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Study Title	The MiniMed™ 780G Glycemic Control and Quality of Life study for the treatment of pediatric and adult subjects with Type 1 Diabetes in France. (EQOL Study)
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Medtronic

Statistical Analysis Plan

Clinical Investigation Plan Title	The MiniMed® 780G Glycemic Control and Quality of Life study for the treatment of pediatric and adult subjects with Type 1 Diabetes in France. (EQOL Study)
Clinical Investigation Plan Identifier	MDT19028328
Clinical Investigation Plan Version	Version 4.0, 22 Oct 2020
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1. Version History

Version	Summary of Changes	Author(s)/Title
1.0 08NOV2022	• First release of the document	[redacted] Sr Statistician

2. List of Abbreviations and Definitions of Terms

Abbreviation	Definition
AHCL	Advanced Hybrid Closed Loop
CGM	Continuous Glucose Monitoring
CI	Confidence Interval
CIP	Clinical Investigation Plan
CL	Closed Loop
CSII	Continuous Subcutaneous Insulin Infusion
DM	Diabetes Mellitus
DTSQ	Diabetes Treatment Satisfaction Questionnaire
DQOL	Diabetes Quality of life
eCRF	Electronic Case Report Form
FDA	Food and Drug Administration
HbA1c	Glycosylated or glycated hemoglobin
HFS	Hypoglycemia Fear Survey
QOL	Quality of Life
SAP	Statistical analysis plan
TIR	Time in Range
T1D	Type 1 Diabetes

3. Introduction

The Medtronic MiniMed™ sensor augmented insulin pumps have been helping insulin requiring patients with diabetes mellitus all around the world for more than two decades. In order to address some of the unmet needs of these patients and to provide them the benefits of newer technologies, Medtronic Diabetes has developed a new Sensor Augmented Pump platform: the MiniMed™ 780G System, also referred as Advanced Hybrid Close Loop system.

The Advanced Hybrid Closed Loop system (AHCL) is based on the MiniMed™ 670G hybrid closed loop system currently in commercial distribution in the United States, Canada and Europe. Relative to the MiniMed™ 670G system, AHCL includes enhancements intended to reduce the frequency of Auto Mode exits and decrease the time spent in hyperglycemia. Advancement such as automatic correction bolusing, sensor glucose based meal bolusing, automatic calibrations of Blood Glucose (BG) measurements transmitted to the pump and a variable target for automatic basal deliveries, all

maximize the time spent in hybrid closed-loop operation, in order to further improve glucose control and overall user satisfaction.

Patients using the AHCL system will not be required to confirm sensor glucose using SMBG (Self-Monitoring of Blood Glucose) measurement before making therapy adjustments based on displayed sensor glucose values.

The advanced algorithm receives continuous glucose monitoring (CGM) data every 5 minutes, and a "basal rate" insulin delivery is computed and adjusted every five minutes. Therefore, standard "basal" insulin that is pre-programmed in regular insulin pump therapy is replaced by the algorithm derived insulin delivery (given as a micro-bolus every 5 minutes). Meals will be announced, and sensor glucose based insulin bolus for a meal will be delivered according to the individualized patient carbohydrate ratio and insulin sensitivity factor.

The MiniMed 780G system is intended for the continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable amounts. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed 780G system includes SmartGuard technology, which can be programmed to provide an automatic adjustment of insulin delivery based on continuous glucose monitoring (CGM) and can suspend the delivery of insulin when the SG value falls below, or is predicted to fall below, predefined threshold values.

The MiniMed™ 780G system received CE (Conformité Européenne) Marking in June 2020. While in the United States, the MiniMed™780G system is for investigational use only, and not approved for sale or distribution.

Several studies were conducted to demonstrate the safety and effectiveness of the MiniMed™ 670G and 780G Systems. However, data regarding the effect on glycemic control, quality of life and treatment satisfaction of MiniMed™ 780G System under the routine practice in France are highly recommended by the French National Authority for Health (HAS).

This is a post-market, non-interventional, prospective, local, single-arm, multi-center non-randomized clinical study of patients (pediatric and adult).

This SAP is based on Protocol Version 4.0 22OCT2020 and other available documents and it will describe the final analysis of the study. The SAP has been prepared in agreement with Medtronic internal procedures and using the STROBE Statement[1] and International Conference Harmonization (ICH) guidelines E3, E6 and E9 as guidelines.

4. Study Objectives

4.1. Primary Objective and Endpoint

The primary objective is to evaluate if the treatment of T1D with MiniMed™ 780G System in pediatric and adult population increases the Time In Range (TIR) at 6 months compared to MiniMed™ 780G System in Manual Mode (with no SmartGuard™ functions) during the run-in period (expected to be approximately 2 weeks). TIR is defined as time spent of sensor glucose values within 70-180mg/dL (3.9–10.0 mmol/L).

The primary endpoint is the change in (%) the time spent within range (TIR) defined as the proportion of sensor glucose concentration within the target range 70-180 mg/dL (3·9–10·0 mmol/L) between baseline and 6 months.

4.2. Secondary Objectives and Endpoints

Secondary objectives will aim at evaluating the difference in time in range, quality of life and treatment satisfaction.

4.2.1. TIR change over time

- Objective: To assess the change overtime of the TIR collected at baseline and every three months until 12 months.
- Endpoint: The Time In Range (TIR) defined as the proportion of sensor glucose concentration within the target range of 70-180 mg/dL (3.9–10.0 mmol/L) every 3 months.

4.2.2. Satisfaction score based on the DTSQc

- Objective: To evaluate satisfaction score based on the DTSQc evaluated at 6 months.
- Endpoint: The different DTSQc versions will be used to assess satisfaction in the following populations:
    - DTSQc Adult (≥18 years old)
    - DTSQc Teenager (13-17 years old)
    - DTSQc Parent (7-12 years old)

4.2.3. Quality of life based on DQoL

- Objective: To evaluate the change from baseline in quality of life based on the DQoL evaluated at 6 and 12 months.
- Endpoint: the DQoL questionnaire will be used and the mean scores will be compared between baseline and 6 and 12 months. The different DQoL versions will be used to assess quality of life in the following populations:

- DQoL Adult (≥18 years old)
- DQoL Adult with Adolescent-oriented items (13-17 years old)

No DQoL version and therefore no collection for patients 7-12 years old

4.2.4. Fear of hypoglycemic events based on the Hypoglycemia Fear Survey (HFS)

- Objective: To evaluate the change from baseline in the fear of hypoglycemic events based on the HFS evaluated at 6 and 12 months.
- Endpoint: the HFS questionnaire will be used and the mean scores will be compared between baseline and 6 and 12 months. The different HFS versions will be used to assess the fear of hypoglycemic events in the following populations:
  - HFS Adult (≥18 years old)
  - HFS Teenager (13-17 years old)
  - HFS Parent (7-12 years old)

4.2.5. Glycemic parameters

- Objective: To evaluate the change of glycemic parameters at baseline and every three months until 12 months and the change in HbA1c from baseline to 6 and 12 months.
- Endpoint: the mean time of sensor glucose values below 70mg/dL and below 54mg/dL, the time of sensor glucose value above 180mg/dL and above 250mg/dL at baseline and every 3 months. The change in HbA1c from baseline to 6 and 12 months follow up.

4.2.6. Satisfaction score on the DTSQs

- Objective: To evaluate the treatment satisfaction score on the DTSQs evaluated at baseline, 6 and 12 months.
- Endpoint: The different DTSQs versions will be used to assess satisfaction in the following populations:
  - DTSQs Adult (≥18 years old)
  - DTSQs Teen (13-17 years old)
  - DTSQs Parent (7-12 years old)

5. Investigation Plan

This study is a local, post-market, non-interventional, prospective, single-arm, multi-center, non-randomized study assessing the glycemic control effect, treatment satisfaction and the quality of

life of patients using MiniMed™ 780G System as per the standard care of practice. This study has a single-arm design which will recruit a maximum of 306 subjects in up to 32 sites in France. At the time of Clinical Investigational Plan finalization, the list of participating sites was not finalized. The complete list, which includes the name, position and address of the investigators responsible for conducting the study, will be available under separate cover and provided to the sites.

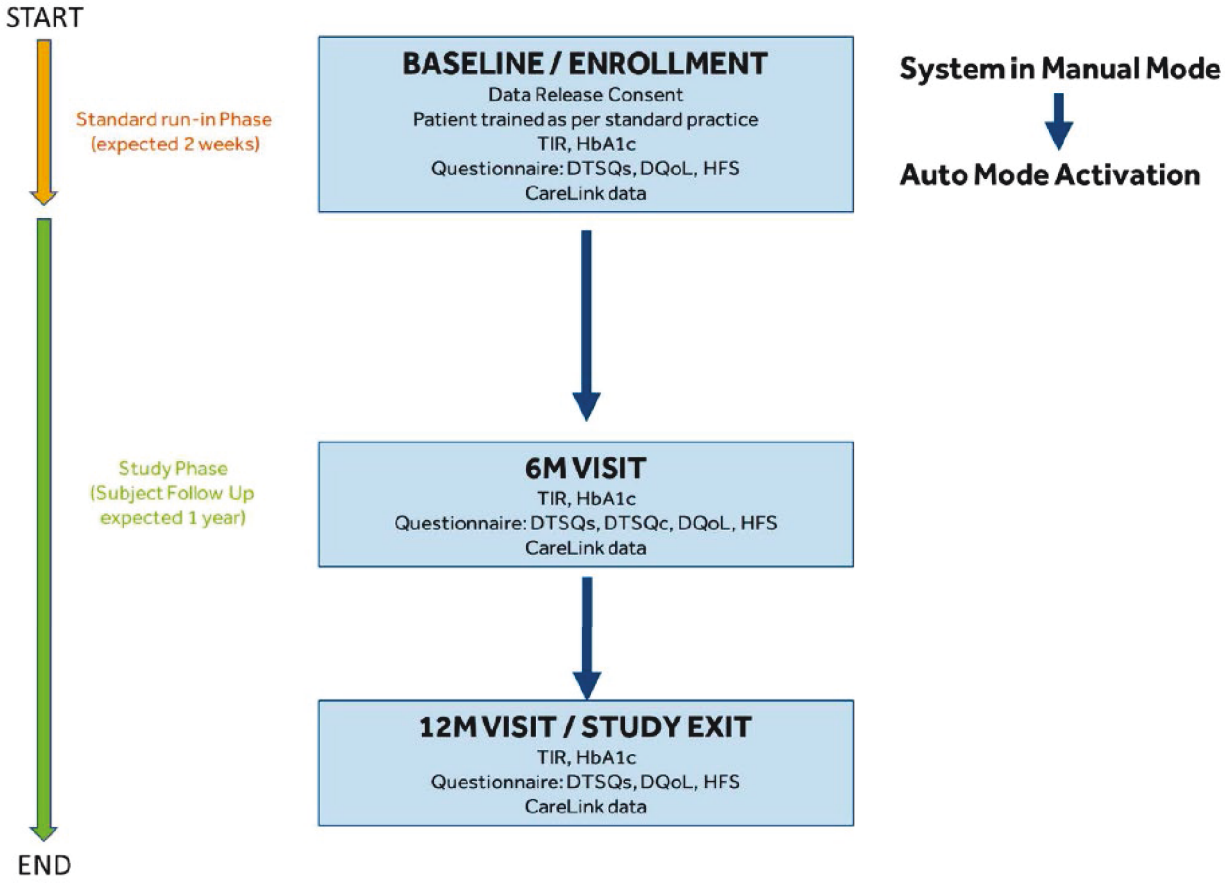
To avoid introduction of bias to the study results due to disproportionate enrollment, enrollment at any individual site shall not exceed 10% (30 subjects) of the total sample size. It is expected that sites enroll a minimum of 10 subjects per site.

Subject enrolled in this study (or his/her parent/legal representative in case of DTSQ and HFS for patients 7-12 years old) will be asked to complete the questionnaires DTSQ, DQoL (if patient is ≥13 years old) and HFS at baseline/enrollment visit and at 6- and 12- month follow-up visits.

The following measures are taken to minimize potential sources of bias:

- A multi-center design is used to ensure a representative sample of physicians providing the treatment and to reach a reasonable enrollment period.
- Site selection will be done per predefined selection criteria.
- Only physicians that have adequate documented experience in diabetes management will participate.
- Site training is performed according to the training & education plan set up for the pump use in order to assure full understanding and engagement to comply with the pump best utilization.
- Consecutive screening and enrollment will be encouraged and enforced as much as possible.

Figure 1: Study design overview



CareLink data uploads from the devices should be done as per clinical practice, i.e. once a week. CareLink data evaluation will be done every 3 months.

An overview of data collection is given in the Table 1.

Table 1: Schedule of assessments

Data collection	Enrollment /Baseline	6-month Follow-up (±45 days)	12-month Follow-up (±45 days)
Data Release Form	√		
Inclusion and exclusion criteria	√		
Demographics	√		
Medical history	√		
HbA1c[1]	√	√	√
Auto Mode Activation Date	√		
Ensure that CareLink™ Personal upload was done[2]	√[4]	√	√
CGM data	√	√	√
Study Exit			√
Study Deviation	Upon occurrence		
QUESTIONNAIRES :			
DTSQs	√	√	√
DTSQc		√	
DQoL[3]	√	√	√
HFS	√	√	√

1. Available HbA1c value collected up to 30 days before enrollment and more or less 30 days from 6-month and 12-month follow up visits can be used.
2. CareLink™ data should be uploaded via Bluetooth connectivity from the devices or via USB connection as per clinical practice, i.e. once a week. CareLink™ Data evaluation will be done every 3 months for secondary objectives.
3. DQoL will not be administered in case patient is between 7 and 12 years old.
4. Baseline CGM data will be collected before Auto Mode activation at the end of the run-in phase

6. Determination of Sample Size

The sample size was determined using a one sample paired test assuming a one-sided type I error rate of 0.05 and a power of 90%. The TIR at baseline is assumed to be 60% and the TIR at 6 months follow up (TIR calculated using overall 6 months CGM data) is assumed to be 63% with same standard deviation as 14% and a correlation as 0.5. Thus, the hypothesis to be tested is:

H0: μTIR6m – μTIR baseline = d0

HA: μTIR6m – μTIR baseline > d0

where d0 = 3 is the expected increase of TIR at 6 months. The sample size needed to demonstrate this hypothesis is 245 paired assessments per subject. The calculation is adjusted for loss-to-follow-up and protocol failures, including potential subjects with less than 70% of the time in Auto Mode and with an assumption considering an attrition rate of 20%. The total number of subjects to be enrolled is 306.

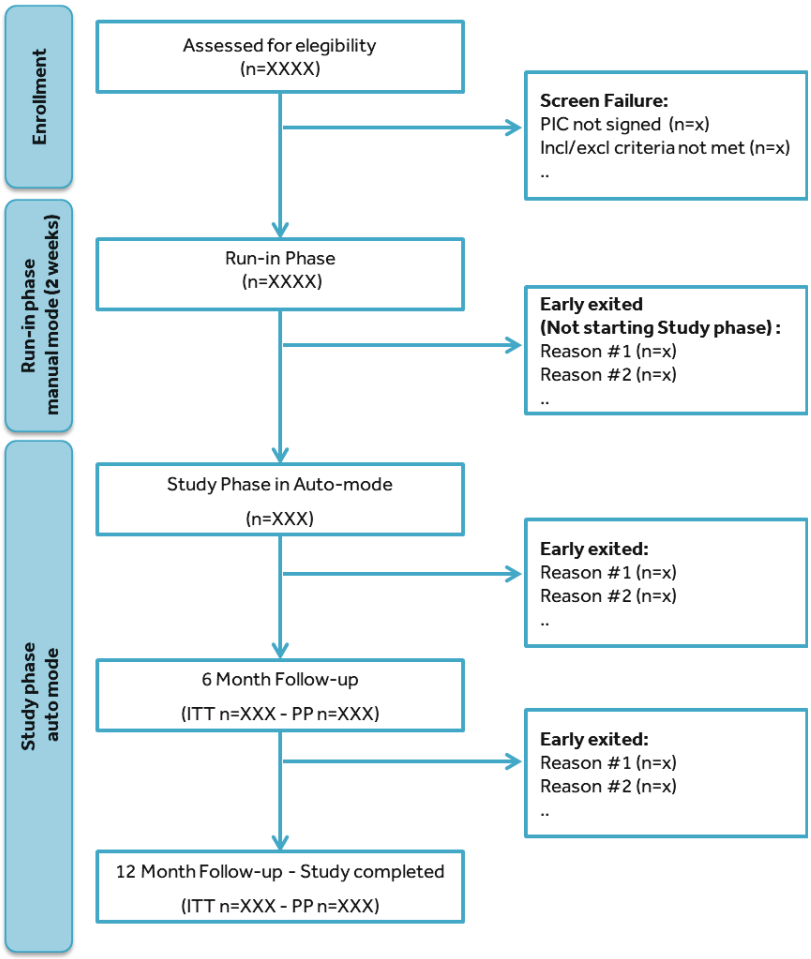
7. Statistical Methods

7.1. Study Subjects

7.1.1. Disposition of Subjects

Disposition of subjects will be reported following the STROBE Statement Checklist. Number of individuals at each stage of study (number of total assessed for eligibility, number enrolled, number analyzed and number with 6-12 months follow-up) will be reported. Reasons for not participation at each stage will be reported where known.

Figure 1 – Flow diagram of Patient Disposition



7.1.2. Clinical Investigation Plan (CIP) Deviations

All deviations will be collected in the case report form, with the type of the deviation and the reason for the deviation. All deviations will be reported in Tables and Listings.

7.1.3. Analysis Sets

The following subject sets will be used for the analysis:

- The Intention To Treat (ITT) includes all patients enrolled in the study with signed Data Release Form, fulfill the inclusion and exclusion criteria. The ITT will be used for all endpoints and safety evaluation.
- The Per Protocol (PP) includes all patients enrolled in the study with signed Data Release Form, fulfill the inclusion and exclusion criteria and having at least 70% of time using the Auto Mode during the 6-month follow up. The PP set will be used for all endpoints.

The primary analysis will be performed on the ITT set . As sensitivity analysis the PP set will be used. The following table shows how each population set will be used for analyses:

Population set	Baseline assessment	Primary Endpoint	Secondary Endpoints	Adverse Events
PP	√	√*	√	
ITT	√	√	√	√

* The primary endpoint on the PP population will be considered as sensitivity analysis

For patients who dropout, the analyses will include all data up to the point of their last data collection.

7.2. General Methodology

Descriptive statistics will be used to summarize patient characteristics. For categorical variables, the description will consist at least of the sample size, numbers of missing data and valid data, the frequency and the percentage of each category. Denominators for calculation of percentages will be taken as the number of subjects with available (not missing or unknown) observations in the specified patients sets and groups unless otherwise stated. Percentages will be presented with no decimal (or one decimal, if appropriate) and rounded to the nearest integer. For continuous variables, the description will consist at least of the sample size (N), number of subjects with non-missing observation (n), mean, standard deviation, standard error, minimum, median and maximum. For n<3, only mean, minimum and maximum will be displayed. In general, minimums and maximums will be presented to the same level of accuracy as the raw data; means and medians will be presented to 1 further decimal place; if appropriate, standard deviation and standard error will be presented to 2 further decimal places.

Device data metrics will be derived in a real-world data setting using all the device data collected during the patient study exposure.

It is anticipated that SAS 9.4 or later (SAS Institute Inc., Cary, NC, USA) will be used to perform all statistical analyses. Statistical tests will be based on a one-sided significance level of 0.05, and possible interaction effects will be evaluated at a significance level of 0.10. No adjustments for multiple comparisons will be performed. Additional exploratory analyses will be conducted as deemed appropriate and described as ad-hoc analysis in the study report.

7.3. Center Pooling

The study is a multicenter trial and a multicenter impact on primary outcomes will be investigated. A description by means of summary statistics on primary outcomes by sites will be provided.

7.4. Handling of Missing, Unused, and Spurious Data and Dropouts

Since the impact of missing data is expected to be small, no imputation of missing data will be performed.

In the case of dates collected at baseline with missing day and/or month the next procedure will be applied. A missing day and month will be imputed using the month 'July 1' and a missing day will be imputed with the day '15'. This applies only to dates related to medical history and baseline information with missing month and/or day.

For per protocol analysis, if HbA1c is collected out of window (-30 days from the date of actual Baseline visit and ± 30 days from the date of actual Follow-up visit), HbA1c will be considered missing for that period/visit.

Outliers and influential observations will be identified via graphical plots. Once outliers or influential observations are identified, the study team will be informed and according to their decision the analysis for primary endpoint may be repeated using a statistical method robust against outliers. Additional exploratory analyses will be conducted as deemed appropriate.

7.5. Adjustments for Multiple Comparisons

No adjustments for multiple comparisons will be performed.

7.6. Demographic and Other Baseline Characteristics

Demographic and Baseline variables will be collected through:

- Demographics: age, sex
- Medical history: HBA1c (collected up to 30 days before enrollment), last treatment, Name of the last pump device, Date of the first pump treatment, Years since diagnose of T1D, Number of severe hypoglycemia in the last year
- Questionnaires: DTSQs, DQoL (except for patients between 7 and 12 years old), HFS

At the end of the run-in period, the following data will be also collected:

- Mean TIR (70-180mg/dL)
- Mean Time spent of sensor glucose value below 70mg/dL and below 54mg/dL
- Mean Time spent of sensor glucose value above 180mg/dL and above 250mg/dL
- Number of bio-chemical hypoglycemic event per week

7.7. Treatment Characteristics

Duration of Study Exposure will be measured in days starting from the point of enrollment (informed consent signed and inclusion/exclusion criteria confirmed) through and including the time of study exit. The study has two phases:

The Run-In phase starts at the Enrolment (Consent date) and it ends at the Auto Mode activation date. It is expected that the Run-In phase will last 2 weeks.

The Study phase starts at the Auto Mode activation (end of Run-In phase) and it ends at 12 month follow up. The study phases exposures are calculated as:

- Duration of study exposure (days) = (Study Exit date – date of Enrollment(Consent) +1).
- Duration of Run-In phase exposure (days) = (date of Automode Activation – date of Enrollment(Consent) +1).
- Duration of Study phase exposure (days) = (date of Study exit – date of Automode Activation +1).

Extent of study exposures will be presented in a summary table.

7.8. Interim Analyses

No interim analysis is planned for this study.

7.9. Evaluation of Objectives

In this section a detailed information about each objective is included together with calculations and derivations of outcome parameters, analysis methods, datasets analyzed (PP and ITT). For each endpoint will be reported at least summary statistics table. All the objectives will consider two study phases calculated as defined in section 7.7. The secondary endpoints on questionnaires will include three subpopulations according to the age at the Consent date: Adult (≥18 years old), Teen (13-17 years old) and Parent (7-12 years old). This subpopulation definition will be maintained over the study visits.

7.9.1. Primary Endpoint

The primary endpoint on efficacy defined as the change of TIR at 6 months, calculated starting from the Auto Mode activation (Study phase) to the 6-months, with baseline (Run-In phase) will be analyzed by means of paired (samples) t-test or Wilcoxon signed rank sum test according to the normal or non-normal distribution.

The TIR will be calculated as the proportion (%) of sensor glucose concentration measurements within the target range of 70-180 mg/dL (3·9–10·0 mmol/L) on the total sensor glucose measurements.

The mean change will be displayed together with their 95% confidence interval (95%CI).

7.9.2. Secondary Endpoints

7.9.3. TIR change over time

The objective is to assess the change of the TIR collected over the Run-in phase and over the Study phase every three months until 12 months. The Time In Range (TIR) will be assessed every 3 months.

The analysis will use multiple data points per patient (baseline, 3, 6, 9 and 12 months). The change over time will be analyzed by means of GEE (generalized estimating equation) models (or mixed models) for continuous outcomes to account for repeated measures using patient as the subject.

The dependent variable will be pre-log transformed depending on normal or non-normal distribution. The model will have the TIR as dependent variables and baseline values and visits. All assumptions for regression models will be assessed by viewing plots of the residual values. Mean with standard errors at each time point will be reported for the TIR and for graphical purpose only separately by population as deemed appropriate.

The adjusted mean change will be displayed together with their 95% confidence interval (95%CI).

7.9.4. Satisfaction score based on the DTSQc

To evaluate the satisfaction score based on the DTSQc evaluated at 6 months. The different DTSQc versions will be used to assess satisfaction in the following populations:

- DTSQc Adult (≥18 years old)
- DTSQc Teen (13-17 years old)
- DTSQc Parent (7-12 years old)

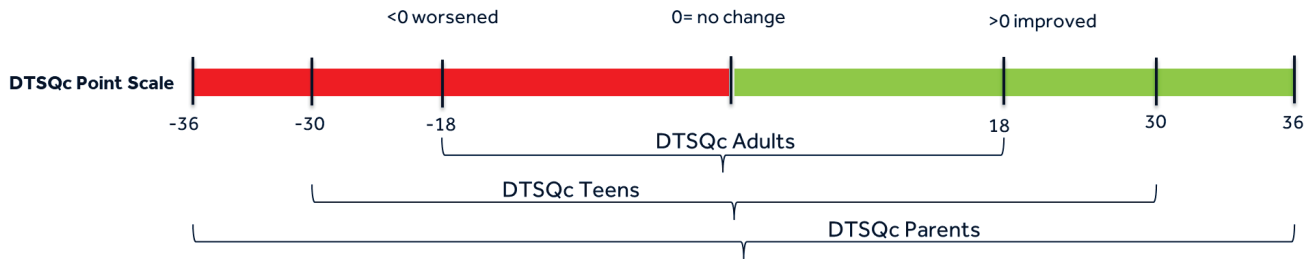
The DTSQc has six items related to treatment satisfaction and two other items assess perceived frequency of hyperglycaemia and hypoglycaemia. Each item has a maximum of 3 (more satisfied now) and a minimum of -3 (less satisfied now) with a midpoint of 0 reflecting no change. The scale total is computed by adding all items excluding two items (2,3) on hypo/hyperglycemia which will be analyzed separately. The scale total will be reported using summary statistics for each population. All values greater than 0 will be defined as an improvement. Although this endpoint was not powered for testing, the DTSQc will be also analyzed by means of one sample Z-score test or Wilcoxon signed rank sum test according to the normal or non-normal distribution.

The scoring system for the scale total by population is the following:

DTSQc Adults: 8 items (-3/3 scores). The scale total is computed by adding 6 items (excluding two items (2,3) on hypo/hyperglycemia that must be analyzed separately), to produce the Treatment Satisfaction score which has a minimum of -18 and 18.

DTSQc Teen: 12 items (-3/3 scores). The total score is computed by adding the 10 items (2 items on hypo/hyperglycemia must be analyzed separately) to produce the Treatment Satisfaction score, which has a minimum of -30 and 30.

DTSQc Parent: 14 items (-3/3 scores). The total score is computed by adding the 12 items (2 items on hypo/hyperglycemia must be analyzed separately) to produce the Treatment Satisfaction score, which has a minimum of -36 and 36.



7.9.5. Quality of life based on DQoL

The objective is to evaluate the change from baseline in quality of life based on the DQoL evaluated at 6 and 12 months. The DQoL total scores will be calculated as the average across the four dimensions (satisfaction, impact, worries about future effects, worries about social effect). The DQoL questionnaire will be used and the mean scores will be compared between baseline and 6 and 12 months.

The different DQoL versions will be used to assess quality of life in the following populations:

- DQoL Adult (≥18 years old)
- DQoL Adult with Adolescent-oriented items (13-17 years old)
- No DQoL version and therefore no collection for patients 7-12 years old

The instrument has 49/46 core items forming four 5-point Likert scale according to the population:

- Satisfaction with treatment (18 items for adult with adolescent-oriented items and 15 for adult)
- Impact of treatment (20 items)
- Worries about future effects of diabetes (4 items)
- Worries about social and vocational issues (7 items)

The instrument also includes 1 generic health item that does not contribute to the scales.

Change from baseline in the DQoL total score will be analyzed at 6 months and at 12 months by means of paired (samples) t-test or Wilcoxon signed rank sum test according to the normal or non-normal distribution. In addition, the mean change will be displayed together with their 95% confidence interval (95%CI).

7.9.6. Fear of hypoglycemic events based on the Hypoglycemia Fear Survey (HFS)

The objective is to evaluate the change from baseline in the fear of hypoglycemic events based on the HFS evaluated at 6 and 12 months over the Study phase. The HFS questionnaire will be used and the mean scores will be compared between baseline and 6 and 12 months. The different HFS versions will be used to assess the fear of hypoglycemic events in the following populations:

- HFS Adult (≥18 years old)
- HFS Teen (13-17 years old)
- HFS Parent (7-12 years old)

The HFS Adult has 33 items for, 15 of them related to behavior and 18 related to worry.

The HFS Teen has 25 items for, 10 of them related to behavior and 15 related to worry.

The HFS Parent has 26 items for, 11 of them related to behavior and 15 related to worry.

All the items with scores: Never, Rarely, Sometimes, Often, Almost Always.

The total score per subject will be calculated as the sum of all item's scores and the average of the total score will be used for the comparison. The HFS total score will be analyzed by means of paired (samples) t-test or Wilcoxon signed rank sum test according to the normal or non-normal distribution. In addition, the mean change will be displayed together with their 95% confidence interval (95%CI).

7.9.7. Glycemic parameters

The objective is to evaluate the change in glycemic parameters at baseline and every three months until 12 months. The time of sensor glucose values below 70mg/dL and below 54mg/dL and the time of sensor glucose value above 180mg/dL and above 250mg/dL will be analyzed by means of GEE (generalized estimating equation) models or random effects models with random intercept as appropriate, for continuous outcomes to account for repeated measures using patient ID as the subject. The dependent variable will be pre-log transformed depending on normal or non-normal distribution. The model will have the glycemic parameter as dependent variable and baseline values and visits as explanatory variables. All assumptions for regression models will be assessed by viewing plots of the residual values. The plot for the mean change over time will be reported for the glycemic parameters and for graphical purpose only separately by population as deemed appropriate.

The HbA1c will be analyzed at 6 months and at 12 months by means of paired (samples) t-test or Wilcoxon signed rank sum test according to the normal or non-normal distribution. In addition, the mean change from baseline to 6 and 12 months, respectively, will be displayed together with their 95% confidence interval (95%CI).

7.9.8. Satisfaction score on the DTSQs

The objective is to evaluate the treatment satisfaction score on the DTSQs evaluated at baseline, 6 and 12 months after the start of the Study phase. The different DTSQs versions will be used to assess satisfaction in the following populations:

- DTSQs Adult (≥18 years old)
- DTSQs Teen (13-17 years old)
- DTSQs Parent (7-12 years old)

The DTSQs total score will be analyzed by means of paired (samples) t-test or Wilcoxon signed rank sum test according to the normal or non-normal distribution. In addition, the mean change will be displayed together with their 95% confidence interval (95%CI).

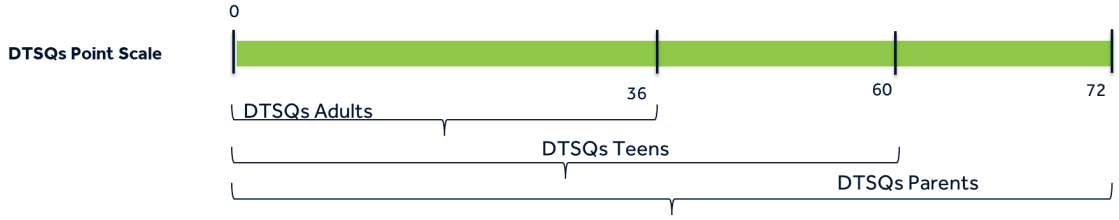
The DTSQs has six items related to treatment satisfaction and two other items assess perceived frequency of hyperglycaemia and hypoglycaemia. Each item has a maximum of 6 (satisfied) and a minimum of 0 (not satisfied). The scale total is computed by adding 6 items (1,4,5,6,7,8) and the 2 items on hypo/hyperglycemia will be analyzed separately. The scale total will be reported by summary statistics overall and by population.

The scoring system for the scale total by population is the following:

DTSQs Adults: 8 items (0-6 scores). The scale total is computed by adding 6 items* (2 items on hypo/hyperglycemia must be analyzed separately), to produce the Treatment Satisfaction score which has a minimum of 0 to a maximum 36.

DTSQs Teen: 12 items (0-6 scores). The scale total is computed by adding 10 items (2 items on hypo/hyperglycemia must be analyzed separately), to produce the Treatment Satisfaction score which has a minimum of 0 and maximum of 60.

DTSQs Parent: 14 items (0-6 scores). The scale total is computed by adding 12 items (2 items on hypo/hyperglycemia must be analyzed separately), to produce the Treatment Satisfaction score which has a minimum of 0 and maximum of 72.



7.10. Safety Evaluation

This is a non-interventional study assessing the glycemic control and Quality of Life of subjects with T1D. Complaint reporting will be done as per local requirements and Medtronic processes, including vigilance reporting for commercially approved products. The number of events of severe hypoglycaemia will be collected and reported by means of summary statistics.

7.11. Health Outcomes Analyses

There are no economic endpoints for this study.

7.12. Changes to Planned Analysis

The analysis described in the CIP could differ from that presented in this SAP due to data availability. Any deviation from the original statistical plan will be described and justified in the final report, as appropriate.

8. Validation Requirements

All collected data will be reviewed for completeness, correctness and consistency. In case of issues, queries will be sent to the investigator to complete, correct or comment the data. To ensure the quality of the results provided for the study in the form of tables, listings and figures, and the derived datasets the following processes are used:

- Statistical programming and analysis will be done by qualified programmer(s) and statistician(s) following applicable procedures and best practices.
- The derived datasets and tables will be validated by a second programmer or statistician.
- Statistical results will be reviewed and confirmed by a second statistician.

The complete set of Tables, Listings, and Figures (TLF) will be 100% checked for accuracy, completeness, and consistency prior to inclusion in the interim or final clinical study report. According to Medtronic SOPs the level I validation (double programming) will be implemented for primary and secondary endpoints, while level II validation (the peer reviewer reviews the code; where appropriate, performs manual calculations or simple programming checks to verify the output) will be implemented for all other outputs.

9. References

1. http://www.strobe-statement.org/index.php?id=available-checklists