.0)	0	0	1(0.6)	1	2	1(0.3)	1	1
Relative	16(8.8)	49	89	11(6.1)	39	72	27(7.5)	88	81
1 - 4 Weeks	9(5.0)	18	33	7(3.9)	12	22	16(4.4)	30	28
5 - 8 Weeks	4(2.2)	8	15	3(1.7)	13	24	7(1.9)	21	19
9 - 12 Weeks	5(2.8)	13	24	3(1.7)	4	7	8(2.2)	17	16
13 - 16 Weeks	5(2.8)	9	16	2(1.1)	5	9	7(1.9)	14	13
>16 Weeks	1(0.6)	1	2	4(2.2)	5	9	5(1.4)	6	6
ISPAD Unclassifiable	28(15.5)	120	219	31(17.3)	168	312	59(16.4)	288	265
1 - 4 Weeks	14(7.7)	25	46	15(8.4)	47	87	29(8.1)	72	66
5 - 8 Weeks	16(8.8)	39	71	12(6.7)	45	83	28(7.8)	84	77
9 - 12 Weeks	12(6.6)	20	37	13(7.3)	41	76	25(6.9)	61	56
13 - 16 Weeks	12(6.6)	34	62	11(6.1)	33	61	23(6.4)	67	62
>16 Weeks	2(1.1)	2	4	2(1.1)	2	4	4(1.1)	4	4

N: Number of subjects, %: Percentage of subjects with the event, E: Number of events, Sympt.: Symptomatic,
R: Event rate per 100 patient year(s) of exposure, ISPAD: International society for pediatric and adolescent diabetes.
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious,
or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)

14.3.1.51 Nocturnal hypoglycaemic episodes by classification and time – treatment emergent -summary – safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	181			179			360		
Confirmed	101(55.8)	316	577	106(59.2)	291	540	207(57.5)	607	558
1 - 4 Weeks	50(27.6)	95	173	40(22.3)	58	108	90(25.0)	153	141
5 - 8 Weeks	36(19.9)	67	122	48(26.8)	62	115	84(23.3)	129	119
9 - 12 Weeks	44(24.3)	66	121	44(24.6)	73	135	88(24.4)	139	128
13 - 16 Weeks	43(23.8)	59	108	43(24.0)	74	137	86(23.9)	133	122
>16 Weeks	20(11.0)	29	53	22(12.3)	24	45	42(11.7)	53	49
ISPAD	134(74.0)	732	1337	134(74.9)	680	1261	268(74.4)	1412	1299
1 - 4 Weeks	82(45.3)	206	376	70(39.1)	131	243	152(42.2)	337	310
5 - 8 Weeks	70(38.7)	160	292	85(47.5)	161	299	155(43.1)	321	295
9 - 12 Weeks	78(43.1)	163	298	80(44.7)	177	328	158(43.9)	340	313
13 - 16 Weeks	68(37.6)	147	268	71(39.7)	155	287	139(38.6)	302	278
>16 Weeks	37(20.4)	56	102	39(21.8)	56	104	76(21.1)	112	103
Severe	1(0.6)	2	4	2(1.1)	2	4	3(0.8)	4	4
1 - 4 Weeks	1(0.6)	1	2	0(0.0)	0	0	1(0.3)	1	1
5 - 8 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
9 - 12 Weeks	1(0.6)	1	2	1(0.6)	1	2	2(0.6)	2	2
13 - 16 Weeks	0(0.0)	0	0	1(0.6)	1	2	1(0.3)	1	1
>16 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
Documented Sympt.	91(50.3)	337	615	90(50.3)	348	645	181(50.3)	685	630
1 - 4 Weeks	47(26.0)	101	184	37(20.7)	59	109	84(23.3)	160	147
5 - 8 Weeks	41(22.7)	81	148	52(29.1)	83	154	93(25.8)	164	151
9 - 12 Weeks	43(23.8)	67	122	48(26.8)	95	176	91(25.3)	162	149
13 - 16 Weeks	38(21.0)	63	115	42(23.5)	83	154	80(22.2)	146	134
>16 Weeks	17(9.4)	25	46	22(12.3)	28	52	39(10.8)	53	49

N: Number of subjects, %: Percentage of subjects with the event, E: Number of events, Sympt.: Symptomatic,
R: Event rate per 100 patient year(s) of exposure, ISPAD: International society for pediatric and adolescent diabetes.
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious,
or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).

Nocturnal hypoglycaemic episodes by classification and time - treatment emergent -summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Asymptomatic	89(49.2)	384	701	86(48.0)	325	603	175(48.6)	709	652
1 - 4 Weeks	46(25.4)	96	175	42(23.5)	69	128	88(24.4)	165	152
5 - 8 Weeks	39(21.5)	79	144	47(26.3)	78	145	86(23.9)	157	144
9 - 12 Weeks	44(24.3)	94	172	47(26.3)	81	150	91(25.3)	175	161
13 - 16 Weeks	42(23.2)	84	153	36(20.1)	71	132	78(21.7)	155	143
>16 Weeks	21(11.6)	31	57	17(9.5)	26	48	38(10.6)	57	52
Probable Sympt.	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
1 - 4 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
5 - 8 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
9 - 12 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
13 - 16 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
>16 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
Relative	5(2.8)	9	16	5(2.8)	5	9	10(2.8)	14	13
1 - 4 Weeks	5(2.8)	8	15	3(1.7)	3	6	8(2.2)	11	10
5 - 8 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
9 - 12 Weeks	1(0.6)	1	2	0(0.0)	0	0	1(0.3)	1	1
13 - 16 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0
>16 Weeks	0(0.0)	0	0	2(1.1)	2	4	2(0.6)	2	2
ISPAD Unclassifiable	4(2.2)	5	9	3(1.7)	17	32	7(1.9)	22	20
1 - 4 Weeks	0(0.0)	0	0	1(0.6)	1	2	1(0.3)	1	1
5 - 8 Weeks	3(1.7)	3	5	2(1.1)	7	13	5(1.4)	10	9
9 - 12 Weeks	1(0.6)	1	2	2(1.1)	5	9	3(0.8)	6	6
13 - 16 Weeks	1(0.6)	1	2	3(1.7)	4	7	4(1.1)	5	5
>16 Weeks	0(0.0)	0	0	0(0.0)	0	0	0(0.0)	0	0

N: Number of subjects, %: Percentage of subjects with the event, E: Number of events, Sympt.: Symptomatic,
R: Event rate per 100 patient year(s) of exposure, ISPAD: International society for pediatric and adolescent diabetes.
Confirmed hypoglycaemia: subject has altered mental status and cannot assist in their care,is semiconscious or unconscious,
or in coma ± convulsions and may require parenteral therapy (glucagon or i.v. glucose) and/or have a recorded PG < 3.1 mmol/L (56mg/dL)
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).

14.3.1.52 Hypoglycaemic episodes - treatment emergent - statistical analysis - full analysis set

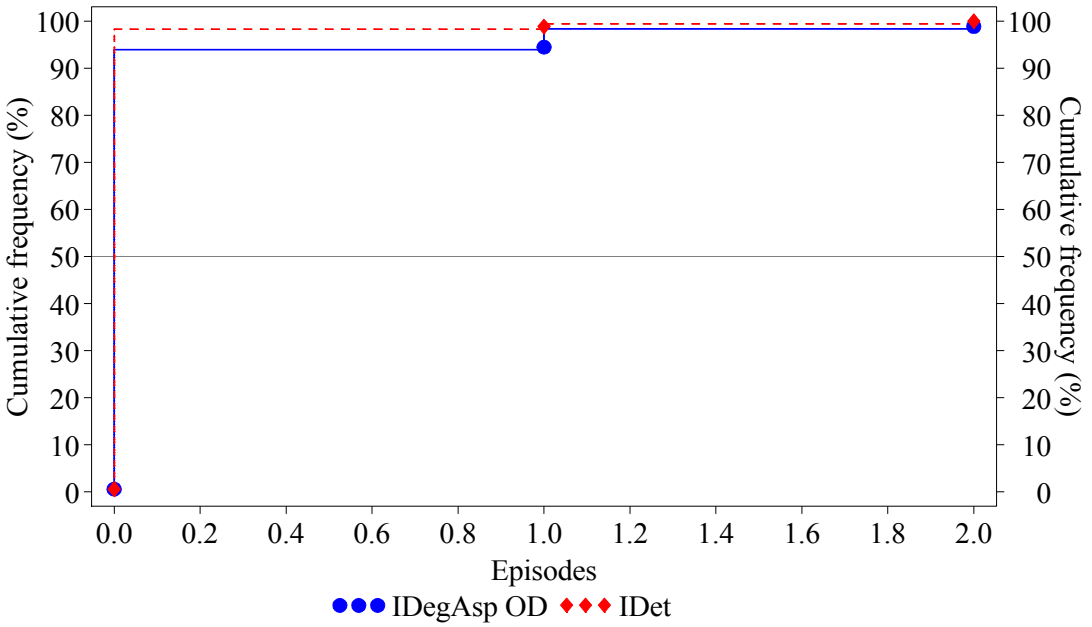
	FAS	N	Estimate	95% CI
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	4311.98	
IDet	180	179	4561.22	
Treatment Ratio				
IDegAsp OD / IDet			0.95	[0.76 ; 1.17]
Severe				
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	15.71	
IDet	180	179	4.91	
Treatment Ratio				
IDegAsp OD / IDet			3.20	[0.88 ; 11.66]

FAS: Full analaysis set, 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 function and the logarithm of the exposure time (100 years) as offset. The model includes treatment,sex,region and age group as fixed effects.

14.3.1.53 Nocturnal confirmed hypoglycaemic episodes – treatment emergent – statistical analysis - full analysis set

	FAS	N	Estimate	95% CI
Confirmed				
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	537.91	
IDet	180	179	492.11	
Treatment Ratio				
IDegAsp OD / IDet			1.09	[0.81 ; 1.48]

FAS: Full analysis set, 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 function and the logarithm of the exposure time (100 years) as offset. The model includes treatment,sex,region and age group as fixed effects.
Nocturnal period: the period between 23:00 and 07:00(both included)



SAFETY: Observed data
SAFETY: Safety analysis set

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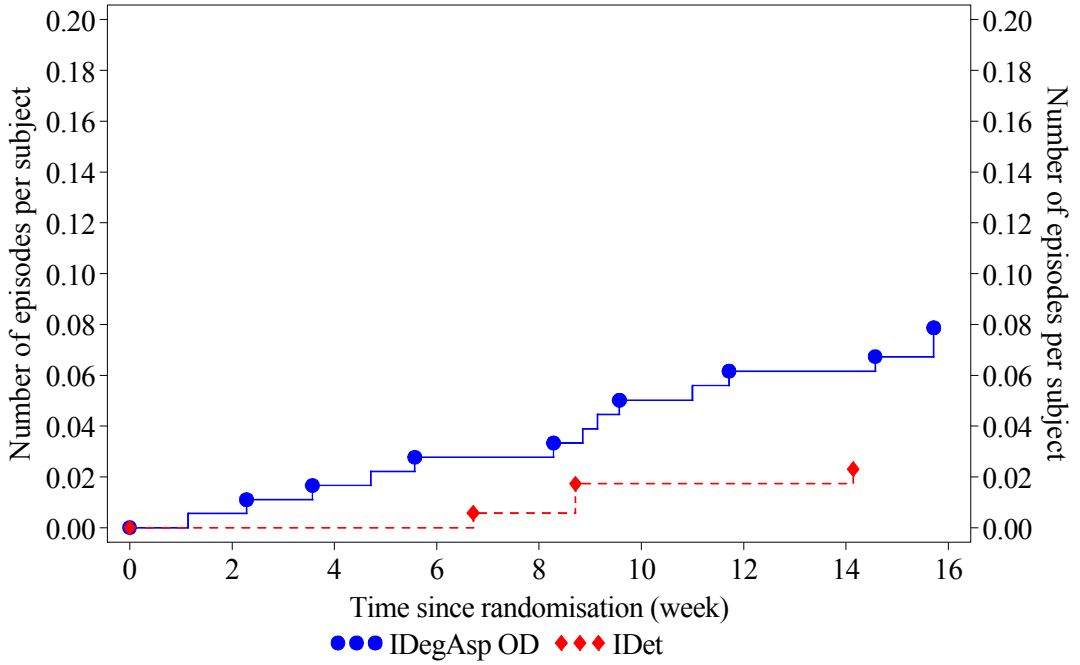
14.3.1.54 Severe hypoglycaemic episodes – treatment emergent - empirical distribution plot - safety analysis set



SAFETY: Safety analysis set

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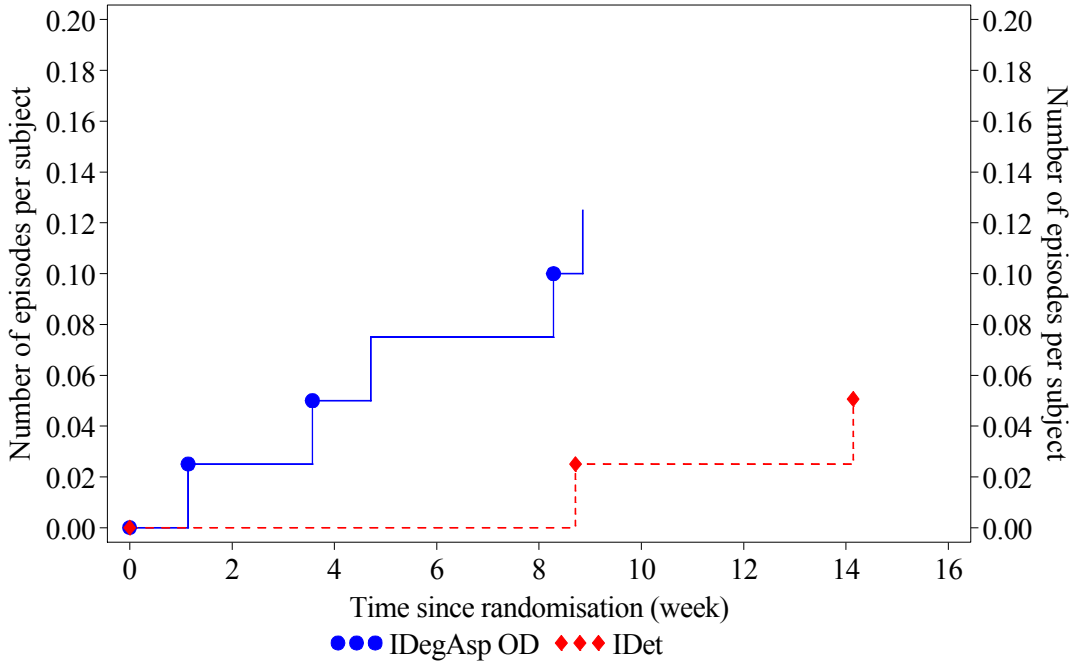
14.3.1.55 Severe hypoglycaemic episodes - treatment emergent - mean cumulative function - safety analysis set



SAFETY: Safety analysis set

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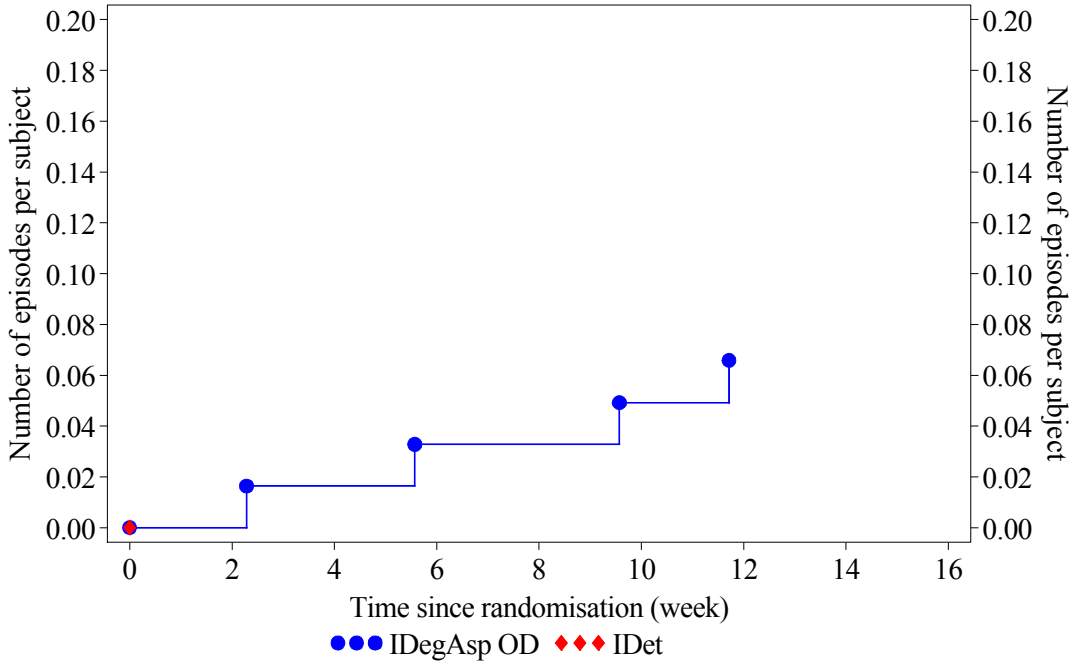
14.3.1.56 Severe hypoglycaemic episodes - treatment emergent - mean cumulative function - children (1-5 years) - safety analysis set



SAFETY: Safety analysis set

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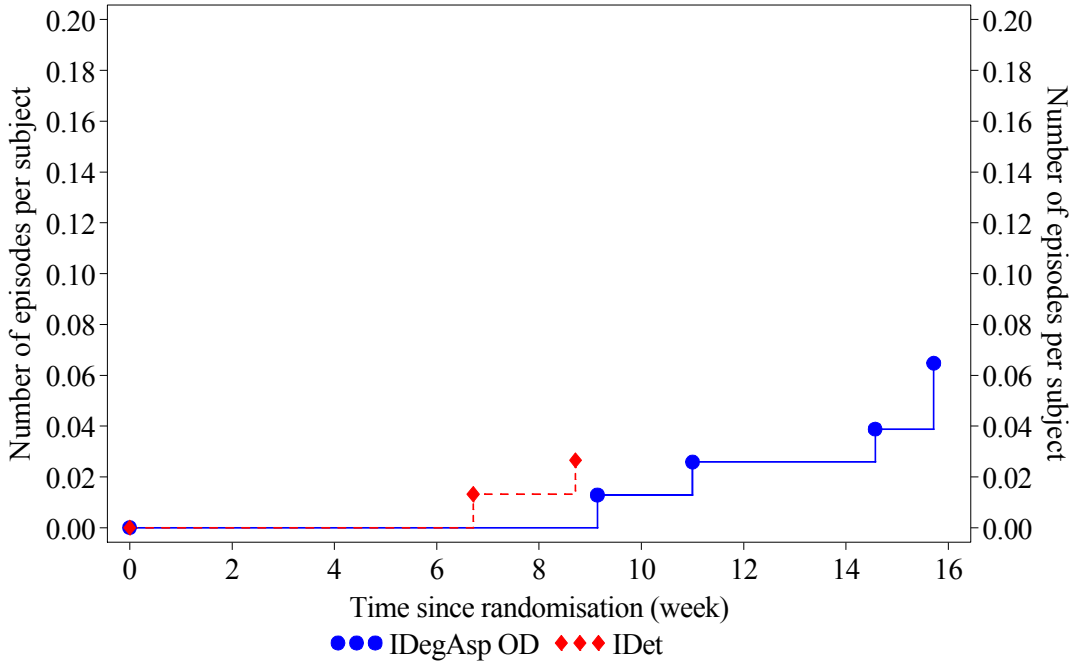
14.3.1.57 Severe hypoglycaemic episodes - treatment emergent - mean cumulative function - children (6-11 years) - safety analysis set



SAFETY: Safety analysis set

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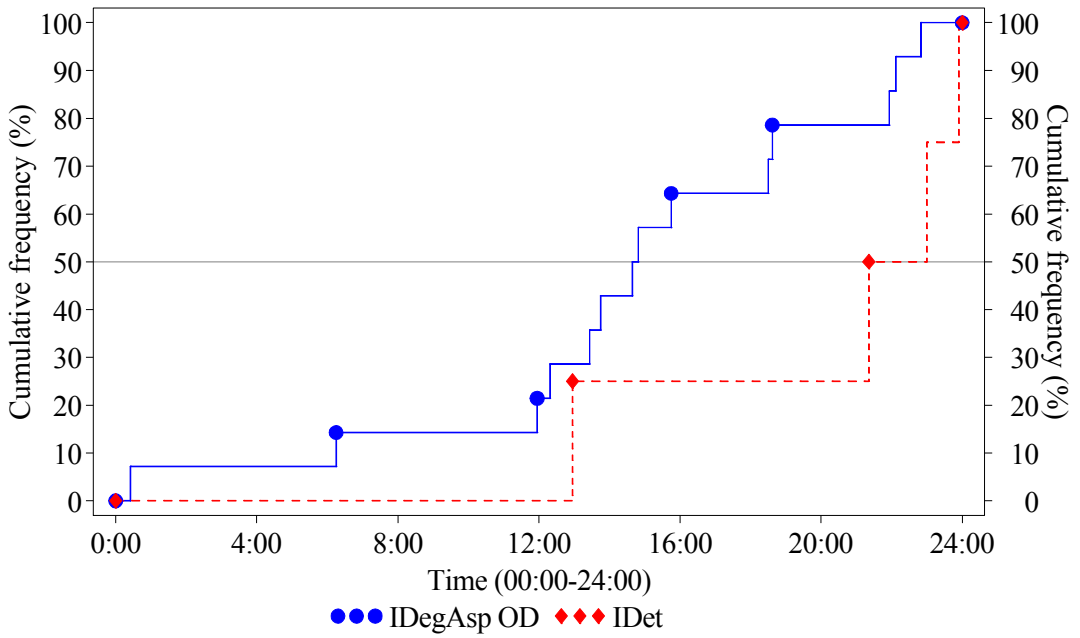
14.3.1.58 Severe hypoglycaemic episodes - treatment emergent - mean cumulative function - adolescents (12-17 years) - safety analysis set



SAFETY
SAFETY: Safety analysis set

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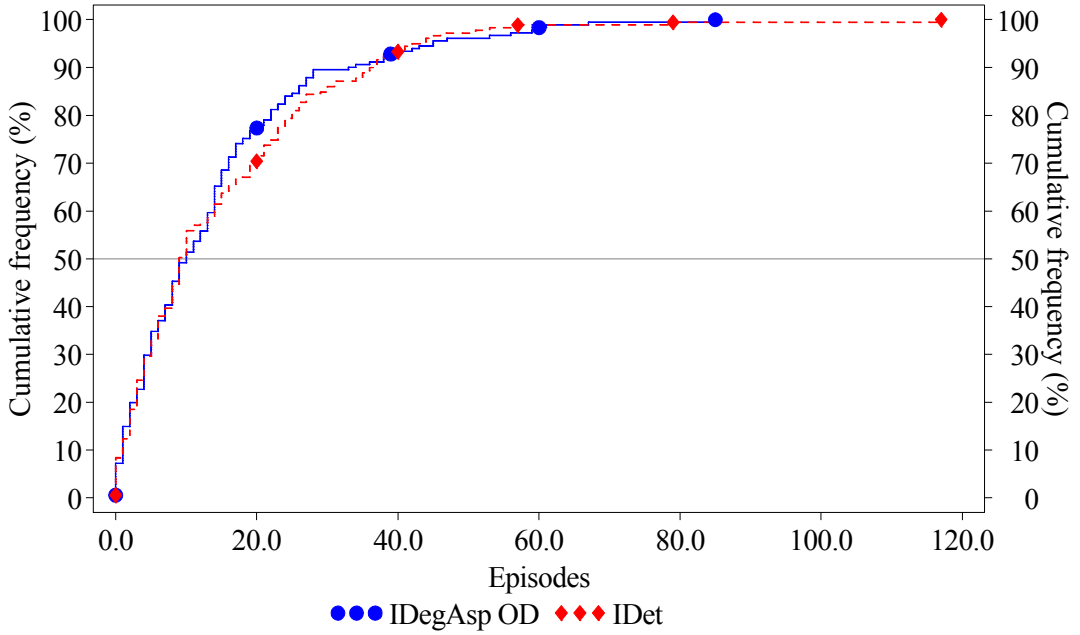
14.3.1.59 Severe hypoglycaemic episodes – treatment emergent - cumulative frequency over day - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set

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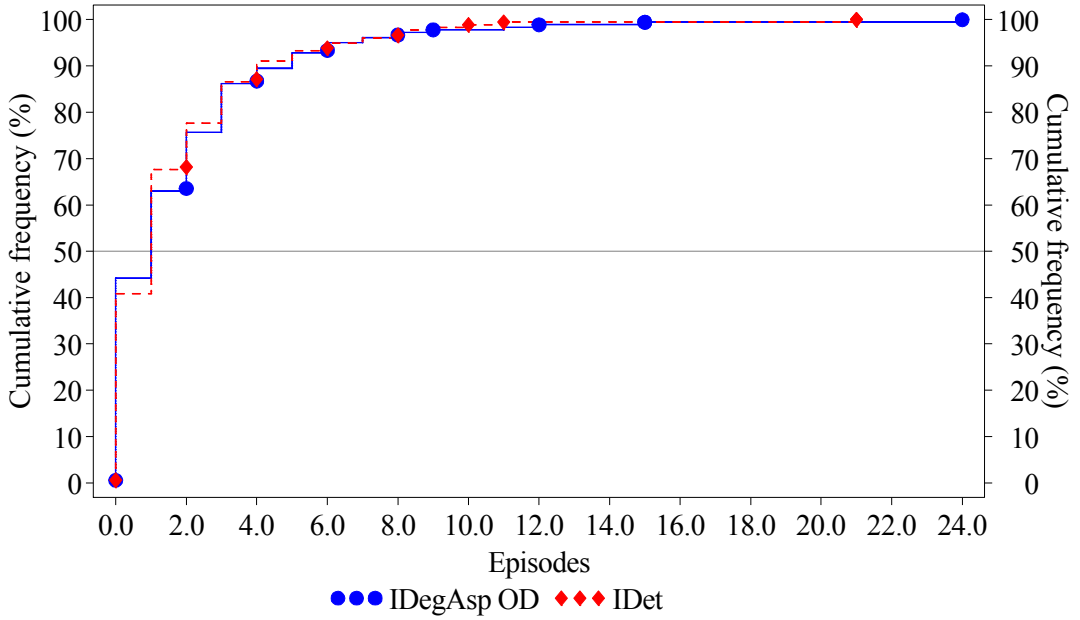
14.3.1.60 Confirmed hypoglycaemic episodes – treatment emergent - empirical distribution plot - safety analysis set



SAFETY; Observed data
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).
SAFETY: Safety analysis set

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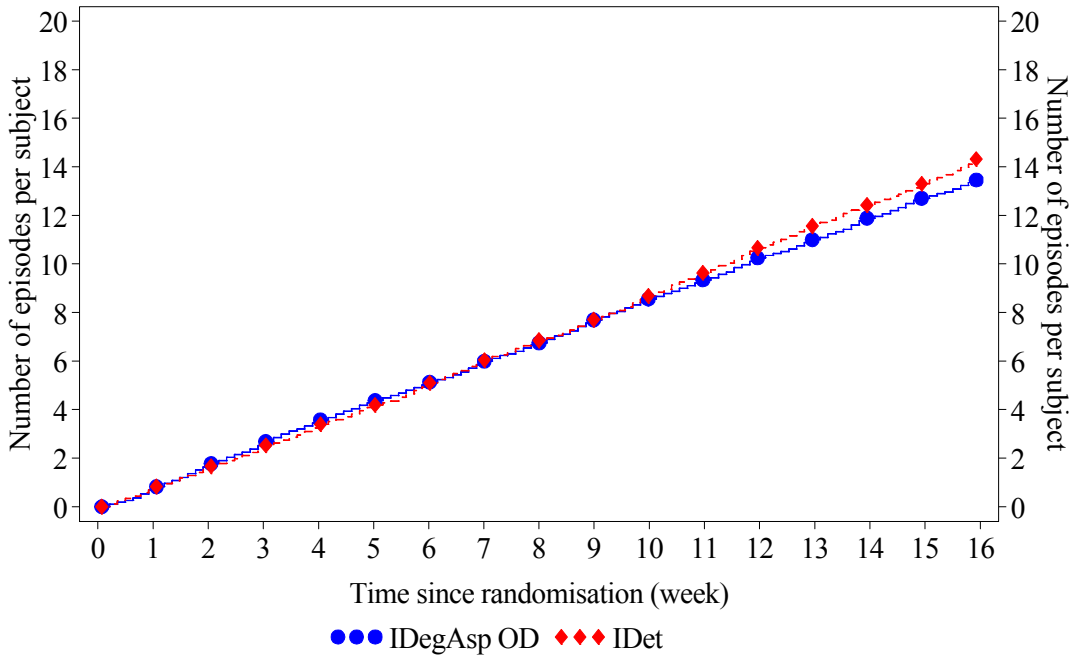
14.3.1.61 Nocturnal confirmed hypoglycaemic episodes – treatment emergent - empirical distribution plot - safety analysis set



SAFETY: Safety analysis set

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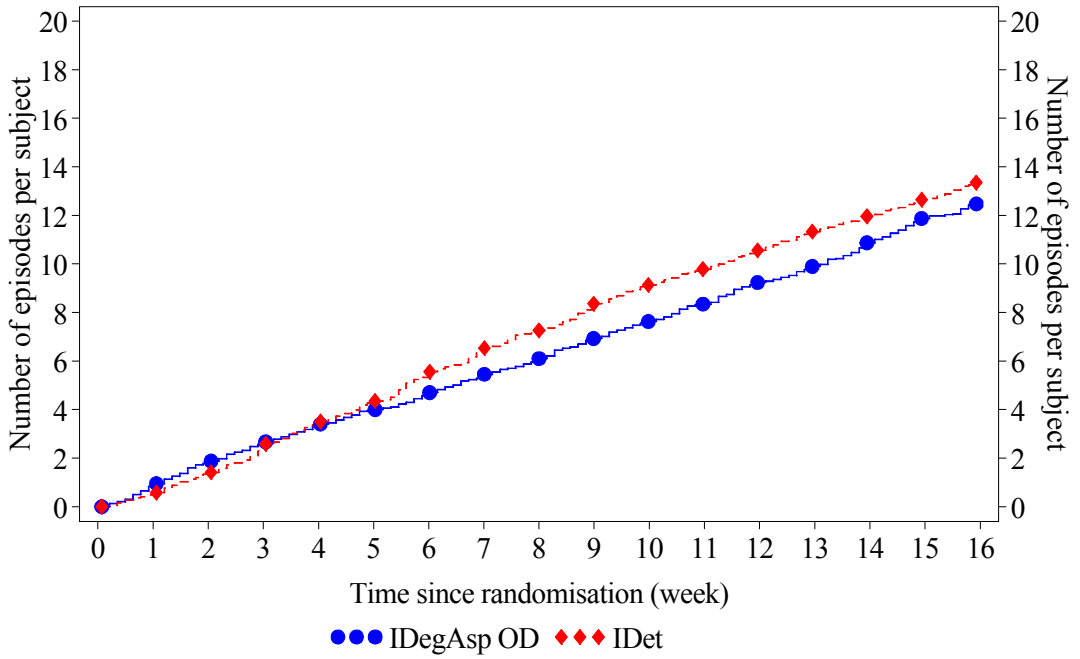
14.3.1.62 Confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - safety analysis set



SAFETY: Safety analysis set

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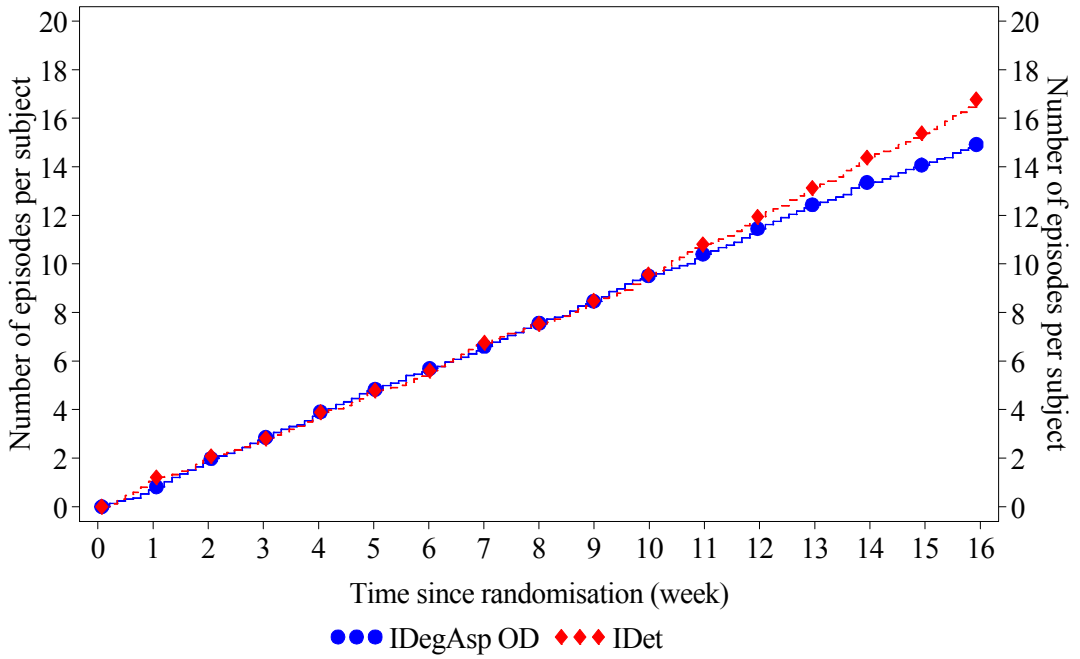
14.3.1.63 Confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - children (1-5 years) - safety analysis set



SAFETY: Safety analysis set

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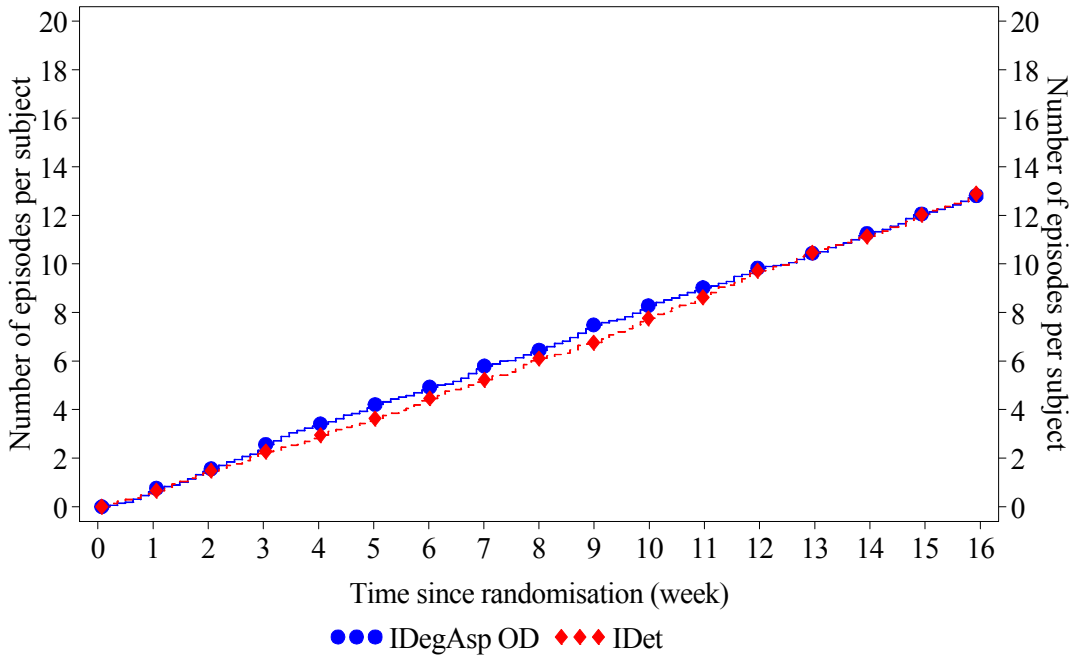
14.3.1.64 Confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - children (6-11 years) - safety analysis set



SAFETY: Safety analysis set

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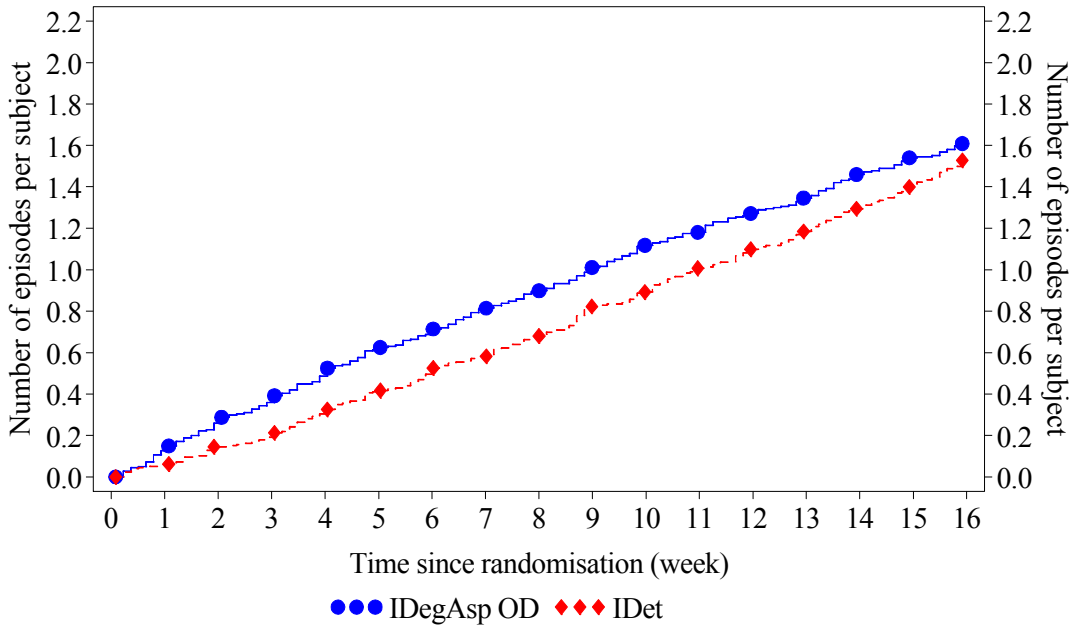
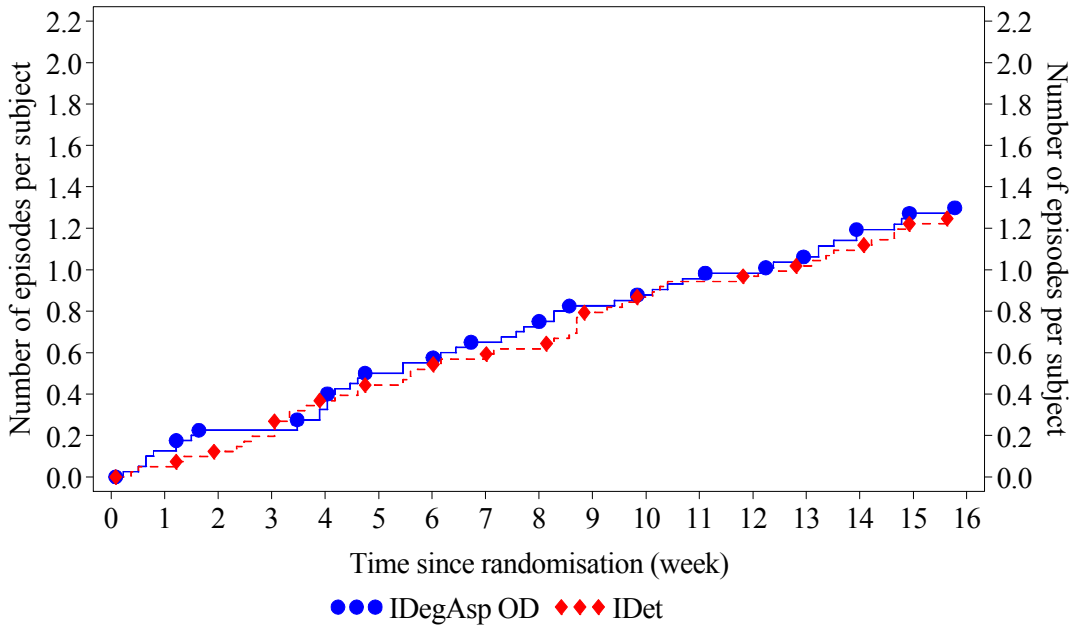
14.3.1.65 Confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - adolescents (12-17 years) - safety analysis set



SAFETY: safety analysis set
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).
nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:16 - fmean_cum_v01.sas/e_hypo_te_conf_noct_mcf_sas.cgm

14.3.1.66 Nocturnal confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - safety analysis set



SAFETY: Safety analysis set
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).
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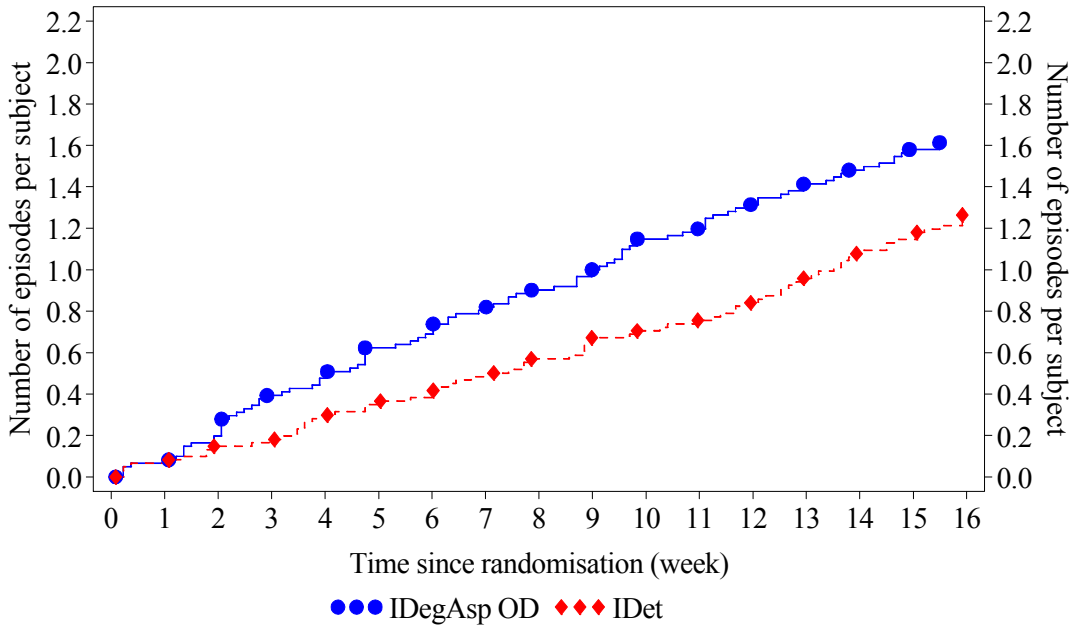
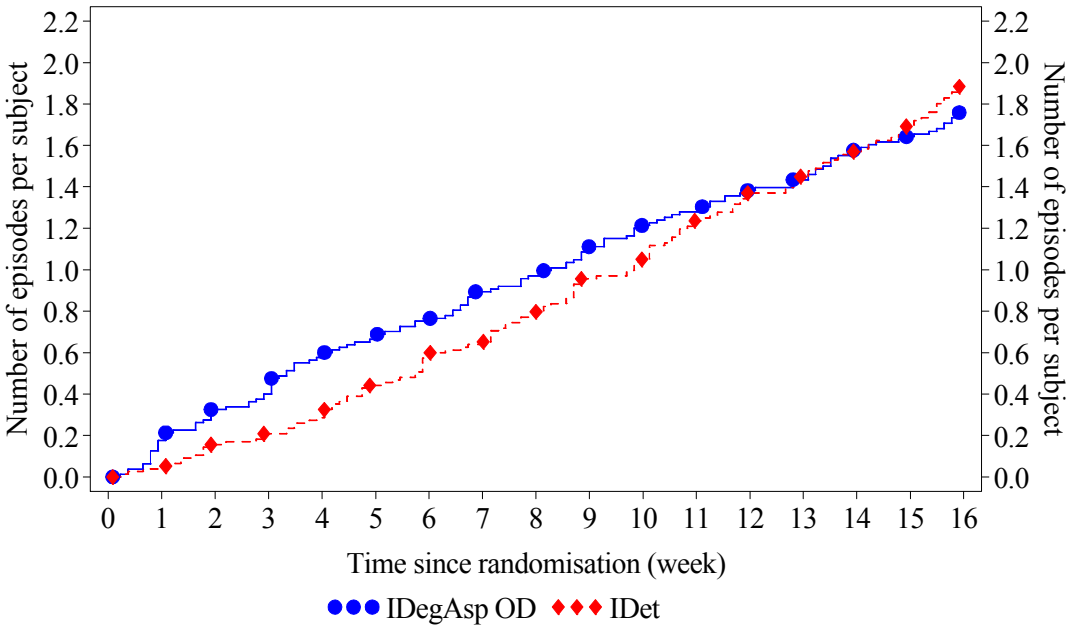
12MAR2015:08:45:17 - fmean_cum_v01.sas/e_hypo_te_conf_noct_mcf_age1_sas.cgm

14.3.1.67 Nocturnal confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - children (1-5 years) - safety analysis set



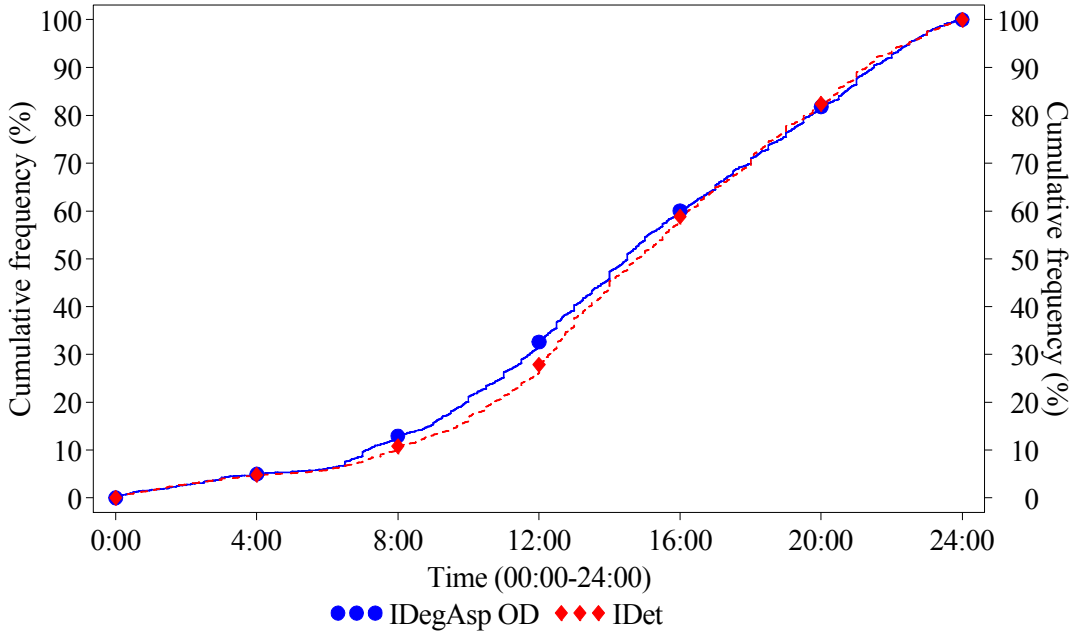
SAFETY: Safety analysis set
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).
nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:16 - fmean_cum_v01.sas/e_hypo_te_conf_noct_mcf_age2_sas.cgm

14.3.1.68 Nocturnal confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - children (6-11 years) - safety analysis set



SAFETY: Safety analysis set
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included).
nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:17 - fmean_cum_v01.sas/e_hypo_te_conf_noct_mcf_age3_sas.cgm

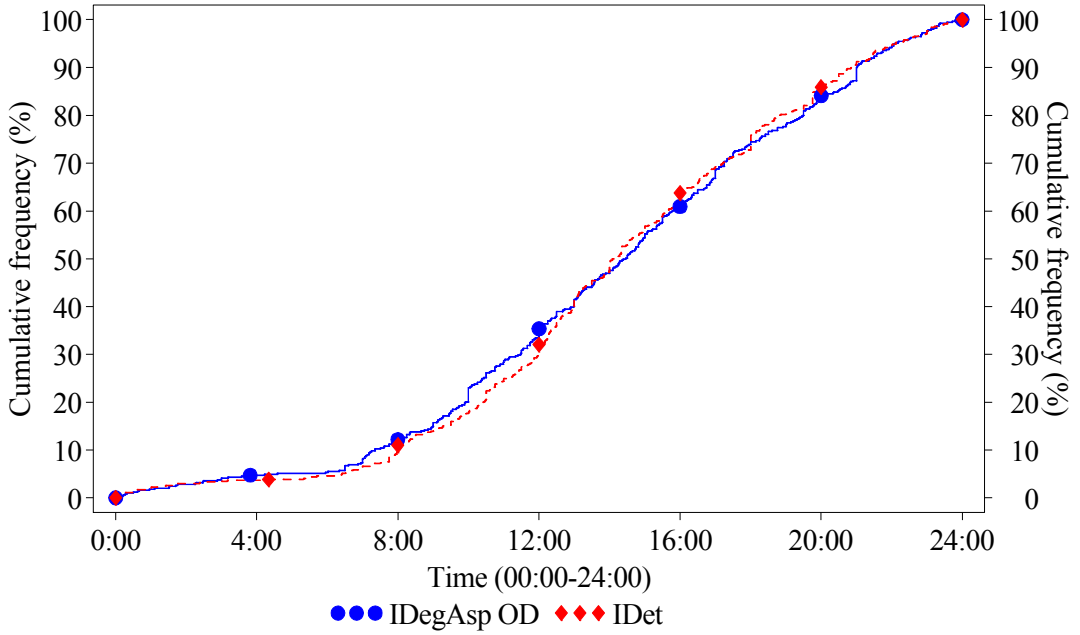
14.3.1.69 Nocturnal confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - adolescents (12-17 years) - safety analysis set



SAFETY
SAFETY: Observed data ,SAFETY :Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:17 - fcum_time_v01.sas/e_hypo_te_conf_cf_day_sas.cgm

14.3.1.70 Confirmed hypoglycaemic episodes – treatment emergent - cumulative frequency over day - safety analysis set



SAFETY
SAFETY: Observed data ,SAFETY :Safety analysis set

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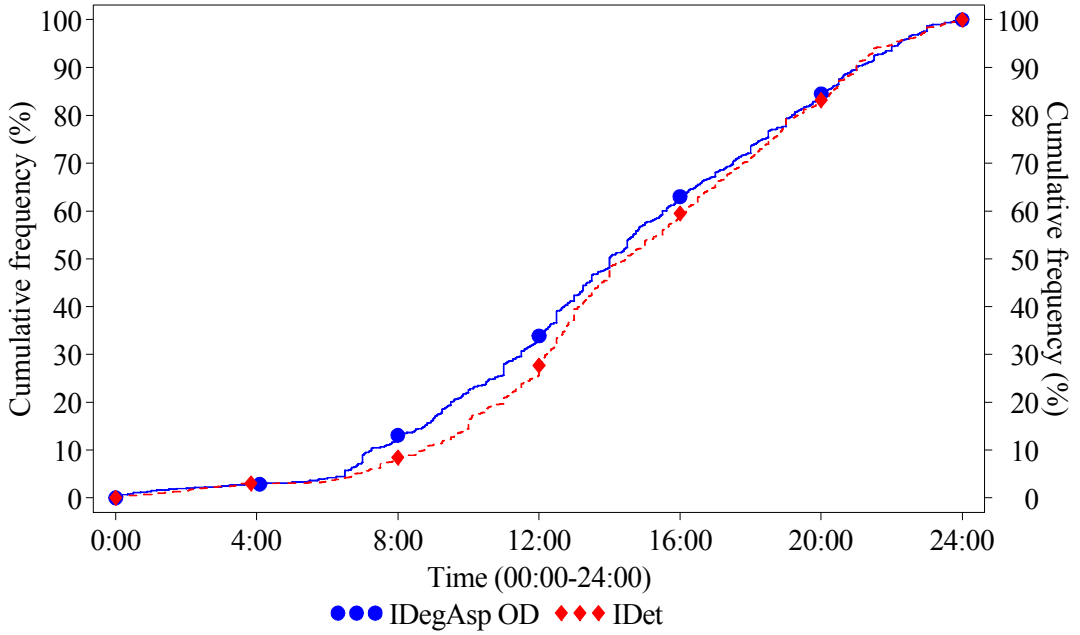
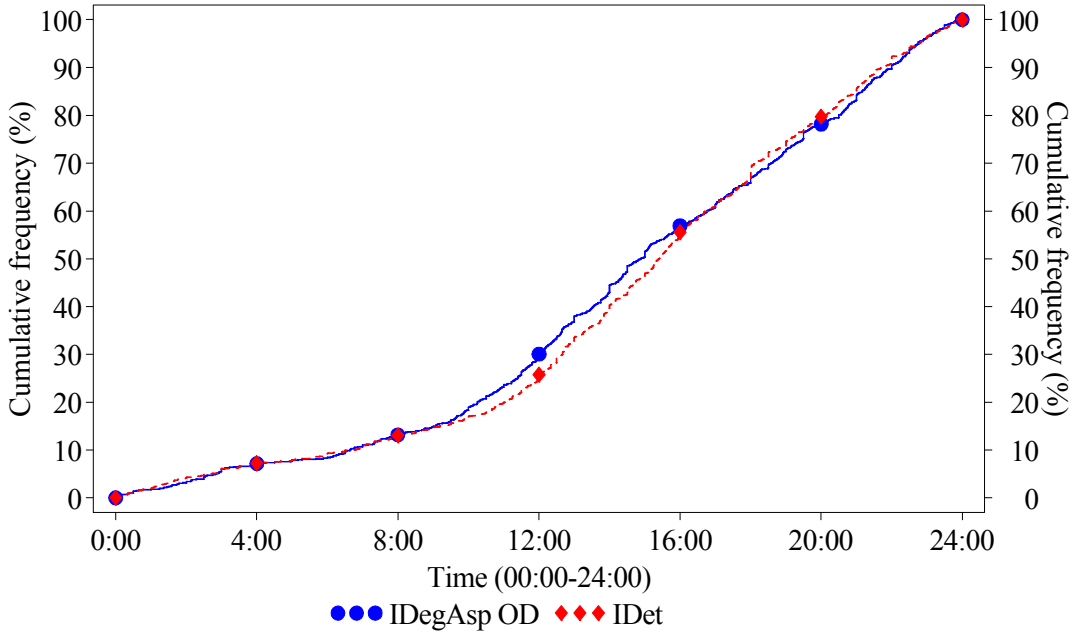
14.3.1.71 Confirmed hypoglycaemic episodes – treatment emergent - cumulative frequency over day – children (1-5 years) - safety analysis set



SAFETY
SAFETY: Observed data ,SAFETY :Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:18 - fcum_time_v01.sas/e_hypo_te_conf_cf_day_age2_sas.cgm

14.3.1.72 Confirmed hypoglycaemic episodes – treatment emergent - cumulative frequency over day – children (6-11 years) - safety analysis set



SAFETY
SAFETY: Observed data ,SAFETY :Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:19 - fcum_time_v01.sas/e_hypo_te_conf_cf_day_age3_sas.cgm

14.3.1.73 Confirmed hypoglycaemic episodes – treatment emergent - cumulative frequency over day – adolescents (12-17 years) - safety analysis set

14.3.1.74 External classified severe hypoglycaemic episodes – treatment emergent - summary - safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R
Number of Subjects	181				179			
All reported severe hypoglycaemia	11	(6.1)	14	26	3	(1.7)	4	7
Externally classified episodes	11	(6.1)	14	26	3	(1.7)	4	7
Severe hypoglycaemia	11	(6.1)	13	24	3	(1.7)	4	7
Altered mental status and cannot assist in their care	6	(3.3)	7	13				
Semiconscious or unconscious	3	(1.7)	3	5	2	(1.1)	3	6
Coma ± convulsions	2	(1.1)	3	5	1	(0.6)	1	2
Not severe hypoglycaemia	1	(0.6)	1	2				

N: Number of subjects, %: Percentage of subjects with the event, E: Number of events
R: Event rate per 100 patient year(s) of exposure

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:45:19 - tsum_hypo_ext_sev_sum.sas/t_ec_hypo_te_sev_sum_sas.txt

14.3.1.75 Hyperglycaemic episodes – treatment emergent – summary - safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R	Total N	(%)	E	R
Number of Subjects	181				179				360			
Hyperglycaemic episodes and subjects looks/feel ill	72	(39.8)	599	1094	73	(40.8)	449	833	145	(40.3)	1048	964

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L
where subject looks/feels ill

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:43 - t_hyper_sum.sas/t_hyper_te_sum_sas.txt

14.3.1.76 Hyperglycaemic episodes by age group – treatment emergent – summary – safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Children (1-5 years)	40				41				81			
Hyperglycaemic episodes and subjects looks/feel ill	19	(47.5)	98	817	14	(34.1)	117	955	33	(40.7)	215	887
Children (6-11 years)	61				61				122			
Hyperglycaemic episodes and subjects looks/feel ill	25	(41.0)	327	1751	25	(41.0)	139	758	50	(41.0)	466	1259
Adolescents (12-17 years)	80				77				157			
Hyperglycaemic episodes and subjects looks/feel ill	28	(35.0)	174	722	34	(44.2)	193	827	62	(39.5)	367	774

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L
where subject looks/feels ill

14.3.1.77 Hyperglycaemic episodes and episodes of ketosis – treatment emergent – summary - safety analysis set

	IDegAsp OD				IDet				Total			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Number of Subjects	181				179				360			
Hyperglycaemic episodes	72	(39.8)	599	1094	73	(40.8)	449	833	145	(40.3)	1048	964
Hyperglycaemic episodes with ketones measured	57	(31.5)	441	805	60	(33.5)	301	558	117	(32.5)	742	683
Hyperglycaemic episodes with ketones > 1.5 mmol/L	4	(2.2)	6	11	8	(4.5)	12	22	12	(3.3)	18	17

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L
where subject looks/feels ill
Ketosis:(blood ketones > 1.5 mmol/L)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:40 - t_hyper_sum.sas/t_hyper_ket_te_sum_sas.txt

14.3.1.78 Hyperglycaemic episodes and episodes of ketosis by age group – treatment emergent – summary - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Children (1-5 years)	40			41			81		
Hyperglycaemic episodes	19 (47.5)	98	817	14 (34.1)	117	955	33 (40.7)	215	887
Hyperglycaemic episodes with ketones measured	18 (45.0)	71	592	11 (26.8)	98	800	29 (35.8)	169	697
Hyperglycaemic episodes with ketones > 1.5 mmol/L	2 (5.0)	3	25	2 (4.9)	4	33	4 (4.9)	7	29
Children (6-11 years)	61			61			122		
Hyperglycaemic episodes	25 (41.0)	327	1751	25 (41.0)	139	758	50 (41.0)	466	1259
Hyperglycaemic episodes with ketones measured	19 (31.1)	258	1381	22 (36.1)	80	436	41 (33.6)	338	913
Hyperglycaemic episodes with ketones > 1.5 mmol/L	1 (1.6)	1	5	3 (4.9)	3	16	4 (3.3)	4	11
Adolescents (12-17 years)	80			77			157		
Hyperglycaemic episodes	28 (35.0)	174	722	34 (44.2)	193	827	62 (39.5)	367	774
Hyperglycaemic episodes with ketones measured	20 (25.0)	112	465	27 (35.1)	123	527	47 (29.9)	235	495
Hyperglycaemic episodes with ketones > 1.5 mmol/L	1 (1.3)	2	8	3 (3.9)	5	21	4 (2.5)	7	15

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L
where subject looks/feels ill
Ketosis:(blood ketones > 1.5 mmol/L)

14.3.1.79 Nocturnal hyperglycaemic episodes – treatment emergent – summary – safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	181			179			360		
Nocturnal hyperglycaemic episodes and subjects looks/feel ill	26 (14.4)	101	184	30 (16.8)	53	98	56 (15.6)	154	142

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L where subject looks/feels ill
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:46 - t_hyper_sum.sas/t_hyper_te_noct_sum_sas.txt

14.3.1.80 Nocturnal hyperglycaemic episodes by age group – treatment emergent – summary – safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Children (1-5 years)	40			41			81		
Nocturnal hyperglycaemic episodes and subjects looks/feel ill	6 (15.0)	9	75	5 (12.2)	7	57	11 (13.6)	16	66
Children (6-11 years)	61			61			122		
Nocturnal hyperglycaemic episodes and subjects looks/feel ill	8 (13.1)	65	348	10 (16.4)	17	93	18 (14.8)	82	222
Adolescents (12-17 years)	80			77			157		
Nocturnal hyperglycaemic episodes and subjects looks/feel ill	12 (15.0)	27	112	15 (19.5)	29	124	27 (17.2)	56	118

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L where subject looks/feels ill
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included)

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:53 - t_hyper_sum.sas/t_hyper_te_noct_sum_age_sas.txt

14.3.1.81 Nocturnal hyperglycaemic episodes and episodes of ketosis – treatment emergent – summary – safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number of Subjects	181			179			360		
Nocturnal hyperglycaemic episodes	26 (14.4)	101	184	30 (16.8)	53	98	56 (15.6)	154	142
Nocturnal hyperglycaemic episodes with ketones measured	21 (11.6)	79	144	17 (9.5)	29	54	38 (10.6)	108	99
Nocturnal hyperglycaemic episodes with ketones > 1.5 mmol/L	1 (0.6)	1	2	2 (1.1)	2	4	3 (0.8)	3	3

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L where subject looks/feels ill
Ketosis:(blood ketones > 1.5 mmol/L)
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included)

14.3.1.82 Nocturnal hyperglycaemic episodes and episodes of ketosis by age group – treatment emergent – summary – safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Children (1-5 years)	40			41			81		
Nocturnal hyperglycaemic episodes	6 (15.0)	9	75	5 (12.2)	7	57	11 (13.6)	16	66
Nocturnal hyperglycaemic episodes with ketones measured	4 (10.0)	6	50	1 (2.4)	2	16	5 (6.2)	8	33
Nocturnal hyperglycaemic episodes with ketones > 1.5 mmol/L	1 (2.5)	1	8	0 (0.0)	0	0	1 (1.2)	1	4
Children (6-11 years)	61			61			122		
Nocturnal hyperglycaemic episodes	8 (13.1)	65	348	10 (16.4)	17	93	18 (14.8)	82	222
Nocturnal hyperglycaemic episodes with ketones measured	7 (11.5)	56	300	6 (9.8)	10	55	13 (10.7)	66	178
Nocturnal hyperglycaemic episodes with ketones > 1.5 mmol/L	0 (0.0)	0	0	0 (0.0)	0	0	0 (0.0)	0	0
Adolescents (12-17 years)	80			77			157		
Nocturnal hyperglycaemic episodes	12 (15.0)	27	112	15 (19.5)	29	124	27 (17.2)	56	118
Nocturnal hyperglycaemic episodes with ketones measured	10 (12.5)	17	71	10 (13.0)	17	73	20 (12.7)	34	72
Nocturnal hyperglycaemic episodes with ketones > 1.5 mmol/L	0 (0.0)	0	0	2 (2.6)	2	9	2 (1.3)	2	4

N: Number of subjects
%: Percentage of subjects with the event
E: Number of events
R: Event rate per 100 patient year(s) of exposure
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L
where subject looks/feels ill
Ketosis:(blood ketones > 1.5 mmol/L)
Nocturnal period: the period between 23:00 p.m. and 07:00 a.m. (both included)

14.3.1.83 Hyperglycaemic episodes - treatment emergent - statistical analysis - full analysis set

	FAS	N	Estimate	95% CI
Hyperglycaemia				
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	823.79	
IDet	180	179	763.54	
Treatment Ratio				
IDegAsp OD / IDet			1.08	[0.64 ; 1.81]

FAS: Full analysis set, 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 function and the logarithm of the exposure time (100 years) as offset. The model includes treatment,sex,region and age group as fixed effects.
Hyperglycaemic episodes: All episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L where subject looks/feels ill.

14.3.1.84 Hyperglycaemic episodes with ketosis – treatment emergent – statistical analysis - full analysis set

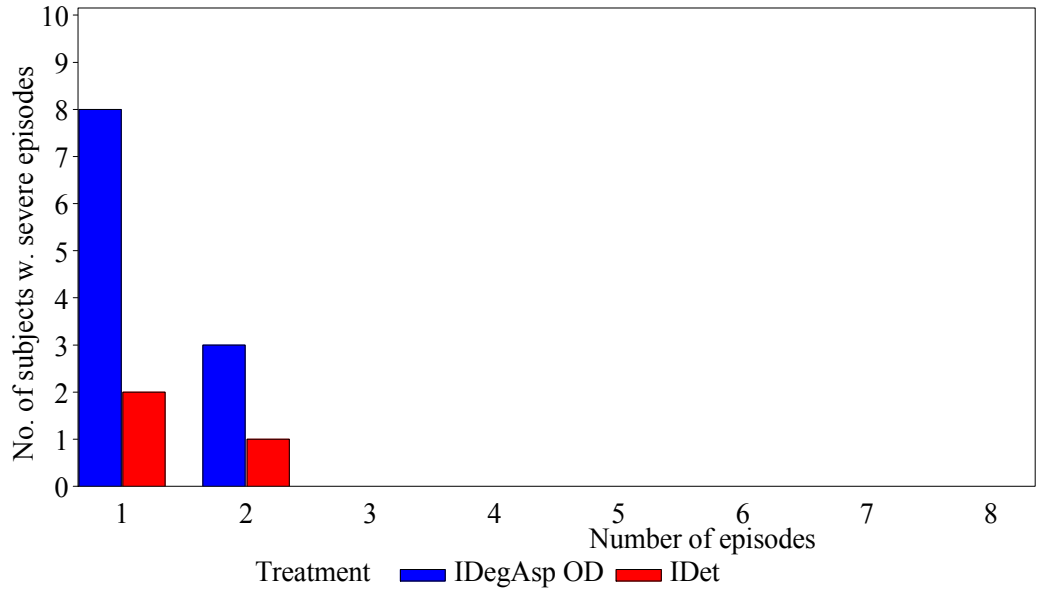
	FAS	N	Estimate	95% CI
Hyperglycaemic episodes with ketosis				
LSMeans, Events per 100 PYE				
IDegAsp OD	182	181	2.41	
IDet	180	179	5.48	
Treatment Ratio				
IDegAsp OD / IDet			0.44	[0.11 ; 1.74]

FAS: Full analysis set, 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 function and the logarithm of the exposure time (100 years) as offset. The model includes treatment,sex,region and age group as fixed effects.
Hyperglycaemic episodes: all episodes registered in hyperglycaemic episode form with plasma glucose > 14.0 mmol/L where subject looks/feels ill
Ketosis: blood ketones > 1.5 mmol/L

14.3.1.85 External classified severe hypoglycaemic episodes by age group – treatment emergent - summary - safety analysis set

	IDegAsp OD N	(%)	E	R	IDet N	(%)	E	R
Children (1-5 years)	40				41			
All reported severe hypoglycaemia	4	(10.0)	5	42	2	(4.9)	2	16
Externally classified episodes	4	(10.0)	5	42	2	(4.9)	2	16
Severe hypoglycaemia	4	(10.0)	5	42	2	(4.9)	2	16
Altered mental status and cannot assist in their care	2	(5.0)	3	25				
Semiconscious or unconscious	2	(5.0)	2	17	1	(2.4)	1	8
Coma ± convulsions					1	(2.4)	1	8
Children (6-11 years)	61				61			
All reported severe hypoglycaemia	3	(4.9)	4	21				
Externally classified episodes	3	(4.9)	4	21				
Severe hypoglycaemia	3	(4.9)	4	21				
Altered mental status and cannot assist in their care	2	(3.3)	2	11				
Coma ± convulsions	1	(1.6)	2	11				
Adolescents (12-17 years)	80				77			
All reported severe hypoglycaemia	4	(5.0)	5	21	1	(1.3)	2	9
Externally classified episodes	4	(5.0)	5	21	1	(1.3)	2	9
Severe hypoglycaemia	4	(5.0)	4	17	1	(1.3)	2	9
Altered mental status and cannot assist in their care	2	(2.5)	2	8				
Semiconscious or unconscious	1	(1.3)	1	4	1	(1.3)	2	9
Coma ± convulsions	1	(1.3)	1	4				
Not severe hypoglycaemia	1	(1.3)	1	4				

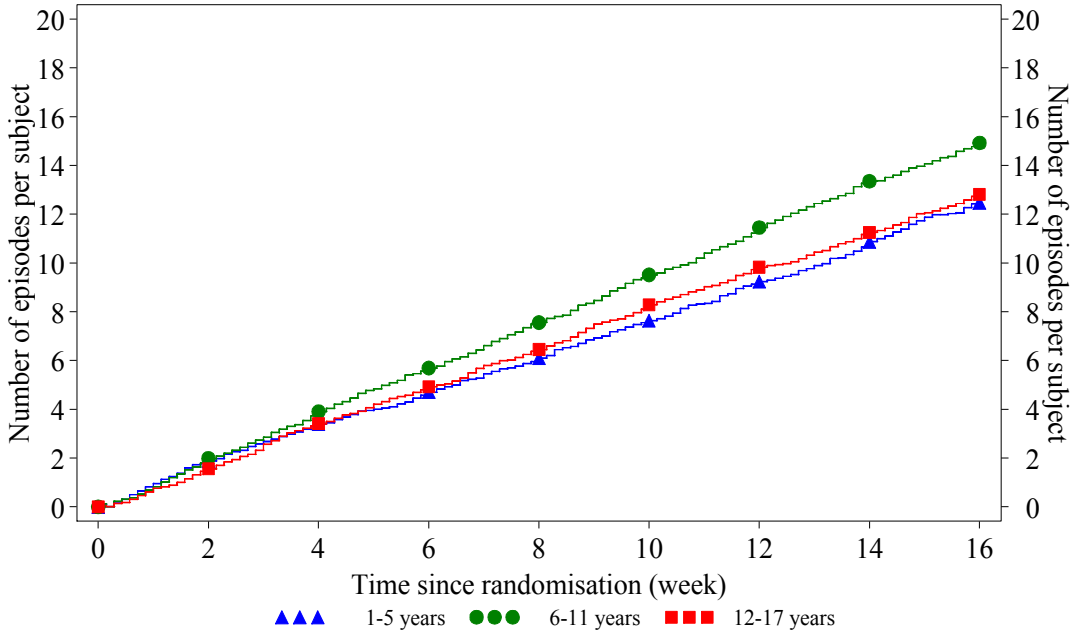
N: Number of subjects, %: Percentage of subjects with the event, E: Number of events
R: Event rate per 100 patient years of exposure



The x-axis denotes observed subject counts of severe hypoglycaemic episodes.
The height of a bar (measured on the y-axis) gives the number of patients experiencing a given number of severe hypoglycaemic episodes.
Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:34 - sev_hypo_bar_plot/e_sev_hypos_barplot.cgm

14.3.1.86 Distribution of severe hypoglycaemic episodes - subject counts against number of episodes - safety analysis set



nn5401/nn5401-3816/er_20150312_ctr
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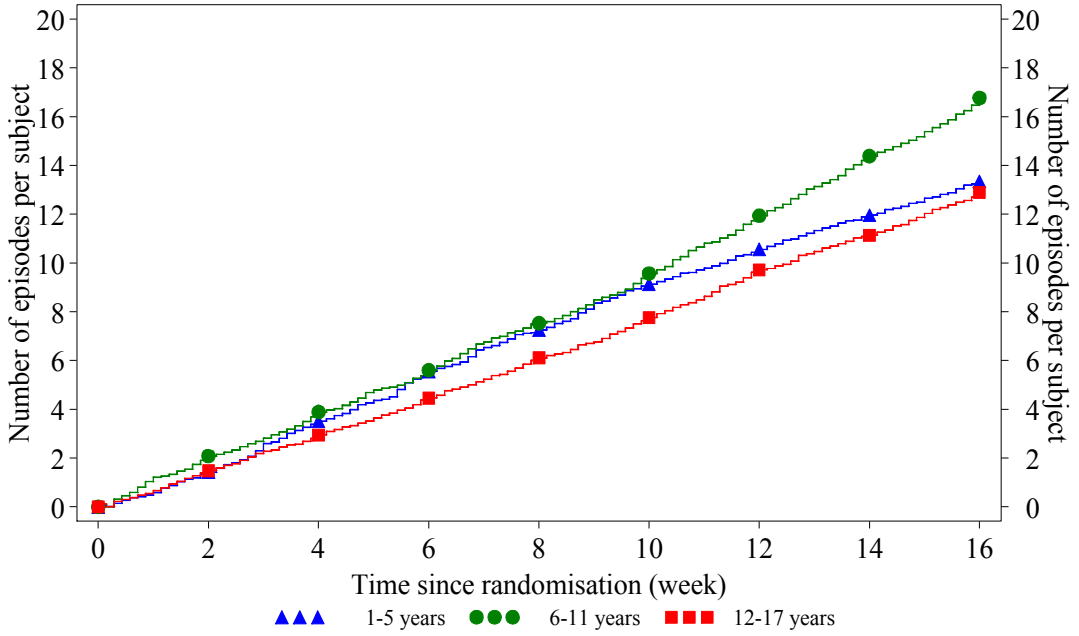
14.3.1.87 Confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - IDegAsp OD - by age group - safety analysis set



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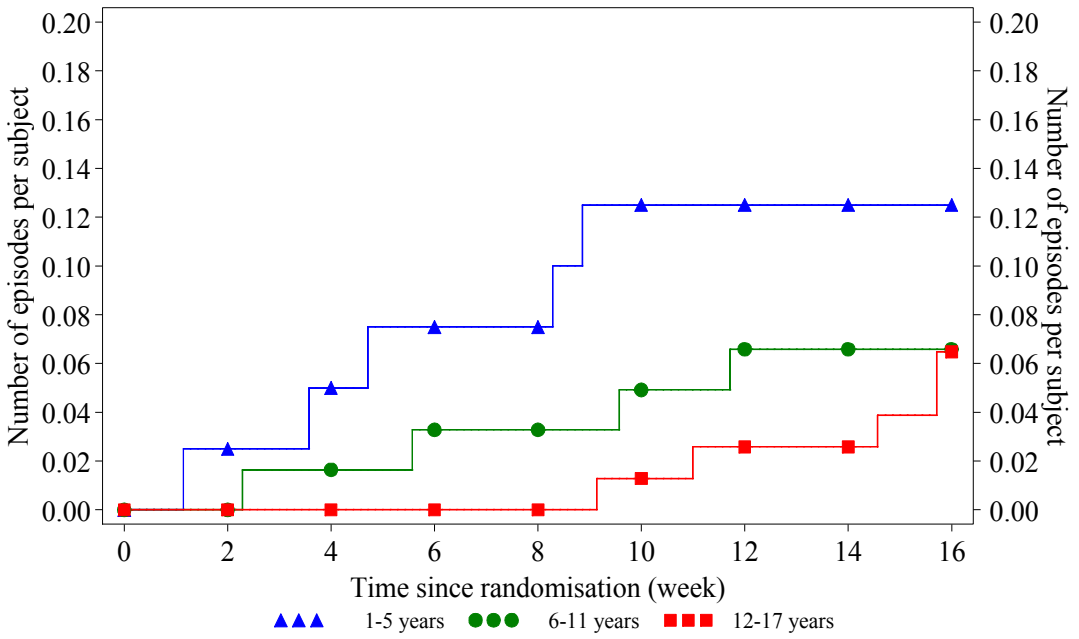
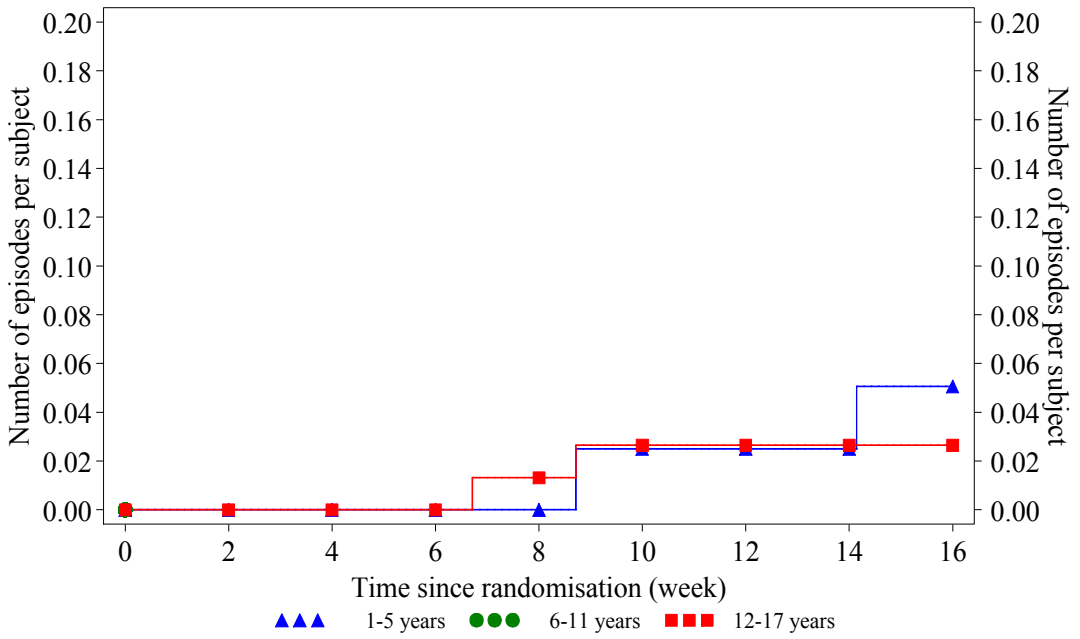
12MAR2015:08:47:13 - fmean_cum.sas/e_hypo_te_conf_mcf_idet_sas.cgm

14.3.1.88 Confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - IDet - by age group - safety analysis set



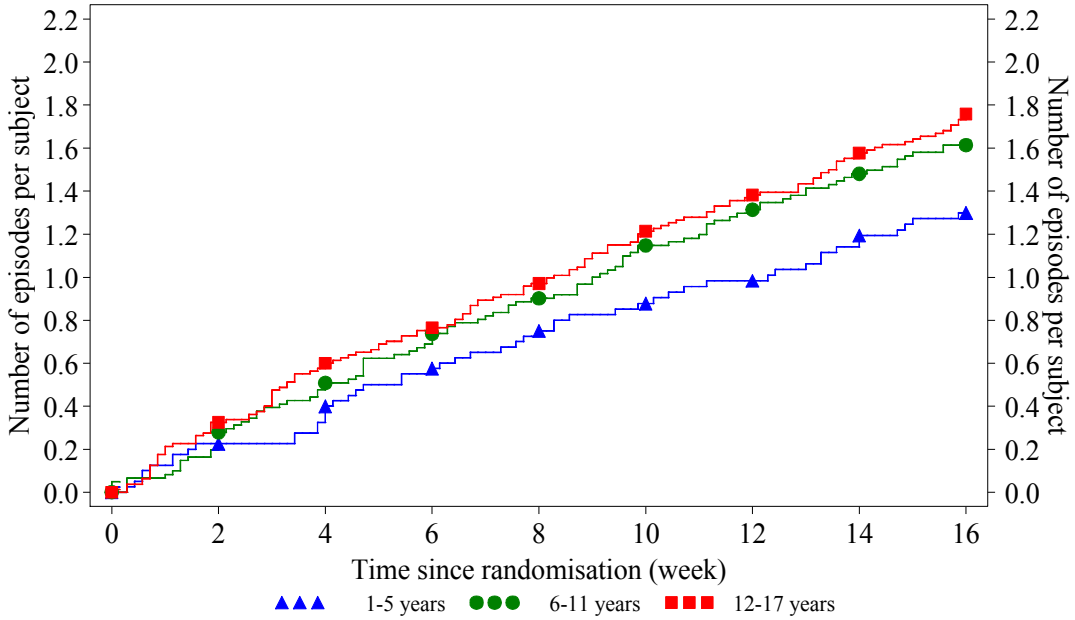
nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:15 - fmean_cum.sas/e_hypo_te_sev_mcf_ideg_sas.cgm

14.3.1.89 Severe hypoglycaemic episodes - treatment emergent - mean cumulative function - IDegAsp OD - by age group - safety analysis set



nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:18 - fmean_cum.sas/e_hypo_te_sev_mcf_idet_sas.cgm

14.3.1.90 Severe hypoglycaemic episodes - treatment emergent - mean cumulative function - IDet - by age group - safety analysis set



Nocturnal period: the period between 23:00 p.m and 07:00 a.m. (both included).

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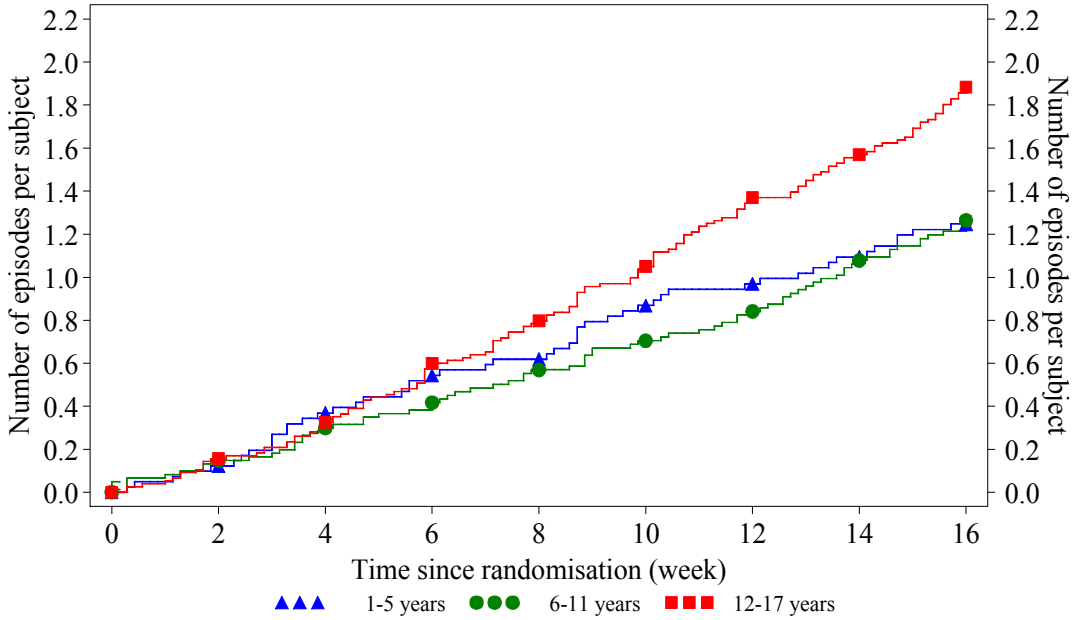
12MAR2015:08:47:21 - fmean_cum.sas/e hypo_te_conf_noct_mcf_ideg_sas.cgm

14.3.1.91 Nocturnal confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - IDegAsp OD - by age group - safety analysis set



Nocturnal period: the period between 23:00 p.m and 07:00 a.m. (both included).

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:23 - fmean_cum.sas/e_hypo_te_conf_noct_mcf_idet_sas.cgm

14.3.1.92 Nocturnal confirmed hypoglycaemic episodes – treatment emergent - mean cumulative function - IDet - by age group - safety analysis set

14.3.1.93 Injection site reactions by system organ class and preferred term possibly or probably related to IDegAsp/Comparator - safety analysis set

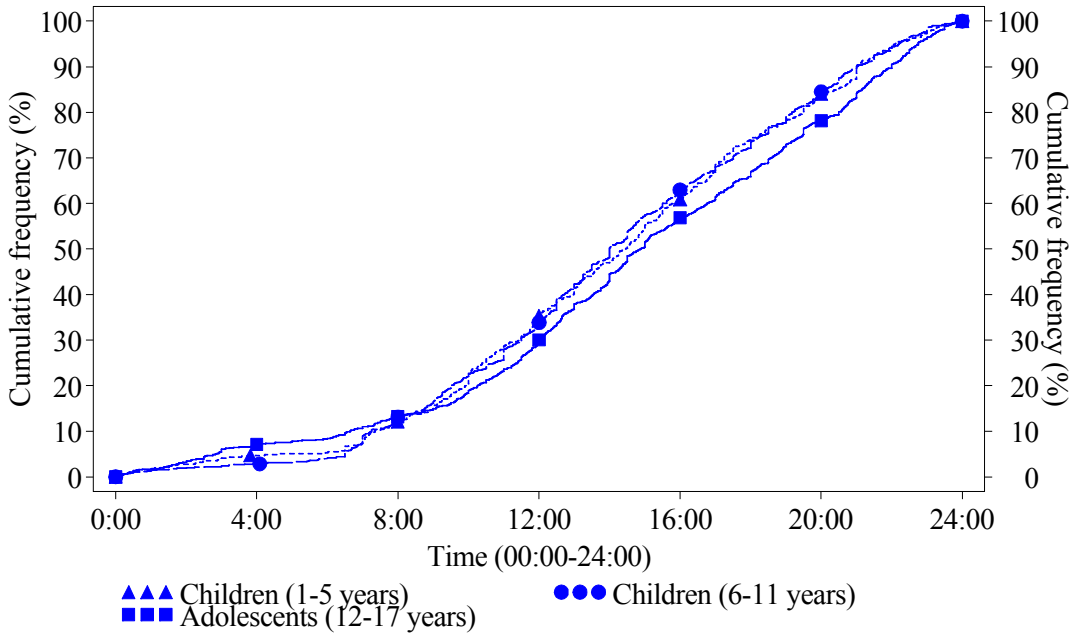
	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number Of Subjects	181			179			360		
Events	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
General Disorders And Administration									
Injection Site Hypertrophy	1 (0.6)	1	2				1 (0.3)	1	1
Injection Site Swelling				1 (0.6)	1	2	1 (0.3)	1	1

N: Number of subjects, %: Percentage of subjects, E: Number of events, R: Event rate per 100 exposure years

14.3.1.94 Injection site reactions by system organ class and preferred term possibly or probably related to bolus insulin - safety analysis set

	IDegAsp OD			IDet			Total		
	N (%)	E	R	N (%)	E	R	N (%)	E	R
Number Of Subjects	181			179			360		
Events	1 (0.6)	1	2	1 (0.6)	1	2	2 (0.6)	2	2
General Disorders And Administration Site Conditions									
Injection Site Hypertrophy	1 (0.6)	1	2				1 (0.3)	1	1
Injection Site Swelling				1 (0.6)	1	2	1 (0.3)	1	1

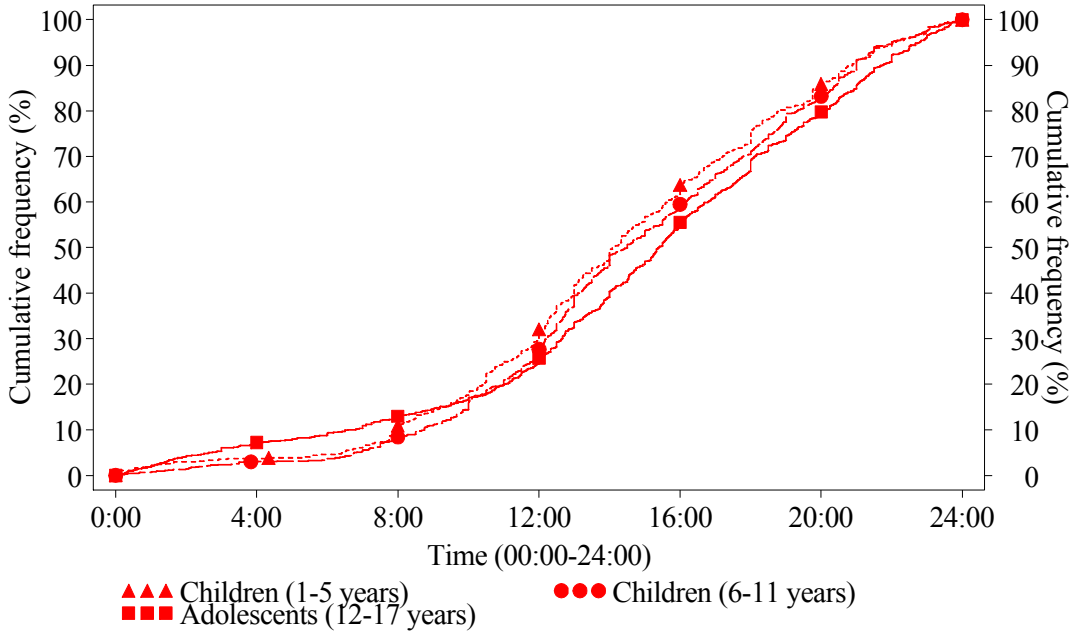
N: Number of subjects, %: Percentage of subjects, E: Number of events, R: Event rate per 100 exposure years



SAFETY;
Safety: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:07 - conf_hyper_cum_oday_fas.sas/e_conf_hypo_te_cum_oday_ideg_fas.cgm

14.3.1.95 Confirmed hypoglycaemic episodes - treatment emergent - cumulative frequency over day - IDegAsp OD - by age group - safety analysis set



SAFETY:
Safety: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:47:08 - conf_hyper_cum_oday_fas.sas/e_conf_hypo_te_cum_oday_idet_fas.cgm

14.3.1.96 Confirmed hypoglycaemic episodes - treatment emergent - cumulative frequency over day - IDet - by age group - safety analysis set

14.3.2 Listings of deaths, other serious and significant adverse events

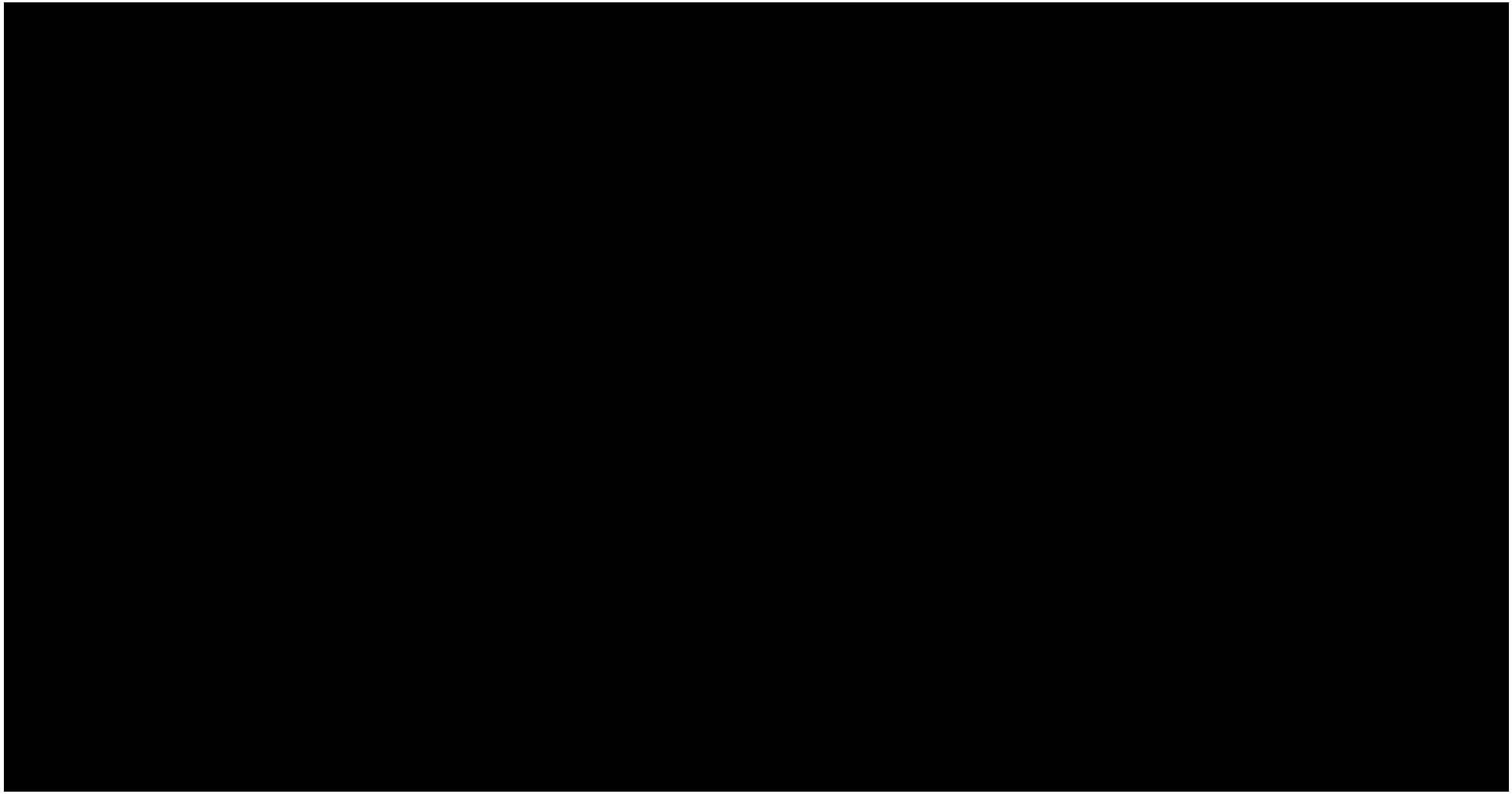
14.3.2.1 Treatment emergent serious adverse events - safety analysis set

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	Device (Y/N)	Relation/ Action

[redacted]

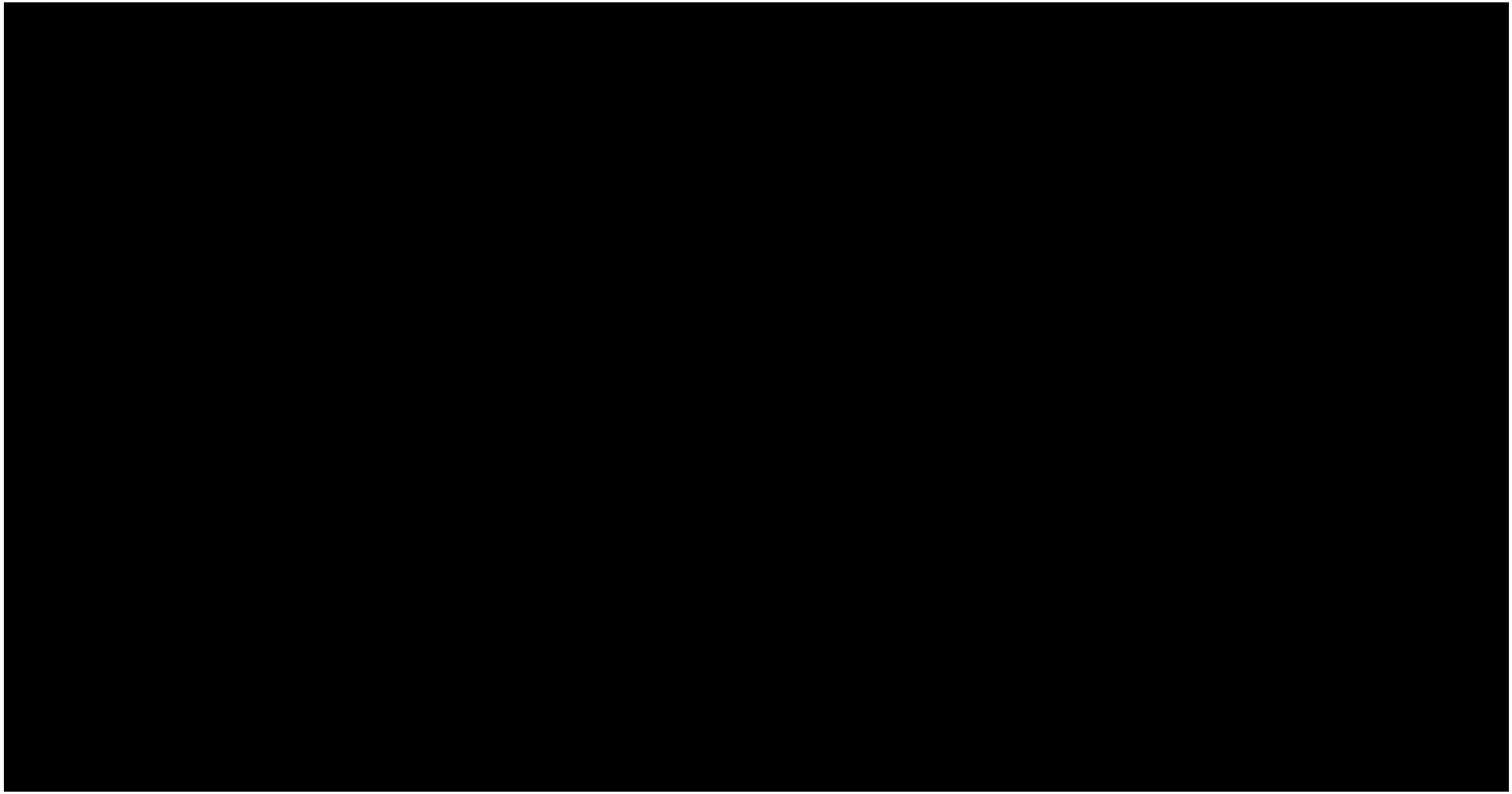
Treatment emergent serious adverse events - safety analysis set

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	Device (Y/N)	Relation/ Action



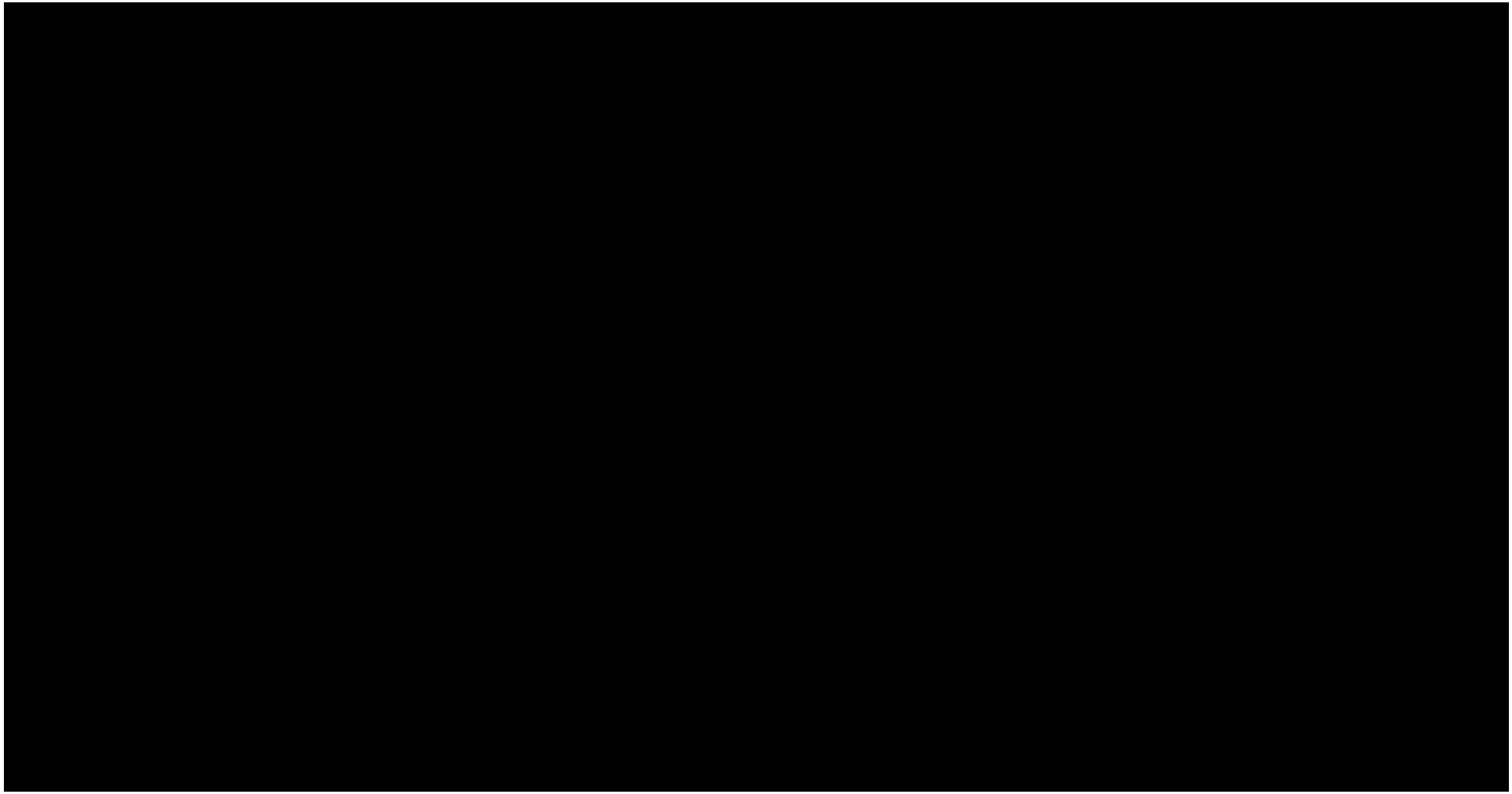
Treatment emergent serious adverse events - safety analysis set

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	Device (Y/N)	Relation/ Action



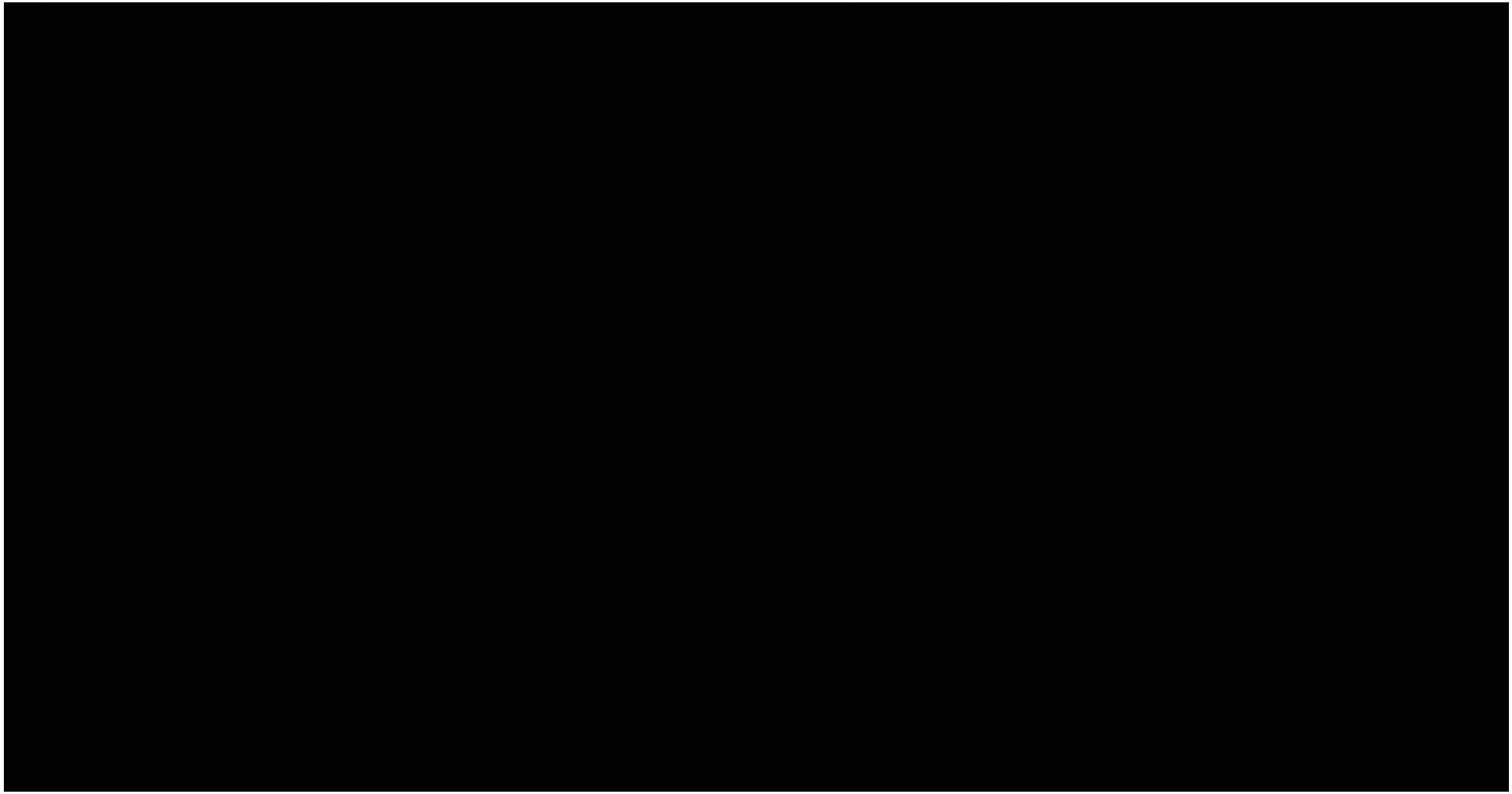
Treatment emergent serious adverse events - safety analysis set

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	Device (Y/N)	Relation/ Action



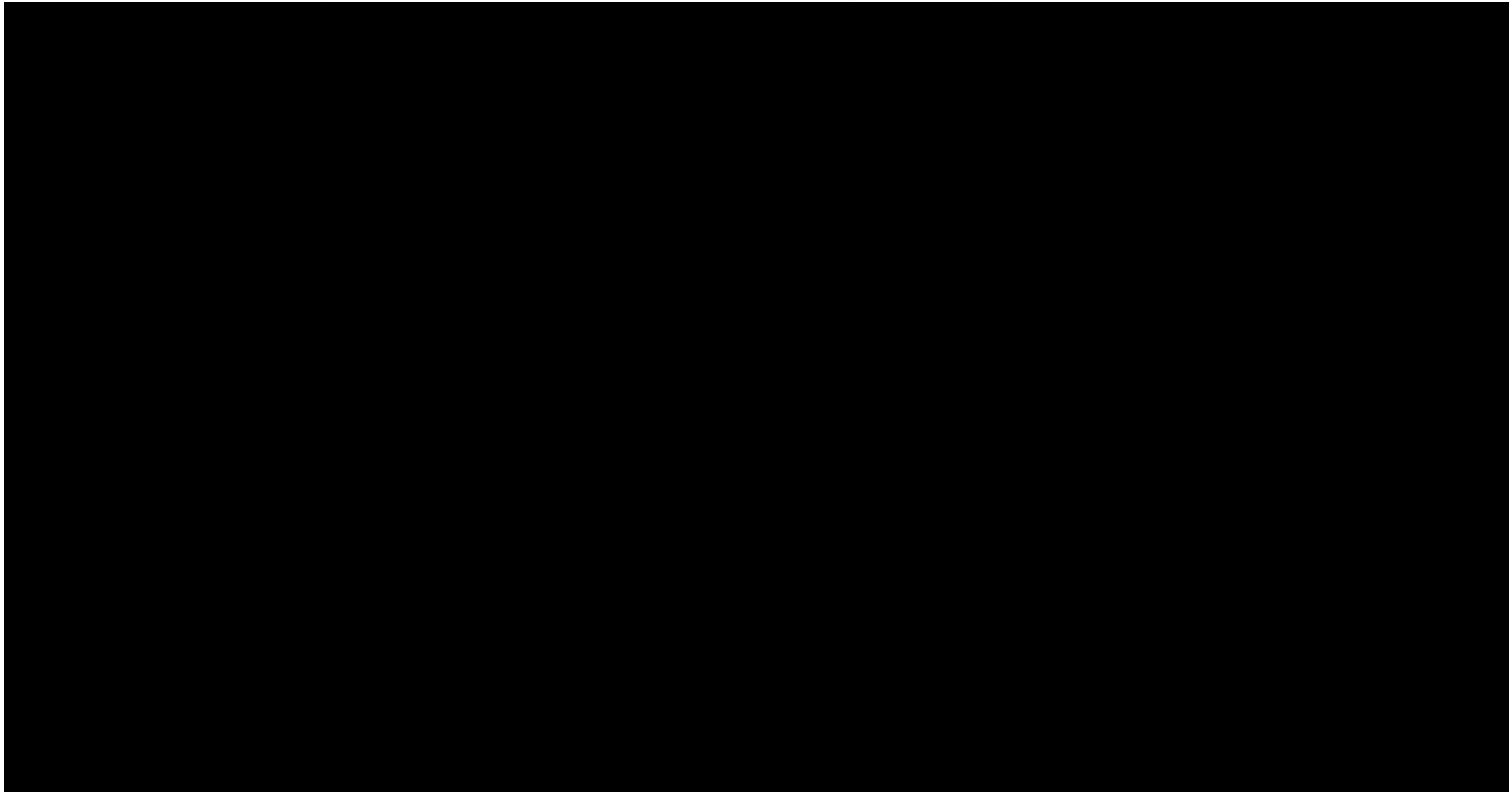
Treatment emergent serious adverse events - safety analysis set

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	Device (Y/N)	Relation/ Action



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	Device (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

14.3.2.3 Treatment emergent adverse events leading to dose reduction of IDegAsp/Comparator - 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	Device (Y/N)	Relation/ Action

[redacted]

Treatment emergent adverse events leading to dose reduction of IDegAsp/Comparator - 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	Device (Y/N)	Relation/ Action
[redacted]									

Treatment emergent adverse events leading to dose reduction of IDegAsp/Comparator - 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	Device (Y/N)	Relation/ Action
[redacted]									

Treatment emergent adverse events leading to dose reduction of IDegAsp/Comparator - 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	Device (Y/N)	Relation/ Action

[redacted]

Treatment emergent adverse events leading to dose reduction of IDegAsp/Comparator - 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	Device (Y/N)	Relation/ Action

[redacted]

14.3.2.4 Treatment emergent adverse events leading to temporary withdrawal of IDegAsp/Comparator - 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	Device (Y/N)	Relation/ Action

[redacted]

14.3.2.5 Adverse events leading to withdrawal - full analysis set

Subject ID/ Treatment/ Age/Sex/BMI	Diag AE No.	(Y/N)/ Link	System Organ Class/ Preferred Term/ Reported Term	Onset Date/ Outcome	Study Day/ Duration (days)	Serious (Y/N)/Trial Severity	Product	Device Relation/ (Y/N)	Action

[redacted]

14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

Ingredient: Insulin Degludec
Trade Name: IDegAsp 30 Penfill (Solution for injection, 100 U/mL)

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

[redacted]

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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 #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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

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Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

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Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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

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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
[redacted]								

Report #: 1

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Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

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Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

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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
[redacted]								

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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

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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
[redacted]								

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[redacted]								

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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
[redacted]								

Report #: 1

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Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

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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

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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
[redacted]								

Report #: 1

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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

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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
[redacted]								

Report #: 1

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Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

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[redacted]								

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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
[redacted]								

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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
[redacted]								

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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
[redacted]								

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[redacted]								

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[redacted]								

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Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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

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NN5401-3816 Case Listing

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Period: 01-Jan-1900 Through 31-Dec-2099

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

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NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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 #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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 #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

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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 #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

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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

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[redacted]								

Report #: 1

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Report #: 1

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[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

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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

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Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

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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
[redacted]								

Report #: 1

NN5401-3816 Case Listing

Date: 28-Nov-2014 08:36:45

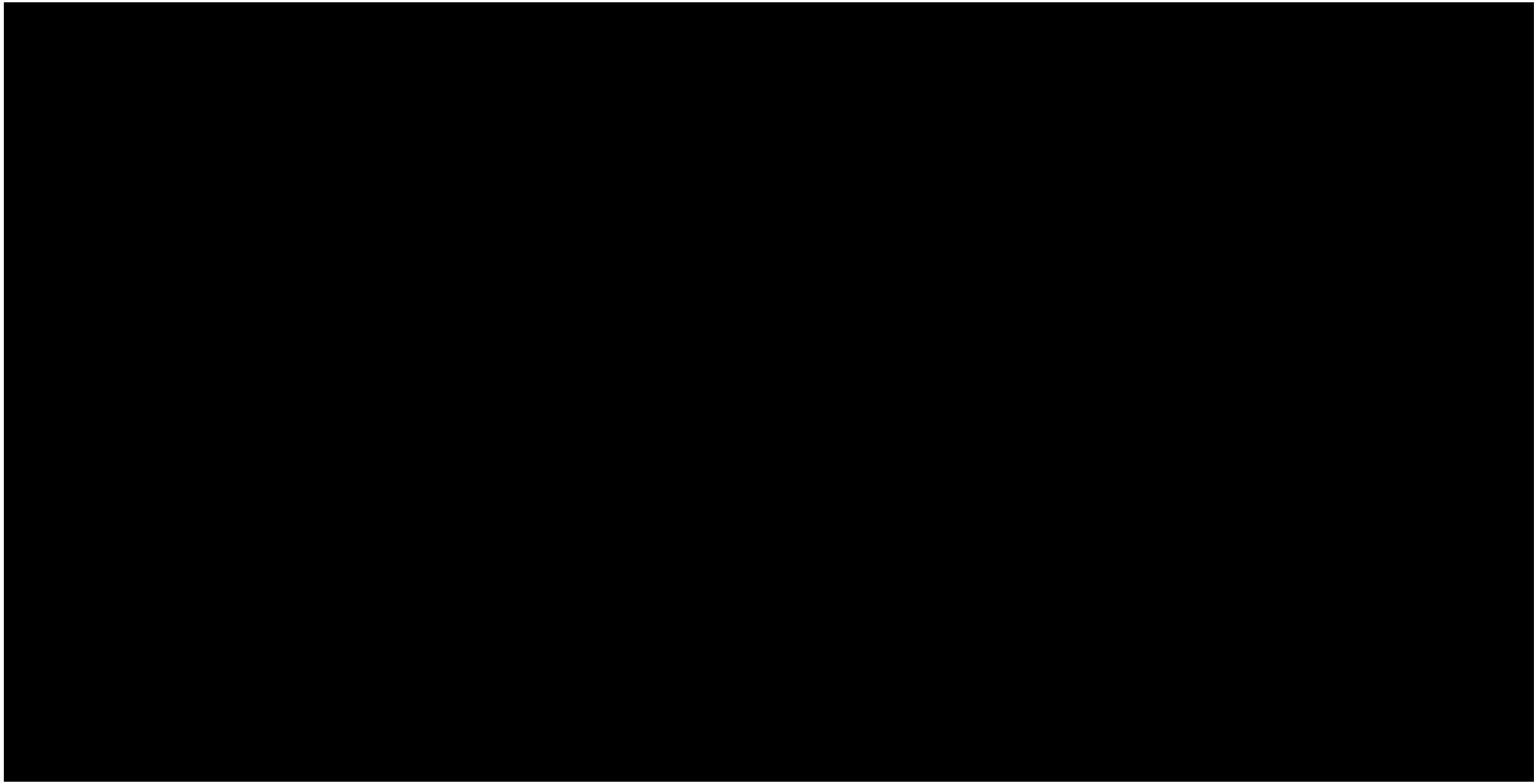
Period: 01-Jan-1900 Through 31-Dec-2099

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
[redacted]								

14.3.4 Abnormal laboratory value listings (by subject)

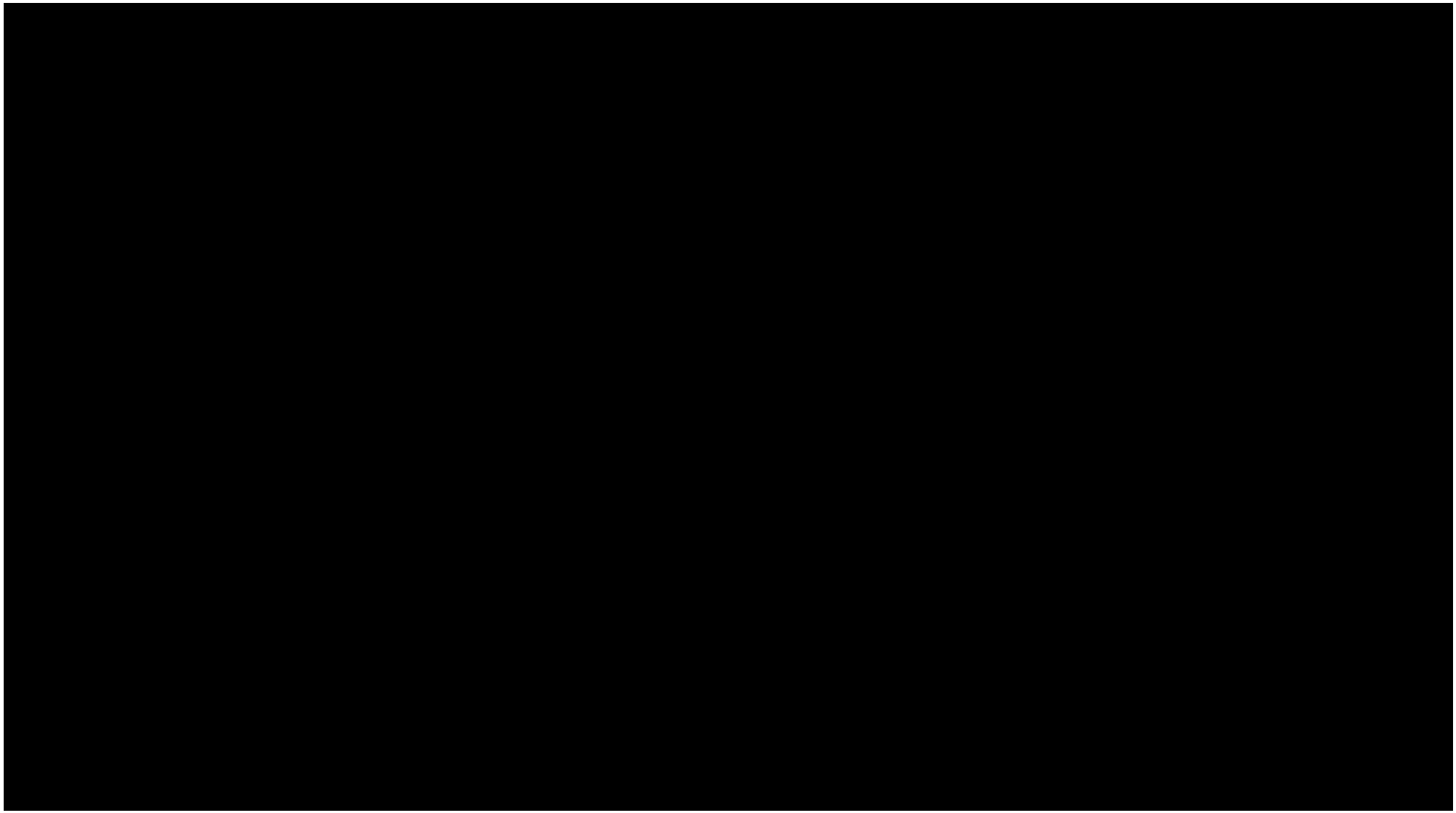
14.3.4.1 Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



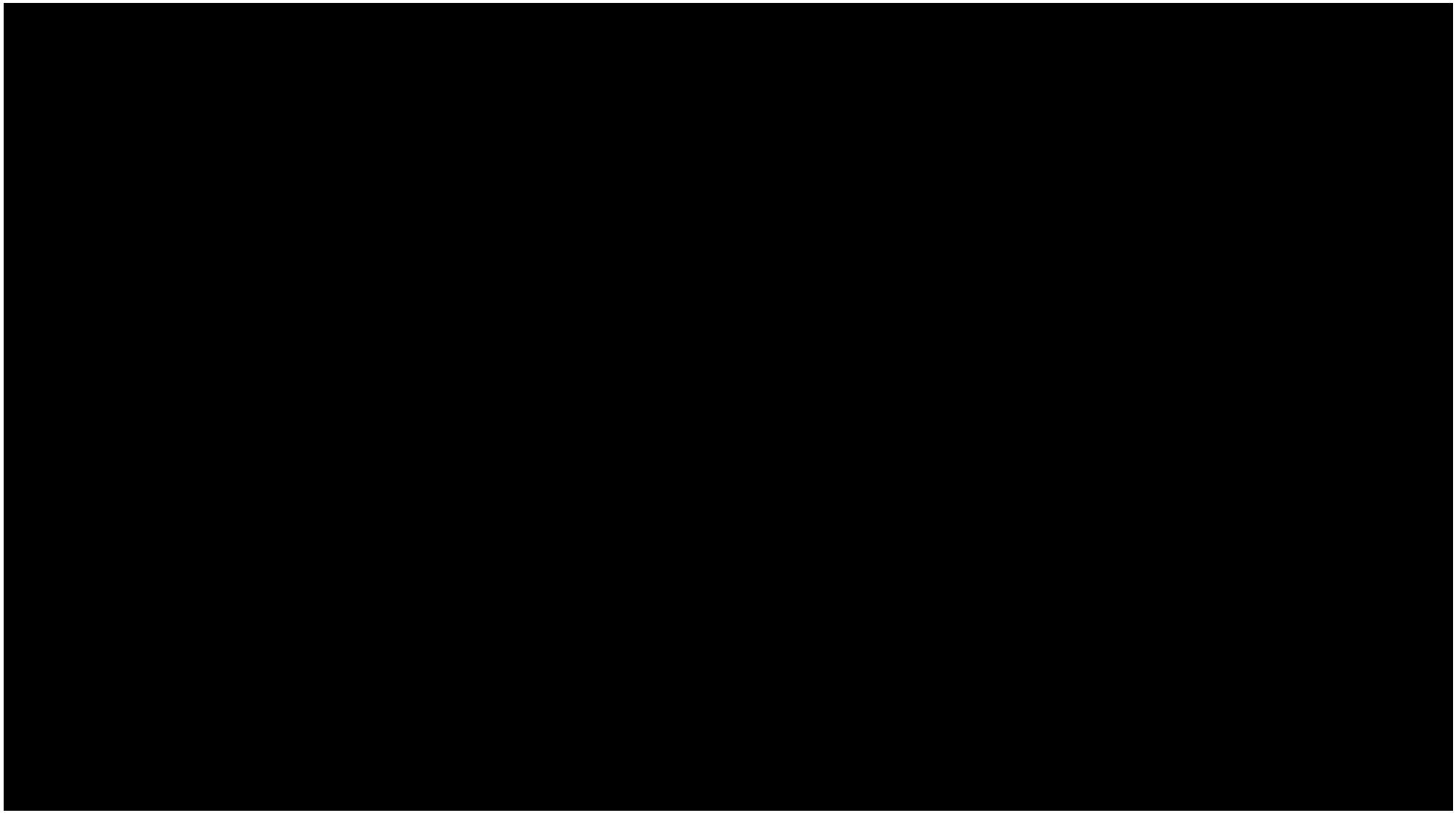
Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



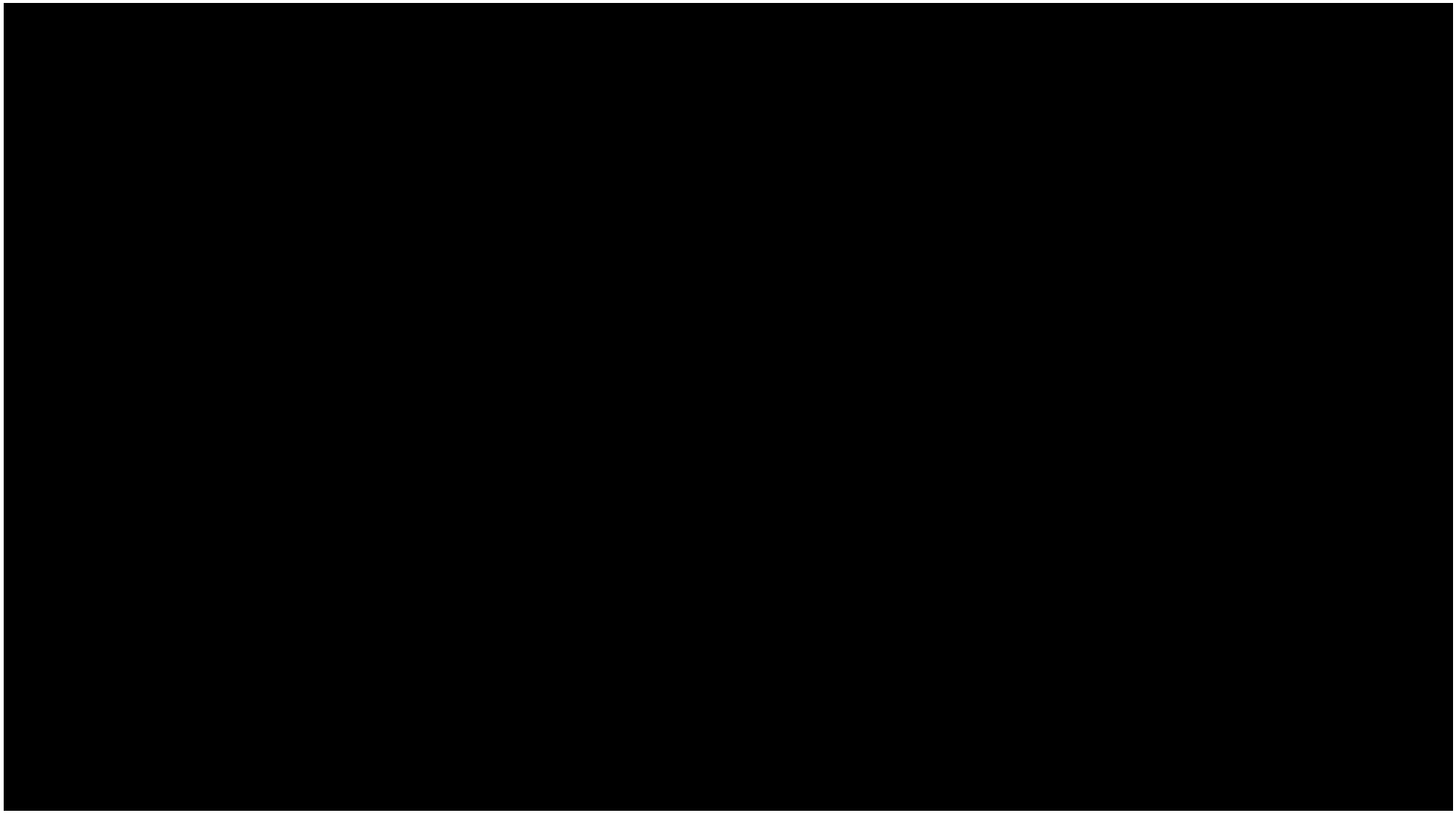
Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



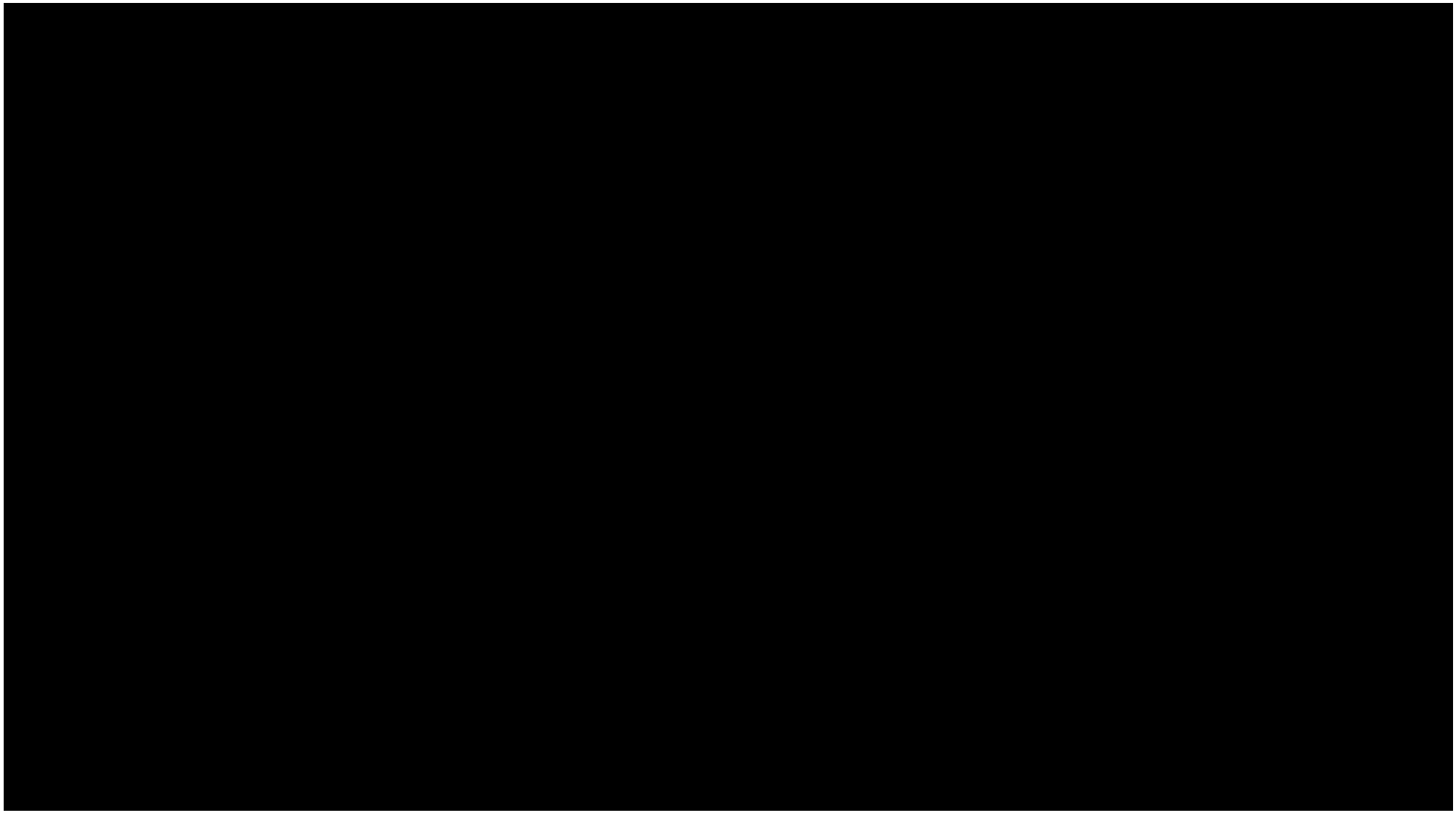
Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



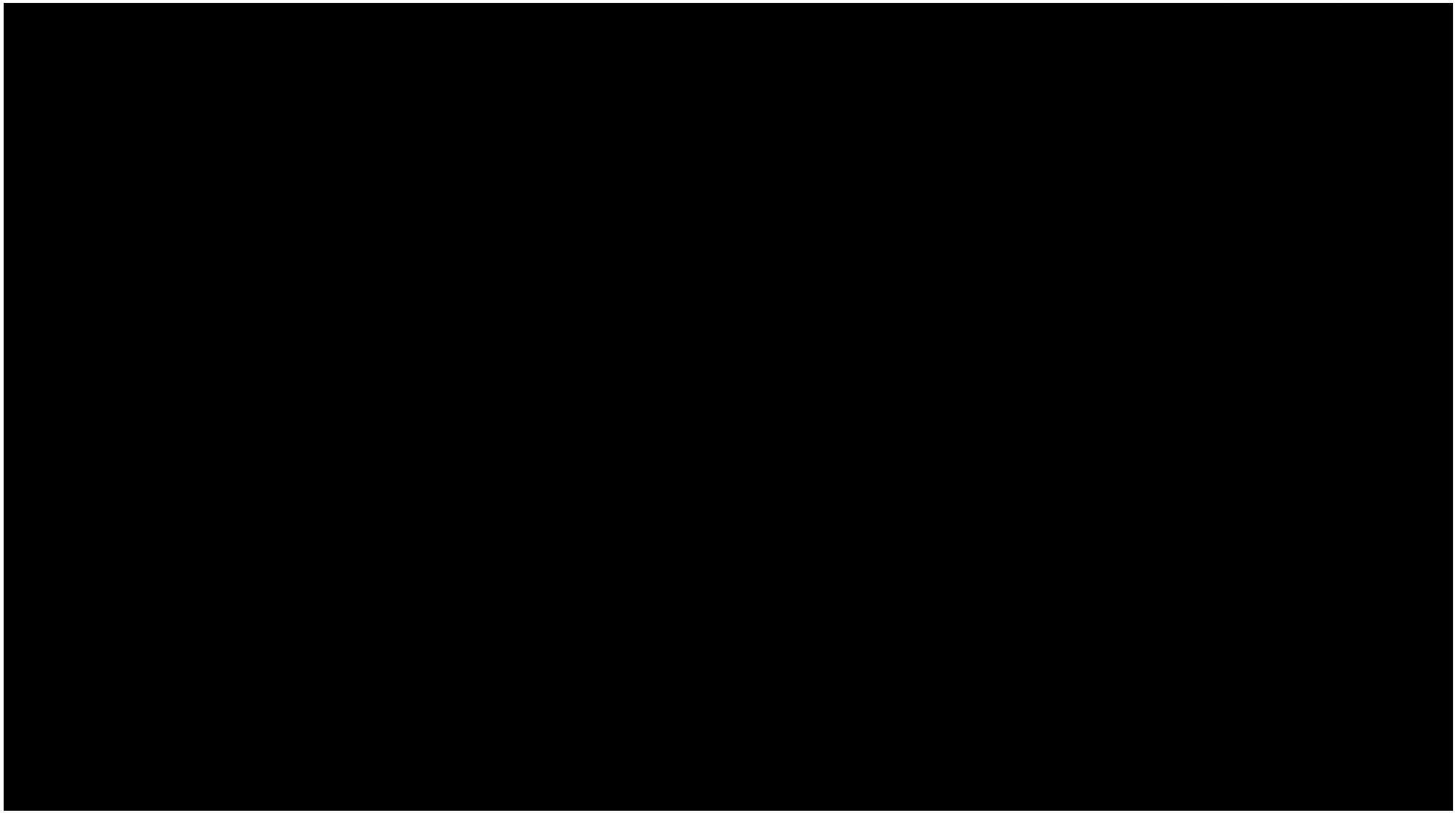
Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



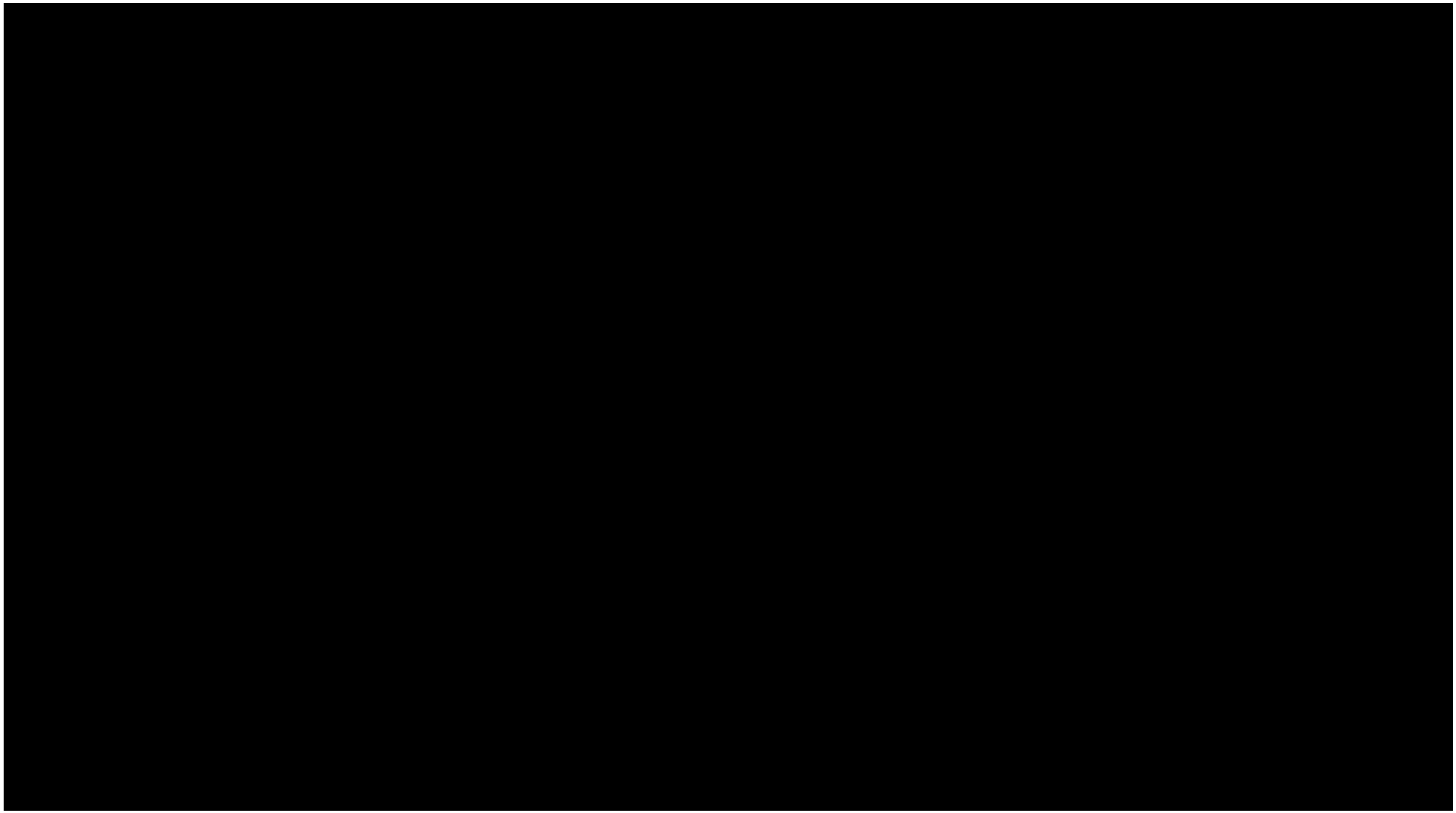
Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



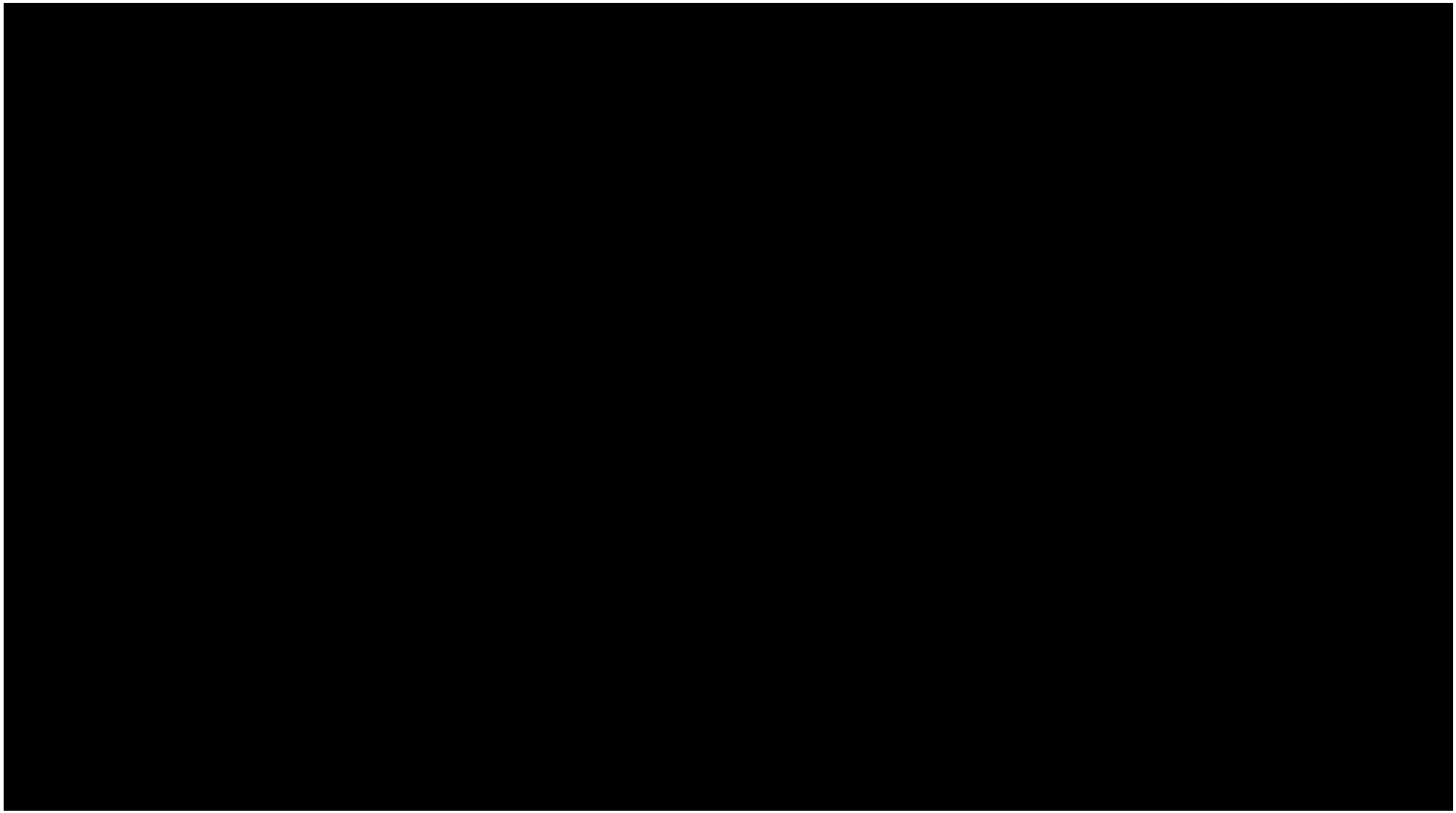
Biochemistry laboratory test results outside reference range - safety analysis set

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

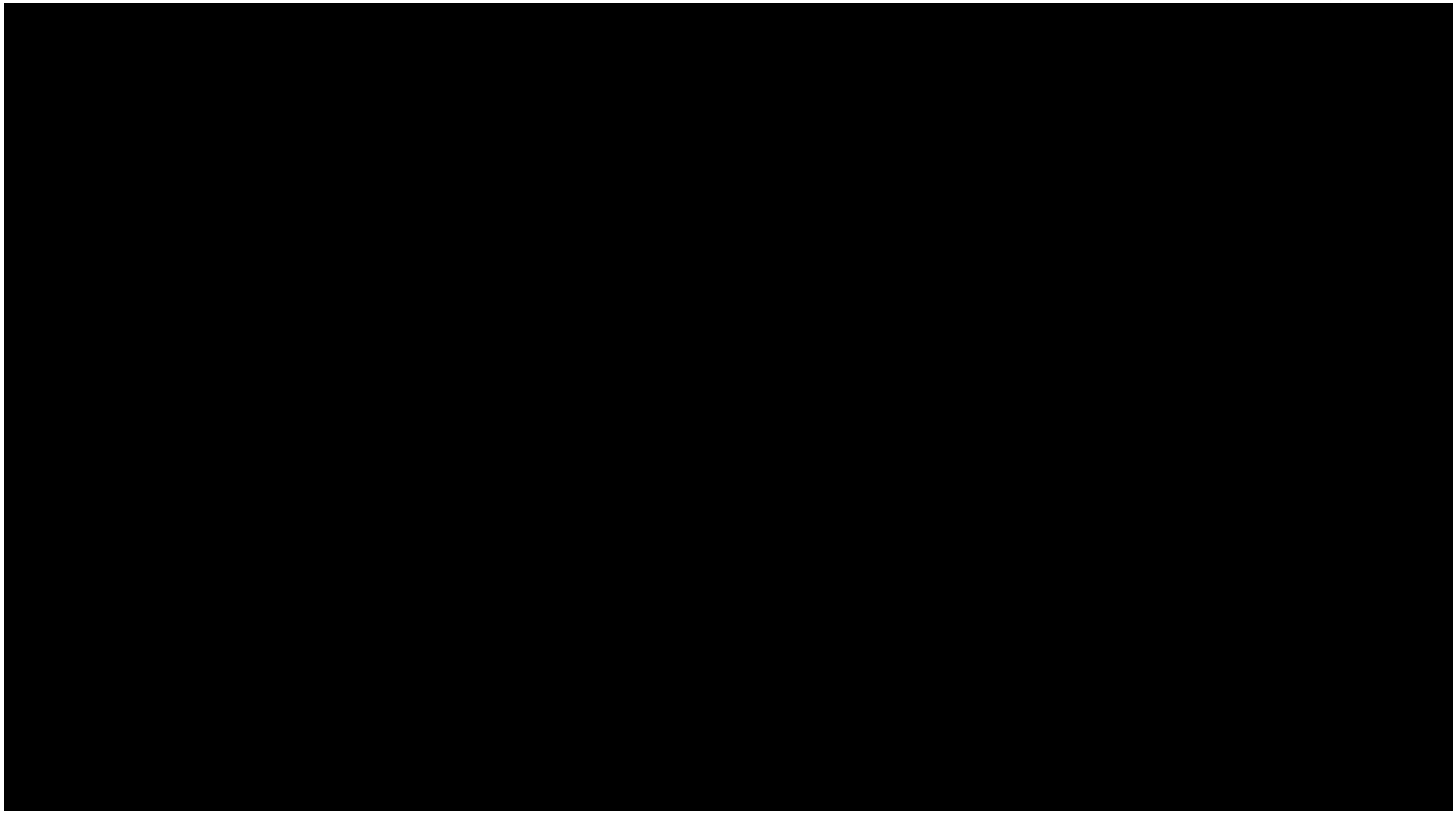


Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
[redacted]									

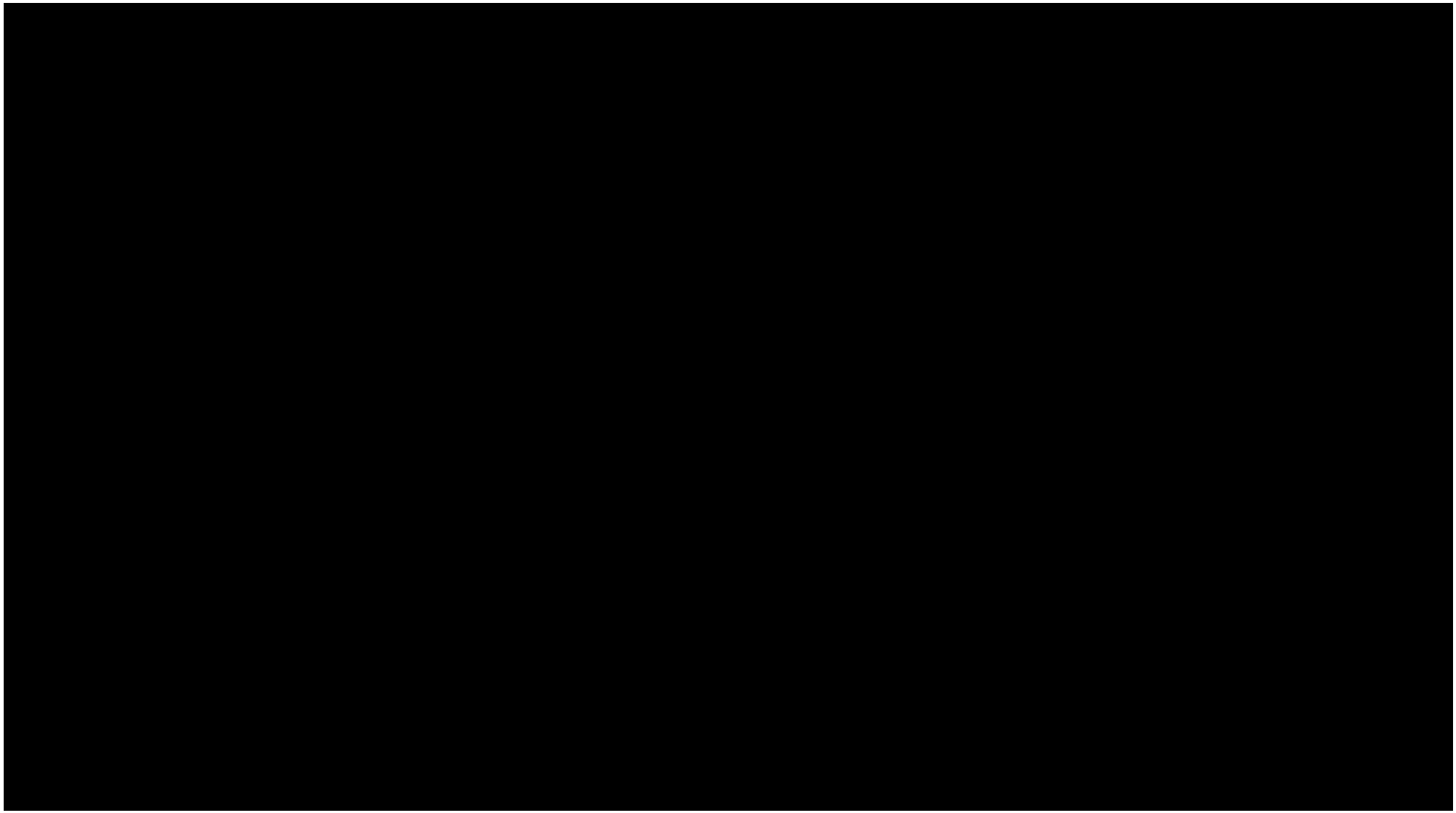
Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



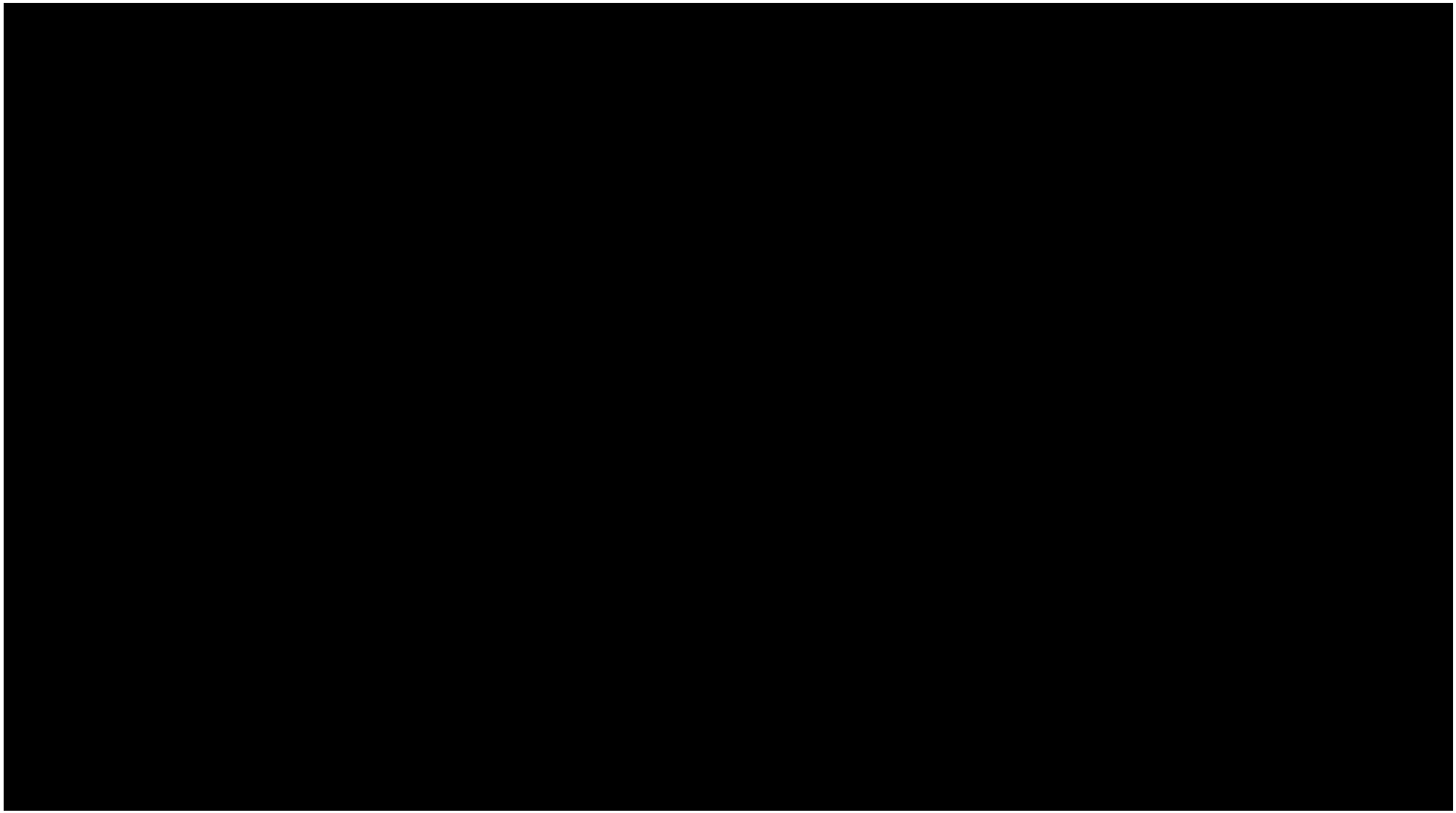
Biochemistry laboratory test results outside reference range - safety analysis set

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

[redacted]

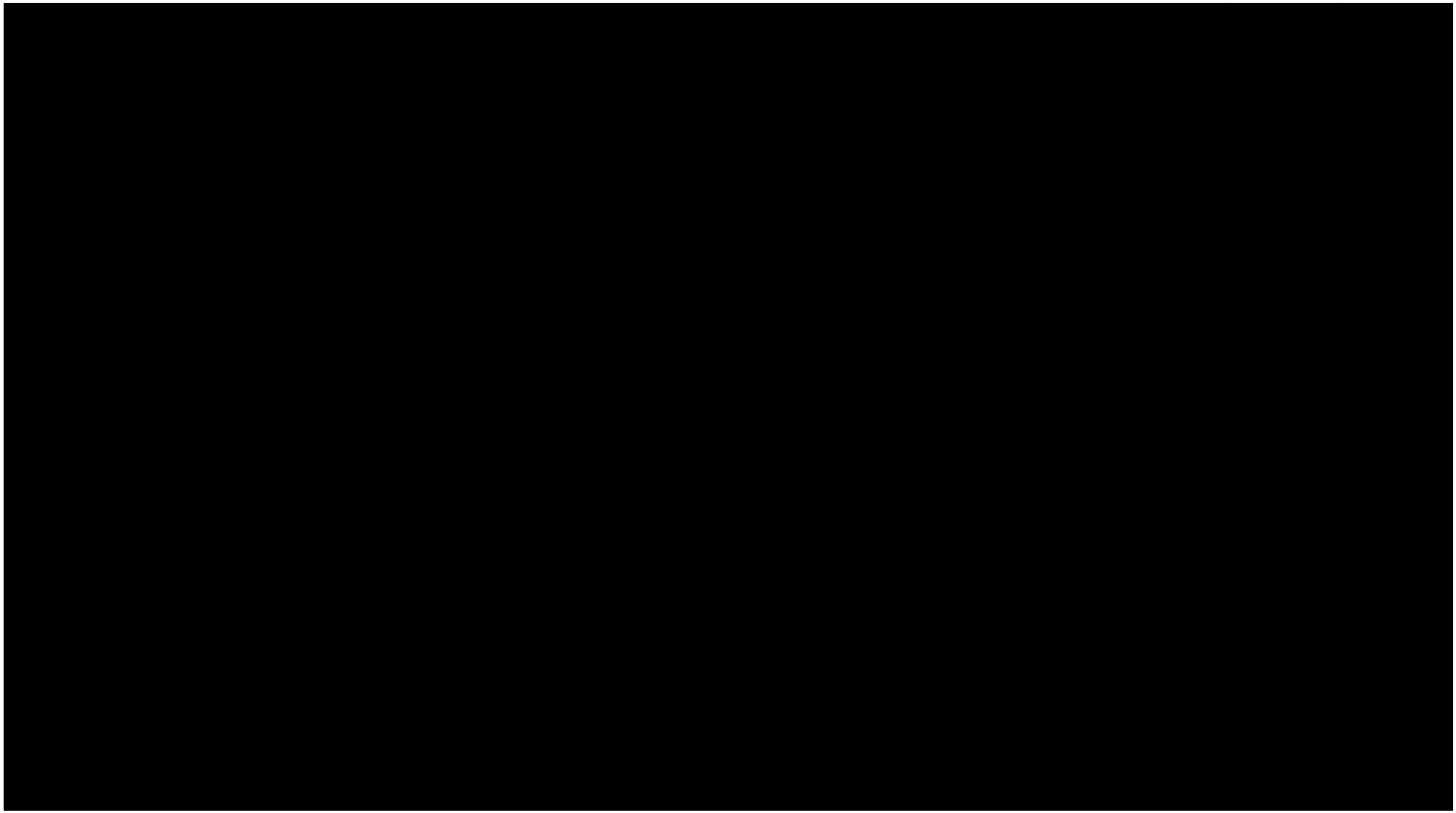
Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range

[redacted]

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



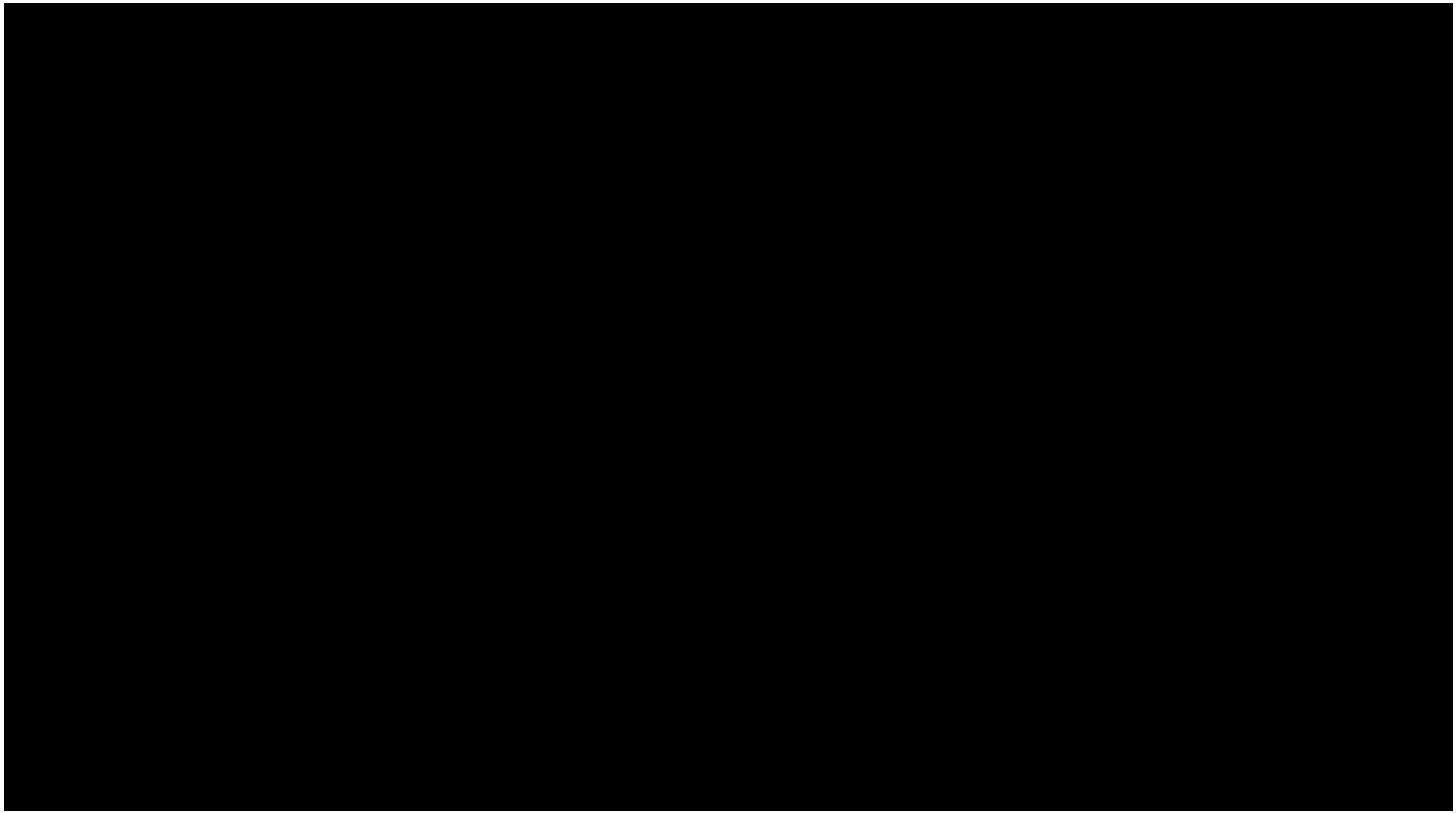
Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range

[redacted]

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

[redacted]

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

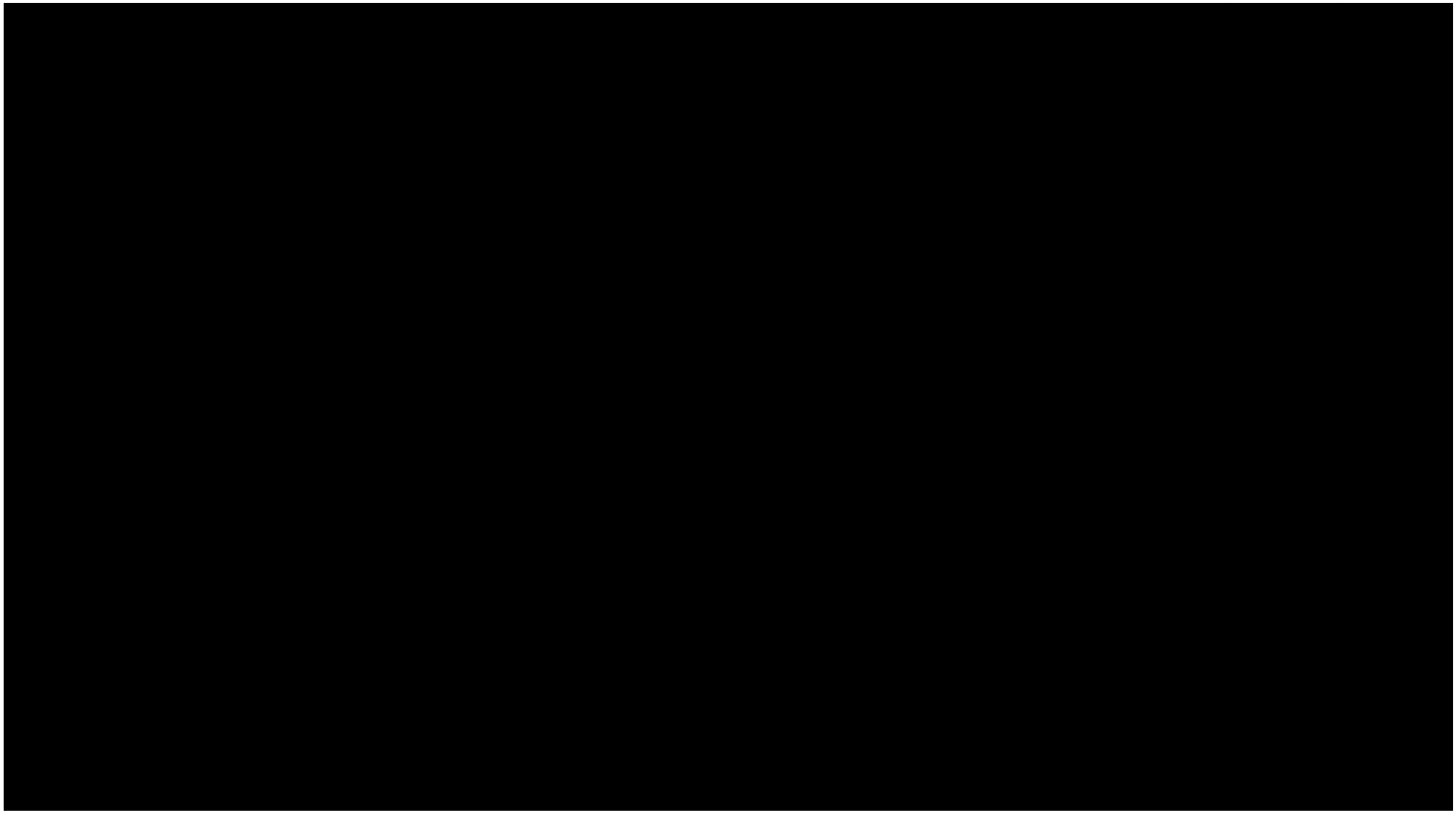
[redacted]

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
[redacted]									

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

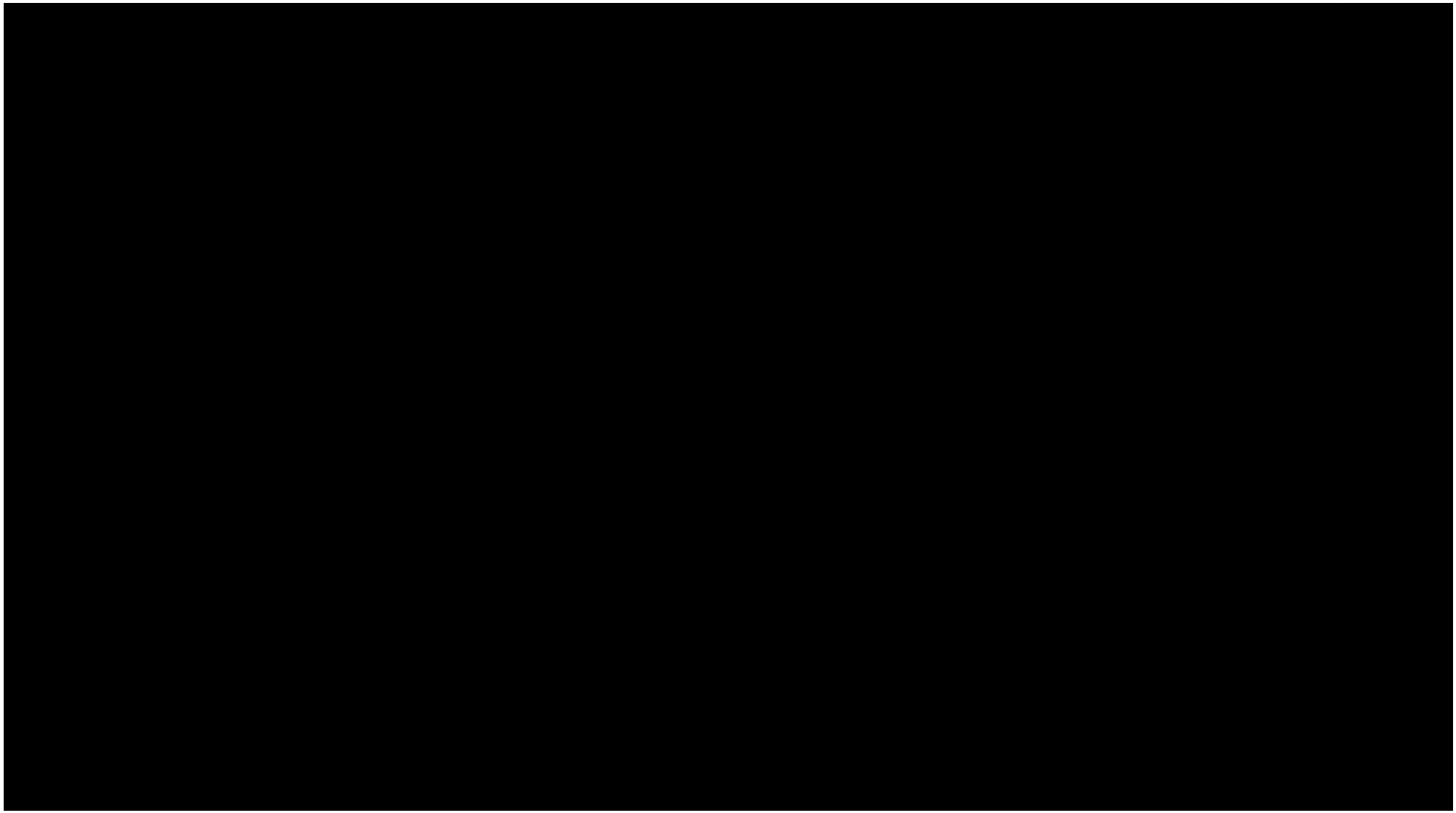


Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
[redacted]									

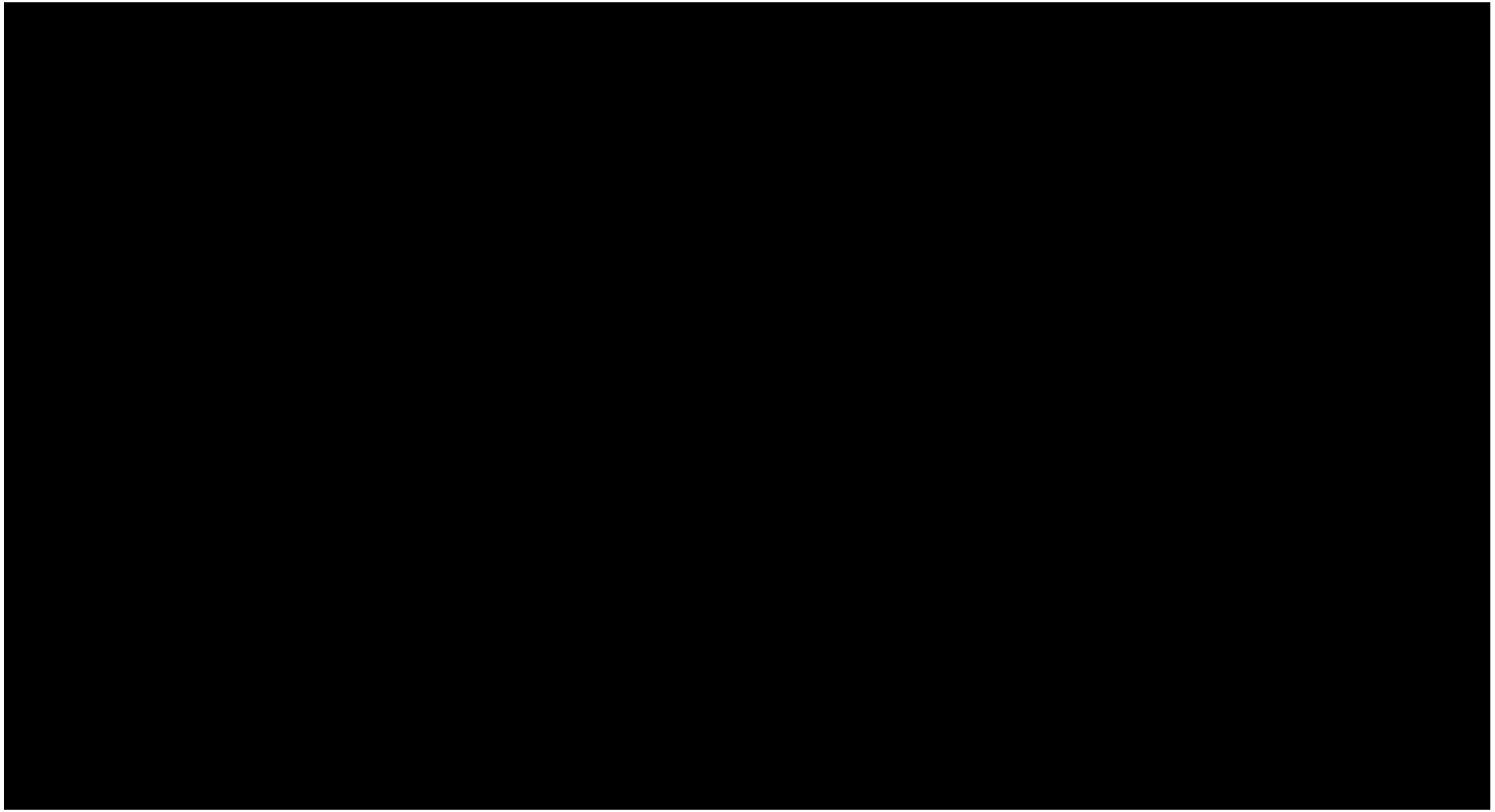
Biochemistry laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



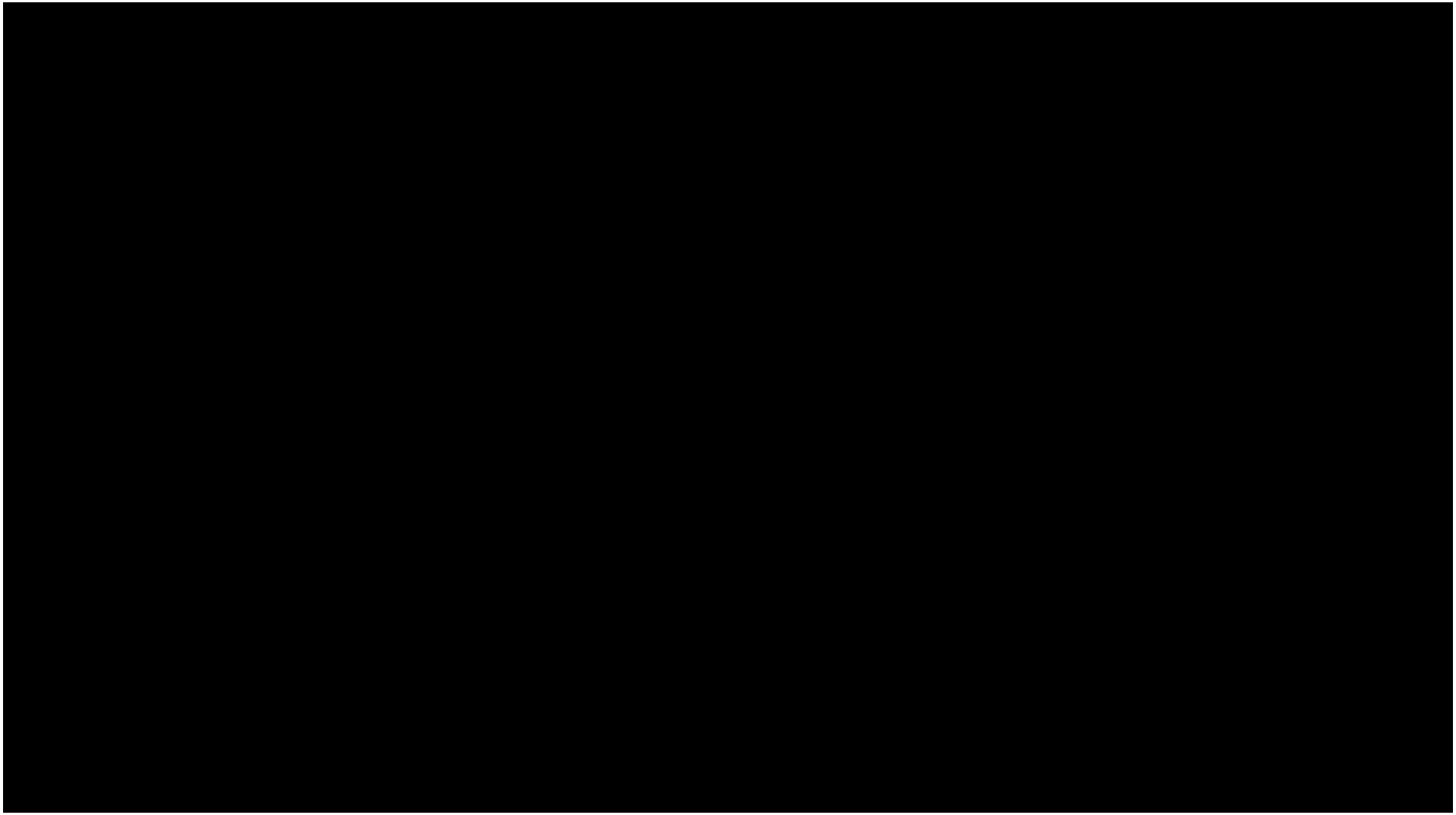
14.3.4.2 Haematology laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



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



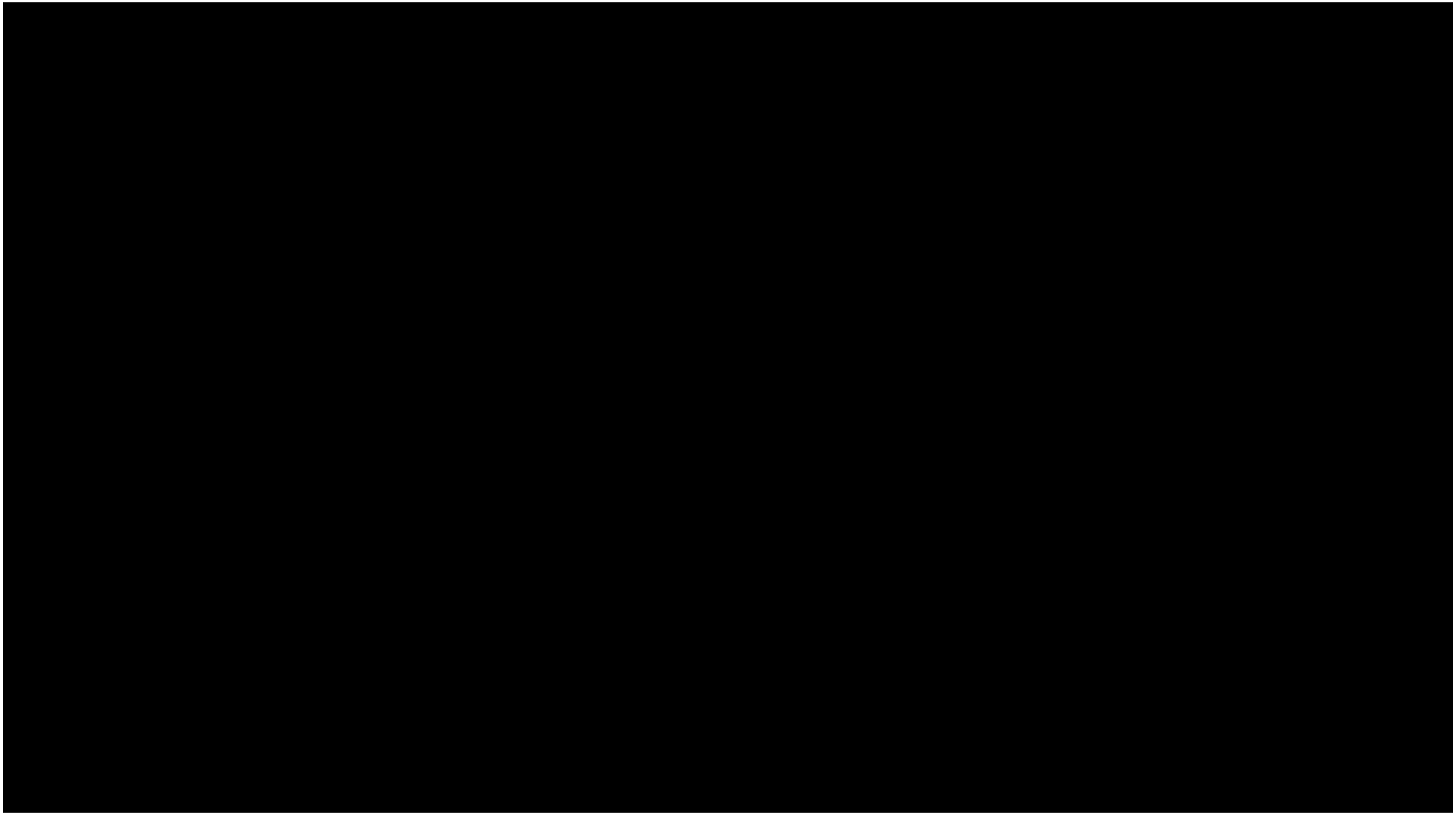
Haematology laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range

[redacted]

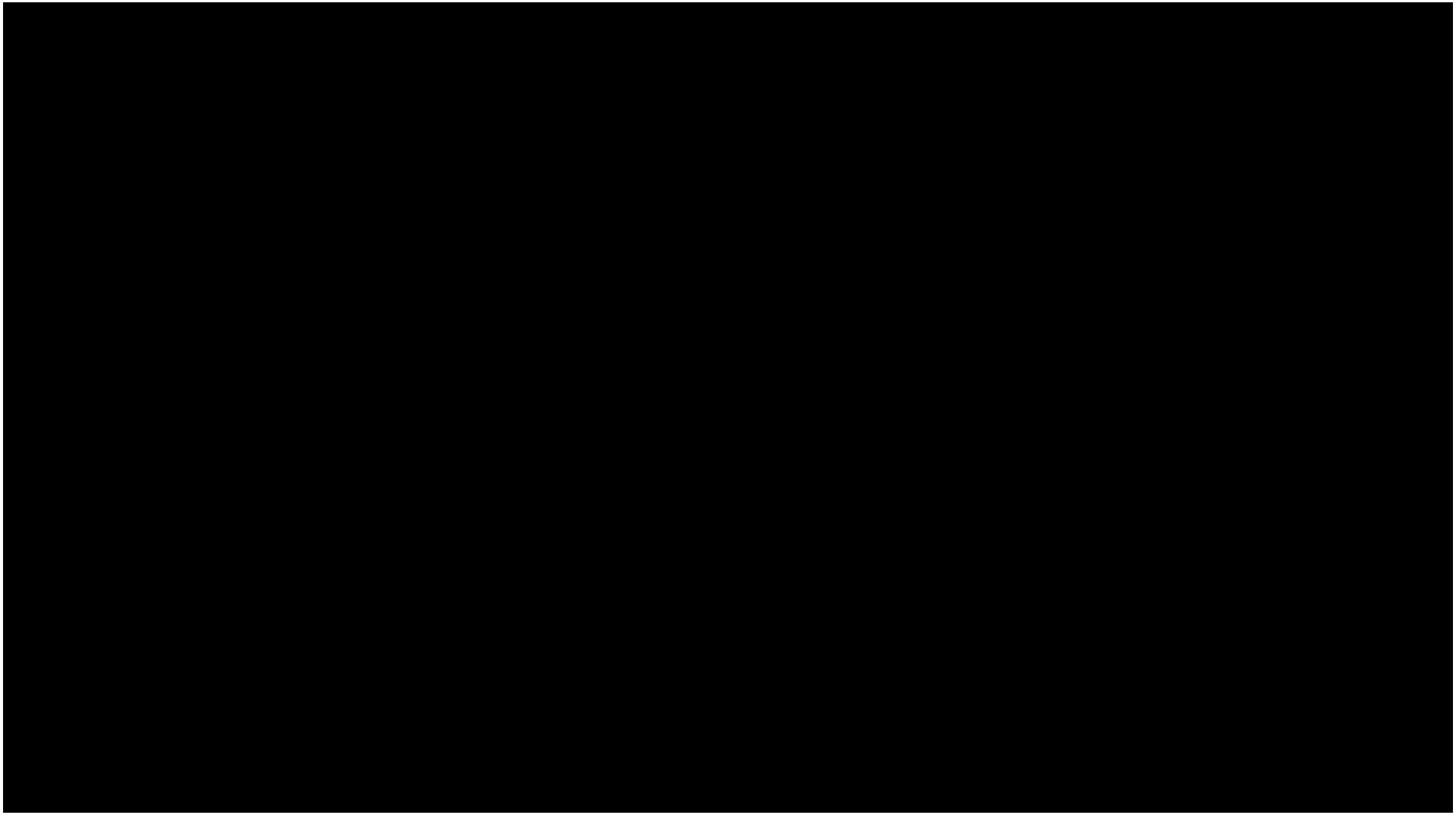
Haematology laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



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



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

[redacted]

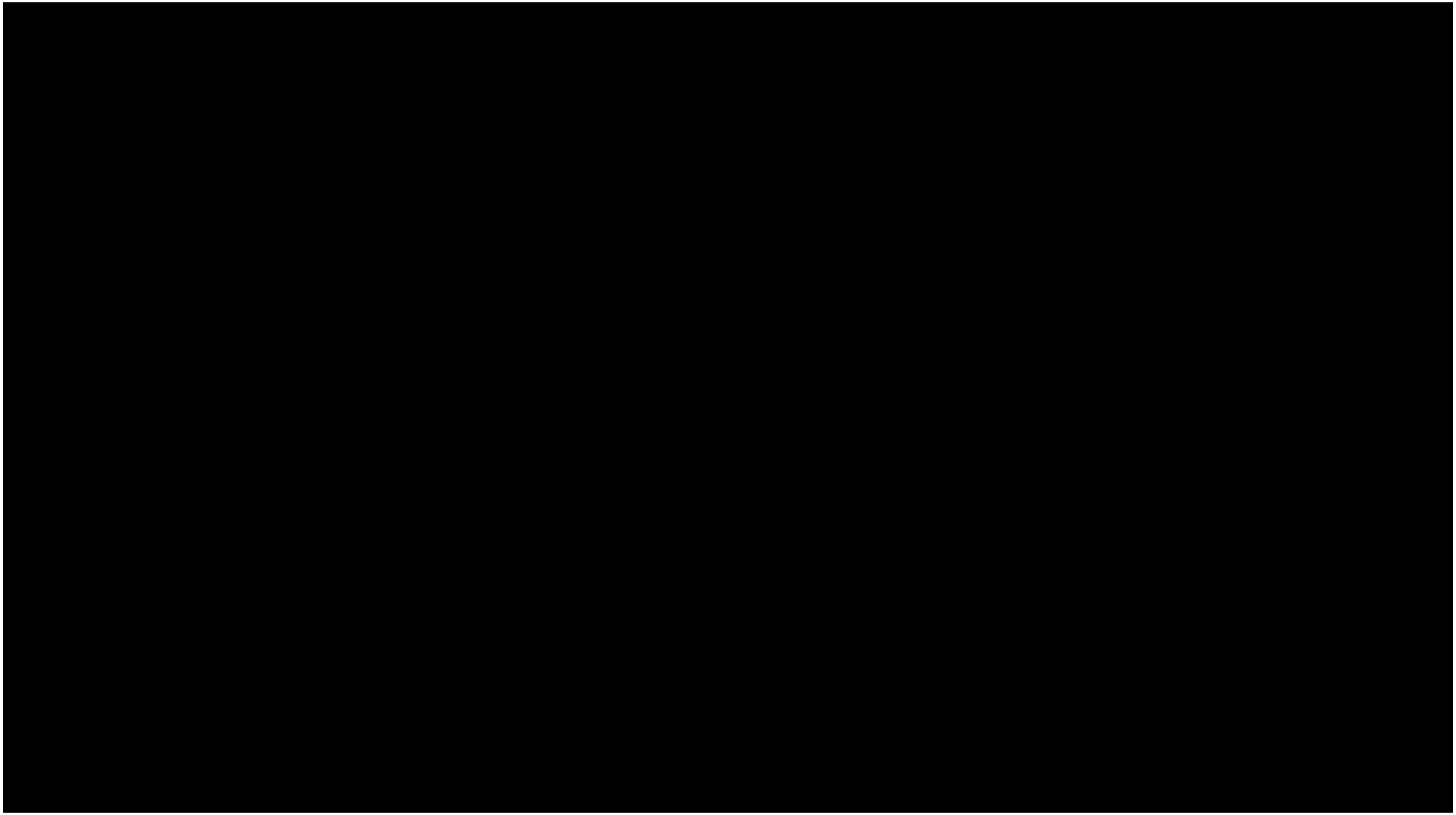
Haematology laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range

[redacted]

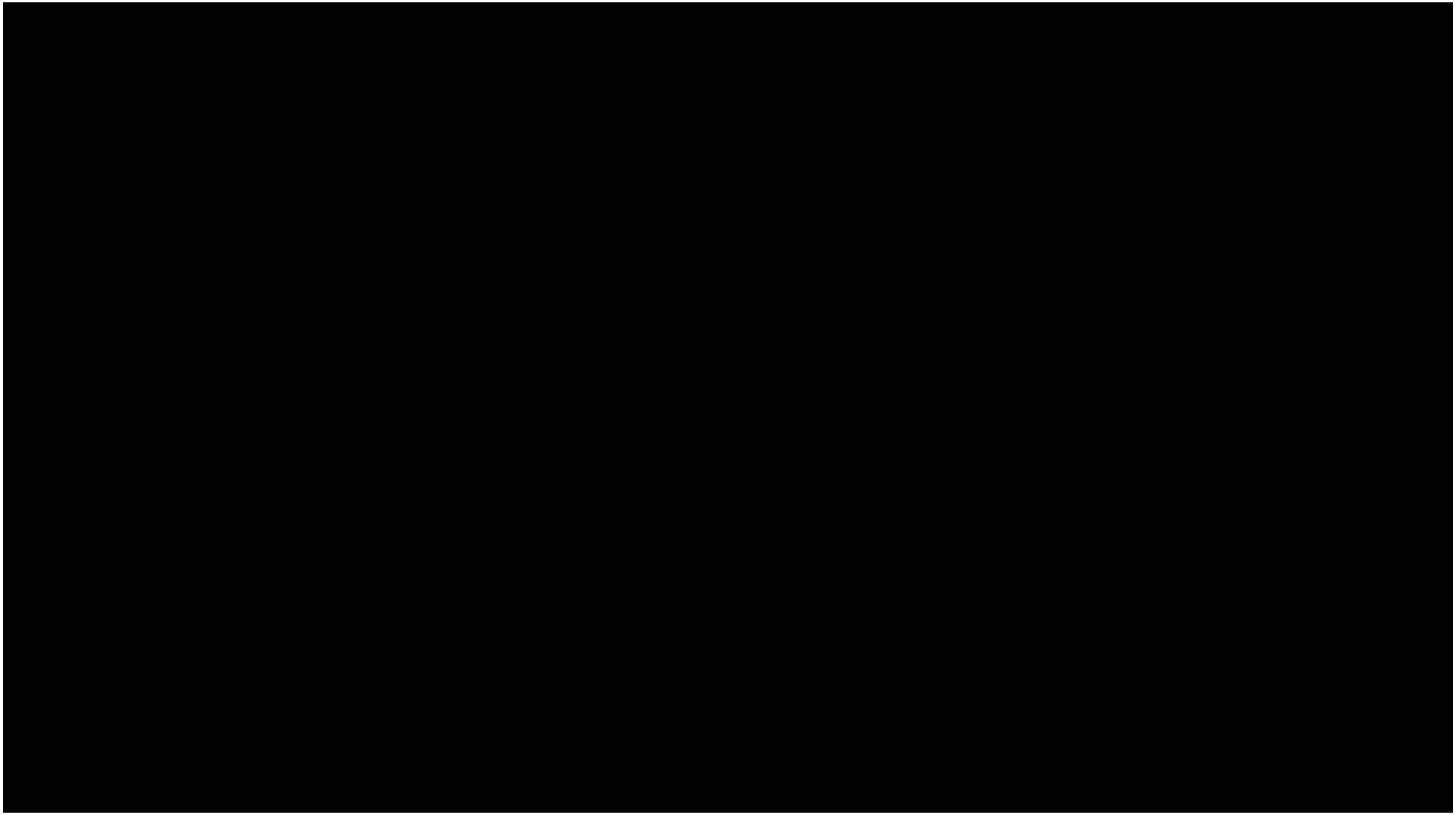
Haematology laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



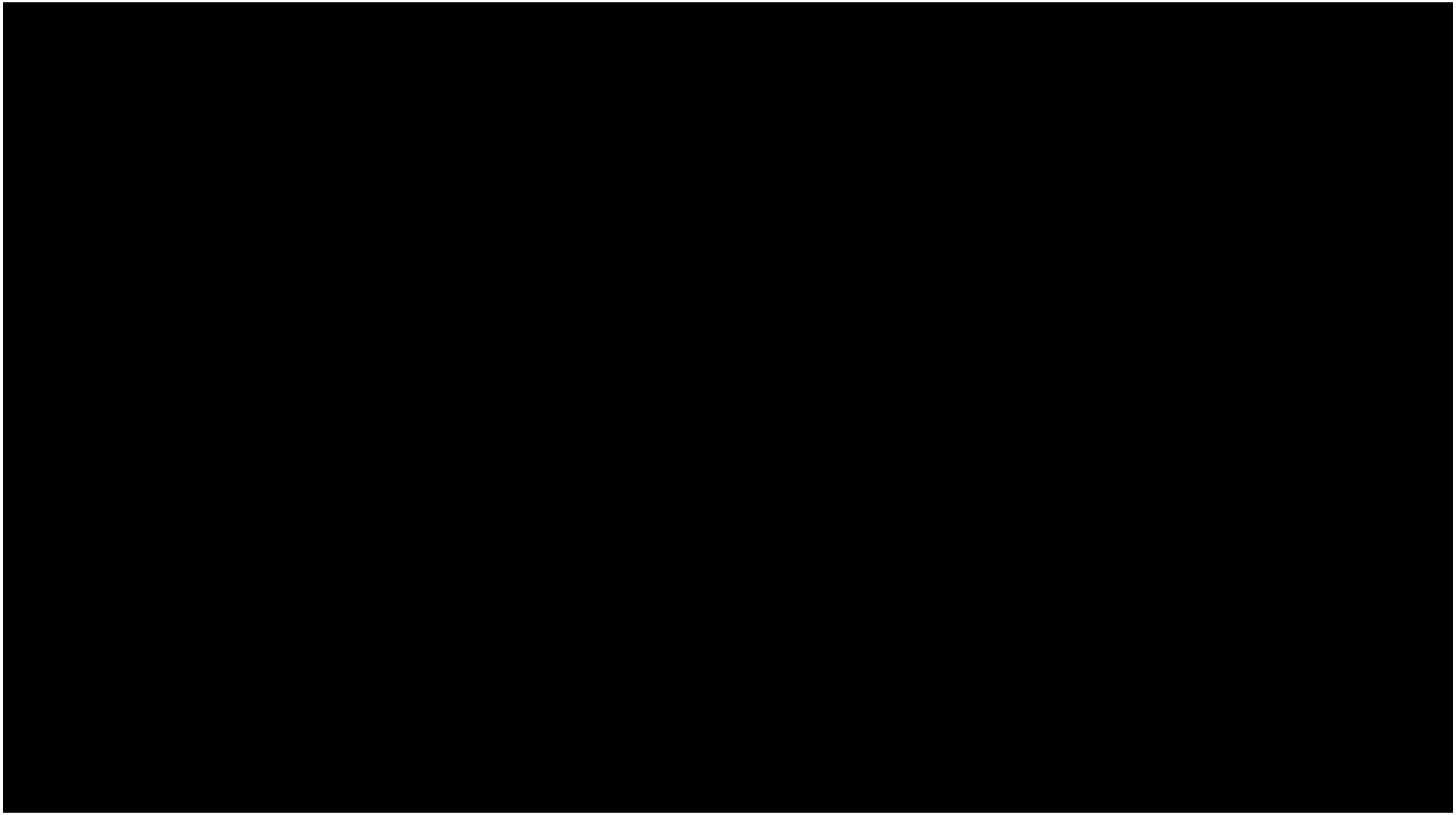
Haematology laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



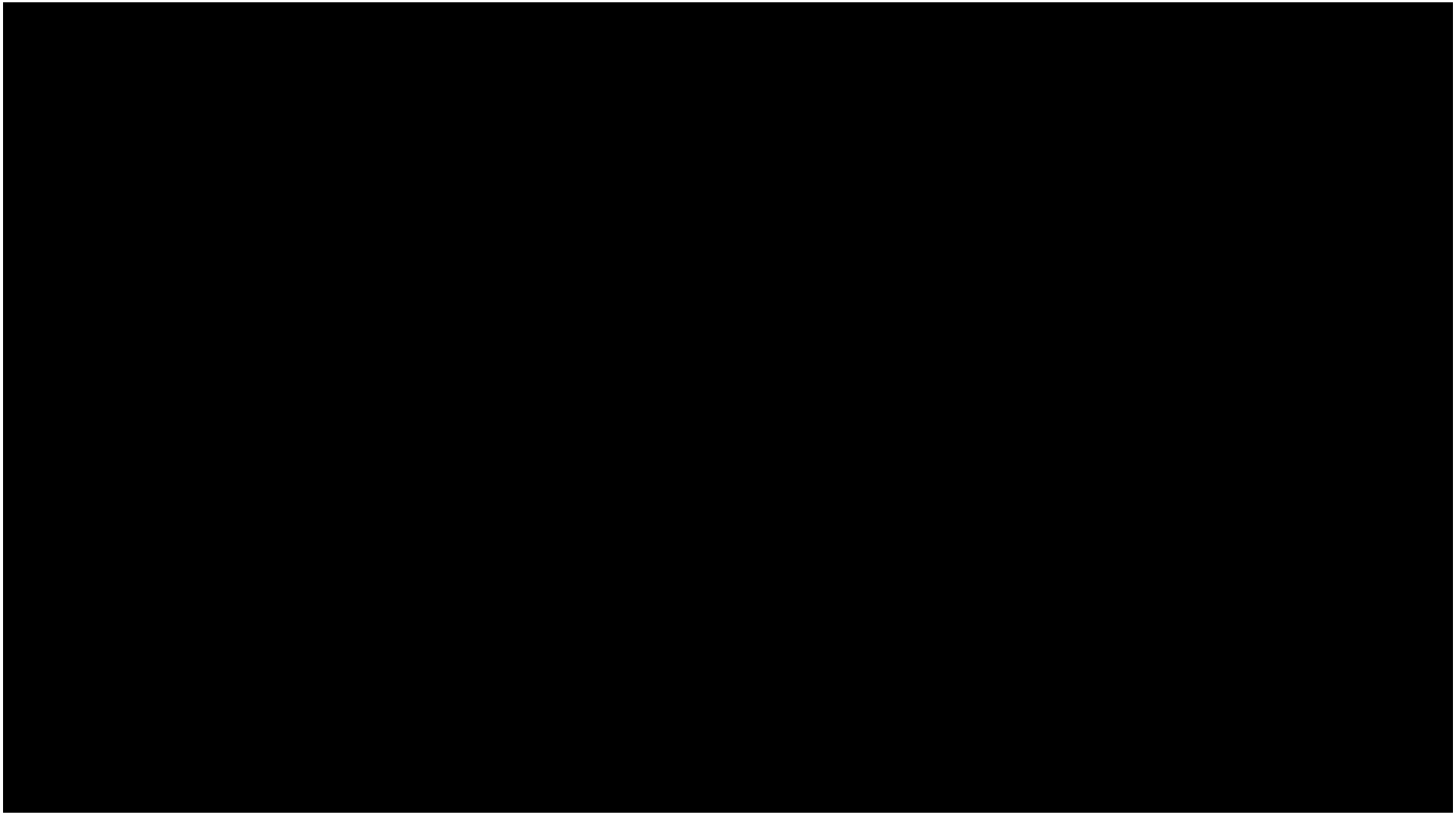
Haematology laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range



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



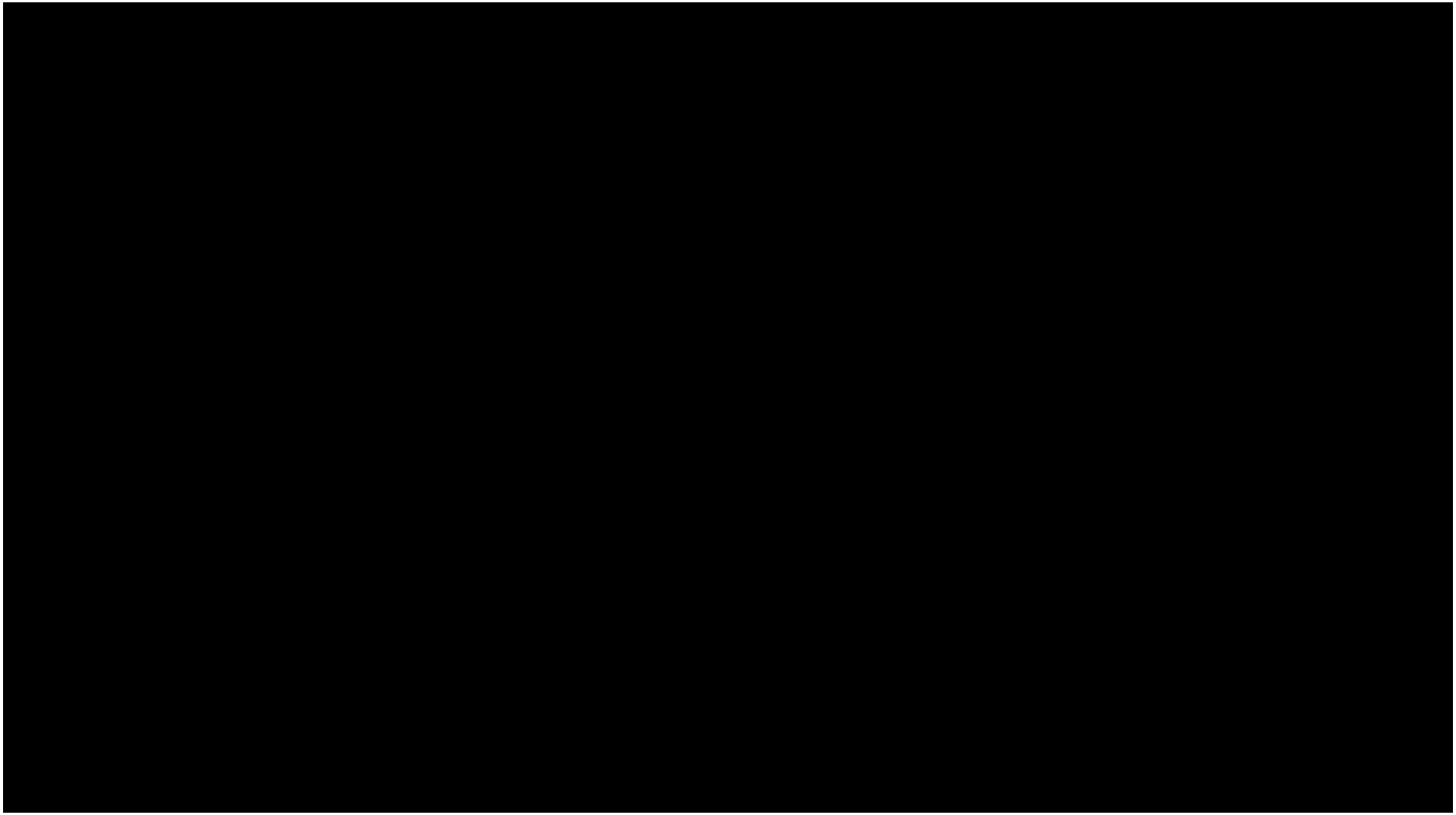
Haematology laboratory test results outside reference range - safety analysis set

Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range

[redacted]

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

[redacted]

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

Lipids laboratory test results outside reference range - safety analysis set

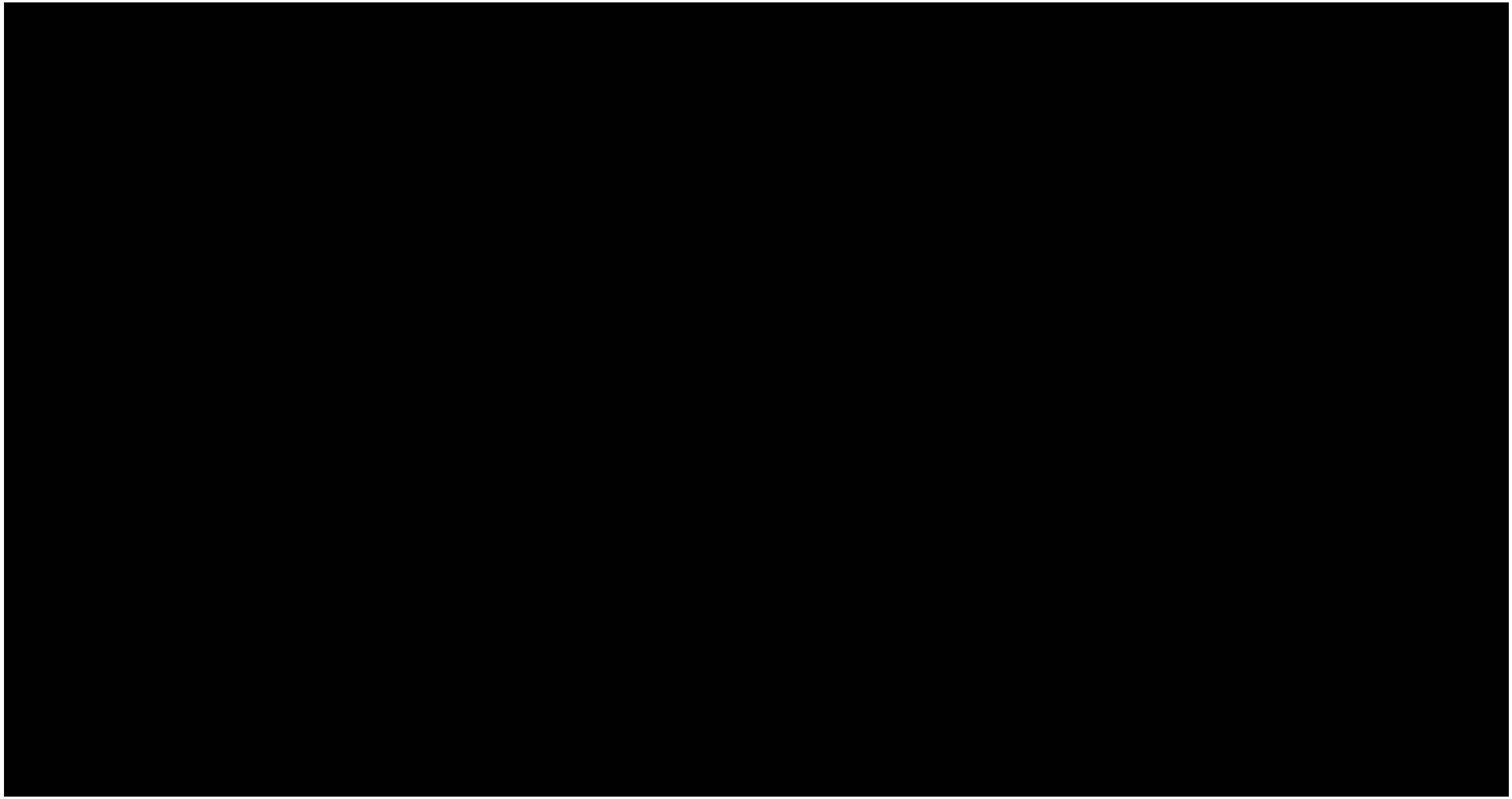
Subject ID	Treatment	Age/Sex/BMI	Visit	Parameter	Value	Unit	Flag	Minimum Range	Maximum Range
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

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
[redacted]									

14.3.5 Laboratory value displays

14.3.5.1 Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
ALAT(U/L)			
Visit 1			
N	180	178	358
Mean (SD)	16 (7)	17 (8)	16 (7)
Median	14	15	15
Min ; Max	7 ; 68	6 ; 66	6 ; 68
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	16 (7)	16 (9)	16 (8)
Median	14	14	14
Min ; Max	7 ; 81	7 ; 110	7 ; 110
Visit 18 (Week 16)			
N	171	163	334
Mean (SD)	15 (5)	16 (10)	16 (8)
Median	14	14	14
Min ; Max	5 ; 45	5 ; 92	5 ; 92
End of trial visit			
N	181	179	360
Mean (SD)	15 (6)	17 (10)	16 (8)
Median	15	14	14
Min ; Max	5 ; 45	5 ; 92	5 ; 92

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Albumin Serum(g/dL)			
Visit 1			
N	180	179	359
Mean (SD)	4.6 (0.2)	4.6 (0.3)	4.6 (0.3)
Median	4.6	4.6	4.6
Min ; Max	3.9 ; 5.2	3.6 ; 5.2	3.6 ; 5.2
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	4.5 (0.3)	4.5 (0.3)	4.5 (0.3)
Median	4.5	4.5	4.5
Min ; Max	3.8 ; 5.2	3.8 ; 5.3	3.8 ; 5.3
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	4.5 (0.2)	4.5 (0.3)	4.5 (0.2)
Median	4.5	4.5	4.5
Min ; Max	3.7 ; 5.2	3.8 ; 5.1	3.7 ; 5.2
End of trial visit			
N	181	179	360
Mean (SD)	4.5 (0.2)	4.5 (0.3)	4.5 (0.2)
Median	4.5	4.5	4.5
Min ; Max	3.6 ; 5.2	3.8 ; 5.1	3.6 ; 5.2

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Alkaline Phosphatase(U/L)			
Visit 1			
N	180	179	359
Mean (SD)	227.6 (99.6)	211.6 (92.1)	219.6 (96.1)
Median	227.0	220.0	224.0
Min ; Max	34.0 ; 668.0	49.0 ; 603.0	34.0 ; 668.0
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	225.6 (112.4)	205.9 (88.9)	215.8 (101.8)
Median	219.5	213.0	214.0
Min ; Max	35.0 ; 973.0	37.0 ; 501.0	35.0 ; 973.0
Visit 18 (Week 16)			
N	170	165	335
Mean (SD)	228.1 (104.4)	204.4 (89.5)	216.4 (97.9)
Median	225.5	205.0	217.0
Min ; Max	37.0 ; 648.0	49.0 ; 520.0	37.0 ; 648.0
End of trial visit			
N	181	179	360
Mean (SD)	228.2 (104.5)	205.2 (88.6)	216.8 (97.4)
Median	227.0	205.0	217.5
Min ; Max	37.0 ; 648.0	49.0 ; 520.0	37.0 ; 648.0

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
SGOT(U/L)			
Visit 1			
N	179	178	357
Mean (SD)	21.93 (8.98)	23.18 (11.41)	22.55 (10.27)
Median	21.00	21.00	21.00
Min ; Max	9.00 ; 111.00	10.00 ; 110.00	9.00 ; 111.00
Visit 14 (Week 12)			
N	171	168	339
Mean (SD)	21.91 (7.34)	21.49 (7.35)	21.70 (7.34)
Median	21.00	20.00	21.00
Min ; Max	10.00 ; 77.00	11.00 ; 54.00	10.00 ; 77.00
Visit 18 (Week 16)			
N	170	163	333
Mean (SD)	21.39 (5.86)	21.81 (8.14)	21.60 (7.06)
Median	21.00	20.00	20.00
Min ; Max	11.00 ; 55.00	10.00 ; 65.00	10.00 ; 65.00
End of trial visit			
N	181	179	360
Mean (SD)	21.49 (5.85)	21.84 (7.98)	21.66 (6.98)
Median	21.00	20.00	21.00
Min ; Max	11.00 ; 55.00	10.00 ; 65.00	10.00 ; 65.00

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Creatinine(umol/L)			
Visit 1			
N	180	178	358
Mean (SD)	52.34 (14.46)	51.10 (14.79)	51.72 (14.62)
Median	50.00	50.00	50.00
Min ; Max	22.00 ; 111.00	24.00 ; 111.00	22.00 ; 111.00
Visit 14 (Week 12)			
N	173	169	342
Mean (SD)	53.09 (15.90)	51.38 (14.87)	52.24 (15.40)
Median	50.00	50.00	50.00
Min ; Max	20.00 ; 107.00	22.00 ; 95.00	20.00 ; 107.00
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	53.57 (15.57)	52.23 (16.43)	52.91 (15.99)
Median	51.50	50.00	50.00
Min ; Max	23.00 ; 110.00	22.00 ; 111.00	22.00 ; 111.00
End of trial visit			
N	181	178	359
Mean (SD)	53.75 (17.11)	51.95 (16.42)	52.86 (16.77)
Median	52.00	49.00	50.00
Min ; Max	23.00 ; 149.00	22.00 ; 111.00	22.00 ; 149.00

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Creatinine(mg/dL)			
Visit 1			
N	180	178	358
Mean (SD)	0.59 (0.16)	0.58 (0.17)	0.59 (0.17)
Median	0.57	0.57	0.57
Min ; Max	0.25 ; 1.26	0.27 ; 1.26	0.25 ; 1.26
Visit 14 (Week 12)			
N	173	169	342
Mean (SD)	0.60 (0.18)	0.58 (0.17)	0.59 (0.17)
Median	0.57	0.57	0.57
Min ; Max	0.23 ; 1.21	0.25 ; 1.07	0.23 ; 1.21
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	0.61 (0.18)	0.59 (0.19)	0.60 (0.18)
Median	0.58	0.57	0.57
Min ; Max	0.26 ; 1.24	0.25 ; 1.26	0.25 ; 1.26
End of trial visit			
N	181	178	359
Mean (SD)	0.61 (0.19)	0.59 (0.19)	0.60 (0.19)
Median	0.59	0.55	0.57
Min ; Max	0.26 ; 1.69	0.25 ; 1.26	0.25 ; 1.69

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Potassium(mmol/L)			
Visit 1			
N	180	178	358
Mean (SD)	4.54 (0.44)	4.56 (0.38)	4.55 (0.41)
Median	4.50	4.55	4.50
Min ; Max	3.30 ; 7.00	3.50 ; 6.00	3.30 ; 7.00
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	4.58 (0.37)	4.55 (0.40)	4.57 (0.39)
Median	4.60	4.50	4.50
Min ; Max	3.60 ; 5.90	3.70 ; 7.00	3.60 ; 7.00
Visit 18 (Week 16)			
N	170	164	334
Mean (SD)	4.56 (0.35)	4.55 (0.44)	4.55 (0.40)
Median	4.55	4.50	4.50
Min ; Max	3.80 ; 5.50	3.40 ; 7.00	3.40 ; 7.00
End of trial visit			
N	181	179	360
Mean (SD)	4.56 (0.35)	4.55 (0.43)	4.56 (0.39)
Median	4.60	4.50	4.50
Min ; Max	3.80 ; 5.50	3.40 ; 7.00	3.40 ; 7.00

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Potassium(mEq/L)			
Visit 1			
N	180	178	358
Mean (SD)	4.54 (0.44)	4.56 (0.38)	4.55 (0.41)
Median	4.50	4.55	4.50
Min ; Max	3.30 ; 7.00	3.50 ; 6.00	3.30 ; 7.00
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	4.58 (0.37)	4.55 (0.40)	4.57 (0.39)
Median	4.60	4.50	4.50
Min ; Max	3.60 ; 5.90	3.70 ; 7.00	3.60 ; 7.00
Visit 18 (Week 16)			
N	170	164	334
Mean (SD)	4.56 (0.35)	4.55 (0.44)	4.55 (0.40)
Median	4.55	4.50	4.50
Min ; Max	3.80 ; 5.50	3.40 ; 7.00	3.40 ; 7.00
End of trial visit			
N	181	179	360
Mean (SD)	4.56 (0.35)	4.55 (0.43)	4.56 (0.39)
Median	4.60	4.50	4.50
Min ; Max	3.80 ; 5.50	3.40 ; 7.00	3.40 ; 7.00

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Sodium(mmol/L)			
Visit 1			
N	180	179	359
Mean (SD)	140.89 (3.24)	140.93 (2.84)	140.91 (3.04)
Median	141.00	141.00	141.00
Min ; Max	132.00 ; 154.00	133.00 ; 151.00	132.00 ; 154.00
Visit 14 (Week 12)			
N	173	169	342
Mean (SD)	139.97 (2.72)	140.30 (3.31)	140.13 (3.02)
Median	140.00	140.00	140.00
Min ; Max	131.00 ; 147.00	131.00 ; 163.00	131.00 ; 163.00
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	140.32 (2.63)	140.77 (3.42)	140.54 (3.05)
Median	140.00	140.00	140.00
Min ; Max	132.00 ; 147.00	132.00 ; 163.00	132.00 ; 163.00
End of trial visit			
N	181	179	360
Mean (SD)	140.34 (2.64)	140.60 (3.48)	140.47 (3.08)
Median	140.00	140.00	140.00
Min ; Max	132.00 ; 147.00	132.00 ; 163.00	132.00 ; 163.00

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Sodium(mEq/L)			
Visit 1			
N	180	179	359
Mean (SD)	140.89 (3.24)	140.93 (2.84)	140.91 (3.04)
Median	141.00	141.00	141.00
Min ; Max	132.00 ; 154.00	133.00 ; 151.00	132.00 ; 154.00
Visit 14 (Week 12)			
N	173	169	342
Mean (SD)	139.97 (2.72)	140.30 (3.31)	140.13 (3.02)
Median	140.00	140.00	140.00
Min ; Max	131.00 ; 147.00	131.00 ; 163.00	131.00 ; 163.00
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	140.32 (2.63)	140.77 (3.42)	140.54 (3.05)
Median	140.00	140.00	140.00
Min ; Max	132.00 ; 147.00	132.00 ; 163.00	132.00 ; 163.00
End of trial visit			
N	181	179	360
Mean (SD)	140.34 (2.64)	140.60 (3.48)	140.47 (3.08)
Median	140.00	140.00	140.00
Min ; Max	132.00 ; 147.00	132.00 ; 163.00	132.00 ; 163.00

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Total Bilirubin(umol/L)			
Visit 1			
N	179	179	358
Mean (SD)	6.18 (4.13)	6.61 (4.93)	6.39 (4.55)
Median	5.00	5.00	5.00
Min ; Max	2.00 ; 27.00	2.00 ; 32.00	2.00 ; 32.00
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	7.11 (5.65)	7.47 (5.51)	7.29 (5.58)
Median	5.00	5.00	5.00
Min ; Max	2.00 ; 39.00	2.00 ; 38.00	2.00 ; 39.00
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	7.00 (5.47)	7.18 (5.66)	7.09 (5.56)
Median	5.00	5.00	5.00
Min ; Max	2.00 ; 43.00	2.00 ; 41.00	2.00 ; 43.00
End of trial visit			
N	181	179	360
Mean (SD)	6.89 (5.40)	7.01 (5.49)	6.95 (5.44)
Median	5.00	5.00	5.00
Min ; Max	2.00 ; 43.00	2.00 ; 41.00	2.00 ; 43.00

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Total Bilirubin(mg/dL)			
Visit 1			
N	179	179	358
Mean (SD)	0.36 (0.24)	0.39 (0.29)	0.37 (0.27)
Median	0.29	0.29	0.29
Min ; Max	0.12 ; 1.58	0.12 ; 1.87	0.12 ; 1.87
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	0.42 (0.33)	0.44 (0.32)	0.43 (0.33)
Median	0.29	0.29	0.29
Min ; Max	0.12 ; 2.28	0.12 ; 2.22	0.12 ; 2.28
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	0.41 (0.32)	0.42 (0.33)	0.41 (0.32)
Median	0.29	0.29	0.29
Min ; Max	0.12 ; 2.51	0.12 ; 2.40	0.12 ; 2.51
End of trial visit			
N	181	179	360
Mean (SD)	0.40 (0.32)	0.41 (0.32)	0.41 (0.32)
Median	0.29	0.29	0.29
Min ; Max	0.12 ; 2.51	0.12 ; 2.40	0.12 ; 2.51

N: Number of subjects, SD: Standard deviation
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

14.3.5.2 Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Ch ALAT(U/L)			
Visit 14 (Week 12)			
N	170	168	338
Mean (SD)	0.3 (7.8)	-0.7 (7.3)	-0.2 (7.6)
Median	0.0	0.0	0.0
Min ; Max	-50.0 ; 45.0	-48.0 ; 46.0	-50.0 ; 46.0
Visit 18 (Week 16)			
N	170	162	332
Mean (SD)	-0.1 (6.9)	-0.2 (9.3)	-0.2 (8.1)
Median	0.0	0.0	0.0
Min ; Max	-48.0 ; 20.0	-53.0 ; 77.0	-53.0 ; 77.0
End of trial visit			
N	180	178	358
Mean (SD)	-0.2 (6.9)	-0.1 (9.1)	-0.2 (8.0)
Median	0.0	0.0	0.0
Min ; Max	-48.0 ; 20.0	-53.0 ; 77.0	-53.0 ; 77.0

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Albumin Serum(g/dL)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	-0.1 (0.3)	-0.1 (0.3)	-0.1 (0.3)
Median	-0.1	-0.1	-0.1
Min ; Max	-0.7 ; 0.8	-0.8 ; 0.9	-0.8 ; 0.9
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	-0.0 (0.3)	-0.1 (0.3)	-0.0 (0.3)
Median	-0.1	0.0	-0.1
Min ; Max	-0.9 ; 0.7	-0.7 ; 0.7	-0.9 ; 0.7
End of trial visit			
N	180	179	359
Mean (SD)	-0.1 (0.3)	-0.1 (0.3)	-0.1 (0.3)
Median	-0.1	0.0	-0.1
Min ; Max	-1.2 ; 0.7	-0.7 ; 0.7	-1.2 ; 0.7

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Alkaline Phosphat(U/L)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	-0.9 (78.4)	-6.1 (38.4)	-3.5 (61.8)
Median	-2.0	-5.0	-3.0
Min ; Max	-464.0 ; 777.0	-153.0 ; 109.0	-464.0 ; 777.0
Visit 18 (Week 16)			
N	169	165	334
Mean (SD)	0.9 (64.7)	-6.6 (41.7)	-2.8 (54.6)
Median	-1.0	-7.0	-3.0
Min ; Max	-437.0 ; 452.0	-195.0 ; 152.0	-437.0 ; 452.0
End of trial visit			
N	180	179	359
Mean (SD)	0.1 (64.2)	-6.4 (40.2)	-3.1 (53.6)
Median	-0.5	-6.0	-3.0
Min ; Max	-437.0 ; 452.0	-195.0 ; 152.0	-437.0 ; 452.0

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch SGOT(U/L)			
Visit 14 (Week 12)			
N	169	167	336
Mean (SD)	-0.02 (9.41)	-1.77 (9.10)	-0.89 (9.28)
Median	0.00	0.00	0.00
Min ; Max	-91.00 ; 35.00	-88.00 ; 10.00	-91.00 ; 35.00
Visit 18 (Week 16)			
N	168	162	330
Mean (SD)	-0.38 (8.64)	-1.41 (9.75)	-0.88 (9.20)
Median	0.00	-1.00	0.00
Min ; Max	-93.00 ; 15.00	-93.00 ; 21.00	-93.00 ; 21.00
End of trial visit			
N	179	178	357
Mean (SD)	-0.46 (8.44)	-1.34 (9.53)	-0.90 (8.99)
Median	0.00	-0.50	0.00
Min ; Max	-93.00 ; 15.00	-93.00 ; 21.00	-93.00 ; 21.00

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Creatinine(umol/L)			
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	0.66 (8.45)	0.21 (7.95)	0.44 (8.20)
Median	0.00	0.00	0.00
Min ; Max	-29.00 ; 44.00	-32.00 ; 34.00	-32.00 ; 44.00
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	0.95 (10.08)	1.17 (9.64)	1.06 (9.85)
Median	0.00	0.00	0.00
Min ; Max	-52.00 ; 59.00	-39.00 ; 46.00	-52.00 ; 59.00
End of trial visit			
N	180	178	358
Mean (SD)	1.51 (12.41)	0.85 (9.60)	1.18 (11.09)
Median	0.00	0.00	0.00
Min ; Max	-52.00 ; 102.00	-39.00 ; 46.00	-52.00 ; 102.00

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Creatinine(mg/dL)			
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	0.01 (0.10)	0.00 (0.09)	0.00 (0.09)
Median	0.00	0.00	0.00
Min ; Max	-0.33 ; 0.50	-0.36 ; 0.38	-0.36 ; 0.50
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	0.01 (0.11)	0.01 (0.11)	0.01 (0.11)
Median	0.00	0.00	0.00
Min ; Max	-0.59 ; 0.67	-0.44 ; 0.52	-0.59 ; 0.67
End of trial visit			
N	180	178	358
Mean (SD)	0.02 (0.14)	0.01 (0.11)	0.01 (0.13)
Median	0.00	0.00	0.00
Min ; Max	-0.59 ; 1.15	-0.44 ; 0.52	-0.59 ; 1.15

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Potassium(mmol/L)			
Visit 14 (Week 12)			
N	171	168	339
Mean (SD)	0.03 (0.49)	-0.02 (0.48)	0.01 (0.48)
Median	0.00	0.00	0.00
Min ; Max	-2.40 ; 1.60	-1.80 ; 2.00	-2.40 ; 2.00
Visit 18 (Week 16)			
N	169	163	332
Mean (SD)	0.01 (0.50)	-0.02 (0.51)	-0.00 (0.51)
Median	0.00	0.00	0.00
Min ; Max	-2.60 ; 1.40	-1.90 ; 2.20	-2.60 ; 2.20
End of trial visit			
N	180	178	358
Mean (SD)	0.02 (0.50)	-0.01 (0.50)	0.01 (0.50)
Median	0.00	0.00	0.00
Min ; Max	-2.60 ; 1.40	-1.90 ; 2.20	-2.60 ; 2.20

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch. Potassium(mEq/L)			
Visit 14 (Week 12)			
N	171	168	339
Mean (SD)	0.03 (0.49)	-0.02 (0.48)	0.01 (0.48)
Median	0.00	0.00	0.00
Min ; Max	-2.40 ; 1.60	-1.80 ; 2.00	-2.40 ; 2.00
Visit 18 (Week 16)			
N	169	163	332
Mean (SD)	0.01 (0.50)	-0.02 (0.51)	-0.00 (0.51)
Median	0.00	0.00	0.00
Min ; Max	-2.60 ; 1.40	-1.90 ; 2.20	-2.60 ; 2.20
End of trial visit			
N	180	178	358
Mean (SD)	0.02 (0.50)	-0.01 (0.50)	0.01 (0.50)
Median	0.00	0.00	0.00
Min ; Max	-2.60 ; 1.40	-1.90 ; 2.20	-2.60 ; 2.20

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Sodium(mmol/L)			
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	-0.95 (3.69)	-0.75 (4.10)	-0.85 (3.89)
Median	-1.00	-1.00	-1.00
Min ; Max	-14.00 ; 12.00	-11.00 ; 27.00	-14.00 ; 27.00
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	-0.59 (3.71)	-0.27 (3.90)	-0.43 (3.80)
Median	-1.00	-1.00	-1.00
Min ; Max	-17.00 ; 9.00	-8.00 ; 27.00	-17.00 ; 27.00
End of trial visit			
N	180	179	359
Mean (SD)	-0.56 (3.63)	-0.32 (3.83)	-0.44 (3.73)
Median	0.00	-1.00	-1.00
Min ; Max	-17.00 ; 9.00	-8.00 ; 27.00	-17.00 ; 27.00

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Sodium(mEq/L)			
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	-0.95 (3.69)	-0.75 (4.10)	-0.85 (3.89)
Median	-1.00	-1.00	-1.00
Min ; Max	-14.00 ; 12.00	-11.00 ; 27.00	-14.00 ; 27.00
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	-0.59 (3.71)	-0.27 (3.90)	-0.43 (3.80)
Median	-1.00	-1.00	-1.00
Min ; Max	-17.00 ; 9.00	-8.00 ; 27.00	-17.00 ; 27.00
End of trial visit			
N	180	179	359
Mean (SD)	-0.56 (3.63)	-0.32 (3.83)	-0.44 (3.73)
Median	0.00	-1.00	-1.00
Min ; Max	-17.00 ; 9.00	-8.00 ; 27.00	-17.00 ; 27.00

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Total Bilirubin(umol/L)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	0.89 (3.84)	0.79 (3.40)	0.84 (3.63)
Median	0.00	0.00	0.00
Min ; Max	-9.00 ; 20.00	-7.00 ; 14.00	-9.00 ; 20.00
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	0.75 (4.02)	0.37 (3.49)	0.57 (3.77)
Median	0.00	0.00	0.00
Min ; Max	-11.00 ; 24.00	-9.00 ; 14.00	-11.00 ; 24.00
End of trial visit			
N	179	179	358
Mean (SD)	0.72 (3.95)	0.40 (3.38)	0.56 (3.68)
Median	0.00	0.00	0.00
Min ; Max	-11.00 ; 24.00	-9.00 ; 14.00	-11.00 ; 24.00

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

Biochemistry by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Total Bilirubin(mg/dL)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	0.05 (0.22)	0.05 (0.20)	0.05 (0.21)
Median	0.00	0.00	0.00
Min ; Max	-0.53 ; 1.17	-0.41 ; 0.82	-0.53 ; 1.17
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	0.04 (0.24)	0.02 (0.20)	0.03 (0.22)
Median	0.00	0.00	0.00
Min ; Max	-0.64 ; 1.40	-0.53 ; 0.82	-0.64 ; 1.40
End of trial visit			
N	179	179	358
Mean (SD)	0.04 (0.23)	0.02 (0.20)	0.03 (0.22)
Median	0.00	0.00	0.00
Min ; Max	-0.64 ; 1.40	-0.53 ; 0.82	-0.64 ; 1.40

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
ALAT: Alanine aminotransferase, SGOT: Serum glutamic oxaloacetic transaminase

14.3.5.3 Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of subjects	181	179	360
Albumin Serum (g/dL)			
Visit 1			
N	180 (100.0)	179 (100.0)	359 (100.0)
Low	0	1 (0.6)	1 (0.3)
Normal	180 (100.0)	178 (99.4)	358 (99.7)
Visit 14 (Week 12)			
N	172 (100.0)	169 (100.0)	341 (100.0)
Normal	172 (100.0)	168 (99.4)	340 (99.7)
High	0	1 (0.6)	1 (0.3)
Visit 18 (Week 16)			
N	172 (100.0)	165 (100.0)	337 (100.0)
Low	1 (0.6)	0	1 (0.3)
Normal	171 (99.4)	165 (100.0)	336 (99.7)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Low	2 (1.1)	0	2 (0.6)
Normal	179 (98.9)	179 (100.0)	358 (99.4)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N	(%)	IDet N	(%)	Total N	(%)
Alanine Aminotransferase Serum (U/L)						
Visit 1						
N	180	(100.0)	178	(100.0)	358	(100.0)
Normal	175	(97.2)	171	(96.1)	346	(96.6)
High	5	(2.8)	7	(3.9)	12	(3.4)
Visit 14 (Week 12)						
N	171	(100.0)	169	(100.0)	340	(100.0)
Normal	165	(96.5)	166	(98.2)	331	(97.4)
High	6	(3.5)	3	(1.8)	9	(2.6)
Visit 18 (Week 16)						
N	171	(100.0)	163	(100.0)	334	(100.0)
Normal	167	(97.7)	156	(95.7)	323	(96.7)
High	4	(2.3)	7	(4.3)	11	(3.3)
End of trial visit						
N	181	(100.0)	179	(100.0)	360	(100.0)
Normal	176	(97.2)	171	(95.5)	347	(96.4)
High	5	(2.8)	8	(4.5)	13	(3.6)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Alkaline Phosphatase Serum (U/L)			
Visit 1			
N	180 (100.0)	179 (100.0)	359 (100.0)
Normal	141 (78.3)	150 (83.8)	291 (81.1)
High	39 (21.7)	29 (16.2)	68 (18.9)
Visit 14 (Week 12)			
N	172 (100.0)	169 (100.0)	341 (100.0)
Normal	143 (83.1)	142 (84.0)	285 (83.6)
High	29 (16.9)	27 (16.0)	56 (16.4)
Visit 18 (Week 16)			
N	170 (100.0)	165 (100.0)	335 (100.0)
Normal	137 (80.6)	140 (84.8)	277 (82.7)
High	33 (19.4)	25 (15.2)	58 (17.3)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	146 (80.7)	151 (84.4)	297 (82.5)
High	35 (19.3)	28 (15.6)	63 (17.5)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N	(%)	IDet N	(%)	Total N	(%)
Creatinine Serum (umol/L)						
Visit 1						
N	180	(100.0)	178	(100.0)	358	(100.0)
Low	13	(7.2)	22	(12.4)	35	(9.8)
Normal	156	(86.7)	145	(81.5)	301	(84.1)
High	11	(6.1)	11	(6.2)	22	(6.1)
Visit 14 (Week 12)						
N	173	(100.0)	169	(100.0)	342	(100.0)
Low	19	(11.0)	18	(10.7)	37	(10.8)
Normal	139	(80.3)	141	(83.4)	280	(81.9)
High	15	(8.7)	10	(5.9)	25	(7.3)
Visit 18 (Week 16)						
N	172	(100.0)	165	(100.0)	337	(100.0)
Low	10	(5.8)	16	(9.7)	26	(7.7)
Normal	146	(84.9)	140	(84.8)	286	(84.9)
High	16	(9.3)	9	(5.5)	25	(7.4)
End of trial visit						
N	181	(100.0)	178	(100.0)	359	(100.0)
Low	10	(5.5)	16	(9.0)	26	(7.2)
Normal	154	(85.1)	150	(84.3)	304	(84.7)
High	17	(9.4)	12	(6.7)	29	(8.1)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N	(%)	IDet N	(%)	Total N	(%)
Creatinine Serum (mg/dL)						
Visit 1						
N	180	(100.0)	178	(100.0)	358	(100.0)
Low	13	(7.2)	22	(12.4)	35	(9.8)
Normal	156	(86.7)	145	(81.5)	301	(84.1)
High	11	(6.1)	11	(6.2)	22	(6.1)
Visit 14 (Week 12)						
N	173	(100.0)	169	(100.0)	342	(100.0)
Low	19	(11.0)	18	(10.7)	37	(10.8)
Normal	139	(80.3)	141	(83.4)	280	(81.9)
High	15	(8.7)	10	(5.9)	25	(7.3)
Visit 18 (Week 16)						
N	172	(100.0)	165	(100.0)	337	(100.0)
Low	10	(5.8)	16	(9.7)	26	(7.7)
Normal	146	(84.9)	140	(84.8)	286	(84.9)
High	16	(9.3)	9	(5.5)	25	(7.4)
End of trial visit						
N	181	(100.0)	178	(100.0)	359	(100.0)
Low	10	(5.5)	16	(9.0)	26	(7.2)
Normal	154	(85.1)	150	(84.3)	304	(84.7)
High	17	(9.4)	12	(6.7)	29	(8.1)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N	(%)	IDet N	(%)	Total N	(%)
Potassium Serum (mmol/L)						
Visit 1						
N	180	(100.0)	178	(100.0)	358	(100.0)
Low	1	(0.6)	0		1	(0.3)
Normal	167	(92.8)	171	(96.1)	338	(94.4)
High	12	(6.7)	7	(3.9)	19	(5.3)
Visit 14 (Week 12)						
N	172	(100.0)	169	(100.0)	341	(100.0)
Normal	157	(91.3)	162	(95.9)	319	(93.5)
High	15	(8.7)	7	(4.1)	22	(6.5)
Visit 18 (Week 16)						
N	170	(100.0)	164	(100.0)	334	(100.0)
Normal	160	(94.1)	154	(93.9)	314	(94.0)
High	10	(5.9)	10	(6.1)	20	(6.0)
End of trial visit						
N	181	(100.0)	179	(100.0)	360	(100.0)
Normal	170	(93.9)	168	(93.9)	338	(93.9)
High	11	(6.1)	11	(6.1)	22	(6.1)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N	(%)	IDet N	(%)	Total N	(%)
Potassium Serum (mEq/L)						
Visit 1						
N	180	(100.0)	178	(100.0)	358	(100.0)
Low	1	(0.6)	0		1	(0.3)
Normal	167	(92.8)	171	(96.1)	338	(94.4)
High	12	(6.7)	7	(3.9)	19	(5.3)
Visit 14 (Week 12)						
N	172	(100.0)	169	(100.0)	341	(100.0)
Normal	157	(91.3)	162	(95.9)	319	(93.5)
High	15	(8.7)	7	(4.1)	22	(6.5)
Visit 18 (Week 16)						
N	170	(100.0)	164	(100.0)	334	(100.0)
Normal	160	(94.1)	154	(93.9)	314	(94.0)
High	10	(5.9)	10	(6.1)	20	(6.0)
End of trial visit						
N	181	(100.0)	179	(100.0)	360	(100.0)
Normal	170	(93.9)	168	(93.9)	338	(93.9)
High	11	(6.1)	11	(6.1)	22	(6.1)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week - summary - safety analysis set

	IDegAsp OD N	(%)	IDet N	(%)	Total N	(%)
Aspartate Aminotransferase Serum (U/L)						
Visit 1						
N	179	(100.0)	178	(100.0)	357	(100.0)
Normal	177	(98.9)	172	(96.6)	349	(97.8)
High	2	(1.1)	6	(3.4)	8	(2.2)
Visit 14 (Week 12)						
N	171	(100.0)	168	(100.0)	339	(100.0)
Normal	169	(98.8)	165	(98.2)	334	(98.5)
High	2	(1.2)	3	(1.8)	5	(1.5)
Visit 18 (Week 16)						
N	170	(100.0)	163	(100.0)	333	(100.0)
Normal	169	(99.4)	160	(98.2)	329	(98.8)
High	1	(0.6)	3	(1.8)	4	(1.2)
End of trial visit						
N	181	(100.0)	179	(100.0)	360	(100.0)
Normal	180	(99.4)	176	(98.3)	356	(98.9)
High	1	(0.6)	3	(1.7)	4	(1.1)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N	(%)	IDet N	(%)	Total N	(%)
Sodium Serum (mmol/L)						
Visit 1						
N	180	(100.0)	179	(100.0)	359	(100.0)
Low	4	(2.2)	3	(1.7)	7	(1.9)
Normal	170	(94.4)	173	(96.6)	343	(95.5)
High	6	(3.3)	3	(1.7)	9	(2.5)
Visit 14 (Week 12)						
N	173	(100.0)	169	(100.0)	342	(100.0)
Low	4	(2.3)	6	(3.6)	10	(2.9)
Normal	169	(97.7)	161	(95.3)	330	(96.5)
High	0		2	(1.2)	2	(0.6)
Visit 18 (Week 16)						
N	172	(100.0)	165	(100.0)	337	(100.0)
Low	3	(1.7)	2	(1.2)	5	(1.5)
Normal	169	(98.3)	159	(96.4)	328	(97.3)
High	0		4	(2.4)	4	(1.2)
End of trial visit						
N	181	(100.0)	179	(100.0)	360	(100.0)
Low	3	(1.7)	4	(2.2)	7	(1.9)
Normal	178	(98.3)	171	(95.5)	349	(96.9)
High	0		4	(2.2)	4	(1.1)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week - summary - safety analysis set

	IDegAsp OD N	(%)	IDet N	(%)	Total N	(%)
Sodium Serum (mEq/L)						
Visit 1						
N	180	(100.0)	179	(100.0)	359	(100.0)
Low	4	(2.2)	3	(1.7)	7	(1.9)
Normal	170	(94.4)	173	(96.6)	343	(95.5)
High	6	(3.3)	3	(1.7)	9	(2.5)
Visit 14 (Week 12)						
N	173	(100.0)	169	(100.0)	342	(100.0)
Low	4	(2.3)	6	(3.6)	10	(2.9)
Normal	169	(97.7)	161	(95.3)	330	(96.5)
High	0		2	(1.2)	2	(0.6)
Visit 18 (Week 16)						
N	172	(100.0)	165	(100.0)	337	(100.0)
Low	3	(1.7)	2	(1.2)	5	(1.5)
Normal	169	(98.3)	159	(96.4)	328	(97.3)
High	0		4	(2.4)	4	(1.2)
End of trial visit						
N	181	(100.0)	179	(100.0)	360	(100.0)
Low	3	(1.7)	4	(2.2)	7	(1.9)
Normal	178	(98.3)	171	(95.5)	349	(96.9)
High	0		4	(2.2)	4	(1.1)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N	(%)	IDet N	(%)	Total N	(%)
Total Bilirubin Serum (umol/L)						
Visit 1						
N	179	(100.0)	179	(100.0)	358	(100.0)
Low	11	(6.1)	8	(4.5)	19	(5.3)
Normal	165	(92.2)	166	(92.7)	331	(92.5)
High	3	(1.7)	5	(2.8)	8	(2.2)
Visit 14 (Week 12)						
N	172	(100.0)	169	(100.0)	341	(100.0)
Low	5	(2.9)	7	(4.1)	12	(3.5)
Normal	161	(93.6)	156	(92.3)	317	(93.0)
High	6	(3.5)	6	(3.6)	12	(3.5)
Visit 18 (Week 16)						
N	172	(100.0)	165	(100.0)	337	(100.0)
Low	7	(4.1)	9	(5.5)	16	(4.7)
Normal	162	(94.2)	152	(92.1)	314	(93.2)
High	3	(1.7)	4	(2.4)	7	(2.1)
End of trial visit						
N	181	(100.0)	179	(100.0)	360	(100.0)
Low	8	(4.4)	9	(5.0)	17	(4.7)
Normal	170	(93.9)	166	(92.7)	336	(93.3)
High	3	(1.7)	4	(2.2)	7	(1.9)

N: Number of subjects, %: Percentage of subjects

Biochemistry by treatment week – summary – safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Total Bilirubin Serum (mg/dL)			
Visit 1			
N	179 (100.0)	179 (100.0)	358 (100.0)
Low	11 (6.1)	8 (4.5)	19 (5.3)
Normal	165 (92.2)	166 (92.7)	331 (92.5)
High	3 (1.7)	5 (2.8)	8 (2.2)
Visit 14 (Week 12)			
N	172 (100.0)	169 (100.0)	341 (100.0)
Low	5 (2.9)	7 (4.1)	12 (3.5)
Normal	161 (93.6)	156 (92.3)	317 (93.0)
High	6 (3.5)	6 (3.6)	12 (3.5)
Visit 18 (Week 16)			
N	172 (100.0)	165 (100.0)	337 (100.0)
Low	7 (4.1)	9 (5.5)	16 (4.7)
Normal	162 (94.2)	152 (92.1)	314 (93.2)
High	3 (1.7)	4 (2.4)	7 (2.1)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Low	8 (4.4)	9 (5.0)	17 (4.7)
Normal	170 (93.9)	166 (92.7)	336 (93.3)
High	3 (1.7)	4 (2.2)	7 (1.9)

N: Number of subjects, %: Percentage of subjects

14.3.5.4 Biochemistry - shift table - baseline to week 16 - safety analysis set

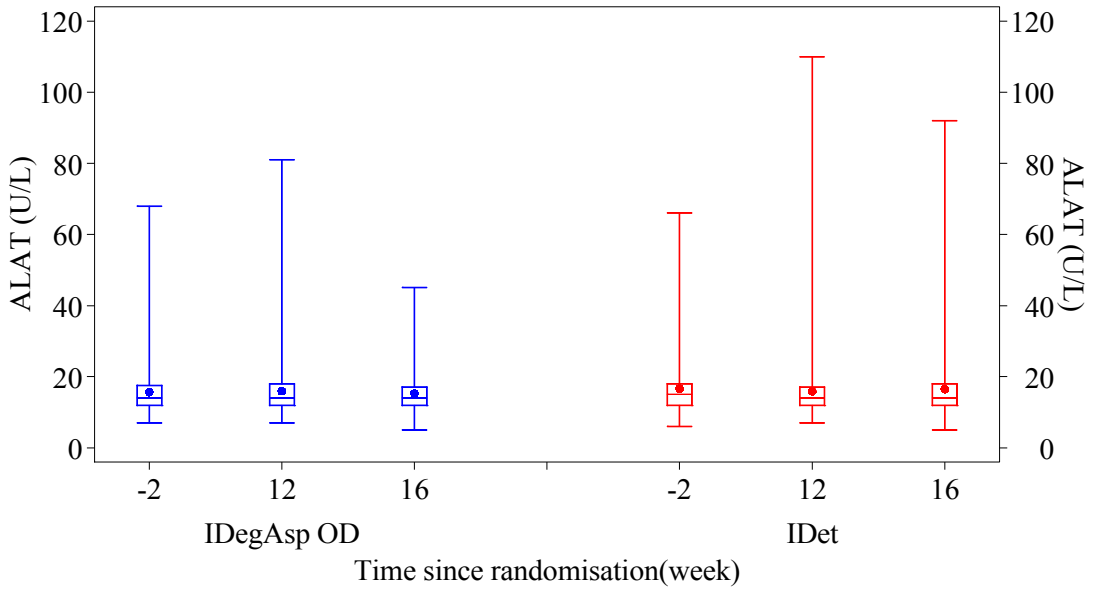
Number of Subjects	IDegAsp OD 181 Baseline				IDet 179 Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 18 (Week 16)								
Alanine Aminotransferase Serum (U/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	163 (90.1)	3 (1.7)	1 (0.6)	0 (0.0)	151 (84.4)	5 (2.8)	0 (0.0)
High	0 (0.0)	3 (1.7)	1 (0.6)	0 (0.0)	0 (0.0)	4 (2.2)	2 (1.1)	1 (0.6)
Missing	0 (0.0)	9 (5.0)	1 (0.6)	0 (0.0)	0 (0.0)	16 (8.9)	0 (0.0)	0 (0.0)
Albumin Serum (g/dL)								
Low	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	170 (93.9)	0 (0.0)	1 (0.6)	1 (0.6)	164 (91.6)	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)	9 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (7.8)	0 (0.0)	0 (0.0)
Alkaline Phosphatase 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	0 (0.0)	126 (69.6)	11 (6.1)	0 (0.0)	0 (0.0)	134 (74.9)	6 (3.4)	0 (0.0)
High	0 (0.0)	6 (3.3)	26 (14.4)	1 (0.6)	0 (0.0)	6 (3.4)	19 (10.6)	0 (0.0)
Missing	0 (0.0)	9 (5.0)	2 (1.1)	0 (0.0)	0 (0.0)	10 (5.6)	4 (2.2)	0 (0.0)
Aspartate 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	0 (0.0)	165 (91.2)	2 (1.1)	2 (1.1)	0 (0.0)	156 (87.2)	3 (1.7)	1 (0.6)
High	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.7)	0 (0.0)
Missing	0 (0.0)	11 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	16 (8.9)	0 (0.0)	0 (0.0)

N: Number of subjects, %: Percentage of subjects

Biochemistry - shift table - baseline to week 16 - safety analysis set

Number of Subjects	IDegAsp OD 181 Baseline				IDet 179 Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 18 (Week 16)								
Creatinine Serum (umol/L)								
Low	4 (2.2)	6 (3.3)	0 (0.0)	0 (0.0)	13 (7.3)	3 (1.7)	0 (0.0)	0 (0.0)
Normal	7 (3.9)	132 (72.9)	6 (3.3)	1 (0.6)	9 (5.0)	126 (70.4)	5 (2.8)	0 (0.0)
High	1 (0.6)	10 (5.5)	5 (2.8)	0 (0.0)	0 (0.0)	4 (2.2)	5 (2.8)	0 (0.0)
Missing	1 (0.6)	8 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	12 (6.7)	1 (0.6)	1 (0.6)
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	1 (0.6)	149 (82.3)	9 (5.0)	1 (0.6)	0 (0.0)	146 (81.6)	7 (3.9)	1 (0.6)
High	0 (0.0)	8 (4.4)	2 (1.1)	0 (0.0)	0 (0.0)	10 (5.6)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	10 (5.5)	1 (0.6)	0 (0.0)	0 (0.0)	15 (8.4)	0 (0.0)	0 (0.0)
Sodium Serum (mmol/L)								
Low	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)
Normal	4 (2.2)	158 (87.3)	6 (3.3)	1 (0.6)	2 (1.1)	155 (86.6)	2 (1.1)	0 (0.0)
High	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.7)	1 (0.6)	0 (0.0)
Missing	0 (0.0)	9 (5.0)	0 (0.0)	0 (0.0)	1 (0.6)	13 (7.3)	0 (0.0)	0 (0.0)
Total Bilirubin Serum (umol/L)								
Low	3 (1.7)	4 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	9 (5.0)	0 (0.0)	0 (0.0)
Normal	5 (2.8)	155 (85.6)	1 (0.6)	1 (0.6)	8 (4.5)	142 (79.3)	2 (1.1)	0 (0.0)
High	0 (0.0)	1 (0.6)	2 (1.1)	0 (0.0)	0 (0.0)	1 (0.6)	3 (1.7)	0 (0.0)
Missing	3 (1.7)	5 (2.8)	0 (0.0)	1 (0.6)	0 (0.0)	14 (7.8)	0 (0.0)	0 (0.0)

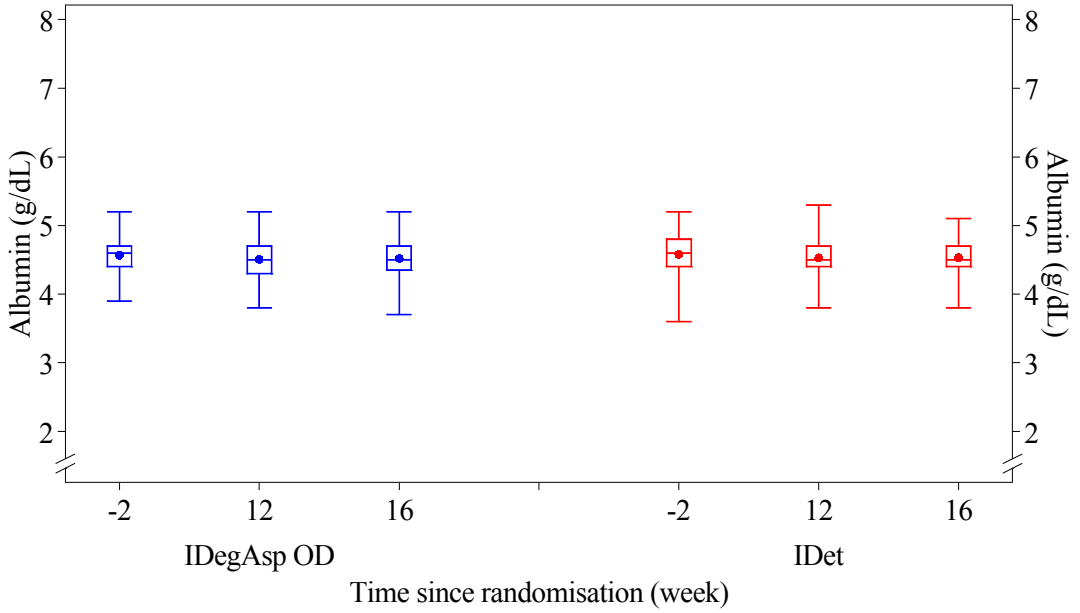
N: Number of subjects, %: Percentage of subjects



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
Lower ref.: Both,Age(0-1)[4],Age(1-17)[5],Age(17-111)[0]
Upper ref.:Male, Age(0-1)[35], Age(17-111)[41]; Female, Age(0-1)[30], Age(17-111)[33];
Both Age(1-17)[30], ALAT : Alanine aminotransferase

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:33 - fbox_numfind_v02.sas/e_ala_amino_s_abs_box_obs_sas.cgm

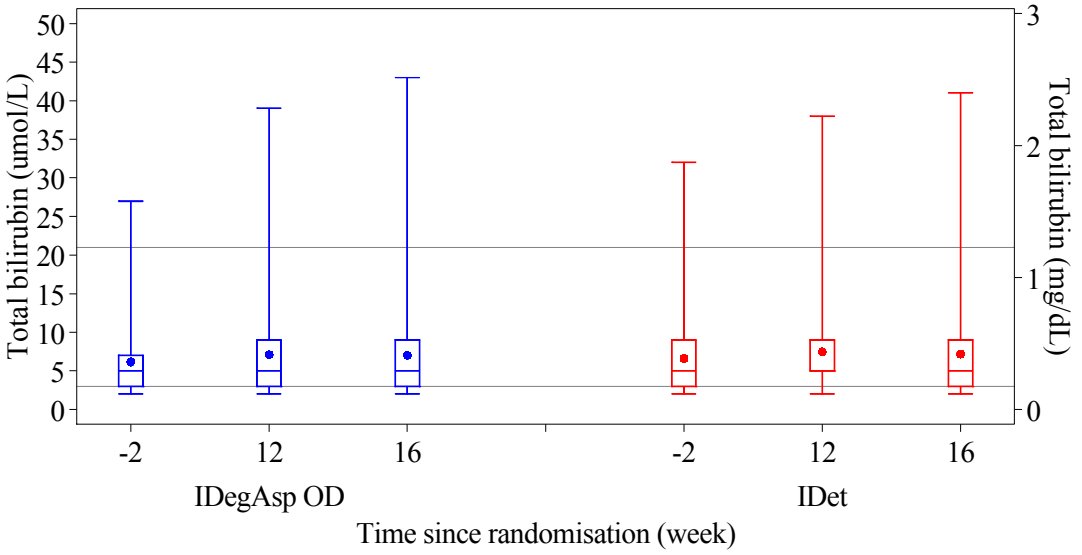
14.3.5.5 Biochemistry - alanine aminotransferase – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; Observed data
Lower ref.: Both,age(1-16)[3.8],age(16-111)[3.5]
Upper ref.:Both,age(1-16)[5.4],age(16-111)[5.2]

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:33 - fbox_numfind_v02.sas/e_albu_s_abs_box_obs_sas.cgm

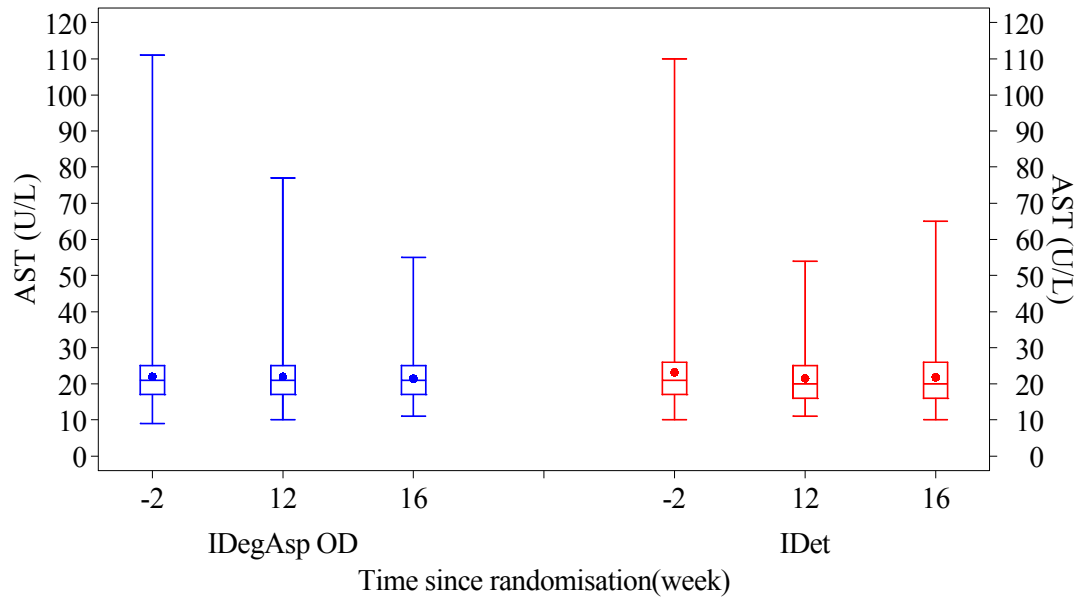
14.3.5.6 Biochemistry - albumin serum – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
Horizontal lines indicate the reference range.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:37 - fbox_numfind_v02.sas/e_t_bilirubin_abs_box_obs_sas.cgm

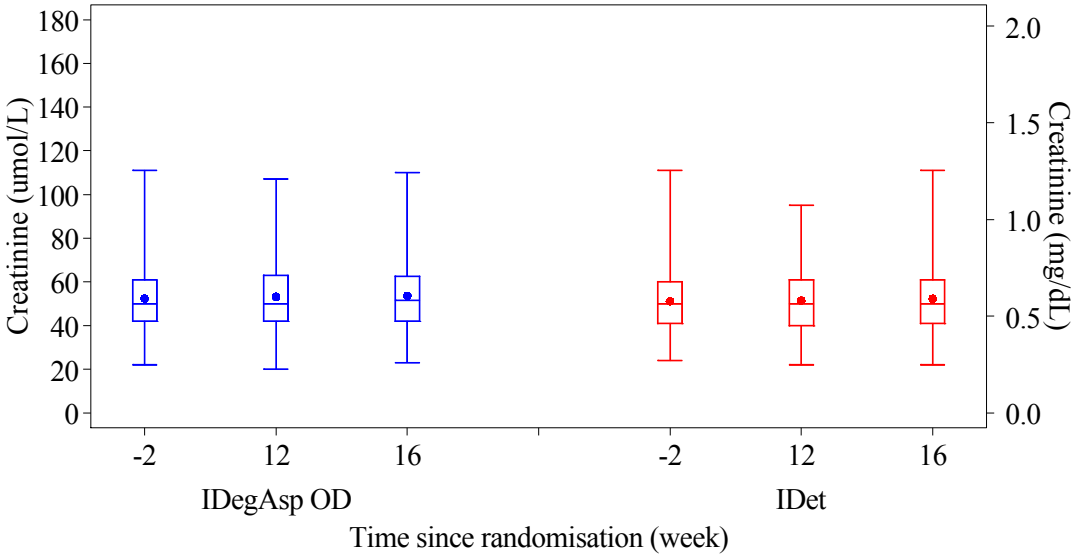
14.3.5.7 Biochemistry - total bilirubin - box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; Observed data
Lower ref: 0; Upper ref: Female: age 1-4 (68), age 4-7 (58), age 7-10 (40), age 10-13 (36), age 13-111 (31); Male: age 1-4 (55), age 4-7 (47), age 7-10 (41), age 10-13 (37), age 13-16 (38), age 16-111 (37)

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:36 - fbox_numfind_v02.sas/e_ast_abs_box_obs_sas.cgm

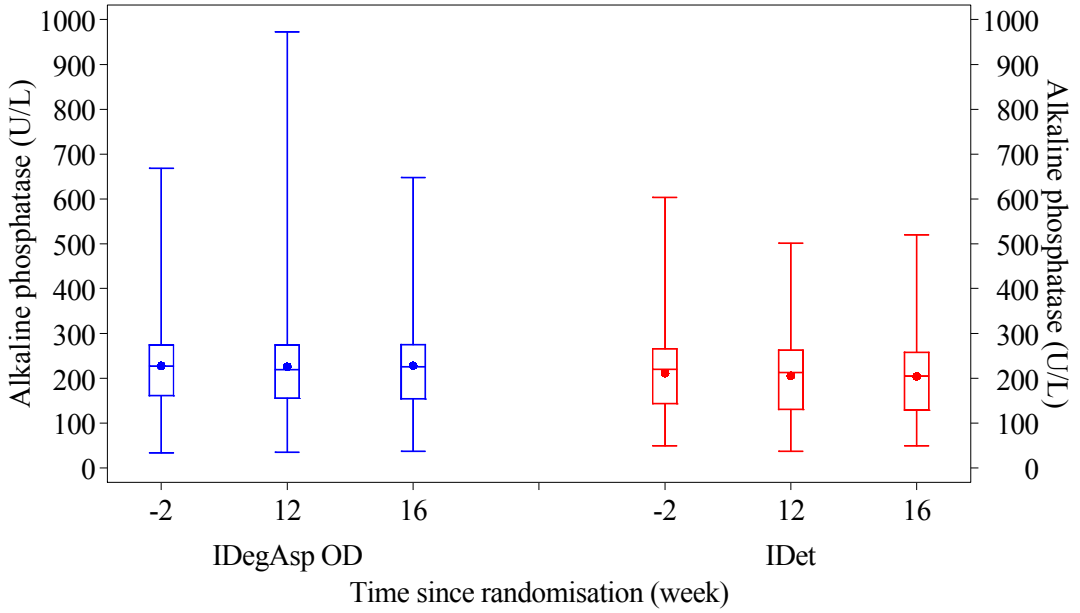
14.3.5.8 Biochemistry - aspartate aminotransferase – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; Observed data
Age 1-3 (L 21, U 36), age 3-5 (L 27, U 42), age 5-7 (L 28, U 52), age 7-9 (L 35, U 53),
age 9-11 (L 34, U 65), age 11-13 (L 47, U 70), age 13-16 (L 50, U 77),
age 16-111 (F: L 44, U 80; M: L 62, U 106) L: Low ref; U: Upper ref

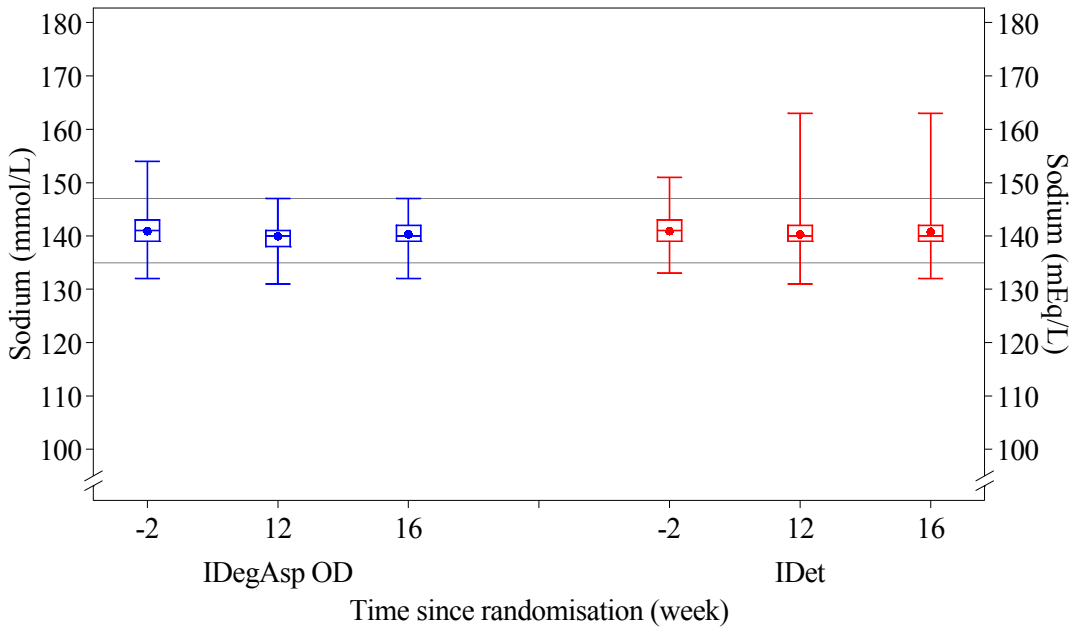
nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:35 - fbox_numfind_v02.sas/e_crea_abs_box_obs_sas.cgm

14.3.5.9 Biochemistry - creatinine – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; Observed data
Lower ref: 0;
Upper ref: Age 1-4 (280), age 4-7 (268), age 7-13 (299), age 13-18 (female 186, male 389)
nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:34 - fbox_numfind_v02.sas/e_alka_phosph_abs_box_obs_sas.cgm

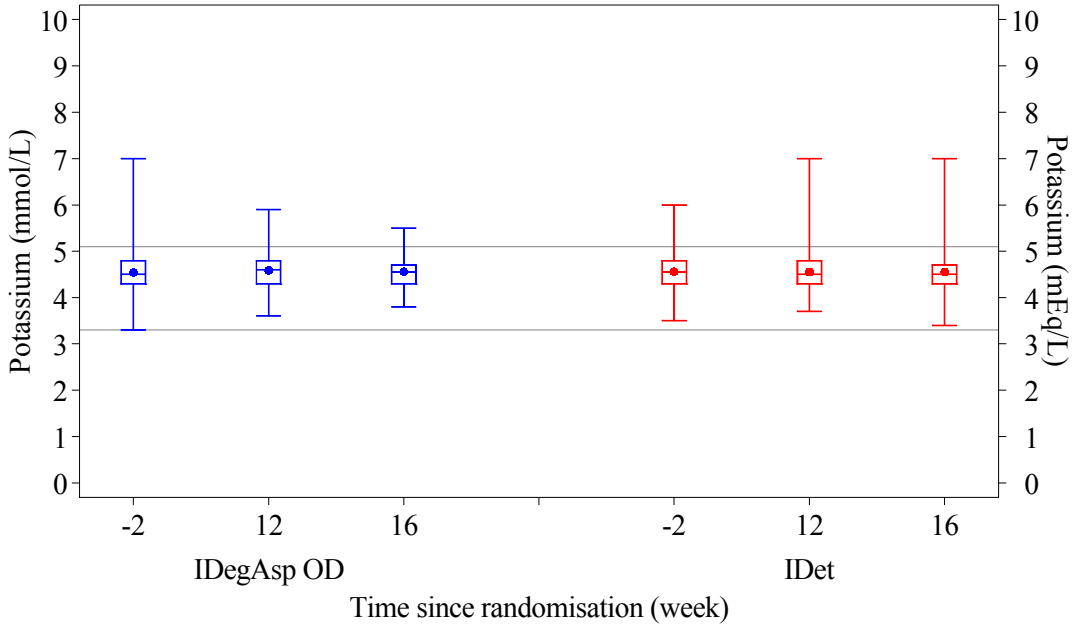
14.3.5.10 Biochemistry - alkaline phosphatase – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
Horizontal lines indicate the reference range.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:36 - fbox_numfind_v02.sas/e_sodium_abs_box_obs_sas.cgm

14.3.5.11 Biochemistry - sodium – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
Horizontal lines indicate the reference range.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:38 - fbox_numfind_v02.sas/e_potas_abs_box_obs_sas.cgm

14.3.5.12 Biochemistry - potassium – box plot - safety analysis set

14.3.5.13 Haematology by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Erythrocytes(10^12/L)			
Visit 1			
N	181	177	358
Mean (SD)	4.73 (0.38)	4.80 (0.39)	4.77 (0.39)
Median	4.70	4.80	4.70
Min ; Max	3.80 ; 6.80	3.70 ; 6.10	3.70 ; 6.80
Visit 14 (Week 12)			
N	172	170	342
Mean (SD)	4.74 (0.35)	4.80 (0.41)	4.77 (0.38)
Median	4.70	4.80	4.70
Min ; Max	4.10 ; 5.70	3.90 ; 6.00	3.90 ; 6.00
Visit 18 (Week 16)			
N	174	162	336
Mean (SD)	4.74 (0.35)	4.80 (0.40)	4.77 (0.37)
Median	4.70	4.80	4.70
Min ; Max	3.90 ; 5.80	4.00 ; 6.00	3.90 ; 6.00
End of trial visit			
N	181	179	360
Mean (SD)	4.74 (0.35)	4.80 (0.40)	4.77 (0.38)
Median	4.70	4.80	4.70
Min ; Max	3.90 ; 5.80	4.00 ; 6.00	3.90 ; 6.00

N: Number of subjects, SD: Standard deviation

Haematology by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Haematocrit(%)			
Visit 1			
N	175	173	348
Mean (SD)	40.33 (3.30)	40.69 (3.15)	40.51 (3.22)
Median	40.30	40.40	40.35
Min ; Max	31.70 ; 54.80	34.20 ; 49.10	31.70 ; 54.80
Visit 14 (Week 12)			
N	165	164	329
Mean (SD)	40.57 (3.49)	40.93 (3.43)	40.75 (3.46)
Median	40.20	40.50	40.40
Min ; Max	30.60 ; 50.70	30.40 ; 51.00	30.40 ; 51.00
Visit 18 (Week 16)			
N	173	159	332
Mean (SD)	40.58 (3.33)	41.02 (3.24)	40.79 (3.29)
Median	40.30	40.80	40.45
Min ; Max	30.30 ; 51.20	35.00 ; 52.10	30.30 ; 52.10
End of trial visit			
N	181	179	360
Mean (SD)	40.65 (3.34)	40.87 (3.33)	40.76 (3.33)
Median	40.40	40.60	40.50
Min ; Max	30.30 ; 51.20	30.40 ; 52.10	30.30 ; 52.10

N: Number of subjects, SD: Standard deviation

Haematology by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Haemoglobin(mmol/L)			
Visit 1			
N	181	177	358
Mean (SD)	8.30 (0.73)	8.37 (0.67)	8.34 (0.70)
Median	8.25	8.37	8.31
Min ; Max	6.14 ; 11.72	6.82 ; 10.17	6.14 ; 11.72
Visit 14 (Week 12)			
N	172	170	342
Mean (SD)	8.33 (0.75)	8.37 (0.68)	8.35 (0.71)
Median	8.25	8.31	8.28
Min ; Max	5.71 ; 10.54	6.51 ; 10.42	5.71 ; 10.54
Visit 18 (Week 16)			
N	174	162	336
Mean (SD)	8.31 (0.73)	8.36 (0.68)	8.33 (0.70)
Median	8.31	8.31	8.31
Min ; Max	5.77 ; 10.36	6.76 ; 10.91	5.77 ; 10.91
End of trial visit			
N	181	179	360
Mean (SD)	8.32 (0.73)	8.35 (0.68)	8.33 (0.70)
Median	8.31	8.31	8.31
Min ; Max	5.77 ; 10.36	6.51 ; 10.91	5.77 ; 10.91

N: Number of subjects, SD: Standard deviation

Haematology by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Haemoglobin(g/dL)			
Visit 1			
N	181	177	358
Mean (SD)	13.38 (1.17)	13.49 (1.08)	13.43 (1.13)
Median	13.29	13.49	13.39
Min ; Max	9.89 ; 18.89	10.99 ; 16.39	9.89 ; 18.89
Visit 14 (Week 12)			
N	172	170	342
Mean (SD)	13.42 (1.20)	13.49 (1.10)	13.46 (1.15)
Median	13.29	13.39	13.34
Min ; Max	9.19 ; 16.99	10.49 ; 16.79	9.19 ; 16.99
Visit 18 (Week 16)			
N	174	162	336
Mean (SD)	13.38 (1.17)	13.47 (1.09)	13.42 (1.13)
Median	13.39	13.39	13.39
Min ; Max	9.29 ; 16.69	10.89 ; 17.59	9.29 ; 17.59
End of trial visit			
N	181	179	360
Mean (SD)	13.40 (1.17)	13.45 (1.10)	13.43 (1.13)
Median	13.39	13.39	13.39
Min ; Max	9.29 ; 16.69	10.49 ; 17.59	9.29 ; 17.59

N: Number of subjects, SD: Standard deviation

Haematology by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Leukocytes(10^9/L)			
Visit 1			
N	181	177	358
Mean (SD)	7.12 (2.17)	7.13 (2.15)	7.12 (2.15)
Median	6.80	6.90	6.90
Min ; Max	3.00 ; 14.80	3.50 ; 17.00	3.00 ; 17.00
Visit 14 (Week 12)			
N	172	170	342
Mean (SD)	6.62 (1.97)	6.86 (2.02)	6.74 (2.00)
Median	6.40	6.70	6.60
Min ; Max	2.90 ; 15.30	2.70 ; 14.60	2.70 ; 15.30
Visit 18 (Week 16)			
N	174	162	336
Mean (SD)	6.66 (1.92)	6.91 (1.87)	6.78 (1.90)
Median	6.40	6.70	6.50
Min ; Max	3.50 ; 13.70	3.30 ; 11.80	3.30 ; 13.70
End of trial visit			
N	181	179	360
Mean (SD)	6.67 (1.92)	6.91 (1.91)	6.79 (1.92)
Median	6.50	6.70	6.50
Min ; Max	3.10 ; 13.70	3.30 ; 13.80	3.10 ; 13.80

N: Number of subjects, SD: Standard deviation

Haematology by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Thrombocytes(10^9/L)			
Visit 1			
N	181	177	358
Mean (SD)	279.30 (70.39)	275.36 (73.10)	277.35 (71.67)
Median	272.00	265.00	268.50
Min ; Max	153.00 ; 658.00	64.00 ; 503.00	64.00 ; 658.00
Visit 14 (Week 12)			
N	171	166	337
Mean (SD)	275.89 (70.50)	269.90 (71.39)	272.94 (70.90)
Median	269.00	263.00	266.00
Min ; Max	154.00 ; 619.00	56.00 ; 515.00	56.00 ; 619.00
Visit 18 (Week 16)			
N	172	157	329
Mean (SD)	279.06 (69.56)	273.10 (72.43)	276.22 (70.90)
Median	268.50	261.00	264.00
Min ; Max	139.00 ; 557.00	55.00 ; 672.00	55.00 ; 672.00
End of trial visit			
N	181	179	360
Mean (SD)	279.47 (69.44)	277.92 (74.94)	278.70 (72.13)
Median	269.00	265.00	265.50
Min ; Max	139.00 ; 557.00	55.00 ; 672.00	55.00 ; 672.00

N: Number of subjects, SD: Standard deviation

14.3.5.14 Haematology by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Ch Erythrocytes(10^12/L)			
Visit 14 (Week 12)			
N	172	168	340
Mean (SD)	0.00 (0.34)	-0.00 (0.31)	0.00 (0.33)
Median	0.00	0.00	0.00
Min ; Max	-2.20 ; 1.60	-0.90 ; 1.60	-2.20 ; 1.60
Visit 18 (Week 16)			
N	174	160	334
Mean (SD)	-0.00 (0.30)	0.01 (0.30)	0.00 (0.30)
Median	0.00	0.00	0.00
Min ; Max	-1.80 ; 0.80	-0.90 ; 1.20	-1.80 ; 1.20
End of trial visit			
N	181	177	358
Mean (SD)	0.01 (0.32)	0.00 (0.30)	0.01 (0.31)
Median	0.00	0.00	0.00
Min ; Max	-1.80 ; 1.60	-0.90 ; 1.20	-1.80 ; 1.60

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

Haematology by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Haematocrit(%)			
Visit 14 (Week 12)			
N	160	159	319
Mean (SD)	0.16 (3.27)	0.18 (2.50)	0.17 (2.91)
Median	0.10	0.20	0.20
Min ; Max	-19.10 ; 17.90	-7.30 ; 12.00	-19.10 ; 17.90
Visit 18 (Week 16)			
N	167	153	320
Mean (SD)	0.18 (2.66)	0.17 (2.32)	0.18 (2.50)
Median	0.50	0.10	0.25
Min ; Max	-14.00 ; 10.80	-5.80 ; 8.00	-14.00 ; 10.80
End of trial visit			
N	175	173	348
Mean (SD)	0.31 (2.94)	0.16 (2.38)	0.23 (2.68)
Median	0.50	0.00	0.20
Min ; Max	-14.00 ; 17.90	-7.30 ; 8.00	-14.00 ; 17.90

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

Haematology by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Haemoglobin(mmol/L)			
Visit 14 (Week 12)			
N	172	168	340
Mean (SD)	0.02 (0.66)	0.01 (0.45)	0.01 (0.57)
Median	0.00	0.00	0.00
Min ; Max	-3.91 ; 3.78	-1.18 ; 1.86	-3.91 ; 3.78
Visit 18 (Week 16)			
N	174	160	334
Mean (SD)	-0.01 (0.55)	-0.02 (0.50)	-0.01 (0.53)
Median	0.00	-0.06	0.00
Min ; Max	-3.47 ; 2.36	-1.86 ; 2.17	-3.47 ; 2.36
End of trial visit			
N	181	177	358
Mean (SD)	0.02 (0.61)	-0.02 (0.49)	-0.00 (0.55)
Median	0.00	-0.06	0.00
Min ; Max	-3.47 ; 3.78	-1.86 ; 2.17	-3.47 ; 3.78

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

Haematology by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Haemoglobin(g/dL)			
Visit 14 (Week 12)			
N	172	168	340
Mean (SD)	0.04 (1.06)	0.01 (0.73)	0.02 (0.91)
Median	0.00	0.00	0.00
Min ; Max	-6.30 ; 6.10	-1.90 ; 3.00	-6.30 ; 6.10
Visit 18 (Week 16)			
N	174	160	334
Mean (SD)	-0.01 (0.89)	-0.03 (0.81)	-0.02 (0.85)
Median	0.00	-0.10	0.00
Min ; Max	-5.60 ; 3.80	-3.00 ; 3.50	-5.60 ; 3.80
End of trial visit			
N	181	177	358
Mean (SD)	0.03 (0.99)	-0.04 (0.78)	-0.01 (0.89)
Median	0.00	-0.10	0.00
Min ; Max	-5.60 ; 6.10	-3.00 ; 3.50	-5.60 ; 6.10

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

Haematology by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Leukocytes(10^9/L)			
Visit 14 (Week 12)			
N	172	168	340
Mean (SD)	-0.53 (1.90)	-0.26 (1.79)	-0.40 (1.85)
Median	-0.40	-0.35	-0.40
Min ; Max	-6.60 ; 8.80	-9.20 ; 5.70	-9.20 ; 8.80
Visit 18 (Week 16)			
N	174	160	334
Mean (SD)	-0.52 (1.82)	-0.16 (1.72)	-0.35 (1.78)
Median	-0.40	-0.20	-0.40
Min ; Max	-6.90 ; 5.50	-6.50 ; 5.00	-6.90 ; 5.50
End of trial visit			
N	181	177	358
Mean (SD)	-0.45 (1.83)	-0.21 (1.74)	-0.33 (1.79)
Median	-0.40	-0.20	-0.30
Min ; Max	-6.90 ; 5.50	-6.50 ; 5.00	-6.90 ; 5.50

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

Haematology by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Thrombocytes(10^9/L)			
Visit 14 (Week 12)			
N	171	164	335
Mean (SD)	0.80 (46.01)	-3.57 (56.42)	-1.34 (51.34)
Median	0.00	-2.00	-1.00
Min ; Max	-123.00 ; 177.00	-261.00 ; 152.00	-261.00 ; 177.00
Visit 18 (Week 16)			
N	172	155	327
Mean (SD)	0.28 (48.73)	1.96 (56.25)	1.08 (52.36)
Median	1.50	0.00	1.00
Min ; Max	-190.00 ; 197.00	-203.00 ; 340.00	-203.00 ; 340.00
End of trial visit			
N	181	177	358
Mean (SD)	0.17 (47.88)	2.07 (60.38)	1.11 (54.35)
Median	1.00	0.00	1.00
Min ; Max	-190.00 ; 197.00	-236.00 ; 340.00	-236.00 ; 340.00

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline

14.3.5.15 Haematology by treatment week – summary – safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	181	179	360
Erythrocytes (10^12/L)			
Visit 1			
N	181 (100.0)	177 (100.0)	358 (100.0)
Low	0	1 (0.6)	1 (0.3)
Normal	173 (95.6)	166 (93.8)	339 (94.7)
High	8 (4.4)	10 (5.6)	18 (5.0)
Visit 14 (Week 12)			
N	172 (100.0)	170 (100.0)	342 (100.0)
Normal	163 (94.8)	158 (92.9)	321 (93.9)
High	9 (5.2)	12 (7.1)	21 (6.1)
Visit 18 (Week 16)			
N	174 (100.0)	162 (100.0)	336 (100.0)
Normal	167 (96.0)	152 (93.8)	319 (94.9)
High	7 (4.0)	10 (6.2)	17 (5.1)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	173 (95.6)	168 (93.9)	341 (94.7)
High	8 (4.4)	11 (6.1)	19 (5.3)

N: Number of subjects, %: Percentage of subjects

Haematology by treatment week – summary – safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Haematocrit Blood (%)			
Visit 1			
N	175 (100.0)	173 (100.0)	348 (100.0)
Low	5 (2.9)	2 (1.2)	7 (2.0)
Normal	160 (91.4)	160 (92.5)	320 (92.0)
High	10 (5.7)	11 (6.4)	21 (6.0)
Visit 14 (Week 12)			
N	165 (100.0)	164 (100.0)	329 (100.0)
Low	2 (1.2)	1 (0.6)	3 (0.9)
Normal	153 (92.7)	152 (92.7)	305 (92.7)
High	10 (6.1)	11 (6.7)	21 (6.4)
Visit 18 (Week 16)			
N	173 (100.0)	159 (100.0)	332 (100.0)
Low	2 (1.2)	1 (0.6)	3 (0.9)
Normal	157 (90.8)	147 (92.5)	304 (91.6)
High	14 (8.1)	11 (6.9)	25 (7.5)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Low	2 (1.1)	1 (0.6)	3 (0.8)
Normal	163 (90.1)	165 (92.2)	328 (91.1)
High	16 (8.8)	13 (7.3)	29 (8.1)

N: Number of subjects, %: Percentage of subjects

Haematology by treatment week – summary – safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Haemoglobin Blood (mmol/L)			
Visit 1			
N	181 (100.0)	177 (100.0)	358 (100.0)
Low	9 (5.0)	4 (2.3)	13 (3.6)
Normal	170 (93.9)	170 (96.0)	340 (95.0)
High	2 (1.1)	3 (1.7)	5 (1.4)
Visit 14 (Week 12)			
N	172 (100.0)	170 (100.0)	342 (100.0)
Low	6 (3.5)	2 (1.2)	8 (2.3)
Normal	162 (94.2)	163 (95.9)	325 (95.0)
High	4 (2.3)	5 (2.9)	9 (2.6)
Visit 18 (Week 16)			
N	174 (100.0)	162 (100.0)	336 (100.0)
Low	8 (4.6)	3 (1.9)	11 (3.3)
Normal	164 (94.3)	155 (95.7)	319 (94.9)
High	2 (1.1)	4 (2.5)	6 (1.8)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Low	8 (4.4)	3 (1.7)	11 (3.1)
Normal	170 (93.9)	172 (96.1)	342 (95.0)
High	3 (1.7)	4 (2.2)	7 (1.9)

N: Number of subjects, %: Percentage of subjects

Haematology by treatment week – summary – safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Haemoglobin Blood (g/dL)			
Visit 1			
N	181 (100.0)	177 (100.0)	358 (100.0)
Low	9 (5.0)	4 (2.3)	13 (3.6)
Normal	170 (93.9)	170 (96.0)	340 (95.0)
High	2 (1.1)	3 (1.7)	5 (1.4)
Visit 14 (Week 12)			
N	172 (100.0)	170 (100.0)	342 (100.0)
Low	6 (3.5)	2 (1.2)	8 (2.3)
Normal	162 (94.2)	163 (95.9)	325 (95.0)
High	4 (2.3)	5 (2.9)	9 (2.6)
Visit 18 (Week 16)			
N	174 (100.0)	162 (100.0)	336 (100.0)
Low	8 (4.6)	3 (1.9)	11 (3.3)
Normal	164 (94.3)	155 (95.7)	319 (94.9)
High	2 (1.1)	4 (2.5)	6 (1.8)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Low	8 (4.4)	3 (1.7)	11 (3.1)
Normal	170 (93.9)	172 (96.1)	342 (95.0)
High	3 (1.7)	4 (2.2)	7 (1.9)

N: Number of subjects, %: Percentage of subjects

Haematology by treatment week - summary - safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Thrombocytes (10^9/L)			
Visit 1			
N	181 (100.0)	177 (100.0)	358 (100.0)
Low	0	2 (1.1)	2 (0.6)
Normal	178 (98.3)	169 (95.5)	347 (96.9)
High	3 (1.7)	6 (3.4)	9 (2.5)
Visit 14 (Week 12)			
N	171 (100.0)	166 (100.0)	337 (100.0)
Low	0	1 (0.6)	1 (0.3)
Normal	169 (98.8)	160 (96.4)	329 (97.6)
High	2 (1.2)	5 (3.0)	7 (2.1)
Visit 18 (Week 16)			
N	172 (100.0)	157 (100.0)	329 (100.0)
Low	1 (0.6)	1 (0.6)	2 (0.6)
Normal	167 (97.1)	154 (98.1)	321 (97.6)
High	4 (2.3)	2 (1.3)	6 (1.8)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Low	1 (0.6)	1 (0.6)	2 (0.6)
Normal	176 (97.2)	173 (96.6)	349 (96.9)
High	4 (2.2)	5 (2.8)	9 (2.5)

N: Number of subjects, %: Percentage of subjects

Haematology by treatment week – summary – safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Leukocytes (10^9/L)			
Visit 1			
N	181 (100.0)	177 (100.0)	358 (100.0)
Low	12 (6.6)	9 (5.1)	21 (5.9)
Normal	159 (87.8)	161 (91.0)	320 (89.4)
High	10 (5.5)	7 (4.0)	17 (4.7)
Visit 14 (Week 12)			
N	172 (100.0)	170 (100.0)	342 (100.0)
Low	11 (6.4)	13 (7.6)	24 (7.0)
Normal	155 (90.1)	152 (89.4)	307 (89.8)
High	6 (3.5)	5 (2.9)	11 (3.2)
Visit 18 (Week 16)			
N	174 (100.0)	162 (100.0)	336 (100.0)
Low	15 (8.6)	11 (6.8)	26 (7.7)
Normal	154 (88.5)	146 (90.1)	300 (89.3)
High	5 (2.9)	5 (3.1)	10 (3.0)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Low	16 (8.8)	12 (6.7)	28 (7.8)
Normal	159 (87.8)	161 (89.9)	320 (88.9)
High	6 (3.3)	6 (3.4)	12 (3.3)

N: Number of subjects, %: Percentage of subjects

14.3.5.16 Haematology - shift table - baseline to week 16 - safety analysis set

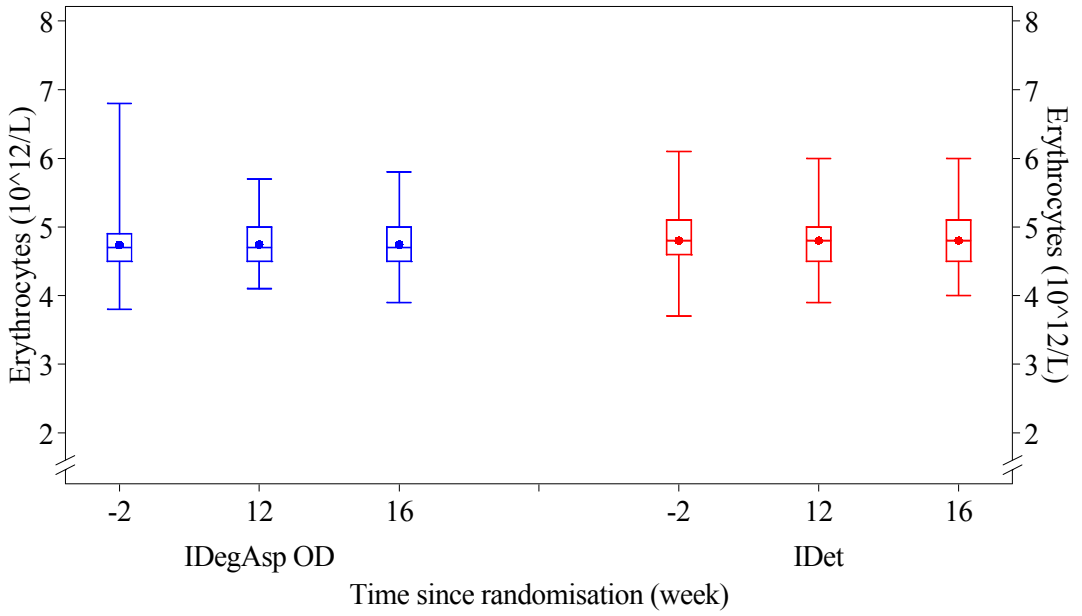
Number of Subjects	IDegAsp OD 181 Baseline				IDet 179 Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 18 (Week 16)								
Erythrocytes (10^12/L)								
Low	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	163 (90.1)	4 (2.2)	0 (0.0)	1 (0.6)	145 (81.0)	4 (2.2)	2 (1.1)
High	0 (0.0)	4 (2.2)	3 (1.7)	0 (0.0)	0 (0.0)	5 (2.8)	5 (2.8)	0 (0.0)
Missing	0 (0.0)	6 (3.3)	1 (0.6)	0 (0.0)	0 (0.0)	16 (8.9)	1 (0.6)	0 (0.0)
Haematocrit Blood (%)								
Low	1 (0.6)	1 (0.6)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	4 (2.2)	143 (79.0)	5 (2.8)	5 (2.8)	0 (0.0)	135 (75.4)	7 (3.9)	5 (2.8)
High	0 (0.0)	9 (5.0)	4 (2.2)	1 (0.6)	0 (0.0)	6 (3.4)	4 (2.2)	1 (0.6)
Missing	0 (0.0)	7 (3.9)	1 (0.6)	0 (0.0)	1 (0.6)	19 (10.6)	0 (0.0)	0 (0.0)
Haemoglobin Blood (mmol/L)								
Low	6 (3.3)	2 (1.1)	0 (0.0)	0 (0.0)	1 (0.6)	2 (1.1)	0 (0.0)	0 (0.0)
Normal	2 (1.1)	160 (88.4)	2 (1.1)	0 (0.0)	3 (1.7)	148 (82.7)	2 (1.1)	2 (1.1)
High	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.7)	1 (0.6)	0 (0.0)
Missing	1 (0.6)	6 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	17 (9.5)	0 (0.0)	0 (0.0)
Leukocytes (10^9/L)								
Low	5 (2.8)	10 (5.5)	0 (0.0)	0 (0.0)	2 (1.1)	9 (5.0)	0 (0.0)	0 (0.0)
Normal	4 (2.2)	144 (79.6)	6 (3.3)	0 (0.0)	6 (3.4)	135 (75.4)	3 (1.7)	2 (1.1)
High	0 (0.0)	1 (0.6)	4 (2.2)	0 (0.0)	0 (0.0)	2 (1.1)	3 (1.7)	0 (0.0)
Missing	3 (1.7)	4 (2.2)	0 (0.0)	0 (0.0)	1 (0.6)	15 (8.4)	1 (0.6)	0 (0.0)

N: Number of subjects, %: Percentage of subjects

Haematology - shift table - baseline to week 16 - safety analysis set

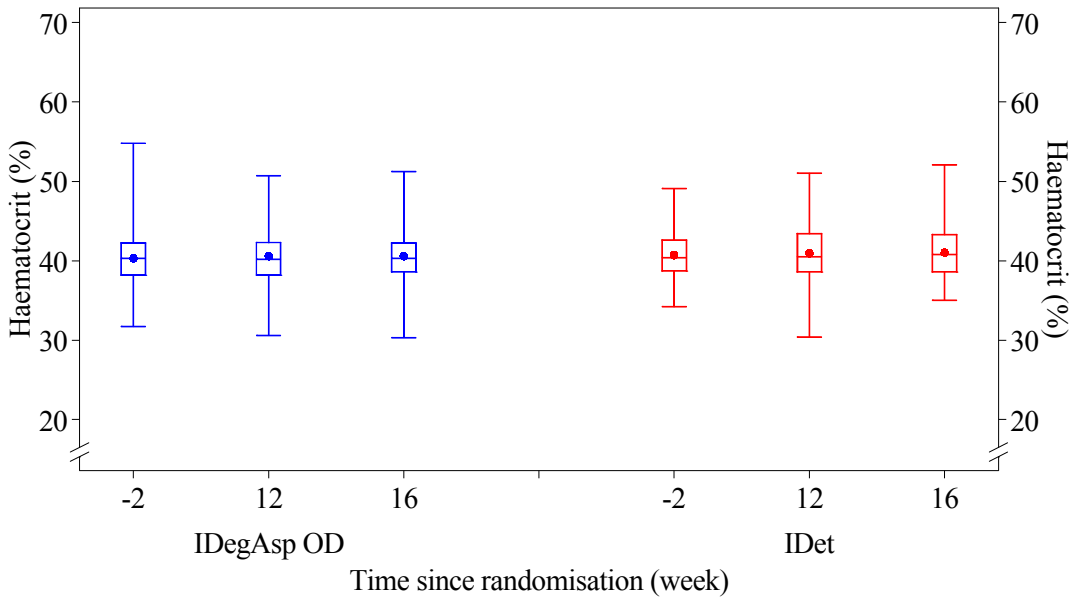
Number of Subjects	IDegAsp OD 181 Baseline				IDet 179 Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 18 (Week 16)								
Thrombocytes (10^9/L)								
Low	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	165 (91.2)	2 (1.1)	0 (0.0)	1 (0.6)	148 (82.7)	3 (1.7)	2 (1.1)
High	0 (0.0)	3 (1.7)	1 (0.6)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)	0 (0.0)
Missing	0 (0.0)	9 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (11.2)	2 (1.1)	0 (0.0)

N: Number of subjects, %: Percentage of subjects



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
Lower ref:Both age(1-6)[3.7],age(6-12)[3.8];Male,age(12-66)[4.1];Female,age(12-66)[3.8]
Upper ref:Both age(1-6)[5.3],age(6-12)[5.1];Male,age(12-66)[5.9];Female,age(12-66)[5.5]
nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:43 - fbox_numfind_v02.sas/e_erythrocyt_abs_box_obs_sas.cgm

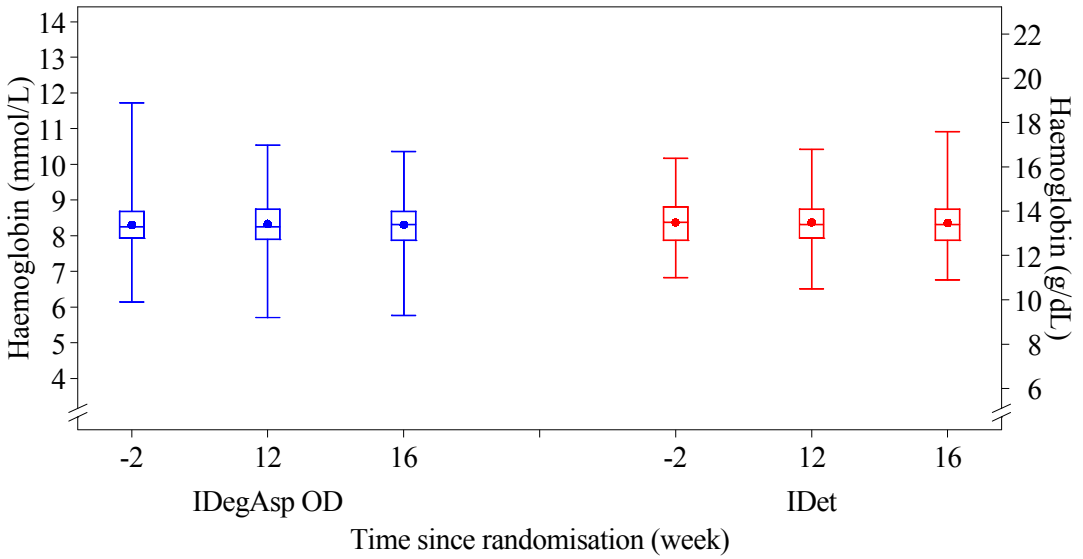
14.3.5.17 Haematology - erythrocytes – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
Lowerref:Both, Age(1-6)[28],Age(6-12)[33];Male,Age(12-18)[37],Male,Age(18-66)[40];
Female,Age(12-66)[35] Upperref:Both, Age(1-6)[42],Age(6-12)[43];
Male,Age(12-18)[51],Male,Age(18-66)[52];Female,Age(12-66)[47]

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:44 - fbox_numfind_v02.sas/e_haematocr_abs_box_obs_sas.cgm

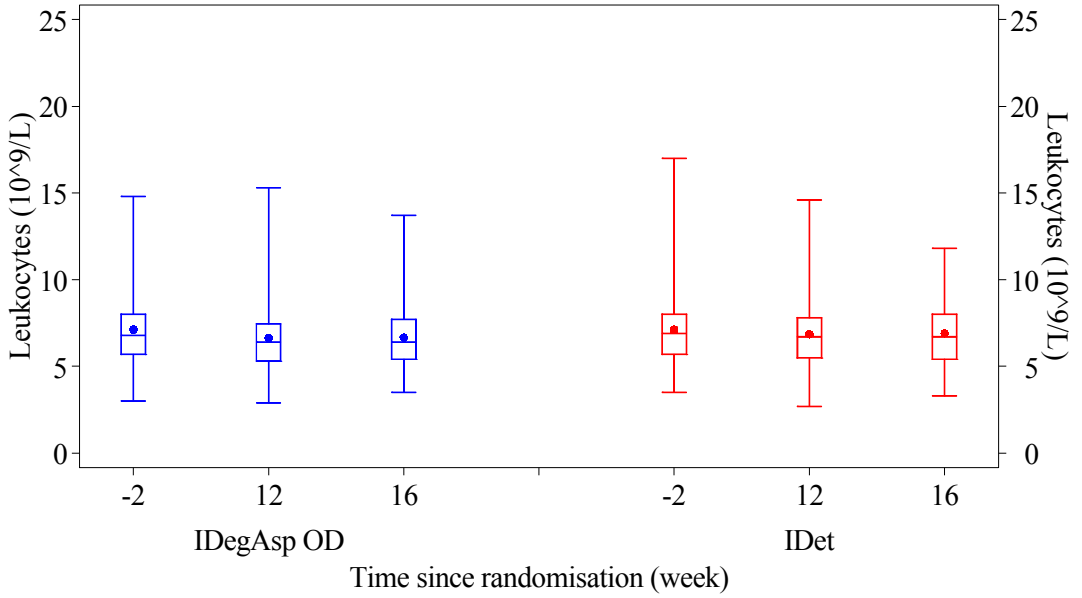
14.3.5.18 Haematology - haematocrit – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; Observed data
Lowerref:Age(1-6)[6.5],age(6-12)[7.1];Male,age(12-18)[7.6],Male,age(18-66)[8.1];
Female,age(12-66)[7.2]; Upperref:Age(1-6)[9.0],age(6-12)[9.3];Male,age(12-18)[10.5]
,Male,age(18-66)[10.9];Female,age(12-66)[10.0]

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:45 - fbox_numfind_v02.sas/e_haemoglob_abs_box_obs_sas.cgm

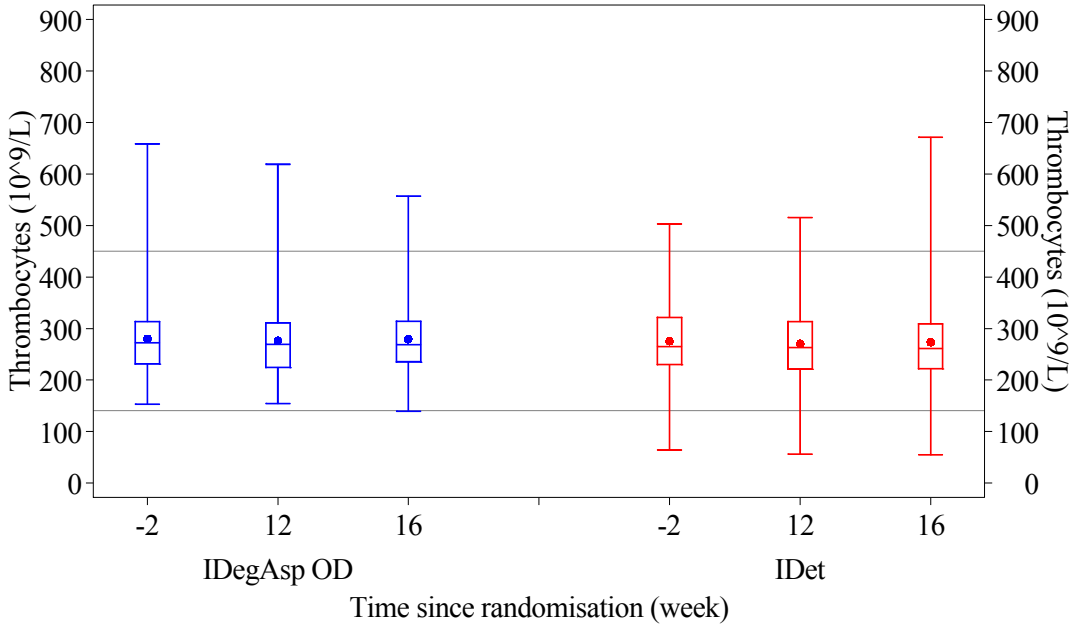
14.3.5.19 Haematology - haemoglobin – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; Observed data
Age 1-2 (F: L 6.5, U 13.0; M: L 6.0, U 13.5) Age 2-6 (F: L 4.9, U 13.2; M: L 5.1, U 13.4)
Age 6-12 (F: L 4.3, U 11.4; M: L 4.3, U 11.0) Age 12-16 (F: L 4.2, U 9.4; M: L 3.8, U 9.8) Age 16-111 (F: L 4.1, U 12.3; M: L 4.1, U 12.3) L: Low ref; U: Upper ref

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:46 - fbox_numfind_v02.sas/e_leukocyt_abs_box_obs_sas.cgm

14.3.5.20 Haematology - leukocytes – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
Horizontal lines indicate the reference range.

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:47 - fbox_numfind_v02.sas/e_thrombocyt_abs_box_obs_sas.cgm

14.3.5.21 Haematology - thrombocytes – box plot - safety analysis set

14.3.5.22 Lipids by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
HDL Cholesterol(mmol/L)			
Visit 1			
N	180	179	359
Mean (SD)	1.59 (0.37)	1.57 (0.39)	1.58 (0.38)
Median	1.60	1.53	1.55
Min ; Max	0.78 ; 2.77	0.65 ; 2.95	0.65 ; 2.95
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	1.56 (0.37)	1.60 (0.36)	1.58 (0.37)
Median	1.53	1.53	1.53
Min ; Max	0.67 ; 2.90	0.88 ; 3.03	0.67 ; 3.03
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	1.58 (0.36)	1.59 (0.36)	1.58 (0.36)
Median	1.53	1.58	1.55
Min ; Max	0.91 ; 3.06	0.80 ; 2.90	0.80 ; 3.06
End of trial visit			
N	181	179	360
Mean (SD)	1.57 (0.36)	1.57 (0.37)	1.57 (0.36)
Median	1.53	1.55	1.53
Min ; Max	0.85 ; 3.06	0.73 ; 2.90	0.73 ; 3.06

N: Number of subjects, SD: Standard deviation
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
HDL Cholesterol(mg/dL)			
Visit 1			
N	180	179	359
Mean (SD)	61.47 (14.16)	60.46 (14.91)	60.97 (14.53)
Median	61.58	59.07	59.85
Min ; Max	30.12 ; 106.95	25.10 ; 113.90	25.10 ; 113.90
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	60.23 (14.44)	61.69 (14.05)	60.95 (14.24)
Median	59.07	59.07	59.07
Min ; Max	25.87 ; 111.97	33.98 ; 116.99	25.87 ; 116.99
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	60.90 (14.00)	61.27 (13.96)	61.08 (13.96)
Median	59.07	61.00	59.85
Min ; Max	35.14 ; 118.15	30.89 ; 111.97	30.89 ; 118.15
End of trial visit			
N	181	179	360
Mean (SD)	60.59 (13.98)	60.54 (14.14)	60.57 (14.04)
Median	59.07	59.85	59.07
Min ; Max	32.82 ; 118.15	28.19 ; 111.97	28.19 ; 118.15

N: Number of subjects, SD: Standard deviation
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
LDL Cholesterol(mmol/L)			
Visit 1			
N	180	179	359
Mean (SD)	2.23 (0.64)	2.31 (0.65)	2.27 (0.64)
Median	2.19	2.28	2.23
Min ; Max	0.88 ; 4.35	0.80 ; 4.90	0.80 ; 4.90
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	2.19 (0.57)	2.29 (0.77)	2.24 (0.68)
Median	2.17	2.23	2.18
Min ; Max	0.80 ; 3.89	0.83 ; 6.14	0.80 ; 6.14
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	2.25 (0.70)	2.32 (0.69)	2.29 (0.69)
Median	2.15	2.28	2.23
Min ; Max	0.96 ; 5.36	0.80 ; 4.82	0.80 ; 5.36
End of trial visit			
N	181	179	360
Mean (SD)	2.27 (0.69)	2.32 (0.70)	2.29 (0.69)
Median	2.18	2.25	2.23
Min ; Max	0.96 ; 5.36	0.80 ; 4.82	0.80 ; 5.36

N: Number of subjects, SD: Standard deviation
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
LDL Cholesterol(mg/dL)			
Visit 1			
N	180	179	359
Mean (SD)	85.98 (24.53)	89.10 (25.22)	87.54 (24.89)
Median	84.56	88.03	86.10
Min ; Max	33.98 ; 167.95	30.89 ; 189.19	30.89 ; 189.19
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	84.62 (22.11)	88.33 (29.70)	86.46 (26.18)
Median	83.59	86.10	84.17
Min ; Max	30.89 ; 150.19	32.05 ; 237.07	30.89 ; 237.07
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	86.94 (27.03)	89.65 (26.62)	88.27 (26.82)
Median	83.01	88.03	86.10
Min ; Max	37.07 ; 206.95	30.89 ; 186.10	30.89 ; 206.95
End of trial visit			
N	181	179	360
Mean (SD)	87.47 (26.57)	89.60 (26.93)	88.53 (26.73)
Median	84.17	86.87	86.10
Min ; Max	37.07 ; 206.95	30.89 ; 186.10	30.89 ; 206.95

N: Number of subjects, SD: Standard deviation
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Total Cholesterol(mmol/L)			
Visit 1			
N	180	179	359
Mean (SD)	4.31 (0.83)	4.34 (0.81)	4.33 (0.82)
Median	4.25	4.30	4.27
Min ; Max	2.69 ; 7.25	2.49 ; 7.43	2.49 ; 7.43
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	4.19 (0.74)	4.33 (0.93)	4.26 (0.84)
Median	4.17	4.25	4.20
Min ; Max	1.99 ; 6.50	2.31 ; 8.55	1.99 ; 8.55
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	4.27 (0.85)	4.39 (0.87)	4.33 (0.86)
Median	4.12	4.20	4.17
Min ; Max	2.67 ; 7.56	2.38 ; 7.25	2.38 ; 7.56
End of trial visit			
N	181	179	360
Mean (SD)	4.29 (0.84)	4.39 (0.88)	4.34 (0.86)
Median	4.14	4.20	4.17
Min ; Max	2.67 ; 7.56	2.38 ; 7.25	2.38 ; 7.56

N: Number of subjects, SD: Standard deviation
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Total Cholesterol(mg/dL)			
Visit 1			
N	180	179	359
Mean (SD)	166.28 (32.17)	167.75 (31.13)	167.01 (31.62)
Median	164.09	166.02	164.86
Min ; Max	103.86 ; 279.92	96.14 ; 286.87	96.14 ; 286.87
Visit 14 (Week 12)			
N	172	169	341
Mean (SD)	161.79 (28.53)	167.14 (35.97)	164.44 (32.50)
Median	161.00	164.09	162.16
Min ; Max	76.83 ; 250.97	89.19 ; 330.12	76.83 ; 330.12
Visit 18 (Week 16)			
N	172	165	337
Mean (SD)	165.00 (32.70)	169.60 (33.40)	167.25 (33.08)
Median	159.07	162.16	161.00
Min ; Max	103.09 ; 291.89	91.89 ; 279.92	91.89 ; 291.89
End of trial visit			
N	181	179	360
Mean (SD)	165.63 (32.43)	169.57 (33.99)	167.59 (33.23)
Median	159.85	162.16	161.00
Min ; Max	103.09 ; 291.89	91.89 ; 279.92	91.89 ; 291.89

N: Number of subjects, SD: Standard deviation
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

14.3.5.23 Lipids by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Ch HDL Cholesterol(mmol/L)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	-0.03 (0.28)	0.02 (0.30)	-0.01 (0.29)
Median	-0.05	0.02	0.00
Min ; Max	-0.88 ; 0.83	-1.01 ; 1.16	-1.01 ; 1.16
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	-0.02 (0.28)	0.01 (0.26)	-0.01 (0.27)
Median	0.00	-0.02	-0.01
Min ; Max	-0.85 ; 0.88	-0.96 ; 0.98	-0.96 ; 0.98
End of trial visit			
N	180	179	359
Mean (SD)	-0.02 (0.27)	0.00 (0.26)	-0.01 (0.27)
Median	0.00	-0.02	0.00
Min ; Max	-0.85 ; 0.88	-0.96 ; 0.98	-0.96 ; 0.98

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch HDL Cholesterol(mg/dL)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	-1.32 (10.92)	0.87 (11.46)	-0.23 (11.23)
Median	-1.93	0.77	0.00
Min ; Max	-33.98 ; 32.05	-39.00 ; 44.79	-39.00 ; 44.79
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	-0.83 (10.72)	0.29 (9.97)	-0.28 (10.36)
Median	0.00	-0.77	-0.39
Min ; Max	-32.82 ; 33.98	-37.07 ; 37.84	-37.07 ; 37.84
End of trial visit			
N	180	179	359
Mean (SD)	-0.87 (10.59)	0.08 (10.12)	-0.39 (10.36)
Median	0.00	-0.77	0.00
Min ; Max	-32.82 ; 33.98	-37.07 ; 37.84	-37.07 ; 37.84

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch LDL Cholesterol(mmol/L)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	-0.02 (0.50)	-0.02 (0.54)	-0.02 (0.52)
Median	0.00	-0.02	-0.01
Min ; Max	-1.63 ; 1.27	-1.91 ; 2.75	-1.91 ; 2.75
Visit 18 (Week 16)			
N	170	165	335
Mean (SD)	0.05 (0.56)	0.00 (0.53)	0.03 (0.54)
Median	0.08	-0.03	0.02
Min ; Max	-2.15 ; 3.78	-1.14 ; 3.01	-2.15 ; 3.78
End of trial visit			
N	180	179	359
Mean (SD)	0.04 (0.55)	0.01 (0.52)	0.03 (0.54)
Median	0.07	0.00	0.00
Min ; Max	-2.15 ; 3.78	-1.14 ; 3.01	-2.15 ; 3.78

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
LDL Cholesterol Ch(mg/dL)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	-0.71 (19.21)	-0.65 (20.87)	-0.68 (20.02)
Median	0.00	-0.77	-0.39
Min ; Max	-62.93 ; 49.03	-73.75 ; 106.18	-73.75 ; 106.18
Visit 18 (Week 16)			
N	170	165	335
Mean (SD)	1.87 (21.47)	0.16 (20.34)	1.03 (20.91)
Median	3.09	-1.16	0.77
Min ; Max	-83.01 ; 145.95	-44.02 ; 116.22	-83.01 ; 145.95
End of trial visit			
N	180	179	359
Mean (SD)	1.57 (21.29)	0.50 (20.18)	1.04 (20.72)
Median	2.70	0.00	0.00
Min ; Max	-83.01 ; 145.95	-44.02 ; 116.22	-83.01 ; 145.95

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Total Cholesterol(mmol/L)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	-0.09 (0.65)	-0.01 (0.66)	-0.05 (0.66)
Median	-0.11	-0.02	-0.08
Min ; Max	-2.67 ; 1.55	-2.62 ; 2.67	-2.67 ; 2.67
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	-0.00 (0.73)	0.04 (0.66)	0.02 (0.70)
Median	0.03	0.00	0.02
Min ; Max	-3.26 ; 4.46	-1.32 ; 3.24	-3.26 ; 4.46
End of trial visit			
N	180	179	359
Mean (SD)	-0.01 (0.74)	0.05 (0.65)	0.02 (0.70)
Median	0.03	0.00	0.00
Min ; Max	-3.26 ; 4.46	-1.32 ; 3.24	-3.26 ; 4.46

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Lipids by treatment week – change from baseline – descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch Total Cholesterol(mg/dL)			
Visit 14 (Week 12)			
N	171	169	340
Mean (SD)	-3.44 (25.05)	-0.29 (25.65)	-1.87 (25.36)
Median	-4.25	-0.77	-3.09
Min ; Max	-103.09 ; 59.85	-101.16 ; 103.09	-103.09 ; 103.09
Visit 18 (Week 16)			
N	171	165	336
Mean (SD)	-0.15 (28.28)	1.51 (25.31)	0.66 (26.84)
Median	1.16	0.00	0.77
Min ; Max	-125.87 ; 172.20	-50.97 ; 125.10	-125.87 ; 172.20
End of trial visit			
N	180	179	359
Mean (SD)	-0.54 (28.40)	1.82 (25.25)	0.64 (26.87)
Median	0.97	0.00	0.00
Min ; Max	-125.87 ; 172.20	-50.97 ; 125.10	-125.87 ; 172.20

N: Number of subjects, SD: Standard deviation, Ch: Change from baseline
HDL: High-density lipoprotein, LDL: Low-density lipoprotein

14.3.5.24 Lipids by treatment week - summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	181	179	360
HDL Cholesterol Serum (mmol/L)			
Visit 1			
N	180 (100.0)	179 (100.0)	359 (100.0)
Low	24 (13.3)	26 (14.5)	50 (13.9)
Normal	156 (86.7)	153 (85.5)	309 (86.1)
Visit 14 (Week 12)			
N	172 (100.0)	169 (100.0)	341 (100.0)
Low	25 (14.5)	16 (9.5)	41 (12.0)
Normal	147 (85.5)	153 (90.5)	300 (88.0)
Visit 18 (Week 16)			
N	172 (100.0)	165 (100.0)	337 (100.0)
Low	22 (12.8)	22 (13.3)	44 (13.1)
Normal	150 (87.2)	143 (86.7)	293 (86.9)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Low	24 (13.3)	27 (15.1)	51 (14.2)
Normal	157 (86.7)	152 (84.9)	309 (85.8)

N: Number of Subjects, %: Percentage of Subjects
HDL: High density lipoprotein, LDL: Low density lipoprotein

Lipids by treatment week - summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
HDL Cholesterol Serum (mg/dL)			
Visit 1			
N	180 (100.0)	179 (100.0)	359 (100.0)
Low	24 (13.3)	26 (14.5)	50 (13.9)
Normal	156 (86.7)	153 (85.5)	309 (86.1)
Visit 14 (Week 12)			
N	172 (100.0)	169 (100.0)	341 (100.0)
Low	25 (14.5)	16 (9.5)	41 (12.0)
Normal	147 (85.5)	153 (90.5)	300 (88.0)
Visit 18 (Week 16)			
N	172 (100.0)	165 (100.0)	337 (100.0)
Low	22 (12.8)	22 (13.3)	44 (13.1)
Normal	150 (87.2)	143 (86.7)	293 (86.9)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Low	24 (13.3)	27 (15.1)	51 (14.2)
Normal	157 (86.7)	152 (84.9)	309 (85.8)

N: Number of Subjects, %: Percentage of Subjects
HDL: High density lipoprotein, LDL: Low density lipoprotein

Lipids by treatment week - summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
LDL Cholesterol serum (mmol/L)			
Visit 1			
N	180 (100.0)	179 (100.0)	359 (100.0)
Normal	152 (84.4)	148 (82.7)	300 (83.6)
High	28 (15.6)	31 (17.3)	59 (16.4)
Visit 14 (Week 12)			
N	172 (100.0)	169 (100.0)	341 (100.0)
Normal	152 (88.4)	137 (81.1)	289 (84.8)
High	20 (11.6)	32 (18.9)	52 (15.2)
Visit 18 (Week 16)			
N	171 (100.0)	165 (100.0)	336 (100.0)
Normal	138 (80.7)	132 (80.0)	270 (80.4)
High	33 (19.3)	33 (20.0)	66 (19.6)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	146 (80.7)	143 (79.9)	289 (80.3)
High	35 (19.3)	36 (20.1)	71 (19.7)

N: Number of Subjects, %: Percentage of Subjects
HDL: High density lipoprotein, LDL: Low density lipoprotein

Lipids by treatment week - summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
LDL Cholesterol serum (mg/dL)			
Visit 1			
N	180 (100.0)	179 (100.0)	359 (100.0)
Normal	152 (84.4)	148 (82.7)	300 (83.6)
High	28 (15.6)	31 (17.3)	59 (16.4)
Visit 14 (Week 12)			
N	172 (100.0)	169 (100.0)	341 (100.0)
Normal	152 (88.4)	137 (81.1)	289 (84.8)
High	20 (11.6)	32 (18.9)	52 (15.2)
Visit 18 (Week 16)			
N	171 (100.0)	165 (100.0)	336 (100.0)
Normal	138 (80.7)	132 (80.0)	270 (80.4)
High	33 (19.3)	33 (20.0)	66 (19.6)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	146 (80.7)	143 (79.9)	289 (80.3)
High	35 (19.3)	36 (20.1)	71 (19.7)

N: Number of Subjects, %: Percentage of Subjects
HDL: High density lipoprotein, LDL: Low density lipoprotein

Lipids by treatment week - summary - Safety Analysis Set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Total Cholesterol Serum (mmol/L)			
Visit 1			
N	180 (100.0)	179 (100.0)	359 (100.0)
Normal	98 (54.4)	99 (55.3)	197 (54.9)
High	82 (45.6)	80 (44.7)	162 (45.1)
Visit 14 (Week 12)			
N	172 (100.0)	169 (100.0)	341 (100.0)
Normal	102 (59.3)	94 (55.6)	196 (57.5)
High	70 (40.7)	75 (44.4)	145 (42.5)
Visit 18 (Week 16)			
N	172 (100.0)	165 (100.0)	337 (100.0)
Normal	102 (59.3)	93 (56.4)	195 (57.9)
High	70 (40.7)	72 (43.6)	142 (42.1)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	106 (58.6)	101 (56.4)	207 (57.5)
High	75 (41.4)	78 (43.6)	153 (42.5)

N: Number of Subjects, %: Percentage of Subjects
HDL: High density lipoprotein, LDL: Low density lipoprotein

Lipids by treatment week - summary - Safety Analysis Set

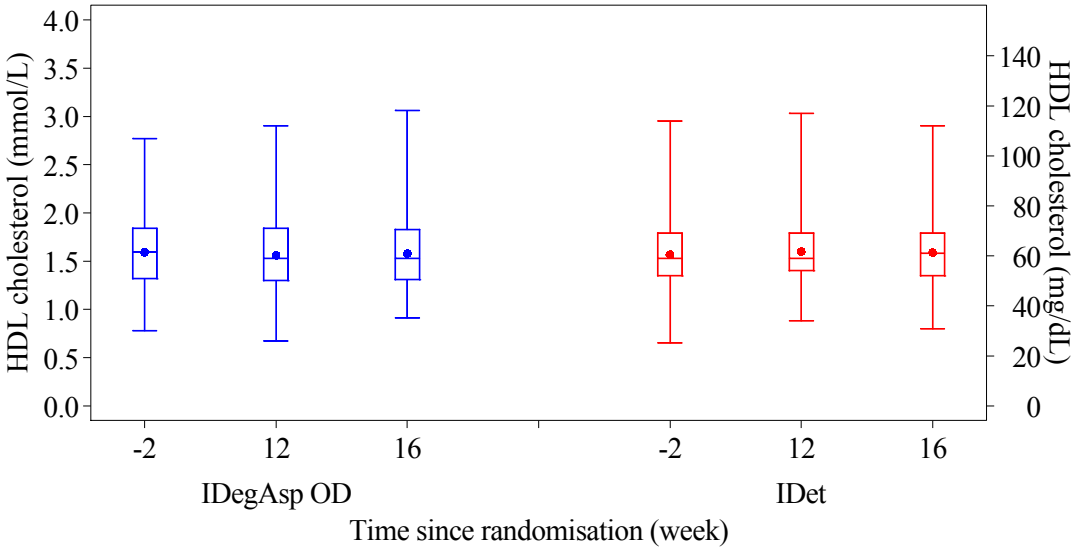
	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Total Cholesterol Serum (mg/dL)			
Visit 1			
N	180 (100.0)	179 (100.0)	359 (100.0)
Normal	98 (54.4)	99 (55.3)	197 (54.9)
High	82 (45.6)	80 (44.7)	162 (45.1)
Visit 14 (Week 12)			
N	172 (100.0)	169 (100.0)	341 (100.0)
Normal	102 (59.3)	94 (55.6)	196 (57.5)
High	70 (40.7)	75 (44.4)	145 (42.5)
Visit 18 (Week 16)			
N	172 (100.0)	165 (100.0)	337 (100.0)
Normal	102 (59.3)	93 (56.4)	195 (57.9)
High	70 (40.7)	72 (43.6)	142 (42.1)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	106 (58.6)	101 (56.4)	207 (57.5)
High	75 (41.4)	78 (43.6)	153 (42.5)

N: Number of Subjects, %: Percentage of Subjects
HDL: High density lipoprotein, LDL: Low density lipoprotein

14.3.5.25 Lipids - shift table - baseline to week 16 - safety analysis set

Number of Subjects	IDegAsp OD 181 Baseline				IDet 179 Baseline			
	Low N (%)	Normal N (%)	High N (%)	Missing N (%)	Low N (%)	Normal N (%)	High N (%)	Missing N (%)
Visit 18 (Week 16)								
HDL Cholesterol Serum (mmol/L)								
Low	9 (5.0)	13 (7.2)	0 (0.0)	0 (0.0)	14 (7.8)	8 (4.5)	0 (0.0)	0 (0.0)
Normal	14 (7.7)	135 (74.6)	0 (0.0)	1 (0.6)	8 (4.5)	135 (75.4)	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	1 (0.6)	8 (4.4)	0 (0.0)	0 (0.0)	4 (2.2)	10 (5.6)	0 (0.0)	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)	129 (71.3)	8 (4.4)	1 (0.6)	0 (0.0)	119 (66.5)	13 (7.3)	0 (0.0)
High	0 (0.0)	15 (8.3)	18 (9.9)	0 (0.0)	0 (0.0)	16 (8.9)	17 (9.5)	0 (0.0)
Missing	0 (0.0)	8 (4.4)	2 (1.1)	0 (0.0)	0 (0.0)	13 (7.3)	1 (0.6)	0 (0.0)
Total 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)	78 (43.1)	23 (12.7)	1 (0.6)	0 (0.0)	73 (40.8)	20 (11.2)	0 (0.0)
High	0 (0.0)	16 (8.8)	54 (29.8)	0 (0.0)	0 (0.0)	18 (10.1)	54 (30.2)	0 (0.0)
Missing	0 (0.0)	4 (2.2)	5 (2.8)	0 (0.0)	0 (0.0)	8 (4.5)	6 (3.4)	0 (0.0)

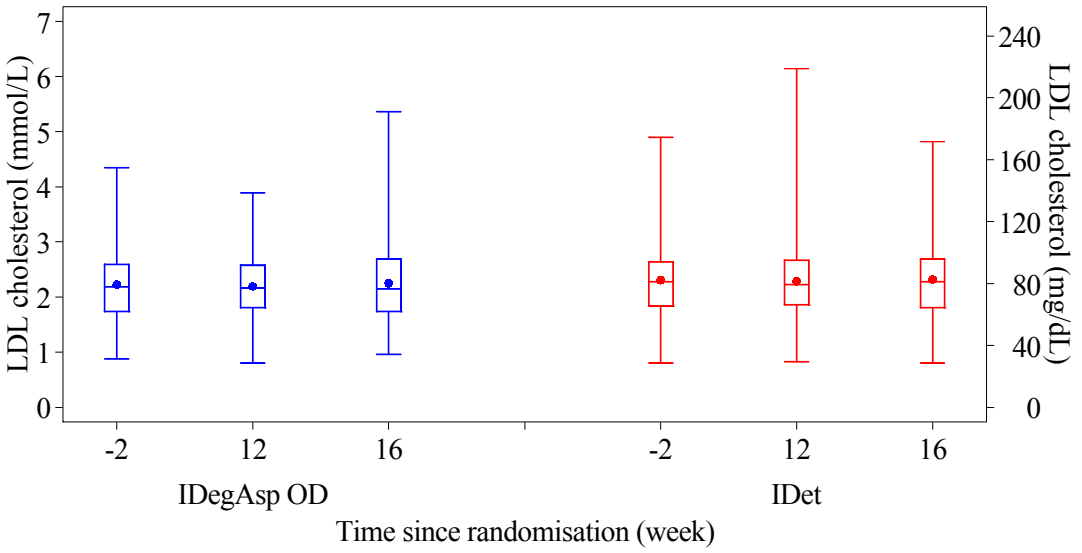
N: Number of subjects, %: Percentage of subjects, HDL: High density lipoprotein, LDL: Low density lipoprotein



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
HDL: High density lipoprotein
Lower ref.: Both,Age(0-18)[1.18], Age(18-111)[1.56];
Upper ref.: Both,Age(0-18)[99.00], Age(18-111)[99.00]

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:52 - fbox_numfind_v02.sas/e_hdl_abs_box_obs_sas.cgm

14.3.5.26 Lipid – HDL cholesterol – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; Observed data
LDL: Low density lipoprotein
Lower ref.: Both, Age(0-18)[0], Age(18-111)[0]
Upper ref.: Both, Age(0-18)[2.84], Age(18-111)[3.36]

nn5401/nn5401-3816/er_20150312_ctr/stats
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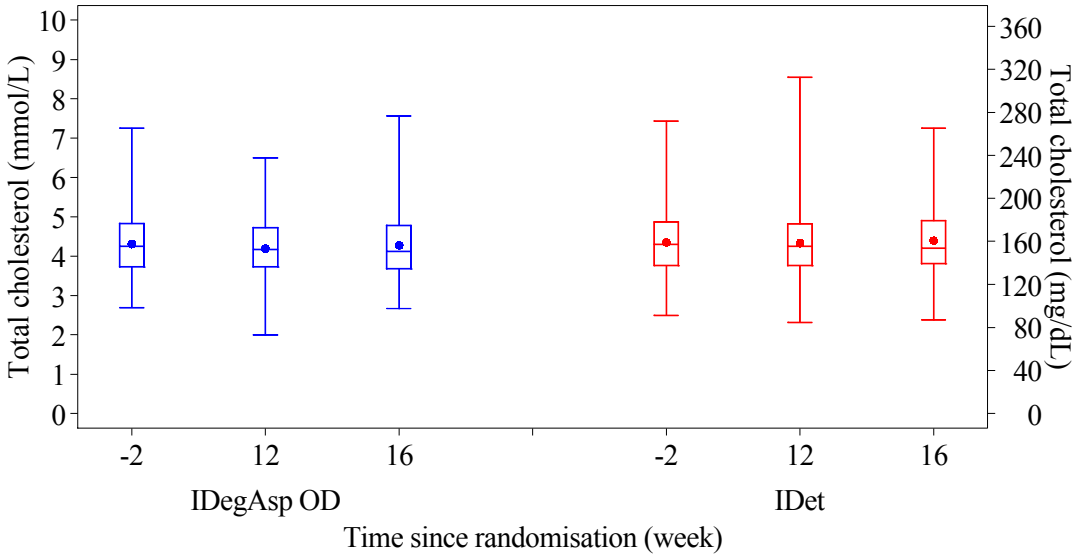
14.3.5.27 Lipid – LDL cholesterol – box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY; Observed data
Lower ref.: Both, Age(0-18)[0], Age(18-111)[0]
Upper ref.: Both, Age(0-18)[4.39], Age(18-111)[5.17]

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:54 - fbox_numfind_v02.sas/e_t_chol_abs_box_obs_sas.cgm

14.3.5.28 Lipid – total cholesterol serum – box plot - safety analysis set

14.3.6 Other safety observations displays

14.3.6.1 Physical examination by treatment week - summary - safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Number of Subjects	181	179	360
Cardiovascular System			
Visit 1			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	178 (98.3)	176 (98.3)	354 (98.3)
Abnormal, Not Clinically Significant	3 (1.7)	3 (1.7)	6 (1.7)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 18 (Week 16)			
N	175 (100.0)	168 (100.0)	343 (100.0)
Normal	173 (98.9)	168 (100.0)	341 (99.4)
Abnormal, Not Clinically Significant	2 (1.1)	0 (0.0)	2 (0.6)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	178 (98.3)	179 (100.0)	357 (99.2)
Abnormal, Not Clinically Significant	3 (1.7)	0 (0.0)	3 (0.8)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, %: Proportion of subjects

Physical examination by treatment week - summary - safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Central and Peripheral Nervous System			
Visit 1			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	180 (99.4)	178 (99.4)	358 (99.4)
Abnormal, Not Clinically Significant	1 (0.6)	1 (0.6)	2 (0.6)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 18 (Week 16)			
N	175 (100.0)	168 (100.0)	343 (100.0)
Normal	174 (99.4)	167 (99.4)	341 (99.4)
Abnormal, Not Clinically Significant	1 (0.6)	1 (0.6)	2 (0.6)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	180 (99.4)	178 (99.4)	358 (99.4)
Abnormal, Not Clinically Significant	1 (0.6)	1 (0.6)	2 (0.6)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, %: Proportion of subjects

Physical examination by treatment week - summary - safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Gastrointestinal System incl. Mouth			
Visit 1			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	180 (99.4)	175 (97.8)	355 (98.6)
Abnormal, Not Clinically Significant	1 (0.6)	4 (2.2)	5 (1.4)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 18 (Week 16)			
N	175 (100.0)	168 (100.0)	343 (100.0)
Normal	174 (99.4)	165 (98.2)	339 (98.8)
Abnormal, Not Clinically Significant	1 (0.6)	3 (1.8)	4 (1.2)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	180 (99.4)	176 (98.3)	356 (98.9)
Abnormal, Not Clinically Significant	1 (0.6)	3 (1.7)	4 (1.1)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, %: Proportion of subjects

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	181 (100.0)	179 (100.0)	360 (100.0)
Normal	161 (89.0)	165 (92.2)	326 (90.6)
Abnormal, Not Clinically Significant	20 (11.0)	14 (7.8)	34 (9.4)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 18 (Week 16)			
N	175 (100.0)	168 (100.0)	343 (100.0)
Normal	164 (93.7)	164 (97.6)	328 (95.6)
Abnormal, Not Clinically Significant	11 (6.3)	4 (2.4)	15 (4.4)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	170 (93.9)	172 (96.1)	342 (95.0)
Abnormal, Not Clinically Significant	11 (6.1)	7 (3.9)	18 (5.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, %: Proportion of subjects

Physical examination by treatment week - summary - safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Musculoskeletal System			
Visit 1			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	171 (94.5)	174 (97.2)	345 (95.8)
Abnormal, Not Clinically Significant	10 (5.5)	5 (2.8)	15 (4.2)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 18 (Week 16)			
N	175 (100.0)	168 (100.0)	343 (100.0)
Normal	164 (93.7)	162 (96.4)	326 (95.0)
Abnormal, Not Clinically Significant	11 (6.3)	6 (3.6)	17 (5.0)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	170 (93.9)	173 (96.6)	343 (95.3)
Abnormal, Not Clinically Significant	11 (6.1)	6 (3.4)	17 (4.7)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, %: Proportion of subjects

Physical examination by treatment week - summary - safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Respiratory System			
Visit 1			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	180 (99.4)	178 (99.4)	358 (99.4)
Abnormal, Not Clinically Significant	1 (0.6)	1 (0.6)	2 (0.6)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
Visit 18 (Week 16)			
N	175 (100.0)	168 (100.0)	343 (100.0)
Normal	174 (99.4)	168 (100.0)	342 (99.7)
Abnormal, Not Clinically Significant	1 (0.6)	0 (0.0)	1 (0.3)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	180 (99.4)	179 (100.0)	359 (99.7)
Abnormal, Not Clinically Significant	1 (0.6)	0 (0.0)	1 (0.3)
Abnormal, Clinically Significant	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, %: Proportion of subjects

Physical examination by treatment week - summary - safety analysis set

	IDegAsp OD N (%)	IDet N (%)	Total N (%)
Skin			
Visit 1			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	153 (84.5)	148 (82.7)	301 (83.6)
Abnormal, Not Clinically Significant	27 (14.9)	30 (16.8)	57 (15.8)
Abnormal, Clinically Significant	1 (0.6)	1 (0.6)	2 (0.6)
Visit 18 (Week 16)			
N	175 (100.0)	168 (100.0)	343 (100.0)
Normal	150 (85.7)	155 (92.3)	305 (88.9)
Abnormal, Not Clinically Significant	23 (13.1)	11 (6.5)	34 (9.9)
Abnormal, Clinically Significant	2 (1.1)	2 (1.2)	4 (1.2)
End of trial visit			
N	181 (100.0)	179 (100.0)	360 (100.0)
Normal	156 (86.2)	164 (91.6)	320 (88.9)
Abnormal, Not Clinically Significant	23 (12.7)	13 (7.3)	36 (10.0)
Abnormal, Clinically Significant	2 (1.1)	2 (1.1)	4 (1.1)

N: Number of subjects, %: Proportion of subjects

14.3.6.2 Vital signs by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Diastolic BP(mmHg)			
Visit 1			
N	180	177	357
Mean (SD)	65.4 (8.5)	65.5 (9.6)	65.4 (9.1)
Median	65.0	65.0	65.0
Min ; Max	40.0 ; 88.0	40.0 ; 99.0	40.0 ; 99.0
Visit 18 (Week 16)			
N	175	167	342
Mean (SD)	65.7 (8.0)	66.0 (8.6)	65.9 (8.3)
Median	65.0	65.0	65.0
Min ; Max	40.0 ; 84.0	40.0 ; 88.0	40.0 ; 88.0
End of trial visit			
N	181	179	360
Mean (SD)	65.6 (8.0)	65.7 (8.8)	65.6 (8.4)
Median	65.0	65.0	65.0
Min ; Max	40.0 ; 84.0	40.0 ; 88.0	40.0 ; 88.0

N: Number of subjects, SD: Standard deviation, BP: Blood pressure

Vital signs by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Systolic BP(mmHg)			
Visit 1			
N	180	177	357
Mean (SD)	106.8 (12.9)	107.5 (12.1)	107.2 (12.5)
Median	105.0	109.0	107.0
Min ; Max	60.0 ; 141.0	70.0 ; 147.0	60.0 ; 147.0
Visit 18 (Week 16)			
N	175	167	342
Mean (SD)	105.6 (12.8)	107.5 (11.5)	106.5 (12.2)
Median	105.0	110.0	107.0
Min ; Max	70.0 ; 134.0	70.0 ; 146.0	70.0 ; 146.0
End of trial visit			
N	181	179	360
Mean (SD)	105.6 (12.6)	107.1 (12.0)	106.3 (12.3)
Median	105.0	109.0	106.0
Min ; Max	70.0 ; 134.0	70.0 ; 146.0	70.0 ; 146.0

N: Number of subjects, SD: Standard deviation, BP: Blood pressure

Vital signs by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Pulse(beats/min)			
Visit 1			
N	180	178	358
Mean (SD)	84.2 (13.0)	81.6 (12.1)	82.9 (12.7)
Median	83.0	81.5	82.0
Min ; Max	50.0 ; 118.0	47.0 ; 121.0	47.0 ; 121.0
Visit 18 (Week 16)			
N	174	167	341
Mean (SD)	82.7 (10.9)	82.3 (11.1)	82.5 (11.0)
Median	82.0	82.0	82.0
Min ; Max	56.0 ; 120.0	51.0 ; 110.0	51.0 ; 120.0
End of trial visit			
N	181	179	360
Mean (SD)	82.8 (11.3)	82.5 (11.2)	82.7 (11.2)
Median	82.0	82.0	82.0
Min ; Max	56.0 ; 120.0	51.0 ; 110.0	51.0 ; 120.0

N: Number of subjects, SD: Standard deviation, BP: Blood pressure

14.3.6.3 Vital signs by treatment week - change from baseline - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Ch. in Diastolic Blood Pressure(mmHg)			
Visit 18 (Week 16)			
N	174	165	339
Mean (SD)	0.3 (8.3)	0.3 (8.2)	0.3 (8.2)
Median	0.0	0.0	0.0
Min ; Max	-30.0 ; 25.0	-20.0 ; 22.0	-30.0 ; 25.0
End of trial visit			
N	180	177	357
Mean (SD)	0.2 (8.2)	0.4 (8.2)	0.3 (8.2)
Median	0.0	0.0	0.0
Min ; Max	-30.0 ; 25.0	-20.0 ; 22.0	-30.0 ; 25.0

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline
nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:45:55 - tdesc_numfind_tpl_t019_v01_3816.sas/t_vital_sign_chb_descp_sas.txt

Vital signs by treatment week - change from baseline - descriptive statistics - safety analysis set

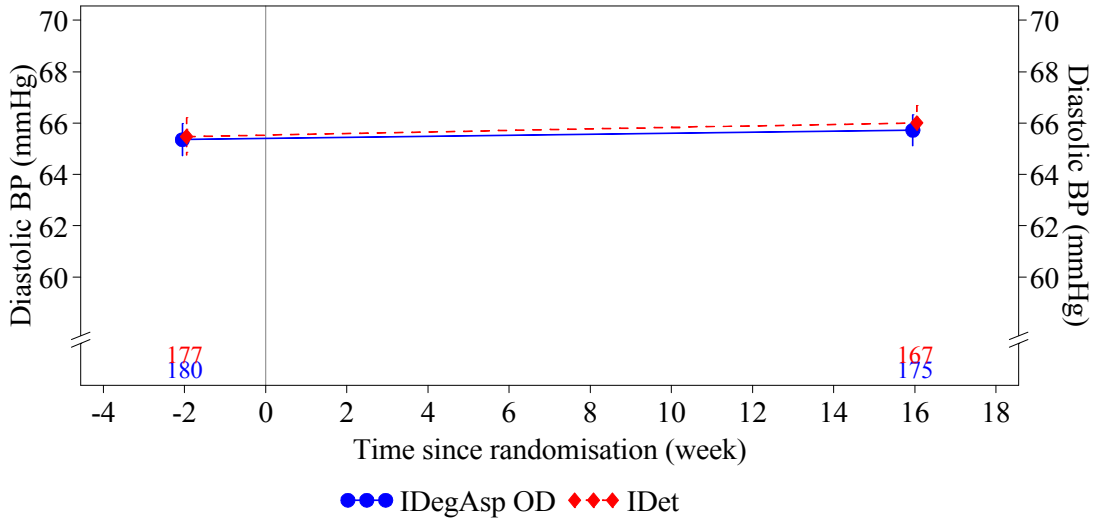
	IDegAsp OD	IDet	Total
Ch. in Systolic Blood Pressure(mmHg)			
Visit 18 (Week 16)			
N	174	165	339
Mean (SD)	-1.1 (11.4)	-0.1 (10.4)	-0.6 (10.9)
Median	0.0	0.0	0.0
Min ; Max	-35.0 ; 28.0	-30.0 ; 26.0	-35.0 ; 28.0
End of trial visit			
N	180	177	357
Mean (SD)	-1.2 (11.3)	-0.2 (10.1)	-0.7 (10.7)
Median	0.0	0.0	0.0
Min ; Max	-35.0 ; 28.0	-30.0 ; 26.0	-35.0 ; 28.0

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline

Vital signs by treatment week - change from baseline - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch. in Pulse(beats/min)			
Visit 18 (Week 16)			
N	173	166	339
Mean (SD)	-1.6 (11.6)	0.9 (11.8)	-0.4 (11.8)
Median	0.0	-0.5	0.0
Min ; Max	-35.0 ; 40.0	-38.0 ; 37.0	-38.0 ; 40.0
End of trial visit			
N	180	178	358
Mean (SD)	-1.4 (11.9)	0.9 (12.0)	-0.2 (12.0)
Median	0.0	0.0	0.0
Min ; Max	-35.0 ; 40.0	-38.0 ; 37.0	-38.0 ; 40.0

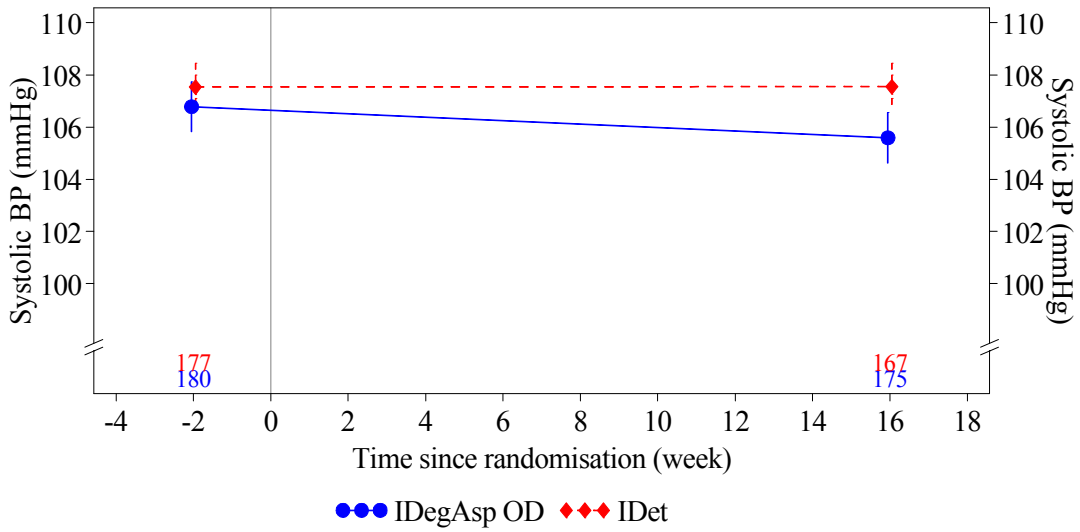
N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
BP: Blood pressure
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:45:56 - fmean_numfind_deg_cust.sas/e_vital_diasto_ab_mean_ob_sas.cgm

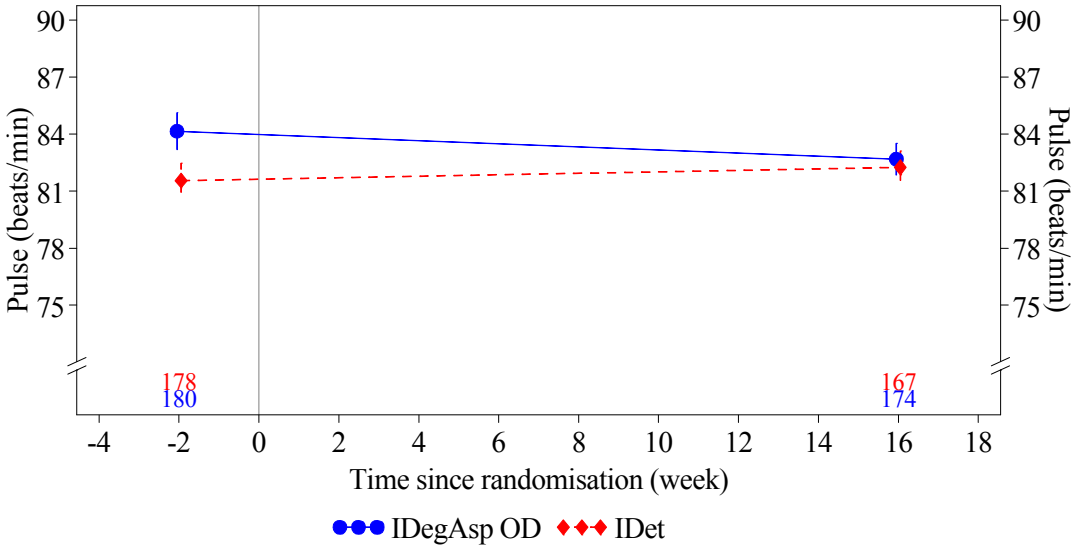
14.3.6.4 Diastolic blood pressure - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
BP: Blood pressure
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:45:57 - fmean_numfind_deg_cust.sas/e_vital_systo_ab_mean_ob_sas.cgm

14.3.6.5 Systolic blood pressure - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:46:00 - fmean_numfind_deg_cust.sas/e_vital_pulse_ab_mean_ob_sas.cgm

14.3.6.6 Pulse - mean plot - safety analysis set

14.3.6.7 Body weight and BMI by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Body Weight(kg)			
Visit 1			
N	180	179	359
Mean (SD)	41.2 (20.6)	42.7 (21.1)	41.9 (20.8)
Median	39.0	40.0	39.4
Min ; Max	12.0 ; 116.7	9.3 ; 104.5	9.3 ; 116.7
Visit 2 (Week 0)			
N	181	179	360
Mean (SD)	41.3 (20.7)	42.9 (21.3)	42.1 (20.9)
Median	39.5	39.8	39.7
Min ; Max	12.1 ; 117.1	9.4 ; 104.4	9.4 ; 117.1
Visit 14 (Week 12)			
N	175	172	347
Mean (SD)	42.3 (20.6)	43.4 (21.3)	42.8 (20.9)
Median	40.2	40.7	40.4
Min ; Max	12.8 ; 119.8	9.8 ; 106.3	9.8 ; 119.8
Visit 18 (Week 16)			
N	175	167	342
Mean (SD)	42.6 (20.6)	44.0 (21.0)	43.3 (20.8)
Median	40.4	42.0	41.4
Min ; Max	13.6 ; 120.7	10.5 ; 108.4	10.5 ; 120.7
End of trial visit			
N	181	179	360
Mean (SD)	42.7 (20.5)	43.6 (21.1)	43.1 (20.8)
Median	41.3	41.8	41.4
Min ; Max	13.6 ; 120.7	10.5 ; 108.4	10.5 ; 120.7

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

Body weight and BMI by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Body Weight(lb)			
Visit 1			
N	180	179	359
Mean (SD)	90.9 (45.3)	94.1 (46.6)	92.5 (45.9)
Median	86.0	88.2	86.9
Min ; Max	26.5 ; 257.2	20.5 ; 230.4	20.5 ; 257.2
Visit 2 (Week 0)			
N	181	179	360
Mean (SD)	91.0 (45.5)	94.5 (46.8)	92.7 (46.2)
Median	87.1	87.7	87.4
Min ; Max	26.7 ; 258.2	20.7 ; 230.2	20.7 ; 258.2
Visit 14 (Week 12)			
N	175	172	347
Mean (SD)	93.2 (45.4)	95.7 (46.9)	94.4 (46.1)
Median	88.6	89.7	89.1
Min ; Max	28.2 ; 264.2	21.6 ; 234.3	21.6 ; 264.2
Visit 18 (Week 16)			
N	175	167	342
Mean (SD)	94.0 (45.4)	97.0 (46.4)	95.5 (45.8)
Median	89.0	92.6	91.3
Min ; Max	30.0 ; 266.0	23.1 ; 239.0	23.1 ; 266.0
End of trial visit			
N	181	179	360
Mean (SD)	94.1 (45.3)	96.1 (46.5)	95.1 (45.8)
Median	91.0	92.2	91.3
Min ; Max	30.0 ; 266.0	23.1 ; 239.0	23.1 ; 266.0

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

Body weight and BMI by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
BMI(kg/m^2)			
Visit 2 (Week 0)			
N	180	178	358
Mean (SD)	19.2 (4.2)	19.6 (4.0)	19.4 (4.1)
Median	18.4	18.5	18.5
Min ; Max	11.0 ; 35.1	12.8 ; 31.9	11.0 ; 35.1
Visit 14 (Week 12)			
N	175	172	347
Mean (SD)	19.4 (4.2)	19.5 (4.0)	19.4 (4.1)
Median	18.4	18.4	18.4
Min ; Max	11.4 ; 34.4	12.9 ; 32.4	11.4 ; 34.4
Visit 18 (Week 16)			
N	175	167	342
Mean (SD)	19.5 (4.2)	19.6 (4.0)	19.5 (4.1)
Median	18.4	18.5	18.5
Min ; Max	11.9 ; 36.1	13.1 ; 33.1	11.9 ; 36.1
End of trial visit			
N	181	179	360
Mean (SD)	19.5 (4.2)	19.6 (4.0)	19.5 (4.1)
Median	18.5	18.5	18.5
Min ; Max	11.9 ; 36.1	13.1 ; 33.1	11.9 ; 36.1

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

14.3.6.8 Body weight and BMI by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	40	41	81
Body Weight(kg)			
Visit 1			
N	39	41	80
Mean (SD)	18.7 (4.0)	17.6 (3.6)	18.1 (3.8)
Median	18.8	18.2	18.3
Min ; Max	12.0 ; 34.0	9.3 ; 28.0	9.3 ; 34.0
Visit 2 (Week 0)			
N	40	41	81
Mean (SD)	18.9 (4.0)	17.7 (3.6)	18.3 (3.8)
Median	18.8	18.1	18.3
Min ; Max	12.1 ; 35.1	9.4 ; 28.1	9.4 ; 35.1
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	19.6 (4.4)	17.9 (3.2)	18.8 (3.9)
Median	19.1	18.4	18.9
Min ; Max	12.8 ; 38.5	9.8 ; 22.9	9.8 ; 38.5
Visit 18 (Week 16)			
N	38	35	73
Mean (SD)	20.0 (4.6)	18.1 (3.2)	19.1 (4.1)
Median	19.4	19.0	19.1
Min ; Max	13.6 ; 40.1	10.5 ; 22.6	10.5 ; 40.1
End of trial visit			
N	40	41	81
Mean (SD)	19.9 (4.6)	18.3 (3.3)	19.1 (4.0)
Median	19.2	18.9	19.0
Min ; Max	13.6 ; 40.1	10.5 ; 27.3	10.5 ; 40.1

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

Body weight and BMI by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

	IDegAsp OD	IDet	Total
Body Weight(lb)			
Visit 1			
N	39	41	80
Mean (SD)	41.2 (8.8)	38.7 (7.9)	39.9 (8.4)
Median	41.4	40.1	40.3
Min ; Max	26.5 ; 75.0	20.5 ; 61.7	20.5 ; 75.0
Visit 2 (Week 0)			
N	40	41	81
Mean (SD)	41.6 (8.8)	39.0 (8.0)	40.3 (8.4)
Median	41.4	39.9	40.3
Min ; Max	26.7 ; 77.4	20.7 ; 61.9	20.7 ; 77.4
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	43.2 (9.7)	39.5 (7.0)	41.3 (8.6)
Median	42.0	40.6	41.7
Min ; Max	28.2 ; 84.8	21.6 ; 50.5	21.6 ; 84.8
Visit 18 (Week 16)			
N	38	35	73
Mean (SD)	44.1 (10.2)	39.9 (7.0)	42.1 (9.0)
Median	42.7	41.9	42.1
Min ; Max	30.0 ; 88.5	23.1 ; 49.8	23.1 ; 88.5
End of trial visit			
N	40	41	81
Mean (SD)	43.8 (10.1)	40.4 (7.3)	42.0 (8.9)
Median	42.3	41.7	41.9
Min ; Max	30.0 ; 88.5	23.1 ; 60.2	23.1 ; 88.5

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

Body weight and BMI by treatment week – descriptive statistics – children (1-5 years) - safety analysis set

	IDegAsp OD	IDet	Total
BMI(kg/m^2)			
Visit 2 (Week 0)			
N	40	41	81
Mean (SD)	16.4 (2.2)	16.2 (1.6)	16.3 (1.9)
Median	16.2	16.1	16.1
Min ; Max	11.0 ; 25.2	12.8 ; 20.6	11.0 ; 25.2
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	16.4 (2.7)	16.0 (1.5)	16.2 (2.1)
Median	16.2	15.9	16.1
Min ; Max	11.4 ; 28.7	12.9 ; 19.7	11.4 ; 28.7
Visit 18 (Week 16)			
N	38	35	73
Mean (SD)	16.6 (2.7)	16.2 (1.4)	16.4 (2.2)
Median	16.3	16.1	16.2
Min ; Max	11.9 ; 28.8	13.4 ; 20.0	11.9 ; 28.8
End of trial visit			
N	40	41	81
Mean (SD)	16.5 (2.6)	16.3 (1.5)	16.4 (2.1)
Median	16.3	16.1	16.2
Min ; Max	11.9 ; 28.8	13.4 ; 20.0	11.9 ; 28.8

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

14.3.6.9 Body weight and BMI by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Body Weight(kg)			
Visit 1			
N	61	61	122
Mean (SD)	32.5 (11.5)	35.1 (9.9)	33.8 (10.8)
Median	30.5	33.6	31.9
Min ; Max	20.0 ; 79.9	21.0 ; 65.9	20.0 ; 79.9
Visit 2 (Week 0)			
N	61	61	122
Mean (SD)	32.6 (11.4)	35.2 (10.0)	33.9 (10.7)
Median	30.4	33.9	32.0
Min ; Max	20.4 ; 78.6	21.0 ; 66.2	20.4 ; 78.6
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	33.5 (11.5)	35.8 (10.2)	34.6 (10.9)
Median	30.9	34.3	32.5
Min ; Max	21.6 ; 79.4	20.0 ; 64.0	20.0 ; 79.4
Visit 18 (Week 16)			
N	60	59	119
Mean (SD)	33.8 (11.3)	36.0 (10.3)	34.9 (10.9)
Median	31.0	34.1	32.5
Min ; Max	21.3 ; 77.0	20.0 ; 62.9	20.0 ; 77.0
End of trial visit			
N	61	61	122
Mean (SD)	34.1 (11.5)	36.1 (10.2)	35.1 (10.8)
Median	31.0	35.0	32.9
Min ; Max	21.3 ; 77.0	20.0 ; 62.9	20.0 ; 77.0

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1
nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:46:02 - tdesc_numfind_tpl_t019_v01_3816.sas/t_bw_bmi_abs_descp_age2_sas.txt

Body weight and BMI by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

	IDegAsp OD	IDet	Total
Body Weight(lb)			
Visit 1			
N	61	61	122
Mean (SD)	71.7 (25.3)	77.4 (21.9)	74.6 (23.7)
Median	67.2	74.1	70.3
Min ; Max	44.2 ; 176.1	46.3 ; 145.3	44.2 ; 176.1
Visit 2 (Week 0)			
N	61	61	122
Mean (SD)	71.9 (25.1)	77.5 (22.0)	74.7 (23.7)
Median	67.0	74.7	70.5
Min ; Max	45.0 ; 173.3	46.3 ; 145.9	45.0 ; 173.3
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	73.9 (25.3)	78.8 (22.6)	76.3 (24.0)
Median	68.1	75.6	71.6
Min ; Max	47.6 ; 175.0	44.1 ; 141.1	44.1 ; 175.0
Visit 18 (Week 16)			
N	60	59	119
Mean (SD)	74.4 (25.0)	79.4 (22.7)	76.9 (23.9)
Median	68.3	75.2	71.6
Min ; Max	47.0 ; 169.8	44.1 ; 138.7	44.1 ; 169.8
End of trial visit			
N	61	61	122
Mean (SD)	75.1 (25.3)	79.7 (22.4)	77.4 (23.9)
Median	68.3	77.2	72.5
Min ; Max	47.0 ; 169.8	44.1 ; 138.7	44.1 ; 169.8

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

Body weight and BMI by treatment week – descriptive statistics – children (6-11 years) - safety analysis set

	IDegAsp OD	IDet	Total
BMI(kg/m^2)			
Visit 2 (Week 0)			
N	61	61	122
Mean (SD)	17.4 (3.3)	18.1 (2.8)	17.8 (3.1)
Median	16.3	17.4	17.1
Min ; Max	13.6 ; 29.6	14.0 ; 25.9	13.6 ; 29.6
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	17.6 (3.2)	18.0 (2.8)	17.8 (3.0)
Median	16.5	17.4	17.0
Min ; Max	13.8 ; 29.4	13.6 ; 26.5	13.6 ; 29.4
Visit 18 (Week 16)			
N	60	59	119
Mean (SD)	17.6 (3.1)	18.0 (2.8)	17.8 (3.0)
Median	16.8	17.3	16.9
Min ; Max	14.0 ; 28.6	13.1 ; 27.0	13.1 ; 28.6
End of trial visit			
N	61	61	122
Mean (SD)	17.7 (3.3)	18.1 (2.8)	17.9 (3.0)
Median	16.8	17.3	17.0
Min ; Max	14.0 ; 28.6	13.1 ; 27.0	13.1 ; 28.6

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

14.3.6.10 Body weight and BMI by treatment week – descriptive statistics – children (12-17 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	77	157
Body Weight(kg)			
Visit 1			
N	80	77	157
Mean (SD)	58.8 (15.1)	62.0 (14.0)	60.4 (14.6)
Median	55.3	61.8	58.4
Min ; Max	35.0 ; 116.7	32.0 ; 104.5	32.0 ; 116.7
Visit 2 (Week 0)			
N	80	77	157
Mean (SD)	59.1 (15.2)	62.4 (14.0)	60.7 (14.7)
Median	55.7	61.8	59.5
Min ; Max	35.0 ; 117.1	32.6 ; 104.4	32.6 ; 117.1
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	60.3 (14.7)	62.9 (13.9)	61.6 (14.3)
Median	56.3	60.2	59.5
Min ; Max	35.7 ; 119.8	35.4 ; 106.3	35.4 ; 119.8
Visit 18 (Week 16)			
N	77	73	150
Mean (SD)	60.7 (14.5)	62.9 (13.7)	61.8 (14.1)
Median	56.8	60.8	60.0
Min ; Max	37.0 ; 120.7	36.0 ; 108.4	36.0 ; 120.7
End of trial visit			
N	80	77	157
Mean (SD)	60.7 (14.2)	62.9 (13.6)	61.8 (13.9)
Median	56.9	61.4	60.2
Min ; Max	37.0 ; 120.7	36.0 ; 108.4	36.0 ; 120.7

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1
nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:46:02 - tdesc_numfind_tpl_t019_v01_3816.sas/t_bw_bmi_abs_descp_age3_sas.txt

Body weight and BMI by treatment week – descriptive statistics – children (12-17 years) - safety analysis set

	IDegAsp OD	IDet	Total
Body Weight(lb)			
Visit 1			
N	80	77	157
Mean (SD)	129.6 (33.3)	136.7 (30.8)	133.1 (32.2)
Median	121.8	136.2	128.7
Min ; Max	77.2 ; 257.2	70.5 ; 230.4	70.5 ; 257.2
Visit 2 (Week 0)			
N	80	77	157
Mean (SD)	130.3 (33.6)	137.5 (31.0)	133.8 (32.4)
Median	122.8	136.2	131.2
Min ; Max	77.2 ; 258.2	71.9 ; 230.2	71.9 ; 258.2
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	132.9 (32.4)	138.7 (30.7)	135.7 (31.6)
Median	124.1	132.7	131.2
Min ; Max	78.7 ; 264.2	78.0 ; 234.3	78.0 ; 264.2
Visit 18 (Week 16)			
N	77	73	150
Mean (SD)	133.8 (31.9)	138.7 (30.3)	136.2 (31.1)
Median	125.2	134.0	132.3
Min ; Max	81.6 ; 266.0	79.4 ; 239.0	79.4 ; 266.0
End of trial visit			
N	80	77	157
Mean (SD)	133.7 (31.4)	138.7 (30.0)	136.2 (30.7)
Median	125.4	135.4	132.7
Min ; Max	81.6 ; 266.0	79.4 ; 239.0	79.4 ; 266.0

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

Body weight and BMI by treatment week – descriptive statistics – children (12-17 years) - safety analysis set

	IDegAsp OD	IDet	Total
BMI(kg/m^2)			
Visit 2 (Week 0)			
N	79	76	155
Mean (SD)	22.0 (3.9)	22.5 (3.8)	22.3 (3.8)
Median	21.4	22.1	21.7
Min ; Max	15.5 ; 35.1	13.8 ; 31.9	13.8 ; 35.1
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	22.2 (3.7)	22.5 (3.7)	22.3 (3.7)
Median	21.6	22.1	21.8
Min ; Max	16.9 ; 34.4	13.9 ; 32.4	13.9 ; 34.4
Visit 18 (Week 16)			
N	77	73	150
Mean (SD)	22.3 (3.8)	22.4 (3.7)	22.4 (3.7)
Median	21.8	21.9	21.8
Min ; Max	16.6 ; 36.1	14.1 ; 33.1	14.1 ; 36.1
End of trial visit			
N	80	77	157
Mean (SD)	22.3 (3.7)	22.5 (3.7)	22.4 (3.7)
Median	21.7	21.9	21.8
Min ; Max	16.6 ; 36.1	14.1 ; 33.1	14.1 ; 36.1

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Height is collected from visit 2 hence BMI is not calculated for visit 1

14.3.6.11 Body weight and BMI by treatment week - change from baseline - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Ch. in Body Weight(kg)			
Visit 14 (Week 12)			
N	175	172	347
Mean (SD)	1.1 (1.7)	0.5 (1.6)	0.8 (1.7)
Median	0.9	0.5	0.7
Min ; Max	-4.0 ; 6.4	-4.5 ; 6.0	-4.5 ; 6.4
Visit 18 (Week 16)			
N	175	167	342
Mean (SD)	1.4 (2.0)	0.7 (1.8)	1.1 (1.9)
Median	1.3	1.0	1.1
Min ; Max	-7.0 ; 7.8	-4.0 ; 5.5	-7.0 ; 7.8
End of trial visit			
N	181	179	360
Mean (SD)	1.4 (2.0)	0.7 (1.9)	1.1 (1.9)
Median	1.2	1.0	1.1
Min ; Max	-7.0 ; 7.8	-5.0 ; 7.6	-7.0 ; 7.8

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Ch.: Change from baseline

Body weight and BMI by treatment week - change from baseline - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch. in Body Weight(lb)			
Visit 14 (Week 12)			
N	175	172	347
Mean (SD)	2.3 (3.7)	1.2 (3.5)	1.8 (3.6)
Median	2.0	1.1	1.5
Min ; Max	-8.8 ; 14.1	-9.9 ; 13.2	-9.9 ; 14.1
Visit 18 (Week 16)			
N	175	167	342
Mean (SD)	3.1 (4.4)	1.7 (3.9)	2.4 (4.2)
Median	2.9	2.2	2.4
Min ; Max	-15.5 ; 17.2	-8.8 ; 12.1	-15.5 ; 17.2
End of trial visit			
N	181	179	360
Mean (SD)	3.1 (4.4)	1.6 (4.1)	2.3 (4.3)
Median	2.6	2.2	2.4
Min ; Max	-15.5 ; 17.2	-11.0 ; 16.7	-15.5 ; 17.2

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Ch.: Change from baseline

Body weight and BMI by treatment week - change from baseline - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Ch. in Derived Body Mass Index(kg/m^2)			
Visit 14 (Week 12)			
N	174	171	345
Mean (SD)	0.2 (0.8)	-0.0 (0.7)	0.1 (0.7)
Median	0.2	0.0	0.1
Min ; Max	-1.9 ; 3.5	-1.7 ; 1.9	-1.9 ; 3.5
Visit 18 (Week 16)			
N	174	166	340
Mean (SD)	0.3 (0.9)	-0.0 (0.8)	0.1 (0.8)
Median	0.3	0.0	0.2
Min ; Max	-2.2 ; 3.7	-2.1 ; 2.3	-2.2 ; 3.7
End of trial visit			
N	180	178	358
Mean (SD)	0.3 (0.9)	-0.0 (0.8)	0.1 (0.8)
Median	0.3	0.0	0.2
Min ; Max	-2.2 ; 3.7	-2.1 ; 2.5	-2.2 ; 3.7

BMI: Body mass index, N: Number of subjects, SD: Standard deviation
Ch.: Change from baseline

14.3.6.12 Body weight and BMI by treatment week – change from baseline - descriptive statistics – children (1-5 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	40	41	81
Ch. in Body Weight(kg)			
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	0.6 (0.7)	0.4 (0.6)	0.5 (0.7)
Median	0.5	0.5	0.5
Min ; Max	-1.3 ; 3.4	-0.9 ; 1.8	-1.3 ; 3.4
Visit 18 (Week 16)			
N	38	35	73
Mean (SD)	1.0 (1.0)	0.6 (0.8)	0.8 (0.9)
Median	1.0	0.7	0.9
Min ; Max	-1.0 ; 5.0	-1.3 ; 2.1	-1.3 ; 5.0
End of trial visit			
N	40	41	81
Mean (SD)	1.0 (1.0)	0.6 (0.8)	0.8 (0.9)
Median	1.0	0.7	0.9
Min ; Max	-1.0 ; 5.0	-1.3 ; 2.1	-1.3 ; 5.0

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline

Body weight and BMI by treatment week – change from baseline - descriptive statistics – children (1-5 years) - safety analysis set

	IDegAsp OD	IDet	Total
Ch. in Body Weight(lb)			
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	1.3 (1.6)	1.0 (1.4)	1.1 (1.5)
Median	1.1	1.1	1.1
Min ; Max	-2.9 ; 7.4	-2.0 ; 4.0	-2.9 ; 7.4
Visit 18 (Week 16)			
N	38	35	73
Mean (SD)	2.2 (2.3)	1.4 (1.8)	1.8 (2.1)
Median	2.2	1.5	2.0
Min ; Max	-2.2 ; 11.1	-2.9 ; 4.6	-2.9 ; 11.1
End of trial visit			
N	40	41	81
Mean (SD)	2.2 (2.3)	1.4 (1.8)	1.8 (2.1)
Median	2.2	1.5	2.0
Min ; Max	-2.2 ; 11.1	-2.9 ; 4.6	-2.9 ; 11.1

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline

Body weight and BMI by treatment week – change from baseline - descriptive statistics – children (1-5 years) - safety analysis set

	IDegAsp OD	IDet	Total
Ch. in Derived Body Mass Index(kg/m^2)			
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	-0.0 (0.9)	-0.1 (0.6)	-0.1 (0.8)
Median	-0.1	-0.1	-0.1
Min ; Max	-1.9 ; 3.5	-1.6 ; 1.0	-1.9 ; 3.5
Visit 18 (Week 16)			
N	38	35	73
Mean (SD)	0.2 (1.0)	0.1 (0.9)	0.1 (0.9)
Median	0.0	-0.0	0.0
Min ; Max	-2.2 ; 3.7	-1.8 ; 2.3	-2.2 ; 3.7
End of trial visit			
N	40	41	81
Mean (SD)	0.2 (1.0)	0.0 (0.8)	0.1 (0.9)
Median	-0.0	0.0	0.0
Min ; Max	-2.2 ; 3.7	-1.8 ; 2.3	-2.2 ; 3.7

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline

14.3.6.13 Body weight and BMI by treatment week – change from baseline - descriptive statistics – children (6-11 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Ch. in Body Weight(kg)			
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	1.2 (1.0)	0.7 (1.1)	1.0 (1.1)
Median	1.0	0.7	1.0
Min ; Max	-1.0 ; 4.9	-2.3 ; 3.1	-2.3 ; 4.9
Visit 18 (Week 16)			
N	60	59	119
Mean (SD)	1.5 (1.3)	1.0 (1.3)	1.2 (1.3)
Median	1.4	1.3	1.4
Min ; Max	-1.6 ; 6.4	-3.3 ; 4.0	-3.3 ; 6.4
End of trial visit			
N	61	61	122
Mean (SD)	1.5 (1.3)	1.0 (1.3)	1.2 (1.3)
Median	1.4	1.3	1.3
Min ; Max	-1.6 ; 6.4	-3.3 ; 4.0	-3.3 ; 6.4

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline

Body weight and BMI by treatment week – change from baseline - descriptive statistics – children (6-11 years) - safety analysis set

	IDegAsp OD	IDet	Total
Ch. in Body Weight(lb)			
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	2.7 (2.3)	1.6 (2.5)	2.1 (2.4)
Median	2.2	1.5	2.2
Min ; Max	-2.2 ; 10.8	-5.0 ; 6.8	-5.0 ; 10.8
Visit 18 (Week 16)			
N	60	59	119
Mean (SD)	3.3 (2.9)	2.2 (2.9)	2.7 (3.0)
Median	3.1	2.9	3.1
Min ; Max	-3.5 ; 14.2	-7.3 ; 8.8	-7.3 ; 14.2
End of trial visit			
N	61	61	122
Mean (SD)	3.2 (2.9)	2.2 (2.9)	2.7 (2.9)
Median	3.1	2.9	2.9
Min ; Max	-3.5 ; 14.2	-7.3 ; 8.8	-7.3 ; 14.2

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline

Body weight and BMI by treatment week – change from baseline - descriptive statistics – children (6-11 years) - safety analysis set

	IDegAsp OD	IDet	Total
Ch. in Derived Body Mass Index(kg/m^2)			
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	0.3 (0.5)	0.0 (0.6)	0.1 (0.6)
Median	0.4	0.1	0.2
Min ; Max	-0.8 ; 1.8	-1.6 ; 1.5	-1.6 ; 1.8
Visit 18 (Week 16)			
N	60	59	119
Mean (SD)	0.3 (0.7)	-0.0 (0.7)	0.1 (0.7)
Median	0.3	0.0	0.2
Min ; Max	-1.3 ; 2.5	-2.1 ; 2.0	-2.1 ; 2.5
End of trial visit			
N	61	61	122
Mean (SD)	0.3 (0.7)	-0.0 (0.7)	0.1 (0.7)
Median	0.3	0.0	0.2
Min ; Max	-1.3 ; 2.5	-2.1 ; 2.0	-2.1 ; 2.5

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline

14.3.6.14 Body weight and BMI by treatment week – change from baseline - descriptive statistics – adolescents (12-17 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	77	157
Ch. in Body Weight(kg)			
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	1.1 (2.3)	0.5 (2.2)	0.8 (2.2)
Median	1.2	0.4	0.8
Min ; Max	-4.0 ; 6.4	-4.5 ; 6.0	-4.5 ; 6.4
Visit 18 (Week 16)			
N	77	73	150
Mean (SD)	1.6 (2.7)	0.6 (2.3)	1.1 (2.5)
Median	1.8	1.0	1.2
Min ; Max	-7.0 ; 7.8	-4.0 ; 5.5	-7.0 ; 7.8
End of trial visit			
N	80	77	157
Mean (SD)	1.6 (2.6)	0.6 (2.5)	1.1 (2.6)
Median	1.8	0.9	1.1
Min ; Max	-7.0 ; 7.8	-5.0 ; 7.6	-7.0 ; 7.8

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline

Body weight and BMI by treatment week – change from baseline - descriptive statistics – adolescents (12-17 years) - safety analysis set

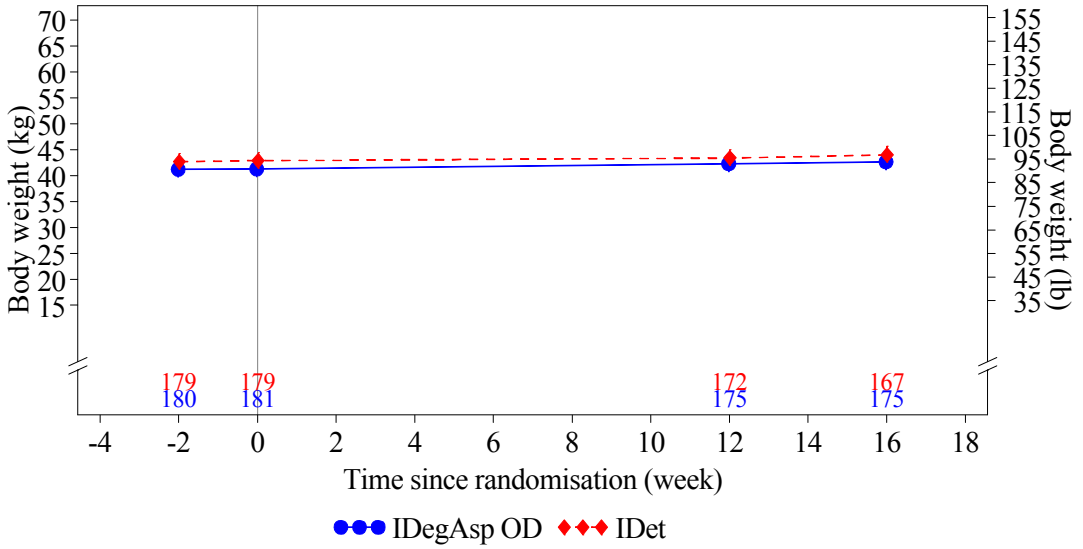
	IDegAsp OD	IDet	Total
Ch. in Body Weight(lb)			
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	2.5 (5.0)	1.0 (4.8)	1.8 (5.0)
Median	2.6	0.8	1.8
Min ; Max	-8.8 ; 14.1	-9.9 ; 13.2	-9.9 ; 14.1
Visit 18 (Week 16)			
N	77	73	150
Mean (SD)	3.5 (5.9)	1.3 (5.1)	2.4 (5.6)
Median	4.0	2.2	2.6
Min ; Max	-15.5 ; 17.2	-8.8 ; 12.1	-15.5 ; 17.2
End of trial visit			
N	80	77	157
Mean (SD)	3.5 (5.8)	1.3 (5.5)	2.4 (5.8)
Median	3.9	2.0	2.4
Min ; Max	-15.5 ; 17.2	-11.0 ; 16.7	-15.5 ; 17.2

N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline

Body weight and BMI by treatment week – change from baseline - descriptive statistics – adolescents (12-17 years) - safety analysis set

	IDegAsp OD	IDet	Total
Ch. in Derived Body Mass Index(kg/m^2)			
Visit 14 (Week 12)			
N	76	73	149
Mean (SD)	0.2 (0.8)	-0.0 (0.8)	0.1 (0.8)
Median	0.2	0.0	0.1
Min ; Max	-1.9 ; 2.0	-1.7 ; 1.9	-1.9 ; 2.0
Visit 18 (Week 16)			
N	76	72	148
Mean (SD)	0.3 (0.9)	-0.0 (0.8)	0.2 (0.9)
Median	0.4	0.1	0.2
Min ; Max	-2.0 ; 2.8	-1.5 ; 1.5	-2.0 ; 2.8
End of trial visit			
N	79	76	155
Mean (SD)	0.3 (0.9)	-0.0 (0.8)	0.2 (0.9)
Median	0.4	0.0	0.2
Min ; Max	-2.0 ; 2.8	-2.1 ; 2.5	-2.1 ; 2.8

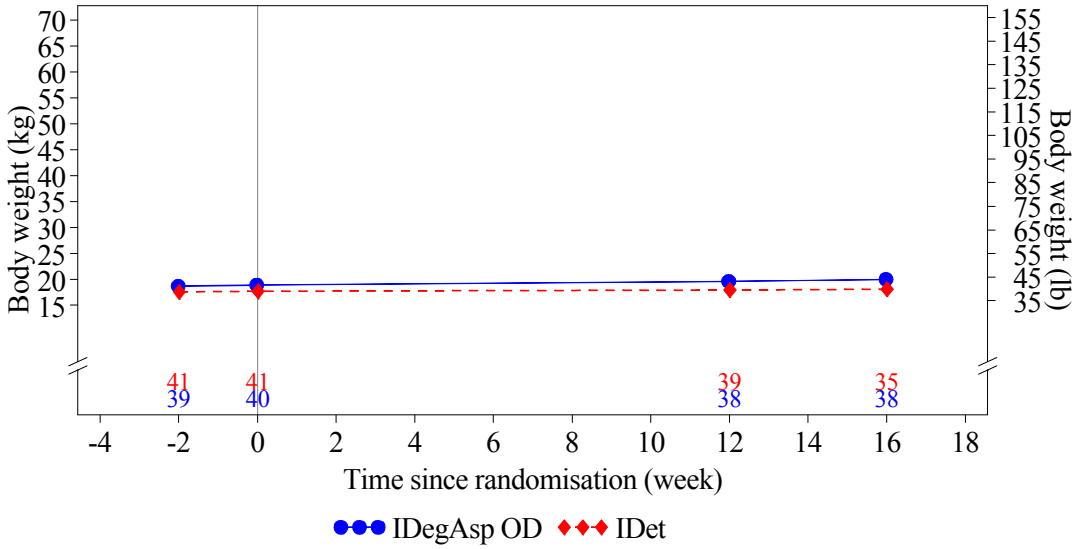
N: Number of subjects, SD: Standard deviation, Ch.: Change from baseline



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:46:07 - fmean_numfind_deg_cust.sas/e_bw_ab_mean_ob_sas.cgm

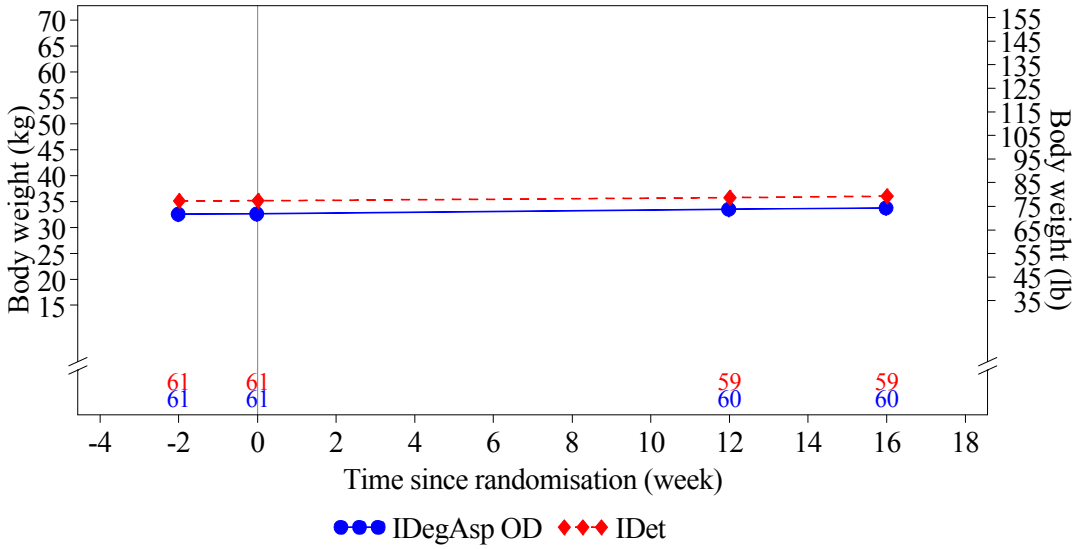
14.3.6.15 Body weight - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:46:08 - fmean_numfind_deg_cust.sas/e_bw_ab_mean_ob_age1_sas.cgm

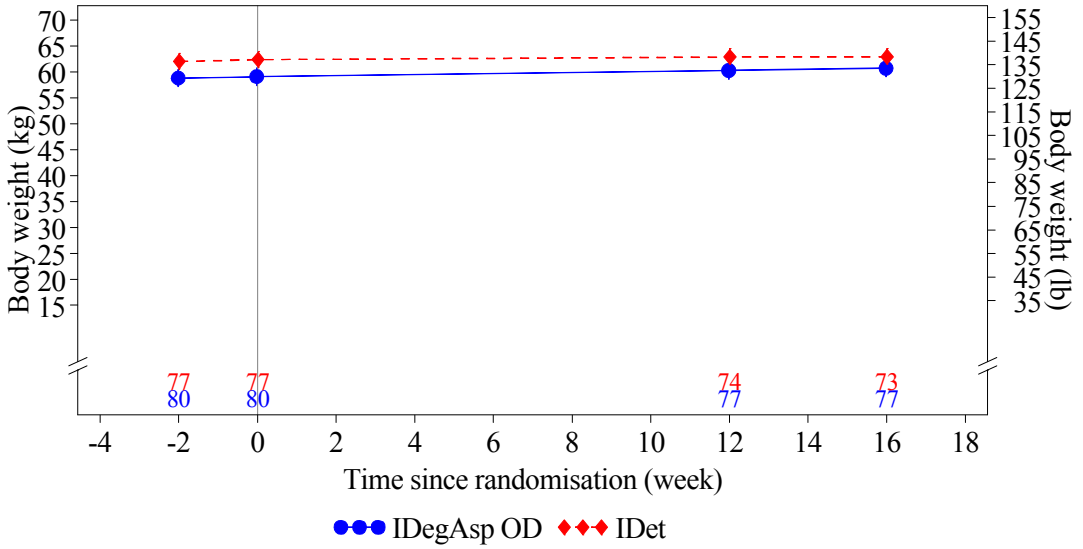
14.3.6.16 Body weight – mean plot – children (1-5 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:46:10 - fmean_numfind_deg_cust.sas/e_bw_ab_mean_ob_age2_sas.cgm

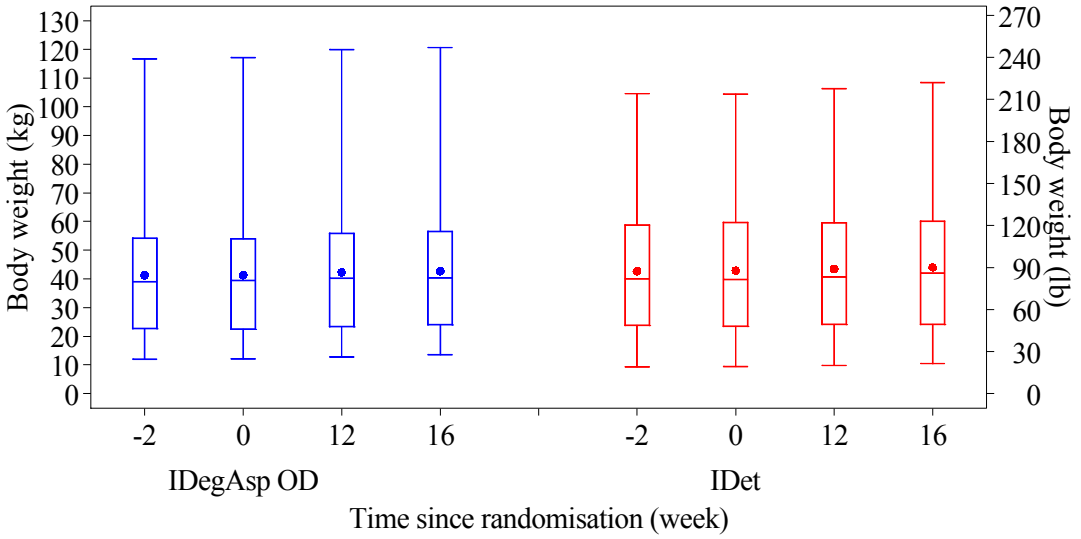
14.3.6.17 Body weight – mean plot – children (6-11 years) - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:46:11 - fmean_numfind_deg_cust.sas/e_bw_ab_mean_ob_age3_sas.cgm

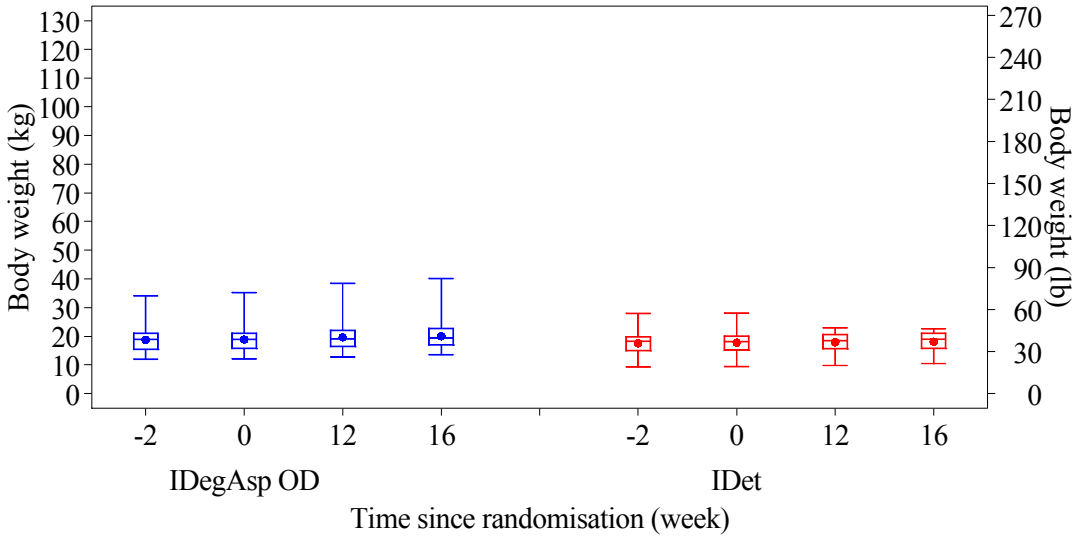
14.3.6.18 Body weight – mean plot – adolescents (12-17 years) - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:46:10 - fbox_numfind_v02.sas/e_bw_abs_box_obs_sas.cgm

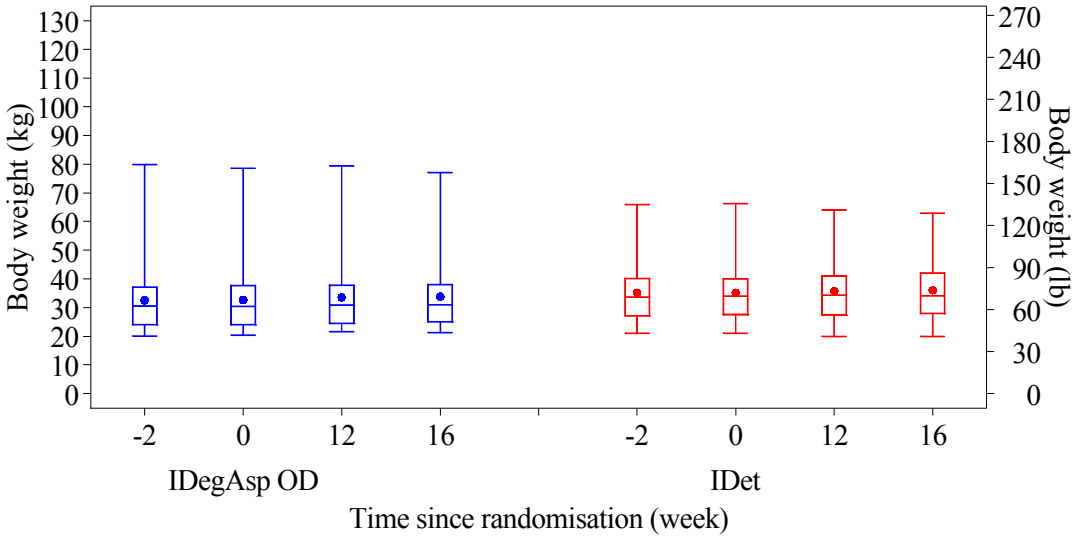
14.3.6.19 Body weight by treatment week - box plot - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:46:11 - fbox_numfind_v02.sas/e_bw_abs_box_obs_age1_sas.cgm

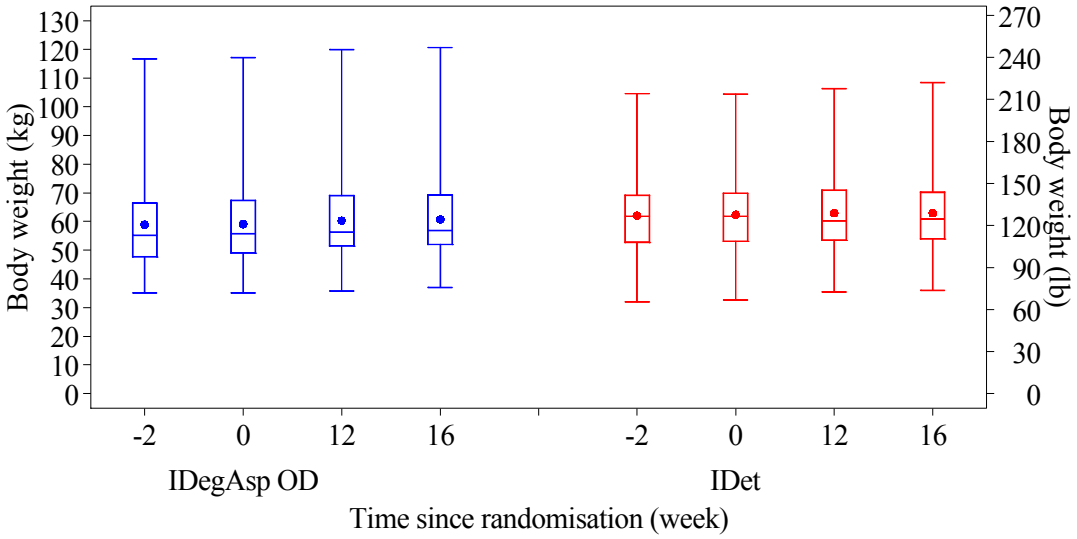
14.3.6.20 Body weight by treatment week - box plot - children (1-5 years) - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:46:12 - fbox_numfind_v02.sas/e_bw_abs_box_obs_age2_sas.cgm

14.3.6.21 Body weight by treatment week - box plot - children (6-11 years) - safety analysis set



Legend: Mean (dot), Median (centre line), 25 & 75 percentiles (box), Max & Min (top & bottom)
SAFETY: Observed data
SAFETY: Safety analysis set

nn5401/nn5401-3816/er_20150312_ctr/stats
12MAR2015:08:46:13 - fbox_numfind_v02.sas/e_bw_abs_box_obs_age3_sas.cgm

14.3.6.22 Body weight by treatment week - box plot - adolescents (12-17 years) - safety analysis set

14.3.6.23 SD score for body weight by treatment week - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
SD score for weight			
Visit 1			
N	180	179	359
Mean (SD)	0.38 (1.13)	0.46 (0.95)	0.42 (1.04)
Median	0.40	0.54	0.47
Min ; Max	-3.20 ; 4.10	-2.45 ; 2.72	-3.20 ; 4.10
Visit 2 (Week 0)			
N	181	179	360
Mean (SD)	0.40 (1.12)	0.47 (0.94)	0.44 (1.03)
Median	0.39	0.52	0.48
Min ; Max	-3.15 ; 4.06	-2.41 ; 2.71	-3.15 ; 4.06
Visit 14 (Week 12)			
N	175	172	347
Mean (SD)	0.42 (1.10)	0.45 (0.92)	0.43 (1.01)
Median	0.32	0.47	0.42
Min ; Max	-2.82 ; 3.74	-2.41 ; 2.75	-2.82 ; 3.74
Visit 18 (Week 16)			
N	175	167	342
Mean (SD)	0.44 (1.09)	0.46 (0.88)	0.45 (0.99)
Median	0.39	0.51	0.49
Min ; Max	-2.64 ; 3.78	-1.87 ; 2.81	-2.64 ; 3.78
End of trial visit			
N	181	179	360
Mean (SD)	0.46 (1.08)	0.46 (0.90)	0.46 (0.99)
Median	0.45	0.51	0.50
Min ; Max	-2.64 ; 3.78	-1.87 ; 2.81	-2.64 ; 3.78

N: Number of subjects, SD: Standard deviation

14.3.6.24 SD score for body weight by treatment week - descriptive statistics – children (1-5 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	40	41	81
SD score for weight			
Visit 1			
N	39	41	80
Mean (SD)	0.37 (1.27)	0.14 (1.04)	0.25 (1.16)
Median	0.60	0.23	0.29
Min ; Max	-3.20 ; 2.97	-2.45 ; 2.59	-3.20 ; 2.97
Visit 2 (Week 0)			
N	40	41	81
Mean (SD)	0.41 (1.24)	0.16 (1.05)	0.29 (1.14)
Median	0.64	0.36	0.38
Min ; Max	-3.15 ; 3.05	-2.41 ; 2.60	-3.15 ; 3.05
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	0.36 (1.20)	0.10 (0.97)	0.23 (1.09)
Median	0.37	0.25	0.28
Min ; Max	-2.82 ; 3.18	-2.41 ; 1.88	-2.82 ; 3.18
Visit 18 (Week 16)			
N	38	35	73
Mean (SD)	0.43 (1.15)	0.17 (0.90)	0.31 (1.04)
Median	0.49	0.24	0.41
Min ; Max	-2.28 ; 3.25	-1.78 ; 1.97	-2.28 ; 3.25
End of trial visit			
N	40	41	81
Mean (SD)	0.47 (1.14)	0.19 (0.96)	0.33 (1.05)
Median	0.53	0.24	0.43
Min ; Max	-2.28 ; 3.25	-1.78 ; 2.45	-2.28 ; 3.25

N: Number of subjects, SD: Standard deviation

14.3.6.25 SD score for body weight by treatment week - descriptive statistics – children (6-11 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
SD score for weight			
Visit 1			
N	61	61	122
Mean (SD)	0.16 (1.18)	0.54 (0.86)	0.35 (1.05)
Median	0.11	0.60	0.29
Min ; Max	-2.43 ; 4.03	-1.97 ; 2.06	-2.43 ; 4.03
Visit 2 (Week 0)			
N	61	61	122
Mean (SD)	0.15 (1.18)	0.53 (0.86)	0.34 (1.04)
Median	0.05	0.60	0.31
Min ; Max	-2.39 ; 3.89	-1.96 ; 2.07	-2.39 ; 3.89
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	0.20 (1.16)	0.49 (0.88)	0.34 (1.04)
Median	0.07	0.50	0.32
Min ; Max	-2.65 ; 3.74	-1.79 ; 2.13	-2.65 ; 3.74
Visit 18 (Week 16)			
N	60	59	119
Mean (SD)	0.20 (1.14)	0.48 (0.87)	0.34 (1.02)
Median	0.08	0.50	0.27
Min ; Max	-2.64 ; 3.66	-1.87 ; 2.15	-2.64 ; 3.66
End of trial visit			
N	61	61	122
Mean (SD)	0.22 (1.14)	0.49 (0.86)	0.35 (1.02)
Median	0.09	0.50	0.28
Min ; Max	-2.64 ; 3.66	-1.87 ; 2.15	-2.64 ; 3.66

N: Number of subjects, SD: Standard deviation, LOCF: Last observation carried forward

14.3.6.26 SD score for body weight by treatment week - descriptive statistics – adolescents (12-17 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	80	77	157
SD score for weight			
Visit 1			
N	80	77	157
Mean (SD)	0.56 (0.99)	0.57 (0.93)	0.57 (0.96)
Median	0.49	0.66	0.57
Min ; Max	-1.59 ; 4.10	-1.61 ; 2.72	-1.61 ; 4.10
Visit 2 (Week 0)			
N	80	77	157
Mean (SD)	0.58 (0.99)	0.60 (0.92)	0.59 (0.95)
Median	0.53	0.64	0.55
Min ; Max	-1.45 ; 4.06	-1.53 ; 2.71	-1.53 ; 4.06
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	0.61 (0.98)	0.60 (0.88)	0.60 (0.93)
Median	0.66	0.60	0.63
Min ; Max	-1.40 ; 3.69	-1.63 ; 2.75	-1.63 ; 3.69
Visit 18 (Week 16)			
N	77	73	150
Mean (SD)	0.63 (0.98)	0.59 (0.87)	0.61 (0.93)
Median	0.68	0.61	0.65
Min ; Max	-1.24 ; 3.78	-1.52 ; 2.81	-1.52 ; 3.78
End of trial visit			
N	80	77	157
Mean (SD)	0.63 (0.97)	0.58 (0.88)	0.60 (0.92)
Median	0.68	0.61	0.65
Min ; Max	-1.24 ; 3.78	-1.52 ; 2.81	-1.52 ; 3.78

N: Number of subjects, SD: Standard deviation

14.3.6.27 SD score for body weight by treatment week - change from baseline - descriptive statistics - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	181	179	360
Change in SD score for weight			
Visit 14 (Week 12)			
N	175	172	347
Mean (SD)	0.04 (0.19)	-0.02 (0.20)	0.01 (0.20)
Median	0.02	-0.02	-0.00
Min ; Max	-0.58 ; 0.52	-0.52 ; 0.46	-0.58 ; 0.52
Visit 18 (Week 16)			
N	175	167	342
Mean (SD)	0.06 (0.24)	-0.02 (0.24)	0.02 (0.24)
Median	0.06	-0.01	0.02
Min ; Max	-0.64 ; 0.91	-0.72 ; 0.74	-0.72 ; 0.91
End of trial visit			
N	181	179	360
Mean (SD)	0.06 (0.24)	-0.02 (0.24)	0.02 (0.24)
Median	0.06	-0.01	0.02
Min ; Max	-0.64 ; 0.91	-0.72 ; 0.74	-0.72 ; 0.91

N: Number of subjects, SD: Standard deviation

14.3.6.28 SD score for body weight by treatment week - change from baseline - descriptive statistics - children (1-5 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	40	41	81
Change in SD score for weight			
Visit 14 (Week 12)			
N	38	39	77
Mean (SD)	0.00 (0.23)	-0.02 (0.25)	-0.01 (0.24)
Median	-0.03	-0.01	-0.03
Min ; Max	-0.58 ; 0.46	-0.52 ; 0.43	-0.58 ; 0.46
Visit 18 (Week 16)			
N	38	35	73
Mean (SD)	0.07 (0.33)	0.03 (0.36)	0.05 (0.34)
Median	0.10	-0.01	0.05
Min ; Max	-0.64 ; 0.91	-0.72 ; 0.74	-0.72 ; 0.91
End of trial visit			
N	40	41	81
Mean (SD)	0.06 (0.33)	0.03 (0.35)	0.05 (0.34)
Median	0.10	-0.01	0.04
Min ; Max	-0.64 ; 0.91	-0.72 ; 0.74	-0.72 ; 0.91

N: Number of subjects, SD: Standard deviation

14.3.6.29 SD score for body weight by treatment week - change from baseline - descriptive statistics - children (6-11 years) - safety analysis set

	IDegAsp OD	IDet	Total
Number of Subjects	61	61	122
Change in SD score for weight			
Visit 14 (Week 12)			
N	60	59	119
Mean (SD)	0.07 (0.16)	-0.03 (0.19)	0.02 (0.18)
Median	0.05	-0.04	0.00
Min ; Max	-0.27 ; 0.42	-0.51 ; 0.35	-0.51 ; 0.42
Visit 18 (Week 16)			
N	60	59	119
Mean (SD)	0.07 (0.21)	-0.04 (0.20)	0.01 (0.21)
Median	0.04	-0.02	0.02
Min ; Max	-0.41 ; 0.47	-0.57 ; 0.35	-0.57 ; 0.47
End of trial visit			
N	61	61	122
Mean (SD)	0.06 (0.21)	-0.04 (0.19)	0.01 (0.21)
Median	0.04	-0.01	0.02
Min ; Max	-0.41 ; 0.47	-0.57 ; 0.35	-0.57 ; 0.47

N: Number of subjects, SD: Standard deviation

14.3.6.30 SD score for body weight by treatment week - change from baseline - descriptive statistics - adolescents (12-17 years) - safety analysis set

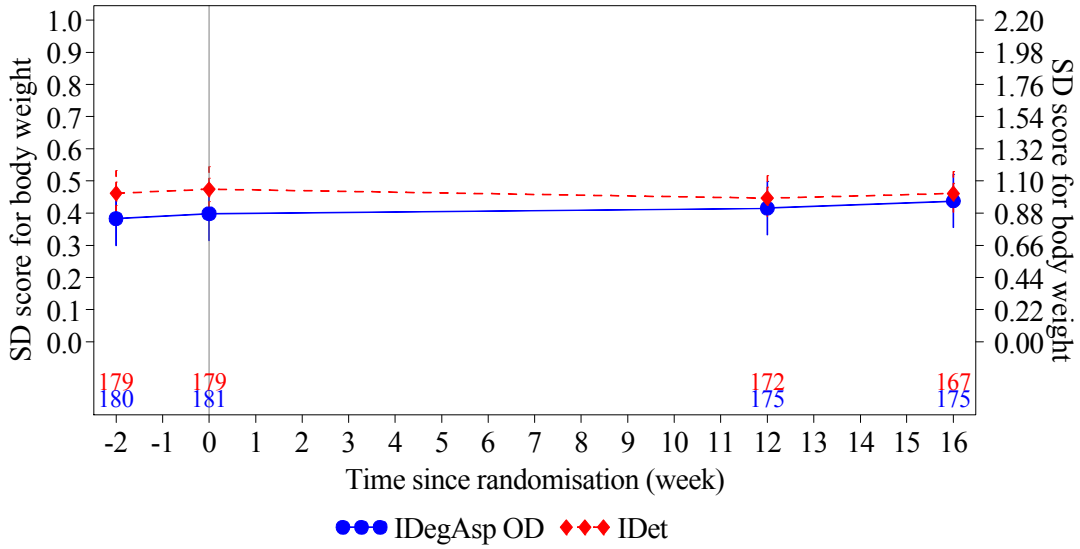
	IDegAsp OD	IDet	Total
Number of Subjects	80	77	157
Change in SD score for weight			
Visit 14 (Week 12)			
N	77	74	151
Mean (SD)	0.03 (0.19)	-0.02 (0.17)	0.01 (0.18)
Median	0.04	-0.02	0.01
Min ; Max	-0.37 ; 0.52	-0.49 ; 0.46	-0.49 ; 0.52
Visit 18 (Week 16)			
N	77	73	150
Mean (SD)	0.05 (0.21)	-0.02 (0.19)	0.02 (0.20)
Median	0.06	-0.01	0.02
Min ; Max	-0.42 ; 0.65	-0.48 ; 0.49	-0.48 ; 0.65
End of trial visit			
N	80	77	157
Mean (SD)	0.05 (0.21)	-0.02 (0.19)	0.02 (0.21)
Median	0.06	-0.01	0.01
Min ; Max	-0.42 ; 0.65	-0.48 ; 0.49	-0.48 ; 0.65

N: Number of subjects, SD: Standard deviation

14.3.6.31 SD score for body weight after 16 weeks of treatment - statistical analysis - full analysis set

	FAS	N	Estimate	SE	95% CI
SD score for body weight					
LSMeans					
IDegAsp OD	182	175	0.49	0.02	
IDet	180	172	0.41	0.02	
Treatment Contrast					
IDegAsp OD - IDet			0.07		[0.02; 0.12]

N: Number of subjects contributing to analysis, CI: Confidence interval,
SE: Standard error of the mean
All SD score (based on observed body weight) measurements available post-randomisation at scheduled measurement times is analysed with a MMRM with an unstructured covariance matrix. The model includes treatment, sex, region, age-group and visit as factors and baseline SD score as covariate. Interactions between visit and all factors and covariates are also included in the model.



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

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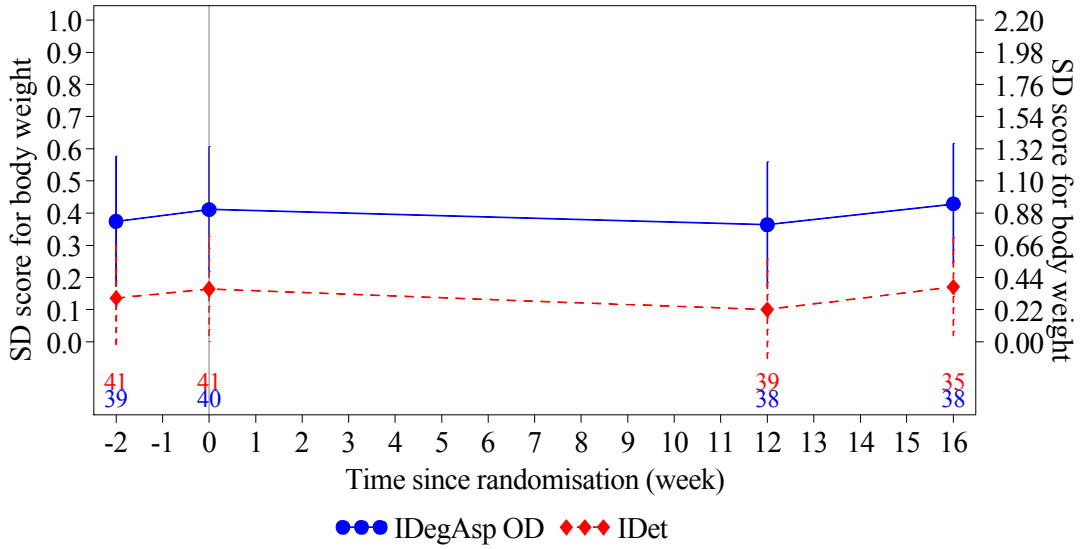
12MAR2015:08:46:16 - fmean_numfind_deg_cust.sas/e_bw_sds_abs_mean_obs_sas.cgm

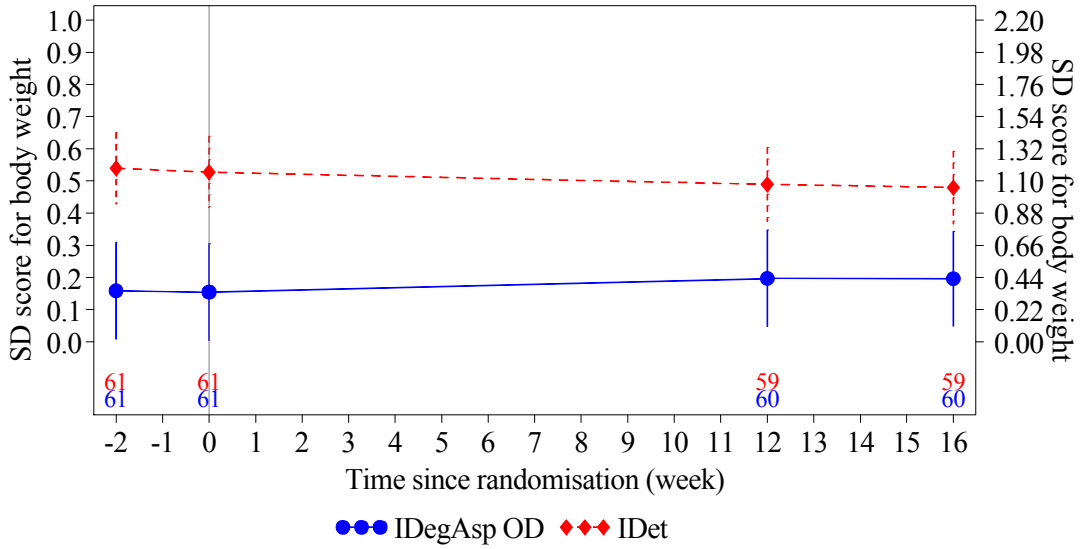
14.3.6.32 SD score for body weight - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:46:17 - fmean_numfind_deg_cust.sas/e_bw_sds_abs_mean_obs_age1_sas.cgm

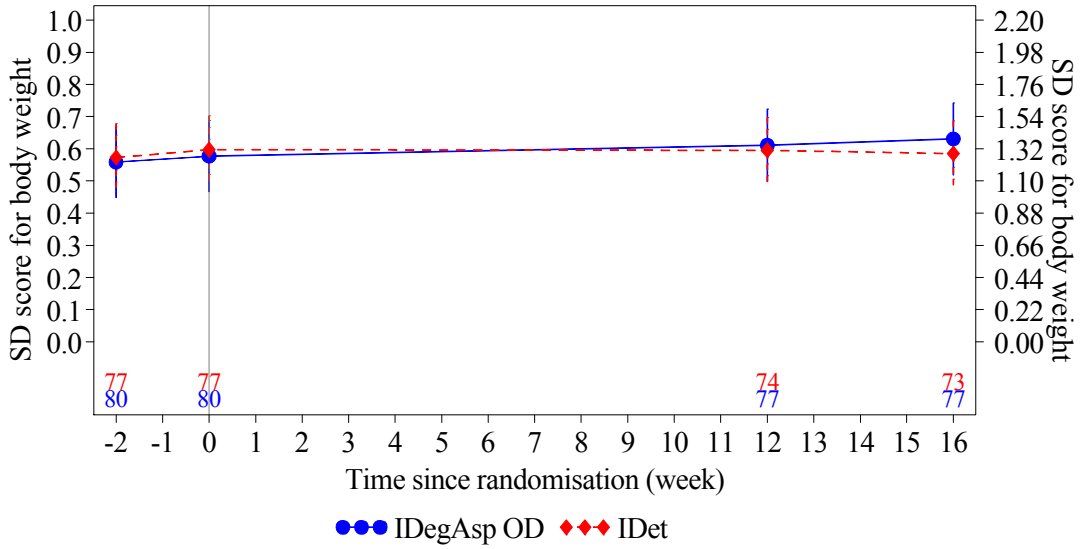
14.3.6.33 SD score for body weight - mean plot - children (1-5 years) - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:46:17 - fmean_numfind_deg_cust.sas/e_bw_sds_abs_mean_obs_age2_sas.cgm

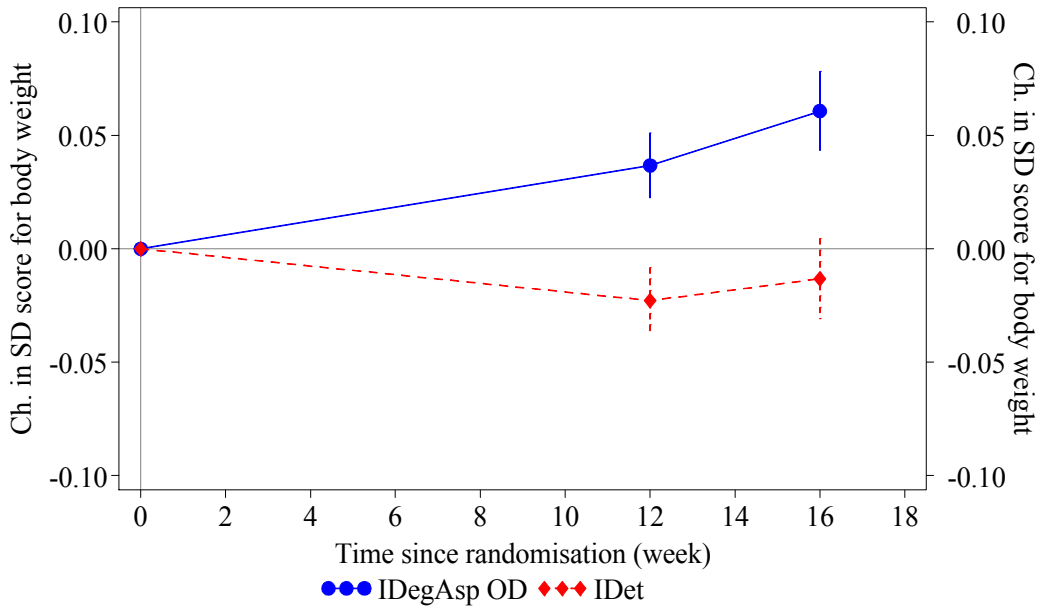
14.3.6.34 SD score for body weight - mean plot - children (6-11 years) - mean plot - safety analysis set



SAFETY: Observed data
SAFETY: Safety analysis set, Error bars: +- Standard error (mean)
Bottom of the plot area: Subjects contributing to the data points.
From the bottom: 1. IDegAsp OD 2. IDet

nn5401/nn5401-3816/er_20150312_ctr
12MAR2015:08:46:18 - fmean_numfind_deg_cust.sas/e_bw_sds_abs_mean_obs_age3_sas.cgm

14.3.6.35 SD score for body weight - mean plot - adolescents (12-17 years) - mean plot - safety analysis set



FAS: MMRM data
FAS: Full analysis set, Error bars: +- Standard error of estimates from MMRM model
MMRM: Mixed model for repeated measurements

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14.3.6.36 SD score for body weight – change from baseline - lsmean plot - full analysis set

14.3.7 Other safety observations listings

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)

[redacted]

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)

[redacted]

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

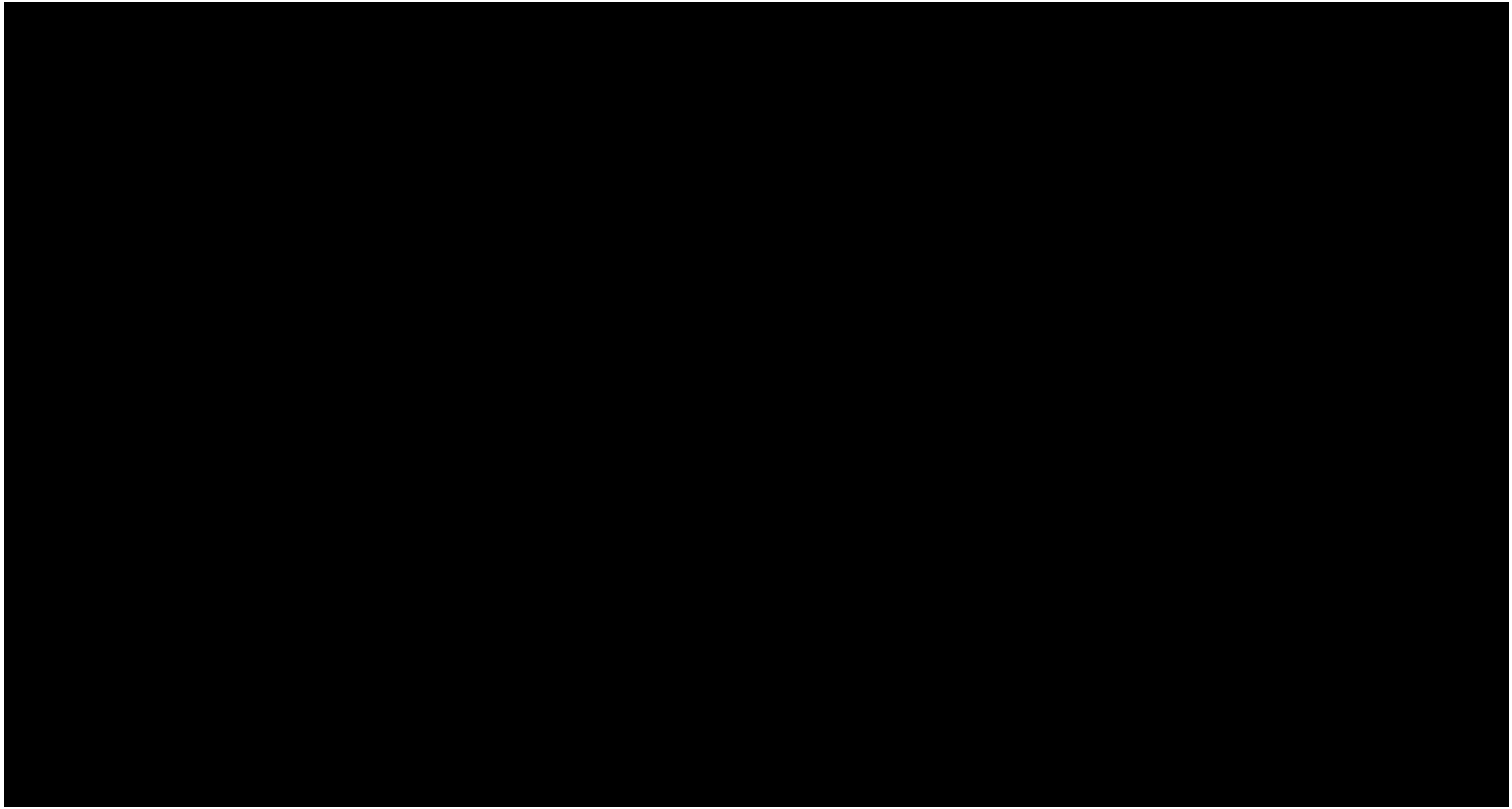
Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (Beats/min)

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)

14.3.7.2 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
[redacted]								

Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	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
[redacted]								

Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	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

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Physical examination findings - safety analysis set

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Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	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

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Physical examination findings - safety analysis set

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Physical examination findings - safety analysis set

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Physical examination findings - safety analysis set

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical examination findings - safety analysis set

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Physical examination findings - safety analysis set

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Physical examination findings - safety analysis set

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Physical examination findings - safety analysis set

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Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
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Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	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

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment
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Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Physical examination findings - safety analysis set

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Physical examination findings - safety analysis set

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

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Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

Physical examination findings - safety analysis set

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Physical examination findings - safety analysis set

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Physical examination findings - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	BMI (kg/m^2)	Visit	Body System	Result	Comment

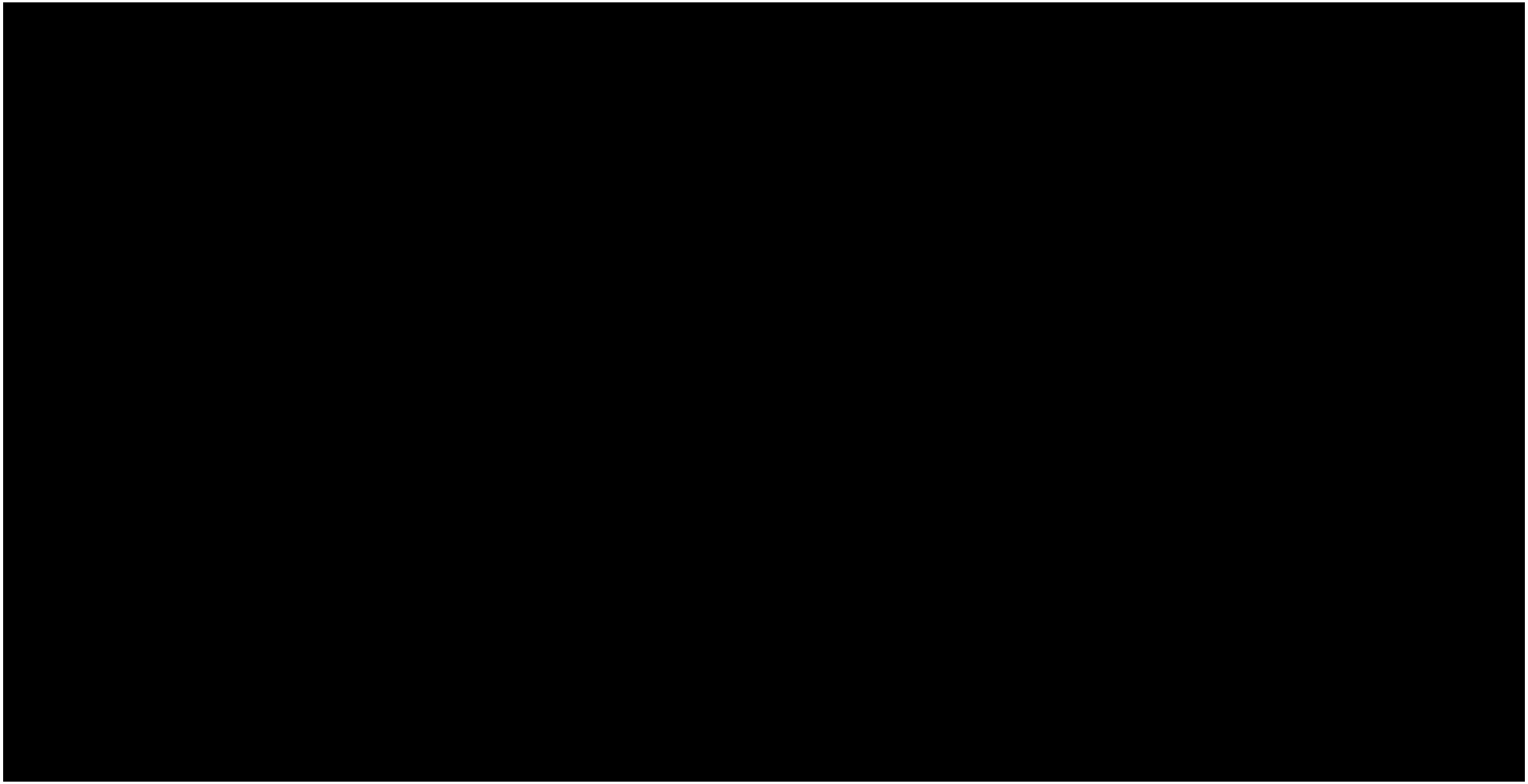
14.3.7.3 Body measurements - safety analysis set

Subject ID	Treatment	Age (yrs)	Sex (M/F)	Visit	Height (m)	Body Weight (kg)	BMI (kg/m^2)

[redacted]

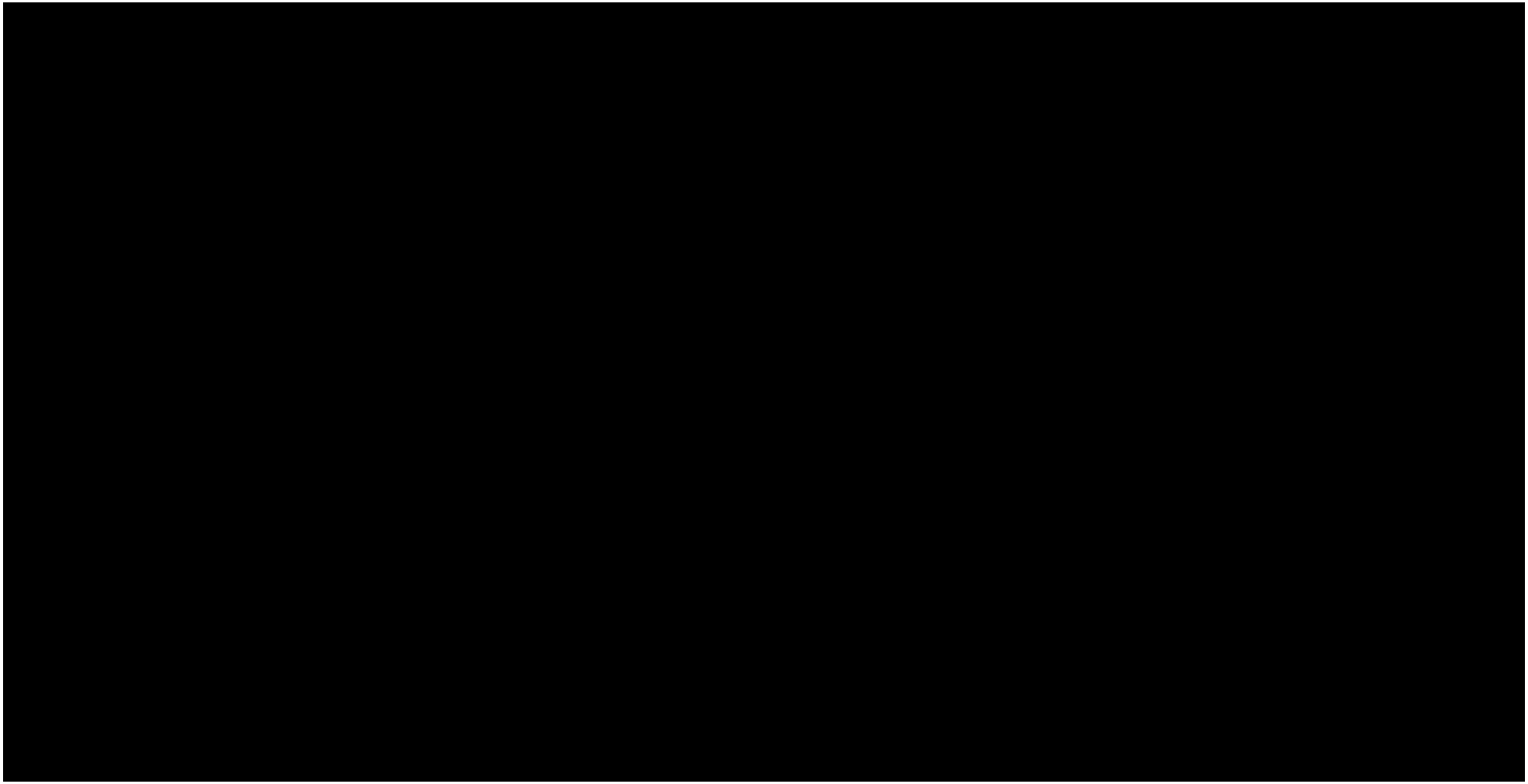
Body measurements - safety analysis set

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)



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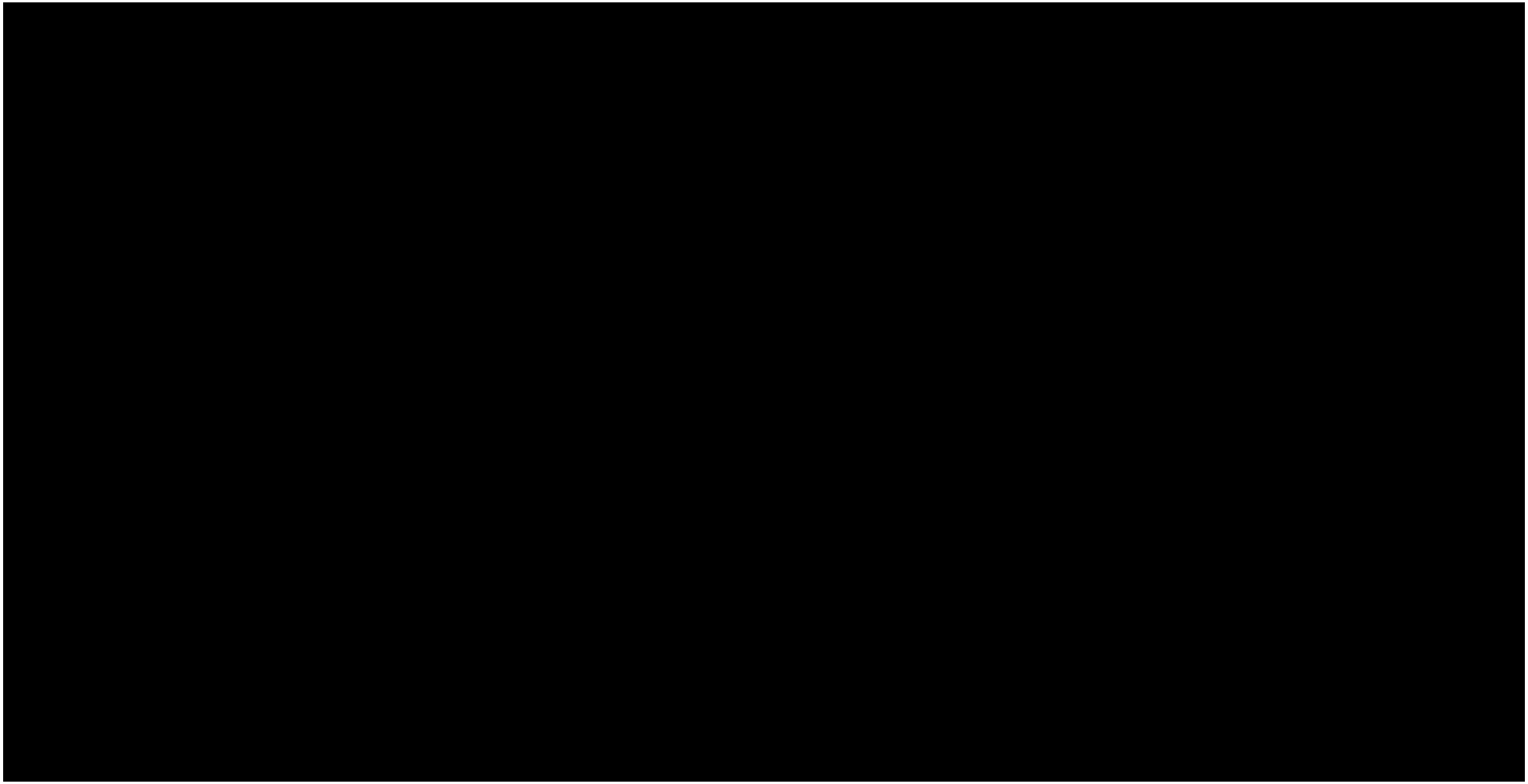

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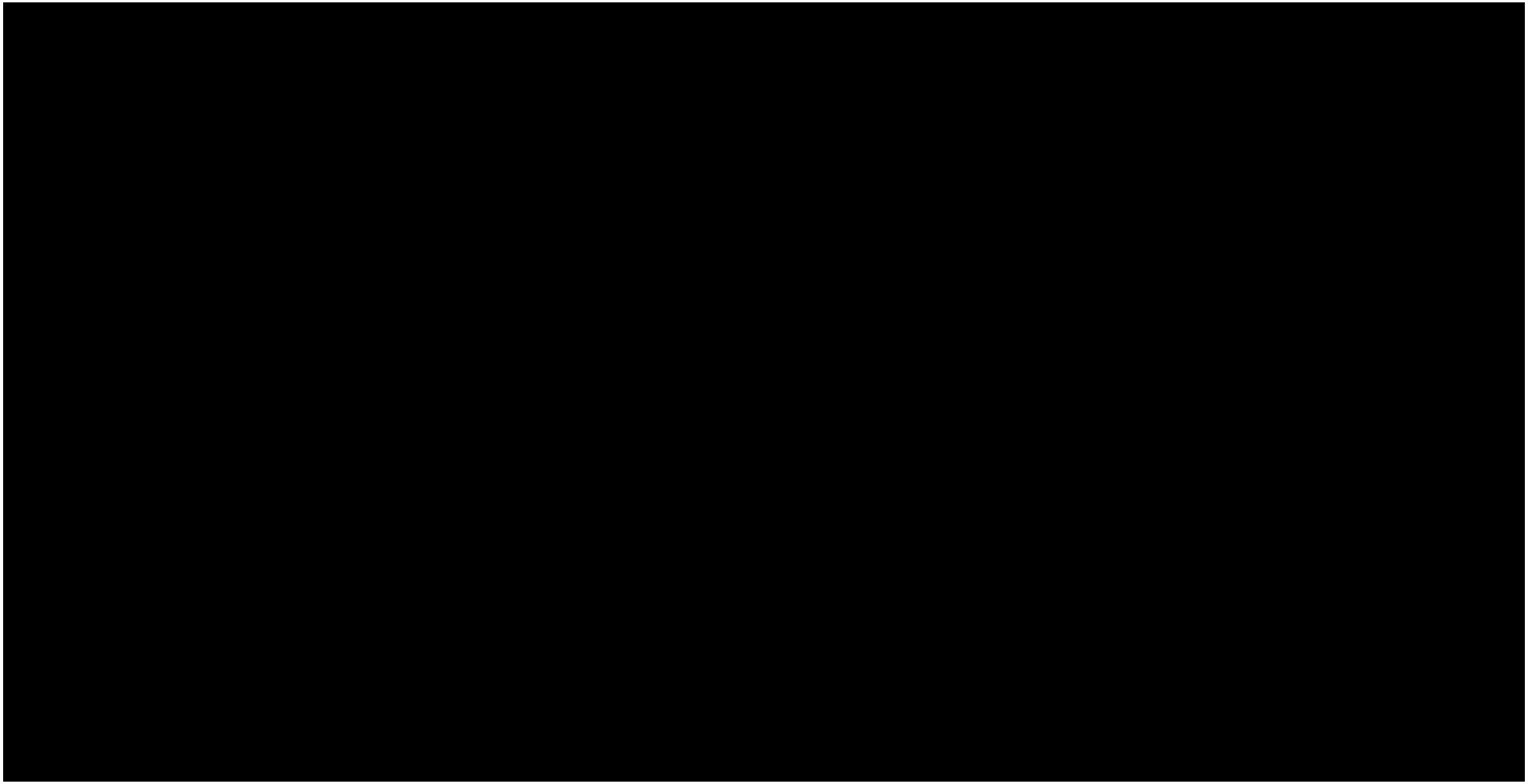

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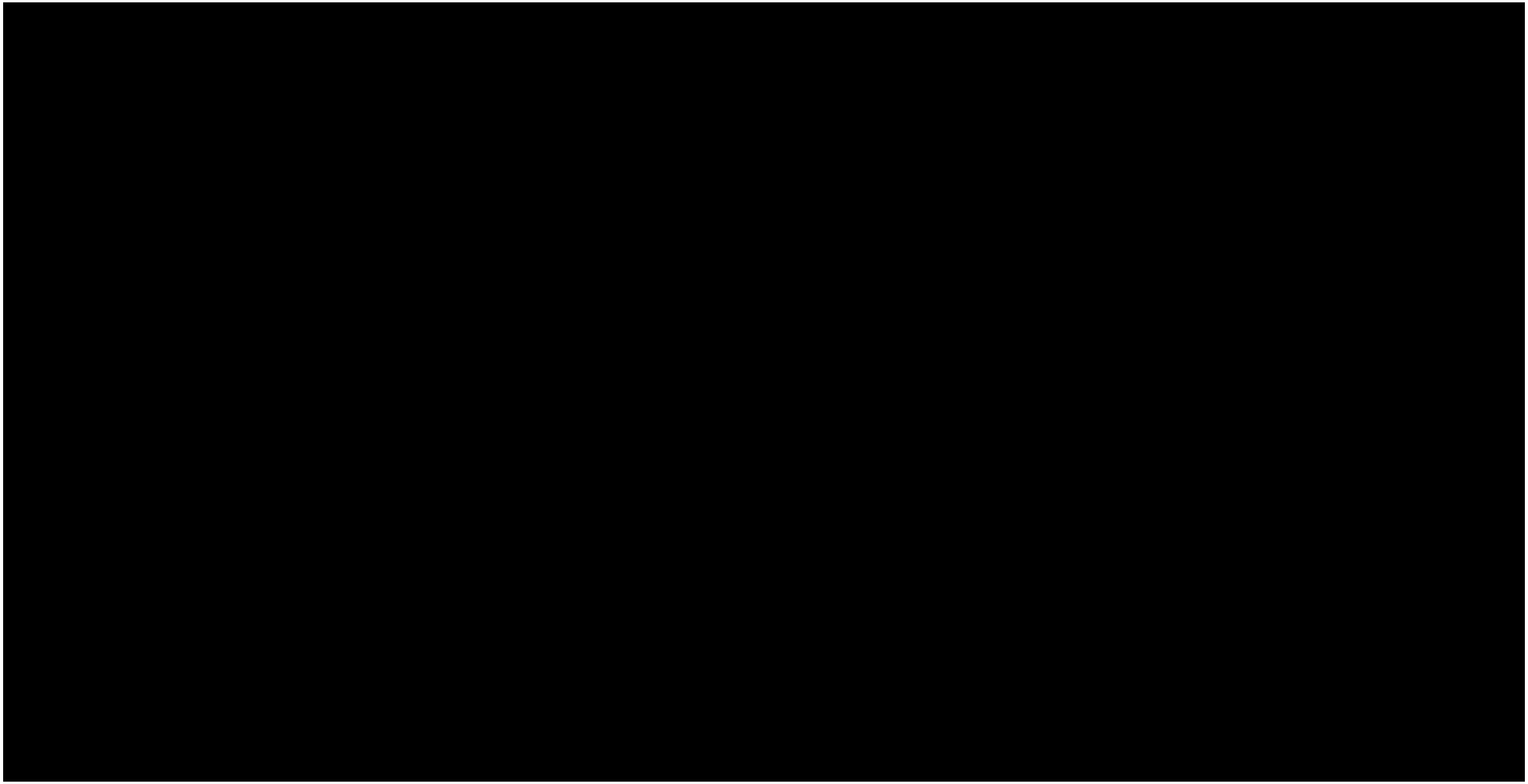

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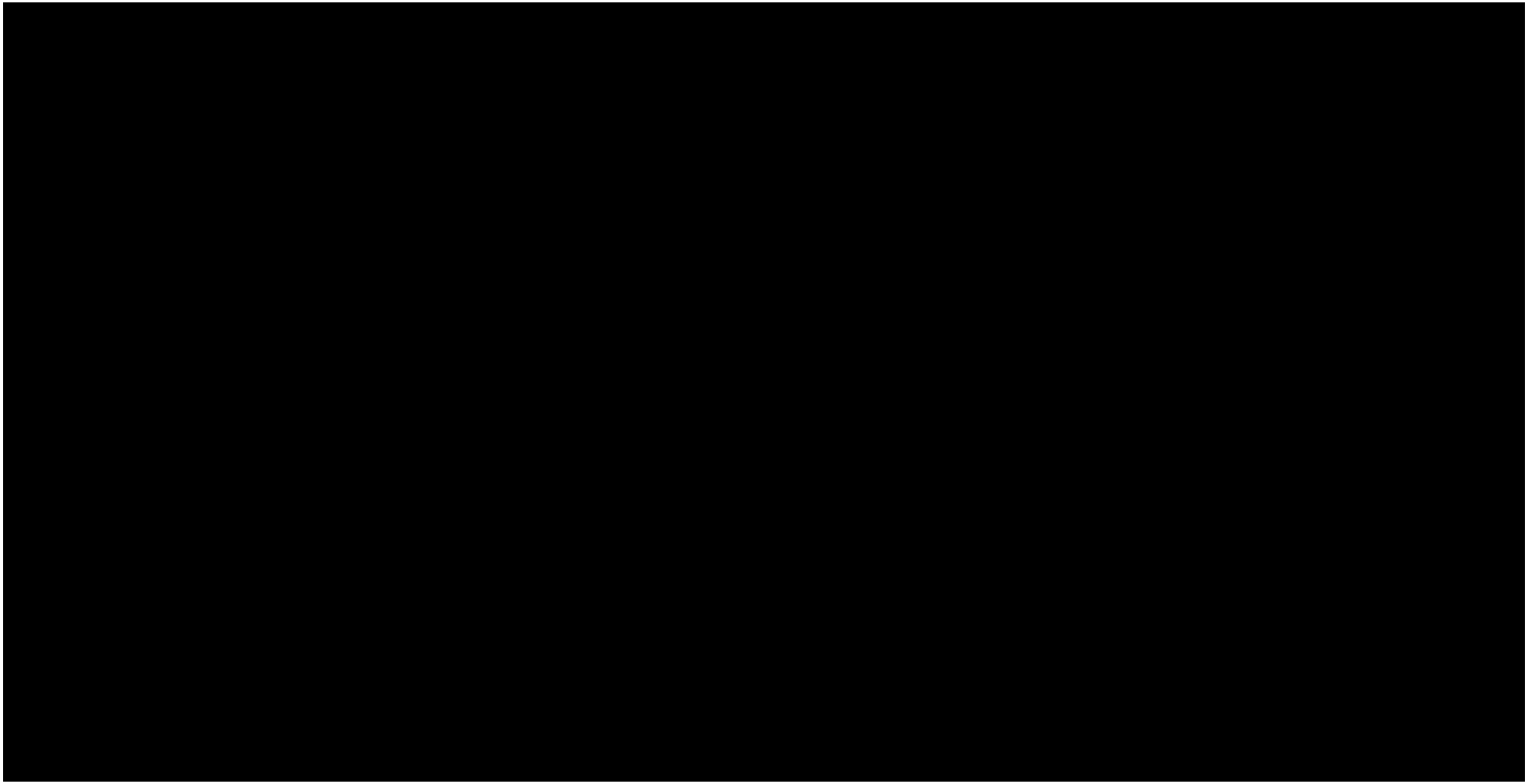

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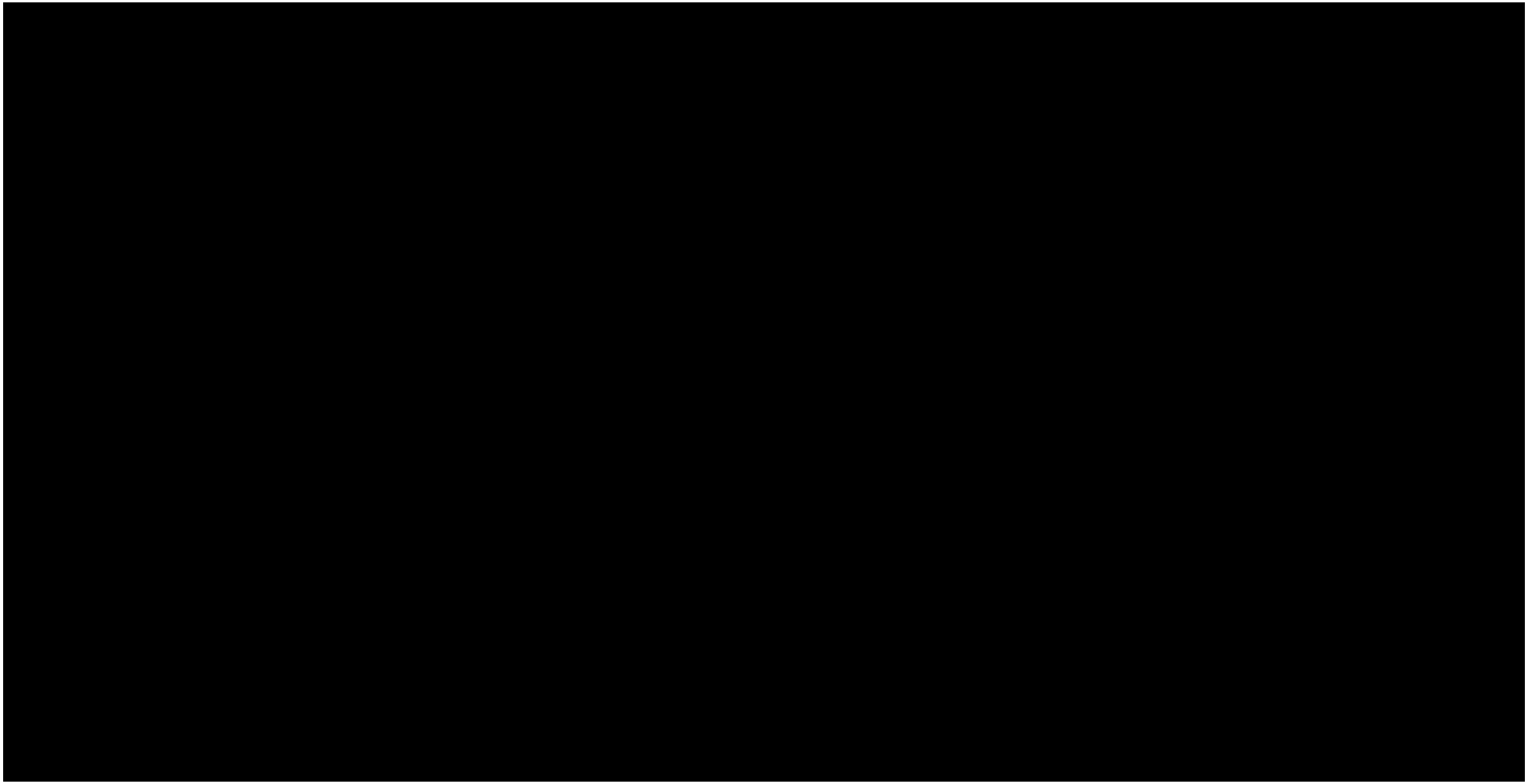

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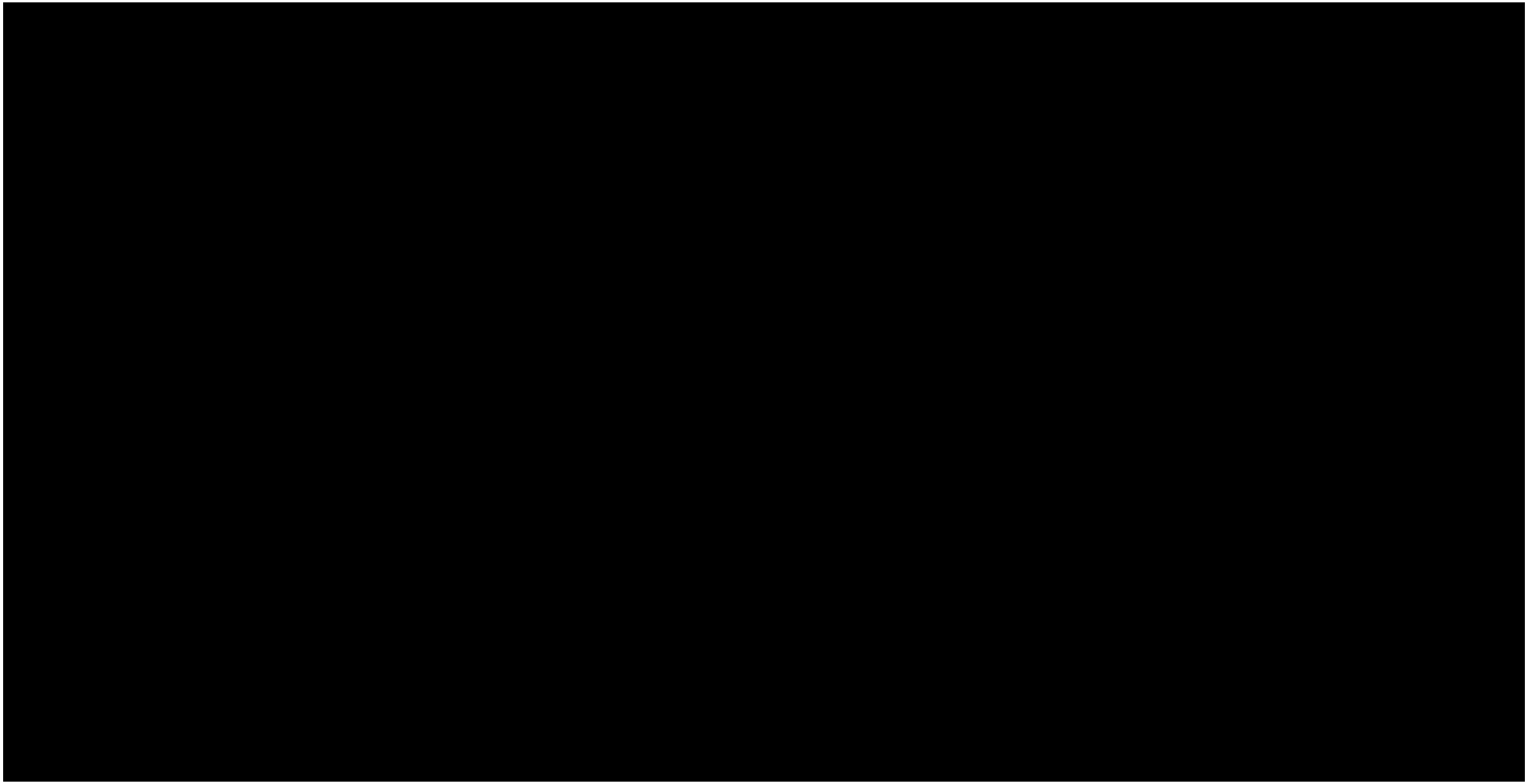

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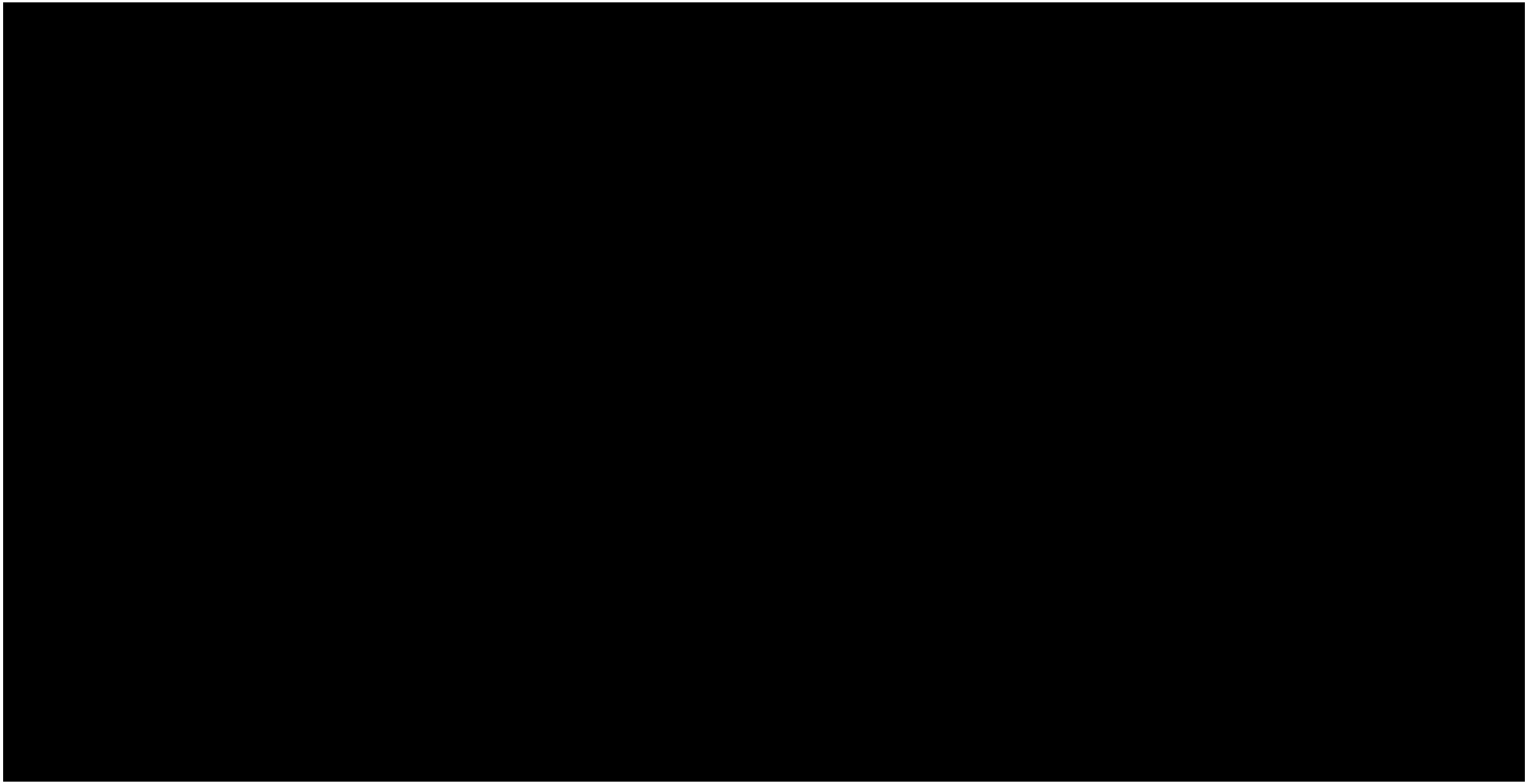

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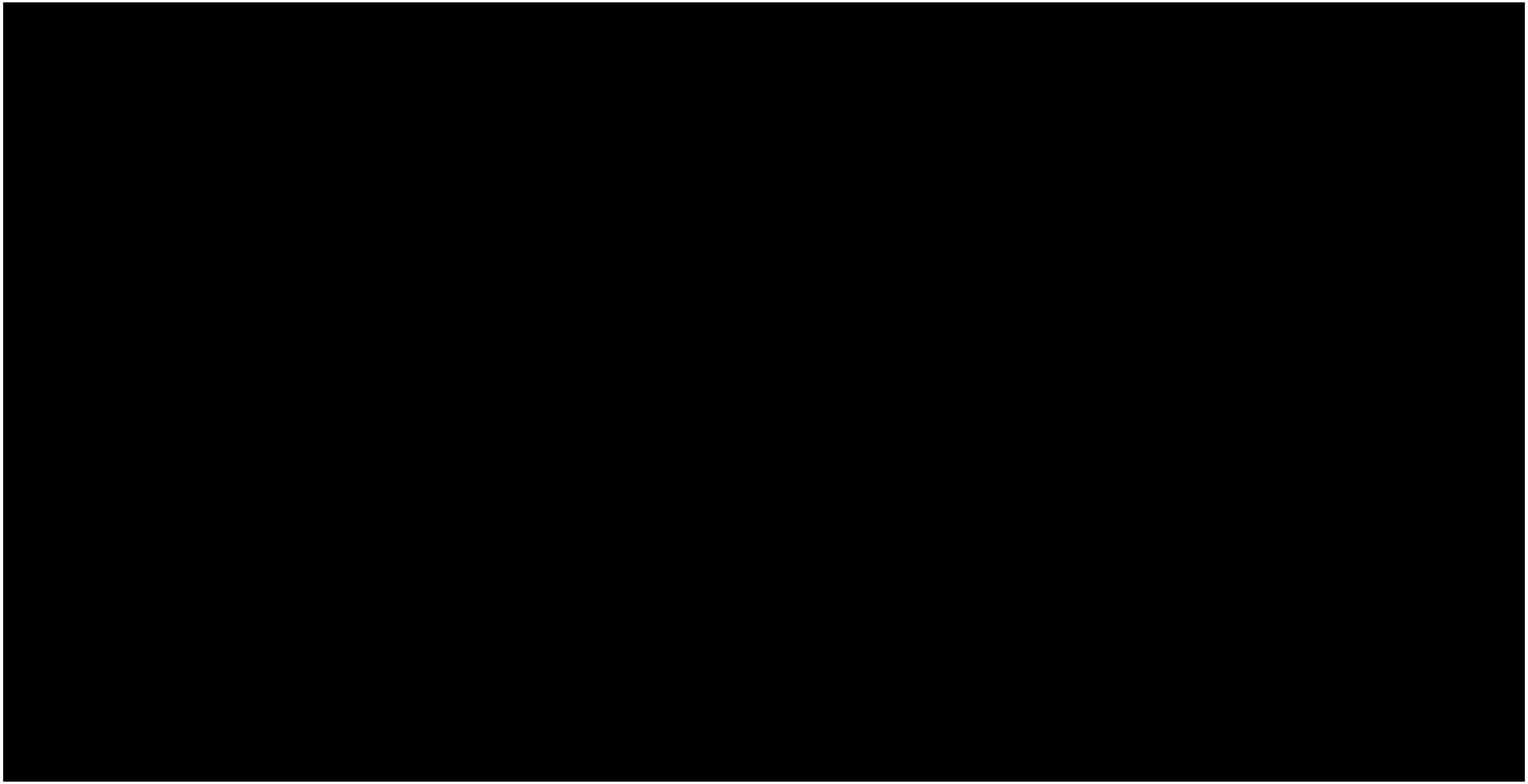

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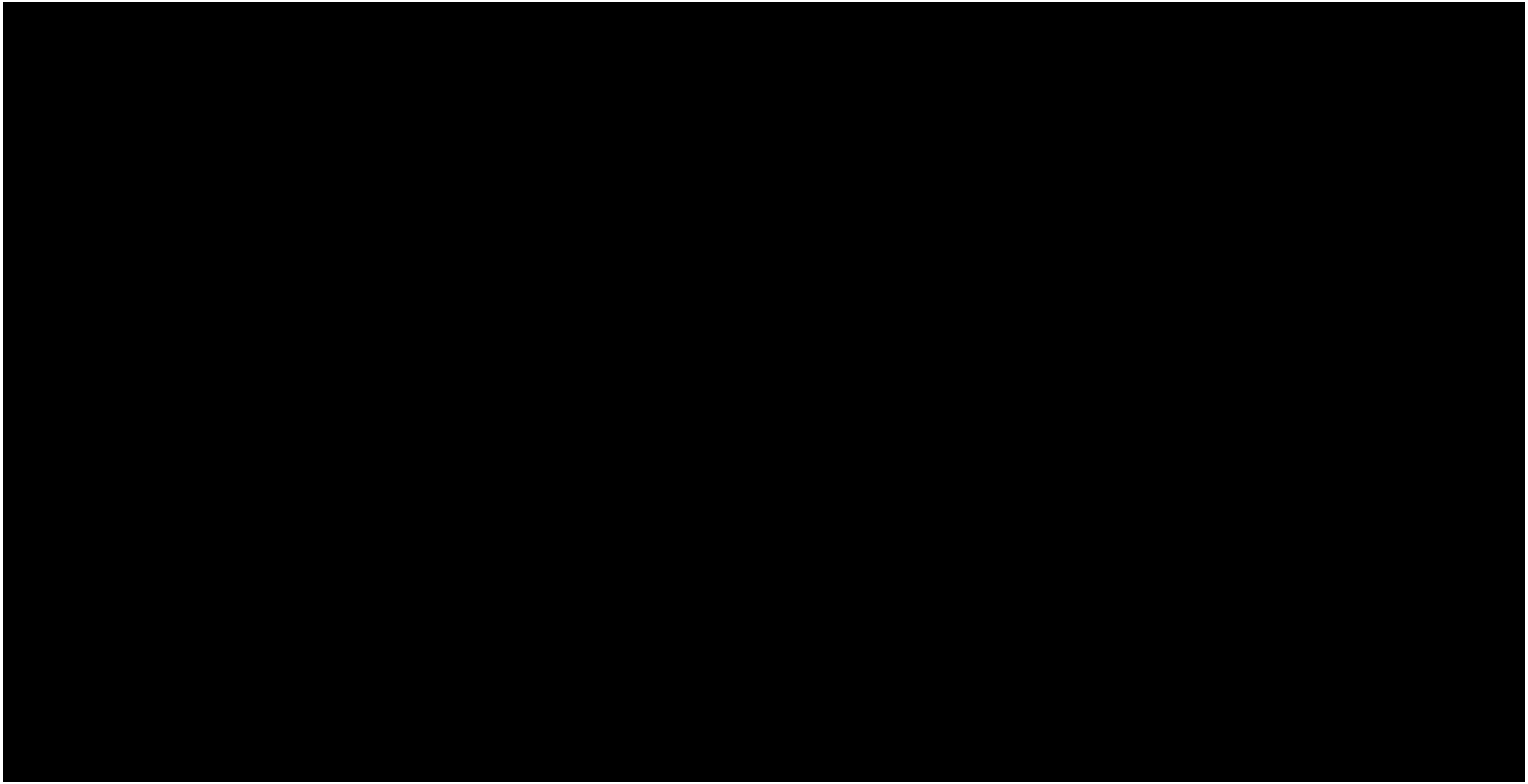

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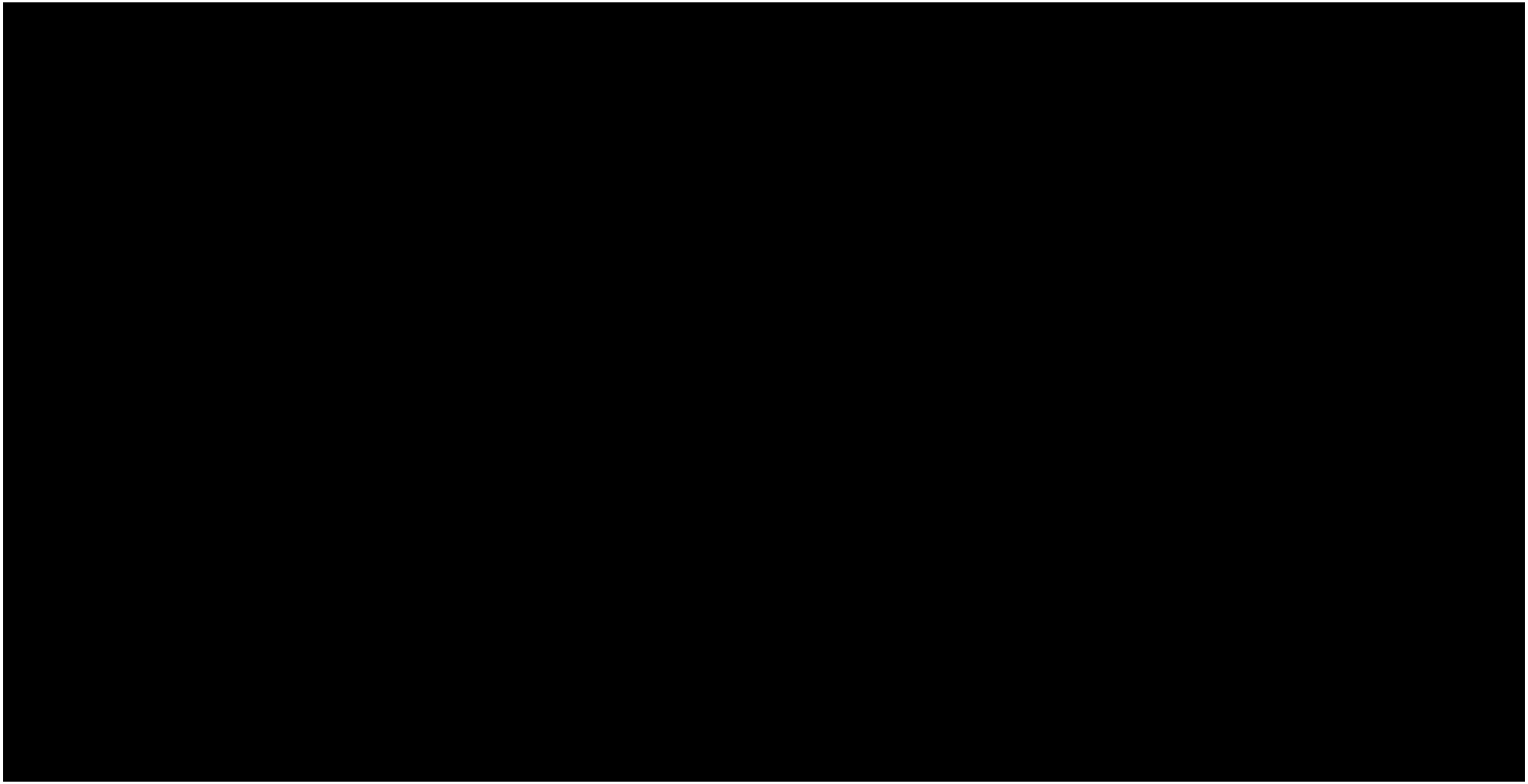

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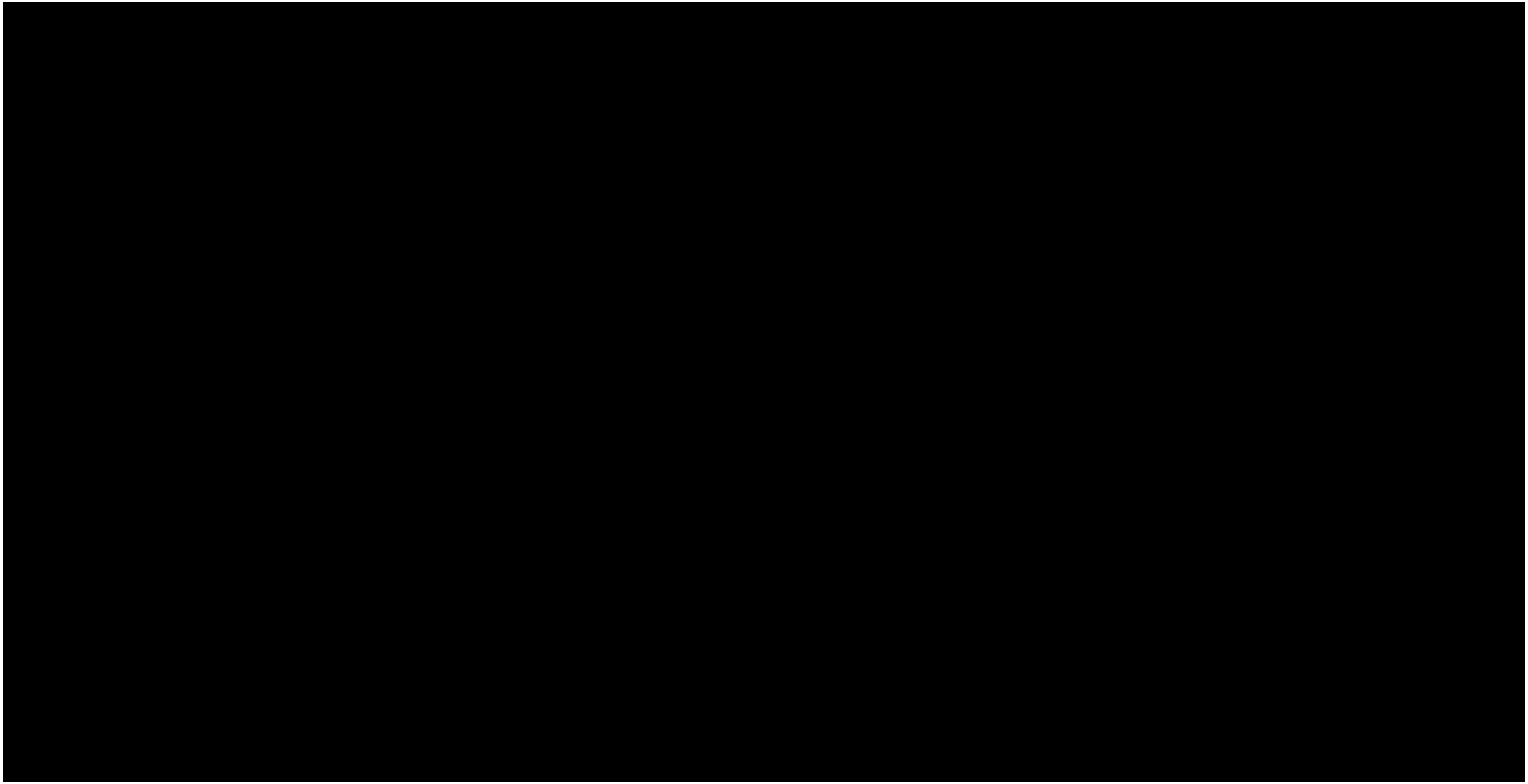

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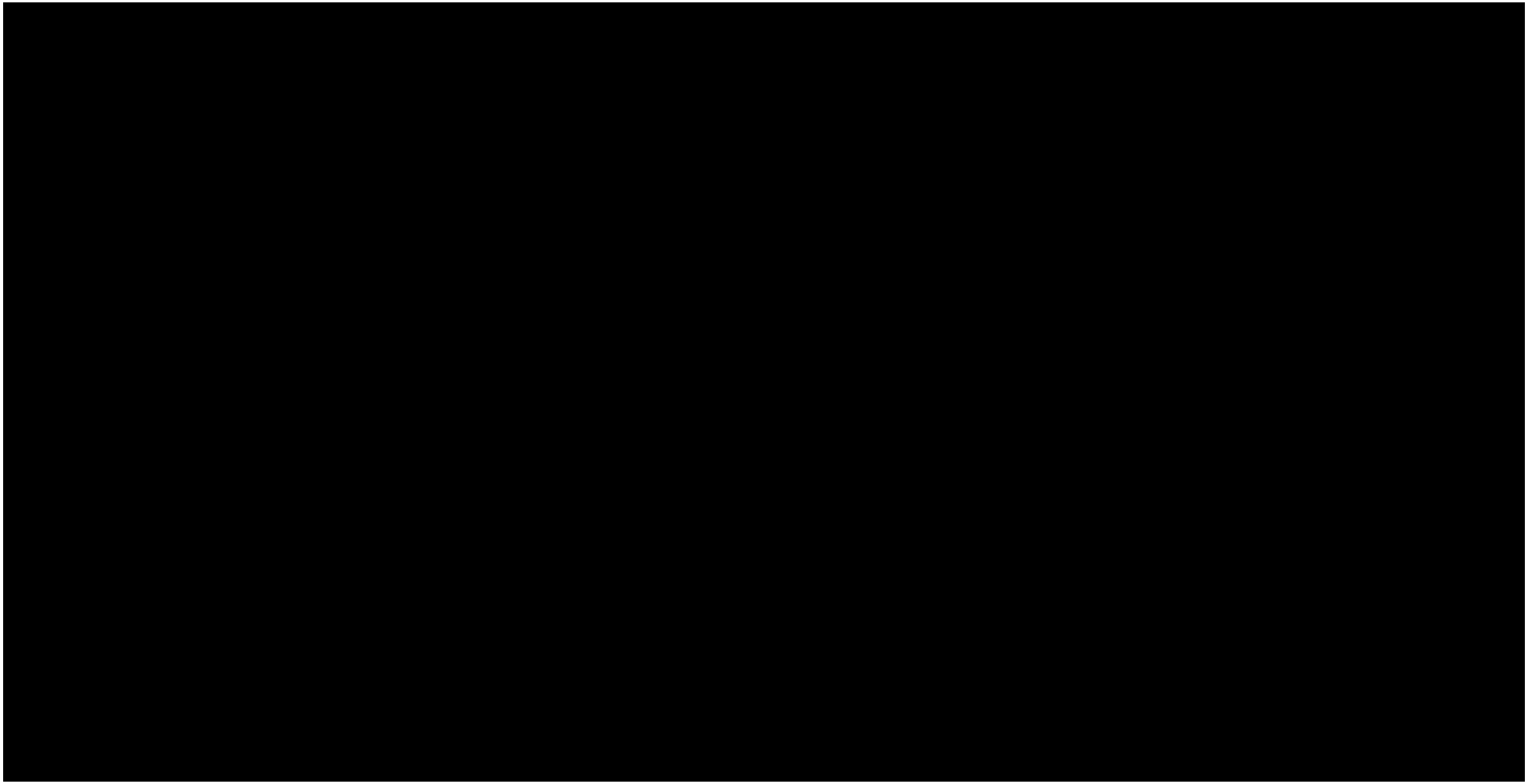

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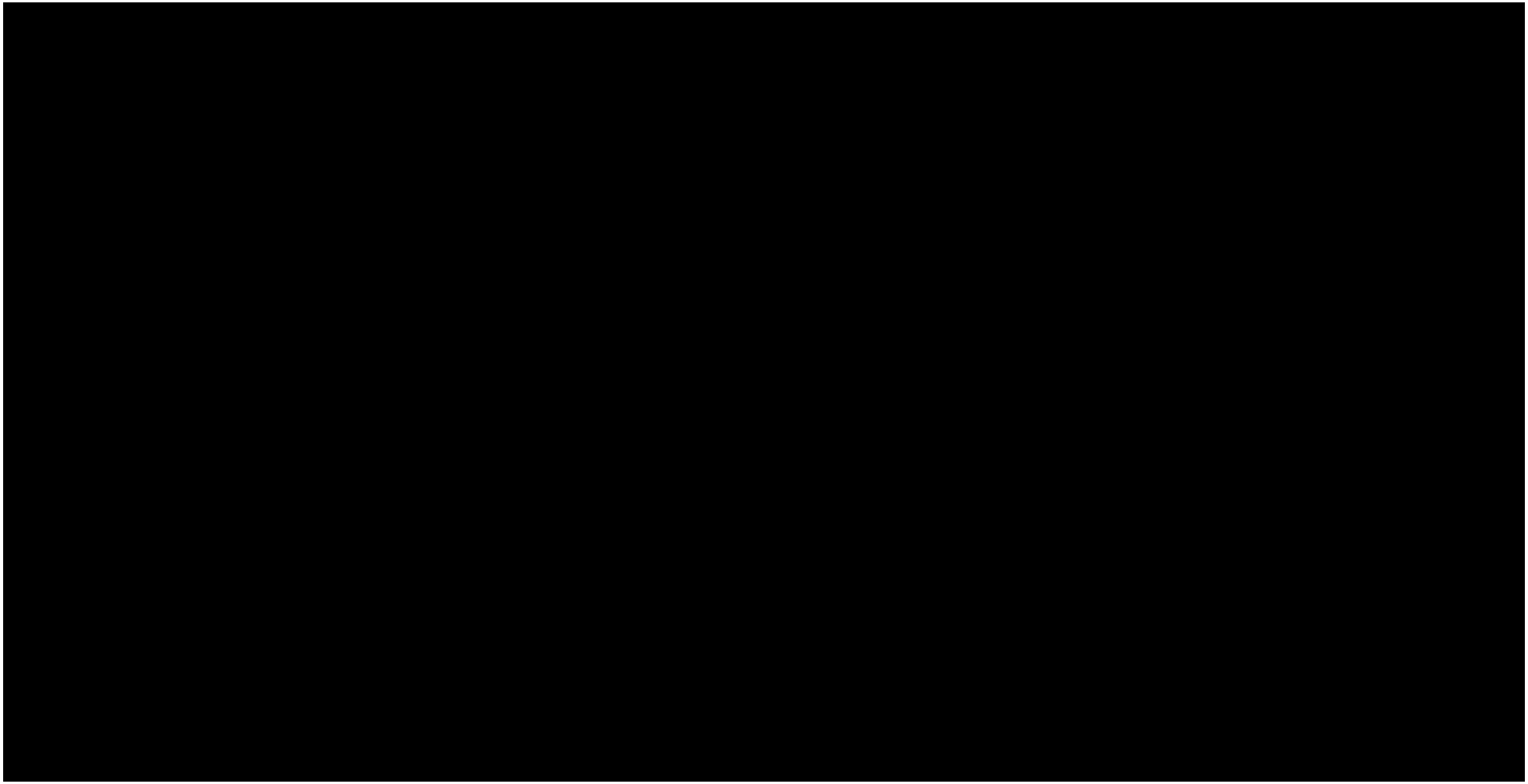

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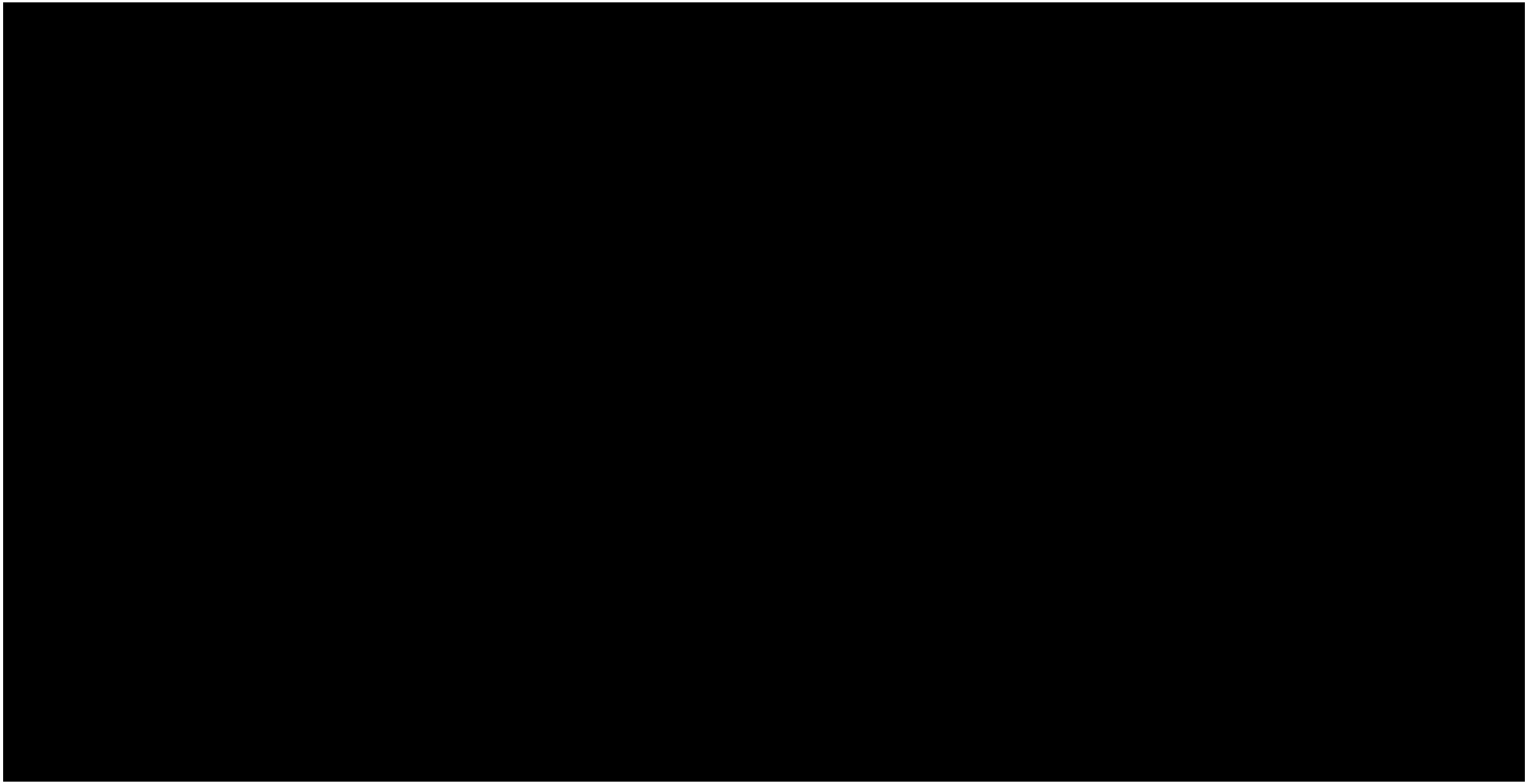

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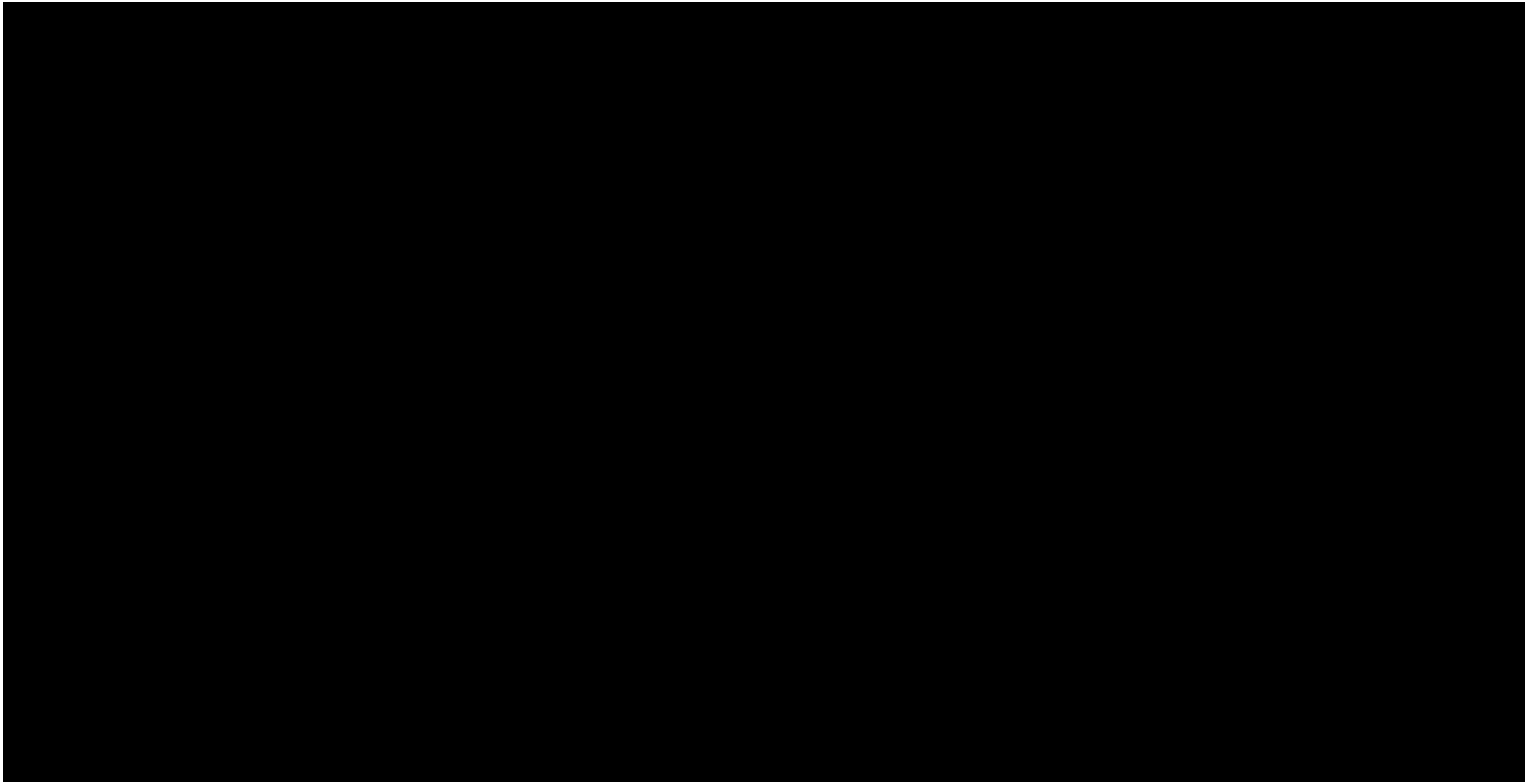

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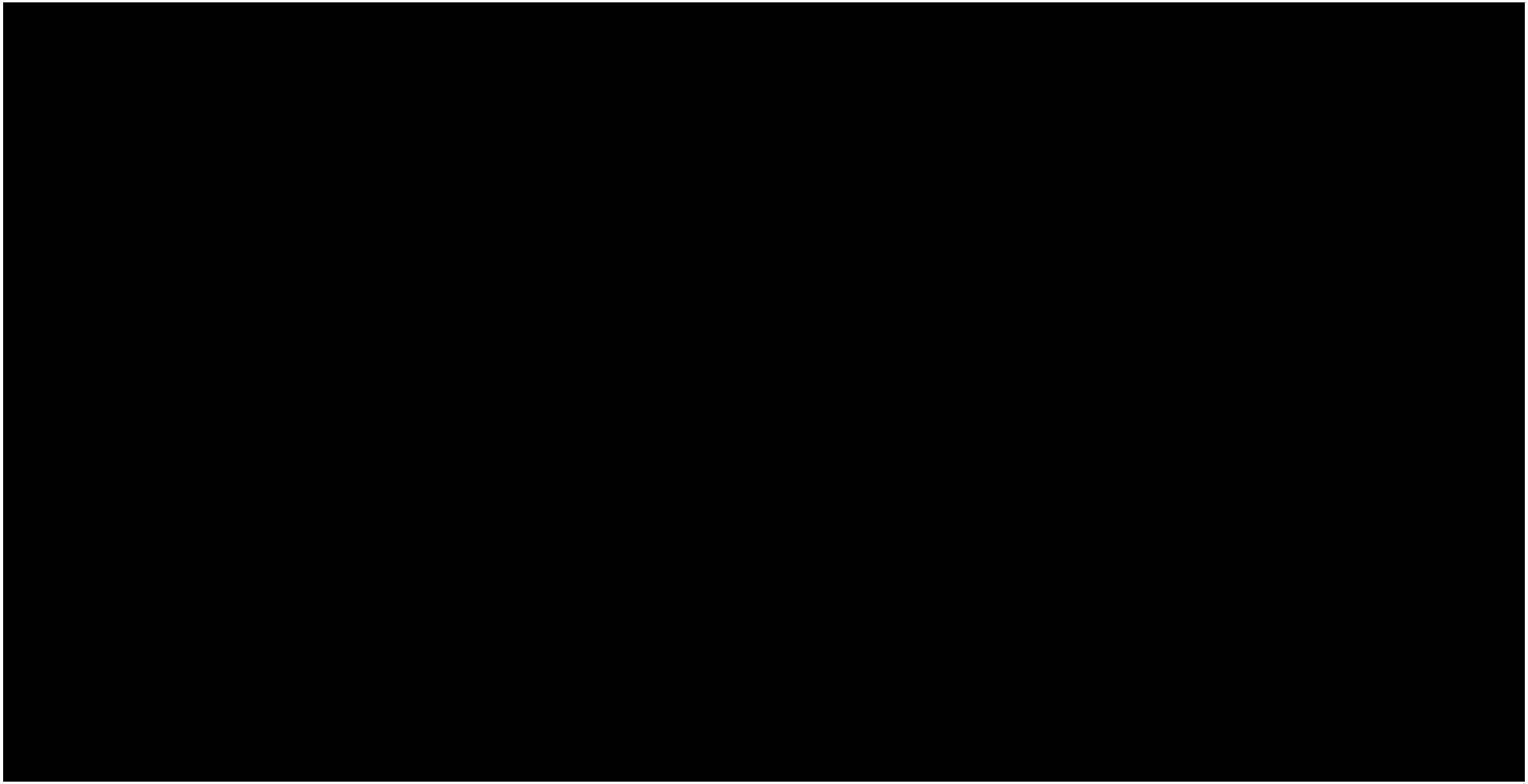

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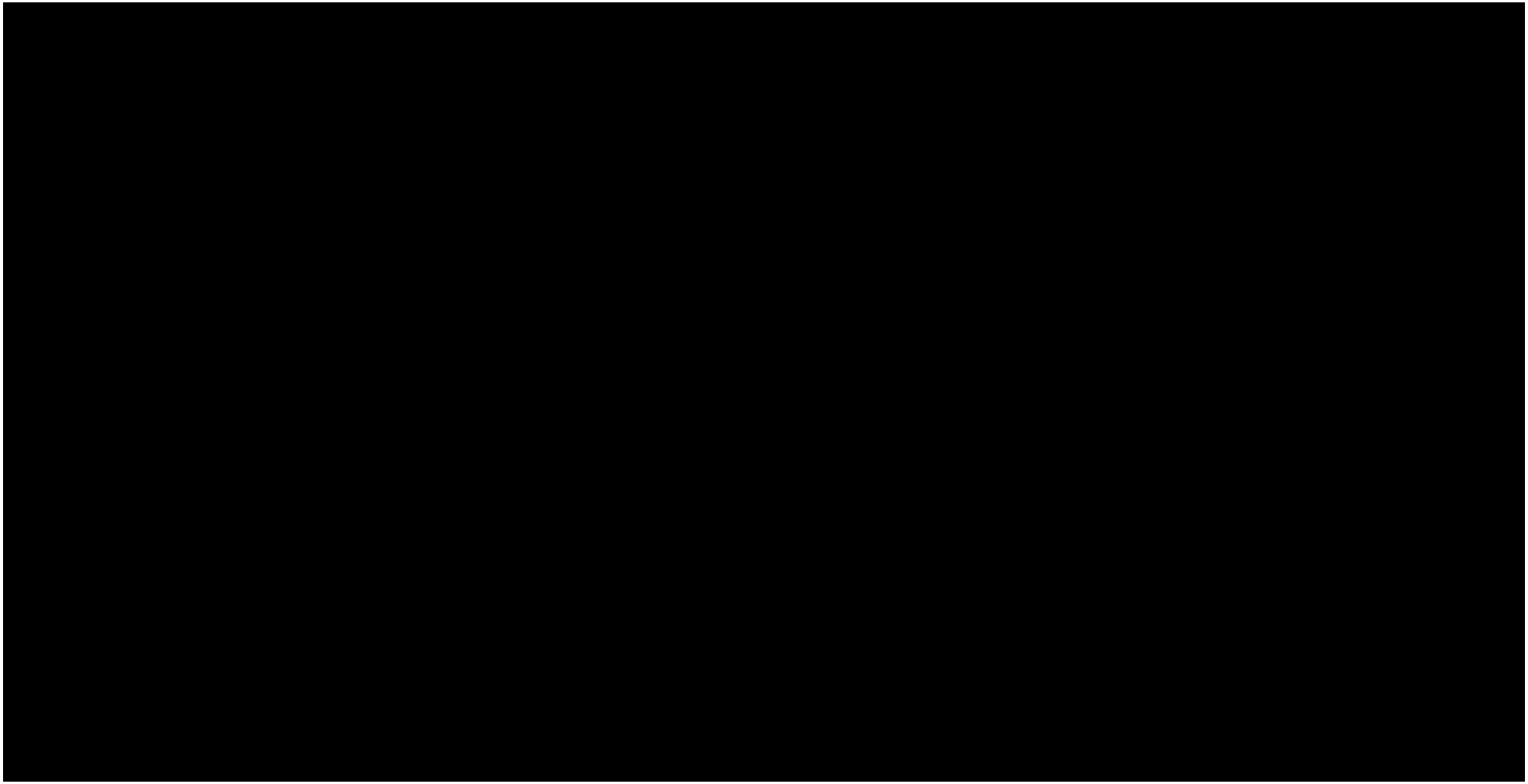

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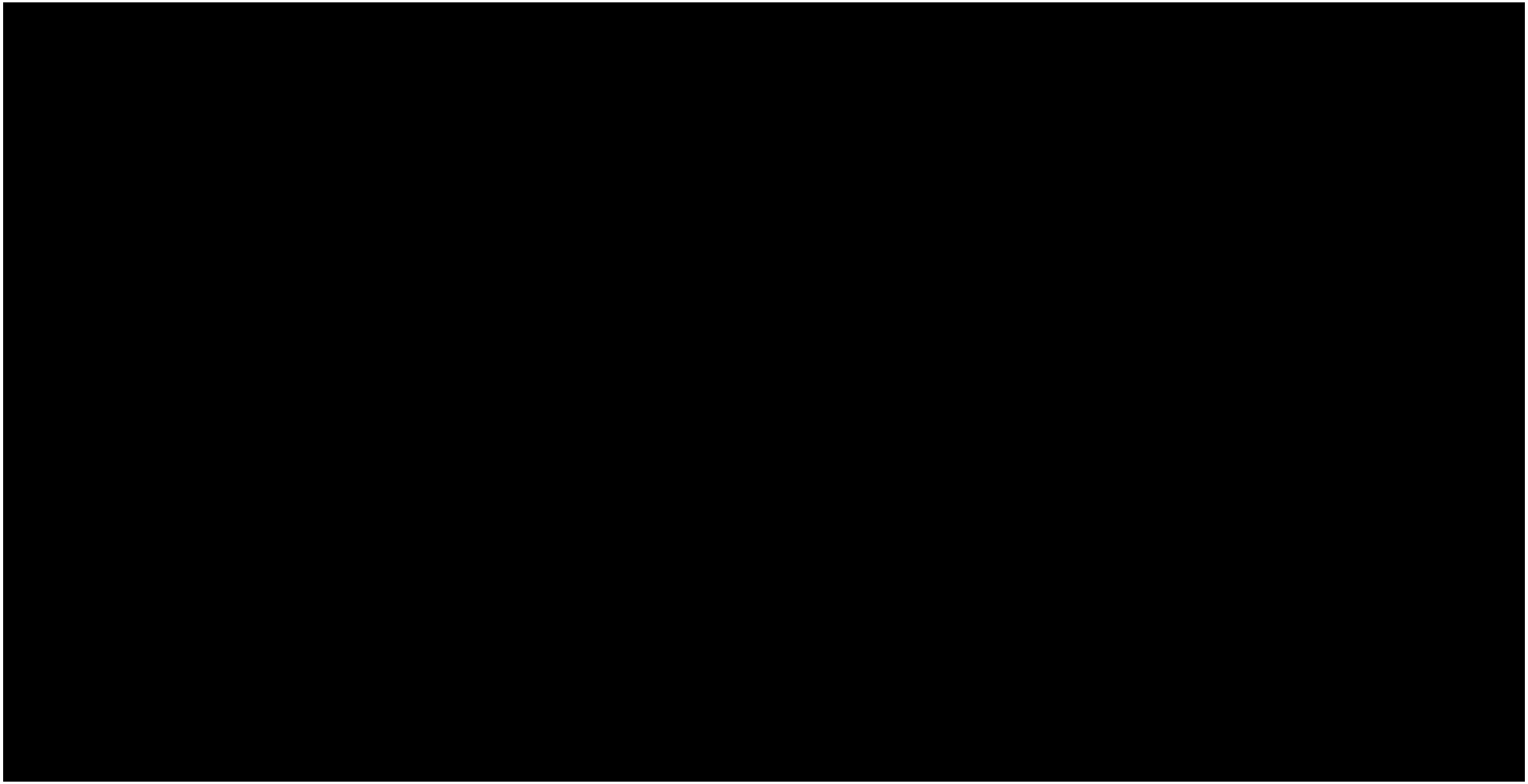

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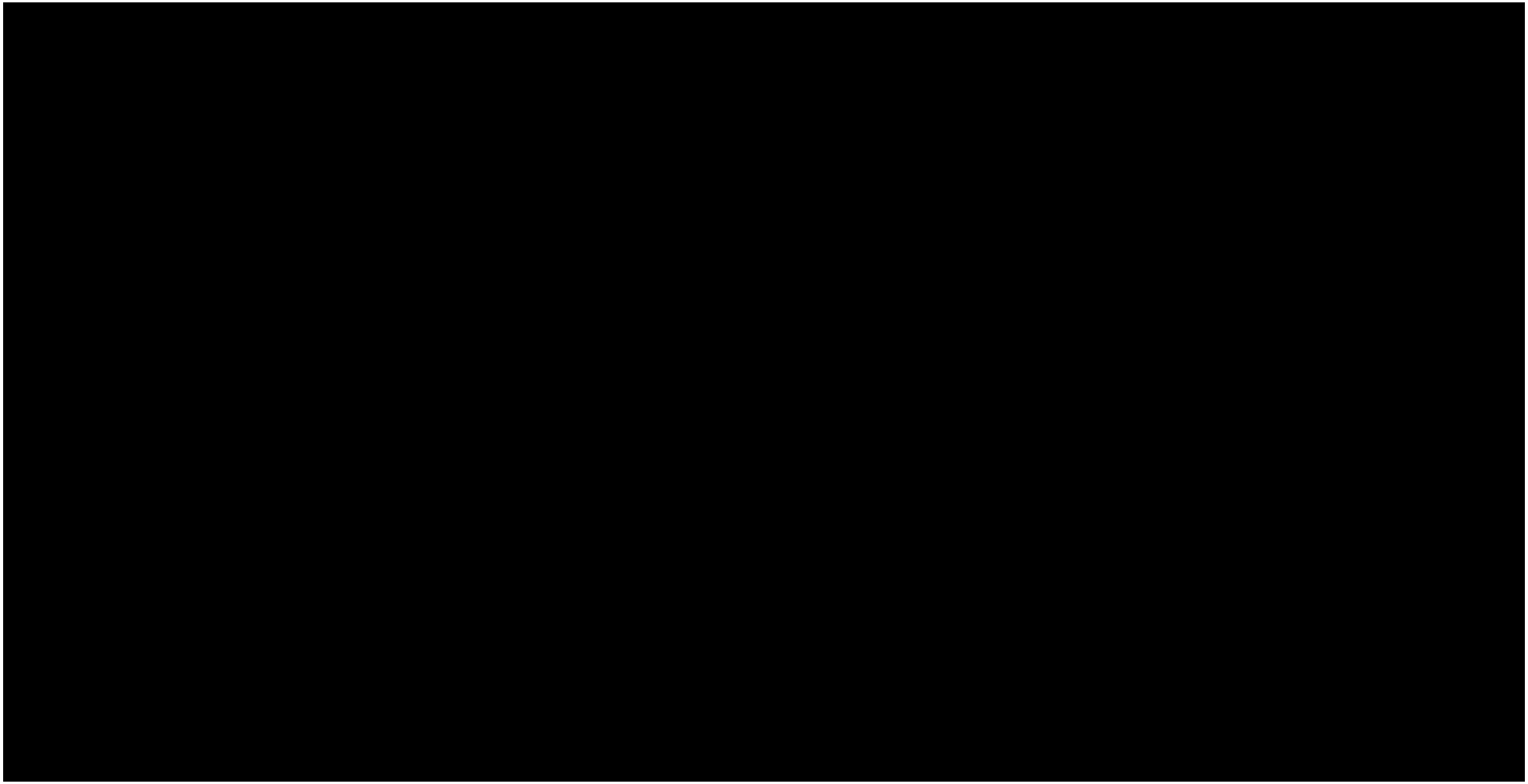

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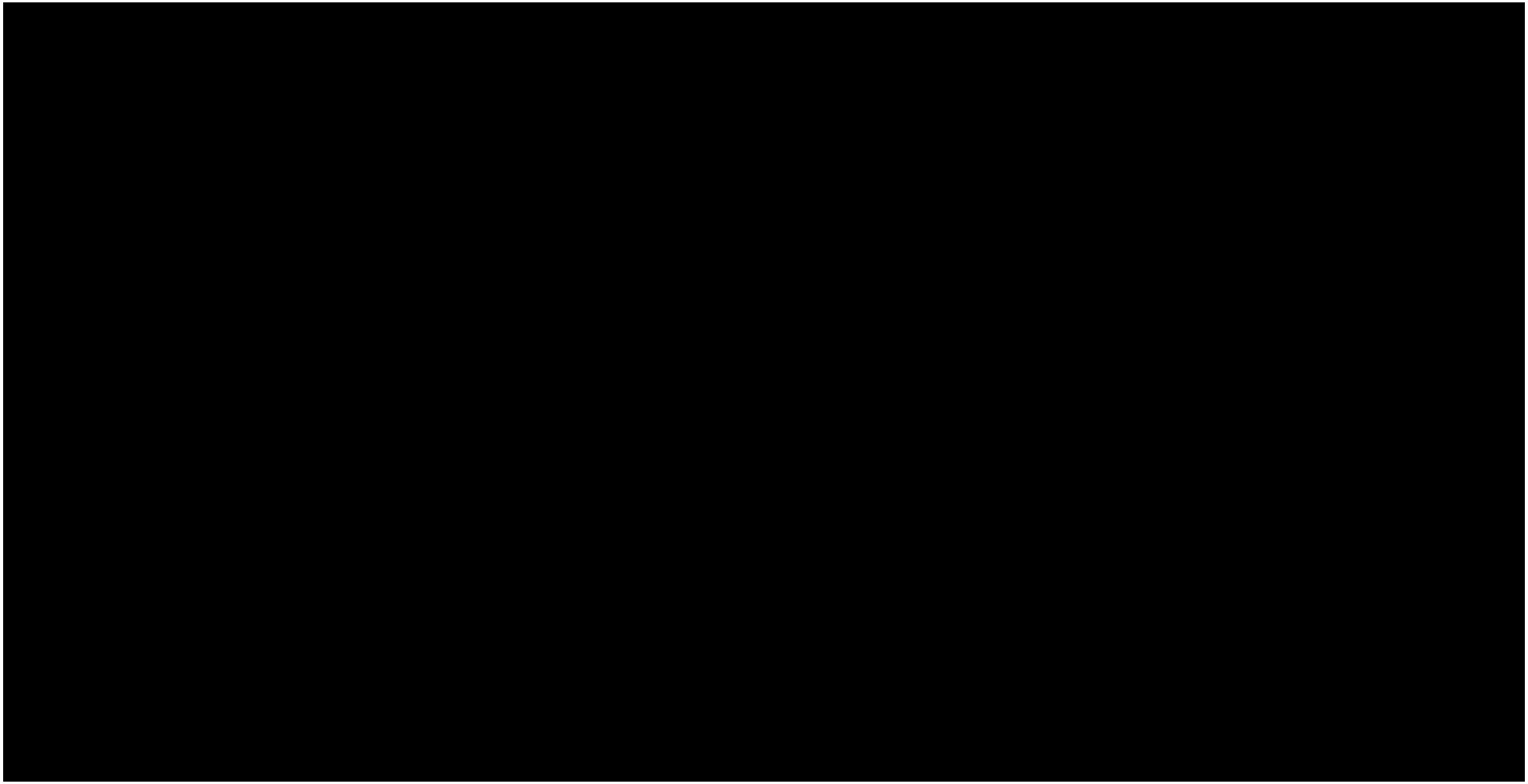

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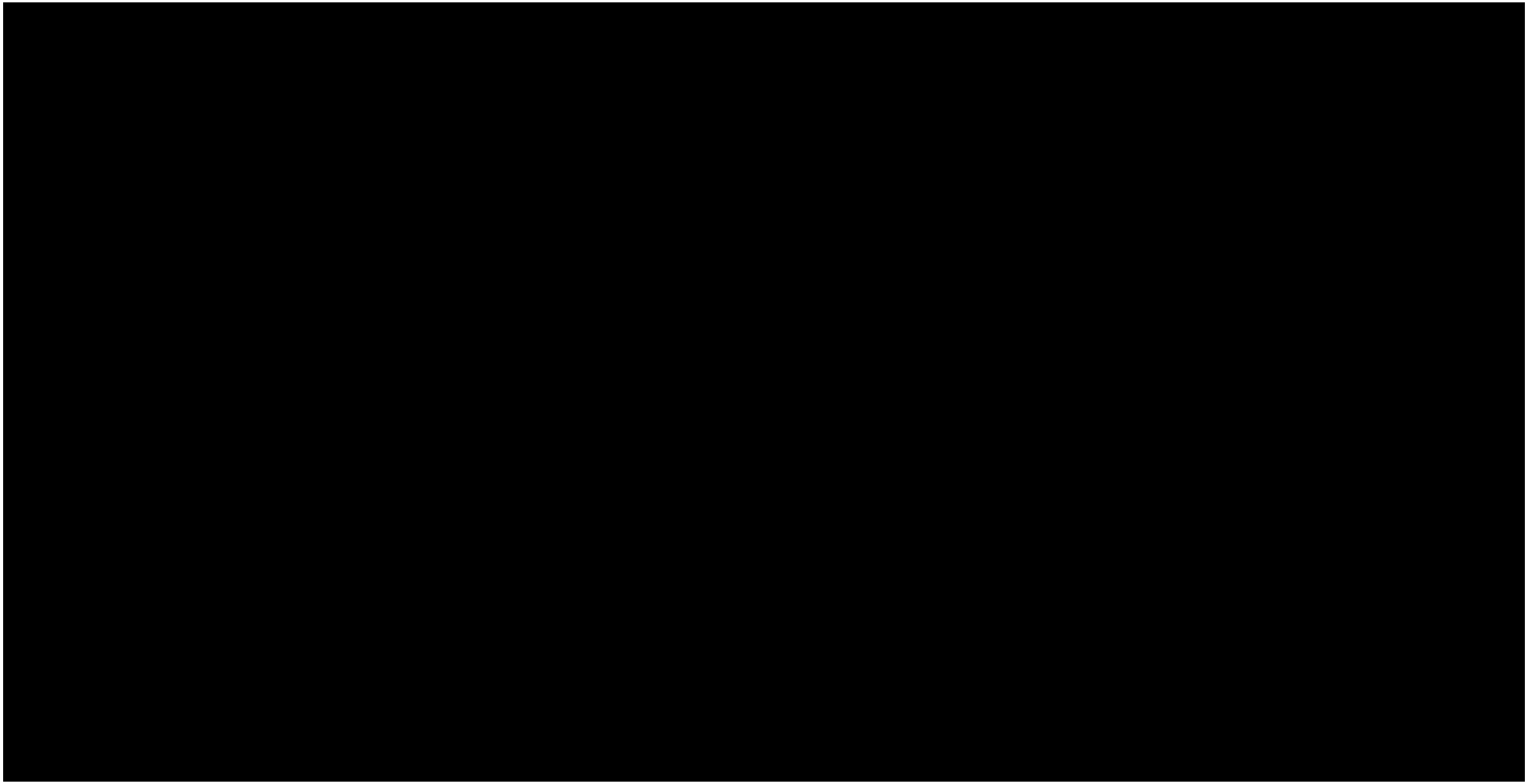

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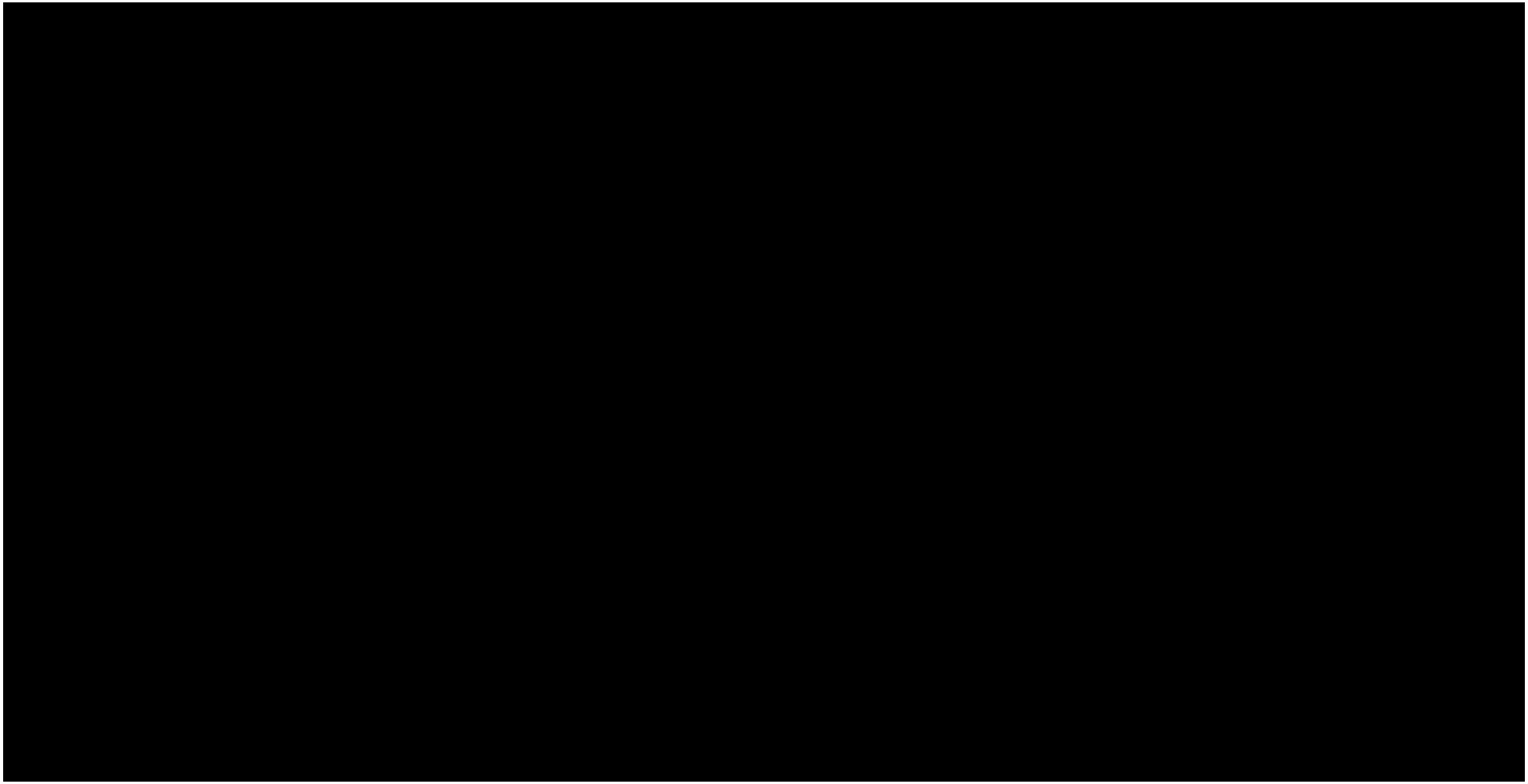

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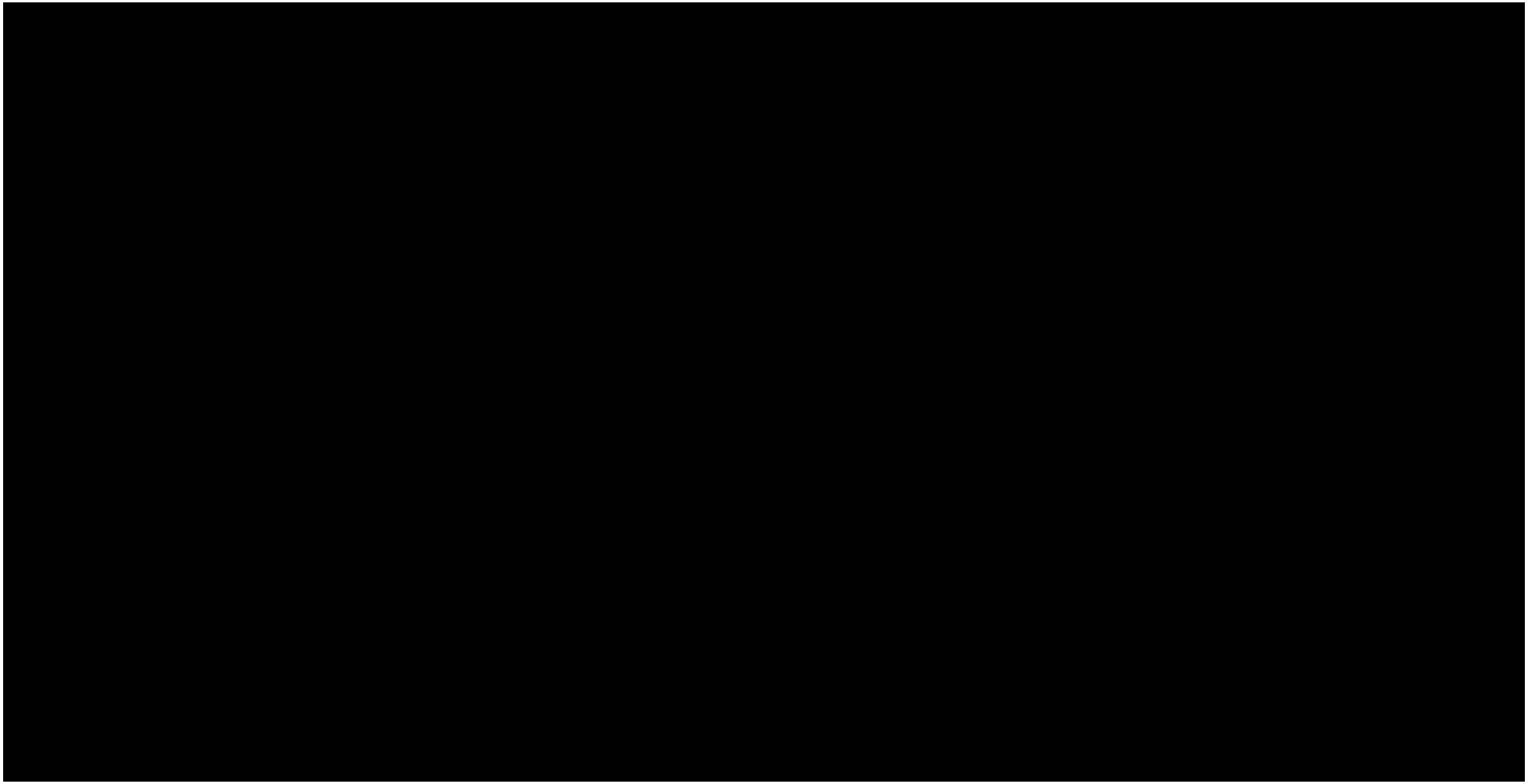

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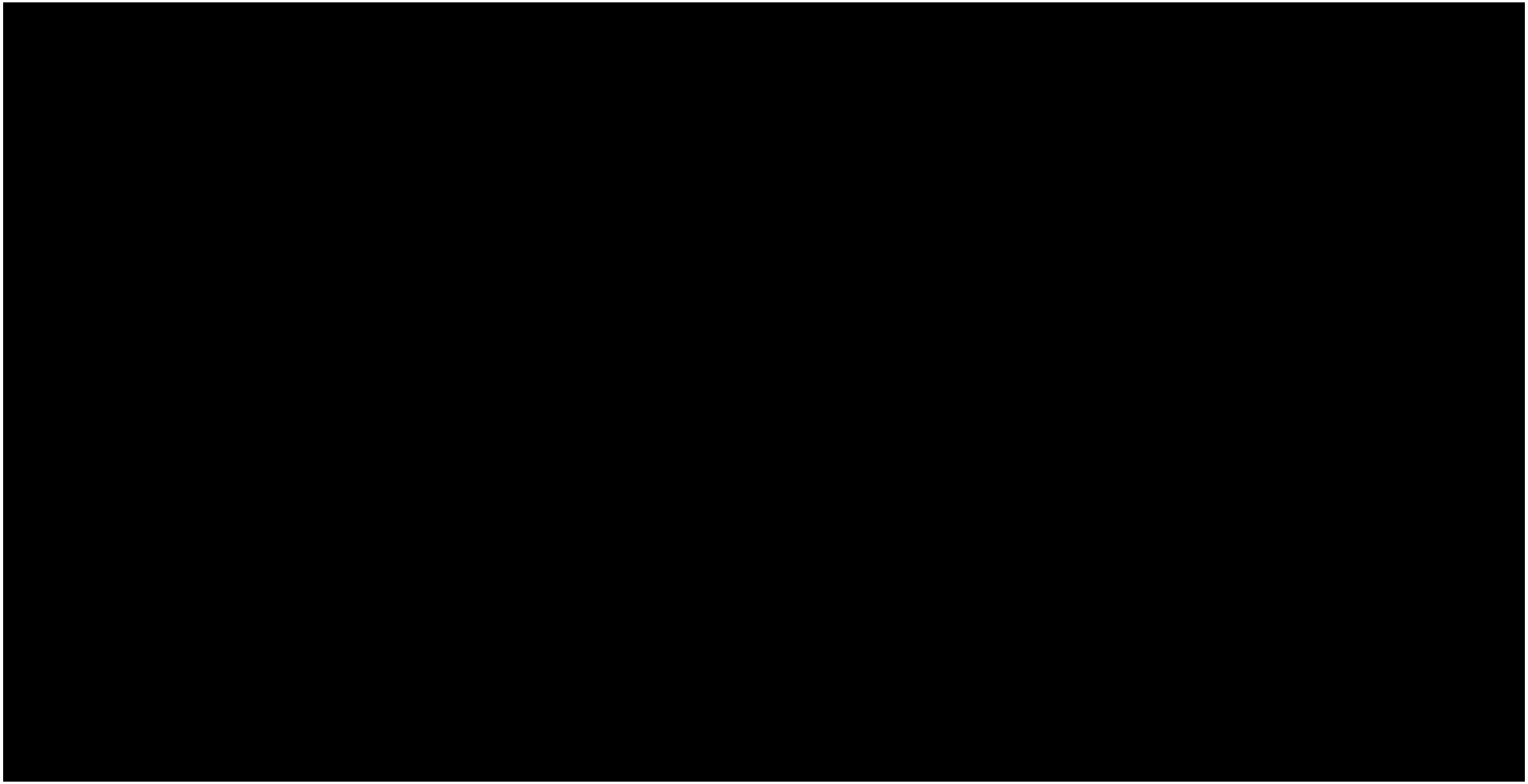

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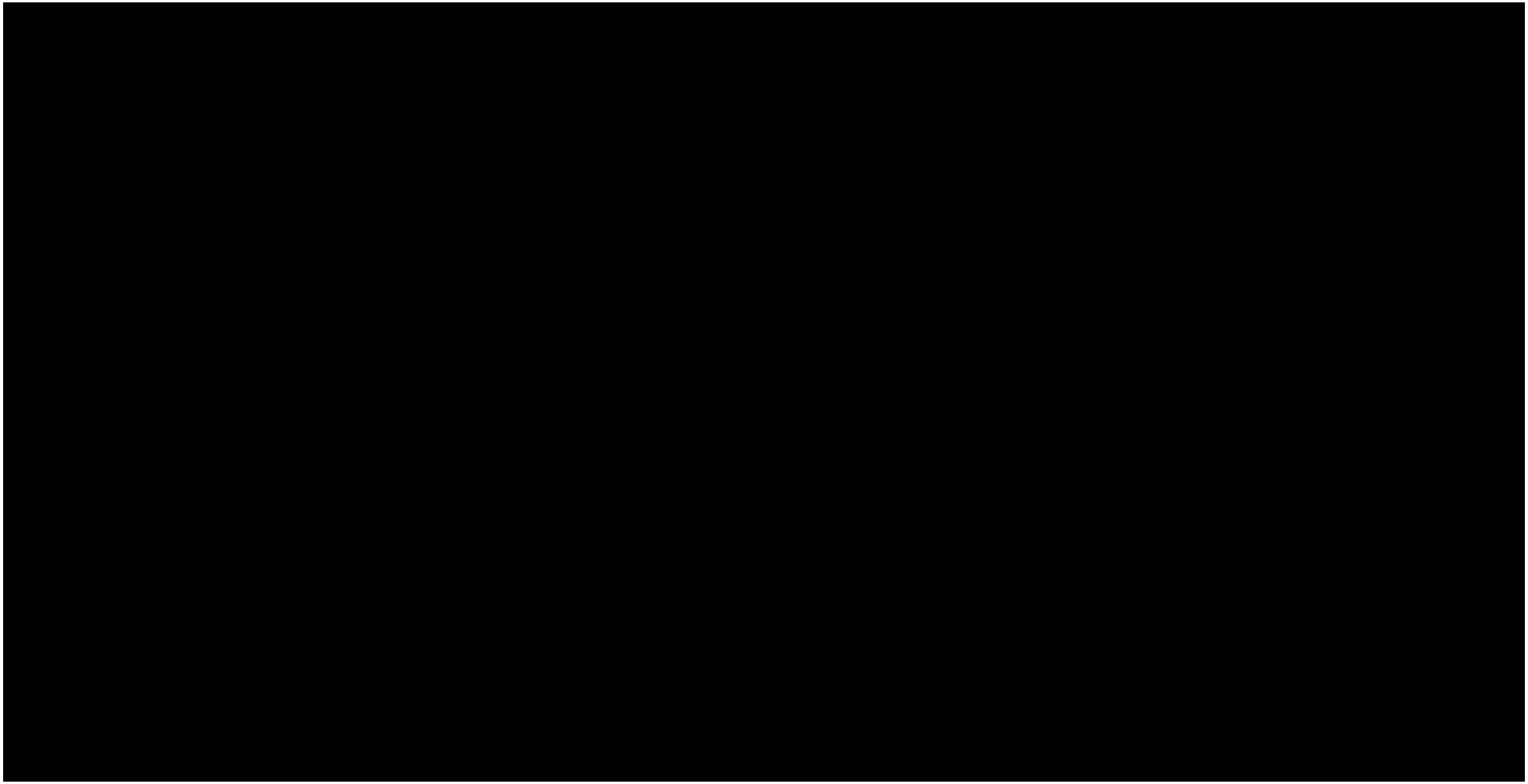

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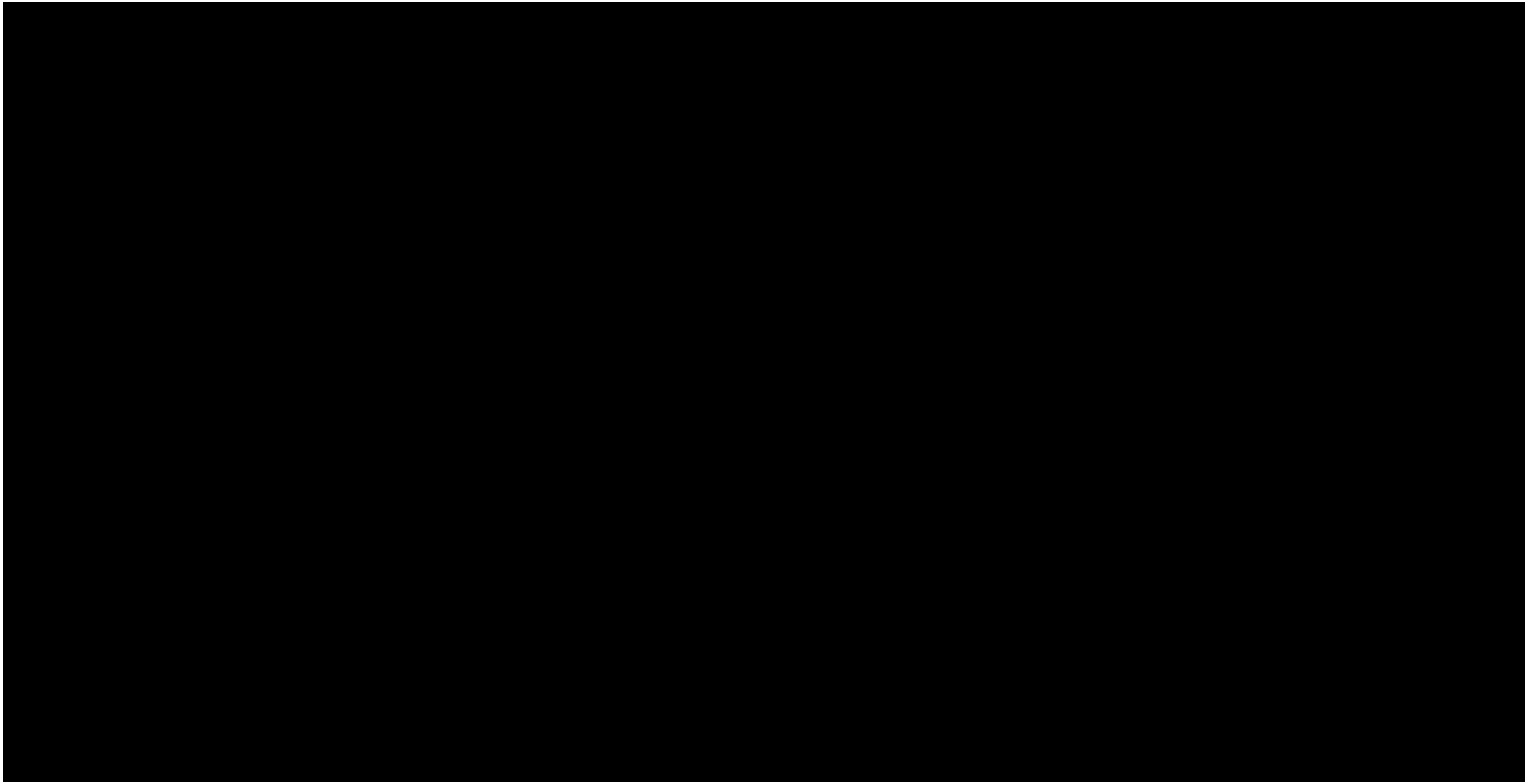

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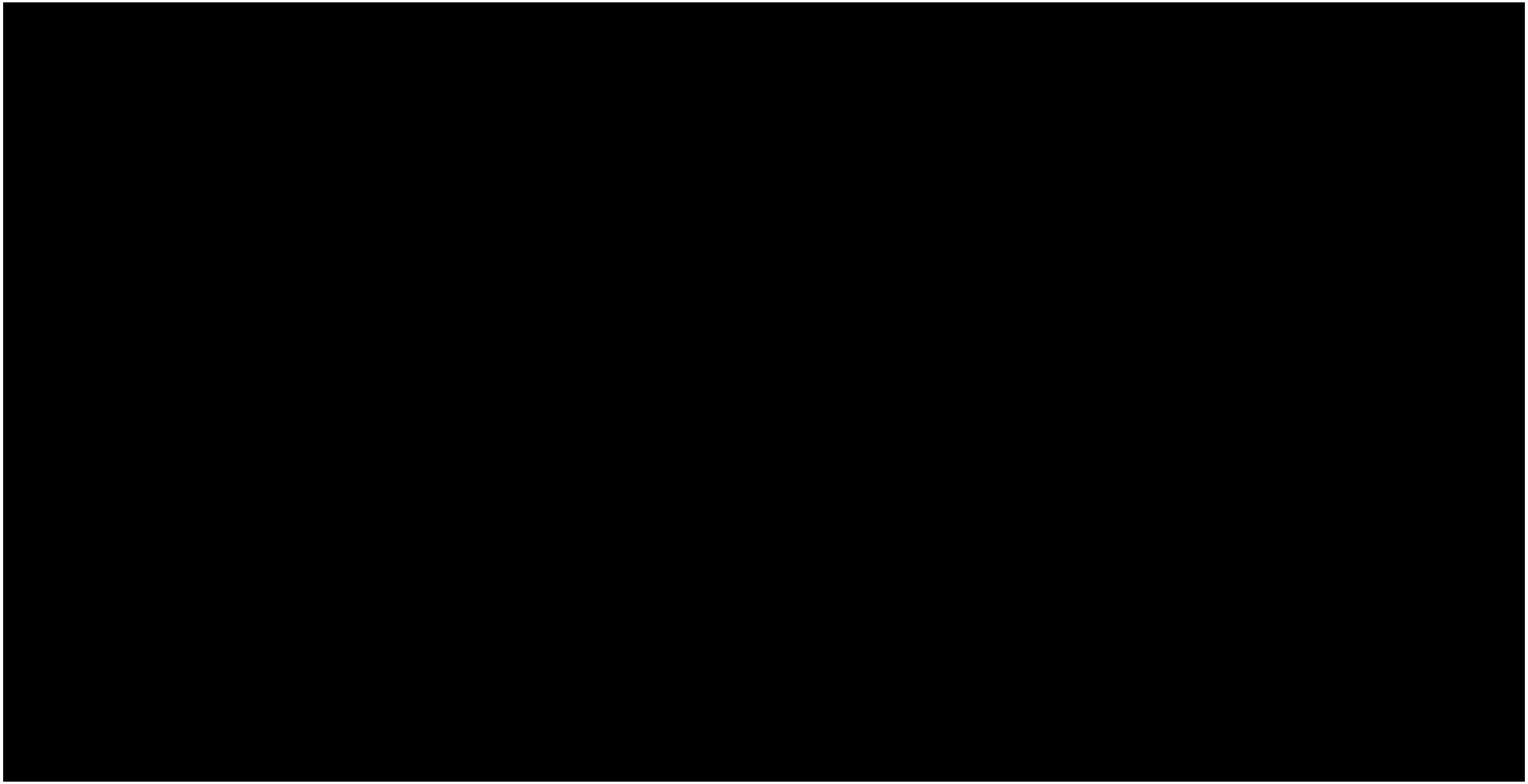

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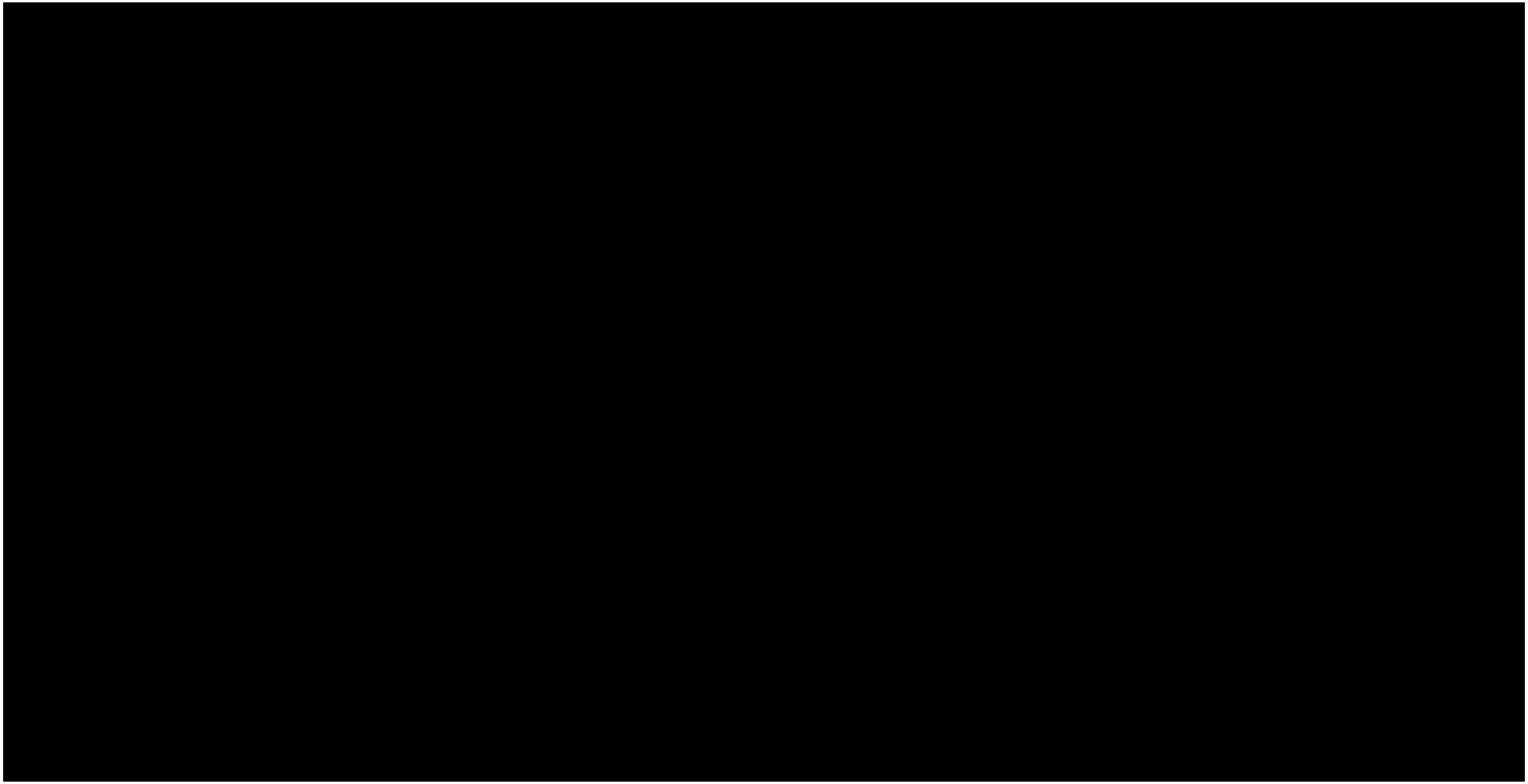

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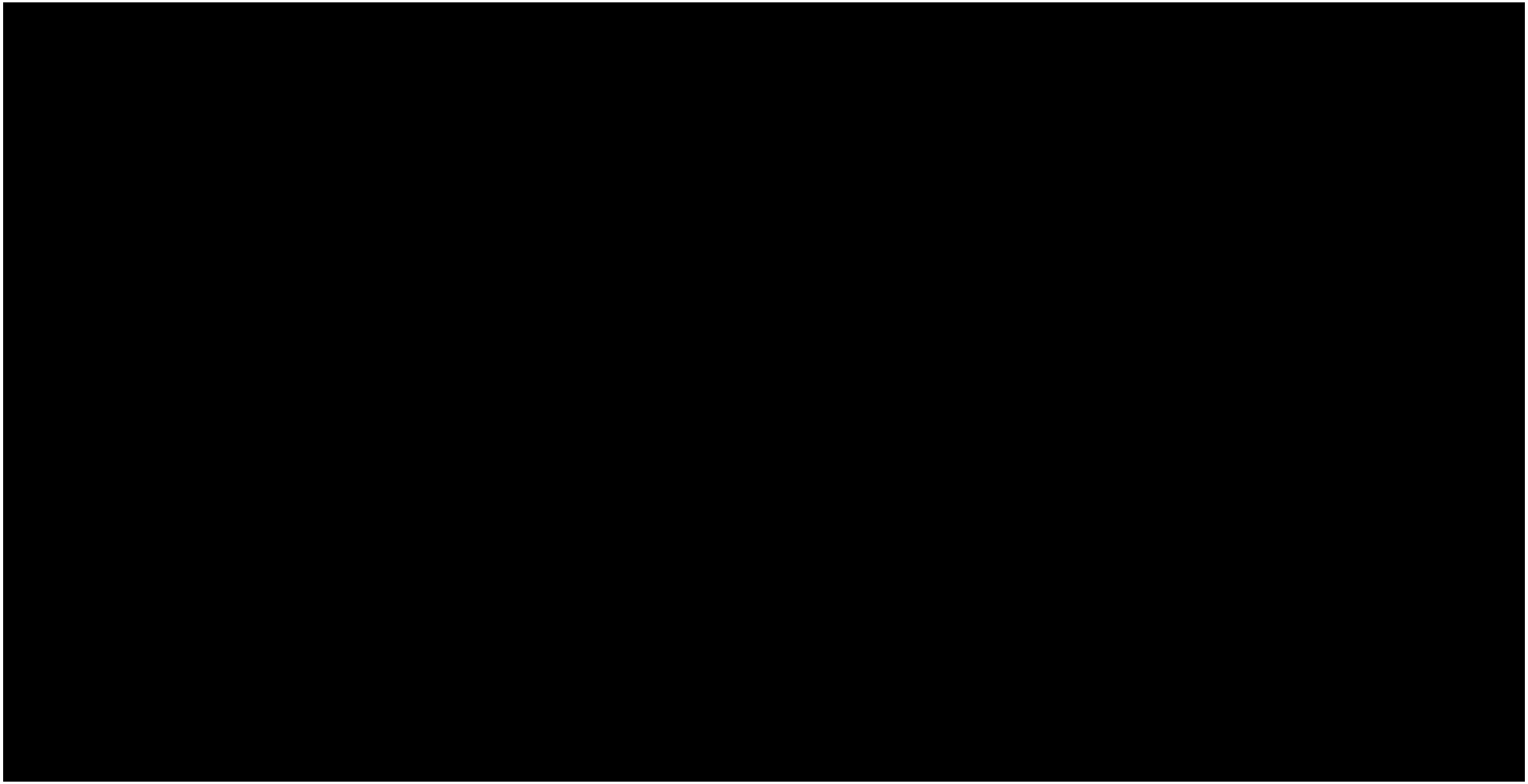

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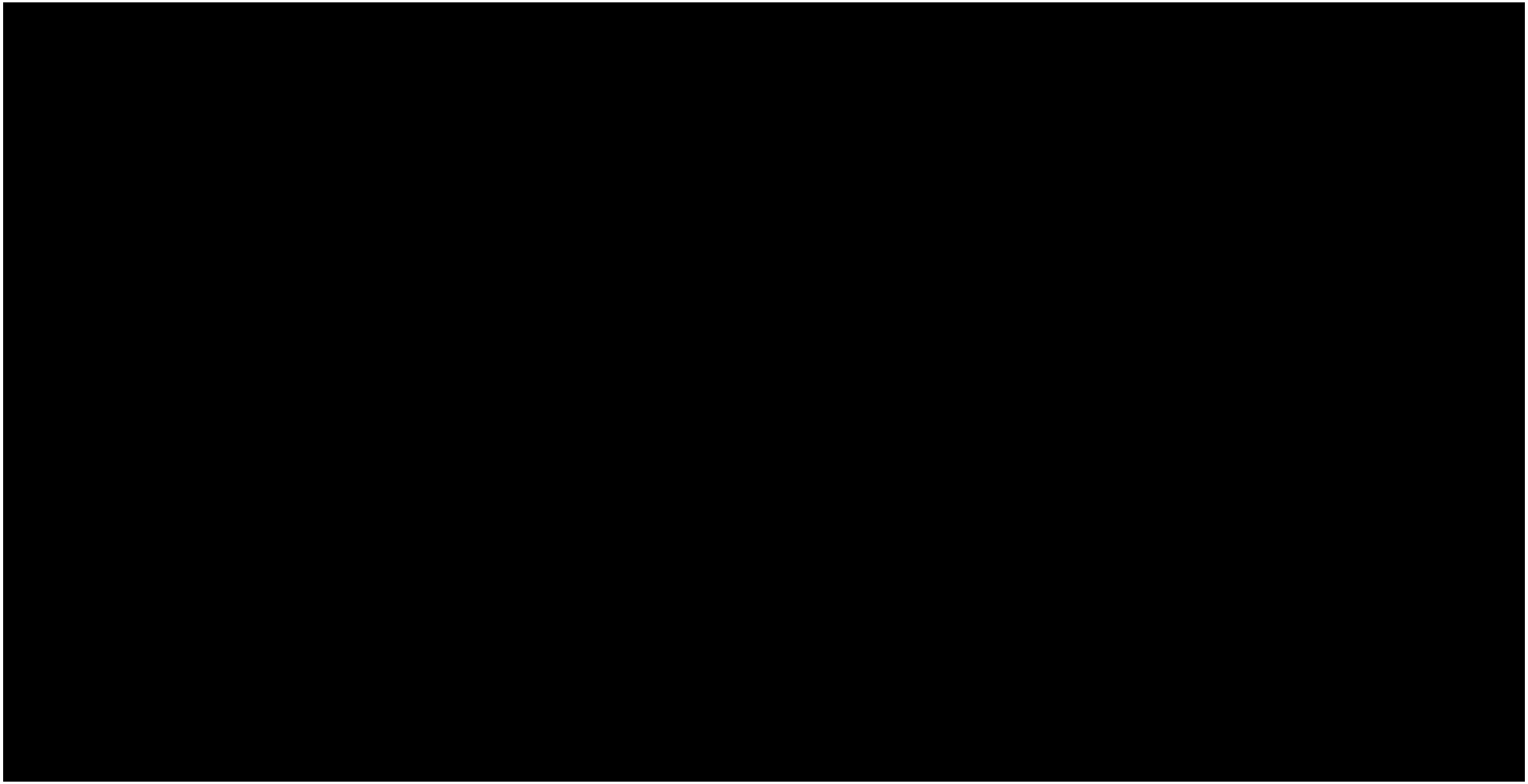

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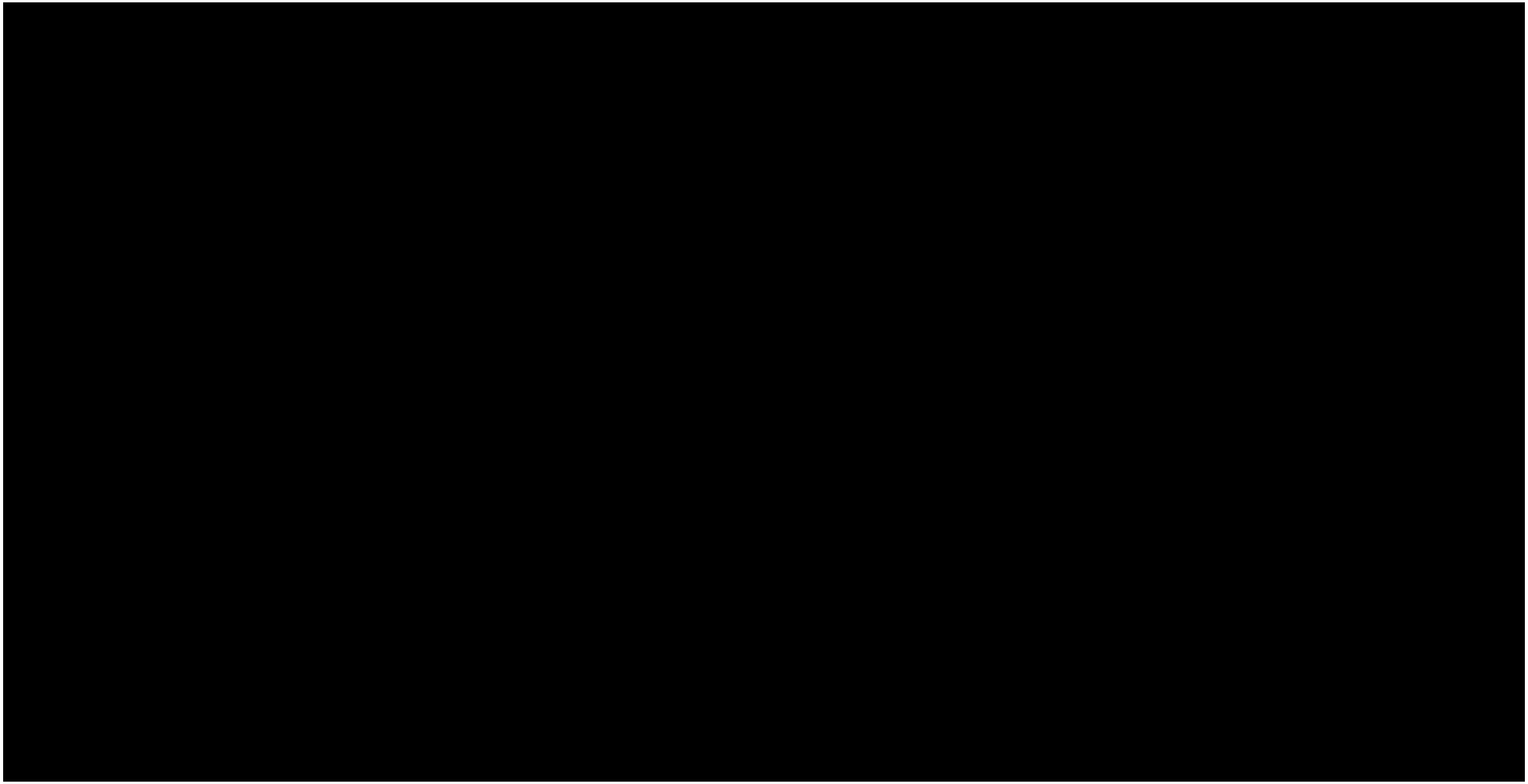

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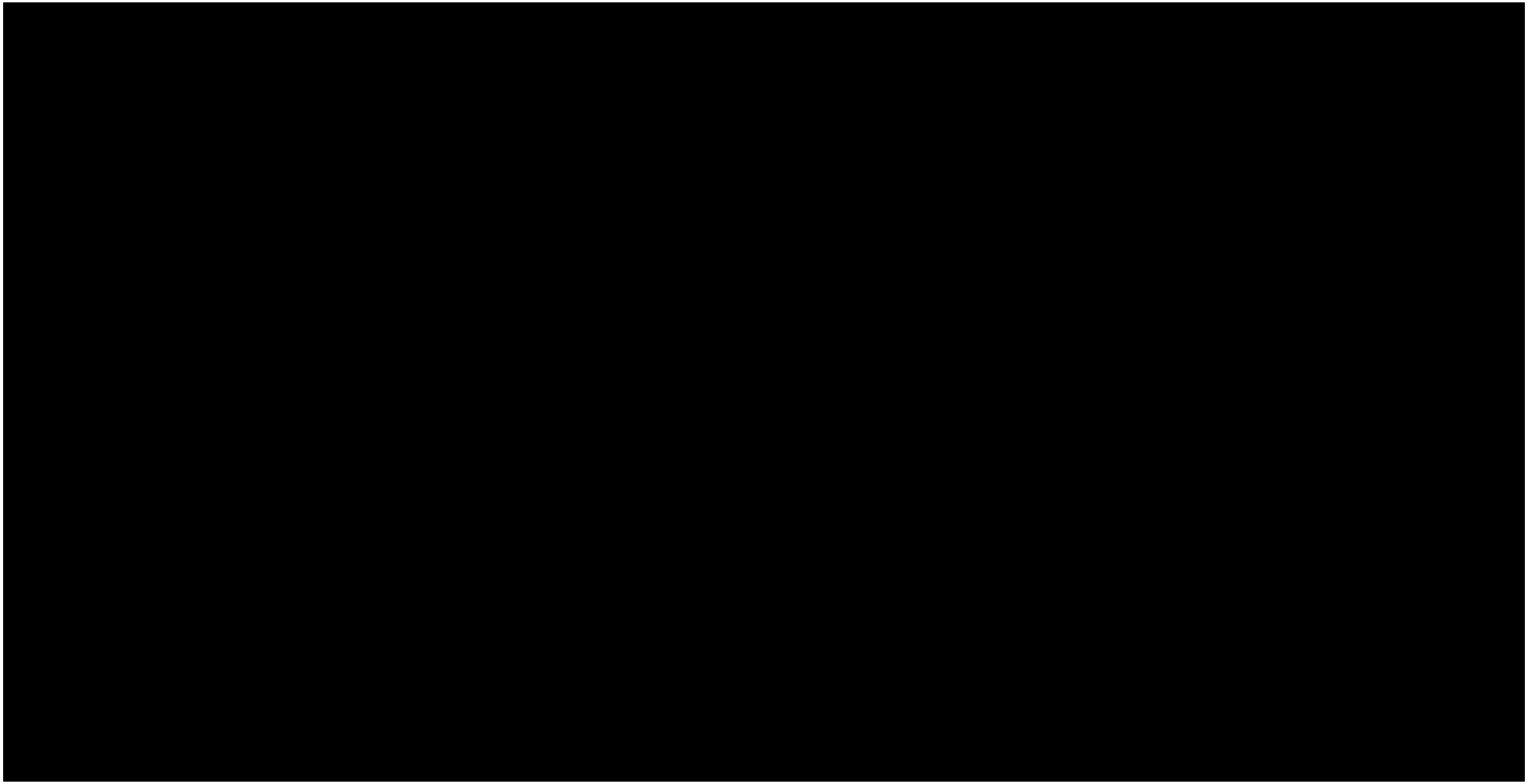

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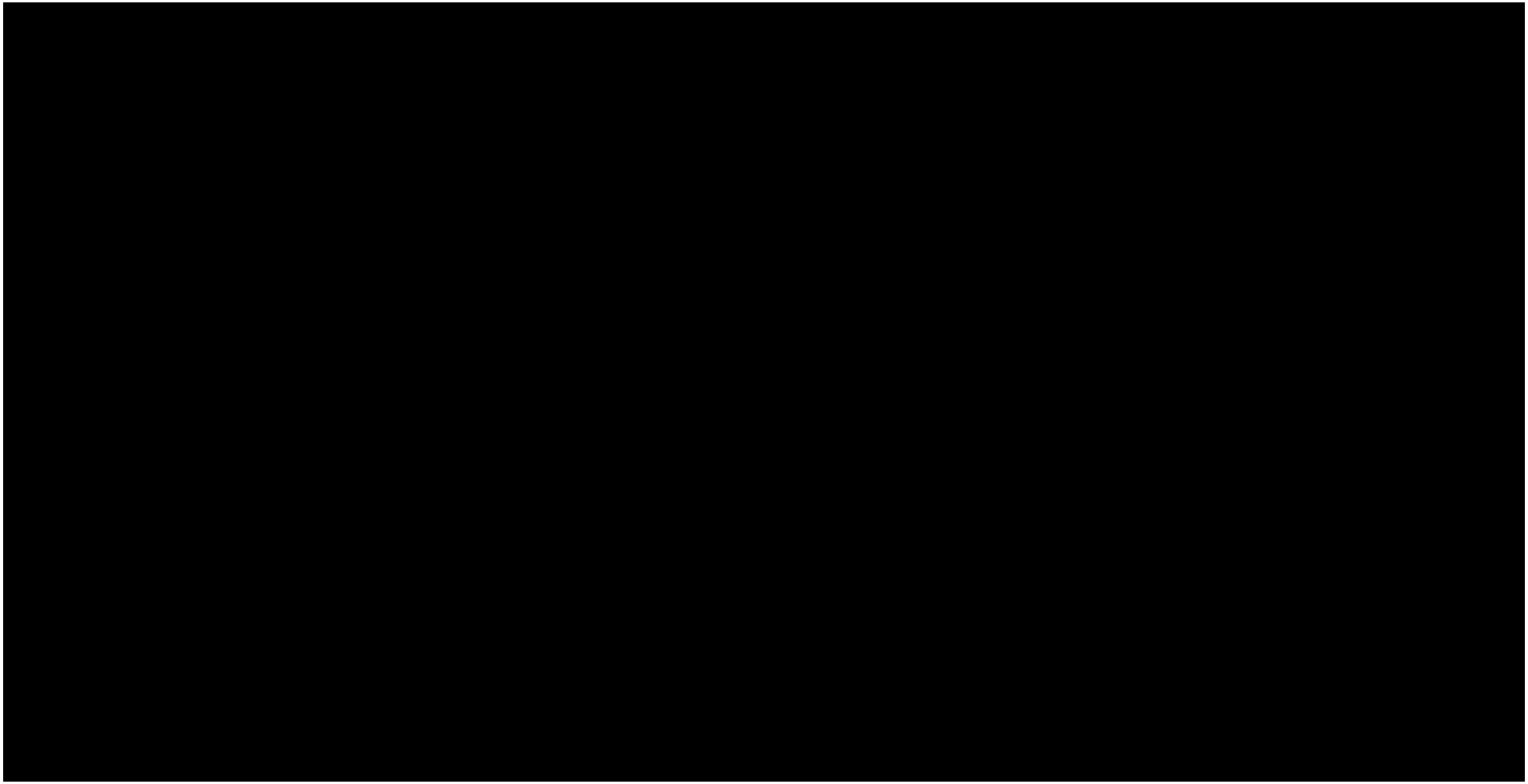

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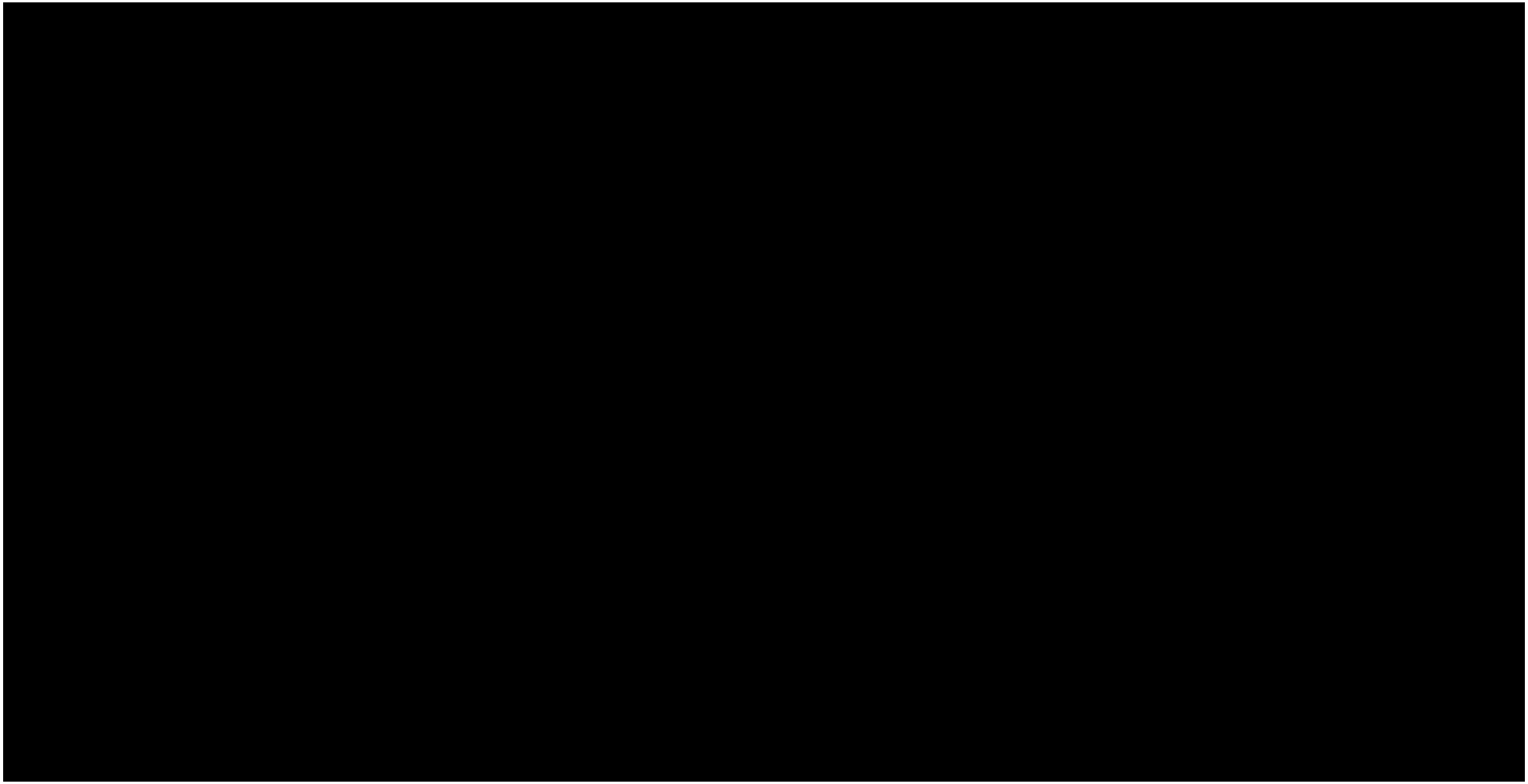

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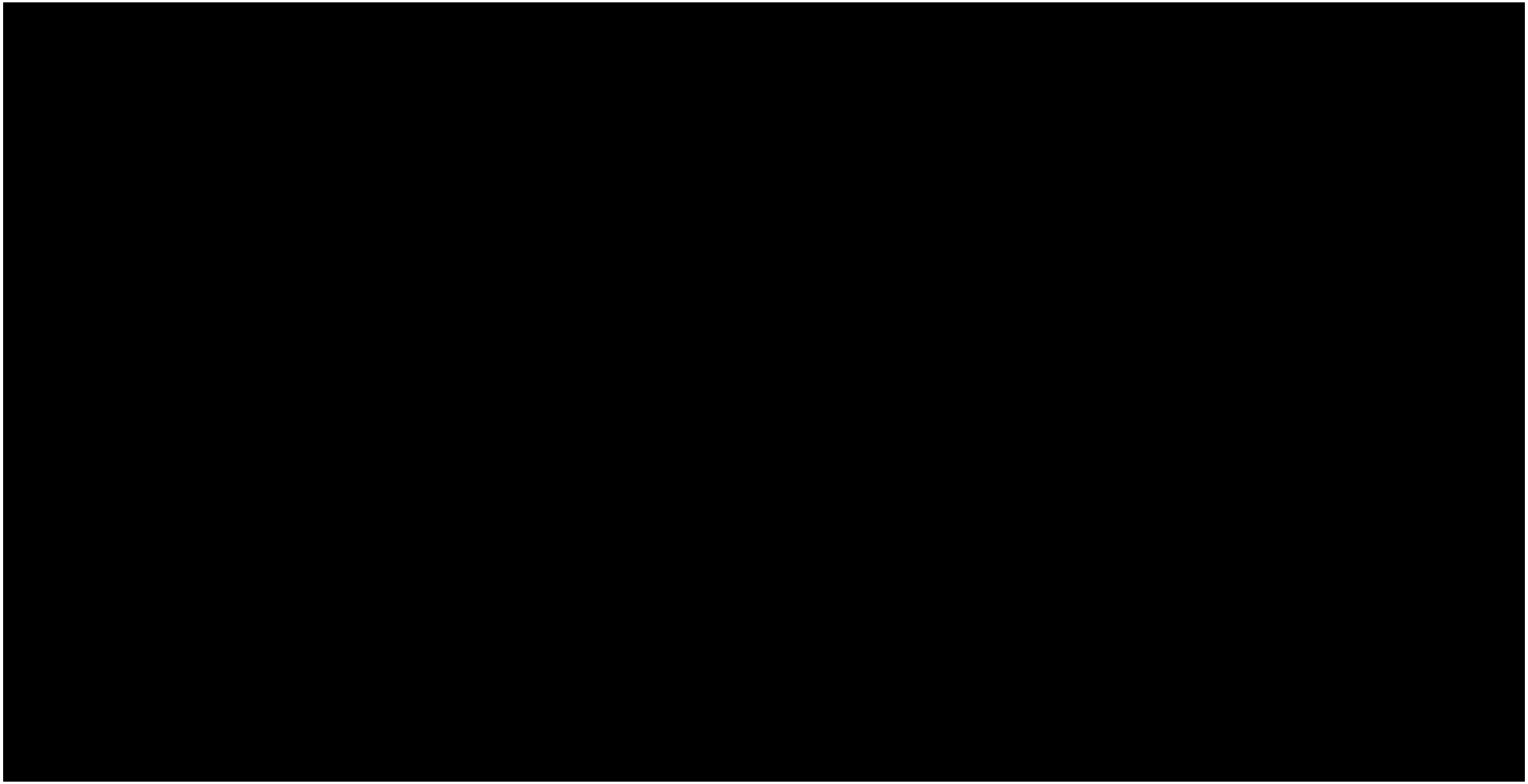

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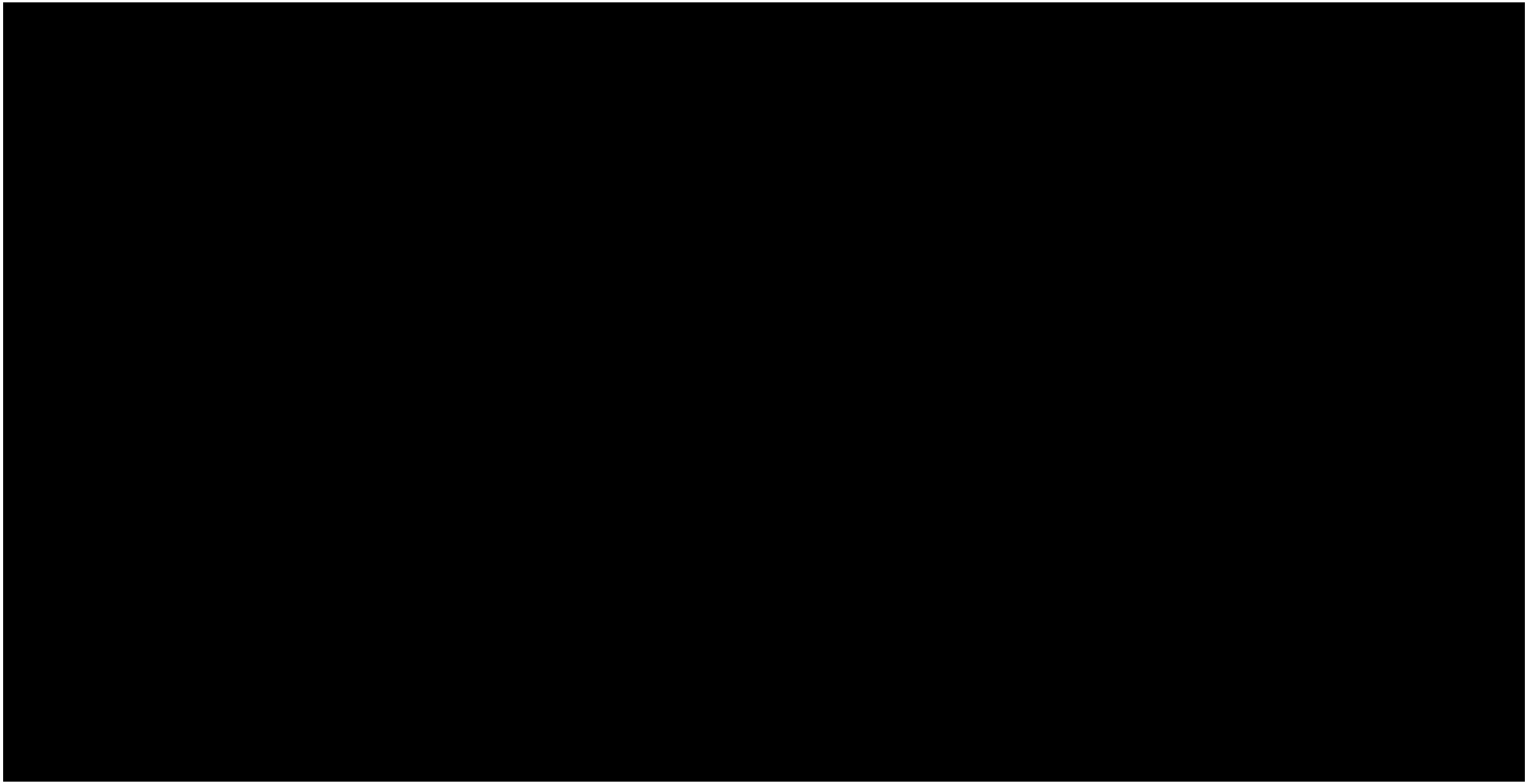

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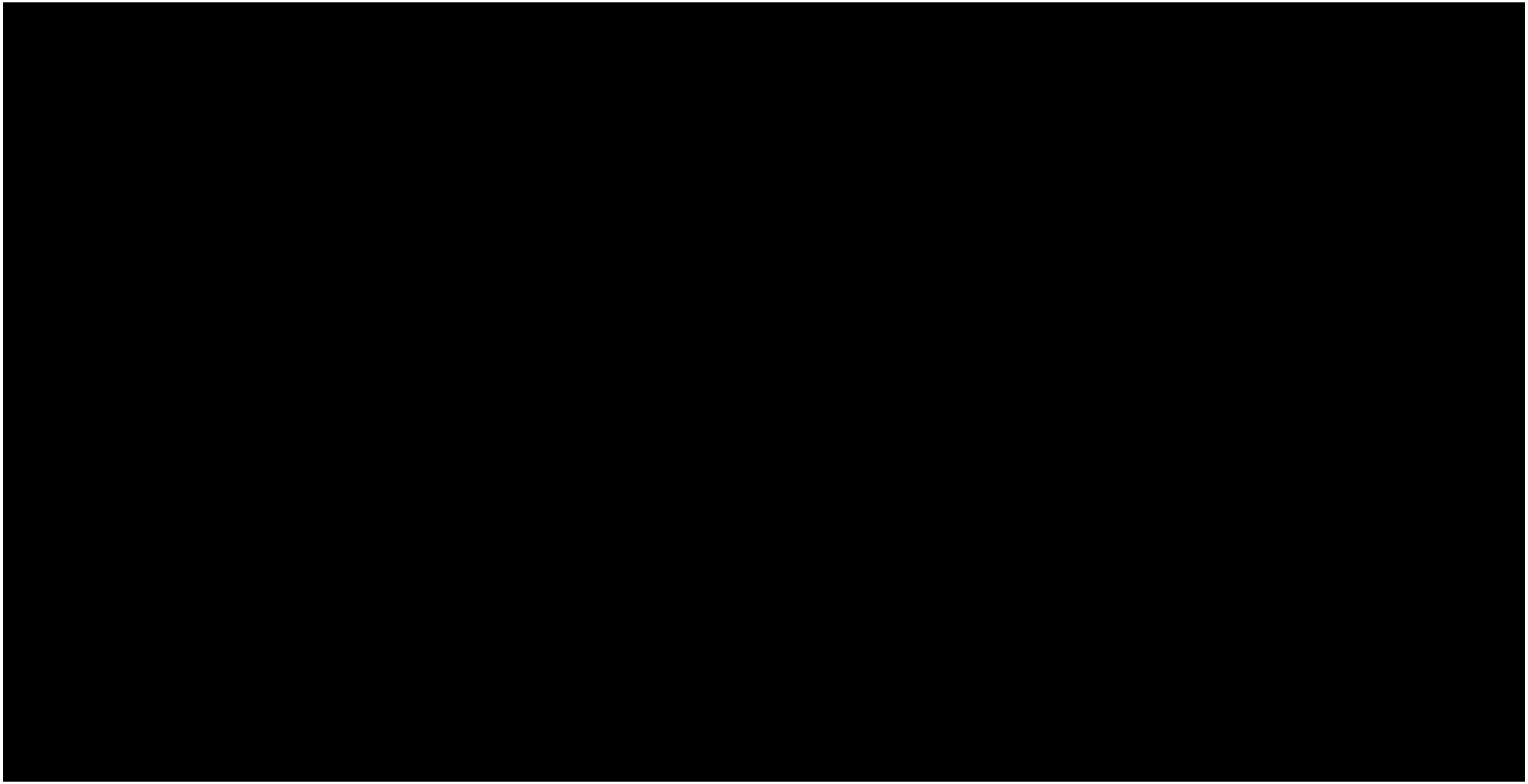

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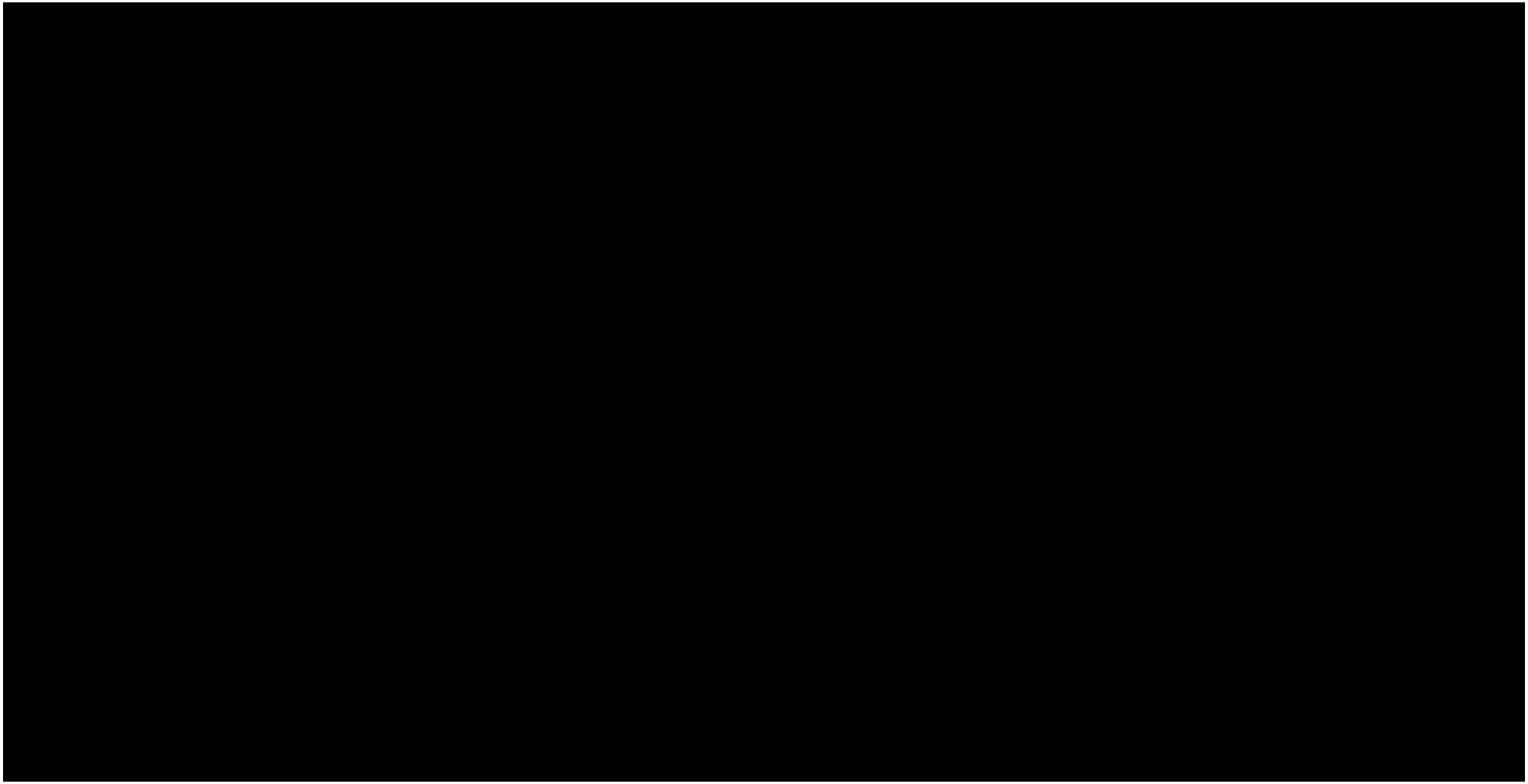

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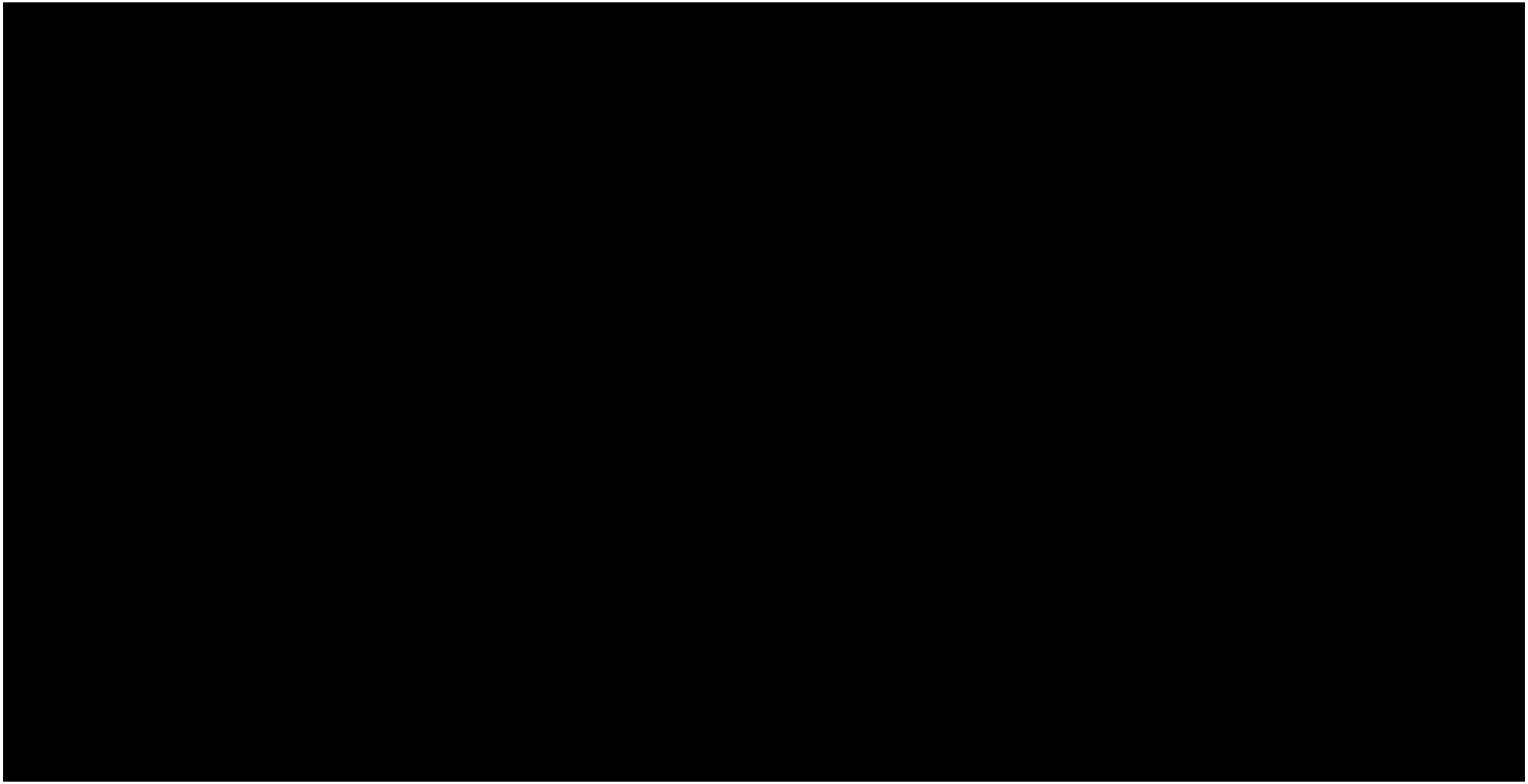

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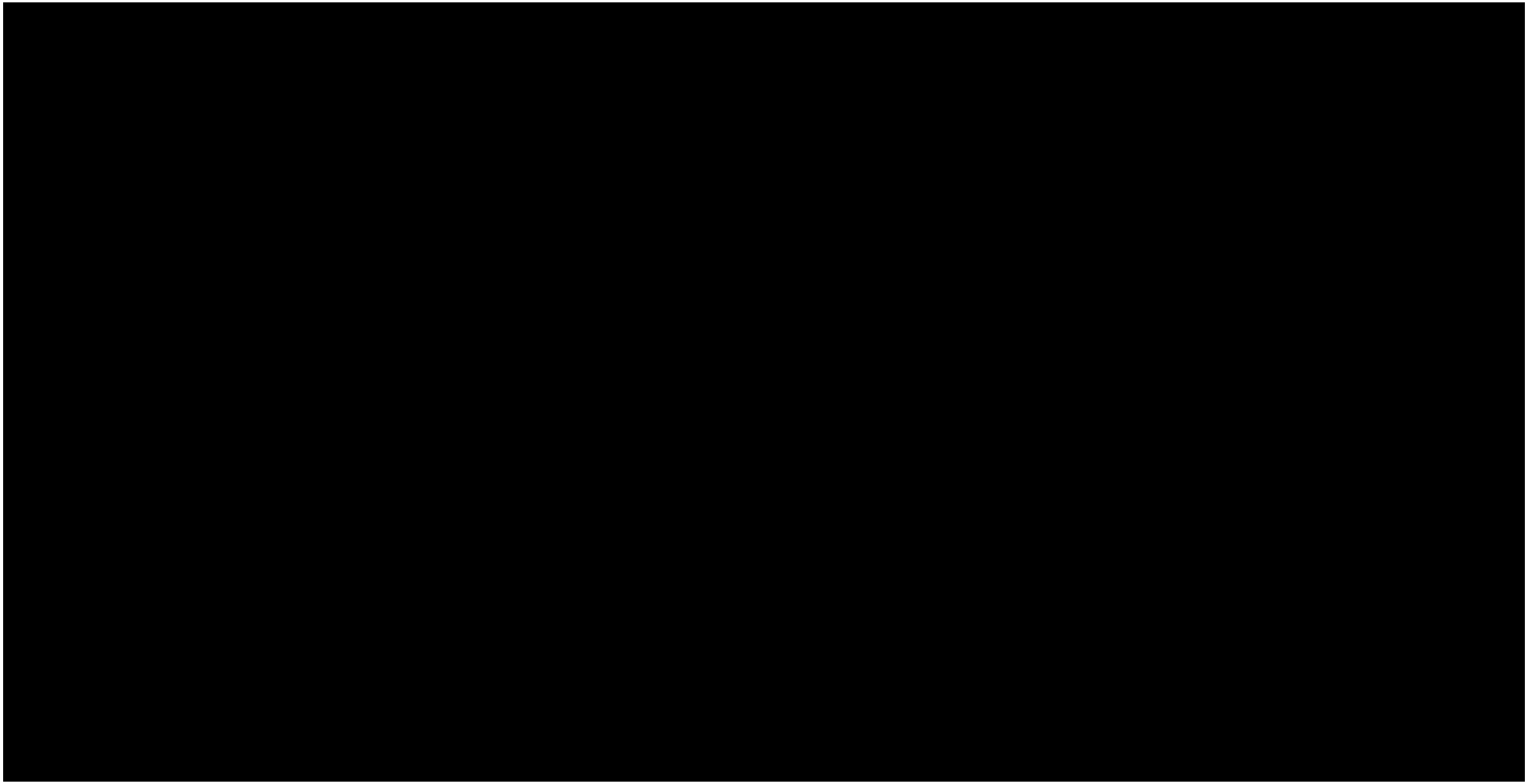

15 Reference list

1 Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Last amended by the 64th WMA General Assembly, Fortaleza, Brazil. World Medical Association. 20 A.D.

2 International Conference on Harmonisation (ICH). ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice. J Postgrad Med 2001; 47(3):199-203.

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. N Engl J Med 1993; 329(14):977-986.

4 American Diabetes Association. Standards of medical care in diabetes--2013. Diabetes Care 2013; 36 Suppl 1:S11-S66.

5 Rewers MJ, Pillay K, de Beufort C, Craig ME, Hanas R, Acerini CL. ISPAD Clinical Practice Consensus Guidelines 2014 Compendium, Assessment and monitoring of glycemic control in children and adolescents with diabetes. 2014.

6 Danne T, Becker D. Paediatric diabetes: achieving practical, effective insulin therapy in type 1 and type 2 diabetes. Acta Paediatr 2007; 96(11):1560-1570.

7 Danne T, Lupke K, Walte K, Von SW, Gall MA. Insulin detemir is characterized by a consistent pharmacokinetic profile across age-groups in children, adolescents, and adults with type 1 diabetes. Diabetes Care 2003; 26(11):3087-3092.

8 Danne T, Becker RH, Heise T, Bittner C, Frick AD, Rave K. Pharmacokinetics, prandial glucose control, and safety of insulin glulisine in children and adolescents with type 1 diabetes. Diabetes Care 2005; 28(9):2100-2105.

9 Mortensen HB, Lindholm A, Olsen BS, Hylleberg B. Rapid appearance and onset of action of insulin aspart in paediatric subjects with type 1 diabetes. Eur J Pediatr 2000; 159(7):483-488.

10 Food and Drug Administration. FDA Code of Federal Regulations, 21 CFR Part 314.126, Adequate and well-controlled studies. 2010.

11 ISPAD Clinical Practice Concensus Guidelines. 2009.

12 Global IDF/ISPAD guideline for Diabetes in Childhood and Adolescence. 2011.

13 European Union. The rules governing medicinal products in the European Union, volume 4, Annex 13, Manufacture of Investigational Products - Brussels. 2003.

14 Bangstad HJ, Danne T, Deeb LC, Jarosz-Chobot P, Urakami T, Hanas R. ISPAD Clinical Practice Consensus Guidelines 2006-2007. Insulin treatment. Pediatr Diabetes 2007; 8(2):88-102.

15 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.

16 Schwartz NS, Clutter WE, Shah SD, Cryer PE. Glycemic thresholds for activation of glucose counterregulatory systems are higher than the threshold for symptoms. J Clin Invest 1987; 79(3):777-781.

17 Food and Drug Administration. Food and Drug Administration, Code of Federal Regulations, Guidance for Industry, Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention. Draft Guidance. Feb 2008.

18 International Conference on Harmonisation. ICH Harmonised Tripartite Guideline. Statistical principles for clinical trials E9. International Conference on Harmonisation E9 Expert Working Group. 5 Feb 1998.

19 EMEA-Committee for Proprietary Medicinal Products. *Points to consider on switching between superiority and non-inferiority*. 27 Jul 2000.

20 National Research Council. The prevention and treatment of missing data in clinical trials. 2010. Washington DC: The National Academies Press.

21 Silverstein J, Copeland K, Plotnick L, Kaufman F, Laffel L, Grey M et al. Care of children and adolescents with type 1 diabetes: a statement of the American Diabetes Association. Diabetes Care 2005 28, 186-212. 2005.

22 Le Floch JP, Levy M, Mosnier-Pudar H, Nobels F, Laroche S, Gonbert S et al. Comparison of once- versus twice-daily administration of insulin detemir, used with mealtime insulin aspart, in basal-bolus therapy for type 1 diabetes: assessment of detemir administration in a progressive treat-to-target trial (ADAPT). Diabetes Care 2009; 32(1):32-37.

23 DeVries JH, Nattrass M, Pieber TR. Refining basal insulin therapy: what have we learned in the age of analogues? Diabetes Metab Res Rev 2007; 23(6):441-454.

24 Seaquist ER, Anderson J, Childs B, Cryer P, Dagogo-Jack S, Fish L et al. Hypoglycemia and Diabetes: A Report of a Workgroup of the American Diabetes Association and The Endocrine Society. J Clin Endocrinol Metab 2013; 98(5):1845-1859.

25 Thalange N, Bereket A, Larsen J, Hiort LC, Peterkova V. Insulin analogues in children with Type 1 diabetes: a 52-week randomized clinical trial. Diabet Med 2013; 30(2):216-225.

26 De L, I, Vague P, Selam JL, Skeie S, Lang H, Draeger E et al. Insulin detemir used in basal-bolus therapy in people with type 1 diabetes is associated with a lower risk of nocturnal hypoglycaemia and less weight gain over 12 months in comparison to NPH insulin. Diabetes Obes Metab 2005; 7(1):73-82.

27 Meneghini LF, Rosenberg KH, Koenen C, Merilainen MJ, Luddeke HJ. Insulin detemir improves glycaemic control with less hypoglycaemia and no weight gain in patients with type 2 diabetes who were insulin naive or treated with NPH or insulin glargine: clinical practice experience from a German subgroup of the PREDICTIVE study. Diabetes Obes Metab 2007; 9(3):418-427.