

Clinical Development

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R092670PSY3007

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 Name will not be provided.
- Date of birth will not be provided, only age in years and grouped to protect PII.
- 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.
- Rater's Initials will not be submitted.
- 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 day cannot be calculated.
- Remove Child-bearing potential information.
- Remove ethnic information.
- Empty comments data will be submitted.
- Remove DNRSLT dataset (its sensitive information). It may reveal subject personal identification information.
- Remove INVEST dataset; it's not a subject level data.
- Remove PROTDESC dataset, it's not a subject level data.
- Remove TI datasets, these are not subject level datasets.
- Remove MEDHIST dataset (its sensitive information).
- Remove HABIT dataset (its sensitive information).
- Remove SURGERY dataset (its sensitive information).
- Subjects with Outcome of 'DEATH' will be removed from all datasets as it is a sensitive information and may reveal subject identifier information.

1.3. Data Files

The R092670PSY3007 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics (DM) – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demographics (DM)
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
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): BIRTHDT, DMACTDT, DMINFDT, DMSCRDT, ETHNIC, ETHNICC, ETHNSPEC, IVID, IVNAME, RACESPEC, SUBJINIT

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

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
SEXC	num	Sex Code		Collected at CRF
SEX	char	Sex		Collected at CRF
RACEC	num	Race Code		Element has been grouped to protect subject PII.
RACE	char	Race		Element has been grouped to protect subject PII.
DCONTRCY	char	De-identify Country Code		Country information will be groped to protect PII.
DCOUNTRY	char	De-identify Country		Country information will be groped to protect PII.
INT1	char	Amendment 1		Collected at CRF
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and DMINFDT not missing then perform below logic to calculate relative day. If DMACTDT less than DMINFDT then (DMACTDT - DMINFDT). Else if DMACTDT is greater than equal to DMINFDT then (DMACTDT - DMINFDT) +1.
DMSCRDY	num	Relative Day of First Trial Related Procedure		If DMSCRDT and DMINFDT not missing then perform below logic to calculate relative day. If DMSCRDT less than DMINFDT then (DMSCRDT - DMINFDT). Else if DMSCRDT is greater than equal to DMINFDT then (DMSCRDT - DMINFDT) +1.
DAGE	char	De-identify Age in Years		If BIRTHDT and DMINFDT not missing then perform below logic to derive age. INT(DMINFDT - BIRTHDT)/365.25 Element has been grouped to protect subject PII.

1.4.2. Adverse Events (AE) – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID, AESEQ
Sorted by	DUSUBJID, AESEQ
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>AEENDT, AEENDTC, AESERREF, AESTDT, AESTDTC, AETERM, AESCONG, AESDISAB, AESDTH, AESHOSPR, AESHOSPP, AESLIFE, AESMIE</p>

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

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF
AEREPRTC	num	Were Any AEs Reported Code		Collected at CRF
AEREPRT	char	Were Any AEs Reported		Collected at CRF
AESEQ	num	AE Sequence Number		Collected at CRF
AECODE	char	AE Dictionary Code		Collected at CRF
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF
AEACTTRTC	num	Action Taken with Treatment Code		Collected at CRF
AEACTTRT	char	Action Taken with Treatment		Collected at CRF
AEOUTC	num	Outcome of Event Code		Collected at CRF
AEOUT	char	Outcome of Event		Collected at CRF
AERELC	num	Relationship to Treatment Code		Collected at CRF
AEREL	char	Relationship to Treatment		Collected at CRF
AESERC	char	Seriousness Criteria Code		Collected at CRF
AESER	char	Seriousness Criteria		Collected at CRF
AESEVC	num	Severity of Event Code		Collected at CRF
AESEV	char	Severity of Event		Collected at CRF
AECONTRTC	num	Concomitant/Additional Treatment Code		Collected at CRF
AECONTRT	char	Concomitant/Additional Treatment		Collected at CRF
AEDECOD1	char	Dictionary-Derived Lower Level Term		Collected at CRF

Variable	Type	Label	Codes	Comments
AEDECOD	char	Dictionary-Derived Term		Collected at CRF
AEBODSYC	char	Body System or Organ Class Code		Collected at CRF
AEBODSYS	char	Body System or Organ Class		Collected at CRF
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and DMINFDT not missing then perform below logic to calculate relative day. If AESTDTC less than DMINFDT then (AESTDTC - DMINFDT). Else if AESTDTC is greater than equal to DMINFDT then (AESTDTC - DMINFDT) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and DMINFDT not missing then perform below logic to calculate relative day. If AEENDTC less than DMINFDT then (AEENDTC - DMINFDT). Else if AEENDTC is greater than equal to DMINFDT then (AEENDTC - DMINFDT) +1.

1.4.3. Abnormal Involuntary Movement Scale – AIMS

Dataset	AIMS
Creating program	aims.sas
Description	Abnormal Involuntary Movement Scale
Unique identifier	DUSUBJID, AIGROUP, AIITEM
Sorted by	DUSUBJID, AIGROUP, AIITEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AIACTDT, AIRATERI

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

Variable	Type	Label	Codes	Comments
AIVTYPEC	num	AIMS Visit Type Code		Collected at CRF
AIVTYPE	char	AIMS Visit Type		Collected at CRF
AIGROUP	char	AIMS Group		Collected at CRF
AIITEM	char	AIMS Item		Collected at CRF
AISCOREC	num	AIMS Score Code		Collected at CRF
AISCORE	char	AIMS Score		Collected at CRF
AIACDY	num	Relative Actual Day of AIMS		<p>If AIACDY and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If AIACDY less than DMINFDT then (AIACDY - DMINFDT). Else if AIACDY is greater than equal to DMINFDT then (AIACDY - DMINFDT) +1.</p>

1.4.4. Barnes Akathisia Scale (BA) – BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia Scale
Unique identifier	DUSUBJID, BAGROUP, BAITEM
Sorted by	DUSUBJID, BAGROUP, BAITEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BAACTDT, BARATERI

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

Variable	Type	Label	Codes	Comments
BAVTYPEC	num	BARS Visit Type Code		Collected at CRF
BAVTYPE	char	BARS Visit Type		Collected at CRF
BAGROUP	char	BARS Group		Collected at CRF
BAITEM	char	BARS Item		Collected at CRF
BAScoreC	num	BARS Score Code		Collected at CRF
BAScore	char	BARS Score		Collected at CRF
BAACTDY	num	Relative Actual Day of BARS		<p>If BAACTDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If BAACTDT less than DMINFDT then (BAACTDT - DMINFDT). Else if BAACTDT is greater than equal to DMINFDT then (BAACTDT - DMINFDT) +1.</p>

1.4.5. Clinical Global Impression (CG) – CGI

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

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

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

1.4.6. Lab Chemistry (LB) – CHEM

Dataset	CHEM
Creating program	chem.sas
Description	Lab Chemistry
Unique identifier	DUSUBJID, VISITNUM, LBVTYPE, LBTYPE, LBTESTC, LBACTDY, LBACTTM, LBPTM, LBFAST, ORGRES, ORGUNIT, LBSTAT
Sorted by	DUSUBJID, VISITNUM, LBVTYPE, LBTYPE, LBTESTC, LBACTDY, LBACTTM, LBPTM, LBFAST, ORGRES, ORGUNIT, LBSTAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ACCNUM, LBACTDT, LBENDT, LBENTM, LBPRVID, LBPRVIDC, LBREASND, LBREF, LBSEQ, TSTCOM

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF
LBVTYPE	char	Lab Visit Type		Collected at CRF
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF
LBPTM	num	Planned Collection Time		Collected at CRF
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF
LBSPECMN	char	Specimen Type		Collected at CRF
DAGEATCL	char	De-identify Subject Age at Collection		Element has been grouped to protect subject PII.
AGEU	char	Subject Age Units		Collected at CRF
LBFASTC	num	Fasted Code		Collected at CRF
LBFAST	char	Fasted		Collected at CRF
LBTYPEC	num	Lab Type Code		Collected at CRF
LBTYPE	char	Lab Type		Collected at CRF
LBTESTC	num	Lab Test Code		Collected at CRF
LBABBR	char	Lab Test Abbreviation		Collected at CRF
LBTEST	char	Lab Test Name		Collected at CRF
LBDESCR	char	Full Test Description		Collected at CRF
LBSTAT	char	Lab Status		Collected at CRF

Variable	Type	Label	Codes	Comments
ORGRES	char	Character Result in Original Units		Collected at CRF
ORGRESN	num	Numeric Result in Original Units		Collected at CRF
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF
ORGUNIT	char	Reported Unit		Collected at CRF
REPUNIT	char	Reported Unit		Collected at CRF
STDRESC	char	Character Result in Standard Units		Collected at CRF
STDRESN	num	Numeric Result in Standard Units		Collected at CRF
STDNRC	char	Normal Range in Char Result in Std Units		Collected at CRF
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF
STDUNIT	char	Standard Units		Collected at CRF
NRIND	char	Normal Range Indicator		Collected at CRF
LBSIGHI	num	Markedly Abn. Range Upper Lim.- Std Units		Collected at CRF
LBSIGLO	num	Markedly Abn. Range Lower Lim.- Std Units		Collected at CRF
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF

Variable	Type	Label	Codes	Comments
LBCVFACT	num	Conventional Conversion Factor		Collected at CRF
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDT not missing then perform below logic to calculate relative day. If LBACTDT less than DMINFDT then (LBACTDT - DMINFDT). Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT - DMINFDT) +1.
LBENDY	num	Relative End Day of Observation		If LBENDT and DMINFDT not missing then perform below logic to calculate relative day. If LBENDT less than DMINFDT then (LBENDT - DMINFDT). Else if LBENDT is greater than equal to DMINFDT then (LBENDT - DMINFDT) +1.

1.4.7. Comments (CT) – COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Comments (CT)
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
SUBJID	char	Subject Number Assigned for De-identity		Empty dataset will be submitted
STUDYID	char	Study Id		Empty dataset will be submitted
USUBJID	char	Unique Subject Id Assign for De-identity		Empty dataset will be submitted
SITEID	char	Site Assigned for De-identity		Empty dataset will be submitted
PHASENUM	num	Phase Number		Empty dataset will be submitted
PHASE	char	Phase		Empty dataset will be submitted
VISITNUM	num	Visit Number		Empty dataset will be submitted
VISIT	char	Visit		Empty dataset will be submitted
CTSEQ	num	Comment Sequence Number		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
DOMAIN	char	Domain of Origin		Empty dataset will be submitted
CTVISIT	char	Visit of Origin		Empty dataset will be submitted

1.4.8. Concomitant Meds (CM) – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant medications
Unique identifier	DUSUBJID, CMSEQ
Sorted by	DUSUBJID, CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CMENDT, CMENDTC, CMREAS, CMREGIM, CMSTDT, CMSTDTC, CMTERM

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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF
PHASE	char	Phase		Collected at CRF
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF
CMGROUP	char	Medication Grouping		Collected at CRF
CMREPRTC	num	Were Any Meds Administered Code		Collected at CRF
CMREPRT	char	Were Any Meds Administered		Collected at CRF
CMSEQ	num	Conmed Sequence Number		Collected at CRF
CMDECOD1	char	Medication Specified Term		Collected at CRF
CMDOSE	num	Dosage		Collected at CRF
CMUNIT	char	Dose Unit		Collected at CRF
CMROUTE	char	Route of Administration		Collected at CRF
CMCAUSC	num	Given for AE Code		Collected at CRF
CMCAUS	char	Given for AE		Collected at CRF
AESEQ	num	AE Sequence Number		Collected at CRF
AESEQ1	num	AE Sequence Number 1		Collected at CRF

Variable	Type	Label	Codes	Comments
AESEQ2	num	AE Sequence Number 2		Collected at CRF
CMPRIORC	num	Med Started Prior to Trial Code		Collected at CRF
CMPRIOR	char	Med Started Prior to Trial		Collected at CRF
CMCONTC	num	Medication Continuing Code		Collected at CRF
CMCONT	char	Medication Continuing		Collected at CRF
CMCLASC	char	ATC Code		Collected at CRF
CMCLASC0	char	ATC Code 0		Collected at CRF
CMCLASC1	char	ATC Code 1		Collected at CRF
CMCLASC2	char	ATC Code 2		Collected at CRF
CMCLASC3	char	ATC Code 3		Collected at CRF
CMCLASC4	char	ATC Code 4		Collected at CRF
CMCLASC5	char	ATC Code 5		Collected at CRF
CMCLASC6	char	ATC Code 6		Collected at CRF
CMCLASC7	char	ATC Code 7		Collected at CRF
CMCLASC8	char	ATC Code 8		Collected at CRF
CMCLASC9	char	ATC Code 9		Collected at CRF
CMCLAS0	char	ATC Text 0		Collected at CRF
CMCLAS1	char	ATC Text 1		Collected at CRF
CMCLAS2	char	ATC Text 2		Collected at CRF
CMCLAS3	char	ATC Text 3		Collected at CRF

Variable	Type	Label	Codes	Comments
CMCLAS4	char	ATC Text 4		Collected at CRF
CMCLAS5	char	ATC Text 5		Collected at CRF
CMCLAS6	char	ATC Text 6		Collected at CRF
CMCLAS7	char	ATC Text 7		Collected at CRF
CMCLAS8	char	ATC Text 8		Collected at CRF
CMCLAS9	char	ATC Text 9		Collected at CRF
CMCODE	char	Medication Dictionary Code		Collected at CRF
CMDECOD	char	Medication Generic Term		Collected at CRF
CMCLAS	char	ATC Text		Collected at CRF
CMDSTDY	num	Relative Start Day of Medication		If CMDSTDTC and DMINFDT not missing then perform below logic to calculate relative day. If CMDSTDTC less than DMINFDT then (CMDSTDTC - DMINFDT). Else if CMDSTDTC is greater than equal to DMINFDT then (CMDSTDTC - DMINFDT) +1.
CMDENDY	num	Relative End Day of Medication		If CMDENDTC and DMINFDT not missing then perform below logic to calculate relative day. If CMDENDTC less than DMINFDT then (CMDENDTC - DMINFDT). Else if CMDENDTC is greater than equal to DMINFDT then (CMDENDTC - DMINFDT) +1.

1.4.9. Diagnosis (DG) – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis (DG)
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA: DGACTION, DGACTIONC, DGACTIOND

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

Variable	Type	Label	Codes	Comments
DIAGNOSC	Num	Diagnosis Code		Collected at CRF
DIAGNOS	char	Diagnosis		Collected at CRF
DGTYPEC	num	Schizophrenia Type Code		Collected at CRF
DGTYPE	char	Schizophrenia Type		Collected at CRF
DDGAGE	char	De-identify Age At First Diag Of Schizo		Element has been grouped to protect subject PII.
DGACTDY	num	Relative actual day of diagnosis		If DGACTDTC and DMINFDT not missing then perform below logic to calculate relative day. If DGACTDTC less than DMINFDT then (DGACTDTC - DMINFDT). Else if DGACTDTC is greater than equal to DMINFDT then (DGACTDTC - DMINFDT) +1.
DGDY	num	Relative Day of Collection		If DGDT and DMINFDT not missing then perform below logic to calculate relative day. If DGDT less than DMINFDT then (DGDT - DMINFDT). Else if DGDT is greater than equal to DMINFDT then (DGDT - DMINFDT) +1.

1.4.10. Disposition (DS) – DISPOSIT

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

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

Variable	Type	Label	Codes	Comments
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF
DSTYPE	char	End of Treatment or Trial		Collected at CRF
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF
DSREASC	num	Reason for Withdrawal/Termination Code		Element has been grouped to protect subject PII.
DSREAS	char	Reason for Withdrawal/Termination		Element has been grouped to protect subject PII.
DSSCRNC	num	Reason for Screen Failure Code		Collected at CRF
DSSCRN	char	Reason for Screen Failure		Collected at CRF
AESEQ	num	AE Sequence Number		Collected at CRF
DSACTDY	num	Relative Actual Day Trial Completion/Withdrawal		If DSACTDT and DMINFDT not missing then perform below logic to calculate relative day. If DSACTDT less than DMINFDT then (DSACTDT - DMINFDT). Else if DSACTDT is greater than equal to DMINFDT then (DSACTDT - DMINFDT) +1.
DEATHDY	num	Relative Actual Day of Death		If DEATHDT and DMINFDT not missing then perform below logic to calculate relative day. If DEATHDT less than DMINFDT then (DEATHDT - DMINFDT). Else if DEATHDT is greater than equal to DMINFDT then (DEATHDT - DMINFDT) +1.

1.4.11. Electrocardiogram (EG) – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram (EG)
Unique identifier	DUSUBJID, PHASENUM, PHASE, VISITNUM, VISIT, EGTESTCD, EGPTMNUM, EGSEQ, EGVTYPE
Sorted by	DUSUBJID, PHASENUM, PHASE, VISITNUM, VISIT, EGTESTCD, EGPTMNUM, EGSEQ, EGVTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BATCHID, EGCHG, EGCHGOTH, EGDT, EGINTOTH, EGPRVID, EGPRVIDC, EGREF, MDS_CODE

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
EGTESTCD	char	ECG Test Short Name		Collected at CRF
EGPTMNUM	num	Planned Time Point Number		Collected at CRF
EGPTM	char	Planned Time Point Name		Collected at CRF
EGACTTM	num	Actual Time of ECG		Collected at CRF
EGPOS	char	Position		Collected at CRF
EGQUAL	char	Qualifier		Collected at CRF
EGTEST	char	ECG Test		Collected at CRF
EGSTRESN	num	Numeric Result in Standard Units		Collected at CRF
EGSTUNIT	char	Standard Units		Collected at CRF
EGSTRESC	char	Character Result in Standard Units		Collected at CRF
EGORRESN	num	Numeric Result in Original Units		Collected at CRF
EGORUNIT	char	Original Units		Collected at CRF
EGINTP	char	Interpretation		Collected at CRF
EGINTPC	num	Interpretation Code		Collected at CRF
EGLEAD	char	Lead Used for Measurement		Collected at CRF
EGND	char	ECG Not Done		Collected at CRF
EGSEQ	num	ECG Sequence Number		Collected at CRF
EGREAD	char	ECG Reader		Collected at CRF

Variable	Type	Label	Codes	Comments
EGREADC	num	ECG Reader Code		Collected at CRF
EGVTYPE	char	ECG Visit Type		Collected at CRF
EGVTYPEC	num	ECG Visit Type Code		Collected at CRF
EGCHGC	num	Sig Change from Prev/Baseline ECG Code		Collected at CRF
EGDY	num	Relative Actual Day of ECG		If EGDT and DMINFDT not missing then perform below logic to calculate relative day. If EGDT less than DMINFDT then (EGDT - DMINFDT). Else if EGDT is greater than equal to DMINFDT then (EGDT - DMINFDT) +1.

1.4.12. Exposure (EX) – Exposure

Dataset	Exposure
Creating program	exposure.sas
Description	Exposure (EX)
Unique identifier	DUSUBJID, EXSTDY
Sorted by	DUSUBJID, EXSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXRATERI, EXSTDT

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

EXSTTM	num	Start Time of Exposure		Collected at CRF
EXSITEC	num	Injection Site Code		Collected at CRF
EXSITE	char	Injection Site		Collected at CRF
EXPOSC	num	Position of Injection Code		Collected at CRF
EXPOS	char	Position of Injection		Collected at CRF
EXSTDY	num	Relative Start Day of Exposure		<p>If EXSTDY and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If EXSTDY less than DMINFDT then (EXSTDY - DMINFDT). Else if EXSTDY is greater than equal to DMINFDT then (EXSTDY - DMINFDT) +1.</p>

1.4.13. Lab Hematology (LB) – HEMAT

Dataset	HEMAT
Creating program	hemat.sas
Description	Lab Hematology (LB)
Unique identifier	DUSUBJID, VISITNUM, LBTESTC
Sorted by	DUSUBJID, VISITNUM, LBTESTC
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values: ACCNUM, LBACTDT, LBENDT, LBENTM, LBPRVID, LBPRVIDC, LBREASND, LBREF, LBSEQ, TSTCOM

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

Variable	Type	Label	Codes	Comments
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF
LBVTYPE	char	Lab Visit Type		Collected at CRF
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF
LBPTM	num	Planned Collection Time		Collected at CRF
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF
LBSPECMN	char	Specimen Type		Collected at CRF
DAGEATCL	char	De-identify Subject Age at Collection		Element has been grouped to protect subject PII.
AGEU	char	Subject Age Units		Collected at CRF
LBFASTC	num	Fasted Code		Collected at CRF
LBFAST	char	Fasted		Collected at CRF
LBTYPESC	num	Lab Type Code		Collected at CRF
LBTYPES	char	Lab Type		Collected at CRF
LBTESTC	num	Lab Test Code		Collected at CRF
LBABBR	char	Lab Test Abbreviation		Collected at CRF
LBTEST	char	Lab Test Name		Collected at CRF
LBDESCR	char	Full Test Description		Collected at CRF
LBSTAT	char	Lab Status		Collected at CRF
ORGRES	char	Character Result in Original Units		Collected at CRF
ORGRESN	num	Numeric Result in Original Units		Collected at CRF

Variable	Type	Label	Codes	Comments
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF
ORGUNIT	char	Reported Unit		Collected at CRF
REPUNIT	char	Reported Unit		Collected at CRF
STDRESC	char	Character Result in Standard Units		Collected at CRF
STDRESN	num	Numeric Result in Standard Units		Collected at CRF
STDNRC	char	Normal Range in Char Result in Std Units		Collected at CRF
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF
STDUNIT	char	Standard Units		Collected at CRF
NRIND	char	Normal Range Indicator		Collected at CRF
LBSIGHI	num	Markedly Abn. Range Upper Lim.-Std Units		Collected at CRF
LBSIGLO	num	Markedly Abn. Range Lower Lim.-Std Units		Collected at CRF
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF
LBCVFACT	num	Conventional Conversion Factor		Collected at CRF

Variable	Type	Label	Codes	Comments
LBACTDY	num	Relative Actual Day of Sample		<p>If LBACTDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If LBACTDT less than DMINFDT then (LBACTDT - DMINFDT). Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT - DMINFDT) +1.</p>
LBENDY	num	Relative End Day of Observation		<p>If LBENDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If LBENDT less than DMINFDT then (LBENDT - DMINFDT). Else if LBENDT is greater than equal to DMINFDT then (LBENDT - DMINFDT) +1.</p>

1.4.14. Hospitalization (HO) – HOSPITAL

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

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

Variable	Type	Label	Codes	Comments
HODISCHC	num	Is Subject Discharged from Hospital		Collected at CRF
HODISCH	char	Is Subject Discharged from Hospital		Collected at CRF
HOSTDY	num	Relative Admission Day of Hospitalization		If HOSTDT and DMINFDT not missing then perform below logic to calculate relative day. If HOSTDT less than DMINFDT then (HOSTDT - DMINFDT). Else if HOSTDT is greater than equal to DMINFDT then (HOSTDT - DMINFDT) +1.
HOENDY	num	Relative Discharge Day of Hospitalization		If HOENDT and DMINFDT not missing then perform below logic to calculate relative day. If HOENDT less than DMINFDT then (HOENDT - DMINFDT). Else if HOENDT is greater than equal to DMINFDT then (HOENDT - DMINFDT) +1.

1.4.15. Inclusion/Exclusion Exceptions (IE) – IE

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

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

Variable	Type	Label	Codes	Comments
IECAT	char	Inclusion/Exclusion Category		Collected at CRF
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF
IESTRESC	char	Exception Criterion Result in Std Format		Collected at CRF
IEORRES	char	Exception Criterion Original Result		Collected at CRF
IEMETC	num	Overall Criteria Met Code		Collected at CRF
IEMET	char	Overall Criteria Met		Collected at CRF
IEDY	num	Relative Day of Collection		<p>If IEDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If IEDT less than DMINFDT then (IEDT - DMINFDT). Else if IEDT is greater than equal to DMINFDT then (IEDT - DMINFDT) +1.</p>

1.4.16. Inve. Eval. of Inj. Site (II) – IVEVINJ

Dataset	IVEVINJ
Creating program	ivevinj.sas
Description	Inve. Eval. of Inj. Site (II)
Unique identifier	DUSUBJID, IEITEM
Sorted by	DUSUBJID, IEITEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IEACTDT, IERATERI

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

Variable	Type	Label	Codes	Comments
IEITEM	char	Evaluation Item		Collected at CRF
IESCOREC	num	Evaluation Score Code		Collected at CRF
IESCORE	char	Evaluation Score		Collected at CRF
IEACTTM	num	Actual Time of Inve. Eval. of Inj. Site		Collected at CRF
IEACTDY	num	Relative Actual Day of Inve. Eval. of Inj. Site		If IEACTDT and DMINFDT not missing then perform below logic to calculate relative day. If IEACTDT less than DMINFDT then (IEACTDT - DMINFDT). Else if IEACTDT is greater than equal to DMINFDT then (IEACTDT - DMINFDT) +1.

1.4.17. Medication Kit (MK) – MEDKIT

Dataset	MEDKIT
Creating program	medkit.sas
Description	Medication Kit
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DISPDT, KITNUM

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

Variable	Type	Label	Codes	Comments
DOSE	num	Dose		Collected at CRF
DOSEUNIT	char	Dose Unit		Collected at CRF
DISPDY	num	Relative Actual Day Kit Dispensed		If DISPDT and DMINFDT not missing then perform below logic to calculate relative day. If DISPDT less than DMINFDT then (DISPDT - DMINFDT). Else if DISPDT is greater than equal to DMINFDT then (DISPDT - DMINFDT) +1.

1.4.18. Positive And Negative Syndrome Scale – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	Positive And Negative Syndrome Scale
Unique identifier	DUSUBJID, PAGROUP, PAITEM
Sorted by	DUSUBJID, PAGROUP, PAITEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAACTDT, PARATERI

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

Variable	Type	Label	Codes	Comments
PAVTYPEC	num	PANSS Visit Type Code		Collected at CRF
PAVTYPE	char	PANSS Visit Type		Collected at CRF
PAGROUP	char	PANSS Group		Collected at CRF
PAITEM	char	PANSS Item		Collected at CRF
PASCOREC	num	PANSS Score Code		Collected at CRF
PASCORE	char	PANSS Score		Collected at CRF
PAACTDY	char	Relative Actual Day of PANSS		<p>If PAACTDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If PAACTDT less than DMINFDT then (PAACTDT - DMINFDT). Else if PAACTDT is greater than equal to DMINFDT then (PAACTDT - DMINFDT) +1.</p>

1.4.19. PK/PD Concentrations (PC) – PCCNC

Dataset	PCCNC
Creating program	pccnc.sas
Description	PK/PD Concentrations
Unique identifier	DUSUBJID, PHASENUM, PHASE, VISITNUM, VISIT, TPT, PCPRMTYP, SAMMAT, PCSPEC, PCSEQ, PCTEST
Sorted by	DUSUBJID, PHASENUM, PHASE, VISITNUM, VISIT, TPT, PCPRMTYP, SAMMAT, PCSPEC, PCSEQ, PCTEST
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SPPRVIDC, SPPRVID, PCPRVIDC, PCPRVID, PCCAT, SAMREF, ACQREF, PCENTM, PCSPCOM, PCSTDT, PCENDT.

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
TPTNUM	num	Planned Time Point Number		Collected at CRF
TPT	char	Planned Time Point		Collected at CRF
PCVTYPEC	num	PK/PD Sample Visit Type Code		Collected at CRF
PCVTYPE	char	PK/PD Sample Visit Type		Collected at CRF
PCPRMTYP	char	Parameter Type		Collected at CRF
SAMMAT	char	Sample Material		Collected at CRF
PCSPEC	char	Specimen Material		Collected at CRF
PCSEQ	num	Sample Sequence Number		Collected at CRF
PCSTTM	num	Start Time of Specimen Collection		Collected at CRF
PCTEST	char	Test Name		Collected at CRF
PCORRESN	num	Numeric Result in Original Units		Collected at CRF
PCORRES	char	Result in Original Units		Collected at CRF
PCORUNIT	char	Original Units		Collected at CRF
PCNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF
PCNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF
PCSTRESN	num	Numeric Result in Standard Units		Collected at CRF
PCSTRESC	char	Character Result in Standard Units		Collected at CRF

Variable	Type	Label	Codes	Comments
PCSTUNIT	char	Standard Units		Collected at CRF
PCSTATC	num	Sample Collection Status Code		Collected at CRF
PCSTAT	char	Sample Collection Status		Collected at CRF
PCSTDT	num	Start Day of Specimen Collection		If PCSTDT and DMINFDT not missing then perform below logic to calculate relative day. If PCSTDT less than DMINFDT then (PCSTDT - DMINFDT). Else if PCSTDT is greater than equal to DMINFDT then (PCSTDT - DMINFDT) +1.
PCENDT	num	End Day of Specimen Collection		If PCENDT and DMINFDT not missing then perform below logic to calculate relative day. If PCENDT less than DMINFDT then (PCENDT - DMINFDT). Else if PCENDT is greater than equal to DMINFDT then (PCENDT - DMINFDT) +1.

1.4.20. Physical Exam (PE) – PE

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

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

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

1.4.21. Protocol Deviation (PV) – PROTDEV

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

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

1.4.22. Pers. And Soc. Performance Scale (PS) – PSP

Dataset	PSP
Creating program	psp.sas
Description	Pers. And Soc. Performance Scale
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PSACTDT, PSRATERI

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

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

1.4.23. Psychiatric History (PY) – PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychiatric History
Unique identifier	DUSUBJID, PYSEQ
Sorted by	DUSUBJID, PYSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PYDIAG, PYENDT, PYENDTC, PYSTDT, PYSTDTC

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

Variable	Type	Label	Codes	Comments
PYHOSPC	num	Hospitalizations for Psychosis Code		Collected at CRF
PYHOSP	char	Hospitalizations for Psychosis		Collected at CRF
PYSEQ	num	Psychiatric History Sequence Number		Collected at CRF
PYSTDY	num	Relative Act. Start Day of Psychosis Trt. (Char)		If PYSTDTC and DMINFDT not missing then perform below logic to calculate relative day. If PYSTDTC less than DMINFDT then (PYSTDTC - DMINFDT). Else if PYSTDTC is greater than equal to DMINFDT then (PYSTDTC - DMINFDT) +1.
PYENDY	num	Relative Act. End Day of Psychosis Trt. (Char)		If PYENDTC and DMINFDT not missing then perform below logic to calculate relative day. If PYENDTC less than DMINFDT then (PYENDTC - DMINFDT). Else if PYENDTC is greater than equal to DMINFDT then (PYENDTC - DMINFDT) +1.

1.4.24. Randomization (RA) – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomization
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RAACTDT, RANDNUM, RASEQ, REGIMEN, SUB

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

Variable	Type	Label	Codes	Comments
TRTGRPC	num	Treatment Group Code		Collected at CRF
TRTGRP	char	Treatment Group		Collected at CRF
RAACTDY	num	Relative Actual Day of Randomization		If RAACTDT and DMINFDT not missing then perform below logic to calculate relative day. If RAACTDT less than DMINFDT then (RAACTDT - DMINFDT). Else if RAACTDT is greater than equal to DMINFDT then (RAACTDT - DMINFDT) +1.

1.4.25. Resource Use Question. (RQ) – RUQ

Dataset	RUQ
Creating program	ruq.sas
Description	Resource Use Question.
Unique identifier	DUSUBJID, RQSEQ
Sorted by	DUSUBJID, RQSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA: RQACCST, RQACCSTC, RQACTDT, RQCHDT, RQCHDTC, RQENDT, RQENDTC, RQOCCST, RQOCCSTC, RQSTDT, RQSTDTC, RQTYPOTH

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

Variable	Type	Label	Codes	Comments
RQGROU PC	char	Group Code		Collected at CRF
RQGROU P	char	Group		Collected at CRF
RQREPR TC	char	Were Any Records Reported Code		Collected at CRF
RQREPR T	char	Were Any Records Reported		Collected at CRF
RQLSTDC	num	Lost Working Days Code		Collected at CRF
RQLSTD	char	Lost Working Days		Collected at CRF
RQDAYLST	num	Number of Working Days Lost		Collected at CRF
RQSEQ	num	Sequence Number		Collected at CRF
RQTYPEC	char	Type of Hospital/Consultation Code		Collected at CRF
RQTYPE	char	Type of Hospital/Consultation		Collected at CRF
RQWARDC	char	Type of Ward Code		Collected at CRF
RQWARD	char	Type of Ward		Collected at CRF
RQRSNC	num	Reason Code		Collected at CRF
RQRSN	char	Reason		Collected at CRF
RQSTON	char	Hospitalization Ongoing Start		Collected at CRF
RQENON	char	Hospitalization Ongoing End		Collected at CRF
RQFREQ	num	Frequency		Collected at CRF
RQNUM	num	Number of consultations		Collected at CRF

Variable	Type	Label	Codes	Comments
RQACTDY	num	Relative Actual Day of Collection		<p>If RQACTDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If RQACTDT less than DMINFDT then $(RQACTDT - DMINFDT)$. Else if RQACTDT is greater than equal to DMINFDT then $(RQACTDT - DMINFDT) + 1$.</p>
RQSTDY	num	Relative Actual Start Day of Event		<p>If RQSTDTC and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If RQSTDTC less than DMINFDT then $(RQSTDTC - DMINFDT)$. Else if RQSTDTC is greater than equal to DMINFDT then $(RQSTDTC - DMINFDT) + 1$.</p>
RQENDY	num	Relative Actual End Day of Event		<p>If RQENDTC and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If RQENDTC less than DMINFDT then $(RQENDTC - DMINFDT)$. Else if RQENDTC is greater than equal to DMINFDT then $(RQENDTC - DMINFDT) + 1$.</p>
RQCHDY	num	Relative Day of Change		<p>If RQCHDTC and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If RQCHDTC less than DMINFDT then $(RQCHDTC - DMINFDT)$. Else if RQCHDTC is greater than equal to DMINFDT then $(RQCHDTC - DMINFDT) + 1$.</p>

1.4.26. SARS (SR) – SARS

Dataset	SARS
Creating program	sars.sas
Description	SARS
Unique identifier	DUSUBJID, SRITEM
Sorted by	DUSUBJID, SRITEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SRACTDT, SRRATERI

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

Variable	Type	Label	Codes	Comments
SRVTYPEPEC	num	SARS Visit Type Code		Collected at CRF
SRVTYPE	char	SARS Visit Type		Collected at CRF
SRITEM	char	SARS Item		Collected at CRF
SRSCOREC	num	SARS Score Code		Collected at CRF
SRSCORE	char	SARS Score		Collected at CRF
SRACTDY	num	Relative Actual Day of SARS		<p>If SRACTDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If SRACTDT less than DMINFDT then (SRACTDT - DMINFDT). Else if SRACTDT is greater than equal to DMINFDT then (SRACTDT - DMINFDT) +1.</p>

1.4.27. Subj. Eval. of Inj. Site (SE) – SUEVINJ

Dataset	SUEVINJ
Creating program	suevinj.sas
Description	Subj. Eval. of Inj. Site
Unique identifier	DUSUBJID, SEITEM
Sorted by	DUSUBJID, SEITEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SEACTDT

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

Variable	Type	Label	Codes	Comments
SEITEM	char	Evaluation Item		Collected at CRF
SESCORE	num	Evaluation Score		Collected at CRF
SEACTTM	num	Actual Time of Subj. Eval. of Inj. Site		Collected at CRF
SEUNIT	char	Unit of Score from VAS Scale		Collected at CRF
SEACTDY	num	Relative Actual Day of Subj. Eval		If SEACTDT and DMINFDT not missing then perform below logic to calculate relative day. If SEACTDT less than DMINFDT then (SEACTDT - DMINFDT). Else if SEACTDT is greater than equal to DMINFDT then (SEACTDT - DMINFDT) +1.

1.4.28. Tolerability Testing (TT) – TOLTEST

Dataset	TOLTEST
Creating program	toltest.sas
Description	Tolerability Testing
Unique identifier	DUSUBJID, TTSEQ
Sorted by	DUSUBJID, TTSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA: TTSTDT

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

Variable	Type	Label	Codes	Comments
TTSEQ	num	Tolerability Testing Sequence Number		Collected at CRF
TPTNUM	num	Planned Time Point Number		Collected at CRF
TPT	char	Planned Time Point Name		Collected at CRF
TTTAKEN	num	Number of Pills Taken		Collected at CRF
TTNAC	num	Tolerability Testing Not Applicable Code		Collected at CRF
TTNA	char	Tolerability Testing Not Applicable		Collected at CRF
TTSTDY	num	Relative Start Day of Tolerability Exposure		<p>If TTSTDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If TTSTDT less than DMINFDT then (TTSTDT - DMINFDT). Else if TTSTDT is greater than equal to DMINFDT then (TTSTDT - DMINFDT) +1.</p>

1.4.29. Lab Urine (LB) – URINE

Dataset	URINE
Creating program	urine.sas
Description	Lab Urine
Unique identifier	DUSUBJID, VISITNUM, LBTESTC, LBSTAT
Sorted by	DUSUBJID, VISITNUM, LBTESTC, LBSTAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ACCNUM, LBACTDT, LBENDT, LBENTM, LBPRVID, LBPRVIDC, LBREASND, LBREF, LBSEQ, TSTCOM

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

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF
LBVTYPE	char	Lab Visit Type		Collected at CRF
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF
LBPTM	num	Planned Collection Time		Collected at CRF
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF
LBSPECMN	char	Specimen Type		Collected at CRF
DAGEATCL	char	De-identify Subject Age at Collection		Element has been grouped to protect subject PII.
AGEU	char	Subject Age Units		Collected at CRF
LBFASTC	num	Fasted Code		Collected at CRF
LBFAST	char	Fasted		Collected at CRF
LBTYPEC	num	Lab Type Code		Collected at CRF
LBTYPE	char	Lab Type		Collected at CRF
LBTESTC	num	Lab Test Code		Collected at CRF
LBABBR	char	Lab Test Abbreviation		Collected at CRF
LBTEST	char	Lab Test Name		Collected at CRF
LBDESCR	char	Full Test Description		Collected at CRF
LBSTAT	char	Lab Status		Collected at CRF
ORGRES	char	Character Result in Original Units		Collected at CRF

Variable	Type	Label	Codes	Comments
ORGRESN	num	Numeric Result in Original Units		Collected at CRF
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF
ORGUNIT	char	Reported Unit		Collected at CRF
REPUNIT	char	Reported Unit		Collected at CRF
STDRESC	char	Character Result in Standard Units		Collected at CRF
STDRESN	num	Numeric Result in Standard Units		Collected at CRF
STDNRC	char	Normal Range in Char Result in Std Units		Collected at CRF
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF
STDUNIT	char	Standard Units		Collected at CRF
NRIND	char	Normal Range Indicator		Collected at CRF
LBSIGHI	num	Markedly Abn. Range Upper Lim.- Std Units		Collected at CRF
LBSIGLO	num	Markedly Abn. Range Lower Lim.- Std Units		Collected at CRF
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF
LBCVFACT	num	Conventional Conversion Factor		Collected at CRF

Variable	Type	Label	Codes	Comments
LBACTDY	num	Relative Actual Day of Sample		<p>If LBACTDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If LBACTDT less than DMINFDT then (LBACTDT - DMINFDT). Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT - DMINFDT) +1.</p>
LBENDY	num	Relative End Day of Observation		<p>If LBENDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If LBENDT less than DMINFDT then (LBENDT - DMINFDT). Else if LBENDT is greater than equal to DMINFDT then (LBENDT - DMINFDT) +1.</p>

1.4.30. Sleep VAS Scale Scores (VA) – VAS

Dataset	VAS
Creating program	vas.sas
Description	Sleep VAS Scale Scores
Unique identifier	DUSUBJID, VASCALE
Sorted by	DUSUBJID, VASCALE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VAACDT

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

Variable	Type	Label	Codes	Comments
VASCALE	char	VAS Scale		Collected at CRF
VASCORE	num	VAS Score (mm)		Collected at CRF
VAACTDY	num	Relative Actual Day of VAS		If VAACTDT and DMINFDT not missing then perform below logic to calculate relative day. If VAACTDT less than DMINFDT then (VAACTDT - DMINFDT). Else if VAACTDT is greater than equal to DMINFDT then (VAACTDT - DMINFDT) +1.

1.4.31. Visit (VI) – VISIT

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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF
PHASE	char	Phase		Collected at CRF
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit		Collected at CRF
VISITDY	num	Relative Visit Day		<p>If VISITDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If VISITDT less than DMINFDT then (VISITDT - DMINFDT). Else if VISITDT is greater than equal to DMINFDT then (VISITDT - DMINFDT) +1.</p>

1.4.32. Vital Signs (VS) – VITAL

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

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

VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF
VSPOS	char	Position		Collected at CRF
DWEIGHT	num	De-identify Weight		Convert data to standardized "kg" unit values and group the values to protect the subject PII information.
VSWTUNIT	char	Weight Unit		All data converted into KGs.
DHEIGHT	num	De-identify Height		Convert data to standardized "cm" unit values and group the values to protect the subject PII information.
VSHTUNIT	char	Height Unit		All data converted into CMs.
PULSE	num	Pulse Rate (bpm)		Collected at CRF
SYSBP	num	Systolic Blood Pressure (mmHg)		Collected at CRF
DIABP	num	Diastolic Blood Pressure (mmHg)		Collected at CRF
TEMP	num	Temperature		Collected at CRF
TEMPUNIT	char	Temperature Unit		Collected at CRF
VSACTDY	num	Relative Actual Day of Vital Signs		If VSACTDT and DMINFDT not missing then perform below logic to calculate relative day. If VSACTDT less than DMINFDT then (VSACTDT - DMINFDT). Else if VSACTDT is greater than equal to DMINFDT then (VSACTDT - DMINFDT) +1.