Submitting Select Clinical Trial Data Sets for Drugs Intended To Treat Human Immunodeficiency Virus-1 Infection

Guidance for Industry

Technical Specifications Document

For questions regarding this technical specifications document, contact CDER at cder-edata@fda.hhs.gov.

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Technical Specifications Document

Revision History

Date	Version	Summary of Revisions
March 2018	1.0	Initial Version

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Contains Nonbinding Recommendations

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

1.0 Introduction

This document provides detailed information and specifications for the content of data sets that should be submitted as part of the sponsor's/applicant's application for drugs intended to treat human immunodeficiency virus (HIV). These specifications also provide an opportunity for dialogue between the sponsor/applicant and reviewers to discuss issues with trial design or study conduct that may affect the content of these analysis data sets. These specifications were built to support the recommendations provided in the guidance for industry entitled "Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment"[2] and reflect the data standards and processes described in the FDA Study Data Technical Conformance Guide.[3]

For questions regarding a specific submission, the sponsor/applicant should contact the review division. For questions about a particular data standard implementation, contact the appropriate contact for data standards issues at cder-edata@fda.hhs.gov. For more general recommendations on the use and submission of standardized study data, the sponsor/applicant should refer to the Study Data Technical Conformance Guide.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only

[1] This technical specifications document has been prepared by the Office of New Drugs and the Office of Translational Sciences in the Center for Drug Evaluation and Research at the Food and Drug Administration. You may submit comments on this guidance at any time. Submit comments to Docket No. FDA-2018-D-1216 (available at https://www.regulations.gov/docket?D=FDA-2018-D-1216) (see the instructions for submitting comments in the docket).
[2] https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm355128.pdf.
[3] https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm384744.pdf.

as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

This document provides detailed data specification for the following data sets:

- **Efficacy Outcomes Data Set (ADEFFOUT).** This is a one-record-per-subject data set that contains a comprehensive set of variables pertaining to the subject and their measures of efficacy. The specification for ADEFFOUT organizes these variables into groupings of subject demographics, baseline characteristics (including prior therapies and genotypic and phenotypic data), subject disposition, measures of efficacy over the time span of the trial, exposure, and important covariates.

- **Adverse Event Analysis Data Set (ADAE**). This is a one-record-per-adverse event-per-subject data set that includes all adverse events reported for a subject during their participation in the trial. Additional variables and specific derivations from the standard Analysis Data Model (ADaM)-compliant ADAE data set are described in Section 4.1. The additional variables should be added to the existing ADAE data set that meets the current ADaM standards. The intent of these additional variables is to aid in the review process.

- **Laboratory Analysis Data Set (ADLB).** This is a one-record-per-lab test, -collection, and -subject data set. The laboratory tests that are most commonly of greatest interest are noted below in Section 5. However, it is acceptable for additional laboratory tests to be included. If the submitted data set is larger than 5 GB, then split the data set according to the laboratory panels of hematology, chemistry, urinalysis, and other (if necessary for miscellaneous tests). This data set should include the ADaM-compliant basic data structure (BDS) laboratory data set, with the addition of specific review division variables.

All data sets include variables that represent derived study days. It is assumed that the anchor date for study day 1 is the date of first dose (TRTSDT) and that this date of first dose is identical or very close to the randomization date (RANDDT). If the date of first dose and the randomization date are not equivalent, sponsors/applicants are required to provide an explanation for this discrepancy.

These three data sets must be accompanied by informative metadata in the form of a compliant Define.xml document that describes the source and derivation of the variables.

2.0 Overview of the Data Set Specifications

Each section below provides a specification that describes the desired content for the data set. The variable names and associated metadata are based on current Clinical Data Interchange

Standards Consortium, Study Data Tabulation Model (CDISC SDTM)[4] and ADaM standards where possible. Each specification includes a column that contains information about each variable, such as the expected content, derivation considerations, or assumptions. If any variable is unclear, sponsors/applicants are encouraged to discuss the expectations with the review division.

Some variables may not be appropriate for all clinical trials. If a sponsor's/applicant's trial did not collect the data necessary to create a specified variable, then it is acceptable to omit the variable in the data sets. Added or omitted variables should be itemized in the Analysis Data Reviewer Guide (ADRG) as a separate table. The programs that were used to create these data sets should also be submitted (See the Study Data Technical Conformance Guide. The variable labels and the variable type noted in the specifications should be used.

[4] https://www.cdisc.org/standards/foundational/sdtm.

3.0 Dataset Specifications for Efficacy Outcomes Data Set - ADEFFOUT

This data set is a one-record-per-subject data set that contains a diverse set of variables. Ideally, all of these variables should be traceable to the submitted tabulations or analysis data sets. Whereas the formation of this data set duplicates information found in other submitted data sets, the compilation of all of these variable concepts into one record facilitates statistical and medical review.

3.1 Baseline Demographic Variables

Variable Name	Variable Label	Type	Comments
STUDYID	Study Identifier	Char	
USUBJID	Unique Subject Identifier	Char	
SUBJID	Subject Identifier for the Study	Char	
SITEID	Study Site Identifier	Char	
SITEGRy	Pooled Site Group y	Char	Character description of the grouping of clinical sites for analysis purposes. All sponsors should start with SITEGR1 and include additional 'y' variables as needed.
INVID	Investigator Identifier	Char	
INVNAM	Investigator Name	Char	
RANDDT	Date of Randomization	Num	
BRTHDTC	Date/Time of Birth	Char	Date/time of birth of the subject in ISO 8601 character format. This date may be partial.
BRTHDT	Date of Birth	Date	Numeric date of birth of the subject with imputation as necessary to account for the collection of a partial date.
AGE	Age	Num	Age expressed in AGEU. Can be derived as (RFSTDTC-BRTHDTC), but BRTHDTC may not be available in all cases (because of subject privacy concerns).
AGEU	Age Units	Char	Expected value: 'Years' Units associated with age. Should be the same across studies when appropriate.
SEX	Sex	Char	Expected values: 'M', 'F' Sex of the subject.
RACE	Race	Char	
RACEGR1	Race Group 1	Char	Expected values: 'WHITE', 'BLACK', 'ASIAN', 'OTHER' This race grouping is required and it is requested that sponsors use this variable name, label, and values.
ETHNIC	Ethnicity	Char	Expected values: 'HISPANIC OR LATINO', 'NOT HISPANIC OR LATINO', 'NOT REPORTED', 'UNKNOWN' Ethnicity of the subject
COUNTRY	Country	Char	Expected values should follow NCI-EVS controlled terminology.
REGION1	Continental Region	Char	This variable indicates the Continent where the study was done
REGIONy	Geographical Region y	Char	This variable indicates the grouping of investigator sites into the "y^{th}" geographical region (REGIONy=REGION2, REGION3, etc.) Even if the randomization strata used

Variable Name	Variable Label	Type	Comments
			geographic region, which would be included in the strata variables below, this variable should be included here as well. Whenever applicable, use expected values of: 'North America', 'South America', 'Oceania', 'Europe', 'Asia', 'Africa', 'Northern Hemisphere', 'Southern Hemisphere'.
SAFFL	Safety Population Flag	Char	Expected Values: 'Y', 'N' Safety population usually includes all patients who took at least one dose of study medication.
ITTFL	ITT Population Flag	Char	Expected Values: 'Y', 'N' ITT population usually includes all patients, randomized. Sometimes this is further restricted to patients who have the disease or symptoms of interest that are pre-specified.
PPROTFL	Per-Protocol Population Flag	Char	Expected Values: 'Y', 'N' Optional and to be included only when defined by the sponsor.
RANDFL	Randomized Population Flag	Char	Expected Values: 'Y', 'N' Randomized Population describes whether the subject was randomized
FASFL	Full Analysis Set Population Flag	Char	Expected Values: 'Y', 'N' Optional and to be included only when defined by the sponsor.

3.2 Treatment Variables

Variable Name	Variable Label	Type	Comments
ARMCD	Planned Arm Code	Char	
ARM	Description of Planned Arm	Char	
TRT01P	Planned Treatment for Period 01	Char	
TRTxxP	Planned Treatment for Period xx	Char	For trials with multiple treatment periods, sponsors should add TRTxxP as needed.
TRT01A	Actual Treatment for Period 01	Char	
TRTxxA	Actual Treatment for Period xx	Char	For trials with multiple treatment periods, sponsors should add TRTxxA as needed.
TRTSEQP	Planned Sequence of Treatments	Char	
TRTSEQA	Actual Sequence of Treatments	Char	

3.3 Treatment Exposure Variables

Variable Name	Variable Label	Type	Comments
TRTSDT	Date of First Exposure to Treatment	Num	In this specification, it is assumed that TRTSDT is the first date of the study drug, excluding background therapies. This date is used as the anchor date for calculation of any study day variable defined within this specification. In most situations, the date of first dose is the same or very close to the date of randomization. If there is a lag between RANDDT and TRTSDT, sponsors should provide an explanation for why this occurred.
TRTEDT	Date of Last Exposure to Treatment	Num	This is the last date of the study drug, excluding background therapies.
TRTDURD	Duration of Treatment	Num	Total duration of treatment in days. This should be the difference between TRTSDT and TRTEDT.
TRTCMP	Compliance to the Study Drug	Num	Treatment compliance (%) to the study drug before discontinuation of the study drug. Background therapies should not be part of this calculation.
BG_TRT	Background Regimen Taken at Trial Start	Char	This variable is a text string that concatenates the values of all HIV-1 treatment background drugs taken at the beginning of the trial. These background drugs may or may not be stopped during the study. Note these background drugs do not refer to any randomized treatments that may be used as background therapy. Please see below for variables that are specific to randomized treatments. The following rules should be used: 1. The generic name of all background drugs should be listed with a ',' between the drug names. It is beneficial to use standard drug dictionary values for generic name (e.g., WHODRUG) 2. If the drug is a fixed dose combination (FDC), then the generic name of the FDC is acceptable. If the background drugs are separate pills, then the generic name of each drug should be listed (e.g., "tenofovir, emtricitabine").
F_BG_TRT	Changes to Background Regimen	Char	This variable is specific to trials in which background drugs are **changed by design as defined in the protocol and not based on any post-randomization outcomes**. Many trials will not have this variable. Note that this variable is not intended to be used for discontinuations of background drugs. This is an optional variable.

3.4 Study Discontinuation Variables

Variable Name	Variable Label	Type	Comments
EOSSTT	End of Study Status	Char	Expected Values: 'COMPLETED', 'ONGOING', 'DISCONTINUED' End of study status. This should be populated for all subjects. If by the last scheduled visit date before database cutoff date the subject is ongoing, the value of this variable should be set to 'ONGOING'. If the subject completed the study according to the protocol, then the variable should be set at 'COMPLETED'. Otherwise, 'DISCONTINUED'.
EOSDT	End of Study Date	Num	For subjects that discontinued the study, this is the date of study discontinuation. For subjects that completed the study, this is the date of the end of study completion. For ongoing subjects, this should be null.
DCSREAS	Reason for Discontinuation From Study	Char	This variable will be populated only when EOSSTT='DISCONTINUED'.
DCSREASP	Reason Spec for Discont From Study	Char	This optional variable further describes the reason for discontinuation from the study.
DSCCOMM	Comments for Discontinuation	Char	Post-hoc findings of the reasons for discontinuation should be described. For example, It is helpful to provide details for "Withdrawal of consent", "Physician decision", "Patient decision", and "Other" categories.
DSCAEON	Any Ongoing AEs When Study Disc	Char	Expected Values: 'Y', 'N' This variable indicates if there were any AEs that were ongoing at the time of study discontinuation.
DSCAETX	Max Tox Grade of Ongoing AE	Char	Expected Values: '1', '2', '3', '4', '5' The highest toxicity level of any adverse event that was ongoing at the time of study discontinuation.
CDCAEDY	Study Day of First CDC Class C Event	Num	This is the study day of the first treatment emergent CDC Class C event.
DTHDTC	Date of Death	ISO8601	The source of this variable should be DM.DTHDTC.
DTHDT	Date of Death	Num	Numeric date of death based on DM.DTHDTC, using imputation as necessary.
DTHDY	Study Day of Death	Num	This death day should use treatment start date as the anchor.
EOSVL	Viral Load at Study Discontinuation	Num	Last available viral load value (in copies/mL) on or before study discontinuation date. Populate this variable only for subjects who discontinued the study.
EOSCD4	CD4 Counts at Study Discontinuation	Num	Populate this variable only for subjects who discontinued the study.

3.5 Study Drug Discontinuation Variables

Variable Name	Variable Label	Type	Comments
EOTSTT	End of Treatment Status	Char	Expected Values: 'COMPLETED', 'ONGOING', 'DISCONTINUED' End of study treatment status. This should be populated for all subjects. If by the last scheduled visit date before database cutoff date the subject is still on the initial treatment at the time of the snapshot, the value of this variable should be set to 'ONGOING'
EOTDT	Date of Discontinuation of Study Drug	Num	If study drug is a combination therapy, for this variable it is considered to be one drug. Of interest is the date that the study drug was discontinued. Note that this date is in regard to study drug discontinuation, not study discontinuation or background drug discontinuation/addition. Background drug changes are handled in next section This date should come from the EX domain and not a discontinuation page. It is possible that this date will be equivalent to TRTEDT (above) but for consistency purposes, this variable should be created even if it is equivalent.
EOTDY	Study Day of Discontinuation Study Drug	Num	Study day associated with the date specified in EOTDT.
DCTREAS	Reason for Discontinuation of Study Drug	Char	The reasons for discontinuation of study drug are typically collected on the Case Report Form (CRF). Examples include adverse event, virologic failure, etc.
DCTREASP	Reason Specify for Discontinuation of Treatment	Char	This optional variable further describes the reason for discontinuation from the study treatment.
EOTCAEON	Any Ongoing AEs When Study Drug Disc	Char	Expected Values: 'Y', 'N' It is helpful for review to know if there were ongoing AEs at the time of study drug discontinuation. It is possible that an AE began during the same time frame of study drug discontinuation, yet the reason for study drug discontinuation may indicate virologic failure, even when the AE may have been a contributing factor. There should be harmonization between this variable and the variable AEONGOIN in ADAE, such that if there is at least one record in ADAE with AEONGOIN='ONGOING', then SDDAEON should ='Y'.
EOTCAETX	Max Tox Grade of Ongoing AE	Char	Expected Values: '1', '2', '3', '4', '5' This is the highest level of the toxicity level for any ongoing AE.
EOTVL	Viral Load at Study Drug Discontinuation	Num	Last available viral load value (in copies/mL) on or before study discontinuation date. Populate this variable only for subjects who discontinued the study drug.
EOTCD4	CD4 Counts at Study Drug Discontinuation	Num	Populate this variable only for subjects who discontinued the study drug.

3.6 Background Drug Changes Variables

The following sets of variables provide information for each time a background drug was discontinued or a new background drug was begun (if applicable).

Variable Name	Variable Label	Type	Comments
This set of variables pertains to the first time a background drug was REMOVED/			
BGR1EDT	Discontinuation Date 1st BG Drug	Num	
BGR1EDY	Discontinuation Day of 1st BG Drug	Num	
BGR1REAS	Reason for Discontinuation of 1st BG Drug	Char	
BGR1NAME	Name of 1st Discontinued BG Drug	Char	Use generic name.
BGR1AEON	Any Ongoing AEs When 1st BG Drug Dsc	Char	Expected Values: 'Y', 'N'
BGR1AETX	Max Tox Grade of Ongo AE When 1st BG Dsc	Char	Expected Values: '1', '2', '3', '4', '5' This is the highest toxicity level of any AEs that were ongoing when the first background drug was discontinued.
This set of variables pertains to the first background drug that was ADDED. This may occur after the removal of the background drug specified in BGR1NAME or without a prior removal of a drug.			
BGA1SDT	Start Date of 1st Added BG Drug	Num	This is the start date of the first new background drug added.
BGA1SDY	Start Day of 1st Added BG Drug	Num	
BGA1NAME	Name of 1st Added BG Drug	Char	
BGA1REAS	Reason 1st BG Drug Was Added	Char	
The following variables pertain to the second time that there was a removal of a background drug (if applicable).			
BGR2EDT	Discontinuation Date 2nd BG Drug	Num	
BGR2EDY	Discontinuation Day of 2nd BG Drug	Num	
BGR2REAS	Reason for Discontinuation of 2nd BG Drug	Char	
BGR2NAME	Name of 2nd Discontinued BG Drug	Char	
BGR2AEON	Any Ongoing AEs When 2nd BG Drug Dsc	Char	Expected Values: 'Y', 'N'
BGR2AETX	Max Tox Grade of Ongo AE When 2nd BG Dsc	Char	Expected Values: '1', '2', '3', '4', '5
This set of variables pertain to the second background drug that as ADDED.			
BGA2SDT	Start Date of 2nd Added BG Drug	Num	
BGA2SDY	Start Day of 2nd Added BG Drug	Num	
BGA2NAME	Name of 2nd Added BG Drug	Char	
BGA2REAS	Reason 2nd BG Drug Was Added	Char	
If there were more than two occurrences of the removal of a drug and/or additions of a new drug, please add similar set of variables using the above variables as a template. Variable names and labels should follow the conventions provided above for variables to result in BGR3EDT - - BGR3AETX (pertaining to drug removal) and BGA3SDT- - BGA3REAS (pertaining to the addition of a new drug).			

3.7 Genotypic and Phenotypic Data for Baseline Background Regimens

Variable Name	Variable Label	Type	Comments
T_PI	Total PIs in BL BG Regimen	Num	
T_NRTI	Total NRTIs in BL BG Regimen	Num	
T_NNRTI	Total NNRTIs BL BG Regimen	Num	
T_FI	Total FIs in BL BG Regimen	Num	
T_II	Total integrase inhibitor in BL BG Regimen	Num	
T_CCR5	Total CCR5 antagonists in BL BG Regimen	Num	
T_x	Total 'x' in BL BG Regimen	Num	For new drug classes that become of interest, additional variables can be added using the convention of T_x, where 'x' represents the drug class. Note that 'x' can be up to 6 characters as needed.
T_TOTAL	Total Number of Antiretrovirals	Num	
Phenotypic Susceptibility Scores (PSS). These are scores for phenotypic susceptibility and come from a viral lab test.			
P_PI	PSS for PI	Num	PSS for PI, including darunavir.
P_NRTI	PSS for NRTI	Num	
P_NNRTI	PSS for NNRTI	Num	
P_FI	PSS for FI	Num	PSS for FI, including enfuvirtide.
P_II	PSS for integrase inhibitor	Num	
P_CCR5	PSS for CCR5 antagonist	Num	
P_TOTAL	Total PSS score	Num	
Genotypic Susceptibility Scores (GSS).			
G_PI	GSS for PI	Num	GSS for PI, including darunavir.
G_NRTI	GSS for NRTI	Num	
G_NNRTI	GSS for NNRTI	Num	
G_FI	GSS for FI	Num	GSS for FI, including enfuvirtide.
G_II	GSS for Integrase Inhibitor	Num	
G_CCR5	GSS for CCR5 Inhibitor	Num	
G_TOTAL	Total GSS Score	Num	

3.8 Background Drug Indicator Variables

Values of '1' (yes) for these variables will be present for those background (BG) drugs in the BG_TRT text string in Table 3.3. Include only those variables that are needed for the given trial to describe the background regimen. Combination drugs should be separated into individual variables for the molecular components. For drugs not mentioned below, use the convention of a 3-character name followed by 'FN'.

Variable Name	Variable Label	Type	Comments
APVFN	Amprenavir (APV) in BG Regimen	Num	Expected Value: '1', null
ATVFN	Atazanavir (ATV) in BG Regimen	Num	Expected Value: '1', null
DRVFN	Darunavir (DRV) in BG Regimen	Num	Expected Value: '1', null
FAPVFN	Fosamprenavir (FAPV) in BG Regimen	Num	Expected Value: '1', null
IDVFN	Indinavir (IDV) in BG Regimen	Num	Expected Value: '1', null
LPVFN	Lopinavir (LPV) in BG Regimen	Num	Expected Value: '1', null
NFVFN	Nelfinavir (NFV) in BG Regimen	Num	Expected Value: '1', null
RTVFN	Ritonavir (RTV) in BG Regimen	Num	Expected Value: '1', null
SQVFN	Saquinavir (SQV) in BG Regimen	Num	Expected Value: '1', null
TPVFN	Tipranavir (TPV) in BG Regimen	Num	Expected Value: '1', null
ABCFN	Abacavir (ABC) in BG Regimen	Num	Expected Value: '1', null
DDIFN	Didanosine (DDI) in BG Regimen	Num	Expected Value: '1', null
FTCFN	Emtricitabine (FTC) in BG Regimen	Num	Expected Value: '1', null
L3TCFN	Lamivudine (3TC) in BG Regimen	Num	Expected Value: '1', null
D4TFN	Stavudine (D4T) in BG Regimen	Num	Expected Value: '1', null
TDFFN	Tenofovir (TDF) in BG Regimen	Num	Expected Value: '1', null
FTCFN	Zalcitabine (FTC) in BG Regimen	Num	Expected Value: '1', null
ZDVFN	Zidovudine (ZDV) in BG Regimen	Num	Expected Value: '1', null
DLVFN	Delavirdine (DLV) in BG Regimen	Num	Expected Value: '1', null
EFVFN	Efavirenz (EFV) in BG Regimen	Num	Expected Value: '1', null

Variable Name	Variable Label	Type	Comments
ETVFN	Etravirine (ETV) in BG Regimen	Num	Expected Value: '1', null
NVPFN	Nevirapine (NVP) in BG Regimen	Num	Expected Value: '1', null
T20FN	Enfuvirtide (T20) in BG Regimen	Num	Expected Value: '1', null
RALFN	Raltegravir (RAL) in BG Regimen	Num	Expected Value: '1', null
MVCFN	Maraviroc (MVC) in BG regimen	Num	Expected Value: '1', null
EVGFN	Elvitgravir (EVG) in BG Regimen	Num	Expected Value: '1', null
COBIFN	Cobicistat (COBI) in BG Regimen	Num	Expected Value: '1', null
DTGFN	Dolutegravir (DTG) in BG Regimen	Num	Expected Value: '1', null

3.9 Baseline Characteristics Variables

Variable Name	Variable Label	Type	Comments
WEIGHTBL	Weight at Baseline (kg)	Num	
HEIGHTBL	Height at Baseline (cm)	Num	
HIPCIRBL	Hip Circumference at Baseline (cm)	Num	
WSTCIRBL	Waist Circumference at Baseline (cm)	Num	
BMIBL	Body Mass Index at Baseline (kg/m2)	Num	
CD4BL	CD4 Count at Baseline	Num	
CD4PCTBL	CD4 Percentage at Baseline	Num	
CD8BL	CD8 Count at Baseline	Num	
CD8PCTBL	CD8 Percentage at Baseline	Num	
CD4CD8BL	Ratio of CD4 to CD8 at Baseline	Num	
VLSCR	Screening HIV Viral Load (copies/mL)	Char	Screening HIV RNA viral load at screening.
VLBL	Baseline HIV Viral Load (copies/mL)	Num	Numeric value of HIV-RNA viral load at baseline. In the rare case that this is missing, last value before baseline should be used.
CCR5HPBL	CCR5 Promoter Haplotype at Baseline	Num	
HBVCOFL	HBV Co-Infection Flag	Char	Expected Values: 'Y', 'N' A flag to indicate the baseline status of HBV co-infection.
HCVCOFL	HCV Co-Infection Flag	Char	Expected Values: 'Y', 'N' A flag to indicate the baseline status of HCV co-infection.

Variable Name	Variable Label	Type	Comments
TBCOFL	TB Co-Infection Flag	Char	Expected Values: 'Y', 'N' A flag to indicate the baseline status of TB co-infection.
TRTHIST	Treatment Experience at Entry of Study	Char	Examples include 'Naïve', 'NRTI-Experienced', 'PI-Experienced' The potential values for this variable are open ended since, as new classes come on market, they will appear in this variable. In general, the value of treatment history describes the study population. If the whole trial is naïve, then still include this variable with a value of Naïve for all subjects. If a subject had multiple treatment experiences, then the values of previous treatment classes should be concatenated.
PRVFFL	Prior Virologic Failure Flag	Char	Expected Values: 'Y', 'N' This flag variable should be based on the criteria used in the protocol.
STRATA	Randomized Strata	Char	This is a text string that describes the combination of individual values of each stratum that were used for randomization of the subject. For example, if there were three strata, this text string would present the subject's value for each of the three strata, such as 'HIV VL<10^5, Prior Therapy, Male'.
STRATy	Randomized Value of Stratum y	Char	This is the subject level value of the y'th 'as randomized' strata that is described by the companion variable STRATyNM. For example, if STRAT1NM='HIV Viral Load', then STRAT1='<10^5 copies/mL'. If the randomization is based on multiple strata, then individual 'y' variables would be created for each stratum.
STRATyNM	Description of Randomized Stratum y	Char	This is a text description of the y'th 'as randomized' strata. The value of this variable describes the stratification factor used for randomization and is intended to be used in tandem with STRATy.

3.10 Additional Baseline Variables

Sponsors can add additional baseline variables as needed for their analysis/trial. However, FDA requests that sponsors discuss these variable proposals with the Division at the EOP2 meeting to allow coordination in the development of standard variable names for consistent use across submissions.

3.11 Variables for Efficacy Measures of Viral Load

Variable Name	Variable Label	Type	Comments
Efficacy Variables for Viral Load Cutoff of 50 copies/mL at Weeks 24, 48, 96, 128, 144 weeks of interest (as applicable).			
V2450FL	Wk 24 Viral Load < 50 copies/mL Flag	Char	Expected Values: 'Y', 'N' Flag variable to indicate whether the viral load at Week 24 was less than 50 copies/mL.
V2450C	Wk 24 Viral Load < 50 copies/mL Category	Char	High level categorization of virologic status from the snapshot algorithm at Week 24, for a cutoff of 50 copies/mL. The values of '1', '2', '3' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 50 copies/mL) '2'=Virologic failure '3'=No virologic data
V2450SC	Wk 24 Viral Load < 50 copies/mL Subcat	Char	Further subcategorization of the virologic status from the snapshot algorithm at Week 24, for a cutoff of 50 copies/mL. The values of '1', '2a', '2b', '2c', '2d', '3a', '3b', '3c' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 50 copies/mL) '2a'=HIV-RNA ≥ 50 copies/mL '2b'=Discontinued because of virologic failure '2c'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was ≥ 50 copies/mL '2d'=OBT changed '3a'=Discontinued because of AE or death '3b'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was < 50 copies/mL '3c'=Missing data during the window but on study Note that there must be alignment of the value of this variable with the value of V24_50C. For example, when V24_50C='2', then V24_50SC can only equal '2a', '2b', '2c', or '2d'.
V4850FL	Wk 48 Viral Load < 50 copies/mL Flag	Char	Expected Values: 'Y', 'N' Flag variable to indicate whether the viral load from the snap-shot algorithm at Week 48 was less than 50 copies/mL
V4850C	Wk 48 Viral Load < 50 copies/mL Category	Char	High-level categorization of virologic status from the snapshot algorithm at Week 48, for a cutoff of 50 copies/mL. The values of '1', '2', '3' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 50 copies/mL) '2'=Virologic failure '3'=No virologic data
V4850SC	Wk 48 Viral Load < 50 copies/mL Subcat	Char	Further subcategorization of the virologic status from the snapshot algorithm at Week 48, for a cutoff of 50 copies/mL. The values of '1', '2a', '2b', '2c', '2d', '3a', '3b', '3c' must be used for this variable with the corresponding definitions:

Variable Name	Variable Label	Type	Comments
			'1'=Virologic success (HIV-RNA < 50 copies/mL) '2a'=HIV-RNA ⩾ 50 copies/mL '2b'=Discontinued because of virologic failure '2c'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was ≥ 50 copies/mL '2d'=OBT changed '3a'=Discontinued because of AE or death '3b'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was < 50 copies/mL '3c'=Missing data during the window but on study Note that there must be alignment of the value of this variable with the value of V48_50C. For example, when V48_50C='2', then V48_50SC can only equal '2a', '2b', '2c', or '2d' .
V9650FL	Wk 96 Viral Load < 50 copies/mL Flag	Char	Expected Values: 'Y', 'N' Flag variable to indicate whether the viral load from the snap-shot algorithm at Week 96 was less than 50 copies/mL
V9650C	Wk 96 Viral Load < 50 copies/mL Category	Char	High level categorization of virologic status from the snap-shot algorithm at Week 96 for a cut-off of 50 copies/mL. The values of '1','2','3' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 50 copies/mL) '2'=Virologic failure '3'=No virologic data
V9650SC	Wk 96 Viral Load < 50 copies/mL Subcat	Char	Further sub-categorization of the virologic status from the snap-shot algorithm at Week 96 for a cut-off of 50 copies/mL. The values of '1','2a',' 2b', '2c', '2d', '3a', '3b', '3c' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 50 copies/mL) '2a'=HIV-RNA ≥ 50 copies/mL '2b'=Discontinued because of virologic failure '2c'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was ≥ 50 copies/mL '2d'=OBT changed '3a'=Discontinued because of AE or death '3b'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was < 50 copies/mL '3c'=Missing data during the window but on study Note that there must be alignment of the value of this variable with the value of V96_50C. For example, when V96_50C='2', then V96_50SC can only equal '2a', '2b', '2c', or '2d' .
Variables for Viral Load Cutoff of 400 copies/mL at Weeks 24, 48, 96, 128, 144 (as applicable)			
V244HFL	Wk 24 Viral Load <400 copies/mL Flag	Char	Expected Values: 'Y', 'N' Flag variable to indicate whether the viral load from the snap-shot algorithm at Week 24 was less than 400 copies/mL
V244HC	Wk 24 Viral Load <400 copies/mL Category	Char	High level categorization of virologic status from the snap-shot algorithm at Week 24 for a cut-off of 400 copies/mL. The values of '1','2','3' must be used for this variable with the corresponding definitions:

Variable Name	Variable Label	Type	Comments
			'1'=Virologic success (HIV-RNA < 400 copies/mL) '2'=Virologic failure '3'=No virologic data
V244HSC	Wk 24 Viral Load <400 copies/mL Subcat	Char	Further sub-categorization of the virologic status from the snap-shot algorithm at Week 24 for a cut-off of 400 copies/mL. The values of '1','2a', '2b', '2c', '2d', '3a', '3b', '3c' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 400 copies/mL) '2a'=HIV-RNA ≥ 400 copies/mL '2b'=Discontinued because of virologic failure '2c'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was ≥ 400 copies/mL '2d'=OBT changed '3a'=Discontinued because of AE or death '3b'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was < 400 copies/mL '3c'=Missing data during the window but on study Note that there must be alignment of the value of this variable with the value of V24400C. For example, when V24400C='2', then V24400SC can only equal '2a', '2b', '2c', or '2d'.
V484HFL	Wk 48 Viral Load <400 copies/mL Flag	Char	Expected Values: 'Y', 'N' Flag variable to indicate whether the viral load from the snapshot algorithm at Week 48 was less than 400 copies/mL.
V484HC	Wk 48 Viral Load <400 copies/mL Category	Char	High-level categorization of virologic status from the snapshot algorithm at Week 48, for a cutoff of 400 copies/mL. The values of '1', '2', '3' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 400 copies/mL) '2'=Virologic failure '3'=No virologic data
V484HSC	Wk 48 Viral Load <400 copies/mL Subcat	Char	Further subcategorization of the virologic status from the snapshot algorithm at Week 48, for a cutoff of 400 copies/mL. The values of '1', '2a', '2b', '2c', '2d', '3a', '3b', '3c' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 400 copies/mL) '2a'=HIV-RNA ≥ 400 copies/mL '2b'=Discontinued because of virologic failure '2c'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was ≥ 400 copies/mL '2d'=OBT changed '3a'=Discontinued because of AE or death '3b'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was < 400 copies/mL '3c'=Missing data during the window but on study Note that there must be alignment of the value of this variable with the value of V48400C. For example, when V48400C='2', then V48400SC can only equal '2a', '2b', '2c', or '2d'.

Variable Name	Variable Label	Type	Comments
V964HFL	Wk 96 Viral Load <400 copies/mL Flag	Char	Expected Values: 'Y', 'N' Flag variable to indicate whether the viral load from the snap-shot algorithm at Week 96 was less than 400 copies/mL
V964HC	Wk 96 Viral Load <400 copies/mL Category	Char	High-level categorization of virologic status from the snapshot algorithm at Week 96, for a cutoff of 400 copies/mL. The values of '1', '2', '3' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 400 copies/mL) '2'=Virologic failure '3'=No virologic data
V964HSC	Wk 96 Viral Load <400 copies/mL Subcat	Char	Further subcategorization of the virologic status from the snapshot algorithm at Week 96, for a cutoff of 400 copies/mL. The values of '1', '2a', '2b', '2c', '2d', '3a', '3b', '3c' must be used for this variable with the corresponding definitions: '1'=Virologic success (HIV-RNA < 400 copies/mL) '2a'=HIV-RNA ≥ 400 copies/mL '2b'=Discontinued because of virologic failure '2c'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was ≥ 400 copies/mL '2d'=OBT changed '3a'=Discontinued because of AE or death '3b'=Discontinued because of other reasons and HIV-1 RNA at the time of discontinuation was < 400 copies/mL '3c'=Missing data during the window but on study Note that there must be alignment of the value of this variable with the value of V96400C. For example, when V96400C='2', then V96400SC can only equal '2a', '2b', '2c', or '2d'.
The following variables and variable labels should be added when there are viral load values past 96 weeks. Sponsors should follow the naming conventions provided here for any 3-digit week of interest (e.g., 128, 144). The value of the week should replace the 'xxx' in the variable names below. All comments and required values provided above apply to these variables. **Variable Name: Variable Label.** Vxxx50FL: Wk xxx Viral Load < 50 copies/mL Flag Vxxx50C: Wk xxx Viral Load < 50 copies/mL Category Vxxx50SC: Wk xxx Viral Load < 50 copies/mL Subcat Vxxx4HFL: Wk xxx Viral Load <400 copies/mL Flag Vxxx4HC: Wk xxx Viral Load <400 copies/mL Category Vxxx4HSC: Wk xxx Viral Load <400 copies/mL Subcat			
The following variables provide the values of the viral load and associated timing variables that were used to derive the above efficacy outcome variables for the given cut point. If viral load observations are not used in the snapshot because of various reasons, these variables should be left blank. There should be no imputation of these values.			
WK24VL	Week 24 HIV-RNA Viral Load	Num	Viral load value corresponding to Week 24.
WK24DY	Study day of Week 24 Viral Load	Num	Study day corresponding to the Week 24 viral load value.
WK24DT	Date of Week 24 Viral Load	Num	Date corresponding to the Week 24 viral load value.
WK48VL	Week 48 HIV-RNA Viral Load	Num	Viral load value corresponding to Week 48.
WK48DY	Study Day of Week 48 Viral Load	Num	Study day corresponding to the Week 48 viral load value.
WK48DT	Date of Week 48 Viral Load	Num	Date corresponding to the Week 48 viral load value.

Variable Name	Variable Label	Type	Comments
WK96VL	Week 96 HIV-RNA Viral Load	Num	Viral load value corresponding to Week 96.
WK96DY	Study Day of Week 96 Viral Load	Num	Study day corresponding to the Week 96 viral load value.
WK96DT	Date of Week 96 Viral Load	Num	Date corresponding to the Week 96 viral load value.
WK128VL	Week 128 HIV-RNA Viral Load	Num	Viral load value corresponding to Week 128.
WK128DY	Study Day of Week 128 Viral Load	Num	Study day corresponding to the Week 128 viral load value.
WK128DT	Date of Week 128 Viral Load	Num	Date corresponding to the Week 128 viral load value.
WK144VL	Week 144 HIV-RNA Viral Load	Num	Viral load value corresponding to Week 144.
WK144DY	Study Day of Week 144 Viral Load	Num	Study day corresponding to the Week 144 viral load value.
WK144DT	Date of Week 144 Viral Load	Num	Date corresponding to the Week 144 viral load value.

3.12 Other Efficacy Variables

Variable Name	Variable Label	Type	Comments
CD448	CD4 Cell Count at Week 48	Num	
CD4CB48	CFB in CD4 Cell Count at Week 48	Num	Note: CFB = change from baseline.
CD4P48	CD4 Cell Count Percentage at Week 48	Num	
CD4PCB48	PCT CFB in CD4 Cell Count at Week 48	Num	Note: PCT CFB= percent change from baseline.
CD496	CD4 Cell Count at Week 96	Num	
CD8CB48	CFB in CD8 Cell Count at Week 48	Num	Note: CFB = change from baseline.
CD8P48	CD8 Cell Count Percentage at Week 48	Num	
CD8PCB48	PCT CFB in CD8 Cell Count at Week 48	Num	Note: PCT CFB= percent change from baseline.
TTLT400	Time to Confirmed Response < 400	Num	This is the number of study days from Day 1 (first dose) until the first confirmed response of less than 400. If the subject never had a confirmed response of less than 400, then set this value to 100000.
TTRB400	Time to 1st Rebound After Confirm Response <400	Num	This is the number of days between the day of the first confirmed response less than 400 (as recorded in TTLT400) and the day of the first rebound.
TTCRS400	Time to Confirmed Resuppression (<400)	Num	This is the number of days between the day of the first rebound (as recorded in TTRB400) and the day of confirmed resuppression of less than 400.
TTLT50	Time to Confirmed Response < 50	Num	This is the number of study days from Day 1 (first dose) until the first confirmed response of less than 50. If the subject never had a confirmed response of less than 50, then set this value to 100000.

Variable Name	Variable Label	Type	Comments
TTRB50	Time to 1st Rebound After Confirm Response <50	Num	This is the number of days between the day of the first confirmed response less than 50 (as recorded in TTLT50) and the day of the first rebound.
TTCRS50	Time to Confirmed Resuppression (<50)	Num	This is the number of days between the day of the first rebound (as recorded in TTRB50) and the day of confirmed resuppression of less than 50.
TTNADIR	Time to First Reached Nadir	Num	
TTRBNADR	Time of Rebound from Nadir	Num	1 log above nadir should be used with a confirmation using a repeat lab measurement that still indicates rebound.

4.0 Dataset Specifications for Adverse Event Analysis Data Set - ADAE

The following issues are considerations for the creation and content of the adverse event data set.

NOTE: Sponsors should follow the ADaM ADAE model when creating this data set. Include all SDTM required and expected variables from AE in this analysis data set.

  - If a sponsor/applicant uses the approach of recording multiple records in AE each time the event changes in severity, relationship, and so forth, then this should be noted in the metadata.
  - Ideally, there would be a methodology to identify groups of records that describe the same continuous AE.
- This specification includes specific variables to indicate whether the AE term falls within the CDC-C classification.
- This specification includes a flag variable that indicates which record had the worst toxicity grade for a given AE (preferred term) when there are multiple occurrences (records) of the same AE.
- Similarly, there are flag variables that indicate the record for each preferred term that had the worst toxicity grade occurring by Week 24, Week 48, and Week 96.

Any deviations from the specifications below should be clearly communicated to the review division. The following variables should be added to the standard ADAE dataset:

4.1 ADAE Specifications

Variable Name	Variable Label	Type	Comments
MDR_VER	MedDRA Coding Dictionary Version	Num	
TRTEMFL	Treatment-Emergent Analysis Flag	Char	Expected Values: 'Y', null A value of 'Y' on a record should indicate a new or worsening AE after taking experimental treatment. Metadata must be clear on the reference dates that are used to define the period of time during which an adverse event is considered treatment emergent.
ASTDT	Analysis Start Date	Num	Created from AESTDTC. Even if AESTDTC contains both a date and time component, ASTDT should reflect just the date portion.
ASTDTF	Analysis Start Date Imputation Flag	Char	Expected Values: 'D', 'M', 'Y' Following CDISC ADaM standards, use this variable to indicate which component of the AE Start date was imputed.
AENDT	Analysis End Date	Num	This is the sponsor version of the numeric adverse event end date. Sponsors may impute this as specified in their analysis plans and is therefore independent, yet may be equivalent to, the AENDTI variable below.
AENDTF	Analysis End Date Imputation Flag	Char	Expected Values: 'D', 'M', 'Y' Following CDISC ADaM standards, use this variable to indicate which component of AENDT was imputed.
ADURN	Analysis Duration (N)	Num	This is the sponsor version of the adverse event duration. Using the numeric date variables for adverse event start and end date (ASTDT and AENDT), calculate the duration in days.
AENDTI	Analysis End Date – DAVP Imputed	Num	This is the review division version of adverse event end date. If AEENDTC is present the derived end date (AENDT) is prior to the date of the end of the study participation or the death date, then AENDTI will be equivalent to AENDT. However, if AEENDTC is missing or the derived/imputed AENDT occurs after study participation, then this date must be imputed using the date of the end of study participation or death date. This is requested so that the duration of the adverse event, relative to the conduct of the trial, can be calculated (see ADURI below).
ADURI	Analysis Duration – DAVP Imputed (N)		This is the review division version of adverse event duration. Using the numeric date variables for adverse event start and the review division end date (AENDTI), calculate the duration in days. It is noted that this duration will be calculated for all adverse events given that there will be an imputed end date (AENDTI) for every event.
AEONGOIN	Ongoing AE	Char	Expected Value: 'ONGOING', null If AE.AEENREF is collected, this variable will be equivalent to AE.AEENREF. This variable should only be populated with 'ONGOING' when AEENDTC is missing. The date used by the sponsor to define the end of the reference period should be specified.
AESEV	Severity /Intensity	Char	Expected Values: 'MILD', 'MODERATE', 'SEVERE'

AERELNST	Relationship to Nonstudy Treatment	Char	
AEOUT	Outcome of Adverse Event	Char	
AETOXGR	Standard Toxicity Grade	Char	The definitions specified in the protocol should be followed
WTOXFL	Overall Worst Toxicity Grade	Char	Expected Value: 'Y', null For each unique preferred term, indicate the record that has the worst toxicity grade during the study
WTOX24FL	Worst Toxicity Grade at 28 Weeks Flag	Char	Expected Value: 'Y', null For each unique preferred term, indicate the record that has the worst toxicity grade that occurred by Week 24
WTOX48FL	Worst Toxicity Grade at 48 Weeks Flag	Char	Expected Value: 'Y', null For each unique preferred term, indicate the record that has the worst toxicity grade that occurred by Week 48
WTOX96FL	Worst Toxicity Grade at 96 Weeks Flag	Char	Expected Value: 'Y', null For each unique preferred term, indicate the record that has the worst toxicity grade that occurred by Week 96
WTX128FL	Worst Toxicity Grade at 128 Weeks Flag	Char	Expected Value: 'Y', null For each unique preferred term, indicate the record that has the worst toxicity grade that occurred by Week 128
WTX144FL	Worst Toxicity Grade at 144 Weeks Flag	Char	Expected Value: 'Y', null For each unique preferred term, indicate the record that has the worst toxicity grade that occurred by Week 144
CDCAEFL	CDC Class C AE Flag	Char	Expected Value: 'Y', null This flag should be used to indicate whether the adverse event is included in the CDC Classification System for HIV infection
CDCAEDY	Study Day of First CDC Class C Event	Num	This is the study day of the first treatment emergent CDC Class C event
CDCAEPT	Preferred Term of the Class C Event	Char	This should be the preferred term used in the CDC Classification System list that specified in the protocol that corresponds to the value of AEDECOD on the record.
TRT01P	Planned Treatment for Period 01	Char	For trials with more than one treatment period, add additional variables TRTxxP as necessary.
TRT01A	Actual Treatment for Period 01	Char	For trials with more than one treatment period, add additional variables TRTxxP as necessary.
TRTP	Planned Treatment	Char	
TRTA	Actual Treatment	Char	
SAFFL	Safety Population Flag	Char	Expected Values: 'Y', 'N'
ITTFL	Intent-To-Treat Population Flag	Char	Expected Values: 'Y', 'N'
PPROTFL	Per-Protocol Population Flag	Char	Expected Values: 'Y', 'N'
RANDFL	Randomized Population Flag	Char	Expected Values: 'Y', 'N'
TRTSDT	Date of First Exposure to Treatment	Num	
TRTEDT	Date of Last Exposure to Treatment	Num	
RANDDT	Date of Randomization	Num	

5.0 Laboratory Analysis Data Set - ADLB

The following issues are considerations for the creation and content of the laboratory analysis data set. Sponsors should follow the ADaM Basic Data Structure (BDS) model when creating this data set.

NOTE: Include all SDTM required and expected variables from LB in this analysis data set.

- Visit windowing and/or inclusion of unscheduled visits may be used in this analysis data set. When records are imputed in any manner, the standard ADaM variable 'DTYPE' should be used.

Of primary interest are lab parameters that fall in the following categories:

- HIV-RNA (viral load)
- Immunologic parameters: cluster of differentiation 4 positive cell counts (absolute count and percentage)
- Lipid laboratory parameters: total cholesterol, low-density lipoprotein, high-density lipoprotein, triglycerides
- Liver laboratory tests: alanine aminotransferase, aspartate aminotransferase, total bilirubin, albumin, total protein, prothrombin time/international normalized ratio, gamma-glutamyl transferase
- Hematology laboratory tests: white blood cell absolute neutrophils, hemoglobin, hematocrit, platelets, eosinophils
- Renal laboratories: blood urea nitrogen, creatinine, creatinine clearance, bicarbonate, phosphate
- Other laboratory tests: sodium, potassium, chloride, bicarbonate, amylase, lipase, creatine phosphokinase

It is acceptable for a sponsor's/applicant's ADLB data set to contain additional parameters beyond those noted above. Similarly, variables in addition to those described below may be included. The following variables should be added to the standard ADLB dataset.

5.1 ADLB Specifications

Variable Name	Variable Label	Type	Comments
USUBJID	Unique Subject Identifier	Char	Unique among all subjects submitted for the drug

Variable Name	Variable Label	Type	Comments
SUBJID	Subject Identifier for the Study	Char	Subject identifier, which should be unique within the study. Often the identifier of the subject as recorded on a CRF.
VISIT	Visit Name	Char	
LBDY	Study Day of Specimen Collection	Num	
AVISIT	Analysis Visit	Char	Ideally, the value of the analysis visit should indicate the week of the trial (e.g. AVISIT='Week 4'). Similarly, the analysis visit associated with baseline should be made clear. It is acceptable if unscheduled visits are included. Ideally, the value of LB.VISIT and/or LB.VISITNUM should easily identify these unscheduled visits.
AVISITN	Analysis Visit	Num	Ideally, the value of the numeric version of the analysis visit should correspond to the week number described in AVISIT (e.g. AVISIT='Week 4', AVISITN=4)
ADTM	Analysis Datetime	Num	
ADT	Analysis Date	Num	
ATM	Analysis Time	Num	
ADY	Analysis Relative Day	Num	If the reference date used to create this analysis study day is different from the reference date used to create LBDY, sponsors should describe the reference date and indicate why a different date was used.
PARAM	Parameter	Char	The lab test unit should be included in this variable
PARAMCD	Parameter Code	Char	Parameter code associated with PARAM. It is helpful when standard values of LBTESTCD are used for PARAMCD
AVAL	Analysis Value	Num	
AVALC	Analysis Value (C)	Char	When the lab parameter has a character value, populate AVALC
ANRLO	Analysis Normal Range Lower Limit	Num	Lower limit for the normal range of the lab measure

Variable Name	Variable Label	Type	Comments
ANRHI	Analysis Normal Range Upper Limit	Num	Upper limit for the normal range of the lab measure
ANL01FL	Analysis Flag 01	Char	Expected Value: 'Y', null This is useful for multiple records within the same analysis week to indicate which record was used for the analysis for that visit week.
DTYPE	Derivation Type	Char	For the case where there are multiple observations and an average or a geometric mean will be used for the observation for the visit window in the analysis instead of a single selected real observation. If this is the case, a new record should be created and the records identified by having some values for these records in ANATYPE variable. The possible value could be 'AVERAGE', or 'GEOMETRIC', or other meaningful values. This should be explained in the define file or SAP.
LBFAST	Fasting Status	Char	Expected Values: 'Y', 'N', 'U', null Indicator used to identify fasting status such as 'N', 'Y', 'U', (unknown), or null if not relevant
BASE	Baseline Value	Num	
BASEC	Baseline Value (C)	Char	When the lab parameter has a character value, populate BASEC
CHG	Change from Baseline	Num	
PHASE	Trial Phase of Study	Char	For review, it is helpful to know when a laboratory measure was collected relative to conduct of the trial. For example, knowing whether a laboratory value was collected after there was a change in the original randomized treatment is important for review. Since this variable concept may need to be more granular than ADaM specific variables such as APHASE, a separate variable is defined. Example values of this variable are provided below yet these are not standard variables and at present there are no unified definitions for this variable since it depends on the study design. Therefore, discussion with the review division is suggested. 'Screening' = indicates records collected prior to first dose

Variable Name	Variable Label	Type	Comments
			'On Treatment' – indicates records collected during the randomized treatment. As long as the subject is on the original randomized treatment, this value is used. Protocol-specified changes of background therapies do not count as changes in randomized treatment nor do treatment interruptions that are allowed by the protocol. 'Follow Up Period' – indicates measures collected after the end of treatment
APHASE	Analysis Phase	Char	Optional variable
APERIOD	Analysis Period	Num	When there is more than one ADaM treatment variable (TRTxxP) defined for the dataset, include APERIOD as appropriate.
ATOXGR	Toxicity Grade Assigned	Char	The lab toxicity grade assigned according to the protocol. This should be only for lab measures, not for the viral load, or CD4 counts.
BTOXGR	Baseline Toxicity Grade assigned	Char	
WTOXFL	Overall Worst Toxicity Grade Flag	Char	Expected Value: 'Y', null For each unique parameter, indicate the record that has the worst toxicity grade during the study
WTOX24FL	Worst Toxicity Grade at 24 Weeks Flag	Char	Expected Value: 'Y', null For each unique parameter, indicate the record that has the worst toxicity grade that occurred by Week 24
WTOX48FL	Worst Toxicity Grade at 48 Weeks Flag	Char	Expected Value: 'Y', null For each unique parameter, indicate the record that has the worst toxicity grade that occurred by Week 48
WTOX96FL	Worst Toxicity Grade at 96 Weeks Flag	Char	Expected Value: 'Y', null For each unique parameter, indicate the record that has the worst toxicity grade that occurred by Week 96
WTX128FL	Worst Toxicity Grade at 128 Weeks Flag	Char	Expected Value: 'Y', null For each unique preferred term, indicate the record that has the worst toxicity grade that occurred by Week 128

Variable Name	Variable Label	Type	Comments
WTX144FL	Worst Toxicity Grade at 144 Weeks Flag	Char	Expected Value: 'Y', null For each unique preferred term, indicate the record that has the worst toxicity grade that occurred by Week 144