Clinical Development

# Galantamine

Gal-Int-2

Anonymisation Data Derivation Specification Document

| | |
|---|---|
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| Status and Version | Release Date | Summary of Key Changes |
|---|---|---|
| | | |
| | | |

# 1. Datasets

## 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

**Part I: Dataset description**

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

**Part II: Variables within dataset**

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

## 1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- 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.
- Datasets containing information that is not required for further analysis will not be submitted. (eg. CODE, DIAGNOS, TRLRAND, TRLLIST, TEMPLATE)
- Dataset containing investigator information is sensitive and hence will not be submitted. (eg.INVEST, RELATED).
- Dataset containing genomic information will not be submitted. (eg. APOEINT2)
- Visit Date(VISIT_D)when Visit=1 will be used as Reference Date to derive relative days (referred as Ref. Date in the document).

## 1.3. Data Files

The Gal-Int-2 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Subject Characteristics – SUBJCHAR

| | |
|---|---|
| **Dataset** | SUBJCHAR |
| **Creating program** | subjchar.sas |
| **Description** | Subject Characteristics |
| **Unique identifier** | DCRFID |
| **Sorted by** | DCRFID |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:<br>MEDNO, INVEST, ZINVEST, INITIALS, BIRTH_D, COGPRB_D, CMSCAN_D, BREAK_D, BREAK_V, DRYRUN, COINVEST<br>Below listed variables were not a part of the Raw dataset. These have been added to retain the Treatment and Country related information in the de-identified datasets:<br>RANDCODE (Source: TRLRAND dataset)<br>RANDGRP (Source: TRLLIST dataset)<br>DCOUNTRY (Source: INVEST dataset) |

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

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| DSITEID | char | SITE NO. ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site No. for De-identity |
| SEX | char | SEX | | Collected at CRF. |
| RACE | char | RACE | | Collected at CRF. |
| HEIGHT | num | HEIGHT | | Collected at CRF. |
| HEIGHT_U | char | HEIGHT UNIT | | Collected at CRF. |
| RELATIVE | char | FIRST DEGREE RELATIVE WITH AD | | Collected at CRF. |
| CHOLINUM | char | CLINICAL TRIALS WITH CHOLINOMIMETICS | | Collected at CRF. |
| BREAK_T | num | TIME CODE BREAKING | | Collected at CRF. |
| ENTRYCOM | char | ENTRY COMPLETED | | Collected at CRF. |
| PREGNANT | char | PREGNANT | | Collected at CRF. |
| DNAAPPR | char | APPROVAL FROM ETHICAL COMMITTEE | | Collected at CRF. |
| DNACONST | char | INFORMED CONSENT OBTAINED | | Collected at CRF. |
| DNAAPOE | char | OBTAINED FOR APO E GENOTYPING | | Collected at CRF. |
| DNASTOR | char | OBTAINED FOR STORAGE | | Collected at CRF. |
| RAND | char | RANDOMIZED AT END OF RUN-IN | | Collected at CRF. |
| RANDCODE | char | RANDOMISATION CODE | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| RANDGRP | char | RANDOMISATION GROUP | | Collected at CRF. |
| DCOUNTRY | char | DE-IDENTIFY COUNTRY | | Element will be grouped to protect PII. |
| 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:<br>AGE= int((REF.DATE – BIRTH_D)/365.25)<br><br>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 DAY SCAN PERFORMED | | 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. |
| BREAK_DY | num | RELATIVE DAY CODE BREAKING | | If BREAK_D and REF.DATE not missing then perform below logic to calculate BREAK_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

| | |
|---|---|
| **Dataset** | ADAS |
| **Creating program** | adas.sas |
| **Description** | Alzheimer's Disease Assessment Scale |
| **Unique identifier** | DCRFID, ADTYPE, ADITEM, ADTRIAL, VISIT |
| **Sorted by** | DCRFID, ADTYPE, ADITEM, ADTRIAL, VISIT |
| **Notes** | |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| ADTYPE | char | TEST | | Collected at CRF. |
| ADTRIAL | char | TRIAL NUMBER | | Collected at CRF. |
| ADITEM | char | ADAS ITEM | | Collected at CRF. |
| ADSCORE | char | ADAS SCORE | | Collected at CRF. |
| ADVALUE | char | VALUE | | Collected at CRF. |
| SORT_NO | num | PREFILL SORT NO | | Collected at CRF. |

### 1.4.3. Administration of Trial Medication – ADMMED

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

| 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. |
| NUMFORM | num | UNITS PER ADMIN. | | Collected at CRF. |
| AMFREQ | char | ADMIN. FREQ. | | Collected at CRF. |
| AMREAS | char | REGIMEN CHANGE REASON | | Collected at CRF. |
| ZAMREAS | char | REGIMEN CHANGE REASON CODE | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| AMFROMDY | num | RELATIVE ADMIN. START 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. END 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. |

### 1.4.4. Adverse Events – AE

| | |
|---|---|
| **Dataset** | AE |
| **Creating program** | ae.sas |
| **Description** | Adverse Events |
| **Unique identifier** | DCRFID, AEPREF, AEWHONUM, AESEQNO |
| **Sorted by** | DCRFID, AEPREF, AEWHONUM, AESEQNO |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:<br>AE_V, AEINCL, PHASE, AEFROM_D, AEFROM_C, AEREMNUM, AETO_D, AETO_C |

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

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| ZAECONRX | 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. |
| AEWHONUM | char | AE WHO CODE | | Collected at CRF. |
| AEPREF | char | ADVERSE EVENT PREFERRED TERM | | Collected at CRF. |
| AESOC | char | ADVERSE EVENT SYSTEM ORGAN CLASS | | Collected at CRF. |
| 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. |

### 1.4.5.CIBIC-Plus – CIBIC

| | |
|---|---|
| **Dataset** | CIBIC |
| **Creating program** | cibic.sas |
| **Description** | CIBIC-Plus |
| **Unique identifier** | DCRFID, CIBIC, VISIT |
| **Sorted by** | DCRFID, CIBIC, VISIT |
| **Notes** | |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| CIBIC | char | SUBJECT STATUS COMPARED TO BASELINE | | Collected at CRF. |
| ZCIBIC | num | SUBJECT STATUS COMPARED TO BASELINE CODE | | Collected at CRF. |

### 1.4.6.Brain MRI – CMRI

| | |
|---|---|
| **Dataset** | CMRI |
| **Creating program** | cmri.sas |
| **Description** | Brain MRI |
| **Unique identifier** | DCRFID, CMSYMP, VISIT |
| **Sorted by** | DCRFID, CMSYMP, VISIT |
| **Notes** | |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| CMSYMP | char | PARAMETERS | | Collected at CRF. |
| CMSEV | char | MRI RESPONSE | | Collected at CRF. |
| CMNUM | char | NUMBER | | Collected at CRF. |
| SORT_NO | num | PREFILL SORT NO | | Collected at CRF. |

## 1.4.7.Concomitant Therapy – COTHER

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

| 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 |
| CTTYPE | char | CO-RX TYPE | | Collected at CRF. |
| CTSEQNO | num | CO-RX SEQ. | | Collected at CRF. |
| CONRX | char | CO-RX | | Collected at CRF. |
| CTSCHED | char | CO-RX DAILY SCHEDULE | | Collected at CRF. |
| CTIND | char | CT INDICATION | | Collected at CRF. |
| CTPRIOR | char | CO-RX PRE-TRIAL | | Collected at CRF. |
| CTONGO | char | CO-RX ONGOING | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| 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. |
| ATCCODE8 | char | ATC CODE 9 | | 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. |

### 1.4.8.DAD-Scale – DAD

| | |
|---|---|
| **Dataset** | DAD |
| **Creating program** | dad.sas |
| **Description** | DAD-Scale |
| **Unique identifier** | DCRFID, DASYMP, VISIT |
| **Sorted by** | DCRFID, DASYMP, VISIT |
| **Notes** | |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| DASYMP | char | DAD ITEM | | Collected at CRF. |
| DASEV | char | YES/NO/NA | | Collected at CRF. |
| SORT_NO | num | PREFILL SORT NO | | Collected at CRF. |

## 1.4.9.Death – DEATH

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

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

## 1.4.10. Protocol Deviation – DEVIATN

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

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

## 1.4.11. Medical History – DISEASES

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

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| DSSYSTEM | char | DISEASE BODY SYSTEM | | Collected at CRF. |
| DSCOND | char | CONDITION | | Collected at CRF. |
| SORT_NO | num | PREFILL SORT NO | | Collected at CRF. |

## 1.4.12. ECG Overall Interpretation – ECG

| | |
|---|---|
| **Dataset** | ECG |
| **Creating program** | ecg.sas |
| **Description** | ECG Overall Interpretation |
| **Unique identifier** | DCRFID, VISIT |
| **Sorted by** | DCRFID, VISIT |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>ECG_D |

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

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| ECGSGNCH | char | SIGNIFICANT CHANGE | | 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. |

### 1.4.13. ECG Abnormalities – ECGABN

| | |
|---|---|
| **Dataset** | ECGABN |
| **Creating program** | ecgabn.sas |
| **Description** | ECG Abnormalities |
| **Unique identifier** | DCRFID, VISIT |
| **Sorted by** | DCRFID, VISIT |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:<br>ECG_D, ECGOTH_V, ECOTH1_V |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| ECG_T | num | ECG TIME | | Collected at CRF. |
| ECGSRCE | char | SOURCE ECG COMMENTS | | Collected at CRF. |
| ECG_DY | num | RELATIVE ECG DAY | | If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D - REF.DATE) +1. |

## 1.4.14. ECG Date and Time (For CRO) – ECGCRCHK

| | |
|---|---|
| **Dataset** | ECGCRCHK |
| **Creating program** | ecgcrchk.sas |
| **Description** | ECG Date and Time (For CRO) |
| **Unique identifier** | DCRFID, ECG_DY |
| **Sorted by** | DCRFID, ECG_DY |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>ECG_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 |
| ECG_T | num | ECG TIME | | Collected at CRF. |
| ECG_DY | num | RELATIVE ECG DAY | | If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D - REF.DATE) +1. |

## 1.4.15. ECG Description – ECGINTRP

| | |
|---|---|
| **Dataset** | ECGINTRP |
| **Creating program** | ecgintrp.sas |
| **Description** | ECG Description |
| **Unique identifier** | DCRFID, EGABNCLS, EGABN, ECG_DY, ECG_T |
| **Sorted by** | DCRFID, EGABNCLS, EGABN, ECG_DY, ECG_T |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>ECG_D |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| ECG_T | num | ECG TIME | | Collected at CRF. |
| EGABNCLS | char | ECG ABNORMALITY CLASS | | Collected at CRF. |

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

### 1.4.16. ECG Measurements – ECGPAR

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

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| ECG_T | num | ECG TIME | | Collected at CRF. |
| ECGPAR | char | ECG PARAMETER | | Collected at CRF. |
| ZECGPAR | char | ECG PARAMETER CODE | | Collected at CRF. |
| ECGVAL | num | ECG MEASUREMENT | | Collected at CRF. |
| SORT_NO | num | PREFILL SORT NO | | 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. Efprep2– EFPREP2

| | |
|---|---|
| **Dataset** | EFPREP2 |
| **Creating program** | efprep2.sas |
| **Description** | Efprep2 |
| **Unique identifier** | DCRFID |
| **Sorted by** | DCRFID |
| **Notes** | |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| INT2RAN | char | INT2RAN | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |

### 1.4.18. Cigarette Smoking – HABIT

| | |
|---|---|
| **Dataset** | HABIT |
| **Creating program** | habit.sas |
| **Description** | Cigarette Smoking |
| **Unique identifier** | DCRFID |
| **Sorted by** | DCRFID |
| **Notes** | |

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

### 1.4.19. Inclusion Criteria – INEX

| | |
|---|---|
| **Dataset** | INEX |
| **Creating program** | inex.sas |
| **Description** | Inclusion Criteria |
| **Unique identifier** | DCRFID, IECRIT |
| **Sorted by** | DCRFID, IECRIT |
| **Notes** | |

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

## 1.4.20. Laboratory Requisition Numbers – LABREF

| | |
|---|---|
| **Dataset** | LABREF |
| **Creating program** | labref.sas |
| **Description** | Laboratory Requisition Numbers |
| **Unique identifier** | DCRFID, LATYPE, VISIT |
| **Sorted by** | DCRFID, LATYPE, VISIT |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>SAMPLE_D, LABID, ZLABID, LABREFNO |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| LATYPE | char | DNA SAMPLE | | Collected at CRF. |
| LSRELCHA | char | CLIN. RELEVANT CHANGES | | 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. |

## 1.4.21. Laboratory Results – LABRES

| | |
|---|---|
| **Dataset** | LABRES |
| **Creating program** | labres.sas |
| **Description** | Laboratory Results |
| **Unique identifier** | DCRFID, LABTEST, SAMPLEDY, SAMPLE_T |
| **Sorted by** | DCRFID, LABTEST, SAMPLEDY, SAMPLE_T |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>SAMPLE_D, 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. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| ZLABTEST | char | LAB. TEST CODE | | Collected at CRF. |
| SAMPLE_T | num | SAMPLING TIME | | Collected at CRF. |
| LABVAL | num | LAB. TEST VALUE | | Collected at CRF. |
| LABVAL_V | char | LAB. TEST VALUE (VERB.) | | Collected at CRF. |
| 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. |
| 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. |

## 1.4.22. Laboratory Sample Info – LABSAM

| | |
|---|---|
| **Dataset** | LABSAM |
| **Creating program** | labsam.sas |
| **Description** | Laboratory Sample Info |
| **Unique identifier** | DCRFID, LABREFNO |
| **Sorted by** | DCRFID, LABREFNO |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:<br>SAMPLE_D, LABID, ZLABID, LSSAME, LSRELCHA, LABREFNO |

| 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 |
| SAMPLE_T | num | SAMPLING TIME | | Collected at CRF. |
| HAEMOLYS | char | SAMPLE HAEMOLYSED | | Collected at CRF. |
| FASTED | char | SUBJECT FASTED | | 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. |

## 1.4.23. Laboratory Urine Results – LABURI

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

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

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| LABTEST | char | LAB. TEST | | Collected at CRF. |
| ZLABTEST | char | LAB. TEST CODE | | Collected at CRF. |
| 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. |

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

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

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

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| MMSYMP | char | MMSE SYMPTOM | | Collected at CRF. |
| MMSEV | num | MMSE SCORE | | Collected at CRF. |
| SORT_NO | num | PREFILL SORT NO | | Collected at CRF. |

### 1.4.25. Neurological Examination – NEUREXAM

| | |
|---|---|
| **Dataset** | NEUREXAM |
| **Creating program** | neurexam.sas |
| **Description** | Neurological Examination |
| **Unique identifier** | DCRFID, NESYSTEM |
| **Sorted by** | DCRFID, NESYSTEM |
| **Notes** | |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| NESYSTEM | char | TEST/SIGNS | | Collected at CRF. |
| NERESULT | char | RESPONSE | | Collected at CRF. |
| SORT_NO | num | PREFILL SORT NO | | Collected at CRF. |

## 1.4.26. Neuropsychiatric Inventory – NPI

| | |
|---|---|
| **Dataset** | NPI |
| **Creating program** | npi.sas |
| **Description** | Neuropsychiatric Inventory |
| **Unique identifier** | DCRFID, NPSYMP, VISIT |
| **Sorted by** | DCRFID, NPSYMP, VISIT |
| **Notes** | |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| NPSYMP | char | NPI SYMPTOM | | Collected at CRF. |
| NPNO | num | NO | | Collected at CRF. |
| NPSYSFRQ | num | FREQUENCY | | Collected at CRF. |
| NPSEV | num | SEVERITY | | Collected at CRF. |
| NPDIST | num | DISTRESS | | Collected at CRF. |
| SORT_NO | num | PREFILL SORT NO | | Collected at CRF. |

## 1.4.27. Phone Contact – PHONE

| | |
|---|---|
| **Dataset** | PHONE |
| **Creating program** | phone.sas |
| **Description** | Phone Contact |
| **Unique identifier** | DCRFID, PHOUTCME, VISIT |
| **Sorted by** | DCRFID, PHOUTCME, VISIT |
| **Notes** | |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| PHONE | char | CONTACTED BY PHONE? | | Collected at CRF. |
| PHOUTCME | char | OUTCOME OF PHONE CONTACT | | Collected at CRF. |
| PHANTEM | char | ANTI-EMETICS PRESRIBED | | Collected at CRF. |
| PHUNSCHD | char | UNSCHEDULED VISIT PLANNED? | | Collected at CRF. |

## 1.4.28. Physical Examination – PHYSEXAM

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

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

## 1.4.29. Date Doses Missed 3 Days Before Blood Dra – PKMISSED

| | |
|---|---|
| **Dataset** | PKMISSED |
| **Creating program** | pkmissed.sas |
| **Description** | Date Doses Missed 3 Days Before Blood Dra |
| **Unique identifier** | DCRFID, PKMISSED, PKSEQNO, VISIT |
| **Sorted by** | DCRFID, PKMISSED, PKSEQNO, VISIT |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>PKMISS_D |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| PKSEQNO | num | SEQUENCE NUMBER | | Collected at CRF. |
| PKMISSED | char | AM/PM DOSE MISSED | | Collected at CRF. |
| PKMISSDY | num | RELATIVE DAY DOSE MISSED | | If PKMISS_D and REF.DATE not missing then perform below logic to calculate PKMISSDY, If PKMISS_D less than REF.DATE then (PKMISS_D - REF.DATE). Else if PKMISS_D is greater than equal to REF.DATE then (PKMISS_D - REF.DATE) +1. |

## 1.4.30. Drug Administration Before Sampling – PLAADM

| | |
|---|---|
| **Dataset** | PLAADM |
| **Creating program** | plaadm.sas |
| **Description** | Drug Administration Before Sampling |
| **Unique identifier** | DCRFID, PLADMSEQ, VISIT |
| **Sorted by** | DCRFID, PLADMSEQ, VISIT |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>PLADM_D |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| PLREFNO | num | PLASMA REF. NO. | | Collected at CRF. |
| PLADM_T | num | DRUG ADMIN. TIME | | Collected at CRF. |
| PLADMSEQ | char | DRUG ADMIN. SEQ. | | Collected at CRF. |

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

## 1.4.31. Plasma Results – PLARES

| | |
|---|---|
| **Dataset** | PLARES |
| **Creating program** | plares.sas |
| **Description** | Plasma Results |
| **Unique identifier** | DCRFID, PLREFNO |
| **Sorted by** | DCRFID, PLREFNO |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>INITIALS, TUBE, PLASMA_D, TUBE_D, MEDNO |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| DRUG | char | STUDY DRUG | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| PLREFNO | num | PLASMA REF. NO. | | Collected at CRF. |
| VISITEXT | char | EXTRA VISIT | | Collected at CRF. |
| PRVAL | num | PLASMA MEASUREMENT | | Collected at CRF. |
| PRFLAG | char | DATA FLAG | | Collected at CRF. |
| PRVAL_U | char | PLASMA UNIT | | Collected at CRF. |
| PRDETECT | num | DETECTION LIMIT | | Collected at CRF. |
| PRSUBST | char | PLASMA SUBSTANCE | | Collected at CRF. |
| PLASMA_T | num | PLASMA SAMPLING TIME | | Collected at CRF. |
| TUBE_T | num | PLASMA SAMPLING TIME ON TUBE | | Collected at CRF. |
| PLASMADY | num | RELATIVE PLASMA SAMPLING DAY | | If PLASMA_D and REF.DATE not missing then perform below logic to calculate PLASMADY, If PLASMA_D less than REF.DATE then (PLASMA_D - REF.DATE). Else if PLASMA_D is greater than equal to REF.DATE then (PLASMA_D - REF.DATE) +1. |
| TUBE_DY | num | RELATIVE PLASMA SAMPLING DAY ON TUBE | | If TUBE_D and REF.DATE not missing then perform below logic to calculate TUBE_DY, If TUBE_D less than REF.DATE then (TUBE_D - REF.DATE). Else if TUBE_D is greater than equal to REF.DATE then (TUBE_D - REF.DATE) +1. |

## 1.4.32. Plasma Results1 – PLARES1

| | |
|---|---|
| **Dataset** | PLARES1 |
| **Creating program** | plares1.sas |
| **Description** | Plasma Results1 |
| **Unique identifier** | DCRFID, PLREFNO |
| **Sorted by** | DCRFID, PLREFNO |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>INITIALS, TUBE, PLASMA_D, MEDNO |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| DRUG | char | STUDY DRUG | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| PLREFNO | num | PLASMA REF. NO. | | Collected at CRF. |
| VISITEXT | char | EXTRA VISIT | | Collected at CRF. |
| PRVAL | num | PLASMA MEASUREMENT | | Collected at CRF. |
| PRFLAG | char | DATA FLAG | | Collected at CRF. |
| PRVAL_U | char | PLASMA UNIT | | Collected at CRF. |
| PRDETECT | char | DETECTION LIMIT | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| PRSUBST | char | PLASMA SUBSTANCE | | Collected at CRF. |
| PLASMA_T | num | PLASMA SAMPLING TIME | | Collected at CRF. |
| TUBE_D | num | PLASMA SAMPLING DATE ON TUBE | | Collected at CRF. |
| TUBE_T | num | PLASMA SAMPLING TIME ON TUBE | | Collected at CRF. |
| PLASMADY | num | RELATIVE PLASMA SAMPLING DAY | | If PLASMA_D and REF.DATE not missing then perform below logic to calculate PLASMADY, If PLASMA_D less than REF.DATE then (PLASMA_D - REF.DATE). Else if PLASMA_D is greater than equal to REF.DATE then (PLASMA_D - REF.DATE) +1. |

### 1.4.33. Plasma Results2 – PLARES2

| | |
|---|---|
| **Dataset** | PLARES2 |
| **Creating program** | plares2.sas |
| **Description** | Plasma Results2 |
| **Unique identifier** | DCRFID, PLREFNO |
| **Sorted by** | DCRFID, PLREFNO |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>INITIALS, TUBE, PLASMA_D, MEDNO |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| DRUG | char | STUDY DRUG | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| PLREFNO | num | PLASMA REF. NO. | | Collected at CRF. |
| VISITEXT | char | EXTRA VISIT | | Collected at CRF. |
| PRVAL | num | PLASMA MEASUREMENT | | Collected at CRF. |
| PRFLAG | char | DATA FLAG | | Collected at CRF. |
| PRVAL_U | char | PLASMA UNIT | | Collected at CRF. |
| PRDETECT | char | DETECTION LIMIT | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| PRSUBST | char | PLASMA SUBSTANCE | | Collected at CRF. |
| PLASMA_T | num | PLASMA SAMPLING TIME | | Collected at CRF. |
| TUBE_D | num | PLASMA SAMPLING DATE ON TUBE | | Collected at CRF. |
| TUBE_T | num | PLASMA SAMPLING TIME ON TUBE | | Collected at CRF. |
| PLASMADY | num | RELATIVE PLASMA SAMPLING DAY | | If PLASMA_D and REF.DATE not missing then perform below logic to calculate PLASMADY, If PLASMA_D less than REF.DATE then (PLASMA_D - REF.DATE). Else if PLASMA_D is greater than equal to REF.DATE then (PLASMA_D - REF.DATE) +1. |

## 1.4.34. Plasma Samples – PLASAM

| | |
|---|---|
| **Dataset** | PLASAM |
| **Creating program** | plasam.sas |
| **Description** | Plasma Samples |
| **Unique identifier** | DCRFID, PLREFNO |
| **Sorted by** | DCRFID, PLREFNO |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>PLASMA_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 |
| PLREFNO | num | PLASMA REF. NO. | | Collected at CRF. |
| PLASMA_T | num | TIME OF PLASMA SAMPLING | | Collected at CRF. |
| PLASMSEQ | char | PLASMA SEQUENCE | | Collected at CRF. |
| PLASMADY | num | RELATIVE DAY OF PLASMA SAMPLING | | If PLASMA_D and REF.DATE not missing then perform below logic to calculate PLASMADY, If PLASMA_D less than REF.DATE then (PLASMA_D - REF.DATE). Else if PLASMA_D is greater than equal to REF.DATE then (PLASMA_D - REF.DATE) +1. |

## 1.4.35. Pittsburgh Sleep Quality Index – PSQI

| | |
|---|---|
| **Dataset** | PSQI |
| **Creating program** | psqi.sas |
| **Description** | Pittsburgh Sleep Quality Index |
| **Unique identifier** | DCRFID, VISIT |
| **Sorted by** | DCRFID, VISIT |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>PS5J_V, PSREST_V |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| PSLPNGT | num | USUAL BED TIME | | Collected at CRF. |
| PSLPAMPM | char | SLEEP AM/PM | | Collected at CRF. |
| PSLPMIN | num | NUMBER OF MINUTES | | Collected at CRF. |
| PSAWAKE | num | USUAL GETTING UP TIME | | Collected at CRF. |
| PAWKAMPM | char | AWAKE AM/PM | | Collected at CRF. |
| PSLPHRS | num | HRS OF SLEEP PER NIGHT | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| PS5A | char | SLEEP WITHIN 30 MINS | | Collected at CRF. |
| PS5B | char | WAKE UP MIDDLE OF NIGHT | | Collected at CRF. |
| PS5C | char | GET UP TO USE BATHROOM | | Collected at CRF. |
| PS5D | char | CANNOT BREATHE COMFORTABLY | | Collected at CRF. |
| PS5E | char | COUGH OR SNORE LOUDLY | | Collected at CRF. |
| PS5F | char | FEEL TOO COLD | | Collected at CRF. |
| PS5G | char | FEEL TOO HOT | | Collected at CRF. |
| PS5H | char | HAD BAD DREAMS | | Collected at CRF. |
| PS5I | char | HAVE PAIN | | Collected at CRF. |
| PS5J | char | OTHER REASONS TROUBLE SLEEPING? | | Collected at CRF. |
| PSQUAL | char | SLEEP QUALITY | | Collected at CRF. |
| PSMED | char | TAKEN MEDS TO SLEEP | | Collected at CRF. |
| PSOCIAL | char | STAYING AWAKE WHILE DRIVING,... | | Collected at CRF. |
| PSENTHUS | char | ENOUGH ENTHUSIASM... | | Collected at CRF. |
| PSCALE | char | PERSON COMPLETING SCALE SLEEPS IN | | Collected at CRF. |
| PSNORE | char | LOUD SNORING | | Collected at CRF. |
| PSPAUSE | char | LONG PAUSES BETWEEN BREATHES DUR SLEEP | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| PSTWITCH | char | LEGS TWITCH OR JERK DURING SLEEP | | Collected at CRF. |
| PSCONFUS | char | EPISODES OF DISORIENT OR CONFUS DUR SLEP | | Collected at CRF. |
| PSREST | char | RESTLESSNESS DURING SLEEP | | Collected at CRF. |

### 1.4.36. Related AEs for Trial Termination or Death – RELAE

| | |
|---|---|
| **Dataset** | RELAE |
| **Creating program** | relae.sas |
| **Description** | Related AEs for Trial Termination or Death |
| **Unique identifier** | DCRFID, RATYPE, AESEQNO |
| **Sorted by** | DCRFID, RATYPE, AESEQNO |
| **Notes** | |

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

## 1.4.37. Trial Description – TRLDESC

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

| 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. |
| DESIGN | char | DESIGN | | Collected at CRF. |
| MULTCENT | char | MULTICENTRE | | Collected at CRF. |
| BLKSIZE | num | BLOCK SIZE | | Collected at CRF. |
| INDICAT | char | INDICATION | | Collected at CRF. |
| AGEGRP | char | AGE GROUP | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| SPECPOP | char | SPECIAL POPULATION | | Collected at CRF. |
| SUBJTYPE | char | SUBJECT TYPE | | Collected at CRF. |
| PRVPROT | char | PREV. PROTOCOL | | Collected at CRF. |

### 1.4.38. Trial Regimen – TRLREGM

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

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

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| 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 | SEQMENT DURATION | | Collected at CRF. |
| TMDUR_U | char | DURATION UNIT | | Collected at CRF. |

## 1.4.39. Trial Disposition – TRLTERM

| | |
|---|---|
| **Dataset** | TRLTERM |
| **Creating program** | trlterm.sas |
| **Description** | Trial Disposition |
| **Unique identifier** | DCRFID |
| **Sorted by** | DCRFID |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>TTFROM_D, TTREAS_V |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| TTTYPE | char | TERM. TYPE | | Collected at CRF. |
| TTREAS | char | TERM. REASON | | Collected at CRF. |
| TTFROMDY | num | RELATIVE DISCON STUDY MED 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. |

## 1.4.40. Visit General Info – VISIT

| | |
|---|---|
| **Dataset** | VISIT |
| **Creating program** | visit.sas |
| **Description** | Visit General Info |
| **Unique identifier** | DCRFID, VISIT |
| **Sorted by** | DCRFID, VISIT |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>VISIT_D, ADVIS_D, NPRATER, NPDATE_D, PSINITS, PSDATE_D, CIBIC_D |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| PSYMED | char | PSYCHOTROPIC MEDICATIONS | | Collected at CRF. |
| ADVIS_T | num | ADAS VISIT TIME | | Collected at CRF. |
| ADAS_T | num | TIME LAST STUDY MED DOSE | | Collected at CRF. |
| MISSDOSE | char | MISSED DOSES | | Collected at CRF. |
| NPRMCARE | char | PRIMARY CAREGIVER INTERVIEWD (NPI) | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| NPRMCAR1 | char | SAME CAREGIVER AT BASELINE? (NPI) | | Collected at CRF. |
| PSCARENA | char | CAREGIVER NOT AVAILABLE (PSQI) | | 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. |
| PEND | char | PHYS EXAM 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. |
| NPDATEDY | num | RELATIVE NPI VISIT DAY (NPI) | | If NPDATE_D and REF.DATE not missing then perform below logic to calculate NPDATEDY, If NPDATE_D less than REF.DATE then (NPDATE_D - REF.DATE). Else if NPDATE_D is greater than equal to REF.DATE then (NPDATE_D - REF.DATE) +1. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| PSDATEDY | num | RELATIVE PSQI VISIT DAY (PSQI) | | If PSDATE_D and REF.DATE not missing then perform below logic to calculate PSDATEDY, If PSDATE_D less than REF.DATE then (PSDATE_D - REF.DATE). Else if PSDATE_D is greater than equal to REF.DATE then (PSDATE_D - REF.DATE) +1. |
| CIBIC_DY | num | RELATIVE CIBIC VISIT 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

| | |
|---|---|
| **Dataset** | VITSIGN |
| **Creating program** | vitsign.sas |
| **Description** | Vital Signs |
| **Unique identifier** | DCRFID, VISIT |
| **Sorted by** | DCRFID, VISIT |
| **Notes** | |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF. |
| VISIT | num | VISIT | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| DCRFID | char | CRF ID ASSIGNED FOR DE-IDENTITY | | Randomly assigned Crf ID for De-identity |
| WEIGHT | num | WEIGHT | | Collected at CRF. |
| WEIGHT_U | char | WEIGHT UNIT | | Collected at CRF. |
| PULSE | num | PULSE, 1/MIN | | Collected at CRF. |
| SBP | num | SYSTOLIC BP, MMHG | | Collected at CRF. |
| DBP | num | DIASTOLIC BP, MMHG | | Collected at CRF. |