

Clinical Development

**Topirimate<sup>®</sup>**

**CAPSS-168**

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	12 APR 2016

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

## 1. Datasets

### 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

#### Part I: Dataset description

Dataset	Name of dataset
Creating Program	The program that created the dataset
Description	Short description
Unique Identifier	Unique key
Sorted by	Sort key
Notes	Any useful notes

#### Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Codes	Codelist name
Comments	Variable source derivation explanation if variable derived.

### 1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/ Anonymisation data guidelines standards with the following exceptions:

- Subject initials will not be provided due to sensitivity of the data.
- 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+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Pharmacokinetics Dataset will not be submitted due to sensitivity of information.
- Remove "Other" free text terms.
- Remove the free text verbatim terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial, Bottle, lot, kit number will not be provided.

- Central Lab Specimen Label Number will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Specimen ID will not be submitted due to sensitivity of data.
- Completely missing variables will not be included in the De-Identified datasets.
- Dataset collected for reconciliation purpose will not be submitted.(ex.LABEL)
- MEDCODE dataset will not be submitted as it contains information regarding medication code number.

### 1.3. Data Files

The CAPSS-168 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the CAPSS-168 CSR data from the following folders.

## 1.4. Data Domains

### 1.4.1. Demographics – DEMOG

<b>Dataset</b>	DEMOG
<b>Creating program</b>	demog.sas
<b>Description</b>	Demographic Data
<b>Unique identifier</b>	DINV, DSUBJECT
<b>Sorted by</b>	DINV, DSUBJECT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, CONSDTN, CONSDT, RACEOT, BIRTHDTN, BIRTHDT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
RACE	num	RACE		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACEF	char	DECODE, RACE		Collected at CRF.
SEX	num	SEX		Collected at CRF.
SEXF	char	DECODE, SEX		Collected at CRF.
AGE	char	AGE IN YEARS		Date of birth is collected but can not be submitted as per HIPAA rules. Hence deriving AGE element. Derivation follows below rule: AGE= floor((CONSDT - BIRTHDT)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.

## 1.4.2. Adverse Events – ADVE

<b>Dataset</b>	ADVE
<b>Creating program</b>	adve.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	DINV,DSUBJECT, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PTINITS, EVENT_ID, PAGE, VERBATIM, AESTDTN, AESTDT, AESPDTN, AESPDT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.
NOAE	num	CHECK IF NO ADVERSE EVENT		Collected at CRF.
AECODE	char	AE DICTIONARY CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
SEXAE	char	GENDER		Collected at CRF.
BODYSYS	char	BODY SYSTEM		Collected at CRF.
PREF_TRM	char	PREFERRED TERM		Collected at CRF.
ONGOING	num	ONGOING		Collected at CRF.
ONGOINGF	char	DECODE, ONGOING		Collected at CRF.
OUTCOME	num	OUTCOME		Collected at CRF.
OUTCOMEF	char	DECODE, OUTCOME		Collected at CRF.
AESEV	num	AE SEVERITY		Collected at CRF.
AESEVF	char	DECODE, AE SEVERITY		Collected at CRF.
SAE	num	SAE		Collected at CRF.
SAEF	char	DECODE, SAE		Collected at CRF.
AEREL	num	AE RELATIONSHIP TO STUDY DRUG		Collected at CRF.
AERELF	char	DECODE, AE RELATIONSHIP TO STUDY DRUG		Collected at CRF.
AEACT	num	AE ACTION TAKEN		Collected at CRF.
AEACTF	char	DECODE, AE ACTION TAKEN		Collected at CRF.
CONCOM	num	CON.MEDS GIVEN		Collected at CRF.
CONCOMF	char	DECODE, CON.MEDS GIVEN		Collected at CRF.
LSTPG	num	CHECK IF LAST PAGE		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESTDY	num	RELATIVE START DAY		If AESTDT and CONSDT not missing then perform below logic to calculate AESTDY, If AESTDT less than CONSDT then (AESTDT - CONSDT).Else if AESTDT is greater than equal to CONSDT then (AESTDT- CONSDT) +1.
AESP DY	num	RELATIVE STOP DAY		If AESPDT and CONSDT not missing then perform below logic to calculate AESP DY, If AESPDT less than CONSDT then (AESPDT - CONSDT).Else if AESPDT is greater than equal to CONSDT then (AESPDT- CONSDT) +1.

## 1.4.3. Brief Psychiatric Rating Scale – BRIEFRAT

<b>Dataset</b>	BRIEFRAT
<b>Creating program</b>	briefrat.sas
<b>Description</b>	Brief Psychiatric Rating Scale
<b>Unique identifier</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, RATINIT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.
SYMPTOM	char	SYMPTOM DESCRIPTION		Collected at CRF.
RATING	num	BRIEF RATING SCORE		Collected at CRF.

Variable	Type	Label	Codes	Comments
RATINGF	char	DECODE, BRIEF RATING SCORE		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.

#### 1.4.4. Clinical Global Impressions Scale – CLINGLOB

<b>Dataset</b>	CLINGLOB
<b>Creating program</b>	clinglob.sas
<b>Description</b>	Clinical Global Impressions Scale
<b>Unique identifier</b>	DINV,DSUBJECT, EVENT_ID
<b>Sorted by</b>	DINV,DSUBJECT, EVENT_ID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, RATINIT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.

Variable	Type	Label	Codes	Comments
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SEVILL	num	SEVERITY OF ILLNESS		Collected at CRF.
SEVILLF	char	DECODE, SEVERITY OF ILLNESS		Collected at CRF.
IMPROV	num	GLOBAL IMPROVEMENT		Collected at CRF.
IMPROVF	char	DECODE, GLOBAL IMPROVEMENT		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT-CONSDT) +1.

## 1.4.5. Completion / Discontinuation Summary – COMPLETE

<b>Dataset</b>	COMPLETE
<b>Creating program</b>	complete.sas
<b>Description</b>	Completion / Discontinuation Summary
<b>Unique identifier</b>	DINV, DSUBJECT
<b>Sorted by</b>	DINV, DSUBJECT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PTINITS, EVENT_ID, VISDTN, VISDT, PAGE, LASTVDTN, LASTVDT, OTHSPEC, TAPERDTN, TAPERDT, BLINDDTN, BLINDDT, BLINDTM, BLINDTX, SIGDTN, SIGDT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
COMPLETE	num	SUBJECT COMPLETED DOUBLE BLIND?		Collected at CRF.

Variable	Type	Label	Codes	Comments
COMPLETEF	char	DECODE, SUBJECT COMPLETED DOUBLE BLIND?		Collected at CRF.
REASON	num	REASON FOR DISCONTINUATION		Collected at CRF.
REASONF	char	DECODE, REASON FOR DISCONTINUATION		Collected at CRF.
LOCSPEC	num	LACK OF EFFICACY, SPECIFY		Collected at CRF.
LOCSPECF	char	DECODE, LACK OF EFFICACY, SPECIFY		Collected at CRF.
TAPER	num	DID SUBJECT TAPER MEDICATION?		Collected at CRF.
TAPERF	char	DECODE, DID SUBJECT TAPER MEDICATION?		Collected at CRF.
UNBLIND	num	WAS MEDICATION UNBLINDED?		Collected at CRF.
UNBLINDF	char	DECODE, WAS MEDICATION UNBLINDED?		Collected at CRF.
INVSIG	num	INVESTIGATOR SIGNATURE PRESENT		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.

Variable	Type	Label	Codes	Comments
LASTVDY	num	RELATIVE DAY OF LAST VISIT		If LASTVDT and CONSDT not missing then perform below logic to calculate LASTVDY, If LASTVDT less than CONSDT then (LASTVDT - CONSDT).Else if LASTVDT is greater than equal to CONSDT then (LASTVDT- CONSDT) +1.
TAPERDY	num	RELATIVE DAY OF MEDICATION TAPER		If TAPERDT and CONSDT not missing then perform below logic to calculate TAPERDY, If TAPERDT less than CONSDT then (TAPERDT - CONSDT).Else if TAPERDT is greater than equal to CONSDT then (TAPERDT- CONSDT) +1.
SIGDY	num	RELATIVE DAY OF SIGNATURE		If SIGDT and CONSDT not missing then perform below logic to calculate SIGDY, If SIGDT less than CONSDT then (SIGDT - CONSDT).Else if SIGDT is greater than equal to CONSDT then (SIGDT- CONSDT) +1.

## 1.4.6.Recent / Concomitant Medication – CONMEDS

<b>Dataset</b>	CONMEDS
<b>Creating program</b>	conmeds.sas
<b>Description</b>	Recent / Concomitant Medication
<b>Unique identifier</b>	DINV,DSUBJECT, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PTINITS, VISDTN, VISDT, PAGE, VERBATIM, INDICT, DRGSTDN, DRGSTD, DRGSPDTN, DRGSPDT, REASON

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.
DRUGCODE	char	DRUG CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUGDESC	char	CODED DRUG DESCRIPTION		Collected at CRF.
ATC_CD	char	ANATOMIC CODE		Collected at CRF.
ATC_TEXT	char	ANATOMIC DESCRIPTION		Collected at CRF.
GENDESC	char	GENERIC DESCRIPTION		Collected at CRF.
PHRMCLAS	char	PHARMACOLOGICAL CLASS		Collected at CRF.
THERCLAS	char	THERAPEUTIC CLASS		Collected at CRF.
ROUTE	char	ROUTE OF ADMINISTRATION		Collected at CRF.
TOTDOSE	char	TOTAL DAILY DOSE		Collected at CRF.
ONGOING	num	ONGOING		Collected at CRF.
ONGOINGF	char	DECODE, ONGOING		Collected at CRF.
LSTPG	num	CHECK IF LAST PAGE		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.

Variable	Type	Label	Codes	Comments
DRGSTDY	num	RELATIVE DRUG START DAY		If DRGSTDT and CONSDT not missing then perform below logic to calculate DRGSTDY, If DRGSTDT less than CONSDT then (DRGSTDT - CONSDT).Else if DRGSTDT is greater than equal to CONSDT then (DRGSTDT- CONSDT) +1.
DRGSPDY	num	RELATIVE DRUG STOP DAY		If DRGSPDT and CONSDT not missing then perform below logic to calculate DRGSPDY, If DRGSPDT less than CONSDT then (DRGSPDT - CONSDT).Else if DRGSPDT is greater than equal to CONSDT then (DRGSPDT- CONSDT) +1.

## 1.4.7. Drug Accountability Record – DRUGDISP

<b>Dataset</b>	DRUGDISP
<b>Creating program</b>	drugdisp.sas
<b>Description</b>	Drug Accountability Record
<b>Unique identifier</b>	DINV,DSUBJECT ,DISPDTY,BOTNUM, TABSRET, RETDY, DOSE
<b>Sorted by</b>	DINV,DSUBJECT ,DISPDTY,BOTNUM, TABSRET, RETDY, DOSE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PTINITS, EVENT_ID, PAGE, DISPDTN, DISPDT, RETDTN, RETDT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
BOTNUM	num	BOTTLE NUMBER		Collected at CRF.
TABSDISP	num	NUMBER TABLETS DISPENSED		Collected at CRF.
DOSE	num	DOSE		Collected at CRF.
TABSRET	num	NUMBER TABLETS RETURNED		Collected at CRF.

Variable	Type	Label	Codes	Comments
DISPDY	num	RELATIVE DAY DISPENSED		If DISPDT and CONSDT not missing then perform below logic to calculate DISPDY, If DISPDT less than CONSDT then (DISPDT - CONSDT).Else if DISPDT is greater than equal to CONSDT then (DISPDT- CONSDT) +1.
RETDY	num	RELATIVE DAY RETURNED		If RETDT and CONSDT not missing then perform below logic to calculate RETDY, If RETDT less than CONSDT then (RETDY - CONSDT).Else if RETDT is greater than equal to CONSDT then (RETDY- CONSDT) +1.

## 1.4.8. Structured Clinical Interview for DSMIV Axis I Disorders – DSMIV

<b>Dataset</b>	DSMIV
<b>Creating program</b>	dsmiv.sas
<b>Description</b>	Structured Clinical Interview for DSMIV Axis I Disorders
<b>Unique identifier</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PTINITS, VISDTN, VISDT, PAGE, DESCRIBE, GUSTAT, GUSTATF, FATIGUE, FATIGUEF, VIVIDDF, VIVIDDF, INSOMN, INSOMNF, APPETITE, APPETITF, PMOTOR, PMOTORF</p>

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPISODE	char	EPISODE NAME		Collected at CRF.
EPISODEF	char	DECODE, EPISODE NAME		Collected at CRF.
ORDER	char	QUESTION ORDER		Collected at CRF.
DSMIVTX	char	DSMIV QUESTION TEXT		Collected at CRF.
DSMIV	char	DSMIV RATING		Collected at CRF.
ELEMOOD	num	ELEVATED MOOD		Collected at CRF.
ELEMOODF	char	DECODE, ELEVATED MOOD		Collected at CRF.
IRITMOOD	num	IRRITABLE MOOD		Collected at CRF.
IRITMOOF	char	DECODE, IRRITABLE MOOD		Collected at CRF.
RELDEL	num	RELIGIOUS DELUSIONS		Collected at CRF.
RELDEL F	char	DECODE, RELIGIOUS DELUSIONS		Collected at CRF.
GUILT	num	DELUSIONS OF GUILT		Collected at CRF.
GUILTF	char	DECODE, DELUSIONS OF GUILT		Collected at CRF.
JEALOUS	num	JEALOUS DELUSIONS		Collected at CRF.
JEALOUS F	char	DECODE, JEALOUS DELUSIONS		Collected at CRF.
EROTO	num	EROTOMANIC DELUSIONS		Collected at CRF.
EROTO F	char	DECODE, EROTOMANIC DELUSIONS		Collected at CRF.
OLFACT	num	OLFACTORY		Collected at CRF.

Variable	Type	Label	Codes	Comments
OLFACF	char	DECODE, OLFACTORY		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT - CONSDT) +1.

#### 1.4.9. Electrocardiogram – ECG

<b>Dataset</b>	ECG
<b>Creating program</b>	ecg.sas
<b>Description</b>	Electrocardiogram
<b>Unique identifier</b>	DINV, DSUBJECT
<b>Sorted by</b>	DINV, DSUBJECT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, ECGDTN, ECGDT, COMMENT1, COMMENT2

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.

Variable	Type	Label	Codes	Comments
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
FINDING	num	ECG FINDING		Collected at CRF.
FINDINGF	char	DECODE, ECG FINDING		Collected at CRF.
CLINSIG	num	CLINICALLY SIGNIFICANT?		Collected at CRF.
CLINSIGF	char	DECODE, CLINICALLY SIGNIFICANT?		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT-CONSDT) +1.
ECGDY	num	RELATIVE DAY ECG PERFORMED		If ECGDT and CONSDT not missing then perform below logic to calculate ECGDY, If ECGDT less than CONSDT then (ECGDT - CONSDT).Else if ECGDT is greater than equal to CONSDT then (ECGDT-CONSDT) +1.

## 1.4.10. Entrance Criteria – ENTRANCE

<b>Dataset</b>	ENTRANCE
<b>Creating program</b>	entrance.sas
<b>Description</b>	Entrance Criteria
<b>Unique identifier</b>	DINV, DSUBJECT
<b>Sorted by</b>	DINV, DSUBJECT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PTINITS, VISDTN, VISDT, PAGE, INCNUM2, INCDESC1, INCDESC2, EXCDESC1, EXCDESC2, EXCEPTX, MONITOR, EXCEPDTN, EXCEPDT, SIGDTN, SIGDT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SATISFYC	num	DOES SUBJECT SATISFY CRITERIA?		Collected at CRF.

Variable	Type	Label	Codes	Comments
SATISFYF	char	DECODE, DOES SUBJECT SATISFY CRITERIA?		Collected at CRF.
INCNUM1	num	INCLUSION CRITERIA NUMBER 1		Collected at CRF.
EXCNUM1	num	EXCLUSION CRITERIA NUMBER 1		Collected at CRF.
EXCNUM2	num	EXCLUSION CRITERIA NUMBER 2		Collected at CRF.
EXCEPT	num	WAS EXCEPTION GRANTED?		Collected at CRF.
EXCEPTF	char	DECODE, WAS EXCEPTION GRANTED?		Collected at CRF.
DSMCRIT	num	DSMIV CRITERIA NUMBER		Collected at CRF.
INVSIG	num	INVESTIGATOR SIGNATURE PRESENT		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.

Variable	Type	Label	Codes	Comments
EXCEPDY	num	RELATIVE DAY OF EXCEPTION		If EXCEPDT and CONSDT not missing then perform below logic to calculate EXCEPDY, If EXCEPDT less than CONSDT then (EXCEPDT - CONSDT).Else if EXCEPDT is greater than equal to CONSDT then (EXCEPDT- CONSDT) +1.
SIGDY	num	RELATIVE DAY OF SIGNATURE		If SIGDT and CONSDT not missing then perform below logic to calculate SIGDY, If SIGDT less than CONSDT then (SIGDT - CONSDT).Else if SIGDT is greater than equal to CONSDT then (SIGDT- CONSDT) +1.

## 1.4.11. Family Psychiatric History – FAMHIST

<b>Dataset</b>	FAMHIST
<b>Creating program</b>	famhist.sas
<b>Description</b>	Family Psychiatric History
<b>Unique identifier</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.
DISORDER	num	DISORDER		Collected at CRF.
DISORDEF	char	DECODE, DISORDER		Collected at CRF.

Variable	Type	Label	Codes	Comments
HISTORY	num	FAMILY HISTORY		Collected at CRF.
HISTORYF	char	DECODE, FAMILY HISTORY		Collected at CRF.
MEMBER	num	MEMBER		Collected at CRF.
MEMBERF	char	DECODE, MEMBER		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, if VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT - CONSDT) +1.

## 1.4.12. Global Assessment Scale – GAS

<b>Dataset</b>	GAS
<b>Creating program</b>	gas.sas
<b>Description</b>	Global Assessment Scale
<b>Unique identifier</b>	DINV,DSUBJECT, EVENT_ID
<b>Sorted by</b>	DINV,DSUBJECT, EVENT_ID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, RATINIT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.

Variable	Type	Label	Codes	Comments
GAS	num	SUBJECT GAS RATING		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.

#### 1.4.13. Central Laboratory Data – LABD

<b>Dataset</b>	LABD
<b>Creating program</b>	labd.sas
<b>Description</b>	Central Laboratory Data
<b>Unique identifier</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PTINITS, VISDTN, VISDT, BIRTHDTN, BIRTHDT, SEX , SEXF, LABDTN, LABDT, ACCNO, CHILD POT, DOSESTDN, DOSESTD, DOSESTTM, DOSENDTN, DOSENDT, DOSENDTM, RETVIS13, FASTING, COMMENT1, COMMENT2

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
LABTM	num	LAB COLLECTION TIME		Collected at CRF.
VISITYPE	char	VISIT TYPE		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.
LABTEST	char	LAB TEST		Collected at CRF.
LABCD	char	LAB TEST CODE		Collected at CRF.
UNIT	char	UNIT		Collected at CRF.
LABTYPE	char	LAB RESULT TYPE		Collected at CRF.
RESULTN	num	LAB RESULT NUMERIC		Collected at CRF.
LABLOW	num	LAB NORMAL LOW		Collected at CRF.
LABHIGH	num	LAB NORMAL HIGH		Collected at CRF.
RESULTNN	char	RESULT NON NUMERIC		Collected at CRF.
CLINSTAT	char	LAB CLINICAL STATUS		Collected at CRF.
LABGROUP	char	LAB GROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT-CONSDT) +1.
LABDY	num	RELATIVE LAB DAY		If LABDT and CONSDT not missing then perform below logic to calculate LABDY, If LABDT less than CONSDT then (LABDT - CONSDT).Else if LABDT is greater than equal to CONSDT then (LABDT-CONSDT) +1.

## 1.4.14. Laboratory Analyses – LABS

<b>Dataset</b>	LABS
<b>Creating program</b>	labs.sas
<b>Description</b>	Laboratory Analyses
<b>Unique identifier</b>	DINV,DSUBJECT, EVENT_ID
<b>Sorted by</b>	DINV,DSUBJECT, EVENT_ID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, REASPEC, LDMSDTN, LDMSDT, VENIDTN, VENIDT, LMEDDTN, LMEDDT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
COLLECT	num	WERE ALL SAMPLES COLLECTED?		Collected at CRF.

Variable	Type	Label	Codes	Comments
COLLECTF	char	DECODE, WERE ALL SAMPLES COLLECTED?		Collected at CRF.
LDMSTM	num	TIME OF MOOD STABILIZER		Collected at CRF.
VENITM	num	TIME OF VENIPUNCTURE		Collected at CRF.
WBLOOD	num	WHOLE BLOOD SAMPLES COLLECTED?		Collected at CRF.
WBLOODF	char	DECODE, WHOLE BLOOD SAMPLES COLLECTED?		Collected at CRF.
LMEDTM	num	TIME OF STUDY MEDICATION		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.
LDMSDY	num	RELATIVE DAY OF MOOD STABILIZER		If LDMSDT and CONSDT not missing then perform below logic to calculate LDMSDY, If LDMSDT less than CONSDT then (LDMSDT - CONSDT).Else if LDMSDT is greater than equal to CONSDT then (LDMSDT- CONSDT) +1.

Variable	Type	Label	Codes	Comments
VENIDY	num	RELATIVE DAY OF VENIPUNCTURE		If VENIDT and CONSDT not missing then perform below logic to calculate VENIDY, If VENIDT less than CONSDT then (VENIDT - CONSDT).Else if VENIDT is greater than equal to CONSDT then (VENIDT- CONSDT) +1.
LMEDDY	num	RELATIVE DAY OF STUDY MEDICATION		If LMEDDT and CONSDT not missing then perform below logic to calculate LMEDDY, If LMEDDT less than CONSDT then (LMEDDT - CONSDT).Else if LMEDDT is greater than equal to CONSDT then (LMEDDT- CONSDT) +1.

## 1.4.15. Medical History – MEDHIST

<b>Dataset</b>	MEDHIST
<b>Creating program</b>	medhist.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, OTHSPEC, HISTDES1, HISTDES2

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.
SYSTEM	char	SYSTEM		Collected at CRF.
HISTORY	num	HISTORY		Collected at CRF.

Variable	Type	Label	Codes	Comments
HISTORYF	char	DECODE, HISTORY		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT - CONSDT) +1.

#### 1.4.16. Montgomery-Asberg Depression Rating Scale – MONTGOM

<b>Dataset</b>	MONTGOM
<b>Creating program</b>	montgom.sas
<b>Description</b>	Montgomery-Asberg Depression Rating Scale
<b>Unique identifier</b>	DINV,DSUBJECT, EVENT_ID
<b>Sorted by</b>	DINV,DSUBJECT, EVENT_ID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, RATINIT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.

Variable	Type	Label	Codes	Comments
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
APPSAD	num	APPARENT SADNESS		Collected at CRF.
APPSADF	char	DECODE, APPARENT SADNESS		Collected at CRF.
REPSAD	num	REPORTED SADNESS		Collected at CRF.
REPSADF	char	DECODE, REPORTED SADNESS		Collected at CRF.
ITENSION	num	INNER TENSION		Collected at CRF.
ITENSIOF	char	DECODE, INNER TENSION		Collected at CRF.
RSLEEP	num	REDUCED SLEEP		Collected at CRF.
RSLEEPEF	char	DECODE, REDUCED SLEEP		Collected at CRF.
RAPPET	num	REDUCED APPETITE		Collected at CRF.
RAPPETF	char	DECODE, REDUCED APPETITE		Collected at CRF.
CDIFFIC	num	CONCENTRATION DIFFICULTIES		Collected at CRF.
CDIFFICF	char	DECODE, CONCENTRATION DIFFICULTIES		Collected at CRF.
LASSITUD	num	LASSITUDE		Collected at CRF.
LASSITUF	char	DECODE, LASSITUDE		Collected at CRF.
ITOFEEL	num	INABILITY TO FEEL		Collected at CRF.
ITOFEELEF	char	DECODE, INABILITY TO FEEL		Collected at CRF.

Variable	Type	Label	Codes	Comments
PTHOUGHT	num	PESSIMISTIC THOUGHTS		Collected at CRF.
PTHOUGHF	char	DECODE, PESSIMISTIC THOUGHTS		Collected at CRF.
STHOUGHT	num	SUICIDAL THOUGHTS		Collected at CRF.
STHOUGHF	char	DECODE, SUICIDAL THOUGHTS		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.

## 1.4.17. Past Medications – PASTMEDS

<b>Dataset</b>	PASTMEDS
<b>Creating program</b>	pastmeds.sas
<b>Description</b>	Past Medications
<b>Unique identifier</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:  PTINITS, VISDTN, VISDT, PAGE, VERBATIM, INDICT, DRGSTDN, DRGSTD, DRGSPDTN, DRGSPDT, DISCREAS

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.
DRUGCODE	char	DRUG CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUGDESC	char	CODED DRUG DESCRIPTION		Collected at CRF.
ATC_CD	char	ANATOMIC CODE		Collected at CRF.
ATC_TEXT	char	ANATOMIC DESCRIPTION		Collected at CRF.
GENDESC	char	GENERIC DESCRIPTION		Collected at CRF.
PHRMCLAS	char	PHARMACOLOGICAL CLASS		Collected at CRF.
THERCLAS	char	THERAPEUTIC CLASS		Collected at CRF.
ROUTE	char	ROUTE OF ADMINISTRATION		Collected at CRF.
TOTDOSE	char	TOTAL DAILY DOSE		Collected at CRF.
LSTPG	num	CHECK IF LAST PAGE		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.
DRGSTDY	num	RELATIVE DRUG START DAY		If DRGSTDT and CONSDT not missing then perform below logic to calculate DRGSTDY, If DRGSTDT less than CONSDT then (DRGSTDT - CONSDT).Else if DRGSTDT is greater than equal to CONSDT then (DRGSTDT- CONSDT) +1.
DRGSPDY	num	RELATIVE DRUG STOP DAY		If DRGSPDT and CONSDT not missing then perform below logic to calculate DRGSPDY, If DRGSPDT less than CONSDT then (DRGSPDT - CONSDT).Else if DRGSPDT is greater than equal to CONSDT then (DRGSPDT- CONSDT) +1.

## 1.4.18. Complete Physical Examination – PHYSICAL

<b>Dataset</b>	PHYSICAL
<b>Creating program</b>	physical.sas
<b>Description</b>	Complete Physical Examination
<b>Unique identifier</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, EXAMDTN, EXAMDT, OTHSPEC, ABNORMTX

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
NOTDONE	num	NOT DONE		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.
SYSTEM	char	SYSTEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
NORMAB	num	NORMAL ABNORMAL		Collected at CRF.
NORMABF	char	DECODE, NORMAL ABNORMAL		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.
EXAMDY	num	RELATIVE DAY OF EXAMINATION		If EXAMDT and CONSDT not missing then perform below logic to calculate EXAMDY, If EXAMDT less than CONSDT then (EXAMDT - CONSDT).Else if EXAMDT is greater than equal to CONSDT then (EXAMDT- CONSDT) +1.

## 1.4.19. Subject Psychiatric History – PSYCHIST

<b>Dataset</b>	PHYSICAL
<b>Creating program</b>	physical.sas
<b>Description</b>	Complete Physical Examination
<b>Unique identifier</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT,EVENT_ID, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, REPSPTD,REPSPTDN,REPSTDT,REPSTDTN

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PRIORMAN	num	LAST 12 MONTHS PRIOR MANIC EPISODES		Collected at CRF.
TOTMAN	num	TOTAL MANIC EPISODES		Collected at CRF.

Variable	Type	Label	Codes	Comments
FIRSTMAN	char	AGE OF FIRST MANIC EPISODE		If firstman is greater than 89 then group to '90+' otherwise FIRSTMAN = FIRSTMAN. Grouping will be performed based on HIPAA privacy rules.
PRIORDEP	num	LAST 12 MONTHS PRIOR DEPRESSED EPISODES		Collected at CRF.
TOTDEP	num	TOTAL DEPRESSED EPISODES		Collected at CRF.
FIRSTDEP	char	AGE OF FIRST DEPRESSED EPISODE		If firstdep is greater than 89 then group to '90+' otherwise FIRSTDEP = FIRSTDEP. Grouping will be performed based on HIPAA privacy rules.
PRIORMIX	num	LAST 12 MONTHS PRIOR MIXED EPISODES		Collected at CRF.
TOTMIX	num	TOTAL MIXED EPISODES		Collected at CRF.
FIRSTMIX	char	AGE OF FIRST MIXED EPISODE		If firstmix is greater than 89 then group to '90+' otherwise FIRSTMIX = FIRSTMIX. Grouping will be performed based on HIPAA privacy rules.
EPISODE	num	MOST RECENT EPISODE?		Collected at CRF.
EPISODEF	char	DECODE, MOST RECENT EPISODE?		Collected at CRF.
ONGOING	num	ONGOING		Collected at CRF.
NUMHOSP	num	NUMBER OF HOSPITALIZATIONS		Collected at CRF.
PSYCHO	num	EXPERIENCED PSYCHOTIC EPISODE?		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSYCHOF	char	DECODE, EXPERIENCED PSYCHOTIC EPISODE?		Collected at CRF.
PSYCHNUM	num	HOW MANY EPISODES?		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.
REPSTDY	num	RELATIVE MOST RECENT EPISODE START DAY		If REPSTDY and CONSDT not missing then perform below logic to calculate REPSTDY, If REPSTDY less than CONSDT then (REPSTDY - CONSDT).Else if REPSTDY is greater than equal to CONSDT then (REPSTDY- CONSDT) +1.
RESPDY	num	RELATIVE MOST RECENT EPISODE STOP DAY		If RESPDY and CONSDT not missing then perform below logic to calculate RESPDY, If RESPDY less than CONSDT then (RESPDY - CONSDT).Else if RESPDY is greater than equal to CONSDT then (RESPDY- CONSDT) +1.

## 1.4.20. Study Medication Dosing – SMED

<b>Dataset</b>	SMED
<b>Creating program</b>	smed.sas
<b>Description</b>	Study Medication Dosing
<b>Unique identifier</b>	DINV,DSUBJECT,SEQNUM
<b>Sorted by</b>	DINV,DSUBJECT, SEQNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PTINITS, EVENT_ID, PAGE, FDOSEDTN, FDOSEDT, LDOSEDTN, LDOSEDT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
SEQNUM	num	SEQUENCE NUMBER		Collected at CRF.
DOSE	num	DOSAGE PRESCRIBED		Collected at CRF.
LSTPG	num	CHECK IF LAST PAGE		Collected at CRF.

Variable	Type	Label	Codes	Comments
FDOSEDY	num	RELATIVE DAY OF FIRST DOSE		If FDOSEDT and CONSDT not missing then perform below logic to calculate FDOSEDY, If FDOSEDT less than CONSDT then (FDOSEDT - CONSDT).Else if FDOSEDT is greater than equal to CONSDT then (FDOSEDT- CONSDT) +1.
LDOSEDY	num	RELATIVE DAY OF LAST DOSE		If LDOSEDT and CONSDT not missing then perform below logic to calculate LDOSEDY, If LDOSEDT less than CONSDT then (LDOSEDT - CONSDT).Else if LDOSEDT is greater than equal to CONSDT then (LDOSEDT- CONSDT) +1.

## 1.4.21. Vital Signs – VITALS

<b>Dataset</b>	VITALS
<b>Creating program</b>	vitals.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DINV,DSUBJECT, EVENT_ID
<b>Sorted by</b>	DINV,DSUBJECT, EVENT_ID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
NOTREQ	num	VISIT A1 NOT REQUIRED		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHTU	char	HEIGHT UNITS		Collected at CRF.

Variable	Type	Label	Codes	Comments
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHTU	char	WEIGHT UNITS		Collected at CRF.
TEMP	num	TEMPERATURE		Collected at CRF.
TEMPU	char	TEMPERATURE UNITS		Collected at CRF.
SYST	num	SYSTOLIC BLOOD PRESSURE		Collected at CRF.
DIAST	num	DIASTOLIC BLOOD PRESSURE		Collected at CRF.
PULSE	num	PULSE		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT - CONSDT) +1.

## 1.4.22. Young Mania Rating Scale – YMRS

<b>Dataset</b>	YMRS
<b>Creating program</b>	ymrs.sas
<b>Description</b>	Young Mania Rating Scale
<b>Unique identifier</b>	DINV,DSUBJECT, EVENT_ID
<b>Sorted by</b>	DINV,DSUBJECT, EVENT_ID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PTINITS, VISDTN, VISDT, PAGE, RATINIT

Variable	Type	Label	Codes	Comments
PROTO	char	PROTOCOL NUMBER		Collected at CRF.
DINV	num	INVESTIGATOR NO ASSIGNED FOR DE-IDENTITY		Randomly assigned investigator number for de-identity.
DSUBJECT	num	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for de-identity.
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
ELVMOOD	num	ELEVATED MOOD		Collected at CRF.
ELVMOODF	char	DECODE, ELEVATED MOOD		Collected at CRF.
INCMOTOR	num	INCREASED MOTOR ACTIVITY		Collected at CRF.

Variable	Type	Label	Codes	Comments
INCMOTOF	char	DECODE, INCREASED MOTOR ACTIVITY		Collected at CRF.
SEXINT	num	SEXUAL INTEREST		Collected at CRF.
SEXINTF	char	DECODE, SEXUAL INTEREST		Collected at CRF.
SLEEP	num	SLEEP		Collected at CRF.
SLEEPF	char	DECODE, SLEEP		Collected at CRF.
IRRITAB	num	IRRITABILITY		Collected at CRF.
IRRITABF	char	DECODE, IRRITABILITY		Collected at CRF.
SPEECH	num	SPEECH		Collected at CRF.
SPEECHF	char	DECODE, SPEECH		Collected at CRF.
LANGUAGE	num	LANGUAGE		Collected at CRF.
LANGUAGEF	char	DECODE, LANGUAGE		Collected at CRF.
CONTENT	num	CONTENT		Collected at CRF.
CONTENTF	char	DECODE, CONTENT		Collected at CRF.
DISRUPT	num	DISRUPTIVE		Collected at CRF.
DISRUPTF	char	DECODE, DISRUPTIVE		Collected at CRF.
APPEARNC	num	APPEARANCE		Collected at CRF.
APPEARNF	char	DECODE, APPEARANCE		Collected at CRF.
INSIGHT	num	INSIGHT		Collected at CRF.
INSIGHTF	char	DECODE, INSIGHT		Collected at CRF.

Variable	Type	Label	Codes	Comments
TOTRAT	num	TOTAL RATING		Collected at CRF.
VISDY	num	RELATIVE VISIT DAY		If VISDT and CONSDT not missing then perform below logic to calculate VISDY, If VISDT less than CONSDT then (VISDT - CONSDT).Else if VISDT is greater than equal to CONSDT then (VISDT- CONSDT) +1.