

Clinical Development

## Galantamine

Gal-Int-3

Anonymisation Data Derivation Specification Document

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

## 1. Datasets

### 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

#### Part I: Dataset description

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

#### Part II: Variables within dataset

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

### 1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Datasets with zero observation will not be submitted (ex. DIAGNOS)
- Dataset containing investigator information, which is sensitive and hence will not be submitted. (ex. INVEST)
- Remarks dataset will be submitted with zero observation due to sensitivity of data.
- LABCOM dataset will contain only date and time variables after removing the sensitive information from the dataset. Hence this dataset will be dropped from the de-identified dataset.
- 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-Int-3 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:<br/>INITIALS, MEDNO, ZINVEST, COINVEST, ZCOINVES, BIRTH_D, PRVTRIAL, PRVCRFID</p> <p>Below listed variables were not a part of the Raw dataset. These have been added to retain information in the de-identified datasets:<br/>DCOUNTRY (Source: INVEST dataset)<br/>RANDGRP (Source: RANDOM dataset)</p> |

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

| Variable | Type | Label               | Codes | Comments   |
|----------|------|---------------------|-------|--|
| HEIGHT   | num  | HEIGHT              |       | Collected at CRF.  |
| HEIGHT_U | char | HEIGHT UNIT         |       | 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.  |
| BATCHNO  | num  | BATCH NO.           |       | Collected at CRF.  |
| DCOUNTRY | char | DE-IDENTIFY COUNTRY |       | Element will be grouped to protect PII.  |
| RANDGRP  | char | RANDOMISATION GROUP |       | Collected at CRF.  |
| AGE      | char | AGE IN YEARS        |       | <p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule:</p> $\text{AGE} = \text{int}((\text{REF.DATE} - \text{BIRTH\_D}) / 365.25)$ <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p> |



## 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                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.                        |
| VISIT    | num  | VISIT                         |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| 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.                        |
| SORT_NO  | num  | PREFILL SORT NO               |       | Collected at CRF.                        |

## 1.4.3. 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,NUMFORM,AMFROMDY,AMTO_DY  |
| <b>Sorted by</b>         | DCRFID,SEGMENT,PHASE,NUMFORM,AMFROMDY,AMTO_DY  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>AMFROM_D,AMTO_D,AMSCHEM |

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIAL ID.                     |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| PHASE    | char | TRIAL PHASE                   |       | Collected at CRF.                        |
| SEGMENT  | num  | TRIAL SEGMENT SEQ.            |       | Collected at CRF.                        |
| AMSEQ    | num  | AM SEQUENCE NUMBER            |       | 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.                        |
| AMDOSE   | num  | DOSE SCHEDULE                 |       | Collected at CRF.                        |

| Variable | Type | Label                    | Codes | Comments  |
|----------|------|--------------------------|-------|---|
| AMDOSE_U | char | DOSE SCHEDULE UNIT       |       | Collected at CRF.   |
| AMFROMDY | num  | RELATIVE ADMIN. FROM DAY |       | If AMFROM_D and REF.DATE not missing then perform below logic to calculate AMFROMDY, If AMFROM_D less than REF.DATE then (AMFROM_D - REF.DATE). Else if AMFROM_D is greater than equal to REF.DATE then (AMFROM_D-REF.DATE) +1. |
| AMTO_DY  | num  | RELATIVE ADMIN. TO DAY   |       | If AMTO_D and REF.DATE not missing then perform below logic to calculate AMTO_DY, If AMTO_D less than REF.DATE then (AMTO_D - REF.DATE). Else if AMTO_D is greater than equal to REF.DATE then (AMTO_D- REF.DATE) +1.           |

## 1.4.4. Adverse Events - AE

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | AE  |
| <b>Creating program</b>  | ae.sas  |
| <b>Description</b>       | Adverse Events  |
| <b>Unique identifier</b> | DCRFID, AEPREF, AEWHONUM, AESEQNO   |
| <b>Sorted by</b>         | DCRFID, AEPREF, AEWHONUM, 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:<br>AE_V, PHASE, AEFROM_D, AETO_D, ADREMNUM |

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIAL ID.                     |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| AESEQNO  | num  | AE SEQ.                       |       | Collected at CRF.                        |
| AEINCL   | char | AE INCLUDED TERM              |       | Collected at CRF.                        |
| 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.  |
| 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.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:<br>CRACT_V |

| Variable | Type | Label                           | Codes | Comments                                 |
|----------|------|---------------------------------|-------|--|
| TRIAL    | char | TRIAL ID.                       |       | Collected at CRF.                        |
| VISIT    | num  | VISIT                           |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY   |       | Randomly assigned Crf ID for De-identity |
| CRACTIV  | char | ACTIVITIES                      |       | Collected at CRF.                        |
| CRSEQNO  | num  | CR SEQUENCE NUMBER              |       | Collected at CRF.                        |
| CRNOTDNE | char | DONE                            |       | Collected at CRF.                        |
| CRTMHR   | num  | DAILY HOURS SPENT ON ACTIVITY   |       | Collected at CRF.                        |
| CRTMMIN  | num  | DAILY MINUTES SPENT ON ACTIVITY |       | Collected at CRF.                        |
| SORT_NO  | num  | PREFILL SORT NO                 |       | Collected at CRF.                        |

## 1.4.6. Concomitant Therapy – COTHER

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | COTHER  |
| <b>Creating program</b>  | cother.sas  |
| <b>Description</b>       | Concomitant Therapy   |
| <b>Unique identifier</b> | DCRFID,RXPREF,CTTYPE,CTSEQNO  |
| <b>Sorted by</b>         | DCRFID,RXPREF,CTTYPE,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:<br>CONRX_V,CTIND_V,CTFROM_D,CTTO_D,ATCCODE9,ATCTEXT9 |

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIAL ID.                     |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN 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 | 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.                        |

| Variable | Type | Label          | Codes | Comments          |
|----------|------|----------------|-------|-------------------|
| CTTO_C   | char | CO-RX END CODE |       | Collected at CRF. |
| RXWHONUM | char | WHO DRUG CODE  |       | Collected at CRF. |
| ATCCODE0 | char | ATC CODE 1     |       | Collected at CRF. |
| ATCCODE1 | char | ATC CODE 2     |       | Collected at CRF. |
| ATCCODE2 | char | ATC CODE 3     |       | Collected at CRF. |
| ATCCODE3 | char | ATC CODE 4     |       | Collected at CRF. |
| ATCCODE4 | char | ATC CODE 5     |       | Collected at CRF. |
| ATCCODE5 | char | ATC CODE 6     |       | Collected at CRF. |
| ATCCODE6 | char | ATC CODE 7     |       | Collected at CRF. |
| ATCCODE7 | char | ATC CODE 8     |       | Collected at CRF. |
| ATCCODE8 | char | ATC CODE 9     |       | Collected at CRF. |
| ATCTEXT0 | char | ATC TEXT 1     |       | Collected at CRF. |
| ATCTEXT1 | char | ATC TEXT 2     |       | Collected at CRF. |
| ATCTEXT2 | char | ATC TEXT 3     |       | Collected at CRF. |
| ATCTEXT3 | char | ATC TEXT 4     |       | Collected at CRF. |
| ATCTEXT4 | char | ATC TEXT 5     |       | Collected at CRF. |
| ATCTEXT5 | char | ATC TEXT 6     |       | Collected at CRF. |
| ATCTEXT6 | char | ATC TEXT 7     |       | Collected at CRF. |
| ATCTEXT7 | char | ATC TEXT 8     |       | Collected at CRF. |
| ATCTEXT8 | char | ATC TEXT 9     |       | Collected at CRF. |
| RXPREF   | char | PREFERRED NAME |       | Collected at CRF. |



| Variable | Type | Label                   | Codes | Comments   |
|----------|------|-------------------------|-------|--|
| CTFROMDY | num  | RELATIVE CO-RXSTART 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-RXEND 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.            |

## 1.4.7. DAD-Scale – DAD

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

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIAL ID.                     |       | Collected at CRF.                        |
| VISIT    | num  | VISIT                         |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| DASYMP   | char | SYMPTOM                       |       | Collected at CRF.                        |
| DASEV    | char | SEVERITY                      |       | Collected at CRF.                        |
| SORT_NO  | num  | PREFILL SORT NO               |       | Collected at CRF.                        |

## 1.4.8.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 or due to missing values:<br>DEATH_D,DTREAS_V |

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

## 1.4.9. 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:<br>DEVIAT_V |

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

## 1.4.10. Medical History – DISEASES

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | DISEASES   |
| <b>Creating program</b>  | diseases.sas   |
| <b>Description</b>       | Medical History  |
| <b>Unique identifier</b> | DCRFID,DSSYSTEM,SORT_NO  |
| <b>Sorted by</b>         | DCRFID,DSSYSTEM,SORT_NO  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>DISEAS_V,DISEASE |

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN 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.                        |

## 1.4.11. 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, ECG_DY   |
| <b>Sorted by</b>         | DCRFID, EGRELCHA, ECG_DY   |
| <b>Notes</b>             | 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 | TRIALID.                        |       | Collected at CRF.  |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY   |       | Randomly assigned Crf ID for De-identity   |
| ECGSRCE  | char | SOURCE ECG COMMENTS             |       | Collected at CRF.  |
| EGLIMITS | char | ECG WITHIN NORMAL LIMITS        |       | Collected at CRF.  |
| 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. |

## 1.4.12. ECG Abnormalities – ECGABN

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

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

### 1.4.13. ECG Evaluation – ECGEVAL

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | ECGEVAL  |
| <b>Creating program</b>  | ecgeval.sas  |
| <b>Description</b>       | ECG Evaluation   |
| <b>Unique identifier</b> | DCRFID,EEASPECT,EEEVAL,ECG_DY  |
| <b>Sorted by</b>         | DCRFID,EEASPECT,EEEVAL,ECG_DY  |
| <b>Notes</b>             | 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 | TRIALID.                      |       | Collected at CRF.  |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity   |
| EEASPECT | char | ECG ASPECT                    |       | Collected at CRF.  |
| 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. |



## 1.4.14. ECG Measurements – ECGPAR

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | ECGPAR   |
| <b>Creating program</b>  | ecgpar.sas   |
| <b>Description</b>       | ECG Measurements   |
| <b>Unique identifier</b> | DCRFID, ECGPAR, ECG_D  |
| <b>Sorted by</b>         | DCRFID, ECGPAR, ECG_D  |
| <b>Notes</b>             | 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 ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity  |
| 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. |

## 1.4.15. Inclusion/Exclusion Criteria – INEX

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

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| IETYPE   | char | TYPE OF SELECTION CRITERIA    |       | Collected at CRF.                        |
| IECRIT   | char | SELECTION CRITERIA            |       | Collected at CRF.                        |
| ZIECRIT  | num  | SELECTION CRITERIA CODE       |       | Collected at CRF.                        |
| IEYN     | char | NON-ELIGIBILITY EXPR.         |       | Collected at CRF.                        |
| SORT_NO  | num  | PREFILL SORT NO               |       | Collected at CRF.                        |

## 1.4.16. Resource Use: Institutionalization – INSTITUT

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | INSTITUT   |
| <b>Creating program</b>  | institut.sas   |
| <b>Description</b>       | Resource Use: Institutionalization   |
| <b>Unique identifier</b> | DCRFID,VISIT,INSTTYPE,INFROMDY,INTO_DY   |
| <b>Sorted by</b>         | DCRFID,VISIT,INSTTYPE,INFROMDY,INTO_DY   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>INFROM_D,INTO_D |

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.                        |
| VISIT    | num  | VISIT                         |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| INSTTYPE | char | TYPE OF INSTITUTION           |       | Collected at CRF.                        |
| ZINSTTYP | num  | TYPE OF INSTITUTION CODE      |       | Collected at CRF.                        |
| WARDTYPE | char | TYPE OF WARD                  |       | Collected at CRF.                        |
| ZWARDTYP | char | TYPE OF WARD CODE             |       | Collected at CRF.                        |
| INSEQNO  | num  | IN SEQUENCE NUMBER            |       | Collected at CRF.                        |
| INPRIOR  | char | ONGOING FROM                  |       | Collected at CRF.                        |
| INONGO   | char | ONGOING TO                    |       | Collected at CRF.                        |

| Variable | Type | Label             | Codes | Comments  |
|----------|------|-------------------|-------|---|
| INFROMDY | num  | RELATIVE FROM DAY |       | If INFROM_D and REF.DATE not missing then perform below logic to calculate INFROMDY, If INFROM_D less than REF.DATE then (INFROM_D - REF.DATE). Else if INFROM_D is greater than equal to REF.DATE then (INFROM_D - REF.DATE) +1. |
| INTO_DY  | num  | RELATIVE TO DAY   |       | If INTO_D and REF.DATE not missing then perform below logic to calculate INTO_DY, If INTO_D less than REF.DATE then (INTO_D - REF.DATE). Else if INTO_D is greater than equal to REF.DATE then (INTO_D - REF.DATE) +1.            |

## 1.4.17. Laboratory Normal Ranges – LABNOR

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | LABNOR   |
| <b>Creating program</b>  | labnor.sas   |
| <b>Description</b>       | Laboratory Normal Ranges   |
| <b>Unique identifier</b> | LABTEST LABLOW LABUPP  |
| <b>Sorted by</b>         | LABTEST LABLOW LABUPP  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br>LABID,ZLABID, AGEFROM, AGETO, AGE_U,WGHTFROM,WGHTTO,WGHT_U, SEX |

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

## 1.4.18. Laboratory Requisition Numbers – LABREF

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | LABREF   |
| <b>Creating program</b>  | labref.sas   |
| <b>Description</b>       | Laboratory Requisition Numbers   |
| <b>Unique identifier</b> | DCRFID,LSRELCHA,TYPE   |
| <b>Sorted by</b>         | DCRFID,LSRELCHA,TYPE   |
| <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:<br>LABREFNO,LABID,ZLABID,LSSAME |

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| LSRELCHA | char | CLIN. RELEVANT CHANGES        |       | Collected at CRF.                        |
| TYPE     | char | TYPE                          |       | Collected at CRF.                        |

## 1.4.19. Laboratory Results – LABRES

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | LABRES   |
| <b>Creating program</b>  | labres.sas   |
| <b>Description</b>       | Laboratory Results   |
| <b>Unique identifier</b> | DCRFID,LABTEST,LABVAL,SAMPLE_T,SAMPLEDY  |
| <b>Sorted by</b>         | DCRFID,LABTEST,LABVAL,SAMPLE_T,SAMPLEDY  |
| <b>Notes</b>             | 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 | TRIALID.                      |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| LABTEST  | char | LAB. TEST                     |       | Collected at CRF.                        |
| ZLABTEST | char | LAB. TEST CODE                |       | Collected at CRF.                        |
| 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.                        |

| Variable | Type | Label                       | Codes | Comments   |
|----------|------|-----------------------------|-------|--|
| 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. |



### 1.4.20. Laboratory Sample Info – LABSAM

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

| Variable | Type | Label                         | Codes | Comments   |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.  |
| DCRFID   | char | CRF ID ASSIGN 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.  |
| LSRELCHA | char | CLIN. SIGNIFICANT CHANGES     |       | 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. |

### 1.4.21. 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,LUVAL,SAMPLE_T,SAMPLEDY   |
| <b>Sorted by</b>         | DCRFID,LABTEST,LUVAL,SAMPLE_T,SAMPLEDY   |
| <b>Notes</b>             | 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 | TRIALID.                      |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| LABTEST  | char | LAB. TEST                     |       | Collected at CRF.                        |
| ZLABTEST | char | LAB. TEST CODE                |       | Collected at CRF.                        |
| SAMPLE_T | num  | SAMPLING TIME                 |       | Collected at CRF.                        |
| LUVAL    | char | URINE VALUE                   |       | Collected at CRF.                        |
| LUVAL_V  | char | URINE VALUE (VERB.)           |       | Collected at CRF.                        |
| LABTSTNO | num  | LAB. TEST NUMBER              |       | Collected at CRF.                        |
| LABCLASS | char | LAB CLASS                     |       | Collected at CRF.                        |

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

#### 1.4.22. Resource Use: Outpatient Services – OUTPAT

|                          |                                   |
|--------------------------|-----------------------------------|
| <b>Dataset</b>           | OUTPAT                            |
| <b>Creating program</b>  | outpat.sas                        |
| <b>Description</b>       | Resource Use: Outpatient Services |
| <b>Unique identifier</b> | DCRFID,VISIT,SERVICE              |
| <b>Sorted by</b>         | DCRFID,VISIT,SERVICE              |
| <b>Notes</b>             |                                   |

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.                        |
| VISIT    | num  | VISIT                         |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| SERVICE  | char | OUTPATIENT SERVICE            |       | Collected at CRF.                        |
| SERVUSED | char | SERVICE USED?                 |       | Collected at CRF.                        |

| Variable | Type | Label           | Codes | Comments          |
|----------|------|-----------------|-------|-------------------|
| SERVNO   | num  | SERVICE NUMBER  |       | Collected at CRF. |
| SORT_NO  | num  | PREFILL SORT NO |       | Collected at CRF. |

#### 1.4.23. General Well-Being Index – PGWBI

|                          |                          |
|--------------------------|--------------------------|
| <b>Dataset</b>           | PGWBI                    |
| <b>Creating program</b>  | pgwbi.sas                |
| <b>Description</b>       | General Well-Being Index |
| <b>Unique identifier</b> | DCRFID,VISIT,PGITEM      |
| <b>Sorted by</b>         | DCRFID,VISIT,PGITEM      |
| <b>Notes</b>             |                          |

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.                        |
| VISIT    | num  | VISIT                         |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| PGITEM   | char | GENERAL WELL-BEING ITEM       |       | Collected at CRF.                        |
| PGSCORE  | char | GENERAL WELL-BEING SCORE      |       | Collected at CRF.                        |

| Variable | Type | Label                         | Codes | Comments          |
|----------|------|-------------------------------|-------|-------------------|
| ZPGSCORE | num  | GENERAL WELL-BEING SCORE CODE |       | Collected at CRF. |
| SORT_NO  | num  | PREFILL SORT NO               |       | Collected at CRF. |

#### 1.4.24. Phone Contact – PHONE

|                          |               |
|--------------------------|---------------|
| <b>Dataset</b>           | PHONE         |
| <b>Creating program</b>  | phone.sas     |
| <b>Description</b>       | Phone Contact |
| <b>Unique identifier</b> | DCRFID,VISIT  |
| <b>Sorted by</b>         | DCRFID,VISIT  |
| <b>Notes</b>             |               |

| Variable | Type | Label                         | Codes | Comments                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.                        |
| VISIT    | num  | VISIT                         |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| PHONE    | char | CONTACTED BY PHONE?           |       | Collected at CRF.                        |
| PHOUTCOM | char | OUTCOME OF PHONE CONTACT      |       | Collected at CRF.                        |

| Variable | Type | Label                     | Codes | Comments          |
|----------|------|---------------------------|-------|-------------------|
| PHANTEM  | char | ANTI-EMETICS PRESCRIBED   |       | Collected at CRF. |
| PHUNSCHD | char | UNSCHEDULED VISIT PLANNES |       | Collected at CRF. |

#### 1.4.25. Physical Examination – PHYSEXAM

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | PHYSEXAM  |
| <b>Creating program</b>  | physexam.sas  |
| <b>Description</b>       | Physical Examination  |
| <b>Unique identifier</b> | DCRFID,PESYSTEM,VISIT   |
| <b>Sorted by</b>         | DCRFID,PESYSTEM,VISIT   |
| <b>Notes</b>             | 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 ASSIGN 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.                        |

| Variable | Type | Label           | Codes | Comments          |
|----------|------|-----------------|-------|-------------------|
| EXAM     | char | PHYS. EXAM.     |       | Collected at CRF. |
| SORT_NO  | num  | PREFILL SORT NO |       | Collected at CRF. |

#### 1.4.26. 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                                 |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIAL ID.                     |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Randomly assigned Crf ID for De-identity |
| RATYPE   | char | AE CONSEQUENCE                |       | Collected at CRF.                        |
| AESEQNO  | num  | AE SEQ.                       |       | Collected at CRF.                        |

## 1.4.27. 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 data is sensitive data, contains free text information. Will be submitted empty dataset. |

| Variable | Type | Label                         | Codes | Comments                      |
|----------|------|-------------------------------|-------|-------------------------------|
| TRIAL    | char | TRIALID.                      |       | Empty data will be submitted. |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY |       | Empty data will be submitted. |
| RCSEQNO  | num  | REMARK LINE NO.               |       | Empty data will be submitted. |
| REMARKDY | num  | RELATIVE REMARKDAY            |       | Empty data will be submitted. |



### 1.4.28. Trial Disposition – TRLTERM

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | TRLTERM  |
| <b>Creating program</b>  | trlterm.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:<br>TTFROM_D,TTREAS_V |

| Variable | Type | Label                         | Codes | Comments   |
|----------|------|-------------------------------|-------|--|
| TRIAL    | char | TRIALID.                      |       | Collected at CRF.  |
| DCRFID   | char | CRF ID ASSIGN 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 LAST CONTACT DAY     |       | If TTFROM_D and REF.DATE not missing then perform below logic to calculate TTFROMDY, If TTFROM_D less than REF.DATE then (TTFROM_D - REF.DATE). Else if TTFROM_D is greater than equal to REF.DATE then (TTFROM_D- REF.DATE) +1. |

## 1.4.29. 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:<br>VISIT_D,ADAS_D,CIBIC_D,DAD_D,GWBS_D,INITGWBS |

| Variable | Type | Label                           | Codes | Comments                                 |
|----------|------|---------------------------------|-------|--|
| TRIAL    | char | TRIALID.                        |       | Collected at CRF.                        |
| VISIT    | num  | VISIT                           |       | Collected at CRF.                        |
| DCRFID   | char | CRF ID ASSIGN FOR DE-IDENTITY   |       | Randomly assigned Crf ID for De-identity |
| CARQUEST | char | QUEST.SCALE CAREGIVER AVAILABLE |       | Collected at CRF.                        |
| OUTPATNT | char | OUTPATIENT SERVICE USED         |       | Collected at CRF.                        |
| INSTITUT | char | STAYED IN INSTITUTION?          |       | Collected at CRF.                        |
| ADAS_T   | num  | ADAS TIME                       |       | Collected at CRF.                        |
| PSYCHED  | char | PSYCHOTROPIC MEDICATION 48 HRS  |       | Collected at CRF.                        |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| CIBIC    | char | CIBIC : GLOBAL IMPRESSION OF CHANGE      |       | Collected at CRF.   |
| ZCIBIC   | num  | CIBIC : GLOBAL IMPRESSION OF CHANGE CODE |       | Collected at CRF.   |
| CARDAD   | char | DAD SCALE : CAREGIVER AVAILABLE          |       | Collected at CRF.   |
| CARGWBS  | char | GWBS : INF./FAMILY CAREGIVER AVAILABLE   |       | Collected at CRF.   |
| ECGNOB   | char | ECG OBTAINED                             |       | Collected at CRF.   |
| LABNOB   | char | LABO OBTAINED                            |       | 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. |
| ADAS_DY  | num  | RELATIVE ADASDAY                         |       | If ADAS_D and REF.DATE not missing then perform below logic to calculate ADAS_DY, If ADAS_D less than REF.DATE then (ADAS_D - REF.DATE). Else if ADAS_D is greater than equal to REF.DATE then (ADAS_D- REF.DATE) +1.       |
| CIBIC_DY | num  | RELATIVE CIBICDAY                        |       | 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. |

| Variable | Type | Label             | Codes | Comments  |
|----------|------|-------------------|-------|---|
| DAD_DY   | num  | RELATIVE DAY DAD  |       | If DAD_D and REF.DATE not missing then perform below logic to calculate DAD_DY, If DAD_D less than REF.DATE then (DAD_D - REF.DATE). Else if DAD_D is greater than equal to REF.DATE then (DAD_D- REF.DATE) +1.       |
| GWBS_DY  | num  | RELATIVE DAY GWBS |       | If GWBS_D and REF.DATE not missing then perform below logic to calculate GWBS_DY, If GWBS_D less than REF.DATE then (GWBS_D - REF.DATE). Else if GWBS_D is greater than equal to REF.DATE then (GWBS_D- REF.DATE) +1. |

### 1.4.30. Vital Signs – VITSIGN

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

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

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