

Clinical Development

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R076477-SCH-303

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 (years) shown in group 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.
- Subjects with ages grouped to protect PII.
- Subject diagnose and diabetes age grouped to protect PII.
- Remove the free text verbatim terms.
- Remove "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.

- 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.
- 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 (Investigator information). Its not subject level data.
- Remove PROTDESC dataset. Its not subject level data.
- AE WHO submitted so AE domain will be removed.
- FAMHIST, HABIT, MEDHIST and SURGERY dataset will be removed (due to sensitive information); it may reveal participant identification information.
- Country information will be grouped to protect PII.
- Race information will be grouped to protect PII.
- Age information will be grouped in all domains (if available) to protect PII.
- Vitals (Height and Weight) information will be grouped to protect PII.
- Subjects with Outcome of 'DEATH' will be removed from all datasets; It's a sensitive data can easily reveal subjects identifier information.

1.3. Data Files

The R076477-SCH-303 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 missing values: DMSCRDT, SUBJINIT, DMACTDT, IVID, IVNAME, BIRTHDT, DMINFDT, RACESPEC, ETHNICC, ETHNIC

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 ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF

Variable	Type	Label	Codes	Comments
PHASENUM	CHAR	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
SEXC	NUM	Sex Code		Collected at CRF
SEX	CHAR	Sex		Collected at CRF
RACEC	NUM	Race Code		Grouping element to protect subject PII.
RACE	CHAR	Race		Grouping element to protect subject PII.
DCONTRYC	CHAR	De-identify Country Code		Grouping element to protect subject PII.
DCOUNTRY	CHAR	De-identify Country		Grouping element to protect subject PII.
PAGENUM	NUM	Page Number		Collected at CRF
DMSCRDY	NUM	Relative Day of First Trial Rel Pro		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.
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.

Variable	Type	Label	Codes	Comments
DAGE	num	De-identify Age in Years		If BIRTHDT and DMINFDT not missing then perform below logic to derive age. INT(DMINFDT - BIRTHDT)/365.25 Group age to protect PII.

1.4.2. Adverse Events (AE) - AEWHO

Dataset	AEWHO
Creating program	aewho.sas
Description	Adverse Events (AE)
Unique identifier	DUSUBJID, AESEQ, AECODE
Sorted by	DUSUBJID, AESEQ, AECODE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AETERM, AESTDT, AEENDT, AESTDTC, AEENDTC, AESERREF

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

Variable	Type	Label	Codes	Comments
DSUBJID	CHAR	Subject Number Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		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
AEBODSYS	CHAR	WHO Body System		Collected at CRF
AEBODSYC	CHAR	Body System Code		Collected at CRF
AEDECOD1	CHAR	WHO Included Term		Collected at CRF
AEACTTRC	NUM	Action Taken with Treatment Code		Collected at CRF
AEACTTRT	CHAR	Action Taken with Treatment		Collected at CRF
AEOUTC	NUM	Outcome of Event Code		Collected at CRF
AEOUT	CHAR	Outcome of Event		Collected at CRF
AERELC	NUM	Relationship to Treatment Code		Collected at CRF

Variable	Type	Label	Codes	Comments
AEREL	CHAR	Relationship to Treatment		Collected at CRF
AESERC	NUM	Seriousness Criteria Code		Collected at CRF
AESER	CHAR	Seriousness Criteria		Collected at CRF
AESEVC	NUM	Severity of Event Code		Collected at CRF
AESEV	CHAR	Severity of Event		Collected at CRF
AECONTRC	NUM	Concomitant/Additional Treatment Code		Collected at CRF
AECONTRT	CHAR	Concomitant/Additional Treatment Given		Collected at CRF
AEDECOD	CHAR	WHO Preferred Term		Collected at CRF
AECODE	CHAR	AE Dictionary Code		Collected at CRF
SOC1	CHAR	AE System Organ Class 1		Collected at CRF
SOC2	CHAR	AE System Organ Class 2		Collected at CRF
SOC3	CHAR	AE System Organ Class 3		Collected at CRF
AESTDY	NUM	Relative Actual Start Day of Event		<p>If AESTDTC and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If AESTDTC less than DMINFDT then (AESTDTC - DMINFDT). Else if AESTDTC is greater than equal to DMINFDT then (AESTDTC - DMINFDT) +1.</p>

Variable	Type	Label	Codes	Comments
AEENDY	NUM	Relative Actual End Day of Event		<p>If AEENDTC and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If AEENDTC less than DMINFDT then (AEENDTC - DMINFDT). Else if AEENDTC is greater than equal to DMINFDT then (AEENDTC - DMINFDT) +1.</p>

1.4.3. Abnormal Involuntary Movement Scale - AIMS

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

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

Variable	Type	Label	Codes	Comments
DSUBJID	CHAR	Subject Number Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
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	Score		Collected at CRF
AIACDY	NUM	Relative Actual Day of AIMS		If AIACDT and DMINFDT not missing then perform below logic to calculate relative day. If AIACDT less than DMINFDT then (AIACDT - DMINFDT). Else if AIACDT is greater than equal to DMINFDT then (AIACDT - DMINFDT) +1.

1.4.4. Barnes Akathisia Scale (BA) - BARS

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

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF

Variable	Type	Label	Codes	Comments
PAGNUM	NUM	Page Number		Collected at CRF
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	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 (CG)
Unique identifier	DUSUBJID, CGSEV, VISIT
Sorted by	DUSUBJID, CGSEV, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CGRATERI, CGACTDT

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF

Variable	Type	Label	Codes	Comments
CGSEVC	NUM	CGI Severity Code		Collected at CRF
CGSEV	CHAR	CGI Severity		Collected at CRF
PAGNUM	NUM	Page Number		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. Laboratory Data - Chemistry (CL) - CHEM

Dataset	CHEM
Creating program	chem.sas
Description	Laboratory Data - Chemistry (CL)
Unique identifier	DUSUBJID, LBSEQ, LBVTYPE, LBTYPE, LBTEST, VISIT, LBTMLBL, LBACTTM
Sorted by	DUSUBJID, LBSEQ, LBVTYPE, LBTYPE, LBTEST, VISIT, LBTMLBL, LBACTTM

Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LBACTDT, LBPRVIDC, LBPRVID, LBREF, BATCHID
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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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
LBTESTC	NUM	Lab Test Code		Collected at CRF
STDUNIT	CHAR	Standard Units		Collected at CRF
LBVTYPE	CHAR	Lab Visit Type		Collected at CRF
LBPTM	NUM	Planned Collection Time		Collected at CRF
LBTYPEC	NUM	Lab Type Code		Collected at CRF

Variable	Type	Label	Codes	Comments
LBCVRES	NUM	Result in Conventional Units		Collected at CRF
LBCVUNIT	CHAR	Conventional Units		Collected at CRF
LBACTTM	NUM	Actual Time of Lab Sample		Collected at CRF
ORGUNIT	CHAR	Original Units		Collected at CRF
LBVTYPEC	NUM	Lab Visit Type Code		Collected at CRF
LBTMLBL	CHAR	Pre-determined collection times		Collected at CRF
ORGRESN	NUM	Numeric lab result		Collected at CRF
ORGRES	CHAR	Character lab result		Collected at CRF
NRIND	CHAR	High/Low Lab Value Flag		Collected at CRF
ORGNRHI	NUM	Upper limit for the lab normal range		Collected at CRF
ORGNRLO	NUM	Lower limit for the lab normal range		Collected at CRF
STDNRLO	NUM	S.I. lower limit		Collected at CRF
STDRESN	NUM	S.I. numeric result		Collected at CRF
STDNRHI	NUM	S.I. upper limit		Collected at CRF
DLAGE	CHAR	De-identify Age: time of visit		Grouping element to protect subject PII.
LAGEUNIT	CHAR	Age Unit (M or Y)		Collected at CRF
LBSEQ	NUM	Unique record id within protocol		Collected at CRF
LBFASCTC	NUM	Fasted Code		Collected at CRF

Variable	Type	Label	Codes	Comments
LBFAS	CHAR	Fasted		Collected at CRF
LBSIFACT	NUM	Std. Intl. Conversion Factor		Collected at CRF
LBTEST	CHAR	Lab Test Name		Collected at CRF
LBDESCR	CHAR	Full Test Description		Collected at CRF
LBTYPE	CHAR	Lab Type		Collected at CRF
LBABBR	CHAR	Lab Abbreviation		Collected at CRF
LBSIGLO	NUM	Significant Range Low		Collected at CRF
LBSIGHI	NUM	Significant Range High		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.

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
STUDYID	CHAR	Study Id		Empty data will be submitted.
DUSUBJID	CHAR	Unique Subject Id Assign for De-identity		Empty data will be submitted.
DSUBJID	CHAR	Assigned for De-identify		Empty data will be submitted.
DSITEID	CHAR	Site Assigned for De-identity		Empty data will be submitted.
VISITNUM	NUM	Visit Id		Empty data will be submitted.
VISIT	CHAR	Visit		Empty data will be submitted.
PHASENUM	NUM	Phase Number		Empty data will be submitted.
PHASE	CHAR	Phase		Empty data will be submitted.
PAGNUM	NUM	Page Number		Empty data will be submitted.
CTSEQ	NUM	Comment Sequence Number		Empty data will be submitted.
DOMAIN	CHAR	Domain of Origin		Empty data will be submitted.

1.4.8. Concomitant Meds (CM) - CONMED

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

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
CMREPRTC	NUM	Were Any Meds Administered/Changed Code		Collected at CRF
CMGROUPC	NUM	Medication Grouping Code		Collected at CRF
CMTYPEC	NUM	Prior/Concomitant Medication Code		Collected at CRF
CMREPRT	CHAR	Were Any Meds Administered/Changed		Collected at CRF
CMGROUP	CHAR	Medication Grouping		Collected at CRF
CMTYPE	CHAR	Prior/Concomitant Medication		Collected at CRF
CMSEQ	NUM	Conmed Sequence Number		Collected at CRF
CMDECOD1	CHAR	Medication Specified Term		Collected at CRF
CMROUTE	CHAR	Route		Collected at CRF
CMCONTC	NUM	Medication Continuing Code		Collected at CRF
CMCONT	CHAR	Medication Continuing		Collected at CRF
CMPRIORC	NUM	Med Started Prior to Trial Code		Collected at CRF
CMPRIOR	CHAR	Med Started Prior to Trial		Collected at CRF

Variable	Type	Label	Codes	Comments
AESEQ	NUM	AE Sequence Number		Collected at CRF
CMCAUSC	NUM	Cause of Concom/Drug/Therapy Code		Collected at CRF
CMCAUS	CHAR	Cause of Concom/Drug/Therapy		Collected at CRF
CMDOSE	NUM	Dosage		Collected at CRF
CMUNIT	CHAR	Dose Unit		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

Variable	Type	Label	Codes	Comments
CMCLAS2	CHAR	ATC Text 2		Collected at CRF
CMCLAS3	CHAR	ATC Text 3		Collected at CRF
CMCLAS4	CHAR	ATC Text 4		Collected at CRF
CMCLAS5	CHAR	ATC Text 5		Collected at CRF
CMCLAS6	CHAR	ATC Text 6		Collected at CRF
CMCLAS7	CHAR	ATC Text 7		Collected at CRF
CMCLAS8	CHAR	ATC Text 8		Collected at CRF
CMCLAS9	CHAR	ATC Text 9		Collected at CRF
CMCODE	CHAR	Medication Dictionary Code		Collected at CRF
CMDECOD	CHAR	Medication Generic Term		Collected at CRF
CMCLAS	CHAR	ATC Text		Collected at CRF
CMSTDY	NUM	Relative Actual Start Day of Medication		<p>If CMSTDTC and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If CMSTDTC less than DMINFDT then (CMSTDTC - DMINFDT). Else if CMSTDTC is greater than equal to DMINFDT then (CMSTDTC - DMINFDT) +1.</p>
CMENDY	NUM	Relative Actual End Day of Medication		<p>If CMENDTC and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If CMENDTC less than DMINFDT then (CMENDTC - DMINFDT). Else if CMENDTC is greater than equal to DMINFDT then (CMENDTC - DMINFDT) +1.</p>

1.4.9. Diagnosis (DG) - DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis (DG)
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Not Applicable.

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF

Variable	Type	Label	Codes	Comments
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
DGTYPEC	NUM	Schizophrenia Type Code		Collected at CRF
DGTYPE	CHAR	Schizophrenia Type		Collected at CRF
DIAGNOSC	NUM	Diagnosis Code		Collected at CRF
DIAGNOS	CHAR	Diagnosis		Collected at CRF
DDGAGE	CHAR	De-identify Age at Diagnosis of SCH		Grouping element to protect subject PII information.

1.4.10. Diabetes Related History (DH) - DIAHIST

Dataset	DIAHIST
Creating program	diahist.sas
Description	Diabetes Related History (DH)
Unique identifier	DUSUBJID, DHDIAG
Sorted by	DUSUBJID, DHDIAG
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DHACTDT, DHCHILD

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
DHDIAG	CHAR	Diagnosis		Collected at CRF
DHHISTC	NUM	Diabetes History Code		Collected at CRF
DHHIST	CHAR	Diabetes History		Collected at CRF
DDHAGE	CHAR	De-identify Age at Diagnosis		Grouping element to protect subject PII information.
DHACTDY	NUM	Relative Actual Day of Diabetes History		If DHACTDT and DMINFDT not missing then perform below logic to calculate relative day. If DHACTDT less than DMINFDT then (DHACTDT - DMINFDT). Else if DHACTDT is greater than equal to DMINFDT then (DHACTDT - DMINFDT) +1.

1.4.11. 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: DSACTDT, DRSOTH, DSRABKDT, DEATHDT, PREGDUDT, DSRABKRS, DSRABKTM

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF

Variable	Type	Label	Codes	Comments
PHASE	CHAR	Phase		Collected at CRF
DSTYPEC	NUM	End of Treatment or Trial Code		Collected at CRF
DSTYPE	CHAR	End of Treatment or Trial		Collected at CRF
DSREASC	NUM	Reason for Withdrawal/Termination Code		Collected at CRF
DSREAS	CHAR	Reason for Withdrawal/Termination		Collected at CRF
DSSTATC	NUM	Subject Completed Treatment/Trial Code		Collected at CRF
DSSTAT	CHAR	Subject Completed Treatment/Trial		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
DSOLC	NUM	Continue into Open Label Code		Collected at CRF
DSOL	CHAR	Continue into Open Label		Collected at CRF
DSSCRNC	NUM	Screen Failure Code		Collected at CRF
DSSCRN	CHAR	Screen Failure		Collected at CRF
AESEQ	NUM	AE Sequence Number		Collected at CRF
DSACTDY	NUM	Relative Actual Day Trial Comp/Withdra		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.

Variable	Type	Label	Codes	Comments
DSRABKDY	NUM	Relative Actual Day Rando. Code Broken		If DSRABKDT and DMINFDT not missing then perform below logic to calculate relative day. If DSRABKDT less than DMINFDT then (DSRABKDT - DMINFDT). Else if DSRABKDT is greater than equal to DMINFDT then (DSRABKDT - DMINFDT) +1.

1.4.12. Electrocardiogram (EG) - ECG

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

Variable	Type	Label	Codes	Comments
DSUBJID	CHAR	Subject Number Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
EGTESTCD	CHAR	ECG Test Short Name		Collected at CRF
EGPTMNUM	NUM	Label of Planned Elapsed Time		Collected at CRF
EGPTM	CHAR	Planned Elapsed Time of ECG		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	Result Numeric in Standard Units		Collected at CRF
EGSTUNIT	CHAR	Standard Units		Collected at CRF
EGSTRESC	CHAR	Result Character		Collected at CRF
EGORRESN	NUM	Result Numeric in Original Units		Collected at CRF
EGORUNIT	CHAR	Original Units		Collected at CRF

Variable	Type	Label	Codes	Comments
EGINTPC	NUM	Interpretation Code		Collected at CRF
EGINTP	CHAR	Interpretation		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
EGREADC	NUM	ECG Reader Code		Collected at CRF
EGREAD	CHAR	ECG Reader		Collected at CRF
EGVTYPEC	NUM	ECG Visit Type Code		Collected at CRF
EGVTYPE	CHAR	ECG Visit Type		Collected at CRF
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.

1.4.13. Enrollment (EN) - ENROLL

Dataset	ENROLL
Creating program	enroll.sas
Description	Enrollment (EN)
Unique identifier	DUSUBJID, ENSEQ
Sorted by	DUSUBJID, ENSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ENACTDT, ENTEXT

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
ENCRIT	CHAR	Inclusion or Exclusion Criterion		Collected at CRF

Variable	Type	Label	Codes	Comments
ENSEQ	NUM	Criterion Sequence Number		Collected at CRF
ENCRESC	NUM	Criterion Result Code		Collected at CRF
ENCRES	CHAR	Criterion Result		Collected at CRF
ENACTDY	NUM	Relative Actual Day of Enrollment		If ENACTDT and DMINFDT not missing then perform below logic to calculate relative day. If ENACTDT less than DMINFDT then (ENACTDT - DMINFDT). Else if ENACTDT is greater than equal to DMINFDT then (ENACTDT - DMINFDT) +1.

1.4.14. Exposure (EX) - EXPOSURE

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

Variable	Type	Label	Codes	Comments
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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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
EXSEQ	NUM	Exposure Sequence Number		Collected at CRF
EXGIVENA	NUM	Number of A Capsules Taken		Collected at CRF
EXGIVENB	NUM	Number of B Capsules Taken		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>

Variable	Type	Label	Codes	Comments
EXENDY	NUM	Relative End Day of Exposure		<p>If EXENDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If EXENDT less than DMINFDT then (EXENDT - DMINFDT). Else if EXENDT is greater than equal to DMINFDT then (EXENDT - DMINFDT) +1.</p>

1.4.15. Laboratory Data - Hematology (HL) - HEMAT

Dataset	HEMAT
Creating program	hemat.sas
Description	Laboratory Data - Hematology (HL)
Unique identifier	DUSUBJID, LBSEQ, LBVTYPE, LBTYPE, LBTEST, VISIT, LBTMLBL, LBACTTM
Sorted by	DUSUBJID, LBSEQ, LBVTYPE, LBTYPE, LBTEST, VISIT, LBTMLBL, LBACTTM
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>LBACTDT, LBPRVIDC, LBPRVID, LBREF, BATCHID</p>

Variable	Type	Label	Codes	Comments
STUDYID	CHAR	Study Id		Collected at CRF

Variable	Type	Label	Codes	Comments
DUSUBJID	CHAR	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	CHAR	Subject Number Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
LBTESTC	NUM	Lab Test Code		Collected at CRF
STDUNIT	CHAR	Standard Units		Collected at CRF
LBVTYPE	CHAR	Lab Visit Type		Collected at CRF
LBPTM	NUM	Planned Collection Time		Collected at CRF
LBTYPEC	NUM	Lab Type Code		Collected at CRF
LBCVRES	NUM	Result in Conventional Units		Collected at CRF
LBCVUNIT	CHAR	Conventional Units		Collected at CRF
LBACTTM	NUM	Actual Time of Lab Sample		Collected at CRF
ORGUNIT	CHAR	Original Units		Collected at CRF
LBVTYPEC	NUM	Lab Visit Type Code		Collected at CRF
LBTMLBL	CHAR	Pre-determined collection times		Collected at CRF
ORGRESN	NUM	Numeric lab result		Collected at CRF

Variable	Type	Label	Codes	Comments
ORGRES	CHAR	Character lab result		Collected at CRF
NRIND	CHAR	High/Low Lab Value Flag		Collected at CRF
ORGNRHI	NUM	Upper limit for the lab normal range		Collected at CRF
ORGNRLO	NUM	Lower limit for the lab normal range		Collected at CRF
STDNRLO	NUM	S.I. lower limit		Collected at CRF
STDRESN	NUM	S.I. numeric result		Collected at CRF
STDNRHI	NUM	S.I. upper limit		Collected at CRF
DLAGE	CHAR	De-identify Age: time of visit		Grouping element to protect subject PII.
LAGEUNIT	CHAR	Age Unit (M or Y)		Collected at CRF
LBSEQ	NUM	Unique record id within protocol		Collected at CRF
LBFASTC	NUM	Fasted Code		Collected at CRF
LBFAST	CHAR	Fasted		Collected at CRF
LBSIFACT	NUM	Std. Intl. Conversion Factor		Collected at CRF
LBTEST	CHAR	Lab Test Name		Collected at CRF
LBDESCR	CHAR	Full Test Description		Collected at CRF
LBTYPE	CHAR	Lab Type		Collected at CRF
LBABBR	CHAR	Lab Abbreviation		Collected at CRF
LBSIGLO	NUM	Significant Range Low		Collected at CRF
LBSIGHI	NUM	Significant Range High		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>

1.4.16. Hospitalization (HO) - HOSPITAL

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

Variable	Type	Label	Codes	Comments
STUDYID	CHAR	Study Id		Collected at CRF

Variable	Type	Label	Codes	Comments
DUSUBJID	CHAR	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	CHAR	Subject Number Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
HODISCHC	NUM	Was the Subject Discharged Code		Collected at CRF
HODISCH	CHAR	Was the Subject Discharged		Collected at CRF
HOSTDY	NUM	Relative Admission Day of Hosp.		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		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.

1.4.17. Intake (IT) - INTAKE

Dataset	INTAKE
Creating program	intake.sas
Description	Intake (IT)
Unique identifier	DUSUBJID, ITTYPE, ITACTTM, VISIT
Sorted by	DUSUBJID, ITTYPE, ITACTTM, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ACQREF, ITACTDT, ITPRVIDC, ITPRVID

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF

Variable	Type	Label	Codes	Comments
ITTYPE	CHAR	Intake Type		Collected at CRF
ITACTTM	NUM	Actual Time of Intake		Collected at CRF
ITACTDY	NUM	Relative Actual Day of Intake		If ITACTDT and DMINFDT not missing then perform below logic to calculate relative day. If ITACTDT less than DMINFDT then (ITACTDT - DMINFDT). Else if ITACTDT is greater than equal to DMINFDT then (ITACTDT - DMINFDT) +1.

1.4.18. Medication Kit (MK) - MEDKIT

Dataset	MEDKIT
Creating program	medkit.sas
Description	Medication Kit (MK)
Unique identifier	DUSUBJID, VISIT, DISPDY
Sorted by	DUSUBJID, VISIT, DISPDY

Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: KITNUM, DISPDT
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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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		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.

1.4.19. Positive And Negative Syndrome Scale - PANSS

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

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF

Variable	Type	Label	Codes	Comments
PAGNUM	NUM	Page Number		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	NUM	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>

1.4.20. PC Concentrations (PC) - PCCNC

Dataset	PCCNC
Creating program	pccnc.sas
Description	PC Concentrations (PC)
Unique identifier	DUSUBJID, PCSEQ, PCTEST, PCLOQ, TPTNUM, VISIT
Sorted by	DUSUBJID, PCSEQ, PCTEST, PCLOQ, TPTNUM, VISIT
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>PCSTDT, PCPRVIDC, PCPRVID, ACQREF, SPPRVIDC, SPPRVID, SAMREF, PCSPCOM, PCENDT, PCENTM, PCLBREF, PCCAT, PCREAS, PCRSOTH</p>

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF

Variable	Type	Label	Codes	Comments
PHASE	CHAR	Phase		Collected at CRF
TPT	CHAR	Planned Timepoint Name		Collected at CRF
TPTNUM	NUM	Planned Timepoint		Collected at CRF
PCSTTM	NUM	Start Time of Collection (24hr clock)		Collected at CRF
PCSPEC	CHAR	Specimen Material		Collected at CRF
SAMMAT	CHAR	Sample Material		Collected at CRF
PCSEQ	NUM	Sample Sequence Number		Collected at CRF
PCTEST	CHAR	Test Name		Collected at CRF
PCORRES	CHAR	Result in Original Units		Collected at CRF
PCORUNIT	CHAR	Original Unit		Collected at CRF
PCORRESN	NUM	Analysis numeric Result in Original Unit		Collected at CRF
PCSTRESC	CHAR	Character Result in Std Units		Collected at CRF
PCSTUNIT	CHAR	Standard Units		Collected at CRF
PCSTRESN	NUM	Analysis Numeric Result in Std Units		Collected at CRF
PCLOQ	CHAR	Limit of Quantification		Collected at CRF
PCPRMTYP	CHAR	Parameter Type		Collected at CRF
PCVTYPEC	NUM	PK/PD Sample Visit Type Code		Collected at CRF

Variable	Type	Label	Codes	Comments
PCVTYPE	CHAR	PK/PD Sample Visit Type		Collected at CRF
PCNRLO	NUM	Normal Range Lower Limit		Collected at CRF
PCNRHI	NUM	Normal Range Upper Limit		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
PCTAKENC	NUM	Was Sample Taken Code		Collected at CRF
PCTAKEN	CHAR	Was Sample Taken		Collected at CRF
PCSTDY	NUM	Relative Start Day of Speci. Collection		<p>If PCSTDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If PCSTDT less than DMINFDT then (PCSTDT - DMINFDT). Else if PCSTDT is greater than equal to DMINFDT then (PCSTDT - DMINFDT) +1.</p>

1.4.21. Physical Exam (PE) - PE

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

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF

Variable	Type	Label	Codes	Comments
PAGNUM	NUM	Page Number		Collected at CRF
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>

1.4.22. Protocol Deviation (PV) - PROTDEV

Dataset	PROTDEV
Creating program	protdev.sas
Description	Protocol Deviation (PV)
Unique identifier	DUSUBJID, PVSEQ
Sorted by	DUSUBJID, 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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID 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

1.4.23. Personal & Social Performance Scl (PS) - PSP

Dataset	PSP
Creating program	psp.sas
Description	Personal & Social Performance Scl (PS)
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PSRATERI, PSACTDT

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF

Variable	Type	Label	Codes	Comments
PSSCORE	NUM	PSP Score		Collected at CRF
PAGNUM	NUM	Page Number		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.

1.4.24. Psychiatric History (PY) - PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychiatric History (PY)
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: PYEPIDTC, PYEPIDT, PYDIAG, PYSTDT, PYSTDT, PYENDTC, PYENDT

Variable	Type	Label	Codes	Comments
STUDYID	CHAR	Study Id		Collected at CRF

Variable	Type	Label	Codes	Comments
DUSUBJID	CHAR	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	CHAR	Subject Number Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
PYSEQ	NUM	Psychiatric History Sequence Number		Collected at CRF
PYEPIDY	NUM	Relative Day of Last Acute Psycho. Symp.		If PYEPIDTC and DMINFDT not missing then perform below logic to calculate relative day. If PYEPIDTC less than DMINFDT then (PYEPIDTC - DMINFDT). Else if PYEPIDTC is greater than equal to DMINFDT then (PYEPIDTC - DMINFDT) +1.
PYSTDY	NUM	Relative Start Day of Psycho. Treatment		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.

Variable	Type	Label	Codes	Comments
PYENDY	NUM	Relative End Day of Psychosis Treatment		<p>If PYENDTC and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If PYENDTC less than DMINFDT then (PYENDTC - DMINFDT). Else if PYENDTC is greater than equal to DMINFDT then (PYENDTC - DMINFDT) +1.</p>

1.4.25. Randomization (RA) - RANDOM

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

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

Variable	Type	Label	Codes	Comments
DSUBJID	CHAR	Subject Number Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
RASEQ	NUM	Randomization Sequence Number		Collected at CRF
TRTGRPC	NUM	Treatment Group Code		Collected at CRF
TRTGRP	CHAR	Treatment Group		Collected at CRF
DOSE	CHAR	Dose		Collected at CRF
DRUG	CHAR	Drug		Collected at CRF
DURATION	CHAR	Duration		Collected at CRF
FORMULAT	CHAR	Formulation		Collected at CRF
FREQ	CHAR	Frequency		Collected at CRF
INSTRUCT	CHAR	Instructions		Collected at CRF
ROUTE	CHAR	Route		Collected at CRF
STRENGTH	CHAR	Strength		Collected at CRF

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

1.4.26. SARS (SR) - SARS

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

Variable	Type	Label	Codes	Comments
STUDYID	CHAR	Study Id		Collected at CRF

Variable	Type	Label	Codes	Comments
DUSUBJID	CHAR	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	CHAR	Subject Number Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF
SRVTYPEC	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	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. SQLS-R4 (SQ) - SQLSR4

Dataset	SQLSR4
Creating program	Sqlsr4.sas
Description	SQLS-R4 (SQ)
Unique identifier	DUSUBJID, SQSEQ, SQITEM, VISIT
Sorted by	DUSUBJID, SQSEQ, SQITEM, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SQACTDT

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF

Variable	Type	Label	Codes	Comments
PAGNUM	NUM	Page Number		Collected at CRF
SQSEQ	NUM	SQLSR4 Sequence Number		Collected at CRF
SQITEM	CHAR	SQLSR4 Item		Collected at CRF
SQSCOREC	NUM	Score Code		Collected at CRF
SQSCORE	CHAR	Score		Collected at CRF
SQACTDY	NUM	Relative Actual Day of SQLS-R4		<p>If SQACTDT and DMINFDT not missing then perform below logic to calculate relative day.</p> <p>If SQACTDT less than DMINFDT then (SQACTDT - DMINFDT). Else if SQACTDT is greater than equal to DMINFDT then (SQACTDT - DMINFDT) +1.</p>

1.4.28. Laboratory Data - Urinalysis (UR) - URINE

Dataset	URINE
Creating program	urine.sas
Description	Laboratory Data - Urinalysis (UR)
Unique identifier	DUSUBJID, LBSEQ, LBVTYPE, LBTYPE, LBTEST, VISIT, LBTMLBL, LBACTTM
Sorted by	DUSUBJID, LBSEQ, LBVTYPE, LBTYPE, LBTEST, VISIT, LBTMLBL, LBACTTM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LBACTDT, LBPRVIDC, LBPRVID, LBREF, BATCHID

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF

Variable	Type	Label	Codes	Comments
LBTESTC	NUM	Lab Test Code		Collected at CRF
STDUNIT	CHAR	Standard Units		Collected at CRF
LBVTYPE	CHAR	Lab Visit Type		Collected at CRF
LBPTM	NUM	Planned Collection Time		Collected at CRF
LBTYPES	NUM	Lab Type Code		Collected at CRF
LBCVRES	NUM	Result in Conventional Units		Collected at CRF
LBCVUNIT	CHAR	Conventional Units		Collected at CRF
LBACTTM	NUM	Actual Time of Lab Sample		Collected at CRF
ORGUNIT	CHAR	Original Units		Collected at CRF
LBVTYPEC	NUM	Lab Visit Type Code		Collected at CRF
LBTMLBL	CHAR	Pre-determined collection times		Collected at CRF
ORGRESN	NUM	Numeric lab result		Collected at CRF
ORGRES	CHAR	Character lab result		Collected at CRF
NRIND	CHAR	High/Low Lab Value Flag		Collected at CRF
ORGNRHI	NUM	Upper limit for the lab normal range		Collected at CRF
ORGNRLO	NUM	Lower limit for the lab normal range		Collected at CRF
STDNRLO	NUM	S.I. lower limit		Collected at CRF
STDRESN	NUM	S.I. numeric result		Collected at CRF

Variable	Type	Label	Codes	Comments
STDNRHI	NUM	S.I. upper limit		Collected at CRF
DLAGE	CHAR	De-identify Age: time of visit		Grouping element to protect subject PII.
LAGEUNIT	CHAR	Age Unit (M or Y)		Collected at CRF
LBSEQ	NUM	Unique record id within protocol		Collected at CRF
LBFASC	NUM	Fasted Code		Collected at CRF
LBFAS	CHAR	Fasted		Collected at CRF
LBSIFACT	NUM	Std. Intl. Conversion Factor		Collected at CRF
LBTEST	CHAR	Lab Test Name		Collected at CRF
LBDESCR	CHAR	Full Test Description		Collected at CRF
LBTYPE	CHAR	Lab Type		Collected at CRF
LBABBR	CHAR	Lab Abbreviation		Collected at CRF
LBSIGLO	NUM	Significant Range Low		Collected at CRF
LBSIGHI	NUM	Significant Range High		Collected at CRF
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>

1.4.29. Sleep VAS Scale Scores (VA) - VAS

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

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 ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF

Variable	Type	Label	Codes	Comments
PAGNUM	NUM	Page Number		Collected at CRF
VASCORE	NUM	VAS Score (mm)		Collected at CRF
VASCALE	CHAR	VAS Scale		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.

1.4.30. Visit (VI) - VISIT

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

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

Variable	Type	Label	Codes	Comments
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>

1.4.31. Vital Signs (VS) - VITAL

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

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

Variable	Type	Label	Codes	Comments
DSUBJID	CHAR	Subject Number Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	CHAR	Site Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITNUM	NUM	Visit Id		Collected at CRF
VISIT	CHAR	Visit		Collected at CRF
PHASENUM	NUM	Phase Number		Collected at CRF
PHASE	CHAR	Phase		Collected at CRF
VSSEQ	NUM	Vital Signs Sequence Number		Collected at CRF
PULSE	NUM	Pulse Rate (bpm)		Collected at CRF
TEMP	NUM	Temperature		Collected at CRF
TEMPUNIT	CHAR	Temperature Unit		Collected at CRF
SYSBP	NUM	Systolic Blood Pressure (mmHg)		Collected at CRF
DIABP	NUM	Diastolic Blood Pressure (mmHg)		Collected at CRF
VSVTYPEC	NUM	Vital Signs Visit Type Code		Collected at CRF
VSVTYPE	CHAR	Vital Signs Visit Type		Collected at CRF
VSPOS	CHAR	Position		Collected at CRF
DWEIGHT	CHAR	De-identify Weight		Grouping element to protect subject PII information.
VSWTUNIT	CHAR	Weight Unit		Collected at CRF
PAGNUM	NUM	Page Number		Collected at CRF

Variable	Type	Label	Codes	Comments
DHEIGHT	CHAR	De-identify Height		Grouping element to protect subject PII information.
VSHTUNIT	CHAR	Height 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.