



Consortium for Advancing Management and Prevention of Cancer in People with HIV Data Commons (AMC-DC)

Data Standardization Plan for Pharmacokinetics

Template v2.0; 07APR2021

Assay Plan v3.0; 14OCT2026

TABLE OF CONTENTS

1.	GLOSSARY	3
2.	INTRODUCTION	3
3.	RAW DATA FILES AND FORMAT	3
4.	LABORATORY DATA PRE-PROCESSING.....	4
4.1	Data Pre-Processing Steps.....	4
4.2	Processed Data Files and Format	4
4.3	Analytic Data Files and Format.....	7
5.	EXPERIMENTAL INFORMATION AND KEY META DATA DESCRIPTORS.....	10
6.	QUALITY METRICS.....	14
7.	MANIFEST OF FILE COLLECTION TO BE SUBMITTED TO THE ODMC	14
8.	ODMC DATA PROCESSING	15
9.	APPROVAL.....	16

1. GLOSSARY

Data Formats: A collection of requirements / templates to ensure that the data adheres to a certain standard including minimal required data elements, accepted values, control vocabulary and/or ontologies to be used for certain fields.

Meta data: Collection of data to be collected about the data. This includes information about each field to be collected for a certain assay, experimental information such as instrument, instrument configuration, measurement unit/description, descriptions of the file collection, and other information that is valuable for analysis. Minimal meta data descriptors are a subset of meta data that are considered to be essential.

Operations and Data Management Center (ODMC): provides operational, logistical, communications, contracting, protocol development, site management, data and specimen management, monitoring, regulatory and medical monitoring support to the AMC.

Statistics and Data Analysis Center (SDAC): provides statistical design and analysis of AMC studies.

AMC Network Research Laboratories (NRLs): provide expertise in virology, viral oncology (e.g., KSHV, HPV, EBV), pharmacology, pathology, hematopathology, genomics, and advanced HIV diagnostics for correlative studies in support of AMC clinical trials.

Data Standardization Teams: Develop Data Standardization Plans for each assay type specifying expected data pre-processing, sample quality metrics, data formats, data processing workflows, and experimental meta data descriptors.

2. INTRODUCTION

This document outlines specifications for raw data files/formats, data pre-processing, sample quality metrics, and experimental meta data descriptors for the following assays: pharmacokinetic analysis.

Data submitted to the ODMC must follow the standards included in this document. This includes laboratory data generated by AMC network research laboratories (NRLs) and affiliate laboratories.

For each PK dataset, the following tables will be provided along with a manifest of the files:

1. Processed data in [Protocol ID]_[assay]_[drug]_[date]_exp_data.csv, format details in Table 2
2. Analytic data in [Protocol ID]_[assay]_[drug]_[date]_analytic_data.csv, details in Table 3
3. Experimental metadata in [Protocol ID]_[assay]_[date]_exp_metadata.csv, details in Table 4
4. Quality metrics in [Protocol ID]_[assay]_[drug]_[date]_analytic_data.csv, details in Table 5

Multiple processed data files and analytic data files will be provided if testing occurred for multiple drugs.

Instructions for data uploads are available on the AMC Data Commons website.

3. RAW DATA FILES AND FORMAT

Raw data files will not be provided for PK datasets.

4. LABORATORY DATA PRE-PROCESSING

4.1 Data Pre-Processing Steps

The following data pre-processing steps will be performed:

Table 1: Data Pre-Processing Overview

Step ID	Process Description	Process Details	Software	Input File Type	Output File Type
1	Assess precision and accuracy (PnA) for each run	Calculate the percentage deviation from the nominal concentrations. The acceptable limits include 75% of calibrators and 67% of QCs to be within 15% ($LOQ \leq 20\%$) from the nominal concentration. In-study PnA will be tabulated to ensure methods remain robust and reliable.	See Instrument in [Protocol ID]_[assay]_[date]_exp_metadata.csv	.csv	.csv
2	Tabulate data with the dosing information		Excel	.csv	Excel; completed concentration-time profile
3	PK analysis	[details pending provision of high-level overview]	[details pending provision of high-level overview]	.xlsx	.xlsx

4.2 Processed Data Files and Format

Processed data will be submitted in the following data format. Requirements for collection are noted in the last column titled “Collection Requirement”. Laboratory-processed data will be submitted in a [.csv] file to the ODMC.

- Filename will be [Protocol ID]_[assay]_[drug]_[date]_exp_data.csv
- The data must have the columns listed exactly as in the “Variable Name” column in the table below. Included values must be included as listed in the “Validation Rules” column in the table below.

Table 2: Variables to be Submitted in [Protocol ID]_[assay]_[drug]_[date]_exp_data.csv

Variable Name	Type	Length	Description	Column Unit	Validation Rules	Collection Requirement
Participant ID	Char	13	Participant ID	N/A	Participant ID will either be ####-####-#### or ####-####-##### format	Required
Drug	Char	50	Drug name	N/A	--	Required
Dose ([units])	Num	5	Drug dose	To be defined per protocol	Must match dosing value(s) associated with study.	Required
Cycle	Num	2	Cycle of drug	N/A	Must match number of cycles specified in the protocol (typically between 1-3).	Required if drug administered in a cycle
Cycle Day	Num	3	Day of cycle	N/A	--	Required if drug administered in a cycle
Infusion Duration	Num	5,2	Length of infusion	Hr	--	Optional
Kinetic Time	Num	6,2	Actual time since dose administration	Hr	--	Required
Protocol Defined Timepoint	Char	30	Protocol specified time since dose administration. Trough is utilized exclusively to confirm the validity of the same time point. If a timepoint is not considered a true trough sample, it will be noted accordingly in the comments for the corresponding timepoint.	Hr	--	Required

Variable Name	Type	Length	Description	Column Unit	Validation Rules	Collection Requirement
Specimen ID	Num	9	Specimen number, refers to the GlobalTrace barcode number printed on each cryovial	N/A	Maximum of 9 characters long.	Required
[Drug Name] Total Calculated Data Concentration ([units])	Char	12	Total drug concentration in specified units in “Concentration Unit”	See Unit in [Protocol ID]_[assay]_[date]_exp_meta data.csv	If result is below the LLOQ for the specified assay and run, report result BLQ	Required
Dilution	Num	1-3	Dilution of the sample injected in the machine	N/A		Required
[Drug Name] Unbound Calculated Data Concentration ([units])	Char	12	Unbound drug concentration in specified units in “Concentration Unit”	See Unit in [Protocol ID]_[assay]_[date]_exp_meta data.csv	If result is below the LLOQ for the specified assay and run, report result as BLQ	Required if unbound drug analyzed
[If applicable, Metabolite Name] Calculated Data Concentration ([units])	Char	12	Total drug metabolite concentration in specified units in “Concentration Unit”	See Unit in [Protocol ID]_[assay]_[date]_exp_meta data.csv	If result is below the LLOQ for the specified assay and run, report result as BLQ	Required if metabolite of drug analyzed
[If applicable, Metabolite Name] Dilution	Num	1-3	Dilution of the sample injected in the machine for metabolite concentration measurement	N/A		Required if metabolite of drug analyzed
[If applicable, Metabolite Name]	Char	12	Unbound drug metabolite concentration in specified	See Unit in	If result is below the LLOQ for the specified	Required if unbound metabolite of drug

Variable Name	Type	Length	Description	Column Unit	Validation Rules	Collection Requirement
Unbound Calculated Data Concentration ([units])			units in “Concentration Unit”	[Protocol ID]_[assay]_[date]_exp_metadata.csv	assay and run, report result as BLQ	analyzed
Comment	Char	500	Specimen-Level Result Comment Text or Cancellation Reason, where applicable	N/A	--	Optional

4.3 Analytic Data Files and Format

Analytic data will be submitted in the following processed data format. Requirements for collection are noted in the last column titled “Collection Requirement”. Laboratory-processed data will be submitted in a .csv file to the ODMC.

- Filename will be [Protocol ID]_[assay]_[drug]_[date]_analytic_data.csv
- The data must have the columns listed exactly as in the “Variable Name” column in the table below. Included values must be included as listed in the “Controlled Vocabulary” and “Validation Rules” columns in the table below.

Table 3: Variables to be Submitted in [Protocol ID]_[assay]_[drug]_[date]_analytic_data.csv

Variable Name	Type	Length	Description	Controlled Vocabulary	Validation Rules	Collection Requirement
Protocol	Char	5	Protocol ID	--	Must match ODMC-specified value for the study	Required
Assay	Char	4	Assay name	PK	Must match one of the values listed in the Controlled Vocabulary column	Required
Participant ID	Char	11-13	Participant ID	N/A	Participant ID will either be ###-###-### or ###-###-##### format	Required

Variable Name	Type	Length	Description	Controlled Vocabulary	Validation Rules	Collection Requirement
Enrollment Stratum	Char	50	Enrollment Stratum	To be defined per protocol	Must match protocol nomenclature	Optional
Enrollment Stratum Details	Char	50	Enrollment Stratum Details	To be defined per protocol	Must match protocol nomenclature	Optional
Analyte	Char	50	Analyte	To be defined per protocol	Must match one of the values listed in the Controlled Vocabulary column	Required
$C_{\max}$ ([units]) ¹	Num	13,4	Maximum concentration	--	Null or positive value	Optional
$T_{\max}$ ([units]) ¹	Num	13,4	Time to $C_{\max}$	--	Null or positive value; reported in Hours	Optional
$T_{1/2}$ ([units]) ¹	Num	13,4	Terminal half-life	--	Null or positive value; reported in Hours	Optional
AUC_{last} ([units])	Num	13,4	Area under the plasma concentration-time curve (AUC) value was calculated to last time point	--	Null or positive value	Optional
AUC_{trust} ([units])	Num	13, 4	Area under the plasma concentration-time curve (AUC) value calculated at the last trusted timepoint	--	Null or positive value	Optional

Variable Name	Type	Length	Description	Controlled Vocabulary	Validation Rules	Collection Requirement
$AUC_{trustdef}$	[TBD]	[TBD]	Definition of last trusted timepoint for AUC	--	Null or positive value	Required if AUC_{trust} is reported
AUC_{Tau} ([units])	Num	13, 4	Area under the plasma concentration-time curve (AUC) value during the dosing interval	--	Null or positive value	Optional
AUC_{inf} ([units])	Num	13,4	Area under the plasma concentration-time curve (AUC) value extrapolated to infinity	--	Null or positive value	Optional
Cl_s ([units])	Num	13,4	Systemic clearance	--	Null or positive value	Optional
Cl_s/F ([units])	Num	13,4	Apparent clearance	--	Null or positive value	Optional
V ([units])	Num	13,4	Volume of distribution	--	Null or positive value	Optional
V/F ([units])	Num	13,4	Apparent Volume of distribution	--	Null or positive value	Optional
$C_{ss,max}$ ([units])	Num	13,4	Steady-state maximum concentration	--	Null or positive value	Optional

Variable Name	Type	Length	Description	Controlled Vocabulary	Validation Rules	Collection Requirement
C _{ss,min} ([units])	Num	13,4	Steady-state minimum concentration (trough sample)	--	Null or positive value	Optional
C _{average} ([units])	Num	13,4	Average concentration	--	Null or positive value	Optional
Comments	Char	200	Participant-Level Result Comment Text or Cancellation Reason, where applicable	--	--	Optional

¹ For studies where PK parameters are measured multiple times after each dose, standard nomenclature is followed for naming these e.g., C_{max1}, C_{max2}, T_{max1}, T_{max2}

5. EXPERIMENTAL INFORMATION AND KEY META DATA DESCRIPTORS

Experimental meta data descriptors will be collected and reported in the following format. Requirements for collection are noted in the last column titled “Collection Requirement”. Experimental meta data descriptors will be submitted in a .csv file to the ODMC.

- Filename will be [Protocol ID]_[assay]_[date]_exp_metadata.csv
- The data must have the columns listed exactly as in the “Variable Name” column. Included values must be included as listed in the “Controlled Vocabulary” and “Validation Rules” columns in the table below.

Table 4: Variables to be Submitted in [Protocol ID]_[assay]_[date]_exp_metadata.csv

Variable Name	Type	Length	Description	Controlled Vocabulary	Existing Standard/Link	Validation Rules	Collection Requirement
Protocol	Char	5	Protocol	--	--	Must match ODMC-specified value for the study	Required

Variable Name	Type	Length	Description	Controlled Vocabulary	Existing Standard/Link	Validation Rules	Collection Requirement
Assay Type	Char	50	Assay type Name	PK	--	Must match the value listed in the Controlled Vocabulary column	Required
Assay	Char	50	Assay Name	ELISA, LC/Mass spec	--	Must match one of the values listed in the Controlled Vocabulary column	Required
Lab	Char	25	Testing Laboratory Name	AMC Pharmacology Core Covance – Chantilly Covance - Madison Gill Lab Frontage Laboratories Cambridge Biomedical	--	Must match one of the values listed in the Controlled Vocabulary column	Required
Lab Institution	Char	50	Testing Laboratory Institution	Johns Hopkins University Covance Covance University of South Carolina - Norris Hospital Frontage	--	Must match one of the values listed in the Controlled Vocabulary column	Required

Variable Name	Type	Length	Description	Controlled Vocabulary	Existing Standard/Link	Validation Rules	Collection Requirement
				Laboratories Cambridge Biomedical			
PI	Char	25	Testing Laboratory Principal Investigator	M. Rudek P. Gill	--	Must match one of the values listed in the Controlled Vocabulary column	Required for university-based laboratories
Specimen Type	Char	25	Specimen Type	PBMC, Serum, Plasma, Whole Blood	--	Must match one of the values listed in the Controlled Vocabulary column	Required
Instrument	Char	50	Instrument	SCIEX 4500 MS/MS, SCIEX 5500 MS/MS, SCIEX 5500 QTrap, SCIEX 6500+ MS/MS		Must match one of the values listed in the Controlled Vocabulary column	Required
PK Software	Char	50	PK Software	WinNonlin, PUMAS, NONMEM	--	Must match one of the values listed in the Controlled Vocabulary column	Required
PK Software Version	Num	4	PK Software	--	--	Must be in X.X format (i.e.,8.4)	Required

Variable Name	Type	Length	Description	Controlled Vocabulary	Existing Standard/Link	Validation Rules	Collection Requirement
Analyte A	Char	20	Analyte	<i>To be defined per protocol</i>		Must match one of the values listed in the Controlled Vocabulary column	Required
Analyte B	Char	20	Analyte	<i>To be defined per protocol B</i>		Must match one of the values in the Controlled Vocabulary column	As needed. Can be used to represent unbound concentrations
LLOQ [Analyte] ([units]) ¹	Num	5,2	Lower limit of quantification of assay	--	--	Format must be xx.xx	Required
ULOQ [Analyte] ([units]) ¹	Num	7,2	Upper limit of quantification of assay	--	--	Format must be xxxx.xx	Required
Max dilution validated	Num	1-3	Maximum dilution validated for the samples				Required
Controls	Char	50	Experimental controls			Must match one of the values listed in the Controlled Vocabulary column	Required

¹ Multiple Analytes and/or drug metabolites will require multiple columns to be defined per-project/study.

6. QUALITY METRICS

Sample quality metrics will be collected and reported in the following format. Requirements for collection are noted in the last column titled “Collection Requirement”. Sample quality metrics will be submitted in a .csv file to the ODMC. For PK datasets, the below variables will be appended to [Protocol ID]_[assay]_[drug]_[date]_analytic_data.csv.

- Variables will be included in [Protocol ID]_[assay]_[drug]_[date]_analytic_data.csv
- The data must have the columns listed exactly as in the “Variable Name” column in the table below. Included values must be included as listed in the “Validation Rules” column in the table below.

Table 5: Quality variables to be Submitted in [Protocol ID]_[assay]_[drug]_[date]_analytic_data.csv

Variable Name	Type	Length	Description	Validation Rules	Collection Requirement
Protocol	Char	5	Protocol ID	Must match ODMC-specified value for the study	Required
Specimen ID	Num	9	Specimen number, refers to the GlobalTrace barcode number printed on each cryovial	Maximum of 9 characters long.	Required
Days Between Collection and Testing	Num	4	Days between date of specimen collection and date of specimen testing	--	Required
Freeze/Thaw Cycles	Num	1	Specimen analyzed with this number of freeze/thaw cycles	Expected to be between 0-4	Preferred

7. MANIFEST OF FILE COLLECTION TO BE SUBMITTED TO THE ODMC

The manifest of the file collection describes the collection of files that are expected along with the transferred files to ensure the integrity of the collection. The following files are expected to be listed in the manifest, at minimum: [Protocol ID]_[assay]_[drug]_[date]_exp_data.csv, [Protocol ID]_[assay]_[drug]_[date]_analytic_data.csv, [Protocol ID]_[assay]_[date]_exp_metadata.csv, [Protocol ID]_[assay]_[date]_exp_manifest.csv.

Manifests will be submitted in a .csv to the ODMC. Requirements for collection are noted in the last column titled “Collection Requirement”.

- Filename will be [Protocol ID]_[assay]_[date]_exp_manifest.csv
- The data must have the columns listed exactly as in the “Variable Name” column. Included values must be included as listed in the “Controlled Vocabulary” and “Validation Rules” columns in the table below.

Table 6: Variables to be Submitted in [Protocol ID]_[assay]_[date]_exp_manifest.csv

Variable Name	Type	Length	Description	Controlled Vocabulary	Reference	Validation Rules	Collection Requirement
Protocol	Char	5	Protocol ID	--	N/A	Must match ODMC-specified value for the study	Required
File Name	Char	256	Name of the file	--	N/A	--	Required
File Type	Char	256	Type of the file	Processed, Analytic, Metadata, Quality Metrics	N/A	Must match one of the values listed in the Controlled Vocabulary column	Required
sha256sum	Char	256	sha256 Checksum	--	AMC Data Commons Data Preparation Manual	--	Required
Timestamp	yyyy-mm-dd hh:mm		Data / Time of file creation	--	N/A	--	Required

Assay results will be reviewed for accuracy and compliance with specified data standards by the laboratory staff prior to transfer per the laboratory's procedures and SOPs.

8. ODMC DATA PROCESSING

Results reported as BLQ will be replaced with <[LLOQ] for the applicable metabolite with [LLOQ] being replaced with the actual LLOQ value.

Quality metrics shown in Table 5 will be extracted into standard quality metric data tables.

9. APPROVAL

Data Standardization Plan Approval	
By signing this data transfer plan, I approve of the included specifications.	
Laboratory Resource Committee Chair:	
Signature: <i>Jeffrey Bethony</i>	Electronically signed by: Jeffrey Bethony Reason: I am Approving this document Date: Oct 14, 2026 16:31:06 ADT
_____ Jeffrey Bethony, PhD	_____ 10/14/2026 Date