

Clinical Development

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RIS-USA-102

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 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.
- INVEST dataset contains Investigator information, which is sensitive. Hence, this dataset will not be submitted.
- Datasets containing insignificant information will not be submitted (ex. TEMPLATE, TRLLIST).
- Dataset containing death related information is sensitive and hence will not be submitted (ex. DEATH).
- For Randomized subjects, VISIT. VISIT_D (VISIT DATE when VISITNO=1) will be used as Reference Date (referred as REF.DATE in the document) to derive relative days.

1.3. Data Files

The RIS-USA-102 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	DCRFID
Sorted by	DCRFID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: MEDNO,INVEST,ZINVEST,INITIALS,BIRTH_D,ADMIS_D,RBIRTH_D,RSITEID, COINVEST,ZCOINVES</p> <p>Below listed variables were not part of the Raw dataset. These have been added to retain the Subject Characteristics related information in the de-identified datasets: COUNTRY (Source: INVEST dataset) RANDCODE (Source: TRLLIST dataset)</p>

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
CUREPIS	char	CURRENT EPISODE		Collected at CRF.
PATEPIS	char	PATTERN OF EPISODES		Collected at CRF.
MOODSTAB	char	MOOD STABILIZER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	SITE ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Site id for De-Identity
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
DISCVIS	num	D/C VISIT		Collected at CRF.
DRYRUN	char	DRY_RUN READY		Collected at CRF.
PREGNANT	char	PREGNANT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
RANDCODE	char	RANDOMISATION CODE		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.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
ADMIS_DY	num	RELATIVE HOSPITAL ADMISSION DAY		If ADMIS_D and REF.DATE not missing then perform below logic to calculate ADMIS_DY, If ADMIS_D less than REF.DATE then (ADMIS_D - REF.DATE). Else if ADMIS_D is greater than equal to REF.DATE then (ADMIS_D- REF.DATE) +1.

1.4.2.ADMINISTRATION OF TRIAL MEDICATION – ADMMED

Dataset	ADMMED
Creating program	admmmed.sas
Description	ADMINISTRATION OF TRIAL MEDICATION
Unique identifier	DCRFID,AMREAS,AMFREQ,AMTO_DY
Sorted by	DCRFID,AMREAS,AMFREQ,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: AMDOSE,AMFROM_D,AMTO_D

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
BOX	char	BOX		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
AMDOSE_U	char	DOSE UNIT		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
ZAMREAS	char	REGIMEN CHANGE REASON CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
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	DCRFID, AEPREF, AETO_DY, AESEQNO
Sorted by	DCRFID, AEPREF, AETO_DY, AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, AE_V, AEFROM_D, AETO_D, SAEREFNO

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
AEINCL	char	AE INCLUDED TERM		Collected at CRF.
AEPREF	char	ADVERSE EVENT PREFERRED TERM		Collected at CRF.
AESOC	char	ADVERSE EVENT SYSTEM ORGAN CLASS		Collected at CRF.
AEWHONUM	char	AE WHO CODE		Collected at CRF.
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.
ZAESV	num	AE SEVERITY CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AECONRX	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.
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.
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.BPRS – BPRS

Dataset	BPRS
Creating program	bprs.sas
Description	BPRS
Unique identifier	DCRFID,BPITEM,VISIT
Sorted by	DCRFID,BPITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
ZBPITEM	char	BPRS ITEM		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
BPITEM	char	BPRS ITEM		Collected at CRF.
ZBPScore	num	BPRS SCORE CODE		Collected at CRF.
BPSCORE	char	BPRS SCORE		Collected at CRF.

1.4.5.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.

1.4.6. CONCOMITANT THERAPY – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	CONCOMITANT THERAPY
Unique identifier	DCRFID,CONRX,CTTYPE,CTFROMDY,CTSEQNO
Sorted by	DCRFID,CONRX,CTTYPE,CTFROMDY,CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CTIND,CONRX_V,CTFROM_D,CTFROM_C,CTTO_D,CTTO_C,ATCCODE8, ATCCODE9

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.
CTIND_V	char	INDICATION (VERB.)		Collected at CRF.
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCCODE0	char	ATC CODE 1		Collected at CRF.
ATCCODE1	char	ATC CODE 2		Collected at CRF.
ATCCODE2	char	ATC CODE 3		Collected at CRF.
ATCCODE3	char	ATC CODE 4		Collected at CRF.
ATCCODE4	char	ATC CODE 5		Collected at CRF.
ATCCODE5	char	ATC CODE 6		Collected at CRF.
ATCCODE6	char	ATC CODE 7		Collected at CRF.
ATCCODE7	char	ATC CODE 8		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.

1.4.7.DEVIATION – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	DEVIATION
Unique identifier	DCRFID,TRIAL,DEVIAT,ZDEVIAT
Sorted by	DCRFID,TRIAL,DEVIAT,ZDEVIAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DEVIAT_V

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

1.4.8. DIAGNOSIS – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	DIAGNOSIS
Unique identifier	DCRFID,TRIAL,DIAGN,ZDIAGN
Sorted by	DCRFID,TRIAL,DIAGN,ZDIAGN
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
DIAGN	char	DIAGNOSIS		Collected at CRF.
ZDIAGN	char	DIAGNOSIS CODE		Collected at CRF.

1.4.9.PREVIOUS AND CONCOMITANT DISEASES – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	PREVIOUS AND CONCOMITANT DISEASES
Unique identifier	DCRFID,DSSYSTEM,DSCOND,SORT_NO
Sorted by	DCRFID,DSSYSTEM,DSCOND,SORT_NO
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
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.

1.4.10. ELECTROCARDIOGRAM – ECG

Dataset	ECG
Creating program	ecg.sas
Description	ELECTROCARDIOGRAM
Unique identifier	DCRFID,EGLIMITS,ECGSRCE,ECG_DY
Sorted by	DCRFID,EGLIMITS,ECGSRCE,ECG_DY
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
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
ECGSRCE	char	SOURCE ECG COMMENTS		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.
EGRELCHA	char	CLIN. RELEVANT 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.

1.4.11. ECG OTHER ABNORMALITIES – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG OTHER ABNORMALITIES
Unique identifier	DCRFID,ECGSRCE,ECG_DY
Sorted by	DCRFID,ECGSRCE,ECG_DY
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
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
ECGSRCE	char	SOURCE ECG COMMENTS		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.

1.4.12. ECGEVAL – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	ECGEVAL
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

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

1.4.13. ELECTROCARDIOGRAM MEASUREMENTS – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ELECTROCARDIOGRAM MEASUREMENTS
Unique identifier	DCRFID,ECGPAR,ECG_DY
Sorted by	DCRFID,ECGPAR,ECG_DY
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
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
ECGPAR	char	ECG PARAMETER		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.
ZECGPAR	char	ECG PARAMETER CODE		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. ESRS – ESRS

Dataset	ESRS
Creating program	esrs.sas
Description	ESRS
Unique identifier	DCRFID,ESGROUP,ESITEM,VISIT
Sorted by	DCRFID,ESGROUP,ESITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
ZESITEM	char	ESRS ITEM CODE		Collected at CRF.
ZESGROUP	char	ESRS SUBGROUP CODE		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
ESITEM	char	ESRS ITEM		Collected at CRF.
ESGROUP	char	ESRS SUBGROUP		Collected at CRF.
ESSCORE	num	ESRS SCORE		Collected at CRF.

1.4.15. HAMD – HAMD

Dataset	HAMD
Creating program	hamd.sas
Description	HAMD
Unique identifier	DCRFID,HAITEM,HASCORE,VISIT
Sorted by	DCRFID,HAITEM,HASCORE,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
ZHAITEM	char	HAMD ITEM CODE		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
HAITEM	char	HAMD ITEM		Collected at CRF.
HASCORE	num	HAMD SCORE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.16. INCLUSION-EXCLUSION CRITERIA – INEX

Dataset	INEX
Creating program	inex.sas
Description	INCLUSION-EXCLUSION CRITERIA
Unique identifier	DCRFID,IETYPE,IECRIT,VISIT
Sorted by	DCRFID,IETYPE,IECRIT,VISIT
Notes	

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

1.4.17. LABORATORY NORMAL – LABNOR

Dataset	LABNOR
Creating program	labnor.sas
Description	LABORATORY NORMAL
Unique identifier	LABTEST
Sorted by	LABTEST
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

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LNFROM_D	num	RANGE APPLIC. FROM		Collected at CRF.
LNT0_D	num	RANGE APPLIC. TO		Collected at CRF.
LNSEQNO	num	LAB. NORMAL SEQ.		Collected at CRF.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.
LABUPP	num	UPPER NORMAL LIMIT		Collected at CRF.
AGEFROM	num	LOWER AGE LIMIT		Collected at CRF.
AGETO	num	UPPER AGE LIMIT		Collected at CRF.
AGE_U	char	AGE UNIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
WGHTFROM	num	LOWER WEIGHT LIMIT		Collected at CRF.
WGHTTO	num	UPPER WEIGHT LIMIT		Collected at CRF.
WGHT_U	char	WEIGHT UNIT		Collected at CRF.
SEX	char	SEX CLASSIFICATION		Collected at CRF.

1.4.18. LABORATORY RESULTS – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	LABORATORY RESULTS
Unique identifier	DCRFID,LABTEST, LABVAL ,SAMPLEDY
Sorted by	DCRFID,LABTEST, LABVAL ,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D,LABID,ZLABID

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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 NO.		Collected at CRF.
LABCLASS	char	LAB. TEST 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.

1.4.19. LABORATORY SAMPLE – LABSAM

Dataset	LABSAM
Creating program	labsam.sas
Description	LABORATORY SAMPLE
Unique identifier	DCRFID,HAEMOLYS,SAMPLEDY,SAMPLE_T
Sorted by	DCRFID,HAEMOLYS,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,FASTED,LABREFNO,LSSAME,LSRELCHA

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		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.

1.4.20. LABORATORY URINE RESULTS – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	LABORATORY URINE RESULTS
Unique identifier	DCRFID,LABCLASS ,LABTEST,LABTSTNO,SAMPLEDY
Sorted by	DCRFID, LABCLASS ,LABTEST,LABTSTNO,SAMPLEDY
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,LUVAL_V

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		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.
LABTSTNO	num	LAB. TEST NO.		Collected at CRF.
LABCLASS	char	LAB. TEST 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.

1.4.21. MDSTAB – MDSTAB

Dataset	MDSTAB
Creating program	mdstab.sas
Description	MDSTAB
Unique identifier	DCRFID,MDSTAB,MDFROMDY,MDSEQNO
Sorted by	DCRFID,MDSTAB,MDFROMDY,MDSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MDSTAB_V,MDFROM_D,MDTO_D,ATCCODE1,ATCCODE2,ATCCODE3, ATCCODE4,ATCCODE5,ATCCODE6,ATCCODE7,ATCCODE8,ATCCODE9,MDIND

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
MDSTAB	char	MOOD STABILIZERS		Collected at CRF.
MDSEQNO	num	MOOD STABILIZERS SEQ		Collected at CRF.
MDSCHED	char	MOOD STABILIZERS DAILY SCHEDULE		Collected at CRF.
MDIND_V	char	MOOD STABILIZERS INDICATION (VERB.)		Collected at CRF.
MDPRIOR	char	MOOD STABILIZERS PRE-TRIAL		Collected at CRF.
MDFROM_C	char	MOOD STABILIZERS START CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
MDONGO	char	MOOD STABILIZERS ONGOING		Collected at CRF.
MDTO_C	char	MOOD STABILIZERS END CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 1		Collected at CRF.
MDFROMDY	num	RELATIVE MOOD STABILIZERS START DAY		If MDFROM_D and REF.DATE not missing then perform below logic to calculate MDFROMDY, If MDFROM_D less than REF.DATE then (MDFROM_D - REF.DATE). Else if MDFROM_D is greater than equal to REF.DATE then (MDFROM_D- REF.DATE) +1.
MDTO_DY	num	RELATIVE MOOD STABILIZERS END DAY		If MDTO_D and REF.DATE not missing then perform below logic to calculate MDTO_DY, If MDTO_D less than REF.DATE then (MDTO_D - REF.DATE). Else if MDTO_D is greater than equal to REF.DATE then (MDTO_D- REF.DATE) +1.

1.4.22. PHYSICAL EXAMINATION – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	PHYSICAL EXAMINATION
Unique identifier	DCRFID,PESYSTEM,VISIT
Sorted by	DCRFID,PESYSTEM,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,EXAM_V

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.

1.4.23. PLASMA RESULTS – PLARES

Dataset	PLARES
Creating program	plares.sas
Description	PLASMA RESULTS
Unique identifier	DCRFID,PRVAL,PLASMADY
Sorted by	DCRFID,PRVAL,PLASMADY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PLASMA_D,PRDETECT

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
PLASMA_T	num	TIME OF PLASMA SAMPLING		Collected at CRF.
PRVAL	num	PLASMA MEASUREMENT		Collected at CRF.
PRVAL_U	char	PLASMA UNIT		Collected at CRF.
PRSUBST	char	PLASMA SUBSTANCE		Collected at CRF.
PLASMADY	num	RELATIVE DAY OF PLASMA SAMPLING		If PLASMA_D and REF.DATE not missing then perform below logic to calculate PLASMADY, If PLASMA_D less than REF.DATE then (PLASMA_D - REF.DATE). Else if PLASMA_D is greater than equal to REF.DATE then (PLASMA_D- REF.DATE) +1.

1.4.24. RELATED AES FOR TERMINATION OR DEATH – RELAE

Dataset	RELAE
Creating program	relae.sas
Description	RELATED AES FOR TERMINATION OR DEATH
Unique identifier	DCRFID,AESEQNO
Sorted by	DCRFID,AESEQNO
Notes	

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

1.4.25. TRIAL DESCRIPTION – TRLDDESC

Dataset	TRLDESC
Creating program	trldesc.sas
Description	TRIAL DESCRIPTION
Unique identifier	COMPOND
Sorted by	COMPOND
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.
ACTCONTR	char	ACTIVE CONTROL		Collected at CRF.
DESIGN	char	DESIGN		Collected at CRF.
MULTCENT	char	MULTICENTRE		Collected at CRF.
BLKSIZE	num	BLOCK SIZE		Collected at CRF.
INDICAT	char	INDICATION		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.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.

1.4.26. RANDOMISATION GROUPS – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	RANDOMISATION GROUPS
Unique identifier	TRIAL,RANDGRP,RANDCODE
Sorted by	TRIAL,RANDGRP,RANDCODE
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.

1.4.27. TRIAL MEDICATION REGIMENS – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	TRIAL MEDICATION REGIMENS
Unique identifier	RANDGRP,PHASE
Sorted by	RANDGRP,PHASE
Notes	

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	TRIAL SEGMENT SEQ.		Collected at CRF.
BOX	char	BOX		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.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
TMFREQ	char	ADMIN. FREQ.		Collected at CRF.
ZTMROUTE	char	ADMIN. ROUTE CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TMROUTE	char	ADMIN. ROUTE		Collected at CRF.
TMDUR	num	SEQMENT DURATION		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

1.4.28. TREATMENT / TRIAL TERMINATION – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.sas
Description	TREATMENT / TRIAL TERMINATION
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TTFROM_D,TTREAS_V

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
TTTYPE	char	TERM. TYPE		Collected at CRF.

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

1.4.29. VISIT REASONS – UNREAS

Dataset	UNREAS
Creating program	unreas.sas
Description	VISIT REASONS
Unique identifier	UNREAS,VISIT
Sorted by	UNREAS,VISIT
Notes	

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

1.4.30. VISITS – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	VISITS
Unique identifier	DCRFID,CGI,VISIT_DY,VISIT
Sorted by	DCRFID,CGI,VISIT_DY,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_D ,HOSDIS_D

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
UNSCHED	char	UNSCHEDULED VISIT SINCE LAST VISIT		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
CGI	char	CLINICAL GLOBAL IMPRESSION		Collected at CRF.
CGICHA	char	CLINICAL GLOBAL IMPRESSION CHANGE		Collected at CRF.
HOSDIS	char	DISCHARGED FROM HOSPITAL		Collected at CRF.
TOTYMRS	num	TOTAL SCORE YMRS		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
HOSDISDY	num	RELATIVE HOSPITAL DISCHARGED DAY		If HOSDIS_D and REF.DATE not missing then perform below logic to calculate HOSDISDY, If HOSDIS_D less than REF.DATE then (HOSDIS_D - REF.DATE). Else if HOSDIS_D is greater than equal to REF.DATE then (HOSDIS_D- REF.DATE) +1.

1.4.31. VITAL SIGNS – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	VITAL SIGNS
Unique identifier	DCRFID,PULSE,VISIT
Sorted by	DCRFID,PULSE,VISIT
Notes	

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

Variable	Type	Label	Codes	Comments
PULSE	num	PULSE, BEATS/MIN		Collected at CRF.
SBP	num	SYSTOLIC BP, MMHG		Collected at CRF.
DBP	num	DIASTOLIC BP, MMHG		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.

1.4.32. YOUNG MANIA RATING SCALE – YMRS

Dataset	YMRS
Creating program	ymrs.sas
Description	YOUNG MANIA RATING SCALE
Unique identifier	DCRFID,YMITEM,VISIT
Sorted by	DCRFID,YMITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
TRIAL	char	TRIAL ID.		Collected at CRF.
ZYMITEM	char	YMRS ITEM CODE		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

Variable	Type	Label	Codes	Comments
YMITEM	char	YMRS ITEM		Collected at CRF.
YMSCORE	num	YMRS SCORE		Collected at CRF.