Clinical Development

Paliperidone®

R076477SCH3020

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
- 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+).
- Subject and center numbers will be assigned in a random manner so they are not matching the subject and center numbers that were used in the actual trial
- Subjects with 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, Vial, Bottle, lot, kit or batch number will not be provided.
- Central Lab Specimen Label ID will not be provided.
- Lab Identifier information will not be provided (eg. LBNAM).
- Partial date’s relative day cannot be calculated.

- Rater's Initial or Patient's Initial will not be provided as it is sensitive. (eg. PARATERI)
- Patient's Initial will not be provided as it is sensitive. (eg. SUBJINIT)
- Dataset containing investigator information is sensitive and hence will not be submitted. (eg. INVEST)
- Dataset having no subject level information will not be submitted. (eg. PROTDESC)
- Dataset containing sensitive information about medication kit will not be submitted. (eg. MEDKIT)
- SURGERY dataset will not be submitted due to sensitivity of information.
- Comments dataset will be submitted with zero observation due to sensitivity of data.
- Completely missing values will not be submitted.
- Randomization Date will be used as Reference Date (REF.DATE) to derive relative days for randomized subjects and Informed Consent Date will be used as Reference Date (REF.DATE) to derive relative days for screen failure subjects.

1.3. Data Files

The R076477SCH3020 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, DMINFDT, RACEC, RACE, RACESPEC, COUNTRYC, ETHNICC, ETHNIC, ETHNSPEC

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

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SEXC	num	Sex Code		Collected at CRF.
SEX	char	Sex		Collected at CRF.
DCOUNTRY	char	De-Identify Country		Element will be grouped to protect PII.
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.
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and REF.DATE not missing then perform below logic to calculate DMACTDY, If DMACTDT less than REF.DATE then (DMACTDT - REF.DATE).Else if DMACTDT is greater than equal to REF.DATE then (DMACTDT- REF.DATE) +1.
DMSCRDY	num	Relative Day of First Trial Related Procedure		If DMSCRDT and REF.DATE not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than REF.DATE then (DMSCRDT - REF.DATE).Else if DMSCRDT is greater than equal to REF.DATE then (DMSCRDT- REF.DATE) +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: AETERM, AEMODIFY, AESTDT, AEENDT, AESTDTC, AEENDTC, AESERREF

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

Variable	Type	Label	Codes	Comments
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.
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.

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

1.4.3. Clinical Global Impression – CGI

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

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

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

1.4.4. Comments – COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CTTERM, CTACTDTC

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Empty Dataset will be submitted.
STUDYID	char	Study Id		Empty Dataset will be submitted.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Empty Dataset will be submitted.
DSITEID	char	Site Assigned for De-Identity		Empty Dataset will be submitted.
PHASENUM	num	Phase Number		Empty Dataset will be submitted.
PHASE	char	Phase		Empty Dataset will be submitted.
VISITNUM	num	Visit Number		Empty Dataset will be submitted.
VISIT	char	Visit		Empty Dataset will be submitted.
CTSEQ	num	Comment Sequence Number		Empty Dataset will be submitted.
DOMAIN	char	Domain of Origin		Empty Dataset will be submitted.
CTVISIT	char	Visit of Origin		Empty Dataset will be submitted.
CTACTDY	num	Relative Actual Day of Comment		Empty Dataset will be submitted.

1.4.5. Compliance – COMP

Dataset	COMP
Creating program	comp.sas
Description	Compliance
Unique identifier	DUSUBJID,PHASENUM,VISITNUM, COMP
Sorted by	DUSUBJID,PHASENUM,VISITNUM, COMP
Notes	

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

1.4.6. Concomitant Meds – 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 missing values: CMTERM, CMMODIFY, CMREGIM, CMREAS, CMSTDTC, CMSTDT, CMENDTC, CMENDT, CMCLASC, CMCLASC8, CMCLASC9, CMCLAS8, CMCLAS9, CMCLAS

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

Variable	Type	Label	Codes	Comments
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMGROUP	char	Medication Grouping		Collected at CRF.
CMREPRTC	num	Were Any Meds Administered Code		Collected at CRF.
CMREPRT	char	Were Any Meds Administered		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMDOSE	num	Dosage		Collected at CRF.
CMUNIT	char	Dose Unit		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMCAUSC	num	Given for AE Code		Collected at CRF.
CMCAUS	char	Given for AE		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AESEQ1	num	AE Sequence Number 1		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
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.
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.
CMCLAS5	char	ATC Text 5		Collected at CRF.
CMCLAS6	char	ATC Text 6		Collected at CRF.
CMCLAS7	char	ATC Text 7		Collected at CRF.
CMCODE	char	Medication Dictionary Code		Collected at CRF.
CMDECOD	char	Medication Generic Term		Collected at CRF.

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

1.4.7. Diagnosis – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis
Unique identifier	DUSUBJID, DGTYPE
Sorted by	DUSUBJID, DGTYPE
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

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

Variable	Type	Label	Codes	Comments
DIAGNOS	char	Diagnosis		Collected at CRF.
DGTYPEC	num	Schizophrenia Type Code		Collected at CRF.
DGTYPE	char	Schizophrenia Type		Collected at CRF.
DGCOURSC	num	Course code		Collected at CRF.
DGCOURSE	char	Course		Collected at CRF.
DGDY	num	Relative Day of Collection		If DGDT and REF.DATE not missing then perform below logic to calculate DGDY, If DGDT less than REF.DATE then (DGDT - REF.DATE).Else if DGDT is greater than equal to REF.DATE then (DGDT-REF.DATE) +1.

1.4.8. Disposition – DISPOSIT

Dataset	DISPOSIT
Creating program	disposit.sas
Description	Disposition
Unique identifier	DUSUBJID, VISITNUM
Sorted by	DUSUBJID, VISITNUM
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, DSRABKDT, DSRABKTM, DSRABKRS

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

Variable	Type	Label	Codes	Comments
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF.
DSTYPE	char	End of Treatment or Trial		Collected at CRF.
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF.
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF.
DSREASC	num	Reason for Withdrawal/Termination Code		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 of Trial Completion/Withdrawal		If DSACTDT and REF.DATE not missing then perform below logic to calculate DSACTDY, If DSACTDT less than REF.DATE then (DSACTDT - REF.DATE).Else if DSACTDT is greater than equal to REF.DATE then (DSACTDT- REF.DATE) +1.

1.4.9. 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, EXREASOT

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

Variable	Type	Label	Codes	Comments
DOSEUNIT	char	Dose Unit		Collected at CRF.
EXREASC	num	Reason for dose change code		Collected at CRF.
EXREAS	char	Reason for dose change		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDT and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDT less than REF.DATE then (EXSTDT - REF.DATE).Else if EXSTDT is greater than equal to REF.DATE then (EXSTDT- REF.DATE) +1.
EXENDY	num	Relative End Day of Exposure		If EXENDT and REF.DATE not missing then perform below logic to calculate EXENDY, If EXENDT less than REF.DATE then (EXENDT - REF.DATE).Else if EXENDT is greater than equal to REF.DATE then (EXENDT- REF.DATE) +1.

1.4.10. Hospitalization – HOSPITAL

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

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

Variable	Type	Label	Codes	Comments
HOONGO	char	Hospitalization Ongoing		Collected at CRF.
HOREASC	num	Reason for hospitalization Code		Collected at CRF.
HOREAS	char	Reason for hospitalization		Collected at CRF.
HOAESEQ	num	Adverse Event Sequence Number		Collected at CRF.
HOSTDY	num	Relative Admission Day of Hospitalization		If HOSTDTC and REF.DATE not missing then perform below logic to calculate HOSTDY, If HOSTDTC less than REF.DATE then (HOSTDTC - REF.DATE).Else if HOSTDTC is greater than equal to REF.DATE then (HOSTDTC- REF.DATE) +1.
HOENDY	num	Relative Discharge Day of Hospitalization		If HOENDTC and REF.DATE not missing then perform below logic to calculate HOENDY, If HOENDTC less than REF.DATE then (HOENDTC - REF.DATE).Else if HOENDTC is greater than equal to REF.DATE then (HOENDTC- REF.DATE) +1.

1.4.11. Inclusion/Exclusion Exceptions – IE

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

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

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

1.4.12. Laboratory Results – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Results
Unique identifier	DUSUBJID,LBSPID,LBCAT,LBTEST,LBDY,XBLNDFL, LBSEQ
Sorted by	DUSUBJID,LBSPID,LBCAT,LBTEST,LBDY,XBLNDFL, LBSEQ
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: XINVNAM, XSUBJIDL, XSUBJINT, XSEXC, XSEX, XBIRTHDT, XRACEC, XRACE, LBNUM, LBNAM, ACCNUM, LBREFID, LBDT, LBENDT, LBENTM, LBSPCCND, SPECCOM, SPECICOM, TSTCOM, XDELTFL, LBTOXGR, LBTOX

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

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTM	num	Time of Specimen Collection		Collected at CRF.
LBTPTNUM	num	Planned Time Point Number		Collected at CRF.
LBTPT	char	Planned Time Point Name		Collected at CRF.
LBSPEC	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	Fasting Status Code		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBCATC	num	Category for Lab Test Code		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSPID	num	Sponsor ID		Collected at CRF.
LBTESTCD	char	Lab Test or Examination Short Name		Collected at CRF.
LBTEST	char	Lab Test or Examination Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
XLBTEST	char	XLBTEST		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORRES	char	Result or Finding in Orig Unit		Collected at CRF.
LBORRESN	num	Numeric Result or Finding in Orig Unit		Collected at CRF.
LBORNRLO	num	Reference Range Lower Limit in Orig Unit		Collected at CRF.
LBORNRHI	num	Reference Range Upper Limit in Orig Unit		Collected at CRF.
LBORRESU	char	Original Units		Collected at CRF.
CNVRESC	char	Conventional Text Result		Collected at CRF.
CNVRESN	num	Conventional Numeric Result		Collected at CRF.
CNVNRLO	num	CNVNRLO		Collected at CRF.
CNVNRHI	num	CNVNRHI		Collected at CRF.
CNVU	char	CNVU		Collected at CRF.
LBSTRESC	char	Character Result/Finding in St. Format		Collected at CRF.
LBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
LBSTNRLO	num	Reference Range Lower Limit-Std Units		Collected at CRF.
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBSTRESU	char	Standard Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.

Variable	Type	Label	Codes	Comments
XEXCLFL	char	XEXCLFL		Collected at CRF.
XBLNDFL	char	XBLNDFL		Collected at CRF.
LBSEQ	num	Lbseq		Collected at CRF.
LBDY	num	Relative Day of Specimen Collection		If LBDT and REF.DATE not missing then perform below logic to calculate LBDY, If LBDT less than REF.DATE then (LBDT - REF.DATE).Else if LBDT is greater than equal to REF.DATE then (LBDT-REF.DATE) +1.

1.4.13. Laboratory Changes – LABREF

Dataset	LABREF
Creating program	labref.sas
Description	Laboratory Changes
Unique identifier	DUSUBJID,VISITNUM, LBRELCH
Sorted by	DUSUBJID,VISITNUM, LBRELCH
Notes	

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

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

1.4.14. Medical History – MEDHIST

Dataset	MEDHIST
Creating program	medhist.sas
Description	Medical History
Unique identifier	DUSUBJID,MHBODSYS, MHSEQ
Sorted by	DUSUBJID,MHBODSYS, MHSEQ
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
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSITEID	char	Site Assigned for De-Identity		Randomly assigned Site for De-Identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
MHSEQ	num	MH Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 REF.DATE not missing then perform below logic to calculate MHACTDY, If MHACTDT less than REF.DATE then (MHACTDT - REF.DATE).Else if MHACTDT is greater than equal to REF.DATE then (MHACTDT- REF.DATE) +1.

1.4.15. Medication Switch – MS

Dataset	MS
Creating program	ms.sas
Description	Medication Switch
Unique identifier	DUSUBJID,VISITNUM, MEDSWRC
Sorted by	DUSUBJID,VISITNUM, MEDSWRC
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDSWROT

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

Variable	Type	Label	Codes	Comments
MEDSWR	char	Medswitch Reason		Collected at CRF.
MEDSWMRC	num	Medswitch Main Reason Code		Collected at CRF.
MEDSWMR	char	Medswitch Main Reason		Collected at CRF.

1.4.16. Positive And Negative Syndrome Scale – PANSS

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

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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-Identity		Randomly assigned Site for De-Identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
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 REF.DATE not missing then perform below logic to calculate PAACTDY, If PAACTDT less than REF.DATE then (PAACTDT - REF.DATE).Else if PAACTDT is greater than equal to REF.DATE then (PAACTDT- REF.DATE) +1.

1.4.17. Physical Exam – PE

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

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

Variable	Type	Label	Codes	Comments
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 REF.DATE not missing then perform below logic to calculate PEACTDY, If PEACTDT less than REF.DATE then (PEACTDT - REF.DATE).Else if PEACTDT is greater than equal to REF.DATE then (PEACTDT- REF.DATE) +1.

1.4.18. Pregnancy – PREGNCY

Dataset	PREGNCY
Creating program	pregncy.sas
Description	Pregnancy
Unique identifier	DUSUBJID, VISITNUM
Sorted by	DUSUBJID, VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PGACTDT

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

Variable	Type	Label	Codes	Comments
PREGRES	char	Pregnancy Test Result		Collected at CRF.
PGACTDY	num	Relative Actual Day of Pregnancy Test		If PGACTDT and REF.DATE not missing then perform below logic to calculate PGACTDY, If PGACTDT less than REF.DATE then (PGACTDT - REF.DATE).Else if PGACTDT is greater than equal to REF.DATE then (PGACTDT- REF.DATE) +1.

1.4.19. 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
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity

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

1.4.20. Psychiatric History – PSYHIST

Dataset	PSYHIST
Creating program	psyhist.sas
Description	Psychiatric History
Unique identifier	DUSUBJID, PYHOSP
Sorted by	DUSUBJID, PYHOSP
Notes	

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

Variable	Type	Label	Codes	Comments
PYHOSPC	num	Hospitalizations for Psychosis Code		Collected at CRF.
PYHOSP	char	Hospitalizations for Psychosis		Collected at CRF.
PYHOSPTO	num	Total previous hospitalizations		Collected at CRF.
PYHOSPNM	num	Previous hospitalizations in past		Collected at CRF.
PYREPRTC	num	Hospitalized code		Collected at CRF.
PYREPRT	char	Hospitalized		Collected at CRF.

1.4.21. Quality of Sleep and Daytime Drowsiness – QSLEEP

Dataset	QSLEEP
Creating program	qsleep.sas
Description	Quality of Sleep and Daytime Drowsiness
Unique identifier	DUSUBJID, QSSLEEP
Sorted by	DUSUBJID, QSSLEEP
Notes	

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSITEID	char	Site Assigned for De-Identity		Randomly assigned Site for De-Identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
QSSLEEP	num	How well slept		Collected at CRF.
QSDROWS	num	How often felt drowsy		Collected at CRF.

1.4.22. Randomization – RANDOM

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

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

Variable	Type	Label	Codes	Comments
RASTR	char	Stratification		Collected at CRF.
RATRC	char	Treatment Code		Collected at CRF.
RATR	char	Treatment		Collected at CRF.

1.4.23. SF-36 Short Form Health Survey – SF-36

Dataset	SF-36
Creating program	sf36.sas
Description	SF-36 Short Form Health Survey
Unique identifier	DUSUBJID,VISITNUM,SFGROUP, SFITEM
Sorted by	DUSUBJID,VISITNUM,SFGROUP, SFITEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SFACTDT

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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-Identity		Randomly assigned Site for De-Identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SFGROUP	char	SF36 Group		Collected at CRF.
SFITEM	char	SF36 Item		Collected at CRF.
SFSCOREC	num	SF36 Score Code		Collected at CRF.
SFSCORE	char	SF36 Score		Collected at CRF.
SFACTDY	num	Relative Actual Day of SF36		If SFACTDT and REF.DATE not missing then perform below logic to calculate SFACTDY, If SFACTDT less than REF.DATE then (SFACTDT - REF.DATE).Else if SFACTDT is greater than equal to REF.DATE then (SFACTDT- REF.DATE) +1.

1.4.24. Trial Inclusion/Exclusion Criteria – TI

Dataset	TI
Creating program	ti.sas
Description	Trial Inclusion/Exclusion Criteria
Unique identifier	IECAT, IESPID
Sorted by	IECAT, IESPID
Notes	SUBJID

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.

1.4.25. Visit – VISIT

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

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

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

1.4.26. Vital Signs – VITAL

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

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

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSITEID	char	Site Assigned for De-Identity		Randomly assigned Site for De-Identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.
VSPOS	char	Position		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
DIABP	num	Diastolic Blood Pressure (mmHg)		Collected at CRF.
VSACTDY	num	Relative Actual Day of Vital Signs		If VSACTDT and REF.DATE not missing then perform below logic to calculate VSACTDY, If VSACTDT less than REF.DATE then (VSACTDT - REF.DATE).Else if VSACTDT is greater than equal to REF.DATE then (VSACTDT- REF.DATE) +1.