

Clinical Development

Paliperidone Palmitate

R092670PSY3012

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.
- Complete missing value 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.
- CO i.e. Comments dataset will be submitted with zero observation due to sensitivity of data.
- Dataset containing subject personal information is sensitive and hence will not be submitted. (ex.SC)
- Dataset does not have any significant information left, after removing sensitive information, for further analysis. Hence, will not be submitted in De-identified datasets (eg. PF, SUPPEX, SUPPQS).
- Dataset containing Medical Kit information will not be submitted. (ex. MK)
- Datasets containing insignificant information will not be submitted. (eg. SUPPSG)
- Pharmacokinetic related information is sensitive. Hence, will not be submitted (e.g. PC, SUPPPC)
- For Randomized subjects, "Subject Reference Start Date" (RFSTDTC) will be used as Reference Date (Referred as REF.DATE in the document) to derive relative day. For Screen Failure subjects, "Date of Informed Consent" (RFICDTC) from DM dataset will be used as a reference date (Referred as REF.DATE in the document) to derive relative days.

1.3. Data Files

The R092670PSY3012 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: RFSTDTC,DTHDTC,RPENDTC,RFICDTC,RFXENDTC,RFXSTDTC,RFENDTC,DMDTC,INVID,INVNAM,BRTHDTC

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
DTHFL	char	Subject Death Flag		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-identity		Randomly assigned Study Site Id for De-identity

Variable	Type	Label	Codes	Comments
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.
AGEU	char	Age Units		Collected at CRF.
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.
ACTARMCD	char	Actual Arm Code		Collected at CRF.
ACTARM	char	Description of Actual Arm		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
DMDY	num	Relative Day of Collection		If DMDTC and REF.DATE not missing then perform below logic to calculate DMDY, If DMDTC less than REF.DATE then (DMDTC - REF.DATE). Else if DMDTC is greater than equal to REF.DATE then (DMDTC - REF.DATE) +1.
RFENDY	num	Relative Subject Reference End Day		If RFENDTC and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDTC less than REF.DATE then (RFENDTC - REF.DATE). Else if RFENDTC is greater than equal to REF.DATE then (RFENDTC - REF.DATE) +1.
RFXSTTM	num	Time of First Study Treatment		If RFXSTDTC contains time part then timepart(RFXSTDTC) else RFXSTTM equal to NULL.

Variable	Type	Label	Codes	Comments
RFXSTDY	num	Relative Day of First Study Treatment		If RFXSTDTC and REF.DATE not missing then perform below logic to calculate RFXSTDY, If RFXSTDTC less than REF.DATE then (RFXSTDTC - REF.DATE). Else if RFXSTDTC is greater than equal to REF.DATE then (RFXSTDTC - REF.DATE) +1.
RFXENTM	num	Time of Last Study Treatment		If RFXENDTC contains time part then timepart(RFXENDTC) else RFXENTM equal to NULL.
RFXENDY	num	Relative Day of Last Study Treatment		If RFXENDTC and REF.DATE not missing then perform below logic to calculate RFXENDY, If RFXENDTC less than REF.DATE then (RFXENDTC - REF.DATE). Else if RFXENDTC is greater than equal to REF.DATE then (RFXENDTC - REF.DATE) +1.
RFPENDY	num	Relative Day of End of Participation		If RFPENDTC and REF.DATE not missing then perform below logic to calculate RFPENDY, If RFPENDTC less than REF.DATE then (RFPENDTC - REF.DATE). Else if RFPENDTC is greater than equal to REF.DATE then (RFPENDTC - REF.DATE) +1.
DTHDY	num	Relative Day of Death		If DTHDTC and REF.DATE not missing then perform below logic to calculate DTHDY, If DTHDTC less than REF.DATE then (DTHDTC - REF.DATE). Else if DTHDTC is greater than equal to REF.DATE then (DTHDTC - REF.DATE) +1.

1.4.2. Supplemental Qualifiers for DM – SUPPDM

Dataset	SUPPDM
Creating program	dm.sas
Description	Supplemental Qualifiers for DM
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: IDVAR,IDVARVAL,QEVAL

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
QNAM	char	Qualifier Variable Name		If QNAM in (RACEW, RACEOTHR, RACEOTH, RACEASUB, RACEAIAN, DMMOYEAR, DMFAYEAR) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.3. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	STUDYID,DUSUBJID,AEDECOD,AESTDY,AESEQ
Sorted by	STUDYID,DUSUBJID,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,AEENDTC,AESTDTC,AEMODIFY

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.
AELLT	char	Lowest Level Term		Collected at CRF.
AELLTCD	num	Lowest Level Term Code		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEPTCD	num	Preferred Term Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEHLT	char	High Level Term		Collected at CRF.
AEHLTCD	num	High Level Term Code		Collected at CRF.
AEHLGT	char	High Level Group Term		Collected at CRF.
AEHLGTCD	num	High Level Group Term Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AEBDSYCD	num	Body System or Organ Class Code		Collected at CRF.
AESOC	char	Primary System Organ Class		Collected at CRF.
AESOCCD	num	Primary System Organ Class Code		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 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.

Variable	Type	Label	Codes	Comments
AESMIE	char	Other Medically Important Serious Event		Collected at CRF.
AECONTRT	char	Concomitant or Additional Trtmnt Given		Collected at CRF.
EPOCH	char	Epoch		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.

1.4.4. Supplemental Qualifiers for AE – SUPPAE

Dataset	SUPPAE
Creating program	ae.sas
Description	Supplemental Qualifiers for AE
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.5.Bio-Specimen – BE

Dataset	BE
Creating program	be.sas
Description	Bio-Specimen
Unique identifier	STUDYID,DUSUBJID,BEDECOD,BESEQ
Sorted by	STUDYID,DUSUBJID,BEDECOD,BESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BESTDTC

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.
BESPID	char	Sponsor-Defined Identifier		Collected at CRF.
BETERM	char	Reported Term for the Bio-specimen Event		Collected at CRF.
BEDECOD	char	Dictionary-Derived Term		Collected at CRF.
BECAT	char	Category for Bio-specimen Event		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

Variable	Type	Label	Codes	Comments
BESTDY	num	Relative Start Day of Bio-specmn 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.

1.4.6. Clinical Events – CE

Dataset	CE
Creating program	ce.sas
Description	Clinical Events
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: CESTDTC

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
CESEQ	num	Sequence Number		Collected at CRF.
CESPID	char	Sponsor-Defined Identifier		Collected at CRF.
CETERM	char	Reported Term for the Clinical Event		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
CESTDY	num	Relative Start Day of Clinical Event		If CESTDTC and REF.DATE not missing then perform below logic to calculate CESTDY, If CESTDTC less than REF.DATE then (CESTDTC - REF.DATE). Else if CESTDTC is greater than equal to REF.DATE then (CESTDTC- REF.DATE) +1.

1.4.7. 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: CMENDTC, CMSTDTC, CMMODIFY

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.
CMTRT	char	Reported Name of Drug, Med, or Therapy		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.

Variable	Type	Label	Codes	Comments
CMCLAS	char	Medication Class		Collected at CRF.
CMCLASCD	char	Medication Class Code		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.
EPOCH	char	Epoch		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.
CMDUR	char	Duration of Medication		Collected at CRF.
CMSTRF	char	Start Relative to Reference Period		Collected at CRF.
CMENRF	char	End Relative to Reference Period		Collected at CRF.

1.4.8. Supplemental Qualifiers for CM – SUPPCM

Dataset	SUPPCM
Creating program	cm.sas
Description	Supplemental Qualifiers for CM
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	

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.
QNAM	char	Qualifier Variable Name		If QNAM in (CMINDOTH) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.
QEVAL	char	Evaluator		Collected at CRF.

1.4.9. Comments – CO

Dataset	CO
Creating program	co.sas
Description	Comments
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comment dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Empty dataset will be submitted
DOMAIN	char	Domain Abbreviation		Empty dataset will be submitted
RDOMAIN	char	Related 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
IDVAR	char	Identifying Variable		Empty dataset will be submitted
IDVARVAL	char	Identifying Variable Value		Empty dataset will be submitted
COEVAL	char	Evaluator		Empty dataset will be submitted

1.4.10. Disposition – DS

Dataset	DS
Creating program	ds.sas
Description	Disposition
Unique identifier	STUDYID,DUSUBJID,DSSTDY,DSDECOD
Sorted by	STUDYID,DUSUBJID,DSSTDY,DSDECOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DSDTC,DSTERM,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.
EPOCH	char	Epoch		Collected at CRF.

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

1.4.11. Supplemental Qualifiers for DS – SUPPDS

Dataset	SUPPDS
Creating program	ds.sas
Description	Supplemental Qualifiers for DS
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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

Variable	Type	Label	Codes	Comments
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.
QNAM	char	Qualifier Variable Name		If QNAM in (PROTVER, DSPREDTC) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.12. Protocol Deviations – DV

Dataset	DV
Creating program	dv.sas
Description	Protocol 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.
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.
DVSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

1.4.13. ECG Test Results – EG

Dataset	EG
Creating program	eg.sas
Description	ECG Test Results
Unique identifier	STUDYID,DUSUBJID,EGCAT,EGTESTCD,EGSEQ
Sorted by	STUDYID,DUSUBJID,EGCAT,EGTESTCD,EGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EGDTC,EGREASND,EGSTAT,EGNAM,EGSPID,EGREFID

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.
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.
EGPOS	char	ECG Position of Subject		Collected at CRF.
EGORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
EGBLFL	char	Baseline Flag		Collected at CRF.
EGEVAL	char	Evaluator		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
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.
EGTPT	char	Planned Time Point Name		Collected at CRF.
EGTPTNUM	num	Planned Time Point Number		Collected at CRF.
EGTM	num	Time of ECG		If EGDTC contains time part then timepart(EGDTC) else EGTM equal to NULL.

1.4.14. Exposure – EX

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

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
EXSEQ	num	Sequence Number		Collected at CRF.
EXSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EXDOSFRM	char	Dose Form		Collected at CRF.
EXLOC	char	Location of Dose Administration		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Epoch		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.

1.4.15. Findings About Events or Interventions – FA

Dataset	FA
Creating program	fa.sas
Description	Findings About Events or Interventions
Unique identifier	STUDYID,DUSUBJID,FATESTCD,VISIT,FASEQ
Sorted by	STUDYID,DUSUBJID,FATESTCD,VISIT,FASEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: FADTC,FABLFL

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
FASEQ	num	Sequence Number		Collected at CRF.
FASPID	char	Sponsor-Defined Identifier		Collected at CRF.
FATESTCD	char	Findings About Test Short Name		Collected at CRF.
FATEST	char	Findings About Test Name		Collected at CRF.
FAOBJ	char	Object of the Observation		Collected at CRF.
FACAT	char	Category for Findings About		Collected at CRF.
FAORRES	char	Result or Finding in Original Units		Collected at CRF.
FAORRESU	char	Original Units		Collected at CRF.
FASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
FASTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
FASTRESU	char	Standard Units		Collected at CRF.
FAEVAL	char	Evaluator		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

Variable	Type	Label	Codes	Comments
FADY	num	Relative Day of Collection		If FADTC and REF.DATE not missing then perform below logic to calculate FADY, If FADTC less than REF.DATE then (FADTC - REF.DATE). Else if FADTC is greater than equal to REF.DATE then (FADTC-REF.DATE) +1.
FATM	num	Time of Collection		If FADTC contains time part then timepart(FADTC) else FATM equal to NULL.

1.4.16. Supplemental Qualifiers for FA – SUPPFA

Dataset	SUPPFA
Creating program	fa.sas
Description	Supplemental Qualifiers for FA
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related 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
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		If QNAM in (FAWRDTC, FAPHODTC, FAINLDTC, FAINGDTC, FAEQDTC, FACSIDTC) then will be converted to relative day.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.17. Healthcare Resource Utilization – HU

Dataset	HU
Creating program	hu.sas
Description	Healthcare Resource Utilization
Unique identifier	STUDYID,DUSUBJID,HUTESTCD,VISITNUM,HUSEQ
Sorted by	STUDYID,DUSUBJID,HUTESTCD,VISITNUM,HUSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HUDTC,HUENDTC,HUSTDTC

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
HUSEQ	num	Sequence Number		Collected at CRF.
HUSPID	char	Sponsor-Defined Identifier		Collected at CRF.
HUTESTCD	char	Resource Utilization Short Name		Collected at CRF.
HUTEST	char	Resource Utilization Name		Collected at CRF.
HUCAT	char	Category of Resource Utilization		Collected at CRF.
HUSCAT	char	Subcategory of Resource Utilization		Collected at CRF.

Variable	Type	Label	Codes	Comments
HUORRES	char	Result or Finding in Original Units		Collected at CRF.
HUSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
HUSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
HUBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
HUDY	num	Relative Day of Measurements		If HUDTC and REF.DATE not missing then perform below logic to calculate HUDY, If HUDTC less than REF.DATE then (HUDTC - REF.DATE). Else if HUDTC is greater than equal to REF.DATE then (HUDTC - REF.DATE) +1.
HUSTDY	num	Relative Start Day of Measurements		If HUSTDTC and REF.DATE not missing then perform below logic to calculate HUSTDY, If HUSTDTC less than REF.DATE then (HUSTDTC - REF.DATE). Else if HUSTDTC is greater than equal to REF.DATE then (HUSTDTC - REF.DATE) +1.
HUENDY	num	Relative End Day of Measurements		If HUENDTC and REF.DATE not missing then perform below logic to calculate HUENDY, If HUENDTC less than REF.DATE then (HUENDTC - REF.DATE). Else if HUENDTC is greater than equal to REF.DATE then (HUENDTC - REF.DATE) +1.
HUSTRF	char	Start Relative to Reference Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
HUENRF	char	End Relative to Reference Period		Collected at CRF.

1.4.18. Supplemental Qualifiers for HU – SUPPHU

Dataset	SUPPHU
Creating program	hu.sas
Description	Supplemental Qualifiers for HU
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.

Variable	Type	Label	Codes	Comments
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.19. Inclusion/Exclusion Exceptions – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Exceptions
Unique identifier	STUDYID,DUSUBJID,IETESTCD,IESEQ
Sorted by	STUDYID,DUSUBJID,IETESTCD,IESEQ
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.
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.

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

1.4.20. Laboratory Test Results – LB

Dataset	LB
Creating program	lb.sas
Description	Laboratory Test Results
Unique identifier	STUDYID,DUSUBJID,LBCAT,LBTESTCD,LBSEQ
Sorted by	STUDYID,DUSUBJID,LBCAT,LBTESTCD,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LBNAM,LBREFID,LBDTC,LBSPID

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.
LBORRES	char	Result or Finding in Original Units		Collected at CRF.
LBORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
LBSTNRC	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSTAT	char	Completion 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.
LBBLFL	char	Baseline Flag		Collected at CRF.
LBFASST	char	Fasting Status		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
LBDY	num	Relative Day of Specimen 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.
LBTM	num	Time of Specimen Collection		If LBDTC contains time part then timepart(LBDTC) else LBTM equal to NULL.

1.4.21. Supplemental Qualifiers for LB – SUPPLB

Dataset	SUPPLB
Creating program	lb.sas
Description	Supplemental Qualifiers for LB
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		If QNAM in (LBRES DTC) then will be converted to relative day.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.22. Medical History – MH

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

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.
MHCAT	char	Category for Medical History		Collected at CRF.
MHSCAT	char	Subcategory for Medical History		Collected at CRF.
MHPRESP	char	Medical History Event Pre-Specified		Collected at CRF.
MHOCCUR	char	Medical History Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
MHDY	num	Relative Day of History Collection		If MHDTC and REF.DATE not missing then perform below logic to calculate MHDY, If MHDTC less than REF.DATE then (MHDTC - REF.DATE). Else if MHDTC is greater than equal to REF.DATE then (MHDTC- REF.DATE) +1.
MHSTDY	num	Relative Start Day of Med Hist 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.
MHENDY	num	Relative End Day of Med Hist Event		If MHENDTC and REF.DATE not missing then perform below logic to calculate MHENDY, If MHENDTC less than REF.DATE then (MHENDTC - REF.DATE). Else if MHENDTC is greater than equal to REF.DATE then (MHENDTC- REF.DATE) +1.
MHENRF	char	End Relative to Reference Period		Collected at CRF.

1.4.23. Supplemental Qualifiers for MH – SUPPMH

Dataset	SUPPMH
Creating program	mh.sas
Description	Supplemental Qualifiers for MH
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.24. Physical Examination – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examination
Unique identifier	STUDYID,DUSUBJID,PETESTCD,VISITNUM
Sorted by	STUDYID,DUSUBJID,PETESTCD,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.
PEORRES	char	Verbatim Examination Finding		Collected at CRF.

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

1.4.25. Questionnaires – QS

Dataset	QS
Creating program	qs.sas
Description	Questionnaires
Unique identifier	STUDYID,DUSUBJID,QSTESTCD,VISITNUM,QSSEQ
Sorted by	STUDYID,DUSUBJID,QSTESTCD,VISITNUM,QSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: QSDTC,QSGRPID,QSSTRESU

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.
QSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		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.
QSEVLINT	char	Evaluation Interval		Collected at CRF.

1.4.26. Randomization – RA

Dataset	RA
Creating program	ra.sas
Description	Randomization
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: RASTDTC,RANUM,ARM,ARMCD

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.
EPOCH	char	Epoch		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.

1.4.27. Supplemental Qualifiers for RA – SUPPRA

Dataset	SUPPRA
Creating program	ra.sas
Description	Supplemental Qualifiers for RA
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related 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
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.28. Related Records – RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	STUDYID,DUSUBJID,IDVAR,IDVARVAL,RELID
Sorted by	STUDYID,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.

Variable	Type	Label	Codes	Comments
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.

1.4.29. Surgery – SG

Dataset	SG
Creating program	sg.sas
Description	Surgery
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: SGTRT,SGINDC,SGDTC

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
SGSEQ	num	Sequence Number		Collected at CRF.
SGSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SGCAT	char	Category for Surgery/Procedure		Collected at CRF.
SGSCAT	char	Subcategory for Surgery/Procedure		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
SGDY	num	Relative Day of Collection		If SGDTC and REF.DATE not missing then perform below logic to calculate SGDY, If SGDTC less than REF.DATE then (SGDTC - REF.DATE). Else if SGDTC is greater than equal to REF.DATE then (SGDTC - REF.DATE) +1.

1.4.30. Substance Use – SU

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

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.
SUPRESP	char	SU Pre-Specified		Collected at CRF.
SUOCCUR	char	SU Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUDOSE	num	Substance Use Consumption		Collected at CRF.
SUDOSU	char	Consumption Units		Collected at CRF.
SUDOSFRQ	char	Use Frequency Per Interval		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
SUDY	num	Relative Day of Collection		If SUDTC and REF.DATE not missing then perform below logic to calculate SUDY, If SUDTC less than REF.DATE then (SUDTC - REF.DATE). Else if SUDTC is greater than equal to REF.DATE then (SUDTC-REF.DATE) +1.
SUENDY	num	Relative End Day of Substance Use		If SUENDTC and REF.DATE not missing then perform below logic to calculate SUENDY, If SUENDTC less than REF.DATE then (SUENDTC - REF.DATE). Else if SUENDTC is greater than equal to REF.DATE then (SUENDTC- REF.DATE) +1.
SUDUR	char	Duration of Substance Use		Collected at CRF.

1.4.31. Supplemental Qualifiers for SU – SUPPSU

Dataset	SUPPSU
Creating program	su.sas
Description	Supplemental Qualifiers for SU
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.32. Subject Visits – SV

Dataset	SV
Creating program	sv.sas
Description	Subject Visits
Unique identifier	STUDYID,DUSUBJID,VISITNUM
Sorted by	STUDYID,DUSUBJID,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

Variable	Type	Label	Codes	Comments
SVSTDY	num	Relative Start Day of Visit		If SVSTDTC and REF.DATE not missing then perform below logic to calculate SVSTDY, If SVSTDTC less than REF.DATE then (SVSTDTC - REF.DATE). Else if SVSTDTC is greater than equal to REF.DATE then (SVSTDTC- REF.DATE) +1.
SVENDY	num	Relative End Day of Visit		If SVENDTC and REF.DATE not missing then perform below logic to calculate SVENDY, If SVENDTC less than REF.DATE then (SVENDTC - REF.DATE). Else if SVENDTC is greater than equal to REF.DATE then (SVENDTC- REF.DATE) +1.
SVUPDES	char	Description of Unplanned Visit		Collected at CRF.

1.4.33. 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	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TIVERS

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

1.4.34. Vital Signs – VS

Dataset	VS
Creating program	vs.sas
Description	Vital Signs
Unique identifier	STUDYID,DUSUBJID,VSTESTCD,VSDY,VISITNUM,VSSEQ
Sorted by	STUDYID,DUSUBJID,VSTESTCD,VSDY,VISITNUM,VSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.
VSPOS	char	Vital Signs Position of Subject		Collected at CRF.
VSORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
VSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		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.

1.4.35. Tolerability Testing – XT

Dataset	XT
Creating program	xt.sas
Description	Tolerability Testing
Unique identifier	STUDYID,DUSUBJID,XTSTDY
Sorted by	STUDYID,DUSUBJID,XTSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: XTSTDTC

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
XTSEQ	num	Sequence Number		Collected at CRF.
XTSPID	char	Sponsor-Defined Identifier		Collected at CRF.
XTRT	char	Name of Actual Treatment		Collected at CRF.
XTCAT	char	Category for Tolerability Testing		Collected at CRF.
XTDOSE	num	Dose per Tolerability Testing		Collected at CRF.
XTDOSU	char	Dose Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Epoch		Collected at CRF.
XTSTDY	num	Relative Day Taken		If XTSTDTC and REF.DATE not missing then perform below logic to calculate XTSTDY, If XTSTDTC less than REF.DATE then (XTSTDTC - REF.DATE). Else if XTSTDTC is greater than equal to REF.DATE then (XTSTDTC- REF.DATE) +1.

1.4.36. Supplemental Qualifiers for XT – SUPPXT

Dataset	SUPPXT
Creating program	xt.sas
Description	Supplemental Qualifiers for XT
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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

Variable	Type	Label	Codes	Comments
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.37. Sample Handling – XZ

Dataset	XZ
Creating program	xz.sas
Description	Sample Handling
Unique identifier	STUDYID,DUSUBJID,XZTESTCD,VISITNUM,XZSEQ
Sorted by	STUDYID,DUSUBJID,XZTESTCD,VISITNUM,XZSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: XZDTC

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
XZSEQ	num	Sequence Number		Collected at CRF.
XZSPID	char	Sponsor-Defined Identifier		Collected at CRF.
XZTESTCD	char	Sample Handling Test Short Name		Collected at CRF.
XZTEST	char	Sample Handling Test Name		Collected at CRF.
XZCAT	char	Category for Sample Handling		Collected at CRF.
XZORRES	char	Result or 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.
XZSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
XZSTRESU	char	Standard Units		Collected at CRF.
XZBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XZDY	num	Relative Day of Sample Handling		If XZDTC and REF.DATE not missing then perform below logic to calculate XZDY, If XZDTC less than REF.DATE then (XZDTC - REF.DATE). Else if XZDTC is greater than equal to REF.DATE then (XZDTC - REF.DATE) + 1.

1.4.38. Supplemental Qualifiers for XZ – SUPPXZ

Dataset	SUPPXZ
Creating program	xz.sas
Description	Supplemental Qualifiers for XZ
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.