

Clinical Development

## Galantamine

Gal\_17\_26

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

## 1. Datasets

### 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

#### Part I: Dataset description

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

#### Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Codes	Code list 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 due to sensitivity of the data.
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and 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 "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Catalog number will not be provided.
- Vial, Bottle, lot, kit number will not be provided.
- Central Lab Specimen Label Number 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.
- Datasets with zero observation will not be submitted (ex. LABNOR, PKOUTL, PKRES)
- Dataset containing investigator information is sensitive and hence will not be submitted. (ex. INVEST)
- Dataset containing sensitive information about medication kit will not be submitted. (ex. BOX)
- PRESURG dataset will not be submitted due to sensitivity of information.
- Remarks dataset will be submitted with zero observation due to sensitivity of data.
- Datasets containing insignificant information will not be submitted(ex. TRLRAND, TRLLIST).
- Visit Date(VISIT\_D) when Visit=1 from VISIT dataset will be used as Reference Date to derive relative days (referred as Ref. Date in the document).

### 1.3. Data Files

The Gal\_17\_26 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:  INVEST,ZINVEST,ZCOUNTRY,INITIALS,BIRTH_D,COGPRB_D,CMSCAN_D,  RAND_D,MEDNO,COINV,ZCOINV,BREAK_D,BREAK_V,RACE_V</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:</p> <p>RANDCODE (Source: TRLRAND dataset)  RANDGRP (Source: TRLLIST dataset)</p>

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

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
ETHNIC	char	ETHNICITY		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
PREGRES	char	PREGNANT		Collected at CRF.
RELATIVE	char	FIRST DEGREE RELATIVES WITH AD		Collected at CRF.
CHOLINOM	char	SUBJECT TAKEN CHOLINOMIMETICS		Collected at CRF.
DNAAPPR	char	DNA APPROVAL		Collected at CRF.
DNADRAW	char	DNA DRAWN		Collected at CRF.
DNACONST	char	INFORMED CONSENT OBTAINED		Collected at CRF.
DNASTOR	char	OBTAINED FOR STORAGE		Collected at CRF.
DNAANAL	char	SPECIFIC DNA ANALYSIS		Collected at CRF.
DISCVIS	num	D/C VISIT		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
BREAK	char	CODE BROKEN ?		Collected at CRF.
DEATHNA	char	EVENT OF DEATH		Collected at CRF.
CONFIRM	char	INCL/EXCL CONFIRMED		Collected at CRF.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.



Variable	Type	Label	Codes	Comments
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
AGE	char	AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: $AGE = \text{int}((REF.DATE - BIRTH\_D) / 365.25)$  If age greater than 89+ years then will be grouped as per HIPAA rules.
COGPRBDY	num	RELATIVE ONSET DAY OF COGNITIVE PROBLEMS		If COGPRB_D and REF.DATE not missing then perform below logic to calculate COGPRBDY, If COGPRB_D less than REF.DATE then (COGPRB_D - REF.DATE). Else if COGPRB_D is greater than equal to REF.DATE then (COGPRB_D - REF.DATE) +1.
CMSCANDY	num	RELATIVE MRI SCAN DAY		If CMSCAN_D and REF.DATE not missing then perform below logic to calculate CMSCANDY, If CMSCAN_D less than REF.DATE then (CMSCAN_D - REF.DATE). Else if CMSCAN_D is greater than equal to REF.DATE then (CMSCAN_D - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RAND_DY	num	RELATIVE RANDOMIZATION DAY		If RAND_D and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_D less than REF.DATE then (RAND_D - REF.DATE). Else if RAND_D is greater than equal to REF.DATE then (RAND_D- REF.DATE) +1.
BREAK_DY	num	RELATIVE DAY CODE BREAKING		If BREAK_D and REF.DATE not missing then perform below logic to calculate RAND_DY, If BREAK_D less than REF.DATE then (BREAK_D- REF.DATE). Else if BREAK_D is greater than equal to REF.DATE then (BREAK_D- REF.DATE) +1.

## 1.4.2. Alzheimer's Disease Assessment Scale – ADAS

<b>Dataset</b>	ADAS
<b>Creating program</b>	adas.sas
<b>Description</b>	Alzheimer's Disease Assessment Scale
<b>Unique identifier</b>	DCRFID,ADTYPE,ADITEM,ADTRIAL,VISIT
<b>Sorted by</b>	DCRFID,ADTYPE,ADITEM,ADTRIAL,VISIT
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
ADTYPE	char	TYPE OF ADAS TEST		Collected at CRF.
ADTRIAL	num	TRIAL SEQUENCE		Collected at CRF.
ADITEM	char	ADAS TEST ITEM		Collected at CRF.
ADSCORE	char	ADAS TEST ITEM SCORE		Collected at CRF.
ADVALUE	num	ADAS TEST ITEM VALUE		Collected at CRF.

## 1.4.3.Activities of Daily Living – ADL

<b>Dataset</b>	ADL
<b>Creating program</b>	adl.sas
<b>Description</b>	Activities of Daily Living
<b>Unique identifier</b>	DCRFID,ALITEM,VISIT
<b>Sorted by</b>	DCRFID,ALITEM,VISIT
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
ALITEM	char	ITEM		Collected at CRF.
ALYESNO	char	YES/NO/DON'T KNOW		Collected at CRF.
ALSCORE	char	SCORE		Collected at CRF.

## 1.4.4. Administration of Trial Medication – ADMMED

<b>Dataset</b>	ADM MED
<b>Creating program</b>	admmed.sas
<b>Description</b>	Administration of Trial Medication
<b>Unique identifier</b>	DCRFID, SEGMENT, PHASE, NUMFORM1, AMFROMDY
<b>Sorted by</b>	DCRFID, SEGMENT, PHASE, NUMFORM1, 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, BOX

Variable	Type	Label	Codes	Comments
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.
SEGMENT	num	SEGMENT		Collected at CRF.
NUMFORM1	num	UNITS PER ADMIN. 1		Collected at CRF.
NUMFORM2	num	UNITS PER ADMIN. 2		Collected at CRF.
AMREAS1	char	REGIMEN CHANGE REASON 1		Collected at CRF.
ZAMREAS1	char	REGIMEN CHANGE REASON 1 CODE		Collected at CRF.
AMREAS2	char	REGIMEN CHANGE REASON 2		Collected at CRF.
ZAMREAS2	char	REGIMEN CHANGE REASON 2 CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
AMDOSE	num	DOSE		Collected at CRF.
AMDOSE_U	char	DOSE UNIT		Collected at CRF.
DOSE	char	CHANGE IN 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. 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.

### 1.4.5. Adverse Events – AE

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	DCRFID, AEPREF, AESEQNO
<b>Sorted by</b>	DCRFID, 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, AEINCL, PHASE, AEFROM_D, AETO_D, SAEREFNO, AESOC1, AESOC2, AESOC3

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

Variable	Type	Label	Codes	Comments
AECONRX	char	AE CO-RX START		Collected at CRF.
ZAECNRX	num	AE CO-RX START CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION CODE		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME CODE		Collected at CRF.
AESER	char	AE SERIOUSNESS		Collected at CRF.
ZAESER	num	AE SERIOUSNESS CODE		Collected at CRF.
AESOC	char	AE SYSTEM ORGAN CLASS		Collected at CRF.
AEWHONUM	char	AE WHO CODE		Collected at CRF.
AEPREF	char	ADVERSE EVENT PREFERRED TERM		Collected at CRF.
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.BAN Administration – BANADM

<b>Dataset</b>	BANADM
<b>Creating program</b>	banadm.sas
<b>Description</b>	BAN Administration
<b>Unique identifier</b>	DCRFID,BAADM_T,BAADM_DY,BAADMSEQ,VISIT
<b>Sorted by</b>	DCRFID,BAADM_T,BAADM_DY,BAADMSEQ,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BAADM_D,SAMREFNO,LABINTNO

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

Variable	Type	Label	Codes	Comments
BAADMSEQ	char	DRUG ADMIN. SEQ.		Collected at CRF.
BAADM_DY	num	RELATIVE DRUG ADMIN. DAY		If BAADM_D and REF.DATE not missing then perform below logic to calculate BAADM_DY, If BAADM_D less than REF.DATE then (BAADM_D - REF.DATE). Else if BAADM_D is greater than equal to REF.DATE then (BAADM_D - REF.DATE) +1.

### 1.4.7.BAN Measurements – BANRES

<b>Dataset</b>	BANRES
<b>Creating program</b>	banres.sas
<b>Description</b>	BAN Measurements
<b>Unique identifier</b>	DCRFID,VISIT,SAMTM_S
<b>Sorted by</b>	DCRFID,VISIT,SAMTM_S
<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,SAMREFNO,LABINTNO,BRINTNO

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SUBST	char	SUBSTANCE		Collected at CRF.
BRVAL	num	BAN MEASUREMENT		Collected at CRF.
BRVAL_V	char	BAN MEASUREMENT (VERB.)		Collected at CRF.
BRVAL_U	char	UNIT		Collected at CRF.
BRQUANT	num	LIMIT OF QUANTIFICATION		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SAMTM_S	char	SCHEDULED TIME		Collected at CRF.

## 1.4.8.Allocation of Caregiver Time Survey – CARETIME

<b>Dataset</b>	CARETIME
<b>Creating program</b>	caretime.sas
<b>Description</b>	Allocation of Caregiver Time Survey
<b>Unique identifier</b>	DCRFID, CRACTIV, CRSEQNO, VISIT
<b>Sorted by</b>	DCRFID, CRACTIV, CRSEQNO, VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CRACT_V1, CRACT_V2

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
CRSEQNO	num	CR SEQUENCE NUMBER		Collected at CRF.
CRACTIV	char	ACTIVITIES		Collected at CRF.
CRNO	char	NO ACTIVITIES		Collected at CRF.
CRYES	char	YES ACTIVITIES		Collected at CRF.
CRTMHR	char	DAILY TIME SPENT ON ACTIVITY(HRS)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRTMMIN	char	DAILY TIME SPENT ON ACTIVITY(MIN)		Collected at CRF.
CRDAY	num	NUMBER OF DAYS ACTIVITY WAS PERFORMED		Collected at CRF.

### 1.4.9.CIBIC-Plus – CIBIC

<b>Dataset</b>	CIBIC
<b>Creating program</b>	cibic.sas
<b>Description</b>	CIBIC-Plus
<b>Unique identifier</b>	DCRFID,CIBIC,VISIT
<b>Sorted by</b>	DCRFID,CIBIC,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CIBICRTR

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

Variable	Type	Label	Codes	Comments
CIBIC	char	SUBJECT STATUS COMPARED TO BASELINE		Collected at CRF.
ZCIBIC	num	SUBJECT STATUS COMPARED TO BASELINE CODE		Collected at CRF.

#### 1.4.10. Brain MRI – CMRI

<b>Dataset</b>	CMRI
<b>Creating program</b>	cmri.sas
<b>Description</b>	Brain MRI
<b>Unique identifier</b>	DCRFID,CMSYMP,VISIT,CMSEQNO
<b>Sorted by</b>	DCRFID,CMSYMP,VISIT,CMSEQNO
<b>Notes</b>	

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

Variable	Type	Label	Codes	Comments
CMSEV	char	RESPONSE		Collected at CRF.
CMNUM	char	NUMBER		Collected at CRF.

#### 1.4.11. Concomitant Therapy – COTHER

<b>Dataset</b>	COTHER
<b>Creating program</b>	cother.sas
<b>Description</b>	Concomitant Therapy
<b>Unique identifier</b>	DCRFID, RXPREF, CTSEQNO
<b>Sorted by</b>	DCRFID, RXPREF, 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: CONRX_V, CTIND_V, CTFROM_D, CTTO_D, ATCCODE1, ATCCODE2, ATCCODE3, ATCCODE4, ATCCODE5, ATCCODE6, ATCCODE7, ATCCODE8, ATCCODE9, ATCTEXT1, ATCTEXT2, ATCTEXT3, ATCTEXT4, ATCTEXT5, ATCTEXT6, ATCTEXT7, ATCTEXT8, ATCTEXT9

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

Variable	Type	Label	Codes	Comments
CONRX	char	CO-RX		Collected at CRF.
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTIND	char	CONCOMITANT MEDICATION INDICATION		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTFROM_C	char	CO-RX START CODE		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
CTTO_C	char	CO-RX END CODE		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
RXPREF	char	PREFERRED NAME		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.



### 1.4.12. Death – DEATH

<b>Dataset</b>	DEATH
<b>Creating program</b>	death.sas
<b>Description</b>	Death
<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: DEATH_D

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

### 1.4.13. Protocol Deviation – DEVIATN

<b>Dataset</b>	DEVIATN
<b>Creating program</b>	deviatn.sas
<b>Description</b>	Protocol Deviation
<b>Unique identifier</b>	DCRFID,DEVIAT,ZDEVIAT
<b>Sorted by</b>	DCRFID,DEVIAT,ZDEVIAT
<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: DVTYPE,DEVIAT_V

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

### 1.4.14. Diagnosis – DIAGNOS

<b>Dataset</b>	DIAGNOS
<b>Creating program</b>	diagnos.sas
<b>Description</b>	Diagnosis
<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: DIAGMON,DIAGYR

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

### 1.4.15. Medical History – DISEASES

<b>Dataset</b>	DISEASES
<b>Creating program</b>	diseases.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	DCRFID,DSSYSTEM,,DSSEQNO
<b>Sorted by</b>	DCRFID,DSSYSTEM,,DSSEQNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DISEAS_V

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

### 1.4.16. ECG Overall Interpretation – ECG

<b>Dataset</b>	ECG
<b>Creating program</b>	ecg.sas
<b>Description</b>	ECG Overall Interpretation
<b>Unique identifier</b>	DCRFID,EGRELCHA,VISIT,ECG_T
<b>Sorted by</b>	DCRFID,EGRELCHA,VISIT,ECG_T
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D,ECGREFNO,ECGINTNO

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.

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

### 1.4.17. ECG Abnormalities – ECGABN

<b>Dataset</b>	ECGABN
<b>Creating program</b>	ecgabn.sas
<b>Description</b>	ECG Abnormalities
<b>Unique identifier</b>	DCRFID, ECGOTH_V, ECG_DY, VISIT
<b>Sorted by</b>	DCRFIDE, CGOTH_V, ECG_DY, VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EASEQNO	num	EA SEQUENCE NUMBER		Collected at CRF.
ECGOTH_V	char	ECG OTHER ABN. (VERB.)		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.

### 1.4.18. ECG Evaluation – ECGEVAL

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

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



Variable	Type	Label	Codes	Comments
EEEVAL	char	ECG EVALUATION		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.

#### 1.4.19. ECG Measurements – ECGPAR

<b>Dataset</b>	ECGPAR
<b>Creating program</b>	ecgpar.sas
<b>Description</b>	ECG Measurements
<b>Unique identifier</b>	DCRFID, ECGPAR, VISIT, ECG_T, EPSEQNO
<b>Sorted by</b>	DCRFID, ECGPAR, VISIT, ECG_T, EPSEQNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EPSEQNO	num	EP SEQUENCE NUMBER		Collected at CRF.
ECGPARG	char	ECG PARAMETER		Collected at CRF.
ECGPARG_U	char	ECG MEASUREMENT UNIT		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		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.

### 1.4.20. ECG Reference – ECGREF

<b>Dataset</b>	ECGREF
<b>Creating program</b>	ecgref.sas
<b>Description</b>	ECG Reference
<b>Unique identifier</b>	DCRFID, EGRELCHA, VISIT
<b>Sorted by</b>	DCRFID, EGRELCHA, VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECGREFNO

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

## 1.4.21. EXIT - 25 Scoring Sheet – EXIT25

<b>Dataset</b>	EXIT25
<b>Creating program</b>	exit25.sas
<b>Description</b>	EXIT - 25 Scoring Sheet
<b>Unique identifier</b>	DCRFID,EXITEM,EXSEQNO,VISIT
<b>Sorted by</b>	DCRFID,EXITEM,EXSEQNO,VISIT
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
EXSEQNO	num	EX SEQUENCE NUMBER		Collected at CRF.
EXITEM	char	EX ITEM		Collected at CRF.
EXNAP	char	EX NAP		Collected at CRF.
EXSCORE	num	EX SCORE		Collected at CRF.

### 1.4.22. Cigarette Smoking – HABIT

<b>Dataset</b>	HABIT
<b>Creating program</b>	habit.sas
<b>Description</b>	Cigarette Smoking
<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
TRIAL	char	TRIALID.		Collected at CRF.
HATYPE	char	HABIT TYPE		Collected at CRF.
HABIT	char	HABIT		Collected at CRF.

## 1.4.23. Hachinski Schemic Score – HACH

<b>Dataset</b>	HACH
<b>Creating program</b>	hach.sas
<b>Description</b>	Hachinski Schemic Score
<b>Unique identifier</b>	DCRFID,HAITEM
<b>Sorted by</b>	DCRFID,HAITEM
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIALID.		Collected at CRF.
HASEQNO	num	HA SEQUENCE NUMBER		Collected at CRF.
HAITEM	char	FEATURE		Collected at CRF.
HARESLT	char	RESULT		Collected at CRF.

### 1.4.24. Inclusion Criteria – INEX

<b>Dataset</b>	INEX
<b>Creating program</b>	inex.sas
<b>Description</b>	Inclusion Criteria
<b>Unique identifier</b>	DCRFID,IECRIT
<b>Sorted by</b>	DCRFID,IECRIT
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIALID.		Collected at CRF.
IETYPE	char	TYPE OF SELECTION CRITERIA		Collected at CRF.
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	char	SELECTION CRITERIA CODE		Collected at CRF.
IEYN	char	NON-ELIGIBILITY EXPR.		Collected at CRF.

## 1.4.25. Laboratory Results – LABRES

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

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
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 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 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 NO.		Collected at CRF.
LABCLASS	char	LAB CLASS		Collected at CRF.
ENZYME	char	ENZYME		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D - REF.DATE) +1.

## 1.4.26. 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, VISIT, LUVAL, SAMPLEDY
<b>Sorted by</b>	DCRFID, LABTEST, VISIT, LUVAL, SAMPLEDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D, LABID, ZLABID, SAMREFNO, LABINTNO

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

Variable	Type	Label	Codes	Comments
LABTSTNO	num	LAB. TEST NO.		Collected at CRF.
LABCLASS	char	LAB CLASS		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D - REF.DATE) +1.

#### 1.4.27. Mini-Mental State Examination – MMSE

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

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
MMSEQNO	num	MM SEQUENCE NUMBER		Collected at CRF.
MMITEM	char	MMSE ITEM		Collected at CRF.
MMSCORE	num	MMSE SCORE		Collected at CRF.

### 1.4.28. Neurological Examination – NEUREXAM

<b>Dataset</b>	NEUREXAM
<b>Creating program</b>	neurexam.sas
<b>Description</b>	Neurological Examination
<b>Unique identifier</b>	DCRFID,NESYSTEM
<b>Sorted by</b>	DCRFID,NESYSTEM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: NEUR_V

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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
NESYSTEM	char	TEST/SIGNS		Collected at CRF.
NERESULT	char	NEURO EXAM RESPONSE		Collected at CRF.

#### 1.4.29. Neuropsychiatric Inventory – NPI

<b>Dataset</b>	NPI
<b>Creating program</b>	npi.sas
<b>Description</b>	Neuropsychiatric Inventory
<b>Unique identifier</b>	DCRFID,NPSYMP,NPSEQNO,VISIT
<b>Sorted by</b>	DCRFID,NPSYMP,NPSEQNO,VISIT
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
NPSEQNO	num	NP SEQUENCE NUMBER		Collected at CRF.
NPSYMP	char	SYMPTOM		Collected at CRF.
NPNO	num	NP NO		Collected at CRF.

Variable	Type	Label	Codes	Comments
NPSYSFRQ	num	FREQUENCY		Collected at CRF.
NPSEV	num	SEVERITY		Collected at CRF.
NPDIST	num	DISTRESS		Collected at CRF.
NPNAP	char	NOT APPLICABLE		Collected at CRF.

#### 1.4.30. Physical Examination – PHYSEXAM

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

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

Variable	Type	Label	Codes	Comments
PESEQNO	num	PE SEQUENCE NUMBER		Collected at CRF.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.
EXAM	char	PHYS. EXAM.		Collected at CRF.

#### 1.4.31. Pre-planned surgery / procedure – PRESURG

<b>Dataset</b>	PRESURG
<b>Creating program</b>	presurg.sas
<b>Description</b>	Pre-planned surgery / procedure
<b>Unique identifier</b>	DCRFID, PSBOSYS, PSSEQNO
<b>Sorted by</b>	DCRFID, PSBOSYS, PSSEQNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PSPROCED, PSSURG_D, PSIND_V

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

Variable	Type	Label	Codes	Comments
PSBOSYS	char	BODY SYSTEM		Collected at CRF.
ZPSBOSYS	num	BODY SYSTEM CODE		Collected at CRF.
PSSURGDY	num	RELATIVE DAY PLANNED SURGERY/PROCEDURE		If PSSURG_D and REF.DATE not missing then perform below logic to calculate PSSURGDY, If PSSURG_D less than REF.DATE then (PSSURG_D - REF.DATE). Else if PSSURG_D is greater than equal to REF.DATE then (PSSURG_D-REF.DATE) +1.

1.4.32. Related AEs for Trial Termination or Death – RELAE

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

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



Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
RATYPE	char	AE CONSEQUENCE		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.

### 1.4.33. Remarks – REMARK

<b>Dataset</b>	REMARK
<b>Creating program</b>	remark.sas
<b>Description</b>	Remarks
<b>Unique identifier</b>	Not Applicable
<b>Sorted by</b>	Not Applicable
<b>Notes</b>	Remarks dataset contains sensitive information. Hence dataset will be submitted with zero observation.

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

### 1.4.34. Subject Socio-Demographics – RESQUEST

<b>Dataset</b>	RESQUEST
<b>Creating program</b>	resquest.sas
<b>Description</b>	Subject Socio-Demographics
<b>Unique identifier</b>	DCRFID,LIVSIT,CAREFAM,SUPERVIS,VISIT
<b>Sorted by</b>	DCRFID,LIVSIT,CAREFAM,SUPERVIS,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CARBIR_D

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
STATUS	char	REFUSED/CAREGIVER NOT AVAIL(A)		Collected at CRF.
LIVSIT	char	USUAL LIVING SITUATION OR HAS CHANGED(A)		Collected at CRF.
SCHOOLED	char	HIGHEST LEVEL OF EDUCATION(A)		Collected at CRF.
CAREFAM	char	AN INFORMAL/FAMILY CAREGIVER(B)		Collected at CRF.
CARSEX	char	CAREGIVERS SEX(B)		Collected at CRF.
CARRELAT	char	CAREGIVER RELATIONSHIP TO SUBJ(B)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CARLIV	char	CAREGIVER LIVING WITH SUBJECT(B)		Collected at CRF.
SUPERVIS	char	NEED TO BE PREVENT DANGERS(C)		Collected at CRF.
TMALNHR	char	LEFT ALONE ON TYPICAL DAY(HRS)(C)		Collected at CRF.
TMALNMIN	char	LEFT ALONE ON TYPICAL DAY(MIN)(C)		Collected at CRF.
TMWKHR	char	LEFT ALONE IN THE PAST WEEK(HRS)(C)		Collected at CRF.
TMWKMIN	char	LEFT ALONE IN THE PAST WEEK(MIN)(C)		Collected at CRF.
TMFREHR	char	FREE TIME WITHOUT ASSISTANCE(HRS)(C)		Collected at CRF.
TMFREMIN	char	FREE TIME WITHOUT ASSISTANCE(MIN)(C)		Collected at CRF.
ASSIST	char	ASSISTANCE TIME SPENT(C)		Collected at CRF.
CARESAME	char	SAME CAREGIVER PROVIDES INFO(B)		Collected at CRF.
CAREVIS	char	CAREGIVER-VISITOR(B)		Collected at CRF.
CARENEW	char	NEW CAREGIVER		Collected at CRF.
CARAGE	char	CAREGIVERS AGE IN YEARS		<p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving CARAGE, element derivation follows below rule:</p> $\text{CARAGE} = \text{int}((\text{REF.DATE} - \text{CARBIR\_D}) / 365.25)$ <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p>

### 1.4.35. PK Blood Sample – SAMPLE

<b>Dataset</b>	SAMPLE
<b>Creating program</b>	sample.sas
<b>Description</b>	PK Blood Sample
<b>Unique identifier</b>	DCRFID,SPECIMEN,SAMPLEDY,SAMPLE_T,VISIT
<b>Sorted by</b>	DCRFID,SPECIMEN,SAMPLEDY,SAMPLE_T,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: SAMPLE_D, LABID,ZLABID,FASTED,SAMREFNO, LABINTNO,SASAME,SARELCHA

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

### 1.4.36. PK Blood Sample Reference – SAMREF

<b>Dataset</b>	SAMREF
<b>Creating program</b>	samref.sas
<b>Description</b>	PK Blood Sample Reference
<b>Unique identifier</b>	DCRFID,SARELCHA,VISIT
<b>Sorted by</b>	DCRFID,SARELCHA,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMREFNO

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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
SARELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.

#### 1.4.37. 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>	Below listed variables will be dropped from dataset due to missing values: SPECPOP

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID		Collected at CRF.
COMPOND	char	COMPOUND NAME		Collected at CRF.
ZCOMPOND	char	COMPOUND NAME CODE		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.
PLACONTR	char	PLACEBO CONTROL		Collected at CRF.
ACTCONTR	char	ACTIVE CONTROL		Collected at CRF.

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.
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.

#### 1.4.38. Trial Regimen – TRLREGM

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

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

Variable	Type	Label	Codes	Comments
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	SEGMENT		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.
FORMULAT	char	FORMULATION		Collected at CRF.
STRENGTH	num	STRENGTH OF 1 UNIT		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN		Collected at CRF.
TMFREQ	char	TRIAL REGIMEN 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.
BLINDING	char	BLINDING		Collected at CRF.



### 1.4.39. Trial Disposition – TRTERM

<b>Dataset</b>	TRTERM
<b>Creating program</b>	trterm.sas
<b>Description</b>	Trial Disposition
<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: TRREAS_V,TRFROM_D

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

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

#### 1.4.40. Visit General Info – VISIT

<b>Dataset</b>	VISIT
<b>Creating program</b>	visit.sas
<b>Description</b>	Visit General Info
<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: VISIT_D,ADVIS_D,RATER,ADL_D,CIBIC_D

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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
ADVIS_T	num	ADAS VISIT TIME		Collected at CRF.
PSYMED	char	PSYCHOTROPIC MEDICATIONS		Collected at CRF.
NPRMCARE	char	WAS INTERVIEWED?		Collected at CRF.
NPRMCAR1	char	WAS INTERVIEWED AT BASELINE?		Collected at CRF.
CAREYN	char	CAREGIVER NOT AVAILABLE		Collected at CRF.
CARESAME	char	BASELINE CAREGIVER		Collected at CRF.
VSND	char	VITAL SIGNS NOT DONE		Collected at CRF.
LABND	char	LAB REF NOT DONE		Collected at CRF.
ECGND	char	ECG NOT DONE		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.
ADVIS_DY	num	RELATIVE ADAS VISIT DAY		If ADVIS_D and REF.DATE not missing then perform below logic to calculate ADVIS_DY, If ADVIS_D less than REF.DATE then (ADVIS_D - REF.DATE). Else if ADVIS_D is greater than equal to REF.DATE then (ADVIS_D - REF.DATE) + 1.

Variable	Type	Label	Codes	Comments
ADL_DY	num	RELATIVE DAY ADL PERFORMED		If ADL_D and REF.DATE not missing then perform below logic to calculate ADL_DY, If ADL_D less than REF.DATE then (ADL_D - REF.DATE). Else if ADL_D is greater than equal to REF.DATE then (ADL_D- REF.DATE) +1.
CIBIC_DY	num	RELATIVE CIBICASSESSMENT DAY		If CIBIC_D and REF.DATE not missing then perform below logic to calculate CIBIC_DY, If CIBIC_D less than REF.DATE then (CIBIC_D - REF.DATE). Else if CIBIC_D is greater than equal to REF.DATE then (CIBIC_D- REF.DATE) +1.

## 1.4.41. Vital Signs – VITSIGN

<b>Dataset</b>	VITSIGN
<b>Creating program</b>	vitsign.sas
<b>Description</b>	Vital Signs
<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
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
PULSE	num	PULSE, 1/MIN		Collected at CRF.
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLICBP, mmHg		Collected at CRF.