

Clinical Development

Paliperidone[®]

R076477-PSZ3003

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.
- Subject and center/site numbers will be assigned in a random manner so they are not matching the subject and center/site numbers that were used in the actual trial.
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- 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.
- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Complete missing value variables will be removed.

- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's relative day cannot be calculated.
- Comments dataset will be submitted with zero observation.
- Lab Name and Lab Identifier information will not be provided.
- Date of Sign. on Informed Consent will be used as Reference Date to derive Relative days.
- Dataset containing Subject Characteristics information will not be submitted due to sensitivity of information (e.g. SC).
- SURGERY related dataset will not be submitted due to sensitivity of information. (e.g. SG)
- Dataset information related to codelists will not be submitted. (e.g. CD)
- Dataset containing information related to Medication Kit numbers will not be submitted (e.g. MK)
- Dataset containing Pharmacogenetic information will not be submitted due to sensitivity of information. (e.g. DNRSLT)

1.3 Data Files

The R076477-PSZ3003 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	DUSUBJID
Sorted by	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, INVID, INVNAM, BRTHDTC, AGEU, DMDTC, MBRTHDTC, FBRTHDTC, RACEA, RACEAIAN, RACEBA ,RACENHOP, RACENR, RACEOTH, RACEOTHR, RACEUNK, RACEW

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

Variable	Type	Label	Codes	Comments
DSITEID	char	Study Site Id Assigned for De-identity		Randomly assigned Study Site Id for De-identity
AGE	char	Age in years		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= int((DSSTDTC – BRTHDTC)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
FAGE	char	Father's Age in years		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: $AGE = \text{int}((DSSTDTC - FBRTHDTC)/365.25)$ If age greater than 89+ years then will be grouped as per HIPAA rules
MAGE	char	Mother's Age in years		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: $AGE = \text{int}((DSSTDTC - MBRTHDTC)/365.25)$ If age greater than 89+ years then will be grouped as per HIPAA rules
DMDY	num	Relative Day of Collection		If DMDTC and DSSTDTC not missing then perform below logic to calculate DMDY, If DMDTC less than DSSTDTC then (DMDTC - DSSTDTC). Else if DMDTC is greater than equal to DSSTDTC then (DMDTC - DSSTDTC) +1.

1.4.2 Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID,AEDECOD,AESTDY,AEENDY,AESEQ
Sorted by	DUSUBJID,AEDECOD,AESTDY,AEENDY,AESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AEREFID, AETERM, AEMODIFY, AESTDTC, AEENDTC

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
AESEQ	num	Sequence Number		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.

Variable	Type	Label	Codes	Comments
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 or 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.
AECONTRT	char	Concomitant or Additional Trtmnt Given		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
AEDICTVS	char	Dictionary Version		Collected at CRF.
AEHLGT	char	High Level Group Term		Collected at CRF.
AEHLT	char	Higher Level Term		Collected at CRF.
AELLT	char	Lower Level Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
AELLTCD	char	Lower Level Term Code		Collected at CRF.
AESHOSPP	char	Prolongs Hospitalization		Collected at CRF.
AESHOSPR	char	Requires Hospitalization		Collected at CRF.
AETRLPRC	char	Related to Trial Procedure		Collected at CRF.
AESTDY	num	Relative Start Day of Adverse Event		If AESTDTC and DSSTDTC not missing then perform below logic to calculate AESTDY, If AESTDTC less than DSSTDTC then (AESTDTC - DSSTDTC).Else if AESTDTC is greater than equal to DSSTDTC then (AESTDTC- DSSTDTC) +1.
AEENDY	num	Relative End Day of Adverse Event		If AEENDTC and DSSTDTC not missing then perform below logic to calculate AEENDY, If AEENDTC less than DSSTDTC then (AEENDTC - DSSTDTC).Else if AEENDTC is greater than equal to DSSTDTC then (AEENDTC- DSSTDTC) +1.

1.4.3 Concomitant Medications – CM

Dataset	CM
Creating program	cm.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID,CMDECOD,CMDOSE,CMDOSFRQ,CMROUTE,CMSTDY,CMSEQ
Sorted by	DUSUBJID,CMDECOD,CMDOSE,CMDOSFRQ,CMROUTE,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, CMMODIFY,CMSTDTC, CMENDTC, AESEQ, AESEQ4, AESEQ5, CMATC10, CMATC11, CMATC12, CMATC13, CMATC14, CMATC8, CMATC9, CMATCCD8, CMATCCD9, CMATCD10, CMATCD11, CMATCD12, CMATCD13, CMATCD14, 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
CMSEQ	num	Sequence Number		Collected at CRF.
CMSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CMDECOD	char	Standardized Medication Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCAT	char	Category for Medication		Collected at CRF.
CMINDC	char	Indication		Collected at CRF.
CMCLAS	char	Medication Class		Collected at CRF.
CMCLASCD	char	Medication Class Code		Collected at CRF.
CMDOSE	num	Dose per Administration		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.
AESEQ1	num	AE Sequence Number 1		Collected at CRF.
AESEQ2	num	AE Sequence Number 2		Collected at CRF.
AESEQ3	num	AE Sequence Number 3		Collected at CRF.
CMATC0	char	ATC Text 0		Collected at CRF.
CMATC1	char	ATC Text 1		Collected at CRF.
CMATC2	char	ATC Text 2		Collected at CRF.
CMATC3	char	ATC Text 3		Collected at CRF.
CMATC4	char	ATC Text 4		Collected at CRF.
CMATC5	char	ATC Text 5		Collected at CRF.
CMATC6	char	ATC Text 6		Collected at CRF.
CMATC7	char	ATC Text 7		Collected at CRF.
CMATCCD0	char	ATC Code 0		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMATCCD1	char	ATC Code 1		Collected at CRF.
CMATCCD2	char	ATC Code 2		Collected at CRF.
CMATCCD3	char	ATC Code 3		Collected at CRF.
CMATCCD4	char	ATC Code 4		Collected at CRF.
CMATCCD5	char	ATC Code 5		Collected at CRF.
CMATCCD6	char	ATC Code 6		Collected at CRF.
CMATCCD7	char	ATC Code 7		Collected at CRF.
CMDICTVS	char	Dictionary version		Collected at CRF.
CMONGO	char	Treatment Ongoing at End of Study		Collected at CRF.
CMPRIOR	char	Treatment Began Prior to Entry		Collected at CRF.
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and DSSTDTC not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than DSSTDTC then (CMSTDTC - DSSTDTC).Else if CMSTDTC is greater than equal to DSSTDTC then (CMSTDTC- DSSTDTC) +1.
CMENDY	num	Relative End Day of Medication		If CMENDTC and DSSTDTC not missing then perform below logic to calculate CMENDY, If CMENDTC less than DSSTDTC then (CMENDTC - DSSTDTC).Else if CMENDTC is greater than equal to DSSTDTC then (CMENDTC- DSSTDTC) +1.

1.4.4 Comments – CO

Dataset	CO
Creating program	co.sas
Description	Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Comments data is sensitive data, contains free text information. Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Empty dataset will be submitted.
DOMAIN	char	Domain Abbreviation		Empty dataset will be submitted.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Empty dataset will be submitted.
COSEQ	num	Sequence Number		Empty dataset will be submitted.
COVAL	char	Comment		Empty dataset will be submitted.
RDOMAIN	char	Related Domain Abbreviation		Empty dataset will be submitted.
COREF	char	Comment Reference		Empty dataset will be submitted.

1.4.5 Disposition – DS

Dataset	DS
Creating program	ds.sas
Description	Disposition
Unique identifier	DUSUBJID,DSDECOD,DSSTDY
Sorted by	DUSUBJID,DSDECOD,DSSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DSTERM, DSDTC, DSSTDTC, AESEQ1, AESEQ2, AESEQ3, AESEQ4, AESEQ5

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.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
DSDY	num	Relative Day of Collection		If DSDTC and DSSTDTC not missing then perform below logic to calculate DSDY, If DSDTC less than DSSTDTC then (DSDTC - DSSTDTC).Else if DSDTC is greater than equal to DSSTDTC then (DSDTC- DSSTDTC) +1.
DSSTDY	num	Relative Start Day of Disposition Event		If DSSTDTC and DSSTDTC not missing then perform below logic to calculate DSSTDY, If DSSTDTC less than DSSTDTC then (DSSTDTC - DSSTDTC).Else if DSSTDTC is greater than equal to DSSTDTC then (DSSTDTC- DSSTDTC) +1.

1.4.6 Protocol Deviations – DV

Dataset	DV
Creating program	dv.sas
Description	Protocol Deviations
Unique identifier	DUSUBJID,DVDECOD,DVSEQ
Sorted by	DUSUBJID,DVDECOD,DVSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DVSCAT, DVTERM, DVSTDTC, DVENDTC

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
DVSEQ	num	Sequence Number		Collected at CRF.
DVCAT	char	Category for Protocol Deviation		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.

1.4.7 ECG Test Results – EG

Dataset	EG
Creating program	eg.sas
Description	ECG Test Results
Unique identifier	DUSUBJID,EGTESTCD,VISITNUM,EGTPTNUM,EGORRES,EGDY
Sorted by	DUSUBJID,EGTESTCD,VISITNUM,EGTPTNUM,EGORRES,EGDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EGREFID, EGSTAT, EGREASND, EGBLFL, EGDTIC

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
EGSEQ	num	Sequence Number		Collected at CRF.
EGGRPID	char	Group ID		Collected at CRF.
EGSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EGTESTCD	char	ECG Test or Examination Short Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGTEST	char	ECG Test or Examination Name		Collected at CRF.
EGCAT	char	Category for ECG		Collected at CRF.
EGSCAT	char	Subcategory for ECG		Collected at CRF.
EGPOS	char	ECG Position of Subject		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.
EGNAM	char	Vendor Name		Collected at CRF.
EGMETHOD	char	Method of ECG Test		Collected at CRF.
EGEVAL	char	Evaluator		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
EGTPTNUM	num	Planned Time Point Number		Collected at CRF.
EGTPT	char	Planned Time Point Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGTM	num	Relative Time of ECG		If EGDTC contains time part then timepart(EGDTC) else EGTM equal to NULL.
EGDY	num	Relative Day of ECG		If EGDTC and DSSTDTC not missing then perform below logic to calculate EGDY, If EGDTC less than DSSTDTC then (EGDTC - DSSTDTC).Else if EGDTC is greater than equal to DSSTDTC then (EGDTC- DSSTDTC) +1.

1.4.8 Exposure – EX

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

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.
EXCAT	char	Category for Treatment		Collected at CRF.
EXDOSTXT	char	Dose Description		Collected at CRF.
EXDOSFRM	char	Dose Form		Collected at CRF.
EXROUTE	char	Route of Administration		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
EXAMONT	num	Amount Administered		Collected at CRF.
EXSTTM	num	Relative Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM equal to NULL.
EXSTDY	num	Relative Start Day of Treatment		If EXSTDTC and DSSTDTC not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than DSSTDTC then (EXSTDTC - DSSTDTC).Else if EXSTDTC is greater than equal to DSSTDTC then (EXSTDTC- DSSTDTC) +1.

Variable	Type	Label	Codes	Comments
EXENDY	num	Relative End Day of Treatment		If EXENDTC and DSSTDTC not missing then perform below logic to calculate EXENDY, If EXENDTC less than DSSTDTC then (EXENDTC - DSSTDTC).Else if EXENDTC is greater than equal to DSSTDTC then (EXENDTC- DSSTDTC) +1.

1.4.9 Inclusion/Exclusion Exceptions – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Exceptions
Unique identifier	DUSUBJID,IETESTCD
Sorted by	DUSUBJID,IETESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IEDTC

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
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.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
IEDY	num	Relative Day of Collection		If IEDTC and DSSTDTC not missing then perform below logic to calculate IEDY, If IEDTC less than DSSTDTC then (IEDTC - DSSTDTC).Else if IEDTC is greater than equal to DSSTDTC then (IEDTC- DSSTDTC) +1.

1.4.10 Laboratory Test Results – LB

Dataset	LB
Creating program	lb.sas
Description	Laboratory Test Results
Unique identifier	DUSUBJID, LBTESTCD, VISITNUM, LBTPPTNUM, LBCAT, LBMETHOD, LBDY
Sorted by	DUSUBJID, LBTESTCD, VISITNUM, LBTPPTNUM, LBCAT, LBMETHOD, LBDY
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, LBNAM, LBLFL, 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.
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 Lab Test		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
LBORNRHI	char	Reference Range Upper Limit in Orig Unit		Collected at CRF.
LBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
LBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
LBSTRESU	char	Standard Units		Collected at CRF.
LBSTNRLO	num	Reference Range Lower Limit-Std Units		Collected at CRF.
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
LBREASND	char	Reason Test Not Done		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBSPCCND	char	Specimen Condition		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBFAS	char	Fasting Status		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
LBTPT	char	Planned Time Point Name		Collected at CRF.
LBTPTNUM	num	Planned Time Point Number		Collected at CRF.
CNVNRHI	num	Conventional Reference Range High		Collected at CRF.
CNVNRLO	num	Conventional Reference Range Low		Collected at CRF.
CNVRESC	char	Conventional Text Result		Collected at CRF.
CNVRESN	num	Conventional Numeric Result		Collected at CRF.
CNVU	char	Conventional Units		Collected at CRF.
LBTM	num	Relative Time of Specimen Collection		If LBDTC contains time part then timepart(LBDTC) else LBTM equal to NULL.
LBDY	num	Relative Day of Specimen Collection		If LBDTC and DSSTDTC not missing then perform below logic to calculate LBDY, If LBDTC less than DSSTDTC then (LBDTC - DSSTDTC).Else if LBDTC is greater than equal to DSSTDTC then (LBDTC- DSSTDTC) +1.

1.4.11 Medical History – MH

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

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.
MHSPID	char	Sponsor-Defined Identifier		Collected at CRF.
MHSCAT	char	Category for Medical History		Collected at CRF.
MHSCAT	char	Subcategory for Medical History		Collected at CRF.

Variable	Type	Label	Codes	Comments
MHOCCUR	char	Medical History Occurrence		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
MHAGE	char	Age at diagnosis		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
MHMEM	char	Family member		Collected at CRF.
MHNUM	num	Number		Collected at CRF.
MHONGO	char	Medical History Ongoing at Study Entry		Collected at CRF.
MHDY	num	Relative Day of History Collection		If MHDTC and DSSTDTC not missing then perform below logic to calculate MHDY, If MHDTC less than DSSTDTC then (MHDTC - DSSTDTC).Else if MHDTC is greater than equal to DSSTDTC then (MHDTC- DSSTDTC) +1.

Variable	Type	Label	Codes	Comments
MHSTDY	num	Relative Start Day of MH Event		If MHSTDTC and DSSTDTC not missing then perform below logic to calculate MHSTDY, If MHSTDTC less than DSSTDTC then (MHSTDTC - DSSTDTC).Else if MHSTDTC is greater than equal to DSSTDTC then (MHSTDTC- DSSTDTC) +1.
MHENDY	num	Relative End Day of Medical History Event		If MHENDTC and DSSTDTC not missing then perform below logic to calculate MHENDY, If MHENDTC less than DSSTDTC then (MHENDTC - DSSTDTC).Else if MHENDTC is greater than equal to DSSTDTC then (MHENDTC- DSSTDTC) +1.

1.4.12 Pharmacokinetic Concentrations – PC

Dataset	PC
Creating program	pc.sas
Description	Pharmacokinetic Concentrations
Unique identifier	DUSUBJID,PCTESTCD,PCSPEC,VISITNUM,PCTPTNUM
Sorted by	DUSUBJID,PCTESTCD,PCSPEC,VISITNUM,PCTPTNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PCREFID, 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
PCSEQ	num	Sequence Number		Collected at CRF.
PCSPID	char	Sponsor-Defined Identifier		Collected at CRF.
PCTESTCD	char	Test Short Name		Collected at CRF.
PCTEST	char	Test Name		Collected at CRF.
PCCAT	char	Category for PK Concentration		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCSCAT	char	Test Subcategory		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 or Finding in Std Units		Collected at CRF.
PCSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
PCSTRESU	char	Standard Units		Collected at CRF.
PCLOQ	num	Lower Limit of Quantitation		Collected at CRF.
PCSTAT	char	Status		Collected at CRF.
PCREASND	char	Reason Test Not Done		Collected at CRF.
PCSPEC	char	Specimen Type		Collected at CRF.
PCSPCCND	char	Specimen Condition		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
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.
PCTM	num	Relative Start Time of Specimen Collection		If PCDTC contains time part then timepart(PCDTC) else PCTM equal to NULL.
PCDY	num	Relative Start Day of Specimen Collection		If PCDTC and DSSTDTC not missing then perform below logic to calculate PCDY, If PCDTC less than DSSTDTC then (PCDTC - DSSTDTC).Else if PCDTC is greater than equal to DSSTDTC then (PCDTC- DSSTDTC) +1.
PCRFTDY	num	Relative Day of Reference Point		If PCRFTDTC and DSSTDTC not missing then perform below logic to calculate PCRFTDY, If PCRFTDTC less than DSSTDTC then (PCRFTDTC - DSSTDTC).Else if PCRFTDTC is greater than equal to DSSTDTC then (PCRFTDTC- DSSTDTC) +1.

1.4.13 Physical Examinations – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examinations
Unique identifier	DUSUBJID,PETESTCD,VISITNUM
Sorted by	DUSUBJID,PETESTCD,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PEORRES, PESTRESN, PESTRESU, PEREASND, PEBLFL, PEDTC

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
PESEQ	num	Sequence Number		Collected at CRF.
PESPID	char	Sponsor-Defined Identifier		Collected at CRF.
PETESTCD	char	Body System Examined Short Name		Collected at CRF.
PETEST	char	Body System Examined		Collected at CRF.
PECAT	char	Category for Examination		Collected at CRF.

Variable	Type	Label	Codes	Comments
PESTRESC	char	Character Result/Finding in Std. Format		Collected at CRF.
PESTAT	char	Examination Status		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
PEDY	num	Relative Day of Examination		If PEDTC and DSSTDTC not missing then perform below logic to calculate PEDY, If PEDTC less than DSSTDTC then (PEDTC - DSSTDTC).Else if PEDTC is greater than equal to DSSTDTC then (PEDTC- DSSTDTC) +1.

1.4.14 Questionnaires – QS

Dataset	QS
Creating program	qs.sas
Description	Questionnaires
Unique identifier	DUSUBJID,QSTESTCD,VISITNUM,QSSCAT
Sorted by	DUSUBJID,QSTESTCD,VISITNUM,QSSCAT
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, QSNAM

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.

Variable	Type	Label	Codes	Comments
QSORRES	char	Finding in Original Units		Collected at CRF.
QSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
QSSTRESN	num	Numeric Finding in Standard Units		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
QSEVAL	char	Evaluator		Collected at CRF.
QSNUM	num	Total score		Collected at CRF.
QSDY	num	Relative Day of Finding		If QSDTC and DSSTDTC not missing then perform below logic to calculate QSDY, If QSDTC less than DSSTDTC then (QSDTC - DSSTDTC).Else if QSDTC is greater than equal to DSSTDTC then (QSDTC- DSSTDTC) +1.

1.4.15 Randomization – RA

Dataset	RA
Creating program	ra.sas
Description	Randomization
Unique identifier	DUSUBJID,RAORIG
Sorted by	DUSUBJID,RAORIG
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, RASTDTC, STRATA1, STRATA2, STRATA3

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.

Variable	Type	Label	Codes	Comments
RAORIG	char	Origin of Randomization Data		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
RAREG	char	Regimen Code		Collected at CRF.
RATRTP	char	Planned Treatment Group		Collected at CRF.
RATRTPN	num	Planned Treatment Group Code		Collected at CRF.
RASTDY	num	Relative Day of Randomization		If RASTDTC and DSSTDTC not missing then perform below logic to calculate RASTDY, If RASTDTC less than DSSTDTC then (RASTDTC - DSSTDTC).Else if RASTDTC is greater than equal to DSSTDTC then (RASTDTC- DSSTDTC) +1.

1.4.16 Related Records – RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Sorted by	RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Notes	Below listed variables will be dropped from dataset due to missing values: RELTYPE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
RELID	char	Relationship Identifier		Collected at CRF.

1.4.17 Substances Use– SU

Dataset	SU
Creating program	su.sas
Description	Substance Use
Unique identifier	DUSUBJID,SUTRT,SUCAT
Sorted by	DUSUBJID,SUTRT,SUCAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUENDTC

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
SUSEQ	num	Sequence Number		Collected at CRF.
SUSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SUTRT	char	Reported Name of Substance		Collected at CRF.
SUCAT	char	Category for Substance Use		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUOCCUR	char	SU Occurrence		Collected at CRF.
SUDOSE	num	Substance Use Consumption		Collected at CRF.
SUDOSU	char	Consumption Units		Collected at CRF.
SUDOSFRQ	char	Use Frequency Per Interval		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
SUDUR	char	Duration of Substance Use		Collected at CRF.
SUAGE	char	Age		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
SUNUM	num	Number of consumptions		Collected at CRF.
SUMEM	char	Lack of memory		Collected at CRF.
SUCON	char	Expression of concern		Collected at CRF.
SUNON	char	No treatment		Collected at CRF.
SUOU	char	Outpatient		Collected at CRF.
SUGR	char	Voluntary group		Collected at CRF.
SUIN	char	Inpatient		Collected at CRF.
COQM	char	Medical Consequence		Collected at CRF.
COQL	char	Legal consequence		Collected at CRF.

Variable	Type	Label	Codes	Comments
COQS	char	Social Consequence		Collected at CRF.
SUPAS1	char	Past stimulant		Collected at CRF.
SUPAS2	char	Past hypnotic		Collected at CRF.
SUPAS3	char	Past cocaine		Collected at CRF.
SUPAS4	char	Past opioid		Collected at CRF.
SUPAS5	char	Past hallucinogen		Collected at CRF.
SUPAS6	char	Past solvent		Collected at CRF.
SUPASOTH	char	Past other		Collected at CRF.

1.4.18 Subject Visits – SV

Dataset	SV
Creating program	sv.sas
Description	Subject Visits
Unique identifier	DUSUBJID,VISITNUM
Sorted by	DUSUBJID,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SVSTDTC, SVENDTC

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
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
SVUPDES	char	Description of Unplanned Visit		Collected at CRF.
SVSTTM	num	Relative Start Time of Visit		If SVSTDTC contains time part then timepart(SVSTDTC) else SVSTTM equal to NULL.

Variable	Type	Label	Codes	Comments
SVSTDY	num	Relative Start Day of Visit		If SVSTDTC and DSSTDTC not missing then perform below logic to calculate SVSTDY, If SVSTDTC less than DSSTDTC then (SVSTDTC - DSSTDTC).Else if SVSTDTC is greater than equal to DSSTDTC then (SVSTDTC- DSSTDTC) +1.

1.4.19 Trial Inclusion/Exclusion Criteria – TI

Dataset	TI
Creating program	ti.sas
Description	Trial Inclusion/Exclusion Criteria
Unique identifier	STUDYID,IETESTCD
Sorted by	STUDYID,IETESTCD
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.

1.4.20 Vital Signs – VS

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

Variable	Type	Label	Codes	Comments
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.
VSPOS	char	Vital Signs Position of Subject		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.
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.
EPOCH	char	Trial Epoch		Collected at CRF.
VSDY	num	Relative Day of Measurements		If VSDTC and DSSTDTC not missing then perform below logic to calculate VSDY, If VSDTC less than DSSTDTC then (VSDTC - DSSTDTC).Else if VSDTC is greater than equal to DSSTDTC then (VSDTC- DSSTDTC) +1.