Clinical Development

Paliperidon®

R074677-PSZ3002

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	08 JUN 2016

Table of contents

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
- Subject and center/site numbers will be assigned in a random manner so they are not matching the subject and center/site numbers that were used in the actual trial
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Remove the free text verbatim terms.
- Remove “Other” free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Central Lab Specimen Label Number will not be provided.
- Complete missing value variables will be removed.

- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's Relative day cannot be calculated.
- Reference number will not be provided.
- COMMENTS dataset will be submitted with zero observations.
- Dataset DNHIST, DNRSLT and DNSAMP containing Pharmacogenetic information will not be submitted.
- Dataset INVEST containing investigator information will not be submitted.
- SURGERY dataset contains sensitive information regarding surgery. Hence, will not be submitted.
- PROTDESC will not be submitted as it does not contain subject level information.
- Informed Consent Date will be used as Reference Date to derive relative days.
- There is an extra subject present in AE, DISPOSIT and VISIT datasets, but for this subject no demographic information is available. Hence, this subject will be dropped from the these datasets.

1.3. Data Files

The R076477-PSZ3002 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demographics
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: SUBJINIT, DMACTDT, DMSCRDT, IVID, IVNAME, BIRTHDT, MBIRTHDT, FBIRTHDT, DMINFDT, RACESPEC, COUNTRYC, ETHNSPEC, DMINFDT2, PUSUBJID

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

Variable	Type	Label	Codes	Comments
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.
SEXC	num	Sex Code		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACEC	num	Race Code		Collected at CRF.
RACE	char	Race		Collected at CRF.
DCOUNTRY	char	De-identify Country		Collected at CRF.
ETHNICC	num	Ethnicity Code		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
DMPREV	char	Did the subj. participate PSZ-3001 Char		Collected at CRF.
DMPREVC	num	Did the subj. participate PSZ-3001		Collected at CRF.
DMPROTID	char	Protocol followed		Collected at CRF.
AGE	char	Age in Years		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= int((DMINFDT – DOB)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.

Variable	Type	Label	Codes	Comments
MAGE	char	Mother's Age in Years		Mother's Date of birth collected but can not be submitted as per HIPAA rules hence deriving MAGE element derivation follows below rule: AGE= int((DMINFDT – DOB)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
FAGE	char	Father's Age in Years		Father's Date of birth collected but can not be submitted as per HIPAA rules hence deriving FAGE element derivation follows below rule: AGE= int((DMINFDT – DOB)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and DMINFDT not missing then perform below logic to calculate DMACTDY, If DMACTDT less than DMINFDT then (DMACTDT - DMINFDT). Else if DMACTDT is greater than equal to DMINFDT then (DMACTDT- DMINFDT) +1.
DMSCRDY	num	Relative Day of First Trial Rel Proc		If DMSCRDT and DMINFDT not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than DMINFDT then (DMSCRDT - DMINFDT). Else if DMSCRDT is greater than equal to DMINFDT then (DMSCRDT- DMINFDT) +1.

Variable	Type	Label	Codes	Comments
DMINF2DY	num	Relative Add Day of Sign. on Inf Consent		If DMINFDT2 and DMINFDT not missing then perform below logic to calculate DMINF2DY, If DMINFDT2 less than DMINFDT then (DMINFDT2 - DMINFDT). Else if DMINFDT2 is greater than equal to DMINFDT then (DMINFDT2- DMINFDT) +1.

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID, AEDECOD, AESEQ
Sorted by	DUSUBJID, AEDECOD, AESEQ
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: 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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
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.
AEACTTRC	num	Action Taken with Treatment Code		Collected at CRF.
AEACTTRT	char	Action Taken with Treatment		Collected at CRF.
AEOUTC	num	Outcome of Event Code		Collected at CRF.
AEOUT	char	Outcome of Event		Collected at CRF.
AERELC	num	Relationship to Treatment Code		Collected at CRF.
AEREL	char	Relationship to Treatment		Collected at CRF.
AESERC	num	Seriousness Criteria Code		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.
AESEVC	num	Severity of Event Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESEV	char	Severity of Event		Collected at CRF.
AECONTRC	num	Concomitant/Additional Treatment Code		Collected at CRF.
AECONTRT	char	Concomitant/Additional Treatment		Collected at CRF.
AESCONG	char	Congenital Anomaly or Birth Defect		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
AESDTH	char	Results in Death		Collected at CRF.
AEHOSPR	char	Hospitalization required		Collected at CRF.
AEHOSPP	char	Prolonged hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESMIE	char	Other Medicaly Important Serious Event		Collected at CRF.
AEDECOD1	char	Dictionary-Derived Lower Level Term		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEBODSYC	char	Body System or Organ Class Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and DMINFDT not missing then perform below logic to calculate AESTDY, If AESTDTC less than DMINFDT then (AESTDTC - DMINFDT). Else if AESTDTC is greater than equal to DMINFDT then (AESTDTC- DMINFDT) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and DMINFDT not missing then perform below logic to calculate AEENDY, If AEENDTC less than DMINFDT then (AEENDTC - DMINFDT). Else if AEENDTC is greater than equal to DMINFDT then (AEENDTC- DMINFDT) +1.

1.4.3. Abnormal Involuntary Movement Scale – AIMS

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

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

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

1.4.4. Barnes Akathisia Rating Scale – BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia Scale
Unique identifier	DUSUBJID, BAGROUP, BAITEM, VISIT
Sorted by	DUSUBJID, BAGROUP, BAITEM, 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 Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
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		If BAACTDT and DMINFDT not missing then perform below logic to calculate BAACTDY, If BAACTDT less than DMINFDT then (BAACTDT - DMINFDT). Else if BAACTDT is greater than equal to DMINFDT then (BAACTDT- DMINFDT) +1.

1.4.5. Children's Global Assessment Scale – CGAS

Dataset	CGAS
Creating program	cgas.sas
Description	Children's Global Assessment Scale
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: CARATERI, CAACTDT

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

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

1.4.6. Clinical Global Impression – CGI

Dataset	CGI
Creating program	cgi.sas
Description	Clinical Global Impression
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

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

1.4.7. Laboratory Results (Chemistry) – CHEM

Dataset	CHEM
Creating program	chem.sas
Description	Laboratory Results (Chemistry)
Unique identifier	DUSUBJID, LBDESCR, VISIT, LBSTAT
Sorted by	DUSUBJID, LBDESCR, VISIT, LBSTAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: LBPRVIDC, LBPRVID, ACCNUM, LBREF, LBACTDT, LBTMLBL, LBENDT, LBENTM, TSTCOM, STDNRC, LBSEQ, LBSIGHI, LBSIGLO, LBCVFACT, LBREASND

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

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	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	Original 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.
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.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, If LBACTDT less than DMINFDT then (LBACTDT - DMINFDT). Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1.

1.4.8. Basic Cognitive Testing – COGBAT

Dataset	COGBAT
Creating program	cogbat.sas
Description	Basic Cognitive Testing
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 or due to repetition of the information: SUBJINIT, CBACTDT, CBRATERI, GENDER

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

Variable	Type	Label	Codes	Comments
FTDR	num	Finger Tapping Dom Hand - Raw		Collected at CRF.
FTDS	num	Finger Tapping Dom Hand - Scaled		Collected at CRF.
FTNDR	num	Finger Tapping Non Dom Hand - Raw		Collected at CRF.
FTNDS	num	Finger Tapping Non Dom Hand - Scaled		Collected at CRF.
DSWW	char	WISC IV or WAIS III used for Digit Span		Collected at CRF.
DSR	num	Digit Span - Raw		Collected at CRF.
DSS	num	Digit Span - Scaled		Collected at CRF.
CVLTC	char	Calif Verb Learn Test - Child or Vers II		Collected at CRF.
CVLTTTR	num	Calif Verb Learn Test - Tot Trials, Raw		Collected at CRF.
CVLTTTS	num	Calif Verb Learn Test - Tot Trials, Scal		Collected at CRF.
CVLTT1R	num	Calif Verb Learn Test - Trial 1, Raw		Collected at CRF.
CVLTT1S	num	Calif Verb Learn Test - Trial 1, Scaled		Collected at CRF.
CVLTT5R	num	Calif Verb Learn Test - Trial 5, Raw		Collected at CRF.

Variable	Type	Label	Codes	Comments
CVLTT5S	num	Calif Verb Learn Test - Trial 5, Scaled		Collected at CRF.
CVLTBR	num	Calif Verb Learn Test - Trial B, Raw		Collected at CRF.
CVLTBS	num	Calif Verb Learn Test - Trial B, Scaled		Collected at CRF.
CVLTSDFR	num	Calif Verb Learn Test - S Del Fr Rec Raw		Collected at CRF.
CVLTSDFS	num	Calif Verb Learn Test - S Del Fr Rec Sca		Collected at CRF.
CVLTSDCR	num	Calif Verb Learn Test - S Del Cu Rec Raw		Collected at CRF.
CVLTSDCS	num	Calif Verb Learn Test - S Del Cu Rec Sca		Collected at CRF.
CVLTLDFR	num	Calif Verb Learn Test - L Del Fr Rec Raw		Collected at CRF.
CVLTLDFS	num	Calif Verb Learn Test - L Del Fr Rec Sca		Collected at CRF.
CVLTLDCR	num	Calif Verb Learn Test - L Del Cu Rec Raw		Collected at CRF.
CVLTLDCS	num	Calif Verb Learn Test - L Del Cu Rec Sca		Collected at CRF.
CVLTPR	num	Calif Verb Learn Test - Persev, Raw		Collected at CRF.

Variable	Type	Label	Codes	Comments
CVLTPS	num	Calif Verb Learn Test - Persev, Scaled		Collected at CRF.
CVLTHR	num	Calif Verb Learn Test - Hits, Raw		Collected at CRF.
CVLTHS	num	Calif Verb Learn Test - Hits, Scaled		Collected at CRF.
TOMT	num	Theory of Mind Total		Collected at CRF.
TOMFO	num	Theory of Mind First Order		Collected at CRF.
TOMSO	num	Theory of Mind Second Order		Collected at CRF.
TOMTO	num	Theory of Mind Third Order		Collected at CRF.
TOMR	num	Theory of Mind Reality		Collected at CRF.
TOMRE	num	Theory of Mind Reciprocity		Collected at CRF.
TOMD	num	Theory of Mind Deception		Collected at CRF.
TOMC	num	Theory of Mind Cheating		Collected at CRF.
CODINGR	num	Coding Raw		Collected at CRF.
CODINGS	num	Coding Scaled		Collected at CRF.
RCFTTR	num	Rey Complex Fig Test - Total Raw		Collected at CRF.
RCFTTS	num	Rey Complex Fig Test - Total Scaled		Collected at CRF.
RCFTCTR	num	Rey Complex Fig Test - Copy Time Raw		Collected at CRF.

Variable	Type	Label	Codes	Comments
RCFTCTS	num	Rey Complex Fig Test - Copy Time Scaled		Collected at CRF.
RCFTIR	num	Rey Complex Fig Test - Immed Rec Raw		Collected at CRF.
RCFTIS	num	Rey Complex Fig Test - Immed Rec Scaled		Collected at CRF.
RCFTDR	num	Rey Complex Fig Test - Del Rec Raw		Collected at CRF.
RCFTDS	num	Rey Complex Fig Test - Del Rec Scaled		Collected at CRF.
RCFTRR	num	Rey Complex Fig Test - Recognition Raw		Collected at CRF.
RCFTRS	num	Rey Complex Fig Test - Recognition Sca		Collected at CRF.
FASR	num	Phonetic Verbal Fluency - Raw		Collected at CRF.
FASS	num	Phonetic Verbal Fluency - Scaled		Collected at CRF.
ANIMALR	num	Semantic Verbal Fluency - Raw		Collected at CRF.
ANIMALS	num	Semantic Verbal Fluency - Scaled		Collected at CRF.
WRAMLSTR	num	Wide Range Ass of Mem and Learn Stor T R		Collected at CRF.
WRAMLSTS	num	Wide Range Ass of Mem and Learn Stor T S		Collected at CRF.

Variable	Type	Label	Codes	Comments
WRAMLDTR	num	Wide Range Ass of Mem and Learn Del T R		Collected at CRF.
WRAMLDTS	num	Wide Range Ass of Mem and Learn Del T S		Collected at CRF.
WRAMLRTR	num	Wide Range Ass of Mem and Learn Rec T R		Collected at CRF.
WRAMLRTS	num	Wide Range Ass of Mem and Learn Rec T S		Collected at CRF.
WCSTTER	num	Wisc Card Sort Test Tot Err - Raw		Collected at CRF.
WCSTTES	num	Wisc Card Sort Test Tot Err - Scaled		Collected at CRF.
WCSTPRR	num	Wisc Card Sort Test Persev Respons - Raw		Collected at CRF.
WCSTPRS	num	Wisc Card Sort Test Persev Respons - Sca		Collected at CRF.
WCSTPER	num	Wisc Card Sort Test Tot Persev Err - Raw		Collected at CRF.
WCSTPES	num	Wisc Card Sort Test Tot Persev Err - Sca		Collected at CRF.
WCSTNPER	num	Wisc Card Sort Test Tot n-Persev Err - R		Collected at CRF.
WCSTNPES	num	Wisc Card Sort Test Tot n-Persev Err - s		Collected at CRF.

Variable	Type	Label	Codes	Comments
WCSTTCR	num	Wisc Card Sort Test Tot Cat - Raw		Collected at CRF.
WCSTTCS	num	Wisc Card Sort Test Tot Cat - Scaled		Collected at CRF.
WCSTTR	num	Wisc Card Sort Test Tot Trials - Raw		Collected at CRF.
WCSTTS	num	Wisc Card Sort Test Tot Trials - Scaled		Collected at CRF.
TRIALATR	num	Trails Part A Time - Raw		Collected at CRF.
TRIALATS	num	Trails Part A Time - Scaled		Collected at CRF.
TRIALAER	num	Trails Part A Total Errors - Raw		Collected at CRF.
TRIALBTR	num	Trails Part B Time - Raw		Collected at CRF.
TRIALBTS	num	Trails Part B Time - Scaled		Collected at CRF.
TRIALBER	num	Trails Part B Total Errors - Raw		Collected at CRF.
CCT1TR	num	Child Color Trails Test 1 Time - Raw		Collected at CRF.
CCT1TS	num	Child Color Trails Test 1 Time - Scaled		Collected at CRF.
CCT1ER	num	Child Color Trails Test 1 Err - Raw		Collected at CRF.
IIT1R	num	Child Color Trails Test 1 Interf Ind - R		Collected at CRF.

Variable	Type	Label	Codes	Comments
IIT1S	num	Child Color Trails Test 1 Interf Ind - S		Collected at CRF.
CCT2TR	num	Child Color Trails Test 2 Time - Raw		Collected at CRF.
CCT2TS	num	Child Color Trails Test 2 Time - Scaled		Collected at CRF.
CCT2ER	num	Child Color Trails Test 2 Err - Raw		Collected at CRF.
IIT2R	num	Child Color Trails Test 2 Interf Ind - R		Collected at CRF.
IIT2S	num	Child Color Trails Test 2 Interf Ind - S		Collected at CRF.
CBACTDY	num	Relative Day of Assessment		If CBACTDT and DMINFDT not missing then perform below logic to calculate CBACTDY, If CBACTDT less than DMINFDT then (CBACTDT - DMINFDT). Else if CBACTDT is greater than equal to DMINFDT then (CBACTDT- DMINFDT) +1.

1.4.9. Comments – COMMENTS

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

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	Subject Number Assigned for De-identity		Empty data will be submitted.
DSITEID	char	Site Assigned for De-identity		Empty data will be submitted.
PHASENUM	num	Phase Number		Empty data will be submitted.
PHASE	char	Phase		Empty data will be submitted.
VISITNUM	num	Visit Number		Empty data will be submitted.
VISIT	char	Visit		Empty data will be submitted.
CTSEQ	num	Comment Sequence Number		Empty data will be submitted.

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

1.4.10. Concomitant Drug/Therapy – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant Meds
Unique identifier	DUSUBJID, CMDECOD, CMGROUP, CMSEQ
Sorted by	DUSUBJID, CMDECOD, CMGROUP, CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: CMTERM, CMREAS, CMSTDTC, CMSTDT, CMENDTC, CMENDT, CMCLASC, CMCLASC9, CMCLAS9, CMCLAS

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

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.
CMREGIM	char	Regimen (Dose + Frequency)		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.

Variable	Type	Label	Codes	Comments
AESEQ1	num	AE Sequence Number 1		Collected at CRF.
AESEQ2	num	AE Sequence Number 2		Collected at CRF.
CMPRIORC	num	Med Started Prior to Trial Code		Collected at CRF.
CMPRIOR	char	Med Started Prior to Trial		Collected at CRF.
CMCONTC	num	Medication Continuing Code		Collected at CRF.
CMCONT	char	Medication Continuing		Collected at CRF.
CMCLASC0	char	ATC Code 0		Collected at CRF.
CMCLASC1	char	ATC Code 1		Collected at CRF.
CMCLASC2	char	ATC Code 2		Collected at CRF.
CMCLASC3	char	ATC Code 3		Collected at CRF.
CMCLASC4	char	ATC Code 4		Collected at CRF.
CMCLASC5	char	ATC Code 5		Collected at CRF.
CMCLASC6	char	ATC Code 6		Collected at CRF.
CMCLASC7	char	ATC Code 7		Collected at CRF.
CMCLASC8	char	ATC Code 8		Collected at CRF.
CMCLAS0	char	ATC Text 0		Collected at CRF.
CMCLAS1	char	ATC Text 1		Collected at CRF.
CMCLAS2	char	ATC Text 2		Collected at CRF.
CMCLAS3	char	ATC Text 3		Collected at CRF.
CMCLAS4	char	ATC Text 4		Collected at CRF.

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

1.4.11. Columbia-Suicide Severity Rating Scale – CSSRS

Dataset	CSSRS
Creating program	cssrs.sas
Description	Columbia-Suicide Severity Rating Scale
Unique identifier	DUSUBJID, SCSCOR, VISIT
Sorted by	DUSUBJID, SCSCOR, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CSDT

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

Variable	Type	Label	Codes	Comments
SCSCOR	char	CSSRS score		Collected at CRF.
SCSCORC	num	CSSRS score code		Collected at CRF.
CSDY	num	Relative CSSRS day		If CSDT and DMINFDT not missing then perform below logic to calculate CSDY, If CSDT less than DMINFDT then (CSDT - DMINFDT). Else if CSDT is greater than equal to DMINFDT then (CSDT-DMINFDT) +1.

1.4.12. Schizophrenia Diagnosis – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Schizophrenia Diagnosis
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: DGACTDTC, DGACTDT, DGDT, SDIAGNC4, SDIAGN4, SDIAGNC5, SDIAGN5

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

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
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.
DGAGE	char	Age At First Diagnosis Of Schizophrenia		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
SDIAGNC1	num	Secondary Diagnosis Code 1		Collected at CRF.
SDIAGN1	char	Secondary Diagnosis 1		Collected at CRF.
SDIAGNC2	num	Secondary Diagnosis Code 2		Collected at CRF.
SDIAGN2	char	Secondary Diagnosis 2		Collected at CRF.
SDIAGNC3	num	Secondary Diagnosis Code 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
SDIAGN3	char	Secondary Diagnosis 3		Collected at CRF.
DGDY	num	Relative Day of Collection		If DGDT and DMINFDT not missing then perform below logic to calculate DGDY, If DGDT less than DMINFDT then (DGDT - DMINFDT). Else if DGDT is greater than equal to DMINFDT then (DGDT-DMINFDT) +1.

1.4.13. Diabetes Related History – DIAHIST

Dataset	DIAHIST
Creating program	diahist.sas
Description	Diabetes Related History
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 or due to missing values: 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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DHDIAG	char	Diagnosis		Collected at CRF.
DHHISTC	num	Diabetes History Code		Collected at CRF.
DHHIST	char	Diabetes History		Collected at CRF.
DHAGE	char	Age at Diagnosis		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DHACTDY	num	Relative Actual Day of Diabetes Rel Hist		If DHACTDT and DMINFDT not missing then perform below logic to calculate DHACTDY, If DHACTDT less than DMINFDT then (DHACTDT - DMINFDT). Else if DHACTDT is greater than equal to DMINFDT then (DHACTDT- DMINFDT) +1.

1.4.14. End Of Trial Information – DISPOSIT

Dataset	DISPOSIT
Creating program	disposit.sas
Description	End Of Trial Information
Unique identifier	DUSUBJID, DSTYPE, DSSTAT
Sorted by	DUSUBJID, DSTYPE, DSSTAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DSACTDT, PREGDUDT, DEATHDT, DSRSOTH

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

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

1.4.15. Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DUSUBJID, EGTESTCD, VISIT, EGSEQ
Sorted by	DUSUBJID, EGTESTCD, VISIT, EGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: EGREF, EGDT, EGPTM, EGPOS, EGPRVID, EGPRVIDC, EGND, EGCHG, EGCHGC, BATCHID, EGINTOTH, EGCHGOTH

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

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
EGTESTCD	char	ECG Test Short Name		Collected at CRF.
EGPTMNUM	num	Planned Time Point Number		Collected at CRF.
EGACTTM	num	Actual Time of ECG		Collected at CRF.
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.
EGSEQ	num	ECG Sequence Number		Collected at CRF.
EGREAD	char	ECG Reader		Collected at CRF.
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.

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

1.4.16. Exposure – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Exposure
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: EXSTDT, EXENDT

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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DOSE	num	Dose per Administration		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDT and DMINFDT not missing then perform below logic to calculate EXSTDY, If EXSTDT less than DMINFDT then (EXSTDT - DMINFDT). Else if EXSTDT is greater than equal to DMINFDT then (EXSTDT- DMINFDT) +1.
EXENDY	num	Relative End Day of Exposure		If EXENDT and DMINFDT not missing then perform below logic to calculate EXENDY, If EXENDT less than DMINFDT then (EXENDT - DMINFDT). Else if EXENDT is greater than equal to DMINFDT then (EXENDT- DMINFDT) +1.

1.4.17. Family History – FAMHIST

Dataset	FAMHIST
Creating program	famhist.sas
Description	Family History
Unique identifier	DUSUBJID, VISIT, FHDTYPE
Sorted by	DUSUBJID, VISIT, FHDTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: FHACTDT

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

Variable	Type	Label	Codes	Comments
FHMEM	char	Family Member		Collected at CRF.
FHDTYPE	char	Diabetes Types		Collected at CRF.
FHHIST	char	Relatives History of Diabetes		Collected at CRF.
FHHISTC	num	Relatives History of Diabetes Code		Collected at CRF.
FHACTDY	num	Relative Actual Day of Collection		If FHACTDT and DMINFDT not missing then perform below logic to calculate FHACTDY, If FHACTDT less than DMINFDT then (FHACTDT - DMINFDT). Else if FHACTDT is greater than equal to DMINFDT then (FHACTDT- DMINFDT) +1.

1.4.18. Habit – HABIT

Dataset	HABIT
Creating program	habit.sas
Description	Habit
Unique identifier	DUSUBJID, VISIT, HAACTDY
Sorted by	DUSUBJID, VISIT, HAACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: HAACTDT, HAENDT

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

Variable	Type	Label	Codes	Comments
HASMOCUC	num	Does Subject Currently Smoke Code		Collected at CRF.
HASMOCU	char	Does Subject Currently Smoke		Collected at CRF.
HACGTNUM	num	Number of Cigarettes		Collected at CRF.
HACGRNUM	num	Number of Cigars		Collected at CRF.
HAPIPNUM	num	Number of Pipes		Collected at CRF.
HASMOPSC	num	Has Subject Smoked in the Past Code		Collected at CRF.
HASMOPS	char	Has Subject Smoked in the Past		Collected at CRF.
HAYEAR	num	Number of Years Subject Has Smoked		Collected at CRF.
HACAFUSC	num	Does subject use caffeine products Code		Collected at CRF.
HACAFUS	char	Does subject use caffeine products		Collected at CRF.
HACOFNUM	num	Coffee		Collected at CRF.
HATEANUM	num	Tea		Collected at CRF.
HAENENUM	num	Energy Drinks		Collected at CRF.
HASOFNUM	num	Soft Drinks		Collected at CRF.

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

1.4.19. Laboratory Results (Hematology) – HEMAT

Dataset	HEMAT
Creating program	hemat.sas
Description	Laboratory Results (Hematology)
Unique identifier	DUSUBJID, LBTEST, VISIT, LBSTAT
Sorted by	DUSUBJID, LBDTEST, VISIT, LBSTAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: LBPRVIDC, LBPRVID, ACCNUM, LBREF, LBACTDT, LBTMLBL, LBENDT, LBENTM, TSTCOM, STDNRC, LBSEQ, LBSIGHI, LBSIGLO, LBCVFACT, LBREASND

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

Variable	Type	Label	Codes	Comments
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.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	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.

Variable	Type	Label	Codes	Comments
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.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGUNIT	char	Original 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.
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.

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

1.4.20. Inclusion/Exclusion Exceptions – IE

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

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

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IESPID	char	Sponsor-defined Identifier		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		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.

Variable	Type	Label	Codes	Comments
IEMET	char	Overall Criteria Met		Collected at CRF.
IEDY	num	Relative Day of Collection		If IEDT and DMINFDT not missing then perform below logic to calculate IEDY, If IEDT less than DMINFDT then (IEDT - DMINFDT). Else if IEDT is greater than equal to DMINFDT then (IEDT-DMINFDT) +1.

1.4.21. Kiddie-Sads-Present and Lifetime Version - KSADS

Dataset	KSADS
Creating program	ksads.sas
Description	Kiddie-Sads-Present and Lifetime Version
Unique identifier	DUSUBJID, KSGROUP, KSITEM
Sorted by	DUSUBJID, KSGROUP, KSITEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: KSACTDT

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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
KSGROUP	char	KSADS Group		Collected at CRF.
KSITEM	char	KSADS Item		Collected at CRF.
KSSCOREC	num	KSADS Score Code		Collected at CRF.
KSSCORE	char	KSADS Score		Collected at CRF.
KSACTDY	num	Relative Actual Day of KSADS		If KSACTDT and DMINFDT not missing then perform below logic to calculate KSACTDY, If KSACTDT less than DMINFDT then (KSACTDT - DMINFDT). Else if KSACTDT is greater than equal to DMINFDT then (KSACTDT- DMINFDT) +1.

1.4.22. Meas-Treat Res to Imp Cognition in Schiz - MATRICS

Dataset	MATRICS
Creating program	matrics.sas
Description	Meas-Treat Res to Imp Cognition in Schiz
Unique identifier	DUSUBJID, MTTEST, VISIT
Sorted by	DUSUBJID, MTTEST, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MTOTHER

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

Variable	Type	Label	Codes	Comments
MTTEST	char	Test		Collected at CRF.
MTDONEC	num	Have all tests of the MATRICS been done		Collected at CRF.
MTDONE	char	Have all tests of the MATRICS been done		Collected at CRF.
MTREASOC	num	Reason not performed code		Collected at CRF.
MTREASON	char	Reason not performed code		Collected at CRF.

1.4.23. Medical History – MEDHIST

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

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

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
MHSEQ	num	MH Sequence Number		Collected at CRF.
MHBODSYC	num	Body System Code		Collected at CRF.
MHBODSYS	char	Body System		Collected at CRF.
MHSTATC	num	Condition Code		Collected at CRF.
MHSTAT	char	Condition		Collected at CRF.
MHACTDY	num	Relative Actual Day of Collection		If MHACTDT and DMINFDT not missing then perform below logic to calculate MHACTDY, If MHACTDT less than DMINFDT then (MHACTDT - DMINFDT). Else if MHACTDT is greater than equal to DMINFDT then (MHACTDT- DMINFDT) +1.

1.4.24. Positive And Negative Syndrome Scale For Schizophrenia – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	Positive and Negative Syndrome Scale For Schizophrenia
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 Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

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

1.4.25. Physical Examination – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examination
Unique identifier	DUSUBJID, PEBODSYS, VISIT
Sorted by	DUSUBJID, PEBODSYS, VISIT
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
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

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

1.4.26. Protocol Deviation – PROTDEV

Dataset	PROTDEV
Creating program	protdev.sas
Description	Protocol Deviation
Unique identifier	DUSUBJID, PVDECOD, PVSEQ
Sorted by	DUSUBJID, PVDECOD, 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
PHASE	char	Phase		Collected at CRF.
PVSEQ	num	Protocol Deviation Seq Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

1.4.27. Psychotic History – PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychiatric History
Unique identifier	DUSUBJID, PYDIAG, PYSEQ
Sorted by	DUSUBJID, PYDIAG, PYSEQ
Notes	Below listed variables will be dropped from dataset due to repetition of the information: PYSTDTC, PYSTDT, PYENDTC, PYENDT, PYEPIDT

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

Variable	Type	Label	Codes	Comments
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.
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.
PYDIAG	char	Diagnosis		Collected at CRF.
PYSTDY	num	Relative Act Start Day of Psychosis Trt		If PYSTDTC and DMINFDT not missing then perform below logic to calculate PYSTDY, 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		If PYENDTC and DMINFDT not missing then perform below logic to calculate PYENDY, If PYENDTC less than DMINFDT then (PYENDTC - DMINFDT). Else if PYENDTC is greater than equal to DMINFDT then (PYENDTC- DMINFDT) +1.
PYEPIDY	num	Relative Day of Last Acute Psy Syndrome		If PYEPIDT and DMINFDT not missing then perform below logic to calculate PYEPIDY, If PYEPIDT less than DMINFDT then (PYEPIDT - DMINFDT). Else if PYEPIDT is greater than equal to DMINFDT then (PYEPIDT- DMINFDT) +1.

1.4.28. Simpson - Angus Scale – SARS

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

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

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

1.4.29. Sexual Maturity Rating(Tanner Staging)– TANSEX

Dataset	TANSEX
Creating program	tansex.sas
Description	Sexual Maturity Rating(Tanner Staging)
Unique identifier	DUSUBJID, TSTYPE, TSSTA, VISIT
Sorted by	DUSUBJID, TSTYPE, TSSTA, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TSACTDT

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

Variable	Type	Label	Codes	Comments
TSSEQ	num	Sequence number of set		Collected at CRF.
TSTYPEC	num	Type of Sexual Maturity Code		Collected at CRF.
TSTYPE	char	Type of Sexual Maturity		Collected at CRF.
TSSTANUM	num	Stage Number of Sexual Maturity		Collected at CRF.
TSSTA	char	Stage Number of Sexual Maturity		Collected at CRF.
TSSTAGE	char	Stage of Sexual Maturity		Collected at CRF.
TSACTDY	num	Relative Actual Day of Sexual Maturity		If TSACTDT and DMINFDT not missing then perform below logic to calculate TSACTDY, If TSACTDT less than DMINFDT then (TSACTDT - DMINFDT). Else if TSACTDT is greater than equal to DMINFDT then (TSACTDT- DMINFDT) +1.

1.4.30. Trial Inclusion/Exclusion Criteria –TI

Dataset	TI
Creating program	ti.sas
Description	Trial Inclusion/Exclusion Criteria
Unique identifier	IETESTCD
Sorted by	IETESTCD
Notes	

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

1.4.31. Laboratory Results (Urine) – URINE

Dataset	URINE
Creating program	urine.sas
Description	Laboratory Results (Urine)
Unique identifier	DUSUBJID, LBDESCR, LBSTAT, VISIT
Sorted by	DUSUBJID, LBDESCR, LBSTAT, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: LBPRVIDC, LBPRVID, ACCNUM, LBACTDT, LBTMLBL, LBENDT, LBENTM, TSTCOM, STDNRC, LBSEQ, LBSIGHI, LBSIGLO, LBCVFACT, LBREASND, LBREF

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

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	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	Original 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.
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.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, If LBACTDT less than DMINFDT then (LBACTDT - DMINFDT). Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1.

1.4.32. Sleep Vas Scale Scores – VAS

Dataset	VAS
Creating program	vas.sas
Description	Sleep VAS Scale Scores
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: VAACTDT

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

Variable	Type	Label	Codes	Comments
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 VAACTDY, If VAACTDT less than DMINFDT then (VAACTDT - DMINFDT). Else if VAACTDT is greater than equal to DMINFDT then (VAACTDT- DMINFDT) +1.

1.4.33. Visit – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit
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 Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
VISITDY	num	Relative Visit Day		If VISITDT and DMINFDT not missing then perform below logic to calculate VISITDY, If VISITDT less than DMINFDT then (VISITDT - DMINFDT). Else if VISITDT is greater than equal to DMINFDT then (VISITDT- DMINFDT) +1.

1.4.34. Vital Signs – VITAL

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

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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.
VSPOS	char	Position		Collected at CRF.
VSWEIGHT	num	Weight		Collected at CRF.
VSWTUNIT	char	Weight Unit		Collected at CRF.
VSHEIGHT	num	Height		Collected at CRF.
VSHTUNIT	char	Height Unit		Collected at CRF.
VSWAIST	num	Waist		Collected at CRF.
VSWSUNIT	char	Waist Unit		Collected at CRF.
PULSE	num	Pulse Rate (bpm)		Collected at CRF.
SYSBP	num	Systolic Blood Pressure (mmHg)		Collected at CRF.
DIABP	num	Diastolic Blood Pressure (mmHg)		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 VSACTDY, If VSACTDT less than DMINFDT then (VSACTDT - DMINFDT). Else if VSACTDT is greater than equal to DMINFDT then (VSACTDT- DMINFDT) +1.