Clinical Development

JNJ-28431754

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Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided.
- Investigator Name will not be provided.
- Date of birth will not be provided, only age in years.
- 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.
- Subjects with age grouped to protect PII as per HIPAA.
- 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, BT and ML data domains require to have time information for secondary data analysis ; –TM element will be derived before dropping original date element.
- BS domain xxTESTCD was contains "DATE/ TIME" information as a response in xxORRES/xxSTRESC then relative day will be derived and original date will be removed as per HIPAA.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove ethnic information.
- Empty comments data will be submitted.
- Due to sensitive information SC dataset will be removed.
- Country will be grouped as regions to protect PII.
- MB/SUPPMB and MS data contain microbiological information related to study and hence will not be submitted.
- SG data contain surgery information that can be very specific to subject and hence reveal subject identity. Hence SG data will not be submitted.
- DP/SUPPDP, HO/SUPPHO, PC/SUPPPC, PE and QS domains are not submitted.

1.3. Data Files

The 2843175DIA2001 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DM

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

Variable	Type	Label	Codes	Comments
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
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. 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. 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

Dataset	SUPPDM
Creating program	Dm.sas
Description	Supplemental Qualifiers of 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) then DROP.
QLABEL	char	Qualifier Variable Label		Collected at CRF
QVAL	char	Data Value		Collected at CRF
QORIG	char	Origin		Collected at CRF

1.4.3. Adverse Events-AE

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

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

Variable	Type	Label	Codes	Comments
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	Relative End Day of Adverse Event		If AEENDTC and RFSTDTC not missing then perform below logic to calculate relative day. If AEENDTC less than RFSTDTC then (AEENDTC - RFSTDTC). Else if AEENDTC is greater than equal to RFSTDTC then (AEENDTC - RFSTDTC) +1.

1.4.4. Supplemental Qualifiers-SUPPAE

Dataset	SUPPAE
Creating program	ae.sas
Description	Supplemental Qualifiers of AE
Unique identifier	DUSUBJID,IDVAR, IDVARVAL,QNAM
Sorted by	DUSUBJID,IDVAR, IDVARVAL,QNAM
Notes	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 (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. Blood Sugar-BS

Dataset	BS
Creating program	bs.sas
Description	Blood Sugar
Unique identifier	DUSUBJID,BSTESTCD,BSCAT,BSSPID
Sorted by	DUSUBJID,BSTESTCD,BSCAT,BSSPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BSNRIND, BSDTC

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
BSSEQ	num	Sequence Number		Collected at CRF
BSSPID	char	Sponsor-Defined Identifier		Collected at CRF
BSTESTCD	char	Test or Examination Short Name		Collected at CRF
BSTEST	char	Test or Examination Name		Collected at CRF
BSCAT	char	Category for Blood Sugar		Collected at CRF
BSSCAT	char	Subcategory for Blood Sugar		Collected at CRF

BSORRES	char	Result or Finding in Original Units		Collected at CRF
BSORRESU	char	Original Units		Collected at CRF
BSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF
BSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF
BSSTRESU	char	Standard Unit		Collected at CRF
BSSTAT	char	Not done		Collected at CRF
BSMETHOD	char	Method of measured blood sugar		Collected at CRF
BSDY	num	Study Day of Blood Sugar		Collected at CRF

1.4.6. Blood Test-BT

Dataset	BT
Creating program	Bt.sas
Description	Blood Test
Unique identifier	DUSUBJID,BTTESTCD,BTSEQ
Sorted by	DUSUBJID,BTTESTCD,BTSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BTGRPID,BTDRVFL, BTDTC

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
BTSEQ	num	Sequence Number		Collected at CRF
BTSPID	char	Sponsor-Defined Identifier		Collected at CRF
BTTESTCD	char	Blood Test Short Name		Collected at CRF
BTTEST	char	Blood Test Name		Collected at CRF
BTCAT	char	Category for Blood Test		Collected at CRF
BTSCAT	char	Subcategory for Blood Test		Collected at CRF

Variable	Type	Label	Codes	Comments
BTORRES	char	Result or Finding in Original Units		Collected at CRF
BTORRESU	char	Original Units		Collected at CRF
BTSTRESC	char	Character Result/Finding in Std Format		Collected at CRF
BTSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF
BTSTRESU	char	Standard Units		Collected at CRF
BTNRIND	char	Reference Range Indicator		Collected at CRF
BTSTAT	char	Blood test Status		Collected at CRF
BTNAM	char	Vendor Name		Collected at CRF
BTSPEC	char	Specimen Type		Collected at CRF
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
EPOCH	char	Trial Epoch		Collected at CRF
BTDY	num	Study Day of Blood Test		Collected at CRF
BTTPT	char	Planned Time Point Name		Collected at CRF
BTTPTNUM	num	Planned Time Point Number		Collected at CRF
BTTPTREF	char	Time Point Reference		Collected at CRF

1.4.7. Supplemental Qualifiers-SUPPBT

Dataset	SUPPBT
Creating program	bt.sas
Description	Supplemental Qualifiers of BT
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	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= BTMLDTC then BTMLDY & BTMLTM will be created which captures Relative Day and Time part of BTMLDTC respectively. BTMLDTC will be dropped.
QLABEL	char	Qualifier Variable Label		Collected at CRF

Variable	Type	Label	Codes	Comments
QVAL	char	Data Value		If QNAM= BTMLDTC and RFSTDTC not missing then perform below logic to calculate BTMLDY, If QVAL less than RFSTDTC then (QVAL - RFSTDTC). Else if QVAL is greater than equal to RFSTDTC then (QVAL - RFSTDTC) +1. If QNAM= BTMLDTC has time part value then BTMLTM =timepart(BTMLDTC) else BTMLTM equal to NULL.
QORIG	char	Origin		Collected at CRF

1.4.8. Concomitant Medications-CM

Dataset	CM
Creating program	cm.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID,CMDECOD,CMSTDY,CMSPID
Sorted by	DUSUBJID,CMDECOD,CMSTDY,CMSPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CMGRPID,CMTRT, CMMODIFY, CMSTAT, CMREASND, CMDOSRGM, CMSTDTC, CMENDTC

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
CMINDC	char	Indication		Collected at CRF
CMCLAS	char	Medication Class		Collected at CRF

Variable	Type	Label	Codes	Comments
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
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
CMENRF	char	End Relative to Reference Period		Collected at CRF

1.4.9. Supplemental Qualifiers-SUPPCM

Dataset	SUPPCM
Creating program	cm.sas
Description	Supplemental Qualifiers of CM
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	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=CMINDOTH then DROP.
QLABEL	char	Qualifier Variable Label		Collected at CRF
QVAL	char	Data Value		Collected at CRF
QORIG	char	Origin		Collected at CRF

1.4.10. Comments-CO

Dataset	CO
Creating program	co.sas
Description	Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	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.
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.

1.4.11. Drug Accountability-DA

Dataset	DA
Creating program	da.sas
Description	Drug Accountability
Unique identifier	DUSUBJID,DATESTCD,DASEQ
Sorted by	DUSUBJID,DATESTCD,DASEQ
Notes	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	Medication Identification code		Collected at CRF
DATEST	char	Medication Identification		Collected at CRF
DACAT	char	Category of Assessment		Collected at CRF
DAORRES	char	Finding in Original Units		Collected at CRF

Variable	Type	Label	Codes	Comments
DASTRESC	char	Character Result/Finding in Std Format		Collected at CRF
DASTRESN	num	Numeric Result/Finding in Std Format		Collected at CRF
DATPT	char	Dose Timing		Collected at CRF
DADY	num	Relative Day Returned		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.

1.4.12. Diabetes History-DC

Dataset	DC
Creating program	dc.sas
Description	Diabetes History
Unique identifier	DUSUBJID,DCTESTCD,DCDY
Sorted by	DUSUBJID,DCTESTCD,DCDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DCDTC

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
DCSEQ	num	Sequence Number		Collected at CRF
DCSPID	char	Sponsor-Defined Identifier		Collected at CRF
DCTESTCD	char	Disease Characteristic Short Name		Collected at CRF
DCTEST	char	Disease Characteristic Name		Collected at CRF
DCCAT	char	Category for Disease Characteristic		Collected at CRF
DCSCAT	char	Subcategory for Disease Characteristic		Collected at CRF

Variable	Type	Label	Codes	Comments
DCORRES	char	Result or Finding in Original Units		Collected at CRF
DCSTRESC	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
DCDY	num	Relative Day of Collection		If DCDTC and RFSTDTC not missing then perform below logic to calculate relative day. If DCDTC less than RFSTDTC then (DCDTC - RFSTDTC). Else if DCDTC is greater than equal to RFSTDTC then (DCDTC - RFSTDTC) +1.

1.4.13. Diet and Exercise-DE

Dataset	DE
Creating program	de.sas
Description	Diet and Exercise
Unique identifier	DUSUBJID,DETESTCD,DEDY
Sorted by	DUSUBJID,DETESTCD,DEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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	Study Day of Specimen Collection		Collected at CRF

1.4.14. Disposition-DS

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

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
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
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. 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

Dataset	SUPPDS
Creating program	ds.sas
Description	Supplemental Qualifiers of DS
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	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

1.4.16. Protocol Deviations – DV

Dataset	DV
Creating program	dv.sas
Description	Protocol Deviations
Unique identifier	DUSUBJID,DVDECOD
Sorted by	DUSUBJID,DVDECOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DVTERM, DVSTDTC, DVENDTC

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

1.4.17. ECG Test Results - EG

Dataset	EG
Creating program	eg.sas
Description	ECG Test Results
Unique identifier	DUSUBJID,EGTESTCD,EGSEQ
Sorted by	DUSUBJID,EGTESTCD,EGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EGREFID, EGSPID, EGCAT, EGSTAT, EGREASND, EGNAM, EGDTC

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
EGDRVFL	char	Derived 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

1.4.18. Exposure-EX

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

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
EXROUTE	char	Route of Administration		Collected at CRF
EPOCH	char	Trial Epoch		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
VISITNUM	num	Visit Number		Collected at CRF
EXSTDY	num	Relative Start Day of Treatment		If EXSTDTC and RFSTDTC not missing then perform below logic to calculate relative day. If EXSTDTC less than RFSTDTC then (EXSTDTC - RFSTDTC). Else if EXSTDTC is greater than equal to RFSTDTC then (EXSTDTC - RFSTDTC) +1.

1.4.19. Hypoglycemia Education and Counseling-HC

Dataset	HC
Creating program	hc.sas
Description	Hypoglycemia Education and Counseling
Unique identifier	DUSUBJID,HCTESTCD,HCSEQ
Sorted by	DUSUBJID,HCTESTCD,HCSEQ
Notes	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

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	Study Day of Specimen Collection		Collected at CRF

1.4.20. Hypoglycemic Event-HE

Dataset	HE
Creating program	he.sas
Description	Hypoglycemic Event
Unique identifier	DUSUBJID,HEDECOD,HESPID
Sorted by	DUSUBJID,HEDECOD,HESPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: HETERM,HEDTC,HESTDTC

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
HESEQ	num	Sequence Number		Collected at CRF
HESPID	char	Sponsor-Defined Identifier		Collected at CRF
HEDECOD	char	Standardized Term		Collected at CRF
HECAT	char	Category for Hypoglycemia Event		Collected at CRF
HEOCCUR	char	Hypoglycemia Event Occurrence		Collected at CRF
HESTDY	num	Relative Day of Hypoglycemia episode		If HESTDTC and RFSTDTC not missing then perform below logic to calculate relative day. If HESTDTC less than RFSTDTC then (HESTDTC - RFSTDTC). Else if HESTDTC is greater than equal to RFSTDTC then (HESTDTC - RFSTDTC) +1.

1.4.21. Inclusion/Exclusion Exceptions-IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Exceptions
Unique identifier	DUSUBJID,IETESTCD,IESPID
Sorted by	DUSUBJID,IETESTCD,IESPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: VISIT, VISITNUM, 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
IESCAT	char	Inclusion/Exclusion Subcategory		Collected at CRF

Variable	Type	Label	Codes	Comments
IEORRES	char	I/E Criterion Original Result		Collected at CRF
IESTRESC	char	I/E Criterion Result in Std Format		Collected at CRF
IEDY	num	Study Day of Collection		Collected at CRF

1.4.22. Laboratory Test Results-LB

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

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
LBSEQ	num	Sequence Number		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
LBSCAT	char	Subcategory for Lab Test		Collected at CRF
LBORRES	char	Result or Finding in Original Units		Collected at CRF
LBORRESU	char	Original Units		Collected at CRF
LBORNRLO	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
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

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
LBBLFL	char	Baseline 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.
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.

1.4.23. Supplemental Qualifiers-SUPPLB

Dataset	SUPPLB
Creating program	lb.sas
Description	Supplemental Qualifiers of LB
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	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

1.4.24. Medical History-MH

Dataset	MH
Creating program	mh.sas
Description	Medical History
Unique identifier	DUSUBJID,MHDECOD,MHSPID
Sorted by	DUSUBJID,MHDECOD,MHSPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MHGRPID, MHTERM, MHMODIFY, MHOCCUR, MHSTAT, MHREASND, MHSTDTC,MHENDTC,MHDTC

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
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. If MHDTC less than RFSTDTC then (MHDTC - RFSTDTC). Else if MHDTC is greater than equal to RFSTDTC then (MHDTC - RFSTDTC) +1.

1.4.25. Supplemental Qualifiers-SUPPMH

Dataset	SUPPMH
Creating program	mh.sas
Description	Supplemental Qualifiers of MH
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	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

1.4.26. Mixed Meal Tolerance Test-ML

Dataset	ML
Creating program	ml.sas
Description	Mixed Meal Tolerance Test
Unique identifier	DUSUBJID,MLSPID
Sorted by	DUSUBJID,MLSPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MLDTC,MLSTDTC,MLENDTC

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
EPOCH	char	Trial Epoch		Collected at CRF

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.
MLENTM	num	End Time of Meal		If MLENDTC contains time part then timepart(MLENDTC) else MLENTM equal to NULL.
MLENDY	num	Relative End Day of Meal		If MLENDTC and RFSTDTC not missing then perform below logic to calculate relative day. If MLENDTC less than RFSTDTC then (MLENDTC - RFSTDTC). Else if MLENDTC is greater than equal to RFSTDTC then (MLENDTC - 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.

1.4.27. Supplemental Qualifiers-SUPPML

Dataset	SUPPML
Creating program	ml.sas
Description	Supplemental Qualifiers of ML
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	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= MLDOSDTC then MLDOSDY & MLDOSTM will be created which captures Relative Day and Time part of MLDOSDTC respectively. MLDOSDTC will be dropped.
QLABEL	char	Qualifier Variable Label		Collected at CRF

QVAL	char	Data Value		If QNAM= MLDOSDTC and RFSTDTC not missing then perform below logic to calculate MLDOSDY, If QVAL less than RFSTDTC then (QVAL - RFSTDTC). Else if QVAL is greater than equal to RFSTDTC then (QVAL - RFSTDTC) +1. If QNAM= MLDOSDTC has time part value then MLDOSDY =timepart(QVAL) else MLDOSDY equal to NULL.
QORIG	char	Origin		Collected at CRF

1.4.28. Related Records-RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Sorted by	RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Notes	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

1.4.29. Substance Use-SU

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

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
EPOCH	char	Trial Epoch		Collected at CRF
SUENDY	num	Relative End Day of Substance Use		If SUENDTC and RFSTDTC not missing then perform below logic to calculate relative day. If SUENDTC less than RFSTDTC then (SUENDTC - RFSTDTC). Else if SUENDTC is greater than equal to RFSTDTC then (SUENDTC - RFSTDTC) +1.

1.4.30. Supplemental Qualifiers-SUPPSU

Dataset	SUPPSU
Creating program	su.sas
Description	Supplemental Qualifiers of SU
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	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

1.4.31. Subject Visits-SV

Dataset	SV
Creating program	sv.sas
Description	Subject Visits
Unique identifier	DUSUBJID,VISITNUM
Sorted by	DUSUBJID,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SVSTDTC,SVENDTC, SVUPDES

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
EPOCH	char	Trial Epoch		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. Trial Inclusion/Exclusion Criteria-TI

Dataset	TI
Creating program	ti.sas
Description	Trial Inclusion/Exclusion Criteria
Unique identifier	DOMAIN,IECAT,IETESTCD
Sorted by	DOMAIN,IECAT,IETESTCD
Notes	Below listed variables will be dropped from dataset due to missing values: TIRL

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

1.4.33. Vital Signs-VS

Dataset	VS
Creating program	vs.sas
Description	Vital Signs
Unique identifier	DUSUBJID,VSTESTCD,VSSEQ
Sorted by	DUSUBJID,VSTESTCD,VSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: VSDRVFL, 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

VSPOS	char	Vital Signs Position of Subject		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
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