

Clinical Development

Risperidone[®]

RIS-USA-240

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.
- REMARK dataset will be submitted with zero observation due to sensitivity of data.
- TRLLIST dataset will not be submitted since it contain Medication number(MEDNO), which are sensitive information.
- Datasets which are containing zero observation will not be submitted (ex. LABNOR, PKOUTL, PTATCSEL, RANDGRP and PKRES).
- Dataset containing investigator information, which is sensitive and hence these datasets will not be submitted (ex. INVEST).
- Dataset containing death related information, which is sensitive and hence these datasets will not be submitted (ex. DEATH).
- Datasets containing insignificant information will not be submitted (ex. TEMPLATE,MAP).
- For randomized subjects, SUBJCHAR.RAND_D will be used as Reference Date (referred as REF. DATE in the document) to derive relative days. For screen failure subjects, VISIT.VISIT_D (WHEN VISIT=0) will be used as a Reference date (referred as REF. DATE in the document) to derive relative day.

1.3. Data Files

The RIS-USA-240 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	<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 or due to missing values: MEDNO,INVEST,ZINVEST,INITIALS,BIRTH_D,BREAK_D,BREAK_V,ZCOUNTRY, RAND_D,COINV,ZCOINV,BATCHNO,PSYDCH_D,SUIC_D,MANIC_D,RAPCYC_D, HISCYCLO,LABNA,VSNA,YMNA</p> <p>Below listed variable was not a part of the Raw dataset. This has been added to retain the Treatment related information in the de-identified datasets: RANDCODE (Source: TRLLIST dataset)</p>

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.

Variable	Type	Label	Codes	Comments
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
DEATHNA	char	EVENT OF DEATH		Collected at CRF.
BREAK	char	CODE BROKEN ?		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.
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
RAND	char	SUBJECT ELIGIBLE FOR RANDOMIZATION		Collected at CRF.
PRVDNA	char	DNA SAMPLE ALREADY TAKEN		Collected at CRF.
PRVDNTRL	char	PREVIOUS DNA TRIAL		Collected at CRF.
DNACONST	char	DNA CONSENT		Collected at CRF.
DNAANAL	char	OBTAINED FOR ANALYSIS		Collected at CRF.
DNASTOR	char	OBTAINED FOR STORAGE		Collected at CRF.
HISBIP1	char	HISTORY BIPOLAR I DISORDER		Collected at CRF.
MANICEP	char	MANIC EPISODE		Collected at CRF.
MIXEDEP	char	MIXED EPISODES		Collected at CRF.
MANICNO	num	NUMBER MANIC EPISODES		Collected at CRF.
MIXEDNO	num	NUMBER MIXED EPISODES		Collected at CRF.

Variable	Type	Label	Codes	Comments
DEPNO	num	NUMBER DEPRESS EPISODES		Collected at CRF.
PSYCH1NO	num	NUMBER PSYCHOTIC EPISODES		Collected at CRF.
ONAGE	char	ONSET AGE FOR BIPOLAR DISORDER		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
TIMEAGE	char	AGE OF FIRST PSYCH HOSPITALIZATION		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DRUGAGE	char	AGE OF FIRST PHARMA TREATMENT		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HOSPNO	num	NUMBER PREVIOUS PSYCH HOSPITALIZATIONS		Collected at CRF.
SUICNO	num	NUMBER SUICIDE ATTEMPTS		Collected at CRF.
RAPCYC	char	RAPID CYCLING		Collected at CRF.
CYCYRNO	num	NUMBER CYCLES IN LAST YEAR		Collected at CRF.
HISBIP2	char	BIPOLAR II DISORDER		Collected at CRF.
HISHYPO	char	HYPOMANIC EPISODES		Collected at CRF.
HYPONO	num	NUMBER HYPOMANIC EPISODES		Collected at CRF.
CYCLONO	num	CYCLOTHYMIC NUMBER CYCLOTHMEA EP		Collected at CRF.
SUBTREAT	char	TREATED FOR SUBSTANCE ABUSE		Collected at CRF.
SUBSTAT	char	SUBSTANCE HOSPITAL STATUS		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
PSYDCHDY	num	RELATIVE DISCHARGE DAY FROM PSYCH UNIT		If PSYDCH_D and REF.DATE not missing then perform below logic to calculate PSYDCHDY, If PSYDCH_D less than REF.DATE then (PSYDCH_D - REF.DATE). Else if PSYDCH_D is greater than equal to REF.DATE then (PSYDCH_D- REF.DATE) +1.
SUIC_DY	num	RELATIVE DAY MOST RECENT SUICIDE ATTEMPT		If SUIC_D and REF.DATE not missing then perform below logic to calculate SUIC_DY, If SUIC_D less than REF.DATE then (SUIC_D - REF.DATE). Else if SUIC_D is greater than equal to REF.DATE then (SUIC_D- REF.DATE) +1.
MANIC_DY	num	RELATIVE DAY FIRST MANIC EPISODE		If MANIC_D and REF.DATE not missing then perform below logic to calculate MANIC_DY, If MANIC_D less than REF.DATE then (MANIC_D - REF.DATE). Else if MANIC_D is greater than equal to REF.DATE then (MANIC_D- REF.DATE) +1.
RAPCYCDY	num	RELATIVE DAY RAPID CYCLING DIAGNOSIS		If RAPCYC_D and REF.DATE not missing then perform below logic to calculate RAPCYCDY, If RAPCYC_D less than REF.DATE then (RAPCYC_D - REF.DATE). Else if RAPCYC_D is greater than equal to REF.DATE then (RAPCYC_D- REF.DATE) +1.

1.4.2.ADMINISTRATION OF TRIAL MEDICATION (AM) – ADMMED

Dataset	ADMMED
Creating program	admmed.sas
Description	ADMINISTRATION OF TRIAL MEDICATION (AM)
Unique identifier	DCRFID,AMFROMDY
Sorted by	DCRFID,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,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.
NUMAM	num	TOTAL TABLETS TAKEN PER DAY.		Collected at CRF.
NUMFORM1	num	UNITS PER ADMIN. (BOX1)		Collected at CRF.
NUMFORM2	num	UNITS PER ADMIN. (BOX2)		Collected at CRF.
NUMFORM3	num	UNITS PER ADMIN. (BOX3)		Collected at CRF.
NUMFORM4	num	UNITS PER ADMIN. (BOX4)		Collected at CRF.
NUMFORM5	num	UNITS PER ADMIN. (BOX5)		Collected at CRF.

Variable	Type	Label	Codes	Comments
NUMFORM6	num	UNITS PER ADMIN. (BOX6)		Collected at CRF.
AMNONE1	char	ADMIN. NONE		Collected at CRF.
AMNONE2	char	ADMIN. NONE		Collected at CRF.
NUMFORMA	num	UNITS PER ADMIN. (BOXA)		Collected at CRF.
NUMFORMB	num	UNITS PER ADMIN. (BOXB)		Collected at CRF.
NUMFORMC	num	UNITS PER ADMIN. (BOXC)		Collected at CRF.
NUMFORMD	num	UNITS PER ADMIN. (BOXD)		Collected at CRF.
NUMFORME	num	UNITS PER ADMIN. (BOXE)		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,AESOC, AEPREF,AEFROMDY,AESEQNO
Sorted by	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,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.
AEINCL	char	AE INCLUDED TERM		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.

Variable	Type	Label	Codes	Comments
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.
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.DRUG ADMINISTRATION BEFORE SAMPLING (BA) – BANADM

Dataset	BANADM
Creating program	banadm.sas
Description	DRUG ADMINISTRATION BEFORE SAMPLING (BA)
Unique identifier	DCRFID,BAADM_DY,BAADMSEQ
Sorted by	DCRFID,BAADM_DY,BAADMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMREFNO,BAADM_D,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.
BAADM_T	num	DRUG ADMIN. TIME		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
BAADMSEQ	char	DRUG ADMIN. SEQ.		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.

1.4.5.BANRES – BANRES

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

Variable	Type	Label	Codes	Comments
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SAMTM_S	char	SCHEDULED TIME		Collected at CRF.
SUBST	char	SUBSTANCE		Collected at CRF.

Variable	Type	Label	Codes	Comments
BRVAL	num	BAN MEASUREMENT		Collected at CRF.
BRVAL_V	char	BAN MEASUREMENT (VERB.)		Collected at CRF.
BRVAL_U	char	UNIT		Collected at CRF.
BRQUANT	num	LIMIT OF QUANTIFICATION		Collected at CRF.
TRIAL	char	TRIAL ID.		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. CONCOMITANT THERAPY (CT) – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	CONCOMITANT THERAPY (CT)
Unique identifier	DCRFID,CTTYPE ,CONRX,CTFROMDY,CTSEQNO
Sorted by	DCRFID,CTTYPE ,CONRX,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: CONRX_V,CTIND,CTFROM_D,CTFROM_C,CTTO_D,CTTO_C, ATCCODE5, ATCCODE6,ATCCODE7,ATCCODE8,ATCCODE9,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 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_V	char	INDICATION (VERB.)		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
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.
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.
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.

1.4.8.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.

1.4.9. 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
DIAGN	char	DIAGNOSIS		Collected at CRF.
ZDIAGN	char	DIAGNOSIS CODE		Collected at CRF.
SCID	char	SCID DIAGNOSIS		Collected at CRF.
ZSCID	char	SCID DIAGNOSIS CODE		Collected at CRF.
DIAGDIF	char	CHANGED SINCE SCREENING		Collected at CRF.
RANDIAG	char	CURRENT CLINICAL DIAGNOSIS		Collected at CRF.
ZRANDIAG	char	CURRENT CLINICAL DIAGNOSIS CODE		Collected at CRF.

1.4.10. PREVIOUS AND CONCOMITANT DISEASES (DS) – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	PREVIOUS AND CONCOMITANT DISEASES (DS)
Unique identifier	DCRFID,DSSYSTEM,DSCOND
Sorted by	DCRFID,DSSYSTEM,DSCOND
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.

1.4.11. ELECTROCARDIOGRAM (EG) – ECG

Dataset	ECG
Creating program	ecg.sas
Description	ELECTROCARDIOGRAM (EG)
Unique identifier	DCRFID,ECGSRCE,VISIT,ECG_DY
Sorted by	DCRFID,ECGSRCE,VISIT,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
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.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.
EGRELCHA	char	CLIN. SIGNIFICANT CHANGES		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.

1.4.12. ECG OTHER ABNORMALITIES (EA) – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG OTHER ABNORMALITIES (EA)
Unique identifier	DCRFID,VISIT,EASEQNO
Sorted by	DCRFID,VISIT,EASEQNO
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
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.

Variable	Type	Label	Codes	Comments
EASEQNO	num	SEQUENCE NUMBER		Collected at CRF.
ECGOTH_V	char	ECG OTHER ABN. (VERB.)		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.

1.4.13. ELECTROCARDIOGRAM EVALUATION (EE) – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	ELECTROCARDIOGRAM EVALUATION (EE)
Unique identifier	DCRFID,EEASPECT,EEEVAL,VISIT,ECG_DY
Sorted by	DCRFID,EEASPECT,EEEVAL,VISIT,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
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.
ECGSRCE	char	SOURCE ECG DATA		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.

1.4.14. ELECTROCARDIOGRAM MEASUREMENTS (EP) – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ELECTROCARDIOGRAM MEASUREMENTS (EP)
Unique identifier	DCRFID,ECGPAR,VISIT,ECG_DY,EPSEQNO
Sorted by	DCRFID,ECGPAR,VISIT,ECG_DY,EPSEQNO
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
ECG_T	num	ECG TIME		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.
ECGPAR_U	char	ECG MEASUREMENT UNIT		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.

1.4.15. EXTRAPYRAMIDAL SYMPTOM RATING SCALE – ESRS

Dataset	ESRS
Creating program	esrs.sas
Description	EXTRAPYRAMIDAL SYMPTOM RATING SCALE
Unique identifier	DCRFID,ESGROUP,ESITEM,VISIT
Sorted by	DCRFID,ESGROUP,ESITEM,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.
ESSEQNO	num	ESRS SEQUENCE NUMBER		Collected at CRF.
ESGROUP	char	ESRS SUBGROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
ESITEM	char	ESRS ITEM		Collected at CRF.
ESSCORE	char	ESRS SCORE		Collected at CRF.
ZESSCORE	num	ESRS SCORE CODE		Collected at CRF.

1.4.16. HOSPITAL RELATED AES – HOSAE

Dataset	HOSAE
Creating program	hosae.sas
Description	HOSPITAL RELATED AES
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.
AESEQNO	num	AE SEQ.		Collected at CRF.

1.4.17. HOSPITAL STATUS – HOSPITAL

Dataset	HOSPITAL
Creating program	hospital.sas
Description	HOSPITAL STATUS
Unique identifier	DCRFID,HOFROMDY
Sorted by	DCRFID,HOFROMDY
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.
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.

Variable	Type	Label	Codes	Comments
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.

1.4.18. INCLUSION-EXCLUSION CRITERIA (IE) – INEX

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

1.4.19. LAB RESULT – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	LAB RESULT
Unique identifier	DCRFID,LABTEST,SAMPLEDY
Sorted by	DCRFID,LABTEST,SAMPLEDY
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.
VISIT	num	VISIT		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 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.

1.4.20. LABORATORY URINE RESULTS (LU) – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	LABORATORY URINE RESULTS (LU)
Unique identifier	DCRFID,LABTEST,SAMPLEDY
Sorted by	DCRFID,LABTEST,SAMPLEDY
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.
VISIT	num	VISIT		Collected at CRF.
LUVAL	char	URINE VALUE		Collected at CRF.
LUVAL_V	char	URINE VALUE (VERB.)		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.

1.4.21. MONTGOMERY/ASBERG DEPRESSION SCALE (MA) – MADRS

Dataset	MADRS
Creating program	madr.sas
Description	MONTGOMERY/ASBERG DEPRESSION SCALE (MA)
Unique identifier	DCRFID,MAITEM,VISIT
Sorted by	DCRFID,MAITEM,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.
MASEQNO	num	MADRS SEQUENCE NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
MAITEM	char	MADRS ITEM		Collected at CRF.
MASCORE	char	MADRS SCORE		Collected at CRF.
ZMASCORE	num	MADRS SCORE CODE		Collected at CRF.

1.4.22. POS. AND NEG. SYNDROM SCALE (PA) – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	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.
PASEQNO	num	PANSS SEQUENCE NUMBER		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.

1.4.23. PHYSICAL EXAMINATION (PE) – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	PHYSICAL EXAMINATION (PE)
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_V,EXAM

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.

1.4.24. PREVIOUS THERAPY (PT) – PRETHER

Dataset	PRETHER
Creating program	prether.sas
Description	PREVIOUS THERAPY (PT)
Unique identifier	DCRFID,PRVRX,PTFROMDY,PTSEQNO
Sorted by	DCRFID,PRVRX,PTFROMDY,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,PTFROM_D,PTTO_D,PTAE_V,ATCCODE2,ATCCODE3, ATCCODE4,ATCCODE5,ATCCODE6,ATCCODE7,ATCCODE8,ATCCODE9, ATCTEXT2,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 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.
PTIND_V	char	PREV. RX INDICATION VERBATIM		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
ATCTEXT1	char	ATC TEXT 1		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.

1.4.25. PSYCHIATRIC HISTORY AND STATUS (PS) – PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	PSYCHIATRIC HISTORY AND STATUS (PS)
Unique identifier	DCRFID,PSYDIS,PSYCOND,PSSEQNO
Sorted by	DCRFID,PSYDIS,PSYCOND,PSSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PSYHIS_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
PSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PSYDIS	char	PSYCHIATRIC DISORDER		Collected at CRF.
PSYCOND	char	PSYCHIATRIC CONDITION		Collected at CRF.

1.4.26. 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,RATYPE
Sorted by	DCRFID,RATYPE
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.

1.4.27. REMARKS AND COMMENTS (RC) – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	REMARKS AND COMMENTS (RC)
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Remark dataset contains sensitive information. Hence dataset will be submitted with zero observation.

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

1.4.28. SAMPLES (SA) – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	SAMPLES (SA)
Unique identifier	DCRFID,SPECIMEN,SAMTYPE,SAMTM_S,VISIT,SAMPLEDY
Sorted by	DCRFID,SPECIMEN,SAMTYPE,SAMTM_S,VISIT,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,FASTED,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.
VISIT	num	VISIT		Collected at CRF.
SAMTM_S	char	SCHEDULED TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		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.

1.4.29. SAMPLE REQUISITION NUMBERS (SF) – SAMREF

Dataset	SAMREF
Creating program	samref.sas
Description	SAMPLE REQUISITION NUMBERS (SF)
Unique identifier	DCRFID,SAMTYPE,SAMTM_S,VISIT,SAMPLEDY
Sorted by	DCRFID,SAMTYPE,SAMTM_S,VISIT,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,SAMREFNO,SFADDSAM

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
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMTM_S	char	SCHEDULED TIME		Collected at CRF.
SARELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.30. 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.

1.4.31. RANDOMISATION GROUPS (TR) – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	RANDOMISATION GROUPS (TR)
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.

1.4.32. TRIAL MEDICATION REGIMENS (TM) – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	TRIAL MEDICATION REGIMENS (TM)
Unique identifier	RANDGRP
Sorted by	RANDGRP
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	SEGMENT		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.

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

1.4.33. TRIAL TERMINATION REASON (TT) – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.sas
Description	TRIAL TERMINATION REASON (TT)
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
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
TTPHASE	char	TERM. PHASE		Collected at CRF.
TTTYPE	char	TERM. TYPE		Collected at CRF.
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.

1.4.34. 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,YMINIT,PAINIT,CGIINIT,GASINIT,MAINIT,ESINIT,ESNA

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.
PREVMED	char	LORAZEPAM WITHIN 8 HOURS		Collected at CRF.
CGISEV	char	CLINICAL GLOBAL IMPRESSION SEVERITY		Collected at CRF.
GASSCORE	num	GLOBAL ASSESSMENT SCALE SCORE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CGINA	char	CGI NOT APPLICABLE		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.

1.4.35. 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.

Variable	Type	Label	Codes	Comments
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
WEIGHT	num	WEIGHT		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.
TEMP_U	char	BODY TEMP. UNIT		Collected at CRF.

1.4.36. YOUNG MANIA RATING SCALE (YM) – YMRS

Dataset	YMRS
Creating program	ymrs.sas
Description	YOUNG MANIA RATING SCALE (YM)
Unique identifier	DCRFID,YMITEM,VISIT
Sorted by	DCRFID,YMITEM,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.
YMSEQNO	num	YMRS SEQUENCE NUMBER		Collected at CRF.

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