

Clinical Development

JNJ-16232411

R076477SCA3002

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final Version
Date	March 09, 2015

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Table of contents

Clinical Development	1
1. Datasets	4
1.1. Specifications Introduction	4
1.2. Guidelines for Preparing Data.....	4
1.3. Data Files.....	5
1.4. Data Domains.....	6
1.4.1. Demographics – DEMOG	6
1.4.2. Adverse Events – AE.....	7
1.4.3. Abnormal Involuntary Movement Scale – AIMS.....	11
1.4.4. Barnes Akathisia Rating Scale – BARS	12
1.4.5. Clinical Global Impression - SSD – CGI	13
1.4.6. Comments – COMMENTS	15
1.4.7. Concomitant Medication – CONMED	16
1.4.8. Disposition – DISPOSIT	18
1.4.9. Electrocardiogram – ECG	21
1.4.10. Food Intake – FI.....	24
1.4.11. Hamilton Depression Rating Scale – HAMD.....	25
1.4.12. Hospital Admission and Discharge Summary – HOSPADM	26
1.4.13. Inclusion Exclusion – IE	28
1.4.14. InterSePT Scale for Suicidal Thinking – ISST.....	29
1.4.15. Interactive Voice Response System – IVRS	31
1.4.16. Laboratory – LAB.....	32
1.4.17. Study Medication Accountability – MEDKIT	34
1.4.18. Positive And Negative Syndrome Scale – PANSS	36
1.4.19. Physical Examination – PE.....	37
1.4.20. Urine Pregnancy Screen – PREGNCY.....	38
1.4.21. Protocol Deviations – PROTDEV.....	40
1.4.22. Psychiatric History – PSYHIST.....	41

1.4.23. Randomization – RANDOM..... 44

1.4.24. Simpson Angus Scale – SAS..... 46

1.4.25. Visits – VISIT 47

1.4.26. Vital Signs – VITAL..... 48

1.4.27. Young Mania Rating Scale – YMRS..... 50

1.4.28. Unblinded Subject Randomization File – UNBLIND 51

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.
- Investigator Name and initials will not be provided.
- Date of birth will not be provided, only age in years.
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Subject's age grouped to protect PII.
- Subject's psychiatric diagnosis age grouped to protect PII.
- Subject's psychiatric symptoms treatment age grouped to protect PII.
- Subject's first psychiatric hospitalization age grouped to protect PII.
- Country information will be grouped to protect PII.
- 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.
- 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.
- Complete missing value variables will be removed.
- Partial date's relative days cannot be calculated.
- Remove Child-bearing potential information.
- Remove ethnicity information.
- Empty comments data will be submitted.
- ECGDATE and LABASS datasets were meant for data reconciliation purpose, will be removed.
- Remove DNRSLT, MEDHIST, SUBST, TU, UDS datasets (it is sensitive information). It may reveal subject personal identification information.
- Country information will be grouped to protect PII.

1.3. Data Files

The R076477SCA3002 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demographics
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:</p> <p>PHASE, PHASENUM, SUBJINIT, BIRTHDT, BIRTHDTC, DMINFDT, DMINFDTC, RACEOT, ETHNIC, EDUSTAT, EMPSTAT, LIVSTAT, CBPOT, CBPOTC, RACEASN, RACEASNC</p>

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF
SEX	char	Sex		Collected at CRF
SEXC	char	Sex Code		Collected at CRF
RACE	char	Race		Grouping element to protect subject PII information.
AGE	num	Age in Years		Grouping element to protect subject PII. If BIRTHDTC and DMINFDTC not missing then perform below logic to derive age. INT(DMINFDTC - BIRTHDTC)/365.25

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID, DSUBJECT, AESEQ, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, AESEQ, VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, PHASENUM, AETERM, AESTDT, AEENDT, AESERREF, AESTDTC AEENDTC, AECONG, AECONGC

Variable	Type	Label	Codes	Comments
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Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
AEREPR	char	Were any AEs reported		Collected at CRF
AEREPRC	char	Were any AEs reported code		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
AEREL	char	Relationship to Treatment		Collected at CRF
AERELC	num	Relationship to Treatment Code		Collected at CRF
AESEV	char	Severity of Event		Collected at CRF
AESEVC	num	Severity of Event Code		Collected at CRF
AECONM	char	Conmed for AE/SAE?		Collected at CRF
AECONMC	num	Conmed for AE/SAE? Code		Collected at CRF

Variable	Type	Label	Codes	Comments
AEDEATH	char	Death		Collected at CRF
AEDEATHC	char	Death Code		Collected at CRF
AEHOSP	char	Hospitalization Required		Collected at CRF
AEHOSPC	char	Hospitalization Code		Collected at CRF
AEIMED	char	Important Medical Event		Collected at CRF
AEIMEDC	char	Important Medical Event Code		Collected at CRF
AELIFET	char	Life Threatening		Collected at CRF
AELIFETC	char	Life Threatening Code		Collected at CRF
AEPSDIS	char	Persistent/Significant Disability		Collected at CRF
AEPSDISC	char	Persistent/Significant Disability Code		Collected at CRF
AEPHOSP	char	Prolonged Hospitalization Required		Collected at CRF
AEPHOSPC	char	Prolonged Hospitalization Code		Collected at CRF
PT_NAME	char	MedDra Preferred Term		Collected at CRF
PT_NAMEC	char	MedDra Preferred Term Code		Collected at CRF
SOC_NAME	char	MedDra System Organ Class Term		Collected at CRF
SOCNAMEC	char	MedDra System Organ Class Term Code		Collected at CRF
LLTNAMEC	char	MedDra Low Level Term Code		Collected at CRF
LLT_NAME	char	MedDra Low Level Term		Collected at CRF

Variable	Type	Label	Codes	Comments
HLTNAMEC	char	MedDra High Level Term Code		Collected at CRF
HLT_NAME	char	MedDra High Level Term		Collected at CRF
HGTNAMEC	char	MedDra High Level Group Term Code		Collected at CRF
HGT_NAME	char	MedDra High Level Group Term		Collected at CRF
AEDICTDM	char	MedDra Dictionary Version		Collected at CRF
AESTDY	num	Relative Actual Start Day of Event		<p>If AESTDTC and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If AESTDTC less than DMINFDTC then (AESTDTC- DMINFDTC). Else if AESTDTC is greater than equal to DMINFDTC then (AESTDTC- DMINFDTC) +1.</p>
AEENDY	num	Relative Actual End Day of Event		<p>If AEENDTC and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If AEENDTC less than DMINFDTC then (AEENDTC- DMINFDTC). Else if AEENDTC is greater than equal to DMINFDTC then (AEENDTC- DMINFDTC) +1.</p>

1.4.3. Abnormal Involuntary Movement Scale – AIMS

Dataset	AIMS
Creating program	aims.sas
Description	Abnormal Involuntary Movement Scale
Unique identifier	DUSUBJID, DSUBJECT, AISEQ, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, AISEQ, VISITNUM
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
AISEQ	num	AIMS sequence number		Collected at CRF
AIGROUP	char	AIMS Group		Collected at CRF
AIITEM	char	AIMS Item		Collected at CRF

Variable	Type	Label	Codes	Comments
AISCORE	char	Score		Collected at CRF
AISCOREC	num	Coded Score		Collected at CRF

1.4.4. Barnes Akathisia Rating Scale – BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia Rating Scale
Unique identifier	DUSUBJID, DSUBJECT, BASEQ, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, BASEQ, VISITNUM
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	VISIT		Collected at CRF
BASEQ	num	BARS sequence number		Collected at CRF
BAGROUP	char	BARS Group		Collected at CRF
BAITEM	char	BARS Item		Collected at CRF
BASCORE	char	Score		Collected at CRF
BASCOREC	num	Coded Score		Collected at CRF

1.4.5. Clinical Global Impression - SSD – CGI

Dataset	CGI
Creating program	cgi.sas
Description	Clinical Global Impression - Severity Schizoaffective Disorder
Unique identifier	DUSUBJID, DSUBJECT, CGSEQ, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, CGSEQ, VISITNUM
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF

Variable	Type	Label	Codes	Comments
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
CGSEQ	num	CGI sequence number		Collected at CRF
CGITEM	char	CGI Item		Collected at CRF
CGCAT	char	CGI Category		Collected at CRF
CGSEVC	num	CGI Severity Code		Collected at CRF
CGSEV	char	CGI Severity		Collected at CRF
CGCHGC	num	CGI Change Code		Collected at CRF
CGCHG	char	CGI Change		Collected at CRF

1.4.6. Comments – COMMENTS

Dataset	COMMENTS
Creating program	comments.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.

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Empty data will be submitted.
SITE	char	Site		Empty data will be submitted.
SUBJECT	char	SUBJNUM		Empty data will be submitted.
USUBJID	char	Unique Subject ID		Empty data will be submitted.
VISITNUM	num	Visit Number		Empty data will be submitted.
DOMAIN	char	Domain of Origin		Empty data will be submitted.
DOMAINC	char	Domain of Origin Code		Empty data will be submitted.
VISIT	char	Visit		Empty data will be submitted.
VISITC	char	Visit Code		Empty data will be submitted.

1.4.7. Concomitant Medication – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant Medication
Unique identifier	DUSUBJID, DSUBJECT, CMSEQ, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, CMSEQ, VISITNUM
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:</p> <p>PHASE, PHASENUM, CMTERM, CMREAS, CMSTDT, CMENDT, CMSTDTC, CMENDTC, CMREGIM, CMREGUNT</p>

Variable	Type	Label	Codes	Comments
CMTYPE	char	Medication type		Collected at CRF
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF

Variable	Type	Label	Codes	Comments
CMCAT	char	Concomitant medication category		Collected at CRF
CMTYPEC	num	Medication type Code		Collected at CRF
CMSTATC	num	No Concomitant Medication Code		Collected at CRF
CMSTAT	char	No Concomitant Medication		Collected at CRF
CMAENO	char	Concomitant Medication AE number		Collected at CRF
CMSEQ	num	Conmed Sequence Number		Collected at CRF
CMROUTE	char	Route of Administration		Collected at CRF
CMROUTE C	char	Route of Administration Code		Collected at CRF
CMCONT	char	Medication Continuing		Collected at CRF
CMCONT C	char	Medication Continuing Code		Collected at CRF
CMDECOD	char	Medication Generic Term		Collected at CRF
CMCODE	char	Medication Dictionary Code		Collected at CRF
CMPN	char	Preferred Medication Name		Collected at CRF
ATCCODE	char	ATC Code		Collected at CRF
ATCTEXT	char	ATC Text		Collected at CRF

Variable	Type	Label	Codes	Comments
CMSTDY	num	Relative Actual Start Day of Medication		If CMSTDTC and DMINFDTC not missing then perform below logic to calculate relative day. If CMSTDTC less than DMINFDTC then (CMSTDTC- DMINFDTC). Else if CMSTDTC is greater than equal to DMINFDTC then (CMSTDTC- DMINFDTC) +1.
CMENDY	num	Relative Actual End Day of Medication		If CMENDTC and DMINFDTC not missing then perform below logic to calculate relative day. If CMENDTC less than DMINFDTC then (CMENDTC- DMINFDTC). Else if CMENDTC is greater than equal to DMINFDTC then (CMENDTC- DMINFDTC) +1.

1.4.8. Disposition – DISPOSIT

Dataset	DISPOSIT
Creating program	disposit.sas
Description	Disposition
Unique identifier	DUSUBJID, DSUBJECT, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, PHASENUM, DSACTDT, DSDOSDT, DRSOTH, DSACTDTC, DSDOSDTC

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
DSTYPE	char	End of Treatment or Trial		Collected at CRF
DSTYPEC	char	End of Treatment or Trial Code		Collected at CRF
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF
DSSTATC	char	Subject Completed Treatment/Trial Code		Collected at CRF
DSREAS	char	Reason for Withdrawal/Termination		Collected at CRF
DSREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF
DSCONT	char	Subject continued day 43		Collected at CRF
DSCONTC	char	Subject continued day 42 code		Collected at CRF

Variable	Type	Label	Codes	Comments
DSACTDY	num	Relative Actual Day Trial Completion/Withdrawal		<p>If DSACTDTC and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If DSACTDTC less than DMINFDTC then (DSACTDTC- DMINFDTC). Else if DSACTDTC is greater than equal to DMINFDTC then (DSACTDTC- DMINFDTC) +1.</p>
DSDOSDY	num	Relative Day of Last Dose		<p>If DSDOSDTC and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If DSDOSDTC less than DMINFDTC then (DSDOSDTC- DMINFDTC). Else if DSDOSDTC is greater than equal to DMINFDTC then (DSDOSDTC- DMINFDTC) +1.</p>

1.4.9. Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DUSUBJID, DSUBJECT, EGTEST, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, EGTEST, VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RECDT, EGDT, DIAGC8, DIAGC9, DIAGC10, DIAGT8, DIAGT9, DIAGT10, EGDRCOM, EGDRCOM2, RECDTC, EGDTTC

Variable	Type	Label	Codes	Comments
TRIAL	char	Protocol Name		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
VISIT	char	Visit		Collected at CRF
EGACTTM	num	Time of ECG		Collected at CRF
EGTESTC	char	ECG Test code		Collected at CRF
EGTEST	char	ECG Test name		Collected at CRF
EGRESN	num	ECG Test numeric		Collected at CRF

Variable	Type	Label	Codes	Comments
EGRESC	char	ECG Test character		Collected at CRF
RATE	char	Heart Rate		Collected at CRF
EGINTPC	char	ECG Assessment Code		Collected at CRF
EGINTP	char	ECG Assessment Text		Collected at CRF
EGCHGC	char	Comparison Code		Collected at CRF
EGCHG	char	Comparison Text		Collected at CRF
DIAGC1	char	Diagnostic Code 1		Collected at CRF
DIAGC2	char	Diagnostic Code 2		Collected at CRF
DIAGC3	char	Diagnostic Code 3		Collected at CRF
DIAGC4	char	Diagnostic Code 4		Collected at CRF
DIAGC5	char	Diagnostic Code 5		Collected at CRF
DIAGC6	char	Diagnostic Code 6		Collected at CRF
DIAGC7	char	Diagnostic Code 7		Collected at CRF
DIAGT1	char	Diagnostic Text 1		Collected at CRF
DIAGT2	char	Diagnostic Text 2		Collected at CRF
DIAGT3	char	Diagnostic Text 3		Collected at CRF
DIAGT4	char	Diagnostic Text 4		Collected at CRF

Variable	Type	Label	Codes	Comments
DIAGT5	char	Diagnostic Text 5		Collected at CRF
DIAGT6	char	Diagnostic Text 6		Collected at CRF
DIAGT7	char	Diagnostic Text 7		Collected at CRF
EGLDPQC	char	Lead PQRST Code		Collected at CRF
EGLDPQ	char	Lead PQRST Text		Collected at CRF
EGLDRRC	char	Lead RR Code		Collected at CRF
EGLDRR	char	Lead RR Text		Collected at CRF
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
RECDY	num	Relative Received Day		If RECDTC and DMINFDTC not missing then perform below logic to calculate relative day. If RECDTC less than DMINFDTC then (RECDTC-DMINFDTC). Else if RECDTC is greater than equal to DMINFDTC then (RECDTC- DMINFDTC) +1.
EGDY	num	Relative Day of ECG		If EGDTC and DMINFDTC not missing then perform below logic to calculate relative day. If EGDTC less than DMINFDTC then (EGDTC-DMINFDTC). Else if EGDTC is greater than equal to DMINFDTC then (EGDTC- DMINFDTC) +1.

1.4.10. Food Intake – FI

Dataset	FI
Creating program	fi.sas
Description	Food Intake
Unique identifier	DUSUBJID, DSUBJECT, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, VISITNUM
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
FIBFAST	char	Breakfast taken?		Collected at CRF
FITIME	num	Breakfast time		Collected at CRF
FITYPE	char	Breakfast type		Collected at CRF

Variable	Type	Label	Codes	Comments
FIINTM	num	Medication intake time		Collected at CRF

1.4.11. Hamilton Depression Rating Scale – HAMD

Dataset	HAMD
Creating program	hamd.sas
Description	Hamilton Depression Rating Scale
Unique identifier	DUSUBJID, DSUBJECT, HASEQ, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, HASEQ, VISITNUM
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF

Variable	Type	Label	Codes	Comments
HASEQ	num	HAMD sequence number		Collected at CRF
HAITEM	char	HAMD item		Collected at CRF
HASCORE	char	HAMD score		Collected at CRF
HASCOREC	num	HAMD score code		Collected at CRF
HATOTAL	num	HAMD total score		Collected at CRF

1.4.12. Hospital Admission and Discharge Summary – HOSPADM

Dataset	HOSPADM
Creating program	hospadm.sas
Description	Psychiatric Hospital Admission and Discharge Summary
Unique identifier	DUSUBJID, DSUBJECT, HOSEQ, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, HOSEQ, VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, PHASENUM, HOSTDT, HOENDT, HOSPEC, HOSTDTC, HOENDTC, HODISTOC, HODISTO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF

Variable	Type	Label	Codes	Comments
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
HOSEQ	num	Hospital Admission sequence number		Collected at CRF
HOREHO	char	Subject re-hospitalized?		Collected at CRF
HOREHOC	char	Subject re-hospitalized? Code		Collected at CRF
HOREAS	char	Reason for hospitalization		Collected at CRF
HOREASC	num	Reason code		Collected at CRF
HOSTDY	num	Relative Day of Hospital Admission		If HOSTDTC and DMINFDTC not missing then perform below logic to calculate relative day. If HOSTDTC less than DMINFDTC then (HOSTDTC-DMINFDTC). Else if HOSTDTC is greater than equal to DMINFDTC then (HOSTDTC- DMINFDTC) +1.
HOENDY	num	Relative Day of Hospital Discharge		If HOENDTC and DMINFDTC not missing then perform below logic to calculate relative day. If HOENDTC less than DMINFDTC then (HOENDTC-DMINFDTC). Else if HOENDTC is greater than equal to DMINFDTC then (HOENDTC- DMINFDTC) +1.

1.4.13. Inclusion Exclusion – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion Exclusion
Unique identifier	DUSUBJID, DSUBJECT, IESEQ, VISITNUM, IETEST
Sorted by	DUSUBJID, DSUBJECT, IESEQ, VISITNUM, IETEST
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
IECAT	char	Inclusion/Exclusion Category		Collected at CRF
IESEQ	num	Inclusion/Exclusion sequence number		Collected at CRF

Variable	Type	Label	Codes	Comments
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF
IEORRES	char	IE Criterion Original Result		Collected at CRF
IEORRESC	char	IE Criterion Original Result Code		Collected at CRF

1.4.14. InterSePT Scale for Suicidal Thinking – ISST

Dataset	ISST
Creating program	isst.sas
Description	InterSePT Scale for Suicidal Thinking
Unique identifier	DUSUBJID, DSUBJECT, ISSEQ, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, ISSEQ, VISITNUM
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
ISITEM	char	ISST item		Collected at CRF
ISSEQ	num	ISST sequence		Collected at CRF
ISSCOREC	num	ISST score code		Collected at CRF
ISSCORE	char	ISST score		Collected at CRF

1.4.15. Interactive Voice Response System – IVRS

Dataset	IVRS
Creating program	ivrs.sas
Description	Interactive Voice Response System
Unique identifier	DUSUBJID, DSUBJECT, VISITNUM, DISPDY, RAACTDY
Sorted by	DUSUBJID, DSUBJECT, VISITNUM, DISPDY, RAACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: KITNUM, DISPDT, RAACTDT, RANDNUM

Variable	Type	Label	Codes	Comments
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
VISITNUM	char	Visit Number		Collected at CRF
DSTRATA	char	Strata Assigned for De-identity		Randomly assigned Strata for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DISPDY	num	Relative Actual Day Kit Dispensed		If DISPDT and DMINFDTC not missing then perform below logic to calculate relative day. If DISPDT less than DMINFDTC then (DISPDT - DMINFDTC). Else if DISPDT is greater than equal to DMINFDTC then (DISPDT - DMINFDTC) +1.

Variable	Type	Label	Codes	Comments
RAACTDY	num	Relative Actual Day of Randomization		<p>If RAACTDT and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If RAACTDT less than DMINFDTC then (RAACTDT - DMINFDTC). Else if RAACTDT is greater than equal to DMINFDTC then (RAACTDT - DMINFDTC) +1.</p>

1.4.16. Laboratory – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory
Unique identifier	DUSUBJID, DSUBJECT, LBTEST, VISITNUM, LBACTDY, LBACTTM
Sorted by	DUSUBJID, DSUBJECT, LBTEST, VISITNUM, LBACTDY, LBACTTM
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>LBREF, LBACTDT, LBRECDT</p> <p>Note: Protocol unplanned tests will be removed from data; it may reveal participant information.</p>

Variable	Type	Label	Codes	Comments
TRIAL	char	Study ID		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity

Variable	Type	Label	Codes	Comments
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
VISIT	char	Visit		Collected at CRF
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF
LBTYPE	char	Laboratory type		Collected at CRF
LBTESTC	char	Lab Test Code		Collected at CRF
LBTEST	char	Lab Test Name		Collected at CRF
ORGRES	char	Character lab result		Collected at CRF
ORGRESN	num	Numeric lab result		Collected at CRF
ORGUNIT	char	Original Units		Collected at CRF
STDRESN	num	S.I. Numeric Results		Collected at CRF
STDUNIT	char	S.I. Units		Collected at CRF
ORGRRC	char	Reference range textual		Collected at CRF
ORGNRLO	num	Lower limit for the lab normal range		Collected at CRF
ORGNRHI	num	Upper limit for the lab normal range		Collected at CRF
STDNRLO	num	S.I. lower limit		Collected at CRF
STDNRHI	num	S.I. upper limit		Collected at CRF
NRIND	char	High/Low Lab Value Flag		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
VISITNUM	num	Visit Number		Collected at CRF
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDTC not missing then perform below logic to calculate relative day. If LBACTDT less than DMINFDTC then (LBACTDT-DMINFDTC). Else if LBACTDT is greater than equal to DMINFDTC then (LBACTDT- DMINFDTC) +1.
LBRECDY	num	Relative Received Day		If LBRECDT and DMINFDTC not missing then perform below logic to calculate relative day. If LBRECDT less than DMINFDTC then (LBRECDT-DMINFDTC). Else if LBRECDT is greater than equal to DMINFDTC then (LBRECDT- DMINFDTC) +1.

1.4.17. Study Medication Accountability – MEDKIT

Dataset	MEDKIT
Creating program	medkit.sas
Description	Study Medication Dispensation/ return
Unique identifier	DUSUBJID, DSUBJECT, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, PHASENUM, KITNUM, DISPDT, RETDT, DISPDT, RETDTC

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
DISNUM	num	Number Dispensed		Collected at CRF
RETNUM	num	Number Returned		Collected at CRF
TAKNUM	num	Number Taken		Collected at CRF
DISPDY	num	Relative Actual Day Kit Dispensed		If DISPDC and DMINFDTC not missing then perform below logic to calculate relative day. If DISPDC less than DMINFDTC then (DISPDC-DMINFDTC). Else if DISPDC is greater than equal to DMINFDTC then (DISPDC- DMINFDTC) +1.
RETDY	num	Relative Actual Day Kit Returned		If RETDTC and DMINFDTC not missing then perform below logic to calculate relative day. If RETDTC less than DMINFDTC then (RETDTC-DMINFDTC). Else if RETDTC is greater than equal to DMINFDTC then (RETDTC- DMINFDTC) +1.

1.4.18. Positive And Negative Syndrome Scale – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	Positive And Negative Syndrome Scale for Schizophrenia (with total)
Unique identifier	DUSUBJID, DSUBJECT, PASEQ, VISITNUM
Sorted by	DUSUBJID, DSUBJECT, PASEQ, VISITNUM
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
PASEQ	num	PANSS sequence number		Collected at CRF
PAGROUP	char	PANSS Group		Collected at CRF
PAITEM	char	PANNS Item		Collected at CRF

Variable	Type	Label	Codes	Comments
PASSCORE	char	PANSS Score		Collected at CRF
PASSCOREC	num	PANSS Coded Score		Collected at CRF
PATOTAL	num	PANSS Total		Collected at CRF

1.4.19. Physical Examination – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examination
Unique identifier	DUSUBJID,DSUBJECT,PESEQ,VISITNUM
Sorted by	DUSUBJID,DSUBJECT,PESEQ,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, PHASENUM, PEFIND

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
PEBODSYS	char	Body System		Collected at CRF
PESEQ	num	Phys Sequence Number		Collected at CRF
PESTAT	char	Exam Result		Collected at CRF

1.4.20. Urine Pregnancy Screen – PREGNCY

Dataset	PREGNCY
Creating program	pregncy.sas
Description	Urine Pregnancy Screen
Unique identifier	DUSUBJID,DSUBJECT,VISITNUM
Sorted by	DUSUBJID,DSUBJECT,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, PHASENUM, PACTDT, PACTDTC

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF

Variable	Type	Label	Codes	Comments
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
PGSTAT	char	Pregnancy Test status		Collected at CRF
PGSTATC	char	Pregnancy Test status code		Collected at CRF
PGNA	char	Pregnancy Test not applicable		Collected at CRF
PGRES	char	Pregnancy Test Result		Collected at CRF
PGRESC	char	Pregnancy Test Result Code		Collected at CRF
PGACTDY	num	Relative Actual Day of Pregnancy Test		<p>If PGACTDTC and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If PGACTDTC less than DMINFDTC then (PGACTDTC- DMINFDTC). Else if PGACTDTC is greater than equal to DMINFDTC then (PGACTDTC- DMINFDTC) +1.</p>

1.4.21. Protocol Deviations – PROTDEV

Dataset	PROTDEV
Creating program	protdev.sas
Description	Protocol Deviations
Unique identifier	DSUBJID
Sorted by	DSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DEVIAT_V

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DEVIAT	char	Deviation Category		Collected at CRF
ZDEVIAT	char	Deviation Class		Collected at CRF
DVTYPE	char	Deviation Type		Collected at CRF

1.4.22. Psychiatric History – PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychiatric History
Unique identifier	DUSUBJID,DSUBJECT,VISITNUM
Sorted by	DUSUBJID,DSUBJECT,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, PHASENUM, PYSPEC, PYSCHDT, PYSTDT, PYCURDT, PYSCHDTC, PYSTDTC, PYCURDTC, PYSUIC, PYSUICC, PYSUNUM, PYSUTMC, PYSUTM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
PYAGE	num	Psychiatric diagnosis age		Grouping element to protect subject PII information.

Variable	Type	Label	Codes	Comments
PYSYMP	num	Psychiatric symptoms treatment age		Grouping element to protect subject PII information.
PYSCHZC	char	Schizophrenia diagnosis code		Collected at CRF
PYSCHZ	char	Schizophrenia diagnosis		Collected at CRF
PYBIDC	char	Bi-polar disorder diagnosis code		Collected at CRF
PYBID	char	Bi-polar disorder diagnosis		Collected at CRF
PYDEPC	char	Depression diagnosis code		Collected at CRF
PYDEP	char	Depression diagnosis		Collected at CRF
PYOTHC	char	Other diagnosis code		Collected at CRF
PYOTH	char	Other diagnosis		Collected at CRF
PYCDIAG	char	Current schizophrenic diagnosis		Collected at CRF
PYHOAGE	num	First psychiatric hospitalization age		Grouping element to protect subject PII information.
PYHOSP1	num	Hospitalizations within 12 months		Collected at CRF
PYHOSP2	num	Hospitalizations between 13-24		Collected at CRF
PYHOSP3	num	Hospitalizations greater than 24		Collected at CRF
PYHOSP4	char	Hospitalizations greater than 24 unknown		Collected at CRF
PYHOSP4C	char	Hospitalizations > 24 unknown code		Collected at CRF
PYLSTHO	char	Last psychiatric hospitalization		Collected at CRF

Variable	Type	Label	Codes	Comments
PYSCHDY	num	Relative Day of first schizophrenic diagnosis		<p>If PYSCHDTC and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If PYSCHDTC less than DMINFDTC then (PYSCHDTC- DMINFDTC). Else if PYSCHDTC is greater than equal to DMINFDTC then (PYSCHDTC- DMINFDTC) +1.</p>
PYSTDY	num	Relative Onset Day of current episode		<p>If PYSTDTC and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If PYSTDTC less than DMINFDTC then (PYSTDTC- DMINFDTC). Else if PYSTDTC is greater than equal to DMINFDTC then (PYSTDTC- DMINFDTC) +1.</p>
PYCURDY	num	Relative Day of current hospital admission		<p>If PYCURDTC and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If PYCURDTC less than DMINFDTC then (PYCURDTC- DMINFDTC). Else if PYCURDTC is greater than equal to DMINFDTC then (PYCURDTC- DMINFDTC) +1.</p>

1.4.23. Randomization – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomization
Unique identifier	DUSUBJID,DSUBJECT,VISITNUM
Sorted by	DUSUBJID,DSUBJECT,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, PHASENUM, RAACTDT, RAFDDT, RANSTATC, RANMOODC, RAACTDTC, RAFTDDTC

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
RANSTAT	char	Randomization status		Collected at CRF
RANSTATC	char	Randomization status		Collected at CRF

Variable	Type	Label	Codes	Comments
RANMOOD	char	Antidepressants or mood stabilizers		Collected at CRF
RANMOODC	char	Antidepressants or mood stabilizers code		Collected at CRF
RANREAS	char	Reason not randomized		Collected at CRF
RAACTDY	num	Relative Actual Day of Randomization		If RAACTDTC and DMINFDTTC not missing then perform below logic to calculate relative day. If RAACTDTC less than DMINFDTTC then (RAACTDTC- DMINFDTTC). Else if RAACTDTC is greater than equal to DMINFDTTC then (RAACTDTC- DMINFDTTC) +1.
RAFDDY	num	Relative Day of first dose		If RAFDDTC and DMINFDTTC not missing then perform below logic to calculate relative day. If RAFDDTC less than DMINFDTTC then (RAFDDTC- DMINFDTTC). Else if RAFDDTC is greater than equal to DMINFDTTC then (RAFDDTC- DMINFDTTC) +1.

1.4.24. Simpson Angus Scale – SAS

Dataset	SAS
Creating program	sas.sas
Description	Simpson Angus Scale
Unique identifier	DUSUBJID,DSUBJECT,SASEQ,VISITNUM
Sorted by	DUSUBJID,DSUBJECT,SASEQ,VISITNUM
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM.

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
SASEQ	num	SAS sequence number		Collected at CRF
SASCAC	num	SAS scale code		Collected at CRF

SASCA	char	SAS scale		Collected at CRF
SAITEM	char	SAS item		Collected at CRF

1.4.25. Visits – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visits
Unique identifier	DUSUBJID,DSUBJECT,VISITNUM
Sorted by	DUSUBJID,DSUBJECT,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PHASE, PHASENUM, VISITDT, VISITDTC

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

VISIT	char	Visit		Collected at CRF
VISITDY	num	Relative Visit Day		<p>If VISITDTC and DMINFDTC not missing then perform below logic to calculate relative day.</p> <p>If VISITDTC less than DMINFDTC then (VISITDTC- DMINFDTC). Else if VISITDTC is greater than equal to DMINFDTC then (VISITDTC- DMINFDTC) +1.</p>

1.4.26. Vital Signs – VITAL

Dataset	Vital
Creating program	vital.sas
Description	Vital Signs
Unique identifier	DUSUBJID,DSUBJECT,VISITNUM
Sorted by	DUSUBJID,DSUBJECT,VISITNUM
Notes	<p>Below listed variables will be dropped from dataset due to missing values:</p> <p>PHASE, PHASENUM.</p>

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
WEIGHT	num	Weight		Convert data to standardized "kg" unit values. Grouping element to protect subject PII.
WTUNIT	char	Weight unit		All data converted into KGs.
HEIGHT	num	Height		Convert data to standardized "cm" unit values. Grouping element to protect subject PII.
HTUNIT	char	Height unit		All data converted into CMs.
PULSESU	num	Pulse Rate bpm (supine after 5 min)		Collected at CRF
TEMP	num	Temperature		Collected at CRF
TEMPUNIT	char	Temperature Unit		Collected at CRF
SYSBPSU	num	Systolic BP mmHg (supine after 5 min)		Collected at CRF
DIABPSU	num	Diastolic BP mmHg (supine after 5 min)		Collected at CRF
RESP	num	Respiration Rate (/min)		Collected at CRF
PULSEST	num	Pulse Rate bpm (standing after 2 min)		Collected at CRF
SYSBPST	num	Systolic BP mmHg (standing after 2 min)		Collected at CRF

Variable	Type	Label	Codes	Comments
DIABPST	num	Diastolic BP mmHg (standing after 2 min)		Collected at CRF

1.4.27. Young Mania Rating Scale – YMRS

Dataset	YMRS
Creating program	ymrs.sas
Description	Young Mania Rating Scale
Unique identifier	DUSUBJID,DSUBJECT,YMSEQ,VISITNUM
Sorted by	DUSUBJID,DSUBJECT,YMSEQ,VISITNUM
Notes	Below listed variables will be dropped from dataset due to missing values: PHASE, PHASENUM.

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF
DSITE	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJECT	char	SUBJNUM Assigned for De-identity		Randomly assigned SUBJNUM for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF
YMSEQ	num	YMRS sequence number		Collected at CRF
YMITEM	char	YMRS item		Collected at CRF
YMSCOREC	num	YMRS score code		Collected at CRF
YMSCORE	char	YMRS score		Collected at CRF
YMTOTAL	num	YMRS total score		Collected at CRF

1.4.28. Unblinded Subject Randomization File – UNBLIND

Dataset	UNBLIND
Creating program	unblind.sas
Description	Unblinded Subject Randomization File
Unique identifier	DSUBJID
Sorted by	DSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJINIT, SITEID, KITNUM, BIRTH_DT, DISPDT, RAACTDT, RANDNUM

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DCONTRYC	char	Country Code Assign for De-identity		Grouping element to protect subject PII.
DOSE	char	Description of kit assigned		Collected at CRF
TREAT	char	Treatment Group		Collected at CRF
VISITNUM	num	Visit Number		Collected at CRF