

Clinical Development

**Paliperidone Palmitate<sup>®</sup>**

**R092670-SCH201**

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	22 APR 2016

Property of Janssen

Confidential

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

## Table of contents

Clinical Development .....	1
1 Datasets .....	5
1.1 Specifications Introduction .....	5
1.2 Guidelines for Preparing Data.....	5
1.3 Data Files.....	6
1.4 Data Domains.....	7
1.4.1 Demographics – DEMOG .....	7
1.4.2 Adverse Event – AE .....	10
1.4.3 Adverse Event Meddra – AEMEDDRA.....	13
1.4.4 Abnormal Involuntary Movement Scale – AIMS.....	17
1.4.5 Barnes Akathisia Rating Scale – BARS .....	19
1.4.6 Time Of Bowel Movements – BOWMOVE .....	21
1.4.7 Clinical Global Impression – CGI .....	22
1.4.8 Chem – CHEM .....	24
1.4.9 Comments – COMMENTS .....	27
1.4.10 Concomitant Drug/Therapy – CONMED .....	28
1.4.11 Dacnsnt – DACNSNT.....	33
1.4.12 Schizophrenia Diagnosis – DIAGNOS .....	35
1.4.13 End Of Trial Information – DISPOSIT.....	37
1.4.14 Electrocardiogram – ECG .....	39
1.4.15 Inclusion Exclusion Criteria – ENROLL.....	42
1.4.16 Administration Of Study Medication – EXPOSURE .....	44
1.4.17 Habit – HABIT .....	46
1.4.18 Hematology – HEMAT .....	48
1.4.19 Hospitalization Status – HOSPITAL.....	51
1.4.20 Investigator Evaluation Of Injection Site – IVEVINJ .....	53
1.4.21 Medical History – MEDHIST .....	55
1.4.22 Positive And Negative Syndrome Scale For Schizophrenia – PANSS .....	57
1.4.23 Blood Sampling For Pharmacokinetics – PCCNC.....	59

1.4.24	Blood Sampling For Pharmacokinetics(ONC) – PCCONC .....	62
1.4.25	Pharmacokinetics Sample – PCSAMP .....	65
1.4.26	Physical Examination – PE.....	68
1.4.27	Protocol Deviation – PROTDEV .....	70
1.4.28	Psychotic History – PSYHIST.....	71
1.4.29	Randomisation – RANDOM.....	74
1.4.30	Simpson-Angus Rating Scale – SARS .....	76
1.4.31	Subject Evaluation of Injection Site – SUEVINJ .....	78
1.4.32	Urine – URINE.....	80
1.4.33	Visit – VISIT.....	83
1.4.34	Vital Signs – VITAL .....	84

<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	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.
- Lab Identifier information 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.
- Dataset "COMMENT" will be submitted with zero observation.
- Lab Name information will not be provided.
- Variables with completely missing values will not be submitted.
- Specimen ID will not be submitted due to sensitivity of data.
- Pharmacokinetics Dataset will not be submitted due to sensitivity of information (e.g. DASAMP, DNRESULT and DNRSLT).
- Dataset containing Investigator Information will not be submitted due to sensitivity of information (e.g. INVEST).
- SURGERY dataset will not be submitted due to sensitivity of information.
- Dataset having Code lists, Normal ranges and having no Patient level information will not be submitted (e.g. LABCONV, LBSIGRG, PROTDESC).
- MEDKIT dataset will not be submitted as it contains information regarding medication code number.
- Informed Consent Date is used as Reference Date to calculate Relative Day.

### 1.3 Data Files

The R092670SCH201 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 missing values: SUBJINIT, DMACTDT, IVID, IVNAME, BIRTHDT, DMINFDT, RACESPEC, COUNTRYC, PAGNUM, DMSCRDT

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		Group element to protect PII.
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{floor}((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
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and DMINFDT not missing then perform below logic to calculate DMACTDY, If DMACTDT less than DMINFDT then (DMACTDT - DMINFDT).Else if DMACTDT is greater than equal to DMINFDT then (DMACTDT- DMINFDT) +1.
DMSCRDY	num	Relative Day of First Trial Rel. Procedure.		If DMSCRDT and DMINFDT not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than DMINFDT then (DMSCRDT - DMINFDT).Else if DMSCRDT is greater than equal to DMINFDT then (DMSCRDT- DMINFDT) +1.

## 1.4.2 Adverse Event – AE

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Event
<b>Unique identifier</b>	DUSUBJID,VISIT,AEDECOD, AESEQ
<b>Sorted by</b>	DUSUBJID,VISIT,AEDECOD, AESEQ
<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, 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.
AESEQ	num	AE Sequence Number		Collected at CRF.
AEBODSYC	char	Body System Code		Collected at CRF.
AEBODSYS	char	WHO Body System		Collected at CRF.
AEDECOD1	char	WHO Included Term		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.

Variable	Type	Label	Codes	Comments
AECONTRT	char	Concomitant/Additional Treatment		Collected at CRF.
AEDECOD	char	WHO Preferred Term		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
SOC1	char	AE System Organ Class 1		Collected at CRF.
SOC2	char	AE System Organ Class 2		Collected at CRF.
SOC3	char	AE System Organ Class 3		Collected at CRF.
AEREPRT	char	Were any AEs Reported		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 Adverse Event Meddra – AEMEDDRA

<b>Dataset</b>	AEMEDDRA
<b>Creating program</b>	aemeddra.sas
<b>Description</b>	Adverse Event Meddra
<b>Unique identifier</b>	DUSUBJID,VISIT,AEDECODW, AESEQ
<b>Sorted by</b>	DUSUBJID,VISIT,AEDECODW, AESEQ
<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, AEBODSYS, AETERM, AESTDT, AEENDT, AESTDTC, AEENDTC

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.
AEREPRTC	num	Were any AEs Reported Code		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AECTTRC	num	Action Taken with Treatment Code		Collected at CRF.
AECTTRT	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.
AESERREF	char	Serious AE Reference Number		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.

Variable	Type	Label	Codes	Comments
AECONTRT	char	Concomitant/Additional Treatment		Collected at CRF.
AEDCOD1W	char	WHO Included Term		Collected at CRF.
AEDECODW	char	WHO Preferred Term		Collected at CRF.
AEBODSCW	char	WHO Body System Code		Collected at CRF.
AEBODSYW	char	WHO Body System		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF.
SOC1W	char	WHO AE System Organ Class 1		Collected at CRF.
SOC2W	char	WHO AE System Organ Class 2		Collected at CRF.
SOC3W	char	WHO AE System Organ Class 3		Collected at CRF.
AEREPRT	char	Were any AEs Reported		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and DMINFDT not missing then perform below logic to calculate AESTDY, If AESTDTC less than DMINFDT then (AESTDTC - DMINFDT).Else if AESTDTC is greater than equal to DMINFDT then (AESTDTC- DMINFDT) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and DMINFDT not missing then perform below logic to calculate AEENDY, If AEENDTC less than DMINFDT then (AEENDTC - DMINFDT).Else if AEENDTC is greater than equal to DMINFDT then (AEENDTC- DMINFDT) +1.



## 1.4.4 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,VISIT, AIITEM
<b>Sorted by</b>	DUSUBJID,VISIT, AIITEM
<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: AIACTDT, AIRATERI, 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.

Variable	Type	Label	Codes	Comments
AIVTYPEC	num	AIMS Visit Type Code		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.
AIVTYPE	char	AIMS Visit Type		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.

### 1.4.5 Barnes Akathisia Rating Scale – BARS

<b>Dataset</b>	BARS
<b>Creating program</b>	bars.sas
<b>Description</b>	Barnes Akathisia Rating Scale
<b>Unique identifier</b>	DUSUBJID,VISIT,BAGROUP, BAITEM
<b>Sorted by</b>	DUSUBJID,VISIT,BAGROUP, BAITEM
<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: BAACTDT, PAGNUM, BARATERI

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
BAVTYPEC	num	BARS Visit Type Code		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.
BAVTYPE	char	BARS Visit Type		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.

## 1.4.6 Time Of Bowel Movements – BOWMOVE

<b>Dataset</b>	BOWMOVE
<b>Creating program</b>	bowmove.sas
<b>Description</b>	Time Of Bowel Movements
<b>Unique identifier</b>	DUSUBJID,VISIT, BMACTTM
<b>Sorted by</b>	DUSUBJID,VISIT, BMACTTM
<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: BMACTDT, 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.

Variable	Type	Label	Codes	Comments
BMSEQ	num	Sequence Number		Collected at CRF.
BMACTTM	num	Actual Time of Bowel Movement		Collected at CRF.
BMACTDY	num	Relative Actual Day of Bowel Movement		If BMACTDT and DMINFDT not missing then perform below logic to calculate BMACTDY, If BMACTDT less than DMINFDT then (BMACTDT - DMINFDT).Else if BMACTDT is greater than equal to DMINFDT then (BMACTDT- DMINFDT) +1.

#### 1.4.7 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,VISIT, CGSEV
<b>Sorted by</b>	DUSUBJID,VISIT, CGSEV
<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: CGACTDT, PAGNUM, CGRATERI

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.
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.

## 1.4.8 Chemistry – CHEM

<b>Dataset</b>	CHEM
<b>Creating program</b>	chem.sas
<b>Description</b>	Chemistry
<b>Unique identifier</b>	DUSUBJID,VISIT,LBVTTYPE, LBTEST
<b>Sorted by</b>	DUSUBJID,VISIT,LBVTTYPE, LBTEST
<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: LBACTDT, LBPTM, 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.



Variable	Type	Label	Codes	Comments
LBTESTC	num	Lab Test Code		Collected at CRF.
STDUNIT	char	Standard Units		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.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBSIGLO	num	Significant Range Low		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSIGHI	num	Significant Range High		Collected at CRF.
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDRESN	num	Analysis Num Result in Std Units		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		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.
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.

## 1.4.9 Comments – COMMENTS

<b>Dataset</b>	COMMENTS
<b>Creating program</b>	comments.sas
<b>Description</b>	Comments
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<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.
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.
CTSEQ	num	Comment Sequence Number		Empty dataset will be submitted.
CTACTDY	num	Relative Actual Day of Comment		Empty dataset will be submitted.

## 1.4.10 Concomitant Drug/Therapy – CONMED

<b>Dataset</b>	CONMED
<b>Creating program</b>	conmed.sas
<b>Description</b>	Concomitant Drug/Therapy
<b>Unique identifier</b>	DUSUBJID,VISIT,CMGROUP,CMTYPE,CMSTDY, CMSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,CMGROUP,CMTYPE,CMSTDY, CMSEQ
<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, CMSTDT, CMTERM, CMREAS, CMENDT, CMSTDTC, CMENDTC, CMCLASC, CMCLAS

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
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.
CMGROU PC	num	Medication Grouping Code		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMREPR TC	num	Were Any Meds Administered/Changed Code		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMREGIM	char	Regimen (Dose And Frequency)		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.
AESEQ	num	AE Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
CMGROUP	char	Medication Grouping		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMREPR	char	Were Any Meds Administered/Changed		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.

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



## 1.4.11 DNA Informed Consent – DACNSNT

<b>Dataset</b>	DACNSNT
<b>Creating program</b>	dacnsnt.sas
<b>Description</b>	DNA Informed Consent
<b>Unique identifier</b>	DUSUBJID,VISIT,DCCNSNT, DCSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,DCCNSNT, DCSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DCINFDT

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
DCSEQ	num	DNA Consent seq		Collected at CRF.
DCCNSNTC	num	Informed Consent Signed Code		Collected at CRF.
DCCNSNT	char	Informed Consent Signed		Collected at CRF.
DCSTUDYC	num	Scope - Study Specific Testing Code		Collected at CRF.
DCSTUDY	char	Scope - Study Specific Testing		Collected at CRF.
DCSTOREC	num	Scope - Storage for Future Use Code		Collected at CRF.
DCSTORE	char	Scope - Storage for Future Use		Collected at CRF.
DCINFDY	num	Relative Day of Sign on Informed Consent		If DCINFDT and DMINFDT not missing then perform below logic to calculate DCINFDY, If DCINFDT less than DMINFDT then (DCINFDT - DMINFDT).Else if DCINFDT is greater than equal to DMINFDT then (DCINFDT- DMINFDT) +1.

## 1.4.12 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 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
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
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.
DGTYPEC	num	Schizophrenia Type Code		Collected at CRF.
DGTYPE	char	Schizophrenia Type		Collected at CRF.
DIAGNOSC	num	Diagnosis Code		Collected at CRF.
DIAGNOS	char	Diagnosis		Collected at CRF.

## 1.4.13 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: PAGNUM, DSACTDT, DRSOTH, DSRABKDT, DEATHDT, PREGDUDT, DSSEQ, DSRABKRS, DSSNOTH

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.

Variable	Type	Label	Codes	Comments
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
DSTYPEC	num	End of Treatment/Trial Code		Collected at CRF.
DSTYPE	char	End of Treatment/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.
DSSCRNC	num	Reason for Screen Failure Code		Collected at CRF.
DSSCRN	char	Reason for Screen Failure		Collected at CRF.
DSACTDY	num	Relative Act. Day Trial Compl./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.

## 1.4.14 Electrocardiogram – ECG

<b>Dataset</b>	ECG
<b>Creating program</b>	ecg.sas
<b>Description</b>	Electrocardiogram
<b>Unique identifier</b>	DUSUBJID,VISIT,EGTESTCD,EGVTYPE, EGSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,EGTESTCD,EGVTYPE, 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, EGPTM, 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.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
EGTESTCD	char	ECG Test Short Name		Collected at CRF.
EGPTMNUM	num	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.



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

## 1.4.15 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,VISIT,ENCRIT,ENCRES, ENTEXT
<b>Sorted by</b>	DUSUBJID,VISIT,ENCRIT,ENCRES, ENTEXT
<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: ENACTDT, 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.

Variable	Type	Label	Codes	Comments
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.

## 1.4.16 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, 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: EXSTDT, 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.

Variable	Type	Label	Codes	Comments
EXSTTM	num	Start Time of Exposure		Collected at CRF.
EXPOS	char	Position of Injection		Collected at CRF.
DOSE	num	Dose per Administration		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
ACTTRT	char	Drug/Therapy		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.

## 1.4.17 Habit – HABIT

<b>Dataset</b>	HABIT
<b>Creating program</b>	habit.sas
<b>Description</b>	Habit
<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: HAENDTC, HAACDT

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
HASMOCUC	num	Does Subject Currently Smoke?		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		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		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.

## 1.4.18 Hematology – HEMAT

<b>Dataset</b>	HEMAT
<b>Creating program</b>	hemat.sas
<b>Description</b>	Hematology
<b>Unique identifier</b>	DUSUBJID,VISIT,LBTESTC, LBVTYPE
<b>Sorted by</b>	DUSUBJID,VISIT,LBTESTC, LBVTYPE
<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: LBACTDT, LBPTM, ORGRES, 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.



Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
STDUNIT	char	Standard Units		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.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBSIGLO	num	Significant Range Low		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBSIGHI	num	Significant Range High		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDRESN	num	Analysis Num Result in Std Units		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LAGE	char	Age: time of visit		Collected at CRF.
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.
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.

## 1.4.19 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: HOSTDT, HOENDT, 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.

Variable	Type	Label	Codes	Comments
HODISCHC	num	Is Subject Discharged from Hospital		Collected at CRF.
HODISCH	char	Is Subject Discharged from Hospital		Collected at CRF.
HOSTDY	num	Relative Admission Day of Curr. Hosp		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.

## 1.4.20 Investigator Evaluation Of Injection Site – IVEVINJ

<b>Dataset</b>	IVEVINJ
<b>Creating program</b>	ivevinj.sas
<b>Description</b>	Investigator Evaluation Of Injection Site
<b>Unique identifier</b>	DUSUBJID,VISIT,IEITEM,IESCORE, IESCHD
<b>Sorted by</b>	DUSUBJID,VISIT,IEITEM,IESCORE, IESCHD
<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: IEACTDT, PAGNUM, IERATERI

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
IEACTTM	num	Actual Time of IVEVINJ		Collected at CRF.
IEITEM	char	Item		Collected at CRF.
IESCOREC	num	Evaluation Score Code		Collected at CRF.
IESCORE	char	Evaluation Score		Collected at CRF.
IESCHD	char	Scheduled Time		Collected at CRF.
IEACTDY	num	Relative Actual Day of IVEVINJ		If IEACTDT and DMINFDT not missing then perform below logic to calculate IEACTDY, If IEACTDT less than DMINFDT then (IEACTDT - DMINFDT).Else if IEACTDT is greater than equal to DMINFDT then (IEACTDT- DMINFDT) +1.

## 1.4.21 Medical History – MEDHIST

<b>Dataset</b>	MEDHIST
<b>Creating program</b>	medhist.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	DUSUBJID,VISIT, MHBODSYS
<b>Sorted by</b>	DUSUBJID,VISIT, MHBODSYS
<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: MHACTDT, PAGNUM, MHTERM

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



## 1.4.22 Positive And Negative Syndrome Scale For Schizophrenia – PANSS

<b>Dataset</b>	PANSS
<b>Creating program</b>	panss.sas
<b>Description</b>	Positive And Negative Syndrome Scale For Schizophrenia
<b>Unique identifier</b>	DUSUBJID,VISIT,PHASE,PAGROUP, PAITEM
<b>Sorted by</b>	DUSUBJID,VISIT,PHASE,PAGROUP, PAITEM
<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: PAACTDT, PAGNUM, PARATERI

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
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.

## 1.4.23 Blood Sampling For Pharmacokinetics – PCCNC

<b>Dataset</b>	PCCNC
<b>Creating program</b>	pccnc.sas
<b>Description</b>	Blood Sampling For Pharmacokinetics
<b>Unique identifier</b>	DUSUBJID,VISIT,TPT, PCSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,TPT, PCSEQ
<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, PCPRVIDC, PCPRVID, SAMREF, ACQREF, PCLBREF, PCSTDT, PCENDT, PCSPCOM

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

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

Variable	Type	Label	Codes	Comments
PCORUNIT	char	Original Units		Collected at CRF.
PCSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
PCSTRESC	char	Character Result in Standard Units		Collected at CRF.
PCSTUNIT	char	Standard Units		Collected at CRF.
PCNRLO	num	Normal Range Lower Limit		Collected at CRF.
PCNRHI	num	Normal Range Upper Limit		Collected at CRF.
PCLOQ	char	Limit of Quantification		Collected at CRF.
PCNDC	num	Sample Not Done Code		Collected at CRF.
PCND	char	Sample Not Done		Collected at CRF.
PCSTDY	num	Relative Start Day of Specimen Collection		If PCSTDT and DMINFDT not missing then perform below logic to calculate PCSTDY, If PCSTDT less than DMINFDT then (PCSTDT - DMINFDT).Else if PCSTDT is greater than equal to DMINFDT then (PCSTDT- DMINFDT) +1.
PCENDY	num	Relative End Day of Specimen Collection		If PCENDT and DMINFDT not missing then perform below logic to calculate PCENDY, If PCENDT less than DMINFDT then (PCENDT - DMINFDT).Else if PCENDT is greater than equal to DMINFDT then (PCENDT- DMINFDT) +1.

## 1.4.24 Blood Sampling For Pharmacokinetics (ONC) – PCCONC

<b>Dataset</b>	PCCONC
<b>Creating program</b>	pcconc.sas
<b>Description</b>	Blood Sampling For Pharmacokinetics (ONC)
<b>Unique identifier</b>	DUSUBJID,VISIT,TPT, PCSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,TPT, PCSEQ
<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, PCPRVIDC, PCPRVID, SAMREF, ACQREF, PCLBREF, PCSTDT, PCENDT, PCSPCOM

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

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

Variable	Type	Label	Codes	Comments
PCORUNIT	char	Original Units		Collected at CRF.
PCSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
PCSTRESC	char	Character Result in Standard Units		Collected at CRF.
PCSTUNIT	char	Standard Units		Collected at CRF.
PCNRLO	num	Normal Range Lower Limit		Collected at CRF.
PCNRHI	num	Normal Range Upper Limit		Collected at CRF.
PCLOQ	char	Limit of Quantification		Collected at CRF.
PCNDC	num	Sample Not Done Code		Collected at CRF.
PCND	char	Sample Not Done		Collected at CRF.
PCSTDY	num	Relative Start Day of Specimen Collection		If PCSTDT and DMINFDT not missing then perform below logic to calculate PCSTDY, If PCSTDT less than DMINFDT then (PCSTDT - DMINFDT).Else if PCSTDT is greater than equal to DMINFDT then (PCSTDT- DMINFDT) +1.
PCENDY	num	Relative End Day of Specimen Collection		If PCENDT and DMINFDT not missing then perform below logic to calculate PCENDY, If PCENDT less than DMINFDT then (PCENDT - DMINFDT).Else if PCENDT is greater than equal to DMINFDT then (PCENDT- DMINFDT) +1.



## 1.4.25 Pharmacokinetics Sample – PCSAMP

<b>Dataset</b>	PCSAMP
<b>Creating program</b>	pcsamp.sas
<b>Description</b>	Pharmacokinetics Sample
<b>Unique identifier</b>	DUSUBJID,VISIT, TPT
<b>Sorted by</b>	DUSUBJID,VISIT, TPT
<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: SPVOL, SPSTDT, SAMREF, ACQREF, SPCOM, SPENDT, SPPRVID, 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
SAMSEQ	num	Sample Sequence Number		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
SPPRVIDC	num	Provider ID Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
SPNDC	num	Sample Not Done Code		Collected at CRF.
SPVLUNIT	char	Sample Volume Unit		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit ID		Collected at CRF.
TPTNUM	num	Planned Timepoint		Collected at CRF.
TPT	char	Planned Timepoint		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.
SPCAT	char	PK/PD Sample Category		Collected at CRF.
SPENTM	num	Sample End Time		Collected at CRF.
SPPH	num	Sample pH		Collected at CRF.
SPND	char	Sample Not Done		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 Sample End Day		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.

## 1.4.26 Physical Examination – PE

<b>Dataset</b>	PE
<b>Creating program</b>	pe.sas
<b>Description</b>	Physical Examination
<b>Unique identifier</b>	DUSUBJID,VISIT,PHASE,PEBODSYS,PEACTDY, PESEQ
<b>Sorted by</b>	DUSUBJID,VISIT,PHASE,PEBODSYS,PEACTDY, 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 or due to missing values: PEACTDT, PAGNUM, PESYSOTH, PEFIND

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
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.
PESEQ	num	Phys Exam Sequence Number		Collected at CRF.
PEBODSYC	num	Body System Code		Collected at CRF.
PEBODSYS	char	Body System		Collected at CRF.
PESTATC	num	Phys Exam Result Code		Collected at CRF.
PESTAT	char	Phys Exam Result		Collected at CRF.
PEACTDY	num	Relative Actual Day of Phys Exam		If PEACTIONDT and DMINFDT not missing then perform below logic to calculate PEACTIONDY, If PEACTIONDT less than DMINFDT then (PEACTIONDT - DMINFDT).Else if PEACTIONDT is greater than equal to DMINFDT then (PEACTIONDT- DMINFDT) +1.

## 1.4.27 Protocol Deviation – PROTDEV

<b>Dataset</b>	PROTDEV
<b>Creating program</b>	protdev.sas
<b>Description</b>	Protocol Deviation
<b>Unique identifier</b>	DUSUBJID,VISIT,PVDECOD, PVSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,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.

#### 1.4.28 Psychotic History – PSYHIST

<b>Dataset</b>	PSYHIST
<b>Creating program</b>	psyhist.sas
<b>Description</b>	Psychotic History
<b>Unique identifier</b>	DUSUBJID,VISIT,PYDIAG,PYEPIDY, PYSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,PYDIAG,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 non significant elements: PAGNUM, PYEPIDTC, PYEPIDT, PYSTDTC, PYSTDT, 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

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.
PYSEQ	num	Psychiatric History Sequence Number		Collected at CRF.
PYDIAG	char	Diagnosis		Collected at CRF.
PYEPIDY	num	Relative Day of Last Psychotic Episode		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.



Variable	Type	Label	Codes	Comments
PYSTDY	num	Relative Act. Start Day of Psycho Trt.		If PYSTDTC and DMINFDT not missing then perform below logic to calculate PYSTDY, If PYSTDTC less than DMINFDT then (PYSTDTC - DMINFDT).Else if PYSTDTC is greater than equal to DMINFDT then (PYSTDTC- DMINFDT) +1.
PYENDY	num	Relative Act. End Day of Psychosis Trt.		If PYENDTC and DMINFDT not missing then perform below logic to calculate PYENDY, If PYENDTC less than DMINFDT then (PYENDTC - DMINFDT).Else if PYENDTC is greater than equal to DMINFDT then (PYENDTC- DMINFDT) +1.

## 1.4.29 Randomisation – RANDOM

<b>Dataset</b>	RANDOM
<b>Creating program</b>	random.sas
<b>Description</b>	Randomisation
<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: RAACTDT, RANDNUM, RAUBDT, PAGNUM, 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.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
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 Rating Scale – SARS

<b>Dataset</b>	SARS
<b>Creating program</b>	sars.sas
<b>Description</b>	Simpson-Angus Rating Scale
<b>Unique identifier</b>	DUSUBJID,VISIT, SRTITEM
<b>Sorted by</b>	DUSUBJID,VISIT, SRTITEM
<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.

Variable	Type	Label	Codes	Comments
SRVTYPEC	num	SARS Visit Type Code		Collected at CRF.
SRITEM	char	SARS Item		Collected at CRF.
SRSCOREC	num	SARS Score Code		Collected at CRF.
SRVTYPE	char	SARS Visit Type		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 Subject Evaluation of Injection Site – SUEVINJ

<b>Dataset</b>	SUEVINJ
<b>Creating program</b>	suevinj.sas
<b>Description</b>	Subject Evaluation Of Injection Site
<b>Unique identifier</b>	DUSUBJID,VISIT, SEITEM
<b>Sorted by</b>	DUSUBJID,VISIT, SEITEM
<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: SEACTDT, 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.

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

## 1.4.32 Urine – URINE

<b>Dataset</b>	URINE
<b>Creating program</b>	urine.sas
<b>Description</b>	Urine
<b>Unique identifier</b>	DUSUBJID,VISIT,LBTEST,LBVTYPE, LBACTDY
<b>Sorted by</b>	DUSUBJID,VISIT,LBTEST,LBVTYPE, LBACTDY
<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: LBACTDT, LBPTM, LBPRVIDC, LBSIGLO, LBSIGHI, LBPRVID, LBREF, BATCHID, LBFASCT, LBFASCT

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.
LBTESTC	num	Lab Test Code		Collected at CRF.
STDUNIT	char	Standard Units		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.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDRESN	num	Analysis Num Result in Std Units		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LAGE	char	Age: time of visit		Collected at CRF.
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.
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 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
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.
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.

#### 1.4.34 Vital Signs – VITAL

<b>Dataset</b>	VITAL
<b>Creating program</b>	vital.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DUSUBJID,VISIT,VSACTDY, VSSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,VSACTDY, 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: PAGNUM, VSACTDT

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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
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.
PULSE	num	Pulse Rate (bpm)		Collected at CRF.
SYSBP	num	Systolic Blood Pressure (mmHg)		Collected at CRF.
DIABP	num	Diastolic Blood Pressure (mmHg)		Collected at CRF.
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.
BMI	num	Body Mass Index (kg/m <sup>2</sup> )		Collected at CRF.
VSWEIGHT	num	Weight		Collected at CRF.
VSWTUNIT	char	Weight Unit		Collected at CRF.
VSHEIGHT	num	Height		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.