Clinical Development

Golimumab

ART3001

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.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- SC dataset will not be submitted as it contains Subject characteristics information which is sensitive.
- GE dataset will not be submitted as it contains Genotype information which is sensitive.
- After removing sensitive information, dataset does not have any useful information for further analysis. Hence, dataset will not be submitted. (eg. SUPPDM)
- SV. SVSTDT (when VISIT="Screening") will be used as Reference Date (Referred as REF.DATE in the document) to derive relative day.

1.3.   Data Files

The ART3001 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 or due to missing values: RACEA,RACEAIAN,RACEBA,RACENHOP,RACEOTH,RACEOTHR,RACEUNK, INVNAM,RFSTDT,RFENDTM,BRTHDT,RFSTDTM,RFENDT,RFSTTM, BRTHTM, RFENTM,BRTHDTC,INVID,RFENDTC,BRTHDTM,RACENR,RFSTDTC, RACEW

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	Site Identifier Assigned for De-identity		Randomly assigned Site Identifier 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.

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 or due to repetition of the information or due to missing values: AEENDTM,AEMODIFY,AEREFID,AESTDT,AEENDTC,AESTDTC,AEENTM,AEENDT, AETERM,AESTDTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
AESEQ	num	Sequence Number		Collected at CRF.
AESPID	char	Sponsor-Defined Identifier		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AESEV	char	Severity/Intensity		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESER	char	Serious Event		Collected at CRF.
AEACN	char	Action Taken with Study Treatment		Collected at CRF.
AEREL	char	Causality		Collected at CRF.
AEOUT	char	Outcome of Adverse Event		Collected at CRF.
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.
AESTTM	num	Start Time of Adverse Event		Collected at CRF.
AEDICTVS	char	Dictionary Version		Collected at CRF.
AEHLGT	char	High Level Group Term		Collected at CRF.
AEHLT	char	Higher Level Term		Collected at CRF.
AEINF	char	Infection		Collected at CRF.
AEINFRCT	char	Infusion Related Reaction		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEINFTX	char	Infection Treated		Collected at CRF.
AELLT	char	Lower Level Term		Collected at CRF.
AELLTCD	char	Lower Level Term Code		Collected at CRF.
AESHOSPP	char	Prolongs Hospitalization		Collected at CRF.
AESHOSPR	char	Requires Hospitalization		Collected at CRF.
AETRLPRC	char	Related to Trial Procedure		Collected at CRF.
AESTDY	num	Relative Start Day of Adverse Event		If AESTDT and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDT less than REF.DATE then (AESTDT - REF.DATE). Else if AESTDT is greater than equal to REF.DATE then (AESTDT- REF.DATE) +1.
AEENDY	num	Relative End Day of Adverse Event		If AEENDT and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDT less than REF.DATE then (AEENDT - REF.DATE). Else if AEENDT is greater than equal to REF.DATE then (AEENDT- REF.DATE) +1.

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.
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.

1.4.4. Clinical Findings – CF

Dataset	CF
Creating program	cf.sas
Description	Clinical Findings
Unique identifier	STUDYID,DUSUBJID,CFTESTCD,CFSEQ
Sorted by	STUDYID,DUSUBJID,CFTESTCD,CFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: CFDTM,CFENDTM,CFENTM,CFENDT,CFSTDTM,CFSTTM,CFSTDT, CFTM,CFDT, CFENDTC,CFSTDTC,CFDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
CFSEQ	num	Sequence Number		Collected at CRF.
CFSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CFEVAL	char	Evaluator		Collected at CRF.
CFTESTCD	char	Short Name of Examination		Collected at CRF.
CFMETHOD	char	Method of Test or Examination		Collected at CRF.

Variable	Type	Label	Codes	Comments
CFTEST	char	Name of Examination		Collected at CRF.
CFCAT	char	Category for Clinical Finding		Collected at CRF.
CFORRES	char	Result or Finding in Original Units		Collected at CRF.
CFORRESU	char	Original Units		Collected at CRF.
CFSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
CFSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
CFSTRESU	char	Standard Units		Collected at CRF.
CFRESCAT	char	Result Category		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CFTRTRQ	char	TB Treatment Required		Collected at CRF.
CMSEQ	num	CM Sequence Number 1		Collected at CRF.
CMSEQ1	num	CM Sequence Number 2		Collected at CRF.
TBADM	char	Administrator		Collected at CRF.
CMSEQ2	num	CM Sequence Number 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
CFDY	num	Relative Day of Collection		If CFDT and REF.DATE not missing then perform below logic to calculate CFDY, If CFDT less than REF.DATE then (CFDT - REF.DATE). Else if CFDT is greater than equal to REF.DATE then (CFDT- REF.DATE) +1.
CFENDY	num	Relative End day of Clinical Finding		If CFENDT and REF.DATE not missing then perform below logic to calculate CFENDY, If CFENDT less than REF.DATE then (CFENDT - REF.DATE). Else if CFENDT is greater than equal to REF.DATE then (CFENDT- REF.DATE) +1.

1.4.5. Supplemental Qualifiers for CF – SUPPCF

Dataset	SUPPCF
Creating program	cf.sas
Description	Supplemental Qualifiers for CF
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.

1.4.6. 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 or due to repetition of the information or due to missing values: CMENDTM,CMENDT,CMSTDTM,CMSTTM,CMENDTC,CMSTDTC,CMDOSRGM, CMMODIFY,CMSTDT,CMENTM, CMINDOTH

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.
CMDECOD	char	Standardized Medication Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCAT	char	Category for Medication		Collected at CRF.
CMOCCUR	char	CM Occurrence		Collected at CRF.
CMINDC	char	Indication		Collected at CRF.
CMCLAS	char	Medication Class		Collected at CRF.
CMCLASCD	char	Medication Class Code		Collected at CRF.
CMDOSE	num	Dose per Administration		Collected at CRF.
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.
AESEQ	num	AE Sequence Number		Collected at CRF.
AESEQ1	num	AE Sequence Number 1		Collected at CRF.
AESEQ2	num	AE Sequence Number 2		Collected at CRF.
CMATC0	char	ATC Text 0		Collected at CRF.
CMATC1	char	ATC Text 1		Collected at CRF.
CMATC2	char	ATC Text 2		Collected at CRF.
CMATC3	char	ATC Text 3		Collected at CRF.
CMATC4	char	ATC Text 4		Collected at CRF.
CMATC5	char	ATC Text 5		Collected at CRF.
CMATC6	char	ATC Text 6		Collected at CRF.
CMATC7	char	ATC Text 7		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMATC8	char	ATC Text 8		Collected at CRF.
CMATCCD0	char	ATC Code 0		Collected at CRF.
CMATCCD1	char	ATC Code 1		Collected at CRF.
CMATCCD2	char	ATC Code 2		Collected at CRF.
CMATCCD3	char	ATC Code 3		Collected at CRF.
CMATCCD4	char	ATC Code 4		Collected at CRF.
CMATCCD5	char	ATC Code 5		Collected at CRF.
CMATCCD6	char	ATC Code 6		Collected at CRF.
CMATCCD7	char	ATC Code 7		Collected at CRF.
CMATCCD8	char	ATC Code 8		Collected at CRF.
CMCDOS	char	Cumulative Dose		Collected at CRF.
CMDICTVS	char	Dictionary version		Collected at CRF.
CMDURCH	char	Duration of Use		Collected at CRF.
CMMXDOS	char	Maximum Dose		Collected at CRF.
CMMXDSU	char	Maximum Dose Unit		Collected at CRF.
CMONGO	char	Treatment Ongoing at End of Study		Collected at CRF.
CMPRIOR	char	Treatment Began Prior to Entry		Collected at CRF.
CMSCDOS	char	Screening Dose		Collected at CRF.
CMSCDSU	char	Screening Dose Unit		Collected at CRF.
CMTMSNC	char	Time Since Administration		Collected at CRF.
CMTPT	char	Timepoint Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMSTDY	num	Relative Start Day of Medication		If CMSTDT and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDT less than REF.DATE then (CMSTDT - REF.DATE). Else if CMSTDT is greater than equal to REF.DATE then (CMSTDT- REF.DATE) +1.
CMENDY	num	Relative End Day of Medication		If CMENDT and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDT less than REF.DATE then (CMENDT - REF.DATE). Else if CMENDT is greater than equal to REF.DATE then (CMENDT- REF.DATE) +1.

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		If QNAM in (CMINDOTH) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.8. Disease Characteristics – DC

Dataset	DC
Creating program	dc.sas
Description	Disease Characteristics
Unique identifier	STUDYID,DUSUBJID,DCTESTCD,DCSEQ
Sorted by	STUDYID,DUSUBJID,DCTESTCD,DCSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: DCTM,DCSTRESU,DCDTC,DCDTM,DCDT,DCSTRESN,DCORRESU,DCREASND

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DCSEQ	num	Sequence Number		Collected at CRF.
DCSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DCTESTCD	char	Disease Characteristic Short Name		Collected at CRF.
DCTEST	char	Disease Characteristic Name		Collected at CRF.
DCCAT	char	Category for Disease Characteristic		Collected at CRF.
DCLOC	char	Joint Location		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCSTAT	char	Status		Collected at CRF.
DCORRES	char	Result or Finding in Original Units		Collected at CRF.
DCSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
DCEVAL	char	Evaluator		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCDY	num	Relative Day of Collection		If DCDT and REF.DATE not missing then perform below logic to calculate DCDY, If DCDT less than REF.DATE then (DCDT - REF.DATE). Else if DCDT is greater than equal to REF.DATE then (DCDT-REF.DATE) +1.

1.4.9. 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 or due to repetition of the information: DSTERM,RANUM,DSSTDTC,RAORD,DTHREAS,DSSTDT,DSSTDTM, RASEED

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSSEQ	num	Sequence Number		Collected at CRF.
DSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DSDECOD	char	Standardized Disposition Term		Collected at CRF.
DSCAT	char	Category for Disposition Event		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Trial Epoch		Collected at CRF.
DSSTTM	num	Start Time of Disposition Event		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
EESCP	char	Subject Met Early Escape Criteria		Collected at CRF.
RAIMBAL1	num	Imbalance if Assigned tx 1		Collected at CRF.
RAIMBAL2	num	Imbalance if Assigned tx 2		Collected at CRF.
RAPRB1	num	Prob. of tx 1 Allocation		Collected at CRF.
RAPRB2	num	Prob. of tx 2 Allocation		Collected at CRF.
DSTWSTD	char	Worsening of study disease		Collected at CRF.
STRATA1	num	Stratification 1		Collected at CRF.
STRATA2	char	Stratification 2		Collected at CRF.
AESEQ1	num	AE Sequence Number 1		Collected at CRF.
AESEQ2	num	AE Sequence Number 2		Collected at CRF.
AESEQ3	num	AE Sequence Number 3		Collected at CRF.
AESEQ4	num	AE Sequence Number 4		Collected at CRF.
AESEQ5	num	AE Sequence Number 5		Collected at CRF.
DSSTDY	num	Relative Start Day of Disposition Event		If DSSTDT and REF.DATE not missing then perform below logic to calculate DSSTDY, If DSSTDT less than REF.DATE then (DSSTDT - REF.DATE). Else if DSSTDT is greater than equal to REF.DATE then (DSSTDT- REF.DATE) +1.

1.4.10.   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.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		If QNAM in (DTHREAS) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.11. Protocol Deviations – DV

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DVSEQ	num	Sequence Number		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

1.4.12. 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 repetition of the information or due to missing values: EXENDTM,EXINDTC,EXENDT,EXTRT,EXENDTC,EXDOSE,EXADJ,EXLOT, EXDOSTXT,EXDOSFRM,EXADJOTH,EXSTDT,EXSTDTC,EXDPDTC,EXSTDTM

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.
EXCAT	char	Category for Treatment		Collected at CRF.
EXDOSU	char	Dose Units		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
EXSTTM	num	Start Time of Treatment		Collected at CRF.
EXENTM	num	End Time of Treatment		Collected at CRF.
EXAMONT	num	Amount Administered		Collected at CRF.
EXAMONTU	char	Amount Administered in units		Collected at CRF.
EXINRPT	char	Infusion Interrupted?		Collected at CRF.
EXPLCBO	char	Normal Saline		Collected at CRF.
EXTOTADM	char	Total volume administered?		Collected at CRF.
EXVWDRWN	char	Total Volume Withdrawn from Vial		Collected at CRF.
EXVWDRWU	char	Volume Withdrawn Units		Collected at CRF.
EXSTDY	num	Relative Start Day of Treatment		If EXSTDT and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDT less than REF.DATE then (EXSTDT - REF.DATE). Else if EXSTDT is greater than equal to REF.DATE then (EXSTDT- REF.DATE) +1.
EXENDY	num	Relative End Day of Treatment		If EXENDT and REF.DATE not missing then perform below logic to calculate EXENDY, If EXENDT less than REF.DATE then (EXENDT - REF.DATE). Else if EXENDT is greater than equal to REF.DATE then (EXENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
EXDPDY	num	Relative Day Prepared		If EXDPDTC and REF.DATE not missing then perform below logic to calculate EXDPDY, If EXDPDTC less than REF.DATE then (EXDPDTC - REF.DATE). Else if EXDPDTC is greater than equal to REF.DATE then (EXDPDTC- REF.DATE) +1.
EXINTM	num	Interruption Time		If EXINDTC contains time part then timepart(EXINDTC) else EXINTM equal to NULL.
EXINDY	num	Relative Interruption Day		If EXINDTC and REF.DATE not missing then perform below logic to calculate EXINDY, If EXINDTC less than REF.DATE then (EXINDTC - REF.DATE). Else if EXINDTC is greater than equal to REF.DATE then (EXINDTC- REF.DATE) +1.

1.4.13. 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		If QNAM in (EXINDTC,EXDPDTC) 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.

1.4.14.   Inclusion/Exclusion Exceptions – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Exceptions
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 or due to repetition of the information or due to missing values: IEDT,IEDTM,IETM,IEDTC,IESCAT

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.

Variable	Type	Label	Codes	Comments
IEORRES	char	I/E Criterion Original Result		Collected at CRF.
IESTRESC	char	I/E Criterion Result in Std Format		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
IEDY	num	Relative Day of Collection		If IEDT and REF.DATE not missing then perform below logic to calculate IEDY, If IEDT less than REF.DATE then (IEDT - REF.DATE). Else if IEDT is greater than equal to REF.DATE then (IEDT-REF.DATE) +1.

1.4.15.   Intervention Findings – IF

Dataset	IF
Creating program	if.sas
Description	Intervention Findings
Unique identifier	STUDYID,DUSUBJID,IFTESTCD,IFSEQ
Sorted by	STUDYID,DUSUBJID,IFTESTCD,IFSEQ
Notes	

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
IFSEQ	num	Sequence Number		Collected at CRF.
IFSPID	char	Sponsor-Defined Identifier		Collected at CRF.
IFTESTCD	char	Body System Examined Short Name		Collected at CRF.
IFTEST	char	Body System Examined		Collected at CRF.
IFCAT	char	Category for Examination		Collected at CRF.
IFORRES	char	Verbatim Examination Finding		Collected at CRF.
IFORRESU	char	Examination Finding Unit		Collected at CRF.
IFSTRESC	char	Character Result/Finding in Std. Format		Collected at CRF.
IFSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
IFSTRESU	char	Standard Units		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMSEQ1	num	CM Sequence Number 1		Collected at CRF.
CMSEQ2	num	CM Sequence Number 2		Collected at CRF.
CMSEQ3	num	CM Sequence Number 3		Collected at CRF.

1.4.16. Supplemental Qualifiers for IF – SUPPIF

Dataset	SUPPIF
Creating program	if.sas
Description	Supplemental Qualifiers for IF
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.

1.4.17. Laboratory Test Results – LB

Dataset	LB
Creating program	lb.sas
Description	Laboratory Test Results
Unique identifier	STUDYID,DUSUBJID,LBTEST,LBDY,VISIT,LBSEQ
Sorted by	STUDYID,DUSUBJID,LBTEST,LBDY,VISIT,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LBREFID,CNVNRLO,LBNAM,LBSTNRLQ,LBDTC,CNVRESN,LBFAST,CNVNRHI, LBTPT,LBTPTNUM,LBDT,CNVU,CNVRESC,LBBLFL,LBSCAT,LBDTM

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.
LBSPID	char	Sponsor-Defined Identifier		Collected at CRF.
LBTESTCD	char	LAB Test or Examination Short Name		Collected at CRF.
LBTEST	char	LAB Test or Examination Name		Collected at CRF.

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.
LBSTNRC	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
LBSTRESU	char	Standard Units		Collected at CRF.
LBSTNRLO	num	Reference Range Lower Limit-Std Units		Collected at CRF.
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBSPCCND	char	Specimen Condition		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBTM	num	Time of Specimen Collection		Collected at CRF.
LBFSV	num	Indicates Final Safety Visit Lab		Collected at CRF.
LBRETST	num	Indicates Retest done		Collected at CRF.
LBSTNRHQ	char	Std Ref Range Upper Limit Qualifier		Collected at CRF.
LBDY	num	Relative Day of Specimen Collection		If LBDT and REF.DATE not missing then perform below logic to calculate LBDY, If LBDT less than REF.DATE then (LBDT - REF.DATE). Else if LBDT is greater than equal to REF.DATE then (LBDT-REF.DATE) +1.

1.4.18.   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		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.19.   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 repetition of the information or due to missing values: MHSTDT,MHDECOD,MHSTDTC,MHTERM,MHDTC,MHSTTM,MHDT, MHSTDTM,MHTM,MHDTM

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.
MHOCCUR	char	Medical History Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
MHONGO	char	Medical History Ongoing at Study Entry		Collected at CRF.
MHTRT	char	Required Therapy		Collected at CRF.
MHSTDY	num	Relative Start Day of Med History Event		If MHSTDT and REF.DATE not missing then perform below logic to calculate MHSTDY, If MHSTDT less than REF.DATE then (MHSTDT - REF.DATE). Else if MHSTDT is greater than equal to REF.DATE then (MHSTDT- 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: 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.

1.4.21.   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 or due to repetition of the information or due to missing values: PCRFTDTC,PCRFTDT,PCRFTDTM,PCRFTTM,PCDTM,PCDT,PCDTC,PCNAM, PCSTAT,PCREFID, PCLABCOM

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.
PCSPID	char	Sponsor-Defined Identifier		Collected at CRF.
PCTESTCD	char	Test Short Name		Collected at CRF.
PCTEST	char	Test Name		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 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.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
PCTPT	char	Planned Time point Name		Collected at CRF.
PCTPTNUM	num	Planned Time point Number		Collected at CRF.
PCTM	num	Start Time of Specimen Collection		Collected at CRF.
PCLLOQ	num	Lower Limit of Quantification		Collected at CRF.
PCDY	num	Relative Start Day of Specmen Collection		If PCDT and REF.DATE not missing then perform below logic to calculate PCDY, If PCDT less than REF.DATE then (PCDT - REF.DATE). Else if PCDT is greater than equal to REF.DATE then (PCDT-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	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 (PCLABCOM) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.23.   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 or due to repetition of the information or due to missing values: QSEVLINT,QSTPTNUM,QSTPT,QSBLFL,QSDTC,QSDT,QSDTM,QSSTAT,QSTM

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

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

1.4.24.   Related Records – RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	STUDYID,DUSUBJID,IDVAR,IDVARVAL,RELID
Sorted by	STUDYID,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 or due to repetition of the information or due to missing values: SGSTDTC,SGSTDTM,SGSTDT,SGDECOD,SGSTTM

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.
SGOCCUR	char	Surgery/Procedure Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
SGINDC	char	Indication		Collected at CRF.
SGLOC	char	Location of Surgery/Procedure		Collected at CRF.
SGTMSNC	char	Time Since Procedure		Collected at CRF.
SGSTDY	num	Relative Start Day of Surgery/Procedure		If SGSTDT and REF.DATE not missing then perform below logic to calculate SGSTDY, If SGSTDT less than REF.DATE then (SGSTDT - REF.DATE). Else if SGSTDT is greater than equal to REF.DATE then (SGSTDT- 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.

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.

1.4.27. Substance Use – SU

Dataset	SU
Creating program	su.sas
Description	Substance Use
Unique identifier	STUDYID,DUSUBJID,SUCAT,SUSEQ
Sorted by	STUDYID,DUSUBJID,SUCAT,SUSEQ
Notes	Below listed variables will be dropped from dataset due to missing values: VISITDY

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
SUSEQ	num	Sequence Number		Collected at CRF.
SUSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SUTRT	char	Reported Name of Substance		Collected at CRF.
SUCAT	char	Category for Substance Use		Collected at CRF.
SUOCCUR	char	SU Occurrence		Collected at CRF.
SUDOSE	num	Substance Use Consumption		Collected at CRF.
SUDOSU	char	Consumption Units		Collected at CRF.
SUDOSFRQ	char	Use Frequency Per Interval		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
SUDUR	char	Duration of Substance Use		Collected at CRF.
SUALSTAT	char	Alcohol Intake Status		Collected at CRF.
SUSMSTAT	char	Smoking Status		Collected at CRF.

1.4.28. 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.
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.

1.4.29. Subject Visits – SV

Dataset	SV
Creating program	sv.sas
Description	Subject Visits
Unique identifier	STUDYID,DUSUBJID,SVSTDY,VISIT
Sorted by	STUDYID,DUSUBJID,SVSTDY,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: SVENDT,SVSTDTM,SVSTDT,SVENDTC,SVENTM,SVSTDTC,SVSTTM,SVENDTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
SVSTDY	num	Relative Start Day of Visit		If SVSTDT and REF.DATE not missing then perform below logic to calculate SVSTDY, If SVSTDT less than REF.DATE then (SVSTDT - REF.DATE). Else if SVSTDT is greater than equal to REF.DATE then (SVSTDT- REF.DATE) +1.
SVENDY	num	Relative End Day of Visit		If SVENDT and REF.DATE not missing then perform below logic to calculate SVENDY, If SVENDT less than REF.DATE then (SVENDT - REF.DATE). Else if SVENDT is greater than equal to REF.DATE then (SVENDT- REF.DATE) +1.

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.

Variable	Type	Label	Codes	Comments
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.
TISTDTC	char	char Start Date/Time of I/E Criterion		Collected at CRF.
TIENDTC	char	End Date/Time of I/E Criterion		Collected at CRF.
TISTDT	num	Start Date of I/E Criterion		Collected at CRF.
TISTTM	num	Start Time of I/E Criterion		Collected at CRF.
TISTDTM	num	Start Date/Time of I/E Criterion		Collected at CRF.
TIENDT	num	End Date of I/E Criterion		Collected at CRF.
TIENTM	num	End Time of I/E Criterion		Collected at CRF.
TIENDTM	num	End Date/Time of I/E Criterion		Collected at CRF.

1.4.31. 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 or due to repetition of the information or due to missing values: VSDTM,VSDT,VSBLFL,VSDTC,VSTM

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.
VSCAT	char	Category for Vital Signs		Collected at CRF.
VSORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSORRESU	char	Original Units		Collected at CRF.
VSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
VSSTRESU	char	Standard Units		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VSTPT	char	Planned Time Point Name		Collected at CRF.
VSTPTNUM	num	Planned Time Point Number		Collected at CRF.
VSDY	num	Relative Day of Measurements		If VSDT and REF.DATE not missing then perform below logic to calculate VSDY, If VSDT less than REF.DATE then (VSDT - REF.DATE). Else if VSDT is greater than equal to REF.DATE then (VSDT-REF.DATE) +1.

1.4.32. Antibodies to Study Agent – XA

Dataset	XA
Creating program	xa.sas
Description	Antibodies to Study Agent
Unique identifier	STUDYID,DUSUBJID,XATEST,XADY,XASEQ
Sorted by	STUDYID,DUSUBJID,XATEST,XADY,XASEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: XADTM,XADT,XADTC,XANAM,XASTAT

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
XASEQ	num	Sequence Number		Collected at CRF.
XASPID	char	Sponsor-Defined Identifier		Collected at CRF.
XATESTCD	char	Short Name of Measurement		Collected at CRF.
XATEST	char	Name of Measurement		Collected at CRF.
XAORRES	char	Result or Finding in Original Units		Collected at CRF.
XAORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XASTRESN	num	Numeric Result/Finding in Std Units		Collected at CRF.
XASTRESU	char	Standard Units		Collected at CRF.
XASPEC	char	Specimen Type		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
XATPT	char	Planned Timepoint Name		Collected at CRF.
XATPTNUM	num	Planned Time point Number		Collected at CRF.
XATM	num	Time of Collection		Collected at CRF.
XADY	num	Relative Day of Collection		If XADT and REF.DATE not missing then perform below logic to calculate XADY, If XADT less than REF.DATE then (XADT - REF.DATE). Else if XADT is greater than equal to REF.DATE then (XADT- REF.DATE) +1.

1.4.33.   Imaging – XI

Dataset	XI
Creating program	xi.sas
Description	Imaging
Unique identifier	STUDYID,DUSUBJID,XITEST,XIDY,XISEQ
Sorted by	STUDYID,DUSUBJID,XITEST,XIDY,XISEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: XIREFID,XIGRPID,XINAM,XISTRESN,XITM,XIDT,XIDTC,XIBLFL,XIDTM

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.

Variable	Type	Label	Codes	Comments
XISCAT	char	Subcategory for imaging		Collected at CRF.
XIORRES	char	Result or Finding in Original Units		Collected at CRF.
XISTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XISTAT	char	XI Status		Collected at CRF.
XIREASND	char	Reason XI Not Performed		Collected at CRF.
XILOC	char	Location of Imaging Test		Collected at CRF.
XIMETHOD	char	Method of XI Test		Collected at CRF.
XIEVAL	char	Evaluator		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
XIDY	num	Relative Day of imaging		If XIDT and REF.DATE not missing then perform below logic to calculate XIDY, If XIDT less than REF.DATE then (XIDT - REF.DATE). Else if XIDT is greater than equal to REF.DATE then (XIDT-REF.DATE) +1.

1.4.34. Supplemental Qualifiers for XI – SUPPXI

Dataset	SUPPXI
Creating program	xi.sas
Description	Supplemental Qualifiers for XI
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM,QVAL
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM,QVAL
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 (XIOOWIN) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.