

Clinical Development

PALIPERIDONE

R076477-SCH-1010

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	01 DEC 2017

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 (DM) – DEMOG	7
1.4.2. Adverse Events (AE) – AE	9
1.4.3. AIMS (AI) – AIMS.....	12
1.4.4. Barnes Akathisia Scale (BA) – BARS	14
1.4.5. Clinical Global Impression (CG) – CGI	16
1.4.6. Laboratory Data - Hematology (CL) – CHEM.....	18
1.4.7. Comments (CT) – COMMENTS.....	21
1.4.8. Concomitant Meds (CM) – CONMED.....	22
1.4.9. Diagnosis (DG) – DIAGNOS.....	25
1.4.10. Disposition (DS) – DISPOSIT	27
1.4.11. Enrollment (EN) – ENROLL	29
1.4.12. Exposure (EX) – EXPOSURE	31
1.4.13. Laboratory Data - Hematology (HL) – HEMAT	33
1.4.14. Lbsigr – LBSIGRG	36
1.4.15. Leeds Sleep Ev. Quest – LSEQ	37
1.4.16. Medical History (MH) – MEDHIST	39
1.4.17. PANSS (PA) – PANSS.....	41
1.4.18. PC Concentrations – PCCNC.....	43
1.4.19. PKPD Concentrations from JJPRD – PCCONC.....	45
1.4.20. PK/PD Sample (SP) – PCSAMP.....	48
1.4.21. Physical Exam (PE) – PE.....	50
1.4.22. Protocol Description (PD) – PROTDESC.....	52
1.4.23. Polysomnography Data (PS) – PSG	53
1.4.24. Psychiatric History (PH) – PSYHIST	55
1.4.25. Randomization (RA) – RANDOM.....	57

1.4.26. SARS (SR) – SARS 59

1.4.27. Laboratory Data - Urinalysis (UR) – URINE..... 61

1.4.28. Visit Date (VI) – VISIT 64

1.4.29. Vital Signs (VS) – VITAL..... 65

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- COMMENTS dataset will be submitted with zero observation due to sensitivity of data.
- Datasets with zero observation will not be submitted (ex. PROTDEV).
- Dataset containing investigator information is sensitive and hence will not be submitted (ex. INVEST).
- DEMOG.DMINFDT (Date of Sign. on Informed Consent) will be used as Reference Date (referred as REF.DATE in the document) to derive relative days.

1.3. Data Files

The R076477-SCH-1010 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics (DM) – DEMOG

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

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		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		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and REF.DATE not missing then perform below logic to calculate DMACTDY, If DMACTDT less than REF.DATE then (DMACTDT - REF.DATE). Else if DMACTDT is greater than equal to REF.DATE then (DMACTDT- REF.DATE) +1.
DMSCRDY	num	Relative Day of First Trial Related Proc		If DMSCRDT and REF.DATE not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than REF.DATE then (DMSCRDT - REF.DATE). Else if DMSCRDT is greater than equal to REF.DATE then (DMSCRDT- REF.DATE) +1.

1.4.2. Adverse Events (AE) – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events (AE)
Unique identifier	DUSUBJID,AEBODSYW,AEDECODW,AESTDY,AESEQ
Sorted by	DUSUBJID,AEBODSYW,AEDECODW,AESTDY,AESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: AETERM,AESTDT,AESTDTC,AEENDT,AEENDTC,AESERREF,SOC3W

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

Variable	Type	Label	Codes	Comments
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
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.
AESTTM	num	Start Time of AE		Collected at CRF.
AESEVC	num	Severity of Event Code		Collected at CRF.
AESEV	char	Severity of Event		Collected at CRF.
AEACTTRC	num	Action Taken with Treatment Code		Collected at CRF.
AEACTTRT	char	Action Taken with Treatment		Collected at CRF.
AECONTRC	num	Concomitant/Additional Treatment Code		Collected at CRF.
AECONTRT	char	Concomitant/Additional Treatment		Collected at CRF.
AERELC	num	Relationship to Treatment Code		Collected at CRF.
AEREL	char	Relationship to Treatment		Collected at CRF.
AEOUTC	num	Outcome of Event Code		Collected at CRF.
AEOUT	char	Outcome of Event		Collected at CRF.
AEENDTM	num	End Time of AE		Collected at CRF.
AESERC	num	Seriousness Criteria Code		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEBODSCW	char	Body System Code		Collected at CRF.
AEDCOD1W	char	WHO Included Term		Collected at CRF.
AEBODSYW	char	WHO Body System		Collected at CRF.
AEDECODW	char	WHO Preferred Term		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
AECODEW	char	AE Dictionary Code		Collected at CRF.
SOC1W	char	AE System Organ Class 1		Collected at CRF.
SOC2W	char	AE System Organ Class 2		Collected at CRF.
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF.
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC- REF.DATE) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC- REF.DATE) +1.

1.4.3.AIMS (AI) – AIMS

Dataset	AIMS
Creating program	aims.sas
Description	AIMS (AI)
Unique identifier	DUSUBJID,AIGROUP,AIITEM,AIACTDY
Sorted by	DUSUBJID,AIGROUP,AIITEM,AIACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AIRATERI,AIACTDT

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

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

1.4.4. Barnes Akathisia Scale (BA) – BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia Scale (BA)
Unique identifier	DUSUBJID,BAGROUP,BAITEM,BAACTDY
Sorted by	DUSUBJID,BAGROUP,BAITEM,BAACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BARATERI,BAACTDT

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

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
BAVTYPEC	num	BARS visit type code		Collected at CRF.
BAVTYPE	char	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	BARS Score		Collected at CRF.
BAACTDY	num	Relative Actual Day of BARS		If BAACTDT and REF.DATE not missing then perform below logic to calculate BAACTDY, If BAACTDT less than REF.DATE then (BAACTDT - REF.DATE). Else if BAACTDT is greater than equal to REF.DATE then (BAACTDT - REF.DATE) +1.

1.4.5. Clinical Global Impression (CG) – CGI

Dataset	CGI
Creating program	cgi.sas
Description	Clinical Global Impression (CG)
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CGRATERI,CGACTDT

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

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
CGSEVC	num	CGI Severity Code		Collected at CRF.
CGSEV	char	CGI Severity		Collected at CRF.
CGACTDY	num	Relative CGI Actual Day		If CGACTDT and REF.DATE not missing then perform below logic to calculate CGACTDY, If CGACTDT less than REF.DATE then (CGACTDT - REF.DATE). Else if CGACTDT is greater than equal to REF.DATE then (CGACTDT- REF.DATE) +1.

1.4.6.Laboratory Data - Hematology (CL) – CHEM

Dataset	CHEM
Creating program	chem.sas
Description	Laboratory Data - Hematology (CL)
Unique identifier	DUSUBJID,PHASE,LBTEST,LBACTDY
Sorted by	DUSUBJID,PHASE,LBTEST,LBACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: LABSPEC,LBPRVID,LBACTDT,LBTMLBL,LBPRVIDC,LABNAME,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
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.
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGRES	char	Character Result in 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.
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LAGE	char	Age: time of visit		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
LAGEUNIT	char	Age Unit (M or Y)		Collected at CRF.
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.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and REF.DATE not missing then perform below logic to calculate LBACTDY, If LBACTDT less than REF.DATE then (LBACTDT - REF.DATE). Else if LBACTDT is greater than equal to REF.DATE then (LBACTDT- REF.DATE) +1.

1.4.7. Comments (CT) – COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Comments (CT)
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comments dataset contains sensitive information. Hence dataset will be submitted with zero observation.

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
PHASENUM	num	Phase Number		Empty dataset will be submitted
PHASE	char	Phase		Empty dataset will be submitted
VISITNUM	num	Visit Number		Empty dataset will be submitted
VISIT	char	Visit		Empty dataset will be submitted
CTSEQ	num	Comment Sequence Number		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
CTPAGE	num	CRF Page Number		Empty dataset will be submitted
PAGNUM	num	Page Number		Empty dataset will be submitted
DOMAIN	char	Domain of Origin		Empty dataset will be submitted

1.4.8. Concomitant Meds (CM) – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant Meds (CM)
Unique identifier	DUSUBJID,CMDECOD,CMSTDY,CMSEQ
Sorted by	DUSUBJID,CMDECOD,CMSTDY,CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: CMSTDT,CMTERM,CMREAS,CMENDT,CMSTDTC,CMENDTC,CMCLASC,CMCLASC3,CMCLASC4,CMCLASC5,CMCLASC6,CMCLASC7,CMCLASC8,CMCLASC9,CMCLAS3,CMCLAS4,CMCLAS5,CMCLAS6,CMCLAS7,CMCLAS8,CMCLAS9,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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMREPRC	num	Were Any Meds Administered Code		Collected at CRF.
CMREPR	char	Were Any Meds Administered		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMREGIM	char	Regimen (Dose & 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.

Variable	Type	Label	Codes	Comments
CMSTTM	num	Start Time of Medication		Collected at CRF.
CMENDTM	num	End Time of Medication		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.
CMCAUSC	num	Given for AE Code		Collected at CRF.
CMCAUS	char	Given for AE		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.
CMCLAS0	char	ATC Text 0		Collected at CRF.
CMCLAS1	char	ATC Text 1		Collected at CRF.
CMCLAS2	char	ATC Text 2		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 REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC- REF.DATE) +1.
CMENDY	num	Relative Actual End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC- REF.DATE) +1.

1.4.9. Diagnosis (DG) – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis (DG)
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DGOTH,DGACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
DIAGNOSC	num	Diagnosis Code		Collected at CRF.
DIAGNOS	char	Diagnosis		Collected at CRF.
DGTYPEC	num	Diagnosis Type Code		Collected at CRF.
DGTYPE	char	Diagnosis Type		Collected at CRF.
DGACTDY	num	Relative Actual Day of Diagnosis		If DGACTDT and REF.DATE not missing then perform below logic to calculate DGACTDY, If DGACTDT less than REF.DATE then (DGACTDT - REF.DATE). Else if DGACTDT is greater than equal to REF.DATE then (DGACTDT- REF.DATE) +1.

1.4.10. Disposition (DS) – DISPOSIT

Dataset	DISPOSIT
Creating program	disposit.sas
Description	Disposition (DS)
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DSEND, DSEND, DSACTDT, DSR SOTH, DSRABKDT, DEATHDT, PREGDUDT, DSSEQ, DSRABKRS

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

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

1.4.11. Enrollment (EN) – ENROLL

Dataset	ENROLL
Creating program	enroll.sas
Description	Enrollment (EN)
Unique identifier	DUSUBJID,ENTEXT,ENACTDY
Sorted by	DUSUBJID,ENTEXT,ENACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ENACTDT

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

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		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 REF.DATE not missing then perform below logic to calculate ENACTDY, If ENACTDT less than REF.DATE then (ENACTDT - REF.DATE). Else if ENACTDT is greater than equal to REF.DATE then (ENACTDT- REF.DATE) +1.

1.4.12. Exposure (EX) – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Exposure (EX)
Unique identifier	DUSUBJID,PHASE,EXSTDY
Sorted by	DUSUBJID,PHASE,EXSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXSTDT

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

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
EXSTTM	num	Start Time of Exposure		Collected at CRF.
EXPTM	num	Planned Time of Administration		Collected at CRF.
EXTMLBL	char	Label of Planned Administration Time		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDT and REF.DATE not missing then perform below logic to calculate EXSTDY, if EXSTDT less than REF.DATE then (EXSTDT - REF.DATE). Else if EXSTDT is greater than equal to REF.DATE then (EXSTDT- REF.DATE) +1.

1.4.13. Laboratory Data - Hematology (HL) – HEMAT

Dataset	HEMAT
Creating program	hemat.sas
Description	Laboratory Data - Hematology (HL)
Unique identifier	DUSUBJID,PHASE,LBTEST,LBACTDY
Sorted by	DUSUBJID,PHASE,LBTEST,LBACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABSPEC, LBPRVID, LBACTDT, LBTMLBL, ORGRES, LBPRVIDC, LABNAME, 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
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
ORGRESN	num	Numeric Result in 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.
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard 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.

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

1.4.14. Lbsigr – LBSIGRG

Dataset	LBSIGRG
Creating program	lbsigr.sas
Description	Lbsigr
Unique identifier	LBTEST
Sorted by	LBTEST
Notes	

Variable	Type	Label	Codes	Comments
LBTESTC	num	Lbtestc		Collected at CRF.
STDUNIT	char	Stdunit		Collected at CRF.
STDCFACT	char	Stdcfact		Collected at CRF.
DOMAIN	char	Domain		Collected at CRF.
LBTEST	char	Lbtest		Collected at CRF.
SEX	char	Sex		Collected at CRF.
AGELOW	num	Age Low		Collected at CRF.
AGEHIGH	num	Age High		Collected at CRF.
UNIT	char	Unit		Collected at CRF.
LBSIGLO	char	Lbsig Low		Collected at CRF.
LBSIGHI	char	Lbsig High		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBCOMMLO	num	Lbcomm Low		Collected at CRF.
LBCOMMHI	num	Lbcomm High		Collected at CRF.

1.4.15. Leeds Sleep Ev. Quest – LSEQ

Dataset	LSEQ
Creating program	lseq.sas
Description	Leeds Sleep Ev. Quest
Unique identifier	DUSUBJID,PHASE,LSACTDY,LSSEQ
Sorted by	DUSUBJID,PHASE,LSACTDY,LSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LSACTDT

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.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
LSACTTM	char	Actual Time of Leeds Sleep Ev. Quest		Collected at CRF.
LSSEQ	num	Leeds Sleep Ev. Quest Sequence Number		Collected at CRF.
LSRESN	num	Leeds Sleep Ev. Quest Result (mm)		Collected at CRF.
LSACTDY	num	Relative Act Day of Leeds Sleep Ev. Quest		If LSACTDT and REF.DATE not missing then perform below logic to calculate LSACTDY, If LSACTDT less than REF.DATE then (LSACTDT - REF.DATE). Else if LSACTDT is greater than equal to REF.DATE then (LSACTDT- REF.DATE) +1.

1.4.16. Medical History (MH) – MEDHIST

Dataset	MEDHIST
Creating program	medhist.sas
Description	Medical History (MH)
Unique identifier	DUSUBJID,MHBODSYS,MHACTDY
Sorted by	DUSUBJID,MHBODSYS,MHACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MHACTDT,MHTERM

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

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		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 REF.DATE not missing then perform below logic to calculate MHACTDY, If MHACTDT less than REF.DATE then (MHACTDT - REF.DATE). Else if MHACTDT is greater than equal to REF.DATE then (MHACTDT- REF.DATE) +1.

1.4.17. PANSS (PA) – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	PANSS (PA)
Unique identifier	DUSUBJID,PHASE,PAGROUP,PAITEM,PAACTDY
Sorted by	DUSUBJID,PHASE,PAGROUP,PAITEM,PAACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PARATERI,PAACTDT

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

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
PAVTYPEC	num	PANNS Visit Type Code		Collected at CRF.
PAVTYPE	char	PANNS Visit Type		Collected at CRF.
PAGROUP	char	PANSS Subgroup		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 PANSS Actual Day		If PAACTDT and REF.DATE not missing then perform below logic to calculate PAACTDY, If PAACTDT less than REF.DATE then (PAACTDT - REF.DATE). Else if PAACTDT is greater than equal to REF.DATE then (PAACTDT - REF.DATE) +1.

1.4.18. PC Concentrations – PCCNC

Dataset	PCCNC
Creating program	pccnc.sas
Description	PC Concentrations
Unique identifier	DUSUBJID,TPT,VISIT
Sorted by	DUSUBJID,TPT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ACQREF,SAMREF,PCPRVIDC,PCPRVID,PCLBREF,PCSPCOM,PCSTDT

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PCSTAT	char	Sample Status		Collected at CRF.
SPPRVIDC	num	Sample Provider Id Code		Collected at CRF.
SPPRVID	char	Sample Provider Id		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
TPTNUM	num	Planned Time Point Number		Collected at CRF.
TPT	char	Planned Time Point Name		Collected at CRF.
PCSEQ	num	Sample Sequence Number		Collected at CRF.
PCCAT	char	Category of Sample		Collected at CRF.
PCSPEC	char	Specimen Material		Collected at CRF.
PCPRMTYP	char	Parameter Type		Collected at CRF.
PCTEST	char	Test Name		Collected at CRF.
PCORRES	char	Result in Original Units		Collected at CRF.
PCORUNIT	char	Original Units		Collected at CRF.
PCORRESN	num	Numeric Result in Original Units		Collected at CRF.
PCSTRESC	char	Character Result in Standard Units		Collected at CRF.
PCSTUNIT	char	Standard Units		Collected at CRF.
PCSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
PCLOQ	char	Limit of Quantification		Collected at CRF.
PCNRHI	num	Normal Range Upper Limit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCNRLO	num	Normal Range Lower Limit		Collected at CRF.
PCVTYPEC	num	PK/PD Sample Visit Type Code		Collected at CRF.
PCVTYPE	char	PK/PD Sample Visit Type		Collected at CRF.
PCSTTM	num	Start Time of Specimen Collection		Collected at CRF.
PCSTDY	num	Relative Strt Day of Specimen Collection		If PCSTDT and REF.DATE not missing then perform below logic to calculate PCSTDY, If PCSTDT less than REF.DATE then (PCSTDT - REF.DATE). Else if PCSTDT is greater than equal to REF.DATE then (PCSTDT- REF.DATE) +1.

1.4.19. PKPD Concentrations from JJPRD – PCCONC

Dataset	PCCONC
Creating program	pcconc.sas
Description	PKPD Concentrations from JJPRD
Unique identifier	DUSUBJID,TPT,VISIT
Sorted by	DUSUBJID,TPT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PCPRVIDC ,SAMREF,PCPRVID,PCLBREF

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASE	char	Phase		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
PCCAT	char	Category for Test or Examination		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
TPTNUM	num	Planned Time Point Number		Collected at CRF.
TPT	char	Planned Time Point Number		Collected at CRF.
PCSEQ	num	Sample Sequence Number		Collected at CRF.
PCSPEC	char	Specimen Material		Collected at CRF.
PCPRMTYP	char	Parameter Type		Collected at CRF.
PCTEST	char	Test Name		Collected at CRF.
PCORRES	char	Result in Original Units		Collected at CRF.
PCORUNIT	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCORRESN	num	Numeric Result in Original Units		Collected at CRF.
PCSTRESC	char	Character Result in Standard Units		Collected at CRF.
PCSTUNIT	char	Standard Units		Collected at CRF.
PCSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
PCLOQ	char	Limit of Quantification		Collected at CRF.
PCNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
PCNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.

1.4.20. PK/PD Sample (SP) – PCSAMP

Dataset	PCSAMP
Creating program	pcsamp.sas
Description	PK/PD Sample (SP)
Unique identifier	DUSUBJID,PHASE,SPSTAT,TPT,VISIT
Sorted by	DUSUBJID,PHASE,SPSTAT,TPT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SPPRVIDC,SPPRVID,SPSTDT,ACQREF,SAMREF,SPCOM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
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
PAGNUM	num	Page Number		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	Category for Test or Examination		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.

Variable	Type	Label	Codes	Comments
TPTNUM	num	Planned Time Point Number		Collected at CRF.
TPT	char	Planned Time Point Number		Collected at CRF.
SAMSEQ	num	Sample Sequence Number		Collected at CRF.
SPSTTM	num	Start Time of Specimen Collection		Collected at CRF.
SPSTATC	num	Sample Status Code		Collected at CRF.
SPSTAT	char	Sample Status		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase Number		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period Number		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Number		Collected at CRF.
PCPRMTYP	char	Parameter Type		Collected at CRF.
SPSTDY	num	Relative Strt Day of Specimen Collection		If SPSTDT and REF.DATE not missing then perform below logic to calculate SPSTDY, If SPSTDT less than REF.DATE then (SPSTDT - REF.DATE). Else if SPSTDT is greater than equal to REF.DATE then (SPSTDT- REF.DATE) +1.

1.4.21. Physical Exam (PE) – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Exam (PE)
Unique identifier	DUSUBJID,VISITNUM,PESEQ
Sorted by	DUSUBJID,VISITNUM,PESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
PEVTYPEC	num	PE Visit Type Code		Collected at CRF.
PEVTYPE	char	PE Visit Type		Collected at CRF.
PESEQ	num	Phys Sequence Number		Collected at CRF.
PEBODSYC	num	Body System Code		Collected at CRF.
PEBODSYS	char	Body System		Collected at CRF.
PESTATC	num	Exam Result Code		Collected at CRF.
PESTAT	char	Exam Result		Collected at CRF.
PEFIND	char	Description of Exam Findings		Collected at CRF.
PEACTDY	num	Relative Actual Day of Phys Exam		If PEACTDT and REF.DATE not missing then perform below logic to calculate PEACTDY, If PEACTDT less than REF.DATE then (PEACTDT - REF.DATE). Else if PEACTDT is greater than equal to REF.DATE then (PEACTDT- REF.DATE) +1.

1.4.22. Protocol Description (PD) – PROTDESC

Dataset	PROTDESC
Creating program	protdesc.sas
Description	Protocol Description (PD)
Unique identifier	STUDYID
Sorted by	STUDYID
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
COMPND	char	Compound Number		Collected at CRF.
COMPND	char	Compound Name		Collected at CRF.
BLINDING	char	Blinding Level		Collected at CRF.
ACTCONTR	char	Active Control		Collected at CRF.
PLACONTR	char	Placebo Control		Collected at CRF.
DESIGN	char	Trial Design		Collected at CRF.
MULTCENT	char	Multi Center		Collected at CRF.
INDICAT	char	Indication		Collected at CRF.
DEVPROID	char	Development Program Id		Collected at CRF.
AGEGRP	char	Age Group		Collected at CRF.
SPECPOP	char	Special Population		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUBJTYPE	char	Subject Type		Collected at CRF.
PROCSTUD	char	Preceding Study Id		Collected at CRF.
STUDPHAS	char	Phase of Study		Collected at CRF.
CRDMVR	char	CRDM Version Number		Collected at CRF.

1.4.23. Polysomnography Data (PS) – PSG

Dataset	PSG
Creating program	psg.sas
Description	Polysomnography Data (PS)
Unique identifier	DUSUBJID,PHASE,PSTEST,PSSTDY
Sorted by	DUSUBJID,PHASE,PSTEST,PSSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PSSTDT,PSPRVIDC,PSPRVID,PSRAINIT

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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PSSTTM	num	Polysomnography start time		Collected at CRF.
PSTESTC	char	Polysomnography Test Code		Collected at CRF.
PSUNIT	char	Polysomnography Test Unit		Collected at CRF.
PSRESN	num	Polysomnography Test Result(Numeric)		Collected at CRF.
PSVTYPEC	num	Visit Type Code		Collected at CRF.
PSVTYPE	char	Visit Type		Collected at CRF.
PSTEST	char	Polysomnography Test Description		Collected at CRF.
PSSTDY	num	Relative Polysomnography Start Day		If PSSTDT and REF.DATE not missing then perform below logic to calculate PSSTDY, If PSSTDT less than REF.DATE then (PSSTDT - REF.DATE). Else if PSSTDT is greater than equal to REF.DATE then (PSSTDT- REF.DATE) +1.

1.4.24. Psychiatric History (PH) – PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychiatric History (PH)
Unique identifier	DUSUBJID,PHASE
Sorted by	DUSUBJID,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: PHLREDT,PHLREDTC

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

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
PHAGE	char	Age at First Diagnosis		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
PHLREDY	num	Relative Day of Last Relapse(Char)		If PHLREDTC and REF.DATE not missing then perform below logic to calculate PHLREDY, If PHLREDTC less than REF.DATE then (PHLREDTC - REF.DATE). Else if PHLREDTC is greater than equal to REF.DATE then (PHLREDTC- REF.DATE) +1.

1.4.25. Randomization (RA) – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomization (RA)
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RAACTDT,RANDNUM,SUB

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

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
RASEQ	num	Randomization Sequence Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
REGIMEN	char	Regimen Code		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DURATION	char	Duration		Collected at CRF.
DOSE	char	Dose		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 REF.DATE not missing then perform below logic to calculate RAACTDY, If RAACTDT less than REF.DATE then (RAACTDT - REF.DATE). Else if RAACTDT is greater than equal to REF.DATE then (RAACTDT- REF.DATE) +1.

1.4.26. SARS (SR) – SARS

Dataset	SARS
Creating program	sars.sas
Description	SARS (SR)
Unique identifier	DUSUBJID,PHASE,SRITEM,VISIT
Sorted by	DUSUBJID,PHASE,SRITEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SRRATERI,SRACTDT

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

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

1.4.27. Laboratory Data - Urinalysis (UR) – URINE

Dataset	URINE
Creating program	urine.sas
Description	Laboratory Data - Urinalysis (UR)
Unique identifier	DUSUBJID,PHASE,LBTEST,VISIT
Sorted by	DUSUBJID,PHASE,LBTEST,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABSPEC,LBPRVID,LBACTDT,LBPRVIDC,LABNAME,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
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGRES	char	Character Result in 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.
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LAGE	char	Age: time of visit		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
LAGEUNIT	char	Age Unit (M or Y)		Collected at CRF.
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.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and REF.DATE not missing then perform below logic to calculate LBACTDY, If LBACTDT less than REF.DATE then (LBACTDT - REF.DATE). Else if LBACTDT is greater than equal to REF.DATE then (LBACTDT- REF.DATE) +1.

1.4.28. Visit Date (VI) – VISIT

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

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

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
VISITDY	num	Relative Visit Day		If VISITDT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDT less than REF.DATE then (VISITDT - REF.DATE). Else if VISITDT is greater than equal to REF.DATE then (VISITDT- REF.DATE) +1.

1.4.29. Vital Signs (VS) – VITAL

Dataset	VITAL
Creating program	vital.sas
Description	Vital Signs (VS)
Unique identifier	DUSUBJID,PHASE,VSTEST,VSACTDY,VSSEQ
Sorted by	DUSUBJID,PHASE,VSTEST,VSACTDY,VSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: VSACTDT,VSTMLBL,VSACTTM,VSORRES,VSSTRESN,VSSTRESC,VSSTUNIT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSPTM	num	Planned Elapsed Time of Meas.		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSTEST	char	Vital Signs Test Short Name		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.
VSPOS	char	Position		Collected at CRF.
VSORRESN	num	Numeric Result in Original Units		Collected at CRF.

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