

Clinical Development

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28431754DIA3012

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 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.
- SUPPEX will not be submitted as it contains zero observation.

1.3. Data Files

The 28431754DIA3012 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, 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		Element has been grouped to protect PII.
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. 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

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID,AEDECOD,AESTDY,AESPID
Sorted by	DUSUBJID,AEDECOD,AESTDY,AESPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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

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 variable 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. Clinical Events-CE

Dataset	CE
Creating program	ce.sas
Description	Clinical Events
Unique identifier	DUSUBJID, CETERM ,CESPID
Sorted by	DUSUBJID, CETERM , CESPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: 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

Dataset	SUPPCE
Creating program	ce.sas
Description	Supplemental Qualifiers of CE
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	Below listed variable 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

1.4.7. Clinical Findings-CF

Dataset	CF
Creating program	cf.sas
Description	Clinical Findings
Unique identifier	DUSUBJID, CFTESTCD ,CFSPID
Sorted by	DUSUBJID, CFTESTCD ,CFSPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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
CFCAT	char	Category of Question		Collected at CRF

Variable	Type	Label	Codes	Comments
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

Dataset	SUPPCF
Creating program	cf.sas
Description	Supplemental Qualifiers of CF
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	Below listed variable 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=CFADJDTC then CFADJDY will be created which captures Relative Day of CFADJDTC. CFADJDTC will be dropped.
QLABEL	char	Qualifier Variable Label		Collected at CRF

Variable	Type	Label	Codes	Comments
QVAL	char	Data Value		If QNAM= CFADJDTC and RFSTDTC not missing then perform below logic to calculate CFADJDY, 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

1.4.9. 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: 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

Dataset	CM
Creating program	cm.sas
Description	Supplemental Qualifiers of CM
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	Below listed variable 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=CMRSDTC then CMRSDY will be created which captures Relative Day of CMRSDTC. CMRSDTC will be dropped.
QLABEL	char	Qualifier Variable Label		Collected at CRF

Variable	Type	Label	Codes	Comments
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

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.

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

Dataset	DA
Creating program	da.sas
Description	Drug Accountability
Unique identifier	DUSUBJID, DATESTCD,DASPID
Sorted by	DUSUBJID, DATESTCD, DASPID
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

Variable	Type	Label	Codes	Comments
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.		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

Dataset	DE
Creating program	de.sas
Description	Diet and Exercise
Unique identifier	DUSUBJID, DETESTCD, VISITNUM
Sorted by	DUSUBJID, DETESTCD, VISITNUM
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	Relative Day of Finding		If DEDTC and RFSTDTC not missing then perform below logic to calculate relative day. 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

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
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. 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 variable will be dropped from dataset due to missing values: QEVAL

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

Variable	Type	Label	Codes	Comments
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, DVSPID, DVSEQ
Sorted by	DUSUBJID, DVDECOD, DVSPID, DVSEQ
Notes	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
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF
DVSPID	char	Sponsor-Defined Identifier		Collected at CRF

1.4.17. Supplemental Qualifiers-SUPPDV

Dataset	SUPPDV
Creating program	dv.sas
Description	Supplemental Qualifiers of DV
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	Below listed variable 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

Variable	Type	Label	Codes	Comments
QORIG	char	Origin		Collected at CRF

1.4.18. Exploratory Samples-EC

Dataset	EC
Creating program	ec.sas
Description	Exploratory Samples
Unique identifier	DUSUBJID, ECTESTCD, ECSPID
Sorted by	DUSUBJID, ECTESTCD, ECSPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EPOCH,ECDTC

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

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: 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

Dataset	EX
Creating program	ex.sas
Description	Exposure
Unique identifier	DUSUBJID,EXTRT,EXSPID
Sorted by	DUSUBJID,EXTRT,EXSPID
Notes	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

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. 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. 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

Dataset	HC
Creating program	hc.sas
Description	Hypoglycemic Education and Counseling
Unique identifier	DUSUBJID,HCTESTCD,VISITNUM
Sorted by	DUSUBJID,HCTESTCD,VISITNUM
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	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

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 due to missing values: 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

Dataset	LB
Creating program	lb.sas
Description	Laboratory Test Results
Unique identifier	DUSUBJID, LBTESTCD, LBSEQ
Sorted by	DUSUBJID, LBTESTCD, LBSEQ
Notes	<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, LBNAM, LBSPCCND, LBDRVFL, LBREASND, LBTOX, LBTOXGR, LBDTC, LBENDTC, LBTPT, LBTPTNUM</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
LDBLFL	char	Baseline Flag		Collected at CRF
LDBFAST	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
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

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 variable 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 (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

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

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 variable 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. 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 variable will be dropped from dataset 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

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

1.4.29. 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

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>

1.4.30. Supplemental Qualifiers - SUPPSV

Dataset	SUPPSV
Creating program	sv.sas
Description	Supplemental Qualifiers of SV
Unique identifier	DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	DUSUBJID, IDVAR, IDVARVAL, QNAM
Notes	Below listed variable 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 (SVREASND) then DROP.
QLABEL	char	Qualifier Variable Label		Collected at CRF
QVAL	char	Data Value		Collected at CRF
QORIG	char	Origin		Collected at CRF

1.4.31. 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
Note	

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

1.4.32. 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: 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

Variable	Type	Label	Codes	Comments
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