

Clinical Development

RISPERIDONE[®]

RIS-BIP-302

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.
- Lab Identifier information 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.
- Partial date's relative day cannot be calculated.
- Dataset "REMARK " will be submitted with zero observation.
- Lab Name information will not be provided.
- Variables with completely missing values will not be submitted.
- Informed Consent Date is used as Reference Date to calculate Relative Day.

1.3 Data Files

The RIS-BIP-302 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4 Data Domains

1.4.1 Subject Background And Demographics – SUB

Dataset	SUB
Creating program	sub.sas
Description	Subject Background And Demographics
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: INITIALS, BIRTH_D, CONSNT_D, INVEST, PGCON_D, MEDNO, RACE_V, RAND_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
DSITEID	num	SITE ID ASSIGNED FOR DE-IDENTITY		Randomly assigned site id for de-identity
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.

Variable	Type	Label	Codes	Comments
FUTUCON	char	GET CONSENT FOR FUTURE STORAGE AND TESTING?		Collected at CRF.
IMEDCON	char	GET CONSENT FOR IMMEDIATE TESTING?		Collected at CRF.
PGCON	char	PHARMACOGENOMIC SAMPLING CONSENT ?		Collected at CRF.
PRECRIT	char	SUBJECT MEET ALL ENTRY CRITERIA?		Collected at CRF.
RACE	char	RACE		Collected at CRF.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGE	char	AGE IN YEARS		<p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule:</p> $\text{AGE} = \text{int}((\text{CONSNT_D} - \text{BIRTH_D}) / 365.25)$ <p>If age greater than 89+ years then will be grouped as per HIPAA rules</p>
PGCON_DY	num	RELATIVE DAY OF PHARMACOGENOMIC SAMPLING		<p>If PGCON_D and CONSNT_D not missing then perform below logic to calculate PGCON_DY, if PGCON_D less than CONSNT_D then (PGCON_D - CONSNT_D). Else if PGCON_D is greater than equal to CONSNT_D then (PGCON_D - CONSNT_D) + 1.</p>
RAND_DY	num	RELATIVE RANDOMIZATION DAY		<p>If RAND_D and CONSNT_D not missing then perform below logic to calculate RAND_DY, if RAND_D less than CONSNT_D then (RAND_D - CONSNT_D). Else if RAND_D is greater than equal to CONSNT_D then (RAND_D - CONSNT_D) + 1.</p>

1.4.2 Study Drug Administration – ADMMED

Dataset	ADMMED
Creating program	admmmed.sas
Description	Study Drug Administration
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: ADM_COM, ADM_D, ADMINI, KITNO, RETAI_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
ADM_T	num	ADMINISTRATION TIME		Collected at CRF.
AMDOSE	char	STUDY DOSE		Collected at CRF.
AMDOSE_U	char	STUDY DOSE UNITS		Collected at CRF.
INJSITE	char	INJECTION SITE		Collected at CRF.
PHASE	char	PHASE		Collected at CRF.
NOTADM	char	NOT DISPENSED?		Collected at CRF.
RETAIYN	char	KIT RETAINED? (Yes/No)		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT NO.		Collected at CRF.
ADM_DY	num	RELATIVE ADMINISTERED DAY		If ADM_D and CONSNT_D not missing then perform below logic to calculate ADM_DY, If ADM_D less than CONSNT_D then (ADM_D - CONSNT_D).Else if ADM_D is greater than equal to CONSNT_D then (ADM_D- CONSNT_D) +1.

1.4.3 Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DCRFID,PTNAME,LLTNAME,AEFROMDY, AETODY
Sorted by	DCRFID,PTNAME,LLTNAME,AEFROMDY, AETODY
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: AE_V, AEFROM_D, AEFROM_C, AETO_C, AETO_D, SAEREFNO

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
AEACT	char	AE ACTION TAKEN		Collected at CRF.
AECONRX	char	AE CO-RX START		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.
AESER	char	AE SERIOUSNESS		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.
HLTCODE	num	10 DIGIT CODE FOR HIGHER LVL TERM		Collected at CRF.
HLTNAME	char	FULL NAME FOR HIGHER LVL TERM		Collected at CRF.
HLGTCODE	num	HLGT CODE		Collected at CRF.
HLGTNAME	char	HLGT NAME		Collected at CRF.
LLTCODE	num	8 DIGIT CODE TO IDENTIFY LOWER LVL TERM		Collected at CRF.
LLTNAME	char	FULL NAME FOR LOWER LVL TERM		Collected at CRF.
PTCODE	num	8 DIGIT CODE TO IDENTIFY PREFERRED TERM		Collected at CRF.

Variable	Type	Label	Codes	Comments
PTSOC CD	num	PRIMARY SOC FOR PT		Collected at CRF.
PTNAME	char	FULL NAME FOR PREFERRED TERM		Collected at CRF.
PSOCFG	char	FLAG FOR PRIMARY SOC		Collected at CRF.
SOCABRV	char	SOC ABBREVIATION		Collected at CRF.
SOC CODE	num	10 DIGIT CODE FOR SYSTEM ORGAN CLASS		Collected at CRF.
SOCNAME	char	FULL NAME FOR SYSTEM ORGAN CLASS		Collected at CRF.
ZA ESEV	num	AE SEVERITY NUMERIC		Collected at CRF.
ZA ESER	num	AE SERIOUSNESS NUMERIC		Collected at CRF.
ZA RELAT	num	AE DRUG RELATION NUMERIC		Collected at CRF.
ZA EACT	num	AE ACTION TAKEN NUMERIC		Collected at CRF.
ZA EOUT	num	AE OUTCOME NUMERIC		Collected at CRF.
AEFROMDY	num	RELATIVE AE START DAY		If AEFROM_C and CONSNT_D not missing then perform below logic to calculate AEFROMDY, If AEFROM_C less than CONSNT_D then (AEFROM_C - CONSNT_D).Else if AEFROM_C is greater than equal to CONSNT_D then (AEFROM_C- CONSNT_D) +1.

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

1.4.4 Abnormal Involuntary Movement Scale – AIMS

Dataset	AIMS
Creating program	aims.sas
Description	Abnormal Involuntary Movement Scale
Unique identifier	DCRFID,VISIT,PARAM, SUBPARAM
Sorted by	DCRFID,VISIT,PARAM, SUBPARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.

Variable	Type	Label	Codes	Comments
PARAM	char	PARAMETER		Collected at CRF.
PARSEQNO	num	PARAMETER SEQ. NO		Collected at CRF.
SUBPARAM	char	SUB-PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.5 Barnes Akathisia Rating Scale – BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia Rating Scale
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
PARSEQNO	num	PARAMETER SEQ. NO		Collected at CRF.
VALUE	num	VALUE OF PARAMETER		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.6 Clinical Global Impression of Change – CGIC

Dataset	CGIC
Creating program	cgic.sas
Description	Clinical Global Impression of Change
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.7 Clinical Global Impression of Severity – CGIS

Dataset	CGIS
Creating program	cgis.sas
Description	Clinical Global Impression of Severity
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.

Variable	Type	Label	Codes	Comments
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.8 Comorbidities – COMORBID

Dataset	COMORBID
Creating program	comorbid.sas
Description	Comorbidities
Unique identifier	DCRFID,CMDSM4CD,CMNONE, CMDSMDY
Sorted by	DCRFID,CMDSM4CD,CMNONE, CMDSMDY
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: CMDSM_C, CMDSM_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
CMDSM4CD	char	DIAGNOSIS IV CODE		Collected at CRF.
CMNONE	char	NONE (PSYC. HIST.) AXIS I		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMDSMDY	num	RELATIVE DIAGNOSIS DAY		If CMDSM_C and CONSNT_D not missing then perform below logic to calculate CMDSMDY, If CMDSM_C less than CONSNT_D then (CMDSM_C - CONSNT_D).Else if CMDSM_C is greater than equal to CONSNT_D then (CMDSM_C- CONSNT_D) +1.

1.4.9 Previous Bipolar Concomitant Meds – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Previous Bipolar Concomitant Meds
Unique identifier	DCRFID,ATCCODE,CTFROMDY,CTTODY, CTSEQNO
Sorted by	DCRFID,ATCCODE,CTFROMDY,CTTODY, 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: CONRX_V, CTDOSEC, CTFROM_D, CTFROM_C, CTROUTE, CTTO_D, CTTO_C

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
ATCCODE	char	ATC CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONRX	char	CO-RX WHO DRUG TERM		Collected at CRF.
CTDOSE	num	CO-RX DOSE		Collected at CRF.
CTMEDYN	char	MEDICATION TAKEN?		Collected at CRF.
CTONGO	char	CO-RX ONGOING (Yes/No)		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CTSCHED	char	DOSING SCHEDULE		Collected at CRF.
CTTYPE	char	PREVIOUS BIPOLAR MEDS OR PRIOR/CONCOM MEDS		Collected at CRF.
CTUNIT	char	CO-RX UNIT		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
XATC	char	ATC CLASS		Collected at CRF.
XGENERIC	char	WHO GENERIC TERM		Collected at CRF.
CTFROMDY	num	RELATIVE CO-RX START DAY		If CTFROM_C and CONSNT_D not missing then perform below logic to calculate CTFROMDY, if CTFROM_C less than CONSNT_D then (CTFROM_C - CONSNT_D).Else if CTFROM_C is greater than equal to CONSNT_D then (CTFROM_C- CONSNT_D) +1.

Variable	Type	Label	Codes	Comments
CTTODY	num	RELATIVE CO-RX END DAY		If CTTO_C and CONSNT_D not missing then perform below logic to calculate CTTODY, If CTTO_C less than CONSNT_D then (CTTO_C - CONSNT_D).Else if CTTO_C is greater than equal to CONSNT_D then (CTTO_C - CONSNT_D) +1.

1.4.10 Protocol Deviation – DEVIATN

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

Variable	Type	Label	Codes	Comments
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
ZDEVIAT	char	CLASSIFICATION OF THE PROTOCOL DEVIATION OR NO TREATMENT		Collected at CRF.
DEVIAT	char	CLASSIFICATION OF THE PROTOCOL DEVIATION OR NO TREATMENT		Collected at CRF.
DVTYPE	char	DEVIATION TYPE		Collected at CRF.

1.4.11 Medical And Surgery History – DISEASE

Dataset	DISEASE
Creating program	disease.sas
Description	Medical And Surgery History
Unique identifier	DCRFID,PTNAME,LLTNAME,SOCNAME, DSSEQNO
Sorted by	DCRFID,PTNAME,LLTNAME,SOCNAME, DSSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DSREAS_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
DSACTYN	char	DISEASE ACTIVE OR NOT ACTIVE?		Collected at CRF.
DSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
HLTCODE	num	10 DIGIT CODE FOR HIGHER LVL TERM		Collected at CRF.
HLTNAME	char	FULL NAME FOR HIGHER LVL TERM		Collected at CRF.
HLGTCODE	num	HLGT CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
HLGTNAME	char	HLGT NAME		Collected at CRF.
LLTCODE	num	8 DIGIT CODE TO IDENTIFY LOWER LVL TERM		Collected at CRF.
LLTNAME	char	FULL NAME FOR LOWER LVL TERM		Collected at CRF.
PSOCFG	char	FLAG FOR PRIMARY SOC		Collected at CRF.
PTCODE	num	8 DIGIT CODE TO IDENTIFY PREFERRED TERM		Collected at CRF.
PTNAME	char	FULL NAME FOR PREFERRED TERM		Collected at CRF.
PTSOCOD	num	PRIMARY SOC FOR PT		Collected at CRF.
SOCODE	num	10 DIGIT CODE FOR SYSTEM ORGAN CLASS		Collected at CRF.
SOCNAME	char	FULL NAME FOR SYSTEM ORGAN CLASS		Collected at CRF.
SOCABRV	char	SOC ABBREVIATION		Collected at CRF.

1.4.12 Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DCRFID,VISIT,PARAM,ECG_DY, ECG_T
Sorted by	DCRFID,VISIT,PARAM, ECG_DY, ECG_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGSRCE, 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
VISIT	num	VISIT NO.		Collected at CRF.
ECG_T	num	ECG TIME		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.

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

1.4.13 ECG Categorical Data – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	Ecg Categorical Data
Unique identifier	DCRFID,VISIT,PARAM,ECG_DY, ECG_T
Sorted by	DCRFID,VISIT,PARAM,ECG_DY, ECG_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DVALUE, ECG_D, VALUE

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 NO.		Collected at CRF.
ECG_T	num	ECG TIME		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and CONSNT_D not missing then perform below logic to calculate ECG_DY, If ECG_D less than CONSNT_D then (ECG_D - CONSNT_D).Else if ECG_D is greater than equal to CONSNT_D then (ECG_D- CONSNT_D) +1.

1.4.14 ECG Evaluation – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	Ecg Evaluation
Unique identifier	DCRFID,VISIT,PARAM,ECG_DY, ECG_T
Sorted by	DCRFID,VISIT,PARAM,ECG_DY, ECG_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGSRCE

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
ECG_T	num	ECG TIME		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and CONSNT_D not missing then perform below logic to calculate ECG_DY, If ECG_D less than CONSNT_D then (ECG_D - CONSNT_D).Else if ECG_D is greater than equal to CONSNT_D then (ECG_D- CONSNT_D) +1.

1.4.15 ECG Parameters – EGCPAR

Dataset	EGCPAR
Creating program	ecgpar.sas
Description	Ecg Parameters
Unique identifier	DCRFID,VISIT,PARAM,ECG_DY, ECG_T
Sorted by	DCRFID,VISIT,PARAM,ECG_DY, ECG_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGSRCE

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.
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT NO.		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and CONSNT_D not missing then perform below logic to calculate ECG_DY, If ECG_D less than CONSNT_D then (ECG_D - CONSNT_D).Else if ECG_D is greater than equal to CONSNT_D then (ECG_D- CONSNT_D) +1.

1.4.16 Emergency – EMERG

Dataset	EMERG
Creating program	emerg.sas
Description	Emergency
Unique identifier	DCRFID,VISIT,DVALUE, EFROMDY
Sorted by	DCRFID,VISIT,DVALUE, EFROMDY
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: EFROM_C, EFROM_D, ETO_C, ETO_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 NO.		Collected at CRF.

Variable	Type	Label	Codes	Comments
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
EFROMDY	num	RELATIVE FROM DAY		If EFROM_C and CONSNT_D not missing then perform below logic to calculate EFROMDY, If EFROM_C less than CONSNT_D then (EFROM_C - CONSNT_D).Else if EFROM_C is greater than equal to CONSNT_D then (EFROM_C- CONSNT_D) +1.
ETODY	num	RELATIVE TO DAY		If ETO_C and CONSNT_D not missing then perform below logic to calculate ETODY, If ETO_C less than CONSNT_D then (ETO_C - CONSNT_D).Else if ETO_C is greater than equal to CONSNT_D then (ETO_C- CONSNT_D) +1.

1.4.17 Physical Exam Data – EXAM

Dataset	EXAM
Creating program	exam.sas
Description	Physical Exam Data
Unique identifier	DCRFID,VISIT, PESYSTEM
Sorted by	DCRFID,VISIT, PESYSTEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXAM_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
PEOTHER	char	PHYSICAL EXAM OTHER BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.
PESEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.18 Global Assessment of Functions Scale – GAF

Dataset	GAF
Creating program	gaf.sas
Description	Global Assessment Of Functions Scale
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
GASCORE	num	RATING		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.19 Hospitalization – HOSP

Dataset	HOSP
Creating program	hosp.sas
Description	Hospitalization
Unique identifier	DCRFID,VISIT,PARAM,HDVALUE, HFROM_DY
Sorted by	DCRFID,VISIT,PARAM,HDVALUE, HFROM_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HFROM_D, HTO_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 NO.		Collected at CRF.
HVALUE	num	TYPE OF HOSPITAL CODE		Collected at CRF.
HDVALUE	char	TYPE OF HOSPITAL		Collected at CRF.
ONGOYN	char	ONGOING		Collected at CRF.
PARAM	char	PARAMETER D: HOSPITALIZATION		Collected at CRF.
RDVALUE	char	REASON HOSPITALIZED		Collected at CRF.

Variable	Type	Label	Codes	Comments
RVALUE	num	REASON HOSPITALIZED CODE		Collected at CRF.
WVALUE	num	TYPE OF WARD CODE		Collected at CRF.
WDVALUE	char	TYPE OF WARD		Collected at CRF.
HFROM_DY	num	RELATIVE FROM DAY		If HFROM_D and CONSNT_D not missing then perform below logic to calculate HFROM_DY, If HFROM_D less than CONSNT_D then (HFROM_D - CONSNT_D).Else if HFROM_D is greater than equal to CONSNT_D then (HFROM_D- CONSNT_D) +1.
HTO_DY	num	RELATIVE TO DAY		If HTO_D and CONSNT_D not missing then perform below logic to calculate HTO_DY, If HTO_D less than CONSNT_D then (HTO_D - CONSNT_D).Else if HTO_D is greater than equal to CONSNT_D then (HTO_D- CONSNT_D) +1.

1.4.20 Inclusion and Exclusion Criteria – INEX

Dataset	INEX
Creating program	inex.sas
Description	Inclusion and Exclusion Criteria
Unique identifier	DCRFID, IECRIT
Sorted by	DCRFID, 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
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
IESEQNO	num	SEQUENCE NO.		Collected at CRF.
IETYPE	char	TYPE OF SELECTION CRITERIA		Collected at CRF.
IEYN	char	RESULTS OF SELECTION CRITERIA		Collected at CRF.

1.4.21 Rev Intersept Scale For Suicidal Thinking – ISST

Dataset	ISST
Creating program	isst.sas
Description	Rev Intersept Scale For Suicidal Thinking
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
PARSEQNO	num	PARAMETER SEQ. NO		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.22 Laboratory Results – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	Laboratory Results
Unique identifier	DCRFID,VISIT,LABTEST,LABVAL, LABCLASS
Sorted by	DCRFID,VISIT,LABTEST,LABVAL, LABCLASS
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: SEX, SAMPLE_D, LABID, ZLABID, LABVAL_V, REFNO, LABTSTNO

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 NO.		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LABORATORY TEST		Collected at CRF.
ZLABTEST	char	LABORATORY TEST		Collected at CRF.
LABVAL	num	LABORATORY TEST VALUE		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.
LABUPP	num	UPPER NORMAL LIMIT		Collected at CRF.

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

1.4.23 Montgomery-Asberg Depression Rating Scale – MADRS

Dataset	MADRS
Creating program	madrs.sas
Description	Montgomery-Asberg Depression Rating Scale
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
PARSEQNO	num	PARAMETER SEQ. NO		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.24 Psychotic History – PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychotic History
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: HOSP0_D, HOSP1_D, HOSP0_C, HOSP1_C

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
BIPRELT	char	ANY FIRST DEGREE RELATIVES HAVE BIPOLAR DISORDER?		Collected at CRF.
CABUSYN	char	HAS PATIENT EXPERIENCED ABUSE IN THEIR CHILDHOOD/TEEN YRS.?		Collected at CRF.
CABEMOT	char	EMOTIONAL ABUSE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CABPHYS	char	PHYSICAL(NON-SEXUAL) ABUSE		Collected at CRF.
CABSEX	char	SEXUAL ABUSE		Collected at CRF.
CABUSP	char	UNSPECIFIED		Collected at CRF.
DEPRELT	char	NON-BIPOLAR DEPRESSION		Collected at CRF.
PSY6MTH	num	NUMBER OF PSYCHIATRIC EPISODES IN PAST 6 MONTHS		Collected at CRF.
PSY12MTH	num	NUMBER OF PSYCHIATRIC EPISODES IN PAST 12 MONTHS		Collected at CRF.
DP6MTH	num	NUMBER OF DEPRESSIVE EPISODES IN PAST 6 MONTHS		Collected at CRF.
DP12MTH	num	NUMBER OF DEPRESSIVE EPISODES IN PAST 12 MONTHS		Collected at CRF.
MAN6MTH	num	NUMBER OF MANIC TYPE EPISODES IN PAST 6 MONTHS		Collected at CRF.
MAN12MTH	num	NUMBER OF MANIC TYPE EPISODES IN PAST 12 MONTHS		Collected at CRF.

Variable	Type	Label	Codes	Comments
MIX6MTH	num	NUMBER OF MIXED TYPE EPISODES IN PAST 6 MONTHS		Collected at CRF.
MIX12MTH	num	NUMBER OF MIXED TYPE EPISODES IN PAST 12 MONTHS		Collected at CRF.
UN6MTH	num	NUMBER OF UNSPECIFIED EPISODES IN PAST 6 MONTHS		Collected at CRF.
UN12MTH	num	NUMBER OF UNSPECIFIED EPISODES IN PAST 12 MONTHS		Collected at CRF.
DSMDIAG	char	AXIS_I		Collected at CRF.
DSMAGE	char	AGE AT ONSET OF BIPOLAR DISORDER DSM_IV DIAGNOSIS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
EPITYPE	char	MOST RECENT TYPE OF EPISODE		Collected at CRF.
FDTHAGE	char	IF NO, AGE OF PATIENT AT FATHER'S DEATH		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HOSP	num	NUMBER OF PSYCHIATRIC HOSPITALIZATIONS		Collected at CRF.
PALIVYN	char	ARE BOTH PARENTS ALIVE?		Collected at CRF.

Variable	Type	Label	Codes	Comments
MDTHAGE	char	IF NO, AGE OF PATIENT AT MOTHER'S DEATH		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
SCHRELT	char	ANY FIRST DEGREE RELATIVES HAVE SCHIZOPHRENIA?		Collected at CRF.
SUICD2YR	num	NUMBER OF SUICIDE ATTEMPTS IN PAST 2 YRS?		Collected at CRF.
SUICDALL	num	NUMBER OF SUICIDE ATTEMPTS IN LIFETIME?		Collected at CRF.
TREATAGE	char	AGE AT FIRST PHARMACOLOGIC TREATMENT FOR PSYCHIATRIC SYMPTOM		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HOSPODY	num	RELATIVE DAY OF MOST RECENT EPISODE		If HOSPO_C and CONSNT_D not missing then perform below logic to calculate HOSPODY, If HOSPO_C less than CONSNT_D then (HOSPO_C - CONSNT_D).Else if HOSPO_C is greater than equal to CONSNT_D then (HOSPO_C - CONSNT_D) +1.
HOSP1DY	num	RELATIVE DAY OF LAST HOSPITALIZATION (DISCHARGE)		If HOSP1_C and CONSNT_D not missing then perform below logic to calculate HOSP1DY, If HOSP1_C less than CONSNT_D then (HOSP1_C - CONSNT_D).Else if HOSP1_C is greater than equal to CONSNT_D then (HOSP1_C - CONSNT_D) +1.

1.4.25 Investigator Comments – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	Investigator Comments
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: INITIALS, REMARK_V, REMARK_C, REMARK_D</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.
RMPAGE	char	DATASET NAME COMMENT REFERS TO		Empty dataset will be submitted.
REMARKDY	num	RELATIVE DAY OF COMMENT		Empty dataset will be submitted.

1.4.26 Remission Criteria Summary – REMCRIT

Dataset	REMCRIT
Creating program	remcrit.sas
Description	Remission Criteria Summary
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
CRISIS	char	CRISIS INTERVENTION?		Collected at CRF.
MEDINCR	char	INCREASED MEDICATIONS AND DOSES OF PSYCHOTROPIC MEDS?		Collected at CRF.
MOOD	char	MET DSM-IV-TR CRITERIA FOR ACTIVE MOOD DISORDER?		Collected at CRF.
SCORES	char	YMRS AND MADRS TOTAL SCORES REMAIN >=10 AND CGI-BP-S >=3?		Collected at CRF.

1.4.27 Rmb Results – RMB

Dataset	RMB
Creating program	rmb.sas
Description	Rmb Results
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: RMB_D, RMBADJ_D, RMBREL_C, RMBREL_D, RMBSUIC, RMBROU_D, RMBRAJ_D, RMBRON_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
DSITEID	num	SITE ID ASSIGNED FOR DE-IDENTITY		Randomly assigned site id for de-identity
RMBREL	char	MEET RELAPSE CRITERIA BASED ON RMB		Collected at CRF.
RMBMED	char	SIG. CHANGE IN TAU OR ADDITIONAL BP MEDIC		Collected at CRF.

Variable	Type	Label	Codes	Comments
RMBSCALE	char	SCALE AND DSM-IV MOOD CRITERIA		Collected at CRF.
RMBTYPE	char	TYPE OF EPISODE		Collected at CRF.
RMB_DY	num	RELATIVE RMB MEETING DAY		If RMB_D and CONSNT_D not missing then perform below logic to calculate RMB_DY, If RMB_D less than CONSNT_D then (RMB_D - CONSNT_D).Else if RMB_D is greater than equal to CONSNT_D then (RMB_D- CONSNT_D) +1.
RMBADJDY	num	RELATIVE RMB ADJUDICATION DAY		If RMBADJ_D and CONSNT_D not missing then perform below logic to calculate RMBADJDY, If RMBADJ_D less than CONSNT_D then (RMBADJ_D - CONSNT_D).Else if RMBADJ_D is greater than equal to CONSNT_D then (RMBADJ_D- CONSNT_D) +1.
RMBRELDY	num	RELATIVE RMB-ASSIGNED DAY OF RELAPSE		If RMBREL_C and CONSNT_D not missing then perform below logic to calculate RMBRELDY, If RMBREL_C less than CONSNT_D then (RMBREL_C - CONSNT_D).Else if RMBREL_C is greater than equal to CONSNT_D then (RMBREL_C- CONSNT_D) +1.
RMBROUDY	num	RELATIVE RMB MEETING DAY		If RMBROU_D and CONSNT_D not missing then perform below logic to calculate RMBROUDY, If RMBROU_D less than CONSNT_D then (RMBROU_D - CONSNT_D).Else if RMBROU_D is greater than equal to CONSNT_D then (RMBROU_D- CONSNT_D) +1.

Variable	Type	Label	Codes	Comments
RMBRAJDY	num	RELATIVE ROUGHENING ADJUDICATION DAY		If RMBRAJ_D and CONSNT_D not missing then perform below logic to calculate RMBRAJDY, If RMBRAJ_D less than CONSNT_D then (RMBRAJ_D - CONSNT_D).Else if RMBRAJ_D is greater than equal to CONSNT_D then (RMBRAJ_D- CONSNT_D) +1.
RMBRONDY	num	RELATIVE DAY OF ONSET OF ROUGHENING		If RMBRON_D and CONSNT_D not missing then perform below logic to calculate RMBRONDY, If RMBRON_D less than CONSNT_D then (RMBRON_D - CONSNT_D).Else if RMBRON_D is greater than equal to CONSNT_D then (RMBRON_D- CONSNT_D) +1.

1.4.28 Resource Utilization Questionnaire – RUQ

Dataset	RUQ
Creating program	ruq.sas
Description	Resource Utilization Questionnaire
Unique identifier	DCRFID,VISIT,PARAM, SUBPARAM
Sorted by	DCRFID,VISIT,PARAM, SUBPARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT NO.		Collected at CRF.
PARSEQNO	num	PARAMETER SEQ. NO		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
SUBPARAM	char	SUB-PARAMETER		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
VALUE	num	VALUE OF PARAM / SUBPARAM		Collected at CRF.

1.4.29 Sample – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	Sample
Unique identifier	DCRFID,VISIT, SAMTYPE
Sorted by	DCRFID,VISIT, SAMTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: REFNO, SAMPLE_D, SAMPLE_T

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 NO.		Collected at CRF.
SAMNOTDN	char	SAMPLE COLLECTED? (Yes/No)		Collected at CRF.
SAMTYPE	char	TYPE OF TEST SCHEDULE ('UNSCHEDULED', 'RETEST' or 'N/A')		Collected at CRF.

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

1.4.30 Simpson-Angus Rating Scale – SAS

Dataset	SAS
Creating program	sas.sas
Description	Simpson-Angus Rating Scale
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.

Variable	Type	Label	Codes	Comments
PARAM	char	PARAMETER		Collected at CRF.
PARSEQNO	num	PARAMETER SEQ. NO		Collected at CRF.
VALUE	num	VALUE OF PARAMETER		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.31 Sheehan Disability Scale – SDS

Dataset	SDS
Creating program	sds.sas
Description	Sheehan Disability Scale
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.

Variable	Type	Label	Codes	Comments
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.32 Short Form 36 Health Survey – SF36

Dataset	SF36
Creating program	sf36.sas
Description	Short Form 36 Health Survey
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
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
PARSEQNO	num	PARAMETER SEQ. NO		Collected at CRF.
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.

Variable	Type	Label	Codes	Comments
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.33 Substance Use – SUBSTANC

Dataset	SUBSTANC
Creating program	substanc.sas
Description	Substance Use
Unique identifier	DCRFID,SUBABSYN, SUBVAL_D,SUBFRMDY
Sorted by	DCRFID,SUBABSYN, SUBVAL_D,SUBFRMDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBFRM_C, SUBTO_C, SUBVAL_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
SUBABSYN	char	HISTORY OF DRUG ABUSE		Collected at CRF.
SUBONGO	char	ONGOING (IF 'ONGO')		Collected at CRF.
SUBVAL	num	SUBSTANCE CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUBVAL_D	char	SUBSTANCE		Collected at CRF.

1.4.34 Timeline Follow-Back of Substance Use ALC – TLFBALC

Dataset	TLFBALC
Creating program	tlfbalc.sas
Description	Timeline Follow-Back of Substance Use ALC
Unique identifier	DCRFID,VISIT,AMT,COST, ALC_DY
Sorted by	DCRFID,VISIT,AMT,COST, ALC_DY
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: ALC_D, MONTH, DAY, YEAR

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
AMT	num	QUANTITY		Collected at CRF.
COST	num	COST		Collected at CRF.
ALCNONE	char	ALCOHOL NONE		Collected at CRF.
ALCND	char	ALCOHOL NOT DONE		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT NO.		Collected at CRF.
ALC_DY	num	RELATIVE DAY OF ALCOHOL CONSUMP		If ALC_D and CONSNT_D not missing then perform below logic to calculate ALC_DY, If ALC_D less than CONSNT_D then (ALC_D - CONSNT_D).Else if ALC_D is greater than equal to CONSNT_D then (ALC_D- CONSNT_D) +1.

1.4.35 Timeline Follow-Back of Substance Use SUB – TLFBSUB

Dataset	TLFBSUB
Creating program	tlfbsub.sas
Description	Timeline Follow-Back of Substance Use SUB
Unique identifier	DCRFID,VISIT,COST,SUBSTAN, SUBSTNDY
Sorted by	DCRFID,VISIT,COST,SUBSTAN, SUBSTNDY
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: MONTH, DAY, YEAR, SUBSTN_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
COST	num	COST		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUBSTAN	char	TYPE OF SUBSTANCE		Collected at CRF.
SUBNONE	char	SUBSTANCE NONE		Collected at CRF.
SUBND	char	SUBSTANCE NOT DONE		Collected at CRF.
USE	char	SUBSTANCE USE (Y OR N)?		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.
SUBSTNDY	num	RELATIVE DAY OF SUBSTANCE USE		If SUBSTN_D and CONSNT_D not missing then perform below logic to calculate SUBSTNDY, If SUBSTN_D less than CONSNT_D then (SUBSTN_D - CONSNT_D).Else if SUBSTN_D is greater than equal to CONSNT_D then (SUBSTN_D- CONSNT_D) +1.

1.4.36 Tobacco Use – TOBACCO

Dataset	TOBACCO
Creating program	tobacco.sas
Description	Tobacco Use
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: TOBA0Q_Y, OTHTBC

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
CIGARET	char	SMOKE CIGARETTES		Collected at CRF.
CTOBACCO	char	CHEW CHEWING TOBACCO		Collected at CRF.
DIPTIM	num	TIME OF FIRST DIP EACH DAY		Collected at CRF.
NUMCHEW	num	NUMBER OF YEARS PATIENT CHEWS		Collected at CRF.
NUMCIG	num	NUMBER OF CIGARETTES PATIENT SMOKES PER DAY		Collected at CRF.

Variable	Type	Label	Codes	Comments
NUMDIP	num	NUMBER OF TIMES PATIENT DIPS PER DAY		Collected at CRF.
SMOKTIM	num	TIME OF FIRST CIGARETTE SMOKE		Collected at CRF.
SMOKYR	num	NUMBER OF YEARS PATIENT SMOKES		Collected at CRF.
TOBA1	char	USE TOBACCO PRODUCTS CURRENTLY		Collected at CRF.
TOBA0	char	USE TOBACCO PRODUCTS IN PAST		Collected at CRF.
TOBA0_Y	num	YEARS USED TOBACCO PRODUCTS IN PAST		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.37 Phase/Termination Data – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.sas
Description	Phase/Termination Data
Unique identifier	DCRFID, TTPHASE, TTREAS
Sorted by	DCRFID, TTPHASE, TTREAS
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: NREM_D, NREM_C, TTFROM_D, TTFROM_C, 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
DB	char	ENTER DOUBLE BLIND?		Collected at CRF.
NRC	char	CONTINUE AS NRC?		Collected at CRF.
RDO	char	RETRIEVED DROP OUT?		Collected at CRF.
TTTYPE	char	DID PATIENT COMPLETE STUDY (COMPLETED/DISCONTINUED)		Collected at CRF.
TTPHASE	char	TERMINATION PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TTREAS	char	TERM. REASON		Collected at CRF.
TTREASNO	num	TERM. SEQ.		Collected at CRF.
NREMDY	num	RELATIVE DAY CONTINUED AS NRC PATIENT		If NREM_C and CONSNT_D not missing then perform below logic to calculate NREMDY, If NREM_C less than CONSNT_D then (NREM_C - CONSNT_D).Else if NREM_C is greater than equal to CONSNT_D then (NREM_C - CONSNT_D) +1.
TTFROMDY	num	RELATIVE DAY OF COMPLETED TRIAL		If TTFROM_C and CONSNT_D not missing then perform below logic to calculate TTFROMDY, If TTFROM_C less than CONSNT_D then (TTFROM_C - CONSNT_D).Else if TTFROM_C is greater than equal to CONSNT_D then (TTFROM_C - CONSNT_D) +1.

1.4.38 Subject Visits – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Subject Visits
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

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 NO.		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and CONSNT_D not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than CONSNT_D then (VISIT_D - CONSNT_D).Else if VISIT_D is greater than equal to CONSNT_D then (VISIT_D- CONSNT_D) +1.

1.4.39 Vital Sign Data – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	Vital Sign Data
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset due to missing values: DVALUE

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
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.

1.4.40 Young mania rating scale – YMRS

Dataset	YMRS
Creating program	ymrs.sas
Description	Young mania rating scale
Unique identifier	DCRFID,VISIT,PARAM
Sorted by	DCRFID,VISIT,PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RATERINI

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
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
PARSEQNO	num	PARAMETER SEQ. NO		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
VISIT	num	VISIT NO.		Collected at CRF.