Clinical Development

Paliperidone®

R076477-SCH305

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	20 Apr 2016

Property of Janssen
Confidential
May not be used, divulged, published or otherwise disclosed
without the consent of Janssen

Table of contents

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's Relative day cannot be calculated.
- Reference number will not be provided.
- COMMENTS dataset will be submitted with zero observations..
- Dataset INVEST containing investigator information will not be submitted.
- Dataset MEDKIT containing information regarding Medical-Kit number will not be submitted.
- SURGERY dataset contains sensitive information regarding surgery. Hence, will not be submitted.
- Labname information will not be submitted (e.g. LBPRVID, LBPRVID, ITPRVID, LBPRVID).
- Dataset does not have any subject level information will not be submitted. (eg. PROTDESC).
- Dataset containing Pharmacogenetic information will not be submitted due to sensitivity of information. (eg. DNRSLT)
- Informed Consent Date will be used as Reference Date to derive relative days.

1.3. Data Files

The R076477-SCH305 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 non significant elements: DMSCRDT, SUBJINIT, DMACTDT, IVID, IVNAME, BIRTHDT, DMINFDT, RACESPEC, PAGNUM, COUNTRYC

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 Id		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		Collected at CRF.
RACE	char	Race		Collected at CRF.
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		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= floor((DMINFDT – DOB)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.

Variable	Type	Label	Codes	Comments
DMSCRDY	num	Relative Day of First Trial Related Proc		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.
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.

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Event
Unique identifier	DUSUBJID,AEBODSCW, AESEQ
Sorted by	DUSUBJID,AEBODSCW, 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 Id		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.
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.
AEDCOD1W	char	WHO Included Term		Collected at CRF.
AEBODSCW	char	Body System Code		Collected at CRF.
AEBODSYW	char	Body System		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF.
AECODEW	char	AE Dictionary Code		Collected at CRF.
AEDECODW	char	WHO Preferred Term		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
SOC1W	char	AE System Organ Class 1		Collected at CRF.
SOC2W	char	AE System Organ Class 2		Collected at CRF.
SOC3W	char	AE System Organ Class 3		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,VISIT, AIITEM
Sorted by	DUSUBJID,VISIT, AIITEM
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, AIACTDT

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 Id		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	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,VISIT,BAGROUP, BAITEM
Sorted by	DUSUBJID,VISIT,BAGROUP, BAITEM
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 Id		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	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, 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, 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 Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
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. Chemistry – CHEM

Dataset	CHEM
Creating program	chem.sas
Description	Chemistry
Unique identifier	DUSUBJID,VISIT,LBVTYPE,LBTEST, LBACTDY
Sorted by	DUSUBJID,VISIT,LBVTYPE,LBTEST, LBACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LBPTM, LBFASTC, LBFAST, LBACTDT, LBPRVIDC, LBPRVID, LBREF, BATCHID

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBCVRES	num	Result in Conventional Units		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBTMLBL	char	Pre-determined collection times		Collected at CRF.
ORGRESN	num	Numeric lab result		Collected at CRF.
ORGRES	char	Character lab result		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	High/Low Lab Value Flag		Collected at CRF.
ORGNRHI	num	Upper limit for the lab normal range		Collected at CRF.
ORGNRLO	num	Lower limit for the lab normal range		Collected at CRF.
STDNRLO	num	S.I. lower limit		Collected at CRF.
STDRESN	num	S.I. numeric result		Collected at CRF.
STDNRHI	num	S.I. upper limit		Collected at CRF.
LAGE	char	Age: 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 (M or Y)		Collected at CRF.
LBSEQ	num	RSM unique record id within protocol		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBABBR	char	Lab Abbreviation		Collected at CRF.
LBSIGLO	num	Significant Range Low		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSIGHI	num	Significant Range High		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
STUDYID	char	Study Id		Empty data will be submitted.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Empty data will be submitted.

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

1.4.8. Concomitant Drug/Therapy – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant Drug/Therapy
Unique identifier	DUSUBJID,VISIT,CMGROUP,CMCLASC0,CMSTDY, CMSEQ
Sorted by	DUSUBJID,VISIT,CMGROUP,CMCLASC0,CMSTDY, CMSEQ
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: PAGNUM, CMCLASC, AESEQ, CMSTDT, CMTERM, CMREAS, CMENDT, CMREGIM, CMSTDTC, CMENDTC

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMREPRTC	num	Were Any Meds Administered/Changed Code		Collected at CRF.
CMGROUPC	num	Medication Grouping Code		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMREPRT	char	Were Any Meds Administered/Changed		Collected at CRF.
CMGROUP	char	Medication Grouping		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMROUTE	char	Route		Collected at CRF.
CMCONTC	num	Medication Continuing Code		Collected at CRF.
CMCONT	char	Medication Continuing		Collected at CRF.
CMPRIORC	num	Med Started Prior to Trial Code		Collected at CRF.
CMPRIOR	char	Med Started Prior to Trial		Collected at CRF.
CMCAUSC	num	Cause of Concom/Drug/Therapy Code		Collected at CRF.
CMCAUS	char	Cause of Concom/Drug/Therapy		Collected at CRF.
CMDOSE	num	Dosage		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMUNIT	char	Dose Unit		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.
CMCLAS	char	ATC Text		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. Schizophrenia 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 due to non significant elements: PAGNUM

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DGTYPEC	num	Schizophrenia Type Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
DGTYPE	char	Schizophrenia Type		Collected at CRF.
DIAGNOSC	num	Diagnosis Code		Collected at CRF.
DIAGNOS	char	Diagnosis		Collected at CRF.
DGAGE	char	Age at 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.

1.4.10. Diabetes-Related History – DIAHIST

Dataset	DIAHIST
Creating program	diahist.sas
Description	Diagnosis History
Unique identifier	DUSUBJID, DHDIAG
Sorted by	DUSUBJID, DHDIAG
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, DHACTDT

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DHCHILD	num	Number of Children Born Weight >10 lbs		Collected at CRF.
DHDIAG	char	Diagnosis		Collected at CRF.
DHHISTC	num	Diabetes History Code		Collected at CRF.
DHHIST	char	Diabetes History		Collected at CRF.
DHAGE	char	Age at Diagnosis		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DHACTDY	num	Relative Actual Day of Diabetes Rel Hist		If DHACTDT and DMINFDT not missing then perform below logic to calculate DHACTDY, If DHACTDT less than DMINFDT then (DHACTDT - DMINFDT).Else if DHACTDT is greater than equal to DMINFDT then (DHACTDT- DMINFDT) +1.

1.4.11. End Of Trial Information – 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 or due to missing values: PAGNUM, DEATHDT, PREGDUDT, DSACTDT, DSRSOTH, DSRABKDT, DSRABKRS, DSRABKTM

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 Id		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.
DSREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF.
DSREAS	char	Reason for Withdrawal/Termination		Collected at CRF.
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF.
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF.
DSOLC	num	Continue into Open Label Code		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
DSSCRNC	num	Screen Failure Code		Collected at CRF.
DSSCRN	char	Screen Failure		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
DSACTDY	num	Relative Actual Day Trial Compl/Withdraw		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.

1.4.12. Electrocardiogram – ECG

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

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGTESTCD	char	ECG Test Short Name		Collected at CRF.
EGPTMNUM	num	Label of Planned Elapsed Time		Collected at CRF.
EGPTM	char	Planned Elapsed Time of ECG		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	Result Numeric in Standard Units		Collected at CRF.
EGSTUNIT	char	Standard Units		Collected at CRF.
EGSTRESC	char	Result Character		Collected at CRF.
EGORRESN	num	Result Numeric 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.
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.

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.

1.4.13. Enrollment – ENROLL

Dataset	ENROLL
Creating program	enroll.sas
Description	Enrollment
Unique identifier	DUSUBJID, ENTEXT
Sorted by	DUSUBJID, ENTEXT
Notes	Below listed variables will be dropped from dataset 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

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
ENCRIT	char	Inclusion or Exclusion Criterion		Collected at CRF.
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.

1.4.14. Exposure – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Exposure
Unique identifier	DUSUBJID, EXSTDY
Sorted by	DUSUBJID, EXSTDY
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, EXSTRDT, EXENDDT, 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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXGIVENA	num	Number of A Capsules Taken		Collected at CRF.
EXGIVENB	num	Number of B Capsules Taken		Collected at CRF.
EXGIVENC	num	Number of C Capsules Taken		Collected at CRF.
EXSTRDY	num	Relative Start Day of Med. Taken from W1 Medkit		If EXSTRDT and DMINFDT not missing then perform below logic to calculate EXSTRDY, If EXSTRDT less than DMINFDT then (EXSTRDT - DMINFDT).Else if EXSTRDT is greater than equal to DMINFDT then (EXSTRDT- DMINFDT) +1.
EXENDDY	num	Relative End Day of Med. Taken from W1 Medkit		If EXENDDT and DMINFDT not missing then perform below logic to calculate EXENDDY, If EXENDDT less than DMINFDT then (EXENDDT - DMINFDT).Else if EXENDDT is greater than equal to DMINFDT then (EXENDDT- DMINFDT) +1.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDT and DMINFDT not missing then perform below logic to calculate EXSTDY, If EXSTDT less than DMINFDT then (EXSTDT - DMINFDT).Else if EXSTDT is greater than equal to DMINFDT then (EXSTDT- DMINFDT) +1.
EXENDY	num	Relative End Day of Exposure		If EXENDT and DMINFDT not missing then perform below logic to calculate EXENDY, If EXENDT less than DMINFDT then (EXENDT - DMINFDT).Else if EXENDT is greater than equal to DMINFDT then (EXENDT- DMINFDT) +1.

1.4.15. Family History – FAMHIST

Dataset	FAMHIST
Creating program	famhist.sas
Description	Family History
Unique identifier	DUSUBJID, FHMEM
Sorted by	DUSUBJID, FHMEM
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, FHACTDT

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
FHHISTC	num	Relatives History of Diabetes Code		Collected at CRF.
FHHIST	char	Relatives History of Diabetes		Collected at CRF.
FHMEM	char	Family Member		Collected at CRF.
FHDTYPE	char	Diabetes Types		Collected at CRF.
FHACTDY	num	Relative Actual Day of Collection		If FHACTDT and DMINFDT not missing then perform below logic to calculate FHACTDY, If FHACTDT less than DMINFDT then (FHACTDT - DMINFDT).Else if FHACTDT is greater than equal to DMINFDT then (FHACTDT- DMINFDT) +1.

1.4.16. Habit – HABIT

Dataset	HABIT
Creating program	habit.sas
Description	Habit
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, HAACTDT, 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 Id		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 Collection		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.

1.4.17. Hematology – HEMAT

Dataset	HEMAT
Creating program	hemat.sas
Description	Hematology
Unique identifier	DUSUBJID,VISIT,LBVTYPE, LBTEST
Sorted by	DUSUBJID,VISIT,LBVTYPE, LBTEST
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LBPTM, LBFASTC, LBFAST, LBACTDT, LBPRVIDC, LBPRVID, LBREF, BATCHID, LBSEQ

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDUNIT	char	Standard Units		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBCVRES	num	Result in Conventional Units		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBTMLBL	char	Pre-determined collection times		Collected at CRF.
ORGRESN	num	Numeric lab result		Collected at CRF.
ORGRES	char	Character lab result		Collected at CRF.
NRIND	char	High/Low Lab Value Flag		Collected at CRF.
ORGNRHI	num	Upper limit for the lab normal range		Collected at CRF.
ORGNRLO	num	Lower limit for the lab normal range		Collected at CRF.
STDNRLO	num	S.I. lower limit		Collected at CRF.
STDRESN	num	S.I. numeric result		Collected at CRF.
STDNRHI	num	S.I. upper limit		Collected at CRF.

Variable	Type	Label	Codes	Comments
LAGE	char	Age: 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 (M or Y)		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBABBR	char	Lab Abbreviation		Collected at CRF.
LBSIGLO	num	Significant Range Low		Collected at CRF.
LBSIGHI	num	Significant Range High		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.

1.4.18. Hospitalisation – HOSPITAL

Dataset	HOSPITAL
Creating program	hospital.sas
Description	Hospitalisation
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, HOSTDT, HOENDT

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
HODISCHC	num	Was the Subject Discharged Code		Collected at CRF.
HODISCH	char	Was the Subject Discharged		Collected at CRF.
HOSTDY	num	Relative Admission Day of Hospitalization		If HOSTDT and DMINFDT not missing then perform below logic to calculate HOSTDY, If HOSTDT less than DMINFDT then (HOSTDT - DMINFDT).Else if HOSTDT is greater than equal to DMINFDT then (HOSTDT- DMINFDT) +1.
HOENDY	num	Relative Discharge Day		If HOENDT and DMINFDT not missing then perform below logic to calculate HOENDY, If HOENDT less than DMINFDT then (HOENDT - DMINFDT).Else if HOENDT is greater than equal to DMINFDT then (HOENDT- DMINFDT) +1.

1.4.19. Drug Intake – INTAKE

Dataset	INTAKE
Creating program	intake.sas
Description	Drug Intake
Unique identifier	DUSUBJID,VISIT,ITTYPE, ITACTDY
Sorted by	DUSUBJID,VISIT,ITTYPE, ITACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ACQREF, ITACTDT, ITPRVIDC, ITPRVID

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
ITTYPE	char	Intake Type		Collected at CRF.

Variable	Type	Label	Codes	Comments
ITACTTM	num	Actual Time of Intake		Collected at CRF.
ITACTDY	num	Relative Actual Day of Intake		If ITACTDT and DMINFDT not missing then perform below logic to calculate ITACTDY, If ITACTDT less than DMINFDT then (ITACTDT - DMINFDT).Else if ITACTDT is greater than equal to DMINFDT then (ITACTDT- DMINFDT) +1.

1.4.20. Medical History – MEDHIST

Dataset	MEDHIST
Creating program	medhist.sas
Description	Medical History
Unique identifier	DUSUBJID,MHBODSYS, MHSEQ
Sorted by	DUSUBJID,MHBODSYS, MHSEQ
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, MHTERM, MHACTDT

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
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.

1.4.21. Positive And Negative Syndrome Scale For Schizophrenia – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	Positive And Negative Syndrome Scale For Schizophrenia
Unique identifier	DUSUBJID,VISIT, PAITEM
Sorted by	DUSUBJID,VISIT, PAITEM
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, PARATERI, PAACTDT

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.22. Blood Sampling For Pharmacokinetics – PCCNC

Dataset	PCCNC
Creating program	pccnc.sas
Description	Blood Sampling For Pharmacokinetics
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 or due to missing values: PAGNUM, PCSTRESC, PCSTUNIT, PCSTRESN, PCENDT, PCNRLO, PCNRHI, PCENTM, PCREAS, PCRSOTH, PCSTDT, PCPRVIDC, PCPRVID, ACQREF, SAMREF, PCLBREF, PCSCOM

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
TPT	char	Planned Timepoint Name		Collected at CRF.
TPTNUM	num	Planned Timepoint		Collected at CRF.
PCSTTM	num	Start Time of Collection (24hr clock)		Collected at CRF.
PCSPEC	char	Specimen Material		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
SPPRVIDC	num	Sample Provider ID Code		Collected at CRF.
SPPRVID	char	Sample Provider ID		Collected at CRF.
PCSEQ	num	Sample Sequence Number		Collected at CRF.
PCTEST	char	Test Name		Collected at CRF.
PCORRES	char	Result in Original Units		Collected at CRF.
PCORUNIT	char	Original Unit		Collected at CRF.
PCORRESN	num	Analysis numeric Result in Original Unit		Collected at CRF.
PCLOQ	char	Limit of Quantification		Collected at CRF.
PCPRMTYP	char	Parameter Type		Collected at CRF.
PCVTYPEC	num	PK/PD Sample Visit Type Code		Collected at CRF.
PCVTYPE	char	PK/PD Sample Visit Type		Collected at CRF.
PCCAT	char	Category for Test or Examination		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCTAKENC	num	Was Sample Taken Code		Collected at CRF.
PCTAKEN	char	Was Sample Taken		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.

1.4.23. Blood Sampling For Pharmacokinetics– PCCONC

Dataset	PCCONC
Creating program	pcconc.sas
Description	Blood Sampling For Pharmacokinetics
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 missing values: PCSTRESC, PCSTUNIT, PCSTRESN, PCNRLO, PCNRHI, PCPRVIDC, PCPRVID, SAMREF, PCLBREF

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PCSEQ	num	Sample Sequence Number		Collected at CRF.
TPTNUM	num	Planned Timepoint Number		Collected at CRF.
TPT	char	Planned Timepoint Name		Collected at CRF.
PCPRMTYP	char	Parameter Type		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
PCSPEC	char	Specimen Material		Collected at CRF.
PCTEST	char	Test Name		Collected at CRF.
PCORRES	char	Result in Original Units		Collected at CRF.
PCORUNIT	char	Original Unit		Collected at CRF.
PCORRESN	num	Analysis numeric Result in Original Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCLOQ	char	Limit of Quantification		Collected at CRF.
PCCAT	char	Category for Test or Examination		Collected at CRF.

1.4.24. Pharmacokinetics Sample– PCSAMP

Dataset	PCSAMP
Creating program	pcsamp.sas
Description	Pharmacokinetics Sample
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 or due to missing values: PAGNUM, SPENDT, SPENTM, SPREAS, SPRSOTH, SPSTDT, SPPRVIDC, SPPRVID, SAMREF, ACQREF, SPCOM

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SAMSEQ	num	Sample Sequence Number		Collected at CRF.
SPTAKENC	num	Was Sample Taken Code?		Collected at CRF.
SPTAKEN	char	Was Sample Taken ?		Collected at CRF.
TPTNUM	num	Planned Timepoint Number		Collected at CRF.
TPT	char	Planned Time Point Name		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
SPSTTM	num	Start Time of Collection (24 hr clock)		Collected at CRF.
SPVTYPEC	num	PK/PD Sample Visit Type Code		Collected at CRF.
SPVTYPE	char	PK/PD Sample Visit Type		Collected at CRF.

Variable	Type	Label	Codes	Comments
SPCAT	char	Category for Test or Examination		Collected at CRF.
SPSTDY	num	Relative Start Day of Specimen Collection		If SPSTDT and DMINFDT not missing then perform below logic to calculate SPSTDY, If SPSTDT less than DMINFDT then (SPSTDT - DMINFDT).Else if SPSTDT is greater than equal to DMINFDT then (SPSTDT- DMINFDT) +1.

1.4.25. Physical Examination – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examination
Unique identifier	DUSUBJID,VISIT,PEBODSYS, PESEQ
Sorted by	DUSUBJID,VISIT,PEBODSYS, PESEQ
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, PEFIND, PEACTDT

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
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 PEACTDT and DMINFDT not missing then perform below logic to calculate PEACTDY, If PEACTDT less than DMINFDT then (PEACTDT - DMINFDT).Else if PEACTDT is greater than equal to DMINFDT then (PEACTDT- DMINFDT) +1.

1.4.26. Protdev – PROTDEV

Dataset	PROTDEV
Creating program	protdev.sas
Description	Protdev
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.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		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.

1.4.27. Personal And Social Performance Scale – PSP

Dataset	PSP
Creating program	psp.sas
Description	Personal And Social Performance Scale
Unique identifier	DUSUBJID,VISIT, PASACTDY
Sorted by	DUSUBJID,VISIT, PASACTDY
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

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 Id		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.

1.4.28. Psychotic History – PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychotic History
Unique identifier	DUSUBJID,PYSTDY, PYSEQ
Sorted by	DUSUBJID,PYSTDY, 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: PAGNUM, PYEPIDTC, PYEPIDT, PYDIAG, PYSTDT, PYSTDTC, PYENDTC, PYENDT

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PYSEQ	num	Psychiatric History Sequence Number		Collected at CRF.
PYEPIDY	num	Relative Day of Lst Acute Psychotic Symp		If PYEPIDTC and DMINFDT not missing then perform below logic to calculate PYEPIDY, If PYEPIDTC less than DMINFDT then (PYEPIDTC - DMINFDT).Else if PYEPIDTC is greater than equal to DMINFDT then (PYEPIDTC- DMINFDT) +1.
PYSTDY	num	Relative Start Day of Psychosis Trtmt		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 End Day of Psychosis Treatment		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.

1.4.29. Randomisation – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomisation
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, SUB, RAACTDT, RANDNUM

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
RASEQ	num	Randomization Sequence Number		Collected at CRF.
REGIMEN	char	Regimen		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DOSE	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.
INSTRUCT	char	Instructions		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.

1.4.30. Simpson - Angus Scale – SARS

Dataset	SARS
Creating program	sars.sas
Description	Simpson - Angus Scale
Unique identifier	DUSUBJID,VISIT,SRITEM, SRACTDY
Sorted by	DUSUBJID,VISIT,SRITEM, SRACTDY
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 Id		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	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.

1.4.31. SQLS-R4 – SQLSR4

Dataset	SQLSR4
Creating program	sqlsr4.sas
Description	SQLS-R4
Unique identifier	DUSUBJID,VISIT, SQITEM
Sorted by	DUSUBJID,VISIT, SQITEM
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, SQACTDT

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SQSEQ	num	SQLSR4 Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
SQITEM	char	SQLSR4 Item		Collected at CRF.
SQSCOREC	num	Score Code		Collected at CRF.
SQSCORE	char	Score		Collected at CRF.
SQACTDY	num	Relative Actual Day of SQLS-R4		If SQACTDT and DMINFDT not missing then perform below logic to calculate SQACTDY, If SQACTDT less than DMINFDT then (SQACTDT - DMINFDT).Else if SQACTDT is greater than equal to DMINFDT then (SQACTDT- DMINFDT) +1.

1.4.32. Urine – URINE

Dataset	URINE
Creating program	urine.sas
Description	Urine
Unique identifier	DUSUBJID,VISIT,LBVTYPE, LBTEST
Sorted by	DUSUBJID,VISIT,LBVTYPE, LBTEST
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LBPTM, LBFASTC, LBFAST, LBSIGLO, LBSIGHI, LBACTDT, LBPRVIDC, LBPRVID, LBREF, BATCHID, LBSEQ

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDUNIT	char	Standard Units		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBCVRES	num	Result in Conventional Units		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBTMLBL	char	Pre-determined collection times		Collected at CRF.
ORGRESN	num	Numeric lab result		Collected at CRF.
ORGRES	char	Character lab result		Collected at CRF.
NRIND	char	High/Low Lab Value Flag		Collected at CRF.
ORGNRHI	num	Upper limit for the lab normal range		Collected at CRF.
ORGNRLO	num	Lower limit for the lab normal range		Collected at CRF.
STDNRLO	num	S.I. lower limit		Collected at CRF.
STDRESN	num	S.I. numeric result		Collected at CRF.
STDNRHI	num	S.I. upper limit		Collected at CRF.

Variable	Type	Label	Codes	Comments
LAGE	char	Age: 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 (M or Y)		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBABBR	char	Lab Abbreviation		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, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, VAACTDT

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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VASCORE	num	VAS Score (mm)		Collected at CRF.

Variable	Type	Label	Codes	Comments
VASCALE	char	VAS Scale		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, VISITDY
Sorted by	DUSUBJID,VISIT, VISITDY
Notes	

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 Id		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,VISIT,VSACTDY, VSSEQ
Sorted by	DUSUBJID,VISIT,VSACTDY, VSSEQ
Notes	Below listed variables will be dropped from dataset 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
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 Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PULSE	num	Pulse Rate (bpm)		Collected at CRF.
TEMP	num	Temperature		Collected at CRF.
TEMPUNIT	char	Temperature Unit		Collected at CRF.
SYSBP	num	Systolic Blood Pressure (mmHg)		Collected at CRF.
DIABP	num	Diastolic Blood Pressure (mmHg)		Collected at CRF.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
VSVTYPE	char	Vital Signs Visit Type		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.
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.