

Clinical Development

CNTO148

UCO2001

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	06MAY2019

Property of Janssen

Confidential

May not be used, divulged, published or otherwise disclosed
without the consent of Janssen

Table of contents

Clinical Development.....	1
1. Datasets.....	5
1.1. Specifications Introduction	5
1.2. Guidelines for Preparing Data.....	5
1.3. Data Files	6
1.4. Data Domains	7
1.4.1. Demographics – DM.....	7
1.4.2. Adverse Events – AE	10
1.4.3. Supplemental Qualifiers for AE – SUPPAE	13
1.4.4. Biospecimen Events – BE.....	14
1.4.5. Concomitant Medications – CM	15
1.4.6. Supplemental Qualifiers for CM – SUPPCM	17
1.4.7. Comments – CO	18
1.4.8. Clinical Supply – CS.....	19
1.4.9. Disposition – DS.....	20
1.4.10. Protocol Deviations – DV.....	21
1.4.11. Exposure – EX.....	23
1.4.12. Supplemental Qualifiers for EX – SUPPEX.....	25
1.4.13. Findings About Events or Interventions – FA	26
1.4.14. Supplemental Qualifiers for FA – SUPPFA	28
1.4.15. Inclusion/Exclusion Criterion Not Met – IE.....	29
1.4.16. Laboratory Test Results – LB.....	31
1.4.17. Supplemental Qualifiers for LB – SUPPLB.....	34
1.4.18. Microbiology Specimen – MB.....	35
1.4.19. Medical History – MH.....	37
1.4.20. Supplemental Qualifiers for MH – SUPPMH	38
1.4.21. Microscopic Findings – MI	40
1.4.22. Pharmacokinetic Concentrations – PC.....	42
1.4.23. Procedure – PR.....	44
1.4.24. Questionnaires – QS.....	45
1.4.25. Related Records – RELREC.....	47

1.4.26.	Surgery – SG.....	48
1.4.27.	Supplemental Qualifiers for SG – SUPPSG	49
1.4.28.	Substance Use – SU	50
1.4.29.	Supplemental Qualifiers for SU – SUPPSU	52
1.4.30.	Subject Visits – SV	53
1.4.31.	Trial Inclusion/Exclusion Criteria – TI.....	54
1.4.32.	Vital Signs – VS	55
1.4.33.	Immunogenicity Evaluations – XA.....	57
1.4.34.	Biomarker Data – XB.....	59
1.4.35.	Gastrointestinal System Findings – XG.....	61
1.4.36.	Imaging – XI	63
1.4.37.	Supplemental Qualifiers for XI – SUPPXI	64
1.4.38.	Sample Handling Demographics – XZ	65
1.4.39.	Randomization – ZR.....	67

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Empty comments data will be submitted due to sensitivity of data.
- Due to sensitive information SUPPDM datasets will be removed.
- DM.RFICDTC ("Date of Informed Consent") will be used as Reference Date to derive relative day. Variable RFICDTC will be dropped from de-identified DM dataset.

1.3. Data Files

The UCO2001 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: RFSTDTC,RFPENDTC,RFICDTC,DTHDTC,DTHFL,RFENDTC,DMDTC,BRTHDTC, RFXSTDTC,RFXENDTC

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
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.

Variable	Type	Label	Codes	Comments
AGEU	char	Age Units		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
ACTARMCD	char	Actual Arm Code		Collected at CRF.
ACTARM	char	Description of Actual Arm		Collected at CRF.
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
DMDY	num	Relative Day of Collection		If DMDTC and REF.DATE not missing then perform below logic to calculate DMDY, If DMDTC less than REF.DATE then (DMDTC - REF.DATE). Else if DMDTC is greater than equal to REF.DATE then (DMDTC - REF.DATE) +1.
RFSTTM	num	Subject Reference Start Time		If RFSTDTC contains time part then timepart(RFSTDTC) else RFSTTM equal to NULL.
RFSTDY	num	Relative Subject Reference Start Day		If RFSTDTC and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDTC less than REF.DATE then (RFSTDTC - REF.DATE). Else if RFSTDTC is greater than equal to REF.DATE then (RFSTDTC - REF.DATE) +1.

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

1.4.2. Adverse Events – AE

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

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.
AELLT	char	Lowest Level Term		Collected at CRF.
AELLTCD	num	Lowest Level Term Code		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEPTCD	num	Preferred Term Code		Collected at CRF.
AEHLT	char	High Level Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEHLTCD	num	High Level Term Code		Collected at CRF.
AEHLGT	char	High Level Group Term		Collected at CRF.
AEHLGTCD	num	High Level Group Term Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AEBDSYCD	num	Body System or Organ Class Code		Collected at CRF.
AESOC	char	Primary System Organ Class		Collected at CRF.
AESOCCD	num	Primary System Organ Class Code		Collected at CRF.
AESEV	char	Severity/Intensity		Collected at CRF.
AESER	char	Serious Event		Collected at CRF.
AEACN	char	Action Taken with Study Treatment		Collected at CRF.
AEREL	char	Causality		Collected at CRF.
AEOUT	char	Outcome of Adverse Event		Collected at CRF.
AESCONG	char	Congenital Anomaly or Birth Defect		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
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.
AECONTRT	char	Concomitant or Additional Trtmt Given		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Epoch		Collected at CRF.
AESTDY	num	Relative Start Day of Adverse Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC - REF.DATE) +1.
AEENDY	num	Relative End Day of Adverse Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC - REF.DATE) +1.
AESTTM	num	Start Time of Adverse Event		If AESTDTC contains time part then timepart(AESTDTC) else AESTTM equal to NULL.
AEENTM	num	End Time of Adverse Event		If AEENDTC contains time part then timepart(AEENDTC) else AEENTM equal to NULL.

1.4.3. Supplemental Qualifiers for AE – SUPPAE

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
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 (AEINJOTH, AEINJST) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.4. Biospecimen Events – BE

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
BESEQ	num	Sequence Number		Collected at CRF.
BESPID	char	Sponsor-Defined Identifier		Collected at CRF.
BECAT	char	Category for Bio-specimen Event		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
BESTDY	num	Relative Start Day of Bio-specimen Event		If BESTDTC and REF.DATE not missing then perform below logic to calculate BESTDY, If BESTDTC less than REF.DATE then (BESTDTC - REF.DATE). Else if BESTDTC is greater than equal to REF.DATE then (BESTDTC - REF.DATE) +1.

1.4.5. Concomitant Medications – CM

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
CMSEQ	num	Sequence Number		Collected at CRF.
CMSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CMTRT	char	Reported Name of Drug, Med, or Therapy		Collected at CRF.
CMDECOD	char	Standardized Medication Name		Collected at CRF.
CMCAT	char	Category for Medication		Collected at CRF.
CMINDC	char	Indication		Collected at CRF.
CMCLAS	char	Medication Class		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCLASCD	char	Medication Class Code		Collected at CRF.
CMDOSTXT	char	Dose Description		Collected at CRF.
CMDOSU	char	Dose Units		Collected at CRF.
CMDOSFRM	char	Dose Form		Collected at CRF.
CMDOSFRQ	char	Dosing Frequency per Interval		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC - REF.DATE) +1.
CMENDY	num	Relative End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC - REF.DATE) +1.
CMSTRF	char	Start Relative to Reference Period		Collected at CRF.
CMENRF	char	End Relative to Reference Period		Collected at CRF.
CMSTTM	num	Start Time of Medication		If CMSTDTC contains time part then timepart(CMSTDTC) else CMSTTM equal to NULL.
CMENTM	num	End Time of Medication		If CMENDTC contains time part then timepart(CMENDTC) else CMENTM equal to NULL.

1.4.6. 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 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.
QEVAL	char	Evaluator		Collected at CRF.

1.4.7. Comments – CO

Dataset	CO
Creating program	co.sas
Description	Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Comment dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Empty dataset will be submitted
DOMAIN	char	Domain Abbreviation		Empty dataset will be submitted
RDOMAIN	char	Related Domain Abbreviation		Empty dataset will be submitted
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Empty dataset will be submitted
COSEQ	num	Sequence Number		Empty dataset will be submitted
IDVAR	char	Identifying Variable		Empty dataset will be submitted
IDVARVAL	char	Identifying Variable Value		Empty dataset will be submitted

1.4.8.Clinical Supply – CS

Dataset	CS
Creating program	cs.sas
Description	Clinical Supply
Unique identifier	STUDYID,DUSUBJID,CSSEQ
Sorted by	STUDYID,DUSUBJID,CSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CSLOTNUM,CSMKNUM

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
CSSEQ	num	Sequence Number		Collected at CRF.
CSTRT	char	Name of Actual Treatment		Collected at CRF.

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: DSSTDTC,DSTERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSSEQ	num	Sequence Number		Collected at CRF.
DSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DSDECOD	char	Standardized Disposition Term		Collected at CRF.
DSCAT	char	Category for Disposition Event		Collected at CRF.
DSSCAT	char	Subcategory for Disposition Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Epoch		Collected at CRF.
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.

1.4.10. Protocol Deviations – DV

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DVSEQ	num	Sequence Number		Collected at CRF.

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

1.4.11. 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: EXSTDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
EXSEQ	num	Sequence Number		Collected at CRF.
EXSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EXTRT	char	Name of Actual Treatment		Collected at CRF.
EXCAT	char	Category for Treatment		Collected at CRF.
EXDOSE	num	Dose per Administration		Collected at CRF.
EXDOSU	char	Dose Units		Collected at CRF.
EXDOSFRM	char	Dose Form		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXLOC	char	Location of Dose Administration		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
EXSTDY	num	Relative Start Day of Treatment		If EXSTDTC and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE). Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC- REF.DATE) +1.
EXSTTM	num	Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM 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: 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 (EXSYRNG, EXLOCOTH) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.13. Findings About Events or Interventions – FA

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

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.
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		Collected at CRF.

Variable	Type	Label	Codes	Comments
FASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
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: 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 (FAOTHR1, FAOTHR2, FAOTHR3) 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. Inclusion/Exclusion Criterion Not Met – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Criterion Not Met
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.
IESTRESC	char	I/E Criterion Result in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
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.

1.4.16. 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 missing values: LBFAST,LBNAM,LBSCAT,LBSPID,LBREFID,LBGRPID,LBENDY,LBTPTRF,LBELTM, LBTPTNUM,LBTPT,LBENDTC,LBDTC,LBLLOQ

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.
LBORRES	char	Result or Finding in Original Units		Collected at CRF.
LBORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
LBSTNRC	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSTAT	char	Completion Status		Collected at CRF.
LBREASND	char	Reason Test Not Done		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBSPCCND	char	Specimen Condition		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBBLFL	char	Baseline Flag		Collected at CRF.
LBTOX	char	Toxicity		Collected at CRF.

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

1.4.17. Supplemental Qualifiers for LB – SUPPLB

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		If QNAM in (LBRESBTC) 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.

1.4.18. Microbiology Specimen – MB

Dataset	MB
Creating program	mb.sas
Description	Microbiology Specimen
Unique identifier	STUDYID,DUSUBJID,MBTEST,MBDY,MBSEQ
Sorted by	STUDYID,DUSUBJID,MBTEST,MBDY,MBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MBNAM,MBDTC,MBSTRESU,MBRFTDTC,MBTPTREF,MBELTM,MBTPTNUM, MBTPT,MBDRVFL,MBLOC,MBMETHOD,MBORRESU,MBSCAT,MBSPID, MBREFID

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
MBSEQ	num	Sequence Number		Collected at CRF.
MBGRPID	char	Group ID		Collected at CRF.
MBTESTCD	char	Microbiology Test or Finding Short Name		Collected at CRF.
MBTEST	char	Microbiology Test or Finding Name		Collected at CRF.
MBCAT	char	Category for Microbiology Finding		Collected at CRF.

Variable	Type	Label	Codes	Comments
MBORRES	char	Result or Finding in Original Units		Collected at CRF.
MBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
MBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
MBRESCAT	char	Result Category		Collected at CRF.
MBSTAT	char	Completion Status		Collected at CRF.
MBREASND	char	Reason Microbiology Not Performed		Collected at CRF.
MBSPEC	char	Specimen Type		Collected at CRF.
MBSPCCND	char	Specimen Condition		Collected at CRF.
MBBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
MBDY	num	Relative Day of Specimen Collection		If MBDTC and REF.DATE not missing then perform below logic to calculate MBDY, If MBDTC less than REF.DATE then (MBDTC - REF.DATE). Else if MBDTC is greater than equal to REF.DATE then (MBDTC - REF.DATE) + 1.
MBTM	num	Time of Specimen Collection		If MBDTC contains time part then timepart(MBDTC) else MBTM equal to NULL.

1.4.19. Medical History – MH

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
MHSEQ	num	Sequence Number		Collected at CRF.
MHSPID	char	Sponsor-Defined Identifier		Collected at CRF.
MHTERM	char	Reported Term for the Medical History		Collected at CRF.
MHCAT	char	Category for Medical History		Collected at CRF.
MHOCCUR	char	Medical History Occurrence		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	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 Med. History Event		If MHSTDTC and REF.DATE not missing then perform below logic to calculate MHSTDY, If MHSTDTC less than REF.DATE then (MHSTDTC- REF.DATE). Else if MHSTDTC is greater than equal to REF.DATE then (MHSTDTC- REF.DATE) +1.

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. Microscopic Findings – MI

Dataset	MI
Creating program	mi.sas
Description	Microscopic Findings
Unique identifier	STUDYID,DUSUBJID,MITEST,MIDY,MISEQ
Sorted by	STUDYID,DUSUBJID,MITEST,MIDY,MISEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MIDTC,MIREFID,MIMETHOD,MISPCND,MINAM,MISTRESU,MISTRESN, MIORRESU,MISCAT,MIGRPID

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
MISEQ	num	Sequence Number		Collected at CRF.
MISPID	char	Sponsor-Defined Identifier		Collected at CRF.
MITESTCD	char	Microscopic Examination Short Name		Collected at CRF.
MITEST	char	Microscopic Examination Name		Collected at CRF.
MICAT	char	Category for Microscopic Finding		Collected at CRF.
MIORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
MISTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
MISTAT	char	Completion Status		Collected at CRF.
MIREASND	char	Reason Not Done		Collected at CRF.
MISPEC	char	Specimen Material Type		Collected at CRF.
MILOC	char	Specimen Collection Location		Collected at CRF.
MIBLFL	char	Baseline Flag		Collected at CRF.
MIEVAL	char	Evaluator		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
MIDY	num	Relative Day of Specimen Collection		If MIDTC and REF.DATE not missing then perform below logic to calculate MIDY, If MIDTC less than REF.DATE then (MIDTC - REF.DATE). Else if MIDTC is greater than equal to REF.DATE then (MIDTC - REF.DATE) + 1.
MITM	num	Time of Specimen Collection		If MIDTC contains time part then timepart(MIDTC) else MITM equal to NULL.

1.4.22. Pharmacokinetic Concentrations – PC

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

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	Pharmacokinetic Test Short Name		Collected at CRF.
PCTEST	char	Pharmacokinetic Test Name		Collected at CRF.
PCCAT	char	Test Category		Collected at CRF.
PCORRES	char	Result or Finding in Original Units		Collected at CRF.
PCORRESU	char	Original Units		Collected at CRF.

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

1.4.23. Procedure – PR

Dataset	PR
Creating program	pr.sas
Description	Procedure
Unique identifier	STUDYID,DUSUBJID,PRCAT,PRSTDY,PRSEQ
Sorted by	STUDYID,DUSUBJID,PRCAT,PRSTDY,PRSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PRSTDTC

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
PRSEQ	num	Sequence Number		Collected at CRF.
PRSPID	char	Sponsor-Defined Identifier		Collected at CRF.
PRTRT	char	Name of Procedure		Collected at CRF.
PRCAT	char	Category for Procedure		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

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

1.4.24. 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: 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.

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

1.4.25. Related Records – RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Notes	Below listed variables will be dropped from dataset due to missing values: RELTYPE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
RELID	char	Relationship Identifier		Collected at CRF.

1.4.26. Surgery – SG

Dataset	SG
Creating program	sg.sas
Description	Surgery
Unique identifier	STUDYID,DUSUBJID,SGTRT,SGSEQ
Sorted by	STUDYID,DUSUBJID,SGTRT,SGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SGENDTC,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.
EPOCH	char	Epoch		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.
SGENDY	num	Relative End Day of Surgery/Procedure		If SGENDTC and REF.DATE not missing then perform below logic to calculate SGENDY, If SGENDTC less than REF.DATE then (SGENDTC - REF.DATE). Else if SGENDTC is greater than equal to REF.DATE then (SGENDTC - REF.DATE) +1.
SGENRF	char	End Relative to Reference Period		Collected at CRF.

1.4.27. 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.

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.

1.4.28. Substance Use – SU

Dataset	SU
Creating program	su.sas
Description	Substance Use
Unique identifier	STUDYID,DUSUBJID,SUTRT,SUSEQ
Sorted by	STUDYID,DUSUBJID,SUTRT,SUSEQ
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
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.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

1.4.29. 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.

1.4.30. Subject Visits – SV

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
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.
SVSTTM	num	Start Time of Visit		If SVSTDTC contains time part then timepart(SVSTDTC) else SVSTTM equal to NULL.
SVENTM	num	End Time of Visit		If SVENDTC contains time part then timepart(SVENDTC) else SVENTM equal to NULL.

1.4.31. Trial Inclusion/Exclusion Criteria – TI

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

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

Variable	Type	Label	Codes	Comments
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
TIVERS	char	Protocol Criteria Versions		Collected at CRF.

1.4.32. Vital Signs – VS

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VSSEQ	num	Sequence Number		Collected at CRF.
VSSPID	char	Sponsor-Defined Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSORRES	char	Result or Finding in Original Units		Collected at CRF.
VSORRESU	char	Original Units		Collected at CRF.
VSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
VSSTRESU	char	Standard Units		Collected at CRF.
VSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
VSDY	num	Relative Day of Measurements		If VSDTC and REF.DATE not missing then perform below logic to calculate VSDY, If VSDTC less than REF.DATE then (VSDTC - REF.DATE). Else if VSDTC is greater than equal to REF.DATE then (VSDTC - REF.DATE) + 1.
VSTM	num	Time of Measurements		If VSDTC contains time part then timepart(VSDTC) else VSTM equal to NULL.

1.4.33. Immunogenicity Evaluations – XA

Dataset	XA
Creating program	xa.sas
Description	Immunogenicity Evaluations
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 missing values: XADTC,XANAM,XAREASND,XAREFID

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	Immunogenicity Test Short Name		Collected at CRF.
XATEST	char	Immunogenicity Test Name		Collected at CRF.
XACAT	char	Test Category		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 Standard Units		Collected at CRF.
XASTRESU	char	Standard Units		Collected at CRF.
XASTAT	char	Completion Status		Collected at CRF.
XASPEC	char	Specimen Material Type		Collected at CRF.
XALLOQ	num	Lower Limit of Quantitation		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XADY	num	Relative Day of Specimen Collection		If XADTC and REF.DATE not missing then perform below logic to calculate XADY, If XADTC less than REF.DATE then (XADTC - REF.DATE). Else if XADTC is greater than equal to REF.DATE then (XADTC - REF.DATE) + 1.
XATPT	char	Planned Time Point Name		Collected at CRF.
XATPTNUM	num	Planned Time Point Number		Collected at CRF.
XATM	num	Time of Specimen Collection		If XADTC contains time part then timepart(XADTC) else XATM equal to NULL.

1.4.34. Biomarker Data – XB

Dataset	XB
Creating program	xb.sas
Description	Biomarker Data
Unique identifier	STUDYID,DUSUBJID,XBTEST,XBDY,XBSEQ
Sorted by	STUDYID,DUSUBJID,XBTEST,XBDY,XBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: XBSPID,XBREFID,XBGRPID,XBDTC,XBULOQ,XBLLOQ,XBBLFL,XBNAM,XBNRIND, XBSTNRHQ,XBSTNRHI,XBSTNRLQ,XBSTNRLO,XBORNRI,XBORNRLQ

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
XBSEQ	num	Sequence Number		Collected at CRF.
XBTESTCD	char	Biomarker Short Name		Collected at CRF.
XBTEST	char	Biomarker Name		Collected at CRF.
XBCAT	char	Category for Biomarker		Collected at CRF.
XBORRES	char	Result or Finding in Original Units		Collected at CRF.
XBORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
XBSTRESU	char	Standard Units		Collected at CRF.
XBSTAT	char	Status		Collected at CRF.
XBREASND	char	Reason Test Not Done		Collected at CRF.
XBSPEC	char	Specimen Type		Collected at CRF.
XBLOC	char	Specimen location		Collected at CRF.
XBMETHOD	char	Method of Test or Examination		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XBDY	num	Relative Day of Specimen Collection		If XBDTC and REF.DATE not missing then perform below logic to calculate XBDY, If XBDTC less than REF.DATE then (XBDTC - REF.DATE). Else if XBDTC is greater than equal to REF.DATE then (XBDTC - REF.DATE) +1.
XBRETEST	char	Retest flag		Collected at CRF.
XBQCFAIL	char	QC Failure flag		Collected at CRF.
XBTM	num	Time of Specimen Collection		If XBDTC contains time part then timepart(XBDTC) else XBTM equal to NULL.

1.4.35. Gastrointestinal System Findings – XG

Dataset	XG
Creating program	xg.sas
Description	Gastrointestinal System Findings
Unique identifier	STUDYID,DUSUBJID,XGTEST,XGDY,XGSEQ
Sorted by	STUDYID,DUSUBJID,XGTEST,XGDY,XGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: XGDTC,XGNAM,XGLNKID,XGSPID,XGREFID,XGGRPID

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
XGSEQ	num	Sequence Number		Collected at CRF.
XGTESTCD	char	Endoscopy Information Short Name		Collected at CRF.
XGTEST	char	Endoscopy Information Name		Collected at CRF.
XGCAT	char	Category for Endoscopy Information		Collected at CRF.
XGSCAT	char	Subcategory for Endoscopy Information		Collected at CRF.

Variable	Type	Label	Codes	Comments
XGORRES	char	Result or Finding in Original Units		Collected at CRF.
XGSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XGBLFL	char	Baseline Flag		Collected at CRF.
XGEVAL	char	Evaluator		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XGDY	num	Relative Day of Endoscopy Information		If XGDTC and REF.DATE not missing then perform below logic to calculate XGDY, If XGDTC less than REF.DATE then (XGDTC - REF.DATE). Else if XGDTC is greater than equal to REF.DATE then (XGDTC - REF.DATE) + 1.
XGTM	num	Time of Endoscopy Information		If XGDTC contains time part then timepart(XGDTC) else XGTM equal to NULL.

1.4.36. Imaging – XI

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

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.
XIBLFL	char	Baseline Flag		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XIDY	num	Relative Day of Imaging		If XIDTC and REF.DATE not missing then perform below logic to calculate XIDY, If XIDTC less than REF.DATE then (XIDTC - REF.DATE). Else if XIDTC is greater than equal to REF.DATE then (XIDTC - REF.DATE) + 1.

1.4.37. Supplemental Qualifiers for XI – SUPPXI

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.

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.

1.4.38. Sample Handling Demographics – XZ

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

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
XZSEQ	num	Sequence Number		Collected at CRF.
XZSPID	char	Sponsor-Defined Identifier		Collected at CRF.
XZTESTCD	char	Sample Handling Test Short Name		Collected at CRF.
XZTEST	char	Sample Handling Test Name		Collected at CRF.
XZCAT	char	Category for Sample Handling		Collected at CRF.
XZORRES	char	Result or Finding in Original Units		Collected at CRF.
XZORRESU	char	Original Units		Collected at CRF.
XZSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XZSPEC	char	Sample Type		Collected at CRF.
XZBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XZDY	num	Relative Day of Sample Handling		If XZDTC and REF.DATE not missing then perform below logic to calculate XZDY, If XZDTC less than REF.DATE then (XZDTC - REF.DATE). Else if XZDTC is greater than equal to REF.DATE then (XZDTC - REF.DATE) + 1.

1.4.39. Randomization – ZR

Dataset	ZR
Creating program	zr.sas
Description	Randomization
Unique identifier	STUDYID,DUSUBJID,ZRTEST,ZRDY,ZRSEQ
Sorted by	STUDYID,DUSUBJID,ZRTEST,ZRDY,ZRSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ZRDTC,ZRNAM,ZRSCAT,ZRREFID,ZRGRPID

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
ZRSEQ	num	Sequence Number		Collected at CRF.
ZRSPID	char	Sponsor-Defined Identifier		Collected at CRF.
ZRTESTCD	char	Randomization Test Short Name		Collected at CRF.
ZRTEST	char	Randomization Test Name		Collected at CRF.
ZRCAT	char	Category for Randomization Test		Collected at CRF.
ZRORRES	char	Result or Finding in Original Units		Collected at CRF.
ZRORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZRSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
ZRSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
ZRSTRESU	char	Standard Units		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
ZRDY	num	Relative Day of Randomization		If ZRDTC and REF.DATE not missing then perform below logic to calculate ZRDY, If ZRDTC less than REF.DATE then (ZRDTC - REF.DATE). Else if ZRDTC is greater than equal to REF.DATE then (ZRDTC - REF.DATE) +1.

Clinical Development

CNTO148

UCO3001

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	14 MAY 2019

Property of Janssen
Confidential
May not be used, divulged, published or otherwise disclosed
without the consent of Janssen

Table of contents

Clinical Development.....	1
1. Datasets.....	5
1.1. Specifications Introduction	5
1.2. Guidelines for Preparing Data.....	5
1.3. Data Files	6
1.4. Data Domains	7
1.4.1. Demographics – DM.....	7
1.4.2. Adverse Events – AE	10
1.4.3. Supplemental Qualifiers for AE – SUPPAE	13
1.4.4. Biospecimen Events – BE.....	14
1.4.5. Concomitant Medications – CM	15
1.4.6. Supplemental Qualifiers for CM – SUPPCM	17
1.4.7. Disposition – DS.....	18
1.4.8. Protocol Deviations – DV.....	20
1.4.9. Exposure – EX.....	21
1.4.10. Supplemental Qualifiers for EX – SUPPEX.....	23
1.4.11. Findings About Events or Interventions – FA	24
1.4.12. Supplemental Qualifiers for FA – SUPPFA	26
1.4.13. Hospitalization – HO.....	27
1.4.14. Supplemental Qualifiers for HO – SUPPHO.....	28
1.4.15. Inclusion/Exclusion Criterion Not Met – IE.....	29
1.4.16. Laboratory Test Results – LB.....	31
1.4.17. Medical History – MH	33
1.4.18. Physical Examination – PE	36
1.4.19. Questionnaires – QS.....	38

1.4.20. Related Records – RELREC.....40

1.4.21. Substance Use – SU41

1.4.22. Supplemental Qualifiers for SU – SUPPSU42

1.4.23. Subject Visits – SV43

1.4.24. Trial Inclusion/Exclusion Criteria – TI.....44

1.4.25. Vital Signs – VS45

1.4.26. Imaging – XI47

1.4.27. Sample Handling – XZ49

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Datasets with zero observation will not be submitted (Eg: CO, SUPPLB etc).
- DM.RFICDTC ("Date of Informed Consent") will be used as Reference Date (referred as REF. DATE in the document) to derive relative day.

1.3. Data Files

The UCO3001 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: BRTHDTC,RFICDTC,RFSTDTC,RFENDTC,RFSTDTC,RFXENDTC,DMDTC,DTHDTC,VISITDY,DTHFL,RFPENDTC

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
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.

Variable	Type	Label	Codes	Comments
AGEU	char	Age Units		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
ACTARMCD	char	Actual Arm Code		Collected at CRF.
ACTARM	char	Description of Actual Arm		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DMDY	num	Relative Day of Collection		If DMDTC and REF.DATE not missing then perform below logic to calculate DMDY, If DMDTC less than REF.DATE then (DMDTC - REF.DATE). Else if DMDTC is greater than equal to REF.DATE then (DMDTC- REF.DATE) +1.
RFSTTM	num	Subject Reference Start Time		If RFSTDTC contains time part then timepart(RFSTDTC) else RFSTTM equal to NULL.
RFSTDY	num	Relative Subject Reference Start Day		If RFSTDTC and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDTC less than REF.DATE then (RFSTDTC - REF.DATE). Else if RFSTDTC is greater than equal to REF.DATE then (RFSTDTC- REF.DATE) +1.

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

1.4.2. Adverse Events – AE

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
AESEQ	num	Sequence Number		Collected at CRF.
AESPID	char	Sponsor-Defined Identifier		Collected at CRF.
AELLT	char	Lowest Level Term		Collected at CRF.
AELLTCD	num	Lowest Level Term Code		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEPTCD	num	Preferred Term Code		Collected at CRF.
AEHLT	char	High Level Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEHLTCD	num	High Level Term Code		Collected at CRF.
AEHLGT	char	High Level Group Term		Collected at CRF.
AEHLGTCD	num	High Level Group Term Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AEBDSYCD	num	Body System or Organ Class Code		Collected at CRF.
AESOC	char	Primary System Organ Class		Collected at CRF.
AESOCDD	num	Primary System Organ Class Code		Collected at CRF.
AELOC	char	Location of Event		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.

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

1.4.3. Supplemental Qualifiers for AE – SUPPAE

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
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. Biospecimen Events – BE

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
BESEQ	num	Sequence Number		Collected at CRF.
BESPID	char	Sponsor-Defined Identifier		Collected at CRF.
BETERM	char	Reported Term for the Bio-specimen Event		Collected at CRF.
BEDECOD	char	Dictionary-Derived Term		Collected at CRF.
BECAT	char	Category for Bio-specimen Event		Collected at CRF.

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

1.4.5. Concomitant Medications – CM

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
CMSEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CMDECOD	char	Standardized Medication Name		Collected at CRF.
CMCAT	char	Category for Medication		Collected at CRF.
CMRESP	char	CM Pre-Specified		Collected at CRF.
CMOCCUR	char	CM Occurrence		Collected at CRF.
CMSTAT	char	Completion Status		Collected at CRF.
CMINDC	char	Indication		Collected at CRF.
CMDOSTXT	char	Dose Description		Collected at CRF.
CMDOSU	char	Dose Units		Collected at CRF.
CMDOSFRQ	char	Dosing Frequency per Interval		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC - REF.DATE) +1.
CMENDY	num	Relative End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC - REF.DATE) +1.
CMSTRF	char	Start Relative to Reference Period		Collected at CRF.

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

1.4.6. 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.
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, CMSPEC, CMTRTOTH) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.

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

1.4.7. Disposition – DS

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSSEQ	num	Sequence Number		Collected at CRF.
DSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DSDECOD	char	Standardized Disposition Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSCAT	char	Category for Disposition Event		Collected at CRF.
DSSCAT	char	Subcategory for Disposition Event		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
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.

1.4.8. Protocol Deviations – DV

Dataset	DV
Creating program	dv.sas
Description	Protocol Deviations
Unique identifier	STUDYID,DUSUBJID,DVDECOD,DVSEQ
Sorted by	STUDYID,DUSUBJID,DVDECOD,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.
DVSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

1.4.9.Exposure – EX

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
EXSEQ	num	Sequence Number		Collected at CRF.
EXSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EXTRT	char	Name of Actual Treatment		Collected at CRF.
EXCAT	char	Category for Treatment		Collected at CRF.
EXSCAT	char	Subcategory for Treatment		Collected at CRF.
EXDOSE	num	Dose per Administration		Collected at CRF.
EXDOSU	char	Dose Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXDOSFRM	char	Dose Form		Collected at CRF.
EXDOSTOT	num	Total Daily Dose		Collected at CRF.
EXROUTE	char	Route of Administration		Collected at CRF.
EXLOC	char	Location of Dose Administration		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
EXSTDY	num	Relative Start Day of Treatment		If EXSTDTC and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE). Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC - REF.DATE) +1.
EXSTTM	num	Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM equal to NULL.

1.4.10. 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 (MKNUM) 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. Findings About Events or Interventions – FA

Dataset	FA
Creating program	fa.sas
Description	Findings About Events or Interventions
Unique identifier	STUDYID,DUSUBJID,FATEST,FADY,FASEQ
Sorted by	STUDYID,DUSUBJID,FATEST,FADY,FASEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: FASPID,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.
FATESTCD	char	Findings About Test Short Name		Collected at CRF.
FATEST	char	Findings About Test Name		Collected at CRF.
FAOBJ	char	Object of the Observation		Collected at CRF.
FACAT	char	Category for Findings About		Collected at CRF.
FASCAT	char	Subcategory for Findings About		Collected at CRF.
FAORRES	char	Result or Finding in Original Units		Collected at CRF.

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

1.4.12. 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: 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 (CM6AMI5, CM6COR6, CM6IMM5) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.13. Hospitalization – HO

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

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.
EPOCH	char	Epoch		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOSTDY	num	Relative Start Day of Hospital 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 Hospital 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.
HOENRF	char	End Relative to Reference Period		Collected at CRF.

1.4.14. 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: 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.

1.4.15. Inclusion/Exclusion Criterion Not Met – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Criterion Not Met
Unique identifier	STUDYID,DUSUBJID,IETESTCD,IESEQ
Sorted by	STUDYID,DUSUBJID,IETESTCD,IESEQ
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
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.
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.
EPOCH	char	Epoch		Collected at CRF.

1.4.16. 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 missing values: LBSPID,LBDTC,LBSTAT

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.
LBORRES	char	Result or Finding in Original Units		Collected at CRF.
LBORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
LBSTNRC	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

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	Time of Specimen Collection		If LBDTC contains time part then timepart(LBDTC) else LBTM equal to NULL.

1.4.17. Medical History – MH

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
MHSEQ	num	Sequence Number		Collected at CRF.
MHSPID	char	Sponsor-Defined Identifier		Collected at CRF.
MHLLT	char	Lowest Level Term		Collected at CRF.
MHLLTCD	num	Lowest Level Term Code		Collected at CRF.
MHDECOD	char	Dictionary-Derived Term		Collected at CRF.
MHPTCD	num	Preferred Term Code		Collected at CRF.
MHHLT	char	High Level Term		Collected at CRF.
MHHLTCD	num	High Level Term Code		Collected at CRF.
MHHLGT	char	High Level Group Term		Collected at CRF.
MHHLGTC	num	High Level Group Term Code		Collected at CRF.
MHCAT	char	Category for Medical History		Collected at CRF.
MHPRESP	char	Medical History Event Pre-Specified		Collected at CRF.
MHOCCUR	char	Medical History Occurrence		Collected at CRF.
MHSTAT	char	Completion Status		Collected at CRF.
MHBODSYS	char	Body System or Organ Class		Collected at CRF.
MHBDSYCD	num	Body System or Organ Class Code		Collected at CRF.
MHSOC	char	Primary System Organ Class		Collected at CRF.
MHSOCCD	num	Primary System Organ Class Code		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

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

1.4.18. Physical Examination – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examination
Unique identifier	STUDYID,DUSUBJID,PETEST,PEDY,PESEQ
Sorted by	STUDYID,DUSUBJID,PETEST,PEDY,PESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PEDTC

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
PESEQ	num	Sequence Number		Collected at CRF.
PESPID	char	Sponsor-Defined Identifier		Collected at CRF.
PETESTCD	char	Body System Examined Short Name		Collected at CRF.
PETEST	char	Body System Examined		Collected at CRF.
PEORRES	char	Verbatim Examination Finding		Collected at CRF.
PESTRESC	char	Character Result/Finding in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
PESTAT	char	Completion Status		Collected at CRF.
PEBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
PEDY	num	Relative Day of Examination		If PEDTC and REF.DATE not missing then perform below logic to calculate PEDY, If PEDTC less than REF.DATE then (PEDTC - REF.DATE). Else if PEDTC is greater than equal to REF.DATE then (PEDTC - REF.DATE) + 1.

1.4.19. 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: 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.
QSSCAT	char	Subcategory for Question		Collected at CRF.
QSORRES	char	Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
QSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
QSSTRESN	num	Numeric Finding in Standard Units		Collected at CRF.
QSSTAT	char	Completion Status		Collected at CRF.
QSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
QSDY	num	Relative Day of Finding		If QSDTC and REF.DATE not missing then perform below logic to calculate QSDY, If QSDTC less than REF.DATE then (QSDTC - REF.DATE). Else if QSDTC is greater than equal to REF.DATE then (QSDTC - REF.DATE) +1.

1.4.20. Related Records – RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Notes	Below listed variables will be dropped from dataset due to missing values: RELTYPE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
RELID	char	Relationship Identifier		Collected at CRF.

1.4.21. Substance Use – SU

Dataset	SU
Creating program	su.sas
Description	Substance Use
Unique identifier	STUDYID,DUSUBJID,SUTRT,SUSEQ
Sorted by	STUDYID,DUSUBJID,SUTRT,SUSEQ
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
SUSEQ	num	Sequence Number		Collected at CRF.
SUSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SUTRT	char	Reported Name of Substance		Collected at CRF.
SUPRESP	char	SU Pre-Specified		Collected at CRF.
SUOCCUR	char	SU Occurrence		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

1.4.22. 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.

1.4.23. Subject Visits – SV

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.

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

1.4.24. Trial Inclusion/Exclusion Criteria – TI

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

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

Variable	Type	Label	Codes	Comments
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.

1.4.25. Vital Signs – VS

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VSSEQ	num	Sequence Number		Collected at CRF.
VSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSORRES	char	Result or Finding in Original Units		Collected at CRF.
VSORRESU	char	Original Units		Collected at CRF.
VSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
VSSTRESU	char	Standard Units		Collected at CRF.
VSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
VSDY	num	Relative Day of Measurements		If VSDTC and REF.DATE not missing then perform below logic to calculate VSDY, If VSDTC less than REF.DATE then (VSDTC - REF.DATE). Else if VSDTC is greater than equal to REF.DATE then (VSDTC-REF.DATE) +1.

1.4.26. Imaging – XI

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

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.
XITESTCD	char	Imaging Test or Examination Short Name		Collected at CRF.
XITEST	char	Imaging Test or Examination Name		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.

Variable	Type	Label	Codes	Comments
XISTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
XIBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XIDY	num	Relative Day of Imaging		If XIDTC and REF.DATE not missing then perform below logic to calculate XIDY, If XIDTC less than REF.DATE then (XIDTC - REF.DATE). Else if XIDTC is greater than equal to REF.DATE then (XIDTC - REF.DATE) + 1.

1.4.27. Sample Handling – XZ

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
XZSEQ	num	Sequence Number		Collected at CRF.
XZSPID	char	Sponsor-Defined Identifier		Collected at CRF.
XZTESTCD	char	Sample Handling Test Short Name		Collected at CRF.
XZTEST	char	Sample Handling Test Name		Collected at CRF.
XZCAT	char	Category for Sample Handling		Collected at CRF.
XZORRES	char	Result or Finding in Original Units		Collected at CRF.
XZSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.

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

Clinical Development

CNTO148UCO3001

CSRW68

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	14MAY2019

Property of Janssen

Confidential

May not be used, divulged, published or otherwise disclosed
without the consent of Janssen

Table of contents

Clinical Development.....	1
1. Datasets.....	5
1.1. Specifications Introduction	5
1.2. Guidelines for Preparing Data.....	5
1.3. Data Files	6
1.4. Data Domains	7
1.4.1. Demographics – DM.....	7
1.4.2. Adverse Events – AE	10
1.4.3. Supplemental Qualifiers for AE – SUPPAE	13
1.4.4. Bio-Specimen – BE	14
1.4.5. Codelist – CD	15
1.4.6. Concomitant Medications – CM	16
1.4.7. Supplemental Qualifiers for CM – SUPPCM	18
1.4.8. Computational Method – COMPMETH.....	19
1.4.9. CS – CS	20
1.4.10. Dataset Level Metadata – DATADEF.....	21
1.4.11. Disposition – DS.....	22
1.4.12. Protocol Deviations – DV.....	24
1.4.13. Exposure – EX.....	25
1.4.14. Supplemental Qualifiers for EX – SUPPEX.....	27
1.4.15. Findings About Events or Interventions – FA	28
1.4.16. Supplemental Qualifiers for FA – SUPPFA	30
1.4.17. Hospitalization – HO.....	31
1.4.18. Supplemental Qualifiers for HO – SUPPHO.....	32
1.4.19. Inclusion/Exclusion Criterion Not Met – IE.....	33
1.4.20. Laboratory Test Results – LB	35
1.4.21. Medical History – MH	37
1.4.22. MK – MK.....	40
1.4.23. Pharmacokinetic Concentrations – PC.....	41
1.4.24. Physical Examination– PE	43
1.4.25. Questionnaire – QS	45

1.4.26.	RA – RA	47
1.4.27.	Related Records – RELREC.....	49
1.4.28.	Study Level Metadata – STUDYDEF.....	50
1.4.29.	Substance Use – SU	51
1.4.30.	Supplemental Qualifiers for SU – SUPPSU	52
1.4.31.	Subject Visits – SV	53
1.4.32.	Trial Inclusion/Exclusion Criteria – TI.....	54
1.4.33.	Value-Level Metadata – VALDEF.....	55
1.4.34.	Variable Level Metadata – VARDEF.....	56
1.4.35.	Vital Signs – VS	58
1.4.36.	Antibodies to study Agent – XA	60
1.4.37.	Imaging – XI	62
1.4.38.	Sample Handling – XZ	64

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Empty comments data will be submitted due to sensitivity of data.
- DM.RFICDTC ("Date of Informed Consent") will be used as Reference Date (referred as REF. DATE in the document) to derive relative day.

1.3. Data Files

The CSRW68 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: RFICDTC,DMDTC,RFXSTDTC,VISITDY,BRTHDTC,DTHFL,DTHDTC,RFPENDTC, RFXENDTC,RFENDTC,RFSTDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
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.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
ACTARMCD	char	Actual Arm Code		Collected at CRF.
ACTARM	char	Description of Actual Arm		Collected at CRF.
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DMDY	num	Relative Day of Collection		If DMDTC and REF.DATE not missing then perform below logic to calculate DMDY, If DMDTC less than REF.DATE then (DMDTC - REF.DATE). Else if DMDTC is greater than equal to REF.DATE then (DMDTC- REF.DATE) +1.
RFSTTM	num	Subject Reference Start Time		If RFSTDTC contains time part then timepart(RFSTDTC) else RFSTTM equal to NULL.

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

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

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: AEENDTC,AESTDTC,AETERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
AESEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESPID	char	Sponsor-Defined Identifier		Collected at CRF.
AELLT	char	Lowest Level Term		Collected at CRF.
AELLTCD	num	Lowest Level Term Code		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEPTCD	num	Preferred Term Code		Collected at CRF.
AEHLT	char	High Level Term		Collected at CRF.
AEHLTCD	num	High Level Term Code		Collected at CRF.
AEHLGT	char	High Level Group Term		Collected at CRF.
AEHLGTC	num	High Level Group Term Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AEBDSYCD	num	Body System or Organ Class Code		Collected at CRF.
AESOC	char	Primary System Organ Class		Collected at CRF.
AESOCCD	num	Primary System Organ Class Code		Collected at CRF.
AELOC	char	Location of Event		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.

Variable	Type	Label	Codes	Comments
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.
EPOCH	char	Epoch		Collected at CRF.
AESTDY	num	Relative Start Day of Adverse Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC - REF.DATE) +1.
AEENDY	num	Relative End Day of Adverse Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC - REF.DATE) +1.
AESTTM	num	Start Time of Adverse Event		If AESTDTC contains time part then timepart(AESTDTC) else AESTTM equal to NULL.

1.4.3. Supplemental Qualifiers for AE – SUPPAE

Dataset	SUPPAE
Creating program	suppae.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.Bio-Specimen – BE

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
BESEQ	num	Sequence Number		Collected at CRF.
BESPID	char	Sponsor-Defined Identifier		Collected at CRF.
BETERM	char	Reported Term for the Bio-specimen Event		Collected at CRF.
BEDECOD	char	Dictionary-Derived Term		Collected at CRF.
BECAT	char	Category for Bio-specimen Event		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

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

1.4.5.Codelist – CD

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

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

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

1.4.6. Concomitant Medications – CM

Dataset	CM
Creating program	cm.sas
Description	Concomitant Medications
Unique identifier	STUDYID,DUSUBJID,CMSTDY,CMSEQ
Sorted by	STUDYID,DUSUBJID,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.

Variable	Type	Label	Codes	Comments
CMCAT	char	Category for Medication		Collected at CRF.
COMPRES	char	CM Pre-Specified		Collected at CRF.
CMOCCUR	char	CM Occurrence		Collected at CRF.
CMSTAT	char	Completion Status		Collected at CRF.
CMINDC	char	Indication		Collected at CRF.
CMDOSTXT	char	Dose Description		Collected at CRF.
CMDOSU	char	Dose Units		Collected at CRF.
CMDOSFRQ	char	Dosing Frequency per Interval		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC - REF.DATE) +1.
CMENDY	num	Relative End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC - REF.DATE) +1.
CMSTRF	char	Start Relative to Reference Period		Collected at CRF.
CMENRF	char	End Relative to Reference Period		Collected at CRF.

1.4.7. Supplemental Qualifiers for CM – SUPPCM

Dataset	SUPPCM
Creating program	suppcm.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.
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, CMSPEC, CMTRTOTH) 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. Computational Method – COMPMETH

Dataset	COMPMETH
Creating program	compmeth.sas
Description	Computational Method
Unique identifier	MTHNAM,MTHDESC
Sorted by	MTHNAM,MTHDESC
Notes	

Variable	Type	Label	Codes	Comments
MTHNAM	char	Computation Method Name		Collected at CRF.
MTHDESC	char	Description		Collected at CRF.
MTHDESC1	char	Description 1		Collected at CRF.
MTHDESC2	char	Description 2		Collected at CRF.
MTHDESC3	char	Description 3		Collected at CRF.
MTHDESC4	char	Description 4		Collected at CRF.

1.4.9.CS – CS

Dataset	CS
Creating program	cs.sas
Description	CS
Unique identifier	STUDYID,DUSUBJID,CSTRT,CSSTDY,CSSEQ
Sorted by	STUDYID,DUSUBJID,CSTRT,CSSTDY,CSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CSLOTNUM,CSSTDTC,CSSPID

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
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study Site Id for De-Identity
CSSEQ	num	Sequence Number		Collected at CRF.
CSTRT	char	Treatment		Collected at CRF.
CSDOSE	num	Treatment Dose		Collected at CRF.
CSDOSU	char	Dose Unit		Collected at CRF.
CSSTTM	num	Time of Medication Kit Dispensed		If CSSTDTC contains time part then timepart(CSSTDTC) else CSSTTM equal to NULL.

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

1.4.10. Dataset Level Metadata – DATADEF

Dataset	DATADEF
Creating program	datadef.sas
Description	Dataset Level Metadata
Unique identifier	CLASSNM,DATASET
Sorted by	CLASSNM,DATASET
Notes	

Variable	Type	Label	Codes	Comments
CLASSNM	char	Dataset Class		Collected at CRF.
DATASET	char	Dataset Name		Collected at CRF.
DSLABEL	char	Dataset Label		Collected at CRF.
STRUCTRE	char	Structure		Collected at CRF.
REPEAT	char	Repeating		Collected at CRF.
PURPOSE	char	Purpose of the Data		Collected at CRF.

Variable	Type	Label	Codes	Comments
REFDATA	char	Reference Data		Collected at CRF.
KEYS	char	Logical Key Order		Collected at CRF.
DSORDER	char	Dataset Order		Collected at CRF.

1.4.11. Disposition – DS

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSSEQ	num	Sequence Number		Collected at CRF.
DSSPID	char	Sponsor-Defined Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
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.

1.4.12. Protocol Deviations – DV

Dataset	DV
Creating program	dv.sas
Description	Protocol Deviations
Unique identifier	STUDYID,DUSUBJID,DVDECOD,DVSEQ
Sorted by	STUDYID,DUSUBJID,DVDECOD,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.
DVSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

1.4.13. Exposure – EX

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
EXSEQ	num	Sequence Number		Collected at CRF.
EXSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EXTRT	char	Name of Actual Treatment		Collected at CRF.
EXCAT	char	Category for Treatment		Collected at CRF.
EXSCAT	char	Subcategory for Treatment		Collected at CRF.
EXDOSE	num	Dose per Administration		Collected at CRF.
EXDOSU	char	Dose Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXDOSFRM	char	Dose Form		Collected at CRF.
EXDOSTOT	num	Total Daily Dose		Collected at CRF.
EXROUTE	char	Route of Administration		Collected at CRF.
EXLOC	char	Location of Dose Administration		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
EXSTDY	num	Relative Start Day of Treatment		If EXSTDTC and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE). Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC - REF.DATE) +1.
EXSTTM	num	Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM equal to NULL.

1.4.14. Supplemental Qualifiers for EX – SUPPEX

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

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

1.4.15. Findings About Events or Interventions – FA

Dataset	FA
Creating program	fa.sas
Description	Findings About Events or Interventions
Unique identifier	STUDYID,DUSUBJID,FADY,FASEQ
Sorted by	STUDYID,DUSUBJID,FADY,FASEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: FASPID,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.
FATESTCD	char	Findings About Test Short Name		Collected at CRF.
FATEST	char	Findings About Test Name		Collected at CRF.
FAOBJ	char	Object of the Observation		Collected at CRF.
FACAT	char	Category for Findings About		Collected at CRF.
FASCAT	char	Subcategory for Findings About		Collected at CRF.
FAORRES	char	Result or Finding in Original Units		Collected at CRF.

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

1.4.16. Supplemental Qualifiers for FA – SUPPFA

Dataset	SUPPFA
Creating program	suppfa.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: 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 (CM6AMI5, CM6COR6, CM6IMM5) 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. Hospitalization – HO

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

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.
EPOCH	char	Epoch		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOSTDY	num	Relative Start Day of Hospitalization		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 Hospitalization		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.
HOENRF	char	End Relative to Reference Period		Collected at CRF.

1.4.18. Supplemental Qualifiers for HO – SUPPHO

Dataset	SUPPHO
Creating program	suppho.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: 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.

1.4.19. Inclusion/Exclusion Criterion Not Met – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Criterion Not Met
Unique identifier	STUDYID,DUSUBJID,IETESTCD,IESEQ
Sorted by	STUDYID,DUSUBJID,IETESTCD,IESEQ
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
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.
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.
EPOCH	char	Epoch		Collected at CRF.

1.4.20. 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 missing values: LBSPID,LBDTC,LBSTAT

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.
LBORRES	char	Result or Finding in Original Units		Collected at CRF.
LBORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
LBSTNRC	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

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	Time of Specimen Collection		If LBDTC contains time part then timepart(LBDTC) else LBTM equal to NULL.

1.4.21. Medical History – MH

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
MHSEQ	num	Sequence Number		Collected at CRF.
MHSPID	char	Sponsor-Defined Identifier		Collected at CRF.
MHLLT	char	Lowest Level Term		Collected at CRF.
MHLLTCD	num	Lowest Level Term Code		Collected at CRF.
MHDECOD	char	Dictionary-Derived Term		Collected at CRF.
MHPTCD	num	Preferred Term Code		Collected at CRF.
MHHLT	char	High Level Term		Collected at CRF.
MHHLTCD	num	High Level Term Code		Collected at CRF.
MHHLGT	char	High Level Group Term		Collected at CRF.
MHHLGTC	num	High Level Group Term Code		Collected at CRF.
MHCAT	char	Category for Medical History		Collected at CRF.
MHPRESP	char	Medical History Event Pre-Specified		Collected at CRF.
MHOCCUR	char	Medical History Occurrence		Collected at CRF.
MHSTAT	char	Completion Status		Collected at CRF.
MHBODSYS	char	Body System or Organ Class		Collected at CRF.
MHBDSYCD	num	Body System or Organ Class Code		Collected at CRF.
MHSOC	char	Primary System Organ Class		Collected at CRF.
MHSOCCD	num	Primary System Organ Class Code		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	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 Medical History		If MHSTDTC and REF.DATE not missing then perform below logic to calculate MHSTDY, If MHSTDTC less than REF.DATE then (MHSTDTC - REF.DATE). Else if MHSTDTC is greater than equal to REF.DATE then (MHSTDTC- REF.DATE) +1.
MHENRF	char	End Relative to Reference Period		Collected at CRF.

1.4.22. MK – MK

Dataset	MK
Creating program	mk.sas
Description	MK
Unique identifier	STUDYID,DUSUBJID,MKTRT,MKSTDY,MKSEQ
Sorted by	STUDYID,DUSUBJID,MKTRT,MKSTDY,MKSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MKNUM,MKSTDTC,MKSPID

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
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study Site Id for De-Identity
MKSEQ	num	Sequence Number		Collected at CRF.
MKTRT	char	Name of actual treatment		Collected at CRF.
MKSTTM	num	Time of Medication Kit Dispensed		If MKSTDTC contains time part then timepart(MKSTDTC) else MKSTTM equal to NULL.

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

1.4.23. Pharmacokinetic Concentrations – PC

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

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.

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

Variable	Type	Label	Codes	Comments
PCTPTNUM	num	Planned Time Point Number		Collected at CRF.
PCTM	num	Time of Specimen Collection		If PCDTC contains time part then timepart(PCDTC) else PCTM equal to NULL.

1.4.24. Physical Examination– PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examination
Unique identifier	STUDYID,DUSUBJID,PETEST,PEDY,PESEQ
Sorted by	STUDYID,DUSUBJID,PETEST,PEDY,PESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PEDTC

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
PESEQ	num	Sequence Number		Collected at CRF.
PESPID	char	Sponsor-Defined Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
PETESTCD	char	Body System Examined Short Name		Collected at CRF.
PETEST	char	Body System Examined		Collected at CRF.
PEORRES	char	Verbatim Examination Finding		Collected at CRF.
PESTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
PESTAT	char	Completion Status		Collected at CRF.
PEBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
PEDY	num	Relative Day of Examination		If PEDTC and REF.DATE not missing then perform below logic to calculate PEDY, If PEDTC less than REF.DATE then (PEDTC - REF.DATE). Else if PEDTC is greater than equal to REF.DATE then (PEDTC - REF.DATE) + 1.

1.4.25. Questionnaire – QS

Dataset	QS
Creating program	qs.sas
Description	Questionnaire
Unique identifier	STUDYID,DUSUBJID,QSTEST,QSDY
Sorted by	STUDYID,DUSUBJID,QSTEST,QSDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: 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.
QSSCAT	char	Subcategory for Question		Collected at CRF.
QSORRES	char	Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
QSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
QSSTRESN	num	Numeric Finding in Standard Units		Collected at CRF.
QSSTAT	char	Completion Status		Collected at CRF.
QSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
QSDY	num	Relative Day of Finding		If QSDTC and REF.DATE not missing then perform below logic to calculate QSDY, If QSDTC less than REF.DATE then (QSDTC - REF.DATE). Else if QSDTC is greater than equal to REF.DATE then (QSDTC - REF.DATE) +1.

1.4.26. RA – RA

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

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.
ARM	char	Planned Arm		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.
RAORIG	char	Origin of Randomization Data		Collected at CRF.

Variable	Type	Label	Codes	Comments
RAORDER	num	Subject Randomization Order		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
RASTTM	num	Time of Randomization		If RASTDTC contains time part then timepart(RASTDTC) else RASTTM equal to NULL.
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.

1.4.27. Related Records – RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,RELID
Notes	Below listed variables will be dropped from dataset due to missing values: RELTYPE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
RELID	char	Relationship Identifier		Collected at CRF.

1.4.28. Study Level Metadata – STUDYDEF

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

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

1.4.29. Substance Use – SU

Dataset	SU
Creating program	su.sas
Description	Substance Use
Unique identifier	STUDYID,DUSUBJID,SUTRT
Sorted by	STUDYID,DUSUBJID,SUTRT
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
SUSEQ	num	Sequence Number		Collected at CRF.
SUSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SUTRT	char	Reported Name of Substance		Collected at CRF.
SUPRESP	char	SU Pre-Specified		Collected at CRF.
SUOCCUR	char	SU Occurrence		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

1.4.30. Supplemental Qualifiers for SU – SUPPSU

Dataset	SUPPSU
Creating program	suppsu.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.

1.4.31. Subject Visits – SV

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
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.

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

1.4.32. Trial Inclusion/Exclusion Criteria – TI

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

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

1.4.33. Value-Level Metadata – VALDEF

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

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

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

1.4.34. Variable Level Metadata – VARDEF

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

Variable	Type	Label	Codes	Comments
DATASET	char	Dataset Name		Collected at CRF.
VARNAME	char	SDTM Variable		Collected at CRF.
VARLABEL	char	SDTM Variable Label		Collected at CRF.
DATATYPE	char	Data Type		Collected at CRF.
LNGTH	char	Length		Collected at CRF.
DECDIG	char	Decimal Digits		Collected at CRF.

Variable	Type	Label	Codes	Comments
ORIGIN	char	Origin of the Variable		Collected at CRF.
VARROLE	char	Role		Collected at CRF.
CORE	char	Core		Collected at CRF.
VARKEY	char	Logical Key Order		Collected at CRF.
VARORDER	char	Variable Order		Collected at CRF.
CODELST	char	Codelist Name		Collected at CRF.
VALUELST	char	Value List		Collected at CRF.
COMMENTS	char	Comment		Collected at CRF.
CRFPAGE	char	CRF Page Number		Collected at CRF.
COMPMETH	char	Computational Method		Collected at CRF.

1.4.35. Vital Signs – VS

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VSSEQ	num	Sequence Number		Collected at CRF.
VSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSORRES	char	Result or Finding in Original Units		Collected at CRF.
VSORRESU	char	Original Units		Collected at CRF.

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

1.4.36. Antibodies to study Agent – XA

Dataset	XA
Creating program	xa.sas
Description	Antibodies to study Agent
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: XADTC,XANAM

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.
XAREFID	char	Reference ID		Collected at CRF.
XASPID	char	Sponsor-Defined Identifier		Collected at CRF.
XATESTCD	char	Pharmacokinetic Test Short Name		Collected at CRF.
XATEST	char	Pharmacokinetic Test Name		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 Standard Units		Collected at CRF.
XASTRESU	char	Standard Units		Collected at CRF.
XASPEC	char	Specimen Material Type		Collected at CRF.
XALLOQ	num	Lower Limit of Quantitation		Collected at CRF.
XABLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XADY	num	Relative Day of Specimen Collection		If XADTC and REF.DATE not missing then perform below logic to calculate XADY, If XADTC less than REF.DATE then (XADTC - REF.DATE). Else if XADTC is greater than equal to REF.DATE then (XADTC - REF.DATE) + 1.
XATPT	char	Planned Time Point Name		Collected at CRF.
XATPTNUM	num	Planned Time Point Number		Collected at CRF.
XATM	num	Time of Specimen Collection		If XADTC contains time part then timepart(XADTC) else XATM equal to NULL.

1.4.37. Imaging – XI

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
XISEQ	num	Sequence Number		Collected at CRF.
XITESTCD	char	Imaging Test or Examination Short Name		Collected at CRF.
XITEST	char	Imaging Test or Examination Name		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.

Variable	Type	Label	Codes	Comments
XISTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
XIBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XIDY	num	Relative Day of Imaging		If XIDTC and REF.DATE not missing then perform below logic to calculate XIDY, If XIDTC less than REF.DATE then (XIDTC - REF.DATE). Else if XIDTC is greater than equal to REF.DATE then (XIDTC - REF.DATE) + 1.

1.4.38. Sample Handling – XZ

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
XZSEQ	num	Sequence Number		Collected at CRF.
XZSPID	char	Sponsor-Defined Identifier		Collected at CRF.
XZTESTCD	char	Test or Examination Short Name		Collected at CRF.
XZTEST	char	Test or Examination Name		Collected at CRF.
XZCAT	char	Category		Collected at CRF.
XZORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XZSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
XZDY	num	Relative Day of Specimen Collection		If XZDTC and REF.DATE not missing then perform below logic to calculate XZDY, If XZDTC less than REF.DATE then (XZDTC - REF.DATE). Else if XZDTC is greater than equal to REF.DATE then (XZDTC - REF.DATE) +1.
XZTM	num	Time of Sample Handling		If XZDTC contains time part then timepart(XZDTC) else XZTM equal to NULL.