

Clinical Development

**Risperidone<sup>®</sup>**

JNJ410397\_USA001

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	31 MAY 2017

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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.
- 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.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- XVITSIGN. VISIT\_D (VISIT DATE 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 JNJ410397\_USA001 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. DEMOGRAPHICS – XDEMOG

<b>Dataset</b>	XDEMOG
<b>Creating program</b>	xdemog.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 missing values: MEDNO,BIRTH_D,INITIALS,XDIAGN,XDIAGDAT,PERPROT,SYMPDATE

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
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
XAGE	char	AGE (Years)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
XWEIGHT	num	WEIGHT (Kg)		Collected at CRF.
XHEIGHT	num	HEIGHT (Cm)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
ITT	char	INTENT-TO-TREAT		Collected at CRF.
BMI	num	BODY MASS INDEX		Collected at CRF.
WEIGHT	num	WEIGHT (lb)		Collected at CRF.
HEIGHT	num	HEIGHT (inch)		Collected at CRF.
SMOKE	char	SMOKING HISTORY		Collected at CRF.
ALCOHOL	char	ALCOHOL COMSUMPTION		Collected at CRF.
FAMHIST	char	FAMILY HISTORY		Collected at CRF.
DURASYMP	num	DURATION OF SYMPTOMS (yr)		Collected at CRF.
DURADIAG	num	DURATION (yr) SCHIZOPHRENIA		Collected at CRF.
XDIAGDY	num	RELATIVE DIAGNOSIS DAY		If XDIAGDAT and REF.DATE not missing then perform below logic to calculate XDIAGDY, If XDIAGDAT less than REF.DATE then (XDIAGDAT - REF.DATE). Else if XDIAGDAT is greater than equal to REF.DATE then (XDIAGDAT- REF.DATE) +1.
SYMPDY	num	RELATIVE FIRST PSYCHOTIC SYMPTOM DAY		If SYMPDATE and REF.DATE not missing then perform below logic to calculate SYMPDY, If SYMPDATE less than REF.DATE then (SYMPDATE - REF.DATE). Else if SYMPDATE is greater than equal to REF.DATE then (SYMPDATE- REF.DATE) +1.

## 1.4.2. ADMSUM – ADMSUM

<b>Dataset</b>	ADMSUM
<b>Creating program</b>	admsum.sas
<b>Description</b>	ADMSUM
<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: SEGMENT ,PERPROT

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.
TREAT	char	TREATMENT		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.



Variable	Type	Label	Codes	Comments
XTOTDUR	num	TOTAL DURATION(DAYS)		Collected at CRF.
XRXDUR	num	TREATMENT DURATION(DAYS)		Collected at CRF.
XRXMEANA	num	MEAN DOSE(INCLUDING DAYS OFF DRUG)		Collected at CRF.
XRXMEANB	num	MEAN DOSE(DAYS ON DRUG ONLY)		Collected at CRF.
XRXMINA	num	MINIMUM DOSE(INCLUDING DAYS OFF DRUG)		Collected at CRF.
XRXMINEB	num	MINIMUM DOSE (DAYS ON DRUG ONLY)		Collected at CRF.
XRXMAXA	num	MAXIMUM DOSE		Collected at CRF.
XRXMODA	num	MODE DOSE(INCLUDING DAYS OFF DRUG)		Collected at CRF.
XRXMODB	num	MODE DOSE(DAYS ON DRUG ONLY)		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.

## 1.4.3. ABNORMAL INVOLUNTARY MOVEMENT SCALE – AIMS

<b>Dataset</b>	AIMS
<b>Creating program</b>	aims.sas
<b>Description</b>	ABNORMAL INVOLUNTARY MOVEMENT SCALE
<b>Unique identifier</b>	DCRFID,XPHASE,PARAM,VISIT
<b>Sorted by</b>	DCRFID,XPHASE,PARAM,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: PERPROT,VISIT_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
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
VISIT	num	VISIT NUMBER		Collected at CRF.
VISIT_T	num	VISIT TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
XPHASE	char	STUDY PHASE		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM BASELINE		Collected at CRF.
AI11	char	DENTAL 1-PROBLEM W/TEETH		Collected at CRF.
AI12	char	DENTAL 2-WEAR DENTURES		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.

## 1.4.4. ADMINISTRATION OF TRIAL MEDICATION – XADMMED

<b>Dataset</b>	XADMMED
<b>Creating program</b>	xadmmed.sas
<b>Description</b>	ADMINISTRATION OF TRIAL MEDICATION
<b>Unique identifier</b>	DCRFID,AMFROMDY
<b>Sorted by</b>	DCRFID,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,PERPROT,XAMFROM,XAMTO,XAMREAS

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	TRIAL SEGMENT SEQ.		Collected at CRF.
AMFROM_T	num	ADMIN. FROM TIME		Collected at CRF.
AMTO_T	num	ADMIN. TO TIME		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
XDUR	num	DURATION(DAYS)		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
XSTR_U	char	STRENGTH UNIT		Collected at CRF.
XTDD	char	TOTAL DAILY DOSE		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.
XAMFRMTM	num	REGIMEN START TIME		If XAMFROM contains time part then timepart(XAMFROM) else XAMFRMTM equal to NULL.
XAMFRMDY	num	RELATIVE REGIMEN START DAY		If XAMFROM and REF.DATE not missing then perform below logic to calculate XAMFRMDY, If XAMFROM less than REF.DATE then (XAMFROM - REF.DATE). Else if XAMFROM is greater than equal to REF.DATE then (XAMFROM- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
XAMTOTM	num	REGIMEN TO TIME		If XAMTO contains time part then timepart(XAMTO) else XAMTOTM equal to NULL.
XAMTODY	num	RELATIVE REGIMEN TO DAY		If XAMTO and REF.DATE not missing then perform below logic to calculate XAMTODY, If XAMTO less than REF.DATE then (XAMTO - REF.DATE). Else if XAMTO is greater than equal to REF.DATE then (XAMTO- REF.DATE) +1.

#### 1.4.5. ADVERSE EVENTS – XAE

<b>Dataset</b>	XAE
<b>Creating program</b>	xae.sas
<b>Description</b>	ADVERSE EVENTS
<b>Unique identifier</b>	DCRFID,PPHASE,AEPREF,AESEQNO
<b>Sorted by</b>	DCRFID,PPHASE,AEPREF,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,PERPROT,AEINCL,AEFROM_D,AEFROM_C,AETO_D,AETO_C, AECONRX,ZAECONRX,SEGMENT,AESER,ZAESER

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
AESEQNO	num	AE SEQUENCE NUMBER		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
EPS	char	EPS ADVERSE EVENT		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESV	num	AE SEVERITY CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.
ZAERELAT	num	AE DRUGRELATION CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME CODE		Collected at CRF.
SAEREFNO	char	ADREM CASE NO.		Collected at CRF.
AEWHONUM	char	AE WHO CODE		Collected at CRF.
AEPREF	char	AE PREFERRED TERM		Collected at CRF.
AESOC	char	AE SYSTEM ORGAN CLASS		Collected at CRF.
PPHASE	char	TRIAL PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
XTE	char	AE TREATMENT EM.		Collected at CRF.
XONSETDS	char	ONSET DOSE		Collected at CRF.
XONSETDY	num	DAYS TO ONSET		Collected at CRF.
XDYSONDS	char	DAYS ON ONSET DOSE		Collected at CRF.
XAEDUR	num	DURATION IN PHASE		Collected at CRF.
XTAEDUR	char	TOTAL DURATION		Collected at CRF.
XREACH	num	THERAPEUTIC REACH, DAYS		Collected at CRF.
XINREACH	char	AE IN REACH?		Collected at CRF.
XSTR_U	char	FORM. UNIT		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		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 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.



## 1.4.6. XBPRS – XBPRS

<b>Dataset</b>	XBPRS
<b>Creating program</b>	xbprs.sas
<b>Description</b>	XBPRS
<b>Unique identifier</b>	DCRFID, XPHASE, PARAM, VISIT
<b>Sorted by</b>	DCRFID, XPHASE, PARAM, 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, PERPROT, DVALUE, DBASE, RANDLIST

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
PARAM	char	PARAMETER		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
XTREAT	char	TREATMENT		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM BASELINE		Collected at CRF.
RELDAY	num	DAYS IN PHASE		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.

## 1.4.7. XCGI – XCGI

<b>Dataset</b>	XCGI
<b>Creating program</b>	xcgi.sas
<b>Description</b>	XCGI
<b>Unique identifier</b>	DCRFID,XPHASE,PARAM,VISIT
<b>Sorted by</b>	DCRFID,XPHASE,PARAM,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,PERPROT

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
XTIME	char	TIME INTERVAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCHANGE	num	PCT CHANGE FROM BASELINE		Collected at CRF.
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
DBASE	char	VALUE DESC. AT BASELINE		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
XAGE	char	AGE (Years)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
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.

## 1.4.8. CONCOMITANT THERAPY – XCOTHER

<b>Dataset</b>	XCOTHER
<b>Creating program</b>	xcother.sas
<b>Description</b>	CONCOMITANT THERAPY
<b>Unique identifier</b>	DCRFID, XPHASE, RXWHONUM, CTFROMDY, CTTO_DY
<b>Sorted by</b>	DCRFID, XPHASE, RXWHONUM, CTFROMDY, CTTO_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: CTSEQNO, CTTYPER, CONRX_V, PERPROT, XGENERIC, XATC, CTFROM_D, CTFROM_C, CTTO_D, CTTO_C, CTPRIOR, CTONGO, CTIND, EPS, CTFROM_T, CTTO_T

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
CONRX	char	WHO DRUG TERM		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.

Variable	Type	Label	Codes	Comments
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE	char	ATC CODE		Collected at CRF.
CTSCHED	char	DAILY SCHEDULE		Collected at CRF.
CTIND_V	char	INDICATION (VERB.)		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		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.
CTTO_DY	num	RELATIVE CO_RX END 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. PREVIOUS AND CONCOMITANT DISEASES – XDISEASE

<b>Dataset</b>	XDISEASE
<b>Creating program</b>	xdisease.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,DSCOND ,PERPROT

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.
DSCLIN	char	CLINICALLY SIGNIFICANT		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.

## 1.4.10. ELECTROCARDIOGRAM MEASUREMENTS – XECGPARG

<b>Dataset</b>	XECGPARG
<b>Creating program</b>	xecgparg.sas
<b>Description</b>	ELECTROCARDIOGRAM MEASUREMENTS
<b>Unique identifier</b>	DCRFID,PARAM,VISIT,XTIME
<b>Sorted by</b>	DCRFID,PARAM,VISIT,XTIME
<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: PERPROT,DVALUE,DBASE,ECG_D,ABNCHANG

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
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
PARAM	char	ECG PARAMETER		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.



Variable	Type	Label	Codes	Comments
XTIME	char	TIME INTERVAL		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM BASELINE		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
ABNCLASS	char	ABNORMALITY CLASS (VALUES)		Collected at CRF.
ECG_DY	num	RELATIVE VISIT 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.

## 1.4.11. XESRS – XESRS

<b>Dataset</b>	XESRS
<b>Creating program</b>	xesrs.sas
<b>Description</b>	XESRS
<b>Unique identifier</b>	DCRFID,PARAM,VISIT
<b>Sorted by</b>	DCRFID,PARAM,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,PERPROT

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.
XTIME	char	TIME INTERVAL		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
SEQUE	num	TIME PRIORITY		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
XTREAT	char	TREATMENT		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM BASELINE		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
ZESGROUP	char	CODE ESRS-GROUP CODE		Collected at CRF.
ZPARAM	char	CODE ESRS-PARAMETER CODE		Collected at CRF.
ESGROUP	char	ESRS-GROUP		Collected at CRF.
PARAM	char	ESRS-PARAMETER		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.

## 1.4.12. XEXAM – XEXAM

<b>Dataset</b>	XEXAM
<b>Creating program</b>	xexam.sas
<b>Description</b>	XEXAM
<b>Unique identifier</b>	DCRFID,XPHASE,PARAM,VISIT
<b>Sorted by</b>	DCRFID,XPHASE,PARAM,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,PERPROT,EXAM_V,EXAM,SORT_NO

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
PARAM	char	PARAMETER		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
XTREAT	char	TREATMENT		Collected at CRF.
VALUE	char	VALUE		Collected at CRF.
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
RELDAY	num	DAYS IN PHASE		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.

## 1.4.13. LABORATORY RESULTS – XLABRES

<b>Dataset</b>	XLABRES
<b>Creating program</b>	xlabres.sas
<b>Description</b>	LABORATORY RESULTS
<b>Unique identifier</b>	DCRFID,LABTEST,REGION,SAMPLEDY,XTIME
<b>Sorted by</b>	DCRFID,LABTEST,REGION,SAMPLEDY,XTIME
<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,LABID,LABVAL_V,XDYSONDS,XSTR_U,AMFROM_D, PERPROT,TXBEGDT,TXENDDT

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
ZLABTEST	char	LAB.TEST CODE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB.TEST		Collected at CRF.
LABTSTNO	num	LAB.TEST NUMBER		Collected at CRF.
LABCLASS	char	LABCLASS		Collected at CRF.
ENZYME	char	ENZYME		Collected at CRF.
LABVAL	num	LAB.TEST VALUE		Collected at CRF.
LABTST_U	char	TEST UNIT		Collected at CRF.
SIVALUE	num	STANDARD VALUE		Collected at CRF.
SIUNIT	char	STANDARD INTERNATIONAL UNIT		Collected at CRF.
CFACTOR	num	CONVERSION FACTOR		Collected at CRF.
LABLOW	num	LOWER LIMIT		Collected at CRF.
LABUPP	num	UPPER LIMIT		Collected at CRF.
LOWPATHO	num	LOWER PATHOLOGICAL LIMIT		Collected at CRF.
UPPPATHO	num	UPPER PATHOLOGICAL LIMIT		Collected at CRF.
REGION	char	REGION OF THE VALUE		Collected at CRF.
SHIFTBAS	char	SHIFT VERSUS BASELINE		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
XAGE	char	AGE (Years)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
XWEIGHT	num	WEIGHT (Kg)		Collected at CRF.
XONSETDS	char	ONSET DOSE		Collected at CRF.

Variable	Type	Label	Codes	Comments
XTREAT	char	TREATMENT		Collected at CRF.
RELDAY	num	RELDAY		Collected at CRF.
INTERVAL	num	INTERVAL		Collected at CRF.
SEQUSE	num	TIME PRIORITY		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
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.
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.
TXBEGDY	num	RELATIVE TREATMENT BEGIN DAY		If TXBEGDT and REF.DATE not missing then perform below logic to calculate TXBEGDY, If TXBEGDT less than REF.DATE then (TXBEGDT - REF.DATE). Else if TXBEGDT is greater than equal to REF.DATE then (TXBEGDT- REF.DATE) +1.
TXENDDY	num	RELATIVE TREATMENT END DAY		If TXENDDT and REF.DATE not missing then perform below logic to calculate TXENDDY, If TXENDDT less than REF.DATE then (TXENDDT - REF.DATE). Else if TXENDDT is greater than equal to REF.DATE then (TXENDDT- REF.DATE) +1.



## 1.4.14. XLABSAM – XLABSAM

<b>Dataset</b>	XLABSAM
<b>Creating program</b>	xlabsam.sas
<b>Description</b>	XLABSAM
<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,XSTR_U,AMFROM_D,PERPROT,TXBEGDT,TXENDDT

Variable	Type	Label	Codes	Comments
XTIME	char	TIME INTERVAL		Collected at CRF.
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID for De-identity
XAGE	char	AGE (Years)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
XWEIGHT	num	WEIGHT (Kg)		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
XDYSONDS	char	DAYS ON ONSET DOSE		Collected at CRF.
XONSETDS	char	ONSET DOSE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
RELDAY	num	RELDAY		Collected at CRF.
INTERVAL	num	INTERVAL		Collected at CRF.
SEQUSE	num	TIME PRIORITY		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLE 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.
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.

Variable	Type	Label	Codes	Comments
TXBEGDY	num	RELATIVE TREATMENT BEGIN DAY		If TXBEGDT and REF.DATE not missing then perform below logic to calculate TXBEGDY, If TXBEGDT less than REF.DATE then (TXBEGDT - REF.DATE). Else if TXBEGDT is greater than equal to REF.DATE then (TXBEGDT- REF.DATE) +1.
TXENDDY	num	RELATIVE TREATMENT END DAY		If TXENDDT and REF.DATE not missing then perform below logic to calculate TXENDDY, If TXENDDT less than REF.DATE then (TXENDDT - REF.DATE). Else if TXENDDT is greater than equal to REF.DATE then (TXENDDT- REF.DATE) +1.

## 1.4.15. LABORATORY URINE RESULTS – XLABURI

<b>Dataset</b>	XLABURI
<b>Creating program</b>	xlaburi.sas
<b>Description</b>	LABORATORY URINE RESULTS
<b>Unique identifier</b>	DCRFID,LABTEST,SAMPLEDY,XTIME
<b>Sorted by</b>	DCRFID,LABTEST,SAMPLEDY,XTIME
<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,LABID,ENZYME,LABVAL_V,LABTST_U,SIUNIT,CFACTOR, LABLOW,LABUPP,LOWPATHO,UPPPATHO,REGION,XDYSONDS,XSTR_U, AMFROM_D,PERPROT,TXBEGDT,TXENDDT

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
ZLABTEST	char	LAB.TEST CODE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB.TEST		Collected at CRF.
LABTSTNO	num	LAB.TEST NUMBER		Collected at CRF.
LABCLASS	char	LABCLASS		Collected at CRF.
LABVAL	num	LAB.TEST VALUE		Collected at CRF.
SIVALUE	num	STANDARD VALUE		Collected at CRF.
SHIFTBAS	char	SHIFT VERSUS BASELINE		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
XAGE	char	AGE (Years)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
XWEIGHT	num	WEIGHT (Kg)		Collected at CRF.
XONSETDS	char	ONSET DOSE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
RELDAY	num	RELDAY		Collected at CRF.
INTERVAL	num	INTERVAL		Collected at CRF.
SEQUSE	num	TIME PRIORITY		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
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.

Variable	Type	Label	Codes	Comments
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.
TXBEGDY	num	RELATIVE TREATMENT BEGIN DAY		If TXBEGDT and REF.DATE not missing then perform below logic to calculate TXBEGDY, If TXBEGDT less than REF.DATE then (TXBEGDT - REF.DATE). Else if TXBEGDT is greater than equal to REF.DATE then (TXBEGDT- REF.DATE) +1.
TXENDDY	num	RELATIVE TREATMENT END DAY		If TXENDDT and REF.DATE not missing then perform below logic to calculate TXENDDY, If TXENDDT less than REF.DATE then (TXENDDT - REF.DATE). Else if TXENDDT is greater than equal to REF.DATE then (TXENDDT- REF.DATE) +1.

## 1.4.16. XPRETHER – XPRETHER

<b>Dataset</b>	XPRETHER
<b>Creating program</b>	xprether.sas
<b>Description</b>	XPRETHER
<b>Unique identifier</b>	DCRFID,PRVRX,PTFROMDY,PTTO_DY
<b>Sorted by</b>	DCRFID,PRVRX,PTFROMDY,PTTO_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: ATCCODE,PERPROT,PRVRX_V,PTAE_V,PTEFFECT,PTFROM_C, PTFROM_D,PTSEQNO,PTTO_C,PTTO_D,PTTYPE,RXWHONUM, XATC,XGENERIC

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID for De-identity
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
ITT	char	INTENT-TO-TREAT		Collected at CRF.
PRVRX	char	PREV. RX		Collected at CRF.
PTDUR	char	PREV. RX DURATION		Collected at CRF.
PTDUR_U	char	PREV. RX DURATION UNIT		Collected at CRF.
PTSCHED	char	DAILY SCHEDULE		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	RACE		Group element to protect PII.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
PTFROMDY	num	RELATIVE START DAY OF THERAPY		If PTFROM_D and REF.DATE not missing then perform below logic to calculate PTFROMDY, If PTFROM_D less than REF.DATE then (PTFROM_D - REF.DATE). Else if PTFROM_D is greater than equal to REF.DATE then (PTFROM_D- REF.DATE) +1.
PTTO_DY	num	RELATIVE END DAY OF THERAPY		If PTTO_D and REF.DATE not missing then perform below logic to calculate PTTO_DY, If PTTO_D less than REF.DATE then (PTTO_D - REF.DATE). Else if PTTO_D is greater than equal to REF.DATE then (PTTO_D- REF.DATE) +1.



## 1.4.17. XSANS – XSANS

<b>Dataset</b>	XSANS
<b>Creating program</b>	xsans.sas
<b>Description</b>	XSANS
<b>Unique identifier</b>	DCRFID,XPHASE,PARAM,VISIT
<b>Sorted by</b>	DCRFID,XPHASE,PARAM,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: PERPROT,VISIT_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
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
VISIT	num	VISIT NUMBER		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM BASELINE		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.

## 1.4.18. XSUB – XSUB

<b>Dataset</b>	XSUB
<b>Creating program</b>	xsub.sas
<b>Description</b>	XSUB
<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: PERPROT, TXBEGDT, TXENDDT

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID for De-identity
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
ITT	char	INTENT-TO-TREAT		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
TRIAL	char	TRIAL ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
TXBEGDY	num	RELATIVE TREATMENT BEGIN DAY		If TXBEGDT and REF.DATE not missing then perform below logic to calculate TXBEGDY, If TXBEGDT less than REF.DATE then (TXBEGDT - REF.DATE). Else if TXBEGDT is greater than equal to REF.DATE then (TXBEGDT- REF.DATE) +1.
TXENDDY	num	RELATIVE TREATMENT END DAY		If TXENDDT and REF.DATE not missing then perform below logic to calculate TXENDDY, If TXENDDT less than REF.DATE then (TXENDDT - REF.DATE). Else if TXENDDT is greater than equal to REF.DATE then (TXENDDT- REF.DATE) +1.

#### 1.4.19. TREATMENT / TRIAL TERMINATION – XTRLTERM

<b>Dataset</b>	XTRLTERM
<b>Creating program</b>	xtrlterm.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: PERPROT,TTFROM_D,TTFROM_T,TTREAS_V,ORREAS_V

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

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID for De-identity
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
TTTYPE	char	TERM. TYPE		Collected at CRF.
TTRELDAY	num	DAYS IN PHASE		Collected at CRF.
TTREAS	char	TERM. REASON		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.

## 1.4.20. VITAL SIGNS – XVITSIGN

<b>Dataset</b>	XVITSIGN
<b>Creating program</b>	xvitsign.sas
<b>Description</b>	VITAL SIGNS
<b>Unique identifier</b>	DCRFID,PARAM,VISIT
<b>Sorted by</b>	DCRFID,PARAM,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,PERPROT,DVALUE,DBASE

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
PARAM	char	PARAMETER		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITEID for De-identity
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Group element to protect PII.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM BASELINE		Collected at CRF.
VSPOS	char	VITAL SIGNS POSITION		Collected at CRF.
ABNCLASS	char	ABNORMALITY CLASS		Collected at CRF.
SEQUSE	num	TIME PRIORITY		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.