Clinical Development

Risperidone

RIS-BIM-3003

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.
- Central Lab Specimen Label Number will not be provided.
- Complete missing value variables will be removed.

- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- To derive relative day the first visit date will be used and it will be referred as REF.DATE.
- Partial date's Relative day cannot be calculated.
- Reference number will not be provided.
- REMARK dataset will be submitted with zero observations.
- INVEST dataset will not be submitted as it contains detailed information related to Investigator of study.
- In datasets LABRES, LABURI, SAMPLE and SAMREF, variable LABID contains Lab Name "COVANCE" which is sensitive. Hence it will not be submitted.

1.3. Data Files

The RIS-BIM-3003 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	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, MANIC_D, MIXED_D, DEP_D, RAPCYC_D, PSYDCH_D, SUICNO, SUIC_D, RAND_D, ZCOUNTRY, BREAK_D, BREAK_V, ENTRYCOM, DRYRUN, COINV, ZCOINV

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.
MANICNO	num	NUMBER MANIC EPISODES		Collected at CRF.

Variable	Type	Label	Codes	Comments
MIXEDNO	num	NUMBER MIXED EPISODES		Collected at CRF.
DEPNO	num	NUMBER DEPRESS EPISODES		Collected at CRF.
RAPCYC	char	RAPID CYCLING		Collected at CRF.
CYCYRNO	num	NUMBER MOOD EPISODES IN LAST YR		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.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
ALCOHOL	char	HISTORY OF ALCOHOL ABUSE		Collected at CRF.
SUBTREAT	char	HX OF OTHER SUBSTANCE ABUSE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
BREAK	char	CODE BROKEN?		Collected at CRF.

Variable	Type	Label	Codes	Comments
DISCVIS	num	D/C VISIT		Collected at CRF.
DSITEID	char	SITE ASSIGNED FOR DE-IDENTITY		Randomly assigned site for de-identity
SUBTYPE	char	SUBJECT GROUP		Collected at CRF.
ACUTEEP	char	TYPE OF ACUTE EPISODE		Collected at CRF.
HOSPITAL	char	HOSPITALIZED AT END OF PERIOD II?		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= int((REF.DATE – BIRTH_D)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
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.
MIXED_DY	num	RELATIVE DAY FIRST MIXED EPISODE		If MIXED_D and REF.DATE not missing then perform below logic to calculate MIXED_DY, If MIXED_D less than REF.DATE then (MIXED_D - REF.DATE).Else if MIXED_D is greater than equal to REF.DATE then (MIXED_D- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DEP_DY	num	RELATIVE DAY FIRST DEPRESS EPISODE		If DEP_D and REF.DATE not missing then perform below logic to calculate DEP_DY, If DEP_D less than REF.DATE then (DEP_D - REF.DATE).Else if DEP_D is greater than equal to REF.DATE then (DEP_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.
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.
RAND_DY	num	RELATIVE RANDOMISATION DAY		If RAND_D and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_D less than REF.DATE then (RAND_D - REF.DATE).Else if RAND_D is greater than equal to REF.DATE then (RAND_D- REF.DATE) +1.

1.4.2. Administration of Trial Medication - ADMMED

Dataset	ADMMED
Creating program	admmed.sas
Description	Administration of trial medication
Unique identifier	DCRFID, PHASE, AMFROMDY
Sorted by	DCRFID, PHASE, 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, AMFREQ, AMREAS, ZAMREAS

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.
BOX	char	BOX		Collected at CRF.
AMDOSE	num	DOSE		Collected at CRF.
AMDOSE_U	char	DOSE UNIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
AMFROMDY	num	RELATIVE ADMIN. FROM DAY		If AMFROM_D and REF.DATE not missing then perform below logic to calculate AMFROMDY, If AMFROM_D less than REF.DATE then (AMFROM_D - REF.DATE).Else if AMFROM_D is greater than equal to REF.DATE then (AMFROM_D- REF.DATE) +1.
AMTO_DY	num	RELATIVE ADMIN. TO DAY		If AMTO_D and REF.DATE not missing then perform below logic to calculate AMTO_DY, If AMTO_D less than REF.DATE then (AMTO_D - REF.DATE).Else if AMTO_D is greater than equal to REF.DATE then (AMTO_D- REF.DATE) +1.

1.4.3. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Event
Unique identifier	DCRFID, AEBODSYS, AESEQNO
Sorted by	DCRFID, AEBODSYS, AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: AE_V, AEINCL, PHASE, AEFROM_D, AEFROM_C, AEFROM, AETO_D, AETO_C, AETO, SAEREFNO, AESOC, AEWHONUM, AEPREF, AESOC1, AESOC2, AESOC3

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.
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.
AECONRX	char	AE CO-RX START		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZAECONRX	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.
AEDECOD1	char	DICTIONARY-DERIVED LOWER LEVEL TERM		Collected at CRF.
AEDECOD	char	DICTIONARY-DERIVED TERM		Collected at CRF.
AEBODSYC	char	BODY SYSTEM OR ORGAN CLASS CODE		Collected at CRF.
AEBODSYS	char	BODY SYSTEM OR ORGAN CLASS		Collected at CRF.
AECODE	char	AE DICTIONARY CODE		Collected at CRF.
AEDICTDM	char	ADVERSE EVENTS DICTIONARY		Collected at CRF.
AEFROMDY	num	RELATIVE AE FROM DAY		If AEFROM and REF.DATE not missing then perform below logic to calculate AEFROMDY, If AEFROM less than REF.DATE then (AEFROM - REF.DATE).Else if AEFROM is greater than equal to REF.DATE then (AEFROM- REF.DATE) +1.

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

1.4.4. Con. Therapy - For Insomnia and Agitation – CONAE

Dataset	CONAE
Creating program	conae.sas
Description	Con. Therapy - For Insomnia and Agitation
Unique identifier	DCRFID, CTTYPE, CTSEQNO, AESEQNO
Sorted by	DCRFID, CTTYPE, CTSEQNO, AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CONRX_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
AESEQNO	num	AE SEQ.		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.

1.4.5. Con. Therapy(Excl Insomnia and Agitation) - COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Con. Therapy(Excl Insomnia and Agitation)
Unique identifier	DCRFID, RXWHONUM, ATCCODE0, CTSEQNO
Sorted by	DCRFID, RXWHONUM, ATCCODE0, CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: CONRX_V, CONRX, CTIND_V, CTIND, CTFROM_D, CTFROM_C, CTFROM, CTTO_D, CTTO_C, CTTO, 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.
CTTYPE	char	CO-RX TYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
CTDOSE	num	TOTAL DAILY DOSE (MG)		Collected at CRF.
CTDUR	char	HOW LONG STABLE ON MED		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.

Variable	Type	Label	Codes	Comments
ATCTEXT6	char	ATC TEXT 6		Collected at CRF.
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 and REF.DATE not missing then perform below logic to calculate CTFROMDY, If CTFROM less than REF.DATE then (CTFROM - REF.DATE).Else if CTFROM is greater than equal to REF.DATE then (CTFROM- REF.DATE) +1.
CTTODY	num	RELATIVE CO-RX END DAY		If CTTO and REF.DATE not missing then perform below logic to calculate CTTODY, If CTTO less than REF.DATE then (CTTO - REF.DATE).Else if CTTO is greater than equal to REF.DATE then (CTTO- REF.DATE) +1.

1.4.6. Protocol Deviation – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	Protocol Deviation
Unique identifier	DCRFID, DVTYPE
Sorted by	DCRFID, DVTYPE
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, DEVIAT

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
ZDEVIAT	char	DEVIATION		Collected at CRF.

1.4.7. Med. And Surgical Hist., Con. Diseases – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Med. And Surgical Hist., Con. Diseases
Unique identifier	DCRFID, DSSYSTEM
Sorted by	DCRFID, DSSYSTEM
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 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.

1.4.8. Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DCRFID, VISIT, EGRESULT, ECG_DY
Sorted by	DCRFID, VISIT, EGRESULT, ECG_DY
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, EGRELCHA, LEADQT, ECGINTNO, ECGREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id 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.
EGRESULT	char	ECG RESULT		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT 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.

1.4.9. ECG Categorical Data – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG Categorical Data
Unique identifier	DCRFID, VISIT, EASEQNO, ECG_DY
Sorted by	DCRFID, VISIT, EASEQNO, ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGOTH_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

Variable	Type	Label	Codes	Comments
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EASEQNO	num	SEQUENCE NUMBER		Collected at CRF.
VISIT	num	VISIT 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.

1.4.10. ECG Evaluation – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	ECG Evaluation
Unique identifier	DCRFID, VISIT, ECG_DY
Sorted by	DCRFID, VISIT, ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EEASPECT	char	ECG ASPECT		Collected at CRF.
EEEVAL	char	ECG EVALUATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT 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.

1.4.11. ECG Parameter – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ECG Parameter
Unique identifier	DCRFID, VISIT, ECGPAR, ECGVAL, ECG_DY
Sorted by	DCRFID, VISIT, ECGPAR, ECGVAL, ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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

Variable	Type	Label	Codes	Comments
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.
VISIT	num	VISIT 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.

1.4.12. ECG Reference – ECGREF

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EGRELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
VISIT	num	VISIT 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. 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.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT NUMBER		Collected at CRF.
ESGROUP	char	ESRS SUBGROUP		Collected at CRF.
ESITEM	char	ESRS ITEM		Collected at CRF.
ZESSCORE	num	ESRS SCORE		Collected at CRF.
ESSCORE	char	ESRS SCORE		Collected at CRF.

1.4.14. Inclusion and Exclusion Criteria – INEX

Dataset	INEX
Creating program	inex.sas
Description	Inclusion and Exclusion Criteria
Unique identifier	DCRFID, IETYPE, IECRIT
Sorted by	DCRFID, 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 crf id for de-identity
IETYPE	char	TYPE OF SELECTION CRITERIA		Collected at CRF.
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	num	SELECTION CRITERIA		Collected at CRF.
IEYN	char	ELIGIBILITY EXPR.		Collected at CRF.
VISIT	num	VISIT NUMBER		Collected at CRF.

1.4.15. Intensive Resource Use Questionnaire – IRQ

Dataset	IRQ
Creating program	irq.sas
Description	Intensive Resource Use Questionnaire
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 or due to missing values: IRQREL_D, IRQSDAYS

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 NUMBER		Collected at CRF.
IRQRELNA	char	RELAPSE (NOT APPLICABLE)		Collected at CRF.
IRQNOWRK	char	LOSE WORK DAYS?		Collected at CRF.
IRQWDAYS	num	NUMBER OF WORKING DAYS LOST		Collected at CRF.
IRQNOSCH	char	LOSE SCHOOL DAYS?		Collected at CRF.

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

1.4.16. IRQ Discharge – IRQDISCH

Dataset	IRQDISCH
Creating program	irqdisch.sas
Description	IRQ Discharge
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: IDS_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
VISIT	num	VISIT NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
IDSNO	char	SUBJECT ELIGIABLE		Collected at CRF.
IDSSEQ	num	LINE NUMBER		Collected at CRF.
IDSREAS	char	MAIN REASON NOT DISCHARGED		Collected at CRF.
ZIDSREAS	num	MAIN REASON NOT DISCHARGED		Collected at CRF.
IDS_DY	num	RELATIVE DAY ELIGIBLE FOR DISCHARGE		If IDS_D and REF.DATE not missing then perform below logic to calculate IDS_DY, If IDS_D less than REF.DATE then (IDS_D - REF.DATE).Else if IDS_D is greater than equal to REF.DATE then (IDS_D-REF.DATE) +1.

1.4.17. IRQ Emergency Room – IRQER

Dataset	IRQER
Creating program	irqer.sas
Description	IRQ Emergency Room
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: IER_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
VISIT	num	VISIT NUMBER		Collected at CRF.
IERNA	char	NOT APPLICABLE		Collected at CRF.
IERNO	char	EMERGENCY ROOM		Collected at CRF.
IERSEQ	num	SEQUENCE NUMBER		Collected at CRF.
IERREAS	char	REASON FOR TREAMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZIERREAS	num	REASON FOR TREAMENT		Collected at CRF.
IER_DY	num	RELATIVE DAY OF ER VISIT		If IER_D and REF.DATE not missing then perform below logic to calculate IER_DY, If IER_D less than REF.DATE then (IER_D - REF.DATE).Else if IER_D is greater than equal to REF.DATE then (IER_D-REF.DATE) +1.

1.4.18. IRQ Hospitalisation – IRQHOSP

Dataset	IRQHOSP
Creating program	irqhosp.sas
Description	IRQ Hospitalisation
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: 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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT NUMBER		Collected at CRF.
HOYESNO	char	NO HOSPITALIZATION DURING OL		Collected at CRF.
HOSEQ	num	SEQUENCE NUMBER		Collected at CRF.
HOHOSP	char	TYPE OF HOSPITAL		Collected at CRF.
ZHOHOSP	num	TYPE OF HOSPITAL		Collected at CRF.
HOUNIT	char	TYPE OF WARD		Collected at CRF.
ZHOUNIT	char	TYPE OF WARD		Collected at CRF.
HOREAS	char	REASON FOR ADMISSION/CHANGE		Collected at CRF.
ZHOREAS	num	REASON FOR ADMISSION/CHANGE		Collected at CRF.
HOONGO	char	ONGOING?		Collected at CRF.
HOFROMDY	num	RELATIVE HOSPITALIZATION FROM DAY		If HOFROM_D and REF.DATE not missing then perform below logic to calculate HOFROMDY, If HOFROM_D less than REF.DATE then (HOFROM_D - REF.DATE).Else if HOFROM_D is greater than equal to REF.DATE then (HOFROM_D- REF.DATE) +1.
HOTO_DY	num	RELATIVE HOSPITALIZATION TO DAY		If HOTO_D and REF.DATE not missing then perform below logic to calculate HOTO_DY, If HOTO_D less than REF.DATE then (HOTO_D - REF.DATE).Else if HOTO_D is greater than equal to REF.DATE then (HOTO_D- REF.DATE) +1.

1.4.19. IRQ Livelihood – IRQLIVE

Dataset	IRQLIVE
Creating program	irqlive.sas
Description	IRQ Livelihood
Unique identifier	DCRFID, VISIT
Sorted by	DCRFID, VISIT
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 NUMBER		Collected at CRF.
ILIVE01	num	PCT AT HOME, ALONE		Collected at CRF.
ILIVE02	num	PCT AT HOME,WITH FAMILY/FRIENDS		Collected at CRF.
ILIVE03	num	PCT HOMELESS		Collected at CRF.
ILIVE04	num	PCT PSYCHIATRIC INSTITUTION		Collected at CRF.
ILIVE05	num	PCT SHELTERED LIVING		Collected at CRF.
ILIVE06	num	PCT PRISON		Collected at CRF.

Variable	Type	Label	Codes	Comments
ILIVE07	num	PCT SKILLED NURSING FACILITY		Collected at CRF.
ILIVE08	num	PCT INTERM CARE		Collected at CRF.
ILIVE09	num	PCT SUPERVISED GROUP		Collected at CRF.
ILIVE10	num	PCT TRANSITIONAL GROUP		Collected at CRF.
ILIVE11	num	PCT FAMILY FOSTER CARE		Collected at CRF.
ILIVE12	num	PCT COOP APT SUPERVISED		Collected at CRF.
ILIVE13	num	PCT COOP APT UNSUPERVISED		Collected at CRF.
ILIVE14	num	PCT BOARD AND CARE HOME		Collected at CRF.
ILIVE15	num	PCT BOARDING HOUSE W/MEALS		Collected at CRF.
ILIVE16	num	PCT ROOMING OR BOARDING HOUSE, NO MEALS		Collected at CRF.
ILIVE17	num	PCT NO CURRENT RESIDENCE		Collected at CRF.
ILIVE18	num	PCT NO INFORMATION		Collected at CRF.

1.4.20. Irqouttx – IRQOUTTX

Dataset	IRQOUTTX
Creating program	irqouttx.sas
Description	Irqouttx
Unique identifier	DCRFID, VISIT
Sorted by	DCRFID, VISIT
Notes	Below listed variables will be dropped from dataset due to missing values: ITXREA2, ZITXREA2

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 NUMBER		Collected at CRF.
ITXSEQ	num	SEQUENCE NUMBER		Collected at CRF.
ITXTYPE	char	TYPE OF SERVICE PROVIDER		Collected at CRF.
ZITXTYPE	num	TYPE OF SERVICE PROVIDER		Collected at CRF.
ITXREAS	char	PRIMARY REASON		Collected at CRF.
ZITXREAS	num	PRIMARY REASON		Collected at CRF.
ITXCONS	num	NUMBER OF CONSULTATIONS		Collected at CRF.

Variable	Type	Label	Codes	Comments
ITXHRS	num	NUMBER OF HOURS		Collected at CRF.
ITXNO	char	OUTPATIENT CONSULTATION SINCE LAST VISIT		Collected at CRF.

1.4.21. Irqphosp – IRQPHOSP

Dataset	IRQPHOSP
Creating program	irqphosp.sas
Description	Irqphosp
Unique identifier	DCRFID, VISIT
Sorted by	DCRFID, VISIT
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 NUMBER		Collected at CRF.
IPHNO	char	DAY/NIGHT CLINIC SINCE LAST VISIT		Collected at CRF.
IPHSEQ	num	SEQUENCE NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
IPHPROG	char	PART OF OUTREACH PROGRAM		Collected at CRF.
IPHCLIN	char	TYPE OF CLINIC		Collected at CRF.
IPHTYPE	char	TYPE OF HOSPITAL		Collected at CRF.
ZIPHTYPE	num	TYPE OF HOSPITAL		Collected at CRF.
IPHREAS	char	REASON HOSPITALIZED		Collected at CRF.
ZIPHREAS	num	REASON HOSPITALIZED		Collected at CRF.
IPHDAYS	num	NUMBER OF DAYS SINCE LAST VISIT		Collected at CRF.

1.4.22. IRQ Occupation Status – IRQPROD

Dataset	IRQPROD
Creating program	irqprod.sas
Description	IRQ Occupation Status
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: IPR_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
VISIT	num	VISIT NUMBER		Collected at CRF.
IPRNO	char	EMPLOYMENT STATUS CHANGE		Collected at CRF.
IPRSEQ	num	SEQUENCE NUMBER		Collected at CRF.
IPROCC	char	NEW OCCUPAATIONAL STATUS		Collected at CRF.
IPRREAS	char	REASON FOR CHANGE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZIPRREAS	num	REASON FOR CHANGE		Collected at CRF.
IPR_DY	num	RELATIVE DAY OF CHANGE		If IPR_D and REF.DATE not missing then perform below logic to calculate IPR_DY, If IPR_D less than REF.DATE then (IPR_D - REF.DATE).Else if IPR_D is greater than equal to REF.DATE then (IPR_D-REF.DATE) +1.

1.4.23. IVRS Data by Visit – IVRS

Dataset	IVRS
Creating program	ivrs.sas
Description	IVRS Data by Visit
Unique identifier	DCRFID, PERIOD, VISITDY
Sorted by	DCRFID, PERIOD, VISITDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COUNTRY, DOB, RANDDT, MEDNO, KITID, VISITDT

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

Variable	Type	Label	Codes	Comments
PERIOD	num	PERIOD		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
DSITE	char	SITE ASSSIGNED FOR DE-IDENTITY		Randomly assigned site for de-identity
RANDDY	num	RELATIVE RANDOMIZATION DATE		If RANDDT and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDDT less than REF.DATE then (RANDDT - REF.DATE).Else if RANDDT is greater than equal to REF.DATE then (RANDDT- REF.DATE) +1.
VISITDY	num	RELATIVE VISIT DATE		If VISITDT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDT less than REF.DATE then (VISITDT - REF.DATE).Else if VISITDT is greater than equal to REF.DATE then (VISITDT- REF.DATE) +1.

1.4.24. Laboratory Results – LABRES

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

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

1.4.25. Laboratory Results (Urine) – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	Laboratory Results (Urine)
Unique identifier	DCRFID, LABTEST, LUVAL, VISIT
Sorted by	DCRFID, LABTEST, LUVAL, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D, LABID, ZLABID, LUVAL_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.
LUVAL	char	URINE VALUE		Collected at CRF.
VISIT	num	VISIT NUMBER		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.

1.4.26. Montgomery and Asberg Dep. Rating Scale – MADRS

Dataset	MADRS
Creating program	madrs.sas
Description	Montgomery and Asberg Dep. Rating Scale
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 crf id for de-identity
VISIT	num	VISIT 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		Collected at CRF.

1.4.27. Nodata – NODATA

Dataset	NODATA
Creating program	nodata.sas
Description	Nodata
Unique identifier	DCRFID, NDSEQNO
Sorted by	DCRFID, NDSEQNO
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
NDSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
NDFROM	num	NO DATA START		Collected at CRF.
NDTO	num	NO DATA END		Collected at CRF.

1.4.28. Physical Examination – PHYSEXAM

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

1.4.29. Pre-Planned Surgery / Procedure – PPSURG

Dataset	PPSURG
Creating program	ppsurg.sas
Description	Pre-Planned Surgery / Procedure
Unique identifier	DCRFID, PSSURG
Sorted by	DCRFID, PSSURG
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PSSURG_V, PSSURG, PSIND_V, PSIND, PSDATE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
PSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
DSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PSDY	num	RELATIVE DAY OF SURGERY		If PSDATE and REF.DATE not missing then perform below logic to calculate PSDY, If PSDATE less than REF.DATE then (PSDATE - REF.DATE).Else if PSDATE is greater than equal to REF.DATE then (PSDATE-REF.DATE) +1.

1.4.30. Previous Bipolar Therapy – PRETHER

Dataset	PRETHER
Creating program	prether.sas
Description	Previous Bipolar Therapy
Unique identifier	DCRFID, RXWHONUM, PTSEQNO
Sorted by	DCRFID, RXWHONUM, 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, PRVRX, PTSCHED, PTFROM_D, PTTO_D, 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
PTSEQNO	num	PREV. RX SEQ.		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCCODE3	char	ATC CODE 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 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.

1.4.31. 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.

1.4.32. Remarks – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	Remarks
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Remark data is sensitive data, contains free text information. Empty dataset will be submitted.

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

1.4.33. Resource Utilization Questionnaire – RUQ

Dataset	RUQ
Creating program	ruq.sas
Description	Resource Utilization Questionnaire
Unique identifier	DCRFID, RUITEM, RUQ_DY
Sorted by	DCRFID, RUITEM, RUQ_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RUQ_D, RUQ_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
VISIT	num	VISIT NUMBER		Collected at CRF.
RUGROUP	char	GROUP		Collected at CRF.
SEQNO	num	SEQUENCE NUMBER		Collected at CRF.
RUITEM	char	RUQ ITEM DESCRIPTION		Collected at CRF.
RUDESC	char	RUQ DESCRIPTION		Collected at CRF.

Variable	Type	Label	Codes	Comments
RUSCORE	num	RUQ SCORE		Collected at CRF.
RUQ_DY	num	RELATIVE RUQ DAY		If RUQ_D and REF.DATE not missing then perform below logic to calculate RUQ_DY, If RUQ_D less than REF.DATE then (RUQ_D - REF.DATE).Else if RUQ_D is greater than equal to REF.DATE then (RUQ_D- REF.DATE) +1.

1.4.34. Resource Utilization Questionnaire – RUQ2

Dataset	RUQ2
Creating program	ruq2.sas
Description	Resource Utilization Questionnaire
Unique identifier	DCRFID, R2SEQNO, VISIT
Sorted by	DCRFID, R2SEQNO, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: R2FROM_D, R2TO_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
VISIT	num	VISIT NUMBER		Collected at CRF.
R2YESNO	char	OVER THE PAST MONTH?		Collected at CRF.
R2SEQNO	num	SEQUENCE NUMBER		Collected at CRF.
R2REAS	char	EMERGENCY ROOM REASON		Collected at CRF.
ZR2REAS	num	EMERGENCY ROOM REASON		Collected at CRF.
R2FROMDY	num	RELATIVE EMERGENCY ROOM FROM DAY		If R2FROM_D and REF.DATE not missing then perform below logic to calculate R2FROMDY, If R2FROM_D less than REF.DATE then (R2FROM_D - REF.DATE).Else if R2FROM_D is greater than equal to REF.DATE then (R2FROM_D- REF.DATE) +1.
R2TO_DY	num	RELATIVE EMERGENCY ROOM TO DAY		If R2TO_D and REF.DATE not missing then perform below logic to calculate R2TO_DY, If R2TO_D less than REF.DATE then (R2TO_D - REF.DATE).Else if R2TO_D is greater than equal to REF.DATE then (R2TO_D- REF.DATE) +1.

1.4.35. Resource Utilization Questionnaire – RUQ3

Dataset	RUQ3
Creating program	ruq3.sas
Description	Resource Utilization Questionnaire
Unique identifier	DCRFID, R3SEQNO, VISIT
Sorted by	DCRFID, R3SEQNO, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: R3FROM_D, R3TO_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
VISIT	num	VISIT NUMBER		Collected at CRF.
R3YESNO	char	SUBJECT HOSPITALIZED?		Collected at CRF.
R3SEQNO	num	SEQUENCE NUMBER		Collected at CRF.
R3HOSP	char	TYPE OF HOSPITAL		Collected at CRF.
ZR3HOSP	num	TYPE OF HOSPITAL		Collected at CRF.
R3UNIT	char	TYPE OF WARD/UNIT		Collected at CRF.
ZR3UNIT	num	TYPE OF WARD/UNIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
R3REAS	char	HOSPITALIZATION REASON		Collected at CRF.
ZR3REAS	num	HOSPITALIZATION REASON		Collected at CRF.
R3ONGO	char	ONGOING?		Collected at CRF.
R3FROMDY	num	RELATIVE HOSPITALIZATION FROM DAY		If R3FROM_D and REF.DATE not missing then perform below logic to calculate R3FROMDY, If R3FROM_D less than REF.DATE then (R3FROM_D - REF.DATE).Else if R3FROM_D is greater than equal to REF.DATE then (R3FROM_D- REF.DATE) +1.
R3TO_DY	num	RELATIVE HOSPITALIZATION TO DAY		If R3TO_D and REF.DATE not missing then perform below logic to calculate R3TO_DY, If R3TO_D less than REF.DATE then (R3TO_D - REF.DATE).Else if R3TO_D is greater than equal to REF.DATE then (R3TO_D- REF.DATE) +1.

1.4.36. Sample – SAMPLE

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned 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.
FASTED	char	SUBJECT FASTED		Collected at CRF.
VISIT	num	VISIT NUMBER		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.

1.4.37. Sample Reference – SAMREF

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

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

Variable	Type	Label	Codes	Comments
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SARELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
VISIT	num	VISIT NUMBER		Collected at CRF.

1.4.38. SF-36 Health Survey – SF36

Dataset	SF36
Creating program	sf36.sas
Description	SF-36 Health Survey
Unique identifier	DCRFID, SFITEM, VISIT
Sorted by	DCRFID, SFITEM, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SF36_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
VISIT	num	VISIT NUMBER		Collected at CRF.
SF36VERS	num	SF36 VERSION NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
SFITEM	char	SF-36 ITEM		Collected at CRF.
SFSCORE	char	SF-36 SCORE		Collected at CRF.
ZSFSCORE	num	SF-36 SCORE		Collected at CRF.
SF36_DY	num	RELATIVE VISIT DAY		If SF36_D and REF.DATE not missing then perform below logic to calculate SF36_DY, If SF36_D less than REF.DATE then (SF36_D - REF.DATE).Else if SF36_D is greater than equal to REF.DATE then (SF36_D- REF.DATE) +1.

1.4.39. Trial Description – TRLDESC

Dataset	TRLDESC
Creating program	trldesc.sas
Description	Trial Description
Unique identifier	TRIAL
Sorted by	TRIAL
Notes	Below listed variables will be dropped from dataset due to missing values: SPECPOP

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
COMPOND	char	COMPOUND NAME		Collected at CRF.
ZCOMPOND	char	COMPOUND NAME		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.
PLACONTR	char	PLACEBO CONTROL		Collected at CRF.
ACTCONTR	char	ACTIVE CONTROL		Collected at CRF.
DESIGN	char	DESIGN		Collected at CRF.
MULTCENT	char	MULTICENTRE		Collected at CRF.
INDICAT	char	INDICATION		Collected at CRF.
AGEGRP	char	AGE GROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.

1.4.40. Trial Randomization Details – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	Trial Randomization Details
Unique identifier	TRIAL, RANDGRP
Sorted by	TRIAL, RANDGRP
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.

1.4.41. Treatment Regimen – TRLREGM

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	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.

1.4.42. Treatment Termination – TRTERM

Dataset	TRTERM
Creating program	trterm.sas
Description	Treatment Termination
Unique identifier	DCRFID, TRTYPE
Sorted by	DCRFID, TRTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TRFROM_D, TRREAS_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
TRTYPE	char	TYPE OF TERMINATION		Collected at CRF.
TRSTATE	char	STATE OF TERMINATION		Collected at CRF.
TRRLNR1	char	DSM-IV BIPOLAR EPISODE		Collected at CRF.
TRRLNR2	char	TREATMENT INTERVENTION		Collected at CRF.
TRRLNR3	char	HOSPITALIZATION FOR EPISODE		Collected at CRF.
TRRLNR4	char	SYMPTOM SEVERITY EXCEEDS CRITERIA		Collected at CRF.
TRRLNR5	char	DOSE INCR/SUPPL NEEDED		Collected at CRF.
TRPERIOD	char	PERIOD OF DISCONTINUATION		Collected at CRF.
TRREAS	char	TERM. REASON		Collected at CRF.
TRCONTYN	char	SUBJECT CONTINUE?		Collected at CRF.
TRCNTTYP	char	SUBJECT CONTINUE TYPE		Collected at CRF.
TRFROMDY	num	RELATIVE LAST DAY OF TREATMENT/TRIAL		If TRFROM_D and REF.DATE not missing then perform below logic to calculate TRFROMDY, If TRFROM_D less than REF.DATE then (TRFROM_D - REF.DATE).Else if TRFROM_D is greater than equal to REF.DATE then (TRFROM_D- REF.DATE) +1.

1.4.43. Visit – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit
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, CGIINIT, MAINIT, ESINIT, PSINIT

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 NUMBER		Collected at CRF.
PREVMED	char	INSOMNIA/AGITATION WITHIN 8 HOURS		Collected at CRF.
CGISEV	char	CLINICAL GLOBAL IMPRESSION SEVERITY		Collected at CRF.
YMNA	char	YMRS NOT APPLICABLE		Collected at CRF.
PRENA	char	PRE-ASSESSMENT NOT APPLICABLE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CGINA	char	CGI NOT APPLICABLE		Collected at CRF.
MANA	char	MADRS NOT APPLICABLE		Collected at CRF.
ESNA	char	ESRS NOT APPLICABLE		Collected at CRF.
PSNA	char	PSP NOT APPLICABLE		Collected at CRF.
PSPSCORE	num	PERSONAL AND SOCIAL PERFORMANCE		Collected at CRF.
PENA	char	PHYSICAL EXAM NOT APPLICABLE		Collected at CRF.
SAMPNA	char	SAMPLE REF NOT APPLICABLE		Collected at CRF.
VITNA	char	VITAL NOT APPLICABLE		Collected at CRF.
IRQDNA	char	HOSPITALIZATION REVIEW NA		Collected at CRF.
IRQNA	char	RESOLUTION OF RELAPSE NA		Collected at CRF.
IERNA	char	EMERGENCY ROOM NA		Collected at CRF.
IPHNA	char	PARTIAL HOSPITAL NA		Collected at CRF.
ILIVENA	char	DAILY LIVING NA		Collected at CRF.
IPRNA	char	PRODUCTIVITY NA		Collected at CRF.
IRQNA2	char	PRODUCTIVITY NA (PAGE 8010)		Collected at CRF.

Variable	Type	Label	Codes	Comments
ITXNA	char	OUTPATIENT TREATMENT NA		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.

1.4.44. 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 NUMBER		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.

Variable	Type	Label	Codes	Comments
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
POSITION	char	POSITION		Collected at CRF.
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLIC BP, mmHg		Collected at CRF.
PULSE	num	PULSE, beats/min		Collected at CRF.

1.4.45. Young Mania Rating Scale – YMRS

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

Variable	Type	Label	Codes	Comments
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 NUMBER		Collected at CRF.
YMITEM	char	YMRS ITEM		Collected at CRF.

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