

Clinical Development

**JNJ-28431754**

28431754DIA3002

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 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 to have 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 28431754DIA3002 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:  RFSTDTC, RFENDTC, INVID, INVNAM, BRTHDTC, ETHNIC, DMDTC

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
AGE	char	Age		If age is greater than 89 then group to "90+" otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Age Units		Collected at CRF

Variable	Type	Label	Codes	Comments
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 will be grouped to protect PII
DMDY	num	Relative Day of Collection		<p>If DMDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If DMDTC less than RFSTDTC then (DMDTC - RFSTDTC). Else if DMDTC is greater than equal to RFSTDTC then (DMDTC - RFSTDTC) +1.</p>
RFENDY	num	Relative Subject Reference End Day		<p>If RFENDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If RFENDTC less than RFSTDTC then (RFENDTC - RFSTDTC). Else if RFENDTC is greater than equal to RFSTDTC then (RFENDTC - RFSTDTC) +1.</p>



### 1.4.2. Supplemental Qualifiers (SUPPDM) – SUPPDM

Dataset	SUPPDM
Creating program	dm.sas
Description	Supplementary Qualifier for DM
Unique identifier	DUSUBJID, QNAM
Sorted by	DUSUBJID, QNAM
Notes	Below listed variables will be dropped from dataset due to missing values:  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 (RACEA, RACEAIAN, RACEBA, RACENHOP, RACEOTH, RACEOTHR, RACEW, RANUM, PVSUBJID) then drop. If QNAM eq "LSTMKDTC" then derive LSTMKDY (Relative Day) and drop LSTMKDTC.
QLABEL	char	Qualifier Variable Label		Collected at CRF
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

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID, AEDECOD ,AESPID
Sorted by	DUSUBJID, AEDECOD ,AESPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:  AEGRPID,AEREFID, AETERM,AEMODIFY,AESCONG,AESDISAB, AESDTH,AESHOSP,AESLIFE,AESMIE,AESTDTC,AEENDTC,EPOCH

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
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

Variable	Type	Label	Codes	Comments
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) – SUPPAE

<b>Dataset</b>	SUPPAE
<b>Creating program</b>	ae.sas
<b>Description</b>	Supplementary Qualifier for 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:  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

Variable	Type	Label	Codes	Comments
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, CESPID
<b>Sorted by</b>	DUSUBJID, 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:  CESTDTC, CEENDTC, EPOCH

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

Variable	Type	Label	Codes	Comments
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) – SUPPCE

<b>Dataset</b>	SUPPCE
<b>Creating program</b>	ce.sas
<b>Description</b>	Supplementary Qualifier for 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 from dataset due to missing values:  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

Variable	Type	Label	Codes	Comments
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, CFSPID, CFTESTCD
<b>Sorted by</b>	DUSUBJID, CFSPID, CFTESTCD
<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:  CFDTC, EPOCH

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, SKINLOC, OTHDIAG, MLSYMP, APPEAR, SYMPASSO, SUBJSYM) then drop.

Variable	Type	Label	Codes	Comments
CFTEST	char	Question Name		Collected at CRF
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		If CFDTC and RFSTDTC not missing then perform below logic to calculate relative day.  If CFDTC less than RFSTDTC then (CFDTC- RFSTDTC). Else if CFDTC is greater than equal to RFSTDTC then (CFDTC- RFSTDTC) +1.

### 1.4.8. Supplemental Qualifiers (SUPPCF) – SUPPCF

<b>Dataset</b>	SUPPCF
<b>Creating program</b>	cf.sas
<b>Description</b>	Supplementary Qualifier for 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 from dataset due to missing values:  QEVAL
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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

### 1.4.9. Concomitant Medications – CM

<b>Dataset</b>	CM
<b>Creating program</b>	cm.sas
<b>Description</b>	Concomitant Medications
<b>Unique identifier</b>	DUSUBJID, CMSPID
<b>Sorted by</b>	DUSUBJID, CMSPID



<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>CMGRPID, CMTRT, CMMODIFY, CMSTDTC, CMENDTC, CMDUR, CMENRF</p>
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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
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) – SUPPCM

<b>Dataset</b>	SUPPCM
<b>Creating program</b>	cm.sas
<b>Description</b>	Supplementary Qualifier for 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 from dataset due to missing values:  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. If QNAM eq "CMRSDTC" then derive CMRSDY (Relative Day) and drop CMRSDTC.

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, 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

#### 1.4.11. 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 created
DOMAIN	char	Domain Abbreviation		Empty dataset will be created
RDOMAIN	char	Related Domain Abbreviation		Empty dataset will be created
DUSUBJID	char	Unique Subject Id Assign for De-identity		Empty dataset will be created
COSEQ	num	Sequence Number		Empty dataset will be created

Variable	Type	Label	Codes	Comments
IDVAR	char	Identifying Variable		Empty dataset will be created
IDVARVAL	char	Identifying Variable Value		Empty dataset will be created

#### 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, DASPID, DATESTCD
<b>Sorted by</b>	DUSUBJID, DASPID, DATESTCD
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:  DADTC

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
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

Variable	Type	Label	Codes	Comments
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.		If DADTC and RFSTDTC not missing then perform below logic to calculate relative day. If DADTC less than RFSTDTC then (DADTC - RFSTDTC). Else if DADTC is greater than equal to RFSTDTC then (DADTC - RFSTDTC) +1.

#### 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, DESPID, DETESTCD, VISITNUM
<b>Sorted by</b>	DUSUBJID, DESPID, DETESTCD, VISITNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA:  DEDTC

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
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
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		<p>If DEDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If DEDTC less than RFSTDTC then (DEDTC - RFSTDTC). Else if DEDTC is greater than equal to RFSTDTC then (DEDTC - RFSTDTC) +1.</p>

## 1.4.14. Disposition – DS

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

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
VISIT	char	Visit Name		Collected at CRF
VISITNUM	num	Visit Number		Collected at CRF
EPOCH	char	Trial Epoch		Collected at CRF

Variable	Type	Label	Codes	Comments
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. 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) – SUPPDS

<b>Dataset</b>	SUPPDS
<b>Creating program</b>	ds.sas
<b>Description</b>	Supplementary Qualifier for 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:  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



Variable	Type	Label	Codes	Comments
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, DVSPID, DVDECOD, DVSEQ
<b>Sorted by</b>	DUSUBJID, DVSPID, DVDECOD, DVSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:  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

Variable	Type	Label	Codes	Comments
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF
DVSPID	char	Sponsor-Defined Identifier		Collected at CRF

#### 1.4.17. Supplemental Qualifiers (SUPPDV) – SUPPDV

<b>Dataset</b>	SUPPDV
<b>Creating program</b>	dv.sas
<b>Description</b>	Supplementary Qualifier for 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: 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, DVTERM4) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF
QVAL	char	Data Value		Collected at CRF
QORIG	char	Origin		Collected at CRF

## 1.4.18. Exploratory Samples – EC

<b>Dataset</b>	EC
<b>Creating program</b>	ec.sas
<b>Description</b>	Exploratory Samples
<b>Unique identifier</b>	DUSUBJID, ECSPID, ECTESTCD
<b>Sorted by</b>	DUSUBJID, ECSPID, ECTESTCD
<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:  ECDTC, EPOCH

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
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		If ECDTC and RFSTDTC not missing then perform below logic to calculate relative day.  If ECDTC less than RFSTDTC then ( ECDTC - RFSTDTC ). Else if ECDTC is greater than equal to RFSTDTC then ( ECDTC - RFSTDTC ) +1.

### 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, EGSPID
<b>Sorted by</b>	DUSUBJID, EGSPID
<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:  EGREFID, EGCAT, EGMETHOD, EGDTC, EGTPPTNUM, EGTPPT

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

Variable	Type	Label	Codes	Comments
EGSPID	char	Sponsor-Defined Identifier		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
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, EXSPID
<b>Sorted by</b>	DUSUBJID, EXSPID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:  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
EXDOSFRQ	char	Dosing Frequency Per Interval		Collected at CRF
EPOCH	char	Trial Epoch		Collected at CRF

Variable	Type	Label	Codes	Comments
EXENDY	num	Relative End Day of Treatment		<p>If EXENDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If EXENDTC less than RFSTDTC then (EXENDTC - RFSTDTC). Else if EXENDTC is greater than equal to RFSTDTC then (EXENDTC - RFSTDTC) +1.</p>
EXSTDY	num	Relative Start Day of Treatment		<p>If EXSTDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If EXSTDTC less than RFSTDTC then (EXSTDTC - RFSTDTC). Else if EXSTDTC is greater than equal to RFSTDTC then (EXSTDTC - RFSTDTC) +1.</p>

## 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, HCSPID
<b>Sorted by</b>	DUSUBJID, HCSPID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:  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
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



Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF
EPOCH	char	Trial Epoch		Collected at CRF
HCDY	num	Relative Day of Finding		If HCDTC and RFSTDTC not missing then perform below logic to calculate relative day.  If HCDTC less than RFSTDTC then (HCDTC - RFSTDTC). Else if HCDTC is greater than equal to RFSTDTC then (HCDTC - RFSTDTC) +1.

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, IESPID
<b>Sorted by</b>	DUSUBJID, 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 records:  IEDTC

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
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
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, LBSPID, LBTESTCD, LBSEQ
<b>Sorted by</b>	DUSUBJID, LBSPID, LBTESTCD, LBSEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>LBREFID, LBSCAT, LBREASND, LBNAM, LBSPCCND, LBTOX, LBTOXGR, LBSTC, 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
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

Variable	Type	Label	Codes	Comments
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
LBORNRHI	char	Reference Range Upper Limit in Orig Unit		Collected at CRF
LBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF
LBSTNRC	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
LBSTNRLO	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
LBSTAT	char	Lab Status		Collected at CRF
LBSPEC	char	Specimen Type		Collected at CRF
LBMETHOD	char	Method of Test or Examination		Collected at CRF
LBLFL	char	Baseline Flag		Collected at CRF
LBDRVFL	char	Derived Flag		Collected at CRF
LBFAST	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.

Variable	Type	Label	Codes	Comments
LBENTM	num	End Time of Specimen Collection		If LBENDTC contains time part then timepart (LBENDTC) else LBENTM equal to NULL.
LBENDY	num	Relative End Day of Specimen Collection		If LBENDTC and RFSTDTC not missing then perform below logic to calculate relative day.  If LBENDTC less than RFSTDTC then (LBENDTC - RFSTDTC). Else if LBENDTC is greater than equal to RFSTDTC then (LBENDTC - RFSTDTC) +1.

#### 1.4.24. Supplemental Qualifiers (SUPPLB) – SUPPLB

<b>Dataset</b>	SUPPLB
<b>Creating program</b>	Lb.sas
<b>Description</b>	Supplemental Qualifiers for 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:  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

Variable	Type	Label	Codes	Comments
QNAM	char	Qualifier Variable Name		If QNAM in (ALRTNP) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF
QVAL	char	Data Value		Collected at CRF
QORIG	char	Origin		Collected at CRF

### 1.4.25. Medical History – MH

<b>Dataset</b>	MH
<b>Creating program</b>	Mh.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	DUSUBJID, MHSPID, MHDECOD, MHSEQ
<b>Sorted by</b>	DUSUBJID, MHSPID, MHDECOD, 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 elements:  MHTERM, MHMODIFY, MHSTAT, MHREASND, MHDTC, MHSTDTC, MHENDTC

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

Variable	Type	Label	Codes	Comments
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
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		<p>If MHDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If MHDTC less than RFSTDTC then (MHDTC - RFSTDTC). Else if MHDTC is greater than equal to RFSTDTC then (MHDTC - RFSTDTC) +1.</p>
MHSTDY	num	Relative Start Day of MH Event		<p>If MHSTDTC and RFSTDTC not missing then perform below logic to calculate relative day.</p> <p>If MHSTDTC less than RFSTDTC then (MHSTDTC - RFSTDTC). Else if MHSTDTC is greater than equal to RFSTDTC then (MHSTDTC - RFSTDTC) +1.</p>

## 1.4.26. Supplemental Qualifiers (SUPPMH) – SUPPMH

<b>Dataset</b>	SUPPMH
<b>Creating program</b>	Mh.sas
<b>Description</b>	Supplemental Qualifiers for 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:  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, MLSPID, MLTRT, MLTPTNUM
<b>Sorted by</b>	DUSUBJID, MLSPID, MLTRT, MLTPTNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing elements:  MLDOSE, MLDOSU, MLDTC, MLSTDTC, MLENDTC, 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
MLTPTNUM	num	Planned Time Point Number		Collected at CRF
MLTPTREF	char	Time Point Reference		Collected at CRF

Variable	Type	Label	Codes	Comments
MLDY	num	Relative Day of MMTT		If MLDTC and RFSTDTC not missing then perform below logic to calculate relative day.  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.  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.  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>	Questionnaires
<b>Unique identifier</b>	DUSUBJID, QSTESTCD, QSCAT, QSSCAT, VISITNUM, QSDY
<b>Sorted by</b>	DUSUBJID, QSTESTCD, QSCAT, QSSCAT, VISITNUM, QSDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing elements:  QSDRVFL, QSDTC

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
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

Variable	Type	Label	Codes	Comments
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
QSNAM	char	Vendor Name		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:  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
<b>Sorted by</b>	DUSUBJID, SUTRT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:  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
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
SUSTDY	num	Relative Start Day of Substance Use		If SUSTDTC and RFSTDTC not missing then perform below logic to calculate relative day.  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
<b>Sorted by</b>	DUSUBJID, VISITNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing elements:  SVSTDTC, SVENDTC

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
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF

Variable	Type	Label	Codes	Comments
EPOCH	char	Trial Epoch		Collected at CRF
SVSPID	char	Sponsor-Defined Identifier		Collected at CRF
SVSTDY	num	Relative Start Day of Visit		If SVSTDTC and RFSTDTC not missing then perform below logic to calculate relative day. If SVSTDTC less than RFSTDTC then (SVSTDTC - RFSTDTC). Else if SVSTDTC is greater than equal to RFSTDTC then (SVSTDTC - RFSTDTC) +1.

### 1.4.32. Supplemental Qualifiers (SUPPSV) – SUPPSV

<b>Dataset</b>	SUPPSV
<b>Creating program</b>	sv.sas
<b>Description</b>	Supplemental Qualifiers for 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:  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

Variable	Type	Label	Codes	Comments
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, IETESTCD
<b>Sorted by</b>	DOMAIN, IETESTCD
<b>Notes</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, VSSEQ, VSTESTCD, VISITNUM
<b>Sorted by</b>	DUSUBJID, VSSEQ, VSTESTCD, VISITNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:  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
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