

Clinical Development

**Risperidone<sup>®</sup>**

RIS-BMN-3001

Anonymisation Data Derivation Specification Document

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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
- 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.
- Complete missing value variables will be removed.
- Lab Identifier information 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.
- Comments dataset will be submitted with zero observation due to sensitivity of data.
- Element containing insignificant information will not be submitted. (eg. LBTMLBL)
- Dataset containing investigator information is sensitive and hence will not be submitted. (eg. INVEST)
- Dataset having no subject level information will not be submitted. (eg. PROTDESC)
- Datasets which are empty as input, will not be submitted. (eg. IMMUNO)

### 1.3. Data Files

The RIS-BMN-3001 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Demographics - DEMOG

<b>Dataset</b>	DEMOG
<b>Creating program</b>	demog.sas
<b>Description</b>	Demographics
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SUBJINIT, DMACTDT, DMSCRDT, IVNAME, BIRTHDT, IVID, DMINFDT, RACESPEC, COUNTRYC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
SEXC	num	Sex Code		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACEC	num	Race Code		Collected at CRF.
RACE	char	Race		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
ETHNICC	num	Ethnicity Code		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
AGE	char	Age in years		<p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule:</p> $\text{AGE} = \text{int}((\text{DMINFDT} - \text{BIRTHDT}) / 365.25)$ <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p>



Variable	Type	Label	Codes	Comments
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and DMINFDT not missing then perform below logic to calculate DMACTDY, If DMACTDT less than DMINFDT then (DMACTDT - DMINFDT).Else if DMACTDT is greater than equal to DMINFDT then (DMACTDT- DMINFDT) +1.
DMSCRDY	num	Relative Day of First Trial Related Proc		If DMSCRDT and DMINFDT not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than DMINFDT then (DMSCRDT - DMINFDT).Else if DMSCRDT is greater than equal to DMINFDT then (DMSCRDT- DMINFDT) +1.

## 1.4.2. Adverse Events - AE

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events (AE)
<b>Unique identifier</b>	DUSUBJID,AEDECOD1,AESEQ
<b>Sorted by</b>	DUSUBJID,AEDECOD1,AESEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: AETERM,AESTDTC,AESTDT, AEENDTC,AEENDT,AESERREF,AESCONG

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEREPRTC	num	Were Any AEs Reported Code		Collected at CRF.
AEREPR	char	Were Any AEs Reported		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AEACTTRC	num	Action Taken with Treatment Code		Collected at CRF.
AEACTTRT	char	Action Taken with Treatment		Collected at CRF.
AEOUTC	num	Outcome of Event Code		Collected at CRF.
AEOUT	char	Outcome of Event		Collected at CRF.
AERELC	num	Relationship to Treatment Code		Collected at CRF.
AEREL	char	Relationship to Treatment		Collected at CRF.
AESERC	num	Seriousness Criteria Code		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.
AESEVC	num	Severity of Event Code		Collected at CRF.
AESEV	char	Severity of Event		Collected at CRF.
AECONTRC	num	Concomitant/Additional Treatment Code		Collected at CRF.
AECONTRT	char	Concomitant/Additional Treatment		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
AESDTH	char	Results in Death		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESHOSPR	char	Hospitalization required		Collected at CRF.
AESHOSPP	char	Prolonged hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESMIE	char	Other Medically Important Serious Event		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF.
AEDECOD1	char	Dictionary-Derived Lower Level Term		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEBODSYC	char	Body System or Organ Class Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and DMINFDT not missing then perform below logic to calculate AESTDY, If AESTDTC less than DMINFDT then (AESTDTC - DMINFDT).Else if AESTDTC is greater than equal to DMINFDT then (AESTDTC- DMINFDT) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and DMINFDT not missing then perform below logic to calculate AEENDY, If AEENDTC less than DMINFDT then (AEENDTC - DMINFDT).Else if AEENDTC is greater than equal to DMINFDT then (AEENDTC- DMINFDT) +1.

## 1.4.3. Bipolar Disorder History - BIPHIST

<b>Dataset</b>	BIPHIST
<b>Creating program</b>	biphist.sas
<b>Description</b>	Bipolar Disorder History (BP)
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: MANICDTC,MANICDT,MIXEDDTC,MIXEDDT,DEPDTC,DEPDT,RAPCYDTC, RAPCYDT,PSYDCDTC,PSYDCDT,SUICDTC,SUICDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
MANICNO	num	Number of prior manic episodes		Collected at CRF.
MIXEDNO	num	Number of prior mixed episodes		Collected at CRF.
DEPNO	num	Number of prior depressive episodes		Collected at CRF.
RAPCYCC	num	Rapid cycling		Collected at CRF.
RAPCYC	char	Rapid cycling		Collected at CRF.
CYCYRNO	num	Number of episodes of mood disturbances		Collected at CRF.
ONAGE	char	Age of diagnosis of bipolar disorder		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
TIMEAGE	char	Age at first psychiatric hospitalization		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DRUGAGE	char	Age at first pharmacologic treatment		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HOSPNO	num	Number of prev psych hospitalizations		Collected at CRF.
SUICNO	num	Number of suicide attempts		Collected at CRF.

Variable	Type	Label	Codes	Comments
MANICDY	num	Relative Day of first manic episode		If MANICDTC and DMINFDT not missing then perform below logic to calculate MANICDY, If MANICDTC less than DMINFDT then (MANICDTC - DMINFDT).Else if MANICDTC is greater than equal to DMINFDT then (MANICDTC- DMINFDT) +1.
MIXEDDY	num	Relative Day of first mixed episode		If MIXEDDTC and DMINFDT not missing then perform below logic to calculate MIXEDDY, If MIXEDDTC less than DMINFDT then (MIXEDDTC - DMINFDT).Else if MIXEDDTC is greater than equal to DMINFDT then (MIXEDDTC- DMINFDT) +1.
DEPDY	num	Relative Day of first depressive episode		If DEPDTTC and DMINFDT not missing then perform below logic to calculate DEPDY, If DEPDTTC less than DMINFDT then (DEPDTTC - DMINFDT).Else if DEPDTTC is greater than equal to DMINFDT then (DEPDTTC- DMINFDT) +1.
RAPCYDY	num	Relative Day diagnosis of rapid cycling		If RAPCYDTC and DMINFDT not missing then perform below logic to calculate RAPCYDY, If RAPCYDTC less than DMINFDT then (RAPCYDTC - DMINFDT).Else if RAPCYDTC is greater than equal to DMINFDT then (RAPCYDTC- DMINFDT) +1.

Variable	Type	Label	Codes	Comments
PSYDCDY	num	Relative Day of most resent discharge		If PSYDCDTC and DMINFDT not missing then perform below logic to calculate PSYDCDY, If PSYDCDTC less than DMINFDT then (PSYDCDTC - DMINFDT).Else if PSYDCDTC is greater than equal to DMINFDT then (PSYDCDTC- DMINFDT) +1.
SUICDY	num	Relative Day most recent suicide attempt		If SUICDTC and DMINFDT not missing then perform below logic to calculate SUICDY, If SUICDTC less than DMINFDT then (SUICDTC - DMINFDT).Else if SUICDTC is greater than equal to DMINFDT then (SUICDTC- DMINFDT) +1.



## 1.4.4. Clinical Global Impression – Severity - CGI

<b>Dataset</b>	CGI
<b>Creating program</b>	cgi.sas
<b>Description</b>	Clinical Global Impression - Severity
<b>Unique identifier</b>	DUSUBJID,CGSEV,VISIT
<b>Sorted by</b>	DUSUBJID,CGSEV,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CGACTDT,CGRATERI

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
CGSEVC	num	CGI Severity Code		Collected at CRF.
CGSEV	char	CGI Severity		Collected at CRF.
CGACTDY	num	Relative Actual Day of CGI		If CGACTDT and DMINFDT not missing then perform below logic to calculate CGACTDY, If CGACTDT less than DMINFDT then (CGACTDT - DMINFDT).Else if CGACTDT is greater than equal to DMINFDT then (CGACTDT- DMINFDT) +1.

## 1.4.5.Laboratory Results(Chemistry) - CHEM

<b>Dataset</b>	CHEM
<b>Creating program</b>	chem.sas
<b>Description</b>	Laboratory Results(Chemistry)
<b>Unique identifier</b>	DUSUBJID, LBTEST, VISIT
<b>Sorted by</b>	DUSUBJID, LBTEST, VISIT
<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:  LBPRVIDC, LBPRVID, LBREF, LBACTDT, LBTMLBL, LBENDT, LBENTM, STDNRC, LBTOXGR, LBTOX, LBSEQ, LBSIFACT, LBCVFACT, LBREASND, ACCNUM, TSTCOM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	Fasting Status Code		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
REPUNIT	char	Original Units		Collected at CRF.
CNVRESC	char	Conventional Text Result		Collected at CRF.
CNVRESN	num	Conventional Numeric Result		Collected at CRF.
CNVNRLO	num	CNVNRLO		Collected at CRF.
CNVNRHI	num	CNVNRHI		Collected at CRF.
LBCVUNIT	char	CNVU		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDNRLO	num	Normal Range in Lower Limit in Std Units		Collected at CRF.
STDNRHI	num	Normal Range in Upper Limit in Std Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	Reference Range Indicator		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, if LBACTDT less than DMINFDT then (LBACTDT - DMINFDT).Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1.

#### 1.4.6. Comments - COMMENTS

<b>Dataset</b>	COMMENTS
<b>Creating program</b>	comments.sas
<b>Description</b>	Comments
<b>Unique identifier</b>	Not Applicable
<b>Sorted by</b>	Not Applicable
<b>Notes</b>	Comments data is sensitive data, contains free text information. Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Empty dataset will be submitted.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Empty dataset will be submitted.
DSITEID	char	Site Assigned for De-identity		Empty dataset will be submitted.
PHASENUM	num	Phase Number		Empty dataset will be submitted.
PHASE	char	Phase		Empty dataset will be submitted.
VISITNUM	num	Visit Number		Empty dataset will be submitted.
VISIT	char	Visit		Empty dataset will be submitted.
CTSEQ	num	Comment Sequence Number		Empty dataset will be submitted.
DOMAIN	char	Domain of Origin		Empty dataset will be submitted.
CTACTDY	num	Relative Actual Day of Comment		Empty dataset will be submitted.

## 1.4.7. Concomitant Meds - CONMED

<b>Dataset</b>	CONMED
<b>Creating program</b>	conmed.sas
<b>Description</b>	Concomitant Meds (CM)
<b>Unique identifier</b>	DUSUBJID,CMDECOD,CMGROUP,CMSEQ
<b>Sorted by</b>	DUSUBJID,CMDECOD,CMGROUP,CMSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: CMTERM,CMREGIM,CMREAS,CMSTDTC,CMSTDT,CMENDTC,CMENDT, CMCLASC,CMCLAS

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.



Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMGROUP	char	Medication Grouping		Collected at CRF.
CMREPRTC	num	Were Any Meds Administered Code		Collected at CRF.
CMREPRT	char	Were Any Meds Administered		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMDOSE	num	Dosage		Collected at CRF.
CMUNIT	char	Dose Unit		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMCAUSC	num	Given for AE Code		Collected at CRF.
CMCAUS	char	Given for AE		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AESEQ1	num	AE Sequence Number 1		Collected at CRF.
AESEQ2	num	AE Sequence Number 2		Collected at CRF.
CMPRIORC	num	Med Started Prior to Trial Code		Collected at CRF.
CMPRIOR	char	Med Started Prior to Trial		Collected at CRF.
CMCONTC	num	Medication Continuing Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCONT	char	Medication Continuing		Collected at CRF.
CMCLASC0	char	ATC Code 0		Collected at CRF.
CMCLASC1	char	ATC Code 1		Collected at CRF.
CMCLASC2	char	ATC Code 2		Collected at CRF.
CMCLASC3	char	ATC Code 3		Collected at CRF.
CMCLASC4	char	ATC Code 4		Collected at CRF.
CMCLASC5	char	ATC Code 5		Collected at CRF.
CMCLASC6	char	ATC Code 6		Collected at CRF.
CMCLASC7	char	ATC Code 7		Collected at CRF.
CMCLASC8	char	ATC Code 8		Collected at CRF.
CMCLASC9	char	ATC Code 9		Collected at CRF.
CMCLAS0	char	ATC Text 0		Collected at CRF.
CMCLAS1	char	ATC Text 1		Collected at CRF.
CMCLAS2	char	ATC Text 2		Collected at CRF.
CMCLAS3	char	ATC Text 3		Collected at CRF.
CMCLAS4	char	ATC Text 4		Collected at CRF.
CMCLAS5	char	ATC Text 5		Collected at CRF.
CMCLAS6	char	ATC Text 6		Collected at CRF.
CMCLAS7	char	ATC Text 7		Collected at CRF.
CMCLAS8	char	ATC Text 8		Collected at CRF.
CMCLAS9	char	ATC Text 9		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCODE	char	Medication Dictionary Code		Collected at CRF.
CMDECOD	char	Medication Generic Term		Collected at CRF.
CMSTDY	num	Relative Actual Start Day of Medication		If CMSTDTC and DMINFDT not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than DMINFDT then (CMSTDTC - DMINFDT).Else if CMSTDTC is greater than equal to DMINFDT then (CMSTDTC- DMINFDT) +1.
CMENDY	num	Relative Actual End Day of Medication		If CMENDTC and DMINFDT not missing then perform below logic to calculate CMENDY, If CMENDTC less than DMINFDT then (CMENDTC - DMINFDT).Else if CMENDTC is greater than equal to DMINFDT then (CMENDTC- DMINFDT) +1.

## 1.4.8. Entry criteria for Period III - CRIT

<b>Dataset</b>	CRIT
<b>Creating program</b>	crit.sas
<b>Description</b>	Entry criteria for P III (CI)
<b>Unique identifier</b>	DUSUBJID,CIITEM
<b>Sorted by</b>	DUSUBJID,CIITEM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CIACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
CIITEM	char	CRIT Item		Collected at CRF.
CISCOREC	num	CRIT Score Code		Collected at CRF.
CISCORE	char	CRIT Score		Collected at CRF.
CIACTDY	num	Relative Actual Day		If CIACTDT and DMINFDT not missing then perform below logic to calculate CIACTDY, If CIACTDT less than DMINFDT then (CIACTDT - DMINFDT).Else if CIACTDT is greater than equal to DMINFDT then (CIACTDT- DMINFDT) +1.

## 1.4.9. Diagnosis - DIAGNOS

<b>Dataset</b>	DIAGNOS
<b>Creating program</b>	diagnos.sas
<b>Description</b>	Diagnosis (DG)
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: DGDT,DGACTDTC,DGACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUBTYPEC	num	Subject type		Collected at CRF.
SUBTYPE	char	Subject type		Collected at CRF.
DIAGNOS	char	Primary Diagnosis		Collected at CRF.
DIAGNOSC	num	Primary Diagnosis Code		Collected at CRF.
DGTYPEC	num	Current Episode Code		Collected at CRF.
DGTYPE	char	Current Episode		Collected at CRF.
SDIAGN1	char	Secondary Diagnosis 1		Collected at CRF.
SDIAGNC1	num	Secondary Diagnosis Code 1		Collected at CRF.
SDIAGN2	char	Secondary Diagnosis 2		Collected at CRF.
SDIAGNC2	num	Secondary Diagnosis Code 2		Collected at CRF.
SDIAGN3	char	Secondary Diagnosis 3		Collected at CRF.
SDIAGNC3	num	Secondary Diagnosis Code 3		Collected at CRF.
DGACTDY	num	Relative Actual Day of Diagnosis		If DGACTDTC and DMINFDT not missing then perform below logic to calculate DGACTDY, If DGACTDTC less than DMINFDT then (DGACTDTC - DMINFDT).Else if DGACTDTC is greater than equal to DMINFDT then (DGACTDTC- DMINFDT) +1.

## 1.4.10. Disposition - DISPOSIT

<b>Dataset</b>	DISPOSIT
<b>Creating program</b>	disposit.sas
<b>Description</b>	Disposition (DS)
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DSACTDT,PREGDUDT,DEATHDT,DSRSOTH,DSRABKDT,DSRABKTM,DSRABKRS

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.



Variable	Type	Label	Codes	Comments
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF.
DSTYPE	char	End of Treatment or Trial		Collected at CRF.
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF.
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF.
DSREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF.
DSREAS	char	Reason for Withdrawal/Termination		Collected at CRF.
DSSCRNC	num	Reason for Screen Failure Code		Collected at CRF.
DSSCRN	char	Reason for Screen Failure		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
DSCMRSC	num	Completion Reason Code		Collected at CRF.
DSCMRS	char	Completion Reason		Collected at CRF.
DSRECURC	num	Type of Recurrence Code		Collected at CRF.
DSRECUR	char	Type of Recurrence		Collected at CRF.
DSACTDY	num	Relative Actual Day Trial Completion/Withdrawal		If DSACTDT and DMINFDT not missing then perform below logic to calculate DSACTDY, If DSACTDT less than DMINFDT then (DSACTDT - DMINFDT). Else if DSACTDT is greater than equal to DMINFDT then (DSACTDT- DMINFDT) +1.

## 1.4.11. Electrocardiogram - ECG

<b>Dataset</b>	ECG
<b>Creating program</b>	ecg.sas
<b>Description</b>	Electrocardiogram (EG)
<b>Unique identifier</b>	DUSUBJID,EGTESTCD,EGACTTM, EGSEQ
<b>Sorted by</b>	DUSUBJID,EGTESTCD,EGACTTM, EGSEQ
<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: EGREF,EGDT,EGPTM,EGPRVIDC,EGPRVID,EGLEAD,EGND,EGCHGC,EGCHG, BATCHID,EGCHGOTH,XSUBJINT,XBIRTHDT,EGINTOTH,XSEX

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGTESTCD	char	ECG Test Short Name		Collected at CRF.
EGPTMNUM	num	Planned Time Point Number		Collected at CRF.
EGACTTM	num	Actual Time of ECG		Collected at CRF.
EGPOS	char	Position		Collected at CRF.
EGQUAL	char	Qualifier		Collected at CRF.
EGTEST	char	ECG Test		Collected at CRF.
EGSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
EGSTUNIT	char	Standard Units		Collected at CRF.
EGSTRESC	char	Character Result in Standard Units		Collected at CRF.
EGORRESN	num	Numeric Result in Original Units		Collected at CRF.
EGORUNIT	char	Original Units		Collected at CRF.
EGINTPC	num	Interpretation Code		Collected at CRF.
EGINTP	char	Interpretation		Collected at CRF.
EGSEQ	num	ECG Sequence Number		Collected at CRF.
EGREADC	num	ECG Reader Code		Collected at CRF.
EGREAD	char	ECG Reader		Collected at CRF.
EGVTYPEC	num	ECG Visit Type Code		Collected at CRF.
EGVTYPE	char	ECG Visit Type		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGDY	num	Relative Actual Day of ECG		If EGDT and DMINFDT not missing then perform below logic to calculate EGDY, If EGDT less than DMINFDT then (EGDT - DMINFDT).Else if EGDT is greater than equal to DMINFDT then (EGDT - DMINFDT) +1.

#### 1.4.12. Extrapyramidal Symptom Rating Scale - ESRS

<b>Dataset</b>	ESRS
<b>Creating program</b>	esrs.sas
<b>Description</b>	Extrapyramidal Symptom Rating Scale
<b>Unique identifier</b>	DUSUBJID,PHASENUM,ESSCORE
<b>Sorted by</b>	DUSUBJID,PHASENUM,ESSCORE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ESRATERI,ESACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
ESGROUP	char	ESRS Group		Collected at CRF.
ESITEM	char	ESRS Item		Collected at CRF.
ESSCOREC	num	ESRS Score Code		Collected at CRF.
ESSCORE	char	ESRS Score		Collected at CRF.
ESACTDY	num	Relative Actual Day of ESRS		If ESACTDT and DMINFDT not missing then perform below logic to calculate ESACTDY, If ESACTDT less than DMINFDT then (ESACTDT - DMINFDT).Else if ESACTDT is greater than equal to DMINFDT then (ESACTDT- DMINFDT) +1.

## 1.4.13. Exposure - EXPOSURE

<b>Dataset</b>	EXPOSURE
<b>Creating program</b>	exposure.sas
<b>Description</b>	Exposure (EX)
<b>Unique identifier</b>	DUSUBJID,VISIT,EXSTDT,EXENDT,EXSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,EXSTDT,EXENDT,EXSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXSTDT,EXENDT,KITNUM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTTRT	char	Actual Treatment		Collected at CRF.
EXREPRTC	num	Where there any medications taken		Collected at CRF.
EXREPRT	char	Where there any medications taken		Collected at CRF.
EXSEQ	num	Sequence Number		Collected at CRF.
EXGIVEN	num	Number of tablets taken		Collected at CRF.
DOSE	num	Dose per Administration		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDY and DMINFDT not missing then perform below logic to calculate EXSTDY, If EXSTDY less than DMINFDT then (EXSTDY - DMINFDT).Else if EXSTDY is greater than equal to DMINFDT then (EXSTDY- DMINFDT) +1.
EXENDY	num	Relative End Day of Exposure		If EXENDY and DMINFDT not missing then perform below logic to calculate EXENDY, If EXENDY less than DMINFDT then (EXENDY - DMINFDT).Else if EXENDY is greater than equal to DMINFDT then (EXENDY- DMINFDT) +1.

## 1.4.14. Substance Dependence History - HABIT

<b>Dataset</b>	HABIT
<b>Creating program</b>	habit.sas
<b>Description</b>	Substance Dependence History (HA)
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HAACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.



Variable	Type	Label	Codes	Comments
HAALCC	num	Alcohol abuse Code		Collected at CRF.
HAALC	char	Alcohol abuse		Collected at CRF.
HAO THC	num	Other abuse Code		Collected at CRF.
HAOTH	char	Other abuse		Collected at CRF.
HAACTDY	num	Relative Actual Day of Smoking Habit		If HAACTDT and DMINFDT not missing then perform below logic to calculate HAACTDY, If HAACTDT less than DMINFDT then (HAACTDT - DMINFDT). Else if HAACTDT is greater than equal to DMINFDT then (HAACTDT - DMINFDT) +1.

## 1.4.15. Laboratory Results(Hematology) - HEMAT

<b>Dataset</b>	HEMAT
<b>Creating program</b>	hemat.sas
<b>Description</b>	Laboratory Results(Hematology)
<b>Unique identifier</b>	DUSUBJID, LBTEST, ORGRES, VISIT
<b>Sorted by</b>	DUSUBJID, LBTEST, ORGRES, VISIT
<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: LBPRVIDC, LBPRVID, ACCNUM, LBREF, LBACTDT, LBTMLBL, LBENDT, LBENTM, STDNRC, LBTOXGR, LBTOX, LBSEQ, LBSIFACT, LBCVFACT, LBREASND, TSTCOM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	Fasting Status Code		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
REPUNIT	char	Original Units		Collected at CRF.
CNVRESC	char	Conventional Text Result		Collected at CRF.
CNVRESN	num	Conventional Numeric Result		Collected at CRF.
CNVNRLO	num	CNVNRLO		Collected at CRF.
CNVNRHI	num	CNVNRHI		Collected at CRF.
LBCVUNIT	char	CNVU		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDNRLO	num	Normal Range in Lower Limit in Std Units		Collected at CRF.
STDNRHI	num	Normal Range in Upper Limit in Std Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	Reference Range Indicator		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, if LBACTDT less than DMINFDT then (LBACTDT - DMINFDT).Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1.

#### 1.4.16. Hospitalization - HOSPITAL

<b>Dataset</b>	HOSPITAL
<b>Creating program</b>	hospital.sas
<b>Description</b>	Hospitalization (HO)
<b>Unique identifier</b>	DUSUBJID, VISITNUM
<b>Sorted by</b>	DUSUBJID, VISITNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HOENDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
HOSTATC	num	Subject Hospitalization status		Collected at CRF.
HOSTAT	char	Subject Hospitalization status		Collected at CRF.
HODISCHC	num	Is Subject Discharged from Hospital		Collected at CRF.
HODISCH	char	Is Subject Discharged from Hospital		Collected at CRF.
HOENDY	num	Relative Discharge Day of Hospitalization		If HOENDT and DMINFDT not missing then perform below logic to calculate HOENDY, If HOENDT less than DMINFDT then (HOENDT - DMINFDT).Else if HOENDT is greater than equal to DMINFDT then (HOENDT- DMINFDT) +1.

## 1.4.17. Inclusion/Exclusion Exceptions - IE

<b>Dataset</b>	IE
<b>Creating program</b>	ie.sas
<b>Description</b>	Inclusion/Exclusion Exceptions (IE)
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IEDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
IEMETC	num	Overall Criteria Met Code		Collected at CRF.
IEMET	char	Overall Criteria Met		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IESPID	char	Sponsor-defined Identifier		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.

Variable	Type	Label	Codes	Comments
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IEORRES	char	Exception Criterion Original Result		Collected at CRF.
IESTRESC	char	Exception Criterion Result in Std Format		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
IEDY	num	Relative Day of Collection		If IEDT and DMINFDT not missing then perform below logic to calculate IEDY, If IEDT less than DMINFDT then (IEDT - DMINFDT).Else if IEDT is greater than equal to DMINFDT then (IEDT - DMINFDT) +1.



## 1.4.18. Montgomery-Asberg Depression Rating Scale - MADRS

<b>Dataset</b>	MADRS
<b>Creating program</b>	madsr.sas
<b>Description</b>	Montgomery-Asberg Depression Rating Scale
<b>Unique identifier</b>	DUSUBJID,VISITNUM,MAITEM
<b>Sorted by</b>	DUSUBJID,VISITNUM,MAITEM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MAACTDT,MARATERI

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
MAITEM	char	MADRS Item		Collected at CRF.
MASCOREC	num	MADRS Score Code		Collected at CRF.
MASCORE	char	MADRS Score		Collected at CRF.
MAACTDY	num	Relative Actual Day of MADRS		If MAACTDT and DMINFDT not missing then perform below logic to calculate MAACTDY, If MAACTDT less than DMINFDT then (MAACTDT - DMINFDT).Else if MAACTDT is greater than equal to DMINFDT then (MAACTDT- DMINFDT) +1.

## 1.4.19. Medical History - MEDHIST

<b>Dataset</b>	MEDHIST
<b>Creating program</b>	medhist.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	DUSUBJID,MHBODSYS
<b>Sorted by</b>	DUSUBJID,MHBODSYS
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MHACTDT,MHTERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
MHSEQ	num	MH Sequence Number		Collected at CRF.
MHBODSYC	num	Body System Code		Collected at CRF.
MHBODSYS	char	Body System		Collected at CRF.
MHSTATC	num	Condition Code		Collected at CRF.
MHSTAT	char	Condition		Collected at CRF.
MHACTDY	num	Relative Actual Day of Collection		If MHACTDT and DMINFDT not missing then perform below logic to calculate MHACTDY, If MHACTDT less than DMINFDT then (MHACTDT - DMINFDT).Else if MHACTDT is greater than equal to DMINFDT then (MHACTDT- DMINFDT) +1.

## 1.4.20. Physical Exam - PE

<b>Dataset</b>	PE
<b>Creating program</b>	pe.sas
<b>Description</b>	Physical Exam
<b>Unique identifier</b>	DUSUBJID,PEBODSYS,VISIT
<b>Sorted by</b>	DUSUBJID,PEBODSYS,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PEACTDT,PEFIND

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PESEQ	num	Phys Sequence Number		Collected at CRF.
PEBODSYC	num	Body System Code		Collected at CRF.
PEBODSYS	char	Body System		Collected at CRF.
PESTATC	num	Exam Result Code		Collected at CRF.
PESTAT	char	Exam Result		Collected at CRF.
PEACTDY	num	Relative Actual Day of Phys Exam		If PEACTIONDT and DMINFDT not missing then perform below logic to calculate PEACTIONDY, If PEACTIONDT less than DMINFDT then (PEACTIONDT - DMINFDT).Else if PEACTIONDT is greater than equal to DMINFDT then (PEACTIONDT- DMINFDT) +1.

## 1.4.21. Pre-ass. for Insomnia or Agitation - PREVMED

<b>Dataset</b>	PREVMED
<b>Creating program</b>	prevmed.sas
<b>Description</b>	Pre-ass. for Insomnia or Agitation
<b>Unique identifier</b>	DUSUBJID,VISITNUM
<b>Sorted by</b>	DUSUBJID,VISITNUM
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PREVMEDC	num	Insomnia or agitation med received		Collected at CRF.
PREVMED	char	Insomnia or agitation med received		Collected at CRF.

#### 1.4.22. Protocol Deviation - PROTDEV

<b>Dataset</b>	PROTDEV
<b>Creating program</b>	protdev.sas
<b>Description</b>	Protocol Deviation
<b>Unique identifier</b>	DUSUBJID,PVDECOD,PVSEQ
<b>Sorted by</b>	DUSUBJID,PVDECOD,PVSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PVTERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity



Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase Number		Collected at CRF.
PVSEQ	num	Protocol Deviation Seq Number		Collected at CRF.
PVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

## 1.4.23. Personal And Social Performance Scale - PSP

<b>Dataset</b>	PSP
<b>Creating program</b>	psp.sas
<b>Description</b>	Personal And Social Performance Scale
<b>Unique identifier</b>	DUSUBJID,PSSCORE,VISIT
<b>Sorted by</b>	DUSUBJID,PSSCORE,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PSACTDT,PSRATERI

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSSCORE	num	PSP Score		Collected at CRF.
PSACTDY	num	Relative Actual Day of PSP		If PSACTDT and DMINFDT not missing then perform below logic to calculate PSACTDY, If PSACTDT less than DMINFDT then (PSACTDT - DMINFDT).Else if PSACTDT is greater than equal to DMINFDT then (PSACTDT- DMINFDT) +1.

#### 1.4.24. Randomization - RANDOM

<b>Dataset</b>	RANDOM
<b>Creating program</b>	random.sas
<b>Description</b>	Randomization
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<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: RAACTDT,RANDNUM,RASEQ,REGIMEN,RADOSE,DRUG,DURATION, FORMULAT,FREQ,ROUTE,STRENGTH,SUB,INSTRUCT,PERIOD,PRDNUM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
TRTGRPC	char	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
RAACTDY	num	Relative Actual Day of Randomization		If RAACTDT and DMINFDT not missing then perform below logic to calculate RAACTDY, If RAACTDT less than DMINFDT then (RAACTDT - DMINFDT).Else if RAACTDT is greater than equal to DMINFDT then (RAACTDT- DMINFDT) +1.

## 1.4.25. Recurrence - RECUR

<b>Dataset</b>	RECUR
<b>Creating program</b>	recur.sas
<b>Description</b>	Recurrence
<b>Unique identifier</b>	DUSUBJID,PHASENUM,VISITNUM,RCITEM
<b>Sorted by</b>	DUSUBJID,PHASENUM,VISITNUM,RCITEM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RCACTDT,RCRECDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
RCITEM	char	Recurrence Item		Collected at CRF.
RCSCOREC	num	Recurrence Score		Collected at CRF.
RCSCORE	char	Recurrence Score		Collected at CRF.
RCACTDY	num	Relative Actual day of assessment		If RCACTDT and DMINFDT not missing then perform below logic to calculate RCACTDY, If RCACTDT less than DMINFDT then (RCACTDT - DMINFDT).Else if RCACTDT is greater than equal to DMINFDT then (RCACTDT- DMINFDT) +1.
RCRECDY	num	Relative Recurrence Day		If RCRECDT and DMINFDT not missing then perform below logic to calculate RCRECDY, If RCRECDT less than DMINFDT then (RCRECDT - DMINFDT).Else if RCRECDT is greater than equal to DMINFDT then (RCRECDT- DMINFDT) +1.

## 1.4.26. Criteria for Non-Responder - RESP

<b>Dataset</b>	RESP
<b>Creating program</b>	resp.sas
<b>Description</b>	Criteria for Non-Responder
<b>Unique identifier</b>	DUSUBJID,VISITNUM,RPITEM
<b>Sorted by</b>	DUSUBJID,VISITNUM,RPITEM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RPACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
RPITEM	char	RESP Item		Collected at CRF.
RPSCOREC	num	RESP Score Code		Collected at CRF.
RPSCORE	char	RESP Score		Collected at CRF.
RPACTDY	num	Relative Actual day		If RPACTDT and DMINFDT not missing then perform below logic to calculate RPACTDY, If RPACTDT less than DMINFDT then (RPACTDT - DMINFDT).Else if RPACTDT is greater than equal to DMINFDT then (RPACTDT- DMINFDT) +1.

#### 1.4.27. Resource Use Question - RUQ

<b>Dataset</b>	RUQ
<b>Creating program</b>	ruq.sas
<b>Description</b>	Resource Use Question
<b>Unique identifier</b>	DUSUBJID,RQGROUP,RQITEM,VISITNUM,RQSEQ
<b>Sorted by</b>	DUSUBJID,RQGROUP,RQITEM,VISITNUM,RQSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: RQACTDT,RQOTH,RQSTDTC,RQSTDT,RQENDTC,RQENDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.



Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
RQGROUPC	char	RUQ Group Code		Collected at CRF.
RQGROUP	char	RUQ Group		Collected at CRF.
RQREPTC	num	RUQ Reported Code		Collected at CRF.
RQREPT	char	RUQ Reported		Collected at CRF.
RQSEQ	num	RUQ Sequence number		Collected at CRF.
RQITEM	char	RUQ Item		Collected at CRF.
RQSCOREC	char	RUQ Score Code		Collected at CRF.
RQSCORE	char	RUQ Score		Collected at CRF.
RQREASC	num	RUQ Reason Code		Collected at CRF.
RQREAS	char	RUQ Reason		Collected at CRF.
RQWARDC	num	RUQ Ward		Collected at CRF.
RQWARD	char	RUQ Ward		Collected at CRF.

Variable	Type	Label	Codes	Comments
RQTYPEC	num	RUQ Type		Collected at CRF.
RQTYPE	char	RUQ Type		Collected at CRF.
RQSTONC	num	RUQ Prior		Collected at CRF.
RQSTON	char	RUQ Prior		Collected at CRF.
RQENONC	num	RUQ Ongoing		Collected at CRF.
RQENON	char	RUQ Ongoing		Collected at CRF.
RQACTDY	num	Relative RUQ Actual Day		If RQACTDT and DMINFDT not missing then perform below logic to calculate RQACTDY, If RQACTDT less than DMINFDT then (RQACTDT - DMINFDT).Else if RQACTDT is greater than equal to DMINFDT then (RQACTDT- DMINFDT) +1.
RQSTDY	num	Relative RUQ Start day		If RQSTDTC and DMINFDT not missing then perform below logic to calculate RQSTDY, If RQSTDTC less than DMINFDT then (RQSTDTC - DMINFDT).Else if RQSTDTC is greater than equal to DMINFDT then (RQSTDTC- DMINFDT) +1.
RQENDY	num	Relative RUQ End day		If RQENDTC and DMINFDT not missing then perform below logic to calculate RQENDY, If RQENDTC less than DMINFDT then (RQENDTC - DMINFDT).Else if RQENDTC is greater than equal to DMINFDT then (RQENDTC- DMINFDT) +1.

## 1.4.28. SF-36 Short Form Health Survey - SF36

<b>Dataset</b>	SF36
<b>Creating program</b>	sf36.sas
<b>Description</b>	SF-36 Short Form Health Survey
<b>Unique identifier</b>	DUSUBJID,SFGROUP,SFITEM,SFSCORE
<b>Sorted by</b>	DUSUBJID,SFGROUP,SFITEM,SFSCORE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SFACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
SFGROUP	char	SF36 Group		Collected at CRF.
SFITEM	char	SF36 Item		Collected at CRF.
SFSCOREC	num	SF36 Score Code		Collected at CRF.
SFSCORE	char	SF36 Score		Collected at CRF.
SFACTDY	num	Relative Actual Day of SF36		If SFACTDT and DMINFDT not missing then perform below logic to calculate SFACTDY, If SFACTDT less than DMINFDT then (SFACTDT - DMINFDT).Else if SFACTDT is greater than equal to DMINFDT then (SFACTDT- DMINFDT) +1.

#### 1.4.29. Trial Inclusion/Exclusion Criteria - TI

<b>Dataset</b>	TI
<b>Creating program</b>	ti.sas
<b>Description</b>	Trial Inclusion/Exclusion Criteria
<b>Unique identifier</b>	STUDYID, IETEST
<b>Sorted by</b>	STUDYID, IETEST
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IESPID	char	Sponsor-defined Identifier		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.

#### 1.4.30. Tolerability Testing - TOLTEST

<b>Dataset</b>	TOLTEST
<b>Creating program</b>	toltest.sas
<b>Description</b>	Tolerability testing
<b>Unique identifier</b>	DUSUBJID,TPT
<b>Sorted by</b>	DUSUBJID,TPT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TTSTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
TTNAC	num	Tolerability Testing Not Applicable Code		Collected at CRF.
TTNA	char	Tolerability Testing Not Applicable		Collected at CRF.
TPTNUM	num	Planned Time Point Number		Collected at CRF.
TPT	char	Planned Time Point Number		Collected at CRF.
TTTAKEN	num	Number of Pills Taken		Collected at CRF.
TTSTDY	num	Relative Start Day of Tolerability Exposer		If TTSTDT and DMINFDT not missing then perform below logic to calculate TTSTDY, If TTSTDT less than DMINFDT then (TTSTDT - DMINFDT).Else if TTSTDT is greater than equal to DMINFDT then (TTSTDT- DMINFDT) +1.

## 1.4.31. Laboratory Results(Urinalysis) - URINE

<b>Dataset</b>	URINE
<b>Creating program</b>	urine.sas
<b>Description</b>	Laboratory Results(Urinalysis)
<b>Unique identifier</b>	DUSUBJID, LBTEST
<b>Sorted by</b>	DUSUBJID, LBTEST
<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:  LBPRVIDC, LBPRVID, ACCNUM, LBREF, LBACTDT, LBTMLBL, LBENDT, LBENTM, STDNRC, LBTOXGR, LBTOX, LBSEQ, LBSIFACT, LBCVFACT, LBREASND, TSTCOM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	Fasting Status Code		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.



Variable	Type	Label	Codes	Comments
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
REPUNIT	char	Original Units		Collected at CRF.
CNVRESC	char	Conventional Text Result		Collected at CRF.
CNVRESN	num	Conventional Numeric Result		Collected at CRF.
CNVNRLO	num	CNVNRLO		Collected at CRF.
CNVNRHI	num	CNVNRHI		Collected at CRF.
LBCVUNIT	char	CNVU		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDNRLO	num	Normal Range in Lower Limit in Std Units		Collected at CRF.
STDNRHI	num	Normal Range in Upper Limit in Std Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	Reference Range Indicator		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, if LBACTDT less than DMINFDT then (LBACTDT - DMINFDT).Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1.

#### 1.4.32. Visit - VISIT

<b>Dataset</b>	VISIT
<b>Creating program</b>	visit.sas
<b>Description</b>	Visit
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISITDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITDY	num	Relative Visit Day		If VISITDT and DMINFDT not missing then perform below logic to calculate VISITDY, If VISITDT less than DMINFDT then (VISITDT - DMINFDT).Else if VISITDT is greater than equal to DMINFDT then (VISITDT- DMINFDT) +1.

## 1.4.33. Vital Signs - VITAL

<b>Dataset</b>	VITAL
<b>Creating program</b>	vital.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DUSUBJID, VSVTYPE, VISIT, VSSEQ
<b>Sorted by</b>	DUSUBJID, VSVTYPE, VISIT, VSSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VSACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.
VSPOS	char	Position		Collected at CRF.
VSWEIGHT	num	Weight		Collected at CRF.
VSWTUNIT	char	Weight Unit		Collected at CRF.
VSHEIGHT	num	Height		Collected at CRF.
VSHTUNIT	char	Height Unit		Collected at CRF.
PULSE	num	Pulse Rate (bpm)		Collected at CRF.
SYSBP	num	Systolic Blood Pressure (mmHg)		Collected at CRF.
DIABP	num	Diastolic Blood Pressure (mmHg)		Collected at CRF.
VSACTDY	num	Relative Actual Day of Vital Signs		If VSACTDT and DMINFDT not missing then perform below logic to calculate VSACTDY, If VSACTDT less than DMINFDT then (VSACTDT - DMINFDT).Else if VSACTDT is greater than equal to DMINFDT then (VSACTDT- DMINFDT) +1.

## 1.4.34. 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>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: YMACTDT,YMRATERI

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
YMITEM	char	YMRS Item		Collected at CRF.
YMSCOREC	num	YMRS Score Code		Collected at CRF.
YMSCORE	char	YMRS Score		Collected at CRF.
YMACTDY	num	Relative Actual Day of YMRS		If YMACTDT and DMINFDT not missing then perform below logic to calculate YMACTDY, If YMACTDT less than DMINFDT then (YMACTDT - DMINFDT).Else if YMACTDT is greater than equal to DMINFDT then (YMACTDT- DMINFDT) +1.