

Clinical Development

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PALM_JPN4

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

Dataset	Name of dataset
Creating Program	The program that created the dataset
Description	Short description
Unique Identifier	Unique key
Sorted by	Sort key
Notes	Any useful notes

Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Codes	Codelist name
Comments	Variable source derivation explanation if variable derived.

1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/ Anonymisation data guidelines standards with the following exceptions:

- Subject initials will not be provided.
- Investigator Information will not be provided.
- Date of birth will not be provided, only age in years will be provided.
- Age will be grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Remove the free text verbatim terms.
- Remove "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial and Bottle number will not be provided.

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Remove SC (Subject Characteristics) dataset (its sensitive information). It may reveal subject personal identification information.
- For randomized subjects, DM.RFSTDTC will be used as Reference Date to derive relative days (referred as REF. DATE in the document). For screen failure subjects, DS.DSSTDTC (when DSDECOD="INFORMED CONSENT OBTAINED") will be used as a Reference date to derive relative days (referred as REF. DATE in the document).

1.3. Data Files

The PALM_JPN4 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DM

Dataset	DM
Creating program	dm.sas
Description	Demographics
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RFSTDTC,RFENDTC,BRTHDTC,ARMCD,ARM,SITENAM,RACEA1,RACEA2, RACEA3,RACEA4,RACEOTH,RACEOTHR

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study Site Id for De-Identity
AGE	char	Age		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.

Variable	Type	Label	Codes	Comments
AGEU	char	Age Units		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
RACEUNK	char	Race - Unknown		Collected at CRF.
RACENR	char	Race - Not Reported		Collected at CRF.
HOSP	char	Hospitalization at study entry		Collected at CRF.

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	STUDYID,DUSUBJID,AEBODSYS,AEDECOD,AESTDY,AESEQ
Sorted by	STUDYID,DUSUBJID,AEBODSYS,AEDECOD,AESTDY,AESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AETERM,AECAT,AESCAT,AESTDTC,AEENDTC,AEHOSDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
AESEQ	num	Sequence Number		Collected at CRF.
AEGRPID	char	Group ID		Collected at CRF.
AESPID	char	Sponsor-Defined Identifier		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AESEV	char	Severity/Intensity		Collected at CRF.
AESER	char	Serious Event		Collected at CRF.
AEACN	char	Action Taken with Study Treatment		Collected at CRF.
AEREL	char	Causality		Collected at CRF.
AEOUT	char	Outcome of Adverse Event		Collected at CRF.
AESCONG	char	Congenital Anomaly of Birth Defect		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
AESDTH	char	Results in Death		Collected at CRF.
AESHOSP	char	Requires or Prolongs Hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESMIE	char	Other Medically Important Serious Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
AECONTRT	char	Concomitant or Additional Trtmnt Given		Collected at CRF.
AESTDY	num	Relative Start Day of Adverse Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC - REF.DATE) + 1.
AEENDY	num	Relative End Day of Adverse Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC - REF.DATE) + 1.
AELLTCD	char	Lowest Level Term Code		Collected at CRF.
AELLT	char	Lowest Level Term		Collected at CRF.
AEPTCD	char	Dictionary-Derived Term Code		Collected at CRF.
AEBSCD	char	Body System or Organ Class Code		Collected at CRF.
AEDICTVS	char	Dictionary Version		Collected at CRF.
AESHOSPP	char	Did the event prolong hospitalization		Collected at CRF.
AESHOSPR	char	Did the event require hospitalization		Collected at CRF.
AETRLPRC	char	Related to Trial Procedure		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
AEHOSDY	num	Relative Hospitalization Day		If AEHOSDTC and REF.DATE not missing then perform below logic to calculate AEHOSDY, If AEHOSDTC less than REF.DATE then (AEHOSDTC- REF.DATE). Else if AEHOSDTC is greater than equal to REF.DATE then (AEHOSDTC- REF.DATE) +1.

1.4.3. Bio-Specimen Events – BE

Dataset	BE
Creating program	be.sas
Description	Bio-Specimen Events
Unique identifier	STUDYID, DUSUBJID, BEDECOD, BESTDY, BESEQ
Sorted by	STUDYID, DUSUBJID, BEDECOD, BESTDY, BESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BESPID, BETERM, BESCAT, BEBODSYS, BEDTC, BESTDTC, BEENDTC, BEENDY

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
BESEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
BEDECOD	char	Dictionary-Derived Term		Collected at CRF.
BECAT	char	Category for Bio-specimen Event		Collected at CRF.
BESTDY	num	Relative Start Day of Bio-specimen Event		If BESTDTC and REF.DATE not missing then perform below logic to calculate BESTDY, If BESTDTC less than REF.DATE then (BESTDTC - REF.DATE). Else if BESTDTC is greater than equal to REF.DATE then (BESTDTC - REF.DATE) +1.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

1.4.4. Controlled Terminology Definition – CD

Dataset	CD
Creating program	cd.sas
Description	Controlled Terminology Definition
Unique identifier	CODELST, DECOD
Sorted by	CODELST, DECOD
Notes	

Variable	Type	Label	Codes	Comments
CODELST	char	Codelist Name		Collected at CRF.
DATATYPE	char	Type of Codelist		Collected at CRF.
CODEVAL	char	Beginning Value		Collected at CRF.
RNK	char	Rank Order		Collected at CRF.

Variable	Type	Label	Codes	Comments
DECOD	char	Controlled Term Value		Collected at CRF.
REFERENC	char	Controlled Term Reference		Collected at CRF.
DICTNRY	char	Name of External Dictionary		Collected at CRF.
VERSION	char	Dictionary Version Number		Collected at CRF.

1.4.5. Concomitant Medications – CM

Dataset	CM
Creating program	cm.sas
Description	Concomitant Medications
Unique identifier	STUDYID, DUSUBJID, CMDECOD, CMSTDY, CMSEQ
Sorted by	STUDYID, DUSUBJID, CMDECOD, CMSTDY, CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CMTRT, CMSCAT, CMCLAS, CMCLASCD, CMSTDTC, CMENDTC, CMTRTCD, CMINDOTH

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
CMSEQ	num	Sequence Number		Collected at CRF.
CMGRPID	char	Group ID		Collected at CRF.
CMSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CMDECOD	char	Standardized Medication Name		Collected at CRF.
CMCAT	char	Category for Medication		Collected at CRF.
CMINDC	char	Indication		Collected at CRF.
CMDOSTXT	char	Dose Description		Collected at CRF.
CMDOSU	char	Dose Units		Collected at CRF.
CMDOSFRQ	char	Dosing Frequency Per Interval		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC - REF.DATE) +1.
CMENDY	num	Relative End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC - REF.DATE) +1.
AESEQE	char	Indication AE number(s)		Collected at CRF.
AESEQE1	char	Indication AE number(s)1		Collected at CRF.
AESEQE2	char	Indication AE number(s)2		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMPRIOR	char	Started prior to 28d before IC		Collected at CRF.
CMONGO	char	Ongoing at IC		Collected at CRF.
CMPRIOR2	char	Started prior to IC		Collected at CRF.
CMONGO2	char	Ongoing at end of study		Collected at CRF.
CMPRIOR3	char	Started prior to PANSS evaluation		Collected at CRF.
TTDAY	num	Number of Tolerability Testing Days		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

1.4.6. Dataset Level Metadata – DATADEF

Dataset	DATADEF
Creating program	datadef.sas
Description	Dataset Level Metadata
Unique identifier	DSORDER
Sorted by	DSORDER
Notes	

Variable	Type	Label	Codes	Comments
CLASSNM	char	Dataset Class		Collected at CRF.
DATASET	char	Dataset Name		Collected at CRF.
DSLABEL	char	Dataset Label		Collected at CRF.

Variable	Type	Label	Codes	Comments
STRUCTRE	char	Structure		Collected at CRF.
REPEAT	char	Repeating		Collected at CRF.
PURPOSE	char	Purpose of the Data		Collected at CRF.
REFDATA	char	Reference Data		Collected at CRF.
KEYS	char	Logical Key Order		Collected at CRF.
DSORDER	char	Dataset Order		Collected at CRF.

1.4.7.Disease Characteristics – DC

Dataset	DC
Creating program	dc.sas
Description	Disease Characteristics
Unique identifier	STUDYID,DUSUBJID,DCTESTCD,DCSEQ
Sorted by	STUDYID,DUSUBJID,DCTESTCD,DCSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DCSPID,VISITDY

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DCSEQ	num	Sequence Number		Collected at CRF.
DCTESTCD	char	Disease Characteristic Short Name		Collected at CRF.
DCTEST	char	Disease Characteristic Name		Collected at CRF.
DCCAT	char	Category for Disease Characteristic		Collected at CRF.
DCORRES	char	Result or Finding in Original Units		Collected at CRF.
DCSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

1.4.8.Disposition – DS

Dataset	DS
Creating program	ds.sas
Description	Disposition
Unique identifier	STUDYID,DUSUBJID,DSDECOD,DSSTDY,DSSEQ
Sorted by	STUDYID,DUSUBJID,DSDECOD,DSSTDY,DSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DSTERM,VISITDY,DSSTDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSSEQ	num	Sequence Number		Collected at CRF.
DSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DSDECOD	char	Standardized Disposition Term		Collected at CRF.
DSCAT	char	Category for Disposition Event		Collected at CRF.
DSSCAT	char	Subcategory for Disposition Event		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSSTDY	num	Relative Start Day of Disposition Event		If DSSTDTC and REF.DATE not missing then perform below logic to calculate DSSTDY, If DSSTDTC less than REF.DATE then (DSSTDTC- REF.DATE). Else if DSSTDTC is greater than equal to REF.DATE then (DSSTDTC- REF.DATE) +1.
AESEQE	char	AE Log Line Number		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
DSSTTM	num	Start Time of Disposition Event		If DSSTDTC contains time part then timepart(DSSTDTC) else DSSTTM equal to NULL.

1.4.9. Violations/Deviations – DV

Dataset	DV
Creating program	dv.sas
Description	Violations/Deviations
Unique identifier	STUDYID, DUSUBJID, DVDECOD, DVSEQ
Sorted by	STUDYID, DUSUBJID, DVDECOD, DVSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DVTERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DVSEQ	num	Sequence Number		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

1.4.10. ECG – EG

Dataset	EG
Creating program	eg.sas
Description	ECG
Unique identifier	STUDYID,DUSUBJID,EGTEST,EGDY,EGSEQ
Sorted by	STUDYID,DUSUBJID,EGTEST,EGDY,EGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EGREFID,EGSCAT,EGNRIND,EGBLFL,EGEVAL,EGDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
EGSEQ	num	Sequence Number		Collected at CRF.
EGSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EGTESTCD	char	ECG Test or Examination Short Name		Collected at CRF.
EGTEST	char	ECG Test or Examination Name		Collected at CRF.
EGCAT	char	Category for ECG		Collected at CRF.
EGORRES	char	Result or Finding in Original Units		Collected at CRF.
EGORRESU	char	Original Units		Collected at CRF.
EGSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
EGSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
EGSTRESU	char	Standard Units		Collected at CRF.
EGMETHOD	char	Method of ECG Test		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGDY	num	Relative Day of ECG		If EGDTC and REF.DATE not missing then perform below logic to calculate EGDY, If EGDTC less than REF.DATE then (EGDTC - REF.DATE). Else if EGDTC is greater than equal to REF.DATE then (EGDTC - REF.DATE) + 1.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
EGTM	num	Time of ECG		If EGDTC contains time part then timepart(EGDTC) else EGTM equal to NULL.

1.4.11. Exposure – EX

Dataset	EX
Creating program	ex.sas
Description	Exposure
Unique identifier	STUDYID, DUSUBJID, EXSTDY, EXSEQ
Sorted by	STUDYID, DUSUBJID, EXSTDY, EXSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EXTRT, EXCAT, EXSCAT, EXDOSE, EXDOSU, EXSTDTC, EXENDTC, EXENDY

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
EXSEQ	num	Sequence Number		Collected at CRF.
EXSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EXDOSFRM	char	Dose Form		Collected at CRF.
EXROUTE	char	Route of Administration		Collected at CRF.
EXLOC	char	Location of Dose Administration		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EXSTDY	num	Relative Start Day of Treatment		If EXSTDTC and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE). Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC - REF.DATE) +1.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
EXSTTM	num	Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM equal to NULL.

1.4.12. Inclusion/Exclusion Criterion Not Met – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Criterion Not Met
Unique identifier	STUDYID,DUSUBJID,IETESTCD,IESEQ
Sorted by	STUDYID,DUSUBJID,IETESTCD,IESEQ
Notes	Below listed variables will be dropped from dataset due to missing values: IESCAT,VISITDY

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
IESEQ	num	Sequence Number		Collected at CRF.
IESPID	char	Sponsor-Defined Identifier		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IEORRES	char	I/E Criterion Original Result		Collected at CRF.
IESTRESC	char	I/E Criterion Result in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

1.4.13. Laboratory Test Results – LB

Dataset	LB
Creating program	lb.sas
Description	Laboratory Test Results
Unique identifier	STUDYID,DUSUBJID,LBTEST,LBDY,LBSEQ
Sorted by	STUDYID,DUSUBJID,LBTEST,LBDY,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LBREFID,LBSPID,LBSCAT,LBBLFL,LBDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
LBSEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBTESTCD	char	Lab Test or Examination Short Name		Collected at CRF.
LBTEST	char	Lab Test or Examination Name		Collected at CRF.
LBCAT	char	Category for LabTest		Collected at CRF.
LBORRES	char	Result or Finding in Original Units		Collected at CRF.
LBORRESU	char	Original Units		Collected at CRF.
LBORNRL0	char	Reference Range Lower Limit in Orig Unit		Collected at CRF.
LBORNRLHI	char	Reference Range Upper Limit in Orig Unit		Collected at CRF.
LBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
LBSTNR0	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
LBSTRESU	char	Standard Units		Collected at CRF.
LBSTNR0	num	Reference Range Lower Limit-Std Unit		Collected at CRF.
LBSTNRHI	num	Reference Range Upper Limit-Std Unit		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSPCCND	char	Specimen Condition		Collected at CRF.
LBFAS	char	Fasting Status		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
LBDY	num	Relative Day of Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC - REF.DATE) + 1.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

1.4.14. Medical History – MH

Dataset	MH
Creating program	mh.sas
Description	Medical History
Unique identifier	STUDYID,DUSUBJID,MHDECOD,MHSEQ
Sorted by	STUDYID,DUSUBJID,MHDECOD,MHSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MHSPID,MHTERM,VISITDY,MHSTDTC,LSDST

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
MHSEQ	num	Sequence Number		Collected at CRF.
MHGRPID	char	Group ID		Collected at CRF.
MHDECOD	char	Dictionary-Derived Term		Collected at CRF.
MHCAT	char	Category for Medical History		Collected at CRF.
MHSCAT	char	Subcategory for Medical History		Collected at CRF.
MHBODSYS	char	Body System or Organ Class		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
MHLLTCD	char	Lowest Level Term Code		Collected at CRF.
MHLLT	char	Lowest Level Term		Collected at CRF.
MHPTCD	char	Dictionary-Derived Term Code		Collected at CRF.
MHBSCD	char	Body System or Organ Class Code		Collected at CRF.
MHDICTVS	char	Dictionary Version		Collected at CRF.
MHONGO	char	Condition Ongoing at Study Entry		Collected at CRF.
LDSDTF	char	Schizophrenia relapse		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
MHSTDY	num	Relative Start Day of Med History Event		If MHSTDTC and REF.DATE not missing then perform below logic to calculate MHSTDY, If MHSTDTC less than REF.DATE then (MHSTDTC - REF.DATE). Else if MHSTDTC is greater than equal to REF.DATE then (MHSTDTC - REF.DATE) +1.
LDSDY	num	Relative Latest Relapse Day		If LDSDT and REF.DATE not missing then perform below logic to calculate LDSDY, If LDSDT less than REF.DATE then (LSDT - REF.DATE). Else if LDSDT is greater than equal to REF.DATE then (LSDT - REF.DATE) +1.

1.4.15. Medication Kit – MK

Dataset	MK
Creating program	mk.sas
Description	Medication Kit
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MKTRT,MKSTDTC,MKNUM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
MKSEQ	num	Sequence Number		Collected at CRF.
MKSPID	char	Sponsor-Defined Identifier		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
MKSTDY	num	Relative Day of Medication Kit Dispensed		If MKSTDTC and REF.DATE not missing then perform below logic to calculate MKSTDY, If MKSTDTC less than REF.DATE then (MKSTDTC - REF.DATE). Else if MKSTDTC is greater than equal to REF.DATE then (MKSTDTC - REF.DATE) +1.

1.4.16. Pharmacokinetic Concentrations – PC

Dataset	PC
Creating program	pc.sas
Description	Pharmacokinetic Concentrations
Unique identifier	STUDYID,DUSUBJID,PCTEST,PCDY,PCSEQ
Sorted by	STUDYID,DUSUBJID,PCTEST,PCDY,PCSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PCREFID,PCSPID,PCNAM,PCDTC,PCRFTDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
PCSEQ	num	Sequence Number		Collected at CRF.
PCTESTCD	char	Test Short Name		Collected at CRF.
PCTEST	char	Test Name		Collected at CRF.
PCORRES	char	Result or Finding in Original Units		Collected at CRF.
PCORRESU	char	Original Units		Collected at CRF.
PCSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
PCSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
PCSTRESU	char	Standard Units		Collected at CRF.
PCSPEC	char	Specimen Material Type		Collected at CRF.
PCLOQ	num	Lower Limit of Quantitation		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
PCDY	num	Relative Start Day of Spec Collection		If PCDTDC and REF.DATE not missing then perform below logic to calculate PCDY, If PCDTDC less than REF.DATE then (PCDTDC - REF.DATE). Else if PCDTDC is greater than equal to REF.DATE then (PCDTDC - REF.DATE) +1.
PCTPT	char	Planned Time point Name		Collected at CRF.
PCTPTNUM	num	Planned Time point Number		Collected at CRF.
PCPURPOS	char	Purpose of Sample		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCSAMMAT	char	Sample Material		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
PCTM	num	Start Time of Spec Collection		If PCDTC contains time part then timepart(PCDTC) else PCTM equal to NULL.

1.4.17. Pharmacogenomics Findings – PF

Dataset	PF
Creating program	pf.sas
Description	Pharmacogenomics Findings
Unique identifier	STUDYID,DUSUBJID,PFDY,PFSEQ
Sorted by	STUDYID,DUSUBJID,PFDY,PFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PFSPID,PFTESTCD,PFTEST,PFMETHOD,PFSCAT,PFSTRESC,PFSTRESN,PFSTRESU,VISITDY,PFDC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
PFSEQ	num	Sequence Number		Collected at CRF.
PFCAT	char	Category for Lab Test		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
PFDY	num	Relative Day of Test		If PFDTC and REF.DATE not missing then perform below logic to calculate PFDY, If PFDTC less than REF.DATE then (PFDTC - REF.DATE). Else if PFDTC is greater than equal to REF.DATE then (PFDTC - REF.DATE) +1.
PFREAS	char	Reason for additional sample		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

1.4.18. Questionnaires – QS

Dataset	QS
Creating program	qs.sas
Description	Questionnaires
Unique identifier	STUDYID, DUSUBJID, QSTEST, QSDY, QSSEQ
Sorted by	STUDYID, DUSUBJID, QSTEST, QSDY, QSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: QSBLFL, QSDTC, RATINIT, REATDTC, LEATDTC, FSATDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
QSSEQ	num	Sequence Number		Collected at CRF.
QSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
QSTESTCD	char	Question Short Name		Collected at CRF.
QSTEST	char	Question Name		Collected at CRF.
QSCAT	char	Category of Question		Collected at CRF.
QSSCAT	char	Subcategory for Question		Collected at CRF.
QSORRES	char	Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
QSORRESU	char	Original Units		Collected at CRF.
QSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
QSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
QSSTRESU	char	Standard Units		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
QSDY	num	Relative Day of Finding		If QSDTC and REF.DATE not missing then perform below logic to calculate QSDY, If QSDTC less than REF.DATE then (QSDTC - REF.DATE). Else if QSDTC is greater than equal to REF.DATE then (QSDTC-REF.DATE) +1.
SUBENU	num	Total Number		Collected at CRF.
SUBE1BE	char	Non-Suicidal Self-Injurious Behavior		Collected at CRF.
ACAT1	char	Actual Lethality/Medical Damage-Recent		Collected at CRF.
ACAT2	char	Potential Lethality-Recent		Collected at CRF.
ACAT3	char	Actual Lethality/Medical Damage-Lethal		Collected at CRF.
ACAT4	char	Potential Lethality-Lethal		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACAT5	char	Actual Lethality/Medical Damage-Initial		Collected at CRF.
ACAT6	char	Potential Lethality-Initial		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
REATDY	num	Relative Most Recent Attempt Day		If REATDTC and REF.DATE not missing then perform below logic to calculate REATDY, If REATDTC less than REF.DATE then (REATDTC - REF.DATE). Else if REATDTC is greater than equal to REF.DATE then (REATDTC - REF.DATE) + 1.
LEATDY	num	Relative Most Lethal Attempt Day		If LEATDTC and REF.DATE not missing then perform below logic to calculate LEATDY, If LEATDTC less than REF.DATE then (LEATDTC - REF.DATE). Else if LEATDTC is greater than equal to REF.DATE then (LEATDTC - REF.DATE) + 1.
FSATDY	num	Relative Initial/ First Attempt Day		If FSATDTC and REF.DATE not missing then perform below logic to calculate FSATDY, If FSATDTC less than REF.DATE then (FSATDTC - REF.DATE). Else if FSATDTC is greater than equal to REF.DATE then (FSATDTC - REF.DATE) + 1.

1.4.19. Randomization – RA

Dataset	RA
Creating program	ra.sas
Description	Randomization
Unique identifier	STUDYID,DUSUBJID,RASEQ
Sorted by	STUDYID,DUSUBJID,RASEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ARMCD,ARM,RANUM,COHORT,RASTDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study Site Id for De-Identity
RASEQ	num	Sequence Number		Collected at CRF.
RASPID	char	Sponsor-Defined Identifier		Collected at CRF.
RAORIG	char	Origin of Randomization Data		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
RASTDY	num	Relative Day of Randomization		If RASTDTC and REF.DATE not missing then perform below logic to calculate RASTDY, If RASTDTC less than REF.DATE then (RASTDTC - REF.DATE). Else if RASTDTC is greater than equal to REF.DATE then (RASTDTC - REF.DATE) +1.

1.4.20. Surgery – SG

Dataset	SG
Creating program	sg.sas
Description	Surgery
Unique identifier	STUDYID,DUSUBJID,SGCAT,SGSEQ
Sorted by	STUDYID,DUSUBJID,SGCAT,SGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SGDECOD,SGPLNDTC,SGINDC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
SGSEQ	num	Sequence Number		Collected at CRF.
SGGRPID	char	Group ID		Collected at CRF.
SGSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SGTRT	char	Reported Name of Surgery/Procedure		Collected at CRF.
SGCAT	char	Category for Surgery/Procedure		Collected at CRF.
SGSCAT	char	Subcategory for Surgery/Procedure		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
SGPLNDY	num	Relative Planned Day of Surgery		If SGPLNDTC and REF.DATE not missing then perform below logic to calculate SGPLNDY, If SGPLNDTC less than REF.DATE then (SGPLNDTC- REF.DATE). Else if SGPLNDTC is greater than equal to REF.DATE then (SGPLNDTC- REF.DATE) +1.

1.4.21. Study Level Metadata – STUDYDEF

Dataset	STUDYDEF
Creating program	studydef.sas
Description	Study Level Metadata
Unique identifier	STUDYID
Sorted by	STUDYID
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
METAVS	char	Metadata Version Number		Collected at CRF.
JSTDVS	char	J&J Pharma Standard Version		Collected at CRF.
SDTMIGVS	char	CDISC SDTMIG Version Number		Collected at CRF.

1.4.22. Value Level Metadata – VALDEF

Dataset	VALDEF
Creating program	valdef.sas
Description	Value Level Metadata
Unique identifier	VALUEOID,VALVAL
Sorted by	VALUEOID,VALVAL
Notes	

Variable	Type	Label	Codes	Comments
VALUEOID	char	Value List		Collected at CRF.
VALVAL	char	Value		Collected at CRF.
VALLABEL	char	Label		Collected at CRF.
DATATYPE	char	Data Type		Collected at CRF.
LNGTH	char	Length		Collected at CRF.
DECDIG	char	Decimal Digits		Collected at CRF.
NUMFMT	char	Display Format		Collected at CRF.
ORIGIN	char	Origin of the Variable		Collected at CRF.
VARORDER	char	Variable Order		Collected at CRF.
CODELST	char	Codelist Name		Collected at CRF.
VALUELST	char	SDTM Controlled Terms/format		Collected at CRF.
COMMENTS	char	Comment		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRFPAGE	char	CRF Page Number		Collected at CRF.
COMPMETH	char	Computational Method		Collected at CRF.

1.4.23. Variable Level Metadata – VARDEF

Dataset	VARDEF
Creating program	vardef.sas
Description	Variable Level Metadata
Unique identifier	DATASET,VARNAME
Sorted by	DATASET,VARNAME
Notes	

Variable	Type	Label	Codes	Comments
DATASET	char	Dataset Name		Collected at CRF.
VARIABLE	char	SDTM Variable		Collected at CRF.
VARLABEL	char	SDTM Variable Label		Collected at CRF.
DATATYPE	char	Data Type		Collected at CRF.
LNTH	char	Length		Collected at CRF.
DECDIG	char	Decimal Digits		Collected at CRF.
NUMFMT	char	Display Format		Collected at CRF.
ORIGIN	char	Origin of the Variable		Collected at CRF.

Variable	Type	Label	Codes	Comments
VARROLE	char	Role		Collected at CRF.
CORE	char	Core		Collected at CRF.
MANDATRY	char	Mandatory		Collected at CRF.
VARKEY	char	Logical Key Order		Collected at CRF.
VARORDER	char	Variable Order		Collected at CRF.
CODELST	char	Codelist Name		Collected at CRF.
VALUELST	char	Value List		Collected at CRF.
CRFPAGE	char	CRF Page Number		Collected at CRF.
COMMENTS	char	Comment		Collected at CRF.
COMPMETH	char	Computational Method		Collected at CRF.
SUPPID	char	Suppelemental Qualfier Identifer		Collected at CRF.
SUPPEVAL	char	Evaluator		Collected at CRF.

1.4.24. Vital Signs – VS

Dataset	VS
Creating program	vs.sas
Description	Vital Signs
Unique identifier	STUDYID,DUSUBJID,VSTESTCD,VSDY,VSSEQ
Sorted by	STUDYID,DUSUBJID,VSTESTCD,VSDY,VSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: VSCAT,VSSCAT,VSPOS,VSBLFL,VSDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VSSEQ	num	Sequence Number		Collected at CRF.
VSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSORRES	char	Result or Finding in Original Units		Collected at CRF.
VSORRESU	char	Original Units		Collected at CRF.
VSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
VSSTRESU	char	Standard Units		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
VSDY	num	Relative Day of Measurements		If VSDTC and REF.DATE not missing then perform below logic to calculate VSDY, If VSDTC less than REF.DATE then (VSDTC - REF.DATE). Else if VSDTC is greater than equal to REF.DATE then (VSDTC - REF.DATE) +1.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

1.4.25. DNA sample – XZ

Dataset	XZ
Creating program	xz.sas
Description	DNA sample
Unique identifier	STUDYID,DUSUBJID,XZTESTCD
Sorted by	STUDYID,DUSUBJID,XZTESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: XZSPID,XZSCAT,XZSTRESN,XZSTRESU,XZBLFL,VISITDY,XZDTC,XZDY

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
XZSEQ	num	Sequence Number		Collected at CRF.
XZTESTCD	char	Question Short Name		Collected at CRF.
XZTEST	char	Question Name		Collected at CRF.
XZCAT	char	Category of DNA sample		Collected at CRF.
XZORRES	char	Finding in Original Units		Collected at CRF.
XZORRESU	char	Original Units		Collected at CRF.
XZSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity