Clinical Development

Topirimate®

TOP-PDMD-005

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's relative day cannot be calculated.
- Comments dataset will be submitted with zero observation.
- Screening Visit Date will be used as Reference Date to derive relative days.
- Lab Name and Lab Identifier information will not be provided. (eg. LABNAME, LABLOC)
- Rater's Initial or Patient's Initial will not be provided as it is sensitive. (eg. RATINIT)
- Dataset containing Investigator information will not be submitted. (eg. INVNAM)
- Dataset information related to lab conversion units will not be submitted. (eg. LABCONV, LABNORMS and LABNORM)
- Dataset containing personal information related to subjects will not be submitted. (eg. PATINFO, PREMORB)

1.3.   Data Files

The TOP-PDMD-005 CSR Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4.   Data Domains

1.4.1. Demography – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demography
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, EVDATE, EVDATEN, BIRTHDT, BIRTHDTN,RACESPEC

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DSCTRY	char	DE-IDENTIFY STUDY COUNTRY		Group element to protect PII.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient 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
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
SEX	num	SEX		Collected at CRF.
SEXF	char	DECODE, SEX		Collected at CRF.
RACE	num	RACE		Collected at CRF.
RACEF	char	DECODE, RACE		Collected at CRF.
TRTGRP	char	TREATMENT GROUP		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= floor((DEMOG.EVDATE − BIRTHDT)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Center Number For De-Identity

1.4.2. Adverse Events Details – ADVEDTL

Dataset	ADVEDTL
Creating program	advedtl.sas
Description	Adverse Events Details
Unique identifier	DPATNO,EVENT_ID,BODYSYS,PREF_TRM,ENTRYNO
Sorted by	DPATNO,EVENT_ID,BODYSYS,PREF_TRM,ENTRYNO
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 non significant elements or due to missing values: SCTRY, PAG_NAME, VERBATIM, ADVCODE2, ADVDESC2, ONSETDT, ONSETDTN, STOPDT, STOPDTN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
ADVCODE	char	DICTIONARY CODE ASSIGNED TO AE		Collected at CRF.
ADVDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
OUTCOME	num	AE OUTCOME		Collected at CRF.
OUTCOMEF	char	DECODE, AE OUTCOME		Collected at CRF.
SEVERITY	num	SEVERITY OF AE		Collected at CRF.
SEVERITF	char	DECODE, SEVERITY OF AE		Collected at CRF.
SERIOUS	num	WAS AE SERIOUS?		Collected at CRF.
SERIOUSF	char	DECODE, WAS AE SERIOUS?		Collected at CRF.
DRUGREL	num	WAS AE RELATED TO DRUG?		Collected at CRF.
DRUGRELF	char	DECODE, WAS AE RELATED TO DRUG?		Collected at CRF.
ACTION	num	ACTION TAKEN		Collected at CRF.
ACTIONF	char	DECODE, ACTION TAKEN		Collected at CRF.
CONCOM	num	WERE CONCURRENT MEDS GIVEN?		Collected at CRF.
CONCOMF	char	DECODE, WERE CONCURRENT MEDS GIVEN?		Collected at CRF.
SEXAE	char	GENDER		Collected at CRF.
BODYSYS	char	BODY SYSTEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
PREF_TRM	char	PREFERRED TERM		Collected at CRF.
ONSETDY	num	RELATIVE DAY OF ONSET		If ONSETDT and DEMOG.EVDATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than DEMOG.EVDATE then (ONSETDT - DEMOG.EVDATE).Else if ONSETDT is greater than equal to DEMOG.EVDATE then (ONSETDT- DEMOG.EVDATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOPDT and DEMOG.EVDATE not missing then perform below logic to calculate STOPDY, If STOPDT less than DEMOG.EVDATE then (STOPDT - DEMOG.EVDATE).Else if STOPDT is greater than equal to DEMOG.EVDATE then (STOPDT- DEMOG.EVDATE) +1.

1.4.3. Advehdr – ADVEHDR

Dataset	ADVEHDR
Creating program	advehdr.sas
Description	Advehdr
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: SCTRY, PAG_NAME, EVDATE, EVDATEN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVEXP	Num	WERE THERE ANY TREATMENT EMERGENT AES?		Collected at CRF.
ADVEXPF	Char	DECODE, WERE THERE ANY AES?		Collected at CRF.

1.4.4. Advepers – ADVEPERS

Dataset	ADVEPERS
Creating program	advepers.sas
Description	Advepers
Unique identifier	DPATNO,EVENT_ID,BODYSYS,PREF_TRM,ENTRYNO
Sorted by	DPATNO,EVENT_ID,BODYSYS,PREF_TRM,ENTRYNO
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 non significant elements or due to missing values: SCTRY, PAG_NAME, EVDATE, EVDATEN, LCONTDT, LCONTDTN, VERBATIM, ONSETDT, ONSETDTN, STOPDT, STOPDTN, SEVERITY, SEVERITF, SERIOUS, SERIOUSF, DRUGREL, DRUGRELF, CNO, B_STATUS

Variable	Type	Label	Codes	Comments
DRUG	Char	DRUG CODE		Collected at CRF.
TAREA	Char	INDICATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	Char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	Char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	Char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	Char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	Num	PHASE OF STUDY		Collected at CRF.
PHASEF	Char	DECODE, PHASE OF STUDY		Collected at CRF.
ENTRYNO	Num	ENTRY NUMBER		Collected at CRF.
ADVCODE	Char	INCLUDED TERM CODE		Collected at CRF.
ADVDESC	Char	INCLUDED TERM 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.
OUTCOME	Num	OUTCOME		Collected at CRF.
OUTCOMEF	Char	DECODE, OUTCOME		Collected at CRF.
LCONTDY	Num	RELATIVE DAY OF LAST SUBJECT CONTACT		If LCONTDT and DEMOG.EVDATE not missing then perform below logic to calculate LCONTDY, If LCONTDT less than DEMOG.EVDATE then (LCONTDT - DEMOG.EVDATE).Else if LCONTDT is greater than equal to DEMOG.EVDATE then (LCONTDT- DEMOG.EVDATE) +1.

Variable	Type	Label	Codes	Comments
ONSETDY	Num	RELATIVE DAY OF ONSET		If ONSETDT and DEMOG.EVDATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than DEMOG.EVDATE then (ONSETDT - DEMOG.EVDATE).Else if ONSETDT is greater than equal to DEMOG.EVDATE then (ONSETDT- DEMOG.EVDATE) +1.
STOPDY	Num	RELATIVE RESOLVED DAY		If STOPDT and DEMOG.EVDATE not missing then perform below logic to calculate STOPDY, If STOPDT less than DEMOG.EVDATE then (STOPDT - DEMOG.EVDATE).Else if STOPDT is greater than equal to DEMOG.EVDATE then (STOPDT- DEMOG.EVDATE) +1.

1.4.5. Advethr – ADVETHR

Dataset	ADVETHR
Creating program	advethr.sas
Description	Advethr
Unique identifier	DPATNO,EVENT_ID,DRUGCODE,ENTRYNO
Sorted by	DPATNO,EVENT_ID,DRUGCODE,ENTRYNO
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 non significant elements or due to missing values: SCTRY, PAG_NAME, VERBATIM, DRUGCOD2, DRUGDES2, ONSETDT, ONSETDTN, STOPDT, STOPDTN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
DRUGCODE	char	DRUG CODE		Collected at CRF.
DRUGDESC	char	DRUG DESCRIPTION		Collected at CRF.
ATC_CD	char	ANATOMIC CODE		Collected at CRF.
GENDESC	char	GENERIC DESCRIPTION		Collected at CRF.
ATC_TEXT	char	ANATOMIC DESCRIPTION		Collected at CRF.
PHRMCLAS	char	PHARMACOLOGICAL CLASS		Collected at CRF.
THERCLAS	char	THERAPEUTIC CLASS		Collected at CRF.
THRYPNO	num	THERAPY NUMBER		Collected at CRF.
ONSETDY	num	RELATIVE DAY OF ONSET		If ONSETDT and DEMOG.EVDATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than DEMOG.EVDATE then (ONSETDT - DEMOG.EVDATE).Else if ONSETDT is greater than equal to DEMOG.EVDATE then (ONSETDT- DEMOG.EVDATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOPDT and DEMOG.EVDATE not missing then perform below logic to calculate STOPDY, If STOPDT less than DEMOG.EVDATE then (STOPDT - DEMOG.EVDATE).Else if STOPDT is greater than equal to DEMOG.EVDATE then (STOPDT- DEMOG.EVDATE) +1.

1.4.6. Brief Psychiatric Rating Scale – BRIEFRAT

Dataset	BRIEFRAT
Creating program	briefrat.sas
Description	Brief Psychiatric Rating Scale
Unique identifier	DPATNO,EVENT_ID,SYMPTOMF
Sorted by	DPATNO,EVENT_ID,SYMPTOMF
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN, RATINIT

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
EVTIME	num	TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
SYMPTOM	num	SYMPTOM		Collected at CRF.
SYMPTOMF	char	DECODE, SYMPTOM		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.
SEVERITF	char	DECODE, SEVERITY		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE- DEMOG.EVDATE) +1.

1.4.7. Clinical Global Impressions Scale – CLINGLOB

Dataset	CLINGLOB
Creating program	clinglob.sas
Description	Clinical Global Impressions Scale
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
EVTIME	num	TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
CLINGLOB	num	CLINICAL GLOBAL SEVERITY		Collected at CRF.
CLINGLOF	char	DECODE, CLINICAL GLOBAL SEVERITY		Collected at CRF.
CLINIMPR	num	CLINICAL GLOBAL IMPROVEMENT		Collected at CRF.
CLINIMPF	char	DECODE, CLINICAL GLOBAL IMPROVEMENT		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.

1.4.8. Comments – COMMENT

Dataset	COMMENT
Creating program	comment.sas
Description	Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Comments data is sensitive data, contains free text information. Will be submitted empty dataset.
	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: SCTRY, PAG_NAME, EVDATE, EVDATEN, COMMENT

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Empty data will be submitted.
TAREA	char	INDICATION		Empty data will be submitted.
PNO	char	PROTOCOL NUMBER		Empty data will be submitted.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Empty data will be submitted.
EVENT_ID	char	VISIT IDENTIFIER		Empty data will be submitted.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Empty data will be submitted.
PHASE	num	PHASE OF STUDY		Empty data will be submitted.

Variable	Type	Label	Codes	Comments
PHASEF	char	DECODE, PHASE OF STUDY		Empty data will be submitted.
ENTRYNO	num	ENTRY NUMBER		Empty data will be submitted.
MODNAME	char	MODULE TO WHICH COMMENT RELATES		Empty data will be submitted.
EVDY	num	RELATIVE VISIT DAY		Empty data will be submitted.

1.4.9. Completion / Discontinuation Summary – COMPDTL

Dataset	COMPDTL
Creating program	compdtl.sas
Description	Completion / Discontinuation Summary
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
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 non significant elements or due to missing values: SCTRY, PAG_NAME, EVDATE, EVDATEN, VERBATIM, ADVCODE2, ADVDESC2

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
ADVCODE	char	DICTIONARY CODE ASSIGNED TO AE		Collected at CRF.
ADVDESC	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.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.

1.4.10.   Comphdr – COMPHDR

Dataset	COMPHDR
Creating program	comphdr.sas
Description	Comphdr
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements or due to missing values: SCTRY, PAG_NAME, EVDATE, EVDATEN, STATUSDT, STATUSDN, DEATHDT, DEATHDTN, LASTDT, LASTDTN, OTHRSPEC

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
STATUS	num	SUBJECT COMPLETED PROCEDURES		Collected at CRF.
STATUSF	char	DECODE, SUBJECT COMPLETED PROCEDURES		Collected at CRF.
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
REASONF	char	DECODE, REASON FOR WITHDRAWAL		Collected at CRF.
LACKSEV	num	SEVERITY, LACK OF EFFICACY		Collected at CRF.
LACKSEVF	char	DECODE, SEVERITY, LACK OF EFFICACY		Collected at CRF.
ENTERNXT	num	WILL CONTINUE INTO OPEN LABEL		Collected at CRF.
ENTERNXF	char	DECODE, WILL CONTINUE INTO OPEN LABEL		Collected at CRF.
DEATH	num	SUBJECT DIED DURING STUDY		Collected at CRF.
DEATHF	char	DECODE, SUBJECT DIED DURING STUDY		Collected at CRF.
VISNUM	num	VISIT NUMBER		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to EVDATE then (EVDATE- DEMOG.EVDATE) +1.

Variable	Type	Label	Codes	Comments
STATUSDY	num	RELATIVE DAY OF COMPLETION OR WITHDRAWAL		If STATUSDT and DEMOG.EVDATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than DEMOG.EVDATE then (STATUSDT - DEMOG.EVDATE).Else if STATUSDT is greater than equal to DEMOG.EVDATE then (STATUSDT- DEMOG.EVDATE) +1.

1.4.11.   Cocurrent Medication(Concomitant) – CURMDTL

Dataset	CURMDTL
Creating program	curmdtl.sas
Description	Cocurrent Medication(Concomitant)
Unique identifier	DPATNO,EVENT_ID,ROUTEF,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ROUTEF,ENTRYNO
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 non significant elements or due to missing values: SCTRY, PAG_NAME, VERBATIM, DRUGCOD2, DRUGDES2, INDICT, STARTDT, STARTDTN, STOPDT, STOPDTN, FORTAE, FORTAEF

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
DRUGCODE	char	DRUG CODE		Collected at CRF.
DRUGDESC	char	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.
ROUTEF	char	DECODE, ROUTE OF ADMINISTRATION		Collected at CRF.
TOTDOSE	char	TOTAL DAILY DOSE		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
CONT	num	IS THE DRUG CONTINUING		Collected at CRF.
CONTF	char	DECODE, IS THE DRUG CONTINUING		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRN	char	IF THE DRUG IS TAKEN AS NEEDED		Collected at CRF.
STARTDY	num	RELATIVE START DAY		If STARTDT and DEMOG.EVDATE not missing then perform below logic to calculate STARTDY, If STARTDT less than DEMOG.EVDATE then (STARTDT - DEMOG.EVDATE).Else if STARTDT is greater than equal to DEMOG.EVDATE then (STARTDT- DEMOG.EVDATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOPDT and DEMOG.EVDATE not missing then perform below logic to calculate STOPDY, If STOPDT less than DEMOG.EVDATE then (STOPDT - DEMOG.EVDATE).Else if STOPDT is greater than equal to DEMOG.EVDATE then (STOPDT- DEMOG.EVDATE) +1.

1.4.12.   Curmhdr – CURMHDR

Dataset	CURMHDR
Creating program	curmhdr.sas
Description	Curmhdr
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONMED	num	DID PATIENT RECEIVE CONC MEDICATION?		Collected at CRF.
CONMEDF	char	DECODE, DID PATIENT RECEIVE CONC MED?		Collected at CRF.
EVDY	num	RELATIVE DAY OF SAE		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.

1.4.13.   SCID DSMIV Axis I Disorders – DSMIV

Dataset	DSMIV
Creating program	dsmiv.sas
Description	SCID DSMIV Axis I Disorders
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSMIV	num	DSMIV FOR MANIC OR MIXED EPISODE		Collected at CRF.
DSMIVF	char	DECODE,DSMIV FOR MANIC OR MIXED EPISODE		Collected at CRF.
DSMIV2	num	EPISODE MANIC OR MIXED		Collected at CRF.
DSMIV2F	char	DECODE, EPISODE MANIC OR MIXED		Collected at CRF.
DSMIV3	num	DSMIV FOR MAJOR DEPRESSIVE EPISODE		Collected at CRF.
DSMIV3F	char	DECODE,DSMIV FOR MAJOR DEPRESSIVE EPISOD		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.

1.4.14.   Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DPATNO,EVENT_ID,VISITYPF,EVDY
Sorted by	DPATNO,EVENT_ID,VISITYPF,EVDY
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 non significant elements or due to missing values: SCTRY, INIT, PAG_NAME, BIRTHDT, BIRTHDTN, SEX, SEXF, ECGID, EVDATE, EVDATEN, DICODC, DICODS, DOCCOMMT, LABCOMMT

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
VISITYPE	num	VISIT TYPE		Collected at CRF.
VISITYPF	char	DECODE, VISIT TYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
ECGTIME	char	TIME OF ECG		Collected at CRF.
RATE	num	RATE		Collected at CRF.
QRS	num	QRS INTERVAL		Collected at CRF.
PR	num	PR INTERVAL		Collected at CRF.
QTC	num	QTC INTERVAL		Collected at CRF.
QRSAXIS	char	QRS AXIS		Collected at CRF.
NORMAB	num	OVERALL ECG ASSESSMENT		Collected at CRF.
NORMABF	char	DECODE, OVERALL ECG ASSESSMENT		Collected at CRF.
COMPCODE	num	COMPARISON CODE		Collected at CRF.
COMPCODF	char	DECODE, COMPARISON CODE		Collected at CRF.
DICOD	num	DIAGNOSTIC CODE		Collected at CRF.
EVDY	num	RELATIVE DAY OF ECG		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.

1.4.15. Inclusion/Exclusion Criteria – ENTRANCE

Dataset	ENTRANCE
Creating program	entrance.sas
Description	Inclusion/Exclusion Criteria
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN, INCLNSAT, EXCLNSAT, YMRSRSN, GASRSN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
SATISFYC	num	SUBJECT SATISFIES CRITERIA		Collected at CRF.
SATISFYF	char	DECODE, SUBJECT SATISFIES CRITERIA		Collected at CRF.
INCNUM	num	INCLUSION NUMBER		Collected at CRF.
INCWAV	char	WAIVER FORM SIGNED		Collected at CRF.
EXCNUM	num	EXCLUSION NUMBER		Collected at CRF.
EXCWAV	char	WAIVER FORM SIGNED		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.

1.4.16.   Family Psychiatric History – FAMHIST

Dataset	FAMHIST
Creating program	famhist.sas
Description	Family Psychiatric History
Unique identifier	DPATNO,EVENT_ID,DISORDEF,ENTRYNO
Sorted by	DPATNO,EVENT_ID,DISORDEF,ENTRYNO
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DISORDER	num	DISORDER		Collected at CRF.
DISORDEF	char	DECODE, DISORDER		Collected at CRF.
CONDITN	num	HAS HISTORY?		Collected at CRF.
CONDITNF	char	DECODE, HAS HISTORY?		Collected at CRF.
MEMBER	num	MEMBER		Collected at CRF.
MEMBERF	char	DECODE, MEMBER		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.

1.4.17.   Global Assessment Scale – GAS

Dataset	GAS
Creating program	gas.sas
Description	Global Assessment Scale
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN, RATINIT

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
EVTIME	num	TIME		Collected at CRF.

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

1.4.18. Hospitalisation Details – HOSPDTL

Dataset	HOSPDTL
Creating program	hospdtl.sas
Description	Hospitalisation Details
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN, READDT, READDTN, REDISDT, REDISDTN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.
READDY	num	RELATIVE DAY OF READMISSION		If READDT and DEMOG.EVDATE not missing then perform below logic to calculate READDY, If READDT less than DEMOG.EVDATE then (READDT - DEMOG.EVDATE).Else if READDT is greater than equal to DEMOG.EVDATE then (READDT-DEMOG.EVDATE) +1.
REDISDY	num	RELATIVE DAY OF DISCHARGE		If REDISDT and DEMOG.EVDATE not missing then perform below logic to calculate REDISDY, If REDISDT less than DEMOG.EVDATE then (REDISDT - DEMOG.EVDATE).Else if REDISDT is greater than equal to DEMOG.EVDATE then (REDISDT-DEMOG.EVDATE) +1.

1.4.19.   Hosphdr – HOSPHDR

Dataset	HOSPHDR
Creating program	hosphdr.sas
Description	Hosphdr
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN, DISCHDT, DISCHDTN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
DISCHARG	num	SUBJECT DISCHARGED?		Collected at CRF.

Variable	Type	Label	Codes	Comments
DISCHARF	char	DECODE, SUBJECT DISCHARGED?		Collected at CRF.
READMIN	num	DID SUBJECT HAVE READMISSION?		Collected at CRF.
READMINF	char	DECODE, DID SUBJECT HAVE READMISSION?		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.
DISCHDY	num	RELATIVE DAY OF DISCHARGE		If DISCHDT and DEMOG.EVDATE not missing then perform below logic to calculate DISCHDY, If DISCHDT less than DEMOG.EVDATE then (DISCHDT - DEMOG.EVDATE).Else if DISCHDT is greater than equal to DEMOG.EVDATE then (DISCHDT- DEMOG.EVDATE) +1.

1.4.20.   Idmclsts – IDMCLSTS

Dataset	IDMCLSTS
Creating program	idmclsts.sas
Description	Idmclsts
Unique identifier	DPATNO, IDMCS
Sorted by	DPATNO, IDMCS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: COMMENTS

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
IDMCS	char	IDMCS		Collected at CRF.

1.4.21.   Laboratory Dosages – LABDOSE

Dataset	LABDOSE
Creating program	labdose.sas
Description	Laboratory Dosages
Unique identifier	DPATNO,EVENT_ID,SAMPDY
Sorted by	DPATNO,EVENT_ID,SAMPDY
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 non significant elements: SCTRY, PAG_NAME, ACCNO, INIT, SAMPDT, SAMPDTN, DOSEDATE, DOSEDATN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPTIME	num	SAMPLE TIME		Collected at CRF.
DOSETIME	num	DOSE TIME		Collected at CRF.
SAMPDY	num	RELATIVE DAY TEST PERFORMED		If SAMPDT and DEMOG.EVDATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than DEMOG.EVDATE then (SAMPDT - DEMOG.EVDATE).Else if SAMPDT is greater than equal to DEMOG.EVDATE then (SAMPDT-DEMOG.EVDATE) +1.
DOSEDY	num	RELATIVE DOSE DAY		If DOSEDATE and DEMOG.EVDATE not missing then perform below logic to calculate ONSETDT, If DOSEDATE less than DEMOG.EVDATE then (DOSEDATE - DEMOG.EVDATE).Else if DOSEDATE is greater than equal to DEMOG.EVDATE then (DOSEDATE- DEMOG.EVDATE) +1.

1.4.22. Laboratory Analyses – LABS

Dataset	LABS
Creating program	labs.sas
Description	Laboratory Analyses
Unique identifier	DPATNO,EVENT_ID,LABTST,SAMPDY
Sorted by	DPATNO,EVENT_ID,LABTST,SAMPDY
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 non significant elements or due to missing values: SCTRY, PAG_NAME, SEX, SEXF, INIT, BIRTHDT, BIRTHDTN, LABSPEC, SAMPDT, SAMPDTN, LABLOC, LABNAME, ACCNO, BATCHID, TUPID

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITYPE	num	TYPE OF LAB TEST		Collected at CRF.
VISITYPF	char	DECODE, TYPE OF LAB TEST		Collected at CRF.
LABTST	char	LAB TEST		Collected at CRF.
LABDESC	char	LAB DESCRIPTION		Collected at CRF.
LABCODE	char	LAB TEST CODE		Collected at CRF.
COLLECT	char	PRE-DETERMINED COLLECTION TIMES		Collected at CRF.
SAMPTIME	char	TIME PERFORMED		Collected at CRF.
RESULT	num	NUMERIC LAB RESULT		Collected at CRF.
CRESULT	char	CHARACTER LAB RESULT		Collected at CRF.
UNIT	char	LABORATORY UNIT		Collected at CRF.
UNITCODE	num	LABORATORY UNIT CODE		Collected at CRF.
FLAG	char	HIGH LOW LAB VALUE FLAG		Collected at CRF.
LORANGE	num	CONVENTIONAL LOWER LIMIT		Collected at CRF.
HIRANGE	num	CONVENTIONAL UPPER LIMIT		Collected at CRF.
RESULTSI	num	S.I. NUMERIC RESULTS		Collected at CRF.
UNITSI	char	PRI TRANSLATED UNIT		Collected at CRF.
UCODESI	num	PRI TRANSLATED UNIT CODE		Collected at CRF.
SILORNG	num	S.I. LOWER LIMIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SIHIRNG	num	S.I. UPPER LIMIT		Collected at CRF.
SAMPDY	num	RELATIVE DAY TEST PERFORMED		If SAMPDT and DEMOG.EVDATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than DEMOG.EVDATE then (SAMPDT - DEMOG.EVDATE).Else if SAMPDT is greater than equal to DEMOG.EVDATE then (SAMPDT-DEMOG.EVDATE) +1.

1.4.23. Medical History – MHIST

Dataset	MHIST
Creating program	mhist.sas
Description	Medical History
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
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 non significant elements or due to missing values: SCTRY, PAG_NAME, EVDATE, EVDATEN, VERBATIM, ABNCODE

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
SYSTEM	num	SYSTEM		Collected at CRF.
SYSTEMF	char	DECODE, SYSTEM		Collected at CRF.
NORMAB	num	NORMAL OR ABNORMAL		Collected at CRF.
NORMABF	char	DECODE, NORMAL OR ABNORMAL		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE- DEMOG.EVDATE) +1.

1.4.24.   Montgomery Depression Rating Scale – MONTGOM

Dataset	MONTGOM
Creating program	montgom.sas
Description	Montgomery Depression Rating Scale
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN, RATINIT

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
EVTIME	num	TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
RSLEEPF	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.
ITOFEELF	char	DECODE, INABILITY TO FEEL		Collected at CRF.
PTHOUGHT	num	PESSIMISTIC THOUGHTS		Collected at CRF.
PTHOUGHF	char	DECODE, PESSIMISTIC THOUGHTS		Collected at CRF.
STHOUGHT	num	SUICIDAL THOUGHTS		Collected at CRF.

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

1.4.25.   Plasma Concentration – PLASMA

Dataset	PLASMA
Creating program	plasma.sas
Description	Plasma Concentration
Unique identifier	DPATNO,EVENT_ID,VISITYPF
Sorted by	DPATNO,EVENT_ID,VISITYPF
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 non significant elements or due to missing values: SCTRY, PAG_NAME, ACCNO, INIT, SEX, SEXF, BIRTHDT, BIRTHDTN, SAMPDT, SAMPDTN, DOSEDATE, DOSEDATN, LABLOC, LABNAME, LABSPEC, BATCHID, LORANGE, HIRANGE, RESULTSI, SILORNG, SIHIRNG

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
VISITYPE	num	TYPE OF LAB TEST		Collected at CRF.
VISITYPF	char	DECODE, TYPE OF LAB TEST		Collected at CRF.
COLLECT	char	PRE-DETERMINED COLLECTION TIMES		Collected at CRF.
SAMPTIME	num	SAMPLE TIME		Collected at CRF.
DOSETIME	num	DOSE TIME		Collected at CRF.
LABCODE	char	LAB TEST CODE		Collected at CRF.
RESULT	num	RESULT (NUMERIC)		Collected at CRF.
CRESULT	char	RESULT (CHAR)		Collected at CRF.
UNITCODE	num	LABORATORY UNIT CODE		Collected at CRF.
FLAG	char	HIGH LOW LAB VALUE FLAG		Collected at CRF.
UCODESI	num	PRI TRANSLATED UNIT CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPDY	num	RELATIVE DAY TEST PERFORMED		If SAMPDT and DEMOG.EVDATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than DEMOG.EVDATE then (SAMPDT - DEMOG.EVDATE).Else if SAMPDT is greater than equal to DEMOG.EVDATE then (SAMPDT-DEMOG.EVDATE) +1.
DOSEDY	num	RELATIVE DOSE DAY		If DOSEDATE and DEMOG.EVDATE not missing then perform below logic to calculate DOSEDY, If DOSEDATE less than DEMOG.EVDATE then (DOSEDATE - DEMOG.EVDATE).Else if DOSEDATE is greater than equal to DEMOG.EVDATE then (DOSEDATE- DEMOG.EVDATE) +1.

1.4.26.   Pregnancy – PREG

Dataset	PREG
Creating program	preg.sas
Description	Pregnancy
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
PREG	num	SUBJECT BECAME PREGNANT?		Collected at CRF.

Variable	Type	Label	Codes	Comments
PREGF	char	DECODE, SUBJECT BECAME PREGNANT?		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.

1.4.27.   Psychiatric History – PSYCHIST

Dataset	PSYCHIST
Creating program	psychist.sas
Description	Psychiatric History
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN, ONSETCUR, ONSETCUN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
MANIC	num	NUMBER OF MANIC EPISODES		Collected at CRF.

Variable	Type	Label	Codes	Comments
DEPRESS	num	NUMBER OF DEPRESSIVE DISORDER		Collected at CRF.
TOTMANIC	num	TOTAL PRIOR MANIC EPISODES		Collected at CRF.
TOTDEPP	num	TOTAL EPISODES DEPRESSIVE		Collected at CRF.
ONSETMAN	char	AGE OF FIRST MANIC EPISODE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
ONSETDEP	char	AGE OF FIRST MAJOR DEPRESSION		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
NODEP	num	NO MAJOR DEPRESSION		Collected at CRF.
NODEPF	char	DECODE, NO MAJOR DEPRESSION		Collected at CRF.
MANMIX	num	IS EPISODE MANIC OR MIXED?		Collected at CRF.
MANMIXF	char	DECODE, IS EPISODE MANIC OR MIXED?		Collected at CRF.
SEVCURR	num	SEVERITY OF CURRENT EPISODE		Collected at CRF.
SEVCURRF	char	DECODE, SEVERITY OF CURRENT EPISODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE- DEMOG.EVDATE) +1.
ONSETDY	num	RELATIVE DAY OF ONSET		If ONSETCUR and DEMOG.EVDATE not missing then perform below logic to calculate ONSETDT, If ONSETCUR less than DEMOG.EVDATE then (ONSETCUR - DEMOG.EVDATE).Else if ONSETCUR is greater than equal to DEMOG.EVDATE then (ONSETCUR- DEMOG.EVDATE) +1.

1.4.28.   Quality of Life – QOL

Dataset	QOL
Creating program	qol.sas
Description	Quality of Life
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, EVDATE_, EVDATEN, PAG_NAME

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
M1	num	HAS YOUR DAILY LIFE BEEN FULL?		Collected at CRF.
M1F	char	DECODE, HAS YOUR DAILY LIFE BEEN FULL?		Collected at CRF.
M2	num	DID YOU FEEL DEPRESSED?		Collected at CRF.
M2F	char	DECODE, DID YOU FEEL DEPRESSED?		Collected at CRF.
M3	num	HAVE YOU FELT LOVED AND WANTED?		Collected at CRF.
M3F	char	DECODE, HAVE YOU FELT LOVED AND WANTED?		Collected at CRF.
M4	num	HAVE YOU BEEN VERY NERVOUS?		Collected at CRF.
M4F	char	DECODE, HAVE YOU BEEN VERY NERVOUS?		Collected at CRF.
M5	num	HAVE YOU BEEN IN FIRM CONTROL?		Collected at CRF.
M5F	char	DECODE, HAVE YOU BEEN IN FIRM CONTROL?		Collected at CRF.
M6	num	HAVE YOU FELT TENSE?		Collected at CRF.
M6F	char	DECODE, HAVE YOU FELT TENSE?		Collected at CRF.
M7	num	HAVE YOU FELT CALM?		Collected at CRF.

Variable	Type	Label	Codes	Comments
M7F	char	DECODE, HAVE YOU FELT CALM?		Collected at CRF.
M8	num	HAVE YOU FELT STABLE?		Collected at CRF.
M8F	char	DECODE, HAVE YOU FELT STABLE?		Collected at CRF.
M9	num	HAVE YOU FELT DOWNHEARTED?		Collected at CRF.
M9F	char	DECODE, HAVE YOU FELT DOWNHEARTED?		Collected at CRF.
M10	num	HAVE YOU FELT RESTLESS?		Collected at CRF.
M10F	char	DECODE, HAVE YOU FELT RESTLESS?		Collected at CRF.
M11	num	HAVE YOU BEEN MOODY?		Collected at CRF.
M11F	char	DECODE, HAVE YOU BEEN MOODY?		Collected at CRF.
M12	num	HAVE YOU FELT CHEERFUL?		Collected at CRF.
M12F	char	DECODE, HAVE YOU FELT CHEERFUL?		Collected at CRF.
M13	num	HAVE YOU BEEN IN LOW SPIRITS?		Collected at CRF.
M13F	char	DECODE, HAVE YOU BEEN IN LOW SPIRITS?		Collected at CRF.
M14	num	HAVE YOU BEEN A HAPPY PERSON?		Collected at CRF.

Variable	Type	Label	Codes	Comments
M14F	char	DECODE, HAVE YOU BEEN A HAPPY PERSON?		Collected at CRF.
M15	num	NOTHING TO LOOK FORWARD TO?		Collected at CRF.
M15F	char	DECODE, NOTHING TO LOOK FORWARD TO?		Collected at CRF.
M16	num	HAVE YOU FELT DOWN IN THE DUMPS?		Collected at CRF.
M16F	char	DECODE, HAVE YOU FELT DOWN IN THE DUMPS?		Collected at CRF.
M17	num	HAVE YOU BEEN ANXIOUS?		Collected at CRF.
M17F	char	DECODE, HAVE YOU BEEN ANXIOUS?		Collected at CRF.
GH1	num	GENERAL HEALTH		Collected at CRF.
GH1F	char	DECODE, GENERAL HEALTH		Collected at CRF.
Q2SF36	num	HEALTH COMPARED TO ONE YEAR AGO		Collected at CRF.
Q2SF36F	char	DECODE, HEALTH COMPARED TO ONE YEAR AGO		Collected at CRF.
PF1	num	VIGOROUS ACTIVITIES		Collected at CRF.
PF1F	char	DECODE, VIGOROUS ACTIVITIES		Collected at CRF.
PF2	num	MODERATE ACTIVITIES		Collected at CRF.

Variable	Type	Label	Codes	Comments
PF2F	char	DECODE, MODERATE ACTIVITIES		Collected at CRF.
PF3	num	LIFTING OR CARRYING GROCERIES		Collected at CRF.
PF3F	char	DECODE, LIFTING OR CARRYING GROCERIES		Collected at CRF.
PF4	num	CLIMBING SEVERAL FLIGHTS		Collected at CRF.
PF4F	char	DECODE, CLIMBING SEVERAL FLIGHTS		Collected at CRF.
PF5	num	CLIMBING ONE FLIGHT OF STAIRS		Collected at CRF.
PF5F	char	DECODE, CLIMBING ONE FLIGHT OF STAIRS		Collected at CRF.
PF6	num	BENDING, KNEELING, OR STOOPING		Collected at CRF.
PF6F	char	DECODE, BENDING, KNEELING, OR STOOPING		Collected at CRF.
PF7	num	WALKING MORE THAN A MILE		Collected at CRF.
PF7F	char	DECODE, WALKING MORE THAN A MILE		Collected at CRF.
PF8	num	WALKING SEVERAL BLOCKS		Collected at CRF.
PF8F	char	DECODE, WALKING SEVERAL BLOCKS		Collected at CRF.
PF9	num	WALKING ONE BLOCK		Collected at CRF.

Variable	Type	Label	Codes	Comments
PF9F	char	DECODE, WALKING ONE BLOCK		Collected at CRF.
PF10	num	BATHING OR DRESSING YOURSELF		Collected at CRF.
PF10F	char	DECODE, BATHING OR DRESSING YOURSELF		Collected at CRF.
RP1	num	AMOUNT OF TIME ON WORK		Collected at CRF.
RP1F	char	DECODE, AMOUNT OF TIME ON WORK		Collected at CRF.
RP2	num	ACCOMPLISHED LESS		Collected at CRF.
RP2F	char	DECODE, ACCOMPLISHED LESS		Collected at CRF.
RP3	num	LIMITED IN THE KIND OF WORK		Collected at CRF.
RP3F	char	DECODE, LIMITED IN THE KIND OF WORK		Collected at CRF.
RP4	num	HAD DIFFICULTY PERFORMING WORK		Collected at CRF.
RP4F	char	DECODE, HAD DIFFICULTY PERFORMING WORK		Collected at CRF.
RE1	num	AMOUNT OF TIME ON WORK		Collected at CRF.
RE1F	char	DECODE, AMOUNT OF TIME ON WORK		Collected at CRF.
RE2	num	ACCOMPLISHED LESS		Collected at CRF.

Variable	Type	Label	Codes	Comments
RE2F	char	DECODE, ACCOMPLISHED LESS		Collected at CRF.
RE3	num	DID NOT WORK AS CAREFULLY		Collected at CRF.
RE3F	char	DECODE, DID NOT WORK AS CAREFULLY		Collected at CRF.
SF1	num	INTERFERED WITH SOCIAL ACT		Collected at CRF.
SF1F	char	DECODE, INTERFERED WITH SOCIAL ACT		Collected at CRF.
BP1	num	HOW MUCH BODILY PAIN?		Collected at CRF.
BP1F	char	DECODE, HOW MUCH BODILY PAIN?		Collected at CRF.
BP2	num	HOW MUCH DID PAIN INTERFERE?		Collected at CRF.
BP2F	char	DECODE, HOW MUCH DID PAIN INTERFERE?		Collected at CRF.
VT1	num	DID YOU FEEL FULL OF PEP?		Collected at CRF.
VT1F	char	DECODE, DID YOU FEEL FULL OF PEP?		Collected at CRF.
VT2	num	DID YOU HAVE A LOT OF ENERGY?		Collected at CRF.
VT2F	char	DECODE, DID YOU HAVE A LOT OF ENERGY?		Collected at CRF.
VT3	num	DID YOU FEEL WORN OUT?		Collected at CRF.

Variable	Type	Label	Codes	Comments
VT3F	char	DECODE, DID YOU FEEL WORN OUT?		Collected at CRF.
VT4	num	DID YOU FEEL TIRED?		Collected at CRF.
VT4F	char	DECODE, DID YOU FEEL TIRED?		Collected at CRF.
SF2	num	4 WEEKS INTERFERED SOCIAL ACT		Collected at CRF.
SF2F	char	DECODE, 4 WEEKS INTERFERED SOCIAL ACT		Collected at CRF.
GH2	num	I SEEM TO GET SICK EASIER		Collected at CRF.
GH2F	char	DECODE, I SEEM TO GET SICK EASIER		Collected at CRF.
GH3	num	I AM AS HEALTHY AS ANYBODY		Collected at CRF.
GH3F	char	DECODE, I AM AS HEALTHY AS ANYBODY		Collected at CRF.
GH4	num	I EXPECT MY HEALTH TO GET WORSE		Collected at CRF.
GH4F	char	DECODE, I EXPECT MY HEALTH TO GET WORSE		Collected at CRF.
GH5	num	MY HEALTH IS EXCELLENT		Collected at CRF.
GH5F	char	DECODE, MY HEALTH IS EXCELLENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SRS1	num	DO YOU HAVE A HUSBAND OR WIFE?		Collected at CRF.
SRS1F	char	DECODE, DO YOU HAVE A HUSBAND OR WIFE?		Collected at CRF.
SRS2	num	RATE RELATIONSHIP WITH SPOUSE?		Collected at CRF.
SRS2F	char	DECODE, RATE RELATIONSHIP WITH SPOUSE?		Collected at CRF.
SRS3	num	RATE RELATION WITH RELATIVES?		Collected at CRF.
SRS3F	char	DECODE, RATE RELATION WITH RELATIVES?		Collected at CRF.
SRS4	num	RATE RELATIONSHIP WITH FRIENDS?		Collected at CRF.
SRS4F	char	DECODE, RATE RELATIONSHIP WITH FRIENDS?		Collected at CRF.
TIMESP	num	HOW MUCH TIME TO COMPLETE QOL?		Collected at CRF.
COMP	num	WERE YOU ABLE TO COMPLETE?		Collected at CRF.
COMPF	char	DECODE, WERE YOU ABLE TO COMPLETE?		Collected at CRF.
COOP	num	PLEASE RATE COOPERATIVENESS		Collected at CRF.

Variable	Type	Label	Codes	Comments
COOPF	char	DECODE, PLEASE RATE COOPERATIVENESS		Collected at CRF.
RELIAB	num	HOW RELIABLE IS THE HRQOL INFO?		Collected at CRF.
RELIABF	char	DECODE, HOW RELIABLE IS THE HRQOL INFO?		Collected at CRF.
EVDY	num	RELATIVE EVENT DAY		If EVDATEN and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATEN less than DEMOG.EVDATE then (EVDATEN - DEMOG.EVDATE).Else if EVDATEN is greater than equal to DEMOG.EVDATE then (EVDATEN-DEMOG.EVDATE) +1.

1.4.29.   Smed – SMED

Dataset	SMED
Creating program	smed.sas
Description	Smed
Unique identifier	DPATNO,EVENT_ID,NOMEDS,ENTRYNO
Sorted by	DPATNO,EVENT_ID,NOMEDS,ENTRYNO
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 non significant elements or due to missing values: SCTRY, PAG_NAME, CARDF, CARD, MEDSTRDT, MEDSTRDN, MEDSTPDT, MEDSTPDN, PERIOD

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
AM1	num	AM TAB 1		Collected at CRF.
AM2	num	AM TAB 2		Collected at CRF.
AM3	num	AM TAB 3		Collected at CRF.
PM4	num	PM TAB 4		Collected at CRF.
PM5	num	PM TAB 5		Collected at CRF.
PM6	num	PM TAB 6		Collected at CRF.
NOMEDS	num	NO MEDS TAKEN		Collected at CRF.
TOTDOSE	num	TOTAL DAILY DOSE		Collected at CRF.
MEDSTRDY	num	RELATIVE START DAY		If MEDSTRDT and DEMOG.EVDATE not missing then perform below logic to calculate MEDSTRDY, If MEDSTRDT less than DEMOG.EVDATE then (MEDSTRDT - DEMOG.EVDATE).Else if MEDSTRDT is greater than equal to DEMOG.EVDATE then (MEDSTRDT- DEMOG.EVDATE) +1.
MEDSTPDY	num	RELATIVE STOP DAY		If MEDSTPDT and DEMOG.EVDATE not missing then perform below logic to calculate MEDSTPDY, If MEDSTPDT less than DEMOG.EVDATE then (MEDSTPDT - DEMOG.EVDATE).Else if MEDSTPDT is greater than equal to DEMOG.EVDATE then (MEDSTPDT- DEMOG.EVDATE) +1.

1.4.30.   Vital Signs – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
VISITYPE	num	VISIT TYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITYPF	char	DECODE, VISIT TYPE		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
TEMP	num	TEMPERATURE		Collected at CRF.
TEMPUNIT	char	TEMPERATURE UNIT		Collected at CRF.
SYST	num	SYSTOLIC BLOOD PRESSURE		Collected at CRF.
DIAST	num	DIASTOLIC BLOOD PRESSURE		Collected at CRF.
PULS	num	PULSE RATE		Collected at CRF.
WGT	num	WEIGHT		Collected at CRF.
WGTUNIT	char	WEIGHT UNIT		Collected at CRF.
RESP	num	RESPIRATION RATE		Collected at CRF.
HGT	num	HEIGHT		Collected at CRF.
HGTUNIT	char	HEIGHT UNIT		Collected at CRF.
WAIST	num	WAIST CIRCUMFERENCE		Collected at CRF.
WAISTUNT	char	WAIST UNIT		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.

1.4.31.   Young Mania Rating Scale – YOUNGSCL

Dataset	YOUNGSCL
Creating program	youngscl.sas
Description	Young Mania Rating Scale
Unique identifier	DPATNO, EVENT_ID
Sorted by	DPATNO, EVENT_ID
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 non significant elements: SCTRY, PAG_NAME, EVDATE, EVDATEN, PMEDSPEC, RATINIT

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE		Collected at CRF.
TAREA	char	INDICATION		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number For De-Identity
EVENT_ID	char	VISIT IDENTIFIER		Collected at CRF.
EVENT_IF	char	DECODE, VISIT IDENTIFIER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
PHASEF	char	DECODE, PHASE OF STUDY		Collected at CRF.
EVTIME	num	TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
ELVMOOD	num	ELEVATED MOOD		Collected at CRF.
ELVMOODF	char	DECODE, ELEVATED MOOD		Collected at CRF.
INCMOTOR	num	INCREASED MOTOR ACTIVITY		Collected at CRF.
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.
LANGUAGF	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.

Variable	Type	Label	Codes	Comments
INSIGHT	num	INSIGHT		Collected at CRF.
INSIGHTF	char	DECODE, INSIGHT		Collected at CRF.
PSYMED	num	WAS PSYCHOTROPIC MED TAKEN?		Collected at CRF.
PSYMEDF	char	DECODE, WAS PSYCHOTROPIC MED TAKEN?		Collected at CRF.
WHENTAK	num	HOURS PRIOR TAKEN		Collected at CRF.
EVDY	num	RELATIVE VISIT DAY		If EVDATE and DEMOG.EVDATE not missing then perform below logic to calculate EVDY, If EVDATE less than DEMOG.EVDATE then (EVDATE - DEMOG.EVDATE).Else if EVDATE is greater than equal to DEMOG.EVDATE then (EVDATE-DEMOG.EVDATE) +1.