

Clinical Development

Paliperidone Palmitate[®]

R092670-PSY3006

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided
- Subject and center/site numbers will be assigned in a random manner so they are not matching the subject and center/site numbers that were used in the actual trial
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Remove the free text verbatim terms.
- Remove "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial, Bottle, lot, kit number will not be provided.
- Complete missing value variables will be removed.
- 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.
- Partial date's relative day cannot be calculated.
- Datasets containing pharmacogenetic information will be submitted. (eg. DNRSLT)
- 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)
- Dataset containing sensitive information about medication kit will not be submitted. (eg. MEDKIT)
- SURGERY dataset will not be submitted due to sensitivity of information.
- Comments dataset will be submitted with zero observation due to sensitivity of data.

1.3. Data Files

The R092670-PSY3006 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	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 missing values: SUBJINIT,DMACTDT,DMSCRDT,IVID,IVNAME,BIRTHDT,DMINFDT,RACESPEC, COUNTRYC,ETHNSPEC

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

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
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.
INTF	char	Amendment INT4		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,AESEQ
Sorted by	DUSUBJID,AEDECOD,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: AETERM,AESTDT,AEENDT,AESTDTC,AEENDTC,AESERREF

Variable	Type	Label	Codes	Comments
AESEQ	num	AE Sequence Number		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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.
AEREPRTC	num	Were Any AEs Reported Code		Collected at CRF.
AEREPRT	char	Were Any AEs Reported		Collected at CRF.
AECODE	char	AE Dictionary Code		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.

Variable	Type	Label	Codes	Comments
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.
AEHOSPR	char	Hospitalization required		Collected at CRF.
AEHOSPP	char	Prolonged hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESMIE	char	Other Medicaly Important Serious Event		Collected at CRF.
AEDECOD1	char	Dictionary-Derived Lower Level Term		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEBODSYC	char	Body System or Organ Class Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.

Variable	Type	Label	Codes	Comments
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,AITEM,VISIT
Sorted by	DUSUBJID,AIGROUP,AITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AIRATERI,AIACDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
AIVTYPEC	num	AIMS Visit Type Code		Collected at CRF.
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 Scale - BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia 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: BARATERI,BAACTDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
BAVTYPEC	num	BARS Visit Type Code		Collected at CRF.
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: CGRATERI,CGACTDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
CGSEVC	num	CGI Severity Code		Collected at CRF.
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(Chemistry)
Unique identifier	DUSUBJID,LBDESCR,LBSTAT,LBACTDY,VISIT
Sorted by	DUSUBJID,LBDESCR,LBSTAT,LBACTDY,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: LBPRVIDC,LBPRVID,ACCNUM,LBREF,LBACTDT,LBTMLBL,LBENDT,LBENTM, TSTCOM,STDNRC,LBSEQ,LBSIGHI,LBSIGLO,LBCVFACT,LBREASND

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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.
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.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	Fasting Status Code		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBTYPESC	num	Lab Type Code		Collected at CRF.
LBTYPES	char	Lab Type		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGRESN	num	Numeric 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.
ORGUNIT	char	Original Units		Collected at CRF.
REPUNIT	char	Original Units		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDRESN	num	Numeric 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.
STDUNIT	char	Standard Units		Collected at CRF.
NRIND	char	Reference Range Indicator		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		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. Empty dataset will be submitted.

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

Variable	Type	Label	Codes	Comments
DOMAIN	char	Domain of Origin		Empty dataset will be submitted.
CTVISIT	char	Visit 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 missing values: CMTERM,CMREGIM,CMREAS,CMSTDTC,CMSTDT,CMENDTC,CMENDT, CMCLASC,CMCLAS

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
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
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.
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.

Variable	Type	Label	Codes	Comments
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.
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.

Variable	Type	Label	Codes	Comments
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.
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 missing values: DGACTION, DGACTION, DGDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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: DSACTDT,PREGDUDT,DEATHDT,DSRSOTH,DSRABKDT,DSRABKTM,DSRABKRS

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

Variable	Type	Label	Codes	Comments
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.
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,EGPRVID,EGPOS,EGPRVIDC,EGCHG,EGND,EGCHGC, BATCHID,EGINTOTH,EGCHGOTH

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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.
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.
EGREAD	char	ECG Reader		Collected at CRF.
EGORRESN	num	Numeric Result in Original Units		Collected at CRF.
EGVTYPE	char	ECG Visit Type		Collected at CRF.
EGORUNIT	char	Original Units		Collected at CRF.
EGINTPC	num	Interpretation Code		Collected at CRF.
EGLEAD	char	Lead Used for Measurement		Collected at CRF.
EGSEQ	num	ECG Sequence Number		Collected at CRF.
EGREADDC	num	ECG Reader Code		Collected at CRF.
EGVTYPEC	num	ECG Visit Type Code		Collected at CRF.
EGINTP	char	Interpretation		Collected at CRF.

Variable	Type	Label	Codes	Comments
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. Exposure - EXPOSURE

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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
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
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.
EXRELAT	char	Related to Injection		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
DOSE	num	Dose		Collected at CRF.
EXSTTM	num	Start Time of Exposure		Collected at CRF.
EXGIVEN	num	Number of Pills, etc Given		Collected at CRF.
EXSITEC	num	Injection Site Code		Collected at CRF.
EXSITE	char	Injection Site		Collected at CRF.
EXPOSC	num	Position of Injection Code		Collected at CRF.
EXPOS	char	Position of Injection		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.

Variable	Type	Label	Codes	Comments
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.

1.4.13. Global Impressions of Sexual Function - GISF

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

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

1.4.14. Smoking Habit - HABIT

Dataset	HABIT
Creating program	habit.sas
Description	Smoking Habit
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HAACTDT,HAENDTC

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

1.4.15. Laboratory Results(Hematology) - HEMAT

Dataset	HEMAT
Creating program	hemat.sas
Description	Laboratory Results(Hematology)
Unique identifier	DUSUBJID,LBDESCR,LBSTAT,LBACTDY
Sorted by	DUSUBJID,LBDESCR,LBSTAT,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: LBPRVIDC,LBPRVID,ACCNUM,LBREF,LBACTDT,LBTMLBL,LBENDT,LBENTM, TSTCOM,STDNRC,LBSEQ,LBSIGHI,LBSIGLO,LBCVFACT,LBREASND

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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.
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.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	Fasting Status Code		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBTYPESC	num	Lab Type Code		Collected at CRF.
LBTYPES	char	Lab Type		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGRESN	num	Numeric 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.
ORGUNIT	char	Original Units		Collected at CRF.
REPUNIT	char	Original Units		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDRESN	num	Numeric 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.
STDUNIT	char	Standard Units		Collected at CRF.
NRIND	char	Reference Range Indicator		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		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.

1.4.16. Inclusion/Exclusion Exceptions - IE

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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IESPID	char	Sponsor-defined Identifier		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IESTRESC	char	Exception Criterion Result in Std Format		Collected at CRF.
IEORRES	char	Exception Criterion Original Result		Collected at CRF.
IEMETC	num	Overall Criteria Met Code		Collected at CRF.
IEMET	char	Overall Criteria Met		Collected at CRF.
IEDY	num	Relative Day of Collection		If IEDT and DMINFDT not missing then perform below logic to calculate IEDY, If IEDT less than DMINFDT then (IEDT - DMINFDT). Else if IEDT is greater than equal to DMINFDT then (IEDT - 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,IERELAT,VISIT
Sorted by	DUSUBJID,IEITEM,IERELAT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IERATERI,IEACTDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
IERELAT	char	Related to Injection		Collected at CRF.
IEITEM	char	Evaluation Item		Collected at CRF.
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: MHACTDT,MHTERM

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
MHSEQ	num	MH Sequence Number		Collected at CRF.
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. Positive and Negative Syndrome Scale - PANSS

Dataset	PANSS
Creating program	panss.sas
Description	Positive and Negative Syndrome Scale
Unique identifier	DUSUBJID,PAGROUP,PAITEM,VISIT
Sorted by	DUSUBJID,PAGROUP,PAITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PARATERI,PAACTDT

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

1.4.20. PKPD Concentrations - PCCNC

Dataset	PCCNC
Creating program	pccnc.sas
Description	PKPD Concentrations
Unique identifier	DUSUBJID,VISIT,PCTEST
Sorted by	DUSUBJID,VISIT,PCTEST
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SPPRVIDC,SPPRVID,PCPRVIDC,PCPRVID,SAMREF,ACQREF,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.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
TPTNUM	num	Planned Time Point Number		Collected at CRF.
TPT	char	Planned Time Point		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.
PCORRES	char	Result in Original Units		Collected at CRF.
PCORUNIT	char	Original Units		Collected at CRF.
PCNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
PCNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
PCSTRESC	char	Character Result in Standard Units		Collected at CRF.
PCSTUNIT	char	Standard Units		Collected at CRF.
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.

1.4.21. 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: PEACTDT,PEFIND

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
PESEQ	num	Phys Sequence Number		Collected at CRF.
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 DMINFDT not missing then perform below logic to calculate PEACTION, If PEACTION less than DMINFDT then (PEACTION - DMINFDT). Else if PEACTION is greater than equal to DMINFDT then (PEACTION- DMINFDT) +1.

1.4.22. 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.

Variable	Type	Label	Codes	Comments
PVSEQ	num	Protocol Deviation Seq Number		Collected at CRF.
PVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

1.4.23. 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: PSRATERI,PSACTDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
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
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.
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.

1.4.24. Pittsburg Sleep Quality Index - PSQI

Dataset	PSQI
Creating program	psqi.sas
Description	Pittsburg Sleep Quality Index
Unique identifier	DUSUBJID,QIITEM,VISIT
Sorted by	DUSUBJID,QIITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: QIACTDT,QIRSOTH

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
QIITEM	char	PSQI Item		Collected at CRF.
QISCOREC	num	PSQI Score Code		Collected at CRF.
QISCORE	char	PSQI Score		Collected at CRF.
QIACTDY	num	Relative PSQI Actual day		If QIACTDT and DMINFDT not missing then perform below logic to calculate QIACTDY, If QIACTDT less than DMINFDT then (QIACTDT - DMINFDT). Else if QIACTDT is greater than equal to DMINFDT then (QIACTDT- DMINFDT) +1.

1.4.25. Psychiatric History - PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychiatric History
Unique identifier	DUSUBJID,PYHOSP,PYSEQ
Sorted by	DUSUBJID,PYHOSP,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: PYDIAG,PYSTDT, PYSTDT, PYENDTC, PYENDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
PYHOSPC	num	Hospitalizations for Psychosis Code		Collected at CRF.
PYHOSP	char	Hospitalizations for Psychosis		Collected at CRF.
PYSEQ	num	Psychiatric History Sequence Number		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 missing values: RAACTDT,RANDNUM,SUB,INSTRUCT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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.
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. 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: SRRATERI,SRACTDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
SRVTYPEC	num	SARS Visit Type Code		Collected at CRF.
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.

1.4.28. Schedule for Deficit Syndrome - SDS

Dataset	SDS
Creating program	sds.sas
Description	Schedule for Deficit Syndrome
Unique identifier	DUSUBJID,SDITEM,VISIT
Sorted by	DUSUBJID,SDITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SDACTDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
SDGROUP	char	SDS Group		Collected at CRF.
SDITEM	char	SDS Item		Collected at CRF.
SDSCOREC	num	SDS Score Code		Collected at CRF.
SDSCORE	char	SDS Score		Collected at CRF.
SDACTDY	num	Relative Actual day of SDS		If SDACTDT and DMINFDT not missing then perform below logic to calculate SDACTDY, If SDACTDT less than DMINFDT then (SDACTDT - DMINFDT). Else if SDACTDT is greater than equal to DMINFDT then (SDACTDT- 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,SERELAT,VISIT
Sorted by	DUSUBJID,SEITEM,SERELAT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SEACTDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
SERELAT	char	Related to Injection		Collected at CRF.
SEITEM	char	Evaluation Item		Collected at CRF.
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. Trial Inclusion/Exclusion Criteria - TI

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IESPID	char	Sponsor-defined Identifier		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.

1.4.31. Tolerability Testing - TOLTEST

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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
TTSEQ	num	Tolerability Testing Sequence Number		Collected at CRF.
TPTNUM	num	Planned Time Point Number		Collected at CRF.
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.

1.4.32. Laboratory Results(Urine) - URINE

Dataset	URINE
Creating program	urine.sas
Description	Laboratory Results(Urine)
Unique identifier	DUSUBJID,LBDESCR,LBSTAT,LBACTDY,LBACTTM
Sorted by	DUSUBJID,LBDESCR,LBSTAT,LBACTDY,LBACTTM
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: LBPRVIDC,LBPRVID,ACCNUM,LBREF,LBACTDT,LBTMLBL,LBENDT,LBENTM, TSTCOM,STDNRC,LBSEQ,LBSIGHI,LBSIGLO,LBCVFACT,LBREASND

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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.
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.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	Fasting Status Code		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGRESN	num	Numeric 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.
ORGUNIT	char	Original Units		Collected at CRF.
REPUNIT	char	Original Units		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDRESN	num	Numeric 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.
STDUNIT	char	Standard Units		Collected at CRF.
NRIND	char	Reference Range Indicator		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		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.

1.4.33. Sleep VAS Scale Scores - VAS

Dataset	VAS
Creating program	vas.sas
Description	Sleep VAS Scale Scores
Unique identifier	DUSUBJID,VASCALE,VISIT
Sorted by	DUSUBJID,VASCALE,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VAACDTT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id 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
VASCALE	char	VAS Scale		Collected at CRF.
VASCORE	num	VAS Score (mm)		Collected at CRF.
VAACTDY	num	Relative Actual Day of VAS		If VAACTDT and DMINFDT not missing then perform below logic to calculate VAACTDY, If VAACTDT less than DMINFDT then (VAACTDT - DMINFDT). Else if VAACTDT is greater than equal to DMINFDT then (VAACTDT- DMINFDT) +1.

1.4.34. 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: VISITDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

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
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.
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.

1.4.35. 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: VSACTDT

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

Variable	Type	Label	Codes	Comments
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.
VSWAIST	num	Waist		Collected at CRF.
VWSUNIT	char	Waist 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.
TEMPUNIT	char	Temperature Unit		Collected at CRF.
RESP	num	Respiration Rate (/min)		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.