STATISTICAL ANALYSIS PLAN

A Phase 1, Double-Blind, Single Ascending Dose Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of TRL345 in Healthy Volunteers

Protocol No: TRL345-102
Final Protocol Date: 08 March 2023
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Compound Name: TRL345

Celerion Project CA34470
Final Version 1.0
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STATISTICAL ANALYSIS PLAN SIGNATURE PAGE

Compound Name: TRL345

Protocol: TRL345-102

Study Title: A Phase 1, Double-Blind, Single Ascending Dose Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of TRL345 in Healthy Volunteers

Issue Date: 22 November 2023

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1. INTRODUCTION

The following statistical analysis plan (SAP) provides the framework for the analysis and presentation of the data from this study. Any changes made from the planned analysis described in the protocol or after finalization of this SAP will be documented in the Clinical Study Report (CSR). The section referred to as "Table, Figure, and Listing Shells" within this SAP describes the Clinical Data Interchange Standards Consortium (CDISC) input in order to provide traceability to the corresponding tables, figures, and listings (TFLs). Analysis data model (ADaM) is the source for tables and figures (as well as listings that may contain derived data) and study data tabulation model (SDTM) is the source for the data listings.

Any additional exploratory analyses not addressed within this SAP and/or driven by the data, or requested by Trellis Bioscience, Inc. will be considered out of scope and must be described in the CSR.

Celerion will not revise the SAP in the case that a dose level is adjusted, removed, repeated, or added. Instead, it should be noted that treatments will be appropriately described and summarized in the TFLs. In the case that a dose level and regimen is repeated, the data will be pooled and summarized by dose levels. In the case that the protocol is amended to modify the conduct then the SAP may need to be revised.

2. OBJECTIVES AND ENDPOINTS

Objectives	Endpoints
Primary	
To assess the safety and tolerability of TRL345 when administered intravenously (IV) as a single dose in healthy adult volunteers	Incidence and severity of abnormal physical exam findings, serum chemistries and hematology, vital signs (temperature, blood pressure, heart rate), adverse events (AEs), and incidence of serious adverse events (SAEs)
Secondary	
To characterize the pharmacokinetics (PK) of a single IV infusion of TRL345 overall and by dose group (DG)	C_{max}, C_{min}, CL, Vss, and t½, overall and by DG will be calculated by using serum concentrations of TRL345 determined by an enzyme-linked immunosorbent assay (ELISA)
To assess the immunogenicity of TRL345 as measured by anti-drug antibodies (ADAs)	Incidence of baseline and investigational product (IP)-emergent ADA (i.e., anti-TRL345 antibodies) in serum will be determined by an ELISA method.

Objectives	Endpoints
Exploratory	
To explore the pharmacodynamics (PD) of TRL345 in an ex vivo study using serum samples to explore the capacity of various concentrations of TRL345 to neutralize human cytomegalovirus (HCMV) in human serum*	The proportion of samples with TRL345 concentrations within prespecified ranges that are associated with neutralization of HCMV in human serum
To explore if there are any differences in AEs, clinical labs, or PK across DGs to explore if there are any signs of off-target binding of TRL345	Gastrointestinal and central nervous system (CNS) AEs will be compared across DGs for any qualitative or quantitative differences in such events. Lactic acid dehydrogenase (LDH), high-sensitivity C-reactive protein (hsCRP), interleukin (IL)-1alpha, estimated AUC, and estimated t½ will also be compared across DGs.

Note: * This objective is not covered by this SAP as this analysis will not be performed by Celerion. The results for this objective will not be reported in the Celerion provided CSR.

3. STUDY DESIGN

This study is designed to meet the objectives outlined in Section 2.

This is a Phase 1, first-in-human (FIH), double-blind, single ascending dose (SAD) study to assess the safety, PK, PD, and preliminary activity of TRL345. Healthy subjects aged 18-65, inclusive, will be screened.

Subjects who meet all inclusion and no exclusion criteria, will be enrolled into the study, assigned to a DG, and randomized to receive TRL345 or placebo. Each DG will include 8 subjects; 6 will receive TRL345 and 2 will receive placebo. An established ELISA assay available in commercial laboratories to detect Immunoglobulin (Ig) G antibodies against CMV will be used to determine serostatus of subjects prior to randomization. Dosing of the first two subjects (one randomized to TRL345 and one randomized to placebo) in each DG will be done on the same day. Dosing of the other subjects will occur at least 72 hours after the first two subjects have been dosed and following review of the blinded safety data from the first two subjects in the DG by the Principal Investigator (PI) and Sponsor. After all subjects within a DG have completed Day 15, a Safety Monitoring Committee (SMC) will review all available safety data through Day 15 prior to making a recommendation regarding escalation to the next higher DG.

Subjects will be admitted to a Phase 1 research unit prior to the IV administration of a single dose of TRL345 or placebo. In order to maintain the blind, subjects will be dosed as follows: DG1 will receive 1 mg/kg of TRL345 or 0.1 mL/kg of placebo and DG2 will receive 10 mg/kg of TRL345 or 1 mL/kg of placebo. All subjects (randomized to either TRL345 or placebo) will receive IP infused over 60 minutes.

Subjects will be closely monitored for AEs and SAEs, including infusion reactions (IRs), from the onset of the infusion through discharge from the Phase 1 research unit. Subjects will be assessed for safety and tolerability, including AEs and SAEs, at each follow-up visit after discharge through Day 76. A physical exam, vital signs, and routine clinical lab tests (chemistry and hematology) will be done on Days 1, 2, 3, 8, 15, 29, and 43. An electrocardiogram (ECG) will be done on Days 1 and 8.

Serum for PK will be collected on Days 1 (0, 1, 2, 4, 6, 12 hours after start of infusion), 2 (24 hours after start of infusion), and 3 (48 hours after start of infusion), and on Days 8, 15, 29, 43, and 76.

Serum samples ADA analysis will be taken on Days 1, 8, 29, 43, and 76 for measurement of anti-TRL345 antibody levels. Samples taken on Days 1, 43, and 76 will be analyzed using an ELISA method. Samples collected on Days 8 and 29 will be held for exploratory analysis, if warranted, based on Day 43 and Day 76 ADA analysis results. The proportion of subjects with detectable anti-TRL345 antibody responses prior to dosing and IP-emergent anti-TRL345 antibodies will be reported.

Serum samples for PD assessment will be collected on Days 1 (pre-infusion and 1 hour after start of infusion), 15, 29, 43, and 76 for ex vivo PD assessments, which will be conducted at Professor McVoy's lab as defined in a separate protocol, whereby the dosed participants of the study will remain anonymous.

Additional serum samples will also be obtained on Days 1 (pre-infusion), 3, 8, 15, 29, and 43 for possible additional exploratory analyses that may be necessary to further explore any unexpected safety or tolerability observations.

4. ANALYSIS POPULATIONS

Safety Population

The Safety Population will include all subjects who received any portion of the study drug or placebo.

Pharmacokinetic Population

The PK Population will include all subjects in the Safety Population who completed at least 1 PK blood draw sample.

Pharmacokinetic Analysis Population

The PK Analysis Population, a subset of the PK Population, will include all subjects who complied sufficiently with the protocol and have ample serum TRL345 concentration data to display an evaluable PK profile (e.g., exposure to treatment, availability of measurements, and absence of major protocol violations). The PK Analysis Population will be used in concentration summaries, PK parameter summaries.

Note: If subjects experienced issues that affect exposure to study drug (e.g., emesis, dosing errors, incomplete data, significant drug carryover, important protocol violation, sample processing errors), data will be reviewed by the study pharmacokineticist and evaluated for exclusion from the PK Analysis Population on a case-by-case basis. All subjects excluded from the PK Analysis Population will be documented.

All available data will be included in the concentration and PK parameter listings/tables to the extent possible.

Immunogenicity Population

The Immunogenicity Population will include all subjects in the Safety Population who have at least 1 ADA sample.

5. TREATMENT DESCRIPTIONS

For safety, PK, and ADA TFLs, subjects will be grouped according to the actual treatment received.

Treatments are described as follows:

Dose Group	Treatment	Short Description	Long Description
1	A	1 mg/kg TRL345	A single 1-hour intravenous infusion of 1 mg/kg TRL345 (Dose Group 1)
2	B	10 mg/kg TRL345	A single 1-hour intravenous infusion of 10 mg/kg TRL345 (Dose Group 2)
1 and 2	P	Pooled Placebo	A single 1-hour intravenous infusion of matching placebo (Dose Groups 1 and 2)

6. PHARMACOKINETIC ANALYSIS

6.1 Investigational Product and Pharmacokinetic Analyte Information

TRL345 will be supplied as a sterile solution for infusion. TRL345 is a human IgG1kappa (G1m1,17 (z,a); Km3 allotype) monoclonal antibody cloned from human B lymphocytes which targets the highly conserved AD-2, Site I epitope on the gB viral glycoprotein of the HCMV.

6.2 Bioanalytical Method

Serum concentrations of TRL345 will be determined using an 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 TRL345 will be determined during validation of the ELISA.

6.3 Pharmacokinetic Concentrations

Measurements and Collection Schedule

Blood samples for the determination of TRL345 in serum will be collected for all subjects at the following time points:

- Day 1: Predose (imputed as time 0) and approximately 1 hour ± 15 minutes (end of infusion [EOI]), 2 hours ± 15 minutes, 4 hours ± 15 minutes, 6 hours ± 15 minutes, and 12 hours ± 15 minutes post-start of infusion (SOI)
- Days 2 (24 hours ± 1 hour post-SOI), 3 (48 hours ± 1 hour post-SOI), 8 (168 hours post-SOI), 15 (336 hours post-SOI), 29 (672 hours post-SOI), 43 (1008 hours post-SOI), and 76 (1800 hours post-SOI)

All concentration data, as received from the bioanalytical lab, will be listed by subjects, treatment, and nominal time in an appendix. If there are any significant protocol deviations (e.g., significant time deviations from nominal sample times), some individual concentration data may be excluded from mean data presentations (e.g., descriptive statistics for concentrations at specific nominal time points and mean concentration-time plots). No concentration values will be imputed for missing or not reported samples (NS or NR), unless predose. All deviations and excluded data will be provided and discussed in the CSR.

6.4 Noncompartmental Pharmacokinetic Analysis and Parameter Calculation

6.4.1 Serum TRL345 Pharmacokinetic Parameters

The appropriate noncompartmental PK parameters will be calculated from the serum TRL345 concentration-time data using Phoenix® WinNonlin® Version 8.3.4 or higher. Actual sample times will be used in the calculations of the PK parameters. The calculation of the actual time for TRL345 will be in respect to the SOI of TRL345 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 Serum TRL345 Pharmacokinetic Parameters to be Calculated

Parameter	Label to be Used in the Text, Tables, and Figures*	Definition	Method of Determination
$AUC_{0\text{-tlast}}$	AUClast	Area under the concentration-time curve from time 0 to the time of the last observed/measured non-zero concentration	Calculated using the Linear Trapezoidal with Linear Interpolation Method
$AUC_{0\text{-inf}}$	AUC0-inf	Area under the concentration-time curve from time 0 extrapolated to infinity	Calculated as AUC0-inf = AUC0-tlast + (Clast/Kel) where Clast is the last observed/measured concentration
$AUC_{\%extrap}$	AUC%extrap	Percent of AUC0-inf extrapolated	Calculated as AUC%extrap = (1 – (AUC0-tlast/AUC0-inf)) × 100
C_{eoi}	Ceoi	Concentration at the end of infusion	Taken directly from bioanalytical data
C_{min}	Cmin	Minimum observed concentration following a single dose corresponding to the single IV dose administration	Taken directly from bioanalytical data
C_{max}	Cmax	Maximum observed concentration	Taken directly from bioanalytical data
T_{min}	Tmin	Time of minimum observed concentration (Cmin) following a single dose corresponding to the single IV dose administration	Taken from clinical database as the difference in the time of administration and the time of the blood draw which is associated with the Cmax
T_{max}	Tmax	Time to reach Cmax; if Cmax occurs at more than 1 time point, Tmax is defined as the first time point with this value	Taken from clinical database as the difference in the time of administration and the time of the blood draw which is associated with the Cmax
T_{last}	Tlast	Time of the last measurable concentration	Taken from clinical database as the difference in the time of administration and the time of the blood draw which is associated with the Clast
λ_z	Kel	Apparent first-order terminal elimination rate constant	The negative of the slope of a linear regression of the log(concentration)-time curve for all concentrations > LLOQ
$t_{½}$	t½	Apparent first-order terminal elimination half-life	Calculated as t½ = 0.693/Kel

Parameter	Label to be Used in the Text, Tables, and Figures*	Definition	Method of Determination
CL	CL	Total serum clearance after IV administration	Calculated as CL = Dose/(AUC0-inf)
Vss	Vss	Apparent volume of distribution estimated at steady state following a single IV dose administration	Calculated as Vss = MRT0-inf • CL

*In the text of the CSR, subscripts will be used in parameter names, as appropriate. However, in post-text tables and listings, subscripts will not be used in parameter names.

PK parameters will not be calculated for subjects with less than 3 consecutive postdose time points with quantifiable concentrations. Subjects for whom there are insufficient data to calculate the PK parameters will be included in the concentration tables and individual concentration-time figures and flagged to exclude from the summaries.

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

The Kel will be determined using linear regressions composed of at least 3 data points. Furthermore, the Kel will not be assigned if 1) the terminal elimination phase is not apparent, 2) Tmax is one of the last 3 data points, or 3) the R^2 value is less than 0.75. In cases where the Kel interval is not assigned, the values of Kel and Kel-dependent parameters (i.e., AUC0-inf, AUC%extrap, t½, CL, 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 value and Kel-dependent parameters (i.e., AUC0inf, AUC%extrap, t½, CL, and Vss) may not be presented, as judged appropriate and in accordance with Celerion standard operating procedures (SOPs).

6.5 Data Summarization and Presentation

All TRL345 serum concentrations and/or PK parameters descriptive statistics will be generated using SAS® Version 9.4 or higher.

The serum concentrations of TRL345 will be listed and summarized by dose group, treatment and time point for all subjects in the PK Population. Serum concentrations of TRL345 will be presented with the same level of precision as received from the bioanalytical laboratory (i.e., 3 significant figures). Summary statistics, including sample size (n), arithmetic mean (mean), standard deviation (SD), coefficient of variation (CV%), standard error of the mean (SEM), minimum, median, maximum, and range will be calculated for all nominal concentration time points. Excluded subjects or data 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 tables but will be set to zero or missing as described in Section 6.4.1 for the calculation of summary statistics and footnoted accordingly.

Mean and individual serum TRL345 concentration-time profiles will be presented on linear and semi-log scales. Individual concentration-time profiles will be based on actual sample times, and mean concentration-time profiles will be based on nominal sample times. Linear mean plots will be presented with and without SD. When there are significant (> 3%) time deviations from nominal sample time points, some concentrations may be excluded from the summary statistics and any corresponding summary figures.

TRL345 PK parameters will be listed and summarized by treatment for all subjects in the PK Analysis Population. PK parameters will be reported to 3 significant figures for individual parameters, with the exception of Cmax, (Ceoi, if warranted) and Cmin which will be presented with same level of precision as received from the bioanalytical laboratory and Tmax, which will be presented with 2 decimal places. Summary statistics (n, mean, SD, CV%, SEM, minimum, median, maximum, range, geometric mean (Geom Mean), and geometric CV% (Geom CV%) will be presented for all 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/range in same precision as in bioanalytical data (i.e., 3 significant figures) and/or parameter output, mean/median/Geom Mean in one more level of precision than minimum/maximum/range, SD/SEM in one more level of precision than mean/median/Geom Mean, n will be presented as an integer, and CV%/Geom CV% will be presented to the nearest tenth.

6.6 Preliminary Data and Interim Analysis

Celerion Biometrics will not perform preliminary or interim analyses.

7. IMMUNOGENICITY

7.1 Bioanalytical Method

Blood samples for immunogenicity will be tested using ELISA for antibodies to TRL345 at Celerion, Lincoln, Nebraska.

7.2 Immunogenicity Concentrations

Measurements and Collection Schedule

Blood samples for ADA will be collected and analyzed for all subjects at the following time points:

- Day 1: Baseline
- Days 8 (168 hours post-SOI), 29 (672 hours post-SOI), 43 (1008 hours post-SOI), and 76 (1800 hours post-SOI)

7.3 Data Summarization and Presentation

The ADA presence will be summarized with frequency counts and percentages for the Immunogenicity Population by treatment (pooled placebo, active treatments, active treatment total) at baseline and each post baseline time point. ADA results will be listed for each subject by time point.

8. SAFETY

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

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

The level of precision will be presented as follows: minimum/maximum/range in the same precision as in the database, mean/median in one more precision level than minimum/maximum/range, SD in one more precision level than mean/median, and n will be presented as an integer. Percentages will be presented as an integer.

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

Baseline will be the result closest and prior to start of dosing unless otherwise stated. Summaries for post-baseline time points will not include rechecks, unscheduled, or early termination measurements.

Tables summarizing safety data by assessment time point will only include summaries for baseline and post-baseline time points.

8.1 Subject Disposition

Subjects will be summarized by the number and percent of subjects dosed, completed the study, and discontinued the study (with discontinuation reasons) by treatment (pooled placebo, active treatment, active treatment total) and overall.

8.2 Protocol Deviations

Protocol deviations are captured by the clinical site and provided in the CSR in a similar format to that provided by the clinical site. Protocol deviations are not edited or processed in SAS®.

8.3 Demographics

Descriptive statistics will be calculated for continuous variables (age, body mass index, height, and weight) by treatment (pooled placebo, active treatment, active treatment total) and overall. Age will be approximated by subtracting the year of birth from the year of informed consent. If year of informed consent – year of birth is one more than the protocol maximum age (65) then the age approximation will be year of informed consent – year of birth – 1. Descriptive statistics for body mass index, height, and weight will be calculated using screening measurements.

Frequency counts will be provided for categorical variables (sex, race, and ethnicity) by treatment (pooled placebo, active treatment, active treatment total) and overall.

8.4 Adverse Events

All AEs occurring during this clinical trial will be coded using the Medical Dictionary for Regulatory Activities (MedDRA®), Version 26.1.

All AEs captured in the database will be listed in a by-subject data listing including dose group, verbatim term, coded term, treatment, onset date/time, resolution date/time, frequency, severity, relationship to study product, action, and whether the AE is an IR; however, only treatment-emergent AEs (TEAEs) will be summarized.

A TEAE is defined as an AE that is starting at the time of or after the start of study product administration. Each TEAE will be attributed to the treatment based on the onset date and time of the AE compared to that of the respective treatment administration start date and time.

If the onset time of an AE is missing and the onset date is the same as or occurs after 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 the number of subjects reporting the TEAE and as a percent of the number of subjects dosed by treatment (pooled placebo, active treatment, active treatment total) and

overall. The number of TEAEs will be tabulated in a similar manner. A table, which summarizes the number of TEAEs by Preferred Term, severity, and relationship to study product, will also be included.

SAEs if present, will also be listed. Applicable narratives will be included in the CSR.

8.5 Clinical Laboratory Tests (Chemistry and Hematology)

Clinical laboratory tests will be measured at the following time points:

Clinical Laboratory Panels	**Time Point**		
	Period	CRF/Listing Day and Hour	Table
Chemistry, Hematology	Screening		NA
	1	Day -1 Hour -23.00/-22.75*^ Day 2 Hour 24.00 Day 3 Hour 48.00^ Day 8 Hour 168.00 Day 15 Hour 336.00*^ Day 29 Hour 672.00*^ Day 43 Hour 1008.00^	Baseline Day 2 Day 3 Day 8 Day 15 Day 29 Day 43

Time points in the CRF/Listing column are approximated/based on the blank CRF and it should be noted that the data listings will reflect the data found in the final subject CRFs.
If applicable, an early termination assessment will be performed.
*hsCRP and LDH will be collected at these time points and included in the Chemistry TFLs.
^NT-proBNP and IL-1α will be collected at these time points and included in the Chemistry TFLs.
NA = Not applicable (individual result(s) may be required for baseline)

Clinical laboratory results will be presented in standard international (SI) units. Out-of-reference range flags will be recorded as follows: high (H) and low (L) for numerical results and did-not-match (*) for categorical results.

Out-of-reference range values and corresponding recheck results will be listed.

For all numeric laboratory values, descriptive statistics will be presented for each laboratory test by assessment time point and treatment (pooled placebo and active treatment). Change from baseline will be summarized in a similar manner. For all numeric laboratory tests, the mean value calculated for each assessment time point and treatment will be compared to the reference range and flagged if outside of the reference range (* if above the reference range and ^ if below the reference range). In the event there is more than one reference range for a laboratory test, the comparison will be made against the lowest of the lower ranges and the highest of the higher ranges.

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

8.6 Vital Signs

Vital signs will be measured at the following time points:

Parameter	Time Point		
	Period	CRF/Listing Day and Hour	Table
Blood Pressure, Pulse, Temperature	Screening		NA
	1	Day 1 Hour -0.75	Baseline
		Day 1 Hour 0.25	Day 1, Hour 0.25
		Day 1 Hour 0.50	Day 1, Hour 0.50
		Day 1 Hour 0.85	Day 1, Hour 1
		Day 1 Hour 1.85	Day 1, Hour 2
		Day 1 Hour 5.00	Day 1, Hour 5
		Day 2 Hour 23.85	Day 2
		Day 3 Hour 47.85	Day 3
		Day 8 Hour 167.92	Day 8
		Day 15 Hour 335.85	Day 15
		Day 29 Hour 671.85	Day 29
		Day 43 Hour 1007.85	Day 43

Time points in the CRF/Listing column are approximated/based on the blank CRF and it should be noted that the data listing will reflect the data found in the final subject CRFs.
If applicable, an early termination assessment will be performed.
NA = Not applicable (individual result(s) may be required for baseline)

Descriptive statistics will be presented for vital signs measurements by assessment time point and treatment (pooled placebo and active treatment). Change from baseline will be summarized in a similar manner.

8.7 Electrocardiogram

ECGs will be measured at the following time points:

Parameter	Time Point		
	Period	CRF/Listing Day and Hour	Table
HR, RR, PR, QRS, QT, QTcF	Screening		Baseline
	1	Day 1 Hour 4.75, 4.77, 4.78	Day 1
		Day 8 Hour 167.75, 167.77, 167.78	Day 8

Time points in the CRF/Listing column are approximated/based on the blank CRF and it should be noted that the data listing will reflect the data found in the final subject CRFs.

ECGs will be collected in triplicate. The triplicate measures will be averaged and rounded to the nearest tenth. The averages will be used in all summaries.

Only valid ECGs will be used to calculate average ECG values for each parameter that will be used in the analysis. Valid ECGs do not include records of questionable quality. These include, but are not limited to, records with an associated comment indicating an artifact, lead reversal, wandering lead, etc. ECGs collected in error will also not be classified as valid ECGs. After excluding these ECGs, the remaining ECGs for the respective triplicate set will

be assessed against a time window of 10 minutes. A triplicate ECG set is expected to be performed within a 5-minute window but a 10-minute window is selected to increase the likelihood of having a full triplicate ECG set for the calculation of the average ECG value. The start of the window for a given postdose time point will be equivalent to the time of the first valid ECG. ECGs that fall outside of the 10-minute window will not be considered valid ECGs. At a given time point, if it is not possible to form a complete ECG triplicate set of valid results, the average will be calculated using the available valid results, i.e., the average of 2 valid ECGs or the single valid ECG result will be used in the analysis. Averaged ECG values will be displayed to the nearest tenth and used in the analysis.

Descriptive statistics will be presented for the by-subject averages of each ECG parameter by assessment time point and treatment (pooled placebo and active treatment). Change from baseline will be summarized in a similar manner. Baseline is defined as the average of the valid ECG set closest and prior to start of dosing which may include unscheduled assessments. This will typically be the average of the triplicate ECG set collected at Screening. At postdose time points, the average of the first valid ECG set will be used in the analysis. Postdose unscheduled and early termination measurements will not be included in summaries.

All ECG data will be listed by-subject and QTc values > 450 msec will be flagged. A separate by-subject listing will be provided to display the ECG average values to be used during analysis where QTc average values > 450 msec and increase from baseline > 30 msec will be flagged.

8.8 Prior and Concomitant Medications

Prior and concomitant medications recorded during the study will be coded with the World Health Organization (WHO) Drug Dictionary Version 01-Sep-2023_b3 and listed.

8.9 Physical Examination

Abnormal physical examination findings will be reported as medical history or AEs. All data found in the CRF will be listed.

9. SUMMARY OF CHANGES FROM PROTOCOL-PLANNED ANALYSIS

The protocol states that the following safety data will be summarized: physical examinations, medical history, disease history, concomitant medications, SAEs, AEs leading to discontinuation from study, AEs leading to discontinuation of study product, AEs within a specified time interval from dosing, and lab abnormalities (by severity). However, these analyses will not be performed and are not included in this SAP.

The protocol states that the all subjects receiving TRL345 will be included in the analyses. However, the Pharmacokinetic Population and the Pharmacokinetic Analysis Population were defined in this SAP for the PK analyses.

10. SUMMARY TABLES, FIGURES, AND LISTINGS

Summary tables and figures are numbered following the International Council on Harmonization (ICH) structure but may be renumbered as appropriate during the compilation of the tables and figures for the CSR. Note that all summary tables and figures will be generated using SAS® Version 9.4 or higher, as appropriate.

In-text tables and figures will be generated as RTF and all other tables and listings will be generated as SAS® LST format and converted to MS Word for inclusion in the CSR. In compliance with Celerion Procedure Guides (PG)/SOPs, SAS® outputs will not be manually edited.

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:

Number	Title	Shell
Table 10-1	Disposition Summary (Safety Population)	IDS

Section 11:

Number	Title	Shell
Table 11-1	Demographic Summary (Safety Population)	IDEM
Table 11-2	Summary of Serum TRL345 Pharmacokinetic Parameters Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Pharmacokinetic Analysis Population)	ITPPar1
Table 11-3	Summary of Serum TRL345 ADA Detection Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 or Placebo (Immunogenicity Population)	IIST
Figure 11-1	Arithmetic Mean Serum TRL345 Concentration Versus Time Profiles Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Linear Scale) (Pharmacokinetic Analysis Population)	PFPConc2

Section 12:

Number	Title	Shell
Table 12-1	Treatment-Emergent Adverse Event Frequency by Treatment - Number of Subjects Reporting the Event (% of Subjects Dosed) (Safety Population)	IAES

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 renumbered as appropriate during the compilation of the report.

14.1 Demographic Data Summary Tables

Number	Title	Shell
Table 14.1.1	Disposition Summary (Safety Population)	CDS
Table 14.1.2	Demographic Summary (Safety Population)	CDEM

14.2 Pharmacokinetic and Immunogenicity Data Summary Tables and Figures

14.2.1 Serum TRL345 Tables

Number	Title	Shell
Table 14.2.1.1	Serum TRL345 Concentrations (µg/mL) Following Administration of a Single 1-Hour Intravenous Infusion of 1 mg/kg TRL345 (Treatment A) (Pharmacokinetic Analysis Population)	CPConc1
Table 14.2.1.2	Serum TRL345 Concentrations (µg/mL) Following Administration of a Single 1-Hour Intravenous Infusion of 10 mg/kg TRL345 (Treatment B) (Pharmacokinetic Analysis Population)	CPConc1
Table 14.2.1.3	Serum TRL345 Concentrations (µg/mL) Following Administration of a Single 1-Hour Intravenous Infusion of Matching Placebo (Treatment P) (Pharmacokinetic Analysis Population)	CPConc1
Table 14.2.1.4	Serum TRL345 Pharmacokinetic Parameters Following Administration of a Single 1-Hour Intravenous Infusion of 1 mg/kg TRL345 (Treatment A) (Pharmacokinetic Analysis Population)	CPPar1

Number	Title	Shell
Table 14.2.1.5	Serum TRL345 Pharmacokinetic Parameters Following Administration of a Single 1-Hour Intravenous Infusion of 10 mg/kg TRL345 (Treatment B) (Pharmacokinetic Analysis Population)	CPPar1

14.2.2 Serum TRL345 Figures

Number	Title	Shell
Figure 14.2.2.1	Arithmetic Mean (SD) Serum TRL345 Concentration Versus Time Profiles Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Linear Scale) (Pharmacokinetic Analysis Population)	PFPConc1
Figure 14.2.2.2	Arithmetic Mean Serum TRL345 Concentration Versus Time Profiles Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Linear Scale) (Pharmacokinetic Analysis Population)	PFPConc2
Figure 14.2.2.3	Arithmetic Mean Serum TRL345 Concentration Versus Time Profiles Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Semi-log Scale) (Pharmacokinetic Analysis Population)	PFPConc3

14.2.3 Serum TRL345 Immunogenicity Tables

Number	Title	Shell
Table 14.2.3.1	Serum TRL345 ADA Detection Summary Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 or Placebo (Immunogenicity Population)	ADAD

14.3 Safety Data Summary Tables

14.3.1 Displays of Adverse Events

Number	Title	Shell
Table 14.3.1.1	Treatment-Emergent Adverse Event Frequency by Treatment – Number of Subjects Reporting the Event (% of Subjects Dosed) (Safety Population)	CAES
Table 14.3.1.2	Treatment-Emergent Adverse Event Frequency by Treatment – Number of Adverse Events (% of Total Adverse Events) (Safety Population)	CAEE

Number	Title	Shell
Table 14.3.1.3	Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Product – Number of Adverse Events (Safety Population)	CAESR

14.3.2 Listings of Deaths, other Serious and Significant Adverse Events

Number	Title	Shell
Table 14.3.2.1	Serious Adverse Events (Safety Population)	16.2.7

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

14.3.4 Abnormal Laboratory Value Listing (each subject)

Number	Title	Shell
Table 14.3.4.1	Out-of-Range Values and Recheck Results – Chemistry (Safety Population)	CLBO
Table 14.3.4.2	Out-of-Range Values and Recheck Results – Hematology (Safety Population)	

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

Number	Title	Shell
Table 14.3.5.1	Clinical Laboratory Summary and Change From Baseline – Chemistry (Safety Population)	CLBD
Table 14.3.5.2	Clinical Laboratory Shift From Baseline – Chemistry (Safety Population)	CLBS
Table 14.3.5.3	Clinical Laboratory Summary and Change From Baseline – Hematology (Safety Population)	CLBD
Table 14.3.5.4	Clinical Laboratory Shift From Baseline – Hematology (Safety Population)	CLBS
Table 14.3.5.5	Vital Sign Summary and Change From Baseline (Safety Population)	CVS
Table 14.3.5.6	12-Lead Electrocardiogram Summary and Change From Baseline (Safety Population)	CEG

10.3 Section 16 Data Listings

Note: Hepatitis and HIV results that are provided by the clinical laboratory will not be presented in subject data listings and will not be included in any database transfer. All data will be presented as outlined in the CRF (i.e., time point information will be consistent with the CRF data).

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

16.1.9 Statistical Methods

Number	Title
Appendix 16.1.9.1	Statistical Analysis Plan

16.1.10 Clinical Laboratory Reference Ranges

Number	Title
Appendix 16.1.10.1	Clinical Laboratory Reference Ranges

16.2 Subject Data Listings

16.2.1 Subject Discontinuation

Number	Title
Appendix 16.2.1.1	Subject Disposition (Safety Population)

16.2.2 Protocol Deviations

Number	Title
Appendix 16.2.2.1	Protocol Deviations

16.2.3 Subjects Excluded From the Pharmacokinetic and Immunogenicity Analysis

Number	Title
Appendix 16.2.3.1	Subjects Excluded From the Pharmacokinetic Analysis
Appendix 16.2.3.2	Subjects Excluded From the Immunogenicity Analysis

Note: Appendices in sections 16.2.2 and 16.2.3 are generated in MS Word for inclusion in the CSR.

16.2.4 Demographic Data

Number	Title
Appendix 16.2.4.1	Demographics (Safety Population)
Appendix 16.2.4.2	Physical Examination (I of II) (Safety Population)
Appendix 16.2.4.3	Physical Examination (II of II) (Safety Population)
Appendix 16.2.4.4	Physical Examination Descriptions (Safety Population)
Appendix 16.2.4.5	Medical History (Safety Population)
Appendix 16.2.4.6	Substance Use (Safety Population)

16.2.5 Compliance and/or Drug Concentration Data

Number	Title
Appendix 16.2.5.1	Subject Eligibility (Safety Population)
Appendix 16.2.5.2	Test Compound Description
Appendix 16.2.5.3	Test Compound Administration Times (Safety Population)
Appendix 16.2.5.4	Prior and Concomitant Medications (Safety Population)
Appendix 16.2.5.5	Pharmacokinetic Blood Draw Times and Serum TRL345 Concentration Data (Safety Population)
Appendix 16.2.5.6	Immunogenicity Blood Draw Times and ADA Results (Safety Population)
Appendix 16.2.5.7	Interleukin-1 Alpha Blood Draw Times and Concentration Data (Safety Population)
Appendix 16.2.5.8	Pharmacodynamic Blood Draw Times (Safety Population)
Appendix 16.2.5.9	Possible Exploratory Analyses Data Blood Draw Times (Safety Population)

16.2.6 Individual Efficacy/Pharmacokinetic/Pharmacodynamic Response Data

Number	Title	Shell
Appendix 16.2.6.1	Individual Serum TRL345 Concentration Versus Time Profiles Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Linear and Semi-log Scale) Subject <#>	PFPConc5

Number	Title	Shell
Appendix 16.2.6.2	Intervals (Hours) Used for Determination of Serum TRL345 Kel Values (Pharmacokinetic Analysis Population)	CPKel2

16.2.7 Adverse Events Listings

Number	Title
Appendix 16.2.7.1	Adverse Events (Safety Population)
Appendix 16.2.7.2	Details for Serious Adverse Events (Safety Population) *This listing will be removed if no serious adverse events are reported.*

16.2.8 Clinical Laboratory Reports

Number	Title
Appendix 16.2.8.1	Clinical Laboratory Report - Chemistry (Safety Population)
Appendix 16.2.8.2	Clinical Laboratory Report - Hematology (Safety Population)
Appendix 16.2.8.3	Clinical Laboratory Report - Coagulation (Safety Population)
Appendix 16.2.8.4	Clinical Laboratory Report - Urine Drug Screening (Safety Population)
Appendix 16.2.8.5	Clinical Laboratory Report - Other (Safety Population)
Appendix 16.2.8.6	Vital Signs (Safety Population)
Appendix 16.2.8.7	12-Lead Electrocardiogram (Safety Population)
Appendix 16.2.8.8	12-Lead Electrocardiogram – Average of Triplicates (Safety Population)

11. TABLE, FIGURE, AND LISTING 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 in-text tables will be presented in Times New Roman font size 9 and post-text tables will be presented in Courier New font size 9. In-text tables and figures will be generated as RTF and all other tables and listings will be generated as SAS® LST format and converted to MS Word for inclusion in the CSR. In compliance with Celerion PGs/SOPs, SAS® outputs will not be manually edited. Tables and figures will be generated from ADaM datasets created in accordance with CDISC guidance (ADaM Model 2.1 and ADaM implementation Guide 1.1).

11.1 In-text Summary Tables Shells

Table IDS Disposition Summary (Safety Population)

	Treatment				
Category	**P**	**A**	**B**	**Active Total**	**Overall**
Dosed	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Completed Study	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Study	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<Reason>	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

Treatment A: A single 1-hour intravenous infusion of 1 mg/kg TRL345 (Dose Group 1)
Treatment B: A single 1-hour intravenous infusion of 10 mg/kg TRL345 (Dose Group 2)
Treatment P: A single 1-hour intravenous infusion of matching placebo (Dose Groups 1 and 2)

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

Table IDEM Demographic Summary (Safety Population)

		Treatment				
Trait	**Category/Statistic**	**P**	**A**	**B**	**Active Total**	**Overall**
Sex	Female	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	Male	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Race	Asian	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	Black or African American	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	White	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Ethnicity	Hispanic or Latino	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	Not Hispanic or Latino	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Age (yr)	n	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX
	Range	XX	XX	XX	XX	XX
Body Mass Index (kg/m^2)	n	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX
	Range	XX	XX	XX	XX	XX
Height (cm)	n	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX
	Range	XX	XX	XX	XX	XX

		Treatment				
Trait	**Category/Statistic**	**P**	**A**	**B**	**Active Total**	**Overall**
Weight (kg)	n	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX
	Range	XX	XX	XX	XX	XX

Treatment A: < >
Treatment B: < >
Treatment P: < >
Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.

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

Table ITPPar1 Summary of Serum TRL345 Pharmacokinetic Parameters Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Pharmacokinetic Analysis Population)

	Treatment	
Pharmacokinetic Parameters	**A (N = X)**	**B (N = X)**
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]
Treatment A: A single 1-hour intravenous infusion of 1 mg/kg TRL345 (Dose Group 1) Treatment B: A single 1-hour intravenous infusion of 10 mg/kg TRL345 (Dose Group 2) Treatment P: A single 1-hour intravenous infusion of matching placebo (Dose Groups 1 and 2) AUCs $C_{max,}$ $C_{min, and}$ $C_{eoi,}$ values are presented as geometric mean (geometric CV%). $T_{max,}$ $T_{min.}$ and $T_{last\ values}$ are presented as median (min, max). Other parameters are presented as arithmetic mean ± SD. Source: Tables 14.2.1.4 to 14.2.1.5 Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM		

Notes for Generating the Actual Table:

Presentation of Data:

- The following PK parameters will be presented in the following order and with following units for TRL345 after single 1-hour Intravenous infusion: AUC0-tlast (µg*hr/mL), AUC0-inf (µg*hr/mL), AUC%extrap (%), Cmin (µg/mL), Cmax (µg/mL), Ceoi (µg/mL), Tmax (hr), Tmin (hr), Tlast (hr), Kel (1/hr), t½ (hr), CL (L/hr), and Vss (L/Kg).
- N will be presented as an integer (with no decimal);
- Summary statistics will be presented with same precision as defined in post-text shells.

Table IIST Summary of Serum TRL345 ADA Detection Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 or Placebo (Immunogenicity Population)

	Treatment			
ADA Positive	**P (N = X)**	**A (N = X)**	**B (N = X)**	**Active Total (N = X)**
Baseline	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 8	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 29	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 43	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 76	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Overall ADA Positive	X (XX%)	X (XX%)	X (XX%)	X (XX%)

Treatment A: A single 1-hour intravenous infusion of 1 mg/kg TRL345 (Dose Group 1)
Treatment B: A single 1-hour intravenous infusion of 10 mg/kg TRL345 (Dose Group 2)
Treatment P: A single 1-hour intravenous infusion of matching placebo (Dose Groups 1 and 2)
ADA Positive: Subject with a confirmed positive ADA result.
Baseline is the last measurement collected prior to start of dosing.
Overall indicates the number of subjects who had a positive ADA result at one or more time point.
Percentage is relative to the number of subjects (N) dosed
ADA = Anti-drug antibody

Source: Table 14.2.3.1
Program: /CAXXXXX/sas_prg/stsas/intext/PROGRAMNAME.sas DDMMMYYYY HH:MM

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

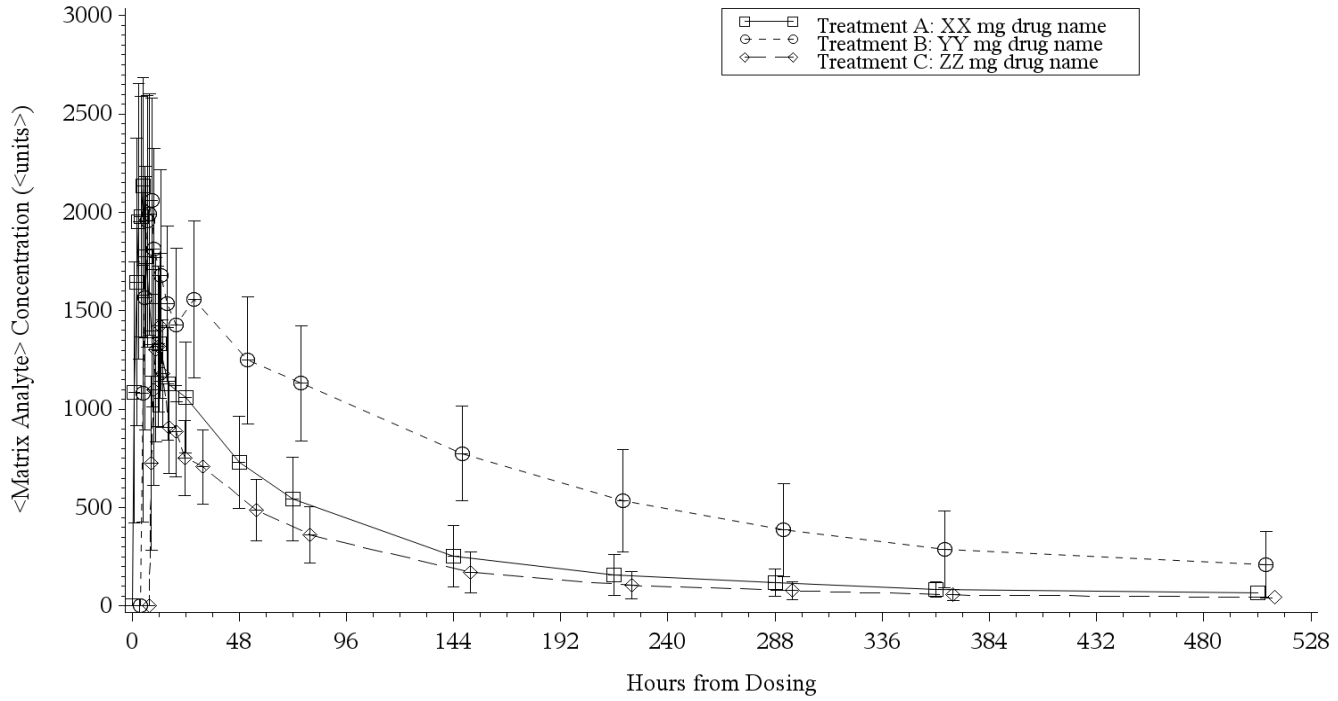
	Treatment				
Adverse Event	**P (N = X)**	**A (N = X)**	**B (N = X)**	**Active Total (N = X)**	**Overall (N = X)**
Number of Subjects With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Number of Subjects Without TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Visual blurred	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Gastrointestinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dyspepsia	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nausea	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal and connective tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Back pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Muscle cramps	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nervous system disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Headache	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Reproductive system and breast disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Vaginal discharge	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Respiratory, thoracic and mediastinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Epistaxis	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Skin and subcutaneous tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Sweating increased	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

	Treatment				
Adverse Event	**P (N = X)**	**A (N = X)**	**B (N = X)**	**Active Total (N = X)**	**Overall (N = X)**
Treatment A: < > Treatment B: < > Treatment P: < > Although a subject may have had 2 or more adverse events, the subject is counted only once within a category. The same subject may appear in different categories. Adverse events are classified according to MedDRA Version 26.1. TEAEs = Treatment-emergent adverse events Source: Table 14.3.1.1 Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM					

11.2 Figures Shells

Figure PFPConc1

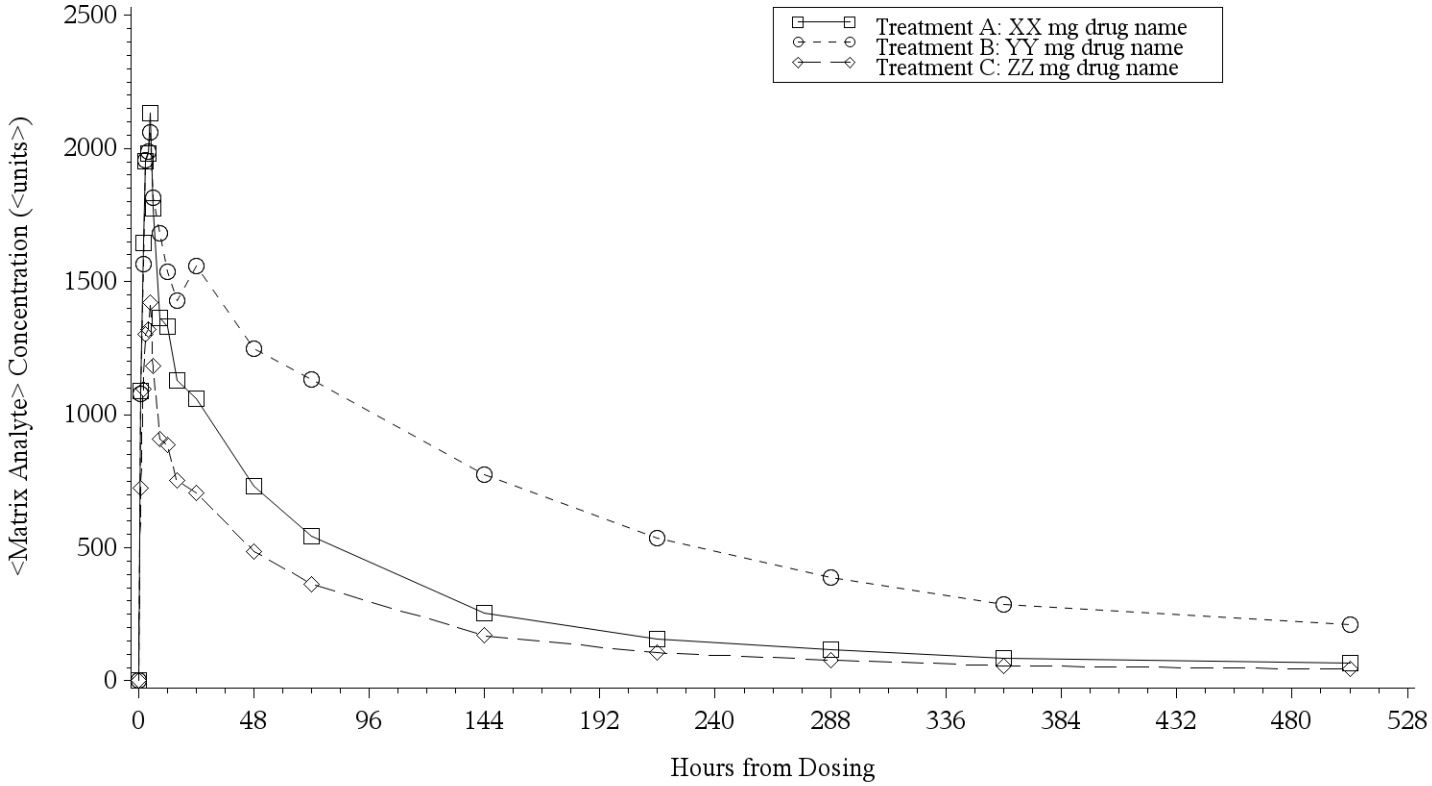
Arithmetic Mean (SD) Serum TRL345 Concentration Versus Time Profiles Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Linear Scale) (Pharmacokinetic Analysis Population)



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 PFPConc2

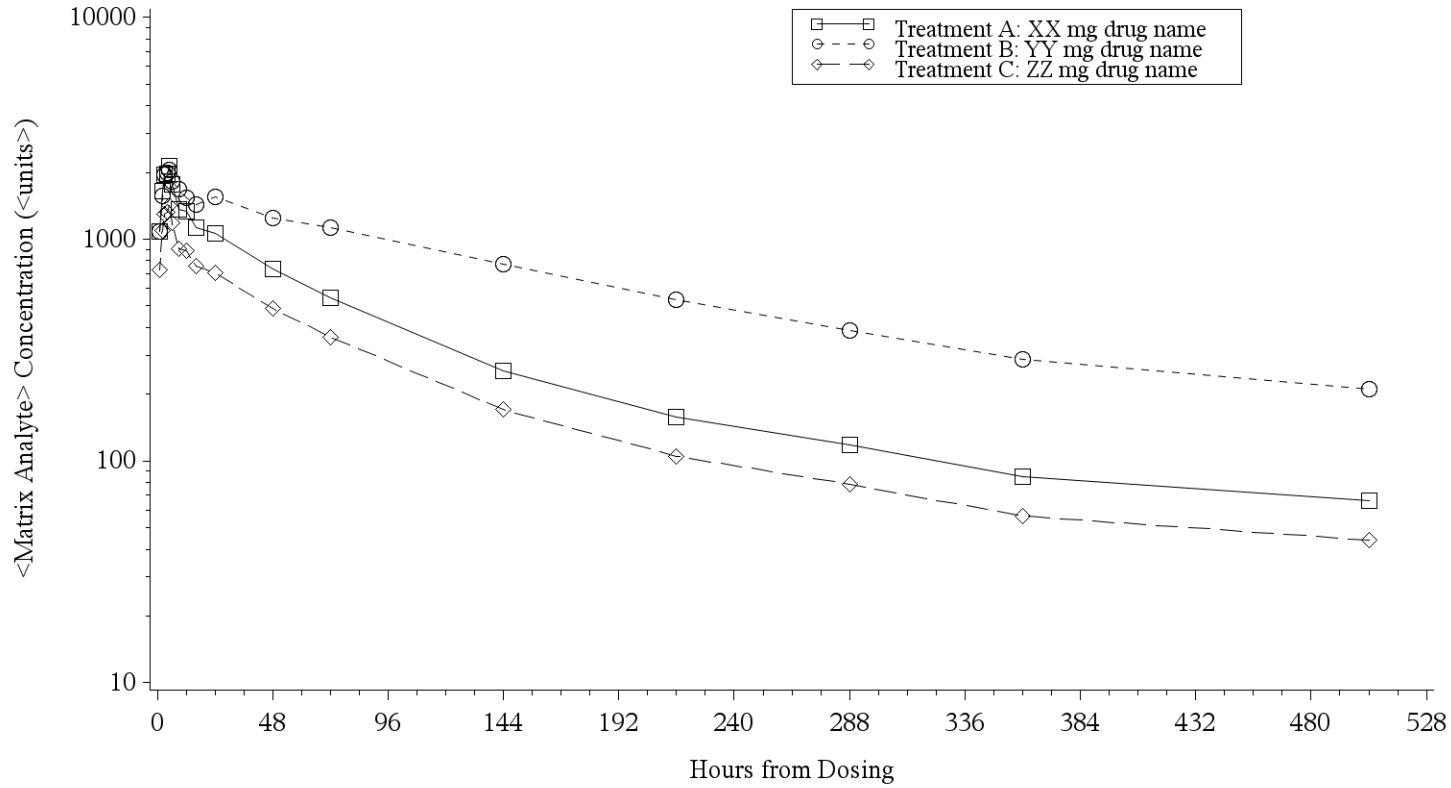
Arithmetic Mean Serum TRL345 Concentration Versus Time Profiles Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Linear Scale) (Pharmacokinetic Analysis Population)



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

Figure PFPConc3

Arithmetic Mean Serum TRL345 Concentration Versus Time Profiles Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Semi-log Scale) (Pharmacokinetic Analysis Population)



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

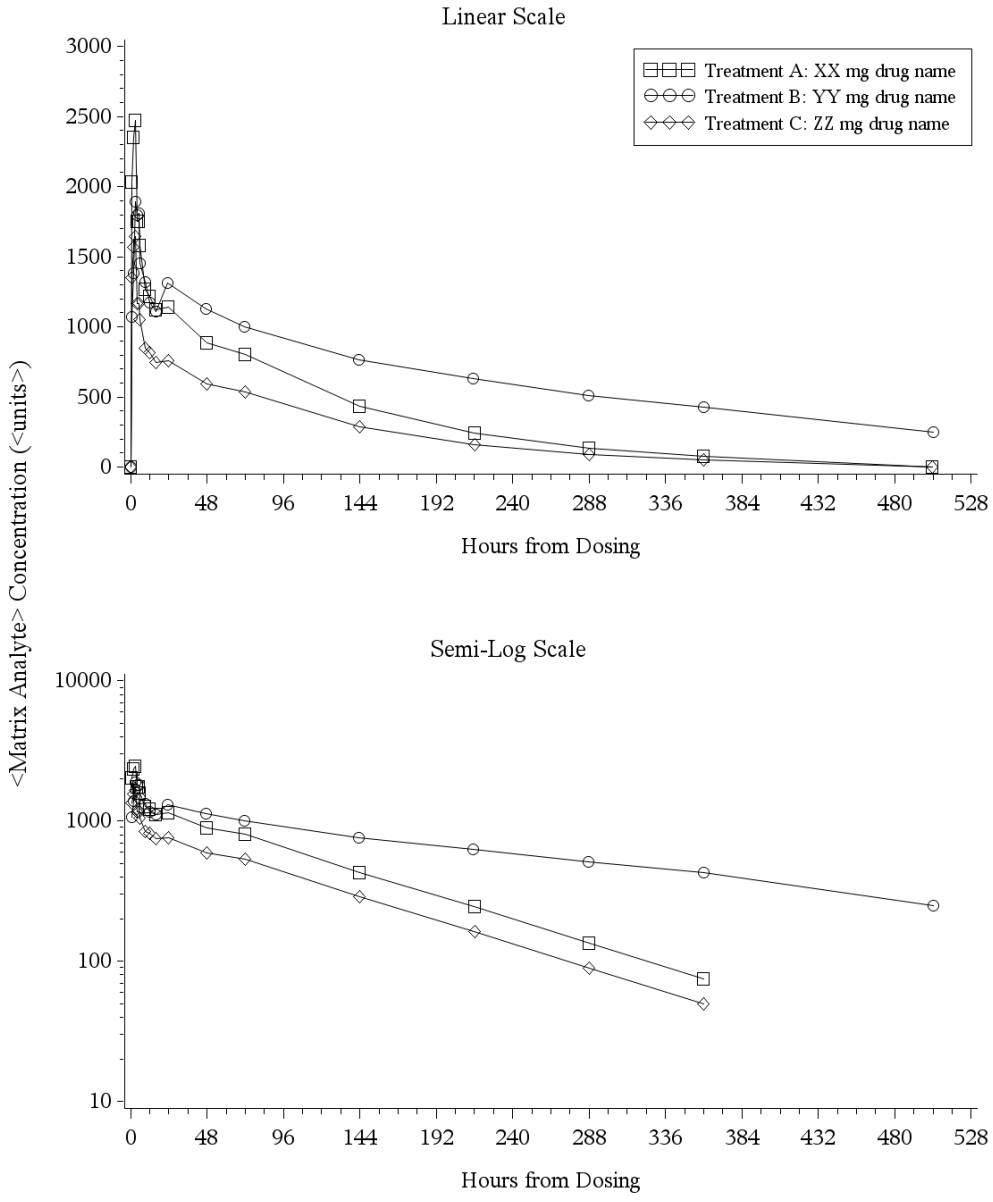
Notes for Generating the Actual Mean Figures:

For the arithmetic mean serum TRL345 versus time profiles:

- Legend will be "1 mg/kg TRL345", "10 mg/kg TRL345.
- Y-axis label will be "Serum TRL345 Concentration (µg/mL)".
- X- axis label will be "Hours From Start of Infusion"
- For figures with SD, add the footnote: Treatments B is shifted to the right for ease of reading."

Appendix PFPConc5

Individual Serum TRL345 Concentration Versus Time Profiles Following Administration of a Single 1-Hour Intravenous Infusion of TRL345 (Linear and Semi-log Scale) 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 Figures:

For the individual serum TRL345 versus time profiles:

- Legend will be "1 mg/kg TRL345", "10 mg/kg TRL345".
- Y-axis label will be "Serum TRL345 Concentration (µg/mL)".
- X-axis label will be "Hours From Start of Infusion"

11.3 Section 14 Summary Tables Shells

Table CDS Disposition Summary (Safety Population)

	Treatment				
Category	P	A	B	Active Total	Overall
Dosed	XX (XXX%)	XX (XXX%)	XX (XXX%)	XX (XXX%)	XX (XXX%)
Completed Study	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Study	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
<Reason>	X (XX%)	X (XX%)	X (XX%)	X (X%)	X (X%)

Treatment A: A single 1-hour intravenous infusion of 1 mg/kg TRL345 (Dose Group 1)
Treatment B: A single 1-hour intravenous infusion of 10 mg/kg TRL345 (Dose Group 2)
Treatment P: A single 1-hour intravenous infusion of matching placebo (Dose Groups 1 and 2)

Source: ADaM.ADSL
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1programname2022Q1.sas DDMMMYYYY HH:MM

Table CDEM Demographic Summary (Safety Population)

		Treatment				
Trait	Category/Statistic	P	A	B	Active Total	Overall
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black or African American	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ethnicity	Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX
	Range	XX	XX	XX	XX	XX
Body Mass Index (kg/m^2)	n	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX
	Range	XX	XX	XX	XX	XX

Treatment A: < >
Treatment B: < >
Treatment P: < >
Descriptive statistics for body mass index, height, and weight are calculated using screening measurements.
Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CPConc1 Serum TRL345 Concentrations (µg/mL) Following Administration of a Single 1-Hour Intravenous Infusion of 1 mg/kg TRL345 (Treatment A) (Pharmacokinetic Analysis Population)

	Sample Times								
Subject	Day 1						- Day 2 -	- Day 3 -	-Day 8 -
Number	Predose	1	2	4	6	12	24	48	168
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
Range	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.XX ug/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:

Presentation of Data:

- Concentrations will be presented to same precision as in bio data.
- The level of precision for each concentrations statistic will be presented as follows: minimum/maximum/range in same precision as in bioanalytical data (i.e., 3 significant figures) and/or concentrations output, mean/median in one more level of precision than minimum/maximum/range, SD/SEM in one more level of precision than mean/median, n will be presented as an integer, and CV%/Geom CV% will be presented to one decimal place.

Programmer Note:
- Wrap concentrations for all days into 1 table with a "Day" column header and "Nominal Time" sub-column header.
- PK time points are as follows:
  - Day 1: Predose (imputed as time 0) and approximately 1 hour ± 15 minutes (end of infusion [EOI]), 2 hours ± 15 minutes, 4 hours ± 15 minutes, 6 hours ± 15 minutes, and 12 hours ± 15 minutes post-start of infusion (SOI)
  - Days 2 (24 hours ± 1 hour post-SOI), 3 (48 hours ± 1 hour post-SOI), 8 (168 hours post-SOI), 15 (336 hours post-SOI), 29 (672 hours post-SOI), 43 (1008 hours post-SOI), and 76 (1800 hours post-SOI)

Program: /CAXXXXX/sas_prg/pksas/adam_conc.sas DDMMMYYYY HH:MM

Table CPPar1 Serum TRL345 Pharmacokinetic Parameters Following Administration of a Single 1-Hour Intravenous Infusion of 1 mg/kg TRL345 (Treatment A) (Pharmacokinetic Analysis 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
Range	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

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

Notes for Generating the Actual Tables:

Presentation of Data:

- PK parameters will be presented in the following order and with following units for TRL345 after single 1-hour Intravenous infusion: AUC0-tlast (µg*hr/mL), AUC0-inf (µg*hr/mL), AUC%extrap (%), Cmin (µg/mL), Cmax (µg/mL), Ceoi (µg/mL), Tmax (hr), Tmin (hr), Tlast (hr), Kel (1/hr), t½ (hr), CL (L/hr), and Vss (L/Kg).
- PK parameters will be reported to 3 significant figures for individual parameters, with the exception of Cmin and Cmax, which will be presented with same level of precision as received from the bioanalytical laboratory, and Tmax, which will be presented with 2 decimal places.
- The level of precision for each parameter statistic will be presented as follows: minimum/maximum/range in same precision as in bioanalytical data (i.e., 3 significant figures) and/or parameter output, mean/median/Geom Mean in one more level of precision than minimum/maximum/range, SD/SEM in one more level of precision than mean/median/Geom Mean, n will be presented as an integer, and CV%/Geom CV% will be presented to one decimal place.

Table ADAD Serum TRL345 ADA Detection Summary Following a Single 1-Hour Intravenous Infusion of TRL345 or Placebo (Immunogenicity Population)

	Treatment			
	P	A	B	Active Total
ADA Result	(N = X)	(N = X)	(N = X)	(N = X)
Baseline				
ADA Unevaluable (%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
ADA Negative (%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
ADA Positive (%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
1:X	X (XX%)	X (XX%)	X (XX%)	X (XX%)
1:XX	X (XX%)	X (XX%)	X (XX%)	X (XX%)
1:XXX	X (XX%)	X (XX%)	X (XX%)	X (XX%)
<Days 8, 29 and 43 will be repeated >				
Day 76				
ADA Unevaluable (%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
ADA Negative (%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
ADA Positive (%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
1:X	X (XX%)	X (XX%)	X (XX%)	X (XX%)
1:XX	X (XX%)	X (XX%)	X (XX%)	X (XX%)
1:XXX	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Overall				
ADA Unevaluable (%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
ADA Negative (%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
ADA Positive (%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

Treatment A: A single 1-hour intravenous infusion of 1 mg/kg TRL345 (Dose Group 1)
Treatment B: A single 1-hour intravenous infusion of 10 mg/kg TRL345 (Dose Group 2)
Treatment P: A single 1-hour intravenous infusion of matching placebo (Dose Groups 1 and 2)
Baseline is the last measurement collected prior to start of dosing.
Overall indicates the number of subjects who had a ADA positive result at one or more time points.
Percentage is relative to the number of subjects (N) dosed.
ADA = Anti-drug antibody; ADA positive = Subject with a confirmed positive ADA result

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

Notes for Generating the Actual Table:

Programmer Notes:

- ADA time points are as follows:
  - Day 1: Baseline
  - Days 8 (168 hours post-SOI), 29 (672 hours post-SOI), 43 (1008 hours post-SOI), 76 (1800 hours post-SOI)
- Present confirmatory assay results.
- The 'X' in 1:X, 1:XX, and 1:XXX will be replaced with values that will be provided by the PKist. The rows with 'ADA unevaluable (%)', 'ADA negative (%)', and 'ADA positive (%)' represent overall ratios (%), and the 1:X, 1:XX, and 1:XXX (titers) rows are subsets of that overall ratio (%).

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

	Treatment				
Adverse Event	P (N = X)	A (N = X)	B (N = X)	Active Total (N = X)	Overall (N = X)
Number of Subjects With TEAEs	X (X%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Number of Subjects Without TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Vision blurred	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Gastrointestinal disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Dyspepsia	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Nausea	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Musculoskeletal and connective tissue disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Back pain	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Muscle cramps	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Musculoskeletal pain	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Nervous system disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Headache	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reproductive system and breast disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Vaginal discharge	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Respiratory, thoracic and mediastinal disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Epistaxis	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)

Treatment A: < >
Treatment B: < >
Treatment P: < >
Although a subject may have had 2 or more adverse events, the subject is counted only once within a category. The same subject may appear in different categories.
Adverse events are classified according to MedDRA Version 26.1.
TEAEs = Treatment-emergent adverse events

Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

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

	Treatment				
Adverse Event	P	A	B	Active Total	Overall
Number of TEAEs	X	X	X	X	X
Eye disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Vision blurred	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Gastrointestinal disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Dyspepsia	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Nausea	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Musculoskeletal and connective tissue disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Back pain	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Muscle cramps	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Musculoskeletal pain	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Nervous system disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Headache	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reproductive system and breast disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Vaginal discharge	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Respiratory, thoracic and mediastinal disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Epistaxis	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Skin and subcutaneous tissue disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Sweating increased	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)

Treatment A: < >
Treatment B: < >
Treatment P: < >
Adverse events are classified according to MedDRA Version 26.1.
TEAEs = Treatment-emergent adverse events

Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

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

Adverse Event	Treatment	Number of Subjects With TEAEs	Number of TEAEs	Severity Grade				Relationship to Study Product	
				1	2	3	4	Likely	Unlikely
Abdominal pain	A	X	X	X	X	X	X	X	X
Constipation	B	X	X	X	X	X	X	X	X
Dry throat	P	X	X	X	X	X	X	X	X
Dysmenorrhoea	B	X	X	X	X	X	X	X	X
Headache	A	X	X	X	X	X	X	X	X
	P	X	X	X	X	X	X	X	X
Myalgia	B	X	X	X	X	X	X	X	X
	P	X	X	X	X	X	X	X	X
	B	X	X	X	X	X	X	X	X
	A	X	X	X	X	X	X	X	X
	Active Total	X	X	X	X	X	X	X	X
	Overall	X	X	X	X	X	X	X	X

Treatment A: < >
Treatment B: < >
Treatment P: < >
Adverse events are classified according to MedDRA Version 26.1.
TEAEs = Treatment-emergent adverse events
Severity Grade: 1 = Mild (Grade 1); 2 = Moderate (Grade 2); 3 = Severe (Grade 3); 4 = Potentially life threatening (Grade 4)

Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table 14.3.2.1 Serious Adverse Events (Safety Population)

Will match format of Appendix 16.2.7

Or contain statement as follows:

"There were no events that met this criteria."

Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CLBO Out-of-Range Values and Recheck Results - <Clinical Laboratory Panel> (Safety Population)

Dose Group	Subject Number	Age/ Sex	Study Period	Treatment	Day	Hour	Date	Time	Parameter1 <Range> (Unit)	Parameter2 <Range> (Unit)	Parameter3 <Range> (Unit)	Parameter4 <Range> (Unit)
1	0001	XX/X	Screen				DDMMMYYYY	HH:MM:SS	XX H		XX L	XX H
			1	A	-X	-X.XX	DDMMMYYYY	HH:MM:SS	XX L	XX L		XX L

Programmer Note: Replace Parameter1, 2 etc. with actual lab tests in the study. Sort unscheduled assessment and early termination chronologically with other scheduled assessments and rechecks. Recheck should be sorted with the scheduled time point the recheck is for. Unscheduled and Early Termination records should only be included if they are out of range or recheck results.

Treatment A: < >
Treatment B: < >
Treatment P: < >
F = Female; M = Male
H = Above reference range; L = Below reference range

Source: < >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CLBD Clinical Laboratory Summary and Change From Baseline - <Clinical Laboratory Panel> (Safety Population)

Laboratory Test (units)	Reference Range	Time Point	Statistic	Treatment P (N = X)	Treatment A (N = X)	Treatment B (N = X)	Change From Baseline P	Change From Baseline A	Change From Baseline B
Testname (unit)	< - >#	Baseline	n	X	X	X			
			Mean	X.X*	X.X	X.X			
			SD	X.XX	X.XX	X.XX			
			Minimum	XX	XX	XX			
			Median	X.X	X.X	X.X			
			Maximum	XX	XX	XX			
			Range	XX	XX	XX			
		Day 2	n	X	X	X	X	X	X
			Mean	X.X	X.X^	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX
			Range	XX	XX	XX	XX	XX	XX

Programmer Note: Treatment means at specific time points will be flagged (with a * or ^) if they are above or below the reference range. This only applies to the clinical laboratory treatment results (i.e., not the change from baseline or any other endpoints). Time Point column will match those found in the Clinical Laboratory Tests section of the SAP.

Treatment A: < >
Treatment B: < >
Treatment P: < >
Baseline is the last measurement collected prior to start of dosing.
= Lowest of the lower ranges and highest of the higher ranges are used. Refer to Appendix 16.1.10.1 for the breakdown.
* = Above reference range; ^ = Below reference range

Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

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

			Baseline L			Baseline N			Baseline H		
			Postdose			Postdose			Postdose		
Laboratory Test (units)	Treatment	Time Point	L	N	H	L	N	H	L	N	H
Testname (unit)	P	Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 3	X	XX	X	X	XX	X	X	XX	X
		Day 8	X	XX	X	X	XX	X	X	XX	X
		Day 15	X	XX	X	X	XX	X	X	XX	X
		Day 29	X	XX	X	X	XX	X	X	XX	X
		Day 43	X	XX	X	X	XX	X	X	XX	X
	A	Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 3	X	XX	X	X	XX	X	X	XX	X
		Day 8	X	XX	X	X	XX	X	X	XX	X
		Day 15	X	XX	X	X	XX	X	X	XX	X
		Day 29	X	XX	X	X	XX	X	X	XX	X
		Day 43	X	XX	X	X	XX	X	X	XX	X
	B	Day 2	X	XX	X	X	XX	X	X	XX	X

<similar to above for all treatments/time points>

Programmer Note: Time Point column will match those found in the Clinical Laboratory Tests section of the SAP.

Treatment A: < >
Treatment B: < >
Treatment P: < >
Baseline is the last measurement collected prior to start of dosing.
N = Within reference range; L = Below reference range; H = Above reference range

Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CVS Vital Sign Summary and Change From Baseline (Safety Population)

			Treatment			Change From Baseline		
			P	A	B			
Vital Sign (units)	Time Point	Statistic	(N = X)	(N = X)	(N = X)	P	A	B
Testname (unit)	Baseline	n	X	X	X			
		Mean	X.X	X.X	X.X			
		SD	X.XX	X.XX	X.XX			
		Minimum	XX	XX	XX			
		Median	X.X	X.X	X.X			
		Maximum	XX	XX	XX			
		Range	XX	XX	XX			
	Day 1, Hour 0.25	n	X	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX	XX
		Range	XX	XX	XX	XX	XX	XX

Programmer Note: Time Point column will match those found in Vital Signs Section of the SAP.

Treatment A: < >
Treatment B: < >
Treatment P: < >
Baseline is the last measurement collected prior to start of dosing.

Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CEG 12-Lead Electrocardiogram Summary and Change From Baseline (Safety Population)

			Treatment			Change From Baseline		
			P	A	B			
Measurement (units)	Time Point	Statistic	(N = X)	(N = X)	(N = X)	P	A	B
Testname (unit)	Baseline	n	X	X	X			
		Mean	X.X	X.X	X.X			
		SD	X.XX	X.XX	X.XX			
		Minimum	XX	XX	XX			
		Median	X.X	X.X	X.X			
		Maximum	XX	XX	XX			
		Range	XX	XX	XX			
	Day 1	n	X	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX	XX
		Range	XX	XX	XX	XX	XX	XX

Programmer Note: Time Point column will match those found in Electrocardiogram section of the SAP.

Treatment A: < >
Treatment B: < >
Treatment P: < >
Baseline is the last measurement collected prior to start of dosing.

Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

11.4 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 report. Listings will be generated from data created in accordance with SDTM Model 1.7 with Implementation Guide 3.3 or higher. Listings with derived data (i.e., triplicate ECGs) may be created from the ADaM data. All listings will be presented in Courier New size font 9. Time point information will match that found in the CRF.

Appendix 16.1.10.1 Clinical Laboratory Reference Ranges

Laboratory Group	Test Name	Sex	Age Category	Reference Range	Unit
Chemistry	Testname1	MALE		XX - XXX	mEq/L
	Testname2	MALE	0-25	XX - XXX	U/L
			26-99	XX - XXX	U/L
<similar for all other tests, note that age will only be presented when different reference range exists>					
Hematology	<similar to Chemistry>				
Urine Drug Screening	Amphetamines	MALE		NOT DETECTED	

Source: SDTM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.1.1 Subject Disposition (Safety Population)

			End of Treatment				End of Study			
Dose Group	Subject Number	Randomized /Actual Treatment	Did Subject Prematurely Discontinue?	Treatment Discontinuation Date	Primary Treatment Discontinuation Reason	Specify	Did Subject Complete the Study?	Date of Completion or Discontinuation	Primary Study Discontinuation Reason	Specify
1	0001	A/A	No				Yes	DDMMMYYYY		
	0002	P/P	No				No	DDMMMYYYY	Personal Reason	XXXXXXXX
	0003	A/A	Yes	DDMMMYYYY	Adverse Event	XXXXXXX	No	DDMMMYYYY	Other	XXXXXXXX

Programmer Note: Subject numbers will be presented as contained in clinical database (i.e. 0001, etc.)

Treatment A: A single 1-hour intravenous infusion of 1 mg/kg TRL345 (Dose Group 1)
Treatment B: A single 1-hour intravenous infusion of 10 mg/kg TRL345 (Dose Group 2)
Treatment P: A single 1-hour intravenous infusion of matching placebo (Dose Groups 1 and 2)

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.4.1 Demographics (Safety Population)

Dose Group	Subject Number	Year of Birth	Age (yr)	Sex	Race	Ethnicity	Height (cm)	Weight (kg)	Body Mass Index (kg/m²)	Informed Consent Date
1	0001	YYYY	47	Male	< >	Not Hispanic or Latino	XXX	XX.X	XX.XX	DDMMMYYYY
	0002	<similar to above.								

Age is approximated as year of informed consent – year of birth. There will be a subtraction of 1 if the difference in years is 1 more than the age specified in the inclusion criteria.
Screening measurements are presented for height, weight, and body mass index.

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.4.2 Physical Examination (I of II) (Safety Population)

Dose Group	Subject Number	Study Period	Treatment	Day	Hour	Date	Was Physical Exam Performed?	System1	System2	System3	System4	System5	System6
1	0001	Screen				DDMMMYYYY	Yes	NORMAL	NORMAL	NORMAL	NORMAL	NORMAL	NORMAL
		1	A	-1	23.00	DDMMMYYYY	Yes	ABNORMAL*	NORMAL	NORMAL	NORMAL	NORMAL	NORMAL
				2	27.50	DDMMMYYYY	Yes	NORMAL	NORMAL	NORMAL	NORMAL	NORMAL	NORMAL

Programmer Note: Appendix 16.2.4.3 will resemble Appendix 16.2.4.2.

Treatment A: < >
Treatment B: < >
Treatment P: < >
* = See Appendix 16.2.4.4 Physical Examination Descriptions
HEENT = Head, eyes, ears, nose, throat

Source: SDTM.< >; ADaM.< >
Program: /CAXXXX/sas_prg/stsas/programname2022Q1.sas DDMMMYYYY HH:MM

Appendix 16.2.4.4 Physical Examination Descriptions (Safety Population)

Dose Group	Subject Number	Study Period	Treatment	Day	Hour	Date	System	Result	Description or Comment
1	0001	1	A	X	XX.XX	DDMMMYYYY	Skin	ABNORMAL	RIGHT CHEST SCAR-NCS

Treatment A: < >
Treatment B: < >
Treatment P: < >
NCS = Not clinically significant

Source: SDTM.< >; ADaM.< >
Program: /CAXXXX/sas_prg/stsas/programname2022Q1.sas DDMMMYYYY HH:MM

Appendix 16.2.4.5 Medical History (Safety Population)

Dose Group	Subject Number	Any History?	Condition or Event	Date Start	Date End	Ongoing?
1	0001	No				
	0002	Yes	< >	YYYY		Yes
	<note date can be YYYY, MONYYYY, or DDMONYYYY based on individual subjects data>					

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.4.6 Substance Use (Safety Population)

Dose Group	Subject Number	Substance	Description of Use	Start Date	End Date
1	0001	Tobacco Use	0-4 CIGARETTES WEEK	DDMONYYYY	DDMONYYYY
			NON-SMOKER	DDMONYYYY	
	0002	Tobacco Use	NON-SMOKER	DDMONYYYY	

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.1 Subject Eligibility (Safety Population)

Dose Group	Subject Number	Study Period	Did subject meet all eligibility criteria?	Criterion Not Met
1	0001	Screen	Yes	
	0002	Screen	No	Exclusion 5
				<criterion not met will only be presented if if populated>

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.2 Test Compound Description

CRF Treatment Description	Form	Route
< >	SOLUTION	INJECTION IV INFUSION

IV = Intravenous

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.3 Test Compound Administration Times (Safety Population)

Dose Group	Subject Number	Study Period	Treatment	Day	Interval	Dose Date	Dose Start Time	Dose End Time	Compound	Planned Dosage	Comments
1	0001	1	A	1	0.00 TO 1.00	DDMONYYYY	HH:MM:SS	HH:MM:SS	TRL345	1 mg/kg	<This column prints only if data is Present>

Treatment A: < >
Treatment B: < >
Treatment P: < >

Source: SDTM.< >; ADaM. < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.4 Prior and Concomitant Medications (Safety Population)

Dose Group	Subject Number	Treat-ment	Prior?	Medication (WHO DD)	Dosage	Route	Start Date	Start Time	End Date	End Time	Frequency	Indication	Ongoing?
1	0001			None									
	0002			None									
	0003		Yes	CETIRIZINE (CETIRIZINE)	X MG	BY MOUTH	DDMONYYYY		DDMONYYYY	HH:MM	XXXXXXX	XXXXXXX	No
		A	No	PARACETAMOL (PARACETAMOL)	X MG	XXXXXXXXX	DDMONYYYY	HH:MM	XXXXXXXXX	HH:MM	XXXXXXXX	XXXXXXXX	XX

Treatment A: < >
Treatment B: < >
Treatment P: < >
Concomitant medications are coded with WHO Drug Dictionary Version 01-Sep-2023_b3.
Prior is defined as a medication administered prior to start of dosing.
WHO DD = World Health Organization Drug Dictionary

Source: SDTM.< >; ADaM. < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendices 16.2.5.6 through 16.2.5.7_will be in the following format:

Appendix 16.2.5.5 Pharmacokinetic Blood Draw Times and Serum TRL345 Concentration Data (Safety Population)

Dose group	Subject Number	Study Period	Treatment	Blood Draw Day	Blood Draw Hour	Blood Draw Date	Blood Draw Time	Elapsed Time From SOI (Hour)	Serum TRL345 Concentration (µg/mL)	Comments
1	0001	1	A	1	-0.05	DDMONYYYY	HH:MM:SS	0.0	X.XX	
					1.00	DDMONYYYY	HH:MM:SS	1.065	X.XX	
					3.00	DDMONYYYY	HH:MM:SS	3.190	X.XX	Late Draw
				< >						
				2	24.00	DDMONYYYY	HH:MM:SS	0.0	X.XX	
<similar for all other time points and subjects>										

Treatment A: **<>**
Treatment B: **<>**
Treatment P: **<>**

Program: /CAXXXXX/sas_prg/pksas/standardlis/pk_bld.sas DDMMMYYYY HH:MM

Appendix 16.2.5.6 Immunogenicity Blood Draw Times and ADA Results (Safety Population)

Dose Group	Subject Number	Study Period	Treatment	Blood Draw Day	Blood Draw Hour	Blood Draw Date	Blood Draw Time	Screening Result	Confirmatory Result	Titer Value	Comments
S1	0001	1	A	1	-0.50	DDMONYYYY	HH:MM:SS	XXXXXXXXXX	XXXXXXXXXX	XXXXX	
				8	720.00	DDMONYYYY	HH:MM:SS	XXXXXXXXXX	XXXXXXXXXX	XXXXX	
				29	1392.00	DDMONYYYY	HH:MM:SS	XXXXXXXXXX	XXXXXXXXX	XXXXX	
				43	2064.00	DDMONYYYY	HH:MM:SS	XXXXXXXXXX	XXXXXXXXXX	XXXXX	
				<similar for all other time points and subjects>							

Treatment A: < >
Treatment B: < >
Treatment P: < >

Program: /CAXXXXX/sas_prg/pksas/standardlis/pk_bld.sas DDMMMYYYY HH:MM

Appendix 16.2.5.7 Interleukin-1 Alpha Blood Draw Times and Concentration Data (Safety Population)

Dose group	Subject Number	Study Period	Treatment	Blood Draw Day	Blood Draw Hour	Blood Draw Date	Blood Draw Time	Elapsed Time From Start of Infusion (Hour)	Serum IL-1 alpha Concentration (µg/mL)	Comments
1	0001	1	A	Baseline	-22.75	DDMONYYYY	HH:MM:SS	0.0	X.XX	
				3	48.00	DDMONYYYY	HH:MM:SS	1.065	X.XX	
				15	336.00	DDMONYYYY	HH:MM:SS	3.190	X.XX	Late Draw
				29	672.00	DDMONYYYY	HH:MM:SS	3.190	X.XX	
				43	1008.00	DDMONYYYY	HH:MM:SS	0.0	X.XX	
<similar for all other time points and subjects>										

Treatment A: **<>**
Treatment B: **<>**
Treatment P: **<>**

Program: /CAXXXXX/sas_prg/pksas/standardlis/pk_bld.sas DDMMMYYYY HH:MM

Appendix 16.2.5.8 Pharmacodynamic Blood Draw Times (Safety Population

Dose group	Subject Number	Study Period	Treatment	Blood Draw Day	Blood Draw Hour	Blood Draw Date	Blood Draw Time	Elapsed Time From Start of Infusion (Hour)	Comments
1	0001	1	A	1	-0.25	DDMONYYYY	HH:MM:SS	0.0	
					1.00	DDMONYYYY	HH:MM:SS	1.065	
				15	336.00	DDMONYYYY	HH:MM:SS	3.190	Late Draw
				29	672.00	DDMONYYYY	HH:MM:SS	3.190	
				43	1008.00	DDMONYYYY	HH:MM:SS	0.0	
			<similar for all other time points and subjects>						

Treatment A: **<>**
Treatment B: **<>**
Treatment P: **<>**

Program: /CAXXXXX/sas_prg/pksas/standardlis/pk_bld.sas DDMMMYYYY HH:MM

Appendix 16.2.5.9 Possible Exploratory Analyses Data Blood Draw Times (Safety Population)

Dose group	Subject Number	Study Period	Treatment	Blood Draw Day	Blood Draw Hour	Blood Draw Date	Blood Draw Time	Elapsed Time From Start of Infusion (Hour)	Comments
1	0001	1	A	1	-0.25	DDMONYYYY	HH:MM:SS	0.0	
				3	48.00	DDMONYYYY	HH:MM:SS	1.065	
				8	168.00	DDMONYYYY	HH:MM:SS	3.190	Late Draw
				15	336.00	DDMONYYYY	HH:MM:SS	3.190	
				29	672.00	DDMONYYYY	HH:MM:SS	0.0	
<similar for all other time points and subjects>									

Treatment A: **<>**
Treatment B: **<>**
Treatment P: **<>**

Program: /CAXXXXX/sas_prg/pksas/standardlis/pk_bld.sas DDMMMYYYY HH:MM

Appendices 16.2.6.2 will be in the following format:

Table CPKel2 Intervals (Hours) Used for Determination of Serum TRL345 Kel Values (Pharmacokinetic Analysis Population)

Dose Group	Subject Number	Treatment	Interval	R2	n
X	X	X	XX.X - XX.X	X.XXX	X
X	X	X	XX.X - XX.X	X.XXX	X
X	X	X	XX.X - XX.X	X.XXX	X
X	X	X	XX.X - XX.X	X.XXX	X
X	X	X	XX.X - XX.X	X.XXX	X
X	X	X	XX.X - XX.X	X.XXX	X

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

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

Notes for Generating the Actual Table:

Presentation of Data:

- Interval start and stop times will be presented to 1 decimal or 3 sig figures min;
- R2 will be presented to 3 decimals;
- n will be presented as an integer (with no decimal)

Appendix 16.2.7.1 Adverse Events (Safety Population)

Dose Group	Subject Number	Age/ Sex	Treatment	TE?	System Organ Class/ Preferred Term (Verbatim)	Time From Last Dose (DD:HH:MM)	Date:Time Start/ End Duration (DD:HH:MM)	Serious/ Outcome	Severity/ Frequency	Study Product Relationship/ Action	IR?*
1	0001	30/F			None						
	0002	24/M			None						
	0003	52/M	A	Yes	XXXXXXXXXXXX/ XXXXXXXXXXXXXXXX (XXXXXXXXXX)	XX:XX:XX	DDMONYYYY:HH:MM/ DDMONYYYY:HH:MM 00:23:15	No/ Recovered/ Resolved	Moderate (Grade 2)/ Intermittent	Likely/ Drug Withdrawn	No
				Yes	<similar to above>						

Programmer Note: AEs should be presented start date/time order for each suject.

Treatment A: < >
Treatment B: < >
Treatment P: < >
Adverse events are classified according to MedDRA Version 26.1.
*Is adverse event an infusion reaction?
TE = Treatment-emergent
F = Female; M = Male

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.7.2 Details for Serious Adverse Events (Safety Population)

Dose Group	Subject Number	Age/ Sex	Treat-ment	TE?	System Organ Class/ Preferred Term (Verbatim)	Date:Time Start/ End Duration (DD:HH:MM)	Serious Event?	Congenital Anomaly/ Birth Defect?	Persistent or Significant Disability or Incapacity?	Hospital-ization?	Life-Threat?	Important Medical Event?	Death?
1	0003	52/M	A	Yes	XXXXXXXXXXX/ XXXXXXXXXXXXXXXXX (XXXXXXXXXXX)	DDMONYYYY:HH:MM/ DDMONYYYY:HH:MM 00:23:15	Yes	No	No	Yes	No	Yes: < >	No

Programmer Note: If Serious = Yes then present AEs in this listing otherwise please do not include this listing.

Treatment A: < >
Treatment B: < >
Treatment P: < >
Adverse events are classified according to MedDRA Version 26.1.
TE = _Treatment-emergent
F = Female; M = Male

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendices 16.2.8.2 – 16.2.8.5 will resemble 16.2.8.1.

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Appendix 16.2.8.1 Clinical Laboratory Report - Chemistry (Safety Population)

Dose Group	Subject Number	Age/ Sex	Study Period	Treat-ment	Day	Hour	Date	Time	Chloride M: 97-105 (mEq/L)	Potassium M: 3.7-5.2 (mEq/L)	Phosphorus M: 2.4-4.4 (mg/dL)	Sodium M: 135-143 (mEq/L)
1	0001	XX/M	Screen				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X	XXX H
			1	A	-1	-23.00	DDMONYYYY	HH:MM:SS	XXX H	X.X	X.X	XXX H
			Recheck				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X	XXX

<similar to above for all subjects/time points>

Treatment A: < >
Treatment B: < >
Treatment P: < >
F = Female; M = Male
H = Above reference range; L = Below reference range

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.8.6 Vital Signs (Safety Population)

Dose Group	Subject Number	Age/ Sex	Study Period	Treatment	Day	Hour	Date	Time	Blood Pressure (mmHg) Position	Blood Pressure (mmHg) Systolic/Diastolic	Pulse (bpm)	Temperature (°C)	Weight (kg)
1	0001	30/F	Screen				DDMONYYYY	HH:MM:SS					XX.X
									SEM5	XXX/ XX	XX	XX.X	
						R		HH:MM:SS	SEM5	XXX/ XX			
						R		HH:MM:SS	SEM5	XXX/ XX			
			1	A	-1	-22.25	DDMONYYYY	HH:MM:SS					XX.X
					1	-0.75	DDMONYYYY	HH:MM:SS	SEM5	XXX/ XX	XX	XX.X	

Treatment A: < >
Treatment B: < >
Treatment P: < >
F = Female; M = Male
SEM5 = 5-minutes semi-recumbent; R = Recheck value

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.8.7 12-Lead Electrocardiogram (Safety Population)

Dose Group	Subject Number	Age/ Sex	Study Period	Treat-ment	Day	Hour	Date	Time	Result	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)	Specify/Comments
1	0001	30/F	Screen				DDMONYYYY	X:XX:XX*	WNL	XX	XXX	XX	XX	XXX	XXX	EARLY REPOLARIZATION; LEFT AXIS DEVIATION
							DDMONYYYY	X:XX:XX*	WNL	XX	XXX	XX	XX	XXX	XXX	
							DDMONYYYY	X:XX:XX*	WNL	XX	XXX	XX	XX	XXX	XXX	
			1	A	1	4.75	DDMONYYYY	XX:XX:XX*	ANCS	XX	XXX	XX	XX	XXX	410	LEFT AXIS DEVIATION
						4.77	DDMONYYYY	XX:XX:XX*	< >	XX	XXX	XX	XX	XXX	441	SINUS BRADYCARDIA
						4.78	DDMONYYYY	XX:XX:XX*	< >	XX	XXX	XX	XX	XXX	451#	

Treatment A: < >
Treatment B: < >
Treatment P: < >
F = Female; M = Male
WNL = Within normal limits; ANCS = Abnormal, not clinically significant
QTcF = QT corrected for heart rate using Fridericia's correction
* = Assessment used in calculation of average that is used during analysis
# = QTc value greater than 450 msec

Source: SDTM.< >; ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.8.9 12-Lead Electrocardiogram – Average of Triplicates (Safety Population)

Dose Group	Subject Number	Age/ Sex	Treatment	Time Point	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)
1	0001	30/F	A	Baseline	XX.X	XX.X	XX.X	XX.X	XX.X	410.2
				Day 1	XX.X	XX.X	XX.X	XX.X	XX.X	451.4 #@
				Day 8	XX.X	XX.X	XX.X	XX.X	XX.X	434.5

Programmer Note: Averaged triplicate values will be displayed to the nearest tenth.

Treatment A: < >
Treatment B: < >
Treatment P: < >
This listing only presents average triplicate 12-lead electrocardiogram results used during analysis.
Baseline is the last measurement collected prior to start of dosing.
F = Female; M = Male
QTcF = QT corrected for heart rate using Fridericia's correction
# = QTc value greater than 450 msec; @ = QTc change from baseline greater than 30 msec

Source: ADaM.< >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM