

Clinical Development

Risperidone

RIS-INT-69

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

- Lab Identifier information will not be provided.
- 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.
- Partial date's relative day cannot be calculated.
- REMARK dataset will be submitted with zero observations.
- Datasets with zero records as input will not be submitted. (eg: CTATCSEL, ECGABN, LABNOR, and PTATCSEL)
- Dataset containing information which is not useful for further analysis will not be submitted. (eg. TRLLIST, TRLDESC)
- Dataset containing Investigator information will not be submitted. (eg. INVEST)
- Dataset information related to code lists will not be submitted. (eg. CODE)
- VISIT.VISIT_D will be used as Reference Date to derive relative days for all subjects.

1.3. Data Files

The RIS-INT-69 CSR 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 or due to missing values:</p> <p>MEDNO, INVEST, ZINVEST, INITIALS, BIRTH_D, RAND2_D, MEDNO2, BREAK_D, BREAK_V, ZCOUNTRY, RAND_D, PRVDNA, PRVDNTRL, PRVDNCRF, COINV, ZCOINV, BATCHNO, PSYDCH_D, SUICNO, SUIC_D, MANIC_D, RAPCYC_D</p>

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRT1COMP	char	COMPLETE PART 1		Collected at CRF.
CONTINU	char	CONTINUE TO NEXT PART?		Collected at CRF.
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	num	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	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.
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.
HISCYCLO	char	CYCLOTHYMIC DISORDER		Collected at CRF.
CYCLONO	num	CYCLOTHYMIC NUMBER CYCLOTHMEA EP		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUBTREAT	char	TREATED FOR SUBSTANCE ABUSE		Collected at CRF.
SUBSTAT	char	SUBSTANCE HOSPITAL STATUS		Collected at CRF.
AGE	char	AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: $AGE = \text{int}((\text{VISIT.VISIT_D} - \text{BIRTH_D})/365.25)$ If age greater than 89+ years then will be grouped as per HIPAA rules.
BREAK_DY	num	RELATIVE DAY CODE BREAKING		If BREAK_D and VISIT.VISIT_D not missing then perform below logic to calculate BREAK_DY, If BREAK_D less than VISIT.VISIT_D then (BREAK_D - VISIT.VISIT_D).Else if BREAK_D is greater than equal to VISIT.VISIT_D then (BREAK_D - VISIT.VISIT_D) +1.
RAND_DY	num	RELATIVE RANDOMIZATION DAY		If RAND_D and VISIT.VISIT_D not missing then perform below logic to calculate RAND_DY, If RAND_D less than VISIT.VISIT_D then (RAND_D - VISIT.VISIT_D).Else if RAND_D is greater than equal to VISIT.VISIT_D then (RAND_D - VISIT.VISIT_D) +1.

Variable	Type	Label	Codes	Comments
RAND2_DY	num	RELATIVE PART 2/ OPEN LABEL RANDOMIZATION DAY		If RAND2_D and VISIT.VISIT_D not missing then perform below logic to calculate RAND2_DY, If RAND2_D less than VISIT.VISIT_D then (RAND2_D - VISIT.VISIT_D).Else if RAND2_D is greater than equal to VISIT.VISIT_D then (RAND2_D- VISIT.VISIT_D) +1.
PSYDCHDY	num	RELATIVE DISCHARGE DAY FROM PSYCH UNIT		If PSYDCH_D and VISIT.VISIT_D not missing then perform below logic to calculate PSYDCHDY, If PSYDCH_D less than VISIT.VISIT_D then (PSYDCH_D - VISIT.VISIT_D).Else if PSYDCH_D is greater than equal to VISIT.VISIT_D then (PSYDCH_D- VISIT.VISIT_D) +1.
MANIC_DY	num	RELATIVE DAY FIRST MANIC EPISODE		If MANIC_D and VISIT.VISIT_D not missing then perform below logic to calculate MANIC_DY, If MANIC_D less than VISIT.VISIT_D then (MANIC_D - VISIT.VISIT_D).Else if MANIC_D is greater than equal to VISIT.VISIT_D then (MANIC_D- VISIT.VISIT_D) +1.
RAPCYCDY	num	RELATIVE DAY RAPID CYCLING DIAGNOSIS		If RAPCYC_D and VISIT.VISIT_D not missing then perform below logic to calculate RAPCYCDY, If RAPCYC_D less than VISIT.VISIT_D then (RAPCYC_D - VISIT.VISIT_D).Else if RAPCYC_D is greater than equal to VISIT.VISIT_D then (RAPCYC_D- VISIT.VISIT_D) +1.

1.4.2. Administration of Trial Medication – ADMMED

Dataset	ADMED
Creating program	admmed.sas
Description	Administration of Trial Medication
Unique identifier	DCRFID,SEGMENT, AMFROMDY
Sorted by	DCRFID,SEGMENT,AMFROMDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AMFROM_D, AMTO_D, NUMFORM, 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 crf id for de-identity
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	SEGMENT		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.
AMNONE	char	ADMIN. NONE		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
ZAMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
AMFROMDY	num	RELATIVE ADMIN. FROM DAY		If AMFROM_D and VISIT.VISIT_D not missing then perform below logic to calculate AMFROMDY, If AMFROM_D less than VISIT.VISIT_D then (AMFROM_D - VISIT.VISIT_D).Else if AMFROM_D is greater than equal to VISIT.VISIT_D then (AMFROM_D- VISIT.VISIT_D) +1.
AMTO_DY	num	RELATIVE ADMIN. TO DAY		If AMTO_D and VISIT.VISIT_D not missing then perform below logic to calculate AMTO_DY, If AMTO_D less than VISIT.VISIT_D then (AMTO_D - VISIT.VISIT_D).Else if AMTO_D is greater than equal to VISIT.VISIT_D then (AMTO_D- VISIT.VISIT_D) +1.

1.4.3. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DCRFID,ZAESER,AESOC,AEWHONUM,AESEQNO,AEFROMDY,AETO_DY,ZAESEV,ZAEACT,ZAECONRX,ZAERELAT,ZAEOUT
Sorted by	DCRFID,ZAESER,AESOC,AEWHONUM,AESEQNO,AEFROMDY,AETO_DY,ZAESEV,ZAEACT,ZAECONRX,ZAERELAT,ZAEOUT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AE_V, AEINCL, PHASE, AEFROM_D, AETO_D, 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 crf id for de-identity
AESEQNO	num	AE SEQ.		Collected at CRF.
AEFROM_C	char	AE FROM CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESEV	num	AE SEVERITY		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN		Collected at CRF.

Variable	Type	Label	Codes	Comments
AECONRX	char	AE CO-RX START		Collected at CRF.
ZAEMONRX	num	AE CO-RX START		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME		Collected at CRF.
AESER	char	AE SERIOUSNESS		Collected at CRF.
ZAESER	num	AE SERIOUSNESS		Collected at CRF.
AESOC	char	AE SYSTEM ORGAN CLASS		Collected at CRF.
AEWHONUM	char	AE WHO CODE		Collected at CRF.
AEPREF	char	ADVERSE EVENT PREFERRED TERM		Collected at CRF.
AESOC1	char	AE SYSTEM ORGAN CLASS 1		Collected at CRF.
AESOC2	char	AE SYSTEM ORGAN CLASS 2		Collected at CRF.
AESOC3	char	AE SYSTEM ORGAN CLASS 3		Collected at CRF.
AEFROMDY	num	RELATIVE AE FROM DAY		If AEFROM_D and VISIT.VISIT_D not missing then perform below logic to calculate AEFROMDY, If AEFROM_D less than VISIT.VISIT_D then (AEFROM_D - VISIT.VISIT_D).Else if AEFROM_D is greater than equal to VISIT.VISIT_D then (AEFROM_D- VISIT.VISIT_D) +1.

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

1.4.4. Brief Psychiatric Rating Scale – BPRS

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
BPITEM	char	BPRS ITEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
BPSCORE	char	BPRS SCORE		Collected at CRF.
ZBPSCORE	num	BPRS SCORE		Collected at CRF.

1.4.5. Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,ATCCODE1,CTSEQNO,CTTYPE,CTSCHED,CTPRIOR,CTFROMDY, CTONGO,RXWHONUM,ATCCODE0
Sorted by	DCRFID,ATCCODE1,CTSEQNO,CTTYPE,CTSCHED,CTPRIOR,CTFROMDY, CTONGO,RXWHONUM,ATCCODE0
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, CONRX, CTIND_V, CTIND, CTFROM_D, CTFROM_C, CTTO_D, CTTO_C, ATCCODE9, ATCTEXT9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTTYPE	char	CO-RX TYPE		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.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCCODE3	char	ATC CODE 3		Collected at CRF.
ATCCODE4	char	ATC CODE 4		Collected at CRF.
ATCCODE5	char	ATC CODE 5		Collected at CRF.
ATCCODE6	char	ATC CODE 6		Collected at CRF.
ATCCODE7	char	ATC CODE 7		Collected at CRF.
ATCCODE8	char	ATC CODE 8		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
ATCTEXT7	char	ATC TEXT 7		Collected at CRF.
ATCTEXT8	char	ATC TEXT 8		Collected at CRF.
RXPREF	char	PREFERRED NAME		Collected at CRF.
CTFROMDY	num	RELATIVE CO-RX START DAY		If CTFROM_D and VISIT.VISIT_D not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than VISIT.VISIT_D then (CTFROM_D - VISIT.VISIT_D).Else if CTFROM_D is greater than equal to VISIT.VISIT_D then (CTFROM_D- VISIT.VISIT_D) +1.
CTTO_DY	num	RELATIVE CO-RX END DAY		If CTTO_D and VISIT.VISIT_D not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than VISIT.VISIT_D then (CTTO_D - VISIT.VISIT_D).Else if CTTO_D is greater than equal to VISIT.VISIT_D then (CTTO_D- VISIT.VISIT_D) +1.

1.4.6. Death Report – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death Report
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DEATH_D, DTREAS_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
DTREAS	char	DEATH CAUSE		Collected at CRF.
DEATH_DY	num	RELATIVE DEATH DAY		If DEATH_D and VISIT.VISIT_D not missing then perform below logic to calculate DEATH_DY, If DEATH_D less than VISIT.VISIT_D then (DEATH_D - VISIT.VISIT_D).Else if DEATH_D is greater than equal to VISIT.VISIT_D then (DEATH_D - VISIT.VISIT_D) +1.

1.4.7. Protocol Deviation – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	Protocol Deviation
Unique identifier	DCRFID,ZDEVIAT
Sorted by	DCRFID,ZDEVIAT
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 crf id for de-identity
DEVIAT	char	DEVIATION		Collected at CRF.
ZDEVIAT	char	DEVIATION		Collected at CRF.

1.4.8. Current Clinical Diagnosis – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Current Clinical Diagnosis
Unique identifier	DCRFID,ZDIAGN,ZSCID,DIAGDIF,ZRANDIAG
Sorted by	DCRFID,ZDIAGN,ZSCID,DIAGDIF,ZRANDIAG
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
DIAGN	char	DIAGNOSIS		Collected at CRF.
ZDIAGN	char	DIAGNOSIS		Collected at CRF.
SCID	char	SCID DIAGNOSIS		Collected at CRF.
ZSCID	char	SCID DIAGNOSIS		Collected at CRF.
DIAGDIF	char	CHANGED SINCE SCREENING		Collected at CRF.
RANDIAG	char	CURRENT CLINICAL DIAGNOSIS		Collected at CRF.
ZRANDIAG	char	CURRENT CLINICAL DIAGNOSIS		Collected at CRF.

1.4.9. Medical and Surgical History, Concomitant Diseases – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Medical and Surgical History, Concomitant Diseases
Unique identifier	DCRFID,DSSEQNO,DSSYSTEM,DSCOND
Sorted by	DCRFID,DSSEQNO,DSSYSTEM,DSCOND
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DISEAS_V, DISEASE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
DSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.

1.4.10. Electrocardiogram – ECG

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
LEADQT	char	LEAD QT		Collected at CRF.
EGRESULT	char	ECG RESULT		Collected at CRF.

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

1.4.11. ECG Evaluation – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	ECG Evaluation
Unique identifier	DCRFID,ECG_DY,ECG_T,EEASPECT,EEVAL
Sorted by	DCRFID,ECG_DY,ECG_T,EEASPECT,EEVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: ECG_D, ECGINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity

Variable	Type	Label	Codes	Comments
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 VISIT.VISIT_D not missing then perform below logic to calculate ECG_DY, If ECG_D less than VISIT.VISIT_D then (ECG_D - VISIT.VISIT_D).Else if ECG_D is greater than equal to VISIT.VISIT_D then (ECG_D- VISIT.VISIT_D) +1.

1.4.12. ECG Parameter – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ECG Parameter
Unique identifier	DCRFID,ECG_DY,ECG_T,ECGPAR,EPSEQNO,ECGVAL
Sorted by	DCRFID,ECG_DY,ECG_T,ECGPAR,EPSEQNO,ECGVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: ECG_D, ECGVAL_V, ECGINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
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 VISIT.VISIT_D not missing then perform below logic to calculate ECG_DY, If ECG_D less than VISIT.VISIT_D then (ECG_D - VISIT.VISIT_D).Else if ECG_D is greater than equal to VISIT.VISIT_D then (ECG_D- VISIT.VISIT_D) +1.

1.4.13. ECG Reference – ECGREF

Dataset	ECGREF
Creating program	ecgref.sas
Description	ECG Reference
Unique identifier	DCRFID,ECG_DY,ECG_T,EGRELCHA,VISIT
Sorted by	DCRFID,ECG_DY,ECG_T,EGRELCHA,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity

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

1.4.14. Extrapyramidal Symptom Rating Scale – ESRS

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

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

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
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		Collected at CRF.

1.4.15. Hospital Related Aes – HOSAE

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity

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

1.4.16. Hospital Status Form – HOSPITAL

Dataset	HOSPITAL
Creating program	hospital.sas
Description	Hospital Status Form
Unique identifier	DCRFID,HOSEQNO,HOFROMDY,HOONGO
Sorted by	DCRFID,HOSEQNO,HOFROMDY,HOONGO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: HOFROM_D, HOTO_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
HOSEQNO	num	HOSPITAL SEQUENCE NUMBER		Collected at CRF.
HOONGO	char	ADMISSION ONGOING?		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOFROMDY	num	RELATIVE ADMISSION DAY		If HOFROM_D and VISIT.VISIT_D not missing then perform below logic to calculate HOFROMDY, If HOFROM_D less than VISIT.VISIT_D then (HOFROM_D - VISIT.VISIT_D).Else if HOFROM_D is greater than equal to VISIT.VISIT_D then (HOFROM_D- VISIT.VISIT_D) +1.
HOTO_DY	num	RELATIVE DISCHARGE DAY		If HOTO_D and VISIT.VISIT_D not missing then perform below logic to calculate HOTO_DY, If HOTO_D less than VISIT.VISIT_D then (HOTO_D - VISIT.VISIT_D).Else if HOTO_D is greater than equal to VISIT.VISIT_D then (HOTO_D- VISIT.VISIT_D) +1.

1.4.17. Inclusion and Exclusion Criteria – INEX

Dataset	INEX
Creating program	inex.sas
Description	Inclusion and Exclusion Criteria
Unique identifier	DCRFID,IETYPE,ZIECRIT
Sorted by	DCRFID,IETYPE,ZIECRIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
IETYPE	char	TYPE OF INCLUSION CRITERIA		Collected at CRF.
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	num	SELECTION CRITERIA		Collected at CRF.
IEYN	char	NON-ELIGIBILITY EXPR.		Collected at CRF.

1.4.18. Laboratory Results – LABRES

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

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

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

1.4.19. Laboratory Results (Urine) – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	Laboratory Results (Urine)
Unique identifier	DCRFID,SAMTYPE,SAMPLEDY,SAMPLE_T,ZLABTEST,VISIT
Sorted by	DCRFID,SAMTYPE,SAMPLEDY,SAMPLE_T,ZLABTEST,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D, LABID, ZLABID, SAMREFNO, LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST		Collected at CRF.
LUVAL	char	URINE VALUE		Collected at CRF.
LUVAL_V	char	URINE VALUE (VERB.)		Collected at CRF.

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

1.4.20. Montgomery and Asberg Depression Rating Scale – MADRS

Dataset	MADRS
Creating program	mads.sas
Description	Montgomery and Asberg Depression Rating Scale
Unique identifier	DCRFID,VISIT,MAITEM
Sorted by	DCRFID,VISIT,MAITEM
Notes	

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

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
MAITEM	char	MADRS ITEM		Collected at CRF.
MASCORE	char	MADRS SCORE		Collected at CRF.
ZMASCORE	num	MADRS SCORE		Collected at CRF.

1.4.21. Physical Examination – PHYSEXAM

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity

Variable	Type	Label	Codes	Comments
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.

1.4.22. Previous Bipolar Medication – PRETHER

Dataset	PRETHER
Creating program	prether.sas
Description	Previous Bipolar Medication
Unique identifier	DCRFID,PTSEQNO,PTTO_DY,RXWHONUM
Sorted by	DCRFID,PTSEQNO,PTTO_DY,RXWHONUM
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, PTSCHED,PTIND, PTIND_V, PTFROM_D, PTTO_D, PTAE_V, ATCCODE4, ATCCODE5, ATCCODE6, ATCCODE7, ATCCODE8, ATCCODE9, ATCTEXT4, ATCTEXT5, ATCTEXT6, ATCTEXT7, ATCTEXT8, ATCTEXT9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity

Variable	Type	Label	Codes	Comments
PTSEQNO	num	PREV. RX SEQ.		Collected at CRF.
PRVRX	char	PREV. RX		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCCODE3	char	ATC CODE 3		Collected at CRF.
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.
RXPREF	char	PREFERRED NAME		Collected at CRF.
PTFROMDY	num	RELATIVE PREV. RX START DAY		If PTFROM_D and VISIT.VISIT_D not missing then perform below logic to calculate PTFROMDY, If PTFROM_D less than VISIT.VISIT_D then (PTFROM_D - VISIT.VISIT_D).Else if PTFROM_D is greater than equal to VISIT.VISIT_D then (PTFROM_D- VISIT.VISIT_D) +1.
PTTO_DY	num	RELATIVE PREV. RX END DAY		If PTTO_D and VISIT.VISIT_D not missing then perform below logic to calculate PTTO_DY, If PTTO_D less than VISIT.VISIT_D then (PTTO_D - VISIT.VISIT_D).Else if PTTO_D is greater than equal to VISIT.VISIT_D then (PTTO_D- VISIT.VISIT_D) +1.

1.4.23. Psychiatric History and Status – PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychiatric History and Status
Unique identifier	DCRFID,PSSEQNO
Sorted by	DCRFID,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 crf id for de-identity
PSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PSYDIS	char	PSYCHIATRIC DISORDER		Collected at CRF.
PSYCOND	char	PSYCHIATRIC CONDITION		Collected at CRF.

1.4.24. Randomization Group – RANDGRP

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.

1.4.25. Related Adverse Events – RELAE

Dataset	RELAE
Creating program	relae.sas
Description	Related Adverse Events
Unique identifier	DCRFID,AESEQNO
Sorted by	DCRFID,AESEQNO
Notes	

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

1.4.26. Remarks – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	Remarks
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	<p>Remark data is sensitive data, contains free text information. Empty dataset will be submitted.</p> <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RMITEM_V, REMARK_V, RMTYPE</p>

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.

1.4.27. Sample – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	Sample
Unique identifier	DCRFID,SPECIMEN,SAMTYPE,SAMPLEDY,SAMPLE_T,VISIT,SAMTM_S
Sorted by	DCRFID,SPECIMEN,SAMTYPE,SAMPLEDY,SAMPLE_T,VISIT,SAMTM_S
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, SASAME, SARELCHA, LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SAMTM_S	char	SCHEDULED TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and VISIT.VISIT_D not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than VISIT.VISIT_D then (SAMPLE_D - VISIT.VISIT_D).Else if SAMPLE_D is greater than equal to VISIT.VISIT_D then (SAMPLE_D- VISIT.VISIT_D) +1.

1.4.28. Sample Reference – SAMREF

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SARELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and VISIT.VISIT_D not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than VISIT.VISIT_D then (SAMPLE_D - VISIT.VISIT_D).Else if SAMPLE_D is greater than equal to VISIT.VISIT_D then (SAMPLE_D- VISIT.VISIT_D) +1.

1.4.29. Trial Randomization Details – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	Trial Randomization Details
Unique identifier	RANDCODE
Sorted by	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.

1.4.30. Trial Regimen – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	Trial Regimen
Unique identifier	SEGMENT,BOX
Sorted by	SEGMENT,BOX
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.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
TMFREQ	char	ADMIN. FREQ.		Collected at CRF.

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

1.4.31. Trial Termination – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.sas
Description	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
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity

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

1.4.32. Visit – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit
Unique identifier	DCRFID,VISIT,VISIT_DY
Sorted by	DCRFID,VISIT,VISIT_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_D, YMINIT, CGIINIT, GASINIT, MAINIT, BPINIT, ESINIT

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

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
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.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and VISIT.VISIT_D not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than VISIT.VISIT_D then (VISIT_D - VISIT.VISIT_D).Else if VISIT_D is greater than equal to VISIT.VISIT_D then (VISIT_D- VISIT.VISIT_D) +1.

1.4.33. Vital Signs – VITSIGN

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
POSITION	char	POSITION		Collected at CRF.
PULSE	num	PULSE, beats/min		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLIC BP, mmHg		Collected at CRF.

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

1.4.34. Young Mania Rating Scale – YMRS

Dataset	YMRS
Creating program	ymrs.sas
Description	Young Mania Rating Scale
Unique identifier	DCRFID,VISIT,YMITEM
Sorted by	DCRFID,VISIT,YMITEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
YMITEM	char	YMRS ITEM		Collected at CRF.
YMSCORE	char	YMRS SCORE		Collected at CRF.
ZYMSCORE	num	YMRS SCORE		Collected at CRF.