

Clinical Development

Infliximab

REMICADECRD3001

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	Code list 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 due to sensitivity of the data.
- 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 "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Catalog number will not be provided.
- Vial, Bottle, lot, kit number will not be provided.
- Central Lab Specimen Label Number will not be provided.

- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-identified datasets.
- Dataset containing sensitive information about clinical supply unit will not be submitted(ex. CS)
- Dataset containing subject personal information is sensitive and hence will not be submitted. (ex.SC)
- Start date of disposition event (DSSTDTC) when DSDECOD ="INFORMED CONSENT OBTAINED" from DS dataset will be used as reference date to derive relative days (referred as Ref. Date in the document).

1.3. Data Files

The REMICADECRD3001 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: RFSTDTC,RFENDTC,INVNAM,BRTHDTC,DMDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity.
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity.
DSITEID	char	Study Site Id Assigned for De-identity		Randomly assigned 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.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
RFSTTM	num	Relative 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.
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.

1.4.2. Supplemental Qualifiers for DM – SUPPDM

Dataset	SUPPDM
Creating program	dm.sas
Description	Supplemental Qualifiers for DM
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: IDVAR, IDVARVAL

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 ("DMAGE", "RASTDTC", "RAESCDTC", "RACEW", "RACEOTHR", "RACEOTH", "RACEBA ", "BRMBRK", "SITEBRK")then drop. if QNAM in ("RAESCDTC", "BRMBRK", "SITEBRK"),then will be converted to relative day.
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.
QEVAL	char	Evaluator		Collected at CRF.

1.4.3. 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 or due to missing values: AEREFID,AETERM,AESTDTC,AEENDTC

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
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.
AESCONG	char	Congenital Anomaly or Birth Defect		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
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.
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.

Variable	Type	Label	Codes	Comments
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	Relative Start Time of Adverse Event		If AESTDTC contains time part then timepart(AESTDTC) else AESTTM equal to NULL.
AEENTM	num	Relative End Time of Adverse Event		If AEENDTC contains time part then timepart(AEENDTC) else AEENTM equal to NULL.

1.4.4. Supplemental Qualifiers for AE – SUPPAE

Dataset	SUPPAE
Creating program	suppae.sas
Description	Supplemental Qualifiers for AE
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	

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.
QEVAL	char	Evaluator		Collected at CRF.

1.4.5. Clinical Events – CE

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

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.
CEPRESP	char	Clinical Event Pre-Specified		Collected at CRF.
CETERM	char	Reported Term for the Clinical Event		Collected at CRF.
CECAT	char	Category for Clinical Event		Collected at CRF.
CEOCCUR	char	Clinical Event Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
CEDY	num	Relative Day of Event Collection		If CEDTC and REF.DATE not missing then perform below logic to calculate CEDY, If CEDTC less than REF.DATE then (CEDTC - REF.DATE). Else if CEDTC is greater than equal to REF.DATE then (CEDTC-REF.DATE) +1.

1.4.6. Supplemental Qualifiers for CE – SUPPCE

Dataset	SUPPCE
Creating program	ce.sas
Description	Supplemental Qualifiers for CE
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.

1.4.7. 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: CMTRT,CMSTDTC,CMENDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity.
CMSEQ	num	Sequence Number		Collected at CRF.
CMSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CMDECOD	char	Standardized Medication Name		Collected at CRF.
CMCAT	char	Category for Medication		Collected at CRF.
CMOCCUR	char	CM Occurrence		Collected at CRF.
CMSTAT	char	Concomitant Medication Status		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMINDC	char	Indication		Collected at CRF.
CMCLAS	char	Medication Class		Collected at CRF.
CMCLASCD	char	Medication Class Code		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.
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.
CMDUR	char	Duration of Medication		Collected at CRF.
CMSTRF	char	Start Relative to Reference Period		Collected at CRF.

1.4.8. 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	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity.
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		If QNAM = "CMINDOTH" then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.
QEVAL	char	Evaluator		Collected at CRF.

1.4.9. Disposition – DS

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity.
DSSEQ	num	Sequence Number		Collected at CRF.
DSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DSDECOD	char	Standardized Disposition Term		Collected at CRF.
DSCAT	char	Category for Disposition Event		Collected at CRF.
DSSCAT	char	Subcategory for Disposition Event		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	Relative Start Time of Disposition Event		If DSSTDTC contains time part then timepart(DSSTDTC) else DSSTTM equal to NULL.

1.4.10. 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: DVTERM,DVSTDTC, DVREFID

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.
DVSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.11. Exposure – EX

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

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

Variable	Type	Label	Codes	Comments
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	Relative Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM equal to NULL.
EXENTM	num	Relative End Time of Treatment		If EXENDTC contains time part then timepart(EXENDTC) else EXENTM equal to NULL.

1.4.12. 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: QEQVAL

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.
QEQVAL	char	Qualifier Variable Name		If QEQVAL in ("VIALNO9", "VIALNO8", "VIALNO7", "VIALNO6", "VIALNO5", "VIALNO4", "VIALNO3", "VIALNO2", "VIALNO10", "VIALNO1", "DPPRPDTC", "DPOTHSPE ") then drop. If QEQVAL = "DPPRPDTC " then will be converted to relative day.

Variable	Type	Label	Codes	Comments
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.13. Findings About Events or Interventions – FA

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

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.

Variable	Type	Label	Codes	Comments
FASPID	char	Sponsor-Defined Identifier		Collected at CRF.
FATESTCD	char	Findings About Test Short Name		Collected at CRF.
FATEST	char	Findings About Test Name		Collected at CRF.
FACAT	char	Category for Findings About		Collected at CRF.
FASCAT	char	Subcategory for Findings About		Collected at CRF.
FAORRES	char	Result or Finding in Original Units		Element will be grouped to convert date values to relative day.
FASTRESC	char	Character Result/Finding in Std Format		Element will be grouped to convert date values to relative day.
FABLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.

1.4.14. Supplemental Qualifiers for FA – SUPPFA

Dataset	SUPPFA
Creating program	fa.sas
Description	Supplemental Qualifiers for FA
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: QVAL

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 = "FAOBJOTH" then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.15. Hospitalization – HO

Dataset	HO
Creating program	ho.sas
Description	Hospitalization
Unique identifier	STUDYID,DUSUBJID,HOTERM,HOSTDY
Sorted by	STUDYID,DUSUBJID,HOTERM,HOSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HOSTDTC,HOENDTC

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.
HOSEQ	num	Sequence Number		Collected at CRF.
HOSPID	char	Sponsor-Defined Identifier		Collected at CRF.
HOTERM	char	Reported Term for the Hospitalization		Collected at CRF.
HOOCUR	char	Hospitalization Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOSTDY	num	Relative Start Day of Hosp Event		If HOSTDTC and REF.DATE not missing then perform below logic to calculate HOSTDY, If HOSTDTC less than REF.DATE then (HOSTDTC - REF.DATE). Else if HOSTDTC is greater than equal to REF.DATE then (HOSTDTC- REF.DATE) +1.
HOENDY	num	Relative End Day of Hosp Event		If HOENDTC and REF.DATE not missing then perform below logic to calculate HOENDY, If HOENDTC less than REF.DATE then (HOENDTC - REF.DATE). Else if HOENDTC is greater than equal to REF.DATE then (HOENDTC- REF.DATE) +1.

1.4.16. Supplemental Qualifiers for HO – SUPPHO

Dataset	SUPPHO
Creating program	ho.sas
Description	Supplemental Qualifiers for HO
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: QVAL

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 = "HODIAG" then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.17. Inclusion/Exclusion Exceptions – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Exceptions
Unique identifier	STUDYID,DUSUBJID,IETESTCD,IESEQ
Sorted by	STUDYID,DUSUBJID,IETESTCD,IESEQ
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.
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.

1.4.18. Laboratory Test Results – LB

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

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.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORRESU	char	Original Units		Collected at CRF.
LBORNRL0	char	Reference Range Lower Limit in Orig Unit		Collected at CRF.
LBORNRHI	char	Reference Range Upper Limit in Orig Unit		Collected at CRF.
LBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
LBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
LBSTRESU	char	Standard Units		Collected at CRF.
LBSTNRLO	num	Reference Range Lower Limit-Std Units		Collected at CRF.
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
LBREASND	char	Reason Test Not Done		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBSPCCND	char	Specimen Condition		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
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	Relative Time of Specimen Collection		If LBDTC contains time part then timepart(LBDTC) else LBTM equal to NULL.

1.4.19. Medical History – MH

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

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.
MHTERM	char	Reported Term for the Medical History		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
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
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 MH 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.
MHENDY	num	Relative End Day of MH Event		If MHENDTC and REF.DATE not missing then perform below logic to calculate MHENDY, If MHENDTC less than REF.DATE then (MHENDTC - REF.DATE). Else if MHENDTC is greater than equal to REF.DATE then (MHENDTC- REF.DATE) +1.

1.4.20. 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: QVAL

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.

1.4.21. Pharmacokinetic Concentrations – PC

Dataset	PC
Creating program	pc.sas
Description	Pharmacokinetic Concentrations
Unique identifier	STUDYID,DUSUBJID,PCCAT,PCTESTCD,PCSEQ
Sorted by	STUDYID,DUSUBJID,PCCAT,PCTESTCD,PCSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PCREFID,PCSPID,PCENDTC,PCNAM,PCDTC,PCSTAT

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.
PCTESTCD	char	Test Short Name		Collected at CRF.
PCTEST	char	Test Name		Collected at CRF.
PCCAT	char	Category for PK Concentration		Collected at CRF.
PCORRES	char	Result or Finding in Original Units		Collected at CRF.
PCORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCSTRESC	char	Character Result or Finding in Std Units		Collected at CRF.
PCSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
PCSTRESU	char	Standard Units		Collected at CRF.
PCSPEC	char	Specimen Type		Collected at CRF.
PCMETHOD	char	Method of Test or Examination		Collected at CRF.
PCBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
PCTPT	char	Planned Time point Name		Collected at CRF.
PCTPTNUM	num	Planned Time point Number		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.

1.4.22. Supplemental Qualifiers for PC – SUPPPC

Dataset	SUPPPC
Creating program	pc.sas
Description	Supplemental Qualifiers for PC
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	

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.
QEVAL	char	Evaluator		Collected at CRF.

1.4.23. Questionnaires – QS

Dataset	QS
Creating program	qs.sas
Description	Questionnaires
Unique identifier	STUDYID,DUSUBJID,QSTESTCD,QSCAT,QSORRES,QSSPID
Sorted by	STUDYID,DUSUBJID,QSTESTCD,QSCAT,QSORRES,QSSPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: QSDTC

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

Variable	Type	Label	Codes	Comments
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	Status of Question		Collected at CRF.
QSBFLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial 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.

1.4.24. Supplemental Qualifiers for QS – SUPPQS

Dataset	SUPPQS
Creating program	qs.sas
Description	Supplemental Qualifiers for QS
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: QVAL

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

1.4.25. Randomization – RA

Dataset	RA
Creating program	ra.sas
Description	Randomization
Unique identifier	STUDYID,DUSUBJID,ARMCD,VISITNUM,RAORIG,RASTDY
Sorted by	STUDYID,DUSUBJID,ARMCD,VISITNUM,RAORIG,RASTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANUM,RAESCDTC,RASTDTC

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 Study Site Id for De-identity.
RASEQ	num	Sequence Number		Collected at CRF.
RASPID	char	Sponsor-Defined Identifier		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
ARM	char	Description of Planned Arm		Collected at CRF.
RADOSESC	char	Indication of Dose Escalation		Collected at CRF.
RAESCVST	char	Visit of Dose Escalation		Collected at CRF.
RAORIG	char	Origin of Randomization Data		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
RAESCTM	num	Relative Time of Dose Escalation		If RAESCDTC contains time part then timepart(RAESCDTC) else RAESCTM equal to NULL.
RAESCDY	num	Relative Day of Dose Escalation		If RAESCDTC and REF.DATE not missing then perform below logic to calculate RAESCDY, If RAESCDTC less than REF.DATE then (RAESCDTC - REF.DATE). Else if RAESCDTC is greater than equal to REF.DATE then (RAESCDTC- REF.DATE) +1.
RASTTM	num	Relative Time of Randomization		If RASTDTC contains time part then timepart(RASTDTC) else RASTTM equal to NULL.

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

1.4.26. Supplemental Qualifiers for RA – SUPPRA

Dataset	SUPPRA
Creating program	ra.sas
Description	Supplemental Qualifiers for RA
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	

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 ("BRMBRK", "SITEBRK") then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.
QEVAL	char	Evaluator		Collected at CRF.

1.4.27. Surgery – SG

Dataset	SG
Creating program	sg.sas
Description	Surgery
Unique identifier	STUDYID,DUSUBJID,SGTRT,SGCAT,SGSTDY
Sorted by	STUDYID,DUSUBJID,SGTRT,SGCAT,SGSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.
SGTRT	char	Reported Name of Surgery/Procedure		Collected at CRF.
SGCAT	char	Category for Surgery/Procedure		Collected at CRF.
SGSCAT	char	Subcategory for Surgery/Procedure		Collected at CRF.
SGLOC	char	Location of Surgery/Procedure		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.28. 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.

Variable	Type	Label	Codes	Comments
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.29. 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: 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.
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.
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.
SVSTTM	num	Relative Start Time of Visit		If SVSTDTC contains time part then timepart(SVSTDTC) else SVSTTM equal to NULL.
SVENTM	num	Relative End Time of Visit		If SVENDTC contains time part then timepart(SVENDTC) else SVENTM equal to NULL.

1.4.30. 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	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.

1.4.31. Vital Signs – VS

Dataset	VS
Creating program	vs.sas
Description	Vital Signs
Unique identifier	STUDYID,DUSUBJID,VSTESTCD,VSDY,VISITNUM,VSSPID
Sorted by	STUDYID,DUSUBJID,VSTESTCD,VSDY,VISITNUM,VSSPID
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.
VSSTAT	char	Vitals Status		Collected at CRF.
VSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial 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.

1.4.32. Imaging – XI

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

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.
XISPID	char	Sponsor-Defined Identifier		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.
XIORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XISTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XIMETHOD	char	Method of XI Test		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.
EPOCH	char	Trial 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.