

Clinical Development

**JNJ-28431754**

28431754DIA3006

Anonymisation Data Derivation Specification Document

|                  |                    |
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|---------------------------|---------------------|-------------------------------|
|                           |                     |                               |
|                           |                     |                               |

## 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 Name will not be provided.
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Remove 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.
- LB and ML data domains require having time information for secondary data analysis; –TM element will be derived before dropping original date element.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove ethnic information.
- Empty comments data will be submitted.
- Remove SC dataset. It contains only subject initial information.
- Remove SG dataset; It contains Subject Surgery related data, which is sensitive.

### 1.3. Data Files

The 28431754DIA3006 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Demographics – DM

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | DM   |
| <b>Creating program</b>  | dm.sas   |
| <b>Description</b>       | Demographics   |
| <b>Unique identifier</b> | DUSUBJID   |
| <b>Sorted by</b>         | DUSUBJID   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>RFSTDTC, BRTHDTC, ETHNIC, INVID, INVNAM,DMDTC,RFENDTC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| DSUBJID  | char | Subject Id Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DSITEID  | char | Study Site Id Assigned for De-identity   |       | Randomly assigned Site ID for De-identity           |

| Variable | Type | Label                              | Codes | Comments   |
|----------|------|------------------------------------|-------|--|
| AGE      | char | Age                                |       | If age is greater than 89 then group to "90+" otherwise AGE=AGE.<br>Grouping will be performed based on HIPAA privacy rules.   |
| AGEU     | char | Age Units                          |       | Collected at CRF   |
| SEX      | char | Sex                                |       | Collected at CRF   |
| RACE     | char | Race                               |       | Element has been grouped to protect PII.   |
| ARMCD    | char | Planned Arm Code                   |       | Collected at CRF   |
| ARM      | char | Description of Planned Arm         |       | Collected at CRF   |
| DCOUNTRY | char | De-identify Country                |       | Element has been grouped to protect PII.   |
| DMDY     | num  | Relative Day of Collection         |       | If DMDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br><br>If DMDTC less than RFSTDTC then (DMDTC - RFSTDTC). Else if DMDTC is greater than equal to RFSTDTC then (DMDTC - RFSTDTC) +1.           |
| RFENDY   | num  | Relative Subject Reference End Day |       | If RFENDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br><br>If RFENDTC less than RFSTDTC then (RFENDTC - RFSTDTC). Else if RFENDTC is greater than equal to RFSTDTC then (RFENDTC - RFSTDTC) +1. |



## 1.4.2. Supplemental Qualifiers-SUPPDM

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | SUPPDM   |
| <b>Creating program</b>  | dm.sas   |
| <b>Description</b>       | Supplemental Qualifiers of DM  |
| <b>Unique identifier</b> | DUSUBJID, QNAM   |
| <b>Sorted by</b>         | DUSUBJID, QNAM   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>IDVAR, IDVARVAL, QEVAL |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF   |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity  |
| QNAM     | char | Qualifier Variable Name                  |       | If QNAM in (PVSUBJID, RACEA, RACEAIAN, RACEBA, RACENHOP, RACEOTH, RACEOTHR, RACEW, RANUM) then DROP.<br><br>If QNAM=LSTMKDTC then LSTMKDY will be created which captures Relative Day of LSTMKDTC. LSTMKDTC will be dropped. |
| QLABEL   | char | Qualifier Variable Label                 |       | Collected at CRF   |

| Variable | Type | Label      | Codes | Comments  |
|----------|------|------------|-------|---|
| QVAL     | char | Data Value |       | If QNAM= LSTMKDTC and RFSTDTC not missing then perform below logic to calculate LSTMKDY, If QVAL less than RFSTDTC then (QVAL - RFSTDTC). Else if QVAL is greater than equal to RFSTDTC then (QVAL - RFSTDTC) +1. |
| QORIG    | char | Origin     |       | Collected at CRF  |

### 1.4.3. Adverse Events-AE

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | AE  |
| <b>Creating program</b>  | ae.sas  |
| <b>Description</b>       | Adverse Events  |
| <b>Unique identifier</b> | DUSUBJID,AEDECOD,AESTDY,AEENDY,AESPID   |
| <b>Sorted by</b>         | DUSUBJID,AEDECOD,AESTDY,AEENDY,AESPID   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>AETERM,AEMODIFY,AESCONG,AESDISAB,AESDTH,AESHOSP,AESLIFE, AESMIE,AESTDTC, AEENDTC |

| Variable | Type | Label               | Codes | Comments         |
|----------|------|---------------------|-------|------------------|
| STUDYID  | char | Study Identifier    |       | Collected at CRF |
| DOMAIN   | char | Domain Abbreviation |       | Collected at CRF |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| AESEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| AESPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| AEDECOD  | char | Dictionary-Derived Term                  |       | Collected at CRF                                     |
| AEBODSYS | char | Body System or Organ Class               |       | Collected at CRF                                     |
| AESEV    | char | Severity/Intensity                       |       | Collected at CRF                                     |
| AESER    | char | Serious Event                            |       | Collected at CRF                                     |
| AEACN    | char | Action Taken with Study Treatment        |       | Collected at CRF                                     |
| AEREL    | char | Causality                                |       | Collected at CRF                                     |
| AEOUT    | char | Outcome of Adverse Event                 |       | Collected at CRF                                     |
| AECONTRT | char | Concomitant or Additional Trtmnt Given   |       | Collected at CRF                                     |
| AESTDY   | num  | Study Day of Start of Adverse Event      |       | Collected at CRF                                     |
| AEENDY   | num  | Study Day of End of Adverse Event        |       | Collected at CRF                                     |

## 1.4.4. Supplemental Qualifiers-SUPPAE

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SUPPAE  |
| <b>Creating program</b>  | ae.sas  |
| <b>Description</b>       | Supplemental Qualifiers of AE   |
| <b>Unique identifier</b> | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Sorted by</b>         | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>QEVAL |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF                                    |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF                                    |
| QNAM     | char | Qualifier Variable Name                  |       | If QNAM in (AESHOSPP, AESHOSPR) then DROP.          |
| QLABEL   | char | Qualifier Variable Label                 |       | Collected at CRF                                    |
| QVAL     | char | Data Value                               |       | Collected at CRF                                    |
| QORIG    | char | Origin                                   |       | Collected at CRF                                    |

## 1.4.5. Clinical Events-CE

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | CE   |
| <b>Creating program</b>  | ce.sas   |
| <b>Description</b>       | Clinical Events  |
| <b>Unique identifier</b> | DUSUBJID, CETERM ,CESPID   |
| <b>Sorted by</b>         | DUSUBJID, CETERM , CESPID  |
| <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><br>CESTDTC, CEENDTC, CEENDY |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| CESEQ    | num  | Sequence Number                          |       | Collected at CRF                                    |
| CESPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                    |
| CETERM   | char | Reported Term for the Clinical Event     |       | Collected at CRF                                    |
| CECAT    | char | Category for Clinical Event              |       | Collected at CRF                                    |
| CESTDY   | num  | Study Day of Start Clinical Event        |       | Collected at CRF                                    |
| CEDUR    | char | Duration of Clinical Event               |       | Collected at CRF                                    |

## 1.4.6. Supplemental Qualifiers-SUPPCE

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | SUPPCE   |
| <b>Creating program</b>  | ce.sas   |
| <b>Description</b>       | Supplemental Qualifiers of CE  |
| <b>Unique identifier</b> | DUSUBJID, IDVAR, IDVARVAL, QNAM  |
| <b>Sorted by</b>         | DUSUBJID, IDVAR, IDVARVAL, QNAM  |
| <b>Notes</b>             | Below listed variables will be dropped due to missing values:<br><br>QEVAL |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF                                    |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF                                    |
| QNAM     | char | Qualifier Variable Name                  |       | Collected at CRF                                    |
| QLABEL   | char | Qualifier Variable Label                 |       | Collected at CRF                                    |
| QVAL     | char | Data Value                               |       | Collected at CRF                                    |
| QORIG    | char | Origin                                   |       | Collected at CRF                                    |

## 1.4.7. Clinical Findings-CF

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | CF   |
| <b>Creating program</b>  | cf.sas   |
| <b>Description</b>       | Clinical Findings  |
| <b>Unique identifier</b> | DUSUBJID, CFTESTCD ,CFSPID   |
| <b>Sorted by</b>         | DUSUBJID, CFTESTCD ,CFSPID   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>CFDTC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF  |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF  |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity.                            |
| CFSEQ    | num  | Sequence Number                          |       | Collected at CRF  |
| CFSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF  |
| CFTESTCD | char | Question Short Name                      |       | If CFTESTCD in (FRAACCT, OTHDIAG, MLSYMP, APPEAR, SYMPASSO, SUBJSYM) then drop. |
| CFTEST   | char | Question Name                            |       | Collected at CRF  |

| Variable | Type | Label                                  | Codes | Comments  |
|----------|------|--|-------|---|
| CFCAT    | char | Category of Question                   |       | Collected at CRF  |
| CFSCAT   | char | Subcategory for Question               |       | Collected at CRF  |
| CFORRES  | char | Finding in Original Units              |       | Collected at CRF  |
| CFORRESU | char | Original Units                         |       | Collected at CRF  |
| CFSTRESC | char | Character Result/Finding in Std Format |       | Collected at CRF  |
| CFSTRESN | num  | Numeric Finding in Standard Units      |       | Collected at CRF  |
| CFSTRESU | char | Standard Units                         |       | Collected at CRF  |
| CFMETHOD | char | Method of Test                         |       | Collected at CRF  |
| CFEVAL   | char | Evaluator                              |       | Collected at CRF  |
| CFDY     | num  | Relative Day of Finding                |       | <p>If CFDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If CFDTC less than RFSTDTC then (CFDTC - RFSTDTC). Else if CFDTC is greater than equal to RFSTDTC then (CFDTC - RFSTDTC) +1.</p> |



## 1.4.8. Supplemental Qualifiers-SUPPCF

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | SUPPCF   |
| <b>Creating program</b>  | cf.sas   |
| <b>Description</b>       | Supplemental Qualifiers of CF  |
| <b>Unique identifier</b> | DUSUBJID, IDVAR, IDVARVAL, QNAM  |
| <b>Sorted by</b>         | DUSUBJID, IDVAR, IDVARVAL, QNAM  |
| <b>Notes</b>             | Below listed variables will be dropped due to missing values:<br><br>QEVAL |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF   |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity  |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF   |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF   |
| QNAM     | char | Qualifier Variable Name                  |       | If QNAM in (CFADJDTC /CFDTHDTC) then CFADJDY , CFDTHDY will be created which captures Relative Day of CFADJDTC /CFDTHDTC respectively. CFADJDTC ,CFDTHDTC will be dropped. |
| QLABEL   | char | Qualifier Variable Label                 |       | Collected at CRF   |

| Variable | Type | Label      | Codes | Comments   |
|----------|------|------------|-------|--|
| QVAL     | char | Data Value |       | If QNAM= CFADJDTC or CFDTHDTC and RFSTDTC not missing then perform below logic to calculate CFADJDY/ CFDTHDY,<br>If QVAL less than RFSTDTC then (QVAL - RFSTDTC).<br>Else if QVAL is greater than equal to RFSTDTC then (QVAL - RFSTDTC) +1. |
| QORIG    | char | Origin     |       | Collected at CRF   |

#### 1.4.9. Concomitant Medications-CM

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | CM   |
| <b>Creating program</b>  | cm.sas   |
| <b>Description</b>       | Concomitant Medications  |
| <b>Unique identifier</b> | DUSUBJID,CMDECOD,CMSTDY,CMSPID   |
| <b>Sorted by</b>         | DUSUBJID,CMDECOD,CMSTDY,CMSPID   |
| <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><br>CMTRT, CMMODIFY, CMSTDTC, CMENDTC, CMDUR, CMENRF |

| Variable | Type | Label               | Codes | Comments         |
|----------|------|---------------------|-------|------------------|
| STUDYID  | char | Study Identifier    |       | Collected at CRF |
| DOMAIN   | char | Domain Abbreviation |       | Collected at CRF |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| CMSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| CMSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| CMDECOD  | char | Standardized Medication Name             |       | Collected at CRF                                     |
| CMCAT    | char | Category for Medication                  |       | Collected at CRF                                     |
| CMSCAT   | char | Subcategory for Medication               |       | Collected at CRF                                     |
| CMOCCUR  | char | CM Occurrence                            |       | Collected at CRF                                     |
| CMINDC   | char | Indication                               |       | Collected at CRF                                     |
| CMCLAS   | char | Medication Class                         |       | Collected at CRF                                     |
| CMCLASCD | char | Medication Class Code                    |       | Collected at CRF                                     |
| CMDOSE   | num  | Dose per Administration                  |       | Collected at CRF                                     |
| CMDOSTXT | char | Dose Description                         |       | Collected at CRF                                     |
| CMDOSU   | char | Dose Units                               |       | Collected at CRF                                     |
| CMDOSFRQ | char | Dosing Frequency Per Interval            |       | Collected at CRF                                     |
| CMDOSTOT | num  | Total Daily Dose                         |       | Collected at CRF                                     |
| CMROUTE  | char | Route of Administration                  |       | Collected at CRF                                     |
| CMSTDY   | num  | Study Day of Start of Medication         |       | Collected at CRF                                     |
| CMENDY   | num  | Study Day of End of Medication           |       | Collected at CRF                                     |

## 1.4.10. Supplemental Qualifiers-SUPPCM

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | CM   |
| <b>Creating program</b>  | cm.sas   |
| <b>Description</b>       | Supplemental Qualifiers of CM  |
| <b>Unique identifier</b> | DUSUBJID, IDVAR, IDVARVAL, QNAM  |
| <b>Sorted by</b>         | DUSUBJID, IDVAR, IDVARVAL, QNAM  |
| <b>Notes</b>             | Below listed variables will be dropped due to missing values:<br><br>QEVAL |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF  |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF  |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity   |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF  |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF  |
| QNAM     | char | Qualifier Variable Name                  |       | If QNAM in (CMINDOTH) then DROP<br><br>If QNAM= CMRSDTC then CMRSY will be created which captures Relative Day of CMRSDTC. CMRSDTC will be dropped. |

| Variable | Type | Label                    | Codes | Comments   |
|----------|------|--------------------------|-------|--|
| QLABEL   | char | Qualifier Variable Label |       | Collected at CRF   |
| QVAL     | char | Data Value               |       | If QNAM= CMRSDTC and RFSTDTC not missing then perform below logic to calculate CMRSDY<br>If QVAL less than RFSTDTC then (QVAL - RFSTDTC).<br>Else if QVAL is greater than equal to RFSTDTC then (QVAL - RFSTDTC) +1. |
| QORIG    | char | Origin                   |       | Collected at CRF   |

#### 1.4.11. Comments-CO

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | CO  |
| <b>Creating program</b>  | co.sas  |
| <b>Description</b>       | Comments  |
| <b>Unique identifier</b> | Not Applicable  |
| <b>Sorted by</b>         | Not Applicable  |
| <b>Notes</b>             | Comments data is sensitive data, contains free text information. Will be submitted empty dataset. |

| Variable | Type | Label                       | Codes | Comments                         |
|----------|------|-----------------------------|-------|----------------------------------|
| STUDYID  | char | Study Identifier            |       | Empty dataset will be submitted. |
| DOMAIN   | char | Domain Abbreviation         |       | Empty dataset will be submitted. |
| RDOMAIN  | char | Related Domain Abbreviation |       | Empty dataset will be submitted. |

| Variable | Type | Label                                    | Codes | Comments                         |
|----------|------|--|-------|----------------------------------|
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Empty dataset will be submitted. |
| COSEQ    | num  | Sequence Number                          |       | Empty dataset will be submitted. |
| IDVAR    | char | Identifying Variable                     |       | Empty dataset will be submitted. |
| IDVARVAL | char | Identifying Variable Value               |       | Empty dataset will be submitted. |

#### 1.4.12. Drug Accountability-DA

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | DA  |
| <b>Creating program</b>  | da.sas  |
| <b>Description</b>       | Drug Accountability   |
| <b>Unique identifier</b> | DUSUBJID, DATESTCD,DASPID   |
| <b>Sorted by</b>         | DUSUBJID, DATESTCD, DASPID  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines :<br><br>DADTC |

| Variable | Type | Label            | Codes | Comments         |
|----------|------|------------------|-------|------------------|
| STUDYID  | char | Study Identifier |       | Collected at CRF |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF  |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity.  |
| DASEQ    | num  | Sequence Number                          |       | Collected at CRF  |
| DASPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF  |
| DATESTCD | char | Short Name of Accountability Assessment  |       | Collected at CRF  |
| DATEST   | char | Name of Accountability Assessment        |       | Collected at CRF  |
| DAORRES  | char | Accountability Assessment in Or. Units   |       | Collected at CRF  |
| DASTRESC | char | Accountability Assessment in Std Format  |       | Collected at CRF  |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF  |
| VISIT    | char | Visit Name                               |       | Collected at CRF  |
| EPOCH    | char | Trial Epoch                              |       | Collected at CRF  |
| DADY     | num  | Relative Day of Drug Accountability Ass. |       | <p>If DADTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If DADTC less than RFSTDTC then (DADTC - RFSTDTC). Else if DADTC is greater than equal to RFSTDTC then (DADTC - RFSTDTC) +1.</p> |

## 1.4.13. Diet and Exercise-DE

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | DE   |
| <b>Creating program</b>  | de.sas   |
| <b>Description</b>       | Diet and Exercise  |
| <b>Unique identifier</b> | DUSUBJID, DETESTCD, VISITNUM,DESPID  |
| <b>Sorted by</b>         | DUSUBJID, DETESTCD, VISITNUM, DESPID   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>DEDTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| DESEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| DESPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| DETESTCD | char | Diet and Exercise Short Name             |       | Collected at CRF                                     |
| DETEST   | char | Diet and Exercise Name                   |       | Collected at CRF                                     |
| DECAT    | char | Category for Finding                     |       | Collected at CRF                                     |
| DEORRES  | char | Finding in Original Units                |       | Collected at CRF                                     |



| Variable | Type | Label                                  | Codes | Comments   |
|----------|------|--|-------|--|
| DESTRESC | char | Character Result/Finding in Std Format |       | Collected at CRF   |
| VISITNUM | num  | Visit Number                           |       | Collected at CRF   |
| VISIT    | char | Visit Name                             |       | Collected at CRF   |
| EPOCH    | char | Trial Epoch                            |       | Collected at CRF   |
| DEDY     | num  | Relative Day of Finding                |       | If DEDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br>If DEDTC less than RFSTDTC then (DEDTC - RFSTDTC). Else if DEDTC is greater than equal to RFSTDTC then (DEDTC - RFSTDTC) +1. |

## 1.4.14. Disposition-DS

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | DS  |
| <b>Creating program</b>  | ds.sas  |
| <b>Description</b>       | Disposition   |
| <b>Unique identifier</b> | DUSUBJID, DSDECOD, DSSPID   |
| <b>Sorted by</b>         | DUSUBJID, DSDECOD, DSSPID   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>DSTERM, DSSTDTC, DSDTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| DSSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| DSSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| DSDECOD  | char | Standardized Disposition Term            |       | Collected at CRF                                     |
| DSCAT    | char | Category for Disposition Event           |       | Collected at CRF                                     |
| DSSCAT   | char | Subcategory for Disposition Event        |       | Collected at CRF                                     |
| VISIT    | char | Visit Name                               |       | Collected at CRF                                     |

| Variable | Type | Label                                   | Codes | Comments   |
|----------|------|---|-------|--|
| VISITNUM | num  | Visit Number                            |       | Collected at CRF   |
| EPOCH    | char | Trial Epoch                             |       | Collected at CRF   |
| DSSTDY   | num  | Study Day of Start of Disposition Event |       | Collected at CRF   |
| DSDY     | num  | Relative Day of Collection              |       | If DSDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br><br>If DSDTC less than RFSTDTC then (DSDTC - RFSTDTC). Else if DSDTC is greater than equal to RFSTDTC then (DSDTC - RFSTDTC) +1. |

## 1.4.15. Supplemental Qualifiers-SUPPDS

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SUPPDS  |
| <b>Creating program</b>  | ds.sas  |
| <b>Description</b>       | Supplemental Qualifiers of DS   |
| <b>Unique identifier</b> | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Sorted by</b>         | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>QEVAL |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF                                    |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF                                    |
| QNAM     | char | Qualifier Variable Name                  |       | Collected at CRF                                    |
| QLABEL   | char | Qualifier Variable Label                 |       | Collected at CRF                                    |
| QVAL     | char | Data Value                               |       | Collected at CRF                                    |
| QORIG    | char | Origin                                   |       | Collected at CRF                                    |

## 1.4.16. Protocol Deviations-DV

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | DV  |
| <b>Creating program</b>  | dv.sas  |
| <b>Description</b>       | Protocol Deviations   |
| <b>Unique identifier</b> | DUSUBJID, DVDECOD, DVSPID, DVSEQ  |
| <b>Sorted by</b>         | DUSUBJID, DVDECOD, DVSPID, DVSEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>DVTERM |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| DVSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| DVDECOD  | char | Protocol Deviation Coded Term            |       | Collected at CRF                                     |
| DVSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |

## 1.4.17. Supplemental Qualifiers-SUPPDV

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SUPPDV  |
| <b>Creating program</b>  | dv.sas  |
| <b>Description</b>       | Supplemental Qualifiers of DV   |
| <b>Unique identifier</b> | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Sorted by</b>         | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br><br>QEVAL |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF                                    |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF                                    |
| QNAM     | char | Qualifier Variable Name                  |       | If QNAM in (DVTERM1, DVTERM2, DVTERM3) then DROP.   |
| QLABEL   | char | Qualifier Variable Label                 |       | Collected at CRF                                    |
| QVAL     | char | Data Value                               |       | Collected at CRF                                    |

| Variable | Type | Label  | Codes | Comments         |
|----------|------|--------|-------|------------------|
| QORIG    | char | Origin |       | Collected at CRF |

#### 1.4.18. Exploratory Samples-EC

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | EC  |
| <b>Creating program</b>  | ec.sas  |
| <b>Description</b>       | Exploratory Samples   |
| <b>Unique identifier</b> | DUSUBJID, ECTESTCD, ECSPID  |
| <b>Sorted by</b>         | DUSUBJID, ECTESTCD, ECSPID  |
| <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><br>EPOCH,ECBTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| ECSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| ECSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| ECTESTCD | char | Test Short Name                          |       | Collected at CRF                                     |

| Variable | Type | Label                                   | Codes | Comments  |
|----------|------|---|-------|---|
| ECTEST   | char | Test                                    |       | Collected at CRF  |
| ECCAT    | char | Category                                |       | Collected at CRF  |
| ECORRES  | char | Verbatim Finding                        |       | Collected at CRF  |
| ECORRESU | char | Original Units                          |       | Collected at CRF  |
| ECSTRESC | char | Character Result/Finding in Std. Format |       | Collected at CRF  |
| ECDY     | num  | Relative Day                            |       | <p>If ECDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If ECDTC less than RFSTDTC then (ECDTC - RFSTDTC). Else if ECDTC is greater than equal to RFSTDTC then (ECDTC - RFSTDTC) +1.</p> |



## 1.4.19. ECG Test Results-EG

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | EG   |
| <b>Creating program</b>  | eg.sas   |
| <b>Description</b>       | ECG Test Results   |
| <b>Unique identifier</b> | DUSUBJID, EGTESTCD, EGSEQ  |
| <b>Sorted by</b>         | DUSUBJID, EGTESTCD, EGSEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>EGREFID, EGDTIC, EGSPID |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| EGSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| EGTESTCD | char | ECG Test or Examination Short Name       |       | Collected at CRF                                     |
| EGTEST   | char | ECG Test or Examination Name             |       | Collected at CRF                                     |
| EGPOS    | char | ECG Position of Subject                  |       | Collected at CRF                                     |
| EGORRES  | char | Result or Finding in Original Units      |       | Collected at CRF                                     |
| EGORRESU | char | Original Units                           |       | Collected at CRF                                     |

| Variable | Type | Label                                    | Codes | Comments         |
|----------|------|--|-------|------------------|
| EGSTRESC | char | Character Result/Finding in Std Format   |       | Collected at CRF |
| EGSTRESN | num  | Numeric Result/Finding in Standard Units |       | Collected at CRF |
| EGSTRESU | char | Standard Units                           |       | Collected at CRF |
| EGBLFL   | char | Baseline Flag                            |       | Collected at CRF |
| EGEVAL   | char | Evaluator                                |       | Collected at CRF |
| VISIT    | char | Visit Name                               |       | Collected at CRF |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF |
| EGDY     | num  | Study Day of ECG                         |       | Collected at CRF |
| EPOCH    | char | Trial Epoch                              |       | Collected at CRF |

## 1.4.20. Exposure-EX

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | EX   |
| <b>Creating program</b>  | ex.sas   |
| <b>Description</b>       | Exposure   |
| <b>Unique identifier</b> | DUSUBJID,EXTRT,EXSPID  |
| <b>Sorted by</b>         | DUSUBJID,EXTRT,EXSPID  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>EXSTDTC,EXENDTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| EXSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| EXSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| EXTRT    | char | Name of Actual Treatment                 |       | Collected at CRF                                     |
| EXDOSE   | num  | Dose per Administration                  |       | Collected at CRF                                     |
| EXDOSU   | char | Dose Units                               |       | Collected at CRF                                     |
| EXDOSFRM | char | Dose Form                                |       | Collected at CRF                                     |

| Variable | Type | Label                           | Codes | Comments   |
|----------|------|---------------------------------|-------|--|
| EXDOSFRQ | char | Dosing Frequency Per Interval   |       | Collected at CRF   |
| EPOCH    | char | Trial Epoch                     |       | Collected at CRF   |
| EXENDY   | num  | Relative End Day of Treatment   |       | If EXENDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br><br>If EXENDTC less than RFSTDTC then (EXENDTC - RFSTDTC). Else if EXENDTC is greater than equal to RFSTDTC then (EXENDTC - RFSTDTC) +1. |
| EXSTDY   | num  | Relative Start Day of Treatment |       | If EXSTDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br><br>If EXSTDTC less than RFSTDTC then (EXSTDTC - RFSTDTC). Else if EXSTDTC is greater than equal to RFSTDTC then (EXSTDTC - RFSTDTC) +1. |

## 1.4.21. Hypoglycemic Education and Counseling-HC

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | HC   |
| <b>Creating program</b>  | hc.sas   |
| <b>Description</b>       | Hypoglycemic Education and Counseling  |
| <b>Unique identifier</b> | DUSUBJID,HCTESTCD,HCSEQ  |
| <b>Sorted by</b>         | DUSUBJID,HCTESTCD,HCSEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>HCDTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| HCSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| HCSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| HCTESTCD | char | Hypoglycemia Edu. and Counsel Short Name |       | Collected at CRF                                     |
| HCTEST   | char | Hypoglycemia Education and Counseling    |       | Collected at CRF                                     |
| HCCAT    | char | Category for Finding                     |       | Collected at CRF                                     |

| Variable | Type | Label                                  | Codes | Comments  |
|----------|------|--|-------|---|
| HCORRES  | char | Finding in Original Units              |       | Collected at CRF  |
| HCSTRESC | char | Character Result/Finding in Std Format |       | Collected at CRF  |
| VISITNUM | num  | Visit Number                           |       | Collected at CRF  |
| VISIT    | char | Visit Name                             |       | Collected at CRF  |
| EPOCH    | char | Trial Epoch                            |       | Collected at CRF  |
| HCDY     | num  | Relative Day of Finding                |       | <p>If HCDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If HCDTC less than RFSTDTC then (HCDTC - RFSTDTC). Else if HCDTC is greater than equal to RFSTDTC then (HCDTC - RFSTDTC) +1.</p> |

## 1.4.22. Inclusion/Exclusion Exceptions-IE

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | IE  |
| <b>Creating program</b>  | ie.sas  |
| <b>Description</b>       | Inclusion/Exclusion Exceptions  |
| <b>Unique identifier</b> | DUSUBJID,IETESTCD,IESPID  |
| <b>Sorted by</b>         | DUSUBJID,IETESTCD,IESPID  |
| <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><br>IEDTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| IESEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| IESPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| IETESTCD | char | Inclusion/Exclusion Criterion Short Name |       | Collected at CRF                                     |
| IETEST   | char | Inclusion/Exclusion Criterion            |       | Collected at CRF                                     |
| IECAT    | char | Inclusion/Exclusion Category             |       | Collected at CRF                                     |
| IEORRES  | char | I/E Criterion Original Result            |       | Collected at CRF                                     |

| Variable | Type | Label                              | Codes | Comments         |
|----------|------|------------------------------------|-------|------------------|
| IESTRESC | char | I/E Criterion Result in Std Format |       | Collected at CRF |

### 1.4.23. Laboratory Test Results-LB

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | LB   |
| <b>Creating program</b>  | lb.sas   |
| <b>Description</b>       | Laboratory Test Results  |
| <b>Unique identifier</b> | DUSUBJID, LBTESTCD, LBSEQ  |
| <b>Sorted by</b>         | DUSUBJID, LBTESTCD, LBSEQ  |
| <b>Notes</b>             | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:</p> <p>LBREFID, LBSCAT, LBSPCCND, LBREASND, LBNAM, LBTOX, LBTOXGR, LBDC, LBENDTC</p> <p>Note: Protocol unplanned tests will be removed; it may reveal participant information.</p> |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| LBSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |



| Variable  | Type | Label                                    | Codes | Comments         |
|-----------|------|--|-------|------------------|
| LBGRPID   | char | Group ID                                 |       | Collected at CRF |
| LBSPID    | char | Sponsor-Defined Identifier               |       | Collected at CRF |
| LBTESTCD  | char | LAB Test or Examination Short Name       |       | Collected at CRF |
| LBTEST    | char | LAB Test or Examination Name             |       | Collected at CRF |
| LBCAT     | char | Category for Lab Test                    |       | Collected at CRF |
| LBORRES   | char | Result or Finding in Original Units      |       | Collected at CRF |
| LBORRESU  | char | Original Units                           |       | Collected at CRF |
| LBORNRL0  | char | Reference Range Lower Limit in Orig Unit |       | Collected at CRF |
| LBORNRLHI | char | Reference Range Upper Limit in Orig Unit |       | Collected at CRF |
| LBSTRESC  | char | Character Result/Finding in Std Format   |       | Collected at CRF |
| LBSTNR0   | char | Reference Range for Char Rslt-Std Units  |       | Collected at CRF |
| LBSTRESN  | num  | Numeric Result/Finding in Standard Units |       | Collected at CRF |
| LBSTRESU  | char | Standard Units                           |       | Collected at CRF |
| LBSTNR0   | num  | Reference Range Lower Limit-Std Units    |       | Collected at CRF |
| LBSTNRHI  | num  | Reference Range Upper Limit-Std Units    |       | Collected at CRF |
| LBNRIND   | char | Reference Range Indicator                |       | Collected at CRF |

| Variable | Type | Label                            | Codes | Comments  |
|----------|------|----------------------------------|-------|---|
| LBSTAT   | char | Lab Status                       |       | Collected at CRF  |
| LBSPEC   | char | Specimen Type                    |       | Collected at CRF  |
| LBMETHOD | char | Method of Test or Examination    |       | Collected at CRF  |
| LDDLFL   | char | Baseline Flag                    |       | Collected at CRF  |
| LDDRVL   | char | Derived Flag                     |       | Collected at CRF  |
| LDFAST   | char | Fasting Status                   |       | Collected at CRF  |
| VISIT    | char | Visit Name                       |       | Collected at CRF  |
| VISITNUM | num  | Visit Number                     |       | Collected at CRF  |
| LBDY     | num  | Study Day of Specimen Collection |       | Collected at CRF  |
| LBTPT    | char | Planned Time Point Name          |       | Collected at CRF  |
| LBTPTNUM | num  | Planned Time Point Number        |       | Collected at CRF  |
| EPOCH    | char | Trial Epoch                      |       | Collected at CRF  |
| LBTM     | num  | Time of Specimen Collection      |       | If LBDTC contains time part then timepart(LBDTC) else LBTM equal to NULL. |

## 1.4.24. Supplemental Qualifiers-SUPPLB

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SUPPLB  |
| <b>Creating program</b>  | lb.sas  |
| <b>Description</b>       | Supplemental Qualifiers of LB   |
| <b>Unique identifier</b> | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Sorted by</b>         | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>QEVAL |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF                                    |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF                                    |
| QNAM     | char | Qualifier Variable Name                  |       | Collected at CRF                                    |
| QLABEL   | char | Qualifier Variable Label                 |       | Collected at CRF                                    |
| QVAL     | char | Data Value                               |       | Collected at CRF                                    |
| QORIG    | char | Origin                                   |       | Collected at CRF                                    |

## 1.4.25. Medical History-MH

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | MH   |
| <b>Creating program</b>  | mh.sas   |
| <b>Description</b>       | Medical History  |
| <b>Unique identifier</b> | DUSUBJID,MHDECOD,MHSPID,MHSEQ  |
| <b>Sorted by</b>         | DUSUBJID,MHDECOD,MHSPID,MHSEQ  |
| <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><br>MHTERM, MHMODIFY, MHSTAT, MHREASND, MHENDTC,MHDTTC,MHSTDTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| MHSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| MHSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| MHDECOD  | char | Dictionary-Derived Term                  |       | Collected at CRF                                     |
| MHCAT    | char | Category for Medical History             |       | Collected at CRF                                     |
| MHSCAT   | char | Subcategory for Medical History          |       | Collected at CRF                                     |
| MHOCCUR  | char | Medical History Occurrence               |       | Collected at CRF                                     |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| MHBODSYS | char | Body System or Organ Class               |       | Collected at CRF   |
| VISIT    | char | Visit Name                               |       | Collected at CRF   |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF   |
| EPOCH    | char | Trial Epoch                              |       | Collected at CRF   |
| MHDY     | num  | Relative Day of History Collection       |       | If MHDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br>If MHDTC less than RFSTDTC then (MHDTC - RFSTDTC). Else if MHDTC is greater than equal to RFSTDTC then (MHDTC - RFSTDTC) +1.           |
| MHSTDY   | num  | Relative Start Day of Medi History Event |       | If MHSTDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br>If MHSTDTC less than RFSTDTC then (MHSTDTC - RFSTDTC). Else if MHSTDTC is greater than equal to RFSTDTC then (MHSTDTC - RFSTDTC) +1. |

## 1.4.26. Supplemental Qualifiers-SUPPMH

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SUPPMH  |
| <b>Creating program</b>  | mh.sas  |
| <b>Description</b>       | Supplemental Qualifiers of MH   |
| <b>Unique identifier</b> | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Sorted by</b>         | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br><br>QEVAL |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF                                    |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF                                    |
| QNAM     | char | Qualifier Variable Name                  |       | Collected at CRF                                    |
| QLABEL   | char | Qualifier Variable Label                 |       | Collected at CRF                                    |
| QVAL     | char | Data Value                               |       | Collected at CRF                                    |
| QORIG    | char | Origin                                   |       | Collected at CRF                                    |

## 1.4.27. Meals-ML

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | ML   |
| <b>Creating program</b>  | ml.sas   |
| <b>Description</b>       | Meals  |
| <b>Unique identifier</b> | DUSUBJID,VISITNUM,MLSPID   |
| <b>Sorted by</b>         | DUSUBJID,VISITNUM,MLSPID   |
| <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><br>MLDOSE, MLDOSU, MLENDTC,MLDTC,MLSTDTC,MLRFTDTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| MLSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| MLSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| MLTRT    | char | Name of Meal                             |       | Collected at CRF                                     |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                     |
| VISIT    | char | Visit Name                               |       | Collected at CRF                                     |
| MLTPT    | char | Planned Time Point Name                  |       | Collected at CRF                                     |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| MLTPTNUM | num  | Planned Time Point Number                |       | Collected at CRF  |
| MLTPTREF | char | Time Point Reference                     |       | Collected at CRF  |
| MLDY     | num  | Relative Day of MMTT                     |       | If MLDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br><br>If MLDTC less than RFSTDTC then (MLDTC - RFSTDTC). Else if MLDTC is greater than equal to RFSTDTC then (MLDTC - RFSTDTC) +1.                |
| MLRFTTM  | num  | Act Time of dose of study agent          |       | If MLRFTDTC contains time part then timepart(MLRFTDTC) else MLRFTTM equal to NULL   |
| MLRFTDY  | num  | Relative Act Time of dose of study agent |       | If MLRFTDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br><br>If MLRFTDTC less than RFSTDTC then (MLRFTDTC - RFSTDTC). Else if MLRFTDTC is greater than equal to RFSTDTC then (MLRFTDTC - RFSTDTC) +1. |
| MLSTTM   | num  | Start time of meal                       |       | If MLSTDTC contains time part then timepart(MLSTDTC) else MLSTTM equal to NULL  |
| MLSTDY   | num  | Relative Start Day of Meal               |       | If MLSTDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br><br>If MLSTDTC less than RFSTDTC then (MLSTDTC - RFSTDTC). Else if MLSTDTC is greater than equal to RFSTDTC then (MLSTDTC - RFSTDTC) +1.      |



## 1.4.28. Questionnaires-QS

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | QS  |
| <b>Creating program</b>  | qs.sas  |
| <b>Description</b>       | Questionnaire   |
| <b>Unique identifier</b> | DUSUBJID,QSTESTCD,VISITNUM,QSSEQ  |
| <b>Sorted by</b>         | DUSUBJID,QSTESTCD,VISITNUM, QSSEQ   |
| <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><br>QSDRVFL, QSDTC, QSNAM |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| QSSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| QSSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| QSTESTCD | char | Question Short Name                      |       | Collected at CRF                                     |
| QSTEST   | char | Question Name                            |       | Collected at CRF                                     |
| QSCAT    | char | Category of Question                     |       | Collected at CRF                                     |
| QSSCAT   | char | Subcategory for Question                 |       | Collected at CRF                                     |

| Variable | Type | Label                                  | Codes | Comments         |
|----------|------|--|-------|------------------|
| QSORRES  | char | Finding in Original Units              |       | Collected at CRF |
| QSSTRESC | char | Character Result/Finding in Std Format |       | Collected at CRF |
| QSSTRESN | num  | Numeric Finding in Standard Units      |       | Collected at CRF |
| QSBFL    | char | Baseline Flag                          |       | Collected at CRF |
| VISIT    | char | Visit Name                             |       | Collected at CRF |
| VISITNUM | num  | Visit Number                           |       | Collected at CRF |
| QSDY     | num  | Study Day of Finding                   |       | Collected at CRF |
| EPOCH    | char | Trial Epoch                            |       | Collected at CRF |

### 1.4.29. Related Records - RELREC

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | RELREC   |
| <b>Creating program</b>  | relrec.sas   |
| <b>Description</b>       | Related Records  |
| <b>Unique identifier</b> | RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID  |
| <b>Sorted by</b>         | RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID  |
| <b>Notes</b>             | Below listed variables will be dropped due to missing values:<br><br>RELTYPE |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF                                    |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF                                    |
| RELID    | char | Relationship Identifier                  |       | Collected at CRF                                    |

## 1.4.30. Substance Use - SU

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | SU   |
| <b>Creating program</b>  | su.sas   |
| <b>Description</b>       | Substance Use  |
| <b>Unique identifier</b> | DUSUBJID,SUTRT,SUSPID  |
| <b>Sorted by</b>         | DUSUBJID,SUTRT,SUSPID  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>SUSTDTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| SUSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| SUSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| SUTRT    | char | Reported Name of Substance               |       | Collected at CRF                                     |
| SUCAT    | char | Category for Substance Use               |       | Collected at CRF                                     |
| SUOCCUR  | char | SU Occurrence                            |       | Collected at CRF                                     |
| VISIT    | char | Visit Name                               |       | Collected at CRF                                     |

| Variable | Type | Label                               | Codes | Comments   |
|----------|------|-------------------------------------|-------|--|
| VISITNUM | num  | Visit Number                        |       | Collected at CRF   |
| SUSTDY   | num  | Relative Start Day of Substance Use |       | If SUSTDTC and RFSTDTC not missing then perform below logic to calculate relative day.<br><br>If SUSTDTC less than RFSTDTC then (SUSTDTC - RFSTDTC). Else if SUSTDTC is greater than equal to RFSTDTC then (SUSTDTC - RFSTDTC) +1. |

#### 1.4.31. Subject Visits - SV

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SV  |
| <b>Creating program</b>  | sv.sas  |
| <b>Description</b>       | Subject Visits  |
| <b>Unique identifier</b> | DUSUBJID,VISITNUM,SVSPID  |
| <b>Sorted by</b>         | DUSUBJID,VISITNUM,SVSPID  |
| <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><br>SVSTDTC,SVENDTC |

| Variable | Type | Label               | Codes | Comments         |
|----------|------|---------------------|-------|------------------|
| STUDYID  | char | Study Identifier    |       | Collected at CRF |
| DOMAIN   | char | Domain Abbreviation |       | Collected at CRF |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity.  |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF  |
| VISIT    | char | Visit Name                               |       | Collected at CRF  |
| EPOCH    | char | Trial Epoch                              |       | Collected at CRF  |
| SVSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF  |
| SVSTDY   | num  | Relative Start Day of Visit              |       | <p>If SVSTDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If SVSTDTC less than RFSTDTC then (SVSTDTC - RFSTDTC). Else if SVSTDTC is greater than equal to RFSTDTC then (SVSTDTC - RFSTDTC) +1.</p> |

## 1.4.32. Supplemental Qualifiers - SUPPSV

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SUPPSV  |
| <b>Creating program</b>  | sv.sas  |
| <b>Description</b>       | Supplemental Qualifiers of SV   |
| <b>Unique identifier</b> | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Sorted by</b>         | DUSUBJID, IDVAR, IDVARVAL, QNAM   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>QEVAL, COL2 |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                    |
| RDOMAIN  | char | Related Domain Abbreviation              |       | Collected at CRF                                    |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| IDVAR    | char | Identifying Variable                     |       | Collected at CRF                                    |
| IDVARVAL | char | Identifying Variable Value               |       | Collected at CRF                                    |
| QNAM     | char | Qualifier Variable Name                  |       | IF QNAM in (SVREASND) then DROP.                    |
| QLABEL   | char | Qualifier Variable Label                 |       | Collected at CRF                                    |
| QVAL     | char | Data Value                               |       | Collected at CRF                                    |
| QORIG    | char | Origin                                   |       | Collected at CRF                                    |

## 1.4.33. Trial Inclusion/Exclusion Criteria-TI

|                          |                                    |
|--------------------------|------------------------------------|
| <b>Dataset</b>           | TI                                 |
| <b>Creating program</b>  | ti.sas                             |
| <b>Description</b>       | Trial Inclusion/Exclusion Criteria |
| <b>Unique identifier</b> | DOMAIN,IECAT,IETESTCD              |
| <b>Sorted by</b>         | DOMAIN,IECAT,IETESTCD              |
| <b>Note</b>              |                                    |

| Variable | Type | Label                                    | Codes | Comments      |
|----------|------|--|-------|---------------|
| STUDYID  | char | Study Identifier                         |       | Protocol data |
| DOMAIN   | char | Domain Abbreviation                      |       | Protocol data |
| IETESTCD | char | Inclusion/Exclusion Criterion Short Name |       | Protocol data |
| IETEST   | char | Inclusion/Exclusion Criterion            |       | Protocol data |
| IECAT    | char | Inclusion/Exclusion Category             |       | Protocol data |



## 1.4.34. Vital Signs-VS

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | VS   |
| <b>Creating program</b>  | vs.sas   |
| <b>Description</b>       | Vital Signs  |
| <b>Unique identifier</b> | DUSUBJID,VSTESTCD,VSSEQ  |
| <b>Sorted by</b>         | DUSUBJID,VSTESTCD,VSSEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>VSDTC |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| STUDYID  | char | Study Identifier                         |       | Collected at CRF                                     |
| DOMAIN   | char | Domain Abbreviation                      |       | Collected at CRF                                     |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity. |
| VSSEQ    | num  | Sequence Number                          |       | Collected at CRF                                     |
| VSSPID   | char | Sponsor-Defined Identifier               |       | Collected at CRF                                     |
| VSTESTCD | char | Vital Signs Test Short Name              |       | Collected at CRF                                     |
| VSTEST   | char | Vital Signs Test Name                    |       | Collected at CRF                                     |
| VSORRES  | char | Result or Finding in Original Units      |       | Collected at CRF                                     |

| Variable | Type | Label                                    | Codes | Comments         |
|----------|------|--|-------|------------------|
| VSORRESU | char | Original Units                           |       | Collected at CRF |
| VSSTRESC | char | Character Result/Finding in Std Format   |       | Collected at CRF |
| VSSTRESN | num  | Numeric Result/Finding in Standard Units |       | Collected at CRF |
| VSSTRESU | char | Standard Units                           |       | Collected at CRF |
| VSBLFL   | char | Baseline Flag                            |       | Collected at CRF |
| VSDRVFL  | char | Derived Flag                             |       | Collected at CRF |
| VISIT    | char | Visit Name                               |       | Collected at CRF |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF |
| VSDY     | num  | Study Day of Vital Signs                 |       | Collected at CRF |
| EPOCH    | char | Trial Epoch                              |       | Collected at CRF |