

Clinical Development

**Risperidone<sup>®</sup>**

RIS-USA-63

Anonymisation Data Derivation Specification Document

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<b>Status and Version</b>	<b>Release Date</b>	<b>Summary of Key Changes</b>

## 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.
- Vial, Bottle, lot, kit number will not be provided.
- Central Lab Specimen Label Number will not be provided.
- Complete missing value variables will be removed.

- 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.
- Variables with completely missing values will not be submitted.
- Datasets with zero records as input will not be submitted.  
(eg: DEVIATN,DIAGNOS,RELATED)
- Dataset containing Investigator information will not be submitted.  
(eg. INVEST)
- TRLLIST dataset will not be submitted since it contain sensitive information, for example Medication number(MEDNO).
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided..
- Date of Study Entry(ENTDATE) from SUBJCHAR dataset will be used as Reference Date (referred as REF.DATE in the document) to derive Relative days.

### 1.3. Data Files

The RIS-USA-63 CSR Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Subject Characteristics– SUBJCHAR

<b>Dataset</b>	SUBJCHAR
<b>Creating program</b>	subjchar.sas
<b>Description</b>	Subject Characteristics
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	<p>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:  MEDNO,INVEST,ZINVEST,COINV,ZCOINV,INITIALS,BIRTH_D,BREAK,BREAK_D,BREAK_V,BREAK_T,PREGNANT,DRYRUN,ENTRYCOM,PRVTRIAL,PRVCRFID,DISCVIS,RAND_D,ENTDATE</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	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
DSITEID	char	SITE ASSIGNED FOR DE-IDENTITY		Randomly assigned Site for De-identity
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.
AGE	char	AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGE_U	char	AGE UNIT		Collected at CRF.
RBATCH	char	BATCH NUMBER		Collected at CRF.
AGEDEM	char	AGE ONSET DEMENTIA		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEBEH	char	AGE AT ONSET BEHAV.		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEINST	char	AGE AT FIRST INSTIT		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
NUMPREV	num	NUMBER PREV INSTIT		Collected at CRF.
STAY	num	LENGTH CUR. INSTIT		Collected at CRF.
ABEHKN	char	AGE UNKNOWN		Collected at CRF.
ADEMKN	char	AGE UNKNOWN		Collected at CRF.

Variable	Type	Label	Codes	Comments
AINSKN	char	AGE UNKNOWN		Collected at CRF.
DEMENT	char	DSM-IV DIAGNOSIS		Collected at CRF.
DEMON	char	ONSET		Collected at CRF.
DEMTYPE0	char	0. DEMENTIA TYPE		Collected at CRF.
DEMTYPE1	char	1. DEMENTIA TYPE		Collected at CRF.
DEMTYPE2	char	2. DEMENTIA TYPE		Collected at CRF.
DEMTYPE3	char	3. DEMENTIA TYPE		Collected at CRF.
EVALUBLE	char	EVALUABLE ?		Collected at CRF.
NUMKN	char	TIMES UNKNOWN		Collected at CRF.
TG	char	TREATMENT GROUP		Collected at CRF.
RANDCODE	char	TRIAL GROUP CODE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.

## 1.4.2. Administration of Trial Medication– ADMMED

<b>Dataset</b>	ADMED
<b>Creating program</b>	admmed.sas
<b>Description</b>	Administration of Trial Medication
<b>Unique identifier</b>	DCRFID, PHASE, SEGMENT, AMFROMDY
<b>Sorted by</b>	DCRFID, PHASE, SEGMENT, AMFROMDY
<b>Notes</b>	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, AMREAS, ZAMREAS, AMDOSE, AMDOSE_U, AMSCHED, INVEST

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
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
BOX	char	BOX		Collected at CRF.
AMFROM_T	num	ADMIN. FROM TIME		Collected at CRF.
AMTO_T	num	ADMIN. TO TIME		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.

Variable	Type	Label	Codes	Comments
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
XTDD	num	TOTAL DAILY DOSE		Collected at CRF.
XTREAT	char	STUDY MEDICATION		Collected at CRF.
XSTR_U	char	XSTR_U		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. TODAY		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

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	DCRFID,AESOC,AEPREF,AEFROMDY,AESEQNO
<b>Sorted by</b>	DCRFID,AESOC,AEPREF,AEFROMDY,AESEQNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AE_V,PHASE,AEFROM_D,AEFROM_C,AEFROM_T,AETO_D,AETO_C, AETO_T,AECONRX,ZAECONRX,SAEREFNO,CRFNO,PERIOD

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 SEQ.		Collected at CRF.
AEINCL	char	AE INCLUDED TERM		Collected at CRF.
ZAESEV	num	AE SEVERITY CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
AEWHONUM	char	AE WHO CODE		Collected at CRF.
AEPREF	char	ADVERSE EVENT PREFERRED TERM		Collected at CRF.
AESOC	char	ADVERSE EVENT SYSTEM ORGAN CLASS		Collected at CRF.
AESEV	char	AE SEVERITY		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.
AETO_DY	num	RELATIVE AE TODAY		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.B37modes – B37MODES

<b>Dataset</b>	B37MODES
<b>Creating program</b>	b37modes.sas
<b>Description</b>	B37modes
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
RIS63MOD	num	THE MOST FREQUENT VALUE, SMTDD		Collected at CRF.

## 1.4.5.Code – CODE

<b>Dataset</b>	CODE
<b>Creating program</b>	code.sas
<b>Description</b>	Code
<b>Unique identifier</b>	TRIAL, CODELIST
<b>Sorted by</b>	TRIAL, CODELIST
<b>Notes</b>	

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.

## 1.4.6. Concomitant Therapy – COTHER

<b>Dataset</b>	COTHER
<b>Creating program</b>	cother.sas
<b>Description</b>	Concomitant Therapy
<b>Unique identifier</b>	DCRFID,CONRX,CTFROMDY,CTSEQNO
<b>Sorted by</b>	DCRFID,CONRX,CTFROMDY,CTSEQNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CTTYPE,CONRX_V,CTSCHED,CTIND_V,CTIND,CTFROM_D,CTFROM_C, CTFROM_T,CTTO_D,CTTO_C,CTTO_T,ATCCODE8,ATCCODE9,CMSTART

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
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCCODE1	char	ATC CODE 2		Collected at CRF.
ATCCODE2	char	ATC CODE 3		Collected at CRF.
ATCCODE3	char	ATC CODE 4		Collected at CRF.
ATCCODE4	char	ATC CODE 5		Collected at CRF.
ATCCODE5	char	ATC CODE 6		Collected at CRF.
ATCCODE6	char	ATC CODE 7		Collected at CRF.
ATCCODE7	char	ATC CODE 8		Collected at CRF.
CTWHO	char	CTWHO		Collected at CRF.
CTFROMDY	num	RELATIVE CO-RX START 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.
CMSTRTDY	num	RELATIVE START DAY		If CMSTART and REF.DATE not missing then perform below logic to calculate CMSTRTDY, If CMSTART less than REF.DATE then (CMSTART - REF.DATE). Else if CMSTART is greater than equal to REF.DATE then (CMSTART - REF.DATE) +1.

## 1.4.7. Demographics – DEMOG

<b>Dataset</b>	DEMOG
<b>Creating program</b>	demog.sas
<b>Description</b>	Demographics
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INV,CRFNO,INITIALS,ENTDATE,BDATE

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
RACE	char	RACE		Collected at CRF.
SEX	char	SEX		Collected at CRF.
HT	num	HEIGHT		Collected at CRF.
HTUNIT	char	HEIGHT UNIT		Collected at CRF.
RBATCH	char	BATCH NUMBER		Collected at CRF.
DEMENT	char	DSM-IV DIAGNOSIS		Collected at CRF.
DEMON	char	ONSET		Collected at CRF.
DEMTYPE0	char	0. DEMENTIA TYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DEMTYPE1	char	1. DEMENTIA TYPE		Collected at CRF.
DEMTYPE2	char	2. DEMENTIA TYPE		Collected at CRF.
DEMTYPE3	char	3. DEMENTIA TYPE		Collected at CRF.
AGEDEM	char	AGE ONSET DEMENTIA		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
ADEMKN	char	AGE UNKNOWN		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEBEH	char	AGE AT ONSET BEHAV.		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
ABEHKN	char	AGE UNKNOWN		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEINST	char	AGE AT FIRST INSTIT		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AINSKN	char	AGE UNKNOWN		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
NUMPREV	num	NUMBER PREV INSTIT		Collected at CRF.
NUMKN	char	TIMES UNKNOWN		Collected at CRF.
STAY	num	LENGTH CUR. INSTIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGE	char	AGE (YRS)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
TG	char	TREATMENT GROUP		Collected at CRF.
EVALUBLE	char	EVALUABLE ?		Collected at CRF.

#### 1.4.8.Previous and Concomitant Diseases – DISEASES

<b>Dataset</b>	DISEASES
<b>Creating program</b>	diseases.sas
<b>Description</b>	Previous and Concomitant Diseases
<b>Unique identifier</b>	DCRFID,DSSYSTEM
<b>Sorted by</b>	DCRFID,DSSYSTEM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DISEAS_V,MHDATE

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
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSCOND	char	CLINICALLY SIGNIFICANT Y/N ?		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
MHDY	num	RELATIVE MED HXVISIT DAY		If MHDATE and REF.DATE not missing then perform below logic to calculate MHDY, If MHDATE less than REF.DATE then (MHDATE - REF.DATE). Else if MHDATE is greater than equal to REF.DATE then (MHDATE- REF.DATE) +1.

#### 1.4.9. Electrocardiogram – ECG

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.
EGRELCHA	char	CLIN. RELEVANT CHANGES		Collected at CRF.
VISIT	num	VISIT NUMBER		Collected at CRF.
EGRHYTHM	char	RHYTHM		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.

## 1.4.10. ECG Other Abnormalities – ECGABN

<b>Dataset</b>	ECGABN
<b>Creating program</b>	ecgabn.sas
<b>Description</b>	ECG Other Abnormalities
<b>Unique identifier</b>	DCRFID,ECGDY
<b>Sorted by</b>	DCRFID,ECGDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CRFID,ECGSRCE,ECG_D,ECG_T,EASEQNO,ECGDATE,ECGOTH_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
VISIT	num	VISIT NUMBER		Collected at CRF.
ECGDY	num	RELATIVE ECG VISIT DAY		If ECGDATE and REF.DATE not missing then perform below logic to calculate ECGDY, If ECGDATE less than REF.DATE then (ECGDATE - REF.DATE). Else if ECGDATE is greater than equal to REF.DATE then (ECGDATE- REF.DATE) +1.

## 1.4.11. Electrocardiogram Measurements – ECGPAR

<b>Dataset</b>	ECGPAR
<b>Creating program</b>	ecgpar.sas
<b>Description</b>	Electrocardiogram Measurements
<b>Unique identifier</b>	DCRFID, ECGPAR, ECGDY
<b>Sorted by</b>	DCRFID, ECGPAR, ECGDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ECGSRCE, ECG_D, ECG_T, ECGPAR_U, ECGDATE

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
ECGPAR	char	ECG PARAMETER		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
VISIT	num	VISIT NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZECGP	char	ECG PARAMETER CODE		Collected at CRF.
ECGDY	num	RELATIVE ECG VISIT DAY		If ECGDATE and REF.DATE not missing then perform below logic to calculate ECGDY, If ECGDATE less than REF.DATE then (ECGDATE - REF.DATE). Else if ECGDATE is greater than equal to REF.DATE then (ECGDATE- REF.DATE) +1.

#### 1.4.12. Fasting – FAST

<b>Dataset</b>	FAST
<b>Creating program</b>	fast.sas
<b>Description</b>	Fasting
<b>Unique identifier</b>	PHASE,FADATE
<b>Sorted by</b>	PHASE,FADATE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST

Variable	Type	Label	Codes	Comments
FADATE	num	FAST DATE		Collected at CRF.
NFA1	char	NFA1		Collected at CRF.
NFA2	char	NFA2		Collected at CRF.

Variable	Type	Label	Codes	Comments
NFA3	char	NFA3		Collected at CRF.
NFA4	char	NFA4		Collected at CRF.
NFA5	char	NFA5		Collected at CRF.
NFA6A	char	NFA6A		Collected at CRF.
NFA6B	char	NFA6B		Collected at CRF.
NFA6C	char	NFA6C		Collected at CRF.
NFA6D	char	NFA6D		Collected at CRF.
NFA6E	char	NFA6E		Collected at CRF.
NFA7A	char	NFA7A		Collected at CRF.
NFA7B	char	NFA7B		Collected at CRF.
NFA7C	char	NFA7C		Collected at CRF.
NFA7D	char	NFA7D		Collected at CRF.
NFA7E	char	NFA7E		Collected at CRF.
NFA7F	char	NFA7F		Collected at CRF.
PHASE	char	PHASE		Collected at CRF.

### 1.4.13. Laboratory Normal Ranges – LABNOR

<b>Dataset</b>	LABNOR
<b>Creating program</b>	labnor.sas
<b>Description</b>	Laboratory Normal Ranges
<b>Unique identifier</b>	LABTEST,LNFROM_D
<b>Sorted by</b>	LABTEST,LNFROM_D
<b>Notes</b>	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: LABID,WGHTFROM,WGHTTO

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB. TEST		Collected at CRF.
LNFROM_D	num	RANGE APPLIC. FROM		Collected at CRF.
LNT0_D	num	RANGE APPLIC. TO		Collected at CRF.
LNSEQNO	num	LAB. NORMAL SEQ.		Collected at CRF.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.
LABUPP	num	UPPER NORMAL LIMIT		Collected at CRF.
AGEFROM	num	LOWER AGE LIMIT		Collected at CRF.
AGETO	num	UPPER AGE LIMIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGE_U	char	AGE UNIT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
ZLABTEST	char	ARROW_CODE		Collected at CRF.

#### 1.4.14. Laboratory Results – LABRES

<b>Dataset</b>	LABRES
<b>Creating program</b>	labres.sas
<b>Description</b>	Laboratory Results
<b>Unique identifier</b>	DCRFID, LABTEST, SAMPLEDY
<b>Sorted by</b>	DCRFID, LABTEST, SAMPLEDY
<b>Notes</b>	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: SAMPLE_D, SAMPLE_T, LABID, SEX

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
LABTEST	char	LAB. TEST		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE		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.
LOWPATHO	num	LOWER PATH. LIMIT		Collected at CRF.
UPPPATHO	num	UPPER PATH. LIMIT		Collected at CRF.
CFACTOR	num	CONVERSION FACTOR		Collected at CRF.
SIUNIT	char	STANDARD INTL. UNIT		Collected at CRF.
LABTSTNO	num	LAB. TEST NO.		Collected at CRF.
LABCLASS	char	LAB. TEST 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.

### 1.4.15. Labsam – LABSAM

<b>Dataset</b>	LABSAM
<b>Creating program</b>	labsam.sas
<b>Description</b>	Labsam
<b>Unique identifier</b>	DCRFID,SAMPLEDY
<b>Sorted by</b>	DCRFID,SAMPLEDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,SAMPLE_T,LABID,HAEMOLYS,FASTED,LABREFNO,LSRELCHA

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
LSSAME	char	SAME NORMAL RANGES		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.

### 1.4.16. Laboratory Urine Results – LABURI

<b>Dataset</b>	LABURI
<b>Creating program</b>	laburi.sas
<b>Description</b>	Laboratory Urine Results
<b>Unique identifier</b>	DCRFID,LABTEST,SAMPLEDY
<b>Sorted by</b>	DCRFID,LABTEST,SAMPLEDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,SAMPLE_T,LABID,LUVAL,LABVAL

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
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LUVAL_V	char	URINE VALUE		Collected at CRF.
LABTSTNO	num	LAB. TEST NO.		Collected at CRF.
LABCLASS	char	LAB. TEST CLASS		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.

### 1.4.17. Lbcsrng – LBCSRNGE

<b>Dataset</b>	LBCSRNGE
<b>Creating program</b>	lbcsrng.sas
<b>Description</b>	Lbcsrng
<b>Unique identifier</b>	LABTEST
<b>Sorted by</b>	LABTEST
<b>Notes</b>	Below listed variables will be dropped from dataset due to repetition of the information or due to missing values: LABDATE,SEX

Variable	Type	Label	Codes	Comments
LABTEST	char	LABTEST		Collected at CRF.
LABUNIT	char	LABUNIT		Collected at CRF.
AGELOW	num	AGELOW		Collected at CRF.
AGEHIGH	num	AGEHIGH		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABSITE	char	LABSITE		Collected at CRF.
LABHIGH	num	LABHIGH		Collected at CRF.
LABLOW	num	LABLOW		Collected at CRF.

#### 1.4.18. Mms – MMS

<b>Dataset</b>	MMS
<b>Creating program</b>	mms.sas
<b>Description</b>	Mms
<b>Unique identifier</b>	DCRFID,MMDY
<b>Sorted by</b>	DCRFID,MMDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,CRFNO,MMDATE

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VNBR	num	VISIT NUMBER		Collected at CRF.
PERIOD	char	STUDY PHASE		Collected at CRF.
MMS1	num	1. ORIENT: TOTAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
MMS2	num	2. REGISTRATION		Collected at CRF.
MMS3	num	3. ATTNTN & CALCLTN		Collected at CRF.
MMS4	num	4. RECALL		Collected at CRF.
MMS5	num	5. LANG: NAMING		Collected at CRF.
MMS6	num	6. LANG: REPETITN		Collected at CRF.
MMS7	num	7. LANG: 3-STGE CMM		Collected at CRF.
MMS8	num	8. LANG: READING		Collected at CRF.
MMS9	num	9. LANG: WRITING		Collected at CRF.
MMS10	num	10. LANG: COPYING		Collected at CRF.
MMDY	num	RELATIVE MMSE DAY		If MMDATE and REF.DATE not missing then perform below logic to calculate MMDY, If MMDATE less than REF.DATE then (MMDATE - REF.DATE). Else if MMDATE is greater than equal to REF.DATE then (MMDATE- REF.DATE) +1.

## 1.4.19. Neuro Examination – NEUROEXM

<b>Dataset</b>	NEUROEXM
<b>Creating program</b>	neuroexm.sas
<b>Description</b>	Neuro Examination
<b>Unique identifier</b>	DCRFID,NEUROEXM,NEDY
<b>Sorted by</b>	DCRFID,NEUROEXM,NEDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: NEDATE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
NEUROEXM	char	LABEL OF FORMER VARIABLE		Collected at CRF.

Variable	Type	Label	Codes	Comments
NERESULT	char	NERESULT		Collected at CRF.
NEDY	num	RELATIVE NEURO VISDAY		If NEDATE and REF.DATE not missing then perform below logic to calculate NEDY, If NEDATE less than REF.DATE then (NEDATE - REF.DATE). Else if NEDATE is greater than equal to REF.DATE then (NEDATE- REF.DATE) +1.

#### 1.4.20. Neurohx – NEUROHX

<b>Dataset</b>	NEUROHX
<b>Creating program</b>	neurohx.sas
<b>Description</b>	Neurohx
<b>Unique identifier</b>	DCRFID,NRX_V,NSTARTDY,NSTOPDY
<b>Sorted by</b>	DCRFID,NRX_V,NSTARTDY,NSTOPDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: NSTART,NSTOP

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

Variable	Type	Label	Codes	Comments
NSEQ	num	SEQUENCE NUMBER		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
NSTARTDY	num	RELATIVE START DAY		If NSTART and REF.DATE not missing then perform below logic to calculate NSTARTDY, If NSTART less than REF.DATE then (NSTART - REF.DATE). Else if NSTART is greater than equal to REF.DATE then (NSTART- REF.DATE) +1.
NSTOPDY	num	RELATIVE STOP DAY		If NSTOP and REF.DATE not missing then perform below logic to calculate NSTOPDY, If NSTOP less than REF.DATE then (NSTOP - REF.DATE). Else if NSTOP is greater than equal to REF.DATE then (NSTOP- REF.DATE) +1.

## 1.4.21. Physical Examination – PHYSEXAM

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.
PEDY	num	RELATIVE PHYSICAL VISIT DAY		If PEDATE and REF.DATE not missing then perform below logic to calculate PEDY, If PEDATE less than REF.DATE then (PEDATE - REF.DATE). Else if PEDATE is greater than equal to REF.DATE then (PEDATE- REF.DATE) +1.

#### 1.4.22. Plasma – PLASMA

<b>Dataset</b>	PLASMA
<b>Creating program</b>	plasma.sas
<b>Description</b>	Plasma
<b>Unique identifier</b>	DCRFID, PLASMADY
<b>Sorted by</b>	DCRFID, PLASMADY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PLASMA_D, INITIALS

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

Variable	Type	Label	Codes	Comments
DOSE	char	DOSE		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SUM	num	SUM		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
PLASMADY	num	RELATIVE PL DAY		If PLASMA_D and REF.DATE not missing then perform below logic to calculate PLASMADY, If PLASMA_D less than REF.DATE then (PLASMA_D - REF.DATE). Else if PLASMA_D is greater than equal to REF.DATE then (PLASMA_D - REF.DATE) +1.

## 1.4.23. Psms – PSMS

<b>Dataset</b>	PSMS
<b>Creating program</b>	psms.sas
<b>Description</b>	Psms
<b>Unique identifier</b>	DCRFID, PSMS, PSDY
<b>Sorted by</b>	DCRFID, PSMS, PSDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PSDATE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
PSMS	char	LABEL OF FORMER VARIABLE		Collected at CRF.
PSMSRESU	char	PSMS. RESULT		Collected at CRF.
PSDY	num	RELATIVE PSMS DAY		If PDATE and REF.DATE not missing then perform below logic to calculate PSDY, If PDATE less than REF.DATE then (PDATE - REF.DATE). Else if PDATE is greater than equal to REF.DATE then (PDATE- REF.DATE) +1.

## 1.4.24. Related AEs for Termination or Death – RELAE

<b>Dataset</b>	RELAE
<b>Creating program</b>	relae.sas
<b>Description</b>	Related AEs for Termination or Death
<b>Unique identifier</b>	DCRFID,AESEQNO
<b>Sorted by</b>	DCRFID,AESEQNO
<b>Notes</b>	

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
RATYPE	char	AE CONSEQUENCE		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.

## 1.4.25. Resmed – RESMED

<b>Dataset</b>	RESMED
<b>Creating program</b>	resmed.sas
<b>Description</b>	Resmed
<b>Unique identifier</b>	DCRFID,RESRX,RESSEQ
<b>Sorted by</b>	DCRFID,RESRX,RESSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RESRX_V,RESSTART,RESSTOP

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
RESSEQ	num	RESCUE SEQUENCE		Collected at CRF.
RESDOSE	char	DOSE		Collected at CRF.
RESFREQ	num	NUMBER OF TIMES/DAY		Collected at CRF.
RESRX	char	RESCUE		Collected at CRF.
RESONGO	char	ONGOING AFT STUDY?		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.

Variable	Type	Label	Codes	Comments
RESTRTDY	num	RELATIVE START DAY		If RESSTART and REF.DATE not missing then perform below logic to calculate RESTRTDY, If RESSTART less than REF.DATE then (RESSTART - REF.DATE). Else if RESSTART is greater than equal to REF.DATE then (RESSTART- REF.DATE) +1.
RESTOPDY	num	RELATIVE STOP DAY		If RESSTOP and REF.DATE not missing then perform below logic to calculate RESTOPDY, If RESSTOP less than REF.DATE then (RESSTOP - REF.DATE). Else if RESSTOP is greater than equal to REF.DATE then (RESSTOP- REF.DATE) +1.

## 1.4.26. Study Medication – STUDYMED

<b>Dataset</b>	STUDYMED
<b>Creating program</b>	studymed.sas
<b>Description</b>	study Medication
<b>Unique identifier</b>	DCRFID,SMDRUG,SMSTRTDY
<b>Sorted by</b>	DCRFID,SMDRUG,SMSTRTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INV,CRFNO,SMSTART,SMSTOP

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
PERIOD	char	STUDY PHASE		Collected at CRF.
SMDRUG	char	STUDY MEDICATION		Collected at CRF.
SMTDD	num	TOTAL DAILY DOSE		Collected at CRF.
SMCOUNT	num	NO. CAPSULE/TABLET		Collected at CRF.
PHASE	char	PHASE OF STUDY (WASH,TITR,FIXD)		Collected at CRF.

Variable	Type	Label	Codes	Comments
SMSTRTDY	num	RELATIVE START DAY		If SMSTART and REF.DATE not missing then perform below logic to calculate SMSTRTDY, If SMSTART less than REF.DATE then (SMSTART - REF.DATE). Else if SMSTART is greater than equal to REF.DATE then (SMSTART- REF.DATE) +1.
SMSTOPDY	num	RELATIVE STOP DAY		If SMSTOP and REF.DATE not missing then perform below logic to calculate SMSTOPDY, If SMSTOP less than REF.DATE then (SMSTOP - REF.DATE). Else if SMSTOP is greater than equal to REF.DATE then (SMSTOP- REF.DATE) +1.

#### 1.4.27. Trial Description – TRLDDESC

<b>Dataset</b>	TRLDESC
<b>Creating program</b>	trldesc.sas
<b>Description</b>	Trial Description
<b>Unique identifier</b>	TRIAL
<b>Sorted by</b>	TRIAL
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
COMPOND	char	COMPOUND NAME		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
BLKSIZE	num	BLOCK SIZE		Collected at CRF.
INDICAT	char	INDICATION		Collected at CRF.
AGEGRP	char	AGE GROUP		Collected at CRF.
SPECPOP	char	SPECIAL POPULATION		Collected at CRF.
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.
PRVTRIAL	char	PREV. TRIAL		Collected at CRF.

## 1.4.28. Randomisation Groups – TRLRAND

<b>Dataset</b>	TRLRAND
<b>Creating program</b>	trlrand.sas
<b>Description</b>	Randomisation Groups
<b>Unique identifier</b>	TRIAL,RANDGRP
<b>Sorted by</b>	TRIAL,RANDGRP
<b>Notes</b>	

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

## 1.4.29. Trial Medication Regimens – TRLREGM

<b>Dataset</b>	TRLREGM
<b>Creating program</b>	trlregm.sas
<b>Description</b>	Trial Medication Regimens
<b>Unique identifier</b>	TRIAL,RANDGRP,PHASE
<b>Sorted by</b>	TRIAL,RANDGRP,PHASE
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: BLINDING

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		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.

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

#### 1.4.30. Treatment/ Trial Termination – TRLTERM

<b>Dataset</b>	TRLTERM
<b>Creating program</b>	trlterm.sas
<b>Description</b>	Treatment / Trial Termination
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: TTFROM_D, TTFROM_T, TTREAS_V, RXSTOP, CSCONT

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
TTTYPE	char	TERM. TYPE		Collected at CRF.
TTREAS	char	TERM. REASON		Collected at CRF.
CSDCREAS	char	DISCONTINUE REASON		Collected at CRF.
PERIOD	char	STUDY PHASE		Collected at CRF.
TTFROMDY	num	RELATIVE LAST CONTACT DAY		If TTFROM_D and REF.DATE not missing then perform below logic to calculate TTFROMDY, If TTFROM_D less than REF.DATE then (TTFROM_D - REF.DATE). Else if TTFROM_D is greater than equal to REF.DATE then (TTFROM_D - REF.DATE) +1.
RXSTOPDY	num	RELATIVE STOP DAY		If RXSTOP and REF.DATE not missing then perform below logic to calculate RXSTOPDY, If RXSTOP less than REF.DATE then (RXSTOP - REF.DATE). Else if RXSTOP is greater than equal to REF.DATE then (RXSTOP - REF.DATE) +1.

## 1.4.31. Visits – VISIT

<b>Dataset</b>	VISIT
<b>Creating program</b>	visit.sas
<b>Description</b>	Visits
<b>Unique identifier</b>	DCRFID,VISIT
<b>Sorted by</b>	DCRFID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: VISIT_D,VISIT_T

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

## 1.4.32. Vital Signs – VITSIGN

<b>Dataset</b>	VITSIGN
<b>Creating program</b>	vitsign.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DCRFID,VISIT
<b>Sorted by</b>	DCRFID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VSDATE

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

Variable	Type	Label	Codes	Comments
RESPRATE	num	RESPIRATION RATE, BREATHS/MIN		Collected at CRF.
TEMP	num	BODY TEMP.		Collected at CRF.
TEMP_U	char	BODY TEMP. UNIT		Collected at CRF.
VSSUPSYS	num	BP SYSTOLIC SUP		Collected at CRF.
VSSUPDIA	num	BP DIASTOLIC SUP		Collected at CRF.
VSDY	num	RELATIVE VITALS VISIT DAY		If VSDATE and REF.DATE not missing then perform below logic to calculate VSDY, If VSDATE less than REF.DATE then (VSDATE - REF.DATE). Else if VSDATE is greater than equal to REF.DATE then (VSDATE- REF.DATE) +1.

### 1.4.33. Xesrsitm – XESRSITM

<b>Dataset</b>	XESRSITM
<b>Creating program</b>	xesrsitm.sas
<b>Description</b>	Xesrsitm
<b>Unique identifier</b>	DCRFID,EFDY,VNBR,PAR
<b>Sorted by</b>	DCRFID,EFDY,VNBR,PAR
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,EFDY,ORIGINV

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VNBR	num	VISIT NUMBER		Collected at CRF.
PERIOD	char	STUDY PHASE		Collected at CRF.
TG	char	TREATMENT GROUP		Collected at CRF.
EVALUBLE	char	EVALUABLE ?		Collected at CRF.
EFEVAL	char	EFEVAL		Collected at CRF.
PAR	num	PAR		Collected at CRF.
ZESGROUP	char	ZESGROUP		Collected at CRF.
ESGROUP	char	ESGROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
VALUE	num	VALUE		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TDD	num	TDD		Collected at CRF.
V2DATE	num	V2DATE		Collected at CRF.
OVNBR	num	ORIGINAL VISIT NUMBER		Collected at CRF.
RELDAY	num	RELDAY		Collected at CRF.
MODENDPT	num	MODENDPT		Collected at CRF.
BASE	num	BASE		Collected at CRF.
BASEEVAL	char	BASEEVAL		Collected at CRF.
DIFF	num	DIFF		Collected at CRF.
EFDY	num	RELATIVE EFDAY		If EFDATE and REF.DATE not missing then perform below logic to calculate EFDY, If EFDATE less than REF.DATE then (EFDATE - REF.DATE). Else if EFDATE is greater than equal to REF.DATE then (EFDATE- REF.DATE) +1.

## 1.4.34. Xfstmmsi – XFSTMMSI

<b>Dataset</b>	XFSTMMSI
<b>Creating program</b>	xfstmmsi.sas
<b>Description</b>	Xfstmmsi
<b>Unique identifier</b>	DCRFID,EFDY,VNBR,PAR
<b>Sorted by</b>	DCRFID,EFDY,VNBR,PAR
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,EFDATE,V2DATE,ORIGINV

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VNBR	num	VISIT NUMBER		Collected at CRF.
PERIOD	char	STUDY PHASE		Collected at CRF.
TG	char	TREATMENT GROUP		Collected at CRF.
EVALUBLE	char	EVALUABLE ?		Collected at CRF.
EFEVAL	char	EFEVAL		Collected at CRF.
PAR	num	PAR		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.

Variable	Type	Label	Codes	Comments
TDD	num	TDD		Collected at CRF.
OVNBR	num	ORIGINAL VISIT NUMBER		Collected at CRF.
RELDAY	num	RELDAY		Collected at CRF.
MODENDPT	num	MODENDPT		Collected at CRF.
BASE	num	BASE		Collected at CRF.
BASEEVAL	char	BASEEVAL		Collected at CRF.
SOMNLENT	char	SOMNLENT		Collected at CRF.
DIFF	num	DIFF		Collected at CRF.
EFDY	num	RELATIVE MMSE DAY		If EFDATE and REF.DATE not missing then perform below logic to calculate EFDY, If EFDATE less than REF.DATE then (EFDATE - REF.DATE). Else if EFDATE is greater than equal to REF.DATE then (EFDATE- REF.DATE) +1.
V2DY	num	RELATIVE MMSE DAY		If V2DATE and REF.DATE not missing then perform below logic to calculate V2DY, If V2DATE less than REF.DATE then (V2DATE - REF.DATE). Else if V2DATE is greater than equal to REF.DATE then (V2DATE- REF.DATE) +1.

## 1.4.35. Xvitlecg – XVITLECG

<b>Dataset</b>	XVITLECG
<b>Creating program</b>	xvitlecg.sas
<b>Description</b>	Xvitlecg
<b>Unique identifier</b>	DCRFID,EFDY,VNBR,PAR
<b>Sorted by</b>	DCRFID,EFDY,VNBR,PAR
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,EFDATE,SMSTART,V2DATE,ORIGINV

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VNBR	num	VISIT NUMBER		Collected at CRF.
PERIOD	char	STUDY PHASE		Collected at CRF.
TG	char	TREATMENT GROUP		Collected at CRF.
EVALUBLE	char	EVALUABLE ?		Collected at CRF.
EFEVAL	char	EFEVAL		Collected at CRF.
PAR	num	PAR		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.

Variable	Type	Label	Codes	Comments
TDD	num	TDD		Collected at CRF.
OVNBR	num	ORIGINAL VISIT NUMBER		Collected at CRF.
RELDAY	num	RELDAY		Collected at CRF.
MODENDPT	num	MODENDPT		Collected at CRF.
BASE	num	BASE		Collected at CRF.
BASEEVAL	char	BASEEVAL		Collected at CRF.
DIFF	num	DIFF		Collected at CRF.
EFDY	num	RELATIVE VITALS VISIT DAY		If EFDATE and REF.DATE not missing then perform below logic to calculate EFDY, If EFDATE less than REF.DATE then (EFDATE - REF.DATE). Else if EFDATE is greater than equal to REF.DATE then (EFDATE- REF.DATE) +1.
SMSTRTDY	num	RELATIVE START DAY		If SMSTART and REF.DATE not missing then perform below logic to calculate SMSTRTDY, If SMSTART less than REF.DATE then (SMSTART - REF.DATE). Else if SMSTART is greater than equal to REF.DATE then (SMSTART- REF.DATE) +1.
V2DY	num	RELATIVE VITALS VISIT DAY		If V2DATE and REF.DATE not missing then perform below logic to calculate V2DY, If V2DATE less than REF.DATE then (V2DATE - REF.DATE). Else if V2DATE is greater than equal to REF.DATE then (V2DATE- REF.DATE) +1.

## 1.4.36. Plasma - XXPLASMA

<b>Dataset</b>	XXPLASMA
<b>Creating program</b>	xxplasma.sas
<b>Description</b>	Plasma
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST, ZINVEST, MEDNO, SAMPLE_D

Variable	Type	Label	Codes	Comments
TRIAL	char	PROTOCOL NUMBER		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.
RACE	char	RACE		Collected at CRF.
SEX	char	SEX		Collected at CRF.
LSTDO	num	DOSE ADMINISTRATION		Collected at CRF.
LSTDO_U	char	DOSE ADMINISTRATION UNIT		Collected at CRF.
SAMPLE_T	char	BLOOD SAMPLING TIME		Collected at CRF.
VISIT	num	VISIT NUMBER		Collected at CRF.
SUBST	char	SUBSTANCE		Collected at CRF.
BRVAL	num	CONCENTRATION VALUE		Collected at CRF.

Variable	Type	Label	Codes	Comments
BRVAL_V	char	CONCENTRATION VALUE		Collected at CRF.
BRVAL_U	char	CONCENTRATION VALUE UNIT		Collected at CRF.
BRQUANT	num	QUANTIFICATION LIMIT		Collected at CRF.
WEIGHT	num	WEIGHT VALUE		Collected at CRF.
HEIGHT	num	HEIGHT,CM		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
HEIGHT_U	char	XHEIGHT UNIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
DSITEID	char	SITE ASSIGNED FOR DE-IDENTITY		Randomly assigned Site for De-identity
AGE	char	AGE IN YEARS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
SAMPLEDY	num	RELATIVE BLOOD 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.