STATISTICAL ANALYSIS PLAN REVIEW AND APPROVAL

SAP Version Number: VERSION 2.0

Protocol/Study Number: TMB-302 (IM)

Title: A Phase 3 Study of the Safety of Trogarzo® Administered as an Undiluted "IV Push" over a Reduced Interval or as an Intramuscular Injection in Clinically Stable HIV-1 Infected Trogarzo® Experienced Patients and Healthy HIV-uninfected Volunteers

Approval for:

- ☒ SAP Text
- ☒ Mock Tables
- ☒ Mock Listings
- ☐ Other, specify:

Change Control Log

Author/Date	Page/Paragraph	Version Number	Description of Change	Reason for Change
Jennifer Fulton/01APR2022		1.0	Initial versions	
Jennifer Fulton/25AUG2022	SAP – page 17	2.0	Addendum describing analysis of re-enrolled subjects	Protocol Amendment 7
Jennifer Fulton/25AUG2022	SAP – section 4.5 page 14 MTB – page 11 and 12	2.0	SAP - Statement added in section 4.5 indicating both arithmetic and geometric means will be presented for Ctrough analysis MTB – titles and additional table added for Ctrough arithmetic and geometric means	Requests by Thera statistician
Jennifer Fulton/25AUG2022	MTB and MLS – several items	2.0	Minor formatting updates to reflect decisions during programming	Decisions by lead programmer

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TaiMed Biologics, Inc.

Protocol TMB-302 (IM)

A Phase 3 Study of the Safety of Trogarzo® Administered as an Undiluted "IV Push" over a Reduced Interval or as an Intramuscular Injection in Clinically Stable HIV-1 Infected Trogarzo® Experienced Patients and Healthy HIV-uninfected Volunteers

Statistical Analysis Plan

August 25, 2022
Version 2.0

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Table of Contents

1. Introduction

This document outlines the planned statistical analyses for data collected within the scope of the TaiMed protocol TMB-302, focusing on the Intramuscular (IM) Injection portion only, which was introduced with Amendment 5 (protocol v6.1). This statistical analysis plan (SAP) applies to the most recent version of the study protocol (v6.2 dated 15 Nov 2021) and will be updated as necessary if future protocol amendments warrant an update to the manner of analysis. This document was prepared in accordance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline E3: Structure and Content of Clinical Study Reports [1].

2. Study Overview

2.1. Study Design

The IM portion of this Phase 3 study is designed to assess the safety and pharmacokinetic (PK) profile (trough concentration and serum area under the curve [AUC]) of 800 mg Trogarzo® once every two weeks administered via IM administration of Trogarzo® compared with the approved Trogarzo® administration (IV infusion) (diluted in 250 mL normal saline administered intravenously over 15 minutes). At the end of the study, the HIV stable subjects will return to IV infusion administration. The study will also assess the maintenance of established virologic control, characterize changes in the viral susceptibility/resistance in HIV infected subjects, and the development of anti-drug antibodies in all subjects as secondary endpoints. If deemed comparable to administration by IV infusion, administration by IM would be desirable to improve the logistics of administration by eliminating the need for saline bags and infusion apparatus as well as improving convenience for subjects and physicians.

The IM Group will comprise twenty (20) subjects receiving Trogarzo® as an IM injection. Subjects completing the IV push portion of the study (from the Sentinel and Core Groups) are eligible to participate in the IM Group.

<u>IM Group: HIV infected subjects</u>
The HIV infected subjects in the IM Group (subject numbers XX-501 – XX-5nn where XX is the site number and nn is the last subject number) will be enrolled. Subjects will receive the first two doses of study drug in accordance with the Trogarzo® prescribing information (diluted in normal saline and administered over 15 minutes via IVI) at Day 1 and again at Day 15. The next four doses of Trogarzo® through Day 71 (10 weeks) will be administered as an IM injection. At Day 85 (12 weeks), IM Group subjects will revert to diluted IVI dosing over 15 minutes in accordance with the Trogarzo® prescribing information.

<u>IM Group: HIV uninfected subjects</u>
The HIV uninfected subjects in the IM Group (subject numbers XX-601 – XX-6nn) will be enrolled.

Pre-Steady State Phase: Subjects will receive a 2000 mg infusion over 60 minutes on Day minus 55 followed by 3 doses of 800 mg infusion over 15 minutes on Days minus 41, 27, and Day minus 13. On Day 1 the subjects will enter the Study Treatment Phase.

Study Treatment Phase: HIV uninfected subjects in the IM Group will receive the first two doses of Trogarzo® in accordance with the prescribing information (diluted in 250 mL normal saline and administered over 15 minutes via IVI) at Day 1 and again at Day 15. The next four doses of Trogarzo® will be administered as an IM injection. HIV uninfected subjects will discontinue dosing after the Day 71 study drug administration.

All HIV infected study subjects in both Groups will be observed for 15 minutes after each study drug administration, and HIV uninfected subjects will be observed for 60 minutes. All adverse events (AEs) will be recorded. Vital signs will be measured and recorded at the beginning and end of this observation period.

For the PK profile of Trogarzo® following IM administrations, pre-dose samples will be collected at selected time points, along with samples at 2, 7, 10, and 14 days post-dose for the last two doses of study drug (via IVI), and for the last two IM injection doses for all subjects.

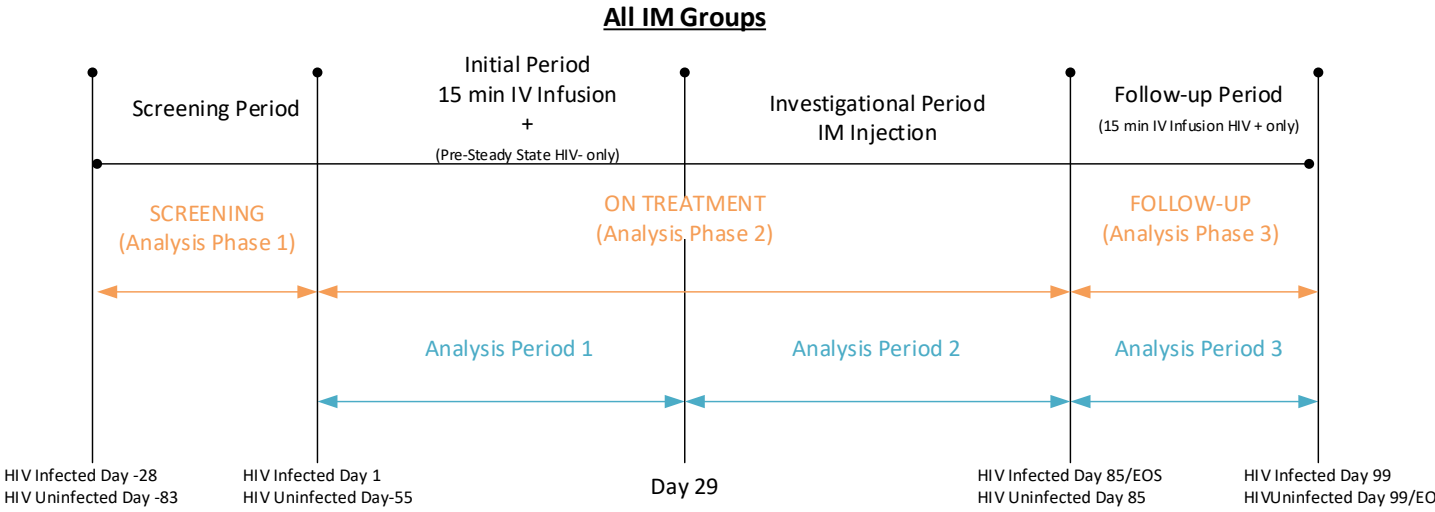
Safety Assessments

Safety assessments will include the following through End of Study for each Group:

- Physical examinations
- Vital sign measurements
- Clinical laboratory parameters (hematology, serum chemistry, urinalysis and $CD4^+$ T-cell count)
- Monitoring of AEs and concomitant medications
- Anti-Trogarzo® antibody levels (immunogenicity of Trogarzo®)
- Injection site reactions in subjects receiving Trogarzo® IM

Laboratory samples will be collected every two weeks, at visits where Trogarzo® is administered. Beginning at Day 29 (4 weeks), non-laboratory safety assessments will be performed as scheduled through Day 99 (14 weeks) for the IM HIV uninfected Group, and through Day 85 (12 weeks) for the IM HIV infected Group.

The figure below illustrates the Analysis Phases and Periods to be utilized.



2.2. Study Objectives

2.2.1. Primary

The primary objectives of the IM portion of this study are to:

- Evaluate the safety of Trogarzo® administered by IM injection in clinically-stable human immunodeficiency virus type-1 (HIV-1) infected subjects with at least 3 months of stable treatment with a Trogarzo®-containing antiretroviral (ARV) regimen or healthy HIV uninfected volunteers
- Compare the trough serum drug concentration after IVI with the diluted drug to the trough serum concentration after IM injection of undiluted Trogarzo®

2.2.2. Secondary

The secondary objectives of this study are to:

- Assess HIV-1 viral load for IV Infusion compared to IM injection in HIV-1 infected subjects only.
- Characterize noted HIV-1 sensitivity/susceptibility changes in participants with an increase in plasma viral load to levels above 1,000 copies/mL on two consecutive measurements at least 2 weeks apart in HIV-1 infected subjects only.
- Determine the presence and significance of anti-Trogarzo® antibodies, if any (immunogenicity of Trogarzo®)

- Compare the AUC after IVI with the diluted drug to the AUC after IM injection of undiluted Trogarzo®

2.2.3. Exploratory

An additional exploratory objective is to assess the subject reported outcomes captured in the HIVTSQ, SMSQ, and Preference questionnaires.

2.3. Study Drug Dosage and Administration

The study drug, Trogarzo®, is a humanized IgG4 monoclonal antibody (MAb) approved for use in treatment-experienced patients in combination with other ARV agents for the treatment of multi-drug resistant HIV-1 infection and is administered via IV.

Maintenance doses of 800 mg Trogarzo® will be administered to all study subjects every two weeks throughout their participation in the study.

The Day1 and Day 15 doses will be administered as diluted IVs (IV Infusion - 800 mg in 250mL normal saline; 3.2 mg/mL) over 15 minutes in accordance with Trogarzo® prescribing information. Subsequent Trogarzo® doses on study will be administered via IM injection (see Study Design for more detail).

All HIV infected subjects will continue on all other ARV medications as prescribed by the primary care provider throughout study participation. Any changes in ARV treatment will be recorded with reasons for treatment modification. All HIV infected patients will return to routine Trogarzo® administration via IV Infusion over 15 minutes in accordance with the prescribing information after completing participation in the study.

2.4. Procedures

2.4.1. Subject Identification

Once consent is obtained and study eligibility has been determined, a subject will be enrolled into the study and will be assigned a Participant Identification (PID) number. The 5-digit PID number will consist of a 2-digit site number and a 3-digit sequential subject number. Note: The protocol allows subjects who completed the IVP portion of the study to re-enroll into the IM portion of the study. For the purpose of analysis, the IM and IVP portions will be treated as separate studies, and new PIDs will be assigned. However the CDISC rules for subjects with multiple enrollments will be applied with regard to the variables. USUBJID (the same across all studies/enrollments) and SUBJID (unique to each study/enrollment).

2.4.2. Randomization

This will be an open-label, non-randomized study.

2.4.3. Blinding/Unblinding

There will be no blinding/unblinding considerations for this open-label, non-randomized study.

2.4.4. Replacement

If a subject in the study is discontinued due to any reason other than safety as detailed in Section 4.3 (Safety Monitoring and Toxicity Management Plan) of the study protocol, another subject may be enrolled to replace the lost subject to achieve a total of 20 subjects successfully completing participation in the study.

Study participants who:
1. miss 2 consecutive visits or
2. have more than one treatment visit out of window or
3. have 3 non-treatment visits over 4 weeks that are out of window will be discontinued from the study and replaced.

3. Statistical Analysis Considerations

3.1. Sample Size

Anticipated enrollment in the IM portion is 20 subjects from 4 sites in the United States.

3.2. Analysis Populations

3.2.1. Intent-to-Treat (ITT) Population

The ITT population is defined as all subjects enrolled into the study. Subject disposition will be based on the ITT population. The ITT Analysis Set will be used for the AUC and trough serum drug concentration and the secondary effectiveness analysis (assessment of the HIV-1 viral loads).

3.2.2. Safety (SAF) Population

All subjects who receive at least one partial dose of study drug will be included in the SAF Population. Subjects will be analyzed according to the treatment (dose regimen) they actually received. The SAF Population will be used for the safety analyses.

3.3. Data Handling

3.3.1. Measurement Times

The nominal visit time point entered on the electronic case report forms (eCRFs) will be used. Subjects are asked to adhere to the following visit schedule:

IM HIV infected Group

- Study drug administration visits with safety assessments will take place once every two weeks beginning at Day 1 and continuing through Day 85 (12 weeks).
- IM HIV infected Group subjects will be asked to return for the final study assessments indicated for the EOS and Follow-up visits at Days 85 (12 weeks) and 99 (14 weeks), respectively. Subjects who are discontinued or who withdraw from the study prematurely are also requested to complete the assessments for these two study visits. (Refer to the Schedule of Events tables in the protocol for details on procedures for each scheduled study visit and for PK sampling time points.)

IM HIV uninfected Group

- Study drug administration visits with safety assessments will take place once every two weeks beginning at Day -55 and continuing through Day 71 (10 weeks).
- IM HIV uninfected Group subjects will be asked to return for the final study assessments indicated for the EOS and Follow-up visits at Days 99 (14 weeks) and 113 (16 weeks), respectively. Subjects who are discontinued or who withdraw from the study prematurely are also requested to complete the assessments for these two study visits. (Refer to the Schedule of Events tables in the protocol for details on procedures for each scheduled study visit and for PK sampling time points.)

3.3.2. Clinical Laboratory Data Handling Conventions

If a subject has multiple results in the clinical laboratory data for the Screening visit, only the last result prior to the first dose of study drug will be included in the analysis. If a subject has multiple results (retests) for subsequent visits, the retest results will only be included in the analysis if the subject does not have a value recorded for the original assessment at the given visit.

3.3.3. Baseline Values

Baseline is defined as the last assessment prior to the first dose of study drug (Day 1 for all HIV infected subjects, Day -55 for HIV uninfected subjects).

3.3.4. Missing Data Conventions

Subjects with missing data at Baseline will use the last Screening visit value as their Baseline result. Unless otherwise specified, missing data for subsequent visits will be considered missing at random and will not be imputed. If necessary, imputation of partial dates may be performed during the data analysis and will be documented (e.g., missing month=July; missing day=15).

3.4. Statistical Methods

3.4.1. General Overview and Plan of Analysis

The data collected are intended primarily for clinical review and interpretation. The analysis of study data will be primarily descriptive, with emphasis on tabular and graphical displays. Descriptive statistics will be used to guide decisions as to the clinical relevance of findings. Unless otherwise stated, p-values will be determined only if they appear to be warranted from the summary statistics.

Where applicable, summaries will be displayed in the following subject groupings:

- IM HIV infected
- IM HIV uninfected
- Total

In addition, the safety and efficacy summaries will present results grouped by analysis periods, where applicable:

- IM HIV infected: Initial Period (15 min IV Infusion); Investigational Period (IM Injection); Follow-up Period (15 min IV Infusion)
- IM HIV uninfected: Pre-Steady State + IV Infusion Period; Investigational Period (IM Injection); Follow-up Period

For continuous data, descriptive statistics will be presented as number of subjects (n), mean, standard deviation, median, minimum, and maximum. For categorical data, the frequency and percentage of subjects in each category will be presented. Percentages will be based on non-missing data unless otherwise specified.

Data collected during this study will be assigned to the appropriate Analysis Phase, Analysis Period, and Analysis Sub period (where applicable) in which it occurred. The assignment will be based on the visit date, or in the case of cumulative data such as AEs and concomitant procedures, based on the start date. Tables, listings, and graphs will reflect the assignments. A complete description of the phases, periods, and sub periods for the HIV infected and HIV uninfected groups can be found in Appendix 1.

Data will be described and analyzed using the SAS System Version 9 (SAS Institute Inc., Cary, NC, SAS System). Individual subject data will be presented in subject data listings.

4. Statistical Analysis

4.1. Subject Disposition

The number of subjects in the ITT and SAF Populations will be tabulated.

Study completion data will be summarized for all enrolled subjects. The number and percent of subjects who complete treatment; discontinue study medication prematurely; or discontinue the study prematurely will be tabulated. The primary reason for premature discontinuation of study medication and/or discontinuation from study participation will be tabulated. Any additional reason(s) for premature discontinuation of study medication will also be tabulated. A listing of all enrolled subjects will be provided.

4.2. Demographic and Physical Characteristics

Summary statistics will be presented for demographic and other Baseline characteristics for the ITT Population. Tabulations for age, sex, ethnicity (Hispanic/Latino, Not Hispanic or Latino, Unknown), and race (American Indian/Alaska Native, Asian, Black/African American, Native Hawaiian/Other Pacific Islander, White, Unknown, or Other) will be presented. Age (years) will be calculated as the integer part of [(date of screening - date of birth + 1)/365.25]. Baseline physical characteristics, such as height (cm) and weight (kg), will also be summarized.

A listing of demographic and Baseline characteristics will be presented, as well as a listing of medical history.

4.3. Analysis of Safety and Tolerability

Safety and tolerability will be assessed by both clinical and laboratory examinations. Summary statistics will be presented by AEs; hematology and serum chemistry; vital signs, and abnormal physical examination findings in the SAF Population. Clinical laboratory values outside the normal ranges will be flagged in subject data listings. Non-numeric data will be presented in subject data listings, but will not be summarized.

4.3.1. Extent of Study Drug Exposure

Summary statistics will be presented for the cumulative dose (mg) and duration of treatment received by the subjects in the SAF Population. Duration of treatment will be represented as number of days from first dose of study drug. Corresponding listings will also be generated for study drug administration.

4.3.2. AEs

All AEs will be coded using MedDRA dictionary version 22.0. The use of another version will not be considered a violation of the SAP, nor require an amendment to the plan. All summary tables will be based on coded preferred terms (PTs), instead of verbatim terms. The categories and definitions of severity and causal relationship for

all AEs, including the criteria for which an AE is to be classified as "serious," are as described in the protocol (Section 8).

A treatment-emergent AE (TEAE) is defined as any event not present before exposure to study drug or any event already present that worsens in either intensity or frequency following exposure to study drug. All AEs entered on the Adverse Events eCRF will be analyzed as TEAEs. A TEAE with missing severity or relationship will be considered severe or related, respectively.

The overall incidence of TEAEs will be summarized for all subjects in the SAF Population. The number and percentage of subjects having the following will be tabulated:

- TEAE
- Serious TEAE
- TEAE leading to discontinuation
- TEAE with outcome of death
- Suspected Adverse Reaction
- Severe (Grade 3 or 4) TEAE
- Class C TEAE per the Centers for Disease Control and Prevention (CDC) Classification System for HIV Infection

The overall incidence of TEAEs will also be summarized by System Organ Class (SOC), and by SOC and PT. The number and percentage of subjects reporting an event, as well as the number of events reported by the subjects will be tabulated. The incidence of serious TEAEs and TEAEs leading to study discontinuation (if any) will be summarized in the same manner. If there are multiple occurrences of the same TEAE within any SOC or PT for the same subject, only the first occurrence will be counted.

The incidence of TEAEs by severity/grade (Mild, Moderate, Severe, or Potentially life-threatening, Death) and by relationship to study drug (Suspected Adverse Reaction or Unrelated), and the incidence of serious AEs (SAEs) by relationship to study drug, will also be summarized.

All other AEs will be classified as non-TEAEs and identified in listings only. Serious TEAEs, TEAEs leading to study discontinuation, and TEAEs with an outcome of death will be presented in separate listings, if needed.

4.3.3. Clinical Laboratory Parameters

Summary statistics will be presented for laboratory measurements overall for all subjects in the SAF Population. The following analytes will be tabulated/listed:

- **Hematology**: complete white blood cell count with differential, hemoglobin, hematocrit, and platelets.

- **Serum chemistry profile**: albumin, alkaline phosphatase, alanine aminotransferase (ALT), amylase, aspartate aminotransferase (AST), blood urea nitrogen, calcium, chloride, creatine phosphokinase, creatinine, direct bilirubin, gamma glutamyl transferase, glucose, lactate dehydrogenase magnesium, phosphorus, potassium, sodium, total bilirubin, total protein, and uric acid. In addition, eGFR will be presented using the following formula: $eGFR = 1.86 \times [Creatinine/88.4]^{-1.154} \times [Age]^{-0.203} \times [0.742 \text{ if female}] \times [1.210 \text{ if Black}]$.
- **CD4+ Cell Counts**

Urinalysis results will be presented in a data listing and will include results from microscopic testing only. Pregnancy test, Serum Follicle-Stimulating Hormone (FSH) test, Hepatitis Serology, C-reactive Protein, Prothrombin Time and Partial Thromboplastin Time, and Viral Resistance Testing will also be presented in data listings only.

Normal ranges for the laboratory parameters will be provided by the laboratory that performed the assessments. All normal ranges will be standardized and results will be reported in standard units. The tables will include summary statistics for the assessments and the changes from Baseline to each subsequent time point of measurement. A table of subjects with abnormal (i.e., outside normal range) laboratory assessments will also be presented as a frequency of the incidence of each DAIDS toxicity grade (1 – 4) and route of administration.

Potentially Clinically Significant (PCS) criteria may be applied to laboratory parameters as clinically indicated, and if applied, will be summarized as described above. PCS is defined as a laboratory value that is lower or higher than a laboratory's normal range limits.

Note: Electronic clinical laboratory data will be received at Westat. Data reconciliation will be performed to resolve any discrepancies with the Oracle database. Details of data receipt will be described in the Data Receipt Plan.

4.3.4. Vital Signs

Summary statistics for vital signs and weight will be presented overall for all subjects in the SAF Population for all scheduled visits. Actual values and changes from Baseline will be summarized for all visits where collected.

4.3.5. Physical Examination Findings

A complete physical examination will be conducted at Screening and targeted physical exams will be conducted at every visit from Day 1 through Day 99 (14 weeks). Physical examination findings at each scheduled visit will be summarized overall for all subjects in the SAF Population. The number and percent of subjects with abnormal findings by body system will be tabulated.

4.3.6. Medications and Procedures

All prescriptions or over-the-counter medications continued at the start of the trial or started during the trial, and different from the study drug will be recorded. All of these medications will be coded using WHO Drug Dictionary (March 2019). The use of another version will not be considered a violation of the SAP, nor require an amendment to the plan. Both the coded terms and verbatim terms will be presented in data listings for:

- Concomitant procedures (procedures are not coded)
- Previous and Concomitant medications
- ART medications – only for HIV infected subjects

4.4. Questionnaires

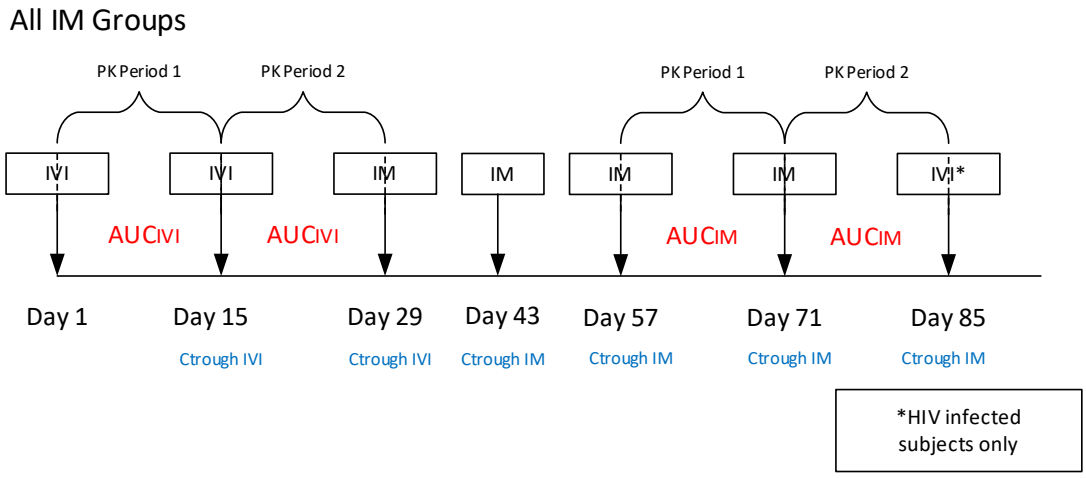
Participants in the IM Group will be asked to complete questionnaires to assess their satisfaction with the different modes of Trogarzo® administration. HIV infected participants in the IM Group will complete the HIVTSQ status version (HIVTSQs12) at Day 29 regarding IVI administration and at Day 85 regarding IM administration. In addition, they will also complete the change version of the questionnaire (HIVTSQc12) following completion of the IM portion of the study (Day 85). HIV uninfected participants will complete the SMSQ status version (SMSQs) at Day 29 regarding IVI administration and at Day 85 regarding IM administration. In addition, they will also complete the change version of the questionnaire (SMSQc) following completion of the IM portion of the study (Day 85). Instructions and questionnaires are provided in Appendix D of the protocol. Summary statistics by visit will be presented for all subjects who answered each question. Paired results of the HIVTSQs12 at Day 85 vs Day 29, and paired results of the SMSQs at Day 85 vs Day 29, will be compared using the Wilcoxon signed-rank test.

All subjects will also be asked to answer the following one-question Preference Assessment (not associated with the above questionnaires) at Day 85: “For the past 8 weeks you have received IM injections every 2 weeks. Today we would like you to compare your experience on the IM injections with the IV infusion you received previously during this study. Which type of administration do you prefer?”. Results will be presented in a frequency table summarizing the incidence of each possible answer.

4.5. PK

The PK endpoints are to compare the trough serum drug concentration and AUC after IV Infusion with the diluted drug to the trough concentration and AUC after IM injection with the undiluted drug. Serum concentrations will be used to estimate PK parameters. PK parameters will be estimated for all subjects by non-compartmental analysis of the serum concentration-time data. Missing data will not be imputed. The trough concentrations and AUC for IM injection and IV infusions over 15 minutes will be

estimated. The following graphic illustrates the time points at which the C_{trough} and AUC values will be estimated.



The C_{trough} values for all IM injection and all IV infusions over 15 minutes will be estimated. A PK bridge will be demonstrated if the proportion of subjects with mean C_{trough} equal to or exceeding the threshold of 300 ng/mL are comparable for IV infusion over 15 minutes to IM injection. Both the geometric and arithmetic mean Ctrough will be calculated and analysis results will be presented for both means. Analysis will be conducted by pooling all the C_{trough} measurements into two groups (IVI=Reference; IMTest) and dichotomizing the C_{trough} data (< 300 ng/mL=1; ≥300 ng/mL=0). Fisher's exact test for comparing two independent binomial proportions will be conducted initially to test for equality of the proportions. In a subsequent test, the PK bridge will be based on relative risk assuming that the binary data in the two infusion groups are independent samples. Two one-sided tests of significance (TOST) will be carried out for the pair of hypotheses, H_{0a}: $\rho \leq \rho_0$ versus H_{1a}: $\rho > \rho_0$ and H_{0b}: $\rho \geq \rho_1$ versus H_{1b}: $\rho < \rho_1$. Rejection of both H_{0a} and H_{0b} would mean that the relative risk lies in the zone of equivalence. The syntax below will be used in SAS to carry out the score test with $\rho_0 = 0.8$, and $\rho_1 = 1.25$.

```
proc freq data=<filename> order=data;
tables group*Ctrough/relrisk(equivalence margin=(.80, 1.25)
method=FM);
weight count;
format Ctrough Ctrough.;
run;
```

Details of reported outputs from the analysis will be displayed in the mock tables and will include relative risk, equivalence limits, 90% confidence limits, and TOST p-values of lower margin, upper margin, and overall. Missing data will not be imputed or used in the analysis. In addition, the two-tailed p-value from Fisher's exact test will be presented to provide additional supporting evidence for equality of binomial proportions between the two administrative routes in the C_{trough} cutoff at 300 ng/mL.

A 90% confidence interval of log transform of the ratio of the geometric means for IM injection to IV infusion will be calculated. Additionally, the PK bridge between the IM injection and IV infusion is demonstrated for AUC if the 90% confidence interval of log transform of the ratio of the geometric means for IM injection (test product) to IV infusion (reference product) for the 20 subjects in the study is within a 80%-125% criteria.

In accordance with the FDA Guidance (2001) [2], SAS PROC MIXED will be used to fit a factor-analytic variance-covariance structure using the FA0(2) option to the ln-transformed AUC data by subject, group (HIV+ or HIV-), PK period, and infusion type (IVI=Reference; IM=Test) to estimate 80%-125% criteria. For each type of administration, subject-level AUC data will be labeled as PK Period 1 or PK Period 2 corresponding to the graphic above. Unless a subject has missing data for both administration routes and both periods, the subject's data will be included in the analysis because SAS PROC MIXED can handle missing data. Details of reported outputs from the analysis will be displayed in the mock tables and will include mean estimate and its lower and upper bounds.

The following SAS code syntax will be used to calculate estimates:

```
proc mixed data=lnauc method=reml;
class infusiontype population period ;
model lnauc= population period infusiontype/ddfm=kenwardroger;
random infusiontype /type=FA0(2) subject=subject;
repeated/group=infusiontype subject=subject;
estimate 'T-R' infusiontype 1 -1/cl alpha=0.1;
ods output estimates=test;
data test;
set test;
meanrat= exp (estimate); * Estimated mean ratio on original scale;
lowerb=exp(lower); * Lower bound on original scale;
upperb=exp(upper); * Upper bound on original scale;
proc print data=test noobs;
var meanrat lowerb upperb;
run;
```

4.6. Secondary Efficacy Endpoint

Assessment of the HIV-1 viral load measurements in HIV-1 infected subjects will be made as a secondary endpoint by comparing the mean viral load (log_{10} and copies/ml) at all visits when subjects received an approved IV infusion over 15 minutes to the visits when receiving an IM injection. The comparison is objective, no statistical tests will be performed. Note: Prior to calculating change from Baseline in viral load, the log_{10} value of each measurement will be calculated and will be rounded to one decimal point.

4.7. Graphical Displays

In addition to the tables and listings described above, the following graphical displays will also be included for in HIV-1 infected subjects:

- Mean (+/- Standard Error [SE]) viral load levels (log_{10} copies/mL) at all scheduled visits;
- Mean (+/- SE) change from Baseline in viral load levels (log 10 copies/mL) at all scheduled visits;
- Mean (+/- SE) CD4+ cell count (cells/mm^3) at all scheduled visits; and
- Mean (+/- SE) change from Baseline in CD4+ T-cell count (cells/mm^3) at all scheduled visits.

4.8. Exploratory/Other Analyses

Exploratory statistical analyses will examine any noted changes in HIV-1 drug sensitivity/susceptibility in participants with an increase in plasma viral load to levels above 1,000 copies/mL on two consecutive measurements at least 2 weeks apart. These reports will be prepared separately from the report prepared in accordance with the rest of this SAP.

5. References

1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (1995, November 30) Guideline E3: *Structure and Content of Clinical Study Reports.* Retrieved from http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html.
2. Guidance for Industry. Statistical Approaches to Establishing Bioequivalence. Food and Drug Administration, CDER January 2001. (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-approaches-establishing-bioequivalence)

Addendum

Protocol v7.0 (Amendment 6) for the TMB-302 study includes the following update that affects the analysis of the data:

> Note: HIV-infected subjects who are enrolled in the IM injection study and are unable to adhere to the study schedule for IM dosing due to factors outside the study will be discontinued. Re-enrollment of HIV-infected IM Group subjects will be allowed after a Discontinuation Visit and Screening Visit are completed provided that inclusion/exclusion criteria continue to be satisfied and dosing after discontinuation is resumed according to the Trogarzo® Prescribing Information. For re-enrolling subjects, the inclusion criteria for stable a Trogarzo®-containing ARV regimen is satisfied with a loading dose of 2000mg IVI and at least one maintenance dose of 800mg IVI given according to Trogarzo® labeling prior to Day 1 enrollment. (Section 3.1 Overall Design)

Additionally with regard to data collection, Protocol v7.0 states:

> PK visits between Baseline and Day 29 will not be required for HIV-infected subjects participating in the IM portion of TMB-302 who have re-enrolled after receiving a 2000mg loading dose and one 800 mg dose of Trogarzo® by IVI prior to study re-enrollment since these PK samples will already have been collected during initial study participation. (Table 1 Schedule of Events for IM Group (HIV-Infected and HIV-Uninfected Subjects)

For the purposes of analysis:

1. Subjects who re-enroll will be assigned a new subject ID, and all data will be collected where possible during the second enrollment, with the exception of PK as described above.

2. While all collected data will be submitted for review as part of the CDISC data package:

    a. PK data for re-enrolled subjects will be combined such that data collected on Day 1 – Day 29 from the first enrollment and data collected after Day 29 from the second enrollment provide one linear set of results with no overlapping. No data collected after Day 29 from the first enrollment will be included in the analyses of the re-enrolled subjects.

    b. For all data other than PK, only data collected during the second enrollment will be presented in the analyses.

TaiMed Biologics, Inc.

Protocol TMB-302 (IM)

A Phase 3 Study of the Safety of Trogarzo® Administered as an Undiluted "IV Push" over a Reduced Interval or as an Intramuscular Injection in Clinically Stable HIV-1 Infected Trogarzo® Experienced Patients and Healthy HIV Uninfected Volunteers

Mock Statistical Listings

August 25, 2022
Version 2.0

TaiMed Biologics, USA Corp.
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Director, Design &Analysis Function

Westat

Contents

Notes Applicable to All Listings

General Programming Notes:

1. There are a few listings that might fit as they are or might have to be split once we see the output with actual data.
2. All listings should start with and be sorted by Group (Sentinel or IM), Subject ID (concatenation of site number and Subject number), and visit date as appropriate.
3. If columns with specific text should be widened due to the amount of text, it is up to the programmer's discretion. However, please keep to the industry standard margin of 1 inch on bottom and sides and 1.25 inches on the top. Font is Courier New 8 point.
4. For all dates used, character format dates to capture partial dates. Use dashes where a month or day is missing. If entire date is missing just leave blank. i.e., - JAN2011 or 01—2011.
5. If a programming note appears on the mock listing indicating that the footnote should appear only on the first page, this means the first page of output contains all footnotes and ONLY footnotes. All subsequent pages contain data with one footnote that says "Refer to page 1 for footnotes".
6. Some of the mock tables display numbers rather than x's. The numbers are meaningless and are for example only. Where visit names are displayed in tables, these are examples as well. Correct visit names for the TMB-302 study should be displayed in the actual output.
7. Each listing should include all applicable data, even if only a subset of the full set of treatment groups is displayed in the mocks.
8. Sort each listing by Group and then Subject ID where applicable.
9. Add "Period" to any applicable listing as the data dictates. Some listings below have period added with example values.

Listing 16.2.1.1
Subject Disposition

Group	Subject ID	Screened	ITT Population [1]	SAF Population [2]
IM HIV Infected	XX-XXX	YES	YES	YES
	XX-XXX	YES	YES	YES
IM HIV Uninfected	XX-XXX	YES	YES	YES
	XX-XXX	YES	YES	YES

[1] Intent-to-Treat (ITT) Population consists of all Subjects enrolled into the study.
[2] Safety (SAF) Population consists of Subjects receiving at least one partial dose of study drug.

Listing 16.2.1.2
Discontinuation

Group	Subject ID	Study Discontinuation Date	Date of Last Study Treatment	Completed Study Treatment	Reason for Treatment Discontinuation	Completed Study	Reason for Study Discontinuation	Death Date
IM HIV Infected	XX-XXX	YYYY-MM-DD	YYYY-MM-DD	YES/NO	XXXXXXXXXX	YES/NO	XXXXXXXXXX	YYYY-MM-DD
IM HIV Uninfected	XX-XXX	YYYY-MM-DD	YYYY-MM-DD	YES/NO	XXXXXXXXXX	YES/NO	XXXXXXXXXX	YYYY-MM-DD

Westat (Created on DDMMYYYY)
S:\TMB302\DA_IM \SAS\L_DISCRSN.SAS

Listing 16.2.2.1
Protocol Violations

Group	Subject ID	Visit	Start Date	Stop Date	Violation Code	Details of Violation
IM HIV Infected	XX-XXX	XXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXXX
IM HIV Uninfected	XX-XXX	XXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXXX

Westat (Created on DDMMMYYYY)
S:\TMB302\DA_IM \SAS\L_PROTVIOS.SAS

Listing 16.2.2.2
Protocol Deviations

Group	Subject ID	Visit	Start Date	Stop Date	Deviation Code	Details of Deviation	Approval Obtained	Date of Approval
IM HIV Infected	XX-XXX	XXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXXX	Yes/No	YYYY-MM-DD
IM HIV Uninfected	XX-XXX	XXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXXX	Yes/No	YYYY-MM-DD

Listing 16.2.2.3
Inclusion/Exclusion Criteria Violations/Deviations

Group	Subject ID	Date of Informed Consent	Time of Informed Consent (hh:mm)	Will this Subject be Enrolled	Criterion Type and Number [1]
IM HIV Infected	XX-XXX	YYYY-MM-DD	XX:XX	Yes/No	EXC XXX/INC XXX
IM HIV Uninfected	XX-XXX	YYYY-MM-DD	XX:XX	Yes/No	EXC XXX/INC XXX

Listing 16.2.3.1
Demographic Characteristics

Group	Subject ID	Date of Birth	Age (years) [1]	Ethnicity	Race	Sex
IM HIV Infected	XX-XXX	YYYY-MM-DD	XX	Hispanic or Latino	American Indian or Alaska Native	M/F
	XX-XXX	YYYY-MM-DD	XX	Neither Hispanic nor Latino Unknown	Black or African American White Native Hawaiian or Other Pacific Islander Other Unknown	M/F
IM HIV Infected	XX-XXX	YYYY-MM-DD	XX	Hispanic or Latino	American Indian or Alaska Native	M/F
	XX-XXX	YYYY-MM-DD	XX	Neither Hispanic nor Latino Unknown	Black or African American White Native Hawaiian or Other Pacific Islander Other Unknown	M/F

[1] Age = Age at Screening.

Westat (Created on DDMMMYYYY)
S:\TMB302\DA_IM \SAS\L_DEMOG.SAS

Listing 16.2.3.2
Medical History

Group	Subject ID	Medical Condition/Surgery	Start Date	Stop Date	CDC AIDS-Defining Condition
IM HIV Infected	XX-XXX	XXXXXXXXXXXXX	YYYY-MM-DD	YYYY-MM-DD or ONGOING	YES/NO
IM HIV Uninfected	XX-XXX	XXXXXXXXXXXXX	YYYY-MM-DD	YYYY-MM-DD or ONGOING	YES/NO

Listing 16.2.4.1
Study Drug Administration

Group	Subject ID	Visit	Visit Date	Method of Administration [1]	Start Time (hh:mm)	Stop Time (hh:mm)	Administration Site	Administration Side	Inj 1 Volume (mL) Start/End	Inj 2 Volume (mL) Start/End	Entire Dose Delivered	Reason if No or Interrupted
IM HIV Infected	XX-XXX	XXXXXX	YYYY-MM-DD	XXXX	XX.XX	XX.XX	XXXXXXXXXXXXX	XXXXX	XXX/XXX	XXX/XXX	Yes w/ Interruption	XXXXXXXXXX
IM HIV Uninfected	XX-XXX	XXXXXX	YYYY-MM-DD	XXXX	XX.XX	XX.XX	XXXXXXXXXXXXX	XXXXX	XXX/XXX	XXX/XXX	Yes w/ Interruption	XXXXXXXXXX

[1] Method of Administration: Inf 60m = IV Infusion 60 minutes, Inf 15m = IV Infusion 15 minutes, IM Inj = Intramuscular Injection

Westat (Created on DDMMMYYYY)
S:\TMB302\DA_IM \SAS\L_DRUGAMIN.SAS

Listing 16.2.4.2
ART Exposure [1]

Group	Subject ID	Medication	Standardized Medication Name [2]	Indication	Start Date	Stop Date	Period [3]	Dose	Unit	Route	Frequency
IM HIV Infected	XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	XXXX	XXXX	XXXX	XXXXX	XX
	XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	XXXX	XXXX	XXXX	XXXXX	XX

[1] ART medications beginning from 3 months prior to Screening visit.
[2] Medications were coded with WHO Drug Dictionary Version March, 2019.
[3] Period represents the timeframe when the medication was STARTED.

Westat (Created on DDMMMYYYY)
S:\TMB302\DA_IM \SAS\L_ARTEXP.SAS

Listing 16.2.4.3
Concomitant Medications [1]

Group	Subject ID	Medication	Standardized Medication Name [2]	Indication	Start Date	Stop Date	Period [3]	Dose	Unit	Route	Frequency
IM HIV Infected	XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	XXXXX	XXXX	XXXX	XXXXX	XX
IM HIV Uninfected	XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	XXXXX	XXXX	XXXX	XXXXX	XX

[1] Medications taken on or after screening visit.
[2] Medications were coded with WHO Drug Dictionary Version March, 2019.
[3] Period represents the timeframe when the medication was STARTED.

Westat (Created on DDMMMYYYY)
S:\TMB302\DA_IM \SAS\L_CONMED.SAS

Listing 16.2.4.4
Post-Administration Observation

Group	Subject ID	Visit	Visit Date	Observed After Study Drug	Start Time of Observation (hh:mm)	End Time of Observation (hh:mm)	Comments
IM HIV Infected	XX-XXX	XXX	YYYY-MM-DD	YES/NO	XX:XX	XX:XX	XXXXXXXXXXXXXXXX
IM HIV Uninfected	XX-XXX	XXX	YYYY-MM-DD	YES/NO	XX:XX	XX:XX	XXXXXXXXXXXXXXXX

Westat (Created on DDMMMYYYY)
S:\TMB302\DA_IM \SAS\L_POSTINJECT.SAS

Listing 16.2.5
PK Results

Group	Subject ID	Visit	Visit Date (Study Day)	Period [1]	Scheduled Time point	Time of Collection (hh:mm)	Concentration (ng/mL) [2]	AUC(day*ug/mL) [3]
IM HIV Infected	XX-XXX	XXX	YYYY-MM-DD (xx)	XXX	XXX	XX:XX	XXX	XXX
IM HIV Uninfected	XX-XXX	XXX	YYYY-MM-DD (xx)	XXX	XXX	XX:XX	XXX*	XXX

[1] Period represents the timeframe when the visit took place. NOTE - When labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.

[2] *Indicates TROUGH value.

[3] AUC calculated for Day 1 to Day 15, Day 15 to 29,Day 57 to Day 71 Day 71 to Day 85 (IM Groups).

Westat (Created on DDMMYYYY)
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Listing 16.2.6
Viral Load

Group	Subject ID	Virologic Failure?[1]	Visit	Visit Date (Study Day)	Period[2]	Treatment Date (Study Day) [3]	Viral Load (log10 cp/mL) [4]	Chg from Baseline (log10 cp/mL)	HIV-1 RNA (cp/mL) [4]
IM	XX-XXX	Y/N	XXXX	YYYY-MM-DD(XX)	XXXX	YYYY-MM-DD(XX)	XX	XX	XX
HIV Infected			XXXX						XX
			XXXX						XX
			XXXX	YYYY-MM-DD(XX)	XXXX	YYYY-MM-DD(XX)	XX	XX	XX
			XXXX						XX
			XXXX						XX
	XX-XXX	Y/N	XXXX	YYYY-MM-DD(XX)	XXXX	YYYY-MM-DD(XX)	XX	XX	XX
			XXXX						XX
	XX-XXX	Y/N	XXXX	YYYY-MM-DD(XX)	XXXX	YYYY-MM-DD(XX)	XX	XX	XX
			XXXX						XX
			XXXX	YYYY-MM-DD(XX)	XXXX	YYYY-MM-DD(XX)	XX	XX	XX
			XXXX						XX
			XXXX						XX
	XX-XXX	Y/N	XXXX	YYYY-MM-DD(XX)	XXXX	YYYY-MM-DD(XX)	XX	XX	XX
			XXXX						XX

[1] Y = Virologic Failure per protocol: Viremic subjects experience a sustained >0.5 log increase in plasma HIV-1 RNA from baseline. OR
A sustained VL>200 copies/mL if subject VL was <50 copies/mL at baseline.
Note: Sustained is defined as two consecutive viral load determinations at least 2 weeks apart.
[2] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[3] Last treatment prior to viral load measurement.
[4] *=below 400 copies/mL; **=below 50 copies/mL. HIV-1 RNA level results below level of quantitation are coded as target detected (TD) or target not detected (TND).

Westat (Created on DDMMMYYYY)
S:\TMB302\DA_IM \SAS\L_VL.SAS

Listing 16.2.7.1
Treatment Emergent Adverse Events [1]

Group	Subject ID	System Organ Class	Preferred Term [2]	Adverse Event Verbatim	Start Date (Study Day)	Stop Date (Study Day)	Period [3]	Sev./ Grade [4]	SAE	Caus. [5]	Action Taken [6]	Outcm. [7]	CDC AIDS-Defining Cond.
IM HIV-infected	XX-XXX	XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	X	X
		XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	X	X
IM HIV-uninfected	XX-XXX	XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	X	X
		XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	X	X

[1] Adverse events occurring on or after the date of first dose of study medication.
[2] Adverse events are coded using MedDRA Version 22.0.
[3] Period represents the timeframe when the adverse event STARTED.
[4] Severity/Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Potentially Life Threatening, 5=Death.
[5] Causality: 0=Unrelated, 4=Suspected Adverse Reaction.
[6] Action Taken: 0=None, 1=Medication Given, 2=Non-Medication Therapy, 3=Suspended Study Drug, 4=Permanently Discontinued Study Drug, 99=Other.
[7] Outcome: 1=Resolved, 2=Resolved w/sequelae, 3=Ongoing, 4=Worsened, 5=Death, 7=Chronic/Stable, 98=Unknown.

Notes to programmer: Confirm that footnotes match final version of CRF and coding used in data.

Westat (Created on DDMMMYYYY)
S:\TMB302\DA_IM \SAS\L_AE.SAS

Listing 16.2.7.2
Treatment Emergent Serious Adverse Events [1]

Group	Subject ID	System Organ Class	Preferred Term [2]	Adverse Event Verbatim	Start Date (Study Day)	Stop Date (Study Day)	Period [3]	Sev./ Grade [4]	Caus. [5]	Action Taken [6]	Outcm. [7]	CDC AIDS-Defining Cond.
IM HIV-infected	XX-XXX	XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	X
IM HIV-uninfected	XX-XXX	XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	X

[1] Adverse events occurring on or after the date of first dose of study medication.
[2] Adverse events are coded using MedDRA Version 22.0.
[3] Period represents the timeframe when the adverse event STARTED.
[4] Severity/Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Potentially Life Threatening, 5=Death.
[5] Causality: 0=Unrelated, 4=Suspected Adverse Reaction.
[6] Action Taken: 0=None, 1=Medication Given, 2=Non-Medication Therapy, 3=Suspended Study Drug, 4=Permanently Discontinued Study Drug, 99=Other.
[7] Outcome: 1=Resolved, 2=Resolved w/sequelae, 3=Ongoing, 4=Worsened, 5=Death, 7=Chronic/Stable, 98=Unknown.

Notes to programmer: Confirm that footnotes match final version of CRF and coding used in data.

Westat (Created on DDMMMYYYY)
S:\TMB302\DA_IM \SAS\L_SAE.SAS

Listing 16.2.7.3
Treatment Emergent Adverse Events [1] Leading to Study Discontinuation or Death

Group	Subject ID	System Organ Class	Preferred Term [2]	Adverse Event Verbatim	Start Date (Study Day)	Stop Date (Study Day)	Period [3]	Sev./ Grade [4]	SAE	Caus. [5]	Action Taken [6]	Outcm. [7]	CDC AIDS-Defining Cond.
IM HIV-infected	XX-XXX	XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	
		XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	
IM HIV-uninfected	XX-XXX	XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	
		XXXXXXXXXXX	XXXXXXXX	XXXXXXXXXX	YYYY-MM-DD(XX)	YYYY-MM-DD(XX)	XXXX	X	N/Y	X	X	X	

[1] Adverse events occurring on or after the date of first dose of study medication.
[2] Adverse events are coded using MedDRA Version 22.0.
[3] Period represents the timeframe when the adverse event STARTED.
[4] Severity/Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Potentially Life Threatening, 5=Death.
[5] Causality: 0=Unrelated, 4=Suspected Adverse Reaction.
[6] Action Taken: 0=None, 1=Medication Given, 2=Non-Medication Therapy, 3=Suspended Study Drug, 4=Permanently Discontinued Study Drug, 99=Other.
[7] Outcome: 1=Resolved, 2=Resolved w/sequelae, 3=Ongoing, 4=Worsened, 5=Death, 7=Chronic/Stable, 98=Unknown.

Notes to programmer: Confirm that footnotes match final version of CRF and coding used in data.

Westat (Created on DDMMMYYYY)
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Listing 16.2.8.1
Clinical Laboratory Test
Hematology

Group	Subject ID	Visit	Date of Sample (Study Day)	Period[1]	Test	Result (L/H)[2]	Unit	Lower Limit of Normal	Upper Limit of Normal	Potentially Clinically Significant[3]
IM	XX-XXX	XXXXX	YYYY-MM-DD(XX)	XXXX	XXXXXXXXX	XXX	XX	XX	XX	YES/NO
HIV-					XXXXXXXXX	XXX	XX	XX	XX	YES/NO
Infected					XXXXXXXXX	XXX	XX	XX	XX	YES/NO
IM	XX-XXX	XXXXX	YYYY-MM-DD(XX)	XXXX	XXXXXXXXX	XXX	XX	XX	XX	YES/NO
HIV-					XXXXXXXXX	XXX	XX	XX	XX	YES/NO
Uninfected					XXXXXXXXX	XXX	XX	XX	XX	YES/NO

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] L = Below lower limit of normal; H = Above upper limit of normal.
[3] Potentially Clinically Significant is defined as having a result either below the lower limit of normal or above the upper limit of normal.

Westat (Created on DDMMMYYYY)
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Listing 16.2.8.2
Clinical Laboratory Test
Chemistry

Group	Subject ID	Visit	Date of Sample (Study Day)	Period [1]	Test	Result (L/H)[2]	Unit	Limit of Normal	Limit of Normal	Clinically Significant[3]
IM	XX-XXX	XXXXX	YYYY-MM-DD(XX)	XXXX	XXXXXXXXX	XXX	XX	XX	XX	YES/NO
HIV-					XXXXXXXXX	XXX	XX	XX	XX	YES/NO
Infected					XXXXXXXXX	XXX	XX	XX	XX	YES/NO
IM	XX-XXX	XXXXX	YYYY-MM-DD(XX)	XXXX	XXXXXXXXX	XXX	XX	XX	XX	YES/NO
HIV-					XXXXXXXXX	XXX	XX	XX	XX	YES/NO
Uninfected					XXXXXXXXX	XXX	XX	XX	XX	YES/NO

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] L = Below lower limit of normal; H = Above upper limit of normal.
[3] Potentially Clinically Significant is defined as having a result either below the lower limit of normal or above the upper limit of normal.

Westat (Created on DDMMMYYYY)
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Listing 16.2.8.3
Clinical Laboratory Test
Urinalysis

Group	Subject ID	Visit	Date of Sample (Study Day)	Period [1]	Test	Unit	Result
IM HIV-Infected	XX-XXX	XXXXX	YYYY-MM-DD (XX)	XXXXXX	XXXXXXXXX	XX	XXXX
		XXXXX	YYYY-MM-DD (XX)	XXXXXX	XXXXXXXXX	XX	XXXX
		XXXXX	YYYY-MM-DD (XX)	XXXXXX	XXXXXXXXX	XX	XXXX
IM HIV-Uninfected	XX-XXX	XXXXX	YYYY-MM-DD (XX)	XXXXXX	XXXXXXXXX	XX	XXXX
		XXXXX	YYYY-MM-DD (XX)	XXXXXX	XXXXXXXXX	XX	XXXX
		XXXXX	YYYY-MM-DD (XX)	XXXXXX	XXXXXXXXX	XX	XXXX

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.

Listing 16.2.8.4
CD4+ Cell Count (cells/mm^3)

Group	Subject ID	Visit	Visit Date (Study Day)	Period[1]	Absolute CD4+ Cell Count (cells/mm^3) [2]	CD4+ Cell Count Pct Change from Baseline (%) [3]	CD4+Cell Count(%)	WBC(10^9/L)
IM HIV Infected	XX-XXX	XXXXXXX	YYYY-MM-DD (XX)	XXXX	XXX	XXXX	XXXX	X.XX
IM HIV Uninfected	XX-XXX	XXXXXXX	YYYY-MM-DD (XX)	XXXX	XXX	XXXX	XXXX	X.XX

[1] Period represents the timeframe when the visit took place. Note – Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] *=below 200 cells/mm^3
[3] Calculated as (visit value - baseline)/baseline*100%

Westat (Created on DDMMMYYYY)
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Listing 16.2.8.5
Abnormal Laboratory Results

Group	Subject ID	Visit	Date of Sample (Study Day)	Period [1]	Category	Test	Result (L/H)[2]	Unit	Lower Limit of Normal	Upper Limit of Normal
IM HIV Infected	XX-XXX	XXXXX	YYYY-MM-DD(XX)	XXXX	CHEMISTRY	XXXXXXXX	XXX(X)	X/X	XXX	XXX
						XXXXXXXX	XXX(X)	X/X	XXX	XXX
					HEMATOLOGY	XXXXXXXX	XXX(X)	X/X	XXX	XXX
						XXXXXXXX	XXX(X)	X/X	XXX	XXX
IM HIV Uninfected	XX-XXX	XXXXX	YYYY-MM-DD(XX)	XXXX	CHEMISTRY	XXXXXXXX	XXX(X)	X/X	XXX	XXX
						XXXXXXXX	XXX(X)	X/X	XXX	XXX
					HEMATOLOGY	XXXXXXXX	XXX(X)	X/X	XXX	XXX
						XXXXXXXX	XXX(X)	X/X	XXX	XXX

…

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] L = Below lower limit of normal; H = Above upper limit of normal.

Listing 16.2.8.6
Other Laboratory Tests

Group	Subject ID	Visit	Date of Sample (Study Day)	Period [1]	Test	Result (L/H)[2]	Unit	Limit of Normal	Limit of Normal	Clinically Significant[3]
IM	XX-XXX	XXXXX	YYYY-MM-DD(XX)	XXXX	XXXXXXXXX	XXX	XX	XX	XX	YES/NO
HIV-					XXXXXXXXX	XXX	XX	XX	XX	YES/NO
Infected					XXXXXXXXX	XXX	XX	XX	XX	YES/NO
IM	XX-XXX	XXXXX	YYYY-MM-DD(XX)	XXXX	XXXXXXXXX	XXX	XX	XX	XX	YES/NO
HIV-					XXXXXXXXX	XXX	XX	XX	XX	YES/NO
Uninfected					XXXXXXXXX	XXX	XX	XX	XX	YES/NO

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] L = Below lower limit of normal; H = Above upper limit of normal.
[3] Potentially Clinically Significant is defined as having a result either below the lower limit of normal or above the upper limit of normal.

Listing 16.2.9
Vital Signs

Group	Subject ID	Visit	Visit Date	Scheduled Time Point	Time (hh:mm)	Period [1]	Height (cm)	Weight (kg)	Temp. (C) [2]	Heart Rate (bpm) [2]	Resp. Rate (breaths/min) [2]	Systolic Blood Pressure (mmHg) [2]	Diastolic Blood Pressure (mmHg) [2]
IM HIV-infected	XX-XXX	XXXX	YYYY-MM-DD	XXX	XX:XX	XXXX	XXX	XX	XX.X	XX	XX	XX	XX
		XXXX	YYYY-MM-DD	XXX	XX:XX	XXXX	XXX	XX	XX.X	XX	XX	XX	XX
		XXXX	YYYY-MM-DD	XXX	XX:XX	XXXX	XXX	XX	XX.X	XX	XX	XX	XX
IM HIV-uninfected	XX-XXX	XXXX	YYYY-MM-DD	XXX	XX:XX	XXXX	XXX	XX	XX.X	XX	XX	XX	XX

[1] Period represents the timeframe when the visit took place.
[2] *Denotes Potentially Clinically Significant Vital Signs outside of these ranges: Temperature: 36.44-37.22 C; Heart Rate: 60-110 bpm; Respiration rate: 12-20 breaths per minute; Blood Pressure: Systolic 100-140 mmHg; Diastolic 60-90 mmHg.

Westat (Created on DDMMMYYYY)
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Listing 16.2.10
Abnormal Physical Examinations

Group	Subject ID	Visit	Visit Date	Period [1]	Performed at Visit	Body System	Status (Details)
IM HIV Infected	XX-XXX	XXXX	YYYY-MM-DD	XXXX	Yes/No	Cardiovascular	Normal
						Lymphatic	Abnormal: provide details
						Respiratory	Not Done
						Abdomen	Not Required
						Extremities	Normal
						Neurological	Normal
						Additional PE Findings (list assessment name)	Abnormal: provide details
IM HIV Uninfected	XX-XXX	XXXX	YYYY-MM-DD	XXXX	Yes/No	Cardiovascular	Normal
						Lymphatic	Abnormal: provide details
						Respiratory	Not Done
						Abdomen	Not Required
						Extremities	Normal
						Neurological	Normal
						Additional PE Findings (list assessment name)	Abnormal: provide details

[1] Period represents the timeframe when the visit took place.

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Listing 16.2.11.1
HIV Treatment Satisfaction Questionnaire

Group	Subject ID	Visit	Questions	Responses
IM HIV Infected	XX-XXX	XXXX	How satisfied are you with your current treatment?	XXXXXXX
			How well controlled do you feel your HIV has been recently?	XXXXXXX
			How satisfied are you with any side effects of your present treatment?	XXXXXXX

Westat (Created on DDMMMYYYY)
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Listing 16.2.11.2
Study Medication Satisfaction Questionnaire

Group	Subject ID	Visit	Questions	Responses
				XXXXXXXX
IM HIV Uninfected	XX-XXX	XXXX	How satisfied are you with your current study medication?	
			How satisfied are you with any side effects of your present study medication?	XXXXXXXX

Westat (Created on DDMMMYYYY)
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Listing 16.2.11.3
Preference Assessment

Group	Subject ID	Visit	Questions	Responses
IM HIV Infected	XX-XXX	XXXX	Which type of medication do you prefer?	XXXXXXXX
IM HIV Uninfected	XX-XXX	XXXX	Which type of medication do you prefer?	XXXXXXXX

Westat (Created on DDMMMYYYY)
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TaiMed Biologics, Inc.

Protocol TMB-302 (IM)

A Phase 3 Study of the Safety of Trogarzo® Administered as an Undiluted "IV Push" over a Reduced Interval or as an Intramuscular Injection in Clinically Stable HIV-1 Infected Trogarzo® Experienced Patients and Healthy HIV Uninfected Volunteers

Mock Statistical Tables

August 26, 2022
Version 2.0

TaiMed Biologics, USA Corp.
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Biostatistician

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Director, Design &Analysis Function

Westat

Contents

Notes Applicable to All Tables

General Programming Notes:

1. The tables will be programmed to show aggregate data only.
2. Review the data prior to programming. Check the data for inconsistencies and anomalies. Report suspected data errors to the lead programmer who can determine if they should be addressed by DM.
3. Follow the Quality Control Plans (\\Westat.com\dfs\CTWRKGRP\PUBLIC\Resources\DA\QC_Plans) for Tables, Listings, and Graphs. Perform the quality checks, using the Checklist.
4. Always check the population totals. All subjects should be accounted for in all tables. A row for "Unknown" or "Missing" values can be added to any table as appropriate to account for all subjects.
5. For summary statistics: N should always be an integer; minimum and maximum should have the same number of significant digits as is present in the data; mean and median should be calculated to be one additional significant digit than the data collected; standard deviation should be calculated to be two additional significant digits than the data collected.
6. Percentages should be calculated to one decimal place. The true number of treated subjects, which appears at the top of columns in most tables should be calculated once in libnames.sas and put into macro variables to ensure consistency. This number should not be re-calculated when calculating percentages.
7. Follow the mocks, especially regarding details, such as titles, capitalization, order of columns and row labels, and footnotes. Standard table formatting may be followed, as some mocks may have been created due to space/pagination considerations. The visit names in the mocks are examples only. Consult the protocol and SAP and present all scheduled visits for the item in question.
8. Additional footnotes may be required to fully/more accurately describe the contents of a table (decided during development). Consult project leader and lead biostatistician with questions.

Table 14.1.1
Subject Disposition

	IM HIV Infected (N=XX) n (%)	IM HIV Uninfected (N=XX) n (%)	Total (N=XX) n (%)
Study Populations			
Screened	n	n	n
Intent-to-Treat (ITT) [1]	n (xx.x%)	n (xx.x%)	n (xx.x%)
Safety (SAF) [2]	n (xx.x%)	n (xx.x%)	n (xx.x%)
Study Completion Status			
Completed Study Per Protocol	n (xx.x%)	n (xx.x%)	n (xx.x%)
Ongoing in Study	n (xx.x%)	n (xx.x%)	n (xx.x%)
Discontinued Study Prematurely	n (xx.x%)	n (xx.x%)	n (xx.x%)
Treatment Completion Status			
Completed Treatment Per Protocol	n (xx.x%)	n (xx.x%)	n (xx.x%)
Continuing Treatment	n (xx.x%)	n (xx.x%)	n (xx.x%)
Discontinued Treatment Prematurely	n (xx.x%)	n (xx.x%)	n (xx.x%)

N = All subjects enrolled (displayed according to assigned treatment), and denominator for percentage calculations.
[1] ITT Population consists of all subjects enrolled into the study.
[2] SAF Population consists of subjects receiving at least one partial dose of study drug.

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Table 14.1.2
Reasons for Discontinuation
Intent-To-Treat Population

	IM HIV Infected (N=XX) n (%)	IM HIV Uninfected (N=XX) n(%)	Total (N=XX) n(%)
Discontinued Study Prematurely	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Reasons for Study Discontinuation			
Adverse Event	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Grade 3 or higher related laboratory assessment[1]	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Required a medication prohibited by the protocol	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Investigator's Decision	n XXX.X%)	n XXX.X%)	n XXX.X%)
Consent Withdrawn or Voluntary Withdrawal	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Administrative Decision	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Protocol Violation	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Subject Non-compliant	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Lost to follow-up	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Pregnancy	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Other	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Discontinued Treatment Prematurely	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Reasons for Treatment Discontinuation			
Adverse Event	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Grade 3 or higher related laboratory assessment[1]	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Required a medication prohibited by the protocol	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Investigator's Decision	n XXX.X%)	n XXX.X%)	n(XXX.X%)
Consent Withdrawn or Voluntary Withdrawal	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Administrative Decision	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Protocol Violation	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Subject Non-compliant	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Lost to follow-up	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Pregnancy	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Death	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Other	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)

N = All subjects enrolled. Denominator for subcategory percentage calculations is the total number of subjects who discontinued study or treatment.

[1] Had a confirmed laboratory safety assessment result of Grade 3 or higher severity which was considered drug related.

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S:\TMB302\DA_IM\SAS\t_discrsn

Table 14.1.3
Demographic and Screening Characteristics
Intent-To-Treat (ITT) Population

		IM HIV Infected (N=XX)	IM HIV Uninfected (N=XX)	Total (N=XX)
Sex	Male	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Female	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Ethnicity	Hispanic or Latino	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Neither Hispanic nor Latino	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Unknown	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Race [1]	American Indian or Alaska Native	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Black or African American	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	White	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Asian	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Native Hawaiian or Other Pacific Islander	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Other	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Unknown		XX	XX
Age (years)	N	XX	XX.X(XX.XX)	XX.X(XX.XX)
	Mean(SD)	XX.X(XX.XX)	XX.X	XX.X
	Median	XX.X	XX - XX	XX - XX
	25%-75%	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX		
			XX	XX
Height (cm)	N	XX	XX.X(XX.XX)	XX.X(XX.XX)
	Mean(SD)	XX.X(XX.XX)	XX.X	XX.X
	Median	XX.X	XX - XX	XX - XX
	25%-75%	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX		
			XX	XX
Weight (kg)	N	XX	XX.XX(XX.XXX	XX.XX(XX.XXX)
	Mean(SD)	XX.XX(XX.XXX)	XX.XX	XX.XX
	Median	XX.XX	XX.X - XX.X	XX.X - XX.X
	25%-75%	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X
	Min-Max	XX.X - XX.X		

N = All subjects enrolled, and denominator for percentage calculations.
[1] One or more race(s) may be recorded, therefore, a patient may be counted in more than one category and percentages may add up to more than 100%.
NOTE: The table shows data at Screening visit. If vital signs are missing at the Screening visit, the measurement at the Day 1 visit is used.

Westat (Created on DDMMYYYY)
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Table 14.1.3
Demographic and Screening Characteristics (continued)
Intent-To-Treat (ITT) Population

		IM HIV Infected (N=XX)	IM HIV Uninfected (N=XX)	Total (N=XX)
Temperature (C)	N	XX	XX	XX
	Mean(SD)	XX.XX(XX.XXX)	XX.XX(XX.XXX)	XX.XX(XX.XXX)
	Median	XX.XX	XX.XX	XX.XX
	25%-75%	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X
	Min-Max	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X
Heart Rate (beats/min)	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX
Respiration Rate (breaths/min)	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX
Systolic Blood Pressure (mmHg)	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX
Diastolic Blood Pressure (mmHg)	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX

N = All subjects enrolled, and denominator for percentage calculations.
[1] One or more race(s) may be recorded, therefore, a patient may be counted in more than one category and percentages may add up to more than 100%.
NOTE: The table shows data at Screening visit. If vital signs are missing at the Screening visit, the measurement at the Day 1 visit is used.

Westat (Created on DDMMYYYY)
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Table 14.1.4
Summary of Concomitant Medications
Intent-To-Treat Population

Medication Preferred Term	IM HIV Infected (N=XX) n (%)	IM HIV Uninfected (N=XX) n(%)	Total (N=XX) n(%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n XXX.X%)	n XXX.X%)	n XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)

N = All subjects enrolled.

Note to Programmer: Include only CMCAT = 'GENERAL MEDICATIONS' and use CMDECOD for "Medication Preferred Term". Medications are not

Table 14.1.5
Summary of Protocol Violations and Deviations
Intent-To-Treat Population

	IM HIV Infected (N=XX) n (%)	IM HIV Uninfected (N=XX) n(%)	Total (N=XX) n(%)
Protocol Violations	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	n XXX.X%)	n XXX.X%)	n XXX.X%)
Protocol Deviations	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
XXXXXXXXXXXXXXXX	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)

N = All subjects enrolled.

Note to Programmer: Use DVCAT to differentiate violations from deviations, and use DVDECOD for the first column of the table.

Westat (Created on DDMMYYYY)
S:\TMB302\DA_IM\SAS\t_protvios

Table 14.2.1
Comparison of Geometric Mean Trough Concentrations for IM Injection to 15 Minute IV Infusions
Intent-to-Treat Population

Analysis Type	Results
Proportion of Subjects with Geometric Mean	
Ctrough >= 300 ng/ml (%)	n/NT (%)
15 Minute IV Infusion	n/NT (%)
IM Injection	
	xxxx
Relative Risk	
	(xxxx, xxxx)
90% Confidence Limits	
	xxxx
TOST P-values [1]	xxxx
Lower Margin	xxxx
Overall	
Upper Margin	
	xxxx
Fisher's exact test 2-tailed P-Value [2]	

[1] Two one-sided tests of significance (TOST) using Farrington-Manning Method and z-statistics, within an 80%-125% criteria.
H0: P1 / P2 <= Lower Margin or >= Upper Margin of the equivalence limits
2] Fishers Exact test H0: P1 is not different from P2

Note to Programmer: SAS code provided in SAP. Any subject with at least some non-missing PK data is included

Westat (Created on DDMMYYYY)
S:\TMB302\DA_IM\SAS\t_trough1

Table 14.2.2
Comparison of Arithmetic Mean Trough Concentrations for IM Injection to 15 Minute IV Infusions
Intent-to-Treat Population

Analysis Type	Results
Proportion of Subjects with Arithmetic Mean Ctrough >= 300 ng/ml (%)	n/NT (%)
15 Minute IV Infusion	n/NT (%)
IM Injection	
	xxxx
Relative Risk	
	(xxxx, xxxx)
90% Confidence Limits	
	xxxx
TOST P-values [1]	xxxx
Lower Margin	xxxx
Overall	
Upper Margin	
	xxxx
Fisher's exact test 2-tailed P-Value [2]	

[1] Two one-sided tests of significance (TOST) using Farrington-Manning Method and z-statistics, within an 80%-125% criteria.
H0: P1 / P2 <= Lower Margin or >= Upper Margin of the equivalence limits
2] Fishers Exact test H0: P1 is not different from P2

Note to Programmer: SAS code provided in SAP. Any subject with at least some non-missing PK data is included

Westat (Created on DDMMYYYY)
S:\TMB302\DA_IM\SAS\t_trough2

Table 14.2.3
90% Confidence Interval of the LOG Transform of the Ratio of the Geometric Means of AUC for IM Injection to 15 Minute IV Infusion
Intent-to-Treat Population

Analysis Type	Results
Type 3 Tests of Fixed Effects	
PK Period[2]	
F Value(df)	xxxx
Pr > F	xxxx
Administration Route(IVI or IM)	
F Value(df)	xxxx
Pr > F	xxxx
Group (HIV+ or HIV-)	
F Value	xxxx
Pr > F	xxxx
Estimates (IM/IVI)	
Estimate (Standard Error)	xxxx(xxxx)
t Value (df)	xxxx (xx)
Pf > |t|	xxxx
90% Confidence Interval	(xxxxx, xxxxx)
Back Transformed Estimates	
Mean Geometric Ratio	xxxx
90% Confidence Interval [3]	(xxxxx, xxxxx)

[1] A pharmacokinetic bridge between the IM injection and IV infusion is demonstrated for AUC if the 90% confidence interval of log transform of the ratio of the geometric means for IM Injection (test product) to IV infusion (reference product) for the enrolled subjects in the study is within an 80%-125% criteria.
[2] To provide more substantial data, PK parameters were calculated twice for each subject, described as PK Period in the statistical analysis plan. [3] A pharmacokinetic bridge between the IM injection and IV infusion is demonstrated for AUC if the 90% confidence interval of log transform of the ratio of the geometric means for IM Injection (test product) to IV infusion (reference product) for the enrolled subjects in the study iswithin an 80%-125% criteria.

Note to Programmer: SAS code provided in SAP. Any subject with at least some non-missing PK data is included.

Table 14.2.4.1
Viral Load (copies/mL) and Changes from Baseline
Intent-to-Treat Population – IM HIV Infected
Total and by Period

		IM HIV Infected (N=XX)		
		Initial Period 15 min IV Infusion	Investigational Period IM Injection	Follow-up Period 15 min IV Infusion
Baseline [1]	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX - XX		
	Min-Max	XX - XX		
Day 15	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX - XX		
	Min-Max	XX - XX		
Change from Baseline	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX - XX		
	Min-Max	XX - XX		
Day 29	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX - XX		
…	Min-Max	XX - XX		
End of Study				
…				
Change from Baseline				

N = All subjects in the ITT Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

Westat (Created on DDMMYYYY)
S:\TMB302\DA_IM\SAS\t_vl1

Table 14.2.4.2

Viral Load (log10 copies/mL) and Changes from Baseline
Intent-to-Treat Population – IM HIV Uninfected
Total and by Period

		IM HIV Uninfected (N=XX)		
		Initial Period 15 min IV Infusion	Investigational Period IM Injection	Follow-up Period 15 min IV Infusion
Baseline [1]	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX – XX		
Day 15	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX – XX		
Change from Baseline	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX – XX		
Day 29	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
…	Min-Max	XX – XX		
End of Study				
…				
Change from Baseline				

N = All subjects in the ITT Population (displayed according to actual treatment received), and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

Westat (Created on DDMMYYYY)
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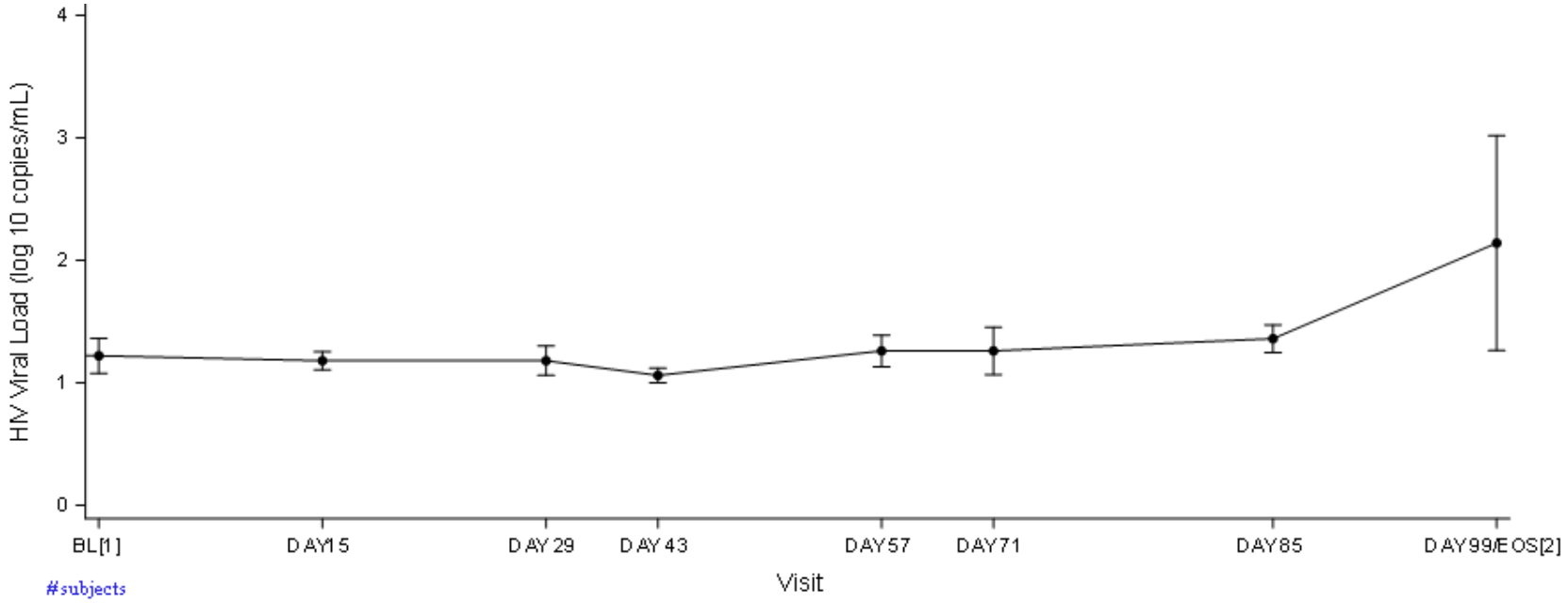
Graph 14.2.4.3
Mean (+/- SE) Viral Load (log 10 copies/mL)
Intent-to-Treat Population



[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration. When Screening is the only value, it becomes Baseline and is counted in the Baseline row and not in the Screening row.

[2] End of Study is Day 85 for subjects in the IM HIV Infected Group.

Note to programmer: This is an example from a previous study. Only actual scheduled visits should be displayed.

Westat (Created on DDMMYYYY)
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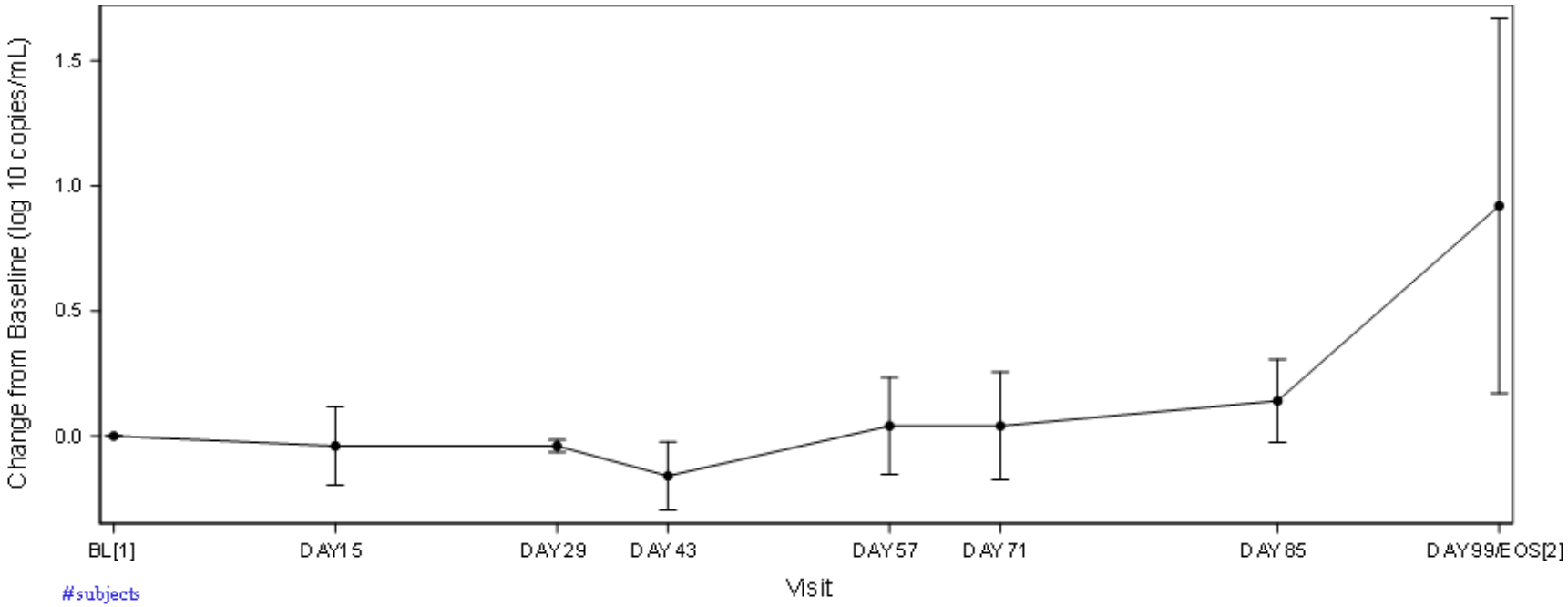
Graph 14.2.4.4
Mean (+/- SE) Change from Baseline in Viral Load (log 10 copies/mL)
Intent-to-Treat Population



[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration. When Screening is the only value, it becomes Baseline and is counted in the Baseline row and not in the Screening row.

[2] End of Study is Day 85 for subjects in the IM HIV Infected Group.

Westat (Created on DDMMYYYY)
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Table 14.3.1.1.1
Treatment-Emergent Adverse Events Summary
Safety Population

	IM HIV Infected (N=XX)	IM HIV Uninfected (N=XX)	Total (N=XX)
TEAE [1]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Serious TEAE [2]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE with Death Outcome	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Leading to Discontinuation	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Suspected Adverse Reaction[3]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Severe TEAE [4]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Class C TEAE [5]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
TEAE = Treatment-Emergent Adverse Event.
NOTE: Identical TEAEs are counted only once per subject.
[1] Number(%) of subjects with at least one TEAE.
[2] Number(%) of subjects with at least one serious TEAE, excluding death, as identified by the investigator.
[3] Possibly related to study drug.
[4] Severity/Grade 3 or higher (severe or potentially life threatening).
[5] Per the CDC Classification System for HIV Infection.

Table 14.3.1.2.1
Overall Incidence of Treatment-Emergent Adverse Events
Safety Population

Body System	Preferred Term [1]	IM HIV Infected (N=XX)	IM HIV Uninfected (N=XX)	Total (N=XX)
Overall[2]	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: Identical TEAEs are counted only once per subject.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System; "Events" represents number of TEAEs reported by the subject(s).
[2] Number(%) of subjects with at least one TEAE in any Body System.

Westat (Created on DDMMYYYY)
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Table 14.3.1.3.1
Incidence of Treatment-Emergent Adverse Events by Severity/Grade
Safety Population

		IM HIV Infected (N=XX)					
Body System	Preferred Term[1]	Any Grade [2]	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Pot. Life Threatening (Grade 4)	Death (Grade 5)
Overall [3]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the most severe occurrence, regardless of relationship to study drug.
[1] “ALL TERMS” represents number(%) of subjects with at least one TEAE within that Body System;
“Events” represents number of TEAEs reported by the subject(s).
[2] Adverse Events with missing severity grade are included in this column only.
[3] Number(%)of subjects with at least one TEAE in any Body System.

Note to programmer: Repeat this table for the IM HIV Uninfected Group and Total,all under the same table number.

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Table 14.3.1.4.1
Incidence of Treatment-Emergent Adverse Events by Relationship to Study Drug
Safety Population

		IM HIV Infected (N=XX)		IM HIV Uninfected (N=XX)		Total (N=XX)	
Body System	Preferred Term[1]	Suspected Adverse Reaction [3]	Unrelated	Suspected Adverse Reaction [3]	Unrelated	Suspected Adverse Reaction [3]	Unrelated
Overall[2]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the highest relationship, regardless of severity/grade.
[1] “ALL TERMS” represents number(%) of subjects with at least one TEAE within that Body System;
“Events” represents number of TEAEs reported by the subject(s).
[2] Number(%)of subjects with at least one TEAE in any Body System.
[3] Possibly related to study drug.

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Table 14.3.1.5.1
Overall Incidence of Serious Adverse Events
Safety Population

Note to programmer: Repeat above for SERIOUS Adverse Events with the footnote updated as below.

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: Identical SAEs are counted only once per subject.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of SAEs reported by the subject(s).
[2] Number(%) of subjects with at least one SAE in any Body System.

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Table 14.3.1.6.1
Incidence of Serious Adverse Events by Relationship to Study Drug
Safety Population

Note to programmer: Repeat tables above for SERIOUS Adverse Events with the footnote updated as below.

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: The table shows related SAEs (per subject) with the highest relationship, regardless of severity/grade.
[1] "ALL TERMS" represents number(%) of subjects with at least one SAE within that Body System;
"Events" represents number of SAEs reported by the subject(s)
[2] Number(%) of subjects with at least one SAE in any Body System.

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Table 14.3.1.7.1
Treatment-Emergent Adverse Events Leading to Study Discontinuation
Safety Population

Note to programmer: Repeat tables above for Adverse Events LEADING TO STUDY DISCONTINUATION (same footnote).

Table 14.3.2.1
Abnormal Laboratory Results by DAIDS Toxicity Grade [1] and Route of Administration
Safety Population – IM HIV Infected Group

	IM HIV Infected (N=XX)				
Test/Route of Administration [2]	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Analyte 1					
IV Infusion (Day 1 – Day 29)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
IM Injection (Day 30 – Day 85)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Follow-up (Day 86 – Day 99)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Analyte 2					
IV Infusion(Day 1 – Day 29)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
IM Injection(Day 30 – Day 85)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Follow-up (Day 86 – Day 99)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)

N= All Subjects enrolled (displayed according to assigned treatment) and denominator for percentage calculations.
[1] If a subject reported more than one abnormal result for a given analyte at any point during the study, only the result with the highest grade is counted.
[2] Indicates the route of administration by which the subject was receiving study drug at the time the laboratory result was recorded.

Note to programmer: 1) Use TRTA to create the rows within each analyte. 2) For each value of PARAMCD select the highest grade for each subject, regardless of visit or period. 3) Count the frequency by analyte, period, and grade.
Only include analytes with abnormal results in the data in this table.

Table 14.3.2.2
Abnormal Laboratory Results by DAIDS Toxicity Grade [1] and Route of Administration
Safety Population – IM HIV Uninfected Group

	IM HIV Uninfected (N=XX)				
Test/Route of Administration [2]	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Analyte 1					
IV Infusion (Day 1 – Day 29)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
IM Injection (Day 30 – Day 85)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Follow-up (Day 86 – Day 99)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Analyte 2					
IV Infusion (Day 1 – Day 29)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
IM Injection (Day 30 – Day 85)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Follow-up (Day 86 – Day 99)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)

N= All Subjects enrolled (displayed according to assigned treatment) and denominator for percentage calculations.
[1] If a subject reported more than one abnormal result for a given analyte at any point during the study, only the result with the highest grade is counted.
[2] Indicates the route of administration by which the subject was receiving study drug at the time the laboratory result was recorded. The pre-steady state period is not included.

Note to programmer: 1) Use TRTA to create the rows within each analyte. 2) For each value of PARAMCD select the highest grade for each subject, regardless of visit or period. 3) Count the frequency by analyte, period, and grade.
Only include analytes with abnormal results in the data in this table.

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Table 14.3.2.3.1
Hematology – Clinical Laboratory Assessments and Changes from Baseline
Safety Population
Hemoglobin (gm/dL)

		IM HIV Infected (N=XX)	IM HIV Uninfected (N=XX)	Total (N=XX)
Baseline [1]	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 15	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Change from Baseline	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 29	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
…	Min-Max	XX – XX	XX - XX	XX - XX
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded prior to the first dose administration.

[2] End of Study is Day 85 for subjects in the IM Group.

Note to Programmer:

1) This table will show all scheduled visits and will be repeated for each continuous Hematology parameter listed in the SAP. Increment the last digit of the table number for each additional analyte.

2) At any visit subjects can only be on one of the dose administrations, so only one column will have results, and therefore there is no need for a total column.

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Table 14.3.2.4.1
Chemistry - Clinical Laboratory Assessments and Changes from Baseline
Safety Population
BUN (mg/dL)

Note to programmer: Repeat Tables above for CHEMISTRY analytes, incrementing x for each new analyte.

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Table 14.3.2.5.1
CD4+ T-Cell Counts (cells/mm^3) and Changes from Baseline
Safety Population

		IM HIV Infected (N=XX)	IM HIV Uninfected (N=XX)	Total (N=XX)
Baseline [1]	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 15	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Change from Baseline	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 29	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
…	Min-Max	XX – XX	XX - XX	XX - XX
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded prior to the first dose administration.

[2] End of Study is Day 85 for subjects in the IM Group.

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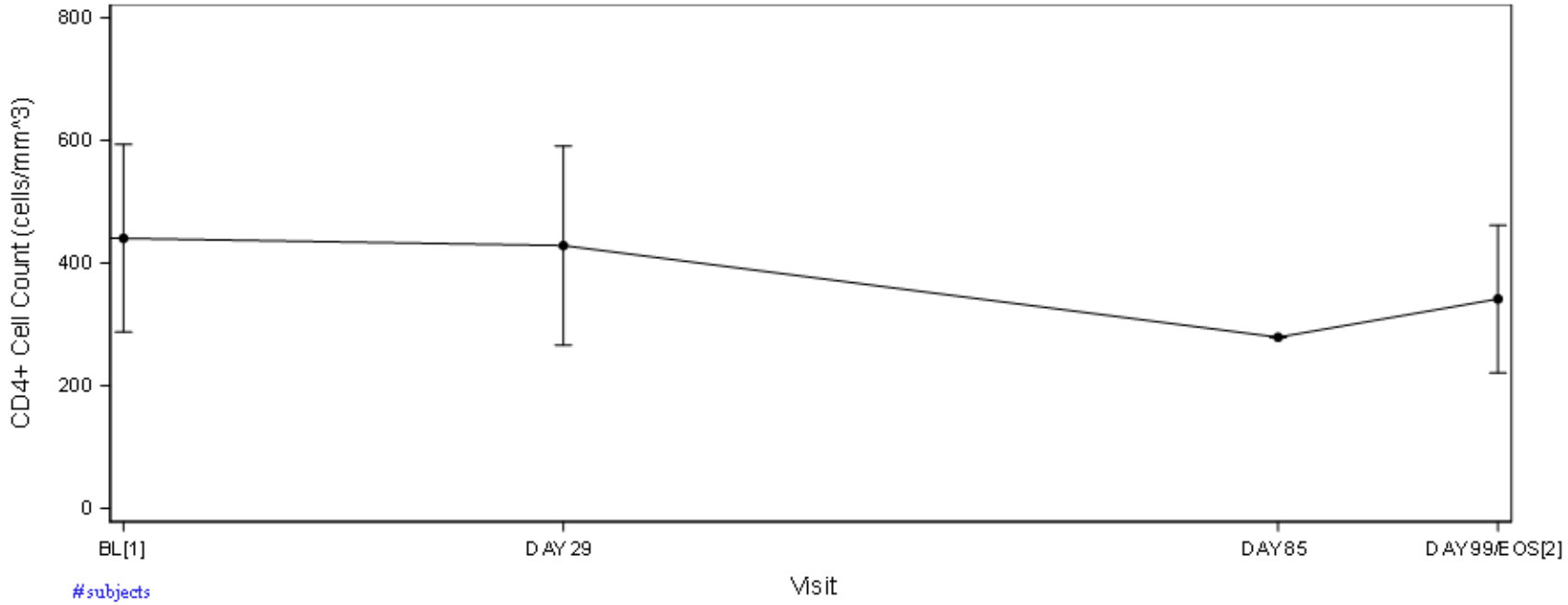
Graph 14.3.2.5.4
Mean (+/- SE) CD4+ T-Cell Counts (cells/mm^3)
Safety Population



[1] Baseline is the last analyte value recorded on Day 1,prior to the first dose administration. When Screening is the only value, it becomes Baseline and is counted in the Baseline row and not in the Screening row.

[2] End of Study is Day 85 for subjects in the IM HIV Infected Group.

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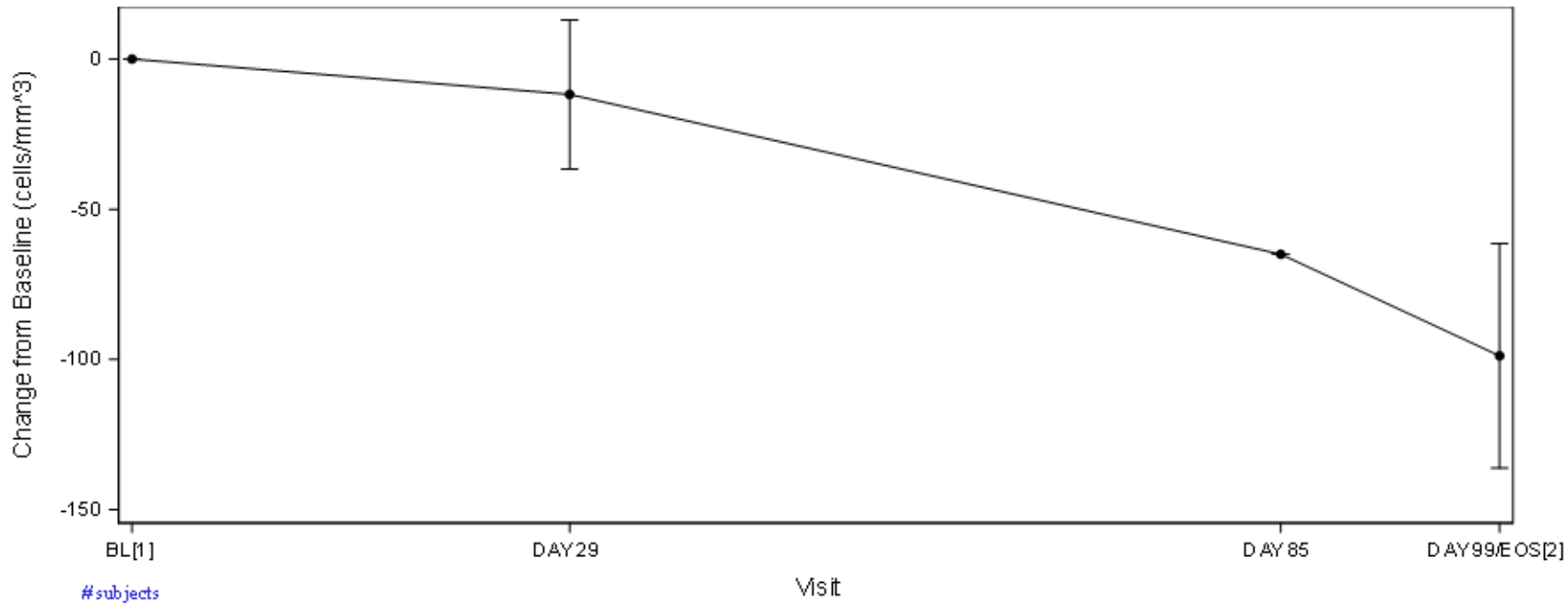
Graph 14.3.2.5.5
Mean (+/- SE) Change from Baseline CD4+ T-Cell Counts (cells/mm^3)
Safety Population



[1] Baseline is the last analyte value recorded on Day 1,prior to the first dose administration. When Screening is the only value, it becomes Baseline and is counted in the Baseline row and not in the Screening row.

[2] End of Study is Day 85 for subjects in the IM HIV Infected Group.

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Table 14.3.3.1
Vital Signs and Changes from Baseline
Safety Population
Weight (kg)

Note to programmer: Repeat above for VITAL SIGNS, incrementing x for each new VITAL SIGN (Temperature, Pulse, Respiration Rate, and Blood Pressure). Report only the visits where vital signs were collected, and change "analyte" to "vital sign" in the footnote.

Where collected, the pre-dose, post-dose (immediate) and post-dose (15 minutes) values will be presented for each visit. Label visits in the table like this example: Day 15 Pre, Day 15 Post, Day 15 Post 15 min.

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Table 14.3.4.1
Abnormal Physical Examination Findings

Safety Population

		IM HIV Infected (N=XX)	IM HIV Uninfected (N=XX)	Total (N=XX)
Baseline [1]	Skin	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	HEENT	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lymph Nodes	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lungs/Chest	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Heart	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Abdomen	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Genital/Rectal	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Extremities	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Neurological	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Day 15	Skin	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	HEENT	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lymph Nodes	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lungs/Chest	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Heart	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Abdomen	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Genital/Rectal	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Extremities	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Neurological	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
…				
End of Study [2]	Skin	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	HEENT	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lymph Nodes	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lungs/Chest	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Heart	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Abdomen	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Genital/Rectal	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Extremities	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Neurological	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

N = All subjects in the Safety Population, and denominator for percentage calculations.
[1] Baseline is the last analyte value recorded, prior to the first dose administration.
[2] End of Study is Day 85 for subjects in the IM Group.

Note to Programmer: Include all visit days that Physical Exam is recorded.

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Table 14.3.5.1
Summary of Study Drug Administration
Safety Population

		IM HIV Infected (N=XX)	IM HIV Uninfected (N=XX)	Total (N=XX)
Cumulative Dose (mg)	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX
Duration of Treatment (days from first dose)	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX

N = All subjects in the Safety Population.

Table 14.4.1
HIV Treatment Satisfaction Questionnaires
Intent-to-Treat Population – HIV Infected Group

		IM HIV Infected (N=XX)			
Questions		HIVTSQs (Day 29)	HIVTSQs (Day 85)	P-Value [1]	HIVTSQc (Day 85)
	N	XX	XX	xxxx	XX
How satisfied are you	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)		XX.X(XX.XX)
With your current	Median	XX.X	XX.X		XX.X
treatment?	25%-75%	XX – XX	XX – XX		XX – XX
	Min-Max	XX – XX	XX - XX		XX - XX
How well controlled do	N	XX	XX	xxxx	XX
You feel your HIV has been	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)		XX.X(XX.XX)
recently?	Median	XX.X	XX.X		XX.X
	25%-75%	XX – XX	XX – XX		XX – XX
	Min-Max	XX – XX	XX - XX		XX - XX
How satisfied are you with	N	XX	XX	xxxx	XX
any side effects of your	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)		XX.X(XX.XX)
present treatment?	Median	XX.X	XX.X		XX.X
	25%-75%	XX – XX	XX – XX		XX – XX
	Min-Max	XX – XX	XX - XX		XX - XX
How satisfied are you with	N	XX	XX	xxxx	XX
the demands made by your	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)		XX.X(XX.XX)
current treatment	Median	XX.X	XX.X		XX.X
	25%-75%	XX – XX	XX – XX		XX – XX
…	Min-Max	XX – XX	XX - XX		XX - XX

N = All subjects in the Intent-to-Treat Population, and denominator for percentage calculations.

[1] Wilcoxon signed rank test comparing paired change in mean response at Day 29 to Day 85.

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Table 14.4.2
Study Medication Satisfaction Questionnaires
Intent-to-Treat Population – HIV Uninfected Group

		IM HIV Uninfected (N=XX)			
Questions		SMSQs (Day 29)	SMSQs (Day 85)	P-value [1]	SMSQc (Day 85)
	N	XX	XX	xxxx	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)		XX.X(XX.XX)
How satisfied are you with your	Median	XX.X	XX.X		XX.X
current study medication?	25%-75%	XX – XX	XX – XX		XX – XX
	Min-Max	XX – XX	XX - XX		XX - XX
How satisfied are you with any	N	XX	XX	xxxx	XX
side effects of your present	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)		XX.X(XX.XX)
study medication?	Median	XX.X	XX.X		XX.X
	25%-75%	XX – XX	XX – XX		XX – XX
	Min-Max	XX – XX	XX - XX		XX - XX
How satisfied are you with	N	XX	XX	xxxx	XX
the demands made by your	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)		XX.X(XX.XX)
current study medication?	Median	XX.X	XX.X		XX.X
	25%-75%	XX – XX	XX – XX		XX – XX
	Min-Max	XX – XX	XX - XX		XX - XX
How convenient have you been	N	XX	XX	xxxx	XX
finding your study	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)		XX.X(XX.XX)
Medication to be recently?	Median	XX.X	XX.X		XX.X
	25%-75%	XX – XX	XX – XX		XX – XX
…	Min-Max	XX – XX	XX - XX		XX - XX

N = All subjects in the Intent-to-Treat Population, and denominator for percentage calculations.
[1] Wilcoxon signed rank test comparing paired change in mean response at Day 29 to Day 85.

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Table 14.4.3
Preference Assessment
Intent-to-Treat Population

		IM HIV Infected (N=XX)	IM HIV Uninfected (N=XX)	Total (N=XX)
Which type of administration do you prefer?	IV Infusion	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	IM Injection	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

Full question text: For the past 8 weeks you have received IM injections every 2 weeks. Today we would like you to compare your experience on the IM injections with the IV infusion you received previously during this study. Which type of administration do you prefer?
N = All subjects in the Intent-to-Treat Population, and denominator for percentage calculations.

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SUPPLEMENTAL TABLES (ANALYSIS BY PERIOD)

Table 14.3.1.1.2
Treatment-Emergent Adverse Events Summary
Safety Population – IM HIV Infected
By Period

	IM HIV Infected (N=XX)			
	Initial Period 15 min IV Infusion	Investigational Period IM Injection	Follow-up Period 15 min IV Infusion	Total
TEAE [1]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Serious TEAE [2]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE with Death Outcome	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Leading to Discontinuation	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Related to Study Drug [3]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Severe TEAE [4]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Class C TEAE [5]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
TEAE = Treatment-Emergent Adverse Event.
NOTE: Identical TEAEs are counted only once per subject.
[1] Number(%) of subjects with at least one TEAE.
[2] Number(%) of subjects with at least one serious TEAE, excluding death, as identified by the investigator.
[3] Definitely, probably, or possibly.
[4] Severity/Grade 3 or higher (severe or potentially life threatening).
[5] Per the CDC Classification System for HIV Infection.

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Table 14.3.1.1.3
Treatment-Emergent Adverse Events Summary
Safety Population – IM HIV Uninfected
By Period

	IM HIV Uninfected (N=XX)			
	Pre-Steady State + IV Infusions Period	Investigational Period IM Injection	Follow-up Period	Total
TEAE [1]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Serious TEAE [2]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE with Death Outcome	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Leading to Discontinuation	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Suspected Adverse Reaction [3]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Severe TEAE [4]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Class C TEAE [5]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

N = All subjects in the Safety Population (displayed according to actual treatment received),and denominator for percentage calculations.
TEAE = Treatment-Emergent Adverse Event.
NOTE: Identical TEAEs are counted only once per subject.
[1] Number(%) of subjects with at least one TEAE.
[2] Number(%) of subjects with at least one serious TEAE, excluding death, as identified by the investigator.
[3] Possibly related to study drug.
[4] Severity/Grade 3 or higher (severe or potentially life threatening).
[5] Per the CDC Classification System for HIV Infection.

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Table 14.3.1.2.2
Overall Incidence of Treatment-Emergent Adverse Events
Safety Population - IM HIV Infected
By Period

		IM HIV Infected (N=XX)			
Body System	Preferred Term [1]	Initial Period 15 min IV Infusion	Investigational Period IM Injection	Follow-up Period 15 min IV Infusion	Total
Overall[2]	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: Identical TEAEs are counted only once per subject.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Number(%) of subjects with at least one TEAE in any Body System.

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Table 14.3.1.2.3
Overall Incidence of Treatment-Emergent Adverse Events
Safety Population - IM HIV Uninfected
By Period

		IM HIV Uninfected (N=XX)			
			Investigational Period		
Body System	Preferred Term [1]	Pre-Steady State + IV Infusions Period	IM Injection	Follow-up Period	Total
Overall[2]	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: Identical TEAEs are counted only once per subject.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Number(%) of subjects with at least one TEAE in any Body System.

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Table 14.3.1.3.2
Incidence of Treatment-Emergent Adverse Events by Severity/Grade
Safety Population – IM HIV Infected
By Period

		IM HIV Infected (N=XX)					
		Initial Period 15min IV Infusion					
Body System	Preferred Term[1]	Any Grade [2]	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Pot. Life Threatening (Grade 4)	Death (Grade 5)
Overall [3]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the most severe occurrence, regardless of relationship to study drug.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Adverse Events with missing severity grade are included in this column only.
[3] Number(%)of subjects with at least one TEAE in any Body System.

Note to programmer: Repeat this table HIV infHIV infthe investigational period and follow-up period, all under the same table number.

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Table 14.3.1.3.3
Incidence of Treatment-Emergent Adverse Events by Severity/Grade
Safety Population – IM HIV Uninfected
By Period

		IM HIV Uninfected (N=XX)					
		Pre-Steady State + IV Infusions Period					
Body System	Preferred Term[1]	Any Grade [2]	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Pot. Life Threatening (Grade 4)	Death (Grade 5)
Overall [3]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the most severe occurrence, regardless of relationship to study drug.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Adverse Events with missing severity grade are included in this column only.
[3] Number(%)of subjects with at least one TEAE in any Body System.

Note to programmer: Repeat this table the investigational period and follow-up period, all under the same table number.
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Table 14.3.1.4.2
Incidence of Treatment-Emergent Adverse Events by Relationship to Study Drug
Safety Population - IM HIV Infected
By Period

		IM HIV Infected (N=XX)	
		Initial Period 15 min Infusion	
Body System	Preferred Term[1]	Suspected Adverse Reaction [3]	Unrelated
Overall[2]	ALL TERMS	n (XXX.X%)	n (XXX.X%)
	Events	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the highest relationship, regardless of severity/grade.
[1] “ALL TERMS” represents number(%) of subjects with at least one TEAE within that Body System; “Events” represents number of TEAEs reported by the subject(s).
[2] Number(%)of subjects with at least one TEAE in any Body System.
[3] Possibly related to study drug.

Note to programmer: Repeat this table the investigational period and follow-up period, all under the same table number

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Table 14.3.1.4.3
Incidence of Treatment-Emergent Adverse Events by Relationship to Study Drug
Safety Population – IM HIV Uninfected
By Period

		IM HIV Uninfected (N=XX)	
		Pre-Steady State + IV Infusions Period	
Body System	Preferred Term[1]	Suspected Adverse Reaction [3]	Unrelated
Overall[2]	ALL TERMS	n (XXX.X%)	n (XXX.X%)
	Events	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)
	Events	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the highest relationship, regardless of severity/grade.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System; "Events" represents number of TEAEs reported by the subject(s).
[2] Number(%)of subjects with at least one TEAE in any Body System.
[3] Possibly related to study drug.

Note to programmer: Repeat this table the investigational period and follow-up period, all under the same table number.

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Table 14.3.1.5.x
Overall Incidence of Serious Adverse Events
Safety Population – xx Group

Note to programmer: Repeat above for SERIOUS Adverse Events with the footnote updated as below.

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: Identical SAEs are counted only once per subject.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of SAEs reported by the subject(s).
[2] Number(%) of subjects with at least one SAE in any Body System.

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Table 14.3.1.6.x
Incidence of Serious Adverse Events by Relationship to Study Drug
Safety Population – xx Group

Note to programmer: Repeat tables above for SERIOUS Adverse Events with the footnote updated as below.

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: The table shows related SAEs (per subject) with the highest relationship, regardless of severity/grade.
[1] "ALL TERMS" represents number(%) of subjects with at least one SAE within that Body System;
"Events" represents number of SAEs reported by the subject(s)
[2] Number(%) of subjects with at least one SAE in any Body System.

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Table 14.3.1.7.x
Treatment-Emergent Adverse Events Leading to Study Discontinuation
Safety Population – xx Group

Note to programmer: Repeat tables above for Adverse Events LEADING TO STUDY DISCONTINUATION (same footnote).

Table 14.3.2.3.2
Hematology – Clinical Laboratory Assessments and Changes from Baseline
Safety Population – IM HIV Infected
By Period
Hemoglobin (gm/dL)

		IM HIV Infected (N=XX)		
		Initial Period 15 min IV Infusion	Investigational Period IM Injection	Follow-up Period 15 min IV Infusion
Baseline [1]	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX – XX	XX – XX
Day 15	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX – XX	XX – XX
Change from Baseline	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX – XX	XX – XX
Day 29	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
…	Min-Max	XX – XX	XX – XX	XX – XX
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 85 for subjects in the IM Group.

Note to Programmer:

1) This table will show all scheduled visits and will be repeated for each continuous Hematology parameter listed in the SAP. Increment the last digit of the table number for each additional analyte.

2) At any visit subjects can only be on one of the dose administrations, so only one column will have results, and therefore there is no need for a total column.

Table 14.3.2.**3.3**
Hematology – Clinical Laboratory Assessments and Changes from Baseline
Safety Population – IM HIV Uninfected
By Period
Hemoglobin (gm/dL)

		IM HIV Uninfected (N=XX)		
		Pre-Steady State + IV Infusions Period	Investigational Period IM Injection	Follow-up Period
Baseline [1]	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 15	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Change from Baseline	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 29	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
…	Min-Max	XX – XX	XX - XX	XX - XX
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded prior to the first dose administration.

[2] End of Study is Day 99for subjects in the IM HIV Uninfected Group.

Note to Programmer:

1) This table will show all scheduled visits and will be repeated for each continuous Hematology parameter listed in the SAP. Increment the last digit of the table number for each additional analyte.

2) At any visit subjects can only be on one of the dose administrations, so only one column will have results, and therefore there is no need for a total column.

Table 14.3.2.4.X
Chemistry - Clinical Laboratory Assessments and Changes from Baseline
Safety Population – xx Group
BUN (mg/dL)

Note to programmer: Repeat Tables above for CHEMISTRY analytes, incrementing x for each new analyte.

Table 14.3.2.5.2
CD4+ T-Cell Counts (cells/mm^3) and Changes from Baseline
Safety Population– IM HIV Infected
By Period

		IM HIV Infected (N=XX)		
		Initial Period 15 min IV Infusion	Investigational Period IM Injection	Follow-up Period 15 minute IV Infusion
Baseline [1]	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 15	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Change from Baseline	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 29	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
…	Min-Max	XX – XX	XX - XX	XX - XX
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the IM HIV Infected Group.

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Table 14.3.2.5.3
CD4+ T-Cell Counts (cells/mm^3) and Changes from Baseline
Safety Population – IM HIV Uninfected
By Period

		IM HIV Uninfected (N=XX)		
		Pre-Steady State + IV Infusions Period	Investigational Period IM Injection	Follow-up Period
Baseline [1]	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 15	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Change from Baseline	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
	Min-Max	XX – XX	XX - XX	XX - XX
Day 29	N	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X
	25%-75%	XX – XX	XX – XX	XX – XX
…	Min-Max	XX – XX	XX - XX	XX - XX
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded prior to the first dose administration.

[2] End of Study is Day 99for subjects in the IM HIV Uninfected Group.

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Table 14.3.3.X
Vital Signs and Changes from Baseline
Safety Population – xx Group
By Period
Weight (kg)

Note to programmer: Repeat above for VITAL SIGNS, incrementing x for each new VITAL SIGN (Temperature, Pulse, Respiration Rate, and Blood Pressure). Report only the visits where vital signs were collected, and change "analyte" to "vital sign" in the footnote.

Where collected, the pre-dose, post-dose (immediate) and post-dose (15 minutes) values will be presented for each visit. Label visits in the table like this example: Day 15 Pre, Day 15 Post, Day 15 Post 15 min.

Table 14.3.4.2
Abnormal Physical Examination Findings
Safety Population – IM HIV Infected
By Period

		IM HIV Infected (N=XX)		
		Initial Period 15 min IV Infusion	Investigational Period IM Injection	Follow-up Period 15 minute IV Infusion
Baseline [1]	Skin	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	HEENT	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lymph Nodes	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lungs/Chest	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Heart	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Abdomen	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Genital/Rectal	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Extremities	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Neurological	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Day 15	Skin	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	HEENT	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lymph Nodes	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lungs/Chest	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Heart	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Abdomen	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Genital/Rectal	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Extremities	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Neurological	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
…				
End of Study [2]	Skin	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	HEENT	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lymph Nodes	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lungs/Chest	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Heart	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Abdomen	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Genital/Rectal	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Extremities	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Neurological	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

N = All subjects in the Safety Population, and denominator for percentage calculations.
[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.
[2] End of Study is Day 85 for subjects in the IM Group.

Note to Programmer: Include all visit days that Physical Exam is recorded.

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Table 14.3.4.3
Abnormal Physical Examination Findings
Safety Population – IM HIV Uninfected
By Period

		IM HIV Uninfected (N=XX)		
		Pre-Steady State + IV Infusions Period	Investigational Period IM Injection	Follow-up Period
Baseline [1]	Skin	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	HEENT	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lymph Nodes	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lungs/Chest	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Heart	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Abdomen	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Genital/Rectal	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Extremities	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Neurological	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Day 15	Skin	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	HEENT	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lymph Nodes	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lungs/Chest	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Heart	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Abdomen	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Genital/Rectal	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Extremities	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Neurological	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
…				
End of Study [2]	Skin	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	HEENT	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lymph Nodes	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Lungs/Chest	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Heart	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Abdomen	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Genital/Rectal	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Extremities	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Neurological	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

N = All subjects in the Safety Population, and denominator for percentage calculations.
[1] Baseline is the last analyte value recorded prior to the first dose administration.
[2] End of Study is Day 99for subjects in the IM HIV Uninfected Group.

Note to Programmer: Include all visit days that Physical Exam is recorded.

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TaiMed Biologics, Inc.

Protocol TMB-302

A Phase 3 Study of the Safety of Trogarzo® Administered as an Undiluted "IV Push" over a Reduced Interval in Clinically Stable HIV-1 Infected Trogarzo® Experienced Patients and Healthy HIV-uninfected Volunteers

Statistical Analysis Plan

August 17, 2021
Final Version 3

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Table of Contents

1. Introduction

This document outlines the planned statistical analyses for data collected within the scope of the TaiMed protocol TMB-302, entitled "A Phase 3 Study of the Safety of Trogarzo® Administered as an Undiluted "IV Push" over a Reduced Interval in Clinically Stable HIV-1 Infected Trogarzo® Experienced Patients. This statistical analysis plan (SAP) applies to the most recent version of the study protocol (dated 15 Oct 2020) and will be updated as necessary if future protocol amendments warrant an update to the manner of analysis. This document was prepared in accordance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline E3: Structure and Content of Clinical Study Reports [1].

2. Study Overview

2.1. Study Design

This Phase 3 study is designed to assess the safety and pharmacokinetic (PK) profile (serum area under the curve [AUC] and trough concentration) of 800 mg Trogarzo® once every two weeks administered via intravenous push (IV push) (undiluted drug administered over 30 seconds) compared with the approved Trogarzo® administration (IV infusion) (diluted in 250 mL normal saline administered intravenously over 15 minutes). The study enrolls HIV stable subjects and healthy HIV-uninfected volunteers who are treated with 800 mg of Trogarzo® every two weeks administered via IV infusion in combination with an optimized background regimen (OBR). At the end of the study, the HIV stable subjects will return to IV infusion administration. The study will also assess the maintenance of established virologic control, and characterize changes in the viral susceptibility/resistance and the development of anti-drug antibodies as secondary endpoints. If deemed comparable to administration by IV infusion, administration by IV push would be desirable to improve the logistics of administration by eliminating the need for saline bags and infusion apparatus as well as improving convenience for subjects and physicians.

Twenty subjects will be enrolled into the study. The first five subjects enrolled will comprise the Sentinel Group. Subjects six through twenty will be the Core Group. Subjects in the Core Group will not be screened until the Sentinel Group has completed Day 99 (14 weeks) of the study and the Data Monitoring Committee (DMC) has reviewed the data accumulated and given approval for enrollment of the Core Group to proceed.

<u>Sentinel Group</u>
Subjects in the Sentinel Group will receive an 800 mg maintenance dose of Trogarzo® in accordance with the prescribing information (diluted in 250 mL normal saline and administered over 15 minutes via IV infusion) at Day 1/Baseline and again at Day 15. Every two weeks thereafter through Day 85 (12 weeks), subsequent maintenance doses

will be administered at increasing concentrations and over decreasing intervals according to the following schedule:

- Day 1/Baseline: 800 mg diluted in 250 mL normal saline (at 3.2 mg/mL) via IV Infusion over 15 minutes per approved Trogarzo® prescribing information
- Day 15 (2 weeks): 800 mg diluted in 250 mL normal saline (at 3.2 mg/mL) via IV Infusion over 15 minutes per approved Trogarzo® prescribing information
- Day 29 (4 weeks): 800 mg diluted in 50 mL normal saline (at 16 mg/mL) via IV Infusion over 10 minutes
- Day 43 (6 weeks): 800 mg diluted in 16 mL normal saline (at 50 mg/mL) via IV Bolus over 5 minutes
- Day 57 (8 weeks): 800 mg diluted in 8 mL normal saline (at 100 mg/mL) via IV Bolus over 1 minute
- Day 71 (10 weeks): 800 mg undiluted (at 150 mg/mL) via IV push over 30 seconds
- Day 85 (12 weeks): 800 mg undiluted (at 150 mg/mL) via IV push over 30 seconds
- Day 99 (14 weeks), End of Study (EOS) visit: 800 mg diluted in 250 mL normal saline (at 3.2 mg/mL) via IV Infusion over 15 minutes per approved Trogarzo® prescribing information

Core Group: HIV-infected subjects

After DMC review and approval, the Core Group (subject numbers six (6) through twenty (20)) will be enrolled. Subjects in the Core Group will also receive an 800 mg maintenance dose of Trogarzo® in accordance with the prescribing information (diluted in 250 mL normal saline and administered over 15 minutes via IV infusion) at Day 1/Baseline and again at Day 15. Every two weeks thereafter through Day 71 (10 weeks), maintenance doses will be administered via undiluted IV push over 30 seconds. At Day 84 (12 weeks), Core Group subjects will revert to diluted IV infusion dosing over 15 minutes in accordance with the Trogarzo® prescribing information.

- Day 1/Baseline: 800 mg diluted in 250 mL normal saline (at 3.2 mg/mL) via IV Infusion over 15 minutes per approved Trogarzo® prescribing information
- Day 15 (2 weeks): 800 mg diluted in 250 mL normal saline (at 3.2 mg/mL) via IV Infusion over 15 minutes per approved Trogarzo® prescribing information
- Day 29 (4 weeks): 800 mg undiluted (at 150 mg/mL) via IV push over 30 seconds
- Day 43 (6 weeks): 800 mg undiluted (at 150 mg/mL) via IV push over 30 seconds
- Day 57 (8 weeks): 800 mg undiluted (at 150 mg/mL) via IV push over 30 seconds
- Day 71 (10 weeks): 800 mg undiluted (at 150 mg/mL) via IV push over 30 seconds
- Day 85 (12 weeks), EOS visit: 800 mg diluted in 250 mL normal saline (at 3.2 mg/mL) via IV Infusion over 15 minutes per approved Trogarzo® prescribing information

Core Group: HIV-uninfected subjects

Pre-Steady State Phase: Subjects will receive a 2000 mg infusion over 60 minutes on Day minus 55 followed by 3 doses of 800 mg infusion over 15 minutes on Days minus 41, 27, and Day minus 13. On Day 1 the subjects will enter the Study Treatment Phase.

Study Treatment Phase: These HIV-uninfected subjects will receive an 800 mg dose of Trogarzo® in accordance with the prescribing information (diluted in 250 mL normal saline and administered over 15 minutes via IV infusion) at Day 1/Baseline and again at Day 15. Every two weeks thereafter through Day 71 (10 weeks), subsequent doses will be administered via undiluted IV Push over 30 seconds. After the Day 71 infusion, HIV-uninfected Core Group subjects discontinue Trogarzo® infusion therapy.

All HIV-infected study subjects in both Groups will be observed for 15 minutes after each study drug administration, and HIV-uninfected subjects will be observed for 60 minutes. All adverse events (AEs) will be recorded. Vital signs will be measured and recorded at the beginning and end of this observation period.

PK samples will be collected during the study to evaluate serum concentrations and the PK profile of Trogarzo®. In particular, data will be collected to compare serum drug concentrations (AUC and trough) after IV infusion of the 800 mg diluted drug over 15 minutes to IV push of the undiluted drug over 30 seconds. Pre-dose samples will be collected at selected time points, along with samples at 1, 24, and 72 hours post-dose, and 7 and 14 days post-dose for the first two doses of study drug (via IV Infusion) for HIV-infected participants and after steady state is achieved in HIV-uninfected healthy volunteers, and for all, of the 30-second IV push doses for all subjects in both Groups. Samples collected at 24 and 72 hour post-dose time points, and those collected at 7-day post-dose time points when a study visit is not otherwise already scheduled will require additional visits for PK sample collection only.

Subjects will be monitored for safety through 28 days after the last administration of Trogarzo® on study (from Day 85 (12 weeks) through Day 113 (16 weeks) for the Sentinel Group and HIV-infected Core Group, and from Day 71 (10 weeks) through Day 98 (14 weeks) for the HIV-uninfected Core Group).

Safety Assessments

Safety assessments will include the following through End of Study for each Group:

- Physical examinations
- Vital sign measurements
- Clinical laboratory parameters (hematology, serum chemistry, urinalysis and $CD4^+$ T-cell count)
- Monitoring of AEs and concomitant medications
- Anti-Trogarzo® antibody levels (immunogenicity of Trogarzo®)

Laboratory samples will be collected every two weeks, at visits where Trogarzo® is administered. Beginning at Day 29 (4 weeks), non-laboratory safety assessments will be performed weekly through Day 99 (14 weeks) for the Sentinel Group and Core HIV-uninfected Group, and through Day 85 (12 weeks) for the Core HIV-infected Group.

2.2. Study Objectives

2.2.1. Primary

The primary objectives of this study are to:

- Evaluate the safety of Trogarzo® administered as an undiluted IV push over 30 seconds in clinically-stable human immunodeficiency virus type-1 (HIV-1) infected subjects with at least 3 months of stable treatment with a Trogarzo®-containing antiretroviral (ARV) regimen or healthy HIV-uninfected volunteers
- Compare the AUC and trough serum drug concentration after IV infusion with the diluted drug to the AUC and trough concentration after IV push with the undiluted drug

2.2.2. Secondary

The secondary objectives of this study are to:

- Assess HIV-1 viral load for IV Infusion compared to IV push in HIV-1 infected subjects only.
- Characterize noted HIV-1 sensitivity/susceptibility changes in participants with an increase in plasma viral load to levels above 1,000 copies/mL on two consecutive measurements at least 2 weeks apart in HIV-1 infected subjects only.
- Determine the presence and significance of anti-Trogarzo® antibodies, if any (immunogenicity of Trogarzo®)

2.3. Study Drug Dosage and Administration

The study drug, Trogarzo®, is a humanized IgG4 monoclonal antibody (MAb) approved for use in treatment-experienced patients in combination with other ARV agents for the treatment of multi-drug resistant HIV-1 infection and is administered via IV.

Maintenance doses of 800 mg Trogarzo® will be administered to all study subjects every two weeks throughout their participation in the study.

The Day1/Baseline and Day 15 doses will be administered as diluted IVs (IV Infusion - 800 mg in 250mL normal saline; 3.2 mg/mL) over 15 minutes in accordance with Trogarzo® prescribing information. Subsequent Trogarzo® doses on study will be administered at increased concentration over a shorter interval (< 15 minutes – see Study Design for more detail).

All patients will continue on all other ARV medications as prescribed by the primary care provider throughout study participation. Any changes in ARV treatment will be recorded with reasons for treatment modification. All patients will return to routine Trogarzo® administration via IV Infusion over 15 minutes in accordance with the prescribing information after completing participation in the study.

2.4. Procedures

2.4.1. Subject Identification

Once consent is obtained and study eligibility has been determined, a subject will be enrolled into the study and will be assigned a Participant Identification (PID) number. The 5-digit PID number will consist of a 2-digit site number and a 3-digit sequential subject number.

2.4.2. Randomization

This will be an open-label, non-randomized study.

2.4.3. Blinding/Unblinding

There will be no blinding/unblinding considerations for this open-label, non-randomized study.

2.4.4. Replacement

If a subject in the study is discontinued due to any reason other than safety as detailed in Section 4.3 (Safety Monitoring and Toxicity Management Plan) of the study protocol, another subject may be enrolled to replace the lost subject to achieve a total of 20 subjects successfully completing participation in the study.

Study participants who:
1. miss 2 consecutive visits or
2. have more than one treatment visit out of window or
3. have 3 non-treatment visits over 4 weeks that are out of window will be discontinued from the study and replaced.

3. Statistical Analysis Considerations

3.1. Sample Size

Anticipated enrollment is 20 subjects from approximately 7 to 8 sites in the United States.

3.2. Analysis Populations

3.2.1. Intent-to-Treat (ITT) Population

The ITT population is defined as all subjects enrolled into the study. Subject disposition will be based on the ITT population. The ITT Analysis Set will be used for the AUC and trough serum drug concentration and the secondary effectiveness analysis (assessment of the HIV-1 viral loads).

3.2.2. Safety (SAF) Population

All subjects who receive at least one partial dose of study drug will be included in the SAF Population. Subjects will be analyzed according to the treatment (dose regimen) they actually received. The SAF Population will be used for the safety analyses.

3.3. Data Handling

3.3.1. Measurement Times

The nominal visit time point entered on the electronic case report forms (eCRFs) will be used. Subjects are asked to adhere to the following visit schedule:

Sentinel Group

- Study drug administration visits with safety assessments take place every two weeks beginning at Day 1/Baseline and continuing through Day 99 (14 weeks).
- Sentinel Group subjects will be asked to return for the final study assessments indicated for the EOS and Follow-up visits at Days 99 (14 weeks) and 113 (16 weeks), respectively. Subjects who are discontinued or who withdraw from the study prematurely are also requested to complete the assessments for these two study visits. (Refer to the Schedule of Events tables in the protocol for details on procedures for each scheduled study visit and for PK sampling time points.)

Core HIV-infected Group

- Study drug administration visits with safety assessments will take place once every two weeks beginning at Day 1/Baseline and continuing through Day 85 (12 weeks).
- Core HIV-infected Group subjects will be asked to return for the final study assessments indicated for the EOS and Follow-up visits at Days 85 (12 weeks) and 99 (14 weeks), respectively. Subjects who are discontinued or who withdraw from the study prematurely are also requested to complete the assessments for these two study visits. (Refer to the Schedule of Events tables in the protocol for details on procedures for each scheduled study visit and for PK sampling time points.)

Core HIV-uninfected Group

- Study drug administration visits with safety assessments will take place once every two weeks beginning at Day 1/Baseline and continuing through Day 71 (10 weeks).
- Core HIV-uninfected Group subjects will be asked to return for the final study assessments indicated for the EOS/Days 99 visit (14 weeks). Subjects who are discontinued or who withdraw from the study prematurely are also requested to complete the assessments for these two study visits. (Refer to the Schedule of Events tables in the protocol for details on procedures for each scheduled study visit and for PK sampling time points.)

3.3.2. Clinical Laboratory Data Handling Conventions

If a subject has multiple results in the clinical laboratory data for the Screening visit, only the last result prior to the first dose of study drug will be included in the analysis. If a subject has multiple results (retests) for subsequent visits, the retest results will only be included in the analysis if the subject does not have a value recorded for the original assessment at the given visit.

3.3.3. Baseline Values

Baseline is defined as the last assessment prior to the first dose of study drug (Day 1 for all HIV infected subjects, Day -55 for HIV uninfected subjects).

3.3.4. Missing Data Conventions

Subjects with missing data at Day 1/Baseline will use the Screening visit value as their Day 1/Baseline result. Unless otherwise specified, missing data for subsequent visits will be considered missing at random and will not be imputed. If necessary, imputation of partial dates may be performed during the data analysis and will be documented (e.g., missing month=July; missing day=15).

3.4. Statistical Methods

3.4.1. General Overview and Plan of Analysis

The data collected are intended primarily for clinical review and interpretation. The analysis of study data will be primarily descriptive, with emphasis on tabular and graphical displays. Descriptive statistics will be used to guide decisions as to the clinical relevance of findings. Unless otherwise stated, p-values will be determined only if they appear to be warranted from the summary statistics.

Where applicable, summaries will be displayed in the following subject groupings:

1) Sentinel Group;

2) Core HIV-infected Group;
Core HIV-uninfected Group and
3) Total.

In addition, the safety and efficacy summaries will present results for each of the dosing methods (IV push over 30 seconds, Infusion or Bolus over 10, 5, and 1 minute, and all IV infusions over 15 minutes).

For continuous data, descriptive statistics will be presented as number of subjects (n), mean, standard deviation, median, minimum, and maximum. For categorical data, the frequency and percentage of subjects in each category will be presented. Percentages will be based on non-missing data unless otherwise specified.

Data collected during this study will be assigned to the appropriate Analysis Phase, Analysis Period, and Analysis Subperiod (where applicable) in which it occurred. The assignment will be based on the visit date, or in the case of cumulative data such as AEs and concomitant procedures, based on the start date. Tables, listings, and graphs will reflect the assignments. A complete description of the phases, periods, and subperiods for the Sentinel and Core groups can be found in Appendix 1.

Data will be described and analyzed using the SAS System Version 9 (SAS Institute Inc., Cary, NC, SAS System). Individual subject data will be presented in subject data listings.

4. Statistical Analysis

4.1. Subject Disposition

The number of subjects in the ITT and SAF Populations will be tabulated.

Study completion data will be summarized for all enrolled subjects. The number and percent of subjects who complete treatment; discontinue study medication prematurely; or discontinue the study prematurely will be tabulated. The primary reason for premature discontinuation of study medication and/or discontinuation from study participation will be tabulated. Any additional reason(s) for premature discontinuation of study medication will also be tabulated. A listing of all enrolled subjects will be provided.

4.2. Demographic and Physical Characteristics

Summary statistics will be presented for demographic and other Baseline characteristics for the ITT Population. Tabulations for age, sex, ethnicity (Hispanic/Latino, Not Hispanic or Latino, Unknown), and race (American Indian/Alaska Native, Asian, Black/African American, Native Hawaiian/Other Pacific Islander, White, Unknown, or Other) will be

presented. Age (years) will be calculated as the integer part of [(date of screening - date of birth + 1)/365.25]. Baseline physical characteristics, such as height (cm) and weight (kg), will also be summarized.

A listing of demographic and Baseline characteristics will be presented, as well as a listing of medical history.

4.3. Analysis of Safety and Tolerability

Safety and tolerability will be assessed by both clinical and laboratory examinations. Summary statistics will be presented by AEs; hematology and serum chemistry; vital signs, (changes from Baseline and clinically significant findings); and abnormal physical examination findings in the SAF Population. Clinical laboratory values outside the normal ranges will be flagged in subject data listings. Non-numeric data will be presented in subject data listings, but will not be summarized.

4.3.1. Extent of Study Drug Exposure

Summary statistics will be presented for the cumulative dose (mg) and duration of treatment received by the subjects in the SAF Population. Duration of treatment will be represented as number of days from first dose of study drug. Corresponding listings will also be generated for study drug administration.

4.3.2. AEs

All AEs will be coded using MedDRA dictionary version 22.0. The use of another version will not be considered a violation of the SAP, nor require an amendment to the plan. All summary tables will be based on coded preferred terms (PTs), instead of verbatim terms. The categories and definitions of severity and causal relationship for all AEs, including the criteria for which an AE is to be classified as "serious," are as described in the protocol (Section 8).

A treatment-emergent AE (TEAE) is defined as any event not present before exposure to study drug or any event already present that worsens in either intensity or frequency following exposure to study drug. All AEs entered on the Adverse Events eCRF will be analyzed as TEAEs. A TEAE with missing severity or relationship will be considered severe or related, respectively.

The overall incidence of TEAEs will be summarized for all subjects in the SAF Population. The number and percentage of subjects having the following will be tabulated:

- TEAE
- Serious TEAE
- TEAE leading to discontinuation
- TEAE with outcome of death

- TEAE related to study drug (definitely, probably, or possibly)
- Severe TEAE
- Class C TEAE per the Centers for Disease Control and Prevention (CDC) Classification System for HIV Infection

The overall incidence of TEAEs will also be summarized by System Organ Class (SOC), and by SOC and PT. The number and percentage of subjects reporting an event, as well as the number of events reported by the subjects will be tabulated. The incidence of serious TEAEs and TEAEs leading to study discontinuation (if any) will be summarized in the same manner. If there are multiple occurrences of the same TEAE within any SOC or PT for the same subject, only the first occurrence will be counted.

The incidence of TEAEs by severity/grade (mild, moderate, severe, or potentially life-threatening) and by relationship to study drug (unrelated, possibly related, probably related, and definitely related), and the incidence of serious AEs (SAEs) by relationship to study drug, will also be summarized.

All other AEs will be classified as non-TEAEs and identified in listings only. Serious TEAEs, TEAEs leading to study discontinuation, and TEAEs with an outcome of death will be presented in separate listings, if needed.

4.3.3. Clinical Laboratory Parameters

Summary statistics will be presented for laboratory measurements overall for all subjects in the SAF Population. Urinalysis results will be presented in a listing only. The following analytes will be tabulated/listed:

- **Hematology**: complete white blood cell count with differential, hemoglobin, hematocrit, and platelets.
- **Serum chemistry profile**: albumin, alkaline phosphatase, alanine aminotransferase (ALT), amylase, aspartate aminotransferase (AST), blood urea nitrogen, calcium, chloride, creatine phosphokinase, creatinine, direct bilirubin, gamma glutamyl transferase, glucose, lactate dehydrogenase magnesium, phosphorus, potassium, sodium, total bilirubin, total protein, and uric acid. In addition, eGFR will be presented using the following formula: $eGFR = 1.86 \times [Creatinine/88.4]^{-1.154} \times [Age]^{-0.203} \times [0.742 \text{ if female}] \times [1.210 \text{ if Black}]$.
- **CD4+ Cell Counts**

Urinalysis results will be presented in a data listing and will include results from microscopic testing only. Pregnancy test, Serum Follicle-Stimulating Hormone (FSH) test, Hepatitis Serology, C-reactive Protein, and Viral Resistance Testing will also be presented in a data listing only.

Normal ranges for the laboratory parameters will be provided by the laboratory that performed the assessments. All normal ranges will be standardized and results will be reported in standard units. The tables will include summary statistics for the assessments and the changes from Baseline to each subsequent time point of measurement. A listing of subjects with abnormal (i.e., outside normal range) laboratory assessments will also be presented.

Potentially Clinically Significant (PCS) criteria may be applied to laboratory parameters as clinically indicated, and if applied, will be summarized as described above. PCS is defined as a laboratory value that is lower or higher than a laboratory's normal range limits.

Note: Electronic clinical laboratory data will be received at Westat. Data reconciliation will be performed to resolve any discrepancies with the Oracle database. Details of data receipt will be described in the Data Receipt Plan.

4.3.4. Vital Signs

Summary statistics for vital signs and weight will be presented overall for all subjects in the SAF Population for all scheduled visits. Actual values and changes from Baseline will be summarized for all visits where collected.

4.3.5. Physical Examination Findings

A complete physical examination will be conducted at Screening and targeted physical exams will be conducted at every visit from Day 1 through Day 99 (14 weeks). Physical examination findings at each scheduled visit will be summarized overall for all subjects in the SAF Population. The number and percent of subjects with abnormal findings by body system will be tabulated.

4.3.6. Medications

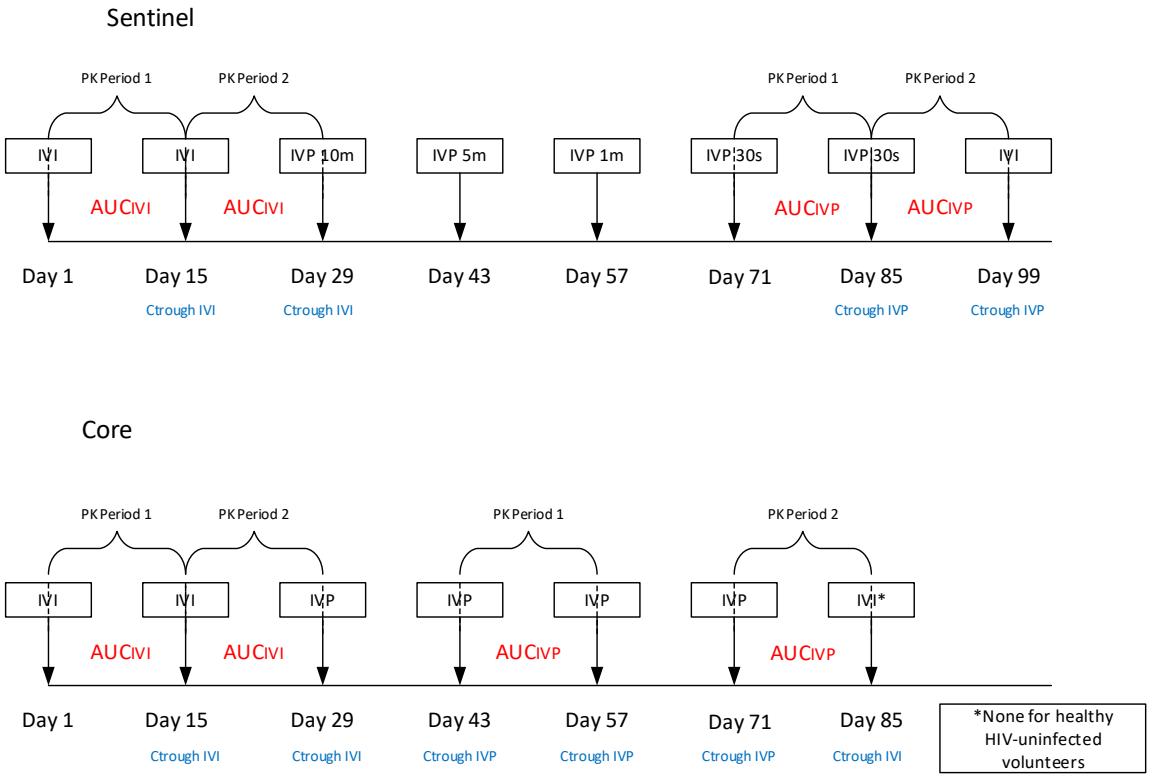
All prescriptions or over-the-counter medications continued at the start of the trial or started during the trial, and different from the study drug will be recorded. All of these medications will be coded using WHO Drug Dictionary (March 2019). The use of another version will not be considered a violation of the SAP, nor require an amendment to the plan. Both the coded terms and verbatim terms will be presented in data listings for:

- Concomitant procedures (procedures are not coded)
- Previous and Concomitant medications
- ART medications – only for HIV infected subjects

4.4. PK

The primary PK endpoints are to compare the AUC and trough serum drug concentration after IV Infusion with the diluted drug to the AUC and trough concentration after IV push with the undiluted drug. Serum concentrations will be used to estimate PK parameters.

PK parameters will be estimated for all subjects by non-compartmental analysis of the serum concentration-time data. Missing data will not be imputed. The AUC and trough concentrations for IV push infusions over 30 seconds and IV infusions over 15 minutes will be estimated. The following graphic illustrates the time points at which the AUC and C_{trough} values will be estimated.



A 90% confidence interval of log transform of the ratio of the geometric means for IV push to IV infusion will be calculated. A PK bridge between the IV push and IV infusion is demonstrated for AUC if the 90% confidence interval of log transform of the ratio of the geometric means for IV push (test product) to IV infusion (reference product) for the 20 subjects in the study is within a 80%-125% criteria.

In accordance with the FDA Guidance (2001) [2], SAS PROC MIXED will be used to fit a factor-analytic variance-covariance structure using the FA0(2) option to the ln-transformed AUC data by subject, population (sentinel or core), PK period, and infusion type (IVI=Reference; IVP=Test) to estimate 80%-125% criteria. For each infusion type, subject-level AUC data will be labeled as PK Period 1 or PK Period 2 corresponding to the graphic above. Unless a subject has missing data for both administration routes and both periods, the subject's data will be included in the analysis because SAS PROC MIXED can handle missing data. Details of reported outputs from the analysis will be displayed in the mock tables and will include mean estimate and its lower and upper bounds.

The following SAS code syntax will be used to calculate estimates:

```
proc mixed data=lnauc method=reml;
class infusiontype population period ;
model lnauc= population period infusiontype/ddfm=kenwardroger;
random infusiontype /type=FA0(2) subject=subject;
repeated/group=infusiontype subject=subject;
estimate 'T-R' infusiontype 1 -1/cl alpha=0.1;
ods output estimates=test;
data test;
set test;
meanrat= exp (estimate); * Estimated mean ratio on original scale;
lowerb=exp(lower); * Lower bound on original scale;
upperb=exp(upper); * Upper bound on original scale;
proc print data=test noobs;
var meanrat lowerb upperb;
run;
```

The C_{trough} values for all IV push and all IV infusions over 15 minutes will be estimated. Additionally, the PK bridge will be demonstrated if the proportion of subjects with average C_{trough} equal to or exceeding the threshold of 300 ng/mL are comparable for IV infusion over 15 minutes to IV push over 30 seconds. Analysis will be conducted by pooling all the C_{trough} measurements into two groups (IVI=Reference; IVP=Test) and dichotomizing the C_{trough} data (< 300 ng/mL=1; ≥300 ng/mL=0). Fisher's exact test for comparing two independent binomial proportions will be conducted initially to test for equality of the proportions. In a subsequent test, the PK bridge will be based on relative risk assuming that the binary data in the two infusion groups are independent samples. Two one-sided tests of significance (TOST) will be carried out for the pair of hypotheses, H_{0a}: $\rho \leq \rho_0$ versus H_{1a}: $\rho > \rho_0$ and H_{0b}: $\rho \geq \rho_1$ versus H_{1b}: $\rho < \rho_1$. Rejection of both H_{0a} and H_{0b} would mean that the relative risk lies in the zone of equivalence. The syntax below will be used in SAS to carry out the score test with $\rho_0 = 0.8$, and $\rho_1 = 1.25$.

```
proc freq data=<filename> order=data;
tables group*Ctrough/relrisk(equivalence margin=(.80, 1.25)
method=FM);
weight count;
format Ctrough Ctrough.;
run;
```

Details of reported outputs from the analysis will be displayed in the mock tables and will include relative risk, equivalence limits, 90% confidence limits, and TOST p-values of lower margin, upper margin, and overall. Missing data will not be imputed or used in the analysis. In addition, the two-tailed p-value from Fisher's exact test will be presented to provide additional supporting evidence for equality of binomial proportions between the two administrative routes in the Ctrough cutoff at 300 ng/mL.

4.5. Secondary Efficacy Endpoint

Assessment of the HIV-1 viral load measurements in HIV-1 infected subjects will be made as a secondary endpoint by comparing the mean viral load (log10 and copies/ml) at all visits when subjects received an approved IV infusion over 15 minutes to the visits when receiving an IV push over 30 seconds. Note: Prior to calculating change from Baseline in viral load, the log10 value of each measurement will be calculated and will be rounded to one decimal point.

Study subjects will be considered virologic failures if:

1. Viremic subjects experience a sustained >0.5 log increase in plasma HIV-1 RNA from Baseline

or

2. A sustained viral load>200 copies/mL if subject viral load was <50 copies/mL at Baseline

that cannot be explained by intercurrent illness, a change in adherence to the background regimen, or unanticipated changes to the background regimen. Note: Sustained is defined as two consecutive viral load determinations at least 2 weeks apart.

The proportion of subjects who experienced virologic failure at any time during the study will be summarized.

4.6. Graphical Displays

In addition to the tables and listings described above, the following graphical displays will also be included for in HIV-1 infected subjects:

- Mean (+/- Standard Error [SE]) viral load levels (copies/mL) at all scheduled visits;
- Mean (+/- SE) change from Baseline in viral load levels (copies/mL) at all scheduled visits;
- Mean (+/- SE) CD4+ cell count (cells/mm^3) at all scheduled visits; and
- Mean (+/- SE) change from Baseline in CD4+ T-cell count (cells/mm^3) at all scheduled visits.

4.7. Exploratory/Other Analyses

Exploratory statistical analyses will examine any noted changes in HIV-1 drug sensitivity/susceptibility in participants with an increase in plasma viral load to levels above 1,000 copies/mL on two consecutive measurements at least 2 weeks apart. These reports will be prepared separately from the report prepared in accordance with the rest of this SAP.

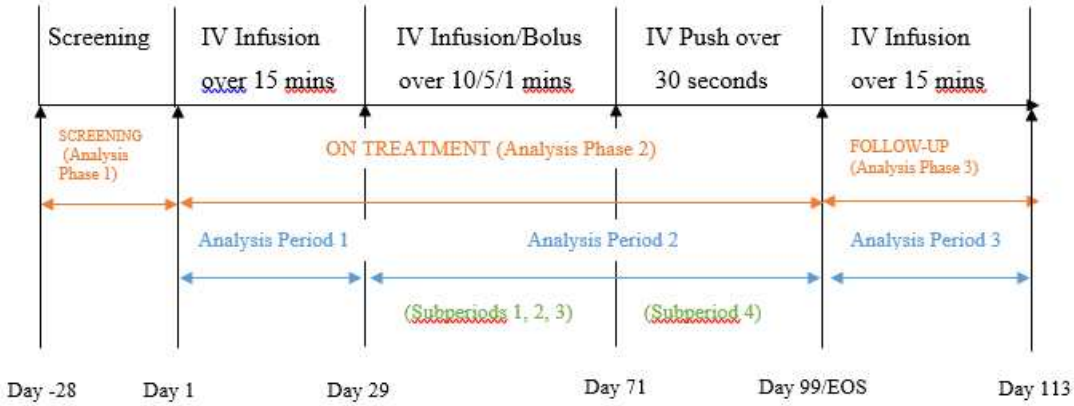
5. References

1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (1995, November 30) Guideline E3: *Structure and Content of Clinical Study Reports.* Retrieved from http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html.
2. Guidance for Industry. Statistical Approaches to Establishing Bioequivalence. Food and Drug Administration, CDER January 2001. (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-approaches-establishing-bioequivalence)

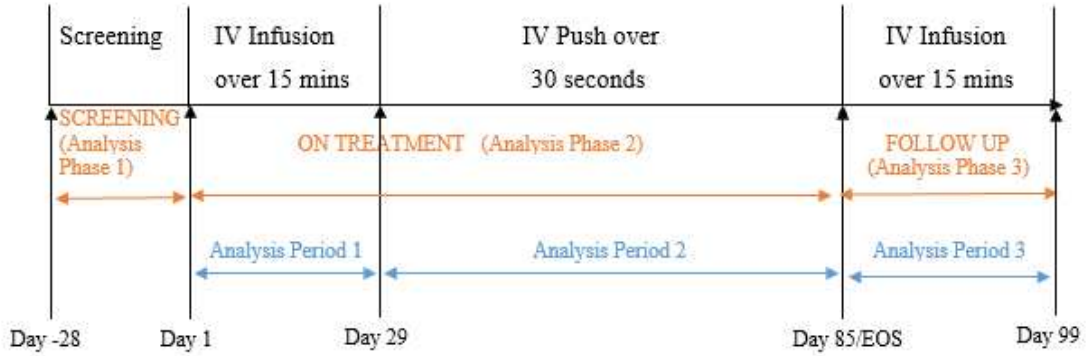
Appendix 1

Analysis Phases, Periods, and Subperiods

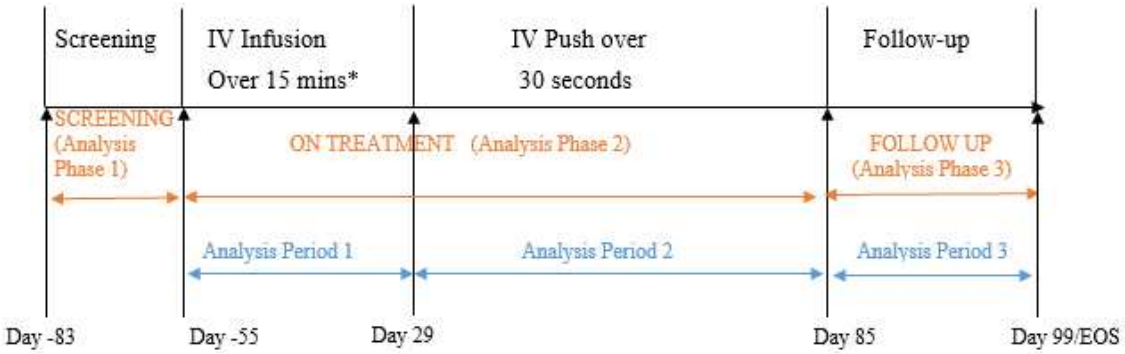
Sentinel Group (ARM="SENTINEL")



Core HIV-infected Group (ARM="CORE")



Core HIV-uninfected Group (ARM="CORE UNINFECTED")



*The first infusion during this period is 2000mg over 60 mins but all other infusions during this period are 800mg over 15 mins.

TaiMed Biologics, Inc.

Protocol TMB-302

A Phase 3 Study of the Safety of Trogarzo® Administered as an Undiluted "IV Push" over a Reduced Interval in Clinically Stable HIV-1 Infected Trogarzo® Experienced Patients and Healthy HIV-uninfected Volunteers

Mock Statistical Listings

August 17, 2021

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Contents

Notes Applicable to All Listings

General Programming Notes:

1. There are a few listings that might fit as they are or might have to be split once we see the output with actual data.
2. All listings should start with and be sorted by Group (Sentinel or Core), Subject ID (concatenation of site number and Subject number), and visit date as appropriate.
3. If columns with specific text should be widened due to the amount of text, it is up to the programmer's discretion. However, please keep to the industry standard margin of 1 inch on bottom and sides and 1.25 inches on the top. Font is Courier New 8 point.
4. For all dates used, character format dates to capture partial dates. Use dashes where a month or day is missing. If entire date is missing just leave blank. i.e., - JAN2011 or 01—2011.
5. If a programming note appears on the mock listing indicating that the footnote should appear only on the first page, this means the first page of output contains all footnotes and ONLY footnotes. All subsequent pages contain data with one footnote that says "Refer to page 1 for footnotes".
6. Some of the mock tables display numbers rather than x's. The numbers are meaningless and are for example only. Where visit names are displayed in tables, these are examples as well. Correct visit names for the TMB-302 study should be displayed in the actual output.
7. Each listing should include all applicable data, even if only a subset of the full set of treatment groups is displayed in the mocks.
8. Sort each listing by Group and then Subject ID where applicable.
9. Add "Period" to any applicable listing as the data dictates. Some listings below have period added with example values.

Listing 16.2.1.1
Subject Disposition

Group	Subject ID	Screened	ITT Population [1]	SAF Population [2]
Sentinel	302-XX-XXX	YES	YES	YES
	302-XX-XXX	YES	YES	YES
Core HIV-infected	302-XX-XXX	YES	YES	YES
	302-XX-XXX	YES	YES	YES
Core HIV-uninfected	302-XX-XXX	YES	YES	YES
	302-XX-XXX	YES	YES	YES

[1] Intent-to-Treat (ITT) Population consists of all Subjects enrolled into the study.
[2] Safety (SAF) Population consists of Subjects receiving at least one partial dose of study drug.

Listing 16.2.1.2
Discontinuation

Group	Subject ID	Study Discontinuation Date	Date of Last Study Treatment	Completed Study Treatment	Reason for Treatment Discontinuation	Completed Study	Reason for Study Discontinuation	Death Date
Sentinel	302-XX-XXX	20161101	20161004	NO	CONSENT WITHDRAWN OR VOLUNTARY WITHDRAWAL	NO	CONSENT WITHDRAWN OR VOLUNTARY WITHDRAWAL	
	302-XX-XXX	20160920	20160823	NO	ADVERSE EVENT-SEVERE DRUG RASH AND FEVER OF 1 WEEK.	NO	ADVERSE EVENT-SEVERE DRUG RASH AND FEVER OF 1 WEEK.	
Core HIV-infected	302-XX-XXX	20160517	20160421	NO	INVESTIGATORS DECISION-INVESTIGATORS DECISION	NO	INVESTIGATORS DECISION-LACK OF CLINICAL PROGRESSION	
Core HIV-uninfected	302-XX-XXX	20161101	20160810	NO	INVESTIGATORS DECISION-SUBJECT NEVER CAME TO FOLOOW UP VISIT BECAUSE NEVER RECOVERED FROM PCP	NO	INVESTIGATORS DECISION-SUBJECT NEVER CAME TO F/UP VISIT BECAUSE NEVER RECOVERED FROM PNEUMONIA	

Listing 16.2.2.1
Text of Inclusion and Exclusion Criteria

Criterion Type	Criterion Number	Criterion Text [1]
Inclusion	1	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	2	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	…	
	8	
Exclusion	1	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	2	
	…	
	10	

[1] Full detailed text:

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Listing 16.2.2.2
Protocol Violations

Group	Subject ID	Visit	Start Date	Stop Date	Violation Code	Details of Violation	Approval Obtained	Date of Approval
Sentinel	302-XX-XXX	XXXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXXX	Yes/No	YYYY-MM-DD
Core HIV-infected	302-XX-XXX	XXXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXX	Yes/No	YYYY-MM-DD
Core HIV-uninfected	302-XX-XXX	XXXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXX	Yes/No	YYYY-MM-DD

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Listing 16.2.2.3
Protocol Deviations

Group	Subject ID	Visit	Start Date	Stop Date	Deviation Code	Details of Deviation	Approval Obtained	Date of Approval
Sentinel	302-XX-XXX	XXXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXXXX	Yes/No	YYYY-MM-DD
Core HIV-infected	302-XX-XXX	XXXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXXX	Yes/No	YYYY-MM-DD
Core HIV-uninfected	302-XX-XXX	XXXXXX	YYYY-MM-DD	YYYY-MM-DD	XXX	XXXXXXXXXX	Yes/No	YYYY-MM-DD

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Listing 16.2.2.4
Inclusion/Exclusion Criteria Violations/Deviations

Group	Subject ID	Date of Informed Consent	Time of Informed Consent (hh:mm)	Will this Subject be Enrolled	Criterion Type and Number [1]
Sentinel	302-XX-XXX	YYYY-MM-DD	XX:XX	Yes/No	EXC XXX/INC XXX
Core HIV-infected	302-XX-XXX	YYYY-MM-DD	XX:XX	Yes/No	EXC XXX/INC XXX
Core HIV-uninfected	302-XX-XXX	YYYY-MM-DD	XX:XX	Yes/No	EXC XXX/INC XXX

[1] Refer to Listing 16.2.2.1 for text.

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Listing 16.2.3.1
Demographic Characteristics

Group	Subject ID	Date of Birth	Age (years) [1]	Ethnicity	Race	Sex
Sentinel	302-XX-XXX	1962-01-22	54	NOT HISPANIC OR LATINO	BLACK OR AFRICAN AMERICAN	M
	302-XX-XXX	1954-11-26	61	NOT HISPANIC OR LATINO	WHITE	M
Core HIV-infected	302-XX-XXX	1988-02-11	28	NOT HISPANIC OR LATINO	BLACK OR AFRICAN AMERICAN	M
	302-XX-XXX	1960-12-16	55	HISPANIC OR LATINO	UNKNOWN	M
Core HIV-uninfected	302-XX-XXX	1988-02-11	28	NOT HISPANIC OR LATINO	BLACK OR AFRICAN AMERICAN	M
	302-XX-XXX	1960-12-16	55	HISPANIC OR LATINO	UNKNOWN	M

[1] Age = Age at Screening.

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Listing 16.2.3.2
Medical History

Group	Subject ID	Medical Condition/Surgery	Start Date	Stop Date	CDC AIDS-Defining Condition
Sentinel	302-XX-XXX	XXXXXXXXXXXXXX	YYYY-MM-DD	YYYY-MM-DD or ONGOING	NO
Core HIV-infected	302-XX-XXX	XXXXXXXXXXXXXX	YYYY-MM-DD	YYYY-MM-DD or ONGOING	YES
Core HIV-uninfected	302-XX-XXX	XXXXXXXXXXXXXX	YYYY-MM-DD	YYYY-MM-DD or ONGOING	YES

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Listing 16.2.4.1
Study Drug Administration

Group	Subject ID	Visit	Visit Date	Method of Administration [1]	Start Time (hh:mm:ss)	Stop Time (hh:mm:ss)	Administration Site	Infusion Side	Starting Volume (mL)	Ending Volume (mL)	Entire Dose Delivered	Reason if No or Interrupted
Sentinel	302-XX-XXX	XXXXXXX	YYYY-MM-DD	Inf 15m	XX.XX:XX	XX.XX:XX	Cephalic Vein	Left	XXX	XXX	Yes	XXXXXXXXXX
		XXXXXXX	YYYY-MM-DD	Inf 10m	XX.XX:XX	XX.XX:XX	Other Vein: specify	Right			No	
									XXX	XXX		
Core HIV-infected	302-XX-XXX	XXXXXXX	YYYY-MM-DD	Bolus 1m	XX.XX:XX	XX.XX:XX	Cephalic Vein	Left	XXX	XXX	Yes w/ Interruption	XXXXXXXXXX
Core HIV-uninfected	302-XX-XXX	XXXXXXX	YYYY-MM-DD	Bolus 1m	XX.XX:XX	XX.XX:XX	Cephalic Vein	Left	XXX	XXX	Yes w/ Interruption	XXXXXXXXXX

[1] Method of Administration: Inf 15m = IV Infusion 15 minutes, Inf 10m = IV Infusion 10 minutes, Bolus 5m = IV Bolus 5 minutes, Bolus 1m = IV Bolus 1 minute, Push 30s = IV Push 30 seconds

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Listing 16.2.4.2
ART Exposure [1]

Group	Subject ID	Medication	Standardized Medication Name [2]	Indication	Start Date	Stop Date	Period[3]	Dose	Unit	Route	Frequency
Sentinel	302-XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	Inf 15m/ Inf 10m/	XXXX	XXXX	XXXXX	XX
Core HIV-infected	302-XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	Bolus 5m/ Bolus 1m/ Push 30s/ Screening	XXXX	XXXX	XXXXX	XX
Core HIV-uninfected	302-XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	Bolus 5m/ Bolus 1m/ Push 30s/ Screening	XXXX	XXXX	XXXXX	XX

[1] ART medications beginning from 3 months prior to Screening visit.
[2] Medications were coded with WHO Drug Dictionary Version March, 2019.
[3] Period represents the timeframe when the medication was STARTED.

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Listing 16.2.4.3
Concomitant Medications [1]

Group	Subject ID	Medication	Standardized Medication Name [2]	Indication	Start Date	Stop Date	Period[3]	Dose	Unit	Route	Frequency
Sentinel	302-XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	Inf 15m/ Inf 10m/	XXXX	XXXX	XXXXX	XX
Core HIV-infected	302-XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	Push 30s/ Screening	XXXX	XXXX	XXXXX	XX
Core HIV-uninfected	302-XX-XXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	YYYY-MM-DD	YYYY-MM-DD Or ONGOING	Push 30s/ Screening	XXXX	XXXX	XXXXX	XX

[1] Medications taken on or after Screening visit.
[2] Medications were coded with WHO Drug Dictionary Version March, 2019.
[3] Period represents the timeframe when the medication was STARTED.

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Listing 16.2.4.4
Concomitant Procedures [1]

Group	Subject ID	Procedure	Procedure Date	Period[2]	Reason
Sentinel	302-XX-XXX	XXXXXXXX	YYYY-MM-DD	Inf 15m/ Inf 10m/ Bolus 5m/	XXXXXXXX: specify
Core HIV-infected	302-XX-XXX	XXXXXXXX	YYYY-MM-DD	Inf 15m/ Inf 10m/ Bolus 5m/	XXXXXXXX
Core HIV-uninfected	302-XX-XXX	XXXXXXXX	YYYY-MM-DD	Bolus 1m/ Push 30s/ Screening	XXXXXXXX

[1] Procedures occurring on or after the Day 1 visit.
[2] Period represents the timeframe when the procedure took place.

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Listing 16.2.5.1
Post-Administration Observation

Group	Subject ID	Visit	Visit Date	Observed After Study Drug	Start Time of Observation (hh:mm)	End Time of Observation (hh:mm)	Comments
Sentinel	302-XX-XXX	XXX	YYYY-MM-DD	YES	XX:XX	XX:XX	XXXXXXXXXXXXXXXX
Core HIV-infected	302-XX-XXX	XXX	YYYY-MM-DD	NO	XX:XX	XX:XX	XXXXXXXXXXXXXXXX
Core HIV-uninfected	302-XX-XXX	XXX	YYYY-MM-DD	NO	XX:XX	XX:XX	XXXXXXXXXXXXXXXX

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Listing 16.2.5.2
PK Results

Group	Subject ID	Visit	Visit Date (Study Day)	Period [1]	Scheduled Time point	Time of Collection (hh:mm)	Concentration (ng/mL) [2]	AUC(day*ug/mL) [3]
Sentinel	302-XX-XXX	XXX	YYYY-MM-DD (xx)	XXX	XXX	XX:XX	xxx	xxx
Core HIV-infected	302-XX-XXX	XXX	YYYY-MM-DD (xx)	XXX	XXX	XX:XX	xxx*	xxx
Core HIV-uninfected	302-XX-XXX	XXX	YYYY-MM-DD (xx)	XXX	XXX	XX:XX	xxx	xxx

[1] Period represents the timeframe when the visit took place. NOTE - When labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.

[2] *Indicates TROUGH value.

[3] AUC calculated for Day 1 to Day 15, Day 15 to 29, Day 71 to Day 85, Day 85 to Day 99 (Sentinel Group) and Day 1 to Day 15, Day 15 to 29, Day 43 to Day 57, Day 71 to Day 85 (Core Groups).

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Listing 16.2.5.3
Viral Load

Group	Subject ID	Virologic Failure?[1]	Visit	Visit Date (Study Day)	Period[2]	Treatment Date (Study Day) [3]	Viral Load (log10 cp/mL) [4]	Chg from Baseline (log10 cp/mL)	HIV-1 RNA (cp/mL) [4]
Sentinel	302-XX-XXX	Y	DAY 0	2016-08-22	Inf 15m	2016-08-10 (159)	1.0		TND**
			DAY 14						73700
			WEEK 12						73700
			WEEK 16	2016-11-14 (84)	Inf 10m	2016-10-31 (245)	1.3	-3.6	TD**
			WEEK 20					0	73700
			WEEK 24						73700
	302-XX-XXX	N	DAY 0	2016-09-07	Bolus 1m	2016-08-24 (154)	1.3		TD**
			DAY 14						6530
Core HIV-infected	302-XX-XXX	Y	DAY 0	2016-08-22	Inf 15m	2016-08-10 (159)	1.0		TND**
			DAY 14						73700
			WEEK 12						73700
			WEEK 16	2016-11-14 (84)	Inf 10m	2016-10-31 (245)	1.3	-3.6	TD**
			WEEK 20					0	73700
			WEEK 24						73700
	302-XX-XXX	N	DAY 0	2016-09-07	Bolus 1m	2016-08-24 (154)	1.3		TD**
			DAY 14						6530
Core HIV-uninfected	302-XX-XXX	Y	DAY 0	2016-08-22	Inf 15m	2016-08-10 (159)	1.0		TND**
			DAY 14						73700
			WEEK 12						73700
			WEEK 16	2016-11-14 (84)	Inf 10m	2016-10-31 (245)	1.3	-3.6	TD**
			WEEK 20					0	73700
			WEEK 24						73700
	302-XX-XXX	N	DAY 0	2016-09-07	Bolus 1m	2016-08-24 (154)	1.3		TD**
			DAY 14						6530

[1] Y = Virologic Failure per protocol: Viremic subjects experience a sustained >0.5 log increase in plasma HIV-1 RNA from baseline. OR
A sustained VL>200 copies/mL if subject VL was <50 copies/mL at baseline.
Note: Sustained is defined as two consecutive viral load determinations at least 2 weeks apart.
[2] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[3] Last treatment prior to viral load measurement.
[4] *=below 400 copies/mL; **=below 50 copies/mL. HIV-1 RNA level results below level of quantitation are coded as target detected (TD) or target not detected (TND).

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Listing 16.2.6.1
Treatment Emergent Adverse Events [1]

Group	Subject ID	System Organ Class	Preferred Term [2]	Adverse Event Verbatim	Start Date (Study Day)	Stop Date (Study Day)	Period [3]	Sev./ Grade [4]	SAE	Caus. [5]	Action Taken [6]	Outcm. [7]	CDC AIDS-Defining Cond.
Sentinel	302-XX-XXX	MUSCULOSKELETAL AND CONNECTIVE TISSUE	ARTHRALGIA	MILD PAIN (DUE TO FALL AT	20160923 (283)	20161010 (300)	Inf15m	1	N	0	0	1	N
Core HIV-infected	302-XX-XXX	NERVOUS SYSTEM DISORDERS	HEADACHE	WORSENING HEADACHES	20160516 (3)	20160524 (11)	Bolus1m	2	Y	4	4	1	N
		INVESTIGATIONS	BREATH SOUNDS ABNORMAL	DECREASED BREATH SOUNDS	20160520 (7)	20160609 (27)	Push30s	1	N	0	0	1	N
Core HIV-uninfected	302-XX-XXX	NERVOUS SYSTEM DISORDERS	HEADACHE	WORSENING HEADACHES	20160516 (3)	20160524 (11)	Bolus1m	2	Y	4	4	1	N
		INVESTIGATIONS	BREATH SOUNDS ABNORMAL	DECREASED BREATH SOUNDS	20160520 (7)	20160609 (27)	Push30s	1	N	0	0	1	N

[1] Adverse events occurring on or after the Day 1 visit.
[2] Adverse events are coded using MedDRA Version 22.0.
[3] Period represents the timeframe when the adverse event STARTED.
[4] Severity/Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Potentially Life Threatening, 5=Death.
[5] Causality: 0=Unrelated, 1=Possible, 2=Probable, 3=Definite.
[6] Action Taken: 0=None, 1=Medication Given, 2=Non-Medication Therapy, 3=Suspended Study Drug, 4=Permanently Discontinued Study Drug, 99=Other.
[7] Outcome: 1=Resolved, 2=Resolved w/sequelae, 3=Ongoing, 4=Worsened, 5=Death, 7=Chronic/Stable, 98=Unknown.

Westat (Created on DDMMMYYYY)
S:\TMB302\DA\SAS\L_AE.SAS

Notes to programmer: Confirm that footnotes match final version of CRF and coding used in data.

Listing 16.2.6.2
Treatment Emergent Serious Adverse Events [1]

Group	Subject ID	System Organ Class	Preferred Term [2]	Adverse Event Verbatim	Start Date (Study Day)	Stop Date (Study Day)	Period [3]	Sev./ Grade [4]	Caus. [5]	Action Taken [6]	Outcm. [7]	CDC AIDS-Defining Cond.
Sentinel	302-XX-XXX	MUSCULOSKELETAL AND CONNECTIVE TISSUE	ARTHRALGIA	MILD PAIN (DUE TO FALL AT	20160923 (283)	20161010 (300)	Inf15m	1	0	0	1	N
Core HIV-infected	302-XX-XXX	NERVOUS SYSTEM DISORDERS	HEADACHE	WORSENING HEADACHES	20160516 (3)	20160524 (11)	Bolus1m	2	4	4	1	N
		INVESTIGATIONS	BREATH SOUNDS ABNORMAL	DECREASED BREATH SOUNDS	20160520 (7)	20160609 (27)	Push30s	1	0	0	1	N
Core HIV-uninfected	302-XX-XXX	NERVOUS SYSTEM DISORDERS	HEADACHE	WORSENING HEADACHES	20160516 (3)	20160524 (11)	Bolus1m	2	4	4	1	N
		INVESTIGATIONS	BREATH SOUNDS ABNORMAL	DECREASED BREATH SOUNDS	20160520 (7)	20160609 (27)	Push30s	1	0	0	1	N

[1] Adverse events occurring on or after the Day 1 visit.
[2] Adverse events are coded using MedDRA Version 22.0.
[3] Period represents the timeframe when the adverse event STARTED.
[4] Severity/Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Potentially Life Threatening, 5=Death.
[5] Causality: 0=Unrelated, 1=Possible, 2=Probable, 3=Definite.
[6] Action Taken: 0=None, 1=Medication Given, 2=Non-Medication Therapy, 3=Suspended Study Drug, 4=Permanently Discontinued Study Drug, 99=Other.
[7] Outcome: 1=Resolved, 2=Resolved w/sequelae, 3=Ongoing, 4=Worsened, 5=Death, 7=Chronic/Stable, 98=Unknown.

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Listing 16.2.6.3
Treatment Emergent Adverse Events [1] Leading to Study Discontinuation or Death

Group	Subject ID	System Organ Class	Preferred Term [2]	Adverse Event Verbatim	Start Date (Study Day)	Stop Date (Study Day)	Period [3]	Sev./ Grade [4]	SAE	Caus. [5]	Action Taken [6]	Outcm. [7]	CDC AIDS-Defining Cond.
Sentinel	302-XX-XXX	MUSCULOSKELETAL AND CONNECTIVE TISSUE	ARTHRALGIA	MILD PAIN (DUE TO FALL AT	20160923 (283)	20161010 (300)	Inf15m	1	N	0	0	1	N
Core HIV-infected	302-XX-XXX	NERVOUS SYSTEM DISORDERS	HEADACHE	WORSENING HEADACHES	20160516 (3)	20160524 (11)	Bolus1m	2	Y	4	4	1	N
		INVESTIGATIONS	BREATH SOUNDS ABNORMAL	DECREASED BREATH SOUNDS	20160520 (7)	20160609 (27)	Push30s	1	N	0	0	1	N
Core HIV-uninfected	302-XX-XXX	NERVOUS SYSTEM DISORDERS	HEADACHE	WORSENING HEADACHES	20160516 (3)	20160524 (11)	Bolus1m	2	Y	4	4	1	N
		INVESTIGATIONS	BREATH SOUNDS ABNORMAL	DECREASED BREATH SOUNDS	20160520 (7)	20160609 (27)	Push30s	1	N	0	0	1	N

[1] Adverse events occurring on or after the Day 1 visit.
[2] Adverse events are coded using MedDRA Version 22.0.
[3] Period represents the timeframe when the adverse event STARTED.
[4] Severity/Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Potentially Life Threatening, 5=Death.
[5] Causality: 0=Unrelated, 1=Possible, 2=Probable, 3=Definite.
[6] Action Taken: 0=None, 1=Medication Given, 2=Non-Medication Therapy, 3=Suspended Study Drug, 4=Permanently Discontinued Study Drug, 99=Other.
[7] Outcome: 1=Resolved, 2=Resolved w/sequelae, 3=Ongoing, 4=Worsened, 5=Death, 7=Chronic/Stable, 98=Unknown.

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Listing 16.2.7.1.1
Clinical Laboratory Test
Hematology

Group	Subject ID	Visit	Date of Sample (Study Day)	Period[1]	Test	Result (L/H)[2]	Unit	Lower Limit of Normal	Upper Limit of Normal	Potentially Clinically Significant[3]
Sentinel	302-XX-XXX	XXXXXXXXX	2016-03-04 (-172)	XXXXXXXX	Basophils	0	10^9/L	0	0.2	
					Basophils/Total Cells	0	%	0	2	
					Eosinophils	0.02	10^9/L	0	0.57	
					Eosinophils/Total Cells	1	%	0	6.8	
					Hematocrit	0.31(L)	Proportion of 1	0.39	0.54	YES
	302-XX-XXX	XXXXXXXXX	2016-11-14 (84)	XXXXXXXX	Hemoglobin	106(L)	g/L	127	181	YES
					Leukocytes	1.62(L)	10^9/L	3.8	10.7	YES
					Lymphocytes	0.6(L)	10^9/L	0.91	4.28	YES
					Lymphocytes/Total Cells	37	%	15.4	48.5	
					Monocytes	0.16	10^9/L	0.12	0.92	
					Monocytes/Total Cells	10	%	2.6	10.1	
					Neutrophils	0.84(L)	10^9/L	1.96	7.23	YES
					Neutrophils/Total Cells	52	%	40.5	75	
					Platelets	278	10^9/L	140	400	
Core HIV-infected	302-XX-XXX	XXXXXXXXX	2016-11-14 (84)	XXXXXXXX	Basophils	0.08	10^9/L	0	0.2	
					Basophils/Total Cells	2.3(H)	%	0	2	YES
					Eosinophils	0.19	10^9/L	0	0.57	
					Eosinophils/Total Cells	5.5	%	0	6.8	
					Hematocrit	0.39	Proportion of 1	0.39	0.54	
Core HIV-uninfected	302-XX-XXX	XXXXXXXXX	2016-11-14 (84)	XXXXXXXX	Basophils	0.08	10^9/L	0	0.2	
					Basophils/Total Cells	2.3(H)	%	0	2	YES
					Eosinophils	0.19	10^9/L	0	0.57	
					Eosinophils/Total Cells	5.5	%	0	6.8	

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] L = Below lower limit of normal; H = Above upper limit of normal.
[3] Potentially Clinically Significant is defined as having a result either below the lower limit of normal or above the upper limit of normal.

Listing 16.2.7.1.2
Clinical Laboratory Test
Chemistry

Group	Subject ID	Visit	Date of Sample (Study Day)	Period [1]	Test	Result (L/H)[2]	Unit	Lower Limit of Normal	Upper Limit of Normal	Clinically Significant[3]
Sentinel	302-XX-XXX	XXXXXXX	2016-03-04 (-172)	PRE-TREAT	Alanine Aminotransferase	21	U/L	6	43	
					Albumin	36	g/L	33	49	
					Alkaline Phosphatase	100	U/L	35	131	
					Amylase	167(H)	U/L	28	120	YES
	302-XX-XXX	XXXXXXX	2016-11-14 (84)	XXXXXXXX	Alanine Aminotransferase	18	U/L	6	43	
					Albumin	38	g/L	33	49	
					Alkaline Phosphatase	131	U/L	35	131	
					Amylase	158(H)	U/L	28	120	YES
					Aspartate Aminotransferase	20	U/L	11	36	
Core HIV-infected	302-XX-XXX	XXXXXXX	2016-03-04 (-172)	PRE-TREAT	Alanine Aminotransferase	21	U/L	6	43	
					Albumin	36	g/L	33	49	
					Alkaline Phosphatase	100	U/L	35	131	
					Amylase	167(H)	U/L	28	120	YES
	302-XX-XXX	XXXXXXX	2016-11-14 (84)	XXXXXXXX	Alanine Aminotransferase	18	U/L	6	43	
					Albumin	38	g/L	33	49	
					Alkaline Phosphatase	131	U/L	35	131	
					Amylase	158(H)	U/L	28	120	YES
					Aspartate Aminotransferase	20	U/L	11	36	
Core HIV-uninfected	302-XX-XXX	XXXXXXX	2016-03-04 (-172)	PRE-TREAT	Alanine Aminotransferase	21	U/L	6	43	
					Albumin	36	g/L	33	49	
					Alkaline Phosphatase	100	U/L	35	131	
					Amylase	167(H)	U/L	28	120	YES
	302-XX-XXX	XXXXXXX	2016-11-14 (84)	XXXXXXXX	Alanine Aminotransferase	18	U/L	6	43	
					Albumin	38	g/L	33	49	
					Alkaline Phosphatase	131	U/L	35	131	
					Amylase	158(H)	U/L	28	120	YES
					Aspartate Aminotransferase	20	U/L	11	36	

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] L = Below lower limit of normal; H = Above upper limit of normal.
[3] Potentially Clinically Significant is defined as having a result either below the lower limit of normal or above the upper limit of normal.

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Listing 16.2.7.1.3
Clinical Laboratory Test
Urinalysis

Group	Subject ID	Visit	Date of Sample (Study Day)	Period [1]	Test	Unit	Result
Sentinel	302-XX-XXX	XXXXXXXX	2016-03-04 (-172)	XXXXXX	Calcium Oxalate Crystals		Present
					Hyaline Casts	/LPF	2
					Sediment Examination		Positive
		XXXXXXXX	2016-11-14 (84)	XXXXXX	Sediment Examination		Positive
		XXXXXXXX	2017-02-06 (168)	XXXXXX	Sediment Examination		Positive
	302-XX-XXX	XXXXXXXX	2016-03-16 (92)	XXXXXX	Mucous Threads		Present
		XXXXXXXX	2016-03-23 (99)	XXXXXX	Calcium Oxalate Crystals		Present
					Sediment Examination		Positive
		XXXXXXXX	2017-02-23 (436)	XXXXXX	Amorphous Crystals		Present
					Sediment Examination		Positive
Core HIV-infected	302-XX-XXX	XXXXXXXX	2016-04-07 (-37)	XXXXXX	Sediment Examination		Positive
		XXXXXXXX	2016-05-13 (0)	XXXXXX	Sediment Examination		Positive
		XXXXXXXX	2016-05-20 (7)	XXXXXX	Hyaline Casts	/LPF	2
					Sediment Examination		Positive
Core HIV-uninfected	302-XX-XXX	XXXXXXXX	2016-04-07 (-37)	XXXXXX	Sediment Examination		Positive
		XXXXXXXX	2016-05-13 (0)	XXXXXX	Sediment Examination		Positive
		XXXXXXXX	2016-05-20 (7)	XXXXXX	Hyaline Casts	/LPF	2
					Sediment Examination		Positive

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.

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Listing 16.2.7.1.4
CD4+ Cell Count (cells/mm^3)

Group	Subject ID	Visit	Visit Date (Study Day)	Period[1]	Absolute CD4+ Cell Count (cells/mm^3) [2]	CD4+ Cell Count Pct Change from Baseline (%) [3]	CD4+Cell Count(%)	WBC(10^9/L)
Sentinel	302-XX-XXX	XXXXXXX	YYYY-MM-DD (XX)	Inf 15m/ Inf 10m/ Bolus 5m/	XXX*	XXXX	XXXX	X.XX
Core HIV-infected	302-XX-XXX	XXXXXXX	YYYY-MM-DD (XX)	Bolus 1m/ Push 30s/ Screening	XXX	XXXX	XXXX	X.XX
Core HIV-uninfected	302-XX-XXX	XXXXXXX	YYYY-MM-DD (XX)	Bolus 1m/ Push 30s/ Screening	XXX	XXXX	XXXX	X.XX

[1] Period represents the timeframe when the visit took place. Note – Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] *=below 200 cells/mm^3
[3] Calculated as (visit value - baseline)/baseline*100%

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Listing 16.2.7.1.5
Abnormal Laboratory Results

Group	Subject ID	Visit	Date of Sample (Study Day)	Period [1]	Category	Test	Result (L/H)[2]	Unit	Lower Limit of Normal	Upper Limit of Normal
Sentinel	302-XX-XXXX	XXXXXXXXX	2016-03-04 (-172)	PRE-TREAT	CHEMISTRY	Amylase	167(H)	U/L	28	120
						Direct Bilirubin	1(L)	umol/L	2	7
					HEMATOLOGY	Hematocrit	0.31(L)	Proportion of 1	0.39	0.54
						Hemoglobin	106(L)	g/L	127	181
						Leukocytes	1.62(L)	10^9/L	3.8	10.7
						Lymphocytes	0.6(L)	10^9/L	0.91	4.28
						Neutrophils	0.84(L)	10^9/L	1.96	7.23
	302-XX-XXX	XXXXXXXXX	2016-11-14 (84)	XXXXXXXX	CHEMISTRY	Amylase	158(H)	U/L	28	120
						Bilirubin	1.5(L)	umol/L	3	21
						Direct Bilirubin	1(L)	umol/L	2	7
					HEMATOLOGY	Basophils/Total Cells	2.3(H)	%	0	2
						Leukocytes	3.47(L)	10^9/L	3.8	10.7
						Neutrophils	1.37(L)	10^9/L	1.96	7.23
						Neutrophils/Total Cells	39.5(L)	%	40.5	75
Core HIV-infected	302-XX-XXX	XXXXXXXXX	2017-02-06 (168)	XXXXXXXX	CHEMISTRY	Amylase	133(H)	U/L	28	120
						Direct Bilirubin	1(L)	umol/L	2	7
					HEMATOLOGY	Hematocrit	0.37(L)	Proportion of 1	0.39	0.54
						Hemoglobin	124(L)	g/L	127	181
	302-XX-XXX	XXXXXXXXX	2016-03-23 (99)	XXXXXXXX	CHEMISTRY	Alanine Aminotransferase	68(H)	U/L	6	43
						Aspartate Aminotransferase	59(H)	U/L	11	36
						Cholesterol	3.03(L)	mmol/L	4.53	7.71
						Creatine Kinase	393(H)	U/L	39	308
Core HIV-uninfected	302-XX-XXX	XXXXXXXXX	2017-02-06 (168)	XXXXXXXX	CHEMISTRY	Amylase	133(H)	U/L	28	120
						Direct Bilirubin	1(L)	umol/L	2	7
					HEMATOLOGY	Hematocrit	0.37(L)	Proportion of 1	0.39	0.54
						Hemoglobin	124(L)	g/L	127	181

…

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] L = Below lower limit of normal; H = Above upper limit of normal.
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Listing 16.2.7.1.6
Other Laboratory Results

Group	Subject ID	Visit	Date of Sample (Study Day)	Category	Period [1]	Test	Result (L/H)[1]	Unit	Lower Limit of Normal	Upper Limit of Normal	Potentially Clinically Significant[2]
Sentinel	302-XX-XXXX	XXXXXXXXX	2016-03-04 (-172)	CHEMISTRY	XXXXXX	Amylase	167(H)	U/L	28	120	YES
						Direct Bilirubin	1(L)	umol/L	2	7	YES
				HEMATOLOGY	XXXXXX	Hematocrit	0.31(L)	Proportion of 1	0.39	0.54	YES
						Hemoglobin	106(L)	g/L	127	181	YES
						Leukocytes	1.62(L)	10^9/L	3.8	10.7	YES
						Lymphocytes	0.6(L)	10^9/L	0.91	4.28	YES
						Neutrophils	0.84(L)	10^9/L	1.96	7.23	YES
Core HIV-infected	302-XX-XXX	XXXXXXXXX	2016-11-14 (84)	CHEMISTRY	XXXXXX	Amylase	158(H)	U/L	28	120	YES
						Bilirubin	1.5(L)	umol/L	3	21	YES
						Direct Bilirubin	1(L)	umol/L	2	7	YES
Core HIV-uninfected	302-XX-XXX	XXXXXXXXX	2016-11-14 (84)	CHEMISTRY	XXXXXX	Amylase	158(H)	U/L	28	120	YES
						Bilirubin	1.5(L)	umol/L	3	21	YES
						Direct Bilirubin	1(L)	umol/L	2	7	YES

[1] Period represents the timeframe when the visit took place. NOTE - Since labs are assessed pre-dose, the value of PERIOD in the lab listings will be previous to the value of PERIOD in listings for post-dose assessments.
[2] L = Below lower limit of normal; H = Above upper limit of normal.
[3] Potentially Clinically Significant is defined as having a result either below the lower limit of normal or above the upper limit of normal.

Listing 16.2.7.1.7
Viral Resistance Testing

Group	Subject ID	Visit	Visit Date	Test Type	Reverse Transcriptase (Resistance) [1]	Protease (Resistance) [1]	Integrase Genese (Resistance) [1]	Trop-ism	Entry Inhibitors (Resistance) Ibal-izumab	Mara-viroc	Enfu-virt-ide
Sentinel	302-xx-xxx	SCREENING	2015-09-08	Geno	Abacavir (Y) Stavudine (P) Tenofovir (Y) Zidovudine (P) Delavirdine (N) Didanosine (Y) Efavirenz (N)	Atazanavir (ATV) (N) Tipranavir (P) Atazanavir (ATV/r) (P) Darunavir (Y) Fosamprenavir (P)	Dolutegravir (Y) Elvitegravir (Y) Raltegravir (Y)	DM	Y	Y	Y
				Pheno	Abacavir (Y) Stavudine (Y) Tenofovir (Y) Zidovudine (Y) Delavirdine (N) Didanosine (Y) Efavirenz (N)	Atazanavir (ATV) (Y) Tipranavir (Y) Atazanavir (ATV/r) (Y) Darunavir (Y) Fosamprenavir (Y)	Dolutegravir (Y) Elvitegravir (Y) Raltegravir (Y)				
		WEEK 9	2015-11-03	Geno	Abacavir (P) Stavudine (N)	Atazanavir (ATV) (N) Tipranavir (P)	Dolutegravir (Y)	DM	N	Y	Y
Core HIV-infected	302-xx-xxx	SCREENING	2015-09-08	Geno	Abacavir (Y) Stavudine (P) Tenofovir (Y)	Atazanavir (ATV) (N) Tipranavir (P)	Dolutegravir (Y)	DM	Y	Y	Y
…											
				Pheno	Abacavir (Y) Stavudine (Y) Tenofovir (Y)	Atazanavir (ATV) (Y) Tipranavir (Y)	Dolutegravir (Y)				
…											
Core HIV-uninfected	302-xx-xxx	SCREENING	2015-09-08	Geno	Abacavir (Y)	Atazanavir (ATV) (N)	Dolutegravir (Y)	DM	Y	Y	Y

[1] Abbreviations for Resistance: Y = Sensitive, P = Partially Sensitive, N = Resistant

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Listing 16.2.7.2
Vital Signs

Group	Subject ID	Visit	Visit Date	Scheduled Time Point	Time (hh:mm)	Period [1]	Height (cm)	Weight (kg)	Temp. (C) [2]	Heart Rate (bpm) [2]	Resp. Rate (breaths/min) [2]	Systolic Blood Pressure (mmHg) [2]	Diastolic Blood Pressure (mmHg) [2]
Sentinel	302-XX-XXX	Screening	2015-08-04			PRE-TREAT	170	69	36.5	62	16	129	85
		Day 0	2015-08-31			XXXXXX		69	36.9	81	16	108	68
		Day 1	2015-09-08	Pre-Admin	10:45	XXXXXX			36.9	74	15	127	76
			2015-09-08	Start of Obs	11:00	XXXXXX			36.8	76	16	110	69
			2015-09-08	End of Obs	11:15	XXXXXX			36.8	76	16	110	69
		Day 36	2015-09-22			XXXXXX			36.9	82	15	103	68
		Day 85/EOS	2015-10-06			XXXXXX			36.4*	67	16	126	83
Core HIV-infected	302-XX-XXX	Screening	2015-08-05			XXXXXX	179	83	36.6	69	15	124	85
Core HIV-uninfected	302-XX-XXX	Screening	2015-08-05			XXXXXX	179	83	36.6	69	15	124	85

[1] Period represents the timeframe when the visit took place.
[2] *Denotes Potentially Clinically Significant Vital Signs outside of these ranges: Temperature: 36.44-37.22 C; Heart Rate: 60-110 bpm; Respiration rate: 12-20 breaths per minute; Blood Pressure: Systolic 100-140 mmHg; Diastolic 60-90 mmHg.

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Listing 16.2.7.3
Physical Examinations

Group	Subject ID	Visit	Visit Date	Period[1]	Performed at Visit	Body System	Status (Details)
Sentinel	302-XX-XXX	Screening	YYYY-MM-DD	PRE-TREAT	Yes/No	HEENT	Normal
						Cardiovascular	Abnormal: provide details
						Musculoskeletal	Not Done
						Lymphatic	Not Required
						Respiratory	Normal
						Gastrointestinal	Normal
						Skin	Normal
						Neurological	Normal
						Additional PE Findings (list assessment name)	Abnormal: provide details
Core HIV-infected	302-XX-XXX	Day 0	YYYY-MM-DD	IVI 15MIN PRE	Yes/No	Cardiovascular	Normal
						Lymphatic	Abnormal: provide details
						Respiratory	Not Done
						Abdomen	Not Required
						Extremities	Normal
						Neurological	Normal
						Additional PE Findings (list assessment name)	Abnormal: provide details
Core HIV-uninfected	302-XX-XXX	Day 0	YYYY-MM-DD	IVI 10MIN	Yes/No	Cardiovascular	Normal
						Lymphatic	Abnormal: provide details
						Respiratory	Not Done
						Abdomen	Not Required
						Extremities	Normal
						Neurological	Normal
						Additional PE Findings (list assessment name)	Abnormal: provide details

[1] Period represents the timeframe when the visit took place.

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TaiMed Biologics, Inc.

Protocol TMB-302

A Phase 3 Study of the Safety of Trogarzo® Administered as an Undiluted "IV Push" over a Reduced Interval in Clinically Stable HIV-1 Infected Trogarzo® Experienced Patients and Healthy HIV-uninfected Volunteers

Mock Statistical Tables

August 17, 2021

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Contents

Notes Applicable to All Tables

General Programming Notes:

1. The tables will be programmed to show aggregate data only.
2. Review the data prior to programming. Check the data for inconsistencies and anomalies. Report suspected data errors to the lead programmer who can determine if they should be addressed by DM.
3. Follow the Quality Control Plans (\\Westat.com\dfs\CTWRKGRP\PUBLIC\Resources\DA\QC_Plans) for Tables, Listings, and Graphs. Perform the quality checks, using the Checklist.
4. Always check the population totals. All subjects should be accounted for in all tables. A row for "Unknown" or "Missing" values can be added to any table as appropriate to account for all subjects.
5. For summary statistics: N should always be an integer; minimum and maximum should have the same number of significant digits as is present in the data; mean and median should be calculated to be one additional significant digit than the data collected; standard deviation should be calculated to be two additional significant digits than the data collected.
6. Percentages should be calculated to one decimal place. The true number of treated subjects, which appears at the top of columns in most tables should be calculated once in libnames.sas and put into macro variables to ensure consistency. This number should not be re-calculated when calculating percentages.
7. Follow the mocks, especially regarding details, such as titles, capitalization, order of columns and row labels, and footnotes. Standard table formatting may be followed, as some mocks may have been created due to space/pagination considerations. The visit names in the mocks are examples only. Consult the protocol and SAP and present all scheduled visits for the item in question.
8. Additional footnotes may be required to fully/more accurately describe the contents of a table (decided during development). Consult project leader and lead biostatistician with questions.

Table 14.1.1
Subject Disposition

	Sentinel Group (N=XX) n (%)	Core HIV-infected Group (N=XX) n (%)	Core HIV-uninfected Group (N=XX) n (%)	Total (N=XX) n (%)
Study Populations				
Screened	n	n	n	n
Intent-to-Treat (ITT) [1]	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Safety (SAF) [2]	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Study Completion Status				
Completed Study Per Protocol	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Ongoing in Study	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Discontinued Study Prematurely	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Treatment Completion Status				
Completed Treatment Per Protocol	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Continuing Treatment	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Discontinued Treatment Prematurely	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)

N = All subjects enrolled (displayed according to assigned treatment), and denominator for percentage calculations.
[1] ITT Population consists of all subjects enrolled into the study.
[2] SAF Population consists of subjects receiving at least one partial dose of study drug.

Table 14.1.2
Reasons for Discontinuation
Intent-To-Treat Population

	Sentinel Group (N=XX) N(%)	Core HIV-infected Group (N=XX) N(%)	Core HIV-uninfected Group (N=XX) N(%)	Total (N=XX) N(%)
Discontinued Study Prematurely	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Reasons for Study Discontinuation				
Adverse Event	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Grade 3 or higher related laboratory assessment[1] [1]	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Required a medication prohibited by the protocol	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Investigator's Decision	n(XXX.X%)	n XXX.X%)	n XXX.X%)	n(XXX.X%)
Consent Withdrawn or Voluntary Withdrawal	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Administrative Decision	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Protocol Violation	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Subject Non-compliant	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Lost to follow-up	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Pregnancy	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Other	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Discontinued Treatment Prematurely	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Reasons for Treatment Discontinuation				
Adverse Event	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Grade 3 or higher related laboratory assessment[1] [1]	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Required a medication prohibited by the protocol	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Investigator's Decision	n(XXX.X%)	n XXX.X%)	n XXX.X%)	n(XXX.X%)
Consent Withdrawn or Voluntary Withdrawal	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Administrative Decision	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Protocol Violation	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Subject Non-compliant	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Lost to follow-up	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Pregnancy	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Death	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Other	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)

N = All subjects enrolled. Denominator for subcategory percentage calculations is the total number of subjects who discontinued study or treatment.
[1] Had a confirmed laboratory safety assessment result of Grade 3 or higher severity which was considered drug related.

Table 14.1.3
Demographic and Screening Characteristics
Intent-To-Treat (ITT) Population

		Sentinel Group (N=XX)	Core HIV-infected Group (N=XX)	Core HIV-uninfected Group (N=XX)	Total (N=XX)
Sex	Male	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Female	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Ethnicity	Hispanic or Latino	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Neither Hispanic nor Latino	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Unknown	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Race [1]	American Indian or Alaska Native	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Black or African American	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	White	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Native Hawaiian or Other Pacific	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Islander	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Other	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
	Unknown	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)	n(XXX.X%)
Age (years)	N	XX	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX	XX - XX
Height (cm)	N	XX	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX	XX - XX
Weight (kg)	N	XX	XX	XX	XX
	Mean(SD)	XX.XX(XX.XXX)	XX.XX(XX.XXX)	XX.XX(XX.XXX)	XX.XX(XX.XXX)
	Median	XX.XX	XX.XX	XX.XX	XX.XX
	25%-75%	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X
	Min-Max	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X

N = All subjects enrolled, and denominator for percentage calculations.
[1] One or more race(s) may be recorded, therefore, a patient may be counted in more than one category and percentages may add up to more than 100%.
NOTE: The table shows data at Screening visit. If vital signs are missing at the Screening visit, the measurement at the Day 1 visit is used.

Table 14.1.3
Demographic and Screening Characteristics (continued)
Intent-To-Treat (ITT) Population

		Sentinel Group (N=XX)	Core HIV-infected Group (N=XX)	Core HIV-uninfected Group (N=XX)	Total (N=XX)
Temperature (C)	N	XX	XX	XX	XX
	Mean(SD)	XX.XX(XX.XXX)	XX.XX(XX.XXX)	XX.XX(XX.XXX)	XX.XX(XX.XXX)
	Median	XX.XX	XX.XX	XX.XX	XX.XX
	25%-75%	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X
	Min-Max	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X	XX.X - XX.X
Heart Rate (beats/min)	N	XX	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX	XX - XX
Respiration Rate (breaths/min)	N	XX	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX	XX - XX
Systolic Blood Pressure (mmHg)	N	XX	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX	XX - XX
Diastolic Blood Pressure (mmHg)	N	XX	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX	XX - XX

N = All subjects enrolled, and denominator for percentage calculations.
[1] One or more race(s) may be recorded, therefore, a patient may be counted in more than one category and percentages may add up to more than 100%.
NOTE: The table shows data at Screening visit. If vital signs are missing at the Screening visit, the measurement at the Day 1 visit is used.

Table 14.2.1
90% Confidence Interval of the LOG Transform of the Ratio of the Geometric Means of AUC For 30 Second IV Push to 15 Minute IV Infusion
Intent-to-Treat Population (Sentinel and Core Subjects Pooled)

Analysis Type	Results
Type 3 Tests of Fixed Effects	
PK Period	
F Value	xxxx
Pr > F	xxxx
Administration Route	
F Value	xxxx
Pr > F	xxxx
Group (Sentinel or Core)	
F Value	xxxx
Pr > F	xxxx
Estimates (30 Second IV Push/15 Minute IV Infusion)	
Estimate (Standard Error)	xxxx(xxxx)
t Value (df)	xxxx (xx)
Pf > |t|	xxxx
90% Confidence Interval	(xxxxx, xxxxx)
Back Transformed Estimates	
Mean Geometric Ratio	xxxx
90% Confidence Interval [1]	(xxxxx, xxxxx)

[1] A pharmacokinetic bridge between the IV push and IV infusion is demonstrated for AUC if the 90% confidence interval of log transform of the ratio of the geometric means for IV Push (test product) to IV infusion (reference product) for the enrolled subjects in the study is within an 80%-125% criteria.

Note to Programmer: SAS code provided in SAP. Any subject with at least some non-missing PK data is included.

Table 14.2.2
Comparison of Trough Concentrations for 30 Second IV Push to 15 Minute IV Infusions
Intent-to-Treat Population (Sentinel and Core Subjects Pooled)

Analysis Type	Results
Proportion of Subjects with Average Ctrough >= 300 ng/ml (%)	
15 Minute IV Infusion	n/NT (%)
30 Second IV Push	n/NT (%)
Relative Risk	xxxx
90% Confidence Limits	(xxxx, xxxx)
TOST P-values [1]	
Lower Margin	xxxx
Upper Margin	xxxx
Overall	xxxx
Fisher's exact test 2-tailed P-Value	xxxx

[1] Two one-sided tests of significance (TOST) using Farrington-Manning Method and z-statistics, within an 80%-125% criteria.

Note to Programmer: SAS code provided in SAP. Any subject with at least some non-missing PK data is included.

Table 14.2.3.1
Viral Load (copies/mL) and Changes from Baseline
Intent-to-Treat Population – Sentinel Group

		Sentinel Group(N=XX)					
		Initial Period 15 minute IV Infusion	Investigational Period 10 min IV Infusion	Investigational Period 5 min Bolus	Investigational Period 1 min Bolus	Investigational Period 30 sec IV Push	Follow-up Period 15 min IVInfusion
Baseline [1]	N	XX					
	Mean(SD)	XX.X(XX.XX)					
	Median	XX.X					
	25%-75%	XX – XX					
	Min-Max	XX - XX					
Day 15	N	XX					
	Mean(SD)	XX.X(XX.XX)					
	Median	XX.X					
	25%-75%	XX – XX					
	Min-Max	XX - XX					
Change from Baseline	N	XX					
	Mean(SD)	XX.X(XX.XX)					
	Median	XX.X					
	25%-75%	XX – XX					
	Min-Max	XX - XX					
Day 29	N		XX				
	Mean(SD)		XX.X(XX.XX)				
	Median		XX.X				
	25%-75%		XX – XX				
…	Min-Max		XX - XX				
…							
End of Study [2]							
…							
Change from Baseline							

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Table 14.2.3.2
Viral Load (copies/mL) and Changes from Baseline
Intent-to-Treat Population – Core HIV-infected Group

		Core HIV-infected Group (N=XX)			
		Initial Period 15 min IV Infusion	Investigational Period 30 sec IV Push	Follow-up Period 15 min	IV Infusion
Baseline [1]	N	XX			
	Mean(SD)	XX.X(XX.XX)			
	Median	XX.X			
	25%-75%	XX – XX			
	Min-Max	XX – XX			
Day 15	N	XX			
	Mean(SD)	XX.X(XX.XX)			
	Median	XX.X			
	25%-75%	XX – XX			
	Min-Max	XX – XX			
Change from Baseline	N	XX			
	Mean(SD)	XX.X(XX.XX)			
	Median	XX.X			
	25%-75%	XX – XX			
	Min-Max	XX – XX			
Day 29	N		XX		
	Mean(SD)		XX.X(XX.XX)		
	Median		XX.X		
	25%-75%		XX – XX		
…	Min-Max		XX – XX		
…					
End of Study [2]					
…					
Change from Baseline					

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Table 14.2.4.1
Viral Load (log10 copies/mL) and Changes from Baseline
Intent-to-Treat Population – Sentinel Group

		Sentinel Group (N=XX)				
		Initial Period 15 minute IV Infusion	Investigational Period 10 min IV Infusion	Investigational Period 5 min Bolus	Investigational Period 1 min Bolus	Investigational Period 30 sec IV Push	Follow-up Period 15 min IV Infusion
Baseline [1]	N		XX				
	Mean(SD)		XX.X(XX.XX)				
	Median		XX.X				
	25%-75%		XX – XX				
	Min-Max		XX – XX				
Day 15	N		XX				
	Mean(SD)		XX.X(XX.XX)				
	Median		XX.X				
	25%-75%		XX – XX				
	Min-Max		XX – XX				
Change from Baseline	N		XX				
	Mean(SD)		XX.X(XX.XX)				
	Median		XX.X				
	25%-75%		XX – XX				
	Min-Max		XX – XX				
Day 29	N			XX			
	Mean(SD)			XX.X(XX.XX)			
	Median			XX.X			
	25%-75%			XX – XX			
	Min-Max			XX – XX			
…							
…							
End of Study [2]							
…							
Change from Baseline							

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Table 14.2.4.2
Viral Load (log10 copies/mL) and Changes from Baseline
Intent-to-Treat Population – Core HIV-infected Group

		Core HIV-infected Group (N=XX)		
		Initial Period 15 min IV Infusion	Investigational Period 30 sec IV Push	Follow-up Period 15 min IV Infusion
Baseline [1]	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX – XX		
Day 15	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX – XX		
Change from Baseline	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX – XX		
Day 29	N		XX	
	Mean(SD)		XX.X(XX.XX)	
	Median		XX.X	
	25%-75%		XX – XX	
	Min-Max		XX – XX	
…				
…				
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Grou

Table 14.3.1.1.1
Treatment-Emergent Adverse Events Summary
Safety Population – Sentinel Group

	Sentinel Group (N=XX)						
	Initial Period 15 minute IV Infusion	Investigational Period 10 min IV Infusion	Investigational Period 5 min Bolus	Investigational Period 1 min Bolus	Investigational Period 30 sec IV Push	Follow-up Period 15 minute IV Infusion	Total
TEAE [1]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Serious TEAE [2]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE with Death Outcome	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Leading to Discontinuation	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Related to Study Drug [3]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Severe TEAE [4]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Class C TEAE [5]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
TEAE = Treatment-Emergent Adverse Event.
NOTE: Identical TEAEs are counted only once per subject.
[1] Number(%) of subjects with at least one TEAE.
[2] Number(%) of subjects with at least one serious TEAE, excluding death, as identified by the investigator.
[3] Definitely, probably, or possibly.
[4] Severity/Grade 3 or higher (severe or potentially life threatening).
[5] Per the CDC Classification System for HIV Infection.

Table 14.3.1.1.2
Treatment-Emergent Adverse Events Summary
Safety Population – Core HIV-infected Group

	Core HIV-infected Group (N=XX)			
	Initial Period 15 min IV Infusion	Investigational Period 30 sec IV Push	Follow-up Period 15 min IV Infusion	Total
TEAE [1]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Serious TEAE [2]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE with Death Outcome	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Leading to Discontinuation	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Related to Study Drug [3]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Severe TEAE [4]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Class C TEAE [5]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
TEAE = Treatment-Emergent Adverse Event.
NOTE: Identical TEAEs are counted only once per subject.
[1] Number(%) of subjects with at least one TEAE.
[2] Number(%) of subjects with at least one serious TEAE, excluding death, as identified by the investigator.
[3] Definitely, probably, or possibly.
[4] Severity/Grade 3 or higher (severe or potentially life threatening).
[5] Per the CDC Classification System for HIV Infection.

Table 14.3.1.1.3
Treatment-Emergent Adverse Events Summary
Safety Population – Core HIV-uninfected Group

	Core HIV-uninfected Group (N=XX)			
	Pre-Steady State + IV Infusions Period	Investigational Period 30 sec IV Pushes	Follow-up Period	Total
TEAE [1]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Serious TEAE [2]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE with Death Outcome	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Leading to Discontinuation	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
TEAE Related to Study Drug [3]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Severe TEAE [4]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
Class C TEAE [5]	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
TEAE = Treatment-Emergent Adverse Event.
NOTE: Identical TEAEs are counted only once per subject.
[1] Number(%) of subjects with at least one TEAE.
[2] Number(%) of subjects with at least one serious TEAE, excluding death, as identified by the investigator.
[3] Definitely, probably, or possibly.
[4] Severity/Grade 3 or higher (severe or potentially life threatening).
[5] Per the CDC Classification System for HIV Infection.

Table 14.3.1.2.1
Overall Incidence of Treatment-Emergent Adverse Events
Safety Population – Sentinel Group

		Sentinel Group (N=XX)						
Body System	Preferred Term [1]	Initial Period 15 min IV Infusion	Investigational Period 10 min IV Infusion	Investigational Period 5 min Bolus	Investigational Period 1 min Bolus	Investigational Period 30 sec IV Push	Follow-up Period 15 minute IV Infusion	Total
Overall[2]	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: Identical TEAEs are counted only once per subject.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Number(%) of subjects with at least one TEAE in any Body System.

Table 14.3.1.2.2
Overall Incidence of Treatment-Emergent Adverse Events
Safety Population - Core HIV-infected Group

		Core HIV-infected Group (N=XX)			
Body System	Preferred Term [1]	Initial Period 15 min IV Infusion	Investigational Period 30 sec IV Push	Follow-up Period 15 min IV Infusion	Total
Overall[2]	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: Identical TEAEs are counted only once per subject.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Number(%) of subjects with at least one TEAE in any Body System.

Table 14.3.1.2.3
Overall Incidence of Treatment-Emergent Adverse Events
Safety Population - Core HIV-uninfected Group

		Core HIV-uninfected Group (N=XX)			
Body System	Preferred Term [1]	Pre-Steady State + IV Infusions Period	Investigational Period 30 sec IV Push	Follow-up Period	Total
Overall[2]	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
XXXXXXX	ALL TERMS	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n
	XXXXX	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)	n (xxx.x%)
	Events	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: Identical TEAEs are counted only once per subject.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Number(%) of subjects with at least one TEAE in any Body System.

Table 14.3.1.3.1
Incidence of Treatment-Emergent Adverse Events by Severity/Grade
Safety Population – Sentinel Group

		Sentinel Group (N=XX)					
		Initial Period 15 minute IV Infusion					
Body System	Preferred Term[1]	Any Grade [2]	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Pot. Life Threatening (Grade 4)	Death (Grade 5)
Overall [3]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	N

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the most severe occurrence, regardless of relationship to study drug.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Adverse Events with missing severity grade are included in this column only.
[3] Number(%)of subjects with at least one TEAE in any Body System.

Note to programmer: Repeat this table for each of the 5 Sentinel periods plus Sentinel total, all under the same table number.

Table 14.3.1.3.2
Incidence of Treatment-Emergent Adverse Events by Severity/Grade
Safety Population – Core HIV-infected Group

		Core HIV-infected Group (N=XX)					
		Initial Period 15 minute IV Infusion					
Body System	Preferred Term[1]	Any Grade [2]	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Pot. Life Threatening (Grade 4)	Death (Grade 5)
Overall [3]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the most severe occurrence, regardless of relationship to study drug.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Adverse Events with missing severity grade are included in this column only.
[3] Number(%)of subjects with at least one TEAE in any Body System.

Note to programmer: Repeat this table for each of the 3 Core HIV-infected periods plus Core HIV-infected total, all under the same table number.

Table 14.3.1.3.3
Incidence of Treatment-Emergent Adverse Events by Severity/Grade
Safety Population – Core HIV-uninfected Group

		Core HIV-uninfected Group (N=XX)					
		Pre-Steady State + IV Infusions Period					
Body System	Preferred Term[1]	Any Grade [2]	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Pot. Life Threatening (Grade 4)	Death (Grade 5)
Overall [3]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the most severe occurrence, regardless of relationship to study drug.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Adverse Events with missing severity grade are included in this column only.
[3] Number(%)of subjects with at least one TEAE in any Body System.

Note to programmer: Repeat this table for each of the 3 Core HIV-uninfected periods plus Core HIV-uninfected total, all under the same table number..

Table 14.3.1.4.1
Incidence of Treatment-Emergent Adverse Events by Relationship to Study Drug
Safety Population – Sentinel Group

		Sentinel Group (N=XX)			
		Initial Period 15 minute IV Infusion			
Body System	Preferred Term[1]	Definitely Related	Probably Related	Possibly Related	Unrelated
Overall[2]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the highest relationship, regardless of severity/grade.
[1] “ALL TERMS” represents number(%) of subjects with at least one TEAE within that Body System;
“Events” represents number of TEAEs reported by the subject(s).
[2] Number(%)of subjects with at least one TEAE in any Body System.

Note to programmer: Repeat this table for each of the 5 Sentinel periods plus Sentinel total, all under the same table number.

Table 14.3.1.4.2
Incidence of Treatment-Emergent Adverse Events by Relationship to Study Drug
Safety Population – Core HIV-infected Group

		Core HIV-infected Group (N=XX)			
		Initial Period 15 minute IV Infusion			
Body System	Preferred Term[1]	Definitely Related	Probably Related	Possibly Related	Unrelated
Overall[2]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the highest relationship, regardless of severity/grade.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Number(%)of subjects with at least one TEAE in any Body System.

Note to programmer: Repeat this table for each of the 3 Core HIV-infected periods plus Core HIV-infected total, all under the same table number.

Table 14.3.1.4.3
Incidence of Treatment-Emergent Adverse Events by Relationship to Study Drug
Safety Population – Core HIV-uninfected Group

		Core HIV-uninfected Group (N=XX)			
		Pre-Steady State + IV Infusions Period			
Body System	Preferred Term[1]	Definitely Related	Probably Related	Possibly Related	Unrelated
Overall[2]	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
XXXXXXXX	ALL TERMS	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n
	XXXXX	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)	n (XXX.X%)
	Events	n	n	n	n

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
The table shows TEAEs (per subject) with the highest relationship, regardless of severity/grade.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of TEAEs reported by the subject(s).
[2] Number(%)of subjects with at least one TEAE in any Body System.

Note to programmer: Repeat this table for each of the 3 Core HIV-uninfected periods plus Core HIV-uninfected total, all under the same table number.

Table 14.3.1.5.x
Overall Incidence of Serious Adverse Events
Safety Population – xx Group

Note to programmer: Repeat above for SERIOUS Adverse Events with the footnote updated as below.

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: Identical SAEs are counted only once per subject.
[1] "ALL TERMS" represents number(%) of subjects with at least one TEAE within that Body System;
"Events" represents number of SAEs reported by the subject(s).
[2] Number(%) of subjects with at least one SAE in any Body System.

Table 14.3.1.6.x
Incidence of Serious Adverse Events by Relationship to Study Drug
Safety Population – xx Group

Note to programmer: Repeat tables above for SERIOUS Adverse Events with the footnote updated as below.

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.
NOTE: The table shows related SAEs (per subject) with the highest relationship, regardless of severity/grade.
[1] "ALL TERMS" represents number(%) of subjects with at least one SAE within that Body System;
"Events" represents number of SAEs reported by the subject(s)
[2] Number(%) of subjects with at least one SAE in any Body System.

Table 14.3.1.7.x
Treatment-Emergent Adverse Events Leading to Study Discontinuation
Safety Population – xx Group

Note to programmer: Repeat tables above for Adverse Events LEADING TO STUDY DISCONTINUATION (same footnote).

Table 14.3.2.1.1.x
Hematology – Clinical Laboratory Assessments and Changes from Baseline
Safety Population – Sentinel Group
Hemoglobin (gm/dL)

		Sentinel Group(N=XX)					
		Initial Period 15 min IV Infusion	Investigational Period 10 min IV Infusion	Investigational Period 5 min Bolus	Investigational Period 1 min Bolus	Investigational Period 30 sec IV Push	Follow-up 15 minute IV Infusion
Baseline [1]	N	XX					
	Mean(SD)	XX.X(XX.XX)					
	Median	XX.X					
	25%-75%	XX - XX					
	Min-Max	XX - XX					
Day 15	N	XX					
	Mean(SD)	XX.X(XX.XX)					
	Median	XX.X					
	25%-75%	XX - XX					
	Min-Max	XX - XX					
Change from Baseline	N	XX					
	Mean(SD)	XX.X(XX.XX)					
	Median	XX.X					
	25%-75%	XX - XX					
	Min-Max	XX - XX					
…							
End of Study [2]							
…							
Change from Baseline							

N = All subjects in the Safety Population (displayed according to actual treatment received), and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Note to Programmer:

1) This table will show all scheduled visits and will be repeated for each continuous Hematology parameter listed in the SAP. Increment the last digit of the table number for each additional analyte.

2) At any visit subjects can only be on one of the dose administrations, so only one column will have results, and therefore there is no need for a total column.

Table 14.3.2.1.2.x
Hematology – Clinical Laboratory Assessments and Changes from Baseline
Safety Population – Core HIV-infected Group
Hemoglobin (gm/dL)

		Core HIV-infected Group (N=XX)		
		Initial Period 15 min IV Infusion	Investigational Period 30 sec IV Push	Follow-up Period 15 min IV Infusion
Baseline [1]	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Day 15	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Change from Baseline	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Day 29	N		XX	
	Mean(SD)		XX.X(XX.XX)	
	Median		XX.X	
	25%-75%		XX – XX	
…	Min-Max		XX - XX	
…				
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Table 14.3.2.1.3.x
Hematology – Clinical Laboratory Assessments and Changes from Baseline
Safety Population – Core HIV-uninfected Group
Hemoglobin (gm/dL)

		Core HIV-uninfected Group (N=XX)		
		Pre-Steady State + IV Infusions Period	Investigational Period 30 sec IV Push	Follow-up Period
Baseline [1]	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Day 15	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Change from Baseline	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
…				
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Table 14.3.2.2.1.x
Chemistry - Clinical Laboratory Assessments and Changes from Baseline
Safety Population – xx Group
BUN (mg/dL)

Note to programmer: Repeat Tables above for CHEMISTRY analytes, incrementing x for each new analyte.

Table 14.3.2.3.1
CD4+ T-Cell Counts (cells/mm^3) and Changes from Baseline
Safety Population – Sentinel Group

		Sentinel Group (N=XX)					
		Initial Period 15 min IV Infusion	Investigational Period 10 min IV Infusion	Investigational Period 5 min Bolus	Investigational Period 1 min Bolus	Investigational Period 30 sec IV Push	Follow-up Period 15 minute IV Infusion
Baseline [1]	N	XX					
	Mean(SD)	XX.X(XX.XX)					
	Median	XX.X					
	25%-75%	XX – XX					
	Min-Max	XX - XX					
Day 15	N	XX					
	Mean(SD)	XX.X(XX.XX)					
	Median	XX.X					
	25%-75%	XX – XX					
	Min-Max	XX - XX					
Change from Baseline	N	XX					
	Mean(SD)	XX.X(XX.XX)					
	Median	XX.X					
	25%-75%	XX – XX					
	Min-Max	XX - XX					
Day 29	N		XX				
	Mean(SD)		XX.X(XX.XX)				
	Median		XX.X				
	25%-75%		XX – XX				
…	Min-Max		XX - XX				
…							
End of Study [2]							
…							
Change from Baseline							

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Table 14.3.2.3.2
CD4+ T-Cell Counts (cells/mm^3) and Changes from Baseline
Safety Population – Core HIV-infected Group

		Core HIV-infected Group (N=XX)		
		Initial Period 15 min IV Infusion	Investigational Period 30 sec IV Push	Follow-up Period 15 minute IV Infusion
Baseline [1]	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Day 15	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Change from Baseline	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Day 29	N		XX	
	Mean(SD)		XX.X(XX.XX)	
	Median		XX.X	
	25%-75%		XX – XX	
…	Min-Max		XX - XX	
…				
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Table 14.3.2.3.3
CD4+ T-Cell Counts (cells/mm^3) and Changes from Baseline
Safety Population – Core HIV-uninfected Group

		Core HIV-uninfected Group (N=XX)		
		Pre-Steady State + IV Infusions Period	Investigational Period 30 sec IV Push	Follow-up Period
Baseline [1]	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Day 15	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Change from Baseline	N	XX		
	Mean(SD)	XX.X(XX.XX)		
	Median	XX.X		
	25%-75%	XX – XX		
	Min-Max	XX - XX		
Day 29	N		XX	
	Mean(SD)		XX.X(XX.XX)	
	Median		XX.X	
	25%-75%		XX – XX	
…	Min-Max		XX - XX	
…				
End of Study [2]				
…				
Change from Baseline				

N = All subjects in the Safety Population, and denominator for percentage calculations.

[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.

[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Table 14.3.3.1.1.x
Vital Signs and Changes from Baseline
Safety Population – xx Group
Weight (kg)

Note to programmer: Repeat above for VITAL SIGNS, incrementing x for each new VITAL SIGN (Temperature, Pulse, Respiration Rate, and Blood Pressure). Report only the visits where vital signs were collected, and change "analyte" to "vital sign" in the footnote.

Where collected, the pre-dose, post-dose (immediate) and post-dose (15 minutes) values will be presented for each visit. Label visits in the table like this example: Day 15 Pre, Day 15 Post, Day 15 Post 15 min.

Table 14.3.3.2.1
Abnormal Physical Examination Findings
Safety Population – Sentinel Group

Sentinel Group(N=XX)

		Initial Period 15 minute IV Infusion	Investigational Period 10 min IV Infusion	Investigational Period 5 min Bolus	Investigational Period 1 min Bolus	Investigational Period 30 sec IV Push	Follow-up Period 15 minute IV Infusion
Baseline [1]	Skin	n (xxx.x%)					
	HEENT	n (xxx.x%)					
	Lymph Nodes	n (xxx.x%)					
	Lungs/Chest	n (xxx.x%)					
	Heart	n (xxx.x%)					
	Abdomen	n (xxx.x%)					
	Genital/Rectal	n (xxx.x%)					
	Extremities	n (xxx.x%)					
	Neurological	n (xxx.x%)					
Day 15	Skin	n (xxx.x%)					
	HEENT	n (xxx.x%)					
	Lymph Nodes	n (xxx.x%)					
	Lungs/Chest	n (xxx.x%)					
	Heart	n (xxx.x%)					
	Abdomen	n (xxx.x%)					
	Genital/Rectal	n (xxx.x%)					
	Extremities	n (xxx.x%)					
	Neurological	n (xxx.x%)					
…							
End of Study [2]	Skin						n (xxx.x%)
	HEENT						n (xxx.x%)
	Lymph Nodes						n (xxx.x%)
	Lungs/Chest						n (xxx.x%)
	Heart						n (xxx.x%)
	Abdomen						n (xxx.x%)
	Genital/Rectal						n (xxx.x%)
	Extremities						n (xxx.x%)
	Neurological						n (xxx.x%)

N = All subjects in the Safety Population, and denominator for percentage calculations.
[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.
[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.
Note to Programmer: Include all visit days that Physical Exam is recorded.

Table 14.3.3.2.2
Abnormal Physical Examination Findings
Safety Population – Core HIV-infected Group

		Core HIV-infected Group (N=XX)		
		Initial Period 15 min IV Infusion	Investigational Period 30 sec IV Push	Follow-up Period 15 minute IV Infusion
Baseline [1]	Skin	n (xxx.x%)		
	HEENT	n (xxx.x%)		
	Lymph Nodes	n (xxx.x%)		
	Lungs/Chest	n (xxx.x%)		
	Heart	n (xxx.x%)		
	Abdomen	n (xxx.x%)		
	Genital/Rectal	n (xxx.x%)		
	Extremities	n (xxx.x%)		
	Neurological	n (xxx.x%)		
Day 15	Skin	n (xxx.x%)		
	HEENT	n (xxx.x%)		
	Lymph Nodes	n (xxx.x%)		
	Lungs/Chest	n (xxx.x%)		
	Heart	n (xxx.x%)		
	Abdomen	n (xxx.x%)		
	Genital/Rectal	n (xxx.x%)		
	Extremities	n (xxx.x%)		
	Neurological	n (xxx.x%)		
…				
End of Study [2]	Skin			n (xxx.x%)
	HEENT			n (xxx.x%)
	Lymph Nodes			n (xxx.x%)
	Lungs/Chest			n (xxx.x%)
	Heart			n (xxx.x%)
	Abdomen			n (xxx.x%)
	Genital/Rectal			n (xxx.x%)
	Extremities			n (xxx.x%)
	Neurological			n (xxx.x%)

N = All subjects in the Safety Population, and denominator for percentage calculations.
[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.
[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Note to Programmer: Include all visit days that Physical Exam is recorded.

Table 14.3.3.2.3
Abnormal Physical Examination Findings
Safety Population – Core HIV-uninfected Group

		Core HIV-uninfected Group (N=XX)		
		Pre-Steady State + IV Infusion Period	Investigational Period 30 sec IV Push	Follow-up Period
Baseline [1]	Skin	n (xxx.x%)		
	HEENT	n (xxx.x%)		
	Lymph Nodes	n (xxx.x%)		
	Lungs/Chest	n (xxx.x%)		
	Heart	n (xxx.x%)		
	Abdomen	n (xxx.x%)		
	Genital/Rectal	n (xxx.x%)		
	Extremities	n (xxx.x%)		
	Neurological	n (xxx.x%)		
Day 15	Skin	n (xxx.x%)		
	HEENT	n (xxx.x%)		
	Lymph Nodes	n (xxx.x%)		
	Lungs/Chest	n (xxx.x%)		
	Heart	n (xxx.x%)		
	Abdomen	n (xxx.x%)		
	Genital/Rectal	n (xxx.x%)		
	Extremities	n (xxx.x%)		
	Neurological	n (xxx.x%)		
…				
End of Study [2]	Skin			n (xxx.x%)
	HEENT			n (xxx.x%)
	Lymph Nodes			n (xxx.x%)
	Lungs/Chest			n (xxx.x%)
	Heart			n (xxx.x%)
	Abdomen			n (xxx.x%)
	Genital/Rectal			n (xxx.x%)
	Extremities			n (xxx.x%)
	Neurological			n (xxx.x%)

N = All subjects in the Safety Population, and denominator for percentage calculations.
[1] Baseline is the last analyte value recorded on Day 1, prior to the first dose administration.
[2] End of Study is Day 99 for subjects in the Sentinel Group and Day 85 for subjects in the Core Group.

Note to Programmer: Include all visit days that Physical Exam is recorded.

Table 14.4.1
Summary of Study Drug Administration
Safety Population

		Sentinel Group (N=XX)	Core HIV-infected Group (N=XX)	Core HIV-uninfected Group (N=XX)	Total (N=XX)
Cumulative Dose (mg)	N	XX	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX	XX - XX
Duration of Treatment (days from first dose)	N	XX	XX	XX	XX
	Mean(SD)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)	XX.X(XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X
	25%-75%	XX - XX	XX - XX	XX - XX	XX - XX
	Min-Max	XX - XX	XX - XX	XX - XX	XX - XX

N = All subjects in the Safety Population.