Clinical Development

CNTO148

CNTO148PSA3001

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Dataset with insignificant information will not be submitted. For example- COMPMETH
- Datasets with sensitive information will not be submitted. For example- SUPPDM,SUPPDA
- DM.RFICDTC ("Date of Informed Consent") will be used as Reference Date to derive relative day.

1.3. Data Files

The CNTO148PSA3001 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	STUDYID, DUSUBJID
Sorted by	STUDYID, DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DMDTC, DTHDTC, RFICDTC, BRTHDTC, INVNAM, RFXSTDTC, RFPENDTC, RFENDTC, RFXENDTC, RFSTDTC

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
DTHFL	char	Subject Death Flag		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-identity		Randomly assigned Study 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		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
ACTARMCD	char	Actual Arm Code		Collected at CRF.
ACTARM	char	Description of Actual Arm		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
DMDY	num	Relative Day of Collection		If DMDTC and REF.DATE not missing then perform below logic to calculate DMDY, If DMDTC less than REF.DATE then (DMDTC - REF.DATE). Else if DMDTC is greater than equal to REF.DATE then (DMDTC- REF.DATE) +1.
RFSTTM	num	Subject Reference Start Time		If RFSTDTC contains time part then timepart(RFSTDTC) else RFSTTM equal to NULL.
RFSTDY	num	Relative Subject Reference Start Day		If RFSTDTC and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDTC less than REF.DATE then (RFSTDTC - REF.DATE). Else if RFSTDTC is greater than equal to REF.DATE then (RFSTDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RFENDY	num	Relative Subject Reference End Day		If RFENDTC and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDTC less than REF.DATE then (RFENDTC - REF.DATE). Else if RFENDTC is greater than equal to REF.DATE then (RFENDTC- REF.DATE) +1.
RFXSTTM	num	Time of First Study Treatment		If RFXSTDTC contains time part then timepart(RFXSTDTC) else RFXSTTM equal to NULL.
RFXSTDY	num	Relative Day of First Study Treatment		If RFXSTDTC and REF.DATE not missing then perform below logic to calculate RFXSTDY, If RFXSTDTC less than REF.DATE then (RFXSTDTC - REF.DATE). Else if RFXSTDTC is greater than equal to REF.DATE then (RFXSTDTC- REF.DATE) +1.
RFXENTM	num	Time of Last Study Treatment		If RFXENDTC contains time part then timepart(RFXENDTC) else RFXENTM equal to NULL.
RFXENDY	num	Relative Day of Last Study Treatment		If RFXENDTC and REF.DATE not missing then perform below logic to calculate RFXENDY, If RFXENDTC less than REF.DATE then (RFXENDTC - REF.DATE). Else if RFXENDTC is greater than equal to REF.DATE then (RFXENDTC- REF.DATE) +1.
RFPENTM	num	Time of End of Participation		If RFPENDTC contains time part then timepart(RFPENDTC) else RFPENTM equal to NULL.
RFPENDY	num	Relative Day of End of Participation		If RFPENDTC and REF.DATE not missing then perform below logic to calculate RFPENDY, If RFPENDTC less than REF.DATE then (RFPENDTC - REF.DATE). Else if RFPENDTC is greater than equal to REF.DATE then (RFPENDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DTHDY	num	Relative Day of Death		If DTHDTC and REF.DATE not missing then perform below logic to calculate DTHDY, If DTHDTC less than REF.DATE then (DTHDTC - REF.DATE). Else if DTHDTC is greater than equal to REF.DATE then (DTHDTC- REF.DATE) +1.

1.4.2. Adverse Events – AE

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

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.

Variable	Type	Label	Codes	Comments
AELLT	char	Lowest Level Term		Collected at CRF.
AELLTCD	num	Lowest Level Term Code		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEPTCD	num	Preferred Term Code		Collected at CRF.
AEHLT	char	High Level Term		Collected at CRF.
AEHLTCD	num	High Level Term Code		Collected at CRF.
AEHLGT	char	High Level Group Term		Collected at CRF.
AEHLGTCD	num	High Level Group Term Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AEBDSYCD	num	Body System or Organ Class Code		Collected at CRF.
AESOC	char	Primary System Organ Class		Collected at CRF.
AESOCCD	num	Primary System Organ Class Code		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.
AESCONG	char	Congenital Anomaly or Birth Defect		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESDTH	char	Results in Death		Collected at CRF.
AESHOSP	char	Requires or Prolongs Hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESMIE	char	Other Medically Important Serious Event		Collected at CRF.
AECONTRT	char	Concomitant or Additional Trtmnt Given		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
AESTDY	num	Relative Start Day of Adverse Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC- REF.DATE) +1.
AEENDY	num	Relative End Day of Adverse Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC- REF.DATE) +1.
AESTTM	num	Start Time of Adverse Event		If AESTDTC contains time part then timepart(AESTDTC) else AESTTM equal to NULL.

1.4.3. Supplemental Qualifiers for AE – SUPPAE

Dataset	SUPPAE
Creating program	ae.sas
Description	Supplemental Qualifiers for AE
Unique identifier	STUDYID, RDOMAIN, DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	STUDYID, RDOMAIN, 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.
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		If QNAM in (AERSNDTH) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity

1.4.4. Bio-Specimen – BE

Dataset	BE
Creating program	be.sas
Description	Bio-Specimen
Unique identifier	STUDYID, DUSUBJID, BEDECOD, BESEQ
Sorted by	STUDYID, DUSUBJID, BEDECOD, BESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BETERM, BESTDTC

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
BESEQ	num	Sequence Number		Collected at CRF.
BESPID	char	Sponsor-Defined Identifier		Collected at CRF.
BEDECOD	char	Dictionary-Derived Term		Collected at CRF.
BECAT	char	Category for Bio-specimen Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Epoch		Collected at CRF.
BESTDY	num	Relative Start Day of Bio-specimen Event		If BESTDTC and REF.DATE not missing then perform below logic to calculate BESTDY, If BESTDTC less than REF.DATE then (BESTDTC - REF.DATE). Else if BESTDTC is greater than equal to REF.DATE then (BESTDTC- REF.DATE) +1.

1.4.5. Controlled Terminology Definition – CD

Dataset	CD
Creating program	cd.sas
Description	Controlled Terminology Definition
Unique identifier	CODELST, DECOD
Sorted by	CODELST, DECOD
Notes	Below listed variables will be dropped from dataset due to missing values: RNK

Variable	Type	Label	Codes	Comments
CODELST	char	Codelist Name		Collected at CRF.
DATATYPE	char	Type of Codelist		Collected at CRF.
CODEVAL	char	Beginning Value		Collected at CRF.
DECOD	char	Controlled Term Value		Collected at CRF.
REFERENC	char	Controlled Term Reference		Collected at CRF.

Variable	Type	Label	Codes	Comments
DICTNRY	char	Name of External Dictionary		Collected at CRF.
VERSION	char	Dictionary Version Number		Collected at CRF.

1.4.6. Concomitant Medications – CM

Dataset	CM
Creating program	cm.sas
Description	Concomitant Medications
Unique identifier	STUDYID,DUSUBJID,CMDECOD,CMSTDY,CMSEQ
Sorted by	STUDYID,DUSUBJID,CMDECOD,CMSTDY,CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CMENDTC,CMSTDTC

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.
CMTRT	char	Reported Name of Drug, Med, or Therapy		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMDECOD	char	Standardized Medication Name		Collected at CRF.
CMCAT	char	Category for Medication		Collected at CRF.
CMPRESP	char	CM Pre-Specified		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.
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.
CMLOC	char	Location of Dose Administration		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CMENDY	num	Relative End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC- REF.DATE) +1.
CMSTRF	char	Start Relative to Reference Period		Collected at CRF.
CMENRF	char	End Relative to Reference Period		Collected at CRF.
CMSTTM	num	Start Time of Medication		If CMSTDTC contains time part then timepart(CMSTDTC) else CMSTTM equal to NULL.
CMENTM	num	End Time of Medication		If CMENDTC contains time part then timepart(CMENDTC) else CMENTM equal to NULL.

1.4.7. Supplemental Qualifiers for CM – SUPPCM

Dataset	SUPPCM
Creating program	cm.sas
Description	Supplemental Qualifiers for CM
Unique identifier	STUDYID, RDOMAIN, DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	STUDYID, RDOMAIN, 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.

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.

1.4.8. Drug Accountability – DA

Dataset	DA
Creating program	da.sas
Description	Drug Accountability
Unique identifier	STUDYID,DUSUBJID,DATESTCD,VISIT,DASEQ
Sorted by	STUDYID,DUSUBJID,DATESTCD,VISIT,DASEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DAREFID,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.
DACAT	char	Category of Assessment		Collected at CRF.
DAORRES	char	Assessment Result in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAORRESU	char	Original Units		Collected at CRF.
DASTRESC	char	Assessment Result in Std Format		Collected at CRF.
DASTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
DASTRESU	char	Assessment Standard Units		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
DADY	num	Relative Day Accountability Assessment		If DADTC and REF.DATE not missing then perform below logic to calculate DADY, If DADTC less than REF.DATE then (DADTC - REF.DATE). Else if DADTC is greater than equal to REF.DATE then (DADTC-REF.DATE) +1.

1.4.9. Dataset Level Metadata – DATADEF

Dataset	DATADEF
Creating program	datadef.sas
Description	Dataset Level Metadata
Unique identifier	DSORDER
Sorted by	DSORDER
Notes	

Variable	Type	Label	Codes	Comments
CLASSNM	char	Dataset Class		Collected at CRF.
DATASET	char	Dataset Name		Collected at CRF.
DSLABEL	char	Dataset Label		Collected at CRF.
STRUCTRE	char	Structure		Collected at CRF.
REPEAT	char	Repeating		Collected at CRF.
PURPOSE	char	Purpose of the Data		Collected at CRF.
REFDATA	char	Reference Data		Collected at CRF.
KEYS	char	Logical Key Order		Collected at CRF.
DSORDER	char	Dataset Order		Collected at CRF.

1.4.10. Disposition – DS

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

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.
EPOCH	char	Epoch		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSSTDY	num	Relative Start Day of Disposition Event		If DSSTDTC and REF.DATE not missing then perform below logic to calculate DSSTDY, If DSSTDTC less than REF.DATE then (DSSTDTC - REF.DATE). Else if DSSTDTC is greater than equal to REF.DATE then (DSSTDTC- REF.DATE) +1.
DSSTTM	num	Start Time of Disposition Event		If DSSTDTC contains time part then timepart(DSSTDTC) else DSSTTM equal to NULL.

1.4.11. Supplemental Qualifiers for DS – SUPPDS

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

Variable	Type	Label	Codes	Comments
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.

1.4.12. Protocol Deviations – DV

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

Variable	Type	Label	Codes	Comments
DVSEQ	num	Sequence Number		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
DVCAT	char	Category for Protocol Deviation		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
DVSTDY	num	Relative Start Day of Deviation		If DVSTDTC and REF.DATE not missing then perform below logic to calculate DVSTDY, If DVSTDTC less than REF.DATE then (DVSTDTC - REF.DATE). Else if DVSTDTC is greater than equal to REF.DATE then (DVSTDTC- REF.DATE) +1.
DVENDY	num	Relative End Day of Deviation		If DVENDTC and REF.DATE not missing then perform below logic to calculate DVENDY, If DVENDTC less than REF.DATE then (DVENDTC - REF.DATE). Else if DVENDTC is greater than equal to REF.DATE then (DVENDTC- REF.DATE) +1.

1.4.13. Exposure – EX

Dataset	EX
Creating program	ex.sas
Description	Exposure
Unique identifier	STUDYID,DUSUBJID,EXSTDY,EXSEQ
Sorted by	STUDYID,DUSUBJID,EXSTDY,EXSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EXENDTC,EXDOSE,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.
EXDOSU	char	Dose Units		Collected at CRF.
EXDOSFRM	char	Dose Form		Collected at CRF.
EXDOSTOT	num	Total Daily Dose		Collected at CRF.
EXROUTE	char	Route of Administration		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXTRTV	char	Treatment Vehicle		Collected at CRF.
EXVAMT	num	Treatment Vehicle Amount		Collected at CRF.
EXVAMTU	char	Treatment Vehicle Amount Units		Collected at CRF.
EXADJ	char	Reason for Dose Adjustment		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
EXSTDY	num	Relative Start Day of Treatment		If EXSTDTC and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE). Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC- REF.DATE) +1.
EXENDY	num	Relative End Day of Treatment		If EXENDTC and REF.DATE not missing then perform below logic to calculate EXENDY, If EXENDTC less than REF.DATE then (EXENDTC - REF.DATE). Else if EXENDTC is greater than equal to REF.DATE then (EXENDTC- REF.DATE) +1.
EXSTTM	num	Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM equal to NULL.
EXENTM	num	End Time of Treatment		If EXENDTC contains time part then timepart(EXENDTC) else EXENTM equal to NULL.

1.4.14. Supplemental Qualifiers for EX – SUPPEX

Dataset	SUPPEX
Creating program	ex.sas
Description	Supplemental Qualifiers for EX
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,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.

1.4.15. Findings About Events or Interventions – FA

Dataset	FA
Creating program	fa.sas
Description	Findings About Events or Interventions
Unique identifier	STUDYID,DUSUBJID,FADY,FASEQ
Sorted by	STUDYID,DUSUBJID,FADY,FASEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: FADTC,FASPID

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
FASEQ	num	Sequence Number		Collected at CRF.
FATESTCD	char	Findings About Test Short Name		Collected at CRF.
FATEST	char	Findings About Test Name		Collected at CRF.
FAOBJ	char	Object of the Observation		Collected at CRF.
FACAT	char	Category for Findings About		Collected at CRF.
FAORRES	char	Result or Finding in Original Units		Collected at CRF.
FAORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
FASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
FASTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
FASTRESU	char	Standard Units		Collected at CRF.
FABLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
FADY	num	Relative Day of Collection		If FADTC and REF.DATE not missing then perform below logic to calculate FADY, If FADTC less than REF.DATE then (FADTC - REF.DATE). Else if FADTC is greater than equal to REF.DATE then (FADTC-REF.DATE) +1.
FATPT	char	Planned Time Point Name		Collected at CRF.
FATPTNUM	num	Planned Time Point Number		Collected at CRF.
FAEVLINT	char	Evaluation Interval		Collected at CRF.

1.4.16. Inclusion/Exclusion Criteria Not Met – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Criteria Not Met
Unique identifier	STUDYID,DUSUBJID,IETESTCD
Sorted by	STUDYID,DUSUBJID,IETESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
IEDY	num	Relative Day of Collection		If IEDTC and REF.DATE not missing then perform below logic to calculate IEDY, If IEDTC less than REF.DATE then (IEDTC - REF.DATE). Else if IEDTC is greater than equal to REF.DATE then (IEDTC-REF.DATE) +1.

1.4.17. Immunogenicity Specimen Assessments – IS

Dataset	IS
Creating program	is.sas
Description	Immunogenicity Specimen Assessments
Unique identifier	STUDYID,DUSUBJID,ISTESTCD,VISIT
Sorted by	STUDYID,DUSUBJID,ISTESTCD,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ISLLOQ,ISDTC,ISNAM

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
ISSEQ	num	Sequence Number		Collected at CRF.
ISREFID	char	Reference ID		Collected at CRF.
ISSPID	char	Sponsor-Defined Identifier		Collected at CRF.
ISTESTCD	char	Immunogenicity Test/Exam Short Name		Collected at CRF.
ISTEST	char	Immunogenicity Test or Examination Name		Collected at CRF.
ISCAT	char	Category for Immunogenicity Test		Collected at CRF.

Variable	Type	Label	Codes	Comments
ISORRES	char	Result or Finding in Original Units		Collected at CRF.
ISORRESU	char	Original Units		Collected at CRF.
ISSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
ISSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
ISSTRESU	char	Standard Units		Collected at CRF.
ISSTAT	char	Completion Status		Collected at CRF.
ISREASND	char	Reason Not Done		Collected at CRF.
ISSPEC	char	Specimen Type		Collected at CRF.
ISBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
ISDY	num	Relative Day of Specimen Collection		If ISDTC and REF.DATE not missing then perform below logic to calculate ISDY, If ISDTC less than REF.DATE then (ISDTC - REF.DATE). Else if ISDTC is greater than equal to REF.DATE then (ISDTC-REF.DATE) +1.
ISTPT	char	Planned Time Point Name		Collected at CRF.
ISTPTNUM	num	Planned Time Point Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
ISTM	num	Time of Specimen Collection		If ISDTC contains time part then timepart(ISDTC) else ISTM equal to NULL.

1.4.18. Laboratory Test Results – LB

Dataset	LB
Creating program	lb.sas
Description	Laboratory Test Results
Unique identifier	STUDYID,DUSUBJID,LBTEST,VISIT,LBSEQ
Sorted by	STUDYID,DUSUBJID,LBTEST,VISIT,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LBDTC,LBNAM,LBSPID,LBREFID

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.
LBTESTCD	char	Lab Test or Examination Short Name		Collected at CRF.
LBTEST	char	Lab Test or Examination Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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.
LBSTNRC	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSTAT	char	Completion Status		Collected at CRF.
LBREASND	char	Reason Test Not Done		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBSPCCND	char	Specimen Condition		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBBLFL	char	Baseline Flag		Collected at CRF.
LBTOX	char	Toxicity		Collected at CRF.
LBTOXGR	char	Standard Toxicity Grade		Collected at CRF.
LBLLOQ	num	Lower Limit of Quantitation		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC-REF.DATE) +1.
LBTM	num	Time of Specimen Collection		If LBDTC contains time part then timepart(LBDTC) else LBTM equal to NULL.

1.4.19. Supplemental Qualifiers for LB – SUPPLB

Dataset	SUPPLB
Creating program	lb.sas
Description	Supplemental Qualifiers for LB
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,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 (LBRESDTC) then will be converted to relative day.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.20. Medical History – MH

Dataset	MH
Creating program	mh.sas
Description	Medical History
Unique identifier	STUDYID,DUSUBJID,MHCAT,MHSTDY,MHSEQ
Sorted by	STUDYID,DUSUBJID,MHCAT,MHSTDY,MHSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MHSTDTC,MHDTC,EPOCH,MHTERM

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.
MHCAT	char	Category for Medical History		Collected at CRF.
MHSCAT	char	Subcategory for Medical History		Collected at CRF.
MHPRESP	char	Medical History Event Pre-Specified		Collected at CRF.
MHOCCUR	char	Medical History Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
MHDY	num	Relative Day of History Collection		If MHDTC and REF.DATE not missing then perform below logic to calculate MHDY, If MHDTC less than REF.DATE then (MHDTC - REF.DATE). Else if MHDTC is greater than equal to REF.DATE then (MHDTC- REF.DATE) +1.
MHSTDY	num	Relative Start Day of Med History Event		If MHSTDTC and REF.DATE not missing then perform below logic to calculate MHSTDY, If MHSTDTC less than REF.DATE then (MHSTDTC - REF.DATE). Else if MHSTDTC is greater than equal to REF.DATE then (MHSTDTC- REF.DATE) +1.
MHENRF	char	End Relative to Reference Period		Collected at CRF.

1.4.21. Supplemental Qualifiers for MH – SUPPMH

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

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.

1.4.22. Pharmacokinetic Concentrations – PC

Dataset	PC
Creating program	pc.sas
Description	Pharmacokinetic Concentrations
Unique identifier	STUDYID,DUSUBJID,PCTEST,PCDY,PCSEQ
Sorted by	STUDYID,DUSUBJID,PCTEST,PCDY,PCSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PCDTC,PCNAM

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
PCSEQ	num	Sequence Number		Collected at CRF.
PCREFID	char	Reference ID		Collected at CRF.
PCSPID	char	Sponsor-Defined Identifier		Collected at CRF.
PCTESTCD	char	Pharmacokinetic Test Short Name		Collected at CRF.
PCTEST	char	Pharmacokinetic Test Name		Collected at CRF.
PCCAT	char	Test Category		Collected at CRF.
PCORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCORRESU	char	Original Units		Collected at CRF.
PCSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
PCSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
PCSTRESU	char	Standard Units		Collected at CRF.
PCSTAT	char	Completion Status		Collected at CRF.
PCREASND	char	Reason Test Not Done		Collected at CRF.
PCSPEC	char	Specimen Material Type		Collected at CRF.
PCBLFL	char	Baseline Flag		Collected at CRF.
PCLLOQ	num	Lower Limit of Quantitation		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
PCDY	num	Relative Day of Specimen Collection		If PCDTC and REF.DATE not missing then perform below logic to calculate PCDY, If PCDTC less than REF.DATE then (PCDTC - REF.DATE). Else if PCDTC is greater than equal to REF.DATE then (PCDTC-REF.DATE) +1.
PCTPT	char	Planned Time Point Name		Collected at CRF.
PCTPTNUM	num	Planned Time Point Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCTM	num	Time of Specimen Collection		If PCDTC contains time part then timepart(PCDTC) else PCTM equal to NULL.

1.4.23. Questionnaires – QS

Dataset	QS
Creating program	qs.sas
Description	Questionnaires
Unique identifier	STUDYID,DUSUBJID,QSTEST,QSDY,QSSEQ
Sorted by	STUDYID,DUSUBJID,QSTEST,QSDY,QSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: QSNAM,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.

Variable	Type	Label	Codes	Comments
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.
QSORRESU	char	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.
QSSTRESU	char	Standard Units		Collected at CRF.
QSSTAT	char	Completion Status		Collected at CRF.
QSREASND	char	Reason Not Performed		Collected at CRF.
QSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
QSDY	num	Relative Day of Finding		If QSDTC and REF.DATE not missing then perform below logic to calculate QSDY, If QSDTC less than REF.DATE then (QSDTC - REF.DATE). Else if QSDTC is greater than equal to REF.DATE then (QSDTC-REF.DATE) +1.
QSEVLINT	char	Evaluation Interval		Collected at CRF.
QSTM	num	Time of Finding		If QSDTC contains time part then timepart(QSDTC) else QSTM equal to NULL.

1.4.24. Related Records – RELREC

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

1.4.25. Surgery – SG

Dataset	SG
Creating program	sg.sas
Description	Surgery
Unique identifier	STUDYID,DUSUBJID,SGCAT,SGSTDY,SGSEQ
Sorted by	STUDYID,DUSUBJID,SGCAT,SGSTDY,SGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SGTRT,SGSTDTC

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
SGSEQ	num	Sequence Number		Collected at CRF.
SGSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SGCAT	char	Category for Surgery/Procedure		Collected at CRF.
SGSCAT	char	Subcategory for Surgery/Procedure		Collected at CRF.
SGINDC	char	Indication		Collected at CRF.
SGLOC	char	Location of Surgery/Procedure		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Epoch		Collected at CRF.
SGSTDY	num	Relative Start Day of Surgery/Procedure		If SGSTDTC and REF.DATE not missing then perform below logic to calculate SGSTDY, If SGSTDTC less than REF.DATE then (SGSTDTC - REF.DATE). Else if SGSTDTC is greater than equal to REF.DATE then (SGSTDTC- REF.DATE) +1.

1.4.26. Supplemental Qualifiers for SG – SUPPSG

Dataset	SUPPSG
Creating program	sg.sas
Description	Supplemental Qualifiers for SG
Unique identifier	STUDYID, RDOMAIN, DUSUBJID, IDVAR, IDVARVAL, QNAM
Sorted by	STUDYID, RDOMAIN, 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.

Variable	Type	Label	Codes	Comments
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		If QNAM in (SGPLNDTC) then will be converted to relative day.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.27. Standardized MedDRA Queries – SMQ191

Dataset	SMQ191
Creating program	smq191.sas
Description	Standardized MedDRA Queries
Unique identifier	SMQ,SUB_SMQ1,SUB_SMQ2,SUB_SMQ3,SUB_SMQ4,PTCD
Sorted by	SMQ,SUB_SMQ1,SUB_SMQ2,SUB_SMQ3,SUB_SMQ4,PTCD
Notes	

Variable	Type	Label	Codes	Comments
SMQ	char	Standardized MedDRA Queries		Collected at CRF.
SUB_SMQ1	char	First sub SMQ		Collected at CRF.
SUB_SMQ2	char	Second sub SMQ		Collected at CRF.
SUB_SMQ3	char	Third sub SMQ		Collected at CRF.
SUB_SMQ4	char	Fourth sub SMQ		Collected at CRF.

Variable	Type	Label	Codes	Comments
SCOPE	char	Scope of Preferred term		Collected at CRF.
CATEGORY	char	Category		Collected at CRF.
PT	char	Preferred Term		Collected at CRF.
PTCD	num	Preferred Term		Collected at CRF.

1.4.28. Skin Response – SR

Dataset	SR
Creating program	sr.sas
Description	Skin Response
Unique identifier	STUDYID,DUSUBJID,SRTESTCD,VISIT
Sorted by	STUDYID,DUSUBJID,SRTESTCD,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SRDTC

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
SRSEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
SRGRPID	char	Group ID		Collected at CRF.
SRSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SRTESTCD	char	Skin Response Test or Exam Short Name		Collected at CRF.
SRTEST	char	Skin Response Test or Examination Name		Collected at CRF.
SROBJ	char	Object of the Observation		Collected at CRF.
SRCAT	char	Category for Test		Collected at CRF.
SRORRES	char	Results or Findings in Original Units		Collected at CRF.
SRORRESU	char	Original Units		Collected at CRF.
SRSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
SRSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
SRSTRESU	char	Standard Units		Collected at CRF.
SRSTAT	char	Completion Status		Collected at CRF.
SRREASND	char	Reason Not Done		Collected at CRF.
SRBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Epoch		Collected at CRF.
SRDY	num	Relative Day of Collection		If SRDTC and REF.DATE not missing then perform below logic to calculate SRDY, If SRDTC less than REF.DATE then (SRDTC - REF.DATE). Else if SRDTC is greater than equal to REF.DATE then (SRDTC-REF.DATE) +1.

1.4.29. Study Level Metadata – STUDYDEF

Dataset	STUDYDEF
Creating program	studydef.sas
Description	Study Level Metadata
Unique identifier	STUDYID
Sorted by	STUDYID
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
METAVS	char	Metadata Version Number		Collected at CRF.
JJSTDVS	char	J&J Pharma Standards Version Number		Collected at CRF.
SDTMIGVS	char	CDISC SDTMIG Version Number		Collected at CRF.

1.4.30. Substance Use – SU

Dataset	SU
Creating program	su.sas
Description	Substance Use
Unique identifier	STUDYID,DUSUBJID,SUTRT
Sorted by	STUDYID,DUSUBJID,SUTRT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EPOCH,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.
SUPRESP	char	SU Pre-Specified		Collected at CRF.
SUOCCUR	char	SU Occurrence		Collected at CRF.
SUDOSE	num	Substance Use Consumption		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUDOSU	char	Consumption Units		Collected at CRF.
SUDOSFRQ	char	Use Frequency Per Interval		Collected at CRF.
SUENDY	num	Relative End Day of Substance Use		If SUENDTC and REF.DATE not missing then perform below logic to calculate SUENDY, If SUENDTC less than REF.DATE then (SUENDTC - REF.DATE). Else if SUENDTC is greater than equal to REF.DATE then (SUENDTC- REF.DATE) +1.
SUDUR	char	Duration of Substance Use		Collected at CRF.

1.4.31. Supplemental Qualifiers for SU – SUPPSU

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

Variable	Type	Label	Codes	Comments
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.

1.4.32. Subject Visits – SV

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

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
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
SVSTDY	num	Relative Start Day of Visit		If SVSTDTC and REF.DATE not missing then perform below logic to calculate SVSTDY, If SVSTDTC less than REF.DATE then (SVSTDTC - REF.DATE). Else if SVSTDTC is greater than equal to REF.DATE then (SVSTDTC- REF.DATE) +1.
SVENDY	num	Relative End Day of Visit		If SVENDTC and REF.DATE not missing then perform below logic to calculate SVENDY, If SVENDTC less than REF.DATE then (SVENDTC - REF.DATE). Else if SVENDTC is greater than equal to REF.DATE then (SVENDTC- REF.DATE) +1.

1.4.33. Trial Inclusion/Exclusion Criteria – TI

Dataset	TI
Creating program	ti.sas
Description	Trial Inclusion/Exclusion Criteria
Unique identifier	STUDYID,IETESTCD
Sorted by	STUDYID,IETESTCD
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
IETESTCD	char	Incl/Excl Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.

1.4.34. Value Level Metadata – VALDEF

Dataset	VALDEF
Creating program	valdef.sas
Description	Value Level Metadata
Unique identifier	VALUEOID,VALVAL
Sorted by	VALUEOID,VALVAL
Notes	Below listed variables will be dropped from dataset due to missing values: NUMFMT

Variable	Type	Label	Codes	Comments
VALUEOID	char	Value List		Collected at CRF.
VALVAL	char	Value		Collected at CRF.
VALLABEL	char	Label		Collected at CRF.
DATATYPE	char	Data Type		Collected at CRF.
LNGTH	char	Length		Collected at CRF.
DECDIG	char	Decimal Digits		Collected at CRF.
ORIGIN	char	Origin of the Variable		Collected at CRF.
VARORDER	char	Variable Order		Collected at CRF.
CODELST	char	Codelist Name		Collected at CRF.
VALUELST	char	SDTM Controlled Terms/format		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
COMMENTS	char	Comment		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRFPAGE	char	CRF Page Number		Collected at CRF.
COMPMETH	char	Computational Method		Collected at CRF.

1.4.35. Variable Level Metadata – VARDEF

Dataset	VARDEF
Creating program	vardef.sas
Description	Variable Level Metadata
Unique identifier	DATASET,VARNAME
Sorted by	DATASET,VARNAME
Notes	Below listed variables will be dropped from dataset due to missing values: NUMFMT

Variable	Type	Label	Codes	Comments
DATASET	char	Dataset Name		Collected at CRF.
VARNAME	char	SDTM Variable		Collected at CRF.
VARLABEL	char	SDTM Variable Label		Collected at CRF.
DATATYPE	char	Data Type		Collected at CRF.
LNGTH	char	Length		Collected at CRF.
DECDIG	char	Decimal Digits		Collected at CRF.
ORIGIN	char	Origin of the Variable		Collected at CRF.
VARROLE	char	Role		Collected at CRF.

Variable	Type	Label	Codes	Comments
CORE	char	Core		Collected at CRF.
MANDATRY	char	Mandatory		Collected at CRF.
VARKEY	char	Logical Key Order		Collected at CRF.
VARORDER	char	Variable Order		Collected at CRF.
CODELST	char	Codelist Name		Collected at CRF.
VALUELST	char	Value List		Collected at CRF.
COMMENTS	char	Comment		Collected at CRF.
CRFPAGE	char	CRF Page Number		Collected at CRF.
COMPMETH	char	Computational Method		Collected at CRF.

1.4.36. Vital Signs – VS

Dataset	VS
Creating program	vs.sas
Description	Vital Signs
Unique identifier	STUDYID, DUSUBJID, VSTESTCD, VSDY, VSSEQ
Sorted by	STUDYID, DUSUBJID, VSTESTCD, VSDY, 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.
VSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
VSDY	num	Relative Day of Measurements		If VSDTC and REF.DATE not missing then perform below logic to calculate VSDY, If VSDTC less than REF.DATE then (VSDTC - REF.DATE). Else if VSDTC is greater than equal to REF.DATE then (VSDTC-REF.DATE) +1.
VSTM	num	Time of Measurements		If VSDTC contains time part then timepart(VSDTC) else VSTM equal to NULL.

1.4.37. Targeted Physical Examination – XE

Dataset	XE
Creating program	xe.sas
Description	Targeted Physical Examination
Unique identifier	STUDYID,DUSUBJID,XETESTCD,XEDY,XESEQ
Sorted by	STUDYID,DUSUBJID,XETESTCD,XEDY,XESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: XEDTC,XENAM,XEREASND,XESTAT,XESTRESN

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
XESEQ	num	Sequence Number		Collected at CRF.
XESPID	char	Sponsor-Defined Identifier		Collected at CRF.
XETESTCD	char	Examination Short Name		Collected at CRF.
XETEST	char	Examination		Collected at CRF.
XECAT	char	Category for Examination		Collected at CRF.
XEORRES	char	Result or Finding in Original Units		Collected at CRF.
XESTRESC	char	Character Result/Finding in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
XELOC	char	Location of Examination Finding		Collected at CRF.
XEBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XEDY	num	Relative Day of Examination		If XEDTC and REF.DATE not missing then perform below logic to calculate XEDY, If XEDTC less than REF.DATE then (XEDTC - REF.DATE). Else if XEDTC is greater than equal to REF.DATE then (XEDTC-REF.DATE) +1.
XETM	num	Time of Examination		If XEDTC contains time part then timepart(XEDTC) else XETM equal to NULL.

1.4.38. Imaging – XI

Dataset	XI
Creating program	xi.sas
Description	Imaging
Unique identifier	STUDYID,DUSUBJID,XITESTCD,XIDY,XISEQ
Sorted by	STUDYID,DUSUBJID,XITESTCD,XIDY,XISEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: XIDTC,XINAM,XIREASND,XISTAT,XISPID

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
XISEQ	num	Sequence Number		Collected at CRF.
XIGRPID	char	Group ID		Collected at CRF.
XIREFID	char	Reference ID		Collected at CRF.
XITESTCD	char	Imaging Test or Examination Short Name		Collected at CRF.
XITEST	char	Imaging Test or Examination Name		Collected at CRF.
XICAT	char	Category for imaging		Collected at CRF.
XISCAT	char	Subcategory for Imaging		Collected at CRF.

Variable	Type	Label	Codes	Comments
XIORRES	char	Result or Finding in Original Units		Collected at CRF.
XISTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XISTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
XILOC	char	Location of Imaging Test		Collected at CRF.
XIMETHOD	char	Method of Test or Examination		Collected at CRF.
XIBLFL	char	Baseline Flag		Collected at CRF.
XIEVAL	char	Evaluator		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XIDY	num	Relative Day of Imaging		If XIDTC and REF.DATE not missing then perform below logic to calculate XIDY, If XIDTC less than REF.DATE then (XIDTC - REF.DATE). Else if XIDTC is greater than equal to REF.DATE then (XIDTC-REF.DATE) +1.

1.4.39. Supplemental Qualifiers for XI – SUPPXI

Dataset	SUPPXI
Creating program	xi.sas
Description	Supplemental Qualifiers for XI
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,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.

1.4.40. Sample Handling – XZ

Dataset	XZ
Creating program	xz.sas
Description	Sample Handling
Unique identifier	STUDYID,DUSUBJID,XZTESTCD
Sorted by	STUDYID,DUSUBJID,XZTESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: XZDTC,VISITNUM

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
XZSEQ	num	Sequence Number		Collected at CRF.
XZSPID	char	Sponsor-Defined Identifier		Collected at CRF.
XZTESTCD	char	Sample Handling Test Short Name		Collected at CRF.
XZTEST	char	Sample Handling Test Name		Collected at CRF.
XZCAT	char	Category for Sample Handling		Collected at CRF.
XZORRES	char	Result or Finding in Original Units		Collected at CRF.
XZORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XZSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XZSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
XZSTRESU	char	Standard Units		Collected at CRF.
XZSPEC	char	Sample Type		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XZDY	num	Relative Day of Sample Handling		If XZDTC and REF.DATE not missing then perform below logic to calculate XZDY, If XZDTC less than REF.DATE then (XZDTC - REF.DATE). Else if XZDTC is greater than equal to REF.DATE then (XZDTC-REF.DATE) +1.

1.4.41. Randomization– ZR

Dataset	ZR
Creating program	zr.sas
Description	Randomization
Unique identifier	STUDYID,DUSUBJID,ZRTESTCD
Sorted by	STUDYID,DUSUBJID,ZRTESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ZRDTC,ZRNAM

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
ZRSEQ	num	Sequence Number		Collected at CRF.
ZRTESTCD	char	Randomization Test Short Name		Collected at CRF.
ZRTEST	char	Randomization Test Name		Collected at CRF.
ZRCAT	char	Category for Randomization Test		Collected at CRF.
ZRSCAT	char	Subcategory for Randomization Test		Collected at CRF.
ZRORRES	char	Result or Finding in Original Units		Collected at CRF.
ZRSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
ZRDY	num	Relative Day of Randomization		If ZRDTC and REF.DATE not missing then perform below logic to calculate ZRDY, If ZRDTC less than REF.DATE then (ZRDTC - REF.DATE). Else if ZRDTC is greater than equal to REF.DATE then (ZRDTC-REF.DATE) +1.
ZRTM	num	Time of Randomization		If ZRDTC contains time part then timepart(ZRDTC) else ZRTM equal to NULL.