

Clinical Development

CONSTATRE[®]

RIS-SCH-302

Anonymisation Data Derivation Specification Document

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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 Sequence Number will not be provided.
- Drug Record 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.
- Dataset with zero observation will not be submitted (BANADM,BANRES, DEATH, ECGABN,LABNOR, PKOUTL, PKRES).
- INVEST and DNRSLT dataset will not be submitted due to sensitive information.
- MAP dataset will not be submitted as it is not useful for further analysis.
- VISIT.VISIT_D (when VISIT=1) will be used as Reference Date (referred as REF. DATE in the document) to derive relative days.

1.3. Data Files

The RIS-SCH-302 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. SUBJECT CHARACTERISTICS (SC) – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	SUBJECT CHARACTERISTICS (SC)
Unique identifier	DCRFID
Sorted by	DCRFID
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: MEDNO,INVEST,ZINVEST,INITIALS,BIRTH_D,BREAK_D,BREAK_V,DRYRUN, ZCOUNTRY,RAND_D,COINV,ZCOINV,BATCHNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
ETHNIC	char	ETHNICITY (HISPANIC/LATINO?)		Collected at CRF.
DEATHNA	char	EVENT OF DEATH		Collected at CRF.
BREAK	char	CODE BROKEN ?		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITE NO ASSIGNED FOR DE-IDENTITY		Randomly assigned site no for De-Identity
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.
DISCVIS	num	D/C VISIT		Collected at CRF.
HOSPND	char	NOT HOSPITALIZED		Collected at CRF.
HOSCRNA	char	HOSPITALIZATION AT SCREENING		Collected at CRF.
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.
AMNA	char	EXTRA TITRATION DAYS 8-10		Collected at CRF.
NXTTRIAL	char	ENTER OPEN-LABEL TRIAL		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
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.

1.4.2. ADMINISTRATION OF TRIAL MEDICATION (AM) – ADMMED

Dataset	ADMED
Creating program	admmed.sas
Description	ADMINISTRATION OF TRIAL MEDICATION (AM)
Unique identifier	DCRFID,SEGMENT,AMDAY,AMTO_DY
Sorted by	DCRFID,SEGMENT,AMDAY,AMTO_DY
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,BOX,AMFREQ,AMDOSE,AMDOSE_U

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	SEGMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
AMDAY	num	ADMIN. DAY		Collected at CRF.
CARD	char	ADMIN. CARD		Collected at CRF.
NUMFORM1	num	UNITS PER ADMIN. (ROW1)		Collected at CRF.
NUMFORM2	num	UNITS PER ADMIN. (ROW2)		Collected at CRF.
NUMFORM3	num	UNITS PER ADMIN. (ROW3)		Collected at CRF.
NUMFORM4	num	UNITS PER ADMIN. (ROW4)		Collected at CRF.
NUMFORM5	num	UNITS PER ADMIN. (ROW5)		Collected at CRF.
NUMFORM6	num	UNITS PER ADMIN. (ROW6)		Collected at CRF.
NUMFORM7	num	UNITS PER ADMIN. (ROW7)		Collected at CRF.
AMNONE	char	NO TABLET TAKEN		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
ZAMREAS	char	REGIMEN CHANGE REASON (CODE)		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) – AE

Dataset	AE
Creating program	ae.sas
Description	ADVERSE EVENTS (AE)
Unique identifier	DCRFID, AEPREF, AESEQNO
Sorted by	DCRFID, AEPREF, 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, AEFROM_C, AETO_D, AETO_C, SAEREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
AESEQNO	num	AE SEQ.		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESV	num	AE SEVERITY (CODE)		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN (CODE)		Collected at CRF.
AECNRX	char	AE CO-RX START		Collected at CRF.
ZAECONRX	num	AE CO-RX START (CODE)		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZAERELAT	num	AE DRUG RELATION (CODE)		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME (CODE)		Collected at CRF.
AESER	char	AE SERIOUSNESS		Collected at CRF.
ZAESER	num	AE SERIOUSNESS (CODE)		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.
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 (AI) – AIMS

Dataset	AIMS
Creating program	aims.sas
Description	ABNORMAL INVOLUNTARY MOVEMENT SCALE (AI)
Unique identifier	DCRFID,AIGROUP,AIITEM,VISIT
Sorted by	DCRFID,AIGROUP,AIITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid 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 (CODE)		Collected at CRF.

1.4.5. BARNES AKATHISIA RATING SCLAE (BA) – BARS

Dataset	BARS
Creating program	bars.sas
Description	BARNES AKATHISIA RATING SCLAE (BA)
Unique identifier	DCRFID,BAGROUP,BAITEM,VISIT
Sorted by	DCRFID,BAGROUP,BAITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid 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 (CODE)		Collected at CRF.

1.4.6. DICTIONARY VERSION CONTROL – CODE

Dataset	CODE
Creating program	code.sas
Description	DICTIONARY VERSION CONTROL
Unique identifier	CODELIST
Sorted by	CODELIST
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
CODELIST	char	CODELIST		Collected at CRF.
VALID_D	num	VALID DATE		Collected at CRF.

1.4.7. COTHER AE RELATED TABLE (AC) – CONAE

Dataset	CONAE
Creating program	conae.sas
Description	COTHER AE RELATED TABLE (AC)
Unique identifier	DCRFID,CTTYPE,AESEQNO,CTSEQNO
Sorted by	DCRFID,CTTYPE,AESEQNO,CTSEQNO
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
AESEQNO	num	AE SEQ.		Collected at CRF.
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX_V	char	CO-RX (VERB.)		Collected at CRF.

1.4.8. CONCOMITANT THERAPY (CT) – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	CONCOMITANT THERAPY (CT)
Unique identifier	DCRFID,CTTYPE,RXPREF,CTSEQNO
Sorted by	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 missing values: CONRX_V,CTIND_V,CTFROM_D,CTFROM_C,CTTO_D,CTTO_C

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CONRX	char	CO-RX		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.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
CTPREF	char	INDICATION PREFERRED TERM		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
ATCCODE8	char	ATC CODE 8		Collected at CRF.
ATCCODE9	char	ATC CODE 9		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.
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.
ATCTEXT8	char	ATC TEXT 8		Collected at CRF.
ATCTEXT9	char	ATC TEXT 9		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.9. DEVIATION (DV) – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	DEVIATION (DV)
Unique identifier	DCRFID,DEVIAT
Sorted by	DCRFID,DEVIAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DVTYPE,DEVIAT_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
DEVIAT	char	DEVIATION		Collected at CRF.
ZDEVIAT	char	DEVIATION (CODE)		Collected at CRF.

1.4.10. DIAGNOSIS (DX) – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	DIAGNOSIS (DX)
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

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

1.4.11. PREVIOUS AND CONCOMITANT DISEASES (DS) – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	PREVIOUS AND CONCOMITANT DISEASES (DS)
Unique identifier	DCRFID,DSSYSTEM,DSSEQNO
Sorted by	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 crfid for De-Identity
DSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.

1.4.12. DNA SAMPLE (DN) – DNA

Dataset	DNA
Creating program	dna.sas
Description	DNA SAMPLE (DN)
Unique identifier	DCRFID,DNSEQ
Sorted by	DCRFID,DNSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DNINF_D,DNREAS

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
VISIT	num	VISIT		Collected at CRF.
DNSEQ	num	DNA SEQ.		Collected at CRF.
DNCNSNT	char	DNA CONSENT FORM SIGNED		Collected at CRF.
DNSTUDY	char	DNA STUDY SPECIFIC TESTING		Collected at CRF.
DNSTORE	char	DNA STORAGE FOR FUTURE TESTING		Collected at CRF.

Variable	Type	Label	Codes	Comments
DNSAMP	char	DNA SAMPLE OBTAINED		Collected at CRF.
DNINF_DY	num	RELATIVE DNA INFORMED CONSENT DAY		If DNINF_D and REF.DATE not missing then perform below logic to calculate DNINF_DY, If DNINF_D less than REF.DATE then (DNINF_D - REF.DATE). Else if DNINF_D is greater than equal to REF.DATE then (DNINF_D- REF.DATE) +1.

1.4.13. ELECTROCARDIOGRAM (EG) – ECG

Dataset	ECG
Creating program	ecg.sas
Description	ELECTROCARDIOGRAM (EG)
Unique identifier	DCRFID,EGRESULT,ECG_T
Sorted by	DCRFID,EGRESULT,ECG_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ECG_D,ECGSRCE,EGLIMITS,EGRELCHA,LEADQT,ECGINTNO,ECGREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
ECG_T	num	ECG TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGRESULT	char	ECG RESULT		Collected at CRF.
VISIT	num	VISIT		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. ELECTROCARDIOGRAM EVALUATION (EE) – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	ELECTROCARDIOGRAM EVALUATION (EE)
Unique identifier	DCRFID,EEASPECT,EEEVAL,ECG_DY
Sorted by	DCRFID,EEASPECT,EEEVAL,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D,ECGSRCE,ECGINTNO

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

Variable	Type	Label	Codes	Comments
ECG_T	num	ECG TIME		Collected at CRF.
EEASPECT	char	ECG ASPECT		Collected at CRF.
EEVAL	char	ECG EVALUATION		Collected at CRF.
VISIT	num	VISIT		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 MEASUREMENTS (EP) – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ELECTROCARDIOGRAM MEASUREMENTS (EP)
Unique identifier	DCRFID,ECGPAR,ECGVAL,ECG_T,ECG_DY
Sorted by	DCRFID,ECGPAR,ECGVAL,ECG_T,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D,ECGSRCE,ECGINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
ECG_T	num	ECG TIME		Collected at CRF.
ECGPAR	char	ECG PARAMETER		Collected at CRF.
EPSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.
ECGPAR_U	char	ECG MEASUREMENT UNIT		Collected at CRF.
ECGVAL_V	char	ECG MEASUREMENT (VERB.)		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		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 (ER) – ECGREF

Dataset	ECGREF
Creating program	ecgref.sas
Description	ELECTROCARDIOGRAM (ER)
Unique identifier	DCRFID,VISIT
Sorted by	DCRFID,VISIT
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 crfid for De-Identity
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGRELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
VISIT	num	VISIT		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 (HA) – HOSAE

Dataset	HOSAE
Creating program	hosae.sas
Description	HOSPITAL RELATED AES (HA)
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

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

Variable	Type	Label	Codes	Comments
AESEQNO	num	AE SEQ.		Collected at CRF.
SOCIAL	char	SOCIAL REASON		Collected at CRF.

1.4.18. HOSPITAL STATUS (HO) – HOSPITAL

Dataset	HOSPITAL
Creating program	hospital.sas
Description	HOSPITAL STATUS (HO)
Unique identifier	DCRFID,HOSEQNO
Sorted by	DCRFID,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 crfid for De-Identity
HOSEQNO	num	HOSPITAL SEQUENCE NUMBER		Collected at CRF.
HOONGO	char	ADMISSION ONGOING?		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 (IE) – INEX

Dataset	INEX
Creating program	inex.sas
Description	INCLUSION-EXCLUSION CRITERIA (IE)
Unique identifier	DCRFID,IETYPE,ZIECRIT
Sorted by	DCRFID,IETYPE,ZIECRIT
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 crfid for De-Identity
IETYPE	char	TYPE OF SELECTION CRITERIA		Collected at CRF.
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	num	SELECTION CRITERIA (CODE)		Collected at CRF.
IEYN	char	ELIGIBILITY EXPR.		Collected at CRF.

1.4.20. LABORATORY RESULTS (LR) – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	LABORATORY RESULTS (LR)
Unique identifier	DCRFID,LABCLASS,ZLABTEST,LABVAL,VISIT
Sorted by	DCRFID,LABCLASS,ZLABTEST,LABVAL,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D,LABID,ZLABID,SAMREFNO,LABINTNO

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

Variable	Type	Label	Codes	Comments
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 (CODE)		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.
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 (LU) – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	LABORATORY URINE RESULTS (LU)
Unique identifier	DCRFID,LABCLASS,ZLABTEST,VISIT
Sorted by	DCRFID,LABCLASS,ZLABTEST,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D,LABID,ZLABID,SAMREFNO,LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid 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 (CODE)		Collected at CRF.
LUVAL	char	URINE VALUE		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 (ND) – NODATA

Dataset	NODATA
Creating program	nodata.sas
Description	NO DATA ON VISITS/PAGES (ND)
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

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

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

1.4.23. NON-PHARMACOLOGIC THERAPY (NP) – NPHATHER

Dataset	NPHATHER
Creating program	nphather.sas
Description	NON-PHARMACOLOGIC THERAPY (NP)
Unique identifier	DCRFID,NPTHER,NPDAY,VISIT
Sorted by	DCRFID,NPTHER,NPDAY,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
VISIT	num	VISIT		Collected at CRF.
NPTHER	char	NON-PHARMACOLOGIC THERAPY		Collected at CRF.
NPYESNO	char	NON-PHARMACOLOGIC THERAPY, YESNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
NPTPWK	char	NON-PHARMACOLOGIC THERAPY TIME		Collected at CRF.
NPDAY	char	DAY		Collected at CRF.

1.4.24. KIDDIE, POS. AND NEG. SYNDROM SCALE (PA) – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	KIDDIE, POS. AND NEG. SYNDROM SCALE (PA)
Unique identifier	DCRFID,PAGROUP,PAITEM,VISIT
Sorted by	DCRFID,PAGROUP,PAITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid 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
PASSCORE	char	PANSS SCORE		Collected at CRF.
ZPASSCORE	num	PANSS SCORE (CODE)		Collected at CRF.

1.4.25. PHYSICAL EXAMINATION (PE) – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	PHYSICAL EXAMINATION (PE)
Unique identifier	DCRFID,PESYSTEM,PERESULT,VISIT
Sorted by	DCRFID,PESYSTEM,PERESULT,VISIT
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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
VISIT	num	VISIT		Collected at CRF.
PESEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXAM	char	PHYS. EXAM.		Collected at CRF.

1.4.26. PRE-PLANNED SURGERY / PROCEDURE (PS) – PPSURG

Dataset	PPSURG
Creating program	ppsurg.sas
Description	PRE-PLANNED SURGERY / PROCEDURE (PS)
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset due to missing values: PSSURG,PSIND_V,PSIND,PSDATE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
PSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
DSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PSSURG_V	char	PRE-PLANNED SURGERY (VERB)		Collected at CRF.

1.4.27. PREVIOUS THERAPY (PT) – PRETHER

Dataset	PRETHER
Creating program	prether.sas
Description	PREVIOUS THERAPY (PT)
Unique identifier	DCRFID,PRVRX,RXPREF,PTSEQNO
Sorted by	DCRFID,PRVRX,RXPREF,PTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PRVRX_V,PTIND_V,PTIND,PTFROM_D,PTADM_D,PTTO_D,PTAE_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
PTSEQNO	num	PREV. RX SEQ.		Collected at CRF.
PRVRX	char	PREV. RX		Collected at CRF.
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.
ATCCODE3	char	ATC CODE 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
ATCCODE8	char	ATC CODE 8		Collected at CRF.
ATCCODE9	char	ATC CODE 9		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.
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.
ATCTEXT8	char	ATC TEXT 8		Collected at CRF.
ATCTEXT9	char	ATC TEXT 9		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.

Variable	Type	Label	Codes	Comments
PTADM_DY	num	RELATIVE PREV. RX LAST ADMIN. DAY		If PTADM_D and REF.DATE not missing then perform below logic to calculate PTADM_DY, If PTADM_D less than REF.DATE then (PTADM_D - REF.DATE). Else if PTADM_D is greater than equal to REF.DATE then (PTADM_D- REF.DATE) +1.

1.4.28. RANDOMISATION GROUP FOR EACH SUBJCHAR – RANDGRP

Dataset	RANDGRP
Creating program	randgrp.sas
Description	RANDOMISATION GROUP FOR EACH SUBJCHAR
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDNO</p> <p>Below listed variable were not part of the Raw dataset. These have been added to retain the Randomisation related information in the de-identified datasets: RANDCODE (Source: TRLLIST dataset)</p>

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 crfid for De-Identity
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.

1.4.29. RELATED AES FOR TERMINATION OR DEATH(RA) – RELAE

Dataset	RELAE
Creating program	relae.sas
Description	RELATED AES FOR TERMINATION OR DEATH(RA)
Unique identifier	DCRFID,AESEQNO
Sorted by	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 crfid for De-Identity
RATYPE	char	AE CONSEQUENCE		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.

1.4.30. REMARKS AND COMMENTS (RM) – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	REMARKS AND COMMENTS (RM)
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Remark data is sensitive data, contains free text information. Will be submitted empty dataset.

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

1.4.31. SAMPLES (SA) – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	SAMPLES (SA)
Unique identifier	DCRFID,SPECIMEN,FASTED,VISIT
Sorted by	DCRFID,SPECIMEN,FASTED,VISIT
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, SAMTM_S

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

1.4.32. SAMPLE REQUISITION NUMBERS (SR) – SAMREF

Dataset	SAMREF
Creating program	samref.sas
Description	SAMPLE REQUISITION NUMBERS (SR)
Unique identifier	DCRFID,SAMTYPE,VISIT
Sorted by	DCRFID,SAMTYPE,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMREFNO,LABID,ZLABID,SAMTM_S,SAMPLE_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
SASEQ	num	SAMPLE SEQ		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.

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

1.4.33. SIMPSON AND ANGUS RATING SCALE (SR) – SARS

Dataset	SARS
Creating program	sars.sas
Description	SIMPSON AND ANGUS RATING SCALE (SR)
Unique identifier	DCRFID,SAITEM,SASCORE,VISIT
Sorted by	DCRFID,SAITEM,SASCORE,VISIT
Notes	

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

Variable	Type	Label	Codes	Comments
SAITEM	char	SIMPSON AND ANGUS ITEM		Collected at CRF.
SASCORE	char	SIMPSON AND ANGUS SCORE		Collected at CRF.
ZSASCORE	num	SIMPSON AND ANGUS SCORE (CODE)		Collected at CRF.

1.4.34. TRIAL DESCRIPTION (TD) – TRLDDESC

Dataset	TRLDESC
Creating program	trldesc.sas
Description	TRIAL DESCRIPTION (TD)
Unique identifier	TRIAL
Sorted by	TRIAL
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
COMPOND	char	COMPOUND NAME		Collected at CRF.
ZCOMPOND	char	COMPOUND NAME (CODE)		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.
PLACONTR	char	PLACEBO CONTROL		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTCONTR	char	ACTIVE CONTROL		Collected at CRF.
DESIGN	char	DESIGN		Collected at CRF.
MULTCENT	char	MULTICENTRE		Collected at CRF.
INDICAT	char	INDICATION		Collected at CRF.
AGEGRP	char	AGE GROUP		Collected at CRF.
SPECPOP	char	SPECIAL POPULATION		Collected at CRF.
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.

1.4.35. RANDOMISATION GROUPS (TN) – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	RANDOMISATION GROUPS (TN)
Unique identifier	RANDGRP
Sorted by	RANDGRP
Notes	

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

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

1.4.36. TRIAL MEDICATION REGIMENS (TM) – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	TRIAL MEDICATION REGIMENS (TM)
Unique identifier	RANDGRP,PHASE,SEGMENT,BOX
Sorted by	RANDGRP,PHASE,SEGMENT,BOX
Notes	Below listed variables will be dropped from dataset due to missing values: TMDUR

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.
BOX	char	BOX		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
FORMULAT	char	FORMULATION		Collected at CRF.
STRENGTH	num	STRENGTH OF 1 UNIT		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
TMFREQ	char	ADMIN. FREQ.		Collected at CRF.
TMROUTE	char	ADMIN. ROUTE		Collected at CRF.
ZTMROUTE	char	ADMIN. ROUTE (CODE)		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

1.4.37. TREATMENT / TRIAL TERMINATION (TR) – TRTERM

Dataset	TRTERM
Creating program	trterm.sas
Description	TREATMENT / TRIAL TERMINATION (TR)
Unique identifier	DCRFID
Sorted by	DCRFID
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 crfid for De-Identity
TRTYPE	char	TYPE OF TERMINATION		Collected at CRF.
TRSTATE	char	STATE OF TERMINATION		Collected at CRF.
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.

1.4.38. VISITS (VI) – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	VISITS (VI)
Unique identifier	DCRFID,VISIT
Sorted by	DCRFID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_D,PAINIT,AIINIT,SAINIT,BAINIT,CGIINIT,CGASINIT

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
VISIT	num	VISIT		Collected at CRF.
CGIS	char	CLINICAL GLOBAL IMPRESSION SEVERITY		Collected at CRF.
CGII	char	CLINICAL GLOBAL IMPRESSION IMPROVEMENT		Collected at CRF.
PREVMED	char	INSOMNIA & AGITATION MED WITHIN 8HRS		Collected at CRF.
TANNER1	num	TANNER STAGE:BREAST/GENITAL DEVELOPMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
TANNER2	num	TANNER STAGE:PUBIC HAIR GROWTH		Collected at CRF.
ECGND	char	ECG DATA NOT DONE		Collected at CRF.
VSND	char	VITAL SIGN NOT DONE		Collected at CRF.
LABND	char	LAB DATA NOT DONE		Collected at CRF.
CGAS	num	CGAS SCORE		Collected at CRF.
AIMSND	char	AIMS NOT DONE		Collected at CRF.
BARSND	char	BARS NOT DONE		Collected at CRF.
SARSND	char	SARS NOT DONE		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.

1.4.39. VITAL SIGNS (VS) – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	VITAL SIGNS (VS)
Unique identifier	DCRFID,POSITION,VISIT
Sorted by	DCRFID,POSITION,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-Identity
VISIT	num	VISIT		Collected at CRF.
POSITION	char	POSITION		Collected at CRF.
PULSE	num	PULSE, beats/min		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLIC BP, mmHg		Collected at CRF.
TEMP	num	BODY TEMP.		Collected at CRF.

Variable	Type	Label	Codes	Comments
TEMP_U	char	BODY TEMP. UNIT		Collected at CRF.
RESPRATE	num	RESPIRATION RATE		Collected at CRF.