STATISTICAL ANALYSIS PLAN
FOR CLINICAL STUDY REPORT

A PHASE 2B RANDOMIZED, ACTIVE-CONTROLLED, STAGED, OPEN-LABEL TRIAL TO INVESTIGATE SAFETY AND EFFICACY OF BMS-955176 IN COMBINATION WITH DOLUTEGRAVIR AND ATAZANAVIR (WITH OR WITHOUT RITONAVIR) IN TREATMENT-EXPERIENCED HIV-1 INFECTED ADULTS

PROTOCOL AI468048

VERSION # 2.0

TABLE OF CONTENTS

LIST OF TABLES

1 BACKGROUND AND RATIONALE

Despite advances in prevention and care, HIV/AIDS remains a significant epidemic in both the US and worldwide. AIDS remains the 6th leading cause of death, internationally. Globally, approximately 35 million people were living with HIV infection in 2013. A number of these patients include those who are treatment-experienced. Note: the use of the term "treatment-experienced" herein refers to subjects who have failed at least one or two antiretroviral (ARV) regimens and who may be harboring drug resistant virus (current or archived) to at least one drug class.

In contrast to current HIV treatment guidelines for treatment-naïve patients, the recommended composition of combination antiretroviral therapy (cART) is far less uniform for treatment-experienced subjects. The level of detail in the DHHS and EACS guidelines leads to a lack of uniformity in treatment for patients in later lines of therapy. Moreover, drug related toxicities (both short and longer term) in treatment-experienced subjects necessitate vigilance and continued monitoring. Thus, there is a need for new and efficacious agents with novel mechanisms of action (MOA) and favorable safety/tolerability profiles. Given the aging HIV-1 infected population and overall fewer number of ARV options for treatment-experienced patients, there is a need for a more simplified regimen that may have a better long-term safety profile such as that of a nucleoside- and booster-sparing cART regimen. This study evaluates the merits of a nucleoside-sparing cART regimen and a nucleoside/booster-sparing cART regimen in Stage 1 and 2, respectively.

Given the afore-mentioned challenges with existing treatment in ARV treatment-experienced adults, the two primary objectives of this two stage, Phase 2b study are to: 1) To study the efficacy of one dose (120mg) of BMS-955176 (a novel HIV-1 maturation inhibitor) when given in combination with atazanavir boosted with ritonavir (ATV/r) 300/100mg and dolutegravir (DTG) 50mg in Stage 1, and 2) to study the efficacy of two doses (120 and 180mg) of BMS-955176 when given in combination with unboosted ATV 400mg and DTG 50mg in Stage 2.

Ultimately this Phase 2b clinical trial will provide supportive data in the context of a therapeutic dose of BMS-955176 and the clinical safety/efficacy/resistance of the proposed component(s) of a single tablet regimen (STR, that is also a nucleoside/ritonavir sparing ARV strategy) for Phase 3 trial development in HIV-1 infected treatment-experienced subjects. Specifically, two arms in Stage 2 will contain the individual ARV components of a potential STR: BMS-955176, ATV, and DTG.

Research Hypothesis:

This Phase 2b study will evaluate whether the combination of BMS-955176 with ATV (with or without RTV) and DTG is efficacious, safe, and well-tolerated in HIV-1 infected treatment-experience adults.

Schedule of Analyses:

A first interim analysis will be conducted after approximately 50% of the randomized subjects have completed 24 weeks of therapy in Stage 1. This analysis will use the BMS equivalent of SDTM (Study Data Tabulation Model) data to facilitate the development of models for population pharmacokinetics, exposure-response relationships and viral kinetics.

A second interim analysis will be conducted after the last subject has completed 24 weeks of therapy in Stage 1. This will be a complete analysis of the available efficacy, safety and resistance data.

An interim analysis might be conducted after the last randomized subject in Stage 1 is on tratment for 48 weeks in case the continuation dose couldn't be selected based on the Week 24 results.

An interim analysis will be conducted after the last randomized subject in Stage 2 is on treatment for 24 weeks. The expectation is that the last subject in Stage 1 will have completed the Week 96 visit by that time.

An interim analysis will be conducted after the last randomized subject in Stage 2 completes the Week 48 visit. The analyses related to the first 48 weeks of treatment for Stage 2 will be performed.

The final analysis will be conducted after the last randomized subject in Stage 2 completes the Week 96 visit.

2 OBJECTIVES

2.1 Study Design

This is a randomized, active-controlled, staged, open-label clinical trial.

The screening period begins on the day the subject signs on the informed consent form. If the subject meets all eligibility criteria, the subject is to be randomized within the 42-day screening period.

Approximately 200 treatment-experienced HIV-1 subjects will be randomized to one of five treatment arms (approximately 40 per arm) in a staged fashion.

The data from the Week 24 analysis of Stage 1 and AI468038, including safety, efficacy and pharmacokinetics, will be examined to trigger the start of Stage 2 and confirm the two doses of BMS-955176 for study in Stage 2.

Stage 1:

In Stage 1, approximately 80 subjects will be randomly assigned 1:1 to one of two treatment arms and on Day 1, they will begin dosing with:

- Arm 1: BMS-955176 120mg QD + ATV/r 300/100mg QD + DTG 50mg QD, or

- Arm 2: TDF 300mg QD + ATV/r 300/100mg QD + DTG 50mg QD.

Stage 2:

In Stage 2, approximately 120 subjects will be randomly assigned 1:1:1 to one of three treatment arms and on Day 1, they will begin dosing with:

- Arm 3: BMS-955176 120 mg QD + ATV 400 mg QD + DTG 50 mg QD, or
- Arm 4: BMS-955176 180 mg QD + ATV 400 mg QD + DTG 50 mg QD, or
- Arm 5: TDF 300 mg QD + ATV/r 300/100 mg QD + DTG 50 mg QD.

Subjects in all arms will have the opportunity to participate in an elective Intensive PK substudy visit at Week 2 (window for visit: Day 12-16). Approximately 60 subjects, 12 subjects from each arm, are expected to participate in the substudy; BMS may allow the substudy to over-enroll in an effort to have a sufficient number of complete datasets.

Subjects are expected to be treated for the duration of 96 weeks. After Day 1 and the optional Intensive PK visit at Week 2, subjects are required to attend 12 more in-clinic study visits over the 96-week treatment period, as follows:

- Visits are conducted every 4 weeks from Week 4 through Week 16
- Visits are conducted every 8 weeks from Week 24 through Week 48
- Visits are conducted every 12 weeks from Week 60 through Week 96

Selection of Continuation Dose and Switch for Stage 1

Once all subjects in Stage 1 have reached Week 24, BMS will conduct an interim analysis of efficacy, safety, resistance and pharmacokinetics. An analysis of virologic futility will also occur at Week 24. If Arm 1 meets criteria for virologic futility at Week 24, the clinical trial will be terminated.

Based upon the Week 24 analysis of Arms 1 and 2, combined with the Week 24 analysis of all arms in the parallel AI468038 study, a continuation dose of BMS-955176 for Arm 1 will be selected for subjects in Arm 1. Subjects in the BMS-955176 treatment arm 1 may subsequently be transitioned to a selected continuation dose of BMS-955176. Subjects in the Arm containing TDF (i.e., Arm 2) will continue with the TDF treatment regimen. The assigned backbone will remain unaltered. The Week 24 efficacy, safety and pharmacokinetic analyses from Stage 1 and study AI468038 will also trigger the start of Stage 2. If the continuation dose cannot be clearly identified using the Week 24 data, the study will continue in original fashion until an analysis of the Week 48 data can be performed and the continuation dose is selected. If a continuation dose cannot be selected based upon the Week 24 data, this does not preclude the ability to start recruitment of Stage 2.

After the continuation dose is selected and once all of the logistics have been completed globally, the transition of the subjects in Arm 1 to the continuation dose will occur. It is anticipated that this transition will occur on or after all subjects have reached Week 48.

Selection of Continuation Dose and Switch for Stage 2

Once all subjects in Stage 2 have reached Week 24, BMS will conduct an interim analysis of efficacy, safety, resistance and pharmacokinetics. An analysis of virologic futility will also occur at Week 24. If a BMS-955176 dose arm meets criteria for virologic futility at Week 24, subjects in said arm will begin dosing with the next highest available remaining dose of BMS-955176.

The totality of data from AI468038 and AI468048 (Stage 1 and 2) will be used to select a continuation dose of BMS-955176 for Arms 3 and 4. Subjects in the BMS-955176 treatment arms 3 and 4 will subsequently be transitioned to the selected continuation dose of BMS-955176. It is anticipated that this transition may occur on or after all subjects in Stage 2 have reached Week 48. The assigned backbone will not change. Subjects in the TDF-containing arm (i.e., Arm 5) will continue with their assigned treatment regimen.

2.2 Treatment Assignment

Approximately 200 treatment-experienced HIV-1 subjects will be randomized to one of five treatment arms (approximately 40 per arm) in a staged fashion.

Stage 1:

In Stage 1, approximately 80 subjects will be randomly assigned 1:1 to one of two treatment arms:

- Arm 1: BMS-955176 120mg QD + ATV/r 300/100mg QD + DTG 50mg QD, or
- Arm 2: TDF 300mg QD + ATV/r 300/100mg QD + DTG 50mg QD.

Stage 2:

In Stage 2, approximately 120 subjects will be randomly assigned 1:1:1 to one of three treatment arms:

- Arm 3: BMS-955176 120mg QD + ATV 400mg QD + DTG 50mg QD, or
- Arm 4: BMS-955176 180mg QD + ATV 400mg QD + DTG 50mg QD, or
- Arm 5: TDF 300mg QD + ATV/r 300/100mg QD + DTG 50mg QD.

2.3 Blinding and Unblinding

This is an open-label study.

2.4 Protocol Amendments

The following protocol amendments and administrative letters have been processed and changes that may affect the statistical analysis are listed below:

- Amendment 1 (Jan 28, 2015 - site specific):
  - Permit the collection and storage of blood samples for use in future exploratory pharmacogenetic research.

- Amendment 2 (Jan 28, 2015 - country specific, Brazil)
  - To comply with the Brazilian law in force regarding post study access to therapy.
- Amendment 3 (Feb 13, 2015 - country specific, Argentina)
  - In response to a request from the Argentinean Health Authority: in case of pregnancy the study drug should be permanently discontinued.
- Amendment 4 (March 19, 2015)
  - Incorporated information that more clarifies the Week 24 data (consisting of efficacy, safety and pharmacokinetic data) to be used to confirm the doses for Stage 2 and to trigger the start of Stage 2 of the study relative to other analyses conducted under the protocol for other purposes.
  - Removed the requirement that all sparse PK samples need to be collected as pre-AM dose samples. Only one visit Weeks 4-24 (as opposed to all visits Week 4-24) needs to be performed in the morning and to have the blood collected as a pre-AM dose sampling.
- Amendment 5 (June 3, 2015)
  - To mitigate the risk of randomizing subjects infected with HIV-1 with an unknown efficacy profile, exclusion criteria have been modified to now exclude subjects with Clade AE as well as those subjects who have failed a previous boosted PI- or Integrase strand transfer inhibitor (INSTI)-containing regimen for which resistance analyses were not conducted at the time of failure.
  - Pregnancy was added as a reason to be discontinued from the study and the practice of Rescreening was more clearly defined, an administrative change was made to clearly indicate that AIDS History is taken at Screening.
  - At Week 24, a Time to Loss of Virologic Response analysis will be conducted as a sensitivity analysis that compliments the snapshot analysis, and a definition of virologic rebound was added.
- Amendment 6 (July 15, 2015 - country specific: Argentina)
  - Section 3.2: Eliminate bullet d) in order to be consistent with local regulations.

3 ENDPOINTS

3.1 Primary

Primary Objective Stage 1

- To assess the antiviral efficacy of BMS-955176 120mg, and a TDF 300mg-containing arm, each when given in combination with ATV/r 300/100mg and DTG 50mg by determining the proportion of treatment-experienced subjects with plasma HIV-1 RNA < 40c/mL at Week 24 in Stage 1.

Primary Objective Stage 2

- To assess the antiviral efficacy of two doses (120 and 180mg) of BMS-955176, each when given in combination with unboosted ATV 400mg and DTG 50mg, and to assess the antiviral efficacy of TDF 300mg when given in combination with ATV/r 300/100mg and DTG 50mg

by determining the proportion of treatment-experienced subjects with plasma HIV-1 RNA < 40c/mL at Week 24 in Stage 2.

3.2 Secondary

- To assess the antiviral efficacy of BMS-955176 Arms, and TDF-containing regimens (TDF + ATV/r + DTG), by determining the proportion of treatment-experienced subjects with plasma HIV-1 RNA < 40c/mL at Weeks 48 and 96
- To assess the antiviral efficacy of BMS-955176 Arms, and TDF-containing regimens, by determining the proportion of treatment-experienced subjects with plasma HIV-1 RNA < 200c/mL at Weeks 24, 48, 96
- To assess the emergence of HIV drug resistance in samples selected for drug resistance testing
- To assess efficacy of BMS-955176 Arms, and TDF-containing regimens, by using the mean changes from baseline in $\log_{10}$ HIV-1 RNA, CD4+ T-cell counts, and percentage of CD4+ T-cells
- To assess the safety and tolerability of BMS-955176 in treatment-experienced subjects by measuring frequency of SAEs and AEs leading to discontinuation
- To assess disease progression as measured by the occurrence of new AIDS defining events (CDC Class C events)
- To characterize the pharmacokinetics of BMS-955176 when co-administered with ATV (with or without ritonavir) and DTG in treatment-experienced HIV-1 infected subjects.

3.3 Exploratory

- To determine the effect of BMS-955176 Arms, and TDF-containing regimens, on renal clinical parameters and biomarkers through Weeks 48 and 96
- To determine the effect of BMS-955176 Arms, and TDF-containing regimens, on bone biomarkers through Weeks 12 and 24
- To assess the impact of baseline (pre-therapy) Gag polymorphisms on the efficacy of BMS-955176 by determining the proportion of treatment-experienced subjects with plasma HIV-1 RNA < 40c/mL, HIV-1 RNA < 200c/mL, and the changes from baseline in $\log_{10}$ HIV-1 RNA at Weeks 24, 48 and 96, by baseline polymorphisms
- To characterize the steady-state plasma PK of DTG when co-administered with BMS-955176 and ATV (with or without RTV) in treatment-experienced subjects. The effect of BMS-955176 on DTG PK in the presence of ATV (without RTV) may be assessed relative to historical data
- To compare steady-state exposures of DTG when co-administered with BMS-955176 and ATV/RTV to DTG when co-administered with TDF and ATV/RTV
- To characterize the PK of ATV when co-administered with DTG and BMS-955176, with or without RTV
- To explore PK/PD and PK/viral kinetic (VK) relationships between BMS-955176, ATV, and/or DTG exposure and both efficacy and safety endpoints

- To assess the impact of the study therapies on health-related quality of life measures.

4 ENDPOINTS

4.1 Primary Endpoints

- Proportion of subjects with plasma HIV-1 RNA < 40c/mL at Week 24 for Stage 1, assessed using the snapshot algorithm
- Proportion of subjects with plasma HIV-1 RNA < 40c/mL at Week 24 for Stage 2, assessed using the snapshot algorithm

4.2 Secondary Endpoints

- Proportion of subjects with plasma HIV-1 RNA < 40c/mL at Weeks 48 and 96, assessed using the snapshot algorithm
- Proportion of subjects with plasma HIV-1 RNA < 200c/mL at Weeks 24, 48 and 96, assessed using the snapshot algorithm
- Emergence of HIV drug resistance among samples selected for drug resistance testing will be assessed using the most recent version of the IAS-USA list of HIV-1 drug resistance mutations
- Changes from baseline in $\log_{10}$ HIV-1 RNA and in CD4+ T-cell counts, and changes in the percentage of CD4+ T-cells over time will be assessed using on-treatment laboratory results, and pre-specified visit windows
- Frequency of SAEs and AEs leading to discontinuation will be tabulated directly from the case report forms (CRFs). The summary will count the number of subjects that have at least one event
- Occurrence of new AIDS defining events will be tabulated from the CRFs. The summary will count the number of subjects that have at least one event
- Steady state PK parameters of BMS-955176: C_{max}, T_{max}, C_{tau}, C_0 and AUC(TAU) will be assessed using the intensive PK data, collected at Week 2 from a subset of subjects

4.3 Exploratory Endpoints

- Changes from baseline in renal biomarkers over time will be assessed using on-treatment laboratory results, and pre-specified visit windows
- Changes from baseline in bone biomarkers over time will be assessed using on-treatment laboratory results, and pre-specified visit windows
- Proportion of subjects with plasma HIV-1 RNA < c/mL and HIV-1 RNA < 200c/mL at Weeks 24, 48 and 96, by baseline polymorphism, will be assessed using the snapshot algorithm. The changes from baseline in $\log_{10}$ HIV-1 RNA at Weeks 24, 48 and 96, by baseline polymorphism will be assessed using on-treatment laboratory results, and pre-specified visit windows.
- Steady-state PK parameters of DTG: C_{max}, T_{max}, C_{tau}, C_0 and AUC(TAU) will be assessed using the intensive PK data, collected at Week 2 from a subset of subjects

- Steady-state PK parameters of ATV: C_{max}, T_{max}, C_{tau}, C_0 and AUC(TAU) will be assessed using the intensive PK data, collected at Week 2 from a subset of subjects
- Population PK modeling to obtain population-derived average steady state exposure of BMS-955176 that will be used in exposure-response and PK/VK assessments. The population PK, exposure-response, and viral kinetic analyses will be described in a separate analysis plan.
- Quality of life is assessed using the EQ-5D-3L and the Functional Assessment of HIV Infection (FAHI) instruments.

5 SAMPLE SIZE AND POWER

This is an estimation study, without statistical testing, and hence there are no power considerations.

It is expected that response rate for the primary endpoint for all five arms will be somewhere around 80%. With this response rate, and 40 subjects per arm, an exact Clopper-Pearson 95% confidence interval would run from roughly 64% to 91%.

6 STUDY PERIODS, TREATMENT REGIMENS AND POPULATIONS FOR ANALYSES

6.1 Study Periods

This study consists of the following periods:

- Screening (or Pre-randomization) Period: begins on the day the subject signs the informed consent and continues through Day 1 prior to dosing. The screening period last about 42 days.
- Open-label Treatment Period (or On-treatment Period): begins on the first day of open-label therapy and ends after 96 weeks of dosing or early termination, whichever comes first.

6.2 Treatment Regimens

The treatment regimens are defined as follows:

- As-randomized refers to the treatment regimen assigned at randomization. Accrual, disposition, demographic and baseline characteristics, protocol deviations and efficacy results will be presented as-randomized.
- As-treated refers to the actual treatment regimen received. Subjects who receive an incorrect study therapy for the entire period of treatment are grouped according to the first incorrect study regimen received. Otherwise, subjects are grouped according to their randomized treatment regimen. Subjects who never receive study therapy, have their as-treated treatment regimen coded as “missing”. Results for exposure, concomitant medication, resistance, safety and PK parameters, and outcomes research scales will be presented as-treated.

6.3 Populations for Analyses

Populations for analyses consist of enrolled, randomized and treated subjects:

- Enrolled subjects are those who signed an informed consent form and were assigned a Patient Identification number (PID).
- Randomized subjects are enrolled subjects who received a treatment assignment from the IVRS. The randomized subjects will be used to assess subject disposition.
- Treated subjects (also referred to as mITT analysis set) are randomized subjects who received at least 1 dose of study therapy. The treated subjects will be used to assess demography and baseline characteristics, protocol deviations, exposure, concomitant medication, efficacy, resistance, safety and outcomes research scales.
- PK population is defined as all treated subjects who have any available concentration-time data. The evaluable PK population is a sub-population including all treated subjects who have adequate PK profiles.

7 STATISTICAL ANALYSIS

This section describes the analyses for the Week 24 primary analysis and the Week 48 and 96 secondary analyses.

Analyses do not exclude data obtained after the start of prohibited medication, unless otherwise specified.

7.1 General Methods

This is an estimation study. Formal comparisons of treatment arms will not be performed except for the virologic futility analyses performed at Week 24 of Stage 1 and Stage 2 (see Section 7.5.4).

Presentations will present treatment arms as the original treatment arms, before the potential movement to the continuation BMS-955176 dose. Data from Arms 2 and 5 will not be pooled unless otherwise specified. Separate outputs will be created for each stage unless otherwise specified.

Categorical variables will be tabulated with counts and percentages.

Continuous variables will be summarized with univariate statistics.

Subjects must have a baseline measurement and at least one on-treatment measurement to be evaluable for change from baseline analyses. All data will be displayed for statistics that do not depend on a baseline measurement.

Laboratory parameters will be summarized using SI and US values and units.

Statistical analyses are carried out in SAS version 9.1.3 (Statistical Analysis System, SAS Institute, North Caroline, USA) or higher, unless otherwise indicated.

7.2 Study Conduct

Protocol deviations that are programmable from the database and that could potentially affect the interpretability of the study results are deemed relevant protocol deviations. Relevant protocol deviations occurring during the study, are determined prior to unblinding. The proportion of subjects with relevant protocol deviations through the analysis time point is summarized by treatment arm and overall for the treated subjects.

The list of relevant deviations is provided below:

- Subjects with Screening plasma HIV-1 RNA < 400c/mL
- Subjects with Screening CD4 T-cell count < 50cells/mm^3
- Subjects with Screening Estimated eGFR < 60mL/min (CKD-EPI formula)
- Subjects resistant to study drugs (unboosted ATV, FC < 2.2; DTG; and TDF) based on Screening genotype/phenotype report(s)
- Subjects who received the wrong study medication
- Subjects who took prohibited concomitant medications, as specified in the protocol, for more than 3 consecutive days.
- Subjects with gaps in study medication dosing greater than 3 consecutive days.

7.3 Study Population

7.3.1 Subject Disposition

The disposition of subjects will be summarized separately for the pre-randomization period and the on-treatment period.

The pre-randomization status will be summarized for all enrolled subjects. This summary will include the number of subjects enrolled, randomized, not randomized and the reasons for not being randomized.

The end of Week 96 subject status will be summarized by treatment arm and overall for the randomized subjects. This summary will include the number of subjects randomized, completing Week 96 and not completing Week 96. The reasons for not completing Week 96 will also be included.

A separate output will summarize the number of subjects in each population.

Subjects enrolled and randomized will be summarized by country and study site. . Enrollment by age group is summarized analogously. Age groups are: in utero; preterm newborn (gestational age < 37 weeks); newborns (0 to 27 days); infants and toddlers (28 days to 23 months); children (2 to 11 years); adolescents (12 to 17 years); adults (18 to 64 years); adults (65 to 84 years); adults (≥ 85 years).

7.3.2 Demographics and Other Characteristics

All baseline presentations will identify subjects with missing measurements. In tabulations of categorical variables, percentages are based on subjects with measurements.

7.3.2.1 Demographics and Other Baseline Characteristics

Demographic and other baseline characteristics (including disease characteristics) will be summarized by as-randomized treatment arm and overall for the treated subjects. Available demographic characteristics will also be summarized for subjects enrolled but not randomized.

Table 7.3.2.1-1: Demographic Characteristics

Characteristic	Summarized as	Categories
Gender	Categorical	Male, Female
Age	Continuous and Categorical	< 50 , ≥ 50 years
Race	Categorical	White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other
Ethnicity (US only)	Categorical	Hispanic/Latino Non Hispanic/Latino
Geographic Region	Categorical	Europe Asia Australia South America North America Africa

Table 7.3.2.1-2: Baseline Disease Characteristics

Characteristic	Summarized as	Categories
Plasma HIV-1 RNA	Continuous (log_{10}c/mL) and Categorical	<30,000c/mL 30,000 to < 100,000c/mL 100,000 to < 500,000c/ mL ≥ 500,000c/mL
CD4+ T-cell count	Continuous and Categorical	<50cells/mm^3 50 to < 100cells/mm^3 100 to < 200cells/mm^3 200 to < 350cells/mm^3 350 to < 500cells/mm^3 ≥ 500cells/mm^3
CD4+ T-cell percentage	Continuous	
CD8+ T-cell count	Continuous	
HIV-1 Subtype	Categorical	
IC_{50} for BMS-955176	Continuous	
IC50 Fold Change for BMS-955176	Categorical	< 1.0 1.0 to < 5 5 to < 10 10 to < 100 100 to < 500 >= 500

Table 7.3.2.1-3: Other Baseline Characteristics

Characteristic	Summarized as	Categories
Height	Continuous	
Weight	Continuous	
BMI	Continuous	
Hematology: Hemoglobin, Absolute Neutrophil Count(ANC), Platelets, White Blood Cell Count (WBC)	Categorical	Normal, Grade 1, Grade 2, Grade 3, Grade 4
Liver Function Tests: Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Albumin, serum, low Alkaline Phosphatase, Total Bilirubin	Categorical	Normal, Grade 1, Grade 2, Grade 3, Grade 4
Enzymes: Creatinine Kinase (CK), Lipase	Categorical	Normal, Grade 1, Grade 2, Grade 3, Grade 4
Renal Function Tests: Creatinine, Creatinine Clearance (eGFR), Uric Acid	Categorical	Normal, Grade 1, Grade 2, Grade 3, Grade 4
Electrolytes: Bicarbonate, serum, low Calcium, serum, high Calcium, serum, low Potassium, serum, high Potassium, serum, low Sodium, serum, high Sodium, serum, low	Categorical	Normal, Grade 1, Grade 2, Grade 3, Grade 4,
Fasting Lipids: Total Cholesterol, LDL-Cholesterol, Triglycerides	Categorical	Normal, Grade 1, Grade 2, Grade 3, Grade 4
Fasting Glucose: Glucose, serum, high Glucose, serum, low	Categorical	Normal, Grade 1, Grade 2, Grade 3, Grade 4,

Baseline laboratory values are graded using the DAIDS Toxicity Grades tables as presented in Appendix 3 of the protocol.

Physical examination findings at baseline will be summarized by randomized treatment group and overall.

7.3.2.2 Pre-treatment CDC Class C AIDS Events

Pre-treatment CDC Class C AIDS events (as collected on the AIDS defining events CRF page) will be summarized by as-treated treatment arm and overall for the treated subjects. Pre-treatment events are those with an onset before the start of any study therapy. Documented clinical diagnoses are used to define AIDS (see Protocol Appendix 2).

7.3.2.3 Previous Medication

Previous medications are defined as those medications that are taken before the start of any study therapy. Previous medications will be summarized by as-treated treatment arm and overall for the treated subjects. Medications are presented alphabetically by anatomic class, therapeutic class and generic name. The WHO dictionary is used to code the non-study medication.

7.3.2.4 Baseline Resistance

Phenotypic resistance to a drug is defined as a fold change (i.e., ratio of the 50% inhibitory concentration (IC_{50}) of the clinical isolate to the IC_{50} of the reference strain) which is greater than the cut-off for reduced susceptibility.

The number of subjects with phenotypic resistance at baseline will be summarized for all treated subjects, for subjects who had on-study resistance testing done and for treated subjects that are identified as protocol defined virologic failures (see Protocol Section 5.4.1.3) using the following, mutually exclusive categories:

- No resistance to drugs in any class
- ≥ 1 NRTI
- ≥ 1 NNRTI
- ≥ 1 PI
- ≥ 1 INI
- ≥ 1 NRTI and ≥ 1 NNRTI
- ≥ 1 NRTI and ≥ 1 PI
- ≥ 1 NRTI and ≥ 1 INI
- ≥ 1 NNRTI and ≥ 1 PI
- ≥ 1 NNRTI and ≥ 1 INI
- ≥ 1 PI and ≥ 1 INI
- ≥ 1 NRTI and ≥ 1 NNRTI and ≥ 1 PI
- ≥ 1 NRTI and ≥ 1 NNRTI and ≥ 1 INI

- ≥ 1 NRTI and ≥ 1 PI and ≥ 1 INI
- ≥ 1 NNRTI and ≥ 1 PI and ≥ 1 INI
- ≥ 1 NRTI and ≥ 1 NNRTI and ≥ 1 PI and ≥ 1 INI

The number of subjects with phenotypic resistance will also be summarized by class and drug name.

The genotypic resistance profile at baseline will be summarized by treatment arm for all treated subjects, for subjects who had on-study resistance testing done and for treated subjects that are identified as protocol defined virologic failures. Tabulations will present genotypable isolates, those with PI substitutions from genotypable isolates, those with selected RT substitutions from genotypable isolates, and those with integrase substitutions from genotypable isolates using the most current version of the International AIDS Society-USA (IAS-USA) list (see APPENDIX 2). The genotypic resistance profile at baseline will also be summarized by baseline HIV subtype for all treated subjects.

In addition, baseline gag polymorphisms at positions 362, 364, 369 and 370 (relative to the wild type HxB2) will be summarized by treatment arm. This list of positions might be updated. The summary will report single mutations and combinations of mutations. The baseline gag polymorphisms at selected positions will also be summarized by baseline HIV subtype for all treated subjects.

Any deviation from the wild type virus (HxB2) in baseline gag sequencing will be summarized for treated subjects by treatment arm. This summary will also be provided by baseline HIV subtype.

The summaries for gag will be provided for treated subjects, for treated subjects who had on-study resistance testing done and for treated subjects that are identified as protocol defined virologic failures.

7.4 Extent of Exposure

Extent of exposure is presented for treated subjects by as-treated treatment arm.

7.4.1 Study Therapy

Time (in days) on study therapy will be summarized by treatment arm. Time on study therapy is defined as the difference between the earliest last dose date of any component of the treatment arm and the first dose date of study treatment plus 1 day.

Time on study therapy and average daily dose will be summarized for each individual drug component by treatment arm. Time on an individual drug component is defined as the number of days between the first dose date and the last dose date of the drug. The average daily dose is the total amount of drug in grams divided by the number of days between the first dose date and the last dose date of the drug.

The time on BMS-955176 and average daily dose after the switch to the continuation dose will be summarized for subjects who switched to the continuation dose after Week 24, rather than starting on the continuation dose at the time of randomization. Time on BMS-955176 continuation dose is defined as the difference between the last dose date of continuation dosing and the first dose date of continuation dosing plus 1 day.

7.4.2 Discontinuation of Study Therapy

Time (in days) on any study therapy will be described by a Kaplan-Meier curve and life table with the Kaplan-Meier estimates.

Discontinuations from study therapy are considered events in this analysis. For subjects who have not discontinued, time on study therapy is censored at the last recorded dose stop date of any study therapy. For the purpose of this analysis, we will consider the start date and event/censor date regardless of any interruptions.

7.4.3 Interruption or Delay of Study Therapy

Interruptions of study therapy greater than 3 consecutive days will be summarized by treatment arm and for each drug in the regimen. Interruptions are identified from complete dosing records in which either the number of units per day or the number of doses per day is zero.

7.4.4 Concomitant Therapy

Concomitant medications are defined as those taken at any time on or after the start date of study therapy and before or on the last dose date of study therapy. Concomitant medications will be summarized by treatment arm and overall for the treated subjects. Medications are presented alphabetically by anatomic class, therapeutic class and generic name. The WHO dictionary is used to code the non-study medication.

7.5 Efficacy

Efficacy endpoints are evaluated for treated subjects by as-randomized treatment arm during the treatment period through a specific analysis week. Measurements obtained on treatment and before or on the analysis week date (see Section 8.2) will be included.

7.5.1 Primary Efficacy Endpoint: Proportion of Subjects with Plasma HIV-1 RNA < 40c/mL at the Week 24 Snapshot

The primary efficacy endpoint is the proportion of subjects with plasma HIV-1 RNA < 40c/mL at the Week 24 snapshot. The primary analysis will be based on a modified ITT (mITT) approach. A sensitivity analysis will be conducted using an observed values approach. The two approaches will be implemented as follows:

- Modified ITT: The numerator will be based on subjects with plasma HIV-1 RNA < 40c/mL at Week 24. The denominator will be based on all treated subjects.

- Observed values: Similar to the mITT approach, the numerator will be based on subjects with plasma HIV-1 RNA < 40c/mL at Week 24. However, the denominator will be based on treated subjects with plasma HIV-1 RNA at Week 24.

Response rates will be tabulated by treatment arm with exact (Clopper-Pearson) binomial 95% confidence intervals.

This endpoint is assessed with the snapshot algorithm. The snapshot algorithm is described in detail in Appendix 1 of the CDER (2013) draft guidance[1] on developing antiretroviral drugs (see also APPENDIX 1 of this SAP). If the draft guidance is superseded, and development timelines permit any needed changes, the instructions from the new guidance should be followed.

The main principle of the snapshot analysis is that the primary efficacy endpoint is intended to be primarily a virologic endpoint and not a clinical endpoint. The snapshot algorithm follows a "Virology First" hierarchy. The hierarchy for assessing percentages is "HIV-1 RNA < Limit of Detection" or "HIV-1 RNA ≥ Limit of Detection" first for any given time window followed by reasons for "No Virologic Data in the Window".

The snapshot approach algorithm is based on the event occurring within a visit window which is outlined in Section 8.1.

Optimized Background Therapy (OBT) Substitutions

Changes in background therapy are not allowed per protocol. Subjects who do change their dose for TDF in the event of treatment-limiting renal toxicity will be considered virologic failure if they have HIV-1 RNA > 40 at the time of the change.

Movement of a subject to the continuation dose of BMS-955176 will not be a cause for classifying a subject as a virologic failure.

The snapshot analysis must include a table that is of the same format shown in Table B (line 1209) of the draft guidance. A more detailed presentation that breaks down the FDA categories into finer detail, may also be provided. The snapshot analysis will be accompanied by a detailed listing that facilitates finding the patients in each category described in the table.

The snapshot analysis is supplemented by a Time to Loss of Virologic Response (TLOVR) analysis at Weeks 24. Analyses are presented for the randomized treatment groups both separately and combined. TLOVR analyses are described in APPENDIX 3.

7.5.1.1 Summaries of Primary Efficacy Endpoint Within Subgroups

The primary efficacy endpoint will be summarized within the following subgroups using the mITT and the observed values approach:

- Baseline viral load: < 100,000c/mL, ≥ 100,000c/mL
- Baseline CD4 category: < 100cells/mm^3, 100 to < 200cells/mm^3, 200 to < 350cells/mm^3, 350 to < 500cells/mm^3, ≥ 500cells/mm^3
- Gender

- Race
- HIV-1 clade

7.5.2 Secondary Efficacy Endpoints

7.5.2.1 Proportion of Subjects with Plasma HIV-1 RNA < 40c/mL at Weeks 48 and 96

The proportion of subjects with HIV1 RNA < 40c/mL at Weeks 48 and 96 will be assessed analogously to the primary efficacy endpoint using the snapshot algorithm. Summaries within subgroups identified for the primary analysis will be provided for Week 48 and 96 using the mITT and the observed values approach. Also a time to loss of virologic response analysis will be done.

7.5.2.2 Proportion of Subjects with Plasma HIV-1 RNA < 200c/mL at the Week 24, 48 and 96 Snapshot

The proportion of subjects with plasma HIV-1 RNA < 200c/mL at Week 24, 48 and 96 will be summarized using mITT and the observed values approach, analogously to the primary efficacy endpoint using the snapshot algorithm. No summaries within subgroups will be provided.

7.5.2.3 Change from Baseline in Plasma HIV-1 RNA (log_{10}) over Time

The change from baseline in plasma HIV-1 RNA (log_{10}) will be summarized over time for the treated subjects using observed values. The mean changes from baseline will be plotted at each scheduled visit (except Week 2) through Week 96 by treatment arm, with error bars representing 1 standard error. The change from baseline in plasma HIV-1 RNA (log_{10}) at Week 24, 48 and 96 will be presented graphically using box plots. The change from baseline will also be provided for the subgroups identified for the primary analysis.

7.5.2.4 Changes from Baseline in CD4+ and CD8+ T-cell Count over Time

CD4+ and CD8+ T-cell counts and changes from baseline will be summarized at each scheduled visit through Week 96 by treatment arm using observed values. The mean changes from baseline will be plotted at each scheduled visit through Week 96 by treatment arm, with error bars representing 1 standard error. The change from baseline in CD4+ and CD8/ T-cell counts at Week 24, 48 and 96 will be presented graphically using box plots. Also the percentage of CD4+ T-cells and changes from baseline will be summarized at each scheduled visit through Week 96. The change from baseline will also be provided for the subgroups identified for the primary analysis.

7.5.2.5 Newly-emergent Genotypic Substitutions, IC_{50} Fold Changes from Baseline and Newly-emergent Gag Polymorphisms

Viral resistance is measured using the "PhenoSense GT plus Integrase" assay from Monogram (LabCorp). The PhenoSense GT plus Integrase is used to determine both genotypic and phenotypic resistance to Nucleoside Reverse Transcriptase Inhibitors (NRTIs), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs), Integrase Inhibitors (INIs), and Protease Inhibitors (PIs). The "PhenoSense Gag" assay is used for determining phenotypic susceptibility to BMS-955176. HIV-1 Gag sequencing data will be obtained from the NGS-Gag Quantitative Sequencing (QS) assay.

Genotypic substitutions and phenotypic resistance profiles focus on subjects with on-treatment isolates.

Newly emergent phenotypic resistance to a drug is defined as a baseline fold change ≤ the cut-off for reduced susceptibility and an on-treatment fold change > the cut-off for reduced susceptibility. The newly emergent phenotypic resistance profile (using all on-treatment isolates) will be tabulated by treatment arm for treated subjects with on-treatment resistance testing done.

Newly emergent phenotypic resistance to BMS-955176 is defined as a baseline fold change IC50 ≤ 3 and an on-treatment fold change IC50 > 3. The newly emergent phenotypic resistance to BMS-955176 (using all on-treatment isolates) will be tabulated by treatment arm for treated subjects with on-treatment resistance testing done.

Newly emergent genotypic substitutions (using all on-treatment isolates) are tabulated by treatment arm for treated subjects with on-treatment resistance testing done. The presentation will be similar to the one for baseline genotypic substitutions.

The maximum change from baseline in BMS-955176 IC_{50} and the maximum BMS-955176 fold change IC_{50} (FC-IC50) through Week 96 will be summarized for all treated subjects with on-treatment phenotypic resistance profile. In addition, the proportion of subjects with a > 3 fold increase from baseline in BMS-955176 FC-IC50 (i.e., BMS-955176 FC-IC50 on-treatment divided by BMS-955176 FC-IC50 at baseline > 3) will be summarized. The Gag polymorphisms will be summarized for subjects with a > 3 fold increase from baseline in BMS-955176 FC-IC50. These summaries will use all of the data present in the database at the time of lock.

Newly emergent Gag polymorphisms at the selected positions will be summarized by treatment arm for treated subjects with on-treatment resistance testing done, overall and by baseline HIV subtype. In addition, any newly emergent Gag deviation will be summarized for treated subjects with on-treatment resistance testing done, overall and by baseline HIV subtype.

All summaries described in this section will also be provided for treated subjects that are identified as protocol defined virologic failures.

Protocol Defined Virologic Failure (PDVF) is defined by a subject meeting one of the following criteria (see Protocol, Section 5.4.1.2):

- Confirmed > 1 log10c/mL increase in HIV-1 RNA at any time above nadir level where nadir is ≥ 40c/mL
- Confirmed HIV-1 RNA ≥ 400c/mL after Week 24
- Confirmed HIV-1 RNA ≥ 40c/mL if prior suppression to < 40c/mL
- Failure to have the last on-treatment HIV-1 RNA to < 400c/mL within Week 24, 48, or 96 week snapshot window
- Failure to achieve > 1 log10c/mL decrease in HIV-1 RNA by Week 8

7.5.3 Exploratory Efficacy Endpoints

7.5.3.1 Proportion of Subjects with Plasma HIV-1 RNA within Certain Range over Time

The proportion of subjects with HIV-1 RNA:

- < 40c/mL
- 40 to < 100c/mL
- 100 to < 200c/mL
- 200 to < 400c/mL
- > 400c/mL

will be presented by visit using the observed values approach.

7.5.3.2 Efficacy Summaries by Baseline Gag Polymorphisms

To assess the impact of baseline gag polymorphisms the following efficacy endpoints will be summarized by all combinations of baseline gag polymorphisms at selected positions:

- Proportion of subjects with plasma HIV-1 RNA < 40c/mL at Weeks 24, 48 and 96
- Proportion of subjects with plasma HIV-1 RNA < 200c/mL at Weeks 24, 48 and 96
- Change from baseline in $\log_{10}$ HIV-1 RNA at Weeks 4, 8, 12, 24, 48 and 96

7.5.4 Futility Analysis

An analysis of virologic futility will be performed at Week 24 when the last randomized subject in Stage 1 completes the Week 24 visit. This analysis will be conducted to evaluate whether the BMS-955176 arm shows significantly worse antiviral efficacy than the TDF arm. The proportion of subjects with HIV-1 RNA < 40c/mL at Week 24 will be evaluated using the FDA snapshot algorithm. The comparison of the BMS-955176 arm to the TDF arm will be made with one-sided Fisher's exacts test, conducted at the 0.01 probability level.

An analysis of virologic futility will also be performed at Week 24 when the last randomized subject in Stage 2 completes the Week 24 visit. This analysis will be conducted to evaluate

whether the BMS-955176 arms show significantly worse antiviral efficacy than the TDF arm in Stage 2. The proportion of subjects with HIV-1 RNA < 40c/mL at Week 24 will be evaluated using the snapshot algorithm. The comparisons of Arms 3 and 4 (BMS-955176) to Arm 5 (TDF) will each be made with a one-sided, Fisher's exact test, conducted at the 0.01 probability level.

7.6 Safety

Safety endpoints include the frequency of adverse events (AEs), serious adverse events (SAEs), non-serious adverse events, CDC Class C AIDS events, adverse events leading to discontinuations, deaths and other significant adverse events as reported on case report forms. Other safety endpoints include laboratory abnormalities, changes in laboratory parameters, changes in vital signs and physical measurements, and ECGs. Safety endpoints will not be evaluated through a specific analysis week. All safety data available in the database at the time of the lock will be included.

Safety summaries are provided for treated subjects by as-treated treatment arm, unless otherwise specified.

7.6.1 Overall Adverse Events

Adverse events will be classified by primary System Organ Class (SOC) and Preferred Term (PT) according to the latest version of the Medical Dictionary for Regulatory Activities (MedDRA) in production at BMS at the time of database lock.

AEs and SAEs with an onset on or after the start of study therapy through 30 days after the last dose of study therapy will be considered as occurring during study therapy. These will be summarized and presented by SOC and PT both in descending order of frequency over all treatment arms, unless otherwise specified.

Table 7.6.1-1: Adverse Event Summaries

Endpoint	During Study Therapy	During Study Therapy, after Switch to Continuation Dose
SAEs	X	X
SAEs leading to death [a]	X	
SAEs related to study therapy and leading to death [a]	X	
Non-SAEs ≥ 5% [a]	X	
AEs leading to discontinuation of study therapy	X	X
AEs - All Grades	X	
AEs - Grade 2 to 4	X	
AEs- Grade 3 to 4	X	

Table 7.6.1-1: Adverse Event Summaries

Endpoint	During Study Therapy	During Study Therapy, after Switch to Continuation Dose
Related AEs - All Grades	X	
Related AEs - Grade 2 to 4	X	
Related AEs - Grade 3 to 4	X	
CDC Class C AIDS Events	X	
Events of Special Interest	X	
Exposure-adjusted Events ≥ 5%	X	
Exposure-adjusted SAEs [a]	X	
Exposure-adjusted SAEs related to study therapy [a]	X	
Exposure-adjusted non-SAEs ≥ 5% [a]	X	

a ClinicalTrials.gov or EudraCT reporting requirement

7.6.2 Deaths

All deaths recorded on the status page, the AE page or SAE page of the CRF will be considered in the analyses. A listing of all deaths that occur will be produced for the enrolled subjects.

7.6.3 Serious Adverse Events

SAEs occurring during study therapy will be summarized by SOC and PT. SAEs leading to death and SAEs related to study therapy and leading to death will be summarized in a similar way.

A listing of all SAEs will be produced, displaying all SAEs (including pre-treatment events) for enrolled subjects.

7.6.4 Serious Adverse Events Emerging After Switch to Continuation Therapy

For subjects who switched to a continuation dose after Week 24, rather than starting on a continuation dose at the time of randomization, SAEs with an onset after the start date of continuation therapy through 30 days after the last dose of study therapy, will be summarized by SOC and PT.

7.6.5 Non-Serious Adverse Events

Non-serious adverse events occurring in at least 5% of the subjects treated will be summarized by SOC and PT.

7.6.6 Adverse Events Leading to Discontinuation of Therapy

Adverse events leading to discontinuation will be summarized by SOC and PT.

7.6.7 Adverse Events Leading to Discontinuation of Therapy After Switch to Continuation Therapy

For subjects who switched to a continuation dose after Week 24, rather than starting on a continuation dose at the time of randomization, AEs leading to discontinuation with an onset after the start date of continuation therapy will be summarized by SOC and PT.

7.6.8 Adverse Events by Relationship

Drug-related adverse events are those with 'related' or missing relationship to study drug. Drug-related adverse events will be summarized by SOC and PT.

7.6.9 Adverse Events by Intensity

Adverse events and drug-related adverse events with the following grades:

- all Grades,
- Grade 2 to Grade 4,
- Grade 3 to Grade 4,

will be summarized by SOC and PT.

Adverse events with missing intensity are included only in the summaries for all grades. If a subject has an adverse event with different intensities over time, then only the greatest intensity will be presented.

7.6.10 CDC Class C AIDS Events

CDC Class C AIDS events will be summarized and presented by SOC and PT.

7.6.11 Adverse Events of Special Interest

Separate summaries will be provided for the following events of special interest: gastrointestinal events. The list of events will be identified before database lock. The definition of gastrointestinal events will be based on existing Standardized MedDRA Queries (SMQs) if existing SMQs support the events of special interest requirements. If needed, a customized SMQ (cSMQ) will be developed. Gastrointestinal events will be summarized by SOC and PT.

7.6.12 Multiple Adverse Events

Several descriptive summaries of adverse events that take into account the number of occurrences that an AE was reported by individual subjects will be provided. In order to prepare these summaries, the CRF data will be processed according to standard BMS algorithms to categorize each line of subject data as a new occurrence or a continuation of an existing event.

This determination will be based upon onset and resolution dates. Each line of subject data will represent the maximum severity observed as well as the last known assessed relationship to study medication by the investigator.

This data will be presented as the rate per 100 years of patient exposure. Exposure to study medication will be calculated according to approved standard BMS algorithms as well.

As an example, if 5 subjects report 7 unique episodes of headache and had a combined cumulative exposure of 20 years to study medication, the incidence rate is reported as 7 / 20 * 100 or 35 cases per 100 patient years of exposure.

For adverse events with multiple occurrences, the following will be provided:

- A table showing the total number and rate (exposure adjusted) of occurrences for general AEs occurring in at least 5% of the subjects treated.
- A listing displaying the unique instances of all AEs (i.e., after duplicates have been eliminated and overlapping and contiguous occurrences of the same event have been collapsed).

Exposure-adjusted summaries will also be provided for SAEs, SAEs related to study therapy and non-SAEs.

7.6.13 Clinical Laboratory Evaluations

Laboratory parameters will be presented using SI and US values and units.

7.6.13.1 Laboratory Abnormalities

The incidence of laboratory abnormalities presenting the worst toxicity grade during the treatment period will be tabulated by treatment arm for all grades (Grades 1, 2, 3, 4) and Grades 3 and 4.

Subjects with at least 1 measurement after the start of study therapy will be included in the summaries. Abnormalities are determined from laboratory measurements analyzed at the central or local laboratory. Grading categories for laboratory tests are determined using the DAIDS grading system (see Appendix 3 of the protocol).

This incidence will be further summarized by baseline toxicity grade.

Treatment emergent abnormalities by toxicity grade (increased to Grades 1, 2, 3, 4, and any grade) will also be summarized by baseline toxicity grade (normal, Grade 1 to 4, not reported) and total analogously. Treatment emergent abnormalities are those with a higher on-treatment toxicity grade than the baseline toxicity grade (including not reported baseline).

7.6.13.2 Laboratory Tests over Time

All summaries of laboratory data over time will use observed values. Visit windows are defined in Section 8.

Observed values and changes from baseline in creatinine and creatinine clearance will be summarized at each scheduled visit by treatment arm.

Observed values, changes from baseline and percent changes from baseline will be summarized over time for the following laboratory tests:

- Fasting Total cholesterol,
- Fasting HDL-cholesterol
- Fasting LDL-cholesterol,
- Fasting Triglycerides.
- Total:HDL cholesterol ratio

Values obtained after the start of serum lipid-reducing agents will be excluded from these lipid summaries. Mean percent changes from baseline using observed values will be plotted at each scheduled visit with error bars representing 1 standard error of the reported statistic.

7.6.14 Electrocardiograms

QRS, PR and QTc Fridericia intervals and changes from baseline will be summarized over time by treatment arm using observed values. Standard 95% confidence intervals for mean changes from baseline will also be provided.

The subject's longest interval observed during the treatment period for these ECG parameters will be summarized categorically by treatment arm using the following categories:

- QRS interval: < 100, 100 to < 110, 110 to < 120, 120 to < 130, 130 to < 140, ≥ 140msec;
- PR interval: < 200, 200 to < 220, 220 to < 240, 240 to < 260, 260 to < 280, 280 to < 300, ≥ 300msec;
- QTcF interval: < 400, 400 to < 425, 425 to < 450, 450 to < 460, 460 to < 470, 470 to < 480, 480 to < 490, ≥ 490msec.

The largest change from baseline in these intervals observed during the treatment period is also summarized categorically by treatment arm using the following categories:

- ΔQRS: < 0, 0 to < 10, 10 to < 20, 20 to < 30, 30 to < 40, ≥ 40msec;
- ΔPR: < 0, 0 to < 20, 20 to < 40, 40 to < 60, 60 to < 80, ≥ 80msec;
- ΔQTcF: < 0, 0 to < 10, 10 to < 20, 20 to < 30, 30 to < 40, ≥ 40msec.

7.6.15 Vital Signs

All summaries of vital signs over time will use observed values. Visit windows are defined in Section 8. Observed values and changes from baseline will be summarized over time. For blood pressure and heart rate, only sitting assessments will be included in the summaries.

Observed values and changes from baseline for body weight and BMI will be summarized over time.

7.7 Clinical Biomarker Assessments

Renal and bone biomarkers values, changes from baseline and percent changes from baseline will be summarized over time using observed values. Visit windows are defined in Section 8.

The renal biomarkers include urinary beta-2-microglobulin/creatinine and fractional excretion of phosphorous (FeP), defined as

- 100 * [(urine phos x serum creatinine) / (serum phos x urine creatinine)]

The bone biomarkers include: N-terminal Propeptide of Type 1 procollagen (P1NP) and Cross-linked C-telopeptide of Type 1 collagen (CTx).

The median change from baseline in FeP over time will be plotted with error bars representing IQR. The median percent change from baseline in P1NP, CTx and urinary beta-2-microglobulin/creatinine over time will be plotted in a similar way.

7.8 Integrated Summaries

For the final analysis (i.e., when the last subject in Stage 2 completed the Week 96 visit), a number of integrated summaries will be provided. These outputs will include 4 columns: one for each of the treatment arms 1, 3 and 4 and one for the TDF containing arms (arms 2 and 5) combined.

The following information will be summarized:

- Week 96 subject status (see Section 7.3.1)
- Demography and baseline disease characteristics (see Section 7.3.2.1)
- Baseline resistance (see Section 7.3.2.4):
  - The number of treated subjects with phenotypic resistance using the earlier mentioned mutually exclusive categories, and by class and drug name.
  - The genotypic resistance profile for all treated subjects.
  - The baseline gag polymorphisms at selected positions.
- Time on study therapy (see Section 7.4.1)
- Newly emergent resistance for treated subjects with on-treatment resistance testing done (see Section 7.5.2.5):
  - Newly emergent phenotypic resistance profile
  - Newly emergent phenotypic resistance to BMS-955176
  - Newly emergent genotypic substitutions
  - Newly emergent Gag polymorphisms at the selected positions
  - Any newly emergent deviation from the wild type virus in Gag sequencing
- Safety (see Section 7.6):
  - Overall AE summary
  - SAEs

- AEs leading to discontinuation
- Grade 2-4 related AEs
- Grade 3-4 AEs
- CDC Class C events
- Gastrointestinal events
- Grade 3-4 laboratory toxicities

7.9 Outcomes Research

7.9.1 EQ-5D-3L

As described in the SAP for BMS study CN162-007, the EuroQol (EQ-5D-3L) provides a simple but effective standardized measure of a subject's quality of life and health state classification[2]. It is intended to provide both a compact descriptive profile and a single index value that will be used in the clinical and economic evaluation of health care. The questionnaire consists of 2 parts, which together are used to build a composite picture of the respondent's health status.

In the first part, the "health state classification", the respondent is asked to indicate his/her current health state, by ticking the most appropriate of three statements about each of the 5 quality of life dimensions: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each of the 3 statements represents an increasing level of severity (1 = no problem, 2 = some or moderate problems, 3 = unable, or extreme problems). The string of five numbers, one for each dimension, indicates the aggregate health state. For example: "11111" indicates perfect health and "33333" indicates the worst health state.

The second part, "Visual Analogue Scale Thermometer", evaluates the respondent's current health-related quality of life by means of a 20cm visual analogue scale (VAS) with endpoints at 100 (best imaginable health state) and 0 (worst imaginable health state).

The scores obtained from the 5 health state dimensions (first part of the questionnaire) will be converted to a US centric utility score based on the algorithm described by Shaw et al[3]. This utility score has range score from -0.019 (worse health state) to a maximum of 1.000 (best health state). APPENDIX 4 contains SAS code for calculating the US centric EQ-5D-3L utility score.

The scores obtained from the 5 health state dimensions will also be converted to a UK centric utility score based on the algorithm described by Dolan[4]. APPENDIX 5 contains SAS code for calculating the UK utility scores.

For both the US centric and UK centric utility scores, values and changes from baseline are summarized as continuous parameters at baseline and all applicable, on-treatment analysis visits. Subjects must have paired measurements at baseline and the analysis visit to be evaluable.

7.9.2 FAHI

The FAHI consists of 5 subscales: Physical Well-Being, Emotional Well-Being, Function and Global Well-Being, Social Well-Being, and Cognitive functioning. Each scale consists of a number of questions, each of which has 5 possible responses: 0, 1, 2, 3 and 4.

A detailed description of the FAHI structure and scoring algorithm is contained in internal BMS document, "FAHI Source Doc (16-DEC-2014).PDF", which is available upon request. A summary of the scoring algorithm is provided below.

Negatively stated items are reversed by subtracting the response from 4. After reversing proper items, all subscale items are summed to a total which is the subscale score. Higher scores indicate better the quality of life. The score for each scale is the prorated sum of the items answered. Thus, if a scale has 10 items, and only 6 are answered, the results of the six questions answered are summed and multiplied by 10. The result is then divided by 6.

- The Physical Well-Being section of the questionnaire contains 13 questions, however only 10 of them are used in scoring the scale. These are questions GP1-GP7, BMT6, HI7 and HI12. Before computing the score for this scale, all of the responses are reversed by subtracting the response from 4.
- The Emotional Well-Being scale consists of 10 items. Before computing the score for this scale, all of the responses are reversed by subtracting the response from 4.
- The Function and Global Well-Being scale consists of 13 items. Only one item, GE3, is reversed before the scale is scored.
- The Social Well-Being scale consists of 8 items. None of these items are reversed before the scale is scored.
- The Cognitive Functioning scale consists of three items. Two of these items, HI8 and HI9, are reversed before the scale is scored.

The scoring of any of the FAHI sub-scales is only considered valid as long as more than 50% of the subscale questions have been answered.

The total score for the FAHI is the sum of prorated scores from each of the five subscales. The overall score for the FAHI is considered valid if all of the subscales are considered to be valid.

The analysis data set includes the overall score and each of the subscale scores by visit for each subject as well as indicator variables that show if the validity condition has been met for each of the subscales, as well as the FAHI overall. Calculations for the FAHI total score and subscale scores use only valid data.

FAHI total scores are summarized as continuous parameters at baseline and all applicable on-treatment analysis visits.

7.10 Pharmacokinetics

The following intensive PK parameters will be summarized (using mean, SD, median, minimum, maximum, geometric mean and %CV) for BMS-955176, DTG and ATV by treatment arm:

- C_{max}: maximum observed plasma concentration
- T_{max}: time of maximum observed plasma concentration
- C_{tau}: observed plasma concentration at the end of a dosing interval
- C_0: observed pre-dose plasma concentration
- AUC(TAU) area under the concentration-time curve in one dosing interval

The Pharmacokinetic (PK) population will be used for all listings. Evaluable PK population will be used for summary statistics and statistical analyses.

Subject plasma concentration-time profiles will be listed and summarized by treatment arm and nominal collection time for each analyte. Plots of individual plasma concentration profiles over time will be provided. Overlay of individual plasma concentration profiles over time will be provided by treatment arm. Plots of mean (+SD) plasma concentration profiles versus time will be presented for each analyte, and all treatments will be superimposed on the same plot for the analyte.

All individual PK parameters will be listed for each analyte including any exclusions and reasons for exclusion from summaries. Summary statistics will be tabulated for each PK parameter by treatment arm. Geometric means and coefficients of variation will be presented for Cmax, AUC(TAU), C_{tau}, and C_0. Medians and ranges will be presented for Tmax.

The effect of BMS-955176 on the exposure of DTG (in the presence of ATV/RTV 300/100mg) will be estimated by the geometric mean ratio, with 90% confidence interval, of the exposure data in Arm 1 over the reference ATV/r arm (Arm 2). These estimates will be generated using general linear models fitted to log-transformed data. The effect of BMS-955176 on the exposure of DTG (in the presence of ATV 400mg) will be estimated by the geometric mean ratio, with 90% confidence intervals, of the exposure data in Arm 3 and Arm 4, separately, over historical data. These estimates will be generated using general linear models fitted to log-transformed data.

The population PK, exposure-response and viral kinetic analyses will be described in a separate analysis plan. Intensive and sparse pharmacokinetic data will be used in population PK, PK/PD and PK/VK.

8 CONVENTIONS

8.1 Derivation of Baseline and On-Treatment Parameters Using Visit Windows

8.1.1 Baseline

Baseline parameters are derived from pre-treatment measurements. Pre-treatment measurements are included for subjects in the following ways:

- For treated subjects: measurements are included through the start of study therapy.
- For randomized subjects who never received study therapy: measurements are included through randomization.
- For enrolled subjects who were never randomized: all available measurements are included.

The following algorithm details the derivation of baseline parameters:

- CD4+ and CD8+ T-cells: the last value on or before the start of study therapy. If there are multiple measurements on the same day from central and local laboratories, then the value from the central laboratory is selected.
- Genotypic and phenotypic parameters: identified from the last typable resistance test on or before the start of study therapy. HIV subtype is identified from the first resistance test at which subtype was assessed. If there are multiple tests on the same day, the last test run is chosen.
- All other parameters: the last value measured on or before the start of study therapy is selected. If there are multiple measurements on the same day, the value with the latest entry date/time is chosen :
  - HIV-1 RNA: Values are assigned a value of 1 more (or 1 less) if an inequality ">" ("<") is present. Values outside the upper (or lower) limit of quantification are assigned a value or 1 more (or 1 less) than the limit. Only values from the central laboratory will be used.

8.1.2 On-Treatment Parameters

Time is measured from the first dose of study therapy.

On-treatment parameters are derived from measurements after the start of study therapy through the last dose of study therapy plus 4 days for efficacy, biomarkers and outcomes research scales, plus 10 days for resistance parameters and plus 30 days for safety.

For the primary and secondary efficacy endpoints of proportion of subjects with plasma HIV-1 RNA < 40c/mL at Weeks 24, 48 and 96, the snapshot algorithm and related window definition will be applied. The snapshot windows shown in the Table 8.1.2-1 below differ from those proposed by the FDA by 1 day. The FDA windowing appears to have the first study day as Day 0, while the table below has the first study day as Day 1.

The windows for other parameters are based on the midpoint between planned study visits. For analysis through Week 96, the visit windows are presented in the following table:

Table 8.1.2-1: Visit Windows

Visit	Target Day	HIV-1 RNA (Snapshot Algorithm)	Other Parameters
B/L	1		≤ 1
2	15		2 - 21
4	29		22 - 43
8	57		44 - 71
12	85		72 - 99
16	113		100 - 141
24	169	127 - 210 (18-30 wks)	142 - 197
32	225		198 - 253
40	281		254 - 309
48	337	295 - 378 (42-54 wks)	310 - 379
60	421		380 - 463
72	505		464 - 547
84	589		548 - 631
96	673	631-714 (90-102 wks)	632 - 715

Study days are calculated as:

- Measurement date - first date of study therapy + 1 day, if measurement date if on or after start date of study therapy.
- Measurement date - first date of study therapy, if measurement date is before start date of study therapy.

Weeks are study days divided by 7.

The following conventions are used to select the value to be used in the analysis:

- HIV-1 RNA: analysis of the proportion of subjects with plasma HIV-1 RNA < 40c/mL at Week 24, 48 and 96 use the last plasma HIV-1 RNA value in the pre-defined visit window following the snapshot algorithm. For all other analyses or summaries of HIV-1 RNA, the value in the visit window that is closest to the target day of the planned visit (as determined by the absolute differences in days between the planned visit and the assessment date) will be used. In case of ties between observations located on different sides of the target day, the earlier assessment will be used. In case of ties located on the same side of the target day

(i.e., more than one value for the same day but different time), the value with the earlier entry date/time will be used. Only values from the central laboratory will be used.

  - Values are assigned a value of 1 more (or 1 less) if an inequality ">" (or "<") is present. Values outside the upper (or lower) limit of quantification are assigned a value of 1 more (or 1 less) than the limit.

- For other laboratory and non-laboratory parameters: if a subject has more than one measurement included within a window, the assessment closest to the target day will be used. In case of ties between observations located on different sides of the target day, the earlier assessment will be used. In case of ties located on the same side of the target day (i.e., more than one value for the same day but different time), the value with the earlier entry date/time will be used.

8.2 Derived Dates

- Start date of any study therapy is the earliest start date of BMS-955176, TDF, ATV, RTV or DTG identified from dosing records with non-missing start date. This date is used to identify treated subjects and to distinguish pre-treatment from any on-study measurements.
- Start date of continuation dosing of study therapy for BMS-955176 is the earliest start date of the continuation dose(s) of BMS-955176 with non-missing daily dose and non-missing start date. This date is used to identify treated subjects receiving the continuation dose(s) of BMS-955176 and to distinguish on-study measurements in the original dosing period from on-study measurements in the continuation dosing period.
- Start date of serum lipid-reducing agents is the earliest start date of any concomitant or post-treatment medication from the therapeutic class 'serumlipidreducing agent'. This date is used to exclude data in longitudinal lipid analyses during treatment.
- Analysis week date is the start date of study therapy plus the upperbound of the window defining the analysis week minus 1 day (see Section 8.1). This date is used to include data through the analysis week.

8.3 Derived Parameters

When deriving a parameter that requires more than one test measurement, the parameter must be derived using measurements from the same collection date, accession number and site code for each test.

8.4 Study Therapy

Time on therapy for each individual drug component is calculated from the first and last dates of dosing, regardless the interruptions. The first date of dosing is the minimum of the dosing start dates, and the last date of dosing is the maximum of dosing stop dates.

8.5 Concomitant Medications

Start and stop date of all concomitant medications are collected on the CRF. In order to classify medication as prior, current or concomitant, partial, missing or invalid start and stop dates will be imputed where possible as follows:

- If the reported start date is missing or invalid and the informed consent date is not missing or invalid, then the imputed start date is set equal to the informed consent date. If the consent date is missing or invalid and the birth date is not missing or invalid, then the imputed start date is set equal to the birth date. If the start date, the consent date and the birth date are all invalid or missing, then the imputed start date is set equal to missing.
- If the reported start date is partially entered, then the imputed start date is set equal to the earliest possible reported start date based on the partial entered reported start date.
- If the reported end date is missing, continuing, unknown or invalid, then the imputed end date is set equal to the most recent database extraction date.
- If the reported end date of the medication is partial, then the imputed end date is set equal to the last possible reported end date based on the partial entered reported end date.

Imputed dates will not appear on the listings of non-study medication.

8.6 Counting Rules for Adverse Events

Where a subject has the same adverse event, based on preferred term, reported multiple times in a single analysis period, the subject will only be counted once at the preferred term level in adverse event frequency tables.

Where a subject has multiple adverse events within the same system organ class in a single analysis period, the subject will only be counted once at the system organ class level in adverse event frequency tables.

When a subject has the same adverse event, based on preferred term, reported multiple times in a single analysis period, the following criteria, in order of precedence, will be used to select the event to be included in the summary tables:

- Relationship to study medication: related events will take precedence over unrelated events.
- Intensity of the event: more intense events will take precedence over less intense events.
- Onset date and time: earlier onset date/time events will take precedence over late onset date/time events.

When reporting adverse events by intensity, summary tables will also be provided based on the most intense event during the analysis period - independent of relationship to study medication. For these tables, the following criteria, in order of precedence, will be used to select the event to be included in the summary tables:

- Intensity of the event
- Onset date and time

8.7 Pharmacokinetic Evaluations

8.7.1 Decimal Places for Pharmacokinetic Data

The number of decimal places displayed in all listings will be determined by the number of decimal places in the raw data.

Unless otherwise specified, minimum and maximum will be reported to the precision as the data collected, one more decimal place for the mean and median, and two more decimal places for the standard deviation. The adjusted geometric mean, geometric mean ratio and the lower and upper limits of confidence interval will be displayed to three decimal places.

8.7.2 Pharmacokinetic Summaries

In-text Tables

For in-text pharmacokinetic tables, coefficient of variation (% CV) will be reported as integers. For other statistics, values of 100 or higher will be presented as integers, values of 10 - < 100 will be displayed to one decimal place, and values of 1 - < 10 will be displayed to two decimal places. Values less than 1 will be displayed to three decimal places. Ratios will also be displayed to three decimal places.

Handling of Non-Quantifiable Concentrations

For the summaries of plasma concentration-time data, concentrations that are less than the lower limit of quantification (LLOQ) should be displayed as "< LLOQ" in the listings and be treated as missing in summary tables and plots. For the purpose of calculating intensive PK parameters, pre-dose concentrations that are less than LLOQ and concentrations prior to the first quantifiable concentration that are less than LLOQ will be set to zero, and all other concentrations less than LLOQ will be set to missing.

Sparse PK concentrations for PK/PD and PK/VK correlations will be calculated by imputing values less than LLOQ as ½ * LLOQ.

All available plasma concentration-time data and derived pharmacokinetic parameter values will be included in the PK data set and listed accordingly.

Treatment of Outliers

Individual plasma concentrations, if deemed to be anomalous, may be excluded from the analysis following a review of available documentation (e.g., bioanalytical report, clinical data). Any such exclusion will be clearly listed in the study report along with justification for exclusion.

Entire plasma concentration-time profiles for a subject may be excluded following review of available documentation (e.g., bioanalytical report, clinical data). However, results of analysis with and without the excluded profiles may be presented in the study report. Any such exclusion will be clearly listed in the study report along with justification for exclusion.

PK Exclusions

Exclusion of one or more parameters or the entire dataset may be considered due to incomplete profile, or there is no sample around the suspected Cmax. In addition, subjects may be excluded from the analysis if they missed doses, had diarrhea, or vomited at or before a time equal to twice the median Tmax for immediate-release products, or vomited at any time during sampling after the administration of modified-release formulations.

9 REFERENCES

An interim analysis will be conducted after the last randomized subject in Stage 1 is on treatment for 24 weeks. The analyses related to the first 24 weeks of treatment for Stage 1 will be performed.

An interim analysis might be conducted after the last randomized subject in Stage 1 is on tratment for 48 weeks in case the continuation dose couldn't be selected based on the Week 24 results.

An interim analysis will be conducted after the last randomized subject in Stage 2 is on treatment for 24 weeks. The expectation is that the last subject in Stage 1 will have completed the Week 96 visit by that time. The analyses related to the first 24 weeks of treatment for Stage 2 will be performed as well as all analyses related to Stage 1 (except the futility analysis).

An interim analysis will be conducted after the last randomized subject in Stage 2 completes the Week 48 visit. The analyses related to the first 48 weeks of treatment for Stage 2 will be performed.

The final analysis will be conducted after the last randomized subject in Stage 2 completes the Week 96 visit. All analyses described in this plan will be performed for both Stages (except the futility analysis). This includes the integrated summaries described in Section 7.8.

APPENDIX 1 SNAPSHOT ALGORITHM

The snapshot algorithm is described in detail in Appendix A of the CDER (2013) draft guidance on developing antiretroviral drugs[1]. If the draft guidance is superseded, and development timelines permit any needed changes, then the instructions from the new guidance should be followed.

In some sections of the draft guidance, the responder cutoff is listed as HIV-1 RNA "< 50copies/mL". This is a carryover from earlier days when the assay limit of detection was 50. Currently approved assays have lower limits. Hence, in implementing the snapshot algorithm, the assay limit of detection will replace the HIV-1 RNA limit of "< 50copies/mL".

The analysis visit windows that appear in Table A of the draft guidance (line 1205) appear to use Day 0 as the start date. Windows that use Day 1 as the start date are in the following table.

Table 9-1: Snapshot Algorithm Analysis Visit Windows

VISIT	Window in Weeks (Weeks indicate end of study week)	Days (Inclusive of start & end points)
Week 24	18 through 30	127 through 210
Week 48	42 through 54	295 through 378
Week 96	90 through 102	631 through 714

Each snapshot analysis includes a summary of virologic outcomes at an analysis visit (e.g., Week 24) that has the same format as Table B (line 1209) of the draft guidance.

Each snapshot analysis may also include a summary of expanded virologic outcomes at an analysis visit. This summary has a similar format to Table B, but also displays the 95% CI for the response category "HIV-1 RNA < 40c/mL", and breaks down the failure category "HIV RNA ≥ 40c/mL" into 4 subcategories. Virologic outcomes are summarized according to the following categories:

- HIV-1 RNA < 40c/mL
- HIV-1 RNA ≥ 40c/mL
  - HIV-1 RNA ≥ 40c/mL in Week 24 window
  - Discontinued study/study drug due to lack of efficacy. This includes subjects who discontinued study therapy due to lack of efficacy at any time from Day 1 through the Week 24 window if this resulted in no on-treatment HIV-1 RNA in the window.
  - Discontinued study/study drug due for other reasons. This includes subjects with last on-treatment HIV-1 RNA ≥ 40c/mL who discontinued study therapy due to any reason except AE, death and lack of efficacy at any time from Day 1 through the Week 24 window if this resulted in no on-treatment HIV-1 RNA in the window.

- No virologic data in Week 24 window
  - Discontinued study/study drug due to AE or death. This includes subjects who discontinued study therapy due to AE or death at any time from Day 1 through the Week 24 window if this resulted in no on-treatment HIV-1 RNA in the window.
  - Discontinued study/study drug for other reasons. This includes subjects with last on-treatment HIV-1 RNA < 40c/mL who discontinued study therapy for other reasons (withdrew consent, lost to follow-up, moved, etc.) at any time from Day 1 through the Week 24 window if this resulted in no on-treatment HIV-1 RNA in the window.
  - On study but missing data in window

Each snapshot analysis may also include a by-subject listing that facilitates finding the subjects in each outcome category. The listing includes: subject ID; age/gender/race; as-randomized treatment group; assessment day; HIV-1 RNA on day of assessment; virologic outcome (HIV-1 RNA < 40c/mL, HIV-1 RNA ≥ 40c/mL, or no virologic data in window); virologic outcome specification (see subcategories in the expanded virologic outcome summary); day of discontinuation of study therapy; and the reason for discontinuation of study therapy. The listing is sorted and paged by treatment group. Within treatment group, the subjects are sorted by virologic outcome and then by the virologic outcome specification.

An analysis data set contains at least the information specified starting on line 1346 (“Datasets for Snapshot Approach”). This analysis data set may contain additional variables, and have multiple uses besides the snapshot analysis.

APPENDIX 2 GENOTYPIC AND PHENOTYPIC RESISTANCE

Genotypic Resistance

Genotypic resistance will be assessed by searching for all:

- RT substitutions
- PI substitutions
- Integrase (IN) substitutions

that are listed in the most current version of the International AIDS Society-USA (IAS-USA) list.

The following table was prepared relative to the IAS-USA list from June/July of 2014[5]. The table describes the categories and subcategories, by which the substitutions will be categorized. In the table below, slashes ("/") between amino acid codes do indicate mixtures. The slashes indicate that any of the amino acids in the list qualify as substitutions.

Table 9-2: Genotypic Substitutions

Category	Description of Relevant Substitutions
Protease Gene	
Any PI substitution	At least one of the PI substitutions listed in the IAS-USA. L10C/F/I/R/V, V11I, G16E, K20I/M/R/T/V, L24I, D30N, V32I, L33F/I/V, E34Q, M36I/L/V, K43T, M46I/L, I47A/V, G48V, I50L/V, F53L/Y, I54A/L/M/S/T/V, Q58E, D60E, I62V, L63P, I64L/M/V, H69K/R, A71I/L/T/V, G73A/C/S/T, T74P, L76V, V77I, V82A/F/I/L/S/T, N83D, I84V, I85V, N88D/S, L89I/M/V, L90M, I93L/M
Major PI Substitutions	Any of the major PI substitutions listed in the IAS-USA D30N, V32I, M46I/L, I47A/V, G48V, I50L/V, I54L/M, Q58E, T74P, L76V, V82A/F/L/S/T, N83D, I84V, N88S, L90M Major PI substitutions are sub-tabulated by codon.
Minor PI Substitutions	Any of the minor PI substitutions listed in the IAS-USA L10C/F/I/R/V, V11I, G16E,

Table 9-2: Genotypic Substitutions

Category	Description of Relevant Substitutions
	K20I/M/R/T/V, L24I , L33F/I/V, E34Q, M36I/L/V, K43T, F53L/Y, I54A/S/V/T, D60E, I62V, L63P, I64L/M/V, H69K/R, A71I/L/T/V, G73A/C/S/T, V77I, V82I, I85V, N88D, L89I/M/V, I93L/M Minor PI substitutions are sub-tabulated by codon.
Reverse Transcriptase Gene Any RT substitution	At least one of the nRTI or NNRTI substitutions listed in the IAS-USA. RT substitutions are sub-tabulated into nRTI and NNRTI substitutions.
nRTI	At least one of the nRTI substitutions listed in the IAS-USA nRTI substitutions are further sub-tabulated into: 69 Insertion Complex, 151 Complex, TAMS and Other.
69 insertion complex	Substitution at codon 69 with a double amino acid insertion and at least one of the following: M41L, A62V, K70R, L210W, T215Y/F, K219Q/E
151 complex	Q151M and at least one of the following: A62V, V75I, F77L, F116Y
Thymidine Analogue-Associated Mutations (TAMS)	At least one of the following: M41L, D67N, K70R, L210W, T215Y/F, K219Q/E
Other	At least one of the other nRTI substitutions not covered above: K65R/E/N, K70E, L74V, Y115F, M184V/I
NNRTI	At least one of the substitutions listed in the IAS-USA for any of the NNRTIs: V90I, A98G, L100I, K101E/H/P, K103N/S,V106A/I/M, V108I, E138A/G/K/Q/R, V179D/F/L/T, Y181C/I/V, Y188C/L/H, G190S/A, H221Y, P225H, F227C, M230I/L. NNRTI substitutions are tabulated by codon.
Integrase Gene Any Integrase Substitutions	At least one of the substitutions listed in the IAS-USA for integrase inhibitors T66I/A/K L74M E92Q/G, T97A

Table 9-2: Genotypic Substitutions

Category	Description of Relevant Substitutions
	F121Y
	E138A/K
	G140A/S
	Y143R/H/C, S147G, Q148H/K/R
	N155H
	Integrase substitutions are tabulated by codon

Phenotypic Resistance

The phenotypic resistance to a drug is defined as a fold change (i.e., ratio of the 50% inhibitory concentration (IC_{50}) of the clinical isolate to the IC_{50} of the reference strain) greater than the cut-off for reduced susceptibility. The following table displays cut-offs used by Monogram Biosciences, Inc. to determine reduced susceptibility to each drug.

The phenotypic resistance status, as determined by Monogram (for ARVs other than BMS-955176) should be available in the clinical database. Hence, programming these cutoffs should be unnecessary.

Note: Monogram may use TFV as a code for tenofovir in phenotypic data files.

Table 9-3: Cut-offs used by Monogram Biosciences to Determine Reduced Susceptibility

Class	Drug	Reduced Susceptibility Cut-off
PI	Atazanovir (ATV)	2.2
	Atazanavir/Ritonavir (ATV/r)	5.2
	Darunavir/Ritonavir (DRV/r)	10
	Fosamprenavir/Ritonavir (AMP/r)	4
	Indinavir/Ritonavir (IDV/r)	10
	Lopinavir/Ritonavir (LPV/r)	9
	Nelfinavir (NFV)	3.6
	Ritonavir (RTV)	2.5
	Saquinavir/Ritonavir (SQV/r)	2.3
	Tipranavir/Ritonavir (TPV/r)	2
NNRTI	Delavirdine (DLV)	6.2
	Efavirenz (EFV)	3
	Etravirine (ETR)	2.9
	Nevirapine (NVP)	4.5

Table 9-3: Cut-offs used by Monogram Biosciences to Determine Reduced Susceptibility

Class	Drug	Reduced Susceptibility Cut-off
	Rilpivirine (RPV)	2.5
NRTI	Abacavir (ABC)	4.5
	Didanosine (ddI)	1.3
	Emtricitabine (FTC)	3.5
	Lamivudine (3TC)	3.5
	Stavudine (d4T)	1.7
	Tenofovir (TDF)	1.4
	Zidovudine (ZDV)	1.9
IN	Raltegravir (RAL)	2.2
	Dolutegravir (DTG)	4
	Elvitegravir (EVG)	3.5

APPENDIX 3 TIME TO LOSS OF VIROLOGIC RESPONSE

This appendix describes the Time to Loss of Virologic Response (TLOVR) algorithm for analyses at Week 24, 48 and 96. The instructions that follow are based on the FDA guidance from 2002[6]. Guidance from the European Union[7] indicates that snapshot analyses should be supplemented by at TLOVR analysis.

For this study, the TLOVR analyses are done on the mITT data sets. The assay limit used in the TLOVR analysis is the limit of detection.

TLOVR has two components, a time-to-failure (life table) analysis, and a tabulation of treatment outcomes at each particular time point (e.g. Week 24).

The time to failure data are analyzed using the Kaplan-Meier method. The presentation will include a K-M curve, estimates of the response rates at the end of weeks 24, 48 and 96 and 95% confidence intervals for the estimate. The time-to-failure analysis is based on the following rules (FDA, 2002):

- "For 2 and 3 below, discard all visits with no data. In what follows, visit means visit with an observed viral load. All available visits, including off-schedule visits and post-week 96 visits, should be used for the calculation. Data should not be interpolated for visits or time points with missing data.
- Subjects who never achieved confirmed HIV RNA levels below the assay limit (on two consecutive visits) before any of the following events will be considered to have failed at time 0.
  a) Death
  b) Introduction of a new antiretroviral drug to the regimen. Exceptions may be made for certain pre-specified changes in background therapy where the reason for change is due to toxicity or intolerance of background therapy and not the study drug or control.
  c) Last available visit
- For all subjects who have confirmed HIV RNA levels below an assay limit (two consecutive visits below an assay limit), the time to failure is the earliest of the choices below, with modification specified in 4:
  a) Time of the event as described in 2b
  b) Time of loss to follow-up
  c) Time of confirmed levels above an assay limit. Confirmed is defined as two consecutive visits greater than an assay limit or one visit greater than an assay limit followed by loss to follow-up.
  d) Time of death
- If the time to virologic failure defined above is immediately preceded by a single missing scheduled visit or multiple consecutive missing scheduled visits, the time of virologic failure is replaced by the time of the first such missing visit."

The tabulation of treatment outcomes shows the proportions of success and failure for various reasons. For a subject, the reason for failure is based on the primary reason for the earliest treatment failure. For any visit, subjects who achieved confirmed virologic success, defined as two consecutive visits below the assay limit of detection, but have not failed according the above loss of virologic success algorithm are considered successes. All others should be classified into the appropriate categories, which are shown in the FDA draft guidance.

The visit windows used in tabulating treatment outcomes are the same visit windows used for the snapshot algorithm. For subjects who failed for multiple reasons at the earliest time of failure, the precedence of failure classification is: death, virologic rebound and then premature discontinuation. For example, if virologic rebound and premature discontinuation occur on the same day, then the reason for failure is virologic rebound.

APPENDIX 4 EQ-5D-3L SCORING PROGRAM - U.S. WEIGHTED

This SAS scoring algorithm was downloaded on January 20, 2015 from:

http://archive.ahrq.gov/professionals/clinicians-providers/resources/rice/EQ5Dscore.html

```
/* EQ-5D U.S. PREFERENCE-WEIGHTED INDEX */

/* Author: PPD */
/* Date:  May 20, 2004 */

/* Program was written with SAS Release 8.02 for Windows. */

/* The scoring algorithm presented below was taken from:  Shaw JW, Johnson JA, Coons SJ.
U.S. Valuation of the EQ-5D Health States:  Development and Testing of the D1 Valuation Model.
Medical Care. Submitted 2004. */

/* This program computes the U.S. preference-weighted index score using self-reported EQ-5D data.
It is presumed that the data set includes the following five variables:

Dimension               Variable Name     Range
-------------------------------------------------
Mobility                MO                1-3
Self-care               SC                1-3
Usual activities        UA                1-3
Pain/discomfort         PD                1-3
Anxiety/depression      AD                1-3
-------------------------------------------------

where a 1 indicates no problems, a 2 indicates moderate problems, and a 3 indicates severe
problems.  The variables containing responses for the five dimensions must be named as above
(in capital letters).  Missing values should be left blank (ie, a '.' should not be substituted
for a missing value).  The index score will not be generated when responses are missing for 1 or
more of the five dimensions.

In the data step, the user should specify the location (LIBNAME) and name of the data set to
be analyzed (DATANAME).  It is recommended that the index values be saved to a new data set
(NEWDATANAME) in the desired library. */

/* SAS Data Step */

data LIBNAME.DATANAME ; set LIBNAME.NEWDATANAME ;
```

```
/* Generate Dummy Variables for Levels 2 and 3 of Five Dimensions */

m1 =0 ;
m2 =0 ;
s1 =0 ;
s2 =0 ;
u1 =0 ;
u2 =0 ;
p1 =0 ;
p2 =0 ;
a1 =0 ;
a2 =0 ;

if MO = 2 then m1 = 1 ;
if MO = 3 then m2 = 1 ;
if SC = 2 then s1 = 1 ;
if SC = 3 then s2 = 1 ;
if UA = 2 then u1 = 1 ;
if UA = 3 then u2 = 1 ;
if PD = 2 then p1 = 1 ;
if PD = 3 then p2 = 1 ;
if AD = 2 then a1 = 1 ;
if AD = 3 then a2 = 1 ;

/* Generate Interaction Terms (I2, I2-squared, I3, I3-squared) */

m0 = 0 ;
s0 = 0 ;
u0 = 0 ;
p0 = 0 ;
a0 = 0 ;

if m1 = 0 and m2 = 0 then m0 = 1 ;
if s1 = 0 and s2 = 0 then s0 = 1 ;
if u1 = 0 and u2 = 0 then u0 = 1 ;
if p1 = 0 and p2 = 0 then p0 = 1 ;
if a1 = 0 and a2 = 0 then a0 = 1 ;

i2 = m1 + s1 + u1 + p1 + a1 ;
i2 = i2 - 1 ;
if i2<0 then i2 = 0 ;
i22 = i2*i2 ;

i3 = m2 + s2 + u2 + p2 + a2 ;
i3 = i3 - 1 ;
if i3<0 then i3 = 0 ;
i32 = i3*i3 ;

/* Generate D1 Term */

i1 = m0 + s0 + u0 + p0 + a0 ;
d1 = 4 - i1 ;
if d1<0 then d1 = 0 ;
```

```
/* Generate Raw Index Score */

pred = .146016*m1 + .557685*m2 + .1753425*s1 + .4711896*s2 + .1397295*u1 + .3742594*u2 + .1728907*p1 + .5371011*p2 + .156223*a1 +
.4501876*a2 + -.1395949*d1 + .0106868*i22  + -.1215579*i3 + -.0147963*i32 ;
EQ_index = 1 - pred ;
if (MO = .) or (SC = .) or (UA = .) or (PD = .) or (AD = .) then EQ_index = .  ;/* Drop Variables Generated by Program */

drop m1 m2 s1 s2 u1 u2 p1 p2 a1 a2 m0 s0 u0 p0 a0 i2 i22 i3 i32 d1 pred nvector ;
run ;
```

APPENDIX 5 EQ-5D-3L SCORING PROGRAM - U.K. WEIGHTED

The following SAS code is an example of computing UK centric utility scores. The code was taken from the BMS SAP for study CN162-007[2].

```
utility = 1;
if mobility=1 then mob=0;
else if mobility=2 then mob=-0.069;
else if mobility=3 then mob=-0.314;

if selfcare=1 then self=0;
else if selfcare=2 then self=-0.104;
else if selfcare=3 then self=-0.214;

if usualact=1 then usual=0;
else if usualact=2 then usual=-0.036;
else if usualact=3 then usual=-0.094;

if paindis=1 then pain=0;
else if paindis=2 then pain=-0.123;
else if paindis=3 then pain=-0.386;

if anxdep=1 then anxiety=0;
else if anxdep=2 then anxiety=-0.071;
else if anxdep=3 then anxiety=-0.236;

utility = utility + mob + self + usual + pain + anxiety;

if mobility in (2,3) or selfcare in (2,3) or usualact in (2,3) or paindis in (2,3) or anxdep in (2,3)
then utility = utility - 0.081;

if mobility=3 or selfcare=3 or usualact=3 or paindis=3 or anxdep=3 then utility = utility -0.269;
```

10 REFERENCES

1. Guidance for industry: Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment. US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER). Draft Guidance. June, 2013.
2. Statistical Analysis Plan for CN162-007, version 2, BMS DCN 930065069
3. Shaw, J.W., et al, 2005, "US Valuation of the EQ-5D Heath States Development and Testing of the D1 Valuation Model", Medical Care, vol. 43, no. 3, 203-220.
4. Dolan P. (1997). Modeling valuations for EuroQol health states, Medical Care, 35, 1095-1108
5. Johnson V, et al., Update of the Drug Resistance Mutations in HIV-1. Topics in HIV Medicine 2013; 21 (1): 4 - 12.
6. Guidance for industry: Antiretroviral Drugs Using Plasma HIV RNA Measurements - Clinical Considerations for Accelerated and Traditional Approval. US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER). October, 2002.
7. Guideline on the clinical development medicinal products for the treatment HIV infection. EMEA/CPMP/EWP/633/02; Rev 3. 2013.

11 DOCUMENT HISTORY

Table 11-1: Document History

Version Number	Author(s)	Description
1.0	PPD	Original version
2.0	PPD	Section 1: update schedule of analyses Section 2.4: add protocol amendment 6 Section 7.2: add relevant protocol deviation related to screening eGFR Section 7.3.2.4: add baseline resistance summaries for treated subjects that are identified as protocol defined virologic failures. Section 7.5.2.5: Include summary for newly emergent phenotypic resistance to BMS-955176. For Gag: add summaries by HIV subtype. Section 7.8: was added to describe the integrated outputs Section 8.1: correct visit window for Weeks 16 and 24, and remove Week 20 Section 9: describe content of the reports in more detail Update Table 10-1 based on 2014 IAS-USA

Appendix to Reporting Analysis Plan for Study AI468048/205892 ---Final Analysis

Compound Number: BMS-955176/GSK3532795

Study Title A Phase 2b Randomized, Active-Controlled, Staged, Open-Label Trial to Investigate Safety and Efficacy of BMS-955176 in Combination with Dolutegravir and Atazanavir (with or without Ritonavir) in Treatment-Experienced HIV-1 Infected Adults

Effective Date: 09 November 2017 (This appendix should be attached to the amendment of Reporting and Analysis Plan for study AI468048/205892 Version 2.0 effective on 15 October 2016).

Description: This appendix describes the plan for the final statistical analyses of study AI468048/205892.

Author's Name, Title and Functional Area:

PPD Data Analyst Statistician, Clinical Statistics

Approved through email by:

PPD Statistics Leader, Clinical Statistics

PPD Director Statistics, Statistics & Programming

PPD Manager, Statistical Programming

PPD Manager, Clinical Data Management

PPD Manager, Clinical Development

PPD Director, Clinical Development, Clinical Investigation Lead

PPD Physician Product Lead

PPD Medical Director/Safety Development Leader, SERM

PPD Head Unit Physician, Medicine Development Leader

PPD Clinical Development Scientist, Operations & Science Leader

TABLE OF CONTENTS

PAGE

1. CHRONOLOGY

15-OCT-2016 Reporting and Analysis Plan for Study AI468048, Version 2.0
09-NOV-2017 Appendix of Analysis Plan for Study AI468048 (Final Analysis)

2. FINAL ANALYSIS

Per the company decision to end this study prior to all subjects reaching the primary endpoint, a simplified approach for the final report has been proposed by the project team. Hence the final analyses for AI468048 study as described in this appendix will be performed on subjects who were enrolled into this study, regardless of study stage, and will supersede what have been previously stated in the finalized BMS RAP Version 2.0. In addition, due to the GCP non-compliance of Site PPD (Dr. Juan Ballesteros in Chile) with ICH GCP E6 (R2) Guidelines, data obtained from this GCP non-compliant site will not be included in the final analyses (e.g., summary tables of selected efficacy and safety data); however, subject data listings will include all subjects enrolled in this study. Subject data listings for the GCP non-compliant Site PPD will also be provided.

The details of the final reporting and analysis plan are described as below:

1) Analysis Populations

   Due to the GCP non-compliance of Site PPD data obtained from this GCP non-compliant site will be excluded in the final analyses.

   Populations for Analyses for this synoptic report are defined as follows:

   - Enrolled subjects are those who signed an informed consent form and were assigned a Patient Identification number (PID).
   - Randomized subjects are enrolled subjects who received a treatment assignment from the IVRS and will be used in subject data listings as specified.
   - Modified Randomized Subjects are enrolled subjects who received a treatment assignment from the IVRS, excluding subjects from Site PPD The modified randomized subjects will be used to assess subject disposition.
   - Treated Subjects are randomized subjects who received at least 1 dose of study therapy and will be used in subject data listings as specified.
   - Modified Treated Subjects are randomized subjects who received at least 1 dose of study therapy, exclude subjects from Site PPD Modified treated subjects will be used to assess demography and baseline characteristics,

protocol deviations, exposure, concomitant medication, efficacy, resistance and safety data.

- Pharmacokinetic (PK) population is defined as all treated subjects who have any available concentration-time data. The evaluable PK population is a sub-population including all treated subjects who have adequate PK profiles.

2) Demographic and baseline characteristic

This report includes the analyses of demographics, baseline characteristics, and baseline resistance data based on Modified Treated Subjects population. Subject data listings will be based on Treated Subjects population.

The detailed outputs for demographic and baseline characteristic data are listed in the Section 3.1 of List of Displays for Study Population.

3) Simplified report on primary efficacy endpoint

Selected summaries and analyses on primary efficacy endpoint will be performed for this final analysis, based on Modified Treated Subjects population. Subject data listings will be based on Treated Subjects population.

The detailed outputs for primary efficacy endpoint data are listed in the Section 3.2 of List of Displays for Efficacy.

4) Secondary and Exploratory Efficacy Endpoints

Analyses for secondary and exploratory efficacy endpoints, including pharmacokinetic and quality of life endpoints, will not be performed except for HIV-1 RNA, CD4+ counts, and drug resistance endpoints (see additional details in Section 3.4, Virology) which are subject to availability of the data and will be analyzed based on Modified Treated Subjects population. There will be no subgroups and no multivariate analysis performed for secondary and exploratory efficacy endpoints for this final analysis. Subject data listings based on Treated Subjects population except PK data which will be based PK population.

The detailed outputs for primary secondary and exploratory efficacy endpoints are listed in the Section 3.2 of List of Displays for Efficacy.

5) Safety displays

Final safety analysis will be summarized based on Modified Treated Subjects population; however, subject data listings will be based on Treated Subjects population. Subject data listings will be based on Treated Subjects population.

The detailed outputs are listed in the Section 3.3 of List of Displays for Safety.

6) Virology

   HIV drug resistance data will be summarized based on Modified Treated Subjects population. Subject data listings will be based on Treated Subjects population.

   The detailed outputs for HIV drug resistance data are listed in the section of List of Display for Virology.

7) General

   The display for TLFs will be based on BMS shells and will not utilize HARP for SAC.

The list of displays has been updated as shown below.

3. LIST OF DISPLAYS

The data displays will be based on the BMS shell as specified in the column of BMS Table number/File Name/BMS Template, where applicable. The details information on BMS shell can be found in the Analysis Data Presentation Plan revision 2.0 for this study.

The following data display numbering will be applied for RAP generated displays:

Section	Tables
Study Population	1.1 to 1.5
Efficacy	2.1 to 2.4
Safety	3.1 to 3.46
Virology	4.1 to 4.9
Section	**Listings**
ICH Listings	1 to 26
Other Listings	27 to 44

3.1. Study Population

3.1.1. Tables

For Table and listing displays, Treated Subjects, Modified Treated Subjects, Randomized Subjects, and Modified Randomized Subjects populations will be used as specified below.

Number	Title	BMS Table number/File Name/BMS Template
1.1	End of Study Subject Status Summary Modified Randomized Subjects	Table S.2.1.1B / rt-ds-statuss1.lst / GS_DS_T_X_005

Number	Title	BMS Table number/File Name/BMS Template
1.2	Populations for Analysis Summary	Table S.2.1.1C / rt-dm-populations1.lst / SS_DM_T_002
1.3	Demographic Characteristics Summary Modified Treated Subjects	Table S.3.1.1 / rt-dm-summarys1.lst / GS_DM_T_X_002
1.4	Summary of Baseline Disease Characteristics Modified Treated Subjects	Table S.3.2.1 / rt-dm-diseases1.lst / SS_DM_T_004
1.5	Summary of Baseline Physical Measurements Modified Treated Subjects	Table S.3.3.1 / rt-pm-bsls1.lst / GS_PM_T_X_001

3.1.2. ICH Listings

Number	Title	BMS Table number/File Name/BMS Template
1	End of Study Subject Status Randomized Subjects	Appendix 2.1.1B / rl-ds-statuss1.lst / GS_DS_L_X_005
2	Randomization Scheme and Codes Randomized Subjects	Appendix 1.9.1 / rl-ds-randcode.lst / SS_DS_L_001
3	Subjects Excluded from Analysis Treated Subjects	Appendix 2.2.1 / rl-dm-excls1.lst / SS_DM_L_001
4	Listing of Relevant Protocol Deviations Randomized Subjects	Table S.2.3.1B / rl-pd-rels1.lst / SS_PD_L_001
5	Demographic Characteristics Treated Subjects	Appendix 3.1.1A / rl-dm-demchars1.lst / GS_DM_L_X_001

Number	Title	BMS Table number/File Name/BMS Template
6	Non-Study Medication Previous and Concomitant Medications Treated Subjects	Appendix 4.2.1 / rl-cm-meds1.lst / GS_CM_L_X_006

3.1.3. Other Listings

Number	Title	BMS Table number/File Name/BMS Template
27	Listing of Batch Numbers Treated Subjects	Appendix 1.7.1 / rl-ex-batch.lst / SS_EX_L_001
28	Summary of Baseline Disease Characteristics Subjects Enrolled but Not Randomized	Appendix 3.2.1A / rt-dm-diseasenrands1.lst / SS_DM_T_004
29	Listing of HIV Disease Characteristics Treated Subjects	Appendix 3.2.1B / rl-dm-diseases1.lst / SS_DM_L_002
30	Physical Examination Treated Subjects	Appendix 3.4.1 / rl-pe-lists1.lst / GS_PE_L_X_001
31	General Medical History Treated Subjects	Appendix 3.7.1 / rl-mh-list1.lst / GS_MH_L_X_001

3.2. Efficacy

Summary and analyses for primary efficacy data, secondary efficacy data and exploratory efficacy data, unless indicated in Section 3.2.1 below, will not be presented for the final analysis except for HIV Drug Resistance data from Modified Treated Subjects who underwent resistance testing will be summarized and presented, see additional details in Section 3.4.

Subject data listings will be provided for primary efficacy data, secondary efficacy data, exploratory efficacy data, and available plasma concentration data based on Treated Subjects population in Sections 3.2.2 and 3.2.3.

3.2.1. Tables

Number	Title	BMS Table number/File Name/BMS Template
2.1	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 Snapshot Modified Treated Subjects	Table S.5.1.1A / rt-vl-resp40w24s1.lst / SS_VL_T_001
2.2	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders by Scheduled Assessments Over Time Modified Treated Subjects (Observed)[1]	Table S.5.1.1E / rt-vl-resp40w24obssubgs1.lst / SS_VL_T_003 (By Weeks 24, 48, and 96 instead of By Subgroup)
2.3	Summary Statistics for Values and Change from Baseline Over Time CD4 Cell Count (cells/uL) Modified Treated Subjects (Observed)[1]	Table S.5.7.1A / rt-lb-cd4s1.lst / SS_VL_T_006 (Without “By Subgroup”)
2.4	Summary Statistics for Values and Change from Baseline Over Time CD4 Cell Percentage Modified Treated Subjects (Observed)[1]	Table S.5.8.1A / rt-lb-cd4pcts1.lst / SS_VL_T_006 (Without “By Subgroup”)

Number	Title	BMS Table number/File Name/BMS Template

1 Add the following footnote to the tables 2.2-2.4:

Note: Modified Treated Subjects (Observed): Consisting of subjects in the Treated Subjects Population excluding subjects who have no HIV-1 RNA result data in the assessment visit windows due to discontinuation and who discontinued on or after the date of site notification of study termination by the sponsor [October 10, 2016], will be used to evaluate efficacy in a sensitivity analysis.

3.2.2. ICH Listings

Number	Title	BMS Table number/File Name/BMS Template
7	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis Data for Subjects in the Week 24 Snapshot Treated Subjects	Appendix 5.1.1A / rl-vl-outcome24s1.lst / SS_VL_L_004

3.2.3. Other Listings

Number	Title	BMS Table number/File Name/BMS Template
32	Listing of HIV-1 RNA Treated Subjects	Appendix 5.1.1D / rl-vl-vllist1.lst / SS_VL_L_005
33	Listing of CD4+ and CD8+ T- Cell Count and Percentages Treated Subjects	Appendix 5.1.1E / rl-lb-cd4cd81.lst / SS_VL_L_005
34	Listing of BMS-955176 Plasma Concentration – Time Data PK Population	Appendix 8.2.1A / rl-pk-cpar1bmss1.lst / MS_PK_L_001
35	Listing of ATV Plasma Concentration – Time Data PK Population	Appendix 8.2.1B / rl-pk-cpar1atvs1.lst / MS_PK_L_001

Number	Title	BMS Table number/File Name/BMS Template
36	Listing of DTG Plasma Concentration – Time Data PK Population	Appendix 8.2.1C / rl-pk-cpar1dtgs1.lst / MS_PK_L_001

3.3. Safety

The Modified Treated Subjects population will be used in the safety summaries and analyses. All treated subjects will be used in the data listings. Subject data listings will be based on Treated Subjects population.

3.3.1. Tables

Number	Title	BMS Table number/File Name/BMS Template
3.1	Extent of Exposure to BMS-955176 Time on Therapy Modified Treated Subjects	Table S.4.1.1A / rt-ex-bmss1.lst / SS_EX_T_001
3.2	Extent of Exposure to Tenofovir Time on Therapy Modified Treated Subjects	Table S.4.1.1B / rt-ex-tdfs1.lst / SS_EX_T_001
3.3	Extent of Exposure to Atazanavir Time on Therapy Modified Treated Subjects	Table S.4.1.1C / rt-ex-atvs1.lst / SS_EX_T_001
3.4	Extent of Exposure to Dolutegravir Time on Therapy Modified Treated Subjects	Table S.4.1.1D / rt-ex-dtgs1.lst / SS_EX_T_001
3.5	Extent of Exposure to Ritonavir Time on Therapy Modified Treated Subjects	Table S.4.1.1E / rt-ex-rtvs1.lst / SS_EX_T_001
3.6	Extent of Exposure to Treatment Regimen Time on Therapy Modified Treated Subjects	Table S.4.1.1F / rt-ex-regimens1.lst / SS_EX_T_001
3.7	Adverse Events Overall Adverse Events Summary Modified Treated Subjects	Table S.6.7.1 rt-ae-overallsums1.lst SS_AE_T_001
3.8	Summary of Serious Adverse Events Modified Treated Subjects	Table S.6.2.1A / rt-ae-saes1.lst / GS_AE_T_X_001
3.9	Summary of Serious Adverse Event With Death As An Outcome Modified Treated Subjects	Table S.6.2.1C / rt-ae-saeldeaths1eu.lst / GS_AE_T_X_001

Number	Title	BMS Table number/File Name/BMS Template
3.10	Summary of Drug Related Serious Adverse Event With Death As An Outcome Modified Treated Subjects	Table S.6.2.2D / rt-ae-relsaeldeaths2eu.lst / GS_AE_T_X_001
3.11	Listing of Serious Adverse Events Modified Treated Subjects	Table S.6.2.1E / rl-ae-saes1.lst / GS_AE_L_S_001
3.12	Death Listing Enrolled Subjects	Table S.6.1.1 / rl-ae-deaths1.lst / SS_AE_L_001
3.13	Summary of Adverse Events Leading to Discontinuation of Study Medication Modified Treated Subjects	Table S.6.3.1A / rt-ae-aediscs1.lst / GS_AE_T_X_001
3.14	Listing of Adverse Event Leading to Discontinuation of Study Medication Modified Treated Subjects	Table S.6.3.1C / rl-ae-discs1.lst / GS_AE_L_X_001
3.15	Summary of Non-Serious Adverse Events Occurring in at Least 5 Percent of Treated Subjects Modified Treated Subjects	Table S.6.5.1A / rt-ae-nsae5pcts1.lst / GS_AE_T_X_001
3.16	Summary of Grade 1 to 4 Adverse Events Modified Treated Subjects	Table S.6.5.1B / rt-ae-grade1to4s1.lst / GS_AE_T_X_001
3.17	Summary of Grade 2 to 4 Adverse Events Modified Treated Subjects	Table S.6.5.1C / rt-ae-grade2to4s1.lst / GS_AE_T_X_001
3.18	Summary of Grade 3 to 4 Adverse Events Modified Treated Subjects	Table S.6.5.1D / rt-ae-grade3to4s1.lst / GS_AE_T_X_001
3.19	Summary of Grade 1 to 4 Related Adverse Events Modified Treated Subjects	Table S.6.5.1E / rt-ae-relateds1.lst / GS_AE_T_X_001

Number	Title	BMS Table number/File Name/BMS Template
3.20	Summary of Grade 2 to 4 Related Adverse Events Modified Treated Subjects	Table S.6.5.1F / rt-ae-relgrade2to4s1.lst / GS_AE_T_X_001
3.21	Summary of Grade 3 to 4 Related Adverse Events Modified Treated Subjects	Table S.6.5.1G / rt-ae-relgrade3to4s1.lst / GS_AE_T_X_001
3.22	Summary of CDC Class C AIDS Events Modified Treated Subjects	Table S.6.4.1A / rt-ae-cdcaes1.lst / GS_AE_T_X_001
3.23	Listing of Adverse Event CDC Class C AIDS Events Modified Treated Subjects	Table S.6.4.1B / rl-ae-cdcaes1.lst / GS_AE_L_X_001
3.24	Summary of Gastrointestinal Events of Special Interest Modified Treated Subjects	Table S.6.4.1C / rt-ae-giaes1.lst / GS_AE_T_X_001
3.25	Listing of Adverse Event Gastrointestinal Events of Special Interest Modified Treated Subjects	Table S.6.4.1D / rl-ae-giaes1.lst / GS_AE_L_X_001
3.26	Summary of Worst Toxicity Grade Modified Treated Subjects	Table S.7.1.1A / rt-lb-toxs1.lst / SS_LB_T_001
3.27	Summary of Grade 3-4 Toxicity Modified Treated Subjects	Table S.7.1.1B / rt-lb-g34toxs1.lst / SS_LB_T_001
3.28	Summary of Treatment-Emergent Abnormalities Modified Treated Subjects	Table S.7.1.1C / rt-lb-etoxs1.lst / SS_LB_T_001
3.29	Summary Statistics for Renal Function Values and Change from Baseline - SI Units Modified Treated Subjects	Table S.7.2.1A / rt-lb-renals1.lst / SS_VL_T_006

Number	Title	BMS Table number/File Name/BMS Template
3.30	Summary Statistics for Renal Function Values and Change from Baseline - US Units Modified Treated Subjects	Table S.7.2.1B / rt-zl-renals1.lst / SS_VL_T_006
3.31	Summary Statistics for Fasting Lipid Values and Change from Baseline - SI Units Modified Treated Subjects	Table S.7.2.1C / rt-lb-lipidss1.lst / SS_VL_T_006
3.32	Summary Statistics for Fasting Lipid Values and Change from Baseline - US Units Modified Treated Subjects	Table S.7.2.1D / rt-zl-lipidss1.lst / SS_VL_T_006
3.33	Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - SI Units Modified Treated Subjects	Table S.7.2.1E / rt-lb-pchglipidss1.lst / SS_VL_T_006
3.34	Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - US Units Modified Treated Subjects	Table S.7.2.1F / rt-zl-pchglipidss1.lst / SS_VL_T_006
3.35	Summary Statistics for Renal Biomarker Values and Change from Baseline - US Units Modified Treated Subjects	Table S.7.5.1A / rt-zl-bmrenals1.lst / SS_VL_T_006
3.36	Summary Statistics for Renal Biomarker Values and Change from Baseline - SI Units Modified Treated Subjects	Table S.7.5.1B / rt-lb-bmrenals1.lst / SS_VL_T_006
3.37	Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - US Units Modified Treated Subjects	Table S.7.5.1C / rt-zl-pchbmrenals1.lst / SS_VL_T_006

Number	Title	BMS Table number/File Name/BMS Template
3.38	Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - SI Units Modified Treated Subjects	Table S.7.5.1D / rt-lb-pchbmrenals1.lst / SS_VL_T_006
3.39	Summary Statistics for Bone Biomarker Values and Change from Baseline - US Units Modified Treated Subjects	Table S.7.5.1E / rt-zl-bmbones1.lst / SS_VL_T_006
3.40	Summary Statistics for Bone Biomarker Values and Change from Baseline - SI Units Modified Treated Subjects	Table S.7.5.1F / rt-lb-bmbones1.lst / SS_VL_T_006
3.41	Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - US Units Modified Treated Subjects	Table S.7.5.1G / rt-zl-pchbmbones1.lst / SS_VL_T_006
3.42	Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - SI Units Modified Treated Subjects	Table S.7.5.1H / rt-lb-pchbmbones1.lst / SS_VL_T_006
3.43	Summary of Electrocardiogram Values and Changes from Baseline over Time Modified Treated Subjects	Appendix 7.3.1A / rt-eg-sumchgs1.lst / SS_EG_T_003
3.44	Summary of Electrocardiogram Change from Baseline Category Modified Treated Subjects	Appendix 7.3.1B / rt-eg-changecats1.lst / SS_EG_T_001
3.35	Summary of Electrocardiogram Category Modified Treated Subjects	Appendix 7.3.1C / rt-eg-cats1.lst / SS_EG_T_002

Number	Title	BMS Table number/File Name/BMS Template
3.46	Summary of Vital Sign Values and Changes from Baseline over Time Modified Treated Subjects	Appendix 7.4.1A / rt-vs-sums1.lst / SS_VL_T_006

3.3.2. ICH Listings

Number	Title	BMS Table number/File Name/BMS Template
8	Listing of Study Medication Exposure by Subject Listing Treated Subjects	Appendix 4.1.1A / rl-ex-lists1.lst / SS_EX_L_001
9	Listing of Adverse Event Treated Subjects	Appendix 6.5.1 / rl-ae-lists1.lst / GS_AEL_X_001
10	Listing of Adverse Event Unique Events Treated Subjects	Appendix 6.6.1 / rl-ae-uniques1.lst / GS_AE_L_U_002
11	Listing of Hematology - SI Units Treated Subjects	Appendix 7.1.1A / rl-lb-hems1.lst / SS_LB_L_001
12	Listing of Liver Function Tests - SI Units Treated Subjects	Appendix 7.1.1B / rl-lb-lfts1.lst / SS_LB_L_001
13	Listing of Enzymes - SI Units Treated Subjects	Appendix 7.1.1C / rl-lb-enzs1.lst / SS_LB_L_001
14	Listing of Renal Function Tests - SI Units Treated Subjects	Appendix 7.1.1D / rl-lb-rfts1.lst / SS_LB_L_001
15	Listing of Electrolytes - SI Units Treated Subjects	Appendix 7.1.1E / rl-lb-elcs1.lst / SS_LB_L_001

Number	Title	BMS Table number/File Name/BMS Template
16	Listing of Fasting Lipids and Glucose – SI Units Treated Subjects	Appendix 7.1.1F / rl-lb-flgs1.lst / SS_LB_L_001
17	Listing of Hematology - US Unit Treated Subjects	Appendix 7.1.1G / rl-zl-hems1.lst / SS_LB_L_001
18	Listing of Liver Function Tests - US Unit Treated Subjects	Appendix 7.1.1H / rl-zl-lfts1.lst / SS_LB_L_001
19	Listing of Enzymes - US Unit Treated Subjects	Appendix 7.1.1I / rl-zl-enzs1.lst / SS_LB_L_001
20	Listing of Renal Function Tests - US Unit Treated Subjects	Appendix 7.1.1J / rl-zl-rfts1.lst / SS_LB_L_001
21	Listing of Electrolytes - US Unit Treated Subjects	Appendix 7.1.1K / rl-zl-elcs1.lst / SS_LB_L_001
22	Listing of Fasting Lipids and Glucose – US Unit Treated Subjects	Appendix 7.1.1L / rl-zl-flgs1.lst / SS_LB_L_001
23	Listing of Differences in Categorization of SI and US Laboratory Test Results Treated Subjects	Appendix 7.1.1M / rl-lb-diffunits1.lst / GS_LB_L_S_008
24	Listing of Pregnancy Test Treated Female Subjects	Appendix 7.1.1N / rl-lb-pregs1.lst / GS_LB_L_X_006
25	Listing of Electrocardiogram Treated Subjects	Appendix 7.3.1D / rl-eg-ecgs1.lst / GS_EG_L_X_001
26	Listing of Vital Signs Treated Subjects	Appendix 7.4.1B / rl-vs-lists1.lst / GS_VS_L_X_006

3.4. Virology

The Modified Treated Subjects population with available virology data will be used in the summaries and analyses. All treated subjects with available virology data will be used in the data listings.

3.4.1. Tables

Number	Title	BMS Table number/File Name/BMS Template
4.1	Baseline Genotypic Resistance Profile Modified Treated Subjects	Table S.3.9.1A / rt-gn-bases1.lst / SS_GN_T_001
4.2	Baseline Gag Polymorphisms at Selected Positions Modified Treated Subjects	Table S.3.9.1C / rt-gn-bslgags1.lst / SS_GN_T_002
4.3	Baseline Gag Polymorphisms at Selected Positions Modified Treated Subjects Identified as Protocol Defined Virologic Failures	Table S.3.9.1J / rt-gn-bslgagpdvfs1.lst / SS_GN_T_002
4.4	Newly Emergent Genotypic Resistance Profile Modified Treated Subjects with On-Treatment Genotypic Resistance Testing	Table S.5.10.1A / rt-gn-news1.lst / SS_GN_T_001
4.5	Newly Emergent Genotypic Resistance Profile Modified Treated Subjects Identified as Protocol Defined Virologic Failures	Table S.5.10.1B / rt-gn-newpdvfs1.lst / SS_GN_T_001
4.6	Emergent Gag Polymorphisms at Selected Positions Modified Treated Subjects with On-Treatment Gag Sequencing	Table S.5.10.1C / rt-gn-newgags1.lst / SS_GN_T_002
4.7	Emergent Gag Polymorphisms at Selected Positions Modified Treated Subjects Identified as Protocol Defined Virologic Failures	Table S.5.10.1D / rt-gn-newgagpdvfs1.lst / SS_GN_T_002

Number	Title	BMS Table number/File Name/BMS Template
4.8	Newly Emergent Phenotypic Resistance Profile Modified Treated Subjects with On-Treatment Phenotypic Resistance Profile	Table S.5.10.1G / rt-pn-news1.lst / SS_PN_T_001
4.9	Newly Emergent Phenotypic Resistance Profile Modified Treated Subjects Identified as Protocol Defined Virologic Failures	Table S.5.10.1H / rt-pn-newpdvfs1.lst / SS_PN_T_001

3.4.2. Other Listings

Number	Title	BMS Table number/File Name/BMS Template
37	Listing of Baseline Genotypic Substitutions Treated Subjects	Appendix 3.9.1B / rl-gn-bsls1.lst / SS_GN_L_001
38	Listing of Baseline Gag Polymorphisms at Selected Positions Treated Subjects	Appendix 3.9.1C / rl-gn-gagbsls1.lst / SS_GN_L_002
39	Listing of Baseline Gag Deviations from Wild Type Virus Treated Subjects	Appendix 3.9.1D / rl-gn-gagbslanys1.lst / SS_GN_L_003
40	Listing of Protocol Defined Virologic Failures Treated Subjects	Not Available / rl-vl-pdvf.lst / SS_VL_L_006
41	Listing of Genotypic Substitutions Treated Subjects with Baseline and On-Treatment Data	Appendix 5.10.1A / rl-gn-ontrts1.lst / SS_GN_L_001
42	Listing of Gag Polymorphisms at Selected Positions Treated Subjects with Baseline and On-Treatment Data	Appendix 5.10.1B / rl-gn-gagontrts1.lst / SS_GN_L_002

Number	Title	BMS Table number/File Name/BMS Template
43	Listing of Newly Emergent Gag Deviations Treated Subjects with Baseline and On-Treatment Data	Appendix 5.10.1C / rl-gn-gagontrts1.lst / SS_GN_L_003
44	Listing of Phenotypic Resistance Treated Subjects with Baseline and On-Treatment Data	Appendix 5.10.1D / rl-pn-ontrt1.lst / SS_PN_L_001

GLOBAL BIOMETRIC SCIENCES
ANALYSIS DATA PRESENTATION PLAN

BMS-955176
HIV MATURATION INHIBITOR
CLINICAL STUDY REPORT FOR AI438-048

DOCUMENT REVISION: 2.0

NEW or MODIFIED **DATA PRESENTATION PLAN** APPROVAL PAGE

DPP for AI468-048 CSR

Version 2.0

☐**Initial Version (1.0)** X **Significant Revision (2.0, etc.)** ☐**Minor Revision (1.1, etc.)**

Prepared by:	PPD Statistician	PPD	Oct 6, 2015 Date
	PPD Statistical Programmer	Signature	Date

Approved by: (Minor changes are approved by Statistician per signature above)

X Study-Specific DPP	PPD GBS Lead or ED Statistical Lead	Signature	Date
	PPD Medical Lead*	Signature	Date
☐ Periodic Safety Update DPP	GBS Lead or ED Statistical Lead	Signature	Date
	Medical Surveillance Team Chair, GPV&E	Signature	Date
☐ Event-Based DPP	GBS Lead or ED Statistical Lead	Signature	Date
☐ Core or Integrated DPP	GBS Lead	Signature	Date
	Medical Lead	Signature	Date
	TA Head, GBS	Signature	Date
	Development Lead	Signature	Date
☐ Summary of Clinical Pharmacology DPP	TA Head, CP&P	Signature	Date
	TA Head, ED GBS	Signature	Date
☐ ECTR Standard DPP	GBS Head of ED or designee	Signature	Date
	VP, ECTR or designee	Signature	Date

**(For ECTR Studies, if there is no Medical Lead, secure approval from the TA Head for Discovery Medicine or Clinical Pharmacology & Pharmacometrics according to the functional area of the Study Director or his/her designee)*

NEW or MODIFIED **DATA PRESENTATION PLAN** APPROVAL PAGE

DPP for AI468-048 CSR

Version 2.0

☐Initial Version (1.0) X Significant Revision (2.0, etc.) ☐Minor Revision (1.1, etc.)

Prepared by:

PPD			
Statistician		Signature	Date
PPD		PPD	Oct 15, 2015
Statistical Programmer		Signature	Date

Approved by: (Minor changes are approved by Statistician PPD

X Study-Specific DPP	PPD GBS Lead or ED Statistical Lead		Oct 15, 2015 Date
	PPD Medical Lead*	Signature	Date
☐ Periodic Safety Update DPP	GBS Lead or ED Statistical Lead	Signature	Date
	Medical Surveillance Team Chair, GPV&E	Signature	Date
☐ Event-Based DPP	GBS Lead or ED Statistical Lead	Signature	Date
☐ Core or Integrated DPP	GBS Lead	Signature	Date
	Medical Lead	Signature	Date
	TA Head, GBS	Signature	Date
	Development Lead	Signature	Date
☐ Summary of Clinical Pharmacology DPP	TA Head, CP&P	Signature	Date
	TA Head, ED GBS	Signature	Date
☐ ECTR Standard DPP	GBS Head of ED or designee	Signature	Date
	VP, ECTR or designee	Signature	Date

**(For ECTR Studies, if there is no Medical Lead, secure approval from the TA Head for Discovery Medicine or Clinical Pharmacology & Pharmacometrics according to the functional area of the Study Director or his/her designee)*

NEW or MODIFIED **DATA PRESENTATION PLAN** APPROVAL PAGE

DPP for AI468-048 CSR

Version 2.0

☐**Initial Version (1.0)** X **Significant Revision (2.0, etc.)** ☐**Minor Revision (1.1, etc.)**

Prepared by:	PPD		
	Statistician	Signature	Date
	PPD		
	Statistical Programmer	Signature	Date

Approved by: (Minor changes are approved by Statistician per signature above)

X Study-Specific DPP	PPD		
	GBS Lead or ED Statistical Lead	Signature	Date
	PPD	PPD	10-15-15
	Medical Lead*	Signature	Date
☐ Periodic Safety Update DPP			
	GBS Lead or ED Statistical Lead	Signature	Date
	Medical Surveillance Team Chair, GPV&E	Signature	Date
☐ Event-Based DPP			
	GBS Lead or ED Statistical Lead	Signature	Date
☐ Core or Integrated DPP			
	GBS Lead	Signature	Date
	Medical Lead	Signature	Date
	TA Head, GBS	Signature	Date
	Development Lead	Signature	Date
☐ Summary of Clinical Pharmacology DPP			
	TA Head, CP&P	Signature	Date
	TA Head, ED GBS	Signature	Date
☐ ECTR Standard DPP			
	GBS Head of ED or designee	Signature	Date
	VP, ECTR or designee	Signature	Date

REVISION HISTORY

Revision	Date	Revised By	Changes Made -- Reasons for the Change
1.0	July 16, 2015	PPD	Original issue
2.0	Oct 6, 2015	PPD	Additional outputs for baseline resistance have been added based on the revised SAP v2.0 (see Tables S.3.9.xH-R) Additional outputs for on-treatment resistance have been added based on the revised SAP v2.0 (see Tables S.5.10.xR-W). Integrated outputs have been added as described in the revised SAP v2.0. Update the schedule of analysis: Week 48 Stage 1 interim analysis only if continuation dose cannot be selected based on Week 24, Stage 1 results. The Week 96 Stage 1 will be performed at the time of Week 24 Stage 2.

TABLE OF CONTENTS

TABLE OF CONTENTS: TEMPLATES

1 LIST OF DATA PRESENTATIONS

1.1 Codes Used for Deliverables

Code	Description
WK24S1	Interim Analysis Week 24, Stage 1
WK48S1	Interim Analysis Week 48, Stage 1*
WK96S1	Final Analysis Week 96, Stage 1 (most likely at the time of Interim Analysis Week 24, Stage 2)
WK24S2	Interim Analysis Week 24, Stage 2
WK48S2	Interim Analysis Week 48, Stage 2
WK96S2	Final Analysis Week 96, Stage 2

*** The Week 48, Stage 1 interim analysis would only be performed in case a continuation dose cannot be selected based on the Week 24, Stage 1 interim analysis.**

Note: in order to make the distinction between the different database locks for each stage, the table numbers should have '-Wkxx' attached to the table numbers mentioned in the rest of the DPP. For example, Table S.2.3.1A will become Table S.2.3.1A-Wk24 for the Stage 1 Week 24 interim analysis. Table S.2.3.2A will become Table S.2.3.2A-Wk48 for the Stage 2 Week 48 analysis.

1.2 List

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
1	Appendix 1.7.1	rl-ex-batchs1.lst	SS_EX_L_001	Listing of Batch Numbers Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
2	Appendix 1.7.2	rl-ex-batchs2.lst	SS_EX_L_001	Listing of Batch Numbers Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
3	Appendix 1.9.1	rl-ds-randcodes1.lst	SS_DS_L_001	Randomization Scheme and Codes Randomized Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
4	Appendix 1.9.2	rl-ds-randcodes2.lst	SS_DS_L_001	Randomization Scheme and Codes Randomized Subjects - Stage 2	WK24S2, WK48S2, WK96S2
5	Appendix 2.1.1E	rt-dm-accruals1.lst	SS_DM_T_001	Accrual Summary Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
6	Appendix 2.1.2E	rt-dm-accruals2.lst	SS_DM_T_001	Accrual Summary Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
7	Table S.2.3.1A	rt-pd-rels1.lst	SS_PD_T_001	Relevant Protocol Deviation Summary Randomized Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
8	Table S.2.3.2A	rt-pd-rels2.lst	SS_PD_T_001	Relevant Protocol Deviation Summary Randomized Subjects - Stage 2	WK24S2, WK48S2, WK96S2
9	Table S.2.3.1B	rl-pd-rels1.lst	SS_PD_L_001	Listing of Relevant Protocol Deviations Randomized Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
10	Table S.2.3.2B	rl-pd-rels2.lst	SS_PD_L_001	Listing of Relevant Protocol Deviations Randomized Subjects - Stage 2	WK24S2, WK48S2, WK96S2
11	Table S.2.1.1A	rt-ds-prerands1.lst	GS_DS_T_T_001	Pre-Randomization Subject Status Enrolled Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
12	Table S.2.1.2A	rt-ds-prerands2.lst	GS_DS_T_T_001	Pre-Randomization Subject Status Enrolled Subjects - Stage 2	WK24S2, WK48S2, WK96S2
13	Appendix 2.1.1A	rl-ds-prerands1.lst	GS_DS_L_S_001	Pre-Randomized Subject Status Enrolled Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
14	Appendix 2.1.2A	rl-ds-prerands2.lst	GS_DS_L_S_001	Pre-Randomized Subject Status Enrolled Subjects - Stage 2	WK24S2, WK48S2, WK96S2
15	Appendix 2.1.1C	rt-dm-enrolls1eu.lst	GS_DM_T_T_005	Enrollment Summary Number of Subjects at Each Study Site by Country Enrolled Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
16	Appendix 2.1.2C	rt-dm-enrolls2eu.lst	GS_DM_T_T_005	Enrollment Summary Number of Subjects at Each Study Site by Country Enrolled Subjects - Stage 2	WK24S2, WK48S2, WK96S2
17	Appendix 2.1.1D	rt-dm-enrages1eu.lst	SS_DM_T_002	Enrollment Summary Number of Subjects per Age Group Enrolled Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
18	Appendix 2.1.2D	rt-dm-enrages2eu.lst	SS_DM_T_002	Enrollment Summary Number of Subjects per Age Group Enrolled Subjects - Stage 2	WK24S2, WK48S2, WK96S2
19	Table S.2.1.1B	rt-ds-statuss1.lst	GS_DS_T_X_005	End of Study Subject Status Summary Randomized Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
20	Table S.2.1.2B	rt-ds-statuss2.lst	GS_DS_T_X_005	End of Study Subject Status Summary Randomized Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
21	Table S.2.1.3B	rt-ds-statuss12.lst	GS_DS_T_X_005	End of Study Subject Status Summary Randomized Subjects - Stage 1 and 2	WK96S2
22	Appendix 2.1.1B	rl-ds-statuss1.lst	GS_DS_L_X_005	End of Study Subject Status Randomized Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
23	Appendix 2.1.2B	rl-ds-statuss2.lst	GS_DS_L_X_005	End of Study Subject Status Randomized Subjects - Stage 2	WK24S2, WK48S2, WK96S2
24	Table S.2.1.1C	rt-dm-populations1.lst	SS_DM_T_002	Populations for Analysis Summary - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
25	Table S.2.1.2C	rt-dm-populations2.lst	SS_DM_T_002	Populations for Analysis Summary - Stage 2	WK24S2, WK48S2, WK96S2
26	Appendix 2.2.1	rl-dm-excls1.lst	SS_DM_L_001	Subjects Excluded from Efficacy Analysis (mITT) Randomized Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
27	Appendix 2.2.2	rl-dm-excls2.lst	SS_DM_L_001	Subjects Excluded from Efficacy Analysis (mITT) Randomized Subjects - Stage 2	WK24S2, WK48S2, WK96S2
28	Table S.3.1.1	rt-dm-summarys1.lst	GS_DM_T_X_002	Demographic Characteristics Summary Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
29	Table S.3.1.2	rt-dm-summarys2.lst	GS_DM_T_X_002	Demographic Characteristics Summary Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
30	Table S.3.1.3	rt-dm-summarys12.lst	GS_DM_T_X_002	Demographic Characteristics Summary Treated Subjects - Stage 1 and 2	WK96S2
31	Appendix 3.1.1B	rt-dm-sumenrolls1.lst	GS_DM_T_T_002	Demographic Characteristics Summary Subjects Enrolled but Not Randomized - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
32	Appendix 3.1.2B	rt-dm-sumenrolls2.lst	GS_DM_T_T_002	Demographic Characteristics Summary Subjects Enrolled but Not Randomized - Stage 2	WK24S2, WK48S2, WK96S2
33	Appendix 3.1.1A	rl-dm-demchars1.lst	GS_DM_L_X_001	Demographic Characteristics Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
34	Appendix 3.1.2A	rl-dm-demchars2.lst	GS_DM_L_X_001	Demographic Characteristics Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
35	Table S.3.2.1	rt-dm-diseases1.lst	SS_DM_T_004	Summary of Baseline Disease Characteristics Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
36	Table S.3.2.2	rt-dm-diseases2.lst	SS_DM_T_004	Summary of Baseline Disease Characteristics Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
37	Table S.3.2.3	rt-dm-diseases12.lst	SS_DM_T_004	Summary of Baseline Disease Characteristics Treated Subjects - Stage 1 and 2	WK96S2
38	Appendix 3.2.1A	rt-dm-diseasenrands1.lst	SS_DM_T_004	Summary of Baseline Disease Characteristics Subjects Enrolled but Not Randomized - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
39	Appendix 3.2.2A	rt-dm-diseasenrands2.lst	SS_DM_T_004	Summary of Baseline Disease Characteristics Subjects Enrolled but Not Randomized - Stage 2	WK24S2, WK48S2, WK96S2
40	Appendix 3.2.1B	rl-dm-diseases1.lst	SS_DM_L_002	Listing of HIV Disease Characteristics Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
41	Appendix 3.2.2B	rl-dm-diseases2.lst	SS_DM_L_002	Listing of HIV Disease Characteristics Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
42	Table S.3.3.1	rt-pm-bsls1.lst	GS_PM_T_X_001	Physical Measurements Summary Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
43	Table S.3.3.2	rt-pm-bsls2.lst	GS_PM_T_X_001	Physical Measurements Summary Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
44	Table S.3.4.1	rt-pe-bslsums1.lst	GS_PE_T_X_001	Physical Examination Summary Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
45	Table S.3.4.2	rt-pe-bslsums2.lst	GS_PE_T_X_001	Physical Examination Summary Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
46	Appendix 3.4.1	rl-pe-lists1.lst	GS_PE_L_X_001	Physical Examination Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
47	Appendix 3.4.2	rl-pe-lists2.lst	GS_PE_L_X_001	Physical Examination Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
48	Table S.3.9.1A	rt-gn-bases1.lst	SS_GN_T_001	Baseline Genotypic Resistance Profile Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
49	Table S.3.9.2A	rt-gn-bases2.lst	SS_GN_T_001	Baseline Genotypic Resistance Profile Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
50	Table S.3.9.3A	rt-gn-bases12.lst	SS_GN_T_001	Baseline Genotypic Resistance Profile Treated Subjects - Stage 1 and 2	WK96S2
51	Appendix 3.9.1A	rt-gn-basebysubtypes1.lst	SS_GN_T_001	Baseline Genotypic Resistance Profile By HIV Subtype Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
52	Appendix 3.9.2A	rt-gn-basebysubtypes2.lst	SS_GN_T_001	Baseline Genotypic Resistance Profile By HIV Subtype Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
53	Table S.3.9.1B	rt-gn-baseots1.lst	SS_GN_T_001	Baseline Genotypic Resistance Profile Treated Subjects with On-Treatment Resistance Testing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
54	Table S.3.9.2B	rt-gn-baseots2.lst	SS_GN_T_001	Baseline Genotypic Resistance Profile Treated Subjects with On-Treatment Resistance Testing - Stage 2	WK24S2, WK48S2, WK96S2
55	Appendix 3.9.1B	rl-gn-bsls1.lst	SS_GN_L_001	Listing of Baseline Genotypic Substitutions Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
56	Appendix 3.9.2B	rl-gn-bsls2.lst	SS_GN_L_001	Listing of Baseline Genotypic Substitutions Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
57	Table S.3.9.1C	rt-gn-bslgags1.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
58	Table S.3.9.2C	rt-gn-bslgags2.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
59	Table S.3.9.3C	rt-gn-bslgags12.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions Treated Subjects - Stage 1 and 2	WK96S2
60	Table S.3.9.1D	rt-gn-bslgagbysubtypes1.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
61	Table S.3.9.2D	rt-gn-bslgagbysubtypes2.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
62	Table S.3.9.3D	rt-gn-bslgagbysubtypes12.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects - Stage 1 and 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
63	Table S.3.9.1H	rt-gn-bslgagontrts1.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions Treated Subjects with On-Treatment Resistance Testing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
64	Table S.3.9.2H	rt-gn-bslgagontrts2.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions Treated Subjects with On-Treatment Resistance Testing - Stage 2	WK24S2, WK48S2, WK96S2
65	Table S.3.9.3H	rt-gn-bslgagontrts12.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2	WK96S2
66	Table S.3.9.1I	rt-gn-bslgagontrtbysubtypes1.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects with On-Treatment Resistance Testing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
67	Table S.3.9.2I	rt-gn-bslgagontrtbysubtypes2.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects with On-Treatment Resistance Testing - Stage 2	WK24S2, WK48S2, WK96S2
68	Table S.3.9.3I	rt-gn-bslgagontrtbysubtypes12.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2	WK96S2
69	Table S.3.9.1J	rt-gn-bslgagpdvfs1.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
70	Table S.3.9.2J	rt-gn-bslgagpdvfs2.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
71	Table S.3.9.3J	rt-gn-bslgagpdvfs12.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
72	Table S.3.9.1K	rt-gn-bslgagpdvfbysubtypes1.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
73	Table S.3.9.2K	rt-gn-bslgagpdvfbysubtypes2.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
74	Table S.3.9.3K	rt-gn-bslgagpdvfbysubtypes12.lst	SS_GN_T_002	Baseline Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
75	Table S.3.9.1E	rt-gn-bslgaganys1.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
76	Table S.3.9.2E	rt-gn-bslgaganys2.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
77	Table S.3.9.3E	rt-gn-bslgaganys12.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus Treated Subjects - Stage 1 and 2	WK96S2
78	Table S.3.9.1L	rt-gn-bslgaganybysubtypes1.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus By HIV Subtype Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
79	Table S.3.9.2L	rt-gn-bslgaganybysubtypes2.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus By HIV Subtype Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
80	Table S.3.9.3L	rt-gn-bslgaganybysubtypes12.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus By HIV Subtype Treated Subjects - Stage 1 and 2	WK96S2
81	Table S.3.9.1M	rt-gn-bslgaganyontrts1.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus Treated Subjects with On-Treatment Resistance Testing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
82	Table S.3.9.2M	rt-gn-bslgaganyontrts2.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus Treated Subjects with On-Treatment Resistance Testing - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
83	Table S.3.9.3M	rt-gn-bslgaganyontrts12.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2	WK96S2
84	Table S.3.9.1N	rt-gn-bslgaganyontrtbysubtypes1.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus By HIV Subtype Treated Subjects with On-Treatment Resistance Testing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
85	Table S.3.9.2N	rt-gn-bslgaganyontrtbysubtypes2.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus By HIV Subtype Treated Subjects with On-Treatment Resistance Testing - Stage 2	WK24S2, WK48S2, WK96S2
86	Table S.3.9.3N	rt-gn-bslgaganyontrtbysubtypes12.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus By HIV Subtype Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2	WK96S2
87	Table S.3.9.1O	rt-gn-bslgaganypdvfs1.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
88	Table S.3.9.2O	rt-gn-bslgaganypdvfs2.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
89	Table S.3.9.3O	rt-gn-bslgaganypdvfs12.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
90	Table S.3.9.1P	rt-gn-bslgaganypdvfbysubtypes1.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
91	Table S.3.9.2P	rt-gn-bslgaganypdvfbysubtypes2.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
92	Table S.3.9.3P	rt-gn-bslgaganypdvfbysubtypes12.lst	SS_GN_T_003	Baseline Gag Deviations from Wild Type Virus By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
93	Appendix 3.9.1C	rl-gn-gagbsls1.lst	SS_GN_L_002	Listing of Baseline Gag Polymorphisms at Selected Positions Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
94	Appendix 3.9.2C	rl-gn-gagbsls2.lst	SS_GN_L_002	Listing of Baseline Gag Polymorphisms at Selected Positions Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
95	Appendix 3.9.1D	rl-gn-gagbslanys1.lst	SS_GN_L_003	Listing of Baseline Gag Deviations from Wild Type Virus Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
96	Appendix 3.9.2D	rl-gn-gagbslanys2.lst	SS_GN_L_003	Listing of Baseline Gag Deviations from Wild Type Virus Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
97	Table S.3.9.1F	rt-pn-bsls1.lst	SS_PN_T_001	Baseline Phenotypic Resistance Categories Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
98	Table S.3.9.2F	rt-pn-bsls2.lst	SS_PN_T_001	Baseline Phenotypic Resistance Categories Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
99	Table S.3.9.3F	rt-pn-bsls12.lst	SS_PN_T_001	Baseline Phenotypic Resistance Categories Treated Subjects - Stage 1 and 2	WK96S2
100	Table S.3.9.1G	rt-pn-bslots1.lst	SS_PN_T_001	Baseline Phenotypic Resistance Categories Treated Subjects with On-Treatment Resistance Testing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
101	Table S.3.9.2G	rt-pn-bslots2.lst	SS_PN_T_001	Baseline Phenotypic Resistance Categories Treated Subjects with On-Treatment Resistance Testing - Stage 2	WK24S2, WK48S2, WK96S2
102	Table S.3.9.3G	rt-pn-bslots12.lst	SS_PN_T_001	Baseline Phenotypic Resistance Categories Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2	WK96S2
103	Table S.3.9.1Q	rt-pn-bslpdvfs1.lst	SS_PN_T_001	Baseline Phenotypic Resistance Categories Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
104	Table S.3.9.2Q	rt-pn-bslpdvfs2.lst	SS_PN_T_001	Baseline Phenotypic Resistance Categories Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
105	Table S.3.9.3Q	rt-pn-bslpdvfs12.lst	SS_PN_T_001	Baseline Phenotypic Resistance Categories Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
106	Table S.3.9.1H	rt-pn-bsldrugs1.lst	SS_PN_T_002	Baseline Phenotypic Resistance by Class and Drug Name Treated Subjects - Stage 1	WK24S1, WK48S1 WK96S1, WK96S2
107	Table S.3.9.2H	rt-pn-bsldrugs2.lst	SS_PN_T_002	Baseline Phenotypic Resistance by Class and Drug Name Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
108	Table S.3.9.3H	rt-pn-bsldrugs12.lst	SS_PN_T_002	Baseline Phenotypic Resistance by Class and Drug Name Treated Subjects - Stage 1 and 2	WK96S2
109	Table S.3.9.1I	rt-pn-bslotrtdrugs1.lst	SS_PN_T_002	Baseline Phenotypic Resistance by Class and Drug Name Treated Subjects with On-Treatment Phenotypic Resistance Testing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
110	Table S.3.9.2I	rt-pn-bslotrtdrugs2.lst	SS_PN_T_002	Baseline Phenotypic Resistance by Class and Drug Name Treated Subjects with On-Treatment Phenotypic Resistance Testing - Stage 2	WK24S2, WK48S2, WK96S2
111	Table S.3.9.3I	rt-pn-bslotrtdrugs12.lst	SS_PN_T_002	Baseline Phenotypic Resistance by Class and Drug Name Treated Subjects with On-Treatment Phenotypic Resistance Testing - Stage 1 and 2	WK96S2
112	Table S.3.9.1R	rt-pn-bsldrugpdvfs1.lst	SS_PN_T_002	Baseline Phenotypic Resistance by Class and Drug Name Treated Subjects with On-Treatment Phenotypic Resistance Testing Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
113	Table S.3.9.2R	rt-pn-bsldrugpdvfs2.lst	SS_PN_T_002	Baseline Phenotypic Resistance by Class and Drug Name Treated Subjects with On-Treatment Phenotypic Resistance Testing Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
114	Table S.3.9.3R	rt-pn-bsldrugpdvfs12.lst	SS_PN_T_002	Baseline Phenotypic Resistance by Class and Drug Name Treated Subjects with On-Treatment Phenotypic Resistance Testing Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
115	Appendix 3.9.1E	rl-pn-bsls1.lst	SS_PN_L_001	Listing of Baseline Phenotypic Resistance Treated Subjects - Stage 1	WK24S1, WK48S1 WK96S1, WK96S2
116	Appendix 3.9.2E	rl-pn-bsls2.lst	SS_PN_L_001	Listing of Baseline Phenotypic Resistance Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
117	Table S.3.5.1	rt-lb-bsltoxs1.lst	GS_LB_T_X_004	Baseline Laboratory Test Results Summary of Toxicity Grade Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
118	Table S.3.5.2	rt-lb-bsltoxs2.lst	GS_LB_T_X_004	Baseline Laboratory Test Results Summary of Toxicity Grade Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
119	Table S.3.6.1	rt-ae-preaidss1.lst	GS_AE_T_X_001	Adverse Events Summary Pre-treatment AIDS Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
120	Table S.3.6.2	rt-ae-preaidss2.lst	GS_AE_T_X_001	Adverse Events Summary Pre-treatment AIDS Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
121	Table S.3.7.1	rt-mh-sums1.lst	GS_MH_T_X_001	General Medical History Summary Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
122	Table S.3.7.2	rt-mh-sums2.lst	GS_MH_T_X_001	General Medical History Summary Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
123	Appendix 3.7.1	rl-mh-lists1.lst	GS_MH_L_X_001	General Medical History Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
124	Appendix 3.7.2	rl-mh-lists2.lst	GS_MH_L_X_001	General Medical History Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
125	Table S.3.8.1	rt-cm-premeds1.lst	GS_CM_T_X_001	Non-Study Medication Summary Previous Medication Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
126	Table S.3.8.2	rt-cm-premeds2.lst	GS_CM_T_X_001	Non-Study Medication Summary Previous Medication Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
127	Table S.4.1.1A	rt-ex-bmss1.lst	SS_EX_T_001	Extent of Exposure to BMS-955176 Time on Therapy Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
128	Table S.4.1.2A	rt-ex-bmss2.lst	SS_EX_T_001	Extent of Exposure to BMS-955176 Time on Therapy Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
129	Table S.4.1.1B	rt-ex-tdfs1.lst	SS_EX_T_001	Extent of Exposure to Tenofovir Time on Therapy Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
130	Table S.4.1.2B	rt-ex-tdfs2.lst	SS_EX_T_001	Extent of Exposure to Tenofovir Time on Therapy Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
131	Table S.4.1.1C	rt-ex-atvs1.lst	SS_EX_T_001	Extent of Exposure to Atazanavir Time on Therapy Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
132	Table S.4.1.2C	rt-ex-atvs2.lst	SS_EX_T_001	Extent of Exposure to Atazanavir Time on Therapy Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
133	Table S.4.1.1D	rt-ex-dtgs1.lst	SS_EX_T_001	Extent of Exposure to Dolutegravir Time on Therapy Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
134	Table S.4.1.2D	rt-ex-dtgs2.lst	SS_EX_T_001	Extent of Exposure to Dolutegravir Time on Therapy Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
135	Table S.4.1.1E	rt-ex-rtvs1.lst	SS_EX_T_001	Extent of Exposure to Ritonavir Time on Therapy Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
136	Table S.4.1.2E	rt-ex-rtvs2.lst	SS_EX_T_001	Extent of Exposure to Ritonavir Time on Therapy Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
137	Table S.4.1.1F	rt-ex-regimens1.lst	SS_EX_T_001	Extent of Exposure to Treatment Regimen Time on Therapy Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
138	Table S.4.1.2F	rt-ex-regimens2.lst	SS_EX_T_001	Extent of Exposure to Treatment Regimen Time on Therapy Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
139	Table S.4.1.3F	rt-ex-regimens12.lst	SS_EX_T_001	Extent of Exposure to Treatment Regimen Time on Therapy Treated Subjects - Stage 1 and 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
140	Table S.4.1.1G	rt-ex-conts1.lst	SS_EX_T_001	Extent of Exposure to BMS-955176 after Switch to Continuation Dose Time on Therapy Treated Subjects who Switched to Continuation Dose - Stage 1	WK96S1, WK96S2
141	Table S.4.1.2G	rt-ex-conts2.lst	SS_EX_T_001	Extent of Exposure to BMS-955176 after Switch to Continuation Dose Time on Therapy Treated Subjects who Switched to Continuation Dose - Stage 2	WK96S2
142	Figure S.4.1.1	rg-ex-kms1	GS_EX_G_001	Time on Study Therapy Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
143	Figure S.4.1.2	rg-ex-kms2	GS_EX_G_001	Time on Study Therapy Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
144	Table S.4.1.1H	rt-ex-kms1.lst	SS_EX_T_002	Time of Study Therapy Life Table (Kaplan-Meier Estimates) Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
145	Table S.4.1.2H	rt-ex-kms2.lst	SS_EX_T_002	Time of Study Therapy Life Table (Kaplan-Meier Estimates) Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
146	Table S.4.1.1I	rt-ex-interrupts1.lst	SS_EX_T_003	Summary of Interruptions in Study Therapy Greater than 3 Days Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
147	Table S.4.1.2I	rt-ex-interrupts2.lst	SS_EX_T_003	Summary of Interruptions in Study Therapy Greater than 3 Days Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
148	Appendix 4.1.1A	rl-ex-lists1.lst	SS_EX_L_001	Study Medication Exposure by Subject Listing Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
149	Appendix 4.1.2A	rl-ex-lists2.lst	SS_EX_L_001	Study Medication Exposure by Subject Listing Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
150	Appendix 4.1.1B	rl-ex-listcdoses1.lst	SS_EX_L_002	Listing of Time on Original and Continuation Dose Treated Subjects - Stage 1	WK96S1, WK96S2
151	Appendix 4.1.2B	rl-ex-listcdoses2.lst	SS_EX_L_002	Listing of Time on Original and Continuation Dose Treated Subjects - Stage 2	WK96S2
152	Table S.4.2.1	rt-cm-conmeds1.lst	GS_CM_T_X_001	Non-Study Medication Summary Concomitant Medication Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
153	Table S.4.2.2	rt-cm-conmeds2.lst	GS_CM_T_X_001	Non-Study Medication Summary Concomitant Medication Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
154	Appendix 4.2.1	rl-cm-meds1.lst	GS_CM_L_X_006	Non-Study Medication Previous and Concomitant Medications Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
155	Appendix 4.2.2	rl-cm-meds2.lst	GS_CM_L_X_006	Non-Study Medication Previous and Concomitant Medications Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
156	Table S.5.1.1A	rt-vl-resp40w24s1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 Snapshot Treated Subjects (mITT) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
157	Table S.5.1.2A	rt-vl-resp40w24s2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 Snapshot Treated Subjects (mITT) - Stage 2	WK24S2, WK48S2, WK96S2
158	Table S.5.1.1C	rt-vl-sumresp40w24s1.lst	SS_VL_T_002	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 Snapshot Treated Subjects (mITT) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
159	Table S.5.1.2C	rt-vl-sumresp40w24s2.lst	SS_VL_T_002	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 Snapshot Treated Subjects (mITT) - Stage 2	WK24S2, WK48S2, WK96S2
160	Table S.5.1.1B	rt-vl-resp40w24subgs1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 Snapshot By Subgroup Treated Subjects (mITT) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
161	Table S.5.1.2B	rt-vl-resp40w24subgs2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 Snapshot By Subgroup Treated Subjects (mITT) - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
162	Table S.5.2.1A	rt-vl-resp40w48s1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 Snapshot Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
163	Table S.5.2.2A	rt-vl-resp40w48s2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 Snapshot Treated Subjects (mITT) - Stage 2	WK48S2, WK96S2
164	Table S.5.2.1C	rt-vl-sumresp40w48s1.lst	SS_VL_T_002	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 Snapshot Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
165	Table S.5.2.2C	rt-vl-sumresp40w48s2.lst	SS_VL_T_002	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 Snapshot Treated Subjects (mITT) - Stage 2	WK48S2, WK96S2
166	Table S.5.2.1B	rt-vl-resp40w48subgs1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 Snapshot By Subgroup Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
167	Table S.5.2.2B	rt-vl-resp40w48subgs2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 Snapshot By Subgroup Treated Subjects (mITT) - Stage 2	WK48S2, WK96S2
168	Table S.5.3.1A	rt-vl-resp40w96s1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 Snapshot Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
169	Table S.5.3.2A	rt-vl-resp40w96s2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 Snapshot Treated Subjects (mITT) - Stage 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
170	Table S.5.3.1C	rt-vl-sumresp40w96s1.lst	SS_VL_T_002	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 Snapshot Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
171	Table S.5.3.2C	rt-vl-sumresp40w96s2.lst	SS_VL_T_002	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 Snapshot Treated Subjects (mITT) - Stage 2	WK96S2
172	Table S.5.3.1B	rt-vl-resp40w96subgs1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 Snapshot By Subgroup Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
173	Table S.5.3.2B	rt-vl-resp40w96subgs2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 Snapshot By Subgroup Treated Subjects (mITT) - Stage 2	WK96S2
174	Table S.5.4.1A	rt-vl-resp200w24s1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 24 Snapshot Treated Subjects (mITT) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
175	Table S.5.4.2A	rt-vl-resp200w24s2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 24 Snapshot Treated Subjects (mITT) - Stage 2	WK24S2, WK48S2, WK96S2
176	Table S.5.4.1B	rt-vl-resp200w24bpolys1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 24 Snapshot By Baseline Gag Polymorphism Treated Subjects (mITT) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
177	Table S.5.4.2B	rt-vl-resp200w24bpolys2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 24 Snapshot By Baseline Gag Polymorphism Treated Subjects (mITT) - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
178	Table S.5.4.1C	rt-vl-resp200w48s1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 48 Snapshot Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
179	Table S.5.4.2C	rt-vl-resp200w48s2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 48 Snapshot Treated Subjects (mITT) - Stage 2	WK48S2, WK96S2
180	Table S.5.4.1D	rt-vl-resp200w48bpolys1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 48 Snapshot By Baseline Gag Polymorphism Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
181	Table S.5.4.2D	rt-vl-resp200w48bpolys2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 48 Snapshot By Baseline Gag Polymorphism Treated Subjects (mITT) - Stage 2	WK48S2, WK96S2
182	Table S.5.4.1E	rt-vl-resp200w96s1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 96 Snapshot Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
183	Table S.5.4.2E	rt-vl-resp200w96s2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 96 Snapshot Treated Subjects (mITT) - Stage 2	WK96S2
184	Table S.5.4.1F	rt-vl-resp200w96bpolys1.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 96 Snapshot By Baseline Gag Polymorphism Treated Subjects (mITT) - Stage 1	WK96S1, WK96S2
185	Table S.5.4.2F	rt-vl-resp200w96bpolys2.lst	SS_VL_T_001	Detailed Summary of HIV-1 RNA < 200 c/mL Proportion of Responders at Week 96 Snapshot By Baseline Gag Polymorphism Treated Subjects (mITT) - Stage 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
186	Table S.5.1.1D	rt-vl-resp40w24obss1.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 Treated Subjects (Observed) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
187	Table S.5.1.2D	rt-vl-resp40w24obss2.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 Treated Subjects (Observed) - Stage 2	WK24S2, WK48S2, WK96S2
188	Table S.5.1.1E	rt-vl-resp40w24obssubgs1.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 By Subgroup Treated Subjects (Observed) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
189	Table S.5.1.2E	rt-vl-resp40w24obssubgs2.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 By Subgroup Treated Subjects (Observed) - Stage 2	WK24S2, WK48S2, WK96S2
190	Table S.5.2.1D	rt-vl-resp40w48obss1.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 Treated Subjects (Observed) - Stage 1	WK96S1, WK96S2
191	Table S.5.2.2D	rt-vl-resp40w48obss2.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 Treated Subjects (Observed) - Stage 2	WK48S2, WK96S2
192	Table S.5.2.1E	rt-vl-resp40w48obssubs1.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 By Subgroup Treated Subjects (Observed) - Stage 1	WK96S1, WK96S2
193	Table S.5.2.2E	rt-vl-resp40w48obssubgs2.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 48 By Subgroup Treated Subjects (Observed) - Stage 2	WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
194	Table S.5.3.1D	rt-vl-resp40w96obss1.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 Treated Subjects (Observed) - Stage 1	WK96S1, WK96S2
195	Table S.5.3.2D	rt-vl-resp40w96obss2.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 Treated Subjects (Observed) - Stage 2	WK96S2
196	Table S.5.3.1E	rt-vl-resp40w96obssubgs1.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 By Subgroup Treated Subjects (Observed) - Stage 1	WK96S1, WK96S2
197	Table S.5.3.2E	rt-vl-resp40w96obssubgs2.lst	SS_VL_T_003	Summary of HIV-1 RNA < 40 c/mL Proportion of Responders at Week 96 By Subgroup Treated Subjects (Observed) - Stage 2	WK96S2
198	Table S.5.5.1A	rt-vl-tlovr24s1.lst	SS_VL_T_004	Summary of Treatment Outcomes at Week 24 Using the TLOVR Algorithm Treated Subjects - Stage 1	WK24S1
199	Table S.5.5.2A	rt-vl-tlovr24s2.lst	SS_VL_T_004	Summary of Treatment Outcomes at Week 24 Using the TLOVR Algorithm Treated Subjects - Stage 2	WK24S2
200	Table S.5.5.1B	rt-vl-tlovr48s1.lst	SS_VL_T_004	Summary of Treatment Outcomes at Week 48 Using the TLOVR Algorithm Treated Subjects - Stage 1	WK48S1
201	Table S.5.5.2B	rt-vl-tlovr48s2.lst	SS_VL_T_004	Summary of Treatment Outcomes at Week 48 Using the TLOVR Algorithm Treated Subjects - Stage 2	WK48S2
202	Table S.5.5.1C	rt-vl-tlovr96s1.lst	SS_VL_T_004	Summary of Treatment Outcomes at Week 96 Using the TLOVR Algorithm Treated Subjects - Stage 1	WK96S1, WK96S2
203	Table S.5.5.2C	rt-vl-tlovr96s2.lst	SS_VL_T_004	Summary of Treatment Outcomes at Week 96 Using the TLOVR Algorithm Treated Subjects - Stage 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
204	Table S.5.5.1D	rt-vl-klmtlovrs1.lst	SS_EX_T_002	Summary of Time to Loss of Virologic Response Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
205	Table S.5.5.2D	rt-vl-klmtlovrs2.lst	SS_EX_T_002	Summary of Time to Loss of Virologic Response Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
206	Figure S.5.5.1E	rg-vl-kmtlovrs1	GS_EX_G_001	Time to Loss of Virologic Response Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
207	Figure S.5.5.2E	rg-vl-kmtlovrs2	GS_EX_G_001	Time to Loss of Virologic Response Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
208	Table S.5.6.1A	rt-vl-props1.lst	SS_VL_T_005	Proportion of Subjects with HIV-1 RNA within Several Ranges Treated Subjects (Observed) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
209	Table S.5.6.2A	rt-vl-props2.lst	SS_VL_T_005	Proportion of Subjects with HIV-1 RNA within Several Ranges Treated Subjects (Observed) - Stage 2	WK24S2, WK48S2, WK96S2
210	Table S.5.6.1B	rt-vl-sumchgs1.lst	SS_VL_T_006	Summary Statistics for Values and Change from Baseline Over Time HIV-1 RNA (log10 c/mL) Overall and by Subgroup Treated Subjects (Observed) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
211	Table S.5.6.2B	rt-vl-sumchgs2.lst	SS_VL_T_006	Summary Statistics for Values and Change from Baseline Over Time HIV-1 RNA (log10 c/mL) Overall and by Subgroup Treated Subjects (Observed) - Stage 2	WK24S2, WK48S2, WK96S2
212	Table S.5.7.1A	rt-lb-cd4s1.lst	SS_VL_T_006	Summary Statistics for Values and Change from Baseline Over Time CD4 Cell Count (cells/uL) Overall and by Subgroup Treated Subjects (Observed) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
213	Table S.5.7.2A	rt-lb-cd4s2.lst	SS_VL_T_006	Summary Statistics for Values and Change from Baseline Over Time CD4 Cell Count (cells/uL) Overall and by Subgroup Treated Subjects (Observed) - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
214	Table S.5.8.1A	rt-lb-cd4pcts1.lst	SS_VL_T_006	Summary Statistics for Values and Change from Baseline Over Time CD4 Cell Percentage Overall and by Subgroup Treated Subjects (Observed) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
215	Table S.5.8.2A	rt-lb-cd4pcts2.lst	SS_VL_T_006	Summary Statistics for Values and Change from Baseline Over Time CD4 Cell Percentage Overall and by Subgroup Treated Subjects (Observed) - Stage 2	WK24S2, WK48S2, WK96S2
216	Table S.5.9.1A	rt-lb-cd8s1.lst	SS_VL_T_006	Summary Statistics for Values and Change from Baseline Over Time CD8 Cell Count (cells/ul) Overall and by Subgroup Treated Subjects (Observed) - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
217	Table S.5.9.2A	rt-lb-cd8s2.lst	SS_VL_T_006	Summary Statistics for Values and Change from Baseline Over Time CD8 Cell Count (cells/ul) Overall and by Subgroup Treated Subjects (Observed) - Stage 2	WK24S2, WK48S2, WK96S2
218	Figure S.5.6.1C	rg-vl-box24s1	GS_LB_G_001	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 24 Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
219	Figure S.5.6.2C	rg-vl-box24s2	GS_LB_G_001	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 24 Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
220	Figure S.5.6.1D	rg-vl-box48s1	GS_LB_G_001	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 48 Treated Subjects - Stage 1	WK96S1, WK96S2
221	Figure S.5.6.2D	rg-vl-box48s2	GS_LB_G_001	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 48 Treated Subjects - Stage 2	WK48S2, WK96S2
222	Figure S.5.6.1E	rg-vl-box96s1	GS_LB_G_001	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 96 Treated Subjects - Stage 1	WK96S1, WK96S2
223	Figure S.5.6.2E	rg-vl-box96s2	GS_LB_G_001	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 96 Treated Subjects - Stage 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
224	Figure S.5.7.1B	rg-lb-cd4box24s1	GS_LB_G_001	CD4 Cell Count (cells/uL) Change from Baseline to Week 24 Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
225	Figure S.5.7.2B	rg-lb-cd4box24s2	GS_LB_G_001	CD4 Cell Count (cells/uL) Change from Baseline to Week 24 Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
226	Figure S.5.7.1C	rg-lb-cd4box48s1	GS_LB_G_001	CD4 Cell Count (cells/uL) Change from Baseline to Week 48 Treated Subjects - Stage 1	WK96S1, WK96S2
227	Figure S.5.7.2C	rg-lb-cd4box48s2	GS_LB_G_001	CD4 Cell Count (cells/uL) Change from Baseline to Week 48 Treated Subjects - Stage 2	WK48S2, WK96S2
228	Figure S.5.7.1D	rg-lb-cd4box96s1	GS_LB_G_001	CD4 Cell Count (cells/uL) Change from Baseline to Week 96 Treated Subjects - Stage 1	WK96S1, WK96S2
229	Figure S.5.7.2D	rg-lb-cd4box96s2	GS_LB_G_001	CD4 Cell Count (cells/uL) Change from Baseline to Week 96 Treated Subjects - Stage 2	WK96S2
230	Figure S.5.9.1B	rg-lb-cd8box24s1	GS_LB_G_001	CD8 Cell Count (cells/uL) Change from Baseline to Week 24 Treated Subjects -Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
231	Figure S.5.9.2B	rg-lb-cd8box24s2	GS_LB_G_001	CD8 Cell Count (cells/uL) Change from Baseline to Week 24 Treated Subjects -Stage 2	WK24S2, WK48S2, WK96S2
232	Figure S.5.9.1C	rg-lb-cd8box48s1	GS_LB_G_001	CD8 Cell Count (cells/uL) Change from Baseline to Week 48 Treated Subjects - Stage 1	WK96S1, WK96S2
233	Figure S.5.9.2C	rg-lb-cd8box48s2	GS_LB_G_001	CD8 Cell Count (cells/uL) Change from Baseline to Week 48 Treated Subjects - Stage 2	WK48S2, WK96S2
234	Figure S.5.9.1D	rg-lb-cd8box96s1	GS_LB_G_001	CD8 Cell Count (cells/uL) Change from Baseline to Week 96 Treated Subjects - Stage 1	WK96S1, WK96S2
235	Figure S.5.9.2D	rg-lb-cd8box96s2	GS_LB_G_001	CD8 Cell Count (cells/uL) Change from Baseline to Week 96 Treated Subjects - Stage 2	WK96S2
236	Figure S.5.6.1F	rg-vl-times1	GS_LB_G_002	HIV-1 RNA (log10 c/mL) Mean Change from Baseline Over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
237	Figure S.5.6.2F	rg-vl-times2	GS_LB_G_002	HIV-1 RNA (log10 c/mL) Mean Change from Baseline Over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
238	Figure S.5.7.1E	rg-lb-cd4times1	GS_LB_G_002	CD4 (cells/uL) Mean Change from Baseline Over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
239	Figure S.5.7.2E	rg-lb-cd4times2	GS_LB_G_002	CD4 (cells/uL) Mean Change from Baseline Over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
240	Figure S.5.9.1E	rg-lb-cd8times1	GS_LB_G_002	CD8 (cells/uL) Mean Change from Baseline Over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
241	Figure S.5.9.2E	rg-lb-cd8times2	GS_LB_G_002	CD8 (cells/uL) Mean Change from Baseline Over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
242	Appendix 5.1.1A	rl-vl-outcome24s1.lst	SS_VL_L_004	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis Data for Subjects in the Week 24 Snapshot Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
243	Appendix 5.1.2A	rl-vl-outcome24s2.lst	SS_VL_L_004	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis Data for Subjects in the Week 24 Snapshot Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
244	Appendix 5.1.1B	rl-vl-outcome48s1.lst	SS_VL_L_004	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis Data for Subjects in the Week 48 Snapshot Treated Subjects - Stage 1	WK96S1, WK96S2
245	Appendix 5.1.2B	rl-vl-outcome48s2.lst	SS_VL_L_004	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis Data for Subjects in the Week 48 Snapshot Treated Subjects - Stage 2	WK48S2, WK96S2
246	Appendix 5.1.1C	rl-vl-outcome96s1.lst	SS_VL_L_004	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis Data for Subjects in the Week 96 Snapshot Treated Subjects - Stage 1	WK96S1, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
247	Appendix 5.1.2C	rl-vl-outcome96s2.lst	SS_VL_L_004	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis Data for Subjects in the Week 96 Snapshot Treated Subjects - Stage 2	WK96S2
248	Appendix 5.1.1D	rl-vl-vllists1.lst	SS_VL_L_005	Listing of HIV-1 RNA Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
249	Appendix 5.1.2D	rl-vl-vllists2.lst	SS_VL_L_005	Listing of HIV-1 RNA Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
250	Appendix 5.1.1E	rl-lb-cd4cd8s1.lst	SS_VL_L_005	Listing of CD4+ and CD8+ T-Cell Count and Percentages Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
251	Appendix 5.1.2E	rl-lb-cd4cd8s2.lst	SS_VL_L_005	Listing of CD4+ and CD8+ T-Cell Count and Percentages Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
252	Table S.5.10.1A	rt-gn-news1.lst	SS_GN_T_001	Newly Emergent Genotypic Resistance Profile Treated Subjects with On-Treatment Genotypic Resistance Testing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
253	Table S.5.10.2A	rt-gn-news2.lst	SS_GN_T_001	Newly Emergent Genotypic Resistance Profile Treated Subjects with On-Treatment Genotypic Resistance Testing - Stage 2	WK24S2, WK48S2, WK96S2
254	Table S.5.10.3A	rt-gn-news12.lst	SS_GN_T_001	Newly Emergent Genotypic Resistance Profile Treated Subjects with On-Treatment Genotypic Resistance Testing - Stage 1 and 2	WK96S2
255	Table S.5.10.1B	rt-gn-newpdvfs1.lst	SS_GN_T_001	Newly Emergent Genotypic Resistance Profile Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
256	Table S.5.10.2B	rt-gn-newpdvfs2.lst	SS_GN_T_001	Newly Emergent Genotypic Resistance Profile Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
257	Table S.5.10.3B	rt-gn-newpdvfs12.lst	SS_GN_T_001	Newly Emergent Genotypic Resistance Profile Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
258	Appendix 5.10.1A	rl-gn-ontrts1.lst	SS_GN_L_001	Listing of Genotypic Substitutions Treated Subjects with Baseline and On-Treatment Data - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
259	Appendix 5.10.2A	rl-gn-ontrts2.lst	SS_GN_L_001	Listing of Genotypic Substitutions Treated Subjects with Baseline and On-Treatment Data - Stage 2	WK24S2, WK48S2, WK96S2
260	Table S.5.10.1C	rt-gn-newgags1.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions Treated Subjects with On-Treatment Gag Sequencing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
261	Table S.5.10.2C	rt-gn-newgags2.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions Treated Subjects with On-Treatment Gag Sequencing - Stage 2	WK24S2, WK48S2, WK96S2
262	Table S.5.10.3C	rt-gn-newgags12.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions Treated Subjects with On-Treatment Gag Sequencing - Stage 1 and 2	WK96S2
263	Table S.5.10.1R	rt-gn-newgagbysubtypes1.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects with On-Treatment Gag Sequencing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
264	Table S.5.10.2R	rt-gn-newgagbysubtypes2.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects with On-Treatment Gag Sequencing - Stage 2	WK24S2, WK48S2, WK96S2
265	Table S.5.10.3R	rt-gn-newgagbysubtypes12.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects with On-Treatment Gag Sequencing - Stage 1 and 2	WK96S2
266	Table S.5.10.1D	rt-gn-newgagpdvfs1.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
267	Table S.5.10.2D	rt-gn-newgagpdvfs2.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
268	Table S.5.10.3D	rt-gn-newgagpdvfs12.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
269	Table S.5.10.1S	rt-gn-newgagpdvfbysubtypes1.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
270	Table S.5.10.2S	rt-gn-newgagpdvfbysubtypes2.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
271	Table S.5.10.3S	rt-gn-newgagpdvfbysubtypes12.lst	SS_GN_T_002	Emergent Gag Polymorphisms at Selected Positions By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
272	Appendix 5.10.1B	rl-gn-gagontrts1.lst	SS_GN_L_002	Listing of Gag Polymorphisms at Selected Positions Treated Subjects with Baseline and On-Treatment Data - Stage 1	WK24S1, WK48S1 WK96S1, WK96S2
273	Appendix 5.10.2B	rl-gn-gagontrts2.lst	SS_GN_L_002	Listing of Gag Polymorphisms at Selected Positions Treated Subjects with Baseline and On-Treatment Data - Stage 2	WK24S2, WK48S2, WK96S2
274	Table S.5.10.1E	rt-gn-anygags1.lst	SS_GN_T_003	Newly Emergent Gag Deviations Treated Subjects with On-Treatment Gag Sequencing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
275	Table S.5.10.2E	rt-gn-anygags2.lst	SS_GN_T_003	Newly Emergent Gag Deviations Treated Subjects with On-Treatment Gag Sequencing - Stage 2	WK24S2, WK48S2, WK96S2
276	Table S.5.10.3E	rt-gn-anygags12.lst	SS_GN_T_003	Newly Emergent Gag Deviations Treated Subjects with On-Treatment Gag Sequencing - Stage 1 and 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
277	Table S.5.10.1T	rt-gn-anygagbysubtypes1.lst	SS_GN_T_003	Newly Emergent Gag Deviations By HIV Subtype Treated Subjects with On-Treatment Gag Sequencing - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
278	Table S.5.10.2T	rt-gn-anygagbysubtypes2.lst	SS_GN_T_003	Newly Emergent Gag Deviations By HIV Subtype Treated Subjects with On-Treatment Gag Sequencing - Stage 2	WK24S2, WK48S2, WK96S2
279	Table S.5.10.3T	rt-gn-anygagbysubtypes12.lst	SS_GN_T_003	Newly Emergent Gag Deviations By HIV Subtype Treated Subjects with On-Treatment Gag Sequencing - Stage 1 and 2	WK96S2
280	Table S.5.10.1F	rt-gn-anygagpdvfs1.lst	SS_GN_T_003	Newly Emergent Gag Deviations Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
281	Table S.5.10.2F	rt-gn-anygagpdvfs2.lst	SS_GN_T_003	Newly Emergent Gag Deviations Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
282	Table S.5.10.3F	rt-gn-anygagpdvfs12.lst	SS_GN_T_003	Newly Emergent Gag Deviations Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
283	Table S.5.10.1U	rt-gn-anygagpdvfbysubtypes1.lst	SS_GN_T_003	Newly Emergent Gag Deviations By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
284	Table S.5.10.2U	rt-gn-anygagpdvfbysubtypes2.lst	SS_GN_T_003	Newly Emergent Gag Deviations By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
285	Table S.5.10.3U	rt-gn-anygagpdvfbysubtypes12.lst	SS_GN_T_003	Newly Emergent Gag Deviations By HIV Subtype Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
286	Appendix 5.10.1C	rl-gn-gagontrts1.lst	SS_GN_L_003	Listing of Newly Emergent Gag Deviations Treated Subjects with Baseline and On-Treatment Data - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
287	Appendix 5.10.2C	rl-gn-gagontrts2.lst	SS_GN_L_003	Listing of Newly Emergent Gag Deviations Treated Subjects with Baseline and On-Treatment Data - Stage 2	WK24S2, WK48S2, WK96S2
288	Table S.5.10.1G	rt-pn-news1.lst	SS_PN_T_001	Newly Emergent Phenotypic Resistance Profile Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
289	Table S.5.10.2G	rt-pn-news2.lst	SS_PN_T_001	Newly Emergent Phenotypic Resistance Profile Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 2	WK24S2, WK48S2, WK96S2
290	Table S.5.10.3G	rt-pn-news12.lst	SS_PN_T_001	Newly Emergent Phenotypic Resistance Profile Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1 and 2	WK96S2
291	Table S.5.10.1H	rt-pn-newpdvfs1.lst	SS_PN_T_001	Newly Emergent Phenotypic Resistance Profile Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
292	Table S.5.10.2H	rt-pn-newpdvfs2.lst	SS_PN_T_001	Newly Emergent Phenotypic Resistance Profile Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
293	Table S.5.10.3H	rt-pn-newpdvfs12.lst	SS_PN_T_001	Newly Emergent Phenotypic Resistance Profile Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
294	Table S.5.10.1I	rt-pn-newdrugs1.lst	SS_PN_T_002	Newly Emergent Phenotypic Resistance by Class and Drug Name Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
295	Table S.5.10.2I	rt-pn-newdrugs2.lst	SS_PN_T_002	Newly Emergent Phenotypic Resistance by Class and Drug Name Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
296	Table S.5.10.3I	rt-pn-newdrugs12.lst	SS_PN_T_002	Newly Emergent Phenotypic Resistance by Class and Drug Name Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1 and 2	WK96S2
297	Table S.5.10.1J	rt-pn-newdrugpdvfs1.lst	SS_PN_T_002	Newly Emergent Phenotypic Resistance by Class and Drug Name Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
298	Table S.5.10.2J	rt-pn-newdrugpdvfs2.lst	SS_PN_T_002	Newly Emergent Phenotypic Resistance by Class and Drug Name Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
299	Table S.5.10.3J	rt-pn-newdrugpdvfs12.lst	SS_PN_T_002	Newly Emergent Phenotypic Resistance by Class and Drug Name Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2	WK96S2
300	Appendix 5.10.1D	rl-pn-ontrts1.lst	SS_PN_L_001	Listing of Phenotypic Resistance Treated Subjects with Baseline and On-Treatment Data - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
301	Appendix 5.10.2D	rl-pn-ontrts2.lst	SS_PN_L_001	Listing of Phenotypic Resistance Treated Subjects with Baseline and On-Treatment Data - Stage 2	WK24S2, WK48S2, WK96S2
302	Table S.5.10.1K	rt-pn-maxic50s1.lst	SS_PN_T_003	Maximum Change from Baseline Summary for BMS-955176 IC50 Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
303	Table S.5.10.2K	rt-pn-maxic50s2.lst	SS_PN_T_003	Maximum Change from Baseline Summary for BMS-955176 IC50 Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 2	WK24S2, WK48S2, WK96S2
304	Table S.5.10.1L	rt-pn-maxic50pdvfs1.lst	SS_PN_T_003	Maximum Change from Baseline Summary for BMS-955176 IC50 Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
305	Table S.5.10.2L	rt-pn-maxic50pdvfs2.lst	SS_PN_T_003	Maximum Change from Baseline Summary for BMS-955176 IC50 Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
306	Table S.5.10.1M	rt-pn-maxic50fcs1.lst	SS_PN_T_003	Summary for Maximum BMS-955176 IC50 Fold Change Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
307	Table S.5.10.2M	rt-pn-maxic50fcs2.lst	SS_PN_T_003	Summary for Maximum BMS-955176 IC50 Fold Change Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 2	WK24S2, WK48S2, WK96S2
308	Table S.5.10.1N	rt-pn-maxic50fcpdvfs1.lst	SS_PN_T_003	Summary for Maximum BMS-955176 IC50 Fold Change Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
309	Table S.5.10.2N	rt-pn-maxic50fcpdvfs2.lst	SS_PN_T_003	Summary for Maximum BMS-955176 IC50 Fold Change Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2	WK24S2, WK48S2, WK96S2
310	Table S.5.10.1O	rt-pn-props1.lst	SS_PN_T_004	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
311	Table S.5.10.2O	rt-pn-props2.lst	SS_PN_T_004	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 2	WK24S2, WK48S2, WK96S2
312	Table S.5.10.3O	rt-pn-props12.lst	SS_PN_T_004	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1 and 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
313	Table S.5.10.1P	rt-pn-proppdvfs1.lst	SS_PN_T_004	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change Treated Subjects Identified as Protocol Defined Virologic Failures with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
314	Table S.5.10.2P	rt-pn-proppdvfs2.lst	SS_PN_T_004	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change Treated Subjects Identified as Protocol Defined Virologic Failures with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 2	WK24S2, WK48S2, WK96S2
315	Table S.5.10.3P	rt-pn-proppdvfs12.lst	SS_PN_T_004	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change Treated Subjects Identified as Protocol Defined Virologic Failures with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1 and 2	WK96S2
316	Table S.5.10.1V	rt-pn-propnews1.lst	SS_PN_T_004	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176 Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
317	Table S.5.10.2V	rt-pn-propnews2.lst	SS_PN_T_004	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176 Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 2	WK24S2, WK48S2, WK96S2
318	Table S.5.10.3V	rt-pn-propnews12.lst	SS_PN_T_004	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176 Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1 and 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
319	Table S.5.10.1W	rt-pn-propnewpdvfs1.lst	SS_PN_T_004	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176 Treated Subjects Identified as Protocol Defined Virologic Failures with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
320	Table S.5.10.2W	rt-pn-propnewpdvfs2.lst	SS_PN_T_004	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176 Treated Subjects Identified as Protocol Defined Virologic Failures with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 2	WK24S2, WK48S2, WK96S2
321	Table S.5.10.3W	rt-pn-propnewpdvfs12.lst	SS_PN_T_004	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176 Treated Subjects Identified as Protocol Defined Virologic Failures with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1 and 2	WK96S2
322	Table S.5.10.1Q	rt-gn-newgagincs1.lst	SS_GN_T_002	Emergent Gag Polymorphisms Treated Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change-Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
323	Table S.5.10.2Q	rt-gn-newgagincs2.lst	SS_GN_T_002	Emergent Gag Polymorphisms Treated Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change-Stage 2	WK24S2, WK48S2, WK96S2
324	Table S.5.10.3Q	rt-gn-newgagincs12.lst	SS_GN_T_002	Emergent Gag Polymorphisms Treated Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change-Stage 1 and 2	WK96S2
325	Table S.5.11.1	rt-vl-futw24s1.lst	SS_VL_T_007	Test for Virologic Futility Based on HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 (mITT) Treated Subjects - Stage 1	WK24S1
326	Table S.5.11.2	rt-vl-futw24s2.lst	SS_VL_T_007	Test for Virologic Futility Based on HIV-1 RNA < 40 c/mL Proportion of Responders at Week 24 (mITT) Treated Subjects - Stage 2	WK24S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
327	Table S.6.7.1	rt-ae-overallsums1.lst	SS_AE_T_001	Adverse Events Overall Adverse Events Summary Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
328	Table S.6.7.2	rt-ae-overallsums2.lst	SS_AE_T_001	Adverse Events Overall Adverse Events Summary Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
329	Table S.6.7.3	rt-ae-overallsums12.lst	SS_AE_T_001	Adverse Events Overall Adverse Events Summary Treated Subjects - Stage 1 and 2	WK96S2
330	Table S.6.1.1	rl-ae-deaths1.lst	SS_AE_L_001	Death Listing Enrolled Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
331	Table S.6.1.2	rl-ae-deaths2.lst	SS_AE_L_001	Death Listing Enrolled Subjects - Stage 2	WK24S2, WK48S2, WK96S2
332	Table S.6.2.1A	rt-ae-saes1.lst	GS_AE_T_X_001	Adverse Event Summary Serious Adverse Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
333	Table S.6.2.2A	rt-ae-saes2.lst	GS_AE_T_X_001	Adverse Event Summary Serious Adverse Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
334	Table S.6.2.3A	rt-ae-saes12.lst	GS_AE_T_X_001	Adverse Event Summary Serious Adverse Events Treated Subjects - Stage 1 and 2	WK96S2
335	Table S.6.2.1B	rt-ae-saeconts1.lst	GS_AE_T_X_001	Adverse Event Summary Serious Adverse Events After Switch to Continuation Dose Treated Subjects - Stage 1	WK96S1, WK96S2
336	Table S.6.2.2B	rt-ae-saeconts2.lst	GS_AE_T_X_001	Adverse Event Summary Serious Adverse Events After Switch to Continuation Dose Treated Subjects - Stage 2	WK96S2
337	Table S.6.2.1C	rt-ae-saeldeaths1eu.lst	GS_AE_T_X_001	Adverse Event Summary Serious Adverse Event With Death As An Outcome Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
338	Table S.6.2.2C	rt-ae-saeldeaths2eu.lst	GS_AE_T_X_001	Adverse Event Summary Serious Adverse Event With Death As An Outcome Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
339	Table S.6.2.1D	rt-ae-relsaeldeaths1eu.lst	GS_AE_T_X_001	Adverse Event Summary Drug Related Serious Adverse Event With Death As An Outcome Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
340	Table S.6.2.2D	rt-ae-relsaeldeaths2eu.lst	GS_AE_T_X_001	Adverse Event Summary Drug Related Serious Adverse Event With Death As An Outcome Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
341	Table S.6.2.1E	rl-ae-saes1.lst	GS_AE_L_S_001	Adverse Event Serious Adverse Events Enrolled Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
342	Table S.6.2.2E	rl-ae-saes2.lst	GS_AE_L_S_001	Adverse Event Serious Adverse Events Enrolled Subjects - Stage 2	WK24S2, WK48S2, WK96S2
343	Table S.6.3.1A	rt-ae-aediscs1.lst	GS_AE_T_X_001	Adverse Event Summary Adverse Events Leading to Discontinuation of Study Medication Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
344	Table S.6.3.2A	rt-ae-aediscs2.lst	GS_AE_T_X_001	Adverse Event Summary Adverse Events Leading to Discontinuation of Study Medication Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
345	Table S.6.3.3A	rt-ae-aediscs12.lst	GS_AE_T_X_001	Adverse Event Summary Adverse Events Leading to Discontinuation of Study Medication Treated Subjects - Stage 1 and 2	WK96S2
346	Table S.6.3.1B	rt-ae-aediscconts1.lst	GS_AE_T_X_001	Adverse Event Summary Adverse Events Leading to Discontinuation of Study Medication After Switch to Continuation Dose Treated Subjects - Stage 1	WK96S1, WK96S2
347	Table S.6.3.2B	rt-ae-aediscconts2.lst	GS_AE_T_X_001	Adverse Event Summary Adverse Events Leading to Discontinuation of Study Medication After Switch to Continuation Dose Treated Subjects - Stage 2	WK96S2
348	Table S.6.3.1C	rl-ae-discs1.lst	GS_AE_L_X_001	Adverse Event Adverse Events Leading to Discontinuation of Study Medication Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
349	Table S.6.3.2C	rl-ae-discs2.lst	GS_AE_L_X_001	Adverse Event Adverse Events Leading to Discontinuation of Study Medication Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
350	Table S.6.5.1A	rt-ae-nsae5pcts1.lst	GS_AE_T_X_001	Adverse Event Summary Non-Serious Adverse Events Occurring in at Least 5 Percent of Treated Subjects Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
351	Table S.6.5.2A	rt-ae-nsae5pcts2.lst	GS_AE_T_X_001	Adverse Event Summary Non-Serious Adverse Events Occurring in at Least 5 Percent of Treated Subjects Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
352	Table S.6.5.1B	rt-ae-grade1to4s1.lst	GS_AE_T_X_001	Adverse Event Summary Grade 1 to 4 Adverse Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
353	Table S.6.5.2B	rt-ae-grade1to4s2.lst	GS_AE_T_X_001	Adverse Event Summary Grade 1 to 4 Adverse Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
354	Table S.6.5.1C	rt-ae-grade2to4s1.lst	GS_AE_T_X_001	Adverse Event Summary Grade 2 to 4 Adverse Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
355	Table S.6.5.2C	rt-ae-grade2to4s2.lst	GS_AE_T_X_001	Adverse Event Summary Grade 2 to 4 Adverse Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
356	Table S.6.5.1D	rt-ae-grade3to4s1.lst	GS_AE_T_X_001	Adverse Event Summary Grade 3 to 4 Adverse Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
357	Table S.6.5.2D	rt-ae-grade3to4s2.lst	GS_AE_T_X_001	Adverse Event Summary Grade 3 to 4 Adverse Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
358	Table S.6.5.3D	rt-ae-grade3to4s12.lst	GS_AE_T_X_001	Adverse Event Summary Grade 3 to 4 Adverse Events Treated Subjects - Stage 1 and 2	WK96S2
359	Table S.6.5.1E	rt-ae-relateds1.lst	GS_AE_T_X_001	Adverse Event Summary Grade 1 to 4 Related Adverse Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
360	Table S.6.5.2E	rt-ae-relateds2.lst	GS_AE_T_X_001	Adverse Event Summary Grade 1 to 4 Related Adverse Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
361	Table S.6.5.1F	rt-ae-relgrade2to4s1.lst	GS_AE_T_X_001	Adverse Event Summary Grade 2 to 4 Related Adverse Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
362	Table S.6.5.2F	rt-ae-relgrade2to4s2.lst	GS_AE_T_X_001	Adverse Event Summary Grade 2 to 4 Related Adverse Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
363	Table S.6.5.3F	rt-ae-relgrade2to4s12.lst	GS_AE_T_X_001	Adverse Event Summary Grade 2 to 4 Related Adverse Events Treated Subjects - Stage 1 and 2	WK96S2
364	Table S.6.5.1G	rt-ae-relgrade3to4s1.lst	GS_AE_T_X_001	Adverse Event Summary Grade 3 to 4 Related Adverse Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
365	Table S.6.5.2G	rt-ae-relgrade3to4s2.lst	GS_AE_T_X_001	Adverse Event Summary Grade 3 to 4 Related Adverse Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
366	Appendix 6.5.1	rl-ae-lists1.lst	GS_AEL_X_001	Adverse Event Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
367	Appendix 6.5.2	rl-ae-lists2.lst	GS_AEL_X_001	Adverse Event Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
368	Table S.6.4.1A	rt-ae-cdcaes1.lst	GS_AE_T_X_001	Adverse Event Summary CDC Class C AIDS Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
369	Table S.6.4.2A	rt-ae-cdcaes2.lst	GS_AE_T_X_001	Adverse Event Summary CDC Class C AIDS Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
370	Table S.6.4.3A	rt-ae-cdcaes12.lst	GS_AE_T_X_001	Adverse Event Summary CDC Class C AIDS Events Treated Subjects - Stage 1 and 2	WK96S2
371	Table S.6.4.1B	rl-ae-cdcaes1.lst	GS_AEL_X_001	Adverse Event CDC Class C AIDS Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
372	Table S.6.4.2B	rl-ae-cdcaes2.lst	GS_AEL_X_001	Adverse Event CDC Class C AIDS Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
373	Table S.6.4.1C	rt-ae-giaes1.lst	GS_AE_T_X_001	Adverse Event Summary Gastrointestinal Events of Special Interest Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
374	Table S.6.4.2C	rt-ae-giaes2.lst	GS_AE_T_X_001	Adverse Event Summary Gastrointestinal Events of Special Interest Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
375	Table S.6.4.3C	rt-ae-giaes12.lst	GS_AE_T_X_001	Adverse Event Summary Gastrointestinal Events of Special Interest Treated Subjects - Stage 1 and 2	WK96S2
376	Table S.6.4.1D	rl-ae-giaes1.lst	GS_AE_L_X_001	Adverse Event Gastrointestinal Events of Special Interest Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
377	Table S.6.4.2D	rl-ae-giaes2.lst	GS_AE_L_X_001	Adverse Event Gastrointestinal Events of Special Interest Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
378	Table S.6.6.1A	rt-ae-expadjusts1.lst	GS_AE_T_M_001	Exposure Adjusted Adverse Events Summary Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
379	Table S.6.6.2A	rt-ae-expadjusts2.lst	GS_AE_T_M_001	Exposure Adjusted Adverse Events Summary Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
380	Table S.6.6.1B	rt-ae-expadjsaes1eu.lst	GS_AE_T_M_001	Exposure Adjusted Adverse Events Summary Including Multiple Occurrences of Unique Adverse Events Treated Subjects - Stage 1 Serious Adverse Events	WK24S1, WK48S1, WK96S1, WK96S2
381	Table S.6.6.2B	rt-ae-expadjsaes2eu.lst	GS_AE_T_M_001	Exposure Adjusted Adverse Events Summary Including Multiple Occurrences of Unique Adverse Events Treated Subjects - Stage 2 Serious Adverse Events	WK24S2, WK48S2, WK96S2
382	Table S.6.6.1C	rt-ae-expadjrelsaes1eu.lst	GS_AE_T_M_001	Exposure Adjusted Adverse Events Summary Including Multiple Occurrences of Unique Adverse Events Treated Subjects - Stage 1 Drug Related Serious Adverse Events	WK24S1, WK48S1, WK96S1, WK96S2
383	Table S.6.6.2C	rt-ae-expadjrelsaes2eu.lst	GS_AE_T_M_001	Exposure Adjusted Adverse Events Summary Including Multiple Occurrences of Unique Adverse Events Treated Subjects - Stage 2 Drug Related Serious Adverse Events	WK24S2, WK48S2, WK96S2
384	Table S.6.6.1D	rt-ae-expadjnsae5pcts1eu.lst	GS_AE_T_M_001	Exposure Adjusted Adverse Event Summary Including Multiple Occurrences of Unique Adverse Events Treated Subjects - Stage 1 Non-Serious Adverse Events Using a Global Cutoff of 5 Percent	WK24S1, WK48S1, WK96S1, WK96S2
385	Table S.6.6.2D	rt-ae-expadjnsae5pcts2eu.lst	GS_AE_T_M_001	Exposure Adjusted Adverse Event Summary Including Multiple Occurrences of Unique Adverse Events Treated Subjects - Stage 2 Non-Serious Adverse Events Using a Global Cutoff of 5 Percent	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
386	Appendix 6.6.1	rl-ae-uniques1.lst	GS_AE_L_U_002	Adverse Event Unique Events Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
387	Appendix 6.6.2	rl-ae-uniques2.lst	GS_AE_L_U_002	Adverse Event Unique Events Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
388	Table S.7.1.1A	rt-lb-toxs1.lst	SS_LB_T_001	Laboratory Test Results Summary of Worst Toxicity Grade Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
389	Table S.7.1.2A	rt-lb-toxs2.lst	SS_LB_T_001	Laboratory Test Results Summary of Worst Toxicity Grade Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
390	Table S.7.1.1B	rt-lb-g34toxs1.lst	SS_LB_T_001	Laboratory Test Results Summary of Grade 3-4 Toxicity Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
391	Table S.7.1.2B	rt-lb-g34toxs2.lst	SS_LB_T_001	Laboratory Test Results Summary of Grade 3-4 Toxicity Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
392	Table S.7.1.3B	rt-lb-g34toxs12.lst	SS_LB_T_001	Laboratory Test Results Summary of Grade 3-4 Toxicity Treated Subjects - Stage 1 and 2	WK96S2
393	Table S.7.1.1C	rt-lb-etoxs1.lst	SS_LB_T_001	Laboratory Test Results Summary of Treatment-Emergent Abnormalities Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
394	Table S.7.1.2C	rt-lb-etoxs2.lst	SS_LB_T_001	Laboratory Test Results Summary of Treatment-Emergent Abnormalities Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
395	Table S.7.2.1A	rt-lb-renals1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Function Values and Change from Baseline - SI Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
396	Table S.7.2.2A	rt-lb-renals2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Function Values and Change from Baseline - SI Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
397	Table S.7.2.1B	rt-zl-renals1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Function Values and Change from Baseline - US Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
398	Table S.7.2.2B	rt-zl-renals2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Function Values and Change from Baseline - US Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
399	Table S.7.2.1C	rt-lb-lipidss1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Fasting Lipid Values and Change from Baseline - SI Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
400	Table S.7.2.2C	rt-lb-lipidss2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Fasting Lipid Values and Change from Baseline - SI Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
401	Table S.7.2.1D	rt-zl-lipidss1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Fasting Lipid Values and Change from Baseline - US Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
402	Table S.7.2.2D	rt-zl-lipidss2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Fasting Lipid Values and Change from Baseline - US Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
403	Table S.7.2.1E	rt-lb-pchglipidss1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - SI Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
404	Table S.7.2.2E	rt-lb-pchglipidss2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - SI Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
405	Table S.7.2.1F	rt-zl-pchglipidss1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - US Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
406	Table S.7.2.2F	rt-zl-pchglipidss2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - US Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
407	Figure S.7.2.1A	rg-lb-tchols1	GS_LB_G_002	Fasting Total Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
408	Figure S.7.2.2A	rg-lb-tchols2	GS_LB_G_002	Fasting Total Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
409	Figure S.7.2.1B	rg-lb-ldlcs1	GS_LB_G_002	Fasting LDL-Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
410	Figure S.7.2.2B	rg-lb-ldlcs2	GS_LB_G_002	Fasting LDL-Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
411	Figure S.7.2.1C	rg-lb-hdlcs1	GS_LB_G_002	Fasting HDL-Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
412	Figure S.7.2.2C	rg-lb-hdlcs2	GS_LB_G_002	Fasting HDL-Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
413	Figure S.7.2.1D	rg-lb-trigs1	GS_LB_G_002	Fasting Total Triglycerides (mg/dL) Mean Percent Change from Baseline Over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
414	Figure S.7.2.2D	rg-lb-trigs2	GS_LB_G_002	Fasting Total Triglycerides (mg/dL) Mean Percent Change from Baseline Over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
415	Appendix 7.1.1A	rl-lb-hems1.lst	SS_LB_L_001	Hematology - SI Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
416	Appendix 7.1.2A	rl-lb-hems2.lst	SS_LB_L_001	Hematology - SI Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
417	Appendix 7.1.1B	rl-lb-lfts1.lst	SS_LB_L_001	Liver Function Tests - SI Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
418	Appendix 7.1.2B	rl-lb-lfts2.lst	SS_LB_L_001	Liver Function Tests - SI Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
419	Appendix 7.1.1C	rl-lb-enzs1.lst	SS_LB_L_001	Enzymes - SI Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
420	Appendix 7.1.2C	rl-lb-enzs2.lst	SS_LB_L_001	Enzymes - SI Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
421	Appendix 7.1.1D	rl-lb-rfts1.lst	SS_LB_L_001	Renal Function Tests - SI Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
422	Appendix 7.1.2D	rl-lb-rfts2.lst	SS_LB_L_001	Renal Function Tests - SI Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
423	Appendix 7.1.1E	rl-lb-elcs1.lst	SS_LB_L_001	Electrolytes - SI Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
424	Appendix 7.1.2E	rl-lb-elcs2.lst	SS_LB_L_001	Electrolytes - SI Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
425	Appendix 7.1.1F	rl-lb-flgs1.lst	SS_LB_L_001	Fasting Lipids and Glucose - SI Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
426	Appendix 7.1.2F	rl-lb-flgs2.lst	SS_LB_L_001	Fasting Lipids and Glucose - SI Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
427	Appendix 7.1.1G	rl-zl-hems1.lst	SS_LB_L_001	Hematology - US Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
428	Appendix 7.1.2G	rl-zl-hems2.lst	SS_LB_L_001	Hematology - US Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
429	Appendix 7.1.1H	rl-zl-lfts1.lst	SS_LB_L_001	Liver Function Tests - US Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
430	Appendix 7.1.2H	rl-zl-lfts2.lst	SS_LB_L_001	Liver Function Tests - US Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
431	Appendix 7.1.1I	rl-zl-enzs1.lst	SS_LB_L_001	Enzymes - US Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
432	Appendix 7.1.2I	rl-zl-enzs2.lst	SS_LB_L_001	Enzymes - US Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
433	Appendix 7.1.1J	rl-zl-rfts1.lst	SS_LB_L_001	Renal Function Tests - US Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
434	Appendix 7.1.2J	rl-zl-rfts2.lst	SS_LB_L_001	Renal Function Tests - US Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
435	Appendix 7.1.1K	rl-zl-elcs1.lst	SS_LB_L_001	Electrolytes - US Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
436	Appendix 7.1.2K	rl-zl-elcs2.lst	SS_LB_L_001	Electrolytes - US Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
437	Appendix 7.1.1L	rl-zl-flgs1.lst	SS_LB_L_001	Fasting Lipids and Glucose - US Units Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
438	Appendix 7.1.2L	rl-zl-flgs2.lst	SS_LB_L_001	Fasting Lipids and Glucose - US Units Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
439	Appendix 7.1.1M	rl-lb-diffunits1.lst	GS_LB_L_S_008	Differences in Categorization of SI and US Laboratory Test Results Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
440	Appendix 7.1.2M	rl-lb-diffunits2.lst	GS_LB_L_S_008	Differences in Categorization of SI and US Laboratory Test Results Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
441	Appendix 7.1.1N	rl-lb-pregs1.lst	GS_LB_L_X_006	Pregnancy Test Treated Female Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
442	Appendix 7.1.2N	rl-lb-pregs2.lst	GS_LB_L_X_006	Pregnancy Test Treated Female Subjects - Stage 2	WK24S2, WK48S2, WK96S2
443	Appendix 7.3.1A	rt-eg-sumchgs1.lst	SS_EG_T_003	Electrocardiogram Summary of Values and Changes from Baseline over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
444	Appendix 7.3.2A	rt-eg-sumchgs2.lst	SS_EG_T_003	Electrocardiogram Summary of Values and Changes from Baseline over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
445	Appendix 7.3.1B	rt-eg-changecats1.lst	SS_EG_T_001	Electrocardiogram Change from Baseline Category Summary Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
446	Appendix 7.3.2B	rt-eg-changecats2.lst	SS_EG_T_001	Electrocardiogram Change from Baseline Category Summary Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
447	Appendix 7.3.1C	rt-eg-cats1.lst	SS_EG_T_002	Electrocardiogram Category Summary Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
448	Appendix 7.3.2C	rt-eg-cats2.lst	SS_EG_T_002	Electrocardiogram Category Summary Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
449	Appendix 7.3.1D	rl-eg-ecgs1.lst	GS_EG_L_X_001	Electrocardiogram Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
450	Appendix 7.3.2D	rl-eg-ecgs2.lst	GS_EG_L_X_001	Electrocardiogram Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
451	Appendix 7.4.1A	rt-vs-sums1.lst	SS_VL_T_006	Vital Sign Summary of Values and Changes from Baseline over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
452	Appendix 7.4.2A	rt-vs-sums2.lst	SS_VL_T_006	Vital Sign Summary of Values and Changes from Baseline over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
453	Appendix 7.4.1B	rl-vs-lists1.lst	GS_VS_L_X_006	Vital Signs Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
454	Appendix 7.4.2B	rl-vs-lists2.lst	GS_VS_L_X_006	Vital Signs Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
455	Appendix 7.4.1C	rt-pm-sums1.lst	SS_VL_T_006	Physical Measurements Summary of Values and Changes from Baseline over Time Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
456	Appendix 7.4.2C	rt-pm-sums2.lst	SS_VL_T_006	Physical Measurements Summary of Values and Changes from Baseline over Time Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
457	Table S.7.5.1A	rt-lb-bmrenals1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Biomarker Values and Change from Baseline - US Units Treated Subjects - Stage 1	WK96S1, WK96S2
458	Table S.7.5.2A	rt-lb-bmrenals2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Biomarker Values and Change from Baseline - US Units Treated Subjects - Stage 2	WK96S2
459	Table S.7.5.1B	rt-zl-bmrenals1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Biomarker Values and Change from Baseline - SI Units Treated Subjects - Stage 1	WK96S1, WK96S2
460	Table S.7.5.2B	rt-zl-bmrenals2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Biomarker Values and Change from Baseline - SI Units Treated Subjects - Stage 2	WK96S2
461	Table S.7.5.1C	rt-lb-pchbmrenals1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - US Units Treated Subjects - Stage 1	WK96S1, WK96S2
462	Table S.7.5.2C	rt-lb-pchbmrenals2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - US Units Treated Subjects - Stage 2	WK96S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
463	Table S.7.5.1D	rt-zl-pchbmrenals1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - SI Units Treated Subjects - Stage 1	WK96S1, WK96S2
464	Table S.7.5.2D	rt-zl-pchbmrenals2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - SI Units Treated Subjects - Stage 2	WK96S2
465	Table S.7.5.1E	rt-lb-bmbones1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Bone Biomarker Values and Change from Baseline - US Units Treated Subjects - Stage 1	WK24S1
466	Table S.7.5.2E	rt-lb-bmbones2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Bone Biomarker Values and Change from Baseline - US Units Treated Subjects - Stage 2	WK24S2
467	Table S.7.5.1F	rt-zl-bmbones1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Bone Biomarker Values and Change from Baseline - SI Units Treated Subjects - Stage 1	WK24S1
468	Table S.7.5.2F	rt-zl-bmbones2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Bone Biomarker Values and Change from Baseline - SI Units Treated Subjects - Stage 2	WK24S2
469	Table S.7.5.1G	rt-lb-pchbmbones1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - US Units Treated Subjects - Stage 1	WK24S1
470	Table S.7.5.2G	rt-lb-pchbmbones2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - US Units Treated Subjects - Stage 2	WK24S2
471	Table S.7.5.1H	rt-zl-pchbmbones1.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - SI Units Treated Subjects - Stage 1	WK24S1
472	Table S.7.5.2H	rt-zl-pchbmbones2.lst	SS_VL_T_006	Laboratory Test Results Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - SI Units Treated Subjects - Stage 2	WK24S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
473	Figure S.7.5.1A	rg-lb-ub2s1	GS_LB_G_002	Urinary Beta-2-Microglobulin/Creatinine Median Percent Change from Baseline Over Time Treated Subjects - Stage 1	WK24S1
474	Figure S.7.5.2A	rg-lb-ub2s2	GS_LB_G_002	Urinary Beta-2-Microglobulin/Creatinine Median Percent Change from Baseline Over Time Treated Subjects - Stage 2	WK24S2
475	Figure S.7.5.1B	rg-lb-feps1	GS_LB_G_002	Fractional Excretion of Phosphorous Median Change from Baseline Over Time Treated Subjects - Stage 1	WK24S1
476	Figure S.7.5.2B	rg-lb-feps2	GS_LB_G_002	Fractional Excretion of Phosphorous Median Change from Baseline Over Time Treated Subjects - Stage 2	WK24S2
477	Figure S.7.5.1C	rg-lb-pchp1nps1	GS_LB_G_002	N-Terminal Propeptide of Type 1 Procollagen Median Percent Change from Baseline Over Time Treated Subjects - Stage 1	WK96S1, WK96S2
478	Figure S.7.5.2C	rg-lb-pchp1nps2	GS_LB_G_002	N-Terminal Propeptide of Type 1 Procollagen Median Percent Change from Baseline Over Time Treated Subjects - Stage 2	WK96S2
479	Figure S.7.5.1D	rg-lb-pchctxs1	GS_LB_G_002	Cross-Linked C-Telopeptide of Type 1 Collagen Median Percent Change from Baseline Over Time Treated Subjects - Stage 1	WK96S1, WK96S2
480	Figure S.7.5.2D	rg-lb-pchctxs2	GS_LB_G_002	Cross-Linked C-Telopeptide of Type 1 Collagen Median Percent Change from Baseline Over Time Treated Subjects - Stage 2	WK96S2
481	Table S.8.1.1A	rt-pk-sumbmss1.lst	MS_PK_T_004	Summary Statistics of BMS-955176 Pharmacokinetic Parameters Evaluable PK Population - Stage 1	WK24S1
482	Table S.8.1.2A	rt-pk-sumbmss2.lst	MS_PK_T_004	Summary Statistics of BMS-955176 Pharmacokinetic Parameters Evaluable PK Population - Stage 2	WK24S2
483	Table S.8.1.1B	rt-pk-sumatvs1.lst	MS_PK_T_004	Summary Statistics of ATV Pharmacokinetic Parameters Evaluable PK Population - Stage 1	WK24S1

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
484	Table S.8.1.2B	rt-pk-sumatvs2.lst	MS_PK_T_004	Summary Statistics of ATV Pharmacokinetic Parameters Evaluable PK Population - Stage 2	WK24S2
485	Table S.8.1.1C	rt-pk-sumdtgs1.lst	MS_PK_T_004	Summary Statistics of DTG Pharmacokinetic Parameters Evaluable PK Population - Stage 1	WK24S1
486	Table S.8.1.2C	rt-pk-sumdtgs2.lst	MS_PK_T_004	Summary Statistics of DTG Pharmacokinetic Parameters Evaluable PK Population - Stage 2	WK24S2
487	Table 9.2.1A	rt-pk-itsumbmss1.lst	MS_PK_T_005	Summary Statistics of BMS-955176 Pharmacokinetic Parameters Evaluable PK Population - Stage 1	WK24S1
488	Table 9.2.2A	rt-pk-itsumbmss2.lst	MS_PK_T_005	Summary Statistics of BMS-955176 Pharmacokinetic Parameters Evaluable PK Population - Stage 2	WK24S2
489	Table 9.3.1A	rt-pk-itsumdtgs1.lst	MS_PK_T_005	Summary Statistics of DTG Pharmacokinetic Parameters Evaluable PK Population - Stage 1	WK24S1
490	Table 9.3.2A	rt-pk-itsumdtgs2.lst	MS_PK_T_005	Summary Statistics of DTG Pharmacokinetic Parameters Evaluable PK Population - Stage 2	WK24S2
491	Table 9.4.1A	rt-pk-itsumatvs1.lst	MS_PK_T_005	Summary Statistics of ATV Pharmacokinetic Parameters Evaluable PK Population - Stage 1	WK24S1
492	Table 9.4.2A	rt-pk-itsumatvs2.lst	MS_PK_T_005	Summary Statistics of ATV Pharmacokinetic Parameters Evaluable PK Population - Stage 2	WK24S2
493	Table S.8.2.5.1A	rt-pk-mixedbmsdtgs1.lst	MS_PK_T_006	Effect of BMS-955176 on Exposure of DTG PK Parameters DTG Cmax, Ctau and AUC(TAU) BMS-955176 120 mg QD+ ATV/r + DTG versus TDF + ATV/r + DTG Evaluable PK Population - Stage 1	WK24S1

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
494	Table S.8.2.5.2A	rt-pk-mixedbms120dtgs2.lst	MS_PK_T_006	Effect of BMS-955176 on Exposure of DTG PK Parameters DTG Cmax, Ctau and AUC(TAU) BMS-955176 120 mg QD+ ATV + DTG versus Historical Data Evaluable PK Population - Stage 2	WK24S2
495	Table S.8.2.5.2B	rt-pk-mixedbms180dtgs2.lst	MS_PK_T_006	Effect of BMS-955176 on Exposure of DTG PK Parameters DTG Cmax, Ctau and AUC(TAU) BMS-955176 180 mg QD+ ATV + DTG versus Historical Data Evaluable PK Population - Stage 2	WK24S2
496	Table 9.3.1.1A	rt-pk-itmixedbmss1.lst	MS_PK_T_007	In-text Table of Effect of BMS-955176 on Exposure of DTG PK Parameters DTG Cmax, Ctau and AUC(TAU) BMS-955176 120 mg QD+ ATV/r + DTG versus TDF + ATV/r + DTG Evaluable PK Population - Stage 1	WK24S1
497	Table 9.3.1.2A	rt-pk-itmixedbms120s2.lst	MS_PK_T_007	In-text Table of Effect of BMS-955176 on Exposure of DTG PK Parameters DTG Cmax, Ctau and AUC(TAU) BMS-955176 120 mg QD+ ATV + DTG versus TDF + ATV/r + DTG Evaluable PK Population - Stage 2	WK24S2
498	Table 9.3.1.2B	rt-pk-itmixedbms180s2.lst	MS_PK_T_007	In-text Table of Effect of BMS-955176 on Exposure of DTG PK Parameters DTG Cmax, Ctau and AUC(TAU) BMS-955176 180 mg QD+ ATV + DTG versus TDF + ATV/r + DTG Evaluable PK Population - Stage 2	WK24S2
499	Appendix 8.2.5A	rl-pk-listbms01s1.lst	MS_PK_L_005	Listing of BMS-955176 Pharmacokinetic Parameters PK Population - Stage 1	WK24S1
500	Appendix 8.2.5A	rl-pk-listbms01s2.lst	MS_PK_L_005	Listing of BMS-955176 Pharmacokinetic Parameters PK Population - Stage 2	WK24S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
501	Appendix 8.2.5B	rl-pk-listatv01s1.lst	MS_PK_L_005	Listing of ATV Pharmacokinetic Parameters PK Population - Stage 1	WK24S1
502	Appendix 8.2.5B	rl-pk-listatv01s2.lst	MS_PK_L_005	Listing of ATV Pharmacokinetic Parameters PK Population - Stage 2	WK24S2
503	Appendix 8.2.5C	rl-pk-listdtg01s1.lst	MS_PK_L_005	Listing of DTG Pharmacokinetic Parameters PK Population - Stage 1	WK24S1
504	Appendix 8.2.5C	rl-pk-listdtg01s2.lst	MS_PK_L_005	Listing of DTG Pharmacokinetic Parameters PK Population - Stage 2	WK24S2
505	Appendix 8.2.1A	rl-pk-cpar1bmss1.lst	MS_PK_L_001	Listing of BMS-955176 Plasma Concentration – Time Data PK Population - Stage 1	WK24S1
506	Appendix 8.2.1A	rl-pk-cpar1bmss2.lst	MS_PK_L_001	Listing of BMS-955176 Plasma Concentration – Time Data PK Population - Stage 2	WK24S2
507	Appendix 8.2.1B	rl-pk-cpar1atvs1.lst	MS_PK_L_001	Listing of ATV Plasma Concentration – Time Data PK Population - Stage 1	WK24S1
508	Appendix 8.2.1B	rl-pk-cpar1atvs2.lst	MS_PK_L_001	Listing of ATV Plasma Concentration – Time Data PK Population - Stage 2	WK24S2
509	Appendix 8.2.1C	rl-pk-cpar1dtgs1.lst	MS_PK_L_001	Listing of DTG Plasma Concentration – Time Data PK Population - Stage 1	WK24S1
510	Appendix 8.2.1C	rl-pk-cpar1dtgs2.lst	MS_PK_L_001	Listing of DTG Plasma Concentration – Time Data PK Population - Stage 2	WK24S2
511	Figure S.8.2.3A	rg-pk-cpar3bmss1.lst	MS_PK_G_002	Plots of Individual BMS-955176 Plasma Concentration Profiles vs. Time Evaluable PK Population - Stage 1	WK24S1
512	Figure S.8.2.3A	rg-pk-cpar3bmss2.lst	MS_PK_G_002	Plots of Individual BMS-955176 Plasma Concentration Profiles vs. Time Evaluable PK Population - Stage 2	WK24S2
513	Figure S.8.2.3B	rg-pk-cpar3atvs1.lst	MS_PK_G_002	Plots of Individual ATV Plasma Concentration Profiles vs. Time Evaluable PK Population- Stage 1	WK24S1
514	Figure S.8.2.3B	rg-pk-cpar3atvs2.lst	MS_PK_G_002	Plots of Individual ATV Plasma Concentration Profiles vs. Time Evaluable PK Population- Stage 2	WK24S2
515	Figure S.8.2.3C	rg-pk-cpar3dtgs1.lst	MS_PK_G_002	Plots of Individual DTG Plasma Concentration Profiles vs. Time Evaluable PK Population - Stage 1	WK24S1

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
516	Figure S.8.2.3C	rg-pk-cpar3dtgs2.lst	MS_PK_G_002	Plots of Individual DTG Plasma Concentration Profiles vs. Time Evaluable PK Population - Stage 2	WK24S2
517	Figure S.8.2.1A	rg-pk-cpar1bmss1.lst	MS_PK_G_001	Overlay of Individual BMS-955176 Plasma Concentration Profile vs. Time by Treatment Evaluable PK Population - Stage 1	WK24S1
518	Figure S.8.2.1A	rg-pk-cpar1bmss2.lst	MS_PK_G_001	Overlay of Individual BMS-955176 Plasma Concentration Profile vs. Time by Treatment Evaluable PK Population - Stage 2	WK24S2
519	Figure S.8.2.1B	rg-pk-cpar1atvs1.lst	MS_PK_G_001	Overlay of Individual ATV Plasma Concentration Profile vs. Time by Treatment Evaluable PK Population - Stage 1	WK24S1
520	Figure S.8.2.1B	rg-pk-cpar1atvs2.lst	MS_PK_G_001	Overlay of Individual ATV Plasma Concentration Profile vs. Time by Treatment Evaluable PK Population - Stage 2	WK24S2
521	Figure S.8.2.1A	rg-pk-cpar1dtgs1.lst	MS_PK_G_001	Overlay of Individual DTG Plasma Concentration Profile vs. Time by Treatment Evaluable PK Population - Stage 1	WK24S1
522	Figure S.8.2.1A	rg-pk-cpar1dtgs2.lst	MS_PK_G_001	Overlay of Individual DTG Plasma Concentration Profile vs. Time by Treatment Evaluable PK Population - Stage 2	WK24S2
523	Figure S.8.2.6A	rg-pk-cpar6bmss1.lst	MS_PK_G_006	Mean (+SD) BMS-955176 Plasma Concentration Profile vs. Time Evaluable PK Population - Stage 1	WK24S1
524	Figure S.8.2.6A	rg-pk-cpar6bmss2.lst	MS_PK_G_006	Mean (+SD) BMS-955176 Plasma Concentration Profile vs. Time Evaluable PK Population - Stage 2	WK24S2
525	Figure S.8.2.6B	rg-pk-cpar6atvs1.lst	MS_PK_G_006	Mean (+SD) ATV Plasma Concentration Profile vs. Time Evaluable PK Population - Stage 1	WK24S1
526	Figure S.8.2.6B	rg-pk-cpar6atvs2.lst	MS_PK_G_006	Mean (+SD) ATV Plasma Concentration Profile vs. Time Evaluable PK Population - Stage 2	WK24S2

No.	Table No.	Output File Name	Template ID	Title and Population	Purpose
527	Figure S.8.2.6C	rg-pk-cpar6dtgs1.lst	MS_PK_G_006	Mean (+SD) DTG Plasma Concentration Profile vs. Time Evaluable PK Population - Stage 1	WK24S1
528	Figure S.8.2.6C	rg-pk-cpar6dtgs2.lst	MS_PK_G_006	Mean (+SD) DTG Plasma Concentration Profile vs. Time Evaluable PK Population - Stage 2	WK24S2
529	Appendix 10.1.1	rt-qs-eq5ds1.lst	SS_VL_T_006	EQ-5D-3L Summary of US and UK Centric Scores and Changes From Baseline Over Time on Treatment Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
530	Appendix 10.1.2	rt-qs-eq5ds2.lst	SS_VL_T_006	EQ-5D-3L Summary of US and UK Centric Scores and Changes From Baseline Over Time on Treatment Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2
531	Appendix 10.2.1	rt-qs-fahis1.lst	SS_VL_T_006	FAHI Summary of Total Scores Over Time on Treatment Treated Subjects - Stage 1	WK24S1, WK48S1, WK96S1, WK96S2
532	Appendix 10.2.2	rt-qs-fahis2.lst	SS_VL_T_006	FAHI Summary of Total Scores Over Time on Treatment Treated Subjects - Stage 2	WK24S2, WK48S2, WK96S2

2 INTRODUCTION

2.1 Guidance for DPP Users and Reviewers

The Analysis Data Presentation Plan (DPP) contains comprehensive specifications for the development of data displays for an analysis.

Templates and Metadata Tables:

Within the Analysis DPP, the following templates will reside:

- **Global Standard Templates (GS):** The layout of these templates is a Global Standard. Global Standard templates will be placed into the DPP without modifications.
- **Project Specific Templates (PS):** The layout of these templates is constructed and described in the Core DPP. Project Specific templates will be placed into the DPP without modifications.
- **For Early Development Only - Model Document Specific Template (MS):** The layout of these templates is constructed and described in the Early Development Standardized DPP Template.
- **Study Specific Templates (SS):** The layout of these templates is constructed for and described in the Analysis DPP.

A **Metadata Table** will contain information on the exact layout for a table, listing or graph.

DPP Conventions:

Text presented within a template and highlighted in grey:

- is a generic indicator for the type of endpoint or phrase that should replace it (Measure or Period for example)
- represents an optional item for a particular template presentation (P-value or Tablets/Capsules, for example).

The highlighted text in grey will remain as such in the template and the appropriate endpoint or phrase and the specifications to include within a specific table or listing in lieu of the highlighted text in grey will be described in the metadata tables. This will allow multiple tables to refer to the same table template.

2.2 Referenced Documents

The following documents were referenced in the creation of this document.

Document	Revision
GBS General Requirements for Statistical Outputs	v [Click to enter version: x.x]
Statistical Analysis Plan	v 2.0

3 GENERAL CRITERIA/CONVENTIONS

3.1 Exceptions to Global and/or Departmental Standards

Location of Documentation	Standards Document	Exception
https://external.bms.com/teams/GBS-bms955176/genprogdocs/Forms/AllItems.aspx	Demographics Domain Requirements Specification	Standards Request #8246: Add countries within geographic regions to Template GS_DM_T_X_002 and GS_DM_T_T_002. Add 2 columns "Geographic Region" and "Country" to end of Template GS_DM_L_X_001.
https://external.bms.com/teams/GBS-bms955176/genprogdocs/Forms/AllItems.aspx	Laboratory Test Results (SI Units) (US Units) Domain Requirements Specifications, Physical Measurements Domain Requirements Specifications, Vital Signs Domain Requirements Specifications	Standards Request #8247, #8251, #8255: Display N, mean, SD, median, IQR for values and changes from baseline over time, with the option to specify absolute or percent changes (see Template SS_VL_T_006).
https://external.bms.com/teams/GBS-bms955176/genprogdocs/Forms/AllItems.aspx	Laboratory Test Results (SI Units) (US Units) Domain Requirements Specifications	Standards Request #8252: Display select lab tests in side-by-side columns in all lab listings, similar to GS_LB_L_S_007, not just LFTs (see Template SS_LB_L_001).
https://external.bms.com/teams/GBS-bms955176/genprogdocs/Forms/AllItems.aspx	Electrocardiogram Domain Requirements Specification	Standards Request #8248: Modify Template GS_EG_T_X_005 to replace min and max with median, Q1, Q3, and add 95% CI for mean change from baseline (see Template SS_EG_T_003).
https://external.bms.com/teams/GBS-bms955176/genprogdocs/Forms/AllItems.aspx	Laboratory Test Results (SI Units) (US Units) Domain Requirements Specifications	Standards Request #8253: Display select toxicities (eg, Grade 1-4) by baseline tox grade categories (all, normal, Grade 1, 2, 3, 4, not reported) with multiple treatment group columns on the same page (see Template SS_LB_T_001).
https://external.bms.com/teams/GBS-bms955176/genprogdocs/Forms/AllItems.aspx	Laboratory Test Results (SI Units) (US Units) Domain Requirements Specifications	Standards Request #8254: Display treatment emergent lab abnormalities (increased to grade 1, increased to grade 2, increased to grade 3, increased to grade 4, increased to any grade) by baseline tox grade categories (all, normal, Grade 1 to 4, not reported) (see Template SS_LB_T_002).

3.2 Populations

Name as to Appear on Output	Name used in SAP (if different)	Definition when no SAP available
Enrolled Subjects		
Randomized Subjects		
Treated Subjects		

Name as to Appear on Output	Name used in SAP (if different)	Definition when no SAP available
PK Population		
Evaluable PK Population		

3.3 Conventions

[Click to enter text]

3.4 Treatment Information

Drug Name	Column Headers to use in Tables	Order Of Column	Label to use in Listings (if different)
Stage 1:			
BMS-955176	BMS-955176 120 mg + ATV/r + DTG	1	
Tenofovir	TDF 300 mg + ATV/r + DTG	2	
Stage 2:			
BMS-955176	BMS-955176 120 mg + ATV + DTG	1	
BMS-955176	BMS-955176 180 mg + ATV + DTG	2	
Tenofovir	TDF 300 mg + ATV/r + DTG	3	
Stage 1 and 2 combined:			
BMS-955176	ST1 BMS-955176 120 mg + ATV/r + DTG	1	
BMS-955176	ST2 BMS-955176 120 mg + ATV + DTG	2	
BMS-955176	ST2 BMS-955176 180 mg + ATV + DTG	3	
Stage 1+Stage 2 Tenofovir	ST1+ST2 TDF 300 mg + ATV/r + DTG	4	

3.5 Graph Criteria/Conventions

Attribute	Parameter	Value/Line
Symbol	BMS-955176 120 mg + ATV/r + DTG	Open triangle
	BMS-955176 120 mg + ATV + DTG	Open circle
	BMS-955176 180 mg + ATV + DTG	Open square

Attribute	Parameter	Value/Line
	TDF 300 mg + ATV/r + DTG	Full circle
Line style	BMS-955176 120 mg + ATV/r + DTG	Dotted line
	BMS-955176 120 mg + ATV + DTG	Dashed
	BMS-955176 180 mg + ATV + DTG	Dashed/Dotted line
	TDF 300 mg + ATV/r + DTG	Solid

4 PRESENTATION PLAN TEMPLATES AND METADATA

4.1 Administrative Appendices

Template SS_EX_L_001: Batch Number Listing

Drug	Commercial Batch Number	Subject ID	Age/Gender/Race	Kit Number	Date Kit Assigned by IVRS
<Drug Name>	XXXXXXXX	PPD	(43/F/B)	XXXXX	10MAR2003
				XXXXX	10MAR2003
			(43/F/B)	XXXXX	10MAR2003
				XXXXX	10MAR2003
				XXXXX	30FEB2004
<Drug Name#2>	XXXXXXXX		(43/F/B)	XXXXX	10MAR2003
				XXXXX	10MAR2003

Parameter	Values
Template ID	SS_EX_L_001
Output File Name	rl-ex-batchs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 1.7.1
Title 1	Listing of Batch Numbers
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_EX_L_001
Output File Name	rl-ex-batchs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 1.7.2
Title 1	Listing of Batch Numbers
Title 2	Treated Subjects - Stage 2

Template SS_DS_L_001: Randomization Scheme and Codes

Subject ID (Age/Gender/Race)	Randomized Treatment Group	Randomization Date	As Treated Treatment Group
PPD (59/F/O)	TRT A	27OCT2003	TRT A
PPD (59/F/O)	TRT A	27OCT2003	TRT B

Parameter	Values
Template ID	SS_DS_L_001
Output File Name	rl-ds-randcodes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 1.9.1
Title 1	Randomization Scheme and Codes
Title 2	Randomized Subjects - Stage 1
Programming notes	Sorted by site and subject identifier. The listing should also be “paged” by site.

Parameter	Values
Template ID	SS_DS_L_001
Output File Name	rl-ds-randcodes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 1.9.2
Title 1	Randomization Scheme and Codes
Title 2	Randomized Subjects - Stage 2
Programming notes	Sorted by site and subject identifier. The listing should also be “paged” by site.

Template SS_DM_T_001: Accrual Summary

Site Treatment Initiation Month	TRT A N=XXX	TRT B N=XXX	TRT C N=XXX	Total N=XXX
Site PPD	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Calendar Month/Year 1	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Calendar Month/Year 2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
...				
Site PPD				
Calendar Month/Year 1	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Calendar Month/Year 2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
...				

Parameter	Values
Template ID	SS_DM_T_001
Output File Name	rt-dm-accruals1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 2.1.1E
Title 1	Accrual Summary
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_DM_T_001
Output File Name	rt-dm-accruals2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 2.1.2E
Title 1	Accrual Summary
Title 2	Treated Subjects - Stage 2

4.2 Study Conduct

4.2.1 Protocol Deviations

Template SS_PD_T_001: Relevant Protocol Deviation Summary

Deviation	Group A N = XX	Group B N = XX	Group C N = XX	Group D N = XX	Total N = XX
ANY DEVIATION	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
INFORMED CONSENT NOT OBTAINED, OR OBTAINED AFTER ENROLLMENT	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
QUALIFYING HIV 1 RNA < 5,000 C/ML OR MISSING PRIOR TO RANDOMIZATION	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
CD4 < 200 CELLS/UL MISSING PRIOR TO RANDOMIZATION	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PRIOR ANTIRETROVIRAL THERAPY ≥ 1 WEEK OF EXPOSURE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Parameter	Values
Template ID	SS_PD_T_001
Output File Name	rt-pd-rels1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.2.3.1A
Title 1	Relevant Protocol Deviation Summary
Title 2	Randomized Subjects - Stage 1
Layout notes	Include the relevant protocol deviations listed in the SAP.

Parameter	Values
Template ID	SS_PD_T_001
Output File Name	rt-pd-rels2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.2.3.2A
Title 1	Relevant Protocol Deviation Summary
Title 2	Randomized Subjects - Stage 2
Layout notes	Include the relevant protocol deviations listed in the SAP.

Template SS_PD_L_001: Relevant Protocol Deviation Listing

```
------------------------------------------------------------------------------------------------------------------------
Subject ID
  (Age/Gender/Race)
    Treatment Group                 Deviation
------------------------------------------------------------------------------------------------------------------------
PPD                                 XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
  (54/M/C)
    TRT B
------------------------------------------------------------------------------------------------------------------------
```

Parameter	Values
Template ID	SS_PD_L_001
Output File Name	rl-pd-rels1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.2.3.1B
Title 1	Listing of Relevant Protocol Deviations
Title 2	Randomized Subjects - Stage 1
Layout notes	Include the relevant protocol deviations listed in the SAP.
Programming notes	Sorted by treatment group, site and subject identifier

Parameter	Values
Template ID	SS_PD_L_001
Output File Name	rl-pd-rels2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.2.3.2B
Title 1	Listing of Relevant Protocol Deviations
Title 2	Randomized Subjects - Stage 2
Layout notes	Include the relevant protocol deviations listed in the SAP.
Programming notes	Sorted by treatment group, site and subject identifier

4.3 Study Population

4.3.1 Disposition of Subjects

Template GS_DS_T_T_001: Pre-Randomization Subject Status

Protocol: TA123456 Draft Page 1 of 1

Pre-Randomized Subject Status Summary
All Enrolled Subjects

	Total
SUBJECTS ENROLLED	468
SUBJECTS RANDOMIZED (%)	445 (95.1)
SUBJECTS NOT RANDOMIZED (%)	23 (4.9)
REASON FOR NOT BEING RANDOMIZED (%)	
SUBJECT WITHDREW CONSENT	4 (0.9)
POOR/NON-COMPLIANCE	3 (0.6)
SUBJECT NO LONGER MEETS STUDY CRITERIA	12 (2.6)
ADMINISTRATIVE REASON BY SPONSOR	1 (0.2)
OTHER	3 (0.6)

Percentages based on subjects enrolled
Program Source: /wwbdm/ndp/prime/gssr/devtest/sta/test/domain_example/status1.sas 16NOV2004:10:37:00

Parameter	Values
Template ID	GS_DS_T_T_001
Output File Name	rt-ds-prerands1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.2.1.1A
Title 1	Pre-Randomization Subject Status
Title 2	Enrolled Subjects - Stage 1
Footnote 1	Percentages based on subjects enrolled.

Parameter	Values
Template ID	GS_DS_T_T_001
Output File Name	rt-ds-prerands2.lst

Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.2.1.2A
Title 1	Pre-Randomization Subject Status
Title 2	Enrolled Subjects - Stage 2
Footnote 1	Percentages based on subjects enrolled.

Template GS_DS_L_S_001: Pre-randomization Subject Status Listing

Protocol: TA123456 Draft Page 1 of 2

Pre-Randomized Subject Status
All Enrolled Subjects

Subject ID (Age/Gender/Race)	Date	Randomized	Reason Subject Will Not be Randomized
PPD (47/M/C)	27OCT2003	YES	
PPD (31/M/C)	05NOV2003	NO	SUBJECT NO LONGER MEETS STUDY CRITERIA: VIRAL LOAD < 50 COPIES AT SCREENING VISIT
PPD (24/F/B)	13FEB2004	YES	
PPD (41/F/C)	09FEB2004	NO	SUBJECT WITHDREW CONSENT: SHE IS AFRAID OF BEGINNING A NEW TREATMENT
PPD (21/F/B)	27NOV2003	YES	
PPD (39/M/C)	09OCT2003	NO	OTHER: SOCIAL SITUATION/PATIENTS WISH
PPD (46/M/C)	05APR2004	YES	
PPD (32/M/C)	05APR2004	YES	
PPD (38/M/C)	05APR2004	NO	LOST TO FOLLOW-UP: 05APR2004
PPD (44/M/C)	25SEP2003	YES	

Program Source: /wwbdm/ndp/prime/gssr/devtest/sta/test/sta_lst.sas 07SEP2004:14:35:00

Parameter	Values
Template ID	GS_DS_L_S_001
Output File Name	rl-ds-prerands1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Appendix 2.1.1A
Title 1	Pre-Randomized Subject Status
Title 2	Enrolled Subjects - Stage 1
Programming notes	Sorted by site and subject identifier

Parameter	Values
Template ID	GS_DS_L_S_001
Output File Name	rl-ds-prerands2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 2.1.2A
Title 1	Pre-Randomized Subject Status
Title 2	Enrolled Subjects - Stage 2
Programming notes	Sorted by site and subject identifier

Template GS_DM_T_T_005 : Enrollment Summary

Protocol: CV123456 Confidential Page 1 of 2

Enrollment Summary
Number Of Subjects At Each Study Site By Country

Country (%) Site Number (%)	ENROLLED N = 200	RANDOMIZED N = 150
AU ALIA	136 (78.0)	109 (72.7)
PPD	10 (5.0)	8 (5.3)
	12 (6.0)	9 (6.0)
	8 (4.0)	6 (4.0)
	9 (4.5)	7 (4.7)
	15 (7.5)	12 (8.0)
	4 (2.0)	3 (2.0)
	7 (3.5)	7 (4.7)
	5 (2.5)	5 (3.3)
	9 (4.5)	8 (5.3)
	8 (4.0)	5 (3.3)
	6 (3.0)	5 (3.3)
	13 (6.5)	10 (6.7)
	5 (2.5)	4 (2.7)
	9 (4.5)	8 (5.3)
	8 (4.0)	7 (4.7)
	7 (3.5)	5 (3.3)
CANADA	49 (24.5)	40 (26.7)
PPD	7 (3.5)	5 (3.3)
	5 (2.5)	3 (2.0)
	5 (2.5)	4 (2.7)
	11 (5.5)	9 (6.0)
	9 (4.5)	8 (5.3)
	6 (3.0)	6 (4.0)
	6 (3.0)	5 (3.3)
CHILE	14(7.0)	12 (8.0)
PPD	7 (3.5)	6 (4.0)

Program Source: /gbs/prod/clin/programs/cv/123/456/country.sas 18FEB2005:10:59:00

Parameter	Values
Template ID	GS_DM_T_T_005

Output File Name	rt-dm-enrolls1eu.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 2.1.1C
Title 1	Enrollment Summary
Title 2	Number of Subjects at Each Study Site by Country
Title 3	Enrolled Subjects - Stage 1

Parameter	Values
Template ID	GS_DM_T_T_005
Output File Name	rt-dm-enrolls2eu.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 2.1.2C
Title 1	Enrollment Summary
Title 2	Number of Subjects at Each Study Site by Country
Title 3	Enrolled Subjects - Stage 2

Template SS_DM_T_002: Counts and Percentages Table

Protocol: AI438XXX

Page 1 of X

<Title 1>
<Title 2>

Subgroup: XXXXXXXXXX Level: XXXXXXXXXXXX

<Col Header 1> (%) <Col Header 2> (%)	Group 1 N = XXX	Group 2 N = XXX
<EVENT 1>	XXX (XXX.X)	XXX (XXX.X)
<SUBEVENT 1>	XXX (XXX.X)	XXX (XXX.X)
...		
<SUBEVENT X>	XXX (XXX.X)	XXX (XXX.X)
... <ADDITIONAL EVENTS>		
<EVENT X>	XXX (XXX.X)	XXX (XXX.X)
<SUBEVENT 1>	XXX (XXX.X)	XXX (XXX.X)
...		
<SUBEVENT X>	XXX (XXX.X)	XXX (XXX.X)

<Footnote 1>
<Footnote 2>
<Footnote 3>
Program Source: <TBD>

DDMMMYYYY:HR:MM:SS

Parameter	Values
Template ID	SS_DM_T_002
Output File Name	rt-dm-enrages1eu.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 2.1.1D
Title 1	Enrollment Summary

Title 2	Number of Subjects per Age Group
Title 3	Enrolled Subjects - Stage 1
Layout notes	Col 1 Header: Age Group (%). Events 1 through 9 are the following (display even if 0 total counts): IN UTERO; PRETERM NEWBORN (GESTATIONAL AGE < 37 WEEKS); NEWBORNS (0 TO 27 DAYS); INFANTS AND TODDLERS (28 DAYS TO 23 MONTHS); CHILDREN (2 TO 11 YEARS); ADOLESCENTS (12 TO 17 YEARS); ADULTS (18 TO 64 YEARS); FROM 65 TO 84 YEARS; 85 YEARS AND OVER.

Parameter	Values
Template ID	SS_DM_T_002
Output File Name	rt-dm-enrages2eu.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 2.1.2D
Title 1	Enrollment Summary
Title 2	Number of Subjects per Age Group
Title 3	Enrolled Subjects - Stage 2
Layout notes	Col 1 Header: Age Group (%). Events 1 through 9 are the following (display even if 0 total counts): IN UTERO; PRETERM NEWBORN (GESTATIONAL AGE < 37 WEEKS); NEWBORNS (0 TO 27 DAYS); INFANTS AND TODDLERS (28 DAYS TO 23 MONTHS); CHILDREN (2 TO 11 YEARS); ADOLESCENTS (12 TO 17 YEARS); ADULTS (18 TO 64 YEARS); FROM 65 TO 84 YEARS; 85 YEARS AND OVER.

Template GS_DS_T_X_005 : End of Study Subjects Status

Protocol: TA123456 Draft Page 1 of 1

End of Study Subject Status Summary
Descriptive text of population basis

	TRT A	TRT B	TRT C	Total
SUBJECTS	150	145	150	445
SUBJECTS COMPLETING THE STUDY (%)	146 (97.3)	142 (97.9)	147 (98.0)	435 (97.8)
SUBJECTS NOT COMPLETING THE STUDY (%)	4 (2.7)	3 (2.1)	3 (2.0)	10 (2.2)
REASON FOR NOT COMPLETING THE STUDY (%)				
LACK OF EFFICACY	1 (0.7)	1 (0.7)	0	2 (0.4)
ADVERSE EVENT	2 (1.3)	0	1 (0.7)	3 (0.7)
SUBJECT WITHDREW CONSENT	1 (0.7)	1 (0.7)	2 (1.3)	4 (0.9)
LOST TO FOLLOW-UP	0	1 (0.7)	0	1 (0.2)

Percentages based on subjects population basis
Program Source: /wwbdm/ndp/prime/gssr/devtest/sta/test/domain_example/status4r.sas 16NOV2004:10:37:00

Parameter	Values
Template ID	GS_DS_T_X_005
Output File Name	rt-ds-statuss1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.2.1.1B
Title 1	End of Study Subject Status Summary
Title 2	Randomized Subjects - Stage 1

Parameter	Values
Template ID	GS_DS_T_X_005
Output File Name	rt-ds-statuss2.lst

Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.2.1.2B
Title 1	End of Study Subject Status Summary
Title 2	Randomized Subjects - Stage 2

Parameter	Values
Template ID	GS_DS_T_X_005
Output File Name	rt-ds-statuss12.lst
Purpose	WK96S2
Table No.	Table S.2.1.3B
Title 1	End of Study Subject Status Summary
Title 2	Randomized Subjects - Stage 1 and 2

Template GS_DS_L_X_005: End of Study Subject Status by Treatment Group

Protocol: TA123456 Draft Page 1 of 2

End of Study Subject Status

Descriptive text of population basis

Treatment Group: TRT A

Subject ID (Age/Gender/Race)	Period	Date	Completed Study	Reason Subject Did Not Complete Study
PPD (48/M/C)	ON STUDY	09JUL2004	YES	
PPD (62/F/C)	ON STUDY	17FEB2004	NO	ADVERSE EVENT: DUE TO AE OF HYPOTHYROIDISM BY MEDICAL MONITOR
PPD (63/F/C)	ON STUDY	29JUN2004	NO	SUBJECT WITHDREW CONSENT: TOO LONG OF COMMUTE, LEAVING AREA FOR SUMMER
PPD (62/F/C)	ON STUDY	14MAY2004	NO	LACK OF EFFICACY: FPG WITH A RESULT OF 15.1 MMOL/L AFTER RETEST
PPD (59/F/C)	ON STUDY		NO	LOST TO FOLLOW-UP
PPD (61/F/C)	ON STUDY	23AUG2004	YES	
PPD (67/M/C)	ON STUDY	10JUN2004	NO	DEATH
PPD (64/M/C)	ON STUDY	23AUG2004	YES	
PPD (67/F/C)	ON STUDY	16APR2004	NO	POOR/NON-COMPLIANCE: MEDICATION NOT TAKEN ACC. TO INVESTIGATOR'S INSTRUCTION
PPD (62/M/C)	ON STUDY	26AUG2004	YES	

Program Source: /wwbdm/ndp/prime/gssr/devtest/sta/test/sta_lst2.sas 07SEP2004:14:35:00

Parameter	Values

Template ID	GS_DS_L_X_005
Output File Name	rl-ds-statuss1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 2.1.1B
Title 1	End of Study Subject Status
Title 2	Randomized Subjects - Stage 1

Parameter	Values
Template ID	GS_DS_L_X_005
Output File Name	rl-ds-statuss2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 2.1.2B
Title 1	End of Study Subject Status
Title 2	Randomized Subjects - Stage 2

Template SS_DM_T_002 : Population Summary

	Trt A	Trt B	Trt C	Trt D	Total
RANDOMIZED SUBJECTS (A)	XX	XX	XX	XX	XX
TREATED SUBJECTS (B)	XX	XX	XX	XX	XX

Parameter	Values
Template ID	SS_DM_T_002
Output File Name	rt-dm-populations1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.2.1.1C
Title 1	Populations for Analysis Summary - Stage 1
Footnote 1	(A) Randomized subjects in the treatment group to which they were randomized.
Footnote 2	(B) Subjects who took at least one dose of study medication in the treatment group to which they were randomized
Footnote 3	unless subjects have never received the study medication they were randomized, in which case subjects will be included
Footnote 4	in the treatment group based on the first treatment received.

Parameter	Values
Template ID	SS_DM_T_002
Output File Name	rt-dm-populations2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.2.1.2C
Title 1	Populations for Analysis Summary - Stage 2
Footnote 1	(A) Randomized subjects in the treatment group to which they were randomized.

Footnote 2	(B) Subjects who took at least one dose of study medication in the treatment group to which they were randomized
Footnote 3	unless subjects have never received the study medication they were randomized, in which case subjects will be included
Footnote 4	in the treatment group based on the first treatment received.

Template SS_DM_L_001: Listing of Subjects Excluded from the Efficacy Analysis

Treatment Group: TRT A

Subject ID (Age/Gender/Race)	Reason Subject Excluded from Efficacy Analysis	Discontinuation Reason
PPD (48/M/C)	RANDOMIZED, BUT NOT TREATED	LOST TO FOLLOW-UP
PPD (62/F/C)	RANDOMIZED, BUT NOT TREATED	SUBJECT WITHDREW CONSENT: TOO LONG OF COMMUTE, LEAVING AREA FOR SUMMER

Parameter	Values
Template ID	SS_DM_L_001
Output File Name	rl-dm-excls1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 2.2.1
Title 1	Subjects Excluded from Efficacy Analysis (mITT)
Title 2	Randomized Subjects - Stage 1
Programming notes	Reason for being excluded should always be: RANDOMIZED, BUT NOT TREATED. Sorted by treatment group, site and subject identifier.

Parameter	Values
Template ID	SS_DM_L_001
Output File Name	rl-dm-excls2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 2.2.2
Title 1	Subjects Excluded from Efficacy Analysis (mITT)
Title 2	Randomized Subjects - Stage 2

Programming notes	Reason for being excluded should always be: RANDOMIZED, BUT NOT TREATED. Sorted by treatment group, site and subject identifier.

4.3.2 Demographics and Baseline Characteristics

Template GS_DM_T_X_002: Demographic Characteristics Summary (incl. 'Not reported' category)

Protocol: CA259001

Draft

Page 1 of 1

Demographic Characteristics Summary
All Treated Subjects

	TRT A N = 1113	TRT B N = 1111	TRT C N = 1107	Total N = 3331
AGE (Units)				
N	1112	1109	1107	3328
MEAN	72	71	72	72
MEDIAN	72	71	71	71
MIN , MAX	0 , 94	0 , 95	59 , 94	0 , 95
Q1 , Q3	66 , 77	66 , 76	66 , 77	66 , 77
STANDARD DEVIATION	7.2	7.7	6.8	7.2
AGE CATEGORIZATION (%)				
< 50	232 (17.3)	248 (18.3)	246 (18.0)	726 (17.9)
>= 50	880 (78.9)	861 (77.1)	861 (78.8)	2602 (78.3)
NOT REPORTED	1 (<0.1)	2 (0.2)	0	3 (<0.1)
GENDER (%)				
MALE	445 (40.1)	437 (39.1)	441 (39.6)	1323 (39.6)
FEMALE	666 (59.7)	669 (60.4)	659 (59.8)	1994 (60.0)
NOT REPORTED	2 (0.2)	5 (0.4)	7 (0.6)	14 (0.4)
RACE (%)				
WHITE	1041 (93.3)	1042 (93.3)	1041 (93.4)	3124 (93.3)
BLACK OR AFRICAN AMERICAN	26 (2.3)	24 (2.1)	20 (2.5)	70 (2.3)
ASIAN	4 (0.4)	5 (0.4)	3 (0.3)	12 (0.4)
OTHER	42 (4.0)	40 (4.1)	42 (3.8)	124 (4.0)
NOT REPORTED	0	0	1 (<0.1)	1 (<0.1)
ETHNICITY (%)				
HISPANIC/LATINO	24 (2.4)	35 (3.1)	33 (2.8)	92 (2.8)
NOT HISPANIC/LATINO	1089 (97.6)	1076 (96.9)	1073 (97.1)	3238 (97.2)
NOT REPORTED	0	0	1 (<0.1)	1 (<0.1)

Program Source: /wwbdm/ndp/prime/gssr/devtest/dem/test/dem_tbl_mod.sas

30DEC2004:14:45:05

Parameter	Values
Template ID	GS_DM_T_X_002
Output File Name	rt-dm-summarys1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.1.1
Title 1	Demographic Characteristics Summary
Title 2	Treated Subjects - Stage 1
Layout notes	See SAP Table 7.3.2.1-1. Add “COUNTRY BY GEOGRAPHIC REGION (%)” after “ETHNICITY (%)”. Indent countries 2 spaces underneath regions.

Parameter	Values
Template ID	GS_DM_T_X_002
Output File Name	rt-dm-summarys2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.1.2
Title 1	Demographic Characteristics Summary
Title 2	Treated Subjects - Stage 2
Layout notes	See SAP Table 7.3.2.1-1. Add “COUNTRY BY GEOGRAPHIC REGION (%)” after “ETHNICITY (%)”. Indent countries 2 spaces underneath regions.

Parameter	Values
Template ID	GS_DM_T_X_002
Output File Name	rt-dm-summarys12.lst
Purpose	WK96S2
Table No.	Table S.3.1.3
Title 1	Demographic Characteristics Summary

Title 2	Treated Subjects - Stage 1 and 2
Layout notes	See SAP Table 7.3.2.1-1. Add “COUNTRY BY GEOGRAPHIC REGION (%)” after “ETHNICITY (%)”. Indent countries 2 spaces underneath regions.

Template GS_DM_T_T_002: Demographic Characteristics Summary (incl. 'Not reported' category)

Protocol: CA259001 Draft Page 1 of 1

Demographic Characteristics Summary
All Treated Subjects

	Total N = 3348
AGE (Units)	
N	3345
MEAN	72
MEDIAN	71
MIN , MAX	0 , 95
Q1 , Q3	66 , 77
STANDARD DEVIATION	7.2
AGE CATEGORIZATION (%)	
< 65	598 (17.9)
65 - 85	2620 (78.3)
NOT REPORTED	3 (<0.1)
GENDER (%)	
MALE	1323 (39.6)
FEMALE	1994 (60.0)
NOT REPORTED	14 (0.4)
RACE (%)	
WHITE	3124 (93.3)
BLACK OR AFRICAN AMERICAN	78 (2.3)
ASIAN	12 (0.4)
OTHER	133 (4.0)
NOT REPORTED	1 (<0.1)
ETHNICITY (%)	
HISPANIC/LATINO	93 (2.8)
NOT HISPANIC/LATINO	3254 (97.2)
NOT REPORTED	1 (<0.1)

Program Source: /wwbdm/ndp/prime/gssr/devtest/dem/test/dem_tbl_mod.sas 30DEC2004:14:46:08

Parameter	Values
Template ID	GS_DM_T_T_002
Output File Name	rt-dm-sumenrolls1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Appendix 3.1.1B
Title 1	Demographic Characteristics Summary
Title 2	Subjects Enrolled but Not Randomized - Stage 1
Layout notes	See SAP Table 7.3.2.1-1. Add “COUNTRY BY GEOGRAPHIC REGION (%)” after “ETHNICITY (%)”. Indent countries 2 spaces underneath regions.

Parameter	Values
Template ID	GS_DM_T_T_002
Output File Name	rt-dm-sumenrolls2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.1.2B
Title 1	Demographic Characteristics Summary
Title 2	Subjects Enrolled but Not Randomized - Stage 2
Layout notes	See SAP Table 7.3.2.1-1. Add “COUNTRY BY GEOGRAPHIC REGION (%)” after “ETHNICITY (%)”. Indent countries 2 spaces underneath regions.

Template GS_DM_L_X_001: Demographics Listing by Treatment Group

Protocol: CV131148 Draft Page 1 of 11

Demographic Characteristics
All Treated Subjects

Treatment Group: TRT A

Subject ID	Informed Consent Date	Birth Date	Age	Gender	Ethnicity	Race
PPD	22NOV2002	PPD 2001	1	MALE	HISPANIC/LATINO	WHITE
	07DEC2003	PPD 2003	10M	MALE		OTHER: WHITE SOUTH AFRICAN
	12JUN2003	PPD 2002	6M	MALE	HISPANIC/LATINO	WHITE
	17FEB2003	PPD 2002	1	MALE	NOT HISPANIC/LATINO	WHITE
	24APR2003	PPD 2001	2	MALE	NOT HISPANIC/LATINO	WHITE
	14MAY2003	PPD 2000	3	FEMALE	NOT HISPANIC/LATINO	WHITE
	25DEC2001	PPD 2001	2D	FEMALE	NOT HISPANIC/LATINO	WHITE

Program Source: /wwbdm/ndp/prime/gssr/devtest/dem/test/dem_lst.sas 30DEC2004:15:50:44

Parameter	Values
Template ID	GS_DM_L_X_001
Output File Name	rl-dm-demchars1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 3.1.1A
Title 1	Demographic Characteristics
Title 2	Treated Subjects - Stage 1
Layout notes	Add 2 columns “Country” and “Geographic Region” after “Race”.

Parameter	Values
Template ID	GS_DM_L_X_001

Output File Name	rl-dm-demchars2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.1.2A
Title 1	Demographic Characteristics
Title 2	Treated Subjects - Stage 2
Layout notes	Add 2 columns “Country” and “Geographic Region” after “Race”.

Template SS_DM_T_004 : Baseline Disease Characteristics

	Group A N = XX	Group B N = XX	Group C N = XX	Group D N = XX	Total N = XX
HIV SUBTYPE					
A	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
B	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<ADDITIONAL SUBTYPES>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Plasma HIV-1 RNA (log10 c/mL)					
N	XX	XX	XX	XX	XX
MEAN	XX.X	XX.X	XX.X	XX.X	XX.X
MEDIAN	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	XX.X , XX.X
Q1 , Q3	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
STANDARD DEVIATION	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
HIV-1 RNA CATEGORIZATION					
< 30,000 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
30,000 to < 100,000 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
100,000 to < 500,000 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 500,000 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
NOT REPORTED	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
CD4+ T-cell counts (cells/uL)					
N	XX	XX	XX	XX	XX
MEAN	XX.X	XX.X	XX.X	XX.X	XX.X
MEDIAN	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	XX.X , XX.X
Q1 , Q3	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
STANDARD DEVIATION	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CD4+ T-cell CATEGORIZATION					
< 50 cells/uL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
50 to < 100 cells/uL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
100 to < 200 cells/uL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
200 to < 350 cells/uL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
350 to < 500 cells/uL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 500 cells/uL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
NOT REPORTED	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
CD4+ T-cell percentage					
N	XX	XX	XX	XX	XX
MEAN	XX.X	XX.X	XX.X	XX.X	XX.X
MEDIAN	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	XX.X , XX.X
Q1 , Q3	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
STANDARD DEVIATION	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX

```
CD8+ T-cell counts (cells/uL)
  N                          XX                 XX                 XX                 XX                 XX
  MEAN                     XX.X               XX.X               XX.X               XX.X               XX.X
  MEDIAN                   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        XX.X , XX.X
  Q1 , Q3                XX.X , XX.X        XX.X , XX.X        XX.X , XX.X        XX.X , XX.X        XX.X , XX.X
  STANDARD DEVIATION       XX.XX              XX.XX              XX.XX              XX.XX              XX.XX

BMS-955176 IC50 (µM)
  N                          XX                 XX                 XX                 XX                 XX
  MEAN                     XX.X               XX.X               XX.X               XX.X               XX.X
  Geometric Mean
 (Coefficient of Variation)
MEDIAN                   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        XX.X , XX.X
  Q1 , Q3                XX.X , XX.X        XX.X , XX.X        XX.X , XX.X        XX.X , XX.X        XX.X , XX.X
  STANDARD DEVIATION       XX.XX              XX.XX              XX.XX              XX.XX              XX.XX

BMS-955176 IC50 FOLD CHANGE
  < 1.0                  xx ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)
  1.0 to < 5.0           xx ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)
  5.0 to < 10            xx ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)
  10  to < 100           xx ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)
  100 to < 500           xx ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)
  >= 500                 xx ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)

AIDS STATUS
  YES                    xx ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)
  NO                     xx ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)         XX ( XX.X)
```

Parameter	Values
Template ID	SS_DM_T_004
Output File Name	rt-dm-diseases1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.2.1
Title 1	Summary of Baseline Disease Characteristics
Title 2	Treated Subjects - Stage 1
Layout notes	Include all HIV subtypes available in the database.

Parameter	Values
Template ID	SS_DM_T_004
Output File Name	rt-dm-diseases2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.2.2
Title 1	Summary of Baseline Disease Characteristics
Title 2	Treated Subjects - Stage 2
Layout notes	Include all HIV subtypes available in the database.

Parameter	Values
Template ID	SS_DM_T_004
Output File Name	rt-dm-diseases12.lst
Purpose	WK96S2
Table No.	Table S.3.2.3
Title 1	Summary of Baseline Disease Characteristics
Title 2	Treated Subjects - Stage 1 and 2
Layout notes	Include all HIV subtypes available in the database.

Parameter	Values
Template ID	SS_DM_T_004
Output File Name	rt-dm-diseasenrands1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 3.2.1A
Title 1	Summary of Baseline Disease Characteristics
Title 2	Subjects Enrolled but Not Randomized - Stage 1

Layout notes	Include only the 'Total' column. Include all HIV subtypes available in the database.

Parameter	Values
Template ID	SS_DM_T_004
Output File Name	rt-dm-diseasenrands2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.2.2A
Title 1	Summary of Baseline Disease Characteristics
Title 2	Subjects Enrolled but Not Randomized - Stage 2
Layout notes	Include only the 'Total' column. Include all HIV subtypes available in the database.

Template SS_DM_L_002: Listing of HIV Disease Characteristics

Treatment Group: TRT A

Subject ID	Plasma HIV-1 Level		CD4+ T-cell count		CD4 T-cell (percent)	CD8+ cells/uL)	HIV Subtype	IC50 (µM)	IC Fold Change
	Result (log10 c/mL)	Category (c/mL)	Result (cells/uL)	Category (cells/uL)					
PPD	x.x	<30,000	xx	< 200	xx	xx	xxxx	xx	xx
	x.x	30,000 to < 100,000	xx	350 to < 500	xx	xx	xxxx	xx	xx
	x.x	100,000 to < 500,000	xx	200 to < 350	xx	xx	xxxx	xx	xx
	x.x	≥ 500,000	xx	200 to < 350	xx	xx	xxxx	xx	xx
	x.x	≥ 500,000	xx	350 to < 500	xx	xx	xxxx	xx	xx
	x.x	≥ 500,000	xx	≥ 500	xx	xx	xxxx	xx	xx
	x.x	≥ 500,000	xx	350 to < 500	xx	xx	xxxx	xx	xx
	x.x	≥ 500,000	xx	350 to < 500	xx	xx	xxxx	xx	xx

Parameter	Values
Template ID	SS_DM_L_002
Output File Name	rl-dm-diseases1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 3.2.1B
Title 1	Listing of HIV Disease Characteristics
Title 2	Treated Subjects - Stage 1
Programming notes	Sorted by treatment group, site and subject identifier

Parameter	Values
Template ID	SS_DM_L_002
Output File Name	rl-dm-diseases2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.2.2B

Title 1	Listing of HIV Disease Characteristics
Title 2	Treated Subjects - Stage 2
Programming notes	Sorted by treatment group, site and subject identifier

Template GS_PM_T_X_001: Physical Measurements Table

Protocol: CA259001 Draft Page 1 of 2

Physical Measurements Summary
All Treated Subjects

Period/Visit	TRT A N = 1366	TRT B N = 1382	TRT C N = 1338	Total N = 4086
SCREENING/DAY -1				
HEIGHT (CM)				
N	1366	1382	1338	4086
MEAN	170.6	170.6	170.6	170.6
MEDIAN	171.0	171.0	171.0	171.0
MIN , MAX	147.3 , 198.1	149.0 , 198.1	143.5 , 198.1	143.5 , 198.1
STANDARD DEVIATION	3.62	3.73	3.69	3.68
WEIGHT (KG)				
N	1366	1382	1338	4086
MEAN	87.7	88.1	88.7	88.2
MEDIAN	85.3	86.5	85.7	85.7
MIN , MAX	51.0 , 158.1	41.5 , 149.2	38.4 , 144.5	38.4 , 158.1
STANDARD DEVIATION	18.63	21.01	19.39	19.71
BODY MASS INDEX (KG/M2)				
N	1366	1382	1338	4086
MEAN	30.11	30.25	30.46	30.27
MEDIAN	29.31	29.74	29.49	29.48
MIN , MAX	17.44 , 54.07	14.19 , 51.02	13.13 , 47.95	13.13 , 54.07
STANDARD DEVIATION	6.252	7.017	6.523	6.607

Program Source: /wwbdm/ndp/prime/gssr/devtest/phm/test/domain_example/phm_tbl1.sas 15DEC2004:16:21:00

Parameter	Values
Template ID	GS_PM_T_X_001
Output File Name	rt-pm-bsls1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.3.1
Title 1	Physical Measurements Summary
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	GS_PM_T_X_001
Output File Name	rt-pm-bsls2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.3.2
Title 1	Physical Measurements Summary
Title 2	Treated Subjects - Stage 2

Template GS_PE_T_X_001: Physical Examination by Treatment Group

Protocol: TA123456

Draft
Physical Examination Summary
All Treated Subjects

Period/Visit	TRT A N = 16	TRT B N = 17	TRT C N = 17	Total N = 50
SCREENING/DAY 1				
SUBJECTS WITH ABNORMAL PHYSICAL EXAMINATION (%)	10 (62.5)	14 (82.4)	14 (82.4)	38 (76.0)
GENERAL APPEARANCE	0	1 (5.9)	0	1 (2.0)
HEAD, EARS, EYES, NOSE, THROAT	5 (31.3)	12 (70.6)	5 (29.4)	22 (44.0)
NECK	0	0	0	0
CARDIOVASCULAR	0	0	0	0
LUNGS	0	0	1 (5.9)	1 (2.0)
ABDOMEN	1 (6.3)	2 (11.8)	1 (5.9)	4 (8.0)
LYMPH NODES	0	0	0	0
GENITOURINARY	0	0	0	0
EXTREMITIES	3 (18.8)	2 (11.8)	4 (23.5)	9 (18.0)
NEUROLOGICAL	0	0	1 (5.9)	1 (2.0)
SKIN	8 (50.0)	10 (58.8)	8 (47.1)	26 (52.0)
MUSCULOSKELETAL	0	1 (5.9)	1 (5.9)	2 (4.0)
OTHER	8 (50.0)	7 (41.2)	8 (47.1)	23 (46.0)
SCREENING/DAY 5				
SUBJECTS WITH ABNORMAL PHYSICAL EXAMINATION (%)	10 (62.5)	14 (82.4)	14 (82.4)	38 (76.0)
GENERAL APPEARANCE	0	1 (5.9)	0	1 (2.0)
HEAD, EARS, EYES, NOSE, THROAT	5 (31.3)	12 (70.6)	5 (29.4)	22 (44.0)
NECK	0	0	0	0
CARDIOVASCULAR	0	0	0	0
LUNGS	0	0	1 (5.9)	1 (2.0)
ABDOMEN	1 (6.3)	2 (11.8)	1 (5.9)	4 (8.0)
LYMPH NODES	0	0	0	0
GENITOURINARY	0	0	0	0
EXTREMITIES	3 (18.8)	2 (11.8)	4 (23.5)	9 (18.0)
NEUROLOGICAL	0	0	1 (5.9)	1 (2.0)
SKIN	8 (50.0)	10 (58.8)	8 (47.1)	26 (52.0)
MUSCULOSKELETAL	0	1 (5.9)	1 (5.9)	2 (4.0)
OTHER	8 (50.0)	7 (41.2)	8 (47.1)	23 (46.0)

Program Source: /wwbdm/ndp/prime/gssr/devtest/mhx/test/domain_example/phx_tbl.sas 21SEP2004:10:31:00

Parameter	Values
Template ID	GS_PE_T_X_001
Output File Name	rt-pe-bslsums1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.4.1
Title 1	Physical Examination Summary
Title 2	Treated Subjects - Stage 1
Layout notes	Include all examinations present in the database.

Parameter	Values
Template ID	GS_PE_T_X_001
Output File Name	rt-pe-bslsums2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.4.2
Title 1	Physical Examination Summary
Title 2	Treated Subjects - Stage 2
Layout notes	Include all examinations present in the database.

Template GS_PE_L_X_001 : Physical Examination Listing by Treatment Group

Protocol: TA123456 Draft Page 1 of 958
Physical Examination
All Treated Subjects

Treatment Group: DRUG C

Subject ID (Age/Gender/Race)	Period Visit Exam Date Study Day	Exanimation Criteria	Exam Result	Abnormality
PPD (46/M/C)	SCREENING A1 PPD -14	GENERAL APPEARANCE	NORMAL	
		HEENT	ABNORMAL	R EYE MILD NYSTIGMUS NCS
		NECK	ABNORMAL	CAROTID PULSES DIMINISHED SYMETRICALLY WITHOUT BRUITS NCS
		CARDIOVASCULAR	ABNORMAL	MSM GRADE I-II / III NCS
		LUNGS	NORMAL	
		ABDOMEN	NORMAL	
		LYMPH NODES	NORMAL	
		GENITOURINARY	NOT DONE	
		EXTREMITIES	ABNORMAL	BILATERAL TRACE NO PITTING ANKLE EDEMA
		NEUROLOGICAL	NORMAL	
		SKIN	ABNORMAL	ABRASION R BENIGN MOLES NEVI & ACROCHORITONS
		MUSCULOSKELETAL	ABNORMAL	BILAT HAND W/MCP&PIP RA CHNGS,TR SYNOVITIS L MCP 3&4,R MCP 3,4,5,TR SYNOVITIS WRIST BILAT,MILD BILAT TRAPESIUS TIGHTNES SYMETRICALLY, SHOULDERS DECR FROM ABDUCT 90 DEGREES SYMETRICALLY W/ANTERIOR TPS
PPD (55/F/C)	PRE-TREAT A3 PPD -1	GENERAL APPEARANCE	NORMAL	
		HEENT	NORMAL	
		NECK	NORMAL	
		CARDIOVASCULAR	NORMAL	
		LUNGS	NORMAL	
		ABDOMEN	NORMAL	

Program Source: /wwbdm/ndp/prime/gssr/devtest/phy/test/phy_lst.sas 28FEB2005:15:09:00

Parameter	Values
Template ID	GS_PE_L_X_001
Output File Name	rl-pe-lists1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Appendix 3.4.1
Title 1	Physical Examination
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	GS_PE_L_X_001
Output File Name	rl-pe-lists2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.4.2
Title 1	Physical Examination
Title 2	Treated Subjects - Stage 2

Template SS_GN_T_001: Baseline Genotypic Resistance Profile

Subgroup: XXXXXXXXXX Level: XXXXXXXXXXXX

	Group A N = XX	Group B N = XX	Group C N = XX	Group D N=XX
TESTED	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
SEQUENCED	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
ANY PI SUBSTITUTIONS	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
PI substitutions#1	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
PI substitutions#2	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
PI substitutions#3	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
PI substitutions#4	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
<ADDITIONAL SUBSTITUTIONS> . . .				
SELECTED RT SUBSTITUTIONS	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
nRTI SUBSTITUTIONS				
nRTI substitutions#1	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
nRTI substitutions#2	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
<ADDITIONAL SUBSTITUTIONS> . . .				
NNRTI SUBSTITUTIONS				
NNRTI substitutions#1	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
NNRTI substitutions#2	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
INTEGRASE (RAL) SUBSTITUTIONS	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
RAL substitutions#1	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-bases1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1A
Title 1	Baseline Genotypic Resistance Profile
Title 2	Treated Subjects - Stage 1
Footnote 1	Mutations extracted from data are based on IAS-USA list updated June 2014.

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-bases2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2A
Title 1	Baseline Genotypic Resistance Profile
Title 2	Treated Subjects - Stage 2
Footnote 1	Mutations extracted from data are based on IAS-USA list updated June 2014.

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-bases12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3A
Title 1	Baseline Genotypic Resistance Profile
Title 2	Treated Subjects - Stage 1 and 2
Footnote 1	Mutations extracted from data are based on IAS-USA list updated June 2014.

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-basebysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 3.9.1A
Title 1	Baseline Genotypic Resistance Profile

Title 2	By HIV Subtype
Title 3	Treated Subjects - Stage 1
Footnote 1	Mutations extracted from data are based on IAS-USA list updated June 2014.

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-basebysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.9.2A
Title 1	Baseline Genotypic Resistance Profile
Title 2	By HIV Subtype
Title 3	Treated Subjects - Stage 2
Footnote 1	Mutations extracted from data are based on IAS-USA list updated June 2014.

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-baseots1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1B
Title 1	Baseline Genotypic Resistance Profile
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 1
Footnote 1	Mutations extracted from data are based on IAS-USA list updated June 2014.

Parameter	Values
Template ID	SS_GN_T_001

Output File Name	rt-gn-baseots2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2B
Title 1	Baseline Genotypic Resistance Profile
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 2
Footnote 1	Mutations extracted from data are based on IAS-USA list updated June 2014.

Template SS_GN_L_001:Genotypic Resistance Listing

Subject ID (Age/Gender/Race) Treatment Group	Current Treatment	Period Visit Date Study Day	RT Substitutions	PI Substitutions	RAL Substitutions
PPD (54/F/C) ATV/r/RAL/TDF	PRE-TREATMENT	PRE-TREATMENT SCREENING PPD -42	Q102K, K103K, K103N, I142I, I142V, C162S, I178L, R211K, A272P, K275R, R277K, Q278H	R41K, Q61H	V72I, S81R, S81S, V113I, T124A, V201I, Y227F, S230N, R231K, V234L, A265V
	ATV300mg QD+RTV100mg QD+ RAL400mg BID+TDF300mg QD	STAGE 1 WE PPD 119	Q102K, K103K, K103N, I142I, I142V, C162S, I178L, R211K, A272P, K275R, R277K, Q278H, P294P, P294S	R41K, Q61H	V72I, V113I, T124A, V201I, Y227F, S230N, R231K, V234L, A265V
PPD (62/M/C) ATV/r/RAL/TDF	PRE-TREATMENT	PRE-TREATMENT SCREENING PPD -38	Q102K, K103N, K122E, K122K, D123D, D123E, D123K, D123N, V179I, V179V, Q207N, H208H, H208Y, R211K, A272P, T286A, V293I, E297K	E35D, M36I, M36M, N37D, R57K, R57R, I62V, L63H, I93L	E10D, M50I, M50M, V72I, L101I, V113I, S119P, T125A, K156N, G193E, G193G, G193K, G193R, V201I, S230N, D232E, V234L, D256E, D278A, Q285P, Q285Q

Parameter	Values
Template ID	SS_GN_L_001
Output File Name	rl-gn-bsls1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 3.9.1B
Title 1	Listing of Baseline Genotypic Substitutions

Title 2	Treated Subjects - Stage 1
Programming notes	Please include only the pre-treatment assessments.

Parameter	Values
Template ID	SS_GN_L_001
Output File Name	rl-gn-bsls2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.9.2B
Title 1	Listing of Baseline Genotypic Substitutions
Title 2	Treated Subjects - Stage 2
Programming notes	Please include only the pre-treatment assessments.

Template SS_GN_T_002: Baseline Gag Polymorphisms at Selected Positions

Subgroup: XXXXXXXXXX Level: XXXXXXXXXXXX

	Group A N = XX	Group B N = XX	Group C N = XX	Group D N=XX
TESTED	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
SEQUENCED	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
SELECTED SUBSTITUTIONS	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITION 362	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITION 364	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITION 369	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITION 370	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 362 AND 364	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 362 AND 369	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 362 AND 370	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 364 AND 369	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 364 AND 370	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 369 AND 370	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 362, 364 AND 369	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 362, 364 AND 370	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 364, 369 AND 370	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
POSITIONS 362, 364, 369 AND 370	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgags1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1C
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgags2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2C
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects - Stage 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgags12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3C
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects - Stage 1 and 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagbysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1D
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagbysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2D
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects - Stage 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagbysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3D
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects - Stage 1 and 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagontrts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1H
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 1

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagontrts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2H
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagontrts12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3H
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagontrtbysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1I
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Resistance Testing - Stage 1

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagontrtbysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2I
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Resistance Testing - Stage 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagontrtbysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3I
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1J
Title 1	Baseline Gag Polymorphisms at Selected Positions

Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2J
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagpdvfs12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3J

Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagpdvfbysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1K
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagpdvfbysubtypes2.lst

Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2K
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-bslgagpdvfbysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3K
Title 1	Baseline Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Template SS_GN_T_003: Baseline Gag Deviations from Wild Type

Subgroup: XXXXXXXXXX Level: XXXXXXXXXXXX

	Group A N = XX	Group B N = XX	Group C N = XX	Group D N=XX
TESTED	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
SEQUENCED	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
ANY DEVIATION	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
DEV 1	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
DEV 2	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
DEV 3	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
DEV 4	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganys1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1E
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects - Stage 1
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganys2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Table S.3.9.2E
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects - Stage 2
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganys12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3E
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects - Stage 1 and 2
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganybysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1L
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	By HIV Subtype
Title 3	Treated Subjects - Stage 1
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values

Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganybysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2L
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	By HIV Subtype
Title 3	Treated Subjects - Stage 2
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganybysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3L
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	By HIV Subtype
Title 3	Treated Subjects - Stage 1 and 2
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganyontrts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1M
Title 1	Baseline Gag Deviations from Wild Type Virus

Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 1
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganyontrts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2M
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 2
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganyontrts12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3M
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganyontrtbysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Table S.3.9.1N
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Resistance Testing - Stage 1
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganyontrtbysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2N
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Resistance Testing - Stage 2
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganyontrtbysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3N
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganypdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1O
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganypdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2O
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL

Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganypdvfs12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3O
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganypdvfbysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1P
Title 1	Baseline Gag Deviations from Wild Type Virus

Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganypdvfbysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2P
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Include any deviation from the wild type virus detected in the database.

Parameter	Values

Template ID	SS_GN_T_003
Output File Name	rt-gn-bslgaganypdvfbysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3P
Title 1	Baseline Gag Deviations from Wild Type Virus
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Include any deviation from the wild type virus detected in the database.

Template SS_GN_L_002: Gag Listing for Selected Positions

Subject ID (Age/Gender/Race) Treatment Group	HIV Subtype	Current Treatment	Period Visit Date Study Day	Position 362	Position 364	Position 369	Position 370
PPD (54/F/C) ATV/r/RAL/TDF	B	PRE-TREATMENT	PRE-TREATMENT SC PPD -42	xxx	xxx	xxx	xxx
		ATV300mg QD+RTV100mg QD+ RAL400mg BID+TDF300mg QD	STAGE 1 WE PPD 119	xxx	xxx	xxx	xxx
PPD (62/M/C) ATV/r/RAL/TDF	C	PRE-TREATMENT	PRE-TREATMENT SCREENING PPD -38	xxx	xxx	xxx	xxx

Parameter	Values
Template ID	SS_GN_L_002
Output File Name	rl-gn-gagbsls1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 3.9.1C
Title 1	Listing of Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects - Stage 1
Programming notes	Please include only the pre-treatment assessments.

Parameter	Values
Template ID	SS_GN_L_002
Output File Name	rl-gn-gagbsls2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.9.2C
Title 1	Listing of Baseline Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects - Stage 2
Programming notes	Please include only the pre-treatment assessments.

Template SS_GN_L_003: Gag Listing of Deviations from the Wild Type Virus

Subject ID (Age/Gender/Race) Treatment Group	HIV Subtype	Current Treatment	Period Visit Date Study Day	Deviations
PPD (54/F/C) ATV/r/RAL/TDF	C	PRE-TREATMENT	PRE-TREATMENT SC PPD -42	xxx, xxx, xxx, xxx
		ATV300mg QD+RTV100mg QD+ RAL400mg BID+TDF300mg QD	STAGE 1 WEEK 16 PPD 119	xxx, xxx, xxx, xxx
PPD (62/M/C) ATV/r/RAL/TDF	B	PRE-TREATMENT	PRE-TREATMENT SC PPD -38	xxx

Parameter	Values
Template ID	SS_GN_L_003
Output File Name	rl-gn-gagbslanys1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 3.9.1D
Title 1	Listing of Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects - Stage 1
Programming notes	Please include only the pre-treatment assessments.

Parameter	Values
Template ID	SS_GN_L_003
Output File Name	rl-gn-gagbslanys2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.9.2D
Title 1	Listing of Baseline Gag Deviations from Wild Type Virus
Title 2	Treated Subjects - Stage 2
Programming notes	Please include only the pre-treatment assessments.

Template SS_PN_T_001: Baseline Phenotypic Resistance Categories

	Group A N = XX	Group B N = XX	Group C N = XX	Group D N=XX
PHENOTYPIC TESTING AT BASELINE	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
PHENOTYPABLE	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
RESISTANCE CATEGORY				
NO RESISTANCE TO DRUGS IN ANY CLASS	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
≥1 NRTI	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
≥1 nNRTI	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
≥1 PI	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
≥1 INI	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 NRTI) AND (≥1 nNRTI)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 NRTI) AND (≥1 PI)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 NRTI) AND (≥1 INI)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 nNRTI) AND (≥1 PI)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 nNRTI) AND (≥1 INI)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 PI) AND (≥1 INI)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 NRTI) AND (≥1 nNRTI) AND (≥1 PI)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 NRTI) AND (≥1 nNRTI) AND (≥1 INI	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 NRTI) AND (≥1 PI) AND (≥1 INI)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 nNRTI) AND (≥1 PI) AND (≥1 INI	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
(≥1 NRTI) AND (≥1 nNRTI) AND (≥1 PI) AND (≥1 INI	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-bsls1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1F
Title 1	Baseline Phenotypic Resistance Categories
Title 2	Treated Subjects - Stage 1

Parameter	Values

Template ID	SS_PN_T_001
Output File Name	rt-pn-bsls2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2F
Title 1	Baseline Phenotypic Resistance Categories
Title 2	Treated Subjects - Stage 2

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-bsls12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3F
Title 1	Baseline Phenotypic Resistance Categories
Title 2	Treated Subjects - Stage 1 and 2

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-bslots1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1G
Title 1	Baseline Phenotypic Resistance Categories
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 1

Parameter	Values
Template ID	SS_PN_T_001

Output File Name	rt-pn-bslots2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2G
Title 1	Baseline Phenotypic Resistance Categories
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 2

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-bslots12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3G
Title 1	Baseline Phenotypic Resistance Categories
Title 2	Treated Subjects with On-Treatment Resistance Testing - Stage 1 and 2

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-bslpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1Q
Title 1	Baseline Phenotypic Resistance Categories
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window

Footnote 5	4) Failure to achieve > 1 log_{10} c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-bslpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2Q
Title 1	Baseline Phenotypic Resistance Categories
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 log_{10} c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 log_{10} c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-bslpdvfs12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3Q
Title 1	Baseline Phenotypic Resistance Categories
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 log_{10} c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL

Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Template SS_PN_T_002: Phenotypic Resistance by Class and Drug Name

	TRT A N = 10	TRT B N = 15	TRT C N = 14	TRT D N = 15	TRT E N = 11
PHENOTYPIC TESTING	10/10 (100.0)	15/15 (100.0)	14/14 (100.0)	15/15 (100.0)	11/11 (100.0)
PHENOTYPABLE	9/10 (90.0)	14/15 (93.3)	14/14 (100.0)	15/15 (100.0)	11/11 (100.0)
PHENOTYPE					
PI	1/9 (11.1)	0/14	1/14 (7.1)	2/15 (13.3)	0/11
AMP	0/9	0/14	0/14	0/15	0/11
AMP/R	0/9	0/14	0/14	0/15	0/11
ATV	1/9 (11.1)	0/14	0/14	1/15 (6.7)	0/11
ATV/R	0/9	0/14	0/14	0/15	0/11
DRV/R	0/9	0/14	0/14	0/15	0/11
IDV/R	0/9	0/14	0/14	0/15	0/11
LPV/R	0/9	0/14	0/14	0/15	0/11
NFV	0/9	0/14	0/14	0/15	0/11
RTV	1/9 (11.1)	0/14	0/14	1/15 (6.7)	0/11
SQV	0/9	0/14	0/14	0/15	0/11
SQV/R	1/9 (11.1)	0/14	0/14	1/15 (6.7)	0/11
TPV/R	1/9 (11.1)	0/14	1/14 (7.1)	2/15 (13.3)	0/11
NNRTI	1/9 (11.1)	2/14 (14.3)	0/14	0/15	1/11 (9.1)
DLV	1/9 (11.1)	1/14 (7.1)	0/14	0/15	1/11 (9.1)
EFV	1/9 (11.1)	1/14 (7.1)	0/14	0/15	1/11 (9.1)
ETR	0/9	0/14	0/14	0/15	0/11
NVP	1/9 (11.1)	0/14	0/14	0/15	1/11 (9.1)
NRTI	1/9 (11.1)	1/14 (7.1)	1/14 (7.1)	0/15	0/11
3TC	0/9	0/14	0/14	0/15	0/11
ABC	0/9	0/14	0/14	0/15	0/11
D4T	0/9	0/14	0/14	0/15	0/11
DDI	0/9	1/14 (7.1)	1/14 (7.1)	0/15	0/11
FTC	0/9	0/14	0/14	0/15	0/11
TFV	1/9 (11.1)	1/14 (7.1)	0/14	0/15	0/11
ZDV	1/9 (11.1)	1/14 (7.1)	0/14	0/15	0/11

Program Source: /projects/bms208451/stats/primary/prog/tables/rt-pn-new.sas 13MAR2015:05:25:28

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-bsldrugs1.lst
Purpose	WK24S1, WK48S1 WK96S1, WK96S2
Table No.	Table S.3.9.1H
Title 1	Baseline Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-bsldrugs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2H
Title 1	Baseline Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects - Stage 2

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-bsldrugs12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3H
Title 1	Baseline Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects - Stage 1 and 2

Parameter	Values

Template ID	SS_PN_T_002
Output File Name	rt-pn-bslotrtdrugs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1I
Title 1	Baseline Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Testing - Stage 1

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-bslotrtdrugs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2I
Title 1	Baseline Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Testing - Stage 2

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-bslotrtdrugs12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3I
Title 1	Baseline Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Testing - Stage 1 and 2

Parameter	Values
Template ID	SS_PN_T_002

Output File Name	rt-pn-bsldrugpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.9.1R
Title 1	Baseline Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Testing
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-bsldrugpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.9.2R
Title 1	Baseline Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Testing
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-bsldrugpdvfs12.lst
Purpose	WK96S2
Table No.	Table S.3.9.3R
Title 1	Baseline Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Testing
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Template SS_PN_L_001: Phenotypic Resistance Listing

Subject ID (Age/Gender/Race) Treatment Group	Current Treatment/ Period/ Visit	Date/ Study Day	BMS-955176 IC50/ IC50 Susc Fold Change	RT IC50/ IC50 Susc Fold Change	PI IC50/ IC50 Susc Fold Change	RAL IC50/ IC50 Susc Fold Change
PPD (43/M/B) BMS-663068 1200 mg QD/ RAL/TDF	PRE-TREATMENT/ PRE-TREATMENT/ SCREENING	PPD -42	0.00017/0.13	3TC (S) 3.79/1.41 ABC (S) 0.7/0.95 D4T (S) 0.66/1.06 DDI (S) 7.52/1.04 FTC (S) 1.13/1.32 TFV (S) 0.996/0.92 ZDV (S) 0.029/1.21 DLV (S) 0.0451/1.63 EFV (S) 0.0054/1.24 ETR (S) 0.0028/1.39 NVP (S) 0.131/1.31	AMP/R (S) 0.0167/1.26 ATV (S) 0.00361/1.18 ATV/R (S) 0.00361/1.18 DRV/R (S) 0.00099/1.28 IDV/R (S) 0.0105/1.34 LPV/R (S) 0.0075/1.24 NFV (S) 0.0248/1.85 RTV (S) 0.0316/1.37 SQV/R (S) 0.0054/1.24 TPV/R (S) 0.1154/1.16	RAL (S) 0.00762/0.88
	BMS1200mg QD+ RAL400mg BID+ TDF300mg QD/ STAGE 1/ WEEK 4	PPD 35	NR/	3TC (S) 3.76/1.41 ABC (S) 0.98/1.04 D4T (S) 0.77/1.06 DDI (S) 9.19/1.12 FTC (S) 1.47/1.26 TFV (S) 0.976/0.99 ZDV (S) 0.047/1.60 DLV (S) 0.0696/1.94 EFV (S) 0.0063/1.50 ETR (S) 0.00326/1.55 NVP (S) 0.185/1.91	AMP/R (S) 0.02/1.56 ATV (S) 0.00414/1.66 ATV/R (S) 0.00414/1.66 DRV/R (S) 0.00142/1.55 IDV/R (S) 0.0119/1.63 LPV/R (S) 0.0068/1.25 NFV (S) 0.0281/2.83 RTV (S) 0.046/1.97 SQV/R (S) 0.0068/1.60 TPV/R (P) 0.1843/2.06	RAL (S) 0.02064/1.33

Parameter	Values
Template ID	SS_PN_L_001
Output File Name	rl-pn-bsls1.lst
Purpose	WK24S1, WK48S1 WK96S1, WK96S2
Table No.	Appendix 3.9.1E
Title 1	Listing of Baseline Phenotypic Resistance
Title 2	Treated Subjects - Stage 1
Footnote 1	Susc = Susceptibility

Footnote 2	P = Partial, R = Resistance, S = Susceptible
Programming notes	Please include only the pre-treatment assessments.

Parameter	Values
Template ID	SS_PN_L_001
Output File Name	rl-pn-bsls2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 3.9.2E
Title 1	Listing of Baseline Phenotypic Resistance
Title 2	Treated Subjects - Stage 2
Footnote 1	Susc = Susceptibility
Footnote 2	P = Partial, R = Resistance, S = Susceptible
Programming notes	Please include only the pre-treatment assessments.

Template GS_LB_T_X_004: Laboratory Toxicity Grade Summary

Protocol: BMS234303 Draft Page 1 of 1
Laboratory Test Results Summary of Worst Toxicity Grade
All Treated Subjects

Lab Test Description Toxicity Grade	Group 1 N = 83	Group 2 N = 50	Group 3 N = 50	Group 4 N = 25	Total N = 208
BLOOD UREA NITROGEN					
CRITERION 1	71 (85.5)	10 (20.0)	0	0	81 (38.9)
CRITERION 2	7 (8.4)	5 (10.0)	0	0	12 (5.8)
NOT REPORTED	5 (0.6)	35 (70.0)	50 (100.0)	25 (100.0)	115 (55.3)
LDL-C/HDL-C RATIO (DIRECT)					
CRITERION 1	33 (39.8)	20 (40.0)	0	0	53 (25.5)
CRITERION 2	39 (47.0)	20 (40.0)	0	0	59 (28.4)
NOT REPORTED	11 (13.3)	10 (20.0)	50 (100.0)	25 (100.0)	96 (46.1)
TOTAL PROTEIN					
CRITERION 1	75 (90.4)	0	10 (20.0)	0	85 (40.9)
CRITERION 2	3 (3.6)	0	2 (4.0)	0	5 (2.4)
NOT REPORTED	5 (0.6)	50 (100.0)	38 (76.0)	25 (100.0)	118 (56.7)
CHLORIDE					
CRITERION 1	74 (89.2)	0	0	20 (80.0)	94 (45.2)
CRITERION 2	4 (4.8)	0	0	2 (8.0)	6 (2.9)
NOT REPORTED	5 (0.6)	50 (100.0)	50 (100.0)	3 (12.0)	108 (51.9)

Toxicity Scale: Descriptive text of toxicity scale
Program Source: /wwbdm/ndp/prime/gssr/devtest/lab/test/labsum.b.sas 07SEP2004:14:35:00

Parameter	Values
Template ID	GS_LB_T_X_004
Output File Name	rt-lb-bsltoxs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.5.1
Title 1	Baseline Laboratory Test Results Summary of Toxicity Grade
Title 2	Treated Subjects - Stage 1

Footnote 1	Toxicity Scale: DAIDS
Programming notes	The laboratory tests to be included in this output are specified in the SAP.

Parameter	Values
Template ID	GS_LB_T_X_004
Output File Name	rt-lb-bsltoxs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.5.2
Title 1	Baseline Laboratory Test Results Summary of Toxicity Grade
Title 2	Treated Subjects - Stage 2
Footnote 1	Toxicity Scale: DAIDS
Programming notes	The laboratory tests to be included in this output are specified in the SAP.

Template GS_AE_T_X_001: Adverse Event Summary by System Organ Class and Preferred Term

Protocol: CV131154

Confidential
Adverse Event Summary
All Treated Subjects

System Organ Class (%) Preferred Term (%)	TRT A N = 200	TRT B N = 959	TRT C N = 482	Total N = 1641
TOTAL SUBJECTS WITH AN EVENT	100 (50.0)	866 (90.3)	417 (86.5)	1383 (89.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	6 (3.0)	51 (5.3)	39 (8.1)	96 (5.9)
ANAEMIA	0	17 (1.8)	16 (3.3)	33 (2.3)
LEUKOPENIA	0	17 (1.8)	5 (1.0)	22 (1.5)
EOSINOPHILIA	0	5 (0.5)	3 (0.6)	8 (0.6)
LYMPHADENOPATHY	0	0	7 (1.5)	7 (0.5)
LEUKOCYTOSIS	0	1 (0.1)	5 (1.0)	6 (0.4)
THROMBOCYTOPENIA	4 (2.0)	4 (0.4)	1 (0.2)	9 (0.5)
IRON DEFICIENCY ANAEMIA	0	2 (0.2)	1 (0.2)	3 (0.2)
BONE MARROW TOXICITY	0	1 (0.1)	1 (0.2)	2 (0.1)
ANAEMIA FOLATE DEFICIENCY	0	1 (0.1)	0	1 (<0.1)
ANAEMIA OF CHRONIC DISEASE	0	1 (0.1)	0	1 (<0.1)
BASOPHILIA	0	1 (0.1)	0	1 (<0.1)
BONE MARROW DEPRESSION	0	1 (0.1)	0	1 (<0.1)
LYMPH NODE PAIN	2	1 (0.1)	0	1 (<0.1)
MONOCYTOSIS	0	0	1 (0.2)	1 (<0.1)
NEUTROPENIA	0	1 (0.1)	0	1 (<0.1)
THROMBOCYTHAEMIA	0	1 (0.1)	0	1 (<0.1)
CARDIAC DISORDERS	10 (5.0)	54 (5.6)	36 (7.5)	100 (6.1)
PALPITATIONS	0	21 (2.2)	8 (1.7)	29 (2.0)
TACHYCARDIA	5 (2.5)	13 (1.4)	4 (0.8)	22 (1.3)
CARDIAC FAILURE CONGESTIVE	5 (2.5)	3 (0.3)	3 (0.6)	11 (0.7)
BRADYCARDIA	0	4 (0.4)	1 (0.2)	5 (0.3)
SINUS BRADYCARDIA	0	1 (0.1)	4 (0.8)	5 (0.3)
ARRHYTHMIA	0	1 (0.1)	3 (0.6)	4 (0.3)
ATRIAL FIBRILLATION	0	2 (0.2)	2 (0.4)	4 (0.3)
UNASSIGNED	1 (0.5)	0	0	1 (<0.1)
UNASSIGNED	1 (0.5)	0	0	1 (<0.1)

MedDRA Version: 7.1
Program Source: /wwbdm/ndp/prime/msr/devtest/test/sample1.sas

18FEB2005:10:59:00

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-preaidss1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.6.1
Title 1	Adverse Events Summary
Title 2	Pre-treatment AIDS Events
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-preaidss2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.6.2
Title 1	Adverse Events Summary
Title 2	Pre-treatment AIDS Events
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

4.3.3 Medical History and Previous Treatments

Template GS_MH_T_X_001: Medical History Summary

Protocol: TA001001 Draft Page 1 of 1

General Medical History Summary
All Treated Subjects

	TRT A N = 16	TRT B N = 17	TRT C N = 17	Total N = 50
SUBJECTS WITH ABNORMAL MEDICAL HISTORY (%)	16 (100.0)	16 (94.1)	16 (94.1)	48 (96.0)
BODY SYSTEM (%)				
HEAD, EYES, EARS, NOSE, THROAT	12 (75.0)	11 (64.7)	10 (58.8)	33 (66.0)
CARDIOVASCULAR	3 (18.8)	5 (29.4)	4 (23.5)	12 (24.0)
PERIPHERAL VASCULAR	0	3 (17.6)	0	3 (6.0)
RESPIRATORY	2 (12.5)	1 (5.9)	1 (5.9)	4 (8.0)
GASTROINTESTINAL	6 (37.5)	5 (29.4)	5 (29.4)	16 (32.0)
HEPATOBILIARY	2 (12.5)	0	1 (5.9)	3 (6.0)
RENAL	2 (12.5)	0	1 (5.9)	3 (6.0)
GENITOURINARY	6 (37.5)	7 (41.2)	6 (35.3)	19 (38.0)
ENDOCRINE-METABOLIC	16 (100.0)	16 (94.1)	16 (94.1)	48 (96.0)
HEMATOLOGIC-LYMPHATIC	0	1 (5.9)	0	1 (2.0)
MUSCULOSKELETAL	11 (68.8)	10 (58.8)	9 (52.9)	30 (60.0)
DERMATOLOGIC	4 (25.0)	6 (35.3)	4 (23.5)	14 (28.0)
NEUROLOGIC	8 (50.0)	5 (29.4)	6 (35.3)	19 (38.0)
PSYCHIATRIC	3 (18.8)	2 (11.8)	3 (17.6)	8 (16.0)
ALLERGIES	3 (18.8)	3 (17.6)	3 (17.6)	9 (18.0)
NEOPLASIA	1 (6.3)	0	0	1 (2.0)
ALCOHOL USE	9 (56.3)	4 (23.5)	8 (47.1)	21 (42.0)
TOBACCO USE	4 (25.0)	6 (35.3)	5 (29.4)	15 (30.0)
DRUG ABUSE	0	0	0	0
OTHER	2 (12.5)	3 (17.6)	2 (11.8)	7 (14.0)

Parameter	Values
Template ID	GS_MH_T_X_001
Output File Name	rt-mh-sums1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.3.7.1
Title 1	General Medical History Summary
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	GS_MH_T_X_001
Output File Name	rt-mh-sums2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.7.2
Title 1	General Medical History Summary
Title 2	Treated Subjects - Stage 2

Template GS_MH_L_X_001: Medical History Listing by Treatment Group

Protocol: CV131148 Draft Page 1 of 100

General Medical History
All Treated Subjects

Treatment Group: TRT A

Subject ID (Age/Gender/Race)	System	Condition(s)
PPD (79/M/C)	HEAD, EARS, EYES, NOSE, THROAT	CEREBRO VASCULAR
	CARDIOVASCULAR	SEE PREVIOUS PAGE
	PERIPHERAL VASCULAR	PERIPHERAL PULSATIONS NOT PALPABLE
	RESPIRATORY	NULOL COPD
	GASTROINTESTINAL	GASTRIC ,ULCER - ANAL BLEEDING - RECTUM POLYP & RESECTION
	ALLERGIES	PENICILLINE
PPD (83/F/C)	CARDIOVASCULAR	CHF
	RESPIRATORY	BRONCHITIS
	GASTROINTESTINAL	CHOLELITHIASIS WITH CHOLECYSECTOMY
	MUSCULOSKELETAL	ARTHROSIS - SPINAL STENOSIS
	PSYCHIATRIC	DEPRESSION

Program Source: /wwbdm/ndp/prime/gssr/devtest/mhx/test/mhx_lst.sas 06APR2004:17:58:02

Parameter	Values
Template ID	GS_MH_L_X_001
Output File Name	rl-mh-lists1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 3.7.1
Title 1	General Medical History
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	GS_MH_L_X_001
Output File Name	rl-mh-lists2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Appendix 3.7.2
Title 1	General Medical History
Title 2	Treated Subjects - Stage 2

Template GS_CM_T_X_001 : Non-Study Medication Summary

Protocol: CV168006 Draft Page 1 of 58

Non-Study Medication Summary
Medication Category
All Treated Subjects

Anatomic Class (%) Therapeutic Class (%) Generic Name (%)	TRT A N = 5443	TRT B N = 6443	TRT C N = 6123	Total N = 19009
TOTAL SUBJECTS USING MEDICATION	6134 (95.2)	6134 (95.2)	5884 (96.1)	19009 (95.6)
ALIMENTARY TRACT & METABOLISM	431 (6.7)	431 (6.7)	425 (6.9)	1287 (6.8)
ANABOLIC STEROID	0	0	1 (<0.1)	1 (<0.1)
PRASTERONE	0	0	1 (<0.1)	1 (<0.1)
ANTACID	31 (0.5)	31 (0.5)	46 (0.8)	108 (0.6)
ALOH/CACO/MGOH	1 (<0.1)	1 (<0.1)	0	2 (<0.1)
ALOH/MAGTRI	0	0	1 (<0.1)	1 (<0.1)
ALOH/MGOH	2 (<0.1)	2 (<0.1)	3 (<0.1)	7 (<0.1)
ALOH/MGOH/OXETAC	2 (<0.1)	1 (<0.1)	0	3 (<0.1)
ANTACID	7 (<0.1)	7 (0.1)	11 (0.2)	25 (0.1)
CACO/FAMO/MGOH	7 (<0.1)	1 (<0.1)	1 (<0.1)	9 (<0.1)
CALCIUM CARBONATE	13 (0.2)	13 (0.2)	22 (0.4)	48 (0.3)
DIHYDROXYALUMINIUM SODIUM CARBINATE	0	0	6 (0.1)	6 (<0.1)
ANTIDIARRHEA/INTEST ANTIINFLAM	2 (<0.1)	2 (< 0.1)	1 (<0.1)	5 (<0.1)
ANTIDIARRHEAL	2 (<0.1)	2 (< 0.1)	1 (<0.1)	5 (<0.1)
ANTIDIARRHEAL MICROORGANISM	5 (<0.1)	5 (0.1)	3 (<0.1)	13 (0.1)
LACTOBACILLUS ACIDOPHILUS	4 (<0.1)	4 (0.1)	3 (<0.1)	11 (0.1)
SACCHAROMYCES BOULARDII	1 (<0.1)	1 (< 0.1)	0	2 (<0.1)
UNASSIGNED	2 (<0.1)	2 (<0.1)	2 (<0.1)	6 (<0.1)
UNASSIGNED	1 (<0.1)	1 (<0.1)	0	2 (<0.1)
UNASSIGNED	1 (<0.1)	1 (<0.1)	2 (<0.1)	4 (<0.1)

Program Source: /wwbdm/ndp/prime/gssr/devtest/checkraw/cmtbl.sas 29OCT2004:18:53:00

Parameter	Values
Template ID	GS_CM_T_X_001
Output File Name	rt-cm-premeds1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Table S.3.8.1
Title 1	Non-Study Medication Summary
Title 2	Previous Medication
Title 3	Treated Subjects - Stage 1
Footnote 1	Previous medication is defined as any medication that was taken before the start of study medication.

Parameter	Values
Template ID	GS_CM_T_X_001
Output File Name	rt-cm-premeds2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.3.8.2
Title 1	Non-Study Medication Summary
Title 2	Previous Medication
Title 3	Treated Subjects - Stage 2
Footnote 1	Previous medication is defined as any medication that was taken before the start of study medication.

4.4 Extent Of Exposure

4.4.1 Study Therapy and Treatment Compliance

Template SS_EX_T_001: Extent of Exposure Summary

	Group A N = XX	Group B N = XX	Group C N = XX	Group D N = XX
N	XX	XX	XX	XX
MEAN	XX.X	XX.X	XX.X	XX.X
MEDIAN	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
Q1 , Q3	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
STANDARD DEVIATION	XX.XX	XX.XX	XX.XX	XX.XX
MEAN DAILY DOSE (mg)	XXX.X	XXX.X	XXX.X	XXX.X

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-bmss1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.4.1.1A
Title 1	Extent of Exposure to BMS-955176
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 1
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-bmss2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.4.1.2A

Title 1	Extent of Exposure to BMS-955176
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 2
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-tdfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.4.1.1B
Title 1	Extent of Exposure to Tenofovir
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 1
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-tdfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.4.1.2B
Title 1	Extent of Exposure to Tenofovir
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 2
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-atvs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.4.1.1C
Title 1	Extent of Exposure to Atazanavir
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 1
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-atvs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.4.1.2C
Title 1	Extent of Exposure to Atazanavir
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 2
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-dtgs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.4.1.1D

Title 1	Extent of Exposure to Dolutegravir
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 1
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-dtgs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.4.1.2D
Title 1	Extent of Exposure to Dolutegravir
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 2
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-rtvs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.4.1.1E
Title 1	Extent of Exposure to Ritonavir
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 1
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-rtvs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.4.1.2E
Title 1	Extent of Exposure to Ritonavir
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 2
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-regimens1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.4.1.1F
Title 1	Extent of Exposure to Treatment Regimen
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 1
Layout notes	Do not include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-regimens2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.4.1.2F

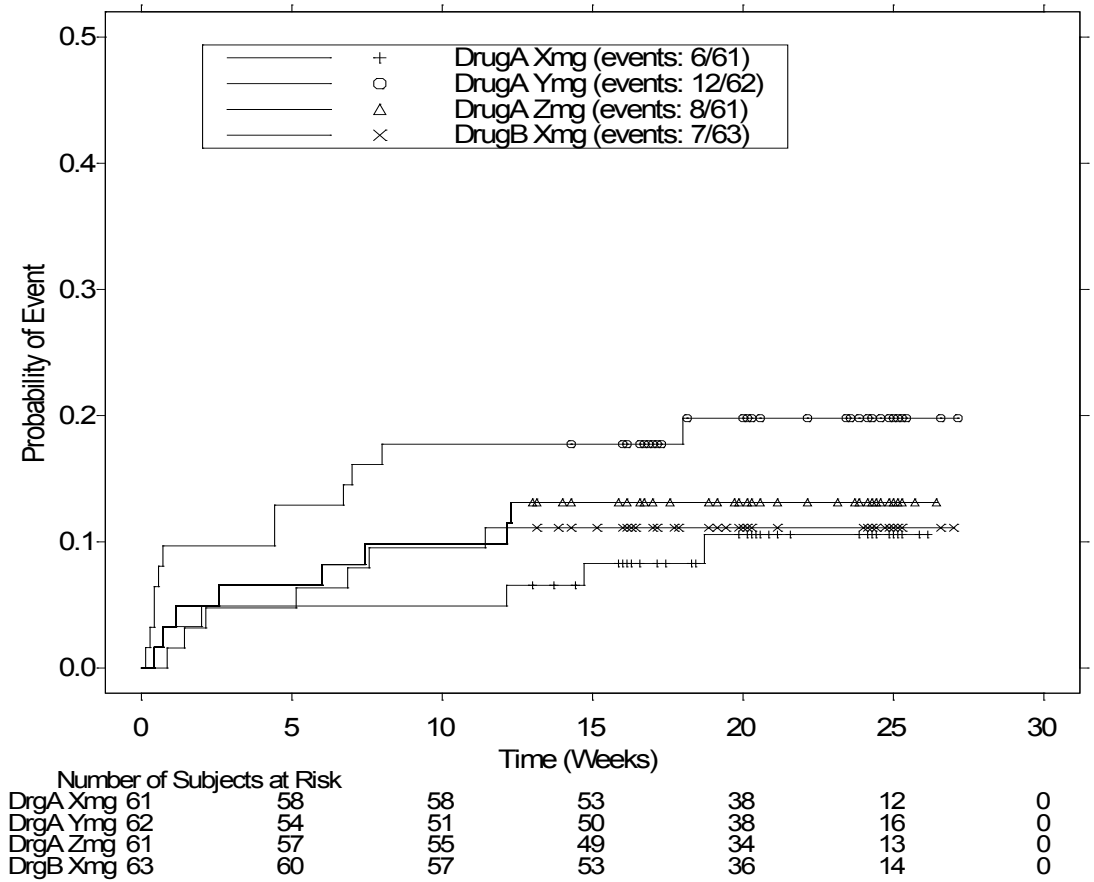
Title 1	Extent of Exposure to Treatment Regimen
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 2
Layout notes	Do not include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-regimens12.lst
Purpose	WK96S2
Table No.	Table S.4.1.3F
Title 1	Extent of Exposure to Treatment Regimen
Title 2	Time on Therapy
Title 3	Treated Subjects - Stage 1 and 2
Layout notes	Do not include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-conts1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.4.1.1G
Title 1	Extent of Exposure to BMS-955176 after Switch to Continuation Dose
Title 2	Time on Therapy
Title 3	Treated Subjects who Switched to Continuation Dose - Stage 1
Layout notes	Include Mean Daily Dose

Parameter	Values
Template ID	SS_EX_T_001
Output File Name	rt-ex-conts2.lst
Purpose	WK96S2
Table No.	Table S.4.1.2G
Title 1	Extent of Exposure to BMS-955176 after Switch to Continuation Dose
Title 2	Time on Therapy
Title 3	Treated Subjects who Switched to Continuation Dose - Stage 2
Layout notes	Include Mean Daily Dose

Template GS_EX_G_001: Kaplan-Meier Plot Grouped by Treatment with Censoring



Serious Events (incl. Deaths) up to 30 days post-trt included
Non-Serious events up to last day of treatement included. Symbols represent censored observatior
<Special Events> are based upon a predefined list of MEDDRA Preferred Terms.
Program Path: /home/banckenf/sgtest
Program Name: sgissue0005.sas 20OCT2008:06:57:24

Parameter	Values
Template ID	GS_EX_G_001
Output File Name	rg-ex-kms1

Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.4.1.1
Title 1	Time on Study Therapy
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: Proportion of Subjects on Study Therapy X-axis label: Time (Weeks)

Parameter	Values
Template ID	GS_EX_G_001
Output File Name	rg-ex-kms2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.4.1.2
Title 1	Time on Study Therapy
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: Proportion of Subjects on Study Therapy X-axis label: Time (Weeks)

Template SS_EX_T_002: Time on Study Therapy Life Table

	Group A (N=194)			GROUP B (N=203)			GROUP C (N=201)		
Week (a)	n	N#	Proportion (%) (95% CI)	n	N#	Proportion (%) (95% CI)	n	N#	Proportion (%) (95% CI)
< 4	0	194	0.0 (0.0- 0.0)	0	203	0.0 (0.0- 0.0)	0	201	0.0 (0.0- 0.0)
4 - < 8	0	189	0.0 (0.0- 0.0)	0	201	0.0 (0.0- 0.0)	0	197	0.0 (0.0- 0.0)
8 - < 12	0	186	0.0 (0.0- 0.0)	0	196	0.0 (0.0- 0.0)	1	194	0.5 (0.0- 1.5)
12 - < 16	0	185	0.0 (0.0- 0.0)	0	193	0.0 (0.0- 0.0)	3	192	1.6 (0.0- 3.3)
16 - < 20	1	184	0.5 (0.0- 1.6)	5	188	2.7 (0.4- 5.0)	5	184	2.6 (0.4- 4.9)
20 - < 24	1	181	0.5 (0.0- 1.6)	5	179	2.7 (0.4- 5.0)	8	181	4.2 (1.4- 7.1)
24 - < 28	1	181	0.5 (0.0- 1.6)	7	179	3.8 (1.0- 6.6)	11	178	5.9 (2.5- 9.3)
28 - < 32	1	180	0.5 (0.0- 1.6)	11	174	6.0 (2.6- 9.5)	18	171	9.8 (5.5-14.0)
32 - < 36	1	180	0.5 (0.0- 1.6)	13	169	7.1 (3.4-10.9)	21	163	11.5 (6.8-16.1)
36 - < 40	1	180	0.5 (0.0- 1.6)	13	164	7.1 (3.4-10.9)	22	156	12.0 (7.3-16.8)
40 - < 44	1	177	0.5 (0.0- 1.6)	14	163	7.7 (3.8-11.6)	25	154	13.8 (8.7-18.8)
44 - < 48	1	175	0.5 (0.0- 1.6)	15	161	8.3 (4.3-12.3)	25	150	13.8 (8.7-18.8)
48 - < 52	1	137	0.5 (0.0- 1.6)	15	129	8.3 (4.3-12.3)	26	116	16.0 (9.5-22.5)
52 - < 56	1	4		15	4		26	4	

Parameter	Values
Template ID	SS_EX_T_002
Output File Name	rt-ex-kms1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.4.1.1H
Title 1	Time of Study Therapy Life Table (Kaplan-Meier Estimates)
Title 2	Treated Subjects - Stage 1
Footnote 1	(a) Cumulative proportion without events at end of interval.

Parameter	Values
Template ID	SS_EX_T_002
Output File Name	rt-ex-kms2.lst

Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.4.1.2H
Title 1	Time of Study Therapy Life Table (Kaplan-Meier Estimates)
Title 2	Treated Subjects - Stage 2
Footnote 1	(a) Cumulative proportion without events at end of interval.

Template SS_EX_T_003: Summary of Interruptions Greater than 3 Days

	Treatment Regimen				
Drug	Group A N = XX	Group B N = XX	Group C N = XX	Group D N = XX	Group E N = XX
DRUG 1					
N	XX	XX	XX	XX	
MEAN	XX.X	XX.X	XX.X	XX.X	
MEDIAN	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	
Q1 , Q3	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	
STANDARD DEVIATION	XX.XX	XX.XX	XX.XX	XX.XX	
DRUG 2					
N	XX	XX	XX	XX	XX
MEAN	XX.X	XX.X	XX.X	XX.X	XX.X
MEDIAN	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	XX.X , XX.X
Q1 , Q3	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
STANDARD DEVIATION	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
DRUG 3					
N	XX	XX	XX	XX	XX
MEAN	XX.X	XX.X	XX.X	XX.X	XX.X
MEDIAN	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	XX.X , XX.X
Q1 , Q3	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
STANDARD DEVIATION	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX

Parameter	Values
Template ID	SS_EX_T_003
Output File Name	rt-ex-interrupts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.4.1.1I
Title 1	Summary of Interruptions in Study Therapy Greater than 3 Days
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_EX_T_003
Output File Name	rt-ex-interrupts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.4.1.2I
Title 1	Summary of Interruptions in Study Therapy Greater than 3 Days
Title 2	Treated Subjects - Stage 2

Template SS_EX_L_001: Study Medication Exposure Listing

Subject Number (Age/Gender/Race) Treatment Group	Drug	Start Date	Stop Date	Daily Dose	Reason for Modification
PPD (50/M/B) BMS-663068 1200 mg QD/RAL/TDF	BMS-663068	04NOV2013	04NOV2013	0	DOSING ERROR
		05NOV2013	15NOV2013	1200	NO CHANGE
		16NOV2013	16NOV2013	0	DOSING ERROR
		17NOV2013	19NOV2013	1200	NO CHANGE
		20NOV2013	31JAN2014	1200	NO CHANGE
		01FEB2014	13FEB2014	0	OTHER
		14FEB2014	06MAY2014	1200	NO CHANGE
		07MAY2014	29JUL2014	1200	NO CHANGE
	RALTEGRAVIR	27OCT2011	10NOV2012	800	NO CHANGE
		11NOV2012	19DEC2012	0	OTHER
		20DEC2012	07FEB2013	800	NO CHANGE
		08FEB2013	08FEB2013	0	DOSING ERROR
		09FEB2013	18MAR2013	800	NO CHANGE
		19MAR2013	19MAR2013	0	DOSING ERROR
		20MAR2013	21MAR2013	800	NO CHANGE
		22MAR2013	23MAR2013	0	DOSING ERROR
		24MAR2013	23SEP2013	800	NO CHANGE
		24SEP2013	25SEP2013	0	DOSING ERROR
		26SEP2013	31JAN2014	800	NO CHANGE
		01FEB2014	13FEB2014	0	OTHER
		14FEB2014	06MAY2014	800	NO CHANGE
		07MAY2014	29JUL2014	800	NO CHANGE
	TENOFOVIR	27OCT2011	10NOV2012	300	NO CHANGE
		11NOV2012	19DEC2012	0	OTHER
		20DEC2012	07FEB2013	300	NO CHANGE
		08FEB2013	08FEB2013	0	DOSING ERROR
		09FEB2013	18MAR2013	300	NO CHANGE
		19MAR2013	19MAR2013	0	DOSING ERROR
		20MAR2013	21MAR2013	300	NO CHANGE
		22MAR2013	23MAR2013	0	DOSING ERROR
		24MAR2013	23SEP2013	300	NO CHANGE

Parameter	Values
Template ID	SS_EX_L_001
Output File Name	rl-ex-lists1.lst

Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 4.1.1A
Title 1	Study Medication Exposure by Subject Listing
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_EX_L_001
Output File Name	rl-ex-lists2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 4.1.2A
Title 1	Study Medication Exposure by Subject Listing
Title 2	Treated Subjects - Stage 2

Template SS_EX_L_002: Study Medication Listing related to Continuation Dose

Treatment Group: DRUG C

Subject Number (Age/Gender/Race)	Tim on Randomized Dose	Date/Study Day of Switch to Continuation Dose	Time on Continuation Dose
PPD	280	PPD / 281	364
PPD	285	/ 286	370
PPD (50/M/B)	298	/ 299	351

Parameter	Values
Template ID	SS_EX_L_002
Output File Name	rl-ex-listcdoses1.lst
Purpose	WK96S1, WK96S2
Table No.	Appendix 4.1.1B
Title 1	Listing of Time on Original and Continuation Dose
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_EX_L_002
Output File Name	rl-ex-listcdoses2.lst
Purpose	WK96S2
Table No.	Appendix 4.1.2B
Title 1	Listing of Time on Original and Continuation Dose
Title 2	Treated Subjects - Stage 2

4.4.2 Concomitant Therapy

Parameter	Values
Template ID	GS_CM_T_X_001
Output File Name	rt-cm-conmeds1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.4.2.1
Title 1	Non-Study Medication Summary
Title 2	Concomitant Medication
Title 3	Treated Subjects - Stage 1

Parameter	Values
Template ID	GS_CM_T_X_001
Output File Name	rt-cm-conmeds2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.4.2.2
Title 1	Non-Study Medication Summary
Title 2	Concomitant Medication
Title 3	Treated Subjects - Stage 2

Template GS_CM_L_X_006: Non-Study Medication Listing by Treatment Group

Protocol: CV181008 Draft Page 1 of 89

Non-Study Medication
Medication Category
All Treated Subjects

Treatment Group: TRT A

Subject ID (Age/Gender/Race)	Period Visit Current Trt	Start Stop Study Day TRD#	Anatomic Class Therapeutic Class Generic Name Reported Medication	Use
PPD (43/F/B)	SHORT TERM WEEK 1 ABC 10	PPD 1 1D	ALIMENTARY TRACT & METABOLISM ORAL BLOOD GLUCOSE LOWERING DRUG METFORMIN GLUCOPHAGE	OTHER
	SHORT TERM WEEK 1 ABC 10	PPD 1 1D	ALIMENTARY TRACT & METABOLISM ORAL BLOOD GLUCOSE LOWERING DRUG GLIPIZIDE GLUCOTROL XL	OTHER
	SHORT TERM WEEK 1 ABC 10	PPD 2 2D	NERVOUS SYSTEM OTHER ANALGESIC & ANTIPYRETIC ACETAMINOPHEN TYLENOL	ADVERSE EVENT
	SHORT TERM WEEK 1 ABC 10	PPD 2 2D	ALIMENTARY TRACT & METABOLISM ORAL BLOOD GLUCOSE LOWERING DRUG GLIPIZIDE GLUCOTROL XL	OTHER
	SHORT TERM WEEK 1 ABC 10	PPD 2 2D	ALIMENTARY TRACT & METABOLISM ORAL BLOOD GLUCOSE LOWERING DRUG METFORMIN GLUCOPHAGE	OTHER

Time relative to most recent dose
Program Source: /wwbdm/ndp/prime/gssr/devtest/checkraw/cmlist.sas 29OCT2004:18:53:00

Parameter	Values
Template ID	GS_CM_L_X_006
Output File Name	rl-cm-meds1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Appendix 4.2.1
Title 1	Non-Study Medication
Title 2	Previous and Concomitant Medications
Title 3	Treated Subjects - Stage 1

Parameter	Values
Template ID	GS_CM_L_X_006
Output File Name	rl-cm-meds2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 4.2.2
Title 1	Non-Study Medication
Title 2	Previous and Concomitant Medications
Title 3	Treated Subjects - Stage 2

4.5 Efficacy Results

Template SS_VL_T_001: Detailed Summary of HIV-1 < Y (by Subgroup)

Subgroup: XXXXXXXXXX Level: XXXXXXXXXXXX

	BMS-986001 100 mg QD/ EFV/3TC N = XX	BMS-986001 200 mg QD/ EFV/3TC N = XX	BMS-986001 400 mg QD/ EFV/3TC N = XX	TDF/EFV/3TC N = XX
NUMBER OF RESPONDERS (A)	57 (87.7)	54 (80.6)	62 (93.9)	88 (88.9)
95% CI	(77.2 - 94.5)	(69.1 - 89.2)	(85.2 - 98.3)	(81.0 - 94.3)
NUMBER OF VIROLOGIC FAILURES	X (XXX.X)	X (XXX.X)	X (XXX.X)	X (XXX.X)
HIV-1 RNA >= 40 c/mL (B)	X (XXX.X)	X (XXX.X)	X (XXX.X)	X (XXX.X)
DISC. STUDY/STUDY DRUG DUE TO LACK OF EFFICACY (C)	X (XXX.X)	X (XXX.X)	X (XXX.X)	X (XXX.X)
DISC. STUDY/STUDY DRUG FOR OTHER REASONS (D)	X (XXX.X)	X (XXX.X)	X (XXX.X)	X (XXX.X)
NO VIROLOGIC DATA				
DISC. STUDY/STUDY DRUG DUE TO AE OR DEATH (E)	0	4 (6.0)	0	2 (2.0)
DISC. STUDY/STUDY DRUG FOR OTHER REASONS (F)	0	0	0	2 (2.0)
MISSING DATA DURING WINDOW BUT ON STUDY	0	0	0	0

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w24s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.1.1A
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24 Snapshot
Title 3	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 24 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.

Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w24s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.1.2A
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24 Snapshot
Title 3	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 24 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Template SS_VL_T_002: Summary of HIV-1 < Y (by Subgroup)

Subgroup: XXXXXXXXXX Level: XXXXXXXXXXXX

	BMS-986001 100 mg QD/ EFV/3TC N = XX	BMS-986001 200 mg QD/ EFV/3TC N = XX	BMS-986001 400 mg QD/ EFV/3TC N = XX	TDF/EFV/3TC N = XX
NUMBER OF RESPONDERS (A)	57 (87.7)	54 (80.6)	62 (93.9)	88 (88.9)
95% CI	(77.2 - 94.5)	(69.1 - 89.2)	(85.2 - 98.3)	(81.0 - 94.3)
NUMBER OF VIROLOGIC FAILURES (B)	X (XXX.X)	X (XXX.X)	X (XXX.X)	X (XXX.X)
NO VIROLOGIC DATA				
DISC. STUDY/STUDY DRUG DUE TO AE OR DEATH (C)	0	4 (6.0)	0	2 (2.0)
DISC. STUDY/STUDY DRUG FOR OTHER REASONS (D)	0	0	0	2 (2.0)
MISSING DATA DURING WINDOW BUT ON STUDY	0	0	0	0

Parameter	Values
Template ID	SS_VL_T_002
Output File Name	rt-vl-sumresp40w24s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.1.1C
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24 Snapshot
Title 3	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects who are >= 50 copies in the visit window. It also includes subjects who discontinued prior to the visit window for lack or loss of efficacy or any reasons except AE and death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 50 c/mL.
Footnote 3	(C) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window

Footnote 4	(D) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_002
Output File Name	rt-vl-sumresp40w24s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.1.2C
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24 Snapshot
Title 3	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects who are >= 50 copies in the visit window. It also includes subjects who discontinued prior to the visit window for lack or loss of efficacy or any reasons except AE and death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 50 c/mL.
Footnote 3	(C) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 4	(D) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w24subgs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.1.1B
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL

Title 2	Proportion of Responders at Week 24 Snapshot
Title 3	By Subgroup
Title 4	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 24 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Baseline Gag Polymorphism: all combinations of baseline gag polymorphisms at selected positions • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w24subgs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.1.2B

Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24 Snapshot
Title 3	By Subgroup
Title 4	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 24 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Baseline Gag Polymorphism: all combinations of baseline gag polymorphisms at selected positions • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w48s1.lst

Purpose	WK96S1, WK96S2
Table No.	Table S.5.2.1A
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 48 Snapshot
Title 3	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 48 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w48s2.lst
Purpose	WK48S2, WK96S2
Table No.	Table S.5.2.2A
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 48 Snapshot
Title 3	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit

	window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 48 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_002
Output File Name	rt-vl-sumresp40w48s1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.2.1C
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 48 Snapshot
Title 3	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects who are >= 50 copies in the visit window. It also includes subjects who discontinued prior to the visit window for lack or loss of efficacy or any reasons except AE and death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 50 c/mL.
Footnote 3	(C) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 4	(D) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL

Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_002
Output File Name	rt-vl-sumresp40w48s2.lst
Purpose	WK48S2, WK96S2
Table No.	Table S.5.2.2C
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 48 Snapshot
Title 3	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects who are >= 50 copies in the visit window. It also includes subjects who discontinued prior to the visit window for lack or loss of efficacy or any reasons except AE and death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 50 c/mL.
Footnote 3	(C) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 4	(D) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w48subgs1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.2.1B
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 48 Snapshot

Title 3	By Subgroup
Title 4	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 48 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Baseline Gag Polymorphism: all combinations of baseline gag polymorphisms at selected positions • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w48subgs2.lst
Purpose	WK48S2, WK96S2
Table No.	Table S.5.2.2B
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL

Title 2	Proportion of Responders at Week 48 Snapshot
Title 3	By Subgroup
Title 4	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 48 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Baseline Gag Polymorphism: all combinations of baseline gag polymorphisms at selected positions • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w96s1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.3.1A

Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 96 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w96s2.lst
Purpose	WK96S2
Table No.	Table S.5.3.2A
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 96 visit window.

Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_002
Output File Name	rt-vl-sumresp40w96s1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.3.1C
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects who are >= 50 copies in the visit window. It also includes subjects who discontinued prior to the visit window for lack or loss of efficacy or any reasons except AE and death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 50 c/mL.
Footnote 3	(C) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 4	(D) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_002
Output File Name	rt-vl-sumresp40w96s2.lst
Purpose	WK96S2
Table No.	Table S.5.3.2C
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects who are >= 50 copies in the visit window. It also includes subjects who discontinued prior to the visit window for lack or loss of efficacy or any reasons except AE and death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 50 c/mL.
Footnote 3	(C) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 4	(D) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w96subgs1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.3.1B
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	By Subgroup
Title 4	Treated Subjects (mITT) - Stage 1

Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 96 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Baseline Gag Polymorphism: all combinations of baseline gag polymorphisms at selected positions • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp40w96subgs2.lst
Purpose	WK96S2
Table No.	Table S.5.3.2B
Title 1	Detailed Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	By Subgroup

Title 4	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 40 c/mL within the Week 96 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 40 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 40 c/mL
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Baseline Gag Polymorphism: all combinations of baseline gag polymorphisms at selected positions • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w24s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.4.1A
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 24 Snapshot

Title 3	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 24 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w24s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.4.2A
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 24 Snapshot
Title 3	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 24 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1

	through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w24bpolys1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.4.1B
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 24 Snapshot
Title 3	By Baseline Gag Polymorphism
Title 4	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 24 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	Subgroups are all combinations of baseline gag polymorphisms at selected positions

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w24bpolys2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.4.2B
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 24 Snapshot
Title 3	By Baseline Gag Polymorphism
Title 4	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 24 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	Subgroups are all combinations of baseline gag polymorphisms at selected positions

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w48s1.lst
Purpose	WK96S1, WK96S2

Table No.	Table S.5.4.1C
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 48 Snapshot
Title 3	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 48 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w48s2.lst
Purpose	WK48S2, WK96S2
Table No.	Table S.5.4.2C
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 48 Snapshot
Title 3	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.

Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 48 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w48bpolys1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.4.1D
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 48 Snapshot
Title 3	By Baseline Gag Polymorphism
Title 4	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 48 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.

Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	Subgroups are all combinations of baseline gag polymorphisms at selected positions

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w48bpolys2.lst
Purpose	WK48S2, WK96S2
Table No.	Table S.5.4.2D
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 48 Snapshot
Title 3	By Baseline Gag Polymorphism
Title 4	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 48 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	Subgroups are all combinations of baseline gag polymorphisms at selected positions

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w96s1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.4.1E
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 96 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w96s2.lst
Purpose	WK96S2
Table No.	Table S.5.4.2E

Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 96 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w96bpolys1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.4.1F
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	By Baseline Gag Polymorphism
Title 4	Treated Subjects (mITT) - Stage 1
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.

Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 96 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >= 200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	Subgroups are all combinations of baseline gag polymorphisms at selected positions

Parameter	Values
Template ID	SS_VL_T_001
Output File Name	rt-vl-resp200w96bpolys2.lst
Purpose	WK96S2
Table No.	Table S.5.4.2F
Title 1	Detailed Summary of HIV-1 RNA < 200 c/mL
Title 2	Proportion of Responders at Week 96 Snapshot
Title 3	By Baseline Gag Polymorphism
Title 4	Treated Subjects (mITT) - Stage 2
Footnote 1	(A) Response is assessed with the snapshot algorithm, which uses the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(B) Includes subjects having HIV-1 RNA >= 200 c/mL within the Week 96 visit window.
Footnote 3	(C) Includes subjects who discontinued due to lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
Footnote 4	(D) Includes subjects who discontinued due to any reasons except AE, death and lack of efficacy at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window and last HIV-1 RNA >=

	200 c/mL.
Footnote 5	(E) Includes patients who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window
Footnote 6	(F) Other includes: withdrew consent, loss to follow-up, moved etc. with last HIV-1 RNA < 200 c/mL
Layout notes	Subgroups are all combinations of baseline gag polymorphisms at selected positions

Template SS_VL_T_003: Proportion of Responders (Observed)

	Group A N = XX	Group B N = XX	Group C N = XX	Group D N = XX
SUBGROUP 1				
NUMBER OF RESPONDERS (a)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
95% CI	(XX.X – XX.X)	(XX.X – XX.X)	(XX.X – XX.X)	(XX.X – XX.X)
SUBGROUP 2				
NUMBER OF RESPONDERS (a)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
95% CI	(XX.X – XX.X)	(XX.X – XX.X)	(XX.X – XX.X)	(XX.X – XX.X)

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w24obss1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.1.1D
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24
Title 3	Treated Subjects (Observed) - Stage 1
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w24obss2.lst

Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.1.2D
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24
Title 3	Treated Subjects (Observed) - Stage 2
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w24obssubgs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.1.1E
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24
Title 3	By Subgroup
Title 4	Treated Subjects (Observed) - Stage 1
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w24obssubgs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.1.2E
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24
Title 3	By Subgroup
Title 4	Treated Subjects (Observed) - Stage 2
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w48obss1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.2.1D

Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 48
Title 3	Treated Subjects (Observed) - Stage 1
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w48obss2.lst
Purpose	WK48S2, WK96S2
Table No.	Table S.5.2.2D
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 48
Title 3	Treated Subjects (Observed) - Stage 2
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w48obssubs1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.2.1E
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 48

Title 3	By Subgroup
Title 4	Treated Subjects (Observed) - Stage 1
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w48obssubgs2.lst
Purpose	WK48S2, WK96S2
Table No.	Table S.5.2.2E
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 48
Title 3	By Subgroup
Title 4	Treated Subjects (Observed) - Stage 2
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander,

	Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w96obss1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.3.1D
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96
Title 3	Treated Subjects (Observed) - Stage 1
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w96obss2.lst
Purpose	WK96S2
Table No.	Table S.5.3.2D
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96
Title 3	Treated Subjects (Observed) - Stage 2
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	No subgroup presentation

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w96obssubgs1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.3.1E
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96
Title 3	By Subgroup
Title 4	Treated Subjects (Observed) - Stage 1
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Parameter	Values
Template ID	SS_VL_T_003
Output File Name	rt-vl-resp40w96obssubgs2.lst
Purpose	WK96S2
Table No.	Table S.5.3.2E
Title 1	Summary of HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 96

Title 3	By Subgroup
Title 4	Treated Subjects (Observed) - Stage 2
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Layout notes	Subgroups are: • Baseline HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: Include all clades available in the database

Template SS_VL_T_004: Treatment Outcomes Table Using the TLOVR Algorithm

Outcome (%)	Trt A N = XXX	Trt B N = XXX
HIV-1 RNA < 40 C/ML (A)	XXX (XXX.X)	XXX (XXX.X)
95% CI	(XXX.X, XXX.X)	(XXX.X, XXX.X)
HIV-1 RNA >= 40 C/ML	XXX (XXX.X)	XXX (XXX.X)
VIROLOGIC REBOUND (B)	XXX (XXX.X)	XXX (XXX.X)
NEVER SUPPRESSED THROUGH WEEK 24 (C)	XXX (XXX.X)	XXX (XXX.X)
DRUG CHANGE DUE TO LACK OF EFFICACY	XXX (XXX.X)	XXX (XXX.X)
DEATH	XXX (XXX.X)	XXX (XXX.X)
DRUG CHANGE OR DISCONTINUATION DUE TO AE	XXX (XXX.X)	XXX (XXX.X)
DRUG CHANGE OR DISCONTINUATION DUE TO OTHER REASONS	XXX (XXX.X)	XXX (XXX.X)

Parameter	Values
Template ID	SS_VL_T_004
Output File Name	rt-vl-tlovr24s1.lst
Purpose	WK24S1
Table No.	Table S.5.5.1A
Title 1	Summary of Treatment Outcomes at Week 24 Using the TLOVR Algorithm
Title 2	Treated Subjects - Stage 1
Footnote 1	(A) Virologic response (HIV-1 RNA < 40 c/mL at >= 2 consecutive visits) through Week 24 without intervening failure.
Footnote 2	(B) Virologic response and subsequent HIV-1 RNA >= 40 c/mL at >= 2 consecutive visits or last visit followed by discontinuation of
Footnote 3	study therapy through Week 24.
Footnote 4	(C) Never achieved virologic response through Week 24.

Parameter	Values
Template ID	SS_VL_T_004

Output File Name	rt-vl-tlovr24s2.lst
Purpose	WK24S2
Table No.	Table S.5.5.2A
Title 1	Summary of Treatment Outcomes at Week 24 Using the TLOVR Algorithm
Title 2	Treated Subjects - Stage 2
Footnote 1	(A) Virologic response (HIV-1 RNA < 40 c/mL at >= 2 consecutive visits) through Week 24 without intervening failure.
Footnote 2	(B) Virologic response and subsequent HIV-1 RNA >= 40 c/mL at >= 2 consecutive visits or last visit followed by discontinuation of
Footnote 3	study therapy through Week 24.
Footnote 4	(C) Never achieved virologic response through Week 24.

Parameter	Values
Template ID	SS_VL_T_004
Output File Name	rt-vl-tlovr48s1.lst
Purpose	WK48S1
Table No.	Table S.5.5.1B
Title 1	Summary of Treatment Outcomes at Week 48 Using the TLOVR Algorithm
Title 2	Treated Subjects - Stage 1
Footnote 1	(A) Virologic response (HIV-1 RNA < 40 c/mL at >= 2 consecutive visits) through Week 48 without intervening failure.
Footnote 2	(B) Virologic response and subsequent HIV-1 RNA >= 40 c/mL at >= 2 consecutive visits or last visit followed by discontinuation of
Footnote 3	study therapy through Week 48.
Footnote 4	(C) Never achieved virologic response through Week 48.

Parameter	Values
Template ID	SS_VL_T_004

Output File Name	rt-vl-tlovr48s2.lst
Purpose	WK48S2
Table No.	Table S.5.5.2B
Title 1	Summary of Treatment Outcomes at Week 48 Using the TLOVR Algorithm
Title 2	Treated Subjects - Stage 2
Footnote 1	(A) Virologic response (HIV-1 RNA < 40 c/mL at >= 2 consecutive visits) through Week 48 without intervening failure.
Footnote 2	(B) Virologic response and subsequent HIV-1 RNA >= 40 c/mL at >= 2 consecutive visits or last visit followed by discontinuation of
Footnote 3	study therapy through Week 48.
Footnote 4	(C) Never achieved virologic response through Week 48.

Parameter	Values
Template ID	SS_VL_T_004
Output File Name	rt-vl-tlovr96s1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.5.5.1C
Title 1	Summary of Treatment Outcomes at Week 96 Using the TLOVR Algorithm
Title 2	Treated Subjects - Stage 1
Footnote 1	(A) Virologic response (HIV-1 RNA < 40 c/mL at >= 2 consecutive visits) through Week 96 without intervening failure.
Footnote 2	(B) Virologic response and subsequent HIV-1 RNA >= 40 c/mL at >= 2 consecutive visits or last visit followed by discontinuation of
Footnote 3	study therapy through Week 96.
Footnote 4	(C) Never achieved virologic response through Week 96.

Parameter	Values
Template ID	SS_VL_T_004

Output File Name	rt-vl-tlovr96s2.lst
Purpose	WK96S2
Table No.	Table S.5.5.2C
Title 1	Summary of Treatment Outcomes at Week 96 Using the TLOVR Algorithm
Title 2	Treated Subjects - Stage 2
Footnote 1	(A) Virologic response (HIV-1 RNA < 40 c/mL at >= 2 consecutive visits) through Week 96 without intervening failure.
Footnote 2	(B) Virologic response and subsequent HIV-1 RNA >= 40 c/mL at >= 2 consecutive visits or last visit followed by discontinuation of
Footnote 3	study therapy through Week 96.
Footnote 4	(C) Never achieved virologic response through Week 96.

Parameter	Values
Template ID	SS_EX_T_002
Output File Name	rt-vl-klmtlovrs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.5.1D
Title 1	Summary of Time to Loss of Virologic Response
Title 2	Treated Subjects - Stage 1
Footnote 1	(a) Cumulative proportion without events at end of interval.
Layout notes	Use 4-week intervals

Parameter	Values
Template ID	SS_EX_T_002
Output File Name	rt-vl-klmtlovrs2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Table S.5.5.2D
Title 1	Summary of Time to Loss of Virologic Response
Title 2	Treated Subjects - Stage 2
Footnote 1	(a) Cumulative proportion without events at end of interval.
Layout notes	Use 4-week intervals

Parameter	Values
Template ID	GS_EX_G_001
Output File Name	rg-vl-kmtlovrs1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.5.5.1E
Title 1	Time to Loss of Virologic Response
Title 2	Treated Subjects - Stage 1
Layout notes	• X-axis label: Weeks • X-axis tick labels: B/L, 4, 8, and every 4 weeks up to timepoint with data in any group • Y-axis label: Percent Without Failure • Y-axis ticks: 0 to 100 by 10 • Censoring symbols: none

Parameter	Values
Template ID	GS_EX_G_001
Output File Name	rg-vl-kmtlovrs2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.5.5.2E
Title 1	Time to Loss of Virologic Response
Title 2	Treated Subjects - Stage 2

Layout notes	• X-axis label: Weeks • X-axis tick labels: B/L, 4, 8, and every 4 weeks up to timepoint with data in any group • Y-axis label: Percent Without Failure • Y-axis ticks: 0 to 100 by 10 • Censoring symbols: none

Template SS_VL_T_005: Proportion of Subjects with HIV-1 RNA within Certain Range

Weeks	Group A N = XX	Group B N = XX	Group C N = XX	Group D N = XX
WEEK 1				
< 40 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
40 to < 100 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
100 to < 200 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
200 to < 400 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
> 400 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WEEK 2				
< 40 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
40 to < 100 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
100 to < 200 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
200 to < 400 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
> 400 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WEEK 4				
< 40 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
40 to < 100 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
100 to < 200 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
200 to < 400 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
> 400 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<additional weeks>				
< 40 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
40 to < 100 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
100 to < 200 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
200 to < 400 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
> 400 c/mL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Parameter	Values
Template ID	SS_VL_T_005
Output File Name	rt-vl-props1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Table S.5.6.1A
Title 1	Proportion of Subjects with HIV-1 RNA within Several Ranges
Title 2	Treated Subjects (Observed) - Stage 1
Programming notes	The following weeks need to be included: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96.

Parameter	Values
Template ID	SS_VL_T_005
Output File Name	rt-vl-props2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.6.2A
Title 1	Proportion of Subjects with HIV-1 RNA within Several Ranges
Title 2	Treated Subjects (Observed) - Stage 2
Programming notes	The following weeks need to be included: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96.

Template SS_VL_T_006 : Summary Statistics Over Time

Protocol: AIxxxXXX

Page 1 of X

<Domain> Summary of Values and Changes From Baseline Over Time
<Title 2>

<Parameter> (<Units>)
Subgroup: XXXXXXXXXX Level: XXXXXXXXXXXX

Period / Visit / Group	N	Mean	SD	Percentiles Q1	Median	Q3	Change From Baseline N	Mean	SD	Q1	Median	Q3
PRE-TRT												
B/L												
Group 1	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X
Group 2	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X
ON TRT												
WK XX												
Group 1	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X
Group 2	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X

... <ADDITIONAL PERIODS AND VISITS>

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-vl-sumchgs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.6.1B
Title 1	Summary Statistics for Values and Change from Baseline Over Time
Title 2	HIV-1 RNA (log10 c/mL)
Title 3	Overall and by Subgroup
Title 4	Treated Subjects (Observed) - Stage 1
Layout notes	The following weeks need to be included for the overall summary: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96. The following weeks need to be included for the subgroup summaries: baseline, Week 24, 48 and 96.

	For the baseline Gag polymorphism: include also Week 4, 8 and 12.
Programming notes	Subgroups are: • Baseline Gag Polymorphism • Baseline Viral Load Category: HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 Category: < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: any clade available in the database

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-vl-sumchgs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.6.2B
Title 1	Summary Statistics for Values and Change from Baseline Over Time
Title 2	HIV-1 RNA (log10 c/mL)
Title 3	Overall and by Subgroup
Title 4	Treated Subjects (Observed) - Stage 2
Layout notes	The following weeks need to be included for the overall summary: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96. The following weeks need to be included for the subgroup summaries: baseline, Week 24, 48 and 96. For the baseline Gag polymorphism: include also Week 4, 8 and 12.
Programming notes	Subgroups are: • Baseline Gag Polymorphism • Baseline Viral Load Category: HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 Category: < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: any clade available in the database

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-cd4s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.7.1A
Title 1	Summary Statistics for Values and Change from Baseline Over Time
Title 2	CD4 Cell Count (cells/uL)
Title 3	Overall and by Subgroup
Title 4	Treated Subjects (Observed) - Stage 1
Layout notes	The following weeks need to be included for the overall summary: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96. The following weeks need to be included for the subgroup summaries: baseline, Week 24, 48 and 96.
Programming notes	Subgroups are: • Baseline Viral Load Category: HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 Category: < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: any clade available in the database

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-cd4s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.7.2A
Title 1	Summary Statistics for Values and Change from Baseline Over Time
Title 2	CD4 Cell Count (cells/uL)

Title 3	Overall and by Subgroup
Title 4	Treated Subjects (Observed) - Stage 2
Layout notes	The following weeks need to be included for the overall summary: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96. The following weeks need to be included for the subgroup summaries: baseline, Week 24, 48 and 96.
Programming notes	Subgroups are: • Baseline Viral Load Category: HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 Category: < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: any clade available in the database

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-cd4pcts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.8.1A
Title 1	Summary Statistics for Values and Change from Baseline Over Time
Title 2	CD4 Cell Percentage
Title 3	Overall and by Subgroup
Title 4	Treated Subjects (Observed) - Stage 1
Layout notes	The following weeks need to be included for the overall summary: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96. The following weeks need to be included for the subgroup summaries: baseline, Week 24, 48 and 96.
Programming notes	Subgroups are: • Baseline Viral Load Category: HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 Category: < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other

	• HIV-1 Clade: any clade available in the database

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-cd4pcts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.8.2A
Title 1	Summary Statistics for Values and Change from Baseline Over Time
Title 2	CD4 Cell Percentage
Title 3	Overall and by Subgroup
Title 4	Treated Subjects (Observed) - Stage 2
Layout notes	The following weeks need to be included for the overall summary: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96. The following weeks need to be included for the subgroup summaries: baseline, Week 24, 48 and 96.
Programming notes	Subgroups are: • Baseline Viral Load Category: HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 Category: < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: any clade available in the database

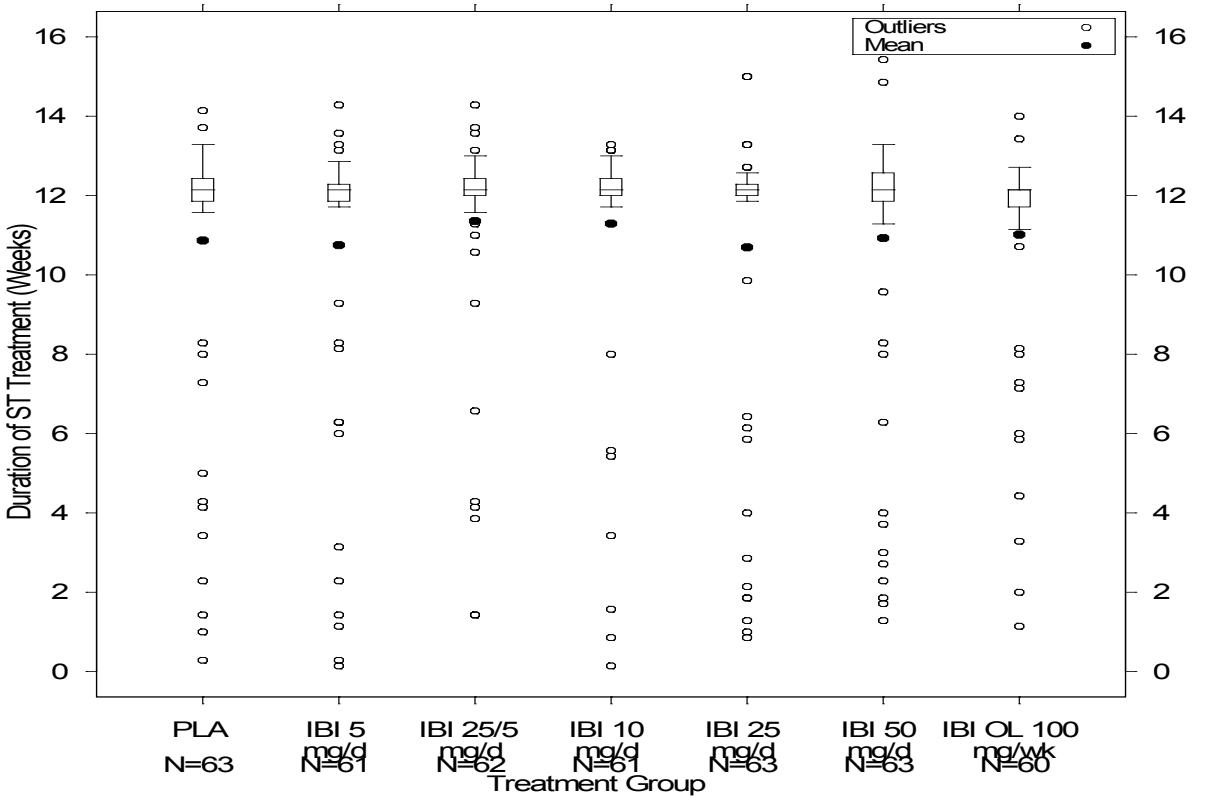
Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-cd8s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.9.1A
Title 1	Summary Statistics for Values and Change from Baseline Over Time

Title 2	CD8 Cell Count (cells/ul)
Title 3	Overall and by Subgroup
Title 4	Treated Subjects (Observed) - Stage 1
Layout notes	The following weeks need to be included for the overall summary: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96. The following weeks need to be included for the subgroup summaries: baseline, Week 24, 48 and 96.
Programming notes	Subgroups are: • Baseline Viral Load Category: HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 Category: < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female • Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: any clade available in the database

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-cd8s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.9.2A
Title 1	Summary Statistics for Values and Change from Baseline Over Time
Title 2	CD8 Cell Count (cells/ul)
Title 3	Overall and by Subgroup
Title 4	Treated Subjects (Observed) - Stage 2
Layout notes	The following weeks need to be included for the overall summary: baseline, Week 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84 and 96. The following weeks need to be included for the subgroup summaries: baseline, Week 24, 48 and 96.
Programming notes	Subgroups are: • Baseline Viral Load Category: HIV-1 RNA < 100,000 c/mL , >=100,000 c/mL • Baseline CD4 Category: < 100, 100 to < 200, 200 to < 350, 350 to < 500, >= 500 cells/uL • Gender: Male, Female

	• Race: White, Black/African American, American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, Other • HIV-1 Clade: any clade available in the database

Template GS_LB_G_001: Box Plot



Duration computed as the difference between the last and first short-term dosing date plus on
Program Path: /home/banckenf/sgtest/boxplot
Program Name: box1.sas RUN DATE: 11SEP2008:15:29:12

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-vl-box24s1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.5.6.1C

Title 1	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 24
Title 2	Treated Subjects - Stage 1
Footnote 1	N is the number of subjects with data at baseline and at Week 24.
Layout notes	Y-axis label: HIV-1 RNA Change from Baseline (log10 c/mL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-vl-box24s2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.5.6.2C
Title 1	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 24
Title 2	Treated Subjects - Stage 2
Footnote 1	N is the number of subjects with data at baseline and at Week 24.
Layout notes	Y-axis label: HIV-1 RNA Change from Baseline (log10 c/mL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-vl-box48s1
Purpose	WK96S1, WK96S2
Table No.	Figure S.5.6.1D
Title 1	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 48
Title 2	Treated Subjects - Stage 1
Footnote 1	N is the number of subjects with data at baseline and at Week 48.

Layout notes	Y-axis label: HIV-1 RNA Change from Baseline (log10 c/mL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-vl-box48s2
Purpose	WK48S2, WK96S2
Table No.	Figure S.5.6.2D
Title 1	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 48
Title 2	Treated Subjects - Stage 2
Footnote 1	N is the number of subjects with data at baseline and at Week 48.
Layout notes	Y-axis label: HIV-1 RNA Change from Baseline (log10 c/mL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-vl-box96s1
Purpose	WK96S1, WK96S2
Table No.	Figure S.5.6.1E
Title 1	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 96
Title 2	Treated Subjects - Stage 1
Footnote 1	N is the number of subjects with data at baseline and at Week 96.
Layout notes	Y-axis label: HIV-1 RNA Change from Baseline (log10 c/mL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-vl-box96s2
Purpose	WK96S2
Table No.	Figure S.5.6.2E
Title 1	HIV-1 RNA (log10 c/mL) Change from Baseline to Week 96
Title 2	Treated Subjects - Stage 2
Footnote 1	N is the number of subjects with data at baseline and at Week 96.
Layout notes	Y-axis label: HIV-1 RNA Change from Baseline (log10 c/mL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd4box24s1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.5.7.1B
Title 1	CD4 Cell Count (cells/uL) Change from Baseline to Week 24
Title 2	Treated Subjects - Stage 1
Footnote 1	N is the number of subjects with data at baseline and at Week 24.
Layout notes	Y-axis label: CD4 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd4box24s2

Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.5.7.2B
Title 1	CD4 Cell Count (cells/uL) Change from Baseline to Week 24
Title 2	Treated Subjects - Stage 2
Footnote 1	N is the number of subjects with data at baseline and at Week 24.
Layout notes	Y-axis label: CD4 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd4box48s1
Purpose	WK96S1, WK96S2
Table No.	Figure S.5.7.1C
Title 1	CD4 Cell Count (cells/uL) Change from Baseline to Week 48
Title 2	Treated Subjects - Stage 1
Footnote 1	N is the number of subjects with data at baseline and at Week 48.
Layout notes	Y-axis label: CD4 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd4box48s2
Purpose	WK48S2, WK96S2
Table No.	Figure S.5.7.2C
Title 1	CD4 Cell Count (cells/uL) Change from Baseline to Week 48

Title 2	Treated Subjects - Stage 2
Footnote 1	N is the number of subjects with data at baseline and at Week 48.
Layout notes	Y-axis label: CD4 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd4box96s1
Purpose	WK96S1, WK96S2
Table No.	Figure S.5.7.1D
Title 1	CD4 Cell Count (cells/uL) Change from Baseline to Week 96
Title 2	Treated Subjects - Stage 1
Footnote 1	N is the number of subjects with data at baseline and at Week 96.
Layout notes	Y-axis label: CD4 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd4box96s2
Purpose	WK96S2
Table No.	Figure S.5.7.2D
Title 1	CD4 Cell Count (cells/uL) Change from Baseline to Week 96
Title 2	Treated Subjects - Stage 2
Footnote 1	N is the number of subjects with data at baseline and at Week 96.
Layout notes	Y-axis label: CD4 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd8box24s1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.5.9.1B
Title 1	CD8 Cell Count (cells/uL) Change from Baseline to Week 24
Title 2	Treated Subjects -Stage 1
Footnote 1	N is the number of subjects with data at baseline and at Week 24.
Layout notes	Y-axis label: CD8 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd8box24s2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.5.9.2B
Title 1	CD8 Cell Count (cells/uL) Change from Baseline to Week 24
Title 2	Treated Subjects -Stage 2
Footnote 1	N is the number of subjects with data at baseline and at Week 24.
Layout notes	Y-axis label: CD8 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001

Output File Name	rg-lb-cd8box48s1
Purpose	WK96S1, WK96S2
Table No.	Figure S.5.9.1C
Title 1	CD8 Cell Count (cells/uL) Change from Baseline to Week 48
Title 2	Treated Subjects - Stage 1
Footnote 1	N is the number of subjects with data at baseline and at Week 48.
Layout notes	Y-axis label: CD8 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

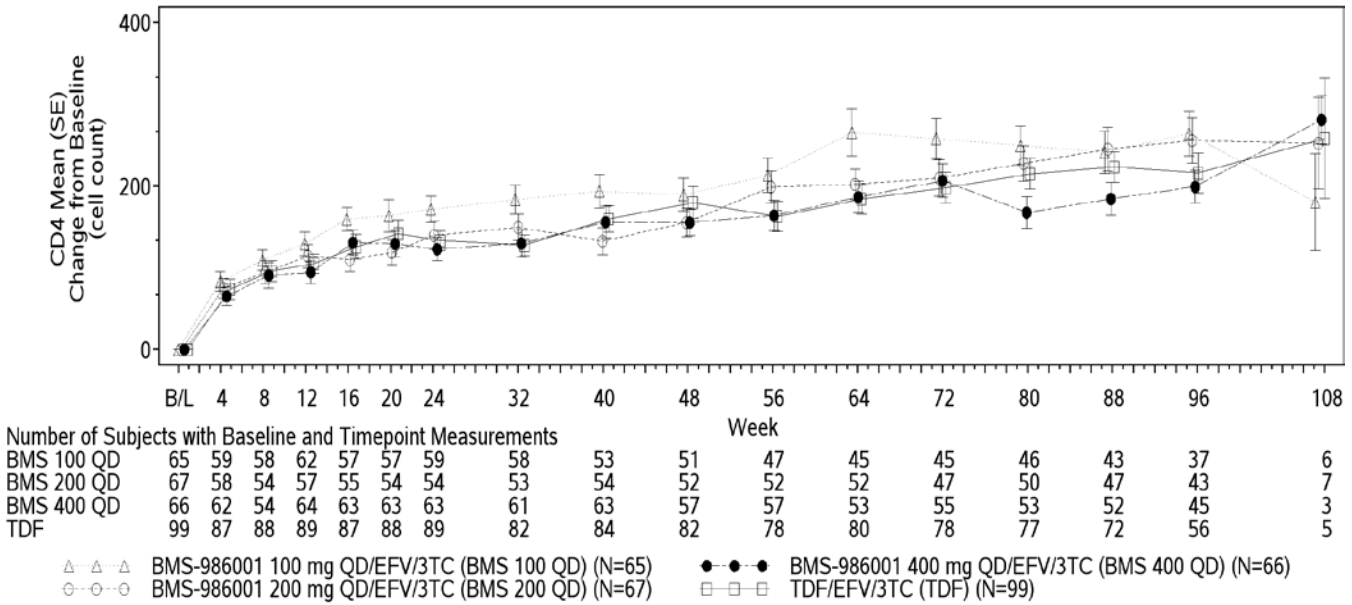
Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd8box48s2
Purpose	WK48S2, WK96S2
Table No.	Figure S.5.9.2C
Title 1	CD8 Cell Count (cells/uL) Change from Baseline to Week 48
Title 2	Treated Subjects - Stage 2
Footnote 1	N is the number of subjects with data at baseline and at Week 48.
Layout notes	Y-axis label: CD8 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd8box96s1
Purpose	WK96S1, WK96S2
Table No.	Figure S.5.9.1D

Title 1	CD8 Cell Count (cells/uL) Change from Baseline to Week 96
Title 2	Treated Subjects - Stage 1
Footnote 1	N is the number of subjects with data at baseline and at Week 96.
Layout notes	Y-axis label: CD8 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Parameter	Values
Template ID	GS_LB_G_001
Output File Name	rg-lb-cd8box96s2
Purpose	WK96S2
Table No.	Figure S.5.9.2D
Title 1	CD8 Cell Count (cells/uL) Change from Baseline to Week 96
Title 2	Treated Subjects - Stage 2
Footnote 1	N is the number of subjects with data at baseline and at Week 96.
Layout notes	Y-axis label: CD8 Cell Count Change from Baseline (cells/uL) X-axis label: Treatment Group

Template GS_L_G_002: Longitudinal Line Plot Grouped by Treatment with Horizontal Shift and Reference Line



Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-vl-times1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.5.6.1F
Title 1	HIV-1 RNA (log10 c/mL) Mean Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: HIV-1 RNA (log10 c/mL) Mean Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values

Template ID	GS_LB_G_002
Output File Name	rg-vl-times2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.5.6.2F
Title 1	HIV-1 RNA (log10 c/mL) Mean Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: HIV-1 RNA (log10 c/mL) Mean Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-cd4times1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.5.7.1E
Title 1	CD4 (cells/uL) Mean Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: CD4 Mean Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-cd4times2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.5.7.2E

Title 1	CD4 (cells/uL) Mean Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: CD4 Mean Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-cd8times1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.5.9.1E
Title 1	CD8 (cells/uL) Mean Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: CD8 Mean Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-cd8times2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.5.9.2E
Title 1	CD8 (cells/uL) Mean Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: CD8 Mean Change from Baseline (SE) X-axis label: Time (Weeks)

	Include horizontal reference line at Y=0.

Template SS_VL_L_004: Listing of Outcomes from Snapshot Analysis

Subject ID (Age/Gender/Race)	Randomized Treatment Group	Assessment Day HIV-1 RNA (c/mL)	Response	Specification	Disc. Day	Disc. Reason
PPD 25/M/C	BMS-986001 600 mg QD/ EFV/3TC	01FEB2013/ 8754	NO VIROLOGIC DATA	DISC. STUDY/STUDY DRUG DUE TO AE OR DEATH	10FEB2013	OTHER
PPD 24/F/B	BMS-986001 1200 mg QD/ EFV/3TC	20DEC2012 <40	RESPONDER			
PPD 26/M/C	BMS-986001 600 mg QD/ EFV/3TC	01MAR2013 1350	VIROLOGIC FAILURE	HIV-1 RNA >= 40 c/mL		

Parameter	Values
Template ID	SS_VL_L_004
Output File Name	rl-vl-outcome24s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 5.1.1A
Title 1	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis
Title 2	Data for Subjects in the Week 24 Snapshot
Title 3	Treated Subjects - Stage 1
Footnote 1	HIV-1 RNA assessments used for the response evaluation are listed.
Programming notes	Listing should be sorted by Treatment group, response and specification.

Parameter	Values
Template ID	SS_VL_L_004
Output File Name	rl-vl-outcome24s2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Appendix 5.1.2A
Title 1	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis
Title 2	Data for Subjects in the Week 24 Snapshot
Title 3	Treated Subjects - Stage 2
Footnote 1	HIV-1 RNA assessments used for the response evaluation are listed.
Programming notes	Listing should be sorted by Treatment group, response and specification.

Parameter	Values
Template ID	SS_VL_L_004
Output File Name	rl-vl-outcome48s1.lst
Purpose	WK96S1, WK96S2
Table No.	Appendix 5.1.1B
Title 1	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis
Title 2	Data for Subjects in the Week 48 Snapshot
Title 3	Treated Subjects - Stage 1
Footnote 1	HIV-1 RNA assessments used for the response evaluation are listed.
Programming notes	Listing should be sorted by Treatment group, response and specification.

Parameter	Values
Template ID	SS_VL_L_004
Output File Name	rl-vl-outcome48s2.lst
Purpose	WK48S2, WK96S2
Table No.	Appendix 5.1.2B
Title 1	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis

Title 2	Data for Subjects in the Week 48 Snapshot
Title 3	Treated Subjects - Stage 2
Footnote 1	HIV-1 RNA assessments used for the response evaluation are listed.
Programming notes	Listing should be sorted by Treatment group, response and specification.

Parameter	Values
Template ID	SS_VL_L_004
Output File Name	rl-vl-outcome96s1.lst
Purpose	WK96S1, WK96S2
Table No.	Appendix 5.1.1C
Title 1	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis
Title 2	Data for Subjects in the Week 96 Snapshot
Title 3	Treated Subjects - Stage 1
Footnote 1	HIV-1 RNA assessments used for the response evaluation are listed.
Programming notes	Listing should be sorted by Treatment group, response and specification.

Parameter	Values
Template ID	SS_VL_L_004
Output File Name	rl-vl-outcome96s2.lst
Purpose	WK96S2
Table No.	Appendix 5.1.2C
Title 1	Listing of Outcomes from HIV-1 RNA < 40 c/mL Snapshot Analysis
Title 2	Data for Subjects in the Week 96 Snapshot
Title 3	Treated Subjects - Stage 2
Footnote 1	HIV-1 RNA assessments used for the response evaluation are listed.

Programming notes	Listing should be sorted by Treatment group, response and specification.

Template SS_VL_L_005: Listing of Viral Load

Treatment Group: DRUG A

Subject ID (Age/Gender/Race)	Current Treatment	Period	Visit	Lab Date	Treatment Start Study Day	HIV-1 RNA (c/mL)	HIV-1 RNA (log10 c/mL)	Assay
--								
PPD		SCRN	A00	PPD	-16	1500000	6.18	U
(56/M/C)	DRUG A 250 MG	ON TRT	B01		1	45000	4.65	S
	DRUG A 300 MG	ON TRT	B02		25	23000	4.36	U
	DRUG A 200 MG	ON TRT	B03		30	450	2.65	S
	DRUG A 200 MG	ON TRT	B04		30	45	1.65	U
PPD		SCRN	A00		-16	1500000	6.18	U
(56/M/C)	DRUG A 250 MG	ON TRT	B01		1	45000	4.65	U
	DRUG A 300 MG	ON TRT	B02		2	23000	4.36	U
	DRUG A 200 MG	ON TRT	B03		5	450	2.65	U
	DRUG A 300 MG	ON TRT	B02		6	23000	4.36	S
	DRUG A 200 MG	ON TRT	B03		7	450	2.65	U
	DRUG A 200 MG	ON TRT	B04		36	45	1.65	U
	DRUG A 300 MG	ON TRT	B05		62	23000	4.36	U
	DRUG A 200 MG	ON TRT	B06		90	450	2.65	S
	DRUG A 200 MG	ON TRT	B06		118	45	1.65	A
	DRUG A 200 MG	ON TRT	B06		146	45	1.65	A

ASSAY: S = ROCHE AMPLICOR STANDARD ASSAY U = ROCHE AMPLICOR ULTRA-SENSITIVE ASSAY A = ABBOTT REALTIME M2000 ASSAY

Parameter	Values
Template ID	SS_VL_L_005
Output File Name	rl-vl-vllists1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 5.1.1D
Title 1	Listing of HIV-1 RNA
Title 2	Treated Subjects - Stage 1

Parameter	Values

Template ID	SS_VL_L_005
Output File Name	rl-vl-vllists2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 5.1.2D
Title 1	Listing of HIV-1 RNA
Title 2	Treated Subjects - Stage 2

Template SS_LB_L_002: Listing of CD4 and CD8

Treatment Group: DRUG A

Subject (Age/Gender/Race)	Period	Visit	Lab Date	Treatment Start Study Day	CD4+ (cells/ul)	CD4+ percentage	CD8+ (cells/ul)	CD8+ percentage
PPD (38/M/B)	PRE-TREATMENT	SCREENING	PPD	-34	557	30.0	937	51.0
	STAGE 1	DAY 1		8	633	31.0	1025	51.0
	STAGE 1	WEEK 2		21	633	31.0	998	49.0
	STAGE 1	WEEK 4		35	583	32.0	842	46.0
	STAGE 1	WEEK 8		62	594	30.0	844	43.0
	STAGE 1	WEEK 12		91	628	39.0	660	40.0
	STAGE 1	WEEK 16		119	650	40.0	613	38.0
	STAGE 1	WEEK 20		145	743	38.0	761	39.0
	STAGE 1	WEEK 24		173	710	42.0	571	34.0
	STAGE 1	WEEK 32		226	642	40.0	567	35.0
	STAGE 1	WEEK 40		285	615	42.0	503	34.0
	STAGE 1	WEEK 48		349	696	45.0	506	33.0
	STAGE 1	WEEK 56		394	727	46.0	515	33.0
	STAGE 1	WEEK 64		453	644	45.0	443	31.0
	STAGE 1	WEEK 72		511	696	46.0	465	31.0
	STAGE 1	WEEK 80		567	630	44.0	399	28.0
	STAGE 1	WEEK 88		622	845	51.0	474	29.0
	STAGE 1	WEEK 96		679	784	47.0	479	29.0
	STAGE 2	WEEK 108		758	772	45.0	491	29.0
	STAGE 2	WEEK 120		848	936	48.0	555	28.0
	STAGE 2	WEEK 132		926	780	47.0	479	29.0
	STAGE 2	WEEK 144		1043	798	49.0	448	27.0

Parameter	Values
Template ID	SS_VL_L_005
Output File Name	rl-lb-cd4cd8s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 5.1.1E
Title 1	Listing of CD4+ and CD8+ T-Cell Count and Percentages
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_VL_L_005
Output File Name	rl-lb-cd4cd8s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 5.1.2E
Title 1	Listing of CD4+ and CD8+ T-Cell Count and Percentages
Title 2	Treated Subjects - Stage 2

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-news1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1A
Title 1	Newly Emergent Genotypic Resistance Profile
Title 2	Treated Subjects with On-Treatment Genotypic Resistance Testing - Stage 1

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-news2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2A
Title 1	Newly Emergent Genotypic Resistance Profile
Title 2	Treated Subjects with On-Treatment Genotypic Resistance Testing - Stage 2

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-news12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3A
Title 1	Newly Emergent Genotypic Resistance Profile
Title 2	Treated Subjects with On-Treatment Genotypic Resistance Testing - Stage 1 and 2

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-newpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1B
Title 1	Newly Emergent Genotypic Resistance Profile
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-newpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Table S.5.10.2B
Title 1	Newly Emergent Genotypic Resistance Profile
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_001
Output File Name	rt-gn-newpdvfs12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3B
Title 1	Newly Emergent Genotypic Resistance Profile
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_L_001
Output File Name	rl-gn-ontrts1.lst

Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 5.10.1A
Title 1	Listing of Genotypic Substitutions
Title 2	Treated Subjects with Baseline and On-Treatment Data - Stage 1

Parameter	Values
Template ID	SS_GN_L_001
Output File Name	rl-gn-ontrts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 5.10.2A
Title 1	Listing of Genotypic Substitutions
Title 2	Treated Subjects with Baseline and On-Treatment Data - Stage 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgags1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1C
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects with On-Treatment Gag Sequencing - Stage 1

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgags2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Table S.5.10.2C
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects with On-Treatment Gag Sequencing - Stage 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgags12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3C
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects with On-Treatment Gag Sequencing - Stage 1 and 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagbysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1R
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Gag Sequencing - Stage 1

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagbysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Table S.5.10.2R
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Gag Sequencing - Stage 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagbysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3R
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Gag Sequencing - Stage 1 and 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1D
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window

Footnote 5	4) Failure to achieve > 1 log_{10} c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2D
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 log_{10} c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 log_{10} c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagpdvfs12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3D
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 log_{10} c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL

Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagpdvfbysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1S
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagpdvfbysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2S
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2

Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagpdvfbysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3S
Title 1	Emergent Gag Polymorphisms at Selected Positions
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_L_002
Output File Name	rl-gn-gagontrts1.lst
Purpose	WK24S1, WK48S1 WK96S1, WK96S2
Table No.	Appendix 5.10.1B

Title 1	Listing of Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects with Baseline and On-Treatment Data - Stage 1

Parameter	Values
Template ID	SS_GN_L_002
Output File Name	rl-gn-gagontrts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 5.10.2B
Title 1	Listing of Gag Polymorphisms at Selected Positions
Title 2	Treated Subjects with Baseline and On-Treatment Data - Stage 2

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygags1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1E
Title 1	Newly Emergent Gag Deviations
Title 2	Treated Subjects with On-Treatment Gag Sequencing - Stage 1

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygags2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2E
Title 1	Newly Emergent Gag Deviations

Title 2	Treated Subjects with On-Treatment Gag Sequencing - Stage 2

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygags12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3E
Title 1	Newly Emergent Gag Deviations
Title 2	Treated Subjects with On-Treatment Gag Sequencing - Stage 1 and 2

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygagbysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1T
Title 1	Newly Emergent Gag Deviations
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Gag Sequencing - Stage 1

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygagbysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2T
Title 1	Newly Emergent Gag Deviations

Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Gag Sequencing - Stage 2

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygagbysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3T
Title 1	Newly Emergent Gag Deviations
Title 2	By HIV Subtype
Title 3	Treated Subjects with On-Treatment Gag Sequencing - Stage 1 and 2

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygagpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1F
Title 1	Newly Emergent Gag Deviations
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygagpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2F
Title 1	Newly Emergent Gag Deviations
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygagpdvfs12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3F
Title 1	Newly Emergent Gag Deviations
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygagpdvfbysubtypes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1U
Title 1	Newly Emergent Gag Deviations
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygagpdvfbysubtypes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2U
Title 1	Newly Emergent Gag Deviations
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL

Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_T_003
Output File Name	rt-gn-anygagpdvfbysubtypes12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3U
Title 1	Newly Emergent Gag Deviations
Title 2	By HIV Subtype
Title 3	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_GN_L_003
Output File Name	rl-gn-gagontrts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 5.10.1C
Title 1	Listing of Newly Emergent Gag Deviations
Title 2	Treated Subjects with Baseline and On-Treatment Data - Stage 1

Parameter	Values
Template ID	SS_GN_L_003
Output File Name	rl-gn-gagontrts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 5.10.2C
Title 1	Listing of Newly Emergent Gag Deviations
Title 2	Treated Subjects with Baseline and On-Treatment Data - Stage 2

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-news1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1G
Title 1	Newly Emergent Phenotypic Resistance Profile
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-news2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2G

Title 1	Newly Emergent Phenotypic Resistance Profile
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 2
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-news12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3G
Title 1	Newly Emergent Phenotypic Resistance Profile
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1 and 2
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-newpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1H
Title 1	Newly Emergent Phenotypic Resistance Profile
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility

Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.
Footnote 3	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 4	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 5	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 6	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 7	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_001
Output File Name	rt-pn-newpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2H
Title 1	Newly Emergent Phenotypic Resistance Profile
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.
Footnote 3	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 4	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 5	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 6	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 7	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_001

Output File Name	rt-pn-newpdvfs12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3H
Title 1	Newly Emergent Phenotypic Resistance Profile
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.
Footnote 3	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 4	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 5	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 6	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 7	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-newdrugs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1I
Title 1	Newly Emergent Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.

Parameter	Values

Template ID	SS_PN_T_002
Output File Name	rt-pn-newdrugs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2I
Title 1	Newly Emergent Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 2
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-newdrugs12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3I
Title 1	Newly Emergent Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1 and 2
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-newdrugpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1J

Title 1	Newly Emergent Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.
Footnote 3	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 4	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 5	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 6	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 7	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-newdrugpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2J
Title 1	Newly Emergent Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.
Footnote 3	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 4	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 5	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 6	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 7	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_002
Output File Name	rt-pn-newdrugpdvfs12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3J
Title 1	Newly Emergent Phenotypic Resistance by Class and Drug Name
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1 and 2
Footnote 1	Newly emergent phenotypic resistance to a drug is defined as a baseline fold change less than or equal to the cut-off for reduced susceptibility
Footnote 2	and an on-treatment fold change greater than the cut-off for reduced susceptibility.
Footnote 3	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 4	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 5	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 6	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 7	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_L_001
Output File Name	rl-pn-ontrts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 5.10.1D
Title 1	Listing of Phenotypic Resistance
Title 2	Treated Subjects with Baseline and On-Treatment Data - Stage 1
Footnote 1	Susc = Susceptibility

Footnote 2	P = Partial, R = Resistance, S = Susceptible

Parameter	Values
Template ID	SS_PN_L_001
Output File Name	rl-pn-ontrts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 5.10.2D
Title 1	Listing of Phenotypic Resistance
Title 2	Treated Subjects with Baseline and On-Treatment Data - Stage 2
Footnote 1	Susc = Susceptibility
Footnote 2	P = Partial, R = Resistance, S = Susceptible

Template SS_PN_T_003: Maximum Change in IC50 Summary

ASSESSMENT	TRT A N = 10	TRT B N = 15	TRT C N = 14	TRT D N = 15
BASELINE				
N	3	11	6	5
MEAN (SD)	0.042480 (0.0276698)	0.012479 (0.0220447)	0.002700 (0.0059675)	0.009394 (0.0149333)
GEOMETRIC MEAN	0.033159	(65.1)	0.001733	(176.7)	0.000490	(221.0)	0.001608	(159.0)
(COEFFICIENT OF VARIATION)				
MAXIMUM ON TREATMENT				
N	2	9	6	5
MEAN (SD)	0.096295 (0.1327734)	0.718214 (1.6357205)	0.121485 (0.2291942)	1.038524 (2.2150816)
GEOMETRIC MEAN	0.021409	(137.9)	0.019219	(227.7)	0.006114	(188.7)	0.022420	(213.3)
(COEFFICIENT OF VARIATION)				
MAXIMUM CHANGE FROM BASELINE				
MEAN (SD)	0.063335 (0.1013496)	0.703029 (1.6328842)	0.118785 (0.2306211)	1.029130 (2.2200751)
MEDIAN	0.063335	0.007120	0.003155	0.041980
MIN , MAX	-0.00833 , 0.13500	-0.00007 , 4.98500	-0.00005 , 0.57797	-0.00011 , 4.99979

Parameter	Values
Template ID	SS_PN_T_003
Output File Name	rt-pn-maxic50s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1K
Title 1	Maximum Change from Baseline Summary for BMS-955176 IC50
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1
Layout notes	Assessment = BMS-955176 IC50

Parameter	Values
Template ID	SS_PN_T_003

Output File Name	rt-pn-maxic50s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2K
Title 1	Maximum Change from Baseline Summary for BMS-955176 IC50
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 2
Layout notes	Assessment = BMS-955176 IC50

Parameter	Values
Template ID	SS_PN_T_003
Output File Name	rt-pn-maxic50pdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1L
Title 1	Maximum Change from Baseline Summary for BMS-955176 IC50
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Assessment = BMS-955176 IC50

Parameter	Values
Template ID	SS_PN_T_003
Output File Name	rt-pn-maxic50pdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Table S.5.10.2L
Title 1	Maximum Change from Baseline Summary for BMS-955176 IC50
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Assessment = BMS-955176 IC50

Parameter	Values
Template ID	SS_PN_T_003
Output File Name	rt-pn-maxic50fcs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1M
Title 1	Summary for Maximum BMS-955176 IC50 Fold Change
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 1
Layout notes	Assessment = BMS-955176 IC50 Fold Change Only include the 'MAXIMUM ON TREATMENT' part

Parameter	Values
Template ID	SS_PN_T_003
Output File Name	rt-pn-maxic50fcs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2M

Title 1	Summary for Maximum BMS-955176 IC50 Fold Change
Title 2	Treated Subjects with On-Treatment Phenotypic Resistance Profile - Stage 2
Layout notes	Assessment = BMS-955176 IC50 Fold Change Only include the 'MAXIMUM ON TREATMENT' part

Parameter	Values
Template ID	SS_PN_T_003
Output File Name	rt-pn-maxic50fcpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1N
Title 1	Summary for Maximum BMS-955176 IC50 Fold Change
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Assessment = BMS-955176 IC50 Fold Change Only include the 'MAXIMUM ON TREATMENT' part

Parameter	Values
Template ID	SS_PN_T_003
Output File Name	rt-pn-maxic50fcpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2N

Title 1	Summary for Maximum BMS-955176 IC50 Fold Change
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Layout notes	Assessment = BMS-955176 IC50 Fold Change Only include the 'MAXIMUM ON TREATMENT' part

Template SS_PN_T_004: Proportion of Subjects with > 3 Fold Increase in IC50 Fold Change

	Group A N = XX	Group B N = XX	Group C N = XX	Group D N = XX
NUMBER (%) OF SUBJECTS	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-props1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1O
Title 1	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change
Title 2	Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1
Footnote 1	A > 3 fold increase from baseline in BMS-955176 FC-IC50 is defined as BMS-955176 FC-IC50 on-treatment divided by BMS-955176 FC-IC50 at baseline >3.

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-props2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2O
Title 1	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change
Title 2	Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 2
Footnote 1	A > 3 fold increase from baseline in BMS-955176 FC-IC50 is defined as BMS-955176 FC-IC50 on-treatment divided by BMS-955176 FC-IC50 at baseline >3.

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-props12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3O
Title 1	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change
Title 2	Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1 and 2
Footnote 1	A > 3 fold increase from baseline in BMS-955176 FC-IC50 is defined as BMS-955176 FC-IC50 on-treatment divided by BMS-955176 FC-IC50 at baseline >3.

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-proppdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1P
Title 1	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures
Title 3	with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1
Footnote 1	A > 3 fold increase from baseline in BMS-955176 FC-IC50 is defined as BMS-955176 FC-IC50 on-treatment divided by BMS-955176 FC-IC50 at baseline >3.
Footnote 2	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 3	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 4	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 5	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 6	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-proppdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2P
Title 1	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures
Title 3	with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 2
Footnote 1	A > 3 fold increase from baseline in BMS-955176 FC-IC50 is defined as BMS-955176 FC-IC50 on-treatment divided by BMS-955176 FC-IC50 at baseline >3.
Footnote 2	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 3	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 4	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 5	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 6	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-proppdvfs12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3P
Title 1	Proportion of Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures
Title 3	with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1 and 2
Footnote 1	A > 3 fold increase from baseline in BMS-955176 FC-IC50 is defined as BMS-955176 FC-IC50 on-treatment divided by BMS-955176 FC-IC50 at baseline >3.

Footnote 2	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 3	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 4	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 5	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 6	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-propnews1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1V
Title 1	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176
Title 2	Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1
Footnote 1	Newly emergent phenotypic resistance to BMS-955176 is defined as a baseline fold change <= 3
Footnote 2	and an on-treatment fold change >3

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-propnews2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2V
Title 1	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176
Title 2	Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 2
Footnote 1	Newly emergent phenotypic resistance to BMS-955176 is defined as a baseline fold change <= 3
Footnote 2	and an on-treatment fold change >3

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-propnews12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3V
Title 1	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176
Title 2	Treated Subjects with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1 and 2
Footnote 1	Newly emergent phenotypic resistance to BMS-955176 is defined as a baseline fold change <= 3
Footnote 2	and an on-treatment fold change >3

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-propnewpdvfs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1W
Title 1	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures
Title 3	with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Footnote 6	Newly emergent phenotypic resistance to BMS-955176 is defined as a baseline fold change <= 3

Footnote 7	and an on-treatment fold change >3

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-propnewpdvfs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2W
Title 1	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures
Title 3	with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Footnote 6	Newly emergent phenotypic resistance to BMS-955176 is defined as a baseline fold change <= 3
Footnote 7	and an on-treatment fold change >3

Parameter	Values
Template ID	SS_PN_T_004
Output File Name	rt-pn-propnewpdvfs12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3W
Title 1	Proportion of Subjects with Newly Emergent Phenotypic Resistance to BMS-955176
Title 2	Treated Subjects Identified as Protocol Defined Virologic Failures

Title 3	with Baseline and On-Treatment Phenotypic Resistance Profile - Stage 1 and 2
Footnote 1	Protocol Defined Virologic Failure is defined by a subject meeting one of the following criteria:
Footnote 2	1) Confirmed > 1 $\log_{10}$ c/mL increase in HIV-1 RNA at anytime above nadir level where nadir is ≥ 40 c/mL
Footnote 3	2) Confirmed HIV-1 RNA ≥ 40 c/mL if prior suppression to < 40 c/mL
Footnote 4	3) Failure to have the last on-treatment HIV-1 RNA to < 400 c/mL within Week 24, 48, or 96 week snapshot window
Footnote 5	4) Failure to achieve > 1 $\log_{10}$ c/mL decrease in HIV-1 RNA by Week 8
Footnote 6	Newly emergent phenotypic resistance to BMS-955176 is defined as a baseline fold change <= 3
Footnote 7	and an on-treatment fold change >3

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagincs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.5.10.1Q
Title 1	Emergent Gag Polymorphisms
Title 2	Treated Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change- Stage 1

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagincs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.5.10.2Q
Title 1	Emergent Gag Polymorphisms
Title 2	Treated Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change- Stage 2

Parameter	Values
Template ID	SS_GN_T_002
Output File Name	rt-gn-newgagincs12.lst
Purpose	WK96S2
Table No.	Table S.5.10.3Q
Title 1	Emergent Gag Polymorphisms
Title 2	Treated Subjects with Greater than 3 Fold Increase in BMS-955176 IC50 Fold Change- Stage 1 and 2

Template SS_VL_T_007: Proportion of Responders (mITT) - Futility Analysis

	Group A N = XX	Group B N = XX	Group C N = XX	Group D N = XX
NUMBER OF RESPONDERS (a)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
95% CI	(XX.X - XX.X)	(XX.X - XX.X)	(XX.X - XX.X)	(XX.X - XX.X)
P-value (b)	xxx	xxx	xxx	

Parameter	Values
Template ID	SS_VL_T_007
Output File Name	rt-vl-futw24s1.lst
Purpose	WK24S1
Table No.	Table S.5.11.1
Title 1	Test for Virologic Futility Based on HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24 (mITT)
Title 3	Treated Subjects - Stage 1
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(b) Based on one-sided Fisher's exact test.

Parameter	Values
Template ID	SS_VL_T_007
Output File Name	rt-vl-futw24s2.lst
Purpose	WK24S2
Table No.	Table S.5.11.2

Title 1	Test for Virologic Futility Based on HIV-1 RNA < 40 c/mL
Title 2	Proportion of Responders at Week 24 (mITT)
Title 3	Treated Subjects - Stage 2
Footnote 1	(a) Response is assessed using the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.
Footnote 2	(b) Based on one-sided Fisher's exact test.

4.6 Safety Results

4.6.1 All Adverse Events

Template SS_AE_T_001: Overall Adverse Events Summary

	TRT A N = XXX	TRT B N = XXX	TRT C N = XXX	All Subjects N = XXXX
SUBJECTS WITH ONE OR MORE ADVERSE EVENTS	XXX (XX.X)	XXX (XX.X)	XX (XX.X)	XXXX (XX.X)
SUBJECTS WHO DIED	XXX (XX.X)	XXX (XX.X)	XX (XX.X)	XXXX (XX.X)
SUBJECTS WITH SERIOUS ADVERSE EVENTS	XXX (XX.X)	XXX (XX.X)	XX (XX.X)	XXXX (XX.X)
SUBJECTS WITH RELATED ADVERSE EVENTS	XXX (XX.X)	XXX (XX.X)	XX (XX.X)	XXXX (XX.X)
SUBJECTS WITH ADVERSE EVENT LEADING TO DISCONTINUATION	XXX (XX.X)	XXX (XX.X)	XX (XX.X)	XXXX (XX.X)

Parameter	Values
Template ID	SS_AE_T_001
Output File Name	rt-ae-overallsums1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.7.1
Title 1	Adverse Events
Title 2	Overall Adverse Events Summary
Title 3	Treated Subjects - Stage 1

Parameter	Values
Template ID	SS_AE_T_001
Output File Name	rt-ae-overallsums2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.7.2
Title 1	Adverse Events
Title 2	Overall Adverse Events Summary
Title 3	Treated Subjects - Stage 2

Parameter	Values
Template ID	SS_AE_T_001
Output File Name	rt-ae-overallsums12.lst
Purpose	WK96S2
Table No.	Table S.6.7.3
Title 1	Adverse Events
Title 2	Overall Adverse Events Summary
Title 3	Treated Subjects - Stage 1 and 2

4.6.2 Deaths

Template SS_AE_L_001: Listing of Death

```
------------------------------------------------------------------------------------------------------------------------

Subject ID
  (Age/Gender/Race)                Current Trt
    Treatment Group                  Period                          Death Date     Death Day      Cause of Death
------------------------------------------------------------------------------------------------------------------------
```

Parameter	Values
Template ID	SS_AE_L_001
Output File Name	rl-ae-deaths1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.1.1
Title 1	Death Listing
Title 2	Enrolled Subjects - Stage 1

Parameter	Values
Template ID	SS_AE_L_001
Output File Name	rl-ae-deaths2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.1.2
Title 1	Death Listing
Title 2	Enrolled Subjects - Stage 2

4.6.3 Serious Adverse Events

Parameter	Values

Template ID	GS_AE_T_X_001
Output File Name	rt-ae-saes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.2.1A
Title 1	Adverse Event Summary
Title 2	Serious Adverse Events
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-saes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.2.2A
Title 1	Adverse Event Summary
Title 2	Serious Adverse Events
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-saes12.lst
Purpose	WK96S2
Table No.	Table S.6.2.3A
Title 1	Adverse Event Summary

Title 2	Serious Adverse Events
Title 3	Treated Subjects - Stage 1 and 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-saeconts1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.6.2.1B
Title 1	Adverse Event Summary
Title 2	Serious Adverse Events After Switch to Continuation Dose
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-saeconts2.lst
Purpose	WK96S2
Table No.	Table S.6.2.2B
Title 1	Adverse Event Summary
Title 2	Serious Adverse Events After Switch to Continuation Dose
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values

Template ID	GS_AE_T_X_001
Output File Name	rt-ae-saeldeaths1eu.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.2.1C
Title 1	Adverse Event Summary
Title 2	Serious Adverse Event With Death As An Outcome
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-saeldeaths2eu.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.2.2C
Title 1	Adverse Event Summary
Title 2	Serious Adverse Event With Death As An Outcome
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-relsaeldeaths1eu.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.2.1D
Title 1	Adverse Event Summary

Title 2	Drug Related Serious Adverse Event With Death As An Outcome
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-relsaeldeaths2eu.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.2.2D
Title 1	Adverse Event Summary
Title 2	Drug Related Serious Adverse Event With Death As An Outcome
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Template GS_AE_L_S_001: Adverse Event Listing (by Subject)

Protocol: IM101031

Confidential
Adverse Event
All Treated Subjects

Subject ID (Age/Gender/Race) Treatment Group	Current Trt Period Visit	Onset Resolution Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL INT	TRT ACT
PPD (55/F/C) ABATACEPT	ABA 10 ON TRT Day 1	PPD 1	1D 7H SAE	GASTROINTESTINAL DISORDERS NAUSEA NAUSEA	5 2	0 1
	ABA 10 ON TRT Day 1	PPD 1	1D 5H AE	SKIN AND SUBCUTANEOUS TISSUE DISORDERS NIGHT SWEATS NIGHT SWEAT	5 2	0 1
	ABA 15 ON TRT Day 58	PPD 58	54D 14H AE	GASTROINTESTINAL DISORDERS STOMATITIS MOUTH SORES	5 1	1 1
	ABA 20 ON TRT Day 167	PPD 167	6D 6H AE	GASTROINTESTINAL DISORDERS STOMATITIS MOUTH SORES	5 2	1 1
	ABA 30 ON TRT Day 218	PPD 218	4D 45M AE	GASTROINTESTINAL DISORDERS STOMATITIS MOUTH SORES	5 1	0 1
PPD (60/M/C) PLACEBO	PLACEBO ON TRT Day 15	PPD 15	1D 10H AE	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS BACK PAIN PAIN IN BACK	5 3	1 5

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS

MedDRA Version: 7.1
Program Source: /wwbdm/ndp/prime/msr/devtest/test/sample21.sas 14JAN2005:16:49:00

Parameter	Values
Template ID	GS_AE_L_S_001
Output File Name	rl-ae-saes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.2.1E
Title 1	Adverse Event
Title 2	Serious Adverse Events
Title 3	Enrolled Subjects - Stage 1
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

Parameter	Values
Template ID	GS_AE_L_S_001
Output File Name	rl-ae-saes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.2.2E
Title 1	Adverse Event
Title 2	Serious Adverse Events

Title 3	Enrolled Subjects - Stage 2
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

4.6.4 Adverse Events Leading to Discontinuation of Study Therapy

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-aediscs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.3.1A
Title 1	Adverse Event Summary
Title 2	Adverse Events Leading to Discontinuation of Study Medication
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-aediscs2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Table S.6.3.2A
Title 1	Adverse Event Summary
Title 2	Adverse Events Leading to Discontinuation of Study Medication
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-aediscs12.lst
Purpose	WK96S2
Table No.	Table S.6.3.3A
Title 1	Adverse Event Summary
Title 2	Adverse Events Leading to Discontinuation of Study Medication
Title 3	Treated Subjects - Stage 1 and 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-aediscconts1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.6.3.1B
Title 1	Adverse Event Summary
Title 2	Adverse Events Leading to Discontinuation of Study Medication After Switch to Continuation Dose
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-aediscconts2.lst
Purpose	WK96S2
Table No.	Table S.6.3.2B
Title 1	Adverse Event Summary
Title 2	Adverse Events Leading to Discontinuation of Study Medication After Switch to Continuation Dose
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Template GS_AE_L_X_001: Adverse Event Listing (by Treatment Group)

Protocol: IM101031

Confidential
Adverse Event
All Treated Subjects

Treatment Group: ABATACEPT

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset Resolution Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL INT	TRT ACT
PPD (55/F/C)	ABA 10 ON TRT Day 1	PPD 1	1D 7H SAE	GASTROINTESTINAL DISORDERS NAUSEA NAUSEA	5 2	0 1
	ABA 10 ON TRT Day 1	1	1D 5H AE	SKIN AND SUBCUTANEOUS TISSUE DISORDERS NIGHT SWEATS NIGHT SWEAT	5 2	0 1
	ABA 15 ON TRT Day 58	58	54D 14H AE	GASTROINTESTINAL DISORDERS STOMATITIS MOUTH SORES	5 1	1 1
	ABA 20 ON TRT Day 167	PPD 167	6D 6H AE	GASTROINTESTINAL DISORDERS STOMATITIS MOUTH SORES	5 2	1 1
	ABA 30 ON TRT Day 218	PPD 218	4D 45M AE	GASTROINTESTINAL DISORDERS STOMATITIS MOUTH SORES	5 1	0 1
	ABA 30 ON TRT Day 297	PPD 297	15D 1H AE	SKIN AND SUBCUTANEOUS TISSUE DISORDERS INGROWN HAIR INGROWN HAIR FOLLICLE	5 2	1 1
PPD (60/M/C)	ABA 10 ON TRT Day 15	PPD 15	1D 10H AE	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS BACK PAIN PAIN IN BACK	5 3	1 5

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 7.1
Program Source: /wwbdm/ndp/prime/msr/devtest/test/sample21.sas 14JAN2005:16:49:00

Parameter	Values
Template ID	GS_AE_L_X_001
Output File Name	rl-ae-discs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.3.1C
Title 1	Adverse Event
Title 2	Adverse Events Leading to Discontinuation of Study Medication
Title 3	Treated Subjects - Stage 1
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

Parameter	Values
Template ID	GS_AE_L_X_001
Output File Name	rl-ae-discs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.3.2C
Title 1	Adverse Event
Title 2	Adverse Events Leading to Discontinuation of Study Medication

Title 3	Treated Subjects - Stage 2
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

4.6.5 Other Significant Adverse Events

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-nsae5pcts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.5.1A
Title 1	Adverse Event Summary
Title 2	Non-Serious Adverse Events Occurring in at Least 5 Percent of Treated Subjects
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x
Programming notes	Apply the 5% cut to preferred terms only, not “TOTAL SUBJECTS WITH AN EVENT” and SOCs.

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-nsae5pcts2.lst

Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.5.2A
Title 1	Adverse Event Summary
Title 2	Non-Serious Adverse Events Occurring in at Least 5 Percent of Treated Subjects
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x
Programming notes	Apply the 5% cut to preferred terms only, not "TOTAL SUBJECTS WITH AN EVENT" and SOCs.

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-grade1to4s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.5.1B
Title 1	Adverse Event Summary
Title 2	Grade 1 to 4 Adverse Events
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-grade1to4s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.5.2B
Title 1	Adverse Event Summary
Title 2	Grade 1 to 4 Adverse Events

Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-grade2to4s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.5.1C
Title 1	Adverse Event Summary
Title 2	Grade 2 to 4 Adverse Events
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-grade2to4s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.5.2C
Title 1	Adverse Event Summary
Title 2	Grade 2 to 4 Adverse Events
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001

Output File Name	rt-ae-grade3to4s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.5.1D
Title 1	Adverse Event Summary
Title 2	Grade 3 to 4 Adverse Events
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-grade3to4s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.5.2D
Title 1	Adverse Event Summary
Title 2	Grade 3 to 4 Adverse Events
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-grade3to4s12.lst
Purpose	WK96S2
Table No.	Table S.6.5.3D
Title 1	Adverse Event Summary
Title 2	Grade 3 to 4 Adverse Events

Title 3	Treated Subjects - Stage 1 and 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-relateds1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.5.1E
Title 1	Adverse Event Summary
Title 2	Grade 1 to 4 Related Adverse Events
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-relateds2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.5.2E
Title 1	Adverse Event Summary
Title 2	Grade 1 to 4 Related Adverse Events
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001

Output File Name	rt-ae-relgrade2to4s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.5.1F
Title 1	Adverse Event Summary
Title 2	Grade 2 to 4 Related Adverse Events
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-relgrade2to4s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.5.2F
Title 1	Adverse Event Summary
Title 2	Grade 2 to 4 Related Adverse Events
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-relgrade2to4s12.lst
Purpose	WK96S2
Table No.	Table S.6.5.3F
Title 1	Adverse Event Summary
Title 2	Grade 2 to 4 Related Adverse Events

Title 3	Treated Subjects - Stage 1 and 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-relgrade3to4s1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.5.1G
Title 1	Adverse Event Summary
Title 2	Grade 3 to 4 Related Adverse Events
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-relgrade3to4s2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.5.2G
Title 1	Adverse Event Summary
Title 2	Grade 3 to 4 Related Adverse Events
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AEL_X_001

Output File Name	rl-ae-lists1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 6.5.1
Title 1	Adverse Event
Title 2	Treated Subjects - Stage 1
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

Parameter	Values
Template ID	GS_AEL_X_001
Output File Name	rl-ae-lists2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 6.5.2
Title 1	Adverse Event
Title 2	Treated Subjects - Stage 2
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 =

	DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-cdcaes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.4.1A
Title 1	Adverse Event Summary
Title 2	CDC Class C AIDS Events
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-cdcaes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.4.2A
Title 1	Adverse Event Summary
Title 2	CDC Class C AIDS Events
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-cdcaes12.lst
Purpose	WK96S2
Table No.	Table S.6.4.3A
Title 1	Adverse Event Summary
Title 2	CDC Class C AIDS Events
Title 3	Treated Subjects - Stage 1 and 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AEL_X_001
Output File Name	rl-ae-cdcaes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.4.1B
Title 1	Adverse Event
Title 2	CDC Class C AIDS Events
Title 3	Treated Subjects - Stage 1
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS

Footnote 7	MedDRA Version XX.X

Parameter	Values
Template ID	GS_AEL_X_001
Output File Name	rl-ae-cdcaes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.4.2B
Title 1	Adverse Event
Title 2	CDC Class C AIDS Events
Title 3	Treated Subjects - Stage 2
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-giaes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.4.1C
Title 1	Adverse Event Summary

Title 2	Gastrointestinal Events of Special Interest
Title 3	Treated Subjects - Stage 1
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-giaes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.4.2C
Title 1	Adverse Event Summary
Title 2	Gastrointestinal Events of Special Interest
Title 3	Treated Subjects - Stage 2
Footnote 1	MedDRA Version x.x

Parameter	Values
Template ID	GS_AE_T_X_001
Output File Name	rt-ae-giaes12.lst
Purpose	WK96S2
Table No.	Table S.6.4.3C
Title 1	Adverse Event Summary
Title 2	Gastrointestinal Events of Special Interest
Title 3	Treated Subjects - Stage 1 and 2
Footnote 1	MedDRA Version x.x

Parameter	Values

Template ID	GS_AE_L_X_001
Output File Name	rl-ae-giaes1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.4.1D
Title 1	Adverse Event
Title 2	Gastrointestinal Events of Special Interest
Title 3	Treated Subjects - Stage 1
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

Parameter	Values
Template ID	GS_AE_L_X_001
Output File Name	rl-ae-giaes2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.4.2D
Title 1	Adverse Event
Title 2	Gastrointestinal Events of Special Interest
Title 3	Treated Subjects - Stage 2
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED

Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

4.6.6 Multiple Adverse Events

Template GS_AE_T_M_001: Exposure Adjusted Adverse Events Summary by SOC and Preferred Term

Protocol: TA123456

Exposure Adjusted Adverse Event Summary
Including Multiple Occurrences of Unique Events
All Treated Subjects

System Organ Class Preferred Term	TRT A (N=477) (P-Y = 218.9) Event Count	TRT A (N=477) (P-Y = 218.9) Rate: (IR/100 P-Y)	TRT B (N=472) (P-Y = 218.3) Event Count	TRT B (N=472) (P-Y = 218.3) Rate: (IR/100 P-Y)	TOTAL (N=949) (P-Y = 437.2) Event Count	TOTAL (N=949) (P-Y = 437.2) Rate: (IR/100 P-Y)
TOTAL EVENTS	6138	2804.0	6128	2807.3	12266	5611.6
INFECTIONS AND INFESTATIONS	616	281.4	566	259.3	1182	271.7
URINARY TRACT INFECTION	179	81.8	179	82.0	358	81.8
CYTOMEGALOVIRUS INFECTION	39	17.8	40	18.3	79	18.1
UPPER RESPIRATORY TRACT INFECTION	27	12.3	26	11.9	53	11.2
NASOPHARYNGITIS	26	11.9	18	8.3	44	10.2
ORAL CANDIDIASIS	23	10.5	14	6.4	37	8.9
BRONCHITIS	23	10.5	13	6.0	36	8.5
GASTROENTERITIS	14	6.4	11	5.0	25	5.4
HERPES ZOSTER	14	6.4	7	3.2	21	4.6
SINUSITIS	12	5.5	4	1.8	16	3.9
INFLUENZA	11	5.0	13	2.0	24	3.5
HERPES SIMPLEX	9	4.1	7	3.2	16	3.3
UROSEPSIS	5	2.3	2	0.9	7	1.2

P-Y = person-years of exposure
Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 /person-years of exposure

MedDRA Version: 13.0
Program Source: /gbs/prod/clin/programs/im/103/maa-renal/emea150/scs/rpt/rt-adae-ae-inc2-m36-v01.sas 02MAR2011:11:04:59

Parameter	Values
Template ID	GS_AE_T_M_001
Output File Name	rt-ae-expadjusts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Table S.6.6.1A
Title 1	Exposure Adjusted Adverse Events Summary
Title 2	Treated Subjects - Stage 1
Footnote 1	P-Y = person-years of exposure
Footnote 2	Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 /person-years of exposure
Footnote 3	MedDRA Version: x.x

Parameter	Values
Template ID	GS_AE_T_M_001
Output File Name	rt-ae-expadjusts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.6.2A
Title 1	Exposure Adjusted Adverse Events Summary
Title 2	Treated Subjects - Stage 2
Footnote 1	P-Y = person-years of exposure
Footnote 2	Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 /person-years of exposure
Footnote 3	MedDRA Version: x.x

Parameter	Values
Template ID	GS_AE_T_M_001
Output File Name	rt-ae-expadjsaes1eu.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.6.1B
Title 1	Exposure Adjusted Adverse Events Summary
Title 2	Including Multiple Occurrences of Unique Adverse Events

Title 3	Treated Subjects - Stage 1
Title 4	Serious Adverse Events
Footnote 1	P-Y = person-years of exposure
Footnote 2	Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 /person-years of exposure
Footnote 3	MedDRA Version: x.x
Programming notes	Subset SAEs then collapse using multiple events macro.

Parameter	Values
Template ID	GS_AE_T_M_001
Output File Name	rt-ae-expadjsaes2eu.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.6.2B
Title 1	Exposure Adjusted Adverse Events Summary
Title 2	Including Multiple Occurrences of Unique Adverse Events
Title 3	Treated Subjects - Stage 2
Title 4	Serious Adverse Events
Footnote 1	P-Y = person-years of exposure
Footnote 2	Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 /person-years of exposure
Footnote 3	MedDRA Version: x.x
Programming notes	Subset SAEs then collapse using multiple events macro.

Parameter	Values
Template ID	GS_AE_T_M_001
Output File Name	rt-ae-expadjrelsaes1eu.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Table S.6.6.1C
Title 1	Exposure Adjusted Adverse Events Summary
Title 2	Including Multiple Occurrences of Unique Adverse Events
Title 3	Treated Subjects - Stage 1
Title 4	Drug Related Serious Adverse Events
Footnote 1	P-Y = person-years of exposure
Footnote 2	Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 /person-years of exposure
Footnote 3	MedDRA Version: x.x
Programming notes	Subset SAEs then collapse using multiple events macro.

Parameter	Values
Template ID	GS_AE_T_M_001
Output File Name	rt-ae-expadjrelsaes2eu.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.6.2C
Title 1	Exposure Adjusted Adverse Events Summary
Title 2	Including Multiple Occurrences of Unique Adverse Events
Title 3	Treated Subjects - Stage 2
Title 4	Drug Related Serious Adverse Events
Footnote 1	P-Y = person-years of exposure
Footnote 2	Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 /person-years of exposure
Footnote 3	MedDRA Version: x.x
Programming notes	Subset SAEs then collapse using multiple events macro.

Parameter	Values

Template ID	GS_AE_T_M_001
Output File Name	rt-ae-expadjnsae5pcts1eu.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.6.6.1D
Title 1	Exposure Adjusted Adverse Event Summary
Title 2	Including Multiple Occurrences of Unique Adverse Events
Title 3	Treated Subjects - Stage 1
Title 4	Non-Serious Adverse Events Using a Global Cutoff of 5 Percent
Footnote 1	P-Y = person-years of exposure. Only events occurring in at least 5% of treated subjects in any group are displayed.
Footnote 2	Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 /person-years of exposure
Footnote 3	MedDRA Version: x.x
Programming notes	Display perferred terms with frequency≥ 5% of treated subjects per rt-ae-nsae5pct.lst. Do not apply the 5% cut to "TOTAL EVENTS" and SOCs Subset NSAEs then collapse using multiple events macro.

Parameter	Values
Template ID	GS_AE_T_M_001
Output File Name	rt-ae-expadjnsae5pcts2eu.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.6.6.2D
Title 1	Exposure Adjusted Adverse Event Summary
Title 2	Including Multiple Occurrences of Unique Adverse Events
Title 3	Treated Subjects - Stage 2
Title 4	Non-Serious Adverse Events Using a Global Cutoff of 5 Percent
Footnote 1	P-Y = person-years of exposure. Only events occurring in at least 5% of treated subjects in any group are displayed.
Footnote 2	Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 /person-years of exposure

Footnote 3	MedDRA Version: x.x
Programming notes	Display perferred terms with frequency≥ 5% of treated subjects per rt-ae-nsae5pct.lst. Do not apply the 5% cut to "TOTAL EVENTS" and SOCs Subset NSAEs then collapse using multiple events macro.

Template GS_AE_L_U_002: Unique Adverse Event Listing

Protocol: IM101031
Page 1 of 95

Adverse Event
Unique Events
All Treated Subjects

Treatment Group: ABATACEPT

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset Resolution Study Day	Dur TRD Type	System Organ Class Preferred Term	REL INT	TRT ACT
PPD (55/F/C)	ABA 10 ON TRT Day 1	PPD 1	1D 7H SAE	GASTROINTESTINAL DISORDERS NAUSEA	5 2	0 1
	ABA 10 ON TRT Day 1	1	1D 5H AE	SKIN AND SUBCUTANEOUS TISSUE DISORDERS NIGHT SWEATS	5 2	0 1
	ABA 15 ON TRT Day 58	58	54D 14H AE	GASTROINTESTINAL DISORDERS STOMATITIS	5 1	1 1
	ABA 20 ON TRT Day 167	PPD 167	6D 6H AE	GASTROINTESTINAL DISORDERS STOMATITIS	5 2	1 1
	ABA 30 ON TRT Day 218	PPD 218	4D 45M AE	GASTROINTESTINAL DISORDERS STOMATITIS	5 1	0 1
PPD (60/M/C)	PLACEBO ON TRT Day 15	PPD 15	1D 10H AE	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS BACK PAIN	5 3	1 5

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS

MedDRA Version: 7.1
Program Source: /wwbdm/ndp/prime/msr/devtest/test/sample21.sas 14JAN2005:16:49:00

Parameter	Values

Template ID	GS_AE_L_U_002
Output File Name	rl-ae-uniques1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 6.6.1
Title 1	Adverse Event
Title 2	Unique Events
Title 3	Treated Subjects - Stage 1
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

Parameter	Values
Template ID	GS_AE_L_U_002
Output File Name	rl-ae-uniques2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 6.6.2
Title 1	Adverse Event
Title 2	Unique Events
Title 3	Treated Subjects - Stage 2
Footnote 1	REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED

Footnote 2	INT (INTENSITY): 1 = MILD 2 = MODERATE 3 = SEVERE 4 = VERY SEVERE
Footnote 3	TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
Footnote 4	ACT (ACTION): 1 = NONE 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DRUG INTERRUPTED 5 = DRUG DISCONTINUED
Footnote 5	DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 6	TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Footnote 7	MedDRA Version XX.X

4.6.7 Clinical Laboratory Evaluations

Template SS_LB_T_001: Laboratory Test Worst Abnormalities Table by Baseline

Protocol: AI438XXX

Page 1 of X

Laboratory Test Summary of <Toxicity Grade Description> Abnormalities
<Title 2>

		Number With Abnormality/Number With Measurement (%)	
		Group 1	Group 2
<Lab Type>	Baseline	N = XXX	N = XXX
<TEST 1>	TOTAL	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	NORMAL	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	GRADE 1	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	GRADE 2	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	GRADE 3	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	GRADE 4	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	NOT REPORTED	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
... <ADDITIONAL TESTS>			
<TEST X>	TOTAL	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	NORMAL	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	GRADE 1	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	GRADE 2	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	GRADE 3	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	GRADE 4	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)
	NOT REPORTED	XXX/XXX (XXX.X)	XXX/XXX (XXX.X)

... <ADDITIONAL LAB TYPES AND TESTS ON SEPARATE PAGES>

Toxicity Scale: DAIDS Version 1.0
<Footnote 2>
<Footnote 3>
Program Source: <TBD>

DDMMMYYYY:HR:MM:SS

Parameter	Values
Template ID	SS_LB_T_001
Output File Name	rt-lb-toxs1.lst

Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.7.1.1A
Title 1	Laboratory Test Results Summary of Worst Toxicity Grade
Title 2	Treated Subjects - Stage 1
Footnote 1	Toxicity Scale: DAIDS
Programming notes	The laboratory tests to be included in this output are specified in the SAP.

Parameter	Values
Template ID	SS_LB_T_001
Output File Name	rt-lb-toxs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.7.1.2A
Title 1	Laboratory Test Results Summary of Worst Toxicity Grade
Title 2	Treated Subjects - Stage 2
Footnote 1	Toxicity Scale: DAIDS
Programming notes	The laboratory tests to be included in this output are specified in the SAP.

Parameter	Values
Template ID	SS_LB_T_001
Output File Name	rt-lb-g34toxs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.7.1.1B
Title 1	Laboratory Test Results
Title 2	Summary of Grade 3-4 Toxicity
Title 3	Treated Subjects - Stage 1

Footnote 1	Toxicity Scale: DAIDS
Programming notes	The laboratory tests to be included in this output are specified in the SAP.

Parameter	Values
Template ID	SS_LB_T_001
Output File Name	rt-lb-g34toxs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.7.1.2B
Title 1	Laboratory Test Results
Title 2	Summary of Grade 3-4 Toxicity
Title 3	Treated Subjects - Stage 2
Footnote 1	Toxicity Scale: DAIDS
Programming notes	The laboratory tests to be included in this output are specified in the SAP.

Parameter	Values
Template ID	SS_LB_T_001
Output File Name	rt-lb-g34toxs12.lst
Purpose	WK96S2
Table No.	Table S.7.1.3B
Title 1	Laboratory Test Results
Title 2	Summary of Grade 3-4 Toxicity
Title 3	Treated Subjects - Stage 1 and 2
Footnote 1	Toxicity Scale: DAIDS
Programming notes	The laboratory tests to be included in this output are specified in the SAP.

Template SS_LB_T_002: Laboratory Test Treatment Emergent Abnormalities Table

Protocol: AI438XXX

Page 1 of X

Laboratory Test Summary of Treatment Emergent Abnormalities
<Title 2>

		Number With Abnormality/Number With Measurement (%)					
			Group 1 N = XXX				
<Lab Type>	Baseline	n	Increased to Grade 1	Increased to Grade 2	Increased to Grade 3	Increased to Grade 4	Increased to Any Grade
<TEST 1>	TOTAL	XXX	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
	NORMAL	XXX	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
	GRADE 1 TO 4	XXX	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
	NOT REPORTED	XXX	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
... <ADDITIONAL TESTS>							
<TEST X>	TOTAL	XXX	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
	NORMAL	XXX	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
	GRADE 1 TO 4	XXX	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
	NOT REPORTED	XXX	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)

<... ADDITIONAL TREATMENT GROUPS AND LAB TYPES ON SEPARATE PAGES>

Toxicity Scale: DAIDS Version 1.0
<Footnote 2>
<Footnote 3>
Program Source: <TBD>

DDMMMYYYY:HR:MM:SS

Parameter	Values
Template ID	SS_LB_T_001
Output File Name	rt-lb-etoxs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.7.1.1C

Title 1	Laboratory Test Results Summary of Treatment-Emergent Abnormalities
Title 2	Treated Subjects - Stage 1
Footnote 1	Toxicity Scale: DAIDS
Programming notes	The laboratory tests to be included in this output are specified in the SAP.

Parameter	Values
Template ID	SS_LB_T_001
Output File Name	rt-lb-etoxs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.7.1.2C
Title 1	Laboratory Test Results Summary of Treatment-Emergent Abnormalities
Title 2	Treated Subjects - Stage 2
Footnote 1	Toxicity Scale: DAIDS
Programming notes	The laboratory tests to be included in this output are specified in the SAP.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-renals1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.7.2.1A
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Function Values and Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 1
Programming notes	Include creatinine and creatinine clearance as renal tests.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-renals2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.7.2.2A
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Function Values and Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 2
Programming notes	Include creatinine and creatinine clearance as renal tests.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-renals1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.7.2.1B
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Function Values and Change from Baseline - US Units
Title 3	Treated Subjects - Stage 1
Programming notes	Include creatinine and creatinine clearance as renal tests.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-renals2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.7.2.2B

Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Function Values and Change from Baseline - US Units
Title 3	Treated Subjects - Stage 2
Programming notes	Include creatinine and creatinine clearance as renal tests.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-lipidss1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.7.2.1C
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Fasting Lipid Values and Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 1
Footnote 1	Values obtained after the start of serum lipid-reducing agents are excluded from the summary.
Programming notes	Include fasting Total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and total:HDL cholesterol ratio

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-lipidss2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.7.2.2C
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Fasting Lipid Values and Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 2
Footnote 1	Values obtained after the start of serum lipid-reducing agents are excluded from the summary.

Programming notes	Include fasting Total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and total:HDL cholesterol ratio

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-lipidss1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.7.2.1D
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Fasting Lipid Values and Change from Baseline - US Units
Title 3	Treated Subjects - Stage 1
Footnote 1	Values obtained after the start of serum lipid-reducing agents are excluded from the summary.
Programming notes	Include fasting Total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and total:HDL cholesterol ratio

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-lipidss2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.7.2.2D
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Fasting Lipid Values and Change from Baseline - US Units
Title 3	Treated Subjects - Stage 2
Footnote 1	Values obtained after the start of serum lipid-reducing agents are excluded from the summary.
Programming notes	Include fasting Total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and total:HDL cholesterol ratio

Parameter	Values

Template ID	SS_VL_T_006
Output File Name	rt-lb-pchglipidss1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.7.2.1E
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 1
Footnote 1	Values obtained after the start of serum lipid-reducing agents are excluded from the summary.
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include fasting Total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and total:HDL cholesterol ratio

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-pchglipidss2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.7.2.2E
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 2
Footnote 1	Values obtained after the start of serum lipid-reducing agents are excluded from the summary.
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include fasting Total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and total:HDL cholesterol ratio

Parameter	Values
Template ID	SS_VL_T_006

Output File Name	rt-zl-pchglipidss1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Table S.7.2.1F
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - US Units
Title 3	Treated Subjects - Stage 1
Footnote 1	Values obtained after the start of serum lipid-reducing agents are excluded from the summary.
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include fasting Total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and total:HDL cholesterol ratio

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-pchglipidss2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Table S.7.2.2F
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Fasting Lipid Values and Percent Change from Baseline - US Units
Title 3	Treated Subjects - Stage 2
Footnote 1	Values obtained after the start of serum lipid-reducing agents are excluded from the summary.
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include fasting Total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and total:HDL cholesterol ratio

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-tchols1

Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.7.2.1A
Title 1	Fasting Total Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: Fasting Total Cholesterol Mean Percent Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-tchols2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.7.2.2A
Title 1	Fasting Total Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: Fasting Total Cholesterol Mean Percent Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-ldlcs1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.7.2.1B
Title 1	Fasting LDL-Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1

Layout notes	Y-axis label: Fasting LDL-Cholesterol Mean Percent Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-ldlcs2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.7.2.2B
Title 1	Fasting LDL-Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: Fasting LDL-Cholesterol Mean Percent Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-hdlcs1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.7.2.1C
Title 1	Fasting HDL-Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: Fasting HDL-Cholesterol Mean Percent Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-hdlcs2
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Figure S.7.2.2C
Title 1	Fasting HDL-Cholesterol (mg/dL) Mean Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: Fasting HDL-Cholesterol Mean Percent Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-trigs1
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Figure S.7.2.1D
Title 1	Fasting Total Triglycerides (mg/dL) Mean Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: Fasting Triglycerides Mean Percent Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-trigs2
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Figure S.7.2.2D
Title 1	Fasting Total Triglycerides (mg/dL) Mean Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: Fasting Triglycerides Mean Percent Change from Baseline (SE) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Template SS_LB_L_001: Laboratory Test Results Listing With Toxicity Grades

Protocol: AI468XXX

Treatment Group: XXXXXXXX

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Lab Date Study Day	<Test 1> (<Units>)	...	<Test X> (<Units>)
PPD (AAA/G/R)	XXXXXXX XXXXXXX XXXXXXX	DDMMMYYYY XXX	XX.X L		XXX.X (X)
	... <ADDITIONAL PERIODS AND VISITS>				
	XXXXXXX XXXXXXX XXXXXXX	DDMMMYYYY XXX	XX.X H		XXX.X (XE)
... <ADDITIONAL SUBJECTS>					

Normal range flag: L = low, H = high
Toxicity Scale: DAIDS Version 1.0(Toxicity Grade; E = Emergent on treatment)
Program Source: <TBD>

DDMMMYYYY:HR:MM:SS

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-hems1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1A
Title 1	Hematology - SI Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Hematology: White Blood Cells (WBC); Neutrophils + Bands, absolute; Red Blood Cells (RBC); Hematocrit; Hemoglobin; Platelets

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-hems2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2A
Title 1	Hematology - SI Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Hematology: White Blood Cells (WBC); Neutrophils + Bands, absolute; Red Blood Cells (RBC); Hematocrit; Hemoglobin; Platelets

Parameter	Values
Template ID	SS_LB_L_001

Output File Name	rl-lb-lfts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1B
Title 1	Liver Function Tests - SI Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Liver Function Tests: Alanine Aminotransferase (ALT); Aspartate Aminotransferase (AST); Total Protein; Albumin; Alkaline Phosphatase; Total Bilirubin; Direct Bilirubin; Indirect Bilirubin

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-lfts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2B
Title 1	Liver Function Tests - SI Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Liver Function Tests: Alanine Aminotransferase (ALT); Aspartate Aminotransferase (AST); Total Protein; Albumin; Alkaline Phosphatase; Total Bilirubin; Direct Bilirubin; Indirect Bilirubin

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-enzs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2

Table No.	Appendix 7.1.1C
Title 1	Enzymes - SI Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Enzymes: Amylase; Creatinine Kinase (CK); Lipase

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-enzs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2C
Title 1	Enzymes - SI Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Enzymes: Amylase; Creatinine Kinase (CK); Lipase

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-rfts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1D
Title 1	Renal Function Tests - SI Units
Title 2	Treated Subjects - Stage 1

Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Renal Function Tests: Blood Urea Nitrogen (BUN); Creatinine; Creatinine Clearance; Uric Acid; Estimated Glomerular Filtration Rate (eGFR) using Cockcroft-Gault

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-rfts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2D
Title 1	Renal Function Tests - SI Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Renal Function Tests: Blood Urea Nitrogen (BUN); Creatinine; Creatinine Clearance; Uric Acid; Estimated Glomerular Filtration Rate (eGFR) using Cockcroft-Gault

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-elcs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1E
Title 1	Electrolytes - SI Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)

Layout notes	Electrolytes: Bicarbonate, serum; Calcium, serum; Chloride, serum; Potassium, serum; Sodium, serum

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-elcs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2E
Title 1	Electrolytes - SI Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Electrolytes: Bicarbonate, serum; Calcium, serum; Chloride, serum; Potassium, serum; Sodium, serum

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-flgs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1F
Title 1	Fasting Lipids and Glucose - SI Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Fasting Lipids: Total Cholesterol; LDL Cholesterol; HDL Cholesterol; Triglycerides; Total:HDL Cholesterol Fasting Glucose: Glucose, serum

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-lb-flgs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2F
Title 1	Fasting Lipids and Glucose - SI Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Fasting Lipids: Total Cholesterol; LDL Cholesterol; HDL Cholesterol; Triglycerides; Total:HDL Cholesterol Fasting Glucose: Glucose, serum

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-hems1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1G
Title 1	Hematology - US Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Hematology: White Blood Cells (WBC); Neutrophils + Bands, absolute; Red Blood Cells (RBC); Hematocrit; Hemoglobin; Platelets

Parameter	Values
Template ID	SS_LB_L_001

Output File Name	rl-zl-hems2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2G
Title 1	Hematology - US Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Hematology: White Blood Cells (WBC); Neutrophils + Bands, absolute; Red Blood Cells (RBC); Hematocrit; Hemoglobin; Platelets

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-lfts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1H
Title 1	Liver Function Tests - US Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Liver Function Tests: Alanine Aminotransferase (ALT); Aspartate Aminotransferase (AST); Total Protein; Albumin; Alkaline Phosphatase; Total Bilirubin; Direct Bilirubin; Indirect Bilirubin

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-lfts2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Appendix 7.1.2H
Title 1	Liver Function Tests - US Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Liver Function Tests: Alanine Aminotransferase (ALT); Aspartate Aminotransferase (AST); Total Protein; Albumin; Alkaline Phosphatase; Total Bilirubin; Direct Bilirubin; Indirect Bilirubin

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-enzs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1I
Title 1	Enzymes - US Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Enzymes: Amylase; Creatinine Kinase (CK); Lipase

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-enzs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2I
Title 1	Enzymes - US Units

Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Enzymes: Amylase; Creatinine Kinase (CK); Lipase

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-rfts1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1J
Title 1	Renal Function Tests - US Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Renal Function Tests: Blood Urea Nitrogen (BUN); Creatinine; Creatinine Clearance; Uric Acid; Estimated Glomerular Filtration Rate (eGFR) using Cockcroft-Gault

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-rfts2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2J
Title 1	Renal Function Tests - US Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high

Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Renal Function Tests: Blood Urea Nitrogen (BUN); Creatinine; Creatinine Clearance; Uric Acid; Estimated Glomerular Filtration Rate (eGFR) using Cockcroft-Gault

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-elcs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1K
Title 1	Electrolytes - US Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Electrolytes: Bicarbonate, serum; Calcium, serum; Chloride, serum; Potassium, serum; Sodium, serum

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-elcs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2K
Title 1	Electrolytes - US Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Electrolytes: Bicarbonate, serum; Calcium, serum; Chloride, serum; Potassium, serum; Sodium, serum

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-flgs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1L
Title 1	Fasting Lipids and Glucose - US Units
Title 2	Treated Subjects - Stage 1
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Fasting Lipids: Total Cholesterol; LDL Cholesterol; HDL Cholesterol; Total:HDL Cholesterol Ratio; Triglycerides Fasting Glucose: Glucose, serum

Parameter	Values
Template ID	SS_LB_L_001
Output File Name	rl-zl-flgs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2L
Title 1	Fasting Lipids and Glucose - US Units
Title 2	Treated Subjects - Stage 2
Footnote 1	Normal range flag: L = low, H = high
Footnote 2	Toxicity Scale: DAIDS Version 1.0 (Toxicity Grade; E = Emergent on treatment)
Layout notes	Fasting Lipids: Total Cholesterol; LDL Cholesterol; HDL Cholesterol; Total:HDL Cholesterol Ratio; Triglycerides Fasting Glucose: Glucose, serum

Template GS_LB_L_S_008: Differences in Categorization of SI and US units

Protocol: AI463022 Draft Page 1 of 1

Differences in Categorization of SI and US Laboratory Test Results
Treated Subjects

Lab Test: Glucose (SI units: mmol/L, US Std Units: mg/dL)

Subject ID (Age/Gender/Race) Treatment Group	Period Visit	Lab Date Study Day	SI Unit Standard Lab Result	SI Unit Normal Range Low	SI Unit Normal Range High	SI Unit Normal Range Flag	SI Unit Toxicity	US Standard Unit Standard Lab Result	US Standard Unit Normal Range Low	US Standard Unit Normal Range High	US Standard Unit Normal Range Flag	US Standard Unit Toxicity
PPD (59/F/O) ENTECAVIR	BASELINE A00	PPD -28	2.1	4.0	5.0	L	GRADE 0	37.8	52.0	65.0	L	GRADE 1
	ON TREATMENT B01	PPD 1	3.1	4.0	5.0	L	GRADE 1	45.8	52.0	65.0	L	GRADE 2
PPD (43/F/C) PLACEBO	ON TREATMENT B02	PPD 14	4.1	4.0	5.0		GRADE 1	53.1	52.0	65.0		GRADE 2
	ON TREATMENT B03	PPD 27	5.6	4.0	5.0		GRADE 2	66.6	39.0	65.0	H	GRADE 3

NORMAL RANGE FLAG: L = LOW H = HIGH + = NO NORMAL RANGES
Toxicity Scale : Descriptive text of toxicity scale

Parameter	Values
Template ID	GS_LB_L_S_008
Output File Name	rl-lb-diffunits1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1M
Title 1	Differences in Categorization of SI and US Laboratory Test Results
Title 2	Treated Subjects - Stage 1
Footnote 1	NORMAL RANGE FLAG: L = LOW H = HIGH + = NO NORMAL RANGES
Footnote 2	Toxicity Scale : DAIDS

Parameter	Values
Template ID	GS_LB_L_S_008
Output File Name	rl-lb-diffunits2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.1.2M
Title 1	Differences in Categorization of SI and US Laboratory Test Results
Title 2	Treated Subjects - Stage 2
Footnote 1	NORMAL RANGE FLAG: L = LOW H = HIGH + = NO NORMAL RANGES
Footnote 2	Toxicity Scale : DAIDS

Template GS_LB_L_X_006: Pregnancy Listing by Treatment Group

Protocol: TA123456

Draft
Pregnancy Test
All Treated Female Subjects

Treatment Group: TRT B

Subject ID (Age/Gender/Race)	Period	Test Date	Study Day	Method	Result	Reason Not done
PPD (59/F/O)	X	PPD	-1	URINE HCG	NEGATIVE	
	Y		28	SERUM HCG	0	
PPD (34/F/B)	X		-1	URINE HCG	NEGATIVE	
	Y		24	URINE HCG	NEGATIVE	
			46	SERUM HCG	0	
PPD (44/F/C)	X		-1			SURGICALLY STERILE
	Y		7			SURGICALLY STERILE

Program Source: /wwbdm/ndp/prime/gssr/devtest/prg/test/prg_lst.sas 07SEP2004:14:35:00

Parameter	Values
Template ID	GS_LB_L_X_006
Output File Name	rl-lb-pregs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.1.1N
Title 1	Pregnancy Test
Title 2	Treated Female Subjects - Stage 1

Parameter	Values
Template ID	GS_LB_L_X_006
Output File Name	rl-lb-pregs2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Appendix 7.1.2N
Title 1	Pregnancy Test
Title 2	Treated Female Subjects - Stage 2

4.6.8 Electrocardiograms

Template SS_EG_T_003 : ECG Summary Table with 95% CI

Protocol: AI438XXX

Page 1 of X

<Domain> Summary of Values and Changes From Baseline Over Time
<Title 2>

<Parameter> (<Units>)
Subgroup: XXXXXXXXXX Level: XXXXXXXXXXXX

Period / Visit / Group	N	Mean	SD	Percentiles Q1	Median	Q3	Change From Baseline N	Mean	SD	95% CI for Mean	Q1	Median	Q3
PRE-TRT													
B/L													
Group 1	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X	XXX	XXX.X	XXX.XX	(XXX.XX, XXX.XX)	XXX.X	XXX.X	XXX.X
Group 2	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X	XXX	XXX.X	XXX.XX	(XXX.XX, XXX.XX)	XXX.X	XXX.X	XXX.X
ON TRT													
WK XX													
Group 1	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X	XXX	XXX.X	XXX.XX	(XXX.XX, XXX.XX)	XXX.X	XXX.X	XXX.X
Group 2	XXX	XXX.X	XXX.XX	XXX.X	XXX.X	XXX.X	XXX	XXX.X	XXX.XX	(XXX.XX, XXX.XX)	XXX.X	XXX.X	XXX.X

... <ADDITIONAL PERIODS AND VISITS>

Parameter	Values
Template ID	SS_EG_T_003
Output File Name	rt-eg-sumchgs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.3.1A
Title 1	Electrocardiogram Summary of Values and Changes from Baseline over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Parameters are specified in SAP, Section 7.6.14.

Parameter	Values
Template ID	SS_EG_T_003

Output File Name	rt-eg-sumchgs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.3.2A
Title 1	Electrocardiogram Summary of Values and Changes from Baseline over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Parameters are specified in SAP, Section 7.6.14.

Template SS_EG_T_001 : ECG Change from Baseline Category Summary

ECG Parameter (unit) Category (%)	BMS-663068 400 mg BID/ RAL/TDF N = 50	BMS-663068 800 mg BID/ RAL/TDF N = 49	BMS-663068 600 mg QD/ RAL/TDF N = 51	BMS-663068 1200 mg QD/ RAL/TDF N = 50	ATV/r/ RAL/TDF N = 51
PR INTERVAL (MSEC)					
<0	4 (8.0)	8 (16.3)	4 (7.8)	7 (14.0)	8 (15.7)
0 to <20	33 (66.0)	30 (61.2)	35 (68.6)	33 (66.0)	28 (54.9)
20 to <40	11 (22.0)	11 (22.4)	11 (21.6)	7 (14.0)	13 (25.5)
40 to <60	0	0	1 (2.0)	1 (2.0)	1 (2.0)
60 to <80	0	0	0	0	0
>=80	0	0	0	0	0
NOT REPORTED	2 (4.0)	0	0	2 (4.0)	1 (2.0)
QRS (MSEC)					
<0	4 (8.0)	6 (12.2)	3 (5.9)	2 (4.0)	6 (11.8)
0 to <10	33 (66.0)	32 (65.3)	37 (72.5)	38 (76.0)	29 (56.9)
10 to <20	9 (18.0)	9 (18.4)	10 (19.6)	6 (12.0)	15 (29.4)
20 to <30	2 (4.0)	2 (4.1)	1 (2.0)	2 (4.0)	0
30 to <40	0	0	0	0	0
>=40	0	0	0	0	0
NOT REPORTED	2 (4.0)	0	0	2 (4.0)	1 (2.0)
QTC [FRIDERICIA] (MSEC)					
<0	6 (12.0)	6 (12.2)	4 (7.8)	3 (6.0)	9 (17.6)
0 to <10	7 (14.0)	8 (16.3)	13 (25.5)	11 (22.0)	13 (25.5)
10 to <20	17 (34.0)	21 (42.9)	18 (35.3)	20 (40.0)	15 (29.4)
20 to <30	11 (22.0)	9 (18.4)	7 (13.7)	10 (20.0)	7 (13.7)
30 to <40	6 (12.0)	2 (4.1)	4 (7.8)	1 (2.0)	5 (9.8)
>=40	1 (2.0)	3 (6.1)	5 (9.8)	3 (6.0)	1 (2.0)
NOT REPORTED	2 (4.0)	0	0	2 (4.0)	1 (2.0)

Parameter	Values
Template ID	SS_EG_T_001
Output File Name	rt-eg-changecats1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.3.1B
Title 1	Electrocardiogram Change from Baseline Category Summary

Title 2	Treated Subjects - Stage 1
Footnote 1	Each subject is counted only once using the longest change observed.

Parameter	Values
Template ID	SS_EG_T_001
Output File Name	rt-eg-changecats2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.3.2B
Title 1	Electrocardiogram Change from Baseline Category Summary
Title 2	Treated Subjects - Stage 2
Footnote 1	Each subject is counted only once using the longest change observed.

Template SS_EG_T_002: ECG Category Summary

ECG Parameter (unit) Category (%)	BMS-663068 400 mg BID/ RAL/TDF N = 50	BMS-663068 800 mg BID/ RAL/TDF N = 49	BMS-663068 600 mg QD/ RAL/TDF N = 51	BMS-663068 1200 mg QD/ RAL/TDF N = 50	ATV/r/ RAL/TDF N = 51
PR INTERVAL (MSEC)					
<200	44 (88.0)	46 (93.9)	46 (90.2)	43 (86.0)	49 (96.1)
200 to <220	4 (8.0)	1 (2.0)	5 (9.8)	5 (10.0)	1 (2.0)
220 to <240	0	2 (4.1)	0	0	0
240 to <260	0	0	0	0	0
260 to <280	0	0	0	0	0
280 to <300	0	0	0	0	0
>=300	0	0	0	0	0
NOT REPORTED	2 (4.0)	0	0	2 (4.0)	1 (2.0)
QRS (MSEC)					
<100	39 (78.0)	40 (81.6)	38 (74.5)	38 (76.0)	33 (64.7)
100 to <110	8 (16.0)	8 (16.3)	12 (23.5)	5 (10.0)	12 (23.5)
110 to <120	1 (2.0)	1 (2.0)	1 (2.0)	5 (10.0)	5 (9.8)
120 to <130	0	0	0	0	0
130 to <140	0	0	0	0	0
>=140	0	0	0	0	0
NOT REPORTED	2 (4.0)	0	0	2 (4.0)	1 (2.0)
QTC [FRIDERICIA] (MSEC)					
<400	1 (2.0)	4 (8.2)	2 (3.9)	2 (4.0)	8 (15.7)
400 to <425	17 (34.0)	14 (28.6)	25 (49.0)	29 (58.0)	21 (41.2)
425 to <450	27 (54.0)	25 (51.0)	17 (33.3)	13 (26.0)	16 (31.4)
450 to <460	3 (6.0)	1 (2.0)	5 (9.8)	2 (4.0)	3 (5.9)
460 to <470	0	5 (10.2)	0	1 (2.0)	2 (3.9)
470 to <480	0	0	0	0	0
480 to <490	0	0	1 (2.0)	0	0
>=490	0	0	1 (2.0)	1 (2.0)	0
NOT REPORTED	2 (4.0)	0	0	2 (4.0)	1 (2.0)

Parameter	Values
Template ID	SS_EG_T_002
Output File Name	rt-eg-cats1.lst

Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.3.1C
Title 1	Electrocardiogram Category Summary
Title 2	Treated Subjects - Stage 1
Footnote 1	Each subject is counted only once using the longest interval observed.

Parameter	Values
Template ID	SS_EG_T_002
Output File Name	rt-eg-cats2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.3.2C
Title 1	Electrocardiogram Category Summary
Title 2	Treated Subjects - Stage 2
Footnote 1	Each subject is counted only once using the longest interval observed.

Template GS_EG_L_X_001: ECG Listing

Protocol: CN138112

Draft
Electrocardiogram
All Treated Subjects

Page 1 of 11

Treatment Group: TRT A

Subject ID (Age/Gender/Race)	Period	Visit	Date	Study Day	Time	TRD#	HR (bpm)	Interval (msec) PR	QRS	QT	QTC	Interpretation
PPD (54/M/C)	SCREENING	Day -1	PPD	-1	09:50	-30D	66	169	91	402	421	NORMAL
PPD (44/F/C)	SCREENING	Day -1		-1	16:47	-1H	103	180	78	346	405	ABNORMAL
PPD (42/M/C)	SCREENING	Day -1		-1	17:11	-32D	87	200	70	334		
PPD (55/M/C)	SCREENING	Day -30		-44	09:50	-29D	65	165	92	383	399	NORMAL
	SCREENING	Day -1		-1	13:53	-2H	77	173	93	383	434	ABNORMAL

Time relative to most recent dose

Program Source: /wwbdm/ndp/prime/gssr/devtest/ecg/test/eg_st.sas

07OCT2004:17:58:00

Parameter	Values
Template ID	GS_EG_L_X_001
Output File Name	rl-eg-ecgs1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.3.1D
Title 1	Electrocardiogram
Title 2	Treated Subjects - Stage 1
Footnote 1	# Time relative to most recent dose

Parameter	Values

Template ID	GS_EG_L_X_001
Output File Name	rl-eg-ecgs2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.3.2D
Title 1	Electrocardiogram
Title 2	Treated Subjects - Stage 2
Footnote 1	# Time relative to most recent dose

4.6.9 Vital Signs and Physical Findings

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-vs-sums1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.4.1A
Title 1	Vital Sign Summary of Values and Changes from Baseline over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Parameters are: Sitting Systolic Blood Pressure, Sitting Diastolic Blood Pressure, Sitting Heart Rate (beats/min), Respiration Rate (/min) and Temperature (C).

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-vs-sums2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.4.2A
Title 1	Vital Sign Summary of Values and Changes from Baseline over Time

Title 2	Treated Subjects - Stage 2
Layout notes	Parameters are: Sitting Systolic Blood Pressure, Sitting Diastolic Blood Pressure, Sitting Heart Rate (beats/min), Respiration Rate (/min) and Temperature (C).

Template GS_VS_L_X_006: Vital Signs Listing by Treatment Group

Protocol: IM101031 Draft Page 1 of 11

Vital Signs
All Treated Subjects

Treatment Group: DRUG A

Subject ID (Age/Gender/Race)	Period	Visit	Date	Study Day	Position	Blood Pressure (mmHg)	Heart Rate (bpm)	Temp (C)	Resp Rate (/Min)
PPD (46/M/C)	SCREENING	DAY -26	PPD	-26	SITTING	138 / 90	64	36.2	32
	PHASE I	DAY 1		1	SITTING	120 / 65	68	36.2	34
					SITTING	126 / 70	72	36.5	33
		DAY 13		13	SITTING	116 / 82	72	36.7	31
					SITTING	120 / 84	68	36.6	30
	PHASE II	DAY 31		31	SITTING	110 / 70	72	36.6	33
					SITTING	122 / 75	80	36.7	32
	PHASE III	DAY 59		59	SITTING	118 / 76	68	36.7	31
					SITTING	122 / 68	68	36.7	32
					STANDING	134 / 78	70		
		DAY 87		87	SITTING	134 / 84	72	36.9	32
					SITTING	130 / 80	70	36.6	33
		DAY 122		122	SITTING	128 / 86	70	36.9	32
					SITTING	124 / 82	70	37.3	31
		DAY 142		142	SITTING	126 / 86	70	36.7	32
					SITTING	130 / 80	78	36.7	33
		DAY 167		167	SITTING	128 / 84	68	37.2	33
					SITTING	132 / 80	70	36.9	32
		DAY 199		199	SITTING	132 / 84	80	36.5	32
					SITTING	130 / 86	78	36.6	30
	POST ST	DAY 223		223	SITTING	128 / 84	76	36.9	32
PPD (56/F/C)	SCREENING	DAY -1		-26	SITTING	138 / 90	64	36.2	32
				1	SITTING	/ 80	68	36.2	34
					SITTING	126 / 70	72	36.5	33
	PHASE I	DAY 7		13	SITTING	116 / 82	72	36.7	31
					SITTING	122 / 75	80	36.6	32
	PHASE II	DAY 14		31	SITTING	110 / 70	72	36.6	32
	PHASE III	DAY 21		87	SITTING	134 / 84	72	37.2	32
					SITTING	130 / 80	70	36.9	33

Program Source: /wwbdm/ndp/prime/gssr/devtest/dem/test/vs_st.sas 07SEP2004:14:35:00

Parameter	Values
Template ID	GS_VS_L_X_006

Output File Name	rl-vs-lists1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.4.1B
Title 1	Vital Signs
Title 2	Treated Subjects - Stage 1

Parameter	Values
Template ID	GS_VS_L_X_006
Output File Name	rl-vs-lists2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.4.2B
Title 1	Vital Signs
Title 2	Treated Subjects - Stage 2

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-pm-sums1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 7.4.1C
Title 1	Physical Measurements Summary of Values and Changes from Baseline over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Parameters are: Weight (kg) and BMI (kg/m2).

Parameter	Values
Template ID	SS_VL_T_006

Output File Name	rt-pm-sums2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 7.4.2C
Title 1	Physical Measurements Summary of Values and Changes from Baseline over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Parameters are: Weight (kg) and BMI (kg/m2).

4.6.10 Other Observations Related to Safety

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-bmrenals1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.7.5.1A
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Biomarker Values and Change from Baseline - US Units
Title 3	Treated Subjects - Stage 1
Programming notes	Include urinary beta-2-microglobilin/creatinine and fractional excretion of phosphorous.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-bmrenals2.lst
Purpose	WK96S2
Table No.	Table S.7.5.2A
Title 1	Laboratory Test Results

Title 2	Summary Statistics for Renal Biomarker Values and Change from Baseline - US Units
Title 3	Treated Subjects - Stage 2
Programming notes	Include urinary beta-2-microglobilin/creatinine and fractional excretion of phosphorous.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-bmrenals1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.7.5.1B
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Biomarker Values and Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 1
Programming notes	Include urinary beta-2-microglobilin/creatinine and fractional excretion of phosphorous.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-bmrenals2.lst
Purpose	WK96S2
Table No.	Table S.7.5.2B
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Biomarker Values and Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 2
Programming notes	Include urinary beta-2-microglobilin/creatinine and fractional excretion of phosphorous.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-pchbmrenals1.lst
Purpose	WK96S1, WK96S2
Table No.	Table S.7.5.1C
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - US Units
Title 3	Treated Subjects - Stage 1
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include urinary beta-2-microglobilin/creatinine and fractional excretion of phosphorous.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-pchbmrenals2.lst
Purpose	WK96S2
Table No.	Table S.7.5.2C
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - US Units
Title 3	Treated Subjects - Stage 2
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include urinary beta-2-microglobilin/creatinine and fractional excretion of phosphorous.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-pchbmrenals1.lst

Purpose	WK96S1, WK96S2
Table No.	Table S.7.5.1D
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 1
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include urinary beta-2-microglobilin/creatinine and fractional excretion of phosphorous.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-pchbmrenals2.lst
Purpose	WK96S2
Table No.	Table S.7.5.2D
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Renal Biomarker Values and Percent Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 2
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include urinary beta-2-microglobilin/creatinine and fractional excretion of phosphorous.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-bmbones1.lst
Purpose	WK24S1
Table No.	Table S.7.5.1E
Title 1	Laboratory Test Results

Title 2	Summary Statistics for Bone Biomarker Values and Change from Baseline - US Units
Title 3	Treated Subjects - Stage 1
Programming notes	Include N-terminal Propeptide of Type 1 procollagen (P1NP) and Cross-linked C-telopeptide of Type 1 collagen (CTx).

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-bmbones2.lst
Purpose	WK24S2
Table No.	Table S.7.5.2E
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Bone Biomarker Values and Change from Baseline - US Units
Title 3	Treated Subjects - Stage 2
Programming notes	Include N-terminal Propeptide of Type 1 procollagen (P1NP) and Cross-linked C-telopeptide of Type 1 collagen (CTx).

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-bmbones1.lst
Purpose	WK24S1
Table No.	Table S.7.5.1F
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Bone Biomarker Values and Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 1
Programming notes	Include N-terminal Propeptide of Type 1 procollagen (P1NP) and Cross-linked C-telopeptide of Type 1 collagen (CTx).

Parameter	Values

Template ID	SS_VL_T_006
Output File Name	rt-zl-bmbones2.lst
Purpose	WK24S2
Table No.	Table S.7.5.2F
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Bone Biomarker Values and Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 2
Programming notes	Include N-terminal Propeptide of Type 1 procollagen (P1NP) and Cross-linked C-telopeptide of Type 1 collagen (CTx).

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-pchbmbones1.lst
Purpose	WK24S1
Table No.	Table S.7.5.1G
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - US Units
Title 3	Treated Subjects - Stage 1
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include N-terminal Propeptide of Type 1 procollagen (P1NP) and Cross-linked C-telopeptide of Type 1 collagen (CTx).

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-lb-pchbmbones2.lst
Purpose	WK24S2
Table No.	Table S.7.5.2G

Title 1	Laboratory Test Results
Title 2	Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - US Units
Title 3	Treated Subjects - Stage 2
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include N-terminal Propeptide of Type 1 procollagen (P1NP) and Cross-linked C-telopeptide of Type 1 collagen (CTx).

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-pchbmbones1.lst
Purpose	WK24S1
Table No.	Table S.7.5.1H
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 1
Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include N-terminal Propeptide of Type 1 procollagen (P1NP) and Cross-linked C-telopeptide of Type 1 collagen (CTx).

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-zl-pchbmbones2.lst
Purpose	WK24S2
Table No.	Table S.7.5.2H
Title 1	Laboratory Test Results
Title 2	Summary Statistics for Bone Biomarker Values and Percent Change from Baseline - SI Units
Title 3	Treated Subjects - Stage 2

Layout notes	Change spanning header to “Percent Change From Baseline”.
Programming notes	Include N-terminal Propeptide of Type 1 procollagen (P1NP) and Cross-linked C-telopeptide of Type 1 collagen (CTx).

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-ub2s1
Purpose	WK24S1
Table No.	Figure S.7.5.1A
Title 1	Urinary Beta-2-Microglobulin/Creatinine Median Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: Urinary Beta-2-Microglobulin/Creatinine Median Percent Change from Baseline (IQR) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-ub2s2
Purpose	WK24S2
Table No.	Figure S.7.5.2A
Title 1	Urinary Beta-2-Microglobulin/Creatinine Median Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: Urinary Beta-2-Microglobulin/Creatinine Median Percent Change from Baseline (IQR) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-feps1
Purpose	WK24S1
Table No.	Figure S.7.5.1B
Title 1	Fractional Excretion of Phosphorous Median Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: Fractional Excretion of Phosphorous Median Change from Baseline (IQR) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-feps2
Purpose	WK24S2
Table No.	Figure S.7.5.2B
Title 1	Fractional Excretion of Phosphorous Median Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: Fractional Excretion of Phosphorous Median Change from Baseline (IQR) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-pchp1nps1
Purpose	WK96S1, WK96S2

Table No.	Figure S.7.5.1C
Title 1	N-Terminal Propeptide of Type 1 Procollagen Median Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: P1NP Median Percent Change from Baseline (IQR) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-pchp1nps2
Purpose	WK96S2
Table No.	Figure S.7.5.2C
Title 1	N-Terminal Propeptide of Type 1 Procollagen Median Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: P1NP Median Percent Change from Baseline (IQR) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-pchctxs1
Purpose	WK96S1, WK96S2
Table No.	Figure S.7.5.1D
Title 1	Cross-Linked C-Telopeptide of Type 1 Collagen Median Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 1
Layout notes	Y-axis label: CTx Median Percent Change from Baseline (IQR)

	X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

Parameter	Values
Template ID	GS_LB_G_002
Output File Name	rg-lb-pchctxs2
Purpose	WK96S2
Table No.	Figure S.7.5.2D
Title 1	Cross-Linked C-Telopeptide of Type 1 Collagen Median Percent Change from Baseline Over Time
Title 2	Treated Subjects - Stage 2
Layout notes	Y-axis label: CTx Median Percent Change from Baseline (IQR) X-axis label: Time (Weeks) Include horizontal reference line at Y=0.

4.7 Pharmacokinetic Results

Template MS_PK_T_004: Summary Statistics for PK Parameters

			TREATMENT		
PARAMETER	UNIT	STATISTIC	A	B	C
Cmax	ng/mL	N	xx	xx	xx
		MEAN	xxxx.xx	xxxx.xx	xxxx.xx
		S.D.	xxxx.xx	xxxx.xx	xxxx.xx
		GEO.MEAN	xxxx.xx	xxxx.xx	xxxx.xx
		%CV	xx	xx	xx
		MEDIAN	xxxx.xx	xxxx.xx	xxxx.xx
		MIN	xxxx.xx	xxxx.xx	xxxx.xx
		MAX	xxxx.xx	xxxx.xx	xxxx.xx
Tmax	h	N	xx	xx	xx
		MEAN	xxxx.xx	xxxx.xx	xxxx.xx
		S.D.	xxxx.xx	xxxx.xx	xxxx.xx
		GEO.MEAN	xxxx.xx	xxxx.xx	xxxx.xx
		%CV	xx	xx	xx
		MEDIAN	xxxx.xx	xxxx.xx	xxxx.xx
		MIN	xxxx.xx	xxxx.xx	xxxx.xx
		MAX	xxxx.xx	xxxx.xx	xxxx.xx
AUC	ng.h/mL	N	xx	xx	xx
		MEAN	xxxx.xx	xxxx.xx	xxxx.xx
		S.D.	xxxx.xx	xxxx.xx	xxxx.xx
		GEO.MEAN	xxxx.xx	xxxx.xx	xxxx.xx
		%CV	xx	xx	xx
		MEDIAN	xxxx.xx	xxxx.xx	xxxx.xx
		MIN	xxxx.xx	xxxx.xx	xxxx.xx
		MAX	xxxx.xx	xxxx.xx	xxxx.xx

Parameter	Values
Template ID	MS_PK_T_004

Output File Name	rt-pk-sumbmss1.lst
Purpose	WK24S1
Table No.	Table S.8.1.1A
Title 1	Summary Statistics of BMS-955176 Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG
Layout notes	PK parameters: Cmax, Tmax, Ctau, C0, AUC(TAU)

Parameter	Values
Template ID	MS_PK_T_004
Output File Name	rt-pk-sumbmss2.lst
Purpose	WK24S2
Table No.	Table S.8.1.2A
Title 1	Summary Statistics of BMS-955176 Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG
Layout notes	PK parameters: Cmax, Tmax, Ctau, C0, AUC(TAU)

Parameter	Values
Template ID	MS_PK_T_004
Output File Name	rt-pk-sumatvs1.lst
Purpose	WK24S1
Table No.	Table S.8.1.1B

Title 1	Summary Statistics of ATV Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Layout notes	PK parameters: Cmax, Tmax, Ctau, C0, AUC(TAU)

Parameter	Values
Template ID	MS_PK_T_004
Output File Name	rt-pk-sumatvs2.lst
Purpose	WK24S2
Table No.	Table S.8.1.2B
Title 1	Summary Statistics of ATV Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Layout notes	PK parameters: Cmax, Tmax, Ctau, C0, AUC(TAU)

Parameter	Values
Template ID	MS_PK_T_004
Output File Name	rt-pk-sumdtgs1.lst
Purpose	WK24S1
Table No.	Table S.8.1.1C
Title 1	Summary Statistics of DTG Pharmacokinetic Parameters

Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Layout notes	PK parameters: Cmax, Tmax, Ctau, C0, AUC(TAU)

Parameter	Values
Template ID	MS_PK_T_004
Output File Name	rt-pk-sumdtgs2.lst
Purpose	WK24S2
Table No.	Table S.8.1.2C
Title 1	Summary Statistics of DTG Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Layout notes	PK parameters: Cmax, Tmax, Ctau, C0, AUC(TAU)

Template MS_PK_T_005: In-text Table for Summary Statistics for PK Parameters

PARAMETER STATISTIC	TREATMENT A	 B	 C
Cmax (ng/mL)			
Geo.Mean [N]	199 [12]	640 [12]	493 [12]
(%CV)	(25)	(21)	(27)
AUC(0-T) (ng.h/mL)			
Geo.Mean [N]	721 [12]	534 [12]	503 [12]
(%CV)	(15)	(27)	(23)
AUC(INF) (ng.h/mL)			
Geo.Mean [N]	696 [12]	612 [12]	523 [12]
(%CV)	(22)	(23)	(21)
Tmax (h)			
Median [N]	4.10 [15]	1.75 [16]	4.00 [16]
(Min - Max)	(3.00 - 6.00)	(1.00 - 5.00)	(3.00 - 8.00)
T-HALF (h)			
Mean [N]	9.70 [15]	8.71 [16]	8.90 [16]
(SD)	(2.862)	(3.912)	(3.762)

Parameter	Values
Template ID	MS_PK_T_005
Output File Name	rt-pk-itsumbmss1.lst
Purpose	WK24S1
Table No.	Table 9.2.1A
Title 1	Summary Statistics of BMS-955176 Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG
Programming notes	This is an in-text table

Parameter	Values
Template ID	MS_PK_T_005
Output File Name	rt-pk-itsumbmss2.lst
Purpose	WK24S2
Table No.	Table 9.2.2A
Title 1	Summary Statistics of BMS-955176 Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG
Programming notes	This is an in-text table

Parameter	Values
Template ID	MS_PK_T_005
Output File Name	rt-pk-itsumdtgs1.lst
Purpose	WK24S1
Table No.	Table 9.3.1A
Title 1	Summary Statistics of DTG Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Programming notes	This is an in-text table

Parameter	Values
Template ID	MS_PK_T_005
Output File Name	rt-pk-itsumdtgs2.lst

Purpose	WK24S2
Table No.	Table 9.3.2A
Title 1	Summary Statistics of DTG Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Programming notes	This is an in-text table

Parameter	Values
Template ID	MS_PK_T_005
Output File Name	rt-pk-itsumatvs1.lst
Purpose	WK24S1
Table No.	Table 9.4.1A
Title 1	Summary Statistics of ATV Pharmacokinetic Parameters
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Programming notes	This is an in-text table

Parameter	Values
Template ID	MS_PK_T_005
Output File Name	rt-pk-itsumatvs2.lst
Purpose	WK24S2
Table No.	Table 9.4.2A
Title 1	Summary Statistics of ATV Pharmacokinetic Parameters

Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Programming notes	This is an in-text table

Template MS_PK_T_006: Statistical Analysis for PK Parameters

PK Parameter

	On Natural Logarithmic Scale						on Original Scale	
TREATMENT AND COMPARISON	ADJUSTED MEAN	STANDARD ERROR	DF	T	Pr > |T|	90% CI	ADJUSTED GEO MEAN	90% CI
A	X.XXX	X.XXX	X.X	XX.XX	0.XXXX	(X.XXX,X.XXX)	XXXX.XXX	(XXXX.XXX,XXXX.XXX)
B	X.XXX	X.XXX	X.X	XX.XX	0.XXXX	(X.XXX,X.XXX)	XXXX.XXX	(XXXX.XXX,XXXX.XXX)
B vs A	X.XXX	X.XXX	X.X	X.XX	0.XXXX	(X.XXX,X.XXX)	X.XXX	(X.XXX,X.XXX)

MODEL INFORMATION

Covariance Structure	- Unstructured
Subject Effect	- USUBJID
Estimation Method	- REML
Residual Variance Method	- None
Fixed Effects SE Method	- Prasad-Rao-Jeske-Kackar-Harville
Degrees of Freedom Method	- Kenward-Roger
Fixed Effects	- TRT SEQ PERIOD USUBJID

Covariance Matrix Block

Row	Col 1	Col 2	COL 3
1	X.XXX	X.XXX	X.XXX
2	X.XXX	X.XXX	X.XXX
3	X.XXX	X.XXX	X.XXX

Parameter	Values
Template ID	MS_PK_T_006
Output File Name	rt-pk-mixedbmsdtgs1.lst
Purpose	WK24S1
Table No.	Table S.8.2.5.1A
Title 1	Effect of BMS-955176 on Exposure of DTG
Title 2	PK Parameters DTG Cmax, Ctau and AUC(TAU)
Title 3	BMS-955176 120 mg QD+ ATV/r + DTG versus TDF + ATV/r + DTG
Title 4	Evaluable PK Population - Stage 1

Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG

Parameter	Values
Template ID	MS_PK_T_006
Output File Name	rt-pk-mixedbms120dtgs2.lst
Purpose	WK24S2
Table No.	Table S.8.2.5.2A
Title 1	Effect of BMS-955176 on Exposure of DTG
Title 2	PK Parameters DTG Cmax, Ctau and AUC(TAU)
Title 3	BMS-955176 120 mg QD+ ATV + DTG versus Historical Data
Title 4	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG F = Historical Data

Parameter	Values
Template ID	MS_PK_T_006
Output File Name	rt-pk-mixedbms180dtgs2.lst
Purpose	WK24S2
Table No.	Table S.8.2.5.2B
Title 1	Effect of BMS-955176 on Exposure of DTG
Title 2	PK Parameters DTG Cmax, Ctau and AUC(TAU)
Title 3	BMS-955176 180 mg QD+ ATV + DTG versus Historical Data
Title 4	Evaluable PK Population - Stage 2
Footnote 1	D = BMS 955176 180 mg QD + ATV + DTG F = Historical Data

Template MS_PK_T_007: In-text Table for Statistical Analysis for PK Parameters

PK PARAMETER	TREATMENT AND COMPARISON	ADJUSTED GEOMETRIC MEAN	90% CI
CMAX(ng/mL)	A	XX.XX	(XX.XX,XX.XX)
	B	XX.XX	(XX.XX,XX.XX)
	B vs A	X.XXX	(X.XXX,X.XXX)
CTAU(ng/mL)	A	XX.XX	(XX.XX,XX.XX)
	B	XX.XX	(XX.XX,XX.XX)
	B vs A	X.XXX	(X.XXX,X.XXX)
AUC(TAU) (ng.h/mL)	A	XX.XX	(XX.XX,XX.XX)
	B	XX.XX	(XX.XX,XX.XX)
	B vs A	X.XXX	(X.XXX,X.XXX)

Parameter	Values
Template ID	MS_PK_T_007
Output File Name	rt-pk-itmixedbmss1.lst
Purpose	WK24S1
Table No.	Table 9.3.1.1A
Title 1	In-text Table of Effect of BMS-955176 on Exposure of DTG
Title 2	PK Parameters DTG Cmax, Ctau and AUC(TAU)
Title 3	BMS-955176 120 mg QD+ ATV/r + DTG versus TDF + ATV/r + DTG
Title 4	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Source: Table S.8.2.5.1A
Programming notes	This is an in-text table

Parameter	Values
Template ID	MS_PK_T_007
Output File Name	rt-pk-itmixedbms120s2.lst
Purpose	WK24S2
Table No.	Table 9.3.1.2A
Title 1	In-text Table of Effect of BMS-955176 on Exposure of DTG
Title 2	PK Parameters DTG Cmax, Ctau and AUC(TAU)
Title 3	BMS-955176 120 mg QD+ ATV + DTG versus TDF + ATV/r + DTG
Title 4	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG F = Historical Data
Footnote 2	Source: Table S.8.2.5.2A
Programming notes	This is an in-text table

Parameter	Values
Template ID	MS_PK_T_007
Output File Name	rt-pk-itmixedbms180s2.lst
Purpose	WK24S2
Table No.	Table 9.3.1.2B
Title 1	In-text Table of Effect of BMS-955176 on Exposure of DTG
Title 2	PK Parameters DTG Cmax, Ctau and AUC(TAU)
Title 3	BMS-955176 180 mg QD+ ATV + DTG versus TDF + ATV/r + DTG
Title 4	Evaluable PK Population - Stage 2
Footnote 1	D = BMS 955176 180 mg QD + ATV + DTG F = Historical Data
Footnote 2	Source: Table S.8.2.5.2B

Programming notes	This is an in-text table

Template MS_PK_L_005: Listing for PK Parameters

Subject	Treatment	Study Day	Cmax (ng/mL)	Tmax (h)	Ctau (ng*h/mL)	C0 (ng*h/mL)	AUC(TAU)	Exclusion Flag
XXXXXXXX-X-X	A	1	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	3
		14	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
XXXXXXXX-X-X	B	1	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
		14	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	

Parameter	Values
Template ID	MS_PK_L_005
Output File Name	rl-pk-listbms01s1.lst
Purpose	WK24S1
Table No.	Appendix 8.2.5A
Title 1	Listing of BMS-955176 Pharmacokinetic Parameters
Title 2	PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Note:# Values are excluded from PK Summary Statistics
Footnote 3	Exclusion Flag Definitions: 1= All Parameters, 2= CMAX, 3= Tmax, 4= Ctau, 5= C0, 6= AUC(TAU)

Parameter	Values
Template ID	MS_PK_L_005
Output File Name	rl-pk-listbms01s2.lst
Purpose	WK24S2
Table No.	Appendix 8.2.5A

Title 1	Listing of BMS-955176 Pharmacokinetic Parameters
Title 2	PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Footnote 2	Note:# Values are excluded from PK Summary Statistics
Footnote 3	Exclusion Flag Definitions: 1= All Parameters, 2= CMAX, 3= Tmax, 4= Ctau, 5= C0, 6= AUC(TAU)

Parameter	Values
Template ID	MS_PK_L_005
Output File Name	rl-pk-listatv01s1.lst
Purpose	WK24S1
Table No.	Appendix 8.2.5B
Title 1	Listing of ATV Pharmacokinetic Parameters
Title 2	PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Note:# Values are excluded from PK Summary Statistics
Footnote 3	Exclusion Flag Definitions: 1= All Parameters, 2= CMAX, 3= Tmax, 4= Ctau, 5= C0, 6= AUC(TAU)

Parameter	Values
Template ID	MS_PK_L_005
Output File Name	rl-pk-listatv01s2.lst
Purpose	WK24S2
Table No.	Appendix 8.2.5B
Title 1	Listing of ATV Pharmacokinetic Parameters

Title 2	PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Footnote 2	Note:# Values are excluded from PK Summary Statistics
Footnote 3	Exclusion Flag Definitions: 1= All Parameters, 2= CMAX, 3= Tmax, 4= Ctau, 5= C0, 6= AUC(TAU)

Parameter	Values
Template ID	MS_PK_L_005
Output File Name	rl-pk-listdtg01s1.lst
Purpose	WK24S1
Table No.	Appendix 8.2.5C
Title 1	Listing of DTG Pharmacokinetic Parameters
Title 2	PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Note:# Values are excluded from PK Summary Statistics
Footnote 3	Exclusion Flag Definitions: 1= All Parameters, 2= CMAX, 3= Tmax, 4= Ctau, 5= C0, 6= AUC(TAU)

Parameter	Values
Template ID	MS_PK_L_005
Output File Name	rl-pk-listdtg01s2.lst
Purpose	WK24S2
Table No.	Appendix 8.2.5C
Title 1	Listing of DTG Pharmacokinetic Parameters
Title 2	PK Population - Stage 2

Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Footnote 2	Note:# Values are excluded from PK Summary Statistics
Footnote 3	Exclusion Flag Definitions: 1= All Parameters, 2= CMAX, 3= Tmax, 4= Ctau, 5= C0, 6= AUC(TAU)

Template MS_PK_L_001: Listing of Plasma Concentration-Time Data

SUBJECT	TREATMENT	STUDY DAY	NOMINAL TIME (h)	ACTUAL TIME (h)	CONCENTRATION (ng/mL)	EXCLUSION FLAG
PPD	A	14	0.00	0.00	<LLQ	
			1.00	1.00	36.39	
			1.50	1.50	100.02	
			2.00	2.00	108.94	
			3.00	3.00	99.00	
			4.00	4.00	79.14	
			8.00	8.00	46.23	
			12.00	12.00	22.94	
			18.00	18.00	15.75	
			24.00	24.00	11.73	
			48.00	48.00	3.30	
			72.00	72.00	1.12	
			96.00	96.00	<LLQ	
			120.00	120.02	<LLQ	
			144.00	144.00	<LLQ	

Parameter	Values
Template ID	MS_PK_L_001
Output File Name	rl-pk-cpar1bmss1.lst
Purpose	WK24S1
Table No.	Appendix 8.2.1A
Title 1	Listing of BMS-955176 Plasma Concentration – Time Data
Title 2	PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Note: <LLQ = Below Lower Limit of Quantification (xx ng/mL)

Parameter	Values
Template ID	MS_PK_L_001
Output File Name	rl-pk-cpar1bmss2.lst
Purpose	WK24S2
Table No.	Appendix 8.2.1A
Title 1	Listing of BMS-955176 Plasma Concentration – Time Data
Title 2	PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Footnote 2	Note: <LLQ = Below Lower Limit of Quantification (xx ng/mL)

Parameter	Values
Template ID	MS_PK_L_001
Output File Name	rl-pk-cpar1atvs1.lst
Purpose	WK24S1
Table No.	Appendix 8.2.1B
Title 1	Listing of ATV Plasma Concentration – Time Data
Title 2	PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Note: <LLQ = Below Lower Limit of Quantification (xx ng/mL)

Parameter	Values
Template ID	MS_PK_L_001

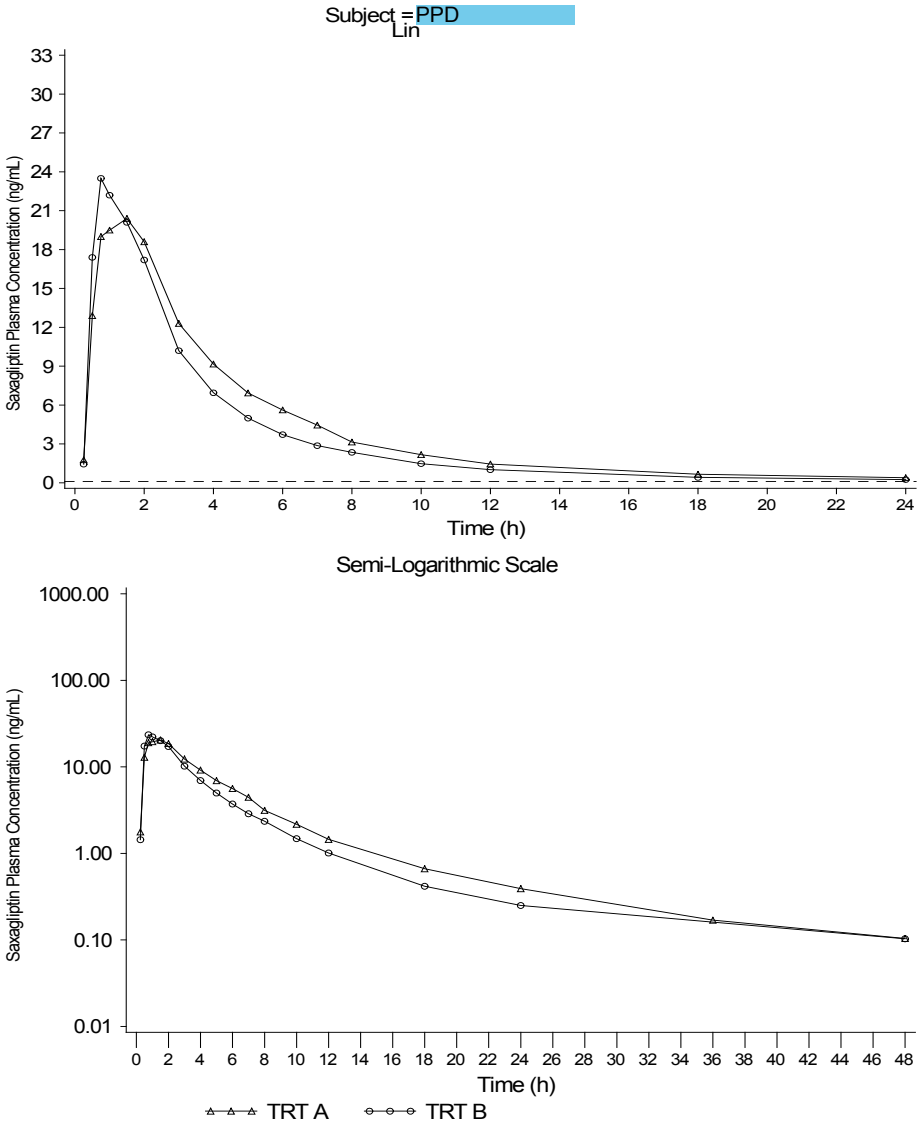
Output File Name	rl-pk-cpar1atvs2.lst
Purpose	WK24S2
Table No.	Appendix 8.2.1B
Title 1	Listing of ATV Plasma Concentration – Time Data
Title 2	PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Footnote 2	Note: <LLQ = Below Lower Limit of Quantification (xx ng/mL)

Parameter	Values
Template ID	MS_PK_L_001
Output File Name	rl-pk-cpar1dtgs1.lst
Purpose	WK24S1
Table No.	Appendix 8.2.1C
Title 1	Listing of DTG Plasma Concentration – Time Data
Title 2	PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Note: <LLQ = Below Lower Limit of Quantification (xx ng/mL)

Parameter	Values
Template ID	MS_PK_L_001
Output File Name	rl-pk-cpar1dtgs2.lst
Purpose	WK24S2

Table No.	Appendix 8.2.1C
Title 1	Listing of DTG Plasma Concentration – Time Data
Title 2	PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Footnote 2	Note: <LLQ = Below Lower Limit of Quantification (xx ng/mL)

Template MS_PK_G_002: Individual Plot of Plasma Concentrations vs. Time



Parameter	Values
Template ID	MS_PK_G_002
Output File Name	rg-pk-cpar3bmss1.lst
Purpose	WK24S1
Table No.	Figure S.8.2.3A
Title 1	Plots of Individual BMS-955176 Plasma Concentration Profiles vs. Time
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Notes: LLOQ – xx ng/mL; <LLOQ values were treated as "missing" for calculation of mean values
Layout notes	x-axis label: time y-axis label: BMS-955176 concentration (ng/mL)
Programming notes	1. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 2. Treatment and/or Study Day overlay, as appropriate 3. Add in dotted line for LLOQ value 4. Cartesian and semi-log plots for each individual subject on the same page

Parameter	Values
Template ID	MS_PK_G_002
Output File Name	rg-pk-cpar3bmss2.lst
Purpose	WK24S2
Table No.	Figure S.8.2.3A
Title 1	Plots of Individual BMS-955176 Plasma Concentration Profiles vs. Time
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG

	D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Footnote 2	Notes: LLOQ – xx ng/mL; <LLOQ values were treated as "missing" for calculation of mean values
Layout notes	x-axis label: time y-axis label: BMS-955176 concentration (ng/mL)
Programming notes	1. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 2. Treatment and/or Study Day overlay, as appropriate 3. Add in dotted line for LLOQ value 4. Cartesian and semi-log plots for each individual subject on the same page

Parameter	Values
Template ID	MS_PK_G_002
Output File Name	rg-pk-cpar3atvs1.lst
Purpose	WK24S1
Table No.	Figure S.8.2.3B
Title 1	Plots of Individual ATV Plasma Concentration Profiles vs. Time
Title 2	Evaluable PK Population- Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Notes: LLOQ – xx ng/mL; <LLOQ values were treated as "missing" for calculation of mean values
Layout notes	x-axis label: time y-axis label: ATV concentration (ng/mL)
Programming notes	1. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences)

	b. Semi-Log Plot over entire time range (to show terminal phase differences 2. Treatment and/or Study Day overlay, as appropriate 3. Add in dotted line for LLOQ value 4. Cartesian and semi-log plots for each individual subject on the same page

Parameter	Values
Template ID	MS_PK_G_002
Output File Name	rg-pk-cpar3atvs2.lst
Purpose	WK24S2
Table No.	Figure S.8.2.3B
Title 1	Plots of Individual ATV Plasma Concentration Profiles vs. Time
Title 2	Evaluable PK Population- Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Footnote 2	Notes: LLOQ – xx ng/mL; <LLOQ values were treated as “missing” for calculation of mean values
Layout notes	x-axis label: time y-axis label: ATV concentration (ng/mL)
Programming notes	1. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 2. Treatment and/or Study Day overlay, as appropriate 3. Add in dotted line for LLOQ value 4. Cartesian and semi-log plots for each individual subject on the same page

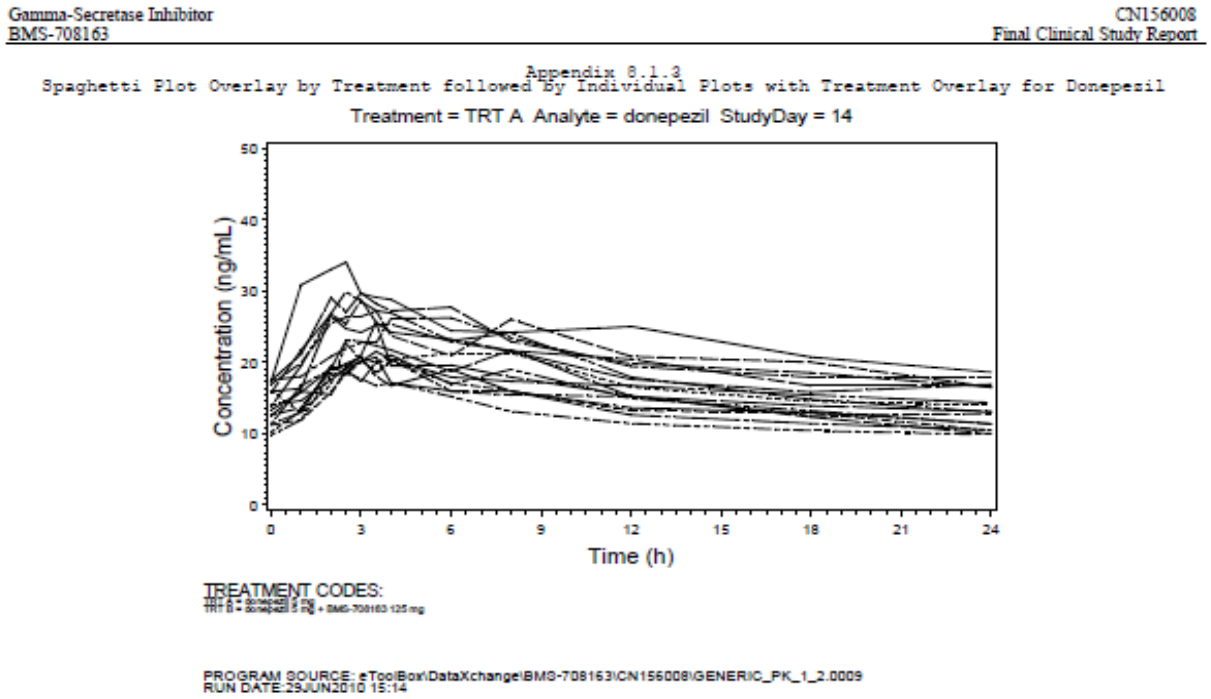
Parameter	Values

Template ID	MS_PK_G_002
Output File Name	rg-pk-cpar3dtgs1.lst
Purpose	WK24S1
Table No.	Figure S.8.2.3C
Title 1	Plots of Individual DTG Plasma Concentration Profiles vs. Time
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Footnote 2	Notes: LLOQ – xx ng/mL; <LLOQ values were treated as "missing" for calculation of mean values
Layout notes	x-axis label: time y-axis label: DTG concentration (ng/mL)
Programming notes	1. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 2. Treatment and/or Study Day overlay, as appropriate 3. Add in dotted line for LLOQ value 4. Cartesian and semi-log plots for each individual subject on the same page

Parameter	Values
Template ID	MS_PK_G_002
Output File Name	rg-pk-cpar3dtgs2.lst
Purpose	WK24S2
Table No.	Figure S.8.2.3C
Title 1	Plots of Individual DTG Plasma Concentration Profiles vs. Time
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG

	E = TDF + ATV/r + DTG
Footnote 2	Notes: LLOQ – xx ng/mL; <LLOQ values were treated as "missing" for calculation of mean values
Layout notes	x-axis label: time y-axis label: DTG concentration (ng/mL)
Programming notes	1. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 2. Treatment and/or Study Day overlay, as appropriate 3. Add in dotted line for LLOQ value 4. Cartesian and semi-log plots for each individual subject on the same page

Template MS_PK_G_001: Overlay of Individual Matrix Concentration vs. Time



Parameter	Values
Template ID	MS_PK_G_001
Output File Name	rg-pk-cpar1bmss1.lst
Purpose	WK24S1
Table No.	Figure S.8.2.1A
Title 1	Overlay of Individual BMS-955176 Plasma Concentration Profile vs. Time by Treatment
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG

	B = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: BMS955176 concentration (ng/mL)
Programming notes	1. Treatment and/or Study Day overlay, as appropriate. 2. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 3. Cartesian and semi-log plots on the same page (sometimes referred to as a spaghetti plot as there are no symbols in the profiles)

Parameter	Values
Template ID	MS_PK_G_001
Output File Name	rg-pk-cpar1bmss2.lst
Purpose	WK24S2
Table No.	Figure S.8.2.1A
Title 1	Overlay of Individual BMS-955176 Plasma Concentration Profile vs. Time by Treatment
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: BMS955176 concentration (ng/mL)
Programming notes	1. Treatment and/or Study Day overlay, as appropriate. 2. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 3. Cartesian and semi-log plots on the same page (sometimes referred to as a spaghetti plot as there are no symbols in the profiles)

Parameter	Values
Template ID	MS_PK_G_001
Output File Name	rg-pk-cpar1atvs1.lst
Purpose	WK24S1
Table No.	Figure S.8.2.1B
Title 1	Overlay of Individual ATV Plasma Concentration Profile vs. Time by Treatment
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 60 mg QD + TDF/FTC B = BMS 955176 120 mg QD + TDF/FTC C = BMS 955176 180 mg QD + TDF/FTC D = EFV 600 mg QD + TDF/FTC
Layout notes	x-axis label: time y-axis label: ATV concentration (ng/mL)
Programming notes	1. Treatment and/or Study Day overlay, as appropriate. 2. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 3. Cartesian and semi-log plots on the same page (sometimes referred to as a spaghetti plot as there are no symbols in the profiles)

Parameter	Values
Template ID	MS_PK_G_001
Output File Name	rg-pk-cpar1atvs2.lst
Purpose	WK24S2
Table No.	Figure S.8.2.1B
Title 1	Overlay of Individual ATV Plasma Concentration Profile vs. Time by Treatment
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG

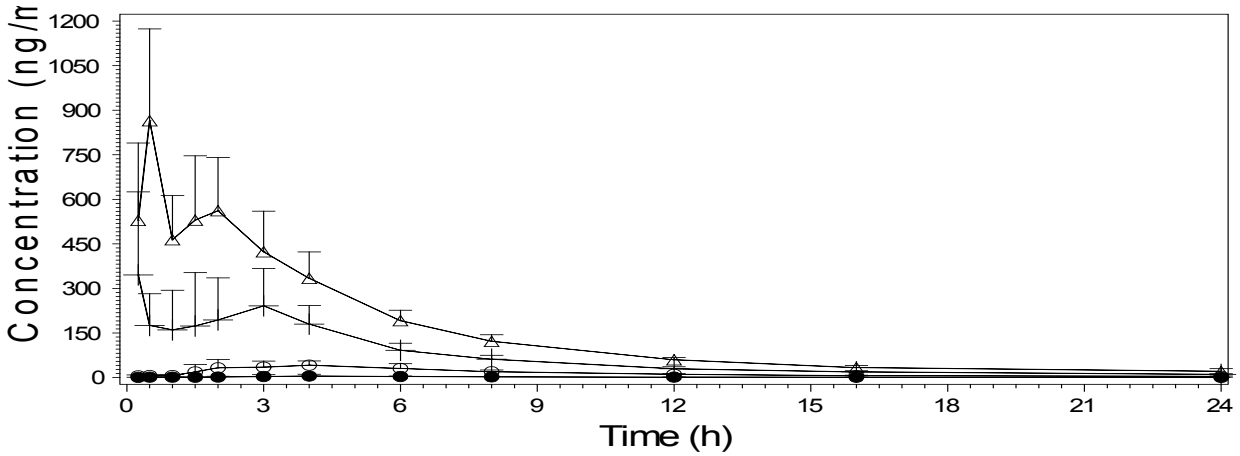
	D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: ATV concentration (ng/mL)
Programming notes	1. Treatment and/or Study Day overlay, as appropriate. 2. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 3. Cartesian and semi-log plots on the same page (sometimes referred to as a spaghetti plot as there are no symbols in the profiles)

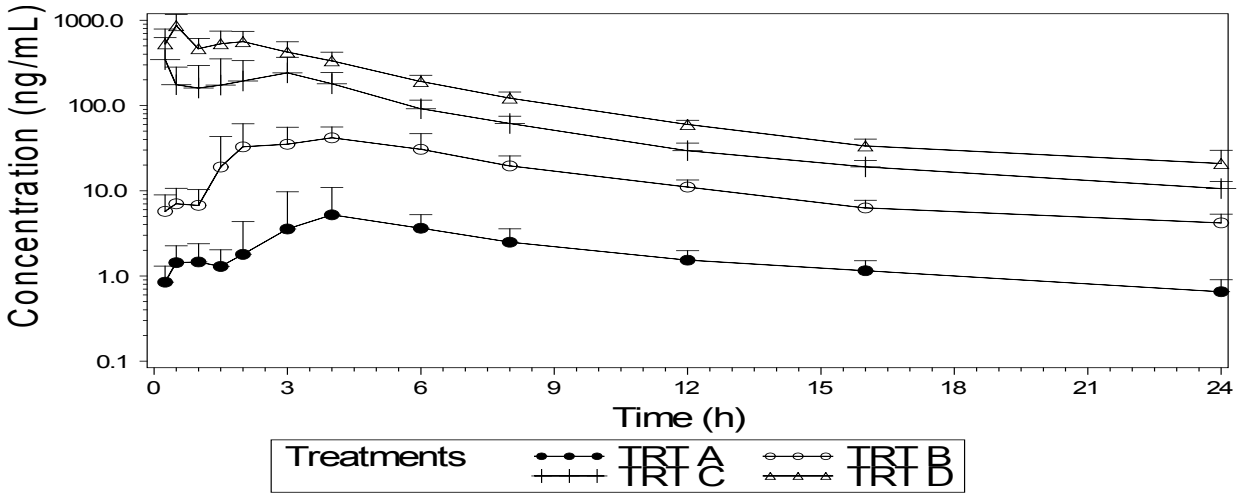
Parameter	Values
Template ID	MS_PK_G_001
Output File Name	rg-pk-cpar1dtgs1.lst
Purpose	WK24S1
Table No.	Figure S.8.2.1A
Title 1	Overlay of Individual DTG Plasma Concentration Profile vs. Time by Treatment
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: DTG concentration (ng/mL)
Programming notes	1. Treatment and/or Study Day overlay, as appropriate. 2. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 3. Cartesian and semi-log plots on the same page (sometimes referred to as a spaghetti plot as there are no symbols in the profiles)

Parameter	Values

Template ID	MS_PK_G_001
Output File Name	rg-pk-cpar1dtgs2.lst
Purpose	WK24S2
Table No.	Figure S.8.2.1A
Title 1	Overlay of Individual DTG Plasma Concentration Profile vs. Time by Treatment
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: DTG concentration (ng/mL)
Programming notes	1. Treatment and/or Study Day overlay, as appropriate. 2. There should be two plots (on same page): a. Cartesian Plot over 24 h or tau (to show Cmax differences) b. Semi-Log Plot over entire time range (to show terminal phase differences 3. Cartesian and semi-log plots on the same page (sometimes referred to as a spaghetti plot as there are no symbols in the profiles)

Template MS_PK_G_006: Mean Plot of Matrix Concentration vs. Time





Parameter	Values
Template ID	MS_PK_G_006
Output File Name	rg-pk-cpar6bmss1.lst
Purpose	WK24S1
Table No.	Figure S.8.2.6A
Title 1	Mean (+SD) BMS-955176 Plasma Concentration Profile vs. Time
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: BMS-955176 concentration (ng/mL)
Programming notes	1. Including SD bar 2. Treatment and/or Study Day overlay, as appropriate 3. There should be two plots (both on same page): a. Linear plot over 24 h or tau (to show Cmax differences) b. Semi-log plot over entire time range if longer than tau (to show terminal phase differences) 4. Add in dotted line for LLOQ 5. in-text figure required (Figure 9.1)

Parameter	Values
Template ID	MS_PK_G_006
Output File Name	rg-pk-cpar6bmss2.lst
Purpose	WK24S2
Table No.	Figure S.8.2.6A
Title 1	Mean (+SD) BMS-955176 Plasma Concentration Profile vs. Time
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG

	D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: BMS-955176 concentration (ng/mL)
Programming notes	1. Including SD bar 2. Treatment and/or Study Day overlay, as appropriate 3. There should be two plots (both on same page): a. Linear plot over 24 h or tau (to show Cmax differences) b. Semi-log plot over entire time range if longer than tau (to show terminal phase differences) 4. Add in dotted line for LLOQ 5. in-text figure required (Figure 9.1)

Parameter	Values
Template ID	MS_PK_G_006
Output File Name	rg-pk-cpar6atvs1.lst
Purpose	WK24S1
Table No.	Figure S.8.2.6B
Title 1	Mean (+SD) ATV Plasma Concentration Profile vs. Time
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: ATV concentration (ng/mL)
Programming notes	1. Including SD bar 2. Treatment and/or Study Day overlay, as appropriate 3. There should be two plots (both on same page): a. Linear plot over 24 h or tau (to show Cmax differences) b. Semi-log plot over entire time range if longer than tau (to show terminal phase differences)

	4. Add in dotted line for LLOQ 5. in-text figure required (Figure 9.1)

Parameter	Values
Template ID	MS_PK_G_006
Output File Name	rg-pk-cpar6atvs2.lst
Purpose	WK24S2
Table No.	Figure S.8.2.6B
Title 1	Mean (+SD) ATV Plasma Concentration Profile vs. Time
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: ATV concentration (ng/mL)
Programming notes	1. Including SD bar 2. Treatment and/or Study Day overlay, as appropriate 3. There should be two plots (both on same page): a. Linear plot over 24 h or tau (to show Cmax differences) b. Semi-log plot over entire time range if longer than tau (to show terminal phase differences) 4. Add in dotted line for LLOQ 5. in-text figure required (Figure 9.1)

Parameter	Values
Template ID	MS_PK_G_006
Output File Name	rg-pk-cpar6dtgs1.lst
Purpose	WK24S1

Table No.	Figure S.8.2.6C
Title 1	Mean (+SD) DTG Plasma Concentration Profile vs. Time
Title 2	Evaluable PK Population - Stage 1
Footnote 1	A = BMS 955176 120 mg QD + ATV/r + DTG B = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: DTG concentration (ng/mL)
Programming notes	1. Including SD bar 2. Treatment and/or Study Day overlay, as appropriate 3. There should be two plots (both on same page): a. Linear plot over 24 h or tau (to show Cmax differences) b. Semi-log plot over entire time range if longer than tau (to show terminal phase differences) 4. Add in dotted line for LLOQ 5. in-text figure required (Figure 9.1)

Parameter	Values
Template ID	MS_PK_G_006
Output File Name	rg-pk-cpar6dtgs2.lst
Purpose	WK24S2
Table No.	Figure S.8.2.6C
Title 1	Mean (+SD) DTG Plasma Concentration Profile vs. Time
Title 2	Evaluable PK Population - Stage 2
Footnote 1	C = BMS 955176 120 mg QD + ATV + DTG D = BMS 955176 180 mg QD + ATV + DTG E = TDF + ATV/r + DTG
Layout notes	x-axis label: time y-axis label: DTG concentration (ng/mL)

Programming notes	1. Including SD bar 2. Treatment and/or Study Day overlay, as appropriate 3. There should be two plots (both on same page): a. Linear plot over 24 h or tau (to show Cmax differences) b. Semi-log plot over entire time range if longer than tau (to show terminal phase differences) 4. Add in dotted line for LLOQ 5. in-text figure required (Figure 9.1)

4.8 Pharmacodynamic Results

Not applicable

4.9 Other Study Results

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-qs-eq5ds1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 10.1.1
Title 1	EQ-5D-3L Summary of US and UK Centric Scores and Changes From Baseline Over Time on Treatment
Title 2	Treated Subjects - Stage 1
Layout notes	Parameters: US Centric Score, UK Centric Score No units.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-qs-eq5ds2.lst
Purpose	WK24S2, WK48S2, WK96S2

Table No.	Appendix 10.1.2
Title 1	EQ-5D-3L Summary of US and UK Centric Scores and Changes From Baseline Over Time on Treatment
Title 2	Treated Subjects - Stage 2
Layout notes	Parameters: US Centric Score, UK Centric Score No units.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-qs-fahis1.lst
Purpose	WK24S1, WK48S1, WK96S1, WK96S2
Table No.	Appendix 10.2.1
Title 1	FAHI Summary of Total Scores Over Time on Treatment
Title 2	Treated Subjects - Stage 1
Layout notes	Do not show title row “Parameter (Units)”. Do not show changes from baseline. No units.

Parameter	Values
Template ID	SS_VL_T_006
Output File Name	rt-qs-fahis2.lst
Purpose	WK24S2, WK48S2, WK96S2
Table No.	Appendix 10.2.2
Title 1	FAHI Summary of Total Scores Over Time on Treatment
Title 2	Treated Subjects - Stage 2
Layout notes	Do not show title row “Parameter (Units)”. Do not show changes from baseline. No units.