Statistical Analysis Plan

A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy/Potency of a Single Dose of Xisomab 3G3, Administered at the Beginning of a Regular Hemodialysis Procedure, in Patients with End-Stage R14.3.5.3enal Disease on Chronic Hemodialysis

Protocol No: 3G3-18-02
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Compound Name: xisomab 3G3

Celerion Project CA23900
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Statistical Analysis Plan Signature Page

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1. INTRODUCTION

The following statistical analysis plan (SAP) provides the framework for the summarization of the data from this study. The SAP may change due to unforeseen circumstances. Any changes made from the planned analysis within the protocol, after the unblinding, or locking of the database will be documented in the clinical study report (CSR). The section referred to as Table Shells within this SAP describes the traceability of the tables, figures, and listings (TFLs) back to the data. Note that the header for this page will be the one used for the main body of the CSR.

Any additional exploratory analyses not addressed within this statistical analysis plan (SAP) and/or driven by the data, or requested by Aronora Inc., will be considered out of scope and must be described in the CSR.

2. OBJECTIVES AND ENDPOINTS

2.1 Objectives

The primary objective of the study is to assess the safety and tolerability of a single dose of xisomab 3G3 when injected through a port into the proximal (arterial) dialysis line immediately after initiation of a hemodialysis (HD) procedure in patients with end stage renal disease (ESRD).

The secondary objectives of the study are as follows:

- To assess the pharmacodynamics (PD) of a single dose of xisomab 3G3 when injected through a port into the proximal (arterial) dialysis line immediately after initiation of a HD procedure in patients with ESRD.
- To assess the efficacy of a single dose of xisomab 3G3 on HD efficiency when injected through a port into the proximal (arterial) dialysis line immediately after initiation of a HD procedure in patients with ESRD.
- To assess the pharmacokinetics (PK) of a single dose of xisomab 3G3 when injected through a port into the proximal (arterial) dialysis line immediately after initiation of a HD procedure in patients with ESRD.

2.2 Endpoints

Primary outcome measures:

- The safety and tolerability of xisomab 3G3 will be evaluated versus pre-treatment and placebo by reviewing number and severity of adverse events and use of concomitant medications, physical examination, vascular access site reaction, bleeding time, and changes in vital signs, ECGs, and clinical laboratory evaluations.

Secondary outcome measures:

- PD using dose-dependency of drug potency, determined by measuring changes in the coagulation parameter (aPTT), and thrombus accumulation (assessed and ranked by visual inspection) within the dialyzer cartridges and total protein accumulation in the HD filter after xisomab 3G3-treatment versus pre-treatment and placebo.
- Hemodialysis efficiency using blood urea nitrogen (BUN) and potassium levels will be measured before and after hemodialysis to calculate URR and Kt/V.

  Note: Kt/V = volume of fluid completely cleared of urea [K = dialyzer clearance (mL/min), t = time of dialysis] and V = volume of water a patients body contains. Formulas to calculate Kt/V and URR are located under Section 7.2.3.

Other outcome measures:

- The following PK parameters will be calculated for xisomab 3G3 in plasma, as appropriate: AUC0-t, AUC0-inf, AUC%extrap, Cmax, Tmax, Kel, t½, CL, and Vss.
- Development of immunity or antibodies against xisomab 3G3 after drug exposure.

3. STUDY DESIGN

This is a phase 2, randomized, double-blind, placebo-controlled, single-dose study of xisomab 3G3 designed to evaluate the safety, efficacy/potency, and PK at 2 dose levels administered to patients with ESRD undergoing HD.

Patients will be enrolled into Cohort 1 or Cohort 2; cohorts will be dosed sequentially. Within a cohort, patients will be randomized to active drug or placebo as summarized below:

Cohort	Treatment	Active:Placebo	Cohort Size
1	Infusion dose of 0.25 mg/kg xisomab 3G3 or placebo	2:1	9-12
2	Infusion dose of 0.5 mg/kg xisomab 3G3 or placebo	2:1	9-12

This study includes a screening period of 28 days prior to checking-in to the clinical research unit on Day -8. From Day -7 (one week prior to dosing on Day 1) through Day -1, all patients will undergo HD 3 times and will be assessed for all scheduled procedures and endpoints before and after each HD session.

On Study Day 1, prior to dosing, patients will undergo baseline measurements followed by initiation of a regular HD procedure, consistently using only one type of dialyzer cartridge in each patient. Immediately after the start of blood perfusion, a single dose of xisomab 3G3 or matching placebo will be injected through a port into the flowing arterial blood in the proximal dialysis line. Patients will continue to undergo HD procedures and scheduled assessments from Day 1 through Day 12.

Study assessments will include physical examinations, vital signs, electrocardiogram (ECGs), clinical laboratory tests, HD vascular access site (AV fistula or AV graft) reaction, antibody titer (immunogenicity), adverse events (AEs), PD blood sampling (coagulation parameters), and PK blood sampling to be performed throughout the study. On Days -7, -5, and -3 and Days 1, 3, 5, and 12, bleeding time from the HD vascular access sites on the AV fistula or AV graft (ladder or buttonhole technique) will be evaluated at the end of the HD session. The dialyzer cartridge will be rinsed and visually inspected at the end of the HD procedure and graded against a standardized visual assessment scale. After visual assessment, the used and rinsed dialyzer cartridge will be frozen and saved for later retained content (deposited blood-derived material) analysis. The number of dialyzer cartridges used for the HD session will be recorded.

All patients who received the study drug or placebo (including patients who terminate the study early) will undergo follow-up procedures at the Clinical Research Unit (CRU) approximately 12 days after dosing.

4. ANALYSIS POPULATIONS

4.1 Analysis Populations

Safety Population
The safety population will include all patients who received at least one dose of study drug (active or placebo).

Pharmacokinetic Population
Samples from all patients receiving the active drug will be assayed even if the patients do not complete the study. All patients receiving the active drug who comply sufficiently with the protocol and display an evaluable PK profile (e.g., exposure to treatment, availability of measurements and absence of major protocol violations) will be included in the statistical analyses.

Pharmacodynamic Population
All patients who received the study drug (active or placebo) and had at least one postdose measurement of any of the PD assessment will be included in the statistical analyses.

4.2 Preliminary Data and Interim Analysis

Celerion has not been contracted to complete any interim safety, PK, and PD analyses.

5. TREATMENT DESCRIPTIONS

Patients will receive a single infusion dose of 0.25 mg/kg xisomab 3G3, 0.5 mg/kg xisomab 3G3, or matching placebo on Day 1 at Hour 0. The dose will be administered proximal to the dialyzer cartridge, into the arterial line immediately after start of HD.

Planned doses for each cohort of the study are as follows:

Cohort 1: 0.25 mg/kg xisomab 3G3 or matching placebo
Cohort 2: 0.5 mg/kg xisomab 3G3 or matching placebo

The patients' weight recorded at check-in will be used to calculate the study drug dose.

Treatments will be described as follows:

Cohort	Treatment	Short Description (used in text)	Long Description (used in Tables Figures and Listings)
Cohorts 1 & 2	P	Placebo (Pooled)	Single IV Infusion of Placebo (Pooled)
Cohort 1	A	0.25 mg/kg xisomab 3G3	Single IV Infusion of 0.25 mg/kg xisomab 3G3
Cohort 2	B	0.5 mg/kg xisomab 3G3	Single IV Infusion of 0.5 mg/kg xisomab 3G3

6. PHARMACOKINETIC ANALYSIS

6.1 Measurements and Collection Schedule

For all patients, blood samples for the determination of free xisomab 3G3 will be collected at predose (hour 0, at least 1 hour prior the start of HD session) and at 0.167, 0.5, 1, 2, 3, 4, 6, 8, 12, 16, 24, 48, 96, 120, 144, and 192 hours after xisomab 3G3 start of infusion.

All concentration data will be included in the calculation of the individual PK parameters, the individual concentration-time plots (based on actual sample times), and in the mean concentration-time plots (based on nominal sample times). However, if there are any significant deviations from nominal sample times, some concentration data may be excluded from mean concentration-time plots and/or additional concentration-time plots of the mean data may be provided. All deviations and excluded data will be provided and discussed in the CSR.

6.2 Bioanalytical Method

Plasma concentrations of xisomab 3G3 will be determined using enzyme-linked immunosorbent assay (ELISA) validated with respect to accuracy, precision,

linearity, sensitivity, and specificity at Celerion, Lincoln, Nebraska. The analytical range (lower limit of quantitation [LLOQ] – upper limit of quantitation [ULOQ]) for xisomab 3G3 is expected to be 50 – 5000 ng/mL.

6.3 Investigational Product and PK Analyte Information

6.3.1 Xisomab 3G3

Xisomab 3G3 is a novel, injectable, therapeutic monoclonal antibody (IgG4, S241P hinge-modified) that prevents activation of the contact (intrinsic) pathway of coagulation and is intended to address the problem of dose limiting bleeding side effects of current antithrombotic agents. Xisomab 3G3 was developed by Aronora, Inc. and is intended for IV administration. The proposed indication for xisomab 3G3 is as a therapeutic treatment of venous thromboembolism. The goal of xisomab 3G3 treatment is to achieve safe anticoagulation for several days with a single dose.

Xisomab 3G3 and matching placebo was supplied as sterile powder for injection via the IV route, upon reconstitution.

The quantity referenced for doses are based on active drug substance (i.e., xisomab 3G3); therefore, dose adjustment is not required for calculation of dose-dependent PK parameters for the parent drug.

6.4 Pharmacokinetic Concentrations

Plasma concentrations of xisomab 3G3 as determined at the collection times and per the bioanalytical method described in Section 6.1 and Section 6.2, respectively, will be used for the calculation of the plasma xisomab 3G3 PK parameters.

6.5 Noncompartmental Pharmacokinetic Analysis and Parameter Calculation

6.5.1 Plasma Pharmacokinetic Parameters

The appropriate noncompartmental PK parameters will be calculated from the plasma free xisomab 3G3 concentration-time data using Phoenix® WinNonlin® Version 7.0 or higher. Actual sample times will be used in the calculations of the PK parameters. The calculation of the actual time for xisomab 3G3 will be in respect to the start of infusion time of xisomab 3G3 on Day 1. All PK parameters included in the protocol are listed in Table 6.1 below, and are defined as appropriate for study design.

Table 6.1. Noncompartmental Pharmacokinetic Parameters to be Calculated

Parameter Label to be Used in the Text, Tables and Figures	Definition	Method of Determination
AUC0-t	Area under the concentration-time curve from time 0 to the time of the last measurable non-zero concentration	Calculated using the Linear Trapezoidal with Linear Interpolation Method
AUC0-inf	Area under the concentration-time curve from time 0 extrapolated to infinity	AUC0-inf = AUC0-t + (Clast/kel) where Clast is the last observed/measured concentration
AUC%extrap	Percent of AUC0-inf extrapolated	AUC%extrap = (1 - AUC0-t/AUC0-inf)*100
AUMC0-inf*	Area under the moment curve from time 0 extrapolated to infinity	AUMC0-inf = AUMC0-t + [(tlast x Clast)/ Kel]+ [Clast/$(Kel)^2$]
Cmax	The maximum observed concentration	Taken directly from bioanalytical data
Tmax	The time to reach Cmax. If the maximum value occurs at more than one time point, Tmax is defined as the first time point with this value	Taken from clinical database as the difference in the start time of the infusion and the time of the blood draw which is associated with the Cmax.
Kel	Apparent first-order terminal elimination rate constant calculated from a semi-log plot of the plasma concentration versus time curve	The parameter will be calculated by linear least-squares regression analysis using the maximum number of points in the terminal log-linear phase (e.g., three or more non-zero plasma concentrations).
t½	Apparent first-order terminal elimination half-life	Calculated as: 0.693/ Kel
CL	The apparent total plasma clearance after IV administration	Calculated as: Dose/(AUC0-inf)
MRT*	Mean residence time of free drug in the systemic circulation when the drug concentrations are extrapolated to infinity	Calculated as: (AUMC0-inf/AUC0-inf) – (T1/2) Where TI is the duration of infusion
Vss	Total apparent volume of distribution following single IV dose administration	Calculated as: MRT x CL

* AUMC0-inf and MRT values will be used for Vss calculation but will not be listed in the PK tables. Note for the programmer: Parameters which are calculated for use in the calculation of a separate parameter but that are not summarized in the PK tables (i.e., AUMC0-inf and MRT) will be included in the study data tabulation model (SDTM) PP(Pharmacokinetic Parameters) domain, but not included in the analysis data model (ADaM) ADPP (Pharmacokinetic Parameters Analysis) domain.

PK parameters will not be calculated for patients with 2 or fewer consecutive time points with detectable concentrations. Subjects for whom there are insufficient data to calculate the PK parameters will be included in the concentration tables only and excluded from the summary statistics.

For the calculation of the PK parameters, plasma concentrations below the limit of quantitation (BLQ) prior to the first quantifiable concentration will be set to 0 and plasma concentrations BLQ after the first quantifiable concentration will be treated as missing.

The Kel will be determined using linear regressions composed of least 3 data points. The Kel will not be assigned if 1) the terminal elimination phase is not apparent, 2) if Tmax is one of the 3 last data points, or 3) if the R^2 value is less than 0.75. In cases where the Kel interval is not assigned, the values of AUC0-inf, AUC%extrap, AUMC0-inf, t½, CL, MRT, and Vss are considered not calculable and will not be reported. Wherever the resulting t½ is more than half as long as the sampling interval, the Kel values and associated parameters (AUC0-inf, AUC%extrap, AUMC0-inf, t½, CL, MRT, and Vss) may not be presented as judged appropriate and in accordance with Celerion SOPs.

6.6 Data Summarization and Presentation of PK Parameters

All plasma xisomab 3G3 PK concentrations and/or PK parameters descriptive statistics will be generated using SAS® version 9.3 or higher. A concentration table will be presented for pooled placebo samples without descriptive statistics.

The plasma concentrations of xisomab 3G3 will be listed and summarized by treatment and time points for all subjects in the PK population. Plasma concentrations of xisomab 3G3 will be presented with the same level of precision as received from the bioanalytical laboratory. Summary statistics, including sample size (n), arithmetic mean (Mean), standard deviation (SD), coefficient of variation (CV%), standard error of the mean (SEM), minimum, median, and maximum will be calculated for all nominal concentration time points. Excluded subjects will be included in the concentration listings, but will be excluded from the summary statistics and noted as such in the tables. All BLQ values will be presented as “BLQ” in the concentration listings and footnoted accordingly.

Mean and individual concentration-time profiles will be presented on linear and semi-log scales. Linear mean plots will be presented with and without SD.

Plasma xisomab 3G3 PK parameters will be listed and summarized by treatment for all subjects in the PK population. Pharmacokinetic parameters will be reported to 3 significant figures for individual parameters, with the exception of t½ and Tmax, which will be presented with 2 decimal places. Summary statistics (n, Mean, SD, CV%, SEM, minimum, median, maximum, geometric mean [Geom Mean] and geometric CV% [Geom CV%]) will be calculated for plasma xisomab 3G3 PK parameters. Excluded subjects will be listed in the PK parameter tables, but will be excluded from the summary statistics and noted as such in the tables.

The level of precision for each concentration and PK parameter statistic will be presented as follows:

- minimum/maximum: in same precision as in the bioanalytical data for concentrations and same precision for PK parameters presentation
- Mean/median/Geom Mean: in one more level of precision than minimum/maximum
- SD/SEM: in one more level of precision than Mean/median/Geom Mean
- n will be presented as an integer
- CV% and Geom CV% will be presented to the nearest tenth

7. PHARMACODYNAMICS

7.1 Pharmacodynamic Assessment

Pharmacodynamic (PD) assessment will include evaluation of drug potency and efficiency of HD.

7.1.1 Drug potency

Drug potency will be evaluated using the following PD markers:

- Thrombus accumulation will be evaluated by a visual inspection of the dialyzer membrane at the end of HD procedures and by a gradation using a standardized visual assessment scale;
- Total protein accumulation within the HD filter will be evaluated using appropriate methods;
- Coagulation parameter (activated partial thromboplastin time [aPTT]).

7.1.2 Efficiency of HD

Efficiency of HD will be assessed by:

- Blood BUN and potassium levels before and after dialysis;
- Length of HD – will be calculated as end time minus start time in hours and presented in individual and mean tables for each treatment;

- Total dialysate urea (measurement of BUN removed over 4 hours of dialysis) will be used to calculate;
  - Single pool Kt/V. The formula to calculate Kt/V is listed under Section 7.2.3.
  - URR measured as the difference between urea pre-dialysis and post-dialysis expressed as a percentage. The formula to calculate URR is listed under Section 7.2.3.

7.2 Data Summarization and Presentation of PD Parameters

7.2.1 aPTT

Sample Collection: Samples for the coagulation parameter (aPTT) will be collected at screening, pre- and post-dialysis on Days -7, -5, -3, 1, 3, 5, and 12. Additional samples for aPTT will be collected following xisomab 3G3/placebo dosing on Day 1 at predose (hour 0, at least 1 hour prior the start of HD session) and at 0.167, 0.5, 1, 2, 3, 4, 6, 8, 12, 16, 24, 48, 96, 120, 144, and 192, hours after xisomab 3G3 start of infusion.

Baseline Calculation Method Following Day 1 Dosing: Following xisomab 3G3 dosing on Day 1, aPTT change from baseline will be calculated by dividing postdose aPTT values from average of pre-dose baseline (the average of pre-dialysis aPTT values on Days -7, -5, -3, and 1 will be calculated as pre-dose baseline).

Fold change in aPTT values: The fold change in aPTT values on Days -7, -5, -3, 1 (only pre- and post-dialysis aPTT values on Day 1), 3, 5, and 12 will be calculated by dividing the post-dialysis aPTT/pre-dialysis aPTT values for each day separately.

aPTT values will be extracted from the clinical laboratory database and descriptive statistics will be generated using SAS® version 9.3 or higher. Following Day 1 xisomab 3G3 dosing, a table will be presented for the aPTT change from baseline with descriptive statistics.

aPTT values will be listed and summarized by treatment and time points in Tables and Figures for all subjects in the Safety Population (2 active dose levels and pooled placebo). aPTT values will be presented with the same level of precision as received from the clinical laboratory database. Summary statistics, including n, Mean, SD, CV%, SEM, minimum, median, and maximum will be calculated for all nominal values time points. Excluded subjects will be included in the aPPT values tables, but will be excluded from the summary statistics and noted as such in the tables.

Mean and individual aPTT values-time and change from baseline-time profiles will be presented on linear scale. Linear mean plots will be presented with and without SD.

The level of precision for the aPPT values summary statistic will be presented as follows:

- minimum/maximum: in same precision as in the clinical laboratory database
- Mean/median: in one more level of precision than minimum/maximum
- SD/SEM: in one more level of precision than Mean/median
- n will be presented as an integer
- CV% will be presented to the nearest tenth

7.2.2 BUN and Potassium:

Sample Collection: Samples for BUN and potassium will be collected pre- and post-dialysis on Days -7, -5, -3, 1, 3, 5, and 12.

Change in BUN and Potassium values: The change in BUN values on Days -7, -5, -3, 1, 3, 5, and 12 will be calculated by subtracting the post-dialysis BUN from the pre-dialysis BUN values for each day separately. The same method will be used for potassium.

Potassium and BUN values will be listed and summarized by treatment and Day in Tables and Figures for all subjects in the Safety Population (2 active dose levels and pooled placebo).

The level of precision for potassium and BUN summary statistic will be the same as per aPTT values listed in Section 7.2.1.

7.2.3 URR and KT/V

The derived PD parameters (URR and KT/V) will be calculated from the pre- and post-dialysis BUN values on Days -7, -5, 1, 3, 5, and 12.

URR will be calculated using the following formula:

URR = (1-(post-dialysis BUN/ pre-dialysis BUN))*100

Kt/V will be calculated using the following formula:

$$sp\frac{Kt}{V} = \ln(R - (0.008 \times t)) + (4 - (3.5 \times R)) \times \frac{UF}{Wt}$$

Where R = BUN Post-dialysis/BUN Pre-dialysis
t = Time of HD
UF = Pre-dialysis Weight – Post-dialysis Weight
Wt = Post-dialysis weight of patient.

URR and Kt/V values will be listed and summarized by treatment and Day in Tables for all subjects in the Safety Population (2 active dose levels and pooled placebo).

The level of precision for URR and Kt/V summary statistic will be the same as per aPTT values listed in Section 7.2.1

7.2.4 Clotting in the Drip Chamber and Dialysis Filter

Visual inspection of clotting in the drip chamber will be recorded 2 hours after start of dialysis and at the end of dialysis on Days -7, -5, -3, 1, 3, 5, and 12.

Visual inspection of clotting in the dialysis filter will be recorded at the end of dialysis on Days -7, -5, -3, 1, 3, 5, and 12.

Summary of clotting values will be listed and summarized by treatment and Day in Tables for all subjects in the Safety Population (2 active dose levels and pooled placebo).

7.2.5 Dialysate Analysis

A 10 mL dialysate sample will be taken at the start and at the end of HD on Days -7, -5, 3, 12 and at 0.5 and 4 hours post dosing on Day 1.

The samples will be sent to Aronora and will be stored for up to 5 years following the last dosing for future analysis (e.g., xisomab 3G3 levels and or urea).

8. SAFETY

All case report form (CRF) data will be listed by subject and chronologically by assessment time points. This will include rechecks, unscheduled assessments, and early termination.

Applicable continuous variables will be summarized using n, arithmetic mean, SD, minimum, median, and maximum. Data from subjects who received the placebo treatment will be pooled across cohorts.

The level of precision will be presented as follows: minimum/maximum in the same precision as in the database, mean/median in one more precision level than minimum/maximum, SD in one more precision level than mean/median, and n will be presented as an integer. Percentages of total frequency counts, if presented, will be reported as whole numbers.

Where individual data points are missing because of dropouts or other reasons, the data will be summarized based on reduced denominators.

8.1 Subject Discontinuation

Subjects will be summarized by number of subjects dosed, completed, and discontinued the study with discontinuation reasons by treatment (two dose levels and pooled placebo and study overall.

8.2 Demographics

Descriptive statistics will be calculated for continuous variables (age, weight, height, and body mass index) and frequency counts will be provided for categorical variables (race, ethnicity, and sex) by treatment and overall. Age will be derived from date of birth to date of first dosing.

8.3 Adverse Events

All adverse events (AEs) occurring during this clinical trial will be coded using the Medical Dictionary for Regulatory Activities (MedDRA®), Version 21.1.

All AEs captured in the database will be listed in by-subject data listings including verbatim term, coded term, treatment, severity, relationship to study medication, and action; however, only treatment-emergent AEs (TEAEs) will be summarized.

A TEAE is defined as an AE that is starting or worsening at the time of or after study drug administration. Each TEAE will be attributed to a treatment based on the onset date and time of the AE. If the onset time of an AE is missing and the onset date is the same as the treatment dosing date, then the AE will be considered treatment emergent. If the onset date of an AE is missing, then the AE will be considered treatment emergent.

TEAEs will be tabulated by System Organ Class (SOC) and Preferred Term. Summary tables will include number of subjects reporting the AE and as percent of number of subjects dosed by treatment and overall. The number of AEs will be tabulated in a similar manner. Tables which tabulate the number of TEAEs by severity and relationship to study treatment will also be included.

Serious adverse events (SAEs), if present, will also be listed. Applicable narratives will be included in the CSR.

8.4 Clinical Laboratory Tests (Serum Chemistry, Hematology, Coagulation and Urinalysis)

Safety serum chemistry, hematology and urinalysis tests are performed at Screening, Day -8 check-in, Day 1 predose, Day 6 and Day 12. For anuric patients, urinalysis may not be performed. Platelet count are collected at start and end of HD on Days -7, -5, -3, 1, 3, 5 and 12 and on Day 6. Platelet count are collected at start and end of HD on Days -7, -5, -3, 1, 3, 5 and 12 and Day 6. aPTT results are presented and discussed in the PD Section 7.2.

Out-of-range values and clinically significant results will be listed.

For all numeric laboratory values, descriptive statistics will be presented for each laboratory test by assessment time point and treatment. Change from baseline will be summarized in a similar manner. Baseline is defined as the result closest and prior to

dose which may include unscheduled results. This will typically be the result collected at predose on Day 1. Postdose unscheduled events or early termination results will not be included in summaries.

For each laboratory test, a shift table will be developed to compare the frequency of the results at baseline (above normal, normal, or below normal) with the respective postdose results.

Coagulation parameters and platelet count will be listed and presented together since they have the same timepoints. Urinalysis test results will be listed only.

8.5 Vital Signs

Vital signs tests (HR, BP, RR and T) will be assessed at Screening, Day -8 check-in, start of HD on Days -7, -5, -3, 1, 3, 5, 8, 10 and 12, 1 hour postdose on Day1, Day 6 discharge or early term and Day 12 follow-up.

Vital sign results will be summarized by dose level, pooled placebo, and time point. Change from baseline will be summarized in a similar way. Baseline is defined as the result closest and prior to the dose on Day 1, which may include unscheduled results, whichever is later. Postdose unscheduled events or early termination results will not be included in summaries.

8.6 Electrocardiogram

Safety ECGs (HR, PR, QRS, QT and Fridericia correction QTcF) will be assessed at Screening, Day -8 check-in, Day 1 predose, Day 6 (discharge or early term) and Day 12 follow-up.

ECG parameters will be summarized by dose level, pooled placebo, and time point. Change from baseline will be summarized in a similar way. Baseline is defined as the result closest and prior to the dose on Day 1, which may include unscheduled results, whichever is later. Postdose unscheduled events or early termination results will not be included in summaries.

The QTcF values that are > 450 ms and increase from baseline > 30 ms, will be flagged in the data listings.

8.7 Concomitant Medications

All concomitant medications recorded during the study will be coded with the WHO Dictionary Version September 2018, B3 and listed.

8.8 Physical Examination

Full physical examinations will be performed at Screening and Day -8 check-in and abbreviated physical examination will be performed on Days 1, 6 and 12. Abnormal findings will be reported as medical history or adverse events. All data found in the CRF will be listed.

8.9 Vascular Access Site Reaction

Vascular access site reaction will be assessed at predose on Day 1 and end of HD on Days 1, 3 and 5. Any new abnormal findings inconsistent with past skin injuries as expected in patient on chronic HD will be reported as AEs.

8.10 Bleeding Time

The time to clot (bleeding time) will be recorded following hemodialysis after the needle is removed from the vascular access site on Days -7, -5, -3, 1, 3, 5 and 12. Summary statistics will be calculated for time to clot by treatment and assessment timepoint.

8.11 Medical History

All medical and surgical histories recorded in the study will be coded with MedDRA®, Version 21.1. and listed.

8.12 Immunogenecity

Development of antibodies against the study drug will be evaluated by determining the anti-drug antibody (ADA) titer.

Blood samples will be collected from each subject for ADA detection prior to dosing on Day 1 and at the end of HD on Day 12. Immunogenicity testing will be done at Celerion, Lincoln, Nebraska.

Summary counts of positive and negative ADA detection will be presented by collection time and treatment.

9. SUMMARY OF CHANGES FROM PROTOCOL-PLANNED ANALYSIS

The length of HD was 3 hours in the protocol and should be approximately 4 hours. The samples collected for BUN and potassium will be at the end of dialysis (approximately 4 hours).

The analyses described in this SAP are aligned with those analyses described in the protocol.

10. SUMMARY TABLES AND FIGURES

Summary tables and figures are numbered following the International Conference on Harmonization (ICH) structure but may be renumbered as appropriate during the compilation of the tables and figures for the CSR. Note that all PK, PD, immunogenicity and Safety summary tables and figures will be generated using SAS®

Version 9.3 or higher and/or using Phoenix® WinNonlin® Version 7.0 or higher for summary PK TFLs, as appropriate.

10.1 In-text Summary Tables and Figures

The following is a list of table and figure titles that will be included in the text of the CSR. Tables and figures will be numbered appropriately during compilation of the CSR.

Section 10:

Table 10-1 Subject Disposition Summary

Section 11:

Table 11-1 Demographic Summary

Table 11-2 Summary of Plasma Xisomab 3G3 Pharmacokinetics Following a Single IV Infusion of 0.25 and 0.5 mg/kg Xisomab 3G3 (Pharmacokinetic Population)

Efficiency of HD:

Table 11-3 Summary of Difference Between Pre- and Post-dialysis BUN and URR – Days -7 to 12 (Safety Population)

Table 11-4 Summary of Difference Between Pre- and Post-dialysis Potassium – Days -7 toSummary 12 (Safety Population)

Table 11-5 Summary of Kt/V Values (Safety Population)

Drug Potency:

Table 11-6 Summary of Difference Between Pre- and Post-dialysis aPTT – Days -7 to 12 (Safety Population)

Table 11-7 Summary of Clotting in the Drip Chamber – Days -7 to 12 (Safety Population)

Table 11-8 Summary of Clotting in the Dialysis Filter – Days -7 to 12 (Safety Population)

Figures

Figure 11-1 Arithmetic Mean Plasma Xisomab 3G3 Concentration Versus Time Following a Single IV Infusion of 0.25 and 0.5 mg/kg Xisomab 3G3 (Linear Scale) (Pharmacokinetic Population)

Figure 11-2 Arithmetic Mean Pre- and Post-dialysis BUN Values – Days -7 to 12 (Linear Scale) (Safety Population)

Figure 11-3 Arithmetic Mean Pre- and Post-dialysis Potassium Values – Days -7 to 12 (Linear Scale) (Safety Population)

10.2 Section 14 Summary Tables and Figures

The following is a list of table and figure titles that will be included in Section 14 of the report. Table and figure titles may be re-numbered as appropriate during the compilation of the report.

14.1 Demographic Data Summary Tables

The following is a list of table and figure titles that will be included in Section 14 of the report. Table and figure titles may be renumbered as appropriate during the compilation of the report.

14.2 Pharmacokinetic and Pharmacodynamic Data Summary Tables and Figures

Pharmacokinetic Tables and Figures

14.2.1. Plasma Pharmacokinetic Xisomab 3G3 Tables and Figures

Pharmacodynamic/Immunogenicity Tables and Figures

14.2.2 BUN Tables and Figures

Table 14.2.2.1.3 Individual and Mean Difference Between Pre- and Post-dialysis BUN Values (unit) and URR – Days -7 to 12 – Placebo (Pooled) (Safety Population)

Programmer Note: ***For Tables 14.2.2.1.1 through 14.2.2.1.3, the difference will be calculated as follows: (Pre-dialysis – Post-dialysis).***

Figure 14.2.2.2.1 Arithmetic Mean Pre- and Post-dialysis BUN Values – Days -7 to 12 (Linear Scale) (Safety Population)

Figure 14.2.2.2.2 Arithmetic Mean (SD) Pre- and Post-dialysis BUN Values – Days -7 to 12 (Linear Scale) (Safety Population)

14.2.3 Potassium Tables and Figures

Table 14.2.3.1.1 Individual and Mean Difference Between Pre- and Post-dialysis Potassium Values (unit) – Days -7 to 12 – 0.25 mg/kg Xisomab 3G3 on Day 1 (Safety Population)

Table 14.2.3.1.2 Individual and Mean Difference Between Pre- and Post-dialysis Potassium Values (unit) – Days -7 to 12 – 0.5 mg/kg Xisomab 3G3 on Day 1 (Safety Population)

Table 14.2.3.1.3 Individual and Mean Difference Between Pre- and Post-dialysis Potassium Values (unit) – Days -7 to 12 – Placebo (Pooled) (Safety Population)

Programmer Note: ***For Tables 14.2.3.1.1 through 14.2.3.1.3, the difference will be calculated as follows: (Pre-dialysis – Post-dialysis).***

Figure 14.2.3.2.1 Arithmetic Mean Pre- and Post-dialysis Potassium Values – Days -7 to 12 (Linear Scale) (Safety Population)

Figure 14.2.3.2.2 Arithmetic Mean (SD) Pre- and Post-dialysis Potassium Values – Days -7 to 12 (Linear Scale) (Safety Population)

14.2.4 Kt/V Tables

Table 14.2.4.1.1 Individual and Mean Kt/V Values (unit) – 0.25 mg/kg Xisomab 3G3 on Day 1 (Safety Population)

Table 14.2.4.1.2 Individual and Mean Kt/V Values (unit) – 0.5 mg/kg Xisomab 3G3 on Day 1 (Safety Population)

Table 14.2.4.1.3 Individual and Mean Kt/V Values (unit) – Placebo (Pooled) (Safety Population)

14.2.5 aPTT Tables and Figures

Table 14.2.5.1.1 Individual and Mean aPTT Values (unit) During the Course of the Study (Days -7 to 12) and Following a Single IV

	Infusion of 0.25 mg/kg Xisomab 3G3 on Day 1 (Safety Population)
Table 14.2.5.1.2	Individual and Mean aPTT Values (unit) During the Course of the Study (Days -7 to 12) and Following a Single IV Infusion of 0.5 mg/kg Xisomab 3G3 on Day 1 (Safety Population)
Table 14.2.5.1.3	Individual and Mean aPTT Values (unit) During the Course of the Study (Days -7 to 12) and Following a Single IV Infusion of Placebo (Pooled) on Day 1 (Safety Population)
Table 14.2.5.1.4	Individual and Mean aPTT Change From Baseline Values (unit) Following a Single IV Infusion of 0.25 mg/kg Xisomab 3G3 on Day 1 (Safety Population)
Table 14.2.5.1.5	Individual and Mean aPTT Change From Baseline Values (unit) Following a Single IV Infusion of 0.5 mg/kg Xisomab 3G3 on Day 1 (Safety Population)
Table 14.2.5.1.6	Individual and Mean aPTT Change From Baseline Values (unit) Following a Single IV Infusion of Placebo (Pooled) – Day 1 (Safety Population)
Programmer Note:	***For Tables 14.2.5.1.4 through 14.2.5.1.6, aPTT baseline will be the average of all pre-dialysis aPTT value on Days -7, -5, -3 and 1, and the change from baseline will be calculated as follows: (post-dialysis/baseline).***
Table 14.2.5.1.7	Individual and Mean Difference Between Pre- and Post-dialysis aPTT Values (unit) – Days -7 to 12 – 0.25 mg/kg Xisomab 3G3 on Day 1 (Safety Population)
Table 14.2.5.1.8	Individual and Mean Difference Between Pre- and Post-dialysis aPTT Values (unit) – Days -7 to 12 – 0.5 mg/kg Xisomab 3G3 on Day 1 (Safety Population)
Table 14.2.5.1.9	Individual and Mean Difference Between Pre- and Post-dialysis aPTT Values (unit) – Days -7 to 12 – Placebo (Pooled) (Safety Population)
Programmer Note:	***For Tables 14.2.5.1.7 through 14.2.5.1.9, the fold change will be calculated by follows: (post-dialysis/pre-dialysis aPTT values) for each day.***
Figure 14.2.5.2.1	Arithmetic Mean aPPT Values Versus Time Following a Single IV Infusion of 0.25 and 0.5 mg/kg Xisomab 3G3 and Placebo (Pooled) – Day 1 (Linear Scale) (Safety Population)

Table 14.3.1.2 Treatment-emergent Adverse Event Frequency by Treatment – Number of Adverse Events (% of Total Adverse Events) (Safety Population)

Table 14.3.1.3 Treatment-emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Drug – Number of Adverse Events (Safety Population)

14.3.2 Listings of Deaths, other Serious and Significant Adverse Events

Table 14.3.2.1 Serious Adverse Events (Safety Population)

<if no serious adverse event occurred, a statement 'No serious adverse event is reported'>

14.3.3 Narratives of Deaths, other Serious and Certain other Significant Adverse Events

14.3.4 Abnormal Laboratory Value Listing (each patient)

Table 14.3.4.1 Out-of-Range Values and Recheck Results – Serum Chemistry (Safety Population)

Table 14.3.4.2 Out-of-Range Values and Recheck Results – Hematology/Coagulation (Safety Population)

Table 14.3.4.3 Out-of-Range Values and Recheck Results – Urinalysis (Safety Population)

14.3.5 Displays of Other Laboratory, Vital Signs, Electrocardiogram, Physical Examination, and Other Safety Data

Table 14.3.5.1 Clinical Laboratory Summary and Change from Baseline – Serum Chemistry (Safety Population)

Table 14.3.5.2 Clinical Laboratory Shift from Baseline – Serum Chemistry (Safety Population)

Table 14.3.5.3 Clinical Laboratory Summary and Change from Baseline – Hematology (Safety Population)

Table 14.3.5.4 Clinical Laboratory Shift from Baseline – Hematology (Safety Population)

Table 14.3.5.5 Clinical Laboratory Summary and Change from Baseline – Coagulation and Platelet Count (Safety Population)

Table 14.3.5.6 Clinical Laboratory Shift from Baseline – Coagulation and Platelet Count (Safety Population)

Table 14.3.5.7 Vital Sign Summary and Change from Baseline (Safety Population)

Table 14.3.5.8 12-Lead Electrocardiogram Summary and Change from Baseline (Safety Population)

Table 14.3.5.9 Frequency of Immunogenicity - ADA Titer (Safety Population)

10.3 Section 16 Data Listings

Data listings are numbered following the ICH structure but may be renumbered as appropriate during the compilation of the TFLs for the CSR. The following is a list of appendix numbers and titles that will be included as data listings:

16.1 Study Information

Appendix 16.1.9 Statistical Methods

Appendix 16.1.10.1 Clinical Laboratory Reference Ranges

16.2 Subject Data Listings

16.2.1 Subject Discontinuation

Appendix 16.2.1 Study Completion/Early Termination (Safety Population)

16.2.2 Protocol Deviations

Appendix 16.2.2 Protocol Deviations

16.2.3 Subjects Excluded from Pharmacokinetic/Pharmcodynamic Analyses

Appendix 16.2.3 Subjects Excluded from Pharmacokinetic/Pharmacodynamic Analyses

<Note: Appendices 16.2.2 and 16.2.3 are generated in MS Word for inclusion in the study report.>

16.2.4 Demographic Data

Appendix 16.2.4.1 Demographics (Safety Population)
Appendix 16.2.4.2 Physical Examination (Safety Population)
Appendix 16.2.4.3 Medical and Surgical History (Safety Population)
Appendix 16.2.4.4 Alcohol Screen (Safety Population)
Appendix 16.2.4.5 Drug Screen (Safety Population)

16.2.5 Compliance and/or Drug Concentration Data

Appendix 16.2.5.1	Subject Eligibility (Safety Population)
Appendix 16.2.5.2	Subject Eligibility at Check-In (Safety Population)
Appendix 16.2.5.3	Test Compound Administration (Safety Population)
Appendix 16.2.5.4	Blood Draw Times for Free xisomab 3G3 PK (Safety Population)
Appendix 16.2.5.5	Blood Draw Times for Free xisomab 3G3 PD (aPTT) (Safety Population)
Appendix 16.2.5.6	Blood Draw Times for Immunogenicity (Safety Population)
Appendix 16.2.5.7	Blood Draw Times for Dialysate Analysis for Kt/V and URR (Safety Population)
Appendix 16.2.5.8.1	Dialyzer Assessment (I of V) (Safety Population)
Appendix 16.2.5.8.2	Dialyzer Assessment (II of V) (Safety Population)
Appendix 16.2.5.8.3	Dialyzer Assessment (III of V) – (Safety Population Number and Volume of Saline Flushes)
Appendix 16.2.5.8.4	Dialyzer Assessment (IV of V) – Clotting in Drip Chamber (Safety Population)
Appendix 16.2.5.8.5	Dialyzer Assessment (V of V) – Clotting in Dialysis Filter (Safety Population)
Appendix 16.2.5.9	Non-Study Procedures (Safety Population)
Appendix 16.2.5.10	Prior and Concomitant Medications (Safety Population)

16.2.6 Individual Pharmacokinetic Response Data

Individual Xisomab 3G3 Figures

Appendix 16.2.6.1.1	Individual Plasma Xisomab 3G3 Concentrations Versus Time Profiles Following a Single IV Infusion of 0.25 mg/kg Xisomab 3G3 (Linear and Semi-Log Scale) for <Subject #>
Appendix 16.2.6.1.2	Individual Plasma Xisomab 3G3 Concentrations Versus Time Profiles Following a Single IV Infusion of 0.5 mg/kg Xisomab 3G3 (Linear and Semi-Log Scale) for <Subject #>
Appendix 16.2.6.2.1	Individual aPTT Values Versus Time Profiles During the Course of the Study (Linear Scale) for <Subject #>

16.2.7 Adverse Events Listings

Appendix 16.2.7.1.1 Adverse Events (I of II) (Safety Population)

Appendix 16.2.7.1.2 Adverse Events (II of II) (Safety Population)

Appendix 16.2.7.2 Adverse Event Preferred Term Classification (Safety Population)

16.2.8 Listings of Individual Laboratory Measurements and Other Safety Observations

Appendix 16.2.8.1.1 Clinical Laboratory Report - Serum Chemistry (Safety Population)

Appendix 16.2.8.1.2 Clinical Laboratory Report - Hematology (Safety Population)

Appendix 16.2.8.1.3 Clinical Laboratory Report – Coagulation and Platelet Count (Safety Population)

Appendix 16.2.8.1.4 Clinical Laboratory Report - Urinalysis (Safety Population)

Appendix 16.2.8.1.5 Clinical Laboratory Report – Additional Tests (Safety Population)

Appendix 16.2.8.1.6 Clinical Laboratory Report - Comments (Safety Population)

Appendix 16.2.8.2 Vital Signs (Safety Population)

Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Appendix 16.2.8.4 Immunogenicity ADA Titer (Safety Population)

11. TABLE AND FIGURE SHELLS

The following table shells provide a framework for the display of data from this study. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this study, but are intended to show the general layout of the tables that will be presented and included in the final report. Unless otherwise noted, all tables will be presented in Times New Roman font size 8. These tables will be generated of the Celerion ADaM Version 2.1 data structure.

11.1 In-text Summary Tables Shells

In-text Table 10-1 will be in the following format:

Table 10-1 Subject Disposition Summary

Table 10-1 Subject Disposition Summary (Safety Population)

	Dose Level of xisomab 3G3		Pooled	
Disposition	**0.25 mg/kg**	**0.5 mg/kg**	**Placebo**	**Overall**
Dosed	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Completed	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued	X (XX%)	X (XX%)	X (XX%)	X (XX%)
<Reason1>	X (XX%)	X (XX%)	X (XX%)	X (XX%)
<Reason2>	X (XX%)	X (XX%)	X (XX%)	X (XX%)

Source: Table 14.1.1
Program: /CAXXXXX/sas_prg/stsas/intext/t_disp.sas DDMMMYYYY HH:MM

In-text Table 11-1 will be in the following format:

Table 11-1 Demographic Summary

Trait	Category/ Statistics	Dose Level of xisomab 3G3		Pooled Placebo	Overall
		0.25 mg/kg	0.5 mg/kg		
Sex	Male	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	Female	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Race	Asian	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	Black or African American	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	White	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Ethnicity	Hispanic or Latino	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	Not Hispanic or Latino	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Age* (yrs)	n	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX
Weight (kg)	n	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX

*Age is calculated at the time of first dosing.
BMI = Body mass index

Source: Table 14.1.2
Program: /CAXXXXX/sas_prg/stsas/intexttest/t_dem.sas DDMMMYYYY HH:MM

Programmer note: also include height and BMI

In-text Table 11-2 will be in the following format:

Table 11-2: Summary of Plasma Xisomab 3G3 Pharmacokinetics Following a Single IV Infusion of 0.25 and 0.5 mg/kg Xisomab 3G3 (Pharmacokinetic Population)

Pharmacokinetic Parameters	Single IV Infusion of 0.25 mg/kg xisomab 3G3	Single IV Infusion of 0.5 mg/kg xisomab 3G3
Param1 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Param2 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Param3 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Param4 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
AUCs and Cmax values are presented as geometric mean and geometric CV%, when available. Tmax values are presented as median (minimum, maximum). Other parameters are presented as arithmetic mean (± SD), or just mean when SD is not available. Source: Tables 14.2.1.4 through 14.2.1.5		

Notes for Generating the Actual Table:

Presentation of Data:

- The following PK parameters will be presented in the following order and with following units: AUC0-t <ng*hr/mL>, AUC0-inf <ng*hr/mL>, AUC%extrap <%>, Cmax <ng/mL>, Tmax <hr>, Kel <1/hr>, t1/2 <hr>, CL <L/hr>, Vss <L>
- n will be presented as an integer (with no decimal);
- Summary statistics will be presented with same precision as defined in post-text shells
- Internal template ITPar1

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

Table 11-3 Summary of Difference Between Pre- and Post-dialysis BUN and URR – Days -7 to 12 (Safety Population)

Mean Blood Urea Nitrogen (Reference Range xx – xx <units>) and URR (Reference Range xx – xx <%>)												
Time Point	Treatments											
	Single IV Infusion of 0.25 mg/kg xisomab 3G3				Single IV Infusion of 0.5 mg/kg xisomab 3G3				Placebo (Pooled)			
	Pre-dialysis (Unit) [n=xx]	Post-dialysis (Unit) [n=xx]	Difference (Unit) [n=xx]	URR (%) (Unit) [n=xx]	Pre-dialysis (Unit) [n=xx]	Post-dialysis (Unit) [n=xx]	Difference (Unit) [n=xx]	URR (%) (Unit) [n=xx]	Pre-dialysis (Unit) [n=xx]	Post-dialysis (Unit) [n=xx]	Difference (Unit) [n=xx]	URR (%) (Unit) [n=xx]
Day -7	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X
Day -5	XXX.X[a]	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X
Day -3	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X
Day 1*	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X
Day 3	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X
Day 5	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X
Day 12	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X	XXX.X	XXX.X	XX.X	XX.X

Difference = Pre-dialysis - Post-dialysis
[a]-n = xx
URR = (1-(post-dialysis BUN/ pre-dialysis BUN))*100
* - Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1
Values will be presented as arithmetic mean

Source: Tables 14.2.2.1.1 through 14.2.2.1.3
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

Notes for Generating the Actual Table:

- n will be presented as an integer (with no decimal);
- Summary statistics will be presented with same precision as defined in post-text shells
- Internal template ITPar1, with the following changes: n will be presented in the column title with more additional columns to be created.

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

Table 11-4 will be in the following format:

Table 11-4 Summary of Difference Between Pre- and Post-dialysis Potassium – Days -7 to 12 (Safety Population)

Mean Potassium (Reference Range xx – xx <units>)									
Time Point	Treatments								
	Single IV Infusion of 0.25 mg/kg xisomab 3G3			Single IV Infusion of 0.5 mg/kg xisomab 3G3			Placebo (Pooled)		
	Pre-dialysis (Unit) [n=xx]	Post-dialysis (Unit) [n=xx]	Difference (Unit) [n=xx]	Pre-dialysis (Unit) [n=xx]	Post-dialysis (Unit) [n=xx]	Difference (Unit) [n=xx]	Pre-dialysis (Unit) [n=xx]	Post-dialysis (Unit) [n=xx]	Difference (Unit) [n=xx]
Day -7	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day -5	XXX.X	XXX.X [a]	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day -3	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 1*	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 3	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 5	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 6	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 12	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X

Difference = Pre-dialysis - Post-dialysis
[a]-n = xx
* - Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1
Values will be presented as arithmetic mean

Source: Tables 14.2.3.1.1 through 14.2.3.1.3
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

Notes for Generating the Actual Table:

- n will be presented as an integer (with no decimal);
- Summary statistics will be presented with same precision as defined in post-text shells
- Internal template ITPar1, with the following changes: n will be presented in the column title with additional columns to be created.

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

Tables 11-6, 12-2 through 12-4 will be in the following format:

Table 11-6 Summary of Difference Between Pre- and Post-dialysis aPTT – Days -7 to 12 (Safety Population)

Mean aPTT (Reference Range xx – xx <units>)									
Time Point	Treatments								
	Single IV Infusion of 0.25 mg/kg xisomab 3G3			Single IV Infusion of 0.5 mg/kg xisomab 3G3			Placebo (Pooled)		
	Pre-dialysis (Unit) [n=xx]	Post-dialysis (Unit) [n=xx]	Fold Change (Unit) [n=xx]	Pre-dialysis (Unit) [n=xx]	Post-dialysis (Unit) [n=xx]	Fold Change (Unit) [n=xx]	Pre-dialysis (Unit) [n=xx]	Post-dialysis (Unit) [n=xx]	Fold Change (Unit) [n=xx]
Day -7	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day -5	XXX.X	XXX.X [a]	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day -3	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 1*	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 3	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 5	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 6	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X
Day 12	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X	XXX.X	XXX.X	XX.X

Fold Change = Post-dialysis/Pre-dialysis
[a]-n = xx
* - Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1
Values will be presented as arithmetic mean

Source: Tables 14.2.5.1.7 through 14.2.5.1.9
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

Notes for Generating the Actual Table:

- n will be presented as an integer (with no decimal);
- Summary statistics will be presented with same precision as defined in post-text shells
- Internal template ITPar1, with the following changes: n will be presented in the column title with additional columns to be created.

For Table 12-2 through 12-5 the source tables will be 14.3.5.5

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

Table 11-5 Summary of Kt/V Values (Safety Population)

Single pool Kt/V															
Time Point	Treatments														
	Single IV Infusion of 0.25 mg/kg xisomab 3G3					Single IV Infusion of 0.5 mg/kg xisomab 3G3					Placebo (Pooled)				
	R (unit) [n=xx]	t (unit) [n=xx]	UF (unit) [n=xx]	Wt (unit) [n=xx]	Kt/V (unit) [n=xx]	R (unit) [n=xx]	t (unit) [n=xx]	UF (unit) [n=xx]	Wt (unit) [n=xx]	Kt/V (unit) [n=xx]	R (unit) [n=xx]	t (unit) [n=xx]	UF (unit) [n=xx]	Wt (unit) [n=xx]	Kt/V (unit) [n=xx]
Day -7	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
Day -5	XX.X	XX.X	XX.X	XX.X[a]	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Day -3	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
Day 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	XX.X	XX.X	XX.X
Day 3	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
Day 5	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
Day 12	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

[a]-n=xx
* - Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1
Values will be presented as arithmetic mean

R= post-dialysis BUN/pre-dialysis BUN))*100
t = Time of HD
UF = Pre-dialysis Weight – Post-dialysis Weight
Wt = Post-dialysis weight of patient
$Kt/V = \ln(R - (0.008 \times t)) + (4 - (3.5 \times R)) \times \frac{UF}{Wt}$

Source: Tables 14.2.4.1.1 through 14.2.4.1.3
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

Notes for Generating the Actual Table:

- n will be presented as an integer (with no decimal);
- Summary statistics will be presented with same precision as defined in post-text shells
- Internal template ITPar1, with the following changes: n will be presented in the column title with more additional columns to be created.

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

Table 11-7 Summary of Clotting in the Drip Chamber – Days -7 to 12 (Safety Population)

Clotting in the Drip Chamber																															
Time Point	Treatments																														
	Single IV Infusion of 0.25 mg/kg xisomab 3G3										Single IV Infusion of 0.25 mg/kg xisomab 3G3										Placebo (Pooled)									
	Category 2 Hours after Start of Dialysis [n=xx]					Category Post-dialysis [n=xx]					Category 2 Hours after Start of Dialysis [n=xx]					Category Post-dialysis [n=xx]					Category 2 Hours after Start of Dialysis [n=xx]					Category Post-dialysis [n=xx]				
	1	2	3a	3b	4	1	2	3a	3b	4	1	2	3a	3b	4	1	2	3a	3b	4	1	2	3a	3b	4	1	2	3a	3b	4
Day -7	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day -5	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day -3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day 1*	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day 3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day 5	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day 12	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day x																														

[a]-n=xx
* - Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1
Values will be presented as arithmetic mean

Source: Table 14.2.6.1
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

Notes for Generating the Actual Table:

- n will be presented as an integer (with no decimal);
- Summary statistics will be presented with same precision as defined in post-text shells
- Internal template ITPar1, with the following changes: n will be presented in the column title with more additional columns to be created.

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

Table 11-8 Summary of Clotting in the Dialysis Filter – Days -7 to 12 (Safety Population)

Clotting in Dialysis Filter															
Time Point	Treatments														
	Single IV Infusion of 0.25 mg/kg xisomab 3G3					Single IV Infusion of 0.25 mg/kg xisomab 3G3					Placebo (Pooled)				
	Category Post-dialysis [n=xx]					Category Post-dialysis [n=xx]					Category Post-dialysis [n=xx]				
	1	2	3a	3b	4	1	2	3a	3b	4	1	2	3a	3b	4
Day -7	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day -5	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day 1*	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day 3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day 5	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day 12	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day x															

[a]-n=xx
* - Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1
Values will be presented as arithmetic mean

Source: Table 14.2.7.1
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

Notes for Generating the Actual Table:

- n will be presented as an integer (with no decimal);
- Summary statistics will be presented with same precision as defined in post-text shells
- Internal template ITPar1, with the following changes: n will be presented in the column title with more additional columns to be created.

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

In-text Table 12-1 will be in the following format:

Table 12-1 Adverse Event Frequency by Treatment - Number of Subjects Reporting the Event (% of Subjects Dosed)

Adverse Event*	Dose Level of xisomab 3G3		Pooled Placebo	Overall
	0.25 mg/kg	0.5 mg/kg		
Number of Subjects With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Number of Subjects Without TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
System Organ Class 1	X (X%)	X (X%)	X (X%)	X (X%)
Preferred Term 1	X (X%)	X (X%)	X (X%)	X (X%)
Preferred Term 2	X (X%)	X (X%)	X (X%)	X (X%)
System Organ Class 2	X (X%)	X (X%)	X (X%)	X (X%)
Preferred Term 1	X (X%)	X (X%)	X (X%)	X (X%)
Preferred Term 2	X (X%)	X (X%)	X (X%)	X (X%)

*Adverse events are classified according to MedDRA Version 21.1.
TEAEs = Treatment-emergent adverse events
If a subject has 2 or more clinical adverse events, the subject is counted only once within a category. The same subject may appear in different categories.

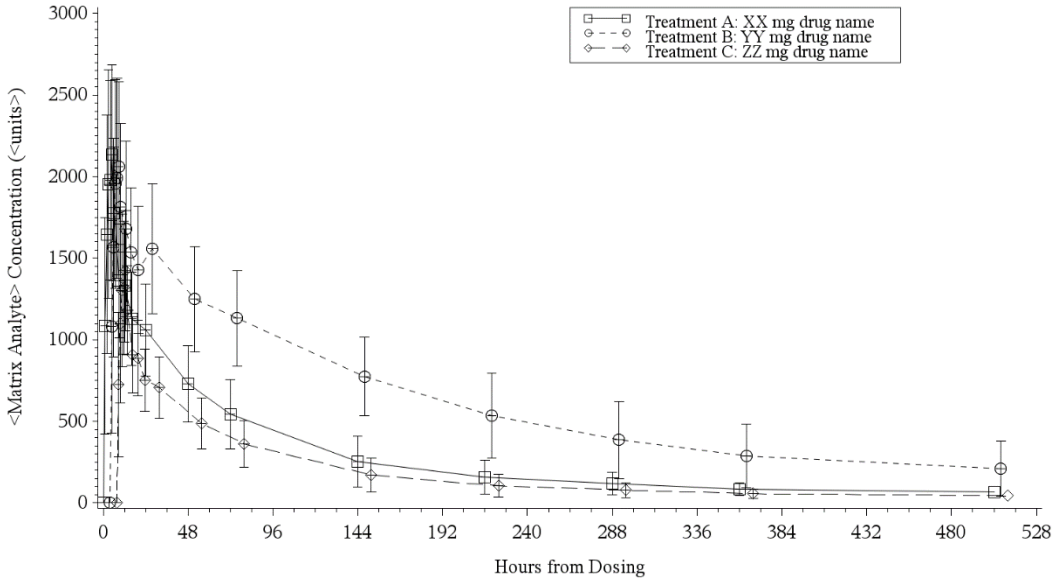
Source: Table 14.3.1.1
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

11.2 Figures Shells

In-text Figures 11-1, 11-4 through 11-6, post-text Figures 14.2.1.2.1 through 14.2.1.2.3, 14.2.5.2.1 through 14.2.5.2.6 and Individual Listings in 16.2.6.1.1, 16.2.6.1.2, and 16.2.6.2.1 will be in the following format:

Figure 14.2.1.2.1

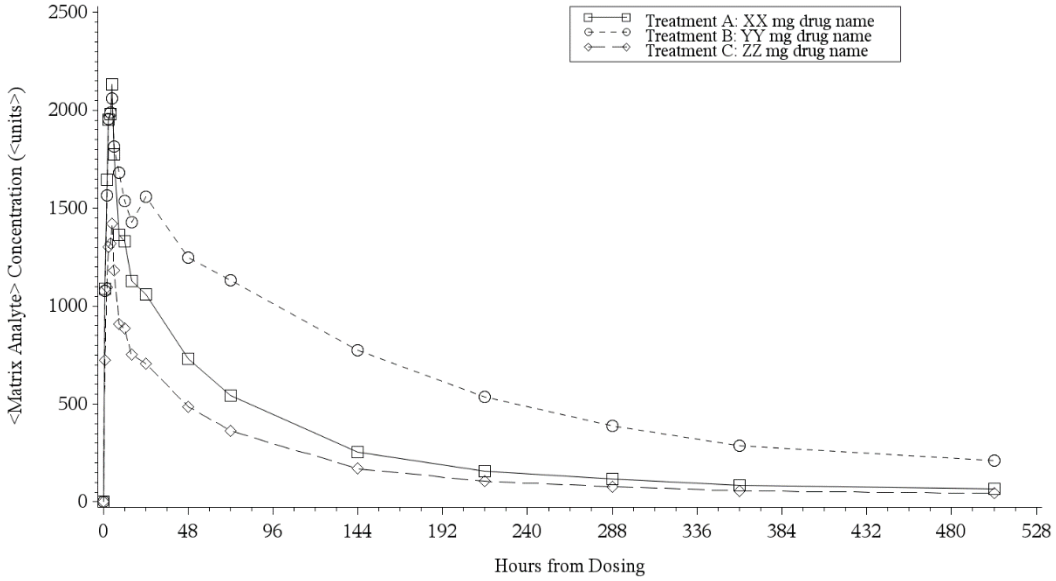
Arithmetic Mean (SD) Plasma Xisomab 3G3 Concentration Versus Time Profiles Following a Single IV Infusion of 0.25 and 0.5 mg/kg Xisomab 3G3 (Linear Scale) (Pharmacokinetic Population)



Treatments B and C are shifted to the right for ease of reading
Program: /CAXXXXX/sas_prg/pksas/adam_meangraph.sas DDMMMYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/meangraph.sas DDMMMYYY HH:MM

Figure 14.2.1.2.2

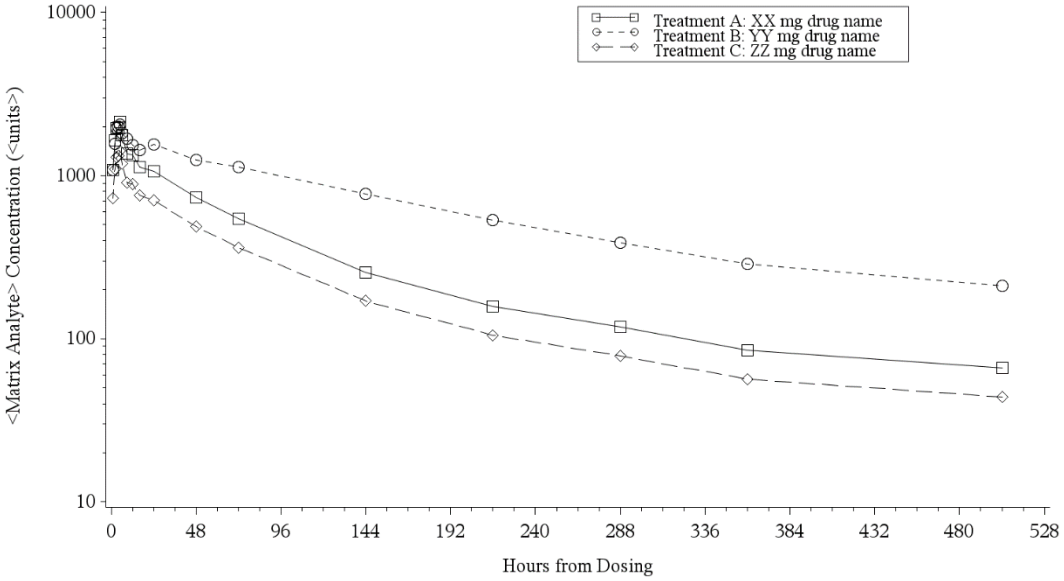
Arithmetic Mean Plasma Xisomab 3G3 Concentration Versus Time Profiles Following a Single IV Infusion of 0.25 and 0.5 mg/kg Xisomab 3G3 (Linear Scale) (Pharmacokinetic Population)



Program: /CAXXXXX/sas_prg/pksas/adam_meangraph.sas DDMMMYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/meangraph.sas DDMMMYYY HH:MM

Figure 14.2.1.2.3

Arithmetic Mean Plasma Xisomab 3G3 Concentration Versus Time Profiles Following a Single IV Infusion of 0.25 and 0.5 mg/kg Xisomab 3G3 (Semi-Log Scale) (Pharmacokinetic Population)



Program: /CAXXXXX/sas_prg/pksas/adam_meangraph.sas DDMMMYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/meangraph.sas DDMMMYYY HH:MM

Notes for Generating the Actual Mean Figure:

- Figures 11-1, 14.2.1.2.1 through 14.2.1.2.3
  - y-axis: Plasma Xisomab 3G3 Concentration (ng/mL)
  - X-axis: Hours From Start of Infusion
- Figures 11-4 and 11-5, 14.2.5.2.1 through 14.2.5.2.4
  - y-axis: Arithmetic Mean aPTT (sec)
  - X-axis: Hours From Start of Infusion
- Figures 11-6, 14.2.5.2.5 and 14.2.5.2.6
  - y-axis: aPTT Mean Change from Baseline (sec)
  - X-axis: Hours From Start of Infusion

Figure Legend: Use the Short Description as presented in Section 5.

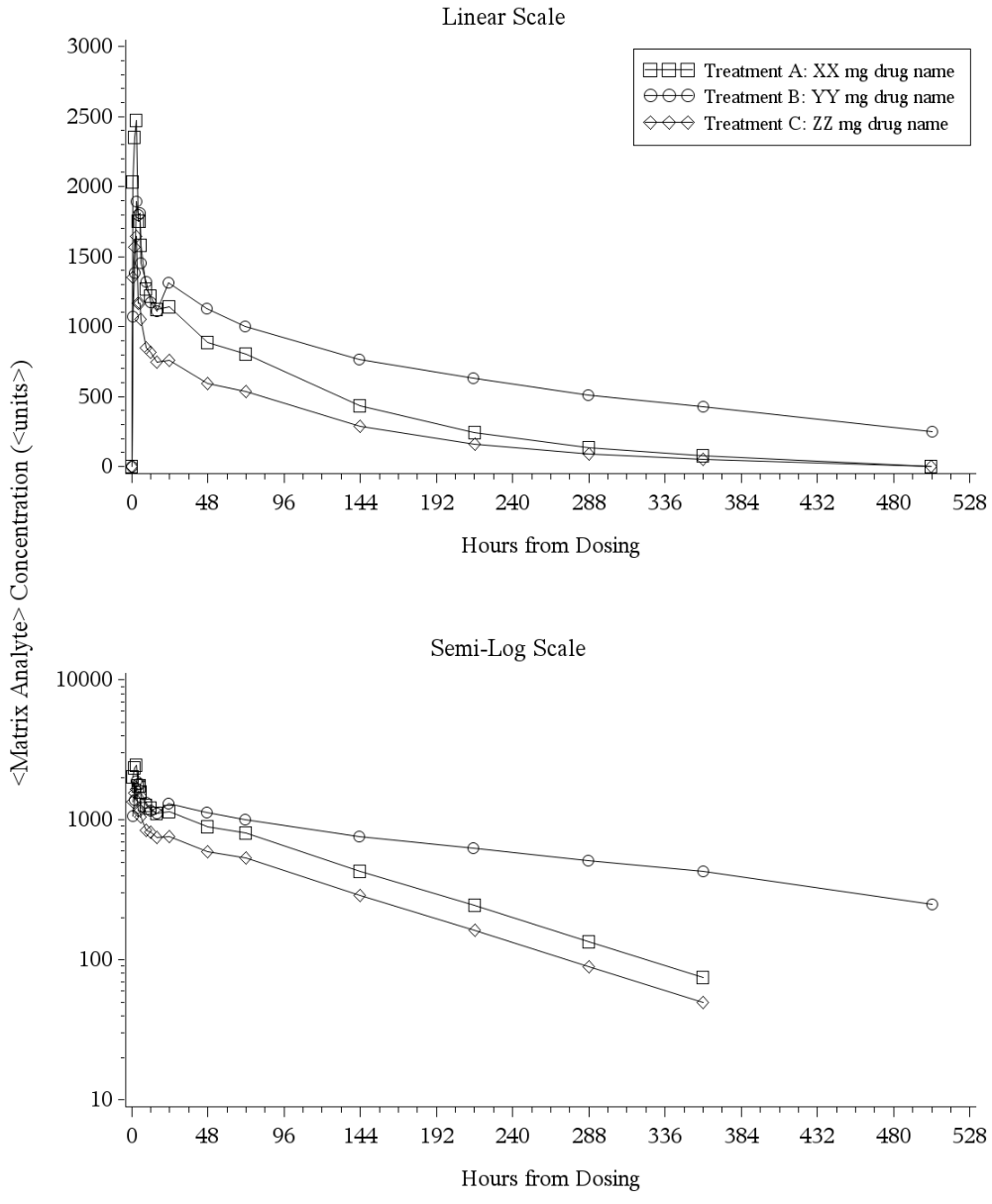
Program: /CAXXXXX/sas_prg/pksas/meangraph.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_meangraph.sas DDMMMYYYY HH:MM

Figures 11-2, 11-3, 11-7, 14.2.2.2.1, 14.2.2.2.2, 14.2.3.2.1, 14.2.3.2.2, 14.2.5.2.7, and 14.2.5.2.8 will be listed as per the above formats with connecting the mean results between the pre- and post-dialysis results within the same day but without connecting the values between days.

- y-axis: <aPTT, Bun, potassium> (unit)
- X-axis: Day

Figures in Appendices 16.2.6.1 and 16.2.6.2 will be in the following format:

Appendix 16.2.6.1.1
Individual Plasma Xisomab 3G3 Concentrations Versus Time Profiles Following a Single IV Infusion of <X> mg/kg Xisomab 3G3 (Linear and Semi-Log Scale) for Subject <#>



Program: /CAXXXXX/sas_prg/pksas/adam_indgraph.sas DDMMMYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/indgraph-all.sas DDMMMYYY HH:MM

Notes for Generating the Actual Individual Figure:

- Appendix 16.2.6.1
  - y-axis: Arithmetic Mean aPTT (sec)
  - X-axis: Hours From Start of Infusion

- Appendix 16.2.6.2
  - y-axis: Plasma Xisomab 3G3 Concentration (ng/mL)
  - X-axis: Hours From Start of Infusion

Figure Legend: Use the Short Description as presented in Section 5.

Program: /CAXXXXX/sas_prg/pksas/indgraph-all.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_indgraph.sas DDMMMYYYY HH:MM

11.3 Section 14 Summary Tables Shells

Table 14.1.1 Subject Disposition Summary (Safety Population)

	Dose Level of Xisomab 3G3			
Disposition	0.25 mg/kg	0.5 mg/kg	Pooled Placebo	Overall
Dosed	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Completed	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Discontinued	X (XX%)	X (XX%)	X (XX%)	X (XX%)
<Reason 1>	X (XX%)	X (XX%)	X (XX%)	X (XX%)
<Reason 2>	X (XX%)	X (XX%)	X (XX%)	X (XX%)

Program: /CAXXXXX/sas_prg/stsas/tab PROGRAMNAME.sas DDMMMYYYY HH:MM

Table 14.1.2 Summary of Demographics (Safety Population)

Trait	Category/ Statistics	Dose Level of Xisomab 3G3		Pooled Placebo	Overall
		0.25 mg/kg	0.5 mg/kg		
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black or African American	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ethnicity	Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age* (yrs)	n	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX
Weight (kg)	n	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX

Programmer Note: This is just a mock table shell. Please use the race categories listed in the CRF. Please also include Height (cm) and BMI (kg/m2).

Note: *Age is calculated at the time of first dosing.

Program: /CAXXXXX/sas_prg/stsas/tab PROGRAMNAME.sas DDMMMYYYY HH:MM

Tables 14.2.1.1.1 through 14.2.1.1.3, 14.2.5.1.1 through 14.2.5.1.6 will be in the following format:

Table 14.2.1.1.1 Plasma Xisomab 3G3 Concentrations (ng/mL) Following a Single IV Infusion of 0.25 mg/kg Xisomab 3G3 (Pharmacokinetic Population)

Subject	Sample Times (hr)								
Number	Predose	XX	XX	XX	XX	XX	XX	XX	XX
X	BLQ	XX	XX	XX	XX	XX	XX	XX	XX
X	BLQ	XX	XX	XX	XX	XX	XX	XX	XX
X	BLQ	XX	XX	XX	XX	XX	XX	XX	XX
n	XX	XX	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%	.	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX

For the calculation of summary statistics, values that are below the limit of quantitation (BLQ) of <X> ng/mL are treated as 0 before the first quantifiable concentration and as missing elsewhere.
. = Value missing or not reportable.

Notes for Generating the Actual Table:

- Please use CPConc1 template
- Per study design needs, the following changes are made to this table relative to Celerion standard: columns <Treatment Sequence> and <Study Period> will be removed.
- Concentrations will be presented to the same precision as in the bio data.
- aPTT values will be presented to the same precision as in the clinical laboratory data.
- Summary statistics presentation with respect to the precision of the bio data or clinical laboratory data: n = integer; Mean and Median +1; SD and SEM +2, Minimum and Maximum +0, CV% to 1 decimal
- PK Time points are: predose (hour 0) and 0.167, 0.5, 1, 2, 3, 4, 6, 8, 12, 16, 24, 48, 96, 120, 144, and 192 hours postdose (additional time points might be added depending on the conduct of the study)
- For Tables 14.2.5.1.1 through 14.2.5.1.3, aPTT values will be reported during the course of the study from Days -7 through 12 with adding "Day" above the "Sampling Time".
- For Tables 14.2.5.1.3 and 14.2.5.1.6, there will be no summary statistics

Program: /CAXXXXX/sas_prg/pksas/pk-conc-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/pk-conc-tables-sig.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_conc.sas DDMMMYYYY HH:MM

Tables 14.2.1.1.4 and 14.2.1.1.5 will be in the following format:

Table 14.2.1.1.4 Plasma Xisomab 3G3 Pharmacokinetic Parameters Following a Single IV Infusion of 0.25 mg/kg Xisomab 3G3 (Pharmacokinetic Population)

	Parameters					
Subject Number	param1 (units)	param2 (units)	param3 (units)	param4 (units)	param5 (units)	param6 (units)
X	XXX	X.XX	XXX	XXX	XX.X	X.XXX
X	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
X	XXX	X.XX	XXX	XXX	XX.X	X.XXX
X	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
X	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
X	X.XX	X.XX	XXX	XXX	XX.X	X.XXX
X	XXX	X.XX	XXX	XXX	XX.X	X.XXX
n	XX	XX	XX	XX	XX	XX
Mean	XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
Median	XX.XX	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Maximum	XXX	X.XX	XXX	XXX	XX.X	X.XXX
Geom Mean	XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Geom CV%	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

. = Value missing or not reportable.

Notes for Generating the Actual Table:

- Please use CPPar1 template
- Per study design needs, the following changes are made to this table relative to Celerion standard: columns <Treatment Sequence> and <Study Period> will be removed.
- PK Parameters will be presented in the following order and with following units: AUC0-t <ng*hr/mL>, AUC0-inf <ng*hr/mL>, AUC%extrap <%>, Cmax <ng/mL>, Tmax <hr>, Kel <1/hr>, T1/2 <hr>, CL <L/hr>, Vss <L>
- n will be presented as an integer (with no decimal);
- Exposure parameters (i.e. AUCs, Cmax, Vss, CL) will be presented with, at maximum, the precision of the bio data, and, at minimum, 3 significant figures (to be determined by the PKist once bio data are received).
    - Summary statistics will be presented with respect to the precision of the bio data: Mean, Median, and Geom Mean = +1; SD and SEM = +2, Minimum and Maximum = +0.
- Time parameters (i.e. Tmax, t1/2) will be presented with 2 decimals.
    - Summary statistics will be presented with respect to the number of decimals: Mean, Median, and Geom Mean = +1; SD and SEM = +2, Minimum and Maximum = +0.
- Values for rate constants (i.e. Kel) will be presented with 3 significant figures.
    - Summary statistics for Kel will be presented as: Mean, Median, and Geom Mean = +1; SD and SEM = +2, Minimum and Maximum = +0.
- CV% and Geom CV% for all parameters will be presented with 1 decimal

Program: /CAXXXXX/sas_prg/pksas/pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_pkparam.sas DDMMMYYYY HH:MM

Table 14.2.1.1.6 will be in the following format:

Table 14.2.1.1.6 Intervals (Hours) Used for Determination of Plasma Xisomab 3G3 Kel Values (Pharmacokinetic Population)

Subject Number	Treatment	Interval	R2	n
X	0.25 mg/kg	XX.X - XX.X	X.XXX	X
X	0.5 mg/kg	XX.X - XX.X	X.XXX	X
X	x	XX.X - XX.X	X.XXX	X
X	X	XX.X - XX.X	X.XXX	X
X	X	XX.X - XX.X	X.XXX	X
X	X	XX.X - XX.X	X.XXX	X

0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3

R2 = Coefficient of determination
n = Number of points used in Kel calculation
. = Kel value not reportable.

Notes for Generating the Actual Table:

- Please use CPKel1 template
- Per study design, the "Treatment Sequence" column will be replaced with 'Treatment" and the data will be presented vertically instead of horizontally.
- Interval start and stop times will be presented to 1 decimal or 3 significant figures minimum
- R2 will be presented to 3 decimals
- n will be presented as an integer

Program: /CAXXXXX/sas_prg/pksas/kel-tables-xover.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_kel.sas DDMMMYYYY HH:MM

Tables 14.2.2.1.1 through 14.2.2.1.3, 14.2.3.1.1 through 14.2.3.1.3 will have the following format:

Table 14.2.3.1.1 Individual and Mean Difference Between Pre- and Post-dialysis Potassium Values (unit) – Days -7 to 12 – 0.25 mg/kg Xisomab 3G3 on Day 1 (Safety Population)

		0.25 mg/kg			0.5 mg/kg			Placebo		
Subject Number	Day	Pre-dialysis (units)	Post-dialysis (units)	Difference (units)	Pre-dialysis (units)	Post-dialysis (units)	Difference (units)	Pre-dialysis (units)	Post-dialysis (units)	Difference (units)
X	-7	XXX	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
X	-7	XX.X	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
X	-7	XX.X	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
X	-7	X.XX	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
X	-7	XXX	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
n		XX	XX	XX	XX	XX	XX	XX	XX	XX
Mean		XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX	XXX.X	XX.XX	X.XXXX
SD		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum		XX.X	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
Median		XX.XX	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX	XXX.X	XX.XX	X.XXXX
Maximum		XXX	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX

0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Difference = Pre-dialysis - Post-dialysis
Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1

Programmer Notes:
For the BUN Tables 14.2.2.1.1 through 14.2.2.1.3 values will be reported at pre- and post-dialysis on Days -7, -5, -3, 1, 3, 5, 6, and 12. The screening values to be reported if not presented in other tables.

For the BUN Tables 14.2.2.1.1 through 14.2.2.1.3, additional column of "URR" will be reported at the right of the "Difference" column (as per Table 11-3 shell), with the following footnotes:

- Difference = Pre-dialysis - Post-dialysis
- Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1
- URR = (1-(post-dialysis BUN/ pre-dialysis BUN))*100

Program: /CAXXXXX/sas_prg/pksas/xxxxxxxx.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/xxxxxxxxx.sas DDMMMYYYY HH:MM

Tables 14.2.5.1.7 through 14.2.5.1.9, 14.2.4.1.1 through 14.2.4.1.3 will have the following format:

Table 14.2.5.1.7 Individual and Mean Difference Between Pre- and Post-dialysis aPTT Values (unit) – Days -7 to 12 – 0.25 mg/kg Xisomab 3G3 on Day 1 (Safety Population)

		0.25 mg/kg			0.5 mg/kg			Placebo		
Subject Number	Day	Pre-dialysis (units)	Post-dialysis (units)	Fold Change (units)	Pre-dialysis (units)	Post-dialysis (units)	Fold Change (units)	Pre-dialysis (units)	Post-dialysis (units)	Fold Change (units)
X	-7	XXX	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
X	-7	XX.X	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
X	-7	XX.X	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
X	-7	X.XX	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
X	-7	XXX	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
n		XX	XX	XX	XX	XX	XX	XX	XX	XX
Mean		XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX	XXX.X	XX.XX	X.XXXX
SD		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum		XX.X	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX
Median		XX.XX	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX	XXX.X	XX.XX	X.XXXX
Maximum		XXX	X.XX	XXX	XXX	XX.X	X.XXX	XXX	XX.X	X.XXX

0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Fold Change = Post-dialysis / Pre-dialysis
Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1

Programmer Notes:
Values will be reported at pre- and post-dialysis on Days -7, -5, -3, 1, 3, 5, 6, and 12.
The screening values to be reported if not presented in other tables.

For Tables 14.2.4.1.1 through 14.2.4.1.3, Kt/V will be reported on Days -7, -5, -3, 1, 3, 5, and 12. Column titles will be the same as per Table 11-5 shell (ie., R, t, UF, Wt, and Kt/V) with the following footnotes:

- Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1
- R = post-dialysis BUN/pre-dialysis BUN))*100
- t = Time of HD
- UF = Pre-dialysis Weight – Post-dialysis Weight
- Wt = Post-dialysis weight of patient
- Kt/V = $\ln(R - (0.008 \times t)) + (4 - (3.5 \times R)) \times \frac{UF}{Wt}$

For the bleeding time table in Section 14.3, values will be reported post-dialysis on Days screening (if available), -7, -5, -3, 1, 3, 5, 8, 10 and 12. There will be only one column underneath each dose as per Table 11-4 shell with the following footnote:

- Single IV infusion of 0.25, 0.5 mg/kg xisomab 3G3 or placebo was administered on Day 1

Program: /CAXXXXX/sas_prg/pksas/xxxxxxxx.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/xxxxxxxxx.sas DDMMMYYYY HH:MM

Tables 14.2.6.1 will be in the following format:

Table 14.2.6.1 Summary of Clotting in the Drip Chamber – Days -7 to 12 (Safety Population)

		0.25 mg/kg Xisomab 3G3					0.5 mg/kg Xisomab 3G3					Pooled Placebo				
		Category*					Category*					Category*				
Day	Time Point	1	2	3a	3b	4	1	2	3a	3b	4	1	2	3a	3b	4
Day -7	2 hr after HD	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	Post HD	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day X	2 hr after HD	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	Post HD	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

<include all days and timepoints>

Note: *Category:1=No detectable clotting, 2=Presence of fibrinous ring or minimum clot affecting less than 5% of chamber space,
3a=Clot formation (affecting more than 5% of but less than 30% of chamber space) but dialysis still possible,
3b=Clot formation (affecting more than 30% of chamber space) but dialysis still possible,
4=Complete occlusion of chamber
HD: hemodialysis

Program: /AAXXXXX/ECR/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Tables 14.2.7.1 will be in the following format:

Table 14.2.7.1 Summary of Clotting in the Dialysis Filter – Days -7 to 12 (Safety Population)

	0.25 mg/kg Xisomab 3G3					0.5 mg/kg Xisomab 3G3					Pooled Placebo				
	Category*					Category*					Category*				
Day	1	2	3a	3b	4	1	2	3a	3b	4	1	2	3a	3b	4
Day -7	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Day X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

<include all days>

Note: *Category:1= No clotting, clean filter, 2= Few blood streaks (affecting less than 5% of the fibers seen at the surface of dialyzer),
3a= More blood streaks (affecting more than 5% but less than 30 % of the fibers seen at the surface of the dialyzer),
3b= More blood streaks (affecting more than 30% of the fibers seen at the surface if the dialyzer),
4=Complete occlusion

Program: /AAXXXXX/ECR/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Table 14.3.1.1 Treatment-Emergent Adverse Event Frequency by Treatment - Number of Subjects Reporting the Event (% of Subjects Dosed) (Safety Population)

	Dose Level of Xisomab 3G3			
Adverse Event*	0.25 mcg/kg	0.5 mcg/kg	Pooled Placebo	Overall
Number of Subjects Dosed	XX (XX%)	XX (XXX%)	XX (XX%)	XX (XXX%)
Number of Subjects With TEAEs^	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Number of Subjects Without TEAEs^	XX (XX%)	XX (XXX%)	XX (XX%)	XX (XXX%)
Nervous system disorders	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Dizziness	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Headache	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Presyncope	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Respiratory, thoracic and mediastinal disorders	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Dry throat	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Oropharyngeal pain	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Sinus congestion	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Sneezing	X (XX%)	X (XX%)	X (XX%)	X (XX%)
General disorders and administration site conditions	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Fatigue	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Thirst	X (XX%)	X (XX%)	X (XX%)	X (XX%)

Note: *Adverse events are classified according to MedDRA Version 21.1. ^ = Treatment-emergent adverse events
If a subject has 2 or more clinical adverse events, the subject is counted only once within a category. The same subject may appear in different categories.

Program: /CAXXXXX/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Table 14.3.1.2 Treatment-Emergent Adverse Event Frequency by Treatment - Number of Adverse Events (% of Total Adverse Events) (Safety Population)

	Dose Level of Xisomab 3G3			
Adverse Event*	0.25 mg/kg	0.5 mg/kg	Pooled Placebo	Overall
Number of TEAEs	X (100%)	X (100%)	X (XX%)	X (XX%)
Nervous system disorders	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Dizziness	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Headache	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Presyncope	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Respiratory, thoracic and mediastinal disorders	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Dry throat	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Oropharyngeal pain	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Sinus congestion	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Sneezing	X (XX%)	X (XX%)	X (XX%)	X (XX%)
General disorders and administration site conditions	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Fatigue	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Thirst	X (XX%)	X (XX%)	X (XX%)	X (XX%)

Note: *Adverse events are classified according to MedDRA Version 21.1. ^ = Treatment-emergent adverse events

Program: /CAXXXXX/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Table 14.3.1.3 Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Drug - Number of Adverse Events (Safety Population)

				Severity				Relationship to Study Drug				
Adverse Event*	Dose Level/ Placebo	Number of Subjects With TEAEs	Number of TEAEs	Grade 1	Grade 2	Grade 3	Grade 4	Unrelated	Unlikely	Possibly	Probably	Likely
Dizziness	X	X	X	X	X	X	X	X	X	X	X	X
	X	X	X	X	X	X	X	X	X	X	X	X
Dry eye	X	X	X	X	X	X	X	X	X	X	X	X
Dry mouth	X	X	X	X	X	X	X	X	X	X	X	X
Dry throat	X	X	X	X	X	X	X	X	X	X	X	X
Ear pain	X	X	X	X	X	X	X	X	X	X	X	X
	X	X	X	X	X	X	X	X	X	X	X	X
Fatigue	X	X	X	X	X	X	X	X	X	X	X	X
Headache	X	X	X	X	X	X	X	X	X	X	X	X
Dizziness	X	X	X	X	X	X	X	X	X	X	X	X
	X	X	X	X	X	X	X	X	X	X	X	X
Hyperhidrosis	X	X	X	X	X	X	X	X	X	X	X	X
Laceration	X	X	X	X	X	X	X	X	X	X	X	X
Limb crushing injury	X	X	X	X	X	X	X	X	X	X	X	X
Muscle twitching	X	X	X	X	X	X	X	X	X	X	X	X
0.25 mg/kg		X	X	X	X	X	X	X	X	X	X	X
0.5 mg/kg		X	X	X	X	X	X	X	X	X	X	X
Placebo		XX	XX	X	X	X	X	X	X	X	X	X
Overall		XX	XX	X	X	X	X	X	X	X	X	X

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
*Adverse events are classified according to MedDRA Version 21.1. TEAE = Treatment-emergent adverse events
If a subject experience the same adverse event (AE) at more than one level of severity during a treatment, each AE is counted separately. If a subject experience the same AE at more than one level of drug relationship during a treatment, each AE is counted separately.
Severity: Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Potentially life-threatening

Program: /CAXXXXX/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Tables 14.3.4.1 to 14.3.4.3 will have the following format:

Table 14.3.4.1 Out-of-Range Values and Clinically Significant Results - Serum Chemistry (Safety Population)

Dose Level/ Placebo	Subject Number	Age#/ Sex	Study Period	Day	Hour	Date	Time	Parameter1 <Range> (Unit)	Parameter2 <Range> (Unit)	Parameter3 <Range> (Unit)	Parameter4 <Range> (Unit)	Parameter5 <Range> (Unit)
XXX <units>	X	XX/X	Screen	.	.	DDMMMYYYY	HH:MM:SS	XX H +				XX L
			1	-X	-XX.XX	DDMMMYYYY	HH:MM:SS	XX L	XX L	XX H	XX L	
			Recheck			DDMMMYYYY	HH:MM:SS				XX	

Programmer Notes: Replace Parameter1, 2 etc. with actual lab tests in the study. Sort unscheduled assessment and early termination chronologically with other scheduled assessments.

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
#Age is calculated at the time of first dosing. F = Female; M = Male
H = Above reference range, L = Below reference range
PI Interpretation: + = Clinically significant

Program: /CAXXXXX/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Tables 14.3.5.1, 14.3.5.3 and 14.3.5.5 will be in the following format:

Table 14.3.5.1 Clinical Laboratory Summary and Change from Baseline - Serum Chemistry (Safety Population)

							Change from Baseline*		
Laboratory Test (unit)	Reference Range	Time Point	Statistic	0.25 mg/kg	0.5 mg/kg	Placebo	0.25 mg/kg	0.5 mg/kg	Placebo
XXXXXXXXX (unit)	X.X-XX.X#	Screen	n	XX	XX	XX			
			Mean	X.XX	X.XX	X.XX			
			SD	X.XXX	X.XXX	X.XXX			
			Minimum	X.XX	X.XX	X.XX			
			Median	X.X	X.X	X.X			
			Maximum	XX.X	XX.X	XX.X			
		Baseline*	n	XX	XX	XX			
			Mean	X.XX	X.XX	X.XX			
			SD	X.XXX	X.XXX	X.XXX			
			Minimum	X.XX	X.XX	X.XX			
			Median	X.X	X.X	X.X			
			Maximum	XX.X	XX.X	XX.X			
		Day X, Hour X.XX	n	XX	XX	XX	XX	XX	XX
			Mean	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			SD	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX
			Minimum	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

<include all timepoints>

Programmer Note: Table 14.3.5.5 will not include timepoints that are summarized in PD endpoint tables in 14.2.

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
# = Lowest of the lower ranges and highest of the higher ranges are used. Refer to Appendix 16.1.10.1 for the breakdown.
* Baseline is defined as the result closest and prior to dose on Day 1.
Programmer note: for PT, INR and PT/INR, the pre-dialysis value will be the baseline value for that day and the "change from baseline" will be the fold change from baseline "ie. Post-dialysis / Pre-dialysis.

Program: /AAXXXXX/ECR/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Tables 14.3.5.2, 14.3.5.4 and 14.3.5.6 will be in the following format:

Table 14.3.5.2 Clinical Laboratory Shift From Baseline - Serum Chemistry (Safety Population)

Laboratory Test (unit)	Dose Level/ Placebo	Time Point	Baseline* L			Baseline* N			Baseline* H		
			L	N	H	L	N	H	L	N	H
XXXXXXX (unit)	XXX <units>	Day X, Hour X.XX	X	XX	X	X	XX	X	X	XX	X

Programmer Note: Table 14.3.5.6 will not include timepoints that are summarized in PD endpoint tables in 14.2.

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
N = Within Normal Range, L = Below Normal Range, H = Above Normal Range
# = Lowest of the lower ranges and highest of the higher ranges are used. Refer to Appendix 16.1.10.1 for the breakdown.
* Baseline is defined as the result closest and prior to dose on Day 1.

Program: /AAXXXXX/ECR/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Table 14.3.5.7 Vital Sign Summary and Change from Baseline (Safety Population)

						Change from Baseline*		
Vital Sign (unit)	Time Point	Statistic	0.25 mg/kg	0.5 mg/kg	Placebo	0.25 mg/kg	0.5 mg/kg	Placebo
XXXXXXXX (unit)	Screen	n	XX	XX	XX			
		Mean	X.XX	X.XX	X.XX			
		SD	X.XXX	X.XXX	X.XXX			
		Minimum	X.XX	X.XX	X.XX			
		Median	X.X	X.X	X.X			
		Maximum	XX.X	XX.X	XX.X			
	<Also include Days -7, -5 and -3>							
	Baseline*	n	XX	XX	XX			
		Mean	X.XX	X.XX	X.XX			
		SD	X.XXX	X.XXX	X.XXX			
		Minimum	X.XX	X.XX	X.XX			
		Median	X.X	X.X	X.X			
		Maximum	XX.X	XX.X	XX.X			
	Day X, Hour X.XX	n	XX	XX	XX	XX	XX	XX
		Mean	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		SD	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX
		Minimum	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		Median	X.X	X.X	X.X	X.X	X.X	X.X
		Maximum	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	<include all postdose timepoints>							

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
* Baseline is defined as the result closest and prior to the dose on Day 1.

Program: /AAXXXXX/ECR/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Table 14.3.5.8 12-Lead Electrocardiogram Summary and Change from Baseline (Safety Population)

						Change from Baseline*		
Measurement (unit)	Time Point	Statistic	0.25 mg/kg	0.5 mg/kg	Placebo	0.25 mg/kg	0.5 mg/kg	Placebo
XXXXXXXXX (unit)	Screen	n	XX	XX	XX			
		Mean	X.XX	X.XX	X.XX			
		SD	X.XXX	X.XXX	X.XXX			
		Minimum	X.XX	X.XX	X.XX			
		Median	X.X	X.X	X.X			
		Maximum	XX.X	XX.X	XX.X			
	Baseline*	n	XX	XX	XX			
		Mean	X.XX	X.XX	X.XX			
		SD	X.XXX	X.XXX	X.XXX			
		Minimum	X.XX	X.XX	X.XX			
		Median	X.X	X.X	X.X			
		Maximum	XX.X	XX.X	XX.X			
	Day X, Hour X.XX	n	XX	XX	XX	XX	XX	XX
		Mean	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		SD	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX
		Minimum	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		Median	X.X	X.X	X.X	X.X	X.X	X.X
		Maximum	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	<include all postdose timepoints>							

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
* Baseline is defined as the result closest and prior to the dose on Day 1.

Program: /AAXXXXX/ECR/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Tables 14.2.12 will be in the following format:

Table 14.5.5.9 Frequency of Immunogenicity - ADA Titer (Safety Population)

	0.25 mg/kg Xisomab 3G3		0.5 mg/kg Xisomab 3G3		Pooled Placebo	
Day	Positive	Negative	Positive	Negative	Positive	Negative
Day 1	X (%)	X (%)	X (%)	X (%)	X (%)	X (%)
Day 12	X (%)	X (%)	X (%)	X (%)	X (%)	X (%)

Note: % is percentage of total subject dosed in each treatment.

Program: /AAXXXXX/ECR/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

12. LISTING SHELLS

The following listing shells provide a framework for the display of data from this study. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this study, but are intended to show the general layout of the listings that will be presented and included in the final CSR. These listings will be generated off of the Celerion SDTM Tabulation Model 1.4 mapped in accordance with SDTM Implementation Guide 3.2. All listings will be presented in Courier New size font 9.

Appendix 16.1.10.1 Clinical Laboratory Reference Ranges

Laboratory Group	Test Name	Sex	Age Category	Reference Range	Unit
Serum Chemistry	Test Name	XXXXXX	XX	XX – XX	units
	Test Name	XXXXXX	XX	XX – XX	units
	Test Name	XXXXXX	XX	XX – XX	units
	Test Name	XXXXXX	XX	XX – XX	units
	Test Name	XXXXXX	XX	XX – XX	units
	Test Name	XXXXXX	XX	XX – XX	units
Hematology	Test Name	XXXXXX	XX	XX – XX	units
	Test Name	XXXXXX	XX	XX – XX	units
	Test Name	XXXXXX	XX	XX – XX	units
	Test Name	XXXXXX	XX	XX – XX	units
	Test Name	XXXXXX	XX	XX – XX	units

<similar for remaining Laboratory Groups and Test Names>

Program: /CAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.1 Study Completion/Early Termination (Safety Population)

Dose Level/ Placebo	Subject Number	Completed Study?	Date	Date of Last Contact	Reason for Discontinuation	Comments
XXX <units>	X	Yes	DDMMMYYYY	DDMMMYYYY		
	X	Yes	DDMMMYYYY	DDMMMYYYY		
	X	Yes	DDMMMYYYY	DDMMMYYYY		
	X	Yes	DDMMMYYYY	DDMMMYYYY		
	X	No	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXX
	X	Yes	DDMMMYYYY	DDMMMYYYY		

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.4.1 Demographics (Safety Population)

Dose Level/ Placebo	Subject Number	Date of Birth	Age* (yrs)	Sex	Race	Ethnicity	Height (cm)	Weight (kg)	Body Mass Index (kg/m^2)	Informed Consent Date
XXX <units>	X	MMMYYYY	XX	AAAAAA	AAAAAAAA	AAAAAAAAAA	XXX	XX.XX	XX.XX	DDMMMYYYY
	X	MMMYYYY	XX	AAAAAA	AAAAAAAA	AAAAAAAAAA	XXX	XX.XX	XX.XX	DDMMMYYYY
	X	MMMYYYY	XX	AAAAAA	AAAAAAAA	AAAAAAAAAA	XXX	XX.XX	XX.XX	DDMMMYYYY
	X	MMMYYYY	XX	AAAAAA	AAAAAAAA	AAAAAAAAAA	XXX	XX.XX	XX.XX	DDMMMYYYY
	X	MMMYYYY	XX	AAAAAA	AAAAAAAA	AAAAAAAAAA	XXX	XX.XX	XX.XX	DDMMMYYYY
	X	MMMYYYY	XX	AAAAAA	AAAAAAAA	AAAAAAAAAA	XXX	XX.XX	XX.XX	DDMMMYYYY
	X	MMMYYYY	XX	AAAAAA	AAAAAAAA	AAAAAAAAAA	XXX	XX.XX	XX.XX	DDMMMYYYY

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
*Age is calculated from the date of first dosing.

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.4.2 Physical Examination (Safety Population)

Dose Level/ Placebo	Subject Number	Period	Day	Time	Date	Body System	Result	Abnormality	Clinical Significance
XXX <units>	X	Screen			DDMMMYYYY	1. General Appearance	Abnormal	XXXXXXXXXXXXXXXXXXXX	NCS

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.4.3 Medical and Surgical Histories (Safety Population)

Dose Level/ Placebo	Subject Number	Seq #	Description	Date of Diagnosis/Surgery Start	End	Ongoing?
XXX <units>	X	X	XXXXXX XXXXX XXXXXXX	DDMMMYYYY		Yes
		X	XXXXXXXXX	DDMMMYYYY	DDMMMYYYY	No
		X	XXXXXXXX XXXXX XXXXXX	DDMMMYYYY	DDMMMYYYY	No

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.4.4 Alcohol Screen (Safety Population)

Dose Level/ Placebo	Subject Number	Visit Date	Type of Sample	Actual Time	Result
XXX <units>	X	DDMMMYYYY	Urine	HH:MM	Negative

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.4.5 Drug Screen (Safety Population)

Dose Level/ Placebo	Subject Number	Visit Date	Type of Sample	Actual Time	Result	If Positive, list all that were positive:
XXX <units>	X	DDMMMYYYY	Urine	HH:MM	Negative	

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.1 Subject Eligibility (Safety Population)

Dose Level/ Placebo	Subject Number	Study Period	Date	Did subject meet all eligibility criteria?	Criterion Not Met*	Specify
XXX <units>	X	Screen	DDMMMYYYY	Yes		
	X	Screen	DDMMMYYYY	Yes		
	X	Screen	DDMMMYYYY	No	EXCLUSION X	XXXXXXXXXXXXXXX XXXX

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.2 Subject Eligibility at Check-In (Safety Population)

Dose Level/ Placebo	Subject Number	Study Period	Date	Does subject continue to meet criteria since Screening?	If No, specify
XXX <units>	X	Check-In	DDMMMYYYY	Yes	

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.3 Test Compound Administration Times (Safety Population)

Dose Level/ Placebo	Subject Number	Period	Day	Time	Dose Date	Start Administered?	End Time	Time	Route	Form	Frequency
XXX <units>	X	XXXX	XX	XX	DDMMMYYYY	Yes	HH:MM:SS	HH:MM:SS	IV Infusion	Injection	Once

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.4 Blood Draw Times for Free XISOMAB 3G3 PK (Safety Population)

Dose Level/ Placebo	Subject Number	Day	Hour	Date	Actual Time	Comments
XXX <units>	X	X	-X.XX	DDMMMYYYY	XX:XX	XXXXXXXXXX
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	XXXXXXXXX
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	XXXXXXXXXX
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
		X	XX.XX	DDMMMYYYY	XX:XX	

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.5 Blood Draw Times for Free XISOMAB 3G3 PD (aPTT) (Safety Population)

Dose Level/ Placebo	Subject Number	Day	Hour	Date	Actual Time	Comments
XXX <units>	X	X	-X.XX	DDMMMYYYY	XX:XX	XXXXXXXXXX
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	XXXXXXXXX
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	XXXXXXXXXX
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
			XX.XX	DDMMMYYYY	XX:XX	
		X	XX.XX	DDMMMYYYY	XX:XX	

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.6 Blood Draw Times for Immunogenicity (Safety Population)

Dose Level/ Placebo	Subject Number	Day	Hour	Date	Actual Time	Comments
XXX <units>	X	1	Predose	DDMMMYYYY	HH:MM	XXXXXXXXXX
		12	Follow-up	DDMMMYYYY	HH:MM	

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.7 Blood Draw Times for Dialysate Analysis for Kt/V and URR (Safety Population)

Dose Level/ Placebo	Subject Number	Day	Hour	Date	Actual Time	Comments
XXX <units>	X	-7	3 hours	DDMMMYYYY	HH:MM	XXXXXXXXXX
		-5	3 hours	DDMMMYYYY	HH:MM	
		1	3 hours	DDMMMYYYY	HH:MM	
		3	3 hours	DDMMMYYYY	HH:MM	
		12	3 hours	DDMMMYYYY	HH:MM	

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.8.1 Dialyzer Assessment (I of V) (Safety Population)

Dose Level/ Placebo	Subject Number	Period	Day	Hemodialysis Time Start	Hemodialysis Time End	Hemodialysis Time Total*	Interrupted Prematurely?	Reason for Interruption	Specify
XXX <units>	X	XXXX	X	HH:MM	HH:MM	HH:MM	Yes		

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
*Total = End time – Start time

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.8.2 Dialyzer Assessment (II of V) (Safety Population)

Dose Level/ Placebo	Subject Number	Day	Hour	Atrial Pressure Time	Atrial Pressure mmHg	Venus Pressure Time	Venus Pressure mmHg	Blood Flow Rate mL/min	Time to Hemostasis Time	Time to Hemostasis Length (min)	Dialysis Filter Collected*?
XXX <units>	X	X	X	HH:MM	XX	HH:MM	XX	XX	HH:MM	XX	Yes

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
* Was the dialysis fi lter collected, sealed and stored < -20 C until shipment?

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.8.3 Dialyzer Assessment (III of V) - Number and Volume of Saline Flushes (Safety Population)

Dose Level/ Placebo	Subject Number	Day	Hour	Saline Flush Number	Time of Flush	Volume (mL)	Total Volume of Flushes (mL)	Total Number of Flushes
XXX <units>	X	X	X	1	HH:MM	XX	XXX	XX
				2	HH:MM	XX		
				3	HH:MM	XX		
				4	HH:MM	XX		
				5	HH:MM	XX		
				6	HH:MM	XX		

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.8.4 Dialyzer Assessment (IV of V) – Clotting in the Drip Chamber(Safety Population)

				2 Hours after Start of Dialysis						End of Dialysis					
					Category*						Category*				
Dose Level/ Placebo	Subject Number	Day	Hour	Time	1	2	3a	3b	4	Time	1	2	3a	3b	4
XXX <units>	X	X	X	HH:MM	X	X	X	X	X	HH:MM	X	X	X	X	X

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
*Category:1=No detectable clotting, 2=Presence of fibrinous ring or minimum clot affecting less than 5% of chamber space,
3a=Clot formation (affecting more than 5% of but less than 30% of chamber space) but dialysis still possible,
3b=Clot formation (affecting more than 30% of chamber space) but dialysis still possible,
4=Complete occlusion of chamber

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.8.5 Dialyzer Assessment (V of V) – Clotting in Dialysis Filter(Safety Population)

		End of Dialysis (or premature interruption)							
					Category*				
Dose Level/ Placebo	Subject Number	Day	Hour	Time	1	2	3a	3b	4
XXX <units>	X	X	X	HH:MM	X	X	X	X	X

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
*Category:1= No clotting, clean filter, 2= Few blood streaks (affecting less than 5% of the fibers seen at the surface of dialyzer),
3a= More blood streaks (affecting more than 5% but less than 30 % of the fibers seen at the surface of the dialyzer),
3b= More blood streaks (affecting more than 30% of the fibers seen at the surface if the dialyzer),
4=Complete occlusion

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.9 Non-Study Producers (Safety Population)

Dose Level/ Placebo	Subject Number	Procedure	Assessment Date	Procedure Date	Procedure Time	Due to Medical History, seq#	Due to AE, AE page#	Overall Procedure Interpretation	Procedure Findings/Comments
XXX <units>	X	None							
		XXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY	HH:MM	XXXXXXX	XX	XXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXX

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/ECR/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.5.10 Prior and Concomitant Medications (Safety Population)

Dose Level/ Placebo	Subject Number	Any Med?	Medication (WHO* Term)	Dosage/ Strength	Form	Route	Start Date	Start Time	Stop Date	Stop Time	Fre-quency	Indication	Con-tinuing?	Prior to Study?	Due to AE?
XXX <units>	X	No	None												
	X	Yes	ACETAMINOPHEN (ACETAMINOPHEN)	620 mg/X	XXX	Oral	DDMMMYYYY	HH:MM	DDMMMYYYY	HH:MM	Once	Toothache	No	X	XX

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
*Concomitant medications are coded with World Health Organization (WHO) Drug Dictionary Version September 2018, B3.
Med = Medication

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.7.1.1 Adverse Events (I of II) (Safety Population)

Dose Level/ Placebo	Subject Number	TE?^	Adverse Event*	Preferred Term	Time From Last Dose (DD:HH:MM)	Onset Date	Onset Time	Resolved Date	Resolved Time	Duration (DD:HH:MM)
XXX <units>	X		None							
	X	Yes	XXXXXXXXXXXX	XXXXXXXXXX XXXXXXX	XX:XX:XX	DDMMMYYYY	XX:XX	DDMMMYYYY	XX:XX	XX:XX:XX

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
*Adverse events are classified according to MedDRA Version 21.1.
^TE = Treatment-emergent

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.7.1.2 Adverse Events (II of II) (Safety Population)

Dose Level/ Placebo	Subject Number	TE?^	Adverse Event	Onset Date	Onset Time	Onset Freq*	Severity/ Intensity	Serious	Outcome	Relationship to Study Drug	Action
XXX <units>	X		None								
	X	Yes	XXXXXXXXXXXXXXXXX	DDMMMYYYY	XX:XX	Inter.	Grade 1 Mild	Not serious	Resolved	XXXXXXXXXXXXXXX	XXXXXXXXX

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
^TE = Treatment-emergent
*Freq represents Frequency: SI = Single Episode, Inter. = Intermittent, Cont. = Continuous

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.7.2 Adverse Event Preferred Term Classification (Safety Population)

Dose Level/ Placebo	Subject Number	TE?^	Adverse Event*	Preferred Term	System Organ Class	Onset Date	Onset Time
XXX <units>	X	Yes	XXXXXXX XXXXX XXXX XXXXXX	XXXXXXXXXX XXXXXXX	XXXXXXXXXXXXXXXXXXXX	DDMMMYYYY	XX:XX

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
*Adverse events are classified according to MedDRA Version 21.1.
^TE = Treatment-emergent

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendices 16.2.8.1.1 to 16.2.8.1.5 will have the following format.

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Appendix 16.2.8.1.1 Clinical Laboratory Report - Serum Chemistry (Safety Population)

Dose Level/ Placebo	Subject Number	Age#/ Sex	Study Period	Day	Hour	Date	Parameter1 < Range> (Unit)	Parameter2 < Range> (Unit)	Parameter3 < Range> (Unit)	Parameter4 < Range> (Unit)	Parameter5 < Range> (Unit)	Parameter6 < Range> (Unit)
XXX <units>	X	XX/X	Screen	.	.	DDMMMYYYY	XX H	XX	XX	XX	XX H	XX
			X	-X	-XX.X	DDMMMYYYY	XX L +	XX L	XX	XX L	XX	XX

Programmer Note: Replace Parameter1, 2 etc. with actual lab tests in the study. Sort unscheduled assessment and early term chronologically with other scheduled assessments.

Programmer Note: All timepoints for coagulation and platelet count should be listed with results and flags.

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
#Age is calculated from the date of first dosing. F = Female; M = Male
H = Above reference range, L = Below reference range
PI interpretation: + = Clinically Significant

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.8.2 Vital Signs (Safety Population)

Dose Level/ Placebo	Subject Number	Period	Day	Hour	Date	Time	Blood Pressure (mmHg) Systolic/Diastolic	Heart Rate (bpm)	Respiration (bpm)	Temperature (°C)	Weight (kg)	Position
XXX <units>	X	Screen	.	.	DDMMMYYYY	XX:XX	XXX/ XX	XX	XX	XX	XX	XXXX
		XXX	-X	-XX.X	DDMMMYYYY	XX:XX	XXX/ XX	XX	XX	XX	XX	XXXXXXXXX
		XXX	X	XX.X	DDMMMYYYY	XX:XX	XXX/ XX	XX				

Programmer Note: Sort unscheduled assessment and early term chronologically with other scheduled assessments.

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM

Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Dose Level/ Placebo	Subject Number	Period	Day	Hour	Date	Time	Result	Heart Rate (bpm)	PR (ms)	QRS (ms)	QT (ms)	QTcF* (ms)	Comments
XXX <units>	X	Screen	.	.	DDMMMYYYY	XX:XX	Normal	XX	XXX	XX	XXX	XXX^#	XXXXXXXXX
		X	X	XX.X	DDMMMYYYY	XX:XX	Normal	XX	XXX	XX	XXX	XXX	
		X	X	XX.X	DDMMMYYYY	XX:XX	Normal	XX	XXX	XX	XXX	XXX	

Programmer Note: Sort unscheduled assessment and early term chronologically with other scheduled assessments.

Note: 0.25 mg/kg: Single IV Infusion of 0.25 mg/kg xisomab 3G3
0.5 mg/kg: Single IV Infusion of 0.5 mg/kg xisomab 3G3
Placebo = pooled placebo
QTcF* = QT corrected for heart rate using Fridericia's correction.
Abnormal, NCS = Abnormal, Not clinically significant
^ = QTcF is > 450 ms
# = QTcF change from baseline is > 30 ms

Program: /AAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMMYYYY HH:MM