STATISTICAL ANALYSIS PLAN

Protocol Title (Number):

Evaluation of the Fractyl Duodenal Remodeling System for the Treatment Type 2 Diabetes

(C-10000)

NCT# 01927562

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Evaluation of the Fractyl Duodenal Remodeling System
for the Treatment of Type 2 Diabetes
C-10000

Sponsor:
Fractyl Laboratories
17 Hartwell Ave.
Lexington, MA 02421

CRO:
Boston Biomedical Associates
100 Crowley Drive, Suite 216
Marlborough, MA 01752

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1 ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
BBA	Boston Biomedical Associates
BMI	Body Mass Index
CRF	Case Report Form
CSR	Clinical Study Report
DMC	Data Monitoring Committee
DMR	Fractyl Duodenal Remodeling System
FIH	First in Human
FPG	Fasting Plasma Glucose
HbA1c	Glycated Hemoglobin
ICF	Informed Consent Form
LS	Long segment duodenal ablation
mg/dL	Milligrams per Deciliter
MMTT	Mixed Meal Tolerance Test
PPG	Post-Prandial Glucose
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SS	Short segment duodenal ablation
T2D	Type 2 Diabetes
UADE	Unanticipated Adverse Device Effect

2 SUMMARY

TITLE	Evaluation of the Fractyl Duodenal Remodeling System for the Treatment of Type 2 Diabetes
PREFACE	This Statistical Analysis Plan (SAP) describes the planned analysis and reporting for Fractyl Laboratories protocol C-10000. This study is being completed to assess the safety and efficacy of Fractyl Duodenal Remodeling System (DMR) for the treatment of Type 2 Diabetes. The following documents were reviewed in preparation of this SAP: • Clinical Research Protocol C-10000, Version 1, Revision Date 05Dec2012 • Clinical Research Protocol C-10000, Version 2, Revision Date 30Sep2013 • Clinical Research Protocol C-10000, Version 3, Revision Date 02Jan2014 • Clinical Research Protocol C-10000, Version 4, Revision Date 06Aug2014 • Clinical Research Protocol C-10000, Version 5, Revision Date 16Oct2014 • Clinical Research Protocol C-10000, Version 6, Revision Date 9NOV2015 • Clinical Research Protocol C-10000, Version 7, Revision Date 10Mar2016
PURPOSE	The purpose of this SAP is to outline the planned analyses in support of the final Clinical Study Report (CSR) for protocol C-10000. Exploratory analyses not necessarily identified in this SAP may be performed to support the clinical development program. Any post-hoc, or unplanned, analyses not identified in this SAP will be clearly identified in the respective CSR.
STUDY OBJECTIVES	The primary objective is to investigate safety and effectiveness of DMR for the treatment of Type 2 Diabetes through 12 months, as well as long-term safety up to 36 months post procedure.t
STUDY DESIGN	This study is a first-in-human, uncontrolled open-label, study to evaluate safety and performance characteristics of the DMR and help define future development program.
ENDPOINTS	Based on the nature of this study (single arm non-controlled evaluation), a specific primary endpoint that defines subject and study success was not defined. In addition, the results will be used to further define the clinical procedures and participant populations that will best respond to the treatment with an optimum safety profile to ensure future success. The study's effectiveness endpoints are: • Reduction in HbA1c levels over the 12 month study period • Change from baseline in Mixed Meal Tolerance Test at 3 months • Reduction in Fasting Blood Glucose levels over the 12 month study period • Reduction in medications to control Type 2 Diabetes over the 12 month study period The study's **safety endpoints** are adverse events, vital signs, and safety laboratory tests and include: • Incidence of device and procedure related adverse events • Increase in pancreatic enzymes indicative of pancreatitis (amylase and lipase) • Incidence rate of significant and/or symptomatic hypoglycemic events

INTERIM ANALYSES	Two interim analyses were conducted: The first analysis was done with subjects (N=39) through 6 months. The second analysis (report C-10300), summarized the interim safety and efficacy results of 57 subjects enrolled in the C-10000 “First-in-Human” (FIH) protocol.
FINAL ANALYSES	All final planned analyses identified in this SAP will be completed after the last subject has completed their last follow up visit.

3 STUDY OBJECTIVES AND ENDPOINTS

3.1 STUDY OBJECTIVE

The primary objective is to investigate safety and effectiveness of DMR for the treatment of Type 2 Diabetes through 12 months, as well as long-term safety up to 36 months post procedure. Note: Protocol V7.0 reduced the follow up from 36 months to 24 months, however some patients had completed through 36-month follow up prior to the approval of Protocol V7.0. Safety assessments include adverse events, hypoglycemia, safety lab including pancreatic enzymes, BP; effectiveness assessments include HbA1c, FPG, MMTT, weight, reduction in medications.

3.2 STUDY ENDPOINTS

Efficacy Endpoints:

1. Reduction in HbA1c levels over the 12 month study period
2. Improvement in Mixed Meal Tolerance Test between baseline and 3 months
3. Reduction in Fasting Blood Glucose levels over the 12 month study period
4. Reduction in medications to control Type 2 Diabetes over the 12 month study period

Screening values are the only pre-treatment values collected for all lab parameters and will be used as the baseline measurement.

Safety Endpoints are adverse events, vital signs, and safety laboratory tests and include:

1. Incidence of device and procedure related adverse events
2. Increase in pancreatic enzymes indicative of pancreatitis (amylase and lipase)
3. Incidence rate of significant and/or symptomatic hypoglycemic events

4 SAMPLE SIZE

Between 40 to 60 subjects undergoing DMR is adequate to provide descriptive analyses on overall efficacy as well as potential predictors of efficacy and to establish an initial safety and efficacy profile.

5 SEQUENCE OF PLANNED ANALYSES

5.1 INTERIM ANALYSES

Two interim analyses were conducted: The first analysis was done with subjects (N=39) through 6 months [1]. The second analysis (report C-10300), summarized the interim safety and efficacy results of 57 subjects enrolled in the C-10000 “First-in-Human” (FIH) protocol.

5.2 FINAL ANALYSES AND REPORTING

All final, planned analyses identified in the protocol and in this SAP will be performed after the last subject has completed the 24 month follow up visit, following database lock. A complete study report based upon the analyses specified in the SAP will be issued.

6 Analysis Populations

6.1 Efficacy Population-As Treated Population (AT)

The primary efficacy population includes all subjects who underwent DMR. The population includes subjects who had long duodenal segment ablation (LS) or short segment ablation (SS). The LS cohort is defined as subjects who had at least three duodenal segments ablated. The SS cohort is defined as subjects with one or two duodenal segments ablated. Subjects were treated with a single catheter device or a dual catheter device, but analysis will not be performed by device type. All efficacy endpoint analyses will be performed for the total population, and for the HbA1c and HOMA-IR parameters by LS/SS.

6.2 Safety Population

The primary safety population includes all patients in whom use of the DMR was attempted, regardless of whether the procedure was successfully completed. Any subjects for whom the DMR could not be completed will be described. All safety analyses will be performed on the total population; adverse event incidence for the single and dual catheter device groups, in addition to the total population, will only be presented in the summary table of adverse events. The population of subjects that had retreatment will be analyzed/presented separately.

7 General Issues for Statistical Analysis

All statistical tests will be 2-sided at alpha level of 0.05 unless stated otherwise. No adjustment for multiple hypothesis testing will be made in this first in human (FIH) study. If there are multiple records within a data analysis interval, the last evaluation record will be used for numeric summary unless stated otherwise.

As illustrated in the Study Flowchart of the protocol, the visit date and time and the collection date and time of study endpoints are regularly scheduled. Baseline will be the specific pre-procedure value as specified in the protocol section 5.2.

7.1 Analysis Software

Analysis data sets, statistical analyses and associated output generated by Boston Biomedical Associates will be generated using Statistical Analysis Systems, SAS® Software version 9.4 or later (Statistical Analysis System, SAS®, release 9.4, SAS Institute, Incorporated, Cary, NC), R version 3.5.1 or later, or Excel 2016. Software will be run on a PC.

7.2 Disposition of Subjects and Withdrawals

Numbers of subjects who signed the informed consent form, who were screening failures, who underwent the DMR, completed the study and were withdrawn during the study will be summarized. Patients who underwent the DMR, the number of subjects that completed the procedure (SS and LS) will be presented as well as the number of patients who partially completed the procedure (SS and LS). The number and percent of subjects in each analysis population will be presented, with percentages based on all enrolled subjects. Subject disposition for the efficacy population (Completed or Early Termination) will be presented by LS/SS and single/dual catheter use. We will account for all subjects who provide written informed consent.

The number and percentage of subjects prematurely withdrawing will be presented overall and by reason of discontinuation.

7.3 Methods for Withdrawals, Missing Data, and Outliers

Efficacy analysis will be performed for observed cases, only. Due to the exploratory nature of the analysis, no imputation will be done for missing data.

7.4 Protocol Violations

Major protocol violations will be summarized in the CSR. This summary will include the overall number and percent of subjects with each violation type. Major violations in this study include protocol deviations which could affect subject safety or efficacy endpoint analysis and are related to:

- Severe violation of study inclusion or exclusion criteria (e.g., HbA1c >10.5%, current use of insulin or other injectable glucose-lowering therapy, BMI >40
- No informed consent
- Use of prohibited medications during study (corticosteroids, weight loss drugs)

7.5 Multiple Comparisons and Multiplicity

There will no adjustment for multiple comparisons in this study.

7.6 Assessment of Homogeneity

There will not be an assessment of homogeneity due to the descriptive nature of the analyses.

8 Demographics and Other Baseline Characteristics

8.1 Demographics and baseline characteristics

Demographics, Type 2 Diabetes (T2D) medical history and baseline values of important variables will be summarized. For continuous variables such as age, height, weight, BMI, BP, HbA1c, FPG, lipid panel, duration of diabetes, OAD use (metformin/sulphonylurea) the descriptive statistics include n, mean, median, standard deviation, minimum, and maximum. For dichotomous variables such as sex, the descriptive statistics include the count in each category, the total n, and the percentage. For percentages, the denominator is the total number of subjects in each treatment group and the numerator is the count in each category. The summaries will be performed for the safety population.

9 Efficacy Analyses

Efficacy analyses will be performed for the total efficacy population. For HbA1c, analyses at 6 months will also be analyzed on the LS/SS sub-populations. A mixed model with repeated measures (MMRM) will be used to analyze change from baseline when more than two post-baseline measures are assessed. The baseline value will be included as a covariate in the model. All efficacy data will be displayed as baseline and change from baseline.

9.1 Primary Efficacy Analysis in LS/Baseline < 10% HbA1c sub-population

Two primary efficacy analyses will be performed. First, DMR effect size will be assessed by analyzing the change in HbA1c from baseline to month 6 for the patients in the LS sub-population with a baseline HbA1c < 10% (the DMR Effect Size sub-population), as this is the patient group that will be studied in future studies. A mixed model with repeated measures (MMRM) will be used to analyze change from baseline. The percentage of patients in the DMR Effect Size sub-population that experienced a decrease in HbA1c at 6 months from baseline will also be summarized.

Second, DMR durability will be assessed in the group of subjects of the DMR Effect Size sub-population who experienced any decrease in HbA1c levels at 6 months (from baseline). In this sub-population, the change in HbA1c at 12 months from baseline will be summarized, and the number and percentage of subjects in this sub-population who experienced any decrease from baseline at month 12 will be summarized.

9.2 CHANGE IN HBA1C (%)

HbA1c will be summarized at baseline, month 1, month 3, month 6, month 9 and month 12 for the total population, and at months 3, 6 and 12 for the LS/SS and single/dual catheter sub-populations using mean, standard deviation and 95% CI. Change from baseline will be summarized at each post-baseline time point. A mixed model with repeated measures (MMRM) will be used to analyze change from baseline.

9.3 MIXED MEAL TOLERANCE TEST

MMTT will be summarized at baseline and month 3 using mean, standard deviation and 95% CI. The measures summarized include FPG, fasting plasma insulin (FPI), postprandial plasma glucose (PPG) at 120 minutes, area under the curve (AUC) for meal challenge plasma glucose from 0 to 120 minutes, delta AUC PPG (increment above FPG) from 0 to 120 minutes, and delta AUC post-prandial plasma insulin (increment above FPI) from 0 to 60 minutes. Area under the curve will be calculated using the trapezoidal rule. Change from baseline to month 3 will be summarized.

9.4 CHANGE IN FASTING PLASMA GLUCOSE (MG/DL)

FPG will be summarized at each time point that it is collected (baseline, month 1, month 3, month 6, month 9 and month 12) using mean, standard deviation and 95% CI. Change from baseline will be summarized at each post-baseline time point. A mixed model with repeated measures (MMRM) will be used to analyze change from baseline.

9.5 CHANGE IN ANTI-DIABETIC MEDICATIONS

The number and percent of subjects with an increase, stable, or reduction in glycemic medications over the 12-month study period will be summarized in a table. The number and percent of subjects with a change in glycemic medications from baseline to month 3, from month 3-6, and from month 6-12 will be summarized in a table. A specific listing will be provided for subjects that discontinued or reduced diabetes medication.

9.6 CHANGE IN HOMA-IR

HOMA-IR will be summarized at each time point (baseline, month 1, month 3, month 6, month 9 and month 12). Change from baseline will be summarized at each post-baseline time point.

9.7 CHANGE IN ALT, AST, AND FIB-4

AST and ALT will be summarized at each time point (baseline, month 1, month 3, month 6, month 9 and month 12) in subjects with elevated ALT and AST at baseline. FIB-4 will be summarized at each time point (baseline, month 1, month 3, month 6, month 9 and month 12). Change from baseline will be summarized at each post-baseline time point for AST, ALT and FIB-4. The presentation of data will include each parameter (AST, ALT, and FIB-4) in tertile groupings based on the baseline value.

9.8 CHANGE IN FASTING PLASMA INSULIN

FPI will be summarized at each time point that it is collected (baseline, month 1, month 3, month 6, month 9 and month 12) using mean, standard deviation and 95% CI. Change from baseline will be summarized at each post-baseline time point.

9.9 Change in Body Weight

Body weight (kg) will be summarized at each time point that it is collected (baseline, month 1, month 3, month 6, month 9 and month 12) using mean, standard deviation and 95% CI. Change from baseline will be summarized at each post-baseline time point.

10 Safety Analyses

Safety analyses will be performed for the safety population. All adverse event data will be tabulated by incidence and events overall and by severity (mild, moderate, severe) and relationship to device or procedure, including overall treatment-emergent adverse events, serious adverse events, deaths, unanticipated adverse device effects, and adverse events leading to study withdrawal. The safety summary table (total incidence/number of events for all AEs, TEAEs, SAEs, Deaths, UADEs, and TEAEs leading to study withdrawal) will present safety for the full safety population, as well as for LS/SS and single/dual catheter sub-populations. All other safety analyses will be presented only for the total safety population.

10.1 Adverse Events

The incidence of all adverse events (AEs) and post-DMR (treatment-emergent AEs [TEAEs] will be summarized. TEAEs will be analyzed as discussed in Section 11 below. Hypoglycemia events captured as adverse events will be recorded.

10.2 Safety Labs

Safety lab values (Hemoglobin, hematocrit, white blood cell count, BUN, calcium, chloride, creatinine, potassium sodium, total bilirubin, alkaline phosphatase, amylase, lipase, total cholesterol, HDL, LDL, triglycerides) will be presented in a table by n, mean, SD, median, min, max for pre-DMR baseline, 3 month, 6 month and last on-study value.

10.3 Other safety parameters

Descriptive statistics for BP and weight will be completed.

11 Adverse Events

Treatment-emergent adverse events (TEAEs), serious adverse events (SAEs), deaths, unanticipated adverse device effects (UADEs), and TEAEs leading to study participation discontinuation will be summarized for the safety population by incidence and events. The severity of each TEAE and relatedness of each TEAE to the device or procedure will be tabulated. TEAE data will be presented through 6 months, > 6 months, and total in the summary safety table, and through 6 months and >6 months in all the SOC by PT tables.

11.1 Summary of Adverse events

A summary of all AEs, TEAEs, TEAEs related to procedure/device, SAEs, SAEs related to procedure/device, TEAEs leading to study participation discontinuation, TEAEs resulting in death will be presented for total population, and for LS/SS and by single/dual catheter device sub-populations. A summary table with incidence of all AEs, TEAEs, Related TEAEs, SAEs, Related SAEs, AEs leading to withdrawal, UADEs, and Deaths will be presented for total population.

11.2 All Treatment-emergent Adverse Events

Summaries of incidence rates and total number of events of individual treatment emergent (TEAEs) by System Organ Class (SOC) and Preferred Term (PT) will be prepared. Because a subject may experience more than one AE, summaries will provide both the number of subjects experiencing at least one event and the number of

events within a reporting period. Percentages provided will be the percent of subjects experiencing one or more adverse events. In addition, incidence of TEAEs will be presented by severity (mild moderate, severe) and by relationship to investigational device or procedure. Subjects experiencing an event within a given PT and SOC more than once will be counted under the maximum severity/relationship experienced.

A listing of all TEAE will include the subject number, TEAE number, days since index procedure, the TEAE SOC and PT, the severity of TEAE, whether the TEAE is classified as serious (SAE), the relationship of the TEAE to the investigational device or procedure, the action taken, the outcome, frequency, and if primary reason for study participation discontinuation.

11.3 Serious Adverse Events

Summaries of incidence and event rates and relationship to the investigational device/procedure of individual SAEs by SOC and PT will be prepared.

11.4 UADE

Summaries of incidence and event rates and relationship to the investigational device/procedure of individual UADEs by SOC and PT will be prepared.

11.5 Adverse Events Leading to Withdrawal

A summary of incidence rates (frequencies and percentages) and relationship to the investigational device/procedure of AEs leading to study withdrawal, by SOC and PT will be prepared for the safety population.

11.6 Deaths

Should any subjects die during the trial, relevant information, including a full patient profile, will be supplied in a data listing.

12 Other Planned Analyses

12.1 Planned Subgroup Analyses

Additional populations include:

- dichotomizing subjects by the linear length of the DMR ablation (i.e., SS vs LS), which will be used to analyze HbA1c and HOMA-IR values over time to demonstrate a dose-response relationship
- baseline HbA1c will be used as a stratification variable (< 10% or >= 10%), which will be used to analyze HbA1c over time
    - the stratified groups will also be displayed with or without oral glucose lowering medication changes in the first 6 months (significant diabetic medication changes will be defined prior to performing the analysis)

13 References

[1] H. Rajagopalan, A. Cherrington, C. Thompson and et al., "Endoscopic Duodenal Mucosal Resurfacing for the Treatment of Type 2 Diabetes: 6-Month Interim Analysis From the First-in-Human Proof-of-Concept Study.," *Diabetes Care,* pp. 39(12):2254-2261, 2016.

14 APPENDIX A: TABLE SHELLS

Table 1. Patient disposition

Table 1a Patient Disposition	
Underwent DMR	N
Completed 12 months of follow-up	% (n/N)
Early Termination	% (n/N)
Reason for Early Termination	
Lost to Follow-Up	% (n/N)
Adverse Event	% (n/N)
Protocol Deviation	% (n/N)
Death	% (n/N)
Other	% (n/N)

Table 1b Duration of Safety Follow-up	
Attempted DMR	N
Completed up to 3 months follow-up	% (n/N)
Completed 3 up to 6 months follow-up	% (n/N)
Completed 6 up to 9 months follow-up	% (n/N)
Completed 9 up to 12 months follow-up	% (n/N)
Completed 12 up to 24 months follow-up	% (n/N)
Completed 24 up to 36 months follow-up	% (n/N)

Table 2. Protocol deviations

Table 2 Protocol Deviations		
	N=XXX	
Category [1]	Number of Deviations [N]	Number of Subjects with Deviation [% (n/N)]
ICF	XX	% (n/N)
Inc/Exc	XX	% (n/N)
…	XX	% (n/N)
	XX	% (n/N)
	XX	% (n/N)
[1] The sponsor granted waivers for protocol deviations in the following categories: Inc/Exc (X), …		

Table 3. Demographic data, data at baseline and medication details

Table 3 Subject Demographics	
Parameter	N=XXX
Age (years)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
Sex [% (n/N)]	
Male	% (n/N)
Female	% (n/N)
Height (cm)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
Weight (kg)	
N	XX
Mean +/-SD	XXX.X +/- XXX.X
Median (Min, Max)	XXX.X (XXX.X, XXX.X)
BMI (kg/m^2)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
Systolic Blood Pressure (mmHg)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
Diastolic Blood Pressure (mmHg)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
Duration of T2D (years)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
HbA1c (%)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
Fasting Plasma Glucose (mg/dL)	
N	XX
Mean +/-SD	XX.X +/- XX.X

Table 3 Subject Demographics	
Median (Min, Max)	XX.X (XX.X, XX.X)
Total Cholesterol (mg/dL)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
LDL-C (mg/dL)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
HDL-C (mg/dL)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
Triglycerides (mg/dL)	
N	XX
Mean +/-SD	XX.X +/- XX.X
Median (Min, Max)	XX.X (XX.X, XX.X)
Oral anti-diabetic medications [% (n/N)]	
Metformin	% (n/N)
Sulfonylurea	% (n/N)

Table 4. Efficacy tables

Table 4 Efficacy Endpoint – HbA1c to 6 months		
	Baseline	Month 6
HbA1c % - Full population	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)
HbA1c % - Short segment	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)
HbA1c % - Long segment	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)
[1] Change from Baseline analyzed using mixed model with repeated measures (MMRM).		

Table 4a Efficacy Endpoint – HbA1c for Full Population						
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
HbA1c %	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
[1] Change from Baseline analyzed using mixed model with repeated measures (MMRM).						

Table 4b Efficacy Endpoint – HbA1c by Short Segment (SS) Long Segment (LS) ablation				
	Baseline	Month 3	Month 6	Month 12
HbA1c %	N=	N=	N=	N=
Short Segment				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
Long Segment				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
[1] Change from Baseline analyzed using mixed model with repeated measures (MMRM).				

Table 4c Number and percentage of 6-month improvers that maintained improvement in HbA1c levels at 12 months			
	Short Segment (SS) N=XXX	Long Segment (LS) N=XXX	Full Population N=XXX
Maintained Improvement (Reduction) in HbA1c levels at 12 months among 6-month improvers	% (n/N)	% (n/N)	% (n/N)

Table 4d Efficacy Endpoint – Change in HbA1c among 6-month improvers that maintained improvement in HbA1c levels at 12 months				
	Baseline	Month 3	Month 6	Month 12
HbA1c % - Full Population	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
HbA1c % - Short Segment	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
HbA1c % - Long Segment	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
[1] Change from Baseline analyzed using mixed model with repeated measures (MMRM)				

Table 4e Efficacy Endpoint – Fasting Plasma Glucose						
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
	N=	N=	N=	N=	N=	N=
Fasting Plasma Glucose (mg/dL)						
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
[1] Change from Baseline analyzed using mixed model with repeated measures (MMRM)						

Table 4f Efficacy Endpoint – Anti-Diabetic Medication			
	Month 3	Month 6	Month 12
Change from Baseline	N=	N=	N=
Increased Dosage of Glycemic Medication [% (n/N)]	% (n/N)	% (n/N)	% (n/N)
Unchanged Dosage of Glycemic Medication [% (n/N)]	% (n/N)	% (n/N)	% (n/N)
Reduced Dosage of Glycemic Medication [% (n/N)]	% (n/N)	% (n/N)	% (n/N)
Change from Month 3		N=	N=
Increased Dosage of Glycemic Medication [% (n/N)]		% (n/N)	% (n/N)
Unchanged Dosage of Glycemic Medication [% (n/N)]		% (n/N)	% (n/N)
Reduced Dosage of Glycemic Medication [% (n/N)]		% (n/N)	% (n/N)
Change from Month 6			N=
Increased Dosage of Glycemic Medication [% (n/N)]			% (n/N)
Unchanged Dosage of Glycemic Medication [% (n/N)]			% (n/N)
Reduced Dosage of Glycemic Medication [% (n/N)]			% (n/N)

Table 4g Efficacy Endpoint – Endpoints with MMTT		
	Baseline	Month 3
Endpoint	N=	N=
Fasting Plasma Glucose (FPG, mg/dL) with MMTT		
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X
95% CI		(XX.X, XX.X)
Postprandial Plasma Glucose (PPG, mg/dL) at 120 minutes		
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X
95% CI		(XX.X, XX.X)
Area Under the Curve (AUC) [1] for Meal Challenge Plasma Glucose from 0 to 120 Minutes		
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X
95% CI		(XX.X, XX.X)
Delta AUC [1] PPG (increment above FPG) from 0 to 120 minutes		
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X
95% CI		(XX.X, XX.X)
Fasting Plasma Insulin (FPI, milliunits/L) with MMTT		
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X
95% CI		(XX.X, XX.X)
Delta AUC [1] Postprandial Plasma Insulin (increment above FPI) from 0 to 60 minutes		
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X
95% CI		(XX.X, XX.X)
[1] AUC calculated using the trapezoidal rule		

Table 4h Change in HOMA-IR						
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
HOMA-IR - Full population	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
HOMA-IR - Short Segment	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
HOMA-IR - Long Segment	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)

Table 4i Change in ALT						
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
ALT (U/L)	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
ALT (U/L) – upper tertile	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
ALT (U/L) – middle tertile	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
ALT (U/L) – lower tertile	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)

Table 4j Change in AST						
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
AST (U/L)	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
AST (U/L) – upper tertile	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
AST (U/L) – middle tertile	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
AST (U/L) – lower tertile	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)

Table 4k Change in FIB-4						
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
FIB-4	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
FIB-4 – upper tertile	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
FIB-4 – middle tertile	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
FIB-4 – lower tertile	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)

Table 4l Fasting Plasma Insulin						
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
Fasting Plasma Insulin (milliunits/L)	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline		XX.X	XX.X	XX.X	XX.X	XX.X
95% CI		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)

Table 4m Body Weight							
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12	Last Available
Weight (kg)	N=	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)

Table 5. Subgroup Analyses

Table 5a Efficacy Endpoint – HbA1c for subjects with baseline HbA1c <10%						
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
HbA1c %	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
HbA1c % [Subjects with medication change]	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
HbA1c % [Subjects without medication change]	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
[1] Change from Baseline analyzed using mixed model with repeated measures (MMRM).						

Table 5b Efficacy Endpoint – HbA1c for subjects with baseline HbA1c >/=10%						
	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
HbA1c %	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
HbA1c % [Subjects with medication change]	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
HbA1c % [Subjects without medication change]	N=	N=	N=	N=	N=	N=
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change from Baseline (SE) [1]		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
95% CI [1]		(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
[1] Change from Baseline analyzed using mixed model with repeated measures (MMRM).						

Table 6. Safety Endpoints

Table 6a Safety Endpoints – Safety Labs				
	Baseline	Month 3	Month 6	Last Available
	N=	N=	N=	N=
Hemoglobin (g/dL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Hematocrit (%)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
WBC (cells/µL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
BUN (mg/dL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Calcium (mg/dL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Chloride (mEq/L)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Creatinine(mg/dL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Potassium (mEq/L)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Sodium (mEq/L)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Total Bilirubin (mg/dL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Alkaline Phosphatase (IU/L)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Amylase (units)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)

Table 6a Safety Endpoints – Safety Labs				
	Baseline	Month 3	Month 6	Last Available
	N=	N=	N=	N=
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Lipase (units)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Total Cholesterol (mg/dL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
HDL (mg/dL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
LDL (mg/dL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Triglycerides (mg/dL)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)

Table 6b Safety Endpoints – Vital Signs			
	Baseline	Month 6	Last Available
	N=	N=	N=
Systolic Blood Pressure (mmHg)			
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Diastolic Blood Pressure (mmHg)			
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)

Table 7. Adverse events data

Table 7.1a Full Population Summary of All Adverse Events						
	Through 6 Months		>6 Months		Total	
	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event
Any Adverse Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Treatment Emergent Adverse Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Serious Adverse Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Unanticipated Adverse Device Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Treatment Emergent Adverse Event Leading to Study Discontinuation	X	% (n/N)	X	% (n/N)	X	% (n/N)
Deaths	X	% (n/N)	X	% (n/N)	X	% (n/N)

Table 7.1b Single Catheter Summary of All Adverse Events						
	Through 6 Months		>6 Months		Total	
[1]	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event
Any Adverse Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Treatment Emergent Adverse Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Serious Adverse Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Unanticipated Adverse Device Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Treatment Emergent Adverse Event Leading to Study Discontinuation	X	% (n/N)	X	% (n/N)	X	% (n/N)
Deaths	X	% (n/N)	X	% (n/N)	X	% (n/N)
[1] As adjudicated or as site-reported if not yet adjudicated.						

Table 7.1c Dual Catheter Summary of All Adverse Events						
	Through 6 Months		>6 Months		Total	
	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event
Any Adverse Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Treatment Emergent Adverse Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Serious Adverse Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Unanticipated Adverse Device Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Investigational Device Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Study Procedure Related Event	X	% (n/N)	X	% (n/N)	X	% (n/N)
Not related to Procedure or Device	X	% (n/N)	X	% (n/N)	X	% (n/N)
Any Treatment Emergent Adverse Event Leading to Study Discontinuation	X	% (n/N)	X	% (n/N)	X	% (n/N)
Deaths	X	% (n/N)	X	% (n/N)	X	% (n/N)
[1] As adjudicated or as site-reported if not yet adjudicated.						

Table 7.2a Full Population Summary of Device or Procedure Related TEAEs		
Interval	# of Evts	% (n/N) of Pts w/Event
0-30 days from procedure	X	% (n/N)
Possibly Related	X	% (n/N)
Probably Related	X	% (n/N)
Definitely Related	X	% (n/N)
31-60 days from procedure	X	% (n/N)
Possibly Related	X	% (n/N)
Probably Related	X	% (n/N)
Definitely Related	X	% (n/N)
61-90 days from procedure	X	% (n/N)
Possibly Related	X	% (n/N)
Probably Related	X	% (n/N)
Definitely Related	X	% (n/N)

Table 7.3a Summary of All TEAEs				
	Through 6 Months		>6 Months	
	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event
All TEAEs	X	% (n/N)	X	% (n/N)
SOC 1	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)
SOC 2	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)

Table 7.3b Summary of TEAEs Related to Device or Procedure								
	Through 6 Months				>6 Months			
	Procedure Related		Device Related		Procedure Related		Device Related	
	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event
All TEAEs	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
SOC 1	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
SOC 2	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)

Table 7.3c Summary of TEAEs by Severity												
	Through 6 Months						>6 Months					
	Mild		Moderate		Severe		Mild		Moderate		Severe	
	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event
All TEAEs	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
SOC 1	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
SOC 2	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)

Table 7.4 Summary of All Serious TEAEs												
	Through 6 Months						>6 Months					
	All Events		Procedure Related		Device Related		All Events		Procedure Related		Device Related	
	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event
Serious TEAEs	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
SOC 1	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
SOC 2	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)	X	% (n/N)

Table 7.5 Summary of All UADEs				
	Through 6 Months		>6 Months	
	# of Evts	% (n/N) of Pts w/Event	# of Evts	% (n/N) of Pts w/Event
All UADEs	X	% (n/N)	X	% (n/N)
SOC 1	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)
SOC 2	X	% (n/N)	X	% (n/N)
PT1	X	% (n/N)	X	% (n/N)
PT2	X	% (n/N)	X	% (n/N)
…	X	% (n/N)	X	% (n/N)

Table 8. DMR procedure summary

Table 8 DMR Procedure Summary				
	Single Catheter SS N=XXX	Single Catheter LS N=XXX	Dual Catheter SS N=XXX	Dual Catheter LS N=XXX
Length of Ablated Duodenum (units)				
Mean +/-SD (N)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)	XX.X +/- XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)

15 APPENDIX B: DATA LISTING SHELLS

Listing 1. Patient Disposition

Listing 1 Patient Disposition						
Site	Subject ID	Date of Procedure	Date of Study Completion	Date of Study Withdrawal	Reason for Early Withdrawal	Date of Death
Site 1	Subj 1	DATE	DATE	DATE	TEXT	DATE
Site 1	Subj 2	DATE	DATE	DATE	TEXT	DATE
…	…	DATE	DATE	DATE	TEXT	DATE
Site X	Subj X	DATE	DATE	DATE	TEXT	DATE
…	…	DATE	DATE	DATE	TEXT	DATE

Listing 2. Demographic and baseline characteristics

Listing 2 Demographic and Baseline Characteristics									
Site	Subject ID	Age (years)	Sex	Height (cm)	BMI (kg/m^2)	Systolic BP (mmHg)	Diastolic BP (mmHg)	Duration of T2D (years)	HbA1c (%)
Site 1	Subj 1	XX	TEXT	XXX.X	XX.X	XXX	XXX	XX	XX.X
Site 1	Subj 2	XX	TEXT	XXX.X	XX.X	XXX	XXX	XX	XX.X
…	…	XX	TEXT	XXX.X	XX.X	XXX	XXX	XX	XX.X
Site X	Subj X	XX	TEXT	XXX.X	XX.X	XXX	XXX	XX	XX.X
…	…	XX	TEXT	XXX.X	XX.X	XXX	XXX	XX	XX.X

Listing 3. Adverse Events

Listing 4 Adverse Events													
Site	Subject ID	SOC	PT	Severity	Onset Date	Resolution Date	Continuing	Action Taken	Relationship to Device or Procedure	TEAE	Serious	UADE	Lead to Study Withdrawal
Site 1	Subj 1	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N	Y/N
Site 1	Subj 2	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N	Y/N
…	…	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N	Y/N
Site X	Subj X	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N	Y/N
…	…	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N	Y/N

Listing 4. Serious Adverse Events

Listing 5 Serious Adverse Events										
Site	Subject ID	SOC	PT	Severity	Onset Date	Resolution Date	Continuing	Action Taken	Relationship to Device or Procedure	Lead to Study Withdrawal
Site 1	Subj 1	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N
Site 1	Subj 2	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N
…	…	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N
Site X	Subj X	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N
…	…	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N

Listing 5. Adverse events leading to study discontinuation

Listing 6 Adverse Events Leading to Study Discontinuation												
Site	Subject ID	SOC	PT	Severity	Onset Date	Resolution Date	Continuing	Action Taken	Relationship to Device or Procedure	TEAE	Serious	UADE
Site 1	Subj 1	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N
Site 1	Subj 2	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N
…	…	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N
Site X	Subj X	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N
…	…	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N	Y/N

Listing 6. Adverse Events with a fatal outcome

Listing 7 Adverse Events with a Fatal Outcome											
Site	Subject ID	SOC	PT	Severity	Onset Date	Resolution Date	Continuing	Action Taken	Relationship to Device or Procedure	TEAE	UADE
Site 1	Subj 1	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N
Site 1	Subj 2	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N
…	…	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N
Site X	Subj X	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N
…	…	TEXT	TEXT	TEXT	DATE	DATE	Y/N	TEXT	TEXT	Y/N	Y/N

16 APPENDIX C: PLANNED FIGURES

1) HbA1c over time for Baseline, 1 month, 3 month, 6 month, 9 month, and 12 month (a. Overall, b. By long vs. short segment ablation, c. By baseline value <10%, >/= 10%, d. By baseline value <10% and change in medications in first 6 months)
2) Bar chart of adverse events over time by time interval and relatedness