

Clinical Development

**Risperidone<sup>®</sup>**

JNJ410397\_USA72

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.
- 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 which 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.
- JHXESRS.ENTDATE (STUDY ENTRY DATE) will be used as Reference Date(referred as REF.DATE in the document) to derive relative day.

### 1.3. Data Files

The JNJ410397\_USA72 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: RANDLIST,INVEST,BIRTH_D,INITIALS,XHEIGHT,AGEFSYMP,AGEFHOSP, FHOSP_D,DURHOSPU,COURSE

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.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.

Variable	Type	Label	Codes	Comments
XAGE	char	AGE		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		Collected at CRF.
DIAGN	char	DIAGNOSIS		Collected at CRF.
DURHOSP	num	DURATION CURRENT HOSPITALIZATION		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
DSITEID	char	SITE ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Site Id for De-identity



## 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: INVEST

Variable	Type	Label	Codes	Comments
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
PHASE	char	STUDY PHASE		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
TREAT	char	TREATMENT		Collected at CRF.
XRMEANA	num	MEAN DOSE, mg (INCLUDES DAYS OFF DRUG)		Collected at CRF.
XTOTDUR	num	TOTAL DURATION, days		Collected at CRF.
XRMEANB	num	MEAN DOSE, mg (DAYS ON DRUG ONLY)		Collected at CRF.
XRMDUR	num	DURATION OF TREATMENT, days		Collected at CRF.

Variable	Type	Label	Codes	Comments
XRMAXA	num	MAXIMUM DOSE, mg		Collected at CRF.
XRMINA	num	MINIMUM DOSE, mg(INCLUDES DAYS OFF DRUG)		Collected at CRF.
XRMINB	num	MINIMUM DOSE, mg (DAYS ON DRUG ONLY)		Collected at CRF.
XRMODA	num	MODE DOSE, mg(INCLUDES DAYS OFF DRUG)		Collected at CRF.
XRMODB	num	MODE DOSE, mg (DAYS ON DRUG ONLY)		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
SEGMENT	num	SEGMENT		Collected at CRF.

## 1.4.3. CONCOMITANT THERAPY - COTHER

<b>Dataset</b>	COTHER
<b>Creating program</b>	cother.sas
<b>Description</b>	CONCOMITANT THERAPY
<b>Unique identifier</b>	DCRFID,CONRX,RXWHONUM,CTSEQNO
<b>Sorted by</b>	DCRFID,CONRX,RXWHONUM,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,CTFROM_D,CTFROM_C, CTFROM_T,CTTO_D,CTTO_C,CTTO_T,ATCCODE8,ATCCODE9,ATCTEXT0, ATCTEXT1,ATCTEXT2,ATCTEXT3,ATCTEXT4,ATCTEXT5,ATCTEXT6,ATCTEXT7, ATCTEXT8,ATCTEXT9,CMSTOP

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
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.
CTIND_V	char	INDICATION (VERB.)		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.

Variable	Type	Label	Codes	Comments
ATCCODE0	char	ATC CODE 1		Collected at CRF.
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.
CMSTOPDY	num	RELATIVE STOP DAY		If CMSTOP and REF.DATE not missing then perform below logic to calculate CMSTOPDY, If CMSTOP less than REF.DATE then (CMSTOP - REF.DATE). Else if CMSTOP is greater than equal to REF.DATE then (CMSTOP- REF.DATE) +1.
OLDCMSDY	num	RELATIVE OLDCMSTA DAY		If OLDCMSTA and REF.DATE not missing then perform below logic to calculate OLDCMSDY, If OLDCMSTA less than REF.DATE then (OLDCMSTA - REF.DATE). Else if OLDCMSTA is greater than equal to REF.DATE then (OLDCMSTA- REF.DATE) +1.

## 1.4.4.JHXESRS - JHXESRS

<b>Dataset</b>	JHXESRS
<b>Creating program</b>	jhxesrs.sas
<b>Description</b>	JHXESRS
<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: EFDATE,CRFNO,INITIALS,ENTDATE,BDATE,CSCDCDTE,EVALUBLE

Variable	Type	Label	Codes	Comments
DSITEID	char	SITE ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Site Id for De-identity
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.
TOTPD	num	ESRS (PARKINSONISM+DYSTONIA+DYSKINESIA)		Collected at CRF.
TOTPDST	num	TOTAL ESRS SCORE (PARKINSONISM+DYSTONIA)		Collected at CRF.
CGIDKSEV	num	CGI - SEVERITY OF DYSKINESIA		Collected at CRF.
CGIPSEV	num	CGI - SEVERITY OF PARKINSONISM		Collected at CRF.

Variable	Type	Label	Codes	Comments
TOTCHOR	num	TOTAL ESRS SCORE (CHOREOATHETOID)		Collected at CRF.
TOTBLM	num	TOTAL ESRS (BUCCO-LINGUO-MASTICATORY)		Collected at CRF.
TOTDK	num	TOTAL ESRS SCORE (DYSKINETIC MOVEMENTS)		Collected at CRF.
TOTDYST	num	TOTAL ESRS SCORE (DYSTONIA)		Collected at CRF.
TOTHYPER	num	TOTAL ESRS SCORE (HYPERKINETIC)		Collected at CRF.
TOTHYPO	num	TOTAL ESRS SCORE (HYPOKINETIC)		Collected at CRF.
TOTPARK	num	TOTAL ESRS SCORE (PARKINSONISM)		Collected at CRF.
TOTQUES	num	TOTAL ESRS SCORE (QUESTIONNAIRE)		Collected at CRF.
TREATMNT	char	RANDOMIZATION GROUP		Collected at CRF.
VISIT	char	VISIT DESCRIPTION		Collected at CRF.
RBATCH	char	BATCH NUMBER		Collected at CRF.
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.
WT	num	WEIGHT		Collected at CRF.
CARRYFWD	char	CARRYFWD		Collected at CRF.
DIAG	char	DIAGNOSIS		Collected at CRF.

Variable	Type	Label	Codes	Comments
TG	char	RANDOMIZATION GROUP		Collected at CRF.
COMPLETE	char	DID THE PAT COMPLETE THE STUDY		Collected at CRF.
DISCREAS	char	REASON FOR DISCONTINUATION		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
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.
CSCDCDY	num	RELATIVE COMPL/DC DAY		If CSCDCDTE and REF.DATE not missing then perform below logic to calculate CSCDCDY, If CSCDCDTE less than REF.DATE then (CSCDCDTE - REF.DATE). Else if CSCDCDTE is greater than equal to REF.DATE then (CSCDCDTE- REF.DATE) +1.

## 1.4.5.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, LNSEQNO
<b>Sorted by</b>	LABTEST, LNFROMDY, LNSEQNO
<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: LABID,ZLABID,WGHTFROM,WGHTTO,WGHT_U

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LNFROM_D	num	RANGE APPLIC. FROM		Collected at CRF.
LNTO_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.

#### 1.4.6.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 missing values: SAMPLE_D,SAMPLE_T,LABID,ZLABID

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.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABLOW	num	LOWER LIMIT		Collected at CRF.
LABUPP	num	UPPER LIMIT		Collected at CRF.
LABTST_U	char	TEST UNIT		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.
SEX	char	SEX		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.

## 1.4.7.LABORATORY RESULTS – LABSAM

<b>Dataset</b>	LABSAM
<b>Creating program</b>	labsam.sas
<b>Description</b>	LABORATORY RESULTS
<b>Unique identifier</b>	DCRFID,VISIT,SAMPLEDY
<b>Sorted by</b>	DCRFID,VISIT,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.
VISIT	num	VISIT		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.

## 1.4.8.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,ZLABID,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	char	URINE VALUE		Collected at CRF.
LUVAL_V	char	URINE VALUE (VERB.)		Collected at CRF.
LABCLASS	char	CLASS		Collected at CRF.
LABTSTNO	num	SEQ_TEST		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.

#### 1.4.9.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.
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.

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

#### 1.4.10. RANDOMISATION GROUPS – TRLRAND

<b>Dataset</b>	TRLRAND
<b>Creating program</b>	trlrand.sas
<b>Description</b>	RANDOMISATION GROUPS
<b>Unique identifier</b>	RANDGRP
<b>Sorted by</b>	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.

## 1.4.11. ADMINISTRATION OF TRIAL MEDICATION – XADMMED

<b>Dataset</b>	XADMMED
<b>Creating program</b>	xadmmmed.sas
<b>Description</b>	ADMINISTRATION OF TRIAL MEDICATION
<b>Unique identifier</b>	DCRFID,RANDGRP,AMFROMDY
<b>Sorted by</b>	DCRFID,RANDGRP,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: INVEST,BOX,AMFROM_D,AMTO_D,AMTO_T,AMREAS,ZAMREAS,XAMFROM,AMFROM,XAMREAS,XAMTO,AMTO

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID for De-identity
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
TRIAL	char	TRIAL ID.		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
AMFROM_T	num	ADMIN. FROM TIME		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
AMDOSE	char	DOSE SCHEDULE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEGMENT	num	TRIAL SEGMENT SEQ.		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.
XTREAT	char	TREATMENT		Collected at CRF.
XTDD	num	TOTAL DAILY DOSE, mg		Collected at CRF.
XDUR	num	DURATION, days		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. 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.



## 1.4.12. XADMSUM – XADMSUM

<b>Dataset</b>	XADMSUM
<b>Creating program</b>	xadmsum.sas
<b>Description</b>	XADMSUM
<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: RANDLIST,INVEST

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.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
XAGE	char	AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
XPHASE	char	STUDY PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
XRXMEANA	num	MEAN DOSE, mg (INCLUDES DAYS OFF DRUG)		Collected at CRF.
XTOTDUR	num	TOTAL DURATION, days		Collected at CRF.
XRXMEANB	num	MEAN DOSE, mg (DAYS ON DRUG ONLY)		Collected at CRF.
XRXDUR	num	DURATION OF TREATMENT, days		Collected at CRF.
XRXMAXA	num	MAXIMUM DOSE, mg		Collected at CRF.
XRXMINA	num	MINIMUM DOSE, mg(INCLUDES DAYS OFF DRUG)		Collected at CRF.
XRXMINB	num	MINIMUM DOSE, mg (DAYS ON DRUG ONLY)		Collected at CRF.
XRXMODA	num	MODE DOSE, mg(INCLUDES DAYS OFF DRUG)		Collected at CRF.
XRXMODB	num	MODE DOSE, mg (DAYS ON DRUG ONLY)		Collected at CRF.
SEGMENT	num	SEGMENT		Collected at CRF.

## 1.4.13. ADVERSE EVENTS – XAE

<b>Dataset</b>	XAE
<b>Creating program</b>	xae.sas
<b>Description</b>	ADVERSE EVENTS
<b>Unique identifier</b>	DCRFID,PPHASE,AEFROMMDY,AESEQNO
<b>Sorted by</b>	DCRFID,PPHASE,AEFROMMDY,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,XINREACH,AEINCL,AEFROM_D,AEFROM_C,AEFROM_T,AETO_D,AETO_C,AETO_T,AECONRX,ZAECONRX,ADREMNUM,RANGLIST,INVEST,BIRTH_D,INITIALS,XHEIGHT,AGEFSYMP,AGEFHOSP,FHOSP_D,DURHOSPU,COURSE

Variable	Type	Label	Codes	Comments
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
XTE	char	TREATMENT EMERGENT		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.
XDYSONDS	char	DAYS ON ONSET DOSE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
PPHASE	char	TRIAL PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
XONSETDS	char	ONSET DOSE		Collected at CRF.
XTAEDUR	char	TOTAL DURATION		Collected at CRF.
XONSETDY	num	DAYS TO ONSET		Collected at CRF.
XAEDUR	num	DURATION IN PHASE		Collected at CRF.
XREACH	num	THERAPEUTIC REACH, days		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
ZAESV	num	AE SEVERITY CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		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	AE PREFERRED TERM		Collected at CRF.
AESOC	char	AE SYSTEM ORGAN CLASS		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
TRIAL	char	TRIAL ID		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.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
XAGE	char	AGE		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		Collected at CRF.
DIAGN	char	DIAGNOSIS		Collected at CRF.
DURHOSP	num	DURATION CURRENT HOSPITALIZATION		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.

## 1.4.14. ADVERSE EVENTS – XAEESRS

<b>Dataset</b>	XAEESRS
<b>Creating program</b>	xaeesrs.sas
<b>Description</b>	ADVERSE EVENTS
<b>Unique identifier</b>	DCRFID,PPHASE,AEFROMDY,AESEQNO
<b>Sorted by</b>	DCRFID,PPHASE,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,AEINCL,AEFROM_D,AEFROM_C,AEFROM_T,AETO_D,AETO_C, AETO_T,AECONRX,ZAECONRX,ADREMNUM,RANDLIST,INVEST,BIRTH_D, INITIALS,XHEIGHT,AGEFSYMP,AGEFHOSP,FHOSP_D,DURHOSPU,COURSE

Variable	Type	Label	Codes	Comments
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
XTE	char	TREATMENT EMERGENT		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.
XDYSONDS	char	DAYS ON ONSET DOSE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
PPHASE	char	TRIAL PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
XTAEDUR	char	TOTAL DURATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
XINREACH	char	BEGAN IN REACH		Collected at CRF.
XONSETDY	num	DAYS TO ONSET		Collected at CRF.
XAEDUR	num	DURATION IN PHASE		Collected at CRF.
XREACH	num	THERAPEUTIC REACH, days		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
ZAESSEV	num	AE SEVERITY CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		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	AE PREFERRED TERM		Collected at CRF.
AESOC	char	AE SYSTEM ORGAN CLASS		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
TRIAL	char	TRIAL ID		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.

Variable	Type	Label	Codes	Comments
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
XAGE	char	AGE		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		Collected at CRF.
DIAGN	char	DIAGNOSIS		Collected at CRF.
DURHOSP	num	DURATION CURRENT HOSPITALIZATION		Collected at CRF.
AGECAT	char	AGECAT		Collected at CRF.
POSUNIT	num	POSUNIT		Collected at CRF.
XONSETDS	char	ONSET DOSE		Collected at CRF.
XSTR_U	char	XSTR_U		Collected at CRF.
AEDC	char	DISCONTINUED DUE TO AN ADVERSE EVENT?		Collected at CRF.
ESRSTOT	num	VISIT ASSESSMENT		Collected at CRF.
ESRS	char	TOTAL ESRS SCORE AT BASELINE		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.

#### 1.4.15. ADVERSE EVENTS – XAETRAN

<b>Dataset</b>	XAETRAN
<b>Creating program</b>	xaetrain.sas
<b>Description</b>	ADVERSE EVENTS
<b>Unique identifier</b>	DCRFID,PPHASE,AEFROMDY,AESEQNO
<b>Sorted by</b>	DCRFID,PPHASE,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,AEINCL,AEFROM_D,AEFROM_C,AEFROM_T,AETO_D,AETO_C,AETO_T, AECONRX,ZAECONRX,ADREMNUM,RANLIST,INVEST,XHEIGHT

Variable	Type	Label	Codes	Comments
XSTR_U	char	STRENGTH UNIT		Collected at CRF.
XTE	char	TREATMENT EMERGENT		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.

Variable	Type	Label	Codes	Comments
XDYSONDS	char	DAYS ON ONSET DOSE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
PPHASE	char	TRIAL PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
XONSETDS	char	ONSET DOSE		Collected at CRF.
XTAEDUR	char	TOTAL DURATION		Collected at CRF.
XINREACH	char	BEGAN IN REACH		Collected at CRF.
XONSETDY	num	DAYS TO ONSET		Collected at CRF.
XAEDUR	num	DURATION IN PHASE		Collected at CRF.
XREACH	num	THERAPEUTIC REACH, days		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
ZAESV	num	AE SEVERITY CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZARELAT	num	AE DRUG RELATION CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		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.

Variable	Type	Label	Codes	Comments
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.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
TRIAL	char	TRIAL ID		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
XAGE	char	AGE		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		Collected at CRF.
DURATION	char	DURATION OF TREATMENT		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.

## 1.4.16. CONCOMITANT THERAPY – XCOTHER

<b>Dataset</b>	XCOTHER
<b>Creating program</b>	xcother.sas
<b>Description</b>	CONCOMITANT THERAPY
<b>Unique identifier</b>	DCRFID,CONRX,RXWHONUM,CTSEQNO
<b>Sorted by</b>	DCRFID,CONRX,RXWHONUM,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: INVEST,CTTYPE,CONRX_V,CTSCHED,CTIND,CTFROM_D,CTFROM_C, CTFROM_T,CTTO_D,CTTO_C,CTTO_T,ATCCODE8,ATCCODE9,ATCTEXT0, ATCTEXT1,ATCTEXT2,ATCTEXT3,ATCTEXT4,ATCTEXT5,ATCTEXT6,ATCTEXT7, ATCTEXT8,ATCTEXT9,CMSTOP

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.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
ITT	char	ALL SUBJECTS		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONRX	char	CO-RX		Collected at CRF.
CTIND_V	char	INDICATION (VERB.)		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.
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.
CMSTOPDY	num	RELATIVE STOP DAY		If CMSTOP and REF.DATE not missing then perform below logic to calculate CMSTOPDY, If CMSTOP less than REF.DATE then (CMSTOP - REF.DATE). Else if CMSTOP is greater than equal to REF.DATE then (CMSTOP- REF.DATE) +1.

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

#### 1.4.17. ELECTROCARDIOGRAM – XECG

<b>Dataset</b>	XECG
<b>Creating program</b>	xecg.sas
<b>Description</b>	ELECTROCARDIOGRAM
<b>Unique identifier</b>	DCRFID,RANDGRP,BASE,XPHASE,VISIT,VISIT_DY
<b>Sorted by</b>	DCRFID,RANDGRP,BASE,XPHASE,VISIT,VISIT_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: RANDLIST,INVEST,BSCSFLAG,CSFLAG,CSHI,CSLOW,DBASE,DVALUE,VISIT_D, XIMPUTE

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.

Variable	Type	Label	Codes	Comments
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
XAGE	char	AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
BASE	num	BASELINE RESULT		Collected at CRF.
DIFF	num	DIFFERENCE		Collected at CRF.
PARAM	char	DESCRIPTION OF CLINICAL ASSESSMENT		Collected at CRF.
XPHASE	char	TRIAL PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
VALUE	num	VISIT RESULT		Collected at CRF.
VISIT	num	VISIT NUMBER		Collected at CRF.
XDYSINPH	num	NUMBER OF DAYS IN CURRENT PHASE		Collected at CRF.
XTIME	char	TIME POINT		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. ELECTROCARDIOGRAM – XECGUS72

<b>Dataset</b>	XECGUS72
<b>Creating program</b>	xecgus72.sas
<b>Description</b>	ELECTROCARDIOGRAM
<b>Unique identifier</b>	DCRFID,RANDGRP,BASE,XPHASE,VISIT,VISIT_DY
<b>Sorted by</b>	DCRFID,RANDGRP,BASE,XPHASE,VISIT,VISIT_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: RANDLIST,INVEST,BIRTH_D,INITIALS,XHEIGHT,AGEFSYMP,AGEFHOSP, FHOSP_D,DURHOSPU,COURSE,BSCSFLAG,CSFLAG,CSHI,CSLOW,DBASE, DVALUE,VISIT_D,XIMPUTE,RELDAY

Variable	Type	Label	Codes	Comments
XTIME	char	TIME POINT		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
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.



Variable	Type	Label	Codes	Comments
XAGE	char	AGE		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		Collected at CRF.
DIAGN	char	DIAGNOSIS		Collected at CRF.
DURHOSP	num	DURATION CURRENT HOSPITALIZATION		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
BASE	num	BASELINE RESULT		Collected at CRF.
DIFF	num	DIFFERENCE		Collected at CRF.
PARAM	char	DESCRIPTION OF CLINICAL ASSESSMENT		Collected at CRF.
XPHASE	char	TRIAL PHASE		Collected at CRF.
VALUE	num	VISIT RESULT		Collected at CRF.
VISIT	num	VISIT NUMBER		Collected at CRF.
XDYSINPH	num	NUMBER OF DAYS IN CURRENT PHASE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
ABNCODE	char	ABNCODE		Collected at CRF.
ABNCODES	char	ABNCODES		Collected at CRF.
ABNBCODE	char	ABNBCODE		Collected at CRF.
ABNINT	char	ABNINT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ABNINTS	char	ABNINTS		Collected at CRF.
ITT	char	ALL SUBJECTS		Collected at CRF.
QTCABN	char	SUBJECTS WITH ABNORMAL QTc POST-BASELINE		Collected at CRF.
QTCPATH	char	SUBJECTS WITH PATHOLOGICAL QTc VALUES		Collected at CRF.
QTCBABN	char	SUBJECTS WITH ABNORMAL QTcb POST-BASELIN		Collected at CRF.
QTCBPATH	char	SUBJECTS WITH PATHOLOGICAL QTcb VALUES		Collected at CRF.
QTCFABN	char	SUBJECTS WITH ABNORMAL QTcf POST-BASELIN		Collected at CRF.
QTCFPATH	char	SUBJECTS WITH PATHOLOGICAL QTcf VALUES		Collected at CRF.
QTL CABN	char	SUBJECTS WITH ABNORMAL QTLC POST-BASELIN		Collected at CRF.
QTLCPATH	char	QTLCPATH		Collected at CRF.
QTCGT60	char	CHANGE OF QTC > 60 MSEC		Collected at CRF.
QTCGE30	char	CHANGE OF QTC >= 30 MSEC		Collected at CRF.
QTL CGT60	char	CHANGE OF QTLC > 60 MSEC		Collected at CRF.
QTL CGE30	char	CHANGE OF QTLC >= 30 MSEC		Collected at CRF.
QTCFGT60	char	CHANGE OF QTCF > 60 MSEC		Collected at CRF.

Variable	Type	Label	Codes	Comments
QTCFGE30	char	CHANGE OF QTCF >= 30 MSEC		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.

#### 1.4.19. LABORATORY – XLAB

<b>Dataset</b>	XLAB
<b>Creating program</b>	xlab.sas
<b>Description</b>	LABORATORY
<b>Unique identifier</b>	DCRFID,XPHASE,LABTEST,SAMPLEDY
<b>Sorted by</b>	DCRFID,XPHASE,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: LABID,XABNCODE,INVEST,RANLIST,SAMPLE_D

Variable	Type	Label	Codes	Comments
BASE	num	BASELINE RESULT		Collected at CRF.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		Collected at CRF.
SIUNIT	char	STANDARD INTL. UNIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
XDOSE	char	DOSE		Collected at CRF.
XREGION	char	REGION OF THE VALUE		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
XDYSONDS	char	DAYS ON DOSE		Collected at CRF.
XDYSINPH	num	DAYS IN PHASE		Collected at CRF.
SHFTDAY0	char	SHIFT VERSUS BASELINE		Collected at CRF.
SIVALUE	num	LAB VALUE IN SI UNIT		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
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
XAGE	char	AGE		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.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
XWEIGHT	num	WEIGHT, KG		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABUPP	num	UPPER NORMAL LIMIT		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.
LABTSTNO	num	LAB. TEST NO		Collected at CRF.
LABCLASS	char	LAB.TEST CLASS		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
ABBREV	char	ABBREVIATION OF LAB TEST NAME		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
PCTCHNG	num	PERCENT CHANGE FROM BASELINE		Collected at CRF.
POSTDAYS	num	NUMBER OF DAYS REL TO STOP DRUG DATE		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. XPANSS – XPANSS

<b>Dataset</b>	XPANSS
<b>Creating program</b>	xpanss.sas
<b>Description</b>	XPANSS
<b>Unique identifier</b>	DCRFID,RANDGRP,XTIME,XPHASE,VISIT,PARAM
<b>Sorted by</b>	DCRFID,RANDGRP,XTIME,XPHASE,VISIT,PARAM
<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: DBASE,XTDDOSE,INVEST,XIMPUTE,RANLIST,VISIT_D

Variable	Type	Label	Codes	Comments
BASE	num	BASELINE ASSESSMENT		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
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
DVALUE	char	VISIT ASSESSMENT DESCRIPTION		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
XCENTER	char	POOLED CENTER		Collected at CRF.
XDYSINPH	num	DAYS IN PHASE		Collected at CRF.
XTIME	char	VISIT SLOT		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.

Variable	Type	Label	Codes	Comments
XPHASE	char	TRIAL PHASE		Collected at CRF.
RANDGRP	char	RANDGRP		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
TRIAL	char	TRIAL ID		Collected at CRF.
VALUE	num	VISIT ASSESSMENT		Collected at CRF.
PARAM_NR	num	PARAMETER NUMBER		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
XAGE	char	AGE		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.

## 1.4.21. XPHASE – XPHASE

<b>Dataset</b>	XPHASE
<b>Creating program</b>	xphase.sas
<b>Description</b>	XPHASE
<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: BNFROM_D,PHFROM_D,PHTO_D,BNTO_D

Variable	Type	Label	Codes	Comments
FSTTRTPH	char	FIRST TREATMENT PHASE		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRF ID for De-identity
TRIAL	char	TRIAL ID		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
REACHPRE	num	REACH BEFORE PHASE		Collected at CRF.
REACHPST	num	REACH AFTER PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.



Variable	Type	Label	Codes	Comments
BNFROMDY	num	RELATIVE BOUNDARY START DAY OF PHASE		If BNFROM_D and REF.DATE not missing then perform below logic to calculate BNFROMDY, If BNFROM_D less than REF.DATE then (BNFROM_D - REF.DATE). Else if BNFROM_D is greater than equal to REF.DATE then (BNFROM_D- REF.DATE) +1.
PHFROMDY	num	RELATIVE START DAY OF PHASE		If PHFROM_D and REF.DATE not missing then perform below logic to calculate PHFROMDY, If PHFROM_D less than REF.DATE then (PHFROM_D - REF.DATE). Else if PHFROM_D is greater than equal to REF.DATE then (PHFROM_D- REF.DATE) +1.
PHTO_DY	num	RELATIVE END DAY OF PHASE		If PHTO_D and REF.DATE not missing then perform below logic to calculate PHTO_DY, If PHTO_D less than REF.DATE then (PHTO_D - REF.DATE). Else if PHTO_D is greater than equal to REF.DATE then (PHTO_D- REF.DATE) +1.
BNTODY	num	RELATIVE BOUNDARY END DAY OF PHASE		If BNTOD_D and REF.DATE not missing then perform below logic to calculate BNTODY, If BNTOD_D less than REF.DATE then (BNTOD_D - REF.DATE). Else if BNTOD_D is greater than equal to REF.DATE then (BNTOD_D- REF.DATE) +1.

## 1.4.22. 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: INVEST

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.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
ITT	char	ALL SUBJECTS		Collected at CRF.

## 1.4.23. TRIAL DESCRIPTION – XTRLDESC

<b>Dataset</b>	XTRLDESC
<b>Creating program</b>	xtrldesc.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.
ZCOMPOND	char	ABBREVIATED COMPOUND NAME CODE		Collected at CRF.
COMPOND	char	COMPOUND NAME		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.
MULTCOUN	char	MULTICOUNTRY		Collected at CRF.
BLKSIZE	num	BLOCK SIZE		Collected at CRF.
INDICAT	char	INDICATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGEGRP	char	AGE GROUP		Collected at CRF.
SPECPOP	char	SPECIAL POPULATION		Collected at CRF.
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVTRIAL	char	PREVIOUS TRIAL		Collected at CRF.

#### 1.4.24. TRIAL MEDICATION REGIMENS – XTRLREGM

<b>Dataset</b>	XTRLREGM
<b>Creating program</b>	xtrlregm.sas
<b>Description</b>	TRIAL MEDICATION REGIMENS
<b>Unique identifier</b>	RANDGRP,TMDUR
<b>Sorted by</b>	RANDGRP,TMDUR
<b>Notes</b>	

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

Variable	Type	Label	Codes	Comments
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
STRENGTH	num	STRENGTH OF 1 UNIT		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
TMFREQ	char	ADMIN FREQ		Collected at CRF.
ZTMROUTE	char	ADMIN ROUTE CODE		Collected at CRF.
TMROUTE	char	ADMIN ROUTE		Collected at CRF.
TMDUR	num	SEGMENT DURATION NUM		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

## 1.4.25. 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: TTFROM_D,TTFROM_T,TTREAS_V,RANGLIST,INVEST

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
TTTYPE	char	TERM. TYPE		Collected at CRF.
TTREAS	char	TERM. REASON		Collected at CRF.
XPHASE	char	XPHASE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.

Variable	Type	Label	Codes	Comments
XAGE	char	AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
XTREAT	char	TREATMENT		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.

## 1.4.26. VITAL SIGNS – XVITLSGN

<b>Dataset</b>	XVITLSGN
<b>Creating program</b>	xvitlsgn.sas
<b>Description</b>	VITAL SIGNS
<b>Unique identifier</b>	DCRFID,RANDGRP,BASE,VISIT,PARAM
<b>Sorted by</b>	DCRFID,RANDGRP,BASE,VISIT,PARAM
<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: RANDLIST,INVEST,BSCSFLAG,CSFLAG,CSHI,CSLOW,DBASE,DVALUE,VISIT_D, XIMPUTE

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.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	PATIENTS RACE		Group element to protect PII.
XAGE	char	AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
BASE	num	BASELINE RESULT		Collected at CRF.



Variable	Type	Label	Codes	Comments
DIFF	num	DIFFERENCE		Collected at CRF.
PARAM	char	DESCRIPTION OF CLINICAL ASSESSMENT		Collected at CRF.
XPHASE	char	TRIAL PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
VALUE	num	VISIT RESULT		Collected at CRF.
VISIT	num	VISIT NUMBER		Collected at CRF.
XDYSINPH	num	NUMBER OF DAYS IN CURRENT PHASE		Collected at CRF.
XTIME	char	TIME POINT		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.