

Clinical Development

**Paliperidone<sup>®</sup>**

R076477SCH302

Anonymisation Data Derivation Specification Document

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<b>Status and Version</b>	<b>Release Date</b>	<b>Summary of Key Changes</b>

## 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	Code list name
Comments	Variable source derivation explanation if variable derived.

### 1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided.
- Investigator Information will not be provided.
- Date of birth will not be provided, only age in years will be provided.
- Age will be grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Remove the free text verbatim terms.
- Remove "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial and Bottle number will not be provided.

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's relative day cannot be calculated
- Dataset containing Pharmacogenetic information will not be submitted due to sensitivity of information. (eg. DNRSLT)
- Dataset containing Investigator information 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 R076477SCH302 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Demographics - DEMOG

<b>Dataset</b>	DEMOG
<b>Creating program</b>	demog.sas
<b>Description</b>	Demographics
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	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,COUNTRYC,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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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		<p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule:  <math>AGE = \text{int}((DMINFDT - BIRTHDT)/365.25)</math></p> <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p>

Variable	Type	Label	Codes	Comments
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.
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

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	DUSUBJID,AEDCOD1W,AESEQ
<b>Sorted by</b>	DUSUBJID,AEDCOD1W,AESEQ
<b>Notes</b>	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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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.
AEBODSYW	char	WHO Body System		Collected at CRF.
AEBODSCW	char	Body System Code		Collected at CRF.
AEDCOD1W	char	WHO Included Term		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF.

Variable	Type	Label	Codes	Comments
AECODEW	char	AE Dictionary Code		Collected at CRF.
AEDECODW	char	WHO Preferred Term		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

<b>Dataset</b>	AIMS
<b>Creating program</b>	aims.sas
<b>Description</b>	Abnormal Involuntary Movement Scale
<b>Unique identifier</b>	DUSUBJID,AIITEM,VISIT
<b>Sorted by</b>	DUSUBJID,AIITEM,VISIT
<b>Notes</b>	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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
AIVTYPEPEC	num	AIMS Visit Type		Collected at CRF.

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

## 1.4.4. Barnes Akathisia Scale - BARS

<b>Dataset</b>	BARS
<b>Creating program</b>	bars.sas
<b>Description</b>	Barnes Akathisia Scale
<b>Unique identifier</b>	DUSUBJID,BAITEM,VISIT
<b>Sorted by</b>	DUSUBJID,BAITEM,VISIT
<b>Notes</b>	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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
BAVTYPEC	num	BARS Visit Type Code		Collected at CRF.

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

## 1.4.5. Clinical Global Impression - CGI

<b>Dataset</b>	CGI
<b>Creating program</b>	cgi.sas
<b>Description</b>	Clinical Global Impression
<b>Unique identifier</b>	DUSUBJID,CGSEV,VISIT
<b>Sorted by</b>	DUSUBJID,CGSEV,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: CGRATERI,PAGNUM,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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
CGSEVC	num	CGI Severity Code		Collected at CRF.

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

#### 1.4.6.Laboratory Results(Chemistry) - CHEM

<b>Dataset</b>	CHEM
<b>Creating program</b>	chem.sas
<b>Description</b>	Laboratory Results(Chemistry)
<b>Unique identifier</b>	DUSUBJID,LBDESCR,VISIT,LBACTTM,LBCVRES
<b>Sorted by</b>	DUSUBJID,LBDESCR,VISIT,LBACTTM,LBCVRES
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:LABSPEC,LBPTM,LBACTDT,LBPRVIDC,LBREF,BATCHID,LBFASTC,LBFAST,LBPRVID

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTYPES	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.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
ORGRESN	num	Numeric lab result		Collected at CRF.
ORGRES	char	Character lab result		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.

Variable	Type	Label	Codes	Comments
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	Lab Sequence Number		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 Test Abbreviation		Collected at CRF.
LBSIGLO	num	Significant Range Low		Collected at CRF.
LBSIGHI	num	Significant Range High		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBTMLBL	char	Label of Planned Collection Time		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

<b>Dataset</b>	COMMENTS
<b>Creating program</b>	comments.sas
<b>Description</b>	Comments
<b>Unique identifier</b>	Not Applicable
<b>Sorted by</b>	Not Applicable
<b>Notes</b>	Comments data is sensitive data, contains free text information. Empty dataset will be submitted.

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

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

## 1.4.8. Concomitant Drug/Therapy: Rescue Med.- CONMED

<b>Dataset</b>	CONMED
<b>Creating program</b>	conmed.sas
<b>Description</b>	Concomitant Drug/Therapy: Rescue Med.
<b>Unique identifier</b>	DUSUBJID,CMDECOD,CMGROUP,CMSEQ
<b>Sorted by</b>	DUSUBJID,CMDECOD,CMGROUP,CMSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:  PAGNUM,CMSTDT,CMTERM,CMREAS,CMENDT,CMREGIM,AESEQ,CMSTDTC,CMENDTC,CMCLASC,CMCLASC8,CMCLASC9,CMCLAS8,CMCLAS9

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASENUM	num	Phase Number		Collected at CRF.
CMREPRTC	num	Were Any Meds Administered/Changed Code		Collected at CRF.
CMGROU PC	num	Medication Grouping Code		Collected at CRF.
CMGROUP	char	Medication Grouping		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMREPRT	char	Were Any Medications Administered/Change		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		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.
CMUNIT	char	Dose Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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.
CMCODE	char	Medication Dictionary Code		Collected at CRF.
CMDECOD	char	Medication Generic Term		Collected at CRF.
CMCLAS	char	ATC Text		Collected at CRF.

Variable	Type	Label	Codes	Comments
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

<b>Dataset</b>	DIAGNOS
<b>Creating program</b>	diagnos.sas
<b>Description</b>	Schizophrenia Diagnosis
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variable will be dropped from dataset due to non significant element: 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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
DIAGNOSC	num	Diagnosis Type		Collected at CRF.

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

<b>Dataset</b>	DIAHIST
<b>Creating program</b>	diahist.sas
<b>Description</b>	Diabetes Related History
<b>Unique identifier</b>	DUSUBJID,DHDIAG
<b>Sorted by</b>	DUSUBJID,DHDIAG
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,DHACTDT

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
DHCHILD	num	Number of Children		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 Collection		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

<b>Dataset</b>	DISPOSIT
<b>Creating program</b>	disposit.sas
<b>Description</b>	End of Trial Information
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	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: DSACTDT,DSRSOTH,DSRABKDT,DEATHDT,PREGDUDT,DSRABKRS,PAGNUM,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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF.
DSTYPE	char	End of Treatment or End of 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	Reason for Screen Failure		Collected at CRF.
DSSCRN	char	Reason for Screen Failure		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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.

## 1.4.12. Electrocardiogram - ECG

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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. Inclusion/Exclusion Criteria - ENROLL

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

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

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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. Administration of Study Medication - EXPOSURE

<b>Dataset</b>	EXPOSURE
<b>Creating program</b>	exposure.sas
<b>Description</b>	Administration of Study Medication
<b>Unique identifier</b>	DUSUBJID,EXSTDY
<b>Sorted by</b>	DUSUBJID,EXSTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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.
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.

## 1.4.15. Family History - FAMHIST

<b>Dataset</b>	FAMHIST
<b>Creating program</b>	famhist.sas
<b>Description</b>	Family History
<b>Unique identifier</b>	DUSUBJID,FHMEM
<b>Sorted by</b>	DUSUBJID,FHMEM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or 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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
FHHISTC	num	Relatives History of Diabetes Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
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. Smoking History - HABIT

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

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
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.
HAIIPNUM	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.

Variable	Type	Label	Codes	Comments
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. Laboratory Results(Hematology) - HEMAT

<b>Dataset</b>	HEMAT
<b>Creating program</b>	hemat.sas
<b>Description</b>	Laboratory Results(Hematology)
<b>Unique identifier</b>	DUSUBJID,LBDESCR,VISIT
<b>Sorted by</b>	DUSUBJID,LBDESCR,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABSPEC,LBPTM,LBACTDT,LBPRVIDC,LBPRVID,LBREF,BATCHID,LBFASTC, LBFAST

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTYPES	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.
ORGRESN	num	Numeric lab result		Collected at CRF.
ORGRES	char	Character lab result		Collected at CRF.
NRIND	char	Normal Range Indicator		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	Lab Sequence Number		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.
LBTYP	char	Lab Type		Collected at CRF.
LBSIGLO	num	Significant Range Low		Collected at CRF.
LBSIGHI	num	Significant Range High		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTMLBL	char	Label of Planned Collection Time		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. Hospitalization Status - HOSPITAL

<b>Dataset</b>	HOSPITAL
<b>Creating program</b>	hospital.sas
<b>Description</b>	Hospitalization Status
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or 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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
HODISCHC	num	Was the Subject Discharged Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
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. Intake - INTAKE

<b>Dataset</b>	INTAKE
<b>Creating program</b>	intake.sas
<b>Description</b>	Intake
<b>Unique identifier</b>	DUSUBJID,ITTYPE,VISIT
<b>Sorted by</b>	DUSUBJID,ITTYPE,VISIT
<b>Notes</b>	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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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

<b>Dataset</b>	MEDHIST
<b>Creating program</b>	medhist.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	DUSUBJID,MHBODSYS,MHSEQ
<b>Sorted by</b>	DUSUBJID,MHBODSYS,MHSEQ
<b>Notes</b>	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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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 - PANSS

<b>Dataset</b>	PANSS
<b>Creating program</b>	panss.sas
<b>Description</b>	Positive And Negative Syndrome Scale
<b>Unique identifier</b>	DUSUBJID,PAITEM,VISIT
<b>Sorted by</b>	DUSUBJID,PAITEM,VISIT
<b>Notes</b>	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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PAGROUP	char	PANSS Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
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. PK Sampling - PCCNC

<b>Dataset</b>	PCCNC
<b>Creating program</b>	pccnc.sas
<b>Description</b>	PK Sampling
<b>Unique identifier</b>	DUSUBJID,TPT,VISIT
<b>Sorted by</b>	DUSUBJID,TPT,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PCSTDT,PCPRVIDC,PCPRVID,ACQREF,SPPRVIDC,SPPRVID,SAMREF,PCSPCOM,PCENDT,PCLBREF,PCREAS,PCRSOTH,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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
TPT	char	Planned Timepoint Name		Collected at CRF.
TPTNUM	num	Planned Timepoint Number		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.
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.
PCSTRESC	char	Character Result in Std Units		Collected at CRF.
PCSTUNIT	char	Standard Units		Collected at CRF.
PCSTRESN	num	Analysis Numeric Result in Std Units		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.
PCNRLO	num	Normal Range Lower Limit		Collected at CRF.
PCNRHI	num	Normal Range Upper Limit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCENTM	num	End Time of Collection (24hr clock)		Collected at CRF.
PCTAKENC	num	Was Sample Taken Code?		Collected at CRF.
PCTAKEN	char	Was Sample Taken ?		Collected at CRF.
PCCAT	char	Category for Test or Examination		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 Speciment 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.

## 1.4.23. PK Sampling(ONC) - PCCONC

<b>Dataset</b>	PCCONC
<b>Creating program</b>	pcconc.sas
<b>Description</b>	PK Sampling(ONC)
<b>Unique identifier</b>	DUSUBJID,TPT,VISIT
<b>Sorted by</b>	DUSUBJID,TPT,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PCPRVIDC,PCPRVID,SAMREF,PCLBREF

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
TPTNUM	num	Planned Timepoint Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
PCSTRESC	char	Character Result in Std Units		Collected at CRF.
PCSTUNIT	char	Standard Units		Collected at CRF.
PCSTRESN	num	Analysis Numeric Result in Std Units		Collected at CRF.
PCLOQ	char	Limit of Quantification		Collected at CRF.
PCNRLO	num	Normal Range Lower Limit		Collected at CRF.
PCNRHI	num	Normal Range Upper Limit		Collected at CRF.
PCCAT	char	Category for Test or Examination		Collected at CRF.
PCSEQ	num	Sample Sequence Number		Collected at CRF.
TPT	char	Planned Timepoint Name		Collected at CRF.

## 1.4.24. Pharmacokinetic Sample - PCSAMP

<b>Dataset</b>	PCSAMP
<b>Creating program</b>	pcsamp.sas
<b>Description</b>	Pharmacokinetic Sample
<b>Unique identifier</b>	DUSUBJID,TPT,VISIT,SPSTDY
<b>Sorted by</b>	DUSUBJID,TPT,VISIT,SPSTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SPSTDT,SPPRVIDC,SPPRVID,SAMREF,ACQREF,SPENDT,SPCOM,SPRSOTH,SPREAS

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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.
SPENTM	num	End Time of Collection (24 hr clock)		Collected at CRF.
SPCAT	char	Category for Test or Examination		Collected at CRF.
TPT	char	Planned Timepoint Name		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.
SPENDY	num	Relative End Day of Specimen Collection		If SPENDT and DMINFDT not missing then perform below logic to calculate SPENDY, If SPENDT less than DMINFDT then (SPENDT - DMINFDT). Else if SPENDT is greater than equal to DMINFDT then (SPENDT- DMINFDT) +1.

## 1.4.25. Physical Examination - PE

<b>Dataset</b>	PE
<b>Creating program</b>	pe.sas
<b>Description</b>	Physical Examination
<b>Unique identifier</b>	DUSUBJID,PEBODSYS,VISIT,PESEQ
<b>Sorted by</b>	DUSUBJID,PEBODSYS,VISIT,PESEQ
<b>Notes</b>	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.
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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PESEQ	num	Phys Sequence Number		Collected at CRF.

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

## 1.4.26. Protocol Deviation - PROTDEV

<b>Dataset</b>	PROTDEV
<b>Creating program</b>	protdev.sas
<b>Description</b>	Protocol Deviation
<b>Unique identifier</b>	DUSUBJID,PVDECOD,PVSEQ
<b>Sorted by</b>	DUSUBJID,PVDECOD,PVSEQ
<b>Notes</b>	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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
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.

#### 1.4.27. Personal And Social Performance Scale - PSP

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

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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. Psychosis History - PSYHIST

<b>Dataset</b>	PSYHIST
<b>Creating program</b>	psyhist.sas
<b>Description</b>	Psychosis History
<b>Unique identifier</b>	DUSUBJID,PYEPIDY,PYSEQ
<b>Sorted by</b>	DUSUBJID,PYEPIDY,PYSEQ
<b>Notes</b>	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,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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PYSEQ	num	Psychiatric History Sequence Number		Collected at CRF.
PYDIAG	char	Diagnosis		Collected at CRF.
PYEPIDY	num	Relative Day of Last Acute Symptom		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 Treatment		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. Randomization - RANDOM

<b>Dataset</b>	RANDOM
<b>Creating program</b>	random.sas
<b>Description</b>	Randomization
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAGNUM,RAACTDT,RANDNUM,SUB

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

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

<b>Dataset</b>	SARS
<b>Creating program</b>	sars.sas
<b>Description</b>	Simpson - Angus Scale
<b>Unique identifier</b>	DUSUBJID,SRITEM,VISIT
<b>Sorted by</b>	DUSUBJID,SRITEM,VISIT
<b>Notes</b>	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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
SRVTYPEC	num	SARS Visit Type		Collected at CRF.

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

## 1.4.31. Sqls-R4- SQLSR4

<b>Dataset</b>	SQLSR4
<b>Creating program</b>	sqlsr4.sas
<b>Description</b>	Sqls-R4
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or 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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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 Collection		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. Laboratory Results(Urine) - URINE

<b>Dataset</b>	URINE
<b>Creating program</b>	urine.sas
<b>Description</b>	Laboratory Results(Urine)
<b>Unique identifier</b>	DUSUBJID,LBDESCR,VISIT
<b>Sorted by</b>	DUSUBJID,LBDESCR,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABSPEC,LBPTM,LBACTDT,LBPRVIDC,LBREF,BATCHID,LBFASTC,LBFAST, LBSIGLO,LBSIGHI,LBPRVID

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDUNIT	char	Standard Units		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTYPES	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.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
ORGRESN	num	Numeric lab result		Collected at CRF.
ORGRES	char	Character lab result		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
NRIND	char	Normal Range Indicator		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.

Variable	Type	Label	Codes	Comments
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 Test Abbreviation		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTMLBL	char	Label of Planned Collection Time		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

<b>Dataset</b>	VAS
<b>Creating program</b>	vas.sas
<b>Description</b>	Sleep Vas Scale Scores
<b>Unique identifier</b>	DUSUBJID,VASCALE,VISIT
<b>Sorted by</b>	DUSUBJID,VASCALE,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,VAACDT

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VASSCORE	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 Collection		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

<b>Dataset</b>	VISIT
<b>Creating program</b>	visit.sas
<b>Description</b>	Visit
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISITDT

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

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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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

<b>Dataset</b>	VITAL
<b>Creating program</b>	vital.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DUSUBJID, VSVTYPE, VISIT, VSSEQ
<b>Sorted by</b>	DUSUBJID, VSVTYPE, VISIT, VSSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: VSACTDT, 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
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		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.
VSHEIGHT	num	Height		Collected at CRF.
VSHTUNIT	char	Height Unit		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.
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.