

Clinical Development

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RIS-BIP-301

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Comments dataset will be submitted with zero observation due to sensitivity of data.
- CONSENT.CONSTND1 ("SAS Consent Date") is used as reference date to derive relative days.

1.3. Data Files

The RIS-BIP-301 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Subject Characteristics – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	Subject Characteristics
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: VISITD1,VISITD2,BIRTHD1,BIRTHD2,RACESP,INIT6,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
AGE	char	Calculated Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
SEX	num	Sex		Collected at CRF.
RACE	num	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFPL6	num	Plate 6		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
VISIT1DY	num	Relative Visit Day		If VISITD1 and CONSNT1D not missing then perform below logic to calculate VISIT1DY, If VISITD1 less than CONSNT1D then (VISITD1 - CONSNT1D). Else if VISITD1 is greater than equal to CONSNT1D then (VISITD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.2. Abnormal Involuntary Movement Scale - AIMS

Dataset	AIMS
Creating program	aims.sas
Description	Abnormal Involuntary Movement Scale
Unique identifier	DCRFID,COMP1DY
Sorted by	DCRFID,COMP1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COMP1D,COMP2D,INIT120,INIT121,INIT157,INIT158,RANDD1,RANDD2, RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
AIMS1	num	Muscles of Facial Expression		Collected at CRF.
AIMS2	num	Lips and Perioral Area		Collected at CRF.
AIMS3	num	Jaw		Collected at CRF.
AIMS4	num	Tongue		Collected at CRF.
AIMS5	num	Upper Extremities		Collected at CRF.
AIMS6	num	Lower Extremities		Collected at CRF.

Variable	Type	Label	Codes	Comments
AIMS7	num	Neck, Shoulders, Hips		Collected at CRF.
AIMS8	num	Severity of Abn Mvmts		Collected at CRF.
AIMS9	num	Incapacitation		Collected at CRF.
AIMS10	num	Awareness of Abn Mvmts		Collected at CRF.
AIMS11	num	Problems w Teeth/Dentures		Collected at CRF.
AIMS12	num	Subject Wears Dentures?		Collected at CRF.
AIMSSUM	num	Calculated Total Score		Collected at CRF.
AIMSF1	num	Coded Question 1		Collected at CRF.
AIMSF2	num	Coded Question 2		Collected at CRF.
AIMSF3	num	Coded Question 3		Collected at CRF.
AIMSF4	num	Coded Question 4		Collected at CRF.
AIMSF5	num	Coded Question 5		Collected at CRF.
AIMSF6	num	Coded Question 6		Collected at CRF.
AIMSF7	num	Coded Question 7		Collected at CRF.
AIMSF8	num	Coded Question 8		Collected at CRF.
AIMSF9	num	Coded Question 9		Collected at CRF.
AIMSF10	num	Coded Question 10		Collected at CRF.
AIMSF11	num	Coded Question 11		Collected at CRF.
AIMSF12	num	Coded Question 12		Collected at CRF.
DFPL120	num	Plate 120		Collected at CRF.
DFPL121	num	Plate 121		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFPL157	num	Plate 157		Collected at CRF.
DFPL158	num	Plate 158		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
COMP1DY	num	Relative AIMS Completed Day		If COMPD1 and CONSNT1D not missing then perform below logic to calculate COMP1DY, If COMPD1 less than CONSNT1D then (COMPD1 - CONSNT1D). Else if COMPD1 is greater than equal to CONSNT1D then (COMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.3. Antidepressant Therapy – ANTIDEP

Dataset	ANTIDEP
Creating program	antidep.sas
Description	Antidepressant Therapy
Unique identifier	DCRFID,CTFREQ,CFROM1DY
Sorted by	DCRFID,CTFREQ,CFROM1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CONRX_V,CFROMD1,CFROMD2,CTOD1,CTOD2,INIT85,RANDD1,RANDD2, RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
ANTIDEP	num	Any Antidepressants?		Collected at CRF.
CTSEQV	num	Verbatim Med Num		Collected at CRF.
CTSEQNO	num	Calculated Med Num		Collected at CRF.
CONRX	char	Preferred Drug Term		Collected at CRF.
CTDOSE	char	Dose		Collected at CRF.
CTUNIT	char	Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTFREQ	char	Frequency		Collected at CRF.
CTROUTE	char	Route		Collected at CRF.
CTONGO	num	Antidepressant Ongoing?		Collected at CRF.
DFPL85	num	Plate 85		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
CFROM1DY	num	Relative Start Day		If CFROMD1 and CONSNT1D not missing then perform below logic to calculate CFROM1DY, If CFROMD1 less than CONSNT1D then (CFROMD1 - CONSNT1D). Else if CFROMD1 is greater than equal to CONSNT1D then (CFROMD1- CONSNT1D) +1.
CTO1DY	num	Relative Stop Day		If CTOD1 and CONSNT1D not missing then perform below logic to calculate CTO1DY, If CTOD1 less than CONSNT1D then (CTOD1 - CONSNT1D). Else if CTOD1 is greater than equal to CONSNT1D then (CTOD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.4. Antipsychotic – ANTIPSY

Dataset	ANTIPSY
Creating program	antipsy.sas
Description	Antipsychotic
Unique identifier	DCRFID,CTFREQ,CFROM1DY
Sorted by	DCRFID,CTFREQ,CFROM1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CONRX_V,CFROMD1,CFROMD2,CTOD1,CTOD2,INIT89,RANDD1,RANDD2, RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
CTSEQV	num	Verbatim Med Num		Collected at CRF.
CTSEQNO	num	Calculated Med Num		Collected at CRF.
CONRX	char	Preferred Drug Term		Collected at CRF.
CTDOSE	char	Dose		Collected at CRF.
CTUNIT	char	Unit		Collected at CRF.
CTFREQ	char	Frequency		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTROUTE	char	Route		Collected at CRF.
CTONGO	num	Ongoing Post-Trial?		Collected at CRF.
DFPL89	num	Plate 89		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
CFROM1DY	num	Relative Start Day		If CFROMD1 and CONSNT1D not missing then perform below logic to calculate CFROM1DY, If CFROMD1 less than CONSNT1D then (CFROMD1 - CONSNT1D). Else if CFROMD1 is greater than equal to CONSNT1D then (CFROMD1- CONSNT1D) +1.
CTO1DY	num	Relative Stop Day		If CTOD1 and CONSNT1D not missing then perform below logic to calculate CTO1DY, If CTOD1 less than CONSNT1D then (CTOD1 - CONSNT1D). Else if CTOD1 is greater than equal to CONSNT1D then (CTOD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.5. Adverse Events – BADR

Dataset	BADR
Creating program	badr.sas
Description	Adverse Events
Unique identifier	DCRFID, AEPREF, AEFROM1DY
Sorted by	DCRFID, AEPREF, AEFROM1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INIT81, AE_V, AEFROMD1, AEFROMD2, AETOD1, AETOD2, RANDD1, RANDD2, RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
AE	num	Any AEs?		Collected at CRF.
AESEQNO	num	Calculated AE Number		Collected at CRF.
AESEQV	num	Verbatim AE Number		Collected at CRF.
AEJOI	char	Data Entry Coding Term		Collected at CRF.
AEINCL	char	WHO 98 Included Term		Collected at CRF.
AEPREF	char	WHO 98 Preferred Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
BDYCLASS	num	WHO 98 Body System		Collected at CRF.
ZAESEV	num	Severity of AE		Collected at CRF.
ZAESER	num	Is AE Serious?		Collected at CRF.
ZAERELAT	num	Relation to Study Drug		Collected at CRF.
ZAEACT1	num	Action Taken?		Collected at CRF.
ZAECONRX	num	ConMed Required?		Collected at CRF.
ZAEOUT	num	Outcome of AE		Collected at CRF.
DFPL81	num	Plate 81		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
AEFROMDY	num	Relative Start Day		If AEFROMD1 and CONSNT1D not missing then perform below logic to calculate AEFROMDY, If AEFROMD1 less than CONSNT1D then (AEFROMD1 - CONSNT1D). Else if AEFROMD1 is greater than equal to CONSNT1D then (AEFROMD1- CONSNT1D) +1.

Variable	Type	Label	Codes	Comments
AETO1DY	num	Relative Stop Day		If AETOD1 and CONSNT1D not missing then perform below logic to calculate AETO1DY, If AETOD1 less than CONSNT1D then (AETOD1 - CONSNT1D). Else if AETOD1 is greater than equal to CONSNT1D then (AETOD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.6. Barnes Akathisia Rating Scale – BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia Rating Scale
Unique identifier	DCRFID,COMP1DY
Sorted by	DCRFID,COMP1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COMP1,COMP2,INIT160,INIT161,INIT129,INIT130,RANDD1,RANDD2, RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
BARS1	num	Objective		Collected at CRF.
BARS2	num	Subjective		Collected at CRF.
BARS3	num	Reported		Collected at CRF.
BARS4	num	Global Clinical Rating		Collected at CRF.
BARSSUM	num	Calculated Total Score		Collected at CRF.
BARSF1	num	Coded Objective		Collected at CRF.

Variable	Type	Label	Codes	Comments
BARSF2	num	Coded Subjective		Collected at CRF.
BARSF3	num	Coded Reported		Collected at CRF.
BARSF4	num	Coded Global Clinical Rating		Collected at CRF.
DFPL160	num	Plate 160		Collected at CRF.
DFPL161	num	Plate 161		Collected at CRF.
DFPL129	num	Plate 129		Collected at CRF.
DFPL130	num	Plate 130		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
COMP1DY	num	Relative BARS Completed Day		If COMPD1 and CONSNT1D not missing then perform below logic to calculate COMP1DY, If COMPD1 less than CONSNT1D then (COMPD1 - CONSNT1D). Else if COMPD1 is greater than equal to CONSNT1D then (COMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.7. ClinicaGlobalImpressionSeveritofIllness – CGIS

Dataset	CGIS
Creating program	cgis.sas
Description	ClinicaGlobalImpressionSeveritofIllness
Unique identifier	DCRFID,CGIS,COMP1DY
Sorted by	DCRFID,CGIS,COMP1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COMP1,COMP2,ASMTBY,INIT100,INIT155,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
CGIS	num	Clinical Global Impression Severity		Collected at CRF.
DFPL100	num	Plate 100		Collected at CRF.
DFPL155	num	Plate 155		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.

Variable	Type	Label	Codes	Comments
COMP1DY	num	Relative CGI-S Performed Day		If COMPD1 and CONSNT1D not missing then perform below logic to calculate COMP1DY, If COMPD1 less than CONSNT1D then (COMPD1 - CONSNT1D). Else if COMPD1 is greater than equal to CONSNT1D then (COMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.8. Comments – COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Comments
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comments dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Empty dataset will be submitted
DCRFID	char	CRF ID Assigned for De-Identity		Empty dataset will be submitted
DFPLATE	num	Plate Number		Empty dataset will be submitted
DFSEQ	num	Visit Number		Empty dataset will be submitted
STRATUM	num	Stratum		Empty dataset will be submitted
RGROUP	num	Treatment Assignment		Empty dataset will be submitted
RAND1DY	num	Relative Randomization Day		Empty dataset will be submitted

1.4.9. OthePsychiatricHistoandDSMComorbidCondit – COMORB

Dataset	COMORB
Creating program	comorb.sas
Description	OthePsychiatricHistoandDSMComorbidCondit
Unique identifier	DCRFID,RAND1DY,CTSEQNO
Sorted by	DCRFID,RAND1DY,CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INIT27,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
CTSEQNO	num	Calculated Sequence Number		Collected at CRF.
COMORB	num	Any Psychiatric History?		Collected at CRF.
COND	char	Psychiatric Condition		Collected at CRF.
STATUS	num	Status of Condition		Collected at CRF.
DFPL27	num	Plate 27		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.

Variable	Type	Label	Codes	Comments
RGROUP	num	Treatment Assignment		Collected at CRF.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.10. Informed Consent – CONSENT

Dataset	CONSENT
Creating program	consent.sas
Description	Informed Consent
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CONSNTD1,CONSNTD2,INIT6,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFPL6	num	Plate 6		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.11. Consta – CONSTA

Dataset	CONSTA
Creating program	consta.sas
Description	Consta
Unique identifier	DCRFID,CFROM1DY
Sorted by	DCRFID,CFROM1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CFROMD1,CFROMD2,INIT71,INIT72,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
CTSEQNO	num	Calculated Record Number		Collected at CRF.
WEEKNO	num	Week of Administration		Collected at CRF.
CTDOSEN	num	Dose		Collected at CRF.
CTUNIT	char	Unit		Collected at CRF.
CTROUTE	char	Route		Collected at CRF.
DFPL71	num	Plate 71		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFPL72	num	Plate 72		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
CFROM1DY	num	Relative Administration Day		If CFROMD1 and CONSNT1D not missing then perform below logic to calculate CFROM1DY, If CFROMD1 less than CONSNT1D then (CFROMD1 - CONSNT1D). Else if CFROMD1 is greater than equal to CONSNT1D then (CFROMD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.12. Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,CONRX,CTFREQ,CTDOSE,CFROM1DY
Sorted by	DCRFID,CONRX,CTFREQ,CTDOSE,CFROM1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CONRX_V,CFROMD1,CFROMD2,CTOD1,CTOD2,INIT69,RANDD1,RANDD2, RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
CONMED	num	Any Conmeds ?		Collected at CRF.
CTSEQV	num	Verbatim Tx Num		Collected at CRF.
CTSEQNO	num	Calculated Tx Num		Collected at CRF.
CONRX	char	Preferred Drug Term		Collected at CRF.
CTDOSE	char	Dose		Collected at CRF.
CTUNIT	char	Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTFREQ	char	Frequency		Collected at CRF.
CTROUTE	char	Route		Collected at CRF.
CTIND_V	char	Indication		Collected at CRF.
CTONGO	num	Ongoing Posttrial?		Collected at CRF.
DFPL69	num	Plate 69		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
CFROM1DY	num	Relative Tx Start Day		If CFROMD1 and CONSNT1D not missing then perform below logic to calculate CFROM1DY, If CFROMD1 less than CONSNT1D then (CFROMD1 - CONSNT1D). Else if CFROMD1 is greater than equal to CONSNT1D then (CFROMD1- CONSNT1D) +1.
CTO1DY	num	Relative Tx Stop Day		If CTOD1 and CONSNT1D not missing then perform below logic to calculate CTO1DY, If CTOD1 less than CONSNT1D then (CTOD1 - CONSNT1D). Else if CTOD1 is greater than equal to CONSNT1D then (CTOD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.13. Medical History – DISEASE

Dataset	DISEASE
Creating program	disease.sas
Description	Medical History
Unique identifier	DCRFID,DSSYSTEM
Sorted by	DCRFID,DSSYSTEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COMP1,COMP2,DISEAS_V,INIT8,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
DSSYSTEM	char	Body System		Collected at CRF.
NORABN	num	Normal/Abnormal?		Collected at CRF.
DFPL8	num	Plate 8		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.

Variable	Type	Label	Codes	Comments
COMP1DY	num	Relative Med Hx Day		If COMPD1 and CONSNT1D not missing then perform below logic to calculate COMP1DY, If COMPD1 less than CONSNT1D then (COMPD1 - CONSNT1D). Else if COMPD1 is greater than equal to CONSNT1D then (COMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.14. EuroQoL Health Questionnaire (EQ-5D) – EQ5D

Dataset	EQ5D
Creating program	eq5d.sas
Description	EuroQoL Health Questionnaire (EQ-5D)
Unique identifier	DCRFID,EUROTHER,COMP1DY
Sorted by	DCRFID,EUROTHER,COMP1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COMP1,COMP2,INIT144,INIT145,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
EQ1	num	EuroQol: Mobility		Collected at CRF.
EQ2	num	EuroQol: Self-Care		Collected at CRF.
EQ3	num	EuroQol: Usual Activities		Collected at CRF.
EQ4	num	EuroQol: Pain		Collected at CRF.
EQ5	num	EuroQol: Anxiety		Collected at CRF.
EQ6	num	EuroQol: Health Today		Collected at CRF.

Variable	Type	Label	Codes	Comments
EUROTHER	num	EuroQol Thermometer		Collected at CRF.
TOTSCORE	num	EQ-5D Score		Collected at CRF.
DFPL144	num	Plate 144		Collected at CRF.
DFPL145	num	Plate 145		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
COMP1DY	num	Relative EuroQol Completed Day		If COMPD1 and CONSNT1D not missing then perform below logic to calculate COMP1DY, If COMPD1 less than CONSNT1D then (COMPD1 - CONSNT1D). Else if COMPD1 is greater than equal to CONSNT1D then (COMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.15. Janssen-Ortho Protocol Exception Waiver – EXCEPTN

Dataset	EXCEPTN
Creating program	exceptn.sas
Description	Janssen-Ortho Protocol Exception Waiver
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EXCEPTD1,EXCEPTD2,INAME,ASKBY,EXCPCOM1,EXCPCOM2,EXCPCOM3, EXCPCOM4,EXCPCOM5,EXCPCOM6,DECIDED1,DECIDED2,SIGNBY,INIT475, RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
EXCL1	num	Exclusion Number 1		Collected at CRF.
EXCL2	num	Exclusion Number 2		Collected at CRF.
EXCL3	num	Exclusion Number 3		Collected at CRF.
EXCL4	num	Exclusion Number 4		Collected at CRF.
INCL1	num	Inclusion Number 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
INCL2	num	Inclusion Number 2		Collected at CRF.
INCL3	num	Inclusion Number 3		Collected at CRF.
INCL4	num	Inclusion Number 4		Collected at CRF.
SIGNED	num	Signed by Monitor/Designee		Collected at CRF.
DFPL475	num	Plate 475		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
EXCEPTDY	num	Relative Exception Granted Day		If EXCEPTD1 and CONSNT1D not missing then perform below logic to calculate EXCEPTDY, If EXCEPTD1 less than CONSNT1D then (EXCEPTD1 - CONSNT1D). Else if EXCEPTD1 is greater than equal to CONSNT1D then (EXCEPTD1- CONSNT1D) +1.
DECIDEDY	num	Relative Decided to Allow pt Day		If DECIDED1 and CONSNT1D not missing then perform below logic to calculate DECIDEDY, If DECIDED1 less than CONSNT1D then (DECIDED1 - CONSNT1D). Else if DECIDED1 is greater than equal to CONSNT1D then (DECIDED1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.16. Final Count of Running Page Entries – FCOUNT

Dataset	FCOUNT
Creating program	fcount.sas
Description	Final Count of Running Page Entries
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CNAME,COUNTD1,COUNTD2,MNAME,SOURCED1,SOURCED2,VAL1D1,VAL1D2,VAL2D1,VAL2D2,COMP1D1,COMP1D2,CLEAND1,CLEAND2,INIT470,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
NO1	num	# Mood Stabilizer		Collected at CRF.
NO2	num	# Antipsychotics		Collected at CRF.
NO3	num	# Antidepressants		Collected at CRF.
NO4	num	# Concomitant Meds		Collected at CRF.
NO5	num	# Adverse Events		Collected at CRF.

Variable	Type	Label	Codes	Comments
NO6	num	# Hospitalisations		Collected at CRF.
NO7	num	# Subsequent Interventions		Collected at CRF.
NO8	num	# Unsched Vitals		Collected at CRF.
NO9	num	# Unsched Serum Levels		Collected at CRF.
NO10	num	# Unsched CGISs		Collected at CRF.
NO11	num	# Unsched AIMSS		Collected at CRF.
NO12	num	# Unsched BARSS		Collected at CRF.
NO13	num	# Unsched SASs		Collected at CRF.
NO14	num	# Unsched YMRSs		Collected at CRF.
NO15	num	# Unsched MADRSs		Collected at CRF.
NO16	num	# Unsched HAM-As		Collected at CRF.
DFPL470	num	Plate 470		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
COUNT1DY	num	Relative Count Day		If COUNTD1 and CONSNT1D not missing then perform below logic to calculate COUNT1DY, If COUNTD1 less than CONSNT1D then (COUNTD1 - CONSNT1D). Else if COUNTD1 is greater than equal to CONSNT1D then (COUNTD1- CONSNT1D) +1.

Variable	Type	Label	Codes	Comments
SOURCEDY	num	Relative 100% Sourced Day		If SOURCED1 and CONSNT1D not missing then perform below logic to calculate SOURCEDY, If SOURCED1 less than CONSNT1D then (SOURCED1 - CONSNT1D). Else if SOURCED1 is greater than equal to CONSNT1D then (SOURCED1- CONSNT1D) +1.
VAL1DY	num	Relative Valn Review 1st Day		If VAL1D1 and CONSNT1D not missing then perform below logic to calculate VAL1DY, If VAL1D1 less than CONSNT1D then (VAL1D1 - CONSNT1D). Else if VAL1D1 is greater than equal to CONSNT1D then (VAL1D1- CONSNT1D) +1.
VAL2DY	num	Relative Valn Review 2nd Day		If VAL2D1 and CONSNT1D not missing then perform below logic to calculate VAL2DY, If VAL2D1 less than CONSNT1D then (VAL2D1 - CONSNT1D). Else if VAL2D1 is greater than equal to CONSNT1D then (VAL2D1- CONSNT1D) +1.
COMP1_DY	num	Relative Valn Clean 1st Day		If COMP1D1 and CONSNT1D not missing then perform below logic to calculate COMP1_DY, If COMP1D1 less than CONSNT1D then (COMP1D1 - CONSNT1D). Else if COMP1D1 is greater than equal to CONSNT1D then (COMP1D1- CONSNT1D) +1.

Variable	Type	Label	Codes	Comments
CLEAN1DY	num	Relative All QCs Resolved Day		If CLEAND1 and CONSNT1D not missing then perform below logic to calculate CLEAN1DY, If CLEAND1 less than CONSNT1D then (CLEAND1 - CONSNT1D). Else if CLEAND1 is greater than equal to CONSNT1D then (CLEAND1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.17. Final Laboratory Data – FINALLAB

Dataset	FINALLAB
Creating program	finallab.sas
Description	Final Laboratory Data
Unique identifier	DCRFID,LABTEST,LABVAL,RAND1DY,DFSEQ
Sorted by	DCRFID,LABTEST,LABVAL,RAND1DY,DFSEQ
Notes	<p>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:</p> <p>INIT,BIRTHD,COLDT,LABVALV,COLLDATE,RECDATE,PATBDATE,REPDATE, PATNAM,PATINIT,PTID,CENTNUM,LABCODE,PATCMNT1,PATCMNT2, PATCMNT3,ACCESN,PATLOC,PHYSID,TESTCMNT,FNAME,XMITCMNT, DATESENT,COM1,RANDD1,RANDD2,RANDNO</p>

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
COMPLETE	num	Trial Completed as per Protocol?		Collected at CRF.
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
SEX	num	Sex		Collected at CRF.
LABTEST	char	Laboratory Test		Collected at CRF.
LABVAL	num	Laboratory Test Value		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABLOW	num	Lower Normal Limit		Collected at CRF.
LABUPP	num	Upper Normal Limit		Collected at CRF.
COLLTIME	num	Collection Time		Collected at CRF.
RECTIME	num	Record Time		Collected at CRF.
XMITID	char	XMIT ID		Collected at CRF.
DPATID	char	Patient ID Assigned for De-Identity		Randomly assigned patient Id for De-Identity
PATSEX	char	Patient Sex		Collected at CRF.
CURRPROT	char	Currprot		Collected at CRF.
FAST	char	Fast		Collected at CRF.
PATCTR	num	Patctr		Collected at CRF.
TPATCTR	num	Tpatctr		Collected at CRF.
R1STAT	num	R1_Stat		Collected at CRF.
R1ACT	num	R1_Action		Collected at CRF.
VISTYPE	char	Visit Type		Collected at CRF.
VISNO	char	Vis_No		Collected at CRF.
NSPEC	num	Number of Spec		Collected at CRF.
TNSPEC	num	Total Number of Spec		Collected at CRF.
R2STAT	num	R2_Stat		Collected at CRF.
R2ACT	num	R2_Action		Collected at CRF.
TESTREQ	char	Test Frequency		Collected at CRF.
TEST	char	Test		Collected at CRF.

Variable	Type	Label	Codes	Comments
RESULT	char	Result		Collected at CRF.
UNITS	char	Units		Collected at CRF.
NORMRAN	char	Normal Range		Collected at CRF.
LOWNORM	char	Low Normal Range		Collected at CRF.
HIGHNORM	char	High Normal Range		Collected at CRF.
CRITRAN	char	Criteria Range		Collected at CRF.
RFLAG	char	R_Flag		Collected at CRF.
NTEST	num	Number of Test		Collected at CRF.
TNTEST	num	Total Number of Test		Collected at CRF.
R3STAT	num	R3_Stat		Collected at CRF.
R3ACT	num	R3_Action		Collected at CRF.
TIMESENT	num	Timesent		Collected at CRF.
NMRESULT	char	Normal Result		Collected at CRF.
VISNAME	char	Visit Name		Collected at CRF.
UNIT	char	Unit		Collected at CRF.
AGE	char	Age		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.

Variable	Type	Label	Codes	Comments
COLLDY	num	Relative Collection Day		If COLLDATE and CONSNT1D not missing then perform below logic to calculate COLLDY, If COLLDATE less than CONSNT1D then (COLLDATE - CONSNT1D). Else if COLLDATE is greater than equal to CONSNT1D then (COLLDATE- CONSNT1D) +1.
RECDY	num	Relative Record Day		If RECDATE and CONSNT1D not missing then perform below logic to calculate RECDY, If RECDATE less than CONSNT1D then (RECDATE - CONSNT1D). Else if RECDATE is greater than equal to CONSNT1D then (RECDATE- CONSNT1D) +1.
REPDY	num	Relative Report Day		If REPDATE and CONSNT1D not missing then perform below logic to calculate REPDY, If REPDATE less than CONSNT1D then (REPDATE - CONSNT1D). Else if REPDATE is greater than equal to CONSNT1D then (REPDATE- CONSNT1D) +1.
SENTDY	num	Relative Sent Day		If DATESENT and CONSNT1D not missing then perform below logic to calculate SENTDY, If DATESENT less than CONSNT1D then (DATESENT - CONSNT1D). Else if DATESENT is greater than equal to CONSNT1D then (DATESENT- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.18. Hamilton Anxiety Scale (HAM-A) – HAMA

Dataset	HAMA
Creating program	hama.sas
Description	Hamilton Anxiety Scale (HAM-A)
Unique identifier	DCRFID,HAMASUM,COMP1DY
Sorted by	DCRFID,HAMASUM,COMP1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COMP1DY,COMP2DY,ASMTBY,INIT101,INIT102,INIT175,INIT176,RANDD1, RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
HAMA1	num	Anxious Mood		Collected at CRF.
HAMA2	num	Tension		Collected at CRF.
HAMA3	num	Fears		Collected at CRF.
HAMA4	num	Insomnia		Collected at CRF.
HAMA5	num	Intellectual		Collected at CRF.
HAMA6	num	Depressed Mood		Collected at CRF.

Variable	Type	Label	Codes	Comments
HAMA7	num	Somatic (Muscular)		Collected at CRF.
HAMA8	num	Somatic (Sensory)		Collected at CRF.
HAMA9	num	Cardiovascular Symptoms		Collected at CRF.
HAMA10	num	Respiratory Symptoms		Collected at CRF.
HAMA11	num	Gastrointestinal Symptoms		Collected at CRF.
HAMA12	num	Genitourinary Symptoms		Collected at CRF.
HAMA13	num	Autonomic Symptoms		Collected at CRF.
HAMA14	num	Interview Behavior		Collected at CRF.
HAMASUM	num	Calculated Total HAMA Score		Collected at CRF.
HAMAF1	num	Formatted HAMA 1		Collected at CRF.
HAMAF2	num	Formatted HAMA 2		Collected at CRF.
HAMAF3	num	Formatted HAMA 3		Collected at CRF.
HAMAF4	num	Formatted HAMA 4		Collected at CRF.
HAMAF5	num	Formatted HAMA 5		Collected at CRF.
HAMAF6	num	Formatted HAMA 6		Collected at CRF.
HAMAF7	num	Formatted HAMA 7		Collected at CRF.
HAMAF8	num	Formatted HAMA 8		Collected at CRF.
HAMAF9	num	Formatted HAMA 9		Collected at CRF.
HAMAF10	num	Formatted HAMA 10		Collected at CRF.
HAMAF11	num	Formatted HAMA 11		Collected at CRF.
HAMAF12	num	Formatted HAMA 12		Collected at CRF.

Variable	Type	Label	Codes	Comments
HAMAF13	num	Formatted HAMA 13		Collected at CRF.
HAMAF14	num	Formatted HAMA 14		Collected at CRF.
RSIGN	num	Rater Signed?		Collected at CRF.
DFPL101	num	Plate 101		Collected at CRF.
DFPL102	num	Plate 102		Collected at CRF.
DFPL175	num	Plate 175		Collected at CRF.
DFPL176	num	Plate 176		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
COMP1DY	num	Relative HAM-A Completed Day		If COMPD1 and CONSNT1D not missing then perform below logic to calculate COMP1DY, If COMPD1 less than CONSNT1D then (COMPD1 - CONSNT1D). Else if COMPD1 is greater than equal to CONSNT1D then (COMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.19. Hospitalizations – HOSP

Dataset	HOSP
Creating program	hosp.sas
Description	Hospitalizations
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: ADMD1,ADMD2,DISCHGD1,DISCHGD2,INIT87,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
HOSP	num	Any Hospitalisations?		Collected at CRF.
HOSPNO	num	Calculated Record Number		Collected at CRF.
HONGO	num	Ongoing Post-Trial?		Collected at CRF.
REASHOSP	num	Reason for Hospitalisation		Collected at CRF.
OTHSP	char	Other Reason, Specify		Collected at CRF.
DFPL87	num	Plate 87		Collected at CRF.

Variable	Type	Label	Codes	Comments
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
ADM1DY	num	Relative Admission Day		If ADMD1 and CONSNT1D not missing then perform below logic to calculate ADM1DY, If ADMD1 less than CONSNT1D then (ADMD1 - CONSNT1D). Else if ADMD1 is greater than equal to CONSNT1D then (ADMD1- CONSNT1D) +1.
DISCHGDY	num	Relative Discharge Day		If DISCHGD1 and CONSNT1D not missing then perform below logic to calculate DISCHGDY, If DISCHGD1 less than CONSNT1D then (DISCHGD1 - CONSNT1D). Else if DISCHGD1 is greater than equal to CONSNT1D then (DISCHGD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.20. Inclusion / Exclusion Criteria – INCLEXCL

Dataset	INCLEXCL
Creating program	inclexcl.sas
Description	Inclusion / Exclusion Criteria
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: VISITD1,VISITD2,INIT200,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
INCLEXCL	num	Did Subject Meet all Criteria?		Collected at CRF.
EXCEPTN	num	Was an Exception Granted?		Collected at CRF.
DFPL200	num	Plate 200		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT1DY	num	Relative Visit Day		If VISITD1 and CONSNT1D not missing then perform below logic to calculate VISIT1DY, If VISITD1 less than CONSNT1D then (VISITD1 - CONSNT1D). Else if VISITD1 is greater than equal to CONSNT1D then (VISITD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.21. Intervention – INTERVEN

Dataset	INTERVEN
Creating program	interven.sas
Description	Intervention
Unique identifier	DCRFID,INTERVEN,INTVEN1DY,DFSEQ
Sorted by	DCRFID,INTERVEN,INTVEN1DY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INTVEND1,INTVEND2,INIT67,INIT74,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
INTERVEN	num	Any Interventions?		Collected at CRF.
INTVEN1	num	Psychiatric Hospitalization		Collected at CRF.
INTVEN2	num	Increase MoodStablzr/Add Psychotropics		Collected at CRF.
INTVEN3	num	Increase Antipsy/Risperdal After Wk 20		Collected at CRF.
INTVEN4	num	Discontinuation for Inefficacy		Collected at CRF.

Variable	Type	Label	Codes	Comments
INTVEN5	num	Discontinuation for Self-Harm/Violence		Collected at CRF.
DFPL67	num	Plate 67		Collected at CRF.
DFPL74	num	Plate 74		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
INTVENDY	num	Relative Intervention Day		If INTVEND1 and CONSNT1D not missing then perform below logic to calculate INTVENDY, If INTVEND1 less than CONSNT1D then (INTVEND1 - CONSNT1D). Else if INTVEND1 is greater than equal to CONSNT1D then (INTVEND1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.22. PrincipallInvestigStateConceDataVerificat – INVSTMT

Dataset	INVSTMT
Creating program	invstmt.sas
Description	PrincipallInvestigStateConceDataVerificat
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SIGND1,SIGND2,INIT91,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
SIGNED	num	Investigator Signed?		Collected at CRF.
DFPL91	num	Plate 91		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.

Variable	Type	Label	Codes	Comments
SIGN1DY	num	Relative Signed Day		If SIGND1 and CONSNT1D not missing then perform below logic to calculate SIGN1DY, If SIGND1 less than CONSNT1D then (SIGND1 - CONSNT1D). Else if SIGND1 is greater than equal to CONSNT1D then (SIGND1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.23. Laboratory Data – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Data
Unique identifier	DCRFID,LRESULT,SAMP1DY
Sorted by	DCRFID,LRESULT,SAMP1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SAMPD1,SAMPD2,INIT21,INIT22,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
FASTED	num	Subject Fasted?		Collected at CRF.
LRESULT	num	Lab Result		Collected at CRF.
DFPL21	num	Plate 21		Collected at CRF.
DFPL22	num	Plate 22		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMP1DY	num	Relative Sample Day		If SAMPD1 and CONSNT1D not missing then perform below logic to calculate SAMP1DY, If SAMPD1 less than CONSNT1D then (SAMPD1 - CONSNT1D). Else if SAMPD1 is greater than equal to CONSNT1D then (SAMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.24. Montgomery-Asberg Depression Ratin Scale – MADRS

Dataset	MADRS
Creating program	madsr.sas
Description	Montgomery-Asberg Depression Ratin Scale
Unique identifier	DCRFID,MADRSV,COMP1DY
Sorted by	DCRFID,MADRSV,COMP1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COMP1D,COMP1D2,ASMTBY,INIT124,INIT125,INIT126,INIT127,INIT171,INIT172,INIT173,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
MADRS1	num	Apparent Sadness		Collected at CRF.
MADRS2	num	Reported Sadness		Collected at CRF.
MADRS3	num	Inner Tension		Collected at CRF.
MADRS4	num	Reduced Sleep		Collected at CRF.
MADRS5	num	Reduced Appetite		Collected at CRF.
MADRS6	num	Concentration Difficulties		Collected at CRF.

Variable	Type	Label	Codes	Comments
MADRS7	num	Lassitude		Collected at CRF.
MADRS8	num	Inability to Feel		Collected at CRF.
MADRS9	num	Pessimistic Thoughts		Collected at CRF.
MADRS10	num	Suicidal Thoughts		Collected at CRF.
MADRSV	num	Verbatim Total Score at Baseline		Collected at CRF.
MADRSF1	num	Formatted Madrs1		Collected at CRF.
MADRSF2	num	Formatted Madrs2		Collected at CRF.
MADRSF3	num	Formatted Madrs3		Collected at CRF.
MADRSF4	num	Formatted Madrs4		Collected at CRF.
MADRSF5	num	Formatted Madrs5		Collected at CRF.
MADRSF6	num	Formatted Madrs6		Collected at CRF.
MADRSF7	num	Formatted Madrs7		Collected at CRF.
MADRSF8	num	Formatted Madrs8		Collected at CRF.
MADRSF9	num	Formatted Madrs9		Collected at CRF.
MADRSF10	num	Formatted Madrs10		Collected at CRF.
MADRSSUM	num	Calculated Total MADRS Score		Collected at CRF.
DFPL124	num	Plate 124		Collected at CRF.
DFPL125	num	Plate 124		Collected at CRF.
DFPL126	num	Plate 124		Collected at CRF.
DFPL127	num	Plate 124		Collected at CRF.
DFPL171	num	Plate 124		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFPL172	num	Plate 124		Collected at CRF.
DFPL173	num	Plate 124		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
COMP1DY	num	Relative MADRS Completed Day		If COMPD1 and CONSNT1D not missing then perform below logic to calculate COMP1DY, If COMPD1 less than CONSNT1D then (COMPD1 - CONSNT1D). Else if COMPD1 is greater than equal to CONSNT1D then (COMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.25. Mood Stabilizing Medications – MOODMED

Dataset	MOODMED
Creating program	moodmed.sas
Description	Mood Stabilizing Medications
Unique identifier	DCRFID,CTFREQ,CTDOSE
Sorted by	DCRFID,CTFREQ,CTDOSE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CFROMD1,CFROMD2,CTOD1,CTOD2,INIT84,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
CTSEQV	num	Verbatim Med Number		Collected at CRF.
CTSEQNO	num	Calculated Med Number		Collected at CRF.
CONRXN	num	Therapy Name		Collected at CRF.
CTDOSE	char	Dose		Collected at CRF.
CTUNIT	char	Unit		Collected at CRF.
CTFREQ	char	Frequency		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTROUTE	char	Route		Collected at CRF.
CTONGO	num	Ongoing?		Collected at CRF.
REASCHG	num	Reason for Dose Change		Collected at CRF.
OTHREAS	char	Other Reason, Specify		Collected at CRF.
DFPL84	num	Plate 84		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
CFROM1DY	num	Relative Start Day		If CFROMD1 and CONSNT1D not missing then perform below logic to calculate CFROM1DY, If CFROMD1 less than CONSNT1D then (CFROMD1 - CONSNT1D). Else if CFROMD1 is greater than equal to CONSNT1D then (CFROMD1- CONSNT1D) +1.
CTO1DY	num	Relative Stop Day		If CTOD1 and CONSNT1D not missing then perform below logic to calculate CTO1DY, If CTOD1 less than CONSNT1D then (CTOD1 - CONSNT1D). Else if CTOD1 is greater than equal to CONSNT1D then (CTOD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.26. Serum level: Mood stabilizer(s) – MOODSTAB

Dataset	MOODSTAB
Creating program	moodstab.sas
Description	Serum level: Mood stabilizer(s)
Unique identifier	DCRFID,MSAMP,MSAMP1DY,DFSEQ
Sorted by	DCRFID,MSAMP,MSAMP1DY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: MSAMPD1,MSAMPD2,INIT29,INIT153,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
MSAMP	num	Sample Drawn?		Collected at CRF.
LITHIUM	num	Lithium		Collected at CRF.
VALPROAT	num	Valproate		Collected at CRF.
DFPL29	num	Plate 29		Collected at CRF.
DFPL153	num	Plate 153		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.

Variable	Type	Label	Codes	Comments
RGROUP	num	Treatment Assignment		Collected at CRF.
MSAMP1DY	num	Relative Sample Day		If MSAMPD1 and CONSNT1D not missing then perform below logic to calculate MSAMP1DY, If MSAMPD1 less than CONSNT1D then (MSAMPD1 - CONSNT1D). Else if MSAMPD1 is greater than equal to CONSNT1D then (MSAMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.27. Physical Examination – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	Physical Examination
Unique identifier	DCRFID,PERESULT,PESYSNO,EXAM1DY,PESEQNO
Sorted by	DCRFID,PERESULT,PESYSNO,EXAM1DY,PESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EXAMD1,EXAMD2,EXAM_V,INIT17,INIT18,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
PERESULT	num	Normal or Abnormal?		Collected at CRF.
PESEQNO	num	Calculated Result Number		Collected at CRF.
PESYSNO	num	Body System Code		Collected at CRF.
DFPL17	num	Plate 17		Collected at CRF.
DFPL18	num	Plate 18		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.

Variable	Type	Label	Codes	Comments
RGROUP	num	Treatment Assignment		Collected at CRF.
EXAM1DY	num	Relative PhysExam Day		If EXAMD1 and CONSNT1D not missing then perform below logic to calculate EXAM1DY, If EXAMD1 less than CONSNT1D then (EXAMD1 - CONSNT1D). Else if EXAMD1 is greater than equal to CONSNT1D then (EXAMD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.28. Urine Pregnancy Test – PREGTST

Dataset	PREGTST
Creating program	pregtst.sas
Description	Urine Pregnancy Test
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: PTESTD1,PTESTD2,INIT21,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
SEX	num	Sex		Collected at CRF.
PTEST	num	Pregnancy Test Result		Collected at CRF.
DFPL21	num	Plate 21		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.

Variable	Type	Label	Codes	Comments
PTEST1DY	num	Relative Pregnancy Test Day		If PTESTD1 and CONSNT1D not missing then perform below logic to calculate PTEST1DY, If PTESTD1 less than CONSNT1D then (PTESTD1 - CONSNT1D). Else if PTESTD1 is greater than equal to CONSNT1D then (PTESTD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.29. Psychiatric History – PSYCHX

Dataset	PSYCHX
Creating program	psychx.sas
Description	Psychiatric History
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DIAGD1,DIAGD2,INIT26,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
DIAG	num	DSM IV Diagnosis		Collected at CRF.
MANIC	num	Manic?		Collected at CRF.
HYPOM	num	Hypomanic?		Collected at CRF.
MIXED	num	Mixed?		Collected at CRF.
DEPRES	num	Depressed?		Collected at CRF.
RCYCLE	num	Rapid Cycling?		Collected at CRF.

Variable	Type	Label	Codes	Comments
MANICNO	num	# of Manic Episodes		Collected at CRF.
HYPOMNO	num	# of Hypomanic Episodes		Collected at CRF.
MIXEDNO	num	# of Mixed Episodes		Collected at CRF.
DEPRESNO	num	# of Depressed Episodes		Collected at CRF.
RCYCLEN0	num	# of Rapid Cycling Episodes		Collected at CRF.
DFPL26	num	Plate 26		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
DIAG1DY	num	Relative Diagnosis Day		If DIAGD1 and CONSNT1D not missing then perform below logic to calculate DIAG1DY, If DIAGD1 less than CONSNT1D then (DIAGD1 - CONSNT1D). Else if DIAGD1 is greater than equal to CONSNT1D then (DIAGD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.30. Randomization – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomization
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: RANDD1,RANDD2,RANDNO,INIT200

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
DFPL200	num	Plate 200		Collected at CRF.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.31. Resource Use Questionnaire – RUQ

Dataset	RUQ
Creating program	ruq.sas
Description	Resource Use Questionnaire
Unique identifier	DCRFID,PSYCHOL,ERVISIT,RAND1DY,DFSEQ
Sorted by	DCRFID,PSYCHOL,ERVISIT,RAND1DY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INIT109,INIT110,INIT111,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
ERVISIT	num	Any ER Visits in Past Month?		Collected at CRF.
ERNUM	num	Number of ER Visits		Collected at CRF.
ERREAS1	char	Reason 1		Collected at CRF.
ERREAS2	char	Reason 2		Collected at CRF.
HOSP	num	Any Hospital Admissions?		Collected at CRF.
HOSPREAS	char	Hospitalization Reason		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOSPNUM	num	Nights Hospitalized		Collected at CRF.
ICUNUM	num	Nights in ICU		Collected at CRF.
GP	num	Family Doctor		Collected at CRF.
PSYCHOL	num	Psychologist		Collected at CRF.
SOCWRK	num	Social Worker		Collected at CRF.
OT	num	Occupational Therapist		Collected at CRF.
PSYCHCRE	num	Psychiatric Day-Care		Collected at CRF.
PSYCHIAT	num	Psychiatrist		Collected at CRF.
HNURSE	num	Home Care Nurse		Collected at CRF.
PNURSE	num	Psychiatric Nurse		Collected at CRF.
SUICIDE	num	Suicide/Crisis Nurse		Collected at CRF.
CLINIC	num	Outpatient Clinic		Collected at CRF.
JOBPAY	num	Has a Paid Job?		Collected at CRF.
JOBTYPE	num	Job Type		Collected at CRF.
JOBLOOK	num	Are you Seeking Paid Work?		Collected at CRF.
SCHOOL	num	Are you Attending School?		Collected at CRF.
EDUTYPE	num	Education type		Collected at CRF.
LEAVE	num	Type of Leave		Collected at CRF.
WORK	num	Did You Work in Past Month?		Collected at CRF.
EXPDAYS	num	Days Expected to Work		Collected at CRF.
ABSDAYS	num	Days Absent From Work		Collected at CRF.

Variable	Type	Label	Codes	Comments
BDDAYS	num	Days Quality of Work Affected by BD		Collected at CRF.
WORKEFCT	num	Effectiveness at Work on BD Days		Collected at CRF.
USUALDAY	num	Days Unable to do Usual Activities		Collected at CRF.
DFPL109	num	Plate 109		Collected at CRF.
DFPL110	num	Plate 110		Collected at CRF.
DFPL111	num	Plate 111		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.32. Simpson-Angus Scale – SAS

Dataset	SAS
Creating program	sas.sas
Description	Simpson-Angus Scale
Unique identifier	DCRFID,SASSUM,COMP1DY
Sorted by	DCRFID,SASSUM,COMP1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COMP1D,COMP1D2,INIT138,INIT139,INIT140,INIT141,INIT163,INIT164, INIT165,INIT166,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
SAS1	num	Gait		Collected at CRF.
SAS2	num	Arm Dropping		Collected at CRF.
SAS3	num	Shoulder Shaking		Collected at CRF.
SAS4	num	Elbow Rigidity		Collected at CRF.
SAS5	num	Wrist Rigidity		Collected at CRF.
SAS6	num	Leg Pendulousness		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAS7	num	Head Dropping		Collected at CRF.
SAS8	num	Glabella Tap		Collected at CRF.
SAS9	num	Tremor		Collected at CRF.
SAS10	num	Salivation		Collected at CRF.
SASSUM	num	Calculated Total Score		Collected at CRF.
SASF1	num	Coded Gait		Collected at CRF.
SASF2	num	Coded Arm Dropping		Collected at CRF.
SASF3	num	Coded Shoulder Shaking		Collected at CRF.
SASF4	num	Coded Elbow Rigidity		Collected at CRF.
SASF5	num	Coded Wrist Rigidity		Collected at CRF.
SASF6	num	Coded Leg Pendulousness		Collected at CRF.
SASF7	num	Coded Head Dropping		Collected at CRF.
SASF8	num	Coded Glabella Tap		Collected at CRF.
SASF9	num	Coded Tremor		Collected at CRF.
SASF10	num	Coded Salivation		Collected at CRF.
DFPL138	num	Plate 138		Collected at CRF.
DFPL139	num	Plate 139		Collected at CRF.
DFPL140	num	Plate 140		Collected at CRF.
DFPL141	num	Plate 141		Collected at CRF.
DFPL163	num	Plate 163		Collected at CRF.
DFPL164	num	Plate 164		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFPL165	num	Plate 165		Collected at CRF.
DFPL166	num	Plate 166		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
COMP1DY	num	Relative Completed Day		If COMPD1 and CONSNT1D not missing then perform below logic to calculate COMP1DY, If COMPD1 less than CONSNT1D then (COMPD1 - CONSNT1D). Else if COMPD1 is greater than equal to CONSNT1D then (COMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.33. Trial Termination – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.sas
Description	Trial Termination
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: LDOSED1,LDOSED2,TTFROMD1,TTFROMD2,INIT90,RANDD1,RANDD2, RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
LDOSENA	num	Last Dose Date Not Applicable		Collected at CRF.
COMPLETE	num	Trial Completed as per Protocol?		Collected at CRF.
TTREAS	num	Reason Trial not Completed		Collected at CRF.
AE1	num	1st AE Number		Collected at CRF.
AE2	num	2nd AE Number		Collected at CRF.
AE3	num	3rd AE Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
AE4	num	4th AE Number		Collected at CRF.
AE5	num	5th AE Number		Collected at CRF.
DUED1	num	SAS Pregnancy Due Date		Collected at CRF.
DUED2	char	String Pregnancy Due Date		Collected at CRF.
DEATHD1	num	SAS Date of Death		Collected at CRF.
DEATHD2	char	String Date of Death		Collected at CRF.
PROTSP	char	Protocol Violation Specify		Collected at CRF.
TTREAS_V	char	Other Reason, Specify		Collected at CRF.
DFPL90	num	Plate 90		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
LDOSE1DY	num	Relative Last Dose Day		If LDOSED1 and CONSNT1D not missing then perform below logic to calculate LDOSE1DY, If LDOSED1 less than CONSNT1D then (LDOSED1 - CONSNT1D). Else if LDOSED1 is greater than equal to CONSNT1D then (LDOSED1- CONSNT1D) +1.

Variable	Type	Label	Codes	Comments
TTFROMDY	num	Relative Termination/EW Day		If TTFROMD1 and CONSNT1D not missing then perform below logic to calculate TTFROMDY, If TTFROMD1 less than CONSNT1D then (TTFROMD1 - CONSNT1D). Else if TTFROMD1 is greater than equal to CONSNT1D then (TTFROMD1 - CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1 - CONSNT1D) +1.

1.4.34. VisualAnalogScalefoSubjSatisfactiwitTrea – VAS

Dataset	VAS
Creating program	vas.sas
Description	VisualAnalogScalefoSubjSatisfactiwitTrea
Unique identifier	DCRFID,VASV,VASNO,RAND1DY,DFSEQ
Sorted by	DCRFID,VASV,VASNO,RAND1DY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INIT107,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
VASNO	num	DF Calculated VAS		Collected at CRF.
VASV	num	Site's VAS Measurement		Collected at CRF.
DFPL107	num	Plate 107		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.

Variable	Type	Label	Codes	Comments
RGROUP	num	Treatment Assignment		Collected at CRF.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.35. Visit Dates – VDATES

Dataset	VDATES
Creating program	vdates.sas
Description	Visit Dates
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EXCEPTD1,EXCEPTD2,RANDD1,RANDD2,RANDNO,CONSNTD1,CONSNTD2, VDAT10,SDAT10,BIRTHD1,BIRTHD2,AGE,SEX,RACE,VDAT20,SDAT20,VDAT40, SDAT40,VDAT50,SDAT50,VDAT60,SDAT60,VDAT70,SDAT70,VDAT80,SDAT80, VDAT90,SDAT90,VDAT100,SDAT100,FIRSTDOS,FIRSTDO2,LASTDOSE, LASTDOS2,LASTAPD1,LASTAPD2,TTFROMD1,TTFROMD2,LASTVD

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
INCLEXCL	num	Did Subject Meet all Criteria?		Collected at CRF.
EXCEPTN	num	Was an Exception granted?		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
DAYDIFF	num	# Days From Consent to 1st Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PLT10	num	Baseline Visit Date Plate		Collected at CRF.
PLT20	num	Eligibility Visit Date Plate		Collected at CRF.
PLT40	num	Visit 4 Date Plate		Collected at CRF.
PLT50	num	Visit 5 Date Plate		Collected at CRF.
PLT60	num	Visit 6 Date Plate		Collected at CRF.
PLT70	num	Visit 7 Date Plate		Collected at CRF.
PLT80	num	Visit 8 Date Plate		Collected at CRF.
PLT90	num	Visit 9 Date Plate		Collected at CRF.
PLT100	num	Final Visit Date in VMap Plate		Collected at CRF.
LDOSENA	num	Last Dose Date on TRLTERM Page NA?		Collected at CRF.
CTONGO	num	Antipsychotic Ongoing Post-Trial?		Collected at CRF.
COMPLETE	num	Trial Completed as per Protocol?		Collected at CRF.
TTREAS	num	Reason Trial not Completed		Collected at CRF.
TTREAS_V	char	Other Reason, Specify		Collected at CRF.
LASTVSQN	num	Most Recent Visit Number		Collected at CRF.
TOT301	num	Total Oral Antipsychotics		Collected at CRF.
YN401	num	Any Antidepressants?		Collected at CRF.
TOT401	num	Total Antidepressants		Collected at CRF.
YN501	num	Any Hospitalisations		Collected at CRF.
TOT501	num	Total Hospitalisations		Collected at CRF.

Variable	Type	Label	Codes	Comments
TOT601	num	TotalSbsqnt Interventions		Collected at CRF.
YN701	num	Any Conmeds ?		Collected at CRF.
TOT701	num	Total Concomitant Therapy		Collected at CRF.
YN801	num	Any AEs?		Collected at CRF.
TOT801	num	Total Adverse Events		Collected at CRF.
TOT901	num	Total Mood Stabilising Meds		Collected at CRF.
TOT1001	num	TotalUnsched Vital Signs		Collected at CRF.
TOT1101	num	TotalUnsched Mood Stabilizers		Collected at CRF.
TOT1201	num	TotalUnsched CGI-S		Collected at CRF.
TOT1301	num	TotalUnsched AIMS		Collected at CRF.
TOT1401	num	TotalUnsched BARS		Collected at CRF.
TOT1501	num	TotalUnsched SAS		Collected at CRF.
TOT1601	num	TotalUnsched YMRS		Collected at CRF.
TOT1701	num	TotalUnsched MADRS		Collected at CRF.
TOT1801	num	TotalUnsched HAMA		Collected at CRF.
EXCEPTDY	num	Relative Exception Granted Day		If EXCEPTD1 and CONSNT1D not missing then perform below logic to calculate EXCEPTDY, If EXCEPTD1 less than CONSNT1D then (EXCEPTD1 - CONSNT1D). Else if EXCEPTD1 is greater than equal to CONSNT1D then (EXCEPTD1- CONSNT1D) +1.

Variable	Type	Label	Codes	Comments
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.
V10DY	num	Relative Baseline Visit Day		If VDAT10 and CONSNT1D not missing then perform below logic to calculate V10DY, If VDAT10 less than CONSNT1D then (VDAT10 - CONSNT1D). Else if VDAT10 is greater than equal to CONSNT1D then (VDAT10- CONSNT1D) +1.
V20DY	num	Relative Eligibility Day		If VDAT20 and CONSNT1D not missing then perform below logic to calculate V20DY, If VDAT20 less than CONSNT1D then (VDAT20 - CONSNT1D). Else if VDAT20 is greater than equal to CONSNT1D then (VDAT20- CONSNT1D) +1.
V40DY	num	Relative Visit 4 Day		If VDAT40 and CONSNT1D not missing then perform below logic to calculate V40DY, If VDAT40 less than CONSNT1D then (VDAT40 - CONSNT1D). Else if VDAT40 is greater than equal to CONSNT1D then (VDAT40- CONSNT1D) +1.
V50DY	num	Relative Visit 5 Day		If VDAT50 and CONSNT1D not missing then perform below logic to calculate V50DY, If VDAT50 less than CONSNT1D then (VDAT50 - CONSNT1D). Else if VDAT50 is greater than equal to CONSNT1D then (VDAT50- CONSNT1D) +1.

Variable	Type	Label	Codes	Comments
V60DY	num	Relative Visit 6 Day		If VDAT60 and CONSNT1D not missing then perform below logic to calculate V60DY, If VDAT60 less than CONSNT1D then (VDAT60 - CONSNT1D). Else if VDAT60 is greater than equal to CONSNT1D then (VDAT60- CONSNT1D) +1.
V70DY	num	Relative Visit 7 Day		If VDAT70 and CONSNT1D not missing then perform below logic to calculate V70DY, If VDAT70 less than CONSNT1D then (VDAT70 - CONSNT1D). Else if VDAT70 is greater than equal to CONSNT1D then (VDAT70- CONSNT1D) +1.
V80DY	num	Relative Visit 8 Day		If VDAT80 and CONSNT1D not missing then perform below logic to calculate V80DY, If VDAT80 less than CONSNT1D then (VDAT80 - CONSNT1D). Else if VDAT80 is greater than equal to CONSNT1D then (VDAT80- CONSNT1D) +1.
V90DY	num	Relative Visit 9 Day		If VDAT90 and CONSNT1D not missing then perform below logic to calculate V90DY, If VDAT90 less than CONSNT1D then (VDAT90 - CONSNT1D). Else if VDAT90 is greater than equal to CONSNT1D then (VDAT90- CONSNT1D) +1.
V100DY	num	Relative Final Visit Day in VMap		If VDAT100 and CONSNT1D not missing then perform below logic to calculate V100DY, If VDAT100 less than CONSNT1D then (VDAT100 - CONSNT1D). Else if VDAT100 is greater than equal to CONSNT1D then (VDAT100- CONSNT1D) +1.

Variable	Type	Label	Codes	Comments
FSTDOSDY	num	Relative First CONSTA Dose Day		If FIRSTDOS and CONSNT1D not missing then perform below logic to calculate FSTDOSDY, If FIRSTDOS less than CONSNT1D then (FIRSTDOS - CONSNT1D). Else if FIRSTDOS is greater than equal to CONSNT1D then (FIRSTDOS- CONSNT1D) +1.
LSTDOSDY	num	Relative Last Dose Day on TRLTERM Pg		If LASTDOSE and CONSNT1D not missing then perform below logic to calculate LSTDOSDY, If LASTDOSE less than CONSNT1D then (LASTDOSE - CONSNT1D). Else if LASTDOSE is greater than equal to CONSNT1D then (LASTDOSE- CONSNT1D) +1.
LASTAPDY	num	Relative Antipsy Page Last Dose Day		If LASTAPD1 and CONSNT1D not missing then perform below logic to calculate LASTAPDY, If LASTAPD1 less than CONSNT1D then (LASTAPD1 - CONSNT1D). Else if LASTAPD1 is greater than equal to CONSNT1D then (LASTAPD1- CONSNT1D) +1.
TTFROMDY	num	Relative Termination/EW Day		If TTFROMD1 and CONSNT1D not missing then perform below logic to calculate TTFROMDY, If TTFROMD1 less than CONSNT1D then (TTFROMD1 - CONSNT1D). Else if TTFROMD1 is greater than equal to CONSNT1D then (TTFROMD1- CONSNT1D) +1.
LASTVDY	num	Relative Most Recent Visit Day		If LASTVD and CONSNT1D not missing then perform below logic to calculate LASTVDY, If LASTVD less than CONSNT1D then (LASTVD - CONSNT1D). Else if LASTVD is greater than equal to CONSNT1D then (LASTVD- CONSNT1D) +1.

1.4.36. Ortho Notification of Protocol Violation – VIOLATN

Dataset	VIOLATN
Creating program	violatn.sas
Description	Ortho Notification of Protocol Violation
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: NOTIFYD1,NOTIFYD2,INAME,DESC1,DESC2,DESC3,DESC4,DESC5,DESC6, ALLOWD1,ALLOWD2,EXCLUDD1,EXCLUDD2,SIGNBY,INIT476,RANDD1, RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
EXCL1	num	Exclusion Number 1		Collected at CRF.
EXCL2	num	Exclusion Number 2		Collected at CRF.
EXCL3	num	Exclusion Number 3		Collected at CRF.
EXCL4	num	Exclusion Number 4		Collected at CRF.
INCL1	num	Inclusion Number 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
INCL2	num	Inclusion Number 2		Collected at CRF.
INCL3	num	Inclusion Number 3		Collected at CRF.
INCL4	num	Inclusion Number 4		Collected at CRF.
SIGNED	num	Signed by Monitor/Designee		Collected at CRF.
DFPL476	num	Plate 476		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
NOTIFYDY	num	Relative Notification Day		If NOTIFYD1 and CONSNT1D not missing then perform below logic to calculate NOTIFYDY, If NOTIFYD1 less than CONSNT1D then (NOTIFYD1 - CONSNT1D). Else if NOTIFYD1 is greater than equal to CONSNT1D then (NOTIFYD1- CONSNT1D) +1.
ALLOW1DY	num	Relative Allow Subj to Stay Day		If ALLOWD1 and CONSNT1D not missing then perform below logic to calculate ALLOW1DY, If ALLOWD1 less than CONSNT1D then (ALLOWD1 - CONSNT1D). Else if ALLOWD1 is greater than equal to CONSNT1D then (ALLOWD1- CONSNT1D) +1.

Variable	Type	Label	Codes	Comments
EXCLUDDY	num	Relative Exclude Subj Day		If EXCLUDD1 and CONSNT1D not missing then perform below logic to calculate EXCLUDDY, If EXCLUDD1 less than CONSNT1D then (EXCLUDD1 - CONSNT1D). Else if EXCLUDD1 is greater than equal to CONSNT1D then (EXCLUDD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.37. Vital Signs – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	Vital Signs
Unique identifier	DCRFID,BMI,VISIT1DY
Sorted by	DCRFID,BMI,VISIT1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: VISITD1,VISITD2,INIT10,INIT11,INIT12,INIT151,RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
WEIGHT	num	Weight		Collected at CRF.
HEIGHT	num	Height		Collected at CRF.
WSTATUS	num	Calculated Weight Status		Collected at CRF.
BMI	num	Calculated BMI		Collected at CRF.
PULSE	num	Pulse		Collected at CRF.
SBP	num	Systolic BP		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBP	num	Diastolic BP		Collected at CRF.
DFPL10	num	Plate 10		Collected at CRF.
DFPL11	num	Plate 11		Collected at CRF.
DFPL12	num	Plate 12		Collected at CRF.
DFPL151	num	Plate 151		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
VISIT1DY	num	Relative Visit Day		If VISITD1 and CONSNT1D not missing then perform below logic to calculate VISIT1DY, If VISITD1 less than CONSNT1D then (VISITD1 - CONSNT1D). Else if VISITD1 is greater than equal to CONSNT1D then (VISITD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.

1.4.38. Young Mania Rating Scale (YMRS) – YMRS

Dataset	YMRS
Creating program	ymrs.sas
Description	Young Mania Rating Scale (YMRS)
Unique identifier	DCRFID,YMRSV,COMP1DY
Sorted by	DCRFID,YMRSV,COMP1DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: COMP1,COMP2,ASMTBY,INIT116,INIT117,INIT118,INIT168,INIT169, RANDD1,RANDD2,RANDNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned centre number for De-Identity
DCRFID	char	CRF ID Assigned for De-Identity		Randomly assigned crfid for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
YMRS1	num	YMRS Q1		Collected at CRF.
YMRS2	num	YMRS Q2		Collected at CRF.
YMRS3	num	YMRS Q3		Collected at CRF.
YMRS4	num	YMRS Q4		Collected at CRF.
YMRS5	num	YMRS Q5		Collected at CRF.
YMRS6	num	YMRS Q6		Collected at CRF.

Variable	Type	Label	Codes	Comments
YMRS7	num	YMRS Q7		Collected at CRF.
YMRS8	num	YMRS Q8		Collected at CRF.
YMRS9	num	YMRS Q9		Collected at CRF.
YMRS10	num	YMRS Q10		Collected at CRF.
YMRS11	num	YMRS Q11		Collected at CRF.
YMRSF1	num	Coded YMRS Q1		Collected at CRF.
YMRSF2	num	Coded YMRS Q2		Collected at CRF.
YMRSF3	num	Coded YMRS Q3		Collected at CRF.
YMRSF4	num	Coded YMRS Q4		Collected at CRF.
YMRSF5	num	Coded YMRS Q5		Collected at CRF.
YMRSF6	num	Coded YMRS Q6		Collected at CRF.
YMRSF7	num	Coded YMRS Q7		Collected at CRF.
YMRSF8	num	Coded YMRS Q8		Collected at CRF.
YMRSF9	num	Coded YMRS Q9		Collected at CRF.
YMRSF10	num	Coded YMRS Q10		Collected at CRF.
YMRSF11	num	Coded YMRS Q11		Collected at CRF.
YMRSV	num	Verbatim Total Score		Collected at CRF.
YMRSSUM	num	SAS Calculated Total Score		Collected at CRF.
DFPL116	num	Plate 116		Collected at CRF.
DFPL117	num	Plate 117		Collected at CRF.
DFPL118	num	Plate 118		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFPL168	num	Plate 168		Collected at CRF.
DFPL169	num	Plate 169		Collected at CRF.
STRATUM	num	Stratum		Collected at CRF.
RGROUP	num	Treatment Assignment		Collected at CRF.
COMP1DY	num	Relative Completed Day		If COMPD1 and CONSNT1D not missing then perform below logic to calculate COMP1DY, If COMPD1 less than CONSNT1D then (COMPD1 - CONSNT1D). Else if COMPD1 is greater than equal to CONSNT1D then (COMPD1- CONSNT1D) +1.
RAND1DY	num	Relative Randomization Day		If RANDD1 and CONSNT1D not missing then perform below logic to calculate RAND1DY, If RANDD1 less than CONSNT1D then (RANDD1 - CONSNT1D). Else if RANDD1 is greater than equal to CONSNT1D then (RANDD1- CONSNT1D) +1.