

Clinical Development

Paliperidone Palmitate[®]

R092670-PSY3002

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 will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- RELATED dataset will not be submitted as it contains subject level sensitive information.
- Dataset containing pharmacogenetic information will not be submitted. (eg. DNRSLT)
- Dataset containing information related to code lists will not be submitted. (eg. CODELIST)
- Element containing insignificant information will not be submitted. (eg. LBTMLBL)
- Dataset containing investigator information is sensitive and hence will not be submitted. (eg. INVEST)
- Dataset having no subject level information will not be submitted. (eg. PROTDESC)
- SURGERY dataset will not be submitted due to sensitivity of information.
- Comments dataset will be submitted with zero observation due to sensitivity of data.
- Informed Consent Date will be used as Reference Date to derive relative days.

1.3. Data Files

The R092670-PSY3002 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demographics
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>PAGNUM,SUBJINIT,DMACTDT,DMSCRDT,IVID,IVNAME,BIRTHDT,DMINFDT, RACESPEC,COUNTRYC,ETHNSPEC</p>

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
SEXC	num	Sex Code		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACEC	num	Race Code		Element will be grouped to protect PII.
RACE	char	Race		Element will be grouped to protect PII.
DCOUNTRY	char	De-identify Country		Element will be grouped to protect PII.
ETHNICC	num	Ethnicity Code		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
AGE	char	Age in Years		<p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule:</p> $\text{AGE} = \text{int}((\text{DMINFDT} - \text{BIRTHDT})/365.25)$ <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p>

Variable	Type	Label	Codes	Comments
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and DMINFDT not missing then perform below logic to calculate DMACTDY, If DMACTDT less than DMINFDT then (DMACTDT - DMINFDT). Else if DMACTDT is greater than equal to DMINFDT then (DMACTDT- DMINFDT) +1.
DMSCRDY	num	Relative Day of First Trial Related Procedure		If DMSCRDT and DMINFDT not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than DMINFDT then (DMSCRDT - DMINFDT). Else if DMSCRDT is greater than equal to DMINFDT then (DMSCRDT- DMINFDT) +1.

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID,AEDECOD,AEDECOD1,AESEQ
Sorted by	DUSUBJID,AEDECOD,AEDECOD1,AESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: PAGNUM,AETERM,AESTDT,AEENDT,AESTDTC,AEENDTC,AESERREF

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEREPRTC	num	Were Any AEs Reported Code		Collected at CRF.
AEREPRT	char	Were Any AEs Reported		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF.
AEACTTRC	num	Action Taken with Treatment Code		Collected at CRF.
AEACTTRT	char	Action Taken with Treatment		Collected at CRF.
AEOUTC	num	Outcome of Event Code		Collected at CRF.
AEOUT	char	Outcome of Event		Collected at CRF.
AERELC	num	Relationship to Treatment Code		Collected at CRF.
AEREL	char	Relationship to Treatment		Collected at CRF.
AESERC	num	Seriousness Criteria Code		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.
AESEVC	num	Severity of Event Code		Collected at CRF.
AESEV	char	Severity of Event		Collected at CRF.
AECONTRC	num	Concomitant/Additional Treatment Code		Collected at CRF.
AECONTRT	char	Concomitant/Additional Treatment		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
AEDECOD1	char	Dictionary-Derived Lower Level Term		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEBODSYC	char	Body System or Organ Class Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and DMINFDT not missing then perform below logic to calculate AESTDY, If AESTDTC less than DMINFDT then (AESTDTC - DMINFDT). Else if AESTDTC is greater than equal to DMINFDT then (AESTDTC- DMINFDT) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and DMINFDT not missing then perform below logic to calculate AEENDY, If AEENDTC less than DMINFDT then (AEENDTC - DMINFDT). Else if AEENDTC is greater than equal to DMINFDT then (AEENDTC- DMINFDT) +1.

1.4.3. Abnormal Involuntary Movement Scale - AIMS

Dataset	AIMS
Creating program	aims.sas
Description	Abnormal Involuntary Movement Scale
Unique identifier	DUSUBJID,AIGROUP,AIITEM,VISIT
Sorted by	DUSUBJID,AIGROUP,AIITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,AIRATERI,AIACDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
AIVTYPEC	num	AIMS Visit Type Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AIVTYPE	char	AIMS Visit Type		Collected at CRF.
AIGROUP	char	AIMS Group		Collected at CRF.
AIITEM	char	AIMS Item		Collected at CRF.
AISCOREC	num	AIMS Score Code		Collected at CRF.
AISCORE	char	AIMS Score		Collected at CRF.
AIACTDY	num	Relative Actual Day of AIMS		If AIACTDT and DMINFDT not missing then perform below logic to calculate AIACTDY, If AIACTDT less than DMINFDT then (AIACTDT - DMINFDT). Else if AIACTDT is greater than equal to DMINFDT then (AIACTDT- DMINFDT) +1.

1.4.4. Barnes Akathisia Rating Scale - BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia Rating Scale
Unique identifier	DUSUBJID,BAGROUP,BAITEM,VISIT
Sorted by	DUSUBJID,BAGROUP,BAITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,BARATERI,BAACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
BAVTYPEC	num	BARS Visit Type Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
BAVTYPE	char	BARS Visit Type		Collected at CRF.
BAGROUP	char	BARS Group		Collected at CRF.
BAITEM	char	BARS Item		Collected at CRF.
BASCOREC	num	BARS Score Code		Collected at CRF.
BASCORE	char	BARS Score		Collected at CRF.
BAACTDY	num	Relative Actual Day of BARS		If BAACTDT and DMINFDT not missing then perform below logic to calculate BAACTDY, If BAACTDT less than DMINFDT then (BAACTDT - DMINFDT). Else if BAACTDT is greater than equal to DMINFDT then (BAACTDT- DMINFDT) +1.

1.4.5. Clinical Global Impression - CGI

Dataset	CGI
Creating program	cgi.sas
Description	Clinical Global Impression
Unique identifier	DUSUBJID,CGSEV,VISIT
Sorted by	DUSUBJID,CGSEV,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,CGRATERI,CGACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
CGSEVC	num	CGI Severity Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
CGSEV	char	CGI Severity		Collected at CRF.
CGACTDY	num	Relative Actual Day of CGI		If CGACTDT and DMINFDT not missing then perform below logic to calculate CGACTDY, If CGACTDT less than DMINFDT then (CGACTDT - DMINFDT). Else if CGACTDT is greater than equal to DMINFDT then (CGACTDT- DMINFDT) +1.

1.4.6.Laboratory Results (Chemistry) - CHEM

Dataset	CHEM
Creating program	chem.sas
Description	Laboratory Results
Unique identifier	DUSUBJID, LBTEST, VISIT
Sorted by	DUSUBJID, LBTEST, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAGNUM, LBTMLBL, LBPRVIDC, LBPRVID, LBREF, LBACTDT, REPUNIT, STDNRC, LBSIGLO, LBSIGHI

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LBFASC	num	Fasted Code		Collected at CRF.
LBFAS	char	Fasted		Collected at CRF.
LAGE	char	Age at Time of Visit		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
LAGEUNIT	char	Age Unit		Collected at CRF.
LBTPEC	num	Lab Type Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBTYPE	char	Lab Type		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, If LBACTDT less than DMINFDT then (LBACTDT - DMINFDT). Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1.

1.4.7. Comments - COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Comments data is sensitive data, contains free text information. Will be submitted empty dataset.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Empty dataset will be submitted.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Empty dataset will be submitted.
DSITEID	char	Site Assigned for De-identity		Empty dataset will be submitted.
PHASENUM	num	Phase Number		Empty dataset will be submitted.
PHASE	char	Phase		Empty dataset will be submitted.
VISITNUM	num	Visit Number		Empty dataset will be submitted.
VISIT	char	Visit		Empty dataset will be submitted.
CTSEQ	num	Comment Sequence Number		Empty dataset will be submitted.
DOMAIN	char	Domain of Origin		Empty dataset will be submitted.

1.4.8. Concomitant Meds - CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant Meds
Unique identifier	DUSUBJID,CMDECOD,CMGROUP,CMSEQ
Sorted by	DUSUBJID,CMDECOD,CMGROUP,CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values: PAGNUM,CMTERM,CMREGIM,CMREAS,CMSTDTC,CMSTDT,CMENDTC,CMENDT,CMCLASC,CMCLAS

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMGROUP	char	Medication Grouping		Collected at CRF.
CMREPRTC	num	Were Any Meds Administered Code		Collected at CRF.
CMREPRT	char	Were Any Meds Administered		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMDOSE	num	Dosage		Collected at CRF.
CMUNIT	char	Dose Unit		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMCAUSC	num	Given for AE Code		Collected at CRF.
CMCAUS	char	Given for AE		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AESEQ1	num	AE Sequence Number 1		Collected at CRF.
AESEQ2	num	AE Sequence Number 2		Collected at CRF.
CMPRIORC	num	Med Started Prior to Trial Code		Collected at CRF.
CMPRIOR	char	Med Started Prior to Trial		Collected at CRF.
CMCONTC	num	Medication Continuing Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCONT	char	Medication Continuing		Collected at CRF.
CMCLASC0	char	ATC Code 0		Collected at CRF.
CMCLASC1	char	ATC Code 1		Collected at CRF.
CMCLASC2	char	ATC Code 2		Collected at CRF.
CMCLASC3	char	ATC Code 3		Collected at CRF.
CMCLASC4	char	ATC Code 4		Collected at CRF.
CMCLASC5	char	ATC Code 5		Collected at CRF.
CMCLASC6	char	ATC Code 6		Collected at CRF.
CMCLASC7	char	ATC Code 7		Collected at CRF.
CMCLASC8	char	ATC Code 8		Collected at CRF.
CMCLASC9	char	ATC Code 9		Collected at CRF.
CMCLAS0	char	ATC Text 0		Collected at CRF.
CMCLAS1	char	ATC Text 1		Collected at CRF.
CMCLAS2	char	ATC Text 2		Collected at CRF.
CMCLAS3	char	ATC Text 3		Collected at CRF.
CMCLAS4	char	ATC Text 4		Collected at CRF.
CMCLAS5	char	ATC Text 5		Collected at CRF.
CMCLAS6	char	ATC Text 6		Collected at CRF.
CMCLAS7	char	ATC Text 7		Collected at CRF.
CMCLAS8	char	ATC Text 8		Collected at CRF.
CMCLAS9	char	ATC Text 9		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCODE	char	Medication Dictionary Code		Collected at CRF.
CMDECOD	char	Medication Generic Term		Collected at CRF.
CMSTDY	num	Relative Actual Start Day of Medication		If CMSTDTC and DMINFDT not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than DMINFDT then (CMSTDTC - DMINFDT). Else if CMSTDTC is greater than equal to DMINFDT then (CMSTDTC- DMINFDT) +1.
CMENDY	num	Relative Actual End Day of Medication		If CMENDTC and DMINFDT not missing then perform below logic to calculate CMENDY, If CMENDTC less than DMINFDT then (CMENDTC - DMINFDT). Else if CMENDTC is greater than equal to DMINFDT then (CMENDTC- DMINFDT) +1.

1.4.9. Diagnosis - DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis
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 non significant elements or due to missing values: PAGNUM,DGACTDTC,DGACTDT,DGDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
DIAGNOSC	num	Diagnosis Code		Collected at CRF.
DIAGNOS	char	Diagnosis		Collected at CRF.
DGTYPEC	num	Schizophrenia Type Code		Collected at CRF.
DGTYPE	char	Schizophrenia Type		Collected at CRF.
DGAGE	char	Age At First Diagnosis Of Schizophrenia		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DGDY	num	Relative Day of Collection		If DGDT and DMINFDT not missing then perform below logic to calculate DGDY, If DGDT less than DMINFDT then (DGDT - DMINFDT). Else if DGDT is greater than equal to DMINFDT then (DGDT - DMINFDT) +1.

1.4.10. Disposition - DISPOSIT

Dataset	DISPOSIT
Creating program	disposit.sas
Description	Disposition
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 non significant elements: PAGNUM,DSACTDT,PREGDUDT,DEATHDT,DSRSOTH,DSRABKDT, DSRABKTM, DSRABKRS

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF.
DSTYPE	char	End of Treatment or Trial		Collected at CRF.
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF.
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF.
DSREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF.
DSREAS	char	Reason for Withdrawal/Termination		Collected at CRF.
DSSCRNC	num	Reason for Screen Failure Code		Collected at CRF.
DSSCRN	char	Reason for Screen Failure		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
DSACTDY	num	Relative Actual Day Trial Completion/Withdrawal		If DSACTDT and DMINFDT not missing then perform below logic to calculate DSACTDY, If DSACTDT less than DMINFDT then (DSACTDT - DMINFDT). Else if DSACTDT is greater than equal to DMINFDT then (DSACTDT- DMINFDT) +1.
PREGDUDY	num	Relative Pregnancy Due Day		If PREGDUDT and DMINFDT not missing then perform below logic to calculate PREGDUDY, If PREGDUDT less than DMINFDT then (PREGDUDT - DMINFDT). Else if PREGDUDT is greater than equal to DMINFDT then (PREGDUDT- DMINFDT) +1.

Variable	Type	Label	Codes	Comments
DEATHDY	num	Relative Actual Day of Death		If DEATHDT and DMINFDT not missing then perform below logic to calculate DEATHDY, If DEATHDT less than DMINFDT then (DEATHDT - DMINFDT). Else if DEATHDT is greater than equal to DMINFDT then (DEATHDT- DMINFDT) +1.

1.4.11. Electrocardiogram - ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DUSUBJID,EGTESTCD,EGDY,EGACTTM,EGSEQ
Sorted by	DUSUBJID,EGTESTCD,EGDY,EGACTTM,EGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: EGREF,EGDT,EGPTM,EGPOS,EGPRVIDC,EGPRVID,EGND,EGCHGC,EGCHG, EGINTOTH,EGCHGOTH

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
EGTESTCD	char	ECG Test Short Name		Collected at CRF.
EGPTMNUM	num	Planned Time Point Number		Collected at CRF.
EGACTTM	num	Actual Time of ECG		Collected at CRF.
EGQUAL	char	Qualifier		Collected at CRF.
EGTEST	char	ECG Test		Collected at CRF.
EGSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
EGSTUNIT	char	Standard Units		Collected at CRF.
EGSTRESC	char	Character Result in Standard Units		Collected at CRF.
EGORRESN	num	Numeric Result in Original Units		Collected at CRF.
EGORUNIT	char	Original Units		Collected at CRF.
EGINTPC	num	Interpretation Code		Collected at CRF.
EGINTP	char	Interpretation		Collected at CRF.
EGLEAD	char	Lead Used for Measurement		Collected at CRF.
EGSEQ	num	ECG Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGREADC	num	ECG Reader Code		Collected at CRF.
EGREAD	char	ECG Reader		Collected at CRF.
EGVTYPEC	num	ECG Visit Type Code		Collected at CRF.
EGVTYPE	char	ECG Visit Type		Collected at CRF.
BATCHID	num	Central ECG batch identifier		Collected at CRF.
MDS_CODE	char	MDS Code		Collected at CRF.
EGDY	num	Relative Actual Day of ECG		If EGDT and DMINFDT not missing then perform below logic to calculate EGDY, If EGDT less than DMINFDT then (EGDT - DMINFDT). Else if EGDT is greater than equal to DMINFDT then (EGDT - DMINFDT) +1.

1.4.12. Enrollment – ENROLL

Dataset	ENROLL
Creating program	enroll.sas
Description	Enrollment
Unique identifier	DUSUBJID,ENCRIT,ENCRES,ENACTDY,ENSEQ
Sorted by	DUSUBJID,ENCRIT,ENCRES,ENACTDY,ENSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,ENACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
ENCRIT	char	Inclusion or Exclusion Criterion		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENSEQ	num	Criterion Sequence Number		Collected at CRF.
ENCRESC	num	Criterion Result Code		Collected at CRF.
ENCRES	char	Criterion Result		Collected at CRF.
ENTEXT	char	Criterion Text		Collected at CRF.
ENACTDY	num	Relative Actual Day of Enrollment		If ENACTDT and DMINFDT not missing then perform below logic to calculate ENACTDY, If ENACTDT less than DMINFDT then (ENACTDT - DMINFDT). Else if ENACTDT is greater than equal to DMINFDT then (ENACTDT - DMINFDT) +1.

1.4.13. Exposure - EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Exposure
Unique identifier	DUSUBJID,EXSTDY,VISIT
Sorted by	DUSUBJID,EXSTDY,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,EXRATERI,EXSTDT,EXENDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
EXSTTM	num	Start Time of Exposure		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXPOSC	num	Position of Injection Code		Collected at CRF.
EXPOS	char	Position of Injection		Collected at CRF.
EXGIVEN	num	Number of Pills, etc Given		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDY and DMINFDT not missing then perform below logic to calculate EXSTDY, If EXSTDY less than DMINFDT then (EXSTDY - DMINFDT). Else if EXSTDY is greater than equal to DMINFDT then (EXSTDY- DMINFDT) +1.
EXENDY	num	Relative End Day of Exposure		If EXENDY and DMINFDT not missing then perform below logic to calculate EXENDY, If EXENDY less than DMINFDT then (EXENDY - DMINFDT). Else if EXENDY is greater than equal to DMINFDT then (EXENDY- DMINFDT) +1.

1.4.14. Global Impressions of Sexual Function - GISF

Dataset	GISF
Creating program	gisf.sas
Description	Global Impressions of Sexual Function
Unique identifier	DUSUBJID,GIGROUP,GIITEM,VISIT
Sorted by	DUSUBJID,GIGROUP,GIITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: GINAC,GINA,PAGNUM,GIACDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity

Variable	Type	Label	Codes	Comments
GIGROUP	char	GISF Group		Collected at CRF.
GIITEM	char	GISF Item		Collected at CRF.
GISCOREC	num	GISF Score Code		Collected at CRF.
GISCORE	char	GISF Score		Collected at CRF.
GIACTDY	num	Relative Actual Day of GISF		If GIACTDT and DMINFDT not missing then perform below logic to calculate GIACTDY, If GIACTDT less than DMINFDT then (GIACTDT - DMINFDT). Else if GIACTDT is greater than equal to DMINFDT then (GIACTDT- DMINFDT) +1.

1.4.15. Smoking Habit - HABIT

Dataset	HABIT
Creating program	habit.sas
Description	Smoking Habit
Unique identifier	DUSUBJID,HACGTNUM,HAACDY
Sorted by	DUSUBJID,HACGTNUM,HAACDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,HAACDT,HAENDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
HASMOCUC	num	Does Subject Currently Smoke Code		Collected at CRF.
HASMOCU	char	Does Subject Currently Smoke		Collected at CRF.
HACGTNUM	num	Number of Cigarettes		Collected at CRF.
HACGRNUM	num	Number of Cigars		Collected at CRF.
HAPIPNUM	num	Number of Pipes		Collected at CRF.
HASMOPSC	num	Has Subject Smoked in the Past Code		Collected at CRF.
HASMOPS	char	Has Subject Smoked in the Past		Collected at CRF.
HAYEAR	num	Number of Years Subject Has Smoked		Collected at CRF.
HAACTDY	num	Relative Actual Day of Smoking Habit		If HAACTDT and DMINFDT not missing then perform below logic to calculate HAACTDY, If HAACTDT less than DMINFDT then (HAACTDT - DMINFDT). Else if HAACTDT is greater than equal to DMINFDT then (HAACTDT- DMINFDT) +1.

1.4.16. Laboratory Results (Hematology) - HEMAT

Dataset	HEMAT
Creating program	hemat.sas
Description	Laboratory Results
Unique identifier	DUSUBJID, LBTEST, VISIT
Sorted by	DUSUBJID, LBTEST, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAGNUM, LBTMLBL, LBPRVID, LBPRVIDC, LBREF, LBACTDT, REPUNIT, STDNRC, LBSIGLO, LBSIGHI

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LBFASCTC	num	Fasted Code		Collected at CRF.
LBFASCT	char	Fasted		Collected at CRF.
LAGE	char	Age at Time of Visit		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
LAGEUNIT	char	Age Unit		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, if LBACTDT less than DMINFDT then (LBACTDT - DMINFDT). Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1.

1.4.17. Investigator Eval. of Inj. Site - IVEVINJ

Dataset	IVEVINJ
Creating program	ivevinj.sas
Description	Investigator Evaluation of Injection Site
Unique identifier	DUSUBJID,IEITEM,IESCORE,IEACTDY,IEACTTM
Sorted by	DUSUBJID,IEITEM,IESCORE,IEACTDY,IEACTTM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,IERATERI,IEACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
IEITEM	char	Evaluation Item		Collected at CRF.

Variable	Type	Label	Codes	Comments
IESCOREC	num	Evaluation Score Code		Collected at CRF.
IESCORE	char	Evaluation Score		Collected at CRF.
IEACTTM	num	Actual Time of Inve. Eval. of Inj. Site		Collected at CRF.
IEACTDY	num	Relative Actual Day of Inve. Eval. of Inj. Site		If IEACTDT and DMINFDT not missing then perform below logic to calculate IEACTDY, If IEACTDT less than DMINFDT then (IEACTDT - DMINFDT). Else if IEACTDT is greater than equal to DMINFDT then (IEACTDT- DMINFDT) +1.

1.4.18. Medical History - MEDHIST

Dataset	MEDHIST
Creating program	medhist.sas
Description	Medical History
Unique identifier	DUSUBJID,MHBODSYS
Sorted by	DUSUBJID,MHBODSYS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,MHACTDT,MHTERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
MHSEQ	num	MH Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
MHBODSYC	num	Body System Code		Collected at CRF.
MHBODSYS	char	Body System		Collected at CRF.
MHSTATC	num	Condition Code		Collected at CRF.
MHSTAT	char	Condition		Collected at CRF.
MHACTDY	num	Relative Actual Day of Collection		If MHACTDT and DMINFDT not missing then perform below logic to calculate MHACTDY, If MHACTDT less than DMINFDT then (MHACTDT - DMINFDT). Else if MHACTDT is greater than equal to DMINFDT then (MHACTDT- DMINFDT) +1.

1.4.19. Medical Kit - MEDKIT

Dataset	MEDKIT
Creating program	medkit.sas
Description	Medical Kit
Unique identifier	DUSUBJID,DOSE,DISPDY
Sorted by	DUSUBJID,DOSE,DISPDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,DISPDT,KITNUM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
MKTYPE	char	Type of Medication Kit		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSEUNIT	char	Dose Unit		Collected at CRF.
DOSE	num	Dose		Collected at CRF.
ADJUST	char	Adjust		Collected at CRF.
DISPDY	num	Relative Actual Day Kit Dispensed		If DISPDT and DMINFDT not missing then perform below logic to calculate DISPDY, If DISPDT less than DMINFDT then (DISPDT - DMINFDT). Else if DISPDT is greater than equal to DMINFDT then (DISPDT - DMINFDT) +1.

1.4.20. Positive and Negative Syndrome Scale - PANSS

Dataset	PANSS
Creating program	panss.sas
Description	Positive and Negative Syndrome Scale
Unique identifier	DUSUBJID,PAITEM,VISIT
Sorted by	DUSUBJID,PAITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PAVTYPEC	num	PANSS Visit Type Code		Collected at CRF.
PAVTYPE	char	PANSS Visit Type		Collected at CRF.
PAGROUP	char	PANSS Group		Collected at CRF.
PAITEM	char	PANSS Item		Collected at CRF.
PASCOREC	num	PANSS Score Code		Collected at CRF.
PASCORE	char	PANSS Score		Collected at CRF.
PAACTDY	num	Relative Actual Day of PANSS		If PAACTDT and DMINFDT not missing then perform below logic to calculate PAACTDY, If PAACTDT less than DMINFDT then (PAACTDT - DMINFDT). Else if PAACTDT is greater than equal to DMINFDT then (PAACTDT- DMINFDT) +1.

1.4.21. Blood Sampling for Pharmacokinetics - PCCNC

Dataset	PCCNC
Creating program	pccnc.sas
Description	Blood Sampling for Pharmacokinetics
Unique identifier	DUSUBJID, PCTEST, VISIT
Sorted by	DUSUBJID, PCTEST, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values: PAGNUM, SPPRVIDC, SPPRVID, PCPRVIDC, PCPRVID, ACQREF, SAMREF, PCLBREF, PCSTDT, PCENDT, PCSPCOM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
TPTNUM	num	Planned Time Point Number		Collected at CRF.
TPT	char	Planned Time Point Name		Collected at CRF.
PCVTYPEC	num	PK/PD Sample Visit Type Code		Collected at CRF.
PCVTYPE	char	PK/PD Sample Visit Type		Collected at CRF.
PCPRMTYP	char	Parameter Type		Collected at CRF.
PCCAT	char	Category for Test or Examination		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
PCSPEC	char	Specimen Material		Collected at CRF.
PCSEQ	num	Sample Sequence Number		Collected at CRF.
PCSTTM	num	Start Time of Specimen Collection		Collected at CRF.
PCENTM	num	End Time of Specimen Collection		Collected at CRF.
PCTEST	char	Test Name		Collected at CRF.
PCORRESN	num	Numeric Result in Original Units		Collected at CRF.
PCORUNIT	char	Original Units		Collected at CRF.
PCORRES	char	Result in Original Units		Collected at CRF.
PCSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
PCSTUNIT	char	Standard Units		Collected at CRF.
PCSTRESC	char	Character Result in Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCSTATC	num	Sample Collection Status Code		Collected at CRF.
PCSTAT	char	Sample Collection Status		Collected at CRF.
PCSTDY	num	Relative Start Day of Specimen Collection		If PCSTDT and DMINFDT not missing then perform below logic to calculate PCSTDY, If PCSTDT less than DMINFDT then (PCSTDT - DMINFDT). Else if PCSTDT is greater than equal to DMINFDT then (PCSTDT - DMINFDT) +1.
PCENDY	num	Relative End Day of Specimen Collection		If PCENDT and DMINFDT not missing then perform below logic to calculate PCENDY, If PCENDT less than DMINFDT then (PCENDT - DMINFDT). Else if PCENDT is greater than equal to DMINFDT then (PCENDT - DMINFDT) +1.

1.4.22. Physical Examination - PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examination
Unique identifier	DUSUBJID,PEBODSYS,VISIT
Sorted by	DUSUBJID,PEBODSYS,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,PEACTDT,PEFIND

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PESEQ	num	Phys Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PEBODSYC	num	Body System Code		Collected at CRF.
PEBODSYS	char	Body System		Collected at CRF.
PESTATC	num	Exam Result Code		Collected at CRF.
PESTAT	char	Exam Result		Collected at CRF.
PEACTDY	num	Relative Actual Day of Phys Exam		If PEACTION and DMINDT not missing then perform below logic to calculate PEACTION, If PEACTION less than DMINDT then (PEACTION - DMINDT). Else if PEACTION is greater than equal to DMINDT then (PEACTION- DMINDT) +1.

1.4.23. Protocol Deviation - PROTDEV

Dataset	PROTDEV
Creating program	protdev.sas
Description	Protocol Deviation
Unique identifier	DUSUBJID,PVDECOD,PVSEQ
Sorted by	DUSUBJID,PVDECOD,PVSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PVTERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PVSEQ	num	Protocol Deviation Seq Number		Collected at CRF.
PVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

1.4.24. Personal And Social Performance Scale - PSP

Dataset	PSP
Creating program	psp.sas
Description	Personal And Social Performance Scale
Unique identifier	DUSUBJID,PSSCORE,VISIT
Sorted by	DUSUBJID,PSSCORE,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,PSRATERI,PSACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSSCORE	num	PSP Score		Collected at CRF.
PSACTDY	num	Relative Actual Day of PSP		If PSACTDT and DMINFDT not missing then perform below logic to calculate PSACTDY, If PSACTDT less than DMINFDT then (PSACTDT - DMINFDT). Else if PSACTDT is greater than equal to DMINFDT then (PSACTDT- DMINFDT) +1.

1.4.25. Psychiatric History - PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychiatric History
Unique identifier	DUSUBJID,PYSEQ
Sorted by	DUSUBJID,PYSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values: PAGNUM,PYHOSPC,PYHOSP,PYSTDT,PYSTDT,PYENDTC,PYENDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PYSEQ	num	Psychiatric History Sequence Number		Collected at CRF.
PYDIAG	char	Diagnosis		Collected at CRF.
PYSTDY	num	Relative Act. Start Day of Psychosis Trt.		If PYSTDTC and DMINFDT not missing then perform below logic to calculate PYSTDY, If PYSTDTC less than DMINFDT then (PYSTDTC - DMINFDT). Else if PYSTDTC is greater than equal to DMINFDT then (PYSTDTC- DMINFDT) +1.
PYENDY	num	Relative Act. End Day of Psychosis Trt.		If PYENDTC and DMINFDT not missing then perform below logic to calculate PYENDY, If PYENDTC less than DMINFDT then (PYENDTC - DMINFDT). Else if PYENDTC is greater than equal to DMINFDT then (PYENDTC- DMINFDT) +1.

1.4.26. Randomization - RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomization
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 non significant elements or due to missing values: PAGNUM,RAACTDT,RANDNUM,SUB,INSTRUCT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
RASEQ	num	Randomization Sequence Number		Collected at CRF.
REGIMEN	char	Regimen Code		Collected at CRF.
RADOSE	char	Dose		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
DURATION	char	Duration		Collected at CRF.
FORMULAT	char	Formulation		Collected at CRF.
FREQ	char	Frequency		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
STRENGTH	char	Strength		Collected at CRF.
RAACTDY	num	Relative Actual Day of Randomization		If RAACTDT and DMINFDT not missing then perform below logic to calculate RAACTDY, If RAACTDT less than DMINFDT then (RAACTDT - DMINFDT). Else if RAACTDT is greater than equal to DMINFDT then (RAACTDT- DMINFDT) +1.

1.4.27. Resource Use Questionnaire - RUQ

Dataset	RUQ
Creating program	ruq.sas
Description	Resource Use Questionnaire
Unique identifier	DUSUBJID,RQGROUP,RQACTDY,RQSEQ
Sorted by	DUSUBJID,RQGROUP,RQACTDY,RQSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values: PAGNUM,RQACTDT,RQLSTDC,RQLSTD,RQDAYLST,RQSTDTC,RQSTDT, RQENDTC,RQENDT,RQCHDTC,RQCHDT,RQTYPOTH

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
RQGROU PC	char	Group Code		Collected at CRF.
RQGROUP	char	Group		Collected at CRF.
RQREPR TC	num	Were Any Records Reported Code		Collected at CRF.
RQREPR T	char	Were Any Records Reported		Collected at CRF.
RQSEQ	num	Sequence Number		Collected at CRF.
RQTYPE C	char	Type of Hospital/Consultation Code		Collected at CRF.
RQTYPE	char	Type of Hospital/Consultation		Collected at CRF.
RQWARD C	char	Type of Ward Code		Collected at CRF.
RQWARD	char	Type of Ward		Collected at CRF.
RQRSNC	num	Reason Code		Collected at CRF.
RQRSN	char	Reason		Collected at CRF.
RQSTON	char	Hospitalization Ongoing Start		Collected at CRF.
RQENON	char	Hospitalization Ongoing End		Collected at CRF.
RQFREQ	num	Frequency		Collected at CRF.
RQNUM	num	Number of Consultations		Collected at CRF.
RQOCCST C	char	Occupational Status Code		Collected at CRF.
RQOCCST	char	Occupational Status		Collected at CRF.
RQACCST C	char	Accommodation Status Code		Collected at CRF.
RQACCST	char	Accommodation Status		Collected at CRF.

Variable	Type	Label	Codes	Comments
RQACTDY	num	Relative Actual Day of Collection		If RQACTDT and DMINFDT not missing then perform below logic to calculate RQACTDY, If RQACTDT less than DMINFDT then (RQACTDT - DMINFDT). Else if RQACTDT is greater than equal to DMINFDT then (RQACTDT- DMINFDT) +1.
RQSTDY	num	Relative Actual Start Day of Event		If RQSTDT and DMINFDT not missing then perform below logic to calculate RQSTDY, If RQSTDT less than DMINFDT then (RQSTDT - DMINFDT). Else if RQSTDT is greater than equal to DMINFDT then (RQSTDT- DMINFDT) +1.
RQENDY	num	Relative Actual End Day of Event		If RQENDTC and DMINFDT not missing then perform below logic to calculate RQENDY, If RQENDTC less than DMINFDT then (RQENDTC - DMINFDT). Else if RQENDTC is greater than equal to DMINFDT then (RQENDTC- DMINFDT) +1.
RQCHDY	num	Relative Day of Change		If RQCHDT and DMINFDT not missing then perform below logic to calculate RQCHDY, If RQCHDT less than DMINFDT then (RQCHDT - DMINFDT). Else if RQCHDT is greater than equal to DMINFDT then (RQCHDT- DMINFDT) +1.

1.4.28. Simpson Angus Rating Scale - SARS

Dataset	SARS
Creating program	sars.sas
Description	Simpson Angus Rating Scale
Unique identifier	DUSUBJID,SRITEM,VISIT
Sorted by	DUSUBJID,SRITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,SRRATERI,SRACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SRVTYPEC	num	SARS Visit Type Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
SRVTYPE	char	SARS Visit Type		Collected at CRF.
SRITEM	char	SARS Item		Collected at CRF.
SRSCOREC	num	SARS Score Code		Collected at CRF.
SRSCORE	char	SARS Score		Collected at CRF.
SRACTDY	num	Relative Actual Day of SARS		If SRACTDT and DMINFDT not missing then perform below logic to calculate SRACTDY, If SRACTDT less than DMINFDT then (SRACTDT - DMINFDT). Else if SRACTDT is greater than equal to DMINFDT then (SRACTDT- DMINFDT) +1.

1.4.29. Subject Eval. of Inj. Site - SUEVINJ

Dataset	SUEVINJ
Creating program	suevinj.sas
Description	Subject Evaluation of Injection Site
Unique identifier	DUSUBJID,SEITEM,VISIT
Sorted by	DUSUBJID,SEITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,SEACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SEITEM	char	Evaluation Item		Collected at CRF.

Variable	Type	Label	Codes	Comments
SESCORE	num	Evaluation Score		Collected at CRF.
SEACTTM	num	Actual Time of Subj. Eval. of Inj. Site		Collected at CRF.
SEUNIT	char	Unit of Score from VAS Scale		Collected at CRF.
SEACTDY	num	Relative Actual Day of Subj. Eval. of Inj. Site		If SEACTDT and DMINFDT not missing then perform below logic to calculate SEACTDY, If SEACTDT less than DMINFDT then (SEACTDT - DMINFDT). Else if SEACTDT is greater than equal to DMINFDT then (SEACTDT- DMINFDT) +1.

1.4.30. Tolerability Testing - TOLTEST

Dataset	TOLTEST
Creating program	toltest.sas
Description	Tolerability Testing
Unique identifier	DUSUBJID,TPT
Sorted by	DUSUBJID,TPT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,TTSTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
TPTNUM	num	Planned Time Point Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
TPT	char	Planned Time Point Name		Collected at CRF.
TTTAKEN	num	Number of Pills Taken		Collected at CRF.
TTNAC	num	Tolerability Testing Not Applicable Code		Collected at CRF.
TTNA	char	Tolerability Testing Not Applicable		Collected at CRF.
TTSTDY	num	Relative Start Day of Tolerability Exposure		If TTSTDT and DMINFDT not missing then perform below logic to calculate TTSTDY, If TTSTDT less than DMINFDT then (TTSTDT - DMINFDT). Else if TTSTDT is greater than equal to DMINFDT then (TTSTDT- DMINFDT) +1.

1.4.31. Laboratory Results (Urine) - URINE

Dataset	URINE
Creating program	urine.sas
Description	Laboratory Results
Unique identifier	DUSUBJID, LBTEST, LBACTDY
Sorted by	DUSUBJID, LBTEST, LBACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAGNUM, LBTMLBL, LBPRVIDC, LBPRVID, LBREF, LBACTDT, REPUNIT, STDNRC, LBSIGLO, LBSIGHI

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LBFASC	num	Fasted Code		Collected at CRF.
LBFASC	char	Fasted		Collected at CRF.
LAGE	char	Age at Time of Visit		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
LAGEUNIT	char	Age Unit		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, if LBACTDT less than DMINFDT then (LBACTDT - DMINFDT). Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1.

1.4.32. Visit - VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,VISITDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly Assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
VISITDY	num	Relative Visit Day		If VISITDT and DMINFDT not missing then perform below logic to calculate VISITDY, If VISITDT less than DMINFDT then (VISITDT - DMINFDT). Else if VISITDT is greater than equal to DMINFDT then (VISITDT- DMINFDT) +1.

1.4.33. Vital Signs - VITAL

Dataset	VITAL
Creating program	vital.sas
Description	Vital Signs
Unique identifier	DUSUBJID,VSVTYPE,VISIT,VSSEQ
Sorted by	DUSUBJID,VSVTYPE,VISIT,VSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,VSACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly Assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.
VSPOS	char	Position		Collected at CRF.
VSWEIGHT	num	Weight		Collected at CRF.
VSWTUNIT	char	Weight Unit		Collected at CRF.
VSHEIGHT	num	Height		Collected at CRF.
VSHTUNIT	char	Height Unit		Collected at CRF.
PULSE	num	Pulse Rate (bpm)		Collected at CRF.
SYSBP	num	Systolic Blood Pressure (mmHg)		Collected at CRF.
DIABP	num	Diastolic Blood Pressure (mmHg)		Collected at CRF.
TEMP	num	Temperature		Collected at CRF.

Variable	Type	Label	Codes	Comments
TEMPUNIT	char	Temperature Unit		Collected at CRF.
VSACTDY	num	Relative Actual Day of Vital Signs		If VSACTDT and DMINFDT not missing then perform below logic to calculate VSACTDY, If VSACTDT less than DMINFDT then (VSACTDT - DMINFDT). Else if VSACTDT is greater than equal to DMINFDT then (VSACTDT- DMINFDT) +1.