STATISTICAL ANALYSIS PLAN

Protocol Number: RD002489

AC Connect School Study

ACCU-CHEK® CONNECT AT SCHOOL (CATS) PEDIATRIC STUDY

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Note: This Statistical Analysis Plan is effective on the date of the last signature

TABLE OF CONTENTS

1 STUDY OBJECTIVES

The primary objective of this study is to assess change in diabetes-related distress among parents/caregivers of school-age children on MDI therapy (PAID- C & T Parent Questionnaire) after 6 months utilization of the ACCU-CHEK® Connect DMS compared with usual care.

The secondary objectives of this study are to assess the changes in the following measures after 3 and 6 months utilization of the ACCU-CHEK® Connect DMS compared with usual care:

- Change in diabetes-related distress among parent/caregiver. (PAID C & T Parent Questionnaires) at 3 months compared to Baseline
- Change in diabetes-related distress among school-age children and adolescents with diabetes. (PAID-C & T Child Questionnaires) at 3 and 6 months
- Change in perceived family conflict among school-age children with diabetes and parent/caregiver. (DFCS-parent and DFCS-youth Questionnaire) at 3 and 6 months
- Change in affect toward blood glucose monitoring (BGM) among school-age children with diabetes and parent/caregiver. (BGMC-parent and BGMC-youth Questionnaire) at 3 and 6 months. Changes in glycemic control: (HbA1c, Percentage in Glucose Target Range, Glycemic Variability, Hypoglycemia)

Intervention Group Only at 6 Months:

Use of, Preference, Satisfaction with the ACCU-CHEK Connect DMS (All)

2 STUDY DESIGN

2.1.1 Study Population

This is a prospective, interventional, multi-center, post-market, 6-months, cluster randomized study, conducted in the US. Eight (8) to thirteen (13) pediatric endocrinology centers across the US are to be randomly assigned to one of 2 treatment groups in a 1:1 allocation. The groups are A) Intervention: using the ACCU-CHEK® Connect Diabetes Management System, or B) Control: Continued use of subjects´ current diabetes devices. To be eligible for the study, children must have a diagnosis of T1D for $\geq$ 3 months, currently managed with multiple daily insulin injections, 6-18 years of age, attending full day school K-12 grades, able to provide

SMBG data for a minimum of 1 month prior to study start, and using a Smartphone capable of downloading the ACCU-CHEK Connect System App (or able to use a Smartphone that is provided). Parents/caregivers and adolescents (18 yrs old) must provide informed consent and children 7-17 yrs old must provide child assent. Parent/caregiver of study subjects must also be using a Smartphone and be able to receive SMS/MMS messages.

Children/adolescents will be excluded if they are on CSII therapy or are planning to transition to CSII during the study, are CGM users or use a remote data sharing system/device such as NightScout, DexCom Share, or Medtronic Connect, are pregnant, or are diagnosed with any clinically significant condition, or have requirements for chronic steroids in adrenal suppressive doses, immune-modulatory medications, or chemotherapy. Subjects will be excluded if they or their parent/caregiver have visual impairment preventing the complete use of the ACCU-CHEK Connect system or if the parent/caregiver is directly involved in the conduct of the study or design of the protocol.

2.1.2 Sample size justification

Change from baseline in PAID-C & T parent, the primary endpoint was used to estimate the sample size requirement for the study. A sample size of 75 per group would be sufficient, with a power of 80% to detect a treatment effect of 0.460 with a significance level of 0.05. Given assumptions of SD of 5 to 16, the sample size would be able to detect treatment group differences of 2.3 (SD=5) to 7.4 (SD=16.0). 100 subjects per group will be enrolled to accommodate attrition.

2.1.3 Study Procedure

All subjects recruited by an Interventional Site will be provided with an ACCU-CHEK® Connect DMS (and up to one additional meter to keep at school), trained in the system's use, and asked to use this system for the following 6 months.

All subjects recruited by a Control site will continue to use their current diabetes management system.

All parents/caregivers independently of the age of their child are also part of the study, and will complete questionnaires about diabetes related stress, system use and other aspects of diabetes.

Furthermore, the health care providers (investigators and study staff) as well as school staff will also be asked to assess their preference in comparison to previously used systems. In order to obtain data prior to study start self-monitored blood glucose (SMBG) data from all subjects will be downloaded at Baseline using Diasend – for the data transfer to the eCRF

During the study the Control sites will continue to download data using Diasend whereas data download at Interventional sites will be managed by ACCU-CHEK® Connect DMS.

Control sites will continue to use data analysis methods according to their current practice for making therapy decision throughout the study. No change in behavior should be introduced by the study in this group and therefore they will not use data downloads via Diasend for therapy decisions, if this is not currently their practice, but they might need to perform downloads via Diasend for eCRF transfer only.

Schedule of Assessments

	Visit 1 Baseline	Visit 2	Visit 3 Month 3	Visit 4 Month 6	Visit 5 -
	Day 1	Week 1 ± 2 days	Week 12 ± 2 weeks	Week 24 ± 2 weeks	2-5 d > V 4
	In Office	Phone Call	In Office	In Office	Phone Call
Informed consent/assent	X				
Check Eligibility and Smartphone compatibility	X				
Pregnancy test, if applicable	X				
Demographic data and other Baseline data	X				
Diabetes Background, Devices, History & Medications	X				
Record number of days diabetes related missed from Work (parent/caregiver) /school (child) in previous 3 months	X		X	X	
Collect height and weight	X		X	X	
HbA1c (Central Lab)	X		X	X	
Administer Questionnaires	X		X	X	
Record brand of current BG meter & serial number.	X				
Download SMBG data using existing site process	X		X[2]	X[2]	
Review and discuss SMBG data with patient/parents and agree on modification of SMBG regimen, if needed.	X		X[1 2]	X[1 2]	
Download current BG meter data using Diasend for eCRF	X		X[2]	X[2]	
Dispense to interventional group • ACCU-CHEK® Connect DMS devices ○ Record BG meter serial number(s) • ACCU-CHEK® Call Center Cards • Smartphone, if applicable	 X[3] X[3] X[3] X[3]				
Perform Training and Set up ACCU-CHEK® Connect DMS (connectivity, portals and invitations)	X[3]				
Record Malfunction of /complaints about any device, if any	X	X	X	X	
Record AE / SAE, if any	X	X	X	X	
Schedule new appointment(s)	X		X		
Follow-up call 2-5 days after Last Visit (only if ongoing AE(s))					X
Update electronic CRF	X	X	X	X	X

[1] Intervention group review data captured in ACCU-CHEK Connect DMS
[2] Control Group review usual care SMBG data with current diabetes management devices
[3] Intervention group only

The following Questionnaires will be completed during the study:

Baseline Visit – Visit 1 (Note: for Intervention Sites – questionnaires are administered prior to ACCU-CHEK® Connect DMS training)

Parent/Caregiver(s)

- PAID - Parent to Child or Teen - dependent on age of child with diabetes
- BGMC - parent
- DFCS - parent

Children with diabetes (8 – 11 years)

- PAID - Child
- DFCS - youth
- BGMC - youth

Adolescent/Teen with diabetes (12-18 years)

- PAID - Teen
- DFCS - youth
- BGMC – youth

12 Week Visit – Visit 3

Parent/Caregiver(s)

- PAID - Parent to Child or Teen - dependent on age of child with diabetes
- BGMC - parent
- DFCS - parent

Children with diabetes (8 – 11 years)

- PAID - Child
- DFCS - youth
- BGMC - youth

Adolescent/Teen with diabetes (12-18 years)

- PAID - Teen
- DFCS - youth

- BGMC – youth

24 Week Visit – Visit 4

Parent/Caregiver(s)

- PAID - Parent to Child or Teen - dependent on age of child with diabetes
- BGMC - parent
- DFCS – parent
- Questionnaire about Use, Preference, Satisfaction (Intervention Group Only)

Children with diabetes (8 – 11 years)

- PAID - Child
- DFCS - youth
- BGMC - youth
- Questionnaire about Use, Preference, Satisfaction (Intervention Group Only)

Adolescent/Teen with diabetes (12-18 years)

- PAID - Teen
- DFCS - youth
- BGMC - youth
- Questionnaire about Use, Preference, Satisfaction (Intervention Group Only)

Additionally, Healthcare Providers and School Nurses/Staff of the intervention group will be asked to complete the Questionnaires about use, preference, and satisfaction.

2.2 Data Collection

Data from the School Nurse Questionnaire will be collected on paper forms and entered into the MARVIN eCRF database via single data entry by data management. HbA1C data received electronically from the central laboratory will be printed out, and entered into the MARVIN eCRF database via single data entry by data management. All other data elements will be entered directly into the eCRF by the site study staff or study subjects (i.e. questionnaires). De-identified SMBG CSV data files from the meter downloads using Diasend will be uploaded into

MARVIN eCRF by the site study staff. The ACCU-CHEK® Connect DMS System will be de-identified, and provided to data management for upload into MARVIN.

3 DEFINITIONS

3.1 Baseline

Baseline will be defined as the date of Visit 1.

3.2 Derived Baseline Characteristics for Child/Adolescent with Diabetes

The following baseline characteristics will be derived from the Pre-Questionnaire measurements:

- Age category (6-7, 8-11, 12-18), in years
- BMI – calculated as weight(kg)/ height (m)^2
- Duration of diabetes: the difference in years between the month/year of diagnosis and the baseline month/year.
- Duration of current diabetes therapy: the difference in years (or months) between start date and the baseline date

3.3 Derived Study Day

For each eCRF visit the actual study day will be defined as the number of days from Visit 1 (Day 1). The calculation for study day will be:

(Day of visit – baseline date) + 1

3.4 Derived Questionnaire Variables

For each of the parent and child questionnaires, total scores will be calculated as the sum of all individual questions. If 10% or less questions are missing on a questionnaire the missing question algorithm for the total score (Section 3.4.1) will be implemented. Otherwise, if > 10% of questions are missing, the total scores will not be calculated. Changes from baseline and % change from baseline in Total Score for each questionnaire will be calculated for each subject at Visits 3 and 4.

3.4.1 Missing Question Imputation for Total Score

For all parent and child questionnaires if <= 10% of questions are missing the following imputation algorithm will be implemented:

1. Sum the values of all completed questions
2. Divide by the number of completed questions
3. Multiply this value by the total number of questions available on the questionnaire

The number of questions that are allowed to be missing for each questionnaire are as follows:

1. PAID Questionnaires: 2 Questions
2. BGMC Questionnaire: 1 Question
3. DFCS Questionnaire: 2 Questions

3.4.2 PAID Questionnaires (PAID-TP, PAID-YP, PAID-T, PAID-C)

Each question ranges in response values between 1 and 6:

- Child version: 1-2 = 'Not a Problem' , 3-4 are 'Medium Problem', and 5-6 are 'Big Problem'
- Teen or Parent versions: 1-2 = 'Not a Problem' , 3-4 are 'Moderate Problem', and 5-6 are 'Serious Problem'

- Derived Total Score (26 questions) ranging between 26 and 156
- Derived change from baseline defined as:

  (Value at Visit – Baseline Value)

- Derived % Change from baseline defined as:

  (Derived Change from baseline / Baseline Value) X 100.

3.4.3 BGMC Questionnaire (Youth, Parent)

Each question ranges in response values between 1 and 3, where 1='Almost Never', 2='Sometimes', and 3='Almost Always'.

- Derived Total Score (8 questions) ranges between 8 and 24

- Derived change from baseline defined as:

  (Value at Visit – Baseline Value)

- Derived % Change from baseline defined as:

  (Derived Change from baseline / Baseline Value) X 100.

3.4.4 DFCS Questionnaire (Youth, Parent)

Each question ranges in response values between 1 and 3, where 1='Almost Never', 2='Sometimes', and 3='Almost Always'.

- Derived Total Score (19 questions) ranges between 19 and 57
- Derived change from baseline defined as:

  (Value at Visit – Baseline Value)

- Derived % Change from baseline defined as:

  (Derived Change from baseline / Baseline Value) X 100.

3.5 Derived Glycemic Control Parameters

3.5.1 HbA1c

At Visits 3 and 4 the following variables will be derived:

- Derived change from baseline defined as:

  (Value at Visit – Baseline Value)

- Derived % Change from baseline defined as:

  (Derived Change from baseline / Baseline Value) X 100.

3.5.2 Blood Glucose Data

Blood glucose readings from the downloaded Diasend meter files or the ACCU-CHEK® Connect DMS System data will be linked to a particular subject by means of the Subject ID number. Cross-checking between the serial number(s) entered into the eCRF and the serial number within each downloaded file will be done to check for missing files.

3.5.2.1 Derived Visit and Visit Intervals

The date of each visit from the eCRF data will be used as a reference date for the dates of BG readings from the subject BG files. Those readings from Diasend download files that occur on or 30 days prior to the baseline visit date will be considered Baseline values. In a similar fashion values between 30 days prior to or on Visit 3 or Visit 4 will be considered Visit 3 or Visit 4 values, respectively.

For Baseline downloads, if there are no readings on the 30th day prior to the visit date, the first day there is a reading will be considered the beginning of the Baseline visit interval. The length of the visit interval for baseline will be calculated as:

(Baseline Date – Date of First day of Baseline interval) +1

Post-baseline intervals will be defined as 30 days for the Intervention group, and a similar length of visit interval as defined for Baseline will apply to the Control group.

It will be assumed that the first date reading for each subject using the ACCU-CHEK® Connect DMS System will be entered after training (post-baseline) even if on the same day as baseline.

3.5.2.2 Derived BG Glycemic Control Parameters

The following derivations will be made from the BG data at each study interval (Baseline, Visit 3, and Visit 4):

- Total number of BG checks during the interval
- SMBG frequency: Average number of daily SMBG measurements per interval will be defined as the total number of BG checks during the visit interval divided by the total number of days in the interval.
- BG Range Flags: Individual BG readings will be flagged as:
  - hypoglycemic reading if < 70 mg/dl (LO)
  - hyperglycemic reading if > 160 mg/dl (HI)
  - within target range 70-160 mg/dl

- Hypoglycemia: Percentage of hypoglycemic measurements defined as the number of hypoglycemic readings in the interval divided by the total number of BG checks in the interval.
- Glucose Target Range: Percentage of Target Range measurements defined as the number of within target range readings in the interval divided by the total number of BG checks in the interval. Values designated as 'LO' or 'HI' in the meter data will be classified as below or above, respectively
- Glycemic Variability
  - Mean of all BG readings per subject within the interval
  - BG variability (as SD of all glucose readings over the interval)

4 DATA SETS TO BE ANALYZED (STUDY POPULATIONS)

4.1 Full Analysis Set (FAS)

The Full Analysis Set Population (FAS) will be all eligible families that have signed an informed consent and completed (with the acceptable level of missing questions to calculate a total score – see section 3.4.1) all questions on the PAID Parent (YP or TP) Questionnaire at both baseline and Visit 4.

4.2 Intent-to-Treat Population (ITT)

The Intent-to-Treat Population (ITT) will be all families that have signed informed consent, and completed (with the acceptable level of missing questions to calculate a total score – see section 3.4.1) at least one Questionnaire (PAID-YP, PAID-TP, PAID-C, PAID-T, BGMC-Y, BGMC-P, DFCS-Y, DFCS-P), at both Baseline and Visit 4.

4.3 Interim Full Analysis Set (IFAS)

The Interim Full Analysis Set Population (IFAS) will be all eligible families that have signed an informed consent and completed (with the acceptable level of missing questions to calculate a

total score – see section 3.4.1) all questions on the PAID Parent (YP or TP) Questionnaire at both baseline and Visit 3.

4.4 Interim Intent-to-Treat Population (IITT)

The Interim Intent-to-Treat Population (IITT) will be all eligible families that have signed informed consent, and completed (with the acceptable level of missing questions to calculate a total score – see section 3.4.1) at least one Questionnaire (PAID-YP, PAID-TP, PAID-C, PAID-T, BGMC-Y, BGMC-P, DFCS-Y, DFCS-P), at both Baseline and Visit 3.

4.5 Safety Population (SAF)

The Safety Population (SAF) will be all eligible families that have signed informed consent/assent and exited the study after participating for at least 1 day in the study.

4.6 BG Analysis Eligibility (BGE)

Eligibility for BG analysis will be defined as an eligible subject that has at least 20 days of BG measurements prior to Visit 1. Analysis of BG data will be performed on both FAS and ITT populations, excluding subjects not eligible for BG analysis.

5 STATISTICAL ANALYSES

5.1 Study Populations

The number and percentage of families within each analysis population and treatment group will be summarized overall and by exclusion reason from each population. The denominator for each population will be the Safety Population.

5.2 Demographics and Baseline Characteristics

Demographic and baseline characteristics will be summarized descriptively for each analysis population and treatment group. Categorical variables will be summarized via counts and percentages, and continuous variables via mean, standard deviation, and range. Demographic and Baseline characteristics will be presented for both FAS and ITT populations.

5.2.1 Parent/Caregiver of Child/Adolescent with Diabetes

Variables from the Parent/Caregiver Pre-Questionnaire or derived baseline characteristics to be summarized are:

- Age
- Gender, race, ethnicity
- Marital Status
- Highest level of education
- Current Employment

5.2.2 Child or Adolescent with Diabetes

Variables from the Baseline Visit for the Child or Adolescent with diabetes or derived baseline characteristics to be summarized are:

- Age (continuous) and categorical: (8 - 11, 12 - 18) at informed consent
- Gender, race, ethnicity
- Height, weight, BMI
- Duration of diabetes
- Duration of this therapy
- Current type of insulin
- Average total daily basal dose, average total daily bolus dose, average number of boluses/day, and whether or not a bolus calculator is used.
- Average frequency of SMBG use
- HbA1c

5.3 Diabetes Management and Diabetes Related Absences

Diabetes management and diabetes related absences will be summarized descriptively for each analysis population and treatment group. Categorical variables will be summarized via counts and percentages, and continuous variables via mean, standard deviation, and range. Demographic and Baseline characteristics will be presented for both FAS and ITT populations.

5.3.1 Parent/Caregiver of Child/Adolescent with Diabetes

Variables from the Parent/Caregiver Pre-Questionnaire to be summarized are:

- Communication method and frequency parent to child
- Primary school staff contact for diabetes communication with parent
- Communication method and frequency parent to school staff
- Number of diabetes related absences in last 3 months due to doctor appointments, illness or other

5.3.2 Child or Adolescent with Diabetes

Variables from the Baseline Visit for the Child or Adolescent with diabetes to be summarized are:

- Prior use of CGM, DMS, or Diabetes management app
- Diabetes management responsibility
- Communication method and frequency child to parent
- Number of diabetes related absences in last 3 months due to doctor appointments, illness or other

5.4 Family Disposition

The number and percent of study subjects who discontinue early along with the reasons for discontinuation will be summarized by study population and treatment group. The number and percent of study subjects present at each study visit will also presented.

5.5 "Efficacy" Analyses

5.5.1 Primary Analysis

The primary analysis variable – change from baseline in PAID – Parent (YP or TP), will be summarized by treatment group at 6 months via descriptive statistics and will be analyzed for treatment group differences by an analysis of covariance (ANCOVA). The model will include the independent variable – change from baseline in PAID, and the baseline covariates of baseline PAID, age of child, and duration of diagnosis. Additionally, the results of a 2-sample

t-test comparing the group means will also be provided. If deviations from normality are significant, non-parametric methods, such as Wilcoxon Rank Sum Tests will be employed. The primary analysis population will be the FAS population.

5.5.2 Secondary Analyses

Secondary objective variables collected in both treatment groups will be summarized by group utilizing descriptive statistics. Statistical comparisons between groups of continuous variables will utilize the same ANCOVA method discussed above substituting the baseline value of the independent parameter, as well as 2-sample t-tests or non-parametric Wilcoxon Rank Sum tests. The following variables will be analyzed:

1. Change from baseline in PAID-parent (YP and TP) at 3 months
2. Change from baseline in DFCS – parents at 3 and 6 months
3. Change from baseline in BGMC-parents at 3 and 6 months
4. Change from baseline in PAID-child (Y or T) at 3 and 6 months
5. Change from baseline in DFCS-child at 3 and 6 months
6. Change from baseline in BGMC-child at 3 and 6 months
7. Changes from baseline in glycemic control (HbA1c, % BG in target, mean BG, SD BG, and % hypoglycemic events) at 3 and 6 months

Secondary objective variables collected in the Intervention treatment group only (ease of use, satisfaction and preference for using the ACCU-CHEK® Connect DMS System by parents, children, school staff, and HCP) will be summarized by question utilizing descriptive statistics of the numerical scale (mean, standard deviation, range and 95% CI) and the distribution of values (number and % of respondents at each level of response).

All secondary analyses will be performed on both the FAS and ITT populations.

5.6 Safety Analyses

The patient incidence of adverse events will be summarized by intervention group, MedDRA System Organ Class and Preferred Term. Such summaries will be displayed for all AEs, AEs by maximum severity, AEs by strongest causality to study device (and any associated pump devices), and AEs leading to withdrawal of study device. A separate analysis of the patient incidence of symptomatic hypoglycemia, severe hypoglycemia (SAE), and diabetic ketoacidosis (SAE) will also be presented.

6 TABLES

Table No.	Title
Table 1.1	Analysis Populations
Table 1.2.1	Demographics and Baseline Characteristics Parent/Caregiver of Child with Diabetes FAS Population
Table 1.2.2	Demographics and Baseline Characteristics Parent/Caregiver of Child with Diabetes ITT Population
Table 1.3.1	Diabetes Management, Communication and Diabetes Related Absences Parent of Child with Diabetes FAS Population
Table 1.3.2	Diabetes Management, Communication and Diabetes Related Absences Parent of Child with Diabetes ITT Population
Table 1.4.1	Demographics and Baseline Characteristics Child with Diabetes FAS Population
Table 1.4.2	Demographics and Baseline Characteristics Child with Diabetes ITT Population
Table 1.5.1	Diabetes Management, Communication and Diabetes Related Absences Child with Diabetes FAS Population
Table 1.5.2	Diabetes Management, Communication and Diabetes Related Absences Child with Diabetes

Table No.	Title
	ITT Population
Table 1.6.1	Summary of Family Disposition Safety Population
Table 1.7.1	Summary of PAID Questionnaire Completion FAS Population
Table 1.7.2	Summary of PAID Questionnaire Completion ITT Population
Table 1.8.1	Summary of BGMC Questionnaire Completion FAS Population
Table 1.8.2	Summary of BGMC Questionnaire Completion ITT Population
Table 1.9.1	Summary of DFCS Questionnaire Completion FAS Population
Table 1.9.2	Summary of DFCS Questionnaire Completion ITT Population
Table 2.1.1	Primary Analysis - PAID - Parent Questionnaire Change from Baseline to Visit 4 in TOTAL PAID SCORE FAS Population
Table 2.2.1.1	Secondary Analysis - PAID - Parent Questionnaire Change from Baseline to Visit 3 in TOTAL PAID SCORE FAS Population
Table 2.2.1.2	Secondary Analysis - PAID - Parent Questionnaire Change from Baseline to Visit 3 in TOTAL PAID SCORE ITT Population
Table 2.2.2.1	Secondary Analysis - PAID - Child Questionnaire Change from Baseline TOTAL PAID SCORE FAS Population
Table 2.2.2.2	Secondary Analysis - PAID - Child Questionnaire Change from Baseline TOTAL PAID SCORE ITT Population
Table 2.2.3.1	Secondary Analysis - PAID - Teen Questionnaire Change from Baseline TOTAL PAID SCORE FAS Population
Table 2.2.3.2	Secondary Analysis - PAID - Teen Questionnaire Change from Baseline TOTAL PAID SCORE ITT Population

Table No.	Title
Table 2.3.1.1	Secondary Analysis - BGMC - Parent Questionnaire Change from Baseline TOTAL BGMC SCORE FAS Population
Table 2.3.1.2	Secondary Analysis - BGMC - Parent Questionnaire Change from Baseline TOTAL BGMC SCORE ITT Population
Table 2.3.2.1	Secondary Analysis - BGMC - Child Questionnaire Change from Baseline TOTAL BGMC SCORE FAS Population
Table 2.3.2.2	Secondary Analysis - BGMC - Child Questionnaire Change from Baseline TOTAL BGMC SCORE ITT Population
Table 2.4.1.1	Secondary Analysis - DFCS - Parent Questionnaire Change from Baseline TOTAL DFCS SCORE FAS Population
Table 2.4.1.2	Secondary Analysis - DFCS - Parent Questionnaire Change from Baseline TOTAL DFCS SCORE ITT Population
Table 2.4.2.1	Secondary Analysis - DFCS - Child Questionnaire Change from Baseline TOTAL DFCS SCORE FAS Population
Table 2.4.2.2	Secondary Analysis - DFCS - Child Questionnaire Change from Baseline TOTAL DFCS SCORE ITT Population
Table 2.5.1.1	Secondary Analysis - Glycemic Control - HbA1c Change from Baseline FAS Population
Table 2.5.1.2	Secondary Analysis - Glycemic Control - HbA1c Change from Baseline ITT Population
Table 2.5.2.1	Secondary Analysis - Glycemic Control - Averge Number of Daily Checks Change from Baseline FAS Population
Table 2.5.2.2	Secondary Analysis - Glycemic Control - Averge Number of Daily Checks Change from Baseline ITT Population
Table 2.5.3.1	Secondary Analysis - Glycemic Control - %BG in Target (70-160 mg/dl) Change from Baseline FAS Population
Table 2.5.3.2	Secondary Analysis - Glycemic Control - %BG in Target (70-160 mg/dl) Change from Baseline ITT Population

Table No.	Title
Table 2.5.4.1	Secondary Analysis - Glycemic Control - Mean BG Change from Baseline FAS Population
Table 2.5.4.2	Secondary Analysis - Glycemic Control - Mean BG Change from Baseline ITT Population
Table 2.5.5.1	Secondary Analysis - Glycemic Control - Standard Deviation (SD) BG Change from Baseline FAS Population
Table 2.5.5.2	Secondary Analysis - Glycemic Control - Standard Deviation (SD) BG Change from Baseline ITT Population
Table 2.5.6.1	Secondary Analysis - Glycemic Control - % Hypoglycemia (< 70 mg/dl) Change from Baseline FAS Population
Table 2.5.6.2	Secondary Analysis - Glycemic Control - % Hypoglycemia (< 70 mg/dl) Change from Baseline ITT Population
Table 2.7.1.1	Exit Questionnaire: Usability Parent/Caregiver of Child with Diabetes FAS Population
Table 2.7.1.2	Exit Questionnaire: Usability Parent/Caregiver of Child with Diabetes ITT Population
Table 2.7.2.1	Exit Questionnaire: Usability Child with Diabetes FAS Population
Table 2.7.2.2	Exit Questionnaire: Usability Child with Diabetes ITT Population
Table 2.8.1.1	Exit Questionnaire: Satisfaction Parent/Caregiver of Child with Diabetes FAS Population
Table 2.8.1.2	Exit Questionnaire: Satisfaction Parent/Caregiver of Child with Diabetes ITT Population
Table 2.8.2.1	Exit Questionnaire: Satisfaction Child with Diabetes FAS Population

Table No.	Title
Table 2.8.2.2	Exit Questionnaire: Satisfaction Child with Diabetes ITT Population
Table 2.9.1.1	End of Study Questionnaire: Preference Parent/Caregiver of Child with Diabetes FAS Population
Table 2.9.1.2	End of Study Questionnaire: Preference Parent/Caregiver of Child with Diabetes ITT Population
Table 2.9.2.1	End of Study Questionnaire: Preference Child with Diabetes FAS Population
Table 2.9.2.2	End of Study Questionnaire: Preference Child with Diabetes ITT Population
Table 2.10.1.1	School Nurse Questionnaire: Preference FAS Population
Table 2.10.1.2	School Nurse Questionnaire: Preference ITT Population
Table 2.10.2.1	School Nurse Questionnaire: Usability FAS Population
Table 2.10.2.2	School Nurse Questionnaire: Usability ITT Population
Table 2.10.3.1	School Nurse Questionnaire: Satisfaction FAS Population
Table 2.10.3.2	School Nurse Questionnaire: Satisfaction ITT Population
Table 2.11.1.1	HCP Questionnaire: Preference FAS Population
Table 2.11.1.2	HCP Questionnaire: Preference ITT Population
Table 2.11.2.1	HCP Questionnaire: Usability FAS Population
Table 2.11.2.2	HCP Questionnaire: Usability ITT Population
Table 2.11.3.1	HCP Questionnaire: Satisfaction HCP Eligibility Population
Table 3.1	Summary of All Adverse Events by MeDRA SOC and Preferred Term Safety Population

Table No.	Title
Table 3.2.1	Summary of All Adverse Events by Maximum Severity Safety Population
Table 3.2.2	Summary of All Adverse Events by Strongest Causality to Study Device Safety Population
Table 3.2.3	Summary of All Adverse Events Leading to Withdrawal from the Study Safety Population
Table 3.3	Summary of Symptomatic Hypoglycemia, Severe Hypoglycemia and Diabetic Ketoacidosis Safety Population

7 LISTINGS

Listing No.	Title
Listing 1	Enrollment and Analysis Populations
Listing 2.1	Inclusion Criteria
Listing 2.2	Exclusion Criteria
Listing 3.1	Demographics - Parents/Caregivers
Listing 3.2	Demographics - Child
Listing 3.3	Intervention Group Training
Listing 4	Diabetes Background and History
Listing 5.1	Diabetes Medication
Listing 5.2	Daily Insulin Dose and Boluses
Listing 6	Diabetes Management and Communication
Listing 7	Diabetes Related Absences

Listing No.	Title
Listing 8.1	BG Device Upload Information to eCRF
Listing 8.2	BG Data from Meters/AcuChek-Connect
Listing 8.3	Summary BG Data
Listing 9.1.1	Problem Areas in Diabetes (PAID) - Parents of Youth (YP) - Part 1
Listing 9.1.2	Problem Areas in Diabetes (PAID) - Parents of Youth (YP) - Part 2
Listing 9.2.1	Problem Areas in Diabetes (PAID) - Parents of Teens (TP) - Part 1
Listing 9.2.2	Problem Areas in Diabetes (PAID) - Parents of Teens (TP) - Part 2
Listing 9.3.1	Problem Areas in Diabetes (PAID) - Child (C) - Part 1
Listing 9.3.2	Problem Areas in Diabetes (PAID) - Child (C) - Part 2
Listing 9.4.1	Problem Areas in Diabetes (PAID) - Teens (T) - Part 1
Listing 9.4.2	Problem Areas in Diabetes (PAID) - Teens (T) - Part 2
Listing 10	Blood Glucose Monitoring Communication Survey (BGMC)
Listing 11.1.1	Diabetes Family Conflict Scale - Parent (DFCS-Parent) - Part 1
Listing 11.1.2	Diabetes Family Conflict Scale - Parent (DFCS-Parent)-Part 2
Listing 11.2.1	Diabetes Family Conflict Scale - Youth (DFCS-Youth) - Part 1
Listing 11.2.2	Diabetes Family Conflict Scale - Youth (DFCS-Youth)-Part 2
Listing 12	Follow-up Visits
Listing 13.1	Parent Post-Questionnaire - Usability - Meter
Listing 13.2	Parent Post-Questionnaire - Usability - Phone App
Listing 13.3	Parent Post-Questionnaire - Usability - Web Portal
Listing 13.4	Parent Post-Questionnaire - Satisfaction
Listing 13.5	Parent Post-Questionnaire - Preference
Listing 13.6	Parent Post-Questionnaire - Comments

Listing No.	Title
Listing 14.1	Child & 18 Yr Old Post-Questionnaire - Usability - Meter
Listing 14.2	Child & 18 Yr Old Post-Questionnaire - Usability - Phone App
Listing 14.3	Child & 18 Yr Old Post-Questionnaire - Usability - Web Portal
Listing 14.4	Child & 18 Yr Old Post-Questionnaire - Satisfaction
Listing 14.5	Child & 18 Yr Old Post-Questionnaire - Preference
Listing 14.6	Child & 18 Yr Old Post-Questionnaire - Comments
Listing 15.1	Adverse Events - Symptomatic Hypoglycemia
Listing 15.2.1	Adverse Events - Other Non-Serious Events - Part 1
Listing 15.2.2	Adverse Events - Other Non-Serious Events - Part 2
Listing 15.3.1	Adverse Events -Serious Events - Part 1
Listing 15.3.2	Adverse Events - Serious Events - Part 2
Listing 15.3.3	Adverse Events - Serious Events - Part 3
Listing 15.3.4	Adverse Events - Serious Events - Part 4
Listing 16.1	Device Defects - Part 1
Listing 16.2	Device Defects - Part 2
Listing 16.3	Device Defects - Part 3
Listing 17	Study Completion
Listing 18.1	School Nurse Questionnaire - Usability - Meter
Listing 18.2	School Nurse Questionnaire - Usability - Phone App
Listing 18.3	School Nurse Questionnaire - Usability - Web Portal
Listing 18.4	School Nurse Questionnaire - Satisfaction
Listing 18.5	School Nurse Questionnaire - Preference
Listing 18.6	School Nurse Questionnaire - Comments

Listing No.	Title
Listing 19.1	HCP Questionnaire - Usability - Meter
Listing 19.2	HCP Questionnaire - Usability - Phone App
Listing 19.3	HCP Questionnaire - Usability - Web Portal
Listing 19.4	HCP Questionnaire - Satisfaction
Listing 19.5	HCP Questionnaire - Preference
Listing 19.6	HCP Questionnaire - Comments

Note: All output templates are contained in a separate document.