

Clinical Development

Risperidone

RIS-USA-232

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- REMARK dataset will be submitted with zero observation due to sensitivity of data.
- Datasets containing insignificant information will not be submitted. (e.g. TEMPLATE, MAP)
- TRLLIST dataset will not be submitted since it contain sensitive information, for example Medication number (MEDNO).
- Dataset containing investigator information is sensitive and hence will not be submitted. (e.g. INVEST).
- Empty dataset will not be submitted (e.g. ECGABN, LABNOR).
- Visit Date (VISIT_D) from VISIT dataset when Visit=1 will be used as Reference Date (referred as REF. DATE in the document) to derive relative days.

1.3. Data Files

The RIS-USA-232 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Subject Characteristics – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	Subject Characteristics
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INITIALS,INVEST,ZINVEST,BIRTH_D,INSTI_D,INSTI_M,INSTI_Y,MEDNO,RAND_D,RBIRTH_D,BREAK_D,BREAK_V,COINV,ZCOINV</p> <p>Below listed variables were not a part of the Raw dataset. These have been added to retain the Treatment related information in the de-identified datasets: RANDCODE (Source: TRLLIST dataset) DCOUNTRY (Source: INVEST dataset)</p>

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
DSITEID	num	SITE NO. ASSIGNED FOR DE-IDENTITY		Randomly assigned Site No. for De-identity

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
DEMAGE	char	ONSET OF SYMPTOMS OF DEMENTIA		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
PSYAGE	char	ONSET OF PSYCHOSIS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DNACONST	char	DNA INFORMED CONSENT BEEN OBTAINED?		Collected at CRF.
DNAANAL	char	OBTAINED FOR ANALYSIS		Collected at CRF.
DNASTOR	char	OBTAINED FOR STORAGE		Collected at CRF.
MMTOTAL	num	MMSE TOTAL SCORE		Collected at CRF.
BREAK	char	CODE BROKEN ?		Collected at CRF.
DEATHNA	char	EVENT OF DEATH		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
BATCHNO	num	BATCH NO.		Collected at CRF.
ECGNA	char	ECG DATA (NA)		Collected at CRF.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Element will be grouped to protect PII.
INSTI_DY	num	RELATIVE DAY CUR. INSTITUTIONALIZATION		If INSTI_DT and REF.DATE not missing then perform below logic to calculate INSTI_DY, If INSTI_DT less than REF.DATE then (INSTI_DT - REF.DATE). Else if INSTI_DT is greater than equal to REF.DATE then (INSTI_DT-REF.DATE)+1.
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((REF.DATE – BIRTH_D)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
RAND_DY	num	RELATIVE RANDOMISATION DAY		If RAND_D and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_D less than REF.DATE then (RAND_D - REF.DATE). Else if RAND_D is greater than equal to REF.DATE then (RAND_D- REF.DATE)+1.

1.4.2. Administration of Trial Medication – ADMMED

Dataset	ADMED
Creating program	admmed.sas
Description	Administration of Trial Medication
Unique identifier	DCRFID, PHASE, AMFROMDY, SEGMENT
Sorted by	DCRFID, PHASE, AMFROMDY, SEGMENT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AMFROM_D, AMTO_D, NUMFORM, BOX, AMFREQ, AMDOSE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	SEGMENT		Collected at CRF.
NUMFORM1	num	UNITS PER ADMIN. (AM)		Collected at CRF.
NUMFORM2	num	UNITS PER ADMIN. (AM)		Collected at CRF.
NUMFORM3	num	UNITS PER ADMIN. (PM)		Collected at CRF.
NUMFORM4	num	UNITS PER ADMIN. (PM)		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
ZAMREAS	char	REGIMEN CHANGE REASON CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
AMDOSE_U	char	DOSE UNIT		Collected at CRF.
AMFROMDY	num	RELATIVE ADMIN. FROM DAY		If AMFROM_D and REF.DATE not missing then perform below logic to calculate AMFROMDY, If AMFROM_D less than REF.DATE then (AMFROM_D - REF.DATE). Else if AMFROM_D is greater than equal to REF.DATE then (AMFROM_D-REF.DATE) +1.
AMTO_DY	num	RELATIVE ADMIN. TO DAY		If AMTO_D and REF.DATE not missing then perform below logic to calculate AMTO_DY, If AMTO_D less than REF.DATE then (AMTO_D - REF.DATE). Else if AMTO_D is greater than equal to REF.DATE then (AMTO_D- REF.DATE) +1.

1.4.3. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DCRFID, AEPREF, AESEQNO
Sorted by	DCRFID, AEPREF, AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AE_V, AEFROM_D, AETO_D, SAEREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
AESEQNO	num	AE SEQ.		Collected at CRF.
AEINCL	char	AE INCLUDED TERM		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
AEFROM_C	char	AE FROM CODE		Collected at CRF.
AETO_C	char	AE TO CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESV	num	AE SEVERITY CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AECONRX	char	AE CO-RX START		Collected at CRF.
ZAECNRX	num	AE CO-RX START CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION CODE		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME CODE		Collected at CRF.
AESER	char	AE SERIOUSNESS		Collected at CRF.
ZAESER	num	AE SERIOUSNESS CODE		Collected at CRF.
AESOC	char	AE SYSTEM ORGAN CLASS		Collected at CRF.
AEWHONUM	char	AE WHO CODE		Collected at CRF.
AEPREF	char	ADVERSE EVENT PREFERRED TERM		Collected at CRF.
AESOC1	char	AE SYSTEM ORGAN CLASS 1		Collected at CRF.
AESOC2	char	AE SYSTEM ORGAN CLASS 2		Collected at CRF.
AESOC3	char	AE SYSTEM ORGAN CLASS 3		Collected at CRF.
AEFROMDY	num	RELATIVE AE FROM DAY		If AEFROM_D and REF.DATE not missing then perform below logic to calculate AEFROMDY, If AEFROM_D less than REF.DATE then (AEFROM_D - REF.DATE). Else if AEFROM_D is greater than equal to REF.DATE then (AEFROM_D - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
AETO_DY	num	RELATIVE AE TO DAY		If AETO_D and REF.DATE not missing then perform below logic to calculate AETO_DY, If AETO_D less than REF.DATE then (AETO_D - REF.DATE). Else if AETO_D is greater than equal to REF.DATE then (AETO_D- REF.DATE) +1.

1.4.4. Abnormal Involuntary Movement Scale – AIMS

Dataset	AIMS
Creating program	aims.sas
Description	Abnormal Involuntary Movement Scale
Unique identifier	DCRFID,AIGROUP,AIITEM,VISIT
Sorted by	DCRFID,AIGROUP,AIITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
AIGROUP	char	GROUP		Collected at CRF.
AIITEM	char	AIMS ITEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
AISCORE	char	AIMS SCORE		Collected at CRF.
ZAISCORE	num	AIMS SCORE CODE		Collected at CRF.

1.4.5. Behavioural Pathology in Alzheimers – BEHAVE

Dataset	BEHAVE
Creating program	behave.sas
Description	Behavioural Pathology in Alzheimers
Unique identifier	DCRFID,BEGROUP,BEITEM,VISIT
Sorted by	DCRFID,BEGROUP,BEITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
BEGROUP	char	BEHAVE SUBGROUP		Collected at CRF.
BEITEM	char	BEHAVE ITEM		Collected at CRF.
BESCORE	char	BEHAVE SCORE		Collected at CRF.
ZBESCORE	num	BEHAVE SCORE CODE		Collected at CRF.

1.4.6.Acute Cerebral Vascular Event – CERVAS

Dataset	CERVAS
Creating program	cervas.sas
Description	Acute Cerebral Vascular Event
Unique identifier	DCRFID,CVTYPE,CVITEM
Sorted by	DCRFID,CVTYPE,CVITEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AEFROM_D,CVTYPE_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
AESEQNO	num	AE SEQUENCE NUMBER		Collected at CRF.
CVSEQ	num	SEQUENCE NUMBER		Collected at CRF.
CVTYPE	char	TYPE		Collected at CRF.
CVITEM	char	CHARACTERISTIC		Collected at CRF.
CVCHANGE	char	UNCHANGED		Collected at CRF.
CVDIAG	char	PROBABLE/POSSIBLE		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEFROMDY	num	RELATIVE DAY OF EVENT		If AEFROM_D and REF.DATE not missing then perform below logic to calculate CVEFRMDY, If AEFROM_D less than REF.DATE then (AEFROM_D - REF.DATE). Else if AEFROM_D is greater than equal to REF.DATE then (AEFROM_D - REF.DATE) +1.
CVTYPEDY	num	RELATIVE DAY OF FINDING/RESOLVING		If CVTYPE_D and REF.DATE not missing then perform below logic to calculate CVTYPEDY, If CVTYPE_D less than REF.DATE then (CVTYPE_D - REF.DATE). Else if CVTYPE_D is greater than equal to REF.DATE then (CVTYPE_D - REF.DATE) +1.

1.4.7.Dictionary Version Control – CODE

Dataset	CODE
Creating program	code.sas
Description	Dictionary Version Control
Unique identifier	TRIAL
Sorted by	TRIAL
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
CODELIST	char	CODELIST		Collected at CRF.
VALID_D	num	VALID DATE		Collected at CRF.

1.4.8. Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,CTTYPE,RXPREF,CTSEQNO
Sorted by	DCRFID,CTTYPE,RXPREF,CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CONRX_V,CTSCHED,CTIND_V,CTFROM_D,CTFROM_C,CTTO_D,ATCCODE9,ATCTEXT9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.
CTIND	char	INDICATION		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
CTTO_C	char	CO-RX END CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCCODE3	char	ATC CODE 3		Collected at CRF.
ATCCODE4	char	ATC CODE 4		Collected at CRF.
ATCCODE5	char	ATC CODE 5		Collected at CRF.
ATCCODE6	char	ATC CODE 6		Collected at CRF.
ATCCODE7	char	ATC CODE 7		Collected at CRF.
ATCCODE8	char	ATC CODE 8		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
ATCTEXT1	char	ATC TEXT 1		Collected at CRF.
ATCTEXT2	char	ATC TEXT 2		Collected at CRF.
ATCTEXT3	char	ATC TEXT 3		Collected at CRF.
ATCTEXT4	char	ATC TEXT 4		Collected at CRF.
ATCTEXT5	char	ATC TEXT 5		Collected at CRF.
ATCTEXT6	char	ATC TEXT 6		Collected at CRF.
ATCTEXT7	char	ATC TEXT 7		Collected at CRF.
ATCTEXT8	char	ATC TEXT 8		Collected at CRF.
RXPREF	char	PREFERRED NAME		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTFROMDY	num	RELATIVE CO-RXSTART DAY		If CTFROM_D and REF.DATE not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than REF.DATE then (CTFROM_D - REF.DATE). Else if CTFROM_D is greater than equal to REF.DATE then (CTFROM_D- REF.DATE) +1.
CTTO_DY	num	RELATIVE CO-RXEND DAY		If CTTO_D and REF.DATE not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than REF.DATE then (CTTO_D - REF.DATE). Else if CTTO_D is greater than equal to REF.DATE then (CTTO_D- REF.DATE) +1.

1.4.9. Death Report – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death Report
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DEATH_D,DTREAS_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
DTREAS	char	DEATH CAUSE		Collected at CRF.
DEATH_DY	num	RELATIVE DEATH DAY		If DEATH_D and REF.DATE not missing then perform below logic to calculate DEATH_DY, If DEATH_D less than REF.DATE then (DEATH_D - REF.DATE). Else if DEATH_D is greater than equal to REF.DATE then (DEATH_D - REF.DATE) +1.

1.4.10. Deviation – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	Deviation
Unique identifier	DCRFID,DVTYPE,DEVIAT,ZDEVIAT
Sorted by	DCRFID,DVTYPE,DEVIAT,ZDEVIAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DEVIAT_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
DVTYPE	char	TYPE OF DEVIATION		Collected at CRF.
DEVIAT	char	DEVIATION		Collected at CRF.
ZDEVIAT	char	DEVIATION CODE		Collected at CRF.

1.4.11. Diagnosis – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis
Unique identifier	DCRFID,DIAGN
Sorted by	DCRFID,DIAGN
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
DSMIV	char	DSM-IV DIAGNOSIS		Collected at CRF.
DIAGN	char	DIAGNOSIS		Collected at CRF.
STAGE	char	STAGE		Collected at CRF.
DIAGNC	num	DIAGNOSISCODE		Collected at CRF.

1.4.12. Previous and Concomitant Diseases – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Previous and Concomitant Diseases
Unique identifier	DCRFID, DSSYSTEM, DSCOND, DSSEQNO
Sorted by	DCRFID, DSSYSTEM, DSCOND, DSSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DISEAS_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
DSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.
DISEASE	char	DISEASE		Collected at CRF.

1.4.13. Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DCRFID,VISIT,ECG_DY,ECG_T
Sorted by	DCRFID,VISIT,ECG_DY,ECG_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ECG_D,EGLIMITS,EGRELCHA, ECGINTNO ,ECGREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
LEADQT	char	LEAD QT		Collected at CRF.
EGRESULT	char	ECG RESULT		Collected at CRF.
ECG_T	char	ECG_T		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGTYPE	char	TYPE OF ECG		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE)+1.

1.4.14. Electrocardiogram Evaluation – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	Electrocardiogram Evaluation
Unique identifier	DCRFID,VISIT,EEASPECT,EEEVAL,ECG_DY,ECG_T
Sorted by	DCRFID,VISIT,EEASPECT,EEEVAL, ECG_DY,ECG_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EEASPECT	char	ECG ASPECT		Collected at CRF.
EEEVAL	char	ECG EVALUATION		Collected at CRF.
ECG_T	num	ECG TIME		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE)+1.

1.4.15. Electrocardiogram Evaluation Measurements – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	Electrocardiogram Evaluation Measurements
Unique identifier	DCRFID, ECGPAR, VISIT, ECG_DY, ECG_T
Sorted by	DCRFID, ECGPAR, VISIT, ECG_DY, ECG_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
ECGPAR	char	ECG PARAMETER		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EPSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.
ECGPAR_U	char	ECG MEASUREMENT UNIT		Collected at CRF.
ECGVAL_V	char	ECG MEASUREMENT (VERB.)		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECG_T	num	ECG TIME		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE)+1.

1.4.16. Electrocardiogram (ER)– ECGREF

Dataset	ECGREF
Creating program	ecgref.sas
Description	Electrocardiogram (ER)
Unique identifier	DCRFID,ECGTYPE,VISIT
Sorted by	DCRFID,ECGTYPE,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ECG_D,EGLIMITS

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGTYPE	char	TYPE OF ECG		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
EGRELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE)+1.

1.4.17. Inclusion-Exclusion Criteria – INEX

Dataset	INEX
Creating program	inex.sas
Description	Inclusion-Exclusion Criteria
Unique identifier	DCRFID,IETYPE,ZIECRIT
Sorted by	DCRFID,IETYPE,ZIECRIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity

Variable	Type	Label	Codes	Comments
IETYPE	char	TYPE OF INCLUSION CRITERIA		Collected at CRF.
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	num	SELECTION CRITERIA CODE		Collected at CRF.
IEYN	char	NON-ELIGIBILITY EXPR.		Collected at CRF.

1.4.18. Modified Jeste and Finkel – JESFIN

Dataset	JESFIN
Creating program	jesfin.sas
Description	Modified Jeste and Finkel
Unique identifier	DCRFID,JESITEM
Sorted by	DCRFID,JESITEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
SEQNO	num	SEQUENCE NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
JESITEM	char	MODIFIED JESTE AND FINKEL		Collected at CRF.
JESSCORE	char	MODIFIED JESTE AND FINKEL SCORE		Collected at CRF.

1.4.19. Laboratory Results – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	Laboratory Results
Unique identifier	DCRFID, LABTEST, LABTSTNO, LABVAL, SAMPLEDY
Sorted by	DCRFID, LABTEST, LABTSTNO, LABVAL, SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D, LABID, ZLABID, SAMREFNO, LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.
LABUPP	num	UPPER NORMAL LIMIT		Collected at CRF.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
LOWPATHO	num	LOWER PATHOLOGICAL LIMIT		Collected at CRF.
UPPPATHO	num	UPPER PATHOLOGICAL LIMIT		Collected at CRF.
CFACTOR	num	CONVERSION FACTOR		Collected at CRF.
SIUNIT	char	STANDARD INTERNATIONAL UNIT		Collected at CRF.
LABTSTNO	num	LAB. TEST NUMBER		Collected at CRF.
LABCLASS	char	LAB CLASS		Collected at CRF.
ENZYME	char	ENZYME		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D - REF.DATE) +1.

1.4.20. Laboratory Urine Results – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	Laboratory Urine Results
Unique identifier	DCRFID,ZLABTEST,SAMPLEDY
Sorted by	DCRFID,ZLABTEST,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D,LABID,ZLABID,SAMREFNO,LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LUVAL	char	URINE VALUE		Collected at CRF.
LUVAL_V	char	URINE VALUE (VERB.)		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTSTNO	num	LAB. TEST NUMBER		Collected at CRF.
LABCLASS	char	LAB CLASS		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D - REF.DATE) +1.

1.4.21. Mini-Mental State Examination – MMSE

Dataset	MMSE
Creating program	mmse.sas
Description	Mini-Mental State Examination
Unique identifier	DCRFID,MMITEM
Sorted by	DCRFID,MMITEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
MMITEM	char	MMSE ITEM		Collected at CRF.
MMSCORE	num	MMSE SCORE		Collected at CRF.

1.4.22. Physical Examination – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	Physical Examination
Unique identifier	DCRFID,VISIT,PESYSTEM,PESEQNO
Sorted by	DCRFID,VISIT,PESYSTEM,PESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXAM_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
PESEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.
EXAM	char	PHYS. EXAM.		Collected at CRF.

1.4.23. Randomisation Group for Each Subjchar – RANDGRP

Dataset	RANDGRP
Creating program	randgrp.sas
Description	Randomisation Group for Each Subjchar
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.

1.4.24. Related AES for Termination or Death – RELAE

Dataset	RELAE
Creating program	relae.sas
Description	Related AES for Termination or Death
Unique identifier	DCRFID,RATYPE,AESEQNO
Sorted by	DCRFID,RATYPE,AESEQNO
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
RATYPE	char	AE CONSEQUENCE		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.

1.4.25. Remarks and Comments – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	Remarks and Comments
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Remark dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Empty dataset will be submitted
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Empty dataset will be submitted
RMSEQNO	num	SEQUENCE NUMBER		Empty dataset will be submitted
RMTYPE	char	REMARKTYPE		Empty dataset will be submitted

1.4.26. Vascular Risk Factor – RISKFACT

Dataset	RISKFACT
Creating program	riskfact.sas
Description	Vascular Risk Factor
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RFHPSTRY,RFISCODY,RFVLHTDY,RFATFIBY,RFLPSTY,RFDBSTY,RFTIASTY,RFASH

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
RFHYPER	char	HYPERTENSION?		Collected at CRF.
RFISCOD	char	ISCHEMICCORONARY DISEASE?		Collected at CRF.
RFVLHTD	char	VALVULAR HEART DISEASE?		Collected at CRF.
RFATFIB	char	ATRIAL FIBRILLATION?		Collected at CRF.
RFPRVAD	char	PERIFERAL VASCULAR DISEASE?		Collected at CRF.
RFSMOK	char	SMOKING?		Collected at CRF.
RFSMOKPK	num	NUMBER OF PACK		Collected at CRF.
RFALCH	char	ALCOHOL ABUSE?		Collected at CRF.

Variable	Type	Label	Codes	Comments
RFALCCUR	char	CURRENTLY USE ALCOHOL?		Collected at CRF.
RFLIPID	char	HYPERCHOLESTEROLEMIA?		Collected at CRF.
RFDIAB	char	DIABETESMELLITUS?		Collected at CRF.
RFTIA	char	TIA?		Collected at CRF.
RFSTROK	char	STROKES?		Collected at CRF.
RFSTRNUM	num	NUMBER OF STROKES		Collected at CRF.
RFISCHEM	char	ISCHEMICSTROKE		Collected at CRF.
RFINTHM	char	INTRACEREBRALHEMORRHAGE		Collected at CRF.
RFUNKNOW	char	UNKNOWN		Collected at CRF.

1.4.27. Samples – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	Samples
Unique identifier	DCRFID,SPECIMEN,VISIT,SAMPLEDY
Sorted by	DCRFID,SPECIMEN,VISIT,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,LABID,ZLABID,FASTED,SAMREFNO,SASAME,LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		Collected at CRF.
SARELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D - REF.DATE) +1.

1.4.28. Sample Requisition Numbers – SAMREF

Dataset	SAMREF
Creating program	samref.sas
Description	Sample Requisition Numbers
Unique identifier	DCRFID,VISIT
Sorted by	DCRFID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LABID,ZLABID,SAMREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
SARELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

1.4.29. Simpson and Angus Rating Scale – SARS

Dataset	SARS
Creating program	sars.sas
Description	Simpson and Angus Rating Scale
Unique identifier	DCRFID,VISIT,SAITEM
Sorted by	DCRFID,VISIT,SAITEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
SASCORE	char	SIMPSON AND ANGUS SCORE		Collected at CRF.
ZSASCORE	num	SIMPSON AND ANGUS SCORE CODE		Collected at CRF.
SAITEM	char	SIMPSON AND ANGUS ITEM		Collected at CRF.

1.4.30. Trial Description – TRLDDESC

Dataset	TRLDESC
Creating program	trldesc.sas
Description	Trial Description
Unique identifier	TRIAL
Sorted by	TRIAL
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
COMPOND	char	COMPOUND NAME		Collected at CRF.
ZCOMPOND	char	COMPOUND NAME CODE		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.
PLACONTR	char	PLACEBO CONTROL		Collected at CRF.
ACTCONTR	char	ACTIVE CONTROL		Collected at CRF.
DESIGN	char	DESIGN		Collected at CRF.
MULTCENT	char	MULTICENTRE		Collected at CRF.
INDICAT	char	INDICATION		Collected at CRF.
AGEGRP	char	AGE GROUP		Collected at CRF.
SPECPOP	char	SPECIAL POPULATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.

1.4.31. Randomization Groups – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	Randomization Groups
Unique identifier	TRIAL,RANDGRP,RANDCODE
Sorted by	TRIAL,RANDGRP,RANDCODE
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.

1.4.32. Trial Medication Regiments – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	Trial Medication Regiments
Unique identifier	TRIAL,RANDGRP,PHASE,SEGMENT,BOX
Sorted by	TRIAL,RANDGRP,PHASE,SEGMENT,BOX
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	SEGMENT		Collected at CRF.
BOX	char	BOX		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.
FORMULAT	char	FORMULATION		Collected at CRF.
STRENGTH	num	STRENGTH OF 1 UNIT		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
TMFREQ	char	ADMIN. FREQ.		Collected at CRF.
TMROUTE	char	ADMIN. ROUTE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZTMROUTE	char	ADMIN. ROUTE CODE		Collected at CRF.
TMDUR	num	SEGMENT DURATION		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

1.4.33. Treatment / Trial Termination – TRTERM

Dataset	TRTERM
Creating program	trterm.sas
Description	Treatment / Trial Termination
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TRREAS_V, TRFROM_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRTYPE	char	TYPE OF TERMINATION		Collected at CRF.
TRSTATE	char	STATE OF TERMINATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRREAS	char	TERM. REASON		Collected at CRF.
TRFROMDY	num	RELATIVE LAST CONTACT DAY		If TRFROM_D and REF.DATE not missing then perform below logic to calculate TRFROMDY, If TRFROM_D less than REF.DATE then (TRFROM_D - REF.DATE). Else if TRFROM_D is greater than equal to REF.DATE then (TRFROM_D- REF.DATE) +1.

1.4.34. Visits – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visits
Unique identifier	DCRFID,VISIT
Sorted by	DCRFID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_D,BEHAVE_D,BEINIT

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABNA	char	LABORATORY DATA (NA)		Collected at CRF.
CGI	char	CLINICAL GLOBAL IMPRESSION		Collected at CRF.
CGICHA	char	CLINICAL GLOBAL IMPRESSION CHANGE		Collected at CRF.
BEHAVE	char	SUBJECT SCORE A 2 IN AT LEAST 1 ?		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and REF.DATE not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than REF.DATE then (VISIT_D - REF.DATE). Else if VISIT_D is greater than equal to REF.DATE then (VISIT_D - REF.DATE) +1.
BEHAVEDY	num	RELATIVE BEHAVE-AD DAY		If BEHAVE_D and REF.DATE not missing then perform below logic to calculate BEHAVEDY, If BEHAVE_D less than REF.DATE then (BEHAVE_D - REF.DATE). Else if BEHAVE_D is greater than equal to REF.DATE then (BEHAVE_D - REF.DATE) +1.

1.4.35. Vital Signs – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	Vital Signs
Unique identifier	DCRFID,VISIT,POSITION,VSTYPE
Sorted by	DCRFID,VISIT,POSITION,VSTYPE
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
POSITION	char	POSITION		Collected at CRF.
VSTYPE	char	TYPE OF VITAL SIGNS		Collected at CRF.
VSDOSE_T	num	TIME OF DOSE		Collected at CRF.
VSTIME	num	TIME OF VITAL SIGNS (24HRS)		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
PULSE	num	PULSE, beats/min		Collected at CRF.
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLICBP, mmHg		Collected at CRF.

1.4.36. X Table for Inclusion/Exclusion Crit – XINEX

Dataset	XINEX
Creating program	xinex.sas
Description	X Table for Inclusion/Exclusion Crit
Unique identifier	DCRFID,IETYPE,IECRIT
Sorted by	DCRFID,IETYPE,IECRIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
IETYPE	char	TYPE OF SELECTION CRITERIA		Collected at CRF.
IECRIT	num	SELECTION CRITERIA		Collected at CRF.
XDESC	char	IN/EX DESCRIPTION		Collected at CRF.