Clinical Development

Risperidone®

RIS-USA-231

Anonymisation Data Derivation Specification Document

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Table of contents

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Lab Identifier information will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's relative day cannot be calculated.
- REMARK dataset will be submitted with zero observations.
- Datasets with zero records as input will not be submitted.
  (eg: DEATH, LABNOR, PDRES, PKOUTL, PKRES)
- Dataset containing information which is not useful for further analysis will not be submitted. (eg. TRLDESC, TRLLIST, MAP)
- Dataset containing Investigator information will not be submitted. (eg. INVEST)
- Dataset information related to code lists will not be submitted. (eg. CODE)
- Screening Date(VISIT.VISIT_D) will be used as Reference Date (referred as REF.DATE in this document) to derive relative days.

1.3. Data Files

The RIS-USA-231 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Subject Characteristics – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	Subject Characteristics
Unique identifier	TRIAL ,DCRFID
Sorted by	TRIAL ,DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDNO,RAND_D, INITIALS, INVEST, ZINVEST, BIRTH_D, BREAK_D, BREAK_V, COINV, ZCOINV

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
DSITEID	num	SITE NO. ASSIGNED FOR DE-IDENTITY		Randomly assigned Site No. For De-Identity.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ONAGE	char	AGE AT ONSET OF FIRST PSYCHOTIC SYMPTOMS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
STARTAGE	char	AGE, START OF FIRST ANTIPSYCHOTIC TREAT		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DIAGAGE	char	AGE AT DIAGNOSIS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
CGAS	num	CGAS SCORE		Collected at CRF.
DNAANAL	char	HAS DNA SAMPLE TAKEN FOR DNA ANALYSIS?		Collected at CRF.
SUBJELIG	char	SUBJECT ELIGIBILITY		Collected at CRF.
RECEIVE	char	SUBJECT DID NOT RECEIVE TRIAL MEDICATION		Collected at CRF.
BREAK	char	CODE BROKEN ?		Collected at CRF.
DEATHNA	char	EVENT OF DEATH		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
DISCVIS	num	D/C VISIT		Collected at CRF.
RACENEW	char	RACE (NEW)		Collected at CRF.
ETHNIC	char	ETHNICITY		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Element grouped to protect PII.

Variable	Type	Label	Codes	Comments
AGE	char	AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= int((VISIT_D – BIRTH_D)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.
RAND_DY	num	RELATIVE RANDOMISATION DAY		If RAND _D and REF. DATE not missing then perform below logic to calculate RAND _DY, If RAND _D less than REF. DATE then (RAND _D - REF. DATE).Else if RAND _D is greater than equal to REF. DATE then (RAND _D- REF. DATE) +1.
BREAK_DY	num	RELATIVE DAY CODE BREAKING		If BREAK_D and REF. DATE not missing then perform below logic to calculate BREAK_DY, If BREAK_D less than REF. DATE then (BREAK_D - REF. DATE).Else if BREAK_D is greater than equal to REF. DATE then (BREAK_D- REF. DATE) +1.

1.4.2. Administration Of Trial Medication – ADMMED

Dataset	ADMMED
Creating program	admmed.sas
Description	Administration Of Trial Medication
Unique identifier	TRIAL,DCRFID,PHASE,SEGMENT,AMFROMDY
Sorted by	TRIAL,DCRFID,PHASE,SEGMENT,AMFROMDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AMFROM_D,AMTO_D,NUMFORM,AMDOSE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	SEGMENT		Collected at CRF.
NUMFORM1	num	MORNING INTAKE OF DOSE		Collected at CRF.
NUMFORM2	num	EVENING INTAKE OF DOSE		Collected at CRF.
AMDOSE_U	char	DOSE UNIT		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
AMREAS1	char	MORNING DOSE CHANGE REASON		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZAMREAS1	char	MORNING DOSE CHANGE REASON		Collected at CRF.
AMREAS2	char	EVENING DOSE CHANGE REASON		Collected at CRF.
ZAMREAS2	char	EVENING DOSE CHANGE REASON		Collected at CRF.
AMFROMDY	num	RELATIVE ADMIN. FROM DAY		If AMFROM_D and REF. DATE not missing then perform below logic to calculate AMFROMDY, If AMFROM_D less than REF. DATE then (AMFROM_D - REF. DATE).Else if AMFROM_D is greater than equal to REF. DATE then (AMFROM_D- REF. DATE) +1.
AMTO_DY	num	RELATIVE ADMIN. TO DAY		If AMTO_D and REF. DATE not missing then perform below logic to calculate AMTO_DY , If AMTO_D less than REF. DATE then (AMTO_D - REF. DATE).Else if AMTO_D is greater than equal to REF. DATE then (AMTO_D- REF. DATE) +1.

1.4.3. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	TRIAL,DCRFID,AESOC,AEPREF,AEFROMDY,AESEQNO
Sorted by	TRIAL,DCRFID,AESOC,AEPREF,AEFROMDY,AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AE_V,AEINCL,PHASE,AEFROM_D,AETO_D,SAEREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
AESEQNO	num	AE SEQ.		Collected at CRF.
AEFROM_C	char	AE FROM CODE		Collected at CRF.
AETO_C	char	AE TO CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESEV	num	AE SEVERITY		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN		Collected at CRF.

Variable	Type	Label	Codes	Comments
AECONRX	char	AE CO-RX START		Collected at CRF.
ZAECONRX	num	AE CO-RX START		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME		Collected at CRF.
AESER	char	AE SERIOUSNESS		Collected at CRF.
ZAESER	num	AE SERIOUSNESS		Collected at CRF.
AESOC	char	AE SYSTEM ORGAN CLASS		Collected at CRF.
AEWHONUM	char	AE WHO CODE		Collected at CRF.
AEPREF	char	ADVERSE EVENT PREFERRED TERM		Collected at CRF.
AESOC1	char	AE SYSTEM ORGAN CLASS 1		Collected at CRF.
AESOC2	char	AE SYSTEM ORGAN CLASS 2		Collected at CRF.
AESOC3	char	AE SYSTEM ORGAN CLASS 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEFROMDY	num	RELATIVE AE FROM DAY		If AEFROM_D and REF. DATE not missing then perform below logic to calculate AEFROMDY, If AEFROM_D less than REF. DATE then (AEFROM_D - REF. DATE).Else if AEFROM_D is greater than equal to REF. DATE then (AEFROM_D- REF. DATE) +1.
AETO_DY	num	RELATIVE AE TO DAY		If AETO_D and REF. DATE not missing then perform below logic to calculate AETO_DY, If AETO_D less than REF. DATE then (AETO_D - REF. DATE).Else if AETO_D is greater than equal to REF. DATE then (AETO_D- REF. DATE) +1.

1.4.4. Abnormal Involuntary Movement Scale – AIMS

Dataset	AIMS
Creating program	aims.sas
Description	Abnormal Involuntary Movement Scale
Unique identifier	TRIAL,DCRFID,VISIT,AIGROUP,AIITEM
Sorted by	TRIAL,DCRFID,VISIT,AIGROUP,AIITEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
AIGROUP	char	GROUP		Collected at CRF.
AIITEM	char	AIMS ITEM		Collected at CRF.
AISCORE	char	AIMS SCORE		Collected at CRF.
ZAISCORE	num	AIMS SCORE		Collected at CRF.

1.4.5. Drug Administration Before Sampling – BANADM

Dataset	BANADM
Creating program	banadm.sas
Description	Drug Administration Before Sampling
Unique identifier	TRIAL,DCRFID,VISIT,SPECIMEN,BAADMDY,BAADMSEQ
Sorted by	TRIAL,DCRFID,VISIT,SPECIMEN,BAADMDY,BAADMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMREFNO,BAADM_D,LABINTNO,TREAT

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
BAADM_T	num	DRUG ADMIN. TIME		Collected at CRF.
BAADMSEQ	char	DRUG ADMIN. SEQ.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
BAADM_DY	num	RELATIVE DRUG ADMIN. DAY		If BAADM_D and REF. DATE not missing then perform below logic to calculate BAADM_DY, If BAADM_D less than REF. DATE then (BAADM_D - REF. DATE).Else if BAADM_D is greater than equal to REF. DATE then (BAADM_D- REF. DATE) +1.

1.4.6. Bioanalysis Results – BANRES

Dataset	BANRES
Creating program	banres.sas
Description	Bioanalysis Results
Unique identifier	TRIAL,DCRFID,VISIT,SAMPLEDY,SUBST,SAMTM_S
Sorted by	TRIAL,DCRFID,VISIT,SAMPLEDY,SUBST,SAMTM_S
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D,SAMREFNO,LABINTNO,BRINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
SUBST	char	SUBSTANCE		Collected at CRF.
BRVAL	num	BAN MEASUREMENT		Collected at CRF.
BRVAL_V	char	BAN MEASUREMENT (VERB.)		Collected at CRF.
BRVAL_U	char	UNIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
BRQUANT	char	LIMIT OF QUANTIFICATION		Collected at CRF.
VISIT	char	VISIT		Collected at CRF.
SAMTM_S	char	SCHEDULED TIME		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF. DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF. DATE then (SAMPLE_D - REF. DATE).Else if SAMPLE_D is greater than equal to REF. DATE then (SAMPLE_D- REF. DATE) +1.

1.4.7. Barnes Akathisia Rating Scale – BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia Rating Scale
Unique identifier	TRIAL,VISIT,DCRFID,BAGROUP,BAITEM
Sorted by	TRIAL,VISIT,DCRFID,BAGROUP,BAITEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
BAGROUP	char	BARS GROUP		Collected at CRF.
BAITEM	char	BARS ITEM		Collected at CRF.
BASCORE	char	BARS SCORE		Collected at CRF.
ZBASCORE	num	BARS SCORE		Collected at CRF.

1.4.8. Cother AE Related Table – CONAE

Dataset	CONAE
Creating program	conae.sas
Description	Cother AE Related Table
Unique identifier	TRIAL,DCRFID,AESEQNO,CTSEQNO
Sorted by	TRIAL,DCRFID,AESEQNO,CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CONRX_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
AESEQNO	num	AE SEQ.		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.

1.4.9. Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
Unique identifier	TRIAL,DCRFID,CTTYPE,RXPREF,CTSEQNO
Sorted by	TRIAL,DCRFID,CTTYPE,RXPREF,CTSEQNO
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: CONRX_V,CONRX,CTIND_V,CTFROM_D,CTTO_D,CTTO_C,ATCCODE8, ATCCODE9,ATCTEXT8,ATCTEXT9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.

Variable	Type	Label	Codes	Comments
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CTPREF	char	INDICATION PREFERRED TERM		Collected at CRF.
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTIND	char	INDICATION		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTFROM_C	char	CO-RX START CODE		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCCODE3	char	ATC CODE 3		Collected at CRF.
ATCCODE4	char	ATC CODE 4		Collected at CRF.
ATCCODE5	char	ATC CODE 5		Collected at CRF.
ATCCODE6	char	ATC CODE 6		Collected at CRF.
ATCCODE7	char	ATC CODE 7		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
ATCTEXT1	char	ATC TEXT 1		Collected at CRF.
ATCTEXT2	char	ATC TEXT 2		Collected at CRF.
ATCTEXT3	char	ATC TEXT 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCTEXT4	char	ATC TEXT 4		Collected at CRF.
ATCTEXT5	char	ATC TEXT 5		Collected at CRF.
ATCTEXT6	char	ATC TEXT 6		Collected at CRF.
ATCTEXT7	char	ATC TEXT 7		Collected at CRF.
RXPREF	char	PREFERRED NAME		Collected at CRF.
CTFROMDY	num	RELATIVE CO-RX START DAY		If CTFROM_D and REF. DATE not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than REF. DATE then (CTFROM_D - REF. DATE).Else if CTFROM_D is greater than equal to REF. DATE then (CTFROM_D- REF. DATE) +1.
CTTO_DY	num	RELATIVE CO-RX END DAY		If CTTO_D and REF. DATE not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than REF. DATE then (CTTO_D - REF. DATE).Else if CTTO_D is greater than equal to REF. DATE then (CTTO_D- REF. DATE) +1.

1.4.10. Deviation – DEVIATN

Dataset	DVIATN
Creating program	deviatn.sas
Description	Deviation
Unique identifier	TRIAL,DCRFID,DEVIAT
Sorted by	TRIAL,DCRFID,DEVIAT
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: DEVIAT_V,ZDEVIAT

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
DVTYPE	char	TYPE OF DEVIATION		Collected at CRF.
DEVIAT	char	DEVIATION		Collected at CRF.

1.4.11. Diagnosis – DIAGNOS

Dataset	DEVIATN
Creating program	deviatn.sas
Description	Diagnosis
Unique identifier	TRIAL ,DCRFID,DXAXIS,DIAGN
Sorted by	TRIAL ,DCRFID,DXAXIS,DIAGN
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
DXAXIS	char	AXIS		Collected at CRF.
DIAGN	char	DIAGNOSIS		Collected at CRF.
ZDIAGN	num	DIAGNOSIS		Collected at CRF.

1.4.12. Previous And Concomitant Diseases – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Previous And Concomitant Diseases
Unique identifier	TRIAL,DCRFID,DSSYSTEM,DSSEQNO
Sorted by	TRIAL,DCRFID,DSSYSTEM,DSSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DISEAS_V,DISEASE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
DSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.

1.4.13. Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	TRIAL,DCRFID,VISIT,ECGDY,EGRELCHA
Sorted by	TRIAL,DCRFID,VISIT,ECGDY,EGRELCHA
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGRELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF. DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF. DATE then (ECG_D - REF. DATE).Else if ECG_D is greater than equal to REF. DATE then (ECG_D- REF. DATE) +1.

1.4.14. ECG Other Abnormalities – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG Other Abnormalities
Unique identifier	TRIAL,DCRFID,VISIT,ECGDY,EASEQNO
Sorted by	TRIAL,DCRFID,VISIT,ECGDY,EASEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D,ECGOTH_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EASEQNO	num	SEQUENCE NUMBER		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF. DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF. DATE then (ECG_D - REF. DATE).Else if ECG_D is greater than equal to REF. DATE then (ECG_D- REF. DATE) +1.

1.4.15. Electrocardiogram Evaluation – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	Electrocardiogram Evaluation
Unique identifier	TRIAL,DCRFID,VISIT,ECGDY,EEASPECT,EEEVAL
Sorted by	TRIAL,DCRFID,VISIT,ECGDY,EEASPECT,EEEVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EEASPECT	char	ECG ASPECT		Collected at CRF.
EEEVAL	char	ECG EVALUATION		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF. DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF. DATE then (ECG_D - REF. DATE).Else if ECG_D is greater than equal to REF. DATE then (ECG_D- REF. DATE) +1.

1.4.16. Electrocardiogram Measurements – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	Electrocardiogram Measurements
Unique identifier	TRIAL,VISIT,DCRFID,ECGDY,ECGPAR
Sorted by	TRIAL,VISIT,DCRFID,ECGDY,ECGPAR
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
ECGPAR	char	ECG PARAMETER		Collected at CRF.
EPSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGPAR_U	char	ECG MEASUREMENT UNIT		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF. DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF. DATE then (ECG_D - REF. DATE).Else if ECG_D is greater than equal to REF. DATE then (ECG_D- REF. DATE) +1.

1.4.17. Hospital Related AEs – HOSAE

Dataset	HOSAE
Creating program	hosae.sas
Description	Hospital Related AEs
Unique identifier	TRIAL,DCRFID,HOSEQNO, AESEQNO
Sorted by	TRIAL,DCRFID,HOSEQNO, AESEQNO
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.

Variable	Type	Label	Codes	Comments
HOSEQNO	num	HOSPITAL SEQUENCE NUMBER		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.

1.4.18. Hospital Status – HOSPITAL

Dataset	HOSPITAL
Creating program	hospital.sas
Description	Hospital Status
Unique identifier	TRIAL,DCRFID,HOTODY,HOSEQNO
Sorted by	TRIAL,DCRFID,HOTODY,HOSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HOFROM_D, HOTO_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
HOSEQNO	num	HOSPITAL SEQUENCE NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOONGO	char	ADMISSION ONGOING?		Collected at CRF.
HOFROMDY	num	RELATIVE ADMISSION DAY		If HOFROM_D and REF. DATE not missing then perform below logic to calculate HOFROMDY, If HOFROM_D less than REF. DATE then (HOFROM_D - REF. DATE).Else if HOFROM_D is greater than equal to REF. DATE then (HOFROM_D- REF. DATE) +1.
HOTO_DY	num	RELATIVE DISCHARGE DAY		If HOTO_D and REF. DATE not missing then perform below logic to calculate HOTO_DY, If HOTO_D less than REF. DATE then (HOTO_D - REF. DATE).Else if HOTO_D is greater than equal to REF. DATE then (HOTO_D- REF. DATE) +1.

1.4.19. Inclusion-Exclusion Criteria – INEX

Dataset	INEX
Creating program	inex.sas
Description	Inclusion-Exclusion Criteria
Unique identifier	TRIAL,DCRFID,IETYPE,IECRIT
Sorted by	TRIAL,DCRFID,IETYPE,IECRIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
IETYPE	char	TYPE OF SELECTION CRITERIA		Collected at CRF.
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	num	SELECTION CRITERIA		Collected at CRF.
IEYN	char	ELIGIBILITY EXPR.		Collected at CRF.

1.4.20. Laboratory Results – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	Laboratory Results
Unique identifier	TRIAL,DCRFID,VISIT,LABTEST,SPECIMEN,SAMPLEDY,SAMPLE_T
Sorted by	TRIAL,DCRFID,VISIT,LABTEST,SPECIMEN,SAMPLEDY,SAMPLE_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D,LABID,ZLABID,LABVAL_V,SAMREFNO,LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABUPP	num	UPPER NORMAL LIMIT		Collected at CRF.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
LOWPATHO	num	LOWER PATHOLOGICAL LIMIT		Collected at CRF.
UPPPATHO	num	UPPER PATHOLOGICAL LIMIT		Collected at CRF.
CFACTOR	num	CONVERSION FACTOR		Collected at CRF.
SIUNIT	char	STANDARD INTERNATIONAL UNIT		Collected at CRF.
LABTSTNO	num	LAB. TEST NUMBER		Collected at CRF.
LABCLASS	char	LAB CLASS		Collected at CRF.
ENZYME	char	ENZYME		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF. DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF. DATE then (SAMPLE_D - REF. DATE).Else if SAMPLE_D is greater than equal to REF. DATE then (SAMPLE_D- REF. DATE) +1.

1.4.21. Laboratory Urine Results – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	Laboratory Urine Results
Unique identifier	TRIAL,DCRFID,VISIT,LABTEST,SPECIMEN,SAMPLEDY,SAMPLE_T
Sorted by	TRIAL,DCRFID,VISIT,LABTEST,SPECIMEN,SAMPLEDY,SAMPLE_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,LABID,ZLABID,LUVAL,SAMREFNO,LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST		Collected at CRF.
LUVAL_V	char	URINE VALUE (VERB.)		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTSTNO	num	LAB. TEST NUMBER		Collected at CRF.
LABCLASS	char	LAB CLASS		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF. DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF. DATE then (SAMPLE_D - REF. DATE).Else if SAMPLE_D is greater than equal to REF. DATE then (SAMPLE_D- REF. DATE) +1.

1.4.22. No Data On Visits/Pages – NODATA

Dataset	NODATA
Creating program	nodata.sas
Description	No Data On Visits/Pages
Unique identifier	TRIAL, DCRFID
Sorted by	TRIAL, DCRFID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.

Variable	Type	Label	Codes	Comments
NDSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
NDFROM	num	NO DATA START		Collected at CRF.
NDTO	num	NO DATA END		Collected at CRF.

1.4.23. Positive And Negative Syndrome Scale – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	Positive And Negative Syndrome Scale
Unique identifier	TRIAL,DCRFID,VISIT,PAGROUP,PAITEM
Sorted by	TRIAL,DCRFID,VISIT,PAGROUP,PAITEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
PAGROUP	char	PANSS SUBGROUP		Collected at CRF.
PAITEM	char	PANSS ITEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
PASCORE	char	PANSS SCORE		Collected at CRF.
ZPASCORE	num	PANSS SCORE		Collected at CRF.

1.4.24. Physical Examination – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	Physical Examination
Unique identifier	TRIAL,DCRFID,VISIT,PESYSTEM, PESEQNO
Sorted by	TRIAL,DCRFID,VISIT,PESYSTEM, PESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EXAM_V, EXAM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
PESEQNO	num	SEQUENCE NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.

1.4.25. Previous Therapy – PRETHER

Dataset	PRETHER
Creating program	prether.sas
Description	Previous Therapy
Unique identifier	TRIAL,DCRFID,RXPREF,PTSEQNO
Sorted by	TRIAL,DCRFID,RXPREF,PTSEQNO
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: PRVRX_V,PRVRX,PTFROM_D,PTTO_D,PTAE_V,ATCCODE3,ATCCODE4, ATCCODE5,ATCCODE6,ATCCODE7,ATCCODE8,ATCCODE9,ATCTEXT3, ATCTEXT4,ATCTEXT5,ATCTEXT6,ATCTEXT7,ATCTEXT8,ATCTEXT9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
PTSEQNO	num	PREV. RX SEQ.		Collected at CRF.

Variable	Type	Label	Codes	Comments
PTSCHED	char	PREV. RX DAILY SCHEDULE		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
ATCTEXT1	char	ATC TEXT 1		Collected at CRF.
ATCTEXT2	char	ATC TEXT 2		Collected at CRF.
RXPREF	char	PREFERRED NAME		Collected at CRF.
PTFROMDY	num	RELATIVE PREV. RX START DAY		If PTFROM_D and REF. DATE not missing then perform below logic to calculate PTFROMDY, If PTFROM_D less than REF. DATE then (PTFROM_D - REF. DATE).Else if PTFROM_D is greater than equal to REF. DATE then (PTFROM_D- REF. DATE) +1.
PTTO_DY	num	RELATIVE PREV. RX END DAY		If PTTO_D and REF. DATE not missing then perform below logic to calculate PTTO_DY, If PTTO_D less than REF. DATE then (PTTO_D - REF. DATE).Else if PTTO_D is greater than equal to REF. DATE then (PTTO_D- REF. DATE) +1.

1.4.26. Randomisation Group For Each Subjchar – RANDGRP

Dataset	RANDGRP
Creating program	randgrp.sas
Description	Randomisation Group For Each Subjchar
Unique identifier	TRIAL,DCRFID
Sorted by	TRIAL,DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.

1.4.27. Related AEs For Termination Or Death – RELAE

Dataset	RELAE
Creating program	relae.sas
Description	Related AEs For Termination Or Death
Unique identifier	TRIAL,DCRFID,AESEQNO
Sorted by	TRIAL,DCRFID,AESEQNO
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
RATYPE	char	AE CONSEQUENCE		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.

1.4.28. Remarks And Comments – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	Remarks And Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Comments data is sensitive data, contains free text information. Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Empty dataset will be submitted.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Empty dataset will be submitted.
RMSEQNO	num	SEQUENCE NUMBER		Empty dataset will be submitted.
RMTYPE	char	REMARK TYPE		Empty dataset will be submitted.

1.4.29. Samples – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	SAMPLES
Unique identifier	TRIAL,DCRFID,VISIT,SPECIMEN,SAMTYPE,SAMTM_S,SAMPLE_D
Sorted by	TRIAL,DCRFID,VISIT,SPECIMEN,SAMTYPE,SAMTM_S,SAMPLE_D
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,LABID,ZLABID,SAMREFNO,SASAME,SARELCHA,LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		Collected at CRF.
FASTED	char	SUBJECT FASTED		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMTM_S	char	SCHEDULED TIME		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF. DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF. DATE then (SAMPLE_D - REF. DATE).Else if SAMPLE_D is greater than equal to REF. DATE then (SAMPLE_D- REF. DATE) +1.

1.4.30. Sample Requisition Numbers – SAMREF

Dataset	SAMREF
Creating program	samref.sas
Description	Sample Requisition Numbers
Unique identifier	TRIAL,DCRFID,VISIT
Sorted by	TRIAL,DCRFID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABID,ZLABID, SPECIMEN, SAMTYPE, SAMREFNO, SFADDSAM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
SARELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.

1.4.31. Simpson And Angus Rating Scale – SARS

Dataset	SARS
Creating program	sars.sas
Description	Simpson And Angus Rating Scale
Unique identifier	TRIAL,DCRFID,VISIT,SAITEM
Sorted by	TRIAL,DCRFID,VISIT,SAITEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
SAITEM	char	SIMPSON AND ANGUS ITEM		Collected at CRF.
SASCORE	char	SIMPSON AND ANGUS SCORE		Collected at CRF.
ZSASCORE	num	SIMPSON AND ANGUS SCORE		Collected at CRF.

1.4.32. Totals – TOTALS

Dataset	TOTALS
Creating program	totals.sas
Description	Totals
Unique identifier	TRIAL,DCRFID,VISIT,TOGROUP,TOITEM
Sorted by	TRIAL,DCRFID,VISIT,TOGROUP,TOITEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
TOGROUP	char	TOTAL GROUP		Collected at CRF.
TOITEM	char	TOTAL ITEM		Collected at CRF.
TOSCORE	num	TOTAL SCORE		Collected at CRF.

1.4.33. Randomisation Groups – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	Randomisation Groups
Unique identifier	TRIAL, RANDGRP
Sorted by	TRIAL, RANDGRP
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.

1.4.34. Trial Medication Regimens – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	Trial Medication Regimens
Unique identifier	TRIAL,RANDGRP,PHASE,SEGMENT
Sorted by	TRIAL,RANDGRP,PHASE,SEGMENT
Notes	Below listed variables will be dropped from dataset due to missing values: BOX,NUMFORM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	SEGMENT		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.
FORMULAT	char	FORMULATION		Collected at CRF.
STRENGTH	num	STRENGTH OF 1 UNIT		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
TMFREQ	char	ADMIN. FREQ.		Collected at CRF.
TMROUTE	char	ADMIN. ROUTE		Collected at CRF.
ZTMROUTE	char	ADMIN. ROUTE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TMDUR	num	SEGMENT DURATION		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

1.4.35. Treatment / Trial Termination – TRTERM

Dataset	TRTERM
Creating program	trterm.sas
Description	Treatment / Trial Termination
Unique identifier	TRIAL,DCRFID,TRTYPE,TRSTATE
Sorted by	TRIAL,DCRFID,TRTYPE,TRSTATE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TRREAS_V,TRFROM_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
TRTYPE	char	TYPE OF TERMINATION		Collected at CRF.
TRSTATE	char	STATE OF TERMINATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRREAS	char	TERM. REASON		Collected at CRF.
TRFROMDY	num	RELATIVE LAST CONTACT DAY		If TRFROM_D and REF. DATE not missing then perform below logic to calculate TRFROMDY, If TRFROM_D less than REF. DATE then (TRFROM_D - REF. DATE).Else if TRFROM_D is greater than equal to REF. DATE then (TRFROM_D- REF. DATE) +1.

1.4.36. VISITS – VISIT

Dataset	VISIT
Creating program	VISIT.sas
Description	Visits
Unique identifier	TRIAL,DCRFID,VISIT
Sorted by	TRIAL,DCRFID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: VISIT_D,PAINIT,CGIINIT,AIINIT,SAINIT,BAINIT,HOSPND

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
PREVMED	char	LORAZEPAM WITHIN 8 HOURS		Collected at CRF.
CGIS	char	CLINICAL GLOBAL IMPRESSION SEVERITY		Collected at CRF.
CGII	char	CLINICAL GLOBAL IMPRESSION IMPROVEMENT		Collected at CRF.
TANNER	num	TANNER STAGE		Collected at CRF.
PREGRES	char	RESULT OF PREGNANCY TEST		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and REF. DATE not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than REF. DATE then (VISIT_D - REF. DATE).Else if VISIT_D is greater than equal to REF. DATE then (VISIT_D- REF. DATE) +1.

1.4.37. Vital Signs – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	Vital Signs
Unique identifier	TRIAL,DCRFID, VISIT
Sorted by	TRIAL,DCRFID, VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID For De-Identity.
VISIT	num	VISIT		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
BMI	num	BMI		Collected at CRF.
BMI_U	char	BMI UNIT		Collected at CRF.
PULSE	num	PULSE, beats/min		Collected at CRF.
POSITION	char	POSITION		Collected at CRF.

Variable	Type	Label	Codes	Comments
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLIC BP, mmHg		Collected at CRF.
TEMP	num	BODY TEMP.		Collected at CRF.
TEMP_U	char	BODY TEMP. UNIT		Collected at CRF.