Statistical Analysis Plan (SAP)

A Prospective Multicenter, Open Label, Non-Randomized, Cross-Over Study Evaluating the Use of the Tablo™ Hemodialysis System In-Center and In-Home by Subjects with End Stage Renal Disease (ESRD) who are on Stable Dialysis Regimens

Study No: 2014-01

Version 3.0
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Revision History

Version 3.0

- Updated variables and analysis descriptions in Sections 3.0, 3.1, 3.2 (newly created for analysis of medical history), 4.1.2, 4.2.2, 4.2.3, 5.1, and 5.2 (newly created to more easily distinguish between safety variables and the subsequent analysis plans). These changes do not impact the primary effectiveness and safety variable definitions and analysis.
- Removed all references to the creation of data listings in the text.
- Modified the TLF list in Section 7.0 to align with analysis changes in the text. TLF list changes include: title modifications, new tables, removal of selected tables, removal of all listings, and renumbering of tables and listings).
- Appendix B: Updated per the changes in text and in Section 7.0.

Version 2.0

- Updated contacts on approval page.
- Revised the study design details to align with Protocol Amendment 7. These revisions were made to the following sections of the SAP:
    - Section 1.1: updated In-Center and In-Home descriptions.
    - Section 1.2: removed references to specific study days and defined treatment period durations using a fixed number of treatments, rather than a fixed number of weeks.
    - Section 1.3: added minor clarifications that assumptions require at least 8 weeks of treatment.
- Updated criteria for inclusion in the per protocol population in Section 2.2.
- Specified a higher SAS version in Section 2.6.

Version 1.1

- In Section 4.1.1, corrected the formula for urea distribution volume (V) so that it incorporates the subject's post-treatment weight, not the pre-treatment weight.

Table of Contents

1.0 Synopsis of Study Design Procedures

This study is a multi-center, prospective, open-label, non-randomized crossover clinical study evaluating the use of the Tablo™ Hemodialysis System In-Center and In-Home by subjects with end stage renal disease (ESRD) who are on stable dialysis regimens and are being adequately dialyzed. The study will be conducted at up to 20 study centers in the U.S. Subjects will be enrolled in the trial for approximately 21 weeks (Four periods – Run-in (In-Center), treatment period 1 (In-Center), In-Home transition and treatment period 2 (In-Home).

The objective of the study is to evaluate the Tablo Hemodialysis System when used In-Center by trained individuals and In-Home by trained subjects.

1.1 Design and Treatment

Subjects will be enrolled in the trial for approximately 21 weeks and will use the Tablo Hemodialysis System for their dialysis treatments according to the schedule outlined in four periods as follows:

- **Run-in, In-Center** – Subjects undergo study staff administered dialysis treatment 4 times/week for 1 week In-Center.

- **Treatment 1, In-Center** – Subjects undergo study staff administered dialysis treatment 4 times/week for 32 treatments (approximately 8 weeks) In-Center. Subjects are expected to undergo no more than 4 complete treatments per week during this treatment period.

- **In-Home Transition** – Subjects undergo device training for the study, perform self-care dialysis 4 times/week for approximately 4 weeks, and are assessed for stability in the new care environment.

- **Treatment 2, In-Home** – Subjects undergo self-care dialysis treatment 4 times/week for 32 treatments (approximately 8 weeks) In-Home. Subjects are expected to undergo no more than 4 complete treatments per week during this treatment period.

1.2 Study Procedures

Inclusion and exclusion criteria will be assessed prior to initiating the In-Center run-in period. Subjects with a diagnosis of ESRD who meet the inclusion and exclusion criteria will be eligible for participation in this study. The In-Center run-in period will take place for one week from Day -7 to Day -1.

Subjects who continue to meet the inclusion and exclusion criteria will enter the first treatment period, which consists of In-Center dialysis using the Tablo

Hemodialysis System. To be considered *enrolled* in the study, the subject must meet all inclusion and exclusion criteria and have started the first study treatment during treatment period 1. The first treatment period will start on Day 1 and continue until the subject completes 32 treatments (approximately 8 weeks, with 4 treatments/week).

Over the approximate four week In-Home transition period, investigational site personnel confirm the Subject or trained care partner is 1) stable in the new care environment, 2) has been appropriately trained on the set up and use of the Tablo Hemodialysis System, and 3) has satisfactorily completed the items of the patient skills assessment. The Subject or trained care partner will be responsible for device set up and initiating therapy under the supervision of study personnel In-Center during the first portion. The second portion of the transition period In-Home will be supervised at the discretion of the investigator.

Subjects or their trained care partner will administer dialysis therapy at home during treatment period 2 according to the investigator's instruction. This In-Home treatment period lasts a total of 32 treatments (approximately 8 weeks, with 4 treatments/week).

During each of the four periods described above, the following assessments will be performed:

- Every treatment: signs and symptoms, subject evaluation of the device, and adverse events.
- Weekly: concomitant medications and pre and post BUN sample collection,
- Monthly: Starting with the baseline evaluation, chemistry and hematology assessments will be performed approximately every four weeks. For analysis purposes, all laboratory results obtained during the baseline evaluation will be considered as the baseline measurements.

1.3 Sample Size

The sample size for the study is based on the primary effectiveness endpoint, weekly standardized Kt/V and the primary safety endpoint, the number of pre-specified, serious, device related, treatment emergent adverse events during a dialysis interval.

A hypothesis test that the treatment period mean weekly standardized Kt/V is statistically significantly greater than 2.1 will be carried out for both the In-Center and In-Home treatment periods. Given that the true treatment period mean Kt/V is 2.5 units, with one-sided α=0.025, a sample size of n=11 subjects, each measured weekly for at least 8 weeks of treatment, will have >90% power to detect that the mean is statistically significantly greater than 2.1 in the treatment period. This sample size calculation assumed a standard deviation of 0.7 units,

based on Sands et al (2009)[1], and a within patient correlation of Kt/V values of ρ=.50. The sample size calculation was based on an asymptotic normal theory one sample test using variance estimates that included covariance terms for repeated (weekly) measurements on each patient with a block diagonal first order autoregressive (AR(1)) covariance structure.

For the safety endpoint, the needed sample size yields an estimate of the rate of pre-specified adverse events per 100 dialysis treatments in each treatment period (In-Center and In-Home use), to a margin of error of less than 1 event per 100 treatments. With a two-sided α=0.05, in order to construct a 95% confidence interval on the rate of pre-specified adverse events per 100 dialysis treatments with half-width less than 1 event per 100 treatments, the sample size required would be n=30 subjects with 4 dialysis intervals per week for a minimum of 8 weeks (i.e., 30 subjects with a minimum of 32 treatments). The sample size calculation was based on an asymptotic normal theory one sample test using variance estimates that included covariance terms for repeated measurements (4 dialysis intervals per week for 8 weeks) on each patient with a block diagonal first order autoregressive (AR(1)) covariance structure. This sample size calculation assumed a standard deviation of 0.8 AEs per dialysis interval and a within patient correlation of pre-specified AE counts of ρ=.50.

Given the sample sizes necessary to satisfy the power requirements for the Kt/V endpoint and the composite safety endpoint, a sample size of n=30 subjects will be needed for the study.

2.0 Data Analysis Considerations

2.1 Types of Analyses

Data analyses will consist of analyzing safety and effectiveness data.

2.2 Analysis Populations

The following analysis populations will be used in the study:

Safety Population – The safety population will consist of all subjects who are enrolled in the study. All safety analyses will be conducted on the safety population.

Intent-to-Treat (ITT) Population – The ITT population will consist of all subjects who are enrolled in the study. The primary analysis set will be the ITT analysis set with no missing value imputation with a sensitivity analysis performed on the ITT with missing value imputation population.

Per-Protocol (PP) Population – The PP population will consist of all subjects who are enrolled in the study, have successfully completed at least 75% of their dialysis treatments, have at least one valid value of the primary effectiveness variable and have no major protocol deviations while enrolled in the study. A successfully completed dialysis treatment is defined as one completed as prescribed by the physician. A major protocol deviation is defined as any protocol deviation that affects the soundness of the data or a subject's rights. Subjects to be excluded from the PP analysis set, and the reasons for their exclusion, will be determined and documented prior to statistical analysis. These decisions will not be outcome-data driven.

The analysis of the primary efficacy endpoint will be conducted on ITT and PP populations.

2.2.1 Subgroup Definitions

There are no subgroup analyses planned for this study.

2.3 Missing Data Conventions

Subjects who did not finish the study but have accumulated partial data for the primary effectiveness endpoint, Kt/V, will have their missing data imputed. Missing data for Kt/V will be imputed by taking the average of the subject's non-missing Kt/V responses. The analysis of imputed data will be used as a sensitivity analysis relative to the primary effectiveness analysis that is conducted on non-imputed data.

For all other endpoints of the study, no missing value imputation will be used. That is, all analyses of endpoints other than the primary effectiveness endpoint will be based on the observed data (i.e., complete case analysis).

2.4 Interim Analyses

No interim analysis is planned for this study.

2.5 Study Center Considerations in the Data Analysis

A study center is defined as a treatment administration site or group of treatment administration sites under the control and supervision of the same Principal Investigator (PI). There will be no selective pooling of study centers.

2.6 Documentation and Other Considerations

The data analyses will be conducted using SAS© Software, version 9.4 or later.

3.0 Analysis of Baseline Characteristics and Disease History

3.1 Patient Characteristics and Demographics

Baseline and demographic characteristics will be summarized for all subjects in the safety population. Continuous variables (age, baseline height, baseline weight, and BMI) will be summarized via mean, standard deviation, median, range, and number of non-missing responses. Categorical variables (gender, race, and ethnicity) will be summarized via counts and percentages.

3.2 Medical History

The number and percentage of subjects reporting each medical history condition and each primary cause of end stage renal disease (ESRD) will be reported in a summary table for all subjects in the safety population.

4.0 Analysis of Effectiveness

4.1 Description of Effectiveness Variables

4.1.1 Description of Primary Effectiveness Variable

The primary effectiveness endpoint is the weekly standardized Kt/V for each subject during the In-Center and In-Home use periods of the study. The site will provide pre and post BUN values, which will be used to compute the single pool (Kt/V) and weekly standardized values (stdKt/V) for inclusion in the study database as follows[2,3]:

$$Kt/V = -\ln(\mathrm{R} - \mathrm{GFAC} * \mathrm{T\_hours}) + (4 - 3.5 * \mathrm{R}) * 0.55 * \mathrm{Weight\ loss/V}$$

$$stdKt/V = \frac{168*(1-\exp\{-Kt/V\})}{t} * \frac{1}{\frac{1-\exp\{-Kt/V\}}{Kt/V} + \frac{168}{N*t} - 1},$$

where

R = ratio of post-dialysis BUN to pre-dialysis BUN;
GFAC = 0.0090 (modification factor based on dialysis frequency of 4/week);
T_hours = dialysis session length, in hours;
V = urea distribution volume, calculated based on gender;
Weight loss = fluid removed as reported by Tablo;
N = number of treatments per week; and
t = treatment time in hours.

If subject is male, then V = 2.447 - (0.09156 x age) + (0.1074 x height) + (0.3362 x weight). If subject is female, then V = -2.097 + (0.1069 x height) + (0.2466 x weight). In both formulas for V, weight is the post-treatment weight as reported by Tablo.

If multiple lab values are drawn for a subject during a given week, then the lab values for BUN in the computation of R will be those from the date/draw on which the site is basing clinical care.

As described in Section 2.3 of this SAP, subjects who have missing data for the single treatment Kt/V values will have their data imputed for a sensitivity analysis of the primary effectiveness endpoint. All Kt/V values that are missing will be replaced in the above formula for stdKt/V by the average of the non-missing Kt/V values for that subject.

For the subgroup analysis of subjects who dialyze 3 times per week, the GFAC modification factor will be set to 0.0080.

4.1.2 Description of Secondary Effectiveness Variables

The secondary effectiveness variables for this study are the following:

- the ultrafiltration (UF) rate (actual and prescribed)
- the UF volume (actual and prescribed)
- treatment time (actual and prescribed)
- UF rate success

4.2 Analysis of Effectiveness Variables

4.2.1 Analysis of Primary Effectiveness Variable

The weekly standardized Kt/V values will be computed for each subject for the In-Center period and for the In-Home period. The following hypotheses will be tested at a one-sided α=0.025 level of significance:

$$\mathbf{H_{a0}}: \mu_{IC} \leq 2.1 \text{ vs. } H_{a1}: \mu_{IC} > 2.1$$

and

$$\mathbf{H_{b0}}: \mu_{IH} \leq 2.1 \text{ vs. } H_{b1}: \mu_{IH} > 2.1$$

where μ_{IC} is the treatment period mean weekly standardized Kt/V value for the In-Center arm and μ_{IH} is the treatment period mean weekly standardized Kt/V value for the In-Home arm. These hypotheses will be tested using the Least

Square Mean for the respective treatment period from a repeated measures analysis of variance (RMANOVA) containing terms for subject, treatment arm (i.e., In-Center treatment period and In-Home treatment period), and time points (weeks) and using an AR(1) covariance structure.

Summary statistics (mean, sample size, standard deviation, minimum, maximum, and median) will be computed on the weekly standardized Kt/V values for each treatment period.

All analyses of the primary effectiveness variable will be performed on the ITT population with no missing value imputation, the ITT population with missing value imputation, and the PP population. The ITT population with no missing value imputation is the primary analysis set.

4.2.2 Analysis of Secondary Effectiveness Variable

The UF rate, UF volume, and treatment time relative to the prescribed ultrafiltration settings will be calculated and reported via Tablo.

The mean and standard deviation of the actual and prescribed UF rate, UF volume, and treatment time will be computed by treatment period across all subjects, where the denominator for the mean calculations will be the total number of treatments in each treatment period for which the subjects contributed non-missing UF data.

Each treatment will be flagged as a success with respect to UF if the actual UF rate is within 10% of the prescribed UF rate. The mean (i.e., success proportion) and standard deviation will be computed by treatment period across all subjects, where the denominator for the mean calculations will be the total number of treatments in each treatment period for which the subjects contributed non-missing UF date.

All analyses of the secondary effectiveness variable will be performed on the ITT population with no missing value imputation and the PP population. The ITT population with no missing value imputation is the primary analysis set.

4.2.3 Other Analyses

Analyses described in this section will be performed on the ITT population with no missing value imputation.

Clinically Significant Alarms
The number and percentage of treatments with each alarm type (air in venous lines, low systolic BP, high venous pressure, low venous pressure, blood leaks, and alarms ending treatment) will be reported by treatment period.

Summary statistics (mean, sample size, standard deviation, minimum, maximum, and median) on the number of alarms per subject will be provided by treatment period, time point, and treatment number for each alarm type.

Time to Resolve or Clear Alarms
Summary statistics (mean, sample size, standard deviation, minimum, maximum, and median) on the time to resolve/clear alarms will be provided by treatment period. All alarm types will be combined for this analysis. The denominator in the mean calculations will be the number of alarms in the respective treatment period.

Prescription Changes
The number of prescription changes made from initial input during each dialysis treatment will be summarized via summary statistics (mean, sample size, standard deviation, minimum, maximum, and median) for each treatment period and time point. The denominator in the mean calculations will be the number of treatments in the respective treatment period and time point.

The number and percentage of treatments that required a prescription change will be computed for each subject by treatment period. The denominator for all percentages will be the number of treatments completed by each subject in the respective treatment period.

Feel Cold and Hypotensive Events
The number and percentage of subjects with at least one reported feel cold event and at least one reported hypotension event will be computed by treatment period. The denominator for all percentages will be the number of ITT subjects.

5.0 Analysis of Safety

5.1 Description of Safety Variables

All study-emergent AEs occurring during the study sessions will be recorded and classified on the basis of the Medical Dictionary for Regulatory Activities (MedDRA®) terminology. Study-emergent AEs are those AEs with an onset on or after the date of first study treatment. All analysis tables of AEs will be relative to study-emergent AEs.

The primary safety analysis variable is the mean number of adverse events (AEs) from the pre-specified list observed during a dialysis interval as follows:

- Serious AE (SAE)
- Allergic Reaction
- Blood Loss

- Hemolytic Reaction
- Infection
- Intra-Dialysis Event
- Vascular Access Complication
- Pyrogenic Reaction

A dialysis interval is defined as the start of one dialysis treatment until the start of the next dialysis treatment. A dialysis interval is further divided as follows:

- *Treatment*: An event that occurs during dialysis treatment onset through completion
- *Interdialytic*: An event that occurs from the end of the subject's treatment to beginning of dialysis treatment set-up of the next treatment
- *Pre-Treatment*: An event that occurs during dialysis treatment set-up until the start of treatment

Any event that occurs during any of these time periods is considered within the same dialysis interval.

The secondary safety analysis variables are defined as follows:

- All other study-emergent AEs
- Clinical labs (Hematology, Chemistry, and Kinetics [Pre/Post BUN])

5.2 Analysis of Safety Variables

The following describes the safety analyses to be performed for the study. Analysis of the primary safety variable will be performed on the ITT population. All other safety analyses will be performed on the safety population.

Pre-specified Adverse Events for Primary Safety Variable
For each treatment period, a 95% confidence interval will be computed on the pre-specified adverse event rate per dialysis interval. This confidence interval will be computed using the Least Square Mean for the respective treatment period from a generalized linear model containing terms for subject, treatment arm and time points (i.e., a repeated measures analysis using GEE) using a Poisson link function and AR(1) covariance structure. If the AE start date/time is missing, the AE will be counted in the interdialytic interval in which it was observed (if available) or will be randomly assigned (during the final data analysis for the study) to one of the interdialytic periods in the treatment period.

Summary statistics (mean, sample size, standard deviation, minimum, maximum, median) will be computed on the number of pre-specified adverse events per dialysis interval for each treatment period. The same summary

statistics will be calculated by treatment period for the rate of pre-specified adverse events per 100 dialysis treatments.

Additional Analyses of Pre-specified Adverse Events
A table will be provided to show the number and percentage of safety population subjects with at least one pre-specified AE by treatment period and overall for each dialysis treatment interval (treatment, interdialytic, pre-treatment).

A summary table will be constructed to display the following with respect to pre-specified AEs:

- Subjects with at least one pre-specified AE
- Maximum severity, per subject
- Highest relationship to device, per subject
- Highest relationship to treatment, per subject
- Subjects with at least one SAE
- Deaths

All Other Study-Emergent Adverse Events
A table will be provided to show the number and percentage of safety population subjects with at least one study-emergent AE by treatment period and overall for each dialysis treatment interval (treatment, interdialytic, pre-treatment). A similar table will also be provided to show the number and percentage of safety population subjects with at least one occurrence of an AE by categorization (pre-specified AEs or all other AEs) by treatment period and overall.

A summary table will be constructed to display the following with respect to all study-emergent AEs:

- Subjects with at least one study-emergent AE
- Maximum severity, per subject
- Highest relationship to device, per subject
- Highest relationship to treatment, per subject
- Subjects with at least one SAE
- Deaths

Laboratory Tests
Clinical laboratory tests will be performed at Baseline and at approximately every four weeks through study completion (with the exception of pre and post BUN, which are captured weekly). For each quantitative laboratory test, summary statistics (mean, standard deviation, median, range, n) on the raw data as well as changes from baseline will be presented by timepoint. If multiple labs were performed at a given timepoint, the lab results from the date the site is basing clinical care from will be used and summarized in the analysis tables. A summary table will be provided to show the results for all lab tests, and additional tables

will be provided to show the results for a subset of the lab tests as well as to show results for selected individual lab tests, as listed in Section 7.0.

A summary table of abnormal lab results will also be provided. All summary statistics (mean, standard deviation, median, range, n) will be computed relative to the lab results that fell outside of specified ranges on the raw data. These ranges will be determined prior to data analysis.

Pre and post BUN summary statistics will be provided in a separate table to show the results by treatment period, time point, and treatment number. Parameters include pre BUN, post BUN, difference in pre and post BUN, and URR, where URR is defined as (pre BUN minus post BUN) divided by (pre BUN).

6.0 Other Relevant Data Analyses/Summaries

6.1 Subject Completion

A table will be constructed with counts and percentages of subjects who completed the study and subjects who withdrew from the study. Of the subjects who withdrew from the study, the number and percent of subjects with each withdrawal reason will be reported.

7.0 List of Analysis Tables, Figures and Listings

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
1	Subject Completion Summary	X	X
2	Demographics and Baseline Data Summary Statistics – Continuous Variables (Safety Population)	X	X
3	Demographics and Baseline Data Summary Statistics – Categorical Variables (Safety Population)	X	X
4	Summary of Medical History Including Cause of ESRD (Safety Population)	X	X
5	Summary of Weekly Standardized Kt/V by Treatment Period (ITT Population)	X	X
6	Summary of Weekly Standardized Kt/V by Treatment Period (ITT Population With Missing Value Imputation)	X	
7	Summary of Weekly Standardized Kt/V by Treatment Period (PP Population)	X	
8	RMANOVA for Weekly Standardized Kt/V – Tests of Fixed Effects (ITT Population)	X	X
9	RMANOVA for Weekly Standardized Kt/V – LS Means and Standard Errors (ITT Population)	X	X
10	RMANOVA for Weekly Standardized Kt/V – Tests of Fixed Effects (ITT Population With Missing Value Imputation)	X	
11	RMANOVA for Weekly Standardized Kt/V – LS Means and Standard Errors (ITT Population With Missing Value Imputation)	X	
12	RMANOVA for Weekly Standardized Kt/V – Tests of Fixed Effects (PP Population)	X	
13	RMANOVA for Weekly Standardized Kt/V – LS Means and Standard Errors (PP Population)	X	
14	Summary of Ultrafiltration Rate and Volume Actual vs. Prescribed by Treatment Period (ITT Population)	X	X
15	Summary of Ultrafiltration Rate and Volume Actual vs. Prescribed by Treatment Period (PP Population)	X	
16	Summary of Pre-Specified Adverse Events for Primary Safety Endpoint by Treatment Period (ITT Population)	X	X
17	Pre-Specified Adverse Events Summary for Each Treatment Interval by Treatment Period and Overall (Safety Population)	X	X
18	Number and Percent of Subjects with Study-Emergent Adverse Events by Treatment Period and Severity, Relationship to Device, Seriousness, and Overall (Safety Population)	X	X
19	Study Emergent Adverse Events Summary for Each Treatment Interval by Treatment Period and Overall (Safety Population)	X	X
20	Number and Percent of Subjects with Pre-Specified Study-Emergent Adverse Events by Treatment Period and Severity, Relationship to Device, Seriousness, and Overall (Safety Population)	X	X

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
21	Study Emergent Adverse Events Summary by Categorization and Overall (Safety Population)	X	X
22	Summary Table of All Clinical Laboratory Parameters (Safety Population)	X	X
23	Summary Table of Specific Laboratory Parameters (Safety Population)	X	X
24	Summary Table of Hematology – HCT (units) (Safety Population)	X	X
25	Summary Table of Hematology – HgB (units) (Safety Population)	X	
26	Summary Table of Chemistry – Sodium (units) (Safety Population)	X	
27	Summary Table of Chemistry – Potassium (units) (Safety Population)	X	
28	Summary Table of Chemistry – Bicarbonate (units) (Safety Population)	X	
29	Summary Table of Chemistry – Albumin (units) (Safety Population)	X	
30	Summary Table of Chemistry – Calcium (units) (Safety Population)	X	
31	Summary Table of Chemistry – Phosphorous (units) (Safety Population)	X	
32	Summary Table of Abnormal Laboratory Values (Safety Population)	X	X
33	Pre and Post BUN Summary Statistics (Safety Population)	X	X
34	Summary Table of Clinically Significant Alarms (ITT Population)	X	X
35	Clinically Significant Alarms Summary Statistics-Air in Venous Lines (ITT Population)	X	X
36	Clinically Significant Alarms Summary Statistics-Low Systolic Blood Pressure (ITT Population)	X	
37	Clinically Significant Alarms Summary Statistics-High Venous Pressure (ITT Population)	X	
38	Clinically Significant Alarms Summary Statistics-Low Venous Pressure (ITT Population)	X	
39	Clinically Significant Alarms Summary Statistics-Blood Leaks (ITT Population)	X	
40	Time to Resolve/Clear Alarms Summary Statistics (ITT Population)	X	X
41	Prescription Changes Summary Statistics - Overall (ITT Population)	X	X
42	Summary Table of Prescription Changes Per Subject by Treatment Period (ITT Population)	X	X
43	Summary Table of Feel Cold and Hypotensive Events (ITT Population)	X	X

8.0 References

[1] Sands et al. *Home hemodialysis: A comparison of in-center and home hemodialysis therapy in a cohort of successful home hemodialysis patients.* ASAIO Journal (2009); 55: 361-368.

[2] Daugirdas et al. *Improved equation for estimating single-pool Kt/V at higher dialysis frequencies.* Nephrol Dial Transplant (2013); 28: 2156-2160.

[3] Leypoldt et al. Seminars in Dialysis, 17(2); March-April 2004.

Appendix A – Tables, Figures and Listing Specifications

Orientation

Tables and figures will be displayed in landscape.

Margins

Margins will be 1 inch on all sides. Table and listing boundaries will not extend into the margins.

Font

Courier New, 8 point.

Headers

The table number will be on the first line of the title. The title area will contain the Sponsor name, the study number, and the name of the table. The title area will contain the page number (Page x of y) on the far right, one line above the name of the table.

Footers

- The first line will be a solid line.
- Next will be any footnotes regarding information displayed in the table.
- Below these footnotes will be displayed “STATKING Clinical Services (Date)” on the far left.
- The last line will display the name of the SAS program that generated the table and (if applicable) the source data reference.

Table Disclaimer

The format of the mock tables shown in the appendix of this Statistical Analysis Plan (SAP) will be the format of the deliverable tables to the extent that Word document constructed tables can match production tables produced by SAS. This formatting includes the content and format of the header and footer areas of the tables. The Sponsor agrees to the format of the tables as shown in the appendix.

Further programming charges will be applicable for changes in the format of tables (including title statements, notes, data dependent footnotes, etc.) made after the approval of the SAP.

Missing Values

All missing values will be displayed on the output tables/listings as blanks.

Display of Study Dates

The date format to be used is yyyy-mm-dd. Missing parts of dates are not shown (i.e., for a missing day value, the value displayed is in yyyy-mm format).

Appendix B – Table Shells

Table 1. Subject Completion Summary
Outset Medical - Study No. 2014-01

	All Enrolled Subjects (N=xxx)
Completed	xx (xx%)
Withdrawn	xx (xx%)
Subject Withdrew Consent	xx (xx%)
Subject Selected for Transplant	xx (xx%)
Subject Transfer	xx (xx%)
Subject Modality Change	xx (xx%)
Subject Prolonged Hospitalization	xx (xx%)
Discontinuation by Physician	xx (xx%)
Discontinuation by Sponsor	xx (xx%)
Lost to Follow-up	xx (xx%)
Death	xx (xx%)
Other	xx (xx%)

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 2. Demographics and Baseline Data Summary Statistics – Continuous Variables
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

Variable	Mean	Std Dev	n	Min	Max	Median
Age (years)	xxx	xxx	xxx	xxx	xxx	xxx
Baseline Height (in)	xxx	xxx	xxx	xxx	xxx	xxx
Baseline Weight (kg)	xxx	xxx	xxx	xxx	xxx	xxx
BMI	xxx	xxx	xxx	xxx	xxx	xxx

Table 3. Demographics and Baseline Data Summary Statistics – Categorical Variables
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

Demographics Variable	Category	Overall (N=xxx)
Gender	Male	xxx (xxx%)
	Female	xxx (xxx%)
	Not Reported	xxx (xxx%)
Race	American Indian or Alaska Native	xxx (xxx%)
	Native Hawaiian or Other Pacific Islander	xxx (xxx%)
	Black or African American	xxx (xxx%)
	White	xxx (xxx%)
	Asian	xxx (xxx%)
	Other	xxx (xxx%)
Ethnicity	Hispanic or Latino	xxx (xxx%)
	Not Hispanic or Latino	xxx (xxx%)
	Unknown	xxx (xxx%)
	Not Reported	xxx (xxx%)

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Page x of y

Table 4. Summary of Medical History Including Cause of ESRD
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

Medical History Variable	Category	Overall (N=xxx)
Condition	Coronary Artery Disease	xxx (xxx%)
	Congestive Heart Failure	xxx (xxx%)
	Ejection Fraction ≤ 30%	xxx (xxx%)
	Diabetes	xxx (xxx%)
	Hypertension	xxx (xxx%)
	Hypotension	xxx (xxx%)
	Hypercholesterolemia	xxx (xxx%)
	Dyslipidemia	xxx (xxx%)
	Carotid Artery Disease	xxx (xxx%)
	Peripheral Artery Disease	xxx (xxx%)
	Arrhythmia	xxx (xxx%)
	Liver Disease	xxx (xxx%)
	Systemic Inflammatory Conditions	xxx (xxx%)
	Systemic Infection	xxx (xxx%)
	Tobacco Use	xxx (xxx%)
	Current	xxx (xxx%)
	Former	xxx (xxx%)
	Anemia	xxx (xxx%)
	Renal Osteodystrophy	xxx (xxx%)
	GI Bleeding	xxx (xxx%)
Primary Cause of ESRD	Hypertension	xxx (xxx%)
	Diabetes	xxx (xxx%)
	Complications with Renal Transplant	xxx (xxx%)
	Renal Failure NOS	xxx (xxx%)
	Glomerulonephritis	xxx (xxx%)
	Polycystic Kidney Disease	xxx (xxx%)
	Other	xxx (xxx%)
	Unspecified	xxx (xxx%)

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 5. Summary of Weekly Standardized Kt/V by Treatment Period
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

Treatment Period	Mean	Std Dev	n	Min	Max	Median
In-Center	xxx	xxx	xxx	xxx	xxx	xxx
In-Home	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

The format of this table will be repeated for the ITT population with missing value imputation and for the PP population.

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Table 8. RMANOVA for Weekly Standardized Kt/V – Tests of Fixed Effects
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

	Tests of Fixed Effects			
Source	NDF	DDF	Type III F	Pr > F
Subject	xx	xx	xxx	xxx
Treatment Period	xx	xx	xxx	xxx
Week	xx	xx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

The format of this table will be repeated for the ITT population with missing value imputation and for the PP population.

Table 9. RMANOVA for Weekly Standardized Kt/V – LS Means and Standard Errors
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

		Least Squares Mean (LSMean) and Standard Error (SE)		
Treatment Effect	Level	LSMean	SE	p-Value[a]
Treatment Period	In-Center	xxx	xxx	xxx
	In-Home	xxx	xxx	xxx

[a] One-sided p-value for test of H0: Mean Weekly Standardized Kt/V ≤ 2.1 vs. H1: Mean Weekly Standardized Kt/V > 2.1.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

The format of this table will be repeated for the ITT population with missing value imputation and for the PP population.

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Table 14. Summary of Ultrafiltration Rate and Volume Actual vs. Prescribed by Treatment Period
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

	In-Center			In-Home		
Treatment Parameter	Mean	Std Dev	n	Mean	Std Dev	n
Prescribed UF Volume	xxx	xxx	xxx	xxx	xxx	xxx
Prescribed Treatment Time	xxx	xxx	xxx	xxx	xxx	xxx
Prescribed UF Rate	xxx	xxx	xxx	xxx	xxx	xxx
Actual UF Volume	xxx	xxx	xxx	xxx	xxx	xxx
Actual Treatment Time	xxx	xxx	xxx	xxx	xxx	xxx
Actual UF Rate	xxx	xxx	xxx	xxx	xxx	xxx
Success Rate[a]	xxx	xxx	xxx	xxx	xxx	xxx

[a] Where success is ultrafiltration rate achieved within 10% of the prescribed rate.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

The format of this table will be repeated for the PP population.

Table 16. Summary of Pre-Specified Adverse Events for Primary Safety Endpoint by Treatment Period
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

	Treatment Period	Mean	95% Confidence Interval	Std Dev	n	Min	Max	Median
Number of Pre-Specified Adverse Events Per Dialysis Interval	In-Center	xxx	(xxx, xxx)	xxx	xxx	xxx	xxx	xxx
	In-Home	xxx	(xxx, xxx)	xxx	xxx	xxx	xxx	xxx
Number of Pre-Specified Adverse Events Per 100 Dialysis Treatments	In-Center	xxx	(xxx, xxx)	xxx	xxx	xxx	xxx	xxx
	In-Home	xxx	(xxx, xxx)	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 17. Pre-Specified Study-Emergent Adverse Events Summary for Each Treatment Interval by Treatment Period and Overall
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

	Treatment Period[a]		
Treatment Interval	In-Center	In-Home	Overall
Pre-Treatment	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Treatment	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Interdialytic	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Counts represent number of subjects with at least one pre-specified study-emergent adverse event with a start date/time in the respective treatment interval and treatment period. The denominator for all percentages is the number of subjects in the safety population.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 18. Number and Percent of Subjects with Study-Emergent Adverse Events by Treatment Period and Severity, Relationship to Device, Seriousness, and Overall
Outset Medical - Study No. 2014-01
Safety Population (N=xxxx)

	Treatment Period[a]		
	In-Center	In-Home	Overall
Subjects with ≥ 1 Adverse Event (AE)	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Maximum AE Severity			
Mild	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Moderate	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Severe	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Highest Relationship of AE to Device			
Not Related [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Related [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Unknown [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Highest Relationship of AE to Treatment			
None [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Unlikely [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Possible [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Probable [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Definitely [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Subjects Experiencing ≥ 1 Serious AE (SAE)	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Deaths	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)

[a] The denominator for all percentages is the number of subjects in the safety population.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 19. Study-Emergent Adverse Events Summary for Each Treatment Interval by Treatment Period and Overall
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

	Treatment Period[a]		
Treatment Interval	In-Center	In-Home	Overall
Pre-Treatment	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Treatment	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Interdialytic	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Counts represent number of subjects with at least one study-emergent adverse event with a start date/time in the respective treatment interval and treatment period. The denominator for all percentages is the number of subjects in the safety population.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 20. Number and Percent of Subjects with Pre-Specified Study-Emergent Adverse Events by Treatment Period and Severity, Relationship to Device, Seriousness, and Overall
Outset Medical - Study No. 2014-01
Safety Population (N=xxxx)

	Treatment Period[a]		
	In-Center	In-Home	Overall
Subjects with ≥ 1 Adverse Event (AE)	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Maximum AE Severity			
Mild	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Moderate	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Severe	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Highest Relationship of AE to Device			
Not Related [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Related [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Unknown [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Highest Relationship of AE to Treatment			
None [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Unlikely [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Possible [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Probable [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Definitely [n(%)]	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Subjects Experiencing ≥ 1 Serious AE (SAE)	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
Deaths	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)

[a] The denominator for all percentages is the number of subjects in the safety population.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 21. Study-Emergent Adverse Events Summary by Categorization and Overall
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

	Treatment Period[a]		
	In-Center	In-Home	Overall
Pre-Specified Adverse Events	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Serious Adverse Event (SAE)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Allergic Reaction	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Blood Loss	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Hemolytic Reaction	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Infection	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Intra-Dialysis Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Vascular Access Complication	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Pyrogenic Reaction	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
All Other Adverse Events	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Counts represent number of subjects with at least one study-emergent adverse event in the respective category with a start date/time in the respective treatment period. The denominator for all percentages is the number of subjects in the safety population.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 22. Summary Table of All Clinical Laboratory Parameters
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

Laboratory Parameter	Data Type[a]	Baseline[b]	In-Center	In-Home
xxx (units)	RAW	xxx	xxx	xxx
	CFB		xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx
	CFB		xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx
	CFB		xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx
	CFB		xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx
	CFB		xxx	xxx

[a] All summary data are reported as mean values.
[b] Baseline value will be taken as the mean value of all baseline measurements.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 23. Summary Table of Specific Clinical Laboratory Parameters
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

		Treatment Period[a]				
		Baseline[b]	In-Center		In-Home	
Laboratory Parameter[c]	Data Type		Treatments 1-16	Treatments 17-32	Treatments 1-16	Treatments 17-32
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx

[a] All summary data are reported as mean values.
[b] Baseline value will be taken as the mean value of all baseline measurements.
[c] Parameters include: platelet count, WBC counts, lymphocytes, lymphocytes %, MID, MID %, GRAN, GRAN %, RBC counts, MCV, MCH, MCHC, RDW, chloride, creatinine, glucose, magnesium, LDH, ferritin, and TSat.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 24. Summary Table of Hematology – HCT (units)
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

	Treatment Period[a]				
	Baseline[b]	In-Center		In-Home	
Data Type		Treatments 1-16	Treatments 17-32	Treatments 1-16	Treatments 17-32
RAW	xxx	xxx	xxx	xxx	xxx
CFB		xxx	xxx	xxx	xxx
RAW	xxx	xxx	xxx	xxx	xxx
CFB		xxx	xxx	xxx	xxx
RAW	xxx	xxx	xxx	xxx	xxx
CFB		xxx	xxx	xxx	xxx
RAW	xxx	xxx	xxx	xxx	xxx
CFB		xxx	xxx	xxx	xxx
RAW	xxx	xxx	xxx	xxx	xxx
CFB		xxx	xxx	xxx	xxx

[a] All summary data are reported as mean values.
[b] Baseline value will be taken as the mean value of all baseline measurements.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

The format of this table will be repeated for each laboratory parameter that will be summarized in individual tables, as listed in Section 7.0.

Table 32. Summary Table of Abnormal Laboratory Values
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

		Treatment Period[a]				
		Baseline	In-Center		In-Home	
Laboratory Parameter	Data Type		Treatments 1-16	Treatments 17-32	Treatments 1-16	Treatments 17-32
Number (%) of Abnormal Lab Values[b]		xxx (xxx%)		xxx (xxx%)		xxx (xxx%)
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx
xxx (units)	RAW	xxx	xxx	xxx	xxx	xxx
	CFB		xxx	xxx	xxx	xxx

[a] All lab-specific summary data are reported as mean values for the subset of results that were abnormal.
[b] Denonminator is the number of non-missing lab values for all subjects, lab parameters, and time points for the respective treatment period.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 33. Pre and Post BUN Summary Statistics
Outset Medical - Study No. 2014-01
Safety Population (N=xxx)

Treatment Period	Time Point	Treatment Number[a]	Parameter[b]	Mean	Std Dev	n	Min	Max	Median
N/A	Week 1	1	Pre BUN	xxx	xxx	xxx	xxx	xxx	xxx
			Post BUN	xxx	xxx	xxx	xxx	xxx	xxx
			Pre BUN - Post BUN	xxx	xxx	xxx	xxx	xxx	xxx
			URR	xxx	xxx	xxx	xxx	xxx	xxx
In-Center	Week 9	4	Pre BUN	xxx	xxx	xxx	xxx	xxx	xxx
			Post BUN	xxx	xxx	xxx	xxx	xxx	xxx
			Pre BUN - Post BUN	xxx	xxx	xxx	xxx	xxx	xxx
			URR	xxx	xxx	xxx	xxx	xxx	xxx
In-Home	Week 19	4	Pre BUN	xxx	xxx	xxx	xxx	xxx	xxx
			Post BUN	xxx	xxx	xxx	xxx	xxx	xxx
			Pre BUN - Post BUN	xxx	xxx	xxx	xxx	xxx	xxx
			URR	xxx	xxx	xxx	xxx	xxx	xxx

[a] Treatment number is relative to the given timepoint, where each week has 4 scheduled treatments.
[b] URR is calculated as (Pre-Post BUN)/(Pre BUN).
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Only selected time points and treatment numbers are shown on this mock table. The final table will display all time points (Weeks 2-9 for In-Center and Weeks 10-19 for In-Home) and all four treatment numbers within each time point.

Table 34. Summary Table of Clinically Significant Alarms
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

	Treatment Period[a]	
Alarm Type	In-Center	In-Home
Air in Venous Lines	xxx (xxx%)	xxx (xxx%)
Low Systolic Blood Pressure	xxx (xxx%)	xxx (xxx%)
High Venous Pressure	xxx (xxx%)	xxx (xxx%)
Low Venous Pressure	xxx (xxx%)	xxx (xxx%)
Blood Leak in Dialyzer	xxx (xxx%)	xxx (xxx%)
Alarms that End Treatment	xxx (xxx%)	xxx (xxx%)

[a] Summaries per treatment period are the number and percentage of treatments with the respective alarm type. The denominator is the number of treatments for all ITT population subjects during the treatment period.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 35. Clinically Significant Alarms Summary Statistics
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

Alarm Type=xxxxxxxxxxxxxx

Treatment Period	Time Point	Treatment Number[a]	Mean	Std Dev	n	Min	Max	Median
N/A	Week 1	1	xxx	xxx	xxx	xxx	xxx	xxx
In-Center	Week 9	4	xxx	xxx	xxx	xxx	xxx	xxx
In-Home	Week 19	4	xxx	xxx	xxx	xxx	xxx	xxx

[a] Treatment number is relative to the given timepoint, where each week has 4 scheduled treatments.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Only selected time points and treatment numbers are shown on this mock table. The final table will display all time points (Weeks 2-9 for In-Center and Weeks 10-19 for In-Home) and all four treatment numbers within each time point. The format of this table will be repeated for alarm type.

Table 40. Time to Resolve/Clear Alarms Summary Statistics
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

Treatment Period	Mean	Std Dev	n	Min	Max	Median
N/A	xxx	xxx	xxx	xxx	xxx	xxx
In-Center	xxx	xxx	xxx	xxx	xxx	xxx
In-Home	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 41. Prescription Changes Summary Statistics - Overall
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

Treatment Period	Time Point	Data Type	Mean	Std Dev	n	Min	Max	Median
N/A	Week 1 (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
In-Center	Treatments 1-16	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		CFB	xxx	xxx	xxx	xxx	xxx	xxx
In-Center	Treatments 17-32	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		CFB	xxx	xxx	xxx	xxx	xxx	xxx
In-Home	Treatments 1-16	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		CFB	xxx	xxx	xxx	xxx	xxx	xxx
In-Home	Treatments 17-32	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		CFB	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 42. Summary Table of Prescription Changes per Subject by Treatment Period
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

	Treatment Period[a]	
Subject No.	In-Center	In-Home
xxx	xxx (xxx%)	xxx (xxx%)
xxx	xxx (xxx%)	xxx (xxx%)

[a] Summaries per treatment period are the number and percentage of treatments that required a prescription change for each subject. The denominator is the number of treatments completed by the subject in the treatment period.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

The final table will include rows for each ITT population subject.

Table 43. Summary Table of Feel Cold and Hypotensive Events
Outset Medical - Study No. 2014-01
ITT Population (N=xxx)

	Treatment Period[a]		
Sign/Symptom	Baseline	In-Center	In-Home
Feel Cold	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Hypotension	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Summaries per treatment period are the number and percentage of subjects who reported at least one incidence of the respective sign/symptom with a start date/time during the treatment period. The denominator is the number of subjects in the ITT population.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas