

Clinical Development

**Risperidone<sup>®</sup>**

RIS-USA-239

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	30 NOV 2017

Property of Janssen

Confidential

May not be used, divulged, published or otherwise disclosed  
without the consent of Janssen

## Table of contents

Clinical Development .....	1
1. Datasets .....	5
1.1. Specifications Introduction .....	5
1.2. Guidelines for Preparing Data.....	5
1.3. Data Files.....	6
1.4. Data Domains.....	7
1.4.1. SUBJECT CHARACTERISTICS (SC) – SUBJCHAR .....	7
1.4.2. ADMINISTRATION OF TRIAL MEDICATION (AM) – ADMMED.....	11
1.4.3. ADVERSE EVENTS (AE) – AE.....	13
1.4.4. DRUG ADMINISTRATION BEFORE SAMPLING (BA) – BANADM.....	15
1.4.5. BANRES – BANRES.....	16
1.4.6. DICTIONARY VERSION CONTROL – CODE .....	17
1.4.7. CONCOMITANT THERAPY (CT) – COTHER.....	18
1.4.8. DEVIATION (DV) – DEVIATN.....	20
1.4.9. DIAGNOSIS (DX) – DIAGNOS .....	21
1.4.10. PREVIOUS AND CONCOMITANT DISEASES (DS) – DISEASES.....	22
1.4.11. ELECTROCARDIOGRAM (EG) – ECG.....	23
1.4.12. ECG OTHER ABNORMALITIES (EA) – ECGABN.....	24
1.4.13. ELECTROCARDIOGRAM EVALUATION (EE) – ECGEVAL.....	25
1.4.14. ELECTROCARDIOGRAM MEASUREMENTS (EP) – ECGPAR.....	26
1.4.15. EXTRAPYRAMIDAL SYMPTOM RATING SCALE – ESRS.....	28
1.4.16. HOSPITAL RELATED AES – HOSAE .....	29
1.4.17. HOSPITAL STATUS – HOSPITAL.....	30
1.4.18. INCLUSION-EXCLUSION CRITERIA (IE) – INEX.....	31
1.4.19. LAB RESULT – LABRES .....	32
1.4.20. LABORATORY URINE RESULTS (LU) – LABURI .....	34
1.4.21. MONTGOMERY/ASBERG DEPRESSION SCALE (MA) – MADRS.....	35
1.4.22. POS. AND NEG. SYNDROM SCALE (PA) – PANSS.....	36
1.4.23. PHYSICAL EXAMINATION (PE) – PHYSEXAM .....	37
1.4.24. PREVIOUS THERAPY (PT) – PRETHER .....	38
1.4.25. PSYCHIATRIC HISTORY AND STATUS – PSYHIST .....	40

1.4.26.	RELATED AES FOR TERMINATION OR DEATH (RA) – RELAE.....	41
1.4.27.	REMARKS AND COMMENTS (RC) – REMARK.....	42
1.4.28.	SAMPLES (SA) – SAMPLE.....	43
1.4.29.	SAMPLE REQUISITION NUMBERS (SF) – SAMREF.....	44
1.4.30.	TRIAL DESCRIPTION (TD) – TRLDESC.....	45
1.4.31.	RANDOMISATION GROUPS (TR) – TRLRAND.....	46
1.4.32.	TRIAL MEDICATION REGIMENS (TM) – TRLREGM.....	47
1.4.33.	TRIAL TERMINATION REASON (TT) – TRLTERM.....	49
1.4.34.	VISITS (VI) – VISIT.....	50
1.4.35.	VITAL SIGNS (VS) – VITSIGN.....	51
1.4.36.	YOUNG MANIA RATING SCALE (YM) – YMRS.....	52

<b>Status and Version</b>	<b>Release Date</b>	<b>Summary of Key Changes</b>

## 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 sensitive information, for example Medication number(MEDNO).
- Dataset with zero observation and zero variable will not be submitted (ex. RANDGRP).
- Datasets with zero observation will not be submitted (ex. LABNOR, PKOUTL and PKRES).
- Dataset containing investigator information is sensitive and hence will not be submitted (ex. INVEST ).
- Dataset containing death related information is sensitive and hence 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-239 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. SUBJECT CHARACTERISTICS (SC) – SUBJCHAR

<b>Dataset</b>	SUBJCHAR
<b>Creating program</b>	subjchar.sas
<b>Description</b>	SUBJECT CHARACTERISTICS (SC)
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	<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,PRVDNA,PRVDNTRL,PRVDNCRF,COINV,ZCOINV,BATCHNO,  PSYDCH_D,SUIC_D,MANIC_D,RAPCYC_D,HISCYCLO</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.
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	BIPOLAR I MANIC EPISODES		Collected at CRF.
MIXEDEP	char	BIPOLAR I MIXED EPISODES		Collected at CRF.
MANICNO	num	BIPOLAR I NUMBER MANIC EPISODES		Collected at CRF.
MIXEDNO	num	BIPOLAR I NUMBER MIXED EPISODES		Collected at CRF.



Variable	Type	Label	Codes	Comments
DEPNO	num	BIPOLAR I NUMBER DEPRESS EPISODES		Collected at CRF.
PSYCH1NO	num	BIPOLAR I 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.

Variable	Type	Label	Codes	Comments
SUBSTAT	char	SUBSTANCE HOSPITAL STATUS		Collected at CRF.
LABNA	char	LABORATORY NOT APPLICABLE		Collected at CRF.
VSNA	char	VITAL SIGNS NOT APPLICABLE		Collected at CRF.
YMNA	char	YMRS NOT APPLICABLE		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.
PSYDCHDY	num	RELATIVE DAY DISCHARGE 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 OF 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.

Variable	Type	Label	Codes	Comments
RAPCYCDY	num	RELATIVE DAY OF 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

<b>Dataset</b>	ADMMED
<b>Creating program</b>	admmed.sas
<b>Description</b>	ADMINISTRATION OF TRIAL MEDICATION (AM)
<b>Unique identifier</b>	DCRFID,AMFROMDY
<b>Sorted by</b>	DCRFID,AMFROMDY
<b>Notes</b>	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,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.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.

Variable	Type	Label	Codes	Comments
AMFREQ	char	ADMIN. FREQ.		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

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	ADVERSE EVENTS (AE)
<b>Unique identifier</b>	DCRFID,AESOC, AEPREF,AEFROMDY,AESEQNO
<b>Sorted by</b>	DCRFID,AESOC, AEPREF,AEFROMDY,AESEQNO
<b>Notes</b>	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

<b>Dataset</b>	BANADM
<b>Creating program</b>	banadm.sas
<b>Description</b>	DRUG ADMINISTRATION BEFORE SAMPLING (BA)
<b>Unique identifier</b>	DCRFID,BAADM_DY,BAADMSEQ
<b>Sorted by</b>	DCRFID,BAADM_DY,BAADMSEQ
<b>Notes</b>	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

<b>Dataset</b>	BANRES
<b>Creating program</b>	banres.sas
<b>Description</b>	BANRES
<b>Unique identifier</b>	SUBST,SAMTM_S,VISIT
<b>Sorted by</b>	SUBST,SAMTM_S,VISIT
<b>Notes</b>	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

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

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

<b>Dataset</b>	COTHER
<b>Creating program</b>	cother.sas
<b>Description</b>	CONCOMITANT THERAPY (CT)
<b>Unique identifier</b>	DCRFID,CTTYPE,CONRX,CTFROMDY,CTSEQNO
<b>Sorted by</b>	DCRFID,CTTYPE,CONRX,CTFROMDY,CTSEQNO
<b>Notes</b>	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,ATCCODE7, ATCCODE8,ATCCODE9,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
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		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.
ATCCODE5	char	ATC CODE 5		Collected at CRF.
ATCCODE6	char	ATC CODE 6		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.
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.

Variable	Type	Label	Codes	Comments
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

<b>Dataset</b>	DEVIATN
<b>Creating program</b>	deviatn.sas
<b>Description</b>	DEVIATION (DV)
<b>Unique identifier</b>	DCRFID,DEVIAT
<b>Sorted by</b>	DCRFID,DEVIAT
<b>Notes</b>	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

<b>Dataset</b>	DIAGNOS
<b>Creating program</b>	diagnos.sas
<b>Description</b>	DIAGNOSIS (DX)
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: RANDIAG,ZRANDIAG

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.

## 1.4.10. PREVIOUS AND CONCOMITANT DISEASES (DS) – DISEASES

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

<b>Dataset</b>	ECG
<b>Creating program</b>	ecg.sas
<b>Description</b>	ELECTROCARDIOGRAM (EG)
<b>Unique identifier</b>	DCRFID,ECGSRCE,VISIT,ECG_DY
<b>Sorted by</b>	DCRFID,ECGSRCE,VISIT,ECG_DY
<b>Notes</b>	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
VISIT	num	VISIT		Collected at CRF.
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.

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

#### 1.4.12. ECG OTHER ABNORMALITIES (EA) – ECGABN

<b>Dataset</b>	ECGABN
<b>Creating program</b>	ecgabn.sas
<b>Description</b>	ECG OTHER ABNORMALITIES (EA)
<b>Unique identifier</b>	DCRFID,VISIT,EASEQNO
<b>Sorted by</b>	DCRFID,VISIT,EASEQNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D,ECGOTH_V

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



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

#### 1.4.13. ELECTROCARDIOGRAM EVALUATION (EE) – ECGEVAL

<b>Dataset</b>	ECGEVAL
<b>Creating program</b>	ecgeval.sas
<b>Description</b>	ELECTROCARDIOGRAM EVALUATION (EE)
<b>Unique identifier</b>	DCRFID,EEASPECT,EEEVAL,VISIT,ECG_DY
<b>Sorted by</b>	DCRFID,EEASPECT,EEEVAL,VISIT,ECG_DY
<b>Notes</b>	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
VISIT	num	VISIT		Collected at CRF.

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.
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

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

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

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
VISIT	num	VISIT		Collected at CRF.
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
ECGPARG	char	ECG PARAMETER		Collected at CRF.
EPSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.
ECGPARG_U	char	ECG MEASUREMENT UNIT		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

## 1.4.15. EXTRAPYRAMIDAL SYMPTOM RATING SCALE – ESRS

<b>Dataset</b>	ESRS
<b>Creating program</b>	esrs.sas
<b>Description</b>	EXTRAPYRAMIDAL SYMPTOM RATING SCALE
<b>Unique identifier</b>	DCRFID,ESGROUP,ESITEM,VISIT
<b>Sorted by</b>	DCRFID,ESGROUP,ESITEM,VISIT
<b>Notes</b>	

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.
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

<b>Dataset</b>	HOSAE
<b>Creating program</b>	hosae.sas
<b>Description</b>	HOSPITAL RELATED AES
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	

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

<b>Dataset</b>	HOSPITAL
<b>Creating program</b>	hospital.sas
<b>Description</b>	HOSPITAL STATUS
<b>Unique identifier</b>	DCRFID,HOFROMDY
<b>Sorted by</b>	DCRFID,HOFROMDY
<b>Notes</b>	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

<b>Dataset</b>	INEX
<b>Creating program</b>	inex.sas
<b>Description</b>	INCLUSION-EXCLUSION CRITERIA (IE)
<b>Unique identifier</b>	CRFID,IETYPE,IECRIT
<b>Sorted by</b>	CRFID,IETYPE,IECRIT
<b>Notes</b>	

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 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.

## 1.4.19. LAB RESULT – LABRES

<b>Dataset</b>	LABRES
<b>Creating program</b>	labres.sas
<b>Description</b>	LAB RESULT
<b>Unique identifier</b>	DCRFID,LABTEST,SAMPLEDY
<b>Sorted by</b>	DCRFID,LABTEST,SAMPLEDY
<b>Notes</b>	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
VISIT	num	VISIT		Collected at CRF.
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.
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

<b>Dataset</b>	LABURI
<b>Creating program</b>	laburi.sas
<b>Description</b>	LABORATORY URINE RESULTS (LU)
<b>Unique identifier</b>	DCRFID,LABTEST,SAMPLEDY
<b>Sorted by</b>	DCRFID,LABTEST,SAMPLEDY
<b>Notes</b>	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.

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

<b>Dataset</b>	MADRS
<b>Creating program</b>	madr.sas
<b>Description</b>	MONTGOMERY/ASBERG DEPRESSION SCALE (MA)
<b>Unique identifier</b>	DCRFID,MAITEM,VISIT
<b>Sorted by</b>	DCRFID,MAITEM,VISIT
<b>Notes</b>	

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

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

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

<b>Dataset</b>	PHYSEXAM
<b>Creating program</b>	physexam.sas
<b>Description</b>	PHYSICAL EXAMINATION (PE)
<b>Unique identifier</b>	DCRFID,PESYSTEM,VISIT
<b>Sorted by</b>	DCRFID,PESYSTEM,VISIT
<b>Notes</b>	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

<b>Dataset</b>	PRETHER
<b>Creating program</b>	prether.sas
<b>Description</b>	PREVIOUS THERAPY (PT)
<b>Unique identifier</b>	DCRFID,PRVRX,PTFROMDY,PTSEQNO
<b>Sorted by</b>	DCRFID,PRVRX,PTFROMDY,PTSEQNO
<b>Notes</b>	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,PTTO_D,PTAE_V,ATCCODE7, ATCCODE8,ATCCODE9,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.
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.

Variable	Type	Label	Codes	Comments
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.
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.
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 – PSYHIST

<b>Dataset</b>	PSYHIST
<b>Creating program</b>	psyhist.sas
<b>Description</b>	PSYCHIATRIC HISTORY AND STATUS
<b>Unique identifier</b>	DCRFID,PSYDIS,PSYCOND,PSSEQNO
<b>Sorted by</b>	DCRFID,PSYDIS,PSYCOND,PSSEQNO
<b>Notes</b>	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

<b>Dataset</b>	RELAE
<b>Creating program</b>	relae.sas
<b>Description</b>	RELATED AES FOR TERMINATION OR DEATH (RA)
<b>Unique identifier</b>	DCRFID,RATYPE
<b>Sorted by</b>	DCRFID,RATYPE
<b>Notes</b>	

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

<b>Dataset</b>	REMARK
<b>Creating program</b>	remark.sas
<b>Description</b>	REMARKS AND COMMENTS (RC)
<b>Unique identifier</b>	Not applicable
<b>Sorted by</b>	Not applicable
<b>Notes</b>	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

<b>Dataset</b>	SAMPLE
<b>Creating program</b>	sample.sas
<b>Description</b>	SAMPLES (SA)
<b>Unique identifier</b>	DCRFID,SPECIMEN,SAMTYPE,SAMTM_S,VISIT,SAMPLEDY
<b>Sorted by</b>	DCRFID,SPECIMEN,SAMTYPE,SAMTM_S,VISIT,SAMPLEDY
<b>Notes</b>	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

<b>Dataset</b>	SAMREF
<b>Creating program</b>	samref.sas
<b>Description</b>	SAMPLE REQUISITION NUMBERS (SF)
<b>Unique identifier</b>	DCRFID,SAMTYPE,SAMTM_S,VISIT,SAMPLEDY
<b>Sorted by</b>	DCRFID,SAMTYPE,SAMTM_S,VISIT,SAMPLEDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABID,ZLABID,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
VISIT	num	VISIT		Collected at CRF.
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMTM_S	char	SCHEDULED TIME		Collected at CRF.
SARELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLE 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

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

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.

Variable	Type	Label	Codes	Comments
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.
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

<b>Dataset</b>	TRLRAND
<b>Creating program</b>	trlrand.sas
<b>Description</b>	RANDOMISATION GROUPS (TR)
<b>Unique identifier</b>	RANDGRP
<b>Sorted by</b>	RANDGRP
<b>Notes</b>	

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

<b>Dataset</b>	TRLREGM
<b>Creating program</b>	trlregm.sas
<b>Description</b>	TRIAL MEDICATION REGIMENS (TM)
<b>Unique identifier</b>	RANDGRP
<b>Sorted by</b>	RANDGRP
<b>Notes</b>	

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

<b>Dataset</b>	TRLTERM
<b>Creating program</b>	trlterm.sas
<b>Description</b>	TRIAL TERMINATION REASON (TT)
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	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
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

<b>Dataset</b>	VISIT
<b>Creating program</b>	visit.sas
<b>Description</b>	VISITS (VI)
<b>Unique identifier</b>	DCRFID,VISIT
<b>Sorted by</b>	DCRFID,VISIT
<b>Notes</b>	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

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.
ESNA	char	ESRS NOT APPLICABLE		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

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

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.
WEIGHT	num	WEIGHT		Collected at CRF.

Variable	Type	Label	Codes	Comments
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
PULSE	num	PULSE, beats/min		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

<b>Dataset</b>	YMRS
<b>Creating program</b>	ymrs.sas
<b>Description</b>	YOUNG MANIA RATING SCALE (YM)
<b>Unique identifier</b>	DCRFID,YMITEM,VISIT
<b>Sorted by</b>	DCRFID,YMITEM,VISIT
<b>Notes</b>	

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.

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